

First Do No Harm

Towards Safer Prescribing in Pregnancy

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Introductions



Denise Astill

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Foetal Anti-Convulsant Syndrome
New Zealand



Dr Janine Ryland (FNZCPHM)

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ACC

A Case To Remember

22 year-old female with generalised epilepsy.

Currently on 1000mgs sodium valproate twice daily.

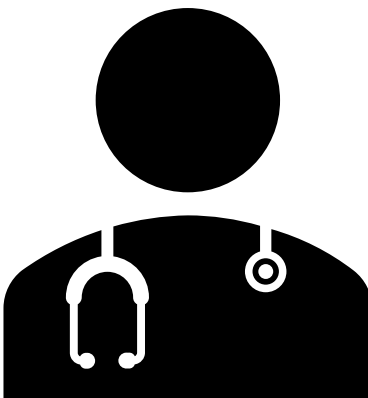
Wants to have a baby.

What advice would you give her?


What are her risks?



What She Was Told



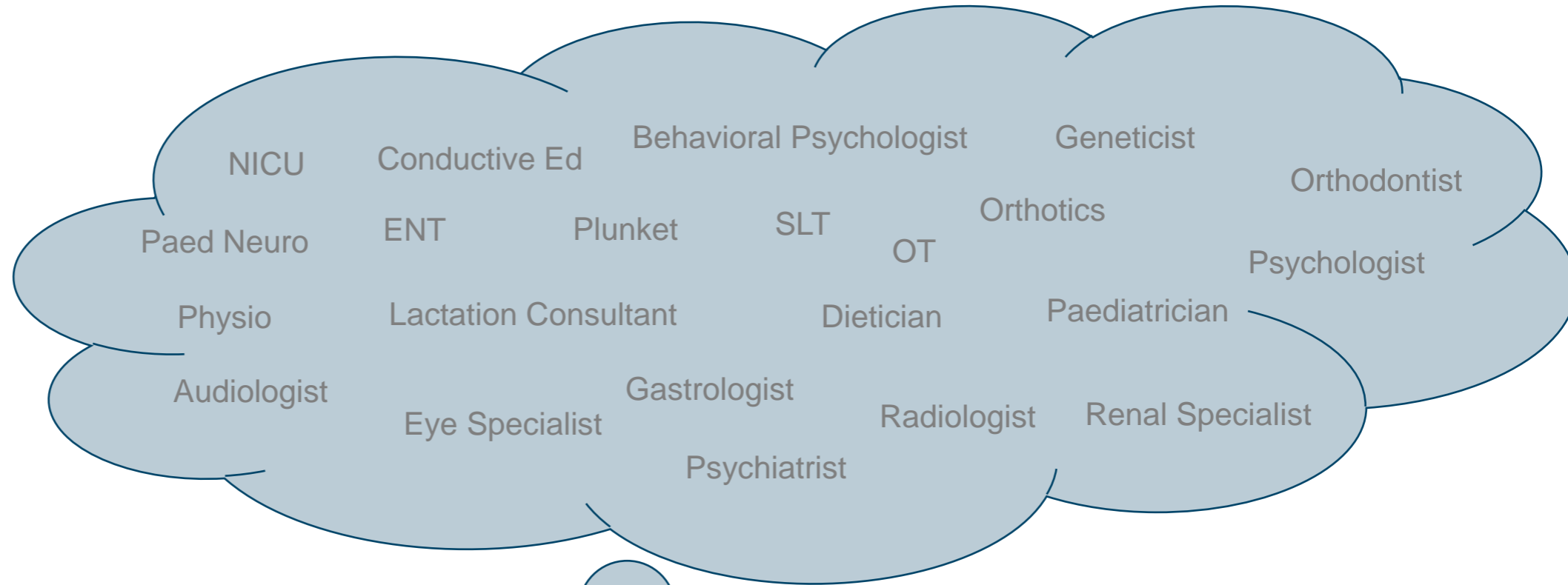
Stay on your medicine and there is a chance of spina bifida, or neural tube effects, but just take your folic acid and your baby will be fine.



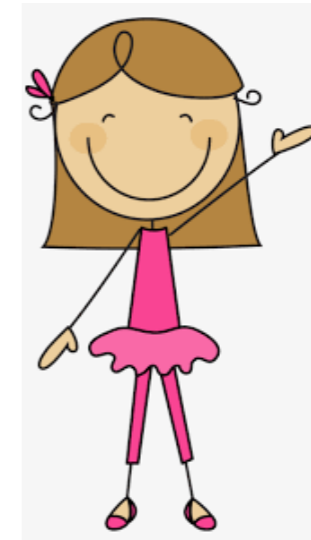
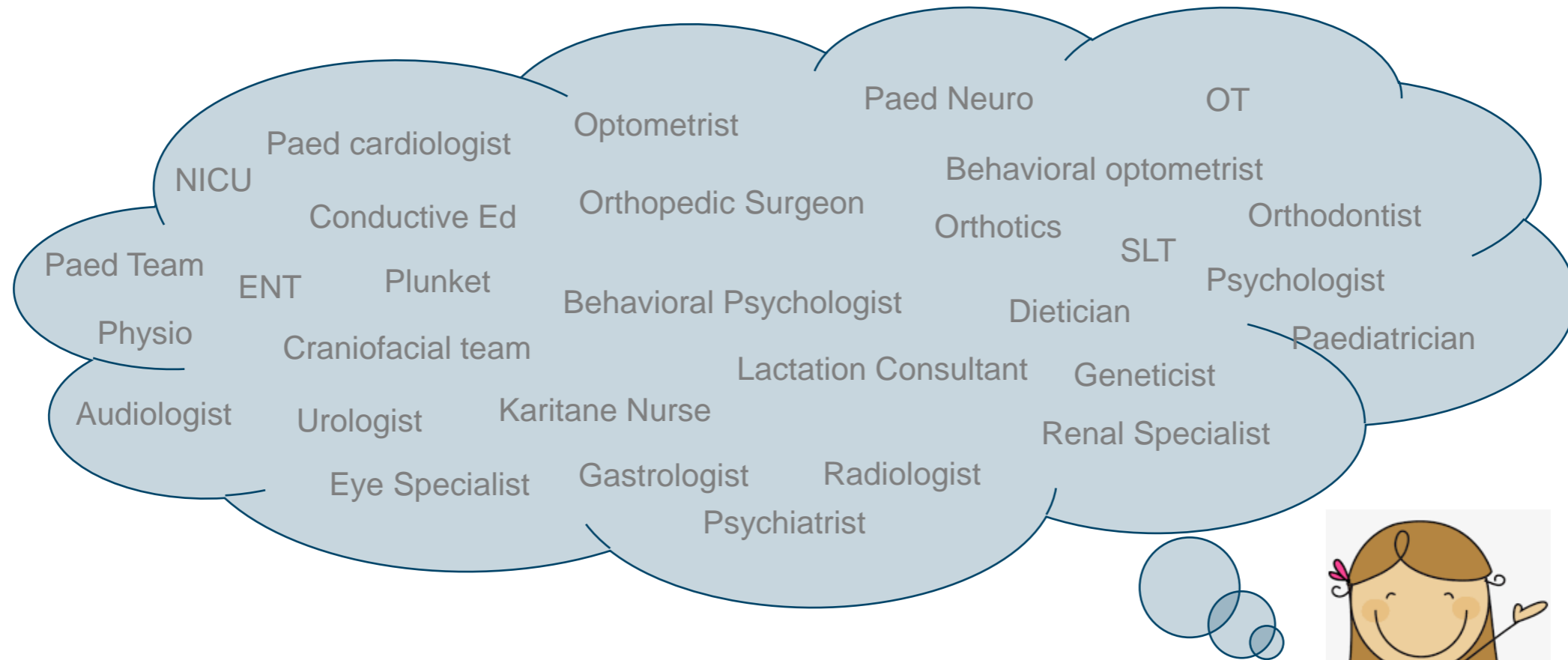
Or..... come off your medicine, you will have more seizures, and your baby will be brain damaged, but the choice is yours.

I'll stay on the medicine and take the folic acid, - sounds like everything will be OK.

Specialists & Therapists Already Seen – Twin I



Specialists & Therapists Already Seen – Twin II



Meet Denise and Cam

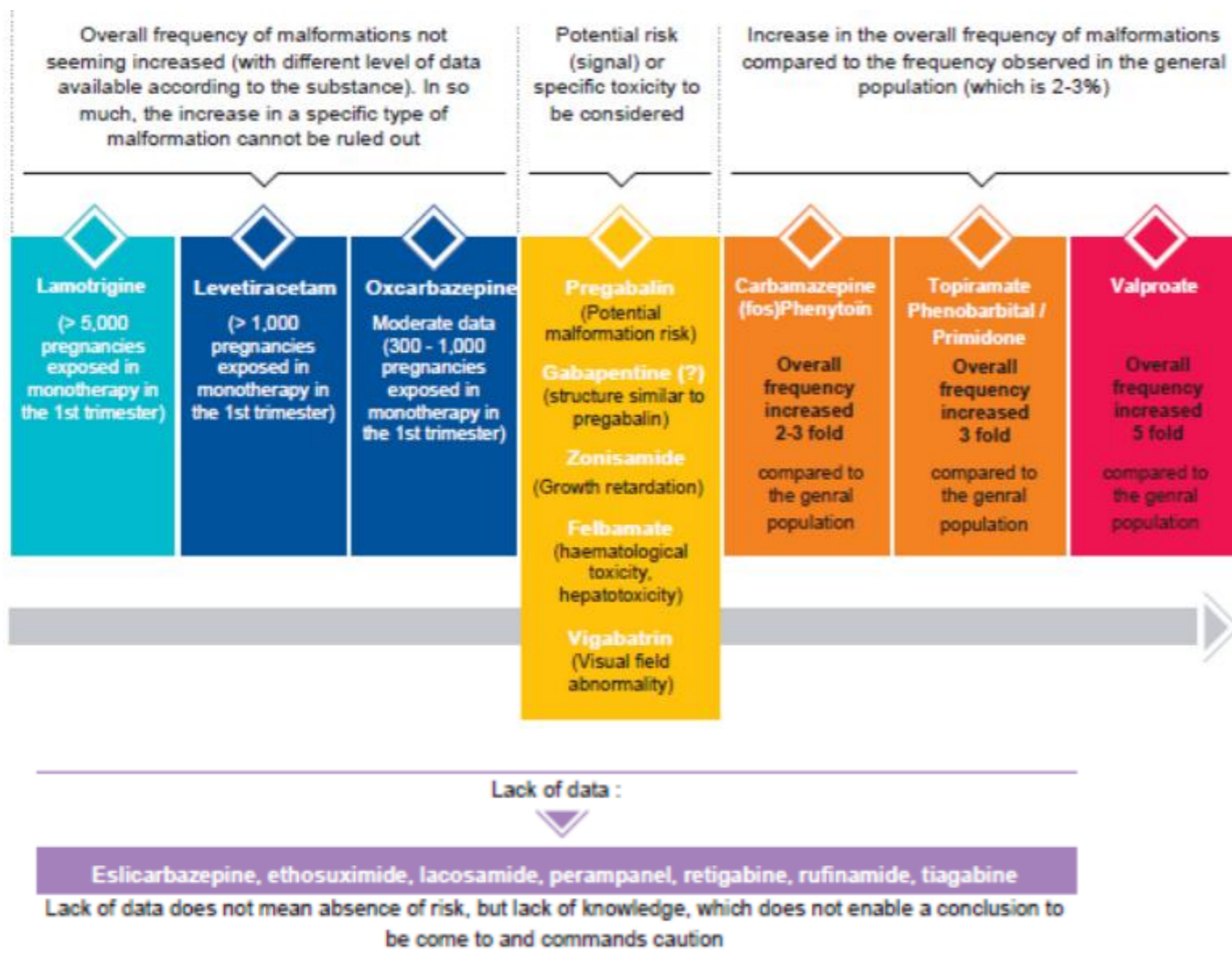


What you will get out of today's session



- Awareness of FACS lived experience
- Importance of informed consent
- System challenges in balancing therapeutic benefit with risks / safety
- Optimisation efforts – past and future
- Ability to reflect on your role & potential to advance system change

FACS - Overall risk of malformations & neurodevelopmental disorders



30 - 40 children in every 100 may have developmental problems.
Cognitive development delay
OR 7.4 (3.00-18.46)

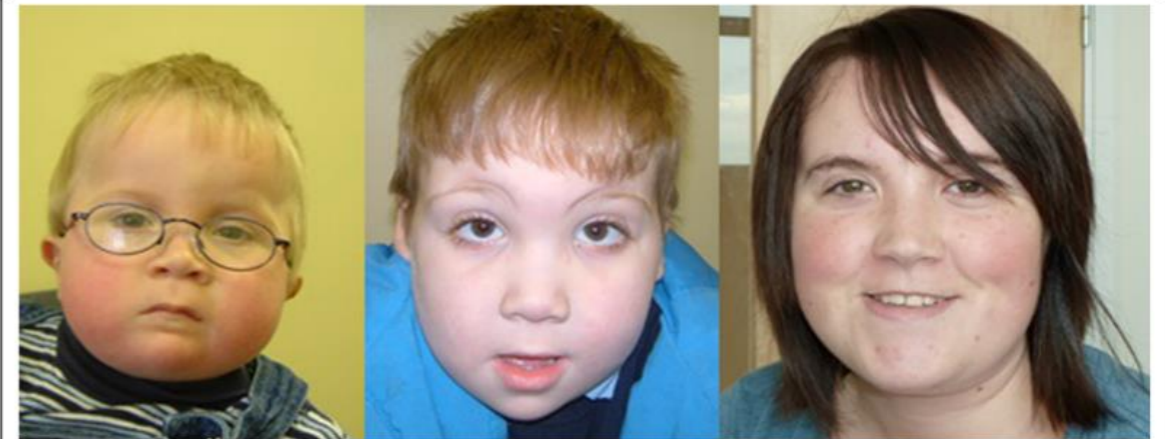
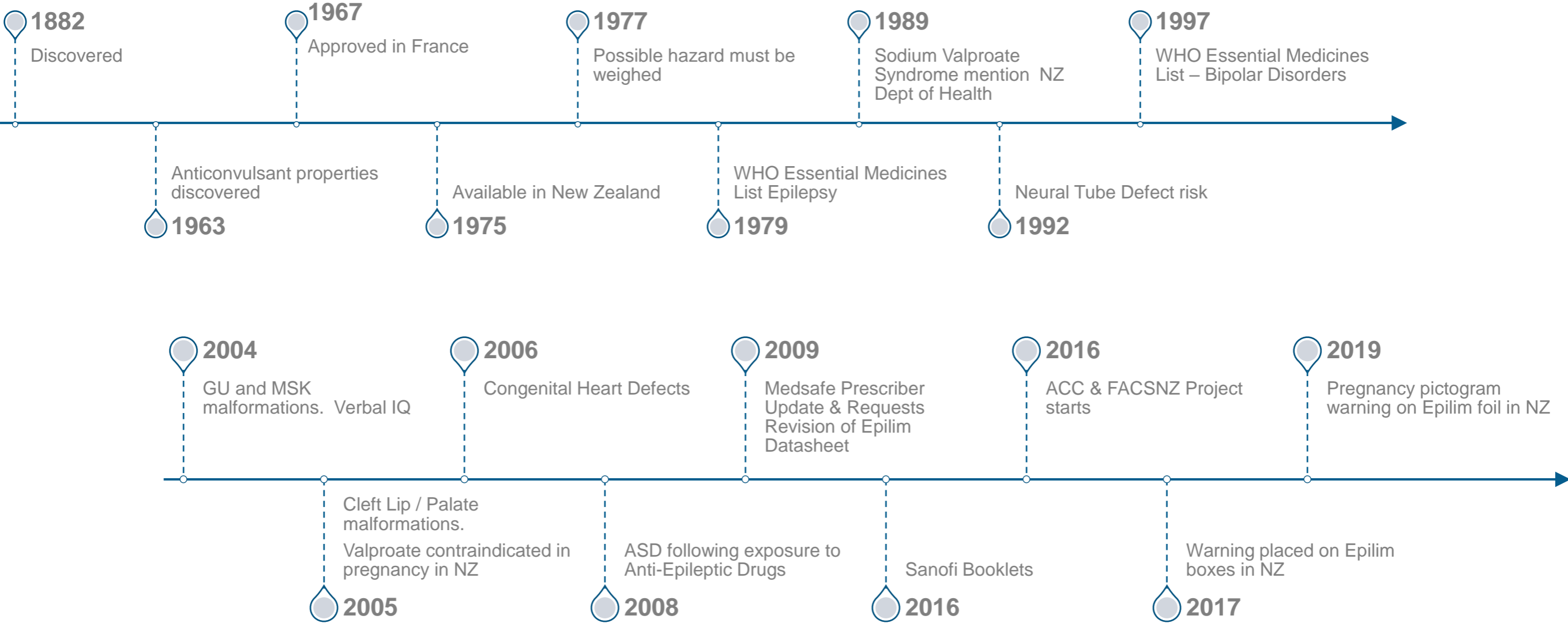


Fig. 2 Facial Features Associated With Valproate Exposure At Different Ages. Note the presence of anteverted nares, small mouth, thin upper lip, everted lower lip, flattening of philtrum, prominent midline to forehead. Features are attenuated but still apparent in young adult

Sodium Valproate – Events Timeline



FACSNZ – Experts by Experience



Support and education for families

Diagnosis support
Advocacy
Networking
Celebration

Recognition and Action for FACS

Support Govt committees
Clinical pathway
FACS as a disability

FACSNZ
Founded 2015

Interventions to reduce risk

Packaging warnings on Epilim and generic packaging
Foil warnings on Epilim
Medicines Act & Therapeutic Products Bill review
Medsafe warning

Public awareness

Bridging clinical and public groups
Schools
Publications





General Practices

741 general practices

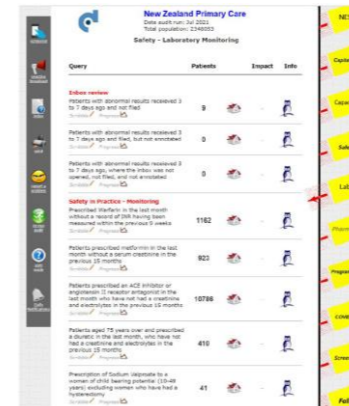
2.8 million patients

Est. 55% NZ
population



Conporto Inbox Notifications

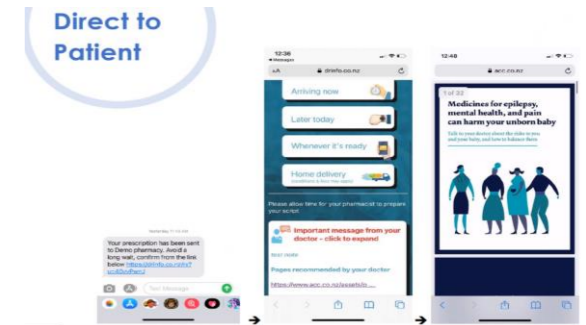
2,396 sodium
valproate inbox
notifications opened
for a patient with a
same day general
practice appointment



Query	Patients	Export	Info
Lab test review Patients with abnormal results received 3 to 7 days ago and not read	9		
Patients with abnormal results received 3 to 7 days ago, where the issue was not opened, not read, and not a result	0		
Patients with abnormal results received 3 to 7 days ago, where the issue was not opened, not read, and not a result	0		
Safety in Practice - Monitoring Prescribed warfarin in the last month without a record of this having been measured within the previous 3 weeks	1162		
Patients prescribed warfarin in the last month without a serum test result in the previous 10 months	823		
Patients prescribed an ACE inhibitor or angiotensin II receptor antagonist in the last month who have not had a potassium and electrolytes in the previous 10 months	10768		
Patients aged 75 years over and prescribed a diuretic in the last month, who have not had a potassium and electrolytes in the previous 10 months	416		
Prescription of Sodium Valproate to a woman of child bearing potential (15-49 years) excluding women who have had a hysterectomy	41		

Dr Info Audits

212 general practices
used the Dr Info
sodium valproate
audit tool in 2021

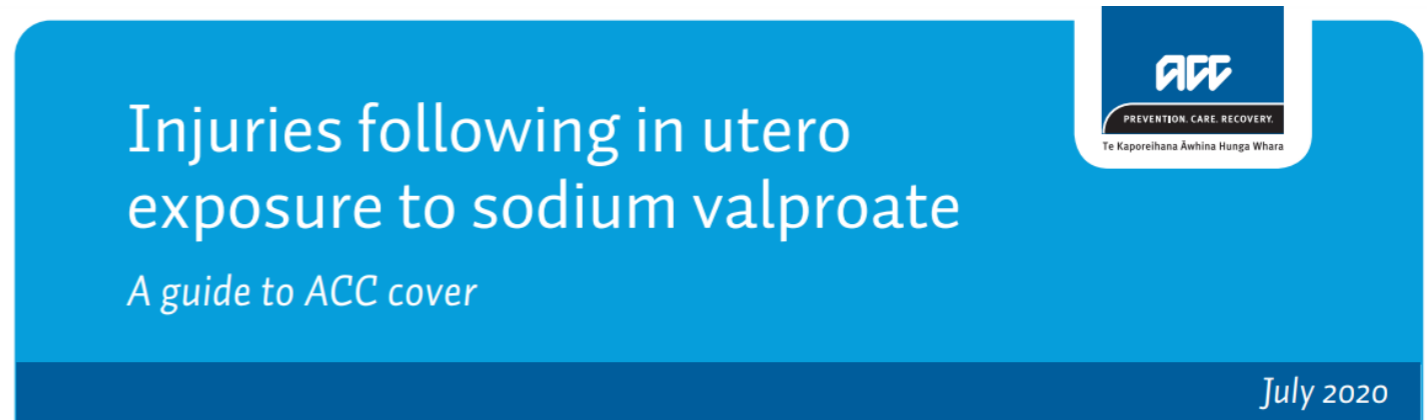


ReScript SMS Direct to Patients

623 patients received
direct nudges in 2021

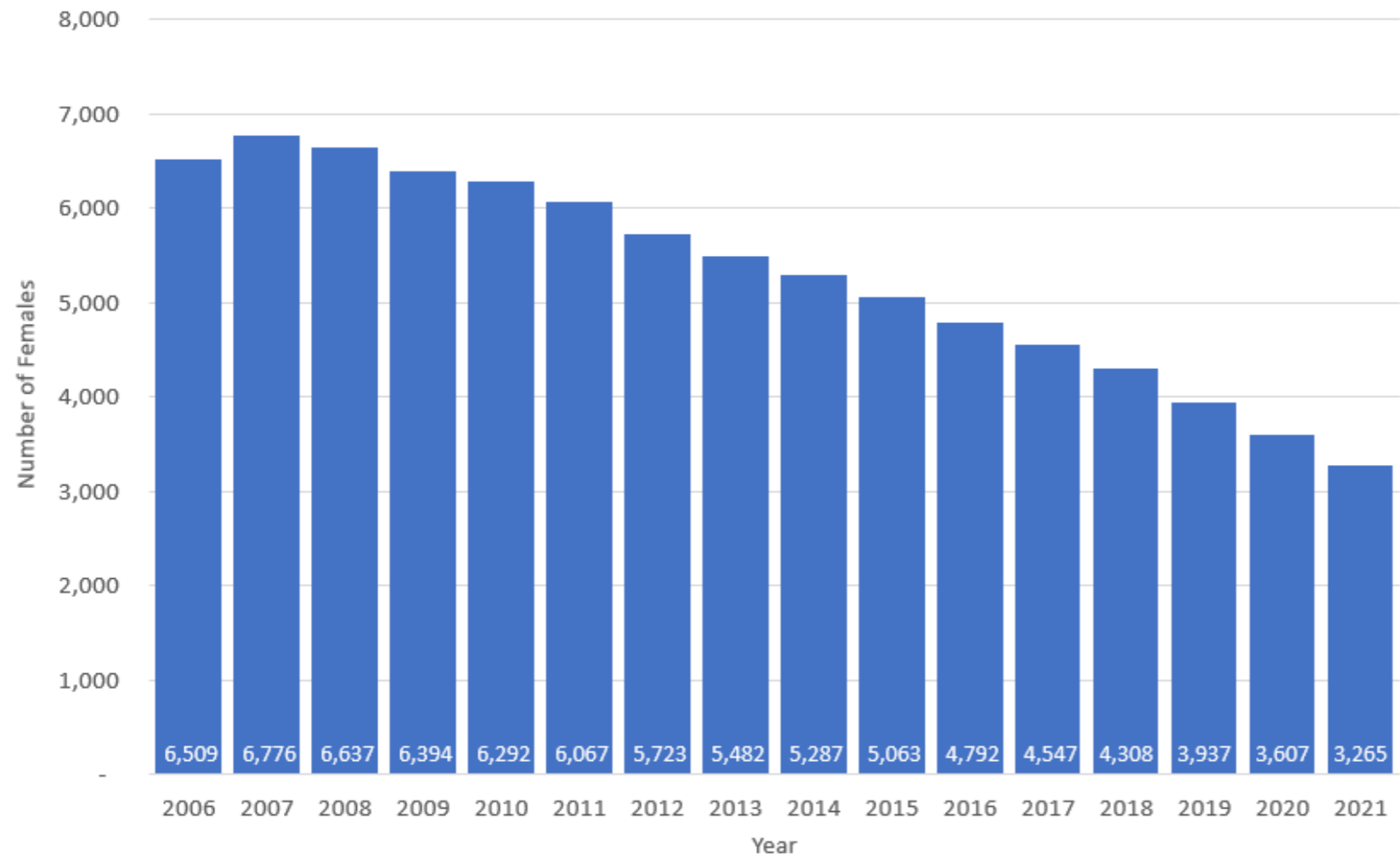
219 patients clicked
on link to ACC
booklet

A Guide to ACC cover



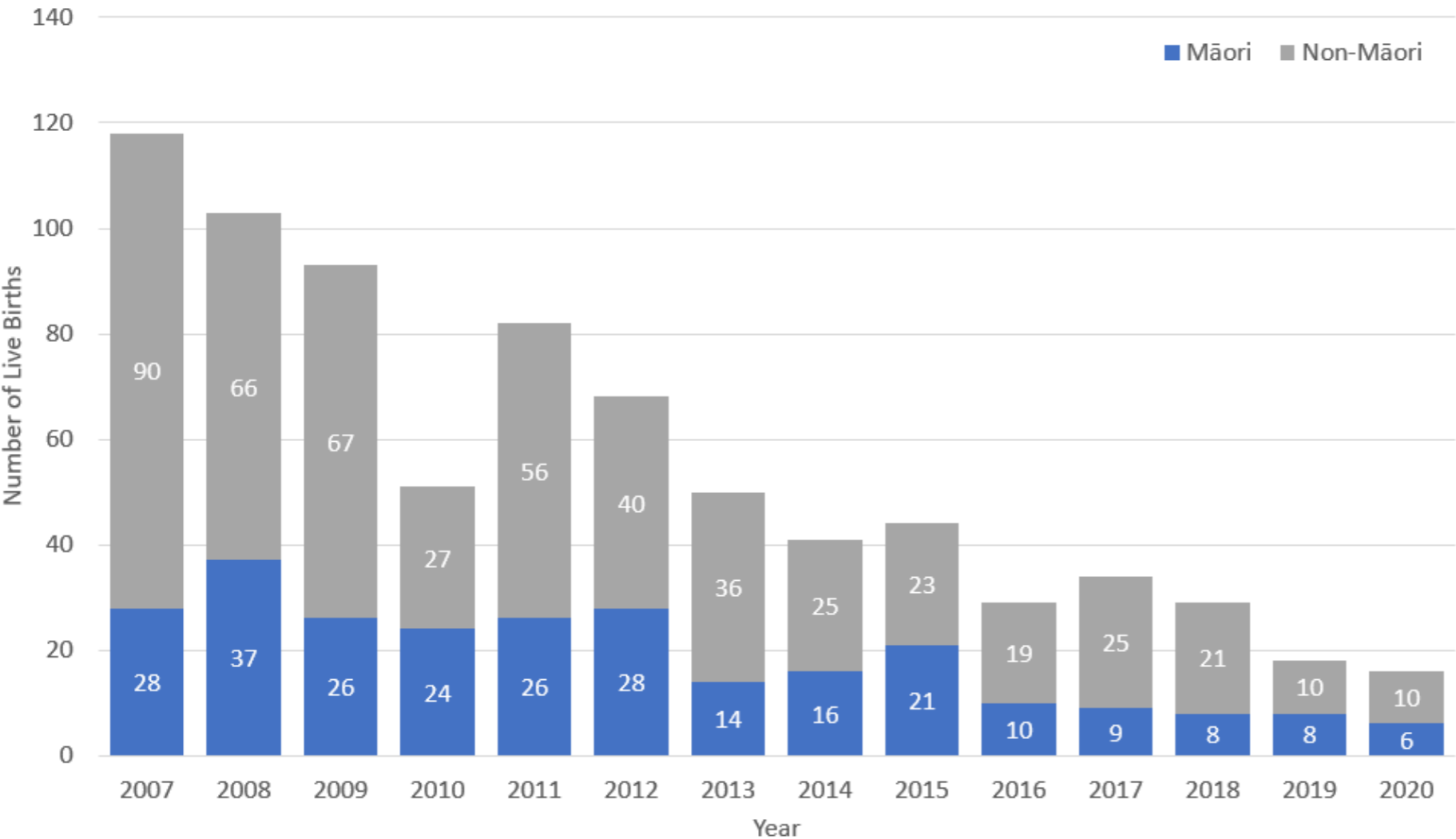
ACC considers each claim on its own merit, taking into account all circumstances of the case.

Sodium Valproate Dispensing to Females, 10 - 50 years, 2006 - 2021



50%
reduction
over 15
years

Number of Live Births with Sodium Valproate Dispensing during Pregnancy, by Year of Delivery, 2007 - 2020



Over 14 years there were:

8 Stillbirths

776 Livebirths

Based on literature we would estimate:

- 78 children born with a congenital malformation
- 233 children with neurodevelopmental problems

ACC has 13 accepted Treatment Injuries claims for Fetal Valproate Syndrome among this cohort

Our Strategic Direction

FACS New Zealand Strategic Priorities and Goals
2021 - 2025



Priority 1: Awareness Raising
Goal 1: The syndromes/spectrum disorder is known and recognised by medical professionals.
Goal 2: Parents and families have access to a range of sources of information to enable them to make informed consent and choice.

Priority 2: Research
Goal 1: The full extent of the problem is known and we have solid data to share.

Priority 3: Support for individuals and families who have been exposed
Goal 1: All individuals and families are empowered to help themselves and each other.

Priority 4: Restorative practice
Goal 1: Families have the opportunity to heal and prevention strategies are in place for others.

Priority 5: Organisation development
Goal 1: FACS NZ is a stable organisation.



foetalsn
Foetal Anti-Convulsant Syndrome New Zealand
Last updated: 13th September 2021

HQSC led Review of Potential System Solutions & Agency Responsibilities



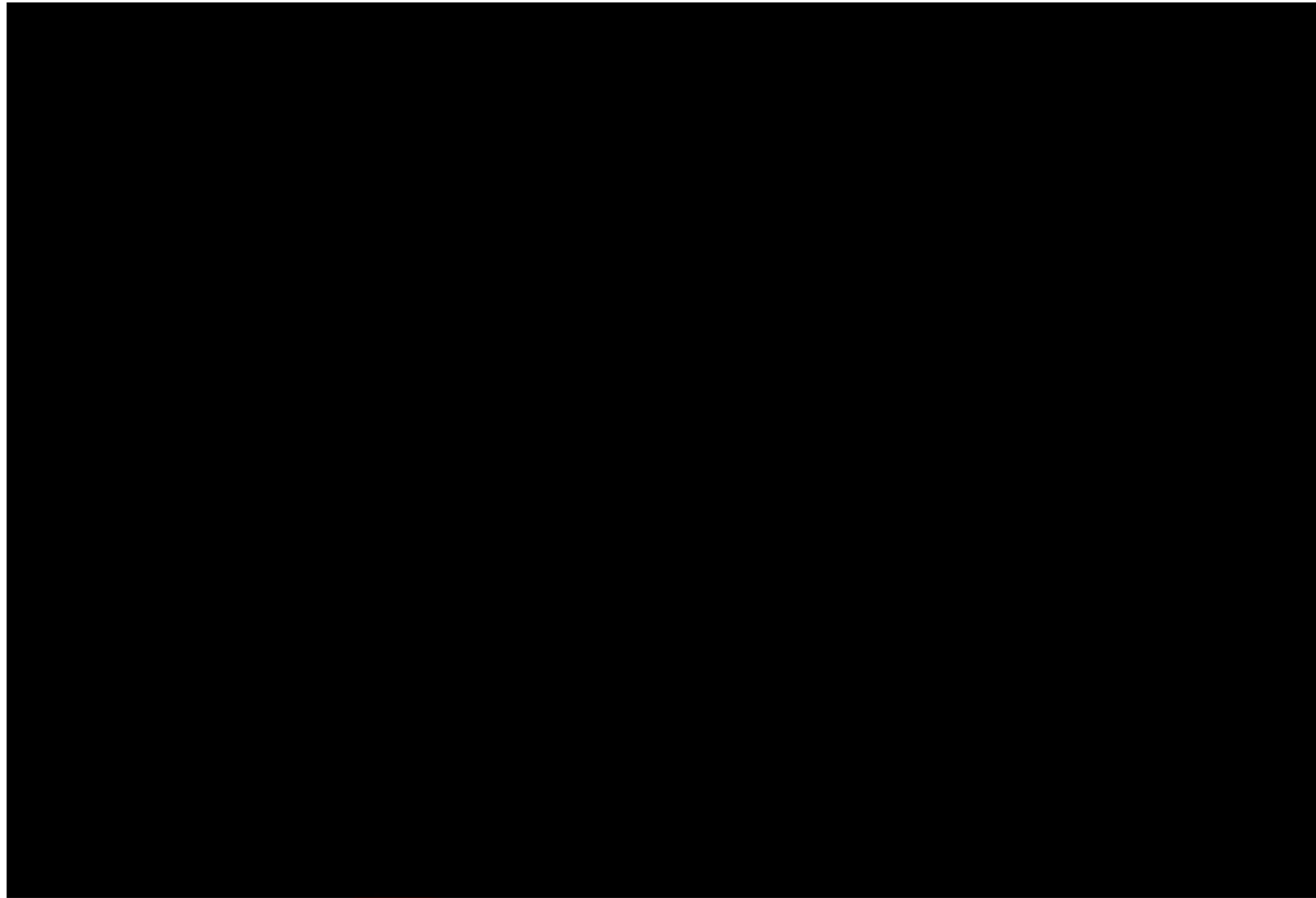
Wellbeing (Health) Solution/s for Detecting and Preventing Harm Events

What Role Can You Play?



- Consider congenital malformation & neurodevelopmental risk profiles when prescribing anti-seizure/mood stabilising medicines
- Ensure informed consent and informed choice
- Consider specialist advice / review
- Ensure assessment and developmental monitoring of children with fetal valproate exposure
- Support family & whānau

This Is Me



Questions / Pātai?

