Neonatal meningitis:
can we do better?

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Incidence of neonatal bacterial meningitis

Location	Period	Incidence /1000 live births	< 2500g
Leeds	1947-60	0.5	
USA (NIH)	1959-66	0.46	1.4
California	1962-87	0.3	2.8
England/Wales	1985-7	0.2	2.5
Oxford Region	1984-91	0.25	
England/Wales	1996-7	0.2	1.7

Etiology of neonatal bacterial meningitis

(% of cases)

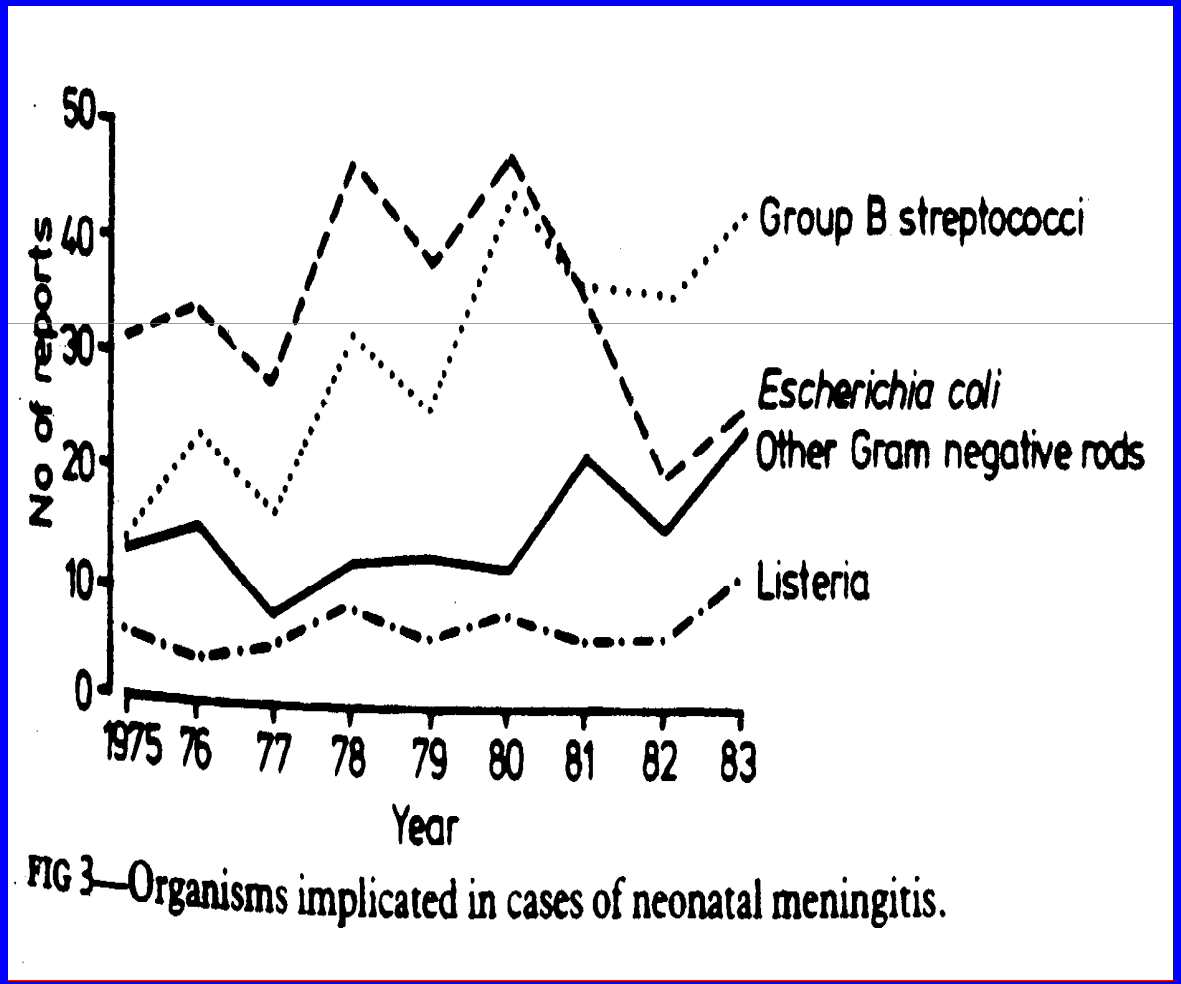
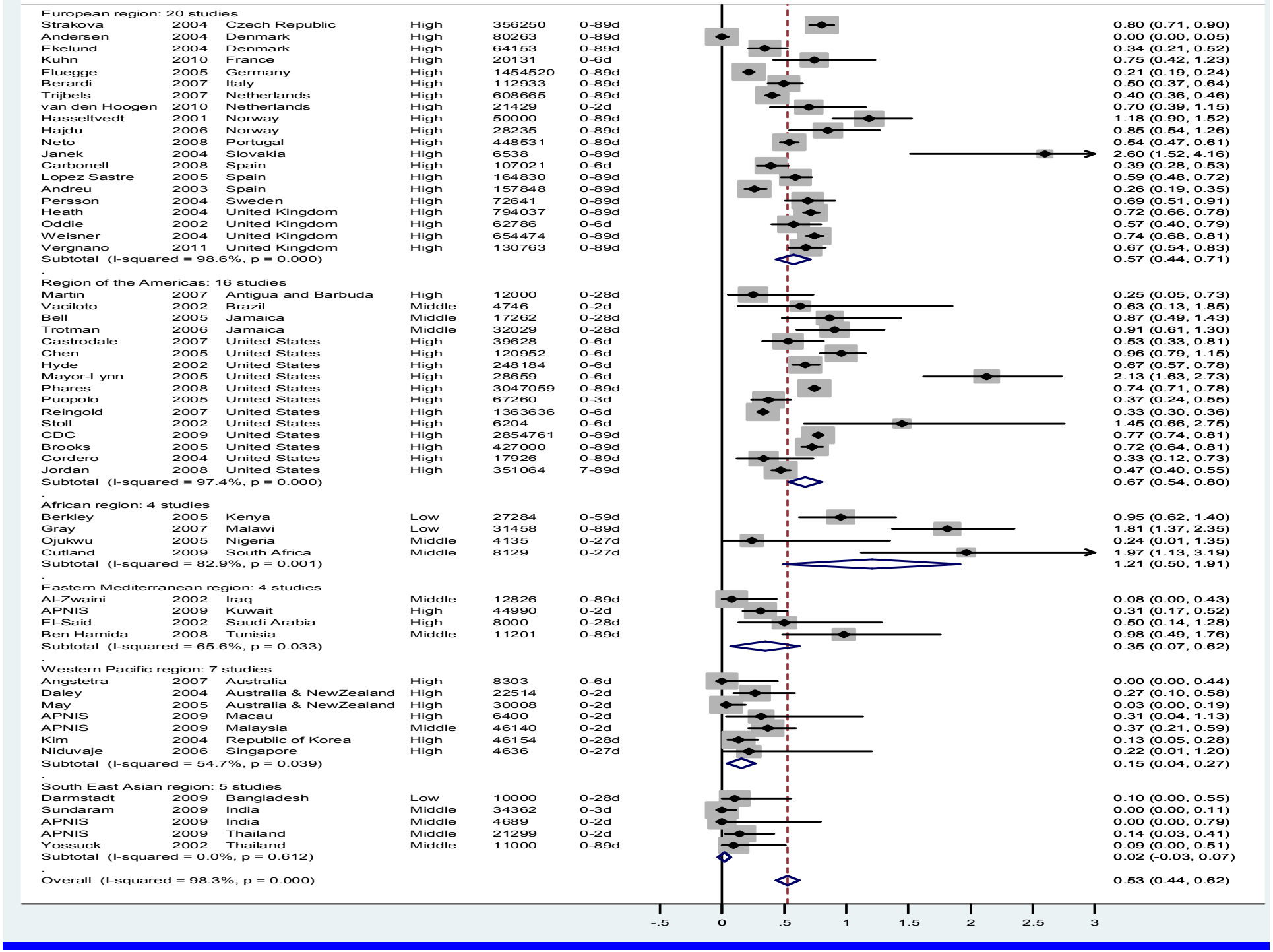


FIG 3—Organisms implicated in cases of neonatal meningitis.

E+W	E+W	UK
1985-7	1996-7	**2010-11** *Preliminary*
39	**48**	**50**
26	**18**	**9**
12	**8**	**9**
6	**6**	**10**
7	**5**	**4**


European region: 20 studies
Strakova 2004 Czech Republic High 356250 0-89d 0.80 (0.71, 0.90)
Andersen 2004 Denmark High 80263 0-89d 0.00 (0.00, 0.05)
Ekelund 2004 Denmark High 64153 0-89d 0.34 (0.21, 0.52)
Kuhn 2010 France High 20131 0-6d 0.75 (0.42, 1.23)
Fluegge 2005 Germany High 1454520 0-89d 0.21 (0.19, 0.24)
Berardi 2007 Italy High 112933 0-89d 0.50 (0.37, 0.64)
Trijbels 2007 Netherlands High 608665 0-89d 0.40 (0.36, 0.46)
van den Hoogen 2010 Netherlands High 21429 0-2d 0.70 (0.39, 1.15)
Hasseltvedt 2001 Norway High 50000 0-89d 1.18 (0.90, 1.52)
Hajdu 2006 Norway High 28235 0-89d 0.85 (0.54, 1.26)
Neto 2008 Portugal High 448531 0-89d 0.54 (0.47, 0.61)
Janek 2004 Slovakia High 6538 0-89d 2.60 (1.52, 4.16)
Carbonell 2008 Spain High 107021 0-6d 0.39 (0.28, 0.53)
Lopez Sastre 2005 Spain High 164830 0-89d 0.59 (0.48, 0.72)
Andreu 2003 Spain High 157848 0-89d 0.26 (0.19, 0.35)
Persson 2004 Sweden High 72641 0-89d 0.69 (0.51, 0.91)
Heath 2004 United Kingdom High 794037 0-89d 0.72 (0.66, 0.78)
Oddie 2002 United Kingdom High 62786 0-6d 0.57 (0.40, 0.79)
Weisner 2004 United Kingdom High 654474 0-89d 0.74 (0.68, 0.81)
Vergnano 2011 United Kingdom High 130763 0-89d 0.67 (0.54, 0.83)
Subtotal (I-squared = 98.6%, p = 0.000) 0.57 (0.44, 0.71)
Region of the Americas: 16 studies
Martin 2007 Antigua and Barbuda High 12000 0-28d 0.25 (0.05, 0.73)
Vaciloto 2002 Brazil Middle 4746 0-2d 0.63 (0.13, 1.85)
Bell 2005 Jamaica Middle 17262 0-28d 0.87 (0.49, 1.43)
Trotman 2006 Jamaica Middle 32029 0-28d 0.91 (0.61, 1.30)
Castrodale 2007 United States High 39628 0-6d 0.53 (0.33, 0.81)
Chen 2005 United States High 120952 0-6d 0.96 (0.79, 1.15)
Hyde 2002 United States High 248184 0-6d 0.67 (0.57, 0.78)
Mayor-Lynn 2005 United States High 28659 0-6d 2.13 (1.63, 2.73)
Phares 2008 United States High 3047059 0-89d 0.74 (0.71, 0.78)
Puopolo 2005 United States High 67260 0-3d 0.37 (0.24, 0.55)
Reingold 2007 United States High 1363636 0-6d 0.33 (0.30, 0.36)
Stoll 2002 United States High 6204 0-6d 1.45 (0.66, 2.75)
CDC 2009 United States High 2854761 0-89d 0.77 (0.74, 0.81)
Brooks 2005 United States High 427000 0-89d 0.72 (0.64, 0.81)
Cordero 2004 United States High 17926 0-89d 0.33 (0.12, 0.73)
Jordan 2008 United States High 351064 7-89d 0.47 (0.40, 0.55)
Subtotal (I-squared = 97.4%, p = 0.000) 0.67 (0.54, 0.80)
African region: 4 studies
Berkley 2005 Kenya Low 27284 0-59d 0.95 (0.62, 1.40)
Gray 2007 Malawi Low 31458 0-89d 1.81 (1.37, 2.35)
Ojukwu 2005 Nigeria Middle 4135 0-27d 0.24 (0.01, 1.35)
Cutland 2009 South Africa Middle 8129 0-27d 1.97 (1.13, 3.19)
Subtotal (I-squared = 82.9%, p = 0.001) 1.21 (0.50, 1.91)
Eastern Mediterranean region: 4 studies
Al-Zwaini 2002 Iraq Middle 12826 0-89d 0.08 (0.00, 0.43)
APNIS 2009 Kuwait High 44990 0-2d 0.31 (0.17, 0.52)
El-Said 2002 Saudi Arabia High 8000 0-28d 0.50 (0.14, 1.28)
Ben Hamida 2008 Tunisia Middle 11201 0-89d 0.98 (0.49, 1.76)
Subtotal (I-squared = 65.6%, p = 0.033) 0.35 (0.07, 0.62)
Western Pacific region: 7 studies
Angstetra 2007 Australia High 8303 0-6d 0.00 (0.00, 0.44)
Daley 2004 Australia & NewZealand High 22514 0-2d 0.27 (0.10, 0.58)
May 2005 Australia & NewZealand High 30008 0-2d 0.03 (0.00, 0.19)
APNIS 2009 Macau High 6400 0-2d 0.31 (0.04, 1.13)
APNIS 2009 Malaysia Middle 46140 0-2d 0.37 (0.21, 0.59)
Kim 2004 Republic of Korea High 46154 0-28d 0.13 (0.05, 0.28)
Niduvaje 2006 Singapore High 4636 0-27d 0.22 (0.01, 1.20)
Subtotal (I-squared = 54.7%, p = 0.039) 0.15 (0.04, 0.27)
South East Asian region: 5 studies
Darmstadt 2009 Bangladesh Low 10000 0-28d 0.10 (0.00, 0.55)
Sundaram 2009 India Middle 34362 0-3d 0.00 (0.00, 0.11)
APNIS 2009 India Middle 4689 0-2d 0.00 (0.00, 0.79)
APNIS 2009 Thailand Middle 21299 0-2d 0.14 (0.03, 0.41)
Yossuck 2002 Thailand Middle 11000 0-89d 0.09 (0.00, 0.51)
Subtotal (I-squared = 0.0%, p = 0.612) 0.02 (-0.03, 0.07)
Overall (I-squared = 98.3%, p = 0.000) 0.53 (0.44, 0.62)
-.5
0
.5
1
1.5
2
2.5
3

Etiology of neonatal bacterial meningitis

Kenya 0-60 days of age (*BMC Infectious Diseases* 2011, 11:301)

Pathogen	% where bacteria isolated (n=86)
Streptococcus pneumoniae	19
Group B Streptococci	15
Haemophilus influenzae	9
Non-typhoidal *Salmonella sp.*	8
Group A Streptococci	6
Enterobacter sp.	6
Escherichia coli	3
Klebsiella pneumoniae	3
Acinetobacter sp.	2
Pseudomonas aeruginosa	2
Group D Streptococci	2
Streptococcus viridans	2
Staphylococcus aureus	2

NEOMEN BPSU 2010-11
the 1st 200 cases

Pathogen	% where bacteria isolated (n=150)
Group B strep	50% (37% < 7 days)
Streptococcus pneumoniae	
Other Gram negative bacteria	
E coli	
Other Gram positive bacteria	
Meningococcus B	
Listeria	4%
Haemophilus influenzae	2%

Enterobacter, Klebsiella, Citrobacter, Pseudomonas, Salmonella, Pasteurella, *ıella*

S.aureus, S.epidermidis, Strep Bovis, Enterococcus

Preliminary data

Neonatal meningitis:
mortality

- E+W 1985-7:
  - GBS 27/112 = 22%
  - E coli 18/72 = 25%

  overall 25%

  (Arch Dis Child 1991;66:603-7)

- E+W 1996-7:
  - GBS 8/69 = 12%
  - E coli 4/26 = 15%

  overall 10%

  (Arch Dis Child Fetal Neonatal Ed 2001;84:F85-9)

- UK 2000-1:
  - GBS 16/109 = 12%

(Lancet 2004;363:292-4)

Neonatal meningitis:
disability at 5 years of age

	1985-7 n = 274	1996-7 n = 166
severe	7%	5%
moderate	18%	18%
mild	24%	26%
none	50%	51%

BMJ 2001;323:1-5; Eur J Pediatr 2005;164:730–4

Long term consequences of infection in VLBW babies

Table 3. Neurodevelopmental Outcomes From Univariate Analyses by Infection Group vs Uninfected Infants

	No./Total (%) With Outcome by Infection Group*				
Outcomes	Uninfected	Clinical Infection	Sepsis Alone	Sepsis Plus NEC	Meningitis With or Without Sepsis
MDI <70	439/2003 (22)	478/1428 (33)‡	661/1791 (37)‡	109/262 (42)‡	70/183 (38)‡
PDI <70	250/1983 (13)	345/1407 (25)‡	472/1762 (27)‡	87/258 (34)‡	49/183 (27)‡
CP	181/2144 (8)	216/1520 (14)‡	328/1906 (17)‡	59/277 (21)‡	37/193 (19)‡
Vision impairment	115/2137 (5)	165/1520 (11)‡	275/1893 (15)‡	45/275 (16)‡	31/193 (16)‡
Hearing impairment	21/2110 (1)	29/1513 (2)†	58/1882 (3)‡	13/271 (5)‡	3/191 (2)
NDI	576/1976 (29)	614/1419 (43)‡	861/1778 (48)‡	142/267 (53)‡	89/184 (48)‡

Neurodevelopmental impairment @ 18-22m

JAMA 2004;292:2357-2365

Neonatal meningitis:
clinical signs

- non-specific and subtle
  (esp. premature infants)
- signs ≡ sepsis

- no published data on timing of onset

NEOMEN BPSU clinical presentation: the 1st 200 cases

Condition	Frequency
Poor feeding	69%
Irritability	65%
Lethargy	61%
Fever ≥ 38.0°C	54%
Poor perfusion	45%
Respiratory distress	36%
Apnoea	25%
Convulsions	**25%**
Temp instability / hypothermia	21%
Vomiting	20%
Bulging fontanelle	**19%***
Comatose	**5%***
Jaundice	3%
Neck stiffness	**3%***

* Late signs?

Preliminary data

Neonatal meningitis:
diagnosis

- Non-specific clinical signs…so:

→ **L.P. needs to be part of a routine screen** for possible sepsis…….

→ but how often are LPs performed?

- ASGNI: 3966 with sepsis; LP in 51% - meningitis in 8%.

Arch Dis Child Fetal Neonatal Ed 2005;90:F324–F327

- NICHD: 9641 VLBW infants:
  - 63% had ≥ 1 BC, 30% had ≥ 1 LP
  - Meningitis in 5% of those with an LP

Pediatrics 2004;113(5):1181-6

- Are cases of meningitis being missed?

Diagnosis of neonatal meningitis

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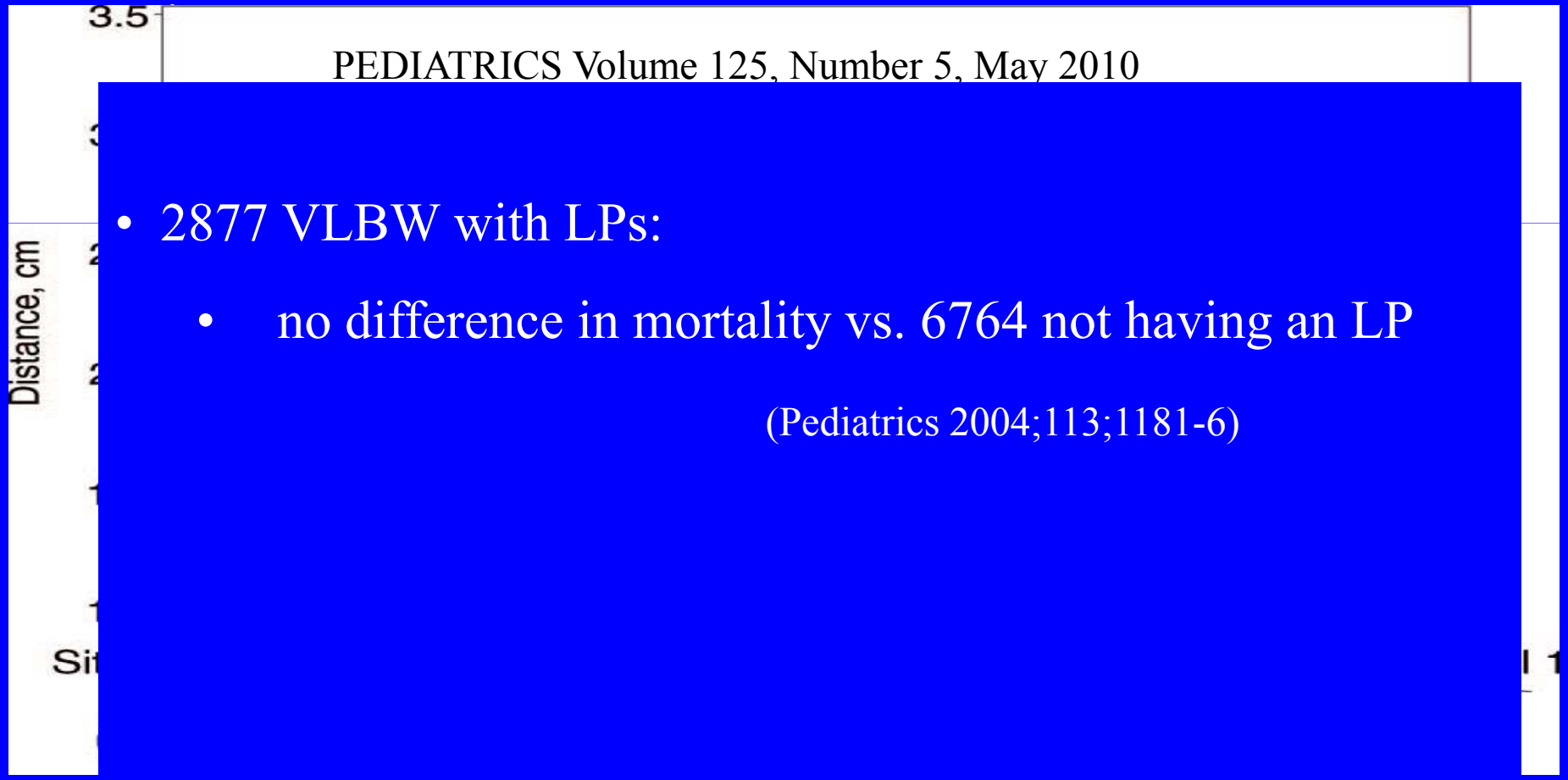
CP	181/2144 (8)	216/1520 (14)‡	328/1906 (17)‡	59/277 (21)‡	37/193 (19)‡
Vision impairment	115/2137 (5)	165/1520 (11)‡	275/1893 (15)‡	45/275 (16)‡	31/193 (16)‡
Hearing impairment	21/2110 (1)	29/1513 (2)†	58/1882 (3)‡	13/271 (5)‡	3/191 (2)
NDI	576/1976 (29)	614/1419 (43)‡	861/1778 (48)‡	142/267 (53)‡	89/184 (48)‡

"Clinical infection" = late-onset cultures –ve & antibiotics ≥ 5 days…but was LP done?

JAMA 2004;292:2357-2365

Neonatal meningitis:
other diagnostic issues

- There are few contraindications to performing a LP



- 2877 VLBW with LPs:
  - no difference in mortality vs. 6764 not having an LP

(Pediatrics 2004;113;1181-6)

Neonatal meningitis:
diagnosis

What is a normal neonatal CSF cell count?

TABLE 2 CSF WBC Counts

Parameter	0–28 d (n = 142), /μL	29–56 d (n = 238), /μL
Value, mean (SD)	9.2 (32.1)	3.1 (5.0)
Upper bound of 95% CI of the mean value	14.5	3.8
Median value[a]	3	2
90th percentile value	12	6
95th percentile value	19	9
IQR	2–6	1–3

PEDIATRICS Volume 125, Number 2, February 2010

Neonatal meningitis:
other diagnostic issues

- a normal CSF white cell count, glucose and protein levels does not exclude meningitis:
  - 9111had LP: 95 meningitis - 13% normal initial CSF

(Pediatrics 2006;117;1094-1100)

TABLE 3. Initial and repeat CSF results in infants with Gram-negative bacteremia

Patient	Cerebrospinal Fluid									Blood Culture
	CSF no	Interval* (hours)	WBC/mm³	PMN (%)	RBC/mm³	Glucose (mg/dl	Protein (mg/dl)	Gram stain	Culture	
1	1		14	7	5	57	84	NOS	No growth	*Escherichia coli*
	2	18	1914	59	5040	45	312	NOS	No growth	
2	1		4	None	142	42	94	NOS	No growth	*Escherichia coli*
	2	24	66	41	730	<10	389	Gram-negative rods	*Escherichia coli*	
3	1		None	None	None	109	76	NOS	No growth	*Pseudomonas aeruginosa,*
	2	24	100	19	None	42	142	NOS	No growth	*Serratia marcescens*
4	1		7	None	10	49	237	NOS	No growth	*Klebsiella pneumoniae*
	2	84	149	48	16	33	412	NOS	No growth	
5	1		4	None	33	61	68	NOS	No growth	*Escherichia coli*
	2	22	42	18	641	84	115	NOS	No growth	
6	1		None	None	1	79	47	NOS	No growth	*Klebsiella pneumoniae*
	2	59	2410	77	1400	57	95	NOS	No growth	

* Time elapsed between the first and the second CSF analysis.
NOS, no organisms seen.

Neonatal meningitis:
other diagnostic issues

What about a traumatic tap?

- 6374 neonates had LP; 1.8% meningitis
  - 40% traumatic (>500 RBC/mm^3)
  - CSF WCC adjusted "down" using several methods (500:1; FBC)
    - Did not improve diagnostic utility & decreased sensitivity

    → If elevated CSF WCC manage as meningitis

PIDJ 2008;27:1047-51

Neonatal meningitis:
other diagnostic issues

- pretreatment with antibiotics does not prevent diagnosis
  - those who received antibiotics 12 -72 h pre LP had significantly ↑ glucose and ↓ protein vs. those who did not receive them or received them < 4h….**but no influence on CSF WBC**

    (Pediatrics 2008;122:726–730)

- UK: 61% of LPs done after antibiotics started

  (Neomen: 1st 200 cases (preliminary data))

Neonatal meningitis:
other diagnostic issues

- there is an important role for non-culture methods of detection (PCR)
  - 62 cases with pre-Rx:
    +ve culture 29%, +ve PCR 58%

    (J infect Chemother 2009; 15:92-8)

Neonatal meningitis:
other diagnostic issues

- but delay in analysis of neonatal CSF may prevent diagnosis….
- Of 19 with baseline WCC > 30, a diagnosis would be missed
  - in 53% if analysed at 2 h
  - in 79% if analysed at 4 h.

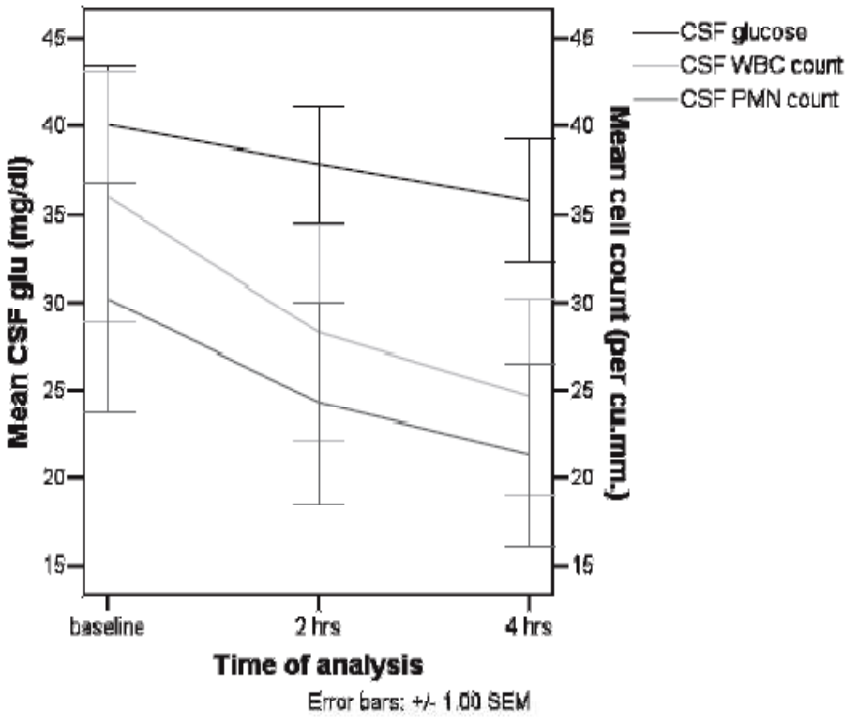


Figure 1 Change in cerebrospinal fluid (CSF) parameters over time. PMN, polymorphonuclear leucocyte; WBC, white blood cell.

(Arch Dis Child Fetal Neonatal Ed 2010;95:F25–F29)

Neonatal meningitis:
diagnosis

- LP only when blood culture comes back +ve?
  - meningitis complicated 22/145 (15%) of EOGBS & 13/23 (57%) of episodes of LOGBS

    Early Human Development 85 (2009) S5–S7.

  - Current practice?:
    - UK: 138 cases invasive GBS <90 days of age
      - 79% had LP

      Arch Dis Child. 2009;94(9):674-80

    - NICHD VLBW infants: 2419 +ve BC
      - 66% had LP

      Pediatrics 2004;113(5):1181-6

Neonatal meningitis:
diagnosis

- BUT **+ve CSF with -ve BC**
  - 45/134 (Stoll et al) (VLBW)
  - 35/92 (Garges et al)
  - 9/27 (Vergnano et al)
  - **43/150 (Okike et al)**

Up to 38% of bacterial meningitis have –ve BC

- Perform a LP if any signs of sepsis in a neonate (and definitely if BC+ve!)
  - LP based on maternal RF only = lower yield

Neonatal meningitis:
diagnosis

- Repeat lumbar puncture at 24–72 hours?
  - Why? Provide reassurance of effective therapy with particularly virulent or resistant organisms, in patients with worsening clinical status, or in those where subtle changes in clinical status may be difficult to discern
  - 134 VLBW infants with meningitis: 67% rpt: 12% +ve
    Pediatrics 2004;113(5):1181-6
  - 118 infants with repeat CSF cultures: 22% repeat +ve
    - No difference in PNA, GA, Bwt, pathogen (median 1448g)
    - Mortality 6/23 (26%) vs. 6/81 (7%) (*P*=0.02)
      Journal of Perinatology (2011) **31,** 425–429

- If CSF culture remains positive, review antibiotic Rx & perform cerebral imaging

Neonatal meningitis: empiric antibiotic therapy

Requirements:

- Cover the most likely pathogens
- Excellent CSF penetration

→ 3rd generation cephalosporins + amoxicillin

Pathogen	% where bacteria isolated (n=150)
Group B strep	50% (37% < 7 days)
Streptococcus pneumoniae	10%
Other Gram negative bacteria	10%
E coli	9%
Other Gram positive bacteria	8%
Meningococcus B	7%
Listeria	4%
Haemophilus influenzae	2%

Neonatal meningitis: Empiric antibiotic therapy

- Infection with *L. monocytogenes* is rare;
  ~ 5% of cases
- Most cases are <7 days of age, in premature infants and are related to maternal infection.
- Traditionally, pregnancy-associated Listeria is considered up to 3 months of age, current data indicate nearly all pregnancy-associated cases present in the first month of life:
  - E+W: 72 cases of listeria meningitis 1990 - 2007, only 1 occurred at > 4 weeks of age*
- Optimal therapy for Listeria infection is a penicillin.

*Personal Communication,, Centre for Infections, Health Protection Agency

Empiric antibiotic therapy

NB. earlier discharge policies from neonatal units

- Ex NNU neonates may have persistent colonisation with resistant bacteria after discharge
  [J Clin Microbiol. 2008;46(2):560-7]

- NICE guidelines

Community

amoxycillin + cefotaxime

Neonatal Unit

cefotaxime + amoxycillin + aminoglycoside;

consider vancomycin

consider meropenem

BPSU study

19% of cases:

E.coli,

Enterobacter, Klebsiella, Citrobacter, Pseudomonas, Salmonella, Pasteurella, Prevotella, Morganella

**www.hpa.org.uk*

Neonatal infections in Asia

Table 3 Sensitivities of Gram-negative organisms causing late-onset sepsis

Organism	C^SG^S	C^SG^R	C^RG^S	C^RG^R (%)	Total
Acinetobacter species	6	4	7	3 (15)	20
Escherichia coli	14	1	5	5 (20)	25
Enterobacter species	11	2	12	3 (11)	28
Klebsiella species	35	2	2	31 (44)	70
Proteus species	0	0	2	1 (33)	3
Pseudomonas species	3	1	6	6 (37)	16
Serratia species	9	0	1	3 (23)	13
Other Gram-negative bacilli	1	0	2	2 (40)	5
Total	79 (44%)	10 (6%)	37 (21%)	54 (30)	180

C, third-generation cephalosporin (cefotaxime or ceftazidime for *Pseudomonas*); G, gentamicin; S, sensitive; R, resistant.

Arch Dis Child Fetal Neonatal Ed. 2009;94(2):F144-8

Neonatal meningitis:
Empiric antibiotic therapy:
audit of current UK policy

- 45% include a cephalosporin
  - In 12%, cephalosporin as monotherapy
- 19% do not include any penicillin

- 5% used a triple combination
  (cephalosporin + a penicillin + aminoglycoside)

Journal of Antimicrobial Chemotherapy (2008) 61, 743–745

Neonatal meningitis:
Empiric antibiotic therapy:
current UK practice

- 82% included a cephalosporin
  - 17%, cephalosporin as monotherapy
- 25% did not include any penicillin

- 9% used a triple combination
  (cephalosporin + a penicillin + aminoglycoside)

- 57% used cefotaxime + pen/amox +/- gentamicin

Neomen: the 1st 200 cases. Unpublished.

Neonatal sepsis / meningitis: risk factors for poor outcome

E.Coli (85/14)	OR (death)
Hypotension on admission	8.4
Hypotension @ 12h	36
Seizures @ 12 h	11

Clin Microbiol Infect 2008; 14: 685–690

GBS (76/5)	OR (death)
Shock @ presentation	24
↓ platelets	42

J Maternal-Fetal and Neonatal Medicine 2008; 21(1): 53–57

All (256/18)	OR (death)
Coma on admission	11

Arch. Dis. Child. Fetal Neonatal Ed. 2001;84;85-89

GBS (237/39)	OR (death)
shock	23
coma	16
Seizures	6

Archives de Pédiatrie 2008 ;15:S126-S132

All (76/25)	p (adverse outcome)
hypotension	<0.001
coma	<0.001
inotropes	<0.001
seizures	<0.001

Pediatrics 2000;106:477– 482

Improving the outcome from neonatal infection

- circulatory support in shock: fluid resuscitation to restore intravascular volume, stabilize blood pressure and maintain adequate oxygenation
  - strict and early goal-directed fluid resuscitation, vasopressor therapy and transfusion of adults with severe sepsis
    (N Engl J Med 2001;345:1368-77)
  - early aggressive fluid resuscitation in children
    (JAMA 1991;266:1242-5)
  - delayed reversal of shock associated with worse outcome; every hour of failure to reverse shock results in doubling of risk of death
    (Pediatrics 2003;112:793-9)

- few high-quality studies have assessed initial fluid therapy in neonates with suspected or confirmed bacterial sepsis / meningitis.

Antibiotics -

Gram negative enteric bacteria

? Need intrathecal antibiotic Rx

- 1971-5; 117 GN meningitis (70% Ecoli); amp / gent +/- IT gent; no difference mortality (32%) or morbidity (36%)

? Need intraventricular antibiotic therapy

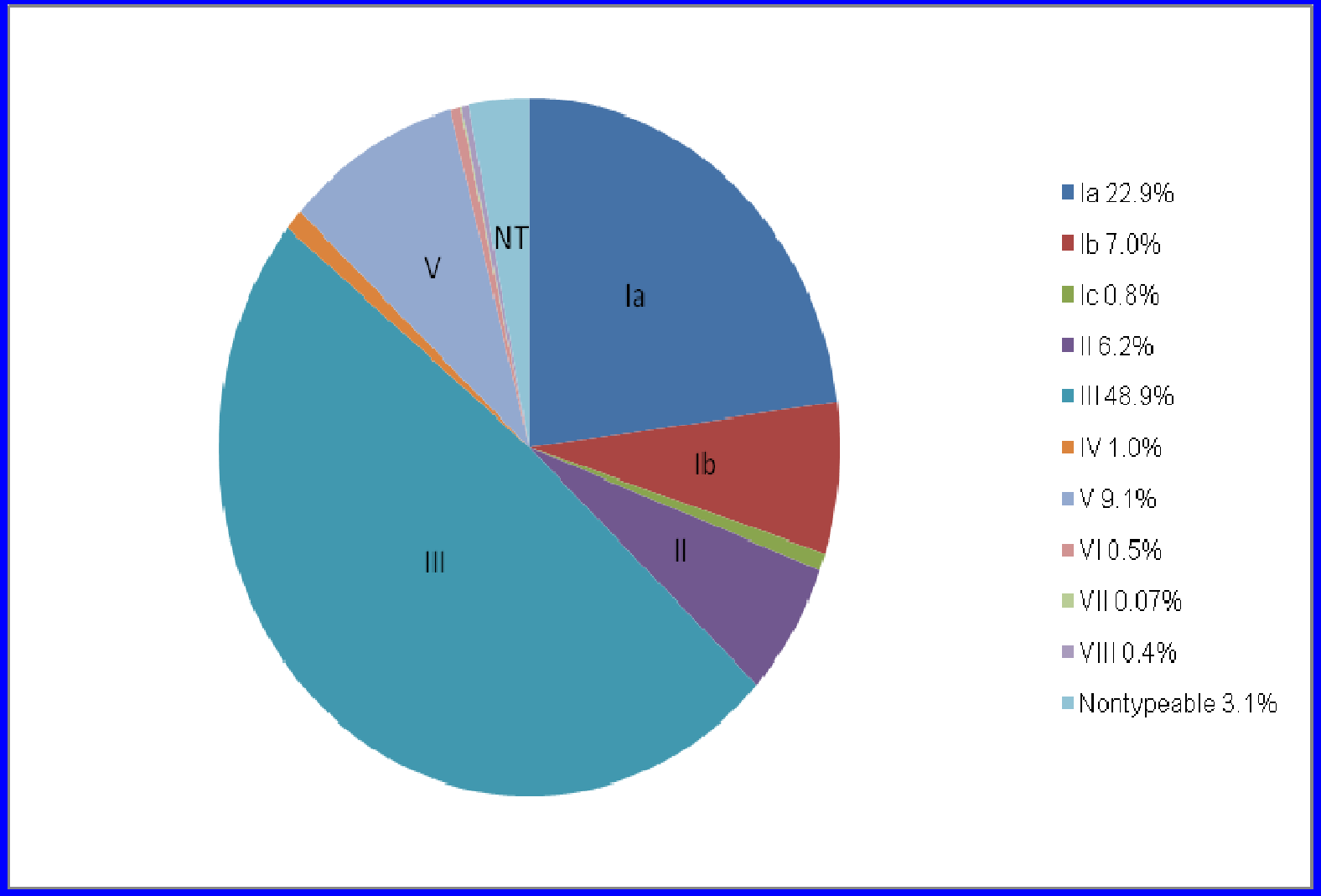
- 1976-9; 71 GN meningitis: 73% ventriculitis; amp / gent +/- IVt gent; mortality 43% IVt vs 13% no IVt gent

J Ped 1976;89:66-72; Lancet 1980: 787-91.

Adjunctive therapy (meningitis)

- Corticosteroids?
  - Study of 52 cases: dex vs no dex
  - (1st dose pre ab), cefotaxime + ampicillin; 1993-5, Jordan: 79% enteric GNB (3 cases GBS).
  - Mortality 22 % CS vs 28% no CS; CNS deficit 30% vs 39% (NS) (Eur J Ped 1999;158:230-3).
- Oral glycerol?
  - Recent paediatric study indicates better outcome than dexamethasone (Clin Infect Dis 2007;45:1277-86).

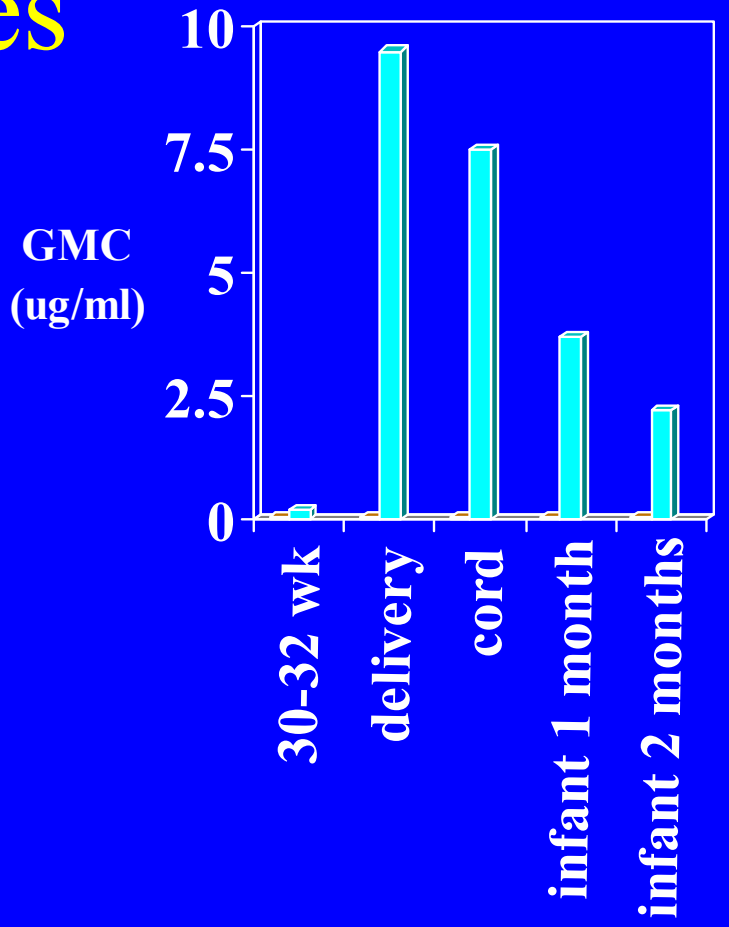
Global GBS serotype distribution, 1980-2011



Edmonds et al. Lancet 2011 (in press)

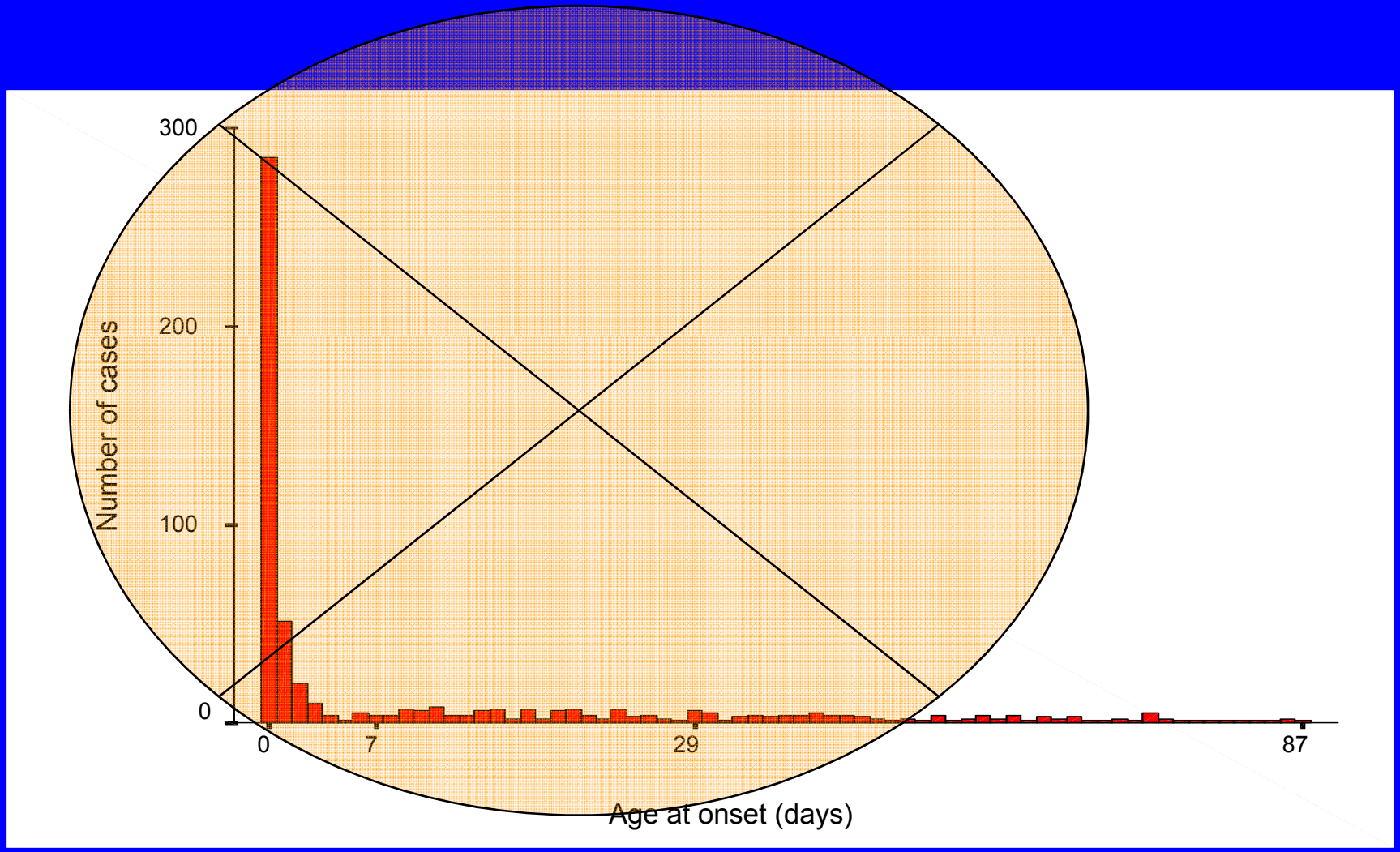
GBS CPS-protein conjugate vaccines

- GBS III PS conjugate vaccine in pregnancy
- III-Tet (20) or saline (10) at 30-32 wk
- well tolerated
- cord / maternal = 0.8



Vaccine 2003;21:3468-72 & ADC 2003;88:375-8

Potential of a GBS vaccine



Lancet 2004; **363:** 292–94

Improving the outcome of neonatal meningitis…can we do better?

Probably YES!

- Better management….
  - Earlier recognition & diagnosis?
  - Earlier use of appropriate (dose/type) empiric and treatment antibiotics?
  - Role for new antibiotics?
  - Better supportive care?
  - Adjunctive therapy?

- Better prevention….

Bacterial meningitis in babies <90 days of age: defining the current burden of disease and identifying opportunities for improving the outcome. (NEOMEN)

Meningitis Research Foundation

Health Protection Agency

Objectives:

To define

- the minimum incidence of meningitis in the UK and Ireland;
- the bacterial pathogens (and the antibiotic resistance profiles);
- the clinical presentation;
- the mortality and short-term complication rates of meningitis;
- the current management.

To identify opportunities for improving the outcome through detailed analysis of early case management relative to an evidence based optimal standard.

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