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Chen Liang, Jihong Liu, Tianchu Lyu, Nadia Ghumman, Berry Campbell

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Abstract

Background: Despite emerging application of clinical decision support systems (CDSS) in pregnancy care and the proliferation of artificial intelligence (AI) over the last decade, it remains understudied regarding the role of AI in CDSS specialized for pregnancy care.

Objective: To identify and synthesize AI augmented CDSS on pregnancy care, CDSS functionality, AI methodologies, and clinical implementation, we reported a narrative review based on empirical studies that examined AI augmented CDSS in pregnancy care

Methods: We retrieved studies that examined AI augmented CDSS in pregnancy care using database queries involved with titles, abstracts, keywords, and MeSH terms. Bibliographic records from their inception to 2022 were retrieved from PubMed/MEDLINE (n=206), EMBASE (n=101), and ACM Digital Library (n=377), followed by eligibility screening and literature review. The eligibility criteria include empirical studies that 1) developed and/or tested AI methods, 2) developed and/or tested CDSS or CDSS components, and 3) focused on pregnancy care. Data of studies used for review and appraisal include title, abstract, keywords, MeSH terms, full text, and supplements. Publications with ancillary information and/or overlapping outcomes were synthesized as one single study. Reviewers independently reviewed and assessed the quality of selected studies.

Results: We identified 30 distinct studies out of 684 studies from their inception to 2022. Topics of clinical applications covered AI augmented CDSS from prenatal, early pregnancy, obstetric care, and postpartum care. Topics of CDSS functions include diagnostic support, clinical prediction, therapeutics recommendation, and knowledge base.

Conclusions: Our review acknowledged recent advances in CDSS studies including early diagnosis of prenatal abnormalities, cost effective surveillance, prenatal ultrasound support, and ontology development. To recommend for future directions, we also noted key gaps from existing studies, including 1) decision support in current childbirth deliveries without using observational data from consequential fetal/maternal outcomes in future pregnancies; 2) scarcity of studies in identifying several high-profile biases from CDSS, including social determinants of health (SDOH) highlighted by the American College of Obstetricians and Gynecologists; and 3) chasm between internally validated CDSS models, external validity, and clinical implementation. Clinical Trial: This study is registered with International Prospective Register of Systematic Reviews (PROSPERO) on 09/05/2023. The registration number is #460907.

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Artificial intelligence augmented clinical decision support systems for pregnancy care: a systematic review

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Keywords: artificial intelligence, biomedical ontologies, clinical decision support systems, implementation science, obstetrics, pregnancy

Conflict of Interest and Financial Disclosure Statements:

Authors disclose no conflict of interest and financial conflict of interest.

PROSPERO registration:

This study is registered with International Prospective Register of Systematic Reviews (PROSPERO) on 09/05/2023. The registration number is #460907.

1 Introduction

In the United States, maternal and newborn outcomes (e.g., maternal and newborn mortality, preterm birth, low birth weight, congenital abnormalities, maternal pregnancy complications) are worse than any other developed nations, where most pregnancy-related mortalities were preventable. [1] Severe maternal mortality and mortality (SMMM) has led to significant short- or long-term consequences impacting not only pregnant individuals but also their families. [2] Across the health care system in the nation, there remains limited numbers of pregnant individuals who have access to evidence-based, comprehensive, and continuous maternity care. [1] Maternity providers often experience insufficient information and limited guidelines to inform clinical decisions, in part because studies conducted in small sample sizes and pregnant and lactating individuals are generally excluded from clinical trials. [3]

To address the chasm, clinical decision support system (CDSS) has broad application in pregnancy care. In the clinical practice guideline provided by the American College of Obstetricians and Gynecologists (ACOG), the role of CDSS was described along the pathway of patient management and was increasingly exposed within the emerging clinical information systems such as electronic health records (EHR). [4] Because pregnancy care often is characterized by multi-modal (e.g., clinical findings, medical imaging, non-invasive prenatal testing, genomics), multi-specialty data (e.g., obstetrics, maternal-fetal medicine, gynecology, reproductive endocrinology and infertility, neonatology), and complex episodes (i.e., from preconception, conception, prenatal, intrapartum, to postpartum), precise and timely clinical decision support requires very high level of EHR interoperability and clinical validity. Within the context of this article, pregnancy care is defined as the health care for mothers and fetus (or newborn) before, during, and after the pregnancy. In addition to improving patient care management, CDSS also plays a critical role in supporting evidence-based medicine and the pathway towards a learning health system, in which CDS bridges the gap between the increasingly available digital data and much demanded actionable knowledge for therapeutics and patient care. [5,6]

Recent evolution of artificial intelligence (AI) and biomedical informatics has led to new frontiers in clinical and translational medicine. Within the scope of this study, we refer the definition of AI in healthcare broadly as the methods and applications that create computer systems capable of activities normally associated with cognitive effort during healthcare. [7] In the field of CDSS, the application of AI has become increasingly prominent in augmenting knowledge discovery, diagnostics support, risk prediction and alarming, chronic disease management, patient monitoring, to name a few. [8] In pregnancy care, emerging research has been exploring how AI augmented CDSS would help improve clinical workflow and patient management. However, with the vast number of clinical guidelines, diverse AI techniques, and different EHR systems and functional modules, the spectrum of capacities and characteristics that such AI augmented CDSS would further improve pregnancy care remains unclear. Increasing numbers of AI studies in obstetrics and gynaecology have been documented. [9–11] However, reviews on how AI augmented CDSS were specialized in pregnancy care have been missing.

A systematic review if desperately needed to fill several gaps in the literature. First, maternal health decisions are preference-sensitive and have been based on limited evidence-based guidelines. Such characteristics require the CDSS to be designed taken into account both the existing clinical guidelines, carefully selected clinical data, and shared patient consent/preference data. The dynamic of these CDSS designing features appears differently in specific episodes and sub-specialty of pregnancy care, which needs to be reviewed systematically yet no existing reviews have achieved this goal. Second, recent AI applications on CDSS for pregnancy care appear to be different from those from one decade ago. Although the concept of AI remains loosely defined, a systematic review is desired to update the state-of-the-art AI methodologies applied to pregnancy related CDSS as well as to provide a timely comparative evaluation against those historical AI technologies. Third, existing literature reviews of either AI applications or CDSS in the field of pregnancy care typically focus on evaluation of various AI methods and the performance of a model (e.g., prediction, classification, information retrieval). No studies have evaluated model performance together with implementation assessment outcomes of the CDSS in real-world settings, which has been a missing perspective of external validity of CDSS studies.

The objective of this study is to provide a systematic review of empirical studies that examined AI augmented CDSS in pregnancy care and inform challenges and opportunities with respect to how findings from these emerging studies would improve pregnancy care using the framework of participants, interventions, comparisons, outcomes, and study design (PICOS) as reference. Specifically, we sought to 1) identify specific maternal care domains where AI augmented CDSS plays a role, 2) characterize current state of CDSS functions, 3) identify limitations, challenges, and future opportunities.

2 Methods

The literature review follows the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). [12] The PRISMA Checklist can be found in the Appendix A.

2.1 Bibliographic database

We searched three electronic bibliographic databases: PubMed/MEDLINE (including MEDLINE and PubMed Central), EMBASE, and ACM Digital Library. PubMed/MEDLINE is a bibliographic database of life sciences and biomedical topics established by the United States National Library of Medicine (NLM) at the National Institutes of Health (NIH) in 1996. PubMed Central was launched in 2000 as a digital counterpart to NLM extensive print full-text journal collection of biomedical and life sciences. Some PMC journals are cross-indexed as MEDLINE journals. EMBASE is a bibliographic database focused on pharmacovigilance. The ACM Digital Library is a comprehensive database of full-text articles and bibliographic literature covering computing and information technology, including biomedical informatics and digital health. Licenses for accessing EMBASE and ACM Digital Library are obtained by the University of South Carolina.

2.2 Search strategy

In PubMed/MEDLINE database, we searched string in the field of “text word”, which includes “title, abstract, other abstract, MeSH terms, MeSH Subheadings, Publication Types, Substance Names, Personal Name as Subject, Corporate Author, Secondary Source, Comment/Correction Notes, and Other Terms”. To supply topics mis-captured or were not precisely captured by “text word”, we also searched string in [MeSH Major Topic]. We adjusted the search strategy used for PubMed/MEDLINE in EMBASE and ACM Digital Library, respectively. We modified the search fields for EMBASE and ACM Digital Library because MeSH is only used in PubMed/MEDLINE and other fields vary in the three bibliographic databases. For all databases, the time of publications was constrained to be including and before 2022. No language restrictions were applied. The search strings mainly incorporated pregnancy procedures, pregnancy outcomes, CDSS models, CDSS methods, and AI methodologies. See Appendix B for search strings and criteria. All electronic reference database searches were completed in January 2023. The search strategy was developed by two authors (CL and TL) with consolidated suggestions received from other authors. The search was performed by NG.

2.3 Assessment of eligibility and biases

One author (NG) removed duplicates when comparing results from each database. In this process, PMID, titles, publications, and authors are used to identify unique publications. To perform eligibility assessment, we used the following inclusion criteria: empirical studies that 1) developed and/or tested AI methods, 2) developed and/or tested CDSS or CDSS components, 3) focused on pregnancy care. Quality and biases of studies were assessed based several criteria adopted from the Risk of Bias 2 (RoB 2) tool [13], which include 1) whether an empirical study, 2) concentration of "pregnancy care", "CDSS", and "AI" in the study, and 3) completeness, clarify, and validity of methods, results, and conclusion as reported in the publications. Full-text manuscripts of potentially relevant studies were reviewed for final inclusion. Following these criteria, two reviewers (TL and NG) independently inspected the candidate publications for inclusion and quality. Discrepancies between the two reviewers were resolved through discussion with a senior reviewer (CL) and then, corrected and finalized. Finally, there were 30 studies selected for review. See Figure 1 for study selection process.

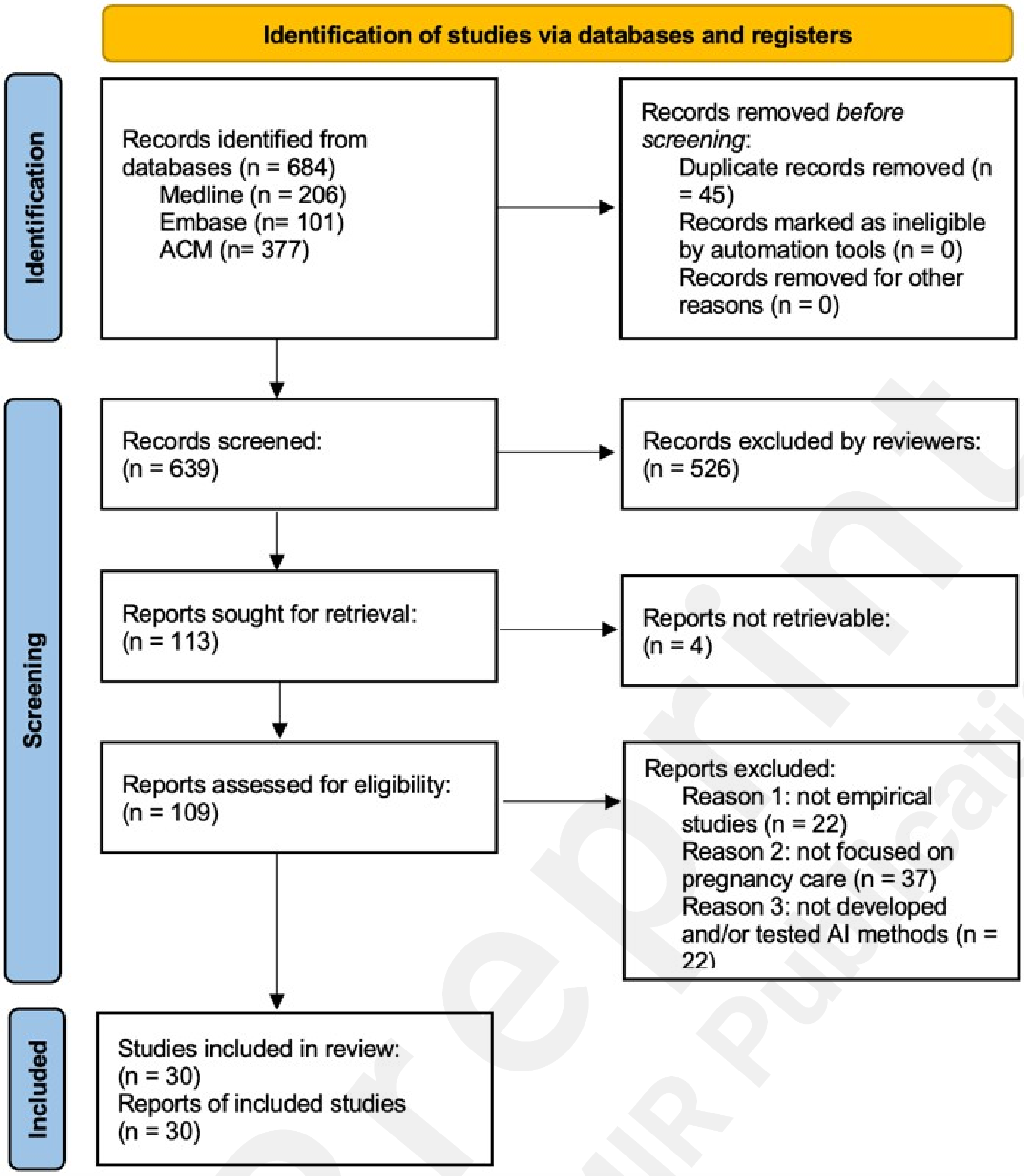

Figure 1. PRISMA flow chart.

2.4 Data synthesis

When authors reported ancillary information (e.g., pilot study), and/or overlapping outcomes of a study reported from different publications, we grouped such publications as one single unit of publications. Two independent coders (CL and TL) extracted the following study information: authors and year, study objectives, pregnancy care applications, CDSS functionality, data source, study population, AI methods, CDSS performance, validation, and implementation. Pregnancy care applications included three categories: prenatal and early pregnancy care, obstetrical care, and postpartum care. In the context of this review, obstetrical complications include maternal (e.g., perinatal hemorrhage, ectopic pregnancy, eclampsia, gestational diabetes), fetal (e.g., miscarriage, stillbirth, preterm birth), and neonatal (e.g., bradycardia, tachyarrhythmia) adverse events. In the context of this review, obstetrical complications include maternal (e.g., perinatal hemorrhage, ectopic pregnancy, eclampsia, gestational diabetes), fetal (e.g., miscarriage, stillbirth, preterm birth), and neonatal (e.g., bradycardia, tachyarrhythmia) adverse events. Of note, these three categories are not mutually exclusive. With respect to CDSS functionality, the definition of clinical prediction refers to prediction of adverse clinical events, outcomes, prognosis; and identification of at-risk individuals with adverse events. With respect to types of validation, internal validation refers to the process of validating the performance of CDSS models inside the context of the study, by which the context of the study means model training set and testing set are partitioned from the same dataset that has a high degree of homogeneity (e.g., from the same clinical site, same patient cohort). Internal validation emphasizes on validity of model accuracy as well as the sample size. External validation refers to the process of validating the performance of CDSS outside the context of the study, which empathizes on the generalizability of the internally validated CDSS to and across other contexts (e.g., clinical sites, patient cohorts, times, data quality).

3 Results

3.1 Study selection and synthesis of results

We included 206 studies from PubMed/MEDLINE, 101 studies from EMBASE, and 377 studies from ACM Digital Library. Removal of studies hit by exclusion criteria and duplicates resulted in 30 distinct studies that met the eligibility criteria (Figure 1). We analyzed the 30 studies and characterized findings into structured themes, summarized in Table 1. Over time, the number of relevant studies has increased except for a dip in 2013-2014 (Figure 2).

Table 1. Summary of reviewed studies.

Study	Study objectives	CDSS functions	Data source	Sample	AI methods	Performance	Validation	Implementation
Woolery et al. (1994) [14]	Expert system for preterm birth risk assessment.	Risk prediction	Registry (multiple sites, USA)	18,890 cases	Expert system, machine learning	ACC 53-88%	External	No
Mongelli et al. (1997) [15]	Develop an expert system for the interpretation of fetal scalp acid-base status.	Risk prediction	Scalp blood samples (single, England)	2,174 samples	Logistic transformations, back-propagation networks, decision tree	NA	Internal	No
Goodwin et al. (2000) [16]	Predict preterm birth.	Risk prediction	EHR (single, USA)	19,970 patients	Rule induction, logistic regression, neural network	Customized (AUC 0.75)	Internal	No
Catley et al. (2006) [17]	Obstetrical outcome estimations in low-risk maternal populations	Risk prediction	Registry (37 sites, Canada)	48,000 cases	ANN	ROC 0.73	Internal	No
Mueller et al. (2006) [18]	Identify predictors to optimize extubation decisions for premature infants.	Risk prediction	EHR (single, USA)	183 infants	ANN, multiple layer regression	AUC >0.9	Internal	Yes
Gorthi et al. (2009) [19]	Predict pregnancy risk based on patterns from clinical parameters.	Risk prediction	Synthetic Cases	200 cases	Decision tree	ACC 82.5	Internal	No
Ocak (2013) [20]	Assess fetal well-being.	Risk prediction	Cardiotocogram (single, USA)	1,831 samples	SVM	ACC 99.3%	Internal	No
Yılmaz et al. (2013) [21]	Determine the fetal state using cardiotocogram data.	Risk prediction	Cardiotocogram (single, USA)	2,126 samples	LS-SVM	ACC 91.62%	Internal	No

Spilka et al. (2014) [22]	Examine cardiotocogram and support decision making. (outcomes: diagnostics and risk)	Diagnostic support	Cardiotocogram (single, USA)	634 samples	Latent class analysis	NA	Internal	No
Jiménez-Serrano et al. (2015) [23]	Detect the postpartum depression during 1st week after childbirth. Towards a mobile health app.	Risk prediction	Registry (7 sites, Spain)	1,880 women	Logistic regression, naïve bayes, SVM, ANN	ANN (ACC 0.79)	Internal	Conceptual
Ravindran et al. (2015) [24]	Assess fetal well-being.	Risk prediction	Cardiotocogram (single, USA)	2,126 samples	Ensemble: k-NN, SVM, Bayesian network, and ELM	ACC 93.61%	External	No
Paydar et al. (2017) [25]	Predict pregnancy outcomes among systemic lupus erythematosus-affected pregnant women.	Risk prediction	EHR (single, Iran)	149 pregnant women	MLP, RBF	MLP (ACC 0.91)	Internal	Conceptual
Dhombres et al. (2017) [26]	Develop a knowledge base for ectopic pregnancy	Knowledge representation	Ultrasound (single, England)	4,260 records	Ontology, NLP	Precision 0.83	Internal	No
Maurice et al. (2017) [26]	Develop a new knowledge base intelligent system for ultrasound imaging.	Knowledge representation	PubMed (single, UK)	NA	Ontology, NLP	F 0.71	Internal	No
Fergus et al. (2018) [27]	Classify caesarean section and vaginal delivery.	Risk prediction	Registry (single, Czechia)	552 pregnancies	Ensemble: RF, SVM, decision tree, ANN, deferred acceptance	Ensemble (AUC 0.96)	Internal	No
Seitinger et al. (2018) [28]	Arden Syntax as medical knowledge representation and processing language in obstetrics.	Knowledge representation	NA	NA	Arden syntax	NA	NA	No
De Ramón Fernández et al. (2019) [29]	Develop a decision support system to make suggestions of early treatment for ectopic pregnancy.	Treatment recommendation	EHR (single, Spain)	406 tubal ectopic pregnancies	Multilayer perception, decision rule, SVM, naïve bayes	SVM (ACC 0.96)	Internal	No
Wang et al. (2019) [30]	Develop a postpartum depression prediction model using EHR.	Risk prediction	EHR (single, USA)	17, 9,980 pregnancies	Logistic regression, SVM, decision tree, naïve bayes,	SVM (AUC 0.79)	Internal	No

					XGB, RF			
Liu et al. (2019) [31]	Predict pregnancies.	Diagnostic support	Mobile app	65276 women	Logistic regression, LSTM	AUC 0.67	External	No
Ye et al. (2020) [32]	Predict GDM and compare their performance with that of logistic regressions.	Risk prediction	EHR (single, China)	22,242 singlet pregnancies	Gradient Boosting Decision Tree, AdaBoost, LightGBM, logistic regression, voting, XGB, decision tree, RF, logistic regression *	GBDT (AUC 0.74, 95% CI 0.71-0.76)	Internal	No
Torres Silva et al. (2020) [33]	Develop readable and minimal syntax for a web CDSS for antenatal care guidelines.	Knowledge representation	NA	NA	Ontology	NA	No	No
Venkatesh et al. (2021)[34]	Predict the risk of postpartum hemorrhage at labor admission.	Risk prediction	EHR (Consortium on Safe Labor, USA)	228,438 deliveries	RF, XGB, logistic regression *, lasso regression *	XGB (C statistic0.93; 95% CI: 0.92-0.93)	External (multi-site, multi-time)	No
Tissot et al. (2021)[35]	Test embedding strategies in performing risk assessment of miscarriage before/during pregnancy.	Risk prediction	EHR (InfoSaude, Brazil)	4,676 pregnancies	Machine learning, ontology embedding	KRAL (F 0.76)	Internal	No
Escobar et al. (2021)[36]	Predict risk of maternal, fetal, and neonatal events.	Risk prediction	EHR (15 sites, USA)	303,678 deliveries	Gradient boosted, logistic regression *	Gradient boosted (AUC 0.786)	External	No
Tao et al. (2021) [37]	Construct a hybrid birth weight predicting classifier.	Risk prediction	EHR (single, China)	5,759 pregnant women	LSTM, CNN, RF, SVM, BPNN, logistic regression	Hybrid LSTM (MRE 5.65 ± 0.4)	Internal	No
Mooney et al. (2021) [38]	Examine RF to predict the occurrence of Hypoxic Ischemic Encephalopathy	Risk prediction	Registry (2 sites, Sweden)	53,000 deliveries	RF	RF (MCC 0.63)	Internal	No
Du et al.	Predict gestational diabetes	Risk	Registry	565	XBG, AdaBoost,	SVM	Internal	No

(2022) [39]	mellitus.	prediction	(single, Ireland)	women	SVM, RF, logistic regression	(AUC 0.79)		
Schmidt et al. (2022) [40]	Predict adverse outcomes in patients with suspected preeclampsia	Risk prediction	Ultrasound (single, Germany)	1,647 patients	Gradient Boosting Decision Tree, RF	GBTree (AUC 0.81)	Internal	No
De Ramón Fernández et al. (2022) [41]	Predict mode of delivery: caesarean section, eutocia vaginal delivery, instrumental vaginal delivery.	Risk prediction	Registry (single, Spain)	10,565 records	MLP, RF, SVM	ACC >90	Internal	No
Hershey et al. (2022) [42]	Predict spontaneous preterm birth.	Risk prediction	surveys, biospecimen (10 centers)	2,390 women	SVM	AUC 0.75	Internal	No

Underline: indicates outcomes of a CDSS model
* Benchmark algorithm
ACC: accuracy
AI: artificial intelligence
ANN: artificial neural network
AUC: area under the receiver operating characteristic
BN: batch normalization
BPNN: back propagation neural network
CDSS: clinical decision support system
CNN: convolutional neural network
EHR: electronic health records
ELM: extreme learning machines
KRAL: knowledge representation & artificial learning framework
k-NN: k-nearest neighbors
LightGBM: light gradient boosting
LS-SVM: least-squares support vector machine
LSTM: long-short term memory
MCC: Matthew's correlation coefficient
MRE: mean relative error
MLP: multilayer perceptron neural network
NLP: natural language processing
RBF: radial basis functions neural network
RF: random forest
SVM: support vector machine
XGB: XGBoost

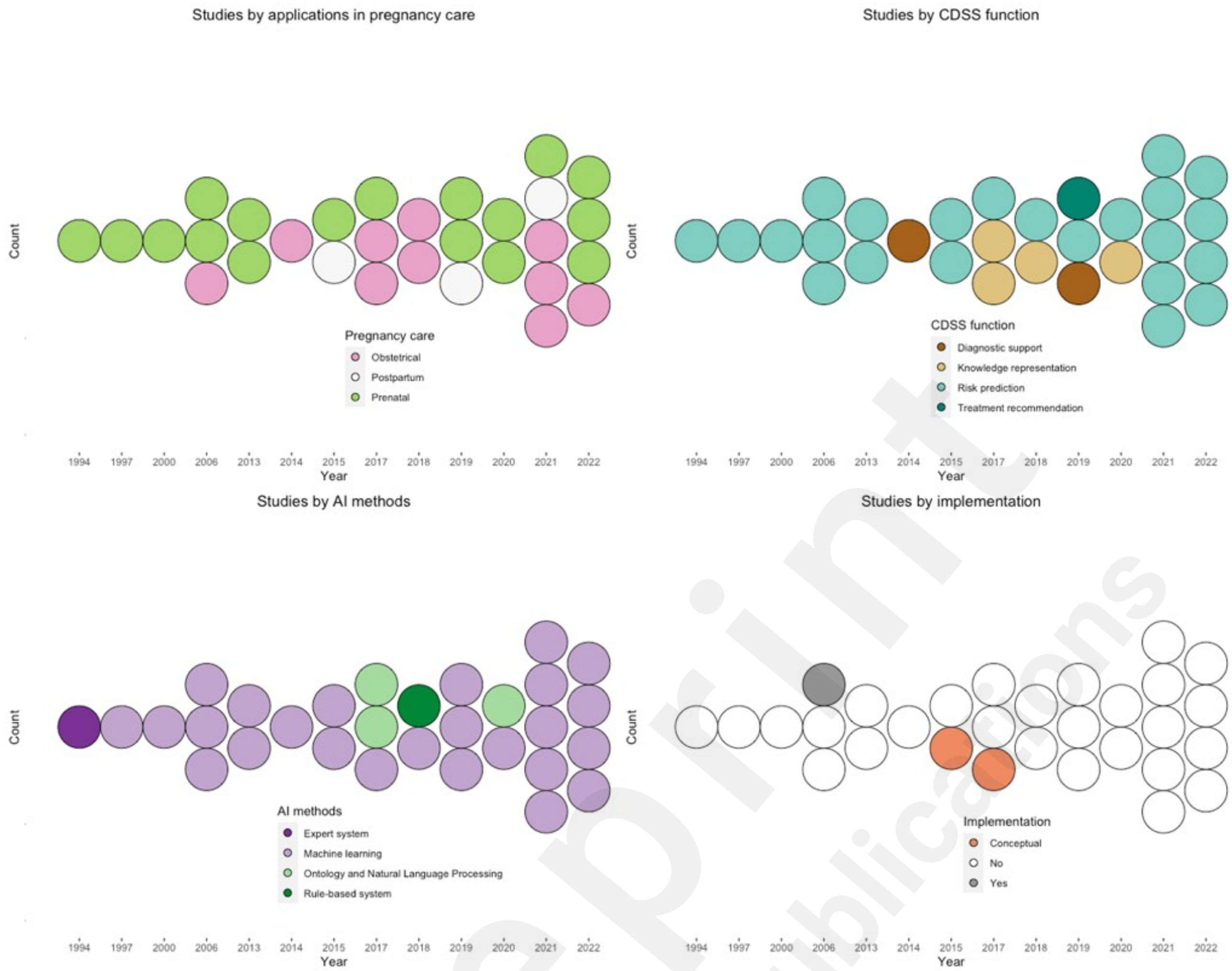

Figure 2. Trends in reviewed studies. Top-left: trends in studies by applications in pregnancy care. Top-right: trends in studies by Clinical Decision Support System function. Bottom-left: trends in studies by Artificial Intelligence methods. Bottom-right: trends in studies by implementation.

3.2 Risk of bias of included studies

Among the 109 studies screened and retrieved, we excluded 22 studies that are not empirically based, 37 studies that pregnancy care is not the primary focus, and 22 studies that do not develop or apply AI methods even though AI related terms are widely used in the publications. This appraisal process resulted in 30 included studies that have reached a full agreement of quality between the two reviewers (TL and NG) after discussing with the third reviewer (CL). See Figure 1 for numbers of included and excluded studies from every step. Following the PRISMA guidelines for assessing the risk of bias of included studies, we summarized the assessment outcome in Figure 3.

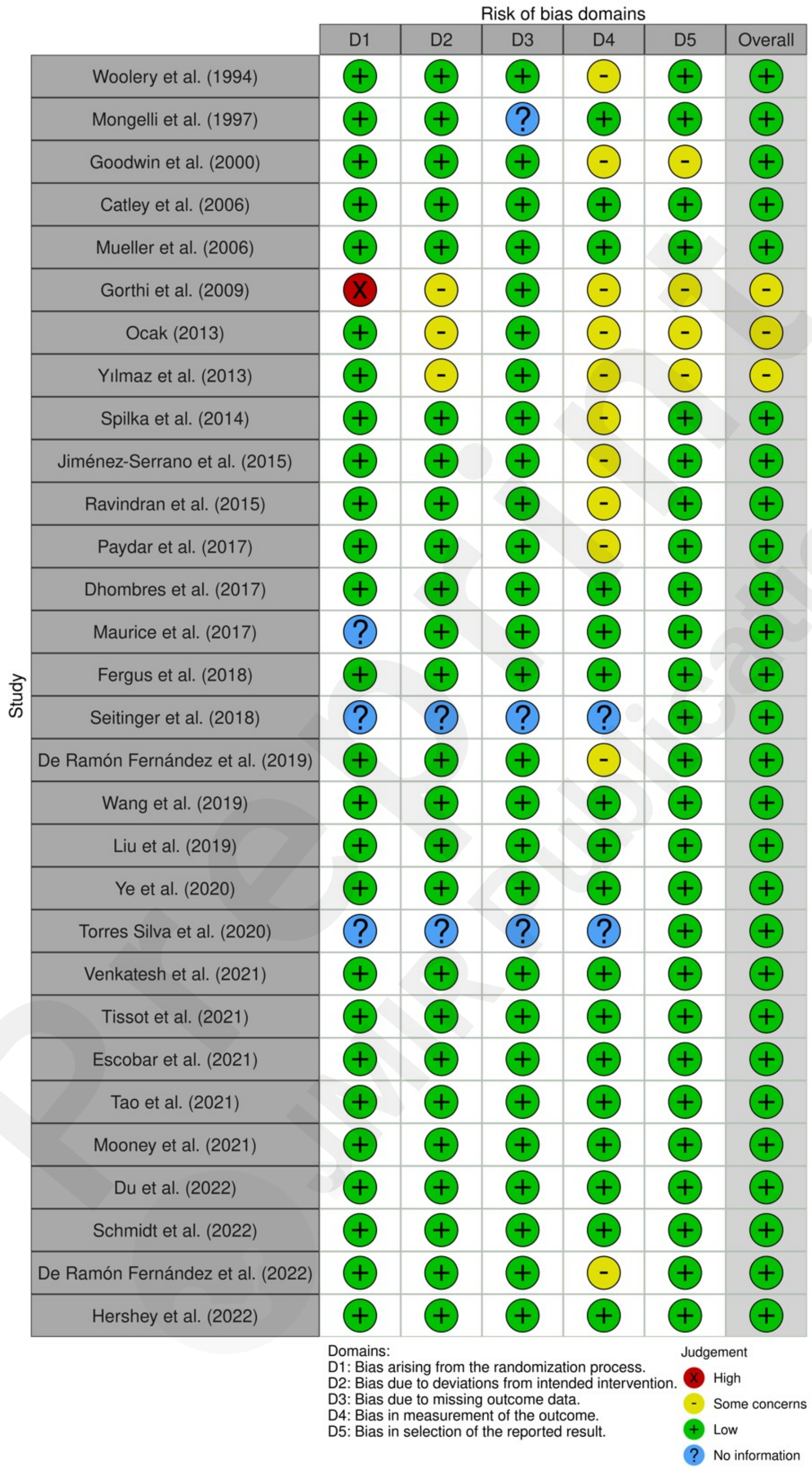

Figure 3. Traffic Light plot for risk-of-bias assessment of included studies.

3.3 Study characteristics: applications in pregnancy care

Prenatal and early pregnancy care (n=17, 56.6%). Detection of maternal and fetal risk factors and abnormalities during prenatal care is most imperative for timely prevention and intervention. Studies using CDSS include prediction of gestational diabetes mellitus [32,39],miscarriage [25,35], and adverse outcomes resulted from preeclampsia [40] using data from medical history and prenatal care visits. Another use case of CDSS has applied to ectopic pregnancy which is a highly risky condition that often leads to maternal morbidity and mortality. [29] Upon diagnosis, choosing adequate treatment is an important clinical decision process to avoid further complications. Machine-learning-based CDSS has been tested to aid providers and patients for better informed clinical decision making following ectopic pregnancy. [29]

Obstetrical care (n=10, 33.3%). As the number of delivering individuals who experience morbidity and mortality remains high and growing in the US and many countries [43], an increasing volume of CDSS studies have been focusing on developing predictive models for early detection of adverse events and among at-risk individuals to be used for timely prevention and intervention. For example, identification of individuals with risks of preterm birth can inform advanced medical care planning at prenatal and perinatal stage. [14,17,42] These studies generally included analyses of risk factors contributing to adverse events, in which machine-learning based studies relies on feature ranking methods for identification of data highly suggestive of adverse outcomes. Another example is computer assisted cardiotocography (CTG) trace interpretation to be used before and/or at labor and delivery for assisting decision making. [22,27,44]

Postpartum care (n=3, 30.0%). CDSS has been used for estimating the risk of postpartum hemorrhage at labor and delivery admission. Postpartum hemorrhage has been a major source of maternal morbidity and mortality, accounting for nearly one third of deaths of birthing individuals. [45] Risk estimation used at clinical practice has been based on stratification of risk factors documented in individuals' medical records using parametric statistic models. In recent CDSS studies researchers have attempted to incorporate nuances beyond known risk factors [34], which may better interpret individual variance, reduce possible biases from traditional guidelines and theoretical frameworks. Another example is risk assessment and screening of postpartum depression, which is a prevalent postpartum disorder but is often underdiagnosed. [23,30]

3.4 Study characteristics: functionality of clinical decision support systems

Diagnostic support (n=2, 6.6%). Diagnostic support is a classic function known since early-stage CDSS. [46] In pregnancy care, this function has been used to assist the interpretation of CTG. [22,27,44] Because CTG interpretation is known to be challenging due to a great inter-reviewer variability; and accurate interpretation of CTG is important for making proper clinical decisions during prenatal care and at labor and delivery (e.g., cesarean vs. vaginal delivery). Diagnostic support has also been applied for identification of pregnancy using data collected from mobile device [31], which may have value for family planning and preventive care.

Clinical risk prediction (n=22, 73.3%). Clinical prediction as a CDSS function was not prevalent at the inception of CDSS and has started to emerge in pregnancy care recently. In pregnancy care, risk prediction tools were broadly used for early detection of adverse maternal and fetal events. Such CDSS applications have been centered around making prediction of adverse events that may benefit from early detection of abnormalities for timely prevention and intervention, such as eclampsia/preeclampsia [36,40], gestational diabetes [32,39], preterm birth [14,17], miscarriage [25,35], perinatal hemorrhage [34,36,40], hypoxic ischemic encephalopathy [38], low birth weight [37], and postpartum depression. [23,30] EHR and medical images were often used for training predictive models. A few studies used data from mobile applications. [23,31]

Therapeutics recommendation (n=2, 6.6%). Mode of delivery is one of the critical clinical decisions to make during obstetric care. Over the last decades, cesarean delivery has been increasing and was found to be associated with increased adverse fetal outcomes as well as adverse maternal outcomes in subsequential childbirth deliveries. [47] CDSS studies have tested the feasibility of using machine learning to make suggestions out of three delivery modes: caesarean section, eutocic vaginal delivery, and instrumental vaginal delivery. [41]

Knowledge base (n=4, 13.3%). CDSS can be categorized as those built on top of knowledge base and those independent to a knowledge base. Several studies reported design and construction of knowledge base that can underpin CDSS specialized for pregnancy care. Among these studies, forms of knowledge base include Arden syntax and ontology that have been widely used for formal representation of clinical guidelines and graph-based medical knowledge, as well as XML as a markdown language for web and mobile-based CDSS applications. Specifically, in support of diagnostics and therapeutics recommendation for ectopic pregnancy, ontology has been used for supporting annotation of medical images (e.g., ultrasound images for obstetrics). [26,48] Arden syntax was used to formalize obstetric clinical guidelines into a knowledge base that supports CDSS functions for obstetrics. [28] XML was used for encoding a knowledge base that underpins mobile app-based CDSS for prenatal care. [33]

3.5 Study characteristics: Artificial Intelligence methodologies and applications

Algorithms. Knowledge base independent CDSS typically rely on computational algorithms for learning about decision boundaries, where supervised algorithms (e.g., classification, prediction, association rules learning) require human-annotated data as gold standard sample whereas unsupervised algorithms (e.g., clustering) find decision boundaries without gold standard. In our review, regression-based algorithms were widely used as benchmark algorithms for clinical prediction tools, diagnostic support, and therapeutants recommendation. Some of the studies used parametric linear statistical models as benchmark. [34] Among supervised machine learning algorithms, support vector machine (SVM), random forest, and gradient boosting algorithms (e.g., XGBoost) have been increasingly adopted and have revealed outstanding performance. Simple neural networks (e.g., multilayer perceptron, artificial neural networks) have been tested as well especially when the feature space of model is not overly large in dimensionality and complex. [17,18,29] To incorporate domain specific medical knowledge and human curated clinical guidelines into machine learning models, embedding of ontology was also used in the field of pregnancy care. [35] Additionally, there was application of deep learning algorithms (e.g., convolutional neural network and recurrent neural network) in the field which has resulted in trained models outperforming other algorithms in comparison. [37]

Knowledge base dependent CDSS typically rely on rules (e.g., if-then, fuzzy logic) or semantic relations (e.g., semantic properties defined by ontology). For example, natural language processing (NLP) tasks (e.g., named entity recognition, semantic reasoning) were applied in conjunction of ontology-based knowledge base for annotation of medical images. [26,48] Studies of rule-based algorithm application also demonstrated feasibility and robust clinical interpretability. [16] With respect to knowledge base design in these CDSS studies, ontology was commonly used to constructing a knowledge base (n=2, 6.6%). [26,48]

Performance evaluation. Majority of the studies (n=28, 93.3%) have tested internal validation at some degree. Validation frameworks used in reviewed studies included hold-out, n-fold cross-validation, and bootstrap or cross- validation. Evaluation metrics used include metrics derived from theory of information retrieval such as precision, recall, F measure, area under the receiver operating characteristics (ROC) curve [49]; metrics based on probabilistic statistics such as mean squared prediction error (MSPE), Matthew's correlation coefficient (MCC), chi-square, and c-index; metrics based on descriptive statistics such as accuracy; and customized accuracy measures. A few studies employed validation design that allowed for computing of confidence intervals [32,34], which enhanced the interpretative capability of validation. There were five studies (16%) that included external validation. [14,24,31,34,36] These studies generally tested CDSS on separate datasets, including those from different clinical sites.

Treatment with possible bias. Biases in data sampling, data processing (e.g., tackling missing data, data normalization), machine model training, validation, and algorithm design could lead to deviated performance and actionable clinical decision resulted from CDSS. Arguably, because clinical decisions are driven by untrained data, ill-sampled training and validation data are seen to bias the AI augmented systems, with which CDSS could be one example yet such an issue have not been addressed in the existing studies. Without recognizing and/or understanding bias in samples, in appropriate imputation methods could also omit or amplify bias. Upon review, we did not find comprehensive treatment and discussion for remediating possible biases during the design and development of CDSS.

3.6 Study characteristics: CDSS implementation

Implementation of CDSS is the final step to incorporate research findings into routine practice. Only a few studies have discussed the conceptual ideas and/or pilot study design of clinical implementation of reported CDSS (n=3, 10.0%).[18,23,25] For implementation studies in a clinical setting, web-based data entry and graphical result presentation were developed for CDSS implementation. [18,25] One study demonstrated the interface of CDSS based on an Android system. [23] We did not see a comprehensive CDSS implementation study design (e.g., usability testing) among the reviewed studies.

4 Discussion

4.1 Principal findings

Over the last decades, we have seen proliferation of AI applications in clinical and translational medicine. However, AI augmented CDSS has not been systematically reviewed in the field of obstetrics and gynaecology. In this study, we assessed related studies by their healthcare applications, CDSS functionality, AI methodology, and clinical implementation with the goal of providing the state of the art of the studies as well as summarizing advantages, limitations, and possible future directions. Overall, we have identified 30 related studies published between 1994 and 2022 with an upward trend. There was a notable increase starting in 2021. All studies used data from EHR, registry, and mobile device, except for those focusing on developing knowledge bases for CDSS. In the field of pregnancy care, functions of existing CDSS include diagnostic support (i.e., imaging support), clinical prediction, therapeutics recommendation, and knowledge base. A list of traditional CDSS functions were not seen in the field of pregnancy care, such including patient safety [e.g., alarms for drug-drug reactions and allergies, computerized provider order entry (CPOE) support], clinical management (e.g., point-of-care alters, info button, prompts for vaccination, outreach, and referral), and administrative management (e.g., assisted medical coding, documentation). [50–52] Architectures of CDSS include both knowledge based dependent and independent, in which ontology remains a primary form for constructing a computerizable knowledge base and was often employed jointly with NLP methods (e.g., named-entity recognition, semantic reasoning). For CDSS that do not rely on a knowledge base, machine learning algorithms (primarily supervised algorithms, including simple neural networks and deep learning) were widely used for learning from empirical data and producing/replicating actionable clinical knowledge. Existing studies confirmed that machine learning, ontology, and NLP have been increasingly applied for modern CDSS in the field of pregnancy care.

4.2 Clinical implication

In review of the potentials and challenges for adopting existing AI augmented CDSS for pregnancy care, there are a few aspects. First, well performed model in individual pregnancy episodes. Existing CDSS have been designed to assist prenatal care, obstetrics, and postpartum care. Majority of the CDSS studies in prenatal care are focused on assisting the prediction of risks such as miscarriage [35], ectopic pregnancy [26,29], gestational diabetes [32,39], preterm birth [14,16,17], and severe maternal mortality and morbidity events during the prenatal episode. [40] Among predictive models of these CDSS studies, reported predictive performance is generally well. However, we noticed it is often missed interpreted in these studies with respect to how early before an adverse event a CDSS can reliably detect the risk and offer clinical decisions, which is an obvious obstacle before these CDSS models can be used for real-world practice. For obstetrics, CDSS studies have explored ways to assist making choices of delivery mode [27,41], extubating decision for preterm infants [18], and diagnostics during the birth and delivery. [22] These applications appear to have the potential to be tested, improved, and adopted in clinical setting. In postpartum care, CDSS applications have performed well on assisting postpartum hemorrhage [53] and depression risk detection. [23,30] When tested and adopted in the real-world scenario, effective data collection could be challenging because of limited patient encounters and access to mobil applications during postpartum.

Second, model interoperability. Aside from the model performance, interoperability is critically important as it determines the degree clinicians can interpret the model output and making sense of contributing factors and nuances a clinical decision is driven from. Knowledge base of CDSS is the most interpretable because any knowledge piece is traceable and can be reasoned in different semantic logics in the knowledge base. Our review has found four studies that used biomedical ontology and semantic web techniques to develop knowledge base for pregnancy risk, antenatal guidelines, ultrasound imaging, and ectopic pregnancy. [26,33,35,48] With respect to CDSS that function as predictive models, two categories were found among the reviewed studies. Parametric models, including regression models [16,18,23,30–32,36,37,39,53], decision trees [15,19,27,30,32,40], shallow neural networks [17,18,23–25,27,29,41] , and expert systems [14,15] can easily reveal decision logic, determinants of a decision as well as their odds to clinicians. Non-parametric models and deep neural networks [20,27,29,37,41,42,44] have the advantage of taking large and high-dimensional data but have limited capability of making the decision mechanism explicit for clinicians.

In addition to the performance and use-case scenario and clinical interpretability of the CDSS, we noticed that data availability and quality have been a pertinent hurdle for developing CDSS for pregnancy care. The reasons are in part unique for pregnancy care in that during prenatal care data are often generated from either hospital, outpatient obstetrics group, and outpatient laboratory, where different laboratory technologies and protocols of data entry are the norm. Different initiation time and frequency of prenatal care is another cause of unevenly collected patient data for CDSS training, in which individuals with late initiation and low frequency are generally associated with worse outcomes [54], yet this inequality is underestimated in the experimental phase of CDSS design and testing leading to possible bias when adopting CDSS for real-world practice.

4.3 Strengths, limitations, and future directions of reviewed studies

Our review has revealed several strengths of CDSS design in pregnancy care. However, because application of AI augmented CDSS in the field remains at its infancy, we also identified a handful of limitations followed by suggestions and future directions.

Towards robustness in internal validation design. Review of existing studies exhibited several strengths in study design. 1) Existing CDSS experiments were generally based on real-world EHR, registry, and mobile device data, in which several studies have used data from multiple clinical centers. [14,17,23,36,38,42] While majority of studies have sufficient sample sizes, a few studies used relatively small samples (n=100~300, see Table 1). 2) Majority of the studies (n=19 out of 26, 73%), excluding knowledge base studies, have tested multiple AI algorithms for comparison with a selected benchmark. 3) Cross validation or hold-out methods were generally used for internal validation. 4) Majority of studies measured F score (including precision and recall), area under ROC curve, and metrics derived from probabilistic statistics for model performance. A few studies used accuracy alone, which may not be sufficient for a fair performance validation. Overall, reported model performance is acceptable (see Table 1).

Clinical plausibility. 1) Majority of studies explicitly stated the clinical use scenarios for the reported CDSS, where the capability of early detection of abnormalities, at-risk pregnancies, and risk factors was generally recognized as core clinical significance of CDSS. Yet, due to the scarcity of prenatal data and difficulties of integrating longitudinal and cross-specialty medical records, early diagnosis and prediction have been limited by data. 2) Existing studies also reflected the challenges of diagnostics and therapeutics recommendations unique for pregnancy care. Such examples include interpretation of CTG and choosing delivery mode. However, medical interpretation such as CTG historically has shown great variance in inter-rater reliability, which warrants repeated evaluations for CDSS design. Additionally, there have been controversial discussions pertaining to how choice of cesarean delivery would adversely affect fetus and maternal outcomes for subsequential pregnancies.

[47] No CDSS studies have considered fetal outcomes maternal outcomes of subsequential pregnancies for choosing delivery mode in the present pregnancy, limiting the clinical value of this line of applications. With respect to clinical scenarios where AI augmented CDSS has applied, we noticed a dearth of research and testing sites in emergency care, which could be an interesting to explore in the future.

Possible biases. Use of CDSS could introduce biases on several occasions. 1) Similar to AI algorithms applied in general clinical practice, bias could be from sampling the data to be used for training and testing CDSS. 2) Racial and ethnic disparities have been well documented in a wide spectrum of maternal mortality and morbidity. [55] For example, using patients sampled from wealthy (or poor) neighborhoods to train a CDSS would introduce bias in their behavior / clinical decision prediction. To mediate, design and clinical implementation of CDSS used for pregnancy care should consider targeted populations and their social determinants of health (SDOH). ACOG has made recommendations for patient screenings to enhance the inclusion of SDOH, avoid stereotyping, acknowledge various forms of racial/ethnical discrimination, and improve clinical decision making that address SDOH. [56] However, existing studies have not included aforementioned considerations and strategies to reduce biases, which are warranted to be set as future directions.

External validation and implementation. Despite brief discussions around conceptual ideas, external validation and implementation were rare in the reviewed CDSS studies. Without external validation, clinical usability of these CDSS when generalized to different patient cohorts, health care systems, and times remains undertested. Challenges for external validation and implementation include substandard interoperability of CDSS models and clinical information systems where a CDSS could be implemented with. Additionally, the implementation of CDSS would require organizational commitment, localized workflow, usability testing, and staff training to be successful. [57] Because of the proliferation of machine learning for CDSS, generalizability of machine learning models has become a new challenge. Future directions are suggested to address these identified knowledge gaps and challenges.

4.3 Limitations of the study

Our review has limitations. Our search strategy is mainly based in keywords and MeSH terms, which may not be comprehensive for capturing CDSS studies that did not explicitly use CDSS related terminologies. Because the notion of CDSS is often loosely defined, we recognize it as a limitation to eligibility criteria in this review. Despite limitations, our results are timely and pertinent which could be used to guide evidence-based clinical practice and future directions for CDSS studies in the field of pregnancy care. This review study also adheres to the PRISMA guidelines and employed two independent reviewers for article selection and evaluation.

4.4 Conclusion

This review summarized state of the art AI-augmented CDSS methods and applications in the field of pregnancy care. This review highlights the proliferation of machine learning-based clinical predictive models and computer aided diagnostics and therapeutics with acceptable internal validity tested. Recent advances in this line of research include 1) CDSS design targeted for early diagnosis of prenatal abnormalities and early detection of at-risk pregnancies for timely prevention and intervention; 2) challenging medical image interpretation and decision making that could use assistance of CDSS; and 3) several knowledge bases needed for specific domains of pregnancy care including, but not limited to, image annotation, adverse events, and clinical guidelines. Future directions are suggested to address possible biases introduced by using AI and CDSS, comprehensive study on external validity and clinical implementation, and continued improvement of clinical plausibility of CDSS.

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Supplementary Files

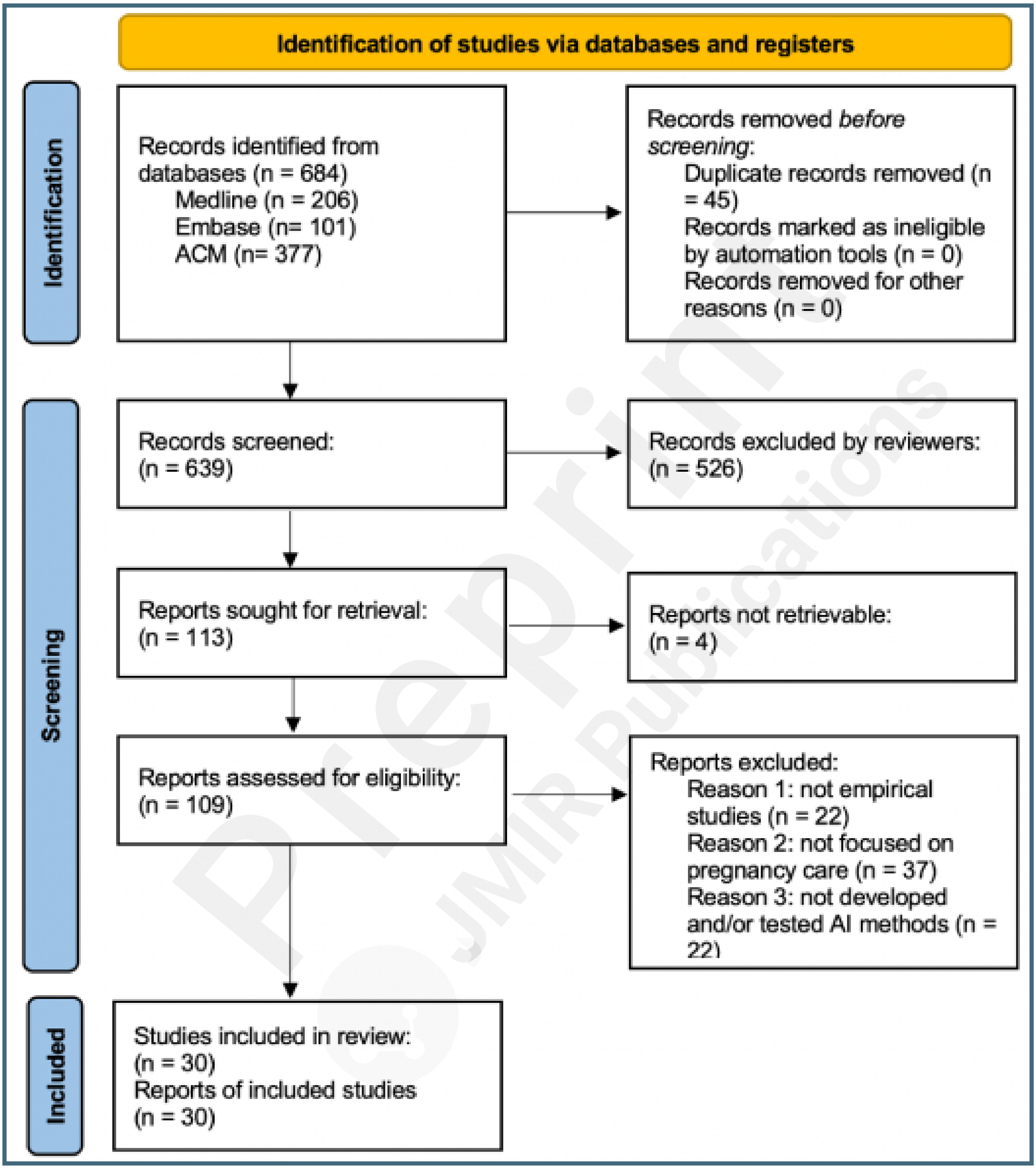
cover letter.
URL: http://asset.jmir.pub/assets/d12151a9f1dc5819af11de7f1fd9c658.pdf

Appendix A ISSM_PRISMA_Checklist.
URL: http://asset.jmir.pub/assets/b894f50682e272ccc12b1e20b1084dcb.pdf

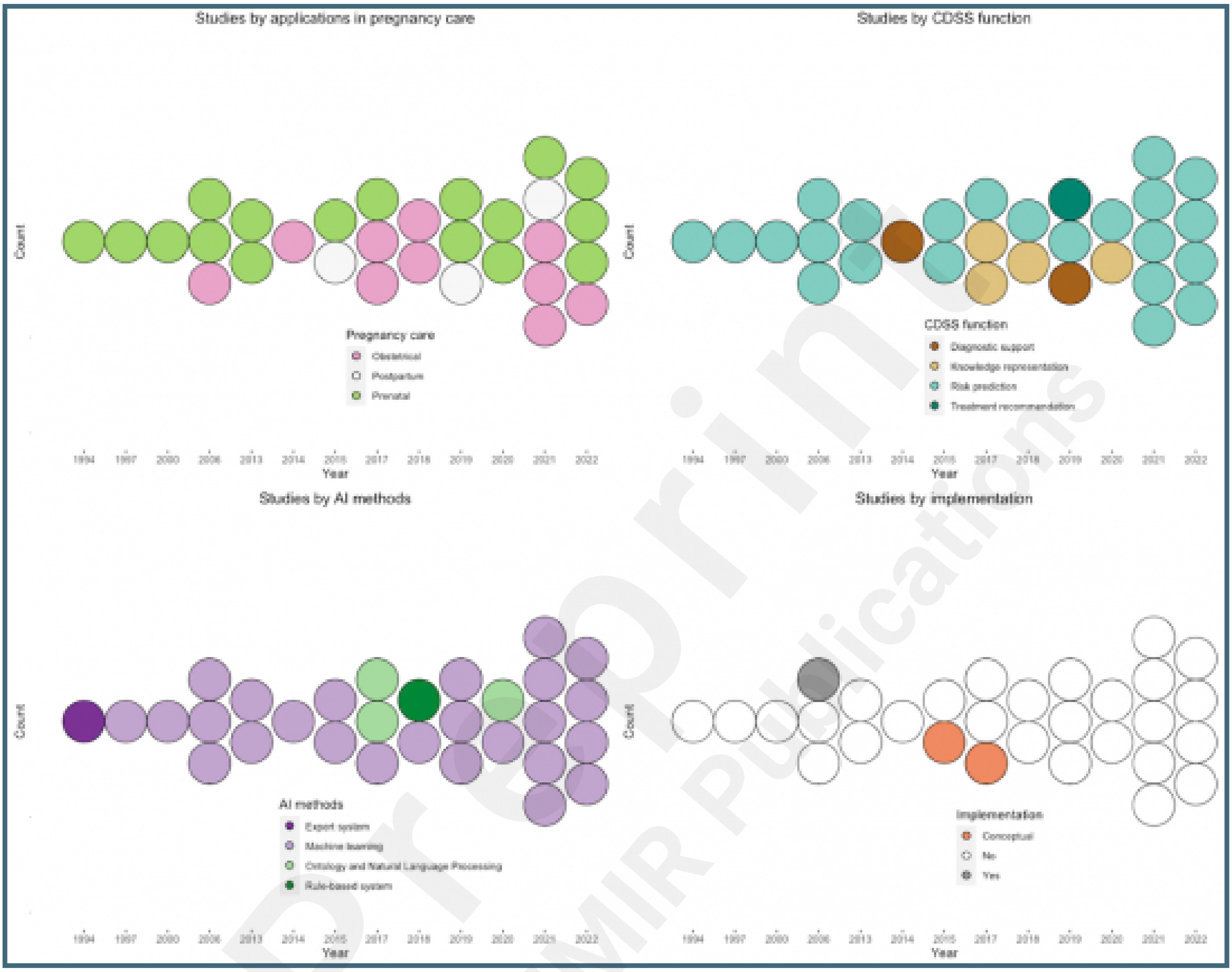
Appendix B search strings.
URL: http://asset.jmir.pub/assets/8fb2c6a4fad918e09944f310cb3fcc18.docx

Figures

PRISMA flow chart.



Trends in reviewed studies. Top-left: trends in studies by applications in pregnancy care. Top-right: trends in studies by Clinical Decision Support System function. Bottom-left: trends in studies by Artificial Intelligence methods. Bottom-right: trends in studies by implementation.



Traffic Light plot for risk-of-bias assessment of included studies.