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Factors influencing fidelity to guideline implementation strategies for improving pain care at cancer centres: a qualitative sub-study of the Stop Cancer PAIN Trial

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Abstract

Background The Stop Cancer PAIN Trial was a phase III pragmatic stepped wedge cluster randomised controlled trial which compared effectiveness of screening and guidelines with or without implementation strategies for improving pain in adults with cancer attending six Australian outpatient comprehensive cancer centres ($n=688$). A system for pain screening was introduced before observation of a 'control' phase. Implementation strategies introduced in the 'intervention' phase included: (1) audit of adherence to guideline recommendations, with feedback to clinical teams; (2) health professional education via an email-administered 'spaced education' module; and (3) a patient education booklet and self-management resource. Selection of strategies was informed by the Capability, Opportunity and Motivation Behaviour (COM-B) Model (Michie et al., 2011) and evidence for each strategy's stand-alone effectiveness. A consultant physician at each centre supported the intervention as a 'clinical champion'. However, fidelity to the intervention was limited, and the Trial did not demonstrate effectiveness. This paper reports a sub-study of the Trial which aimed to identify factors inhibiting or enabling fidelity to inform future guideline implementation initiatives.

Methods The qualitative sub-study enabled in-depth exploration of factors from the perspectives of personnel at each centre. Clinical champions, clinicians and clinic receptionists were invited to participate in semi-structured interviews. Analysis used a framework method and a largely deductive approach based on the COM-B Model.

Results Twenty-four people participated, including 15 physicians, 8 nurses and 1 clinic receptionist. Coding against the COM-B Model identified 'capability' to be the most influential component, with 'opportunity' and 'motivation' playing largely subsidiary roles. Findings suggest that fidelity could have been improved by: considering the readiness for change of each clinical setting; better articulating the intervention's value proposition; defining clinician roles and responsibilities, addressing perceptions that pain care falls beyond oncology clinicians' scopes of practice; integrating the intervention within existing systems and processes; promoting patient-clinician partnerships; investing in clinical champions among senior nursing and junior medical personnel, supported by medical leaders; and planning for slow incremental change rather than rapid uptake.

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Conclusions Future guideline implementation interventions may require a 'meta-implementation' approach based on complex systems theory to successfully integrate multiple strategies.

Trial registration Registry: Australian New Zealand Clinical Trials Registry; number: ACTRN 12615000064505; data: https://www.anzctr.org.au/Trial/Registration/TrialReview.aspxid=367236&isReview=true.

Keywords Cancer, Pain, Guidelines, Implementation, Qualitative

Background

Pain is a common and burdensome symptom in people with cancer [1]. Barriers to pain care occur at all 'levels', including the patient and family (e.g., misconceptions regarding opioids), clinician (e.g. lack of expertise), service (e.g. inadequate referral processes) and healthcare system (e.g. lack of coordination) [2–8]. A recent systematic review suggests that around 40% of cancer patients with pain may not receive adequate management [9]. Research has demonstrated that routine screening and implementation of evidence-based guidelines has potential to improve quality of cancer pain care and outcomes [10–14]. However, experience suggests that clinicians are unlikely to utilise screening results or follow guidelines unless these are supported by targeted strategies [15, 16].

The Stop Cancer PAIN Trial (ACTRN 12615000064505) was a phase III pragmatic stepped wedge cluster randomised controlled trial conducted between 2014 and 2019 which compared the effectiveness of screening and guidelines with or without implementation strategies for improving pain in adults with cancer attending six outpatient comprehensive cancer centres in Australia ($n=688$) [17, 18]. A pen/paper system to screen for pain using 0–10 numerical rating scales (NRS) for worst and average intensity over the past 24 h was introduced to each centre prior to observation of a 'control' phase, in which clinicians were also made aware of the Australian Cancer Pain Management in Adults guidelines [19]. At the beginning of the training phase, trial investigators presented at staff meetings on the importance of better managing pain and the rationale and evidence base for the intervention components. Implementation strategies (collectively termed the 'intervention') were then introduced in a 'training' phase and maintained during an 'intervention' phase as follows: (1) audit of adherence to key guideline recommendations [19] and feedback delivered to clinical teams in one or two cycles; (2) health professional education via a 'Qstream' email-administered 'spaced education' module [20]; and (3) a patient education booklet and self-management resource for completion together with a clinician that included goal setting, a pain diary and pain management plan [21, 22]. Selection of these strategies was informed by the Capability, Opportunity and Motivation Behaviour (COM-B) Model of behaviour change [23], and evidence that each strategy had been separately effective for supporting guideline implementation for other health conditions. The intervention was supported at each centre by a consultant physician who agreed to be a 'clinical champion' [24].

As reported previously [18], the Stop Cancer PAIN Trial found no significant differences between the intervention and the control phases on the trial's primary outcome - the proportion of patients with moderate-severe worst pain intensity who reported a 30% decrease at 1-week follow-up. Fidelity to the intervention was lower than anticipated and variable between centres: only 2/6 centres had two audit cycles rather than one; completion rates for the health professional spaced education varied from 12% to 74% between centres; and the proportion of patients reporting receipt of written information of any kind rose to an average of only 30% (20-44%) versus 22% (2-30%) in the control phase. Unexpectedly, secondary measures of mean, worst and average pain over a 4-week follow-up period improved by 0.5 standard deviation during control as well as intervention phases. However, the lack of a comparison group with no screening system made it difficult to conclude whether improvement in the control phase was due to effects from screening, a Hawthorne effect, or some other explanation.

The current paper reports a sub-study of the Stop Cancer PAIN Trial which aimed to identify factors influencing fidelity to the intervention that might warrant consideration by similar initiatives in the future.

Methods

Design

The intervention, methods and results of the Stop Cancer PAIN trial have been described in previous open-access articles [17, 18]. The sub-study used a qualitative approach with pragmatic orientation to enable in-depth exploration of factors influencing success from the perspectives of clinicians at each participating centre [25]. Clinician views canvassed at interview were considered the most efficient means of identifying barriers and enablers among complex contextual factors at each centre, including personnel's knowledge, attitudes and beliefs towards pain care and the intervention.

The sub-study was approved by the Southwestern Sydney Local Health District Human Research Ethics Committee (HREC/14/LPOOL/479) as part of the overall

trial. All participants gave written informed consent to participate.

Reporting adheres to the consolidated criteria for reporting qualitative research (COREQ) [26].

Participants

Participants were eligible if they were employed on a permanent basis either full- or part-time at a participating centre in a role that provided clinical care to cancer patients or patient-focused administrative support. The clinical champion at each centre was invited to participate by the research team. Other personnel were invited by means of email circulars and verbal invitations during meetings. Given the diverse range of roles at each centre, no limit was set on sample size to canvass as many perspectives as possible.

Data collection

Data were collected by means of semi-structured interviews conducted by one of two researchers, a female pharmacist with experience of medical education for pain management (LR), and a male social scientist with a doctorate (TL). Both interviewers had prior experience in qualitative research and knew some participants through their project roles.

Participants were fully aware of the study purpose before consenting. Interviews were conducted face-to-face or by telephone, with the participant and interviewer being the only people present. Interviews began with open questions about 'what worked' and 'didn't work' across the intervention before focusing on each implementation strategy in more detail and important contextual factors at their centre (see Table 1 for a topic guide, which was developed specifically for this study). Interviewers explicitly invited criticism, expressing a tone of open enquiry and neutrality throughout. Prompts were used as necessary to explore factors identified by participants in more detail. Factors identified at previous interviews were raised at subsequent ones for verification, inviting participants to disagree or agree as they felt appropriate. No requests were received to return transcripts to participants for comment. Interviews were audio-recorded and transcribed verbatim.

Table 1 Interview topic guide

1. Since this project started, what (if anything) has changed at your centre with regard to the screening, assessment, management of cancer pain?
2. What (if anything) has worked well about the strategies introduced to help your centre better screen, assess and manage cancer pain?
3. What (if anything) has not worked well?
4. How could the strategies have been improved?
5. What (if any) other strategies might help?
6. Have the strategies influenced how you work as a team?
7. Have there been any influences on other aspects of patient care?
8. Is there anything else you would like to add that I haven't asked about?

Analysis

Analysis used the framework method [27] and a largely deductive approach based on the same theoretical framework used during intervention design - the COM-B Model [23]. Based on a systematic review, the COM-B Model posits that behaviour change requires three conditions, namely 'capability' (including both psychological and physical capacity), 'opportunity' (all the factors that lie outside the individual that make the behaviour possible or prompt it) and 'motivation' (including habitual processes, emotional responding, as well as analytical decision-making). Initial line-by-line coding categorized data against these conditions according to which best described relationships between factors and behaviours within and across implementation strategies and the levels of patient, clinician and centre. While the COM-B model originally focused directly on human behaviour, it became clear during coding that behaviour was substantially influenced by centre, specialty and disciplinary factors, so these were also considered appropriate foci for coding against COM conditions. To enhance credibility, the same data were coded in different ways where multiple interpretations seemed plausible until coding of further interviews identified consistencies to help with disambiguation. Charting of codes for data within and between centres enabled mapping between the relative contributions made by each condition, summarised as lessons learned for guiding similar initiatives in the future. Dependability was increased by ensuring coding was conducted by two members of the research team (NR, MG) who had no previous involvement in the project but were experienced in qualitative research. Review and discussion with two team members who were involved in the project throughout (TL and ML) was intended to balance 'outsider' and 'insider' perspectives to guard against bias from preconceived interpretations whilst also referencing contextual understanding. Both Excel 2019 (Microsoft) and NVivo V12 (QSR) software were used to help manage different stages of the analytic process.

Results

Twenty-four people participated across the six centres, ranging from one to six participants. Fifteen were physicians (of whom six were clinical champions), eight were nurses, and one was a clinic receptionist. This response rate ranged from 2 to 27% of eligible personnel at each centre. See Table 2 for a more detailed summary

Table 2 Numbers of personnel in various roles at each of six cancer centres participating in interviews ($N=24$)

Centre number	Medical			Nursing[c]			Receptionist	Total
	PM	MO	RO	NP	CNC	RN		
C1	1[a]							1
C2	1[a]	1			1		1	4
C3	2[a]	2			1	1		6
C4		2[a]		1				3
C5	1	1[a]	1	1	1	1		6
C6[b]	3[a]				1			4
Total	8	6	1	2	4	2	1	

PM Palliative medicine physician, *MO* Medical oncologist, *RO* Radiation oncologist, *NP* Nurse practitioner, *CNC* Clinical nurse consultant, *RN* Registered nurse

[a] Includes the centre's clinical champion

[b] Only the palliative care department from this centre participated

[c] Nursing personnel at all the centres except C6 specialised in oncology

of participant roles at each centre. Interviews were a median of 20 min long, with an inter-quartile range of 13 to 28 min.

Capability, opportunity and motivation

Coding against the COM-B Model identified 'capability' to be the component having most influence over intervention success, with 'opportunity' and 'motivation' playing largely subsidiary roles.

Capabilities: Pertinent capabilities were reported to include: a pre-existing, centre-level culture of continuous improvement, communication pathways between senior management and other personnel, established roles and responsibilities for pain care among disciplines and specialties, systems and processes that could readily accommodate the intervention, and a culture of involving patients as partners in care. These capabilities influenced the degree to which personnel and patients had the opportunity and motivation to fully engage with the intervention.

Opportunity and motivation: These elements were most frequently discussed by participants in terms of 'time' that personnel could commit to pain care relative to other responsibilities. Clinical champions were perceived to play a critical role in supporting intervention success but were under-resourced at every centre and challenged by turnover in the role at two. In addition to more systemic drivers, individual personnel's motivation was influenced by the degree to which they accepted the intervention's value proposition at the outset and perceived this to be demonstrated over time.

Interactions between capability, opportunity and motivation are explored below in terms of their implications for similar future initiatives. Findings suggest that fidelity could have been improved by: considering the readiness for change of each clinical setting; better articulating the intervention's value proposition; defining clinician roles and responsibilities, addressing perceptions that pain care falls beyond oncology clinicians' scopes of practice; integrating the intervention within existing systems and processes; promoting patient-clinician partnerships; investing in clinical champions among senior nursing and junior medical personnel, supported by medical leaders; and planning for slow incremental change rather than rapid uptake.

Consider centres' readiness for change

The degree to which centres had a pre-existing culture of continuous improvement was considered important in providing a fertile context for the intervention. At Centre 5, there was a consensus that change of any kind was difficult to instigate, even according to the head of department: "*…because it's new - because we're so entrenched in our ways*" (C5P04 [Centre 5, participant 04] medical oncologist, head of department and clinical champion). At another, the complex centre-level nature of the intervention was perceived to pose particular challenges compared to oncology drug trials with which they were more familiar: "*we haven't been a principal site [in a trial of this kind] previously and I think that's sort of opened up some gaps in knowledge for us and some opportunities for learning in the future … what kind of support we'd need to come with that trial to help it be a success in this culture*" (C3P02 palliative care physician and clinical champion).

Articulate and deliver on the intervention's value proposition

Interviews highlighted the importance of articulating the intervention's value proposition to every member of the workforce and maintaining engagement by demonstrating benefits over time. At Centre 5, some participants perceived that the intervention had been imposed by

management rather than generated from clinical priorities: *"…senior staff say [to researchers] 'come to our clinics, but we expect everyone else to do the work'"* (C5P05 radiation oncologist). This was compounded by a perceived lack of communication about the project, which limited personnels' opportunity to take a more active role even when they were motivated to do so: "*I would have facilitated [the intervention] … but I didn't know about it*" (C5P01 nurse practitioner). Eliciting and maintaining engagement was said to be additionally challenged at this centre by high staff turnover, especially among junior medical officers on rotation: "*it was very accepted by the junior medical staff [but] I think, unfortunately, when there's a relatively high turnover of staff …*" (C5P07 radiation oncology trainee). At two other centres, turnover among personnel required a transition in the role of clinical champion, interrupting support for the intervention while the new incumbents familiarised themselves with the role.

Across centres, participants reported reservations among some of their colleagues regarding the project's fundamental premises, including the assumption that pain care needed improving at their centre ("*they actually felt this trial was a little bit insulting for their clinical skills. There was a bit of eye rolling and 'of course we do that already!'*" (C3P02 palliative care physician and clinical champion)) or that pain warranted a specific focus rather than symptoms more generally: "*I find it more useful when more than one symptom is targeted*" (C5P06 palliative care physician).

More specific criticism was also levelled at each of the intervention strategies as follows.

Pain screening

In the case of screening, two participants questioned the validity of a 0–10 numerical rating scale (NRS) for different reasons: "*sometimes getting the numbers breaks the flow of the narrative" (C6P04 medical oncologist); "they [patients] would say, 'no, I'm not in pain but I have a lot of discomfort when I swallow' - it was in the wording*" C5P02 registered nurse). Even one of the clinical champions felt that screening was redundant where pain was very severe: "*if someone is clearly in a pain crisis, you don't need to be asking … you kind of know what number - they might tell you it's 15 [out of 10]*" (C6P02 palliative care physician and clinical champion). Perceptions of the value of screening were also influenced by the degree to which it led to demonstrable improvements in pain care, which was undermined by problems with establishing an efficient process at some centres: "*I think I've still probably got stray [pain screening] forms on my desk*" (C3P06 palliative care physician). A lack of understanding among personnel and patients about how screening might lead to better pain outcomes was said to result in "*fatigue*" (C5P03 clinical nurse consultant [clinical nurse consultant]; C1P01 palliative care physician and clinical champion), manifest as a downward spiral of effort in, and value from, screening.

Audit and feedback

The audit and feedback strategy attracted limited attention from personnel at most centres: "*I don't think that the audit and feedback were terribly noticeable*" (C4P01 medical oncologist and clinical champion). At the centre where only the palliative care department participated, one participant perceived baseline audit results to be acceptable and therefore demotivating for change: "[*the audit results showed] we were doing a good job even ahead of time … it did sort of make you think – 'well where do we go from here?'*" (C6P04 pain medicine physician). At another centre, motivation among personnel to improve on less favourable audit findings was perceived to depend on whether they prioritised pain care to start with: "*people have come up to me and said, 'Gee, we really did very badly didn't we?' … but they're not necessarily the people who don't treat pain well - that's the problem*" (C1P01 palliative care physician and clinical champion).

Spaced education for health professionals

Participants' opinion on the value of the online spaced education depended on discipline and seniority, with nurses and junior medical officers reporting benefits "(*it gave me a bit more confidence that I was on the right track"* (C5P01 nurse practitioner)) but consultant physicians perceiving the knowledge level too *"basic"* (C6P04 pain medicine physician) or questioning advice from online spaced education that their responses were 'wrong': *"…some of the multiple answers could have been equally valid"* (C504 medical oncologist and clinical champion). Where consultants remained engaged, motivation was said to rely on cultivating "*competition"* between colleagues (C602 palliative care physician and clinical champion). Inevitably, the voluntary nature of online spaced education also meant that only motivated personnel engaged to begin with.

Patient self-management resource

All participants who had used the patient self-management resource perceived at least some value. However, its use was limited by barriers relating to role and process considered below.

Define roles and responsibilities

Among the most commonly voiced barriers was a lack of clarity about which specialties and disciplines should be responsible for pain screening, patient education

and management. This was usually described in terms of a 'lack of time' for pain care relative to other duties afforded greater priority within their scope of practice. Perspectives on roles and responsibilities are considered separately for each aspect of pain care as follows.

Pain screening

While most centres allocated the clinical task of pain screening to clinic receptionists, there was widespread reflection that this had been suboptimal. The only participating clinic receptionist felt that pain screening fell outside her area of responsibility: *"but I'm an administrative person - I don't have anything to do with pain management*" (C2P03 clinic receptionist). Clinician participants across disciplines similarly perceived that pain screening required clinical expertise to assist patients with reporting their pain and triage for urgent follow-up: "*you need somebody talking to the patients, rather than just handing the form, say 'fill this in'*" (C2P04 clinical nurse consultant). One centre that recognised this early on reallocated screening from an administrative to a nursing role, leading to substantial improvements in the completeness and quality of data: "*it made a big difference and certainly improved our ability to recognise people who had pain and allowed access for those people who were in severe pain to medications or at least an assessment … implementation through the clerical staff was not a long-term strategy*" (C1P01 palliative care physician and clinical champion).

Patient education

There was little consensus on which disciplines should be responsible for supporting patients to use the self-management resource, with medical personnel deferring to nurses and vice-versa. Role allocation was challenged by the diverse components within the resource, with each perceived to fall within a different scope of practice: "*pain is something I always do as an assessment … [but] … I'm not managing the pain … I'll review and make recommendations and talk about the pain diaries and discussing their diary with their palliative care doctor or their general practitioner. And I would encourage that process. [But] I wouldn't be the one that's setting the goals on their daily activities and stuff*" (C5P01 nurse practitioner). Some oncology nursing roles were perceived to focus on chemo- or radiotherapy protocols to the exclusion of supportive care unless symptoms arose from, or impeded, treatment. Meanwhile, oncologists tended to interpret their role as solely focused on prescribing rather than also encompassing patient education: "*junior doctors only [have] 15 minutes to take a history and everything. [They] could enter in meds [into the patient resource] if everything else is done by someone else … part of me knows it's [patient resource] important, but the other part of me - I just - when will I have time in my clinical practice to do it?*" (C5P05 radiation oncologist).

Pain management

Some oncologists viewed even pharmacological pain management as peripheral to their scope of practice when consultation time was short, prioritising cancer treatment instead. These participants viewed their role as limited to referring to palliative medicine or pain specialists, especially where pain was believed to have causes other than cancer: "*if the pain is a complex pain where the patient doesn't have evidence of cancer, and it may be treatment-related, then in those scenarios we tend to divert to the chronic pain team*" (C5P07 radiation oncology advanced trainee). While participants from palliative care and pain medicine welcomed referrals for complex cases, they felt that oncologists sometimes referred for pain they could have easily managed themselves: "*what about some regular paracetamol? … These are things that you'd expect any junior doctors, never mind consultants [to have provided advice on]*" (C5P06 palliative care physician).

Integrate within existing systems and processes

Participants from several centres expressed a view that the intervention's complex nature had proven overwhelming for systems and processes at their centres. At two centres, integration was especially challenged by broader infrastructure shifts and process failures that limited receptiveness to further changes. Participants at several centres emphasised the process-driven nature of oncology services and the challenge of changing established processes: "*they have got a pro forma that they use for chemo-immunotherapy review, and pain is not part of it, and that perhaps needs more of an organisational nuance … why doesn't pain feature as a clinical outcome as part of the chemotherapy, immunotherapy review?*" (C6P01 clinical nurse consultant). Participants emphasised the need to integrate pain care into existing processes to help personnel understand what was expected of them: *"…nursing staff were getting them [screening forms] in the patient's files and going, 'what am I supposed to do with this?'*" (C2P04 clinical nurse consultant). Moreover, centres' focus on cancer treatment meant that pain care struggled to gain traction even when a process could be instituted: "*unless pain is the presenting complaint and is at the forefront it goes into those, sorts of, you know, the 'other details'*" (C5P06 palliative care physician). For the palliative care centre, where pain care was already prioritised, there were doubts about how the proposed process improved on those already in place: "*I generally ask pretty detailed questions about pain anyway [so don't*

need patients to be screened in the waiting room]" (C6P04 pain medicine physician).

Suggestions for better integrating the intervention included *"in-building"* (C3P04 medical oncologist) responsibility for the strategies within new staff roles or introducing the strategies gradually by means of a "*multi-step process"* (C5P04 medical oncologist, head of department and clinical champion). Features of two strategies were singled out as having positive potential for supporting existing processes of care. The patient resource was said to "*facilitate communication between the oncology teams and the palliative care team*" (C5P05 radiation oncologist) and serve as a "*visual cue*" (C3P02 medical oncologist) to cover educational topics that "*they might have otherwise forgotten*" (C2P01 palliative care physician and clinical champion). Participants also found the spaced education email administration, spacing and repetition "*easy to manage*" (C2P01 palliative care physician and clinical champion) within their daily routines.

Promote patient-clinician partnership on pain care

Several participants expressed surprise at the prevalence of moderate-severe pain in screening results, and acknowledged that this revealed under-reporting of pain in usual care. Under-reporting was perceived to stem partly from patient expectations that pain from cancer was "*normal*" (C4P03 nurse practitioner) and to be especially common in the context of certain generational or cultural attitudes towards pain and opioids ("*I certainly think there's a cultural element but there's also your elderly patients who you know have been through the war and they're just used to coping with things and you just suck it up … it's like a badge of honour to be able to say 'I'm not one of these pill-takers'*" (C3P03 registered nurse [RN])) or when patients were concerned that reporting pain might reduce their fitness for anti-cancer treatment: "[*patients might think that] if I tell them honestly how crappy I am with other symptoms and pain and everything, then they might stop my chemo"* (C3P02 palliative care physician). Several participants perceived that under-reporting was also due to patients taking an overly passive role in consultations: *"[clinicians assume that] if the patient doesn't bring it up, it's not a problem for them and … then the patient [is] thinking 'the doctor will only talk about important things that are important for me and I won't mention it because obviously it's not important'"* (C3P02 palliative care physician and clinical champion).

The screening component of the intervention was considered to address under-reporting by "*normal[ising]*" pain care, thus encouraging disclosure. The patient resource was also considered helpful for building patient capability to partner with clinicians on pain management by "*encouraging self-efficacy*" (C2P01 palliative care physician and clinical champion) through the tools it provided and its positive message that "*you can get control of your pain*" (C3P02 palliative care physician and clinical champion). It was also perceived to help patients "*keep a record*" (C5P03 clinical nurse consultant) of breakthrough pain and analgesia to discuss in their consultation. However, some participants delineated patient groups who might be less able to use the resource, including those with lower educational levels who struggled to set goals and identify an 'acceptable' level of pain balanced against side-effects from pharmacological management. For these patients, it was suggested that too many resources could be overwhelming rather than supportive: "*it's almost like, the more resources they have, the less resourced there are*" (C5P06 RN). At one centre with an especially diverse demographic, patients were said to require substantial support even to understand the purpose and process of pain screening: "*most [patients] look at you going 'oh, do I have to do anything?' … They don't want to read the [instruction] page which is relatively simple*" (C2P03 clinic receptionist).

Invest in clinical champions

All participants perceived the role of clinical champion to be pivotal to the intervention's success. Champions were perceived to have two major responsibilities: advocating for the intervention among colleagues to boost motivation and providing practical support to build capability.

To be effective advocates, champions were perceived to need support from senior management (*"[leadership of change] it's got to happen from the top*" (C5P02 RN)) as well as established, cordial relationships with colleagues they could leverage to motivate engagement: "*it also relies on the champion's personal relationship with the staff which you're asking to perform these roles and trying to change their management*" (C1P01 palliative care physician and clinical champion). Where champions felt under-supported by management, they relied on moral support from the project team to sustain their advocacy work: "*being the champion, and sometimes being the nagging champion, it actually felt quite nice to have the back-up of other people*" (C1P01 palliative care physician and clinical champion). Both physicians and nurses perceived the champion role might better suit the scope of practice of a junior doctor or senior nurse rather than consultants, based on their willingness to engage and approachability: "*realistically, you're probably always going to get more engagement with registrars compared to consultants, unless it's their own trial*" (C5P07 radiation oncologist); "*just give it [the role] to the CNCs [clinical nurse consultants] because as a general rule they're the*

best at everything and have the best relationships with the patient" (C3P04 medical oncologist).

From a practical perspective, clinical champions were expected to provide human resources for establishing and supporting pain screening and patient education: "*you need a body*" (C2P04 clinical nurse consultant). Unfortunately, however, champions across centres reported having limited time protected for the role within their usual duties: "*there just wasn't the manpower to do that here*" (C3P02 palliative care physician and clinical champion). One suggestion for boosting capacity was to narrow the focus to one clinic and delegate practical tasks to less senior delegates than required for advocacy to render the time commitment more cost-effective: "[*it] might have been better to focus on one clinic and have full-time … junior nurse*" (C5P05 radiation oncologist). This presented an opportunity to train more than one clinical champion to provide better coverage across shifts and safeguard against the risk of losing champions to staff turnover.

Increasing pain awareness is the first step: Plan for slow incremental change rather than rapid uptake

While the barriers above meant only modest practice changes could be achieved, champions at half the centres perceived incremental progress had been made through increasing awareness among personnel regarding pain care as a focus for improvement: "*I think just trying to make pain something that people think about was probably one of the better strategies*" (C1P01 palliative care physician and clinical champion); *it's more at the top of our minds to remember, to screen the pain at every visit*" (C2P01 palliative care physician and clinical champion); "*I think it has highlighted those issues for us and we now need to take this on*" (C5P04 medical oncologist, head of department and clinical champion). Both nursing and medical participants at Centre 5 emphasized the need to be persistent in striving for continuous improvement: "*I think to get practice change, even for well-motivated people, I think it just needs to be pushed … they've done similar things with hand washing for doctors and it's finally getting through*" (C504 medical oncologist and clinical champion); "*it would take more than just one of these kind of programs to get people to change*" (C5P03 clinical nurse consultant). Encouragingly, participants at this and one other centre expected some clinicians to continue using the patient education booklet and resource after the project ended: "*I'd just love to continue using these booklets*" (C5P02 RN); *"[the] patient-held resource has been useful and has been taken up by people and I think they will continue to use those*" (C6P02 palliative care physician and clinical champion).

Discussion

This qualitative sub-study of a cluster randomized controlled trial identified centre-level capabilities to be the most influential factors impeding or facilitating guideline implementation strategies for improving pain care for outpatients with cancer. Findings suggest that future initiatives of this kind should: consider centre readiness for change; articulate and deliver on the intervention's value proposition; define clinician roles and responsibilities; integrate the intervention within existing systems and processes; promote patient partnership; invest in the clinical champion role, drawing from senior nurses and junior doctors, with support from medical leaders and management; and design the initiative around slow incremental change rather than rapid uptake.

Our findings are largely consistent with those from an ethnographic study exploring factors influencing implementation of cancer pain guidelines in Korean hospital cancer units, which identified a 'lack of receptivity for change' to be a key barrier [28]. However, observations from the Korean study suggested that a lack of centre leadership and cultural norms regarding nursing hierarchy were the most important underlying factors, whereas our Australian sample focused more on constraints imposed by centre systems and processes and a lack of clarity regarding disciplinary roles. These factors were consistently emphasized regardless of participants' discipline and seniority, including by one centre's head of department. Consistent with these findings, a recent Australian qualitative sub-study of anxiety/depression guideline implementation in oncology centres found greater role flexibility to be a key factor underpinning organisational readiness for change [29]. This team also provided quantitative evidence consistent with our finding that centres' readiness for change is associated with personnel's perception of benefit from guideline implementation [30]. Future initiatives should work harder to persuade clinicians of the intervention's rationale and evidence base prior to commencement, given that perceptions of coherence and effectiveness are key dimensions of acceptability required for clinicians to invest time and effort [31]. Since our Trial was conducted, evidence has emerged for an impact from cancer symptom screening on survival that could be used persuasively [32]. Furthermore, the spaced education module might be more acceptable if made adjustable to the knowledge levels of a broader range of clinicians.

Other studies on implementation of cancer pain guidelines [11, 13] suggest that structured approaches to process change tend to be more successful than less prescriptive approaches of the kind taken in the Stop Cancer PAIN Trial. We provided centres with guideline implementation strategies but no clear guidance on how

to integrate these within existing contexts - i.e. implementation of the implementation, or 'meta-implementation'. It was wrongly assumed that clinical champions could support integration with centre processes based on their knowledge of local context, but this turned out to be unreasonable given champions' limited time for the role and lack of training in change management. Like most research to date [33, 34], our trial focused largely on the advocacy role played by clinical champions, neglecting more practical and time consuming aspects that our interviews identified to be just as important. We join others in calling for more research on the mechanisms by which clinical champions can optimally facilitate change and ways to maximize their efficacy through training and support [24]. This should include exploration of optimal models by which different aspects of the champion role might be shared between more than one person where no-one is available with all the necessary attributes, as well as ways to ensure sustainability after support from the project team is withdrawn.

Theory-based research suggests that adding complex interventions to complex healthcare systems creates dynamic interplay and feedback loops, making consequences hard to predict [35]. In the current trial, this was likely exacerbated by our attempt to combine multiple strategies targeting patient, clinician and centre levels. We chose each strategy based on evidence for its standalone efficacy, and combined strategies rather than used them singly with the intent of leveraging complementary mechanisms, as recommended by the COM-B Model and US Institute of Medicine [36]. However, findings from our interviews suggest that interactions between the strategies and local processes separated their spheres of influence, precluding intended synergies. The Stop Cancer PAIN Trial is not alone in having over-estimated the value of combining guideline implementation strategies; a recent systematic review found that 8 other multi-component interventions similarly demonstrated limited effects on guideline adherence and patient outcomes [37]. Collectively, these findings suggest that future attempts at combining strategies should consider complex systems theory as well as behaviour change frameworks at each of a number of stages [38]. Alternatively, a more manageable approach for most cancer centres might be to focus on just one component at a time, periodically reviewing progress against SMART goals and, depending on results, supplementing with additional components using plan-do-study cycles [39].

Given the challenges with integrating screening into centre processes, it seems unlikely that improvements in pain scores during the control phase reported in our primary results article were due to the spontaneous use of screening data in consultations [18]. Indeed, while routine use of patient-reported outcome measures (PROMs) in oncology has been researched for more than a quarter-century [40], benefits to patient outcomes have only recently been demonstrated in the context of electronically-administered PROMs (ePROMs) that enable remote self-reporting, real-time feedback to clinicians, and clinician-patient telecommunication [12]. Further research is needed on how best to support clinician engagement with ePROMs, including training on how to use results in partnership with patients to assist shared decision-making and self-management [41].

A worrying finding from the current study was that some or all aspects of pain care were perceived to fall between the scopes of practice for oncology clinicians from each discipline. Clinical practice guidelines emphasize the need for pain care to be inter-disciplinary in recognition of the need for comprehensive assessment, non-pharmacological as well as pharmacological management, and patient education and support for self-management [42]. While the patient self-management resource included in the intervention was perceived to support communication between clinicians and patients, its potential for assisting coordination of care between disciplines was limited where roles and responsibilities were not previously established. Our findings and other research suggest that future initiatives may benefit from 'process mapping' with clinicians to identify where clinical workflow and roles might be reconfigured to incorporate the various aspects of pain care in the most efficient ways that do not substantially add to workload [41].

Patient education has been proven to improve pain outcomes by clinical trials [43, 44], and we have argued previously that supporting pain self-management should be core business for all clinicians working in cancer care [45]. The 'coaching' approach needed to empower patients to recognize themselves as 'experts' on their pain and equal partners with clinicians in its management is iterative rather than a single event, and is ideally built on established and ongoing therapeutic relationships of trust with a particular team member. However, findings from patient education research more generally suggest that patient education and behaviour change is also optimally supported when key messages are reinforced by differing disciplinary perspectives [46]. Results from the current study suggest that these principles of pain care need more formal recognition within the scope of practice of oncology clinicians to ensure they are afforded sufficient time alongside anti-cancer treatment and related supportive care. Findings also indicate that clinicians may require training in the person-centred, partnership-oriented aspects of pain care beyond the educational approach used in the Stop Cancer PAIN Trial and other research [47]. Such training should be repeated regularly to ensure it reaches the majority of personnel at cancer centres, allowing for turnover.

Limitations

The current study had several limitations. Transferability even within Australia is limited by a focus on metropolitan services in only three out of eight jurisdictions. Data relied on clinician perspectives, and the response rate was less than one quarter of personnel at each centre, with the disciplines and specialties of participants being unrepresentative of centre workforces. Over-sampling of medical compared to nursing personnel likely reflects the fact that all clinical champions were medical consultants, while the predominance of palliative care physicians among medical participants presumably arises from the central focus this specialty has on pain care. Notably, our sample included no perspectives from allied health disciplines, despite the important roles these can play in non-pharmacological pain management. Confirmability was threatened by the potential for cognitive bias among researchers towards a favourable view of the intervention given their long-standing investment as members of the project team. We attempted to offset this by explicitly inviting criticism of the intervention from participants, and having the initial analysis conducted by researchers with no prior involvement in the project. A final limitation concerns reliance on the COM-B Model for analysis rather than an alternative framework or more inductive approach. While the COM-B has been widely used to explore barriers and facilitators across a wide range of healthcare interventions, we applied the model in a somewhat novel way to systems and processes as well as individuals' behaviour after finding that participants perceived their agency to be majorly constrained by these. An implementation framework such as the integrated-Promoting Action on Research Implementation in Health Service (i-PARIHS) framework (iPARIHS) [48] or Consolidated Framework for Implementation Research (CFIR) [49] would have conceived of factors and their relationships in alternative ways that might have proven equally informative [50].

Conclusion

This qualitative sub-study elucidated important factors influencing the success of guideline implementation strategies at six cancer centres in the Stop Cancer PAIN Trial. Findings underscore the value that a qualitative approach offers for understanding the role of context when evaluating complex interventions [51]. Ultimately, the Stop Cancer PAIN Trial may have been overly ambitious in the scale of its intervention, especially given limited resources available at each centre. Further research is needed to understand how multi-component guideline implementation strategies can be optimally introduced within the context of local roles, systems and processes.

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Authors' contributions

TL, JP, MA, PMD, TS, DCC, FB, LL, NM and ML contributed to the concept and design of this research. TL, LR, MR, MG and ML contributed to the acquisition, analysis or interpretation of the data. TL and ML contributed to drafting of the manuscript. All authors contributed to revisions of the manuscript and approved the final version.

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Availability of data and materials

The qualitative interview datasets generated and analysed during the current study are not publicly available due to the conditions of ethical approval which acknowledge the risk of participant re-identification.

Declarations

Ethics approval and consent to participate

This research was approved by the Southwestern Sydney Local Health District Human Research Ethics Committee (HREC/14/LPOOL/479). All participants gave written informed consent to participate.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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