ORIGINAL ARTICLE

Developing innovative models of care for cancer survivors: use of implementation science to guide evaluation of appropriateness and feasibility

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Abstract

Purpose Limited understanding of factors affecting uptake and outcomes of different cancer survivorship care models hampers implementation of best practices. We conducted a formative evaluation of stakeholder-perceived acceptability and feasibility of an embedded primary care provider (PCP) survivorship care model.

Methods We identified clinical, operational, and patient stakeholders within Kaiser Permanente Southern California and conducted semi-structured interviews. Analyses were guided by the Consolidated Framework for Implementation Research (CFIR), an integrated framework from the field of implementation science. Deductive thematic categories were derived a priori from CFIR domains; thematic sub-categories were developed inductively.

Results We interviewed 12 stakeholders; multiple themes were identified. Acceptability: oncologists and operational leaders perceived that the model was an acceptable solution to issues of capacity and efficiency with the potential to improve quality; however, several oncologists perceived negative consequences including "[loss of] the joy of medicine." Patients were less enthusiastic, fearing the introduction of "[someone] who doesn't know me." Feasibility: confidence was high that this model can succeed, although there was concern about finding the right PCP and investment in training and staff support. Culture/climate: numerous system-level facilitators were identified, including encouragement of innovation and familiarity with developing new models.

Conclusions Formative evaluation is a critical pre-implementation process. Acceptability and feasibility for this model were high among oncologists and operational leaders but patients were ambivalent. Keys to successful implementation include training and support of engaged PCPs and a patient transition plan introduced early in the care trajectory.

Keywords Cancer survivorship · Survivorship care plans · Implementation science

Introduction

It is well established that cancer survivors are a fast-growing population. The number of survivors in the USA is currently

estimated at 15.5 million and is expected to grow to more than 20 million by the year 2026 [1]. More than two thirds of individuals diagnosed with cancer between 2007 and 2013 will survive at least 5 years [2]. Many cancer survivors face complex post-treatment care needs, and substantial gaps exist in the delivery of survivorship care. Survivors may experience physiological and psychosocial long-term or late effects due to their cancer and its treatment (e.g., peripheral neuropathy, infertility, cardiac dysfunction), in addition to being at risk for recurrence and development of new primary cancers [3–8]. Thus, cancer survivors have both short- and long-term care needs, including preventive care and cancer surveillance services [3, 9]. In addition, survivorship care requires care coordination and effective management of co-morbid conditions, given that many cancer survivors are

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older adults who also have multiple chronic comorbid conditions [10].

Guidelines from the American Society of Clinical Oncology and others provide recommendations for optimal post-treatment care of cancer survivors, including ongoing surveillance and screening to detect recurrence or secondary cancers, detection, and management of long-term and late effects (e.g., physical and psychosocial) of cancer treatment, as well as a focus on wellness (e.g., diet, exercise, etc.) and coordination of care [11, 12]. However, few cancer survivors receive appropriate post-treatment care. Gaps in survivorship care delivery include poorly-coordinated care stemming from inadequate communication between members of multidisciplinary care teams (i.e., between oncologists and primary care providers), a lack of provider education about cancer survivorship, provider/specialist role confusion, and poor transitioning of patients from treatment to post-treatment care [3]. Multiple models of care have been proposed to address these gaps, including consultative or integrated survivorship/long-term follow-up clinics, shared-care models between primary and specialty/oncology care, multidisciplinary and/or nurse-led models, oncology patient-centered medical homes, and primary care or specialist-led models [13, 14]. However, evidence suggests that models of survivorship care adopted within specific practice settings are highly individualized and vary widely in their characteristic components [15]. Factors affecting the uptake of differing models of survivorship care across specific health settings are poorly understood and not well characterized. There is no clear evidence as to which types of providers can and should assume responsibility for the increasing number of cancer survivors [3]. For instance, primary care providers (PCPs) may be unprepared to care for cancer survivors [16–19], yet oncologists are increasingly in demand due to the growing population of cancer survivors compounded by oncology workforce shortages [10, 20].

The use of implementation science, a field dedicated to promoting uptake of practices supported by evidence, may provide new insights into development of survivorship care models. Few health care systems have incorporated implementation science into planning and implementation, particularly in cancer care [16, 21–25]. In this paper, we present the findings from a formative evaluation regarding a new model of care for cancer survivors. The evaluation represents the initial step of an implementation project within a large, integrated healthcare system, Kaiser Permanente Southern California (KPSC). In this qualitative study, we assessed the feasibility and acceptability of a primary care-based model that embeds a specially-trained primary care physician (PCP) within an oncology clinic. This embedded survivorship-specialized PCP would take over management of cancer surveillance and preventive care services for early-stage cancer survivors at the end of active cancer treatment. Our analyses were guided by an implementation science

framework, the Consolidated Framework for Implementation Science [CFIR]) [26]. All study activities were approved by the KPSC Institutional Review Board.

Methods

Participants and recruitment

We identified clinical, operational, and patient stakeholders and conducted in-person semi-structured qualitative interviews, relying on a purposeful snowball sampling technique to identify key stakeholders [27]. Clinical and operational leadership targeted for interviews included decision-makers within the organization, as well as providers most likely to be directly affected by the adoption of the model (primary care, medical oncology, oncology care coordinators). We also identified patients treated with curative intent for breast, colorectal, or lung cancer within the past 5 years. Participation was voluntary, and informed consent was obtained from all individual participants included in the study.

Individual interviews lasted approximately 30–60 min and were conducted using a semi-structured interview guide. Interviews were audio-recorded to obtain a complete, verbatim transcript of the discussion, and all resultant transcripts were imported into qualitative analysis software (ATLAS.ti, version 7) to perform coding and analysis [28].

Interview guide

For clinical and operational stakeholders, the semi-structured interview guide contained questions within the following domains related to the proposed new model of care: (1) acceptability, (2) appropriateness, and (3) feasibility. For patients, the interview guide was structured to elicit participants' perspectives on several key topics, including (1) structure of current survivorship care, (2) post-treatment needs, (3) acceptability and appropriateness, and (4) suggestions for improving acceptability of the model.

Theoretical framework, coding, and analysis

Our analysis of the interview data was guided by CFIR, which is an integrated framework uniting overlapping implementation theories and constructs to provide a pragmatic research model. CFIR has been used in multiple implementation projects, [29] particularly to aid identification of potential barriers and facilitators. The framework can be adapted to a variety of different settings and/or organizational contexts, and it can inform both formative (e.g., developmental, implementation-focused, progress-focused, and interpretive) and summative (e.g., post-implementation) types of evaluation.

A total of 39 CFIR constructs fall into five domains, including (1) intervention characteristics, (2) inner setting, (3) outer setting, (4) individual characteristics, and (5) implementation processes [30]. Intervention characteristics focus on the attributes of the intervention and include constructs such as *evidence strength and quality* (perceptions of the quality and validity of evidence for the intervention), *adaptability* (extent to which stakeholders perceive the intervention can be tailored or refined to meet local needs), and *complexity* (views about how difficult it is to implement the intervention). Inner setting constructs focus on the internal organizational climate and include constructs such as *culture (*organizational norms and values) and *implementation climate* (organizational capacity to both change and support the intervention), whereas outer setting constructs focus on external pressures, including p*eer pressure* (competitive pressure from competing peers or organizations) and *external policies and incentives* (guidelines, mandates, and regulations). Individual characteristics include constructs such as *knowledge and beliefs* (individual attitudes toward the intervention) and *self-efficacy* (extent to which individuals believe they can execute their role in the intervention). Finally, the processes domain focuses on influential factors such as *planning* (identifying appropriate methods for implementation in advance of the rollout) and *engaging* (marketing the intervention to key stakeholders and decision-makers to successfully garner their involvement).

As defined by the framework, researchers can choose to use all 39 constructs to evaluate implementation or instead focus on a subset of relevant constructs. In addition, the framework can be used to guide data collection and analysis, or used only during the analysis phase of the research. We chose not to focus on any specific CFIR constructs prior to analysis, but rather relied on open-ended interviewing techniques to elicit the most salient stakeholder-identified themes related to implementation barriers and facilitators. During analysis, CFIR constructs were then used to organize and interpret stakeholders' perceptions as they relate to acceptability and feasibility, and determine the most critical pre-implementation factors likely to influence adoption of the model within the organizational setting.

A member of the study team trained in qualitative research methods led the coding and analysis of the interview transcripts, first creating a set of deductive codes generated from the central *a priori* research questions. Using a team coding approach, both the lead coder and a second qualitative researcher reviewed a subset of transcripts, applying these deductive coding categories. Emergent themes were also captured inductively via open coding of relevant themes, and hierarchical relationships between primary and secondary themes were identified. Both coders met repeatedly to review and compare application of the codes to the selected transcripts, as well as share analytical insights via memos linked to specific phrases and discuss and resolve any discrepancies in the coding process. All codes were documented in a codebook, which was iteratively refined. Once the coding and review of this initial subset of transcripts was complete, remaining transcripts were coded by the lead coder. Both coders selected a final transcript to team code, meeting again to ensure continuity in the application of the coding schema to all transcripts and finalize the thematic analysis.

Results

We completed a total of 12 interviews: 9 clinical and operational stakeholders participated (2 oncologists, 2 PCPs, 1 cancer care administrator, 2 dual role clinical and operational leaders, and 2 breast cancer care coordinators with nursing training) and cancer survivors (1 lung cancer survivor; 1 breast cancer survivor; 1 colon cancer survivor).

A diverse array of themes and sub-themes were identified from the interview data, and stakeholders' reactions and views of the model fell within several relevant CFIR constructs spanning four out of five of the framework domains, including (a) Relative advantage: stakeholders' perception of the advantage of implementing the intervention [*CFIR domain*: *intervention characteristics*], (b) Culture: norms and values of a given institution [*CFIR domain*: *inner setting*], (c) Implementation climate: shared receptivity of stakeholders to an intervention [*CFIR domain: inner setting*], (d) Tension for change: degree to which stakeholders view current practice as untenable [*CFIR domain: inner setting*], (e) Patient needs and resources: extent to which patients' needs are known and prioritized [*CFIR domain: characteristics of individuals*]; (f) Planning: degree to which method (s) are developed in advance for implementing an intervention [*CFIR domain: processes*], and (g) Engaging: involving appropriate individuals in the implementation and use of the intervention [*CFIR domain: processes*].

Relative advantages

Oncologists and leadership viewed the model as an acceptable solution to issues of capacity and efficiency with the potential to improve quality.

Addressing growing volume of cancer survivors Operational leaders and oncologists acknowledged that the growing number of cancer survivors creates challenges for survivorship care, including (1) patients utilizing oncologists or surgeons for services normally delivered by PCPs, (2) patients seeing both PCPs and oncologists at the same time (duplicating services), and, as a result, (3) potentially limited access to oncologists and surgeons for newly diagnosed patients. As one administrator noted, "… you start multiplying it out year after year … [the number of cancer survivors] will grow quite rapidly...[this model is] absolutely the right thing to do

because you are freeing up your general surgeons' time, your oncologists' time..."

Easing concerns about quality Oncologists and operational leaders were concerned that current practice impinges on the quality of survivorship care, since most PCPs are not appropriately trained in cancer and "...extremely busy these days...and really do not have the time or the expertise any longer to just know inherently what to do for a stage 2 colon cancer [survivor], what to do for a stage 3 colon cancer survivor." Embedding a PCP trained in the short- and long-term effects of cancer treatments, appropriate follow-up tests and procedures, and the psychosocial needs of cancer survivors was viewed as an effective model for mitigating such quality concerns, as well as promoting better interdepartmental integration between oncology and primary care departments:

> "… I think [with] 75% of cancer patients surviving, they deserve the same level of preventive care, except specialized to their needs. I believe by having this type of clinic we can deliver consistent, accurate, more efficient [care], less inappropriate testing … and satisfy the patient …"

Oncologists reported finding it increasingly difficult to focus on the necessary care outside of their patients' cancer-related needs. PCPs were described as more focused on the holistic needs of patients, and thereby better positioned to address both cancer surveillance and non-cancer care needs that are often present during long-term survivorship. An operational leader elaborated, "If you have a [PCP] who really can now add this knowledge of cancer care … it seems so neat to me that you're now going to tie in the whole person whether it's their hypertension, their diabetes or arthritis, the medications they're on...I think that actually does enhance the quality...[and] the service." Ultimately, stakeholders believed this model has the potential to effectively leverage the right survivorship care services and expertise, at the right time, by the right provider.

Culture

Organizational confidence that the Embedded PCP model is feasible and can be successfully implemented within the KPSC setting was high, and several system-level facilitators were identified.

Innovation is a cultural norm Stakeholders view the organization as having a long history of testing and adopting innovative models of care: "We are a constantly learning organization ... I have never found our organization to hold

back on what we need to do … We have numerous alternative models … that are going on [in our] region … so that is what is in our DNA and will carry us forward."

Multi-disciplinary team approach Other stakeholders highlighted the fact that the organization already focuses on a multi-disciplinary approach to care, combined with a robust electronic medical record (EMR) that enhances care coordination.

Integrated structure of cancer care delivery

> "We don't have a fee for service mentality, so nobody's giving up revenue."

Implementation climate

While oncologists and leadership generally viewed the Embedded PCP model as an acceptable and feasible solution to current practice challenges, some stakeholders were less receptive overall, identifying barriers and potential stakeholder resistance to successful implementation.

Oncologists may view the model as a takeaway For instance, several oncologists worried shifting survivorship care to PCP survivorship-specialists would function to take away their most desired patient—the population of cancer survivors who bring "joy to medicine." Another stakeholder pointed out that adding a higher proportion of patients seeking diagnosis and treatment to oncologists' panels would result in a smaller proportion of survivors, which "...could [contribute] to some burnout … seeing those survivorship types [is] easier. I mean they're not on active chemo treatment, they might be on a hormonal treatment, it's just an easier 20-minute visit than a complicated metastatic disease conversation."

Potential to overburden PCP-specialists In addition, PCPs warned about the potential burden on identified PCP survivorship-specialists if tasked with co-managing existing patient panels and new cancer survivors at the same time. An administrator stressed that successful adoption of this model requires that it "...cannot be an add-on to their existing [practice], which is the fear that I heard... because [PCPs are] already quite overwhelmed."

Potentially difficult to attract ideal candidates for the PCP survivorship-specialist position Stakeholders were unified in their concern that finding the ideal physician for the role may be very challenging, because it requires attracting a unique individual with "intrinsic motivation" to semi-specialize in cancer care. In addition, strong patient advocacy skills and resourcefulness, empathy, and a high

degree of comfort addressing patient anxiety and depression were also called out as necessary characteristics for any clinician adopting the role.

Tension for change

Despite identified challenges, stakeholders were generally optimistic about the potential for the model to improve upon current practice, which they conceded will become increasingly untenable as the population of cancer survivors continues to expand. A cancer care administrator echoed the sentiment of other stakeholders, urging the organization to take a proactive approach to meeting the challenges facing survivorship care in the current delivery system, and the model has the potential to improve quality "...[it can] enable us to set up a system behind it as a safety net for the survivor patients, so we don't miss things."

Patient needs and resources

Oncologists and operational leaders were most concerned about overcoming patient resistance to the model, and interviews with patients confirmed this perspective.

Cancer Survivors have high level of attachment to their oncologists In fact, patients were least enthusiastic overall about the model, fearing the loss of a trusted clinician and wary about the introduction of "[someone] who doesn't know me." Survivors said they look to their oncologist—a trusted "cheerleader"—to assuage their fears of recurrence:

> "But I think it's like a security blanket-type of a thing that your oncologist...you build a relationship with them because you see them so often...I saw him before each treatment and I saw him almost after each treatment. If I had a problem in between he'd come in the room and talk to me … If I need him again I want to make sure he's there for me. I don't want to see another oncologist if anything else comes up …" – Lung Cancer Survivor

Patients distrust the expertise of the PCP survivorship-specialist Patients questioned the degree to which the specialist under the new model would truly be a cancer expert on the same level as their current oncologist. In addition, patients were clear that they do not want the burden of being responsible for re-educating a new provider during this transition period and maintain the expectation that the specialist has "...knowledge on you specifically...your treatment...your history...it's more reassuring, more comfortable to walk in [and hear], 'Yeah, I've read your chart. How are you? I see what you've been through.'"

Recommendations

Stakeholders had numerous suggestions for avoiding implementation pitfalls and facilitating adoption of the model. These recommendations can be organized across two of the CFIR framework constructs—*planning* and *engaging*—both of which fall under the *processes* domain (Table 1).

Set the PCP survivorship-specialist up for success
Stakeholders made several observations about ways to increase the likelihood that the PCP survivorship-specialist can be successful in their new role. First, stakeholders were divided as to the ideal breadth of the PCP survivorship-specialist's responsibilities and whether they should address "...all primary care needs or [have a] stricter focus on survivorship care...", but widely agreed that this is a critical question for leadership to decide prior to rolling out the model. Stakeholders also underscored the importance of fully resourcing the new position (e.g., nursing support, adequate clinic space), which they noted is often overlooked when piloting new programs within the organization.

Promote Communication Stakeholders encouraged setting up pathways for strong communication between oncologists and the PCP survivorship-specialist. Furthermore, to address shared concerns that primary care providers in Internal Medicine and Family Medicine may simply refer all their cancer patients to the PCP survivorship-specialist under the proposed model, stakeholders suggested establishing a single-direction referral process initiated by oncologists. Noting that cancer survivors typically have "high-acuity" needs, one individual further elaborated on the importance of controlling and clearly communicating the direction of referrals:

> "I know the primary care doctors are really overloaded, everybody is … .everybody's so overloaded that any time you have a high acuity patient that needs a little more attention, it's great to have somebody to help."

Train the PCP survivorship-specialist To avoid, as one operational leader stated, simply embedding a "relocated PCP doctor" in the oncology clinic, stakeholders called for a training structure that: (1) assigns an oncology preceptor to the trainee, (2) provides opportunities for the trainee to spend sufficient time shadowing specialists in different clinics, and (3) develops a method for testing (and retesting) the PCP survivorship-specialist for competency.

Anticipate and ameliorate patient resistance Broad consensus existed that the key to making the model acceptable will require that oncologists introduce the PCP survivorship-

Table 1 Stakeholder recommendations for successful implementation of the embedded primary care physician (PCP) model, applicable constructs from the Consolidated Framework for Implementation Research (CFIR), and relevant stakeholder quotations

Stakeholder recommendations	CFIR construct	Stakeholder quote
Agree on the breadth of the PCP survivorship-specialist's role and responsibilities	Planning	"… [KP] leadership needs to understand the intricacy and challenge of survivorship … that we cannot ask this [specialist PCP] to handle the complex survivorship care and then expect them to do all of the typical primary care thresholds as well."
Fully resource the new PCP survivorship-specialist position	Planning	"You are going to have the challenge of this person cannot operate alone, but this physician needs an MA. It may need a nurse, or access to a nurse maybe or going to need an exam room or two, probably two exam rooms … yeah, the physical space limitations that we have. And the staffing limitations that we have because we operate on a very, very thin...I do not think you can expect to keep the staffing levels the same way they are."
Set clear referral guidelines from oncology	Planning	Well, I think that you set [referral] guidelines and...at least for us...[and] I am sure everywhere, you have some referral guidelines and so that's just a matter of communication, it's just having the expectations there.
Train specialist well, test and retest for competency	Planning	… I am in favor of setting a somewhat high-ish bar [for training] but that could be an implementation barrier and if it's too high, nobody will want to do this and if it's not high enough, I do not think it will be effective and [patients] might as well just see their regular primary care doctor in their clinic. At least my hypothesis would be just merely co-locating the doctor is not going to do all that much.
Promote communication (across all stakeholders—e.g., health care teams and patients)	Engaging	I take care of patients who have prostate cancer and after their treatment … they have issues with incontinence … And they do not know, they go and they get instructions from the urologist but then they do not see the urologist for several months, so then they go to their primary care doctor and maybe they get conflicting information or they are told, 'Well, go back to your urologist,' and they have just wasted a trip to primary care and I just think it would be more … efficient for everybody if they knew that, 'Okay, now your treatment is through, here's [who] you go to for these problems.'
Address and meet patients' resistance head on	Engaging	Yeah, how do you pitch it?...when you see a patient and you want to refer them to whatever doctor, if you say to that member, 'You are seeing a great doctor. I am going to refer you to [DR. X] because I think you are a survivor. I am so proud, together we have been on this journey, now going forward...[DR. X] has the expertise to take care of you. I am always here for you, but I think that it's okay to transition.' They feel that warm hand-off...that care and they also do not feel like it's a cleaving, it's all or none....so make it a positive … Do not make it a negative … And then how you frame it is key … From the members' standpoint, the earlier you do it, the better.

specialist to patients early on (e.g., during patients' cancer treatment) and effectively endorse the specialist's role by framing the transition (e.g., the "handoff") as an enhancement to care and services, rather than a loss of a trusted oncologist.

A high-level summary of barriers and facilitators is described in Table 2.

Discussion

Overall, acceptability and feasibility for the embedded PCP model of survivorship care was high among oncologists and operational leaders, while PCPs and patients were more lukewarm. Oncologists and operational leaders identified several positive aspects of this model, including the potential to decrease pressure on oncologist schedules (e.g., opening slots for newly diagnosed patients), as well as providing an avenue for high-quality survivorship care and promoting better interdepartmental integration between oncology and primary care departments. Clinicians and operational leaders acknowledge the challenges in finding the right PCPs for this role, and ensuring that adequate training and ongoing support (e.g., nursing staff, health IT infrastructure) are made available. Patients expressed the most ambivalence, with concerns including losing access to their trusted oncologists, having to

Table 2 Stakeholder-identified barriers/facilitators to the proposed embedded primary care physician (PCP) model of cancer survivorship care

Stakeholder perspectives (N = 12)	Oncologists	PCPs	Patients	Leadership
Perceived barriers				
Patient attachment to oncologists very high/ fear losing them	X	X	X	X
Challenge: where to find this unique PCP	X	X		X
Patients do not want to re-educate specialist to their cancer needs			X	
Confusion why it is necessary to start over with a new provider			X	
Regret losing their cancer survivors who bring "joy to medicine"	X			
Perceived Facilitators				
Prime patient for the change/frame discussion, "warm handoff"	X	X	X	X
Potential for improved access to oncologists	X	X		X
Existing expertise to be leveraged in training	X			X
KPSC has a culture of innovation				X

"start over" with—and potentially educate—a new clinician. To mitigate these concerns, a well-planned transition from the oncologist to the PCP survivorship specialist is key. Both organizational-level barriers, such as identifying and training appropriate candidates for the embedded PCP position, and patient-level barriers, such as perception of abandonment and reluctance to "teach" a new clinician, must be addressed for a successful implementation.

Use of an implementation framework, the CFIR, aided in the analysis and interpretation of our data. The CFIR provided a practical framework for understanding stakeholder concerns, describing barriers and facilitators to implementation, and identifying appropriate next steps to implementation. Multi-level (organization, clinician, patient) processes will need to be developed to successfully implement the embedded PCP model. This pre-implementation assessment of the intervention characteristics, implementation climate, available resources and tension for change allowed for a realistic assessment of feasibility, acceptability, and appropriateness of this model to be implemented in this setting.

Our results echo findings from other studies [18, 19, 31]. As found in recent work by Rubenstein et al. and Tonorezo et al., PCPs may lack system support to provide high-quality cancer survivorship care and may feel unprepared to offer comprehensive survivorship care. Additionally, as reported in Hudson et al., cancer survivors are concerned about PCPs assuming their cancer-related follow-up care due to lack of content expertise (e.g., knowledge of cancer treatments). Other studies have found that cancer survivors prefer for the treating oncologist to oversee survivorship care, versus transitioning to a PCP, nurse practitioner, or other clinician [32]. It is likely that PCP-led survivorship care would be comparable to oncologist-led survivorship care, based on findings from randomized trials of PCP vs. oncologist [33]; however, the perceived desirability of this model is low from the patient perspective [34].

This study, which identified multiple barriers and facilitators to the implementation of the embedded PCP model, also had several limitations, including use of convenience sampling (purposive snowball) and a small number of interviews. However, we sought to include diverse stakeholder viewpoints, including oncology clinicians, primary care, nursing/ care coordinators, patients, and operational/administrative roles. By nature, qualitative research is seeking insight and understanding of complex issues, rather than a representative sample. In addition, the integrated nature of the KPSC health care system may have different operational and clinical structures than other settings, such as academic cancer centers.

Operationalization of survivorship models may be improved with integration of implementation science methods, including pre-implementation assessment of feasibility and acceptability. It is critical that we continue to develop and test innovative approaches to care delivery for the growing number of cancer survivors, and to leverage appropriate tools and discoveries from other relevant fields.

Compliance with ethical standards

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

Conflict of interest The authors declare that they have no conflicts of interest.

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