Regulating e-pharmacy in Kenya and India

Challenges and opportunities for access and quality of care in LMIC health systems

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E-pharmacy in low & middle income countries

- Rapidly growing e-pharmacy markets
- An opportunity to address major challenges in medicine ***accessibility and affordability***
- Regulation tends to remain based on brick-&-mortar pharmacy regulation, which is itself poorly implemented
- Pharma regulators lack capacity to monitor online transactions; and the power and resources to control large companies

Analysis

BMJ Global Health

When technology precedes regulation: the challenges and opportunities of e-pharmacy in low-income and middle-income countries

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ABSTRACT

The recent growth of medicine sales online represents a major disruption to pharmacy markets, with COVID-19 encouraging this trend further. While e-pharmacy businesses were initially the preserve of high-income countries, in the past decade they have been growing rapidly in low-income and middle-income countries (LMICs). Public health concerns associated with e-pharmacy include the sale of prescription-only medicines without a prescription and the sale of substandard and falsified medicines. There are also non-health-related risks such as consumer fraud and lack of data privacy. However, e-pharmacy may also have the potential to improve access to medicines. Drawing on existing literature and a set of key informant interviews in Kenya, Nigeria and India, we examine the e-pharmacy regulatory systems in LMICs. None of the study countries had yet enacted a regulatory framework specific to e-pharmacy. Key regulatory challenges included the lack of consensus on regulatory models, lack of regulatory capacity, regulating sales across borders and risks of over-regulation. However, e-pharmacy also presents opportunities to enhance medicine regulation—through consolidation in the sector, and the traceability and transparency that online records offer. The regulatory process needs to be adapted to keep pace with this dynamic landscape and exploit these possibilities. This will require exploration of a range of innovative regulatory options, collaboration with larger, more compliant businesses, and engagement with global regulatory bodies. A key first step must be ensuring that national regulators

Summary box

- The e-pharmacy sector has been rapidly growing in low-income and middle-income countries over the past decade, with the COVID-19 pandemic encouraging a further surge in online sales, and an associated rise in cybercrime.
- Online medicine sales are linked to both public health concerns, such as sale of prescription-only medicines without a prescription, and sale of substandard and falsified medicines; and cyber-security concerns, including consumer fraud and lack of data privacy.
- E-pharmacy may also present opportunities for enhancing access to medicines, particularly for those requiring regular medication for chronic conditions, or with problems accessing traditional pharmacy services.
- Regulation of the sector has not kept pace with these rapidly evolving, dynamic markets which operate with ease across national boundaries, and present distinct regulatory challenges.
- Regulators need to pay greater attention to this sector, ensure they have the technical expertise to supervise it and adapt regulatory process to take advantage of the opportunities e-pharmacy provides for enhancing traceability and transparency of medicine sales.

Project Work-Packages

1. Characterise e-pharmacy markets

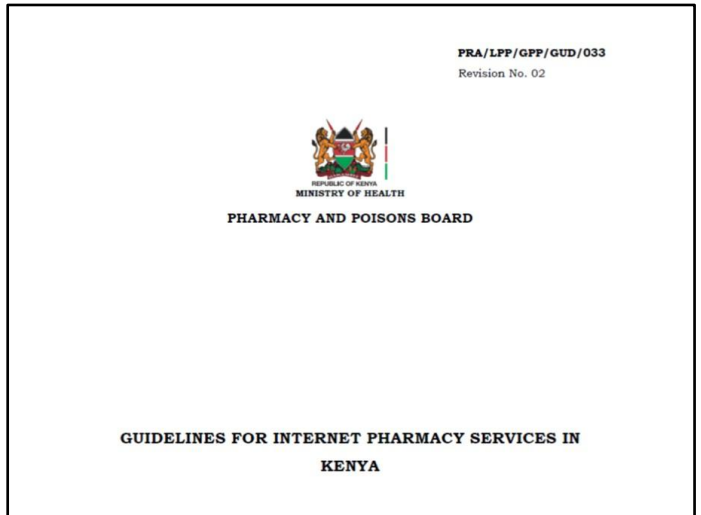
2. Assess performance of e-pharmacies

3. Identify opportunities for strengthening regulation and support

E-pharmacy in Kenya and India

Kenya

- Population – 56 million
- GDP per capita – USD 2,206
- E-pharmacy governed by "Guidelines for internet pharmacy services in Kenya" – revised 2023



PRA/LPP/GPP/GUD/033
Revision No. 02

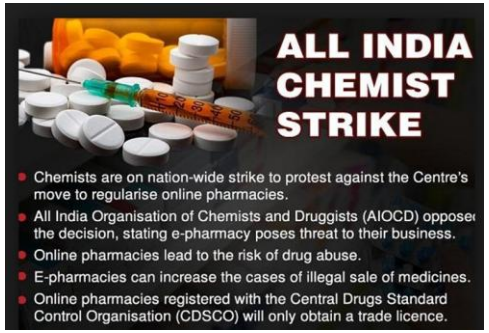
REPUBLIC OF KENYA
MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDELINES FOR INTERNET PHARMACY SERVICES IN KENYA

India

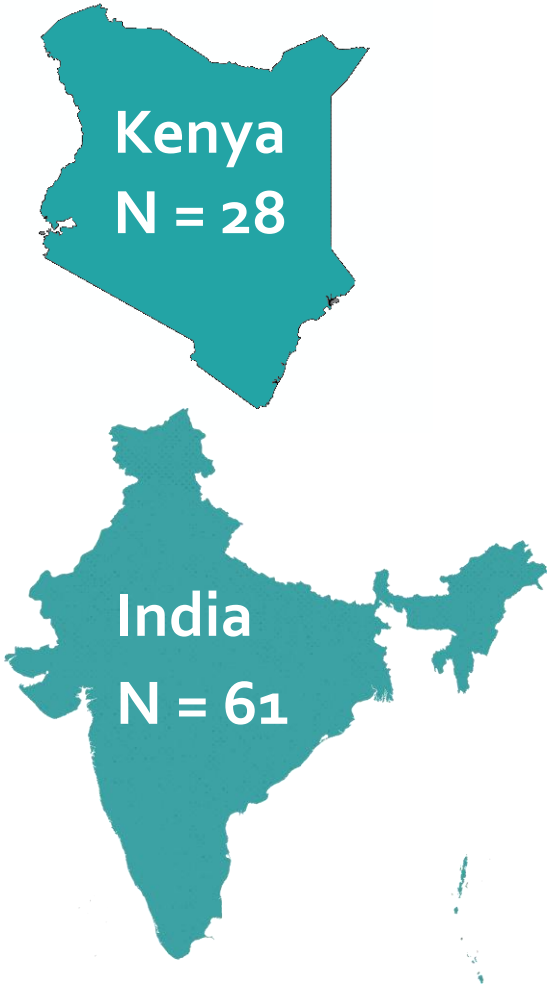
- Population – 1.4 billion
- GDP per capita – USD 2,697
- Draft Rules for the operation of e-pharmacy 2018 - yet to be enacted
- Hotly contested issue



Assessing performance of e-pharmacy

- Universe of e-pharmacies based in India and Kenya identified using typical consumer search strings in Google
- Standardised patient (SP) survey of e-pharmacies, Jun-Nov 2024
- Administered SP cases seeking to purchase prescription-only medicines (POMs):
  - Antibiotic
  - Antihypertensive
  - Insulin
  - NSAID
  - Medical abortion
  - Opioid painkiller
- Source of prescriptions:
  - Kenya – mocked up by research team
  - India – real prescriptions obtained from patients

E-pharmacies identified



SP case scenarios

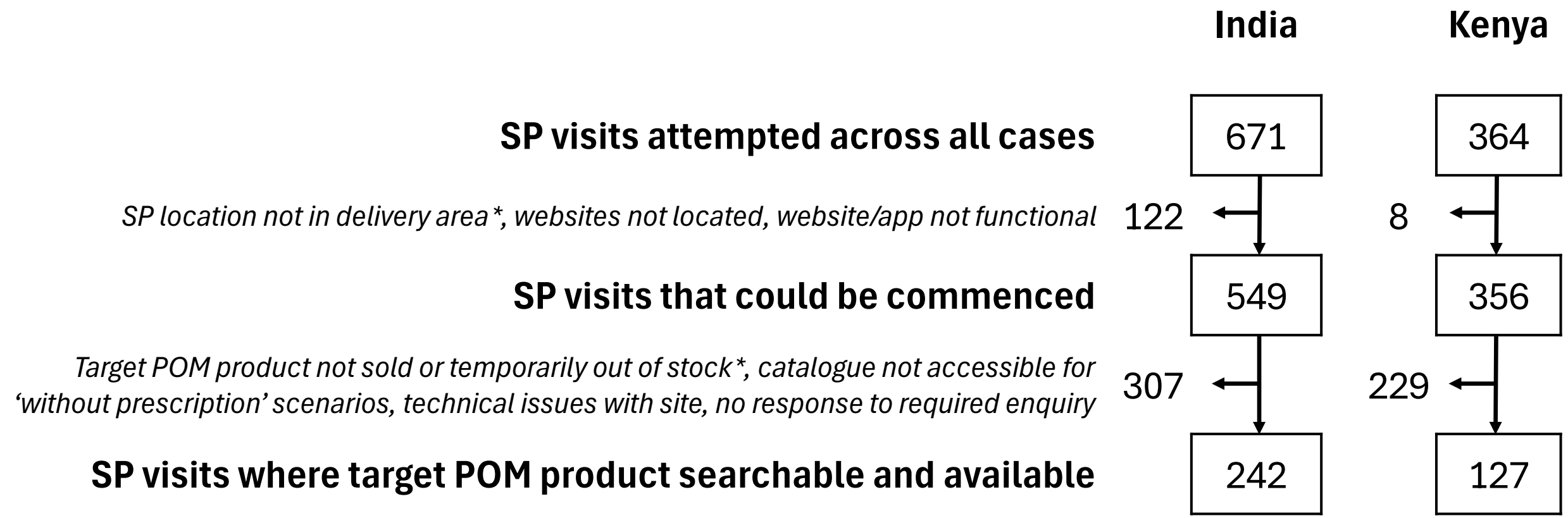
SP case type	Prescription-only medicine	India	Kenya
Correct prescription	Antibiotic (amoxicillin + clavulanic acid)	√	√
	Antihypertensive (amlodipine/nifedipine)	√	√
	Insulin (Mixtard 70/30)	√	√
	Medical abortion (misoprostol + mifepristone)		√
Without prescription	Antibiotic (amoxicillin + clavulanic acid)	√	√
	Antihypertensive (amlodipine/nifedipine)	√	√
	Insulin (Mixtard 70/30)	√	√
	Medical abortion (misoprostol + mifepristone)	√	√
Pharmacy care issues	Prescription with **overdose** (antibiotic)		√
	Request **bulk purchase** of correct prescription (antibiotic)	√	√
	Pregnant SP requests purchase of **contraindication** (diclofenac)	√	√
Online sale prohibited	Opioid (tramadol [+ paracetamol]) – correct prescription	√	√
	Opioid (tramadol [+ paracetamol]) – without prescription	√	√
		11	**13**

Defining correct pharmacy care

% of SP visits managed in line with recommended care and country regulations

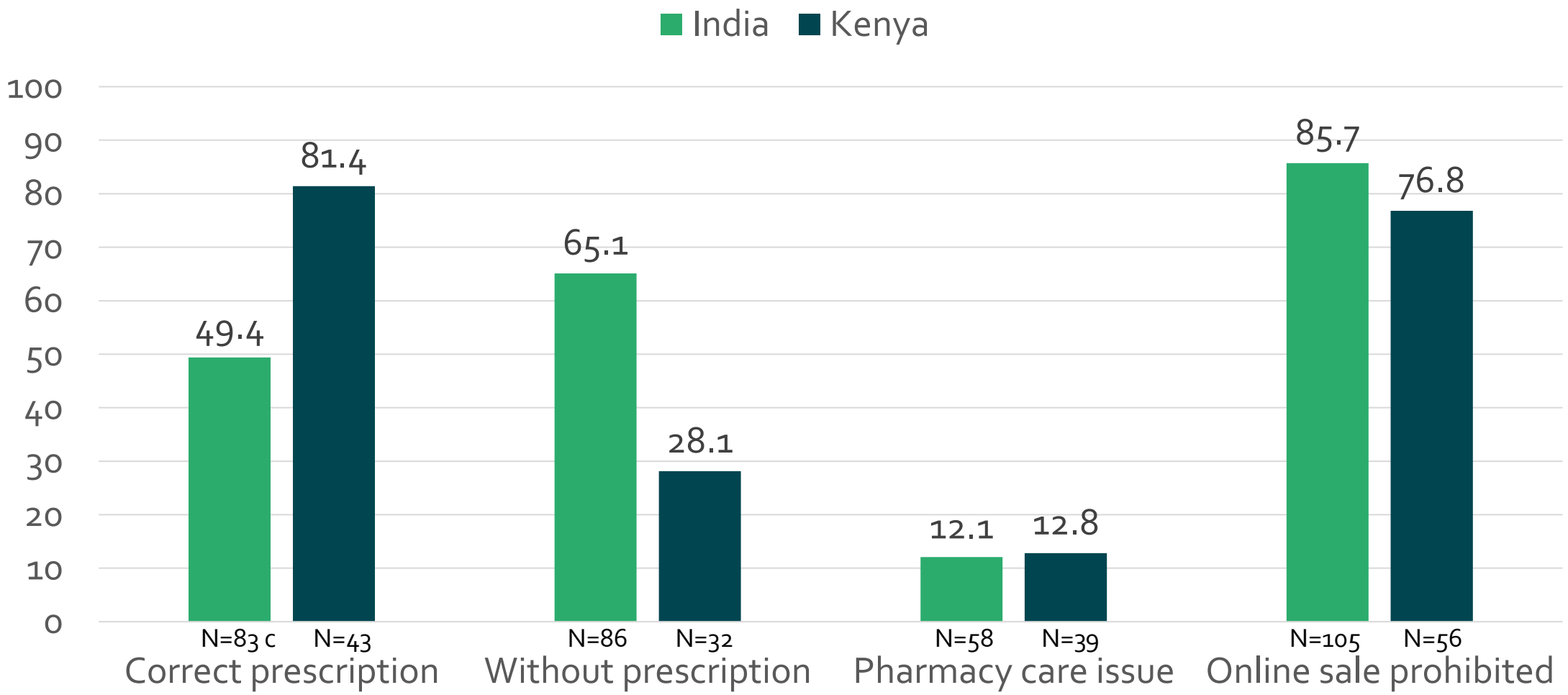
SP case type	Definition of correct pharmacy care
Correct prescription	Requires and accepts provided prescription and POM dispensed according to prescription (of visits where product in stock)
Without prescription	Refuses to dispense POM without prescription OR requires consultation (of visits where product in stock)
Pharmacy care issues	Refuses to dispense POM as requested OR requires consultation or further information (of visits where product in stock)
Online sale prohibited	Product not available for purchase (of all visits)

Results: Description of SP survey samples

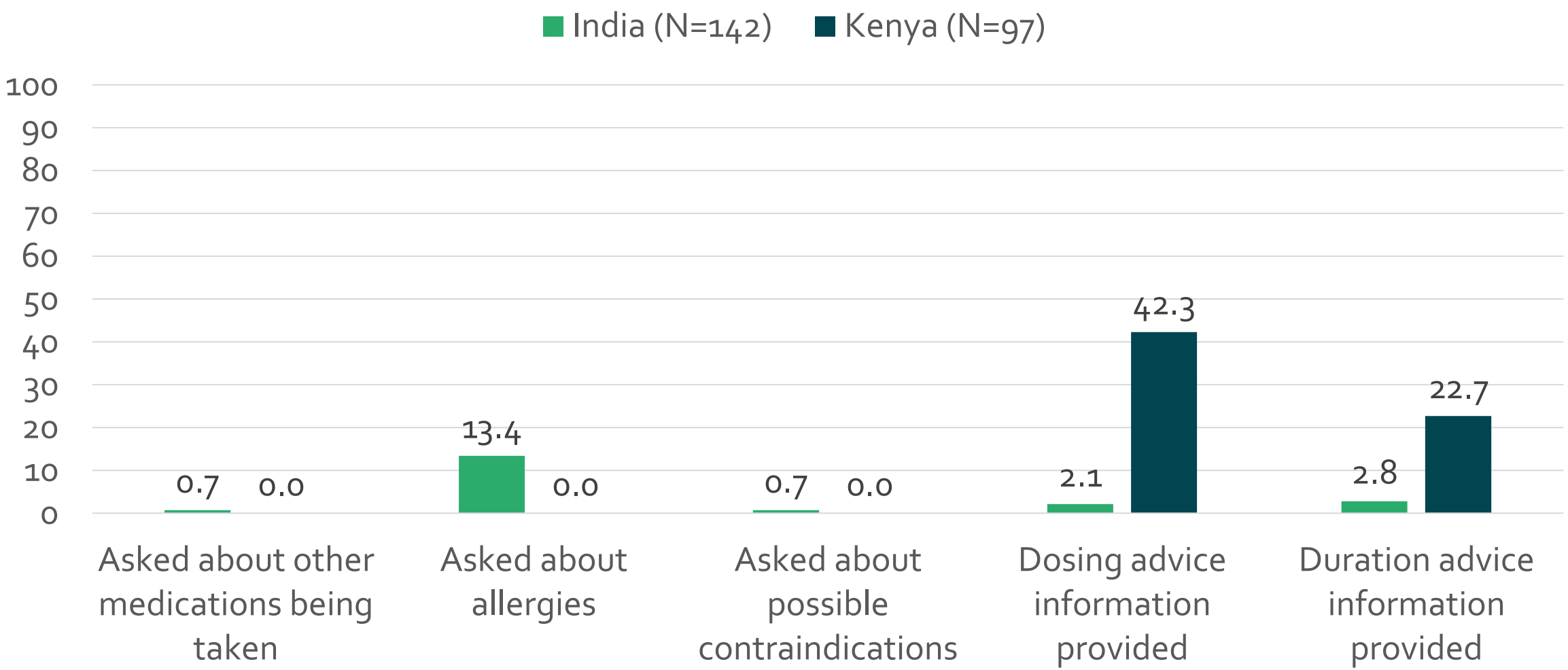


*most frequent reason for dropping out of sample

% of SP cases with correct pharmacy care



Screening and information - % of SPs where:



Do market leaders perform better?

- Earlier analysis of website content showed e-pharmacies with higher visit numbers had higher compliance with regulations and best practices in both countries
- Potentially important implications for average client experience and for regulatory strategies

=> We tested the hypothesis of a positive association between correct pharmacy care and visit numbers

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RESEARCH ARTICLE

The good, the bad, and the ugly: Compliance of e-pharmacies serving India and Kenya with regulatory requirements and best practices

Gautam Satheesh, Sammy Masibo, Sasi Kumar Tiruttani, Irene Khayoni, Benjamin Palafox, Devaki Nambiar, Jaison Joseph, Emmanuel Kweyu, Abdul Salam, Francis Wafula, Catherine Goodman

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Article Authors Metrics Comments Media Coverage

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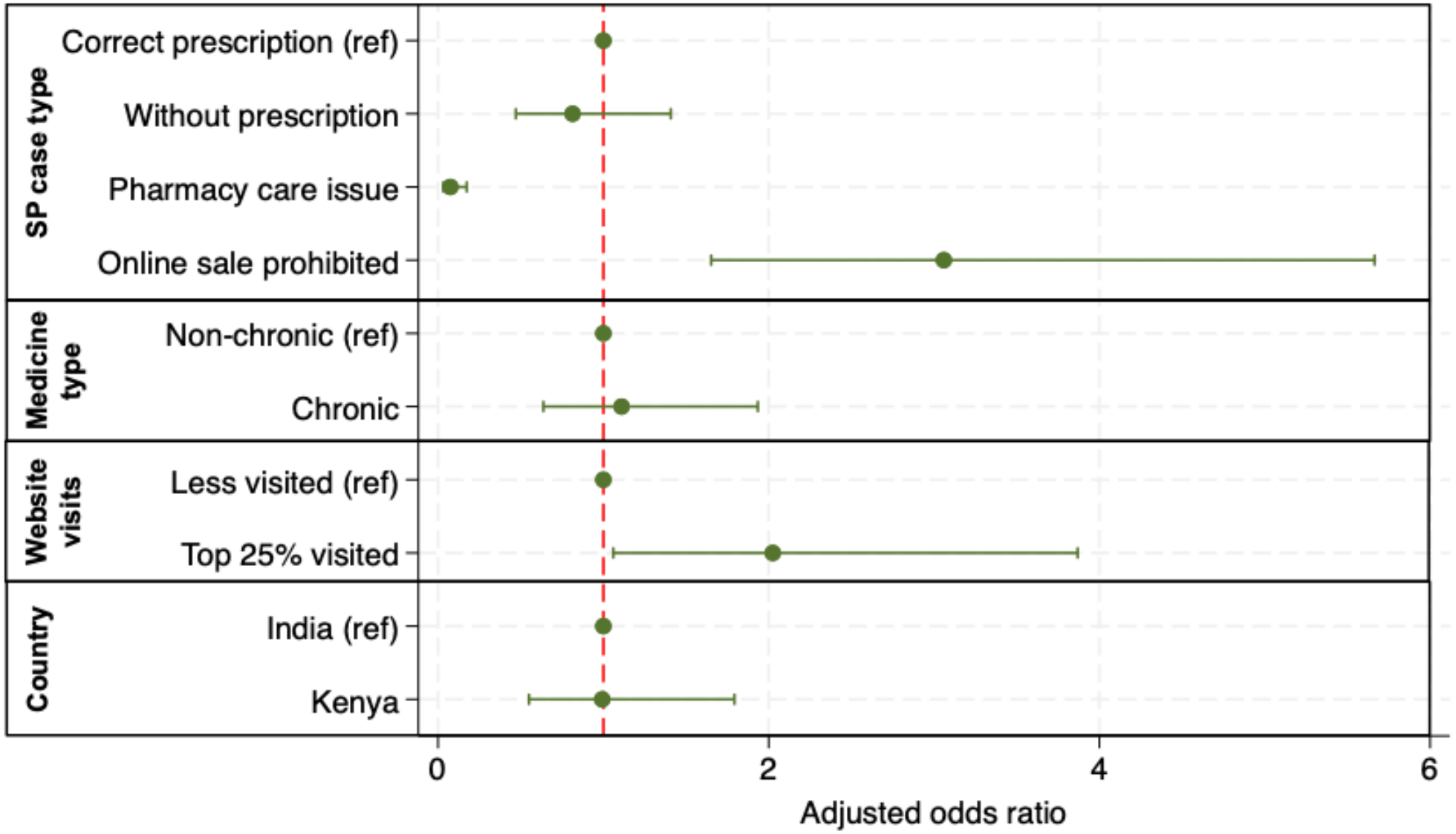
Abstract

As with most technology-driven change, e-pharmacy markets have expanded faster than the pace of regulation, particularly in low- and middle-income countries. We developed and applied a checklist to assess compliance with best practices and regulations by e-pharmacies serving clients in India and Kenya, two countries with contrasting regulatory environments. We defined e-pharmacies as businesses selling prescription-only medicines directly to consumers through websites or apps. We identified the universe of e-pharmacies through online searches, and captured data using a structured questionnaire (Jan–May 2023). We then assessed e-pharmacies against a set of global 'best practice' standards, as well as national regulations (for Kenya) and 'proposed requirements' from local guidelines and draft bills (for India, which had no e-pharmacy-specific regulations). We identified 61 websites and 37 apps serving India, and 26 websites and 3 apps serving Kenya. Regarding best practices, a facility to upload prescriptions was provided by 90% of websites serving India and 58% serving Kenya. Only 16% (India) and 42% (Kenya) provided complete drug information. On average, websites serving Kenya met 8.9 of the 12 (74%) Kenyan regulatory requirements, while those serving India met 7.5 of the 14 (54%) 'proposed requirements'. Only 31% serving Kenya and none serving India displayed required registration numbers. Contrary to regulations/guidelines, many e-pharmacies serving Kenya (62%) and India (34%) listed narcotic/controlled drugs for sale. In both countries, high-traffic websites and e-pharmacies located within the study country had

Determinants of correct management of SPs

- **Dependent variable:** correct pharmacy care for SP visit
- **Independent variables:**
  - *Website traffic* [continuous]: quartiles (Q1-Q4) of estimated visits from similarweb.com
  - *SP case type* [categorical]: Correct prescription (reference), Without prescription, Pharmacy care issues, Online sale prohibited
  - *Medication type* [categorical]: For non-chronic vs. chronic condition
  - *Country*: India vs. Kenya
- **Model:** Fixed-effect logistic regression combined across countries, standard errors accounting for clustering at individual e-pharmacies

Determinants of correct management of SPs



Do brick-and-mortar pharmacies perform better?

- **Comparative Study:** Sub-set of e-pharmacy SP cases repeated in brick-and-mortar retail pharmacies
- **Location:** Nairobi, Kenya and Bengaluru, India
- **Sample size:** 100 retail pharmacies (400 cases in India, 500 cases in Kenya)
- **Sampling approach:** Multi-stage random selection with 'random walk'
- **Timing:** April-June 2025

SP scenarios repeated in B&M pharmacies

SP case type	Prescription-only medicine	India	Kenya
Correct prescription	Antibiotic (amoxicillin + clavulanic acid)		
	Antihypertensive (amlodipine/nifedipine)		
	Insulin (Mixtard 70/30)		
	Medical abortion (misoprostol + mifepristone)		
Without prescription	Antibiotic (amoxicillin + clavulanic acid)		
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	Insulin (Mixtard 70/30)		
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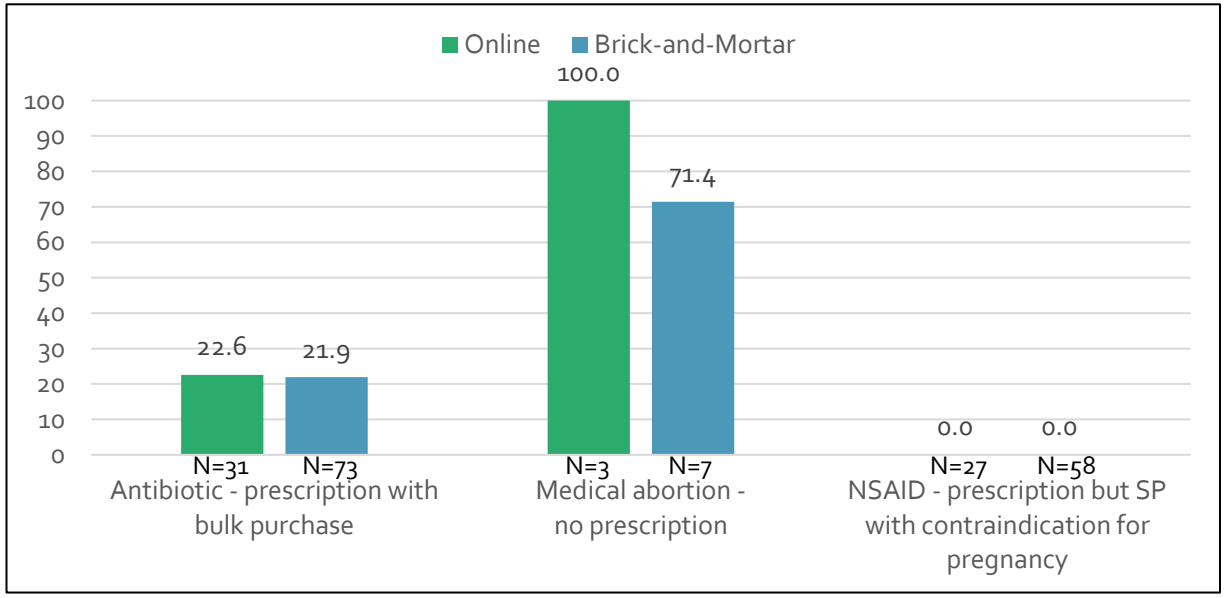
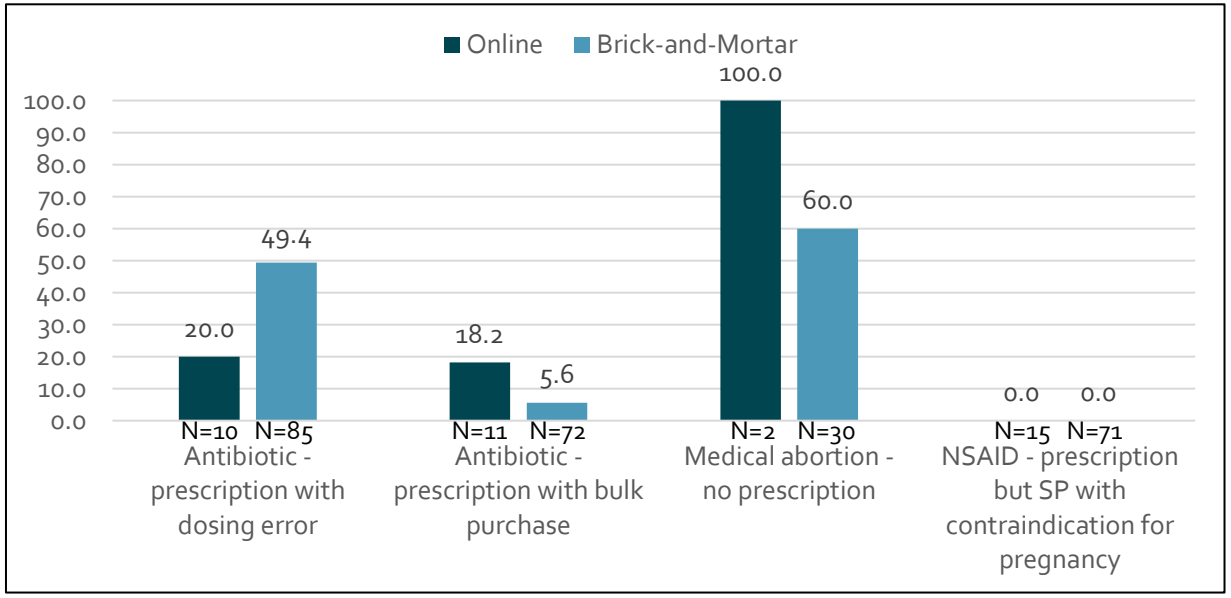
Online sale prohibited	Opioid (tramadol [+ paracetamol]) – correct prescription		
	Opioid (tramadol [+ paracetamol]) – without prescription	√	√
		4	**5**

Correct pharmacy care: comparison with B&M

India

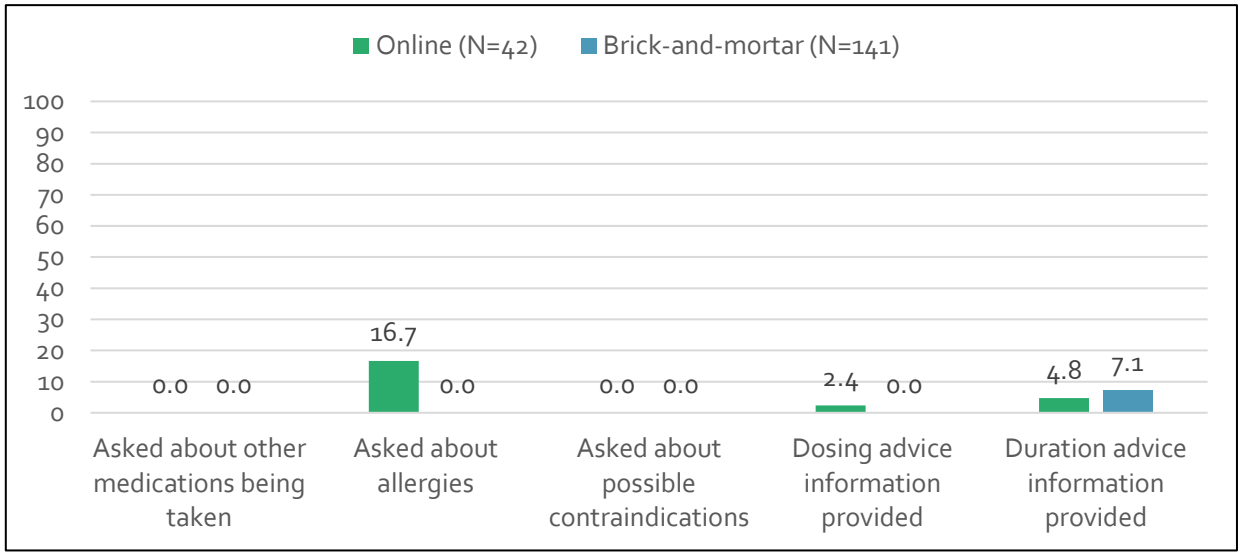


Kenya

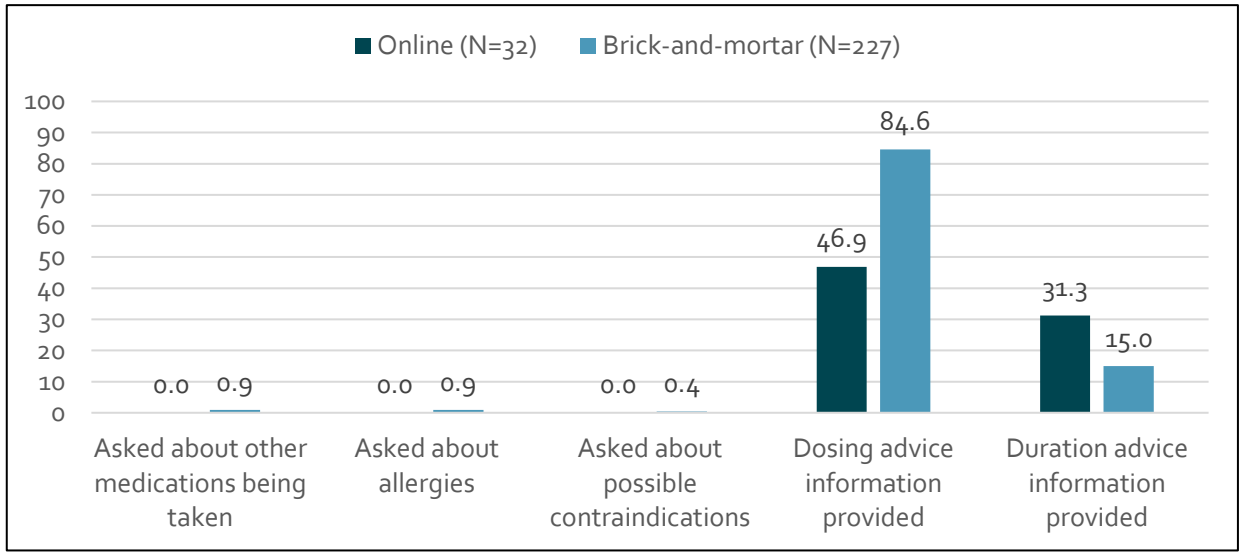


Screening and information: comparison with B&M

India



Kenya



Developing strategies to enhance regulation & support

- Clear scope to improve quality of e-pharmacy care, including among market leaders, and in Kenya where regulation enacted
- Manageable number of e-pharmacies in both countries indicates opportunities to enhance inspection and enforcement

- Exploring options through:
  - **Review of regulations** governing e-pharmacies in 12 countries with relatively developed regulations (Satheesh et al, submitted)
  - **In-depth interviews** on regulatory performance with e-pharmacies, regulators, professional associations & patient groups in India and Kenya
  - **Stakeholder workshops** in India (Oct 25) and Kenya (Nov 25) to discuss regulatory options

Regulatory and Policy Options

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Technical solutions:

- Rx upload facility with AI-assisted checks
- Automated safety checks for contraindications, allergies, interactions
- Integration of e-prescriptions
- Blockchain software to monitor compliance

Risk-based approaches:

- Work with the relatively compliant
- Improve enforcement among the partially
- compliant
- Eliminate the largely non-compliant from the market

Partnership with third parties:

- Domain name registries
- E-marketplaces
- Health insurance organisations
- Accreditation agencies
- Business & consumer organisations

Address the political nature of policy decisions

- Stakeholder consultation across the whole sector
- Consensus building
- Develop momentum for change

Thank you!

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