

Pharmaceutical authentication in Nigeria: importers' and manufacturers' perspectives on mobile authentication services

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ABSTRACT

Background: In 2012, NAFDAC (National Agency for Food and Drug Administration and Control) - the Nigerian foods and medicines regulator - introduced and mandated the use of Mobile Authentication Service (MAS) technology to reduce falsification ('faking') of medicines in Phase I. The MAS processes, perceptions and suggestions of the products' owners need to be investigated.

Objective: This study explored the MAS process, perceptions of importers and manufacturers of medicines (holders of certificates of registration - HCRs) and their suggestions for the way forward.

Methods: Qualitative method guided with the technology acceptance model (TAM) was used. Nine companies graded according to their commercial sizes participated. Transcripts of interviews were coded and analysed.

Results: HCRs bore the costs and were involved in all stages of MAS, but not all HCRs favoured its use. They had divergent perceptions influenced by their commercial sizes. Interest in MAS waned because of problems and reduced publicity. Five MAS service providers assigned a code each, confirmed verification instead of NAFDAC controlling MAS with just one code.

Conclusion: HCRs' perceptions differed in line with their sizes. Problems rendered it unreliable. Forcing MAS on all HCRs and NAFDAC not having the final say, did not look like a good regulatory method.

Key words: NAFDAC; Mobile Authentication Service (MAS); Substandard and Falsified medicines (SF); Holders of Certificate of Registrations (HCRs).

Authentification des produits pharmaceutiques au Nigéria: points de vue des importateurs et des fabricants sur les services d'authentification mobiles

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RÉSUMÉ

Contexte: En 2012, la NAFDAC (Agence nationale pour l'administration et le contrôle des aliments et des médicaments) - l'organisme nigérian de réglementation des aliments et des médicaments - a introduit et rendu obligatoire l'utilisation de la technologie du service d'authentification mobile (MAS) pour réduire la falsification (" contrefaçon ") des médicaments dans la phase I. Les processus MAS, les perceptions et les suggestions des propriétaires des produits doivent être étudiés.

Objectif: Cette étude a exploré le processus MAS, les perceptions des importateurs et fabricants de médicaments (détenteurs de certificats d'enregistrement - HCR) et leurs suggestions pour l'avenir.

Méthode: Une méthode qualitative guidée par le modèle d'acceptation de la technologie (TAM) a été utilisée. Neuf entreprises classées selon leur taille commerciale ont participé à l'étude. Les transcriptions des entretiens ont été codées et analysées.

Résultats: Les HCR ont supporté les coûts et ont été impliqués dans toutes les étapes du MAS, mais tous les HCR n'étaient pas favorables à son utilisation. Leurs perceptions divergentes étaient influencées par leur taille commerciale. L'intérêt pour le MAS a diminué en raison de problèmes et d'une publicité réduite. Cinq fournisseurs de services MAS ont attribué un code chacun, confirmant la vérification au lieu que la NAFDAC ne contrôle le MAS qu'avec un seul code.

Conclusion: Les perceptions des HCR variaient en fonction de leur taille. Les problèmes rencontrés ont rendu le système peu fiable. Le fait d'imposer le MAS à tous les HCR, sans que la NAFDAC ait le dernier mot, ne semblait pas être une bonne méthode de réglementation.

Mots clés: NAFDAC ; Service d'authentification mobile (MAS) ; Médicaments de qualité inférieure et falsifiés (SF) ; Détenteurs de certificats d'enregistrement (HCR).

INTRODUCTION

Circulation of Substandard and Falsified medicines (SF) is a global public health emergency.^{1,2} Many SF medicines circulate online without prescriptions.³ 10.5% of medical products analysed by the World Health Organisation (WHO) failed.⁴ Nigeria reportedly was one of the biggest counterfeit markets in the developing world and SF affects all Nigerian geopolitical zones.⁵⁻⁹ The two main SF issues are: "substandard" and "falsified".

SUBSTANDARD MEDICINES: Also called "out of specification" medicines are those that fail to meet specifications or quality standards, or both.¹⁰ There are accepted concentration ranges of active pharmaceutical ingredients (API), bulk process intermediaries (BPI) and other components used in medicine quality studies as standards, e.g., 85 to 115 %;^{11,12} and 95 to 105 %¹³ for APIs.

FALSIFIED MEDICINES: are products falsely labelled to contain API(s) or BPI(s) or in correct amounts by a registered manufacturer.¹⁰ Misrepresentation of identity, composition, or source are considered 'falsified'.^{4,14} Technology used in curbing SF medicines ranges from sophisticated end-to-end blockchain solutions to straightforward text messaging.¹⁵

To curb falsification, Mobile Authentication Service (MAS) technology was introduced by the Nigerian regulator of foods and medicines, the National Agency for Food and Drug Administration and Control (NAFDAC) in 2012 after a pilot study in 2010 and mandated that all anti-infective (antibiotic, antiparasitic, antiprotozoal and antiviral) medicines manufactured within or imported into Nigeria be MAS technology-compliant as first phase.¹⁶ This empowered consumers to verify sources of medicines using product identifying numbers (PINs) found after scratching packages' MAS panels and sending same to specified Global System Mobile (GSM) short codes using Short Messaging Service (SMS).¹⁶ MAS uses Truscan technology.¹⁵ Twelve years after, how successful MAS is and when its Phase II will commence are unclear.

It is vital that MAS be accepted, usable and used by all stakeholders. The diverse characteristics of the stakeholders make MAS a complex intervention (CI). A CI has several interacting components, dimensions and parts that in isolation or combination, can generate the power of the intervention.¹⁷ Complexity attributes while excluding linear pathways linking interventions, include: number of interacting components; variety of behaviours of stakeholders; number of stakeholders involved; degree of flexibility permitted and the non-standardisation they

are subject to.¹⁸⁻²¹ Identifying, developing, documenting and reproducing suitable methods of evaluation make evaluation of a CI like MAS difficult.^{22,23}

Various studies have been done to measure distinct aspects of MAS intervention in Nigeria,²⁴⁻²⁹ none was found to focus on HCRs who own the products, financed the MAS components and processes, interacted with all the stakeholders and stood to gain or lose financially the most from MAS.

METHODS

Study design: Qualitative method of phenomenology orientation, involving purposive sampling and semi-structured interview guide with open-ended questions was used. HCRs' acceptance of MAS; ease of use its use; usefulness to them; its reliability; problems encountered and suggestions for the way forward for MAS were obtained and analysed by coding the transcript, grouping into sub-themes and themes that formed the findings.

Ethical approval: was obtained from the Lagos University Teaching Hospital Health Research Ethics Committee with assigned number ADM/DSCST/HREC/APP/6129. Participants completed a consent form before interviews.

Study setting: Face-to-face interviews of participating HCRs were conducted in their offices in Lagos and Ogun States, Nigeria.

Study Instrument: The interview guide was adapted from the Technology Acceptance Model (TAM).^{30,31} TAM involves introduction of new devices, processes, methods and use of technology, postulating that when an innovative technology is introduced, several factors influence users' decisions about how and when they would use it. The factors include: (i) Acceptance of Technology (AOT). (ii) Perceived Usefulness (PU), (iii) Perceived Ease-Of-Use (PEOU) and (iv) Perceived Reliability (PR).^{30,31} The interview examined SF medicine challenges experienced by HCRs before the introduction of MAS by NAFDAC, experiences while getting MAS ready and during use, challenges and resolutions, finally eliciting suggestions for ways forward. Literature search, reports in mass and electronic media and interactions with colleagues also aided development of the interview guide.

Study data: Transcripts of audio interviews were used as the data.

Data collection: Data was collected from all HCRs grouped according to their volumes of trade: (a) Multinationals among world's top 10 pharmaceutical companies operating in Nigeria, generating between US\$33.443 bn & US\$72.043 bn per annum in 2022.³² (b) Those among Nigerian top 20 generating less than N12 bn in 2022.³³ (c) Relatively small Nigerian pharmaceutical companies (only importing and distributing). Impromptu questions followed answers given to those asked from the interview guide until the area was clear. Subsequent interviews used the new insights to obtain more facts.

Sample Size: Phenomenologically oriented qualitative method needs 5-25 interviews.³⁴⁻³⁶ Interviews continued until saturation point was reached when no new significantly relevant information was forthcoming. A total of nine interviews were conducted.

Study duration: From October 2022 to July 2023.

Evaluation of data: The transcribed interviews were, along with another researcher, independently coded and jointly harmonised. The coded data was used to form sub-themes and themes, which form the narrative for the findings.

RESULTS

Eight interviews were conducted in Lagos and one in Ogun States in each participant's office, lasting an average of 18 (minimum of 5 and maximum of 22) minutes. One was by a phone call that lasted 5 minutes. Four females and six males participated; two females jointly participated in one company.

Figure 1 summarises the sub-themes and themes which made up the results.

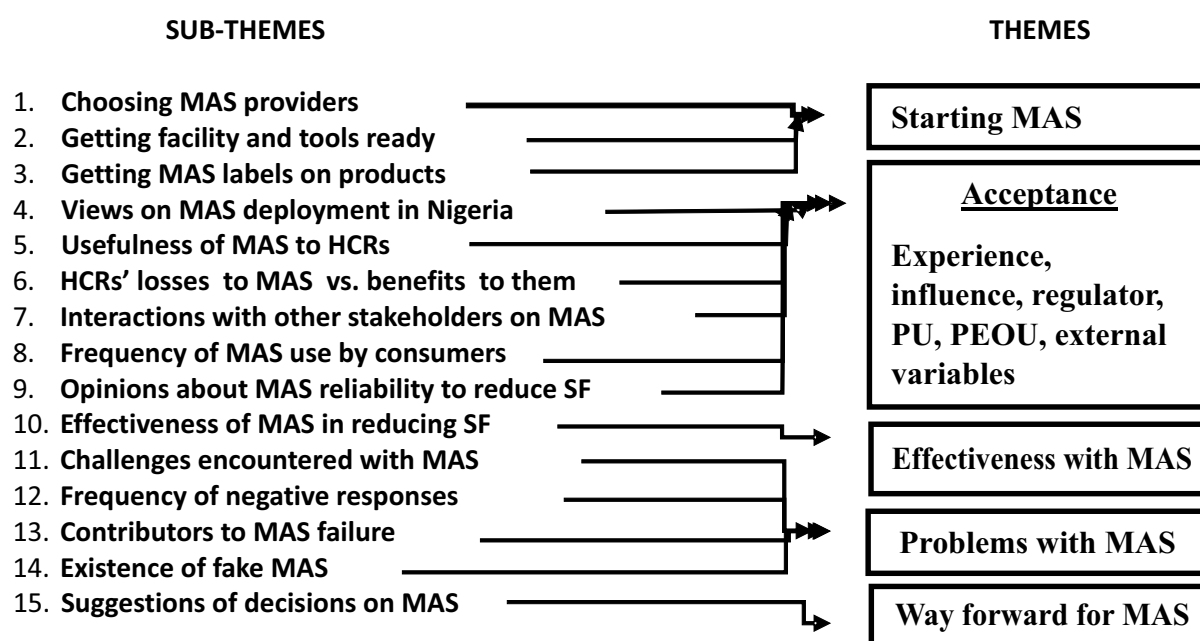


Figure 1: Schematic drawing of the themes

Key

- HCR:** Holders of Certificate of Registration
- MAS:** Mobile Authentication Service
- PU:** Perceived usefulness
- PEOU:** Perceived ease of use
- SF:** Substandard falsified medicine

It was found that HCRs were at the centre of the MAS process, interacting with all stakeholders as shown in figure 2.

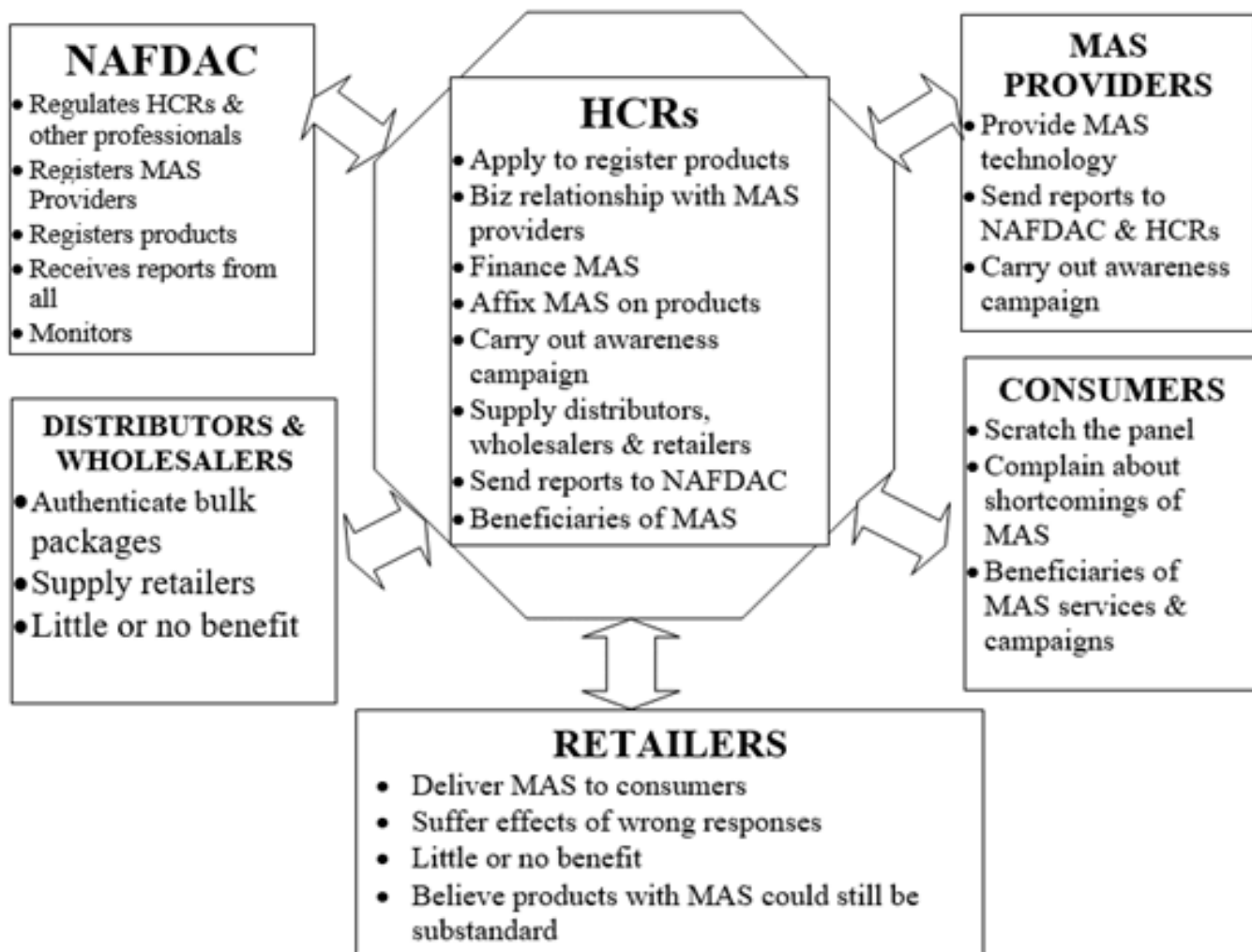


Figure 2: Interaction between HCRs and other stakeholders

Key

- HCR:** Holder of Certificate of Registration
- MAS:** Mobile Authentication Service
- NAFDAC:** National Agency for Food and Drugs Administration and Control

PRE-USE MAS PROCESS: started with each HCR choosing from and negotiating (terms, conditions and costs of MAS label digital contents) with any among five NAFDAC-approved MAS technology providers.

"NAFDAC has given the start-up and the list of service providers to deal with... So, if you have any product in the category, you choose any of the service providers ..." (HCR4)

The tasks and costs of getting MAS labels on the products, creating awareness and resolving arising problems were all done by the HCRs.

Some importers used the services of foreign manufacturers for MAS process:

"For the imported products, the providers send the labels to the foreign partners who put them on the packs." (HCR4)

ACCEPTANCE OF MAS TECHNOLOGY

Acceptance of MAS was influenced thus:

- i. **Costs:** MAS features and awareness campaigns brought in extra costs to HCRs. This discouraged some HCRs.

"Actually, it is too expensive. When cost of MAS is added to the costs of production, it increases the cost of the product in the market." (HCR5). "...you spend a lot of money on awareness, road shows, etc. It's a lot of cost" (HCR5).

- ii. **Community pharmacists:** The community pharmacists (CPs) at the point of service/sale reportedly resisted the use of MAS. They were allegedly not involved in the planning stage.

"CPs resisted it without fully understanding it." (HCR8).

- iii. **Global system mobile (GSM) network:** Transmissions of queries and responses by short message service (SMS) through GSM, reportedly failed often.

"Sometimes, even your SMS would not get to the other end..." (HCR3). "You are using the platform of GSM operators... and if there was a service downturn, it affected message delivery time." (HCR5).

- iv. **HCR's size:** HCRs dealing in not-so-popular products were reluctant users:

"...these fakers... they don't fake products that are not selling, they fake the most selling products of any company" (HCR8).

Another said,

"Some are just not interested. They say that SF issue is for "the big boys"" (HCR5).

One was clearly indifferent,

"... Look! There is nothing to talk about MAS. NAFDAC mandated us to do it. We have complied. Period." (HCR7).

- v. **Peer influence:** Discussions during the HCRs' association (Nigerian Association of Industrial Pharmacists (NAIP)) meetings influenced their attitudes and decisions. The Pharmaceutical Society

of Nigeria (PSN), the regulator (NAFDAC), government (policies), consumers and other stakeholders also influenced HCRs on MAS issues. There were positive influencers: a manufacturing company said,

"With the wholesalers, we do awareness campaign to sensitise, remind and notify them about what is going on..." (HCR5).

There were also negative influencers (within HCRs):

"We also have our colleagues who resist and discourage scratching..." (HCR5).

Non-compliance of at least one HCR discouraged others.

"So, why should some companies be exempted? Why? All these things are issues of compliance" (HCR5).

PERCEIVED EASE OF USE (PEOU) of MAS:

All participants said the GSM network problems negatively affected transmissions of codes and responses "...delay in response because of network problem. That is even the major problem", "...sometimes, even your SMS would not get to the other end..." (HCR5).

To many HCRs, the issue of wrong responses was the most challenging:

"...sometimes we have genuine products with wrong response" (HCR4).

Other challenges included insufficient use of MAS.

"The people are not using it and they should. If the people would use it, counterfeiters would be out of business" (HCR6)

EFFECTIVENESS OF MAS: HCRs could gauge effectiveness and reliability of MAS technology from rates of use, percentages of no-responses and correct:wrong response ratios, all mostly obtainable from backend servers of their MAS providers. Two extreme perceptions emerged:

"MAS is absolutely reliable" (HCR6) and "MAS is not reliable to the extent of above 50%, it cannot even be up to 50%. MAS is still subjective" (HCR4).

While a participant put it high,

"Success rate... May be... I'll say 90%",

another participant went the other way:

"...if I give MAS 40, I can give serialisation 90. So, that's what we should be going into." (HCR3),

while another HCR sounded neutral,

"...it's not perfect, but it's better than nothing" (HCR2).

PROBLEMS WITH MAS: Problems encountered throughout the process included

ADDITIONAL COSTS: This discouraged some HCRs.

"The labels prolong the manufacturing process and timeline" (HCR1); "...having the capacity to affix labels, etc. ... some companies may not feel it's necessary to really spend this much" (HCR2).

ERRORS: Errors during pre-use MAS stage created big problems later.

"Sometimes, while affixing the labels, errors could occur in documenting wrong serial numbers of products that were not affixed" (HCR1) resulting in false negative responses later.

RESISTANCE TO MAS USE: CPs allegedly discouraged its use by consumers.

"CPs resist it without fully understanding it." (HCR5).

NAFDAC'S RESPONSIBILITIES: NAFDAC allegedly had irregular meetings with the stakeholders to r e v i e w MAS

"...it's been a long time since meeting with industries. Almost 2 years" (HCR4) and allegedly loosely controlling MAS:

"So, why should some companies be exempted? Why?" (HCR5). "NAFDAC needs to have more teeth.

The regulation is weak." (HCR5). "...NAFDAC itself needs to strongly hold the regulatory space such that it comes out with clear policy..." (HCR6).

HCRS' SUGGESTIONS ON WAY FORWARD FOR THE MAS: HCRs' suggestions included:

1. More awareness campaigns
2. Using additional means of transmitting queries and responses apart from GSM
3. Using only one code for all the MAS providers
4. Holding the MAS providers accountable
5. Verification responses should come from NAFDAC.

DISCUSSION

Costs of MAS increased prices of products, making MAS unattractive to some HCRs. Some passed MAS issues to their foreign manufacturers, reflective in their perceptions. Many manufacturers, including HCRs had been voluntarily using MAS before NAFDAC mandated it. Most HCRs that earlier experienced falsification of their products embraced it. Conflicting acceptability and effectiveness perceptions were like big versus small HCRs, with the bigger HCRs positively inclined and the smaller ones negatively.

MAS providers as final deciders of authenticity put them (not NAFDAC) in control of verification. NAFDAC, using only one code, would have reduced the complexity of MAS intervention, as the MAS providers had many limiting factors that could lead to problems, like release of the products to the market before activating MAS). MAS technology providers being regulated by a sister agency of government (National Communication Commission - NCC) not under NAFDAC's control makes them an external threat.

The CPs as the last professionals in the MAS process chain were expected to guide the consumers to use MAS. NAFDAC therefore inadvertently placed the CPs in the frontline of the SF 'battle', because when errors were made earlier, like failure of the MAS providers to activate it, an HCR's mix-up, consumers sending incorrect codes, or GSM downtime all resulting in false negative responses, the consumers reportedly blamed the CPs, the only professionals they could express their dissatisfaction to.

Consumers scratching the MAS panel and authenticating with phones introduced more complexity due to differences in genders, ages, ailments, diseases (types, chronic or acute), literacy levels, religions and cultural backgrounds, purchasing capacities, types and capabilities of their mobile phones and national stage of GSM. NAFDAC's MAS started in 2012 when GSM was second generation (2G). By 2023, it was 4G, which expectedly affected successful use of MAS. The professionals along the distribution chain, already conversant with good manufacturing practice (GMP), were better placed to authenticate with the right tools and wherewithal, saving consumers' pharmacy waiting time.

Strength of study: No previous works done on MAS focussed on the HCRs to reveal the pre-MAS process and other vital aspects, despite owning the products and

bearing the costs of MAS.

FUNDING: The research was personally funded.

CONCLUSION

This research reveals that the HCRs were placed in the centre of the MAS process, interacting with all other stakeholders, getting MAS ready for use and monitoring. HCRs were the direct financial gainers or losers from its success or failure. Despite all these, no work was found in literature focussing on them only for in depth understanding of the entire MAS process. Twelve years after its introduction, poor communication infrastructure, waning awareness campaigns, difficulties in transmitting queries and responses, unreliable or no responses to queries, etc. have significantly reduced the interests of the HCRs (and as alleged, other stakeholders) in MAS technology. Also, because HCRs differed in many ways, their perceptions on the usefulness of MAS very much differed. Mandating them all to use MAS did not look like a good regulatory method. Finally, verification should have been left in the hands of the professionals along the distribution chain, using only one verification code, residing in NAFDAC.

RECOMMENDATIONS

1. This study shows that MAS is a complex intervention with many flaws arising from its being made compulsory by NAFDAC without adequate considerations for the stakeholders' diversities and inadequate infrastructures in Nigeria. It therefore should neither have been made compulsory nor involved consumers.
2. To combat SF medicines, all Nigerian pharmacy-related regulatory agencies (NAFDAC, National Drug Law Enforcement Agency (NDLEA) and Pharmacy Council of Nigeria (PCN)) ought to act in synergy to firm up regulation of both the owners of the products (HCRs) and the professionals handling them, with the benefits of tracking and tracing any medicine imported into or manufactured in Nigeria.
3. It is recommended that the European method of authentication called serialisation be considered. It is simpler, does not involve consumers and is much more effective.

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CONFLICT OF INTEREST

No conflict of interest is associated with this work.

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