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RESEARCH ARTICLE

Clinical risk assessment of modelled situations in a pharmaceutical decision support system: a modified e-Delphi exploratory study

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Abstract

Background Pharmaceutical decision support systems (PDSSs) use reasoning software to match patient data to modelled situations likely to cause drug-related problems (DRPs) or adverse drug events. To aid decision-making, modelled situations must be linked to well-defined systemic clinical risks.

Aim To obtain expert consensus on the level of clinical risk for patients associated with each modelled situation that could be addressed using a PDSS.

Method A two-round e-Delphi survey was conducted from February to April 2022, involving 20 experts from four French-speaking countries. Participants had to rate modelled situations on two five-point Likert scales, assessing the likelihood of clinical consequences and their severity. The degree of consensus was determined as the proportion of participants providing risk scores in line with the median. The combined median scores for likelihood and severity provided the level of risk according to the Clinical Risk Situation for Patients (CRiSP) scale, formalized via validated tools.

Results The expert panel achieved consensus (≥ 75% agreement) on 48 out of 52 modelled clinical situations. Among these, 45 were categorized as high or extreme risk. The most common DRP identified was overdosing, accounting for 22% of cases. Furthermore, DRPs involving cardiovascular, psychiatric, and endocrinological drug classes were prevalent, constituting 45, 13, and 9% of cases, respectively.

Conclusion Through consensus, our study identified 45 modelled clinical situations associated with high or extreme risks. This study highlights the interest of using PDSSs to prevent harm in patients and, on a large scale, document the impact of the pharmacist in preventing, intercepting and managing iatrogenic drug risk.

Keywords Clinical decision support system · Drug-related problems · Medication errors · Medication review

Impact statements

- Using modeled situations standardizes large-scale data collection to prevent clinical risks.
- The impact of the clinical pharmacist is more easily documented using the clinical risk level associated with the modeled PDSS situations, rather than that of each pharmaceutical intervention on each patient.
- The modified e-Delphi method and the formalized CRiSP scale, based on validated tools (HAS, SFPC, NHS), allowed us to reach a consensus on clinical risk for most situations, and may be used again for other modeled situations.

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Introduction

The World Health Organization set forth its third global patient safety challenge, aiming to achieve a 50% reduction in severe, medication-related harm over a 5-year period. This goal can be achieved by strengthening prescribing systems at all stages of the medication process [1, 2]. One of the primary objectives of pharmaceutical care activities is also to mitigate drug-related harm. Studies indicate that nearly half of all adverse drug events (ADEs) are preventable [3, 4]. As a result, the prevention, detection, resolution, and recovery of actual or potential drug related problems (DRPs) through pharmaceutical interventions are recognized as critical strategies in reducing ADEs [4–6]. A DRP is defined as "any actual or potential problem relating to therapy for a given patient identified during clinical pharmaceutical assessment, and which will be followed up by a pharmaceutical intervention" [7]. Medication review by hospital pharmacists is an essential safety measure for patients and healthcare professionals alike. Consequently, many countries have mandated this practice due to its potential in preventing various risk scenarios [8, 9]. However, the time-consuming nature of medication review poses challenges for its full implementation in hospitals, thus fostering interest in automated tools that can alert pharmacists to modelled situations associated with risks [10]. In this context, pharmaceutical decision support systems (PDSSs) play a crucial role by providing real-time alerts to pharmacists, resulting in numerous benefits such as reduced morbidity rates, improved prescribing practices, enhanced patient monitoring, streamlined preventive care services, decreased ADE rates, and lower healthcare costs [11–13]. PDSSs consist of deductive inference software, in this case, PharmaClass® software (Keenturtle—F), which uses patient health data and modelled clinical situations derived from pharmaceutical experience with DRPs [14]. The severity of potential harm associated with the likelihood of occurrence in a patient determines the clinical risk of a situation. Several validated assessment scales, including the tool developed by Hatoum, the clinical, economic and organisational (CLEO) scale, and the US National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index, help to determine the clinical impact of pharmacists' interventions [15–17].

For our study, we selected the modelled situations for which we are most often alerted and for which we wanted to determine the clinical risk i.e., the likelihood of the clinical consequence occurring and its possible severity [18]. Our work built on previous studies which had identified situations for inclusion in a PDSS based on consensus indicators, as well as studies exploring the likelihood and severity of prescribing events and harm [19, 20]. As an example, the study by Heed et al. had identified 131 situations detectable by a PDSS to ascertain the likelihood of occurrence of the prescribing event, the likelihood of harm and its severity [19].

Aim

To obtain expert consensus on the level of clinical risk for patients associated with each modelled situation that could be addressed using a PDSS.

Ethics approval

This was a non-interventional study which did not directly involve humans. Therefore, the need for the study protocol to be submitted to the Committee for the Protection of Persons (CPP) was waived. The study was carried out in accordance with the MR-004 reference methodology of the French data protection authority (CNIL).

Method

The Delphi technique, a validated consensus-building method, was used for this clinical research [21]. The process involved two rounds, with the aim of obtaining a single, convergent final opinion from a group of experts [22]. It was an exploratory approach focused on clinical risk and its impact on patients' health.

Formalization of modelled clinical situations

Integrating modelled clinical situations into the PDSS aims to improve the detection of DRPs and their resolution by pharmaceutical intervention. Each situation includes decision-making items regarding patients and medication (e.g. lack of iron supplementation and chronic renal failure), the type of DRP (e.g. untreated indication), its clinical consequence (e.g. complications of anemia), and a strategy to resolve the DRP with a potential pharmaceutical intervention (e.g. iron supplementation) (Fig. 1). To model each clinical situation, a 12-stage process was developed. Each situation was validated by five clinical pharmacists and four clinical experts from different disciplines. The situations were modelled either from clinical recommendations (e.g. European Society of Cardiology, French Diabetes Society), the summary of product characteristics, or clinical cases frequently encountered by pharmacists [14, 23]. Of the 210 modelled situations routinely exploited by the PharmaClass® software in the two hospitals, the 50 situations for which the greatest number of pharmaceutical interventions

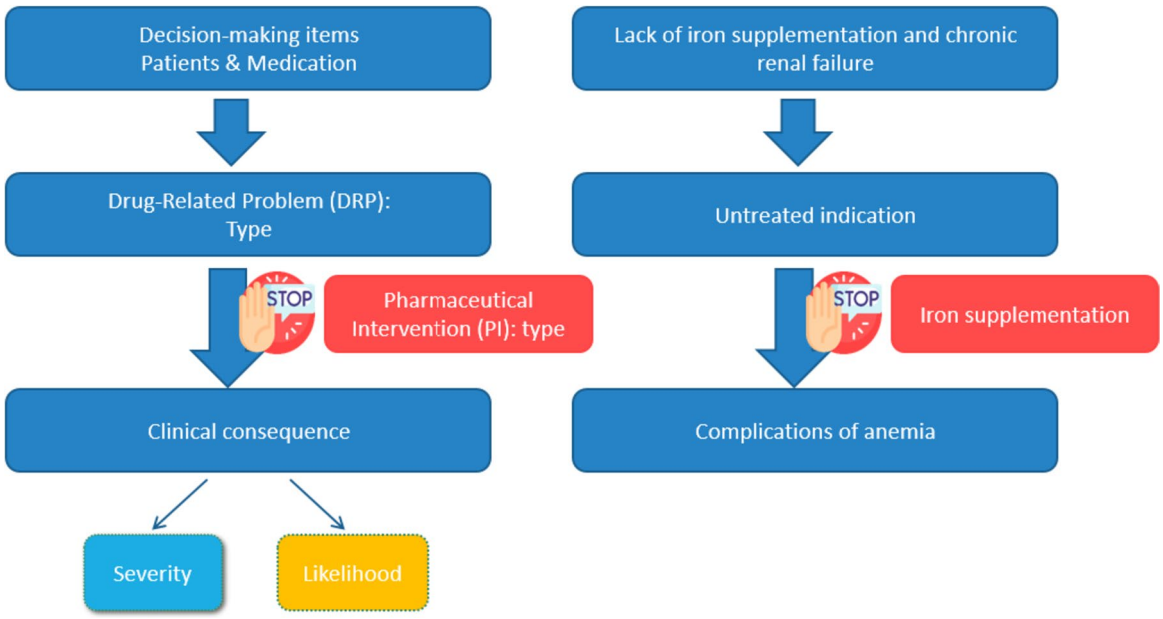

Fig. 1 Characteristics of a modelled situation: general case (left) and example (right)

was required over the period March to August 2021 were selected for this study.

The e-Delphi process

We first set up a pilot group to formalize the Clinical Risk Situation for Patients (CRiSP) scale and pre-test the questionnaire by applying the CRiSP scale to the modelled situations to ensure its suitability. The panel then completed a two-stage e-Delphi survey to rate the clinical risk of each situation. The overall process is summarized in the flow chart (Fig. 2).

a. *Pilot group* To create the pilot group, we invited seven senior clinical pharmacists: three from the general hospital, one from a hospital specialized in psychiatry and three from a university hospital. Some of the members of the pilot group were also in the panel of experts. The pilot group members provided useful feedback on the suitability and readability of the modelled situations. Overall, they reported that the situations were appropriate and clearly presented. However, the wording of certain situations was modified to improve clarity.

The pilot group also assessed the clinical risk of eight situations. The aim was to provide the experts

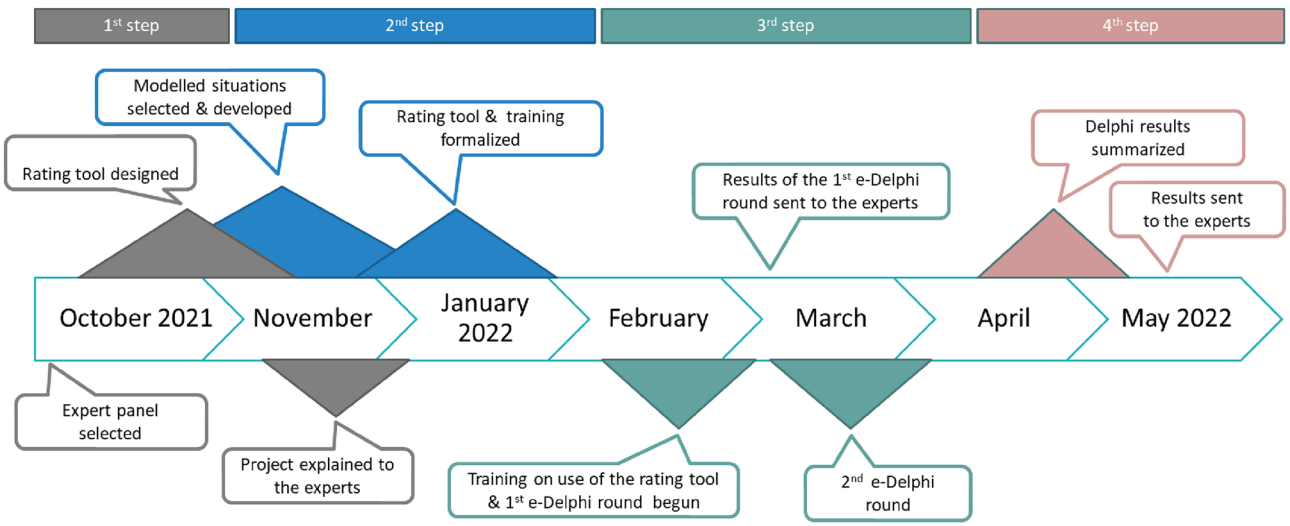

Fig. 2 Flow chart showing the study's chronological progression from selection of the expert panel to results obtained

with examples of scoring in order to train them on the use of the scoring tool. Relevant examples would thus maximize the consistency of the subsequent rating by the panel of experts [24].

b. *Choosing the rating scale* The pilot group also formalized the CRiSP rating scale specifically tailored to the modelled situations using the British National Reporting and Learning System (NRLS) risk matrix. The CRiSP scale combines the severity of the potential clinical consequence with its likelihood of occurrence. It is scored on four levels: extreme, high, moderate, and low (Table 1) [18].

The severity of each potential clinical outcome was determined according to the clinical impact scale for pharmaceutical interventions of the French Society of Clinical Pharmacy, CLEO–2014 [16]. The potential severity scales for medication errors established by the French National Health Authority (HAS) in 2012, the French Society of Clinical Pharmacy in 2013, and the British NRLS scale were also used [18, 25–27]. The CRiSP scale contains a combination of the wording of severity items from the HAS scale (minor, significant, major, critical, and catastrophic) and the description of the corresponding severity items from the CLEO, NRLS and HAS scales. The items "harmful" and "undetermined" from the CLEO scale were excluded.

Regarding the likelihood of the clinical outcome, the wording of the five likelihood levels (rare, unlikely, possible, likely, and almost certain) were taken from the British NRLS scale, and the item descriptions were taken from the NRLS and HAS scales [18, 26].

CRiSP is a combination of these two (severity and likelihood scales) five-point Likert scales. The participants evaluated each situation based on the likelihood of the clinical outcome occurring within 30 days and the severity of the clinical outcome when expressed in a patient.

Participants

Experts were contacted by e-mail or by videoconference via the pharmacists' networks of the two hospitals. A consent form explaining the objectives of the work, the rating tool and the e-Delphi method was signed by each participant.

The field of expertise required was clinical practice for both physicians and pharmacists. Although heterogeneity was observed regarding the discipline and level of experience, this reflected real-life conditions.

Training round for the clinical risk score

To eliminate potential subjective bias, the experts underwent a practice exercise by assessing 8 'sample' situations using an online training questionnaire. Although these situations were different from those evaluated in the study, they were presented in a similar manner. To support the experts in their assessment, they were provided with the median assessment category derived from the pilot group and the level of agreement for both scales (severity and likelihood) for these modelled situations. All questionnaires were completed before beginning the first round of evaluations.

First round

Background information was initially provided, followed by a consent statement, which participants had to complete before gaining access to the questionnaire. The questionnaire was administered through an online platform (Limesurvey®) and launched on February 7th, 2022.

The response rate was calculated based on the number of respondents in relation to the total number of experts contacted. Participants were instructed to evaluate the clinical risk associated with each situation using the severity and likelihood rating scales. Additionally, they were asked to provide comments on the suitability and wording of the situations. A period of three weeks was allocated to complete the questionnaire.

Subsequently, we calculated the median rating category and determined the degree of consensus among participants for each situation. The degree of consensus was measured as the proportion of experts who gave the same rating as the median. The threshold value was set at $\geq 75\%$ in line with the thresholds found in most studies based on the same approach [21, 28]. After the first round, the participants' comments were taken into account, leading to modifications of some of the modelled situations.

Second round

The second round was conducted with a response time of three weeks starting from March 7th, 2022. The response rate was calculated based on the number of respondents relative to the total number of experts consulted. For each situation, participants were provided with their own ratings from the first round, along with the median scores of the expert panel for both severity and likelihood ratings. In cases where the threshold value of $\geq 75\%$ consensus was not reached, experts were asked to re-evaluate the severity or likelihood for the situation.

The experts could adjust their ratings if they had initially differed from the median or maintain their original opinion if they disagreed with the majority

Table 1 CRiSP scale determination tool combining the potential clinical consequence severity and likelihood of occurrence (from the NHS–2013, HAS 2012, SFPC 2014) [16, 18, 26, 27]

Severity \ Likelihood	1 – **Rare** "Never seen" – probably never happens.	2 – **Unlikely** "Seen once in my career" – not expected but possible	3 - **Possible** "Seen in other institutions" – may occur occasionally	4 - **Likely** "Occurs in the institution" – happens but not a persistent problem	5 - **Almost certain** "Experienced in my area of work" - happens repeatedly
5 – **Catastrophic** Potentially life - threatening or death	5	10	15	20	25
4 – **Critical** Permanent clinical consequences for the patient: causing irreversible physical or psychological damage	4	8	12	16	20
3 – **Major** Temporary clinical consequences: treatment or intervention or transfer to another facility, induction or prolongation of hospital stay, causing reversible physical or psychological damage	3	6	9	12	15
2 – **Significant** No clinical consequence, no prolongation of hospital stay. Increased surveillance for the patient	2	4	6	8	10
1 – **Minor** No consequence to the patient. Neither monitoring nor treatment	1	2	3	4	5
1-3 Low risk	4-6 Moderate risk		8-12 High risk		15-25 Extreme risk

view. In such cases, they were encouraged to provide justifications for their choices. At the end of this second round, the degree of consensus was determined for each rating. Situations that achieved consensus with a threshold value of ≥ 75% were used to calculate the clinical risk using the CRiSP rating scale.

Results

Participants

Among the 29 experts consulted, 22 (76%) agreed to participate in the 1st round, one person refused to take part and six experts did not take part due to lack of time. Of the 22 participants, 20 (91%) completed Round 2 but, for some unknown reason, two did not respond. The panelists were 17 pharmacists and five physicians including two geriatricians, two psychiatrists, and one surgeon. They originated from Belgium (n = 2), France (n = 17), Luxembourg (n = 1) and Switzerland (n = 2). The median experience of the experts was 12.5 years (IQR: 13.9; min–max: 1–40) (Table 2).

Modelled situations

During the first round, 50 situations selected were evaluated by the experts. After the first round, with input from the experts' comments and consultation with the pilot group, the number of situations evolved, resulting in 52 situations to be evaluated in the second round. In total, 55 modelled situations were formalized (Fig. 3).

These situations involved drugs for various indications, including cardiovascular (n = 25), central nervous system (n = 14), endocrine (n = 5), infection (n = 5), and

Table 2 Socio-professional and demographic details of the 22 experts who took part in the eDelphi process

Expert	Profession	Type of institution	Nationality	Clinical experience (years)	Sex	Age (years)
E1	Pharmacist	UH	French	40	Female	> 50
E2	Pharmacist	UH	French	30	Male	> 50
E3	Physician	Psychiatric H	French	22	Female	41–50
E4	Pharmacist	UH	Swiss	20	Female	41–50
E5	Pharmacist	H	French	20	Female	41–50
E6	Pharmacist	UH	French	19	Female	41–50
E7	Pharmacist	UH	Swiss	18	Male	41–50
E8	Pharmacist	UH	French	17	Male	41–50
E9	Pharmacist	UH	French	14	Female	30–40
E10	Physician	UH	French	13	Male	30–40
E11	Pharmacist	UH	Belgian	12	Female	30–40
E12	Pharmacist	HC	French	11	Male	30–40
E13	Pharmacist	UH	Belgian	10	Female	30–40
E14	Pharmacist	Psychiatric H	French	8	Male	30–40
E15	Pharmacist	UH	French	7	Male	30–40
E16	Medical intern	UH	French	7	Male	< 30
E17	Pharmacist	HC	Luxembourgish	5.5	Female	< 30
E18	Physician	UH	French	5	Male	< 30
E19	Physician	Psychiatry H	French	5	Male	30–40
E20	Pharmacist	UH	French	4.3	Female	< 30
E21	Pharmacy intern	UH	French	4	Female	< 30
E22	Pharmacy intern	UH	French	1	Female	< 30

UH University hospital

miscellaneous diseases (n = 6). They encompassed 31 different clinical consequences, with "hemorrhage", "cardiac rhythm disorders", and "adverse effects" being the most represented.

According to the SFPC classification, eight out of ten DRPs were represented: overdose (22%), underdose (16%), untreated indications (15%), non-compliance (15%), interactions (13%), non-indicated drug (9%), inappropriate administration/method (7%), adverse reactions (4%). All pharmaceutical intervention types were represented.

Round 1

During the first round, the 50 modelled situations resulted in 100 items to be rated, with 50 for severity and 50 for likelihood. The 22 experts achieved consensus on eight items, with seven related to severity and one to likelihood. The response rate was 100.0%. Experts' comments were considered at the end of this round, leading to modifications by the pilot group for the 50 modelled situations, including the splitting of six situations (one into three situations and one into two situations) and withdrawal of one situation. Other situations that did not reach consensus were re-evaluated in the second round.

Round 2

In the second round, twenty experts participated, with two lost due to remote communication issues. The response rate was 90.9%. Out of the 52 modelled situations, comprising 45 items rated for severity and 51 for likelihood, 48 obtained consensus. Four situations did not reach consensus, with one situation lacking consensus on both severity and likelihood. The other three situations did not reach consensus in terms of likelihood alone.

At the end of the second round, the clinical risk was determined for the 48 modelled situations which had obtained consensus. Overall, the experts reached consensus on the risk category for 48 out of the 52 situations modelled after the two rounds. Among these, 10 situations were classified as having an extreme risk, 35 situations were categorized as high risk, and three situations were identified as moderate risk. None of the situations were classified as low risk. Four situations did not achieve consensus.

Fig. 3 Evolution of the number of modelled situations from selection to the eDelphi rounds

In the 10 situations with an extreme risk, 7 (70%) were related to cardiovascular medication, with clinical consequences such as cardiac arrest (3), hemorrhage (2), or thrombo-embolism (2). Other medication involved infectious diseases and the ineffectiveness of antiretrovirals (1), analgesia with morphine and the lack of laxative leading to constipation or even intestinal occlusion (1), and escitalopram/citalopram in psychiatry with cardiac arrest as a clinical consequence (1).

Discussion

Statement of key findings

The modified e-Delphi method was used to determine the risk levels of forty-eight modelled situations. This enhanced the knowledge base with new characteristics, such as moderate, high, or extreme clinical risk, achieved through consensus.

Strengths and weaknesses

The knowledge base on 210 modelled situations assists the pharmacist in achieving impact on morbidity and mortality when integrated into a PDSS. The aim of this work was to measure the extent of this impact.

However, there were some selection biases concerning experts and modelled situations. Experts were selected through a network to form a heterogeneous panel in terms of expertise and geography. Recommendations and practices between countries may vary. Only five experts were physicians (23%) and only three participants (14%) had less than 5 years of experience.

The e-Delphi consensus method has the advantage of gathering individual responses anonymously. The experts consulted had diverse profiles and experience and were able to express themselves without one voice dominating the others.

The modelled situations were pre-defined, and experts could not add new situations, leading to a suggestibility bias. Nonetheless, the experts' comments helped mitigate this effect. Interpreting and scoring situations may differ from one expert to another, but this possibility was addressed through an online questionnaire for training on the scoring tools before the study.

Interpretation

Among the 35 high-risk situations, cardiovascular drugs (40%) and psychiatric drugs (14%) were most represented. For the three moderate-risk situations, the medications involved were related to endocrinology, hematology, and cardiovascular issues. This distribution can be attributed to the prevalence of cardiovascular drugs in national-level pharmaceutical interventions [29].

Consensus was not reached for three situations due to the trivialization of risk for widely-used drugs ("paracetamol and hepatitis" and "metformin and severe renal failure […]") and ambiguity in one psychotropic drug situation.

Indeed, "psychotropic" and "lithium LP" were initially grouped into one situation. However, comments from the experts led this ambiguous situation to be split into two. Despite this modification, a consensus was still not reached as the experts selected were not familiar with that particular field of pharmacotherapy.

The Challenge

The modelled situations evaluated were general, abstract, clinical case reports, and not specific to individual patients. For experts used to assessing specific patient cases, it was challenging for them to evaluate the potential clinical impact in a relevant manner. However, attributing values to each risk provided a practical alternative to time-consuming case-by-case measurements. The study aimed to give experts a global perception of situations for appropriate evaluation, contributing to a new method with promising indicators and good external validity.

Further research

The e-Delphi method used to determine clinical impact in PDSSs, irrespective of patient profiles, is relatively unexplored in the literature. Thomas et al. developed a list of 80 out of 109 (73%) situations with high frequency or severity amenable to a decision support system. The NHS scales for both severity and likelihood were used to establish clinical risk [20].

Most studies using the Delphi method aim to prioritize a list of items [29–34]. Future research could define clinical risk levels for situations generating the most pharmaceutical interventions on a national scale, emphasizing patient outcomes rather than professional acts [29].

The clinical risk level for each modeled situation and the description of each situation should be included in a shared knowledge base for other clinical pharmacists using a PDSS. The clinical risk of the situations modelled could be assessed by experts specific to the specialty, depending on the type of situation (for example: situations relating to cardiology by clinical pharmacists in cardiology units and cardiologists).

Conclusion

A method for defining the clinical risk level of each situation modeled in a DPSS is proposed. This study identified 45 modelled clinical situations associated with high or extreme risk through consensus. The research highlights the interest of PDSSs for preventing patient harm and documenting, on a large scale, the impact that pharmacists can have in preventing, intercepting and managing iatrogenic drug risk.

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Conflicts of interest The authors have no conflicts of interest to declare.

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