Centre for

CLINICAL EFFECTIVENESS

EVIDENCE CENTRE REPORT

REQUEST:

What is the best method for assessing neonatal jaundice in a multicultural population?

REQUEST MADE BY:

Ms Cheryl Kearney, Women's Health Program, Southern Health Care Network

DATE OF REPORT:

10 September, 1998.

DISCLAIMER

The information in this report is a summary of that available up to August 22 1998. It is primarily designed to give readers a starting point to consider the currently available research evidence. Readers should not use the comments made in isolation and should have read the literature suggested. Readers should also be aware that more appropriate research might have become available since the request was dealt with.

SUMMARY OF FINDINGS

- The current best available evidence on this topic reaches no greater than Level 2 evidence, with the majority of evidence being Level 3 according to NHMRC criteria.
- The current data must be considered with care as the published literature reveals methodological problems and confounding variables with studies to date.
- Findings from the evidence retrieved on neonatal jaundice indicate that multicultural populations are little considered in the literature. For ease of study, or ease of evaluation, 'white' babies are studied most. The most appropriate method found to study a multicultural population is the transcutaneous bilirubinometer. This device uses reflectance technology to scan the underlying yellow colour of the skin, and can be calibrated for different types of ethnic population. Its results correlate very well with serum bilirubin measures, however most authors caution that it cannot replace serum bilirubin measures, but can indicate when SB is required.

Transcutaneous bilirubinometry (TcB) is preferred by many authors to other noninvasive bilirubin methods (for example, the perspex icterometer) as it is objective and unaffected by such things as lighting conditions. There are a number of types of TcBs on the market, costing around US$3,000. The Colormate III has been studied and approved by the United States Food and Drug Administration, but there are a number of other TcBs on the market. However no research could be found to validate them. The study on the Colormate III achieved Level 2 evidence according to NHMRC criteria (being the best evidence of that found).

Information on cost-effectiveness was limited to that from Maisels and Kring (1997) who found that use of the TcB generated savings of about $1600 per annum (in a hospital delivering 5,000 infants annually). Knudsen (1996) declared that use of the TcB reduced by 50% the need for invasive serum bilirubin testing. Tan et al. (1996) claimed "TcB can therefore serve as a simple, convenient and labour saving method for screening for significant neonatal jaundice."

INTRODUCTION

Centre for Clinical Effectiveness

The Centre for Clinical Effectiveness operates an Evidence Centre that accepts requests to identify and critically appraise the available evidence on particular clinical topics. It offers this service to staff of the Southern Health Care Network.

Current request

Ms Cheryl Kearney, a nurse unit manager in the Women's Health Program based at Monash Medical Centre Clayton Campus, requested an evidence review on:

> *What is the best noninvasive method to assess neonatal jaundice in a multicultural population, that is, where the population contains diverse skin colours.*

SEARCH RATIONALE

The Centre for Clinical Effectiveness Evidence Centre searches for best available evidence using a strategy that incorporates two factors:

1. A hierarchy that reflects the methodological quality of an item, that is, the likelihood of systematic bias affecting the research results reported.

2. A desire to limit the amount material provided if adequate, sound, research summaries already exist.

LEVELS OF EVIDENCE

The quality of the evidence presented in this report was systematically assessed and classified according to the NHMRC's *Guidelines for the Development and Implementation of Clinical Practice Guidelines* (1995):

Level I	Evidence obtained from a systematic review or a meta-analysis of at least two relevant randomised controlled trials
Level II	Evidence obtained from at least one properly designed randomised controlled trial
Level III	Evidence from well designed controlled trials without randomisation, well-designed cohort or case-control analytic studies preferably from more than one centre or research group, or multiple time series with or without the intervention
Level IV	Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees

DETAILS OF THE REQUEST

Patients

Full term neonates not yet released from hospital since birth.

Interventions

Noninvasive assessment of neonatal jaundice.

Comparisons

Different assessment tools/methods of assessing bilirubin levels.

Outcomes

100% sensitivity. Decision points for light therapy or exchange transfusion.

SEARCH STRATEGY

Search terms

Condition terms:	hyperbilirubinemia, bilirubin, neonatal jaundice
Patient terms:	neonate, neonatal, newborn, full term
Intervention terms:	bilirubinometry, bilirubinometer, transcutaneous bilirubinometry, serum bilirubin
Skin colour terms:	black, skin tone*, skin color*, skin pigmentation, race, multicultur*
Other terms:	guidelines, protocols

SEARCH REFINEMENTS

Human only; full term babies > 36 weeks; published in any year.

REPORTING CONSTRAINTS

We made an expedient decision to include in the review only those reports whose full text was available to us before 17 August 1998.

DATABASES

We searched the following databases and websites in this order:

- Cochrane Database
- Best Evidence - on CD-ROM
- Evidence-Based Medicine
- ACP Journal Club
- Medline via Ovid Monash
- MEDLINE via PUBMED
- Other relevant databases through OVID
- PsycInfo
- CINAHL
- Core Biomedical Collection
- CURRENT CONTENTS
- Agency for Health Care Policy and Research
- ARIF - Aggressive Research Intelligence Facility
- NHS CRD - Centre for Reviews and Dissemination
- National Library of Medicine
- IDEA TOPICS LIST
- CliniWeb
- DARE
- ScHARR-Lock's Guide to the Evidence
- National Institutes of Health
- Academic Index (full text)
- MedFinder
- Centre for Evidence-Based Medicine
- HIRU
- Centers for Disease Control and Prevention
- FDA
- Health Canada

- Internet Search Engines: HotBot, WebCrawler,
- NEED - NHS Economic Evaluation Database
- HealthStar
- Effectiveness Matters
- Evidence Based Health Policy and Management (UK)
- Clinical Practice Guidelines on the Web
- The Virtual Hospital Clinical Guidelines
- Canadian Medical Association CPG Infobase
- World Health Organization Publications
- AHCPR Guidelines
- Canadian Coordinating Office for Health Technology Assessment
- INAHTA (Intl Network of Agencies for Health Technology Assess)
- HSTAT - Health Services/Technology Assessment Text
- AETS - Health Technology Assessment Agency
- Hand skimming recent relevant journals
- Relevant online conferences, societies, university and hospital departments, search on relevant authors, government sites

RESULTS

From these resources we identified:

Clinical guidelines	0
Systematic reviews	0
Randomised controlled trials	1
Well-designed controlled trials, cohort or case-control analytic studies	7
Concurrent comparisons	0
Descriptive case series	0
Narrative reviews	3

We are reasonably confident these figures represent the most important findings published to date by those considered expert in the field.

OVERALL RESULTS

The three main methods of assessing neonatal jaundice will be evaluated: the icterometer, visual assessment and the transcutaneous bilirubinometer (TcB).

The Icterometer

An icterometer is a plastic strip with alternating stripes of clear and painted perspex and has been in use since 1925 (Schumacher, 1990). The stripes are of increasingly deepening yellow colour which represents increasing severity of jaundice. The hard perspex is pressed against a baby's nose until the skin blanches, then the underlying yellow skin tone is matched to the corresponding shade of yellow. There have been a number of types of icterometer: the "Perspex Icterometer"; the "Ingram icterometer", and the "Gossett icterometer" (Dai, Parry & Krahn, 1997).

Three of the articles which we evaluated had assessed the use of the icterometer (Schumacher, 1990; Dai, Parry & Krahn, 1997; Madlon-Kay, 1997). While non-invasive, cheap and easy to use, the icterometer was considered by these authors as

lacking objectivity, and unable to achieve intra-rater or inter-rater reliability. Madlon-Kay (1997) actually found parents to make more accurate assessments of level of neonatal jaundice using the icterometer, than did nurses or doctors.

Visual Assessment of Jaundice

Visual assessment of neonatal jaundice has always been the most common method of assessing neonatal jaundice and is still widely used. Of concern is the lack of objectivity, intra-rater or inter-rater reliability. This is of critical importance because of the potential for missing the deadly or damaging disease of kernicterus. It is also a method more difficult in the case of non-'white' babies, where one must look at the gums, or palms and soles of the feet. Several writers reported that with ‘black’ or ‘non-white’ babies, visual assessment tends to be abandoned in favour of serum bilirubin measurement.

Surprisingly, the guidelines producted by the American Academy of Pediatrics (AAP) on assessment of neonatal jaundice (1992) recommended visual assessment (or the icterometer) to determine the extent of neonatal jaundice. The guidelines recommend assessing the underlying yellow tone of the skin by blanching the skin in a well-lighted room (not mentioning whether that light be fluorescent, daylight or otherwise). They do not mention the issue of 'non-white' babies, except to suggest that those babies in ethnic groups at risk of G6PD should automatically have an SB.

Madlon-Kay (1997) followed the AAP guidelines in comparing the ability of parents, doctors and nurses to assess neonatal jaundice, including its cephalocaudal progression. Nurses and doctors were asked to 'guess' the serum bilirubin level from their visual assessment. Parents were given instructions on how to estimate level of jaundice. The lack of reliability of visual assessment is emphasised by the fact that parents were more accurate in their assessments of neonatal jaundice than the many doctors and nurses who participated in the study.

Knudsen’s 1992 study, in which Danish babies were visually assessed soon after birth, then regularly thereafter, is typical of the studies which test only white babies, thereby excluding the huge percentage of the population who do not have ‘white’ skin. This study did, however, illustrate that a reading taken soon after birth could set a baseline of skin colour to make later assessments more accurate. Schumacher (1990) warns, however, that other skin chromogens may interfere with accuracy in judging the yellowness of skin.

Transcutaneous Bilirubinometry

For about a decade, machines which measure neonatal jaundice level non-invasively, by skin reflectance, have been available, and numerous studies on them have been published. Their results has been reported to be unaffected by the base colour (melanin component) of the skin (Hanneman et al. 1979; Tan 1982; Knudsen 1996; FDA 1997) and therefore makes it suitable for use on any skin colour.

Transcutaneous bilirubinometers, mostly the AirShields Minolta bilirubinometer (Land Instruments), have been tested both with homogeneous (white) populations (Knudsen 1996) as well as in populations of various skin colours (Hanneman et al. 1979; Tan 1982; Linder et al. 1994; Dai, Krahn & Parry 1996; Tan et al. 1996; Dai, Parry & Krahn 1997; FDA 1997).

An accurate diagnostic tool must correlate well with the gold standard test, in this case: serum bilirubin measurement (SB). Quite a number of controlled research studies have

compared the two tests, TcB and SB (Hanneman et al. 1979; Tan 1982; Linder et al. 1994; Dai, Krahn & Parry 1996; Knudsen 1996; Tan et al. 1996; Dai, Parry & Krahn 1997; FDA 1997; Maisels & Kring 1997) and all show very high correlations between the two, ***r*** being equal to 0.9 in most cases. The FDA study found that the Colormate III bilirubinometer results were better correlated with SB determinations (r=0.90) than were the physicians' visual assessment (r=0.67).

Several of these researchers advise that a TcB result cannot be taken as corresponding exactly with the SB, but can indicate very well when SB testing is advisable. No author states that TcB can be taken to indicate the exact serum bilirubin level.

There are a number of issues raised in the study of neonatal jaundice assessment. These include some already mentioned: that controlled trials require use of the invasive procedure; that such an important test has had such poor methodology. Several other issues will now be considered.

Race Issues

Unfortunately, until recently, most studies of visual estimates of bilirubin level included babies with white skin only. This may have been appropriate in the case of workers like Knudsen in Norway who had a homogeneous white population to draw on. But increasingly in many countries, including Australia, the population is diversifying with regard to skin colour. With the major proportion of the world's population having non-white skin, the challenge is to provide the best care to babies no matter their skin colour.

Madlon-Kay (1997) found race or ethnic group did not affect accuracy of TcB results. However several authors (Tan 1982; Linder et al. 1994; Knudsen 1996) found that the bilirubinometer needed to be calibrated differently for different ethnic groups. It would need to be assessed whether this is a workable possibility for a ward situation.

Dai, Krahn and Parry (1996) cautioned that it may be difficult to judge which calibration guidelines to follow in the case of a particular baby because "a specific ethnic origin cannot be attributable to a single skin colour". Also there must be a decision made about how to approach results from the many mixed race babies. It would be unclear how to calibrate the bilirubinometer in that case. When Linder et al. (1994) tested some mixed race babies in their sample, the babies' results were inconsistent with either of their parent's racial groups, and in fact their results were more similar to the 'white' babies' results.

Technology Issues

The AirShields Minolta jaundice meter frequently described in the literature has changed manufacturer and its new manufacturer could not be found. We could pursue this further if there was interest in using this particular model.

There are a number of other jaundice meters now being produced, the ColorMate III (CCSI, New York), Unistat Bilirubinometer (Leica, Deerfield IL), and the Bilitest (Technomedica, Russia). The ColorMate III has recently received FDA approval in the US, after extensive testing on a large sample of babies from a variety of ethnic groups. No details of studies on other jaundice meters could be found.

In Summary

Knudsen points out the main benefit of transcutaneous bilirubinometry to be: "around 50% of the jaundiced neonates can without risk avoid blood sampling". However, Dai, Parry and Krahn (1997) warn that: "although TcB measurements correlate well with SB levels they cannot accurately predict SB". They do advise that it is a good tool for screening to determine when a lab measurement of SB is needed.

Both Maisel and Kring (1997) and Tan et al. (1996) recommend the use of TcB as a simple, convenient and labour saving method to screen for significant neonatal jaundice which requires SB.

Suggesting improvements to the way transcutaneous bilirubinometry is carried out, Linder et al. (1994) recommend "separating infant populations into ethnic groups...to improve the sensitivity of TcB measures", calibrating the TcB accordingly; and Knudsen (1996) recommends correcting readings for differences in melanin content of the skin.

According to Schumacher (1990), both the icterometer and the transcutaneous bilirubinometer can be used effectively for neonatal jaundice screening, and he believes that the decision to select a method should be made on cost-effectiveness grounds only.

REFERENCES

American Academy of Pediatrics. Practice Parameter: Management of hyperbilirubinemia in the healthy term newborn. Pediatrics 94(4):558-65.

Dai, J; Krahn, J. & Parry, DM; (1996) Clinical impact of transcutaneous bilirubinometry as an adjunctive screen for hyperbilirubinemia. Clinical Biochemistry 29(6):581-6.

Dai, J; Parry, DM; & Krahn, J. (1997) Transcutaneous bilirubinometry: its role in the assessment of neonatal jaundice. Clinical Biochemistry 30:1-9.

Hannemann, RE; Dewitt, DP; Hanley, EJ; Schreiner, RL; & Bonderman, P. (1979) Determination of serum bilirubin by skin reflectance: effect of pigmentation. Pediatr. Res. 13(12):1326-9.

Knudsen, A. (1996) Prediction and non-invasive assessment of neonatal jaundice in the term healthy newborn infant. Acta Paediatrica 85:393-7.

Linder, J; Regev, A; Gazit, G; Carplus, M; Mandelberg, A; Tamir, I; & Reichman, B. Noninvasive determination of neonatal hyperbilirubinemia: standardization for variation in skin color. American Journal of Perinatology 11(3):223-5.

Madlon-Kay, DJ (1997) Recognition of the prsence and severity of newborn jaundice by parents, nurses, physicians and icterometer. Pediatrics 100(3):electronic page 3.

Maisels, MJ; & Kring, E. (1997) Transcutaneous bilirubinometry decreases the need for serum bilirubin measurements and saves money. Pediatrics 99(4):599-601.

Schumacher, RE. (1990) Noninvasive measurements of bilirubin in the newborn. Clinics in Perinatology 17(2):417-35.

Tan, KL. (1982) Transcutaneous bilirubinometry in fullterm Chinese and Malay infants. Acta Paediatrica Scandinavica 71:593-6.

Tan, KL; Chia, HP; and Koh, BC (1996) Transcutaneous bilirubinometry in Chinese, Malay and Indian infants. Acta Paediatrica 85:986-90.

United States. Food and Drug Administration. (1997) FDA information/approval of Colormate III Jaundice Meter.

EVIDENCE REPORT SUMMARY TABLE

ASSESSING NEONATAL JAUNDICE

	NHMRC LEVEL OF EVIDENCE	DESCRIPTION: Patients, Interventions, Comparisons, Outcomes	VALIDITY: Methodology, rigour, selection, opportunities for bias	RESULTS: Generally favourable or unfavourable, specific outcomes of interest, estimate of experimental effect and precision if appropriate	AUTHORS' COMMENTS: Risk/benefit, limitations	REVIEWERS' COMMENTS: Risk/benefit, methodology, conclusions
Knudsen, A. (1996) Prediction and non-invasive assessment of neonatal jaundice in the term healthy newborn infant. Acta Paediatrica 85:393-7.	Narrative Review Level 4	**Patients** healthy newborn infants who are visibly jaundiced **Diagnostic tests** TcB vs SB **Outcome**: plasma bilirubin concentration, jaundice meter readings	Methodology: infants preselected for 'visible' jaundice visually by trained staff. These babies then tested with TcB. A cutoff point was used to decide to send for SB Opportunities for bias: in the visual selection of jaundiced babies; in one cutoff point when children of diff ethnic background may need diff cutoff points	Reasonably high correlation bw SB and TcB, but plasma bilirubin determinations inadequate	" In homogeneous populations …around 50% of the jaundiced neonates can, without risk, avoid blood sampling." "the jaundice meter readings are sensitive to differences in the melanin content of the skin, which is most important when the Jaundice meter is utilized in heterogeneous populations of diff ethnic origins." "Further development of the Jaundice Meter to correct for differences in the melanin content of the skin would enhance the clinical utility of the Jaundice meter in mixed race populations"	
Tan, KL; Chia, HP; and Koh, BC (1996) Transcutaneous bilirubinometry in Chinese, Malay and Indian infants. Acta Paediatrica 85:986-90.	Cross-sectional cohort: Level 3	Patients: 3 groups of babies: Malay, Chinese, Indian Diagnostic tests: TcB vs SB Outcome: TcB level or SB at forehead and chest	Gold standard: SB Patient Spectrum: restricted on purpose	Good correlations between TcB and SB for each of the 3 groups.	"TcB can therefore serve as a simple, convenient and labour saving method for screening for sig. Neonatal jaundice	

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Madlon-Kay, DJ (1997) Recognition of the prsence and severity of newborn jaundice by parents, nurses, physicians and icterometer. Pediatrics 100(3):electronic page 3.	Cross-sectional cohort: Level 3	Patients: normal newborn, Interventions: jaundice assessment, Comparisons: parents assessment, icterometer, doctor assessment, nurse assessment, Outcomes	Diff. Groups examined cephalocaudal progression either visually, or by icterometer	only moderate agreement bw physicians, nurses, and parents. Parent's assessment of cephalocaudal progression was most closely correlated with jaundice level	Study poorly described, and too many different raters included in process	Stated that in previous studies: "the nonpigmented palms and soles are a useful area for clinical inspection."
United States. Food & Drug Administration (1997) Information/approval of Colormate III Jaundice Meter	Level 2 controlled trial	Patients: 1317 newborns, Interventions: TcB measure vs SB vs physician visual assessment, Outcomes serum bilirubin measure, jaundice meter reading	Methodology: study of sequential 1317 newborns by 3 types of test	The jaundice meter reading was more highly correlated with SB than was visual estimate r=0.90, p<0.05 Result was unaffected by race (caucasian, black , hispanic, oriental)	FDA report: "within the first hours after birth, newborn babies are initially measured and periodically monitored by the Colormate III for incremental changes in the yellow content of the skin color as compared to the baseline …measurements. Babies with ...test results indicative of hyperbil. are to be re-evaluated"	
Linder, J; Regev, A; Gazit, G; Carplus, M; Mandelberg, A; Tamir, I; & Reichman, B. (1994) Noninvasive determination of neonatal hyperbilirubinemia: standardization for variation in skin color. American Journal of Perinatology 11(3):223-5.	Cross-sectional cohort study. Level 3	**Patients** healthy full term newborn infants of mixed race **Diagnostic tests** TcB vs SB **Outcome**: plasma bilirubin concentration, jaundice meter readings	**Methodology:** each baby had TcB taken within 4 hrs of birth,each baby who appeared jaundice had both SB and TcB taken simultaneously **Selection:** 389 sequentially delivered babies, opportunities for bias	in 123 infants who appeared jaundiced, TcB readings correlated with SB R=0.90 p<0.01	"Separating infant populations into ethnic groups …improves the sensitivity of TcB measures for the screening of hyperbilirubinemia." "The current study shows that TcB taken shortly after birth can control for variability in skin colour…and may eliminate the necessity to define standardized curves for diff ethnic pop.s"	

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Tan, KL. (1982) Transcutaneous bilirubinometry in fullterm Chinese and Malay infants. Acta Paediatrica Scandinavica 71:593 6.	Cross-sectional cohort study. Level 3	Patients: 68 Chinese and 28 Malay fullterm infants		High correlations between TcB and SB	**"the brown skin pigmentation of Malay infants might have a slightly greater effect on the TcB index than the yellow pigment. Of Chinese babies"**	
Maisels, MJ; & Kring, E. (1997) Transcutaneous bilirubinometry decreases the need for serum bilirubin measurements and saves money. Pediatrics 99(4):599-601.	Cross-sectional cohort study. Level 3	Patients: > 35 wks 356 white newborns	Introduced routine use of TcB after trial of SB vs TcB (using Advanced Instruments Bilirubinometer)	r=0.87, p<0.00001	"TcB is useful screening technique. Meter costs US$3000, but in hospital delivering 5000 infants annually, generates savings ~$1600 per year"	Authors also state the jaundice meter is useful for outpatient pop.
Hannemann, RE, Dewitt, DP, Hanley, EJ, Schreiner, RL; & Bonderman, P. (1979) Determination of serum bilirubin by skin reflectance: effect of pigmentation. Pediatr. Res. 13(12):1326-9.	Cross-sectional cohort study. Level 3	58 white, 45 black full term neonates. Concurrent SB vs reflectance spectra (TcB)	Cohort of both black and white infants tested both by TcB and SB	Regression analyses SB to TcB white r=0.831 black r=0.877	"the relationship bw skin reflectance and SB in full term infants is close to the acceptable limits for clinical use. …skin pigmentation does not obscure this relationship."	Only had abstract to work from.
Schumacher, RE. (1990) Noninvasive measurements of bilirubin in the newborn. Clinics in Perinatology 17(2):417-35.	Narr. Review Level 4	Patients: N/A Measure: TcB vs SB vs icterometer	N/A	Favourable twd all methods	"both new and old transcutaneous devices can serve as effective screening devices. The choice of which device to use depends on its cost-effectiveness in any given clinical setting."	

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Dai, J; Parry, DM; & Krahn, J. (1997) Transcutaneous bilirubinometry: its role in the assessment of neonatal jaundice. Clinical Biochemistry 30:1-9.	Narr. Review Level 4	Patients: N/A Measure: TcB vs SB	N/A	"Black and Arab fullterm infants have higher intecepts than white or Oriental"	"Although TCB measurements correlate well with SB levels they cannot accurately predict serum bilirubin" " TcB cannot be used directly to make decisions…[but is] a good tool for screening to determine when a lab measurement of SB is needed"	
American Academy of Pediatrics. Practice Parameter: Management of hyperbilirubinemia in the healthy term newborn. Pediatrics 94(4):558-65.	Guidelines. Level 3	>36 wks	"The practice parameter of hyperbilirubinemia in healthy term infants was reviewed by the appropriate committees and sections of the AAP"	Recommend visual assessment. State: "use of an icterometer or trans jaundice meter may also be helpful"		Not very stringent guidelines. No single recommended method for assessment. Provides clinical algorithms for jaundice assessment
Dai, J; Krahn, J. & Parry, DM; (1996) Clinical impact of transcutaneous bilirubinometry as an adjunctive screen for hyperbilirubinemia. Clinical Biochemistry 29(6):581-6.	Retrospective case control. Level 3	Patients from a selected 6 month period. Subjects were 45 healthy full term infants who had SBs taken	"it was estimated that use of a jaundice meter could eliminate 43% of the single bilirubin tests done on healthy term neonates"	"variation in skin color as a cause of false neg meter results is probably not a sig. Problem" "a specific ethnic origin cannot be atributable to a single skin color"		