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The promise and limits of medicine traceability in low-resource settings: Lessons from Ghana

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ABSTRACT

Substandard and falsified medicines continue to compromise health systems in low- and middle-income countries. Ghana has introduced pharmaceutical traceability solutions, yet questions remain about adoption patterns across the pharmaceutical supply chain. This study applied the Diffusion of Innovations theory as an analytical lens to determine patterns of uptake, bottlenecks, and determinants of traceability implementation at the system level in Ghana. We employed a mixed-methods exploratory approach drawing on regulatory documents, post-market surveillance reports published between 2019 and 2024, and semi-structured interviews with 150 stakeholders representing all levels of the pharmaceutical supply chain. Qualitative data were coded using Diffusion of Innovations constructs and inductive themes. Quantitative analyses included descriptive statistics, an Adoption Gap Index, correlation modelling, and stage-wise funnel analysis of transitions from awareness to trial and implementation; the usability of five traceability technologies was also tested. Surveillance data revealed fluctuating detection of non-compliant products, with failure rates reaching 17% in 2024. Awareness of traceability tools was universal among regulators and high among importers (88%), but fell sharply among pharmacies (41%) and consumers (22%), with full implementation of only 2% and 0.5%, respectively; Adoption Gap Index values exceeded 95% for both groups. Trial behaviour was strongly associated with eventual implementation ($r = 0.997$), and low-infrastructure solutions such as SMS-based authentication offered the simplest user experience. Based on our Traceability Adoption and Diffusion Model, we propose enforcement, user-centred redesign, low-technology authentication, and feedback loops as interventions to close the adoption gap.

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1. Background

Substandard and counterfeit medicines have become a pervasive issue affecting healthcare worldwide. This is particularly severe in the low and middle-income countries (LMICs) where the medicines regulatory framework is usually underfunded (McManus & Naughton, 2020; Ozawa et al., 2018). The World Health Organization (WHO) has stated that about one (1) out of ten (10) health-related products in LMICs is either counterfeit or of inferior quality (World Health Organization, 2017). Such products do not only lead to poor health outcomes, but they also contribute to the emergence of antimicrobial resistance and undermining trust in local healthcare systems (Ozawa et al., 2018).

Ghana faces a severe and rapidly evolving challenge with substandard and counterfeit medicines. Medicines in high demand such as antibiotics and emergency contraceptives are especially targeted. These product categories are not only therapeutically essential, but also consumed widely, making them ideal targets of counterfeiting (Mante et al., 2024).

In response to these issues, many nations have begun implementing pharmaceutical traceability systems. These systems allow regulators and supply chain participants to track the flow of medicines from the manufacturer all the way to the patient (Kootstra & Kleinhout-Vliek, 2021; Parmaksiz et al., 2020). Traceability of pharmaceutical supply chains refers to the ability to monitor and verify the route of a medicine, ensuring its legitimacy and enabling the rapid identification of counterfeits (Mackey & Nayyar, 2017; Parmaksiz et al., 2020). Common traceability tools include unique product identifiers (serialization), barcodes (GS1 standards), mobile-based authentication methods (QR codes, USSD), and blockchain-based platforms for real-time tracking (Pathak et al., 2023; USAID Global Health Supply Chain Program–Procurement and Supply Management [GHSC-PSM], 2021). These tools are designed to ensure that every single unit of medicine can be verified and tracked (Musamih et al., 2021; GHSC-PSM, 2021).

Ghana has introduced such tools as ProPer Seals, yet their usage is not evenly spread among the stakeholder groups (Mante et al., 2024). The ProPer Seal technology allows a consumer to authenticate the authenticity of the medication through SMS or by scanning QR-code (Mante et al., 2024). Also, small-scale serialization of products (particularly those being financed by donor organizations like the Global Fund) has been tested on GS1 standards. Nevertheless, this is yet to be scaled system wide.

To understand the reason behind the fragmented adoption of such technologies among the stakeholder groups, this research assesses the adoption of traceability systems in the lens of the Diffusion of Innovations (DOI) theory (Rogers, 1995; Rogers et al., 2014). DOI explains how new ideas and practices spread within populations over time, influenced by both the nature of innovation and the social system in which it is adopted (Rogers, 1995; Rogers et al., 2014). This model is useful especially in the explanation of systems which are usually preventive in nature. The benefits of preventive innovations, unlike therapeutic innovations, have long-term and probabilistic benefits (e.g., lower counterfeit risks), rather than tangible, immediate benefits (e.g., improved health outcomes) (Greenhalgh et al., 2004; Rogers et al., 2014). Consequently, uptake may be slow unless they are backed by strong incentives, enforcement procedures or observable societal norms (Gilson, 2012; Rogers, 1995; Rogers et al., 2014).

The application of DOI in the context of Ghana enables the structured analysis of the progress of various stakeholders, including regulators, importers, distributors, pharmacies, and consumers, through the process of innovative adoption, observing where bottlenecks are present. This is the theoretical basis for our proposed Traceability Adoption and Diffusion Model (TADM), offering a practical framework to diagnose gaps and guide targeted interventions across the pharmaceutical supply chain.

2. Methods

2.1. Study design

Our research used a mixed-method exploratory design, through a combination of qualitative-based interviews and quantitative-based document analysis investigating the implementation of pharmaceutical traceability in Ghana. The study explored trends of adoption, barriers to implementation, and the prevalence and monitoring of counterfeit medicines. The research was grounded on the principles of implementation science, namely, the Diffusion of Innovations theory and models of health systems research, which focus on the mutual relationship between a context, stakeholder behavior, and systems-level preparedness (Peters et al., 2013).

2.2. Data sources and collection

2.2.1. Document review

The review of regulatory and programmatic documents was structured to identify the trends in post-market surveillance, traceability policy, and prevalence of counterfeit medicine. Sources of data include Ghana Food and Drugs Authority (FDA) annual reports; Reports by the Ministry of Health (MoH); Pharmacy Council Ghana; Health Facilities Regulatory Authority (HeFRA); Audits and evaluation of donor-supported programs (e.g., Global Fund, USAID). Important variables obtained included: the number of samples tested, the failure rates, most frequently counterfeited products, as well as the technologies applied in surveillance.

2.2.2. Stakeholder interviews

Purposely selected participants (150) in the pharmaceutical supply chain (including Government actors: FDA officials, Pharmacy Council staff, customs officers; Private sector: Importers, manufacturers, wholesalers, and licensed pharmacies; Healthcare professionals: Pharmacists, procurement officers; Consumers: Urban and peri-urban end-users) were interviewed in semi-structured interviews. The participants were recruited using a purposive and snowball sampling, with a focus on people who had an operational, regulatory or user-level experience with traceability systems. The interviews were carried out in English or in Twi, over 30-60 minutes and were taped with the informed consent. All the transcripts were anonymized and stored safely.

2.2.2.1. Interview guide and thematic focus

The interview guide was developed based on the five attributes of the DOI framework and adapted for the Ghanaian pharmaceutical environment. Thematic questions were: Awareness and use of traceability tools (e.g., GS1, RFID); Risk perception of counterfeit medicines; Experience with product authentication or reporting; Barriers to adoption (e.g., infrastructure, cost, training gaps); Recommendations on how traceability can be improved. The guide was pilot tested with 20 respondents and subsequent revisions were made to enhance clarity, relevance and cultural appropriateness.

2.3. Data analysis

2.3.1. Qualitative analysis

Transcripts of the interviews were imported into NVivo 12 and analyzed through deductive thematic coding based on the DOI constructs developed by Rogers: Relative Advantage; Compatibility; Complexity; Trialability; Observability. Inductive codes were included to reflect the emergent themes like gaps in enforcement and constraints related to the stakeholder. The transcripts were independently coded by two researchers. Consensus was used to eliminate the discrepancies so as to achieve inter-coder reliability. Patterns were also synthesized across the categories of stakeholders so as to determine the structural and behavioral barriers to adoption of traceability.

2.3.2. Quantitative analysis

The significance of quantitative data analysis was on:

2.3.2.1. Adoption Gap Index and descriptive statistics

Descriptive statistics were used to present data from FDA surveillance reports: sample volumes, failure rates, product categories; measures of adoption across stakeholder groups: awareness, trial use, and full implementation (n = 150); Adoption Gap Index (AGI), calculated to determine the percentage of stakeholders who know about traceability systems but have not adopted them:

$$\text{AGI (\%)} = [(\text{Awareness} - \text{Implementation}) / \text{Awareness}] \times 100$$

2.3.2.2. Correlation and regression modeling

To determine the relationship among stages of adoption, Pearson correlation coefficients (r) were computed between:

Awareness – Trial: Do stakeholders who are aware of traceability tools tend to try them?

Awareness – Implementation: Does awareness lead to full adoption?

Trial – Implementation: Do those who trial a tool go on to implement it fully?

A multiple linear regression analysis was developed to forecast the implementation behavior based on awareness and trial:

$$\text{Implementation} = -3.54 - 0.11(\text{Awareness}) + 0.99(\text{Trial}); R^2 = 0.997$$

The predictive contribution of each variable was quantified using this model and confirmed the behavioral patterns among the stakeholders.

2.3.2.3. Funnel and diffusion analysis

There was a stage-wise funnel analysis to define the adoption drop-off points within the entire supply chain and the transition rates between: Awareness – Trial (do the aware stakeholders attempt to use traceability tools?) and Trial – Implementation (do those who trial a tool go on to implement it fully?). The leakage rates were calculated per stakeholders' group to highlight where engagement efforts were breaking down. Interviews were also mapped to DOI attributes of each stakeholder group producing composite scores of adoption readiness for Importers; Distributors; Retail Pharmacies; and Consumers.

2.4. Usability testing of technology

Five traceability tools that were assessed based on stakeholder feedback and implementation simulations: GS1 barcoding and portal systems; ProPer Seal (SMS-based authentication); RFID tagging solutions; Blockchain traceability platforms (pilot stage); non-GS1 proprietary barcodes. All the tools were evaluated with regard to: Ease of Use (1-5 Likert scale); Infrastructure Requirements (Low, Moderate, High); Common Barriers (e.g., licensing, equipment, technical literacy).

2.5. Ethical considerations

Ethical approval was obtained from the Humanities and Social Sciences Research Ethics Committee, Kwame Nkrumah University of Science and Technology (HuSSREC/AP122/VOL.1). The study conformed to the ethical standards set out in the Declaration of Helsinki. Informed consent (written or verbal) was obtained from all participants. Anonymity and confidentiality were maintained throughout.

To minimize social desirability bias, interviewers emphasized the non-regulatory, independent nature of the study, especially during interviews with pharmacies, informal providers, or consumers.

3. Results

3.1. Demographic data of stakeholders

Stakeholders consisted of 55 percent of male and 45 percent of female respondents with ages ranging between 22 and 60 years (mean = 35.2, SD = 8.1), which represents a large working population. Pharmacists and the distributors were the largest stakeholder groups (40 and 20 percent, respectively). Regarding educational qualification, most of the respondents had a bachelor's degree (50%), a diploma (30%), and master's degree

holders (15%), and others (5%). The sample was both geographically varied and respondents were mainly represented by the Greater Accra (40%), Ashanti (25%), and Volta (15%), Northern (10%), and Western (10%) (Table 1).

Table 1
Demographic characteristics of study respondents (N = 150)

Variable	Category	n (%)
Gender	Male	91 (60.7%)
	Female	59 (39.3%)
Age	Mean ± SD	35.0 ± 7.9 years
Stakeholder role	Pharmacist	58 (38.7%)
	Distributor	29 (19.3%)
	Importer	14 (9.3%)
	Regulator	23 (15.3%)
	Consumer	26 (17.3%)
Education level	Bachelor's degree	76 (50.7%)
	Diploma	47 (31.3%)
	Master's degree	22 (14.7%)
	Other	5 (3.3%)
Region	Greater Accra	57 (38.0%)
	Ashanti	35 (23.3%)
	Volta	22 (14.7%)
	Northern	19 (12.7%)
	Western	17 (11.3%)

3.2. Status of traceability tools and systems in Ghana

Ghana has implemented various traceability systems such as ProPer Seals and post-market surveillance. Although the ProPer Seals and serialization are applied selectively, that is, to mostly the imports financed by donors, post-market surveillance is even more pervasive, yet the combination with traceability systems is underutilized. GS1 serialization has been proposed but yet to be implemented (Table 2).

Table 2
Traceability systems in Ghana and their implementation status

Traceability system	Description	Implementation status
ProPer Seals	Consumer authentication via QR code or SMS short code for select high-risk imported products.	Partially implemented on selected imported products
GS1 serialization	Barcodes with unique serial numbers applied by some importers/distributors, mostly for donor-funded medicines.	Policy stage
Post-market surveillance (PMS)	Routine inspections and product sampling by FDA teams; limited integration with traceability tools.	Widespread testing activity, but weak traceability integration

3.3. Surveillance data (2019–2024)

3.3.1. Non-compliant products identified in trade

Within the years of 2019 to 2024, there was a substantial amount of variation in the FDA market surveillance activities and the detection of non-compliant pharmaceutical products. The highest rate of non-compliant product was reached in 2019 (124,905) and 2022 (95,093) when the activity in the field was more aggressive and when raids were carried out with targets. The operations of market surveillance remained fairly constant in 2019-2021, but in 2023, the number of surveillance activities has doubled that of the year before. It is important to note that the number of products flunking varied throughout the years, with certain values of 11.4 per cent in 2019 and a maximum of 17 per cent in 2024 through risk-based testing (Fig. 1).

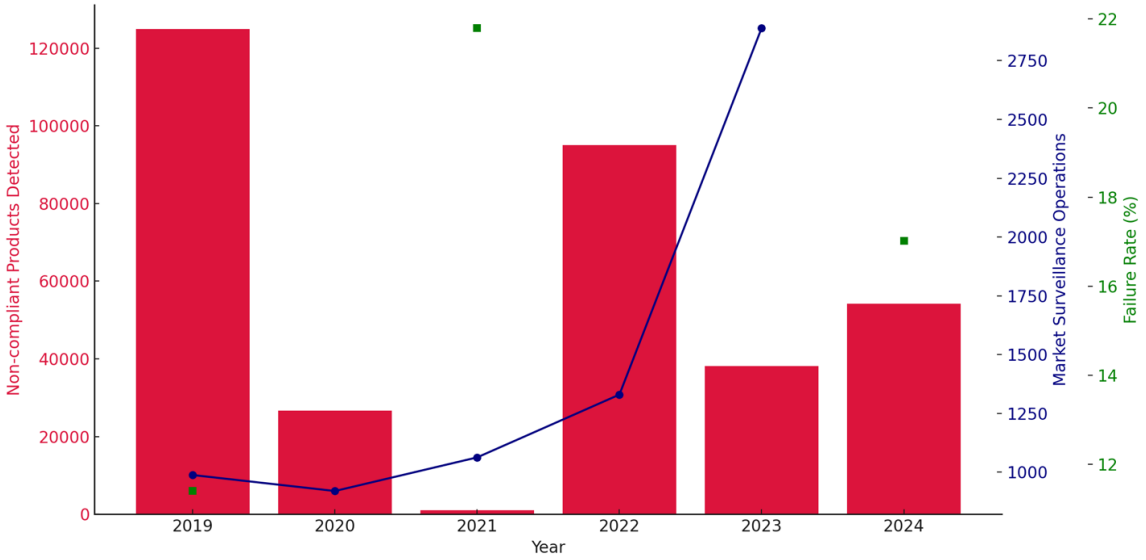


Fig. 1. Non-compliant products detected and product failure rates from FDA market surveillance.

3.3.2. Product sample testing and analysis

Samples of pharmaceutical products analysed by the FDA's Centre of Laboratory Services and Research (CLSR) during 2019 to 2024 vary considerably in the number of received and analyzed samples. There was a high submission of samples in 2020 (7,010) which was more than twice the number of 2,896 which it received in 2019 before slowly decreasing thereafter to 4,280 in 2024. The same trend was observed in volume of analysis, with 6,418 samples having been tested in 2020, 2,380 and 2,440 in 2019 and 2024 respectively.

Although the volume changed, the proportion of received samples analyzed (analysis rate) was over 89% between 2019 and 2023 with a peak of 93.2 in 2023. In 2024, however, it was down to 57 percent, as a result of operational pressures such as shortages of equipment and the forced shutdown of microbiological testing facilities (Fig. 2).

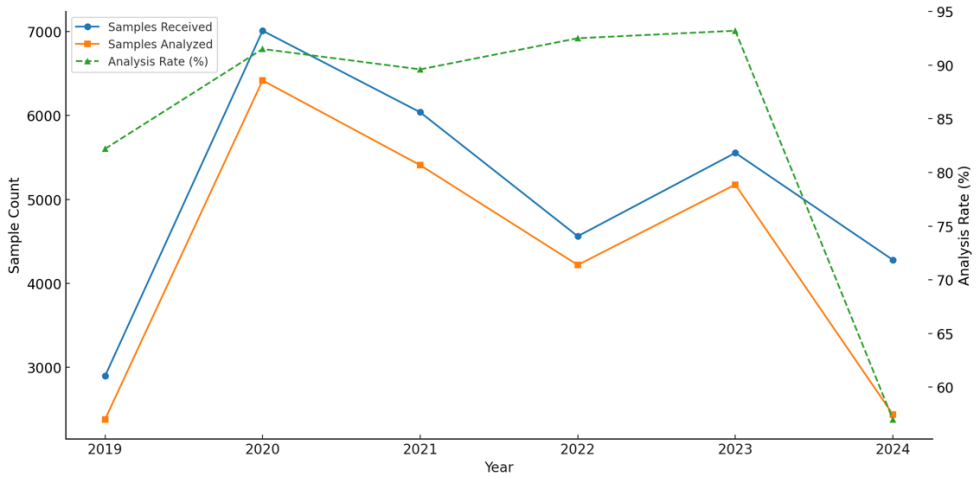


Fig. 2. FDA sample testing and analysis rate (2019–2024).

3.4. Safety monitoring

The most common and the most at-risk groups of pharmaceutical used were identified by the stakeholders as antibiotics (e.g., Amoxicillin-Clavulanic Acid, Ciprofloxacin), antimalarials (e.g., Artemether-Lumefantrine), and emergency contraceptives (e.g., Postinor-2). These items were selected because of their therapeutic value, generalized use and demand in cities and peri-cities. Moreover, an increase in unregistered COVID-19-related herbal and homeopathic products in the period of the pandemic overwhelmed the existing regulation surveillance systems, and counterfeit lifestyle drugs were also announced, namely Sildenafil and vildagliptin-metformin (Galvus Met), but with lower rates (Table 3).

Table 3
Most commonly identified counterfeit drugs by stakeholders

Product category	Common examples	Risk justification
Antibiotics	Amoxicillin + Clavulanic Acid, Ciprofloxacin, Azithromycin	High therapeutic importance, widespread use
Emergency contraceptives	Levonorgestrel (Postinor-2)	High demand, critical timing of use
Antimalarials	Artemether-Lumefantrine (Coartem)	Widespread use in endemic areas
COVID-19 remedies	Unregistered herbal/homeopathic products	Pandemic-driven surge, unregulated market
Lifestyle and chronic disease medicines	Sildenafil (Viagra), vildagliptin-metformin (Galvus Met)	Moderate demand, less regulatory scrutiny

3.5. Assessment of traceability adoption among stakeholders

3.5.1. Overall adoption patterns of traceability tools

The adoption of traceability in the pharmaceutical supply chain in Ghana is characterized by a sharp decrease in the chain of upstream regulatory bodies to the downstream final consumers. Regulators have attained complete awareness and trial (100%), a relatively high degree of full implementation (85%) of the institutional mandates and enforcement capacity, as indicated in Fig. 3. But the supply chain implementation levels decline to a significant extent. Of the importers, 88% have awareness, but only 42% have experimented with a traceability tool, with only 26% having gone to full scale implementation. This decline steadily with the distributor level with only 18% tried traceability solutions, and 9% already adopted it, even though 70% are aware.

Pharmacies and consumers are the most dramatic points of adoption since they are the most important end nodes of the supply chain. Awareness of traceability tools is only reported by 41 percent of pharmacies, and only 2 percent have actually implemented any system. This is because awareness among consumers is only 22 and less than 1 percent of them use any type of traceability mechanism.

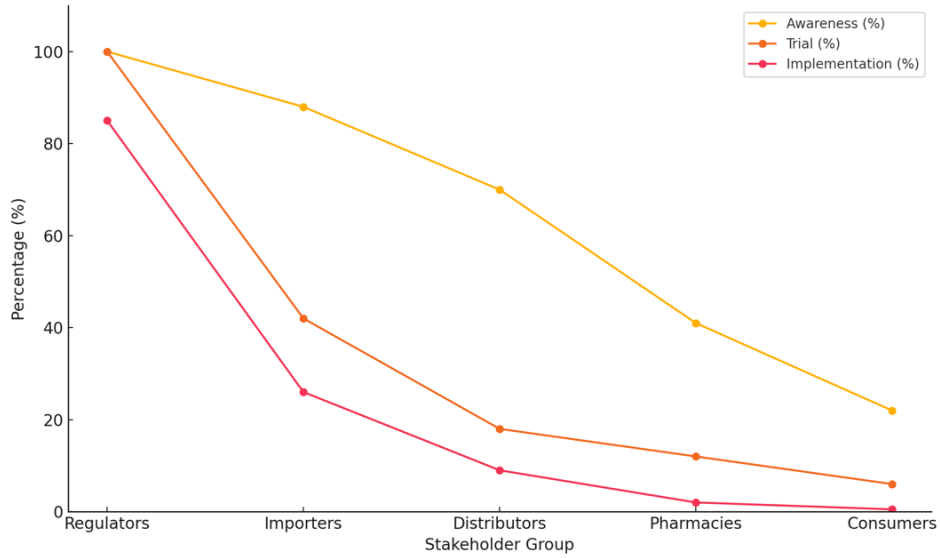


Fig. 3. Traceability adoption by stakeholder group.

3.5.2. Adoption Gap Index (AGI)

Table 4 shows AGI values among the important stakeholders. The AGI of the consumer groups stands at the highest of 97.7. This means that nearly every consumer, who knows about the traceability tools, has not been able to embrace it. The AGI of pharmacies is also highly uninspiring at 95.1, which discloses a significant obstacle in the downstream delivery system of the private healthcare system. Although the rate of its adoption is comparatively high in importers, 87.1% of the distributors who are aware have not adopted traceability mechanisms with a gap of 70.5 still being there even among importers.

Table 4
Adoption Gap Index (AGI) by stakeholder

Stakeholder	Awareness (%)	Implementation (%)	AGI (%)
Importers	88	26	70.5
Distributors	70	9	87.1
Pharmacies	41	2	95.1
Consumers	22	0.5	97.7

3.5.3. Stages of innovation adoption

As shown in Table 5, the relationship between trial and full implementation was nearly perfect (r = 0.997), indicating that stakeholders who engage in trial use are highly likely to fully adopt traceability solutions. Similarly, strong correlations were observed between awareness and trial (r = 0.83), and awareness and implementation (r = 0.80).

Table 5
Correlation matrix of adoption stages

Variable pair	Correlation (r)	Interpretation
Awareness ↔ Trial	0.83	Strong positive correlation
Awareness ↔ Implementation	0.80	Strong positive correlation
Trial ↔ Implementation	0.997	Strong positive correlation

The corresponding Fig. 4 visualizes this adoption gap trajectory, highlighting the steep attrition between awareness and full implementation as one moves downstream in the supply chain.

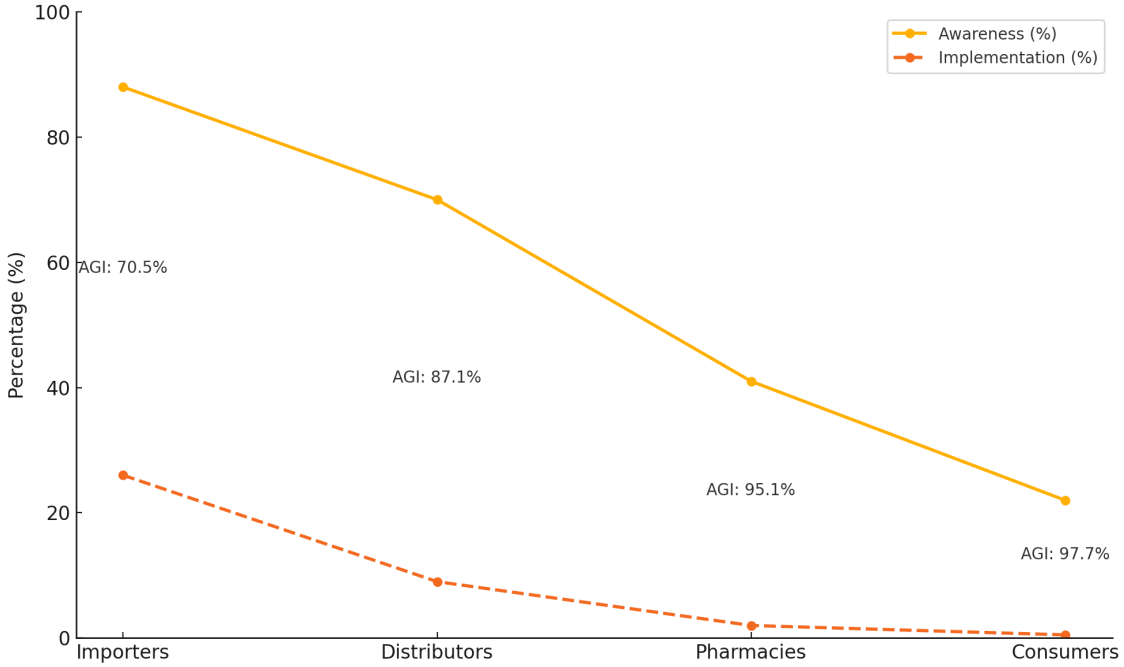


Fig. 4. Awareness versus implementation values.

3.6. Technology usability and accessibility scores

The findings indicate that the traceable tools differ in their convenience, infrastructure requirements, and barriers to implementation. Whereas the least demanding and easiest to use is ProPer Seal (SMS), its impact is minimal due to the lack of awareness. Conversely, GS1 barcodes and blockchain platforms are less user-friendly, more complicated, and require expensive infrastructure. Barcodes and RFID tags are considered to have moderate usability but possess hardware limitations and system compatibility issues (Table 6).

Table 6
Usability and accessibility ratings of traceability tools

Tool/technology	Ease of use (1–5)	Infrastructure requirement	Common barriers
GS1 (barcodes + portal)	2 (Difficult)	High	Licensing costs, complex UI/UX, training needs
ProPer Seal (SMS)	4 (Easy)	Low	Low public awareness, no feedback after scans
RFID tags	3 (Moderate)	High	Hardware costs, warehouse setup, technical integration issues
Blockchain-based systems	2 (Difficult)	High	Lack of local expertise, limited interfaces, power dependency
Standard barcodes (non-GS1)	3 (Moderate)	Moderate	Poor scanner availability, format inconsistency

3.7. Stage-wise drop-off funnel: Diffusion of Innovations

The findings indicate high rates of drop-offs along the adoption pipeline particularly between pharmacies and the consumers. Whereas importers present a comparatively better conversion from awareness to trial (47.7% drop-off) and trial to implementation (38.1% drop-off), the downstream actors have far higher attrition. About 83 percent of adopters are lost between trial and implementation by pharmacies and over 91 percent are lost by consumers (Table 7).

Table 7
Conversion rates and drop-off between adoption stages

Stakeholder	Awareness → Trial (%)	Drop-off	Trial → Implementation (%)	Drop-off
Importers	88 → 42 (47.7%)	−47.7%	42 → 26 (38.1%)	−38.1%
Distributors	70 → 18 (74.3%)	−74.3%	18 → 9 (50.0%)	−50.0%
Pharmacies	41 → 12 (70.7%)	−70.7%	12 → 2 (83.3%)	−83.3%
Consumers	22 → 6 (72.7%)	−72.7%	6 → 0.5 (91.7%)	−91.7%

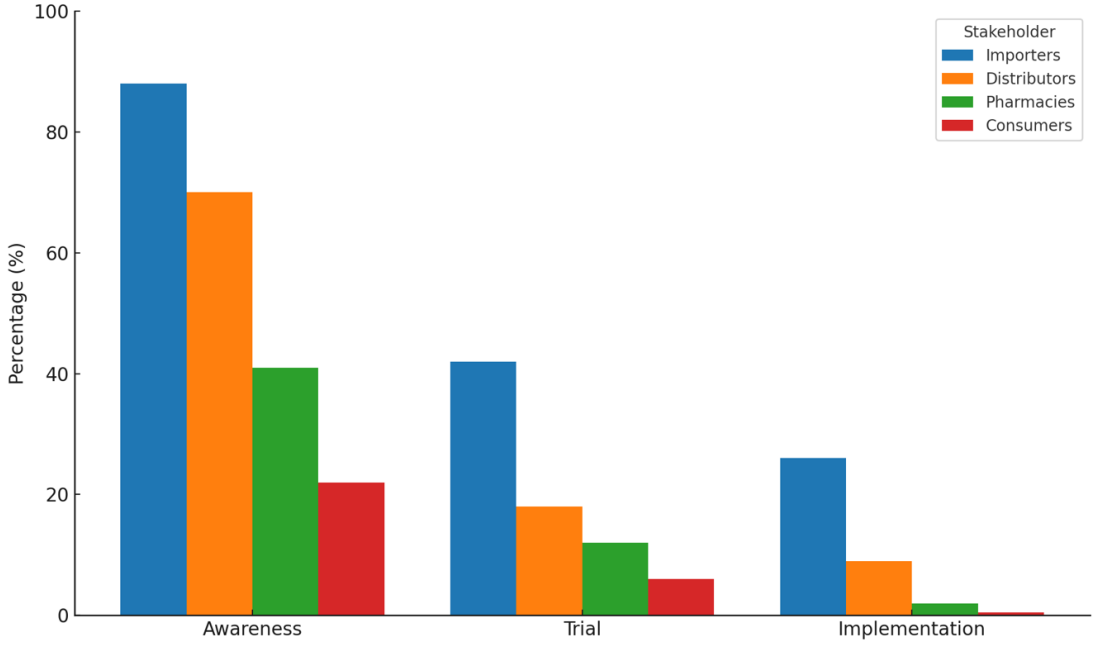


Fig. 5. Conversion rates between adoption stages.

3.8. Diffusion of Innovations (DOI) attribute analysis

These findings synthesize stakeholder narratives and implementation patterns across the five core attributes that shape the likelihood of adoption: *relative advantage*, *compatibility*, *complexity*, *trialability*, and *observability*.

3.8.1. Relative advantage

The results show a large variance in the perceived usefulness of traceability tools across the stakeholder groups. The other reason was that traceability was useful by importers as a regulatory compliance tool, as an exhibition of responsibility to the donor as well as an instrument of inventory control where international funding is involved.

> *"We require traceability for audit trails, particularly for stock that is funded by donors."* — Importer

Conversely, the pharmacies and consumers had low perceived value. A significant number of respondents could not identify any direct benefits of traceability such as saving time, increased sales, and engagement with customers. To these groups, the tools were perceived as just regulatory burden and not enabling ones.

> *"Unless required, we do not see the need. Customers do not ask for verification."* — Pharmacy owner

3.8.2. Compatibility

Compatibility with existing systems and workflows emerged as a major barrier. Many retail pharmacies have manual and paper-based operations, and it is not an easy task to incorporate traceability protocols, which are based on digital infrastructure or barcodes scanning.

> *"We don't have scanners or even smartphones."* — Urban pharmacy staff

The requirements of a traceability system do not match current realities of operation, indicating a low compatibility rating, especially among downstream participants of the supply chain.

3.8.3. Complexity

Traceability systems like GS1 barcoding and mobile authentication services were outlined by the stakeholders as cumbersome and hard to grasp especially at the retail level. Common problems included several interfaces, varied labeling formats and confusion on what to do next after scanning. The level of perceived complexity was high and only 2 percent of the surveyed pharmacies stated that they could perform a complete end-to-end traceability verification without outside support.

> *"I tried the GS1 system and I could not tell whether it was working. No clear steps."* — Pharmacy staff

3.8.4. Trialability

Opportunities for low-risk experimentation with traceability systems were limited. With no donor-funded pilots, there were limited stakeholders with opportunity to test these innovations freely without fear of scrutiny by regulators. Some pharmacies were hesitant because of the lack of confidence in the efficiency of systems or even potential punitive implications.

> *"Trying the system without knowing if it works or helps us makes no sense."* — Pharmacist

3.8.5. Observability

One of the barriers to adopting the traceability systems was the fact that there was no visible impact of working with traceability systems. The respondents indicated that they did not get any feedback or confirmation of the outcome after scanning or reporting products that were suspicious. This lack of reinforcement reduces the desire to use the tools further and also leads to low confidence in the value of the system.

> *"Even when I scan, I do not know what to do after that."* — Pharmacy staff

3.9. Synthesis: diffusion attribute ratings by stakeholder group

Table 8 shows comparative scores of the five attributes of innovation in four key stakeholder groups, including importers, distributors, pharmacies, and consumers. Synthesis indicates a gradual decline in adoption and readiness of the upstream actors (importers). The importers rated the traceability systems highly in terms of the relative advantage and medium in terms of compatibility, which was mainly attributed to exposure to global compliance requirements and excellent infrastructure. On the other hand, all the pharmacies and consumers rated majority of the attributes namely, trialability and observability either low or very low. This was an expression of low user empowerment, digital access and relevance.

Table 8
DOI attribute ratings by stakeholder group

DOI attribute	Importers	Distributors	Pharmacies	Consumers
Relative advantage	High	Medium	Low	Low
Compatibility	Medium	Low	Low	Very low
Complexity	Medium	High	High	High
Trialability	Medium	Low	Very low	Very low
Observability	Low	Low	Very low	Very low

3.10. Stakeholder contribution and resistance matrix

Table 9 highlights how different stakeholders are positioned in terms of their ability and willingness to adopt traceability systems. Regulators are the most prepared, with strong institutional backing, good digital capacity, and very little resistance. Importers also show moderate readiness and openness to adoption. On the other hand, pharmacies and especially consumers face major challenges. Both groups have low digital readiness, limited regulatory support, and high resistance, particularly consumers, who rank the lowest across all categories.

Table 9
Stakeholder contribution and resistance ratings

Stakeholder	Regulatory support	Digital readiness	Resistance level
Regulators	5 (Strong)	4 (High)	1 (Low)
Importers	4	3	2
Distributors	3	2	3
Pharmacies	2	1	4
Consumers	1 (Weak)	1	5 (High)

3.11. Comparative perspective on traceability adoption

A cross-country comparison shows that Ghana lags behind Nigeria and Kenya in traceability implementation, with an estimated uptake of only 15% due to voluntary enforcement, infrastructure challenges, and weak policy coordination. Nigeria, with mandatory enforcement by NAFDAC, has

achieved higher adoption (~40%) despite cost-related barriers. Kenya reports moderate uptake (~20–25%) through pilot projects, but progress is slowed by training and technical integration challenges (Table 10).

Table 10
Cross-country comparison of traceability adoption

Country	Traceability law	Implementation level (%)	Key barrier
Ghana	Partial (voluntary)	~15 (est.)	Infrastructure, policy gaps
Nigeria	Mandatory (NAFDAC)	~40	Cost of compliance
Kenya	Pilot implementation	~20–25	Stakeholder training and onboarding

4. Discussion

Dissemination of pharmaceutical traceability systems in the low and middle-income countries (LMICs), especially in Sub-Saharan Africa, has not been extensive given the growing burden of counterfeit and substandard medicines. This study on the pharmaceutical supply chain in Ghana demonstrates a paradox between the awareness to regulations and its implementation. Ghana Food and Drugs Authority (FDA) has greatly increased its post-market monitoring efforts in 2019 (96 samples tested) and in 2022 (over 95,000 samples tested), the failure rates in quality of products were shocking, reaching 92 percent (Mante et al., 2024). This implies that counterfeited medicines are still finding their ways into the supply chain in large quantities, even though there are improved detection technologies.

The implementation of traceability systems in these settings should be interpreted in the context of the Diffusion of Innovations theory of innovations by Rogers, meaning that such innovations as drug serialization and QR-code authentication should be seen as preventive innovations, as their benefits become apparent by avoiding damage (Rogers, 1995; Rogers et al., 2014). These systems do not have any tangible and instant advantages to the majority of end-users. In Ghana, such a lack of incentives and feedback mechanism adds to the lack of interest towards downstream actors like pharmacies and consumers (Gilson, 2012). The Adoption Gap Indices (AGI) calculated in this study demonstrates that despite the of the traceability tools applicability is rather on the low side. Such differences highlight a behavior gap: the knowledge is not converted into uptake when any innovation does not seem useful or available. This trend is supported by the situation in other LMICs. The acquisition of serialization by manufacturers and importers in Nigeria has greatly improved under the National Agency for Food and Drug Administration and Control (NAFDAC), where there is a compulsory policy of traceability (Adeyeye et al., 2023; National Agency for Food and Drug Administration and Control, 2024). One of the recent studies discovered that the country of Nigeria has an implementation rate of about 40 percent, which is supported by both the regulation and public-private collaboration (Adeyeye et al., 2023; Umar et al., 2025). Conversely, voluntary regime in Ghana only generates 15% of estimated implementation, even though technology is available in the same manner. Kenya demonstrates a medium level of adoption with barcode pilots sponsored by donors yet is struggling with pharmacy-level onboarding and digital literacy (Munyao, 2022).

Our regression model also demonstrates that the most predictive influencer of the complete adoption of traceability systems is trialability. The highest implementation driver is not awareness, but trial behavior (Rogers et al., 2014). This conclusion is supported by the previous studies, which pointed out the necessity to offer low-risk pilot conditions in order to promote the use of the system by small pharmacies and distributors (Fixsen et al., 2009; Haji et al., 2021).

The data gathered during the interview also explains the adoption barriers. Technical complexity, the absence of compatible infrastructure, and ambiguous procedures are commonly mentioned by pharmacies as significant obstacles to the implementation of such a solution as GS1 barcodes (Mante et al., 2024). Other difficulties were observed in Nepal, where the frontline providers were not trained enough and had no confidence in the digital medicine authentication systems, discouraging their use (Haji et al., 2021). Pharmacies in Ghana with no internet connection or barcode readers cannot match traceability standards formed to centralized computerized systems.

Customers are also left out of the traceability ecosystems in a very systematically engineered manner. Although Ghana has a relatively high mobile penetration rate, there is insignificant application of authentication systems (Mante et al., 2024; Naughton et al., 2016). This is manifested in infrastructural and perceptual obstacles. The informal verification tools are frequently valued by end-users as cheaper, brand-recognized, or by word-of-mouth when a scan or a report is not visibly obtained. Consumer confidence in the quality of pharmaceuticals, as Ozawa et al. (2018) identified through a global meta-analysis, is hardly associated with authentication tools but rather based on the aesthetics of packaging and reputation of the retailer.

To counter these complex challenges, the Traceability Adoption and Diffusion Model (TADM) developed traces the stakeholder readiness at the DOI stages. The lopsided flow of diffusion proves that the top-down enforcement is insufficient to create the system-wide security (Gilson, 2012; Greenhalgh et al., 2004). The stakeholder uptake should be facilitated by installing infrastructure, training, incentives, and feedback systems to migrate to full implementation (Fixsen et al., 2009).

The policy suggestions are in alignment with principles of implementation science. These suggestions include creating a national serialization requirement with a gradual implementation, building an interoperable national traceability facility, introducing sandbox pilots in pharmacies, and creating public dashboards to increase observability. The necessity of a technical co-financed approach, centralized data platform, and harmonized protocols is highlighted in previous work (Moalla et al., 2018; Sarkar, 2022), to enhance the uptake of traceability in resource-constrained environments.

5. The Traceability Adoption and Diffusion Model (TADM)

Despite the availability of traceability technologies and increasing regulatory attention, Ghana's pharmaceutical ecosystem has not fully transitioned to a traceable supply chain. Adoption remains fragmented, inconsistent, and overly dependent on a few high-capacity actors. To address this challenge, we propose the Traceability Adoption and Diffusion Model (TADM) — a conceptual framework that captures the stages, actors, and barriers of traceability system adoption in Ghana.

The TADM is built on Rogers' DOI theory (Rogers, 1995; Rogers et al., 2014), which identifies five stages through which an innovation spreads across a social system: Knowledge, Persuasion, Decision, Implementation, and Confirmation. Each stage reflects a deeper level of engagement and commitment to innovation (Rogers, 1995; Rogers et al., 2014). In our model, these stages are mapped against the major stakeholders in Ghana's pharmaceutical supply chain, encompassing regulators, importers, distributors, pharmacies, and consumers.

The regulators (i.e., FDA and Pharmacy Council) are on the top of the diffusion curve, and they are moving out of implementation phase to confirmation phase. This stance is reinforced through solid donor alignment, policy requirements, and technical alliances, and undercut by poor observability, especially in the lack of any consumer-facing dashboards or public measures of performance. The importers are known to be converged between decision and implementation steps, especially those who are involved in donor-funded programs. The compliance incentives and global standards (e.g., GS1) drive their movement in the diffusion pathway, but regulatory fragmentation and cost burden decelerates it (Fig. 6).

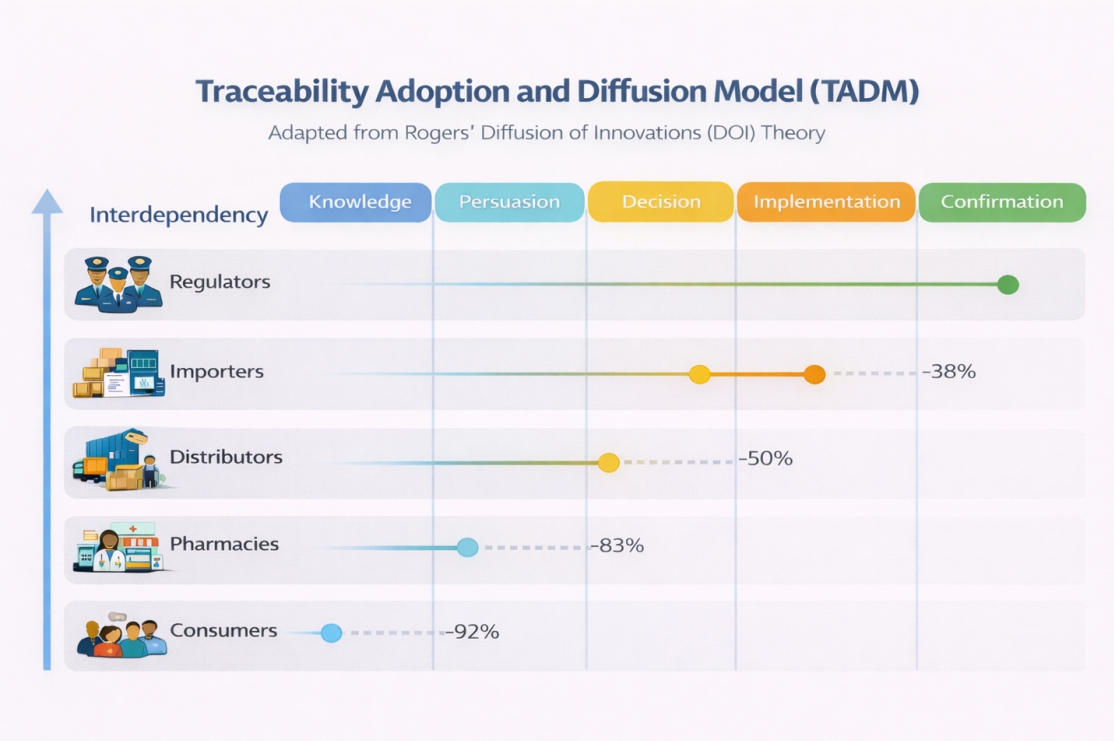


Fig. 6. The Traceability Adoption and Diffusion Model (TADM) for Ghana's pharmaceutical supply chain indicating the major adoption stages; fading segments reflect the drop-off points.

The distributors are still at the persuasion or early decision phases to a large extent. Reputational risks and operational needs are enablers, but infrastructural constraints and the lack of understanding of the return on investment (ROI) are usually barriers to adoption. Pharmacies, which interface most with consumers, are still focused at the knowledge and persuasion levels only. Although they in general advocate for high quality medicines, their advancement is inhibited by their perceived complexity, trialability mechanisms, and the lack of institutional incentives. Consumers, on the other hand, do not show a lot of knowledge of the traceability tools and show minimal interest to participate. Examples of barriers for consumers are health literacy, the lack of feedback following a scan, and the absence of influential stories that show personal value.

Instead of considering traceability as a binary (present or absent) quality, the TADM demonstrates traceability as a series of processes of aligning the institutional capability, technological usability, and perceived value. This processual view is consistent with diffusion and implementation research and mirrors regional evidence from East and West Africa, where adoption has progressed unevenly across stakeholder groups, with persistent lags between pharmacy-level uptake and end-user engagement (Ashiwaju et al., 2023; Benevento et al., 2023; Kudai, 2025; Ogah & Onuoha, 2022).

Notably, the model is not only diagnostic, but it is prescriptive. There is a different intervention point in each stage of diffusion. As an illustration, knowledge can be switched to persuasion as fast as possible with the help of awareness efforts and education in pharmacies (Greenhalgh et al., 2004). The process of transitioning between persuasion and decision is enhanced by trial licenses or sandboxes within urban pilot areas (Fixsen et al., 2009). Implementation at the scale level will involve regulatory incentives; confirmation phase will involve powerful feedback mechanisms like public dashboards and brand recognition programs. These interventions reflect more general principles of implementation science, in which

comparatively small structural changes (e.g. subsidies, training, or digital feedback loops) have disproportionate effects on lasting adoption (Damschroder et al., 2009; Fixsen et al., 2009).

Probably the focus on the interdependence of the stakeholders is the most valuable lesson of the TADM. Verification at the pharmacy level loses its protective function if consumers do not authenticate products, while consumer interpretation without system-level verification yields little practical assurance. The absence of integration between Customs and the procurement system compromises traceability requirement. These relationship dynamics help to shed light on the need of interoperability and coordination, not only among regulatory bodies, but also between the whole pharmaceutical ecosystem.

Placing the experience of traceability in Ghana in this multi-actor, multi-stage framework of diffusion, the TADM supports one of the main arguments of this paper: adoption is not a matter of awareness but rather of structural empowerment and the strengthening of behavior. The path to a completely traceable pharmaceutical system is not a direct one. It has to be constructed in such a manner that the varying pace, constraints and incentives affecting each of the actors along the curve is considered.

6. Limitations

Our research presents valuable evidence regarding the adoption of traceability in the pharmaceutical supply of Ghana, yet it is limited in a number of aspects. To begin with, sampling did not capture informal market players including unlicensed drug dealers whose omission could underestimate the systemic susceptibility of last-mile distribution in Ghana. Secondly, the social desirability effect could have also affected the regulated stakeholder response, including pharmacies who might overrate the compliance out of perceived pressure by the authorities. Thirdly, the Traceability Adoption and Diffusion Model offers a conceptual approach to adoption dynamics, but was generated with cross-sectional data, limiting the ability to infer causal information on stage transitions. Also, there are no longitudinal or observational data to show how stakeholder positions change over time or in reaction to policy interventions. Finally, the generalizability of findings may be limited to Ghana or countries with similar regulatory and infrastructural profiles; adaptation may be necessary for contexts with different governance, digital maturity, or health system architectures.

CRediT authorship contribution statement

P.KM.: Conceptualization, Methodology, Investigation, Laboratory analysis, Data curation, Writing – original draft, review & editing; N.O.A.: Conceptualization, Methodology, Investigation, analysis, Data curation, Writing – review & editing; J.D.: Investigation, Formal analysis, Statistical analysis, Data interpretation, Writing – review & editing.

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Declaration of competing interest

The authors declare no conflict of interest.

Ethics approval

Ethical approval was obtained from the Humanities and Social Sciences Research Ethics Committee, Kwame Nkrumah University of Science and Technology (HuSSREC/AP122/VOL.1). The study conformed to the Declaration of Helsinki, and informed consent (written or verbal) was obtained from all participants.

Data availability

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

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