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A Delphi consensus study introducing a Problem And attRibutes-bAsed DIabetes self-manaGeMent (PARADIGM) intervention for patients with type 2 diabetes

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ABSTRACT

Aim: Encouraging patients to improve their self-management behavior based on a strict definition of the intervention is important for a standardized delivery but, until recently, there was no consensus on the core attributes that define such an intervention. The purpose of this study is to generate a core-attribute based and stakeholder-informed problem-based curriculum for promotion of type 2 diabetes self-management structured around five core attributes derived from a previous concept analysis that defined the intervention.

Methods: Using a Delphi process for consensus achievement, physicians, clinical epidemiologists and allied health care professionals completed eleven rounds of online meetings over 6 months.

Results: Core self-management skills were identified by consensus for each of the five attributes and then used to design a model case and interactions of a problem-based self-management education intervention for delivery in a health care setting. Five model cases and associated interactions were developed by consensus for delivery in group-based and problem-based learning sessions.

Conclusions: The final structured curriculum will be useful to inform and standardize diabetes self-management based on a clear conceptual definition of the intervention and can thus help make the latter more effective tools for encouraging persons with type 2 diabetes to self manage their condition.

1. Introduction

Diabetes Mellitus (DM) is a growing pandemic that poses a significant public health challenge to countries across the globe. It is estimated that the number of people with diabetes in the region will double by 2045 [1], generating significant financial, social and development implications especially in low and middle-income countries [2]. Type 2 diabetes (T2D) is a chronic and complex condition with self-management skills being essential to achieve optimal glycemic control and optimal health outcomes [3]. Diabetes self-management (DSM) is defined as "the ongoing process of facilitating knowledge, skills and abilities necessary for diabetes self-care, delivered by specialized healthcare professionals" [4]. DSM interventions help to encourage those with diabetes to self-manage and empowers them to partner with their healthcare providers for the purpose of achieving their glycemic targets [4]. Several studies have demonstrated the effectiveness of diabetes self-management education and support (DSMES) interventions in improving health outcomes, particularly glycemic control and the prevention of diabetes complications [5,6]. Although the goals of DSMES interventions are clearly defined, there is little consensus regarding which strategies should be adopted to achieve the desired goals, resulting in a heterogenous approach to T2D interventions [6,7].

We have recently defined the operational boundaries of a DSMES

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intervention in terms of five core attributes, three of which were skillsrelated while two were information-related [7]. These five attributes cover all major aspects of self-management education including enabling individuals to cope with, manage, and make informed choices about their treatment. This study now utilizes these attributes to develop a diabetes self-management intervention that uses a problem-based learning (PBL) delivery style. This paper reports the final novel structured intervention based on these attributes and its development process.

2. Methods

The study took place between January and June 2021. The Delphi method was used to identify the content and strategies that can best be employed to develop diabetes self-management educational modules using PBL addressing the five aforementioned attributes discussed previously [7]. These attributes consist of three skills related attributes, problem solving (P), decision making (D), and taking action (A) and two information related attributes, resource utilization (Res), and patient provider relationship (Rel) [7]. The PBL approach is a form of inquiry-based learning and a technique that encourages learners to apply relevant skills and strategies to solve self-identified problems in a simulated "real-world" environment. It has also been used effectively in empowerment-based training in diabetes patient education programs [8,9].

The Delphi method is a technique that collects the opinion of relevant stakeholders. This usually involves consensus development on content with respect to a particular issue with related examples from practice discussed in different discussion rounds [10]. The process terminates when an acceptable degree of consensus is reached [10]. In this study we had two main stages: stakeholder mapping and engagement, followed by a Delphi study. This study was approved by HMC's Institutional Review Board (HMC-IRB NO.:MRC-01-20-963) and Qatar University Institutional Review Board (QU-IRB 1440-EA/20).

2.1. Stage 1: stakeholder mapping and engagement

The steering group consisted of stakeholders in diabetes patient education at Hamad Medical Corporation (HMC), the main health organization in the State of Qatar. The team consisted of diabetes educators, endocrinologists, clinical epidemiologists, and clinical researchers. The consensus development group was led by the chair of the advisory group (first author) for diabetes self-management. Members of the diabetes self-management education group were selected based on their expertize and experience in the field.

2.2. Stage 2 Delphi study

This was structured around the five attributes considered key for a diabetes self-management intervention defined in our previous concept analysis [7]. Important content to be delivered that was consistent with the five attributes was listed exhaustively and subjected to critical discussion. Discussion centered around the baseline content to be conveyed in an intervention related to a specific attribute. Each Delphi round attempted to reach consensus on what information could be dispensed with and what pertinent information was essential. Consensus was considered reached when no changes were made in a particular discussion round. The following five steps were completed in sequential Delphi rounds: (1) Introduction of the concepts of the five attributes; (2) determination of real examples that mimicked clinical practice related to each attribute; (3) scenario building; (4) interaction development and (5) refinement (if required) of the scenarios and interactions.

Due to COVID-19 restrictions, the Delphi study was conducted virtually using Microsoft Teams. The discussion was led by the senior educator (first author) and a clinical epidemiologist and endocrinologist (senior author) to optimize the physician stakeholders' engagement in each round.

3. Summary of Delphi meetings

3.1. Eleven rounds were carried out with the steering group of key stakeholders

3.1.1. First round

The purpose of this meeting was to introduce the five attributes that were published previously [7] and to agree on the content of new educational modules for DSME intervention in relation to these attributes. Stakeholders were asked to provide authentic examples of each attribute [7] derived from their daily practice to be discussed in the next round.

3.1.2. Second round

During this meeting, stakeholders recounted examples from clinical practice that exemplified each of the five attributes. Cases were created based on actual clinical examples witnessed by the educators but subsequently modified to provide a comprehensive teaching case to maximize learning opportunities and target specific learning objectives deemed necessary for people living with diabetes to learn.

The initial cases were discussed after which five educators were tasked with further developing each scenario to ensure it explored all the facets of the attribute under review. We agreed to start with problem solving, and decision-making attribute related cases for the next round.

3.1.3. Third round

The third round comprised elaboration and content clarification of the two case scenarios. Question prompts and answers were devised to support patient-educator interactions at this time.

3.1.4. Fourth round

In round four, the proposed interactions were finalized and approved. The interactions provide relevant questions and discussion prompts to help the facilitator to navigate the discussion, focusing on the relevant attributes and engage the learner in productive dialog that allows learning to proceed.

A further six rounds were conducted for the other three attributes to delineate the learning objectives and develop the PBL scenarios for each of the attributes. At the end of this process, five scenarios were developed in this Delphi process consisting of the following four steps: (1) determination of real examples that mimicked the clinical practice related to each attribute (2) scenario building, (3) interaction development, and (4) refinement (as needed) of the scenarios and interactions. A summary of each of the five case scenarios is included in Table 1. Detailed case scenarios are available in the supplementary file Table S1.

4. Results

4.1. The five model cases developed by consensus

The Delphi process resulted in the attribute centered development of five model cases and their empirical referents (which were converted to interactions). The final model cases are summarized in Table 1, and the complete cases are available in the supplementary file (Table S1).

4.2. Interactions (questions and possible answers)

The Delphi process allowed us to develop the best empirical referents (interactions) related to each model case reflecting each attribute to standardize the delivery mode of the structured education based on these scenarios. These interactions are the core of the intervention program and cover the core aspects that the consensus group felt were the main enablers of coping with, managing, and making informed choices about their management. These will be used to move patient

Table 1

Summary of the case modules.

Case Module Titles	Case Module Summary
Case module 1: Problem solving	A 48-year-old woman, married, has 4 children, lives with her family, works as a teacher, has T2D for 10 years, and has arthritis and neuropathy. Her HbA1c is 9.5% (80 mmol/mol) and BMI is 35 Kg/M2
Case module 2: Decision Making	 R: Metformin 1000 mg BID, Gliclazide 90 mg OD, and Dapagliflozin 10 mg OD. Overwhelming daily life due to family and work burden. She skips meals, medications, and self-glucose monitoring. A new medication was added at her last medical appointment. A 50-year-old man, married, has no children, lives with his family, works in office, has T2D for 20 years,
	and has dyslipidemia, hypertension, and recurrent hypoglycemia. His HbA1c is 10% (86 mmol/mol) and BMI is 30 Kg/ M2
	Rx: Insulin Degludec 30 units SQ in the evening and Aspart insulin 10-units SQ before lunch time, Metformin 1000 mg BID, Empagliflozin 10 mg OD, Dulaglutide 1.5 mg SQ weekly, Valsartan 80 mg OD, and Atorvastatin 10 mg OD.
	Uncontrolled diet, unaware of differentiation between signs of hypo and hyperglycemia signs and symptoms, unfamiliar with the blood glucose target, and facing difficulty in interpretation of blood glucose reading and how to adjust the medications accordingly.
Case module 3: Taking Action	A 42-year-old woman, divorced, lives alone, works as secretary, has T2D for 5 years and has no other co- morbidities HbA1c is 9% (75 mmol/mol) and weight is 85 kg (gained 5 kg since she started the medication). Rx: Metformin 1000 mg BID and Glimepiride 4 mg
	OD. Uncontrolled diet, frequent snacks at night, facing difficulty in reducing her weight, no motivation for physical activity. She decided to stop Glimepiride without physician consultation.
Case module 4: Resource Utilization	A 55-year-old man, married, has no children, lives alone, works as civil engineer, has T2D for 7 years and no other co-morbidities. HbA1c is 11.5% (102 mmol/mol) and his is BMI 28
	Kg/M2 Rx: Metformin 1000 (go Immo) mot and in a band 20 Kg/M2 Rx: Metformin 1000 mg BID, Glargine insulin 15 units SQ in the evening and Empagliflozin 10 mg OD. Lost his job, no insurance, stopped all medications and self-glucose monitoring due to financial problems. He adopted an unhealthy habit (smoking) due to stress.
Case module 5: Patient Provider Relationship	A 45-year-old woman, married, has no children, lives alone, has T2D for 12 years, does not have co- morbidities, started feeling numbness and heat in her foot mainly at night. HbA1c is 10% (86 mmol/mol) and BMI 33 Kg/M2 Rx: Empagliflozin 25 mg OD, Sitagliptin/Metformin 50/1000 mg BID, and recently started Glargine
	insulin 15 units at bedtime. Uncontrolled blood glucose, he stopped taking insulin because of misinformation that insulin may cause death. He has no physical activity nor diet control; he is unaware of available diabetes services.

learning towards these consensuses developed core aspects which will be delivered in a PBL setting thus ensuring the most effective flow of the educational delivery.

For example, through consensus, six key items for the interaction were selected for the problem-solving model case which included maintaining medication organization, avoidance of difficulties with meal planning, maintaining ability to monitor glucose, avoiding hypoglycemia in social settings, navigating difficulties with maintaining healthy eating and avoiding potential social problems associated with common diabetes complications. Similar interactions consisting of key items were developed and agreed by consensus for the other four model cases based on the attribute underpinning the case. These scenarios and interaction are not set in stone and expected to be continuously updated as the program is piloted within the health care system. A summary of the natures of the interactions are depicted in Fig. 1. Detailed interactions are available in Table S1 in the supplementary file. The expected learning outcomes from these interactions are listed in Table 2.

5. Discussion

Currently, DSME is largely focused around outcomes that are audited regularly against expected impact on desired outcomes by independent assessors for quality assurance. For this reason, there have been a proliferation of interventions defined by outcomes to be met while the specific day-to-day tasks or skills patients should learn are left to the health care providers to determine. Some skills taught are purely behavioral, others are a combination of behavioral and psychological, and some are management skills. Providers interpret the delivery of such education based on their experience and expertize. Thus, a plethora of interventions meet the criteria for DSME, yet it is unclear which approach works best. Thus, a gap has been recognized, and encouraging people with T2D to self-manage their condition and selection of the best delivery style have been flagged as a research priority by the Diabetes UK–James Lind Alliance Priority Setting Partnership [11]. This research constitutes a response to this priority through the development of a novel program using a structured approach that has the potential to help people with diabetes to gain an in-depth understanding of their current condition, develop realistic goals, and enable self-directed behavior changes [12].

The case scenarios were developed to facilitate interactive group discussions using a PBL approach, which has been used previously in diabetes patient education programs with demonstrable effectiveness [12-14]. The PBL strategy is consistent with adult learning and empowerment theories and is expected to facilitate needs identification, problem solving, skills and resource understanding and relationship building with the health care provider with a focus on self directed learning. The expectation is that this will enable persons with diabetes to be in control of their own lives with the ability to make informed diabetes-related decisions [13]. These case scenarios were aligned with interactions that help to provide people with diabetes with an effective avenue for "intentionally" practicing needed skills in a safe environment and to engage in a learning process that mimics reality [15]. The intervention can be delivered as group sessions over two days at the start and end of the week. Session 1 would be shorter to generate learning needs and distribute them to the group (approximately 1 h) and in session 2 each member discusses his /her objective in relation to the case. Further, the cases can be sequenced to cater to the needs of the group. Thus, if a group requires additional problem solving or decision-making education and support, these cases can be prioritized and scheduled first.

In conclusion, we have developed a novel problem-based intervention for DSME that makes use of the conceptual definition of such an intervention [7]. There is evidence in the literature for the benefit of such a PBL approach in diabetes patient education with reported gains in clinical outcomes [14] as well as durability of empowerment outcomes for at least one year [12].

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence

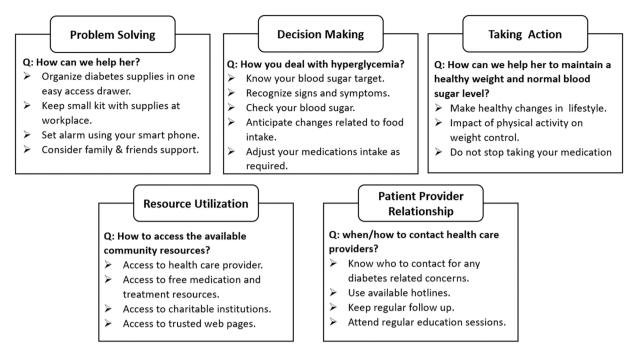


Fig. 1. Example of interaction questions and possible answers.

Table 2

Patient expected learning outcomes.

Attributes	Patient expected learning outcomes
Problem solving	 Demonstrates knowledge of importance and ways to maintain medication adherence across different social situations Demonstrates flexibility in maintaining a healthy meal plan across different life events Demonstrates knowledge of ways to maintain blood sugar monitoring in different environments like work and leisure Demonstrates knowledge of key risk factors for hypoglycemis and methods to overcome them Demonstrates skills to maintain healthy eating in the face of life stresses (e.g. culture, finances, no time, parties etc) Demonstrates knowledge required to overcome barriers with monitoring of complications
Decision making	 Demonstrates knowhow to deal effectively with hypoglycemia events Demonstrates knowhow to deal effectively with hyperglycemia events Can demonstrate a link between common medication and their mechanism of actions Demonstrates skills to decide on best practice on meals outside the home e.g. at events
Taking Action	 Demonstrates knowledge of a healthy weight and normal blood sugar level Demonstrates knowhow in maintaining a healthy diet Demonstrates skills to start and maintain effective physical activity Demonstrates knowledge of key screening regimens to avoid complication. Demonstrates ability to integrate food portions concepts with ingredients
Resource Utilization	 Can describe different types of accessible facilities for medical care and management requirements. Can describe main supportive community resources Demonstrates skills needed to determine and access the available online resources and information
Patient Provider Relationship	 Can describe the role of each health care provider Demonstrates ability to use the various pathways of contacting the health care providers Demonstrates the ability to determine who and when to contact health care providers for management needs

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pcd.2022.05.006.

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