

Decision Support Tool to Improve Decision-Making for PrEP-eligible Black Patients: Development Process and Alpha Testing

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Decision Support Tool to Improve Decision-Making for PrEP-eligible Black Patients: Development Process and Alpha Testing

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Abstract

Background: Black communities in Canada are disproportionately affected by the HIV epidemic. There is currently no patient decision support intervention for Black patients being asked to consider PrEP for HIV prevention, especially in the context of previous studies indicating that most of these patients do have decisional conflict regarding PrEP.

Objective: The aim of this project was to develop a decision support tool to improve decision-making for PrEP-eligible Black clients.

Methods: Using the Ottawa Decision Aids Development and Evaluation Guideline, a multidisciplinary team steered the development and evaluation of the DST in a seven steps process: Assess needs; Assess feasibility; Define the objectives of the aids; Identify the framework of decision support; Select the methods of decision support to be used in the aid; Select the designs and measures to evaluate the aid; and Plan dissemination. Both potential PrEP clients and providers reviewed the DST for usability and provided feedback.

Results: The development process resulted in a web-based DST with 6 sections: Introductory section; Clarify your decision section, Information about the benefits and drawbacks of various prevention methods section; Value clarification exercise section; Identifying support system section; Next steps section. Both potential PrEP clients and PrEP providers expressed satisfaction with the use of the DST.

Conclusions: A decision support tool was developed for PrEP-eligible Black patients to enhance their decision-making process for HIV prevention options. Potential users (Black patients and clinicians) found it usable.

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Original Manuscript

Decision Support Tool to Improve Decision-Making for PrEP-eligible Black Patients: Development Process and Alpha Testing

1.0. Introduction:

Black communities in Canada are disproportionately affected by the Human Immunodeficiency Virus (HIV) epidemic (1). Despite making up 4.3% of the population, Black communities in Ontario accounted for 25% of new HIV infections in 2021 (1-2). Recent epidemiological data indicates that one in every four Black Canadians are living with HIV (3). These data are concerning and provides a basis to develop and implement strategies to increase the acceptance and use of effective tools for HIV prevention in Black communities in Canada. There are multiple options to prevent HIV infection – abstinence, never sharing needles, using a condom the right way, HIV pre-exposure prophylaxis (PrEP), HIV post-exposure prophylaxis (PEP), and HIV treatment as prevention (4). Among these options, PrEP is the most commonly prescribed HIV prevention option for eligible Black Canadians (5). PrEP is an effective HIV prevention medication, which is recommended for communities with high ongoing risk of HIV infection (6-7). However, acceptance of PrEP among Black Canadians is low (5). Factors affecting acceptance of PrEP are multi-dimensional and are related to: lack of knowledge, low perception of risk of HIV acquisition, preference for other prevention options, healthcare providers' attitudes, cost of PrEP, lack of drug coverage, lack of a primary care physician, inadequate consultation time with providers, anti-Black racism, and PrEP stigma (8-13). In addition, for most PrEP-eligible Black Canadians, the availability of multiple options to prevent HIV, and the lack of adequate knowledge about these options, including information on the benefits and drawbacks of these options present decision-making challenges on whether to accept PrEP or not for HIV prevention (12). These challenges underscore the necessity to improve decision making process for Black Canadians who are being asked to consider PrEP for HIV prevention.

There is evidence that Decision Support Tools (DST) can improve the decision-making process for individuals facing healthcare decisions (14-15). A systematic review of literature on DST concluded that DSTs can increase participants' knowledge, increase accuracy of risk perceptions, and congruency between informed values and care choices (14). It also improves both the quality of the decision process and the decision itself. . Decision support interventions involve: 1) establishing rapport and facilitating interactive communication; 2) clarifying the decision and inviting patient participation; 3) assessing the patient's decisional needs; and 4) addressing decisional needs with tailored support. Decision support interventions may be administered using various media such as web-based tools, mobile apps, decision boards, interactive videodiscs, personal computers, audio-guided workbooks, pamphlets, and group presentations (16). Decision support interventions have been developed for various medical therapies, diagnostic tests, preventive therapies, clinical trial entry decisions, and end of life decisions (14,17). However, there is currently no patient decision support intervention for Black patients being asked to consider PrEP for HIV prevention, especially in the context of previous studies indicating that most of these patients do have decisional conflict regarding PrEP (12, 17). Therefore, the aim of this study was to develop and evaluate a decision support intervention to improve decision-making process for Black patients who are

offered PrEP for HIV prevention.

1.1. Theoretical Frameworks

The guideline for Developing and Evaluating Decision Support Intervention developed by the Ottawa Decision Support Group was used to guide the development and evaluation of the PrEP DST (18). The guideline recommends seven steps in developing and evaluating a decision aid (13). These steps include: 1. Assess needs; 2. Assess feasibility; 3. Define the objectives of the aids; 4. Identify the framework of decision support; 5. Select the methods of decision support to be used in the aid; 6. Select the designs and measures to evaluate the aid; and 7. Plan dissemination. In step 4, we selected the Ottawa Decision Support Framework (ODSF) as the framework for the PrEP decision support (19). In step 5, we used the Ottawa Personal Decision Guide (OPDG) to determine the content and interconnectivity of the various sections of the DST (20). The reporting guideline recommended by Coulter et al. was used to guide the reporting of our DST as shown in Figure 1 (21). Coulter et al. recommended 5 themes for documenting the development process of DST; 1. Scoping (the assessment of decisional needs of patients and clinicians); 2. Steering (engagement of multidisciplinary team, and the process used to determine content, design, and distribution plan); 3. Design (How evidence included in the decision support were identified, synthesized, reviewed and appraised, and the development of the prototype); 4. Alpha testing (review by potential users for acceptability and usability); 5. Beta testing (Pilot randomized controlled trial).

2.0. Methods:

2.1. Ethical considerations

Approval for this study was obtained from the Research Ethics Board (REB) of St. Michael Hospital, Unity Health Toronto with the REB #18-022. Verbal consent was obtained from all study participants following detailed explanation of the study purpose and procedure. All study data was de-identified and stored in the hospital's secured server.

2.2. Study setting and recruitment procedure

This study was conducted at MAP Center for Urban Health Solution. MAP is based at St. Michael's Hospital, a fully affiliated University of Toronto teaching and research intensive hospital. The hospital is also a hub for care in downtown Toronto.

Study participants were recruited through St. Michael's Hospital Family Health Teams, and PrEP providers in downtown Toronto.

2.3. Scoping: Assessment of Patients' and Clinicians' Views on Decisional Needs

We conducted key informant interviews of 29 PrEP-eligible Black patients - different gender, sexual orientation, and at different decision-making stages - to understand their decision-making process and to assess their decision support needs for PrEP. The result of this phase of the development process has been reported by Ajiboye et al. (12). We also surveyed 25 PrEP providers (clinical and service providers) to assess needs and preferences for a DST for PrEP-eligible Black patients. The result of the PrEP-providers' survey has been published by Genevieve et al. (22). Data obtained from the patient's interview and providers' survey were used to inform the content, design, and distribution plan for the PrEP DST.

2.4. Steering: Determine Content, Design and Distribution Plan

To guide the development of the PrEP DST, we set up a multi-disciplinary team comprising of researchers, clinicians, PrEP-eligible Black patients, HIV service providers and information technology experts. Participants were selected based on their experience in HIV prevention in Black communities, provision of decision support to PrEP-eligible Black patients, and knowledge of digital health technology design. The team met regularly (weekly initially and then monthly subsequently) to determine the content, design, and distribution plan for the tool. Additionally, we also met as a team or in pairs to identify, synthesize, review, and appraise evidence for inclusion in the tool as well as to review the draft prototype and the results of the alpha testing of the tool. For the content of the tool, we utilized the OPDG to determine the contents and the interconnectivity of the different sections of the tool. The design and the distribution plan were informed by the goal of the DST and the information obtained from the patients' and providers' assessment of decisional needs.

2.5. Design: Evidence Synthesis, Review and Appraisal, and Development of Prototype

2.5.1. Evidence synthesis, review, and appraisal

We utilized several sources to identify evidence for inclusion in the DST. A search of both published and grey literatures was conducted to identify evidence for inclusion in the tool (23-35). We also reviewed data obtained from our study of patients' and providers' assessment of decisional needs (12, 22). Data from our study on assessment of patients' decision support needs and preferences were qualitatively analyzed. Content analysis technique was used to identify words, themes and concepts related to the ODPG. Two members of the steering committee (LN and WA) reviewed the content separately before the final review by the steering committee. We only included words, themes, and concepts in which the committee achieved a high level of agreement. Overall, all the evidence synthesized from the literature were appraised and summarized. Where available, we prioritized evidence from meta-analysis, systematic reviews, randomized control trials and cohort/case control studies for inclusion in the tool. Evidence from the websites of scientific organizations were screened for relevance before inclusion in the tool.

2.5.2: Development of the Prototype

The prototype was developed using the drafting and re-drafting process. CP, RB, and WA wrote the first draft of the script using evidence synthesized from the literature, study on assessment of decisional needs, and websites of scientific organizations. LN reviewed it for completeness and compliance with the OPDG. Subsequently, the multi-disciplinary team reviewed the final prototype using specific criteria such as feasibility, appropriateness, and acceptability to assess the content, design, and the decision support method. The final design was approved by the team after a thorough review of the content, flow, and design.

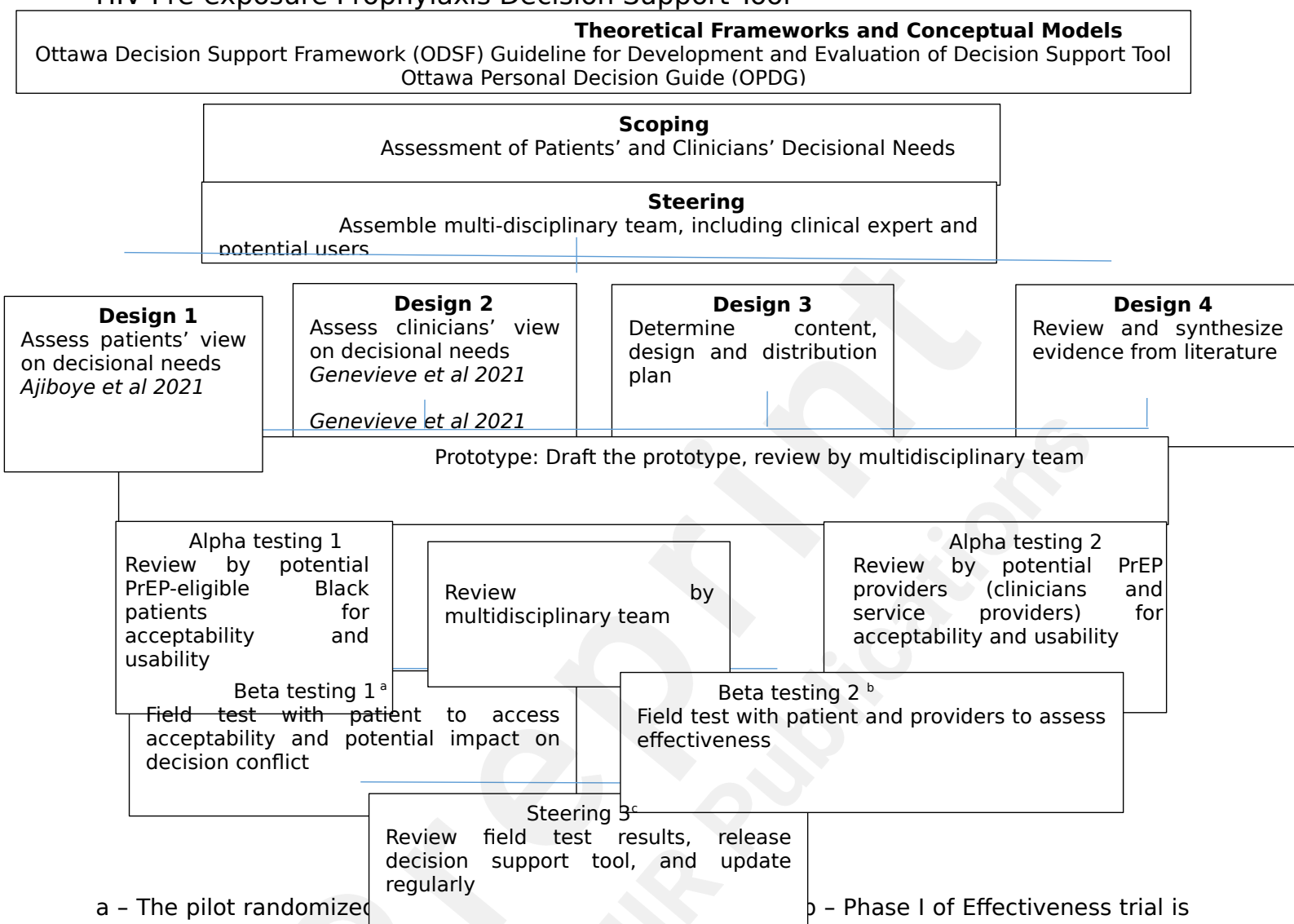
2.6: Alpha testing: review by potential users for acceptability and usability

We recruited potential users – 3 PrEP-eligible clients and 2 PrEP providers to review the DST for acceptability and usability. A link to the web-based DST was sent to all the reviewers so they can view the tool on their own device and provide feedback on the following metrics: task performance (ease of navigating the tool and completion of all the task in the tool), and user satisfaction. Written feedback received from the potential users were reviewed by the multi-

disciplinary team, and useful suggestions were incorporated to improve the tool.



Figure 1: Schematic Presentation of the Development Process and Evaluation of HIV Pre-exposure Prophylaxis Decision Support Tool



a - The pilot randomized controlled trial is being planned

b - Phase I of Effectiveness trial is

c - First initial version of the DST is publicly available in the inventory of patient decision aid maintained by Ottawa Hospital Research Institute on behalf of IPDAS. The next update is planned for 2025



3.0. Results

3.1. Scoping: Assessment of Patients' and Clinicians' Views on Decisional Needs

The result of the assessment of the decisional needs shows that most Black patients experience some form of decisional conflict – uncertainty on whether to accept PrEP for HIV prevention or to use other HIV prevention methods- when offered PrEP for HIV prevention. We also found that these uncertainties were due to lack of adequate information on PrEP, including how it compares to other prevention methods in terms of benefits and risks. In addition, most participants indicated preference for a web-based or digital DST. Based on these results, we determined that the DST will aim to support Black patients to make evidence-based informed decision on whether to use PrEP or not. In addition, we also determined that the DST will not seek to promote the use of PrEP for HIV prevention but rather will support Black patients to make informed and value-based decision on HIV prevention method. The goal is to reduce decision conflict for Black patients, promote evidence-based decision on PrEP, and enhance implementation of the chosen HIV prevention option.

For the providers' survey, we found that most providers (93%) agreed that a DST will complement the service they provide to their PrEP-eligible Black patients (12). They identified Black patients' need for culturally appropriate information on the benefits and risks of PrEP as one of the reasons why a DST would be needed. Most providers (95%) also agreed that a DST will facilitate the conversation on HIV prevention with Black clients (22).

3.2. Steering: Content, Design, and Distribution plan

Using the OPDG, we identified six content sections for the PrEP DST (See additional file 1 for link to the DST). The six sections include: 1) Introduction of the DST; 2) Clarify your decision section; 3) Knowledge section 4) Value clarification exercise section; 5) Support system section; 6) Next steps: To enhance readability and comprehensibility, we used simple words and short sentences, avoided medical jargon, and included a plain language description of any medical term. We adopted a design which includes a step-by-step way of moving through the content of the tool to enhance readability.

For the distribution plan, we utilized the result obtained from the patients' and providers' assessment of decisional need, to determine that the DST will be presented as a web-based tool which can be used before or after the visit to PrEP providers and will be publicly available to any interested PrEP-eligible Black patient.

3.3. Design: Evidence synthesis, review and appraisal, and development of Prototype

3.3.1. Evidence synthesis, review, and appraisal

Clinical evidence on probabilities of outcomes was difficult to find, and where available the evidence was generally weak and sometimes conflicting. Only outcomes obtained from evidence with strong methodology were included in the knowledge section of the DST. Data on the features of various HIV prevention options including the positive and negative features were primarily obtained from the decision needs assessment study, although we supplemented it with evidence from the literature where necessary. This is to ensure that the information included in the DST was all relevant to our target audience – PrEP-eligible Black clients.

3.3.2. Development of Prototype

The prototype development resulted in a tool with six different sections. Section 1 contains a brief introduction of the DST including the objectives and instructions on how to login to access other sections of the tool. In section 2, users are able to clarify the decision being made and the reason for making the decision. Section 3 contains information on the various HIV prevention options, and the positive and negative features of each of the options. We provided additional information on PrEP because this is the most recommended HIV prevention option, which is not well known to most Black clients. If available, we included the probabilities of outcomes of the different options in the information subsection or in the negative or positive features. Section 4 provided a method for users to select and rate the features of HIV prevention options that matter most to them. The outcome of the rating is presented in a visualized form so that users can see how the option selected matches their values. In section 5, users are able to identify and select their support system – individuals that can provide support for the implementation of the decision. Section 6 contains steps and actions the user needs to take to implement decision made, including how to discuss their decision with their healthcare providers or others identified in their support system in section 5.

3.4. Alpha testing: review by potential users for acceptability and usability

All the reviewers reported ease of task performance for all the sections of the DST. Additional comments on task performance centered on the provision of more information to guide the user in performance of the various tasks in the tool. One of the participants expressed it this way....

“can a progress bar be added so that users know how they are progressing in the tasks”?

All reviewers expressed general satisfaction and usefulness of the tool, although the issue of who may likely benefit the most from the tool was also raised. One of the participants expressed it this way...

“I just went through the tool. Overall, I think it provides useful information and resources to help people decide whether or not PrEP is a good decision for them. I do, however, think that it skews toward people who are not yet taking PrEP. I went through the tool as someone who was considering taking PrEP and someone who was debating coming off PrEP just to see if the questions would be different and based on both walkthroughs, I think it’s less useful/applicable for someone who is in the latter category”.

Another reviewer expressed satisfaction with the tool this way....

“Cool! I checked the whole thing out. Very comprehensive. Great work. Thank you for sending.”

4.0. Discussion

Statement of principal findings:

Our study developed a DST to help Black clients decide whether PrEP is a good HIV prevention option. Overall, this study produced a DST that is based on the decisional needs of PrEP-eligible Black clients, acceptable and usable by both potential Black clients and PrEP providers. To the best of our knowledge, our study is the first attempt to characterize Black clients’ decision support needs regarding HIV prevention, and to utilize this information to systematically develop a DST to enhance their decision making for HIV prevention options

(16,17).

Strengths and weaknesses of the study:

Several aspects of this study affirm the rigor of the methodology used for the development of the DST. The use of evidence-based frameworks (ODSF and OPDG) to guide the process of development and alpha testing of the tool conforms to the recommendations of International Patient Decision Aid Standards (IPDAS), which states that patient DSTs should be carefully developed, user-tested and open to scrutiny, with a well-documented and systematically applied development process (36-37). In addition, our study utilized a qualitative approach to evaluate the acceptability and usability of the DST. This qualitative approach allows users the freedom to express their pain point freely when using the tool but does not give the benefits of quantifying users' response (38). The use of mixed methods would have been ideal, but we were constrained by limited resources and time. However, the qualitative approach provided useful feedback that was incorporated into the final version of the DST. One of the major weaknesses of this study is the inability to compare the probabilities of outcomes for the various HIV prevention options. The evidence was not available in the literature, hence we were limited to including what was available. We hope to update the tool once this information is available.

Strength and weakness in relation to other studies, discussing particularly any differences in results

The development process and testing of our DST compared favorably with other studies (14,16,21). Coulter et al (21) noted that key features common to all decision support tools development processes include: scoping, development of a prototype; alpha testing with patients and clinicians in an iterative process; beta testing in real life conditions (field tests); and production of a final version for use and/or further evaluation. The use of evidenced-based framework for the development process made it possible to capture all these key features in our study. In addition, most developers did not describe a distribution strategy for their DST, however, our study identified and described the distribution strategy for the DST during the planning phase (21).

Meaning of the study: possible mechanisms and implications for clinicians or policy makers

This study highlights the benefits of using evidence-based frameworks and a multidisciplinary team to guide the development process of a decision support tool. Secondly, the difficulty of comparing probabilities of outcome in the light of limited evidence can be a major challenge. This challenge can however be minimized by regularly updating the DST once additional evidence becomes available. PrEP providers (clinical or service providers) now have an evidence-based tool that can be used to guide PrEP-eligible clients in making informed decisions about whether to use PrEP or not.

Unanswered questions and future research.

Additional studies will be needed to assess the feasibility of implementing the DST in real life – Beta testing. Secondly, an effectiveness trial will also be needed to ascertain the impact of the DST on decision making, clinical outcomes and utilization of the healthcare system.

Conclusion:

A DST was developed for PrEP-eligible Black patients to enhance their decision-

making process for HIV prevention options. Potential users (Black patients and clinicians) found it usable. Additional studies will be needed to evaluate the feasibility of implementing the DST in real life setting.

Additional file 1: Link to the PrEP DST

<https://decisionaid.ohri.ca/AZsumm.php?ID=2028>



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Declarations:

Funding: Funding for this study was received from Ontario Treatment Network (OHTN) as part of the OHTN Chair Award for HIV Prevention Implementation Science in Black Communities in Canada

Conflicts of interest:

LN, the principal investigator of this study, is also a shareholder of tuliptree systems, LLC—the company that owns the care coordination tool that is used in this study. As such, LN has a direct financial interest in the success of this tool and its continued use as an intervention. LN has accepted a conflict of interest (COI) management agreement with St. Michael's Hospital to minimize any potential undue influence on the study's outcomes. The COI management plan stipulates that LN will neither be involved in the recruitment of participants nor in obtaining informed consent. Additionally, all materials that arise from the results of the research (e.g., reports, publications, presentations, educational materials,) will include a disclosure of LN's relationship with tuliptree systems, LLC.

Ethics approval:

This study was approved by the Research and Ethics Board of St. Michael's Hospital Unity Health Toronto, Canada.

Availability of data and material:

The web-based PrEP DST has been reviewed and approved by IPDAS for public use (39)

Consent to participate:

We sought and obtained consent to participate in the study from all participants. Oral and written consent were sought and received before the study.

Consent to publish: All authors provided consent to publish thorough their involvement in the drafting, review, and final review of the final submission.

Authors' contribution:

WA is a co-investigator in this project. WA prepared and managed the writing and submission of this manuscript. WA, LN, CP, RB, KD were all involved in conceptualization of study, data collection and analysis (except LN due to Conflict), and all contributed to the drafting and review of the manuscript specifically the method and results sections.

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