Practical Implementation of Nursing Science

An Innovative Approach for the Development of an Early Phase Research Unit

ORIGINAL PROJECT

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ABSTRACT

Background: Moving cancer outcomes forward is interdependent on increased participation in clinical trials. There is an increasing need in ambulatory oncology to develop formal structures which enable participation in complex research studies.

Purpose: There was a lack of standardization in operationalizing care delivery for patients participating in complex trials in our Cancer Center, therefore a formal structure was needed. This project describes the framework for development, implementation, and sustainment of our early-phase research infusion unit (EPRU). Approach: Dedicated space, as well as a core team of nurses in the infusion area was identified. Workflow processes and standard operating procedures were initiated. Standard educational requirements and research-focused competency facilitated training compliance. Electronic data reports showed volume trends and along with an acuity tool supported staffing guidelines.

Outcomes: Standardization of processes fostered adherence to research protocol requirements while accommodating increased complex research protocols and volume of patients.

Conclusions: Nurses' professional development is paramount to safe quality care of patients participating in clinical trials. Using an acuity tool to appropriately allocate resources, allows for accommodating increased complexity and volume. Systematizing processes fosters adherence to protocol requirements.

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BACKGROUND

The mission of our health system is to be on the cutting edge of cancer clinical trials research and to participate in the development of newer cancer treatments through unrivaled education, research, and outreach in the diverse communities we serve. This is synergistic with our nursing mission statement of promoting health and wellness by bridging relationships with our local, national, and global communities through advocacy, education, and scientific nursing research.

Our outpatient cancer center is a National Cancer Institute (NCI) designated treatment facility located in an urban metropolitan area that serves a diverse patient population. NCI-designated facilities are recognized for their delivery of cutting-edge cancer treatments in communities across the United States. NCI-designated facilities are also recognized for their leadership and resources, in addition to demonstrating an added depth and breadth of substantial transdisciplinary research that bridges these scientific areas (NCI, 2021). Our institution is a Magnet-designated facility. Magnet hospitals create supportive professional nursing care environments by generating new knowledge through research. This is a requirement to obtain and retain Magnet designation status. Magnet hospitals must build research infrastructures that promote ongoing quality clinical nursing practice to improve patient outcomes (ANCC, 2021).

PROBLEM DESCRIPTION

Phase I trials involve investigational products with limited scientific and clinical data in human subjects or novel combinations of investigational products with limited concomitant use. In Phase I clinical trials, investigational products can be classified as "first-in-human": the first time a human subject receives an investigational product. As such, these are high-acuity patients requiring an intense and expert level of nursing care.

After completing an informal analysis of existing processes in 2018, including a review of incident reports and patient records, an alarming number of study deviations were identified. A study deviation occurs when, without significant consequences, the activities on a study diverge from the Institutional Review Board-approved study protocol (Bhatt, 2012). Our team records, assesses, and develops corrective actions for all deviations that occur during the conduct of clinical trials at our institution. To effectively participate in research, nursing leadership recognized the need for restructuring, a critical step necessary to continue participating in research while maintaining study integrity and preventing deviations.

CONTEXT

While the number of patients enrolled in experimental treatment fluctuates, we have approximately 70 active Phase I clinical trials open for enrollment. In 2021 we had 455 patient accruals. Our cancer infusion center has 56 treatment chairs and 12 beds. There are 68 full-time employed infusion Registered Nurses (RNs), with an average of 28 RNs treating an average daily census of 185 patients. Both solid and liquid tumors comprise the disease groups of patients receiving treatment by the infusion RN at our facility. While the above treatment area existed, there was no dedicated space for treating complex research patients. To effectively deliver care as recognized by the NCI and Magnet, the need for an Early Phase Research Unit (EPRU) was identified. This allowed the patients participating in Phase I clinical trials, and trials with complex visit requirements, an area for treatment.

PURPOSE

As we began working towards establishing this EPRU, it became evident that we needed standard processes and practices for the complex research patients, as these did not already exist. We assessed the existing research landscape and focused on structuring five key target areas: 1) team development and workflow, 2) staffing guidelines, 3) standardization of education, training, and competencies, 4) development of standard research operating procedures and uniform research tools, and 5) collaboration with information technology to generate data reports. This paper outlines a *Phase I Clinical Practice Model* and describes five areas that we standardized to support high-acuity patients in clinical trials.

APPROACH

TARGET AREA 1: TEAM DEVELOPMENT AND WORKFLOW

Team Development

Nurse leaders recognized that a designated team was needed to establish a consistent workflow. A Core Research Infusion Team (A) was developed which was made up of six team member groups. This team consisted of *Core Research Infusion Nurses* (a), who volunteered to work in the EPRU, and a dedicated *Clinical Trial Nurse Clinician* (b), whose role was to lead the Core Research Infusion Team, while acting as a liaison between *Primary Investigators* and their *Individual Clinical Research Teams* (c), *research pharmacists* (d), *nursing leadership* (e), and *hospital administration* (f) (Rudnitzki et al., 2018). Individual clinical research teams and their primary investigators share responsibility for spearheading clinical trials for their specific group and/or disease site.

An EPRU with seven private infusion rooms and two double rooms for treating research patients has created a therapeutic milieu. Under the direction of the Clinical Trial Nurse Clinician and nursing leadership , workflow processes were developed to guide the Core Research Infusion Team and Individual Clinical Research Teams (ONS, 2016). These processes were based on Oncology Nursing Society (ONS) recommendations.

Workflow

Daily Huddles

Daily huddles were initiated by the Core Research Infusion Team. During these huddles, study patients were discussed, complex protocols were reviewed, and research-related questions were addressed prior to the patient's treatment. In addition, monthly meetings with core research team members were implemented, providing an opportunity for the team to discuss clinic challenges, communication issues, and strategies for improvement (Carlson, 2005).

Bimonthly Meetings

Bimonthly meetings with the Core Research Infusion Team, individual clinical research teams, and nursing leadership fostered better working relationships and improvements in workflow-related practices.

Informal Meetings

Informal meetings between the Clinical Trial Nurse Clinician and research pharmacists resulted in the development of consistent processes and pathways and improved communication. These new communication strategies resulted in timely administration of pre-medications and preparation of investigational products. Consistent communication and collaborative efforts across all disciplines have improved working relationships (Carlson, 2005).

TARGET AREA 2: STAFFING GUIDELINES

The American Nurses Association (ANA) describes staffing guidelines as multifactorial, contingent upon a multitude of intricate details with many stakeholders (ANA, 2019). The ANA stresses the importance of staffing guidelines specific to the workplace setting and crucial for maintaining patient safety while ensuring policy and protocol compliance. The literature details the importance of staffing guidelines in ambulatory oncology care settings (Edwards et al., 2017; Liang & Turkcan, 2016; Vortherms et al., 2015), however, the evidence remains sparse regarding staffing guidelines or recommendations for infusion nurses in a Phase I research unit.

Due to the lack of evidence or guidelines for establishing defined staffing levels for infusion nurses participating in Phase I clinical trials, we developed an acuity tool to assess required staffing guidelines for each evaluated trial (Rudnitzki et al., 2018). The acuity tool was developed in partnership with Core Research Infusion Teams and nurse leaders, considering all study procedure time points and the cycle/day of treatment.

As shown in Table 1, the acuity tool required scoring on seven items: 1) frequency of vital signs, 2) electrocardiograms [three-ECGs (triplicate) versus one-ECG (single)], 3) number of research blood draws, 4) administration of multiple medications, 5) Phase I, first-in-human study, first-time administration on our infusion unit, first-time dose escalation for this investigational product,

6) required observation period(s), and 7) complexity score, which is an overall score of the study, which was included if special equipment or supplies were required. The highest score assigned for each item was three, with a total highest score being 21. For example, if vital signs were required pre-dose, post-dose, and one-hour post-dose, a score of three would be plotted. An overall score of 11–14 indicated additional core research infusion staff may be required when multiple high-acuity score study visits were occurring on the same date. A score of 15 or greater demonstrated the need for one-to-one nursing care. Conversely, when low acuity scores were identified, no additional nursing staff was required.

Upon review of an upcoming research study, time points were plotted on the acuity tool and discussed with nursing leadership regarding the potential need for one-to-one staffing (Rudnitzki et al., 2018). This rigorous level of staffing review, in addition to following the ANA principles for nurse staffing (ANA, 2019), has provided insight into the feasibility of conducting the trial in the EPRU at our institution with infusion nurses. As the Core Research Infusion Team became more familiar with various protocols and intensities of the studies, they also began to offer recommendations regarding staffing needs, which were considered when planning the care of the patient in the clinical trial.

The acuity tool continues to be used in advocating for additional resources or staffing for research studies. Over time, modifications have been made in the scoring system to reflect when additional staffing resources are required. With the help of various leaders within our organization, we have transitioned the acuity tool from a paper model to an electronic version using a secure Health Insurance Portability and Accountability Act-compliant web-based application database format.

TARGET AREA 3: STANDARDIZATION OF EDUCATION, TRAINING, AND COMPETENCIES

In 2016, the ANA recognized clinical research nursing as an official nursing specialty and published the scope and standards for practice (ANA, 2016). In 2016, the ONS updated the national standard for oncology clinical trial nurse competencies for obtaining informed consent, educating patients and caregivers, considering ethical issues, administering investigational drugs, collecting biospecimens, and monitoring for side effects (Ness et al., 2016).

Education

Chemotherapy Immunotherapy Certification

The ONS recommends oncology infusion nurses take the *Chemotherapy Immunotherapy Certification Course*, which provides nurses with the tools to provide quality care and safely administer chemotherapy and immunotherapy to patients with cancer (ONS, 2021). It is the standard of practice for all oncology infusion nurses within our institution to have completed this course. Additionally, the oncology nurse is strongly encouraged to obtain board certification from the ONS as an Oncology Certified Nurse.

General Research Education

The professional development of the nursing team is paramount to the safe and quality care of patients participating in clinical trials. General research education sessions are offered bi-annually for all members of the oncology infusion nursing staff. The purpose of these sessions is for all infusion nurses to gain a better appreciation and understanding of clinical trials and enable them to participate in less intensive research protocol training. Although the core research infusion team attended the general education sessions and met the previously described certification requirements, nurse leaders recognized an opportunity to expand the nurses' understanding of clinical trials research, to enhance confidence in emergency management skills, and safely administer investigational agents.

Training

Research and Clinical Training

The Collaborative Institutional Training Initiative (CITI) Program is a set of comprehensive courses that review critical areas associated with human subject research. The Core Research Infusion Nurses are required to complete a set of CITI Training Modules to gain a better understanding of clinical trials research. They are also required to have an Advanced Cardiovascular Life Support

GCO #	INCLUDE # DAYS PER CYCLE	CYCLE/DAY	VITAL SIGNS (1 POINT FOR EACH TIMEPOINT DURING A SINGLE INFUSION)	PKS (1 POINT FOR EACH TIMEPOINT)	EKGS (1 POINT FOR EACH TIMEPOINT EKG; EVERY TRIPLICATE IS 3 POINTS)	# OF DRUGS (1 POINT FOR EACH DRUG; DON'T INCLUDE PRE-MEDS)	OBSERVATION PERIOD (1 POINT FOR EVERY TIMEPOINT)	FIRST TIME IP AGENT BEING ADMINSTERED TO THIS PATIENT; FIH (FIRST TIME EVER ADMINISTERED IN HUMANS); FIH (FIRST IN HUMAN IP AGENT NEVER BEFORE ADMINISTERED AT THE INSTITUTION) FIH (FIRST TIME EVER DOSE ESCALATION FOR THIS IP AGENT) (ANY OF THE ABOVE = 3 POINTS)	MISCELLANEOUS— IF ADDITIONAL POINTS ARE REQUIRED 1 = MILDLY COMPLEX 2 = MODERATELY COMPLEX 3 = VERY COMPLEX	EXPLANATION OF MISCELLANEOUS COLUMN I.E. DURATION OF TREATMENT; MULTIPLE TITRATIONS; HIGH RISK OF REACTION)	TOTAL # OF POINTS	IF POINTS TOTAL >=15, PATIENT NEEDS 1:1 NURSING CARE
											0	No extra care required
											0	No extra care required
											0	No extra care required
											0	No extra care required
											0	No extra care required
											0	No extra care required

Table 1 Acuity Tool.
Key: GCO = Grants and Contracts Office Number; PK = pharmacokinetic (i.e. blood draw); EKG = electrocardiogram; IP = investigational product.

(ACLS) certification, although many reported underutilizations of their ACLS skills and expressed the need to enhance their emergency skill set and comfort level, should an emergency arise. To provide the tools needed for the research team to effectively handle emergency situations, a structured Mock Code Training Program was developed.

Mock Code Training Program

A pre-training program survey developed by the nurse educator and Clinical Trial Nurse Clinician was administered to members of the Core Research Infusion Nurse Team to assess their current knowledge and confidence on 1) the use of the ZOLL defibrillator and code cart and 2) the identification of unstable or fatal heart rhythms. Nurses surveyed were asked to rate their confidence, using a five-point Likert scale, where 1 = very little confidence and 5 = very confident. Pre-survey results identified that 100% of the core research team wished to participate in routine mock code sessions.

A simulated cardiac arrest training program was developed by our oncology nurse educators, consisting of six training sessions. This included: 1) ZOLL defibrillator code roles, 2) recognizing fatal dysrhythmias, 3) code cart and medication education, 4) emergency response system, 5) case scenarios, and 6) putting it all together—simulated cardiac arrest. As shown in Table 2, post-survey results (identical to pre-survey and administered to the same team) found improved confidence in four training sessions.

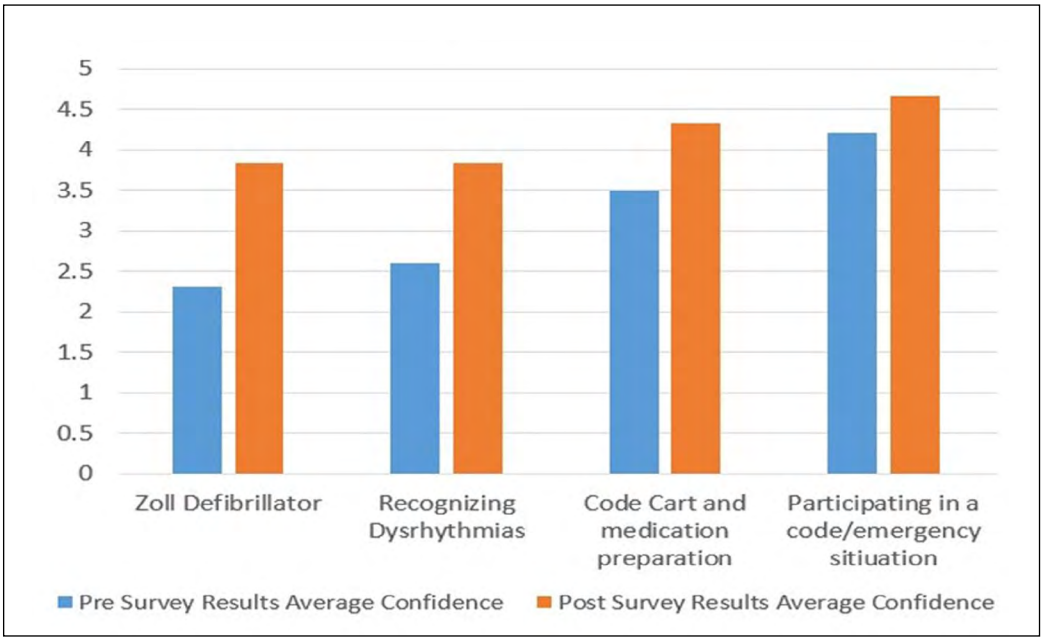

Table 2 Pre/Post Mock Code Survey Results.

Final Competency

A clinical oncology nursing research-focused competency, based on the ONS guidelines (2016), was developed for the Core Research Infusion Nurse Team (Ness et al., 2016). This three-part competency includes CITI training, ACLS certification, and completion of a research competency. This is now a standard requirement for participation in our Core Research Infusion Team. The mock code training program has become a springboard for a cancer center-wide initiative known as "*Emergency Response Simulation Education*," which is offered to all nurses and advanced practice providers. The general research education sessions have sparked an interest among other infusion nurses to consider joining the Core Research Infusion Team.

TARGET AREA 4: DEVELOPMENT OF STANDARD OPERATING PROCEDURES AND UNIFORM RESEARCH TOOLS

Standard Operating Procedures

During the preliminary development phase for our program initiative, complex research study patients and Core Research Infusion Nurses were assigned in various treatment pods throughout the infusion area, not having the support structure they needed from their fellow Core Research

Team members working in different locations. Therefore, it became evident that a dedicated area for the treatment of patients enrolled in highly complex clinical trials was required. This space was identified, and standard operating procedures (SOP) were adopted for assigning the appropriate patients to this research area. With administrative and clinical nurse leadership support, a specialized scheduling letter was developed to enable Clinical Research Teams to request a treatment room in the EPRU, using these SOP guidelines.

Standardized Research Protocol Training Plan

We developed standardized education and training plans, addressing clinical needs for the Core Research Infusion Nurses (Carlson, 2005). To adequately prepare the Core Research Infusion Nurses for administering investigational agents, education and training for the individual clinical research protocols are required. Some research protocols are extraordinarily lengthy, and others lack sufficient detail. As a result, a standard nursing in-service template was developed and piloted to ensure comprehensive and consistent education on the clinical research protocol prior to study initiation. All nursing in-service protocol training documents that were previously in paper format were transitioned to the hospital's online standard electronic educational tool: Portal for Education and the Advancement of Knowledge (PEAK). This format provided resources in an on-demand format for nurses unable to attend nursing in-services, while also providing educational reference. A mandatory electronic sign-off in PEAK before participation in research study protocols is required. For those studies where the use of special equipment is mandated, additional training is provided by the clinical research team or sponsor.

Research Tools

To ensure adherence to stringent research protocol requirements, and to minimize risk for study deviations, the need for standard study procedure checklists was recognized. Existing checklists varied in their format, length, organization, and required detail (i.e. details regarding 3-ECGs if required; windows for study procedure time points when provided by sponsor). As a result, we amended an existing checklist to incorporate a standard format for organizing the study procedure time points and to keep important information and details outlined by the sponsor for the specific cycle and day of treatment as concise as possible and not overlooked.

Study checklists assist in maintaining all study procedure time points for the Core Research Infusion Nurse and the Clinical Research Coordinators. They also assist with collecting data and ensuring that the individual study time points are met. The Clinical Research Team worked together on providing revisions to the checklist. Standard checklists for both simple (Table 3) and complex studies (Table 4) were then implemented. These checklists are now widely used across all Clinical Research Teams. These checklists are also reviewed by the Clinical Trial Nurse Clinician one week prior to treatment. By reviewing study procedure checklists in advance, intensity of the treatment day is determined, assisting in the staggering of research patient schedules, maximizing the use of space, and ensuring an appropriate staffing pattern is in place on treatment days when intense research patients are scheduled.

CYCLE	DAY
Investigator	• Link visit to GCO#
MA:	• CBC • CMP • Research labs
Nurse/Infusion Area	→ Vitals: Include (HR, respiratory rate, BP, and temperature) → **Please document all vital signs and times in EPIC flowsheet** **Pre-dose:** → Vital signs **Post-dose:** → Vital signs
CRC: CRN: Contact #:	

Table 3 Study Procedure Checklist—Simple Research Studies.
Key: MA = Medical Assistant; CBC = Complete Blood Count; CMP = Complete Metabolic Panel; HR = Heart Rate; CRC = Clinical Research Coordinator; CRN = Clinical Research Nurse.

CYCLE	**Day**
Investigator	• Link visit to GCO#:
LAB/MA:	• CBC • CMP • Research labs
Nurse/Infusion Area	**SPECIAL INSTRUCTIONS:** **Vital signs, EKG, and, PK sample draws – DOCUMENT IN EPIC**

Vital Signs	**EKG**	**PK Lab Draw**

POST TREATMENT INSTRUCTIONS:
CRC: CRN: Contact #:

Table 4 Study Procedure Checklist—Complex Research Studies.
Key: CBC = Complete Blood Count;
CMP = Complete Metabolic Panel;
MA = Medical Assistant;
EKG = electrocardiogram;
PK = pharmacokinetic;
CRC = Clinical Research Coordinator;
CRN = Clinical Research Nurse.

TARGET AREA 5: COLLABORATION WITH IT DEPARTMENT

Electronic Reports

No pathway for identifying growth in our research population existed. We did not track numbers of investigational agents administered nor the compliance with the online education system. As a result, electronic reports were generated with the help of the IT department (Harper, 2012). Individual reports provided 1) a list of daily research patients, 2) investigational products administered by staff, and 3) staff compliance in reviewing the educational material pertinent to the research study on the day of treatment via PEAK attestation.

Data Monitoring

Electronic reports captured the number of investigational agents administered each day as well as the administering personnel. These reports provided the patient volume trend; therefore, our team was able to ascertain an increase in the number of investigational agents administered over a specified time. With the capability of sorting the data based on the phase of the research study, we were able to identify increasing numbers of early-phase research studies. The data were then analyzed and regularly shared with nursing leadership and hospital administration, along with the acuity tool. These data demonstrated the increasing volume in daily administration of investigational agents, and the increasing numbers of early-phase research studies. These data were used to advocate for additional staffing and equipment in our EPRU.

Electronic reports also provided the data necessary to facilitate compliance with required educational training prior to administration of investigational agents. Data indicated when staff had not completed the required training and needed follow-up reminders to complete the training. As a result, compliance with required training increased from 35% to 92%. We continue to monitor these reports to ensure staff remain vigilant in reviewing the protocols and associated amendments (Table 5).

Acuity Tool	• Acuity score used to determine appropriate staffing levels • Acuity tool used in pre-planning trial budget to request additional funding from the sponsor on days where additional staffing was needed based on high acuity score • Paper tool converted to electronic version using secure data network server format
Dedicated Research Infusion Area	• Used solely for the treatment of early phase or intense study patients • Empowered charge and Core Research Nurses to cohort appropriate patients on research unit
Use of Data Generated through Electronic Reports	• Assisted in justifying increased staffing based on growth • Compliance in educational training improved from 35% to 92%

Table 5 Metrics for Success.

CONCLUSION

Through process development, standardization of workflow practices, dedicated research teams, collaboration, and the use of technology and data, we designed a program that aligns with the mission of our institution—to be on the cutting edge of cancer clinical trials research (Table 6). With this new structure in place, our volume of early phase clinical trials continues to increase as we actively participate in the development of newer cancer treatments. As the oncology research landscape continues to evolve, the intensity of protocols increases, and the volume of research study continues to expand, we will continue to review and re-assess our nursing standards to ensure we are providing safe, quality, and efficient care. Delineating team responsibilities to enhance outcomes, and reassessing staffing guidelines to accommodate the increasing number of participants and complexity of studies, are continuous components of our work.

Team Development and Workflow	• Dedicated core research infusion nurses identified • Developed workflow processes and clinical research standards • Daily huddles between core research infusion nurses and clinical trial nurse clinician • Established monthly meetings with core research infusion team • Bi-monthly meetings with core research infusion team, individual clinical research teams, and nursing leadership • Consistent communication across all disciplines
Staffing Guidelines	• Developed acuity tool which accounts for study procedure time points (vital sign frequency, EKGs, number of research blood draws) • Scoring system aided in determining need for additional staffing

Standardization of Education, Training, and Competencies	• Infusion nurse training requirements:
	  ◦ ONS chemo-immunotherapy provider card required for all infusion nurses
	  ◦ OCN certification strongly encouraged
	• Additional training requirements for the core research infusion nurse:
	  ◦ ACLS certification
	  ◦ CITI training
	  ◦ Core Research Nurse competency
	• Additional training for core research nurse:
	  ◦ Mock Code Training Program to further enhance emergency skills

Development of Standard Operating Procedures and Uniform Research Tools	• Dedicated infusion area for complex trial patients • Standardization of nursing in-service documents and study procedure checklists • Protocol training via electronic educational tool to provide easily accessible resources

Use of Data and Information Technology (IT)	• Electronic reports developed by IT assisted in:
	  ◦ Trending growth in patient volume as well as increases in early phase and intense research studies
	  ◦ Facilitating compliance with required educational training prior to administration of investigational agents

Table 6 Phase I Clinical Practice Model: Five Key Target Areas Summarized.

While it would have been beneficial to collect data pre-and post-implementation, at this point these data are not available and this is a limitation to our work. However, we will continue to evaluate and validate the work completed to achieve our goal of meeting the needs of our patients in the many diverse communities that we serve. With clearly established and tested guidelines, we envision that our *Phase I Clinical Trial Practice Model* will expand to other oncology care delivery settings within our healthcare system.

COMPETING INTERESTS

The authors have no competing interests to declare.

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