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Incretin-Based Medications in Women and Reproduction: A Systematic Scoping Review and Consensus Guidelines for Clinical Practice

Kate Maslin[1,2] | Jill Shawe[1,2,3] | Sinead Blowers[1,3] | Michael Ceulemans[4,5] | Kathryn Hart[6] | Sam Schoenmakers[7] | Amihai Rottenstreich[8,9] | Heather Hopper[1,2,10] | Mojca Jensterle[11,12] | Angela C. Flynn[13] | Sarah Siegelaar[14] | Annick Bogaerts[1,2,15] | Isy Douek[16] | Nicola Heslehurst[17] | Dries Ceulemans[2,18] | Tricia Tan[19] | Johnathan Pinkney[20,21] | Martin Whyte[22] | Shahrad Taheri[23] | Roland Devlieger[2,18]

[1]School of Nursing and Midwifery, University of Plymouth, Plymouth, Devon, UK | [2]REALIFE Research Group, Research Unit Woman and Child, Department of Development and Regeneration, KU Leuven, Leuven, Belgium | [3]Royal Cornwall NHS Trust, Truro, Cornwall, UK | [4]Research Group Clinical Pharmacology and Pharmacotherapy, Department of Pharmaceutical and Pharmacological Sciences, KU Leuven, Leuven, Belgium | [5]Research Foundation Flanders (FWO), Brussels, Belgium | [6]Discipline of Nutrition, Exercise, Chronobiology and Sleep, Faculty of Health & Medical Sciences, University of Surrey, Guildford, Surrey, UK | [7]Department of Obstetrics and Gynaecology, Erasmus MC University Medical Center, Rotterdam, the Netherlands | [8]Department of Obstetrics and Gynecology, Edith Wolfson Medical Center, Holon, Israel | [9]The Gray Faculty of Medical and Health Sciences, Tel Aviv University, Tel Aviv, Israel | [10]University Hospitals Plymouth NHS Trust, Plymouth, Devon, UK | [11]Department of Endocrinology, Diabetes and Metabolic Diseases, Division of Internal Medicine, University Medical Centre Ljubljana, Ljubljana, Slovenia | [12]Faculty of Medicine, University of Ljubljana, Ljubljana, Slovenia | [13]School of Population Health, Royal College of Surgeons in Ireland, Dublin, Ireland | [14]Department of Endocrinology and Metabolism, Amsterdam Gastroenterology Endocrinology and Metabolism, Amsterdam University Medical Center, University of Amsterdam, Amsterdam, the Netherlands | [15]KU Leuven Child & Youth Institute, Leuven, Belgium | [16]Musgrove Park Hospital, Somerset NHS Foundation Trust, Taunton, Somerset, UK | [17]Population Health Sciences Institute, Faculty of Medical Sciences, Newcastle University, Newcastle, UK | [18]Department of Obstetrics and Gynaecology, University Hospitals Leuven, Leuven, Belgium | [19]Department of Metabolism, Digestion and Reproduction, Imperial College London, London, UK | [20]Peninsula Medical School, University of Plymouth, Plymouth, Devon, UK | [21]Department of Endocrinology, University Hospitals Plymouth NHS Trust, Plymouth, UK | [22]Faculty of Health and Medical Sciences, University of Surrey, Guildford, UK | [23]Marshall University Joan C. Edwards School of Medicine, Huntington, West Virginia, USA

Correspondence: Kate Maslin (kate.maslin@plymouth.ac.uk)

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ABSTRACT

Introduction: Pregnancy concurrent with incretin-based medications is contraindicated due to unknown risk of teratogenicity, as is breastfeeding. The aim of this systematic scoping review was to investigate potential risks and benefits of incretin-based medications in relation to preconception, pregnancy, and postnatal health, and to propose expert guidelines for clinical practice.

Methods: An international expert multidisciplinary group was formed. Research questions relevant to women's reproductive health and incretin-based medications were refined collaboratively, utilizing a lifecourse approach. A systematic search was undertaken on July 23, 2025, across several databases and grey literature sources. Primary data from human studies were prioritized above animal studies. Titles, abstracts, and full text articles were screened independently by two authors. Data were extracted by two people independently using a pre-defined proforma and synthesized narratively. Consensus recommendations were made.

Results: Thirty-four articles were included in the evidence synthesis: 11 randomized trials, nine observational studies, two pharmacovigilance reviews, nine case reports/series, two animal studies, and one ex vivo study. No qualitative studies were

identified. Evidence was found for 18/32 (56.3%) research questions. Most studies related to preconception or pregnancy usage; two addressed contraception, and one was about lactation. The sample size of exposed pregnancies ranged from 1 to 4267. Three studies reported exposure throughout pregnancy. Three studies investigated postpartum usage. One (animal) study had offspring data beyond birth. No studies reported an increase in congenital anomalies.

Conclusion: Clinical practice and research recommendations were made based on current available evidence and evidence gaps, encompassing contraception, preconception, nutritional, pregnancy monitoring, lactation, and longer-term outcomes.

1 | Introduction

Women are disproportionately affected by obesity, which can have detrimental effects on their reproductive health, including difficulties conceiving [1]. Obesity often co-exists with and exacerbates polycystic ovary syndrome (PCOS), a leading cause of infertility affecting an estimated 6%–13% of reproductive-aged women [2]. Globally, obesity affects one-fifth of pregnancies [3] and is associated with adverse perinatal outcomes including gestational diabetes mellitus (GDM), hypertensive disorders of pregnancy, instrumental and caesarean birth, preterm birth, and delivery of large-for-gestational-age (LGA) infants [4, 5]. The risk of these outcomes may be worsened by abnormal glucose tolerance and excessive gestational weight gain (GWG) that occurs in this group [6]. Prioritizing a healthy weight preconception [7], in addition to preventing excessive GWG and limiting postpartum weight retention, are important public health strategies [8], requiring non-stigmatizing approaches and guidance [9].

Incretin-based medications mimic the action of one or more incretin molecules such as glucagon-like peptide-1 (GLP-1) or glucose-dependent insulinotropic polypeptide (GIP). GLP-1 and GIP are secreted in the small intestine postprandially, delaying gastric emptying, increasing insulin secretion and inhibiting glucagon release. Incretin-based medications reduce appetite by activation of the GLP-1 receptors in the brain and are a novel and effective treatment for the management of obesity, demonstrating reduced morbidity and mortality [10, 11]. Several different incretin-based medications are currently licensed internationally for obesity management and more combinations (i.e., among others with glucagon or amylin) are coming to the market. Each varies in molecular weight and half-life which has bearing on their pharmacokinetics, as shown in Table 1. Incretin-based medications promote significant weight loss, more effectively in women than men [10, 12]. Additionally, they may improve metabolic and immunological parameters relevant to women's reproductive health, for example improving ovulatory function and enhancing endometrial receptivity [13]. Figure 1 shows details of the multiorgan sites of action and potential benefits of incretin-based therapy on women's reproductive health.

Pregnancy occurring during or soon after treatment with incretin-based therapy is currently not recommended [8, 14–16] due to potential teratogenicity, based on animal studies [17]. Data on the safe and effective concomitant use of contraception and incretin-based medication are limited [18]. A scoping review [19], published in 2024, found an absence of primary data about the impact of GLP-1 receptor agonists (GLP-1RAs) on the reproductive health of women of childbearing potential; however, that study did not include women with PCOS or diabetes mellitus. Since then, several population-based cohort studies have reported on unintended exposure to GLP-1RAs [20–23]. However, due to the limitations of the study designs and coexistence of type 2 diabetes mellitus (T2DM) in the pregnant population being studied, it remains unclear whether pre-conceptional use of incretin-based therapy is beneficial for pregnancy and offspring outcomes in women living with obesity. The optimal periconceptional timing to commence and discontinue treatment is unknown, particularly due to the risk of weight regain and

TABLE 1 | Overview of the characteristics of the internationally available incretin-based medications as of July 2025.[a]

GLP-1 molecule	Similarity to human GLP-1	Molecular weight (kDa)	Protein binding	Metabolism	Half-life	5× half-life[b]
Dulaglutide	90%	59.7	Undefined	Proteolytic	3.75 days	±19 days
Exenatide[c]	53%	4.19	Undefined	Proteolytic	2.4 h	12 h
Liraglutide	97%	3.75	> 98%	Proteolytic	13 h	±3 days
Lixisenatide	53%	4.86	55%	Proteolytic	3 h	15 h
Semaglutide	94%	4.11	> 99%	Proteolytic	7 days	35 days
Tirzepatide	33%	4.81	99%	Proteolytic	5 days	25 days

Note: Native GLP-1 has a molecular weight of 3.35 kDa and native GIP 4.98 kDa.

[a]These physiochemical and pharmacokinetic properties of individual incretin-based medications can be used to estimate their theoretical potential for transplacental transfer and passage to breast milk.

[b]After approximately five half-lives, about 97% of a medication is eliminated from the body.

[c]The information applies to the active ingredient itself, irrespective of the formulation, as extended-release formulations may substantially prolong the elimination half-life in humans.

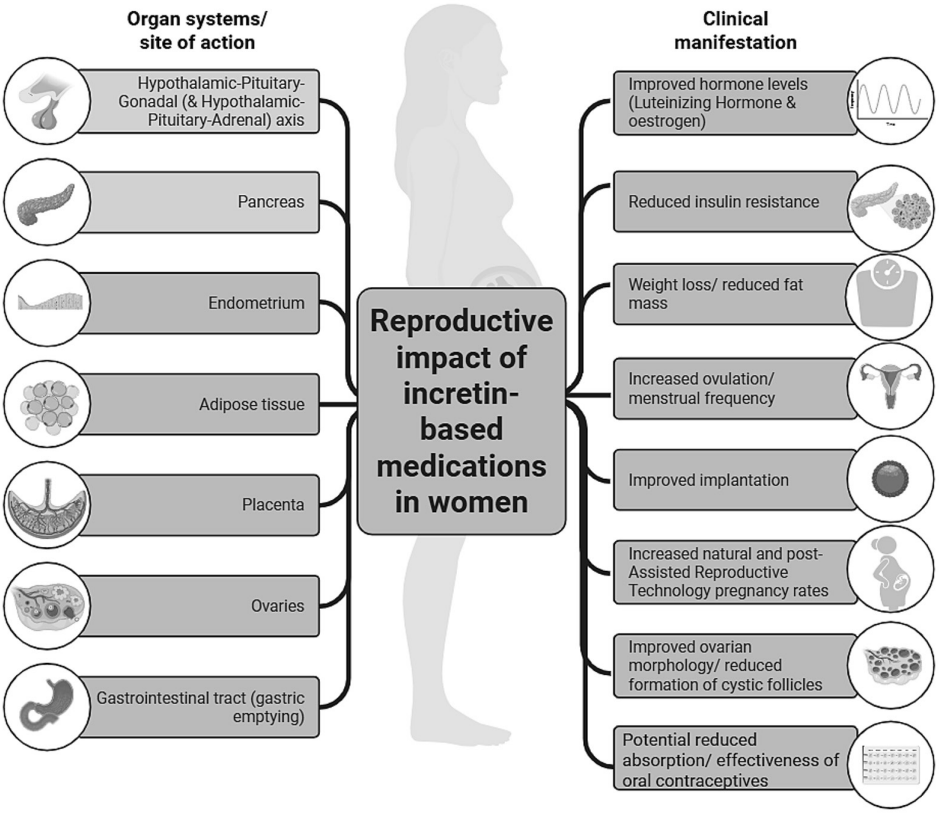

FIGURE 1 | Known reproductive impacts of incretin-based medications in women.

glucose dysregulation when treatment is discontinued [24]. Likewise, although there are emerging data on patterns of use of GLP-1RAs postpartum [25], there is limited knowledge about their use during breastfeeding [26].

Although GLP-1RAs have been conditionally recommended by the World Health Organization for weight loss, in combination with intensive behavioral therapy [27], these recommendations are confined to nonpregnant individuals and do not consider pre- or post-partum usage. Similarly, two recently published consensus guidelines on nutritional priorities during GLP-1RA therapy have not included any information related to preconception, pregnancy, or postpartum life stages [28, 29]. The contraindication of these medications during pregnancy is a barrier limiting the evaluation of their use in those planning pregnancy. However, with appropriate and timely contraceptive counseling, women of reproductive potential should not be disadvantaged in accessing effective obesity medications [30]. Healthcare professionals therefore require practical guidance to inform discussions with and counseling of patients. With the increasing demand for incretin-based medications [31], including procurement from potentially unreliable sources, expert consensus guidelines based on best practice are urgently required to ensure these medications are used as safely and effectively as possible in the periconception and perinatal period. The aim of this project was to establish international clinical practice guidelines for the use of incretin-based medications in women of reproductive potential before, during, and after pregnancy.

2 | Material and Methods

2.1 | Expert Panel Formation

A multidisciplinary international panel of health care professionals and researchers was formed in early 2025. Collectively, the panel had a breadth of experience in pharmacology, teratology, preconception health, nutrition and dietetics, endocrinology, midwifery, obstetrics, fetal medicine, and evidence review. The panel met online monthly, with a follow up in-person meeting in Leuven, Belgium, in November 2025. The objectives of the panel meetings were to establish the key questions to advance scientific knowledge and practice around incretin medications and reproductive health, and to undertake a systematic search and analysis of the literature to produce consensus best practice guidelines. The panel included an information specialist who attended all meetings.

2.2 | Approach, Scope, and Identification of Research Questions

This review used scoping methods, following the search strategy of the Joanna Briggs Institute [32] and the principles of Arksey & O'Malley's framework [33]. The scope of the guidelines was defined with an agreement to focus on women of reproductive potential (18–45 years), and solely on incretin-based medications that are licensed for the management of obesity (rather than those which are being used primarily for

management of T2DM, such as DPP-4 inhibitors). We therefore primarily refer to "incretin-based medications" throughout this manuscript to include both single and dual GLP-1 based medications, although also use the terminology "GLP-1RAs," as per language used in original studies. We use the words "women" and "woman" throughout this paper, recognizing that this reflects the biology and identity of the great majority of those who are childbearing; for the purpose of this paper, these terms include people whose gender identity does not correspond with their birth sex or who may have a non-binary identity.

The overarching research question therefore was: "What is best practice for the use of incretin-based medication for the management of overweight/obesity in women of reproductive potential in relation to preconception, perinatal and postnatal care?" This broad research question was categorized into five key life stage themes, as follows: (1) fertility/preconception, (2) pregnancy (fetal considerations), (3) pregnancy (maternal considerations), (4) early postpartum and lactation/breastfeeding considerations, and (5) longer term postpartum outcomes (for both offspring and mother). A sixth theme covering multidisciplinary team working was also added. Research questions for each stage were formulated and refined until agreement was reached on the priority questions.

2.3 | Search Strategy

The search strategy was designed by an information specialist to find both published and unpublished articles in English from any date up to July 23, 2025. A keyword search strategy based on Population, Intervention and Outcome, combining terms associated with obesity, obesity medication, and fertility/reproductive health was created through an iterative process. Keywords were contributed from group discussions and refined to inform the development of a preliminary search strategy in Ovid Embase to note the scale of the study. The preliminary search strategy was refined by the panel and a full search performed in: Ovid Embase, Ovid EmCare, Ovid Medline, BMJ Best Practice, EBSCO CINAHL, Proquest PsycINFO, UpToDate, TRIP Pro, Cochrane, and British Nursing Index (see Table S1). A list of grey literature sources is shown (Table S2). A combination of free text terms and database-specific headings were used, including identifying keywords and index terms tailored to each information source. The electronic search strategies were peer reviewed in accordance with the PRESS Peer Review of Electronic Search Strategies: 2015 Guideline Statement [34].

2.4 | Screening

All articles found were transferred to RAYYAN software [35] and deduplicated where necessary using the criteria of 96% overall RAYYAN similarity and 100% DOI similarity. Title/abstract screening was undertaken independently by two reviewers using inclusion and exclusion criteria (see Table 2), discussing discrepancies where conflict arose with a third and/or fourth reviewer. Included abstracts were categorized by life course stage themes. Full text screening was undertaken independently by reviewers in pairs.

TABLE 2 | Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
• Women aged 18–45 years • Participant taking incretin-based medications either as mono- or combined pharmacotherapy (specifically exenatide, lixisenatide, dulaglutide, liraglutide, semaglutide, tirzepatide)[a] • Study outcomes include reproductive health outcomes as per research questions.	• Women aged < 18 or > 45 years • Studies about men or male fertility • Incretin-based medications not taken. • Study outcomes do not include reproductive health outcomes as per research questions.

[a]Due to albiglutide being withdrawn from the market in 2018, studies focused on albiglutide were not included in final evidence synthesis.

Grey literature including guidelines, clinical trials, and blogs was screened separately by two reviewers independently. Clinical trial registries were searched, and protocols were considered within the review screening process. In addition to database searching, backward and forward citation tracking on the included articles was conducted, in addition to authors identifying relevant papers (i.e., snowballing).

2.5 | Charting and Summarizing the Data

Data were extracted from the included full text articles by two independent reviewers from each life stage group, using a predefined and tested data collection proforma developed by the group. The data collection form contained information on key study characteristics (e.g., author, year of publication), design and methods (e.g., population characteristics, inclusion criteria), exposure, outcome measures and results. Further details were obtained from manuscript authors where necessary.

For quantitative data, descriptive analyses in the form of percentages and frequency counts were presented within tables, accompanied by narrative summaries. The level of evidence was classified using a standardized approach [36], commonly used in the development of obstetric-related clinical guidelines [37, 38] (see Table 3). Grey literature was only used to answer research questions where clinical research articles were not available. Likewise, animal and ex vivo studies were only included if there was no equivalent human study data. Animal and ex vivo studies were not included in the level of evidence assessment.

TABLE 3 | Classification of evidence levels [36, 37].

Level	Source of evidence
1++	High-quality meta-analyses, systematic reviews of randomized controlled trials or randomized controlled trials with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of randomized controlled trials or randomized controlled trials with a low risk of bias
1−	Meta-analyses, systematic reviews of randomized controlled trials or randomized controlled trials with a high risk of bias
2++	High-quality systematic reviews of case–control or cohort studies or high-quality case–control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case–control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2−	Case–control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytical studies, e.g., case reports, case series
4	Expert opinion

2.6 | Making Consensus Recommendations

Evidence from included studies was discussed at the in-person meeting. Draft recommendations for each research question were written by each life course stage group, taking into consideration the balance of benefits and risks of treatment, quality, quantity, and consistency of evidence, clinical impact, resources, feasibility, and equity [36]. When evidence was lacking, consensus recommendations based on expert clinical experience were made. Research recommendations were also made where gaps existed [36, 37]. The final recommendations were reviewed by all authors, in addition to input from public representatives from Belgium and the United Kingdom.

The protocol was published on Open Science Framework [39]. The conduct and findings of the scoping review were reported in accordance with the PRISMA Extension for Scoping Reviews (PRISMA-ScR) [40] (see Table S3).

3 | Results

3.1 | Literature Search Results

Search results are shown in the PRISMA flowchart (Figure S1). The initial search yielded 41,33 and 9 articles from databases. After removal of duplicates, 7631 remained. After title and abstract screening, 127 full text articles were retrieved and 34 included in the final evidence synthesis (see Tables 4 and 5).

3.2 | Study Characteristics

Of the final 34 articles included, there were 11 randomized trials [44, 46–48, 54–57, 61, 64, 69], nine observational studies [20–23, 26, 43, 50, 52, 60], two pharmacovigilance review studies [62, 68], nine case report/case series [41, 42, 45, 49, 53, 58, 59, 65, 66], two animal studies [63, 67] and one ex vivo study [51]. No qualitative studies were identified. One study was a conference abstract [53]. No other grey literature was included in the final evidence synthesis.

Studies were primarily focused on high-income countries or regions, namely, Europe, the United States, Australia, and the Middle East. The incretin-based medications investigated were exenatide, dulaglutide, semaglutide, liraglutide, and tirzepatide. Some studies analyzed incretins-based medications as a composite group. No studies reported on tirzepatide exclusively, although one conducted post hoc analyses on tirzepatide exposure in pregnancy [22]. Most studies related to preconception/pregnancy usage; two specifically about contraception [44, 69]. Three studies reported data about exposure throughout pregnancy [23, 53, 59]. The sample size of exposed pregnancies/intervention with GLP-1RAs ranged from $n = 1$ (case reports) to $n = 4267$ in an observational study using registry data [22]. Three studies investigated postpartum usage [26, 47, 48]; one specifically related to lactation/breastfeeding

TABLE 4 | Included studies.

First author, year Country	Title	Study design	Level of evidence	Funding source	Research questions
Alghamdi et al. [41], 2023 Saudi Arabia	A Case Report of a Pregnant Woman With Type 2 Diabetes Mellitus Using Dulaglutide During the First Trimester of Pregnancy	Case report	3	No external funding	2a
Burlina et al. [42], 2023 Italy	A Case Report on use of Dulaglutide During the First Weeks of Pregnancy in Woman Affected by Type 2 Diabetes Mellitus	Case report	3	No funding reported	2a
Cesta et al. [21], 2024 Sweden, Iceland, Finland, Norway, Israel, and the United States	Safety of GLP-1 Receptor Agonists and Other Second-Line Antidiabetics in Early Pregnancy	Observational population-based cohort study	2+	EU H2020, NICHD, Research Council of Norway, NordForsk Nordic Program on Health and Welfare	2a, 2b
Choi et al. [43], 2021 Korea	Pregnancy Outcomes After Exposure to GLP-1 Receptor Agonists	Observational study	2−	No external funding	2b, 2c
Dao et al. [20], 2024 Germany, Israel, Italy, Switzerland, and the United Kingdom	Use of GLP1 Receptor Agonists in Early Pregnancy and Reproductive Safety: A Multicentre, Observational, Prospective Cohort Study Based on the Satabases of Six Teratology Information Services	Observational, prospective cohort study.	2+	Swiss National Science Foundation grant number SNSF 320030_214844	2a, 2b, 3g
De La Pena et al. [44], 2017 United States	No Dose Adjustment Is Recommended for Digoxin, Warfarin, Atorvastatin or a Combination Oral Contraceptive When Coadministered With Dulaglutide	Randomized trial with two treatment phases	1−	Eli Lilly	1c
Diab et al. [26], 2024 United States	Subcutaneous Semaglutide During Breastfeeding: Infant Safety Regarding Drug Transfer Into Human Milk	Observational study	2−	Laura W. Bush Institute for Women's Health at Texas Tech University Health Sciences Center grant 16OCT2023	4a
Dogan et al. [45], 2024 Turkey	Case Series: Exposure to Glucagon-Like Peptide-1 Receptor Agonist in the First Trimester of Pregnancy in Two Siblings	Case series	3	No external funding	2a
Elkind-Hirsch et al. [46], 2008 United States	Comparison of Single and Combined Treatment With Exenatide and Metformin on Menstrual Cyclicity in Overweight Women With Polycystic Ovary Syndrome	Randomized open label trial	1+	Amylin Pharmaceuticals Inc./Eli Lilly Corp	1d, 1g

(Continues)

TABLE 4 | (Continued)

First author, year Country	Title	Study design	Level of evidence	Funding source	Research questions
Elkind-Hirsch et al. [47], 2020 United States	Postpartum Treatment With Liraglutide in Combination With Metformin Versus Metformin Monotherapy to Improve Metabolic Status and Reduce Body Weight in Overweight/Obese Women With Recent Gestational Diabetes: A Double-Blind, Randomized, Placebo-Controlled Study	Double blind randomized controlled trial	1−	Novo Nordisk	4d, 5b, 5c
Foghshaard et al. [48], 2024 Denmark	Liraglutide Treatment for the Prevention of Glucose Tolerance Deterioration in Women With Prior Gestational Diabetes Mellitus: A 52-Week Randomized Controlled Clinical Trial	Double blind randomized controlled trial	1+	Novo Nordisk,the Novo Nordisk Foundation, Danish Diabetes Academy, A.P. Moller Foundation and Danielsen Foundation.	5b, 5c
Greco et al. [49], 2015 Italy	Normal Pregnancy Outcome After First-Trimester Exposure to Liraglutide in a Woman With Type 2 Diabetes	Case report	3	No external funding	2a
Hanif et al. [50], 2025 United States	Efficacy and Safety of Glucagon-Like Peptide-1 Receptor Agonist Use During the First Trimester in Pregnant Women With Type 2 Diabetes	Retrospective electronic health record study	2+	None reported	2a, 3e
Hiles et al. [51], 2003 United States	Ex Vivo Human Placental Transfer of the Peptides Pramlintide and Exenatide (Synthetic Exendin-4)	Ex vivo human study	NC	Amylin pharmaceuticals	2b
Hviid et al. [52], 2024 Denmark	GLP-1 Receptor Agonist Treatment in Early Pregnancy and Risk of Pregnancy Complications—A Nationwide Cohort Study (Abstract)	Observational cohort study	2−	Not stated	1b, 2a,2c
Imbroane et al. [22], 2025 United States	Preconception and Early Pregnancy Use of GLP-1 Receptor Agonists in Women With Diabetes—AJOG	Retrospective cohort study	2+	Not stated	1b, 2a, 3e, 3g
Ivanisevic et al. [53], 2018 Croatia	Pregnancy Outcome and Liraglutide Levels in Serum and Umbilical Vein Blood of a Woman With Type 2 Diabetes. A Case Report	Case report	3	Not stated	2a, 2b, 2c

(Continues)

TABLE 4 | (Continued)

First author, year Country	Title	Study design	Level of evidence	Funding source	Research questions
Jensterle et al. [54], 2014 Slovenia	Short-Term Combined Treatment With Liraglutide and Metformin Leads to Significant Weight Loss in Obese Women With Polycystic Ovary Syndrome and Previous Poor Response to Metformin	Randomized open label trial	1–	Grant number 20120047 of the University Medical Center Ljubljana, Slovenia.	1d
Jensterle et al. [55], 2015 Slovenia	Short Term Monotherapy With GLP-1 Receptor Agonist Liraglutide or PDE 4 Inhibitor Roflumilast Is Superior to Metformin in Weight Loss in Obese PCOS Women: A Pilot Randomized Study	Randomized open label trial	1–	Ministry of Health Republic of Slovenia, Tertiary Care Scientific Grant Number 20120047	1d
Kolding et al. [23], 2025 Denmark	Pregnancy Outcomes After Semaglutide Exposure	Observational cohort study	2–	Novo Nordisk foundation	2a, 2c
Kothare et al. [23], 2012 United Kingdom	Effect of Exenatide on the Pharmacokinetics of a Combination Oral Contraceptive in Healthy Women: An Open-Label, Randomised, Crossover Trial	Randomized open label study	1–	Amilyn Pharmaceuticals and Eli Lilly	1c
Li et al. [56], 2022 China	Effect of Metformin and Exenatide on Pregnancy Rate and Pregnancy Outcomes in Overweight or Obese Infertility PCOS Women: Long-Term Follow-Up of an RCT	Follow up of randomized controlled trial	1–	National Natural Science Foundation of China (No. 81200607) and Initial Funds of The Third Affiliated Hospital of Guangzhou Medical University (No. 2017B11)	1e, 1g
Liu et al. [57], 2017 China	Efficacy of Exenatide on Weight Loss, Metabolic Parameters and Pregnancy in Overweight/Obese Polycystic Ovary Syndrome	Randomized open label study	1–	The National Natural Science Foundation of China (No. 81200607) and the project of the Key Laboratory for Major Obstetric Diseases of Guangdong Higher Education Institutes (No. 2012Z05).	1d, 1g, 1h
Livadas et al. [58], 2020 Greece	Liraglutide Administration Improves Hormonal/Metabolic Profile and Reproductive Features in Women With HAIR-AN Syndrome	Case series	3	No external funding	1d, 1g

(Continues)

TABLE 4 | (Continued)

First author, year Country	Title	Study design	Level of evidence	Funding source	Research questions
Molteni et al. [59], 2024 Italy	Use of Dulaglutide in a Pregnant Woman With Type 2 Diabetes Until Third Trimester of Pregnancy	Case study	3	Open access funding provided by Università degli Studi di Pavia within the CRUI-CARE Agreement.	2a, 2c, 3e
Morton et al. [60], 2025 Australia	Pregnancy Outcomes After Incretin Use: A Cohort Analysis	Retrospective cohort study/case series	3	No external funding	2a, 3e
Nylander et al. [61], 2017 Denmark	Effects of Liraglutide on Ovarian Dysfunction in Polycystic Ovary Syndrome: A Randomized Clinical Trial	Randomized clinical trial	1−	Novo Nordisk and Danish Toyota Foundation	1d
Parker et al. [62], 2025 Europe and the United States	Glucagon-Like Peptide 1 (GLP-1) Receptor Agonists' Use During Pregnancy: Safety Data From Regulatory Clinical Trials	Review of regulatory clinical trials prior to market authorisation	2+	No external funding	2a
Qiao et al. [63], 2024 United States	Maternal GLP-1 Receptor Activation Inhibits Fetal Growth	Animal study in mice	3	NIH Grants R21HD112143 (to J.S.), R21HD111199 (to J.S.), R21HD107869 (to J.S.), DK095132 (to J.S.), and DK113007 (to J.S.)	2b, 2c, 3b
Salamun et al. [64], 2018 Slovenia	Liraglutide Increases IVF Pregnancy Rates in Obese PCOS Women With Poor Response to First-Line Reproductive Treatments: A Pilot Randomized Study	Randomized open label pilot study	1−	University Medical Center, Ljubljana. Slovenia, grant number 20140031.	1d,1e, 1h
Skov et al. [65], 2023 Denmark	Semaglutide and Pregnancy	Case report	3	No external funding	2a, 2c
Williams et al. [66], 2009 United States	Case Report: Exenatide Use During Pregnancy	Case report	3	Not stated	2a, 3e
Zhang et al. [67], 2025 China	Semaglutide Ameliorates Metabolic Disorders in Offspring via Regulation of Oocyte ROS of Pre-Pregnancy Obesity Mice	Animal study in mice	NC	No external funding	5g
Zhou et al. [68], 2025	The Safety Profile of Usage of Glucagon-Like Peptide-1 Receptor Agonists in Pregnancy: A Pharmacovigilance Analysis Based on the Food and Drug Administration Adverse Event Reporting System	Pharmacovigilance registry report	2−	No external funding	2a

Abbreviation: NC = not classifiable.

TABLE 5 | Narrative summary of results.

Lifestage 1: Preconception/fertility	
Research question	**Narrative summary of evidence**
1a. How should side-effects of incretin-based medications be managed in the preconception period?	No scientific literature met the inclusion criteria for this research question.
1b. Does preconception use of incretin-based medications reduce the risk of GDM and other perinatal complications?	Imbroane et al.'s [22] retrospective cohort study using US electronic health records found a significant reduction in risk for GDM, preterm birth and hypertensive disorders of pregnancy in those who had a prescription for a GLP-1RA in the 24 months preceding pregnancy compared with no prescription, when matched on age, race, ethnicity and co-morbid conditions (evidence level 2+). Similarly, Hviid et al.'s study [52] using a Danish registry reported a liraglutide prescription ±8 weeks from last menstruation ($n = 93$) was associated with a higher risk of pre-eclampsia, GDM, preterm birth and having a LGA infant (evidence level 2−). However, using a propensity score matching method, there was no evidence of increased risk, indicating liraglutide is not driving the increased risk, but the indication for a GLP-1RA prescription (e.g., diabetes or obesity) is the causal factor.
1c. Is there clinically relevant drug–drug interactions between hormonal contraception and incretin-based medications? What should be advised about contraception and the use of incretins and is this acceptable to users?	Two relevant studies were identified. Kothare et al. [69] investigated the effect of exenatide on the pharmacokinetics of a combination oral contraceptive ($n = 32$), concluding that the oral contraceptive (levonorgestrel 150 μg ethinylestradiol 30 μg) should be taken at least 1 h before exenatide (evidence level 1−). In contrast, de La Pena [44] reported that dulaglutide did not have a clinically significant effect on the absorption of an oral contraceptive (containing 0.25 mg norgestimate and 0.035 ethinylestradiol) (evidence level 1−). No scientific literature was found about the acceptability of contraception advice given to those using incretins or how this advice is perceived or implemented.

(Continues)

TABLE 5 | (Continued)

Lifestage 1: Preconception/fertility	
Research question	**Narrative summary of evidence**
1d. What are the effects of incretin-based medications on clinically and biochemically relevant markers of fertility? (e.g., luteinising hormone, follicle stimulating hormone, oligomenorrhea, anti-mullerian hormone)	All the studies identified for this research question were in women with PCOS. Jensterle et al. [54] found no statistically significant changes in menstrual frequency when women living with PCOS and obesity ($n=36$) were randomized to receive liraglutide for 12 weeks, either alone or in combination with metformin (evidence level 1−). A subsequent randomized study, however, found increased menstrual frequency among women living with PCOS and obesity ($n=45$) when treated with liraglutide for 12 weeks [55]. Liraglutide monotherapy did not improve reproductive endocrine biomarkers in either study. Nylander et al. [61] compared liraglutide with a placebo for 26 weeks ($n=65$), surmising that menstruation may be regulated by change in BMI, rather than any direct effect of liraglutide, since the study drug-effect became non-significant when BMI was added to the model (evidence level 1−). Liu et al. [57] randomized 176 participants with PCOS to either metformin or exenatide for 12 weeks (followed by 12 weeks of metformin monotherapy) showing reduced insulin resistance (over time and relative to metformin), increased menstrual frequency (over time and relative to metformin) and increased natural pregnancy rate (relative to metformin) (evidence level 1−). Similarly, Elkind-Hirsch et al. [46] randomized 60 women with overweight and PCOS to exenatide alone, metformin alone or a combination, for 24 weeks (evidence level 1+). They reported increased menstrual frequency and ovulation in all groups but better outcomes for the combination therapy.
1e. Does the preconceptual use of incretin-based medications enhance outcomes from assisted fertility therapies (including reaching BMI cut-off points when these are used for eligibility as in the United Kingdom National Health Service)?	Salamun et al. [64] found that combined liraglutide and metformin treatment for 12 weeks ($n=27$) prior to assisted reproduction treatment (ART) improved pregnancy rate per embryo transfer versus metformin alone (85.7% vs. 28.6%, $p=0.03$) (evidence level 1−). A randomized controlled trial of women in China with PCOS and infertility ($n=160$) [56] compared treatment with exenatide to metformin for 12 weeks, followed by metformin monotherapy for 12 weeks, prior to ART (if required) (evidence level 1−). At Week 24, 29.2% of the exenatide group conceived spontaneously compared with 14.7% of the metformin group ($p=0.03$). At Week 64, total pregnancy rates were 79.2% and 76% in the exenatide and metformin groups, respectively ($p=0.65$).
1f. How do incretin-based medications affect nutritional status (e.g., vitamin B12, folate, fat-soluble vitamins) in women of reproductive age?	No scientific literature met the inclusion criteria for this research question.
1g. What anthropometric and clinical criteria should guide the selection of women for incretin analog therapy in the preconception period to optimize reproductive and metabolic outcomes?	The evidence for benefit in usage of incretins comes from five studies in women with obesity and PCOS: Elkind Hirsch et al. (evidence level 1+) [46], Li et al. (evidence level 1−) [56], Liu et al. (evidence level 1−) [57], Salamun et al. (evidence level 1−) [64] and Lividas et al. (evidence level 3) [58]. All showed positive effects on reproductive outcomes; however, none had a comparator group without PCOS and/or with a BMI in the recommended range.

(Continues)

TABLE 5 | (Continued)

Lifestage 1: Preconception/fertility	
Research question	**Narrative summary of evidence**
1h. What is the optimal duration of incretin-based medication use in the preconception period to achieve metabolic and reproductive benefits without delaying conception attempts?	As mentioned above (1e), Salamun et al. [64] suggests benefits on pregnancy rate after of combined metformin and liraglutide after a short 12-week pre-ART window (evidence level 1−). This is supported by Liu et al. [57], who showed meaningful metabolic and pregnancy benefits after 12 weeks of exenatide (followed by up to 12 weeks of metformin monotherapy), reporting a natural pregnancy rate of 43.6% in the exenatide group, compared with 18.7% in a metformin monotherapy group ($p < 0.05$) (evidence level 1−).
1i. How should nutritional supplementation and dietary monitoring be tailored during and after incretin therapy in preconception care?	No scientific literature met the inclusion criteria for this research question.
Lifestage 2: Pregnancy (fetal considerations)	
Research question	**Narrative summary of evidence**
2a. Can incretin-based medications safely be continued during pregnancy?	Eighteen studies included in this review report on pregnancies exposed to incretins during pregnancy, mostly inadvertently and during the first trimester only. This includes in total an estimated 1538 exposed pregnancies. Overall, studies do not report an increased risk of major congenital malformations (MCM) following exposure to incretin medications. In large, multinational, population based, retrospective cohorts including $n = 938$ [21] (evidence level 2+) and $n = 163$ (evidence level 2+) [20] GLP-1RA-exposed pregnancies, the risk for MCM was comparable to insulin-exposed pregnancies. Similar findings have been replicated in single country registry studies in Denmark [23] (evidence level 2−) and Korea (evidence level 2−) [43] and in case reports [41, 42, 45, 49, 65, 66] (evidence level 3). Parker et al. [62], using regulatory data of inadvertent pregnancies from multinational clinical trials, reported an incidence of congenital anomalies of 5.3% in the placebo group and 2.7% in the GLP-1RA exposure group ($n = 111$ exposed) (evidence level 2+). Electively terminated pregnancies were 13% in both groups. Although the rate of spontaneous abortions was higher in the exposed group (22% vs. 13%), the rate of nonviable pregnancies, including spontaneous abortions, stillbirths and ectopic pregnancies, was very similar (25.2% and 26.3% in the exposed and placebo groups, respectively). Dao et al. [20] reported no increased risk of pregnancy losses in the GLP-1RA versus the reference groups with diabetes mellitus and overweight/obesity, in both crude and adjusted analyses in a multinational study (evidence level 2+). Three studies report exposure throughout pregnancy [23, 53, 59], with no occurrence of congenital anomalies, however, the number of exposures throughout pregnancy was very small ($n = 16$) (evidence level 3).
2b. What is the transplacental passage of different incretin-based medications? To what extent do incretin-based medications bind GLP-1 receptors on the placenta, and what are the consequences for fetal growth and glucose metabolism?	Human data on placental transfer of GLP-1 receptor agonists remain limited. Evidence from an ex vivo placental perfusion model (exenatide) [51] (evidence level not classified) and cord blood analyses of liraglutide [53] suggests minimal transplacental passage (evidence level 3) [67]. No human information could be found related to whether incretin medications affect placental metabolism and/or accumulate within placental tissue.

(Continues)

TABLE 5 | (Continued)

Lifestage 2: Pregnancy (fetal considerations)	
Research question	**Narrative summary of evidence**
2c. What are the implications of incretin-based medication use (before/during pregnancy) on fetal (growth) monitoring?	Most of the pregnancy exposures to incretin-based medications are either during the periconception period, and at the latest early in the first trimester, with women discontinuing treatment when pregnancy was recognized. There are single case reports [53, 59] (evidence level 3) and cohort subgroups reporting use throughout pregnancy ($n = 14$) (evidence level 2–) [23]. Hviid et al.'s [52] study of liraglutide exposed pregnancies ($n = 93$) determined using propensity matched scoring that higher birth weight in incretin exposed pregnancies is associated with maternal metabolic status, rather than the medication itself (evidence level 2–).
Lifestage 3: Pregnancy (maternal considerations)	
Research question	**Narrative summary**
3a. Does the use of incretins provoke changes in maternal nutritional status?	No scientific literature met the inclusion criteria for this research question.
3b. What is the impact of body composition changes (e.g., loss of lean mass (muscle and bone) vs. fat mass) during GLP-1RA therapy on maternal health during pregnancy?	No evidence from human studies was identified for this research question. A study in mice by Qiao et al. [63] found no significant alterations in maternal body weight or fat mass when semaglutide was injected daily in later pregnancy (evidence level not classified).
3c. How should nutritional supplementation and dietary monitoring be tailored during and after incretin-based therapy in pregnancy care?	No scientific literature met the inclusion criteria for this research question.
3d. Does the use of incretin-based medication provoke profound changes in maternal glucose metabolism, warranting adapted glucose monitoring during pregnancy? Is there any evidence on use of incretins being used in GDM?	There is limited evidence on the effect of preconception use of incretin-based medication on maternal glucose metabolism during pregnancy. Moreover, no studies have evaluated whether their use or discontinuation influences the diagnostic accuracy or interpretation of GDM screening during pregnancy.

(Continues)

TABLE 5 | (Continued)

Lifestage 3: Pregnancy (maternal considerations)	
Research question	**Narrative summary**
3e. Does (previous) incretin-based medication use alter the risk for the development of hypertensive disorders during pregnancy?	Hanif et al. [50] found gestational hypertension was comparable in the GLP-1RA-exposed cohort compared with the control cohort after 42 weeks of follow-up (evidence level 2+). Imbroane et al. [25] reported a reduced risk of hypertensive disorders of pregnancy (OR 0.84, 95% CI, 0.76–0.94) for those exposed to GLP-1RAs 2 years prior to pregnancy, when matched for age, ethnicity, T2DM history, primary hypertension, overweight or obesity (evidence level 2+). Molteni et al. [59] described a single case study who developed gestational hypertension following treatment with dulaglutide and metformin until the 34th gestational week (evidence level 3), as did one individual in an Australian retrospective case series [60] (evidence level 3); both of whom had T2DM.
3f. Does the use of incretin-based medication alter maternal GWG patterns? Is excessive/insufficient weight gain associated with adverse outcomes?	No scientific literature met the inclusion criteria for this research question.
3g. Does the (previous) use of incretin-based medication have any impact on the onset of labor and method of birth (timing/other factors)?	No scientific literature was identified for onset of labor. Caesarean delivery was an outcome reported by Imbroane et al. [22], finding a reduced risk of caesarean delivery in the GLP-1RA exposed group (17.6% vs. 19.7%) and specifically a reduced risk in the tirzepatide exposed subgroup ($n = 426$) (9.6% vs. 16.2%, OR, 0.55; 95% CI,0.37–0.83) (evidence level 2+). In contrast, rates of assisted delivery and caesarean delivery were not significantly different in the GLP-1RA exposed group, diabetes group and overweight/obesity group (46.4%, 49.6%, and 44.4%, respectively) in the multinational study by Dao et al. (evidence level 2+) [20].
3h. What are women's perceptions of use of incretin-based medication during pregnancy?	No scientific literature met the inclusion criteria for this research question.

(Continues)

TABLE 5 | (Continued)

Lifestage 4: Early postpartum and lactation considerations	
Research question	**Narrative summary**
4a. What are the pharmacokinetics of incretin-based medication in relation to breastmilk, and can incretins be safely used during lactation?	Only one human clinical lactation study on GLP-1RA during breastfeeding was identified [26]. In this study of eight participants, semaglutide was not detected in human milk samples collected at 0, 12, and 24 h following weekly subcutaneous administration of 0.25–1 mg semaglutide (evidence level 2−). No adverse effects on infant growth were reported. Most of the participants were more than 6 months postpartum. Milk production and composition were not assessed.
4b. What are the nutritional requirements for women who are breastfeeding and using incretin-based medications and their nursing infants?	No scientific literature met the inclusion criteria for this research question.
4c. What are the short-term nutritional and metabolic risks for women who are breastfeeding and using incretin-based medications and their nursing infants?	No scientific literature met the inclusion criteria for this research question.
4d. How does postpartum use of incretin-based medications affect maternal weight change and does this differ between breastfeeding and non-breastfeeding individuals?	One study was found on postpartum weight change, but breastfeeding mothers were excluded (evidence level 1−) [47]. Further details are shown under research quesion 5c.
Lifestage 5: Long term postpartum implications for offspring and mother	
Research question	**Narrative summary**
5a. When preconception incretin-based therapy for diabetes/obesity is stopped before pregnancy or during pregnancy, should it be restarted after pregnancy and when?	No scientific literature met the inclusion criteria for this research question.
5b. Does postpartum use of incretin-based medication enhance resolution of GDM and/or hypertensive disease of pregnancy?	Two randomized controlled trials assessed the effect of liraglutide on outcomes in people with previous GDM. Results showed that insulin sensitivity significantly improved, as did glucometrics in women up to 1 year postpartum (n =153) treated with liraglutide added to metformin compared with placebo as (evidence level 1−) [47]. No consistent changes in systolic nor diastolic blood pressure were seen with any treatment in this group of participants without hypertension. Foghsgaard et al. [48] investigated the effect of a 52-weeks of liraglutide on glucose tolerance ($n = 104$) (evidence level 1+). The mean duration since the index pregnancy was 5 years. The primary outcome, change in glucose tolerance from baseline to 1 year, significantly improved with liraglutide treatment. However, after wash-out of the intervention, the effect returned to baseline level indicating a medication-dependent rather than a persistent effect. No differences were found in cardiovascular parameters.

(Continues)

TABLE 5 | (Continued)

Lifestage 5: Long term postpartum implications for offspring and mother	
Research question	**Narrative summary**
5c. Does postpartum use of incretin-based medication prevent long-term maternal weight retention and regain?	The same two studies referenced in question 5b provided evidence for this research question. Elkind-Hirsch et al. [47] reported combined liraglutide and metformin therapy was significantly better than metformin monotherapy (mean weight loss 7.2% versus 3.1% respectively, $p = 0.048$) (evidence level 1−). Similarly, Foghsgaard et al. reported that treatment with liraglutide significantly lowered body weight (end-of-treatment difference of 3.9 kg at 52 weeks, $p = 0.012$) (evidence level 1+) [48].
5d. What is the impact of stopping incretin-based medication before/during pregnancy on long term maternal weight regain/retention?	No scientific literature met the inclusion criteria for this research question.
5e. If incretin-based medication pass the placenta, are there any possible long term postnatal effects on offspring from in utero exposure?	No scientific literature met the inclusion criteria for this research question.
5f. Does preconception incretin-based treatment for diabetes reduce future metabolic disease risk in the mother and in the offspring?	No scientific literature met the inclusion criteria for this research question.
5g. Does preconception-based incretin treatment for obesity reduce future metabolic disease risk in the mother and in the offspring?	No human evidence was identified for this research question. An animal study by Zhang et al. [67] found that semaglutide treatment for 22 days in a pre-pregnancy obesity mice model significantly reversed the excess weight, impaired glucose tolerance and increased serum cholesterol levels of their offspring (evidence level not classified).
Theme 6: Multidisciplinary working	
Research question	**Narrative summary**
6a. What is the role of multidisciplinary care (endocrinology, reproductive medicine, dietetics, psychology) in managing incretin analog use in women of reproductive age?	No scientific literature met the inclusion criteria for this research question.

[26]. Only one study (an animal study) [63] included offspring data beyond birth.

Direct evidence was found in relation to 18 of the 32 (56.3%) research questions; for two of these, only animal evidence was available. See Table 4 for an overview of included studies and Table 5 for a narrative summary of results. Details of data extraction are in Table S5.

4 | Discussion

Based on best available evidence, this collaborative project has established recommendations for clinical practice related to the use of incretin-based medications in women of reproductive age before, during, and after pregnancy. However, the current contraindication for use of incretin-based medications in pregnancy and the relative novelty of these medications in the management of obesity meant that evidence was wholly lacking for 14 of 32 (43.8%) research questions. The retrospective nature of studies, coexistence of PCOS in the preconception population and T2DM in the pregnant population being examined further complicates the ability to draw firm conclusions. Where evidence did exist, it was based on inadvertent exposure, with a lack of prospective and/or randomized controlled trials, and an absence of qualitative research. As such, where gaps in evidence from human studies were noted, research recommendations are made.

4.1 | Contraception

The studies included in this review examined the pharmacokinetics of exenatide [69] and dulaglutide [44] in relation to oral contraceptives. Other studies that investigated semaglutide [70] and liraglutide [71], were excluded, as participants were postmenopausal women. Their findings were similar to Kothare [69] and de la Peña [44], reporting no significant interaction between semaglutide or liraglutide and oral contraceptives. A later review by Skelley et al. [72] concluded that tirzepatide reduced the bioavailability of oral hormonal contraceptives compared with other GLP-1RAs, due to its rapid dose escalation and greater delay in gastric emptying. As such, current guidance from the UK College of Sexual and Reproductive Healthcare [18] recommends that individuals should be advised to use contraception while using GLP-1RA, whereas those using tirzepatide and oral contraception should switch to a non-oral contraceptive method, or add a barrier method of contraception, for 4 weeks after initiation and for 4 weeks after each dose increase; but there is no need to add a barrier method of contraception when using semaglutide, dulaglutide, exenatide, lixisenatide, or liraglutide. They also provide specific advice for people who experience severe diarrhea or vomiting during the use of GLP-1RAs. Of note, no evidence was found about the acceptability of contraceptive advice provided, nor about current washout periods recommended by manufacturers prior to conception.

4.2 | Fertility

Most of the current available evidence examining the effect of incretin medications on fertility parameters is in women with PCOS [19]. The independent effect of incretins is not clear as the interventions often co-included metformin. Studies tended to focus on older, less effective agents (i.e., liraglutide and exenatide), which were mostly indicated for T2DM and are now less commonly used [46, 54, 55, 57]. A meta-analysis including 11 RCTs and 840 women with PCOS [73] showed overall that GLP-1RAs can improve ovulatory potential indirectly through metabolic and endocrine optimisation, particularly in women with obesity and PCOS. More evidence is needed on the effect of incretin medications on markers of fertility in women living with obesity without PCOS, in addition to those with PCOS, including whether discontinuing incretin-based medication results in reversal of any improvements.

4.3 | Nutritional Aspects

The effect of incretin-based medications on perinatal health may be direct, due to the medication itself, or indirect related to drug-related malnutrition secondary to appetite suppression. With this in mind, seven research questions were included on the nutritional effects of incretin-based medication. No studies were identified on nutritional status, micronutrient supplementation or monitoring in women during the preconception, pregnancy or postpartum phases. This aligns with a recently published scoping review about dietary assessment in incretin treatment [74]. In the 12 studies included of non-pregnant adults receiving semaglutide or tirzepatide, energy intake decreased by 24%–39%; however, systematic assessment of protein or micronutrient intake was rare. Therefore, even though inadequate macro and micronutrient intake is a plausible and highly likely risk of using incretin-based medications, surprisingly little research exists on this topic in the general public, let alone in the specific life stage before, during or after pregnancy. Existing nutrition consensus guidelines provide specific recommendations on macronutrient intakes, management of gastrointestinal side effects and monitoring of micronutrient deficiencies for adults generally [28, 29, 75]. These can be used as a starting point, but are not designed for preconception, pregnancy or postpartum populations, who have specific needs and may be particularly vulnerable to drug-related malnutrition. Studies of those who become pregnant post-metabolic surgery indicate the risk of widespread nutrient deficiencies of vitamins A, B1, B6, B12, C, D, K, iron, calcium, selenium, and phosphorous [76]. Although the impact of metabolic surgery on nutritional status has a different mechanism to incretin-based medications, and it is generally irreversible, metabolic surgery also impacts secretion of gut-derived hormones, including GLP-1 [77]. In the absence of detailed data on the effect of incretin-based medications on the nutrition-related pregnancy outcomes, the post-metabolic surgery patient group may therefore serve as a relevant reference group highlighting the nutritional risks of appetite suppression before and during pregnancy.

4.4 | Pregnancy: Fetal Concerns

The question of whether incretin-based medications can be continued during pregnancy relates strongly to that of whether these medications increase the risk for congenital anomalies in the offspring. The congenital anomaly risk associated with incretin-based

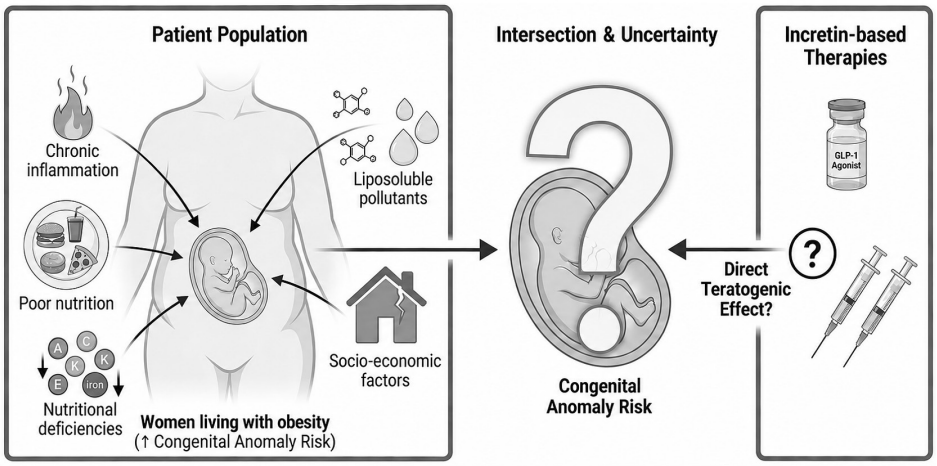

FIGURE 2 | The uncertain relationship between incretin-based therapies, obesity and congenital anomaly risk.

medication use should be differentiated from the baseline risk in the studied population, considering that both maternal obesity and hyperglycemia are associated with an increased risk [78, 79]. Additionally, individuals with obesity and/or diabetes are known to be at risk for micronutrient deficiencies [80]. The co-existence of obesity and food insecurity in pregnancy [81] combined with broader socioeconomic factors may further contribute to poorer pregnancy outcomes. Therefore, the reported risk for congenital anomalies should be interpreted with caution (see Figure 2). Furthermore, this risk could be related to dose, type of medication, and duration and timing of exposure during the embryonic or fetal development, details which are not always available in retrospective studies included in this evidence review [20–22, 52].

Available published human data on incretin-based medication use during the reproductive period are broadly consistent, showing that unintended exposure during the periconception period or in the first trimester does not incur a significant increase in MCMs when compared with insulin-treated T2DM [20, 21, 23, 50]. Ex vivo data show minimal placental transfer of exenatide [51]; however, no human data could be found on whether newer incretin-based medications affect placental metabolism and/or accumulate within placental tissue. Pregnancy outcomes for those who discontinued treatment in the first trimester are reassuring, and adverse outcomes may be explained by maternal comorbidity and environmental factors rather than a side effect of therapy [20, 23, 52]. This contrasts with older animal studies reporting an increased risk of MCM, specifically skeletal anomalies, alongside reduced fetal weight and/or growth [17]. Based on the long half-life of the weekly incretin-based medications, the manufacturers advise to discontinue treatment about 4–8 weeks before conception. Aside from the studies by Parker et al. [62] and Imbraone et al. [22], data on tirzepatide is lacking, noting this is likely to change with time and that newer dual and triple incretin-based medications will be available in the future.

4.5 | Pregnancy: Maternal Concerns

With the exception of one included case study that reported an approximate GWG [59], at the time of conducting the systematic search there were no human data on GWG following incretin use; however, two relevant studies have been published since our searches [82, 83]. In a retrospective cohort study of pregnancies in Massachusetts, United States [82], GLP-1RA exposure pre-pregnancy or discontinuation in early pregnancy was associated with greater GWG and a higher risk of preterm delivery, GDM, and hypertensive disorders of pregnancy, compared with propensity-matched unexposed pregnancies. There was no increased risk of LGA or SGA infants, or caesarean delivery. Similarly, a smaller, single-center study ($n = 243$) found a lower risk of inadequate GWG associated with GLP-1RA use up to 1 year prior to pregnancy, although no significant difference in the risk of excess GWG [83]. These findings may reflect weight regain after GLP-1RA discontinuation, which is well recognized in the general population [84]. It is plausible that the benefits of pre-pregnancy incretin-based medication use on fertility and pregnancy outcomes could be negated or attenuated by medication discontinuation; however, specific evidence on weight trajectories in pregnancy is lacking.

The findings on obstetric outcomes by Maya et al. [82] are in contrast to two other USA-based studies by Hanif [50] and Imbroane [22] included in this review. Maya et al. [82] hypothesize this discrepancy may be due to neither study including insurance status, a socioeconomic indicator and determinant of access to GLP-1RA therapy, in its propensity score model. However, as is the case with many of the retrospective studies, misclassification and timing of the exposure and discontinuity is possible. Hviid et al.'s [52] study using Danish data, also used propensity matching, determining that use of liraglutide pre-pregnancy is not driving the increased obstetric risk, but the indication for a GLP-1RA prescription (e.g., diabetes or obesity) is the potential causal factor.

4.6 | Lactation and Postpartum Outcomes

Concerning safety of use during lactation, only one small study was included in the evidence review [26]. The relatively high molecular weight and extensive protein binding likely explain why semaglutide could not be detected in milk samples in the

study. A non-peer reviewed study published after the systematic search was conducted, examined tirzepatide levels in breastmilk of five lactating women, determining that doses of 2.5–5 mg were not quantifiable in any sample across all participants and time points [85]. These human data do not provide insight into the safety of oral formulations of semaglutide, which contain an absorption enhancer (i.e., sodium salcaprozate) for which no human lactation data are available. Moreover, these agents are protein-based molecules that, if present in breastmilk, would likely undergo proteolytic degradation in the infant gastrointestinal tract. Nevertheless, the endogenous GLP-1 hormone has been detected in human milk, suggesting that the presence of GLP-1RAs could exert biological effects, although the nature of such effects remains unclear. Importantly, the impact of different maternal dose regimens and medication titration schedules on breastmilk composition, maternal nutritional status and infant outcomes remains undetermined. In future clinical lactation studies involving incretin-based medications, particular attention should be given to the calculation of the relative infant dose, as this parameter is less appropriate and requires adjustments for monoclonal antibodies (e.g., dulaglutide, which is bound to an IgG structure) and for parenterally administered medications with low oral bioavailability, extended dosing intervals and prolonged half-lives [86, 87].

Emerging research using prescription data from suggests that GLP1-RAs are being increasingly used postpartum [25, 88]. From a theoretical perspective, the use of incretin-based medications may result in (worsening of) maternal nutritional deficiencies, placing further nutritional risk during a period already characterized by high nutritional demands. Research suggests that many instances of medication-related breastfeeding discontinuation may be avoidable and subject to inconsistent healthcare advice [89]. The use of incretin-based medications in postpartum obesity management therefore needs to be considered on an individual basis. This should take into account the benefits of exclusive breastfeeding for infant health [90] and the knowledge that breastfeeding rates are typically lower in women with obesity due to a number of barriers, such as negative body image and impact of caesarean birth [91].

Currently, the best time to start postpartum treatment for the optimal treatment effect is not known and will also depend on factors such as breastfeeding duration and future pregnancy plans. Examining longer term postpartum implications, it is possible that the use of more potent incretins prolongs the beneficial effects seen in the two included studies [47, 48]. Two planned studies will assess this question [92, 93], but will be using semaglutide, rather than newer more potent treatments, for limited durations and at a sub-optimal dose (of up to 1 mg weekly). Concerning long term postpartum weight retention, cessation of incretin therapy is often followed by rapid weight regain, with a systematic review of 37 studies determining that, in the non-pregnant population, people on average regain weight at a rate of 0.4 kg/month, leading to a projected return to baseline weight after 1.7 years [84]. Similarly, improvements in HbA1c, fasting glucose, total cholesterol, triglycerides, systolic and diastolic blood pressure, all returned to baseline within 1.4 years of treatment cessation. Whether stopping incretin treatment due to pregnancy results in comparable or different long-term weight regain curves and metabolic outcomes after pregnancy is unknown.

No human studies were available describing long term effects of incretin treatment in pregnancy on offspring. Due to the large molecular weight and engineering to bind to albumin with synthetic incretins, it might be that the effects on offspring are indirect effects via the mother using incretin therapy, rather than direct effects of synthetic incretins on the developing fetus via placental or breastmilk transfer.

4.7 | Multidisciplinary Care and Professional Practice

Although some articles outline the importance of individual health care professionals (dietitians, obstetricians/gynecologists) in managing preconception use of GLP-1RAs [94, 95], there were no papers identified that provided specific evidence for multidisciplinary care in this patient group. The role of multidisciplinary team care in management of women with obesity, previous bariatric surgery and/or T2DM in pregnancy is well established by international guidelines [38, 96]. In relation to incretin-based medication us, recent consensus nutrition guidelines on GLP-1RAs recommend referral to a registered dietitian and implementation of intensive behavioral therapy with the support of a multidisciplinary team [29], with other guidelines acknowledging the use of telehealth and/or digital health platforms to engage synchronously with multiple clinicians, including a clinical psychologist and exercise physiologist [30]. The need for health care professional support *before, during, and after* incretin therapy is also recognized [28, 29, 74].

5 | Recommendations

5.1 | Best Practice Recommendations

Based on the available evidence, the following best practice recommendations have been made, noting that this is an emerging area of research. Recommendations are not necessarily based on the highest evidence level classification, but those considered by the expert consensus panel as having the greatest potential impact on care. Figure 3 is a print friendly infographic of key recommendations.

- **Contraception:** Counsel regarding the use of reliable contraception, especially if significant gastrointestinal side effects occur such as vomiting or diarrhea. Specifically, those using tirzepatide will need reliable non-oral contraception.
- **Proactive counseling:** Proactive counseling should be provided on an individual basis to all women regarding the risk of conceiving while using incretin-based medications. Currently, there is no clear evidence to support specific washout periods. If not already discontinued, the medication should be stopped as soon as pregnancy is confirmed. This approach may be considered in selected cases to maintain metabolic benefits, although this approach remains uncertain and the benefits should be carefully balanced against potential fetal risks.
- **Nutrition:** Women of reproductive potential using incretin-based medications should receive dietary counseling to

FIGURE 3 | Print-friendly presentation of best practice recommendations for healthy pregnancies after incretin-based medication use.

optimize nutritional intake and reduce the risk of nutrient deficiencies, alongside physical activity advice. Upon cessation of medication, advice should be provided to mitigate weight regain.

a. Give advice regarding nutrient dense food sources where overall food intake is reduced, to mitigate appetite-driven under-nutrition. This may include suggesting alternatives to foods that are no longer tolerated.
b. Encourage a fiber- and protein-rich diet and adequate hydration as appropriate to manage GI side effects.
c. In line with national and international guidelines, recommend those seeking to conceive take supplemental folic acid and vitamin D and to optimize nutritional status prior to conception wherever possible, bearing in mind that a prenatal multivitamin and mineral supplement may be needed. In the absence of biochemical data, clinical judgment should prevail.
d. For those not seeking to conceive, a general multivitamin and mineral supplement should be recommended.

- **Selection for incretin-based medication therapy:** should prioritize women with greater metabolic burden (i.e., those with PCOS and obesity-related comorbidities) and fertility treatment eligibility needs.
- **Pregnancy:** Incretin-based medication therapy should not be deliberately continued throughout pregnancy. However, for those who have inadvertent exposure during pregnancy, reassurance should be provided that current data shows no increased risk for congenital anomalies following exposure in early pregnancy.
- **Fetal and pregnancy monitoring:**

a. Based on available data, if incretin-based medication *was* discontinued following exposure in early pregnancy, standard obstetric growth surveillance is recommended. Mothers should be directed to register with the appropriate pregnancy exposure registry by contacting the drug company that supplied the medication in question.
b. GWG should be monitored during pregnancy after discontinuation of incretin-based medication.
c. Fetal growth monitoring should be undertaken at least once in the third trimester for women with GWG outside recommendations.
d. Serial fetal growth monitoring is recommended if incretin-based medications are continued during pregnancy/beyond the first trimester.
e. Screening for GDM: When incretin-based medications are discontinued prior to conception, glycaemic testing should be performed according to national guidelines. In case of inadvertent exposure to incretin-based medication, additional glycaemic testing in early pregnancy may be considered to better estimate the risk of GDM.

- **Lactation/breastfeeding:**

a. The use of incretin-based medications during breastfeeding should be assessed on an individual basis, due to lack of evidence. This discussion should balance the well-established benefits of breastfeeding for mother and infant against theoretical risks of infant exposure.
b. If an incretin-based medication is used during breastfeeding, monitor infant growth and developmental milestones and the nutritional status of the lactating woman closely. Maternal micronutrient supplementation and assessment may be required (see nutrition recommendations above).

- **Postpartum use:** incretin-based therapy for women with previous GDM appears to be effective for weight reduction as well as improvement of glycaemic parameters. However, the optimal timing to commence and continue this therapy is unknown and should take into consideration lactation needs.
- **Multidisciplinary team support:** women of reproductive age using incretin-based medication should be supported by a multidisciplinary team, including a registered dietitian. This is particularly relevant for those who are seeking to conceive, during and after pregnancy, and for those who may have other dietary needs.

5.2 | Research Recommendations

The following areas were identified by consensus as needing robust investigation with regard to incretin-based medications and perinatal care.

Preconception

- Exploration of the acceptability, awareness, and adherence to contraception advice among women of reproductive potential using incretin-based medications.
- Further understanding of how side effects of incretin-based medication should be managed to promote medication adherence, optimize nutritional status, and improve preconception health outcomes.
- Assessment of the effect of discontinuation of incretin-based medications prior to conception on rebound (preconceptional and gestational) weight gain, glycemia, and fertility markers.
- Evaluation of incretin-based therapy in women living with obesity and infertility using newer, more effective agents to determine whether fertility treatment BMI thresholds can be reached, in addition to examining whether metabolic improvements increase pregnancy rates.

Pregnancy

- Assessment of micronutrient status and longitudinal changes in women of reproductive potential using

incretin-based medications, particularly focusing on micronutrients important for a healthy pregnancy.

- Human studies regarding the extent of transplacental transfer of the various incretin-based medications.
- Further elucidation of the impact of the binding of incretin-based medications to placental GLP-1 receptors on glycemia, insulin levels, and fetal growth, considering the trimester of exposure.
- Investigation of the molecule-specific and dose-dependent effects of maternal incretin-based medication use during pregnancy on the likelihood of adverse pregnancy and offspring/infant health outcomes (e.g., birth anomalies, miscarriage, stillbirth, small for gestational age, large for gestational age, and gestational age at delivery).

Postpartum

- Assessment of nutritional status, including micronutrient status and body composition of postpartum women using incretin-based medications.
- Exploration of the transfer of incretin-based medications (and excipients in different administration forms) into breast milk, breastmilk composition, infant growth, and developmental outcomes of infants receiving breastmilk during maternal incretin use.
- Assessment of long-term maternal and infant/child health outcomes following perinatal incretin-based medication use.

General

- Investigation of the effect of multidisciplinary health care support before, during and after pregnancy for those using incretin-based medications, including effect on nutritional and reproductive outcomes.
- Assessment of the knowledge, practices, and education needs of health care professionals of incretin-based medications in relation to reproductive health.
- Inclusion of women with lived experience in research on incretin-based medication and reproduction.

5.3 | Strengths and Limitations

The methods used in this scoping review were rigorous, transparent, and followed a defined methodology [32, 34] with systematic searches undertaken by an information specialist, alongside screening and data extraction undertaken by two independent reviewers. As the scoping method seeks to identify all relevant literature regardless of study design, its reach is comprehensive [32]. Classification of evidence levels was assessed using a standardized approach and supported by expert consensus discussion from an international expert multidisciplinary panel. The search considered articles published until the end of July 2025, with more recent studies referenced in the discussion; however, the panel acknowledges this is a fast-moving area of research. Studies about male reproductive health were outside the scope of the guidelines and were not considered.

6 | Conclusion

This systematic scoping review summarizes current evidence on the preconception, pregnancy, and postnatal care of women in relation to incretin-based medications. Consensus-based recommendations on the care of these women are made, alongside research recommendations. Many critical knowledge gaps exist, including uncertainty regarding the need for washout periods prior to conception, the timing of discontinuation of treatment, and the risk of weight regain and associated adverse fertility and obstetric outcomes (including effects on fetal growth), the impact on nutritional status and resultant need for monitoring, the safety of use during breastfeeding/lactation, and the need for long-term follow up. Additionally, qualitative research exploring patient experiences and determining the acceptability of all these aspects is essential. Future research should investigate safety before, during, and after pregnancy, including short- and long-term effects on reproductive health outcomes, incorporating patient and healthcare professionals' viewpoints.

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Conflicts of Interest

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Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Table S1:** Search strategy (EMBASE OVID). **Table S2:** Grey literature and guideline sites. **Table S3:** Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist. **Figure S1:** PRISMA flow diagram. **Table S4:** Data extraction tables for included studies themes 1–3: Fertility/preconception, pregnancy (fetal concerns), and pregnancy (maternal concerns). **Table S5:** Data extraction tables for included studies in themes 4–6: early postpartum and lactation considerations, late postpartum considerations and multidisciplinary team working.