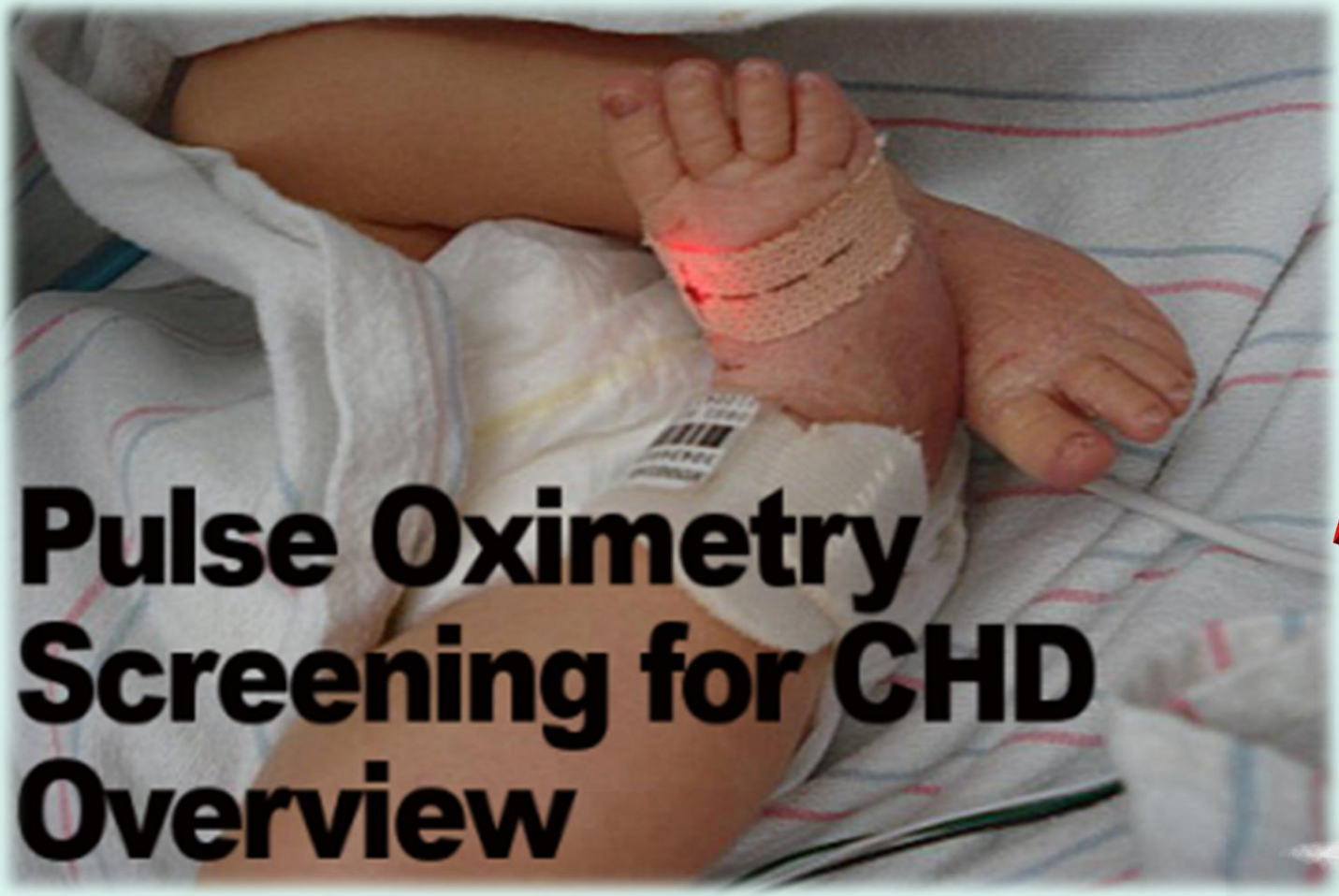
JOURNAL CLUB

以脈衝血氧飽和儀(Pulse oximetry)篩檢危急型先天性心臟病新生兒之準確度

報告人：新生兒加護病房
陳若蘋 護理長

日期：103.07.15

A simple, non-invasive, cheap and widely available piece of equipment can save lives. Pulse oximetry is used standardly in medicine to check oxygen saturation and has been found to be effective in screening for congenital heart defects.



http://pulseoxadvocacy.com/

Pulse oximetry screening for critical congenital heart defects in asymptomatic newborn babies: a systematic review and meta-analysis

Shakila Thangaratinam, Kirtrea Brown, Javier Zamora, Khalid S Khan, Andrew K Ewer

Summary

Background Screening for critical congenital heart defects in newborn babies can aid in early recognition, with the prospect of improved outcome. We assessed the performance of pulse oximetry as a screening method for the detection of critical congenital heart defects in asymptomatic newborn babies.

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the defects in newborn babies.[1] The rationale for use of this method is that most critical congenital heart defects have a degree of hypoxaemia that would not necessarily produce visible cyanosis and therefore might not be clinically

Methods

Search strategy and selection criteria

This systematic review was undertaken with a prospective protocol using recommended methods.[20,21] We searched

前 言

- Congenital heart defects are a leading cause of infant death.
  - Up to 40% of all deaths from congenital defects and 3–7.5% of infant deaths are due to such abnormalities.
- Timely diagnosis improves outcome.
- Pulse oximetry has been developed as a screening method to detect the defects in newborn babies.
  - The rationale for use of this method is that most critical congenital heart defects have a degree of hypoxemia that would not necessarily produce visible cyanosis and therefore might not be clinically detectable.

critical congenital heart defects (CCHD)

- 指在出生一年內(多數在一個月內)需要外科手術矯正或心導管治療的先天性心臟病
  - 如：左心發育不全、肺動脈瓣閉鎖、法洛氏四重症、全肺靜脈回流異常、大動脈轉位、三尖瓣閉鎖、共同動脈幹...等

步驟1　研究探討的問題為何？

研究族群 / 問題 (Population/ Problem)	asymptomatic newborn babies with critical congenital heart defects
介入措施 (Intervention)	screened by pulse oximetry
比較 (Comparison)	None
結果 (Outcomes)	Sensitivity Specificity False positive rate

(診斷型PICO)

步驟2 系統性文獻回顧的品質如何？(FAITH)

Find - 研究是否找到所有的相關證據
良好的文獻搜尋至少應包括二個主要的資料庫，並且加上文獻引用檢索(參考文獻中相 關研究、Web of Science, Scopus 或 Google Scholar)、試驗登錄資料等。文獻搜尋應不只限於英文，並且應同時使用 MeSH 字串及一般檢索詞彙(text words)。

- Searched Medline (1951–2011), Embase (1974–2011), Cochrane Library (2011), and Scisearch (1974–2011) for relevant citations, and hand searched the reference lists of relevant articles for eligible studies.
- Applied no language restrictions.
- We considered both published and unpublished reports for inclusion, including those published in abstract form only.

評讀結果：□是 ✓否 □不清楚

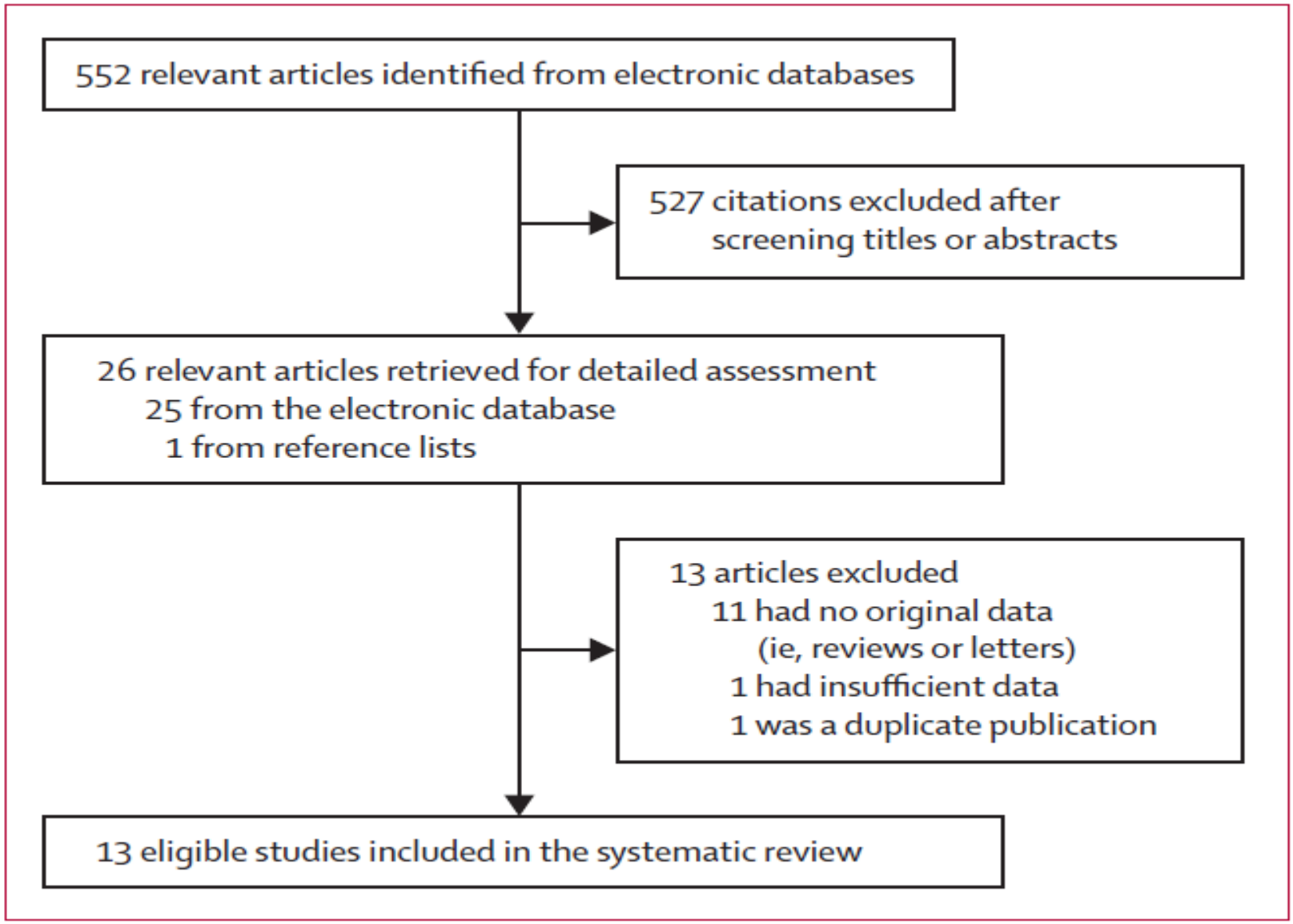

Figure 1: **Study selection**

步驟2 系統性文獻回顧的品質如何？(FAITH)

Appraisal - 文獻是否經過嚴格評讀

應根據不同臨床問題的文章類型，選擇適合的評讀工具，並說明每篇研究的品質
(如針對治療型的臨床問題，選用隨機分配、盲法、及完整追蹤的研究類型)

- We assessed the quality of the included studies against the quality assessment of diagnostic studies criteria, which included assessment of study components including population, test, reference standard, patient outcome, and study design.
- We considered a study to be of good quality if it had
  - prospective consecutive recruitment, adequate description of population, test and reference standard, masking of test and reference standard, full verification of the test with reference standard, and more than 90% follow-up.

quality assessment

Table 2: The QUADAS tool

Item		Yes	No	Unclear
1.	Was the spectrum of patients representative of the patients who will receive the test in practice?	( )	( )	( )
2.	Were selection criteria clearly described?	( )	( )	( )
3.	Is the reference standard likely to correctly classify the target condition?	( )	( )	( )
4.	Is the time period between reference standard and index test short enough to be reasonably sure that the target condition did not change between the two tests?	( )	( )	( )
5.	Did the whole sample or a random selection of the sample, receive verification using a reference standard of diagnosis?	( )	( )	( )
6.	Did patients receive the same reference standard regardless of the index test result?	( )	( )	( )
7.	Was the reference standard independent of the index test (i.e. the index test did not form part of the reference standard)?	( )	( )	( )
8.	Was the execution of the index test described in sufficient detail to permit replication of the test?	( )	( )	( )
9.	Was the execution of the reference standard described in sufficient detail to permit its replication?	( )	( )	( )
10.	Were the index test results interpreted without knowledge of the results of the reference standard?	( )	( )	( )
11.	Were the reference standard results interpreted without knowledge of the results of the index test?	( )	( )	( )
12.	Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?	( )	( )	( )
13.	Were uninterpretable/ intermediate test results reported?	( )	( )	( )
14.	Were withdrawals from the study explained?	( )	( )	( )

Whiting P, Rutjes AWS, Reitsma JB, Bossuyt PM, Kleijnen J. The development of QUADAS: a tool for the quality assessment of studies of diagnostic accuracy included in systematic reviews. *BMC Med Res Methodol* 2003; **3:** 25.

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- Two independent reviewers (ST and AKE) examined the electronic searches and obtained full reports of all citations that were likely to meet the predefined selection criteria ; extracted information about study characteristics, quality, and test results from each selected article.
- Disagreements were resolved by consensus and after discussion with a third reviewer (KSK).

評讀結果：✓是 □否 □不清楚

步驟2 系統性文獻回顧的品質如何？(FAITH)

Included - 是否只納入具良好效度的文章

僅進行文獻判讀是不足夠，系統性文獻回顧只納入至少要有一項研究結果是極小偏誤的試驗。

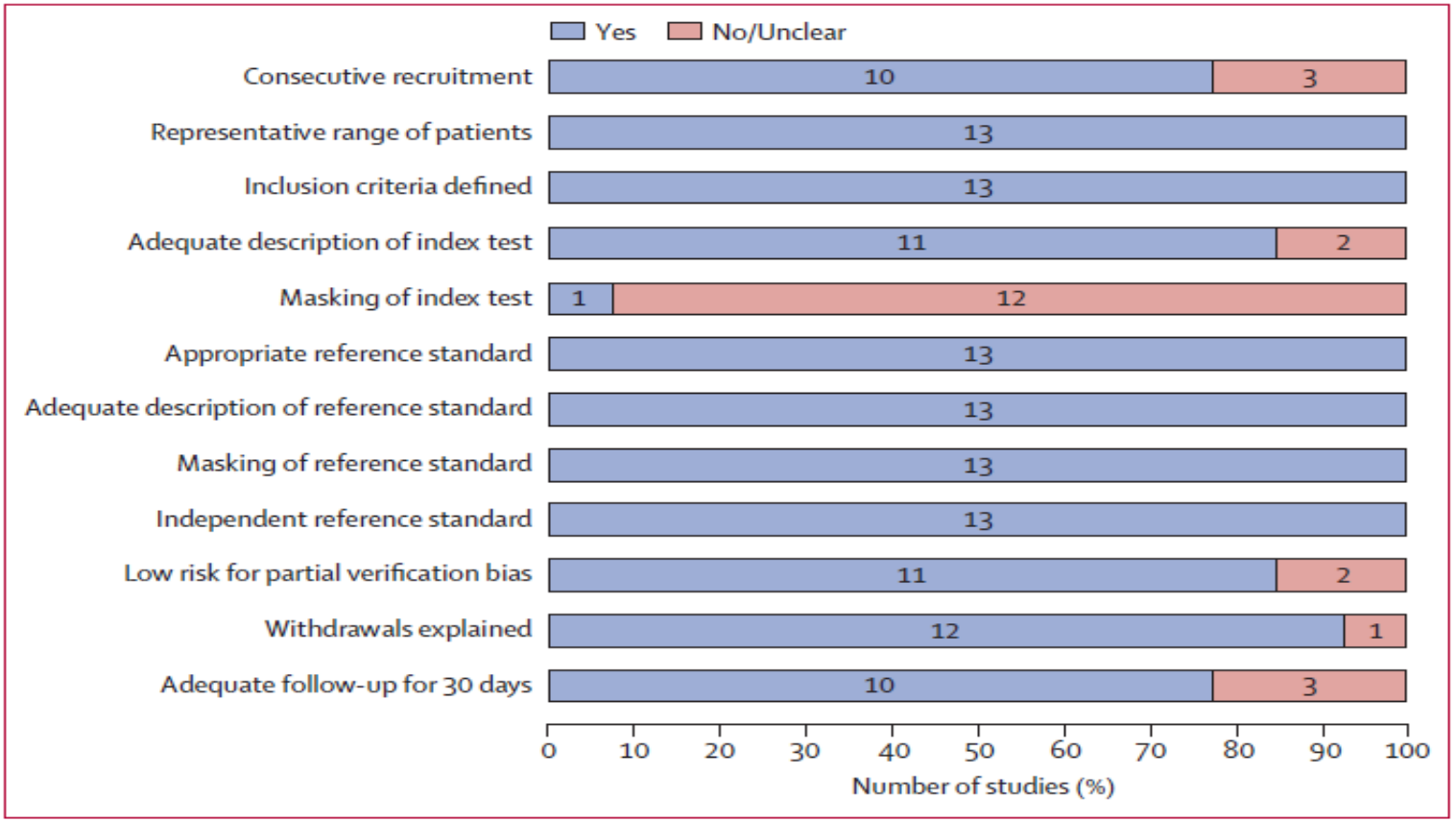

Figure 2: **Quality of included test accuracy studies**

評讀結果：✓是 □否□不清楚

步驟2 系統性文獻回顧的品質如何？(FAITH)

Total up - 作者是否以表格和圖表「總結」試驗結果

應該用至少 1 個摘要表格呈現所納入的試驗結果。若結果相近，可針對結果進行統合分析(meta-analysis)，並以「森林圖」(forest plot)呈現研究結果，最好再加上異質性分析

	Limb	Antenatal diagnosis of CHD	Test timing	Total	True positive	False positive	False negative	True negative	Sensitivity (%; 95% CI)	Specificity (%; 95% CI)	Likelihood ratio positive (%; 95% CI)	Likelihood ratio negative (%; 95% CI)	False-positive rate (%; 95% CI)
Meberg et al (2008)[30]	Foot only	Excluded	<24 h	50 008	27	297	8	49 676	77·1% (59·9–89·6)	99·4% (99·3–99·5)	129·8% (104·9–160·6)	0·23% (0·13–0·43)	0·6% (0·5–0·7)
Bakr et al (2005)[25]	Foot and right hand	Excluded	>24 h†	5211	3	2	0	5206	100·0% (29·2–100·0)	100% (99·9–100·0)	1823·1% (500·1–6646·1)	0·13% (0·01–1·67)	0% (0–0·1)
Arlettaz et al (2006)[24]	Foot only	Included	<24 h	3262	12	12	0	3238	100·0% (73·5–100·0)	99·6 % (99·4–99·8)	250·1% (142·3–439·5)	0·04% (0·01–0·59)	0·4% (0·2–0·6)
Sendelbach et al (2008)[26]	Foot only	Excluded	<24 h	15 233	1	24	0	15 208	100·0% (2·5–100·0)	99·8 % (99·8–99·9)	466·3% (191·0–1138·5)	0·25% (0·02–2·8)	0·2% (0·1–0·2)
Reich et al (2003)[31]*	Foot and right hand	Excluded	>24 h†	2114	0	4	0	2110	..	99·8% (99·5–99·9)	..	..	0·2% (0·1–0·5)
Koppel et al (2003)[29]	Foot only	Excluded	>24 h	11 281	3	1	2	11 275	60·0% (14·7–94·7)	100·0% (100·0–100·0)	6765·6% (839·8–54 506·3)	0·40% (0·14–1·17)	0% (0·0–0·0)
Rosati et al (2005)[34]	Foot only	Excluded	>24 h	5292	2	1	1	5288	66·7 % (9·4–99·2)	100·0% (99·9–100·0)	3526·0% (424·6–29 282·9)	0·33% (0·07–1·70)	0% (0·0–0·1)
Richmond et al (2002)[32]	Foot only	Included	<24 h	5626	8	56	1	5561	88·9% (51·8–99·7)	99·0% (98·7–99·2)	89·2% (62·9–126·3)	0·11% (0·02–0·71)	1% (0·8–1·3)
de Wahl Granelli (2009)[16]	Foot and right hand	Excluded	>24 h†	39 821	19	68	10	39 724	65·5% (45·7–82·1)	99·8% (99·8–99·9)	383·4% (268·8–546·9)	0·35% (0·21–0·57)	0·2% (0·1–0·2)
Riede (2010)[33]	Foot only	Excluded	≥24 h	41 442	14	40	4	41 384	77·8% (52·4–93·6)	99·9% (99·9–99·9)	805·5% (542·0–1197·0)	0·22% (0·09–0·53)	0·1% (0·1–0·1)
Ewer et al (2011)[17]	Foot and right hand	Included	<24 h	20 055	18	177	6	19 854	75·0% (53·3–90·2)	99·1% (99·0–99·2)	84·9% (64·6–111·6)	0·25% (0·13–0·50)	0·9% (0·8–1·0)
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Summary estimate	..	..	..	229 421	..	..	..	..	76·5% (67·7–83·5)	99·9% (99·7–99 9)	549·2% (232·8–1195·6)	0·24% (0·17–0·33)	0·14% (0·06–0·33)

CHD=congenital heart defect. *Studies by Hoke and colleagues and Reich and colleagues excluded from the analysis. †Mean age at testing >24 h after birth.

Table: **Accuracy estimates of primary studies for pulse oximetry in the detection of critical congenital heart defects in newborn babies**

補充說明: Sensitivity vs Specificity

	Disease (+) 生病	Disease (-) 健康
Test Result(+) 陽性	a 真陽性	B 偽陽性
Test Result(-) 陰性	C 偽陰性	d 真陰性

Sensitivity (敏感度)：為有病者診斷結果為陽性的比率=真陽性率=真陽性/生病= a /a+c

Specificity (特異度)：為沒病者診斷結果為陰性的比率=真陰性率=真陰性/健康= d /b+d

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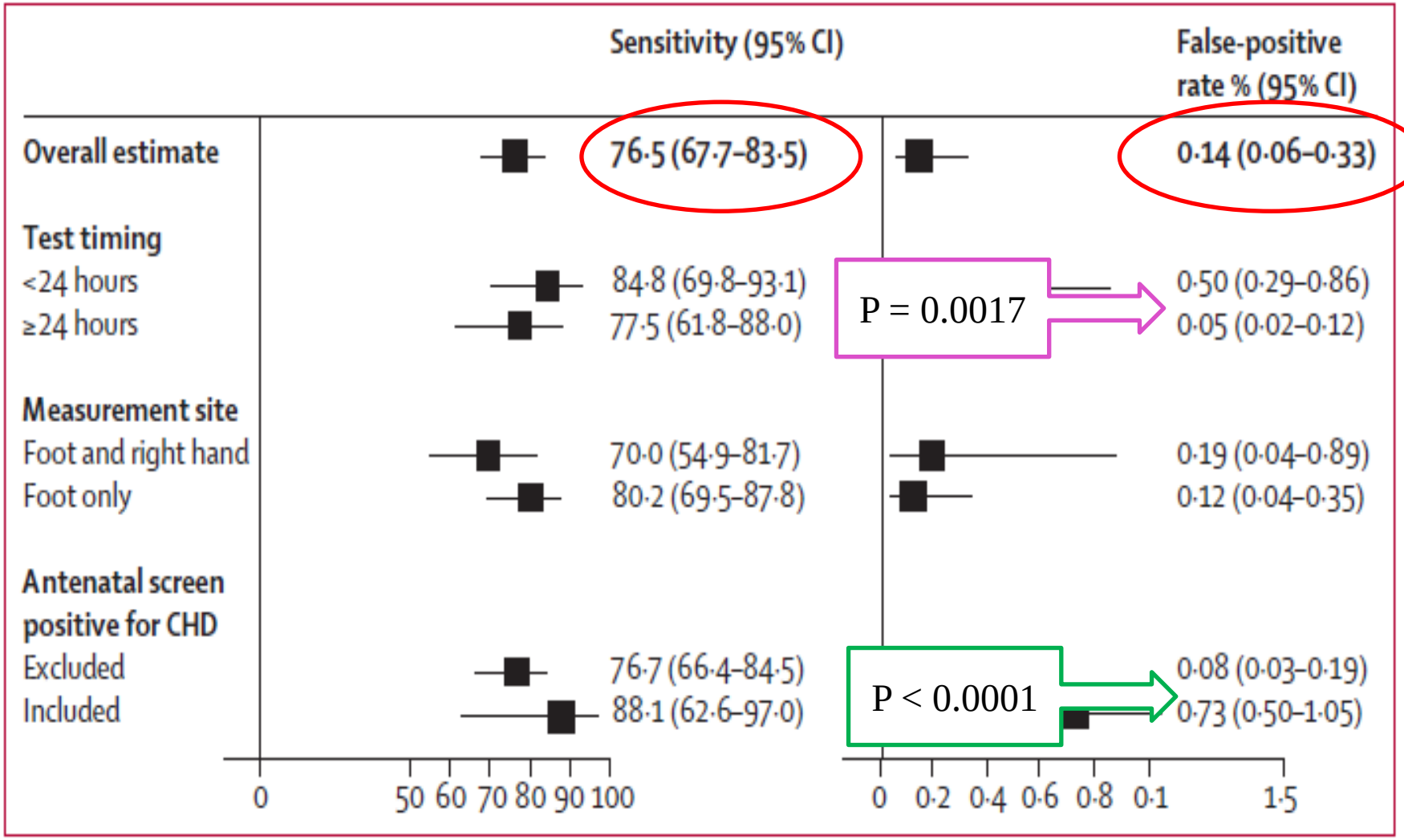

Figure 3: Accuracy estimates based on clinical and test characteristics of pulse oximetry in detection of critical congenital heart defects in newborn babies

CHD=congenital heart defects.

評讀結果：✓是 □否□不清楚

步驟2 系統性文獻回顧的品質如何？(FAITH)

Heterogeneity異質性 - 試驗的結果是否相近

在理想情況下，各個試驗的結果應相近或具同質性，若具有異質性，作者應評估差異是否顯著(卡方檢定)。根據每篇個別研究中不同的**PICO**及研究方法，探討造成異質性的原因。

- This is the case with specificity in which the χ^2 test is highly significant, but heterogeneity is clinically unimportant.

評讀結果： □是 □否 ✓不清楚

結果為何？

使用何種評估方式，療效有多大（是否來自隨機效果）？

- The overall sensitivity of pulse oximetry for detection of critical congenital heart defects (CCRDs) was 76·5% (95% CI 67·7–83·5).
- The specificity was 99·9% (99·7–99·9), with a false-positive rate of 0·14% (0·06–0·33).
- The false-positive rate for detection of CCRDs was particularly low when newborn pulse oximetry was done after 24 h from birth than when it was done before 24 h (0·05% [0·02–0·12] vs 0·50 [0·29–0·86]; p=0·0017).

結論

- Pulse oximetry is highly specific for detection of critical congenital heart defects with moderate sensitivity, that meets criteria for universal screening, especially when done after 24h of birth.

臺北市政府衛生局
市立聯合醫院．健康服務中心

關 ♥ 您

嬰幼兒可能罹患先天性心臟病常見的徵兆

- 易疲倦，面色蒼白，嗜睡或煩躁不安，多汗，劇烈活動或哭鬧後嘴唇及四肢指甲發黑發紫（發紺）。
- 哭聲細微，聲音沙啞，哭鬧或餵食後、活動後易呼吸急促。
- 呼吸急促，吸吮無力，餵奶時常嗆到或拒食或哺餵時間過長。
- 胃口不佳，生長發育遲緩。
- 出冷汗，抵抗力弱，易反覆呼吸道感染或肺炎。
- 看診或預防接種時發現心雜音

若發現寶寶有上述這些徵兆時，請家長儘速帶寶寶至適當的醫療院所接受診治。

若您有任何疑問，請洽詢臺北市民當家熱線1999。

隨時關心孩子♥發展 把握治療黃金時期

新生兒危急型先天性心臟病篩檢

- 臺北市政府衛生局
- 財團法人預防醫學基金會
- 台北病理中心

1999 臺北市民當家熱線

危急型先天性心臟病

篩檢的重要性

先天性心臟病是臨床最常見的先天異常疾病之一，研究資料顯示臺灣地區每1,000位新生兒中約有13名患有先天性心臟病，其中約有1-2名罹患「危急型先天性心臟病」(Critical Congenital Heart Disease, 簡稱CCHD)。

CCHD是指在出生一年內 (多數在一個月內) 需要外科手術矯正或心導管治療的十數種先天性心臟病，主要有左心發育不全症、肺動脈瓣閉鎖、法洛氏四重症、全肺靜脈回流異常、大動脈轉位、三尖瓣閉鎖、共同動脈幹、主動脈窄縮及主動脈弓中斷等疾病。

罹患CCHD的寶寶許多是在出院返家後才出現缺氧發黑發紫 (發紺) 的症狀，有些則可能沒有早期症狀，而直接發生心臟衰竭。若未能即時給予適當治療，將會導致寶寶因此死亡或留下嚴重的神經與心臟後遺症。若能透過CCHD篩檢及早發現，儘速接受妥善、適切的治療，可以有效降低CCHD寶寶的死亡率，並減少不良後遺症的發生。

危急型先天性心臟病

篩檢的時機及方法

新生兒CCHD篩檢是利用脈衝式血氧儀（Pulse Oximeter）在寶寶出生後24 ~ 36小時檢測血氧飽和度，判斷寶寶是否為CCHD的高危險群。檢測方法為：在寶寶的右手及任一腳繫上感測器，與肌膚緊密接觸，約 10 ~ 15分鐘即可測出寶寶的血氧飽和度。

此項檢查並無侵害性，所以不會造成寶寶會受到傷害或感到不適。若寶寶未能通過檢測，將會儘速安排寶寶接受進一步的診斷評估以及後續的醫療處置與治療。

需注意事項

脈衝血氧篩檢無法檢出所有類型的CCHD，依國際間經驗約有25%的CCHD無法藉此檢出。因此通過篩檢，並不代表寶寶絕對不會有任何心臟問題，建議家長務必持續觀察寶寶每個成長階段的發展。無論您的寶寶是否接受或通過新生兒CCHD篩檢，您仍應該從日常生活來觀察寶寶的行為及發展是否有異狀。

背頁列舉一些嬰幼兒可能罹患先天性心臟病的徵兆，供您參考。若發現寶寶有這些徵兆時，請家長儘速帶寶寶至適當的醫療院所接受診治。

若您有任何疑問，請洽詢臺北市民當家熱線1999。

請沿虛線裁下

法定代理人聲明

經由醫護人員充分地告知說明後，本人已完全明瞭「新生兒危急型先天性心臟病」篩檢的內容、目的及重要性，但我仍 **不願意** 讓我的寶寶接受新生兒危急型先天性心臟病篩檢。

母親姓名

母親身份證字號

法定代理人簽名

身份證字號

日期：　　年　　月　　日


NELLCOR
%SpO2
SpO2
/min
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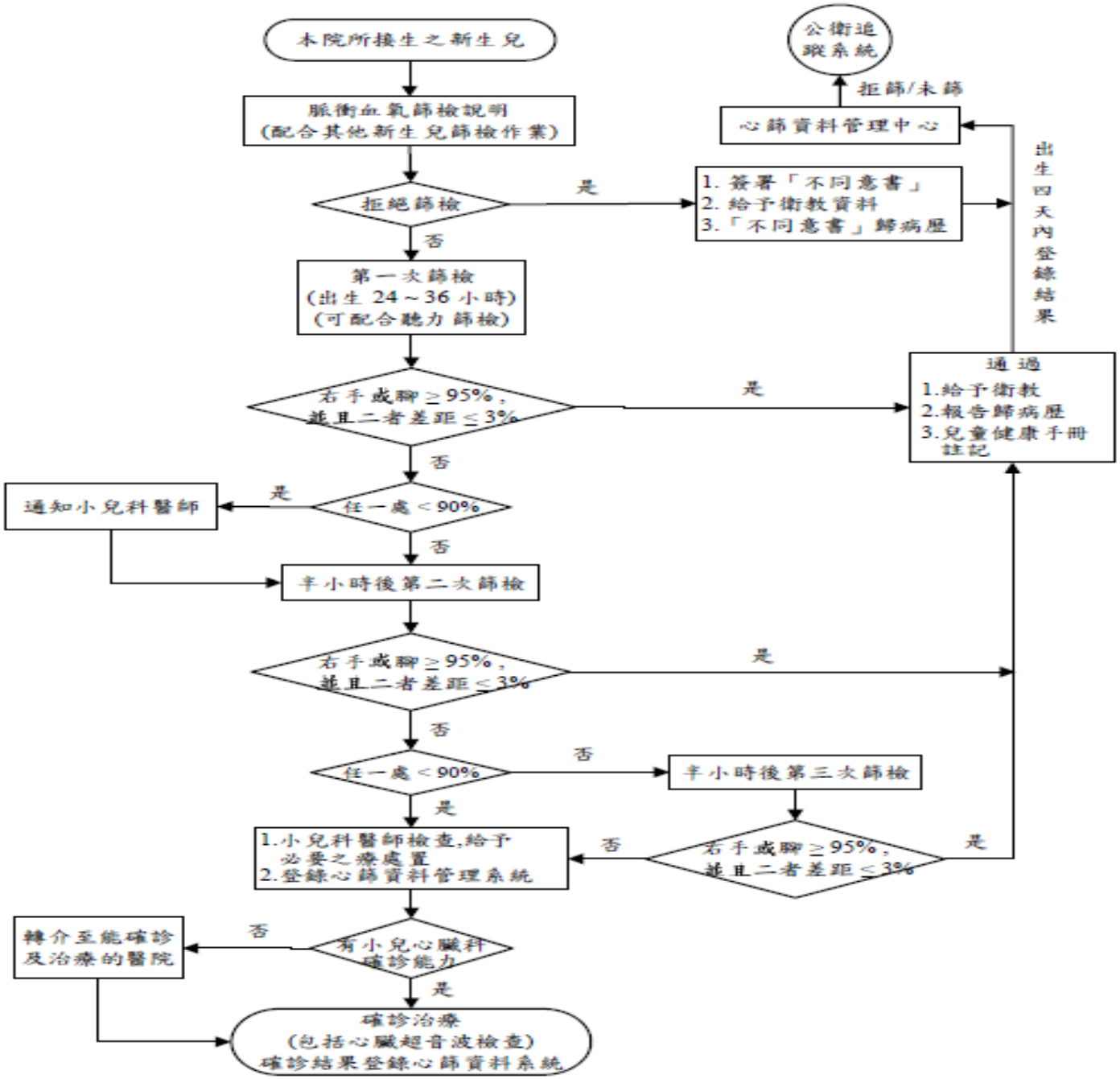
N-500

新生兒危急型先天心臟病篩檢單位作業流程



初步結果

- 自103年4月1日起至103年7月7日共執行161名本院出生的嬰兒
  - ✓ 篩檢陽性：1人
  - ✓ 心臟超音波證實為危急型先天性心臟病：0人 (PDA)

討論

1. 篩檢通過的病人，並未以超音波證實其確無危急型先天性心臟病，因此應無法計算特異性及偽陽性率

2. 執行篩檢，應在檢查前進行說明(風險及利益)，考量病人及家屬在篩檢為陽性、但未確診前的心情(有可能為偽陽性)，尤應謹慎地向家屬解釋檢查結果

討論

- 臨床上，您是否會建議新生兒家屬接受Pulse oximetry篩檢先天危及性心臟病?
- 目前台北市政府補助100元 (自費)

同意(21)