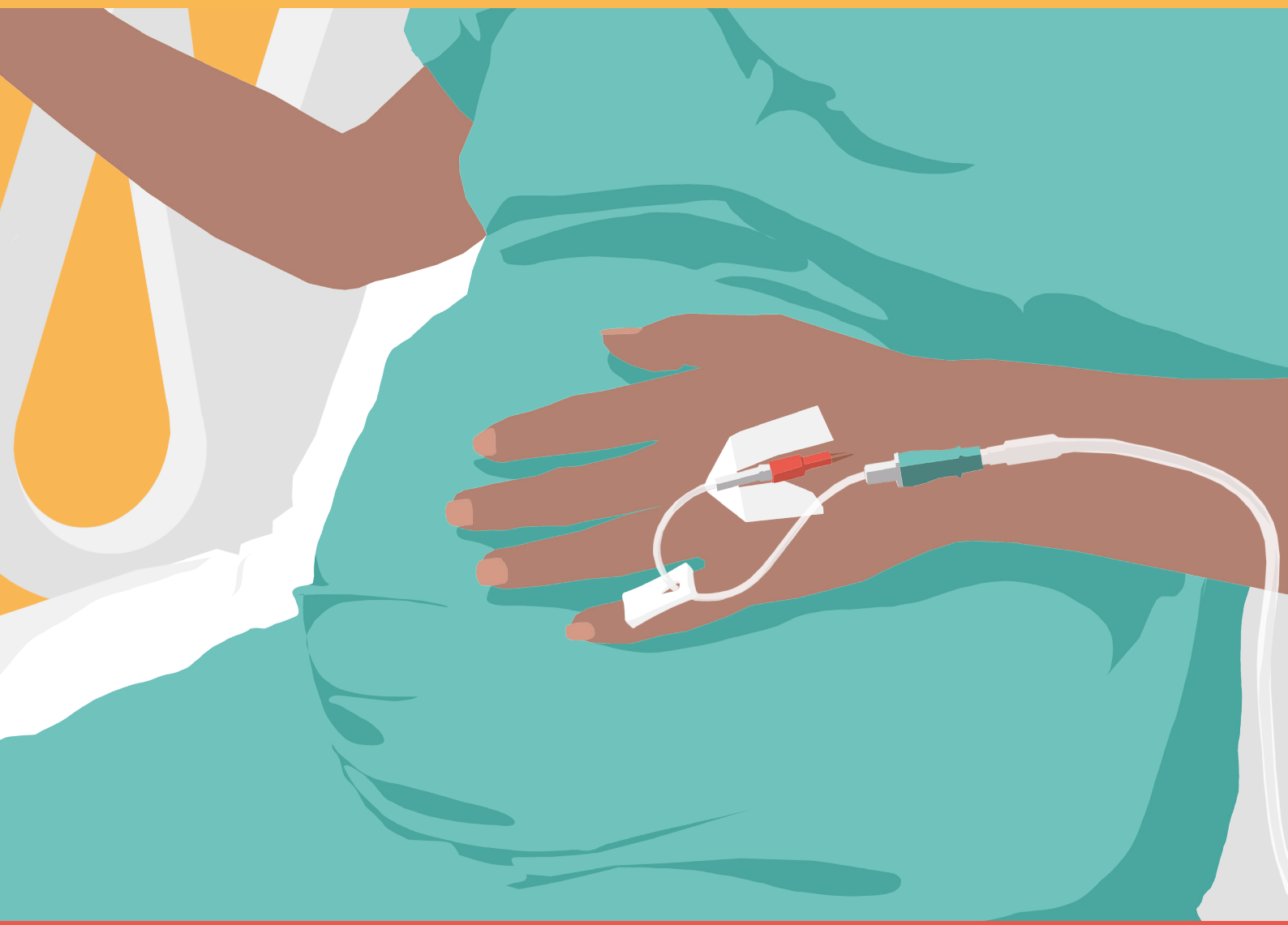
RESEARCH & DEVELOPMENT LANDSCAPE FOR MATERNAL IRON DEFICIENCY ANAEMIA MEDICINES (2000-2023)

JANUARY 2024



AIM
ACCELERATING
INNOVATION FOR MOTHERS

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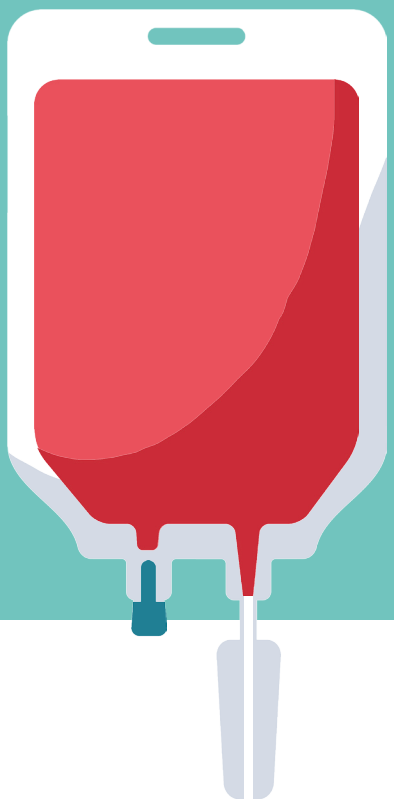


IRON DEFICIENCY ANAEMIA DURING PREGNANCY

An age-old problem with a need for renewed attention

Maternal anaemia is not a new problem. For several years, maternal anaemia has been a major focus of prenatal screening and the subject of international development goals – in 2012, the World Health Assembly committed to halving anaemia prevalence in women of reproductive age by 2025.[1] The impacts of anaemia during pregnancy on maternal and neonatal outcomes are well-documented: anaemia is a risk factor for low birth weight, preterm birth, postpartum haemorrhage, and maternal, perinatal and neonatal mortality.[2] Similarly, the causes of maternal anaemia are well-known, with iron deficiency ranking top of the list.[3] The World Health Organization (WHO) has estimated that 50% of maternal anaemia is iron-responsive, with the figure dropping slightly to 44% in Sub-Saharan Africa.[4]

However, despite concerted sector-wide efforts to address maternal anaemia and the efficacy of iron therapy, the burden of disease continues to be high. According to the WHO, 37% of pregnant women continue to be affected by anaemia.[5] In a 2018 study, researchers estimated that severe anaemia during pregnancy or the postpartum period doubled the risk of maternal death.[6] Moreover, the impacts of the pregnancy-related conditions for which maternal anaemia is a risk factor are significant. Low birth weight and preterm birth are associated with neonatal mortality and morbidity, and impaired cognitive development and growth.[7,8] Postpartum haemorrhage, which has recently been the subject of renewed international attention and effort, is responsible for at least another one-fifth of maternal deaths globally.[9] Unsurprisingly, the burden is greatest in low- and middle-income countries (LMICs).

With recent attention refocusing on a number of these issues – particularly postpartum haemorrhage – maternal anaemia, including that caused by iron-deficiency has been placed back into the spotlight. Given maternal iron deficiency anaemia remains a critical and unsolved challenge, there is a fresh imperative to revisit this age-old condition, including a re-examination of the suite of medicines that are available and under investigation for its prevention and treatment.

THE ACCELERATING INNOVATION FOR MOTHERS (AIM) PROJECT

The Accelerating Innovation for Mothers (AIM) project was established in 2020, spearheaded by the Concept Foundation and delivered in partnership with Policy Cures Research and the Burnet Institute. The goal of this project is to reinvigorate investment and spur research and development (R&D) of maternal health products for significant pregnancy-specific conditions where biomedical product gaps exist. As part of this project, a comprehensive pipeline database of maternal health medicines, diagnostics and devices has been developed for a range of pregnancy-related conditions, including preeclampsia/eclampsia, preterm birth/labour, postpartum haemorrhage, intrauterine growth restriction, fetal distress, maternal environmental enteric dysfunction and maternal iron deficiency anaemia. This report covers insights into the R&D landscape for maternal iron deficiency anaemia medicines.

To be included in the maternal iron deficiency anaemia pipeline database, medicines had to be:

- used to prevent or treat maternal iron deficiency anaemia;
- specifically tested in, indicated for or targeted for use in pregnant women and/or lactating people within the postpartum period (up to 42 days after birth);
- be drugs, biologics or dietary supplements;
- either entirely new entities, existing/repurposed/label extensions, or new formulations or dosing of existing/registered products; and
- either in active discovery/preclinical or clinical development now, or have been in development at one point between 2000 and 2023, or approved and registered for clinical use and/or used currently in clinical treatment (off-label).

Medicines were excluded from the database if they:

- targeted maternal anaemia of different underlying aetiologies (e.g., other micro-nutrient deficiencies such as folate and vitamin B12 deficiency);
- were conventional foods; or were supplements or traditional medicines with relevant indication(s), but not properly dosed/formulated for use.

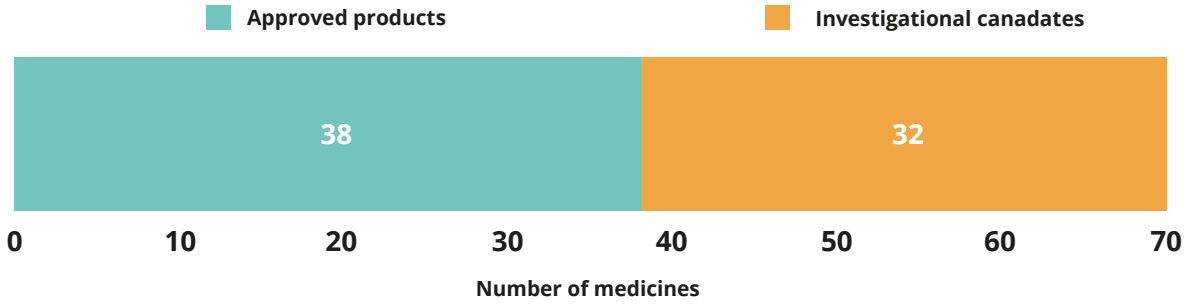
We searched a variety of sources in a stepwise fashion to identify and validate candidates or products. More details on the methodology can be found here.

Where applicable, similar medicines were represented as one record. For example, all multiple micronutrient supplements were grouped together, despite there being numerous variations of this product that each differ slightly in their ingredients and dosages. This pragmatic approach was taken so that the pipeline was not artificially inflated, and so that the information the data presented remained useful.

OVERVIEW OF THE PIPELINE

In total, 70 medicines were identified as in use or investigated for maternal iron deficiency anaemia between 2000 and 2023. Just over half of the medicines were already approved for use during pregnancy (38 products, 54%), with the remaining 32 (46%) in development. Across all medicines, 44 (63%) were in active development with evidence of R&D activity within the last three years, with the remaining 26 (37%) inactive.

Figure 1: Maternal iron deficiency anaemia medicines: approved products vs investigational candidates



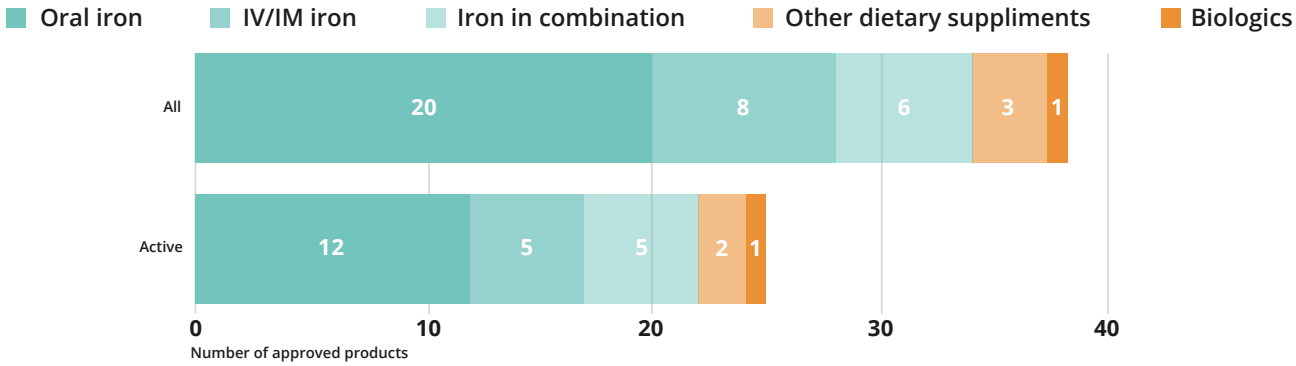
APPROVED PRODUCTS

There were 38 products approved for use to treat maternal iron deficiency anaemia. While this number seems substantial, many of these products are different formulations of iron: 20 candidates were oral iron supplements (53% of approved products) and eight were intramuscular/ intravenous (IM/IV) iron (21%). A further six candidates were iron in combination supplements (16%), including iron and folate combination tablets commonly prescribed for both prevention and treatment of maternal iron deficiency anaemia, and multiple micronutrient supplements used for prevention only.

Beyond iron supplements, there were three candidates (7.9%) which were classified as other dietary supplements. This included Trofin and Neotrofin, two novel anti-anaemics developed by the Cuban National Centre for Biopreparations (BioCen).[10] It also included Punarnava Mandura, a traditional Indian Ayurvedic medicine that is included as part of the national health programme in India for the treatment of maternal iron deficiency anaemia.[11] Finally, there was one biologic, lactoferrin, which is a milk-derived iron-binding glycoprotein capable of enhancing intestinal iron absorption and improving haemoglobin production, though its exact mechanism of action is unknown.[12]

Of the 38 approved products to treat maternal iron deficiency anaemia, 34 products are different formulations of iron.

Figure 2: Approved maternal iron deficiency anaemia medicines by product subtype & development status (active vs inactive)



While all 38 approved products had evidence of use, two-thirds of these were also under active Phase IV investigation (25 products) with ongoing clinical evaluation in the past three years. The smaller proportion of products were not under active research (13 products, 34%). Indeed, there have recently been several large-scale clinical trials testing approved iron formulations in women of reproductive age, including those in LMICs. The Reducing Anemia in Pregnancy in India (RAPIDIRON) trial is testing single doses of IV ferric carboxymaltose, and IV ferric derisomaltose against standard doses of oral iron, for their effect on maternal anaemia and low birth weight. The trial aims to recruit approximately 4320 participants and is estimated to be completed in 2024.[13] Another trial in Malawi, which recently had its results published in May 2023, demonstrated that IV ferric carboxymaltose was safe, but did not reduce anaemia prevalence at 36 weeks' gestation compared with standard-of-care oral iron, or increase birthweight.[14]

Almost all approved products are new chemical entities (NCEs) (36 candidates, 95%), although this largely reflects the high number of different approved iron formulations specifically developed to prevent and treat iron deficiency, rather than entirely novel and distinct products. There are only two repurposed products: Punarnava Mandura, the traditional Indian Ayurvedic medicine approved for a variety of conditions, and ferric citrate hydrate, an oral iron supplement originally approved for hyperphosphatemia in patients with chronic kidney disease.

Figure 3: Approved maternal iron deficiency anaemia medicines by archetype (NCE vs Repurposed)

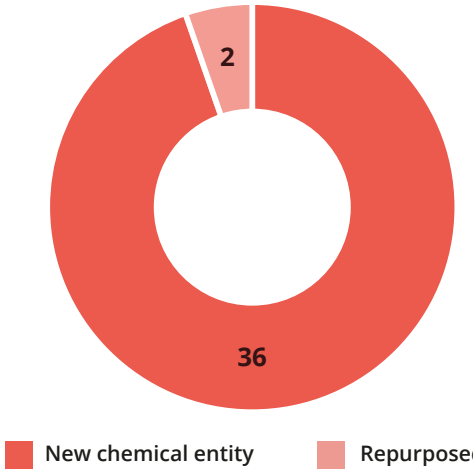
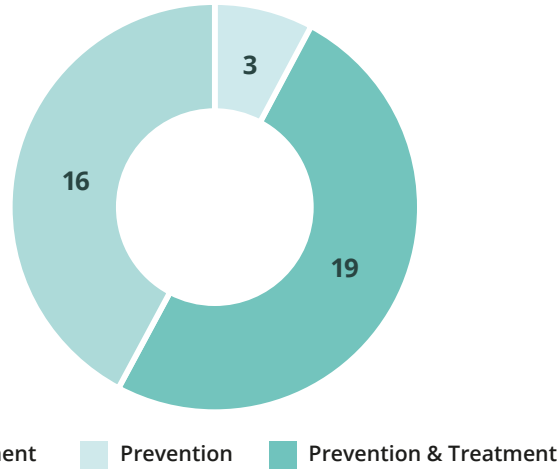


Figure 4: Approved maternal iron deficiency medicines by indication



Nineteen approved products are indicated simultaneously for both prevention & treatment of maternal iron deficiency anaemia. Of the remainder, most are approved for treatment only (16 candidates, 42%), including all eight approved formulations of IM/IV iron. Only three candidates are approved for prevention only (7.9%), including multiple micronutrient supplements, a fixed-combination tablet of iron, folate and iodine, and Spatone Iron-Plus, a naturally occurring iron-rich spa water from Wales. Just over half of the marketed products received approval from a Stringent Regulatory Authority (21 products, 55%). The remaining 17 medicines (45%) received approval from other National Regulatory Authorities, including in Egypt, India and Cuba.

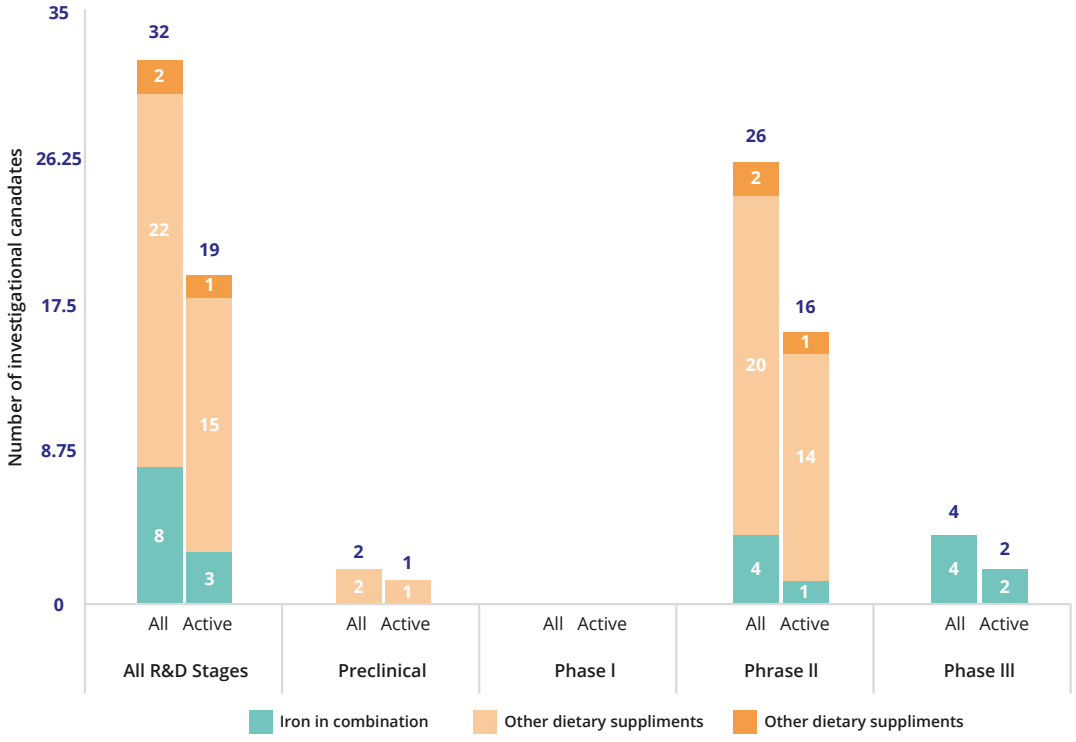
INVESTIGATIONAL CANDIDATES

There were 32 candidates under investigation for maternal iron deficiency anaemia. In contrast to the approved products, there were no formulations of oral or IV/IM iron under investigation. Instead, the largest proportion of candidates being researched are other dietary supplements (22 candidates, 69%), followed by iron in combination supplements (eight candidates, 25%) and biologics (two candidates, 6.3%).

Ten of the other dietary supplements (45%) are traditional Indian Ayurvedic medicines, including Dadimadi Ghrita, Dhatri Lauha and Pandughnivati, with another two traditional Chinese medicines and another traditional Japanese medicine. Other dietary supplements also entail things like bee pollen syrup, pumpkin seed extract and dried fig. It also includes encapsulated placenta, an iron-rich organ that some mothers choose to ingest for its nutrients in raw, cooked, dried or encapsulated form.

Novel iron in combination supplements included iron combined with other minerals, including Vitamin A, Vitamin B2, Vitamin B12, Vitamin D3 and Zinc. To varying degrees of evidence, some of these other minerals play various roles in iron homeostasis. For example, increased levels of Vitamin B2 enhances iron absorption and mobilisation of iron from stores.[15] This category of maternal iron deficiency anaemia medicines also included a lipid-based nutrient supplement, as well as iron and folate in combination with Helicobacter pylori (H. pylori) 'triple-attack' eradication therapy. H. pylori infection is a major risk factor for iron deficiency anaemia, with a study demonstrating that H. pylori treatment resulted in a significantly better response to oral iron supplementation among H. pylori infected pregnant women with iron deficiency anaemia.[16] Similarly, iron and folate in combination with the deworming medicine Albendazole was studied in a trial in Vietnam, reflecting the contribution hookworm infection has on the prevalence of iron deficiency anaemia in tropical and sub-tropical regions.

Figure 5: Investigational maternal iron deficiency anaemia medicines by R&D stage, product type and development status (active vs inactive)



The two biologics under investigation include lactobacillus plantarum 299v and recombinant human erythropoietin, both in Phase II trials. Lactobacillus plantarum 299v is a probiotic that targets the gut microbiome, and has been demonstrated to enhance iron absorption in non-pregnant populations. Recombinant human erythropoietin stimulates the production and maturation of functional erythrocytes, and is indicated for anaemia of other underlying aetiologies, including chronic kidney disease, chemotherapy (in non-myeloid malignancies) and zidovudine HIV therapy.

Of the 32 medicines under investigation, just under 60% (19 candidates) were in active development with evidence of R&D activity within the last three years. The remaining 13 (41%) were inactive, largely due to a lack of evidence of recent R&D, as opposed to product terminations.

Table 1: Investigational maternal iron deficiency anaemia medicines in active development

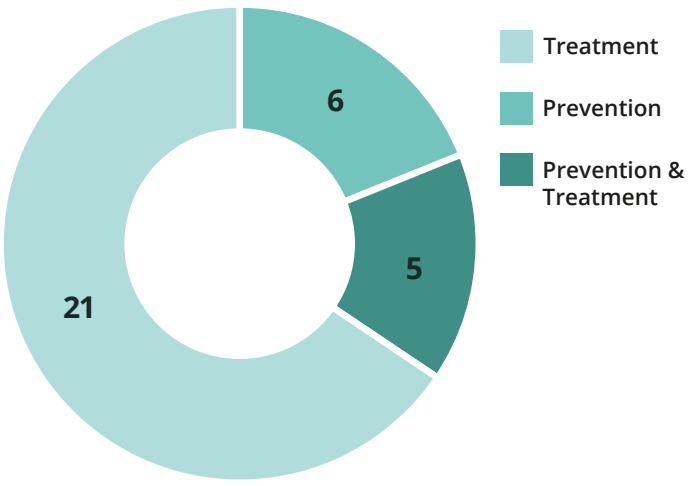
Dietary supplements	
Bee pollen syrup	Lakshmana lauha
Ficus carica L. fruit (dried)	Mandoor Bhasma
Pumpkin seed extract	Ninjin'yoeito
Tanduliyaka	Phoenix dactylifera L. syrup
Shatavari	Drakshadi Avaleha
Moringa oleifera and royal jelly	Draksha ghrita
capsule - fixed combined	Dhatri Lauha
Moringa oleifera	
Dadimashtaka churna	

Iron in combination	Biologics
Vitamin B12 (with iron +/- folic acid)	Lactobacillus plantarum 299v
Zinc (with iron +/- folic acid)	
Vitamin A (with iron +/- folic acid)	

In contrast to approved products, all investigational candidates are repurposed medicines, with zero completely novel compounds under development. This is not surprising, given repurposed medicines can present an easier avenue for R&D in pregnancy-related conditions given they may already be proven safe in pregnancy. However, with no NCEs under investigation, this largely leaves the field void of any true product innovation.

In addition, repurposed candidates by extension often do not require testing of safety in Phase I clinical trials, rather progressing straight to Phase II trials to test efficacy in small cohorts. As such, it also makes sense that over 80% of candidates under investigation for maternal iron deficiency anaemia were in Phase II clinical trials (26 candidates), with none in Phase I. The small number of remaining candidates were split between Phase III clinical trials (four candidates, 13%) and discovery and preclinical stages (two candidates, 6.3%). Medicines in Phase III clinical trials are all represented by iron in combination candidates, including iron and folate in combination with zinc, vitamin A and albendazole, and a lipid-based nutrient supplement. Phase III clinical trials of iron and folate in combination with zinc and vitamin A were most recent, with findings – albeit unfavourable ones – published in 2020: results demonstrated that prenatal zinc and vitamin A supplementation, alongside iron and folate, did not benefit maternal haematological status at delivery.[17]

Figure 6: Investigational maternal iron deficiency anaemia medicines by indication



Two-thirds of candidates being investigated are for treatment only (21 candidates), including all the traditional Indian Ayurvedic medicines. A slightly larger number are studied for prevention alone (six candidates, 19%), half of which are other dietary supplements such as chlorella, encapsulated placenta and pumpkin seed extract. Just five candidates (16%) are studied for both prevention and treatment, either in a single study or across multiple studies.

Since 2000, the global prevalence of anaemia in women of reproductive age has stagnated, while the prevalence of anaemia in pregnant women has dropped only slightly. The goal of halving the prevalence of anaemia in women of reproductive age by 2025 is now effectively out of reach.

IRON FORMULATIONS ABOUND, BUT THE JOB'S NOT DONE

Maternal anaemia continues to be a significant cause of morbidity and mortality, with efforts over the past two decades making a minimal dent on this age-old problem. Since 2000, the global prevalence of anaemia in women of reproductive age has stagnated, while the prevalence of anaemia in pregnant women has dropped only slightly.[18] The goal of halving the prevalence of anaemia in women of reproductive age by 2025 is now effectively out of reach.

On first look at the landscape of medicines for maternal iron deficiency anaemia, this lack of progress may appear surprising. With a total of thirty-eight medicines already approved for maternal iron deficiency anaemia, this figure sits well above the combined total for all other pregnancy-related conditions evaluated as part of the AIM project – ten approved medicines for postpartum haemorrhage, seven for preterm birth/labour, one for preeclampsia/eclampsia, and zero approved medicines for intrauterine growth restriction, fetal distress and maternal environmental enteric dysfunction.[19] Moreover, most of the approved products for maternal iron deficiency anaemia – of which all except three are iron formulations – are proven effective.

There is a disconnect between the availability of effective iron products and any realised improvements in maternal iron deficiency anaemia globally.

Clearly, however, there is a disconnect between the availability of effective iron products and any realised improvements in maternal iron deficiency anaemia globally. Indeed, efficacy in clinical trials does not necessarily translate to real-world results. In the case of maternal iron deficiency anaemia, some of this gap is due to sub-optimal adherence to oral iron, which, particularly at high doses, can cause significant gastrointestinal side-effects.[20],[21] Furthermore, and particularly in LMICs, gut absorption of oral iron may be limited.[22],[23] To effectively meet the needs of women, iron therapy needs to be administered in a format that is well-tolerated and well-absorbed. Accordingly, there are several large-scale clinical trials occurring that are designed to optimise formulations of iron, with a number of these focusing on IV iron. IV iron is an attractive alternative to oral iron, as it bypasses the need for gut absorption and thereby avoids some of the issues associated with oral iron. However, IV iron also has its own drawbacks, with its administration placing a greater burden on public health systems, and lags in infrastructure in LMICs rendering it inaccessible at times.

The limitations of iron therapy may give cause to pursue completely novel avenues of R&D. At present, however, there is a distinct lack of diversity and innovation in the R&D pipeline. There are fewer investigational candidates than approved products, and no completely new compounds are under development. Furthermore, the repurposed medicines that are under evaluation are mostly being tested in small-scale Phase II clinical trials, with only a small handful of candidates having advanced to late-stage Phase III trials. It could be that promising candidates or approaches are being overlooked. For example, gut microbiome therapeutics – including the Lactobacillus Plantarum 299v currently under investigation – may hold potential, particularly given the increasing evidence on the role of the gut microbiome in iron and other nutrient absorption.[22]

The optimisation of iron formulations, combined with R&D of novel products may together offer greater hope for progress in this field. However, product innovation alone will not offer a silver-bullet. For significant advances to be realised in this space, it's likely that much of the solution lies in taking a more holistic approach to prevention and treatment. Underlying causes of maternal iron deficiency anaemia need to be addressed, with consideration of structural inequities that drive generalised nutritional deficits and local disease burdens – such as that of malaria and helminth infections – that can have additive effects. Ultimately, a multi-faceted and integrated approach is imperative to paving a way forward. For now, however, the sub-optimal characteristics of iron, a lack of innovation in the field, and an apparent failure to comprehensively address underlying issues renders imminent improvement unlikely, and targeted gains in maternal health outcomes probably out of reach.

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ANNEXE: Included maternal iron deficiency anaemia medicines by approved product/investigational candidate category and product type

Name	Approved product/ investigational candidate	Product type
Amino acid chelated iron	Approved product	Oral iron
Chinese medicine filling iron agent	Approved product	Oral iron
Ferric citrate hydrate	Approved product	Oral iron
Ferrimanitol ovalbumin	Approved product	Oral iron
Ferrous acetyl aspartate	Approved product	Oral iron
Ferrous asparto glycinate	Approved product	Oral iron
Ferrous bisglycinate	Approved product	Oral iron
Ferrous fumarate	Approved product	Oral iron
Ferrous gluconate	Approved product	Oral iron
Ferrous glycine sulphate	Approved product	Oral iron
Ferrous succinate	Approved product	Oral iron
Ferrous sulfate	Approved product	Oral iron
Heme iron	Approved product	Oral iron
Iron acetyl-transferrin hydroglycerin	Approved product	Oral iron
Iron liposome	Approved product	Oral iron
Iron polymaltose	Approved product	Oral iron
Iron polysaccharide	Approved product	Oral iron
Iron protein succinylate	Approved product	Oral iron
Sodium feredetate	Approved product	Oral iron
Spatone Iron-Plus	Approved product	Oral iron
Ferric carboxymaltose (IV)	Approved product	IV/IM iron
Ferric derisomaltose (IV)	Approved product	IV/IM iron
Ferrous gluconate (IV)	Approved product	IV/IM iron
Ferumoxytol (IV)	Approved product	IV/IM iron
Iron dextran (IV/IM)	Approved product	IV/IM iron
Iron polymaltose (IV)	Approved product	IV/IM iron
Iron sorbitol (IM)	Approved product	IV/IM iron
Iron sucrose (IV)	Approved product	IV/IM iron
Folic acid-iron - fixed combined	Approved product	Iron in combination
Iodine-iron-folic acid - fixed combined	Approved product	Iron in combination
Multiple micronutrient supplement - fixed combined	Approved product	Iron in combination
Sangfer capsule - fixed combined	Approved product	Iron in combination
Serine-iron-folic acid - fixed combined	Approved product	Iron in combination
Vitamin C and iron - fixed combined (+/- folic acid)	Approved product	Iron in combination
Neotrofin	Approved product	Other dietary supplements
Punarnava mandura	Approved product	Other dietary supplements
Trofin	Approved product	Other dietary supplements
Lactoferrin - MA	Approved product	Biologics
Albendazole (with iron + folate)	Investigational candidate	Iron in combination
H. pylori triple attack therapy (with iron + folate)	Investigational candidate	Iron in combination
Lipid based nutrient supplement - fixed combined	Investigational candidate	Iron in combination
Vitamin A (with iron +/- folic acid)	Investigational candidate	Iron in combination
Vitamin B12 (with iron +/- folic acid)	Investigational candidate	Iron in combination
Vitamin B2 (with iron +/- folic acid)	Investigational candidate	Iron in combination
Vitamin D3 (with iron + folic acid)	Investigational candidate	Iron in combination
Zinc (with iron +/- folic acid)	Investigational candidate	Iron in combination
Bee pollen syrup	Investigational candidate	Other dietary supplements
Chlorella	Investigational candidate	Other dietary supplements
Dadimadi ghrita	Investigational candidate	Other dietary supplements
Dadimashtaka churna	Investigational candidate	Other dietary supplements
Dhatri Lauha	Investigational candidate	Other dietary supplements
Draksha ghrita	Investigational candidate	Other dietary supplements
Drakshadi Avaleha	Investigational candidate	Other dietary supplements
Ejiao compound	Investigational candidate	Other dietary supplements
Encapsulated placenta	Investigational candidate	Other dietary supplements
Ficus carica L. fruit (dried)	Investigational candidate	Other dietary supplements
Lakshmana lauha	Investigational candidate	Other dietary supplements
Mandoor bhasma	Investigational candidate	Other dietary supplements
Mojeaga	Investigational candidate	Other dietary supplements
Moringa oleifera	Investigational candidate	Other dietary supplements
Moringa oleifera and royal jelly capsule - fixed combined	Investigational candidate	Other dietary supplements
Ninjin'yoeito	Investigational candidate	Other dietary supplements
Pandughnivati	Investigational candidate	Other dietary supplements
Phoenix dactylifera L. syrup	Investigational candidate	Other dietary supplements
Pumpkin seed extract	Investigational candidate	Other dietary supplements
Shatavari	Investigational candidate	Other dietary supplements
Tanduliyaka	Investigational candidate	Other dietary supplements
Toki-shakuyaku-san - MA	Investigational candidate	Other dietary supplements
Lactobacillus plantarum 299v	Investigational candidate	Biologics
Recombinant human erythropoeitin	Investigational candidate	Biologics

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