The final version of this paper was published in *BJOG* 2015; 122(10):1284-93 with the title:

Methods of classification for women undergoing induction of labour: a systematic review and novel classification system.

Nippita TA, Khambalia AZ, Seeho SK, Trevena JA, Patterson JA, Ford JB, Morris JM, Roberts CL.

At the request of the publisher, this final published version also incorporated another paper entitled:

Induction of labour: the development and application of a novel classification system. Nippita TA, Trevena JA, Ford JB, Patterson JA, Morris JM, Roberts CL.

Methods of classification for women undergoing induction of labour: A systematic review.

Nippita TA, MBBS,¹ Khambalia AZ, PhD,¹ Seeho S, PhD,¹ Morris JM, PhD,¹ Roberts CL, DrPH.¹

1 Clinical and Population Perinatal Health Research, Kolling Institute of Medical Research, University of Sydney, Royal North Shore Hospital, St Leonards, NSW, Australia

Corresponding author: Dr Tanya Nippita

Address: Clinical and Population Perinatal Health Research, Kolling Institute of Medical Research, Level 2, Building 52, Royal North Shore Hospital, St Leonards, NSW 2065, Australia

Email: <u>tanya.nippita@sydney.edu.au</u>

Telephone: (+612) 9462 9801 or (+614) 02 321 392

Running title: Systematic review- Methods of classification for IOL

ABSTRACT

Background: The lack of reproducible methods for classifying women having an induction of labour (IOL) has led to controversies regarding the association of IOL and health outcomes for mother and baby.

Objectives: To identify research papers that describe a methodology for classifying women having an IOL, and to evaluate the utility of these methods of classification for clinical, research and surveillance purposes.

Search strategy: We conducted electronic searches in CINAHL, EMBASE and WEB of KNOWLEDGE from database inception until Oct 2013 and searched reference lists.

Selection criteria: Two reviewers independently assessed eligibility. Studies had to describe a method for classifying women with an IOL using a minimum of two categories, regardless of whether or not this was the main purpose of the study.

Data collection: Data were extracted on study characteristics, quality and results. Prespecified criteria were used to evaluate the utility of these methods of classification for IOL.

Main results: Seven studies met the inclusion criteria. All studies categorised women according to the presence or absence of a medical indication for IOL. Uncertainties and/or deficiencies were identified across all methods of classification related to the criteria of total inclusivity, reproducibility, clinical utility, implementability and data availability limiting their usefulness.

Conclusion: Current methods of classifying women with an IOL are inadequate for clinical, research and surveillance purposes. Limitations with classification systems based on medical indications suggest that an alternative method of classification is required for women having IOL.

PROSPERO Registration number: CRD42014010174.

Key words: labour induction; classification; pregnancy; systematic review.

INTRODUCTION

Induction of labour (IOL) involves artificially stimulating uterine contractions to commence labour,¹ and is most commonly practiced when the risks of continuing the pregnancy are perceived to outweigh the risks of shortening the duration of pregnancy. In high-income countries, IOL is a common intervention; approximately one in four (25.4%) births in Australia in 2010 occurred following IOL,² with similar rates reported in England $(23.3\%)^3$ and the USA (23.3%).⁴

There has been much interest in the relationship between IOL and health outcomes, particularly with regard to its effect on the mode of birth. Large observational studies suggest IOL increases the risk of caesarean delivery.⁵⁻⁷ However, two recent systematic reviews and meta-analyses^{8,9} suggest that the risk of caesarean is reduced by IOL. It has been postulated that these conflicting findings are the result of comparing dissimilar groups of women and the lack of a transparent and reproducible method for classifying women undergoing IOL.¹⁰

Classification systems involve clustering and categorising information according to a set of logical rules. They have great utility as they enable comparison and interpretation of data within and between populations over time.¹¹ A robust method of classification for IOL would allow examination of practice variation as well as associated maternal and perinatal health outcomes amongst homogeneous groups of women having an IOL, thereby leading to better clinical practice. To the best of our knowledge, a review of methods for classifying women having IOL has not been performed. The aims of this systematic review are to identify studies that have utilised

a method for classifying women undertaking IOL and evaluation of the utility of these methods of classification for clinical, research and surveillance purposes.

METHODS

A systematic search of published studies was performed using three electronic databases: CINAHL, EMBASE and WEB OF KNOWLEDGE (also containing MEDLINE) from inception until 31st October 2013. The search terms 'labour induction' (with spelling and word order variations), 'classification', 'schema', 'category', 'classify' and 'nomenclature' were used. Studies were included if they described a method of classifying women having IOL with a minimum of two categories, regardless of whether or not this was the main purpose of the study. Exclusion criteria included non-English language publications; animal or *in vitro* studies; reviews, comments, editorials or guidelines not involving original research; case reports; case series; and randomised controlled trials. The protocol for the systematic review was registered with PROSPERO International Prospective Register of Systematic Reviews (CRD42014010174).

Two investigators (TN and AK) independently screened titles and abstracts for eligibility and assessed the full text of potentially eligible studies using a standardised form. The full text was retrieved for studies considered relevant or potentially relevant from the abstract. Discrepancies between the two investigators were resolved through discussion. The references of included studies were hand searched and those considered relevant were retrieved in full text and assessed for inclusion eligibility. In cases where a conference abstract met inclusion criteria and a full text paper of the study was not identified, the authors were emailed for further information. Data were

independently extracted directly into tables by one investigator (TN) and independently reviewed for completeness and accuracy by two other investigators (AK, SS). Discrepancies were resolved through discussion. Data extracted included study purpose, study design, study inclusion and exclusion criteria, data sources, study period, study population, total number of participants, number of participants included in the method classifying the participants, and details pertinent to the method of classification (such as the number and definition of classification categories).

There are no formally established criteria to evaluate methods of classification for clinical, research and surveillance purposes. Important characteristics of a robust classification method were identified using a recent systematic review on classifications for caesareans¹² and the Robson classification system for caesarean section.¹³ The following pre-specified criteria were used to evaluate methods of classification for IOL: (i) ease (how much effort or time it took to understand the main concept, logic and rules of the classification); (ii) clarity (clear, objective, precise and unambiguous definitions given for each category); (iii) mutually exclusive (each woman being classified can only be placed in a single category opposed to multiple categories); (iv) totally inclusive (each and every woman in the population being classified can be put into a category); (v) prospectively identifiable (each woman can be classified prior to the IOL); (vi) reproducibility (high probability that the same woman will be placed in the same category by different assessors); (vii) availability of data; (viii) implementability (feasibility to introduce and maintain the classification system) and (ix) clinical utility (usefulness of the classification system). Each criterion was scored independently by three investigators (TN, AK, SS): a score of 2 was awarded if the criterion was fulfilled; a score of 1 was awarded if it was unclear

whether the criterion was fulfilled; and a score of 0 indicated that the criterion was not fulfilled. The maximum total score was 18. Final scores were determined after discussion and consensus was reached among the three independent investigators.

RESULTS

Results of search strategy and study characteristics

The search strategy revealed 841 records, of which a total of 8 relevant articles were identified (Figure 1).^{6,10,14-19} One study, which was a published conference abstract¹⁹ was the only study whose primary aim was to classify women having an IOL, but further information and full text publications were not available (email communication with authors). Consequently, as there were insufficient data for review and evaluation, the abstract was excluded.

The main purpose of the 7 remaining studies included measuring rates of IOL among various groups of women, the association of different indications for IOL with mode of delivery, and determining maternal and neonatal outcomes following IOL (Table 1). All studies but Teixeira *et al.*,¹⁸ were retrospective cohort studies. Studies collected data from varying sources and all were performed in developed countries in a range of settings. Teixeira *et al.* collected data using structured interviews and medical records from five public hospitals in Porto, Portugal.¹⁸ Four studies^{10,14,15,17} utilised population-based record-linked data; three in the USA^{10,14,15} and one in Scotland.¹⁷ The remaining two hospital-based studies (one tertiary hospital¹⁶ and one community hospital⁶) used hospital perinatal databases and/or medical records. Most studies examined data collected from the year 2000 onwards;^{10,14,15,18} however, the two hospital-based studies examined data from the 1990s and the Scotland population-

based study by Stock *et al.* included the years 1981 through to 2007.¹⁷ Study sample sizes ranged from 311¹⁶ to 2 350 388 births.¹⁴ The two smallest sample sizes were the hospital-based studies,^{6,16} and the three largest were from the studies that used record-linkage of large administrative databases.^{10,14,17}

Methods of classification for IOL

None of the methods of classification included the total population of pregnant women having an IOL in the study population, with studies varying in their inclusion and exclusion criteria (Table 1). The most common exclusion criterion was multifetal pregnancy. Except for the study by Laughon *et al.*, studies restricted their method for classifying women with an IOL to only those with singleton births.¹⁵ Gestational age at birth was a commonly used inclusion criterion; however, this varied between studies. Three studies included pregnancies that were greater than or equal to 37 weeks gestation at delivery,^{10,14,17} while others included preterm births from 20 weeks gestation¹⁶ or from 24 weeks gestation.^{15,18} The study by Yeast *et al.*, was the only study to include all gestational ages at delivery in their method of classification for IOL.⁶

All methods of classification for women having IOL were based on the presence or absence of a medical indication (Table 2). The category for 'IOL without medical indication' (also called 'elective IOL' or 'non-defined' in some studies) was included in each study. The other categories used to group women having an IOL varied across the studies. The methods of classification for women having an IOL in studies by Ananth *et al.*, Laughon *et al.* and Robson *et al.* included 3 groups: (i) medical indication for IOL; (ii) no medical indication for IOL; and (iii) spontaneous delivery or no recorded IOL (Table 2).¹⁴⁻¹⁶ Laughon *et al.* further classified the 'medical indication for IOL' category using a hierarchical system, stratifying in an author-specified priority order by the particular medical indication. For example, women with premature rupture of membranes (PROM) were always classified according to that indication, but if the woman had an IOL and PROM in addition to another medical indication for IOL, the woman was classified only in the PROM category.¹⁵ This study also classified any IOL as 'indicated IOL' if there was any potential maternal, fetal or obstetric complication of pregnancy, whether or not it was stated as the indication for IOL. Robson *et al.* and Ananth *et al.* each provided a detailed, but non-identical list of indications for induction and used the same three groupings, except that Robson *et al.* included a wider gestation age range; from and including 20 weeks gestation,¹⁶ whereas Ananth *et al.* only included births from 37 to 44 weeks gestation.¹⁴

Teixeria *et al.* and Yeast *et al.* used 2 categories in their method of classification for women having IOL: indicated (termed 'indicated' by both studies) and non-indicated IOL (termed 'non-indicated' by Teixeria *et al.* and 'elective' by Yeast *et al.*) (Table 2).^{6,18} Yeast *et al.* defined the 'indicated' group as a physician assigned primary indication without a precise list of defined indications. In contrast, Teixeira *et al.* described a comprehensive list of indications, and categorised patients as 'indicated' if at least one indication was met. This classification method for IOL was based on the number of indications of IOL (none, one or two or more indications for IOL); however, because only a few women were in the latter group, the analysis used 2

groups: those with none, or at least one indication, for IOL. Teixeira *et al.* did not define the 'non-indicated' category. In Yeast *et al.*, the 'elective IOL' group was defined as all patients who did not have another recorded indication for delivery or associated medical condition that warranted delivery.

The method of classification for women having an IOL in studies by Darney *et al.* and Stock *et al.* included a category of women having an IOL without a medical indication (termed 'elective' by Stock *et al* and 'IOL without medical indication' by Darney *et al.*) and a comparator group of women that did not have an IOL but had 'expectant management'.^{10,17} Thus, both studies excluded women with a medical indication for IOL and used different criteria to define the medical indication for IOL.

Three of the 7 studies cited sources that were used to define the medical and nonmedical indications for women having IOL. Sources included local hospital guidelines,¹⁸ the Joint Commission (USA),¹⁰ the American College of Obstetricians and Gynaecologists (ACOG),¹⁸ the Royal College of Obstetricians and Gynaecologists (RCOG),¹⁸ and the previously named Royal Australian College of Obstetricians and Gynaecologists (RACOG).¹⁶ The medical indications for IOL listed by these guidelines were comprehensive but variable. For example, among studies that cited a source for their inclusion of a medical indication for IOL, macrosomia was only included in one study,¹⁸ and not in the other studies.^{10,16}

Evaluation of methods of classification for IOL

The total scores varied from 9 to 12 out of a maximum score of 18 (Table 3). The studies by Ananth *et al.* and Robson *et al.* scored the highest.^{14,16} Compared with the other methods of classification for IOL, these two methods included clear, prospectively identifiable and unambiguous definitions of the categories for categorising women.

All methods of classification for IOL had mutually exclusive categories; however, none of these classification systems were inclusive of all women having an IOL. For instance, each classification system except that proposed by Laughon *et al.* excluded multifetal gestations; however, Laughon *et al.* only included births from 24 to 41 weeks' gestation.

Five of the classification methods^{6,10,14,16,17} were given a high rating for ease, indicating that a small amount of effort or time was required to understand the main concept, logic and rules of the classification system. The classification methods proposed by Laughon *et al.* and Teixeria *et al.* were assessed as 'unclear'.^{15,18} Laughon *et al.* used a complicated hierarchical system for the category 'indicated inductions' and Teixeira *et al.* classified IOL on the basis of none, one or two or more indications which was based on the perusal of the medical chart.

The criterion clarity, defined as providing clear, objective, precise and unambiguous definitions for each category was fulfilled by 5 of the 7 classification methods.^{10,14,16-18} For example, Robson *et al.* (score of 2) provided precise definitions of medical conditions that were included in the 'indicated' IOL category;¹⁶ whereas, Yeast *et al.* (score of 1) provided ambiguous definitions; stating the 'indicated' IOL category

relied on a physician assigned primary indication for IOL and the elective IOL category included all patients who did not have a recorded indication, or associated medical condition that warranted delivery.⁶

Of the 7 methods of classification for IOL, two did not fulfil the criteria of using prospectively identifiable categories (ability to classify each patient prior to IOL). The studies by Darney *et al.* and Stock *et al.*,^{10,17} used 'expectant management' to categorise pregnant women, such that women in this category remained eligible for an IOL until the onset of labour, and could only be identified following delivery of their baby.

The classification systems rated poorly in the criterion of reproducibility. Four studies utilised classification systems in which reproducibility was not possible^{6,10,15,17} and in another three studies it was unclear whether a woman would be placed into the same category by different assessors.^{14,16,18} Classification systems of IOL that rated poorly on this criterion were those with discordant definitions for the same indication for IOL. For example, postterm pregnancy was defined as commencing from 41 weeks' gestation by Teixeira *et al.*,¹⁸ 40 weeks + 10 days' gestation by Robson *et al.*,¹⁶ and 42 weeks' gestation by Ananth *et al.*¹⁴ Additionally, some of the definitions for IOL was a 'postdate pregnancy', but the gestational ages included for this indication ranged from 36 to 42 weeks' gestation, thus including preterm deliveries and term pregnancies, in addition to postterm pregnancies.⁶

Across all of the classification methods for IOL, the criteria of availability of data, implementability, and clinical utility consistently scored 'unclear' in terms of meeting the requirements of a good classification system (Table 3). Large amounts of accurate data are required for the 7 classification methods for IOL due to the need to determine whether each patient fulfils any of the criteria for the different medical indications. Therefore, it is unclear whether data availability would be fulfilled, depending on the validity of the source data. Due to the complexity of the definitions of the categories of IOL, it would be a challenge to introduce and maintain an accurate classification system, and hence, it was unclear whether the classification system is implementable. The last criterion of clinical utility scored 'unclear' as all the authors used indication for IOL to group women with the challenges and difficulties of reproducibility and availability of data.

DISCUSSION

Main findings

We identified seven studies that used a classification system to categorise women undergoing IOL. None of the current methods of classifying women having IOL are adequate for clinical, research and surveillance purposes. Evaluation of the studies identified uncertainties and/or deficiencies across all methods of classification related to the pre-specified criteria of total inclusivity, reproducibility, clinical utility, implementability and data availability. The overarching limitation of all of the 7 proposed methods for classifying women having IOL is the dependency on using an 'indication' for IOL as the conceptual framework for classification. Of note, these 7 studies were not proposing their classification methods for widespread implementation, uptake, or adoption.

Strengths and limitations

To our knowledge, this is the first study to systematically evaluate methods of classification for women having IOL. Broad, general search criteria were used to encompass all possible ways IOL was classified; however, other terminology by the authors may have been used and we limited the studies to those published in the English language to facilitate interpretation. Of the five papers that were excluded on the basis of the studies published in languages other than English, we only identified one potential paper in a language other than English (French) that had a classification system for IOL and based on the abstract we are confident that this paper would have been excluded as well.²⁰ Additionally, we attempted to reduce bias of the evaluation of the methods of classification by using three independent reviewers.

Interpretation

Evaluation of these classification methods highlights the difficulties and challenges with classifying IOL by the presence or absence of a medical or pregnancy indication. Others have also identified the lack of agreement and distinction between the different indications for IOL.²¹

An indication-based classification system for women having IOL is inferior because of the inherent inconsistencies in this approach. Hospital birth registers have been found to misclassify medical indications for women having an IOL. Robson and colleagues¹⁶ found that their hospital birth register overestimated medical indications for IOL; 29.7% of cases that had a stated medical indication for IOL according to the hospital birth register did not actually fulfil the criteria for the medical indication after careful examination of the medical file. Conversely, another study found that vital statistics information from birth certificates in the US state of Ohio overestimated non-medical indicated IOL by 11-fold, as birth certificates underreported pregnancy and medical complications.²² This study also found large variation among hospitals regarding the accuracy of birth certificate records documenting the medical indication for IOL compared to the medical record. Similarly, a systematic review found that conditions related to pregnancy and pre-existing medical conditions were likely to be underreported in population health data sets.²³ Efforts to improve the accuracy of recording indications for IOL would be resource intensive and potentially impractical.²⁴

Another issue highlighted is the use of prioritisation of a medical indication in deciding the category in which a woman having IOL should be placed. A patient may have multiple medical factors that may be an indication for IOL, but unless the medical notes are examined, it may be unclear which medical condition was the main indication for IOL. Alternatively, an IOL may be recommended due to the multiple medical issues and not a single medical issue being the main indication for IOL. One study¹⁵ has attempted to address this problem by assigning a hierarchical nature to classify the medical indication for IOL. However, the hierarchical method is limited by the accuracy of the data collected, as an omission may completely change the categorisation of the woman having the IOL.

There is a lack of consensus on acceptable indications for IOL and these will change over time. The guidelines of the major professional associations (RCOG, ACOG, Royal Australian and New Zealand College of Obstetricians and Gynaecologists, Society of Obstetricians and Gynaecologists of Canada) have different indications for IOL, with consensus on only 3 of 14 potentially acceptable indications for IOL.²⁵ The

differences in recommendations in the guidelines reflect the paucity of high quality evidence to guide best practice recommendations for IOL regarding those particular conditions. As knowledge improves, the medical indications for IOL are also likely to change; for example, maternal age appears to be associated with increased risk of stillbirth, and there is currently a pilot trial,²⁶ investigating whether IOL at 39 weeks gestation for women over 35 years old improves perinatal outcome compared to expectant management.

An alternative method of classifying women having an IOL is necessary, which is not dependent on the indication for IOL. A useful beginning is to consider the widely accepted method of classifying caesarean section; Robson highlighted similar limitations classifying caesarean sections by indication,¹³ and proposed an alternative method of classification based on four obstetric concepts (number of fetuses, previous obstetric record of the woman, course of labour and delivery, and the gestation of the pregnancy at the time of delivery). The ten group classification for caesarean section has groups that are mutually exclusive, totally inclusive, reproducible, clinically relevant and prospective. An adaptation of this classification system developed for caesarean section may be useful for classifying women having an IOL.

CONCLUSION

The current methods that classify women having an IOL are based on medical indications and have significant limitations. These limitations contribute to the controversy and uncertainty of maternal and perinatal outcomes for IOL. An alternative method of classifying women having an IOL is required.

ACKNOWLEDGEMENTS

We wish to thank Ms Elizabeth Pigott, Faculty Liaison Librarian, Medical Science Libraries, University of Sydney for assisting with the search strategy.

DISCLOSURE OF INTERESTS

The authors declare no conflict of interest.

CONTRIBUTION TO AUTHORSHIP

CR conceived the study and TN wrote the study proposal. CR, AK, and JM contributed to the study design. TN and AK performed the literature search and extracted the relevant studies; TN, AK and SS evaluated the studies. JM provided expertise on clinical application. All authors contributed to interpretation of results, critical review of drafts and accept responsibility for the final manuscript.

DETAILS OF ETHICAL APPROVAL

No ethical approval was required.

FUNDING

Christine Roberts is supported by a NHMRC Senior Research Fellowship (APP1021025). Funding for Amina Khambalia is by an Australian NHMRC Centres for Research Excellence (APP1001066).

REFERENCES

World Health Organisation. WHO recommendations for induction of labour.
 Geneva, Switzerland: WHO Press; 2011.

Li Z, Zeki R, Hilder L, Sullivan E. Australia's mothers and babies 2010.
 Perinatal statistics series no. 27. Cat. no. PER 57. Canberra: AIHW National Perinatal
 Epidemiology and Statistics Unit; 2012.

Hospital Episode Statistics Analysis, Health and Social Care Information
 Centre [Internet]. NHS Maternity Statistics - England, 2012-13. Health and Social
 Care Information Centre; 2013 Dec 5. [cited 2014 July 10]. Available from:
 http://www.hscic.gov.uk/catalogue/PUB12744/nhs-mate-eng-April 2012 to March
 2013-pla-tab.xls

4. Osterman MJ, Martin JA. Recent declines in induction of labor by gestational age. *NCHS data brief* 2014; (155): 1-8.

Ehrenthal DB, Jiang X, Strobino DM. Labor induction and the risk of a cesarean delivery among nulliparous women at term. *Obstet Gynecol* 2010; **116**(1): 35-42.

6. Yeast JD, Jones A, Poskin M. Induction of labor and the relationship to cesarean delivery: A review of 7001 consecutive inductions. *Am J Obstet Gynecol* 1999; **180**(3): 628-33.

7. Heffner LJ, Elkin E, Fretts RC. Impact of labor induction, gestational age, and maternal age on cesarean delivery rates. *Obstet Gynecol* 2003; **102**(2): 287-93.

8. Mishanina E, Rogozinska E, Thatthi T, Uddin-Khan R, Khan KS, Meads C. Use of labour induction and risk of cesarean delivery: a systematic review and metaanalysis. *CMAJ* 2014.

9. Wood S, Cooper S, Ross S. Does induction of labour increase the risk of caesarean section? A systematic review and meta-analysis of trials in women with intact membranes. *BJOG* 2014; **121**(6): 674-85.

10. Darney BG, Snowden JM, Cheng YW, Jacob L, Nicholson JM, Kaimal A, et al. Elective induction of labor at term compared with expectant management: maternal and neonatal outcomes. *Obstet Gynecol* 2013; **122**(4): 761-9.

 Jakob R, Ustun B, Madden R, Sykes C. The WHO Family of International Classifications. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz* 2007; **50**(7): 924-31.

12. Torloni MR, Betran AP, Souza JP, Widmer M, Allen T, Gulmezoglu M, et al.
Classifications for cesarean section: a systematic review. *PLoS One* 2011; 6(1):
e14566.

13. Robson MS. Classification of caesarean sections. *Fetal Matern Med Rev* 2001; **12**(1): 23-39.

14. Ananth CV, Wilcox AJ, Gyamfi-Bannerman C. Obstetrical interventions for term first deliveries in the US. *Paediatr Perinat Epidemiol* 2013; **27**(5): 442-51.

15. Laughon SK, Zhang J, Grewal J, Sundaram R, Beaver J, Reddy UM. Induction of labor in a contemporary obstetric cohort. *Am J Obstet Gynecol* 2012; **206**(6): 486 e1-9.

Robson S, Pridmore B, Dodd J. Outcomes of induced labour. *Aust N Z J Obstet Gynaecol* 1997; **37**(1): 16-9.

17. Stock SJ, Ferguson E, Duffy A, Ford I, Chalmers J, Norman JE. Outcomes of elective induction of labour compared with expectant management: population based study. *BMJ* 2012; **344**: e2838.

18. Teixeira C, Correia S, Barros H. Risk of caesarean section after induced labour: do hospitals make a difference? *BMC Res Notes* 2013; **6**: 214-.

McMillan H, Walsh T, Gannon M, Horgan R, Khawaja N, Collins C, et al.
 Proposal for a standardised classification system for audit of induction of labour. *Am J Obstet Gynecol* 2005; **193**(6): S115-S.

20. Clerte R, Rioux P, Bouvet F, Taurelle R. [An index for induction of labour. A scheme based on Parzen's method (author's transl)]. *J Gynecol Obstet Biol Reprod* (*Paris*) 1980; **9**(8): 909-17.

21. Vogel JP, Gulmezoglu AM, Hofmeyr GJ, Temmerman M. Global perspectives on elective induction of labor. *Clin Obstet Gynecol* 2014; **57**(2): 331-42.

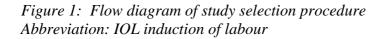
22. Bailit JL. Rates of labor induction without medical indication are overestimated when derived from birth certificate data. *Am J Obstet Gynecol* 2010;
203(3): 269.e1-3.

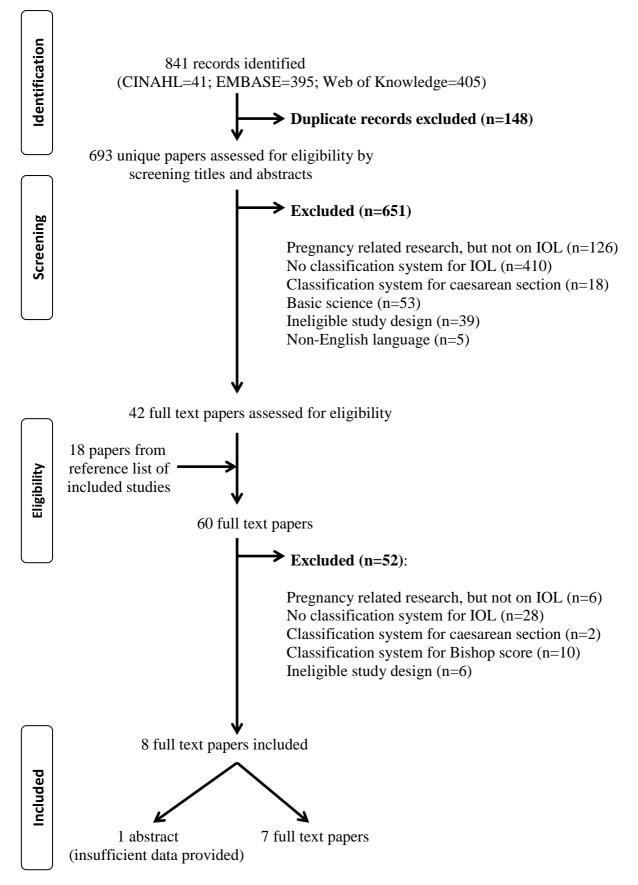
23. Lain SJ, Hadfield RM, Raynes-Greenow CH, Ford JB, Mealing NM, Algert CS, et al. Quality of data in perinatal population health databases: a systematic review. *Med Care* 2012; **50**(4): e7-20.

24. Callaghan WM. Using birth certificate data to determine medically indicated induction rates. *Am J Obstet Gynecol* 2010; **203**(3): 190-1.

25. Chauhan SP AC. Induction of Labor in the United States: A Critical Appraisal of Appropriateness and Reducibility. *Semin Perinatol* 2012; **36**(5): 336-43.

26. Walker KF, Bugg G, Macpherson M, McCormick C, Wildsmith C, Smith G, et al. Induction of labour versus expectant management for nulliparous women over 35 years of age: a multi-centre prospective, randomised controlled trial. *BMC Pregnancy Childbirth* 2012; **12**: 145.





Study and country	Main purpose of study	Design, data sources, total population.	Setting, study period	Inclusion/exclusion criteria	Study population
Ananth <i>et</i> <i>al.</i> 2013. ¹⁴ USA	Describe prevalence and maternal and neonatal outcomes of deliveries classified as: i) 'indicated' deliveries after intervention (IOL/CS), ii) 'non- indicated' deliveries after intervention (IOL/CS); and iii) 'spontaneous deliveries'.	Retrospective cohort. Linked records containing vital health statistics, birth and death certificates. N= 8,557,769	12 states in 2005; 19 states in 2006; 22 states in 2007 and 27 states in 2008 across USA	<i>Inclusion:</i> Primiparous women, singleton live birth, 37-44 weeks' gestation. <i>Exclusion:</i> None specified.	2,350,388
Darney <i>et</i> <i>al</i> . 2013. ¹⁰ USA	Describe maternal and neonatal outcomes of term deliveries classified as: i) 'elective' IOL at term; and ii) 'expectant management'.	Retrospective cohort. Linked records containing death files, birth certificates, hospital discharge data and vital statistics. N= 532,088	All births in hospitals in California, USA, 2006.	<i>Inclusion:</i> Vertex, non-anomalous, singleton live birth; 37-40 weeks' gestation. <i>Exclusion:</i> Breech, fetal anomalies, prior CS, unknown parity, HIV, placenta praevia, hypertension, toxaemia, renal or liver conditions, DM, cardiovascular disease, vasa praevia, coagulation deficiency.	362,154
Laughon <i>et al.</i> 2012. ¹⁵ USA	Describe maternal and neonatal characteristics and vaginal delivery rates of deliveries classified as: i) 'indicated' IOL at term; ii) 'elective'; and no recorded indication'.	Retrospective cohort. Electronic medical records. N= 228, 668	12 clinical centres and 19 hospitals across the USA, 2002-2008.	<i>Inclusion:</i> All births; 24-41 weeks' gestation. First pregnancy only included if multiple pregnancies during study period. <i>Exclusion:</i> None specified.	208, 695
Robson et	Describe prevalence and	Retrospective cohort.	One tertiary	<i>Inclusion:</i> Singleton births; >20	1, 405

Table 1 Characteristics of included studies for systematic review of methods of classification for induction of labour.

<i>al</i> . 1997. ¹⁶ Australia	maternal and neonatal outcomes of deliveries classified as: i) 'defined' indication for IOL, ii) 'non-defined indication' for IOL; and iii) 'spontaneous labour'.	Hospital birth register and medical records. Not reported.	hospital in South Australia, July 1994- June 1995	weeks' gestation. <i>Exclusion</i> : Delivered by planned CS (whether before or after spontaneous labour).	
Stock <i>et</i> <i>al</i> . 2012. ¹⁷ Scotland	Determine maternal and neonatal outcomes of deliveries classified as: i) 'elective' IOL; and; ii) expectant management.	Retrospective cohort. Linked records containing death files, birth certificates, hospital discharge data and vital statistics. N= 1 605 601	Obstetric units in Scotland (midwifery and consultant led), 1981-2007	<i>Inclusion:</i> Singleton births; ≥37 weeks' gestation. <i>Exclusion:</i> Recognised contraindication to IOL including malpresentation, abdominal pregnancy, placenta praevia or previous caesarean section. PROM excluded from IOL group but included in expectant group. Excluded antepartum IUFD in the week of gestation in which IOL performed.	1,271,549
Teixeira <i>et al.</i> 2013. ¹⁸ Portugal	Determine hospital characteristics associated with caesarean section after IOL for deliveries classified as: i) at least one indication for IOL; and ii) no indication for IOL.	Prospective cohort. Structured questionnaire, interview and medical records. N= 8,495	5 public level 3 units in Porto Metropolitan Area, Portugal, April 2005- August 2006	<i>Inclusion:</i> Singleton live birth after IOL; >24 weeks' gestation. <i>Exclusion:</i> None specified.	2,041
Yeast <i>et</i> <i>al</i> . 1999. ⁶ USA	Describe prevalence and birth outcomes of deliveries classified as: i) primary indication for IOL; ii) 'elective' IOL; and iii) 'spontaneous labour'.	Retrospective cohort. Hospital perinatal database. N= 21,160	One community teaching hospital with a perinatal referral centre in state of Missouri,	<i>Inclusion:</i> None specified. <i>Exclusion:</i> Multiple gestations, primary herpes, placenta praevia, abruption placentae, major fetal anomaly, previous classical CS,	18,055

USA, 1990-1997. elective repeat CS, prelabour CS, breech presentation.

Abbreviations: CS caesarean section; IOL induction of labour; IUFD intrauterine fetal death; HIV human immunodeficiency virus; PROM prelabour rupture of membranes; DM diabetes mellitus.

Table 2: Method of	of	classification	used by	included	studies.

Study and source of definition for categoriesInduction with medical indication ("ind or "defined")		Induction without medical indication ("non- indicated", "elective", or "non-defined")	Other categories		
Ananth <i>et al</i> .	'Indicated'	'Non-indicated'	'Spontaneous'		
2013 ¹⁴	IOL or CS performed in the presence of: gestational hypertension, pre-eclampsia,	All remaining CS or IOL or both.	All deliveries without a CS or IOL.		
Source: No eclampsia, chronic hypertension, pre-gestational or gestational diabetes, chorioamniontis, failed cephalic version at \geq 40 week, post term pregnancy \geq 42 weeks; inferred fetal growth restriction (<3 rd centile birthweight for gestational age), prelabour CS in the presence of breech at \geq 39 weeks, labour lasting at least 12hrs, failed trial of labour, fetal intolerance to labour, failed forceps or vacuum extraction.					
Laughon <i>et al</i> .	'Indicated'	'Elective'	'No recorded indication'		
2012. ¹⁵	Author assigned hierarchical system of inclusion.	Recorded as 'non-indicated' on medical record; no	All IOL with no other		
Source: No	PROM classified first, then all potential maternal, fetal or obstetric complications of pregnancy (included chorioamnionitis, decidual haemorrhage/abruption, hypertensive disease including preeclampsia/eclampsia, maternal condition, diabetes, fetal anomaly, stillbirth, suspected fetal macrosomia, fetal condition, maternal fever on admission, history of maternal/obstetric condition, history of fetal condition including IUGR, postdates, prior uterine scar); may have >1 indication. Also included	indication recorded; no medical complications; recorded as postdates delivery with no other recorded indication, but delivered <41 weeks gestation.	obstetric, fetal or maternal conditions of pregnancy, including if no reason for IOL provided.		

	women admitted for labour or delivery for unspecified fetal or maternal reason.		
Robson <i>et al.</i> 1997. ¹⁶	'Defined' PROM >24hours, hypertensive disorders (including chronic renal disease), diabetes	'Non-defined' Induction criteria did not meet those of any 'defined' indication.	'Spontaneous' Not defined by authors.
Source: Yes ¹	mellitus, chorioamnionitis, prolonged pregnancy (>40 weeks and 10 days), intrauterine growth restriction (EFW <10 th centile or if 2 consecutive ultrasounds showed any biometric parameter crossed percentile lines or oligohydramnios or abnormal umbilical artery dopplers, fetal distress (on cardiotocography), fetal demise, isoimmunisation.		
Teixeira <i>et al</i> . 2013. ¹⁸	'Indicated' At least one indication assigned by staff physician	'Non-indicated' Authors do not provide information.	Not applicable.
Source: Yes ²	and reviewed by the database nurse: PROM, hypertension, diabetes mellitus, post term pregnancy (≥41 weeks), fetal growth restriction, maternal diseases that could demand prompt delivery, isoimmunisation, macrosomia, amniotic fluid disorders.		
Yeast <i>et al.</i> 1999. ⁶	'Indicated' Physician assigned primary indication for IOL.	'Elective' No medical complications; no indication recorded.	Not applicable.
Source: No			
Darney <i>et al</i> . 2013. ¹⁰	Not applicable.	'Non-indicated' No medical indication prior to 39 weeks. Excluded: PROM, preeclampsia, eclampsia,	'Expectant management' All other deliveries.

Source: Yes ³		liver/bile tract disorder, amniotic infection, IUGR, fetal distress, abnormal fetal heart rate, Rh and ABO isoimmunisation, antepartum haemorrhage poly/oligohydramnios, poor reproductive history, FMH, premature separation of placenta, IUFD, unstable lie.	
Stock <i>et al.</i> 2012. ¹⁷ Source: No	Not applicable.	'Elective' Excluded: hypertensive or renal disorders, diabetes mellitus, thromboembolic disorders, liver disorders, pre-existing medical disorder, antenatal investigation of abnormality, suspected fetal abnormality or compromise, poor obstetric history. In absence of any conditions being recorded and IOL <41 weeks, IOL considered to be elective.	'Expectant management' Women who were delivered after the gestation to which the comparator IOL was performed.

1 Australian Council of Health Care Standards (ACHS) and Royal Australian College of Obstetricians and Gynaecologists (RACOG) guidelines 2 American College of Obstetricians and Gynecologists (ACOG), Royal College of Obstetricians and Gynaecologists (RCOG) and local guidelines.

3 Joint Commission List of Indications Possibly Justifying Elective Induction prior to 39 weeks (United States)

Abbreviations: CS caesarean section; EFW estimated fetal weight; FMH fetomaternal haemorrhage; IOL induction of labour; IUFD intrauterine fetal death; IUGR intrauterine growth restriction; NA not applicable; PROM prelabour rupture of membranes.

Table 3: Analysis of classification systems.

	Ananth <i>et al.</i> ¹⁴	Darney <i>et al.</i> ¹⁰	Laughon <i>et al.</i> ¹⁵	Robson <i>et al.</i> ¹⁶	Stock <i>et al.</i> ¹⁷	Teixeira <i>et</i> <i>al.</i> <u>ENREF_16</u> ¹⁸	Yeast <i>et</i> $al.^{6}$
Ease							
Small amount of effort or time required to understand main							
concept, logic and rules							
Clarity							
Clear, objective, precise and unambiguous definitions given for							
each category							
Mutually exclusive							
Each woman classified only placed in a single category opposed							
to multiple categories							
Totally inclusive							
Each and every woman classified can be put into a category							
Prospectively identifiable							
Each woman can be classified prior to the induction of labour							
Reproducible							
Probability that same woman is placed in same category by							
different assessors							
Available data							
Implementable							
Feasibility to introduce and maintain the classification system							
Clinical utility							
Usefulness of the classification system							
	12	9	9	12	9	11	10
TOTAL SCORE (maximum score 18)							

Key:

Fulfils criterion (2 points) Unclear whether fulfils criterion (1 point) Tables for: Systematic review- Methods of classification for IOL

Does not fulfil criterion (0 points)