Disclosure Statement

- I have no affiliation (financial or otherwise) with a pharmaceutical, medical device or communications organization.

Minimising Immunisation Pain (MIP) of childhood vaccines: The MIP Pilot Study

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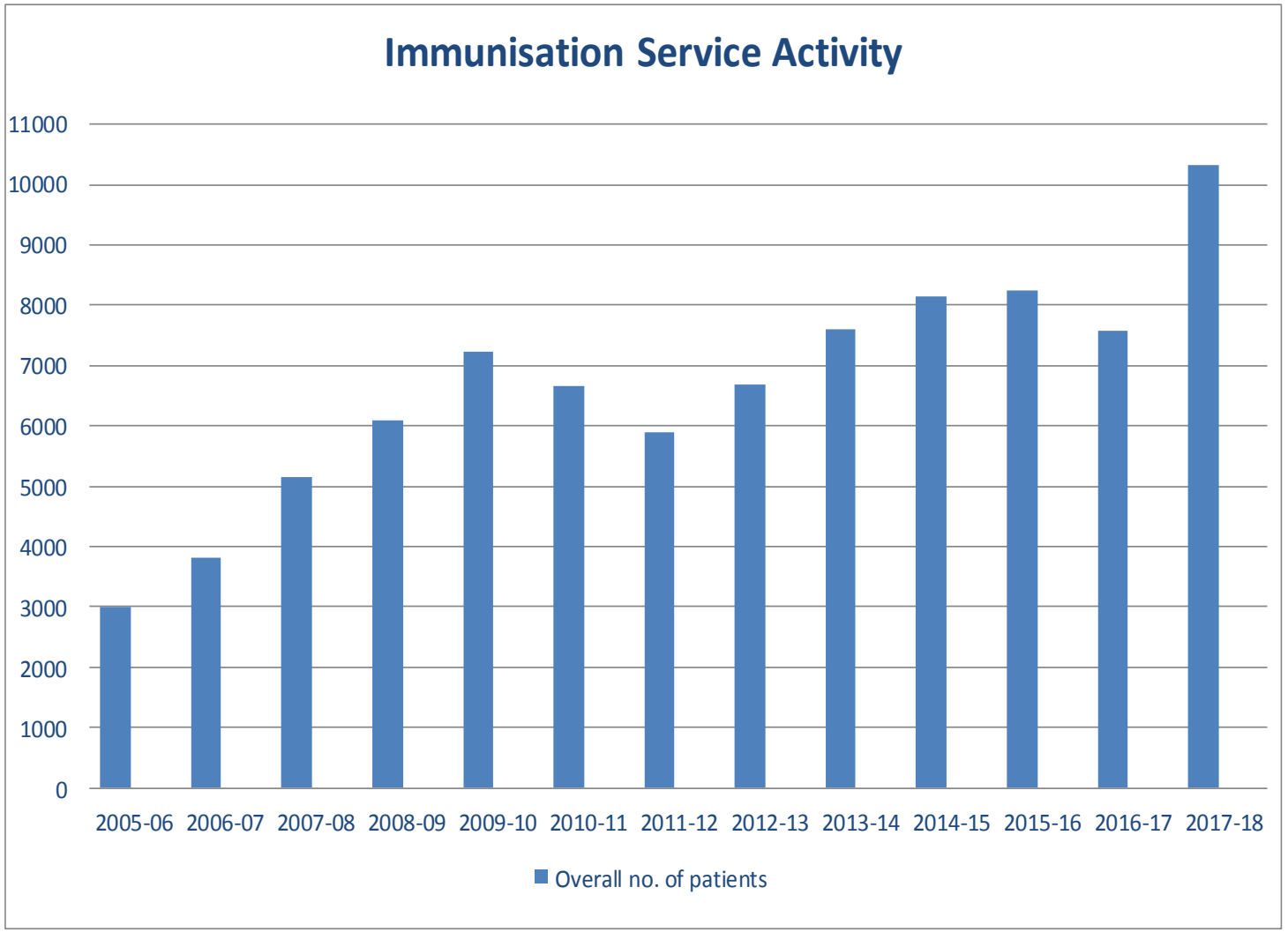
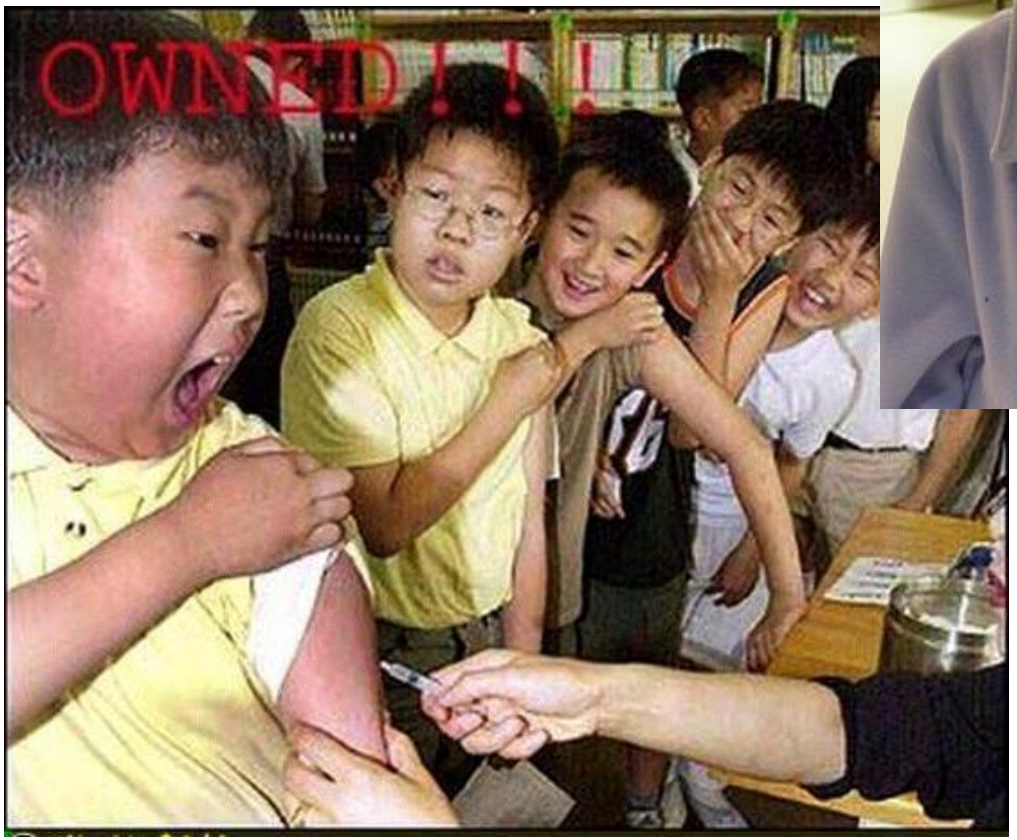
The RCH Immunisation Service

- Three core services:
  - Drop-In Centre
  - Telephone Advice Line
  - Weekly outpatient clinic
- Inpatient immunisation
- Funding through partnerships with the Vic. Dept of Health & Human Services - Immunisation section

Annual Service Activity




OWNED!!!

Background

- Most children dislike needles and are quite anxious about them
- Some develop a considerable fear (needle phobia)
- About 10% of adults have needle phobia[1]
  - onset of needle phobia is prior to age 10 in 70%

1. Ost LG. Blood and Injection phobia: background and cognitive, physiological and behavioural variables. J Abnormal Psychology 1992;101 (1)68 – 74

Background cont…

- A Child's early experiences can determine whether medical help is sought in the future[2]
- Distress with immunisation can also lead to non-adherence with immunisation schedules[3]
- Important to reduce pain and distress when immunising

2. Jenkins, K. Needle Phobia. A Psychological Perspective. British Journal of Anaesthesia 2014; 113(1): 4-6.

3. Schechter, N. et al. (2007). Pain reduction during pediatric immunizations: evidence-based review and recommendations. Pediatrics 119(5), e1184-1198.

Standard care/Distraction Techniques

Bubbles

Toys

Buzzy®

Coolsense®

RCH Immunisation Service and Coolsense®

- RCH Immunisation Service began using device in May 2017
- Used for ages 3.5 yrs – 18 yrs
- Widely accepted and simple to use
- Continual monitoring of effectiveness and safety in all age-groups
- Pilot study commenced late May 2017

Minimising Immunisation Pain (MIP) – Pilot Study

Trial / Pilot Objectives:

1. Determine feasibility for larger RCT
2. Provide data to inform sample size for RCT
3. Measure patient compliance
4. Measure parents perceptions of device effectiveness

MIP – Pilot Study cont.

Study Design/Methods:

- Sequential Randomisation into four groups: 10 children per group = 40 total:

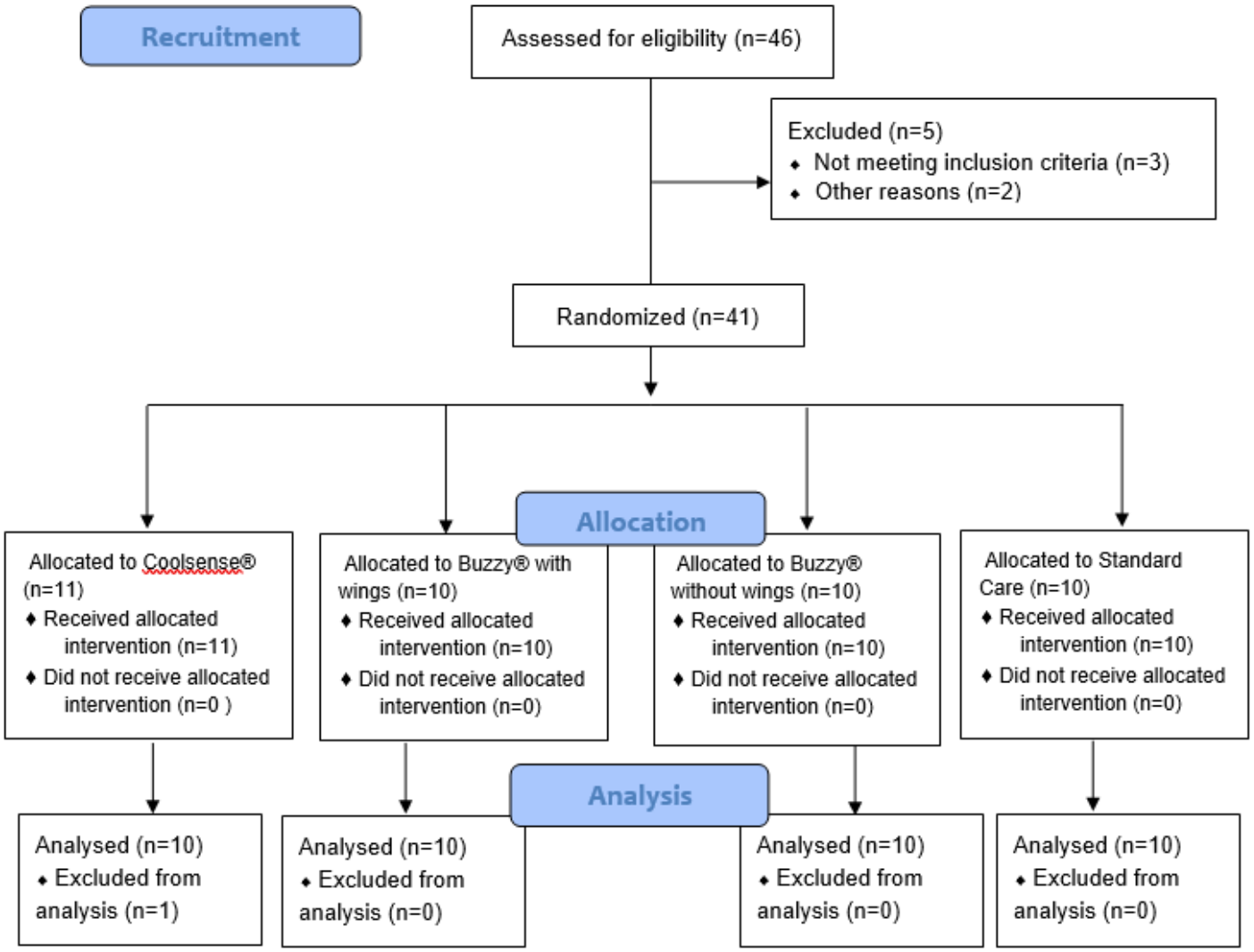
1. **Standard care** – distraction using bubbles
2. **Buzzy® (no wings) and standard care**
3. **Buzzy® (with wings) and standard care**
4. **Coolsense® and standard care**

MIP – Pilot Study cont.

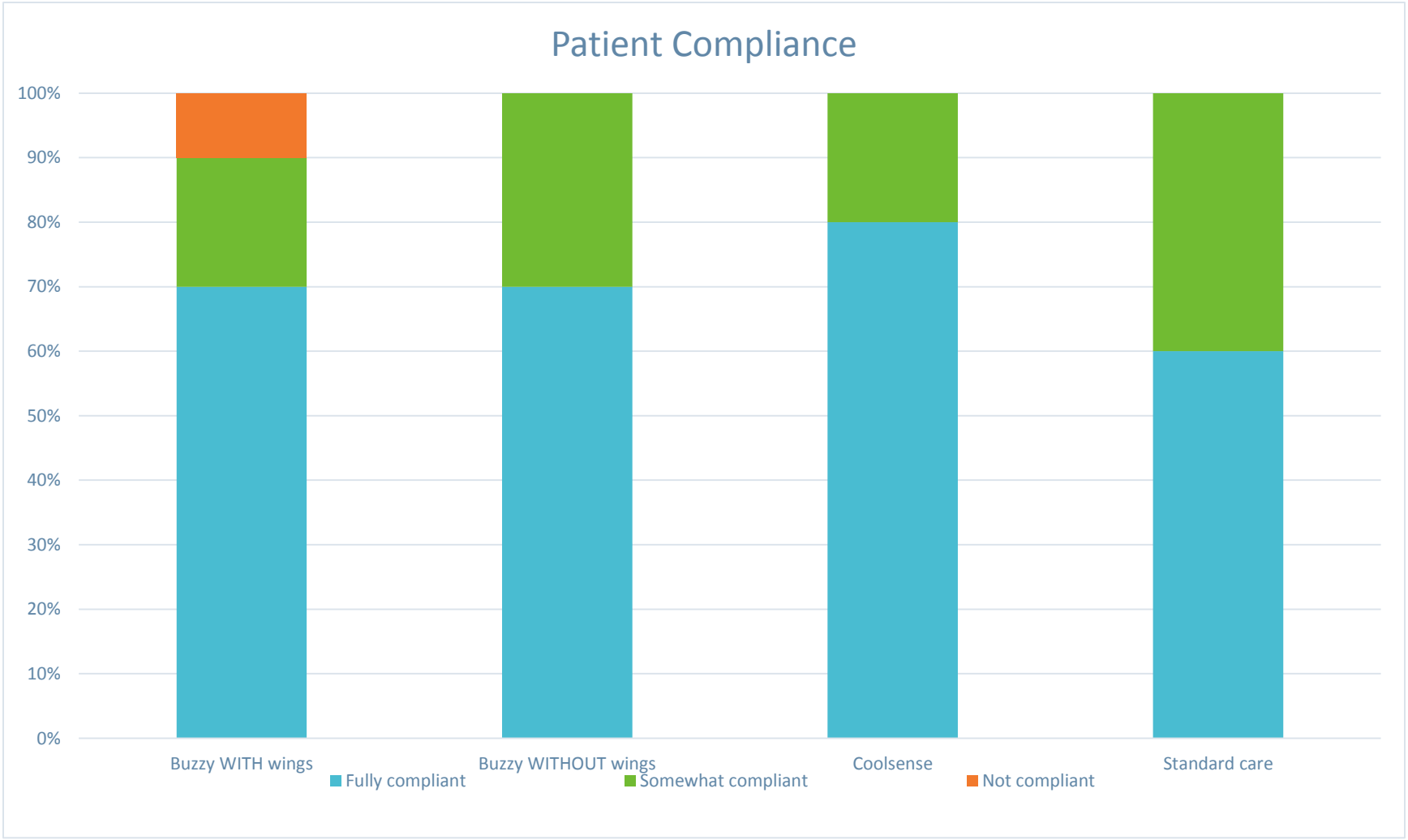
- Inclusion Criteria:
  - All children aged 3.5 to 6 years of age inclusive
  - Presenting for a **single** immunisation

- Exclusion Criteria:
  - Confirmed needle phobia
  - Child with Haemophilia or bleeding disorder
  - Eczema/skin damage at injection site
  - Child with development/behavioural disorder

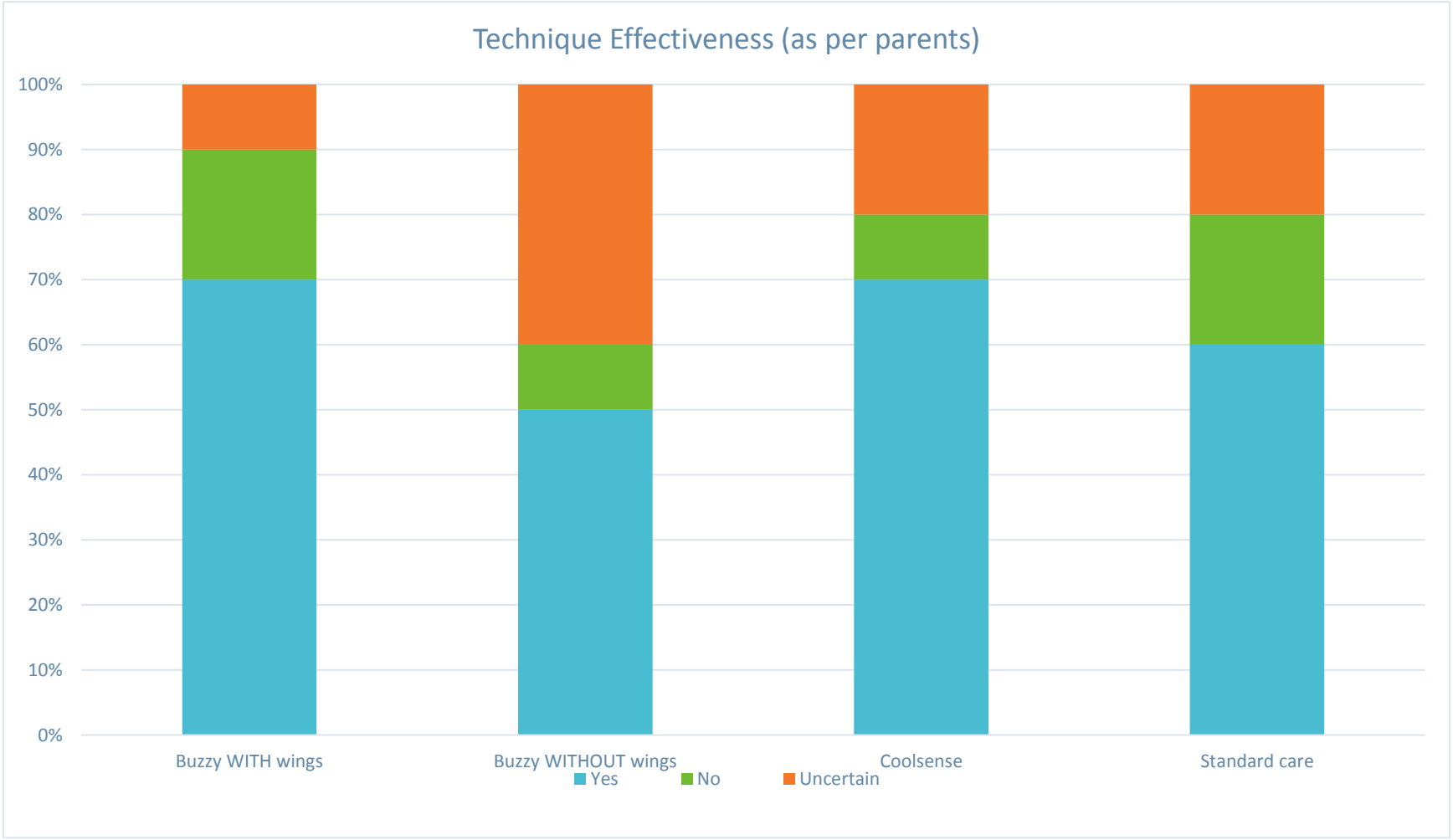
Recruitment and Analysis



Results


Patient Compliance
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Buzzy WITH wings
Buzzy WITHOUT wings
Coolsense
Standard care
Fully compliant
Somewhat compliant
Not compliant

Results cont.



Conclusion

- Timely recruitment (12 days)
- 100% Parent information consent forms completed
- Data Entry streamlined
- Minor amendment made to study protocol
  - Ethics resubmission
  - Staff education
- Feasibility of study design demonstrated
- Sample size for larger RCT calculated

Moving Forward . . . .

- Two larger RCTs to be conducted
  - Younger children (MIPY)
  - Older children (MIPO)
  - 492 participants per group
- Primary outcome evaluate efficacy of devices compared to standard care
- Buzzy® (without wings) removed
- Pain assessment tool for MIPY reviewed

Acknowledgements

- Dr Kirsten Perrett
- Sonja Elia

- RCH Immunisation service nurses, medical and admin
- RCH Comfort Kids
- Templestowe Auxillaries and RCH Foundation
- DHHS Victoria – Immunisation section

Questions?