



# What the Data Tells Us: FCM Landscape Findings

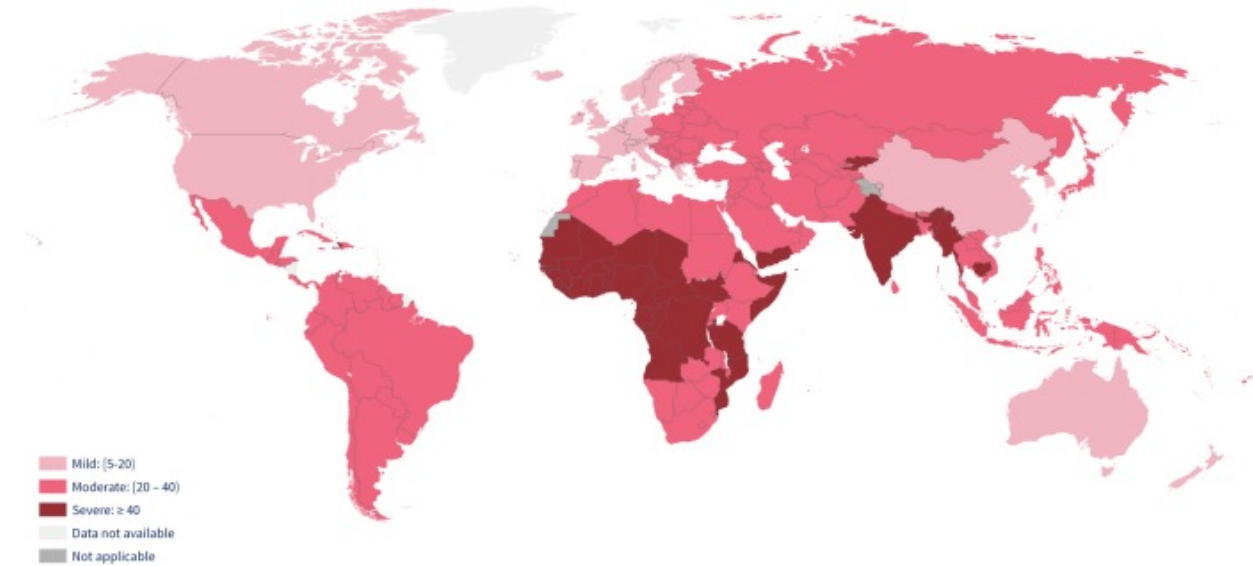
# Maternal anemia is one of the most significant contributors to global maternal mortality



## Pregnant women (age 15-49 years)

**80% of countries** have a moderate to severe burden of anaemia among pregnant women (Figure 10).

**Figure 10.** Prevalence of anaemia in pregnant women (age 15-49 years) in 2023, by country or territory



Source: WHO global anaemia estimates: key findings, 2025.

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## Role of Iron:

- Iron deficiency anemia (IDA) is the most common type of maternal anemia.
- Oral iron therapy is widely used as the first-line treatment, but it is often inadequate for women (e.g., poor absorption, gastrointestinal side effects, and the need for more rapid correction during the later stages of pregnancy).
- Intravenous (IV) iron therapy has emerged as an effective alternative, with newer formulations such as ferric carboxymaltose (FCM) demonstrating superior performance.
- Despite such findings, FCM uptake in low- and middle-income countries has remained limited.

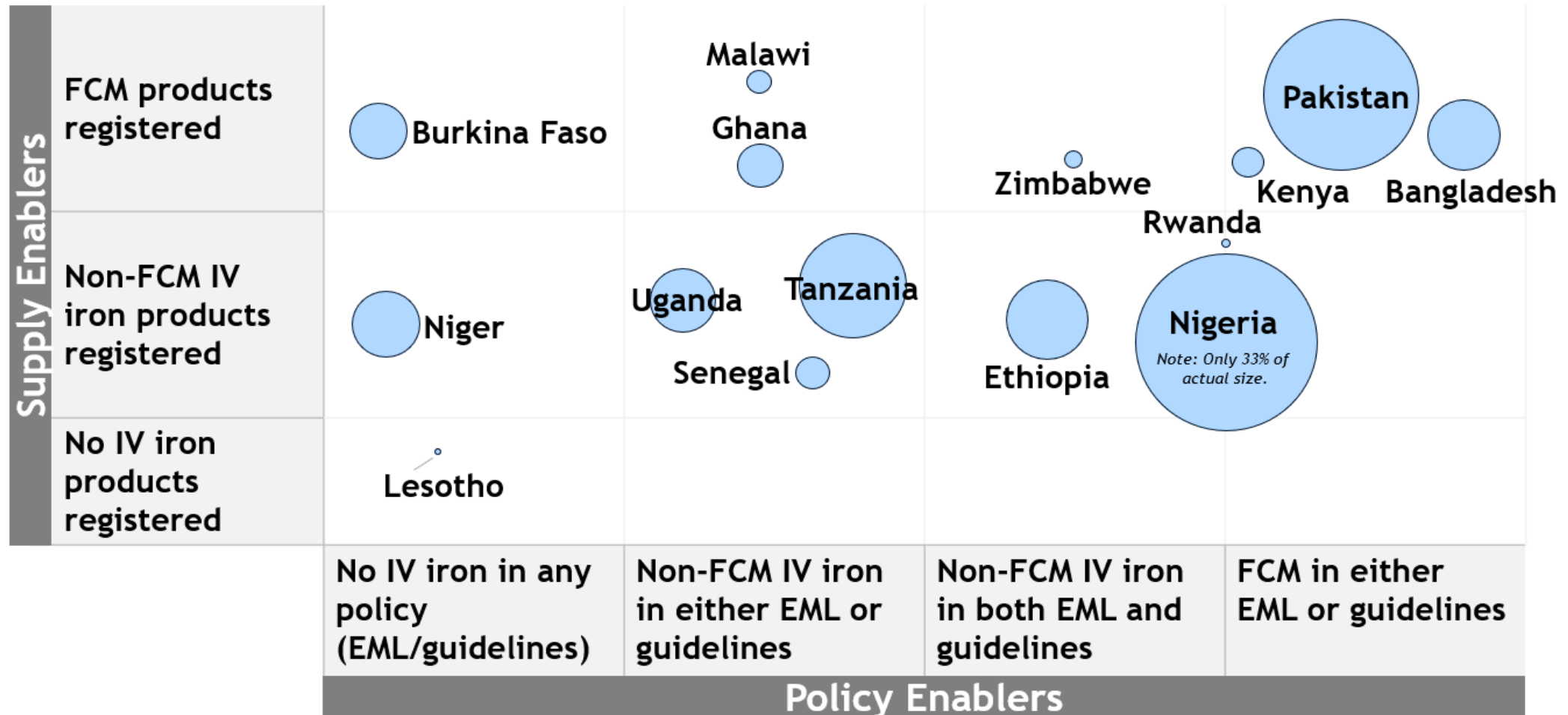
# The Gates Foundation funded a 15-country landscape to understand country interest in, and readiness to, introduce and scale FCM.



<b>Objective</b>	Understand current FCM market landscape, country interest in and readiness to introduce and scale FCM, and projected growth of FCM demand over next 5 years.
<b>Key Country Activities</b>	<p>To support the accelerated nature of this landscape, six countries relied on desk review only, and nine conducted both desk review and stakeholder interviews.</p> <ul style="list-style-type: none"><li>• <i>Desk review only: Ghana, Lesotho, Malawi, Niger, Uganda, Zimbabwe</i></li><li>• <i>Desk review &amp; stakeholder interviews: Bangladesh, Burkina Faso, Ethiopia, Kenya, Nigeria, Pakistan, Rwanda, Senegal, Tanzania</i></li></ul>
<b>Target Population</b>	Pregnant women in their 2nd or 3rd trimester with moderate to severe anemia, attending at least one ANC visit
<b>Outputs</b>	<ol style="list-style-type: none"><li>1) Individual country FCM market analyses, including country-specific enablers and barriers</li><li>2) FCM demand forecast through 2031</li><li>3) cross-country synthesis of findings across market analyses and forecast</li></ol>

*Question:* How many countries have FCM  
in maternal anemia guidelines?

# Five countries' maternal anemia guidelines recommend the use of FCM in the treatment of maternal anemia (Pakistan, Kenya, Bangladesh; Rwanda and Nigeria are actively updating guidelines to include reference to FCM)

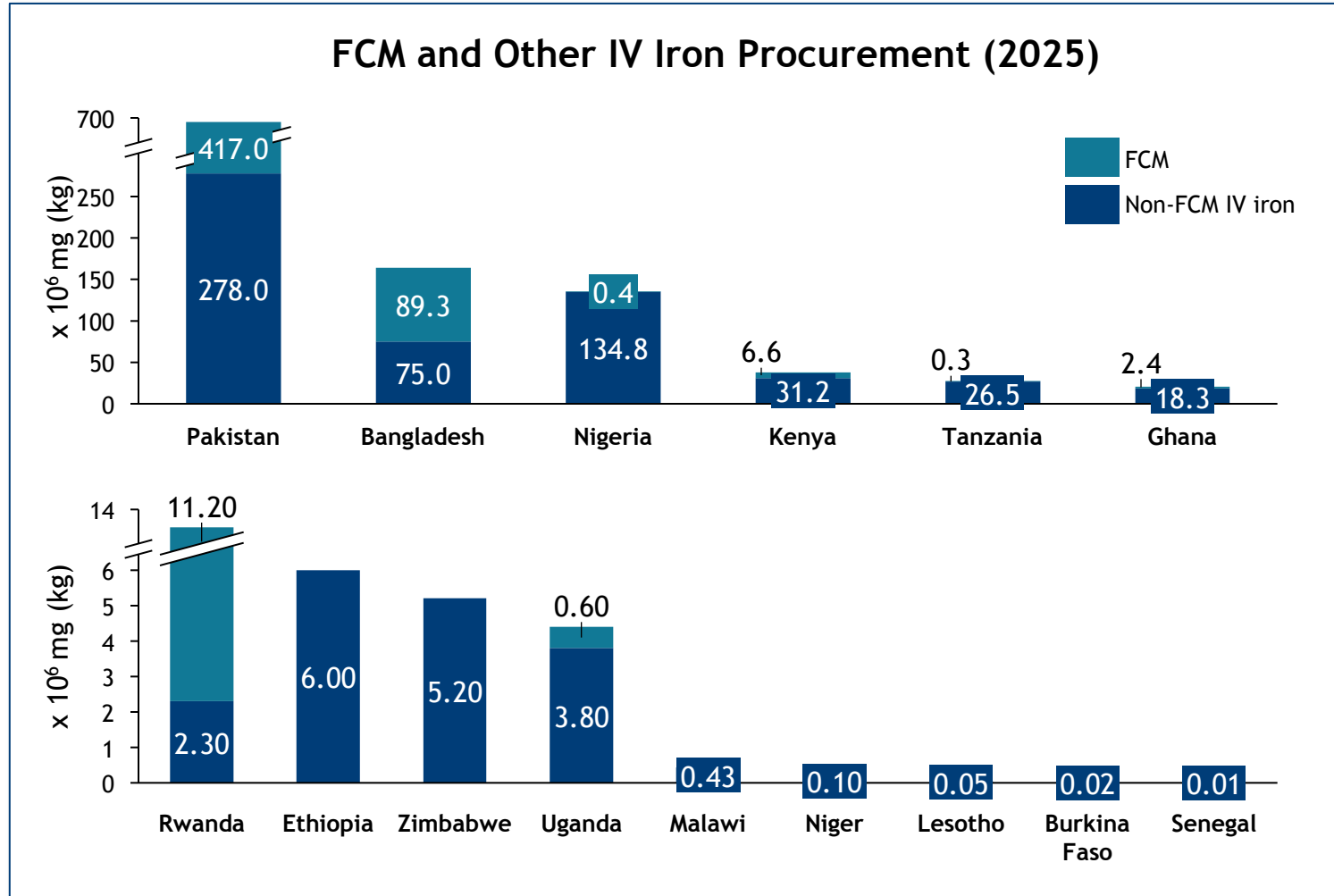


Circle sizes are proportional to each country's target population

Note: "guidelines" refers specifically to maternal iron deficiency anemia guidelines.

***Question:* How many countries showed evidence of FCM procurement in 2025?**

# Eight countries showed evidence of FCM procurement in 2025, driven primarily by the private sector



Note: Evidence of procurement is inferred from an import/export database and interviews; country-level historical procurement data by sector are not available.

# CHAI recently concluded a Gates-funded, 15-country rapid landscape assessment to understand country interest in, and readiness to, introduce and scale FCM



## Key Issue

*Anemia affects ~40% of pregnant women globally and is a significant risk factor for maternal mortality and adverse birth outcomes; iron deficiency anemia (IDA) is leading cause of anemia. Oral iron, standard first-line treatment in many countries, is frequently inadequate due to poor absorption and GI side effects. As an alternative, IV iron has demonstrated strong safety and efficacy, yet uptake in LMICs remains limited.*

## Current Market

- **Where available, FCM is almost exclusively offered in the private sector;** public sector procurement is largely non-existent, primarily due to lack of inclusion on EMLs
- **Delivery is concentrated in higher-level, urban facilities**

## Ministry Perspectives

- **5 countries' maternal anemia guidelines recommend use of FCM in treatment of IDA**
- **Ministries recognize FCM value, but report key concerns across the market pathway**
  - Pre-introduction (e.g., lack of inclusion in guidelines/EML; insufficient evidence on effectiveness and safety; limited product registration), scaling (e.g., weak delivery infrastructure and supply chains; low clinical awareness and limited training), and market shaping (e.g., high commodity pricing)

## Pricing Landscape

- **Pricing signals, though limited in the information gathered, vary widely.** End user prices in the private sector range from ~\$10 USD to ~\$70 USD per 1000mg dose

## Clinical Familiarity

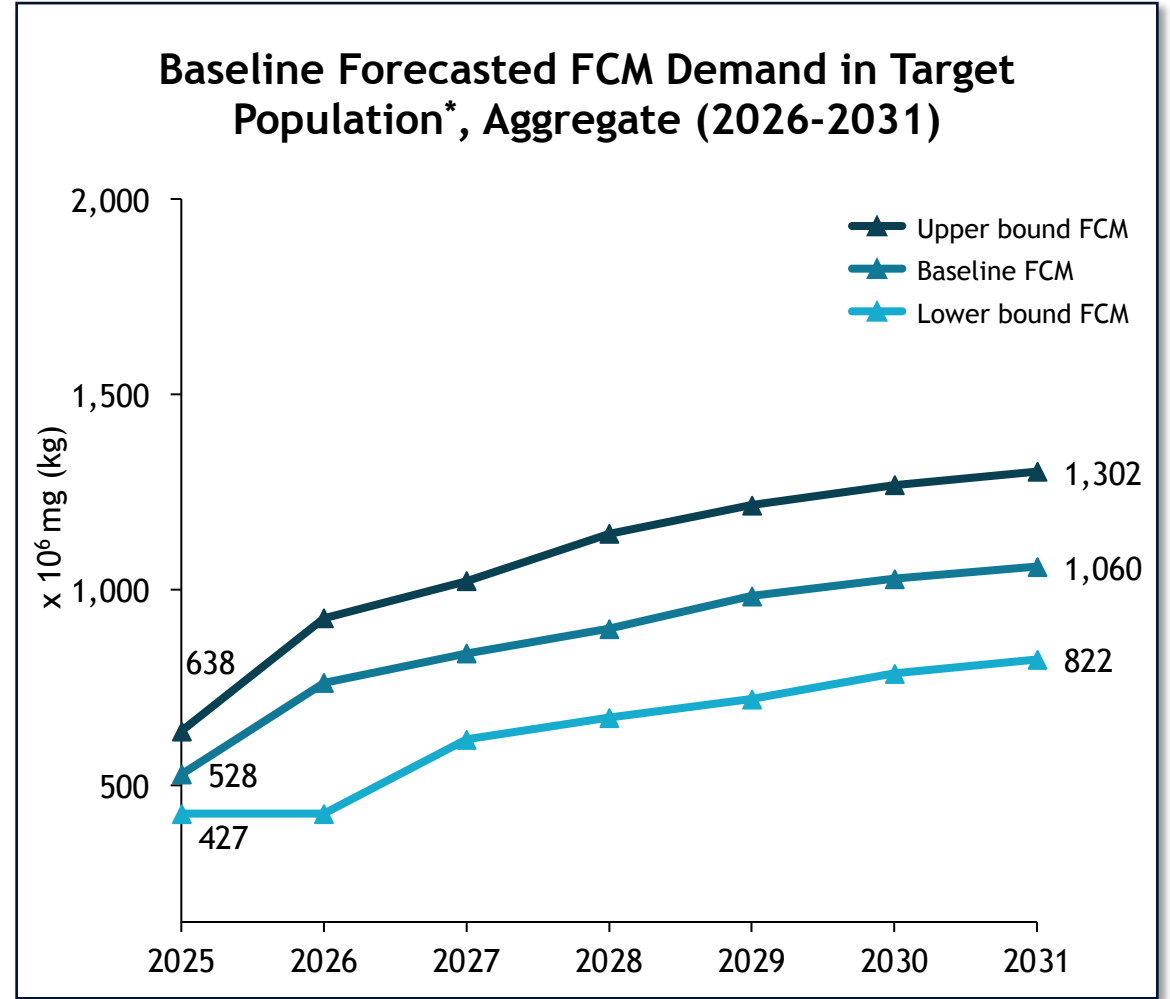
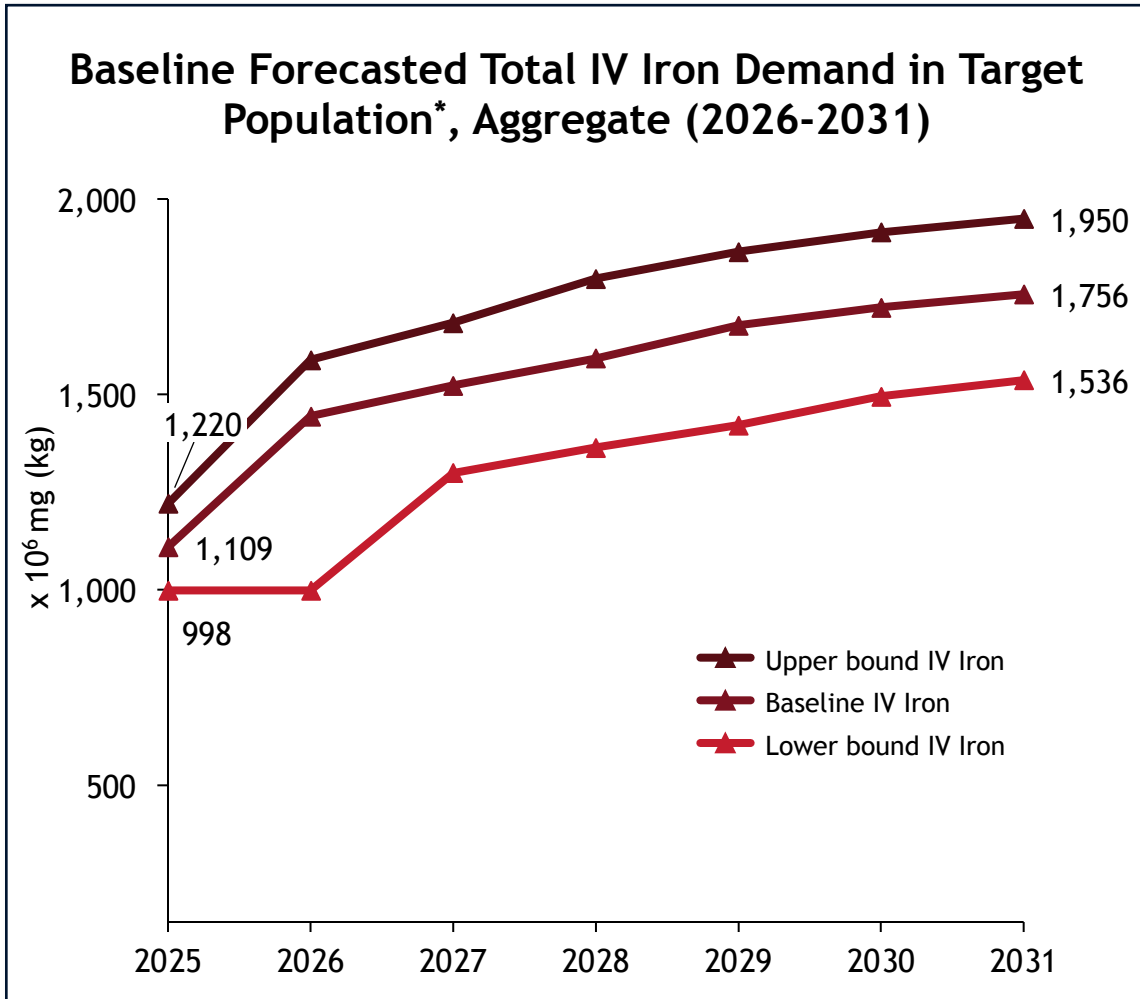
- **Familiarity with FCM shapes clinical preference.** Those familiar with FCM recognize its clinical efficacy and the benefits of single-dose administration, often preferring it, when available, to oral iron.

## Ongoing Challenges

- **Maternal IDA diagnosis is highly constrained by inconsistent screening and limited diagnostic capacity**
- **Despite growing IV Iron and FCM demand over time per the forecast, outstanding need remains significant.** Calculated IV iron need in 2025, based on current guidelines and prevalence data, is greater than 2031 demand for IV iron.



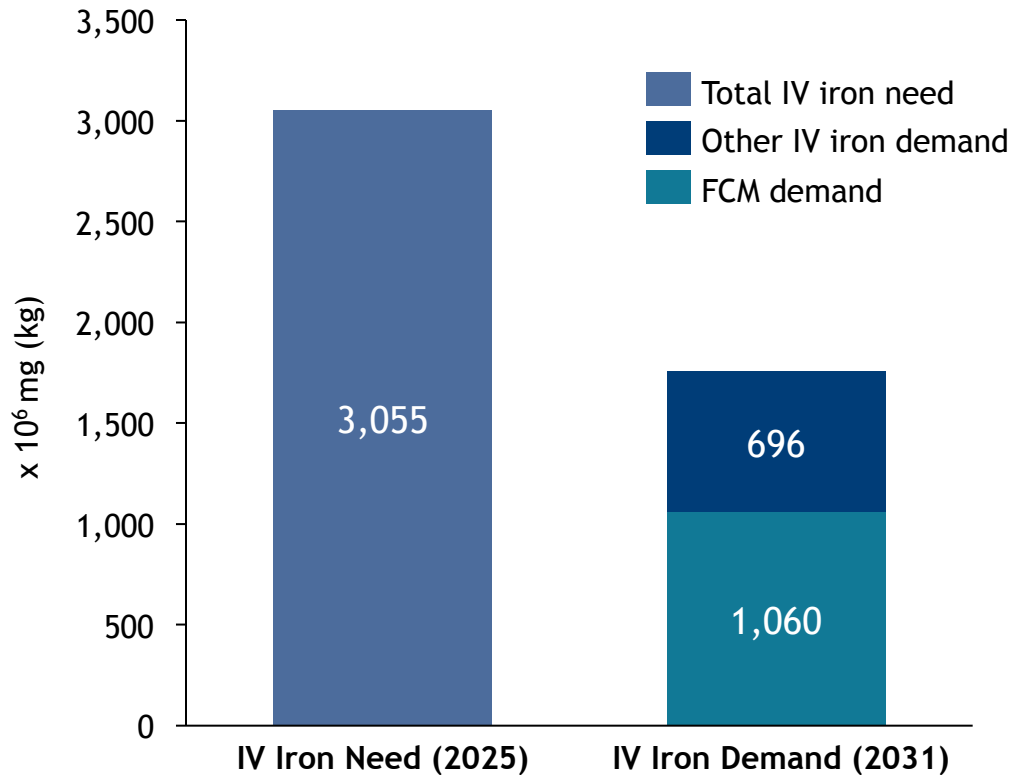
# Under current conditions, demand model shows a steady growth in total IV iron demand and doubling in FCM demand by 2031



# Despite growing IV Iron and FCM demand over time per the forecast, outstanding need remains significant



Baseline IV Iron Need (2025) and Forecasted Demand in Target Population (2031)



When comparing baseline (2025) IV iron need with forecasted (2031) demand, that proxy analysis helps indicate that:

- 1 There remains significant unmet need across assessed markets.
- 2 Policy and guideline changes are necessary to enable commodity availability but are unlikely to fully address this unmet need if system-level barriers limit the conversion of clinical need into treatment utilization.
- 3 Strengthening upstream activities - including screening, diagnosis, and referral pathways - will help ensure that FCM-specific policy adoption and availability result in patient uptake.

Note: IV iron need is expected to grow as guidelines are updated to include FCM/IV iron, thus expanding eligibility to more pregnant women

Note: Eligibility criteria are anemia cases meeting clinical criteria for IV iron treatment per country guidelines. For most in-scope countries, use of IV iron is limited to moderate and severe cases, except in Pakistan, where mild anemia cases are also eligible for IV iron treatment. Source(s): IHME, CHAI analysis

# To grow the FCM market, there are pre-introduction, scale, and market shaping needs, and opportunities to leverage and complement other programs



Example Interventions	
Pre-Intro	<ul style="list-style-type: none"> <li>Disseminate clinical evidence or support implementation studies to inform product rollout</li> <li>Advocate for inclusion of FCM in critical policies (e.g., EML, guidelines)</li> <li>Support costed product introduction strategy, roadmap development, and resource mobilization</li> </ul>
Introduction & Scale-up	<ul style="list-style-type: none"> <li>Close diagnostic and testing gaps through improved coverage of new and existing testing technologies</li> <li>Develop bottleneck assessment to identify weakest points in care continuum and supply chain</li> <li>Conduct provider trainings, leveraging cost-effective training models</li> <li>Strengthen government coordination of product roll-out and sequencing of activities</li> <li>Enable commodity availability through initial catalytic procurement, integration into forecasting and quantification processes, supply planning, and procurement processes</li> <li>Develop commodity financing strategies for long-term sustainability</li> </ul>
Market Shaping	<ul style="list-style-type: none"> <li>Engage manufacturers on business case for registration of quality-assured (QA) FCM products</li> <li>Support publication and dissemination of Emcure/Axmed's \$10 FOB price agreement</li> <li>Engage with manufacturers to support &lt;\$10 FOB price</li> <li>Conduct continued forecasting to specify need and demand to support evaluation of total market volume and opportunity</li> </ul>

Activities across SUPREME, Beginnings Fund, and CHOICES support several of these interventions