

# **A restorative response to harm from Foetal Anticonvulsant Syndrome (FACS)**

**Findings from a survey of affected consumers.**



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## **Introduction**

This paper provides an overview of Foetal anticonvulsant syndrome (FACS) in Aotearoa New Zealand (Aotearoa NZ). It explores who is at risk of harm from FACS and how consumers and whānau are affected. Findings from a survey of FACS NZ community members are shared to illustrate their hopes and wishes for a restorative response. The paper concludes by highlighting equity concerns and suggesting next steps. A one-page report summary is provided in appendix 1.

## **What happened?**

Antiseizure medications (ASMs), previously referred to as anticonvulsant or antiepileptic drugs, are the mainstay of symptomatic epilepsy treatment (Loscher & Klein, 2021, p. 14). Over time, use has been extended to manage psychiatric diagnosis, movement disorders and pain syndromes (Ali et al., 2023; Moores, D'Souza, & Bui, 2021). The developing foetus is at-risk of Foetal anticonvulsant syndrome (FACS) when the maternally consumed medication crosses the placenta (Włodarczyk, Palacios, George, & Finnell, 2012).

FACS is an umbrella term that includes a range of clinical manifestations, including Foetal Valproate Spectrum Disorder (FVSD), which is specifically related to antenatal exposure to sodium valproate (Accident Compensation Corporation, 2020). FACS is characterised by a combination of distinctive features involving the skull and face, physical malformations and/or neurodevelopmental or cognitive impairments (Rasalam et al., 2005).

It is a fact that some ASMs can negatively affect a developing brain (Dreier, Meador, & Christensen, 2022). In-utero exposure to some antiseizure medications is associated with a two-to fivefold increased risk of major congenital malformations, although this risk varies among medications (Moores et al., 2021). A systematic review and network meta-analysis concluded that Valproate is associated with the greatest odds of adverse outcomes, and that oxcarbazepine and lamotrigine were associated with increased risk of autism (Veroniki et al., 2017). Whilst those taking medications during the first three months of pregnancy are at the highest risk, exposure during any time in the pregnancy can be detrimental.

## How did harm from FACS emerge?

The medical and scientific community have been aware for some time that in utero exposure to antiseizure medications is likely to have harmful effects on the developing foetus. As far back as March 1968, Dr. McQueen, the Medical Assessor of the Committee on Adverse Drug Reactions NZ, wrote to the London Committee on Safety in Drugs, expressing his concerns:

*“We have recently had several cases drawn to our attention and there seems reason to believe that these constitute only a small proportion of such cases, the majority probably escaping attention. The Committee is concerned the potential dangers of this group were being lost sight of, since congenital abnormalities of this kind during the early months of pregnancy continue to be reported.”*

During the same time period, congenital birth defects and deaths were also reported to the New Zealand Centre for Adverse Reactions Monitoring e.g., [link](#) The related diagnoses included spina bifida, cleft palate, heart defects, limb malformations, neurodevelopmental delays, and intellectual disability. MedSafe issued an alert warning of the risks of birth defects and developmental problems in 2019. The scale and severity of the harm was collated by the United Kingdom’s 2020 [Independent Medicines and Medical Devices Safety Review](#), which also laid bare the consequences of a healthcare system that does not listen to the experiences of women.

To date, research has focused on studying ‘clinical abnormalities’ and mitigating the risk of FACS harm, but has not examined the patient, family or whānau experience. Globally, harm prevention and engagement strategies have targeted medicine restriction/control policy and the prescribing practices of medical practitioners. A recent New Zealand study that examined medical prescribing practices in 2594 children concluded that these approaches are important (Ali et al., 2023). The researchers proposed that clinician focused ASM teratogenicity messaging is critical and that health policies must consider the socioeconomic factors that influence prescribing practices.

In addition, Te Tāhū Hauora, Health Quality & Safety Commission ordered a system thinking analysis in 2021 which aimed to identify *“opportunities for improvement and potential threats to safe medication administration by people of childbearing potential.”* The report will be published in 2023.

## Who is affected?

The Official Information Act (OIA) 1982 is an Act of the New Zealand Parliament which creates a public right to access information held by government bodies. Some of the data gathered by FACS NZ using the OIA can be found here [link](#). It is used in this paper to illustrate who is affected by FACS.

Figure 1 depicts the number of live births exposed to sodium valproate during pregnancy, by prioritised ethnic group, between 2007-2019. The data was released by the Ministry of Health on the 25<sup>th</sup> of June 2020 (DAstill OIA4723). During this period, a total of 846 live births were exposed to sodium valproate. The percentage of Māori exposed (37%) is significantly higher than would be expected when compared with population data from the 2018 Census (16.5%).

Source Ministry of Health Pharmaceutical Collection, extracted on 25/06/2020  
Ministry of Health National Maternity Collection, extracted on 25/06/2020

Please note that reporting on dispensings of sodium valproate during pregnancy requires an NHI number to be recorded on the pharmaceutical dispensing and the birth record.

Data is only provided for dispensings that are community-dispensed and publicly-funded.

The following formulations of sodium valproate were included: Tab 200 mg EC; Tab 100 mg; Oral liq 200 mg per 5 ml; Tab 500 mg EC

Birth data for 2019 is provisional and subject to change.

Stillbirths and births where the outcome of the pregnancy was not stated have been excluded.

**Number of live births where the childbearing person was dispensed sodium valproate during estimated duration of pregnancy, by prioritised ethnic group of childbearing person, 2007-2019**

Birth year	Māori	Pacific Peoples	Asian	European or Other	Total
2007 - 2019	309	49	18	470	846

**Number of live births where the childbearing person was dispensed sodium valproate during estimated duration of pregnancy, by prioritised ethnic group of childbearing person (Māori / non-Māori) and year, 2007-2019**

Birth year	Māori	Non-Māori	Total
2007	30	94	124
2008	44	72	116
2009	32	71	103
2010	26	32	58
2011	33	53	86
2012	29	44	73
2013	14	41	55
2014	20	25	45
2015	27	24	51
2016	15	21	36
2017	14	26	40
2018	16	20	36
2019	9	14	23
<b>Total</b>	<b>309</b>	<b>537</b>	<b>846</b>

Figure 1: The number of live births exposed to sodium valproate during pregnancy between 2007-2019, by prioritised ethnic group 2007-2019.

An additional OIA (H202105751) extracted data on 17 May 2021. Table 1 illustrates the live births exposed to carbamazepine, phenobarbital, phenytoin, topiramate, clobazam, and lamotrigine between 2016-2020. It is challenging to draw conclusions from the data because people using more than one type of anti-seizure medication can appear in two or more categories.

Table 1. Number of liveborn infants whose mothers were dispensed selected anti-epilepsy drugs during pregnancy				
Year of birth	2016	2017	2018	2019
<b>Māori</b>				
Carbamazepine	19	22	16	17
Clobazam	<5	0	<5	<5
Lamotrigine	25	31	32	31
Phenytoin sodium	<5	<5	<5	0
Topiramate	9	9	7	5
<b>Non-Māori</b>				
Carbamazepine	38	22	30	30
Clobazam	6	<5	10	7
Lamotrigine	76	73	85	92
Phenobarbitone	<5	0	0	<5
Phenytoin sodium	<5	0	0	0
Topiramate	18	30	26	19

Figure 2: The number of live births whose mothers were dispensed selected anti-epileptic drugs during pregnancy.

## Treatment Injuries

Section 32 of the Accident Compensation Act 2001 defines a treatment injury as:

*“A personal injury suffered by a person seeking treatment or received treatment from a Registered Health Professional and caused by treatment and not a necessary part, or ordinary consequence of the treatment, taking into account all the circumstances of the treatment, including the person’s underlying health condition at the time of the treatment, and the clinical knowledge at the time of the treatment.”*

Personal injury is defined as *“a physical injury causing damage to the body. Unless there is evidence of actual damage to the body, it cannot be said that a physical injury has been established.”* (Injury Prevention, Rehabilitation, and Compensation Amendment Act (No 2), Section 32, 2005)

ACC claims for learning and developmental disorders or psychological support require a physical injury to be accepted before other coverage can be considered. FACS NZ submitted an OIA request for ACC treatment injury data in March 2023 (GOV-023199). The data

indicates that between 1 July 2005 and 18 February 2023 a total of 69 cover decisions were made for claims relating to Foetal Valproate Syndrome (FVS)<sup>1</sup>. Of these, 49 were accepted and 20 were declined. Of the 49 accepted claims for FVS, 32 (65 percent) were classified as serious injury claims who will have a lifelong relationship with ACC. There were no fatal treatment injury claims for this group.

Of the 20 declined treatment injury claims for foetal valproate syndrome 4 were from the Te Whatu Ora Southern region. The remaining claims were from several other Te Whatu Ora location regions all with fewer than four declined claims. Southern and Auckland regions appear to have the greatest number of accepted claims, which could indicate a safety issue with prescribing practices, or that doctors in these regions are successfully identifying and submitting claims.

**Regions of accepted claims by 'Te Whatu Ora'**

Southern (formerly Southern DHB)	Te Toka Tumai (formerly Auckland DHB)	Te Pae Hauora o Ruahine o Taranaki MidCentral (formerly Midcentral DHB)	Waikato (formerly Waikato DHB)	Te Tai o Poutini West Coast (formerly West Coast DHB)	Other locations*
13	11	5	4	4	12

\*Claim counts for the remaining Te Whatu Ora locations were all less than four so we grouped these locations together.

Figure 3: Region of accepted claims by Te Whatu Ora

One would expect treatment injury claims to be higher given statements made by the UK Medicines and Healthcare Products Regulation Agency (2021). The agency suggests that if 100 women take a valproate medicine during pregnancy about 10 of their babies will be born with physical birth abnormalities and about 30 to 40 of the 100 children will go on to have disorders affecting their learning and thinking abilities, including autism. Treatment injury ethnicity data indicates that whilst a significant proportion of Māori children were exposed to sodium valproate in pregnancy (309), only five claims have been accepted. The

<sup>1</sup> Foetal Valproate Syndrome/Spectrum Disorder is one of the individual syndromes/spectrum disorders, when the foetus was exposed to sodium valproate only during pregnancy, and no other anti-seizure medicine. FACS is when there is exposure to more than one anti-seizure medicine during pregnancy e.g., sodium valproate and carbamazepine.



number of accepted claims for people identifying as European (n=38) also appears low, reflecting 7% of the children known to be exposed to sodium valproate during pregnancy.

### **Why is FACS NZ advocating for a restorative response?**

The needs of children born with FACS, and their families and whānau are significant and diverse. Affected consumers have argued that current strategies do not adequately address the issues that are important to them, such as informed consent, relational power dynamics and inequity (Waite et al., 2022). For some time, the consumer advocacy group *Foetal Anti-Convulsant Syndrome New Zealand* (FACS NZ) has been advocating for the opportunity for their stories can be heard, captured, and responded to. Other countries have provided this opportunity within a formal Government inquiry (e.g., Cumberlege & The independent medicines and medical devices safety review, 2020).

In 2021, FACS NZ gained endorsement from its board to request a restorative response be provided by the interdependent agencies and professional groups involved in the system that mitigates and responds to harm from antiseizure medications and FACS in particular. FACS NZ are unable to resource or operationalise a restorative response themselves and have approached several agencies seeking formal support. Whilst the people they have spoken to have expressed a desire to support the request, formal action has not yet been realised.

In 2022, FACS NZ started working with a restorative health systems expert to understand what additional actions they could undertake to assist the sector to act. At this stage, it was decided that gathering information from the FACS community would assist the responsible parties to understand what a response might look like, and the potential resources and commitments required.

## **What is a restorative response?**

In contrast to approaches that promote disclosure, communication, and resolution, restorative responses are fundamentally relational in nature. They appreciate that human relationships are at the core of the human experience of the world, are fundamental to human wellbeing and are implicated in our healing (Wailling, Kooijman, Hughes, & O'Hara, 2022).

Whether an act is intentional or not, a restorative response involves working together to repair the harm and to ensure that responsibility is taken for the impacts of the actions or behaviour of individuals, teams or 'the system' more broadly. The focus moves away from understanding what is 'wrong' with an individual, and instead appreciates the human impacts and needs of all the people, whānau, or communities involved (The National Collaborative for Restorative Initiatives in Health, 2023). Restorative responses are a nascent area of development in health systems globally, but there is tentative evidence for their use, with evaluations highlighting positive impacts on human wellbeing as well as financial benefits (Mannat, De Boer, Oates, Rafferty, & Dekker, 2019; Turner et al., 2022; Wailling, Wilkinson, & Marshall, 2020).

In Aotearoa NZ, restorative responses include restorative practices and hohou te rongo (peace-making from a te ao Māori worldview). Both are principles-based and use specific practices or tikanga to create a safe and supportive environment to explore health care harm (The National Collaborative for Restorative Initiatives in Health, 2023). Ideally, all parties affected will come together to safely and respectfully share their different perspectives to build mutual understanding and trust across their differences. When coming together is not possible, healing can still be achieved by hearing and responding to the needs and rights of the people involved.

In 2019, Manatū Hauora commissioned a major and unprecedented restorative response to surgical mesh harm (Wailling, Marshall, & Wilkinson, 2019). The evaluation concluded that a restorative response can meet peoples procedural and psychological needs in ways that current approaches do not (Wailling et al., 2020). The project has

also led to system improvement with the launch of a co-designed female pelvic mesh service in 2023. In 2023, Te Tāhū Hauora, Health Quality & Safety Commission (Te Tāhū Hauora) launched their revised National adverse events policy. The Healing Learning and Improving from Harm policy, came into effect in July, and states that consumers and whānau should be offered an opportunity to participate in a restorative response (Te Tāhū Hauora Health Quality & Safety Commission, 2023).

## Survey Design

A survey was co-designed with the FACS board (appendix 2) in 2022. It used the survey from the surgical mesh response as the starting point and aimed to:

- Understand if and how individuals, families and whānau affected by FACS might like to share their experiences.
- Gather data from FACS NZ members to inform how they would like to share their experiences of FACS with those responsible for acting for repair and prevention.

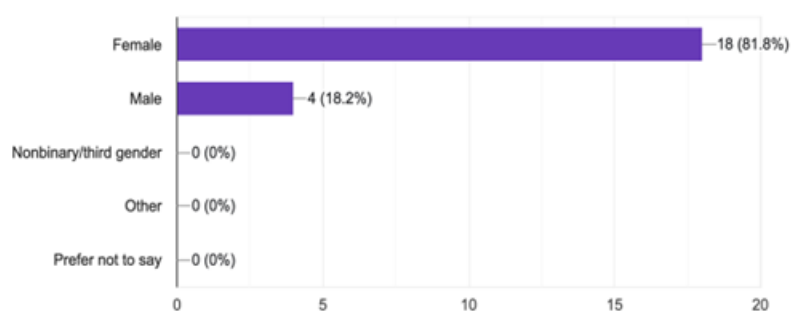
FACS NZ were concerned with mitigating the risk of compounded harm from a number of factors. FACS NZ were offered and decided not to pursue a formal research process, but guidance was sought from an ethics specialist. FACS NZ co-designed the survey and participant information packs in accordance with good research practice. The survey was voluntary and anonymous. Links to support options were provided and included the national counselling line and access to tailored FACS resources. Participant information clearly stated the survey purpose, and that completing the survey did not guarantee a response would occur or that respondents hopes and wishes would be supported.

In January 2023, people who are on a FACS NZ subscribed mailing list and/or FACS NZ parent/guardian private Facebook group were invited to complete the survey. The survey was open for almost three months. Responses were collected by Denise Astill and stored in a secure password protected file. In April 2023, responses were analysed and independently reviewed to produce themes and descriptive statistics.

## Findings

Twenty-two people responded to the survey. It is not possible to calculate the response rate due to use of a non-targeted recruitment strategy. Most respondents identified as women (81.8%), aged 45-54, were European (86.4%), and were living in the Northern region. Sex and ethnicity data is provided in Figure 2.

I identify as:



Which ethnicity do you belong to? Select all that apply to you.

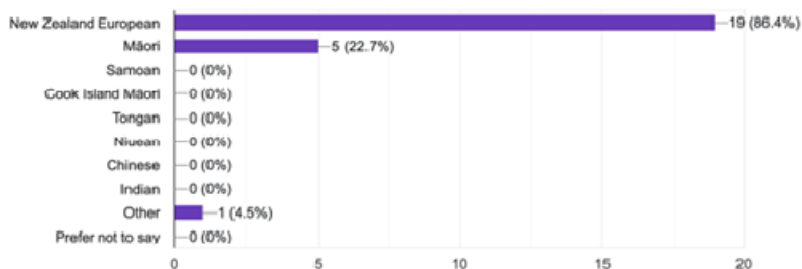


Figure 2: Sex and ethnicity data

The roles most people identified with were (a) a person who took anti-seizure medication when pregnant (54.5%); (b) a parent of a person affected by FACS (40.9%); and (c) family or whānau of someone affected (31.8%). Responses are illustrated in Figure 3.

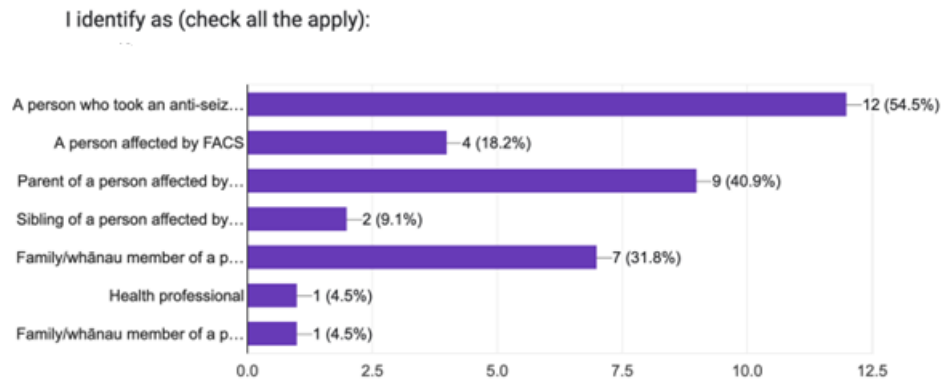


Figure 3: The roles respondents identified with

### How do respondents describe the impacts of FACS harm?

Most respondents (81.9%) indicated that they were experiencing the impacts of the harm severely (everyday), or moderately (most of the time).

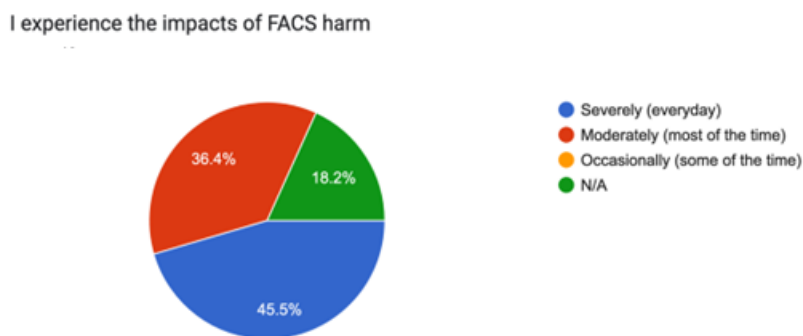


Figure 4: How often respondents experience the impacts of FACS harm

Of those who indicated they were severely affected; the highest representation was from women who took an anti-seizure medicine during pregnancy and are now the parent of a person affected by FACS. In the moderate category there was equal representation from women who took the anti-seizure medicine during pregnancy, and those directly affected by FACS. These findings are important because a recent meta-analysis concluded that mothers of young children with developmental disabilities may have poorer health than those with typically developing children (Masefield et al., 2020). The lifelong impacts, and the financial costs are also cited within the ACC treatment injury literature:

*“FACS has a life-long impact on affected children and their family/whānau. It can cause physical malformations such as heart defects, cleft palate, and spina bifida, as well as learning and behavioural difficulties. The average lifetime cost to ACC of a single FACS claim is estimated at \$7 million. A single severe claim is estimated to cost ACC between \$5 million and \$25 million, which is an indication of the impact on the person.”*

(Accident Compensation Corporation, 2021)

## **What do consumers hope and wish to gain by sharing their experience of FACS?**

Free text comments indicate that most respondents hoped that sharing their experiences would contribute to feeling heard and validated.

*“People [will] finally hear the voices of those who have been affected by FACS. We are often dismissed by different people, and to bring awareness of FACS as it is an invisible disability.”*

Many respondents desired improved relationships with General Practitioners and other health professionals. These relationships were viewed as essential to access care, meet needs, and prevent harm to others in the future. Raising awareness of FACS and how it affected children and their families, was described as essential. Respondents suggested several platforms which could be used to raise awareness including the media, government, health, and education. Specialist training and resources for clinicians, teachers and affected families was deemed important.

Some respondents indicated that sharing their experiences would enable access to desired supports. Desired supports included peer networks, specialist clinical assessment and easier access to treatment injury and other claims. Several comments related to the desire for improved access to education and wellbeing support at school.

## Who do consumers want to listen and respond?

Figure 5 depicts the people consumers wanted to listen and respond to their experiences. Many respondents indicated that it was important to be heard by *“authentic and invested parties who would use the information collected in respectful and morally bound ways.”* The organisations/agencies respondents wanted to share their experiences with included the Accident Compensation Corporation, Manatū Hauora, Medsafe, Te Tāhū Hauora, Health and Disability Commissioner, Ministry of Education, Minister of ACC, Minister of Disability, Whaikaha and The Pharmaceutical Management Agency (PHARMAC).

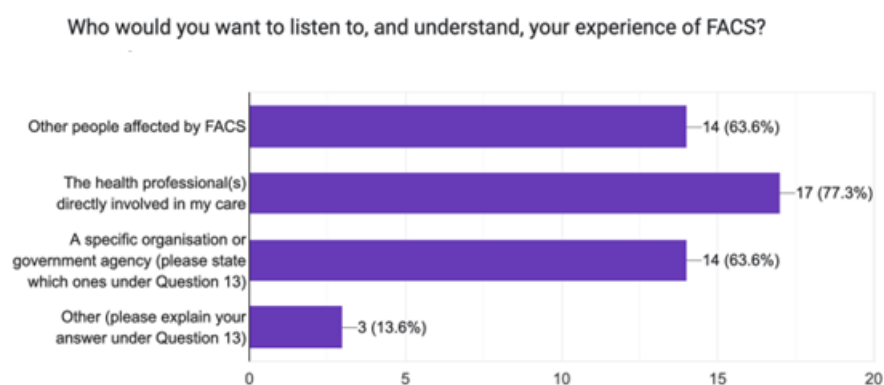


Figure 5: Who respondents wanted to listen and understand their experiences of living with FACS

## How would consumers like to share their experiences?

Approximately half of respondents wanted to share their experience in a story database using letters, surveys pictures or video (Figure 6). Of those that desired an in-person meeting, half indicated a preference for a private meeting. The other half wanted to be with other people affected by FACS, and some indicated that community support was important because *“having a couple of others from our support group there [is important because] we gel, and just get it.”*

I would prefer to share my experience (check all that apply):

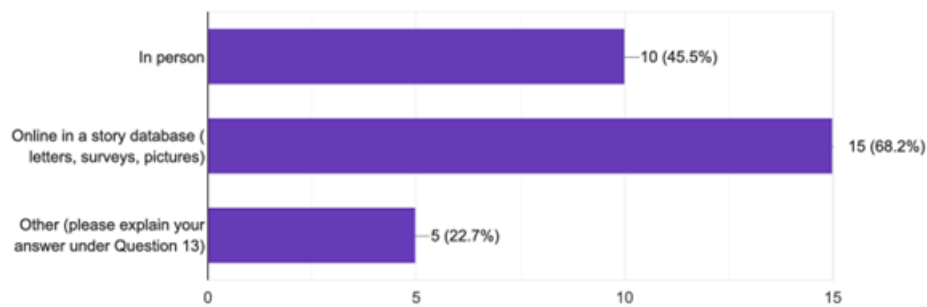


Figure 6: How consumers want to share their experiences

Most comments indicated that respondents would feel safe and supported to share their experience with peer or whānau support, in a safe and quiet environment. Many (61%) indicated that they would feel safe to share their stories with other people who were affected by FACS, but some respondents shared that it was important that children or family were not present. A couple mentioned that appropriate counselling support would be required.

Respondents cited operational challenges to participating, such as travel or childcare. They indicated that certain behaviours would also prevent them from feeling safe to share their experience. These included “*defensive responses*” and other negative interactions they had experienced in the past when contacting health and educational agencies. ACC processes were described as adversarial with one respondent noting that “*we shouldn't have to fight and argue our cases all the time!*” Many people indicated they feared shame or judgement, and that feelings of anxiety and nervousness might inhibit them from participating in person. Preparation and emotional support were seen to be of key importance because:

*“Our time is very precious, undertaking this will be very upsetting and overwhelming for participants. All members of direct family feel impacts.”*



## Equity considerations

The data obtained in OIA requests indicates that Māori are at considerable risk of harm from antiseizure medications, and the authors are not aware of a targeted strategy to address this risk. The small number of Māori respondents to the FACS NZ survey suggests that a Kaupapa Māori engagement and research approach is required to appreciate and evaluate the aspirations and needs of affected Māori whānau and communities at risk of harm from FACS. As this survey invited responses from consumers who are already engaged with FACS NZ, it is likely that other vulnerable groups will require a targeted strategy to seek their views.

## Where to from here?

In August 2023, the report was shared with members of the National Collaborative for Restorative Initiatives in Health to seek their guidance on the next steps.

Members acknowledged that important cross sector work was underway, and affirmed that lived experience and equity considerations must be central to any restorative response to FACS related harm. The Collaborative suggested that FACS NZ could consider pursuing the following options.

- Register adverse events with a care provider under the new national policy Healing, learning and improving from harm: Te whakaora, te ako me te whakapai ake i te kino via their GP or paediatric doctor. The policy now supports individuals to ask for a restorative response, but the Collaborative noted that the 'system' is 5 years away from embedding restorative responses so there is much to do before they will be easily accessible.
- FACS NZ could consider approaching Manatū Hauora to request a systemic response, noting that any response would need cross government commitment and should apply knowledge gained from the Manatū Hauora experience within the surgical mesh programme.

- ACC have undertaken significant pieces of work in treatment injury (TI) prevention for FACS related harm. ACC is open to conversations on how restorative responses may be beneficial across various claim types.
- A need to better understand what is happening for affected Māori and what a hohou te rongu process might involve. The health sector has obligations under Te Tiriti o Waitangi and Māori communities outside of the Collaborative may be supportive partners.
- If consumers are not reporting FACS injury or complaints using existing processes (adverse events, MedSafe, complaints processes) then strategies that support people to be made aware of their rights may be helpful.
- Including restorative response opportunities into the health pathways and Starship hospital guidelines may be helpful.

## Conclusion

FACSNZ has been advocating for a restorative response since 2022. Members of our community want to share their experiences of FACS related harm for numerous reasons and have diverse procedural needs including where, and to whom, and how they want to share their story. To date, it has been challenging to identify who should lead a restorative response that will adequately listen, understand, and respond to the needs of harmed communities. Given that the responsible agencies include health, education and disability a cross government approach is required.

A limitation of the survey is the small number of respondents with Māori not well represented. Given that vulnerable groups are affected by FACS harm, a targeted strategy is required to seek a broader view. Considerable inequity exists and a Kaupapa Māori engagement and evaluation approach will also be required to appreciate and evaluate the aspirations and needs of Māori.

A restorative response can account for the identified complexities because it would be co-designed by all of the affected parties, and facilitated by independent experts who are

invested in responding to the rights and needs of all of the people involved. The National Collaborative has provided some insights as to the next steps that FACS NZ could take to achieve our ambitions. FACS NZ is committed to advocating for a collaborative cross government response that might achieve these aims.

## Appendix 1: Report on a page

- ASMs are being used for epilepsy, mental health conditions, movement disorders, and pain syndromes.
- ASMs can negatively affect a developing brain when exposed during pregnancy.
- FACS is characterised by a combination of distinctive features involving the skull and face, physical malformations, and/or neurodevelopmental or cognitive impairments.
- FACS is an umbrella term that includes a range of clinical manifestations, including Foetal Valproate Spectrum Disorder.
- In Aotearoa NZ a letter dating back to 1968 from the Medical Assessor of the Committee on Adverse Drugs Reactions New Zealand, wrote to London Committee on Safety in Drugs, expressing concerns around anticonvulsants and congenital malformations.
- The Centre on Adverse Reactions Monitoring (in Aotearoa NZ) had reports of congenital birth defects and death with anticonvulsant exposure during pregnancy during the same time period as the above-mentioned letter.
- Live sodium valproate exposed births during 2007-2019 was 846 babies.
  - The percentage of Māori babies exposed was 37 percent, which is significantly higher than expected when compared to the 2018 Census data (16.5%).
- ACC have accepted 49 FACS claims as of March 2023 with 65 percent being classified as serious injury. “The average lifetime cost to ACC of a single FACS claim is estimated at \$7 million. A single severe claim is estimated to cost ACC between \$5 million and \$25 million, which is an indication of the impact on the person.”
  - Only five claims for Māori children have been accepted.
- FACS NZ have been advocating for an opportunity to share their experiences via a restorative process since 2021.
- In 2022 a survey was co-designed with FACS NZ Charitable Trust in 2022 aiming to:
  - Understand if and how individuals, families and whānau affected by FACS might like to share their experiences; and
  - Gather data from FACS NZ members to inform how they would like to share their experiences of FACS with those responsible for acting for repair and prevention.
- There were 22 respondents. 81.8% were from women, aged 45-54, European (86.4%) and lived in the Northern region. 54.5% of respondents were people who took an ASM during pregnancy. 81.9% of respondents identified that they were experiencing the impact of harm severely (everyday), or moderately (most of the time).
- Findings indicate that members of FACS NZ community want to share their story for a variety of reasons, and the choice of where, and to whom, and how they want to share their stories differs. Provision of tailored support was seen to be essential.
- As this survey targeted at consumers who are already engaged with FACS NZ, it is likely that other vulnerable groups will require a targeted strategy to seek their views. Findings indicate that considerable inequity exists and that a Kaupapa Māori engagement approach will also be required to appreciate and evaluate the aspirations and needs of Māori affected or at risk of harm from FACS.

## Appendix 2: Survey

### **Responding to harm from Foetal anticonvulsant syndrome (FACS) INFORMATION FOR PARTICIPANTS**

You are invited to take part in this survey of our members. Please read this information before deciding whether or not to take part. If you decide to participate, thank you. If you decide not to participate, thank you for considering this request.

#### **What is the aim of the survey?**

The survey aims to:

- Understand if and how individuals, families and whānau affected by FACS might like to share their experiences.
- Gather data from FACS NZ members to inform how they would like to share their experiences of FACS with those responsible for acting for repair and prevention.

Taking part in this survey does not guarantee that those harmed will be able to share their experience or that your hopes and wishes can be supported. It is for purposes of trying to establish an understanding of why, how and for whom it is necessary.

#### **How can you help?**

You can complete this survey as an individual or as a family or both. You have been invited to participate because you are a member of the FACS NZ community. We also ask that that you pass the opportunity to anyone who falls into the below categories whom you think might like to participate.

- People who took anti-seizure medicine(s) while they could get pregnant and were not able to give/obtain full informed consent, or make an informed choice, about their treatment.
- People affected by FACS, whether they have a formal diagnosis or not.
- Whānau and family of the previous group.
- People that represent babies that did not survive.
- Medical professionals involved with prescribing, dispensing, or supporting people who take/took anti-seizure medicine(s) while they could get pregnant, or people that have been affected by FACS.

If you agree to take part, you will complete a survey which will ask you questions about the process and will take you approximately 10-20 minutes to complete.

#### **What will happen to the information you give?**

The survey is anonymous, and the answers will be seen by Denise Astill and a researcher. By answering this survey, you are giving consent for us to use your responses in a report. Your answers will remain completely anonymous and unidentifiable. You have the right not to answer a question and can decide to withdraw or change your responses before

submission. Once you submit the survey, it will be impossible to retract your answer. Please do not include any personal identifiable information in your responses.

### **What will the survey produce?**

The results will be analysed by a researcher in partnership with Denise Astill and documented in a report which will be made publicly available on the FACS NZ website. The report will be used in meetings with the agencies involved in responding to FACS to advocate for a meaningful opportunity for our members to share their experiences.

### **If you have any questions or problems, who can you contact?**

We recognise that living with FACS can be distressing. If you feel distressed and would like to talk to someone you can call or text 1737. When someone texts or calls 1737 a counsellor will work with the person to develop a care plan. This could include referral to another service, additional counselling or provision of information and support. At the end of the survey, you will be provided with other sources of information and support you can access if you wish.

If you have any questions about the survey, either now or in the future, please feel free to contact:

Denise Astill [denise@facsnz.com](mailto:denise@facsnz.com)

1. I identify as:

- Male
- Female
- Nonbinary/third gender
- Other
- Prefer not to say
- Prefer to self-describe (must have a text box)

2. Which ethnicity to you belong to? Select all that apply to you:

- New Zealand European
- Māori'
- Samoan
- Cook Island Māori
- Tongan
- Niuean
- Chinese
- Indian
- Other
- Prefer to self-describe (must have a text box)
- Prefer not to say

3. Which age range do you belong to?

- 15-19
- 20-24
- 25-34
- 35-44
- 45-54
- 55-64
- 65-74
- 75 plus

4. What health system region of Aotearoa NZ do you live in?

- Northern: Northland, Waitematā, Auckland and Counties Manukau
- Te Manawa Taki: Waikato, Lakes, Bay of Plenty, Tairāwhiti, Taranaki
- Central: MidCentral, Whanganui, Capital & Coast/Hutt Valley, Hawke's Bay, Wairarapa
- Te Waipounamu: Canterbury/West Coast, Nelson Marlborough, Southern, South Canterbury

5. I identify as (tick all that apply):

- A person who took anti-seizure medication(s) whilst attempting to get pregnant
- A person affected by FACS
- Parent of a person affected by FACS
- Sibling of a person affected by FACS
- Family/whānau member of a person affected by Foetal Anticonvulsant Syndrome (FACS)
- Health professional
- Prefer to self-describe (must have a text box)

6. I experience the impacts of FACS harm

- Severely (everyday)
- Moderately (most of the time)
- Occasionally (some of the time)

7. What are your hopes and wishes for sharing your experience of FACS? (TEXT BOX)

8. Who would you want to listen to, and understand your experience of FACS?

- Other people affected by FACS
- The health professional directly involved in my care

- A specific organisation or government agency (please state which ones – NEEDS TEXT BOX)
- Other, please explain your answer (TEXT BOX)

9. I would prefer to share my experience (tick all that apply)

- In person
- Online in a story database (letters, surveys, pictures)
- Other, please explain you answer (NEEDS TEXT BOX)

10. Which of the following in person options appeals to you?

- Sharing my story in a safe space with other people affected by FACS
- Telling my story in a private setting

11. What might prevent you from sharing your experience in a way that works best for you? (TEXT BOX)

12. What would help you to feel safe and supported to share your experience? (TEXT BOX)

13. Is there anything else that is important for us to know? (TEXT BOX)

### **End of Survey Message**

**Your response has been recorded. Thank you for completing the survey.**

### **Where can I get support and more information?**

If you feel distressed and would like to talk to someone you can call or text 1737. When someone texts or calls 1737 a counsellor will work with the person to develop a care plan. This could include referral to another service, additional counselling or provision of information and support.

If you would like more information about where you can get support for FACS you can connect with:

**FACSNZ** <https://www.facsnz.com/> or email Denise Astill [denise@facsnz.com](mailto:denise@facsnz.com)



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