“If it is not safe, it is not care”[1]

«Less harm, better care – from Resolution to Implementation»

Authors:

Denise Astill, Executive Officer, Foetal Anti-Convulsant Syndrome NZ

Jacqueline (Jacki) Morris, Chairperson, Foetal Anti-Convulsant Syndrome NZ

[1] Dr Tedros Adhanom Ghebreyesus Director-General of the World Health Organization

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Introduction

In 2015-2016 the United Kingdom's Department of Health and the German Federal Ministry of Health joined efforts to initiate a series of annual Global Ministerial Summits dedicated to Patient Safety. The Summit series ultimately aims to generate and promote a global movement for patient safety.

In 2021, the 74th World Health Assembly (WHA) adopted the first ever Global Patient Safety Plan 2021-2030 "Towards eliminating avoidable harm in health care". This WHA decision also mandates the World Health Organization (WHO) to report back on progress in the implementation of the action plan to the assembly in 2023 and thereafter every two years till 2031.

The Fifth Global Ministerial Summit on Patient Safety in 2023 was held in Montreux, Switzerland from 23-24 February. This was delayed from previous years due to the disruptions caused by the COVID-19 pandemic. There were more than 600 participants, with just over 80 countries represented (including Ministers of Health, or their representatives), as well as representatives from OECD, NGO's, patient groups, tertiary providers and various medical professionals.

Please note that whilst we FACSNZ are referring to patients in this report due to terminology used by the World Health Organization, FACSNZ actually identifies with the term consumer.

Acknowledgements

We would like to thank the Lottery Minister’s Discretionary Fund for providing some funding to go towards attending the 5th Global Ministerial Summit 2023, on Patient Safety, in Montreux.

We acknowledge the board of Foetal Anti-Convulsant Syndrome NZ for their support provided to attend this Summit.

We would also like to thank Jan Logie, List member, Green Party for providing written support on FACSNZ attending this Summit.

Acronyms

eHR	Electronic Health Record
FACS	Fetal Anticonvulsant Syndrome
FACSNZ	Foetal Anti-Convulsant Syndrome New Zealand
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
WHA	World Health Assembly
WHO	World Health Organization
MFDS	Ministry of Food and Drug Safety (Korea)

Recommendations from FACSNZ

1. Establishment of a Pregnancy Register
2. Active Post-Marketing Surveillance System- at present in New Zealand we have a passive reporting system.

   With an active post-marketing surveillance system live, real-world data can be used to generate medication safety information and not rely on individuals to initiate adverse event reports. It will identify early warning red flags before bigger harm occurs.

3. Teratogenic department within Manatū Hauora Ministry of Health, that works cross-sectorally.

   Having a teratogenic department separate from the regulator allows for thorough, accountable, transparent work to occur that can identify and produce appropriate interdisciplinary and cross-sector work that must occur. It means that proactive rather than reactive work can happen, ensuring less people are harmed, and more economically sound, and early red flags can be brought into work streams that come for the active post-marketing surveillance. It can also provide a lifelong (if not intergenerational) approach to those already harmed by teratogenic agents whether it be medicine, devices, environmental, drug, or alcohol.

4. Denise Astill and Jacki Morris, be funded by the Government to attend the 6th Global Ministerial Summit 2024 to enable continued dialogue, and carry the Minister of Health's message.

   Denise and Jacki have already demonstrated their expertise at an international level with their meeting in 2019 at the World Health Organization, in Geneva, resulting in a global change for people of child

bearing potential on sodium valproate. (https://www.who.int/news/item/02-05-2023-use-of-valproic-acid-in-women-and-girls-of-childbearing-potential and https://cdn.who.int/media/docs/default-source/brain-health/mhgap_ig_v4_0(08032022).pdf?sfvrsn=696f27df_21)

Without funding it is not financially sustainable for Denise and Jacki to attend. Additionally New Zealand has not had ministerial/Government representation at any previous Summits and it is essential to have New Zealand representation.

5. Manatū Hauora/Ministry of Health, ACC, and Te Tohau Hauora, Hauātanga/HDC to sign the Te tikanga mō te mahi tahi a ngā hinonga hauora ki ngā kiritaki me ngā whānau/Code of expectations for health entities' engagement with consumers and whānau.

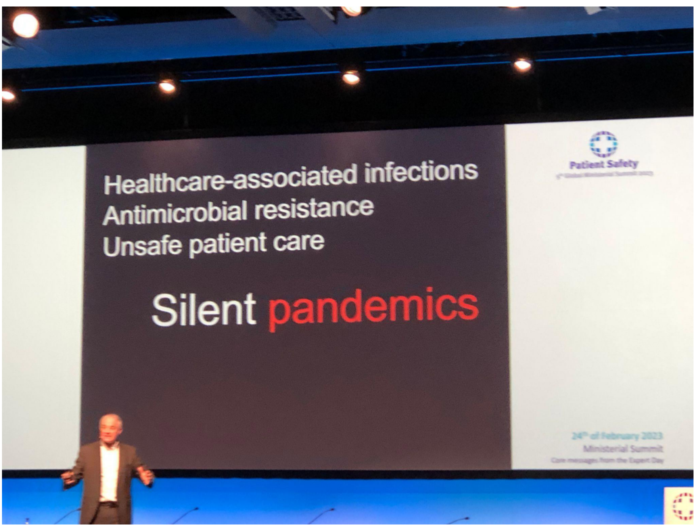
   With having Manatū Hauora/Ministry of Health, ACC, and Te Tohau Hauora, Hauātanga/HDC sign the Te tikanga mō te mahi tahi a ngā hinonga hauora ki ngā kiritaki me ngā whānau/Code of expectations for health entities' engagement with consumers and whānau, it shows commitment that consumers and whānau will always be around every table and co-designing. It is easy to say that the intent is there, but without signing The Code there is no accountability to adhere to it. This is why secondary legislation is essential to ensure that The Code will be adhered to by Manatū Hauora/Ministry of Health, ACC, and Te Tohau Hauora, Hauātanga/HDC.

6. Start work, or continue to work on the Framework for Action, Global Patient Safety Action Plan 2021-2030, with the inclusion of consumers/experts by experience. Denise Astill and Jacki Morris would like to offer their experts by experience knowledge and co-design with the appropriate agencies.

It is essential for New Zealand to advance towards zero harm occurring, and that the Framework from the Global Patient Safety Action Plan is the way forward. As per The Code mentioned above, Denise and Jacki are part of the solution as they are experts by experience, and come with a wealth of knowledge.

2019 World Health Organization

Silent Pandemics



Prof. Didier Pittet (WHO)

We need to acknowledge the fact that we have silent pandemics occurring which need to be addressed with urgency. These silent pandemics are:

- Healthcare-associated infections
- Antimicrobial resistance
- Unsafe patient care

"If it is not safe, it is not care" Dr Tedros Adhanom Ghebreyesus, Director-General, World Health Organization, during his keynote speech at the Summit.

The World Health Organization acknowledges that one patient being harmed is one too many.

It was also stated during the Summit that other healthcare areas must not be ignored during a crisis/pandemic.

Thailand, as an example have continued to work on the Global Patient Safety Action Plan 2021-2030, using safety precautions e.g. they met outside, with appropriate spacing between each person and masked up. Dr Piyawan Limpanyalert, Chief Executive Officer, The Healthcare Accreditation Institute, Thailand, presented at the Summit using the graphic from the Global Patient Safety Action Plan 2021-2030, and outlined the areas that they were currently working on and the areas they are yet to work on. It was clear and concise, and indicated that Thailand is definitely working towards achieving all of the “Framework for Action - The 7x5 Matrix”.

The question arises, where is New Zealand on achieving the strategies outlined in the “Framework for Action”?

Dr Piyawan Limpanyalert (Health Accreditation Institute - Thailand), Denise Astill and Jacki Morris (FACSNZ)

Global Safety Action Plan 2021-2030

The Global Safety Action Plan is a road map that everyone should use, and one that New Zealand has signed up to. Patient safety is one of the most important components of healthcare. We will only achieve this by moving forward together. Community engagement is a cornerstone to patient safety. It must be patient centred, where patients are part of the design.

“Patients and families should be involved at every level of health care, ranging from policy-making and planning, to performance oversight, to fully informed consent and shared decision-making at the point of care.” [2]

If we look at New Zealand we have Te tikanga mō te mahi tahi a ngā hinonga hauora ki ngā kiritaki me ngā whānau/Code of expectations for health entities’ engagement with consumers and whānau, whilst it was set up with the best of intentions, we can already identify flaws. For example Manatū Hauora/Ministry of Health, ACC, and Te Tohau Hauora, Hauātanga/HDC, who are integrated in our health and disability system, have not signed up to the code. Whilst in principal this could be due to legislation, there is no reason why these entities could not sign under secondary legislation. This is something that The Health Consumer Advocacy Alliance (CAA) have been discussing with all the parties listed above.

Patient Safety will be an upcoming agenda item at the World Health Organization’s G7 and G20 meetings.

[2] Global Patient Safety Action Plan

Framework for Action - The 7x5 Matrix

	Strategic objective					
1	Policies to eliminate avoidable harm in health care	1.1 Patient safety policy, strategy and implementation framework	1.2 Resource mobilization and allocation	1.3 Protective legislative measures	1.4 Safety standards, regulation and accreditation	1.5 World Patient Safety Day and Global Patient Safety Challenges
2	High-reliability systems	2.1 Transparency, openness and No blame culture	2.2 Good governance for the health care system	2.3 Leadership capacity for clinical and managerial functions	2.4 Human factors/ ergonomics for health systems resilience	2.5 Patient safety in emergencies and settings of extreme adversity
3	Safety of clinical processes	3.1 Safety of risk-prone clinical procedures	3.2 Global Patient Safety Challenge: *Medication Without Harm*	3.3 Infection prevention and control & antimicrobial resistance	3.4 Safety of medical devices, medicines, blood and vaccines	3.5 Patient safety in primary care and transitions of care
4	Patient and family engagement	4.1 Co-development of policies and programmes with patients	4.2 Learning from patient experience for safety improvement	4.3 Patient advocates and patient safety champions	4.4 Patient safety incident disclosure to victims	4.5 Information and education to patients and families
5	Health worker education, skills and safety	5.1 Patient safety in professional education and training	5.2 Centres of excellence for patient safety education and training	5.3 Patient safety competencies as regulatory requirements	5.4 Linking patient safety with appraisal system of health workers	5.5 Safe working environment for health workers
6	Information, research and risk management	6.1 Patient safety incident reporting and learning systems	6.2 Patient safety information systems	6.3 Patient safety surveillance systems	6.4 Patient safety research programmes	6.5 Digital technology for patient safety
7	Synergy, partnership and solidarity	7.1 Stakeholders engagement	7.2 Common understanding and shared commitment	7.3 Patient safety networks and collaboration	7.4 Cross geographical and multisectoral initiatives for patient safety	7.5 Alignment with technical programmes and initiatives

Investment into patient safety offers an economic return

Medication related harms and errors are not rare events and have significant economic impacts. The OECD has estimated the total cost in OECD countries to be USD 54 billion annually.

Despite increasing awareness of medication safety issues over the last two decades, progress in improving medicine use has stalled. Healthcare systems generally lack robust mechanisms to measure medication safety events. There remains limited investment in harmonising these measures and creating infrastructure interventions for improving medication safety.

Health data infrastructure and monitoring systems to ensure safe medication use have not kept up with the demands placed on systems as medication use has proliferated. This in turn can lead to compounding harms.

Patient perspectives are critical to make health systems more safe and people-centred - and patients are a key source of information about the prevalence of medication-related harms.

Jacki Morris, Katherine de Bienassis (OECD), Niek Klazinga (OECD)

Recommendations to Improve Medication Safety:

Sir Liam Donaldson, Patient Safety Envoy, WHO

Before we can make recommendations we need to acknowledge that no news is not necessarily good news, meaning that just because there aren't adverse effects/harm being reported does not mean it isn't occurring. In fact we can go further by saying that not only is history repeating itself but the same harm is happening to different people in different places. Rather than hoping for zero we need to plan for zero preventable deaths.

<u>How to work towards improving medication safety:</u>

- Enhance real-time information sharing and patient access to data

- Strengthen pharmacovigilance and medication utilisation review systems
- Capture patient experience of medication-related harms and medication side-effects
- Build on the expanded roles of pharmacies and pharmacists
- Promote good prescribing practices and invest in ePrescribing systems
- Evaluate and calibrate the implementation of new medication safety strategies
- Be transparent publicly about how many errors have occurred.

Post-Marketing Surveillance - Passive vs Active

Centre for Adverse Reactions Monitoring (CARM) is the New Zealand database which provides information on adverse reactions to medications and vaccines. It is a purely voluntary reporting system, therefore leading to significant limitations. It is a passive post-marketing surveillance system and, for example, was not designed for reporting of adverse medication reactions to babies in utero.

Countries are moving to active post-marketing surveillance. These are designed specifically to use real-world data to generate medication safety information and do not rely on individuals to initiate adverse event reports. The United States FDA Sentinel Initiative (https://www.sentinelinitiative.org/), is one such programme. It is a national electronic system for monitoring medical products, including medicines, vaccines and medical devices. It gathers information from multiple sources (i.e. eHR systems, administrative data and insurance claim records). The Sentinel programme is now expanding, for example to studying the effects of switching between branded and generic medicines, and to the surveillance of the safety of medical devices.

Countries are also moving towards patient-focused medication safety initiatives. This involves education and access to medication information, patient-reported experiences and targeted interventions to populations. One example of this is Korea's 'knowing medicine correctly' project by MFDS. The project was initiated to increase the public's understanding of medications. It is continuously providing medication safety education for children, adolescents, pregnant women, and older adults.

Disability
Less Harm
Cultural Diversity
Engaging Patients
Trust
Challenges
Community
Safe Prescribing
Proactive
Patient Safety
Equity
Solutions
Patient Centred
Best for the Patient
Investment
Work Together
Better Care
Preventable
Transparency
Safe Procedures
Adapt to Adopt
Kindness
Elimination of Harm

Montreux Charter on Patient Safety –

“Less Harm, Better Care – from Resolution to Implementation”

Launched at the “5th Global Ministerial Summit on Patient Safety”

24 February 2023, Montreux, Switzerland

Context

Ministers, high-level representatives and distinguished experts from all over the world gathered in Montreux on 23 and 24 February 2023 in order to advance their joint endeavour of strengthening Patient Safety globally. They discussed achievements, challenges, priorities and necessary points of action.

The summit marked another key milestone for global developments in Patient Safety.

The Ministers and other participants reaffirmed that patient harm in health care is an urgent public health issue, pertinent to countries of all income settings and geographies and therefore a shared global challenge. Patient Safety is essential for the achievement of universal health coverage and global health security.

Previous achievements

Ministers acknowledged that, in the past decade, significant progress has been achieved. This includes the preceding Global Ministerial Summits on Patient Safety which have raised awareness about the burden of avoidable patient harm in health care and fostered strategic approaches to strengthening Patient Safety.

Past summits contributed in different ways:

- The first summit in London in 2016 served as the springboard for the summit series, initiating a pivotal high-level dialogue between Ministers and other key stakeholders about strengthening Patient Safety globally including through aligning policy and financial systems;

- The second summit in Bonn in 2017 univocally called for establishing a World Patient Safety Day, highlighted economic aspects of patient safety and launched the "3rd WHO Global Patient Safety Challenge: Medication Without Harm";

- The third summit in Tokyo in 2018 positioned Patient Safety as a component of universal health coverage and called for "high level political momentum" towards the delivery of safer care everywhere;

- The fourth summit in Jeddah in 2019 put low- and middle-income countries, who face the most significant proportion of the global burden of harm, prominently on the radar and highlighted the importance of sharing lessons learned and building strategic partnerships.

Ministers also emphasised the importance of the WHO's Global Patient Safety Action Plan 2021-2030 that is providing a comprehensive ten-year roadmap for strengthening Patient Safety. Furthermore, they acknowledged important national and international initiatives and the commitment and tireless work of numerous stakeholders around the world.

Spirit of the “5th Global Ministerial Summit on Patient Safety”

The 5th Global Ministerial Summit on Patient Safety in Montreux was defined by its slogan “Less Harm, Better Care – from Resolution to Implementation”. The Summit served as a catalyst for all countries to focus on narrowing implementation gaps in Patient Safety.

Ministerial debate

The Ministerial debate showed a consensus that:

- Despite progress made so far to address patient safety challenges worldwide, more effort is needed if all patients are to receive tailored care that is safe and of high quality;

- Lessons learned from the COVID-19 crisis hold huge potential to build more resilient health systems and maintain safe and high-quality care, whereby Patient Safety is an essential component;

- The “knowledge gap” in Patient Safety is decreasing; thus, time is ripe to reduce the “implementation gap”;

- Interventions to improve Patient Safety are only effective if they are implemented comprehensively and on a sustained basis with appropriate oversight arrangements;

- Patient Safety interventions need to be implemented in a way that leads to beneficial outcomes for patients;

- Global collaboration, mutual learning and coordination of efforts are crucial and should be underpinned by governance at a global level.

Action points

Participants identified significant action points for Ministers, high-level policy makers and experts from all around the world as follows:

1. Treat Patient Safety as a global public health priority by strengthening implementation of Patient Safety strategies, policies and interventions;

2. Build upon the lessons learned from the COVID-19 pandemic in actions and initiatives to strengthen Patient Safety, such as infection prevention and control and emergency human resources for health care workers. In the context of pandemic preparedness and response as well as building resilient health systems, it is essential to also focus on securing Patient Safety;

3. Deepen partnerships and collaboration on Patient Safety and mutual learning globally across a wide range of sectors, institutions and organisations;

4. Deliver against existing initiatives and actions, namely implementing WHO's "Global Patient Safety Action Plan 2021-2030" as well as ensuring the continued effectiveness of the series of "Global Ministerial Summits on Patient Safety";

5. Ensure adequate governance frameworks at international and national levels, encompassing all health sectors and settings, and defining clear lines of accountability and responsibilities of relevant stakeholders at all levels (political, financial, educational, patient, public);

6. Reinforce a safety learning culture and transparency while promoting public trust across all health care services among all stakeholders, including patients and the public;

7. Plan for sustainability; including building sustainable leadership and human resource capacities, by investing in education and training at all levels and for all

healthcare professions, since implementing Patient Safety is a long-term commitment;

8. Engage and empower patients, families and caregivers in care delivery as well as solutions to advance Patient Safety and reduce avoidable harm in health care;

9. Set appropriate priorities for Patient Safety such as medication safety, infection prevention and control and antimicrobial resistance (e.g. access and excessive antibiotic use);

10. Promote, encourage and support implementation science and research.

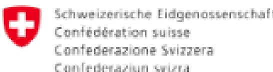
Next steps

Ministers reaffirmed their willingness to continue their close cooperation on strengthening Patient Safety, in the context of the “Global Ministerial Summits on Patient Safety” and in the framework of other inter-national initiatives. They look forward to participating in future editions of the “Global Ministerial Summit on Patient Safety”.

Montreux, Switzerland, 24 February 2023

Written Statements by NGOs

Statement to the Summit by Foetal Anticonvulsant Syndrome NZ:



Swiss Confederation

Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH

Name of the Institution: Foetal Anti-Convulsant Syndrome New Zealand
Signed by: Denise Astill and Jacqueline Morris; www.facsnz.com

Statement

Experts by experience

There are and continue to be systemic failures that people of childbearing potential have and continue to experience in the prescribing of anti-seizure and teratogenic medicines. These failures are causing death or permanent disability to babies that are exposed in utero. This has continued over the last 60 years. Does the international community have the appetite to address this? It has been acknowledged that sodium valproate exposure in pregnancy is bigger than the thalidomide scandal.

The international community has a moral obligation to ensure all people of childbearing potential that are on an anti-seizure/teratogenic medicine receive informed consent and informed choice. Without doing so compounded harm and trauma becomes not only an individual component but an intergenerational one, particularly for women.

The negative social and economic impacts, by not doing so, continues to place a burden on the health and disability systems worldwide.

Whilst it is pleasing to see the World Health Organization address epilepsy through their Intersectoral global action plan, and are aware that anti-seizure medicines are an essential medicine, it is disappointing that the WHO have not prioritised anti-seizure medicine use in pregnancy. So we call to action the World Health Organization to research and publish a technical brief to prioritise the safe prescribing of anti-seizure medicines during pregnancy, including informed consent and informed choice.

NGO's and advocacy groups should not have to be fighting for change, instead they should bearound the table at every level as the Global Patient Safety Plan intended, and be treated as experts by experience.

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OECD (2022), The economics of medication safety: Improving medication safety through collective, real-time learning

https://dx.doi.org/10.1787/9a933261-en

New Zealand Pharmacovigilance Centre

https://nzphvc.otago.ac.nz/carm/

Montreux Charter on Patient Safety - "Less Harm, Better Care - from Resolution to Implementation" *Launched at the 5th Global Ministerial Summit on Patient Safety, 24 February 2023, Montreux, Switzerland*

https://pss2023.ch/wp-content/uploads/2023/03/Montreux_Charter_Patient_Safety_Summit_2023.pdf

Te Tāhū Hauora/Health Quality and Safety Commission, Te tikanga mō te mahi tahi a ngā hinonga hauora ki ngā kiritaki me ngā whānau/Code of expectations for health entities' engagement with consumers and whānau

https://www.hqsc.govt.nz/consumer-hub/engaging-consumers-and-whanau/code-of-expectations-for-health-entities-engagement-with-consumers-and-whanau/

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https://pss2023.ch/wp-content/uploads/2023/03/Written-Statements-by-NGOs_PSS2023.pdf