



Patients for Patient Safety

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6.1 Introduction

The people have a right and duty to participate individually and collectively in the planning and implementation of their own health care—WHO Alma Ata Declaration (1978) [1]

Unsafe care results in approximately 2.6 million deaths per year. It is one of the top 10 causes of death worldwide [2]. Recognizing unsafe care as a growing global burden, in 2019 the 72nd

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World Health Assembly (WHA) [3], the policy setting body for the World Health Organization (WHO), ratified the Global Action on Patient Safety [4]. Through this document, the WHA urged Member States to “work in collaboration with other Member States, civil society organizations, patients’ organizations, professional bodies, academic and research institutions, industry and other relevant stakeholders to promote, prioritize and embed patient safety in all health policies and strategies” [4]. The WHA further urged Member States to “put in place systems for the engagement and empowerment of patients, families and communities (especially those who have been affected by adverse events) in the delivery of safer health care, including capacity building initiatives, networks and associations; and to work with them and civil society, to use their experience of safe and unsafe care positively in order to build safety and harm minimization strategies as well as compensation mechanisms and schemes, into all aspects of the provision of health care, as appropriate” [4].

Simply stated, the WHA, through The Global Action on Patient Safety, called for Member States to democratize healthcare by engaging with the very users of the healthcare system—patients, families, and community members—along with other partners—in the “co-production” of safer healthcare.

In this chapter, I share how preventable harm to my son, Cal, from neonatal jaundice, and the

death of my late husband, Pat, from the failure to communicate a malignant pathology, catapulted me into a global movement of patients, family members, communities, and civil society advocating for safer care that became known as the WHO's Patients for Patient Safety (PFPS) Programme (mentioned in the previous chapter). I along with others around the world who have experienced harm from unsafe care have harnessed our wisdom, our grief, and our anger to courageously partner with passionate thought leaders in healthcare including clinicians, researchers, policy makers, medical educators, and quality improvement experts to co-produce patient safety initiatives to ensure that our healthcare systems "learn" from our adverse events and implement systematic strategies to reduce risk of harm. The real-world examples of co-production within this chapter demonstrate the important role of civil society as well as how patients, families, and communities "that have experienced adverse events can use their experience of safe and unsafe care positively in order to build safety and harm reduction strategies" in developing and developed countries [4].

6.2 What is Co-production in Healthcare?

Co-production is the "interdependent work of users and professionals to design, create, develop, deliver, assess and improve the relationships and actions that contribute to the health of individuals and populations through mutual respect and partnership that notices and invites each participant's unique strengths and expertise" [5]. Co-produced patient safety initiatives are "mutually beneficial...at every level and in every health-related endeavor, from designing educational curricula to setting research priorities to hiring faculty and leadership to operating health organizations" [5]. Patients are not viewed as "'users and choosers' but as 'makers and shapers' [which] allows for planning and implementing new policies that can potentially lead to better health outcomes and patient experiences" [6].

6.3 Background: The Genesis of a Global Movement for Co-production for Safer Care

In 2002, the 55th WHA passed Resolution WHA55.18 which established "the need to promote patient safety as a fundamental principle of all health systems" and resulted in WHO launching the World Alliance for Patient Safety (now known as the WHO Patient Safety Programme) [7, 8]. The World Alliance for Patient Safety consisted of six action programmes, one of which was the Patients for Patient Safety Programme (the PFPS Programme), where I served as the External Lead for 7 years. The PFPS Programme is a global network of committed patients, families, healthcare professionals, and policy makers who are connected by the common objective of promoting safer care through patient involvement. They bravely advocate for and collaborate in patient safety efforts at the local, national, and international levels [9]. These individuals, known as PFPS Champions, teach, offer hope and provide inspiration. They have organized as individuals, networks, patient associations/organizations and in discrete patient programs within established public and civil society structures. Their dedication to co-producing safer healthcare is guided by the seminal document, the London Declaration, which was authored by representatives from 21 countries who had experienced harm directly or indirectly as a result of unsafe care. The London Declaration calls for partnership and the democratization of healthcare to improve patient safety:

The London Declaration

We, Patients for Patient Safety, envision a different world in which healthcare errors are not harming people. We are partners in the effort to prevent all avoidable harm in healthcare. Risk and uncertainty are constant companions. So, we come together in dialogue, participating in care with providers. We unite our strength as advocates for care without harm in the developing as well as the developed world.

We are committed to spread the word from person to person, town to town, country to country. There is a right to safe healthcare and we will not let the current culture of error and denial, continue. We

call for honesty, openness, and transparency. We will make the reduction of healthcare errors as a basic human right that preserves life around the world.

We, Patients for Patient Safety, will be the voice for all people, but especially those who are now unheard. Together as partners, we will collaborate in:

- *Devising and promoting programs for patient safety and patient empowerment.*
- *Developing and driving a constructive dialogue with all partners concerned with patient safety.*
- *Establishing systems for reporting and dealing with healthcare harm on a world-wide basis.*
- *Defining best practices in dealing with healthcare harm of all kinds and promoting those practices throughout the world.*

In honor of those who have died, those left disabled, our loved ones today and the world's children yet to be born, we will strive for excellence, so that all involved in healthcare are as safe as possible as soon as possible. This is our pledge of partnership [10].

By co-producing patient safety initiatives, the PFPS Programme, PFPS Champions, and Member States democratize patient safety and fulfill the promise and potential of the directives stated in both the London Declaration and the WHA Global Action on Patient Safety.

6.4 Co-Production in Research

There is growing awareness that patient engagement in health research is not only ethically important, but leads to evidence for developing the most effective interventions, policy and practice recommendations, and planning for ongoing research [11].

6.4.1 Example: United States

6.4.1.1 Mothers Donating Data: Going from Research to Policy to Practice

My son, Cal, and other newborn babies suffered from preventable brain damage in the United States as a result of the failure to test and treat

neonatal jaundice (hyperbilirubinemia), known as kernicterus. After determining that a pre-discharge bilirubin test would have helped prevent our newborns from suffering, mothers of children with kernicterus formed a nonprofit organization (civil society), Parents of Infants and Children with Kernicterus (PICK) [12]. The PICK Board of Directors, comprised of the mothers, had two specific goals: (1) co-design a safer healthcare system for newborns to include a universal, pre-discharge bilirubin test; and (2) co-design materials to empower parents with information. While the healthcare providers were sympathetic to these mothers, healthcare leaders stated clearly that changes to care or educational materials could not be made based solely on anecdotes; evidence-based research was necessary. PICK partnered with leading published researchers on neonatal jaundice, treating clinicians and patient safety experts to engage in developing the evidence necessary to revise clinical guidelines to include a universal newborn bilirubin test and revised parent education materials to empower parents to help prevent future harm to newborns from elevated bilirubin levels. Through the collaboration with the researchers, the PICK mothers helped to collect and donate clinical data of 125 newborns who were discharged as healthy from the place of birth but subsequently sustained kernicterus. The collection of data became known as the Pilot USA Registry of Kernicterus [13]. PICK formed the Kernicterus Prevention Partnership Coalition that included various governmental agencies, academic institutions, and other stakeholders. These organizations were unified by a nonbinding memorandum of understanding. PICK and the researchers partnered with a leading public health agency to fund and analyze the data, the results of which indicated that kernicterus was an emerging public health issue and that implementation of a universal bilirubin (jaundice) test would help identify newborns at risk of hyperbilirubinemia and reduce the number of cases of kernicterus. PICK also partnered with a leading healthcare system with a large data set of clinical information on newborns. Analysis of their data also supported the implementation of a universal bilirubin

test. A separate governmental health agency also partnered with PICK to fund the co-production, testing and the usability of parent education materials in different populations about the risks of newborn jaundice and included proactive steps they could take to identify and prevent harm to their newborns [14].

The outcome of PICK's co-production in research contributed to the revision of clinical practice guidelines to include a universal pre-discharge bilirubin test [15] and the dissemination of a "Sentinel Event Alert" by a national hospital accreditor with recommendations on newborn jaundice management [16], established kernicterus as a "Never Event" per a national quality measures organization, developed a national parent education campaign [14] and materials and co-developed and co-delivered curricula for continuing medical education courses.

There were many factors that contributed to PICK's achievements. One of the key factors was that a major national government agency invited stakeholders, including patients, to publicly comment at a National Summit on Medical Errors and Patient Safety. The organizers of this summit offered guidance to those unfamiliar with public comment how to best craft their testimony. At that summit, I, testified about the preventable harm that my son had suffered from undiagnosed and untreated neonatal jaundice and advocated for collaboration amongst all stakeholders to prevent future cases. Another success factor was the determination, persistence, and relentless call for action from the community of mothers with children with kernicterus who formed a respected, independent, nonprofit organization with by-laws and objectives to prevent harm to future newborns through a model of partnership. Further these mothers served as a "living repository" of clinical data for research regarding kernicterus unavailable through traditional data collection methods and were the conduit to collecting additional data from mothers across the world with children with kernicterus. This enabled the researchers to actively collaborate with the mothers as subject matter experts. As a result of these factors, deep, trusting, mutually beneficial relationships formed with patient safety experts, cli-

nicians, and leadership in government agencies, research institutions, medical education, and healthcare systems who willingly partnered with the mothers, despite criticism from peers. The healthcare leaders voluntarily helped the mothers gain capacity to be effective advocates for changes in jaundice management protocols. They helped educate the mothers about the structure of the healthcare system, the responsibilities of the various decision-making bodies, the current science and evidence base for management of newborn jaundice and gaps in the literature. They provided guidance and tips on successful storytelling and public speaking skills, partnered as presenters at national conferences and in interviews with media and provided resources, infrastructure and credibility that facilitated the development of the necessary evidence for successful implementation of a systems-based approach to the prevention of kernicterus.

6.4.1.2 Civil Society: Driving Patient-Centered Research to Prevent Diagnostic Errors

Researchers estimate that up to 80,000 deaths per year in US hospitals can be attributed to some form of diagnostic error. Misdiagnosis affects 12 million Americans in ambulatory care settings annually. The National Academy of Medicine's 2015 report, *Improving Diagnosis in Health Care*, highlights the urgent need for a research agenda on the diagnostic process and diagnostic errors and states that "patients are central to the solution" and there is a need to "establish partnerships with patients and families to improve diagnosis [17]. The Society to Improve Diagnosis in Medicine (SIDM), where I serve as the Director of Patient Engagement, is a US-based nonprofit organization (civil society) dedicated to reducing diagnostic errors. We believed that if researchers joined forces with trained patients and family members with lived experience in diagnostic error to co-produce diagnostic safety research projects, the research questions and outcomes would be more relevant, effective, and patient centered. SIDM pursued funding from the Patient-Centered Outcomes Research Institute (PCORI) to (1) recruit patients and family mem-

bers who had experienced diagnostic error and diagnostic safety researchers to co-develop a curriculum that provides patients and family members with the knowledge, skills, and tools to effectively partner in the design, execution, and dissemination of diagnostic research; and (2) collectively co-produce patient-centered research topics and questions to pursue to improve diagnosis [18].

SIDM collaborated with Project Patient Care, an independent nonprofit organization of patients, family members, and patient advocates and the Medstar Institute for Quality and Safety to help recruit the patient and family participants and to develop the curriculum. I led the project that included patients and family members from key disease-related organizations and representatives from Patient and Family Advisory Councils (PFACs) at major healthcare institutions—all who had experienced diagnostic error. Prominent diagnostic researchers from academic medical centers also participated in the project. Together with the project team, the patients and researchers co-produced an innovative, patient-centered curriculum. This curriculum was continuously evaluated and refined to ensure patient engagement in diagnostic research. Applying the knowledge and methods developed in the curriculum, patients and researchers co-produced a list of patient-centered diagnostic research topics and questions for future research. One of these resultant research questions focused on disparities in diagnosis due to visible factors of age, sex, and race/ethnicity. This project was awarded funding for a 2-year research project to be led by SIDM and a major academic institute.

The promising results of SIDM's project are due to several factors. SIDM is an established nonprofit organization (i.e., a civil society organization) that has embedded patient and family engagement as a strategic priority in its mission and dedicated resources to employ a PFPS Champion as a full-time Director of Patient Engagement. Having SIDM develop and lead this project provided the credibility to secure funding from a large national research institute to support staff, the patients, family members, researchers, leadership, as well as an infrastructure designed

to support sustainability. Patients and family members from national disease groups who have firsthand experiences with diagnostic error were invaluable in identifying research questions and topic suggestions that often went unrecognized or unconsidered. The project developed and delivered an innovative, patient-centered training curriculum that enabled patients and family members to effectively distill their personal stories of diagnostic error and participate as true partners in the development of research questions. Because of its success, the curriculum has been replicated in other training efforts in acute care settings and methods and tools from the curriculum have been shared nationally and internationally as an approach to engage patients, family members, and other stakeholders in diagnostic improvement efforts [19].

6.5 Co-production in Medical Professions Education Courses

Patient engagement is a promising avenue in the area of healthcare education. Having real patients articulate their experiences and viewpoints helps those taking part in training to appreciate the patient perspective and the importance of preserving trust between clinicians and patients. These core values are essential to care that is compassionate, quality assured and, above all, safe. Exposure to patient stories during training is valuable and helps to motivate practitioners to improve safety [20].

There is evidence that teaching by patients has a lasting impact in the areas of technical skills interpersonal skills, empathic understanding, and developing an individualized approach to the patient [21].

6.5.1 Example: Mexico

6.5.1.1 Leveraging a Regional Network of PFPS Champions to Enhance Medical Education

According to a study on patient safety in Latin America (IBEAS), “on any given day, 10% of the patients admitted to the hospitals... had experi-

enced some kind of harm due to health care” [22]. Evangelina Vazquez Curiel [23], a PFPS champion and single mother in Mexico whose newborn son experienced harm soon after birth, along with other patients, family members and healthcare professionals in Latin America, identified the lack of patient safety education for healthcare professionals in Latin America as a major contributing factor to unsafe care. She actively collaborated with academic institutions in Mexico, the local Ministry of Health and the Pan American Network of PFPS champions to co-produce an online patient safety course for healthcare professionals in Latin America that would bring patient safety experts, patients, and healthcare professionals from various healthcare systems together. Course co-developers, educators, patients, speakers, and learners are from eight countries—Mexico, Costa Rica, Peru, Paraguay, Uruguay, Ecuador, Chile, and Columbia. The objectives of the course are to (1) continuously train healthcare workers from remote and low-resource settings about patient safety and quality; (2) bring patient safety experts from across the Latin American region together to serve as educators and discussion leaders; (3) raise awareness of health literacy and highlight the role it plays in preventing adverse events; and (4) encourage dialogue between patients, family members, civil society, and healthcare providers/treating professionals to reduce power imbalances. The curriculum is comprised of 11 modules, three of which focus on the WHO Global Challenges (Clean Care is Safer Care [24], Safe Surgery [25], and Medication without Harm [26]). The remaining eight focus on the fundamentals of improving patient safety and quality of care. At the end of the patient safety course, participants receive a certificate from The University of New Mexico of Tula.

Over 2000 healthcare professionals from a myriad of socio-economic backgrounds, practicing in rural public hospitals to small and large private hospitals have participated in the online course. The course was launched in 2016 and continues to be offered in 2020.

The success of the online patient safety course was primarily due to Ms. Vazquez Curiel’s per-

sonal devotion, fervor, and effective networking in advocating for safer care. Because of her capacity to understand and appreciate the challenges of healthcare, and with the credibility of being a PFPS champion, Ms. Vazquez Curiel developed trusting relationships with healthcare leaders in Mexico, the Pan American Health Organization (PAHO), and other patient leaders and advocates in the Americas. Another contributing factor in the co-production and popularity of the online course was the Pan American Network of PFPS which is an informal group of like-minded, patients, family members, healthcare professionals, and policy makers with similar goals and experiences in patient safety that spans 10 countries in the Americas. This network was formed as a result of PAHO/WHO sponsored PFPS workshops. Its goals are to promote patient participation in efforts to improve quality and safety in healthcare and to improve patient skills for dialogue with healthcare planners and policy makers. The formation of the regional network has resulted in a vibrant, connected, multi-stakeholder regional community that shares best practices and risk mitigation strategies [27]. Finally, this course would not have succeeded without the volunteer healthcare professionals’, academic institution leaders’, and educators’ willingness to collaborate with the PFPS community to co-produce a novel curriculum on patient safety that fosters a transparent, safe environment for dialogue about learning from unsafe care.

6.5.2 Example: Denmark

6.5.2.1 Patients as Educators

Communication breakdowns at crucial moments in the provision of healthcare were leading to serious adverse events, including death, in Danish hospitals. The Danish Society for Patient Safety, a civil society organization and member of the WHO PFPS Programme [28], organized The Danish Patients for Patient Safety (The Danish PFPS), a network of volunteer patients and/or family members who had experienced severe medical harm as a result of communication failures, to actively address this issue. The Danish

PFPS group believed that (1) effective communication between patients, family members, and healthcare providers was desperately lacking at crucial moments in the provision of care and that this failure to communicate lead to the serious medical errors; and (2) patients and/or family members who had been affected by adverse events sharing their real-world learning through storytelling would be an impactful method of teaching residents communications skills. Danish PFPS champions collaborated with medical leaders and educators in different regions of Denmark to co-produce and fully implement a live storytelling session as part of the compulsory three-day communication skills course [29]. During the storytelling sessions, a patient or family member from the Danish PFPS described his/her experience with medical error in a manner that highlighted the points in care where the doctor's communication skills, both good and poor, were especially important to the outcome of the care. Immediately after the Danish PFPS champion completed his/her story, the storyteller and communication course instructor guided the medical residents through a structured reflection process. The medical residents were then asked to think about what they could learn from the story and how they might incorporate these lessons into their clinical work.

To date, approximately 2500–2800 medical residents have completed the workshop. Medical residents consistently share that they have a greater appreciation of what the patient or family member experienced and have a better understanding of why truly listening to patients and family members is essential to provide safe and appropriate care. This feedback validated that live storytelling by patients and/or family members is an effective method to explore the human experience of care. As a result, the session has been permanently integrated into the regional standard curriculum for the medical resident communications training course since 2012.

The successful integration of the live storytelling session into the residents' communication course is due to the resolve and determination of Ms. Katrine Kirk, who experienced an adverse event herself, and the Danish PFPS network to

transform their personal stories of unsafe care into learning opportunities coupled with the receptiveness of the Head of Training and the Curriculum Coordinator for residents in the capital region of Denmark who valued the inclusion of patient storytellers as viable “teachers” for medical residents. Together they thoughtfully structured the storytelling session to optimize resident learning while reducing concerns of those instructors trained in traditional, evidence-based teaching methods. Another factor of the success of the adoption of the storytelling course was the ongoing support and capacity building for the PFPS Champions that included presentations skills training offered by the Danish Society for Patient Safety. It was critical for the PFPS Champions to learn how to constructively craft and share their stories in a way that would result in meaningful learning for the residents without being perceived as adversarial. The Danish PFPS Network hopes to spread the idea of patient storytelling in communications training to the rest of Denmark and to systematically analyze the long-term impact and effectiveness.

6.6 Co-production in Healthcare Organization Quality Improvement

Hospitals are increasingly recognizing the crucial role of patients' perspectives in establishing a culture of safety. Many institutions have prioritized engaging patient representatives in the design and nurturing of safety efforts and emphasize transparency in reporting errors and care problems [30].

6.6.1 Example: Egypt

6.6.1.1 Improving Disparities in Care for New Mothers: The Power of Partnership Between a Civil Society Leader and a Public Teaching Hospital

There were significant disparities between the level of care provided to women delivering babies in Cairo at the public maternity teaching hospital versus the private hospital. An Egyptian

member of The Red Crescent, a civil society organization, Nagwa Metwally, now a PFPS champion, along with other concerned community members believed that by integrating local volunteer citizens into the hospital system to observe and document quality and safety issues would help improve the quality of care and experiences of mothers at the public maternity teaching hospital [31]. Ms. Metwally met with the Dean of the medical schools and described the mission of the proposed quality improvement project. She later met with the Director of the public teaching maternity hospital. During this meeting, she thoughtfully and strategically described the envisioned quality improvement project and positioned the project as an “offer to help” and an opportunity for collaboration. This resulted in a partnership at the public maternity teaching hospital that embedded citizen volunteers in the hospital to help improve quality hospital services through observation. The goals of the project included (1) change the culture to be more patient centered; (2) ensure dignity and proper treatment for mothers; (3) create a safe environment in which mothers felt they could share their preferences and request and receive parent education; and (4) provide capacity building to the healthcare team, especially nurses, for the provision of safer and more compassionate care for the new mothers. Ms. Metwally and citizen volunteers joined the hospital team as observers to serve as an “extra set of eyes” to identify and record issues related to the WHO’s Global Patient Safety Challenges [24–26] and the WHO’s patient safety curriculum, which included hospital cleanliness, safe surgery, healthcare provider behavior, glove use, hand hygiene practices, staff and patient interaction, and other safety issues. Over 50 citizen volunteers and some residents served as observers conducting walking “tours” within the hospital noting and documenting safety and care concerns which they would later share with the Director of the hospital for consideration for improvement efforts.

Successes of the quality improvement project included the acceptance of these citizen observ-

ers as part of the hospital team as well as meaningful hospital-level policy changes. For example, policy change affected the hospital’s promotion policy for nurses. The criteria for promotion are now based on efficiency, skill, and education rather than seniority only. The hospital also implemented a new evaluation criterion for medical residents to advance to medical doctors. The medical school adopted a doctor/patient relationship skills evaluation as part of the clinical skills final examination that medical residents must take to become doctors. In addition, there was an overall increase in awareness of patient safety issues, improved hospital cleanliness, as well as a greater use of gloves and hand hygiene practices [32]. The success of the quality improvement in the maternity hospital enabled Ms. Metwally to co-produce similar quality improvement projects in geriatrics and emergency hospitals.

Numerous factors contributed to the success of this co-produced quality improvement effort at the public maternity teaching hospital. The resolve and profound humanitarian commitment by Ms. Metwally and the Red Crescent of which she was a member, was crucial to highlighting the need to improve the equity, patient centeredness, and patient safety for new mothers in the community. Having the backing of a credible, trustworthy civil society organization helped facilitate the connection with the leaders of the medical schools and the hospital. Furthermore, framing the quality improvement project as a “way to help out” as well as demonstrating empathy by acknowledging the challenges that the public hospital faced was key to developing a trusting, respectful collaborative relationship. The willingness of the Dean of the medical schools and the Director of the maternity hospital to partner with Ms. Metwally, the Red Crescent and citizen volunteers to implement an innovative approach to quality improvement demonstrated the courage, humility, integrity, and open-mindedness needed from strong leadership to realize the benefits of this type of collaboration. Despite the fact that none of the partners in this active collaboration had previous training in implementing a co-produced quality improve-

ment project such as this, they were resourceful and successful because of their trust in each other and in the belief that their mutual goal was in the best interest of all involved, was patient centered and improved safety and quality.

6.6.2 Italy

6.6.2.1 Democratizing Healthcare: A Government-Driven/Citizen Partnership to Improve Patient Centeredness

The Italian National Agency for Regional Health (AGENAS) launched a government-driven healthcare organization quality improvement project co-produced with civil society organizations and citizens. The national program was aimed at evaluating and improving the level of patient centeredness in public and private hospitals throughout the country. AGENAS developed an innovative participatory evaluation methodology. The methodology was coordinated by AGENAS and carried out in cooperation with the Active Citizenship Network and the Italian Regions. AGENAS trained teams of healthcare professionals and citizens to go on site visits in public and private hospitals. During the site visits, these teams completed a checklist comprised of 142 items exploring four areas of interest: person-oriented processes, physical accessibility and comfort, access to information and transparency, and patient–professional relationships. Following the site visits, the data was collected and sent to a National Database where it was analyzed and sent back to the regions, hospitals, and teams for local public dissemination. Improvement plans were jointly identified and carried out by hospital professionals and citizens. A Plan-Do-Check-Act process was then carried out by local teams. Over 400 accredited public and private hospitals participated in this national evaluation. Site visits were made by the trained teams comprised of approximately 600 health professionals, 300 citizen associations, and 700 citizens. The overall results of the project indicate a moderately high level of person centered-

ness, especially in the larger hospitals [33]. Where new assessments have been carried out in 2019, there have been significant reports of improvements in all four areas of interest. This Italian national program has shown the effectiveness of co-production of a quality improvement initiative that actively engaged organizations, professionals, and citizens to promote patient centeredness.

A major component of success of the national program to improve person centeredness was the strong leadership at AGENAS that was dedicated to and valued the inclusion of citizens as partners in the quality improvement initiative. Examples of this included actively engaging citizens in all phases of the assessment and improvement cycle, as well as providing feedback and publicly disseminating project results. Another component of success was the strategic partnerships that AGENAS developed to maximize outreach to the citizen community. They formed strong alliances with the regional governments and health agencies and partnered with Active Citizenship Network, the association with the widest expertise in the civic evaluation of quality of health. A further component of success was the national program's commitment to providing training and capacity building to the citizens and other participants to optimize engagement by developing joint training on materials and tools of the participatory assessment of person centeredness. The participatory evaluation methods and tools were then applied to assess patient safety. The success of the national program has led to further implementations of this type of active collaboration between government, healthcare professionals, civil society organizations, and citizens to co-produce healthcare organization quality improvement projects.

6.7 Co-Production in Policy

Patient and family engagement in policy development has gained increasing recognition. For example, patients can be engaged in the development and dissemination of tools, information and educational materials [20].

6.7.1 Example: Canada

6.7.1.1 Working from Within: Co-producing National Policy as an Insider

In Canada, unintended patient harm occurs every 1 min and 18 s throughout the healthcare system, with a death resulting every 13 min and 14 s. To address this growing concern, Patients for Patient Safety Canada (PFPS) [34], a patient program under the Canadian Patient Safety Institute (CPSI) [35], a publicly funded, not for profit corporation and designated WHO Collaborating Centre in Patient Safety and Patient Engagement, has co-produced seminal documents that influence policy at the national level on patient safety. These include the Canadian Disclosure Guidelines [36], Canadian Incident Analysis Framework [37], Engaging Patients in Patient Safety—a Canadian Guide [38], and Five Questions to Ask About Your Medications [39].

More recently, PFPS was engaged in the co-production of the Canadian Quality and Patient Safety (CQPS) Framework, a joint initiative between CPSI and the Health Standards Organization (HSO) [40]. The framework was designed by a multi-stakeholder Advisory Committee, including patient and family members of PFPS, with the specific aim to “establish consensus on quality and patient safety goals for health and social services to focus action and resources that improve patient experience and outcomes and reduce care variation” [41].

Members of PFPS have been active participants in the development and socialization of the CQPS Framework from the outset, as equal players, and regarded as experts through their lived experience and patient advocacy. PFPS Co-Chairs served on the governance Steering Committee and Evaluation Working Group. An independent public affairs firm was commissioned to provide public consultation; an opportunity for all stakeholder groups to provide input into the CQPS Framework. This independent evaluation demonstrated that collective impact initiatives, co-designed and co-led by patients as authentic partners, can be transformational. This collaborative work will continue as the

Framework is implemented, adopted by health systems, and as its impact is evaluated.

The success of PFPS and CPSI and the co-production of patient safety policy improvement efforts is largely due to the integration PFPS into the organizational structure of CPSI as well as the trust and respect that has been developed by having a shared commitment to patient safety and healthcare system improvement.

CPSI made patient engagement a strategic priority and supported the development of a Canadian network of patients and family members which resulted in the formation of PFPS. CPSI assigned a budget and staff to support PFPS and patient engagement. CPSI partners with PFPS in all of its programs, committees, and corporate initiatives, including executive recruitment and strategic planning. This structure is mutually beneficial in that it allows PFPS to leverage CPSI resources, corporate functions and staff expertise and time, and it provides PFPS credibility, increasing their opportunities to integrate the perspective of the patient community into national patient safety improvement efforts. Alternatively, CPSI, benefits from PFPS participation as subject matter experts with lived experience of harm from unsafe care on which to base patient safety policy.

The leadership and patient-centered culture of CPSI were fundamental building blocks for successful partnership and integration of patients into the work of the Institute. Equally, the tenacity of the PFPS patients and family members in advocating for patient needs and the willingness to adapt within a structured environment were necessary for sustainability and co-production of seminal documents and policy projects.

6.8 Conclusion

Patient safety is a growing global concern. Parents, daughters, sons, siblings, other family members, community members, and our dear friends are harmed unnecessarily from unsafe care. It is essential that all stakeholders, especially those who have suffered from adverse

events, have the opportunity to actively collaborate in co-producing patient safety solutions. Those who have experienced adverse events identify gaps in safety and quality and offer wisdom, data, and stories unavailable through traditional sources. Each of these case studies illustrates the power and potential of co-production with patients, families, and communities in research, medical professions education, healthcare quality improvement and policy. Each is different in scope, structure, and purpose and engage different stakeholders at different levels yet they all highlight the necessary building blocks for co-production of patient safety initiatives and each responds to the call made in the London Declaration, the WHO PFPS Programme, and the WHA to place patients at the center of efforts to improve patient safety.

The building blocks include:

1. **Dedicated, resilient patient, family, and community members** who have directly or indirectly experienced unsafe care yet are willing to partner with healthcare decision-makers and learn how to navigate the complexities, structures and limitations of different healthcare systems. They have become accomplished storytellers, networkers and connectors and have gained appreciation of the many challenges that healthcare providers and leaders face while remaining unwilling to accept the status quo.
2. **Courageous, passionate healthcare leaders** with the moral imperative to integrate the patient/citizen community into patient safety improvement efforts. These leaders are visionaries who visibly demonstrate their commitment to listen and learn from others. They value the input from others as highly as their own and integrate what they learn into governance, missions and strategies that promote patient involvement. They hard-wire the necessary resources to overcome political, cultural and financial barriers into budgets and infrastructures that support patient participation.
3. **Capacity building opportunities**
 - **for patients, families and communities** to help them develop the skills to effectively share their personal stories of unsafe care that captures the hearts and minds, builds trust and prompts action from the audiences and to have productive dialogue with healthcare leaders including policy makers, researchers, medical educators and quality improvement experts,
 - **for healthcare professionals and leaders** to learn how to utilize effective patient-centered methods to collaborate, communicate with, listen to and engage with patients, families and community members in a democratic way.
4. **Structure** that establishes how patients, families and communities operate to obtain their goals. There is no one structure that is considered the gold standard for the organization of patients, families and communities. Structures may be formal or informal. Informal structures tend to be loosely organized, autonomous, volunteer patient networks that collaborate with healthcare professionals, leaders and organizations. More formal structures tend to be established patient organizations and associations which operate independently from the healthcare system or government such as civil society organizations. Finally, there are publicly funded structures that embed patients, family and community members into their strategic plans, budgets and activities necessary to achieve organizational goals. Whether formal or informal, it is essential that the structure preserves the values, preferences and outcomes that matter most to patients, families and communities and that these serve as overarching principles that guide the actions and priorities of the safety initiatives. It is also important that the structure facilitates access for patients, families and community members to healthcare decision-makers as well as financial and human resources to systematically analyze the outcomes of co-produced safety initiatives to improve, scale and spread, or disseminate the benefits of implementation and to ensure sustainability.

All stakeholders must accept, value, and support meaningful patient engagement in the co-production of our efforts to improve patient safety including in the design of research, medical education, policy making, and healthcare organization quality improvement.

We must continue to strive to democratize our healthcare. We “must have a powerful voice and role in the decisions and systems that affect... [our] health, and... [be given the] tools that help... [us] to become far more actively engaged... health professionals and institutions must value social equity and the individual in the context of community” [42]. I know this because I have lived it and witnessed the successes.

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