WEB APPENDIX

Neonatal Clinical Examination for Gestational Age Determination:

A systematic literature review

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Web Appendix 1. PRISMA Statement Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2009

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4-5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5-6; Web Appendices 2.1 & 2.2
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6; Web Appendix 2
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7; Web Appendix 2.3
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	6; Web Appendix 2.3
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Web Appendix 3
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	6-7; Figures 1&3; Web Appendix 2.3
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	7
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	Web Appendices 2.4 & 4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	7-8; Web Appendix 2.5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	8-9; Web Appendix 2.6
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	8-9; Web Appendix 2.6

Section/topic	#	Checklist item	Reported on page #	
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	Web Appendix 2.7	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	8-9	
RESULTS				
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	9,17; Figures 1 & 3	
Study characteristics	33-41; 43 (i.e. Tables 1-4,6); Web Appendices 5, 10, & 11			
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	10,17	
Results of individual studies				
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	42 (i.e. Table 5); Figure 2; Web Appendices 7a- b & 8	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	10,17; Web Appendices 6 & 12	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	42 (i.e. Table 5); Web Appendix 8	
DISCUSSION				
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	19-23	
Limitations	imitations 25 Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).		19-23	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	23-24; Figure 4	
FUNDING				
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	1	

Web Appendix 2. Systematic Review Protocol

Diagnostic Accuracy of Methods of Gestational Age Determination Systematic Review Protocol

1. Background

Preterm birth is the leading cause of under-5 child mortality. However, ascertainment of gestational age is limited and challenging in low resource settings. The accurate determination of gestational age in pregnancy and after birth is required in order to identify prematurity and fetal growth restriction, and effectively deliver interventions. The aim of this review is to identify a range of methods currently used to determine gestational age before and after birth, assess the validity of these methods, and identify potential new methods for application in low- and middle-income countries (LMIC).

2. Research questions

- 1) What range of methods are currently available to determine gestational age both before and after birth?
- 2) What are the accuracy, reliability, precision (i.e. validity) of these methods to assess gestational age?
- 3) What methods are available which are currently feasible for LMIC settings?
- 4) What new methods may be applicable to LMIC in the future?

3. Search Strategy

We will conduct automated and manual searches including multiple search engines and databases (Table 1). The databases will include: pubmed, embase, web of science, popline, cochrane library, global health library, WHO regional database, www. clinicaltrials.gov and targeted google searches. There will be no restrictions on language or publication period. The detailed search terms are listed in the Appendix formatted for PubMed.

Database	Website
PubMed/Medline	http://www.ncbi.nlm.nih.gov/pubmed
Embase	http://www.embase.com/
Web of Science	
Popline	
The Cochrane Library	http://www.cochrane.org/
Global Health Library	http://www.globalhealth.org/
World Health Organization Regional Databases:	www.who.int
LILACs, IMEMR, AIM, IMSEAR, WPRIM	
Clinical trials	www.clinicaltrials.gov
Targeted Google searches	

Table 1: Databases and Search engines

Selection Criteria

- a. Inclusion Criteria:
 - i. For Broader Landscape Review:
 - 1. All Inclusive
 - 2. Any Birth: Live births OR stillbirths
 - ii. For Inclusion for diagnostic accuracy
 - 1. Comparison of at least 2 GA estimation methods
 - 2. Report on at least one statistic assessing accuracy of GA
 - determination method
- b. Exclusion Criteria:
 - i. No language exclusions
 - ii. Individual case reports
 - iii. Duplicate studies
 - iv. Editorials or reviews without original data
 - v. No data on accuracy of testing or insufficient data to calculate

Figure 1: Sample Flowchart for Literature Searches



4. Data Abstraction

Data will be extracted into a standard Excel file by two independent reviewers. A sample of the variables to be extracted is shown in Table 2 (full list available in Web Appendix 4). As data are available, a two-by-two table will be constructed for each study to determine the true positives, false positives, true negatives, and false negatives, comparing the test method to the reference standard definition.

Study Characteristics	Reference Standard GA Determination Method	Test GA Estimation Method(s)
 Authors Journal Publication year Country Study design Study setting Population characteristics Sample selection method Total sample size 	 Type/description of method/ test Type/level of training of health worker performing assessment Mean GA [SD] of cohort with reference standard method Total number of preterm <37 weeks; preterm <34 weeks; LBW; SGA % preterm <37 weeks; preterm <34 weeks; LBW; SGA 	 Type/description of reference standard and test method Type/level of health worker performing assessments Mean GA (+ standard deviation) of cohort with reference standard and test methods Mean difference (+ standard deviation) between reference standard vs test method Total number or % of preterm <37 weeks; preterm <34 weeks; LBW; SGA Correlation coefficient with reference standard gestational age Area under the receiver operating curve Cutoff values (if applicable) with corresponding Sensitivity [95%CI] for preterm <37 weeks; preterm <34 weeks; LBW, SGA Specificity [95%CI] for preterm <37 weeks; preterm <34 weeks; LBW, SGA PPV for preterm <37 weeks; preterm <34 weeks; LBW, SGA NPV for preterm <37 weeks; preterm <34 weeks; LBW, SGA NPV for preterm <37 weeks; preterm <34 weeks; LBW, SGA

 Table 2. Sample of Variables in Data Abstraction Table

CI= confidence interval, GA= gestational age, LBW= low birth weight, NPV= negative predictive value, PPV= positive predictive value, SD= standard deviation, SGA= small for gestational age

5. Study Quality Assessment

For studies reporting diagnostic accuracy, methodological quality will be assessed per the Cochrane Diagnostic Test Accuracy Working group recommendations using the QUADAS-2 (Quality Assessment of Diagnostic-Accuracy Studies-2).

All studies will be scored for quality by two independent researchers. If the data reviewers disagree, they will discuss their position in detail, using evidence from the study in question until they reach a compromise. If they do not reach a compromise, the question at hand will be discussed with the research team during a team meeting to arrive at a compromise that the team as a whole agrees with.

Methodological quality will be assessed per the Cochrane Diagnostic Test Accuracy Working Group's recommendations using the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies-2). Individual studies will be evaluated for limitations and biases in the following domains: patient selection, reference standard method, test method, and flow and timing of the study. For each of these domains, a score will be assigned (0=low risk, 1=high risk). A total quality assessment score will be given to each study. Study design will be scored according to whether the sample size was sufficient ($n \ge 50$ vs. n < 50), whether methodology and data were adequately reported, whether subjects were enrolled randomly vs. purposively, whether inappropriate exclusion criteria were avoided, whether the reference standard vs. test method were used independently and users were blinded, whether multiple measurements were taken to assess inter- and or/ intra-rater reliability, whether any quality control measures were undertaken, whether users were trained in the GA assessment method(s), whether thresholds were pre-specified (if applicable), whether the reference standard method was ultrasound (adequate) vs. other (inadequate) method, whether any enrolled subjects were excluded from assessment by either the reference standard method or the test method, whether all enrolled subjects received the same reference standard, and whether any enrolled subjects were excluded from the analysis.

In addition to summarizing study quality, we will also summarize the consistency of definitions of each gestational age method, and the overall generalizability of study results to our target population (newborns in LMICs).

6. Data Analysis

All data will be summarized in study data tables by each major group of methods of gestational age determination. If there is sufficient and adequate quality data to perform pooled analysis, we will conduct meta-analysis with hierarchal bivariate models using the Stata "metandi" command, as per the recommendations of the Cochrane Working Group on Systematic Reviews of Diagnostic Test Accuracy.¹ Hierarchal summary receiver operating characteristic curves will be generated with the "metanplot" command. Coupled forest plots will be generated with Review Manager 5.1. Sub-group analysis and meta-regression may be performed, if required, to explore sources of heterogeneity

7. Study Limitations

The potential limitations we foresee are the paucity of published studies. We therefore will attempt to target numerous search engines and sources in the grey and unpublished literature, as well as targeted Google searches. The study may potentially be limited if the studies found in our search are not representative of global regions.

8. Reporting

We plan to report these findings to public health experts in child and maternal health first by submitting interim and final reports to The Bill & Melinda Gates Foundation, and finally through publication in a peer-reviewed journal. Depending on the findings of the review, this may result in a publication supplement of 2-3 papers.

9. Protocol Registration

The protocol was registered in the PROSPERO International prospective register of systematic reviews, University of York Centre for Reviews and Dissemination (<u>http://www.crd.york.ac.uk/PROSPERO</u>). PROSPERO Registration number: CRD42015020499

Web Appendix 3. Search Terms

	Web Appendix 3. Search Terms											
Date of Original Search	Search Topics	Detailed Search Strings/MeSH Terms	Database (report by each database searched)	# of hits per database	Total Hits Before De- duplication	Total Hits After De- duplication	Total de- duplicated hits for updated searches from June 2016					
3/23/2015	Neonatal Assessment Neonatal Clinical Exam Postnatal Exam	("gestational age"[MeSH Terms] OR "gestational age"[Text Word] OR "premature birth"[MeSH Terms] OR "premature birth"[Text Word] OR preterm[Text Word] OR ptb[Text Word] OR "fetal growth retardation"[MeSH Terms] OR "fetal growth restriction"[Text Word] OR "fetal growth retardation"[Text Word] OR "infant, low birth weight"[MeSH Terms] OR "low birth weight"[All Fields] OR "IUGR"[Text Word] OR "lbw"[Text Word] OR "birth weight"[MeSH Terms] OR "infant, low birth weight"[MeSH Terms]) AND ("neonatal assessment"[All Fields] OR "Infant, Newborn/growth and development"[Mesh] OR "Infant, Newborn/statistics and numerical data"[Mesh] OR "clinical assessment"[All Fields] OR "postnatal exam"[All Fields] OR "postnatal examination"[All Fields] OR "neonatal exam"[All Fields]] OR	Pubmed	2781	3656	3625 (for all neonatal exam searches combined)	237 (for all neonatal exam searches combined)					
3/23/2015	Neonatal Assessment Neonatal Clinical Exam Postnatal Exam	gestational age'/exp OR 'gestational age' OR 'premature'/exp OR 'premature' OR 'prematurity'/exp OR 'prematurity' OR 'preterm birth'/exp OR 'preterm birth' OR 'preterm' OR 'ptb' OR 'intrauterine growth retardation'/exp OR 'intrauterine growth retardation' OR 'intrauterine growth restriction' OR 'fetal growth retardation'/exp OR 'fetal growth retardation' OR 'low birth weight'/exp OR 'low birth weight' OR 'lugr' OR 'lbw' AND ('newborn assessment'/exp OR 'newborn assessment' OR 'neonatal assessment' OR 'neonatal examination' OR 'neonatal exam' OR 'postnatal examination' OR 'postnatal exam')	EMBASE	522								
3/23/2015	Neonatal Assessment Neonatal Clinical Exam Postnatal Exam	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND ("neonatal assessment" OR "infant growth" OR "infant development" OR "newborn clinical assessment" OR "clinical assessment" OR "postnatal examination" OR "newborn examination" OR "postnatal exam" OR "postnatal examination")	Cochrane	168								
3/23/2015	Neonatal Assessment Neonatal Clinical Exam Postnatal Exam	("gestational age" OR "premature birth" OR preterm OR ptb OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR lugr OR lbw OR "birth weight") AND ("neonatal assessment" OR "neonatal clinical examination" OR "newborn assessment" OR "newborn clinical examination" OR "postnatal assessment" OR "postnatal examination" OR "postnatal exam" OR "postnatal clinical examet" OR "postnatal clinical examination" OR "postnatal clinical exam")	Web of Science	63								
3/23/2015	Neonatal Assessment Neonatal Clinical Exam Postnatal Exam	("gestational age" OR "premature birth" OR preterm OR ptb OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR iugr OR Ibw OR "birth weight") AND ("neonatal assessment" OR "neonatal clinical examination" OR "postnatal examination" OR "postnatal examination" OR "postnatal clinical assessment"	Popline	12								
3/23/2015	Neonatal Assessment Neonatal Clinical Exam Postnatal Exam	(tw:(("gestational age" OR "premature birth" OR preterm OR ptb OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR lugr OR lbw OR "birth weight") AND ("neonatal assessment" OR "neonatal clinical examination" OR "newborn assessment" OR "newborn clinical examination" OR "postnatal assessment" OR "postnatal examination" OR "postnatal exam" OR "postnatal clinical examination" OR "OR "neonatal OR "postnatal clinical examination" OR "postnatal clinical exam"))	LILACs/V HL	89								
3/23/2015	Neonatal Assessment Neonatal Clinical Exam Postnatal Exam	("gestational age" OR "premature birth" OR preterm OR ptb OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR lug OR lbw OR "birth weight") AND ("neonatal assessment" OR "neonatal clinical examination" OR "newborn assessment" OR "newborn clinical examination" OR "postnatal assessment" OR "postnatal examination" OR "postnatal exam" OR "postnatal clinical assessment" OR "postnatal clinical examination" OR "postnatal clinical exam")	WPRIM	4								
3/23/2015	Neonatal Assessment Neonatal Clinical Exam Postnatal Exam	neonatal assessment OR neonatal clinical examination OR newborn assessment OR newborn clinical examination OR postnatal assessment OR postnatal examination OR postnatal exam OR postnatal clinical assessment OR postnatal clinical examination OR postnatal clinical exam	Global Health Library	17								
3/23/2015	Neonatal Assessment Neonatal Clinical Exam Postnatal Exam		LILACs/V HL									
3/23/2015	Ballard Score/Exam	("ballard score"[All Fields] OR "ballard examination"[All Fields] OR "ballard exam"[All Fields])	Pubmed	33	118							
3/23/2015	Ballard Score/Exam	'ballard score' OR 'ballard examination' OR 'ballard exam'	EMBASE	52								
3/23/2015	Ballard Score/Exam	"ballard score" OR "ballard examination" OR "ballard exam"	Cochrane	3								
3/23/2015	Ballard Score/Exam	"ballard score" OR "ballard examination" OR "ballard exam"	Web of Science	30								
3/23/2015	Ballard Score/Exam	"ballard score" OR "ballard examination" OR "ballard exam" OR "ballard"	Popline	0								

3/23/2015	Ballard Score/Exam	ballard score OR ballard examination OR ballard exam	Global Health Library	0	
3/23/2015	Dubowitz	"dubowitz score"[All Fields] OR "dubowitz examination"[All Fields] OR ("dubowitz"[tw] AND	Pubmed	54	170
	Score/Exam	(neurolog[tw] OR neurolog'ia[tw] OR neurolog'ifti'[tw] OR neurologa[tw] OR neurologaically[tw] OR neurologen[tw] OR neurologenic[tw] OR neurologie[tw] OR neurologia[tw] OR neurologia[tw] OR neurologia[tw] OR neurologics[tw] OR neurologi[tw] OR neurologia[tw] OR neurologia[tw] OR neurologial[tw] OR neurological[tw] OR neurologic[tw] OR neurological[tw] OR neurological/tw] OR neurologicala[tw] OR neurological(tw] OR neurological(tw] OR neurological/tw] OR neurologicala[tw] OR neurological(tw] OR neurological(tw] OR neurological/tw] OR neurological[tw] OR neurological(tw] OR neurological/tw] OR neurological/tw] OR neurologicals[tw] OR neurological/tw] OR neurological/tw] OR neurologicals[tw] OR neurological/tw] OR neurologicals[tw] OR neurologicals[tw] OR neurological/tw] OR neurologicals[tw] OR neurologicals[tw] OR neurological/tw] OR neurologicals[tw] OR neurologicals[tw] OR neurological/tw] OR neurological(tw] OR neurologicals[tw] OR neurological/tw] OR neurological(tw] OR neurologicals[tw] OR neurologics[tw] OR neurologics[tw] OR neurological(tw] OR neurological[tw] OR neurologics[tw] OR neurologics[tw] OR neurological(tw] OR neurologidal[tw] OR neurologics[tw] OR neurologics[tw] OR neurological(tw] OR neurologis[tw] OR neurologics[tw] OR neurologics[tw] OR neurological(tw] OR neurologis[tw] OR neurologischen[tw] OR neurologischen[tw] OR neurologisen[tw] OR neurologis[tw] OR neurologists[tw] OR neurologism[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologist[tw] OR neurologists[tw] OR neurologists[tw] OR neurologist[tw] OR neurologists[tw] OR neurologists[tw] OR neurologists[tw] OR neurologist[tw] OR neurologists[tw] OR neurologists[tw] OR neurologist[tw] OR neurologist[tw] OR neurologists[tw] OR neurologist[tw] OR neurologist[tw] OR neurologists[tw] OR neurologist[tw] OR neurologist[tw] OR neurologists[tw]			
3/23/2015	Dubowitz Score/Exam	'dubowitz score'/exp OR 'dubowitz score' OR 'dubowitz examination' OR 'dubowitz exam'	EMBASE	66	
3/23/2015	Dubowitz Score/Exam	"dubowitz score" OR "dubowitz examination" OR "dubowitz method"	Cochrane	5	
3/23/2015	Dubowitz Score/Exam	"dubowitz score" OR "dubowitz examination" OR "dubowitz method"	Web of Science	25	
3/23/2015	Dubowitz Score/Exam	"dubowitz score" OR "dubowitz examination" OR "dubowitz method"	Popline	12	
3/23/2015	Dubowitz Score/Exam	dubowitz score OR dubowitz examination OR dubowitz method	Global Health Library	8	
3/23/2015	Capurro Method/ Score/Exam	("capurro method"[All Fields] OR "capurro score"[All Fields] OR "capurro exam"[All Fields] OR "capurro examination"[All Fields] OR "capurro"[tw])	Pubmed	27	239
3/23/2015	Capurro Method/ Score/Exam	'capurro method' OR 'capurro score' OR 'capurro examination' OR 'capurro exam'	EMBASE	16	
3/23/2015	Capurro Method/ Score/Exam	"capurro method" OR "capurro score" OR "capurro exam" OR "capurro examination" OR "capurro"	Cochrane	11	
3/23/2015	Capurro Method/ Score/Exam	"capurro method" OR "capurro score" OR "capurro exam" OR "capurro examination" OR "capurro"	Popline	6	
3/23/2015	Capurro Method/ Score/Exam	"capurro method" OR "capurro score" OR "capurro exam" OR "capurro examination" OR "capurro"	Web of Science	33	
3/23/2015	Capurro Method/ Score/Exam	capurro method OR capurro score OR capurro exam OR capurro examination OR capurro	Global Health Library	146	
3/23/2015	Parkin	(("gestational age"[MeSH Terms] OR "gestational age"[Text Word] OR "premature birth"[MeSH Terms] OR "premature birth"[Text Word] OR preterm[Text Word] OR ptb[Text Word] OR "fetal growth retardation"[MeSH Terms] OR "fetal growth restriction"[Text Word] OR "fetal growth retardation"[Text Word] OR "infant, low birth weight"[MeSH Terms] OR "low birth weight"[All Fields] OR "IUGR"[Text Word] OR "low"[Text Word] OR "birth weight"[MeSH Terms] OR "infant, low birth weight"[MeSH Terms]) AND "parkin j"[All Fields])	Pubmed	13	24
3/23/2015	Parkin	'gestational age/exp OR 'gestational age' OR 'premature'/exp OR 'premature' OR 'prematurity'/exp OR 'prematurity' OR 'preterm birth'/exp OR 'preterm birth' OR 'preterm' OR 'ptb' OR 'intrauterine growth retardation'/exp OR 'intrauterine growth retardation' OR 'intrauterine growth restriction' OR 'fetal growth retardation'/exp OR 'fetal growth retardation' OR 'low birth weight'/exp OR 'low birth weight' OR 'lugr' OR 'lbw' AND 'parkin j'	EMBASE	10	
3/23/2015	Parkin	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND "parkin j"	Cochrane	0	
3/23/2015	Parkin	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND "parkin j"	Popline	1	
3/23/2015	Parkin	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth restriction" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR	Web of	0	

3/23/2015	Parkin	(gestational age OR premature birth OR preterm OR ptb OR fetal growth retardation OR fetal growth restriction OR intrauterine growth retardation OR intrauterine growth restriction OR low birth weight OR IUGR OR Ibw OR birth weight) AND parkin j	Global Health Library	0		
3/23/2015	Eregie	("gestational age"[MeSH Terms] OR "gestational age"[Text Word] OR "premature birth"[MeSH Terms] OR "premature birth"[Text Word] OR preterm[Text Word] OR ptb[Text Word] OR "fetal growth retardation"[MeSH Terms] OR "fetal growth restriction"[Text Word] OR "fetal growth retardation"[Text Word] OR "infant, low birth weight"[MeSH Terms] OR "low birth weight"[All Fields] OR "IUGR"[Text Word] OR "bw"[Text Word] OR "birth weight"[MeSH Terms] OR "infant, low birth weight"[MeSH Terms]) AND "eregie"[All Fields]	18	42		
3/23/2015	Eregie	('gestational age'/exp OR 'gestational age' OR 'premature'/exp OR 'premature' OR 'prematurity'/exp OR 'prematurity' OR 'preterm birth/exp OR 'preterm birth' OR 'preterm' OR 'pto' OR 'intrauterine growth retardation'/exp OR 'intrauterine growth retardation' OR 'intrauterine growth restriction' OR 'fetal growth retardation//exp OR 'fetal growth retardation' OR 'low birth weight'/exp OR 'low birth weight' OR 'ibw') AND 'eregie'	EMBASE	16		
3/23/2015	Eregie	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "Ibw" OR "birth weight") AND "eregie"	Cochrane	0		
3/23/2015	Eregie	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND "eregie"	Web of Science	2		
3/23/2015	Eregie	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND "eregie"	Global Health Library	0		
3/23/2015	Eregie	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "Ibw" OR "birth weight") AND "eregie"	Popline	6		
3/23/2015	Anterior Vascularity of Lens	("gestational age"[MeSH Terms] OR "gestational age"[Text Word] OR "premature birth"[MeSH Terms] OR "premature birth"[Text Word] OR preterm[Text Word] OR ptb[Text Word] OR "fetal growth retardation"[MeSH Terms] OR "fetal growth restriction"[Text Word] OR "fetal growth retardation"[Text Word] OR "infant, low birth weight"[MeSH Terms] OR "low birth weight"[All Fields] OR "IUGR"[Text Word] OR "inbw"[Text Word] OR "birth weight"[MeSH Terms] OR "infant, low birth weight"[MeSH Terms]) AND ((((anterior[All Fields] AND vascularity[All Fields]) OR "lens vessels"[All Fields]) OR "Lens Capsule, Crystalline"[Mesh]) OR "Lens, Crystalline"[Mesh]	Pubmed	173	400	
3/23/2015	Anterior Vascularity of Lens	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "Ibw" OR "birth weight") AND (("anterior" AND "vascularity") OR "lens capsule" OR "crystalline lens capsule" OR "anterior vascularity" OR "lens vessels" OR "lens vessels" OR "lens")	Cochrane	8		
3/23/2015	Anterior Vascularity of Lens	'gestational age/exp OR 'gestational age' OR 'premature//exp OR 'premature' OR 'prematurity/exp OR 'prematurity' OR 'preterm birth'/exp OR 'preterm birth' OR 'preterm' OR 'ptb' OR 'intrauterine growth retardation'/exp OR 'intrauterine growth retardation' OR 'intrauterine growth restriction' OR 'fetal growth retardation'/exp OR 'fetal growth retardation' OR 'intrauterine growth restriction' OR 'fetal growth retardation'/exp OR 'fetal growth retardation' OR 'intrauterine growth restriction' OR 'fetal growth retardation'/exp OR 'leftal growth retardation' OR 'lens capsule' OR 'lens vessels' OR 'lens capsule, crystalline'/exp OR 'lens capsule, crystalline')	EMBASE	47		
3/23/2015	Anterior Vascularity of Lens	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "Ibw" OR "birth weight") AND (("anterior" AND "vascularity") OR "lens capsule" OR "crystalline lens capsule" OR "anterior vascularity" OR "lens vessels" OR "lens vessels" OR "lens")	Web of Science	154		
3/24/2015	Anterior Vascularity of Lens	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND (("anterior" AND "vascularity") OR "lens capsule" OR "crystalline lens capsule" OR "anterior vascularity" OR "lens vessels" OR "lens vessels" OR "lens")	Global Health Libraries	15		
3/23/2015	Anterior Vascularity of Lens	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND (("anterior" AND "vascularity") OR "lens capsule" OR "crystalline lens capsule" OR "anterior vascularity" OR "lens vessels" OR "lens vessels" OR "lens")	Popline	3		
3/23/15	Intermammillary Distance	("gestational age"[MeSH Terms] OR "gestational age"[Text Word] OR "premature birth"[MeSH Terms] OR "premature birth"[Text Word] OR preterm[Text Word] OR ptb[Text Word] OR "fetal growth retardation"[MeSH Terms] OR "fetal growth restriction"[Text Word] OR "fetal growth retardation"[Text Word] OR "infant, iow birth weight"[MeSH Terms] OR "low birth weight"[All Fields] OR "IUGR"[Text Word] OR "inbw"[Text Word] OR "birth weight"[MeSH Terms] OR "infant, iow birth weight"[MeSH Terms]) AND (("intermammillary distance"[All Fields] OR ("Breast/anatomy and histology"[Mesh] OR "Breast/growth and development"[Mesh]))) AND "humans"[MeSH Terms])	Pubmed	72	358	320
3/23/15	Intermammillary Distance	'gestational age/exp OR 'gestational age' OR 'premature'/exp OR 'premature' OR 'prematurity/lexp OR 'prematurity' OR 'preterm birth/lexp OR 'preterm birth' OR 'preterm' OR 'ptb' OR 'intrauterine growth retardation'/exp OR 'intrauterine growth retardation' OR 'intrauterine growth restriction' OR 'fetal growth retardation/lexp OR 'fetal growth retardation' OR 'low birth weight'/exp OR 'low birth weight' OR 'ibu' AND ('intermammillary distance' OR 'breast areola/lexp OR 'nipple/lexp)	EMBASE	121		
3/23/15	Intermammillary Distance	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND ("intermammillary" OR "intermammillary distance" OR "breast anatomy" OR "nipple" OR "breast areola")	Cochrane	32		

					-		
3/23/15	Intermammillary Distance	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "Ibw" OR "birth weight") AND ("intermammillary" OR "intermammillary distance" OR "breast anatomy" OR "nipple" OR "breast areola")	Web of Science	105			
3/23/15	Intermammillary	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR	Global	7			
5/25/15	Distance	"fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND ("intermammillary" OR	Health	ľ			
		"intermammillary distance" OR "breast anatomy" OR "nipple" OR "breast areola")	Libraries				
3/23/15	Intermammillary Distance	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND ("intermammillary" OR "intermammillary distance" OR "breast anatomy" OR "nipple" OR "breast areola")	Popline	21			
3/23/15	Skin Impedance	((("gestational age"[MeSH Terms] OR "gestational age"[Text Word] OR "premature birth"[MeSH Terms] OR "premature birth"[Text Word] OR preterm[Text Word] OR ptb[Text Word] OR "fetal growth retardation"[MeSH Terms] OR "fetal growth restriction"[Text Word] OR "fetal growth retardation"[Text Word] OR "infant, low birth weight"[MeSH Terms] OR "low birth weight"[All Fields] OR "IUGR"[Text Word] OR "lbw"[Text Word] OR "birth weight"[MeSH Terms] OR "infant, low birth weight"[MeSH Terms]])) AND ((("skin"[MeSH Terms] OR "skin"[All Fields]) AND ("electric impedance"[MeSH Terms] OR ("electric"[All Fields] AND "impedance"[All Fields]) OR "electric impedance"[All Fields] OR "impedance"[All Fields] OR "dalvanic Skin Response"[Mesh])))	Pubmed	34	160	109	
3/23/15	Skin Impedance	'gestational age'/exp OR 'gestational age' OR 'premature'/exp OR 'premature' OR 'prematurity' exp OR 'prematurity' OR 'preterm birth'/exp OR 'preterm birth' OR 'preterm' OR 'ptb' OR 'intrauterine growth retardation'/exp OR 'intrauterine growth retardation' OR 'intrauterine growth restriction' OR 'fetal growth retardation'/exp OR 'fetal growth retardation' OR 'low birth weight'/exp OR 'low birth weight' OR 'log' OR 'lbw' AND ('skin conductance'/exp OR ('skin' AND 'impedance'/exp) OR 'electrodermal response//exp OR 'galvanic skin response' OR 'skin impedance')	EMBASE	82			
3/23/15	Skin Impedance	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND ("skin conductance" OR "skin impedance") OR "electrodermal response" OR "galvanic skin response" OR ("skin" AND "impedance"))	Cochrane	6			
3/23/15	Skin Impedance	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND ("skin conductance" OR "skin impedance") OR "electrodermal response" OR "galvanic skin response" OR ("skin" AND "impedance"))	Web of Science	36			
3/23/15	Skin Impedance	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND ("skin conductance" OR "skin impedance") OR "electrodermal response" OR "galvanic skin response" OR ("skin" AND "impedance"))	Global Health Libraries	1			
3/23/15	Skin Impedance	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND ("skin conductance" OR "skin impedance") OR "electrodermal response" OR "galvanic skin response" OR ("skin" AND "impedance"))	Popline	1			
3/23/15	Palmar Crease	("gestational age"[MeSH Terms] OR "gestational age"[Text Word] OR "premature birth"[MeSH Terms] OR "premature birth"[Text Word] OR preterm[Text Word] OR ptb[Text Word] OR "fetal growth retardation"[MeSH Terms] OR "fetal growth restriction"[Text Word] OR "fetal growth retardation"[Text Word] OR "infant, low birth weight"[MeSH Terms] OR "low birth weight"[All Fields] OR "IUGR"[Text Word] OR "lbw"[Text Word] OR "birth weight"[MeSH Terms] OR "infant, low birth weight"[MeSH Terms]) AND ("palmar crease"[All Fields] OR (("Hand/analysis"[Mesh] OR "Hand/anatomy and histology"[Mesh]) OR "Hand Deformities, Congenital"[Mesh]))	Pubmed	297	327	320	
3/23/15	Palmar Crease	'gestational age'/exp OR 'gestational age' OR 'premature'/exp OR 'premature' OR 'prematurity'/exp OR 'prematurity' OR 'preterm birth'/exp OR 'preterm birth' OR 'preterm' OR 'ptb' OR 'intrauterine growth retardation'/exp OR 'intrauterine growth retardation' OR 'intrauterine growth restriction' OR 'fetal growth retardation'/exp OR 'fetal growth retardation' OR 'low birth weight'/exp OR 'low birth weight' OR 'lugr' OR 'lbw' AND (palmar crease'/exp OR 'palmar crease' OR 'hand anatomy and histology' OR 'hand deformities' OR 'hand analysis')	EMBASE	27			
3/23/15	Palmar Crease	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND (("palmar" AND "crease") OR "palmar crease" OR "hand anatomy and histology" OR "hand deformities" OR "hand analysis")	Cochrane	0			
3/23/15	Palmar Crease	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND (("palmar" AND "crease") OR "palmar crease" OR "hand anatomy and histology" OR "hand deformities" OR "hand analysis")	Web of Science	2			
3/23/15	Palmar Crease	("gestational age" OR "premature birth" OR "preterm" OR "ptb" OR "fetal growth retardation" OR "fetal growth restriction" OR "intrauterine growth retardation" OR "intrauterine growth restriction" OR "low birth weight" OR "IUGR" OR "lbw" OR "birth weight") AND (("palmar" AND "crease") OR "palmar crease" OR "hand anatomy and histology" OR "hand deformities" OR "hand analysis")	Popline	1			

Web Appendix 4. Variables in Neonatal Assessment Data Extraction Sheet

Study Ch	naracteristics	
•	Lead Author	• Population characteristics (rural/urban, maternal age,
	Journal	etc.)
•	Publication Year	• Sample Selection/Recruitment Method (Consecutive,
•	Region (1= Africa; 2=Southeast Asia, 3=Other)	Random, Non-Random, etc.)
	Country	Inclusion Criteria
	City & District	Exclusion Criteria
	Study Design (cross-sectional vs. longitudinal; prospective vs.	Stillborn Included (Y/N)
	retrospective)	 Study Period (from MMYY - to MMYY)
	Study Setting (1 = Tertiary Hospital / ICU; 2 = Primary health	Total Sample Size for GA Method Comparison
	center/peripheral facility/clinic; 3 = Community based	Characteristics
	recruitment/rural health post/home visit)	
Referenc	e Standard GA Method	
•	Reference Standard GA Method (Detailed description)	Mean GA
•	Reference Standard Type	 SD and/or 95%CI
٠	If Reference=ultrasound, timing of ultrasound (e.g., 14-19 weeks)	 Definition of preterm used (if not <37 weeks)
٠	Type of health worker performing assessment	% Preterm
	(community health worker, physician, nurse, sonographer,	 % Preterm <34 wks
	radiologist, other non-medical staff, other)	
	e Standard Birthweight	
	Method of reference standard birth weight measurement (open	 SD and/or 95% CI for birth weight
	description)	• % <2500 g
	Type of scale (hanging vs. digital)	• % SGA
	Scale precision	• % LGA
	Mean birthweight	
	Clinical Assessment: Measurement	
	Method Name	Repeat measures done? (Yes/No)
	Was the person performing the assessment blinded to reference	 INTER-Rater Reliability (e.g., Kappa, Bland-Altman
	standard result? (Yes/No)	bias w/ LOA)
•	Type of health worker performing assessment	INTRA-Rater Reliability
	(community health worker, physician, nurse, other non-medical staff, other)	Mean neonatal exam score
	Timing of measurement from birth (e.g., within 24 hours of birth)	SD and/or 95%Cl
•	Timing of measurement non birtin (e.g., within 24 hours of birtin)	Mean GA by test method, if applicable
A	nt (Castational Aga by Nagnatal Assagament va Deference Clanderd	SD and/or 95%Cl
-	nt (Gestational Age by Neonatal Assessment vs. Reference Standard Correlation coefficient (R) with true gestational age	
	Lin's concordance correlation coefficient	 Bland Altman mean difference Bland Altman 95% limits of agreement
	Intraclass correlation coefficient	 What is the trend? Descriptive. Any tests performed?
•		• What is the trend? Descriptive. Any tests performed? Over/Under-estimates?
Validity (Neonatal Assessment to Identify Preterm Births)	Over/onder-ostinidies:
• anulty (Total number of preterm <37 wk by test method	• Kappa (preterm by clinical exam vs. reference
	% preterm <37 wk by test method	standard)
•	ROC-AUC	 Sensitivity, Specificity, PPV, NPV
Validity (Neonatal Assessment to Identify Very Preterm Births (<34 weeks))	
	Cutoff of parameter (e.g., foot length) for predicting preterm <34	• % preterm <34 weeks by test method
	wk, if applicable	 ROC-AUC
	Total number of preterm <34 weeks	 Sensitivity, Specificity, PPV, NPV
	Small for Gestational Age)	
•	Name of reference curve used to define SGA	ROC-AUC
	Number of SGA	 Sensitivity, Specificity, PPV, NPV
-		

Web Appendix 5. Overall Study Table

Author ^a	Year	Place (district/city, country)	Study Setting (NICU,hospital/tertiary care center, primary clinic, community)	GA of cohort included	Sample Size	Reference Standard	Assessment Conducted (i.e. Test Method)
Neonatal Clinic			community)		0120	Reference ofalloard	
Neonatal Onin		Silicit		All gestational ages, 773-	1		
Ahn	2008	South Korea (Incheon)	Tertiary Health Center/NICU	4870g	213	LMP	Ballard
Alexander	1990	USA (South Carolina)	Hospital	20-45 weeks	10794	LMP	Ballard
					2091,		
Alexander ^b	1992	USA (Charleston, South Carolina)	Hospital	28-42 weeks	3480	LMP	Ballard
Alexander c	1992	USA (Charleston, South Carolina)	Hospital	28-44 weeks by Ballard	4193	US, LMP	Ballard
Allan	2009	Australia	Tertiary care hospital/NICU	29-42 weeks	98, 56	US (CRL), LMP	Dubowitz
Amato	1991	Switzerland	NICU, hospital	All Preterm	38	"Obstetrical dates"	Ballard (Physical)
Amiel Tison	1999	France (Paris)	Tertiary Health Center/NICU	37-41 weeks	397	BOE	Amiel-Tison
Aslan	2000	Turkey (Trabzon)	Hospital	All	387	LMP	Eregie
Awoust	1982	Belgium (Brussels)	Tertiary care hospital/NICU	NS	130	US (CRL/BPD)	Dubowitz
						LMP + Clinical Exam	
Ballard	1979	USA	NICU/nursery, Hospital	NS	224	(81: Inaccurate)	Dubowitz, Ballard
Ballard	1991	USA (Cincinnati)	Tertiary Health Center/NICU	20-44 weeks; All GA	578	BOE, LMP	Ballard
				Preterm; 27-35 wks AGA & 28-	60 (AGA),		
Baumann	1993	Switzerland	Tertiary Health Center/NICU	36 wks SGA	29 (SGA)	LMP	Ballard
Bindusha	2014	India (Kerela)	Tertiary Health Center/NICU	Preterm; 28-37 weeks	1000	LMP	Ballard, Bhagwat (Physical)
Capurro	1978	Uruguay (Montevideo)	Tertiary Health Center/NICU	All gestational ages	115	LMP	Capurro, Dubowitz
Cevit	1998	Turkey (Sivas)	NS	LBW; 28-38 weeks; <2500g	91	LMP	Dubowitz, Ballard, Tuncer
		USA (AK, NY, MA, FL, PA, TX,		All GA; <35 wk (53.9%), 36-			
Constantine	1987	WA, CN)	Tertiary Health Center/NICU	37wk (20.8%), >38wk (25.3%)	1246	LMP	Ballard
Dawodu	1977	Nigeria	Tertiary care hospital/NICU	29-43 weeks	100	LMP	Dubowitz
Dombrowski	1992	USA (Detroit, Michigan)	Tertiary Health Center/NICU	24-46 weeks	38818	BOE, LMP	Ballard
Donovan	1995	USA (Maryland)	NICU, hospital	Preterm; All 24-27 weeks	242	BOE	Ballard
Dubowitz	1970	England	Tertiary care hospital/NICU	All gestational ages	167	LMP	Dubowitz
Eregie	1991	Nigeria (Benin City)	Tertiary Health Center/NICU	All gestational ages	262	Dubowitz	Eregie
Eregie	2000	Nigeria (Benin City)	Tertiary Health Center/NICU	All gestational ages	508	LMP	Eregie
Farr	1968	Scotland (Aberden)	Tertiary Health Center/NICU	34-43.5 weeks	82	LMP	Prechtl and Beintema (1964)
Feresu	2002	Zimbabwe (Harare)	Tertiary care hospital/NICU	24-45 weeks	364	LMP	Dubowitz, Ballard
Finnstrom	1972	Sweden (Umea)	Tertiary Health Center/NICU	All gestational ages	174	LMP	Finnstrom
Gagliardi	1992	Italy (Milano)	Tertiary Health Center/NICU	Preterm; <37 weeks; <2500g	227	BOE	Ballard
Hertz	1978	USA	Tertiary care hospital/NICU	All GA	126	LMP (reliable)	Dubowitz
Jaroszewicz	1973	South Africa	Tertiary care hospital/NICU	NS	100	LMP	Dubowitz
		Papua New Guinea (Madang,					
Karl	2015	North Coast)	Primary Health Center	25.5-43.7 weeks; 900g-4250g	623	US	Ballard
Karunasekera	2002	Sri Lanka (Ragama)	Tertiary care hospital/NICU	35-42 weeks	200	US	Dubowitz, Parkin
Klimek	2000	Poland (Cracow)	Tertiary Health Center/NICU	30-43 weeks	800	LMP	Klimek
Kollee	1985	The Netherlands (Nijmeken)	Tertiary Health Center/NICU	NS	229	LMP	Kollee

Author ^a	Year	Place (district/city, country)	Study Setting	GA of cohort included	Sample Size	Reference Standard	Assessments conducted (i.e. Method)
Latis	1981	Italy	Tertiary care hospital/NICU	27-42 weeks	92	LMP	Dubowitz
Laveriano	2015	Peru (Lima)	Tertiary care hospital/NICU	34-42 weeks	167	US	Capurro
Lee	2014	Bangladesh (Sylhet District)	Tertiary care hospital	All GA	192	Ballard	Ballard (inter-rater reliability)
Lee	2016	Bangladesh (Sylhet District)	Community-based	All gestational ages	710	US	Ballard, Eregie, Capurro, Parkin, Bhagwat
Mackanjee	1996	Canada (Ontario)	NICU, hospital	Preterm 23-33 weeks; <1500g	47	LMP	Ballard
Mitchell	1979	England	Tertiary care hospital/NICU	NS	20	LMP	Dubowitz
Moore	2015	Thai Myanmar Border	Tertiary care hospital/NICU	All GA	250	US (CRL)	Dubowitz
Moraes	2000	Brazil (Rio de Janeiro)	Tertiary Health Center/NICU	NS	146	US, BOE, LMP	Ballard
Narayanan	1982	India (New Delhi)	Tertiary Health Center/NICU	All gestational ages	356	LMP	Narayanan, including AVCL
Neufeld	2006	Guatemala (Eastern)	Community based recruitment	All GA; 34.6-43.7 weeks	171	US	Capurro Method A
Nicolopoulos	1976	Greece	Tertiary care hospital/NICU	28-44 weeks	710	LMP	Dubowitz
Oliveira	1999	Brazil (Sao Paulo)	Community center + maternity	NS	50	US, LMP	Capurro
Parkin	1976	England	Tertiary Health Center/NICU	25.2-45.2 weeks	392	LMP	Parkin
Pereira	2013	Brazil (Rio de Janeiro)	Tertiary Health Center/NICU	All gestational ages	961	US	Capurro
Raghu MB	1981	Lusaka, Zambia	Premature Unit, hospital	NS	160	LMP	Dubowitz
Roberts	1979	Wales (Cardiff)	Tertiary care hospital/NICU	NS	118	US (BPD), LMP (Rounded)	Dubowitz
		France (Guandeloupe, French	NICU and NICU referrals,				
Robillard	1992	West Indies)	hospital	LBW; <2500g neonates	384	BOE	Dubowitz
Rosenberg	2009	Bangladesh (Dhaka)	Special Care Nursery, hospital	Preterm; <33 weeks	355	US	Dubowitz, Ballard
Sanders	1991	USA (Baltimore)	NICU, hospital	LBW; <1500gm, >20 wk; <1500g, <37 weeks	110	BOE, LMP	Dubowitz, Ballard
Sasidharan	2009	India (Northern India)	NICU, medical institute	Preterm; 29-35 weeks	129	LMP	Ballard
Cuolanaran	2000			Preterm; 23-30 weeks by LMP,	120		Danara
Scher	1987	USA (Pittsburg, PA)	Tertiary Health Center/NICU	all died after clinical exam	24	US, LMP	Ballard
Serfontein	1978	South Africa	NS	29-40 weeks, BW <2800g	73	Dubowitz	Robinson
Shukla	1987	USA	Hospitals	Preterm; <38 weeks; AGA	25	BOE	Dubowitz
Smith	1999	USA (Houston, Texas)	Tertiary Health Center/NICU	LBW; <2500g	82	BOE	Ballard
Sreekumar	2013	India (Bangalore)	Tertiary Health Center/NICU	24-41.2 weeks	284	BOE	Ballard, Parkin
Sunjoh	2004	Cameroon	Tertiary care hospital/NICU	25-44 weeks	358	LMP	Dubowitz, Ballard, Eregie
Taylor	2010	Gambia	Community Based	All GA	80	US	Ballard (External)
Thi	2015	Vietnam (Hoa Binh)	Tertiary Health Center/NICU	30.0 - 42.0 weeks by LMP	391	US, LMP	Ballard
Tuncer	1981	Turkey (Ankara)	Tertiary care hospital/NICU	27-41 weeks	120	LMP	Dubowitz, Tuncer
Verhoeff	1997	Malawi (Chikwawa & Montfor, Southern Region)	Primary Health Center	All GA	76	LMP	Ballard (External)
Vik	1997	Norway (Bergen)	Tertiary care hospital/NICU	All GA; 20.5% SGA, 4.3% preterm, 6.8% postterm	970	US (BPD), LMP	Dubowitz
Vogt	1981	Norway	Tertiary care hospital/NICU	All GA; 25 SGA infants, 14 LGA infants	380	LMP	Dubowitz, Parkin
Wariyar	1997	UK (Newcastle)	Tertiary Health Center/NICU	All (Range not stated)	347	BOE	Ballard, Dubowitz, Parkin, Robinson
Wylie	2013	Malawi	Tertiary Health Center/NICU	All gestational ages	177	BOE	Ballard

Author ^a	Year	Place (district/city, country)	Study Setting	GA of cohort included	Sample Size	Reference Standard	Assessments conducted (i.e. Method)
Anterior Vascu	lar Capsi	ule of the Lens (AVCL)		÷	-		
Finnstrom	1972	Sweden (Umea)	Tertiary Health Center/NICU	All gestational ages	174	LMP	AVCL
Hittner	1977	USA (Houston)	Jefferson Davis Hospital (Tertiary Care)	lefferson Davis Hospital 27-34 weeks 100			AVCL
Guillory	1980	USA (Houston)	Tertiary care hospital/NICU	Preterm	43	Dubowitz & LMP	AVCL
Hittner	1981	USA (Houston)	Tertiary care hospital/NICU	Preterm & SGA	33	Dubowitz	AVCL
Narayanan	1982	India (New Delhi)	Tertiary Health Center/NICU	All gestational ages	356	LMP	AVCL
Krishnamohan	1982	USA (Connecticut)	NICU, University of Connecticut Hospital & Hartford Hospital	28-32 weeks	30	Ballard & LMP	AVCL
Sasivimokul	1986	Thailand (Bangkok)	Ramithibodi Hospital	LBW infants, all GA included	80	Ballard & LMP	AVCL
Skapinker	1987	South Africa (Johannesburg)	Johannesburg Hospital	<35 weeks	58	Ballard	AVCL
Sanders	1991	USA (Baltimore)	NICU, Johns Hopkins Hospital	<1500gm, >20 wk; <1500g, <37 weeks	89	BOE	AVCL
Baumann	1993	Switzerland (Bern)	University Clinic- Bern	27-35 weeks	89 (60 AGA; 29 SGA)	US	AVCL
Inter-mammilla	ry Distan	ce			· · ·		
Amato	1991	Switzerland (Bern)	Neonatal Unit, University Clinic Berne	Preterm	38	LMP	Inter-mammillary distance
Thawani	2013	India (Dehli)	Neonatology division, University College of Medical Sciences and GTB Hospital	25-42 weeks	1000	New Ballard Score	Inter-mammillary distance

^a Papers may be listed in Table more than once if they contain both neonatal clinical assessment data *and* AVCL or inter-mammillary distance data.
 ² Alexander 1992, "Ethnic variation in postnatal assessments of gestational age: a reappraisal."
 ³ Alexander 1992, "Validity of postnatal assessments of gestational age: a comparison of the method of Ballard et al and early ultrasonography"

Web Appendix 6. Neonatal Clinical Assessment QUADAS-2 Summary.

Overall study quality scores on the 4 domains measured by QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies-2, Whiting et al. 2011) for all neonatal clinical assessment studies (n=48).



Web Appendix 7a. Forrest Plots of Mean Difference Between Dubowitz Score and Reference Standard Gestational Age

Study		%
ID	ES (95% CI)	Weight
US/BOE		
Allan (2009)	0.10 (-0.12, 0.32)	7.69
Rosenburg (2009)	0.56 (0.51, 0.61)	7.88
Vik (1997) 🛛 🛨	-0.20 (-0.27, -0.13)	7.87
Wariyar (1997)	0.71 (0.59, 0.83)	7.82
Robillard (1992)	0.64 (0.45, 0.83)	7.73
Awoust (1982)	0.50 (0.32, 0.68)	7.75
Karunasekera (2002) -	-2.18 (-2.38, -1.98)	7.72
Subtotal (I-squared = 99.4%, p = 0.000)	0.02 (-0.51, 0.55)	54.45
LMP		
Vik (1997) 🛥	-0.40 (-0.49, -0.31)	7.86
Dawodu (1977)	0.38 (0.10, 0.66)	7.56
Sanders (1991)	── 2.80 (2.41, 3.19)	7.25
Sunjoh (2004)	0.50 (0.36, 0.64)	7.81
Latis (1981)	0.44 (0.11, 0.77)	7.43
Allan (2009)	0.30 (0.06, 0.54)	7.64
Subtotal (I-squared = 98.5%, p = 0.000)	0.65 (0.01, 1.30)	45.55
Overall (I-squared = 99.1%, p = 0.000)	0.31 (-0.06, 0.68)	100.00
NOTE: Weights are from random effects analysis		
-3.19 O	н 3.19	

Abbreviations: US= ultrasound, BOE= best obstetric estimate, LMP= last menstrual period, ES= effect size

Study ID	ES (95% CI)	% Weight
US/BOE Rosenburg (2009) —	-0.41 (-0.53, -0.30)	7.80
Gagliardi (1992)	-0.21 (-0.44, 0.02)	7.60
Wylie (2013)	- 0.21 (-0.44, 0.02) - 0.80 (0.40, 1.20)	7.00
Lee (2016)	-0.40 (-0.56, -0.24)	7.73
Smith (1999)	1.40 (1.15, 1.65)	7.55
Ballard (1991)	0.15 (0.03, 0.27)	7.33
Scher (1987)	1.35 (0.28, 2.42)	4.42
Wariyar (1997)	0.57 (0.43, 0.71)	4.42 7.77
Karl (2015)	0.86 (0.67, 1.05)	7.68
Subtotal (I-squared = 97.7%, p = 0.000)	0.40 (-0.00, 0.81)	65.45
Subicial (1-squared = 37.776, p = 0.000)	0.40 (-0.00, 0.01)	00.40
LMP		
Scher (1987)	1.42 (0.49, 2.35)	4.97
Sunjoh (2004)	0.34 (0.18, 0.49)	7.74
Sanders (1991)	2.60 (2.19, 3.01)	7.06
Mackanjee (1996)	<u>− − − − − − − − − − − − − − − − − − − </u>	7.00
Constantine (1987)	0.60 (0.48, 0.72)	7.79
Subtotal (I-squared = 96.7%, p = 0.000)	1.25 (0.64, 1.87)	34.55
		01.00
Overall (I-squared = 97.7%, p = 0.000)	0.70 (0.36, 1.04)	100.00
NOTE: Weights are from random effects analysis		

Web Appendix 7b. Forrest Plots of Mean Difference Between Ballard Score and Reference Standard Gestational Age

Abbreviations: US= ultrasound, BOE= best obstetric estimate, LMP= last menstrual period, ES= effect size

Web Appendix 8. Pooled Data for Agreement and Validity of Neonatal Clinical Assessments, Stratified by Country Income Status

					AGREEMENT						VALIDITY			
					Mean Difference % within 1 week % within 2 weeks					Sensitivity	Specificity			
Assessment Type	# of studies identified	Reference Standard	Country Income Level	N	Pooled Difference	Pooled Std. Dev.	N	Pooled %	N	Pooled %	N	Pooled Sensitivity (%) (95% Cls)	Pooled Specificity (%) (95% Cls)	
			HIC	5	0.349	1.33	3	48.1	3	74.5	0			
	9	US/BOE	LMIC	2	-0.808	0.95	0		0		1	61	99	
Dubowitz	20	20 LMP	HIC	4	0.773	1.50	2	44.7	3	70.5	0			
			LMIC	2	0.477	1.33	2	67.5	3	94.4	1	81.5	98.6	
	14	14 US/BOE	HIC	5	0.570	1.49	2	37.2	2	73.9	1	72.2	97.1	
Ballard			LMIC	4	0.199	2.12	1		1		3	25.0 (18.0, 33.0)	90.0 (88.0, 91.0)	
Dallara	10		HIC	4	1.525	2.17	2	34.7	2	72.6	1	85	81	
	18	LMP	LMIC	1			1		2	95.0	1	68.0	92.0	
0	4		HIC	0			0		0		0			
Capurro	4	US/BOE	LMIC	2	0.11	1.96	2	40.1	3	79.2	3	42.7 (35.6, 50.0)	96.7 (95.7, 97.5)	

Abbreviations: US/BOE= ultrasound or best obstetric estimate; LMP= last menstrual period; HIC= High-income countries (by World Bank definition); LMIC= low-and-middle-income countries; CI= confidence interval

Web Appendix 9. Bias of Neonatal Assessment for Estimating Gestational Age in Small Babies

	Study Setting (district/city, Clinical Reference			Bias in Small Babies	Bias in Small Babies				
Author	Year	country)	Assessment	Standard	Preterm Babies	SGA Babies			
					Dubowitz overestimated gestational age of preterms. For a preterm infant of 34				
					weeks (z-score=0), GA was overestimated by 2.57 weeks (95% LOA: 0.49,				
		Refugee/migrant antenatal			4.65). Mean bias decreased as GA increased (bias changed by -0.35 wks for				
Moore	2015	clinics, Thai-Myanmar border	Dubowitz	US	each 1wk increase in GA).				
		Neonatology Dept,			In a sample of infants <2500g, the Dubowitz overestimated GA in preterm				
Robillard	1992	Guadalupe, French W. Indies	Dubowitz	BOE	infants, with the highest bias in the lowest GAs (28-32wks).				
					In a population of AGA preterm infants (n=25), the Dubowitz tended to				
		New York University-affiliated			overestimate GA, and overestimated by >2wks in 50% of infants.				
Shukla	1987	hospitals; New York, USA	Dubowitz	BOE	Overestimation tended to be greater in lower gestational ages.				
		Neonatology services,							
		Mother and Child Centre,			Dubowitz tended to systematically over estimate GA in preterm infants, with				
		National Social Insurance &			greater overestimation in extremely preterm (<28wk, n=11) infants compared to				
		Central Hospitals; Yaounde,			later preterms (28-31wks, n=34; and 32-36wks, n=71). Mean differences for				
Sunjoh	2004	Cameroon	Dubowitz	LMP	the groups were 1.44wks, 0.59 wks, and 0.61wks respectively.				
					The Dubowitz tended to overestimate GA in infants <34wks. Bias increased as				
Vogt	1981	Tertiary Care Center, Norway	Dubowitz	LMP	GA decreased, with highest overestimation in extremely preterm infants.				
		NICU, Johns Hopkins			In infants <34wks and <1500g, both the Ballard and Dubowitz assessments				
		Hospital; Baltimore,			overestimated GA by an average of 2.7 and 3.0 wks, respectively. As GA				
Sanders	1991	Maryland, USA	Ballard, Dubowitz	BOE	increased, the degree of overestimation by postnatal assessment decreased.				
					Among early preterm babies (<30wks GA; n=105), the original Ballard, New				
			Ballard, New		Ballard, and Dubowitz assessments all systematically overestimated GA by				
Wariyar	1997	Newcastle, UK	Ballard, Dubowitz	US	averages of 3.4, 1.6, and 2.9 wks, respectively.				
					The Ballard overestimated GA in infants <37wks, with the proportion of infants				
		Medical University Hospital;			in which GA was overestimated by 2 or more weeks increasing as GA				
		Charleston, South Carolina,			decreased, and in the lowest GA range of 28-29wks, the Ballard overestimated	The Ballard tended to underestimate the GA of			
Alexander	1992*	USA	Ballard	US	GA by 2 or more weeks in ~50% of those infants.	SGA infants compared to non-SGA infants.			
		8 health facilities, Madang							
		municipality, Papua New							
Karl	2015	Guinea	Ballard	US	The Ballard systematically underestimated GA, increasing in lower GAs.				
						Ballard tended to systematically underestimate			
						GA in SGA infants (n=230), particularly in the			
	0040	Community setting, Sylhet				lower GA ranges, equating to a 2.5-wk			
Lee	2016	district, Bangladesh	Ballard	US		underestimate in a 36-wk SGA infant).			
						For SGA babies, bias of the Ballard for GA			
	4007	8 states (AK, NY, MA, FL,			In a cohort of infants <2500g, the Ballard tended to overestimate GA in infants	dating was 1-1.5 weeks lower than for non-SGA			
Constantine	1987	PA, TX, WA, CN), USA	Ballard	LMP	<37wks, with increased bias towards overestimation in infants <35wks (>1wk).	infants.			
		Chikwawa District Hospital &							
) (a she a a ff	4007	Montfort Hospital, Southern	Delland (Estern 1)						
Verhoeff	1997	Region, Malawi	Ballard (External)	LMP	The external Ballard assessment tended to overestimate GA in preterm infants.				
						The correlation of Ballard score with GA was			
Deuropera	1002	University Clinic-Bern, Bern,	Dellard			lower among SGA infants (0.66; n=29)			
Baumann	1993	Switzerland	Ballard	LMP	no mothed of Pollard at al. and early ultraconography. Am. (Obstat Gunacol: 166(3))	compared to AGA infants (0.91; n=60).			

*Alexander GR, et al. 1992, Validity of postnatal assessments of gestational age: a comparison of the method of Ballard et al. and early ultrasonography. Am J Obstet Gynecol; **166**(3): 891-5. Abbreviations: SGA= small-for gestational-age; AGA= appropriate-size-for-gestational age; GA= gestational age; US= ultrasound; BOE= best obstetric estimate; LMP= last menstrual period

Web Appendix 10. Other Clinical Assessments

					AGREEMENT						VALIDITY				
Author	Year	Study Setting (NICU/hospital/clinic, city/district, country)	Sample Size	GA of cohort	Comparison Method	Correlation coefficient (R) with true gestational age	Mean difference (wks)	SD of mean diff.	Bland Altman 95% LOA [±1.96 SD] (LL, UL) [wks]	% within 1 wk	% within 2 wks	Sensitivity <37wk, % (95%CI)	Specificity <37wk, % (95% CI)	<37 wk PPV	<37 wk NPV
	ULTRASOUND														
High Income C	Countries														
			347	32-42wks	Parkin		0.29	1.24	(-3.3, 4.1)						
Wariyar	1997	Newcastle, UK	105	<30wks	Robinson		0.43	1.31	(-2.1, 3.0)						
Low/Middle Ind	come Cou														
Pereira	2013	Primary and tertiary antenatal clinics, Rio de Janeiro State, Brazil	961	All GA	Capurro							61.0	97.0	74.0	95.0
NI (I I	0000	Community-based recruitment, rural villages,	474				0.40	1.40		44.0	00.0	00.0	07.0	00.0	07.0
Neufeld	2006	Eastern Guatemala	171	All GA	Capurro		-0.48	1.43		44.0	82.0	28.6	97.6	33.3	97.0
Oliveira	1999	Community center & maternity, San Paulo, Brazil	50	NS	Capurro						88.0				
Laveriano	1333		50	34-42	Capullo						00.0				+
(translated)	2014	Instituto Nacional Materno Perinatal, Lima, Peru	167	weeks	Capurro		0.41		(-2.1, 2.9)						
<u> </u>					Parkin		-0.70	2.12	(-4.8, 3.5)			10.0	93.0	12.0	92.0
					Bhagwat		-0.90	2.09	(-5.0, 3.2)			18.0	87.0	11.0	92.0
					Eregie		-2.00	1.76	(-5.4, 1.5)			75.0	58.0	14.0	96.0
Lee	2016	Community setting, Sylhet district, Bangladesh	710	All GA	Capurro		0.40	2.07	(-3.6, 4.5)	38.0	68.0	5.0	96.0	10.0	92.0
Karunasekera	2002	North Colombo Teaching Hospital, Ragama, Sri Lanka	200	35-42 weeks	Parkin		-0.34	1.29							
		NICU & postnatal wards, St. John's Hospital,		24-41.2											1
Sreekumar	2013	Bangalore, India	284	weeks	Parkin		1.50								
LMP															
High Income C		F													
Capurro	1978	Tertiary Care Hospital, Montevide, Uruguay	115	All GA	Capurro	0.9	SE: 1.14								
Vogt	1981	Neonatal unit, hospital, Oslo, Norway	380	All GA	Parkin				±6						
Finnstrom	1972	University Hospital, Umea, Sweden	174	All GA	Finnstrom					78.6	100.0				
Low/Middle Inc	come Cou	untries (LMIC)													
Eregie	2000	Tertiary Care Hospital, Benin City, Nigeria	508, 262 ^a	All GA	Eregie	0.921					94.3				
Sunjoh	2004	Neonatology services, Mother and Child Centre, National Social Insurance & Central Hospitals; Yaounde, Cameroon	358	All GA	Eregie	0.933	0.26	1.38			92.4				
Oliveira	1999	Community center & maternity, San Paulo, Brazil	40	All GA	Capurro						72.5				
Cevit	1998	Tertiary Care Center, Sivas, Turkey	91	Preterm LBW	Tuncer		0.80			57.1	93.4				
Tuncer	1981	NICU, Ankara, Turkey	100	27-41wks	Tuncer	0.945		1			1		1	1	1
Bindusha	2014	Tertiary Care Hospital, Kerala, India	1000	28-37 weeks	Bhagwat (Physical)	0.91	-0.58					<36 wk: 97.7%	<36 wk: 68.5%	<36wk: 94.6%	<36wk: 84.2%
		Kalawati Saran Children's Hospital, New Dehli,				0.31	-0.50		14.57			31.1/0	00.3 //	54.0%	04.270
Narayanan	1982	India (as Deference Standard)	356	All GA	Narayanan				±1.57						
Dubowitz Asse	essment ((as Reference Standard)		20 10 10											
Serfontein	1978	South Africa	73	29-40wks; <2800g	Robinson	0.85									

aN=508 for correlation; N=262 for % agreement. An empty cell indicates that the data was not available in that paper. **Abbreviations**: GA= gestational age, SD= standard deviation, LOA= limits of agreement, LL=lower limit, UL=upper limit, CI= confidence interval, PPV= positive predictive value, NPV=negative predictive value, SE= standard error, NS= not stated

Web Appendix 11. Inter-Rater Reliability

		Study Setting	Sample		Neonatal		Inter-rater re	liability			
Author	Year	(district/city, country)	Size for Inter-Rater	Reference Standard	Clinical Assessment	Карра	Correlation Coefficient	Agreement/Other			
Aslan	2000	Tertiary care center, Turkey	387	LMP	Eregie		R= 0.710 (p=0.043)				
Smith	1999	Tertiary care center, USA	10	BOE	Ballard			Spearman rank correlation test of Ballard scores assigned by the 2 examiners found no significant difference between raters (R=0.85)			
Ballard	1991	Tertiary care center, USA	67	LMP	New Ballard	0.93 (+/- 1 point)	R=0.95	Agreement (+/- 1 score point): 86%			
Moraes (translated)	2000	Tertiary care center, Brazil	52	US	New Ballard	0.74 (Cl: 0.49-0.99)		Intra-class correlation (ICC)=0.88 (CIs: 0.78, 0.93)			
Lee	2013	Tertiary care hospital, Bangladesh	192	Ballard	Ballard	0.7342					
Sasidharan	2009	Tertiary care center, India	129	LMP	New Ballard			Agreement (on day 7 of life): Mean difference between raters= -0.9 wks (95% LOA: -1.12, 0.93)			
Parkin	1976	Tertiary care center, England	101	LMP	Dubowitz			Inter-observer score consistency and score bias was reported for 11 external and 10 neurologic characteristics			
Shukla	1987	Tertiary care center, USA	8	BOE	Dubowitz			No statistically significant differences in GA predicted by the 2 examiners (paired t testing = 0.16, P>0.05)			
Gagliardi	1992	Tertiary care center, Italy	227	US/LMP	Ballard			Agreement: Mean difference between raters= -0.21 wks (95% LOA: -3.8, 3.1)			
Taylor	2010	Community medical station, The Gambia	10	US/LMP	External Ballard		R ² = 0.7				

Abbreviations: LMP= last menstrual period, BOE= best obstetric estimate, US= ultrasound; CI= confidence interval, LOA= limits of agreement, GA= gestational age

Web Appendix 12. Anterior Vascular Capsule of the Lens (AVCL) QUADAS-2 Summary.

Overall study quality scores on the 4 domains measured by QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies-2, Whiting *et al.* 2011) for all studies assessing AVCL gestational age determination (n=10).



References

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