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Consensus Recommendations for Sick Day Medication Guidance for People With Diabetes, Kidney, or Cardiovascular Disease: A Modified Delphi Process

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Abstract

Rationale and Objective: Sick day medication guidance (SDMG) involves withholding or adjusting specific medications in the setting of acute illnesses that could contribute to complications such as hypotension, acute kidney injury (AKI), or hypoglycemia. We sought to achieve consensus among clinical experts on recommendations for SDMG that could be studied in future intervention studies.

Study Design: A modified Delphi process following the Conducting and Reporting Delphi Studies reporting guidelines.

Setting & Participants: An international group of clinicians with expertise relevant to SDMG was recruited through purposive and snowball sampling. A scoping review of the literature was presented, followed by three sequential rounds of development, refinement, and voting on recommendations. Meetings were held virtually and structured to allow participants to provide their input and rapidly prioritize and refine ideas.

Outcomes*:* Opinions of participants were measured as the percentage who agreed with each recommendation, whereas consensus was defined as >75% agreement.

Analytical Approach: Quantitative data were summarized using counts and percentages. A qualitative content analysis was performed to capture the context of the discussion around recommendations and any additional considerations brought forward by participants.

Results: The final panel included 26 clinician participants from four countries and 10 clinical disciplines. Participants reached a consensus on 42 specific recommendations: five regarding the signs and symptoms accompanying volume depletion that should trigger SDMG; six regarding signs that should prompt urgent contact with a health care provider including a reduced level of consciousness, severe vomiting, low blood pressure, presence of ketones, tachycardia, and fever;

and 14 related to scenarios and strategies for patient self-management, including frequent glucose monitoring, checking ketones, fluid intake, and consumption of food to prevent low blood sugars. There was consensus that renin-angiotensin system inhibitors, diuretics, non-steroidal anti-inflammatory drugs, sodium-glucose cotransporter-2 inhibitors, and metformin should be temporarily stopped. Participants recommended that insulin, sulfonylureas, and meglitinides be held only if blood glucose was low and that basal and bolus insulin be increased by 10-20% if blood glucose was elevated. There was consensus on six recommendations related to the resumption of medications within 24-48 hours of the resolution of symptoms and the presence of normal patterns of eating and drinking.

Limitations: Participants were from high-income countries, predominantly Canada. Findings may not be generalizable to implementation in other settings.

Conclusion: A multidisciplinary panel of clinicians reached a consensus on recommendations for SDMG in the presence of signs and symptoms of volume depletion, as well as self-management strategies and medication instructions in this setting. These recommendations may inform the design of future trials of SDMG strategies.

Index words: medications, safety, diabetes, kidney disease, cardiovascular disease, modified Delphi process

Plain Language Summary

Sick day medication guidance (SDMG) is intended to prevent adverse events during acute illness; however, varying recommendations exist. This study included 26 clinical experts in a modified Delphi process to develop consensus SDMG recommendations for patients with diabetes, kidney, or cardiovascular disease. Participants reached a consensus on 42 recommendations for SDMG, including recommendations on the signs and symptoms that should trigger SDMG, the signs that should prompt urgent contact with a health care provider, and scenarios and strategies for patient self-management. Eleven medication classes were recommended to be temporarily stopped or adjusted and guidelines were provided for the resumption of medications. These consensus recommendations may inform the design of studies that examine the effectiveness of different strategies for implementing SDMG.

Introduction

Sick day medication guidance (SDMG) has been recommended by several organizations to prevent potential complications that can arise when people taking medications for chronic conditions, including diabetes mellitus, kidney, and cardiovascular diseases, experience an acute illness.[1-8] SDMG typically involves recommendations for withholding or adjusting specific medications in the setting of acute dehydrating illness that could contribute to complications such as hypotension, acute kidney injury (AKI), diabetic ketoacidosis, or hypoglycemia.[9-11] This guidance is intended to mitigate serious adverse medication complications in the setting of intercurrent illness that could contribute to death or hospitalization.[10,12-17]

A previous scoping review identified 74 documents pertaining to SDMG, however, the majority were guidelines or educational resources, and only 19 were primary research studies.[18] The review highlighted that there was little empirical evidence available to assess the effectiveness of approaches for implementing SDMG into practice, suggesting that further research to design and evaluate SDMG is required. However, there was also notable variation in the specific recommendations included in SDMG resources from different organizations. Before intervention studies can be designed to test the clinical effectiveness of SDMG, additional efforts are needed to establish consensus on the SDMG recommendations for inclusion in future intervention studies.

The objective of this study was to engage expert clinicians in a modified Delphi process to generate consensus recommendations for SDMG that could be used by clinicians and researchers designing future intervention studies.

Methods

Study Design

We conducted a modified Delphi process that followed the Conducting and REporting DElphi Studies reporting guidelines.[19] The items presented in the modified Delphi process were informed by our scoping review of SDMG, a qualitative needs assessment that included primary care clinicians (i.e., family physicians and pharmacists) and people with a chronic condition of interest, specifically diabetes mellitus type 2 (DM-2), chronic kidney disease (CKD), or cardiovascular disease. All session questions were developed and pilot-tested by team members and patient partners to ensure they were appropriate, clear, and comprehensive. Each round of the Delphi process was conducted virtually using the Zoom videoconferencing platform and lasted 90 minutes in duration. Ethics approval for this study was granted by the University of Alberta and University of Calgary Health Research Ethics Boards (ethics approval numbers: Pro00114350 and pSite-21-0024) and all participants provided informed consent.

Recruitment of Participants

International stakeholders were recruited through purposive and snowball sampling and invited to participate in the modified Delphi process if they had clinical expertise in one or more content areas relevant to SDMG including: primary care, pharmacy, nursing, and medical subspecialties (including general internal medicine, endocrinology/diabetology, cardiology/heart failure, and nephrology). Invitations were sent to authors of published primary research studies, guideline statements, reviews, commentaries, and patient or care provider educational resources that addressed the topic of SDMG, regardless of the findings, interpretation, or perspective provided in the publication. Additionally, snowball sampling was used, where invitees could also suggest other individuals to include that had expertise relevant to SDMG. Clinician participants received no financial compensation.

Patient Engagement

Two patient partners (SR and NV) participated in the study as active (non-voting) participants in all three rounds of the modified Delphi process. SR and NV assisted in structuring the research question and designing the Delphi rounds. They presented their stories of lived experience managing medications in the setting of an acute illness in the first session to provide context and framing of the importance of the topic from a patient perspective. In subsequent sessions both patient partners participated in the small group sessions to help ground the discussions of SDMG in a patient-centred context. In all sessions, patient partners contributed to the group discussion, were involved in the interpretation of this study's findings, and in the development of this manuscript. See supplement for the GRIPP2-Short Form Checklist for the Reporting of Patient Engagement in Research.[20]

Structure of the Rounds

This modified Delphi process involved three rounds with discussion and voting (Figure 1). Round One began with stories about personal experiences with SDMG provided by our two patient partners, followed by a presentation of the findings from existing literature identified in the recent scoping review. Subsequently, a full group discussion of current knowledge about SDMG was held, followed by voting on an initial set of recommendations compiled from all resources identified by the scoping review.[18] The Round One statements were categorised into three domains: (1) symptoms or signs of acute illness that should trigger SDMG (n=15 items), (2) actions and self-management advice that should be included in SDMG (n=18 items), and (3) patient groups that would qualify for SDMG and/or specific modifications (n=14 items) (Figure 1). Participants rated (based on importance of individual items) their level of agreement on a 6-point Likert scale (from 0 = strongly disagree to 5 = strongly agree). Responses were measured and reported to participants in real time using Mentimeter Interactive Software

(www.mentimeter.com) during the session. A summary document of the results from the first round were emailed to participants after the first session for further review prior to the second round.

Round Two involved small group discussions based on clinical expertise to further refine the Round One statements in four clinical groups: 1) patients with DM-2 using medications with the potential to cause hypoglycemia (sulfonylureas, meglitinides, insulin), 2) patients with DM-2 using medications that may contribute to volume depletion or hypotension (sodium glucose cotransporter-2 [SGLT-2] inhibitors, glucagon-like peptide-1 [GLP-1] receptor agonists, diuretics, renin-angiotensin-aldosterone system inhibitors), 3) patients with CKD, AKI, or at risk of AKI, and 4) patients with heart failure (HF), with or without CKD. Each group produced revised statements that were subsequently collated and refined by the facilitators from each group into a final list of recommendations. Members of each group were provided with an email summary of their group's revised statement and invited to provide any additional feedback to their group facilitator before finalizing the recommendations for final review in Round Three.

In the final round (Round 3), we presented the revised statements and accompanying contextual statements generated from the discussion to frame each group of recommendations. Participants then voted on their agreement with each recommendation on a binary scale (Disagree or Agree) using Mentimeter Interactive Software. The final recommendations were categorised into three domains (Figure 1): 1) what symptoms or signs of acute illness should trigger SDMG? (n=15 items), 2) what clinical actions should be included in SDMG? (n=15 items) and 3) what medication instructions should be included in SDMG? (n=19 items) A summary document of the results from the final round were emailed to all participants after the session accompanied by a

survey to provide anonymous feedback on their satisfaction with the process and their perception whether they felt their opinions were heard during the process.

Data Analysis

Recommendations from Rounds 1 and 3 were voted on and agreement was measured as the percentage of voting participants who agreed with each individual statement. Participants were able to abstain from voting on items they deemed were outside of their area of clinical expertise. The threshold for consensus was pre-specified at 75% agreement for each statement. Qualitative content analysis was also performed to capture the context around the recommendations developed and the accompanying discussion by participants. Data was obtained from reviewing the session transcripts, comments typed in the Zoom chat box, and field notes collected by three research coordinators attending the sessions. The data was coded using descriptive and pattern coding into categories, and high-level themes.

Results

Participants

From 60 clinicians who were sent an invitation to participate, a total of 26 participated in the modified Delphi process, representing 10 clinical areas of expertise and four countries, including Canada, the United States, Australia, and the UK (Table 1; Supplement 1). Participants worked in various practice settings including outpatient specialty clinics, hospitals, primary care clinics, and community pharmacies. There were 13 male and 13 female participants, with many (n=11) having more than two decades of clinical experience. Nine participants stated they provide SDMG frequently or always to their patients, 10 stated they only sometimes provide SDMG, and seven said they rarely or never provide SDMG.

Round One

Forty-seven recommendations in total were initially put forward to the participants in the first round, and 30 (63.8%) statements reached consensus with 75% or more of the participants voting in agreement (slightly agree to strongly agree) (Supplement 2). Participants agreed (slightly or strongly) with 12 of the 15 statements related to "what symptoms or signs of acute illness should trigger SDMG?", six of the 18 statements related to "what actions should be included in SDMG?", and 12 of the 14 statements related to "which patients should receive SDMG intervention?". There were three main themes identified from the discussion in Round 1 including 1) the lack of evidence supporting SDMG, 2) the effectiveness of current SDMG strategies, and 3) challenges for patients identifying sick days and appropriate responses. These themes and representative quotes are highlighted in Table 2. Participants emphasized that recommendations for SDMG needed to be placed in the context of individual patient needs and abilities, and that recommendations should be used to design interventions for future research, rather than used as guidelines for current clinical practice. In the absence of clinical evidence that interventions for SDMG can prevent harm, participants generally expressed a preference for more conservative general recommendations where they perceived greater potential for benefit over harm.

Round Two

Three overarching themes emerged from the discussions held within the four small group sessions; 1) distinguishing appropriate situations for self-management versus those needing health care provider support, 2) triaging and clarifying symptoms to guide SDMG, and 3) need for refinement of parameters for SDMG recommendations.

1. *Self-Management versus Health Care Provider Support*

Groups identified that SDMG should be centered on patient self-management but provided in tandem with support from their health care provider (HCP). Often there can be limited support immediately available when patients are sick (e.g., overnight, weekends, etc.) and that SDMG could be designed for patients and their care partners to self manage their sick days. It was also acknowledged this may not work for all patients and mechanisms for collaboration and oversight from their HCPs is still essential in providing SDMG. The need for individualising SDMG to the patient and their health literacy was also stressed as important, as illustrated in this quote from one participant:

"Self management is always appropriate as there is limited support and care available for patients when sick, but it should be provided in tandem with the patient trying to engage with their HCP (pharmacists might be the easiest to get in contact with during an acute illness). Also, need to consider patient's capabilities, cognitive function, support network, and health literacy to individualize and implement self management." [Participant 12]

2. *Triaging and clarifying symptoms*

All groups highlighted that focusing SDMG on symptoms and signs of volume depletion was appropriate. However, it was identified that not all SDMG monitoring recommendations listed would apply to all patients and it should be tailored to their chronic condition and personal monitoring access and abilities (e.g., weight, blood pressure, ketones, blood glucose, etc.). One group identified that signs and symptoms could be presented as a traffic light or triage approach. For mild symptoms, patients could self-manage with SDMG and for severe symptoms be informed when to contact emergency care (e.g., syncope), as highlighted in the following comment:

"So, green light would suggest that you can continue and that you are doing well. Yellow might be alerting a healthcare provider (HCP), but not necessarily, it could be a pharmacist or primary care provider, and red-light symptoms would prompt an emergency department visit or calling 911." [Participant 7]

Discussions accentuated the need to emphasize "new or worsening" signs and symptoms, as many patients can experience some of these symptoms as side-effects of their medications or part of their chronic condition:

"So, that really needs to be clear in the guidance that this was a change or worsening and that this applies to all the symptoms, vomiting and diarrhea as well, because those were sometimes common symptoms that these patients would experience at baseline."
[Participant 5]

3. *Refining Parameters of SDMG Recommendations*

Each group discussed areas for refinement of specific SDMG recommendations (e.g., signs and symptoms, medications, and appropriate timeframes). Participants recognised the need for SDMG interventions to be further studied for effectiveness, as well as implementation strategies and education to be tailored for patients and their care partners. Key questions such as, "how to ensure patients correctly identify which medications they need to temporarily stop or resume", while important, were deemed beyond the scope of this modified Delphi process.

Round Three

The revised contextual statements, and list of recommendations created following the synthesis of Round Two discussion are shown in Tables 3 and 4, respectively, categorized under three domains: 1) what signs and symptoms should trigger SDMG? 2) what clinical actions should be included in SDMG?, and 3) what medications should be included in SDMG. Forty-nine recommendations in total were put forward to participants in the final round, and 42 (86%) of them reached consensus with >75% of voting participants agreeing with the recommendation.

Domain 1: Signs and Symptoms to Trigger SDMG

Recommendations that were agreed upon addressed triaging of responses based on severity of signs and symptoms and a patient's ability to replace their fluids (Table 4; Supplement 3). For

example, participants recommended that vomiting resulting in significant fluid loss should trigger a SDMG intervention but that greater than four episodes of vomiting in 12 hours or a patient's inability to keep fluids down should prompt contact with a patient's HCP.

Domain 2: Clinical Actions That Should be Included in SDMG

Participants agreed that the SDMG was appropriate for patient (or caregiver) self-management when there is an absence of severe symptoms, patients are competent and patients (or caregivers) feel capable of coping, and patients can keep up their fluid intake. Alternatively, participants agreed that patients not coping with self-management, with symptoms that have not resolved after 72 hours, or who are unable to keep fluids down should seek assistance and support from their HCP. Participants agreed that SDMG should only be used for temporary self-management until symptoms resolve or for a maximum of 72 hours, whichever comes first. This was in recognition that even mild symptoms that last longer than 72 hours should involve management and support from a patient's HCP. Additionally, participants agreed that patients with DM-2 that have major changes in their blood glucose levels should contact their HCP for advice.

Domain 3: Specific Medication Instructions for SDMG

Out of the 13 recommendations put forward to the participants, 11 medication instruction recommendations achieved consensus for inclusion as part of SDMG. Participants agreed with recommendations for SDMG related to withholding SGLT2i and metformin, adjusting insulin depending on blood glucose and ketones, and withholding sulfonylurea/meglitinide only if blood glucose is low and until it recovers. Participants agreed with including recommendations to withhold angiotensin-converting enzyme inhibitors (ACE-I)/ angiotensin II receptor blockers (ARBs), angiotensin receptor - neprilysin inhibitor (ARNI), diuretics (loop, thiazides, and

potassium sparing), direct renin inhibitors, and non-steroidal anti-inflammatory drugs (NSAIDs) as part of SDMG.

Delphi Process Evaluation

From the 26 participants, 19 responded to the evaluation survey following completion of the Delphi process with all stating they were satisfied or very satisfied with the process and 17 stating they felt the process identified valuable SDMG recommendations to be evaluated in future studies.

Discussion

This modified Delphi process involved an international panel of clinicians from four countries and 10 clinical disciplines. Participants reached consensus on 42 recommendations that can be incorporated into interventions for testing in future clinical trials of SDMG. These included five recommendations for signs and symptoms of volume depletion that should trigger SDMG, six severe signs (reduced level of consciousness, severe vomiting, low blood pressure, presence of ketones, tachycardia, and fever) that should prompt contact with a HCP, and 14 recommendations related to appropriate scenarios and strategies for patient self-management, including frequent glucose monitoring, checking ketones, fluid intake, and consumption of food to prevent low blood sugars. Participants also reached consensus on recommendations related to withholding renin-angiotensin system inhibitors, diuretics, non-steroidal anti-inflammatories, SGLT-2 inhibitors, and metformin, and that insulin, sulfonylureas, meglitinides should be held only if blood glucose was low, while a 10-20% increase in basal and bolus insulin should be made if blood glucose was high. There were six recommendations to guide resumption of medications within 24-48 hours of resolution of symptoms and when eating and drinking normally. Achieving consensus on these clinical recommendations is a fundamental first step to

inform the design of consistent and acceptable SDMG interventions for patients with diabetes, kidney disease or cardiovascular disease experiencing acute dehydrating illnesses. However, further research is required to design the best implementation strategies to support uptake of these recommendations within the setting of clinical care and patient self-management.

This modified Delphi process builds upon our previous scoping review, where we identified several areas of inconsistences in SDMG between organizations and published resources.[18] In particular, existing resources provide variable guidance on use of antihyperglycemic medications and insulin in the setting of intercurrent illness, with some recommending patients continue these medicines, others recommending to stop them, and some suggesting to continue or stop according to blood glucose levels.[1,3,4,8,21-32] Our panel was able to come to consensus in this area and agreed with the recommendations that "*if blood glucose levels are low, hold insulin/sulfonylurea/meglitinide until blood glucose levels recover*" and that "*if blood glucose is more elevated than usual, an empiric 10-20% increase in basal and bolus insulin doses [is recommended]*". Furthermore, although some recent resources for SDMG identified GLP-1 receptor agonists[3,4,26-29,31-34] and sedative medications as medicines to withhold on sick days, our panel did not reach consensus to include these medications in recommendations due to most GLP-1 agonists having long half-lives, risks of adverse events with rapid withdrawal of sedative agents, and since they are not expected to worsen volume depletion during an acute dehydrating illness.

A strength of this modified Delphi process includes the participation of a diverse group of international clinicians with relevant multidisciplinary expertise and experience with development of educational resources for SDMG. However, it is possible that the use of snowball recruitment could have resulted in selection of a more likeminded group of participants.

Reassuringly, participants included a mix of clinicians who provided SDMG rarely as well as frequently, suggesting inclusion of individuals with differing practice behaviours. Due to the travel restrictions associated with the COVID-19 pandemic, this modified Delphi process was undertaken virtually using the Zoom videoconferencing platform and real-time feedback through the Mentimeter Interactive Software. To counter the challenges a virtual environment could potentially pose, we scheduled time within each of the three rounds for questions, discussion, and small group sessions to ensure all voices had an opportunity to be heard and incorporated into the recommendations. This modified Delphi process focused specifically on SDMG for adults, and thus guidance or inference to paediatric settings was beyond the scope of the study. Participants also recognised that the management of type 1 diabetes mellitus is associated with a higher risk of DKA and requires individualized approaches to its management, and that advice should be given early and directly from a patient's HCP. Therefore, development of recommendations specific to this population were not included in this process. Additionally, this modified Delphi process was designed to focus on clinical content for inclusion in SDMG and recommendations for implementation strategies, and thus modes of delivery to patients and HCPs, were considered outside the scope of the study. Further steps are required to develop resources and strategies to effectively communicate these recommendations to patients. Finally, participants were from high-income countries and most were from Canada, therefore the findings may not necessarily be generalizable to other settings, particularly low- and middle-income countries.

Our modified Delphi process has resolved some of the uncertainty and inconsistencies identified from various published studies and resources for SDMG. The recommendations that we developed and achieved consensus on can be used to design interventions to test the

effectiveness of SDMG. However, further research will be required to design and test effective strategies to implement these recommendations into patient care. Previous research has reported that traditional approaches to delivering SDMG are prone to patient error identifying the symptoms that should trigger SDMG and recognizing the appropriate medications to adjust.[35] Future research should test educational strategies, support mechanism, and self-management tools to ensure interventions for SDMG can implement these recommendations as intended. For practising clinicians, we recognize that the findings of this study might help guide support to people with SDMG where they deem it appropriate. However, these recommendations are not intended to form general treatment recommendations or guidelines for current clinical practice but have instead been proposed to promote a consistent and acceptable set of interventions for further implementation and evaluation to close the evidence gap around the effectiveness of SDMG in community settings.

In conclusion, we brought together a multidisciplinary international panel of experts and used a systematic process to establish consensus on specific recommendations for signs and symptoms that should trigger SDMG, scenarios and strategies for self-management versus HCP responses to sick days, and guidance on withdrawal, adjustment, and resumption of medications during and after sick days. These recommendations can be used to identify information for inclusion in clinician and patient facing resources and inform future studies to investigate the effectiveness of SDMG within clinical care and patient self-management strategies.

Supplementary Material

Item S1: Relationships between Disciplines, Professions, and Countries of Participants in the Delphi process (Numbers represent the number of participants in each category and the size of ribbons is proportional to the number participants with each characteristic)

Item S2: Modified Delphi Process Round One Results

Item S3: Modified Delphi Process Round Three Results

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Table 1: Participant Characteristics

	Number of participants (N = 26)	Percentage (%)
Clinical Discipline		
• Nephrologist	8	30.8%
• Endocrinologist	4	15.4%
• Pharmacist	4	15.4%
• Cardiologist	2	7.7%
• Diabetes educator	2	7.7%
• Primary Care Physician	2	7.7%
• General Internist	1	3.8%
• Emergency Physician	1	3.8%
• Nurse Practitioner	1	3.8%
• Clinician Researcher	1	3.8%
Years of Clinical Practice		
• <5 years	2	7.7%
• 5-10 years	3	11.5%
• 10-15 years	6	23.1%
• 15-20 years	4	15.4%
• >20 years	11	42.3%
Country		
• Canada	19	73.1%
• United Kingdom	4	15.4%
• United States	2	7.7%
• Australia	1	3.8%
Type of Practice (total does not sum to 25 as multiple answers were possible)		
• Outpatient Clinic	19	73.1%
• Hospital	15	57.7%
• Primary Care	3	11.5%
• Community Pharmacy	1	3.8%
Age		
• 31-45	7	26.9%
• 46-55	11	42.3%
• 56-65	8	30.8%
Gender		
• Woman	13	50.0%
• Man	13	50.0%
Self-reported Ethnicity		
• Caucasian/White	14	53.8%
• Visible Minority	8	30.8%
• Other	2	7.7%
• Prefer not to answer	2	7.7%
Frequency of Sick Day Medication Guidance		
• Never	1	3.8%
• Rarely	6	23.1%
• Sometimes	10	38.4%
• Frequently	7	26.9%
• Always	2	7.7%
Population Served		
• Between 30,000 and 99,999	1	3.8%

• Between 100,000 and 499,999	4	15.4%
• Between 500,000 and 999,999	4	15.4%
• 1,000,000 and greater	17	65.3%

Table 2: Round One Themes

Theme	Quote
Level of evidence to support SDMG	*"So, I just think we've got to be super careful that this is not exactly a robust area of evidence." [P25]* *"…not to say you can't stop medicines in the context of individual assessment, but real caution about systematic rollout of sick day guidance without a robust evidence base." [P22]*
Effectiveness of current SDMG strategies	*"I think that there's more than just about the medications and the context and I've been thinking about what I say to individual patients and how much I struggle to get the nuance right for an individual and then I'll say something completely different to the next person that comes into clinic." [P2]* *"…generating some parameters or guidance that we might design studies to evaluate whether these strategies are effective and safe rather than.., try to synthesize this limited evidence right now to make any kind of clinical recommendations would not be the direction we are intending to go in." [PI]*
Challenges with defining sick days	*"But I know for us it was just, how do you tell people who this pertains to. You know, it's not just the common cold, it's not just, oh I've got a runny nose, so in our tools we really tried to identify when you are at risk at dehydration and it wasn't even that, it was more like when you were at risk of dehydration, or when you are dehydrated and cannot replace your fluids because technically if you are, you know, at risk of dehydration, but you are able to replenish then you can continue your medications - you aren't dehydrated then, right. So, anyway even the term sick day was actually something that we got stuck on to tell people." [P19]* *"And, it's partly about when to stop something, what to stop, but also what to continue and how to make sure that somebody doesn't just think about the medications, but then thinks about well, how do I decide whenever I'm sick enough or it's too complex that I need to ask for advice." [P2]*

Table 1: Delphi Round Three Contextual Statements

Domain 1: What symptoms or signs of acute illness should trigger SDMG?
Context: Symptoms and signs of acute illness that trigger SDMG should be readily understandable by patients (or caregivers), and help patients identify situations when they are vulnerable or may be developing volume depletion or dehydration in the community. Patients with chronic disease may already experience some degree of these symptoms due to underlying chronic conditions, and some of these symptoms may occur after taking their medications (e.g., nausea and satiety after taking a GLP-1 analogue). Guidance should thus emphasize new or worsening of symptoms or signs, particularly when intake or fluids may not be keeping up with losses. We acknowledge that not all recommendations will apply to all patients. For example, changes in weight, blood pressure, blood glucose, and ketones would only be applicable to those who monitor these at home.
Domain 2: What clinical actions should be included in SDMG?
Context: A graded approach can be used to guide the intensity of support provided for sick day guidance, which may include self-management as well as assistance provided to a patient at home from a health care provider. Self management should be provided in tandem with education and the ability for the patient to engage with their health care provider. The ability to self-manage should be guided by a patient's capabilities, cognitive function, support network, and health literacy. Patients can self-manage if they feel capable, have support, and feel able to cope with monitoring and keeping up with fluid intake (green light) or adjusting insulin in response to blood glucose. Patients that are not coping or who develop severe signs or symptoms of hypovolemia, or those related to heart failure/volume overload or hyperglycemia while holding medications, (red light), should seek medical assistance.
Domain 3: What medication instructions should be included in SDMG?
Context: SDMG includes instructions for patients to temporarily stop medications for a short period of time. This guidance requires appropriate education and tools to allow patients or their care givers to identify the appropriate medications to be stopped during acute illness. These approaches should be co-designed and developed with patients and are beyond the scope of this modified Delphi process. However, it should be made clear that sick day medication is intended only to temporarily stop medications during acute illness and that it is important to resume medications for these chronic conditions when illness has resolved.

**SDMG = sick day medication guidance; GLP-1 = Glucagon-like peptide-1 receptor agonist

Table 4: Delphi Round Three Recommendations and Voting Results

Domain 1: What symptoms or signs of acute illness should trigger SDMG?		
One or more of the following symptoms or signs of volume depletion, when new or more frequent or severe than usual, can be considered triggers to initiate SDMG:		
	Response, (No. agreed / No. of respondents)	**(%)**
Vomiting or diarrhea, resulting in significant fluid losses	25 / 25	100
Anorexia or nausea, resulting is significant decrease in fluid intake	22/25	88
New lightheaded, dizziness, or fainting, particularly with sitting or standing up	22//25	88
Decreased weight (3kg in 2 days)	20/24	83
Decreased urine output	18/24	75
New weakness, lethargy, or fatigue	12/24	50
Increased thirst	7/25	28
New dry mouth, lips, or eyes	2/24	8
The following symptoms and signs should be considered severe enough to prompt contact with a health care provider:		
Reduced level of consciousness or new confusion	25/25	100
Vomiting > 4 times in 12 hours or cannot keep fluids down	24/25	96
Low blood pressure (systolic blood pressure < 80 mmHg; drop of 20 mmHg in systolic; or 10 mmHg in diastolic)	23/25	92
Moderate or high ketones (for patients taking SGLT2i or insulin)	21/23	91
Increased heart rate (increase by 30 bpm)	19/24	79
Fever (temperature > 38 degrees C (101°F) on two measurements)	18/24	75
Extreme thirst	7/24	29
Domain 2: What clinical actions should be included in SDMG?		
Self-management is appropriate when:		
There is an absence of severe symptoms	24/25	96
Patients feel they are able to cope	23/25	92
Patients can keep up with their fluid intake.	21/24	88
Assistance/support from a health care provider should be sought when:		
Patients who feel they are not coping	25/25	100
Signs and symptoms have not resolved within 72 hours	25/25	100
Patients cannot keep up with intake of foods or fluids	24/24	100
Patients are experiencing recurrent low blood glucose readings	24/25	96
Patients experience significant increase in blood glucose not coming down with self-adjustment after 24 h	24/25	96
911, emergency or urgent care should be sought for:		

Difficulty or rapid breathing	24/24	100
Reduced level of consciousness or new confusion	23/24	96
Fainting or falls	17/24	71
Sick day guidance should include the following instructions to reverse volume depletion or dehydration and avoid hypoglycemia or ketoacidosis:		
Patients receiving insulin should receive instructions for more frequent self-monitoring of blood glucose q4-6 hours while awake and for the duration of symptoms	24/24	100
Patients receiving SGLT2i, insulin, or on ketogenic diets should check ketones	19/20	95
Increase fluid intake with limited caffeine, and consider electrolyte replacement solutions	22/24	92
Patients who took their daily dose of sulfonylurea should be instructed to try to eat foods to prevent low blood sugars until the effect of the medication has worn off (~12-24 hours)	18/23	78
Domain 3: What medication instructions should be included in SDMG?		
SDMG should include instructions to temporarily stop these medications:		
SGLT2i (e.g., empagliflozin)	22/23	96
If blood glucose low, hold insulin/sulfonylurea/meglitinide until blood glucose recovers	22/23	96
NSAIDS	21/22	95
Potassium sparing diuretics (e.g., amiloride, spironolactone)	18/19	95
Loop diuretics (e.g., furosemide)	18/19	95
ACE-I/ ARBs (e.g., perindopril, candesartan)	18/20	90
Thiazides/thiazide-like diuretics (e.g., HCTZ, indapamide)	18/20	90
ARNI (sacubitril/valsartan)	15/17	88
If blood glucose more elevated than usual, empiric 10-20% increase in basal and bolus insulin doses (if unsuccessful at lowering blood glucose, contact HCP)	20/23	87
Metformin	19/22	86
Direct Renin Inhibitors (aliskiren)	14/17	82
GLP-1 analogues (e.g., liraglutide)	12/21	57
Sedative medications (e.g. benzodiazepines, Z drugs)	8/17	47
For medication that can be temporarily stopped, stop for:		
Up to three days	24	100
Until signs and symptoms have resolved	21	88
Resuming medications:		
For those that can cause hypoglycemia, they should be resumed at usual doses as soon as symptoms improve and normal eating and drinking resume	23/23	100

Seek assistance from health care provider about their medications when symptoms last > 72h	23/23	100
For those that are volume depleting, they should be resumed at usual doses with 24-48 h or eating and drinking normally	21/22	95
Others than those immediately above, they should be resumed at usually doses within 24-48h of eating and drinking normally	19/20	95

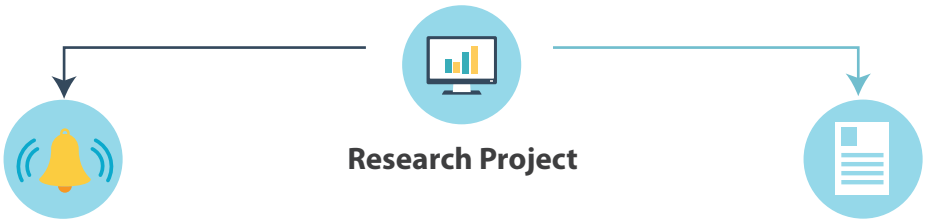
*Dominator varies, as participants were allowed to abstain from voting on items they deemed outside their expertise. Consensus was pre-specified as ≥75% agreement. Items that achieved consensus are written in black, while those that did not are written in grey.

**No. = number; SDMG = sick day medication guidance; HCP = health care provider; GLP-1 = Glucagon-like peptide-1 receptor agonist; NSAIDs = Non-steroidal anti-inflammatory drugs; ARNI = Angiotensin receptor - neprilysin inhibitor; HCTZ = hydrochlorothiazide; SGLT2i = Sodium/glucose cotransporter-2 inhibitors

List of Figures

Figure 1 – Modified Delphi Process Flow Diagram

Abbreviations: SDMG=Sick Day Medication Guidance, T2DM= Type-2 Diabetes Mellitus, BP=Blood Pressure, AKI=Acute Kidney Injury, CKD=Chronic Kidney Disease



Research Project

Needs Assessment
Interviews/focus group with physicians, pharmacists and patients

Scoping Review
Primary research studies, guidelines, educational resources

Modified Delphi Consensus Process Domains
3 Rounds of Stakeholder meetings

Round 1: Overview and Survey

What symptoms or signs of acute illness should trigger SDMG? (n=15 items)

What actions should be included in SDMG? (n=18 items)

Which patients should receive SDMG intervention? (n=14 items)

Ranking of general statements (6-point Likert scale and qualitative analysis of comments/feedback)

Round 2: Focused session statements

Small groups

T2DM-Hypoglycemics

T2DM-Volume/BP

CKD-Post AKI

Heart failure +/- CKD

Refine general statements based on clinical expertise for specific conditions in small groups & Qualitative analysis of comments/feedback provided

Round 3: Obtain consensus on SDMG recommendations

What symptoms or signs of acute illness should trigger SDMG? (n=15 items)

What should be included in SDMG? (n=15 items)

What medication instructions should be included in SDMG (n=19 items)

Ranking of revised statements (Binary scale) for inclusion as SDMG recommendations