USER PERSPECTIVE STUDY

Will Children Actually Take It?

User perspectives on acceptability of minitablet vs conventional small tablet

Insight from 4 countries

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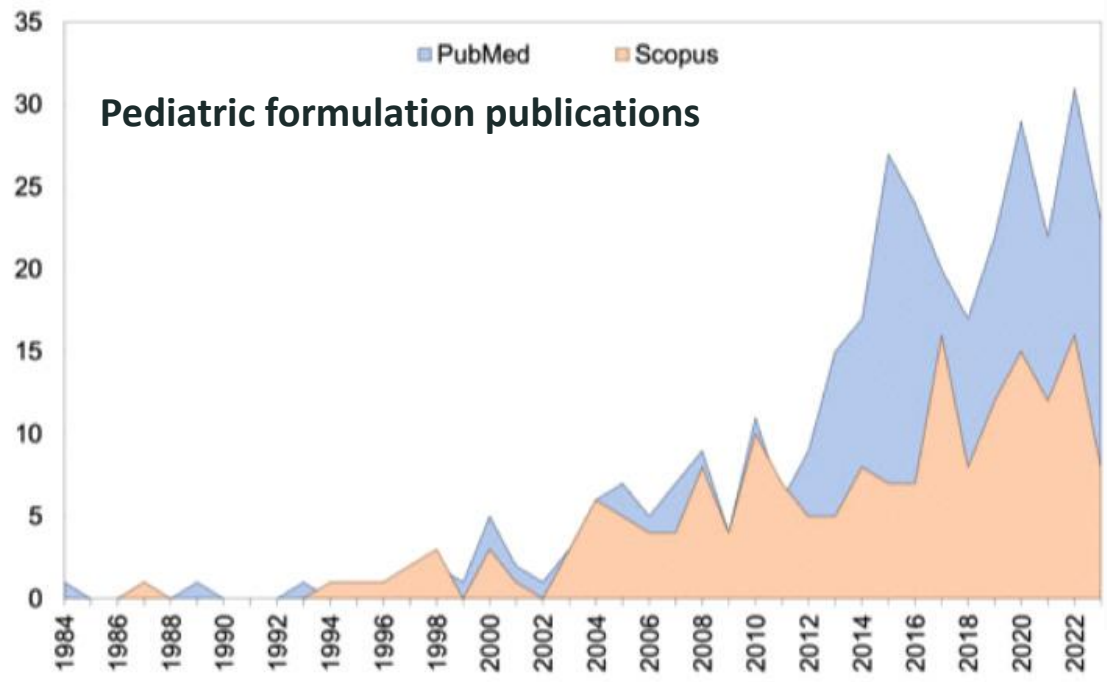
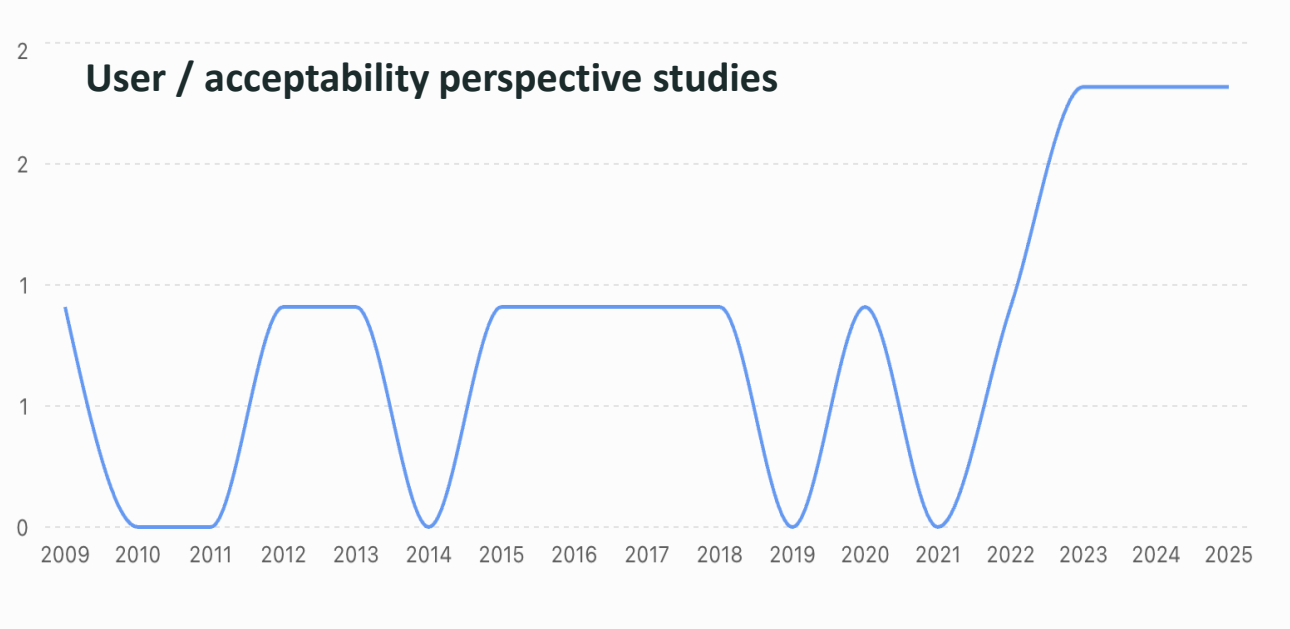
Shaping the Future of Pediatric Formulation Development, June 24-25, 2026,
University of Maryland, Baltimore School of Pharmacy, US

The science has outpaced our understanding of use

Pediatric formulation publications have surged — acceptability research has not kept pace





Approximate number of publications focused on minitablet acceptability, swallowability, palatability or patient preference.

We know more than ever about how to make these formulations

far less about whether children and caregivers will actually use them.

Saikishore Meruva, Aditya B. Singaraju, Bhavani Prasad Vinjamuri, Robert Ternik, William C. Stagner, Current State of Minitablet Product Design: A Review, Journal of Pharmaceutical Sciences, Volume 113, Issue 5, 2024, Pages 1123-1154, ISSN 0022-3549, https://doi.org/10.1016/j.xphs.2024.02.016. (https://www.sciencedirect.com/science/article/pii/S0022354924000558)

Regulators are converging on the same expectation

Patient and user perspective is moving from good practice to formal expectation — across regions

FDA Patient-Focused Drug Development Guidance Series for Enhancing the Incorporation of the Patient's Voice in Medical Product Development and Regulatory Decision Making

A structured program to ensure patient and caregiver input informs medical product development and regulatory decision-making, not just clinical endpoints.

Established expectation, actively used in submissions today

ICH E22 General considerations for patient preference studies - Scientific guideline

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Patient preference studies (PPS) aim to assess the relative desirability or acceptability of actual or potential health interventions, or their characteristics and outcomes. PPS can generate structured insights about the relative importance of characteristics, also referred to as attributes, that are considered by patients when making decisions about drugs. These attributes may include, for example, efficacy or safety outcomes or any other potentially relevant characteristics.

Harmonized across FDA, EMA and other major regulators. Adopted by CHMP Dec 2025; public consultation closed Apr 2026; final adoption expected late 2026.

Not a regional interest — a harmonized global direction

UCL

Regulators want this evidence but flag real gaps

Acknowledged barriers to using preference evidence in regulatory decisions

- Transferability across settings
- Internal validity & data quality
- Lack of standard methodology
- Difficulty synthesizing across studies

Our study: built to close that gap

UK

Nigeria

Brazil

Bangladesh

across 4 countries

Children & caregivers

Structured field assessment

Pediatric age range (0-12yrs)

Objectives

1. Will children accept minitablets?
2. What characteristics matter most?
3. Are preferences consistent across countries?

5 dimensions measured

Acceptability **Swallowability** **Administration prefs** **Handling prefs** **Packaging prefs**

Willingness to use

Designed to test transferability — does what works in one setting hold in another?

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Size and quantity: smaller goes further

Children consistently accept more 1.5mm minitablets than larger sizes across all 4 countries

Perceived swallowability thresholds (max minitablets)

Size				
1.5 mm	≤ 20	≤ 5	≤ 20	≤ 20
3 mm	≤ 10	≤ 5	≤ 10	≤ 10
4 mm	≤ 5	≤ 5	≤ 10	≤ 5

What the field says

A 2025 German study (Klingmann et al.) found children tolerate up to 500 mini-tablets (2mm) — with higher numbers accepted for shorter treatments and in older children.

What our data adds

Thresholds hold broadly but Nigeria shows notably lower tolerance at 1.5mm (≤5 vs ≤20 elsewhere).

Food and drink preferences vary significantly

What children prefer to take minitablets with — directly affects instructions-for-use by market

Fruits & water

Fruits or water preferred

Rice & water

Starchy food pairing preferred

Rice & water

Consistent with Nigeria

Water & milk

Unique milk preference

Instructions-for-use cannot simply say 'take with food'. The preferred food vehicle differs by market. Bangladesh's milk preference, for example, could affect coating integrity and bioavailability decisions.

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Packaging: one clear winner with important variations

Blister leads everywhere, but ranked options and dispensing preferences differ by country

Packaging format preference (ranked 1–4)

Format				
Blister	**#1**	#2	**#1**	**#1**
Sachet	#3	**#1**	#3	#2
Capsule	#2	#3	#2	#3
Stick pack	#4	#4	#4	#4

How they want to count them out

- Exact number
- One-by-one
- Exact number
- Exact number

Nigeria stands out:

Sachet is #1 in Nigeria (not blister), and dispensing is one-by-one, not exact count.

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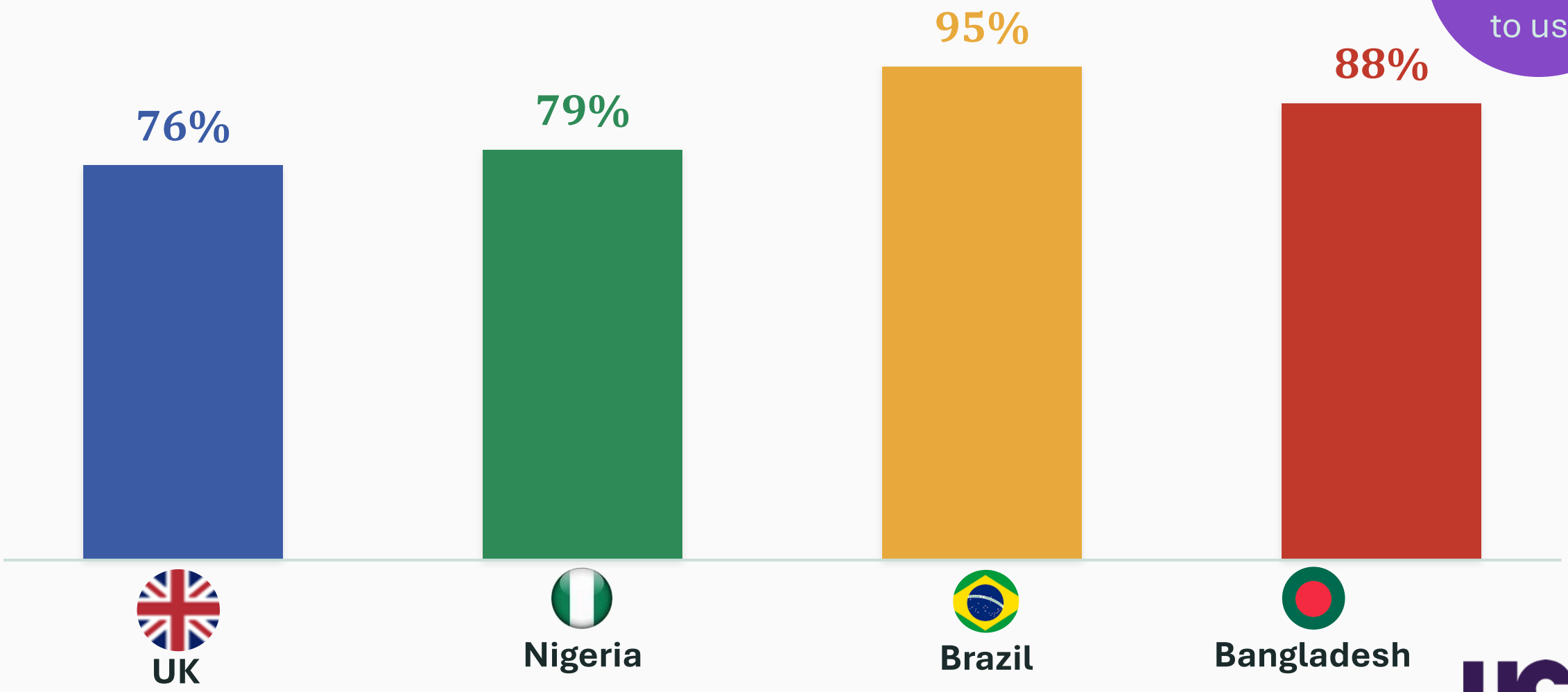
Across every setting, the answer is yes

“Would you take minitablets when sick?”



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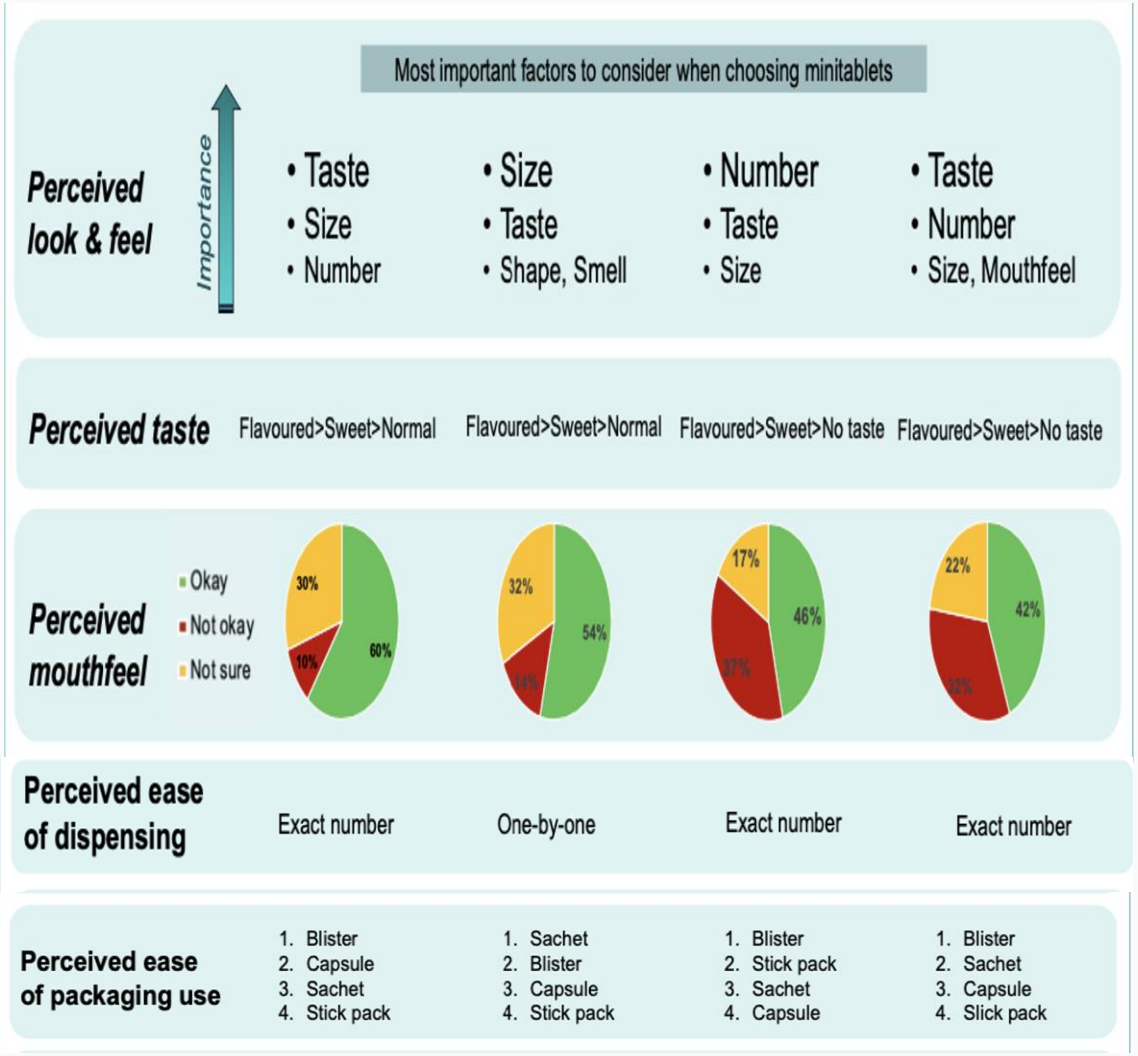
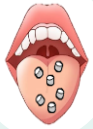
What holds true everywhere

Signals consistent across all 4 countries, despite very different contexts





Taste and size matters everywhere

Appears in top-3 most important factors in all 4 countries. Mouthfeel became less acceptable as minitablet size increased

Flavoured / sweet wins

Preferred over plain or no-taste in every country, with consistent ordering.

Exact-count dispensing preferred

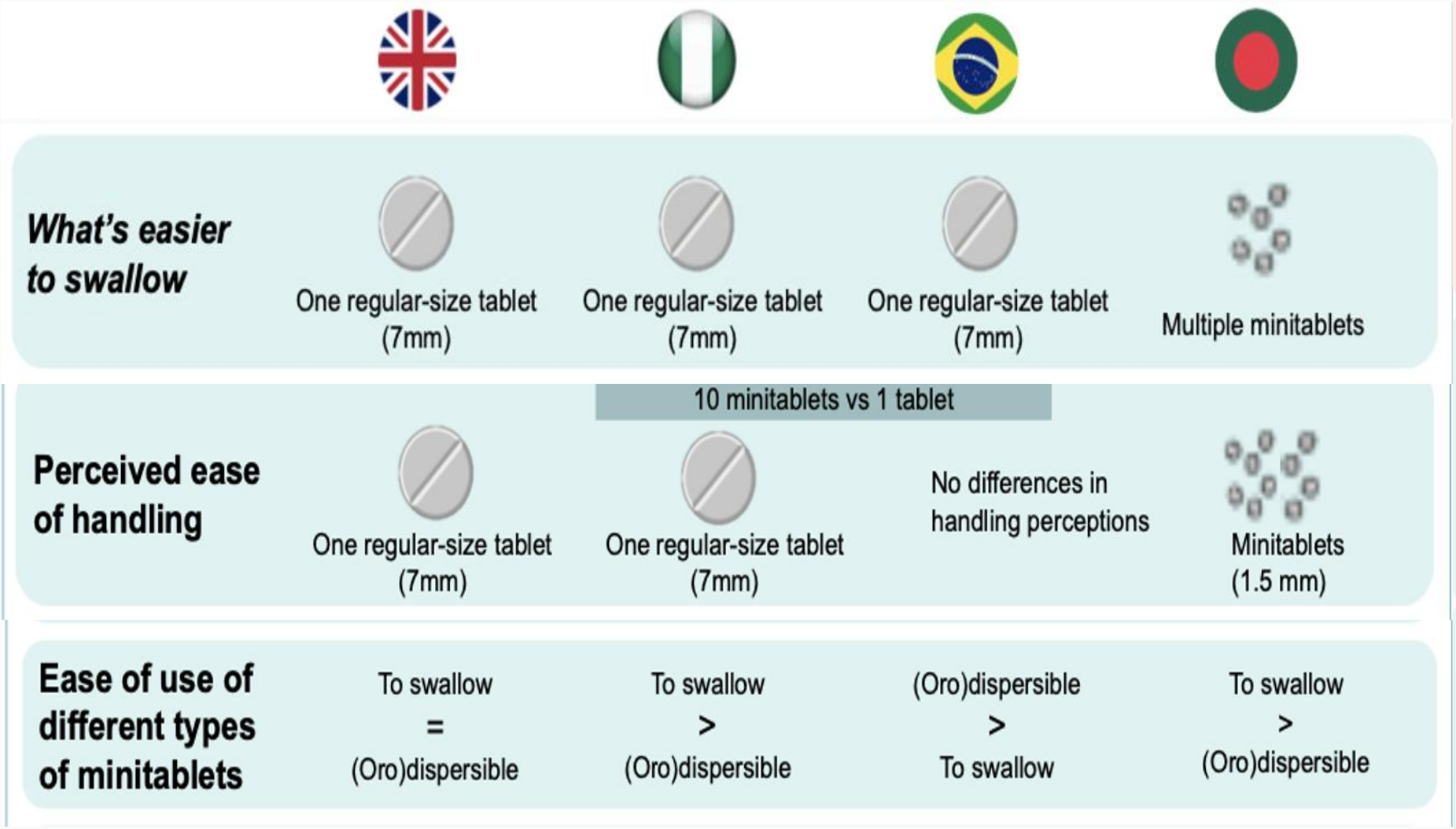
3 of 4 countries want an exact number dispensed (Nigeria: one-by-one).

Blister pack leads everywhere

Ranked #1 in UK, Brazil and Bangladesh. Nigeria's outlier (sachet) is the exception.

One global design insight does not fit all

Where acceptability genuinely diverge by setting



The Bangladesh reversal

In the UK, Nigeria and Brazil, one regular-size tablet is seen as easier to swallow and handle than minitablets. In Bangladesh, that flips. Multiple minitablets are preferred over a single regular tablet and rated easier to handle.

Handling: a 3-way split

UK / NG	Prefer single tablet
BR	No difference perceived
BD	Prefer minitablets

Brazil stands alone on dispersing

UK, Nigeria & Bangladesh prefer swallowing minitablets.
Brazil prefers dispersible

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What this means for industry

Three actionable reads from the cross-country data

One core formulation can travel globally

Flavour, overall acceptability, and blister-pack preference are consistent across settings. Support a single global formulation strategy rather than market-by-market reformulation.

Adapt instructions, dispensing tools & packaging, not the product

Divergence appeared in food vehicle preference, dispensing method, and administration mode (swallow vs. disperse). These are cheaper levers than reformulation: labelling, counting aids, and instructions-for-use tailored by market.

Test with LMIC users early — don't assume HIC intuition applies

Bangladesh reversed the expected preference for a single tablet over multiple minitablets. Nigeria preferred sachets over blisters and one-by-one dispensing. Early testing in target markets de-risks late-stage surprises.

What this means for regulators

Transferability	High willingness (76–95%) and taste/size preference held across 4 very different settings.
Standard methodology	Same structured instrument applied in all 4 countries — a replicable, citable model for cross-market acceptability testing.
Synthesis across studies	Designed from the outset for comparison. Convergence and divergence directly readable from one dataset, not retrofitted across separate studies.

FOR DISCUSSION

This data challenges three assumptions industry and regulators often make by default:

01

How children take it

"Take with water" but food vehicle preference varies by market and may affect dosing compliance and coating integrity.

02

What packaging works

Blister pack, but Nigeria's sachet preference and one-by-one dispensing preference require a different pack design.

03

What counts as acceptable

Tested in our clinical population but swallowability thresholds, handling preferences, and willingness differ meaningfully by setting.

Which of these assumptions matters most for decisions your organisation is making right now?

Minitablet Acceptability Session : Speakers

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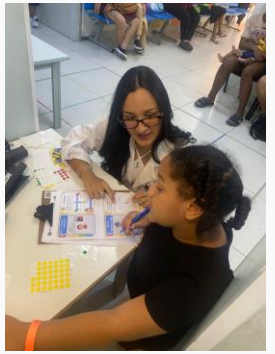
Thank you



Should acceptability evidence from diverse global settings carry more weight in regulatory submissions?

What would it take for industry to design with LMIC users in mind from the start rather than adapting after the fact?

Let's discuss.