



Can congenital CMV screening be integrated into an existing newborn hearing screening program?

Results of a pilot study in Queensland.

# BEST Q Research Team

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- Principal researcher: Dr Rachael Beswick, Healthy Hearing team co-ordinator
- Associate researchers:
  - Ms Delene Thomas, Screening Area Co-ordinator (Central)
  - Dr Michael David, Biostatistician
  - Dr Clare Nouse, Paediatric Infection Specialist
  - Dr Alison Harris, Community Paediatrician
  - Dr Karen Liddle, Paediatrician
  - Dr Luke Jardine, Neonatologist
  - Dr Pieter Koorts, Neonatologist
  - Dr Guan Koh, Neonatologist
  - Mrs Jayne Hegarty, Screening Area Co-ordinator (Southern)
  - Mrs Marissa Edmondson, Screening Area Co-ordinator (Northern)

# Background: Clinical Impacts of cCMV



- Congenital cytomegalovirus (cCMV) is the most common congenital infection in humans, affecting approximately 1% of all live births
- It is **not rare**
- Presents as flu like symptoms in adults – no treatment
- Potential problems occur during pregnancy – **crosses placenta**
- cCMV is recognised as the most common **preventable** infective cause of sensorineural hearing loss in children



# Background: Clinical Impacts of cCMV



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Congenital CMV

15% Symptomatic

85% Asymptomatic

50% SNHL

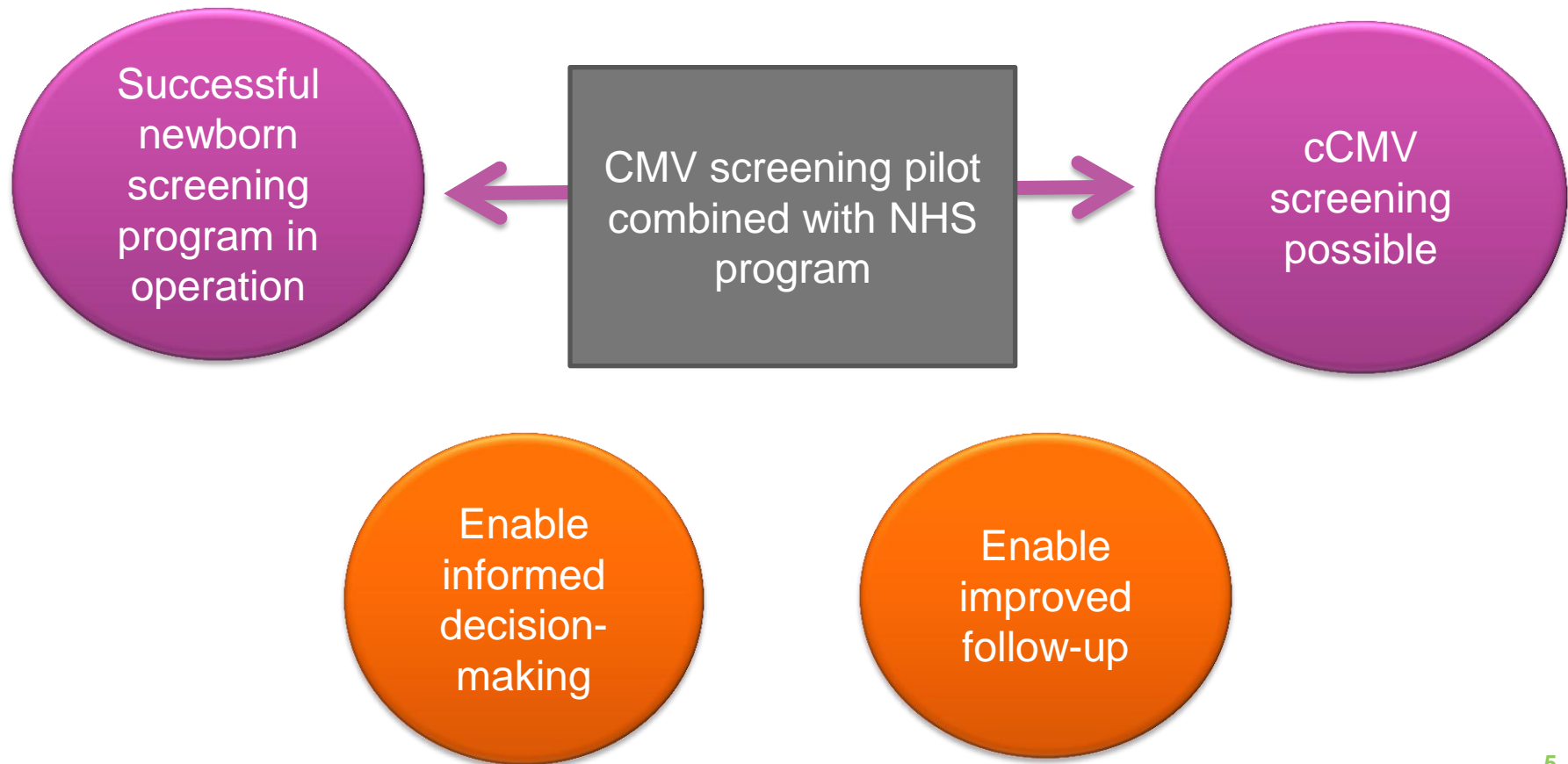
7-15% SNHL



Treatment options are available if detected <28 days

# Rationale for cCMV screening trial

cCMV is common



# The BEST Q Pilot Study: The Benefits of Extended Screening Testing

**AIM:** to investigate the feasibility of targeted salivary cCMV testing in Queensland for infants who are referred to audiology for further assessment, following a 'refer' result on the second newborn hearing screen.

1. Is it feasible to complete the second hearing screen <21 days of age?

2. Is it feasible for salivary cCMV testing to be completed < 21 days of age for infants who refer?

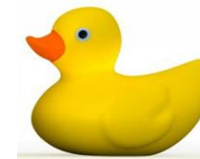
3. Can >95% of newborns who test positive for cCMV have an audiology diagnosis by 28 days old?

4. Can >95% of infants with a positive cCMV result be reviewed by an infectious diseases consultant by 28 days old, and treated if appropriate?

5. What is the prevalence of cCMV in infants who refer on the newborn hearing screen and are subsequently diagnosed with a hearing impairment?

6. What are the cost benefits of targeted cCMV screening and treatment?

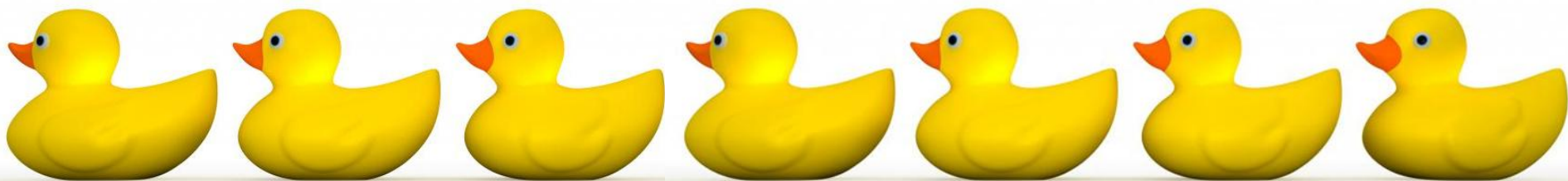
# CMV project – get your ducks in a row Time is everything!!!!



Medically stable  
Meets screening  
eligibility

**BIRTH**

**BY 21 DAYS  
OF LIFE**



# Action plan by 21 days of life



- Infants '**referred**' after newborn hearing AABR2 screening will be offered a salivary swab at the point of referral to audiological services



- **Informed written** consent for the swab will be taken by the Healthy Hearing nurse screener. Attend specific workshop



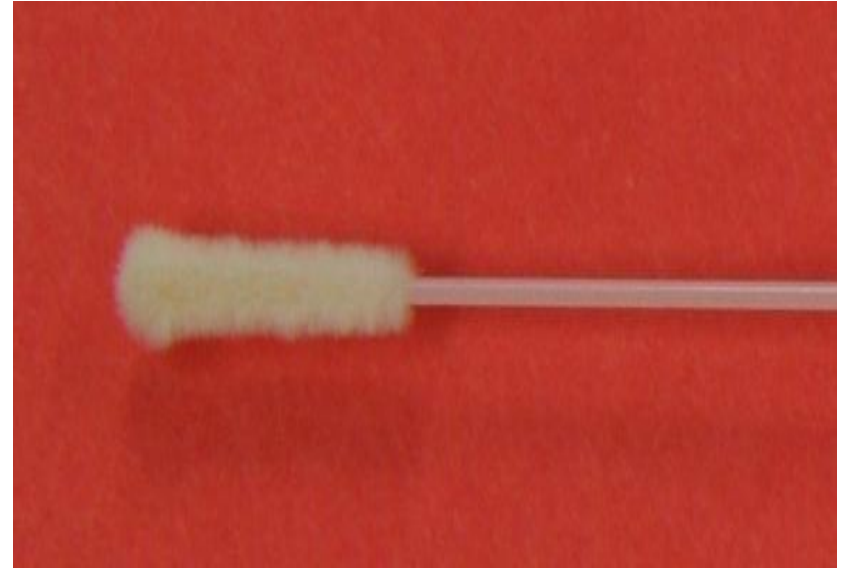
- The screener will take a sample of saliva using a specific **COPAN swab** (not cotton tipped)



- Swabs will be routinely processed and tested for **CMV DNA** by PCR within Pathology Queensland labs



## Development of resources



Wait 1 hour post breast feed, swab insitu for 60 seconds



# CMV project – get your ducks in a row

## Time is everything!!!!

Medically stable  
Meets screening  
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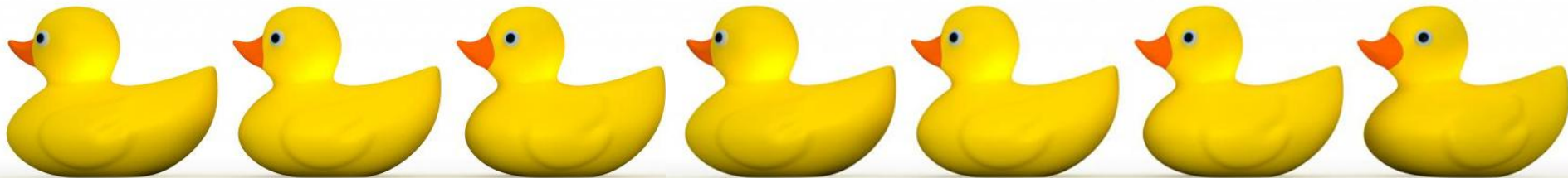
**BIRTH**



**BY 21 DAYS  
OF LIFE**



**BY 28  
DAYS OF  
LIFE**





# Action plan by 28 days of life



- Babies with **positive CMV** saliva results will be **fast tracked to Audiology** for immediate, urgent hearing assessment



- Following a positive result, the **Infectious Diseases Consultant** will discuss treatment options with the family . If treatment is agreed, oral **Valganciclovir** syrup is given for 6 weeks (or 6 months). The baby will be monitored during the drug treatment period



- Negative saliva results will be **notified by letter** to families and GP's within 10 days of the specimen result by the Healthy Hearing team in Brisbane

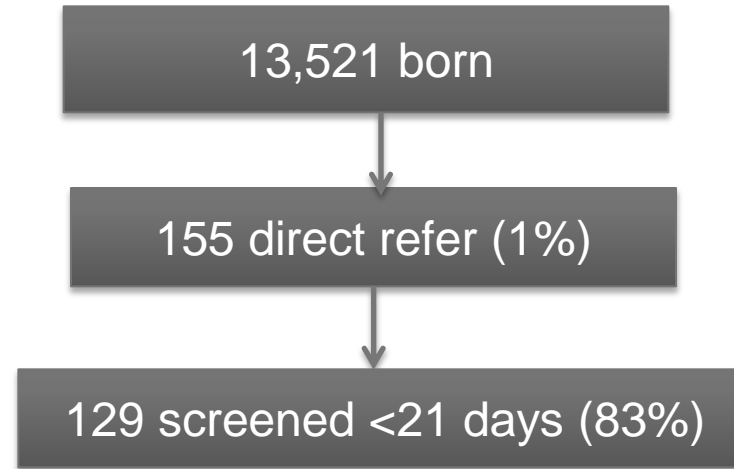


- Saliva swabs will be **disposed** by Pathology as per usual protocol (3 – 12 months)



- **Trigger dates:** **< 21 days** for saliva swab, **< 28 days** for Audiology, Infectious Diseases review and commencement of antiviral medication

## BEST Q – Preliminary results launched 25<sup>th</sup> August at TTH, RBWH, Mater

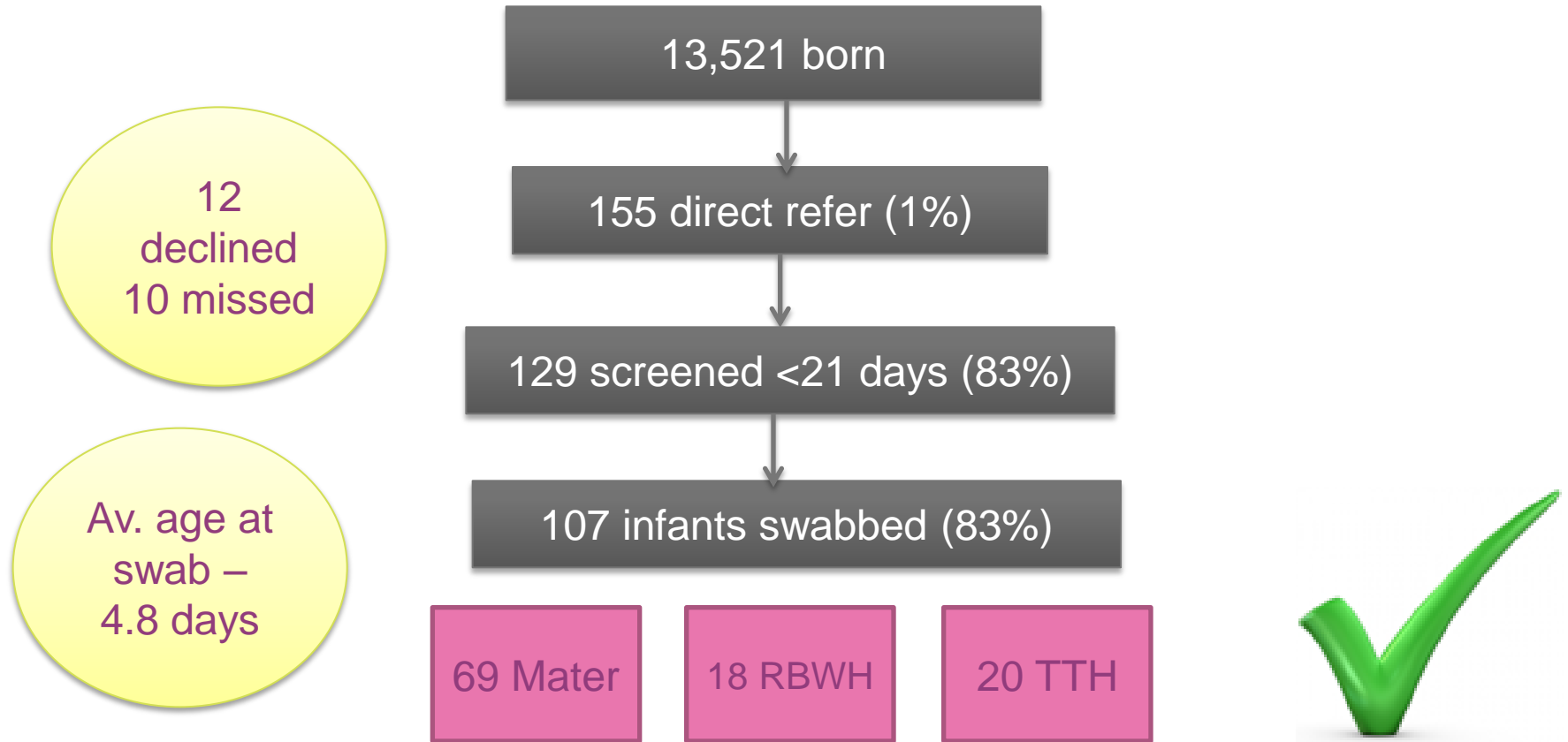


1. Is it feasible to complete the second hearing screen <21 days of age?



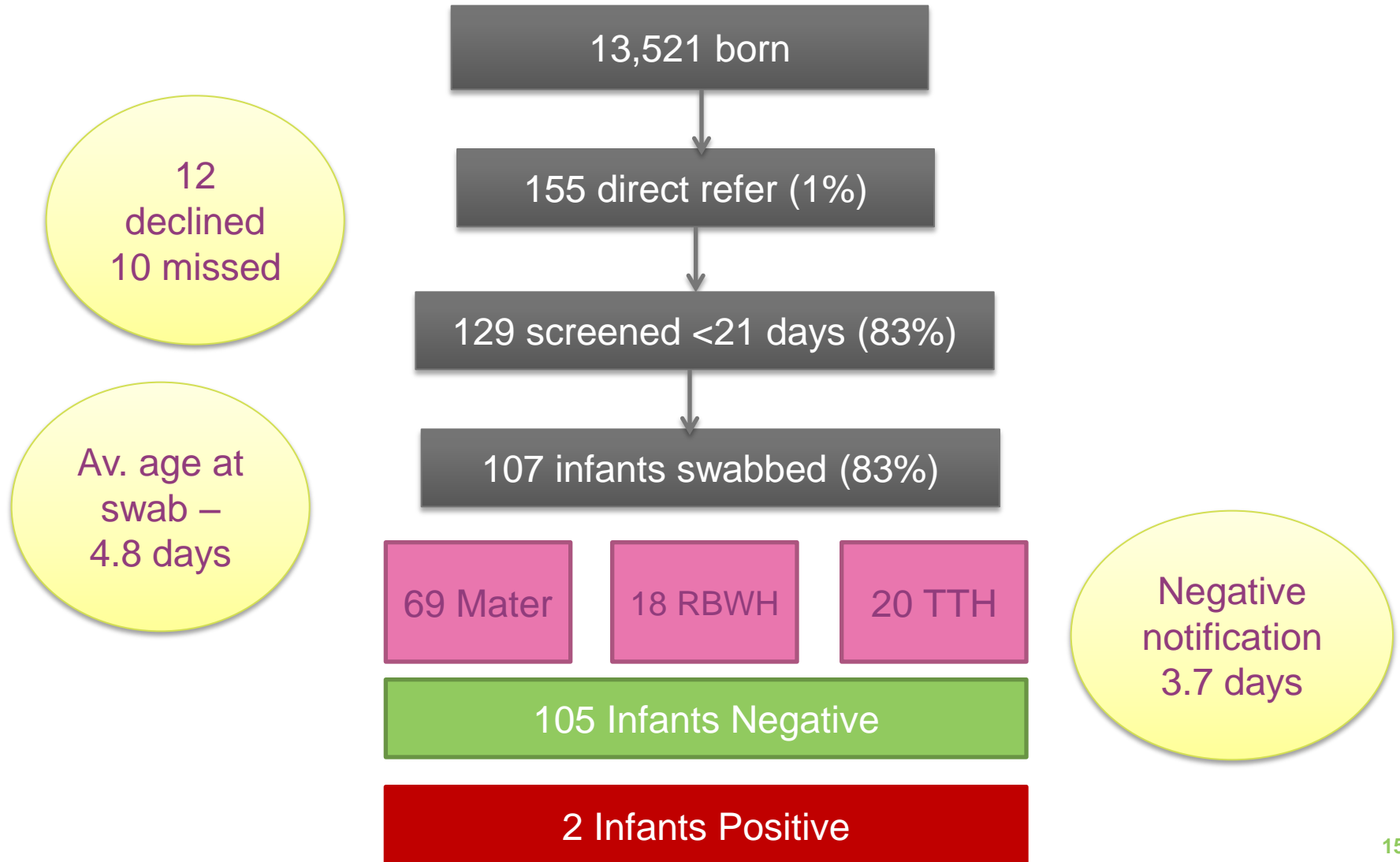


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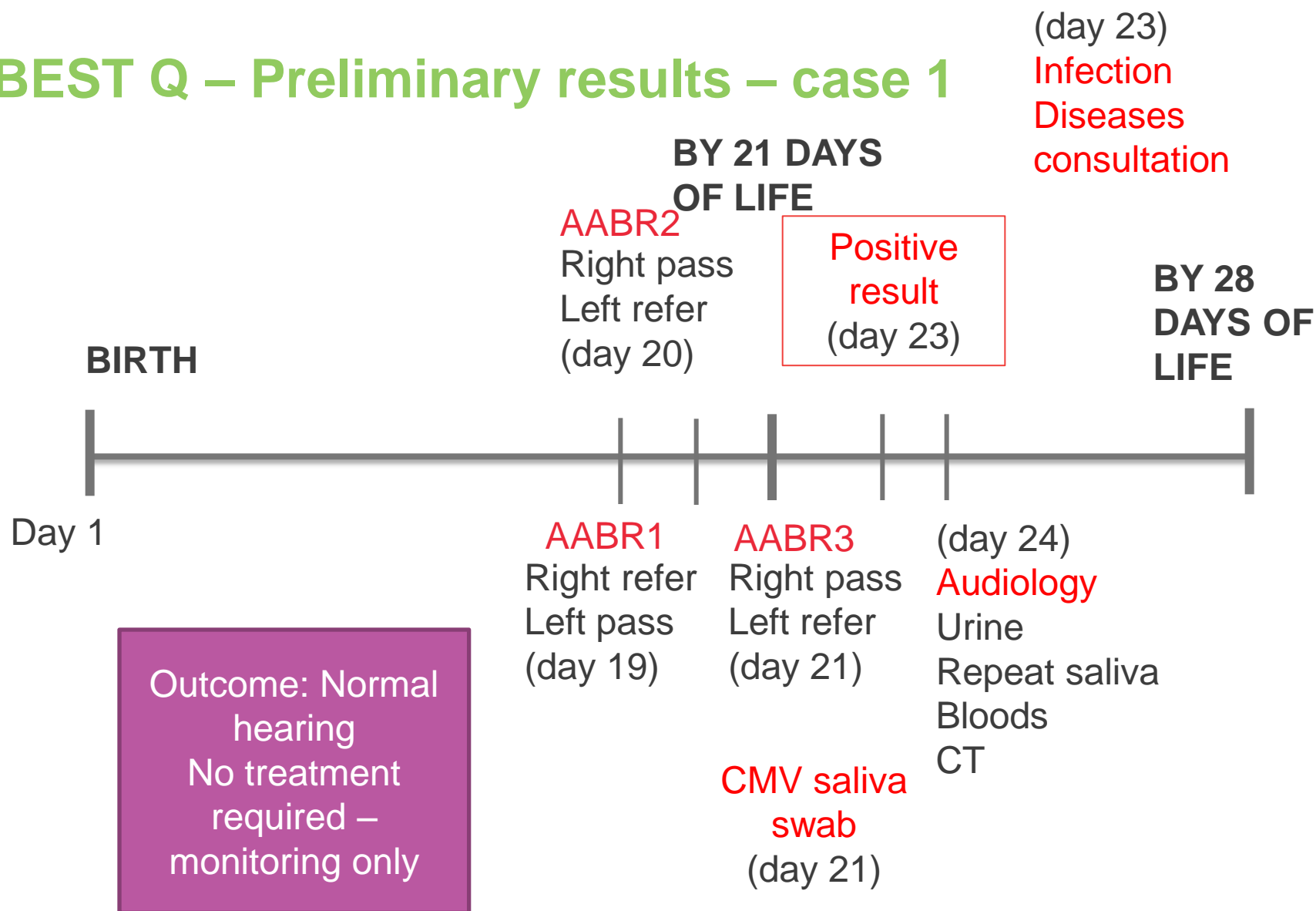


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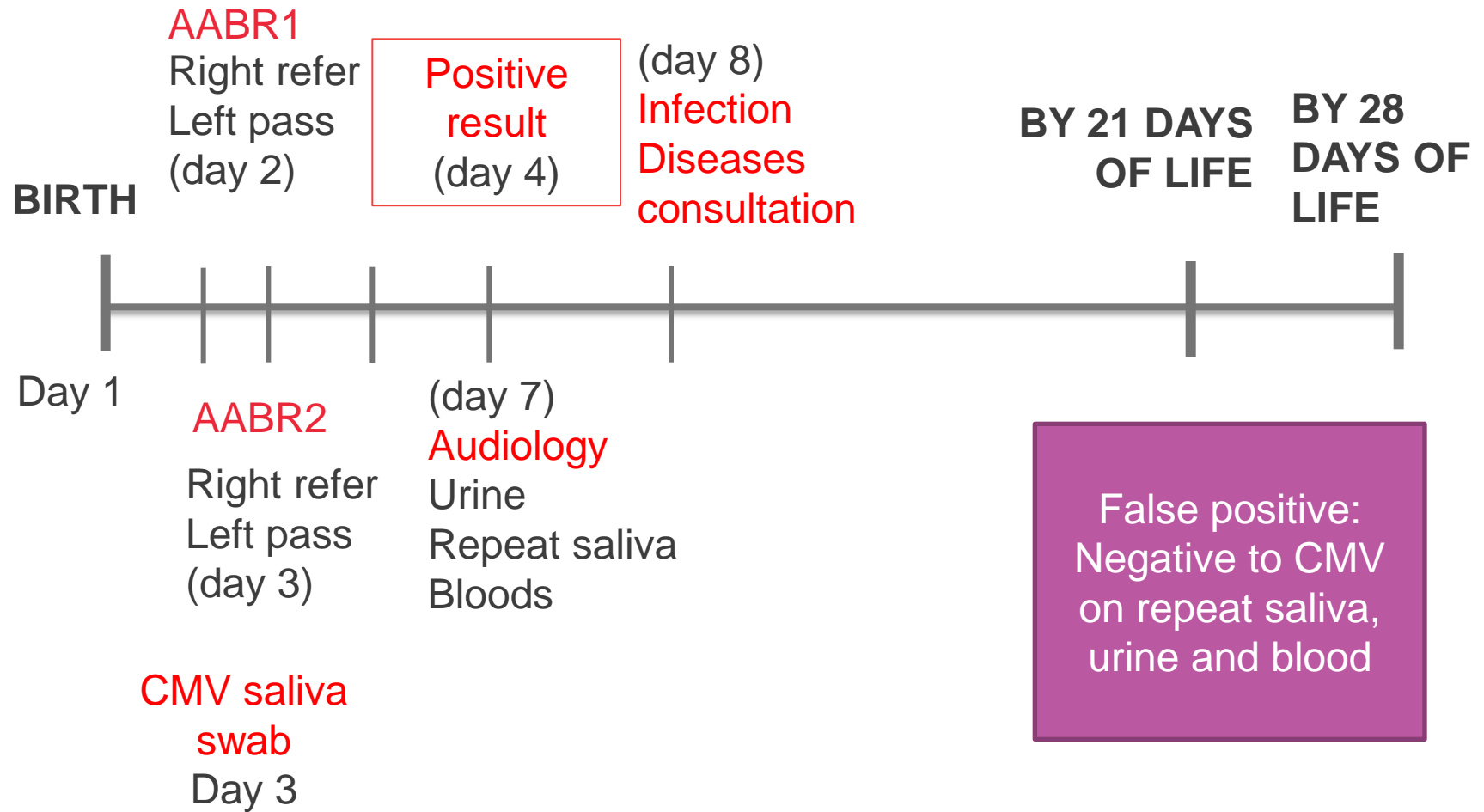
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# BEST Q – Preliminary results – case 1



## BEST Q – Preliminary results – case 2



## BEST Q – Preliminary results

3. Can >95% of newborns who test positive for cCMV have an audiology diagnosis by 28 days old?



4. Can >95% of infants with a positive cCMV result be reviewed by an infectious diseases consultant by 28 days old, and treated if appropriate?





## Future Directions

- Complete trial (Expand to other non-tertiary hospitals?)
  - Since 25<sup>th</sup> August 11 cCMV positives in QLD outside of the study
- Answer research questions including:

5. What is the prevalence of cCMV in infants who refer on the newborn hearing screen and are subsequently diagnosed with a hearing impairment?

6. What are the cost benefits of targeted cCMV screening and treatment?

# Future Directions

If proven successful and cost effective then cCMV screening will be rolled-out statewide alongside the newborn hearing screening program.



## Can congenital CMV screening be integrated into an existing newborn hearing screening program?

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