Neonatal Bilirubin Audit Questionnaire Results

1st September 2010

Great Ormond Street Hospital

Response

28 replies

- 25 prior to deadline 31/07/10
- 3 arrived after deadline but were included

Laboratory methods & practice

Q1: Number of samples per month

- More than 50 per month 23 (82%)
- Less than 50 per month 5 (18%)

Q2, 3, 4: Assay availability

- All laboratories
  - offer total bilirubin for neonates
  - offer conjugated/direct bilirubin for neonates locally
  - offer total and conjugated/direct bilirubin 24/7

Q5: Turnaround times

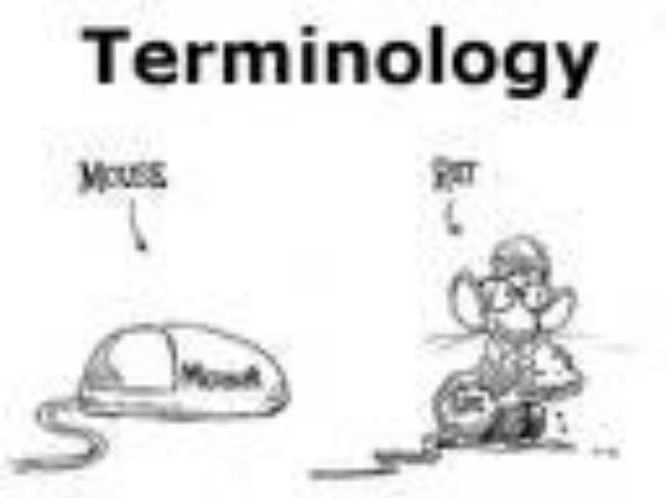
- Routine TAT for total bilirubin < 6 h
  - 26/28 labs – yes (93%)
  - 1 lab > 6 h
  - 1 lab ‘same day’
- Urgent TAT for total bilirubin <2 h
  - All labs
- Routine TAT for conjugated/direct bilirubin < 6 h
  - 27/28 labs – yes (96%)
  - 1 lab > 6 h if routine

Q9 & Q6: methods/sample volumes

Method	**n**	**T.Bilirubin volume µL**	**C.Bilirubin volume µL**	**Dead volume µL**
Roche Modular - Diazo	8	3 - **50**	5.5 – **50**	30 - 50
Abbott Architect - Diazo	5	2 - 4	5	20 – **125**
Beckman Olympus – Diazo/O'Leary	5	8 - 13	2.5 – 15	2.5 - 50
Beckman DxC - Diazo	3	8	10	**200 - 290**
Ortho Vitros - Diazo	3	10	10	35 - **100**
Siemens ADVIA - Vanadate oxidation	2	20	20	20, 30
Cobas/ Cobas Integra	2	2	9	10, 50

Q7: which terms to report (in)direct/ (un)conjugated bilirubin

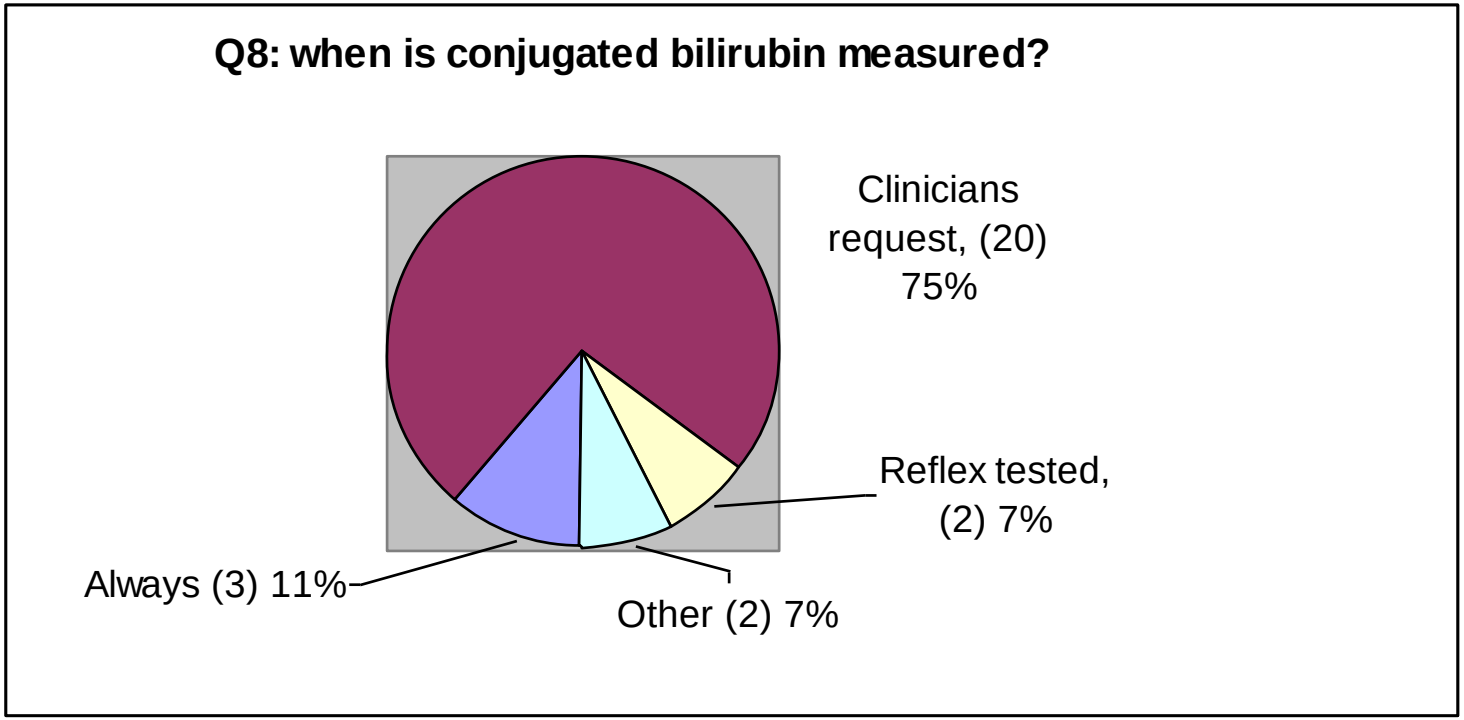
- (Un)conjugated bilirubin 21 (75%)
- (In)direct bilirubin 3 (11%)
- (Un)conjugated & (in)direct 3 (11%)
- No answer 1 (3%)



Q7b: report conjugated bilirubin as percentage of total

- Yes: 4 (14%)
- No: 24 (86%)

Q8: when is conjugated bilirubin measured



Reflex tested if total bilirubin > 20 and 35

<u>Other:</u>

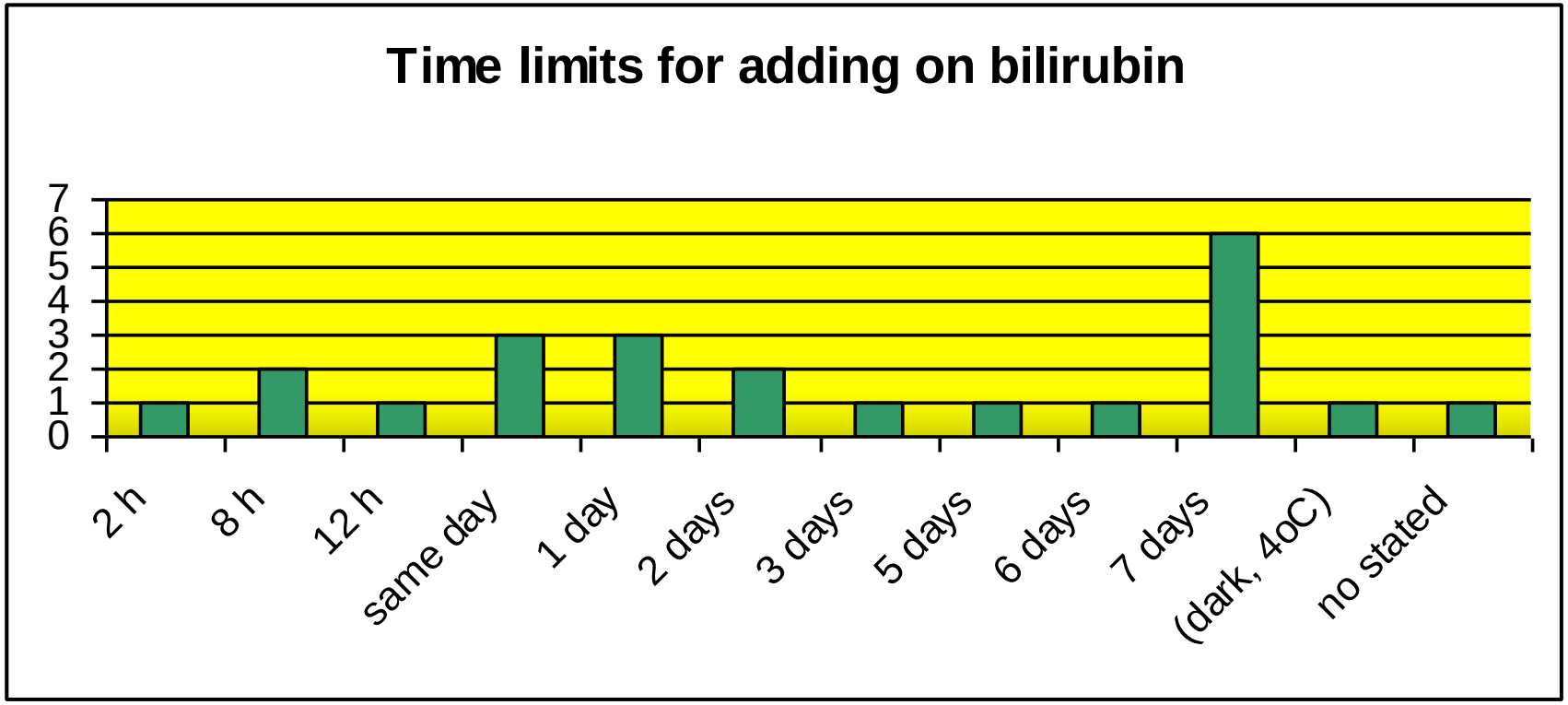
At discretion of duty biochemist

Duty biochemist will add conjugated bilirubin to A&E neonate samples if bilirubin is >50

Q10: adding on bilirubin as additional test

Yes: 22 (78%)

No: 6 (22%)



Q11: analytical ranges

Method	**n**	**T.Bilirubin,** µmol/L	**C.Bilirubin,** µmol/L	
Roche Modular - Diazo	8	1.7 – 513 /598	1.7 – 171/342	
Abbott Architect - Diazo	5	1.7 - 428	1.7 - 256	
Beckman Olympus – Diazo/O'Leary	5	0 – 1000/500	0 – 171/500	
Beckman DxC - Diazo	3	1.7 - 513	1.7 - 171	
Ortho Vitros - Diazo	3	1.7 - 462	0 - 462	
Siemens ADVIA - Vanadate oxidation	2	2 - 598	0 - 256	
Roche Cobas/Cobas Integra	2	1.7 – 650/3250	1.7/2 – 430/860	

Q12: which calibrators

All use **system calibrators** *except*

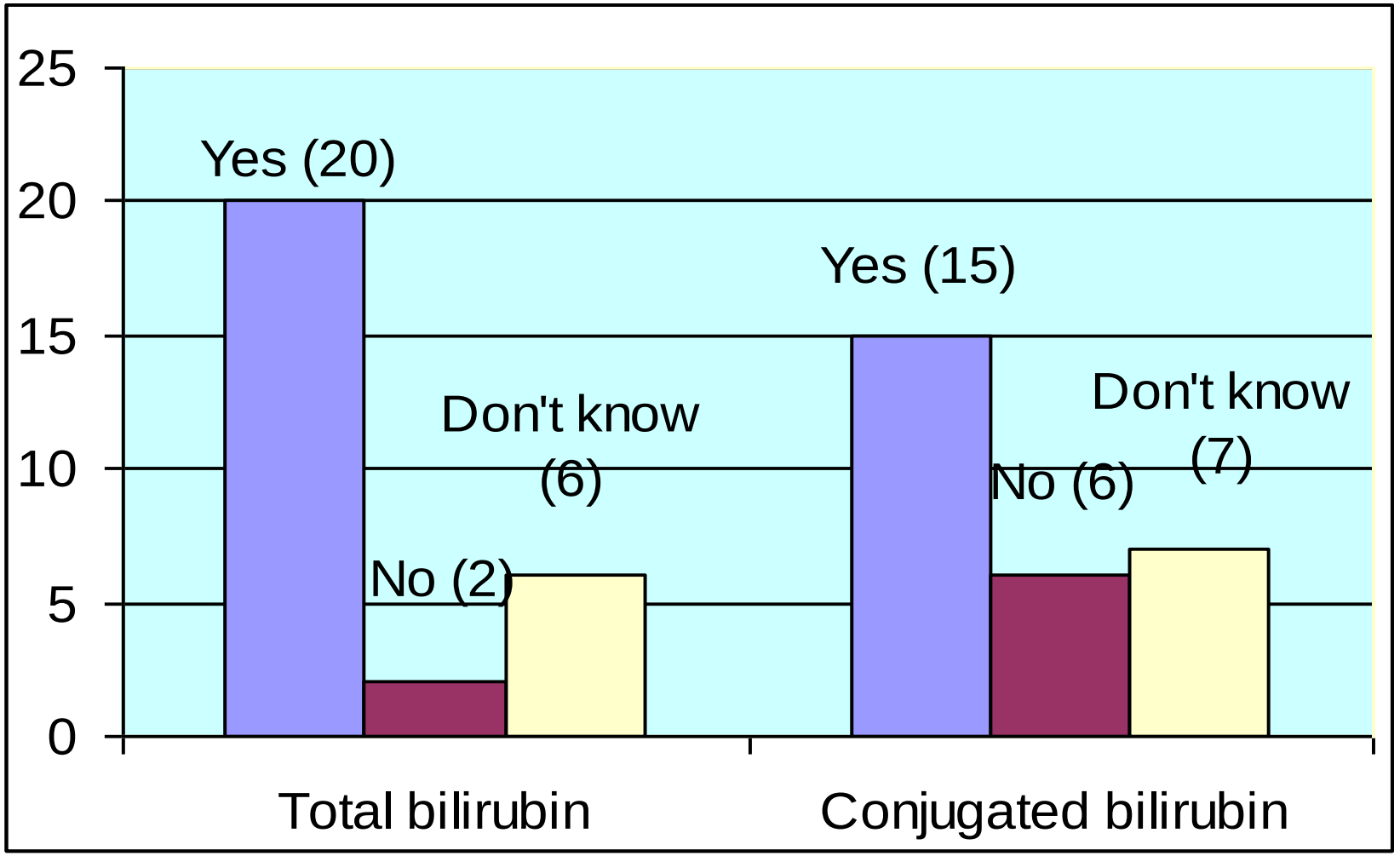
3 Olympus users (Seronorm) and

1 Roche Modular user (BioStat Chem Trek)

Q13: calibrator values

Method	**Points**	**T.Bilirubin** µmol/L	**C.Bilirubin** µmol/L	**n**
Ortho Vitros - Diazo	3/4	14 & 188 & 359	5 &17 & 137 & 308	3
Abbott Architect - Diazo	2	22/29 & 291/321	14 & 140/159	5
Roche Modular - Diazo	1	73/ 83	35/44	8
Beckman Olympus – Diazo/O'Leary	1	61/64/296	129	5
Beckman DxC - Diazo	1	158	40/43	3
Siemens ADVIA - Vanadate oxidation	1	81	65	2
Cobas Integra	1	91	44	2

Q14: is calibrator traceable to SRM/IS?



Q15: State the SRM/IS

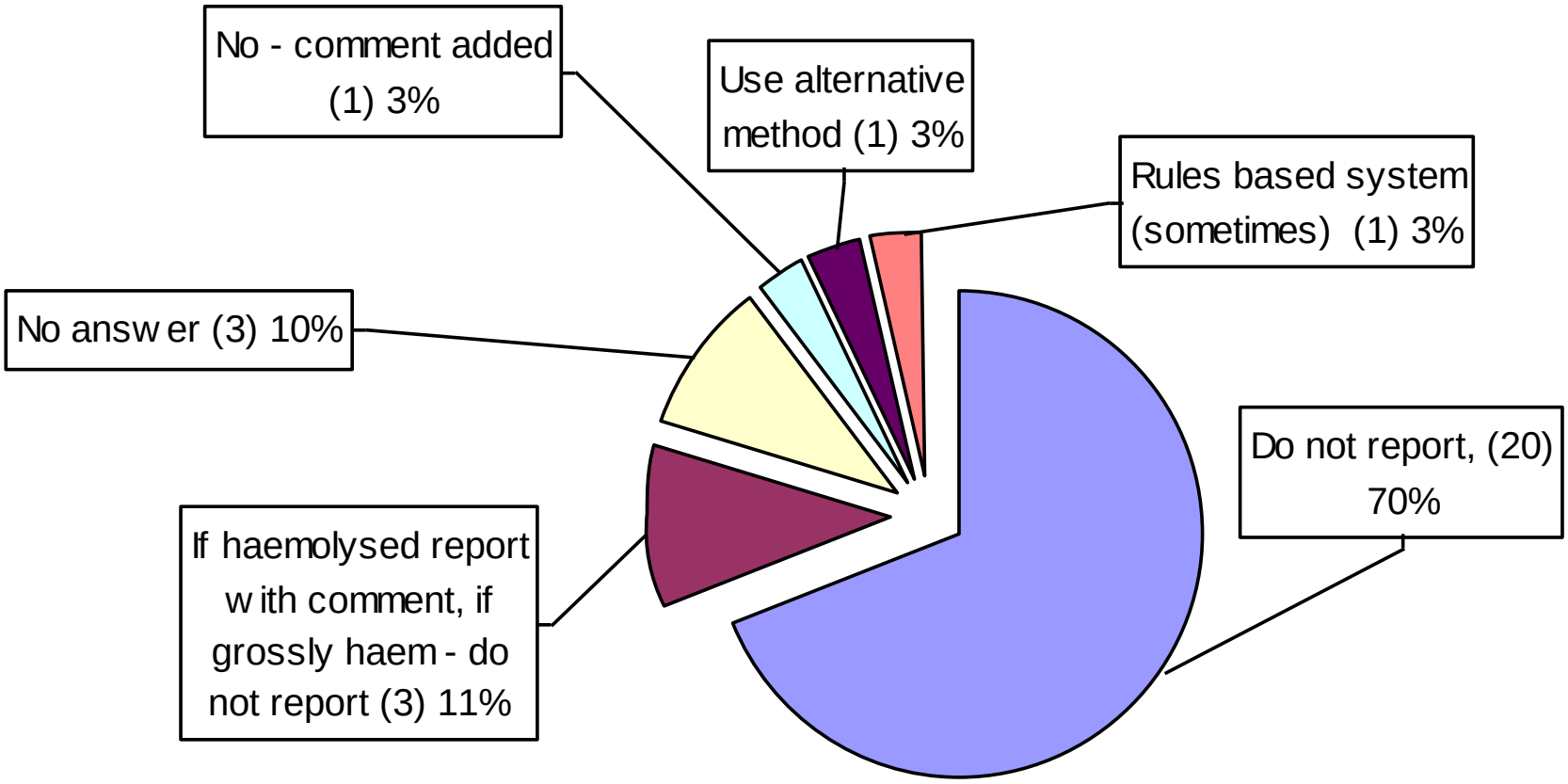
	T.bilirubin	C.Bilirubin
NIST SRM916(a)	16	11
Don't know/ no answer	6	8
Doumas method/JG method	4	5
Ref 1 E66-04	1	1
iso17511	1	0
CRAS DBIL 44.5		1
Gravimetrically prepared std		1
Olympus master		1

Q16: Does haemolysis affect assays?

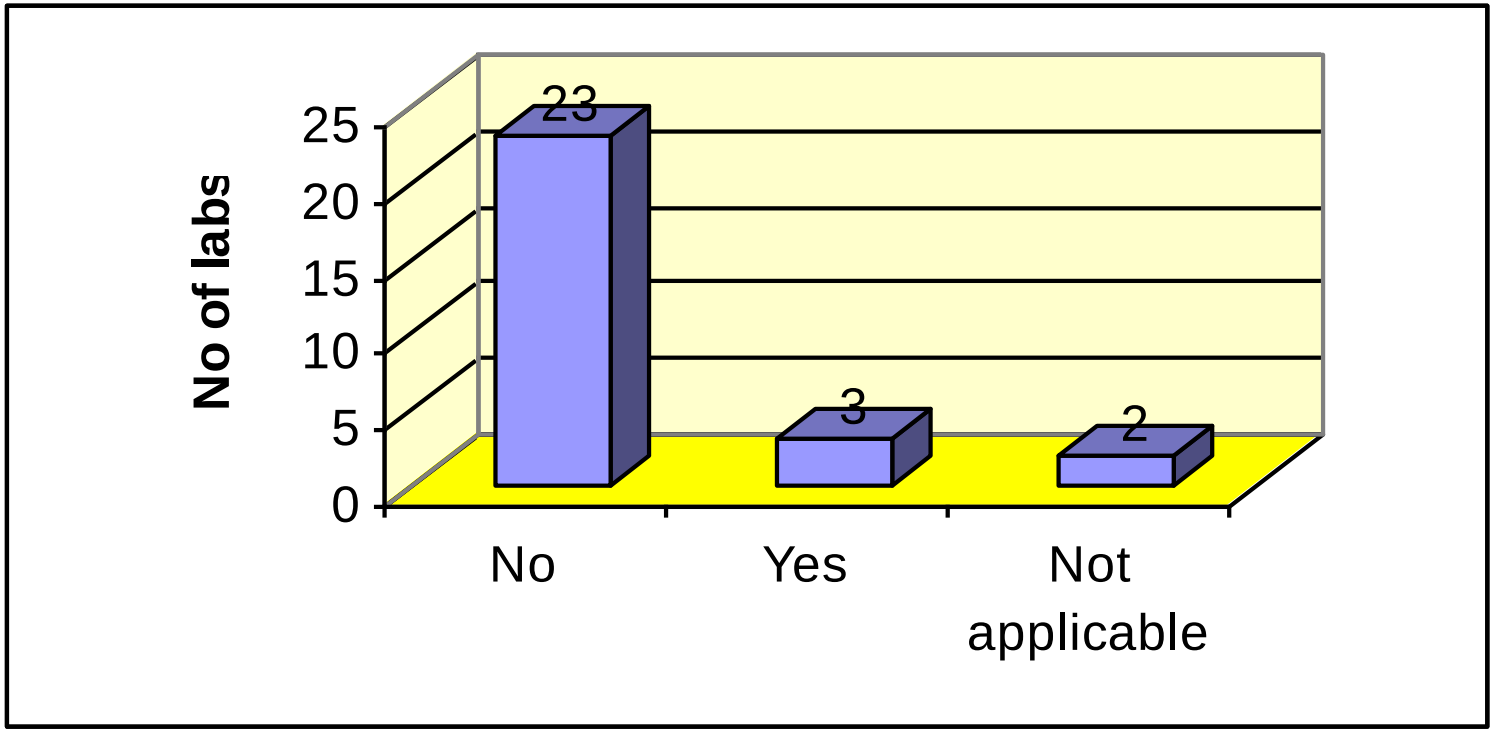
Method	T. Bilirubin ? affected	Level of haemolysis	C. bilrubin, ? affected	Level of haemolysis
Ortho Vitros Diazo	3 of 3	15 g/l	3 of 3	2 g/l
Siemens ADVIA	**1 of 2**	10 g/l	**1 of 2**	5 g/l
Abbott Architect Diazo	5 of 5	10 g/l	**4 of 5**	0.62 g/l
Beckman Olympus Diazo/O'Leary	5 of 5	5 g/l	**4 of 5**	3 g/l, ? any level
Beckman DxC Diazo	**2 of 3**	2 – 3 g/l	**2 of 3**	2 g/l
Cobas Integra	1 of 1	1.4 g/l	1 of 1	0.1 g/l
Roche Modular Diazo	**7 of 8**	Variable answers 0.5 – 10g/l	**7 of 8**	Variable answers 0.25 – 2.5 g/l
Cobas Integra	2 of 2	0.5 -1.4 g/l/	1 of 1	0.1 – 0.25g/l

Assumed HI = 1 mg/dL

Q17: reporting haemolysed samples



Q18: use alternative lab/method if affected by haemolysis



Q19: TBilirubin QC – number of levels

QC 1 (28 labs)	**QC 2 (20 labs)**	**QC 3 (21 labs)**	**QC 4 (7 labs)**	***No of labs***
15 µmol/L (±7)	60 µmol/L (±20)	116 µmol/L (±20)	276 µmol/L (±56)	
X	**x**	**x**	**x**	***2***
X	**x**	**x**		***14***
X		**x**	**X**	***2***
X	**X**			***4***
X		**X**		***3***
X			**x**	***3***

Q19: QC imprecision

	CV% for QC1	CV% for QC2	CV% for QC3	CV% for QC4
T.bilirubin	15 µmol/l ±7	60 µmol/l ±20	116 µmol/l ±20	116 µmol/l ±56
Target	***<10 %***	***<5 %***	***<5 %***	***<3%***
Roche Modular	3 - 14	2 - 11	1 – 16	1.7
Abbott Architect	5 - 8	2 - 9	2 – 4	2 – 3
Beckman Olympus	0.5 – 6	2 – 3	2 – 4	
Beckman DxC	4 - 11	3 - 4	2 – 3	3
Ortho Vitros	4 - 6			2 - 3
Siemens ADVIA	2 – 13	1 – 3	1 - 9	
Cobas Integra	2.4 - 5	2.3 - 5	5	

23 out of 28 labs – met precision targets. Not method related.

Q20: participate in paediatric bilirubin EQA

- 24/28 NEQAS
- 2/28 NEQAS/WEQAS
- 2 no EQA specifically for paediatric bilirubin

WEQAS

UKNEQAS for Paediatric Bilirubin

Point of Care Testing

Q21. POCT Bilirubinometers

- 18/28 Trusts use bilirubinometers (64%)
  - 16/18 used Pfaff (1 also use O'Hara) (89%)
  - 1 lab - Neobil
  - 1 lab – no model stated

Q21. POCT Bilirubinometers

- 10/18 involved in maintenance (56%)
- 9/18 involved in training (50%)
- 17/18 have an SOP (94%)
- iQC 16/18 (89%)
- EQA 18/18 (100%)

  NEQAS 14, WEQAS 3, both 1
- Compared to lab method 14/18 (78%)

Q21. POCT Bilirubinometers

Q21f: Advise that high bilirubins are checked by laboratory

Yes: 12 (67%)

No: 5 (27 %)

No answer: 1

Q21. POCT Bilirubinometers

Q21g: Checking limit if bilirubin (µmol/l)

> 250 (2)

> 280 (1)

> 300 (4)

> 400 (1)

> linear range (620 µmol/L) (1)

No answer (2)

When indicated by phototherapy/ transfusion (3)

Q22. POCT blood gas analysers

8/28 Trusts use BGAs for bilirubin (29%)

- 3 Cobas 221 (38%)
- 2 ILGEM 4000 (25%)
- 2 Radiometer 700 (25%)
- 1 Radiometer AL735 & cobas221 (12%)

Q22. POCT blood gas analysers

- 5/8 involved in maintenance (63%)
- 5/8 involved in training (63%)
- 5/8 have SOP (63%)
- 6/8 iQC (75%)
- 5/8 EQA (63%) NEQAS 2, WEQAS 3

Q22. POCT blood gas analysers

- 1/8 compared to lab method (12%)

- Affected by haemolysis

  yes: 1 (but level unknown)

  No: 4

  Don’t know: 3

Q23: Transcutaneous meters

Only 2/28 - Bilichek, unknown model

- 1 lab involved in maintenance/training

Other comments:

- 1 lab has trialled them
- 1 used to have them

Q24 & Q25: Ictometers & other POCT

Only 1 lab is aware of their hospital using Ictometers

No: 17/28 (61%)

Don’t know: 7/28 (25%)

Old method: 1/28 (4%)

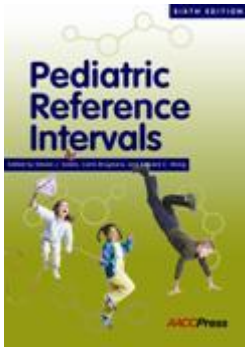
No other POCT devices for bilirubin are used

Reporting / Clinical advice

Reporting/Clinical advice

Q26: Age – related reference ranges?

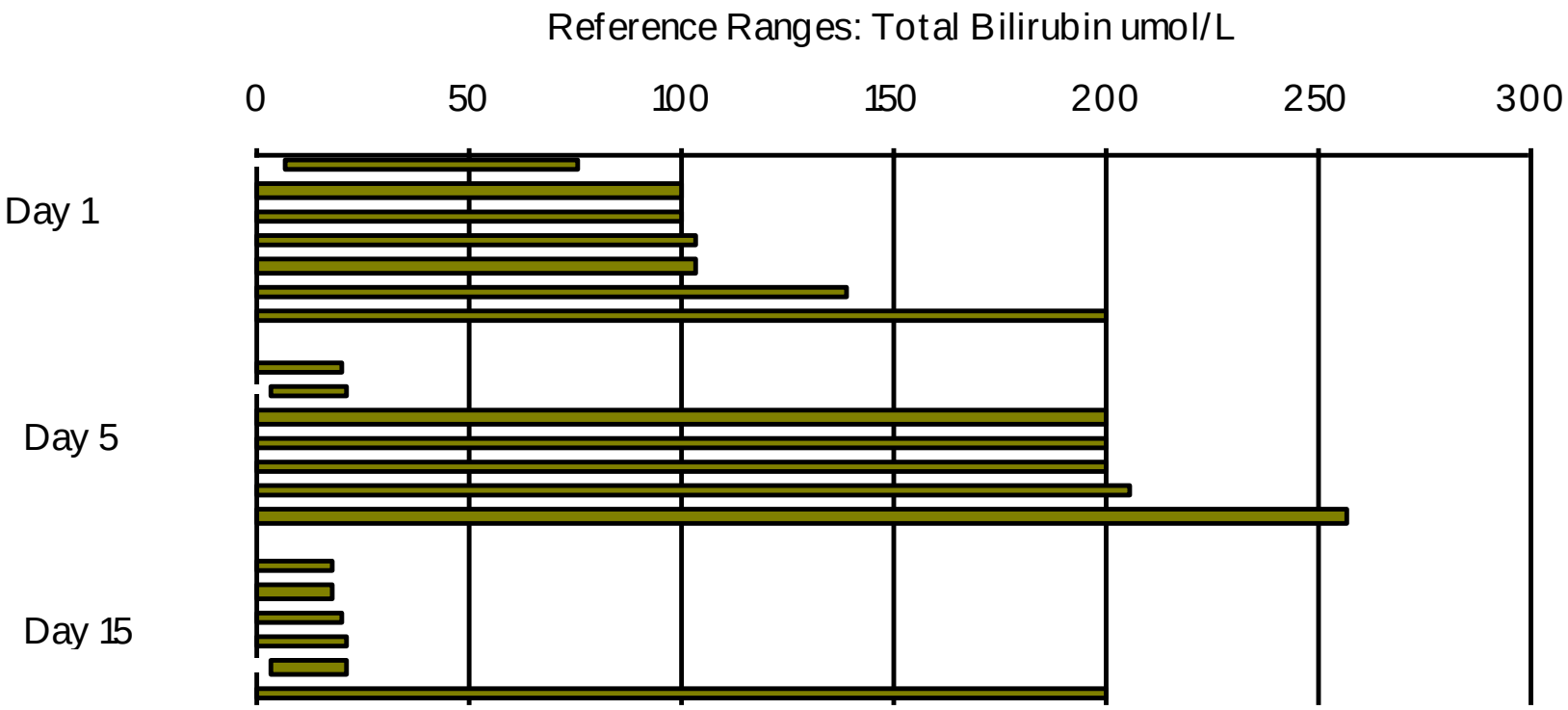
- Yes – 9 (32%)
- No – 19 (68%)



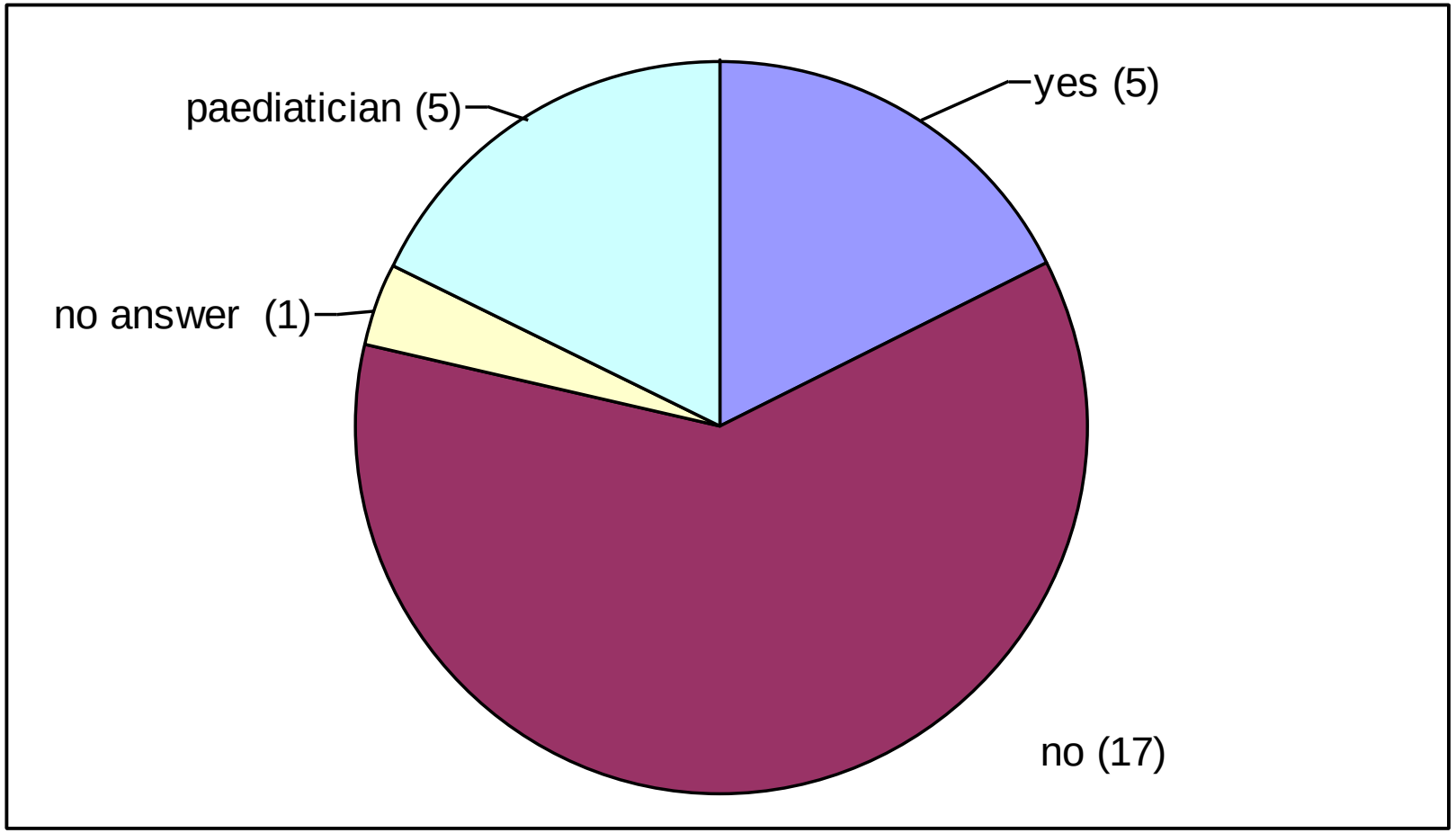
Q27: Provide interpretative comments:

- Yes – 0
- No – 22 (79%)
- Occasionally – 6

Q26: Reference Ranges



Q28: Have policy/protocol for elevated conjugated bilirubin



Q29. Tests for 15 d term infant with conjugated bilirubinaemia

- Top twenty
  – first ten

Galactose-1 PUT	22
Alpha 1 antitrypsin	19
Plasma amino acids	19
Thyroid function tests	17
Urine organic acids	14
Sweat test/IRT/ exclude CF	13
Full blood count	10
Urine amino acids	10
Cortisol	10
Liver function tests	9

Q29. Tests for 15 d term infant with conjugated bilirubinaemia

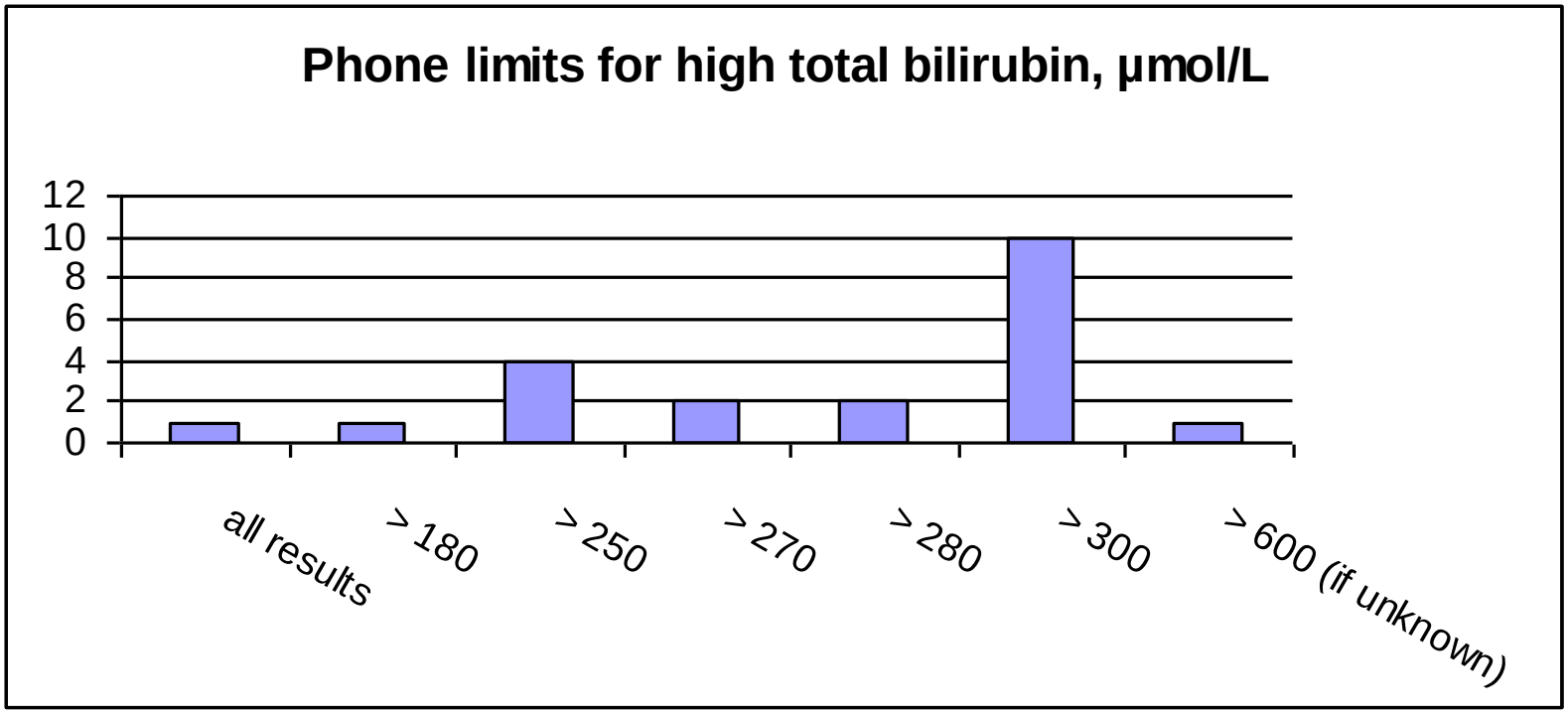
- Next 8

Urine reducing substances	9
Liver US	9
Infection screen	7
VLCFAs	5
Urine bilirubin	4
Glucose 6 P DH	4
Coombes	3
Ammonia	3

Q30: phoning high paediatric bilirubin results?

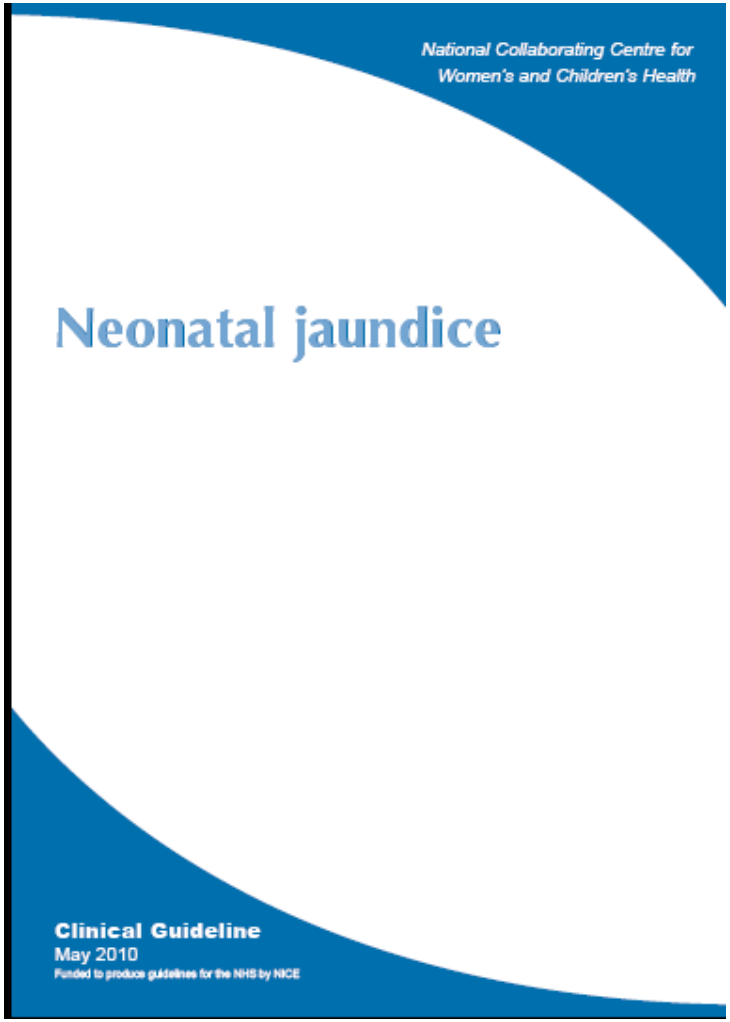
Phone high results

- Yes – 20 No – 8



Q31: Aware of NICE guideline

- Yes – 22 (79%)
- No - 6 (21%)



NICE Neonatal Jaundice Guidelines - Summary

- Published 19 May 2010
- Developed by National Collaborating Centre for Women's and Children's Health
- Recommends substantial change to current practice for detecting & managing jaundice in babies <28 days
- Practical step-by-step guidance for parents, midwives, health visitors, GPs and paediatricians on the *detection* of jaundice in newborn babies, the *prediction* of those likely to develop adverse consequences, and *treatment* options.

NICE Neonatal Jaundice Guidelines - Summary

- Visually examining all babies for jaundice at every opportunity
- Not to rely on visual inspection alone to estimate the bilirubin concentration
- If jaundice is suspected, bilirubin concentration should be measured.
- A transcutaneous bilirubinometer (rather than a blood test) can be used in babies > 35 weeks of gestation and > 24 h
- Urgent *blood test* if jaundiced and <24 h old or < 35 weeks gestation
- Transcutaneous bilirubinometers cannot be relied upon if bilirubin > 250 µmol/L

NICE Neonatal Jaundice Guidelines - Summary

- Most at risk
  - < 38 weeks' gestational age,
  - a sibling w. neonatal jaundice that required phototherapy
  - exclusively breastfed,
  - visible jaundice in the first 24 h of life.
- Previously wide variation in the UK in the bilirubin threshold chosen to initiate phototherapy.
- The NICE guideline clearly outlines the management of babies with hyperbilirubinaemia according to gestational and postnatal ages, with thresholds given for phototherapy, multiple phototherapy, intravenous immunoglobulin, or exchange transfusion.

NICE Neonatal Jaundice Guidelines - Summary

- Need more research - ? universal screening of all babies with transcutaneous bilirubinometers - decrease risk of kernicterus
- Need more research - accuracy of transcutaneous bilirubinometers
- National register of cases of significant hyperbilirubinaemia and kernicterus

NICE Neonatal Jaundice Guidelines - considerations

- Need to be aware of new treatment algorithms
- Need to be aware of the use transcutaneous monitors
- Need to able to provide accurate and precise bilirubin measurements urgently if required – use of phototherapy will be guided by serum bilirubin levels
- Frequent, serum bilirubin measurements are required during phototherapy (4-6 hours initially, 6–12 hours if bilirubin stable or falling) – quick TAT required if meaningful.
- Role in further research