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Improving Lynch syndrome detection: a mixed-methods process evaluation of a hybrid type III effectiveness-implementation trial

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Abstract

Introduction Translating evidence-based practices into real-world healthcare settings is challenging, particularly in the rapidly evolving field of genomics. A pragmatic two-arm cluster-randomized clinical trial (Hide and Seek Project – HaSP) tested two implementation approaches for improving hereditary cancer referral practices with one key distinction: implementation strategies that were designed 1) explicitly using psychological theory, or 2) using healthcare professional intuition. This mixed-methods process evaluation aimed to provide insights into *how* and *why* change occurred by examining contextual determinants, identifying mechanisms of action, and exploring the role of theory.

Methods Post-implementation interviews were conducted with Implementation Leads and clinicians from participating HaSP sites. Transcripts were analysed using a mixed inductive and deductive approach, guided by the updated Consolidated Framework for Implementation Research (2.0). Findings were triangulated with other HaSP process evaluation data sources, including HaSP focus group observations, HaSP research team focus groups, MDT observations, and Implementation Lead project logs. Logic models and case studies were developed to articulate causal processes underlying strategy effectiveness and conditions necessary for implementation success.

Results Eighteen participants from seven HaSP sites were interviewed. Qualitative analysis identified themes related to Lynch syndrome complexity, pandemic disruptions, operational challenges, information technology constraints, multidisciplinary collaboration, cultural determinants, attitudes towards change, the value of theory, adaptations, and implementation support. Within these themes, a total of 39 contextual determinants were identified, with barriers and facilitators spanning 18 CFIR constructs across five domains. Logic models and case studies highlighted a number of mechanisms of action, producing variable clinical outcomes. Process evaluation findings, interpreted together with HaSP trial outcomes, indicate that theory-based implementation strategies may better support Lynch syndrome detection practices compared to intuition-based strategies.

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Conclusions The information gained from this process evaluation deepens understanding of the factors influencing the success of hospital-specific implementation strategies within the HaSP framework. Potential pathways for optimising the effectiveness of the overall HaSP implementation approach have been identified.

Trial registration Australian New Zealand Clinical Trials Registry, ACTRN12618001072202. Registered 27 June 2018, https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=375348&isReview=true.

Keywords Implementation science, Pragmatic clinical trial, Theoretical domains framework, Behaviour change Techniques, Stakeholder intuition, Genetics, Genomics, Cancer, Lynch syndrome

Contributions to the literature

- This process evaluation shows how good implementation is determined by a complex interplay of multilevel factors in health systems.
- Our findings highlight the importance of tailoring implementation strategies to local context by navigating cultural dynamics, engaging stakeholders and addressing contextual barriers to change.
- Documenting both effective and ineffective strategies alongside their mechanisms and contextual determinants provides a roadmap to guide future implementation efforts within and beyond the context of Lynch syndrome.
- This study shows how important it is for clinicians to use pragmatic, tailored strategies that are informed by both theory and intuition to overcome implementation challenges.

Introduction

One of the greatest public health challenges lies in the ability to successfully translate evidence-based practices into real-world settings [1]. It takes an average of 17 years to translate new pieces of evidence into practice, and over half never reach widespread clinical use [2]. Establishing the effectiveness of a new clinical innovation does not guarantee routine uptake in the healthcare setting [3]. Even in the context of tightly controlled implementation trials, the exact same implementation strategy can produce variable outcomes across different settings [4]. However, the potential reasons for this variation are infrequently reported and poorly understood [5]. Understanding *how* and *why* change occurs (or does not occur) is crucial for maximising the public health impact of evidence-based practices and new clinical innovations.

The research-to-practice gap is particularly evident in the field of genomics, where the health system and its workforce are struggling to keep up with rapid advances in research and technology [6–8]. These challenges are evident in Lynch syndrome, an autosomal dominant hereditary cancer predisposition that increases risks of colorectal, gynaecological and other cancer types [9]. Diagnosing Lynch syndrome can have long-term health benefits both for the proband and their at-risk relatives. Identified carriers have access to risk management strategies (such as colonoscopic surveillance, risk-reducing surgery, and aspirin prophylaxis) proven to reduce cancer incidence and mortality [10–12]. Colonoscopic surveillance has been found to reduce the incidence of colorectal cancer among people with Lynch syndrome by 50% and decrease mortality by 65% [13]. Prophylactic surgery has been associated with a 100% prevention rate for endometrial and ovarian cancers among women with Lynch syndrome [11]. Aspirin prophylaxis has been found to reduce incidence of colorectal cancer in people with Lynch syndrome by 35% [14]. Tumour-based testing of Lynch syndrome associated cancers (through mismatch repair immunohistochemistry (MMR IHC) and/or microsatellite instability (MSI) testing) helps identify patients at risk of Lynch syndrome, who warrant specialist genetic testing to confirm the diagnosis. [15]. Despite established clinical and cost effectiveness [16], current evidence demonstrates uptake of the recommended Lynch syndrome tumour testing and referral pathway is suboptimal, signifying missed opportunities for cancer prevention and early detection in Australia and internationally [17–19]. Tackling this issue is particularly challenging due to the complex nature of the Lynch syndrome diagnostic pathway, compounded by a multitude of barriers across patient, clinician, and systems levels [20, 21].

Implementation strategies are targeted approaches designed to facilitate the adoption of evidence-based practices by modifying clinical practice behaviours [22]. These strategies need to be theory-informed, to systematically address the complexity of behaviours in health systems. [22, 23]. Behaviour change techniques (BCTs) are the 'active components' of an implementation strategy hypothesised to change behaviour, whilst mechanisms of action refer to the processes through which BCTs produce their effects [24]. The BCT Taxonomy consolidates a large number of published strategy components designed to alter causal processes influencing behaviour [24]. Theoretically underpinned implementation frameworks can optimise and contextualise the design of behaviour change strategies, whilst increasing opportunities to understand generalizability to other settings [25]. For example, the Theoretical Domains Framework (TDF)

can be used to identify behaviour change determinants which then inform the design of strategies that employ BCTs with known mechanistic links, potentially enhancing strategy effectiveness [26].

While using theory in strategy design enhances learning, there is limited evidence on its effectiveness compared to pragmatic, intuitive approaches based on clinicians' experiential knowledge. The Hide and Seek Project (HaSP) was a cluster randomised controlled trial (RCT), using a hybrid type III effectiveness-implementation design [27]. The aim was to test the effectiveness of a structured implementation approach to improve detection of Lynch syndrome across seven large Australian hospital networks [28]. The HaSP trial compared two different methods for barrier identification and strategy design – one explicitly informed by psychological theory (using BCTs to address TDF barrier domains; 'theory-based' trial arm) and one informed by healthcare professional intuition and tacit knowledge without the explicit use of theory ('intuition-based' trial arm).

Beyond evaluating the comparative clinical effectiveness of the two approaches tested within the HaSP trial, there is a further need to understand the factors influencing successful implementation. Process evaluations are exploratory studies that complement outcome evaluations by understanding the functioning of a strategy in practice, via assessment of strategy outcomes (e.g., the quality and quantity of what is delivered) and contextual determinants (e.g., external factors affecting strategy delivery and function) [29]. Theory-grounded process evaluations can assess whether a strategy alters theoretical constructs proposed to mediate change, enabling testing of causal assumptions [30]. Such information is crucial in guiding decisions among researchers, practitioners and policymakers about the transferability of implementation strategies from one context to another [29].

By conducting a formal, theory-driven process evaluation alongside the HaSP trial, the aim of this study was to gain an in-depth understanding of the factors influencing the effectiveness of hospital-specific strategies developed, and the overarching implementation approaches being tested in the HaSP trial. To achieve this, the objectives were to:

1) Explore the role of explicit theory application for identifying barriers and designing targeted implementation strategies;
2) Identify contextual determinants (barriers and facilitators) influencing implementation success; and
3) Demonstrate the mechanisms of action through which hospital-specific strategies produced their effects.

Methods

Setting – Hide and Seek Project (HaSP) implementation trial

This process evaluation study was conducted alongside the Hide and Seek Project (HaSP) – an implementation trial aimed at improving Lynch syndrome tumour testing and referral practices in Australian hospitals. Detailed HaSP trial procedures have been previously documented [28, 31]. Briefly, HaSP was a cluster RCT testing two structured implementation approaches, differentiated only by the explicit use of theory, for improving Lynch syndrome related molecular tumour testing and risk-appropriate referral practices for colorectal cancer (CRC) patients in seven large Australian hospital networks (clustered by state). Each hospital network was randomly assigned to either the intuition-based (n=3; Hospitals 3, 4, 5) or theory-based (n=4; Hospitals 1, 2, 6, 7) implementation approach.

At each hospital network, a locally employed healthcare professional (e.g., nurse, genetic counsellor) was appointed and trained as an 'Implementation Lead' to coordinate the implementation approach [32]. Implementation Leads oversaw the following phases over a 2-year period: (i) baseline audits of Lynch syndrome pathology testing and referrals among CRC patients, (ii) formation of multidisciplinary "Implementation Teams," (iii) identification of target behaviours to achieve practice change, (iv) identification and confirmation of barriers to change, (v) generation of implementation strategies, (vi) support of staff to implement strategies, and (vii) evaluation of strategy effectiveness using audit and process evaluation data to assess practice and culture change. Clinical data was extracted to demonstrate pre- and post-implementation change, the primary outcome measure being the proportion of patients with risk-appropriate completion of the Lynch syndrome tumour testing and referral pathway (Steinberg J, Chan P, Yap S, Morrow A, Tiernan G, Kang Y-J, et al.: Comparing theory-based and intuition-based implementation approaches to inform successful genomic medicine strategies in practice: a two-arm parallel cluster randomised clinical trial for improving tumour testing and genetics services referral for Lynch syndrome, under review).

HaSP process evaluation design

A mixed-methods, theory-driven process evaluation was undertaken in parallel to the HaSP trial, with full methods described in detail elsewhere [31]. We collected data at multiple time points and included: observation of HaSP implementation focus groups, HaSP research team focus groups, Implementation Lead project logs, and interviews of Implementation Leads and Lynch syndrome stakeholders. A summary of data sources is provided in Table 1.

Table 1 Overview of process evaluation data sources

Measures	Data collection timepoints[a]				Analysis plan			adapt of measurement	Data sources analysed
	T0	T1	T2	T3	Data type	Analysis approach	Coding framework(s)		
IL post-training interviews	X				Qualitative	Thematic analysis	TDF+CFIR[b]	Process evaluation	9 interview transcripts[c]
MDT observation		X	X		Qualitative & quantitative	Descriptive statistics & thematic analysis	TDF+CFIR[b], Proctor's implementation outcomes	Process evaluation	5 MDT observation forms (limited sites: H1, H2, H5 only)
Observation of HaSP implementation focus groups		X			Qualitative	Thematic analysis	TDF+CFIR[b], Proctor's implementation outcomes	HaSP trial & process evaluation	14 process mapping focus groups (average of six-attendees per focus-group) 7 barrier identification focus groups (average 4 attendees per focus group) 11 strategy co-design focus groups (average 5 attendees per focus group)
HaSP research team focus groups			X	X	Qualitative	Thematic analysis	CFIR 2.0	Process evaluation	4 focus groups (average 5 attendees per focus group)
LS stakeholder interviews				X	Qualitative	Thematic analysis	CFIR 2.0, Proctor's implementation outcomes	Process evaluation	18 interview transcripts (1-5 per hospital site)
Implementation Lead project logs		X	X	X	Qualitative & quantitative	Content analysis & descriptive statistics	Proctor's implementation outcomes	Process evaluation	49 project logs

[a] Timepoints throughout the *HaSP* trial: T0 = pre-implementation/baseline (Phase 1 of *HaSP* trial); T1 = early implementation (6 months, Phases 2-5 of *HaSP* trial); T2 = mid-implementation (12 months, Phase 6 of *HaSP* trial); T3 = end of implementation period (18 months, Phase 7 of *HaSP* trial)

[b] Analysis conducted prior to CFIR 2.0 update to include COM-B model of individual-level behaviour

[c] Athough originally planned for seven sites with one designated Implementation Lead (IL) per site, nine interviews were conducted due to 1) the withdrawal of one site after training, and 2) staff changes involving the IL at another site (second interview conducted at T1 for this site)

In this study, we have primarily focused on post-implementation evaluation interviews, with results cross-validated against the complete process evaluation dataset through a rigorous triangulation exercise.

Theoretical orientation

Using a theoretical framework for the process evaluation allowed us identify theoretical constructs and behavioural determinants proposed to mediate change [33]. We used the Consolidated Framework for Implementation Research (CFIR), which is the most widely used framework to identify barriers and facilitators (determinants) to implementation effectiveness[35]. The CFIR comprehensively considers multilevel contextual factors across five domains: the innovation, outer setting, inner setting, individuals, and the implementation process. This is advantageous over other determinant frameworks, which typically consider 1–2 domains. Furthermore, the CFIR 2.0 has been aligned to Proctor's standardised implementation outcomes, to support more robust outcome evaluations [36].

The original CFIR was recently updated to include the COM-B system, which proposes three broad categories of Capability (e.g., skills), Opportunity (e.g., autonomy), and Motivation (e.g., commitment) in shaping individual-level behaviour [37]. The COM-B constructs can each be mapped to domains of the TDF – the framework used in the HaSP trial to explicitly inform strategy design in the theory-based trial arm sites. The CFIR 2.0 therefore provides a complimentary framework for process evaluation analysis, enabling comprehensive insights into both individual- and organisational-level determinants of implementation success.

Participants and recruitment

We used purposive sampling to invite Implementation Leads and Principal Investigators from all seven HaSP sites to participate in post-implementation process evaluation interviews. Through snowball recruitment, Implementation Leads and Principal Investigators were encouraged to forward the email invitation to other clinical stakeholders at their site across the various relevant departments involved in the Lynch syndrome tumour testing and referral pathway (e.g., colorectal surgery, pathology, genetics, medical oncology).

Participants were eligible to participate if they had been involved in the Lynch syndrome tumour testing and referral pathway at any phase of implementation, regardless of whether they were actively involved in the HaSP strategy design or implementation process.

Implementation Leads and Principal Investigators were encouraged to seek a diverse range of perspectives across different departments and levels of seniority. Interviews were conducted within three months of the implementation of hospital-specific strategies. Written consent was obtained by all participants prior to interview. We ceased recruitment once Implementation Leads and/or Principal Investigators agreed that all relevant clinical stakeholders had been invited to participate.

Data collection

In-depth, semi-structured interviews were conducted via telephone by a member of the HaSP research team (EK) with no prior direct involvement in HaSP implementation activities. Open-ended interview questions were designed to explore: overall experiences of the HaSP implementation approach, perceived factors affecting implementation success (guided by CFIR framework), and experiences applying theoretical or intuitive approaches for barrier identification and strategy design. The interview schedule is available in Appendix 1. Interviews were audio-recorded and transcribed verbatim for analysis, with identifiers removed.

Data analysis

Post-implementation interview transcripts were analysed using a mixed deductive and inductive approach. We organized and analysed data using Microsoft Excel and NVivo Version 12 (QSR International, Victoria, Australia). All transcripts were read and line-by-line coded by one member of the research team (AM), with 30% of transcripts independently double coded by a second member of the research team (RB). To reduce potential researcher biases, data were interpreted without knowledge of site-level clinical outcomes. Descriptive codes were assigned to pieces of text, guided by the CFIR 2.0 constructs (while allowing generation of themes outside this framework). Both AM and RB are implementation researchers with experience in qualitative methodology and coding according to the CFIR 2.0 framework. Similar responses were grouped and theme labels generated. AM and RB met regularly to review the coding, and an additional researcher (NT) was available to resolve any discrepancies.

Data triangulation

Results from the post-implementation interview analysis provided foundational data which were then triangulated with other lines of evidence collected throughout the process evaluation. Triangulation enhanced the validity and reliability of our findings by incorporating multiple data sources/methods, thereby minimising the potential biases and limitations associated with any single source/method [38].

Using post-implementation interview data as an anchoring point, AM systematically compared and analysed various process evaluation data sources (e.g., HaSP focus group observations, HaSP research team focus groups, MDT observations, Implementation Lead project logs) to identify convergence, divergence, and complementary information. These triangulated findings were organised into a table format and reviewed and discussed by AM and NT to ensure the validity of the research interpretations.

Logic model development

We performed a secondary analysis of post-implementation qualitative interviews for each hospital site separately. CFIR-coded determinants identified through transcript analysis were incorporated into site logic model components. Logic models were structured according to the Implementation Research Logic Model (IRLM) [39], which consists of the following inputs: determinants, clinical intervention, implementation strategies, mechanisms and outcomes (implementation, service and clinical). The IRLM enables clearer specification of the conceptual linkages between key project elements and the complex interrelationships among determinants that impact the success of implementation efforts [39].

Hospital-specific logic models were initially developed in the strategy design phase of HaSP to demonstrate proposed intended causal mechanisms of change, and were populated with additional information about determinants, mechanisms, and outcomes as process data were analysed. We incorporated qualitative data about contextual moderators within the logic models to demonstrate the CFIR determinants affecting clinical outcomes at each site. We classified determinants as barriers or facilitators to implementation using the symbols (-) or (+) respectively. Various process evaluation data sources (qualitative and quantitative) were examined for additional CFIR determinants beyond those identified through interview transcript analysis, as well as implementation outcomes based on definitions by Proctor et al. [33]. We populated the 'strategies' component based on hospital strategies that were progressed for formal implementation. The 'clinical intervention' component (ensuring risk-appropriate completion of the Lynch syndrome testing and referral pathway') was common across all sites. We populated the 'mechanisms' component based on the targeted barriers of the implementation strategy. For theory-based sites, this was explicitly informed by the TDF, whereas for intuition-based sites no formal theory was used but intuitive barriers were retrospectively mapped to TDF domains. We used clinical data from the HaSP trial to populate service- and clinical- outcomes within the logic models. Caveats to clinical

data interpretation have been described in the HaSP trial clinical outcomes study (Steinberg J, Chan P, Yap S, Morrow A, Tiernan G, Kang Y-J, et al.: Comparing theory-based and intuition-based implementation approaches to inform successful genomic medicine strategies in practice: a two-arm parallel cluster randomised clinical trial for improving tumour testing and genetics services referral for Lynch syndrome, under review).

Case studies

Case studies offer a contextually-rich examination of real-world phenomena that can enhance understanding, uncover patterns, and generate more meaningful insights [40]. We developed two case studies to provide a narrative description of the site logic models and contextualise the factors influencing implementation success. Mechanisms of action were represented using the causal pathway diagram template developed by Lewis et al. [41]. Sites H2 and H4 were selected for the purpose of highlighting the contrasting findings in service-level outcomes discerned through the clinical HaSP trial data analysis, and insights gained from using the theory-based and intuition-based approaches, respectively. (Steinberg J, Chan P, Yap S, Morrow A, Tiernan G, Kang Y-J, et al.: Comparing theory-based and intuition-based implementation approaches to inform successful genomic medicine strategies in practice: a two-arm parallel cluster randomised clinical trial for improving tumour testing and genetics services referral for Lynch syndrome, under review)

Table 2 Participant characteristics (*n*=18)

	N
Age (years)	
25 – 35	3
36 – 45	8
46 – 55	4
56 – 65	1
>65	2
Gender	
Female	9
Male	9
Site	
H1	1
H2	2
H3	1
H4	3
H5	3
H6	5
H7	3
Professional role	
Clinical geneticist	2
Colorectal nurse coordinator	2
Colorectal surgeon	4
Genetic Counsellor	5
Pathologist	2
Clinical researcher	3
Professional experience (years)	
1 – 5	5
6 – 10	6
11 – 15	3
16 – 20	2
>20	2
HaSP Project Role	
Implementation Lead	7
Implementation Team	9
Site Principal Investigator	2

Results

Eighteen participants were recruited and interviewed across seven sites between October 2021 and February 2022. All interviews were conducted by a single researcher (EK). Interviews were 26 min in length on average (range 10 – 50 min). Participant characteristics are summarised in Table 2.

Coding of transcripts identified 18 barriers and 17 facilitators across five domains and 18 constructs of the updated CFIR. Appendix 2 provides the full compilation of these determinants, alongside representative quotes.

Outcomes of the triangulation exercise are provided in Appendix 3. Examination of additional data sources revealed largely convergent lines of evidence in support of the barriers and facilitators identified through HaSP post-implementation interviews. An additional three barriers and one facilitator was identified through the triangulation process.

Thematic analysis

Ten main themes were identified by the thematic analysis: complexities of Lynch syndrome referral, pandemic disruptions, operational challenges, information technology constraints, multidisciplinary collaboration and dynamics, cultural determinants of success, attitudes towards change, tailoring of strategies and the value of theory, flexibility and adaptations, and implementation training and support.

Complexities of Lynch syndrome referral

Several participants highlighted implementation challenges related to the complexity of the Lynch syndrome genetic referral pathway.

Lack of clinical and institutional guidelines made it challenging to reconcile differing perspectives within the implementation team regarding roles and responsibilities surrounding pathology test ordering, result follow-up, and initiation of referrals.

The number of processes, clinicians, departments, and data systems involved in the pathway were perceived by some participants to be excessively complicated and

deeply embedded within the hospital system, therefore more difficult to change [*CFIR Construct: Innovation Complexity*].

> *"They're often quite complicated and embedded. So, things like the electronic medical record at <H3>, and the pathology laboratory information system that we've got – those are the kind of things that you could potentially make differences, and those kinds of things are actually hard to influence." - Pathologist, H3*

> *for that, it's still surprising how slowly the wheels grind in a hospital." - Implementation Lead, H2*

Financial barriers were also identified by participants at one site (H6) as undermining implementation at the hospital-level. Specific strategies, including the introduction of new positions such as patient navigators or nurse coordinators, were rejected due to the need for sustained funding exceeding the existing research budget allocated for strategy implementation [*CFIR Construct: Financing*].

Pandemic disruptions

Participants cited both barriers and facilitators related to the impact of the COVID-19 pandemic on HaSP trial activities [*CFIR Construct: Critical Incidents*].

Health districts enforced directives suspending non-essential hospital research like HaSP trial activities to prioritise the COVID-19 crisis response. Even when study activities resumed, some participants reported a lasting impact on clinician engagement due to competing clinical priorities.

In contrast, several adaptive COVID-19 responses twere reported to facilitate HaSP study progress and potential success. The shift to remote work during the pandemic improved communication, via the use of virtual meeting platforms and increased availability of some clinicians. This appeared to enhance collaboration and decision-making within some implementation teams, demonstrating resilience and flexibility in response to unforeseen events.

> *"It actually improved our communication because we had switched to that culture of everyone being familiar with conferencing technology. So I felt like that was actually an enabler to communication." - Implementation Lead, H5*

Operational challenges

Across all sites, participants reported significant operational challenges that impacted the momentum and potential success of the HaSP implementation approach.

Research ethics and governance processes were consistently frustrating, due to repetition and redundancies across different administrative and legislative tiers [*CFIR Construct: Policies & laws*]. This resulted in significant HaSP trial delays which negatively impactedmomentum and stakeholder engagement.

> *"I maybe had some understanding or expectation of how much red tape and how just slow every process would be, but even as much as you can be prepared*

Information technology constraints

Participants reported several implementation barriers related to the information technology infrastructure involved in Lynch syndrome tumour testing and referral [*CFIR Construct: Structural characteristics—Information Technology Infrastructure*].

Extracting and linking data for the purpose of clinical practice audit involved multiple different databases, with limited integration. At some sites, Implementation Leads completed lengthy manual data cross-checks and cleaning to ensure high data quality. Missing data was frequently reported (e.g., missing tumour pathology test results). Consequently, some clinician stakeholders expressed reservations about the ability to fully capture Lynch syndrome clinical practice at their site, highlighting gaps in the data systems' capacity to identify where patients fall through the cracks or legitimate reasons why referrals might not occur.

Technological implementation strategies, such as database alert systems to flag patients at high-risk of Lynch syndrome or with incomplete pathology tests, were also difficult to implement. Participants expressed frustration that information technology infrastructures could not be easily adapted to incorporate changes, raising additional challenges related to resource allocation and funding necessary for implementing the desired database adaptations.

> *"Despite lots of money being spent on the electronic medical records, it's still clunky and not able to accommodate what would seem to be a fairly simple task of ensuring patients are recognised and nothing's missed in the process's ascertainment of Lynch syndrome. So, really, we couldn't get the IT teams to build in a fail-safe IT system." - CRC surgeon 1, H3*

Multidisciplinary collaboration and dynamics

Most participants highlighted the positive impact of collaboration within and across hospital departments as a

key facilitator for successful implementation [*CFIR Construct: Relational connections*].

Nurturing new and existing relational connections across all key departments (pathology, surgery, oncology, genetics) was important, given the multidisciplinary nature of Lynch syndrome detection. Collaborations were essential for understanding clinical gaps and developing contextually relevant strategies to address them.

> *"It's bringing all the stakeholders to the table and try to understand what the issues might be for each group, and when you're sitting on the other side of the table, you don't always appreciate what the hold-up is or what the issues are. So it was good to see that and work it through and say, "What could a solution look like for this issue?" - Geneticist, H6*

Lack of departmental representation within the HaSP Implementation Teams was perceived to be a barrier for process improvement at three sites.

Cultural determinants of success

Participants' responses highlighted the contrasting ways in which culture played out at different hospital sites.

A patient-centered culture was reported at site (H7), characterized by a strong shared commitment to maintaining a high standard of care, and aiming for zero misses in Lynch syndrome detection. [*CFIR construct: Culture – Recipient centeredness].* This shared commitment fostered strong engagement and high levels of motivation within the implementation team at this site.

> *"For even one person to be missed is really bad in their opinion. It's not good enough unless it's a hundred percent." - Implementation Lead, H6*

A learning-centered culture was also evident across several sites with clinicians actively engaged of cliniciansin critically assessing existing practices, staying informed of new innovations and actively seeking opportunities for improvement [*CFIR construct: Culture – Learning centeredness*]. This shared commitment to continuous learning and improvement appeared to enhance engagement within the Implementation Teams, promoting a culture more conducive to successful implementation.

A strong sense of belonging within a department and team,contributed to a more collaborative environment. In such settings, individuals were more likely to acknowledge the interdependence of their roles in achieving common goals. Embracing a team-oriented mindset was deemed essential for overcoming challenges associated with interdisciplinary initiatives, particularly in the case of Lynch syndrome, facilitating more effective implementation.

In contrast, organizational culture was reported by some participants to pose challenges to effective implementation. In some instances, clinicians viewed their roles and responsibilities in isolation, without a strong sense of collective identity or shared purpose. This 'siloed' approach was cited as a barrier to effective communication, collaboration, and knowledge-exchange across different aspects of Lynch syndrome testing and referral.

> *"The core of the issue is what your attitude to service provision is in an Australian public hospital, whether you regard it as a collection of individuals or whether you regard it as a department and as a team, and [at H5] it's very much a collection of individuals. And so, the people doing it regard it as being no business of theirs what anybody else does." - CRC surgeon, H5*

Attitudes towards change

Several factors appeared to influence clinicians' attitudes towards change and willingness to embrace implementation strategies.

Implementation champions were deemed pivotal in influencing motivation towards change within the Implementation Team, and overall receptivity to the implementation effort [*CFIR Construct: Motivation*]. Implementation champions emerged through various roles. Genetic staff members communicated the significance of Lynch syndrome diagnosis and the potential health impact of practice improvement. In some cases, senior clinicians leveraged their experience and social influence to exert influence among other stakeholders.

> *"The <Principal Investigator> is somebody who is held in high esteem and admiration and respect, very respected, not only within our organisation, but many. So having them there actually opened doors to me that I can imagine would never have been open before." - Implementation Lead, H3*

Pre-implementation audit data influenced tension for change at both individual and collective levels [*CFIR construct: Tension for change; Motivation*]. Many stakeholders (particularly in sites with a strong 'learning-centered' culture) appeared to embrace the audit findings as a motivational catalyst for addressing identified gaps, even when gaps were perceived to be small in relation to absolute case numbers.

> *"Even if you miss one person it's very detrimental, not only to the individual and their family but to the health system as well. So, being able to catch those people that we were previously missing, and it might*

have been only a small handful in the number of hundreds that pass through in a year, but that small handful can be very important. I had a comment from a pathologist that they were ashamed that even one person missed testing." - Implementation Lead, H6

Some clinicians had little motivation for change as they perceived identified gaps as minor and within an acceptable range. These perspectives also had implications for engagement levels among the Implementation Team.

"I was actually pleasantly surprised [by the pre-implementation audit data]... that led me to wonder whether there was much to be gained from applying an implementation process in the second phase of the project because there didn't seem to be much room for improvement." - CRC surgeon 1, H3

Some clinicians were reluctant to change as they were reported to be ingrained in their current practice.

"They just stick with what they believe, but the fact that they all thought that the processes went to work in a different way was interesting in and of itself. They're very set in their ways." - CRC surgeon, H5

Tailoring of strategies and the value of theory

Participants in both trial arms reported value in the use of a structured pathway for designing strategies tailored to local barriers [*CFIR construct: Assessing context, Tailoring strategies*]. This systematic approach was deemed instrumental in helping clinicians navigate the complexities of the Lynch syndrome tumour testing and referral pathway.

Process mapping was reported to be a particularly key component of this process, facilitating shared understanding of different roles and responsibilities, and pinpointing potential gaps within the pathway to focus implementation efforts.

"I think if it's successful, it will be because the detailed processes were able to be mapped out and put together and sort of laid out clearly, wherein I don't think anyone had ever done that before. I don't think anyone actually knew the process, no one knew what we were actually doing." - Geneticist, H7

The TDF was considered useful by all participants in the theory-based arm of the HaSP trial for understanding implementation barriers and designing evidence-based strategies. Some participants reported that the use of the TDF instilled greater confidence among clinicians regarding the potential effectiveness of the strategies being developed.

"[The TDF] really gave interventions in our project a good foundation to work off so that there was something to build on. And I think for the clinicians, it helped them to realise that it was an evidence- or a theory-based approach" - Implementation Lead, H2

In contrast, there were some challenges applying the TDF. Some clinicians expressed difficulty comprehending the theoretically 'abstract' aspects of the TDF, limiting their ability to apply the framework during focus-group discussions. Some participants also observed that the TDF required a shift in mindset from clinicians' usual rapid solution-focused approach, to a more time-intensive process of theory-grounded analysis and strategy development.

"I would tend to have just intuitively guessed what might need changing and done it. But it's given me something to think about another way of doing it. It does seem quite in-depth and quite a lot of work though, but I can see that it might be more beneficial." - Pathologist, H6

The Implementation Lead struggled to maintain stakeholder engagement at one site (H6), amidst frustration surrounding the lengthy process of designing theory-based strategies.

"Keeping that engagement over time and dealing with the frustration of the team. The Principal Investigator said a number of times, "We're surgeons. If there's a problem, find a solution, act on it." - Implementation Lead, H1

Some clinicians felt they could have intuitively developed similar strategies to those informed by the TDF, whilst still recognising the overall utility of the framework in in the context of HaSP.

"When I look at the interventions that we ended with, I still think we could've got there perhaps without a lot of that theory behind it." - Implementation Lead, H7

Flexibility and adaptation

Flexibility of the HaSP implementation approach and research team was acknowledged by participants as essential for adapting to the unique local dynamics, helping to overcome many of the challenges described. Clinical stakeholders valued the HaSP research team's

pragmatic approach in addressing the nuances of each local context, contributing to a positive and collaborative working partnership.

> *"I think that the trial team, the coordinating people, as far as I'm concerned, they've been easy to work with and approachable and sensible, and they've also not made assumptions about what we can and can't do. That side of things has worked as well as, or better than, any equivalent study I've ever taken part in." - CRC surgeon, H5*

Implementation training and support

All participants cited that ongoing implementation support from the HaSP research team played a pivotal role in ensuring the effective delivery of the implementation approach [*CFIR: Access to Knowledge and Information; Implementation Facilitators*].

Regular communication channels established with the HaSP research team instilled greater confidence among the Implementation Leads, and provided opportunities to promptly identify and address challenges.

Focussed implementation training was well-received and provided Implementation Leads with the requisite knowledge and skills for effective HaSP delivery.

> *"The fact that each process was so thoroughly thought out in a step-by-step manner and that there was support all along, even just to bounce ideas or impressions of on how to proceed was really fantastic."- Implementation Lead, H6*
>
> *"I felt confident before a lot of the meetings, but that was because we could really run through it together [with the research team] and say, "Here's the materials. Here's what you're going to present. Here's how you can use some techniques for how to do it." So, that was really, really useful." - Implementation Lead, H2*

Site logic models

For all sites in which interventions were implemented, detailed logic models were developed to demonstrate hypothesised causal pathways and contextual determinants. Logic models for all sites are presented in Appendix 4. An example logic model (Site H1) is provided in Fig. 1.

Strategy effectiveness

Strategies developed through the HaSP approach across all sites have been consolidated alongside trends for patient outcomes at each hospital (noting there was no formal analysis within hospitals due to small patient numbers), and are presented in Table 3.

Illustrative case studies

Case study 1 – Site H2 (theory-based)

Site H2 is a large metropolitan public teaching hospital with an onsite familial cancer clinic. Delays in project initiation were experienced due to lengthy ethics and

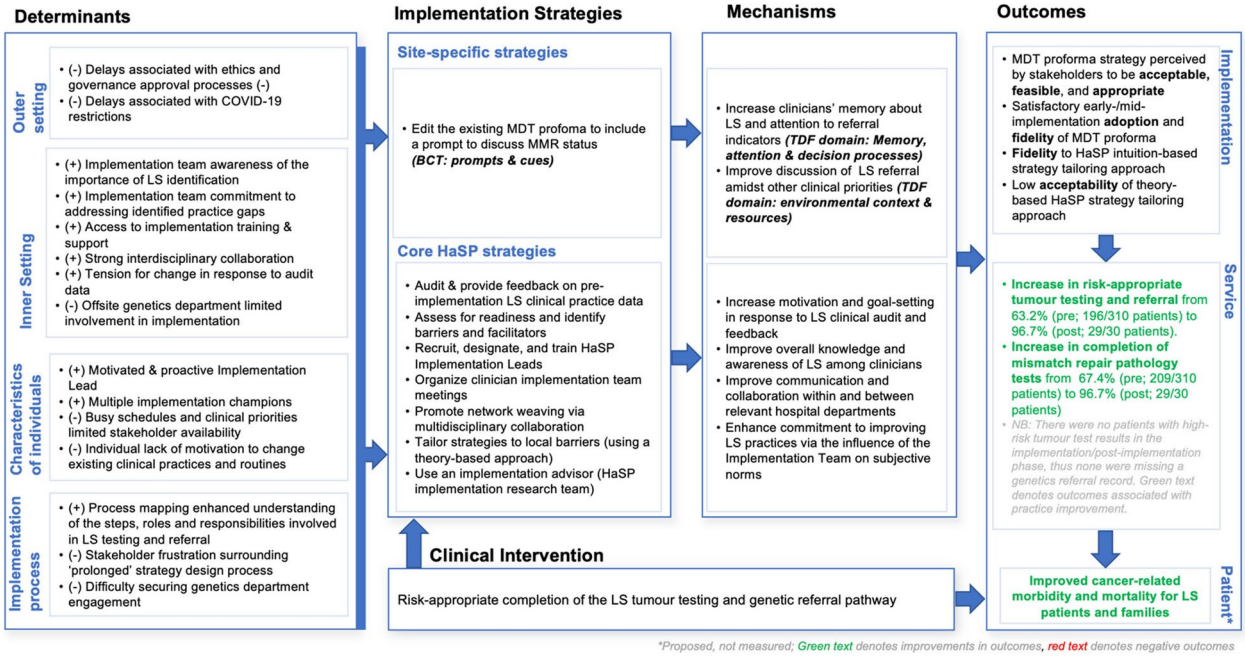

Fig. 1 H1 logic model (theory-based)

Table 3 HaSP implementation strategy effectiveness

Strategy type	Strategy description	Behaviour Change Techniques	Trend in patient outcomes					
			H1[a]	H2[a]	H3[b]	H4[b]	H6[a]	H7[a]
Education and training	Provide an educational resource to guide clinicians on MMR interpretation	*Instruction on how to perform the behaviour*						
	Conduct educational training to upskill clinicians in LS risk assessment	*Instruction on how to perform the behaviour; Information about health consequences*						
MDT meeting strategies	Incorporate an MDT prompt to review and discuss mismatch repair (MMR) results	*Prompts & cues*						
	Ensure presence of genetic counsellor at MDT meetings	*Social support (practical); Restructuring the social environment*						
Tracking and reminder/alert systems	Nurse or MDT coordinator to keep tracking list of patients with outstanding pathology results	*Social support (practical)*						
	Implement alert system where abnormal IHC results are flagged to responsible clinician	*Prompts & cues; Conserving mental resources*						
	Implement regular reminders to adhere to consistent reporting of referrals	*Prompts & cues*						
Process standardisation	Implement clear process for referrals, including confirmation of referral receipts	*Instruction on how to perform the behaviour*						
	Develop standardised language for the pathology reporting of MMR/BRAF	*Social support (practical); Conserving mental resources*						

Key

Trend for improvement in all measured clinical service outcomes relevant to the strategy *(e.g. increase in risk-appropriate tumour testing and referral; increase in completion of MMR pathology tests and reduced proportion of patients with tumour test results indicating high LS risk with no genetic services referral record)*

Mixed trends in measured clinical service outcomes relevant to the strategy *(e.g. improvements in some clinical service outcomes, but not all)*

No improvement trend in any measured clinical service outcomes relevant to the strategy (*e.g. reduction in risk-appropriate tumour testing and referral; reduction in completion of mismatch repair pathology tests and increase in proportion of patients with tumour test results indicating high LS risk with no genetic services referral record)*

Insufficient data to extrapolate meaningful outcomes

H6 is not represented in Table 3 as no hospital-specific strategies were implemented at this site *Abbreviations:IHC* Immunohistochemistry, *MDT* multidisciplinary team, *MMR* Mismatch repair

[a]Sites allocated to theory-based implementation approach

[b]Sites allocated to intuition-based implementation approach

governance processes. At the start, the Implementation Lead secured strong commitment from genetics, surgical, and oncology departments, but was met with resistance from pathology. This led to concerns about the potential success of the implementation effort, given the crucial role of pathology in Lynch syndrome referral.

The Implementation Team appeared highly motivated to improve practice based on the gaps identified in the

pre-implementation audit data. Focus groups were often smaller in attendance due to scheduling challenges. However, the team effectively engaged in meaningful discussions, exchanged perspectives, and leveraged diverse expertise to address the complexities of Lynch syndrome referral. A number of implementation champions emerged (oncologist, genetic counsellor) who advocated for the implementation effort and communicated the importance of Lynch syndrome detection.

The Implementation Team also demonstrated a readiness to explore novel strategies, and appeared engaged in applying theory for implementation strategy design. Three implementation strategies were developed: an educational training session about Lynch syndrome risk assessment, an educational resource, and a standardized language for pathology reporting. Through leveraging pre-existing social and communication channels, the Implementation Lead successfully secured the involvement of the pathology team in the latter stages of the project. This facilitated the implementation of the standardized reporting strategy.

Whilst both educational strategies were well received and achieved strong attendance among the colorectal cancer multidisciplinary team, the standardised language has been inconsistently used in the pathology reports. Nonetheless, post-implementation data revealed improved performance across all measured areas of Lynch syndrome clinical practice, indicating successful implementation at H2. It is possible that implementation champions played a key role in motivating clinician stakeholders to engage with the educational strategy. It is likely that the educational strategy improved knowledge, skills, and beliefs about consequences, and therefore had a positive impact on risk-appropriate tumour testing and referral practices (Fig. 2).

Case study 2 – Site H4 (intuition-based)

Site H4, a large metropolitan public hospital with an onsite familial cancer clinic, encountered initial delays in project initiation due to ethical and governance processes. Regardless, the Implementation Lead successfully formed a multidisciplinary Implementation Team, encompassing all departments key to the Lynch syndrome tumour testing and referral pathway.

Research was well-embedded within the colorectal surgery department, and the Implementation Team demonstrated strong initial commitment to evaluating and improving current clinical practices. However, during early HaSP focus-groups, some stakeholders voiced concerns that the pre-implementation audit data did not accurately reflect practice, and that there were justifiable reasons for the identified gaps and bottlenecks. Within departments such as CRC surgery and pathology, current performance levels were deemed satisfactory, which appeared to reduce their tension for change.

Despite these concerns, the Implementation Team proceeded to develop a suite of nine hospital-specific intuitive strategies, of which six were selected for formal implementation. Some strategies, such as the incorporation of a genetic counsellor into the Multidisciplinary Team (MDT), were proposed prior to the barrier identification stage. This deviated from the intended stepwise approach to strategy tailoring. Although stakeholders perceived these strategies as highly acceptable, feasible,

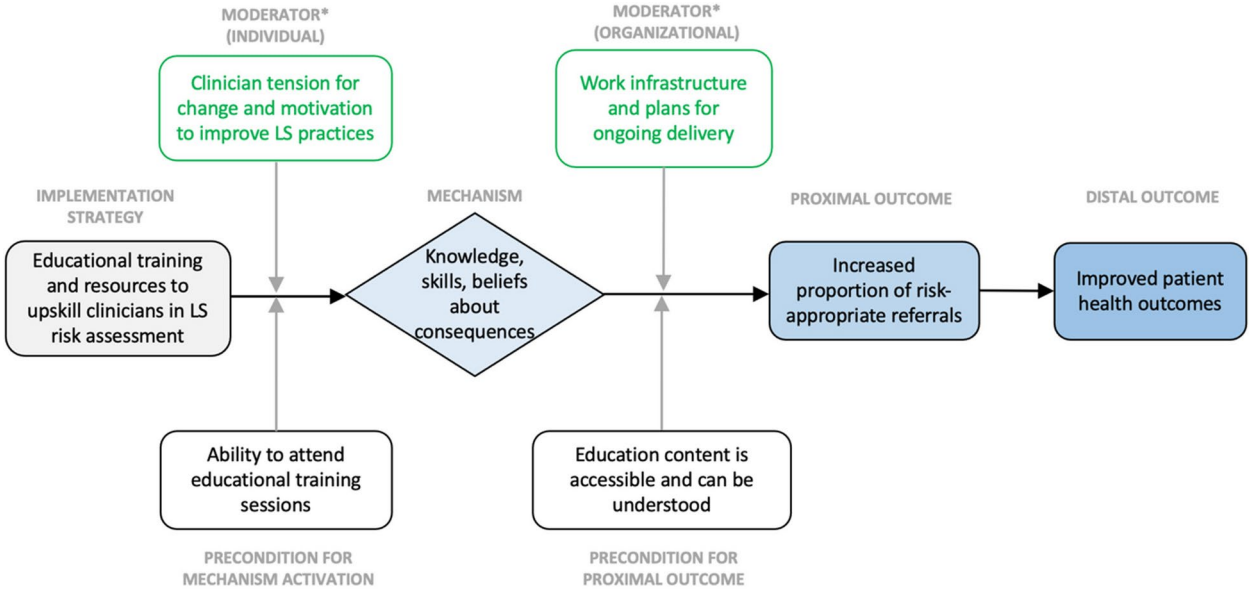

Fig. 2 Example causal pathway H2

and appropriate, their successful implementation hinged on the sustained involvement of two key staff members – a genetic counsellor and a CRC nurse coordinator. Unfortunately, one of these staff members resigned from H4 during the implementation phase, and adoption of the strategy '*genetic counsellor attendance at the MDT*' was not sustained.

Post-implementation data indicated no improvement in Lynch syndrome clinical practices at H4, suggesting unsuccessful implementation. There are several possible explanations. Staff turnover was a significant barrier at H4. This might not have been adequately addressed in strategy development to transfer responsibilities and knowledge and protect sustainment. A potential causal pathway to explain this strategy is demonstrated in Fig. 3. Another possibility is that the introduction of numerous strategies simultaneously, together with reduced tension for change, may have led to a sense of complacency. The perception of multiple safeguards diminished individuals' motivation and sense of responsibility.

Discussion

Findings from this process evaluation highlight the complexity of health systems, and the multi-levelled factors influencing implementation. Comparison of logic models across all sites highlighted both similarities and differences in the mechanisms targeted, and variability in clinical outcomes. Qualitative insights provided contextual understanding of potential barriers and facilitators shaping these outcomes.

The role of theory

The HaSP trial investigated whether explicit use of theory in implementation strategy design leads to more effective implementation, compared with approaches reliant on healthcare professional intuition and tacit knowledge. Hospitals in the theory-based arm of the HASP trial showed a significant reduction in the proportion of patients at high risk of Lynch syndrome without a record of genetics referral, compared to the intuition-based arm. This suggests theory-based approaches to implementation strategy design may better support clinical practice changes for improving Lynch syndrome detection. The ability to definitively establish whether a theory-based approach was more effective in this context was constrained by the rarity of Lynch syndrome and the substantial correlation of patient-level outcomes within hospitals. However, process evaluation findings highlight the advantages and limitations of using theory to design implementation strategies.

Participants in the theory-based arm acknowledged the value of the TDF for barrier analysis and evidence-based strategy development. However, some clinicians faced challenges in conceptualizing and applying behaviour change theory, expressing frustration with the perceived 'intensive' nature of the process. In healthcare settings, clinicians can often find the application of theory to be "abstract, intimidating and irrelevant", and thus tend to develop implementation strategies pragmatically based on tacit, experiential knowledge [23, 42]. Intuitively derived intervention strategies are not necessarily less effective. In fact, clinicians are well-placed to leverage

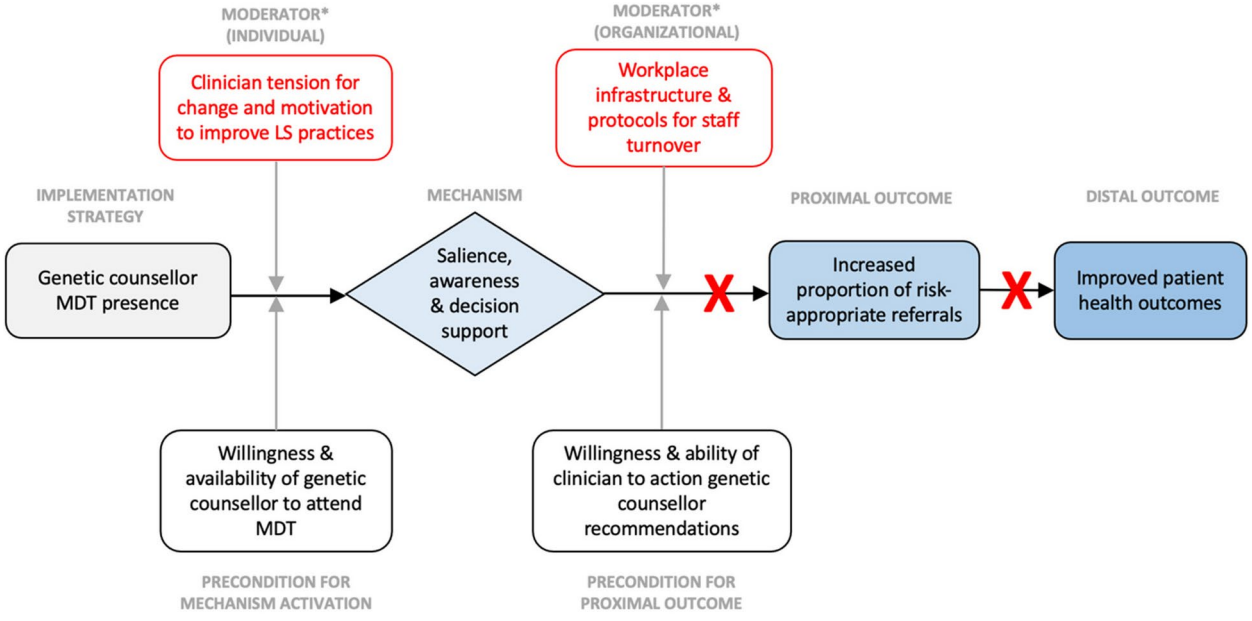

Fig. 3 Example causal pathway H4

their expert understanding of a problem to develop innovative and contextually-relevant solutions [43]. In this study, some clinicians felt they would have arrived at similar strategies intuitively, without the use of the TDF. Even when theories are not explicitly used in their design or reporting, these 'intuitively-derived' strategies may incorporate techniques that align with existing theory [44, 45].

Through reverse analysis, it is possible to identify implicitly enacted BCTs mechanistically linked with a specific domain or construct being targeted for change [45]. Delineating the mechanisms underlying intuitively-derived strategies allows other researchers and clinicians to replicate and adapt them more effectively, whilst also facilitating a deeper understanding of how strategies produce their effects. Retrospective analysis of HaSP intuitively-derived strategies revealed that the most widely used categories of BCTs and mechanistic links were largely similar across the two trial arm sites. However, a theory-guided approach offered a broader range of strategies (and BCTs) to choose from [46]. Recognising the known benefits of theory for enhancing scientific learning, further efforts are needed to bridge the gap between theoretical methods and their practical application within healthcare settings.

HaSP participants universally highlighted the importance of ongoing training and support from the implementation research team to navigate changing health systems and adapt research methods to fit local context. Several clinicians noted that they would consider applying HaSP implementation methods (e.g., implementation mapping) to address other clinical problems in the future. Establishing partnerships with behavioural science and implementation researchers to equip health staff with the skills to lead evidence-based implementation approaches has been previously proposed as a more sustainable strategy for effective translation [43, 47]. Furthermore, evidence indicates that such collaborations enhance the fidelity of implementation program delivery [48]. Our findings demonstrate that adaptations are a necessary reality of real-world implementation. Pragmatic approaches are needed to respond to ongoing changes within the health system [49]. The collaborative partnership between the research team and Implementation Leads played a crucial role in addressing and rapidly responding to emerging issues, ensuring that intended causal mechanisms and the overall trial design were maintained to support program fidelity. This partnership model presents a feasible approach for enhancing implementation effectiveness, fidelity, adaptability, and ongoing sustainability.

Contextual determinants

Qualitative findings highlighted contextual determinants that influenced the success of both hospital-specific strategies and the overall HaSP approach. The complexity of the genetic referral pathway was a prominent barrier to implementation, a finding consistent with previous reports in both the Lynch syndrome literature [50], and genomics more broadly [51]. Innovation complexity appeared to have a flow-on effect on determinants within other CFIR domains, for example: information technology infrastructure (e.g., multiple Lynch syndrome clinical data sources with limited connectivity), work infrastructure (e.g., organisation of roles and responsibilities within and between different hospital departments), relational connections and communications (e.g., information sharing practices between clinicians and departments), and individual capability, opportunity and motivation (e.g., clinicians' integration of complex genetic information into their clinical decision-making processes and workflows).

At the inner setting level, cultural dynamics and multidisciplinary collaboration emerged as crucial determinants of HaSP implementation success. Hospital and departmental cultures that were centered around continuous learning emerged as a facilitator for positive collaboration within the Implementation Teams. These stakeholders demonstrated more open communication, adaptability to change, and a shared commitment to improving patient care. Conversely, the presence of individual and departmental silos appeared to limit information sharing within and across departments at some sites. This resulted in substantial practice variation, lack of a common goal and limited recognition of the interdependencies between various processes within the Lynch syndrome testing and referral pathway.The absence of a shared perception can hinder a positive implementation climate [52], affecting the extent to which a site does (or does not) move toward readiness for change [53]. Although process evaluation data served only summative purposes in the HaSP trial, leveraging real-time CFIR-mapped determinants may be crucial in overcoming cultural barriers for future implementation efforts. By systematically assessing the cultural dynamics influencing implementation, strategies can be iteratively tailored to promote collaboration, communication, and shared goals across departments and stakeholder groups. This proactive approach can help mitigate barriers, enhance readiness for change, and may facilitate more successful implementation of the HaSP program across diverse healthcare settings.

Of interest, there was substantial differences in the way individuals, departments and Implementation Teams responded to the pre-implementation audit data. For sites with a strong 'learning-centered' culture, the audit

data appeared to be a motivational catalyst for practice improvement, even when gaps were considered small relative to absolute case numbers. In contrast, among sites where clinicians perceived the identified gaps as minor and within an acceptable range, there was limited scope for improvement and reduced tension for change. These findings highlight the importance of organizational culture in shaping motivation and response to change [35, 52], and prompt consideration about the process by which audit data is prepared and presented. For example, delivery of feedback by local leaders and comparison of audit data results against peer equivalent hospitals may enhance motivation through social influences [54]. Furthermore, emphasising the long-term health consequences of a single missed Lynch syndrome diagnosis (e.g., missed opportunities for cancer prevention and early-detection for the patient and their at-risk relatives), may reshape perceptions of seemingly 'small' gaps in practice, and the value assigned to behaviour change.

At the individual level, implementation champions appeared to play a crucial role in shaping team dynamics and facilitating change. This aligns with findings from a systematic review of the literature on champions in healthcare settings, which consistently identified positive associations on implementation effectiveness [55]. The impact of champions within the HaSP context was particularly pronounced when there were multiple champions spanning various hospital departments. A study by Soo [56] emphasised the significance of leveraging champions from different organizational positions and networks (e.g. executive champions who held senior leadership roles; clinical department managerial champions; and frontline clinical champions). With the exception of site principal investigators, many of the implementation champions in HaSP naturally emerged at different stages of the trial through involvement in implementation activities, rather than deliberate efforts made at the outset to purposefully designate champions. Employing strategic approaches to identify and prepare implementation champions across key departments may enhance HaSP effectiveness in the future [55].

At the outer setting level, significant project delays were experienced due to pandemic disruptions and lengthy research administration processes, potentially affecting staff engagement and the success of implementation. Whilst disruptions to health service delivery due to COVID-19 have been widely reported [57], our findings also identified a number of adaptive responses. In some instances, the adoption of remote working practices and the use of videoconferencing facilities improved communication within the Implementation Team, facilitating continued progress of the HaSP trial. The delays associated with research administration processes, particularly in the context of ethics and governance reviews, align with the challenges faced by other Australian research teams involved in obtaining approvals for multisite research trials [58, 59]. To assist other research teams in anticipating and navigating these complexities, the HaSP research team have identified a number of opportunities for streamlining these processes to reduce their potential impact on future implementation efforts (Morrow A, Tyedmers E, Debono D, Steinberg J, Chan P, Tiernan G, et al.: Trials and Tribulations: Researcher reflections on navigating the challenges of health system implementation research, forthcoming).

Mechanisms of action

The focus on strategies in colorectal multidisciplinary team meetings (e.g., proformas for Lynch syndrome) highlights the need for coordinated efforts to streamline tumour testing and referralsacross hospital departments [60]. Mechanisms of action addressing clinicians' memory, attention, and decision processes, along with the environmental context influencing Lynch syndrome referral decisions, were found across most sites. Similar strategies were identified in a recent systematic review of genetic referral intervention studies, and were often associated with improved clinical outcomes [61]. Such mechanisms appear to offer a plausible pathway through which busy and time-poor clinicians are more alert to Lynch syndrome risk factors, and have additional resources and support to navigate these complexities. However, in this study, the effectiveness of these strategies varied across sites and appeared to be heavily influenced by an interplay of contextual factors spanning multiple CFIR domains.

In the systematic review by Morrow et al. [61], educational strategies were the most frequently cited approach for improving genetic referral practice across various healthcare contexts. Despite their widespread use, these educational interventions often failed to achieve the desired clinical outcomes, only improvements in knowledge [61]. Conversely in our study, educational strategies were implemented at only one site (H2), though were associated with improvements in all three assessed clinical service outcomes. The success of this strategy at H2 could be attributed in part to the use of a theory-based approach. This likely allowed for tailored educational content addressing specific barriers related to stakeholder beliefs and misconceptions regarding the health benefits of Lynch syndrome diagnosis (TDF domain: Beliefs about consequences), in addition to basic-level knowledge and skills. This finding highlights the potential efficacy of tailored, theoretically-informed educational interventions, suggesting that their impact may be contingent upon the specific barriers and contextual factors at play within a given healthcare setting.

Logic models were a valuable tool in synthesising complexity and providing a visual representation of the conceptual relationships between multiple variables, and the causal mechanisms by which they produce their effects. There have been overwhelming calls for better reporting of implementation strategies in the implementation science literature [62–64]. This requires precise specification of the behaviours to be changed, the BCTs to be used, modes of delivery, and characteristics of the target population [65]. Others must be able to clearly discern the active ingredients of an implementation intervention, and the proposed causal pathways through which they produce the intended effects. The logic models presented in this study serve to facilitate replication of effective implementation interventions across other settings [65]. Whilst logic models have long been used in program evaluation, specifying contextual moderators and mechanisms of action as model components (in addition to the more traditionally used components, e.g., *inputs*, *outputs*, *outcomes*) enhance their relevance for the implementation science field [66]. In this context, opportunities exist to incorporate and test the algorithm recently proposed by Taylor et al. [45], which offers a structured framework to standardize hypothesized behavioural pathways for both theory-driven and intuitive implementation strategies. Incorporating this algorithm may help to overcome challenges and maximize the advantages associated with both the theory-based and intuition-based HaSP approaches, whilst more systematically capturing the complexities of behaviour change processes. This may be particularly useful for addressing more nuanced barriers where theory-driven approaches may be most beneficial.

Opportunities for HaSP trial refinements

Findings from this process evaluation highlight opportunities to strengthen the HaSP implementation approach. In the context of the HaSP trial, CFIR-guided analysis of contextual determinants was used for summative process evaluation purposes only, so as not to influence the HaSP trial outcomes. However, incorporating strategies to address these contextual barriers may enhance success for future implementation efforts. For example, the 'CFIR-ERIC Implementation Strategy Matching Tool' [67] could be incorporated into the HaSP implementation approach to identify implementation strategies that would best address key CFIR-based contextual barriers. Furthermore, assessment of context at the pre-implementation stage may serve to identify sites that may need targeted efforts to enhance organisational readiness prior to initiating the implementation approach [68].

Strengths and limitations

The strengths of this study include the use of a well-validated theory to explore proposed causal mechanisms alongside a large rigorous pragmatic trial of a professional behaviour change intervention. In addition, the use of mixed-methods allowed triangulation of multiple data sources over time to strengthen process evaluation findings. These mixed-methods captured multiple perspectives, including those of clinical stakeholders, Implementation Leads and the HaSP trial researchers. Incorporating these different perspectives provides a more complete picture of the nuanced factors influencing the success of the HaSP trial. We interpreted data without knowledge of site-level clinical outcomes, thereby reducing potential researcher biases (e.g., confirmation bias).

This study is not without limitations. Significant delays caused by COVID-19 and research administrative processes affected data collection for both HaSP and the process evaluation. Consequently, the implementation phase extended beyond the trial's completion date, impacting the research team's ability to collect both implementation and clinical outcome data. For example, ongoing implementation fidelity checklists could not be completed as planned, and post-implementation interviews were conducted at the early implementation stage (rather than mid-late as initially intended). Furthermore, the interpretation of post-implementation interview data may be limited by the potential bias that stakeholders were more likely to participate if they had a positive experience with the HaSP implementation approach. Additionally, certain sites had a limited number of participants, therefore views expressed may not be representative.

Conclusions

This evaluation advances understanding of the complex factors that influence implementation success. Our findings emphasise the need for tailored, theory-informed strategies that consider the cultural context of healthcare settings to enhance implementation. Other researchers can use lessons about effective and ineffective strategies, alongside mechanisms of action and contextual determinants, to guide future implementation efforts within their unique healthcare contexts. These learnings can inform the design of strategies that are more likely to be effective in producing, and sustaining, positive change in the health care system. By understanding the interplay of theory, context, and practical barriers, this study paves the way for more successful and sustainable healthcare implementation strategies.

Supplementary Information

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Supplementary Material 1.

Supplementary Material 2.

Supplementary Material 3.

Supplementary Material 4.

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Authors' contributions
AM, KT, BP, JS and NT conceptualised the study; AM, PC, EK and EH collected and curated the data; AM, RB and NT conducted the formal analysis; AM, KT, BP, DD, EH and NT applied the methodology; AM, JS, EK, DD, EH and NT led the investigation; KT, BP and NT supervised the study; NT acquired the funding. The original draft was written by AM, RB, JS, DD and NT. All authors read and approved the final manuscript.

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Data availability
The data are not publicly available due to privacy or ethical restrictions. Further information is available in the supplementary material or by contacting the corresponding author.

Declarations

Ethics approval and consent to participate
Ethical approval was granted by the Royal Prince Alfred Hospital Human Research Ethics Committee (reference HREC/17/RPAH/542), The research was undertaken in compliance with the Australian Code for the Responsible Conduct of Research and National Statement on Ethical Conduct in Human Research. Informed, written consent was obtained from all study participants. Participant identifiers have been removed, so the person(s) described are not identifiable.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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