

Preliminary National Data on Acute Intussusception in Children Aged ≤ 24 months from the Australian Paediatric Surveillance Unit (APSU)

Lloyd-Johnsen C¹, Zurynski Y^{3,4,5}, Elliott E^{3,4,5}, Richmond P^{6,7}, Krause V⁸, Cook H⁸, Beggs S^{9,10}, Nissen M¹¹, Gold M^{12,13}, Buttery, J^{1,2}, Bines, J^{1,2}, Danchin, M^{1,2}

Murdoch Children's Research Institute¹, Royal Children's Hospital, Melbourne², University of Sydney³, Australian Paediatric Surveillance Unit (APSU)⁴, Children's Hospital at Westmead, Sydney⁵, University of WA⁶, Princess Margaret Hospital for Children, WA⁷, Centre for Disease Control, NT⁸, University of Tasmania⁹, Royal Hobart Hospital, TAS¹⁰, Paediatric Infectious Disease Laboratory and Royal Children's Hospital, QLD¹¹, University of Adelaide¹², Women's and Children's Hospital, SA¹³

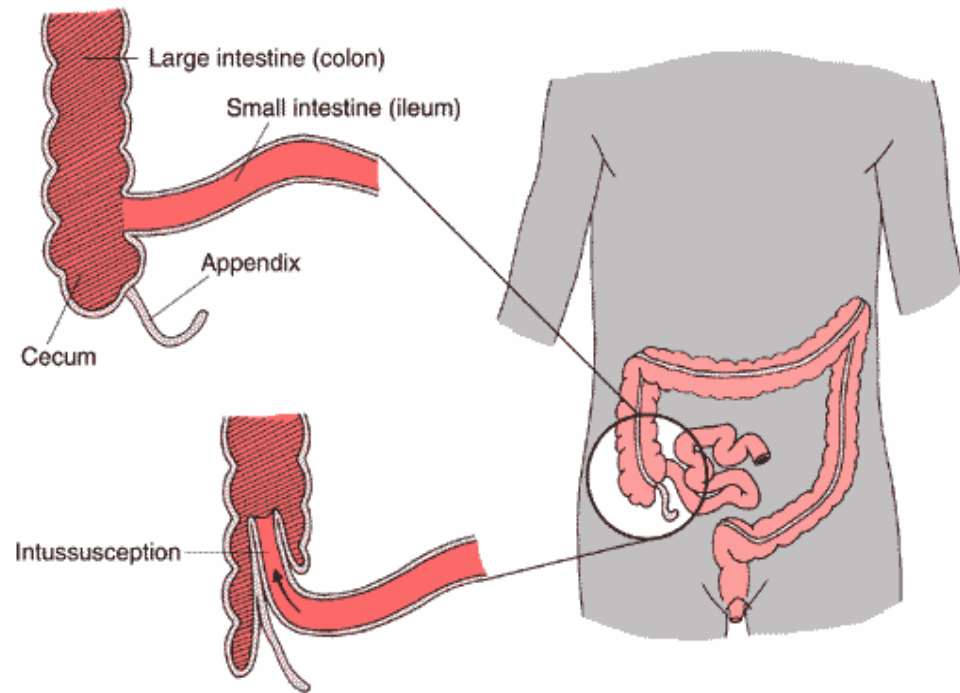
The Australian Paediatric Surveillance Unit (APSU)



- Established in 1993
- Facilitates surveillance of uncommon childhood diseases/conditions
- 17 current studies
- APSU Acute Intussusception Study commenced 1st May 2007

Acute Intussusception (IS)

- Most common cause of bowel obstruction in infants and young children
- ‘Telescoping’ of one portion of the intestine into another
- Incidence of IS <1 in 1000 in developed countries¹
- Estimated 340 annual admissions in children <24mths in Australia²



¹J. Bines and B. Ivanoff, Acute intussusception in infants and children: a global perspective, *Vaccines and Biologicals* WHO/V&B/02.19, World Health Organisation, Geneva (2002) October. Available at: <http://www.who.int/vaccines-documents/DocsPDF02/www640.pdf>.

²Justice, F., J. Carlin, and J. Bines, *Changing epidemiology of intussusception in Australia*. *J Paediatr Child Health*, 2005. 41(9-10): p. 475-8.



Association of rotavirus vaccine (Rotashield®) with IS

- Association of rotavirus vaccine (Rotashield®) with IS
 - <1/10,000 vaccine recipients¹
 - Rare but effective in vaccine withdrawal
 - Greatest risk if >3 months of age at 1st dose²
- Important implications for clinical trials of other rotavirus vaccines
 - Rotarix® (GSK) & Rotateq® (Merck) have been shown to be safe and effective in >65,000 infants

¹Murphy, T.V., et al., *Intussusception among infants given an oral rotavirus vaccine*. N Engl J Med, 2001. **344**(8): p. 564-72.

²Simonsen, L., et al., *More on RotaShield and intussusception: the role of age at the time of vaccination*. J Infect Dis, 2005. **192** Suppl 1: p. S36-43.



Rotavirus vaccines added to NIP

- Rotavirus vaccines introduced on the National Immunisation Program (NIP) from the 1st July 2007.
- Rotarix® (GSK) 2 doses - scheduled at 2 & 4 months
- RotaTeq® (CSL/Merck) 3 doses - scheduled at 2, 4, 6 months
- Each State/Territory provide different vaccines

	Number of Doses	Age of routine administration	States/Territories
Rotarix® (GSK)	2 oral doses (1 mL/dose)	2 and 4 months	ACT, NSW, NT, TAS, WA
RotaTeq® (CSL/Merck)	3 oral doses (2 mL/dose)	2, 4 and 6 months	QLD, SA, VIC



APSU Acute Intussusception Study

Aims of Study:

To document;

- Incidence of acute IS in infants ≤ 24 months
- Temporal relationship between the development of IS and receipt of a rotavirus vaccine or other vaccines
- Clinical presentation, diagnosis, management and short term outcome of IS

Case definition:

All newly diagnosed cases of Acute Intussusception in a child ≤ 24 months confirmed on air/liquid contrast enema, ultrasound or surgery

Methods

Acute Intussusception Study Questionnaire
 Australian Paediatric Surveillance Unit
 Please ring Dr. Margie Daniels on (03) 8341 6445 if you have any questions about this form.

REPORTING CLINICIANS

1. APSU Dr Code/Name: /..... 2. Month/Year of Report:

PATIENT DETAILS

3. First 2 letters of first name: /..... 4. First 2 letters of surname:
 5. Date of Birth: /..... 6. Sex: M F
 7. Postcode of family:

If this patient is primarily cared for by another physician who you believe will report the case, please complete the questionnaire details above this line and return to APSU. Please keep the patient's name and other details in your records. If no other report is received for this child we will contact you for information requested in the remainder of the questionnaire.
 The primary clinician caring for this child is: Name: Hospital:

Instructions: Please answer each question by ticking the appropriate box or writing your response in the space provided.
 DK= Don't Know, NA = Not applicable

Patient History

8. Birth Weight: (kg)
 9. Term / Pre-term (<37 weeks) DK
 10. Is the patient of Indigenous Australian origin? Yes No DK
 11. Date of admission for the current episode of Intussusception: /.....
 12. Has the patient had intussusception before? Yes No DK
 12a. If yes, how many previous episodes? 12b. At what age(s) (months)?
 13. Is there any known history of intussusception in the family? Yes No DK
 14. Has the patient had any previous significant illnesses/hospitalisations/operations? Yes No DK
 14a. If yes, specify age at which illness took place months
 14b. and specify type of illness/operation:

15. According to the current Immunisation Schedule is the patient up to date? Yes No DK
 16. Have you previously reported this case as an adverse event to ADRAC? Yes No DK
 17. Has the child received a rotavirus vaccine? Yes No DK
 17a. If yes, specify type of vaccine and manufacturer: Rotarix®, GSK Rotateq®, Merck
 17b. If yes, specify date: Dose 1: /..... Dose 2: /..... Dose 3: /.....
 18. Did the child receive any other vaccines within the last two weeks? Yes No DK
 18a. If yes, which one(s)?
 HepB DTPa Polio Hib Pneum MMR Mening C Varicella Other:
 18b. Date of last immunisation: /..... DK NA

Medications/Traditional Medicines

19. Is the child currently receiving treatment? Yes No DK
 If yes, please list all medications received within the last week and currently

Date	Medication	Dose

Feeding History

20. What is the patient currently fed? (Tick as many as apply) Breast milk Formula Solids Other
 If other, please specify

21. If breast-fed, until what age was the patient exclusively breast-fed? months Please indicate: Still feeding N/A
 22. Has there been any change to the patients' diet in the last week? Yes No DK
 If yes, specify:

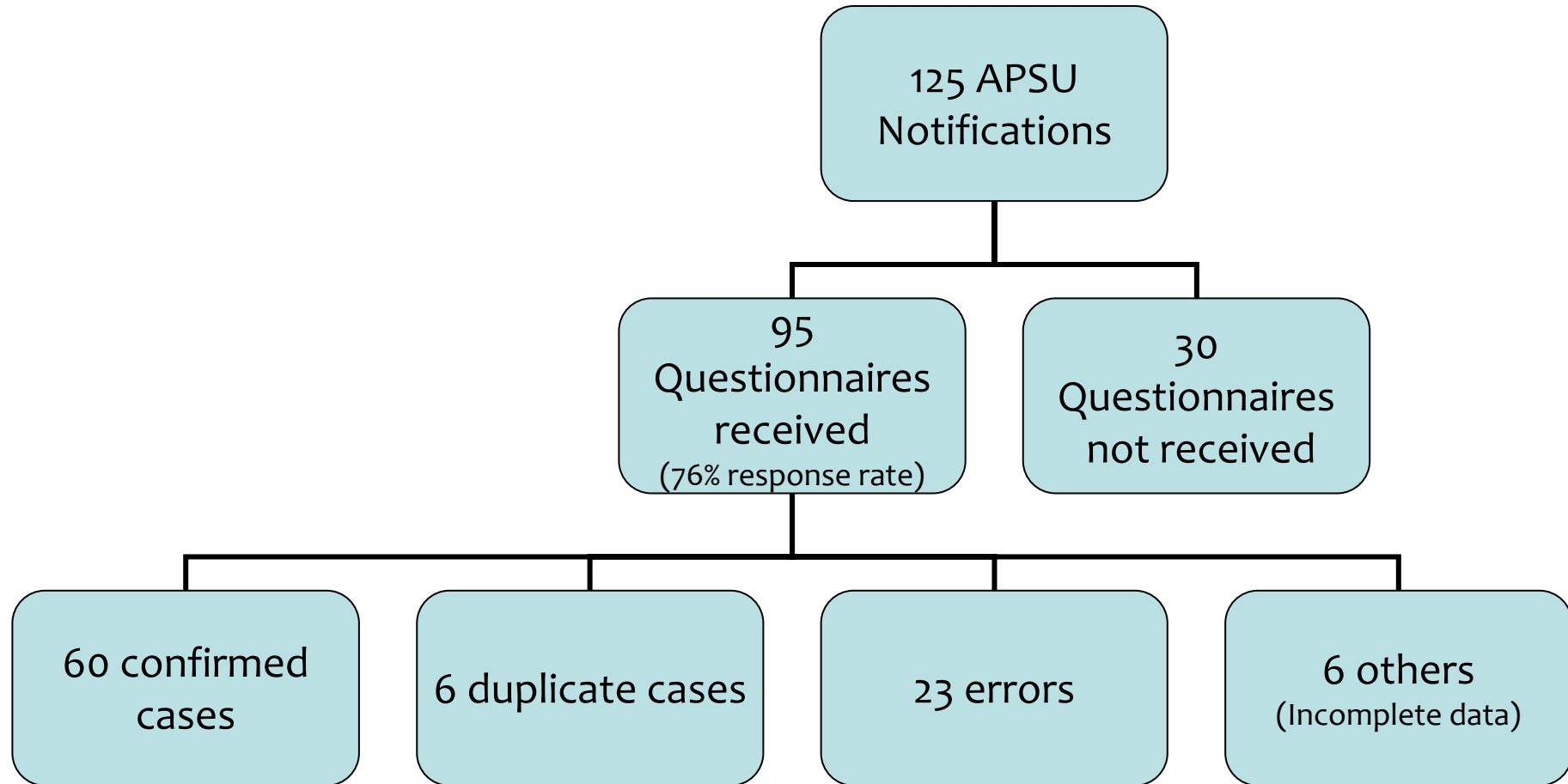
23. Has the patient had any feeding intolerance/food sensitivities? Yes No DK If yes, please describe (eg. egg - rash)

Version 2: 14 June 07

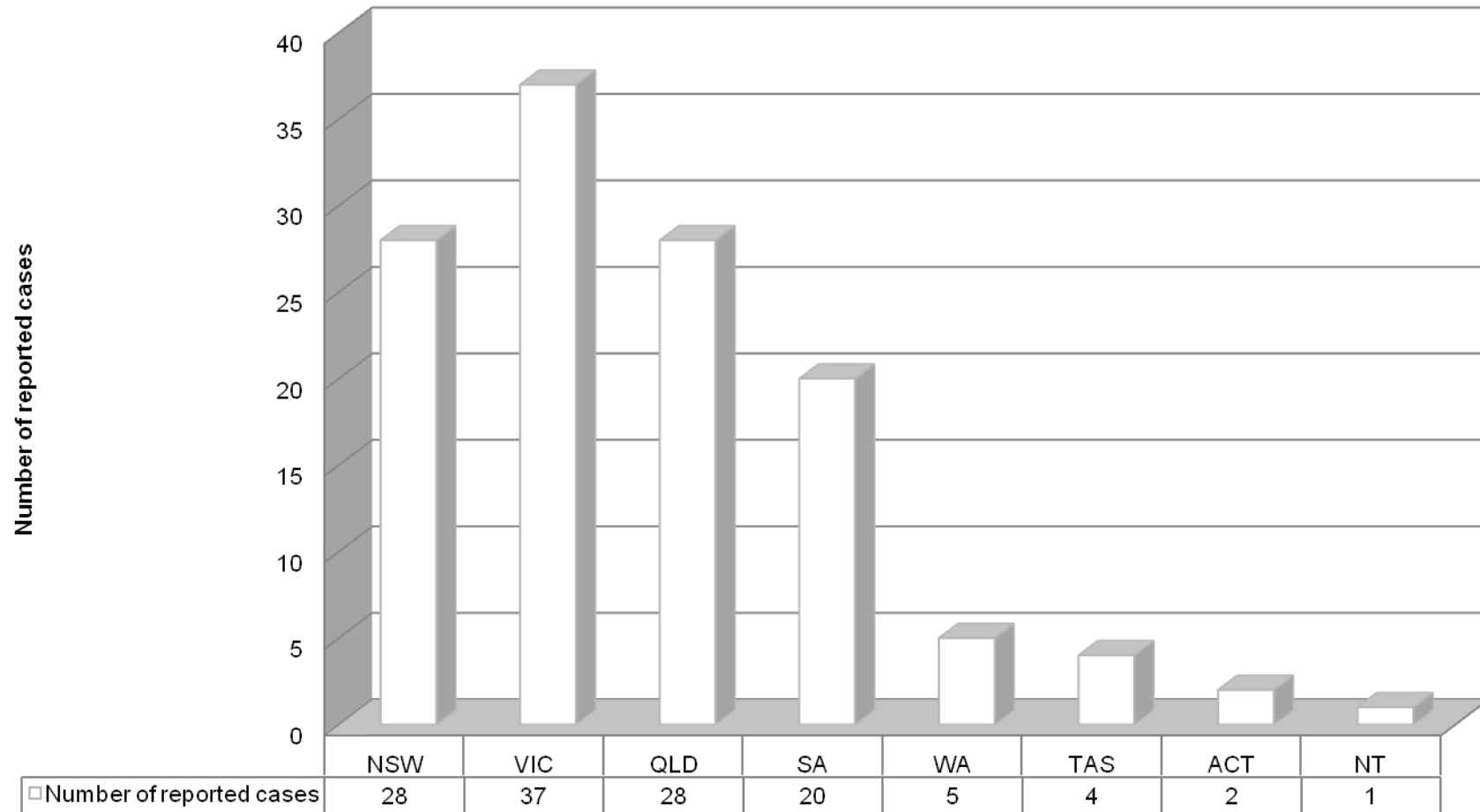
- **Notifications:** Monthly report card/ e-mail sent to Australian paediatricians via the APSU requesting notification
- **Data collection:** Questionnaire data collected to record clinical presentation, diagnosis and management of IS
- **Analysis:** Descriptive statistical analysis conducted using STATA Version 10

APSU Notifications of IS

1st May 2007 to 30th April 2008



State/Territory distribution of reported cases of IS to APSU from 1 May 2007 to 30 April 2008



Preliminary Results:

Clinical Features

Median age 6 months (range 2- 24mths)

37 males/ 23 females

Diagnosis

- 37 (61%) diagnosed using ultrasound

Site & Type IS

- 37 (61%) Ileo-colic/ Ileo-ileo-colic
- 18 (30%) transverse colon & 13 (21%) ascending colon

Symptoms

- 41 (68%) abdominal pain
- 35 (58%) lethargy
- 35 (46%) pallor
- 22 (36%) rectal bleeding

Duration of Symptoms prior Dx

- 15 (25%) <12 hours
- 21 (36%) 12-23 hours
- 16 (27%) 24-48 hours

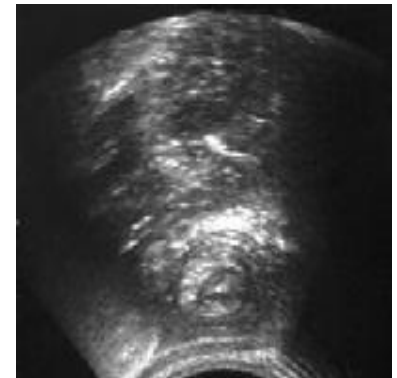
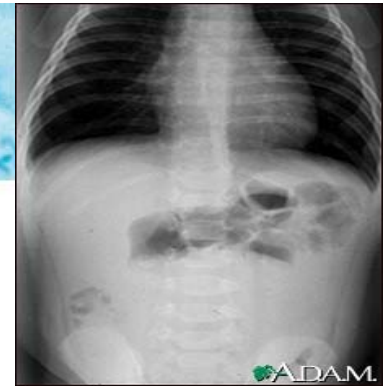
Preliminary Results: Immunisation History



- 45 (75%) of doctors reported patient's immunisations were “up-to-date”
- 6 (10%) received at least 1 dose of rotavirus vaccine 14 days prior to IS episode
 - 4 RotaTeq® (CSL /Merck)
 - 2 Rotarix® (GSK)
- 7 (11%) had received other routine vaccines 14 days prior to IS episode

Preliminary Results: Treatment & Outcomes

- 36 (60%) Air enema reduction
- 22 (36%) Surgical reduction
- Of which;
 - 11 (50%) required bowel resection & 2 (18%) pathological lead point (Meckel's diverticulum)
- All patients discharged alive





Conclusions

- Preliminary data suggests temporal association with rotavirus vaccine and IS in 6 confirmed cases
- Rate of surgical intervention in confirmed cases higher than expected
- Probable under reporting with total of 125 reported cases (only 60 confirmed cases) in 12 months
- Data highlights need for ongoing IS surveillance

Acknowledgements

- Contributors to the APSU
- APSU staff
- **Study Investigators:**
 - Julie Bines
 - Margie Danchin
 - Jim Buttery
 - Yvonne Zurynski
 - Elizabeth Elliott
 - Peter Richmond
 - Viki Krause
 - Heather Cook
 - Sean Beggs
 - Michael Nissen
 - Mike Gold
- Intestinal Failure & Clinical Nutrition Research Group (MCRI)
- Centre Epidemiology & Biostatistics Unit (CEBU)
- Study sponsors: GSK & CSL

References

- Bines, J.E., et al., *Acute intussusception in infants and children as an adverse event following immunization: case definition and guidelines of data collection, analysis, and presentation*. *Vaccine*, 2004. **22**(5-6): p. 569-74.
- Bines, J.E., et al., *Risk factors for intussusception in infants in Vietnam and Australia: adenovirus implicated, but not rotavirus*. *J Pediatr*, 2006. **149**(4): p. 452-60.
- Justice, F., J. Carlin, and J. Bines, *Changing epidemiology of intussusception in Australia*. *J Paediatr Child Health*, 2005. **41**(9-10): p. 475-8.
- Justice, F.A., A.W. Auld, and J.E. Bines, *Intussusception: trends in clinical presentation and management*. *J Gastroenterol Hepatol*, 2006. **21**(5): p. 842-6.
- Justice, F.A., et al., *Accuracy of ultrasonography for the diagnosis of intussusception in infants in Vietnam*. *Pediatr Radiol*, 2007. **37**(2): p. 195-9.
- Murphy, T.V., et al., *Intussusception among infants given an oral rotavirus vaccine*. *N Engl J Med*, 2001. **344**(8): p. 564-72.
- Peter, G. and M.G. Myers, *Intussusception, rotavirus, and oral vaccines: summary of a workshop*. *Pediatrics*, 2002. **110**(6): p. e67.
- Simonsen, L., et al., *More on RotaShield and intussusception: the role of age at the time of vaccination*. *J Infect Dis*, 2005. 192 Suppl 1: p. S36-43.