Group B Strep Support

Meningitis Research Foundation

# Neonatal unit experience:

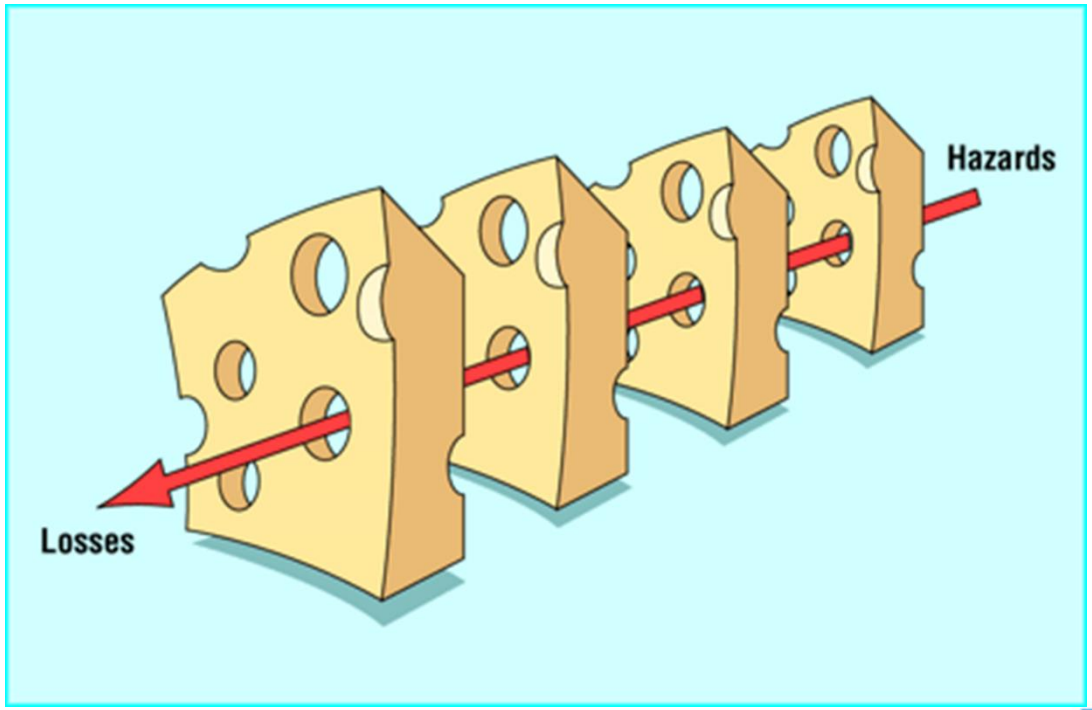
*Dr Richard Nicholl,  Consultant Neonatologist, NWLH NHS Trust*

# can error be prevented?

- limit the incidence
- create systems that will tolerate/contain errors: person, team, task, workplace, institution as whole

# Swiss cheese model: how defences are penetrated

(Reason J,BMJ)



# can error be prevented?

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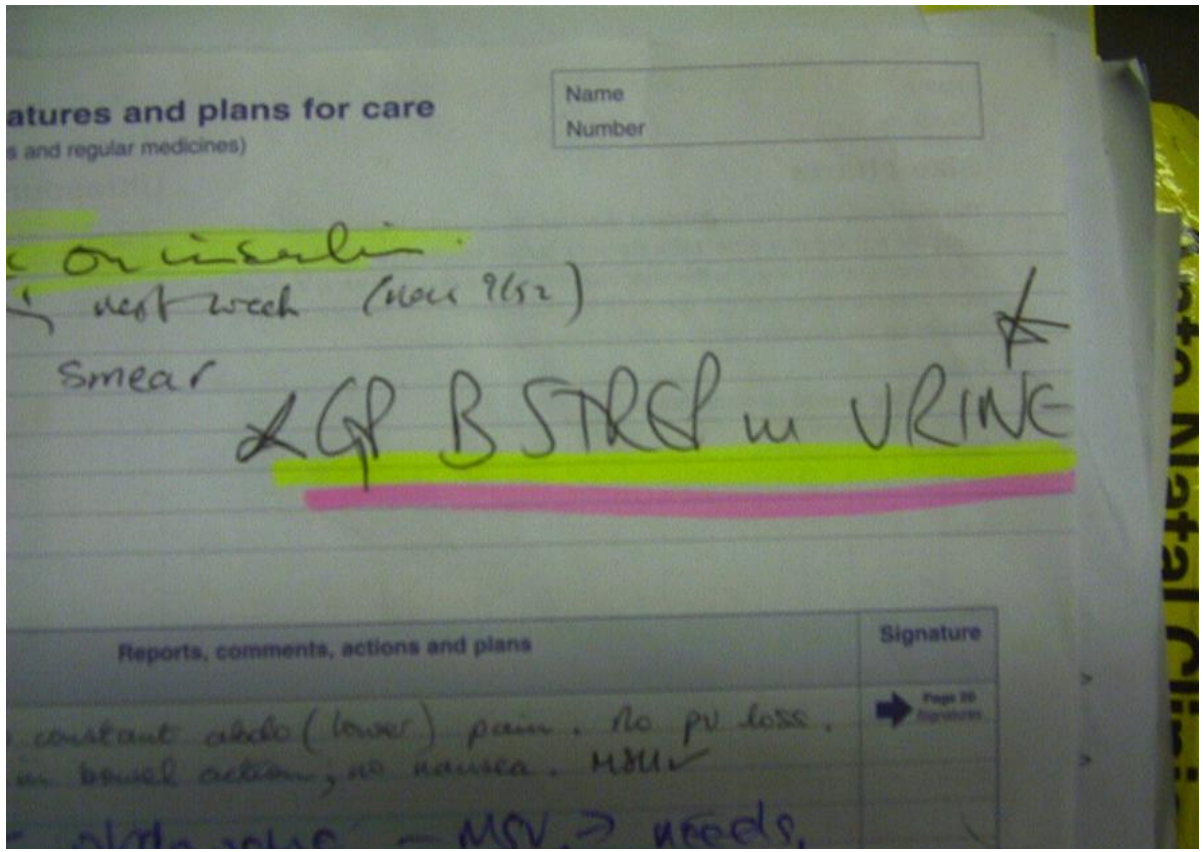
Risk factors for early onset neonatal group B streptococcal sepsis: case-control study
BMJ Aug 2002; 325: 308

- Risk factors: odds ratio ( 95% CI)
- Preterm <37w: 10.4 ( 4-28)
- <34w ; 34 ( 4- 283)
- RoM >18hrs: 25.8 (10-65)
- RoM prelabour : 11 ( 5-26)
- Intrapartum fever: 10 (2-41)

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# Safeguards: different layers

- engineered: alarms, physical barriers
- people: surgeon, physician, nurse
- procedures/admin.

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# Impact on congenital pneumonia and early onset sepsis in neonates*:*

*Dr Reshmi Raychaudhuri, NWLH NHS Trust*

# CONGENITAL PNEUMONIA AND EARLY ONSET NEONATAL SEPSIS AT NORTHWICK PARK HOSPITAL

## HAS OUR GBS SCREENING PROGRAMME MADE A DIFFERENCE?

Dr Reshmi Raychaudhuri, Dr P. Mainie, P. Bassett, Dr G. Rao

3rd November 2015

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# Introduction

- Congenital pneumonia (CP) and early onset sepsis (EOS) are important causes of neonatal morbidity and mortality
- GBS infection is the commonest cause of EOS
- Early onset Group B Streptococcal (EOGBS) infection most frequently presents with sepsis and pneumonia
- Intrapartum antibiotic prophylaxis (IAP) of maternal GBS carriers has reduced the incidence of invasive EOGBS infection in many countries

# Background

- UK incidence of culture-proven EOGBS infection: 0.38 cases per 1000 live births in 2013 (PHE)
- Prospective UK data collected over 1 year for neonates who required a septic screen in the first 72 h of life indicated a combined rate of definite and probable EOGBS infection of **3·6 per 1000 live births***
- This estimate indicates a much greater disease burden in the UK than that suggested by figures of culture-proven sepsis, and lends support to the need for prevention strategies *

***Estimated early-onset group B streptococcal neonatal disease***

*Suzanne Luck, Michael Torny, Katrina d'Agapeyeff, Alison Pitt, Paul Heath, Aoadhan Breathnach, Alison Bedford Russell. Lancet. 2003 Jun 7;361(9373):1953-4*

# Hypothesis

Universal maternal GBS screening + intrapartum antibiotics will reduce the incidence of not only invasive EOGBS, but also early onset neonatal sepsis and congenital pneumonia

# Objective

To review the number of cases of CP and EOS pre and post the introduction of universal maternal GBS screening in March 2014

# Methods

- Search criteria
  - All cases with a diagnosis of ‘sepsis’, ‘sepsis suspected’, ‘sepsis – presumed’, ‘unwell with negative microbiology’, ‘GBS sepsis’ or ‘congenital pneumonia’ on Badgernet (electronic neonatal database)

- Review of electronic and paper case notes of neonatal admissions from March 2011- April 2015

# Inclusion criteria

- Born at NPH after March 2011 and admitted to NNU
- ≥35 weeks gestation
- Cases meeting criteria for EOS and CP

# Case definitions of EOS and CP

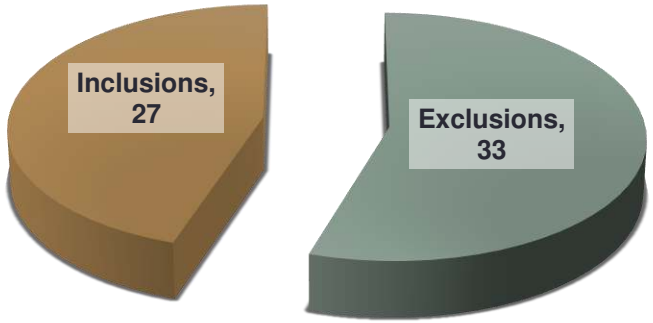
- EMEA definition of EOS
  - 2 clinical and 2 laboratory criteria in the presence of suspected or culture-proven sepsis (with onset <72h)

***European Medicines Agency Expert meeting on Neonatal and Paediatric Sepsis**, London, June 2010*

- CP defined as signs of respiratory distress + abnormal WCC/CRP + CXR changes consistent with infection

***Transient tachypnea of the newborn and congenital pneumonia: a comparative study.** Sandra Costa, Gustavo Rocha, Andreia Leitão & Hercília Guimarães. The Journal of Maternal-Fetal and Neonatal Medicine, 2012; 25(7): 992–994*

# Total infections (EOS + CP)

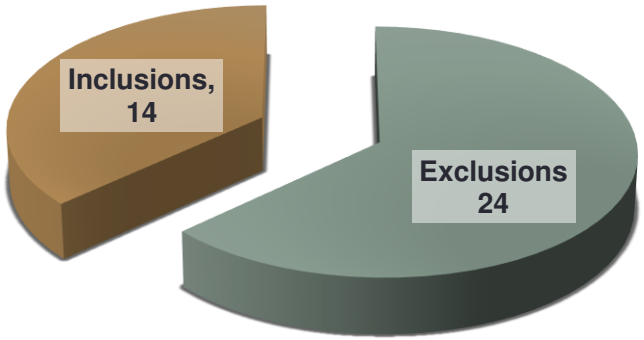



**n = 60**

*Screening*

| | Apr 2011-Mar 2012 | Apr 2012-Mar 2013 | Apr 2013-Feb 2014 | Apr 2014-Mar 2015 |
|---|---|---|---|---|
| **Cases identified** | 20 | 14 | 19 | 7 |
| **Exclusions** | 10 | 6 | 13 | 4 |
| **Total infections** | **10** | **8** | **6** | **3** |
| **Total infections/ 1000 live births** | **1.93** | **1.54** | **1.33** | **0.63** |

# Early Onset Sepsis (EOS)




**n = 38**

*Screening*

| | Apr 2011-Mar 2012 | Apr 2012-Mar 2013 | Apr 2013-Feb 2014 | Apr 2014-Mar 2015 |
|---|---|---|---|---|
| **Cases identified** | 14 | 2 | 15 | 7 |
| **Exclusions** | 8 | 1 | 11 | 4 |
| **EOS cases** | **6** | **1** | **4** | **3*** |
| **EOS cases / 1000 live births** | **1.16** | **0.19** | **0.89** | **0.62** |

*1 mother was GBS colonised and received adequate IAP

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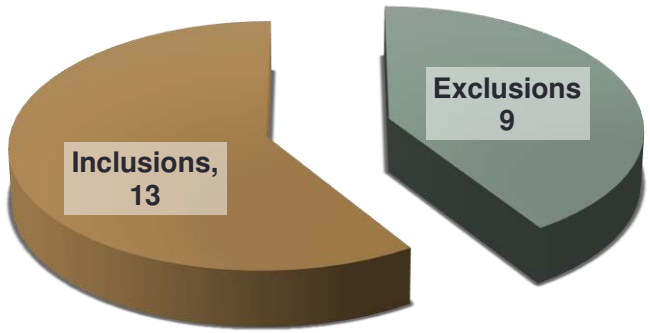
# Congenital pneumonia (CP)




**n = 22**

*Screening*

| | Apr 2011-Mar 2012 | Apr 2012-Mar 2013 | Apr 2013-Feb 2014 | Apr 2014-Mar 2015 |
|---|---|---|---|---|
| **Cases identified** | 6 | 12 | 4 | 0 |
| **Exclusions** | 2 | 5 | 2 | 0 |
| **CP cases** | **4** | **7*** | **2** | **0** |
| **CP cases/1000 live births** | **0.77** | **1.35** | **0.44** | **0** |

*2 babies GBS surface swab positive

# The impact of screening so far

| Category | Pre-screening rate (Apr 2011-Feb 2014) | Post-screening rate (Apr 2014-Mar 2015) | Ratio (95% CI) * | p-value |
|---|---|---|---|---|
| **Total infections** | 1.61 | 0.63 | 0.39 (0.12, 1.29) | 0.12 |
| **EOS** | 0.74 | 0.63 | 0.85 (0.24, 3.03) | 0.8 |
| **CP** | 0.87 | 0 | 0.11 (0.01, 1.79) | 0.12 |

*(*) Calculated as post-screening rate/ pre-screening rate*

# Discussion

- The introduction of universal maternal GBS screening was associated with a reduction in the number of cases of EOS and CP
- No cases of CP so far post introduction of screening
- Rates of reduction not statistically significant
  - Small numbers
  - Only 11 months of post-screening data
- Confounding factors?

# Conclusion

- Bradford Hill criteria for causation
  - Temporal association
  - Biological plausibility
  - Coherence

*Sir Austin Bradford Hill, 1897 - 1991*

- Preliminary data lacking power and statistical significance
- Further studies are necessary to confirm our observations
- Ongoing data collection in progress

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# Acknowledgements

Peter Kilian, Data administrator. Neonatal Unit, Northwick Park Hospital

Eileen Earls, Administrator. Neonatal Unit, Northwick Park Hospital

# THANK YOU

**Table 1.** Clinical and laboratory criteria for inclusion in neonatal sepsis clinical trials defined by the EMA

| Clinical signs | Laboratory signs |
|---|---|
| **Modified body temperature:**<br>• core temperature >38.5°C or <36°C **AND/OR**<br>• temperature instability<br><br>**Cardiovascular instability:**<br>• bradycardia [mean HR <10th percentile for age in the absence of external vagal stimulus, β-blockers or congenital heart disease **OR** otherwise unexplained persistent depression over a 0.5–4 h time period] **OR**<br>• tachycardia [mean HR >2 SD above normal for age in the absence of external stimulus, chronic unexplained persistent elevation over a 0.5–4 h time period] **AND/OR**<br>• rhythm instability<br>• reduced urinary output (<1 mL/kg/h)<br>• hypotension (mean arterial pressure <5th percentile for age)<br>• mottled skin<br>• impaired peripheral perfusion<br><br>**Skin and subcutaneous lesions:**<br>• petechial rash<br>• sclerema<br><br>**Respiratory instability:**<br>• apnoea episodes **OR**<br>• tachypnoea episodes (mean respiratory rate over 2 SD above normal for age) **OR**<br>• increased oxygen requirements **OR**<br>• requirement for ventilatory support<br><br>**Gastrointestinal:**<br>• feeding intolerance<br>• poor sucking<br>• abdominal distension<br><br>**Non-specific:**<br>• irritability<br>• lethargy<br>• hypotonia | **WBCs:**<br>• $<4\times10^9$ cells/L **OR**<br>• $>20\times10^9$ cells/L<br><br>**Immature to total neutrophil ratio (I/T):**<br>• >0.2<br><br>**Platelet count:**<br>• $<100\times10^9$/L<br><br>**CRP:**<br>• >15 mg/L **OR**<br><br>**Procalcitonin:**<br>• ≥2 ng/mL<br><br>**Glucose intolerance** (confirmed at least twice):<br>• hyperglycaemia (blood glucose >180 mg/dL or 10 mM) **OR**<br>• hypoglycaemia (blood glucose <45 mg/dL or 2.5 mM)<br><br>When receiving age-specific normal-range glucose amounts<br><br>**Metabolic acidosis:**<br>• base excess <−10 mEq/L **OR**<br>• serum lactate >2 nM |

HR, heart rate; WBC, white blood cell.