

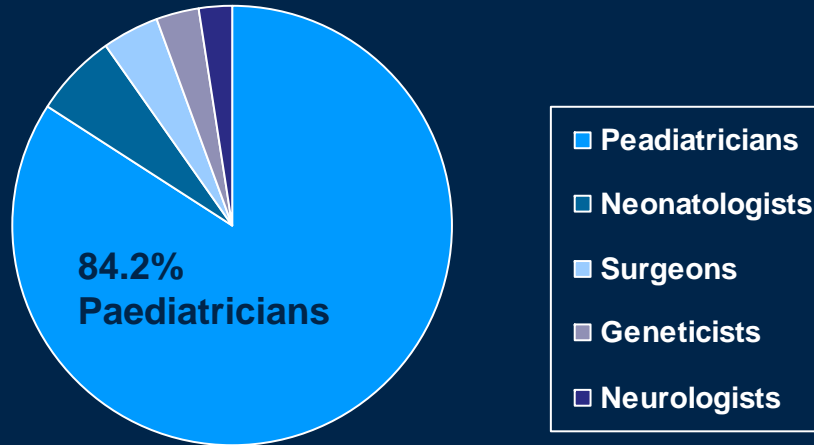
So, You want to do an APSU study? Procedures and Pitfalls

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Australian Paediatric Surveillance Unit



APSU system basics



- Reporting by ~ 1250 clinicians
- Estimated 93% of all Fellows in Paediatrics and Child Health practicing in Australia report to the APSU
- Active monthly reporting
- Up to 16 conditions

PLEASE RETURN THIS CARD EVERY MONTH
EVEN IF YOU HAVE NOTHING TO REPORT

APSU REPORT CARD **AUGUST 2005A**

NOTHING TO REPORT: (Please tick box)

CASE TO REPORT: (Write no. of cases in space below)

- Neonatal/Infant Group B Streptococcal Sepsis
- Hyperinsulinaemic hypoglycaemia of infancy
- Non Tuberculous Mycobacterial Infection
- Haemoglobinopathies (excluding carrier states)
- Hepatitis C virus infection
- RETT syndrome
- Congenital cytomegalovirus infection[#]
- Neonatal herpes simplex virus infection
- Acute flaccid paralysis ^{+#}
- HIV/AIDS/Perinatal exposure to HIV
- Vitamin K deficiency bleeding (includes haemorrhagic disease of the newborn)
- Congenital rubella

[#]See your protocol sheet for details regarding stool/serum specimens.

+Acute flaccid paralysis includes wild and vaccine acquired poliomyelitis, Guillain-Barre, transverse myelitis, traumatic paralysis etc. Please ALSO report cases of Acute flaccid paralysis immediately by telephone to the Polio Laboratory on (03) 9342 2607/3.

**IF YOU REPORT A CASE PLEASE RECORD PATIENT
DETAILS IN YOUR BLUE APSU FOLDER FOR LATER
REFERENCE**

What kinds of conditions can be studied?

- Rare conditions of childhood
- Rare complications of conditions

Why rare conditions?

Few national data available – high impact

Avoids duplication with other schemes

Workload – Clinicians
- Investigators
- APSU

How rare is rare?

- Rule of thumb: 1 in 100,000 incidence in a population under the age of 15 (Neonate to 15 years old)
- Incidence rates per annum for APSU studies ~0.5 to ~10 per 100,000
- More common conditions - short period of surveillance
- Newly diagnosed (incident) cases



What research questions can be answered?

Reporting rate: estimate of incidence


Questionnaire (enhanced data not just numbers)

- Epidemiology
- Known risk factors
- Current diagnostic practice
- Current management practice
- Short-term outcome
- Trends

Limitations

- underreporting / under-ascertainment of cases
- poor coverage of Indigenous and refugee children
- biological specimens

Who can apply to the APSU?

- Any team of researchers / clinicians
 - Need to have appropriate expertise
 - Methodology
 - Condition
 - Representation from each state
 - APSU representative
 - Young/New investigators encouraged
- 

Who decides?

APSU Scientific Review Panel (SRP)

Independent

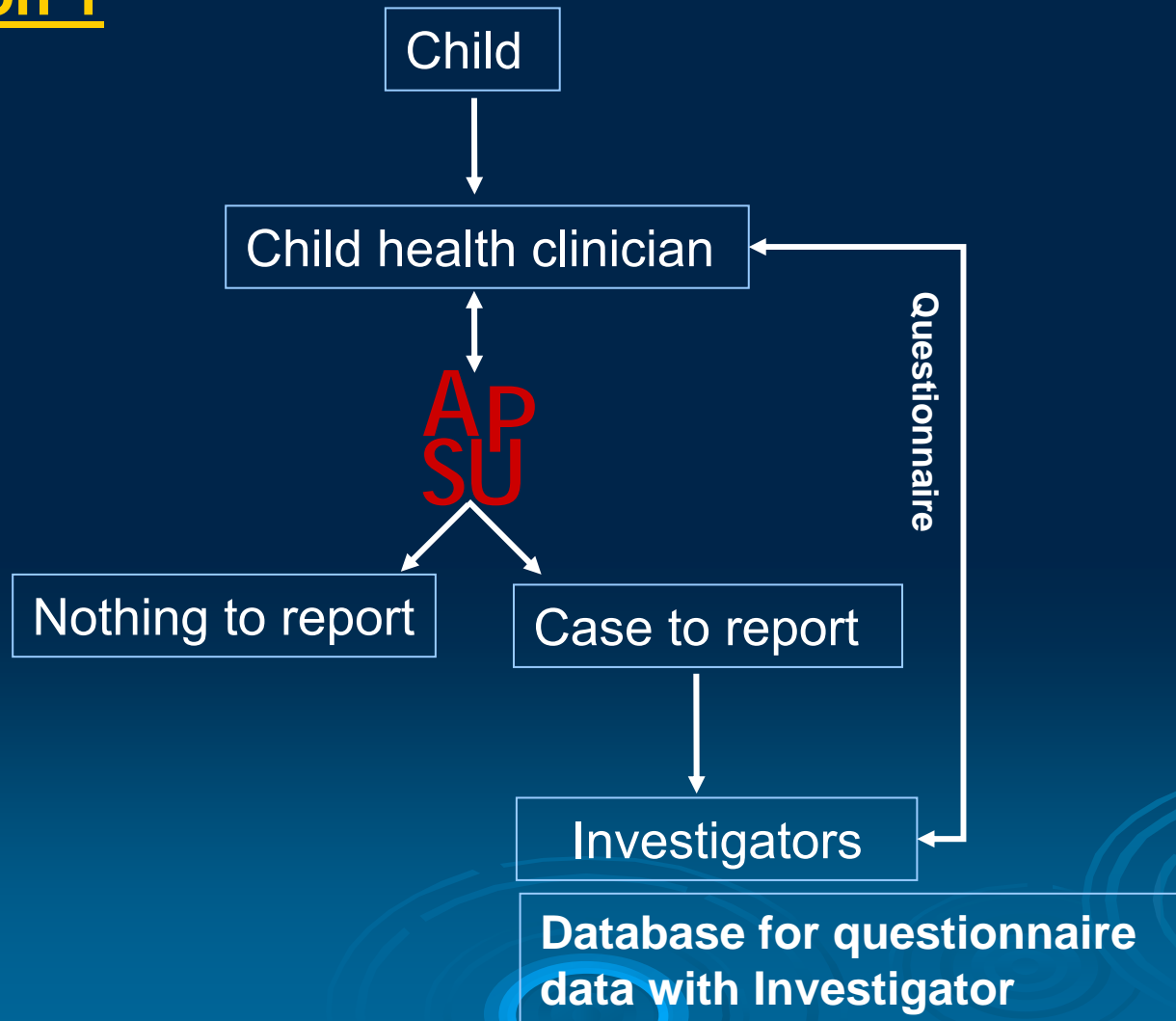
- Epidemiologist
- Clinicians in active clinical practice
- Child health research specialists

APSU director and deputy director



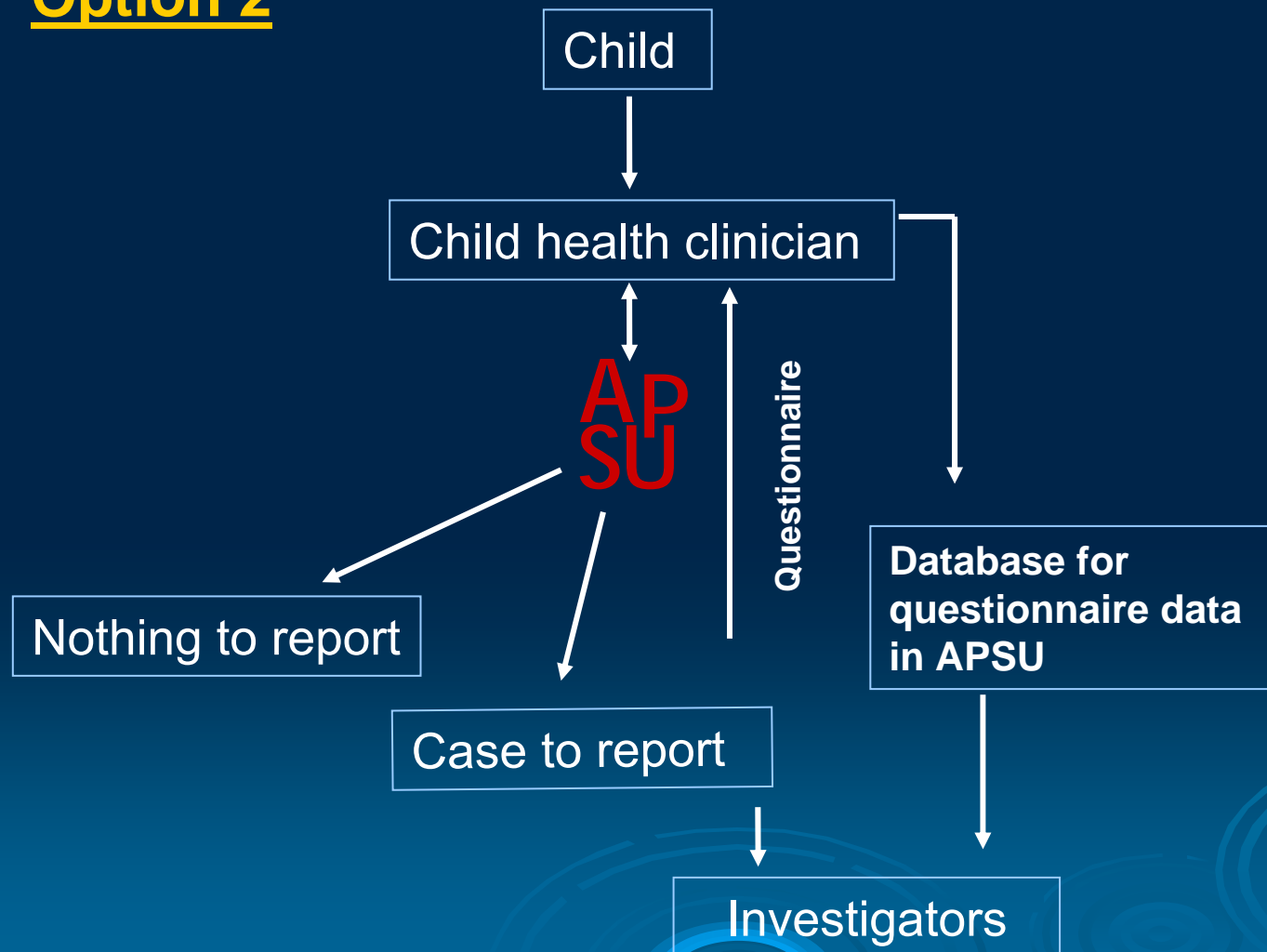
How does it all work?

Option 1



How does it all work?

Option 2



How much does it cost?

Option 1: \$10,000 +GST per annum

Investigator group does the questionnaire data collection

Option 2: \$20,000 +GST per annum

All inclusive option – APSU does the questionnaire data collection; data entry; some analysis

Ethics

- Chief investigator takes responsibility for ethics approval
- Other investigators should provide local committee with approval documents
- Data has minimal identifiers
- Patients / parent is approached by the treating clinician
- No need for multiple applications to multiple institutions (AHEC, NHMRC)

Application Process

Expression of Interest Form

1 page
quick turn around

Full application

~ 5-6 pages long
Draft questionnaire
Formal meeting of the SRP

The process takes about 6 months

Need help? Contact APSU



What do I need to provide in my application?

Achievable aims

Rationale - brief literature review

Clear case definition

Draft questionnaire

Additional sources of ascertaining cases

APSU personnel get involved in the development



What happens when study approved?

- APSU Investigator agreement signed
- Annual fee payed
- Protocol and Questionnaires are distributed to all ~1250 clinicians
- Condition added to the card
- Surveillance starts
- Investigators are notified weekly of number of cases reported

Potential for International Collaboration

➤ International Network of Paediatric Surveillance Units (INOPSU)

- Britain, Canada, NZ – common collaborators
- Shared protocols and methodology
- Concurrent surveillance
- Geographical differences



Representatives of the 14 INOPSU units,
INOPSU Conference London 2006

Pitfalls:

You don't know what you don't know

Number of cases much lower than predicted

- Key informants not included on the APSU database
- Poor publicity / advocacy by research team
- Case definition too narrow
- Incidence much lower than predicted

Number of cases much higher than predicted

- Incidence much higher than predicted
- Certain sub-specialists or clinics see great numbers
- Case definition too wide

➤ Case definition (eg)

Too wide

- Report all children aged ≤ 15 yrs with Vitamin D deficiency

Too narrow


- Report all children aged ≤ 15 yrs with seizures due to Vitamin D deficiency

Just right (or close to !)

- Report all children aged ≤ 15 yrs newly diagnosed with rickets secondary to simple Vitamin D deficiency confirmed biochemically and/or radiologically.
- Biochemical criteria: low 25-hydroxy vitamin D, AND elevated alkaline phosphatase

Pitfalls

Case reports declining over time

- Changes in investigators group
 - Lack of communication among investigators
 - Key informants
 - Change in diagnostic criteria / policy – need to change case definition?
 - Publicity
 - Publications / presentations
- 

Do I have to publish my findings?

YES!

- Peer review journals including J Paed and Child Health
- APSU Bi-annual report
- CDI – infectious / vaccine preventable diseases
- Regular APSU newsletters

In the publication

- acknowledge the APSU and its funders
- acknowledge clinicians by including in the author list, “contributors to the APSU”
- consider acknowledging by name, individual clinicians who notify cases to this study

Have an idea? Then contact us

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