# The Paracetamol Study

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# **Details of collaboration**

The research was led by the National Hauora Coalition (NHC), in collaboration with WēBē, and the Behavioural Insights Team (BIT). NHC initially partnered with BIT-New Zealand which was closely supported by BIT-Australia. However, the New Zealand office closed in October 2021, and their principal started up her own consultancy called WēBē. To ensure continuity, we subsequently partnered with WēBē and BIT-Australia. The University of Otago also supported the project in its early phases.

**NHC** is the largest Māori-led primary health organisation and has a national presence in supporting primary care providers across five Te Whatu Ora (previously District Health Board) areas. NHC is also a claimant in the Wai2575 Health Services and Outcomes Kaupapa Inquiry. Dr Rawiri Mckree Jansen was the Chief Investigator for the study and Dr Ainsleigh Cribb-Su'a was the overall Project Lead.

**WēBē** is a social purpose consultancy that aims to support positive behaviour change, particularly to improve wellbeing and reduce inequities. The Principal of WēBē, Dr Sarah Hayward, works at the interface between te ao Māori (the Māori world) and Western science to inform policy and service design, and has delivered a range of projects that aim to weave behavioural insights with mātauranga Māori through qualitative research and co-design of solutions.

**BIT** is a global social purpose company of over 200 professionals across many offices around the world. BIT creates and applies behavioural insights to drive positive change and help people, communities and organisations thrive. They have demonstrated a record of scientific excellence in social policy research over hundreds of projects across different policy domains. In December 2021, BIT became wholly owned by innovation charity Nesta.

**The University of Otago** is ranked in the top 1% of universities in the world. Their Lecturer in Health Sciences, Dr Anna Tiatia Fa'atoese Latu, provided expertise on paracetamol and coordinated design input from students in the School of Pharmacy.

# Acknowledgements

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And to the whānau who participated in the design or trial phases — thank you for giving generously of your time and whakaaro (thoughts). Your insights have enabled us to learn so much more about how to support whānau to safely administer paracetamol to their tamariki (children).

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### **Executive summary**

Paracetamol is widely used by caregivers and health practitioners to reduce pain and fever.<sup>1</sup> In New Zealand, it is the most common cause for drug overdose-related presentation and admission to hospital across all age groups, and nearly a third of paracetamol-related phone calls to the New Zealand Poisons Information Centre are related to medication errors with young children.<sup>2</sup>

This study used Māori-led qualitative methods and behavioural science to identify/design a syringe and paracetamol label to reduce paracetamol dosing errors. We also investigated the knowledge needs of caregivers and whānau in relation to safely using paracetamol with tamariki Māori (Māori children). The study process followed the Behavioural Insight's Team five TESTS phases: **Target, Explore, Solution, Trial, and Scale.** 

### Target

In the **Target phase** we reviewed the literature to identify strategies and behaviours critical to the safe use of paracetamol.

### **Explore**

In the **Explore phase**, we conducted interviews with 20 caregivers or whānau of tamariki Māori and 8 health practitioners who work with Māori to understand the barriers to accurate paracetamol dosing and identify potential solutions to reduce paracetamol dosing errors. The most promising solutions that emerged from this phase were:

- Free syringes
- Syringes with permanent markings
- Redesigned labels
- Paracetamol wheel (see page 47 for description)
- One-page pānui (poster) or fridge magnet
- YouTube video clip
- A paracetamol app
- Group education
- Scales for whānau

### **Solutions**

In the **Solution phase**, we facilitated two co-design workshops with caregivers or whānau members of tamariki Māori and one with health practitioners to narrow promising solutions. From the co-design workshops emerged two solutions designed to reduce paracetamol dosing errors - to take forward to the next phase:

<sup>&</sup>lt;sup>1</sup> Sheen, C.L., Dillon, J.F., Bateman, D.N., Simpson, K.J., & MacDonald, T.M. (2002). Paracetamol toxicity: Epidemiology, prevention and costs to the health care system. *Q J Med*, **95**: 609-619.

<sup>&</sup>lt;sup>2</sup> Rajanayagam, J., Bishop, J. R., Lewindon, P. J., & Evans, H. M. (2015). Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors. *Archives of Disease in Childhood, 100*(1), 77–80. https://doi.org/10.1136/archdischild-2013-304902

- A whānau Māori/BI informed syringe; and
- A whānau Māori/BI informed paracetamol label.

We next conducted three rounds of user testing with caregivers or whānau members of tamariki Māori and health practitioners to refine the syringe and label. We tested how participants responded to a different key feature of the syringe and label in each round of user testing, as follows:

In Round 1, we tested a dose-limiting device on the plunger of a syringe, along with a corresponding label, shown in Diagram 1 below. We used an Ezy Dose syringe that comes with a dose-limiting dial on the plunger which enables dose limits to be set at 2.5 millilitres (mL), 5mL, 7.5mL, and 10mL.

Diagram 1. Syringe and label tested in Round 1



 In Round 2, following feedback that the dose limiting device was not working as intended, we tested grey-scale bands (to signal dose measurements) on the plunger of a different syringe, along with a corresponding label, shown in Diagram 2 below. The syringe was a customised version of the 5mL Pamol syringe that comes with over-the-counter paracetamol (manufactured by elmplastic and distributed by Aspen Pharmacare Australia).

Diagram 2. Syringe and label tested in Round 2



Paracetamol 250mg/5ml ORANGE FLAVOUR	Dispensing #: 1012345/0 EXPIRES:	The dose must be i	based on your chile	d's weight. For this strength paracetamol, dose as follows:
Prescribed to: Miss Jane Doe	01/12/24	WEIGHT	DOSE	Store at room temperature
		Less than 5kg	Ask your doctor	<ul> <li>Store in a child proof cupboard.</li> <li>Shake bottle at least 10 times before use.</li> </ul>
		5-7kg	1.5mL	<b>E</b> 22259 <b>E</b>
Chur mul		8-9kg	2mL	調整技
Give mL		10-12kg	3mL	
DO NOT give more than 4 doses in 24 hour	S	13-14kg		回線線路
		15-16kg	4.5mL	For further tips Call the Health Line on 0800 611 116, or
Use for PAIN or FEVER.		17-18kg	5mL	Scan the QR Code
STOP dosing if symptoms continue beyond 48hrs (return to your doct	or or pharmacy)	19-20kg	5.5mL	
	or or priarria og jr	21-22kg	6.5mL	My Pharmacy 123 Marie Lio Lane 1234
		23-25kg	7mL	Ph:12345678 Email: scripts@madeup.co.nz
		26-28kg	8mL	
		29-32kg	8.5mL	
WARNING: DO NOT exceed the above dose or combine with other paraceta	mol products.	33-36kg	10mL	
		37-41kg	11mL	
Too much paracetamol can damage your child's kidneys	and liver.	More than 41kg	Ask your doctor	

• In Round 3, after hearing from participants that they didn't use the grey-scale bands, we tested coloured bands on the plunger of a third syringe, along with a corresponding updated label, shown in Diagram 3 below. The syringe was one of several standard 5mL syringes that can be purchased at pharmacies.

Diagram 3. Syringe and label tested in Round 3





Following each round of user testing, we used feedback from participants to make changes to the syringe and label. After learning in Round 3 that the colour bands on the plunger made it unnecessarily complex and the standard syringe was too short, the final (intervention) syringe taken

forward to trial was the 5mL Pamol syringe that comes with over-the-counter paracetamol, along with a corresponding (intervention) label, shown below in Diagram 4.

Diagram 4. Syringe and label taken forward to trial



### Trial

In the **Trial** phase, we conducted a randomised controlled trial to test the effectiveness of our whānau Māori/BI informed intervention syringe and label against conventional measuring devices and labels for liquid paracetamol. Participants were caregivers or whānau, aged 18 years and over, of tamariki Māori younger than 14 years of age. We found that the intervention syringe and label reduced significant paracetamol dosing errors by 70% and increased dosing precision by 34%. Of note, the number of significant overdosing errors was very small (approximately 10 out of 500 participants in the control group, and approximately 3 out of 500 participants in the treatment group).

Although the design of our study doesn't enable us to conclude if it was the intervention syringe or label that improved dosing precision, we were able to show that the lower precision in the control group was not due to whānau misunderstanding the correct dose amount for tamariki. This suggests that the design of the intervention syringe and/or label enabled whānau to more accurately draw out their intended dose of paracetamol compared with conventional measuring devices and labels. A key implication of these findings is that to reduce paracetamol dosing errors and overdosing, whānau should use the intervention syringe and label.

Throughout the study, we also learnt about the knowledge needs of whānau Māori in relation to paracetamol dosing. In the context of this project, 'knowledge needs' refers to the information gaps evident in how caregivers practice administering paracetamol safely, that improved health communication practices could and should address. Some common ideas whānau shared with us that do not align with current best practice in New Zealand<sup>3</sup> include:

- Paracetamol being stored in the fridge;
- Giving more paracetamol to take the pain away faster; and
- Further advice should be sought after 3 days of continuous use (as opposed to the current NZ recommendation of 2 days).

<sup>&</sup>lt;sup>3</sup> See Healthify website: https://healthify.nz/medicines-a-z/p/paracetamol-children/

There was also uncertainty about the different dose strengths of paracetamol available, and whether dose strength corresponded to flavour.<sup>4</sup> There were many other things that caregivers and whānau of tamariki Māori wanted to know about paracetamol such as:

- what is in paracetamol and how it works in the body;
- the pros and cons of dual dosing and when to dual dose;
- how paracetamol should be stored;
- how paracetamol differs to ibuprofen;
- how to remove air bubbles from the syringe;
- whether paracetamol is safe for tamariki and what happens to the liver if tamariki receive an overdose;
- when to use the different strengths of paracetamol;
- why some children seem more affected by paracetamol (e.g., become sleepy) than others; and
- how to dispose of old, expired paracetamol.

Many whānau Māori had also experienced institutional racism in the health system, affecting their trust in some health practitioners.

These findings highlight the importance of health practitioners taking the time to talk with caregivers about the correct dose and strength of paracetamol for their tāmaiti (child), and listen to the challenges, questions and concerns that caregivers may have specific to their situation.

### Scale

We believe there is huge merit in scaling up the solutions arrived at in this study. Ideally, when health practitioners prescribe paracetamol to caregivers or whānau of tamariki weighing 18 kg or under, they should provide them with a free syringe and a whānau/BI informed label, similar to those used in this study. To further increase dosing accuracy, health practitioners should demonstrate how to dose accurately with the syringe and share other important information about paracetamol, such as the consequences of giving too much.

While study participants were the caregivers and whānau of tamariki Māori, we believe the findings of this study are likely to be generalisable to the wider population of caregivers in Aotearoa.

We have three recommendations:

<sup>&</sup>lt;sup>4</sup> After November 2022, the Pharmac-funded Paracare paracetamol liquid that came in the two different strengths and flavours was replaced with two different brands, 'Paracetamol (Ethics)' for the 120mg/5mL strength and 'Pamol' for the 250mg/5mL strength. The new brands of paracetamol maintain the same flavours as their Paracare predecessors: strawberry for the lower strength liquid and orange for the higher strength liquid, but both new brands (and strengths) are colour free.

### **Recommendations**

- 1. Offer all caregivers of children weighing 18kg or lower<sup>5</sup> a free 5mL syringe with every prescription for liquid paracetamol, along with a whānau/BI informed label.
- 2. When prescribing paracetamol, health practitioners should take the time to give caregivers clear information (verbal and in writing) about paracetamol, especially the risks of giving too much, and the space to ask any questions about paracetamol dosing.
- 3. Develop an engaging and whānau informed education campaign that disseminates up-todate, best practice information on the use of paracetamol via a range of different channels and formats such as social media, tv advertising, antenatal and parenting classes, and trusted health organisations.

<sup>&</sup>lt;sup>5</sup> Tamariki over 18kg require a dose of paracetamol larger than 5mL.

### Introduction

### Background

### Paracetamol overdose is common and consequences can be fatal

Paracetamol overdose is the most common form of drug poisoning in many developed countries.<sup>6</sup> The over-administration of paracetamol to children can damage the liver, leading to acute liver failure, and even death. Research on the factors that contribute to paracetamol poisoning in Aotearoa New Zealand and Australia indicates that paracetamol overdose due to medication administration errors, is one<sup>7</sup> of the main causes for paediatric acute liver failure in the two countries<sup>8</sup>. While the incidence of paediatric paracetamol poisoning cases in Aotearoa New Zealand over the last decade was small, such cases are highly dangerous and entirely preventable.

### Errors administering paracetamol to children are common

Research into child medication administration practices suggests that paracetamol dosing errors are common. For example, a cross-sectional study set in a U.S. emergency department asked caregivers of children 10 years old and younger what dose of acetaminophen or ibuprofen they had administered their child in the last 24 hours; upon calculating the appropriate dose based on the child's weight, the study found that 51% of caregivers had dosed incorrectly. <sup>9</sup> Between 2009 and 2012, the New Zealand National Poisons Centre received an average of 804 calls per year relating to child paracetamol ingestion, of which 28% were due to medication errors.<sup>10</sup> A more recent study of contacts made to the New Zealand National Poisons Centre between January 2018 and December 2020, showed that paracetamol was the most common medicine exposure across all age groups.<sup>11</sup> There were 2937 exposures to paracetamol amongst children aged 0-12 years, and over half of these were due to medication errors. This suggests that many more caregivers struggle with accurate paracetamol dosing than the small number who end up in emergency departments.

<sup>&</sup>lt;sup>6</sup> Freeman, N., & Quigley, P. (2015). Care versus convenience: Examining paracetamol overdose in New Zealand and harm reduction strategies through sale and supply. New Zealand Medical Journal, 128(1424): 28-34.

<sup>&</sup>lt;sup>7</sup> North American and UK data suggest that the most common cause of paracetamol poisoning is acute intentional overdose in older children. See Rajanayagam, et al. (2015). Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors. *Archives of Disease in Childhood*, *100*(1), 77–80.

<sup>&</sup>lt;sup>8</sup> Rajanayagam, J., Bishop, J. R., Lewindon, P. J., & Evans, H. M. (2015). Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors. *Archives of Disease in Childhood*, *100*(1), 77–80. https://doi.org/10.1136/archdischild-2013-304902.

<sup>&</sup>lt;sup>9</sup> Li, S. F., Lacher, B., & Crain, E. F. (2000). Acetaminophen and ibuprofen dosing by parents. *Pediatric Emergency Care*, *16*(6), 394–397. https://doi.org/10.1097/00006565-200012000-00003

<sup>&</sup>lt;sup>10</sup> Rajanayagam, J., Bishop, J. R., Lewindon, P. J., & Evans, H. M. (2015). Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors. *Archives of Disease in Childhood*, *100*(1), 77–80. https://doi.org/10.1136/archdischild-2013-304902.

<sup>&</sup>lt;sup>11</sup> Kumpula, E., Paterson, D.A., Pomerleau, A.C. (2022). A retrospective analysis of therapeutic drug exposures in New Zealand National Poisons Centre data 2018-2020. *Australian and New Zealand Journal of Public Health*, *47*(2): page 3. https://doi.org/10.1016/j.anzjph.2023.100027

### Weight-based dosing contributes to administration error

The correct dose of paracetamol is determined by weight. Weight-based dosing adds several cognitive and practical steps to administering medicine, and this raises the potential for dangerous medication errors.<sup>12, 13, 14, 15</sup> In Aotearoa New Zealand and Australia, common errors in medication administration that lead to paediatric acute liver failure are primarily behavioural, and include exceeding recommended doses, increasing dose frequency, and dosing beyond the recommended time period.<sup>16</sup> The factors that contribute to medication error among caregivers are complex and context-specific; for example, difficulty understanding labelled instructions, using an improper measuring device, and using adult regular-strength medicine are among the factors reported by caregivers in previous research as contributing to dosing errors.<sup>17, 18</sup>

### The burden of unintentional medication poisoning is not evenly distributed

All children can be affected by caregiver-administrated medication errors and accidental poisoning. However, the burden of unintentional poisoning is not evenly distributed. There is evidence from New Zealand data that indicates socioeconomic status correlates to accidental poisoning. A review of accidental poisoning hospitalisations of children aged 0-14 years old in New Zealand between 2006-2010 found that of an average of 526.8 admissions a year, there were significantly higher rates of admission for children living in more deprived areas (classed decile 5-10 on the deprivation scale).<sup>19</sup>

There were differences in the rates of poisoning hospital admissions by ethnicity too: NZ European children were represented at a rate of 66.1 per 100,000 (of the Statistics NZ estimated resident population) followed by Māori children at a rate of 64.7 per 100,000, which is significantly higher than the rates for Pacific (36.1 per 100,000) and Asian/Indian (21.9 per 100,000) children<sup>20</sup>. Another New Zealand review of children aged 0-14 years who were hospitalised for unintentional poisoning

<sup>&</sup>lt;sup>12</sup> Walsh K.E., Stille C.J, Mazor K.M., & Gurwitz J.H. Using Home Visits to Understand Medication Errors in Children. In: Henriksen K, Battles JB, Keyes MA, et al., editors. *Advances in Patient Safety: New Directions and Alternative Approaches* (Vol. 4: Technology and Medication Safety). Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Aug. Available from: ncbi.nlm.nih.gov/books/NBK43769/

<sup>&</sup>lt;sup>13</sup> Kaushal, R., Bates, D.W., Landrigan. C., et al. (2001). Medication errors and adverse drug events in pediatric inpatients. *JAMA*, *285*(16): 2114-2120. doi: 10.1001/jama.285.16.2114.

<sup>&</sup>lt;sup>14</sup> McPhillips, H.A., Stille, C.J., Smith, D., et al. (2005). Potential medication dosing errors in outpatient pediatrics. *J Pediatr*, *147*(6): 761-767. doi: 10.1016/j.jpeds.2005.07.043.

<sup>&</sup>lt;sup>15</sup> American Academy of Pediatrics. (2003). Prevention of medication errors in the inpatient setting. *Pediatrics*, *112*: 431-436.

<sup>&</sup>lt;sup>16</sup> Rajanayagam, J., Bishop, J. R., Lewindon, P. J., & Evans, H. M. (2015). Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors. *Archives of Disease in Childhood*, *100*(1), 77–80. https://doi.org/10.1136/archdischild-2013-304902.

<sup>&</sup>lt;sup>17</sup> Rajanayagam, J., Bishop, J. R., Lewindon, P. J., & Evans, H. M. (2015). Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors. *Archives of Disease in Childhood*, *100*(1), 77–80. https://doi.org/10.1136/archdischild-2013-304902.

<sup>&</sup>lt;sup>18</sup> Walsh K.E., Stille C.J, Mazor K.M., & Gurwitz J.H. Using Home Visits to Understand Medication Errors in Children. In: Henriksen K, Battles JB, Keyes MA, et al., editors. *Advances in Patient Safety: New Directions and Alternative Approaches* (Vol. 4: Technology and Medication Safety). Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Aug. Available from: ncbi.nlm.nih.gov/books/NBK43769/

<sup>&</sup>lt;sup>19</sup> Craig, E., Adams, J., Oben, G., Reddington, A., Wicken, A., & Simpson, J. (2013). The health status of children and young people in New Zealand. Dunedin: New Zealand Child and Youth Epidemiology Service, School of Medicine, University of Otago. <u>https://ourarchive.otago.ac.nz/handle/10523/6129?show=full</u>. See Table 85, page 259.

<sup>&</sup>lt;sup>20</sup> Craig, E., Adams, J., Oben, G., Reddington, A., Wicken, A., & Simpson, J. (2013). The health status of children and young people in New Zealand. Dunedin: New Zealand Child and Youth Epidemiology Service, School of Medicine, University of Otago. See Table 92, page 271.

between 2006-2013, found that New Zealand European children accounted for 54.3 percent of cases in this period, tamariki Māori for 31.1 percent, Pacific children for 8.3 percent, Asian children for 4.4 percent, and children whose ethnicity was recorded as 'Other' for 1.9 percent<sup>21</sup>. While these data were collected just over 10 years ago (and a contemporary review would be useful), these numbers are meaningful in: a) demonstrating that tamariki Māori are over-represented in accidental medication poisoning statistics; and b) highlighting a need to understand the factors that contribute to this, and for the health sector to address those factors.

Other evidence indicates that inequities, perpetuating colonising systems and systemic racism continue to impact life expectancy and quality of life for Māori compared with non-Māori in respect to the burden of disease.<sup>22</sup> Poorer education and health outcomes, stigmatisation within the health care system, among other consequences<sup>23, 24</sup> have severe ramifications for health system accessibility and, ultimately, tamariki health, wellbeing and equitable outcomes. Relatedly, previous research has found that many Māori experience the existing public health system as hostile and alienating, and this research has provided recommendations for how to improve the patient provider relationship and foster effective communication.<sup>25</sup> Given these contextualising factors and impacts, this study focused on solutions that work for tamariki Māori but will likely also improve outcomes for other children in New Zealand.

This study's approach was to design solutions that enable caregivers to administer accurate doses of paracetamol to tamariki. In exploring the needs of caregivers administering medicine at home and how to make information on best practice with paracetamol use more accessible, this research extends upon previous work to build the body of research on effective strategies for the safe use of paracetamol and other medicines in the home environment.

### There is little research examining the effectiveness of solutions to improve dosing accuracy

International research has explored the magnitude and causes of problems with administering paracetamol and other medicines to children at home. One study compared the accuracy of a standard 5 millilitre (mL) syringe with a 5mL metal teaspoon and a 5mL calibrated spoon across 277 caregivers, and found the syringe was more consistently accurate.<sup>26</sup> However, few studies have gone a step further and evaluated the effectiveness of redesigned medicine labels or dose measuring devices to enable caregivers to administer medicine safely. One exception was an American study that evaluated the use of colour coding on syringes to reduce paracetamol dosing error; the study used a 20mL syringe with 8 different coloured lines on it, to correspond to 8 different dose volumes.

<sup>&</sup>lt;sup>21</sup> Unpublished Injury Prevention Research Unit (IPRU) data: Child (0-14 years) poisoning hospitalisation 2006-2013 and mortality 2004-2011. Dunedin, New Zealand, University of Otago: 2015, in Safekids Aotearoa, Position Paper: Child Poisoning Prevention. Auckland, Safekids Aotearoa, 2015.

<sup>&</sup>lt;sup>22</sup> New Zealand Productivity Commission. (June 2022). Colonisation, racism and wellbeing: Final report by Haemata Ltd. Retrieved from: <u>NZPC\_Colonisation\_Racism\_Wellbeing\_Final.pdf (productivity.govt.nz)</u>

<sup>&</sup>lt;sup>23</sup> Ministry of Health and University of Otago. (2006). Decades of Disparity III: Ethnic and socioeconomic inequalities in mortality, New Zealand 1981–1999. Wellington. Ministry of Health.

<sup>&</sup>lt;sup>24</sup> Hobbs, M., Ahuriri-Driscoll, A., Marek, L., Campbell, M., Tomintz, M., & Kingham, S. (2019). Reducing health inequity for Māori people in New Zealand. *The Lancet*, *394*(10209), 1613–1614. https://doi.org/10.1016/s0140-6736(19)30044-3

<sup>&</sup>lt;sup>25</sup> Graham, R., & Masters-Awatere, B. (2020). Experiences of Māori of Aotearoa New Zealand's public health system: a systematic review of two decades of published qualitative research. *Australian and New Zealand Journal of Public Health*, *44*(3), 193–200. doi.org/10.1111/1753-6405.12971

<sup>&</sup>lt;sup>26</sup> Beckett, V.L., Tyson, L.D., Carroll, D., et al. (2012). Accurately administering oral medication to children isn't child's play. *Archives of Disease in Childhood*, *97*(1):838–41. DOI: <u>10.1136/adc.2011.212563.14</u>

The authors found that deviation from the recommended dose was lower for the group using the colour-coded syringe compared with the group using conventional methods.<sup>27</sup>

### There are no New Zealand studies examining the effectiveness of solutions to improve dosing accuracy

While Medsafe New Zealand ran a consultation in 2020 with 72 health and industry professionals on whether and how to update paracetamol labels and dose tables<sup>28</sup>, to date, no intervention to improve paracetamol safety has been either developed with the input of consumers, users or whānau, nor evaluated in the context of Aotearoa New Zealand. Doing this work forms a critical step not only to develop solutions that work in Aotearoa New Zealand, but to ensure that strategies to support safe use of paracetamol are equitably effective and culturally appropriate.

### Aims of study

The overall objective of this research is to improve the safe use of paracetamol for tamariki Māori. To achieve this, we aimed to:

- Investigate the knowledge needs of parents, caregivers and whānau related to administering paracetamol to tamariki Māori. This includes understanding any social, material, or accessibility-related factors that impact how paracetamol information and/or dosing devices are accessed and used; and
- 2. Co-design and evaluate the effectiveness of solutions to reduce paracetamol administration errors.

### Research approach

This study used Māori-led qualitative methods and behavioural science, structured by BIT's TESTS project phases— Target, Explore, Solution, Trial, and Scale. This provided the foundation for a participatory, mixed-methods approach, comprised of qualitative interviews and co-design workshops, and a randomised controlled trial (RCT).

The study called for deep expertise in:

- 1. **Te ao Māori-informed** processes and approaches<sup>29</sup> to understand the context for safe paracetamol use, including how the knowledge needs of caregivers are influenced by their home environment and support system, and the broader health care system; and
- 2. **Behavioural science**, including the capabilities, opportunities, and motivations that enable caregivers to perform a given behaviour, and how to change a decision-making environment to help people and communities live happier, healthier lives.

Both te ao Māori principles and behavioural science approaches were therefore integral to this study.

<sup>&</sup>lt;sup>27</sup> Frush K.S., Luo X., Hutchinson P., & Higgins J.N. (2004). Evaluation of a method to reduce over-the-counter medication dosing error. *Arch Pediatr Adolesc Med*, *158*(7):620-4. doi: 10.1001/archpedi.158.7.620. PMID: 15237059.

<sup>&</sup>lt;sup>28</sup> Medsafe. (March 2020). Proposed changes to paracetamol warning and advisory statements. Consultation outcome. https://www.medsafe.govt.nz/consultations/paracetamol-warning-and-advisory-statements-consultation-outcome.pdf
<sup>29</sup> Processes and approaches informed by the Māori world.

### Kaupapa Māori principles

The study was Māori-led and facilitated through a te ao Māori lens by Māori, Pākehā, Pacific and tauiwi researchers from The National Hauora Coalition and the University of Otago. NHC specialises in hauora Māori and is committed to addressing inequity and health and social outcomes. Our strong community relationships, underpinned by Kaupapa Māori-informed research methodology and principles, enabled us to safely involve hundreds of whānau and caregivers in this research and to centre their voices and ideas in the design and testing of solutions to improve the safe use of paracetamol for tamariki.

We drew upon tikanga Māori practices and principles like manaakitanga (kindness, reciprocity, respect and care) by meeting caregivers and whānau in community spaces and contexts, and offering participants koha (gifts) that materially valued their time spent with researchers. As a part of the hauora-enhancing kaupapa (purpose) of this study, the researchers took opportunities to provide health education and information to whānau, and to connect whānau we met to other supports available in their communities (as and when requested).

### **Behavioural science**

Medication administration errors are deeply behavioural, highlighting the need for behavioural science expertise in designing potential solutions. We partnered with the Behavioural Insights Team (BIT) and WēBē to ensure that the team included a high level of expertise on behaviour and drivers of behaviour change. BIT's roots are in government, giving the organisation unique experience in using qualitative research to understand behaviour and improve public policy. The project began with an in-depth discovery phase to better understand the contextual factors affecting target behaviours.

The rest of this report follows this chronological structure of the five TESTS phases: Target, Explore, Solution, Trial, and Scale.

### TARGET: Identifying strategies and behaviours critical to the safe use of paracetamol

In the Target phase of the project we reviewed the literature to confirm the most common reasons for medication administration errors – exceeding the recommended dose, increasing the dose frequency, and prolonging the therapy duration beyond the recommended length. The most common reasons for such dosing errors are as follows:

- **Devices:**<sup>30, 31, 32, 33, 34, 35</sup> Syringes are one of the most accurate measuring devices for liquid paracetamol, but markings on the syringe barrel are not always clearly visible, and caregivers often use other measuring devices in the home such as cups or spoons which may be less accurate.
- Labels and written information: <sup>36, 37, 38, 39</sup> Failing to read or understand labelled instructions.

<sup>&</sup>lt;sup>30</sup> Rajanayagam, J., Bishop, J. R., Lewindon, P. J., & Evans, H. M. (2015). Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors. *Archives of Disease in Childhood*, *100*(1), 77–80. https://doi.org/10.1136/archdischild-2013-304902

<sup>&</sup>lt;sup>31</sup> Walsh K.E., Stille C.J, Mazor K.M., & Gurwitz J.H. Using Home Visits to Understand Medication Errors in Children. In: Henriksen K, Battles JB, Keyes MA, et al., editors. *Advances in Patient Safety: New Directions and Alternative Approaches* (Vol. 4: Technology and Medication Safety). Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Aug. Available from: ncbi.nlm.nih.gov/books/NBK43769/

<sup>&</sup>lt;sup>32</sup> Beckett, V.L., Tyson, L.D., Carroll, D., et al. (2012). Accurately administering oral medication to children isn't child's play. *Archives of Disease in Childhood*, 97(1):838–41. DOI: <u>10.1136/adc.2011.212563.14</u>

<sup>&</sup>lt;sup>33</sup> Ali, R., Shadeed, A., Fitian, H., & Zyoud, S.H. (2020). The difficulties experienced during the preparation and administration of oral drugs by parents at home: A cross-sectional study from Palestine. *BMC Pediatrics*, *20*(198). https://doi.org/10.1186/s12887-020-02105-w

<sup>&</sup>lt;sup>34</sup> You M. A., Nam, S. M., & Son Y. J. (2015). Parental experiences of medication administration to children at home and understanding of adverse drug events. *The Journal of Nursing Research*, *23*(3): 189-196. doi:10.1097/jnr.00000000000000000

<sup>&</sup>lt;sup>35</sup> Sobhani, P., Christopherson, J., Ambrose, P.J., & Corelli, R.L. (2008). Accuracy of oral liquid measuring devices: Comparison of dosing cup and oral dosing syringe. The Annals of Pharmacotherapy, 42(1): 46-52.

<sup>&</sup>lt;sup>36</sup> Rajanayagam, J., Bishop, J. R., Lewindon, P. J., & Evans, H. M. (2015). Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors. *Archives of Disease in Childhood*, *100*(1), 77–80. https://doi.org/10.1136/archdischild-2013-304902

<sup>&</sup>lt;sup>37</sup> Ali, R., Shadeed, A., Fitian, H., & Zyoud, S.H. (2020). The difficulties experienced during the preparation and administration of oral drugs by parents at home: A cross-sectional study from Palestine. *BMC Pediatrics*, *20*(198). https://doi.org/10.1186/s12887-020-02105-w

<sup>&</sup>lt;sup>38</sup> Hellier, E., Edworthy, J., Derbyshire, N., & Costello, A. (2006). Considering the impact of medicine label design characteristics on patient safety. *Ergonomics*, *49*(5–6), 617–630. https://doi.org/10.1080/00140130600568980

<sup>&</sup>lt;sup>39</sup> Bennin F., & Rother H.A. (2015). 'But its just paracetamol': Caregivers' ability to administer over-the-counter painkillers to children with the information provided. *Patient Education and Counselling*, *98*:331-7. www.sciencedirect.com/science/article/pii/ S0738399114004984 (Accessed 16-09-16)

- **Health practitioners' interactions with patients:**<sup>40, 41</sup> Lack of communication or unclear instructions about the amount of paracetamol to give.
- Adult doses:<sup>42</sup> Confusing adult strength paracetamol products with child strength paracetamol products or misunderstanding the different concentrations of paracetamol.
- **Dual doses:**<sup>43</sup> Giving paracetamol at the same time as ibuprofen or other pain killers that also contain paracetamol in them.
- **Knowledge of caregivers:**<sup>44, 45</sup> Caregivers may be unaware of the correct dosage for their child's weight or mistakenly believe that giving more paracetamol will help their child recover faster. They may also be unaware of the potentially serious side-effects of giving too much paracetamol.

This list enabled us to start identifying specific behaviours critical to the accurate dosing of paracetamol, such as using a syringe, reading dose instructions and health practitioners explaining to whānau how to dose paracetamol and the consequences of giving too much paracetamol. This provided us with a starting point for potential strategies or solutions likely to reduce paracetamol dosing errors, which were explored further with whānau and health professionals in the next phase.

SSRN: https://ssrn.com/abstract=3573437 or http://dx.doi.org/10.2139/ssrn.3573437

<sup>&</sup>lt;sup>40</sup> Hassan, Isyaku, Avoiding Medication Errors through Effective Communication in Healthcare Environment (January 29, 2018). *Movement, Health & Exercise*, 7(1), 113-126, 2018. Available at

<sup>&</sup>lt;sup>41</sup> McMahon, S. R., Rimsza, M. E., & Bay, R. C. (1997). Parents Can Dose Liquid Medication Accurately. *Pediatrics*, 100(3), 330–333. https://doi.org/10.1542/peds.100.3.330

<sup>&</sup>lt;sup>42</sup> Rajanayagam, J., Bishop, J. R., Lewindon, P. J., & Evans, H. M. (2015). Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors. *Archives of Disease in Childhood*, *100*(1), 77–80. https://doi.org/10.1136/archdischild-2013-304902

<sup>&</sup>lt;sup>43</sup> Rajanayagam, J., Bishop, J. R., Lewindon, P. J., & Evans, H. M. (2015). Paracetamol-associated acute liver failure in Australian and New Zealand children: high rate of medication errors. *Archives of Disease in Childhood*, *100*(1), 77–80. https://doi.org/10.1136/archdischild-2013-304902

<sup>&</sup>lt;sup>44</sup> McMahon, S. R., Rimsza, M. E., & Bay, R. C. (1997). Parents Can Dose Liquid Medication Accurately. *Pediatrics*, 100(3), 330–333. https://doi.org/10.1542/peds.100.3.330

<sup>&</sup>lt;sup>45</sup> Ali, R., Shadeed, A., Fitian, H., & Zyoud, S.H. (2020). The difficulties experienced during the preparation and administration of oral drugs by parents at home: A cross-sectional study from Palestine. *BMC Pediatrics*, *20*(198). https://doi.org/10.1186/s12887-020-02105-w

# EXPLORE: Interviews with caregivers and health practitioners

The purpose of the Explore phase was to better understand the barriers and enablers to accurate paracetamol dosing for tamariki and to identify potential solutions that might increase dosing accuracy and paracetamol safety.

### Method

### Design

We conducted semi-structured interviews with caregivers of tamariki Māori and health practitioners. The interviews with caregivers were designed to cover: their experiences with giving paracetamol to their child/ren; their whakaaro (thoughts) on the main reasons that caregivers make errors in paracetamol dosing; and their solutions to make it easier to administer accurate doses of paracetamol to tamariki.

The interviews began with offering a karakia, followed by whakawhanaungatanga (establishing relationships), and then a briefing on the aims of the research and an explanation of how participant information would be used. During the discussion about the reasons for paracetamol dosing errors, caregivers were asked to rank, in order of importance to them, the top five most common reasons for paracetamol dosing errors, including: devices, health practitioners' interactions with patients, labels and written information, adult doses, and dual doses. Caregivers were then prompted to explain their rankings.

Caregiver interviews concluded with thanking interviewees for their time, checking if they had any questions about what had been covered, and if they had anything else to add. The facilitator also explained the next steps and asked participants for their address so that their koha could be sent to them.

The interviews with health practitioners were conducted after the caregiver interviews and followed a similar format. They were designed to understand health practitioners' views on the most common causes of dosing errors and solutions for reducing dosing errors. In addition, we wanted to understand the feasibility of caregiver's ideas for reducing paracetamol dosing errors. We again shared the most common reasons for paracetamol dosing errors with health practitioners as a prompt to discuss potential solutions. We also shared, via a PowerPoint presentation (see Appendix 1), a list of ideas that caregivers had already suggested to us so that we could check the feasibility of caregiver's solutions. The semi-structured interview guides for caregivers and health practitioners can be found in Appendix 2 and 3, respectively.

### Recruitment

To recruit caregivers and health practitioners, we used convenience sampling. All interviewees were recruited by Darna Appleyard (NHC) and Anna Latu (University of Otago) through their clinical practices and community networks, including kohanga reo (bilingual primary schools) and waka networks in three main centres: Auckland, Christchurch and Dunedin.

We obtained informed consent from all participants. This involved emailing participants an information sheet and consent form prior to interviews. They were asked to provide basic demographic information via a Google form and to sign a consent form via Adobe Sign. Before beginning the interview questions, the facilitator checked that participants understood:

- participation was voluntary;
- they could withdraw at any time;
- that the interview would be recorded;
- that they would not be identified in any report;
- that the information they provided was completely confidential; and
- how their information would be used.

All interviewees were offered artwork by Māori Tohunga (expert practitioner), Mark Kopua, as a koha to thank them for their time and input, along with a \$40 gift voucher.

### **Data collection**

Interviews with caregivers were conducted online (via Zoom) over December 2021 by Darna Appleyard (NHC) and Anna Latu (University of Otago). One facilitated the korero and the other took notes. Dr Sarah Hayward (representing BIT at the time) attended three of the initial interviews to provide a behavioural lens and to ensure continuity between the interviews conducted with caregivers and later with health practitioners. All caregiver interviews were recorded and transcribed.

Interviews with health practitioners were conducted online (via Zoom) over February to March 2022 by Darna Appleyard (NHC) and Sarah Hayward (BIT) who also took it in turns to facilitate the interview or take notes.

The duration of the interviews ranged from 40 – 60 minutes. Our Māori interviewers had expertise in both whakawhanaungatanga (establishing good relationships) and pharmaceuticals, which enabled us to quickly build rapport and to safely discuss not only whānau knowledge needs but also any social, material, or accessibility-related needs that act as barriers to measuring doses correctly or seeking out trusted information on paracetamol. Additional prompts were posed to participants to encourage further comments and elaboration.

### **Data analysis**

We conducted a thematic analysis of the qualitative data from the interviews to identify the main barriers and enablers to accurate paracetamol dosing, along with potential solutions to reduce paracetamol dosing errors. Based on our explicit questioning of caregivers and health practitioners about their views on each of the common reasons for paracetamol dosing errors (identified during the Target stage), participants' comments could be neatly grouped under each of these areas.

### Participants

We conducted a total of 20 interviews with caregivers (15 women and 5 men) of tamariki Māori. All except one identified as Māori.

We conducted eight interviews with health practitioners who work with whānau Māori. Of these, six were women and two were men. Four were Māori, three were Asian, and one was Pākehā. Occupation-wise, three were general practitioners (GPs), one was a paediatrician, three were nurses, and one was a pharmacist.

### Results

Caregiver and health practitioner comments on each of the common reasons for paracetamol dosing errors reveal the barriers/enablers to accurate dosing, along with potential solutions. We have used the common reasons for paracetamol dosing errors to provide the structure for the results below. Caregivers' comments are in blue. Health practitioners' comments are in orange.

**Devices** 

### **Barriers**

Oral syringes have been shown to administer more accurate doses of liquid paracetamol compared with other measuring devices,<sup>46</sup> and GPs often recommend that caregivers use a syringe when administering liquid paracetamol, especially for young children<sup>47</sup> However, syringes are not typically given out to patients when paracetamol is prescribed. Instead, caregivers must purchase them. Many caregivers and health practitioners suggested that the cost of syringes acts as a barrier to their use and that syringes should be given out for free with prescribed paracetamol.

"Even like the pharmacist, I'm a local down there and they still would make me pay \$2.50 for a syringe. When I'm down there every fortnight, and if I haven't got it off my district nurse, to me, \$2.50, another \$2.50, it's everything. And I know they buy it in thousands. It's not \$2.50, it's blooming 10 cents mate. Why are they putting prices on things like that... a lot of whānau will give a tablespoon because that's the first spoon they grab. That's not fair." – Caregiver

"Yeah, syringes should be free if that's a barrier for whānau. To be given the syringes every time tamariki need to use it but they don't have them at home. They shouldn't feel whakamā (ashamed) to say 'we don't have any syringes and we can't afford them'." – Caregiver

"So maybe just, you can always, just, everyone comes with a syringe, not a teaspoon. Because the syringe is better, easier to administer as well. Yeah. Easier to put into the mouth and then that squirts in rather than a teaspoon." – Caregiver

*"But a syringe is a cost to parents - a few cents or a dollar but might be a lot to some families." –* Health practitioner

"In Malaysia, we give free syringes to patients; Health NZ could look into this." – Health practitioner

Several comments caregivers made about measuring devices suggested that a key barrier to dosing accuracy was using devices that are less accurate than **syringes**.

 <sup>&</sup>lt;sup>46</sup> Sobhani, P., Christopherson, J., Ambrose, P.J., & Corelli, R.L. (2008). Accuracy of oral liquid measuring devices: Comparison of dosing cup and oral dosing syringe. The Annals of Pharmacotherapy, 42(1): 46-52.
 <sup>47</sup> See <u>Paracetamol dosing for children in primary care - bpacnz</u>.

"Yeah, I mean if they don't have, for example, that syringe, then I know parents would just go with a spoonful or something wouldn't they? Or a teaspoon or try and think off the top of their head what that might be equivalent to." – Caregiver

"One time I walked in and he was trying to use the tablespoon to give the... And he was like, 'Ah, that's blah, blah, blah,' and I said 'Just use the...(syringe).' I won't use the words I used but I was like, 'Where's the bloody blah, blah, blah (syringe)? Just use that.' And he was like, 'Ah, it's the same.' I said, 'No, it's not the same because it might not be enough and it might be too much.' So you need to use the right stuff." – Caregiver

Health practitioners agreed that using measuring devices such as spoons could be a barrier to dosing accuracy.

"(A clear little cup with markings) is probably better than nothing. Better than a spoon. Not better than a syringe." – Health practitioner

"Sometimes they use spoons and they are not accurate" - Health practitioner

Even when caregivers had a syringe available, they described how syringes (designed for single use) often lose their markings over time, making it difficult to draw out an accurate dose (see photo 1 of standard 5 mL syringe below).

"I always know, even now, that it's got no marking. That, that's a five mL syringe that I have, even though there's absolutely no markings." – Caregiver

#### **Solutions**

Caregivers were clear that syringes should have more permanent markings.

"I'm very big on unclear markings on the syringes. As soon as the syringe mark... because that's what it does, it rubs off. If you keep washing that thing every time you use it, it wears off." – Caregiver

"And with the devices too, I think it'll be great to have those syringes that didn't rub off." – Caregiver

#### Photo 1: Standard 5mL syringe



Health practitioners agreed that a significant barrier to dosing accuracy was syringes that lost their markings and that it was a good idea to design syringes with more permanent markings. However, a couple of health practitioners speculated that the cost of more permanent markings on syringes could be prohibitive.

"Great idea to make syringes that don't lose markings. Some get whakamā (ashamed) to ask for more syringes. Might be more environmentally friendly." – Health practitioner

"...a standardized syringe with markings that don't fade would be ideal" – Health practitioner

"Too costly to make a special syringe, not economical; additional costs in health care, the money has to come from somewhere." – Health practitioner

Caregivers and health practitioners shared other creative ideas for improving paracetamol syringes:

• Develop a syringe that limits the amount of paracetamol that can be drawn out - caregivers and health practitioners independently suggested this idea, although a health practitioner expressed worry about the cost.

"If they could put like a little device on there, so it limits the amount. Well, I reckon that people would use it properly, because I'd go, "oh, that's different. Oh, how do we use that?" – Caregiver

*"Have a device that limits the amount - like an insulin pen. You dial up 15 units rather than look for a mark; probably cost is the issue." –* Health practitioner

• Develop a purpose-built syringe for administering paracetamol to children under two years of age with some sort of spoon at the end that tamariki can get their mouth around – one caregiver liked this idea and one health practitioner suggested that something similar already existed. However, the device was no longer available, possibly because the spoon at the end had not been practical.

"...because I've got the syringes that have a really big bottom bit, which means my kids can't close their mouth around it and then you've got the really small ones that like they can." – Caregiver

"Special syringe with spoon like thing at end - it was like a hollow spoon and it didn't have ink markings; it had plastic moulded markings on the side of a hollow handle. You would pour it into the handle and get the dose and then tip back onto the spoon. We don't see them any more." – Health practitioner

"You don't really need the spoon to get into little kids; little kids tend to spit it out, so the spoon doesn't help. You tend to stick the syringe in as far as possible to avoid them spitting." – Health practitioner

• Ensure syringes come with a cleaner (so they can be easily reused)

"...because I know a heck of a lot of whānau or I've seen my partner, I ask him to clean the syringe and sometimes you can tell he hasn't cleaned it. So cleaning device because I think that's really, when you buy the syringe, you just have to figure out how to clean it." – Caregiver

• Develop a syringe that glows in the dark, works for any age, and has permanent markings – a caregiver suggested this idea, however, practitioners were concerned that it would encourage caregivers to administer paracetamol to children in the dark.

"I did know that they could be challenging in the middle of the night. So if we could come up with some kind of device that was glow in the dark, worked for any age and measurement and stuck on no matter what, something that made it real simple to do." – Caregiver "..turning on the lights is the wisest thing to do!" – Health practitioner

• Reduce the number of different types of syringes – caregivers and health practitioners were aligned with this idea, with health practitioners indicating that it made sense for caregivers to use only 5mL syringes with younger children and 10mL syringes for older children.

"There was only one type of syringe or like a... because man, they've got all different sizes, and all different looking ones." – Caregiver

"Maybe the 5mL syringe is enough; then you are physically limiting how much they draw in one go. Make the default 5mls for younger kids." – Health practitioner

We also heard ideas for improving the **bottles or containers** that paracetamol comes in, such as:

 Make the lid of paracetamol bottles a squeeze dispenser to enable caregivers to draw out a specific amount – both caregivers and health practitioners thought this idea was worth exploring

"You could have a bottle just like the normal bottle, but the lid is like a dispenser, and you're... like a squeeze dispenser that shoots out a certain amount, that could kick off." – Caregiver

*"Bottles that might enable amounts to be dispensed could be a practical tool."* – Health practitioner

Put markings on the bottle so that people don't have to purchase syringes

"Could like actually put like measurements on a bottle. So every time it's used, if they haven't got a syringe or they got a teaspoon or something, they can just, you know... You know how you have those water bottles and it tells you when you can drink? Maybe have one for medicine." – Caregiver

Provide paracetamol in individual shots that are tailored to the child's weight – health
practitioners suggested this caregiver idea would result in too many different sized dosing
packages which would lead to dispensing errors and create too much waste packaging for
the environment.

"It would be very wasteful and lots of plastic waste, which I hate, but it would save any chance of giving incorrect dosages or it could be an opportunity for some new engineer to think of a new way to do that." – Caregiver

"You would need a whole range for different weight babies. It would increase the risk of dispensing error by the pharmacist." – Health practitioner

"...packing implications." – Health practitioner

Also relevant to devices, there were suggestions that whānau should be given **scales** so they can weigh their tamariki every time they administer paracetamol to determine the correct weight-based dose.

*"If I had a magic wand, I would be giving whānau scales, because then I could weigh my kids every time and know that I'm doing the accurate test." –* Caregiver

"Scales could be given by Plunket or Whānau Ora - given to whānau so they have one in the home." – Health practitioner

In the absence of whānau being given their own scales, health practitioners suggested that caregivers could take their child to the local pharmacy to have them weighed or that scales could be made more widely available, for example in schools or supermarkets. At the same time, health practitioners acknowledged that scales in such locations would have to be replaced and maintenance costs would be high.

"Asked mum when she picked up the prescription to weigh baby at the pharmacy. Left a note on the prescription, please check weight." – Health practitioner

"We complain a lot about the government and funding; but there is only so much in the funding pool. The system can only do so much." – Health practitioner

"The trickiness with scales – we use them in the schools and are always replacing them. So how would you manage the accuracy? Maintenance would be tricky." – Health practitioner

One caregiver suggested that it would be useful to provide whānau with a **timer** to help them remember when to administer paracetamol. However, health practitioners were concerned about the cost and that the timer might act as a trigger for caregivers to administer paracetamol when children didn't need it.

"...who is going to pay for the timer; how long will it get used before it is lost?" – Health practitioner

*"It (a timer) might be a trigger to administer when children don't need it."* – Health practitioner

### Labels and written information

In New Zealand, Medsafe and Pharmac put out guidelines and the minimum requirements for the information that must be included on medicine labels. Requirements for medicine labels include information such as the trade name of the medicine, the name and strength of active ingredients, the expiry date, warning statements, storage conditions, and directions for use.<sup>48, 49</sup> However, paracetamol labels are determined by what the doctor has prescribed and are not standardised across different pharmacies. Pharmacists may put extra information on the prescription paracetamol bottle but this is variable. The writing on prescription labels is often small, bunched together, and relatively difficult to read (see photos in Appendix 4). During this study, we viewed many prescription labels and found that many did not include all the required information.

### **Barriers**

Many of the comments made by caregivers and health practitioners about labels and written information reflected the need to simplify labels, make them easier to understand, and clarify how much or how often to give paracetamol to give tamariki of different weights.

"It is too complicated some of the stuff written on there; what is the pertinent stuff you need to know?" – Health practitioner

<sup>&</sup>lt;sup>48</sup> Medsafe. (2018). Guideline on the regulation of therapeutic products in New Zealand: Labelling of medicines and related products. https://www.medsafe.govt.nz/regulatory/Guideline/GRTPNZ/Part5.pdf

<sup>&</sup>lt;sup>49</sup> Pharmac. (2016). Labelling preferences for prescription pharmaceuticals. https://pharmac.govt.nz/assets/labellingpreferences-2016-06.pdf

"I think, as well, maybe to make it more clear because on this bottle of paracetamol it says every four to six hours. I think that could be put a bit clearer because with my son, I'd give it to him every four hours, especially when he was only just recovering from his surgery, six hours was way too long to wait. But then at the same time, they have the four to six hours there for a reason. So, I think if they made that a bit more clearer about the difference between waiting for four hours to waiting for six hours." – Caregiver

*"Maybe a label that is clearer - the label I have is all words... when people are in a hurry, they might not have time to really read." –* Health practitioner

"When I trained as a GP, I didn't realise they didn't always put the weight and calculated dose on the prescriptions; I'm quite anal about that; there is not a standardized way of doing that. We should standardize how paracetamol is prescribed - make sure there is a weight and amount calculated for weight and dose clearly stated." – Health practitioner

Some comments from caregivers suggested that, not surprisingly, it could be more difficult to understand information on labels when they were stressed or rushed.

"And, you are half asleep, and you're trying to get baby to sleep. And, yeah. That's a real wake up call, actually. I probably, needed it." – Caregiver

#### Solutions

A popular idea was to ensure that all paracetamol bottles include a **simple chart** that shows the correct dosage for different weights.

"I like the paracetamol bottle that has the weights on it because I know that it's weight based, but I know not all my paracetamol bottles have that." – Caregiver

"They grow like anything really quickly, and it would just give me peace of mind instead of having to call a nurse, or a doctor, and just double check." – Caregiver

*"A weight chart would be great." –* Health practitioner

In the event that labels are too small to contain a weight chart or other useful paracetamol information, health practitioners suggested giving out extra **stickers**, **pamphlets**, **or fridge magnets** that contain relevant information.

"Have a clear message that relates to Pamol - about storage, what can happen. (Paracetamol) bottles aren't that massive. So safe medication messages could be on a fridge magnet. They can use that as a reference point." – Health practitioner

"Or could pharmacies stick the extra information onto the paracetamol... So a small leaflet to go with the bottle because this doesn't come from the manufacturer." – Health practitioner

"...pharmacist will thank us for it - if we design a sticker with information we think should be additional; provide it for free to pharmacists; they don't have to think about it... Give rolls of the additional stickers to pharmacists; they will do it." – Health practitioner

One health practitioner suggested a clever alternative to a weight chart, a **paracetamol wheel** (see photo 2 below). Caregivers can move the paracetamol wheel around to match their child's weight and are shown the correct dose for a given paracetamol dose strength. One caregiver suggested that the paracetamol wheel could be designed to go on a fridge magnet.

"Give all patients a circle chart - you can spin it according to the strength of paracetamol and child's weight; gives correct mL dosage to give children; like a spinning wheel." – Health practitioner



### Photo 2. Example paracetamol wheel

Several caregivers and health practitioners also made suggestions about the **label format**, for example that it should be visually eye-popping, or that information should be provided in a visual format.

#### "... Maybe like visually make it popping, eye popping." – Caregiver

"So having visual, examples, not examples, information about paracetamol, but visually, say like a picture of a baby on the weigh (scales) and then, or picture of the baby's weight converting into the dose..." – Caregiver

"Put key information in picture form – for example icons... make it visually appealing for what the person will look for." – Health practitioner

Comments from caregivers and health practitioners also revealed the **type of information** that would be helpful on the label, including:

• Where to store paracetamol (in a cupboard up high)

"Something they can improve I suppose to say where you should store it. That could be another sticker." – Caregiver

"... also the storage info - whether to store in fridge or cupboard." – Health practitioner

• The expiry date of paracetamol

"How long does it hold for?... Does it have an expiry date? Like a use by date as well. Maybe they should put expiry dates on." – Caregiver

"Oh, this is a medicine. It can last forever. Oh, so I can't actually read what the expiry date on the label is, but it's a Pākehā medicine. It'll be all right. Pākehās look all right, so it'll be good for me and my kids. I'll be able to use that. They don't really mean expired, and, look, it looks all right. You can shake the bottle. It still moves around, still got a bit of pink color in. It still looks like it's medicine. I'll just use that. It'll be all right." – Caregiver

"...concern about the label - the expiry date is not stated; this is a very big issue." – Health practitioner

• How to dispose of paracetamol (take unused portions back to the pharmacist to dispose)

"And that (label) doesn't say how you discard of that. I'll just chuck it out." - Caregiver

"Disposing of medicines is a universal problem; people hang onto out-of-date medicines. Proper disposal of paracetamol could became a behaviour for other medicines." – Health practitioner

• A warning about the dangers of giving too much paracetamol

"...if there was some more clearly defined information on the warning label around overdosage or something like that. Yeah, like I said, until the incident with my cousin's child, I wasn't aware that paracetamol could do that, and even just giving the access to information around the potential impacts on the likes of your liver and those sorts of things by too much of it." – Caregiver

"Yes, you could (give a warning about paracetamol)- too much paracetamol could cause liver damage. It depends - a simple warning - if you over-administer, it can cause liver harm; pretty simple." – Health practitioner

One caregiver suggested that pharmacists should use labels with waterproof ink, so they don't run when they get wet.

"Tell them to actually fork out, and buy better printers because that's an inkjet printer that runs, the moment it gets wet. This is a baby's medicine bottle. This gets wet, and it becomes absolutely useless." – Caregiver

### Health practitioners' interactions with patients

#### **Barriers**

Caregivers shared with us some of their negative experiences with health practitioners, including experiences of racism, which had affected their trust in the health system and acted as barriers to accurate paracetamol dosing.

"I don't think that they listened to me, it was the main thing for us, or they didn't take my word for something I said. That's how the miscommunication happened. Yeah, so I felt like I wasn't taken seriously." – Caregiver

"I've always felt like they're very, a little bit dismissive, very kind of, you've only got this much time and I've also had, I personally feel like there's still a level of kind of systemic racism going on, even to the point where I feel like... So my big girl, she's white. She's orange hair, grey blue eyes, white skin. And then you've got my baby whose black like me, black hair, brown eyes. Every time I've taken those two to the accident emergency, I've got very different treatment for my white baby." – Caregiver "Maybe he doesn't look like he... Maybe because he just sits there or.. Culturally something culturally, I don't like to talk about like. You know what I mean? Racial disagreement and stuff like that? But yeah. That's where I'm coming from." – Caregiver

"When we have to go to the Pākehā doctors, we feel like we're made to feel like this big, and it's always the same, and even the admin staff, they don't talk to you very nicely." – Caregiver

"...'Can you pay it? How would you like to pay that?' It's like they're saying, 'Oh, you're not able to pay it. This might be beyond you." – Caregiver

Health practitioners agreed that patient trust was important, indicating that patients are more likely to listen to health practitioners they trust.

"Patients are more liable to listen if it is a doctor or nurse who they trust; so there is the opportunity to ram it in, time and again, and then they would remember that." – Health practitioner

Many comments from caregivers about health practitioners' interactions with patients reflected their desire for health practitioners to give clearer explanations or demonstrations on how to administer paracetamol correctly.

"...for some parents maybe like actually demonstrating, measuring it out, like actually sit there because you know, typically if you're at the doctor you've got baby with you, maybe they actually take you through measuring out that first dose and administering it. I think that could be quite helpful for a lot of people who don't rely too much on the ability to read." – Caregiver

*"Too many doctors with too many different opinions. Nobody's actually giving a real 'This is what you do'." –* Caregiver

"And making sure that the doctors or the nurses explain fully how to administer paracetamol and what dose, correct dose to give them, because if you just say ... the best thing for your child is to give them paracetamol and rest and you'll be like, okay, so how much paracetamol? Instead, the doctor should be like, 'The child needs this amount of paracetamol, this amount of times a day'." – Caregiver

Health practitioners agreed that they should provide clear explanations tailored to the needs of different caregivers and that it was feasible for them to demonstrate to whānau how to administer the correct amount of paracetamol to a child.

*"If have concerns, then I tailor it case by case. It is easy to demonstrate the correct amount, especially if giving a syringe."* – Health practitioner

"I work with high needs populations, so I take the time to explain and repeat the same information. Hopefully it will finally click and they will be able to calculate the dose for themselves in the future." – Health practitioner

*"I think it is feasible to demonstrate the correct amount. With nurses, if they are in the homes, they could offer to do this."* – Health practitioner

Caregivers also thought that when renewing scripts, health practitioners should ask whānau how the paracetamol will be used.

"I can just say it, I don't even have to give a reason to get a script from my doctor now. I can say, 'Hey, oh, we're running out. Can I have a script?' No questions. No - 'Oh, well what will you use it for? You tell me the instances when that would be used.' Nothing." – Caregiver

A key barrier we identified to health professionals taking the time to discuss paracetamol administration and the risks in more detail with patients, is that its use is so normalised within society.

"Because we all used to paracetamol; that is where we go when we have a headache or need pain relief; it is normalised within ourselves. Grab it and take it; no questions." – Health practitioner

"The biggest thing; we give out Pamol like a lolly." – Health practitioner

"Paracetamol is so normalised, it is assumed that it is just Pamol; assumptions around knowing how to use it - not seen as risky; not like you are giving them morphine." – Health practitioner

"..going back to assumption about paracetamol being more benign, I don't think we take as much care when explaining things to patients. We know it damages the liver, but even I would sit there and say you need to give higher doses. For a child, it doesn't take much to get to the lethal dose." – Health practitioner

#### **Solutions**

Related to giving clearer explanations, caregivers wanted health practitioners to check patients' understanding about administering paracetamol and to give them time to ask questions.

"Yeah, for me, because I ask questions all the time. And sometimes my husband's sitting there going, 'Oh.' Giving me the eye like, 'Shush.' But no, man, I think it's really important because sometimes people have communication barriers." – Caregiver

"I want to know next time I'm at the doctor, ask these questions, but to me it feels like I've got my 20 minutes. I've got all my kids with me, I'm being rushed along. I don't feel like I have the time or that they've given me the comfort of time to sit and be like, 'Hey, I'd like to have a chat to you about the paracetamol.' – Caregiver

Aligned with caregiver's comments, health practitioners suggested that to improve understanding, they could ask whānau or rangatahi to repeat back to them the information given, and always ask caregivers if they have questions.

"Sometimes I get them to repeat back to me what I have told them. I always ask if they have any questions; you can kind of read a person and tell if they are not getting it." – Health practitioner

"Yes, talk to rangatahi. I put it to rangatahi to give it to themselves; ask - how many (paracetamol tablets) should you take; how often should you take it? Quiz them to see if they have understood." – Health practitioner

Consistent with findings related to labels, caregivers and health practitioners suggested that health practitioners should also explain that too much paracetamol can damage the liver of tamariki, and how to dispose of medicines.

"Well, I think really, really clear explanation from the doctor of what can happen from giving too much paracetamol, but in human talk, not in doctor talk, not to dehumanise doctors, e hoa ma, sorry, but maybe for some parents, yeah." – Caregiver

"As a health professional, we need to reiterate the dangers of over-use." - Health practitioner

"Important message - yes it (paracetamol) is safe; but you can overdose; giving it regularly all the time should be based on how the baby is going. Important for managing pain and fever; giving too much can be dangerous." – Health practitioner

Health practitioners suggested that pharmacists played an important back-up role, reinforcing paracetamol messages given by doctors or nurses and double checking that prescriptions are correct for children's weight.

"So pharmacists are the second line of defence." – Health practitioner

"Pharmacists check the dose against the weight prescribed; if there is an error, they are really good, they ring up the practice if they think the dose is too high." – Health practitioner

Finally, caregivers suggested that doctors should be educated on natural medicines or rongoa (Maori medicine) and health practitioners agreed this should be standard.

"Maybe if even doctors get educated about other methods of medication, so they don't... That's their default on pain, Pamol. Maybe if they're just made aware of, or it's built into the course that there are other options." – Caregiver

"(Educating doctors about natural medicine) should just be standard; a paper that they do in undergrad. Think it is important. So they have an understanding when whānau ask - this is what I use; what do you think?" – Health practitioner

"(Teaching GPs about natural medicines) could help GPs understand how natural medicines interact with other medicines." – Health practitioner

### Adult doses and dual doses

In New Zealand, prescribed paracetamol is free. Health practitioners can prescribe two different strengths of liquid paracetamol: (1) 120mg/5mL which, up until November 2022, came in a pink suspension with strawberry odour and taste; and (2) 250mg/5mL which, up until November 2022, came in a yellow suspension with an orange odour and taste. Pharmacists dispense the prescribed paracetamol into 100mL, 200mL, 300mL or 500mL bottles, depending on the prescription.

After November 2022, the Pharmac-funded Paracare paracetamol liquid that came in the two different strengths and flavours was replaced with two different brands, 'Paracetamol (Ethics)' for the 120mg/5mL strength and 'Pamol' for the 250mg/5mL strength.<sup>50</sup> So health practitioners can still prescribe the different strengths of paracetamol, which maintain the same flavour as their Paracare predecessors: strawberry for the lower strength liquid and orange for the higher strength liquid. But both new brands and strengths are colour-free.<sup>51</sup> Potentially more confusing for caregivers, Pamol can also be bought 'over the counter' in the two original flavours, but both flavours are at the higher strength of 250mg/5mL and both come in a white suspension. In addition, paracetamol is a component of several multi-ingredient medicines sold over the counter.

<sup>&</sup>lt;sup>50</sup> See: https://pharmac.govt.nz/medicine-funding-and-supply/medicine-notices/paracetamol-liquid.

<sup>&</sup>lt;sup>51</sup> See: https://www.akohiringa.co.nz/education/paracetamol-oral-liquid.

The interviews analysed below were conducted in December 2021.

#### **Barriers**

Caregivers knew that it was bad to give an adult strength dose to a child but they were confused about the different strengths of liquid paracetamol for children and how that was related to children's weight.

"I have no idea, but we've had two different strengths. I think that through you the 15 years that we've been parenting, actually, it's one thing that really is confusing." – Caregiver

We heard examples of caregivers sharing paracetamol between children of different ages and weights.

"I just gave my bottle of medicine to my sister who knows nothing. Her kid's hardly ever sick. And I didn't ask any questions. To me, I'm like, I'm helping out, 'Yep. I've got some here, come and grab it.' But, really I should have been questioning, well what's wrong with her? What does she need? Do you need to go to the after-hours doctors? You shouldn't give your medicine to other people. I know that." – Caregiver

"I know some have more, some have older kids and younger kids and they might have got their paracetamol for the older one, which is a higher strength and then use it for their baby." – Caregiver

One caregiver who suggested giving tamariki a smaller amount of paracetamol did not understand that this would mean having to increase the strength of the suspension (to achieve the same effect).

"...the strawberry flavour one, maybe try and lessen that one, so you're not giving them as much." – Caregiver

There was also confusion about dual dosing, with caregivers having questions about the need for two different medicines and when or why they should be given.

"So, I have no idea whether or not it's a bad thing or a good thing that paracetamol should not be given with ibuprofen or any other painkillers." – Caregiver

*"We know that Ibuprofen's strong, and Paracetamol works sufficiently, but together, is there an issue?" –* Caregiver

Health practitioners suggested that caregivers did not always understand that pain relief medication bought over the counter may have extra paracetamol in it.

*"Ibuprofen (prescribed by the GP) does not cause paracetamol overdosing - Unless the patient buys some additional pain relief product from pharmacy - this is the problem." –* Health practitioner

#### **Solutions**

Health practitioners reduced the risk of caregivers dual dosing by avoiding giving prescriptions for combination medications, especially for painkillers containing added paracetamol. They also pointed out that when they prescribe ibuprofen and paracetamol at the same time, the ibuprofen did not have extra paracetamol in it and, in any case, they would sometimes recommend to caregivers that they alternate giving the two different painkillers to tamariki.

"One of the issues that happens when kiddies are sick - they (caregivers) give a Pamol dose and then a few hours later when baby is still hot, they give another dose, so it is good to give them a second option that is not paracetamol." – Health practitioner

"I tell them - start with the paracetamol, give a 2 hour gap, then give ibuprofen, so between the two different medications there is a two hour gap, but between the paracetamol there is a 4-6 hour gap." – Health practitioner

### **Knowledge of caregivers**

One of our key objectives was to investigate the knowledge needs of caregivers and whānau on the safe use of paracetamol for tamariki Māori. Whānau comments and questions revealed a clear picture about what caregivers would like to know about paracetamol:

• What is in paracetamol; whether there is sugar in paracetamol; and what the 'mg stands for'

*"What is the rest of the shit in the liquid that they're drinking. That isn't Paracetamol."* – Caregiver

"Probably just more conversations about what's in it and what it does for the children, because those are things that I didn't know, so probably lots of others don't know." – Caregiver

"Is there sugar in it? Do you know? Is there sugar in these things that we're fucking feeding our kids, to make it taste better? And, if so, why is it there?" – Caregiver

• How paracetamol works in the body

"And maybe I'd have to become a doctor to know, but I actually have no idea how paracetamol works within your body to do what it does." – Caregiver

• Whether paracetamol is safe for tamariki and what happens to the liver if tamariki receive an overdose

"And I think it would be important to know more about overdosing and the liver damage, because I also don't know much about that either, just from what you had spoken about." – Caregiver

• When to use the different strengths of paracetamol

"So you might have, you might spend a couple of years with a certain strength. And so you get used to a certain dosage and whatnot, next minute a new batch comes in and it's a different strength, then you need to minimise or increase the dosage." – Caregiver

• The pros and cons of dual dosing and when to dual dose

*"But I'm unsure about that dual dosing, because I don't know enough information about it." –* Caregiver

"Yeah. I don't know if that... Is that (dual dosing) even a good thing to do it? I've only done it once for my girl. But seems a lot for a little body. She got sick and on top of being sick, she got more sick. I think being educated more around that would be really good." – Caregiver

How paracetamol should be stored

"Yeah, I'm definitely agreeing that that was an eye opener to know that it's not meant to be in the refrigerator. That's crazy." – Caregiver

• How to dispose of old, expired paracetamol

"No idea (how to dispose of paracetamol), I would have just chucked it out, poured it out the sink." – Caregiver

• Whether paracetamol can be used for anything else besides pain and fever

"Mind you... it would be interesting to know if you could use paracetamol for anything else, but I can't think of what that could be." – Caregiver

• Whether a herbal medicine can be used instead of paracetamol

"So I'm not really a fan of Western medicines. I don't really take pills generally, I'll prefer a more herbal, other approach if possible." – Caregiver

#### **Barriers**

Some caregiver and health practitioner comments revealed gaps in the knowledge of caregivers that could easily lead to paracetamol overdosing. For example, we heard about caregivers who held the **mistaken beliefs** that:

• Paracetamol helps babies to sleep

"So I know some of my friends who had used to put bloody paracetamol in their baby's milk bottle at bedtime, until it went pink, their bottle. So that they have a good night's sleep. I know of two people who have done that, and I used to think that was wicked." – Caregiver

"Some families will give paracetamol for everything; Johnny is not sleeping well so we will give him paracetamol. So need to tell whānau how to use it properly." – Health practitioner

• Giving more paracetamol helps to take away the pain or cure the sickness faster

"So, in the past, so I didn't know this, I said, 'Oh, so our daughter was sick.' They said, 'Give her five mLs a day they reckon, five mLs of this three times a day.' I go, 'Yeah, but she's really, really sick, so I'm going to give her 10 mLs.' She said, 'Nah, it might speed it up.' And I didn't even tell her. I said, 'Nah.' She goes, 'Oh, did you give her medicine?' 'Yep.' 'How much did you give her?' '10.' '10? Why did you give her?' I said, 'Well, she's sick as. I want her to hurry up and get her better.' 'You're not supposed to give her 10'." – Caregiver

"How much did they say you can have? One tablespoon? I drank a half a bottle. Just, nah, man, it's going to work faster. They say acts fast or that sort of stuff on TV, and I thought, oh, yeah, man, this is going to help me get... Glug, glug, glug, glug, glug, glug." – Caregiver

"The baby is still sick so parents just keep dosing." – Health practitioner

• More paracetamol should be given in one dose if a dose has been missed

"...Oh, now we have to give her some more because we missed it by six hours or whatever. We gave them five mils last time and that was every three hours, but it's been five hours. We forgot to give it to her two hours ago, so we have to increase the dose, and then we missed two doses yesterday, so today we'll give her six doses, just to make up for yesterday." – Caregiver

Some caregivers did not understand where the threshold for safe paracetamol use lay relative to the instructions, or that exceeding the instructions a little bit could be harmful to tamariki.

*"It says four times, right? Sometimes we could be like, oh, maybe one more today will be fine. What's it going to do? We don't know. We don't get the answer." – Caregiver* 

There was some concern expressed by health practitioners that some caregivers did not understand that paracetamol doses should be based on a child's weight (not age).

"If Johnny has 5mLs, maybe Sarah can have 5mls but they are different weights; so (a barrier to accurate dosing is) whānau not knowing it depends on weight rather than age." – Health practitioner

#### **Solutions**

Caregivers and health practitioners shared many ideas for how to disseminate accurate information about paracetamol. The first group of ideas related to providing **group education** where information on paracetamol could be shared. Ideas for group education included:

• Training for whanau members who offer (medical) support to other whanau

"But I also think there's something to be said around training, not training, but informing whānau members. So knowing that family members like me are often the go-to for people who have mistrust in the system. And so making sure that if there are those people that you give them the right resources and stuff so that we can tell our whānau what to do, how to do." – Caregiver

 Having a regular NHC facilitated session for mothers – kanohi ki te kanohi or via Zoom – where any whānau can drop in for an hour

"So maybe once a month, or once a fortnight, even since things have been quite good where we can just come, māmās, aunties, whoever, just come for an hour. And just connect so we can start building those little, small and group, important spaces where we're just providing support for one another, and still kind of recreating the village, or the Pā Tūwatawata that we are craving for. Because it's so isolated, it's so isolating e hoa." – Caregiver

Making funding available for mothers to purchase bus tickets to go and meet at a café

"Because that is the problem, we don't know who to trust... because we, unfortunately, we're not living in, you know, as Ngāti Awa. We're not living as Ngāti Awa anymore. We're not living in our 'happy' [place] anymore." – Caregiver

 Integrating information on paracetamol into antenatal classes or postnatal classes run by Plunket

"Sounds a bit silly but there's nothing wrong with little classes like they have for hapū mums or anything like that. There's a lot of that. It being implemented into those classes maybe." – Caregiver

*"I completely gel with having a session (on paracetamol) in postnatal classes as well."* – Health practitioner

"I would like to look back at baby's Plunket book; there should be stuff in there on paracetamol. It should be discussed with providers looking after women postnatally." – Health practitioner
• Having facilitated sessions on paracetamol for students in schools

*"With facilitated sessions, it would be cool to... make them available to schools to take up."* – Health practitioner

Some health practitioners also highlighted the importance of group education about paracetamol for health practitioners.

"Most GPs don't think about paracetamol in this way; if you highlighted to them - there is a problem; I'd love to know how many suffered liver damage, accidental overdose; if you told them, they would say hang on a minute; how can I make it safer?" – Health practitioner

"The Good Fellow unit - pushes out some useful tips every week; Bruce Arrell writes tips; get push notifications via email via the College of GPs. Don't know how widely or deeply read." – Health practitioner

The next group of ideas for building the knowledge of caregivers related to developing an **information campaign** that might include the following elements:

• A social media advertising campaign, with key paracetamol lessons, including YouTube clips, animated videos, and posters

*"I don't know, but I reckon someone should make an ad... Like a social media ad, because who watches TVs now?" – Caregiver* 

"Simple videos on Facebook and Instagram and TikTok - a way that a lot of people get their info. You have a lovely young mama teaching people to use their Pamol and who to call if something goes wrong and aware of the dangers. Like the "How to Dad" man; we could have "How to Mama." – Health practitioner

"Have a YouTube clip and a one-pager on paracetamol." – Health practitioner

"We should do more Facebook live. It goes viral." - Health practitioner

• A one-pager or pānui (poster) with the basic paracetamol facts – from a trusted source such as the NHC – that could be circulated on social media

"And also with my wand... even a one-pager just with some basic facts circulating around social media. So, I've found the last two years, even me, I'm starting to absorb more information, especially with COVID and any kind of homeowner stuff, information I'm easily learning things while I'm just on my IG, Instagram, just doing those random facts. And sometimes those random facts are gold." – Caregiver

• A PowerPoint presentation on paracetamol delivered to whānau before they leave the hospital with their new pēpi (baby)

"I think that if a PowerPoint was made and you had to answer a couple of short questions after watching the PowerPoint, so that there was more understanding on how you give and when you give paracetamol before you leave the hospital, before you take your pēpī home, I think that would help a lot..." – Caregiver

Several caregivers and health practitioners also offered ideas for how **technology** could be used to improve the knowledge of caregivers. This included developing a trusted website that shares facts about paracetamol (similar to <u>Healthify</u> which includes a dose calculator). The most popular technology idea, however, was to develop some sort of **application** that can be used on a smart

phone to provide accurate information about paracetamol, how much to give to children of different weights, and how frequently to give it.

"Maybe, an app or something on my phone where I'm not Googling, so I'm not getting bad information, because I've got an app on my... I go to book my doctors and appointments online, maybe some kind of attachment to that." – Caregiver

"Yeah, like a little device or something that just rings. I know it's terrible to say, because you could do it on your phone or an app. You know, if you have an app on your phone where you can just put that information in, then it goes, rrrr every hour or whatever you're supposed to give it, then I think it would help a lot of parents." – Caregiver

"Yeah, I think if there is some kind of health app that could include little things like that, would be awesome. And that's not just for paracetamol, for anything where dosages and things might need a reminder." – Caregiver

*"It would be awesome to have an app that can calculate dose for weight."* – Health practitioner

"Perhaps make some apps - you can enter strength of paracetamol and child's weight and it comes up with a calculation." – Health practitioner

Health practitioners suggested that a provider app could also be useful but pointed out the potentially large cost of developing any app.

"People who prescribe for children – it is all weight-based. This has relevance for thinking about a provider app - how to change the (dose) amount based on weight. Could have utility in this situation for whānau. But a huge investment - an IT solution." – Health practitioner

The final set of ideas for building whānau knowledge reflected the desire for trusted Māori organisations to play a role in supporting whānau, including:

 Being able to tap into a Māori health organisation (such as NHC) for information about paracetamol

"It'll be just nice as a Māori to be able to tap into an organisation for Māori, just like Pacific Island has that for them. I don't know. But it'll be known because there are places like that around but it's just not in your face like, this is where you can go, this is who you can contact. It'll be really good if there was more of that." – Caregiver

• Developing a Māori healthline type service

"Yeah, not just the people who can speak Māori, but the people who can communicate Māori, who can think Māori, who can be empathetic in the Māori way, those kinds of people. Those are the people that we need." – Caregiver

## Summary of the most promising suggestions taken forward to the Solutions phase

Following interviews with caregivers and health practitioners, the research team discussed the pros and cons of the different solutions that had been suggested and ranked the feasibility of developing them. We also discussed the potential impact of the different solutions on reducing paracetamol dosing errors, as shown in Table 1 below. The solutions we took forward in some form to explore further in the Solutions phase are highlighted in yellow/light orange.

Solution	Pros	Cons	Feasibility (low, medium, high)	Impact (low, medium, high)
DEVICES				
Improve syringes				
Free syringes	Overcomes a key barrier to using an accurate dosing implement	Although individual syringes are relatively cheap, supplying them for free to all caregivers of young tamariki would be relatively expensive for Pharmac	Medium	High
Permanent markings on syringes	Syringes would be easier to read for longer and would not need to be replaced as often	Higher cost of syringe but this offset by syringes lasting for longer	Medium	High
Dose limiter on syringes	Could help to prevent overdosing			Medium
Purpose built syringe with a spoon at the end	e with a to some tamariki many young tamariki who		Low	Low
Syringes that come with a cleaner	Easier to clean syringes	Many syringes are designed to be single use only (which is why they lose their markings over time); cleaner easily lost	Medium	Low
Syringe that glows in the dark	Markings could potentially be seen in low light settings	Could promote unsafe paracetamol dosing practices, ie safer to turn the light on	Low	Low

### Table 1. The pros, cons, feasibility and impact of solutions suggested in the Explore phase

Improve paraceta	mol bottles or packaging			
Squeeze dispenser lid	Would only work if caregiver could dial up a specific amount	Difficult to design and would increase cost significantly; also contra to child resistant lids that are designed to prevent young children from opening the bottle and unintentionally overdosing	Low	Low
Markings on the bottle	Could potentially help caregiver to see how much paracetamol they have measured out	Likely to be a less accurate way of dosing than other measuring devices	Medium	Low
Package paracetamol in individual shots tailored to child's weight	Could provide precises doses to tamariki	Likely to increase dispensing errors (due to needing many different sized shots); packaging waste bad for the environment; whānau not able to use shots with other tamariki; babies change weight quickly so whānau would need to keep changing shot doses; expensive	Low	High
Weigh tamariki				
Give scales to whānau	Popular option with caregivers; would help whānau to determine the correct paracetamol dose	Expensive; difficult to maintain	Low	High
Weigh tamariki at the pharmacy	This is a good option when whānau don't have scales at home; would help caregivers to determine the correct paracetamol dose	Caregivers don't always have tamariki with them when they visit the pharmacist; the cost of travel to the pharmacist is a barrier for many caregivers	Low	High
Other				
Give out timers	Could help prevent caregivers dosing paracetamol too frequently	Could result in caregivers giving more paracetamol to tamariki than necessary	Low	Low
LABELS AND WF	RITTEN INFORMATION			

Include a weight	Convenient way for	Limited space on	High	High
chart	caregivers to determine the correct dose for the weight of their tamariki	paracetamol bottles, but could be designed as a separate label for pharmacists to stick on the paracetamol bottle		
Use stickers, pamphlets, fridge magnets	Useful to have key paracetamol tips in one place	Easier to lose stickers and pamphlets than fridge magnet	High	Medium
Paracetamol wheel	Helps caregivers to determine the correct dose for the weight of their tamariki for a given strength of paracetamol	Some paracetamol wheels already exist but they are not easy to find and may not be straightforward to use	Medium	Medium
Label format				
Visually popping	Could help to make important information (such as warnings about the consequences of overdosing) stand out more and be given the attention it needs	Colour makes labels more expensive; most pharmacies do not have the equipment to print colour labels.	High	Medium
Provide information in pictures	Could be helpful for caregivers who find it difficult to read	Difficult to convey the information needed in pictures	Low	Medium
Other informatio	n wanted on label			
Storage information	Could help to correct a common misconception that paracetamol should be stored in the fridge; could help whānau to store paracetamol in safer locations, since many overdoses are due to tamariki getting paracetamol out of the fridge	Is more to read on a label	High	High
Expiry date	Despite being a MedSafe requirement, most labels for prescribed liquid	Expiry date is unlikely to impact on dosing behaviour	High	Low

	paracetamol don't currently have an expiry date; liquid paracetamol should not be used more than 6-12 months after being dispensed by the pharmacist			
Disposal information	Many caregivers pour old paracetamol down the sink and do not know they can return it to their pharmacist for more environmentally friendly disposal	Disposal information is unlikely to impact on dosing behaviours	High	Low
Warning information	Is already a MedSafe requirement to put warnings on medicine labels; could increase caregivers' understanding of the dangers of giving too much paracetamol	Is more to read on a label	High	Medium
Other				
Water-proof label	Could help caregivers read the label clearly for longer, especially if the bottle gets wet	Higher cost; specialised equipment would be needed to print labels	Medium	Low
HEALTH PRACTI	TIONERS' INTERACTIONS WIT	TH PATIENTS		
Demonstrate how to measure the correct dose	Could help improve caregivers' understanding about how to dose accurately; health practitioners said it is feasible for them to demonstrate how to dose accurately	Would require the health practitioner to have spare paracetamol on hand; requires the health practitioner to have time available	Medium	High
Explain the consequences of giving too much paracetamol	Could help caregivers understand the dangers of giving too much paracetamol	Requires the health practitioner to have time available	High	High
Take the time to	Could help to develop trust	Requires the health	Medium	Medium

check patients' understanding of paracetamol dosing	between health practitioner and caregiver; could help improve caregivers' understanding of paracetamol dosing	practitioner to have time available; if done poorly could be patronising		
When renewing scripts, ask caregivers about how the paracetamol will be used	Could help caregivers dose more accurately if it results in a useful discussion about paracetamol use	If done poorly, this could be interpreted as the health practitioner not trusting caregivers	Medium	Medium
Pharmacists to reinforce key paracetamol messages	Many pharmacists already do this; acts as a check that the right amount of paracetamol has been prescribed	Requires the pharmacist to have time; when pharmacists are busy, they are less likely to do this	High	High
Other				
Educate health practitioners about natural and Māori medicine	Could help health practitioners understand more about what is important to whānau Māori and the potential interactions between natural/Māori medicines and paracetamol; some health practitioners think this should be a standard part of GP training	Would require a systemic shift in health education to provide this education to health practitioners; unlikely to impact caregivers' dosing behaviour	Medium	Low
ADULT DOSES A	ND DUAL DOSES			
Health practitioners avoid giving prescriptions for combination medications	Many health practitioners already do this; helps caregivers to avoid accidentally giving too much paracetamol to tamariki	There are instances when two pain medications may be indicated.	High	High
Health practitioners recommend alternating paracetamol with other pain killers	Many health practitioners already do this; helps caregivers to avoid giving too much paracetamol to tamariki who need additional pain support	Caregivers sometimes confused about when to alternate pain medications and why	High	Medium

KNOWLEDGE O	F CAREGIVERS			
Group education				
Training for whānau members who offer support to other whānau	Whānau members who offer medical advice and support to other whānau are often one of the most trusted sources of information for whānau Māori	Identifying the appropriate bodies to fund this training; challenge in identifying who to provide the training to	Medium	High
NHC session	NHC is a trusted Māori health provider and has a range of platforms that could be used	The time needed to promote and organise accessible sessions for whānau	Medium	Medium
Mum's group	Many Māmā are already part of a Mum's group; could improve social support for some Māmā	The cost of travelling to meet with other mothers; information shared in a Mums group is not always accurate	Medium	Low
Antenatal or Plunket classes	Antenatal and postnatal classes could be an effective way to provide lots of new caregivers with information about paracetamol dosing	Caregivers in antenatal classes are typically very focused on giving birth and are already taking in lots of new information; paracetamol should not be given to pēpi (babies) under 3 months of age without seeing a doctor first	Medium	Medium
Facilitated sessions in schools	Could provide useful information about paracetamol to rangatahi which they could share with their caregivers	Caregivers may forget the paracetamol information in the time between learning it in school and administering it to tamariki; schools already have a crowded curriculum	Medium	Low
Information cam	paign			
Social media, including You Tube clips	An easy way to get paracetamol information to lots of whānau; majority of caregivers use social media	The challenge of tagging and socialising posts to have as wide a reach as possible; different caregivers prefer some social media platforms over others, so it could be hit and miss which caregivers see the paracetamol	High	Medium

		messages		
One-pager or pānui with key paracetamol facts	with key relevant paracetamol		High	Medium
Powerpoint presentation for whānau before they leave the hospital with their pēpi (baby)	Has the potential to provide many new parents with information about paracetamol dosing	New parents already have so much to learn that providing more information on paracetamol may not be the priority and could be overwhelming; paracetamol should not be given to pēpi (babies) under 3 months of age without seeing a doctor first	Low	Low
IT solutions				
Paracetamol app	Could help caregivers to determine the correct dose for the weight of their tamariki; this was a popular idea with caregivers	The app would only be useful if caregivers had it on their device; the cost of developing an app could be significant and would potentially replicate the functions other online resources provide	Medium	Medium
Website	Could work well if a QR code on paracetamol labels links caregivers to a website with key paracetamol tips or in combination with other forms of education	Caregivers need to know about the website or be linked to it; caregivers may not trust the website	Medium	Medium
Māori organisatio	ons			
Be able to access information from a trusted Māori health organisation	Whānau Māori often have more trust in the information they receive from Māori health organisations	Requires health practitioners who work in Māori health organisations to have more time to help caregivers understand paracetamol dosing	Medium	Medium
Māori telehealth	Whānau Māori often have more trust in the information they receive from Māori	Some whānau-centred health lines already exist (eg, Whakarongorau Aotearoa)	Low	Medium

organisation	health organisations	but don't necessarily have expertise in paracetamol use; high cost of developing a new healthline	
		new nearthine	

From this, we developed a short-list of the most promising solutions to take forward to the codesign workshops in the next phase. Although many of the solutions related to health practitioners' interactions with patients are very important, they were not feasible to trial, so we did not develop them further for this study. We took some solutions forward that did not have the highest feasibility or impact scores but had been popular with participants (eg, giving scales to whānau and putting an expiry date on labels).

Below is our short-list, along with a brief description and rationale for each solution. We have also stated the behavioural insights (BI) principles relevant to each potential solution. For a summary of BI principles see *EAST: Four simple ways to apply behavioural insights.*<sup>52</sup>

### **Free syringes**

### **Description:**

Health professionals give out a free syringe whenever liquid paracetamol is prescribed and/or syringes to be made freely available.

### **Rationale:**

Syringes are a more accurate way of administering liquid paracetamol than spoons. However, the cost of buying a syringe is a barrier for many caregivers.

### **BI principles:**

**Easy** - Making free syringes the 'default' makes it easier for caregivers to access syringes.

**Timely** - Giving out a free syringe at the same time as paracetamol is prescribed acts as a timely reminder or prompt to use the more accurate measuring implement.

### Syringes with permanent markings



<sup>&</sup>lt;sup>52</sup> The Behavioural Insights Team. (2014). *EAST: Four simple ways to apply behavioural insights*. https://www.bi.team/publications/east-four-simple-ways-to-apply-behavioural-insights/

### **Description:**

Design reusable syringes with clear, permanent markings on them that don't wear off with repeated use.

### **Rationale:**

Most syringes are designed to be single-use syringes. Their markings wear off with repeated use. This makes it difficult for caregivers to judge the amount of paracetamol in the syringe accurately.

### **BI principles:**

**Easy** - Having markings caregivers can clearly see on the syringe makes it easier to accurately measure the correct paracetamol dose.



**Timely** - Having permanent markings on the syringe ensures paracetamol can be accurately measured at the time needed.

### **Redesigned labels**<sup>53</sup>

### **Description:**

Redesign labels for pharmacists to put on paracetamol bottles that show the paracetamol weight chart. The weight chart shows the correct dose of paracetamol in mL for a child's weight and paracetamol dose strength [120mg/5mL vs 250mg/5mL].

### **Rationale:**

Labels on paracetamol bottles are not standardised in NZ. They are determined by what health professionals write in their prescription. There is not enough room available on current labels to add a weight chart. However, the weight chart could fit on a separate label, and pharmacists are in a good position to put the label on the bottle, especially since they often pour paracetamol from a large bottle into a smaller bottle to give to caregivers. The weight chart on the bottle label acts as a quick reference guide for caregivers to confirm the correct dose. This is especially convenient if they are using paracetamol from the same bottle to give to different tamariki.

### HOW MUCH PARACETAMOL CAN TAMARIKI HAVE? STOP AND MEASURE!

The dose of paracetamol is based off your child's WEIGHT Too much paracetamol can damage your child's kidneys and liver

YOUR CHILD'S WEIGHT	120MG PER 5ML STRENGTH	250MG PER 5ML STRENGTH	TIP: To give your tamariki an accurate dose of		
5KG OR LESS	ASK YOUR DOCTOR	ASK YOUR DOCTOR	paracetamol, ask your pharmacist for a measuring <b>syringe</b> .		
6.5KG	4ML	2ML	REMEMBER:		
8KG	5ML	2.4ML	Your child can have paracetamol every <b>FOUR</b> hours		
10K G	6.3ML	3ML	with a MAXIMUM of FOUR doses in 24 hours		
13K G	8.1ML	4ML	TABLETS:		
15K.G	9.4ML	4.5ML	If your child can swallow tablets they can have: • 1 tablet if 33kg or heavier		
18KG	11.3ML	5.4ML	2 tablets if 66kg or heavier		
20KG	12.5ML	6ML	Use this QR code to access the paracetamol dosing		
25K G	15.6ML	7.5ML			
30KG	18.8ML	9ML	<u> 888</u> 2		
35K G	21.9ML	10.5ML			
40KG	25ML	12ML			
50K G	31.3ML	15ML	Call health line for additional advice 0800 611 116		
			Caitlin, Emilia, Ashiqur, Susie		

### **BI principles:**

**Easy** - As long as parents know their child's weight, having a paracetamol weight chart on the bottle label is a quick and easy way for caregivers to confirm the correct paracetamol dose for different child in mL.

<sup>&</sup>lt;sup>53</sup> Diagram was designed by first year pharmacy students at the University of Otago.

**Timely** - Having a weight chart available on every paracetamol bottle ensures that whānau always have the information to hand when their child needs paracetamol.

### Paracetamol wheel<sup>53</sup>

### **Description:**

Paracetamol wheels show the correct dose of paracetamol in mL for a child's weight (and paracetamol dose strength). They could be designed to go on a fridge magnet. Caregivers move the paracetamol wheel around to match their child's weight and are shown the correct dose (for a given paracetamol dose strength [120mg/5mL vs 250mg/5mL]).

### **Rationale:**

Whānau often have more than one tamariki and as the children's weight increases, the correct paracetamol dose for them changes. Even if caregivers can remember that the correct dose is 15mg/kg, it can be difficult to convert this to mL. A paracetamol wheel makes this calculation much faster and easier, especially if it is in a convenient location, such as on the fridge.



### **BI principles:**

**Easy** - As long as whānau know the weight of their tamariki, having a paracetamol wheel handy at home is a quick and easy way for caregivers to calculate the correct paracetamol dose for their child in mL, especially if the wheel is put somewhere handy and visible such as on the fridge.

**Attractive** - A paracetamol wheel can be designed to be bright and attractive, drawing the attention of caregivers, especially if put somewhere visible such as on the fridge.

### One-page pānui or fridge magnet<sup>53</sup>

### **Description:**

Include best practice tips for using paracetamol safely in a colourful one-page pānui to be given out to caregivers when they are prescribed paracetamol. This could include information such as the importance of shaking the bottle and how to store and dispose of paracetamol. This information could be attached to a fridge magnet. Different magnets, containing different paracetamol tips or messages, could be collected by tamariki or their whānau.

### **Rationale:**

Caregivers told us there are many things they would like to know about paracetamol, including important safety information, but there is not enough room to include all this information on the label. Instead, a one-page pānui could be given out with paracetamol prescriptions. Attaching the information to a fridge



magnet would ensure it was easy to find when needed.

### **BI principles:**

**Easy** - Including the best practice paracetamol safety tips in a one-page pānui or on a fridge magnet makes it easier for caregivers to access all the important information about paracetamol in one convenient location, especially if the information is attached to a fridge magnet so that it doesn't get lost.

**Attractive** - A one-page pānui or fridge magnet/s could be designed to be bright, attractive, and culturally appropriate, drawing the attention of whānau and tamariki.

**Timely** - Including essential information on a fridge magnet helps to ensure that important paracetamol information is available at the time needed.

### YouTube video clip

### **Description:**

Include top tips for using paracetamol safely in a YouTube video-clip, similar to the one already available on <u>Healthify</u>. Caregivers could be texted a link to the video-clip by the health professional prescribing paracetamol, and these could be automatically advertised on streaming services if prompted by AI cues (eg, when googling child/infant pain relief, fever, or GP phone number). The existing Health Navigator video-clip includes information such as the importance of shaking the bottle and how to store and dispose of paracetamol.

### **Rationale:**

Caregivers told us there are many things they would like to know about paracetamol, including important safety information, but there is not enough room to include all this information on the label. Instead, a video clip could be developed and/or shared. Although the Healthify website already has a video-clip on paracetamol use, it is not widely known or accessed by whānau. A video clip could be especially appealing to caregivers for whom reading is not a preferred or accessible option.



### **BI principles:**

**Easy** - Including the best practice paracetamol safety tips in a video clip makes it easier for caregivers to access all the important information about paracetamol in one place. Having health professionals send whānau a link to the video-clip will help to increase access. The video-clip is also an easier option for people with literacy challenges.

**Social** - The Healthify video clip is narrated by a nurse, who caregivers of tamariki Māori may be more likely to identify with (as compared with a Pākehā narrator).

### A paracetamol application (app)<sup>53</sup>

### **Description:**

Develop a free app, containing a number of useful functions to assist caregivers with safe paracetamol dosing. Functions or sections could include: (1) dose calculator (for child's weight and paracetamol dose strength); (2) dose timer (to ensure paracetamol is not given any more frequently than every 4 hours; (3) list of other medications containing paracetamol (to help prevent dual dosing); (4) link to Healthify website (and YouTube video clip on paracetamol use); (5) top tips related to paracetamol use, such as how to store and dispose of paracetamol; (6) frequently asked questions; and (7) Healthline number for more information.



### **Rationale:**

An app could be a convenient, modern way for caregivers to calculate the correct paracetamol dose for different children, potentially with a

timer to ensure that paracetamol is not given too frequently. An app could also contain other important safety information, including other medications with paracetamol, what to do if you suspect paracetamol poisoning, and answers to frequently asked questions. It could also help link caregivers with useful information already available on Health Navigator or to health professionals via Healthline.

### **BI principles:**

**Easy** - An app would enable caregivers to access all the important information about paracetamol in one place, including the ability to easily calculate the correct paracetamol dose for the weight of their child.

**Timely** - Having an app available on the smartphone ensures important paracetamol information, including correct dosage for weight, can be quickly calculated at the time needed.

### **Group education**

### **Description:**

Some form of group education for caregivers or māmā, to be delivered by a trusted health provider, such as National Hauora Coalition or a Well Child Tamariki Ora provider. During an existing session, the health provider would share important safety information about paracetamol, including the importance of basing dose on weight and the consequences of giving too much paracetamol.

### **Rationale:**

There are several key opportunities where māmā gather in groups and key information on paracetamol could be shared.

These include antenatal groups, Well Child Tamariki Ora groups, and less formal mum's groups. Such groups provide an opportunity for māmā to develop health literacy and to support one another.

### **BI principles:**

**Social** - Group education brings people together and represents an opportunity to learn from not only health professionals but our peers.

**Social** - We are more likely to be influenced by information that comes from a trusted source. Health professionals and people like us are often more trusted as credible sources of information.

### Scales for whānau

### **Description:**

Health professionals give out scales to whanau who do not have scales.

### **Rationale:**

Children's weight can change quickly, and many whānau do not have scales available at home. This makes it difficult to determine the correct weight-based paracetamol dose, especially if it has been a while since the tamariki last had paracetamol.



### **BI principles:**

**Timely** - Scales can be used to measure the weight of tamariki accurately at the time paracetamol is being administered.

**Attractive** - Scales could be useful for managing or monitoring other weight-related health concerns such as obesity, high blood pressure, heart disease, or diabetes.

### SOLUTION Part 1: Co-design workshops

The purpose of the co-design workshops was to share with participants the most promising solutions identified so far and seek their further input and ideas on solution design, so that we could then select 2-3 solutions which could be mocked up for user testing.

### Method

### Design

In this phase, we facilitated three **co-design workshops**, one with health practitioners and two with caregivers of tamariki Māori. During each workshop, we began with a karakia and whakawhanaungatanga (establishing good relationships), followed by information on the purpose of the workshop. We then presented the nine promising solutions from the Explore phase, before asking participants to rank and discuss the likely effectiveness of each one. After discussion and deeper consideration of each solution, we asked participants to re-rank the solutions and to brainstorm any further solutions (see workshop slides in Appendix 5).

### Recruitment

We used convenience sampling for the co-design workshops. All participants were recruited by Darna Appleyard (NHC) and Anna Latu (University of Otago) through their clinical practices and community networks in Auckland and Dunedin. A few caregivers had previously been interviewed during the Explore phase.

Prior to beginning the workshops we obtained informed consent from all participants. This involved: checking that participants understood their participation was voluntary; letting them know they could withdraw at any time; that the workshop would be audio-recorded; that they would not be identified in any report; that the information they provided was completely confidential; and explaining how their information would be used. Participants received kai and a koha for their time and input (\$40 gift voucher and artwork by Māori Tohunga, Mark Kopua).

### **Data Collection**

The **co-design workshop** with health practitioners was held in Dunedin in April 2022. The two workshops with caregivers were held in Dunedin in April 2022 and Auckland in May 2022, respectively. All three workshops were kanohi ki te kanohi (face-to-face) and lasted for 3 hours each. The two Dunedin workshops were facilitated by: Darna Appleyard, Anna Latu, Sarah Hayward, and Hone Hurihanganui (Director, Engaging Well). Hone was involved to ensure we engaged in a culturally safe and appropriate way with Māori whānau. The Auckland workshop was facilitated by Darna and Sarah. All three workshops were audio-recorded.

To assess participants' views on the effectiveness of each solution, health practitioners were linked to a google form and asked to rate on a 5-point Likert scale (1 being the lowest impact and 5 being the highest) the likely effectiveness or impact of each solution to reduce paracetamol dosing errors. In contrast, caregivers were given laminated cards, one for each solution, and asked to order each solution from most to least effective.

### Data analysis

We calculated the health practitioners' mean Likert scale ratings (out of 5) for each solution which enabled us to graphically depict the solutions from their most to least preferred. Similarly, for caregivers we used their rankings to show their most to least preferred solutions. The order in which their solutions were ranked (from 1-9) determined the weighting given for each solution, with 1 receiving the highest weight and 9 receiving the lowest weight. We then calculated the total score for each solution. We also captured the key themes that emerged in the supporting discussion to explain the ratings/rankings for each solution.

### Participants

A total of five health practitioners participated in the co-design workshop in Dunedin, of which three were men and two were women (their ethnicity data was not collected). Four health practitioners were pharmacists working for the School of Pharmacy Clinic, University of Dunedin and one working as a community pharmacist. The other participant was a lecturer in the School of Pharmacy, University of Otago.

A total of five caregivers of tamariki Māori participated in the Dunedin workshop and four in the Auckland workshop. There was one man and four women in the Dunedin workshop, all of whom identified as Māori. In the Auckland workshop there was one man and three women, all of whom identified as Māori.

### Results

Each co-design workshop yielded rankings and information specific to each of the nine most promising solutions that had emerged during the Explore phase. Figure 1 below shows the mean health practitioner ratings of the effectiveness of each solution in reducing paracetamol dosing errors.



Figure 1. Mean health practitioner rating

The graph suggests that overall, the five health practitioners thought that making syringes free would have the biggest impact on reducing paracetamol dosing errors. Also rated amongst their top three solutions were redesigning labels and making syringes with permanent markings. Health practitioners gave more mixed ratings for the remaining solutions.

Figure 2 shows the total caregiver score (from across both caregiver workshops) for the effectiveness of each solution in reducing paracetamol dosing errors.



Figure 2. Total whānau score

The figure shows that caregivers also ranked free syringes and redesigned labels as being the top two solutions with the most potential to support whānau to dose their tamariki more accurately. Like health practitioners, caregivers also ranked syringes with permanent markings very highly, but their total score for developing a paracetamol app was slightly higher. Caregiver rankings for the remaining solutions were more variable. Below we share the health practitioner and caregiver views relevant to each solution.

### **Free syringes**

As can be seen from Figure 1, health practitioners suggested that making syringes free would have the biggest impact on reducing paracetamol dosing errors.

"Free syringes would have the most impact. When I worked in a community pharmacy in Wellington, I would ask – 'Do you have something to measure this with?', they would say 'no'. I would say 'Here is a syringe for \$1.50.' When they realized there was a small cost, they would then decline it." – Health practitioner

As can be seen from Figure 2, caregivers also put free syringes at the top of the solutions. When they were asked to order each solution from the most to least effective, seven out of the nine caregivers ranked free syringes first (the most effective).

"I remember being a teen parent; I am a teen parent; when I was younger, I always had to make sure I had enough money before I went somewhere; so having it free for whānau not in a good position is really important." – Caregiver

### **Redesigned labels**

Improving the design of paracetamol labelling received the second highest rating from health practitioners. Health practitioners made several suggestions for improving the label, such as simplifying instructions, including an expiry date, and more clearly differentiating the different strengths of paracetamol.

"Totally agree some label presentations are worse than others." - Health practitioner

*"Simplify dose instructions where possible; try to avoid prescribing small decimal points."* – Health practitioner

"This (the expiry date) could be specified on standardised labelling." - Health practitioner

"Need really clear differentiation between the different strength paracetamol - on the chart AND on the product packaging. Really bold the 120mg per 5mL." – Health practitioner

Caregiver rankings also put improving the design of labels in their top two solutions, with seven out of nine caregivers ranking redesigned labels in the top two solutions. Caregivers also made suggestions for improving paracetamol labels, such as including: an expiry date, storage instructions, a warning that paracetamol can damage the liver if too much is taken, and a QR code that could link caregivers to a website with important paracetamol facts.

"The white sticker one (label) is real basic." – Caregiver

*"Mine (label) had so much missing information - didn't have expiry date on it or didn't say don't keep in fridge." –* Caregiver

"Having too much paracetamol can damage your liver is good to put on the label; you know you can actually get hurt from having paracetamol." – Caregiver

"My sister thinks Pamol solves everything with her kids; she won't wait the 4 hours, she will only wait 2 hours. She didn't have a syringe, so just used a teaspoon. You should put this on the label. She doesn't know it is dangerous." – Caregiver

### Syringes with permanent markings

Health practitioner ratings put syringes with permanent markings as their third most impactful solution. They suggested colour-coding the syringe to support caregivers to give the correct dose.

*"Colour code the syringe - one band of colour for 5 mL; one for 10mL; one for 15mL."* – Health practitioner

Caregivers also emphasised the importance of putting permanent markings on syringes. Overall, it came out as their fourth ranked solution - with five out of nine caregivers ranking permanent markings in their top two solutions. Caregivers placed the permanent markings solution very closely with their third preferred solution, developing a paracetamol app (see comments further down).

"If you are going to charge us (for syringes), at least make them worth charging." – Caregiver

### **Paracetamol wheel**

There was more variation in health practitioners' ratings for the remaining solutions, and caregivers' views diverged somewhat from health practitioners' views when it came to the paracetamol wheel. While health practitioner ratings put the paracetamol wheel as the fourth solution, caregivers had it lower down, possibly because they didn't understand how it would work or didn't think it would be practical.

*"I don't get what that (paracetamol wheel) means. My label has the weight and dose on it."* – Caregiver

"... just another resource; goes home and sits in a corner." – Caregiver

### YouTube video clip

Overall health practitioners thought that online tools such as a YouTube clip (or paracetamol app) could be useful.

### *"(A YouTube clip) can demonstrate how to measure paracetamol correctly."* – Health practitioner

As a demonstration of what a YouTube clip could look like, caregivers were shown the video clip about paracetamol from the <u>Healthify website</u>. Their feedback on the clip suggested they agreed that it contained important messages about paracetamol and could be useful to watch in a doctor's waiting room. However, overall, they were not impressed with the video clip and several said they would flick past it if it appeared on their socials. Some caregivers suggested that they would be more likely to watch a TikTok video that was 'interesting'.

"It feels like a white story." – Caregiver

"I would 100% watch that video because... but other whānau might not because it is too long or too boring." – Caregiver

"(The video clip needs) more Māori flavour." - Caregiver

"(The video clip) could be good in waiting room at Dr's surgery." - Caregiver

"I wouldn't look for this; but if it was in the waiting room of doctor, I'd go 'ahhh'. I wouldn't watch it on Facebook because I would just flick past." – Caregiver

"Personally for me, I wouldn't search for a video; but when younger I would have; but now I am more confident." – Caregiver

*"I wouldn't watch a video on paracetamol; but if it came up on TikTok and was interesting, I might watch it." – Caregiver* 

"The information was good. It was clear information. It was very long. It is something I probably wouldn't search; but I would watch in the doctor's." – Caregiver

### A paracetamol app

While health practitioners rated the paracetamol app sixth, caregivers thought more highly of the solution, rating it third.

"If someone is having trouble reading the basic information, they are unlikely to get more information by navigating an app. Could be more generation X." – Health practitioner

"...by the time you put it (an app) out there, they will be onto somewhere else." – Health practitioner

"(An app) really good cos everyone is on phones and has access to the internet. I would feel more relaxed if my partner or grandparents could use this app. If I taught them how to do it, they would use the app." – Caregiver

"...think husband would benefit." - Caregiver

"Would be good but more for young mums." - Caregiver

Five out of nine caregivers ranked the paracetamol app in their top two solutions. Some caregivers seemed excited about certain features you could include in an app such as a dose timer, a dose calculator for their child's weight, and important information such as signs of a paracetamol overdose.

"It (an app) would be good to know signs of overdose." – Caregiver

"I use apps for everything; like the paracetamol wheel I would lose it, but if on the app I would use it." – Caregiver

"Would be good to put into the app when the last dose was given; useful for blended whānau and shared care arrangements." – Caregiver

"I lost my baby's Well Child Tamariki Ora booklet; I no longer have a record of the vaccinations. So it would be useful to put information into an app or online." – Caregiver

### One-page pānui (poster) or fridge magnet

Overall, health practitioners thought a one-page pānui or fridge magnet could be useful, but compared with the other solutions, they rated it relatively low.

*"One-page pānui or fridge magnet would be good to have at home. The more information out there in different forms the better." –* Health practitioner

Caregiver comments suggested they also thought a one-pager or fridge magnet could be useful, and had suggestions for what should go on it, but others did not think it would be practical.

"...It (a one-pager or fridge magnet) would be awesome. Dad just grabs the bottle and asks me how much do they need. If I wasn't there, he would just estimate how much to give." – Caregiver

"Not good for me and my family; it would just be one of those things that just get put in the house and never touched again." – Caregiver

### **Group education**

Compared with other solutions, health practitioners and caregivers rated group education relatively low. However, this doesn't mean they thought education wasn't important. To the contrary, health practitioners and caregivers suggested more education about paracetamol was needed – for both health practitioners and caregivers. Caregivers liked the idea of receiving some education on paracetamol before they left the hospital with their first child. They also liked the idea of coffee groups with other caregivers.

*"Whoever calculates it (the paracetamol dose) needs to know the safe range. It comes back to training."* – Health practitioner

"When I left the hospital with my babies, I had to do a quiz on car safety and CPR and how to not shake your baby and safe sleeping. Before I was discharged from hospital, I had to do that; so why not go through a video or leaflet and have to answer questions before you go home." – Caregiver

*"I'd love to go to a 'bougie' coffee group!" –* Caregiver

*"I'm involved in many mum's groups and I know group education would help; it would deal with lots of foreign mums who don't have much support." – Caregiver* 

It is possible that the slight mismatch between caregivers' rankings and comments was simply due to concerns about the challenges in making it to group education settings.

"You don't really do that (go to group meetings) when you have kids." - Caregiver

### Scales for whānau

Health practitioners gave scales the lowest rating out of all nine solutions. Some were in favour of giving scales to whānau and others weren't, possibly due to cost or preferring other solutions such as caregivers taking their tamariki to the pharmacy to be weighed.

"I would be in favour of giving people scales. Not everyone will take the time to weigh their tamariki. Those who do are more likely to dose accurately." – Health practitioner

Caregivers' views on scales were mixed. Some quite liked the idea of whānau being given scales, although didn't know what this would look like for babies.

"Everyone should have free easy access to these resources (scales)." – Caregiver

*"Really helpful to have scales; don't want to travel all the way to doctors to get baby's weight."* – Caregiver

*"I rated scales last because we have scales at home, so not important for my whānau."* – Caregiver

"What would scales for 1-5 years look like? There are some cheap \$5-\$10 ones. At accident and medical, they pop sick baby in the scoop." – Caregiver

### **Re-ranking solutions and additional solutions**

There was minimal movement in ratings or rankings when we asked health practitioners and caregivers to re-rate or re-rank the solutions after the discussions on the effectiveness of each solution. If anything, the discussion reaffirmed the importance of redesigning labels and having permanent syringe markings, with one caregiver rating the app slightly higher too.

When participants were asked if they had any other solutions, several of the comments related to combining the solutions that had already been discussed, for example putting a paracetamol wheel on the paracetamol label, combining group education with a one-page pānui, or combining free syringes with permanent markings on the syringes.

Health practitioners suggested a few additional solutions such as having only one strength of paracetamol available in primary care settings. They also wanted to see incentivisation for pharmacists to be able to provide patients with more education in pharmacy settings.

# Summary and design process for the most promising solutions taken forward to user testing

Following the co-design workshops, the research team further considered the pros and cons and feasibility of the different solutions. Given the top ranked solution was free syringes, and participants also rated permanent markings on syringes very highly, we wanted to honour those findings by designing an improved syringe, that, if successful in improving paracetamol dosing accuracy, could potentially be made free to caregivers.

The next most obvious solution to take forward, with universal support from health practitioners and caregivers, was redesigning paracetamol labels. We therefore decided to use feedback from participants and behavioural insights to design a whānau Māori/BI informed syringe and label.

### Whānau Māori/BI informed syringe

We set out to incorporate the creative ideas we had heard to improve syringe design, namely:

- Permanent markings or etchings in the plastic to make it easier to accurately measure the correct dose;
- Colour banding to support dosing accuracy;
- Dose limiter to prevent overdosing; and potentially
- Some form of warning on the syringe such as 'Warning: Do not exceed the recommended dose' to bring attention to the dangers of overdose.

First, we looked to see if there was an existing syringe that incorporated the above design features. The closest we found was an 'Ezy Dose' syringe, manufactured by Apothecary Products in the US.<sup>54</sup> This syringe: (1) was designed to be more than single use (so presumably its markings are resistant to washing); (2) came with a dose limiter (which caregivers could set to 4 different dose limits depending on the weight of their child); (3) and used colours to help caregivers set the correct dose limit (see photo 3 below).

Photo 3. Different angles of the Ezy Dose syringe

<sup>&</sup>lt;sup>54</sup> See: https://shop.apothecaryproducts.com/products/ezy-dose-kids-true-easy-syringe?variant=32038955810875



We initially thought we could improve on the Ezy Dose design by:

- Making is slightly longer and thinner so there is more space between the mL markings (making it easier to see the dose) and putting markings at every mL (the Ezy Dose only has every 2.5mLs marked);
- Using different colours so people who are colour blind don't have any issues using it;
- Having markings at every mL (unlike the Ezy Dose syringe which has markings only at every 2.5mL); and
- A warning on the syringe about the dangers of overdose.

We worked with a 3D printer to incorporate the design features above (see the final design specifications for the 3D printed syringe in Appendix 6). The mocked-up design is shown in the drawings from the 3D printer in Diagram 5 below.

**Diagram 5:** Drawings of mocked-up syringe design by 3D printer (based on Ezy Dose syringe):







The actual 3D printed syringe is shown below in photo 4.

Photo 4. Final product - printed 3D syringe



Unfortunately, the 3D printed version did not work properly (ie, did not suction up liquids adequately) and had several other issues. The permanent mL etchings on the barrel were hard to read and there was a mismatch between the amount you set to dial up (using the coloured dial at the end of the plunger) and the actual dose limits (eg, when the dial was set to 3mL, the dose limit was actually 6mL). There was not enough space to print a legible warning on the syringe and the cost was prohibitive.

We could have then spent more time and money on refining the 3D version. However, the objective of the user testing was to pilot the solution concepts and determine if the dose limiter and colours seemed helpful. We therefore made the decision to use the original Ezy Dose syringe in the first round of user testing. The actual Ezy Dose syringe that we took forward into the first round of user testing is shown in Photo 5 below.

### Photo 5. Ezy Dose syringe used in first round of user testing



### Whānau Māori/BI informed label

We also set out to improve upon the existing paracetamol labels. The design improvements which had been suggested by caregivers or health practitioners included:

- Simplifying the language so the label is easy to read and understand;
- Making the format visually appealing so that important information stands out;
- Providing a weight chart that shows the correct dosage for tamariki of different weights;
- Giving a warning about the consequences of giving too much paracetamol;
- Including the expiry date, storage instructions, and how to dispose of paracetamol (if space); and
- Including a QR code that links caregivers to additional important paracetamol tips

We designed a label using behavioural insights principles<sup>55</sup> that incorporated the features above and which provided instructions on how to use the Ezy Dose syringe. We user tested two versions of the weight chart (Diagram 6 below) to determine which would be easier to read. Note that the colours in the weight chart match the colours on the Ezy Dose syringe that correspond to the four different dose limits.

<sup>&</sup>lt;sup>55</sup> The Behavioural Insights Team. (2012). EAST: Four simple ways to apply behavioural insights. See: chromeextension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.bi.team/wp-content/uploads/2015/07/BIT-Publication-EAST\_FA\_WEB.pdf

#### Diagram 6. Label used in Round 1 of user testing

37-41kg

More than 41kg

11mL

Ask your doctor



### **SOLUTION Part 2: User testing**

The purpose of the user testing was to test and refine the whānau Māori/BI informed syringe and label to arrive at a design to take forward to trial.

### Method

### Design

Following the co-design workshops, we conducted three rounds of **user testing**, with a mix of caregivers of tamariki Māori and health practitioners, iterating the solutions after each round. We used 'lab usability testing', a method in which participants whose characteristics matched those of the target users (in this case caregivers of tamariki Māori) performed typical tasks with our prototype solution.

During the user testing, caregivers were asked to imagine they were going to give paracetamol (of 250mg/5mL strength) to their youngest tamaiti (child). They were asked to use the whānau Māori/BI informed syringe and label to measure out an appropriate amount of paracetamol for their child's weight. We used a paracetamol bottle with a bung at the top, which we understood was sometimes given out with prescribed paracetamol. We then asked caregivers for their feedback on the syringe and label. Note that the paracetamol participants measured out was disposed of and not actually administered to tamariki.

We followed the same procedure for health practitioners except we did not ask health practitioners to simulate dosing paracetamol to their child. Instead, we showed them the whānau Māori/BI informed syringe and label and asked for their feedback on both. For the full user testing protocol, see Appendix 7.

Feedback from participants in the first round of user testing was incorporated into a modified version of our solutions, which became the new prototypes for the second round of user testing. Similarly, feedback from our second round of user testing led to further design modifications that were tested in the third and final round of user testing, before finalising the syringe and label prior to trial.

### Recruitment

We used convenience sampling for the three rounds of user testing. We once again went through NHC's networks to recruit participants from the population targeted as the end users of the solution, namely caregivers of tamariki Māori and health practitioners who work with them. Once again, we sought informed consent from each participant prior to beginning each user testing session. Participants in Round 1 were offered a \$20 gift voucher as a koha for their time and input. When we discovered that each session took longer than expected (lasting 1 hour instead of 30 minutes) we decided to give a \$40 koha to participants who took part in the second and third round of user testing.

### **Data Collection**

The **first round of user testing** was conducted with five caregivers and two health practitioners. The five caregiver sessions were facilitated in Auckland over the course of a day in March 2023 by Dr

Sarah Hayward (WēBē) and Tira Phillipson-Puna (NHC). They were kanohi ki te kanohi. The two health practitioner sessions were facilitated online (via Zoom) in May 2023 by Dr Sarah Hayward and a representative from NHC. Even though the sessions with two health practitioners were conducted a few months after the caregiver sessions, we have included their findings as part of Round 1 because we used the same syringe and label as had been used with Round 1 caregivers.

The **second round of user testing** was conducted with five caregivers. These caregiver sessions were facilitated by Dr Sarah Hayward and Mythily Meher (NHC) in August 2023. Mythily was kanohi ki te kanohi with participants in Auckland, while Sarah dialled in from Wellington.

The **third round of user testing** was conducted with one health practitioner in September 2023. It was facilitated by Dr Sarah Hayward and Mythily Meher online (via Zoom). The breakdown of participants in the user testing is summarised in Table 2 below.

User testing round	Number of caregivers	Number of health practitioners	Total participants
1	5	2	7
2	5	0	5
3	0	1	1
Total	9	3	13

Table 2. Breakdown of caregiver and health practitioner participants in each round of user testing

Each user testing session lasted for about one hour. To balance any ordering effects, we asked half the participants for their feedback on the syringe followed by the label, while for the other half, we asked for their feedback on the label first.

### Data analysis

We collated feedback from participants on the syringe and label. We have summarised the main feedback, using quotes to illustrate the key findings.

### Participants

The user testing involved a total of 13 participants across three rounds, including 10 caregivers of tamariki Māori and 3 health practitioners. All 10 caregivers were women. The estimated weight range of the youngest tamariki across the nine caregivers was 9-50kg.

Of the three health practitioners, two were women and one was a man (the first round had one man and one woman and the third round had one woman). Occupation-wise, the health practitioners were a pharmacist, nurse and GP respectively. Ethnicity data for these participants is unavailable at time of writing.

### Results

The key findings for both the syringe and label and the changes made at each round are summarised below in Table 3 for each round of user testing.

	Solution tested	Main feedback from participants	Feedback incorporated and how?	Solution taken forward to next round			
	ROUND 1						
Syringe		<ul> <li>Participants liked the syringe but caregivers did not know how to set the dose limiter</li> </ul>	✓ We selected a different syringe without a dose limiting device – the 5mL Pamol syringe that is distributed with over-the-counter bottles of Pamol; unlike standard syringes, the Pamol syringe is designed with the numbers on the plunger instead of the barrel. It was designed by elmplastics, a German company that specialises in precision medical devices. We used grey-scale bands as a visual cue of the dose amount instead of a dose-limiting device				
		<ul> <li>Participants wanted finer grade mL markings on the syringe</li> </ul>	✓ Finer grade (0.1 mL markings) on the 5mL Pamol syringe				
		<ul> <li>Caregivers experienced issues with vacuum suctioning</li> </ul>	☑ Different seal on the barrel				

### **Table 3.** Key findings and changes made to syringe and label at each round of user testing

		<ul> <li>Health practitioners thought the width of the syringe could be thinner and longer</li> <li>Syringe size too small for high tamariki weights</li> </ul>	<ul> <li>The Pamol syringe is slightly longer and thinner than the Ezy Dose syringe</li> <li>Did not increase the volume of the syringe because smaller syringes are more appropriate for caregivers of younger tamariki</li> </ul>	
Label	Paracetamol 250mg/5ml ORANGE FLAVOUR Prescribed to Mess Jame Date	<ul> <li>Participants thought the label was an improvement but most caregivers did not read it</li> <li>Participants had a slight preference for</li> </ul>	<ul> <li>The label contains useful information for those who read it</li> <li>Kept weight chart but dropped</li> </ul>	Paracetamol 250mg/Sml ORANGE FLAVOUR       Breast and the present of th
	Twen be concurred safely edge on top of the gampe based on your diverse weeks.           Version of the point of the gampe based on your diverse weeks.           Version of the point of the gampe based on your diverse weeks.           State         State           State         State	<ul> <li>the instructions on the first weight chart but the colours on the second weight chart</li> <li>Participants thought the orange warning band should stand out more</li> </ul>	<ul> <li>the instructions about setting the dose limiter – because these were no longer needed</li> <li>Changed the colour of the warning band to black</li> </ul>	

		<ul> <li>Participants had other suggestions for the format or wording of the label</li> </ul>	<ul> <li>Changed the instructions about giving paracetamol 'every 4-6 hours if experiencing pain or fever' to 'do not give more than 4 doses in 24 hours'</li> <li>Increased the size of the warning that 'too much paracetamol can damage your child's kidneys and liver'</li> <li>Did not make the label water-proof because would be expensive for minimal gain</li> <li>Did not write the numbers in words as well as numbers because this could clutter the label and make it more difficult to read</li> </ul>	
		<ul> <li>Pharmacists can't print coloured labels</li> </ul>	✓ Used grey-scale bands instead of colour after finding out pharmacists cannot print coloured labels	
		<ul> <li>Weight chart only goes up to 41kg</li> </ul>	The potential for paracetamol overdose is more acute for younger, lighter tamariki so we did not add higher weight bands on the weight chart	

		ROUND 2		
Syringe		<ul> <li>Caregivers took a few moments to work out how to read the numbers on the plunger, as it felt 'backwards' (compared with standard syringes), but worked it out quickly and ignored the grey-scale bands</li> </ul>	✓ We opted to use a standard pharmacy-issued 5mL syringe (with grade markings every 0.2mL) and to use colour banding instead of grey-scale bands. We selected the standard syringe specifically to put colour banding on the plunger, which was easier than trying to put coloured bands on the outside barrel	THE REAL PROPERTY OF THE PROPE
	•	<ul> <li>Caregivers wanted colour on the syringe</li> </ul>	☑ Used colour banding instead of grey-scale bands	
	•	<ul> <li>Caregivers wanted the lip of the syringe barrel to be wider</li> </ul>	☑ The lip of the revised syringe was wider	
	•	<ul> <li>Caregivers had other suggestions for improving the syringe</li> </ul>	<ul> <li>Used one colour per mL on the syringe plunger</li> <li>The revised syringe barrel had larger numbers than on the plunger of the Pamol syringe</li> <li>We had previously experimented with using etchings but did not do so due to cost and the challenge of designing etchings</li> </ul>	

			<ul> <li>that are easy to read</li> <li>➤ We did not put a spoon on the end of the syringe because it could be more difficult to use with pēpi (babies) and reduce dosing accuracy</li> <li>➤ We did not put mL markings around the entire plunger because we changed the syringe to one with markings on the barrel</li> </ul>	
Label	Paracetamol 250mg/5ml ORANGE FLAVOUR Prescribed to: Miles Jane Doe GivemL DO NOT give more than 4 doses in 24 hours Use for PAIN or FEVEP STOP dosing if symptoms continue boyond 48hrs (return to your doctor or pharmacy).	<ul> <li>Caregivers read the label and appreciated certain features of it</li> </ul>	Retained key features such as the weight chart, warnings, information about storage, and the Healthline number	Paracetamol 250mg/5ml ORANGE FLAVOUR Prescribed to: Misjane Doe Give mL every 4-6 hours for PAIN or FEVER DO NOT give more than 4 doess in 24 hours STOP giving if still unwell after 2 days (48hrs) - go to your DOCTOR or PHARMACY
	<text></text>	<ul> <li>Caregivers did not see the point of the grey-scale bands and wanted colour bands instead</li> </ul>	☑ Used colour bands on the weight chart to match the syringe	WARNING: Too much paracetamol can damage your child's kidneys and liver           Do NOT exceed the above dose or combine with other paracetamol products           The dose MUST be based on your rhid's weight.           For this strength paracetamol, dose at follow:           Tor this strength accounting the paracetamol of the strength paracetamol, dose at follow:           Strength accounting the paracetamol of the strength paracetamol of the strength paracetamol, dose at follow:           Strength accounting the strength paracetamol of the str
		<ul> <li>Label doesn't tell caregivers how many hours to leave between doses of paracetamol</li> </ul>	Reinstated the instructions to give paracetamol 'every 4-6 hours for pain and fever'	No.04         No.04           No.04         No.04           No.04         No.04

<ul> <li>Caregivers wanted some of the writing to stand out more and be in plainer English</li> </ul>	<ul> <li>Used red to make the warning about potential damage to children's kidneys and stand out and to emphasise that the dose must be based on children's weight.</li> <li>Used plain English - we simplified 'stop dosing if symptoms continue beyond 48 hrs (return to your doctor or pharmacy) to 'stop giving if still unwell after 2 days (48 hrs) - go to your doctor or pharmacy'</li> <li>Increased the font size of the expiry date</li> </ul>	
<ul> <li>Caregivers had other suggestions for the format or wording of the revised label</li> </ul>	<ul> <li>Put a photo of a syringe next to the weight chart to show how the colour bands on the weight chart match the syringe</li> <li>We did not put children's age on the label because it can be misleading and lead to inappropriate dose sizes</li> </ul>	

		ROUND 3			
Syringe	4	• The standard 5mL syringe is too short	✓ Used the Pamol syringe which is slightly longer and thinner than the standard syringe		
		<ul> <li>The colours on the syringe plunger make it too complex and seem unnecessary</li> </ul>	✓ Used the Pamol syringe which does not have colour on the plunger	and the second sec	
		• The width of the colours on the plunger are quite wide - potentially reducing dosing accuracy	✓ Used the Pamol syringe which has fine-grade markings at every tenth of a mL		
		<ul> <li>Use etchings on the syringe so the markings don't rub off</li> </ul>	We did not use etchings due to cost and the challenge of designing etchings that are easy to read		
		<ul> <li>Consider labelling the syringe with the strength of paracetamol that it comes with</li> </ul>	We had previously experimented with putting a warning on the syringe, but did not label the syringe with paracetamol strength as this could cause confusion		
Label	Paracetamol 250mg/5ml ORANGE FLAVOUR Prescribed to: Ms Jane Doe Give mL every 4-6 hours for PAIN or FEVER DO NOT give more than 4 doses in 24 hours STOP gving if still unwell after 2 days (48hrs) - go to your DOCTOR or PHARMACV WARNING: Too much paracetamol can damage your child's kidneys and liver Do NOT exceed the above dose or combine with other paracetamol products	<ul> <li>Use one colour per weight band to increase dosing accuracy</li> </ul>	After deciding against colours on the syringe, we removed the colour bands from the weight chart, but retained one colour - red - to make sure the warning stood out	Paracetamol 250mg/5ml ORANGE FLAVOUR Prescribed to: Name of tamariki GivemL every 4-6 hours for PAIN or FEVER DO NOT give more than 4 doses in 24 hours STOP giving if still unwell after 2 days (48hrs) - go to your DOCTOR or PHARMACY WARNING: Too much paracetamol can damage your child's kidneys and liver DO NOT exceed the above dose or combine with other paracetamol products	
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	<section-header><section-header><section-header><section-header><section-header>      The data data data data data data data dat</section-header></section-header></section-header></section-header></section-header>	<ul> <li>Increase the size of the child's name</li> </ul>	Increased the text size of the child's name	Witiserr         D054           57%         15%           9 table bottle at least 10 times before use           57%         15%           9 table bottle at least 10 times before use           57%         15%           9 table bottle at least 10 times before use           58%         26%           10 table         10%           10 table         10%	
		<ul> <li>Consider using 'to' instead of a hyphen</li> </ul>	Did not use 'to' instead of a hyphen between '4-6 hrs' because this might make the instruction more difficult to read for some caregivers	10, Dennys 1, US 1004, 10, 00, 50 10, 12, 2047 Univ. Teppininum, 10, 10	

Below we unpack these findings further, along with the process we used for arriving at subsequent iterations of the syringe and label after each round of user testing.

### Round 1

### Feedback on Round 1 (Ezy Dose) syringe

#### Participants liked the syringe but did not set the dose limiter

Most participants liked the syringe, including the dose limiter. However, four out of five caregivers did not read the label and therefore did not know to set the correct dose limit before they drew paracetamol out of the bottle.

"I think it (the improved syringe) is so much better – it has both the measurement in mL and the safety dose limiter you can set it to." – Caregiver

#### "I like that option (the dose limiter). Good you can set the maximum." - Caregiver

The consequence of not turning the dial to set the dose limiter was that if the dose limit happened to be set to a lower number of mLs (eg, 2.5mL) than required for the tamaiti (eg, 5mL), the caregiver was unable to draw out enough paracetamol for their child's weight. Conversely, if the dose limit was set at the maximum (10mL) but only a few mLs was required, then the limiter was not providing its intended safeguard against overdosing.

Health practitioners also liked the dose limiter. However, they thought it would only work if a health professional set the dose limiter for caregivers and whānau before giving them the syringe, or at least showed caregivers how to use the dose limiter. They acknowledged that it would likely be too stressful to have to work out how to use the dose limiter when dealing with a crying baby.

"Once you figure out you need to match the colour with the triangle, it (the dose limiter) is good." – Health practitioner

"I don't think whānau should have to set the dose limit; don't think whānau should have to work this out; perhaps the pharmacist could set the limit. That could work." – Health practitioner

#### "Not knowing how to use the dial at the end is a bit of a barrier." – Health practitioner

Instead of using a dose limiter, both health practitioners supported the idea of using an ordinary syringe with four colour bands on the syringe barrel to better cue caregivers to the amount of paracetamol they are drawing into the syringe.

"Colour coding could be cool - if in a coloured rainbow syringe. Colours could match the label, as long as you can see the liquid." – Health practitioner

#### Participants wanted finer grade mL markings on the syringe

Most caregivers and both health practitioners said they would prefer more finely graded markings on the barrel (ie, every 1mL rather than every 2.5mL). Having mL markings only every 2.5mL on the Ezy Dose syringe meant that for dose sizes in between these amounts, caregivers had to estimate the amount they were drawing out.

"A little confusing when you are trying to find exact numbers. So maybe have (for example) 4mL there, so it is easier to stop the syringe in the exact position." – Caregiver

"...mark every mL; need more markings." - Caregiver

*"The main issue (with the syringe) is 2.5mL increments... would want 1mL markings."* – Health practitioner

"...it (the syringe) could be helpful, as long as it had the right measurements, that is more finegrained markings for the doses." – Health practitioner

#### Caregivers experienced issues with vacuum suctioning

There were some issues with the vacuum suctioning of the paracetamol back into the bottle. This was due to the bung at the top of the paracetamol bottle which enabled caregivers to use the syringe to draw out paracetamol while the bottle was tipped upside down. However, when caregivers pulled back on the plunger to draw paracetamol out of the bottle, there was a strong vacuum effect which meant when they let go of the plunger, the plunger was suctioned back into the barrel (and paracetamol into the bottle). This made it more challenging for caregivers to draw up an accurate dose of paracetamol.

"...all the medicine suctioned back in (to the bottle)." - Caregiver

#### "Vacuum bit suctioning back in - made it difficult." - Caregiver

Both health professionals suggested that other syringes also have the vacuum suction issue, but it only seems to be an issue when there is a bung on the paracetamol bottle (because no air can get in or out). We learned that when paracetamol is prescribed, the norm is that bottles don't come with a bung, so the suction effect is less of an issue for prescribed paracetamol.

"Other syringes also have a suction issue, but seems to be an issue only when there is a bung on the paracetamol bottle." – Health practitioner

"The Ezy Dose syringe has a pretty strong seal; pretty solid. With a normal pharmacy prescribed bottle, that (the suction issue) wouldn't happen, because there is (no bung)." – Health practitioner

#### Health practitioners thought the width of syringe could be thinner and longer

One health professional suggested that although the syringe fit into a paracetamol bottle, it might be easier if the syringe was a bit **thinner** to fit inside the paracetamol bottle easier.

"(The syringe is) wide - could fit it in paracetamol bottle, but it is on the wide side." – Health practitioner

The other health professional suggested it could be a bit **longer** to reach the bottom of the paracetamol bottle.

# "Perhaps better if longer? The width is fine; fits into a bottle; it is just with a big bottle, it is hard to get stuff out of the bottom." – Health practitioner

#### Syringe size too small for higher tamariki weights

Caregivers with tamariki who required a dose larger than the 10mL volume of the syringe needed to put the syringe back into the bottle a second time to draw the correct dose. For example, one caregiver with a 50kg child (requiring a 15mL paracetamol dose) needed to first draw up 10mL, followed by another 5mL. This did not seem ideal for maximising dose accuracy. It is clearly the reason that larger syringes are available. Although as tamariki get older (and heavier), they usually switch from liquid paracetamol to tablet or capsule form, which also helps to avoid the issue of needing to take relatively large doses of liquid paracetamol.

### Feedback on Round 1 label

#### Participants thought the label was an improvement but most did not read it

Caregivers and health practitioners thought that the whānau Māori/BI informed label was an improvement on current prescription labels (see Appendix 4).

"Nice and simple; like the coloured dose chart... You can read our label easier. You are really struggling with the standard ones." – Caregiver

"Pretty simple to understand and read." - Caregiver

"Seems pretty straight forward. Says how much to administer... pharmacy labels can be confusing because there are lots of words in one small space" – Health practitioner

"This label is clearer." – Health practitioner

Caregivers reported that the weight chart was particularly useful.

"I think the dosage chart is cool; it is not routinely given." - Caregiver

"The colour chart is good; the fact it is colour coded." – Caregiver

"I like that the weight and dose is given." - Caregiver

Caregivers and health practitioners also commented on features of the label that they appreciated such as:

• The warning that too much paracetamol can damage your child's kidneys and liver

"The warning at bottom re potentially damaging children's liver is good." – Caregiver

• The QR code

"Like the QR code - would scan and have a read for further tips." - Caregiver

• The expiry date

"Good to see an expiry date; most don't have an expiry." - Caregiver

• The information to store paracetamol at room temperature

"I like that it says to store at room temperature."." – Health practitioner

• The weight chart giving children's weights and not ages

"It shows that it is weight based. You have parents guess their child's weight but if age is there (on the label) they just go for their child's age; it sends the wrong message." – Health practitioner

• The encouragement to return to the doctor if symptoms continue beyond 48 hours.

*"Good encouraging whānau to return to doctor if they need to use it for more than 48 hours."* – Health practitioner

However, despite these positive comments, four out of five caregivers did not read the label before drawing out the paracetamol dose, highlighting the importance of making the label eye-catching and visually appealing.

"I didn't read the instructions..." - Caregiver

"To be honest, I didn't look at it. Now looking at it; it's good, really helpful." – Caregiver

*"It would be easy; straightforward; much easier to understand than original ones (labels). But you have to read it!" – Caregiver* 

Consistent with this finding, four out of five caregivers said they would not typically read the label at home either.

# Participants had a slight preference for the instructions on first weight chart but the colours on the second weight chart

Caregivers and health practitioners had a slight preference for the first weight chart (see page 62) but only because the third column made it clearer how they should set the dose limiter. They thought the colour scheme on the second weight chart was slightly easier to read (ie, the white numbers against a coloured background).

"Prefer 1st (weight chart) - because it actually tells you - 'set to blue' - tells me I need to set the syringe to that colour. 2nd (weight chart) - think different colours might differentiate between doses; make it easier to read." – Caregiver

"Easier to see the doses for different weights (on the second weight chart). May not be easier to know what to do with the dial." – Caregiver

"You still need the third column - it spells out the instruction more." – Health practitioner

"Like that the first one (weight chart) actually says: 'set to (a colour)' - but the writing is more difficult to read... stands out more on the 2nd one." – Health practitioner

#### Participants thought the orange warning band should stand out more

Caregivers and health practitioners suggested that the orange warning band (about not giving more than 4 doses in 24 hours) didn't stand out enough.

"...orange for the warning - needs to change - it matches so didn't see it - should be red or something." – Caregiver

" In order highlight the 'DO NOT give more than 4 doses in 24 hours' - agree that it should be a different colour to stand out more." – Health practitioner

"...agree that orange doesn't stand out that much, but I get what you were trying to do with the orange." – Health practitioner

#### Participants had other suggestions for the format or wording of the label

Individual participants shared other feedback on the label:

• Instead of instructing caregivers to give paracetamol every 4-6 hours, instruct them to give a maximum of 4 doses a day - because this stops caregivers from waking tamariki in the middle of the night to give them a dose.

"I always write 4 times a day instead of every 4-6 hours. Tell them to spread it - morning, lunch, afternoon, after dinner – I learnt this in intern year - it stops parents from waking kids in middle of night to give them a dose - those who are sticking rigidly to the instructions." – Health practitioner

• Labels should ideally be water-proof so the writing doesn't rub off.

"Standard kind of labels - can get quite sticky from the paracetamol and peel away, so it would be good to be made of something that can be wiped down without losing the words." – Caregiver

"Good idea to make it water-proof." - Health practitioner

• Write the numbers in words (as well as numbers) because caregivers can get the decimal point mixed up.

"Write number of mL in words as well as numbers - because you can get confused with a decimal point. 3.8mL might be seen as 38 mL. Most colleagues don't do this." – Health practitioner

Importantly, we discovered that pharmacists can't print coloured labels using pharmacy printers and software, so these labels would have to be supplied in separate rolls.

"Can't print coloured label on pharmacy printer. So we just capitalise the main points. Would have to have a separate label machine." – Health practitioner

#### Weight chart only goes up to 41kg

Similar to our observation about the 10mL syringe being too small for heavier tamariki, our weight chart only went up to 41kg, so was not appropriate for heavier children. Given that one child of a caregiver in our sample weighed 50kg, we couldn't use the weight chart to determine the dose, but instead had to use the <u>online dose calculator</u> at the Healthify website. One health practitioner commented that ideally the weight chart should cover doses for larger tamariki, but that it wouldn't be needed very often as most children under three years (for whom liquid paracetamol is most often used) weigh less than 50kg.

"Yes, you probably need this (weight chart to cover doses for larger tamariki), but usually don't have children under 3 up to 50kg." – Health practitioner

The amount of space on the label is also potentially an issue for including heavier weights in the weight chart.

#### Iteration process following Round 1 and solutions taken forward to Round 2

In Round 1 of user testing, we tested how caregivers responded to a dose limiting device on the syringe and a matching label with two different weight charts.

As a result of feedback on the Ezy Dose syringe, we planned for our next syringe version to:

- use colour banding instead of a dose-limiting device'
- have finer-grade mL markings on the barrel; and
- be slightly longer and thinner than the Ezy Dose syringe.

We again searched for existing alternatives and found that the 5mL Pamol syringe that was included in the package for over-the-counter paracetamol met some of these criteria (see photo 6).

Photo 6. 5mL Pamol syringe that is included in the package for over-the-counter paracetamol



This 5mL Pamol syringe had much finer-grade markings and was longer and thinner than the Ezy Dose syringe. The main difference between this Pamol syringe and the Ezy Dose syringe (or standard syringes) is that the mL markings on the Pamol syringe are not on the barrel but on the inside plunger. This means that to measure out the exact dose, caregivers must watch the plunger as they draw out the paracetamol instead of the barrel.

The Pamol syringe was only missing the colour banding. The idea behind the colour banding on the syringe was that it would serve as an additional visual cue (beyond the mL markings) to draw up an accurate dose of paracetamol. It was intended that colours on the syringe would match the colours on a colour-banded weight chart, enabling caregivers to essentially look up the colour for their child's weight and then draw up the paracetamol to match their child's colour. Using a colour-coded syringe has previously been shown to improve dosing accuracy.<sup>9</sup> However, we had received feedback that pharmacists could not print colour labels, and we wanted to match the syringe with the label. We therefore decided to use grey-scale bands instead of colour bands on the syringe (and label).

We investigated the option of going back to the 3D printers or overseas to a Chinese manufacturer to produce the next version of the syringe. There were pros and cons both ways. The New Zealand 3D printers may have been cheaper (because they were only producing a small number of them) and faster, but we had concerns about the quality of a 3D printed syringe which could have led to more iterations, time and cost. On the other hand, the Chinese manufacturers would likely have taken longer and would have printed a minimum of 10,000 syringes. We were also unsure how easy they would be to work with if we wanted changes made to the prototype before proceeding to manufacture thousands of them. With both options having significant obstacles, we decided to experiment with putting the grey-scale colour bands on ourselves.

We also considered using a syringe with a higher volume to accommodate tamariki of higher weights but in the end decided against this. The potential for paracetamol overdosing is more acute for younger, lighter tamariki who need smaller doses of liquid paracetamol. So we concentrated on modifying the 5mL Pamol syringe – which is appropriate for administering paracetamol to tamariki up to 18kg.

A final consideration was whether to put the grey-scale bands on the barrel or plunger of the syringe. During the user testing, we discovered that most prescribed paracetamol bottles don't have a bung in the top of them. This means that caregivers had to put the syringe inside the bottle to draw out the paracetamol dose (rather than tipping the bottle upside down). When the markings are on the syringe barrel, caregivers can't see them (or any grey-scale bands) when the syringe is inside the bottle, making it very difficult to draw up a precise dose of paracetamol. In contrast, when the markings are on the plunger, caregivers can still see the markings (or grey bands) as the dose is drawn out, even when the syringe is deep inside the bottle. It therefore became an easy decision to put the grey bands on the plunger rather than the barrel.

The syringe we took through to Round 2 of user testing is shown at different angles in Photo 7 below, with the plunger both in and out of the barrel.



Photo 7. Syringe used in Round 2 of user testing

Changes to the syringe had implications for changes to the label. As a result of feedback from participants and changes to the syringe, we made the following changes to the label:

- Dropped the instructions about setting the dose limiter because these were no longer needed;
- Changed the instructions about giving paracetamol 'every 4-6 hours if experiencing pain or fever' to 'do not give more than 4 doses in 24 hours' because it simplified the instructions;
- Increased the size of the warning that 'too much paracetamol can damage your child's kidneys and liver' to make it more prominent and eye-catching; and
- Used grey-scale colours on the label and weight chart to decrease the cost and make it more practical for pharmacists.

The label we took through to round 2 of user testing is shown in Diagram 7 below.

Diagram 7. Label used in Round 2 of user testing



WEIGHT	DOSE	Store at room temperature
Less than 5kg	Ask your doctor	<ul> <li>Store in a child proof cupboard.</li> <li>Shake bottle at least 10 times before use.</li> </ul>
5-7kg	1.5mL	
8-9kg	2mL	
10-12kg	3mL	
13-14kg	4mL	
15-16kg	4.5mL	For further tips
17-18kg	5mL	Call the Health Line on 0800 611 116, or Scan the QR Code
19-20kg	5.5mL	
21-22kg	6.5mL	My Pharmacy
23-25kg	7mL	− 123 Made Up Lane, 1234 Ph:12345678 Email: scripts@madeup.co.nz
26-28kg	8mL	
29-32kg	8.5mL	
33-36kg	10mL	
37-41kg	11mL	7
More than 41kg	Ask your doctor	1

### Round 2

### Feedback on Round 2 (Pamol) syringe

# Caregivers took a few moments to work out how to read the numbers on the plunger but worked it out quickly and ignored the grey-scale bands

Most caregivers in our sample were not familiar with the over-the-counter Pamol syringe. They all took a few moments to orient themselves to having to read the dose on the plunger (instead of on the syringe barrel). However, they worked it out quickly and then expressed appreciation that the mL markings could be read even when the syringe was inside the paracetamol bottle.

"Other syringes have markings on the outside of the barrel." - Caregiver

"Makes complete sense that the numbers are on the plunger so you can see them as you draw them out. Half the time with the numbers on the outside, you can't read it properly when in the barrel and they rub off... But you are changing generations of a way of doing something, so is initially confusing..." – Caregiver

"The syringe compares well. The fact the whole syringe doesn't go into the medicine – that is what works for me." – Caregiver

The main finding was that the grey-scale bands on the syringe barrel were meaningless to caregivers. They did not realise that the grey-scale bands matched the bands on the weight chart and therefore did not use the grey-scale bands as a visual cue.

"I don't think people are going to get it because they will not look at the bottle and think that is grey, the same colour as the colour band on the syringe." – Caregiver

"It's not obvious that the grey bands on the syringe match what is on the label." - Caregiver

"What is leading how you measure it – the colours or numbers? – the numbers. The colours (grey bands) didn't mean anything to me." – Caregiver

"At first, when pulling it up, instantly looked at the numbers, not the colours; did not associate the colours with anything. I thought the grey bands were random." – Caregiver

#### Caregivers wanted colour on the syringe

Caregivers suggested that matching coloured bands on the syringe with the label would serve as a better visual cue than the grey-scale bands, and that each mL should have a different colour band.

"Would be good if it was coloured." - Caregiver

"Going back to colour – each mL could have a different colour. At the moment, 2-4 mL is just block grey." – Caregiver

*"Maybe if they (the grey-scale bands) were red and green and orange, then I might have looked closer." – Caregiver* 

"For me with my paranoid eyes, I don't need colour, but for someone stressed, they would potentially need colour on the label and therefore the syringe." – Caregiver

#### Caregivers wanted the lip of the syringe barrel to be wider

A few caregivers suggested that it would be helpful to have a wider lip on the barrel of the syringe – potentially oval in shape – to give their fingers more area to lever off and so that the syringe could be rested on the bottle rim.

*"If the plastic stopper (lip of barrel) was bigger, it would be easier to push my thumb against it. Would be good to have more leverage." –* Caregiver

"Some lips on the barrel of syringes are oval – so you have a bigger bit to place your fingers on. This would allow more space. Doesn't work for my 'Māori fingers'." – Caregiver

#### Caregivers had other suggestions for improving the syringe:

Other suggestions for improving the syringe included:

• Raised text or etchings that don't wash off.

*"Better when the markings are scratched on – encrypted on – don't have to worry about the writing rubbing off." – Caregiver* 

• One colour per mL or weight band rather than a block of colour for 2-3 weight bands.

"Potentially have more colour bands for each dosage instead of a 4kg difference across one colour band." – Caregiver

• Larger numbers on the plunger.

"I would make the syringe numbers bigger." - Caregiver

• A little spoon on the end of the syringe.

"Put a spoon on it! Squirting it into his mouth – can go too fast. Put a little spoon on the end to slow down how quickly it goes into their mouth." – Caregiver

• mL markings that go all away around the plunger (not just half way around) and numbers on both sides of the plunger (not just one) so caregivers don't have to turn the syringe to read the dose.

*"If numbers had been on both sides (of plunger), then would be easier to see them."* – Caregiver

"...need a clear reference point – so put the ring all the way around." – Caregiver

#### Feedback on Round 2 label

#### Caregivers read the label and appreciated certain features of it

Unlike the first round of user testing, four out of five caregivers read the label and indicated that they would usually read the label at home. Similar to the first round, caregivers thought the revised label was an improvement on current prescription labels.

"This label is much more informative than the label that comes with (prescribed paracetamol). It is more informative and is way more user-friendly." – Caregiver

Caregivers said they liked several features of the label including:

• The weight chart

"The (weight) table is great. I really like the table ... Really easy to read." - Caregiver

"The Pamol we have is the prescribed one; the table isn't there. I'm still giving her 7mL because that is what she weighed a long time ago; she has put on weight, but there are no instructions on how much to give her." – Caregiver

• The warnings - too much paracetamol can damage your child's liver

*"But the most important part is the warning about what too much paracetamol will do." –* Caregiver

"Big message I get is too much paracetamol can damage your child's liver. It's a good message; if a young mum – 'gee, I better find something proper to measure this'. I would be able to say to my brother – 'too much paracetamol causes liver damage'." – Caregiver

• Information about paracetamol storage

"I immediately went to 'store at room temperature'." - Caregiver

• Healthline information

"I like the fact that the Health Line number is on the label." - Caregiver

#### Caregivers did not see the point of the grey-scale bands and wanted colour bands instead

An important finding was that the grey-bands on the weight chart were meaningless to caregivers partly because they were grey-scale and did not stand out, and partly because they spanned more than one weight band.

"I don't see the point of the different (grey-scale bands)." – Caregiver

"It wasn't a traffic light so the grey-scale seemed random." - Caregiver

"Grey-scale colour bands would be good for an illiterate person, but the grey colour band is too big... Not enough colour bands to make it fine grade enough." – Caregiver

Similar to the syringe, caregivers thought that colours on the label would be more of a visual cue than grey-scale bands.

"...colour code it, so it stands out." - Caregiver

"I'd like more colour on the label." - Caregiver

*"I'm torn by need for colour." –* Caregiver

#### Label doesn't tell caregivers how many hours to leave between doses of paracetamol

As a result of feedback received in the first round of user testing that the label instructions to give paracetamol every 4-6 hours could be confusing, we had changed the wording to 'do not give more than 4 doses in 24 hours'. However, we discovered that the revised wording meant that caregivers were now doing mental arithmetic to work out how often to give the paracetamol.

"Not more than 4 doses in a 24-hour period' - means every 6 hours. I would have divide 24 by 4 to know how often to give it." – Caregiver

#### Caregivers wanted some of the writing to stand out more and to be in plainer English

Caregivers suggested that the warnings should stand out more, for example by putting them in red (to associate the words with danger) or in larger font. This included the warning in the black band – 'stop dosing if symptoms continue beyond 48 hours'.

"Make it clearer – if symptoms are still going after two days, go to the doctor – this isn't standing out." – Caregiver

"The white on black did not pop it (for the text 'do not give more than 4 doses in 24 hours')." – Caregiver

"The warning would be great if it was in red... would draw attention." - Caregiver

"Anything that says 'Do not' should be much bigger and in a different colour." – Caregiver

Similarly, caregivers wanted some of the other text to be larger, such as the child's name and expiry date.

"Make the expiry date easier to read. It's hard to see at the moment." - Caregiver

Caregivers also thought some of the wording could be simpler or in plainer English. For example, instead of saying 'stop dosing if symptoms continue beyond 48 hours (return to your doctor)', the label could say 'if your child is still unwell after two days, go to doctor'.

"You want it as simple as possible." - Caregiver

"Make it less medical language." - Caregiver

#### Caregivers had other suggestions for the format or wording of the revised label

Caregivers shared other feedback on the label:

• More space between the front and back of the label

"I don't know what the front (of the label) is and what the back is." - Caregiver

• Include ages as well as weights in the weight chart

"It is the weight thing – the weight is good but we should have the age there as well." – Caregiver

• Put a photo or diagram of the syringe next to the weight chart to show how the grey-scale bands on the weight chart match the syringe

"Put photo of a syringe next to the table so you can see how it matches." – Caregiver

#### Iteration process following Round 2 and solutions taken forward to Round 3

In Round 2, we tested grey-scale bands on the syringe plunger and label. Despite challenges with the cost of colour syringes and labels, we wanted to honour the strong theme of caregivers wanting colour on both. This meant that we needed to relook into the feasibility of using colour on the syringe and label. We decided if colour made a significant difference to dosing accuracy, then it could be worth the cost, so we planned for our next syringe version to:

- Use colour banding instead of grey-scale bands; and
- Use one colour per mL.

We weighed up whether to keep the 5mL Pamol over-the-counter syringe as the base syringe or to use a standard 5mL syringe. We found that it was significantly easier for us to put our own coloured bands on the plunger of a standard syringe compared with the Pamol syringe, so we decided to use a standard syringe as the base for our third round of user testing. Even though this meant caregivers would not be able to read the mL markings when the barrel of the syringe was inside the paracetamol bottle, we reasoned that caregivers could 'read' the coloured bands on the syringe plunger to determine the correct dose amount as they extracted paracetamol from the bottle.

We decided that other potential improvements, such as using a wider lip on the syringe barrel, could be explored later. The syringe we took through to Round 3 of user testing is shown in Photo 8 below.

#### Photo 8. Syringe used in Round 3 of user testing





We incorporated most of the feedback received from caregivers on the label, as follows:

- Used colour bands on the weight chart to match the syringe
- Put a photo of a syringe next to the weight chart to show how the colour bands on the weight chart match the syringe
- Used red to make the warning about potential damage to children's kidneys and liver really stand out and to emphasise that the dose must be based on children's weight.
- Increased the size of the expiry date
- Reinstated the instructions to give paracetamol 'every 4-6 hours for pain or fever' to avoid caregivers having to do mental arithmetic

- Used less medical, plainer English– we simplified 'stop dosing if symptoms continue beyond 48 hrs (return to your doctor or pharmacy' to 'stop giving if still unwell after 2 days (48 hrs) – go to your doctor or pharmacy'
- Revised text sizes to make some information more prominent

We also considered whether to put children's age on the label. The label that comes with over-thecounter paracetamol includes children's ages and weight. This can be useful for caregivers who don't know the weight of their tamariki. However, conversations with health practitioners suggested that most were in favour of keeping children's ages off the weight chart, simply because it can be misleading and lead to inappropriate sized doses for many tamariki. They thought it best to leave children's ages off the label to emphasise the importance of paracetamol dosing being based on weight.

The label we took through to round 3 of user testing is shown in Diagram 8 below.

#### Diagram 8. Label used in Round 3 user testing



## Round 3

### Feedback on Round 3 syringe

The one health practitioner who participated in this round was a GP. She made the following key points about the syringe:

• **The standard 5mL syringe is too short** – because it makes it too difficult to draw paracetamol out of a half empty bottle. A longer thinner syringe also makes it easier to administer it to younger children (can slip down the side of their tongue).

"It is really hard to get a small syringe into a bottle that is not full - it gets really messy." – Health practitioner

"Longer syringes are easier for younger babies. The best way to do it is put it down the side of their tongue and push it in there." – Health practitioner

• The colours on the syringe plunger make it too complex – she said she would only read the numbers on the barrel. If colour bands are used, they should be put on the outside of the barrel, not the plunger (to reduce complexity).

*"I immediately notice the colour bands; I wonder what they mean; they don't seem to match with anything."* – Health practitioner

*"It is too complicated; another step to think about. A whole extra step; don't want to give something extra to do."* – Health practitioner

• The width of the colours on the plunger are quite wide (they covered 1mL each) - so they potentially reduce the accuracy of a dose.

"Also a bit problematic - there is a whole blue zone - are you happy to be at the top or bottom of it? It would be easier if there was a thin line on the outside the syringe." – Health practitioner

"I would prefer a coloured ring around the outside of the barrel." – Health practitioner

• Use etchings on the syringe - so the markings don't rub off.

"If you were to reuse it, practical tips (as a parent of a 3 year old child), eventually the markings wear off. It would be good to have them dishwasher safe, or even imprinted." – Health practitioner

• **Consider labelling the syringe** - with the strength of paracetamol that it comes with, i.e. with 120mg/5mL or 250mg/5mL.

*"If you are going to have different doses of paracetamol, label your syringe - call it A or B or 120mg/5mL or 250 mg/5mL. Need to know you have the right syringe." –* Health practitioner

#### Feedback on Round 3 label

The health practitioner provided the following feedback to further refine the label:

• Use one colour per weight band (instead of two grey and two purple colour weight bands) - to increase dosing accuracy.

"Oddly, there are 2 purple doses and two grey doses (on the weight chart). So I think it should be one colour per dose line." – Health practitioner • Increase the size of the child's name - to make it clear which child the dosage applies to.

"The child's name is tiny... Name of the person needs to be nice and clear. This paracetamol belongs to Jane." – Health practitioner

• Consider using 'to' instead of a hyphen - where it says 'every 4-6 hours for pain or fever'.

"(For the words) 'every 4-6 hours', put in a 'to' rather than a hyphen?" – Health practitioner

### Reiteration process following Round 3 and solutions taken forward to trial

Round 3 was primarily a test of the coloured bands on the syringe plunger and label. Although Round 3 was conducted with only one health practitioner, we had confidence in her feedback which was aligned with much of the earlier feedback we had received from other participants. In particular, we could see that the coloured bands on the plunger (and weight chart) were not working as intended. This left us with the option of putting coloured bands on the syringe barrel. However, given the significant issue of not being able to see the syringe barrel when drawing up paracetamol from inside the bottle and the additional costs involved, we decided against the coloured band option.

Instead, we reverted to the 5mL Pamol syringe (tested in Round 2), this time without grey-scale bands (see Photo 9 below). The Pamol syringe was superior to standard syringes on the market and, except for the lack of colour bands, met many of the criteria we originally sought in a syringe:

- A relatively thin barrel to make it easy to read the mL markings and to easily fit inside the paracetamol bottle (and babies' mouths);
- A relatively long barrel to reach paracetamol at the bottom of the paracetamol bottle;
- mL markings at every mL (and extra markings between mLs) for more accurate dosing; and
- mL markings on the plunger to enable caregivers to read the dose even when the syringe is inside the bottle.

If the syringe worked to improve dosing accuracy in the trial, we could add other desirable features (such as permanent markings and a wider lip) later. The syringe we took through to the trial is shown in Photo 9 below. Although we did not design this syringe ourselves, three rounds of user testing led us to this pre-existing syringe, and we were satisfied that it was an improvement on standard syringes.

PAMOL

Photo 9. Pamol syringe used in the trial



To match the label with the syringe, we removed the colour bands from the weight chart. We retained one colour - red - on the label. This was to ensure the warning about potential damage to children's kidneys and liver stood out and to emphasise that the dose must be based on children's weight. We also incorporated the health practitioner's advice to increase the size of the text for the name of the child. The final label we took through to the trial is shown in Diagram 9 below.

#### Diagram 9: Label used in trial



# **TRIAL: Randomised controlled trial**

The purpose of the trial phase was to test the effectiveness of the 5 millilitre (mL) Pamol syringe and whānau Māori/BI informed label against conventional measuring devices and labels in reducing paracetamol dosing errors. Ethics approval for the trial was obtained from the Central Health and Disability Ethics Committee in August 2022.

# Method

## Design

The trial was a randomised control trial with 2 arms (control and intervention).



The intervention we trialled had two components: 1) the 5mL Pamol 'intervention' syringe that comes with over-the-counter paracetamol; and 2) our whānau Māori/BI informed 'intervention' label that can be applied to a paracetamol bottle by the pharmacist. These two solutions were designed to target slightly different aspects of administration (knowledge and behaviour, respectively), and were therefore intended to act in concert to facilitate accurate dosing by minimising the following potential sources of dosing error:

Potential Sources of Dosing Errors				
Targeted by our intervention syringe	Targeted by intervention <b>label</b>	Not targeted by our solutions		
<ul> <li>Not drawing out the appropriate dose from the paracetamol bottle</li> </ul>	<ul> <li>Not knowing the dangers of overdosing on paracetamol</li> </ul>	<ul> <li>Not knowing the current weight of the child</li> </ul>		

<ul> <li>Not knowing the appropriate dose for a child of a given weight</li> </ul>	<ul> <li>Not administering the amount drawn out of the paracetamol bottle correctly to the child</li> </ul>
<ul> <li>Not knowing the appropriate dosage frequency</li> </ul>	<ul> <li>Cultural concordance, clinical education and communication</li> </ul>
<ul> <li>Not knowing the appropriate dosage course</li> </ul>	

Images of the syringes are in Photo 10 below. The key differences are that the intervention syringe was longer and thinner and had measures on the plunger rather than the barrel. Participants in the control group were asked to use an available measuring device most similar to what they would normally use to dose paracetamol. The devices available were a dessert spoon, a 40mL measuring cup, the lid from an over-the-counter paracetamol bottle, and a regular (control) 5mL syringe.

Photo 10: Control and intervention syringes



The label contained a number of components, including:

- Name of recipient
- Dosage amount
- Dosage frequency

- Stated the dosage course (i.e., the maximum number of days to continue dosing for, if symptoms persist, before returning to the GP);
- Stated and used colour to draw attention to the potential damaging effects of paracetamol;
- Provided safe storage information (i.e., storing out of the fridge, shaking before use);
- Provided a warning not to combine with other medicines containing paracetamol;
- Provided a weight chart divided into a series of bands. Each band showed the appropriate dosage range (in mL) for a child who falls within a specified weight range.

See the labels in Diagram 10 below.

Diagram 10. Control and intervention labels

# Control label:



# Intervention label:



WARNING: Too much paracetamol can damage your child's kidneys and liver

DO NOT exceed the above dose or combine with other paracetamol products

#### The dose MUST be based on your child's weight.

#### For this strength paracetamol, dose as follows:

WEIGHT	DOSE
Less than 5kg	AR your doctor
5-7kg	1.5mL
8-94g	2mi.
10-1248	3mL
13-14kg	4mi.
15-16kg	4.5mL
17-18kg	Sml.

٠	Shake	bottle	at least	10 tim	es before	use
	Store a	t room	tempe	rature		

- Store in a child proof cupboard
- Did you know? You can weigh your child at your local pharmacy

For further tips... Call the Health Line on 0800 611 116, or scan the QR Code



Ny Memory 123 Mode Valuers, 1234 Ph 12345678 Brief, scrots@mode.o.cs.rc Prior to recruitment, Dr Sarah Hayward facilitated a half-day 'train-the-trainer' workshop with NHC kaimahi (NHC staff) involved with data collection. They were taught the research protocol (see Appendix 8 for workshop slides) which covered how to:

- recruit participants and gain informed consent;
- randomise participants;
- collect self-report data from participants using the Google form;
- navigate participants through the simulated dosing of paracetamol;
- measure the amount of paracetamol participants measured out from the bottle;
- manage the viscosity of the paracetamol liquid when handling and measuring doses;
- provide feedback to participants after their simulated dosing; and
- the escalation procedure if caregivers did not dose accurately (see Trial protocol in Appendix 9).

The training also provided an opportunity for NHC kaimahi to have a practice run, taking it in turns to play the role of researcher and caregiver. Following this train-the-trainer session, NHC researchers trained additional kaimahi who were employed to help with the trial.

## Recruitment

Liquid paracetamol is typically given to tamariki (children) who are too young to swallow tablets. Tamariki learn to swallow tablets between approximately 6 to 10 years of age,<sup>56</sup> but we heard anecdotally that some caregivers continue to use liquid paracetamol for older tamariki, even up to 14 years. To capture this full age range, and to maximise the available participant pool, individuals were eligible to participate if they are a caregiver to a tamaiti Māori (Māori child) under 14 years old.

We recruited 1000 caregivers of tamariki Māori via the National Hauora Coalition's (NHC) clinical and community provider networks. Some participants were recruited during existing immunisation drives and community events hosted by NHC or NHC providers, or at events where NHC was already present. The range of recruitment sites included: churches; family homes; rangatahi (youth) sport events; hauora (health) events at marae and shopping malls; clinics; community centres; and drop-in centres. Sites were predominantly across the North Island.

NHC kaimahi and our community supporters told people about the trial and checked their eligibility. If caregivers agreed and were eligible, NHC kaimahi talked them through further details of participating in the study (including research aims, use of information, and koha) and gave them the opportunity to provide their informed consent (see trial protocol in Appendix 9). Participants were offered a \$40 koha at the completion of the dose simulation as thanks for their time, which was about 15-25 minutes. Some participants texted their relatives and friends to participate too.

## **Data collection**

Data collection went from September to November 2023. Each NHC kaimahi received a digital form and a printed pre-populated assignment list, which alternated randomly between intervention and

56 See:

https://bpac.org.nz/Supplement/2014/September/pillswallowing.aspx#:~:text=In%20general%2C%20children%20are%20a ble,pills%20at%20a%20younger%20age.

control assignment. NHC kaimahi used this list to assign each participant to either the intervention or control group, on a rolling basis, as participants were recruited.

Our trial simulated the process of drawing up a dose of paracetamol. For prescribed paracetamol, a general practitioner (GP) or nurse prescriber would stipulate on the label (and perhaps reiterate verbally) the exact dose (in mLs) and dose frequency (minimum hours apart for each dose and maximum number of doses per day), and may also stipulate the dosage course (maximum number of days to continue dosing for if symptoms persist before returning to the GP).

Before they measured the dose, we asked caregivers to state whether they had administered paracetamol before, what they usually used to do this, and the current weight of their youngest child so that the NHC kaimahi could determine the exact dose in mL appropriate for a child of that weight (i.e., the **prescribed dose**). If the participant did not know the weight of their child, the NHC kaimahi looked up the average weight of a child of that age using standardised weight charts (see weight charts at the back of the trial protocol in Appendix 9), and informed participants that it is preferable to weigh children if possible. The appropriate dose for the weight was then calculated using the <u>online dose calculator</u> at Healthify, which kaimahi showed to participants. The NHC kaimahi then communicated the prescribed dose to the participant verbally, and by writing it on aa piece of paper. The participant was asked how much paracetamol they intended to draw out (i.e. their **intended dose**), as they drew out the **actual dose** from a standard bottle of paracetamol, which did not have a bung.

If they were in the treatment group, participants used the intervention syringe and label to draw out the paracetamol. If they were in the control group, they used one of a range of dosing implements (a standard 5ml syringe, 40mL measuring cup, dessert spoon, and a Pamol lid). Participants were asked to select the dosing implement closet to the one they normally use at home. If they had never administered paracetamol before or their preferred device was not one of the options, they were shown the range of measuring devices and could choose the one they wanted to use. Along with the device, they were also given a bottle of paracetamol with a typical prescription label.

After participants measured the dose, we asked them to state their hypothetical dosing plan with respect to dose frequency and course. Note that the paracetamol drawn into the syringe was not administered to anyone; it was disposed of immediately after the testing session.

Participants were fully debriefed about the purpose of the study, and if they had made dosing errors or frequency errors, they were provided feedback and additional resources to support appropriate future use of paracetamol.

We also had space on our form to note participants' questions, experiences and insights about paracetamol. If they had any questions, we tried to address these based on medical advice we had within the NHC team, and also offered resources to participants, including an information sheet on paracetamol use made by Waitemata DHB (see Appendix 10) and a te reo Māori resource on safe paracetamol use created by Pharmac (see Appendix 11).

### **Data analysis**

We planned to assess the following key outcomes:

• The primary outcome was the deviation in mL between the measured dose and the prescribed dose (i.e., 'dosing error'). Deviations can be positive (i.e., overdosing) or negative (i.e., underdosing).

- The secondary outcomes were the deviation from the prescribed dose in terms of: a) frequency (number of doses per day); and b) course (number of days to dose before returning to a doctor). In both cases, deviations can be positive (i.e., overdosing) or negative (i.e., underdosing).
- The main exploratory outcome was whether or not the intervention syringe and label would reduce clinically significant overdoses, defined as doses that are in excess of the prescribed dose by 50%.

Our planned primary analysis aimed to test the average difference in mean dosing errors - the actual dose minus the prescribed dose - which accommodated errors that were both positive (overdosing) and negative (underdosing). We had previously chosen this approach because while overdoses may be more of a clinical issue, underdosing is also not desirable from a clinical point of view.

However, during analysis, we found this approach inadequate. If some individuals overdose and some individuals underdose, this could potentially "cancel out" any average difference between the treatment groups. For example, if participants in the control condition make larger errors, but make them symmetrically (i.e. both under and overdosing), we may not have observed an effect. Thus, given that our intervention was designed to increase the precision of doses, we instead elected to use an alternative analysis approach that directly modelled the standard deviation of errors in each group (see Results section for more information).

Analyses were conducted using the statistical programming language R, heteroskedasticity robust linear regression, logistic regression (for binary outcomes), and a non-parametric bootstrap resample method. We controlled for the following covariates in our regression models:

- Relationship to child (e.g. mother/father/grandparent)
- Past experience using an oral syringe to give paracetamol to tamariki (yes/no)
- Weight of child (to nearest kg, estimated by the caregiver)

# Participants

We recruited 1000 participants. One participant was excluded due to an unfeasibly large prescribed dose, which can be presumed to be a data entry error. This participant was excluded, and our final sample was 999 participants. A breakdown of the age of each participant's child by their experience using a syringe to dose paracetamol, and their relationship with their tamaiti (child) are shown in Figures 3 and 4, respectively below.



Figure 3. Age of tamaiti Māori by caregivers' previous experience using a syringe

Figure 4. Relationship of participant to tamaiti Māori



# Results

The broad pattern of results from our trial provides strong evidence that the intervention syringe and label increase the precision of paracetamol dosing and significantly reduce clinically meaningful overdoses. Of note, the number of clinically significant overdosing errors was very small (approximately 10 out of 500 participants in the control group, and approximately 3 out of 500 participants in the trial, participants were more likely to underdose than overdose.

# Participants in the intervention group were 34% more precise than participants in the control group

When dosing accuracy was operationalised as the standard deviation of dosing errors, we found that participants who were in the treatment group had a smaller standard deviation, i.e. better precision.

This can be seen in the distributions of dose errors (measured dose - prescribed dose) in Figure 5 below. Note that most of the data centres around zero, indicating accurate doses. However, there are some negative and positive data points, leading to "tails" on each side of the zero point. Note that in the control group, the point at zero is slightly smaller, and that the tails are slightly larger, indicating a wider spread of errors.





The plot in Figure 6 shows the results of a bootstrap analysis to estimate the standard deviation in each group, which has the advantage of not assuming a normal distribution of data. This analysis resamples the data, creating 10,000 "new" datasets of 999 rows. It then calculates the standard deviation for each of these "new" datasets in order to estimate how reliable this calculation is. The blue bars indicate the counts of standard deviations from each of these resampled datasets for each of the treatment and control groups, while the line and point indicate the highest density interval and median value of the standard deviation respectively.

The final panel shows the difference between the estimated standard deviations for each group, and importantly, the highest density interval does not overlap with zero. This means that there is more than a 95% chance that the treatment group had a smaller standard deviation than the control group. The estimate of the control group standard deviation was 1.9 mL, and the estimate of the treatment group standard deviation was 1.9 mL, and the estimate of the treatment group standard deviation a 34% increase in precision.



Figure 6. Results of bootstrap analysis

# Participants in the intervention group had significantly smaller absolute dosing errors than participants in the control group

To make our trial comparable with previous studies (Frush et al., 2004), we also ran a Wilcoxon rank sum test, which compares the median dose deviation from each group (dose deviation is the absolute percentage deviation of the actual dose to the prescribed dose). Note that while non-parametric, this test still assumes that the variances of the two groups are equal, which is an issue given that the intervention is aimed at decreasing variance.

Using the analysis approach of Frush et al., (2004), we found a significant difference in the median absolute dosing deviation between the control and treatment groups (p < 0.001; median values of 4.2% and 0.8% respectively). This is shown in Figure 7 below.



Figure 7. Median absolute dosing deviation for the control and treatment groups

# Participants in the intervention group were 70% less likely to make a dosing error than the control group

While a number of participants made paracetamol dosing errors, in most cases these errors were too small to be clinically meaningful. Similarly, while not desirable with respect to intended effective dosage, underdosing is not an issue for liver toxicity. Our analyses show that caregivers in the treatment group made both fewer overall overdosing errors, and fewer clinically meaningful (greater than 50% of the prescribed dose) errors.

Figure 8. Probability of making a dosing error more than 50% of the prescribed dose



As shown in Figure 8, when using the intervention syringe and label, participants were 70% less likely to make a clinically significant overdose than participants in the control group (or an absolute percentage point difference of 1.4%). While there were only 13 participants who made these large dosing errors, this low baseline rate is reflective of the low incidence of excess overdoses in the population.

To increase our confidence, we included all doses exceeding the prescribed volume (168 individuals across both groups). We plotted the proportion of these doses for each group in Figure 9 below.



Figure 9. Proportion of paracetamol doses that exceeded the prescribed volume

This shows that regardless of their volume, there were more overdoses in the control group (9.7% versus 7.1%). In combination, these two analyses suggest that the intervention syringe and label help to prevent both small and large paracetamol overdoses.

#### The intervention syringe and label had no effect on dose schedule or frequency

A secondary research question was whether our intervention syringe and label would help caregivers plan future doses in line with clinical recommendations. To answer this question, we asked participants how soon they would give paracetamol again, the maximum number of doses they would give within a 24-hour period, and the number of days in a row they would continue to give this dose to their tamaiti.

Most participants reported the correct dose frequency (no more than 4 doses in 24 hours) and course (return to doctor after two days).

We did not see any significant differences in responses to these questions for participants that received the treatment syringe and label relative to those in the control group. The majority of participants were within the recommended dosing frequency (no more than 4 doses in 24 hours) and dosing schedule (no more than 2 days in a row before returning to the doctor), although participants in the control condition would wait slightly longer to provide another dose on average (5.22 hours versus 4.55 hours). Anecdotally, several participants indicated they would deliberately be more sparing than the recommended dosing frequency and course. Figures 10 and 11 below show participants' responses to questions about how many hours they would wait before giving paracetamol to their tamaiti again and the maximum number of doses in a 24-hour period.

**Figure 10.** Participants' responses to how many hours before giving the second dose of paracetamol to their child



**Figure 11.** Participants' responses to the maximum number of doses they would give in a 24-hour period



This plot excludes values above 10.

# Control participants who chose to use a measurement device they didn't typically use were less accurate at dosing paracetamol.

Halfway through the trial, an inconsistency in the trial protocol was noted. Up until this point, some caregivers in the control group were able to use a measurement device of their choice (rather than the device closest to what they would usually use at home), which meant that although they may normally use a non-syringe device at home, they elected to use a syringe, or another device in the trial. This resulted in 22% of control participants in the first half of the sample choosing to use a measuring device that they did not typically use or that was not available (compared to 9% in the second half of the sample). This means the comparison between the control and treatment group for this first half of the sample was not as intended. After this date, NHC kaimahi were instructed to only allow caregivers in the control group to use what they typically use at home, enabling the intended comparison between the control and treatment. We took this inconsistency into account with a sensitivity analysis. This analysis did not substantially impact the nature of any of our results.

However, this implementation difference did allow us to examine whether participants in the control group who may have been offered a choice of measurement device, rather than using what they typically used, were more or less accurate than participants in the control group who were encouraged to use what they typically used. We repeated the bootstrap analysis (see above) to estimate the standard deviation for each of these groups (see Figure 12 below).

**Figure 12.** Results of bootstrap analysis showing the difference in dosing precision between control participants in the first half of the trial, some of whom had a choice of measuring device, and control participants in the second half of the trial who were asked to select the measuring device they typically use at home



We can see that while the highest density interval overlaps with zero, the control participants that may have been offered a choice had a higher standard deviation. Note that because we are only interested in the control group, the sample here is reduced (n = 488). Note also that the protocol was not delivered consistently across different NHC kaimahi, and the available measurement devices were not exhaustive. This means that we can't be sure that any of these control participants were offered a choice or not. Finally, even when some participants may have been offered a choice, their choice to use a device other than a typical one may be driven by an unobserved latent factor that might also affect dosing accuracy, so any interpretation of this difference should be strictly correlational.

### Measurement/behavioural errors were larger than dose determining errors

Because we asked participants what they intended to measure, as well as what they actually measured, we were able to look at differences between the **prescribed** and **intended** doses (dose determining errors) as well as differences between **intended** and **actual** doses (measurement/behavioural errors). This enabled us to characterise deviations stemming from dose determining errors (i.e. when participants said they intended to measure something different than what was prescribed), and deviations stemming from measurement issues or behaviour differences (i.e. when participants' actual dose measured was different from what they said they intended).

Figure 13. Mean dosing error for dose determining errors and measurement/behavioural errors



Figure 13 above shows the mean dosing error for each type of error. It shows that errors are underdoses on average. This matches anecdotal accounts by NHC kaimahi that many trial participants reported intentionally dosing less than the prescribed amount.

Figure 13 also shows that the measurement/behavioural errors are much larger than dose determining errors. This suggests that interventions targeting measuring behaviour, rather than those targeting dose determination, are likely to be more effective in increasing dosing accuracy. It is also possible that interventions that target caregiver intentions might also have an impact on dosing accuracy.

### Other common themes that emerged during the trial

During their interactions with participants, NHC kaimahi noted other common themes that emerged related to participants' questions, experiences and insights about paracetamol. These were as follows:

- Access to GPs is extremely fraught at present, with many participants saying they took very sick pēpi (babies) straight to hospital emergency, or relied on pharmacies who would prescribe paracetamol, or buy it over-the-counter.
- Many participants shared experiences with the health system that were confusing, demeaning or disempowering, and in such cases, engaging with health systems often meant accepting poor clarity and partial information.
- Trial participants held a range of relationships with the health system, with several participants being health practitioners (with one retired nurse who demonstrated on paper the formula she had used in her career to calculate dose based on the child's weight and the paracetamol dilution).

Questions trial participants asked reflected other things they wanted to know about paracetamol, that had not emerged in the user testing phase such as:

- how it differed to ibuprofen;
- how to remove air bubbles from the syringe; and

• why some children seem more affected by paracetamol (eg, become sleepy) than others.

## Limitations

Our treatment intervention combined two "active" ingredients: the Pamol syringe, and the whānau Māori/BI-informed label. These were notionally designed to impact actual dose accuracy and dosing schedule/frequency, respectively. However, we can't be sure that any differences in actual dosing were not due to the labels (e.g. as a consequence of increased salience), nor that any differences in dosing frequency or schedule were not due to the syringe (e.g. because the syringe is a signal of potential toxicity). In sum, we cannot confidently say whether any of our results are due to the syringe, label, or the combination of the two.

Similarly, for the purposes of this experiment, we used a single 5 mL oral syringe. However, various volumes of syringes exist, and doses for tamariki range beyond the 5 mL volume. Thus, we can't be confident that results would generalise to other types of syringes.

The study was conducted with caregivers of tamariki Māori living in the North Island (primarily Auckland) of New Zealand. We therefore cannot be certain that the findings are representative of whānau Māori living in other parts of the North Island or the South Island.

Finally, we recognise that our experiment took place under ideal lab conditions, and only simulated a dose of paracetamol. The Hawthorne effect - the tendency for people to modify their behaviour when they know they are being observed - is likely to have had an impact, given that participants knew they were being observed by the NHC kaimahi. Real world conditions are likely to differ substantially, with contextual factors and additional stressors (eg, having a sick child) affecting how caregivers dose paracetamol.

# **SCALE:** Discussion and conclusions

In this study we aimed to learn more about the knowledge needs of caregivers and whānau in relation to the safe use of paracetamol for tamariki Māori (Māori children), and we set out to codesign and test whānau Māori/BI informed solutions to reduce paracetamol dosing errors. This is the first study conducted in Aotearoa New Zealand to examine the effectiveness of solutions to improve paracetamol dosing accuracy. It is also the first study to look specifically at the knowledge needs of whānau Māori in relation to paracetamol safety.

### The intervention syringe and label reduced paracetamol overdosing errors by 70%

This study found that our intervention syringe and label reduced large paracetamol overdosing errors by 70%. Participants in the treatment group made fewer large overdoses (in excess of 50% of the prescribed dose) and small overdoses than participants in the control group, who were asked to select the dosing implement they would use at home.

Only a few caregivers (13 in total) measured doses more than 50% of the prescribed dose, but this mirrors the low incidence of significant overdosing in the general population. Our operationalisation of a 'large' overdose as being more than 50% greater than the prescribed dose is lower than Frush et al.'s (2004) study which defined 'serious' paracetamol overdose as more than twice the prescribed

dose.<sup>57</sup> However, repeated paracetamol ingestion can cause liver toxicity in doses only slightly above the maximum daily recommended dose.<sup>58</sup> We therefore consider an overall reduction of 70% in such 'large' overdosing errors to be clinically meaningful.

### The intervention syringe and label increased dosing precision by 34%

We also found that participants in the treatment group were more precise in their measurements than participants in the control group. Around 95% of participants in the control group dosed within a 3.8 mL range around the mean dose. For participants in the treatment group, this range was only 2.5 mL.

These results are consistent with international research which has previously found that oral syringes are more consistently accurate - have a smaller variance in the measured volume of doses - than conventional measuring devices (spoons).<sup>59</sup> Our results also add weight to the finding that dosing accuracy can be improved using a syringe and label compared with conventional measuring implements. We are aware of only one other study that has evaluated solutions to improve dosing accuracy over and above the measuring devices typically used at home. Frush et al. (2004) successfully used colour coding on syringes, along with matching instructions, to reduce paracetamol dosing error (measured as the absolute value of percentage deviation from the prescribed dose).<sup>60</sup> Using the same analysis approach, we also found statistically significance differences in absolute dosing errors, whereby the treatment group's deviation (the absolute percentage deviation of the actual dose to the prescribed dose) was smaller than that of the control.

Across our whole sample, measurement/behavioural errors were larger than dose determining errors - there was a much bigger gap between the intended and actual dose than between the prescribed and intended dose for both the treatment and control groups. This could be because NHC kaimahi stated the correct (prescribed) dose and wrote it down immediately before asking participants to state their intended dose, thereby minimising dose determining errors. However, Frush et al. who left caregivers free to determine the correct (prescribed) dose also found that measurement/behavioural errors were larger than dose determining errors, at least for their control group.

The very small dose determining errors for both treatment and control groups suggests that something about the design of the intervention syringe and/or label enables caregivers to more accurately draw out their intended dose of paracetamol compared with other measuring devices and labels. A key implication of these findings is that to reduce paracetamol dosing errors and overdosing, caregivers should use the intervention syringe and label. For an accessible and equitable outcome, the syringe would need to be free of charge.

Following a 2020 Medsafe consultation looking into ways to improve safe paracetamol dosing following acute liver failure in a young child, it is now mandatory for over-the-counter paracetamol

<sup>&</sup>lt;sup>57</sup> Frush K.S., Luo X., Hutchinson P., & Higgins J.N. (2004). Evaluation of a method to reduce over-the-counter medication dosing error. *Arch Pediatr Adolesc Med*, *158*(7):620-4. doi: 10.1001/archpedi.158.7.620. PMID: 15237059.

<sup>&</sup>lt;sup>58</sup> Acheampong P., & Thomas S.H. (2016). Determinants of hepatotoxicity after repeated supratherapeutic paracetamol ingestion: systematic review of reported cases. *Br J Clin Pharmacol, 82*(4):923–931. doi: 10.1111/bcp.13028

<sup>&</sup>lt;sup>59</sup> Beckett, V.L., Tyson, L.D., Carroll, D., et al. (2012). Accurately administering oral medication to children isn't child's play. *Archives of Disease in Childhood*, *97*(1):838–41. DOI: <u>10.1136/adc.2011.212563.14</u>

<sup>&</sup>lt;sup>60</sup> Frush K.S., Luo X., Hutchinson P., & Higgins J.N. (2004). Evaluation of a method to reduce over-the-counter medication dosing error. *Arch Pediatr Adolesc Med*, *158*(7):620-4. doi: 10.1001/archpedi.158.7.620. PMID: 15237059.

packages to contain a measuring device.<sup>61</sup> However, despite 90% (451/500) of respondents to a New Zealand survey indicating that an accurate measuring device should be provided free with all liquid paracetamol prescribed by doctors or nurses,<sup>62</sup> this has not yet occurred.

# We don't know if it was the intervention syringe or label that improved paracetamol dosing precision

One of the limitations of our trial design is that we cannot confidently say whether the improvement in dosing precision is due to intervention syringe, label, or the combination of the two. Because most caregivers correctly confirmed the dose size in mL they were intending to measure out *before* actually measuring the paracetamol out, we know that the lower precision in the control group was not due to caregivers misunderstanding the correct dose amount for their tamaiti (child). This suggests that the lower dosing precision in the control group is likely due to a failure to use the dosing implement accurately, for example, not knowing how much paracetamol they were measuring out (eg, if using the spoon), getting air bubbles in the standard syringe, or failing to read the mL markings accurately.

Nevertheless, we cannot rule out that the difference in dosing precision between the treatment and control groups could be due to a feature of intervention label. For example, the red warning that paracetamol can damage the kidneys and liver could have potentially made the importance of drawing out an accurate dose more salient to the treatment group.

### It is unclear if the intervention syringe is superior to standard syringes

Similarly, our trial was not designed to test whether the intervention or standard syringe performs better. Given that the standard syringe was the device selected by the majority of control participants when given a choice and it was also the device that the majority of participants (just under 60%) said they used at home with their youngest tamaiti, it might be expected that previous experience with the standard syringe may improve dosing accuracy over the intervention syringe. However, when we explored the differences in dosing errors between control participants who used the standard syringe and treatment participants who used the intervention syringe, the results were inconclusive.

We did find that caregivers with previous experience using a syringe were more precise in their dosing than those with no previous syringe experience, regardless of whether they used the standard or intervention syringe in the trial. Further research would be needed to directly compare the dosing accuracy associated with the different syringes.

# Caregivers of tamariki Māori were more likely to underdose than overdose when administering paracetamol

Overdosing has more serious consequences than underdosing, but in the general population the proportion of caregivers who unintentionally give clinically significant overdoses to children is fairly small (paracetamol is involved in an average of 7.4 poisonings per 100,000 population per year

<sup>&</sup>lt;sup>61</sup> See: https://www.medsafe.govt.nz/consultations/paracetamol-warning-statements-outcome.asp

<sup>&</sup>lt;sup>62</sup> Medsafe. (March 2020). Proposed changes to paracetamol warning and advisory statements. Consultation outcome. See: https://www.medsafe.govt.nz/consultations/paracetamol-warning-and-advisory-statements-consultationoutcome.pdf
where data are available across the world).<sup>63</sup> In our study, we learnt that caregivers were far more likely to underdose than overdose.

Anecdotally during the trial, many participants shared that they worried about giving their child too much paracetamol, and others reported that particular children in their care were strongly affected by a full dose, for example falling asleep rather than simply feeling relief from pain/discomfort, and this worried them. Intentional underdosing could also be due to participants being extra cautious with their dosing amounts under observation. Underdosing could mean that tamariki are not receiving the dose of paracetamol needed to combat pain. This would be undesirable if it contributed to negative experiences for tamariki and their whānau. Further research is needed to determine how a correct weight-based dose might affect babies and children differently, how common it is for caregivers to underdose children, and the impacts of this.

## The intervention label did not make a difference to dosing frequency or course but provides clear information for caregivers when needed

The intervention label did not make a difference to the intended dose frequency or course, even though participants in the user testing preferred the whānau Māori/BI informed label. This may reflect our finding from Round 1 user testing that many participants tend to not read the label. However, as one participant in Round 1 user testing noted, some people always read labels and instructions, and some never do. This is something that health practitioners should take into account when prescribing paracetamol.

It is possible too that the 'lab' conditions of the trial interfered with participants noticing or reading the intervention label. They potentially felt under some social pressure to give the 'correct' answers to NHC kaimahi conducting the trial and could have been listening intently to the instructions, which did not include any specific prompt to look at the label.

We know from the behavioural science literature that a well-designed label can make a positive difference.<sup>64, 65</sup> We therefore believe the intervention label has potential to improve the accuracy of paracetamol dosing, along with the frequency and course of dosing. It uses many behavioural insights principles, including simplified language, providing a weight chart, and drawing attention to the consequences of giving too much paracetamol. The label also incorporates much of the feedback we received from caregivers of tamariki Māori. Further research is necessary, but we believe changes should be made to existing prescription labels to incorporate these improvements.

#### Some syringe and label features didn't work well

During the user testing, we discovered different syringe and label features that *didn't* work for caregivers of tamariki Māori. In Round 1, we tested how caregivers responded to a dose-limiting device on the syringe and a matching label and found that caregivers did not use the dose limiter. It also represented an additional step that could create stress for caregivers trying to give paracetamol to their child. In Round 2, we tested grey-scale bands on the syringe plunger and label and learnt that the grey-scale bands did not attract attention and caregivers ignored them altogether. In Round

<sup>&</sup>lt;sup>63</sup> Chidiac, A.S., Buckley, N.A., Noghrehchi, F., & Cairns, R. (2023). Paracetamol (acetaminophen) overdose and hepatotoxicity: Mechanism, treatment, prevention measures, and estimates of burden of disease. *Expert Opinion on Drug Metabolism and Toxicology*, 19(5): 297-317. <u>https://doi.org/10.1080/17425255.2023.2223959</u>

<sup>&</sup>lt;sup>64</sup> Onwezen, M., Dwyer, L., Fox, T., & Snoek, H. Conditions for the effectiveness of labelling: A systematic literature review. Wageningen University and Research.

<sup>&</sup>lt;sup>65</sup> Shangguan, S. et al. (2019). A meta-analysis of food labeling effects on consumer diet behaviours and industry practices. Am J Prev Med, 56(2): 300-314. doi: <u>10.1016/j.amepre.2018.09.024</u>

3, we tested how caregivers responded to coloured bands on the syringe plunger and label, this time finding that the colours on the plunger made it too complicated. These findings provide useful context for any future work to improve the design of paracetamol syringes and labels.

### Control participants who were offered a choice of measuring implement were less accurate at dosing paracetamol than those who used the implement they usually use at home

An inconsistency in protocol implementation we discovered about halfway through the trial, enabled us to check whether there were any differences in dosing errors between control group participants who may have had a free choice of measuring implement and control group participants who were asked to select the implement they usually use at home. Interestingly, those control participants who may have had a free choice of measuring implement were less accurate in their paracetamol dosing than participants who were asked to select the implement they would usually use at home.

The reduction in dosing accuracy when participants may have been given a choice of implement may reflect that caregivers dose more accurately when they are using a measuring implement they have previous experience with. This would be consistent with our finding that caregivers with previous experience using a syringe were more precise in their dosing than those with no previous syringe experience. In this case, the device caregivers chose more often when they might have been given a choice (and were presumably less experienced with), was the measuring cup. These findings highlight the importance of health practitioners not only explaining the importance of accurate paracetamol dosing, but also showing caregivers how to use their preferred device, preferably a syringe.

## There is a need for more paracetamol education/information for caregivers and whānau

During the study, we learnt lots about paracetamol and we found that caregivers wanted to know more about paracetamol too. The participants we interviewed held many ideas about paracetamol that did not align with best practice (eg, paracetamol should be stored in the fridge; more paracetamol should be given to take away the pain faster; seek further advice after 3 days of continuous use). There was also uncertainty about the different dose strengths of paracetamol available.

Caregivers wanted to understand:

- what is in paracetamol and how it works in the body;
- the pros and cons of dual dosing and when to dual dose;
- how paracetamol should be stored;
- how paracetamol differs to ibuprofen;
- how to remove air bubbles from the syringe;
- whether paracetamol is safe for tamariki and what happens to the liver if tamariki receive an overdose;
- when to use the different strengths of paracetamol;
- why some children seem more affected by paracetamol (eg, become sleepy) than others; and

• how to dispose of old, expired paracetamol.

These findings highlight the importance of health practitioners' interactions with caregivers. Previous research has shown that dosing accuracy for liquid medication is significantly improved when health practitioners demonstrate how to measure the correct dose by pulling back a syringe plunger to the correct measure.<sup>66</sup> One of the reasons health practitioners may not take the time to demonstrate how to dose accurately or to provide further information about paracetamol is related to our finding that paracetamol use is so normalised within our society. Health practitioners may assume that caregivers know how to use it and not consider the potential risks.

Consistent with other New Zealand research, we also found that whānau Māori experienced barriers to accurate paracetamol dosing related to their experiences of institutional racism in the health system, which affected their trust in some health practitioners.<sup>67, 68</sup>

Together these findings emphasise the importance of health practitioners taking the time to talk with caregivers about the correct dose and strength of paracetamol to give their tamariki. Health practitioners should be prepared to demonstrate how to use a syringe and explain the consequences of giving too much paracetamol to tamariki.

There are many other ways that information about paracetamol dosing could be disseminated. Caregivers had many good suggestions for how to improve caregivers' knowledge about paracetamol, including: postnatal classes, funded social coffee meetings, social media (e.g. TikTok), a paracetamol app, and receiving support from trusted Māori health organisations.

## Recommendations

We have three recommendations:

- 1. Offer all caregivers of children weighing 18kg or lower a free 5 mL syringe with every prescription for liquid paracetamol, along with a whānau/BI informed label.
- 2. When prescribing paracetamol, health practitioners take the time to give caregivers clear information about paracetamol, especially the risks of giving too much, and the space to ask questions about paracetamol dosing.
- 3. Develop an education campaign that disseminates up-to-date, best practice information on the use of paracetamol via a range of different channels and formats such as social media, tv advertising, postnatal classes, and trusted health organisations.

## Next steps

We believe there is huge merit in scaling up the solutions arrived at in this study. Ideally, when health practitioners prescribe paracetamol to caregivers of younger tamariki, they should provide caregivers with a syringe and whānau Māori/BI informed label on paracetamol dosing.

<sup>&</sup>lt;sup>66</sup> McMahon, S. R., Rimsza, M. E., & Bay, R. C. (1997). Parents Can Dose Liquid Medication Accurately. *Pediatrics*, 100(3), 330–333. https://doi.org/10.1542/peds.100.3.330

<sup>&</sup>lt;sup>67</sup> Came, H. (2012). Institutional Racism and the Dynamics of Privilege in Public Health (Thesis, Doctor of Philosophy (PhD)). University of Waikato, Hamilton, New Zealand. Retrieved from https://hdl.handle.net/10289/6397

<sup>&</sup>lt;sup>68</sup> Walker, R.C., Abel, S., Palmer, S.C., Walker, C., Heays, N., & Tipene-Leach, D. (2023). "We need a system that's not designed to fail Māori": Experiences of racism related to kidney transplantation in Aotearoa New Zealand. *J Racial Ethn Health Disparities*, *10*(1): 219-227. doi: <u>10.1007/s40615-021-01212-3</u>

Scaling up the intervention syringe to make it widely available would require funding to purchase the Pamol syringes from the manufacturer, Aspen Pharmacare in Australia. Currently they are only available in New Zealand as part of an over-the-counter paracetamol package and are not sold separately.

Scaling up the intervention label would require:

- 1. working with MedSafe and Pharmac to get approval for the new label;
- 2. working with pharmacists to raise their awareness about the new labels; and
- 3. working with label suppliers to get the approved label designed and prepopulated onto labels. Pharmacists buy their labels in bulk from different suppliers around the country.

There are further improvements that could be made to both the syringe (and label) that could be worth exploring. These include widening the lip of the syringe to make it more practical and using engraved mL markings on the barrel to ensure markings don't rub off and syringes are reusable. If cost is not prohibitive, it is also worth exploring putting colour bands on syringe barrels (as opposed to the plunger).

# Appendices

# Appendix 1: PowerPoint presentation for health practitioner interviews



Devices	R
Make syringes free	
Improve syringes for paracetamol	
<ul> <li>Make syringes for paracetamol that don't lose their markings or numbers on the side</li> <li>Develop a purpose-built syringe for administering to under twos, eg with a spoon at the end or a suitable end that tamariki can get their mouths around</li> </ul>	
<ul> <li>Put a device on the syringe that limits the amount of Paracetamol or draws the correct amount</li> </ul>	
<ul> <li>Ensure syringes come with a cleaner (which means they can be easily reused)</li> </ul>	6
Improve bottles containing paracetamol	
<ul> <li>Include a measuring device or markings on the bottle so that people don't have to also purchase syringes.</li> </ul>	AQ.
<ul> <li>Have a bottle where the lid is a squeeze dispenser where you can dial up a certain amount.</li> </ul>	NY D
Improve packaging for paracetamol	
<ul> <li>Package paracetamol in individual shots that are tailored to baby.</li> </ul>	
• Give out Paracetamol packs that contains paracetamol, a syringe, information pamphlet	6
Give whānau scales so they can weigh their tamariki every time.	
Give whanau a timer - to help them remember when to administer paracetamol, how much to give and the frequency, like an administering device that rings	9
<ul> <li>Develop a device that is glow in the dark, works for any age and measurement, with markings that are permanent.</li> </ul>	128







We had a lot of confusion about dual dosing for whānau. Literature says errors can be made if paracetamol is in both products, but whānau had more questions about the need for two medicines and why.

What are your thoughts about prescribing two medicines and why do you think whānau are confused about this process?



Other key themes:

#### • Group education where info on paracetamol shared:

- Training for whanau members who offer (medical) support to other whanau members
- Have a regular NHC facilitated session with Māma- kanohi ki te kanohi or even via Zoom (eg, like Kia ora Māma) where any whānau can drop in just for an hour.
- Make funding available so that Māmās can get their bus tickets to go and meet at a cafe; supported by a trusted entity such as NHC.
- Integrate information on paracetamol into antenatal classes for Māmā or classes run by Plunket.

#### • Information campaign:

- $\circ~$  Develop a social media advertising campaign with key paracetamol lessons, including posters and videos
- Develop a one pager or panui with basic facts from a trusted source (eg, National Hauora Coalition) a meme or graphic or cartoon; circulate on social media. Include tips such as putting celetape over the markings on disposable syringes to keep the numbers on for longer.
- Develop powerpoint with paracetamol info for whanau before they leave hospital with pepi, and whanau have to answer a couple of Qs about it.

#### • IT solutions:

- An app or something on iPhone that can give accurate information about what to use paracetamol for and how much paracetamol to give for your child's weight, how frequently to give it
- Have an IT account that whanau can trust (knowing that it is not just put out by Drs and pakeha) put all the info there.

#### • Māori organisations:

- · Be able to tap into an organisation for Māori for information
- Have Maori on a Healthline type service



#### What whānau would like to know more about paracetamol:

- How Paracetamol works within your body
- How decisions are made regarding giving the different strengths
- What is actually in the Paracetamol?
- Can you use Paracetamol for anything else (besides pain and fever)? Is it the ideal medicine for fever?
- Whether dual dosing (eg, Paracetamol and Ibuprofen) is a good idea or an issue; when to do it
- What 'mg' stands for
- What happens to liver if you overdose your tamariki
- How to reduce side effects; how will children react to paracetamol?
- Is there sugar in paracetamol?
- How paracetamol should be stored (not in the fridge, but in a cupboard)
- How to dispose of old, expired paracetamol
- Is paracetamol even good for the kids? Is it safe? What are the benefits?
- Can we give something herbal instead of paracetamol?

# Appendix 2: Semi-structured interview guide for caregivers

Mihi and whakawhanaungatanga - karakia (what our process will look like)	15 mins
Welcome/Introductions/Whakawhanaungatanga	
Kia Ora, my name is XXXX I am part of a research group wanting to gather information about your understanding of paracetamol and your experiences with health practitioners prescribing paracetamol, as well as your experiences giving paracetamol to your tamaiti/tamariki.	Orient the interviewee and prepare them for the discussion.
Before we start today can I ask if you would like me to open and close our zui with karakia? And then do you mind if my team and I share a little bit about ourselves and why this study is important to us before we get into asking you questions today?.	
(Wait for their response and follow their lead. If yes to karakia timatanga use Whakataka te Hau for karakia whakamutunga use Kia tau.)	Put the interviewee at ease.
Explanation about the aims of the research and why the project is being done	
We have been funded by the Health Research Council, who want to reduce the risk of liver damage or failure that may occur if tamariki receive too much paracetamol for their weight. What our team are wanting to gather from these interviews is your understanding and experiences relating to paracetamol for your tamaiti/tamariki.	
We want to emphasise early that we want to understand your worldview on this kaupapa. <b>No answers are right or wrong</b> – and we are not here to judge you or your experiences. This is absolutely a safe space to share as much or as little as you feel fit. I might also add that this interview is not about me, I will merely ask questions and sit back and let you share. Please take your time to answer.	Build whakawhanaungatanga with the interviewee.
Explain how the information will be used	

<ul> <li>The information gathered will be completely confidential, and will be used to develop solutions that support other whānau to administer paracetamol safely.</li> </ul>	
<ul> <li>We will then test whether the solutions are effective.</li> <li>You will not be identified in any report we write for HRC.</li> </ul>	Check whānau has completed demographics on google form - ethnicity, number and ages of
As a participant you have every right to end the interview or change anything at any stage of the interview process. You have complete autonomy over the data.	children
CHECK AGAIN WHETHER THE PARTICIPANT HAS ANY QUESTIONS AND THAT HAVE FILLED IN THE DEMOGRAPHIC INFO AND SIGNED THE CONSENT FORM	
<b>Structure of interview:</b> Just a heads up there is 4 sections to our interview today	
TURN RECORDER ON AND LET PARTICIPANT KNOW THAT IT IS SWITCHED ON	
Obtain background from participant	
I'd like to start by asking you some questions about yourself:	
<ol> <li>Could you share with me who you are and also who is in your whānau? Probe: Ko wai koe? No hea koe? - Who are you and where you come from?</li> </ol>	
<ol> <li>Can you please tell me about your tamaiti and what you love the most about them? Probe: What types of things do they enjoy doing?</li> </ol>	
Whakaaro	
What is your world view or beliefs on medicines?	[Checklist / Prompts] -
What is your whakaaro on paracetamol?	
Who are the decision makers within your whānau when it comes to taking medicines or paracetamol?	Who in whānau gives paracetamol to tamariki?
	<ul> <li>Circumstances whānau most</li> <li>likely to use paracetamol - (1)</li> <li>tamariki in pain (headache,</li> </ul>

	toothache, teething); (2) cold or flu; (3) fever
Experiences	15mins
Can you please take some time to reflect on the most recent experience you have had giving your child paracetamol and tell me all about it? (highs and lows) Please share as much detail about the experience as you can. Do you remember a time you gave paracetamol when there was lots happening or you were tired or stressed? Can you please share that experience with me?	<ul> <li>[Checklist / Prompts] -</li> <li>Type/form of paracetamol administered - liquid, tablet, capsule</li> <li>Circumstances whānau most likely to use paracetamol - (1) tamariki in pain (headache, toothache, teething); (2) cold or flu; (3) fever</li> <li>How do whānau determine the correct dose - number of</li> </ul>
	mls, weight of child, frequency, duration How paracetamol is stored and where?
Common reasons for errors in paracetamol dosing	30mins
The literature we have looked at talks about the errors that can occur when giving paracetamol. The top five most frequently mentioned reasons for giving the wrong dose of paracetamol were:	[Checklist / Prompts] –
• Devices, ie unclear markings on the syringe	Devices - What device do
• Doctors, ie, lack of communication or unclear instructions about the amount of paracetamol to give	whānau use to measure the paracetamol dose - measuring spoon, measuring cup, syringe?
Labels, ie, difficult to read or understand	
<ul> <li>Adult doses, ie, accidentally giving tamariki an adult dose of paracetamol</li> </ul>	<b>Doctors</b> - Interactions with health professionals -

<ul> <li>Dual dosing, ie, giving paracetamol at the same time as ibuprofen or other pain killers that might also have paracetamol in them</li> </ul>	understanding of instructions and comfort in asking questions
Please rate 1 the most important to 5 the least important for you (allow 3 mins for participant to write down in the chatbox their rankings)	Labels - how closely whānau read labels; how easy labels are to understand
Can you now please explain to me each of your ranked errors and why they are as they are?	Questions whānau have about
What are the reasons that you think other parents or whānau make dosing errors when giving paracetamol to their tamariki?	paracetamol use
Now that you have shared your whakaaro about those dosing errors, do you have any questions about paracetamol use?	
Solutions / Magic Wand	15 mins
If you had a magic wand and could change anything to make it easier to administer accurate doses of paracetamol, what would you change? [ Prompts] -	[Checklist / Prompts] - <b>Devices</b> - What would make measuring devices (eg, syringe) easier to use?
<b>Devices</b> - What would make measuring devices (eg, syringe) easier to use?	Doctors - What information do whānau want from health
<b>Doctors</b> - What information do whānau want from health professionals about paracetamol use with tamariki, ie what information would be most useful?	professionals about paracetamol use with tamariki, ie what information would be most useful?
□Labels - What (written) information do whānau want on paracetamol packets or containers about paracetamol use with tamariki, ie what information would be most useful?	□ Labels - What (written) information do whānau want on paracetamol packets or containers about paracetamol use with tamariki, ie what information would be most useful?
Whakamutunga	10 min
Whakamutunga Do you have any questions on what we have covered in the interview?	
Do you have any questions on what we have covered in the	10 min Optional karakia whakamutunga
Do you have any questions on what we have covered in the interview?	10 min Optional karakia whakamutunga

<b>Ask for their address</b> so that you can send the koha to them. Make sure they receive koha & your contact information, and that you also have an email address to follow up with key findings if they are interested.	University of Otago, New Zealand
This brings us to the end of today's session. I want to thank you again for all your knowledge shared, I will now close the session with karakia. Ngā mihi and thank you for your participation.	

Ensure that:

- The interviewee feels in control of the interview
- The interviewee knows that they can skip questions or stop the interview. Be proactively caring if the interviewee appears frustrated or unhappy.

Other information that might be handy:

#### Liquid paracetamol:

There are the two different liquid paracetamol suspension strengths with their colours-

- Junior Parapaed: 120mg/5mL pink suspension with cherry odour & taste
- Six Plus Parapaed: 250mg/5mL (6 years plus) yellow suspension with orange odour & taste

**Note re correct dose:** Dose is a combination of the strength of the suspension and the number of mL administered. Correct doses for the different suspension strengths are as follows:

Junior Parapaed:

- **Children under 3 months:** a 2.5mL spoonful is suitable for babies who develop fever following vaccination at 2 months. In all other cases use only under medical supervision.
- Children 3 months 1 year: Half to one 5mL spoonful
- Children 1 6 years: one to two 5mL spoonfuls
- Children 6-12 years: two to four 5mL spoonfuls

Six Plus Parapaed:

- Children under 1 year: Not recommended
- Children 1-6 years: Half to one 5mL spoonful
- Children 6-12 years: One to two 5mL spoonfuls
- Adults: Two to four 5 mL spoonfuls

Note re correct frequency (number of times in a day):

**For both Junior Parapead and Six Plus Parapaed:** Repeat dose every 4 – 6 hours as required up to a maximum of 4 doses in 24 hours.

Note re correct duration (how many days in a row):

Do not take for longer than 'a few' days at a time unless advised by a healthcare professional.

Tablet or capsule paracetamol:

**Note:** Tablets or capsules should only be given to tamariki who have learned how to swallow them, typically around 9 years of age.

Note: Different strengths -

- Paracetamol tablets are available in two strengths:
  - 500mg (immediate release)
  - 665mg (modified release)

Note re correct dose:

500mg tablet:

- Children who weigh more than 33 kg: 1 tablet
- Children who weigh more than 66 kg: 2 tablets

665mg tablet:

- Not recommended for adults (or children) weighing less than 60kg
- Adults who weight more than 60kg: 2 tablets

Note for interviewer re correct frequency (number of times in one day):

**500mg:** For children weighing more than 66kg (and adults) - do not give more than 2 tablets per dose. Wait at least 4 hours between doses. Do not give more than 4 doses in 24 hours. So the maximum is eight 500mg tablets per day (or 4 grams in 24 hours).

**665mg:** For adults who weigh more than 60kg: 2 tablets once every 6-8 hours. The maximum is 3 doses in 24 hours, or six tablets per day (4 grams per 24 hours).

Note re duration (how many days in a row):

Do not take for longer than 'a few' days at a time unless advised by a healthcare professional.

# Appendix 3: Semi-structured interview guide for health practitioners

Mihi and whakawhanaungatanga - karakia (what our process will look like)	15 mins		
Welcome/Introductions/Whakawhanaungatanga	Orient the interviewee and		
Kia ora, my name is XXXX, many thanks for your time today. I am part of a research group, made up of the National Hauora Coalition, University of Otago, and Behavioural Insights Team. We are funded by the Health Research Council (HRC) to look into and test what would better help whānau to safely administer paracetamol to their tamariki.	made up of the National Hauora Coalition, Behavioural Insights Team. We are funded ouncil (HRC) to look into and test what		
Before we start today, can I ask if you would like us to open and close our zui with a karakia? And then do you mind if my team and I share a little bit about ourselves and why this study is important to us before we get into asking you questions today?	Put the interviewee at		
(Wait for their response and follow their lead. If yes to karakia timatanga use Whakataka te Hau or Mai it te Tohi Rangi; for karakia whakamutunga use Kia tau.)	ease.		
Share a little bit about yourself and why you are part of the research, then let them know you will explain the purpose of the project and allow them to share who they are when they are okay to start recording			
Ko wai au			
The purpose of the project and interview			
<ul> <li>HRC wants to reduce the risk of liver damage or failure that may occur if tamariki receive too much paracetamol for their weight.</li> </ul>	Build whakawhanaungatanga with the interviewee.		
• We are here to understand your experiences prescribing or discussing paracetamol with whānau, the barriers to the safe administration of paracetamol, and any ideas you might have on how to enable the safe use of paracetamol for tamariki Māori.			
• We want to emphasise early that we want to understand your experiences and ideas on this kaupapa. No answers are right or wrong – and we are not here to judge you or your experiences. This is absolutely a safe space to share as much	Check participant has completed demographics on google form - ethnicity,		

or as little as you feel fit. I might also add that this interview is not about me, I will merely ask questions and sit back and let you share. Please take your time to answer.	age, gender, type of health professional
How the information will be used	
<ul> <li>The information gathered will be completely confidential, and will be used to develop solutions that support whānau to administer paracetamol safely.</li> </ul>	
• We will then test whether the solutions are effective. You will not be identified in any report we write for HRC.	
• As a participant you have every right to end the interview or change anything at any stage of the interview process. You have complete autonomy over the data.	
CHECK WHETHER THE PARTICIPANT HAS ANY QUESTIONS AND IF THEY HAVE FILLED IN THE DEMOGRAPHIC INFO AND SIGNED THE CONSENT FORM	
<b>Structure of interview:</b> Just a heads up there are three sections to our interview today.	
TURN RECORDER ON AND LET PARTICIPANT KNOW THAT IT IS SWITCHED ON	
Obtain background from participant	
Obtain background from participant 1. I'd like to start by asking you to share a little about yourself.	
<ol> <li>I'd like to start by asking you to share a little about yourself.</li> <li>Ko wai koe? No hea koe? - Who are you and where do you come from?How long have you been working as a health practitioner?</li> </ol>	30 mins
1. I'd like to start by asking you to share a little about yourself. Ko wai koe? No hea koe? - Who are you and where do you come from?How long have you been working as a health practitioner? How many staff are in your practice?	30 mins
<ol> <li>I'd like to start by asking you to share a little about yourself.</li> <li>Ko wai koe? No hea koe? - Who are you and where do you come from?How long have you been working as a health practitioner? How many staff are in your practice?</li> <li>Common reasons for errors in paracetamol dosing</li> <li>The literature we have looked at talks about the errors that can occur when whānau give paracetamol to tamariki. The top five most frequently mentioned <i>reasons</i> for giving the wrong dose of</li> </ol>	30 mins
<ol> <li>I'd like to start by asking you to share a little about yourself.</li> <li>Ko wai koe? No hea koe? - Who are you and where do you come from?How long have you been working as a health practitioner? How many staff are in your practice?</li> <li>Common reasons for errors in paracetamol dosing</li> <li>The literature we have looked at talks about the errors that can occur when whānau give paracetamol to tamariki. The top five most frequently mentioned <i>reasons</i> for giving the wrong dose of paracetamol were:</li> </ol>	30 mins
<ol> <li>I'd like to start by asking you to share a little about yourself.</li> <li>Ko wai koe? No hea koe? - Who are you and where do you come from?How long have you been working as a health practitioner? How many staff are in your practice?</li> <li>Common reasons for errors in paracetamol dosing</li> <li>The literature we have looked at talks about the errors that can occur when whānau give paracetamol to tamariki. The top five most frequently mentioned <i>reasons</i> for giving the wrong dose of paracetamol were:         <ul> <li>Devices, ie unclear markings on the syringe</li> <li>Doctors, ie, lack of communication or unclear instructions</li> </ul> </li> </ol>	30 mins
<ol> <li>I'd like to start by asking you to share a little about yourself.</li> <li>Ko wai koe? No hea koe? - Who are you and where do you come from?How long have you been working as a health practitioner? How many staff are in your practice?</li> <li>Common reasons for errors in paracetamol dosing</li> <li>The literature we have looked at talks about the errors that can occur when whānau give paracetamol to tamariki. The top five most frequently mentioned <i>reasons</i> for giving the wrong dose of paracetamol were:         <ul> <li>Devices, ie unclear markings on the syringe</li> <li>Doctors, ie, lack of communication or unclear instructions about the amount of paracetamol to give</li> </ul> </li> </ol>	30 mins

• <b>Dual dosing</b> , ie, giving paracetamol at the same time as ibuprofen or other pain killers that might also have paracetamol in them	
[Share screen - slide 1]	
Solutions / Magic wand	15 mins
2. After seeing these causes of dosing errors, is there anything at the top of your mind that you think would be helpful in reducing paracetamol dosing errors? If you had a magic wand/rākau, what would you change?	
3. We also asked whānau what they thought would be solutions to help reduce paracetamol dosing errors and they had lots of interesting ideas for what could help. I'd like to run through with you some of those ideas to see what you honestly think about them, how feasible or realistic they would be, how worthwhile. As we go through the key ideas from whānau, it would be great if you could take notes about anything you think is really important in your eyes.	
[Show slide 2 onwards and explain top whānau solutions for devices, doctors, and labels].	
4. [When we get to the slide on Drs] - There are so many things that whānau want to know about paracetamol. Have you got your own way of explaining these things to whānau? Have you seen this done well? What do you do/say when prescribing/recommending paracetamol?	
Whakamutunga	5 mins
Do you have any questions on what we have covered in the interview?	Optional karakia whakamutunga (closing)
Thank the interviewee for their time.	use Kia tau.
Remind the interviewee what the <b>next steps</b> are.	See Karakia - prayers, Māori ki Te Whare
<b>Ask for their address</b> so that you can send the koha to them. Make sure they receive koha & your contact information, and that you have an email address to follow up with key findings if they are interested.	Wānanga o Ōtākou, University of Otago, New Zealand
That brings us to the end of today's session. I want to thank you again for all your knowledge shared. I'll now close the session with a karakia.	

- The interviewee feels in control of the interview
- The interviewee knows that they can skip questions or stop the interview. Be proactively caring if the interviewee appears frustrated or unhappy.

# Appendix 4: Photos of paracetamol labels currently in use













Appendix 5: Workshop slides for co-design workshops with whānau and health practitioners





## Outline of focus group

5 mins
10 mins
25 mins
10 mins
25 mins
10 mins
15 mins
5 mins





## A bit about you

Q1. Where is the first place you go to get trusted health information?

Q2. Where is the first place you go to get information on paracetamol?







## 1. Free syringes

#### Description:

Health professionals to give out a free syringe whenever liquid paracetamol is prescribed and/or syringes to be made freely available.

#### Rationale:

Syringes are a more accurate way of administering liquid paracetamol than spoons. But the cost of buying a syringe is a barrier for many whānau.

#### Behavioural Insight (BI) principles:

Easy - Making syringes free the 'default' makes it easier for whanau to access syringes.

**Timely** - Giving out a free syringe at the same time as paracetamol is prescribed acts as a timely reminder or prompt to use the more accurate measuring implement.



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## 2. Syringes with permanent markings

#### Description:

Reusable syringes to be designed with clear, permanent markings on them that don't wear off with repeated use.

#### Rationale:

Most syringes are designed to be single-use syringes. Their markings wear off with repeated use. This makes it difficult for whānau to judge the amount of paracetamol in the syringe accurately.

#### **BI principles:**

**Easy** - Having markings you can clearly see on the syringe makes it easier to accurately measure the correct paracetamol dose.

Timely - Having permanent markings on the syringe ensures paracetamol can be accurately measured at the time needed.



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## 3. Paracetamol wheel

#### Description:

Paracetamol wheels show the correct dose of paracetamol in mL for a child's weight (and paracetamol dose strength). They could be designed to go on a fridge magnet. Caregivers move the paracetamol wheel around to match their child's weight and are shown the correct dose (for a given paracetamol dose strength [120mg/5mL vs 250mg/5mL]).

#### Rationale:

Whānau often have more than one tamariki and as children's weight increases, the correct paracetamol dose for them changes. Even if whānau can remember that the correct dose is <u>15mg/kg</u>, it can be difficult to convert this to mL. A paracetamol wheel makes this calculation much faster and easier, especially if it is in a convenient location, such as on the fridge.

#### BI principles:

Easy - As long as whānau know the weight of their tamariki, having a paracetamol wheel handy at home is a quick and easy way for whānau to calculate the correct paracetamol dose for their child in mL, especially if the wheel is put somewhere handy and visible such as on the fridge.

Attractive - A paracetamol wheel can be designed to be bright and attractive, drawing the attention of whānau, especially if put somewhere visible such as on the fridge.



## 4. Redesigned labels

#### Description:

Labels to be designed for pharmacists to put on paracetamol bottles that show the paracetamol weight chart. Similar to the paracetamol wheel, the weight chart shows the correct dose of paracetamol in mL for a child's weight and paracetamol dose strength [120mg/5mL vs 250mg/5mL].

#### Rationale:

Labels on paracetamol bottles are not standardised in NZ. They are determined by what health professionals write in their prescription. There is not enough room available on current labels to add a weight chart. However, the weight chart could fit on a separate label, and pharmacists are in a good position to put the label on the bottle, especially since they often pour paracetamol from a large bottle into a smaller bottle to give to whanau. The weight chart on the bottle label acts as a quick reference guide for whanau to confirm the correct dose. This is especially convenient if they are using paracetamol from the same bottle to give to different tamariki.

#### BI principles:

Easy - As long as parents know their child's weight, having a paracetamol weight chart on the bottle label is a quick and easy way for whanau to confirm the correct paracetamol dose for different child in mL

Timely - Having a weight chart available on every paracetamol bottle ensures that whānau always have the information to hand when their child needs paracetamol.

#### HOW MUCH PARACETAMOL CAN TAMARIKI HAVE?

STOP AND MEASURE!

The dose of paracetamol is based off your child's WEIGHT ol can da nage your

TOUR CHILD'S MEIGHT	120MG PER SHL STRENGTH	250MG PER SHL STRENGTH	TIP: To give your tamariki an accurate dose of
SKG OR LESS	ASK TOUR DOCTOR	ASK YOUR DOCTOR	paracetamol, ask your pharmacist for a measuring syringe
6.5KG	4ML	296.	REMEMBER
BKG	SHL	2.4ML	Your child can have paracetamol every FOUR hou
10KG	6.3ML	ж	with a MAXIMUM of FOUR doses in 24 hours
13KG	6.96	496.	TABLETS: If your child can swallow
15K.G	9.4ML	4.5ML	<ul> <li>Type: child can swarow</li> <li>tablets they can have:         <ul> <li>1 tablet if 33kg or heavie</li> <li>2 tablets if 66kg or heavie</li> <li>Use this QR code to access the paracetamol dosing calculator!</li> </ul> </li> </ul>
18K.G	11.3ML	5.4ML	
20K.G	12.5ML	6141.	
25K.G	15.6ML	7.5ML	
30K.G	18.8ML	5ML	
35KG	21.9ML	10.5ML	
40KG	25ML	12ML	Call health line for additional
SOKG	31.3ML	15ML	advice 0800 611 116

## 5. One-page pānui or fridge magnet

#### Description:

Top tips for using paracetamol safely to be included in a colourful one page pânui to be given out to whânau when they are prescribed paracetamol. This could include information such as the importance of shaking the bottle and how to store and dispose of paracetamol. This information could be attached to a fridge magnet. Different magnets, containing different paracetamol tips or messages, could be collected by tamariki or their whānau.

#### Rationale:

Whānau told us there are many things they would like to know about paracetamol, including important safety information, but there is not enough room to include all of this information on the label. Instead, a one page pānui could be given out with paracetamol prescriptions. Attaching the information to a fridge magnet would ensure it was easy to find when needed.

#### BI principles:

Easy - Including the top paracetamol safety tips in a one page panui or on a fridge magnet makes it easier for whanau to access all the important information about paracetamol in one convenient location, especially if the information is attached to a fridge magnet so that it doesn't get lost.

Attractive - A one page pānui or fridge magnet/s could be designed to be bright, attractive, and culturally appropriate, drawing the attention of whānau and tamariki.

Timely - Including essential information on a fridge magnet helps to ensure that important paracetamol information is available at the time needed.



- SHAKE WELL for 10 SECONDS before giving paracetamol to Tamariki
- Paracetamol dose is specific to the WEIGHT of your tamariki • MAXIMUM of 4 doses of paracetamol in 24
- hours
   STORE paracetamol in ROOM TEMPERATURE
- WASH the syringe each time before giving paracetamol to your tamariki
- DO NOT give other paracetamol containing
- ProductsCONTACT your friendly pharmacist for further
- CHECK OUT this website for more information https://www.healthnavigator.org.nz/medicines /p/paracetamol



## 6. YouTube video clip

#### Description:

Top tips for using paracetamol safely to be included in a YouTube video-clip, similar to the one already available on <u>Health Navigator</u>. Whanau could be texted a link to the video-clip by the health professional prescribing paracetamol. The existing Health Navigator video-clip includes information such as the importance of shaking the bottle and how to store and dispose of paracetamol.

#### Rationale:



Whānau told us there are many things they would like to know about paracetamol, including important safety information, but there is not enough room to include all of this information on the label. Instead, a video clip could be developed and/or shared. Although the Health Navigator website already has a video-clip on paracetamol use, it is not widely known or accessed by whānau. A video clip could be especially appealing to whānau who struggle with literacy or who don't like to read.



Easy - Including the top paracetamol safety tips in a video clip makes it easier for whānau to access all the important information about paracetamol in one place. Having health professionals send whānau a link to the video-clip will help to increase access. The video-clip is also an easier option for people with literacy challenges.

Social - The Health Navigator video clip is narrated by a nurse, who is likely to be perceived as trustworthy messenger for whānau. Health Navigator Textor Safe use of paracetamol in children

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## 7. Develop an App

#### Description:

An free App to be developed, containing a number of useful functions to assist whānau with safe paracetamol dosing. Functions or sections could include: (1) Dose calculator (for child's weight and paracetamol dose strength); (2) Dose timer (to ensure paracetamol is not given any more frequently than every 4 hours; (3) List of other medications containing paracetamol (to help prevent dual dosing); (4) Link to Health Navigator website (and YouTube video clip on paracetamol use); (5) Top tips related to paracetamol use, such as how to store and dispose of paracetamol; (6) Frequently asked questions; and (7) Healthline number for more information

#### Rationale:

An App could be a convenient, modern way for whānau to calculate the correct paracetamol dose for different children, potentially with a timer to ensure that paracetamol is not given too frequently. An App could also contain other important safety information, including other medications with paracetamol, what to do if you suspect paracetamol poisoning, and answers to frequently asked questions. It could also help link whānau with useful information already available on Health Navigator or to health professionals via Healthline.

#### BI principles:

Easy - An App would enable whānau to access all the important information about paracetamol in one place, including the ability to easily calculate the correct paracetamol dose for the weight of their child.

Timely - Having a App available on the <u>Smart phone</u> ensures important paracetamol information, including correct dosage for weight, can be quickly calculated at the time needed.



## 8. Group education

### Description:

Some form of group education for Māmā, to be delivered by a trusted health provider, such as National Hauora Coalition or a Well Child Tamariki Ora provider. During an existing session, the health provider would share important safety information about paracetamol, including the importance of basing dose on weight and the consequences of giving too much paracetamol.

#### Rationale:

There are several key opportunities where Māmā gather in groups and key information on paracetamol could be shared. These include antenatal groups, Well Child Tamariki Ora groups, and less formal Mum's groups. Such groups provide an opportunity for Māmā to develop health literacy and to support one another.

#### BI principles:

Social - Group education brings people together and represents an opportunity to learn from not only health professionals but our peers.

Social - We are more likely to be influenced by information that comes from a trusted source. Health professionals and people like us are often more trusted as a credible sources of information



### 9. Give out scales to whānau

#### Description:

Health professionals to give out scales to whanau who do not have scales.

#### Rationale:

Children's weight can change quickly, and many whānau do not have scales available at home. This makes it difficult to determine the correct weight-based paracetamol dose, especially if it has been a while since the tamariki last had paracetamol.

#### BI principles:

Timely - Scales can be used to measure the weight of tamariki accurately at the time paracetamol is being administered.

Attractive - Scales could be useful for managing or monitoring other weight-related health concerns such as obesity, high blood pressure, heart disease, or diabetes.





# Exercise 1: Rank the likely effectiveness of each solution

25 mins

- Go to: <u>https://bit.ly/3vhpnDg</u>
- Rank the impact or likely effect of each solution on a scale from 1-10
  - Would this solution work for your whānau?
  - How effective is the solution likely to be in reducing dosing errors for whānau?
  - Would the solution have a big impact for given whanau or individuals?
  - Would the solution solve a widespread problem?

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## Exercise 4: Brainstorm further solutions

- Can you think of any other solutions that could be worth trying to reduce paracetamol dosing errors?
  - Write them down here [connection to google doc] or on sticky notes
  - Give your new solution/s a rank for likely effectiveness
- In the large group, agree the most promising solutions to take forward

15

mins

# Appendix 6: Final design specifications for 3D printed syringe

### Syringe specs for sample syringes - for user testing prior to trial

Type of syringe - Oral syringe with luer slip end/nozzle; reusable;

Barrel colour: clear/translucent

Barrel length: 100mm

Barrel Inner diameter: 14mm

Barrel total volume: 15mL (actually a fraction more - 15.39mL)

**Markings on barrel:** Black markings every half mL, with larger lines for every full mL. Coloured markings at each of the four dose limits to match the same colour as the corresponding dose limit given in the 'pie' at the end of the plunger.

Length of luer slip end/nozzle - 14mm

Plunger total length - 115mm (note this is 15mm longer than the barrel)

**Plunger design** - similar to most syringes, the plunger has four equi-distant 'spines' that run the length of the plunger. The end of the plunger (closest to the syringe tip) needs some sort of rubber stopper that acts to seal the plunger against the barrel. In the Ezy Dose example, a rubber ring nestles between two thin circular plastic ridges at the very end of the plunger.

**Plunger head** - The plunger head (on the opposite end to the rubber seal) should be circular and have four pie-like wedges in different colours on the end of it for caregivers to select between. The four different dose limits should be written in each pie. We have selected four colours that are colour blind friendly, along with the writing that should be in each coloured 'pie':

- #EE442F (red); 3mL
- #BDB8AB (grey); 6mL
- #0F2080 (dark blue); 9mL
- #A95AA1 (purple); 12mL

**Dose limits on plunger:** 'Shelves' need to be built into the plunger - at different lengths along the plunger – to ensure four dose limits: 3mL, 6mL, 9mL, and 12mL. Note that the shelves are small pie shaped pieces of plastic that wedge between two spines on the plunger. Each of the four shelves is wedged between a different set of two spines, at different lengths along the plunger. According to this <u>calculator</u> (using the different mL volumes and 14mm diameter), that would mean placing the shelves along the plunger respectively at:

- 3mL dose limit 80.51mm (from the end of the plunger closest to the tip of the syringe; specifically from the black line made by the rubber o-ring
- 6mL dose limit 61.02mm
- 9 mL dose limit 41.53mm

• 12 mL dose limit - 22.05mm

**Note :** The shelf that locks the syringe at the largest dose limit (12mL) is actually the one closest to the tip of the syringe. It is important that all the above lengths are measured relative to the end of the plunger that is closest to the tip of the barrel - ie, from the line made by the rubber o-ring.

Mechanism that interfaces with the shelves to prevent the plunger being pulled out beyond each dose limit- This is shown in the photo 3 as the orange oval-shaped 'cap' or 'bracket' that goes around the plunger and screws onto the barrel. When it is unscrewed from the barrel, it floats between the end of the barrel and the head of the plunger, but cannot come off the plunger, even when the plunger is pulled fully out of the barrel. In the centre of the orange cap is a cut out circle that the plunger goes through. The circle has a triangular piece sticking out into the centre of the circle. This triangular piece bumps up against the different shelves on the plunger (depending on where the caregiver dials the head of the plunger to), thereby preventing the plunger being pulled out beyond a certain dose limit. There is also a small triangle cut into the orange oval on the same side as the triangular piece that sticks out into the centre of the circle. This 2nd triangle acts as a marker or pointer that caregivers use to dial the correct dose limit for a child within a given weight band.

**Number of syringes** - initially we just need a sample of about 4 syringes for user testing, then we may iterate further, depending on feedback, then we will need a further sample of 6 syringes for the final user testing. We may then further modify the syringe slightly (based on feedback), and will print 1000 for the trial itself.

#### Other details (if possible/not too expensive):

**Permanent etchings** - Grooves cut into the syringe so that a blind person can feel the markings - probably makes sense to put the etchings at the dose limits, ie at 3mL, 6mL, 9mL and 12mL. Etchings should be made the same colour as the corresponding dose limit given in the 'pie' at the end of the plunger.

Writing on the syringe - "Warning: Do not exceed the recommended dose for your child's weight." (in black).

## Appendix 7: User testing protocol

## **Research Questions**

- 1. What kind of syringe can help whanau dose paracetamol more accurately?
- 2. What kind of labels might help whanau dose paracetamol more accurately?
- 3. What current issues do whanau have with existing syringes and labels?

## **Project team**

Role	Name	Email	
National Hauora Coalition (Project Lead)			
Project Lead:	Dr Rawiri McKree Jansen	rawirimj@nhc.maori.nz	
Project Support:	Darna Appleyard	darnaa@nhc.maori.nz	
Behavioural Insights Team (	Project Partner)		
Project Lead:	Sarah Hayward	sarah.hayward@contractors.bi.team	
Research Lead:	Bowen Fung	bowen.fung@bi.team	
Project Support:	Erin Lawn	erin.lawn@bi.team	
Research QA:	Elizabeth Convery	elizabeth.convery@bi.team	
Policy QA:	Karen Tindall	karen.tindall@bi.team	
Other Partners			
University of Otago	Anna Tiatia Fa'atoese Latu	anna.latu@otago.ac.nz	

## Method

### Participants

- Each session will be one-on-one.
  - There will be 2 interviewers (1 speaker + 1 note taker) + 1 interviewee.

#### Interviewers

• The interviewers will be Darna Appleyard (National Hauora Coalition; NHC) and Sarah Hayward (The Behavioural Insights Team; BIT).

#### Interviewees

- We will recruit 10 whānau + 5 health providers.
  - Whānau will be patients of NHC GP clinics.
    - Ideally, <50% will have participated in our previous focus groups.
  - Health providers will be GPs working at NHC GP clinics, or pharmacists working at Otago University.
- Whānau may include a mix of mothers, fathers, and grandparents. Within practical constraints, we will target a higher percentage of Māori mothers, given they are more likely to administer paracetamol to their tamariki compared with Māori fathers or grandparents.
  - ~80% Māori mothers of tamariki aged <14.
  - ~20% Māori fathers or Māori grandparents of tamariki aged <14.
- Interviewees will be reimbursed \$20 each for their time (~15-25 minutes total).

#### Design

#### Approach

We are aiming to get feedback on a custom **oral syringe** for administering paracetamol, and a custom **label** containing paracetamol dosing instructions.

- For whānau, we will use a 'lab usability testing' approach.
  - Whānau will perform typical tasks with a prototype of the syringe and label.
  - Whānau will provide feedback on these prototypes.
- For health providers, we will be sense-checking:
  - Our ideas and prototypes.
  - How we intend to iterate the prototypes, based on the feedback from whānau.

#### **Stages**

- 1. Sense-check design ideas with x2 health providers prior to prototyping.
- 2. Iterate design ideas accordingly and build initial prototypes.
- 3. User-test initial prototypes with x4 whānau, comprising:
  - o x3 Māori mothers;
  - x1 Māori father OR or Māori grandparent
- 4. Sense-check initial prototypes and whānau suggestions with x2 health providers.
- 5. Iterate initial prototypes accordingly and build revised prototypes.
- 6. User-test revised prototypes with x6 whānau, comprising:
  - o x5 Māori mothers;
  - x1 Māori fathers OR Māori grandparent
- 7. Sense-check revised prototypes and whānau suggestions with x1 health provider.

#### Setting

- Sessions with whanau will be conducted in-person.
  - These sessions will be held at NHC GP clinics.

- Sessions with health providers can be conducted online or in-person.
  - In-person sessions will be held at NHC GP clinics or Otago University.

#### **Ethics**

External ethics approval will be sought from an HRC-approved Health and Disability Ethics Committee (HDEC).

#### **Informed consent**

- Whānau attending an appointment at an NHC GP clinic will be approached by the researchers (Darna or Sarah), either before or after their GP appointment. The researchers will explain the purpose of the study and ask whether the whānau is interested in participating, if they meet the following eligibility criteria:
  - o I am Māori
  - 0 I am a caregiver to at least one tamariki Māori aged under 14
- Those who are interested will be taken to a private room to read a *Participant Information and Consent Form* (PICF). The interviewer will walk them through the form and answer any questions.
- The PICF includes plain-language info that addresses the following questions:
  - What is this research about?
  - Who is conducting and paying for this research?
  - What does participation in this research involve?
  - What if I don't want to take part in this research?
  - What information will be collected, and how will it be stored and used?
  - What are the possible benefits of taking part in this research?
  - What are the possible costs or risks of taking part in this research?
  - What happens when the research ends?
  - Who do I contact if I have a question or complaint?
  - Who has approved the research project?
- Those who choose to participate will be asked to sign the Consent Form portion of the form (including their age, gender, and ethnicity), and will be given a copy of the Participant Information portion of the form to keep.
- The interviewer will additionally seek verbal consent to audio record the session.

#### **Escalation procedures**

NOTE: Health providers will not be performing any tasks with the syringe/label (they will merely be providing feedback on these tools), hence these escalation procedures are only relevant to whānau participants).

#### **Dosing errors**

Below is a list of the types of dosing errors that participants can make, and a suggested response for each. Errors can be due to setting the dial incorrectly, drawing the incorrect amount (either too little or too much), or some combination of both.

Participant Action					
Setting the Dial		Drawing the Amount			
Correct	Incorrect	Incorrect (Under)	Correct	Incorrect (Over)	Researcher Response
					Well done, you've drawn out a safe amount of paracetamol for the weight of your tamariki [xkg]. This is important because overdosing can lead to paediatric acute liver failure or even death.
		×			Well done, you've drawn out a safe amount of paracetamol for the weight of your tamariki [xkg]. Notice you've drawn out slightly less than the prescribed dose, so you could increase the dose up to this line if you wanted to. But giving less than the prescribed dose is much safer than giving more, because overdosing can lead to paediatric acute liver failure or even death.
				×	You've drawn a little bit more than the prescribed dose for a tamariki that weighs [xkg], which was [x]ml. But because you turned the dial on the syringe to the correct position based on your tamariki's weight, you've made sure that the amount isn't too far above the prescribed dose— well done.
					[Show participant how to read the label to identify correct ml] It's important to try to give the right dose, because overdosing can lead to paediatric acute liver failure or even death. It often helps to practice. How about you have another go at drawing up the correct amount of paracetamol for your youngest tamariki?
	×				You've drawn out a safe amount of paracetamol for a tamariki that weighs [xkg]. But notice that the dial on the syringe isn't in the right position based on your tamariki's weight. Turning the dial to the correct position is an important first step, as it
			prevents you from accidentally drawing out too much paracetamol. This is important, because overdosing can lead to paediatric acute liver failure or even death. [Show participant how to use the dial]		
---	---	---	--		
×	×		Notice that the dial on the syringe isn't in the right position based on your tamariki's weight. Turning the dial to the correct position is an important first step, as it prevents you from accidentally drawing out too much paracetamol for your tamariki. This is important, because overdosing can lead to paediatric acute liver failure or even death. [Show participant how to use the dial, and how to read the label to identify correct ml] It often helps to practice. How about you have another go at drawing up the correct amount of paracetamol for your youngest tamariki?		
×		×	<text></text>		

[If the participant makes an error upon retrying]:

It's okay, it can be tricky. [Explain the error they have made]. I know you want to make sure you get the right amount for your tamariki. Would it be okay if I asked our Kaimanaaki (Health Coach) to contact you so they can spend a bit longer with you to support you to draw out the right amount?

*If yes* - That's great [collect phone number and email]. Our Kaimanaaki will be in contact soon.

*If no* - You might have lots of other things going on in your life and there are many reasons that it might be difficult for you to dose the correct amount right now. I know it is an inconvenience, but administering too much paracetamol to tamariki can be dangerous, so it is important our Kaimanaaaki spends a bit longer with you to make sure you can dose correctly for your tamariki. They might be able to help you with any other issues you are facing at the moment too.

*If they continue to refuse* - We'd really like to be able to help you and make sure that we keep tamariki safe. Our Kaimanaaki are very good at listening and supporting you with the health of your tamariki. I will ask them to contact you anyway because I know your tamariki are important to you.

#### **Misconceptions about paracetamol**

If a whanau says something that reflects a misconception about paracetamol, the interviewer will:

- Politely explain that this is a common misconception, and provide immediate corrective feedback accordingly, and
- Recommend <u>Health Navigator</u> website if they'd like to read more information about paracetamol safety.

Example misconceptions might include 'paracetamol is very safe' or 'paracetamol should be stored in the fridge'.

If a whānau says something that suggests they use paracetamol in a dangerous way, the interviewer will:

- Politely explain why this is dangerous, and provide immediate corrective feedback accordingly, and
- Refer the whanau back to their GP to provide them with educational support.

Example dangerous behaviours might include allowing tamariki to dose themselves, or putting paracetamol in an infant's bottle.

#### Disclosures that imply serious risk to a child's welfare

Through the course of discussion, a whānau could reveal something unrelated to paracetamol that indicates a serious risk to their child's safety (e.g., abuse from a family member). If this happens, we will refer the whānau back to their GP to provide them with support.

## Guide

#### [Fill in the below details before the session starts]

Participant ID: #X Gender: XXX Age: XXX Ethnicity: XXX Date: X/X/22 XXpm

The order of questions should be adjusted across participants:

- ~50% should be asked syringe questions followed by labelling questions.
- ~50% should be asked labelling questions followed by syringe questions.

#### Consent

#### [Darna or Sarah to approach a prospective interviewee.]

- Kia ora, I'm XXXX and part of a research group made up of the National Hauora Coalition, WēBē/Behavioural Insights Team, and University of Otago. We are working on a project funded by the Health Research Council (HRC) that aims to look into and test what would better help whānau to safely administer paracetamol to their tamariki.
- We would really appreciate your feedback on a new syringe and label we have designed to make it easier to give tamariki an accurate dose of paracetamol.
- We wondered if you have 15-25 minutes today to give us your feedback, either before or after your GP appointment? If not, that's okay—your participation is completely voluntary. Note that if you participate, you won't actually be giving paracetamol to anyone, or consuming any paracetamol.
- In order to be eligible to participate, you must be Māori, and a caregiver to at least one tamariki aged under 14. Does this apply to you?

#### [If they agree, and are eligible, take them through to a private room.]

Before we show you the syringe and label today, can I ask if you would like us to open and close with a karakia? [Wait for their response and follow their lead.]

[Next share a little bit about yourself and why you are part of the research. Let them know you will explain the purpose of the project and how the information will be used and then will give them time to share who they are.]

#### Ko wai au?...

• As I mentioned, the Health Research Council is interested in helping whānau to administer paracetamol to tamariki in the safest way possible. This is important because when tamariki

are given too much paracetamol, it can poison them and damage their liver. While this is quite rare, it is fairly easy to accidentally give too much paracetamol.

- To make it easier to give paracetamol to tamariki safely, we've designed a new syringe and label that we'd love to spend 15-25mins getting your feedback on.
- Your feedback, as well as the feedback of other whānau and health professionals we're speaking to, will be used to help us further improve the syringe and label as needed, before we test them with a larger number of whānau.

#### [Ask if they have any questions so far]

- If you choose to participate today:
  - Any feedback you share will be anonymous, meaning we won't say anything in our final research reports and presentations that will be linkable to you personally.
  - We would only break confidentiality if we uncover a direct and serious risk to safety. If that happened, we would put you back in touch with your GP or nurse, who would then provide you with further education and support.
  - You would also be able to stop today's session or skip any questions at any time, without receiving any penalty or having to explain why you want to stop. You can also withdraw your data after the session is over, as long as you contact me before the next stage of the project, which is likely to start in [month TBC] 2022 (as our syringe and label design will have been finalised by then).

#### [Ask if they have any questions so far]

- Here is a Participant Information and Consent Form for you to look over before we start, which covers what I've just explained to you in a bit more detail. Have a read through that, and let me know once you're finished. If you have any questions, please don't hesitate to ask.
- If you read through the form and decide you'd no longer like to participate, that's completely fine! Otherwise, if you're happy to participate, I'll get you to fill in the details at the bottom of the form and sign it, then we can get started.

[Once they sign the Consent Form section and have filled out the demographic details, give them a copy of the Participant Information section to keep]

- Some final things before we start:
  - I'm not a qualified medical health professional, but have received coaching and oversight from Dr Rawiri Jansen, who is both a GP and the Clinical Director of NHC, regarding safe paracetamol dosage levels, and will do my best throughout today's session to answer any questions you might have. If I don't know the answer, I'll be able to direct you to Dr Jansen for more information.
  - I also want to emphasise that we are not here to judge you or your experiences. We want you to be yourself and feel comfortable answering the questions honestly-this is not a test, and we won't judge you for your answers or for the way you use the syringe! If you find the new syringe or label difficult to use or read or if you have any

questions about paracetamol, that is important information, and we'll provide you with whatever answers we can for the sake of our learning as well as your own.

• Are you comfortable with us audio recording the session today, so we can go back and listen to what you said?

#### \*\*\*Turn on recorder and let participant know that it is switched on\*\*\*

#### Introduction

Before we start, are you comfortable sharing a little bit about yourself:

	Prompt		
Mother or Father	Grandparent	Health Provider	Notes
Would you like to tell us about yourself Where are you from?		Tell me about what you do as a health provider.	[record response here]
Tell us about your whānau or householdHow many tamaraki do you have?	How many grandkids do you have? n/a		[record response here]
What's the name and age of your youngest tamariki?	What's the name and age of your youngest grandchild?		[record response here]
Do you ever give your younger tamariki paracetamol?	Do you ever give your younger grandkids paracetamol?	Do you ever prescribe paracetamol for young children?	[record response here]

## Dosing (whānau only)

- For the first part of the session, I'm going to ask you to pretend that you're giving paracetamol to your youngest tamariki.
- Don't worry, this isn't a test!
- We're just interested in understanding how different people approach this, so we know how we can best help to make paracetamol administration as safe as possible.

Prompt	Notes
Do you know roughly how much [x] weighs? [If they do not know, we can look up the average weight of a child of that age on the MoH chart or Pamol box]	[record the estimated weight]
[Given the estimated weight for their tamariki, calculate the prescribed mL dosage using the Paediatric Dose Calculator on the <u>Health</u> <u>Navigator website</u> (to the closest 0.5 mL). This prescribed dose should then be handwritten on the label]	[record the prescribed dose]
<ul> <li>Here is a bottle of paracetamol, and a syringe that you can use to measure the amount of paracetamol to administer.</li> <li>For this task, I want you to imagine you were giving paracetamol to [x], and put the appropriate amount of paracetamol into the syringe accordingly. Based on the estimated weight of your tamariki, you should put [x] ml into the syringe. You can take as long as you need, no rush!</li> <li>Just to confirm, how many ml are you intending to put into the syringe?</li> </ul>	[record their intended dose, which bracket they set the dial to on the syringe, and the amount drawn into the syringe]
[Give feedback on whether their dose was accurate / inaccurate based on their child's estimated weight, using the Escalation Procedure table]	

#### Feedback

• For the last part of the session, I'm interested in your feedback on the syringe and label that you have seen today.

#### Syringe

Prompt	Summary of Response	Quotes
What do you think about the syringe that we gave you to use?		
How does it compare to other syringes or devices (e.g., measuring cup; teaspoon) you have used?		
Do you have any thoughts about the size (length or width) of the syringe?		
Do you have any thoughts about the plunger (that enables you to limit the dose)?		
Do you have any thoughts about the etchings/markings (grey-scale bands) on the syringe?		
Do you have any thoughts about the warning on the syringe?		
Do you have any suggestions for how we could further improve the syringe?		
<b>Question for whānau only:</b> How easy or difficult do you think it would be to give paracetamol to your tamariki using this syringe?		
Question for health provider only: We spoke to a small number of whānau, who suggested we could improve the syringe by [x]. What do you think about these suggestions?		

#### Label

Prompt	Summary of Response	Quotes
What were your first impressions about the label on the bottle?		
How does it compare to other labels you have seen?		
What, if any, information on the label really stood out to you?		
<b>Question for whānau only:</b> Did you read the label on the bottle?		
<b>Question for whānau only:</b> Do you normally read the label on the bottle?		
Do you find the label on the bottle easy to understand?		
<b>Question for whānau only:</b> Did the guidance on the label influence your actions or how much you put into the syringe? If so, how?		
Do you have any suggestions for how we could improve the label on the bottle?		
<b>Question for whānau only:</b> How easy or difficult do you think it would be to give the correct dose of		

paracetamol to your tamariki if this label was on the bottle?	
Question for health provider only: We spoke to a small number of whānau who suggested we could improve the label by [x]. What do you think about these suggestions?	

#### Debrief

We're now at the end of the session!

We really appreciate you providing us with this feedback about the syringe and label. We will be using the feedback you and other whānau have provided to further improve the syringe and label. We will then test how effective the improved syringe and label are in reducing dosing errors compared with existing syringes and labels.

Do you have any final thoughts you'd like to share or questions for me?

#### Exit

Thank you for your time today! As a token of our thanks, we would like to give you this \$20 shopping voucher for your time and sharing your whakaaro. Once the results of the trial are in, we can also email you a copy of the results if you're interested.

# Appendix 8: Train-the-trainer workshop slides to prepare for trial



tem		Slide number
1.	Whakawhanaungatanga	3
2.	Purpose and orientation to the trial	4
3.	Randomisation, recruitment and informed consent	8
4.	Collecting self report data on the Google form	13
5.	Simulating the dosing of paracetamol – for treatment and control groups	15
6.	Measuring the amount of paracetamol extracted from bottle	17
7.	Providing feedback to whānau and escalation procedure	20



# 2. Purpose & orientation to the trial



#### Purpose

- Overall aim: To support whānau Māori to safely give paracetamol to their tamariki.
- Research aim: To evaluate the effectiveness of an improved syringe and label in reducing paracetamol administration errors.

#### A note re purpose:

Accidental paracetamol poisoning in children is rare, but the consequences can be severe. Giving too much paracetamol to children can lead to iver failure and even death.



5







### **Randomisation sheets**

 Use the ID numbers on the randomisation sheets to work out if your next participant is in the treatment or control group

Q Me	enus 🗧	2 6 5	ີ 100% <del>-</del>   ຄ	% .0 .	123 Defau	
41	*   jx					
	A	В	c	D	E	
1		participant_id	treatment			
2	1	OUUP	Participant choose	05		
3	2	U2XV	Syringe only			
4	3	E2ON	Participant choose	05		
5	4	K934	Syringe only			
6		6V27	Syringe only			
7		7EAN	Participant choose			
8		STVX	Participant choose	es		
9		5VG7	Participant choose	05		
10	9	VDQ0	Syringe only			
11	10	C2T8	Participant choose	05		
12	11	HLWG	Syringe only			
13	12	6XVV	Participant choose	05		
14	13	FFAN	Participant choose	es		
15		YCES	Participant choose	05		
16	15	UQNV	Syringe only			
17	16	JQHO	Syringe only			
18		KYKT	Synnge only			
19	18	7JGL	Participant choose	es		
20		8VHP	Participant choose			
21		BGTP	Participant choose	es		
22	21	0HE2	Syringe only			
23		RNDZ	Participant choose			
24		5LQI	Participant choose	05		
25		1H3D	Syringe only			
26		OSHK	Syringe only			
27		IG94	Synnge only			
28	27	6RIO	Syringe only			
29		EVIA	Syringe only			
30	29	IUC9	Syringe only			

#### Recruitment

- Recruitment via: NHC's clinical and community provider network
- Eligibility to participate in the trial: <u>Must</u> have a tamariki Māori aged *under* 14 years (13 years or younger).
- If participant agrees to participate go through: Parent Information and Consent Form (PICF)



#### Informed consent Let participants know their **RACETAMOL STUDY** participation is: · Anonymous - They and their Kia ora and warm Pacific greetings, data will remain anonymous You are invited to participate in a brief study on ways to help whanau safely administer paracetamol to tamariki Māori. • Voluntary - They can skip What is this research about? any questions or stop at any Accidental paracetamol poisoning in children is rare, but the consequences can be severe. time Giving too much paracetamol to children can lead to liver failure or even death. In this research, we're aiming to reduce paracetamol poisoning by improving the meas and instructions for giving paracetamol to tamariki Māori. uring dev · How we will use their **information** – findings from Who is conducting and paying for this research? the research will be reported This research is being conducted by the National Hauora Coalition (NHC), in partnership with WeBe, the Behavioural Insights Team, and the University of Otago. The research is funded by the Health Research Council of New Zealand. to HRC · Limits of confidentiality -What does participation in this research involve? risk to safety of whānau or 12 tamariki

# 4. Collecting self-report data on the Google form



### Collection of self-report data

#### Follow the trial guide:

 As you ask each question, record the participant's answers in the Google form

#### Demonstration of the Google form:

Click <u>here</u>

#### Any questions?

Time for practice (10 mins) - in pairs

Participant details		
sandshaynard Bosninactors Aklacam Switch accounts	۵	
* Indicates required question		
Name of kaimahi		
Your answer		
Date*		
Date dd/mm/ygyy ⊐		
Time "		
1		
Please enter participant ID (from randomisation sheet)		
Your atomer		
Which condition this participant has been assigned to ( randomisation sheet)?	from *	
Treatment     Control		
Next	Clear form	14

# 5. Simulating the dosing of paracetamol

#### Simulated dosing of paracetamol

Continue to follow the trial guide (noting different protocols for Treatment and Control groups):

- Take a moment to familiarise self with trial guide section – Simulated dosing of paracetamol – for the Treatment group
- · Recap of key points
- Difference between:
  - Prescribed dose
  - o Intended dose
  - o Actual dose

 What if participant doesn't know the weight of their youngest tamariki?

Instruction in the second

- How to calculate the prescribed dose – use the online dose calculator
- Always use 250mg/5mL
- Key differences between Treatment and Control protocols – see pink rows

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6. Measuring the amount of paracetamol extracted from the bottle

# Practice Makes Perfect!

# Measuring the actual amount of paracetamol extracted in mL

**Primary outcome =** the deviation in mL between the prescribed dose and the actual dose

## How to measure the ACTUAL dose for the Treatment group:

- a. Read the exact amount (in mL) on the syringe
- b. Record the exact amount (in mL) in the Google form

## How to measure the ACTUAL dose for the Control group:

- a. Put the full amount of paracetamol measured out into the measuring cylinder
- b. Read the exact amount (in mL) on the measuring cylinder
- c. Record the exact amount (in mL) in the Google form

#### **Time for practice**

- · Break into pairs
- Take it in turns playing the role of Kaimanaaki/researcher and participant
- Practice the protocol for the Treatment Group first then swap roles
- Next practice the protocol for the Control group and then swap roles
- 'Participant' to pretend they don't know their child's weight
- Practise using the online calculator to record the prescribed dose
- Practise measuring the actual amount of paracetamol extracted and recording it in the Google form

Simulated dosing of paracetamol				
<ul> <li>For the next part of the session, I'm going to ask you to pretend that you're giving paracetamol to the youngest <u>tamariky</u>/moko in your care.</li> </ul>				
Record the following information in the google form [section 3 of 4]:				
NTERVENTION group:				
Prompt	Notes			
Put a bottle of paracetamol and the intervention synthese in froat of paraticipant Here is a bottle of paracetamori, and a synthese that you can use to measure the paracetamol out. For this task, if want you to imagine you were giving paracetamot to your youngest tematik, and just the appropriate amount of paracetamol into the synthe accounting.	[google form: teck 'intervention syrings' as the implement the participant will use to measure the dose of paracetamo]			
Before we begin - Do you know the current weight of your youngest tamariki? (Y/N)	[google form: record Y/N]			
Record the weight of their youngest tamariki/moko (f they do not know the weight of their tamariki, look up the wonege weight of a child of their age on the weight cherts in Appendix B)	[google form: record the estimated weight, or the average weight of a child the age of their tamails/moko]			
Calculate the PRESCRIBED doars: Grant the estimated weight for their transmit, Prescharts Doars (Science) on the execution of the Prescharts Doars (Science) on the execution in the Prescharts Doars (Science) on the execution of the to the exact mL). This prescribed doars should then be written down, so the participant can see it. Notes only use the weight chart (If you don't have internet access and therefore cannot use the online calculator.	(google form: record the prescribed dose)			
Ask participant to measure out the correct dose of paracetamol Based on the estimated weight of your tameritik, you should pail by minime the sympe. You can take as long as you need, no rush? MTENDED dose, Just to confirm, how many mi. are you intending to put into the sympe?	(google form: record their intended dose)			
Measure and record the ACTUAL dose: a. Read the amount (in mL) on the syringe b. Record this emount (in mL) in the Google form	(google form: record their actual dose)			

7. Providing feedback to whānau and escalation procedure



### **Providing feedback**

#### Provide feedback to whanau on:

- Whether their dose was accurate / inaccurate based on the weight of their tamariki
- Their intended dosage
   frequency and dosage course

Give whānau a chance to practice getting their dose correct – using the implement they drew the paracetamol out with.



#### Debrief whānau

- Don't forget to brief whānau about the purpose of the study at the very end – let them know about the differences between the Treatment and Control group and which group they were in
- Thank whānau for their time
- Give koha
- Let whānau know we will send them a copy of the results (if they have provided their email address on the PICF).





## Appendix 9: Trial protocol

## **Research Questions**

- Primary question: Does a custom syringe and label reduce paracetamol dosing errors?
- Secondary questions:
  - Does a custom dosing label (and syringe) reduce errors in the **frequency** at which paracetamol is administered?
  - Does a custom dosing label (and syringe) reduce errors in the **dosage course** for which paracetamol is administered?
- Exploratory questions:
  - Does a custom syringe and (dosing label) reduce **clinically significant** paracetamol dosing errors?
  - Are dosing errors due to a failure to draw out the intended amount or a failure to determine what amount is appropriate in the first place?
  - What typical dosing methods do whanau use?

## **Project team**

Role	Name	Email		
National Hauora Coalition (Project Lead)				
Chief Investigator:	Dr Rawiri McKree Jansen	rawirimj@nhc.maori.nz		
Project Lead:	Dr Ainsleigh Cribb-Su'a	ainsleighcs@nhc.maori.nz		
Project support:	Dr Mythily Meher	mythilym@nhc.maori.nz		
Project support:	Tira Phillipson-Puna	tira@nhc.maori.nz		
WēBē (Project partner)				
Project Lead:	Sarah Hayward	sarah.hayward@contractors.bi.team		
Behavioural Insights Team (Project Partner)				
Research Lead:	Bowen Fung	bowen.fung@bi.team		
Project Support:	Erin Lawn	erin.lawn@bi.team		

Research QA:	Elizabeth Convery	elizabeth.convery@bi.team
Policy QA:	Karen Tindall	karen.tindall@bi.team
Other Partners		
University of Otago	Anna Tiatia Fa'atoese Latu	anna.latu@otago.ac.nz

## Method

#### **Participants**

- Each session will be one-on-one.
  - There will be 1 Kaimanaaki/researcher + ~1 caregiver/parent.

#### NHC kaimahi

- The NHC kaimahi involved in conducting the trial will be:
  - o Mythily Meher
  - o Tira Phillipson-Puna
  - o Kim Arrowsmith
  - o Monleigh Ikuia
  - o Ainsleigh Cribb-Su'a
  - o Hinekura Ngataki
  - o Kathryn Chapman

#### **Participants**

- We will recruit 1000 whānau 500 per condition.
  - Whānau will be patients of NHC GP clinics or recruited through NHC's other networks. They must be a caregiver (e.g., mother, father, grandparent, extended family member) to at least one tamariki Māori aged under 14.
- Participants will be reimbursed \$40 each for their time (~20-25 minutes total).

#### Design

#### Approach

We are aiming to test how easy or difficult it is for whānau to give accurate doses of paracetamol using either our custom syringe and label or control implements and label.

- We will use a 'lab usability testing' approach.
  - Whānau in the Intervention group will perform typical tasks with our custom syringe and label.
  - Whānau in the control group will perform typical tasks with their choice of dosing implements and a typical label.

#### Setting

- Sessions with whanau will be conducted in-person.
  - These sessions will be held at NHC GP clinics or in other appropriate settings, where whānau can have some privacy.

#### **Informed consent**

- Whānau attending an appointment at an NHC GP clinic will be approached by the Kaimanaaki/researchers either before or after their GP appointment. They may also be approached in other appropriate settings. The Kaimanaaki/researchers will explain the purpose of the study and ask whether the whānau is interested in participating, if they meet the eligibility criterion ("I am a caregiver to at least one tamariki Māori aged under 14"). If the whānau is interested in participating, the researchers will show them through to a private room at the clinic or another appropriate area.
- Those whanau who are interested will read the *Participant Information and Consent Form* (PICF). The Kaimanaaki/researcher will walk them through the form and answer any questions.
- Those who choose to participate will be asked to sign the Consent Form portion of the form (including their age, gender, and ethnicity), and will be given a copy of the Participant Information portion of the form to keep.

#### **Escalation procedures**

#### Dosing errors

Below is a list of the types of dosing errors that participants can make, and a suggested response for each. Errors can be due to drawing either too little or too much paracetamol.

	Participant Action				
	Drawing the Amount				
Incorrect (Under)	Correct	Incorrect (Over)	Researcher Response		
			Well done, you've drawn out a safe amount of paracetamol for the weight of your tamariki [xkg]. This is important because overdosing can lead to paediatric acute liver failure or even death.		
×			You've drawn out a safe amount of paracetamol		

		for the weight of your tamariki [xkg]. Notice you've drawn out slightly less than the prescribed dose, so you could increase the dose up to this line if you wanted to. But giving less than the prescribed dose is much safer than giving more, because overdosing can lead to paediatric acute liver failure or even death.
	×	You've drawn a bit more than the prescribed dose for a tamariki that weighs [xkg], which was [x]ml. [Show participant how to read the label to identify correct ml and how to draw out the correct amount] It's important to try to give the right dose,
		because overdosing can lead to paediatric acute liver failure or even death. It often helps to practise. How about you have another go at drawing up the correct amount of paracetamol for your youngest tamariki?

#### [If the participant makes an error upon retrying]:

- Explain the error they have made, show them how to read the label and how to draw out the correct amount of paracetamol (if in the control group, using the implement of their choice) for their tamariki
- *Give them another chance to practise drawing out the correct amount of paracetamol*
- IF whānau continue to draw out an incorrect amount, refer them to their GP or nurse for further support to avoid the risk of harm to tamariki due to dosing errors.

#### Misconceptions about paracetamol

If a whānau says something that reflects a misconception about paracetamol, the Kaimanaaki/researcher will:

- Politely explain that this is a common misconception, and provide immediate corrective feedback accordingly, and
- Recommend <u>Healthify</u> website if they'd like to read more information about paracetamol safety.

# Example misconceptions might include 'paracetamol is very safe' or 'paracetamol should be stored in the fridge'.

If a whānau says something that suggests they use paracetamol in a dangerous way, the Kaimanaaki/researcher will:

- Politely explain why this is dangerous, and provide immediate corrective feedback accordingly, and if needed
- Refer the whanau to their GP to provide them with educational support.

## Example dangerous behaviours might include allowing tamariki to dose themselves, or putting paracetamol in an infant's bottle.

If a whānau says something that implies they would administer more than four doses within a 24hour period, or that they would continue to administer doses for more than 48hrs, the interviewer will politely explain why this is dangerous, and provide immediate corrective feedback accordingly.

#### Disclosures that imply serious risk to a child's welfare

Through the course of discussion, a whānau could reveal something unrelated to paracetamol that indicates a serious risk to their child's safety (e.g., abuse from a family member). If this happens, the Kaimanaaki/researcher will provide support if appropriate and/or refer the whānau back to their GP to provide them with support.

## Guide

Date and time: Enter into google form

**Participant ID:** Enter into google form (use the next participant ID from the pre-populated randomisation list)

#### Condition (Treatment or Control): Enter into google form

[Before Kaimanaaki/researcher approaches a potential participant, take a note of which condition the next participant is assigned to and have the correct implements and label ready to go for that condition - **see the Appendix A for a list of everything to have ready**.]

Recruitment

#### [Kaimanaaki to approach a prospective participant.]

- *Kia ora, I'm XXXX and we are working on a research project that aims to look into and test ways to safely give paracetamol to tamariki.*
- The project is completely voluntary and will involve you answering a few questions and drawing out a dose of paracetamol. It will take ~20-25 minutes and we will provide a \$40 PaknSave voucher as a koha.
- Are you a caregiver to at least one tamariki Māori aged under 14? Does this apply to you?
- Would you be willing to participate?

#### Introductions and informed consent

- Karakia (optional)
- Whakawhanaungatanga
- Walk through Participant Information and Consent Form (PICF):
  - o anonymous
  - o can skip any questions or stop at any time
- Ask if they have any questions

#### **Collection of self-report data**

- Ask the participant about their whānau and use their youngest tamaiti or pēpi (baby) in their care as the example of who to measure paracetamol dosage for.

Example prompts				
Mother or Father	Grandparent			
How many tamaraki do you have?	How many moko/grandkids do you have?			
What's the name of your youngest tamariki?	What's the name of your youngest moko?			

Record the following information in the google form [section 2 of 4]: Note: if you do not have internet access, please fill in a hard copy of the google form.

Prompt				
Mother or Father	Grandparent			
What is the age of your youngest tamariki?	What is the age of your youngest moko?			
What is the relationship between you and your youngest tamariki?	What is the relationship between you and your youngest moko?			
Have you ever given paracetamol to your youngest tamariki?	Have you ever given paracetamol to your youngest moko?			
What do you normally use to give your youngest tamariki paracetamol?	What do you normally use to give your youngest moko paracetamol?			
Have you ever used a syringe to give your youngest tamariki paracetamol?	Have you ever used a syringe to give your youngest moko paracetamol?			

## Simulated dosing of paracetamol

• For the next part of the session, I'm going to ask you to pretend that you're giving paracetamol to the youngest tamaiti/tamariki/moko in your care.

# Record the following information in the google form [section 3 of 4]: **INTERVENTION group:**

Prompt	Notes	
Put a bottle of paracetamol and the intervention syringe in front of participant		
Here is a bottle of paracetamol, and a syringe that you can use to measure the paracetamol out.	[google form: tick 'intervention syringe' as the implement the participant will use to measure the dose of paracetamol]	
For this task, I want you to imagine you were giving paracetamol to the youngest tamaiti in your care, and put the appropriate amount of paracetamol into the syringe accordingly.		
Before we begin - Do you know the current weight of this tamaiti? (Y/N)	[google form: record Y/N]	
Record the weight. [If they do not know the weight, look up the average weight of	[google form: record the estimated weight, or the average weight of a child the age of their	

a child of that age on the weight charts in Appendix B].	tamaiti/moko]
Calculate the PRESCRIBED dose: Given the estimated weight for their tamariki, calculate the prescribed mL dosage using the Paediatric Dose Calculator on the <u>Healthify website</u> to the exact mL). This prescribed dose should then be written down, so the participant can see it. Note: only use the weight chart if you don't have internet access and therefore cannot use the online calculator	[google form: record the <b>prescribed</b> dose]
Ask participant to measure out the correct dose of paracetamol Based on the estimated weight of your tamariki, you should put [x] ml into the syringe. You can take as long as you need, no rush! INTENDED dose: Just to confirm, how many mL are you intending to put into the syringe?	[google form: record their <b>intended</b> dose]
<ul><li>Measure and record the ACTUAL dose:</li><li>a. Read the amount (in mL) on the syringe</li><li>b. Record this amount (in mL) in the Google form</li></ul>	[google form: record their <b>actual dose</b> ]
How soon would you give the next dose (hours)?	[google form: record how soon they would give their next dose]
What is the maximum number of doses you would give in 24 hours (1 day)?	[record their intended dosage frequency]
How many days in a row would you keep giving paracetamol to them?	[record their intended dosage course]
<b>Provide feedback:</b> Give feedback on whether their dose was accurate / inaccurate based on their child's estimated weight, and whether their intended dosage frequency and dosage course was appropriate (using the Escalation Procedure table).	

#### **CONTROL** group:

Prompt	Notes
--------	-------

<ul> <li>Put bottle of paracetamol and range of measuring implements in front of participant</li> <li>Here is a bottle of paracetamol, and a range of dosing implements that you can use to measure the paracetamol out.</li> <li>For this task, I want you to imagine you were giving paracetamol to the youngest tamaiti in your care, and select the dosing implement you would use at home.</li> </ul>	[google form: record which implement the participant selected to measure the dose of paracetamol]	
Before we begin - Do you know the current weight of this tamaiti? (Y/N)	[google form: record Y/N]	
Record the weight. [If they do not know the weight, look up the average weight of a child of that age on the weight charts in Appendix B].	[google form: record the estimated weight, or the average weight of a child the age of their tamaiti/moko]	
Calculate the PRESCRIBED dose: Given the estimated weight for their tamaiti, calculate the prescribed mL dosage using the Paediatric Dose Calculator on the <u>Healthify website</u> to the exact mL). This prescribed dose should then be written down, so the participant can see it.	[google form: record the <b>prescribed</b> dose]	
Ask participant to measure out the correct dose of paracetamol Now measure the appropriate amount of paracetamol using the implement you have selected. Based on the estimated weight of your tamaiti, you should measure out [x] ml. You can take as long as you need, no rush! INTENDED dose: Just to confirm, how many ml are you intending to measure out?	[google form: record their <b>intended</b> dose]	
<ul> <li>Measure and record the ACTUAL dose</li> <li>a. Put the full amount of paracetamol measured out into the measuring cylinder</li> <li>b. Read the amount (in mL) on the measuring cyclinder</li> <li>c. Record this amount (in mL) in the google form</li> </ul>	[google form: record their <b>actual dose]</b>	
How soon would you give the next dose (hours)?	[google form: record how soon they would give their	

	next dose]
What is the maximum number of doses you would give in 24 hours (1 day)?	[record their intended dosage frequency]
How many days in a row would you keep giving paracetamol to your tamaiti?	[record their intended dosage course]
Provide feedback:	
Give feedback on whether their dose was accurate / inaccurate based on their child's estimated weight, and whether their intended dosage frequency and dosage course was appropriate (using the Escalation Procedure table).	

#### Debrief

Debrief participants about the purpose of the study. Answer any additional questions they might have.

- We're now at the end of the session! We really appreciate you participating in this study.
- Intervention group: Half of the participants in this study will be using the same syringe and label as you used. These have been custom designed by us to make giving paracetamol easier (show them the key improvements we made to the syringe and label). The other half of our participants will be using more generic dosing implements and label. This will allow us to compare whether our custom syringe and label leads to more accurate dosing, relative to the generic implements and label.
- **Control group:** Half of the participants in this study will have the same choice of implements as you. These dosing implements and label are fairly generic. The other half of our participants will be using a syringe and label that has been custom designed by us to make administering paracetamol easier. This will allow us to compare whether our custom syringe and label leads to more accurate dosing, relative to the generic implements and label].

Do you have any final thoughts you'd like to share or questions for me?

#### Exit

Thank you for your time today! As a token of our thanks, **we would like to give you this \$40 shopping voucher for your time and sharing your whakaaro**. Once the results of the trial are in, we can also email you a copy of the results if you're interested.

[email address] ← record if participant wants to receive a copy of the results (this should be recorded on their Participant Information and Consent Form (PICF)

#### Appendix A: List of things to have ready before approaching each participant

#### Treatment group:

- Trial guide
- Randomisation sheets
- Parent information and consent form (PICF)
- Pamol bottle with usual label removed and our treatment group label on it
- Dosing implement: intervention syringe (treatment group)
- Ensure you have access to the online Google form (to collect participant data)
- Spare hard copies of Google form in case no internet coverage
- Online dose calculator and full weight chart, in case can't use online dose calculator

#### **Control group:**

- Trial guide
- Randomisation sheets
- Parent information and consent form (PICF)
- Pamol bottle with control label stuck over top of existing label on bottle (as happens in real life)
- Dosing implements, including:
  - o 5mL oral syringe (control group)
  - spoon (control group)
  - measuring cup (control group)
  - Pamol lid (control group)
- Ensure you have access to the online Google form (to collect participant data)
- Spare hard copies of Google form in case no internet coverage
- Online dose calculator and full weight chart, in case can't use online dose calculator

#### Appendix B: Growth charts showing average weight per age

### NZ-WHO growth charts

	Girls weight percentile (kg)		Boys weight percentile (kg)		kg)	
Age	9 <sup>th</sup>	50 <sup>th</sup>	91 <sup>st</sup>	9 <sup>th</sup>	50 <sup>th</sup>	91 <sup>st</sup>
1 m	3.4	4.1	4.9	3.6	4.4	5.2
3 m	4.9	5.8	6.9	5.4	6.4	7.4
6 m	5.7	6.8	8.6	6.4	7.4	9.2
1 y	7.6	9.0	10.5	8.3	9.6	11.1
2 y	9.8	11.5	13.6	10.4	12.1	14.2
3 у	11.7	13.9	16.5	12.2	14.3	16.8
4 y	13.5	16	19.5	13.8	16.3	19.4
5 y	15	18.3	22.4	15.3	18.3	22

Pfizer growth charts

	Girls weight percentile (kg)		Boys weight percentile (kg)		kg)	
Age	10 <sup>th</sup>	50 <sup>th</sup>	90 <sup>th</sup>	10 <sup>th</sup>	50 <sup>th</sup>	90 <sup>th</sup>
6 у	16	20.5	25.5	18	21	25.5
7у	19	23	29	14.5	23	24
8 y	21	26	33	22	26	32.5
9 y	23.5	29	38	24	24	37
10 y	26.5	38	44	26	32	42
11 y	30	37.5	50	29	36	48
12 y	33	42	56	32.5	41	54

# Appendix 10: Information sheet on paracetamol use (Waitemata District Health Board)

- What if my child has too much? Too much paracetamol can damage your child's liver
- If your child has had too much, call your doctor, nurse or the Poisons Centre
   0800 POISON (0800 764 766) immediately
- Signs of overdose may include nausea, vomiting, diarrhoea, yellow skin or eyes, poor appetite, confusion or extreme sleepiness

#### Remember

- Ask questions if you have any concerns

  Keep all medicines out of reach and out of
- sight of children
- Before each dose, check if it is still needed
- Know the right dose to give and check the label for the correct strength; do not rely on the colour or flavour to check the strength
- Wait at least 4 hours between doses, give no more than 4 times in 24 hours

- If someone else has been caring for your child, ask if they have given paracetamol, how much and when
- Check other medicines given, they may
   have paracetamol in them
- Always keep medicines in their original bottles, do not refill them from other containers

#### **Contact numbers**

- Healthline has free 24 hour health advice
   0800 611 116
- If your child has had too much, call your doctor, nurse or the Poisons Centre 0800 POISON (0800 764 766) immediately

This is a guide only and not a replacement for advice and care of your doctor, pharmacist (chemist) or nurse



#### Waitemata District Health Board Best Care for Everyone

Giving paracetamol safely to babies and children

Giving too much can be dangerous

#### What is paracetamol?

- It is a medicine to help reduce pain and
- make children with fever feel betterIt will not cause drowsiness or cause your
- child to sleep • It can be used for children and babies over 3
- months old
- Younger babies must see the doctor

#### Does my child need it?

Only give paracetamol if it is necessary

- Use it if your child needs pain reliefUse it if your child feels very hot
- (temperature over 38.5°C) and is miserable
- It is not recommended to routinely give paracetamol before or after regular
- vaccinations unless recommend by your doctor or nurse

#### What is the correct dose?

- The dose depends on your child's weight and the strength of paracetamol
- Weigh your child, then check the dosing table

#### Dosing table

Childs weight(kg)	120mg per 5mL	250mg per 5mL
5kg or less	Ask doctor	Ask doctor
6.5kg	4mL	2mL
8kg	5mL	2.5mL
10kg	6mL	3mL
15kg	9mL	4.5mL
20kg	12mL	6mL
30kg	18mL	9mL
40kg	25mL	12mL

#### Before every dose

- Check your child to see if it is still needed • Wait at least 4 hours between doses; give no
- more than 4 times in 24 hours
- Keep track of doses and check when it was last given before giving it again

Always measure doses exactly

Ask your pharmacist or nurse for an oral syringe

#### **Record of doses**

Name of Child Weight/kg					
Date	120mg/ 5mL	250mg/ 5mL	mL		

#### Where should I keep paracetamol? Keep it in a high place out of reach and out of sight of children

- The most common cause of poisoning is by children helping themselves
- It does not need to be chilled: do not keep it in the fridge
- It should have a child-resistant cap ask your pharmacist
- 178

# Appendix 11: Te reo Māori resource on safe paracetamol use (Pharmac)

CRERERERERE CERERE De la competition de la comp

# Raru whakarato: Wē paracetamol 250 mg i roto i te 5 mL

Mai i te 1 o Noema 2022, kei te whakakapia te wē Paracare paracetamol 250mg i te 5 mL e tētahi momo hou ko Pamol te ingoa.

#### (Te whakahua ko 'pa-ra-SEE-ta-mol')

E tino whakamahia ana te wē paracematol mō te kirikā me te whakamauru mamae, otirā mō te tamariki.

#### He aha te rerekē o Pamol paracetamol?

He rerekē te tae o Pamol paracetamol 250 mg i roto i te 5mL i a Paracare. He āhua mā te tae engari he rite tonu te reka – he rite ki te ārani te reka. He rite tonu te rahi o te kai hohe o roto, ā, he ōrite te mahi.

#### Kia mōhio

He ōrite pea te tae me te reka o ngā rongoā wē rerekē. Mēnā he pātai āu mō ēnei, me kōrero ki tō rata, nēhi, kaitaka rongoā rānei.



He örite pea te tae me te reka o ngā rongoā wē rerekē. Me pānui i te tapanga i ngā wā katoa, ā, me tika te pota mā tō tamaiti. KAUA RAWA e whakawhirinaki ki te tae, kakara, hā rānei.

PHARMAC

#### te reo Māori

## E hia te nui o te paracetamol me whāngai ki taku tamaiti?

→ Kei te taumaha o tō tamaiti te pota paracetamol.

K RK RK RK RK

- → Me ine i te taumaha o tō tamaiti KA tirotiro i te kaha o tō paracetamol.
- → Me whakamahi te tūtohi i konei hei kimi i te pota tika.

## I mua i te whāngai paracetamol ki tō tamaiti:

- Me tirotiro mēnā me whiwhi tonu tō tamaiti.
- KAUA e nui atu i te 4 ngā pota i roto i te 24 haora.
- Me tirotiro i te rā monehu.
- Tirohia ētahi atu rongoā rewharewha, maremare, whurū rānei ka tukuna, he paracetamol pea kei roto.

He mea nui kia kaua e nui atu te whiwhi a tō tamaiti i te pota e tūtohua ana mō te rā. Mēnā ka nui rawa te whiwhi a tō tamaiti i te wā kotahi, i ētahi rā rānei – ka tūkinohia pea e te paracetamol tōna ate.

#### Tūtohi pota paracetamol

Taumaha o te tamaiti	250 mg i roto i te 5 mL
Iti iho i te 5 kg	Me pātai atu ki tō rata, kaitaka rongoā rānei
5 kg	1.5 mL
6 ki te 7 kg	1.5 mL
8 ki te 9 kg	2 mL
10 ki te 12 kg	3 mL
13 ki te 14 kg	4 mL
15 ki te 16 kg	4.5 mL
17 ki te 18 kg	5 mL
19 ki te 20 kg	5.5 mL
21 ki te 22 kg	6.5 mL
23 ki te 25 kg	7 mL
26 ki te 28 kg	8 mL
29 ki te 32 kg	8.5 mL
33 ki te 36 kg	10 mL
37 ki te 41 kg	11 mL
42 ki te 60 kg	12. 5 mL
Nui ake i te 60 kg	15 ki te 20 mL

Mo ētahi atu mohiohio mo te we paracetamol, haere ki pharmac.govt.nz/paracetamol-liquid

