Exploring the user acceptability and feasibility of a clinical decision support tool designed to facilitate timely diagnosis of new-onset type 1 diabetes in children in general practice: A qualitative and simulation study.

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Abstract

Background: Up to half of children with new onset type 1 diabetes present to hospital in diabetic ketoacidosis, a life-threatening condition which can develop as a result of diagnostic delay. Three quarters of Australian children visit their general practitioner (GP) the week prior to presenting to hospital with diabetic ketoacidosis. Our prototype, DIRECT-T1DM, is an electronic clinical decision support tool that promotes immediate point of care testing in general practice to confirm suspicion of diabetes. This avoids laboratory testing, which has been documented internationally as a cause of diagnostic delay.

Objective: In this investigation, we aimed to pilot and assess the feasibility and acceptability of our prototype to GP end users. We also explored the challenges of diagnosing type 1 diabetes in the Australian general practice context.

Methods: Four GPs, a paediatric endocrinologist and a PhD candidate were involved in conceptualising the DIRECT-T1DM prototype, which was developed at The Department of General Practice and Primary Care at The University of Melbourne. Six GPs were recruited via convenience sampling to evaluate the tool. The study involved three phases: (1) a pre-simulation interview; (2) simulated clinical scenarios, and (3) a post-simulation interview. The interview guide was developed using the Consolidated Framework for Implementation Research (CFIR) as a guide. All phases of the study were video, audio and screen recorded. Audio recordings were transcribed by the investigating team. Analysis was carried out utilizing CFIR as the underlying framework.

Results: Major themes were identified among three domains and eight constructs of the CFIR:
(1) Outer setting: Time pressure, difficulty in diagnosing paediatric type 1 diabetes, and secondary care considerations shaped GP needs in relation to DIRECT-T1DM.
(2) Inner setting: DIRECT-T1DM fits within existing workflows, has a high relative priority due to its importance in patient safety, and GPs exhibited high tension for change.
(3) Innovation: Design recommendations included increased alarmist colouring, font style and bolding, specific language, information and guidelines, and inclusion of patient information sheets.

Conclusions: End-user acceptability of DIRECT-T1DM was high. This was largely due to its implications for patient safety and its ‘real time’ nature. DIRECT-T1DM may assist in appropriate management of children with new-onset diabetes, which is an uncommon event in general practice, through safety-netting. Clinical Trial: Not applicable to this investigation.

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Introduction

Type 1 Diabetes (T1D) and Diabetic Ketoacidosis (DKA)

Diabetic ketoacidosis (DKA) is a life-threatening emergency that can occur in up to half of paediatric patients at diagnosis of type 1 diabetes (T1D)(1). DKA occurs due to absolute insulin deficiency, a state of metabolic deterioration that can be a consequence of undiagnosed or untreated T1D(2). A single episode of moderate DKA confers risk for cognitive impairment in a child’s critical

developmental years(3). It also confers risk for coma, and death, even in developed countries such as Australia(2). An episode of DKA is also a traumatic event for both the patient and their caregivers, who report higher levels of post-traumatic stress and anxiety following a DKA admission(4).

Diagnosis of T1D before the point at which the child reaches this critically unwell state is challenging. Early symptoms are non-specific and can often be attributed to more common childhood illnesses, such as an upper respiratory tract infection, or to general childhood growth and development(5). It also requires a level of public awareness of the signs and symptoms of T1D, to facilitate timely presentation to either a GP or tertiary care to receive life-saving insulin treatment(5).

Diagnostic delay exacerbates DKA frequency and severity.

Timely diagnosis and treatment are critical, as a diagnostic delay of even 24 hours following symptom recognition confers a two-fold risk for the development of moderate to severe DKA(6, 7). It has been identified that three quarters of Australian children with T1D presented to their GP the week prior to presenting to hospital(8, 9). Best practice guidelines recommend that GPs conduct on-site point of care testing and immediately refer a child with suspected T1D to hospital for specialist review(10, 11). Diagnostic delay following a visit with a GP can occur due to the provision of an alternate diagnosis(7) and can be compounded by waiting to receive pathology test results prior to referral to confirm suspicions of T1D(9).

Our intervention: DIRECT-T1DM

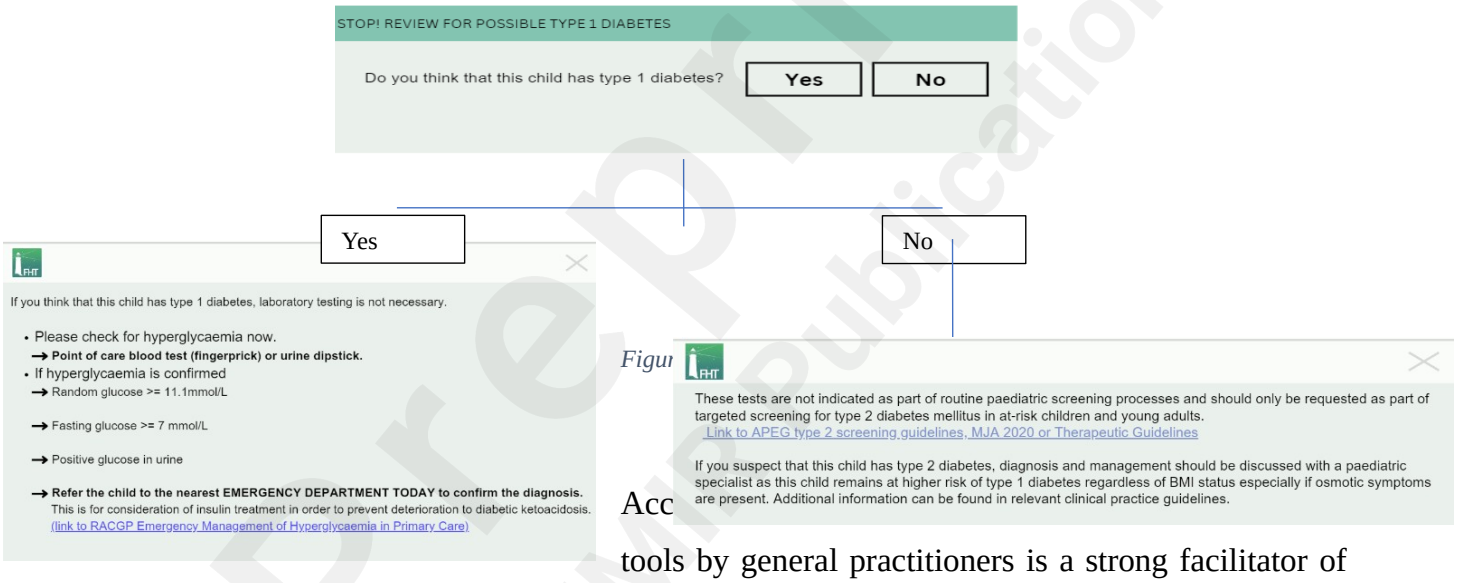
Hospital audits examining pathology test practices among GPs demonstrate that in some children, GPs have correctly identified T1D as a potential diagnosis, but have elected to request pathology tests instead of direct referral for specialist care. Electronic clinical decision support tools have shown promise in serving to promote patient safety, leading to changes in clinician behaviour that are guideline based and prevent adverse clinical outcomes(12).

In response to diagnostic delay arising from the wait associated with receiving confirmatory pathology results, we have devised ‘DIRECT-T1DM: Decision-support for Integrated, Real Time Evaluation and Clinical treatment of Type 1 Diabetes Mellitus.’ DIRECT-T1DM is an electronic clinical decision support tool, that provides a real time alert triggered by the request for a diabetes related pathology test in a child aged less than 18 years without an established diabetes diagnosis. The alert advises GPs suspecting T1D as a possibility to consider point of care testing instead of venous blood tests in a laboratory, facilitating the patient’s timely referral and safety.

DIRECT-T1DM is designed to work within Future Health Today (FHT), a clinical decision support system (CDSS) that has been developed by the University of Melbourne’s Department of General

Practice and Primary Care. FHT is installed in select general practice clinics across Victoria(13) and is compatible with Best Practice and Medical Director, electronic medical record software utilised by GPs to manage patient care(13). FHT currently works as an after-the-fact analysis, by reading electronic medical records on a centralized server within the practice overnight, applying coded algorithms to identify patients who may benefit from further review. An onscreen prompt/pop-up activates when the patient file is opened (usually when the patient returns for a visit) and displays recommendations for patient care. In contrast, DIRECT-T1DM is designed to activate in real time using a combination of information stored in the FHT server and information entered into the EMR during a consultation.

The DIRECT-T1DM pop-up has three components. The initial part of the pop-up (Figure 1) asks the question: 'Do you think that this child has new onset type 1 diabetes?' Depending on the response, clinical advice is provided to the GP regarding recommended next steps.



Figur

Acc tools by general practitioners is a strong facilitator of their use within the community(14). Elements that need to be designed effectively to increase useability and acceptability include: user-friendliness, compatibility with workload and workflow, and decreased relevance of information are barriers to the use of clinical decision support(14). Ascertaining whether these elements are acceptable to GPs is therefore an important aspect of our implementation process.

Aims

The aims of this investigation were to assess the acceptability of the DIRECT-T1DM software program to end-users by testing the program in a simulated clinical environment, and to explore additional factors influencing type 1 diabetes diagnosis that could be used to optimize DIRECT-T1DM.

Methods:

We conducted qualitative interviews with general practitioners to evaluate the acceptability of the DIRECT-T1DM software program. The qualitative interviews were conducted in a simulated environment, in three steps. First, a pre-simulation interview was conducted to understand the prior experience of the general practitioners. Then, simulated clinical scenarios were tested so that general practitioners could evaluate the software in the context of which they would use it. Finally, a post simulation interview took place to evaluate the tool and provide feedback.

Research Team and Reflexivity

CB conducted the interviews with all participants. CB is a female PhD candidate, and the results of these interviews will form part of her thesis. She has prior experience in conducting qualitative interviews with health professionals and works with general practitioners frequently in her research. She had pre-existing professional relationships with three out of the six general practitioners prior to beginning the interview process. One general practitioner interviewee has collaborated with CB in prior research in the same field of DKA prevention, and therefore may have had prior knowledge of existing guidelines and reasoning for implementation of DIRECT-T1DM. BH, JMN and MW are CB's PhD supervisors, who collaborated in the development of DIRECT-T1DM, construction and editing of interview guides, recruitment of participants, discussion and provision of feedback on interviews as they were conducted. They also provided feedback on the results and analyses that emerged from the study and edited this publication. BH is a qualitative and implementation researcher, JMN is an academic general practitioner, and MW is a paediatric endocrinologist and health services researcher.

Software Development

Business requirements and algorithm design documentation for the DIRECT-T1DM prototype were submitted in February of 2023 to the FHT technical team at the University of Melbourne. One of the GPs, paediatric endocrinologist and PhD student are investigators on this project and were involved in early-stage development of the tool. The tool was then presented to an additional three GPs for their feedback on where to improve the design aspect. The design requirements were then passed on to the software developer within the FHT technical team for production of the prototype.

Research Design: Qualitative interviews & Simulation:

GPs were invited to evaluate DIRECT-T1DM at the Digital Health Validitron SimLab at Melbourne Connect, a University of Melbourne facility designed to conduct user-acceptability testing of digital solutions in near live settings (15). This involved a pre-simulation interview, providing them context

about the purpose of the investigation and the prototype; the simulation itself, involving subset of possible five clinical scenarios where the pop-up would be triggered, facilitating on-the-spot feedback for the tool; and a post-simulation interview discussing their experience using the prototype. Each session lasted approximately 60 minutes.

The pre-simulation interview included questions surrounding the GP's experience practicing, practice location, and an estimation of the proportion of paediatric patients that they would see on an average day. It also involved a discussion around T1DM, whether they had diagnosed it before and any challenges involved with this. An explanation of the prototype, its purpose and the simulation were then provided.

The simulation session involved a 'think aloud' protocol(16), where GPs were instructed to be as verbose as possible throughout the clinical scenarios and their interactions with the pop-up. This was done with the intention of collecting on the spot feedback about the pop-up tool from each GP. GPs would engage with two allocated clinical scenarios and were presented with a third if time permitted. All clinical scenarios were designed with GP input. GPs were presented with 2 clinical scenarios, and a third if time permitted. Two out of five scenarios related to a child resenting with symptoms suggestive of T1DM, and the remaining 3 scenarios related to presentations suggestive of type 2 diabetes, polycystic ovary syndrome or where a family sought to discuss screening for T1D in the setting of a positive family history. Clinical scenarios were designed to warrant the request of a diabetes related pathology test, such as HbA1c or fasting blood glucose) and thereby triggering DIRECT-T1DM. Clinical scenarios were presented by the interviewing researcher, not by a patient actor. The reasoning for this was threefold:

(1) The intention of the interviews was to assess acceptability of DIRECT-T1DM, not to test whether GPs were aware of the guidelines. It allowed triggering of the tool so that participants were guaranteed to interact with it and having the researcher deliver the clinical scenarios allowed general practitioners to provide instant feedback as they interacted with the tool.

(2) Paediatric T1D symptoms prior to diagnosis are often vague and non-specific, so a simulated consultation with a patient actor may lead to T1D never being suspected by the GP, and

(3) If GPs suspected diabetes, they may have elected to complete the point of care testing instead of referring for pathology, and therefore never interact with DIRECT-T1DM.

The post-simulation interview was designed using the Consolidated Framework for Implementation Research (CFIR)(17), evaluating GP appraisal of the tool based on several key domains/settings: inner setting, outer setting, innovation, roles, individual characteristics, and implementation process(17). CFIR is a commonly used, comprehensive framework utilized to ascertain key

contextual determinants of success or failure of an intervention, as well as for appraisal of the implementation process, facilitating optimization of interventions before deployment into the broader community(17).

Participant selection and recruitment:

GPs were recruited via email through the personal networks of the investigators, as well as through VicREN, the Victorian Practice Based Research Network(18), and were reimbursed with $200 VISA gift-cards for their time. We aimed to recruit GPs of different genders and different levels of experience. Some non-participants were present during the interviews, including staff running the SimLab as well as additional researchers on the investigating team. Participants were made aware of their presence and introduced to non-participants.

Data collection:

The interview guide designed for all three stages of the study was devised, pilot tested and optimized by CB and BH. Video, audio, and screen recording were completed using SimLab resources. No interviews were repeated. Copies of transcripts and summaries of the results of this study were offered to participants upon request.

Data Analysis:

Analysis was facilitated by NVivo (QSR International, Release 1.6.1 (Version 14), 2022). CB initially familiarized herself with the data, by transcribing the audio recordings verbatim and reading each transcript line by line. The domains and constructs within CFIR (5 domains, 39 constructs) were transposed into the NVivo codebook. CB coded the data, grouping codes deductively into the constructs within CFIR. No domain or construct within the codebook was removed prior to initial analysis. Following initial analysis, themes within CFIR constructs were inductively generated. Following this, domains and constructs that did not pertain to our simulation study were removed. The decision made for this involved charting the existing codes to determine whether they were major or minor themes, and whether they could be assigned to a different CFIR domain. The domains and their related constructs that were removed were: Individual characteristics and roles. It was identified that CFIR constructs within domains did not exist in isolation when appraising our tool, thus visualization of how the themes link from one to the next was undertaken, as demonstrated by Sarkies et al(19). A visual annotation of the design, wording, and packaging of DIRECT-T1DM based on participant feedback has been provided, to assist with readability.

Ethics:

The ethics application for this project was approved by the Human Research Ethics Committee at the

University of Melbourne, Ethics ID: 2023-25185-45082-4.

Results

Figure 2 outlines a summary of key results across three CFIR domains and eight constructs. The results summarised here are expanded upon in subsequent sections.

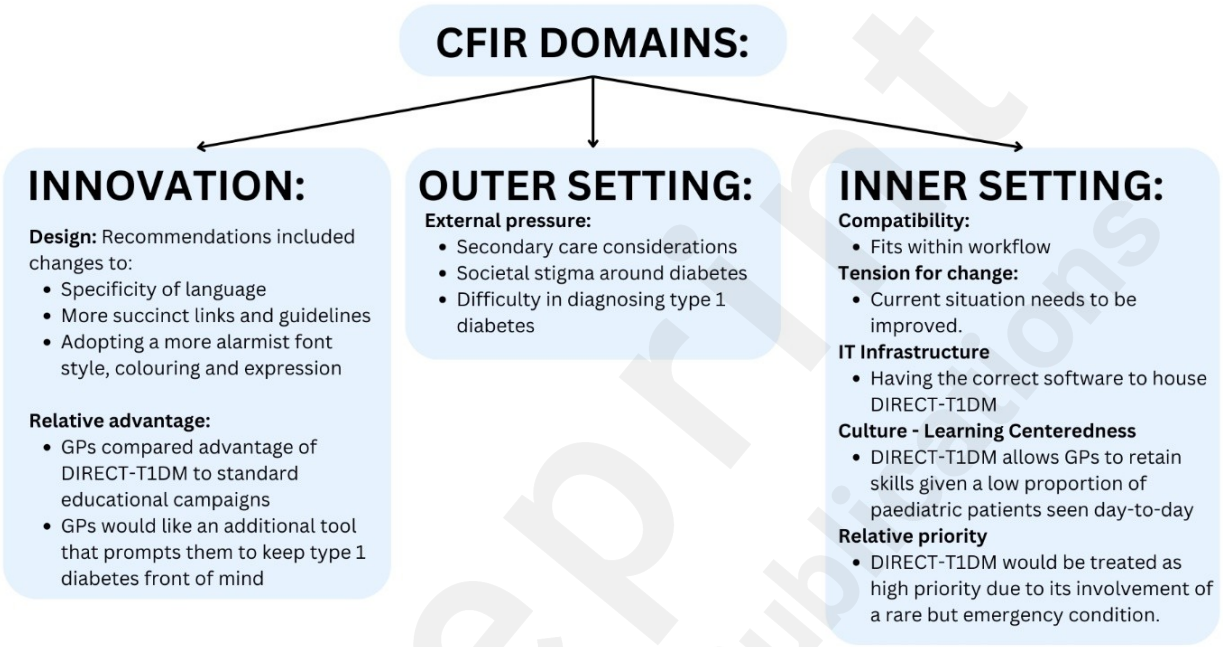


Figure 2 Summary of key results across all CFIR domains.

Participants:

Six GPs were recruited to take part in the simulation study. Participants were diverse in gender, years of GP experience and exposure to clinical decision support systems (CDSS). Two were academic registrars completing their general practice specialty training with less than two years' experience, two had three to five years' experience and two had over 30 years of experience working as a GP. Three had experience of using Future Health Today in their practice. All were familiar with Best Practice medical software. Table 1 summarises the participant demographic information.

Table 1 Participant Demographic Information

GP	Gender	Years practicing	Familiarity with Best Practice	Uses FHT in practice	Diagnosed Paediatric T1D?
GP1	Male	>30	Yes	No	No
GP2	Male	<2	Yes	No	No
GP3	Female	<2	Yes	No	No
GP4	Male	3-5	Yes	Yes	No
GP5	Female	3-5	Yes	Yes	No

GP6	Female	>30	Yes	Yes	Yes (n=1)

Of the six participants interviewed, only one GP had previously diagnosed a child with new onset T1D prior to these interviews. As such, the scenarios were not instances the participants had encountered in practice and their initial responses were based on how they believed they would have responded in practice. Participants were also explicitly asked to interact with the scenarios in a manner that would trigger the prompt (potentially not following best clinical practice), to explore the acceptability and feasibility of the tool. Some GPs reflected on what they would have done in response to each clinical scenario in practice, and whether T1D would have crossed their mind in this case. One GP stated that pre-existing awareness of the investigation before engaging in the interviews would skew a participants' response to the scenarios, especially given the scarcity of T1D presentations in practice. The think-aloud protocol was beneficial for on-the-spot feedback, appraisal, and reflection regarding DIRECT-T1DM, meeting the aims of our investigation. However, it should be noted that the burden on GP participants was increased, when compared to 'near live' scenarios or real life.

> *"I didn't read too much about [T1D] or anything, because sometimes I think it's better walking into something like this a bit fresh..." – GP 5*
> *"Yeah, I think as a participant, you probably overthink things and second guess yourself more than you would do in real life. I think even just taking your history felt really painful just now compared to real life. But that's, I guess that's part of the process. I think though as far as participating in something it's very easy." – GP 3*

INNOVATION DOMAIN:

Acceptability of DIRECT-T1DM:

The CFIR construct we aimed to assess in our interviews primarily involved the Innovation Domain, appraising DIRECT-T1DM itself, its acceptability and proof-of-concept. We found that DIRECT-T1DM was highly acceptable to GPs. This is because DIRECT-T1DM appeared as a result of an action the GP had taken during the consultation. The GPs did not anticipate encountering this tool often, as paediatric patients do not constitute a large proportion of their consultations, and of those paediatric consultations, they do not anticipate requesting many pathology tests. GPs recognized the need for this tool, stating its importance as a safety measure, to prevent potentially fatal sequelae. Design recommendations were offered to optimize DIRECT-T1DM, improving it to address specific GP needs at the point of care, as well as to improve compatibility within GP workflow, workload, and to alleviate pressures that emerge from the Inner and Outer Settings. Major constructs that

emerged from the innovation domain were design and relative advantage. A summary of the key results across all CFIR domains can be found below in Figure 2.

CONSTRUCT 1: Design

In CFIR, design refers to the degree to which the intervention is well packaged and presented(17). Major themes within this construct were surrounding the language, structure, available links, colouring and emphasis within DIRECT-T1DM.

Language and content:

(1) Positing T1D as a possibility, rather than a certainty

During the delivery and think aloud response to the clinical scenarios, it became clear that often, even when 'typical' symptoms of T1D are present, the clinical suspicion of T1D is low. As a result, this indicated that in general, GPs may be requesting diabetes related pathology as one part of a panel of several different tests to ascertain what condition the child has presented with. All GPs participating in our study requested a panel of different pathology tests alongside a blood glucose test when demonstrating what they would do in practice. This led to a design recommendation surrounding an alteration in language used in the initial pop-up. GPs suggested that in most cases, it is likely that they would be uncertain that the child had T1D, as children may not appear emergently unwell. Consequently, they believed that adjusting the language in the initial question from 'Do you think this child has type 1 diabetes?' to 'Is it possible that this child has type 1 diabetes?' would change their immediate reaction to DIRECT-T1DM. They emphasized a shared belief that it is important to still interact with DIRECT-T1DM, even in cases where there is a low degree of suspicion of paediatric T1D and believe that an alteration in language will prompt them to exclude the possibility of DKA through a point of care test before moving on to requesting further pathology.

> *"It's pretty obvious in this case, but what if it wasn't so obvious? What if I said I'd been tired and lost a few kilos, not sure, but nothing is acute though, so it could be just anything else but diabetes, then you do a sugar. It'd be, I wouldn't say I think he had it, I think, is it possible? Yeah, it's possible. So that might prompt me to do the fingerprick test." – GP 6*

> *"It's almost as if the pop up needs to say, instead of saying, do you think this child has? Because that's kind of what's most likely. Yeah, it could be like, is there a chance this child has type one? Something a bit more, not on the balance of probabilities, but more on, you don't want to miss type 1, so is there a chance this child has type 1?" – GP 5*

(2) Increasing language specificity to tailor the tool optimally for the point of care:

There was consensus regarding increasing the specificity of the language within DIRECT-T1DM. In sum, time pressure in practice necessitates pop-up alerts with information that is short, sharp, and directly actionable at the point of care. Increasing specificity of language within the tool will also

decrease the cognitive load required of the GP to interpret it mid-consultation. This is important with our tool, as it is disruptive by design. The initial question *"Do you think that this child has type 1 diabetes?"* was appraised as fitting within the needs of GPs during that point of the consultation, as it was concise and interrupted their clinical decision making at an appropriate point in time.

> *"It's good. It's a simple question. Because it's giving you a differential that you may or may not have." – GP 3*
> *"That's why it's good to be reminded. Hang on, stop, clinical point here. We want you to you know it's really good to check the sugars now because this person at high risk who might need urgent action." – GP 6*

When GPs selected 'Yes' to the initial question, they are prompted to complete a point of care test instead of pathology testing, to prevent deterioration to DKA. GPs agreed that the information provided within this tool was necessary and specific enough for actioning within the time available. The provision of reference ranges and instructions for further management should the child have hyperglycaemia was clear and helpful. More emphasis could have been placed on the initial part of the messaging, to emphasise the purpose of the point of care testing, and decrease the cognitive load required to interpret the messaging within this part of DIRECT-T1DM.

> *"It's really clear - you know what's normal and what's abnormal and when the child needs to go to emergency and how urgently." – GP 3*

> *"I like the fact that it reminds you of the reference ranges for [blood glucose levels]" – GP 2*

> *"I think I'd change it to make [a point of care blood test] really stand out. Yeah. Yeah, maybe even like, a box like. "Please check your pinprick sugar and urine ketones." I would make those stand out, like bang and bang. That's the important information. That's the action. This is what to do with information." – GP 6*

When GPs select 'No' in response to DIRECT-T1DM's initial prompt (Do you think this child has type 1 diabetes?), GPs were confused by the phrase 'not indicated as part of routine paediatric screening processes.' Some pointed out that there are no routine paediatric screening processes in general practice.

> *"[Reading DIRECT-T1DM recommendation] 'These tests are not indicated as part of routine paediatric screening.' I'm a little confused by that." – GP 1*
> *"I guess it's a bit confusing because it's saying you shouldn't use them as a routine screening. There's not really any, not really much routine paediatric screening. Yeah, like there's not bloods that we order on every child. The routine immunization and, you know, once they get to a certain age, cycle screening all that, but I'm not quite sure what that means." – GP 5*

Others believed that the text was too restrictive and prescriptive for the context of general practice. The consensus recommendation was rephrasing of the text to centralise and emphasise its key purpose. One GP also stated that due to its restrictive nature, it would be a recommendation that

would be resented and not utilised in the community.

> *"I would word it differently. "This is only to be requested as part of targeted screening." I think this sounds too prescriptive and that it doesn't…. Because that doesn't take into account experience, what the patient might want, etc, their baseline, you know…. So, I suppose, I don't want that. I would just click out of it and order the test…It would be another annoying, that'd be an annoying pop up for me. Wouldn't be helpful." – GP 6*
> *"Yes, I think less words… So, if you're trying to make people more aware of missing type one diabetes, I would just focus on that rather than sort of talking about routine screening." – GP 5*

Several GPs also reported that they would prefer a brief explanation of what osmotic symptoms are, or to replace this phrasing with more specific language delineating these symptoms instead.

> *"Is this bit about risk? So regardless of BMI status, especially if osmotic symptoms are present. Osmotic symptoms. Would be more helpful if that was a bit more specific." – GP 2*

Positioning on-screen:

GPs reported that available time in clinic to review pop-ups while seeing patients is often limited, and as a result pop-ups that appear may be relegated to lower priority of items they must address during a consultation.

> *"Just with that, it is just time pressure. So, I'm guilty of it. Like if I'm running behind and the pop up will just appear in the background and I probably won't look at it, even though I'm I know I'm supposed to." – GP4*

> *"I just feel sad that I just don't even notice the Future Health Today ones as much now… and I wish I did, but I just don't because, as I said, I think there's so much happening in consultation and it's just another thing, you know. Yeah, it just that's one thing I can ignore and pull my energy into the patient." – GP 6*

However, GPs felt that DIRECT-T1DM's attention grabbing central screen position with bold font, which is different from the location of other FHT prompts, assists them in engaging with the directive in the pop-up, even when this time pressure exists. They felt as though they were less likely to miss this pop-up, even when under pressure to undertake a consultation in a short amount of time or impacted by alert fatigue, and could use the alert to also engage with patients about the importance of referral if required.

> *"As a registrar, I'm acutely aware of the limitation of just the less experience you have, the more likely you are to miss things. So, if you have something to remind you or to make you think naturally, you'll remember the differential that you had, and particularly when you're struck for time, running late, all that, all those factors that make us, rush or forget things and that sort of a safety net for us to remember and to not under- or over-investigate them." – GP 3*
> *"I like that it's, you know, big bold letters. Stop. Consider type one diabetes. I think it's just*

> *the right level of sort of intrusive. You know it, it should pop up and be in the middle of the screen. It's appropriate." – GP 2*

> *"It's also something you could even just show the patient or the parents as well, because if it's a sort of clinical decision-making thing, a lot of people don't like the idea of having to go to emergency... So, this I think is helpful that it's right on the screen there. I use it for drug interactions as well." – GP 5*

Visual structure and design:

GPs indicated that optimizing DIRECT-T1DM to have a more simplistic visual structure will increase their engagement with the tool and contribute significantly to decreasing the cognitive load required to appraise the information held within the tool, allowing them to draw the rest of their attention into the patient during the consultation. GPs all agreed that the clinical recommendations had too many words. Some GPs recommended checkboxes, while others suggested that the information was provided in a two-step structure: (1) complete a point of care test now to prevent deterioration into DKA and (2) reference ranges and further action depending on the point of care results.

> *"...maybe with the first part just have the first line. So please check for hyperglycaemia now and then point of care test and then maybe have another to pop up afterwards....so I think it just breaks it up. That's just probably me, because I think, just I don't like to read too much text on my screen."* – GP 4

Links and guidelines:

GPs who suspected a diagnosis of type 1 diabetes were directed to Royal Australian College of General Practitioners (RACGP) "Management of Hyperglycaemic Emergencies" document; GPs would have preferred it if the link immediately directed them to the flowchart for management. The links providing guidance when type 1 diabetes was not suspected (Management of type 2 diabetes: A handbook for general practice(20), and the APEG Type 2 diabetes screening guidelines(21)) were too long, 198 and 14 pages respectively, and did not contain direct and focused instructions that could direct treatment at the point of care.

> *"If you select the type 2 or you don't think that it's type 1 diabetes, that one I found a little bit more confusing... And that the link didn't really give me any good specific information on a, you know, a child, a child with suspected type 2 diabetes.." – GP 1*

> *"... I think it's a little bit confusing the way it hooks between the type 2 and type 1 and refers to sort of very long guidelines and things. And I think the focus should just be on diagnosis and screening, like management is a sort of tomorrow problem...You're probably not even going to not to find the section in the time frame that you have to make a decision..." – GP 5*

Several GPs suggested also adding a patient information sheet to DIRECT-T1DM, to aid in explaining the child's situation to parents that go to emergency following a visit with the GP.

> *"But when you send the hospital, the other pop up which would be useful would be probably a fact sheet for parents as well…. What diabetes is, what the management is, why we're worried about it and why we have to send to the ED." – GP 2*

Colour, font style and emphasis:

Red colouring was suggested in place of the green colour scheme embedded within DIRECT-T1DM, due to a desire for this to raise alarm among GPs regarding the safety of the child and the urgency of their situation. A more consistent style of font was desired across all parts of DIRECT-T1DM. Other signifiers of emphasis on our tool were desired, such as exclamation marks, bold font, and underlining.

> *"Oh, actually I like the colour, it's calming. But I wonder if red makes it more like… more like a health alert or something, you know. You want it to sort of bang!" – GP 6*

Construct 2: Relative Advantage

Relative advantage refers to the extent to which the innovation is better than existing innovations targeting the same issue, or current practice(17). Two themes emerged when discussing relative advantages with interviewees: (1) Access to CDS compared to GP education or public awareness campaigns and (2) Relative advantage in cases where T1D may not be initially recognized by GPs.

Education programs may be desired alongside DIRECT-T1DM

Some GPs felt that an awareness campaign or GP education may also be helpful in the prevention of DKA and that these preferences would likely vary by GP. Implementation of DIRECT T1DM could benefit from pairing with an awareness campaign.

> *"I think [DIRECT T1DM's] one part of the solution. I think probably awareness raising both with the general public and in general practice. Both of those factors can complement each other." – GP 1*

DIRECT-T1DM should be used in conjunction with other methods in cases where T1D is hard to recognize:

GPs were additionally concerned with whether they are keeping paediatric T1D front of mind during their day-to-day consultations. Some GPs expressed that this could result in delays that would not be addressed by the DIRECT T1D tool which focussed on potentially inappropriate pathology requests. Many GPs stated that they would like a prompt that would help them consider T1D, based on the child's prior medical history or triggered based on the symptom input at that consult. This way, diabetes is kept front of mind, they can complete a finger-prick, and direct future management as is required. DIRECT-T1DM's trigger point, following ordering of diabetes related pathology, may not catch all children who attend general practice with new onset T1D.

> *"It would be great if we had this artificial [intelligence] system that can [read] through the patient history and detect type one [diabetes] for the children and then just [tell the GP] consider [diabetes] or something." – GP 3*
> *"Just trying to think. Like whether it would also be useful and maybe future health today already does this, but like even just weight loss in someone under 18. Like it would almost be good if that could trigger [DIRECT-T1DM] alone." – GP 5*

GPs also felt that diagnosis is also made difficult due to the paediatric setting, as children are unable to verbalise their symptoms as well as an adult may be able to, limiting their capacity to give an accurate history. Children may also vary more widely in their presentation, with symptoms less attributable to T1D.

> *"I think the challenges initially are going to be because they're a child. So, the younger they are, the less capacity they have to give you a history, and you're relying on parents or carers for information. I think the other difficulty with children is that they probably present, maybe less typically and perhaps with symptoms that you might not necessarily associate with you know, diabetes, new onset diabetes." – GP1*

GPs attributed the relative obscurity of T1D related symptoms, combined with the lack of time available in practice as another potential reason why they may elect to order the pathology test externally rather than complete point of care testing. Often symptoms of T1D sit in a 'grey area' and the urgency of a diagnosis may not be apparent, as children may appear well, or not any less well than children with other common conditions, such as viral illnesses.

> *"Yeah. So, it prompts you to do the point of care testing. Yeah, which a barrier often is time. Yeah, I think, yeah. If I'm honest, it's the right thing to do. And we should always do it. But if I'm meeting this child the first time, they're just taking a real long history...maybe it's easier for me to just order the [test] and the blood test form and send along." – GP 3*

> *"Because this guy is, I'm worried about. OK, I'll probably send to hospital. Do you see what I'm saying? So, it's more the grey, the grey area thing. So, I think I think it's a good idea to do it to prompt the GP to do a pinprick at a lower level of suspicion." – GP 6*

INNER SETTING DOMAIN:

The inner setting domain is the setting within which the intervention is implemented(17). In our case, this would be the general practice clinic. The five constructs within the 'Inner setting domain' predominantly assessed in our interviews were tension for change, relative priority, compatibility, learning centeredness and IT infrastructure.

(1) Tension for change:

GPs welcomed the implementation of DIRECT-T1DM, thus recognizing the need for a change to the current practice. Two GPs were also aware of children attending the emergency department in DKA

in part due to delay from pathology test requests, emphasising the need for the implementation of DIRECT-T1DM because of its benefits to patient safety. The other GPs still recognised a need for change to current practice, even if they were not aware of any specific patient circumstance relating to DKA presentation as a result of delayed diagnosis of T1D. They valued the introduction of DIRECT-T1DM because of its purpose as a safety mechanism to ensure that patients in urgent need of care receive it in a timely manner.

> *"You hear about people attending emergency and being diagnosed [with T1D]. So, if someone were to sort of walk into my room with [T1D], I wouldn't mind a sort of slightly alarmist pop up." – GP5*

> *"I'd prefer to do some sort of point of care test whether it's a, you know, a pinprick or a urine, at least to get an idea of where we're at. Yeah, on the spot rather than doing the pathology. So, I think that recommendation is very reasonable." – GP 1*

(2) *Relative priority:*

Despite receiving numerous electronic pop-ups and alerts each day, GPs stated that DIRECT-T1DM would have a higher relative priority when compared to other interventions. This is because they do not anticipate encountering it often, and its purpose in preventing deterioration to DKA heightening the likelihood that they would engage when it does appear.

> *"So, I think yeah, based on that because it's a paediatric age group and cohort then probably wouldn't, you wouldn't get it often, so that when you did get it you would take it seriously" – GP 3*

(3) *Compatibility*

GPs stated that DIRECT-T1DM integrates well with their workflow, as it interrupts their clinical decision-making at the exact right point in time, where they go to press 'print' on a pathology test, giving them the chance to reverse their choice, ascertain the safety of continuing with the pathology testing, and move on from there. GPs found the flow of the instructions within DIRECT-T1DM to be compatible with their workflow, as the provision of reference ranges for blood glucose levels enables them to direct future management on the spot, saving time that would have been spent looking for the appropriate guidelines. As previously stated when appraising intervention design, the structure and visual aspect of the tool could be improved to decrease the cognitive workload placed upon the GP.

> *"And I think it comes up at the right time, like when you're sort of, you know, maybe you're sort of trying to decide do I order bloods and bring them back or do I actually just need to send them now? Like it's a good prompt at that time, or you've got the file open and everything, yeah." – GP 5*

(4) Culture – Learning Centeredness

GPs had a positive attitude toward the implementation of this tool. Most GPs recognized that since they did not see a large proportion of paediatric patients day-to-day, that they may de-skill in how to treat paediatric patients. As a result, they welcomed DIRECT-T1DM as a learning opportunity.

> *"Like it's not that often that I'm ordering a sugar test, in a young person, that it would, you're not going to sort of get pop up fatigue from it. I think it would be generally, especially maybe because we don't see a huge proportion of paediatric patients [in this clinic]... it's almost more necessary I think, because you have to think of what is going to affect them differently as to a 60 year old male or whatever, but they're almost a different species in a lot of ways. So yeah, you kind of deskill a little bit if you're seeing less of them." – GP 5*

Younger doctors recognised that in their teaching practices, there is an emphasis on evidence based, guideline driven tools for learning. As a result, they acknowledged that their practices may be more open to DIRECT-T1DM in comparison to other, non-teaching practices that may not have such a strong emphasis on learning.

> *"From my experience with talking with other clinicians about this, the people who seem the most interested and accepting of it are property more junior or doctors who have maybe graduated, you know, maybe within the last five to 10 years, I think because they're a little less fixed in their in their ways and the way they practice, very guideline driven, very evidence driven and sort of. I think would appreciate these tools whereas I think maybe some older clinicians who have like vast amount of personal experience probably might not be as accepting of it." – GP 2*
>
> *"I think most people would find it helpful, even those that are very experienced, you know, for the most part. Lifelong learners as doctors and really open to changes in guidelines and, you know, being prompted to consider things that may not have. I think teaching practices in particular, and obviously as a registrar, you're in a teaching practice. So yes, most people are pretty open to it." – GP 3*

(5) IT Infrastructure

DIRECT-T1DM requires installation of Future Health Today clinical decision support software. Not all GPs interviewed practiced in clinics with Future Health Today installed. GPs without adequate IT infrastructure reflected that it may be harder to convince practices to install CDSS that sits outside their electronic medical record system than to adopt the DIRECT-T1DM intervention. As a result, this is a barrier that would decrease the usage of DIRECT-T1DM.

> *"That would be the barrier, yes. Not so much the usefulness of the pop up, but actually getting additional software or software that engages with the EMR and has the potential to have privacy issues. I think other general practices are wary of because of data breach episodes..."– GP 1*

Some GPs mentioned that DIRECT-T1DM was similar to adverse drug interaction alerts that are

already embedded within their EMRs (without the use of Future Health Today), and they believed that DIRECT-T1DM could be implemented into community general practice this way. For example, GPs saw this support tool as being a potential integration within EMR Software Best Practice, used by 65.8% of Australian general practices(22).

OUTER SETTING DOMAIN:

The Outer Setting in CFIR refers to the broader context in which the Inner Setting resides(17), this case the broader healthcare system. DIRECT-T1DM could be optimised to fit considerations that exist due to the Outer Setting.

External pressure: Secondary and tertiary care considerations:

Some GPs felt that over-referring to the emergency department (ED) was a consideration when assessing children with potential T1D. GPs were conscious of the exacerbated wait times that exist within emergency departments currently, however, believe that the risk of over-referral was an acceptable risk given the consequences of undiagnosed T1D. DIRECT-T1DM was helpful in reinforcing and encouraging the clinical decision to refer to the emergency department.

> *"I guess there's a risk that, and maybe an acceptable risk, that you over refer to ED, and that you're sending people to ED that just have a viral illness… So yeah, I guess that's a real, it's a consideration right now. It is so swamped." – GP 3*
>
> *"Yeah, I'm probably just going to send them to emergency, but this is kind of good, I think, to back up your decision making or if you're not quite sure you did the right thing." – GP 5*

When engaging with clinical decision support recommendations with type 1 diabetes was suspected, GPs found this to be inclusive in its instructions to refer to the nearest emergency department. This is because not all practices will have access to paediatric endocrinologists, which for some is related to location of practice in relation to tertiary settings. Instead, such practices would refer the child to the nearest emergency department where they are also equipped to treat DKA. In contrast, participants identified that the clinical decision support recommendations for treatment of type 2 diabetes, may not be inclusive of all practices where access to paediatricians for the treatment of type 2 diabetes may be limited, due to wait times and financial barriers. GPs recommended tailoring the information in this section of the pop-up.

> *"I guess this is worth bringing to people's attention. Just to discuss with the paediatric specialists. However, in my current clinic access to paediatric specialist is really challenging. For a variety of reasons: wait times, financial barriers. Yeah. So, I feel like that's good, that's nice, yeah. But in reality, as a GP, you gotta do something while [the patient's] waiting to be seen." – GP3*

External pressure: Societal stigma

Societal stigma surrounding diabetes and pre-conceived expectations regarding the consultation may play a role in how the instructions in the DIRECT-T1DM intervention is communicated. Parents or patients may not expect that they are referred to the emergency department following a visit to the GP for relatively non-specific symptoms.

> *"Definitely, if you come in, and… you've got some something on the screens telling you've got diabetes. Yeah, you'd be pretty distressed. And I think that there's a lot of stigma associated with diabetes. And if you're getting that as a child, it's amplified." – GP 3*
> *"I think it would take a bit of explanation to try and give the parent the idea that there's a couple of types of diabetes, type 1 diabetes, yes, they need regular insulin. But if they don't get their insulin, they get very sick, very quick. Yeah, so, you'd have to sort of really, you know, explain, or emphasize the need for urgent care." – GP 1*

Table 2 summarises how the context provided in the interviews shaped design recommendations pertaining to DIRECT-T1DM.

Table 2 Summary of the relationship between the outer setting, implementation process domain and innovation domain.

Context provided in interviews:	**DIRECT-T1DM design recommendations (INNOVATION DOMAIN)**
Alert fatigue: Pop-ups are easy to disregard.	Advantage of DIRECT-T1DM's central design. Further recommendations were made to increase how alarmist our pop-up was (add red font/colouring, add exclamation marks, add capital letters)
Cognitive load and time pressure: Too much information to appraise to make a decision within the timeframe available.	DIRECT-T1DM has the key information, it should be emphasised further, with links and other information still there, but minimised.
Workflow compatibility: Time availability may play a role in referring the child for external laboratory testing rather than conducting point of care testing.	Further recommendations to increase relative priority of DIRECT-T1DM: alarmist colours, bold font, emphasis on prevention of deterioration to DKA.
Relative advantage: Time availability increases difficulty to recognise when a patient is presenting with T1DM.	Out of scope for DIRECT-T1DM. Further support is required to address this issue.
Relative advantage: Symptoms are non-specific, easily attributable to other, more common illnesses. Safety netting: what happens when you don't even think of T1D as a possible diagnosis?	DIRECT-T1DM is triggered following initial suspicion of T1D, as a diabetes related pathology test is required. Consideration of a complementary decision support tool addressing these concerns would be beneficial.
Relative priority: 'Grey area' cases, pathology testing for T1D is likely at a low level of suspicion	DIRECT-T1DM can improve in communicating the importance of conducting point of care tests, even at a lower-level suspicion of T1D. This includes suggested changes to language, colour of the pop-up, and restructuring of the information in the part of the alert that occurs when GPs suspect T1D.
External pressure: 'Swamped' emergency departments: GP concerns regarding over-referral	DIRECT-T1DM's inclusion of links to guidelines from sources with strong evidence bases (e.g. RACGP) aids in affirming the decision to refer.
External pressure: Paediatric specialists may not be accessible for all clinics in the treatment of adolescent type 2 diabetes	DIRECT-T1DM should include more direct and focused information for the screening, diagnosis and management for adolescent type 2 diabetes and/or polycystic ovary syndrome.
Consumer information: Patients and caregivers may require additional information about diabetes and future management while they are transferred to emergency.	A plain language statement, or information sheet for patients and their caregivers should be included within DIRECT-T1DM, to provide for families where hyperglycaemia is confirmed, and they are sent to the emergency department.

Discussion

Summary

Major themes were identified within seven constructs across four CFIR domains: outer setting, implementation process, inner setting, and innovation. Acceptability of the initial DIRECT-T1DM clinical prompt and recommendations when type 1 diabetes was suspected was strong, because of its straightforward design and the fact that GPs did not anticipate seeing it often, and the severity of the consequences associated with DKA. Design recommendations were driven primarily by desire for information to be highly specific to management at the point of care, as well as to adjust the design packaging to render it more 'alarmist.' Acceptability of recommendations in DIRECT-T1DM when the GP did not suspect type 1 diabetes was mixed: some GPs found that the information provided was not specific enough to children, others appreciated the reminder regarding risk of T1D despite BMI status. One GP found this recommendation not to be useful and would ignore it in practice.

Strengths and weaknesses

The think aloud protocol was advantageous as it allowed for recognition of instantaneous response to the tool. A lot of the feedback about design packaging, relative priority, and usefulness of the tool was collected upon on-the-spot interaction with DIRECT-T1DM. Participants then had a chance to elaborate on their feedback in the post-simulation interviews. This is in line with what previous comparisons between 'think aloud' and 'near live' simulation studies have identified(16). However, it has also been identified that 'think aloud' protocols are not as beneficial when compared to 'near live' protocols when assessing compatibility with workflow and relative priority(16). As a result, our conclusions regarding workflow compatibility and priority may be weakened. Future simulation studies involving GPs can consider the 'think aloud' protocol as a tool for evaluating clinical decision support tools, especially in cases where it is unfeasible to adopt a 'near live setting.' Times where GPs can pause and take a break should be considered within the interview design, as the 'think aloud' process may induce a higher than usual level of burden on the participant.

We elected to recruit a small sample of GPs (n=6). This sample size may pose limitations toward the application of our conclusions to the wider population. Furthermore, the interviewer (CB)

had pre-existing professional relationships with three of the GPs taking part in the simulations prior to the initiation of the study. One GP had collaborated on a different study involving DKA prevention research. We recognise that this may skew perceptions favourably toward DIRECT-T1DM.

Adoption of CFIR(17) allowed for in depth analysis of the effect of different settings, contexts and GP needs on design considerations and optimisations for our tool. We were able to identify critical clinical context surrounding the challenges in diagnosing T1D, and how we can improve our tool to meet the needs that arise because of these challenges. We also identified a need for embedded risk prediction tools in general practice for the development of paediatric T1D, to respond to the challenge of recognising T1D in children with non-specific symptoms in busy general practice.

Comparison to existing research

Prior research has demonstrated that facilitating GP needs within the context of the Inner and Outer Settings is beneficial to intervention adoption(23). Having a short amount of available time in general practice is commonly reported among interviewees, not only in our study, but across the country(24). This influences the amount of time that GPs would like to spend using a clinical decision support tool, emphasising the need to tailor it for useability at the point of care. Secondary care considerations of emergency department over-referral, and patient perception has to our knowledge, not been explored within the research involving early T1D recognition. However, it has in the broader general practice context, where concerns of over-referral(25), and the tool's influence on patient perceptions, as well as communication, have been documented(26). Our study supports that design considerations should involve appraising the time spent understanding and deciding about the information within the tool.

Difficulty in diagnosing paediatric T1D stemmed from a combination of lack of available time in consultation to consider it as a possibility, non-specific presentations, and the relative scarcity of children with T1D in the population. This is consistent with existing qualitative interviews assessing the challenges in receiving a T1D diagnosis(5, 27, 28). The influence of new-onset T1D on a GP's workload was exemplified in our study, as in a combined ~80 years of GP experience, only one patient was diagnosed with new-onset T1D. This is different to existing qualitative interviews which targeted GPs that had previously diagnosed children with new onset T1D. This informs an existing research gap, as the perceptions of GPs who have not previously

seen new-onset T1D in practice may be more reflective of most GPs' experiences and attitudes when encountering a clinical decision support tool, like DIRECT-T1DM. Including GPs without a prior experience diagnosing T1D at new-onset increases the representativeness of GPs' perceptions of the challenges and barriers to diagnosing T1D, and may demonstrate differences in perceptions of how a child may present at new-onset when compared to GPs who have diagnosed T1D in the past.

Existing research studies assessing pathology referrals from general practice are quantitative in nature(6, 9, 29, 30). Our study provides clinical context as to why this may be occurring in general practice. We identified that the burden of time pressure may influence general practitioners to preference laboratory testing instead of point of care testing. Additionally, GPs may have elected to conduct the pathology test instead of point of care testing in cases where their suspicion of T1D is low, as part of a broader panel of tests to narrow down the child's diagnosis. Prior qualitative interviews with general practitioners who have diagnosed a child with new-onset T1D have demonstrated that often the child may present 'well' and not at a level of severity that would induce suspicion of T1D or evoke a sense of urgency to refer to the emergency department(5). Combining our findings with this existing research may demonstrate that pathology tests that delay diagnosis of T1D may be requested in general practice because symptom presentation is not specific enough to diabetes, or severe enough to evoke a sense of urgency from the GP's perspective. This in turn modifies our design considerations for the tool, embedding language that encourages GPs to exclude paediatric T1D as a possibility, even at a lower level of suspicion.

Acceptability of DIRECT-T1DM as a concept was high. This is because of its capacity to increase patient safety, and because GPs did not anticipate encountering the tool often. This is in line with existing research evaluating clinical decision support tools, as timing of advice is important to whether GPs engage with in in practice(14, 31). Design considerations provided by GPs were intended to improve ease of use, fit into workflow, involvement of patients, and the presentation and specificity of advice. Existing research has demonstrated that these are important facets of innovation design, particularly with clinical decision support tools, influencing the degree to which they are utilised in practice(32).

Implications for future research

This study informs the optimisation of DIRECT-T1DM, confirms the likely clinical utility as

well as end-user acceptability. As a consequence of this investigation, alterations to DIRECT T1D will be made, including more alarmist colouring, specific language and guidelines, and a patient information handout will be developed. We anticipate that these optimisations to the tool will enhance useability and acceptability. DIRECT-T1DM could also be integrated into electronic medical record systems such as Best Practice, rather than embedded within Future Health Today, and this important preliminary work informs integration of our tool, ensuring that it is acceptable and useful prior to broader implementation.

All GPs within our study identified a need for an additional clinical decision support tool for the context of new onset paediatric T1D where early symptoms are non-specific and may be under-appreciated by the GP and carers alike. It was noted in this study and in existing literature that usually T1D related symptoms are not deemed serious enough by the patient to be reported as the presenting complaint when attending general practice(5, 27, 28). Since DIRECT-T1DM is triggered upon request of a diabetes related pathology test, it will not address cases where T1D is not ‘front of mind.’ Future research can consider development of risk prediction tools for the purposes of alerting GPs when a child is at high risk of developing T1D prior to the consultation. Our investigation also demonstrates that a ‘think aloud’ protocol is suitable for qualitative evaluation of CDSS tools when it is unfeasible to adopt a near-live simulated protocol.

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Abbreviations:

T1D – type 1 diabetes

DIRECT-T1DM – Decision-support for Integrated, Real Time Evaluation and Clinical treatment of Type 1 Diabetes Mellitus

EMR – Electronic Medical Record

CDSS – clinical decision support system

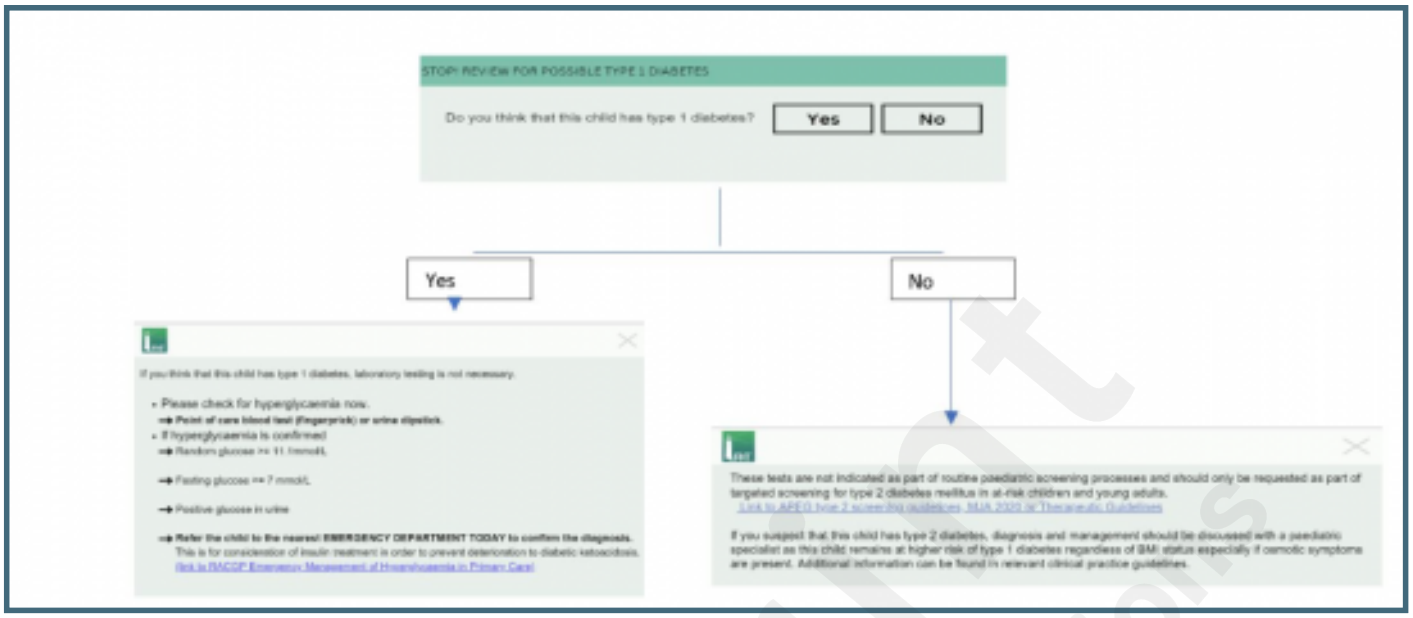
FHT – Future Health Today

CFIR – Consolidated Framework for Implementation Research

Supplementary Files

Figures

DIRECT-T1DM Clinical decision support tool pop-up alert structure.



Summary of key results across all CFIR domains.