HQ1457 – Systems Thinking Analysis to Prevent Fetal Anticonvulsant Syndrome (FACS)

Prepared for
Caroline Tilah
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Provided by:
Karl Bridges
HFEx Ltd

Executive summary

This report delivers on the requirement of the Health Quality & Safety Commission New Zealand (HQSC)[1] to conduct a systems thinking analysis to prevent fetal anticonvulsant syndrome (FACS). HFEx Ltd conducted a system-wide assessment concerning the management of medicines with teratogenic effects to identify opportunities for improvement and potential threats to safe medication administration. The project involved interviewing a range of stakeholders (n=19) to understand their roles and responsibilities associated with FACS prevention. Using the data, a Systems Theoretic Process Analysis (STPA) was conducted and enabled the opportunity to identify potential situations where the governance of teratogenic medication is challenged. The project details responsibilities for each agency involved and concludes with recommendations associated with communications, patient safety and quality of care.

The overarching concern from the systems thinking analysis appears to indicate no clear governance by organisations relating to safety and consumer wellbeing when prescribing teratogenic medication.

[1] While it is customary to refer to the HQSC as 'the commission', we have decide to not to do so in this report due to the need to ensure no readers get confused with the Health Disability Commission, which is also referred to in the report.

Contributors to the report

Dr Karl Bridges, BSc (Hons) MSc PhD CNZHFE C.ErgHF FCIEHF
Director, HFEx Ltd
Karl is director of HFEx Ltd – Investigating, analysing and preventing human error. Karl has 20+ years experience of working in psychology with 15+ years in human factors working across government, transport, utilities, healthcare, defence, IT and academia.

Version control

Date	Version	Name	Comments
17/12/2021	0.1	Karl Bridges	Initial draft provided
20/12/2021	0.2	Karl Bridges	Minor additions concerning: • Explanation of arrows for hierarchical control structure (fig. 3) • Correction of terminology in HCS (app. 4) • Minor tweaks to some terminology concerning HQSC • Added a loss scenario concerning communications (ref to step 7 – What are the loss scenarios?)
04/01/2022	0.3	Karl Bridges	Changes made following HQSC review
18/01/2021	1.0	Karl Bridges	Finalise the report for presentation to stakeholders

Contents

Introduction

Background

Some medications prescribed for epilepsy, bipolar affective disorder and chronic pain have teratogenic side effects, resulting in an increased risk of congenital disabilities, such as spina bifida, heart/organ defects, cleft palate, spectrum learning disorders or stillbirth. Fetal anticonvulsant syndrome (FACS) occurs when the medication crosses the placenta into the developing foetus, often during the highest risk period (first trimester) of pregnancy.

The Accident Compensation Corporation (ACC) have indicated that while there is generally a 2–3% risk of babies being born with malformations, this risk increases to 24% when the mother is exposed to teratogenic medications[2]. Likewise, the risk of autism or learning difficulties increases from 2–7% to 30–40%[3].[4]

The most concerning medications are sodium valproate, carbamazepine, topiramate, phenytoin, hydantoin and primidone[5]. Organisations such as the Centre for Adverse Reactions Monitoring (CARM) began monitoring adverse reactions to medicines in the wake of the thalidomide crisis[6]. Even so, people of childbearing potential are still prescribed these risky medications – in some cases, with little or no knowledge of their teratogenic effects.

In response, many charitable, legislative and healthcare professional-led initiatives have raised awareness of the risks. Many organisations are already cognisant of the issues, with some healthcare specialists proactively guiding consumers away from high-risk medications. However, the challenge for many is that irrespective of the dangers, most of these medications are highly effective in managing the consumer's neurological, physical or mental health issues. Further challenging the prevalence of these medications, is that consumers do not tend to stay with a single health practitioner. Not everyone sees their GP frequently, if at all. Some live in isolated communities, change their surnames over time or lead transient lives. As a result, keeping track of a consumer who is taking a high-risk medication often becomes extremely difficult.

For example[7], a pre-pubescent female diagnosed with epilepsy may be prescribed sodium valproate. With parents working through the emotional impact of their daughter having seizures, discussing the

[2] For example, 1,500 mg or more of sodium valproate.
[3] When exposed to more than 800 mg of sodium valproate.
[4] ACC. (2020). *Medicines for Epilepsy, Mental Health, and Pain Can Harm Your Unborn Baby*. Wellington: ACC. (brochure).
[5] FACS NZ. (2021). *Addressing the Past, Present, and Future for People of Childbearing Potential on Anti-seizure Medicines*. Auckland: FACS NZ.
[6] Following the high numbers of birth defects because of abundant prescribing of thalidomide in the 1950s.
[7] Based on interview data collected during the development of this report.

dangers of the medication during pregnancy when the daughter reaches childbearing potential (maybe in quite a few years) is not likely to be high on the agenda. At the start, the risk of seizures and the implications for the daughter's life will be the focus. Once the medication has stabilised their epilepsy, this apparent risk diminishes, and the medication becomes 'background information'. As the daughter enters puberty, moves out of the family home, moves to a different area and changes their GP, one can see how easy it is for someone not to be considered high risk. As a result, the robustness of the healthcare system and the challenges it faces to keep track of the consumer and make visible the changing nature of risk over time will determine the level of health care provided.

Systems thinking methodologies

The healthcare system is large, making the sociotechnical relationship between people, processes and technology very complex, especially for consumers. Traditional methods of assessing complex sociotechnical systems are likely to struggle, given how the many departments, locales and governing bodies interact. For example, many industries choose the Swiss Cheese Model of accident causation[8] and Human Factors Analysis Classification System[9] (HFACS). However, the underlying philosophy advocates a linear approach to accident and incident causation. That is to say, the approach asserts a direct cause and effect from one sphere of influence (such as management decision-making) upon another (such as subordinate's actions) through the impacts of latent conditions and active failures (illustrated by layers of Swiss cheese full of holes).

The healthcare system appears to benefit from inter-organisational information sharing, including the derivation of policy and its interpretation in day-to-day practices. Unfortunately, the challenges that workers face due to their work environment (for example, rosters, workload, threat and error, communications and a vast array of complexity) have traditionally been overlooked, especially in the aftermath of an adverse event, leaving the workers at risk of making the same mistakes in the future. The very nature of healthcare being a complex and dynamic work environment should necessitate a methodology where the core principles are to tease out and lay bare the complexity and its impact on the worker. For example, illustrating and analysing dynamic and complex systems

[8] Developed by James Reason in 1990, this is a highly respected form of risk modelling that is commonly used for analysing medical errors and patient safety. The metaphor is based on the idea that hazards are prevented from causing harm to patients by a complex system of barriers with inconstant weaknesses – or holes – that open or close at random. When chance allows all holes or weaknesses to align, the hazard can reach the patient and cause harm.

[9] Shappell, S. A., Wiegmann, D. A., & United States. (2000). *The Human Factors Analysis and Classification System – HFACS: Final report*. Washington, DC: Office of Aviation Medicine, U.S. Dept. of Transportation, Federal Aviation Administration.

can be achieved by utilising the Functional Resonance Analysis Method (FRAM)[10]. However, FRAM focuses specifically on behaviour.[11] Whilst potentially being effective in analysing the behavioural decision-making of a healthcare practitioner, for example, the FRAM may not necessarily encapsulate the complexity of how policy afforded by the Ministry of Health translates into the practice of the healthcare worker.[12] In healthcare, there are statements associated with rules, regulations, risks and actions, which in turn assert control over what a worker can and cannot do. Some of this will be behavioural (when to administer medication, for example), and some of it will be process or cognitive related (not necessarily captured by a FRAM approach).

The FRAM approach may be helpful if focusing on the task of an individual or a department, however, given the broader scope of this project, it would result in a map of activity unfathomably large and challenging to comprehend. Therefore, it becomes important to consider more than just the behaviour and look deeper into the broader system. A tool favoured for taking this approach in healthcare is the Systems Engineering Initiative for Patient Safety (SEIPS)[13] approach.

SEIPS has enjoyed considerable exposure to healthcare systems analysis over the past 15 years. At face value, it appears to leverage many different approaches (SHELL, Safety II, systems thinking, task analysis, user experience, human-centred design), which is a testament to its strength. Most methods and models are an evolution of predecessor approaches, which embodies the spirit of continuous improvement in human factors methods and models. The simplicity of SEIPS makes it a favoured approach and embraces the concept of assessing work as done. Indeed, the very nature of it leveraging off so many models makes it appear at face value like a jack-of-all-trades approach. While taking this approach may not be bad, the risk is that the practitioner conducting a SEIPS assessment will skim across the surface of many well-established human factors principles and, as a result, may not necessarily choose the right conceptual rabbit hole to focus their analytic attention on. Human Factors and Ergonomics (HFE) consider the depth of human experience in the workplace on multiple levels in a complex environment. Making its analytical approaches more accessible makes HFE accessible but only to a point.

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[10] Hollnagel, E. (2012). *FRAM: The Functional Resonance Analysis Method*. Farnham, UK: Ashgate.

[11] The terminology of defining a function (or task) as part of its mapping of a complex system is based on an action, f. For example, "T'to boil the kettle"', "T'to take a temperature'". These are verbs in nature, observable (per Erik Hollnagels focus when defining the FRAM), and aside from determining endogenous and exogenous variability is are limited beyond what is observable and less about what is intangible.

[12] Based on interview data, the Ministry of Health is responsible for turning policy into action – in a sense adding the 'how' to the law passed by government. This is further translated by colleges and councils for specialists practitioners, such as obstetricians, midwives and gynacologists.

[13] Carayon, P., Wooldridge, A., Hoonakker, P., Hundt, A.S., & Kelly, M.M. (2020). SEIPS 3.0: Human-centered design of the patient journey for patient safety. *Applied Ergonomics, 84*, 103033.

For example, many individuals know how to apply a bandage to a head wound from learning online, reading a book or watching someone else but not necessarily how to assess for a concussion. Most know the basics, and few know the detail. SEIPS is no different and risks facing the same the problems of overuse experienced by previous highly popular models, such as the Swiss Cheese Model. By the very nature of its simplicity, SEIPS should be utilised by someone with considerable in-depth knowledge of the model and in-depth principles of HFE.

Another tool that attempts to address the complexity of a system is Accimap[14]. Accimap seeks to identify all the core actors (stakeholders, departments, levels of influence) in a complex system and establish links to detail how those links relate. Accimap provides a visual representation of adverse events as part of an investigation, which is ironic given it was initially conceived as a risk analytical model by Jens Rasmussen. However, the detail in how one stakeholder may affect another is not presented. At least not in enough detail to extrapolate weaknesses in the system within its core methodology.

As a result, and after careful consideration, the most appropriate methodology recommended for this project is the Systems Theoretic Accident Model and Process (STAMP)[15]. STAMP is a predictive risk assessment method that allows the analyst to perform a structured and methodological approach to safety analysis within complex systems. Nancy Leveson developed the approach in 2004.[16] An example of using STAMP in healthcare was a study monitoring and tracking diabetes mellitus.[17] The study concluded that:

> "the methodology is specifically appropriate to outline and analyse the control actions inherent in the system, such that unsafe control actions and their related causal factors can be identified, a basic system safety design procedure can be implemented, and potential high-level health losses of the patient can be prevented."[18]

STAMP was also used by Neville Stanton et al. to map key stakeholders and explore potential risk areas in the system and make a series of recommendations to improve the overall systemic safety of

[14] Rasmussen, J. (1997). Risk management in a dynamic society: A modelling problem. *Safety Science, 27* (2–3): 183–213. doi:10.1016/S0925-7535(97)00052-0.
[15] Leveson, N. G. (2011). *Engineering a Safer World: Systems Thinking Applied to Safety*. MIT Press.
[16] Leveson, N. (2004). A new accident model for engineering safer systems. *Safety Science, 42*(4), 237–270.
[17] Bas, E. (2020). STPA methodology in a socio-technical system of monitoring and tracking diabetes mellitus. *Applied Ergonomics, 89*, 103190.
[18] Ibid.

the operation.[19] The approach documented 88 additional unsafe control actions imposed by safety constraints.

> "The STAMP-STPA approach offered qualitatively different insights that would be offered using traditional safety tools … highlighting the importance of pre-existing relationships and interactions between different stakeholders."[20]

About STAMP-STPA

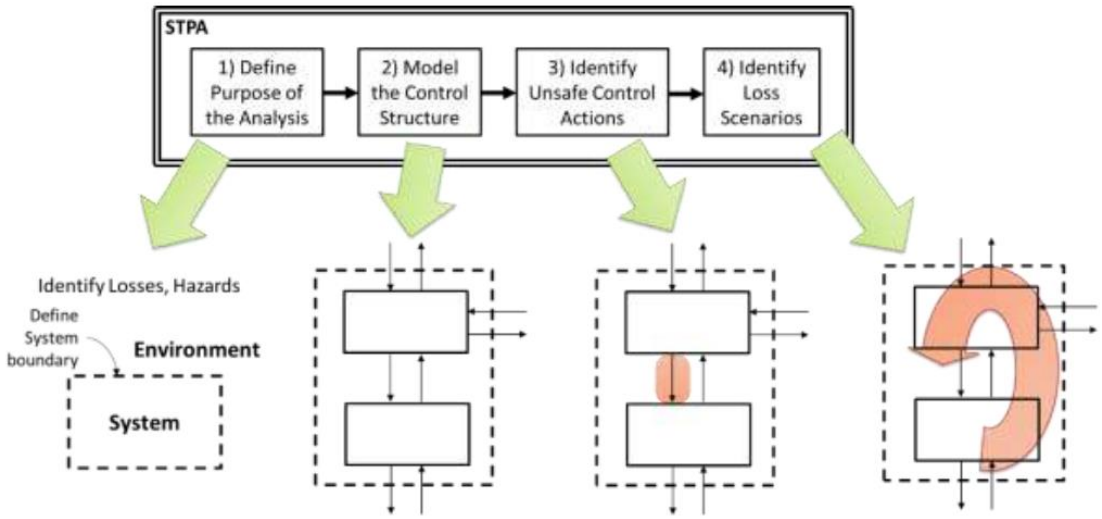
The primary approach of STAMP is to identify inadequacies of control and feedback loops. Many incidents and accidents occur because of flawed processes and requirements. These flaws become evident during the investigation into system component interactions. STAMP focuses on how control and feedback occurs and how it breaks down and, therefore, can be used proactively or in the aftermath of an adverse event. STAMP is an underlying philosophy or way of thinking about systems safety.

In addition, numerous analytical tools were developed by Nancy Leveson addressing an entire product[21] lifecycle. STECA (Systems Theoretic Early Concept Analysis), STPA (Systems Theoretic Process Analysis), STPA-Sec (Systems Theoretic Process Analysis for security risks) and CAST (Causal Analysis Systems Theoretic for adverse event investigations).

The STPA approach considers policy interpretation, organisational design, inter-organisational interactions, decision-making and social and intra-organisational factors. STPA uses high-level system accidents, system hazards, safety design constraints, system safety requirements and hierarchical control structures.[22] STPA has four steps to its methodology, illustrated in figure 1 below.

[19] Stanton, N. A. Harvey, C., & Allison, C. K. (2019). Systems Theoretic Accident Model and Process (STAMP) applied to a Royal Navy Hawk jet missile simulation exercise. *Safety Science, 113*, 461–471.
[20] Ibid.
[21] It is important to note that a 'product' does not necessarily refer to a physical item (for example, a stethoscope) and can include a service offering (such as pharmacovigilance), which of itself becomes productised through guidance, alerts and information.
[22] Leveson, N.G. & Thomas, J.P. (2018). *STPA Handbook*. MIT Partnerships, MA, US.

Figure 1: Overview of the basic STPA method



(Sourced from: Leveson, N.G. & Thomas, J.P. (2018). *STPA Handbook*. MIT Partnerships, MA, US.)

The STPA initially involves ascertaining the purpose of the analysis and identifying the loss scenarios or unacceptable outcomes. Once the scope and losses have been detailed, the analyst develops a map showing all the interacting parts of the system, utilising interview, assessment and analytical data. The diagram, known as the 'hierarchical control structure', details all components involved in controlling hazards and risks, how they interact and control one another and the potential information and feedback passed from one organisation or entity to another. The remaining steps of the processes are less hands-on and more paper based, focusing on understanding the interactions of the numerous entities (organisations, tools, people identified in the structure) within the healthcare system.

The outcome of the analysis is to detail potential areas of weakness in the overall healthcare system and its ability to inform consumers of the teratogenic nature of their medication – allowing healthcare departments and workers to review their practices.

The remainder of this report will detail the method of acquiring data to support the development of the hierarchical control structure and the analysis that followed.

From there, the remaining sections will follow the STPA approach systematically to minimise any risk of confusion.

Finally, the report concludes with recommendations and invites stakeholders to consider the governance, safety and quality of controlling teratogenic medicines.

Method

HQSC provided a list of names of individuals actively involved in cross-agency FACS prevention. HQSC also provided a repository of previous emails and historical documentation[23], resulting in a list of 43 stakeholders from many agencies and consumer groups. An invite to attend a short interview was sent out to all stakeholders (see Appendix 1: Invite for interview).

Stakeholder mapping and participation

Of the 43 individuals invited to attend an interview:

- 19 took part (44.2%)
- 17 did not respond at all after numerous attempts (39.5%)
- three delegated to two individuals (who were both interviewed) (6.9%)
- two are no longer involved with FACS due to changing jobs (4.6%)
- one cancelled the meeting due to a change of plans (2.3%)
- one was too busy with COVID-19 to take part (2.3%).

The only area that was not covered to the project team's satisfaction was paediatric neurology.[24] Numerous attempts to connect with several neurologists via phone and email by the project manager, HQSC and senior leadership were unsuccessful.

Contact and loss scenarios

Per the email presented in Appendix 1, we requested that the stakeholder provide what they thought would be an 'unacceptable outcome' concerning teratogenic medicines and FACS. The unacceptable outcome equates to the 'loss scenario' referred to in the STAMP-STPA methodology. The purpose is to help define the analysis and focus attention on the analytical approach that followed. While the loss scenario may seem obvious at face value, the project team were keen to understand the different views of loss scenarios / unacceptable outcomes that stakeholders might provide.

[23] Provided with permission from agencies and currently stored on external device using FIPS PUB 197 validated standard featuring AES-XTS 256-bit encryption. Subject to secure wipe on project completion.
[24] This is not meant to be a naming and shaming exercise but to draw attention to the gaps of the systems analysis and provide an opportunity for all parties concerned to reflect on their practices – even if that means simply engaging more in the FACS prevention movement.

The unacceptable outcomes, paraphrased from stakeholders' comments, are presented below in no specific order of priority.

- The person experiencing guilt, trauma and/or change of attitude to healthcare
- No informed consent resulting in the birth of a child with FACS
- Lack of awareness / informed consent among people of childbearing potential taking medicine that is teratogenic
- Lack of awareness among doctor and nurse prescribers of medicines that are teratogenic to people of childbearing potential
- Failure to monitor the health of the foetus exposed to a teratogenic medicine in pregnancy
- Failure of IT systems to alert, inform and advise around the risks of specific teratogenic medicines.

The interviews lasted approximately 30–60 minutes, during which time the interviewer took notes. The interviews were conducted via telephone or utilising Voice Over Internet Protocol (VOIP) (for example, MS Teams or Zoom) over a secure Wi-Fi connection. The interview was semi-structured, utilising a list of pool questions (see Appendix 2: Stock interview questions) and incorporated further exploratory questions when warranted. Later interviews, especially those conducted on stakeholders from similar entities within the healthcare system, included more tailored questions and used fewer pool questions. Senior leaders, especially those with limited time capacity, necessitated a focused and tailored questioning regime.

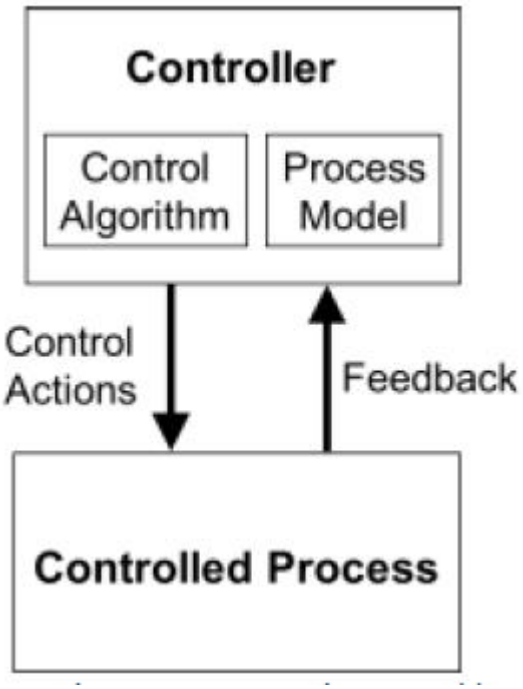
Each stakeholder's view of their organisation's roles and responsibilities enabled understanding how each entity relates to one another (see Appendix 3: Summary of roles and responsibilities). The information led to the development of a hierarchical control structure, following step 2 of the STAMP-STPA methodology. As the interviews progressed, a better understanding of how each agency relates to one another occurred and enabled linkages between them to be defined.

Modelling the hierarchical control structure

The hierarchical control structure presents the healthcare system and its relevant controls and feedback loops in its current state. It focuses purely on the management of teratogenic medication and FACS prevention, and therefore a multitude of facets within each entity has been deliberately omitted.

To understand the structure, before viewing, we recommend reading the following section on the hierarchical control structure.

Figure 2: A basic control loop



(Sourced from: Leveson, N.G. & Thomas, J.P. (2018). *STPA Handbook*. MIT Partnerships, MA, US.)

A hierarchical control structure is composed of control loops, as shown above in **Error! Reference source not found.** above. Each controller can, in turn, become a controlled process, and indeed, each controlled process can become a controller. An example exists within most corporate hierarchies of senior manager → manager → team leader → front-line worker. Orders from senior managers control managers and team leaders, who can also place orders or assert control on those below them.

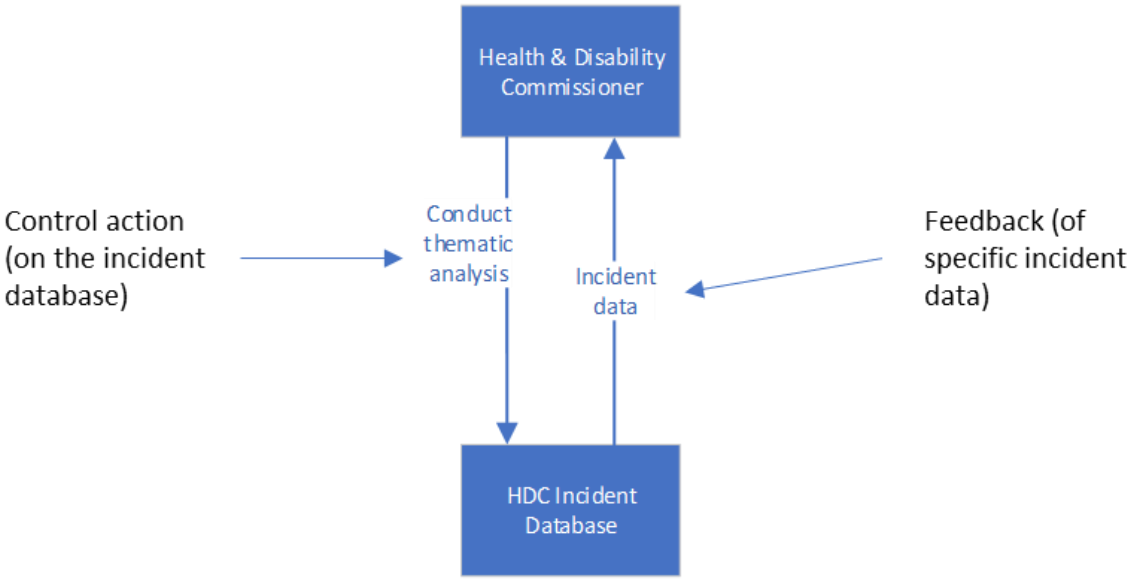
A controller may be a whole department, an individual, a standard or an IT system and can provide simple control actions or enforce rules and regulations.

Other elements of figure 2 that require explanation include the following.

- The control algorithm of any given controller represents the controller's decision-making processes.
- Controllers also have process models, representing the controller's information based on data, memory, attitude or bias to make decisions.

- Arrows pointing down refer to actions of control.
- Arrows point up to indicate an element of feedback (an example of the arrow directions is presented in **Error! Reference source not found.** below).

Figure 3: Explaining the arrow directions used in Appendix 4: Hierarchical control structure



- Arrows that may emanate or terminate from the side of each box are more focused on indicating collaborative information sharing.
- The hierarchical control structure is not robust and is highly dependent on interview data, additional information sent from interviewees and limited reviews of public-facing websites.
- Interviews did not occur for 44% of stakeholders, and as a result, some relevant information could be missing.
- The hierarchical control structure is a functional model and relies on information sent or received.
- The hierarchical control structure does not assume obedience – control and feedback simply indicate the presence of a mechanism to send and receive information.
- Given the size of the hierarchical control structure, individual boxes do not present details of the internal decision-making processes that may take place (the control algorithm and control processes). An exploration takes place later in this report.

Now is an excellent time to review the structure shown in Appendix 4: Hierarchical control structure.

Analysing the interview content using STPA

The development of the hierarchical control structure enables further systems analysis. The analysis determines what controls or constraints need to be in place to minimise the occurrence of any previously identified unacceptable outcomes.

However, it is essential to detail how a breakdown in control occurs for these sorts of outcomes, including the impacts to each entity and the broader healthcare systems' ability to manage teratogenic medicines. Thus, each control action (arrows point down) is assessed by determining how the actions are affected by a series of predetermined negative impacts (such as specific controls not taking place or taking place in a substandard way). This exercise, in many respects, can be construed as a 'what-if' analysis of the identified controls between each entity.

The exercise should give stakeholders the opportunity to query their existing processes to:

- determine their knowledge of specific unsafe actions upon their existing controls
- ensure unsafe control actions do not occur
- assess the benefits of immediate control constraints and system constraints to benefit the entire healthcare system's ability to manage teratogenic medicines.

Some of the terminologies in this analysis may not be conducive to a healthcare environment and may seem more at home in engineering. However, systems thinking and human interaction with complex work environments do not differ regardless of the industry. To further aid understanding of the STPA terminology, **Table 1** presents an explanation of the analytical process that follows.

Table 1: STPA terminology decrypted

Step		STPA approach	In plain English	A healthcare example
1	SYSTEMS	What are the losses?	What are the unacceptable outcomes?	A consumer dying when it could have been avoided
2		What are the system-wide hazards?	What dangerous things, from a systems perspective, can cause a bad loss?	A department working while suffering from widespread fatigue
3		What are the system constraints?	What can we do to avoid or mitigate hazards?	Tools to identify fatigue in oneself and each other
4		What are the responsibilities?	Who will ensure these avoidance or mitigation strategies take place?	The department head ensuring these tools are used
5	ENTITIES (INDIVIDUAL ORGANISATIONS OR TOOLS PRESENT IN THE HIERARCHICAL CONTROL STRUCTURE)	What are the unsafe control actions?	What are the individual actions that could contribute to a system-wide hazard occurring?	Members of staff wishing not to take rest breaks as this leads to more work for their colleagues
6		What are the controller constraints?	What controls could we put in place to stop individual actions that lead to hazardous situations?	A backup team of staff being made available to reduce or spread the workload
7		What are the loss scenarios?	What sort of scenario could drive an unsafe control action, resulting in an unacceptable outcome?	If utopia does not exist: there is no backup staff, resulting in existing workers having to work exceptionally long hours, leading to increased fatigue, human error and a consumer dying

Results

STPA analysis

The analysis adheres to the methodology presented in **Table 1** above to ensure readers can follow the approach closely and understand the conclusions drawn at the end of the report. At each stage of the analysis, a prefix code is added to every item identified, ensuring the conclusions can be traced back to their predetermined, unacceptable outcomes.

The first four steps focus on how each entity can support and enhance the broader healthcare system associated with FACS prevention. Steps 5 to 7 focus on individual entities.

Systems review

Step 1 – What are the losses?

What are the unacceptable outcomes?

Each stakeholder was asked to provide unacceptable outcomes and, as a result, set the foundation for the entire analysis. Each unacceptable outcome or loss is labelled (L) to support traceability as the reader progresses through the analysis. For the purpose of the analysis, the unacceptable outcomes identified by the stakeholders are presented in a sequential order below.

L1	There is a lack of awareness / informed consent among females of childbearing potential taking medicine that is teratogenic.
L2	There is a lack of awareness among doctor and nurse prescribers of medicines that are teratogenic to people of childbearing potential.
L3	IT alert systems fail to achieve their objectives of alerting, informing and advising by making visible the risks of specific teratogenic medicines.
L4	The health of the foetus is not monitored for exposure to a teratogenic medicine in pregnancy.
L5	There is no informed consent resulting in the birth of a child with FACS.
L6	The person experiences guilt, trauma and/or a change of attitude to their healthcare.

Step 2 – What are the system-wide hazards?

What dangerous things, from a systems perspective, can cause a bad loss?

After identifying the losses or unacceptable outcomes, the next step is to determine what system states or conditions would lead to these outcomes from the interview data. It is essential to ensure these are system-level and not individual or component level states. Again, for traceability purposes, the hazards are labelled (H) and traced back to the losses (L) that could result if these system-wide hazards were to occur.

The hazards are presented explicitly at a higher level to focus on the broader system and less on individual entities, which are discussed later in the report.

H1	Alerts and guidance of teratogenic medication are inconsistent. (L1, L2, L3, L5)
H2	Healthcare specialists[25] do not provide an informed consent discussion or take a standard approach to providing informed consent. (L1, L4, L5)
H3	The consumer does not know the teratogenic effects of their medicine. (L1, L5, L6)
H4	Prescribing workers do not know all the medicines that have teratogenic effects in New Zealand. (L1, L2, L3, L4, L5)
H5	Puberty does not trigger a discussion about pregnancy for consumers of childbearing potential while on teratogenic medicines. (L1, L4, L5)
H6	Consumer circumstances[26] are lost or not supported as the consumer transfers between primary, secondary and tertiary healthcare services. (L1, L2, L4)
H7	Healthcare practitioners have limited knowledge of the teratogenic effects of different medications. (L1, L2, L4, L5, L6)
H8	Data concerning medication usage is incomplete on existing IT reporting systems. (L3)
H9	Agencies feel siloed or operate in a siloed manner in regard to information pertinent to FACS prevention.[27] (L1, L2, L3, L4, L5)
H10	Data on complaints and adverse reactions provide only a partial view of the true numbers of people of childbearing potential using teratogenic medication without informed consent. (L3)
H11	The consumer is not heard. (L1, L3, L4, L6)

[25] This includes GPs.
[26] Such as 'circumstances' include whether an informed consent discussion has taken place, who has had that discussion and the heightened risk as a result of their medication.
[27] Per interview data.

Step 3 – What are the system constraints?

What can we do to avoid or mitigate hazards?

A system constraint specifies conditions or behaviours that need to occur to prevent a hazard from occurring – a straightforward process of reversing the terminology of the hazard. The changes to the original hazards as listed at step 2 above are presented in upper case.

SC1	Alerts and guidance around the use of teratogenic medications MUST BE CONSISTENTLY DELIVERED TO THE HEALTHCARE SYSTEM. (H1)
SC2	Healthcare specialists MUST CONDUCT A DISCUSSION AND TAKE A STANDARD APPROACH, TAKING INTO CONSIDERATION WHAT THE CONSUMER WANTS AND NEEDS TO KNOW, WHEN FACILITATING THE PROCESS OF INFORMED CONSENT. (H2)
SC3	The consumer MUST UNDERSTAND THE TERATOGENIC EFFECTS OF THEIR MEDICINE. (H3)
SC4	PRESCRIBING HEALTHCARE WORKERS in New Zealand MUST KNOW ABOUT ALL medicines that have teratogenic effects. (H4)
SC5	Puberty MUST trigger a discussion with consumers of childbearing potential about pregnancy while on teratogenic medicines. (H5)
SC6	ALL relevent consumer circumstances MUST BE INCLUDED AND SUPPORTED as the consumer transfers BETWEEN primary, secondary AND TERTIARY healthcare services. (H6)
SC7	All healthcare practitioners MUST HAVE ROBUST knowledge of the teratogenic effects of different medications. (H7)
SC8	Data concerning medication usage MUST BE COMPLETE BY INCLUDING COMMUNITY AND HOSPITAL DISPENSING DATA. (H8)
SC9	Agencies SHOULD READILY SHARE information pertinent to FACS prevention. (H9)
SC10	Data on complaints and adverse reactions provides MUST PROVIDE A COMPLETE VIEW of the true numbers of people of childbearing potential using teratogenic medication without informed consent. (H10)
SC11	ENSURE THE CONSUMER FEELS THEY have been heard IN TERMS OF THEIR CONCERNS OR ANY QUESTIONS THEY MAY HAVE, AND THEY MUST BE FULLY COGNISANT OF ANY DECISIONS THEY ARE ASKED TO MAKE. (H11)

Step 4 – What are the responsibilities?

Who will ensure these avoidance or mitigation strategies take place?

Now that the system constraints are known, the next step is to propose who may take responsibility for helping create, support and maintain these constraints. Admittedly, this is likely to cause discussion and disagreement between entities, given the fact that assertions are based on current knowledge and a short interview. These suggestions are not intended to insinuate that entities are not taking responsibility and may already be implemented.

Again the items in the tables below are coded and show traceability back to the system constraints. Some of the responsibilities for different entities refer back to the same constraint, which provides the opportunity for collaborative work to take place.

1. Government / Ministers	
R1.1	Present legislation that regulatory bodies can easily translate into policy. (SC1)
R1.2	Ensure legislation is relevant and based on up-to-date information. (SC8, SC9, SC10)
R1.3	Proactively elicit feedback from the healthcare system concerning how policy is being applied in terms of FACS prevention. (SC1, SC9)

2. Ministry of Health	
R2.1	Provide coherent policy and practice guidelines to other entities. (SC1, SC2, SC7)
R2.2	Identify and set achievable targets relevant to the management of teratogenic medicines. (SC8, SC10)
R2.3	Provide adequate funding to agencies to achieve targets relevant to the management of teratogenic medicines. (SC1)
R2.4	Ensure reporting (such as agency reports or data analysis from relevant IT systems) enables the Ministry to operate in a manner that meets the needs of the consumer. (SC8, SC9, SC10)
R2.5	Drive legislative change in accordance with consumers' personal and cultural needs. (SC3, SC6)
R2.6	Respond to requests on pressing issues associated with consumer risk and safety. (SC9, SC10)
R2.7	Make relevant information concerning teratogenic medicines and FACS prevention accessible by ensuring all relevant agencies are providing the same messages. (SC1, SC3, SC4, SC7)

R2.8	Openly share information to all other entities concerning FACS prevention to support collaboration across all groups – both professional and consumer. (SC1, SC2, SC3, SC4, SC7, SC8, SC9, SC10)
R2.9	Review current reports from IT systems to ensure they meet the needs of the Ministry and provide the ability to report on consumer-driven OIA requests associated with FACS prevention. (SC3, SC8, SC10, SC11)
R2.10	All dispensing point-of-sale systems (two in existence at the time of this report) should have an API[28] that feeds relevant information to the Ministry about dispensing teratogenic medicines. (SC3, SC8)
R2.11	The dispensing point-of-sale systems (two in existence at the time of writing this report) should provide data that meet or exceed the Ministry's reporting needs. (SC3, SC8)

3. Health Quality & Safety Commission	
R3.1	Bring together agencies to focus on specific issues around FACS prevention and the prescribing of teratogenic medicine. (SC2)
R3.2	Become the safety and quality centre of messaging associated with teratogenic medicines and FACS prevention. (SC3)
R3.3	Conduct a gaps analysis of opportunities to make better use of soft intelligence (the provision of information across agencies that raises awareness) of ongoing issues, helping the healthcare system to become more responsive. (SC4, SC6, SC8)
R3.4	Regularly review events where a lack of knowledge about teratogenic medicines was a factor for either prescribing health specialists or consumers. (SC2, SC4, SC7)

4. Health and Disability Commissioner	
R4.1	Conduct regular gaps analyses of complaints associated with consumers transferring between primary, secondary and tertiary healthcare services. (SC6, SC11)
R4.2	Ensure consumers can easily make a complaint via the website by obtaining user feedback. (SC10, SC11)

[28] API is the acronym for Application Programming Interface, which is a software intermediary that allows two applications to talk to each other. Each time you use an app like Facebook, send an instant message or check the weather on your phone, you're using an API.

5. Pharmaceutical companies	
R5.1	Provide consumer information (warnings, risks etc.) directly on packaging or in a manner that can be easily copied when bulk medications are split into smaller batches. (SC1, SC3, SC4, SC5)

6. Pharmac	
R6.1	Ensure the website is consumer-friendly by obtaining consumer usability feedback. (SC3, SC4, SC11)
R6.2	Assess whether teratogenic properties should be considered when assessing if medication is fit for purpose. (SC4)
R6.3	Ensure there are contractual agreements with pharmaceutical companies to enable consumer information (warnings, risks, etc.) to be placed directly on packaging or in a manner that can be easily copied when bulk medications are split into smaller batches. (SC1, SC3, SC4, SC5)
R6.4	Develop a contractual agreement with pharmaceutical companies to ensure consumer information (warnings, risks etc.) is placed directly on packaging or in a manner that can be easily copied when bulk medications are split into smaller batches. (SC1, SC3, SC4, SC5)

7. New Zealand Medicines and Medical Devices Safety Authority (Medsafe)	
R7.1	Conduct a healthcare system-wide assessment to confirm that enough post-marketing (safety issues) diligence of medication is taking place or whether there are areas for improvement. (SC4, SC8, SC9, SC10)
R7.2	Proactively work with consumer groups to develop innovate safety messaging for teratogenic properties of medication. (SC3)
R7.3	Ensure the weekly teleconference with CARM is not just focused on serious issues but also provides an opportunity to elicit data on specific consumer-driven enquiries. (SC9, SC11)
R7.4	Ensure all professionals are receiving the medication alerts by developing appropriate reporting mechanisms. (SC10)
R7.5	Given Medafe is a customer of drug companies, ensure the datasheets meet Medsafe's, healthcare professionals' and consumers' needs. (SC3, SC4)
R7.6	Share data on adverse reactions with other agencies and consumers as appropriate. (SC8, SC10)

8. ACC	
R8.1	Ensure the requirements for future Conporto projects are user-centric (meet the needs of healthcare practitioners). (SC2, SC4)
R8.2	Work closely with HQSC to identify synergies and areas where overlaps may occur to make best use of each agency's time, capabilities and skillsets. (SC9)
R8.3	Proactively reach out to healthcare professionals about their consumers who are on teratogenic medicines with a view to encouraging transferring those consumers to safer alternatives. (SC1, SC2, SC6, SC7)
R8.4	Proactively reach out to healthcare professionals concerning their consumers to ensure a discussion occurs around ensuring informed consent has taken place[29] and what that discussion looked like. (SC2)

9. Advisory systems – The New Zealand Formulary (NZF),[30] Best Practice Advocacy Centre New Zealand (bpac[nz]),[31] He Ako Hiringa[32]	
R9.1	Proactively collaborate to ensure messaging is consistent with other advisory systems. (SC2, SC5, SC6, SC7)
R9.2	Conduct a usability review to optimise information presentation and ease of access given the busy schedules of health practitioners. (SC2, SC3, SC5, SC6)
R9.3	Ensure alerts are continuously improved by conducting regular user-led reviews. (SC9, SC10)
R9.4	Ensure any consumer-facing platforms are accessible and user-friendly by proactively acquiring a diverse range of user feedback. (SC3, SC9)

10. CARM	
R10.1	Ensure it is easy for a consumer to submit an adverse reaction report. (SC11)
R10.2	Change CARM's website URL to something more consumer friendly instead of nzphvc.otago.ac.nz/carm/. (SC11)
R10.3	Provide publications focusing on the medication and not just the service. (SC9)

[29] This may need support from the Health and Disability Commission and Health New Zealand.
[30] The NZF provides healthcare professionals with independent clinically validated medicnes information and guidance on best practice. For more information, see the NZF website at: https://nzformulary.org
[31] The bpac[nz] is an independent, not-for-profit organisation that delivers educational and continuing professional development programmes to medical practitioners and other health professional groups in New Zealand.
[32] He Ako Hiringa aims to provide equity-focused education for healthcare professionals delivering primary health care services in New Zealand.

11. All schools, councils, societies and colleges (PSNZ, RNZCOG, RNZGP, RNZP, NZCOM)	
R11.1	Encourage collaboration concerning consumer health and wellbeing around teratogenic medicines. (SC2, SC7, SC8)
R11.2	Work together proactively to improve the process for consumers transferring between primary, secondary and tertiary healthcare services. (SC6)
R11.3	Strive towards consistent messaging around FACS prevention. (SC2)
R11.4	Engage proactively with consumer groups and individual consumers. (SC11)
R11.5	Ensure educational material associated with FACS prevention is consistent and robust. (SC7)
R11.6	Assess and improve existing systems for reviewing teratogenic medicines prescribed to consumers as they reach childbearing potential. (SC5)

12. DHBs / Health New Zealand	
R12.1	Proactively support consistent messaging about FACS prevention across all health practitioner groups. (SC2, SC3, SC6)
R12.2	Proactively engage with consumer groups to identify opportunities for improvements in healthcare. (SC11)
R12.3	Proactively follow up on complaints received by the HDC, HQSC, the Ministry or ACC by conducting systems-thinking-based adverse event reviews. (SC8, SC9)
R12.4	Avoid punitive responses to adverse events, focus on the system and focus on learning opportunities for the whole organisation. (SC2, SC9)
R12.5	Proactively support healthcare staff to ensure that health policy focusing on FACS prevention is user friendly. (SC2, SC7)

13. All primary and secondary health specialists (paediatricians, neurologists, psychiatrists, GPs, obstetricians, gynaecologists and midwives)	
R13.1	Report on issues about accessibility of information concerning teratogenic medication. (SC1, SC3, SC4, SC6)
R13.2	Ensure informed consent takes place about the prescribing of teratogenic medication and is reviewed regularly. (SC2, SC3, SC5, SC6)
R13.3	Identify and monitor patients who are on teratogenic medications. (SC6)
R13.4	Work closely with each other and patients and think long term when deciding to prescribe teratogenic medication to ensure that informed consent is an ongoing process that is renegotiated as risks change. (SC6).

14. Pharmacists	
R14.1	Ensure that informed consent discussions have occurred. (SC3)
R14.2	Have access to information about teratogenic medications and other medications under review concerning FACS prevention. (SC1, SC4, SC6)
R14.3	Utilise a system that provides reporting back to the Ministry of Health to ensure a comprehensive picture of dispensing is provided. (SC8)
R14.4	Proactively commit to informing consumers about the dangers of their medicine concerning FACS prevention. (SC3, SC5, SC6)

Entity review

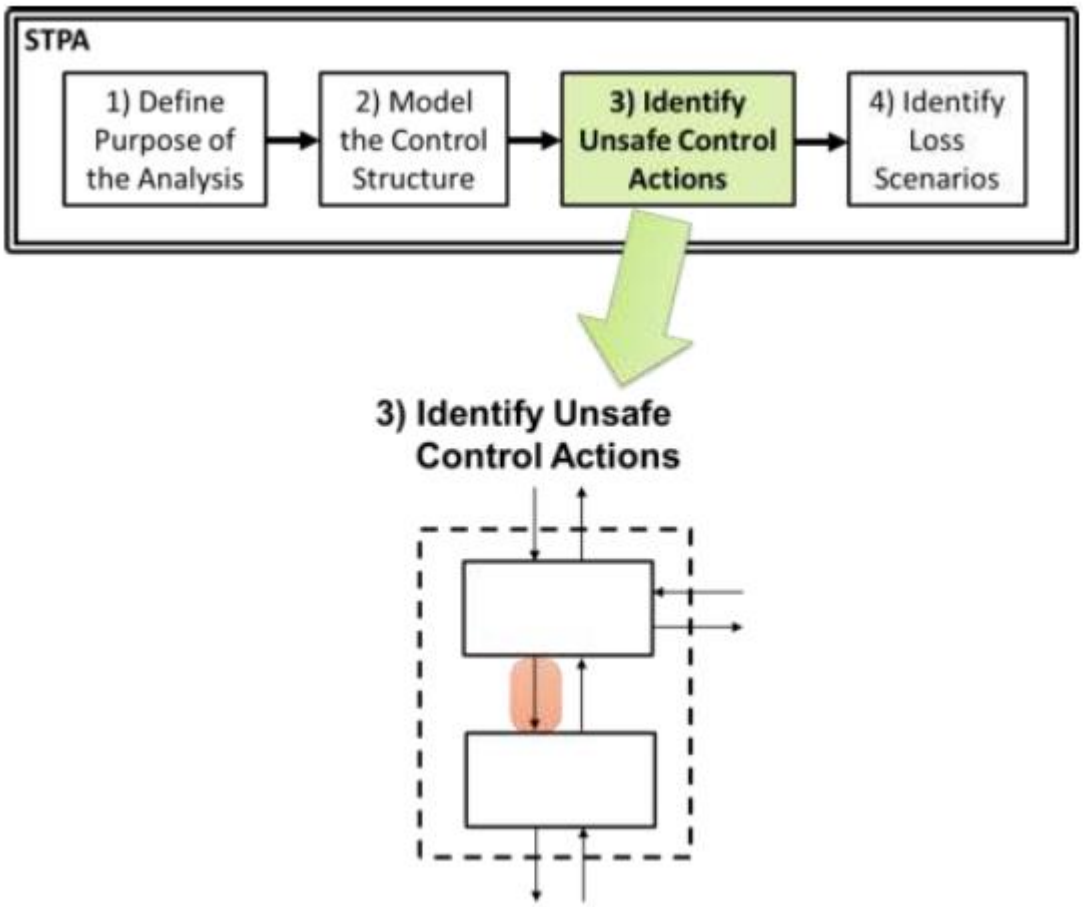
Many entities (organisations, individual roles and IT systems necessary for managing teratogenic medicines) share similar controls, and as a result, these entities will be addressed together.

Even though this review focuses on entities, roles and responsibilities have not been assigned, as with the previous section. Each entity should reflect on whether the items presented below are realistic and what, if anything, they can do within their remit to help reduce the chance of unacceptable outcomes.

Step 5 – What are the unsafe control actions?

What are the individual actions that could contribute to a system-wide hazard occurring?

Figure 4: Identifying unsafe control actions



Unsafe control actions (UCA) are situations where the control does not perform in the manner it was meant to, leading to a potential unexpected situation. The STPA methodology postulates four potential ways for the control action to be unsafe.

1. Not providing the predetermined control action (absence)
2. Providing a control action that leads to an adverse event (imprecision)
3. Providing the control too early, too late or in the wrong order (timeliness)
4. The control action lasting too long or being stopped too soon (moderation).

The table below reviews all control actions taken from the hierarchical control structure in appendix 4 and identifies potential opportunities where they may not occur in the manner intended. Unsafe control actions may not occur or may appear completely unrealistic at face value. However, this exercise enables the opportunity to become aware of undesirable actions that have not necessarily been thought of before.

Control action	Ways the control action is unsafe			
	Absence	**Imprecision**	**Timeliness**	**Moderation**
1. Policy and regulation	UCA1.1 Policy and regulation are not provided.	UCA1.2 Policy and regulation have been misinterpreted.	UCA1.3 Policy and regulation are provided ad hoc.	UCA1.4 Policy is inconsistent across entities in the system.
2. Evaluation of effectiveness (of IT systems)	UCA2.1 IT systems function ineffectively.	UCA2.2 IT systems are in a constant state of change.	UCA2.3 Evaluation of IT system comes too late.	UCA2.4 Evaluation of IT systems is fleeting.
3. Medication information	UCA3.1 Medication information is inaccessible to the consumer.	UCA3.2 Medication information is incomplete or inaccurate.	UCA3.3 Medication information is provided too late to the consumer.	UCA3.4 Medication information is imposed upon the consumer too much.
4. Medication IT alerts	UCA4.1 Medication alerts are not provided.	UCA4.2 Medication alerts are provided with inaccurate information.	UCA4.3 Medication alerts are provided too early. UCA4.4 Medication alerts are provided too late.	UCA4.5 Medication alerts are stopped prematurely.
5. Datasheets	UCA5.1 Datasheets are not provided.	UCA5.2 Datasheets are inaccurate.	UCA5.3 Datasheets are provided too late.	N/A
6. Conducting thematic analysis (on adverse events)	UCA6.1 Thematic analysis of adverse events is not carried out.	UC6.2 The wrong themes in adverse event databases are searched for.	N/A	N/A
7. Education concerning FACS and teratogenic medication	UCA7.1 FACS prevention education is not provided.	UCA7.2 FACS prevention education is inconsistent across specialist groups.	UCA7.3 Education about FACS prevention is provided too early in the curricula.	N/A

Control action	Ways the control action is unsafe			
	Absence	**Imprecision**	**Timeliness**	**Moderation**
8. Diagnostic questioning[33]	UCA8.1 Diagnostic questioning does not take place.	UCA8.2 Diagnostic questioning is driven by practitioner bias.	UCA8.3 Diagnostic questioning occurs after prescription of medications.	N/A
9. Reviewing consumer history	UCA9.1 Consumer history is not reviewed.	UCA9.2 Consumer history is only partially reviewed.	UCA9.3 Consumer history review occurs too late.	N/A
10. Diagnosis, prescriptions and medication guidance	UCA10.1 Diagnosis, medication and guidance is not provided.	UCA10.2 The wrong diagnosis is provided.	N/A	N/A

Step 6 – What are the controller constraints?

What controls could we put in place to stop individual actions that lead to hazardous situations?

Once the individual unsafe control actions have been identified, control constraints can be developed. Similarly to the system constraints in step 3, the antithesis of each unsafe control action is provided.

It is important to note that some controller constraints may be incredibly obvious and overly simplistic. However, even the most simplistic suggestions afford a moment of reflection for each entity.

	Unsafe control actions	**Controller constraints**
UCA1.1	Policy and regulation are not provided.	CC1.1 Policy and regulation concerning teratogenic medication and FACS prevention must be provided.
UCA1.2	Policy and regulation have been misinterpreted.	CC1.2 Policy and regulation must be clear and easily understood.
UCA1.3	Policy and regulation are provided ad hoc.	CC1.3 Policy and regulation are provided in advance and in support of all healthcare capability.
UCA1.4	Policy is inconsistent across entities in the system.	CC1.4 Policy is consistently applied across the entire healthcare system.
UCA2.1	IT systems function ineffectively.	CC2.1 IT systems must function to meet the needs of the user.

[33] Relating questioning of a prescribing healthcare worker.

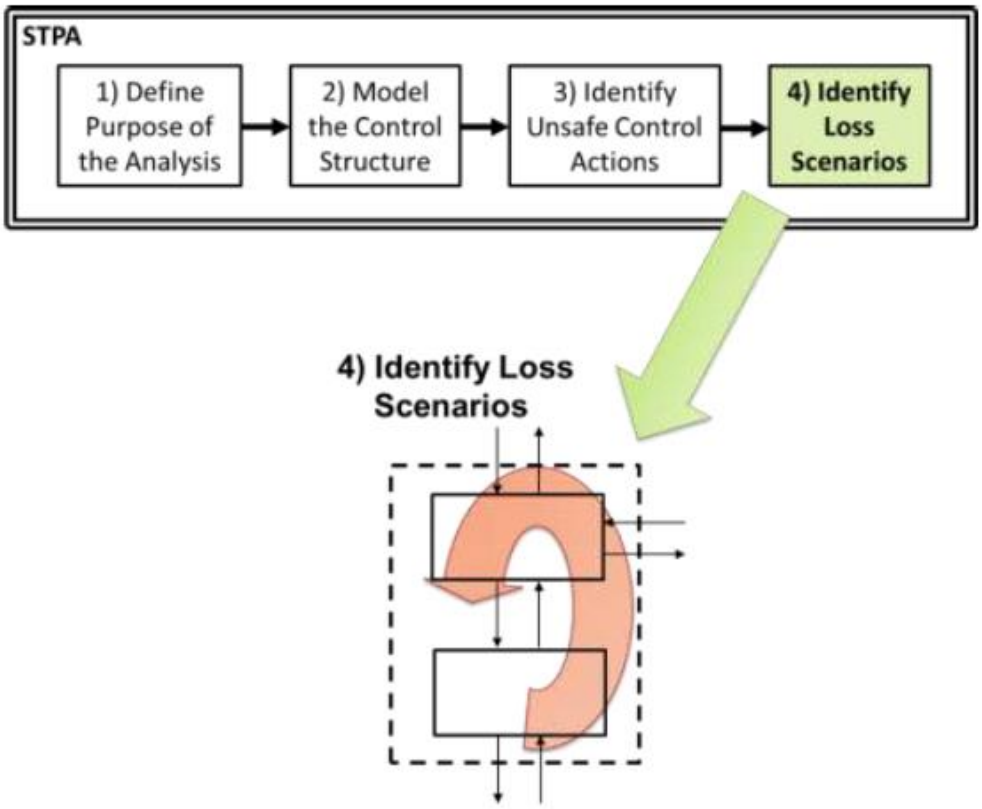
	Unsafe control actions	Controller constraints
UCA2.2	IT systems are in a constant state of change.	CC2.2 IT system roadmaps should be planned and communicated with user groups.
UCA2.3	Evaluation of IT system comes too late.	CC2.3 IT system performance must be monitored regularly.
UCA2.4	Evaluation of IT systems is fleeting.	
UCA3.1	Medication information is inaccessible to the consumer.	CC3.1 Medication information must be provided proactively to the consumer.
UCA3.2	Medication information is incomplete or inaccurate.	CC3.2 Medication information needs to be standardised, accurate and presented in plain language.
UCA3.3	Medication information is provided too late to the consumer.	CC3.3 Medication information should be always available to the consumer to access on prescribing and easily accessible when the consumer wishes to find out more information.
UCA3.4	Medication information is imposed upon the consumer too much.	
UCA4.1	Medication alerts are not provided.	CC4.1 All user groups (both professional and consumer) should receive information about medication alerts.
UCA4.2	Medication alerts are provided with inaccurate information.	CC4.2 Medication alerts should be timely, factual and presented in plain language, meeting the needs of the consumer or user groups.
UCA4.3	Medication alerts are provided too early.	
UCA4.4	Medication alerts are provided too late.	
UCA4.5	Medication alerts are stopped prematurely.	CC4.3 Medication alerts should only be removed if information has changed.
UCA5.1	Datasheets are not provided.	CC5.1 Datasheets should be provided by pharmaceutical companies at all times.
UCA5.2	Datasheets are inaccurate.	CC5.2 Datasheet information should be accurate and presented in plain language for the audience it is meant for.
UCA5.3	Datasheets are provided too late.	CC5.3 Datasheets should be provided before approval of medicine is granted.
UCA6.1	Thematic analysis of adverse events is not carried out.	CC6.1 Consistent analysis of adverse events for trends should be conducted.
UC6.2	The wrong themes in adverse event databases are searched for.	CC6.2 Quality control over thematic analysis should be imposed, e.g., via group collaboration, including consumer groups.

	Unsafe control actions	Controller constraints
UCA7.1	FACS prevention education is not provided.	CC7.1 Education concerning FACS prevention must be provided.
UCA7.2	FACS prevention education is inconsistent across specialist groups.	CC7.2 Education concerning FACS prevention should be openly shared between specialist groups to ensure consistent messaging takes place.
UCA7.3	Education about FACS prevention is provided too early in the curricula.	CC7.3 Education about FACS prevention should be provided towards the end of the curricula.
UCA8.1	Diagnostic questioning does not take place.	CC8.1 Diagnostic questioning must take place.
UCA8.2	Diagnostic questioning is driven by practitioner bias.	CC8.2 Diagnostic questioning should focus on the consumer and their individual circumstances.
UCA8.3	Diagnostic questioning occurs after prescription of medications.	CC8.3 Diagnostic questioning must not occur after prescription of medications.
UCA9.1	Consumer history is not reviewed.	CC9.1 Consumer history should be reviewed regularly.
UCA9.2	Consumer history is only partially reviewed.	CC9.2 Consumer history should be accessible.
UCA9.3	Consumer history review occurs too late.	CC9.3 Consumer history should become a critical early stage in diagnostic assessment.
UCA10.1	Diagnosis, medication and guidance is not provided.	CC10.1 Diagnosis, medication and guidance is provided to the consumer.
UCA10.2	The wrong diagnosis is provided.	CC10.2 Diagnosis, medication and guidance is accurate, accessible and easily understood.

Step 7 – What are the loss scenarios?

What sort of scenario could drive an unsafe control action, resulting in an unacceptable outcome?

Figure 5: Identifying the loss scenarios



Once the unsafe control actions have been identified, it becomes possible to present a series of *loss scenarios* that result in the unacceptable outcomes presented in step 1 of the STPA analysis. These are not likely to be comprehensive, given the limited exposure to the healthcare system during the project. However, they should form a rationale for organisations to consider more detailed and directly relevent potential loss scenarios. The loss scenarios are derived from interview data, follow-up information from interviewees, public-facing information, expertise in sociotechnical systems analysis and human factors. Each loss scenario is traced back to the losses identified in section 1 of the STPA analysis.

Loss scenarios

Policy and regulation

Policy and regulation are likely to change as laws change. They are subject to interpretation and are likely to be tailored to the end user (healthcare professionals). However, policy, regulation and law are at risk of being misinterpreted and misunderstood, especially if the healthcare professional has a psychological and historical schema of how they should conduct their job.

The interviews indicated an advanced level of knowledge about relevant medication. However, there also seemed to be a moderate level of the dogma of knowing which medications work, no doubt based on previous experience with consumers presenting similar symptoms. As a result, healthcare

workers risk experiencing confirmation bias[34] and the availability heuristic[35] during diagnostic and prescriptive activities, which may result in reduced consideration of long-term effects. By not engaging with up-to-date policy through dogma or lack of awareness or understanding, the outcome could be dated professional practice leading to (L6) the person having a negative experience in healthcare or (L5) the birth of a child with FACS.

Evaluation of effectiveness of IT systems / medication information / medication alerts / datasheets

Many IT systems exist in our healthcare sector, and the interviews provided evidence that medication review by healthcare specialists is inconsistent. The IT systems appear lacking on multiple levels, and many agencies responsible for these tools are cognisant of this and in the process of modernising. However, because of the current mode of operation in these IT systems, limited reporting and user-unfriendly presentation of data are compelling stakeholders to be selective around what they read, in some cases, irrespective of the urgency of some material. Indeed, in some cases, critical information is missed from IT alerts (L3) and conveys a limited commitment to FACS prevention to consumer groups and stakeholders. As a result, informed consent (L1) will not occur with some consumers, and there is a risk that prescribers may not necessarily know (L2) all the existing teratogenic medications that are in circulation.

Conducting thematic analysis (on adverse events)

Thematic reviews are being conducted on adverse event investigation data regularly. However, how robust the adverse event information is within databases is less clear. Individuals with little or no knowledge (or even awareness) of human factors conduct many adverse events reviews. Therefore, the findings and data are likely to be quite limited in understanding how adverse events occurred, what critical stakeholders within the adverse event were thinking and why the adverse event unfolded the way it did. As a result, the thematic analysis is likely to be only as good as the available event data. The individual conducting the analysis is likely to suffer in providing quality outputs, irrespective of their knowledge and expertise. As a result, information, advice and alerts (L3) surrounding FACS prevention and prevalence of teratogenic medicines prescribed to people of childbearing potential are likely to suffer.

Education concerning FACS and teratogenic medications

Speaking to numerous healthcare colleges suggests a widespread sense of taking FACS prevention seriously. However, there was little evidence to suggest that the approach is consistent across all entities. For example, the lack of transparency resulted in pre and post-natal care specialists not knowing that teratogenic medications were prescribed for bipolar affective disorder. This lack of knowledge has triggered a suite of preventative actions and supports the need for organisations to share information to ensure this situation does not reoccur. Otherwise, healthcare workers' general lack of awareness (L1, L2) will result; a foetus whose mother is taking teratogenic medication is not monitored (F5) during their first trimester of pregnancy; a child with preventable FACS risks could be

[34] The tendency for a person to look for and support particular theories, opinions, outcomes or findings that favour the person's existing beliefs or values.

[35] Where a person makes judgments about the likelihood of an event based on how easily an example, instance or case comes to mind.

born (L5) and affected consumers will lose trust and willingness to engage in the system (L6), leaving consumer groups on limited funding to pick up the pieces.

Reviewing consumer history

Many healthcare specialists discussed facing increased risk as consumers navigate primary, secondary and tertiary healthcare services even though considering patient history is a core diagnostic activity. The issues were compound when considering the accessibility and affordability of community healthcare services. Cultural awareness and general motivation were also discussed in the interviews, especially if a consumer's experience in primary healthcare wards had not beenfavourable. This situation makes it hard for GPs to keep track of consumers while providing community care to consumers who are unhappy about the care they received in the past, particularly people of childbearing potential who may be on medication without knowing of the teratogenic risks. Therefore, consumers can easily miss out on aspects of community care (L2), and if so, are not likely to engage in an informed consent process (L1), may not even be monitored during pregnancy (L4) and risk the birth of a child with preventable FACS (L5).

Diagnosis, prescriptions and medication guidance

It is not the intention of this report to suggest that mis-prescribing takes place. However, it is plausible based on interview data. Foetal Anit-Convulsant Syndrome New Zealand (FACS NZ) provided evidence of consumers not having the informed consent discussion, and there is no reason to rule out this sort of activity in the future. Indeed, while all stakeholders interviewed are conscientious about FACS prevention, no one could say with confidence that their entire profession shares that degree of conscientiousness. Further, some specialists openly admit to prescribing teratogenic medicines as they feel confident that these are the best drugs on the market. However, other specialists profess (with considerable assertion) to proactively changing the consumer's medication if those consumers fall into their caseload.

Given the diverse approaches, one could not help but consider that in the middle of this juxtaposing is the consumer, their trust in the healthcare system (L6) and what decisions to make concerning the risk of their future child having FACS (L5). For example, should a child be prescribed sodium valproate for epilepsy – especially when the prescribing specialist knows that the consumer will go through considerable upheaval in changing their medication if they decide to start a family later in life?

Situations like this require significant support, commitment and potential cost for the consumer due to repeated consultations. All of which may deter that consumer from engaging with their GP and trying for a family nevertheless.

Communications

Communication breakdowns between healthcare professionals appeared evident. For example, midwives discussed a case where they were not made aware that (teratogenic) mood stabilisers were in circulation. Similarly, GPs don't necessarily get to know when a patient becomes pregnant and only find out during an appointment with the consumer (with baby in arms). Indeed it is not entirely implausible for a female consumer of childbearing potential to be unaware of their medication and certainly not have had the opportunity to provide informed consent (L1).

Consequently, a child is at risk of being born with preventable FACS (L5), or the mother might decide to terminate the pregnancy, leaving them to deal with a broad range of emotional reactions (L6).

Recommendations and conclusions

Step 4 of the STPA analysis detailed numerous responsibilities proposed for each agency or stakeholder, with step 6 bringing all the collateral together to detail out potential loss scenarios. These serve to support recommendations and actions to improve the overall management of teratogenic medicines and are presented below. It is plausible that the analysis and subsequent recommendations highlight deeper issues within the healthcare system (not just FACS related). As a result, some benefit may be gained by broadening these recommendations to address wider concerns as well those associated with managing teratogenic medicines and FACS prevention.

The issues concerning how and who would or should deliver on these recommendations should be discussed within stakeholder groups focusing on FACS prevention.

- Seek and obtain funding to conduct a review of current legislation concerning the management of teratogenic medicines to identify if the legislation is fit for purpose. Engage with consumer groups and key stakeholders to ascertain areas of improvement. Use the evidence from this assessment to develop business cases for improvement projects.
- Seek and obtain funding to investigate the extent to which IT reporting systems can advise and support matters concerning the dispensing of teratogenic medicines to people of childbearing potential. Obtain user requirements (consumer, point of sale, healthcare professional and agency) to ascertain improvements for future IT reporting. Investigate the efficacy of the information provided and identify ways that the presentation of the information can ensure that all practitioners are accessing it. Use the findings from these activities to develop business cases for improvement projects.
- All stakeholders develop a system-wide strategy concerning the sharing of 'soft intelligence' regarding teratogenic medication and FACS prevention. This occurs, and has been proved to be beneficial, but currently takes place in an ad hoc manner.
- Seek and obtain funding into research focusing on the risks to the consumer as they transfer between primary, secondary and tertiary healthcare services with an emphasis on those consumers taking teratogenic medicines who are at, or will soon reach, their child bearing potential.
- Review the process of providing informed consent in practice.[36] What does it look like? When does it occur? Should it be repeated as the risk profile of the consumer changes? Should it be down to the individual and professional judgment of the practitioner, or should it be standardised? Should non-prescribing healthcare workers be able to have that discussion?
- Review the process of training new practitioners and their level of knowledge acquisition concerning teratogenic medicines and FACS prevention. Should consumers or consumer groups be involved in this process?
- Review the current messaging surrounding medication information and alerts – who accesses the alert systems and can the systems be improved?

[36] Focusing beyond the available guidelines and instead focusing on the 'work as done' by the prescribing healthcare worker.

To conclude, the project has delved into the healthcare system to assess how each organisation or tool interacts with one another to raise awareness of the teratogenic risks of medication leading to a child being born with FACS.

Using the STAMP-STPA approach, the analysis has teased out systematically some of the prominent and less noticeable issues that could lead to unacceptable outcomes concerning consumers of childbearing potential and the developing foetus.

The development and provision of the hierarchical control structure in appendix 4 helped formulate some of the control risks inherent in healthcare and provides the opportunity to develop further insights. For example, the presentation of losses, or unacceptable outcomes, at the beginning of the analysis. When stakeholders were encouraged to 'dig deep' to identify what is an unacceptable outcome, the resultant loss statements indicated that informed consent, knowing when to provide it and who to raise awareness of it, became evident.

While the hierarchical control structure may look complex, the prevention of FACS is only the tip of the iceberg for many issues and capabilities that the healthcare system must also consider (for example, COVID-19 vaccination and care).

The analytical findings presented in the previous chapter were based on minimal exposure to key stakeholders, and indeed, those stakeholders may not represent the popular view of their profession. The project is too small to deep dive into any single specialist area. However, that does not mean that doing so would not reveal more information concerning FAC prevention. Indeed, any specialist area or individual entity could benefit from an in-depth hierarchical control structure or other systems analysis approach (such as the functional resonance analysis method, FRAM), and there is no reason that someone with the suitable skills and knowledge could do so.

However, the modus operandi of this project was and has ensured that the management of FACS and teratogenic medicines is a system-wide issue. As a result, all relevant stakeholders should enhance their engagement and collaboration to achieve the common goal of FACS prevention.

Appendix 1: Invite for interview

Good morning (cc=fyi only; bcc=email recipients)

My name is Karl Bridges, and I am a Human Factors Consultant. Caroline Tilah has asked me to conduct a 'systems thinking analysis to prevent Foetal Anti-Convulsant Syndrome (FACS)', and there are a few steps I need to follow initially. First of all, to identify and contact stakeholders, you are one of them, which is why I am emailing today. The next step is to arrange a time to chat with you and ask some questions concerning the administration of high-risk medication - we can do this on Zoom or MS Teams or via a phone call.

Please could you advise what times/days you are available over the next 3–4 weeks – any time or any day is fine with me, assuming I am available. I know some stakeholders work out of regular office hours, and I am willing to accommodate as best as possible.

In your reply email, I would like you to think and let me know, from your perspective and the role you fulfil, what you consider an 'unacceptable outcome concerning the management and administration of medication that could result in FACS.

An unacceptable outcome involves something of value to stakeholders and may vary depending on your responsibility, position and role. Outcomes may include a loss of human life or human injury, property damage, environmental pollution, negative reputation, leaking of sensitive information or any other unacceptable outcome to the stakeholders, as well as the patient and their child.

Many of these examples may be irrelevant to you and indeed irrelevant to FACS, or you may have other previously unmentioned unacceptable losses on your mind. There is no right or wrong answer to this, nor will any judgment be passed on you for your response. I will remove any identifying information concerning your or anyone else's views.

FACS prevention and timely information of health risks to people who could get pregnant are the principal considerations. However, there may be other unacceptable losses, which I don't want to miss.

So, please reply when in the near future and let me know what days (inc weekends) you are free for a chat and your views on the unacceptable outcomes from your perspective.

Kind regards

Appendix 2: Stock interview questions

Good afternoon / morning – Thank you for taking the time to meet up with me today. The purpose of this meeting is for me to get an understanding of you, your role and your organisation and to establish where it fits within the wider management of anti-convulsant, pain and mood stabilisers known to increase the risk of FACS.

I am going to record this interview using a voice recorder – the information you provide is confidential, and the recording is stored on an encrypted hard drive – you can also ask me to stop the recording if you have specific and highly confidential information you wish to divulge. Are you comfortable with me recording?

1. Tell me about your role.
2. Tell me about your organisation.
3. What is your responsibility concerning AED medication at risk of causing FACS?
4. What expectations are upon you to manage AED medication for child bearing mothers?
5. Do you have to report to anyone concerning what you do to manage AED prescriptions to people of child bearing age? Is there any information you have to specifically provide? To whom?
6. What information do you specifically need from those you are responsible for? From whom?
7. Are there any organisations other than yours that you work closely with to manage the risk of FACS on a day-to-day basis? Under what capacity?
8. How do you know that what you are doing is effective in terms of your / your organisation's role to manage the administration of AEDs?
9. Should there be someone at high risk, what would your organisation do, if anything, to intervene?
10. What information would you get that makes you realise something is amiss (i.e., a high rate of woman of childbearing age being on AEDs whilst pregnant)?
11. Are you happy for me to get in touch again if I have any further questions?

Appendix 3: Summary of roles and responsibilities

The roles and responsibilities of participating agencies obtained during the interview process are presented below. The data provided the opportunity to develop the hierarchical control structure presented in appendix 4. The information provided below focuses on the management of teratogenic medication, and thus other aspects of the organisation may be lacking.

ACC: Supporting FACS NZ with preplanned presentations to professional groups; looking through adverse events; evaluating Conporto to see how effective it is; relooking at ACC notifications of SAC1 events to HQSC; liaising with agencies.

FACS NZ: Supporting individuals and families affected by FACS; lobbying government; providing education to healthcare professionals and government; advocating for change.

Health and Disability Commissioner: Managing and resolving complaints; working with agencies to resolve concerns; investigating signficant issues and providing opportunities to learn from investigations.

HQSC: Reviewing and improving safety and quality of care; set up as a separate entity from the Ministry of Health and not influenced by them as a sort of watchdog to challenge what is happening.

Healthcare specialists (psychiatrist, gaenacologist, obstetrician, paediatrician and GPs): Providing support, advice and care to the patient within the remit of their expertise.

Medsafe: Providing medication approvals; assessing post-marketing (safety) issues that have been picked up through CARM and what regulatory action needs to be taken.

Midwifery Council: Regulating midwives in New Zealand – registering; granting practising certificates; dealing with complaints or concerns; taking a role in protecting the public by investigating matters of concern.

Ministry of Health: Advising on governance level; canvassing medication safety, chairing the medicines classifications committee (a ministerial committee); progressing policy to get optimum use out of pharmacies; identifying what the public need from their pharmacy – knowing what is possible and what the pharmacist can do – empowering them to get the best out of their medicines.

New Zealand College of Midwives: Providing practice guidance and advice on best practice professional standards; supporting midwives in their everyday practice.

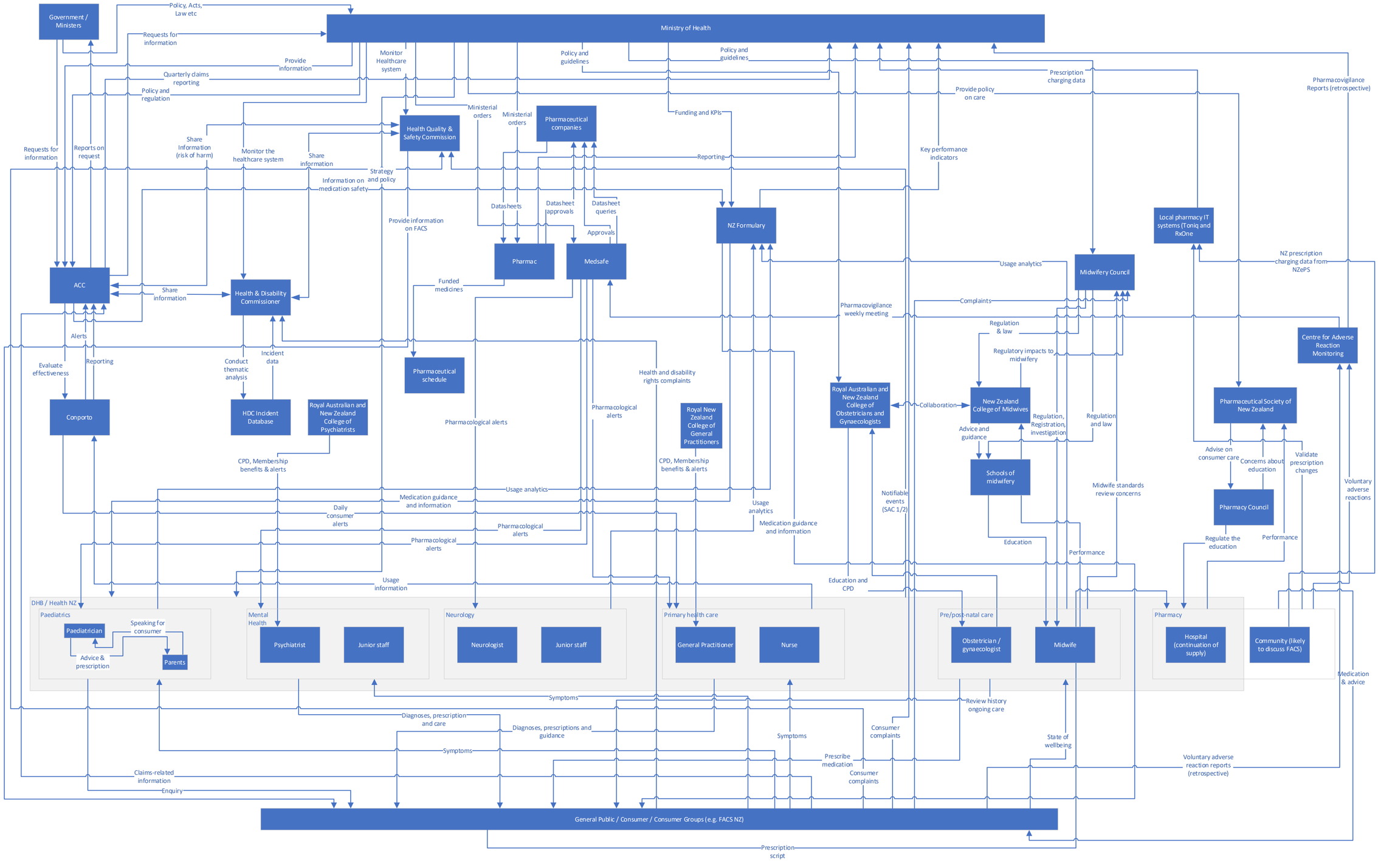
NZ Formulary: Providing a point of care concerning freely available medicine information; providing a release on the first of every month with all-new Pharmac data.

Pharmac: Assessing procurement and funding of pharmaceuticals and devices for purchase, with regard to responsible use; funding an online learning program for prescribers.

Pharmaceutical Society of New Zealand: Professional body for pharmacy (like a college of pharmacies) providing practice advice and regulatory interpretation to ensure the capacity, competence and capability of the profession; providing education and training to enable pharmacists to keep up to date and provide a range of services.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG): The professional body overseeing training and education around obstetrics, gynaecology and women's health.

Appendix 4: Hierarchical control structure



Key of definitions:

- CPD – Continuous Professional Development
- NZePS - The NZ ePrescription Service (NZePS) is a secure channel to prescribe and dispense prescriptions electronically
- Pharmacovigilance - the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem.