

REVIEW ARTICLE

mHealth apps for gestational diabetes mellitus that provide clinical decision support or artificial intelligence: A scoping review

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Abstract

Aims: Gestational diabetes (GDM) is the most common metabolic disorder of pregnancy, requiring complex management and empowerment of those affected. Mobile health (mHealth) applications (apps) are proposed for streamlining healthcare service delivery, extending care relationships into the community, and empowering those affected by prolonged medical disorders to be equal collaborators in their healthcare. This review investigates mHealth apps intended for use with GDM; specifically those powered by artificial intelligence (AI) or providing decision support.

Methods: A scoping review using the novel *Survey Tool approach for collaborative literature Reviews* (STaR) process was performed.

Results: From 18 papers, 11 discrete GDM-based mHealth apps were identified, but only 3 were reasonably mature with only one currently in use in a clinical setting. Two-thirds of the apps provided condition-relevant contextual user feedback that could aid in patient self care. However, although each app targeted one or more components of the GDM clinical pathway, no app addressed the entirety from diagnosis to postpartum.

Conclusions: There are limited mHealth apps for GDM that incorporate AI or AI-based decision support. Many exist only to record patient information like blood glucose readings or diet, provide generic patient education or advice, or to reduce adverse events by providing medication or appointment alerts. Significant barriers remain that continue to limit the adoption of mHealth apps in clinical care settings. Further research and development are needed to deliver intelligent holistic mHealth apps using AI that can truly reduce healthcare resource use and improve outcomes by enabling patient self care in the community.

Graham A. Hitman and Scott McLachlan are Joint senior authors.

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KEYWORDS

apps, artificial intelligence, clinical decision system support, gestational diabetes, mHealth, scoping review

1 | INTRODUCTION

Gestational diabetes mellitus (GDM) is defined as any degree of glucose intolerance with the onset or first recognition during pregnancy and resolving post-partum; globally, it is the most common metabolic disorder of pregnancy, occurring in 2%–25% of pregnancies.¹ The highest prevalence of GDM is in the eastern and southern Asian communities.¹ GDM is typically diagnosed by an Oral Glucose Tolerance Test; however, inconsistencies exist in diagnostic and treatment thresholds both nationally and internationally. Typically, the onset of GDM is either late in the second or early in the third trimester.¹ Risk factors for GDM include obesity, a previous large baby or GDM, a family history of diabetes, ethnic minorities and increasing maternal age.¹ Women with GDM have increased risks of hypertensive disorders of pregnancy, cholestasis and obstructed vaginal delivery due to shoulder dystocia and/or macrosomia. For the neonate, there is an increased chance of hypoglycaemia and development of type 2 diabetes (T2D) in later life.¹ Furthermore, women diagnosed with GDM have an increased susceptibility in later life to subsequent T2D and cardiovascular disease.¹

GDM is usually managed in a secondary hospital clinic setting with multidisciplinary input from diabetologists, obstetricians, specialist midwives and dieticians. Women often face long clinic waiting times and multiple clinician contacts frequently at 2-weekly intervals. Many women with GDM report increased anxiety associated with their pregnancy.² Furthermore, there is a need to tailor approaches to the management of GDM directed to the affected woman and their family combined with a flexible approach by the health-care providers. There are many national and international guidelines to help manage GDM. For some women, attention to diet and/or exercise are sufficient to manage the condition and can be partly managed in a community setting depending on the care-providers clinical guideline. However, many women require metformin and/or insulin, or are at higher obstetric risk, in which case they are managed in secondary care. Women with GDM, must monitor blood glucose levels up to four times each day but frequently wait for the next clinic visit before making changes to diabetes care. The complexities of care for optimal management of women with GDM, make it difficult for them and their treating clinicians to reason the best approach for treatment¹ and places considerable demand on secondary care resources.

What's new?

- The management of gestational diabetes (GDM) requires a complex clinical pathway involving multidisciplinary diabetes and obstetric teams.
- Only 11 GDM-related mobile Health (mHealth) applications (apps) were identified that use a clinical decision system support or artificial intelligence but only 3 were reasonably mature. All apps only addressed a limited part of the pathway; one is approved for clinical use.
- Further research and development is needed to deliver intelligent holistic mHealth apps that can truly reduce healthcare resource use and improve outcomes by enabling women with GDM self care in the community.

Smartphone applications (apps) are one technological approach increasingly promoted to support patient self management and enhance communication between clinicians and women with GDM in community and secondary care settings. Defined by the Global Observatory for eHealth (GOe)³ as the use of mobile and wireless technologies to support achievement of health objectives, mHealth includes the use of mobile phones, smartphones and wearable patient monitoring devices. Currently, there are more than 300,000 mobile health (mHealth) apps available for a broad range of medical disorders.⁴ The majority of mHealth apps only provide medication and appointment reminders and collect patient data.^{5–7} However, with technological solutions like artificial intelligence (AI) and the use of large data sets to identify new knowledge there is the potential to significantly impact many intractable medical problems. Although AI has traditionally been the domain of powerful mainframes and datacentres, new approaches are capable of placing the power of AI directly in the hands of patients.⁸ AI-based mHealth apps are capable of streamlining healthcare, empowering persons with chronic or short-term medical disorders and reducing health service costs, which is also relevant to GDM.⁹

The purpose of clinical decision system support (CDSS) is to enhance clinician-made decisions and to empower people with conditions affecting their care. CDSS can be classified into two types, knowledge based, and

non-knowledge based; in the former, the rules are programmed into the system, and in the latter, an algorithm is used to model the decision as well as the data available and can make use of a person's electronic patient record.¹⁰ Furthermore, in a non-knowledge-based system, the decision uses AI, machine learning (ML) or statistical pattern recognition rather than solely relying on a clinical guideline such as a NICE pathway. For a complex clinical decision pathway such as GDM, this offers the opportunity to afford electronic holistic care tailored to the individual with GDM and the clinical service providing care. Current apps for the management of GDM are largely restricted to blood glucose monitoring and the use of blood glucose data to influence lifestyle and pharmacological treatment decisions.^{11,12} AI or AI-enabled clinical decision support in addition to diagnostic blood glucose, lifestyle and medication advice can also be used to use the wealth of other data collected electronically that impact the holistic care including, for instance, correctly identifying women with GDM, streamlining community to secondary care management, monitoring fetal growth and well-being, delivery decisions and timing, neonatal care and post-natal care/decisions.

The aims of this review are to (a) identify recent mHealth apps supported by AI or AI-enabled clinical decision support; (b) identify the current clinical focus and degree of support and feedback offered by these apps to the woman with GDM; (c) identify the type of AI and tools used; (d) identify how the apps deal with any data they collect and (e) identify the areas of the current clinical guideline that remain unmet by these apps. The rest of this paper is organised as follows: Section 2 presents the methodology used including the newly developed *Survey Tool approach for collaborative literature Reviews* (STaR)¹³ and objectives of this review. The results of the literature search and analysis for each objective are presented in section 3, before the paper concludes with a discussion in section 4.

2 | METHODS

This section describes the literature search, review process and objectives of this scoping mHealth app review.

2.1 | Literature search

Using a university library search engine that aggregates results from PubMed, Medline, ScienceDirect, Scopus, Directory of Open Access Journals, Web of Science and Elsevier, a search was conducted with the terms listed below. Academic peer-reviewed papers were eligible for

inclusion where their title, subject keywords or abstract used four key terms arranged in the following general search queries. We limited the review to works published between 2014 and 2019 to ensure recency due to the rapid pace with which mobile and smart technologies become obsolete and new ones are developed to replace them. We focused initially on the term AI because, as will be shown later, it is a single concise term that is representative of the intelligent systems domain. However, in the final search, the generic terms AI and ML were used; although most of the specific methods would be covered by this we added “neural networks” as this specific method is sufficiently widely used that it is possible papers using this method may not have felt the need to include ML and/or AI as keywords.

“(Gestational Diabetes) AND (Decision Support)”

“(Gestational Diabetes) AND (Artificial Intelligence)”

“(Gestational Diabetes) AND (Machine Learning)”

“(Gestational Diabetes) AND (Neural Networks)”

The returned works were then filtered for those that used the terms: *smartphone*, *mHealth*, *mobile health* or *app*. For inclusion, remaining works had to (i) focus on GDM; (ii) present an mHealth app; (iii) address at least one component of the GDM care pathway (described later) and (iv) encompass or incorporate either *clinical decision support* or an *AI* approach.

2.2 | Review process

Reviews of large collections of papers or complex and cross-domain topics can be complicated and time-consuming.¹³ It can be difficult to maintain consistency and ensure a high-quality result. This review falls across two domains, as it evaluates the context, content and use of software applications in the computing domain, with clinician and patient needs and health utility for those applications in the health domain. Although in the medical domain, it might be appropriate to use an approach like CONSORT or AGREE II to grade the evidence for efficacy of the device and methodology of each paper, in Information Technology (IT) and Computer Science (CS) different review methodologies are used especially prior to a feasibility clinical trial. Given that

this review falls more generally within the IT/CS domain we investigated collaborative literature review methods from those domains, resolving the seven core steps for an IT literature review shown in Figure 1. We also identified that many review approaches focused largely either on the formative steps that instantiate the review (review question identification and paper selection) or on the concluding steps that complete it (write-up and dissemination).

As indicated by the empty cells in Table 1, all ‘established’ review methodologies we investigated failed to describe the approach for undertaking one or more of their core steps. For this reason, our extended project team developed the *Survey Tool approach for collaborative literature Reviews* (STaR) methodology.¹³ STaR defines processes for seven core steps that together provide complete end-to-end workflow with inbuilt training and quality control. STaR aims to provide a high degree of assurance in the review outcome. Following STaR, we established a concept map and review process, used the concept map to frame questions we sought to ask of the literature and developed a standardised digital survey. We provided review process training for reviewers and instructed them on using the digital survey tool. Multiple review cycles were also run to ensure that each paper was reviewed by three different reviewers.

2.3 | Review plan

Our review plan identified four objectives that cover important aspects critical to our understanding of mHealth apps that incorporate clinical decision support or AI for use in GDM care. These are illustrated as the four coloured branches of Figure 2.

2.3.1 | Objective 1 – The type of tool

There are several core elements that can impact the effectiveness of an mHealth app as a tool for individual's positive health change. These include the AI or, more often, the ML approach being applied and the target type of user device. Although ML is a type of AI and in the CS domain would normally be encompassed in that term, we sought ML separately as we found some authors in the medical domain will describe ML solutions without reference to AI. A multitude of different AI or ML methods exist, with each technique being more suited to particular applications.^{14,15} In addition, developing the app for a user device whose hardware or operating system may not fully support all necessary functionalities, or one with limited users due to high device cost or limited availability would severely limit the access to the app for those in the most under-served communities. However, it is those under-served patients who will benefit the most from the app or service enhancement it delivers. For these reasons, we investigated both the types of AI integrated into or used by the app, and the user device architecture that authors had developed their solution to be run on.

2.3.2 | Objective 2 – The privacy and security of data collected by the app

Although an app needs to collect information appropriate to its function, the argument for adoption is difficult to make if the app does not handle those data with appropriate consideration to privacy and security, given the personal nature of medical records. Other surveys have considered the type of data being collected; however, we sought to identify information provided by authors regarding how the collected data were stored and transmitted by their apps.

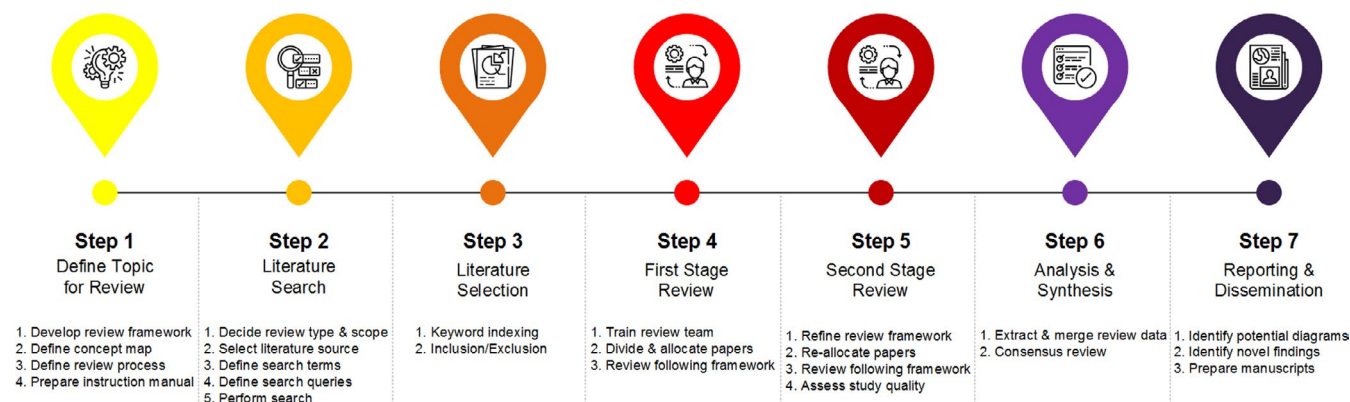


FIGURE 1 The Collaborative Literature Review Process. The steps 1–7 outline the review process used

TABLE 1 Tool support for collaborative literature review process steps

Works	Step 1	Step 2	Step 3	Step 4	Step 5	Step 6	Step 7
	Define topic for review	Literature search	Literature selection	First-stage review	Second-stage review	Analysis and synthesis	Reporting and dissemination
Alias, 2008 (Concept Map)	Concept Map					Concept Map	
Beel, 2011 (Mindmaps)	Mindmaps						Docear
Bandara et al, 2011; (NVivo)	NVivo (partially)		Adobe Acrobat Pro, Endnote, NVivo			NVivo	NVivo, Endnote
Bowes et al 2012 (SLuRp)		SLuRp	SLuRp		SLuRp (partial)	SLuRp	
Fabbri et al 2013 (StArt)	StArt	StArt	StArt			StArt	
Moller et al (2015) (SESRA)	Commissioning the Review Stage (SESRA)	Identification of Research Step (SESRA)	Study Selection, Study Quality Assessment and Data Extraction Steps				Reporting the Review Phase (SESRA)
Ponsard et al, 2016 (PaperQuest)		PaperQuest	PaperQuest (partial)				
This work (STaR)	Concept map – mind- mapping tool	Concept and thematic analysis	Library search tool recommender engine	Reviewer training. Online survey using review manual	Review process QC and additional reviewer training. Online survey using review manual	Data extraction, cleaning and analysis	Collaborative authoring using online word processing environment

Note: The title of each work's *research method* is indicated in parenthesis underneath the short citation for the work. NVivo is a qualitative analysis computer software package. SLuRp is a web-enabled database that supports the management of systematic literature reviews and stands for a Systematic Literature unified Review program. StArt is a computational tool and stands for State of the Art through Systematic Review, SESRA is a web-based automated tool to support the systematic literature review process, PaperQuest is a visualisation tool to support literature review. An empty cell indicates that the author's method did not include an approach for this step of the literature review process.

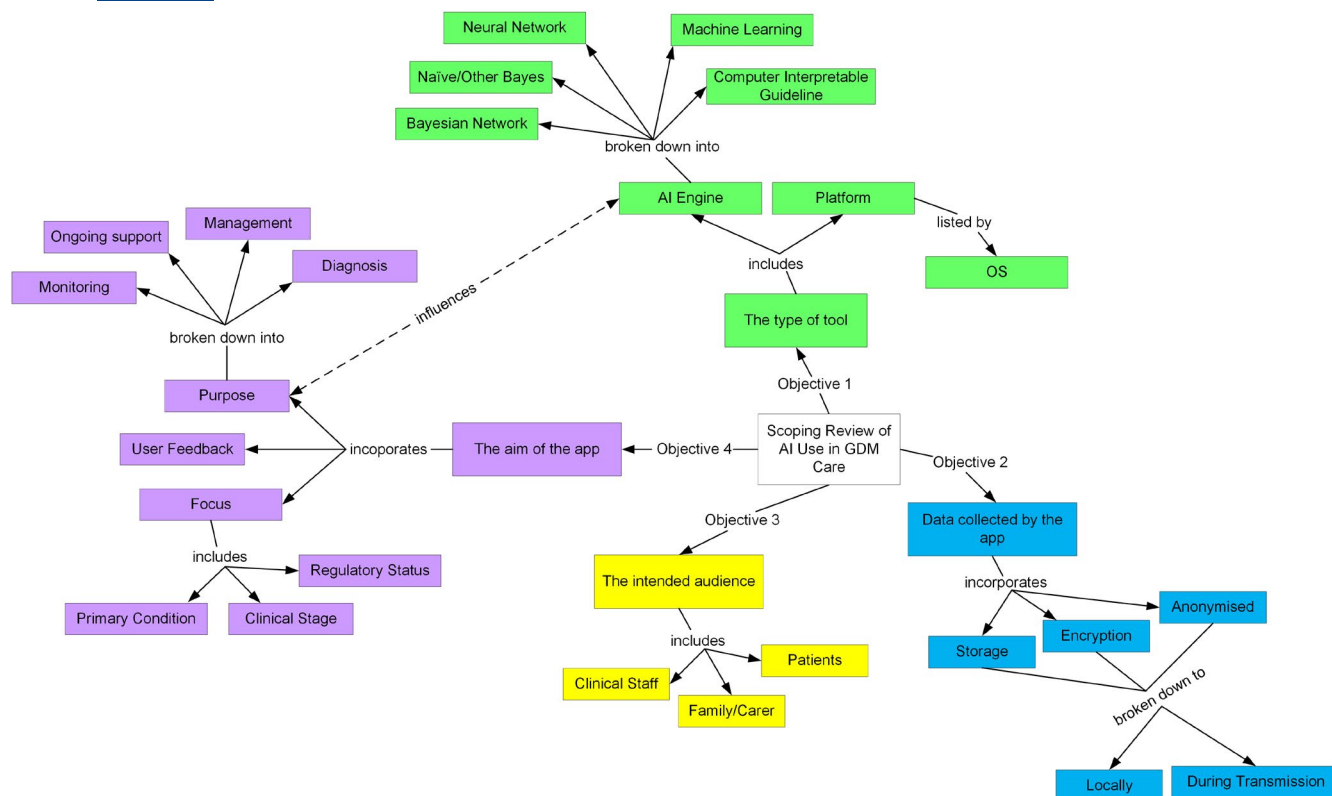


FIGURE 2 Concept map for the review of literature on mHealth apps using AI for GDM. The starting point of the concept map is the central box, Scoping review of AI use in GDM care with objectives 1–4 identified by the coloured boxes. Green boxes = The type of tool; blue = data collected by app; yellow = the intended audience and purple = the aim of the app

2.3.3 | Objective 3 – The intended audience

It is well known that developers should model software not just for the tasks it is intended to be used for, but also, with regard to the needs and characteristics of the user.^{16–18} The mHealth literature tends to focus on a single end-user for the app being described. Often this is the patient with the target condition,^{18,19} and less frequently it was the clinicians who treat them.²⁰ We investigated the intended user/s for each app to evaluate whether the *patient-as-sole-user* focus in most mHealth literature was appropriate.

2.3.4 | Objective 4 – The aim of the app

Smartphone apps are available for a wide range of medical conditions, treatment stages and purposes. It is not uncommon for an app to be designed for a broad primary condition but to have features and functionality capable of providing some support for users with a sub-category, variant or comorbidities of that condition: an example relevant to this review would be an app generally designed for those with T1D or T2D that offers some support specific to

women with GDM, for instance glucose monitoring. For this reason, the primary medical condition, clinical stage and intended purpose for the app were collected.

The reviewer classified each paper into four terms: GDM and either (1) decision support, (2) AI, (3) ML or (4) neural networks. Additionally, they were asked to assess which of the following four domains each app targeted: diagnosis, management, ongoing support or data collection.

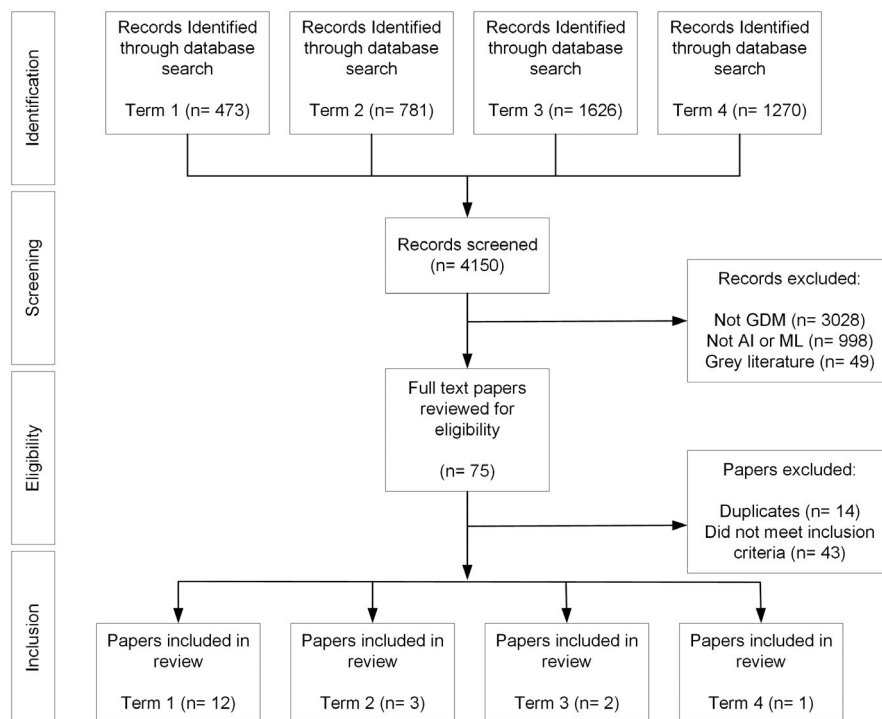
3 | RESULTS

This section presents the results of our review contextualised to the four objectives described in 2.3 above.

3.1 | Literature search and collection results

The literature search identified 52 of 3450 papers for full-text review (Figure 3). Once non-academic texts, duplicates and works not meeting the inclusion criteria were removed, 18 works remained for inclusion in this review.

FIGURE 3 Prisma diagram. Term 1: [Gestational Diabetes] AND [Decision Support]. Term 2: [Gestational Diabetes] AND [Artificial Intelligence]. Term 3: [Gestational Diabetes] AND [Machine Learning]. Term 4: [Gestational Diabetes] AND [Neural Networks]



Of the 18 papers listed in Table 2, 6 represent a corpus of work by various groups on the *MobiGuide* app, 2 focused on the *SineDie* tool and an additional 2 papers originated from a Russian group focussing on aspects of development of their tool for monitoring blood glucose in GDM. The remaining papers were unrelated. Only one paper described a tool (GDM-Health) that is in current use following clinical evaluation.²¹

3.2 | Results – Objective 1

Figure 4 shows the distribution, frequency and AI category of tools identified in the literature and shows that five sub-types of AI were identified. Anecdotally, we also observed that around one-third described an ML approach as AI. This is not unusual as AI and ML are often incorrectly used as synonyms, especially by those working in domains other than the computing sciences. However, as shown in Figure 5, ML is actually subset of AI. Unlike other types of AI that are capable of inference, reasoning and abstracting various human cognitive capabilities, ML solutions are based purely on learning from data they are provided: focusing on the idea that we should just give machines *raw data* and let them learn and draw conclusions from it without the addition of expert input or explicit programming.^{22,23} The initial questions asked of each article concerned the tool being presented and the type of AI used in construction of that tool. The most common tool was an *Application*. An application was identified from the authors' description of a complete solution with elements

that included (a) a patient or clinician user interface and (b) a server or back-end component that incorporated an AI engine or algorithms and other structural components.²⁴ Six works^{24–29} were based on a single core project, *MobiGuide*, and described use of *Computer Interpretable Guidelines* (CIG), a decision support approach constructed from digitised clinical guidelines which authors often formulate as one of the precursor AI methods shown in Figure 5: *the decision tree*.³⁰ *MobiGuide* was described as a *patient-centred personalised decision support system* using patient preferences, their psychosocial context, and the individual's clinical data.²⁴ Algorithmic tools were the next most frequently identified in the literature collection.

ML from *data only* was the most variable AI approach applied, with solutions that were individually an ML algorithm, data collection and analysis tool, and fully developed usable application. *Neural Networks* are one of several supervised learning ML tools. Supervised learning tools incorporate a series of algorithms intended to mimic human thought by attempting to recognise underlying relationships between input data and the outcome sought.³¹ Three solutions described neural network applications.^{32–34} There was also one work³⁵ that described use of the Microsoft Azure AI without classifying the underlying AI engine. Five papers^{21,36–39} failed to describe the AI engine powering their GDM tool. Finally, two papers present applications (GDM-Health and d-GDM) that do not use any AI-based engine.^{21,39} However, these papers were included in the literature collection because they met the requirement of describing an approach for *clinical decision support* in GDM.

TABLE 2 Identified literature for review

First Author	Second Author	Year	Title	Ref #	App Name
San Fung	Widya	2014	Application of a conceptual framework for the modelling and execution of clinical guidelines as networks of concurrent processes	[31]	Un-named ^a
Garcia-Saez	Rigla	2014	Patient-oriented computerized clinical guidelines for mobile decision support in gestational diabetes	[37]	MobiGuide
Douali	Dollon	2015	Personalized prediction of gestational Diabetes	[36]	Un-named
Shalom	Shahar	2015	Implementation of a distributed guideline-based decision support model within a patient-guidance framework	[43]	MobiGuide
Caballero-Ruiz	García-Sáez	2016	Automatic classification of glycaemia measurements	[34]	Sinedie
Bromuri	Puricel	2016	An expert Personal Health System to monitor patients affected by Gestational Diabetes Mellitus: A feasibility study	[44]	Un-named
Caballero-Ruiz	García-Sáez	2017	A web-based clinical decision support system for gestational diabetes: automatic diet prescription and detection of insulin needs	[35]	Sinedie
Peleg (a)	Shahar	2017	Assessment of a personalized and distributed patient guidance system	[39]	MobiGuide
Peleg (b)	Shahar	2017	MobiGuide: a personalized and patient-centric decision-support system and its evaluation in the atrial fibrillation and gestational diabetes domains	[39]	MobiGuide
Abejirinde	Douwes	2018	Pregnant women's experiences with an integrated diagnostic and decision support device for antenatal care in Ghana	[33]	Bliss4Midwives
Mackillop	Hirst	2018	Comparing the efficacy of a mobile phone-based blood glucose management system with standard clinic care in women with gestational diabetes: randomized controlled trial	[30]	GDM-health
Moreira	Rodrigues	2018	Evolutionary radial basis function network for gestational diabetes data analytics	[38]	Un-named
Pustozarov (a)	Popova	2018	Development and evaluation of a mobile personalized blood glucose prediction system for patients with gestational diabetes mellitus	[40]	Un-named
Pustozarov (b)	Popova	2018	Mobile-based decision support system for gestational diabetes mellitus	[41]	Un-named
Rigla	Martinez-Sarriegui	2018	Gestational diabetes management using smart mobile telemedicine	[42]	MobiGuide
Hu	Zhang	2018	SmartCarb: An Intelligent Mobile System to Assist Diet Control for Gestational Diabetes Patients using Deep Learning Neural Networks	[34]	SmartCarb
Volanski	do Prado	2019	d-GDM: A mobile diagnostic decision support system for gestational diabetes	[44]	d-GDM
Srivastava	Khanna	2019	Estimation of gestational diabetes mellitus	[32]	Un-named

^aThis work describes an application framework (not an app) called MADE which that work's authors state in the conclusion is being used as a foundational component in the development of the MobiGuide app.

FIGURE 4 Tool and tool type.

From 18 papers: Blue: Papers in which tool and tool type is/is also described as an algorithm (3/18). Orange: Papers in which tool and tool type is/is also based on data collection and analysis (1/18). Grey: Papers in which tool and tool type is/is also described as an application (16/18)

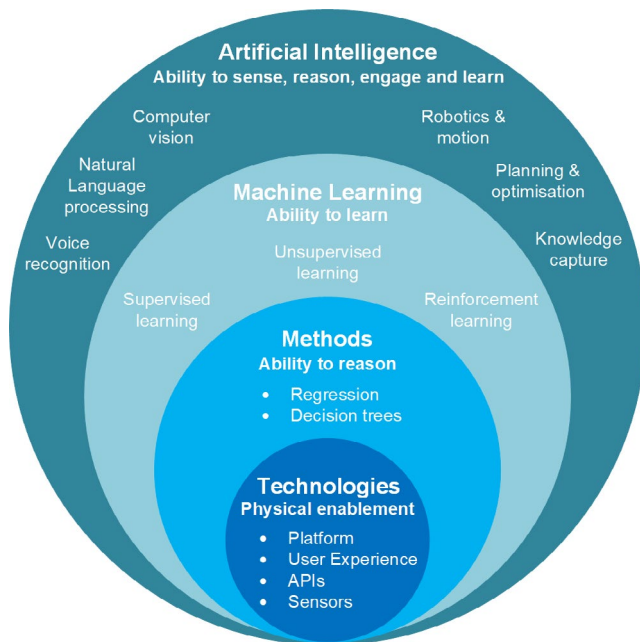
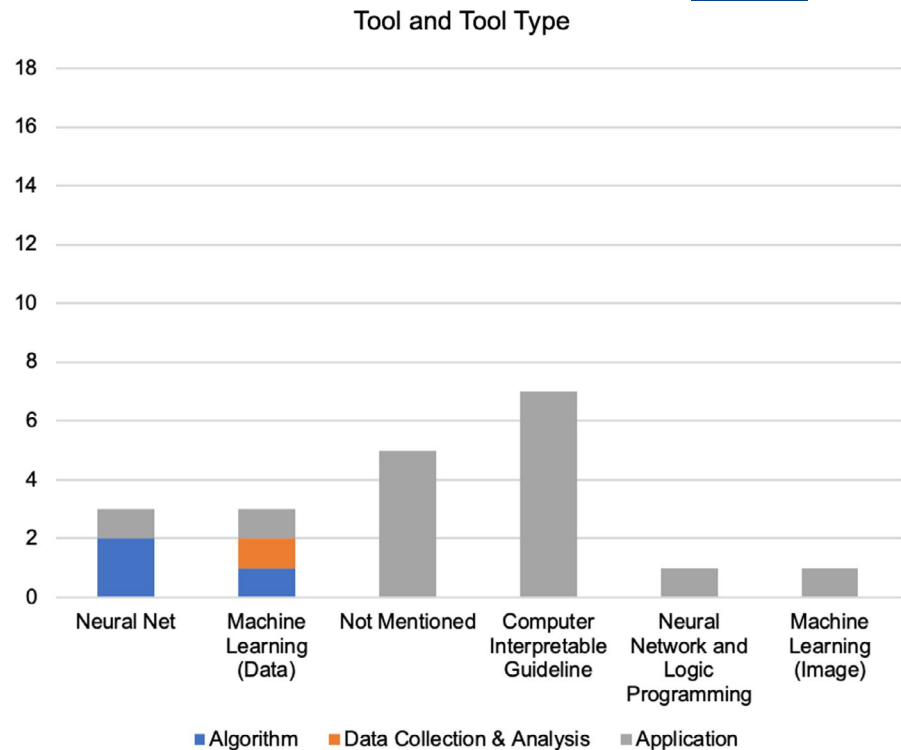


FIGURE 5 Layers of artificial intelligence. This figure demonstrates a progression of technological advancement from the development of tools that enabled data collection, aggregation and integration through to smart methods that could learn new knowledge from that data (ML) and reason with that knowledge (AI). APIs is an abbreviation for Application Programming Interfaces

3.3 | Results -- Objective 2

This objective required reviewers to identify whether the tool collected data and if authors described protecting

privacy and security through the application of anonymisation and encryption technologies. Anonymisation and encryption are requirements for an individual's health data that is being used, stored or transmitted outside of core clinical systems.^{40,41} Additionally, the right to know why data is being collected and how it will be used are rights provided in law in many western countries. For example, in the United Kingdom, these requirements are afforded by application of the EU *General Data Protection Regulation* (GDPR) (<https://gdpr.eu/tag/gdpr/>) and UK *Data Protection Act 2018* (DPA) (<https://www.gov.uk/data-protection>) where *personal data* are involved.

Figure 6 shows that 16 tools collected health data, while one paper made no mention of data collection⁴² and another, according to its author's descriptions, collected none.³⁵ Of those that were collecting data the majority (16) made no mention of whether their software used data encryption or anonymisation to protect users' personal data. Two papers^{43,44} explicitly mentioned encryption; however, for⁴³ this was a single and simple reference to the use of *https* encryption when users accessed their website. Being as the majority of tools collect, store and transmit potentially personally identifying health data, anonymisation and encryption are important and necessary functions that should be used by app developers. Finally, it was also significant to note no mention of the development or inclusion of a privacy policy or any other disclosure notices arising from compliance with privacy, data or medical device regulations.

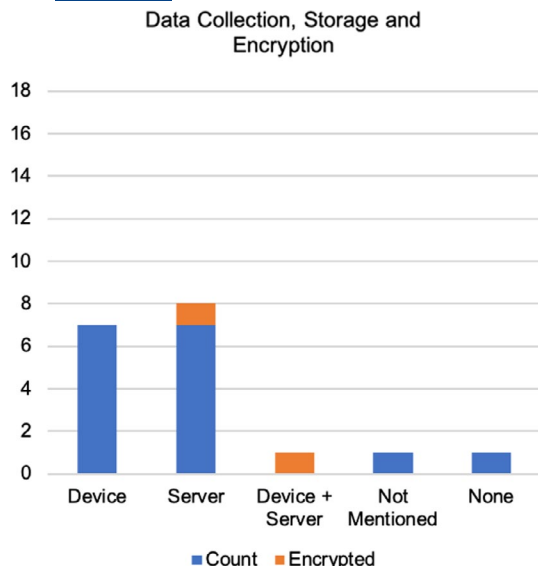


FIGURE 6 Data collection, storage and encryption. From 18 papers: Blue: Papers in which data collection and storage is mentioned (16/18). Orange: Papers in which data encryption is mentioned (2/18)

3.4 | Results – Objective 3

Of the 18 papers (67%), 12 present solutions intended for co-use by women with GDM and their clinicians. Five^{32,35,36,39,42} were intended for clinical or research use only, and it was noted that these were all primarily GDM diagnostic tools. In addition, one work,²⁶ focussed only on the patient-facing portion, or user interface, of the MobiGuide app.

3.5 | Results – Objective 4

3.5.1 | Feedback

Figure 7 shows that 15 works describe provision of feedback which, for 10, was described as contextually appropriate to the specific user's current health status. For example: *your blood sugar level has been high during 3 of the last 4 days. Based on your prescription, you should increase your insulin by 2 units per meal.* By contrast, generic feedback provides responses that are appropriate for all app users that exhibit similar trigger states without inclusion of individual-specific customisation. For example: *Your blood sugar level is high.* Individual-specific contextual feedback should be preferred as it provides responses in real time that are tailored to the individual woman's needs, with an added ability to encourage that appropriate action be taken when the need arises.

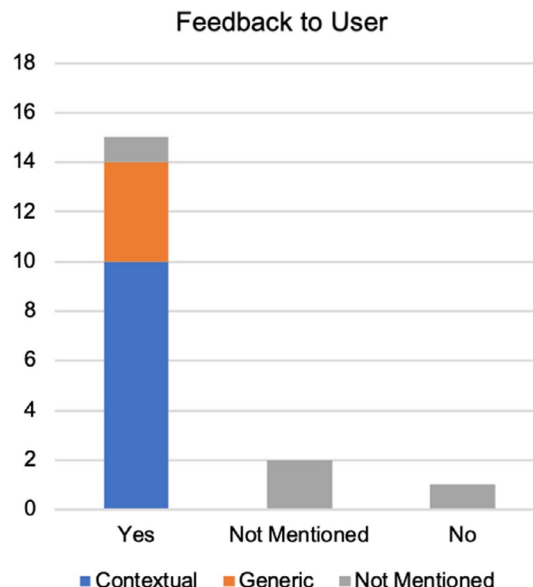


FIGURE 7 Feedback to user. Blue: Papers in which feedback to user is contextual (10/18). Orange: Papers in which feedback to user is generic (4/18). Grey: Papers feedback in which feedback to user is not mentioned (4/18)

3.5.2 | Clinical component

Two MobiGuide papers discussed the use of atrial fibrillation as a second exemplar condition used to validate their approach.^{24,29} As shown in Table 3, the tools described in five works focussed solely on diagnosis of GDM, one focused solely on glycaemic management, and 12 focussed on management of GDM and provision of ongoing patient support. Eight of the presented tools collected patient-generated data between clinical visits.

4 | DISCUSSION

All works in this review focus solely on GDM with the exception of³⁶ that discusses GDM as one of a range of possible pregnancy complications. The aim for most works was to assist women with GDM and their clinical teams to manage and support ongoing care. Most applications collected some data from the woman and almost all that did used that data to generate contextually relevant feedback. Only the GDM-health tool²¹ is currently in clinical use, while MobiGuide and SineDie have at least undergone some clinical evaluation. No other work made mention of whether their tool had, or would be, seeking evaluation and approval from a regulator. Our findings regarding each application to clinical care, classified against the widely accepted NICE GDM clinical pathway, are summarised in Figure 8. As seen in the Prisma diagram

TABLE 3 Clinical focus

Clinical focus						
Main author	Year	Diagnosis	Management	Ongoing support	Data collection between clinical visits	AI type
San Fung	2014		✓	✓		CIG
García-Sáez	2014		✓	✓	✓	CIG
Douali	2015	✓				ML(D)
Shalom	2015		✓	✓		CIG
Caballero-Ruiz	2016		✓		✓	NN
Bromuri	2016		✓	✓	✓	CIG
Caballero-Ruiz	2017		✓	✓	✓	ML(D)
Peleg (a)	2017		✓	✓		CIG
Peleg (b)	2017		✓	✓		CIG
Aberjirinde	2018	✓				NM
Mackillop	2018		✓	✓	✓	NM
Moreira	2018	✓				NN
Hu	2018		✓	✓		NN, ML(I)
Pustozarov (a)	2018		✓	✓	✓	NM
Pustozarov (b)	2018		✓	✓	✓	NM
Rigla	2018		✓	✓	✓	CIG
Srivastava	2019	✓				ML(D)
Volanski	2019	✓				NM

Abbreviations: CIG, Computer Interpretable Guidelines; D, Device; ML(D), machine learning (data); ML(I), machine learning (images); N, none; NM, not mentioned; NN, neural network; S, server.

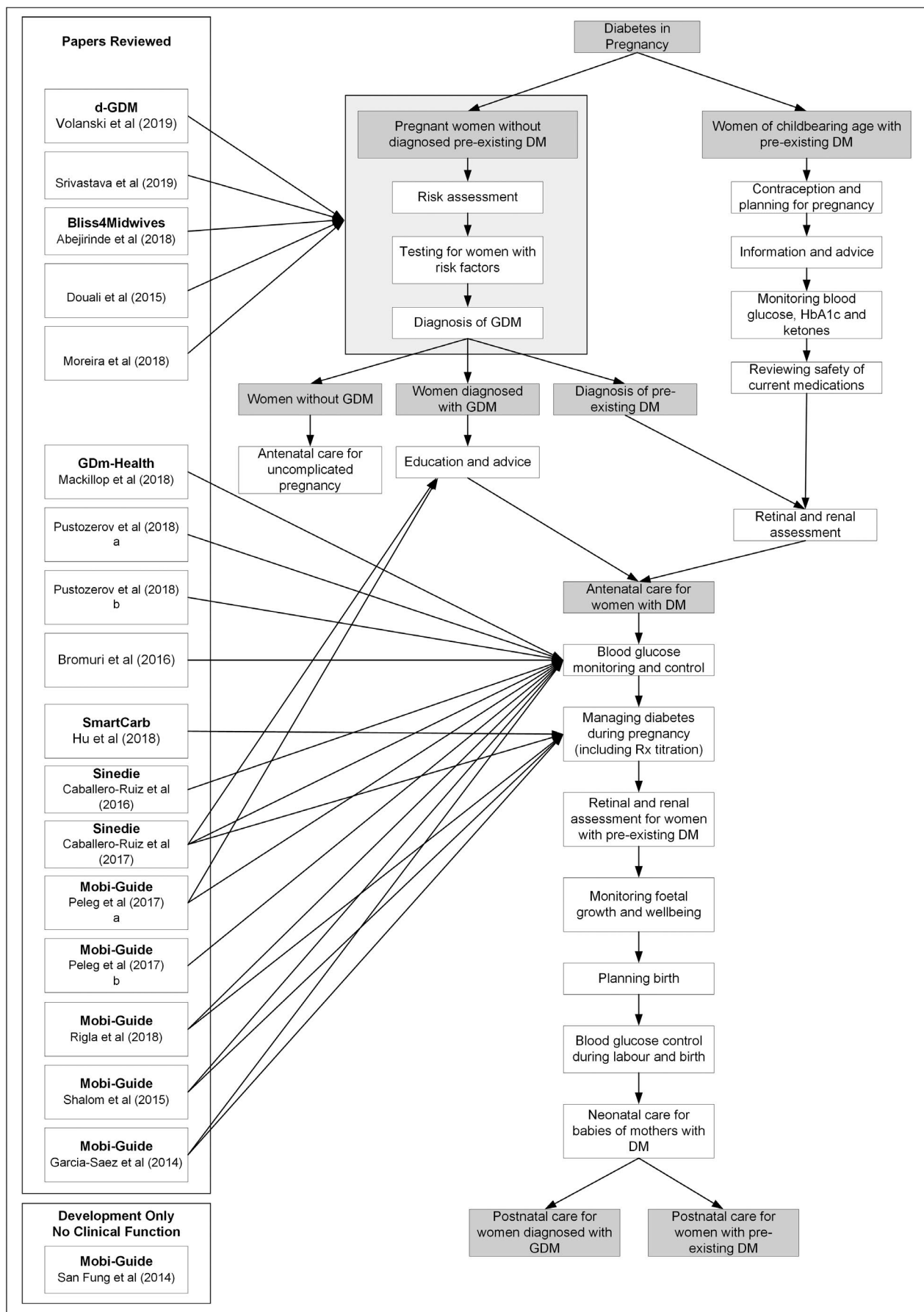


FIGURE 8 Care pathway (Adapted from NICE guidelines for diabetes in Pregnancy NG3) indicating app focus. On the left-hand side are the named apps and the papers reviewed with arrows pointing to the right-hand side of the NICE pathway addressed by the app

(Figure 3) of the 75 papers eligible for review, we had to exclude almost two-thirds ($n = 43$) for not meeting the inclusion criteria by not providing sufficient information on the algorithms used in the app's development.

Figure 8 also shows that no single app was intended to provide holistic support for the entire scope of care for GDM. Each app focuses on either a small subset or single phase of care described in the NICE guideline, absent even of consideration of the other phases or the needs of the mother with GDM and her child that they seek to address. We would contend that for an *app* to be truly useful to the mother with GDM and their health professional team, and achieve universal adoption, that it must encompass all aspects of GDM care.

As previously mentioned, six works in this review reported the aspects of development, testing or a variety of uses based on the same core application: *MobiGuide*. *MobiGuide* is a patient-centred system offering personalised decision support using the woman's preferences, their psychosocial context, and their aggregated clinical data.²⁴ However, as a CDSS it has not undergone a rigorous clinical evaluation such as a randomised clinical trial.¹² *MobiGuide* has received some tangential attention in other areas of the AI domain.^{45,46} Two works in this review reported on the development of an app called *Sinedie*, which was described as a web-based decision support system using self-monitored blood glucose measurements to generate diet advice for the individual, and to flag the possible need for insulin adjustments to the clinician.^{33,43} The *Sinedie* team have recently re-visited their app in response to reduced primary and secondary clinic access for diabetic pregnancies during the COVID-19 outbreak. They have used their app to assist a small number of women ($n = 20$) to remotely manage diet and medication, and in a recently published short paper in 2020, described their strategy to seek continued financial support⁴⁷; however, this web-based clinical decision support system, is yet to be fully evaluated by a randomised clinical trial. In addition, as we were proceeding to writing up this review Pustozarov et al.⁴⁸ released further work on their approach for GDM using a linear regression model (Figure 5), focusing on the prediction of blood glucose responses in women with GDM based on evaluation of the glycaemic index of their food consumption.^{48,49} They are yet to present a fully realised app for use during the GDM affected pregnancy.

This work reviewed a small collection of papers presenting mHealth apps for use in management of GDM. Three reasonably mature mHealth apps (GDM-health, *Sinedie* and *MobiGuide*) specifically aimed at GDM were identified. However, but given no further publications (censored 31 March, 2021), it is unclear whether further development to mature *MobiGuide* is being undertaken.

The remaining works described partial solutions that did not constitute a fully realised app. Only one app (GDM-Health) is in current use within the United Kingdom's National Health Service, providing women with a tool for uploading their daily blood glucose readings to a web-based platform accessible to clinicians. GDM-Health has been subject to randomised clinical trials assessing satisfaction by women with GDM and their carers.¹² None of the apps in this review (a) used AI to predict outcomes; (b) provided women with GDM with a robust approach for self-managed titration of their dose of diabetic medication or (c) provided decision support for the complete GDM pregnancy from diagnosis through to post-natal care. An opportunity exists to improve the AI approaches used within mHealth apps, to ensure these apps provide end-to-end support in pregnancy for women with GDM. This review also shows that current mHealth apps target only a limited number of clinical pathway components of care for the woman with GDM, as is clearly demonstrated in Figure 8 with reference to the NICE GDM care pathway. None of the reviewed apps include monitoring fetal growth and well-being, birth planning, glucose control during labour and birth, the immediate post-natal period or postnatal care and follow-up of women with GDM. Future work should focus on developing the tools that encompass GDM Health so that app(s) can provide holistic care from diagnosis through to the postnatal period. Furthermore, for an mHealth app to be adopted by healthcare providers it will need to be integrated into existing clinical information systems in both primary and secondary care. Only then can GDM mHealth apps be transformative and fully adopted in clinical care.

Patient-facing mHealth apps underpinned by AI-based clinical decision support that can collect health status information, identify potential issues and provide contextual feedback to support patient care, will be an important tool in both improving care within the community and ensuring that health systems can meet the needs of an ever-growing patient population. Several groups are developing relevant AI approaches. For instance, we are adopting a holistic approach (PamBayesian) using a Bayesian method⁵⁰ funded by Engineering and Physical Sciences research Council (EPSRC) directed to a CDSS to encompass the whole GDM pathway from diagnosis to post-partum prevention of type 2 diabetes [<https://pambayesian.org/>]. Other investigators have confined themselves to one component of the pathway, for instance, two groups have addressed the diagnosis of GDM by a ML approach.^{51,52}

Patient-approachable and patient-centred AI tools for use in primary care settings and between clinician visits have been shown to promote patient empowerment, better health outcomes and lower workloads in busy clinical settings.^{53,54} However, building and developing AI tools is

potentially futile if the end users, be they clinician or patient, do not engage with them. Research has identified barriers to the adoption of medical AI that range from issues with the quality and availability of medical data, the lack evidence demonstrating AI impact on clinical decision-making, clinician's resistance to AI and health IT generally, and the cost and time taken to develop these tools.⁵⁴ In addition, often discussed as a need for *responsible, ethical or accountable* AI while being confused as shortcomings arising from social biases or unfairness, is the issue of *explainability*: how was the AI designed, how does it use the data it is given and how did it arrive at *this* decision?.^{13,55} Users employing AI solutions may not feel comfortable until the answers to these questions has been explained, and those called to adjudicate issues arising from AI-mediated decisions will need to be able to scrutinise the AI to identify problem sources and to allay fears. Some also question the safety of AI use in medicine and question whether evidence will ever exist that demonstrates cost-effectiveness. Finally, what is lacking is a better understanding of why different patient groups remain reticent to adopt mHealth apps, and the difficulties that must be addressed for AI-powered tools to gain broader acceptance in the community.

Recent trends towards democratisation of medical knowledge and enhancing the agency of people with health conditions shows they can reduce the burden on strained secondary care systems by gatekeeping and normalising patient self management.⁵⁶ However, in spite of emerging research proving the benefits of AI-driven self management tools, barriers exist at both institutional and individual clinician levels limiting adoption of AI in healthcare.^{53,54} Any proposed AI solution must be capable of addressing these barriers. Although many diabetes apps generally exist only to collect blood glucose or dietary information, several of the apps reviewed in this work are making strides towards relevance, primarily through provision to the patient-user of contextual treatment guidance and knowledge. Given that uptake of and prescription of health-related apps remains low, we must investigate whether there are ways these apps can be made better and consistently encompass a holistic approach.

In conclusion, our scoping review has established that the use of AI to empower women with GDM and aid clinical decision making, by both the women and health professionals providing the GDM service is very limited. Furthermore, for such an mHealth application to be truly useful, it needs to encompass all aspects of the GDM pathway as illustrated in the NICE diabetes in pregnancy care pathway (NG3) (Figure 8). Although many are capable of designing and developing an mHealth app, few consider whether they should. Few published app solutions consider the governance issues arising out of the collection

and use of patient data; especially in something designed to impact (positively, one hopes) patient care and outcomes. Further research in this field is clearly indicated and needs to be backed up by well-designed feasibility and randomised clinical trials. Approaches to clinical management have recently rapidly changed, spurred on by the recent COVID-19 pandemic. Clinical decision system support powered by AI will be an important component of such change in the future.

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CONFLICTS OF INTERESTS

No author identified a competing interest relevant to this research.

AUTHOR CONTRIBUTIONS

BJD prepared the first draft with guidance from SM. BJD, SM, MN'M and MRN performed the scoping literature review. GAH, NEF revised the paper. GAH, NEF and SM supervised the research. GAH and BH provided the clinical context to this work. All authors contributed, commented and approved the final draft.

DATA AVAILABILITY STATEMENT

All relevant data have been made available within the research article.

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