

A Toolkit for Implementation of Clinical Genomic Testing: Using a Combined Stakeholder and Evidence-Driven Approach

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Abstract

BACKGROUND

The complexity of clinical genomics – testing your entire genetic information for health benefit – is a rapidly evolving field demanding swift clinical practice change at multiple levels as widespread testing in healthcare becomes a reality. We aimed to a) describe a combined stakeholder- and evidence-driven approach to developing a toolkit for implementing genomics into the Australian health system, and b) hypothesise key steps in the change to Theoretical Domains Framework (TDF) domains via coded implementation strategies and associated mechanistic links.

METHODS

The TDF was used to analyse interview data from 16 nongenetic medical specialists using genomics in practice. Barriers and enablers were identified for three key target behaviour areas across the genomic testing process: 1) identifying patients, 2) test ordering/reporting, and 3) providing results. Barriers were grouped by distinct TDF domains, and, where barriers overlapped, ‘overarching’ domains were identified. Intuitive enabling strategies generated by clinicians were aligned with identified barriers, and retrospectively coded against evidence-based behaviour change techniques (BCTs). Additional theory-driven strategies were developed to address remaining identified barriers. Using structured expert consensus processes, members of the research team participated in a series of workshops to discuss and agree theory-informed links and propose mechanisms through which specific implementation strategies would address TDF-based barriers.

RESULTS

A total of 32 barriers were coded against TDF domains and constructs, and eight overarching TDF domains were identified on 13 occasions. Across all target behaviour areas, 21 BCTs were represented within the 30 intuitive enabling strategies generated by clinicians, found to be used on 49 occasions. Of these, nine (18%) aligned with a corresponding distinct TDF domain coded barrier that has previously demonstrated statistically significant mechanistic links. 20 new implementation strategies were developed to address nine remaining barriers using a theory-driven approach.

CONCLUSION

This study provides rich detail of crucial stages in intervention development, aiming to ensure implementation strategies are both evidence-informed and contextually appropriate.

All barriers were mapped to the TDF, implementation strategies coded against BCTs, and standardised hypothesised behavioural pathways have been proposed, making potential underlying theory explicit. Next steps will be to test toolkit effectiveness for facilitating scale-up of genomics across Australia.

Contributions To The Literature

This work has:

- Coded clinician barriers to implementation of genomics according to the Theoretical Domains Framework (TDF), and mapped clinicians' intuitive enabling strategies to overcome barriers to implementation with evidence-based behaviour change technique (BCT) definitions.
- Identified the extent to which clinician-generated intuitive enabling strategies to address TDF-coded barriers align with theoretical behaviour change domains and corresponding BCTs that demonstrate evidence of mechanistic links.
- Used evidence-based TDF-BCT mechanistic links to develop strategies to overcome TDF-matched barriers.
- Generated standardised hypothesised behavioural pathways to make potential underlying theory explicit.
- Produced contents for a stakeholder- and evidence-driven toolkit to support Australia-wide implementation of clinical genomic testing.

Background

The use of evidence-based approaches when developing strategies to support the implementation of interventions into practice is highly recommended[1] and, to a certain degree, mandated through requirements for completion of checklists [e.g., Standards for Reporting Implementation Studies (STARI) [2], and Template for Intervention Description and Replication (TIDieR)[3]. In addition to providing a systematic approach to planning and applying an implementation approach, using an evidence-based theory, model or framework can help to ensure that standardised approaches are taken to allow for accurate measurement, identification, replication, and refinement of the active ingredients behind implementation success[4–8]. For example, the Theoretical Domains Framework (TDF) encompasses 14 determinants (originally 12) and 84 component constructs of healthcare professional behaviour change[9, 10] (Table 1). This framework can facilitate exploration of barriers and facilitators to implementing evidence-based behaviours[11], and provides a systematic, evidence-based pathway for intervention design. Classification of barriers and facilitators according to the TDF can inform the selection of targeted behaviour change techniques (BCTs) empirically linked to theoretical determinant constructs[12, 13]. Recent work has established standardised terminology through which to consolidate links between BCT definitions [7] and their mechanisms of action (MoAs) as represented through theoretical constructs (e.g., from the TDF)[9] from the existing evidence base[4]. In healthcare settings, however, the ideals of rigorous theory-driven approaches to implementation are often met with significant yet unpredictable contextual and interpersonal complexities, leading to overlapping barriers[14–16], which must be accounted for and incorporated, but are notoriously difficult to manage and measure[17–19]. Without a record or understanding of the contribution these factors make to the success or failure of implementation efforts, advancing the science of implementation will remain an elusive goal.

Table 1
The Theoretical Domains Framework (Version 2)

Domain (definition)	Constructs
1. Knowledge (An awareness of the existence of something)	<i>Knowledge; Procedural knowledge; Knowledge of task environment</i>
2. Skills (An ability or proficiency acquired through practice)	<i>Skills; Skills development; Competence; Ability; Interpersonal skills; Practice; Skill assessment</i>
3. Social/professional role and identity (A coherent set of behaviours and displayed personal qualities of an individual in a social or work setting)	<i>Professional identity; Professional role; Social identity; Identity; Professional boundaries; Professional confidence; Group identity; Leadership; Organisational commitment</i>
4. Beliefs about capabilities (Acceptance of the truth, reality or validity about an ability, talent or facility that a person can put to constructive use)	<i>Self-confidence; Perceived competence; Self-efficacy; Perceived behavioural control; Beliefs; Self-esteem; Empowerment; Professional confidence</i>
5. Optimism (The confidence that things will happen for the best or that desired goals will be attained)	<i>Optimism; Pessimism; Unrealistic optimism; Identity</i>
6. Beliefs about Consequences (Acceptance of the truth, reality, or validity about outcomes of a behaviour in a given situation)	<i>Beliefs; Outcome expectancies; Characteristics of outcome expectancies; Anticipated regret; Consequents</i>
7. Reinforcement (Increasing the probability of a response by arranging a dependent relationship, or contingency, between the response and a given stimulus)	<i>Rewards; Incentives; Punishment; Consequents; Reinforcement; Contingencies; Sanctions</i>
8. Intentions (A conscious decision to perform a behaviour or a resolve to act in a certain way)	<i>Stability of intentions; Stages of change model; Transtheoretical model and stages of change</i>
9. Goals (Mental representations of outcomes or end states that an individual wants to achieve)	<i>Goals (distal/proximal); Goal priority; Goal/target setting; Goals (autonomous/controlled); Action planning; Implementation intention</i>
10. Memory, attention and decision processes (The ability to retain information, focus selectively on aspects of the environment and choose between two or more alternatives)	<i>Memory; Attention; Attention control; Decision making; Cognitive overload/tiredness</i>
11. Environmental context and resources (Any circumstance of a person's situation or environment that discourages or encourages the development of skills and abilities, independence, social competence and adaptive behaviour)	<i>Environmental stressors; Resources/material resources; Organisational culture/climate; Salient events/critical incidents; Person x environment interaction; Barriers and facilitators</i>

Domain (definition)	Constructs
12. Social influences (Those interpersonal processes that can cause individuals to change their thoughts, feelings, or behaviours)	<i>Social pressure; Social norms; Group conformity; Social comparisons; Group norms; Social support; Power; Intergroup conflict; Alienation; Group identity; Modelling</i>
13. Emotion (A complex reaction pattern, involving experiential, behavioural, and physiological elements, by which the individual attempts to deal with a personally significant matter or event)	<i>Fear; Anxiety; Affect; Stress; Depression; Positive/negative affect; Burn-out</i>
14. Behavioural regulation (Anything aimed at managing or changing objectively observed or measured actions)	<i>Self-monitoring; Breaking habit; Action planning</i>

Challenges for studies that have taken an evidence-based approach to implementation relate to ‘staying true’ to a particular theoretical approach (theoretical fidelity)[20–22] whilst accounting for and responding flexibly to healthcare professional, patient, and system needs[19, 23–30]. These challenges are exacerbated when the intricacies of theory application can be inaccessible to non-experts[5], and slow, relative to demands for rapid evidence translation[19, 30, 31]. Although theory-driven stakeholder co-design methodology is evolving[32–34], theory-based approaches to elicit key barriers to implementation of a particular intervention to inform a theory-driven approach to implementation strategy design often lead to ‘on the spot’ solutions[35]. These solutions may or may not align with theoretical recommendations, and stakeholders may also decide to enact them immediately, despite deviation from the implementation protocol[19, 23, 36]. Although alternative approaches and adaptations may well be effective given the tacit knowledge and experience of clinicians, these solutions are often not recorded, making it difficult to identify the extent to which a) deviation from the theorised core functions have occurred, and b) they are effective.

One recent area of exploration is the role of healthcare professional intuition in the identification of barriers and solutions to implementation, and the extent to which this intuition aligns with theory-driven recommendations[18, 35, 37–40]. Enhancing understanding about the alignment of intuition and theory can tell us more about where healthcare professionals generate relevant implementation strategies (e.g., education/training) to address identified barriers (e.g., knowledge/skills) without the need for in depth use of theory. It can also signal where theory is most needed (e.g., to address more complex barriers such as social influences or emotion) and can be best utilised – potentially making the process of theory guided interventions more efficient. Furthermore, recording and coding these intuitive approaches to implementation strategy design against theory can allow for the study of effects, and contribute to the evidence-base for establishing and explaining the mechanistic links between those strategies that lead to clinical practice change[35, 40].

Clinicogenomics – using the entire genome of a patient to diagnose diseases or adjust medications exclusively for that patient[41] – is a rapidly evolving field and is already demanding swift clinical

practice change at multiple levels as testing in healthcare becomes a reality[42–46]. During 2014–2019, 29 early adopter health system ‘flagships’ across Australia were using clinicogenomics as part of nested research studies belonging to the Australian Genomics and Melbourne Genomics Health Alliance programs[47, 48]. Together these alliances have placed emphasis on understanding, from a service level and clinical practice perspective, how genomic testing can be implemented in healthcare. As a result we have studied clinician emergent and self-organising behaviours (i.e., communal behaviours which create order through interactions) during the implementation of genomics into practice[43]; identified successful emergent behaviours and gaps in practice[44, 49]; and synthesised this information using a theoretical framework[38, 50, 51]. The next phase of this component of the national genomics research program was to use the insights of these early adopters – including the use of intuition and experience for the development of implementation strategies – to co-design a foundation implementation toolkit to facilitate genomic novice nongenetic clinicians translate genomic testing into clinical practice across Australia[52].

Aim

This paper aims to: a) describe the process used to combine stakeholder (non-genetic specialists) and evidence-driven approaches to develop a toolkit for the implementation of genomics into the Australian health system, and b) develop an algorithm to standardise hypothesised key steps in the change to TDF domains via BCT-coded implementation strategies, and the associated mechanistic links. Our objectives were to:

1. Identify and code distinct and overlapping barriers to implementation according to the TDF;
2. Map enabling strategies intuitively generated by clinicians to overcome barriers to implementation with evidence-based BCT definitions;
3. Identify the extent to which the intuitive strategies align with theoretical behaviour change domains and corresponding BCTs that demonstrate evidence of mechanistic links;
4. Use TDF-BCT mechanistic links evidence to develop implementation strategies to overcome TDF-matched barriers.

Methods

Context

The work described here amalgamates results of Stage 1 and Stage 2a of a Type 1 Hybrid study design as part of the Australian Genomics and Melbourne Genomics programmes of research, described in detail elsewhere[38, 52]. To summarise, demonstration projects across 29 disease conditions (early adopter flagships) integrating genomics into clinical settings have been studied to understand emergent and self-organising behaviours among inter-related actors and processes. In stage 1, interview data from 32 participants (16 non-genetic medical specialists and 16 service level professionals) involved in developing the genomics clinical practice systems and approaches across five flagships was synthesised

to generate TDF-based barriers and enablers to undertaking three key tasks (target behaviour areas[1]) crucial for the implementation of genomics [i) ensuring appropriate patients are selected for genomic testing, ii) requesting testing and interpreting the data, and iii) providing results to patients] [52]. In stage 2a, mixed methods were used to conduct process map guided TDF-informed interviews[53] and identify the psychosocial and environmental determinants of change across the three target behaviour areas[50, 52]. This study reports on the results of the triangulation of these data to inform the design of a theory-driven toolkit to support the translation of genomics evidence into clinical practice.

Study design

We conducted an in depth TDF-driven intervention mapping exercise to synthesise findings from the 16 TDF-informed semi-structured interviews with nongenetic medical specialists, who identified factors affecting the implementation of genomics[50] and generated intuitive enabling strategies.

Participants and recruitment

Following research ethical approval (Melbourne Health HREC: HREC/13/MH/326) and governance from participating organisations, interviews were undertaken with nongenetic medical specialists currently working in the field of genomics with either Australian Genomics or Melbourne Genomics. Recruitment details are provided elsewhere[50].

Data collection and procedure

Our starting point was the initial synthesis undertaken on the 16 interview transcripts with nongenetic medical specialists (neurology = 4; cardiology = 1; nephrology = 6; immunology = 2; oncology = 3; including some with leadership roles = 7)[50]. This work coded barriers and enablers according to the TDF across three specific target behaviour areas along the genomics clinical pathway [i) ensuring appropriate patients are selected for genomic testing, ii) requesting testing and interpreting the data, and iii) providing results to patients][52] to identify what factors facilitate or hinder the implementation of genomics into clinical practice by non-genetic specialists. Identified intuitive enabling strategies suggested by participants (as currently utilised or potential implementation strategies) were also matched to barriers that they could directly address.

Taking these carefully coded barriers and enablers as our starting point, we commenced our four-stage approach to data synthesis for theory-driven toolkit development (Figure 1): 1) in depth context clarification and TDF construct coding for the identified barriers and enabling strategies; 2) grouping of overlapping barriers according to overarching TDF domains; 3a) coding intuitive enabling strategies against BCTs[7]; 3b) designing implementation strategies using BCTs[6], and 4) assessing alignment of intuitively derived interventions and theory[4, 6].

Data synthesis

Stage 1 – In depth context clarification and construct coding for identified barriers and enablers: Two authors (SB and NT) held 3 x 4 hour meetings to work through the specific context of each barrier to clarify understanding, and justify the previously identified theoretical links between barriers, distinct TDF domains, and intuitively derived enabling strategy mapping to relevant corresponding barriers. These in-depth discussions revealed the need to refine some initial TDF domain categorisation and mapped enablers for which rationales were documented. This process also aimed to fulfil recommendations by Kok et al.[54] to ensure population, context, and parameters be considered during intervention design.

Stage 2 – grouping of barriers according to overarching TDF domains: Given the recognisable relationships and interdependencies between distinct TDF-coded barriers that emerged through the analysis and further in-depth context clarification discussions, barriers were also grouped according to an overarching TDF domain. This allocation of an overarching domain was important because it was often considered as a driver of or influence on barriers that were related to one another at more a granular level, and indicated the need to consider barriers together, in context, when considering the development of implementation strategies.

Stage 3a – Coding intuitive enabling strategies against BCTs: In a series of 3 x 3 hour meetings (NT, SB, JL), barrier-mapped enablers with sufficient description available directly from the dataset were retrospectively coded against evidence-based BCTs using the most up to date BCT definitions[6, 7] (see additional file 1). For those enablers without enough description available directly from the dataset, the research team further unpicked the context of the barriers they were intended to address (mainly through probing SB, an experienced qualitative researcher immersed in the MG and AG contexts and who undertook all interviews, to understand the nuances of the described barriers) to flesh out the enabler enough to the extent it could also be coded as a BCT. It was decided that guidance from the online BCT-TDF mapping tool[6] *would not* be used to guide the selection of BCTs, at the outset, to minimise the risk of bias (as the full idea or seed for the idea was developed intuitively by clinicians), but rather it would be consulted at the end of this exercise to assess the extent to which these intuitively derived enabling strategies aligned with the most up to date theoretically driven guidance for BCT selection. Theoretically underpinned links were then formally documented using a structured format (see additional file 2) to hypothesise the MoAs for changes to barrier-specific, and subsequently, overarching TDF domains, as a result of intuitively derived context-appropriate implementation strategies (i.e., enablers) retrospectively coded against BCTs. As an example,

The construct of **A** and distinct TDF theme **B** were selected because the clinicians were *doing C behaviour*. The intuitive enabler of **D** is linked to the BCT **E** *because it will do F* to change their **G** (distinct TDF theme) by increasing **H** (overarching TDF theme) *because of X* (explanation).

Stage 3b – designing implementation strategies using BCTs: In a final set of 3 x 4 hour meetings with SB and NT, implementation strategies were designed to address all remaining distinct level barriers (i.e., those without a mapped intuitively derived enabler) through the use of only those BCTs with evidence of mechanistic links with TDF domains[6]. In this stage, we applied a two-tiered approach; that is, we initially

mapped relevant BCTs to the distinct barrier – with the assumption that these then lead to improvements in the overarching barrier – and developed practical implementation strategies. In instances where BCTs were not helping to generate appropriate strategies to address the barrier-specific problem, we addressed the overarching barrier directly (using evidence-based BCTs mapped to the overarching barrier). Using the structured format outlined in additional file 2, theoretically underpinned links were formally documented to hypothesise the MoAs for changes to barrier-specific, and subsequently, overarching TDF domains, as a result of context-specific implementation strategies designed using BCTs designed to address specific TDF domains. As an example:

The construct of **A** and distinct TDF theme **B** were selected because the clinicians *were doing C behaviour*. The strategy of **D** is linked to the BCT **E** *because it will do F* – this should reduce their **G** (***distinct*** TDF theme) and change their **H** (overarching TDF theme) *because of X* (explanation).

OR

The construct of **A** and distinct TDF theme **B** were selected because the clinicians were *doing C behaviour*. The strategy of **D** is linked to the BCT **E** *because it will do F* – this should reduce their **G** (***overarching*** TDF theme) and change their **H** (distinct TDF theme) *because of X* (explanation).

Stage 4 – assessing alignment of intuitively derived enabling strategies and theory: In line with recently reported methods[35], a counting exercise was undertaken to assess the number of barriers and intuitively derived barrier-matched enablers. The number of intuitively derived enablers that aligned with BCTs demonstrating mechanistic links with the associated TDF domains, according to the Theory and Techniques Tool[6], were next counted. This provided the proportion of intuitively derived enabling strategies coded against BCTs that aligned with theoretically matched barriers.

[1] A key feature of the TDF includes the need to establish key target behaviours, however, there are a number of behaviours involved in each steps of: i) ensuring appropriate patients are selected for genomic testing, ii) requesting testing and interpreting the data, and iii) providing results to patients, which were deemed too complex and impractical to break down into individual behaviours and conduct the mapping exercise, as such the decision was made to map barriers to each of these broader target behaviour areas.

Results

Findings are reported in line with the TIDieR template for intervention description and replication (TIDieR) checklist and guide (additional file 4).

A total of 32 distinct barriers (20, 7, and 5 across target behaviour areas 1-3) and 30 experiential or intuitive enablers (20, 4, and 6 across target behaviour areas 1-3) were identified through the initial phase of data analysis. The barriers were coded according to distinct TDF domains, and through in-depth

discussion, coding was refined, constructs were allocated, and overarching TDF domains were assigned to groups of barriers that were interrelated (Figure 2).

Stage 1 – In depth context clarification and construct coding for identified barriers and enablers

In-depth context clarification revealed crucial insights from the lead interviewer (SB) who had assigned the original TDF codes prior to the discussion[50]. This allowed for drilling down barriers and enablers to the construct level, ensured confidence amongst the group that domains assigned to barriers were appropriate, and in instances where there was some uncertainty, provided an opportunity to unpick coding in relation to the context and make amendments where necessary. The need to change TDF domains to which barriers had been assigned occurred in one case for 'target behaviour area 1' (ensure appropriate patients receive testing) and in one case for 'target behaviour area 2' (test selection and variant interpretation). For example, a lay description of a barrier: 'not trained to counsel' was originally coded under the 'knowledge' domain. However, context clarification discussion records indicated: "*clinicians talked about this passionately - they weren't trained to counsel people about genomic testing. Re-thinking and wondering whether skills is a better TDF fit*", and so this barrier was recoded to 'skills' (see additional file 2).

A total of 32 barriers were coded against TDF domains and constructs, with seven domains represented in total and used between one (e.g., 'goals', 'social influences') and six ('skills') times across each target behaviour area. Eighteen TDF constructs were used between one (e.g., *goal priority, professional boundaries*) and three (e.g., *skill development, competence*) times across each target behaviour area (additional file 3). Across all target behaviour areas, there was some overlap of TDF domains (e.g., environmental context and resources, knowledge) and constructs (e.g., *person x environment interaction*). Target behaviour area 1 (TBA1) (ensuring appropriate patients receive testing) produced the largest number of barriers ($n = 20$), and range of TDF domains ($n = 7$) and constructs ($n = 13$).

Stage 2 – grouping of barriers according to overarching TDF domains:

In-depth context clarification also revealed the overlapping nature and interrelatedness of some barriers, to the extent that a decision was made to group barriers according to 'overarching TDF domains'. A total of 13 overarching TDF domains were generated, with seven, four, and two overarching domains represented across target behaviour areas 1-3, respectively, each of which encompassed between one and five individual interrelated barriers. As an example, barriers such as 'lack of clinician genetic literacy' (TDF: knowledge), 'overenthusiastic calling of variants' (TDF: beliefs about capabilities), and 'lack of confidence in calling variants' (TDF: beliefs about capabilities) were coded under a general theme of 'Need for role clarity', with the corresponding overarching TDF domain being 'Professional role and identity'.

Stage 3a – Coding intuitive enablers against BCTs:

A total of 21 BCTs were represented within the 30 intuitive enablers found across target behaviour areas 1-3 (see additional file 2), which were found to be used on 49 occasions ('occasions' refer to any instance a BCT was identified in an intuitively described implementation strategy, noting that each implementation strategy can contain multiple BCTs, and one BCT can be present in multiple different implementation strategies[35]).

Of the 21 BCTs represented, across all three target behaviour areas, the most frequently used were 'conserving mental resources' (represented in seven intuitive enablers), followed by 'social support practical' (represented in six intuitive enablers), and 'credible source' (represented in five intuitive enablers). The largest number of enablers ($n = 20$) was produced to address TBA1, which were represented by 14 different BCTs used between one (e.g., 'graded task') and six ('conserving mental resources') times.

Prior to theory-alignment assessment from the existing evidence-base, using the algorithm described earlier, we hypothesised the MoA for changes to barrier-specific, and subsequently, overarching TDF domains, as a result of intuitively derived context-appropriate enablers retrospectively coded against BCTs, for example (in relation to TBA1 – ensuring appropriate patients receive testing):

The construct of **Decision making** and distinct TDF theme **Memory, attention and decision making** was selected because the clinicians were *confused about the process because it was not clear to them*. The enabler of '**clear referral criteria within an informal checklist**' is linked to the BCT '**conserving mental resources**' because it *provides explicit guidance* - this should reduce the **memory, attention and decision making barrier** (distinct TDF theme) by *simplifying the process*, and enhance their **skills** (overarching TDF theme) for 'doing genomic testing' by *providing clearer circumstances in which to apply genomics in practice*.

Stage 3b – designing new implementation strategies using BCTs

A total of 20 original implementation strategies ($n=9$, $n=7$, and $n=4$ across TBAs 1-3, respectively) were developed to address the nine remaining barriers (that did not have any suggested intuitive enablers) using combinations of 20 BCTs (on 30 occasions) that have previously demonstrated mechanistic links with either individual level ($n = 17$) or overarching ($n = 3$) TDF-coded domains [4, 6] (additional file 2). For example, the populated algorithm in relation to TBA3 – communicating results – would appear as):

The construct of **Person x environment interaction** and TDF theme **Environmental context and resources** was selected because *the clinicians were hampered and frustrated by the long turn-around times for some test results*. The strategy of 'contact point in the labs' and 'develop a test result turnaround time list' is derived from the BCTs '**Social support practical**' and '**adding objects to the environment**' because *clinicians will be able to access accurate information relating to the timing of the tests* - this should reduce the **environmental context and resource barrier** (distinct TDF domain) and, in turn, improve their **emotion** (overarching TDF theme) by *helping them to manage their frustrations around the slow speed of test result turn-around time*.

Of the 20 BCTs, across all three target behaviour areas, the most frequently used were ‘adding objects to the environment’ (used four times), followed by ‘social support practical’ and ‘instruction on how to perform the behaviour’ (each used three times).

Stage 4 – assessing alignment of intuitively derived interventions and theory

Table 2 presents a summary of the alignment of intuitively derived interventions and theory. After cross-referencing against the Theory and Techniques Tool[18], across all three target behaviour areas, we found that of the 49 intuitive enabling strategy occasions in which BCTs were represented, nine (18%) aligned with a corresponding distinct TDF domain coded barrier that has previously demonstrated statistically significant mechanistic links (i.e., theoretical alignment agreed upon by expert consensus AND associations in the intervention literature synthesis). For example, TBA1 = 5/31 (16%) – ‘conserve mental resources’ (TDF domain = memory, attention, and decision making), ‘behavioural practice/rehearsal’ (TDF domain = skills), and ‘social support (practical)’ (TDF domain = environmental context and resources; occurred three times). There were 16 (33%) intuitive strategies coded against BCTs that aligned with a corresponding distinct *or* overarching TDF domain coded barrier, for example TBA1 = 10/31 (32%) – ‘conserve mental resources’ (TDF domain = memory, attention, and decision making) and ‘behavioural practice/rehearsal’ (TDF domain = skills), social support (practical)’ (TDF domain = environmental context and resources; occurred three times); ‘demonstration of the behaviour’ (TDF domain = beliefs about capabilities), ‘salience of consequences’ (TDF domain = beliefs about consequences), ‘behavioural practice/rehearsal’ (beliefs about capabilities), ‘problem solving’ (TDF domain = beliefs about capabilities), and ‘graded task’ (TDF domain = social influences).

Table 2. Alignment of distinct and overarching barriers and intuitive enabling strategies with theoretical recommendations

DISTINCT BARRIER AND ENABLING STRATEGY ALIGNMENT WITH THEORETICAL RECOMMENDATIONS

	Align with theory		Non-links		Inconclusive	No evidence
TBA1	5/31 (16%)	<ul style="list-style-type: none"> • ‘Conserve mental resources’ - Memory, attention, and decision making • ‘Behavioural practice/rehearsal’ – Skills • ‘Social support (practical)’ - environmental context and resources; occurred three times 	4/31 (13%)	<ul style="list-style-type: none"> • ‘Prompts and cues’ -Knowledge • ‘Credible source’ – Skills • ‘Conserve mental resources’ – Professional role and identity; used on two occasions 	5/31 (16%)	17/31 (55%)
TBA2	2/12 (17%)	<ul style="list-style-type: none"> • ‘Information about social and environmental consequences’ – Knowledge • ‘Social support (unspecified)’ - Social influences 	2/12 (17%)	<ul style="list-style-type: none"> • ‘Problem solving’, ‘monitoring of outcomes of behaviour without feedback’ – Professional role and identity 	1/12 (8%)	7/12 (58%)
TBA3	2/6 (33%)	<ul style="list-style-type: none"> • ‘Conserve mental resources’ - Memory, attention, and decision making • ‘Social support (unspecified)’ - Social influences 	1/6 (16%)	<ul style="list-style-type: none"> • ‘Action planning’ - Knowledge 	0/6 (0%)	3/6 (50%)
Total	9/49 (18%)		7/49 (14%)		6/49 (12%)	27/49 (55%)

OVERARCHING BARRIER AND ENABLING STRATEGY ALIGNMENT WITH THEORETICAL RECOMMENDATIONS

	Align with theory		Non-links		Inconclusive	No evidence
TBA1	10/31 (32%)	<ul style="list-style-type: none"> • ‘Conserve mental resources’ - Memory, attention, and decision making • ‘Behavioural practice/rehearsal’ – Skills 	4/31 (13%)	<ul style="list-style-type: none"> • ‘Prompts and cues’ -Knowledge • ‘Credible source’ – Skills • ‘Conserve mental resources’ - Professional role 	5/31 (16%)	12/31 (39%)

		<ul style="list-style-type: none"> • ‘Social support (practical)’ - environmental context and resources; occurred three times • ‘Demonstration of the behaviour’ - Beliefs about capabilities • ‘Salience of consequences’ - Beliefs about consequences • ‘Behavioural practice/rehearsal’ (beliefs about capabilities), ‘problem solving’ - Beliefs about capabilities • ‘Graded task’ - Social influences 		and identity; used on two occasions		
TBA2	4/12 (33%)	<ul style="list-style-type: none"> • ‘Information about social and environmental consequences’ – Knowledge • ‘Social support (unspecified)’ - Social influences • ‘Information about others approval’ - Social influences • ‘Social comparison’ - Social influences 	4/12 (33%)	<ul style="list-style-type: none"> • ‘Problem solving’ - Professional role and identity; used on two occasion • ‘Monitoring of outcomes of behaviour without feedback’ – Professional role and identity • ‘Problem solving’ - Social influences 	2/12 (16%)	2/12 (17%)
TBA3	2/6 (33%)	<ul style="list-style-type: none"> • ‘Conserve mental resources’ - Memory, attention, and decision making • ‘Social support (unspecified)’ - Social influences 	1/6 - (13%)	<ul style="list-style-type: none"> • Action planning’ - Knowledge 	0/6 (0%)	3/6 (50%)
Total	16/49 (33%)		9/49 (18%)		7/49 (14%)	17/49 (35%)

For distinct barriers, six of the 21 BCTs were found to be ‘non-links’ (e.g., BCT-MoA link absent in literature synthesis AND experts in consensus study agreed there was no theoretical link), used on 7/49 (14%) of occasions: TBA1: ‘prompts and cues’ (TDF domain: knowledge), ‘credible source’ (TDF domain = skills), ‘conserve mental resources’ (TDF domain = professional role and identity; used on two occasions); TBA2:

'problem solving' and 'monitoring of outcomes of behaviour without feedback' (TDF domain = professional role and identity); TBA3: 'action planning'(TDF domain: knowledge). However, all of these occasions were in the context of interventions with multiple BCTs coded (see additional file 2), although none of the accompanying BCTs had evidence of mechanistic links (as defined above). Six BCTs were found to be 'non-links' for distinct *or* overarching TDF domain coded barriers used on 9/49 (18%) of occasions: TBA1: no additional non-links found (beyond distinct TDF domains); TBA2: 'problem solving' (TDF domain = professional role and identity; used on two occasions), 'monitoring of outcomes of behaviour without feedback' (TDF domain: professional role and identity), and 'problem solving' (TDF domain = social influences); TBA3: no additional 'non-links' found (beyond distinct TDF domains).

Some of the BCT links to theory were found to be inconclusive. For the distinct barriers, there were six (12%) intuitive strategies coded against BCTs found to be inconclusive and seven (14%) for the distinct *or* overarching barriers. The remaining BCTs had either an absence of evidence to draw conclusions about mechanistic links for distinct barriers [remaining BCTs used on 27/49 (55%) occasions], or distinct *or* overarching barriers [remaining BCTs used on 17/49 (35%) occasions]; or existing evidence from literature and/or expert consensus was deemed 'inconclusive' for distinct barriers [5 BCTs used on 6/49 (12%) occasions], and for distinct *or* overarching barriers [6 BCTs used on 7/49 (14%) occasions]. Additional file 3 provides levels of evidence and details for mechanistic links for all 49 occasions, as derived from the Theory and Techniques Tool.

Discussion

We sought to use healthcare practitioner experience and expertise to co-design an evidence-based toolkit to support the implementation of genomics into the Australian healthcare system via implementation strategies to address key barriers across three target behaviour areas. In line with recommendations[5], our program theory (the TDF) was specified in advance to support the design of implementation strategies. In addition, we aimed to identify existing intuitively initiated strategies or 'on the spot' recommendations for overcoming barriers. Alongside this approach, we developed a novel algorithm to standardise and aid transparency about hypothesised key steps in the change to TDF domains via BCT-coded implementation strategies, and the associated mechanistic links. Highlighting the unavoidable complexity of barriers and enhancing transparency of how these instances have been managed, we not only reported these algorithms for distinct barriers, but also incorporated overarching TDF domains to illustrate the relationships between distinct barriers and other antecedents or knock-on effects (delineated through careful context discussions). Whilst coding to TDF constructs has not typically been applied in the past[11, 13], we found discussing constructs was helpful for context clarification, and was informative over and above domain-level coding for selecting BCTs.

The prominence of distinct TDF domains varied across each target behaviour area (e.g., TDF domain 'skills' was represented six times across TBA1 but did not feature in TBA2 or TBA3, whereas 'environmental context and resources' was represented between one and four times across all three target behaviour areas). This demonstrates the importance of clarifying target behaviours across a clinical

practice process, and the different kinds of barriers representing distinct behavioural drivers that might emerge. Furthermore, our findings highlight what these drivers might stem from or connect to through the additional information presented regarding overarching TDF domains. For example, 'environmental context and resources' was seen three times as a distinct barrier to ensuring appropriate patients are selected for genomic testing (TBA1): a) *takes too long*; b) *unable to join meetings*; c) *lack of genetic counsellor support at offering stage*, but in each instance related to a separate overarching barrier: a) 'beliefs about consequences' – *lack of understanding/appreciation of the value of testing*; b) 'beliefs about capabilities' – *confidence in ability to do genomic testing*; c) 'social influences' – *faith in ability and integrity of others to ensure appropriate patients are tested*.

Previous research has demonstrated the frequent nature of overlapping TDF domains, and some of the challenges this presents with specifying a domain which a particular barrier represents, as well as determining a corresponding BCT that could be used to design an appropriate implementation strategy[14–16]. In providing both the context-based and hypothesised theoretical links between distinct and overarching barriers, plus the mechanistic links to intuitively- and theory-driven BCTs, the transparency of the likely behaviour change pathway from barrier to implementation strategy is enhanced. Furthermore, taking the influencing factors and psychosocial consequences of a barrier on other domains into account produced carefully considered: a) pathways between intuitively derived strategies and their hypothesised mechanistic effects, and b) theory-guided implementation strategy development by taking potential flow on effects into account. This approach may help to illuminate mechanistic effects of interventions that incorporate multiple BCTs, which have previously demonstrated greater impact on behaviour change than those that do not[55].

Using an approach whereby non-genetic medical specialists were asked about factors that help or hinder the implementation of genomics into clinical practice elicited 30 existing or intuitively suggested enablers, which, from purely a problem-solution perspective, were able to be matched to 23 out of the 32 identified barriers (72%). Of the 49 occasions on which 21 BCTs were represented within the 30 intuitively enabling strategies, only nine (18%) were found to align with theoretical recommendations, demonstrating that whilst clinicians are well positioned to develop logical solutions to address a given clinical problem, these solutions retrospectively align with underlying theory only part of the time. The extent of alignment varied both within and between BCTs used. For example, the BCT 'conserve mental resources' was used on eight occasions (across distinct and overarching TDF domains), demonstrated links on three occasions (all with TDF domain 'memory, attention and decision making'), non-links on two occasions (both with TDF domain 'social and professional role and identity'), and for the remaining three occasions there was no evidence available. 'Behavioural practice/rehearsal' was used on three occasions and demonstrated links on two occasions with different TDF domains ('skills' and 'beliefs about capabilities'), and for the remaining occasion there was no evidence available. Furthermore, the nature of the retrospectively mapped BCTs and the accompanying experiential or intuitive suggestions were largely practical (e.g., related to continuously updated information provision, support from experienced genetics colleagues, designing new systems/forms), whereas in many of the instances where no enabler was suggested and required the research team to develop solutions, the barriers were more complex (e.g.,

perceptions about organisational expectations to complete bureaucratic processes associated with feeding results back to patients; slow return of results to feed back to patients which manifested in expressions of frustration). In such circumstances, it may be that theory can be of greater benefit in the design of implementation strategies to address more complex barriers (e.g., belief systems, emotions).

When theory was explicitly used to guide the design of the remaining nine barriers for which no enabler was suggested, four out of the 20 domain-matched BCTs selected were not identified as part of intuitively derived solutions: *incentive (outcome)* – overarching TDF domain: ‘intentions’; *goal setting (behaviour)* – overarching TDF domain: ‘intentions’; *verbal persuasion about capability* – overarching TDF domain: ‘beliefs about capabilities’; and *remove aversive stimulus* – distinct TDF domain: ‘environmental context and resources’. These BCTs may be perceived as more sophisticated than others (e.g., ‘demonstration of the behaviour’; ‘provide information on health consequences’, ‘social support’) and/or require more intricate application for the design of a specific implementation strategy to address a domain-matched barrier. As an example, below are two hypothesised behavioural pathways using ‘incentive’ (*outcome*) and ‘goal setting’ (*behaviour*) – both utilised to address a distinct TDF domain via directly addressing an overarching TDF domain:

The construct of **professional role** and TDF theme **professional role and identity** was selected because *the clinicians perceived challenges associated with the time and effort required to adopt a ‘foreign’ speciality*. The strategy of ‘intrinsic rewards’ is derived from the BCT ‘**incentive (outcome)**’ because it will *highlight the potential to generate the best outcomes for patients and enhance their own reputation if preparation for interpretation meetings (where results are analysed) is made* - this should change their **professional role and identity** (overarching TDF theme) by seeing *how they can incorporate this clinical speciality into their role*, through **intention** (distinct TDF theme) *by enhancing intrinsic motivation for the extra work*.

The construct of **professional role** and TDF theme **professional role and identity** was selected because *the clinicians perceived challenges associated with the time and effort required to adopt a ‘foreign’ speciality*. The strategy of ‘setting a goal to prepare for the discussion’ is linked to the BCT ‘**goal setting (behaviour)**’ because it will *provide a tangible behaviour for clinicians to aim for prior to each discussion* - this should change their **professional role and identity** (overarching TDF theme) by providing *a clear description of how they can incorporate this clinical speciality into their role*, through **intention** (distinct TDF theme) *with a specific clinical behavioural goal*.

Whilst these findings and methodological advances are insightful and important for the field of implementation science and informing health system evidence translation efforts, this research is not without limitations, which point towards avenues for future development and exploration. First, whilst we have proposed an algorithm to illustrate hypothesised behavioural pathways with mechanistic links, these have not been formally tested. Nonetheless, given the increasing calls for standardised reporting of intervention design alongside program theory, this approach at the very least provides a step in the right direction. One alternative or indeed complementary process may be to incorporate the use of recently

proposed ‘implementation logic models’ to demonstrate intended MoAs and proposed causal pathways[56, 57]. Second, the clinician suggested enablers were coded to BCTs based on the descriptive detail available, but it is possible that these described enablers may not have captured the detail required in the BCT descriptions – each intuitive enabler was subject to research team interpretation, and so there is arguably some variation on the extent to which alignment of implementation strategies is completely accurate, and it is possible that some suggested strategies did not have sufficient detail to allow for mapping to be undertaken. Third, it would be difficult to ascertain clarity on the effects of intuitive strategies (whether they were theoretically aligned or not) over theory-guided strategies in this particular context given many were already implemented by healthcare professionals at the time interviews took place. Well designed, controlled implementation trials are needed to assess the difference between intuitive and theory-informed strategies on implementation success[37]. Fourth, the data was collected in 2017 and so it is possible that additional strategies have already been implemented, and/or the genomics landscape has evolved such that some of the barriers/strategies could now be irrelevant; somewhat related, the evidence base for the effectiveness of BCTs for addressing specific TDF domains is also continuously evolving[6, 7, 39]. The time taken to synthesise and standardise this data according to a behavioural pathway algorithm was insurmountable and undoubtedly too slow for health system implementation needs – perhaps more automated approaches are needed to optimise the use of implementation data in a way that more efficiently supports those responsible for implementation.

Conclusion

This work has consolidated a comprehensive list of barriers to the implementation of genomics, and a broad range of implementation strategies to overcome them. All barriers have been mapped to the TDF, implementation strategies coded against BCTs, and standardised hypothesised behavioural pathways make potential underlying theory explicit. Next steps are underway to operationalise the data into a comprehensive, theoretically-informed toolkit allowing clinical teams to select from a range of existing barriers and implementation strategies most relevant for their context[52]. Coding enablers derived from clinician interviews and designing targeted interventions ‘from scratch’ required intensive effort from both the clinical and research teams. The development of a toolkit could facilitate scale-up efforts of genomics, providing an expedited approach to developing theory-informed interventions tailored to local barriers, particularly if such a resource was embedded within an online knowledge learning system.

Abbreviations

BCT Behaviour Change Technique

MoA Mechanism of Action

STARI Standards for Reporting Implementation Studies

TIDieR Template for Intervention Description and Replication

Declarations

Ethics approval and consent to participate: Ethical review was provided by Melbourne Health HREC (HREC/13/MH/326) and governance approval was provided by Austin Health; Australian Genomics Health Alliance; Monash Health; Peter MacCallum Cancer Centre; The Royal Childrens Hospital, Melbourne; and The Royal Melbourne Hospital. Following provision of participant information and an opportunity to ask questions, interviewees were asked to provide verbal consent for participation.

Consent for publication: N/A

Availability of data and materials: All data generated or analysed during this study are included in this published article [and its additional information files]

Competing interests: The author(s) declare(s) that they have no competing interests

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Authors' contributions: NT conceived the idea, led the approach to data analysis, and drafted, and finalised the manuscript. JL contributed to data analysis via group meetings, reviewed, and edited the manuscript. CG, KN, and JB reviewed and edited the manuscript. SB conducted the interviews, contributed to study design and data analysis, and reviewed and edited the manuscript.

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Figures

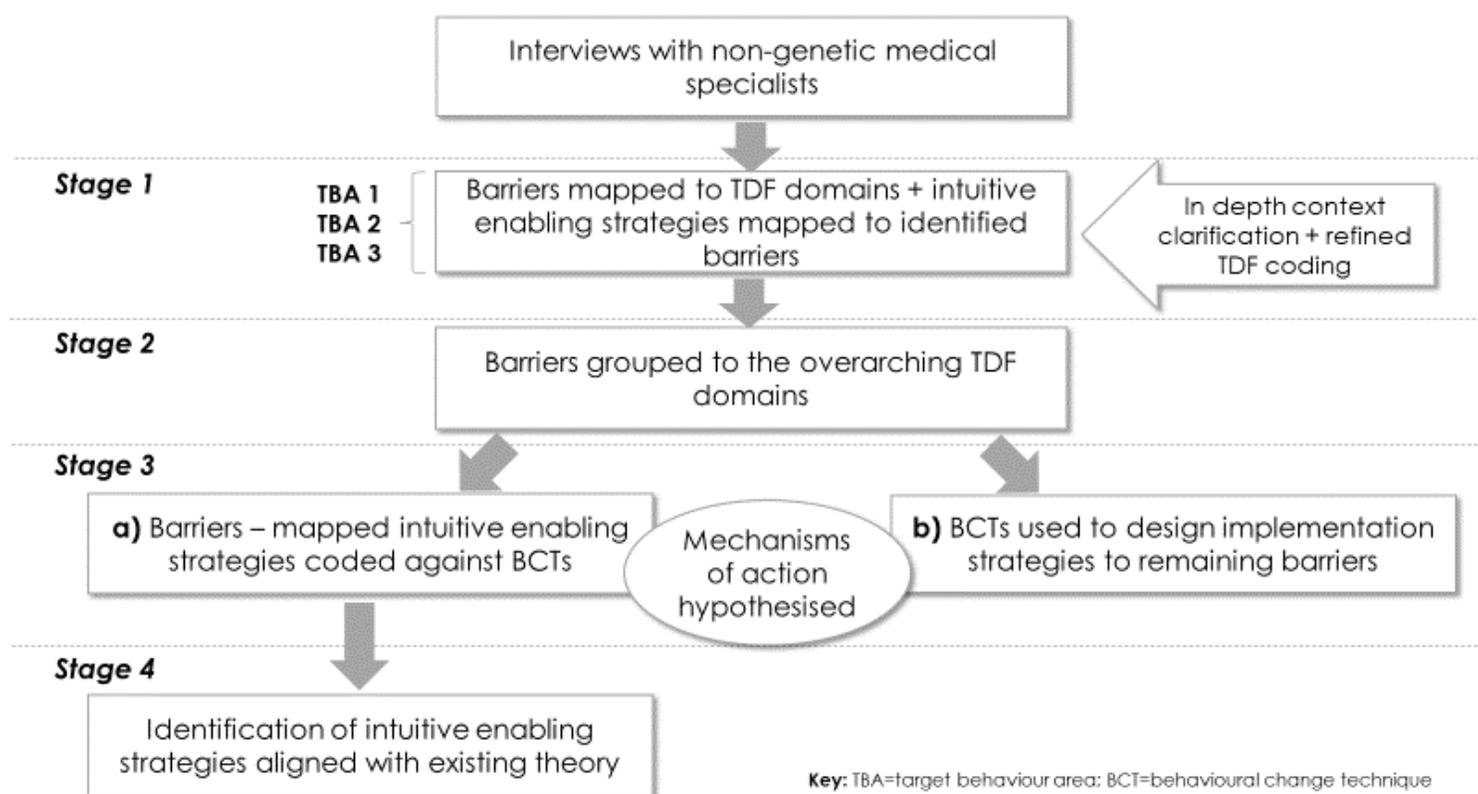


Figure 1

Overview of data synthesis process

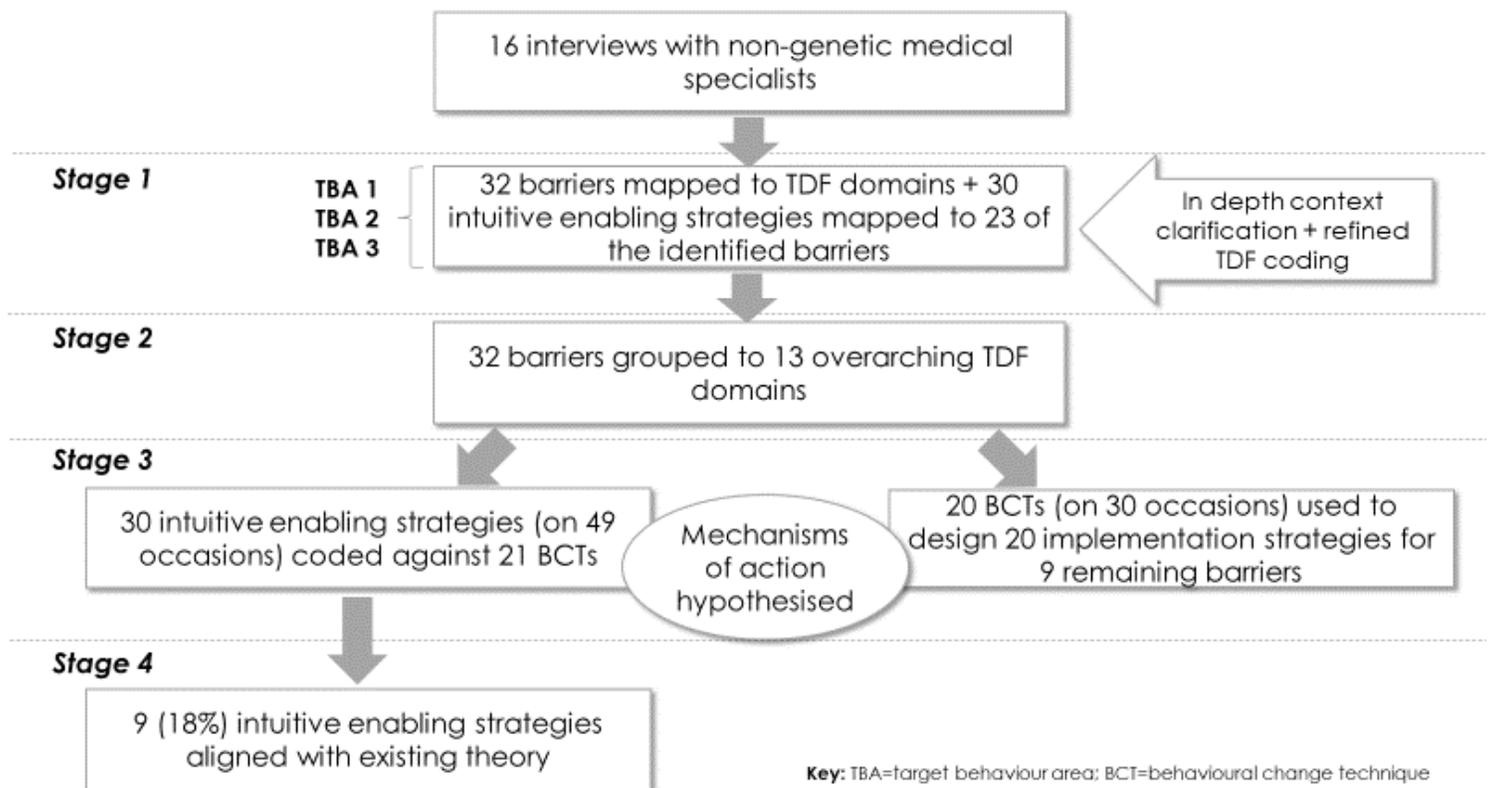


Figure 2

Summary of results of data synthesis

Supplementary Files

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