

# Problem-based shared decision-making in diabetes care: a secondary analysis of video-recorded encounters

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#### **ABSTRACT**

Objectives To describe the range of collaborative approaches to shared decision-making (SDM) observed in clinical encounters of patients with diabetes and their clinicians.

Design A secondary analysis of videorecordings obtained in a randomised trial comparing usual diabetes primary care with or without using a within-encounter conversation SDM tool.

Setting Using the purposeful SDM framework, we classified the forms of SDM observed in a random sample of 100 video-recorded clinical encounters of patients with type 2 diabetes in primary care.

Main outcome measures We assessed the correlation between the extent to which each form of SDM was used and patient involvement (OPTION12-scale).

Results We observed at least one instance of SDM in 86 of 100 encounters. In 31 (36%) of these 86 encounters, we found only one form of SDM, in 25 (29%) two forms, and in 30 (35%), we found ≥3 forms of SDM. In these encounters, 196 instances of SDM were identified, with weighing alternatives (n=64 of 196, 33%), negotiating conflicting desires (n=59, 30%) and problemsolving (n=70, 36%) being similarly prevalent and developing existential insight accounting for only 1% (n=3) of instances. Only the form of SDM focused on weighing alternatives was correlated with a higher OPTION12-score. More forms of SDM were used when medications were changed (2.4 SDM forms (SD 1.48) vs 1.8 (SD 1.46); p=0.050). Conclusions After considering forms of SDM

Conclusions After considering forms of SDM beyond weighing alternatives, SDM was present in most encounters. Clinicians and patients often used different forms of SDM within the same encounter. Recognising a range of SDM forms that clinicians and patients use to respond to problematic situations, as demonstrated in this study, opens new lines of research, education and practice that may advance patient-centred, evidence-based care.

#### Introduction

Biomedical and technological advances in healthcare have resulted in an increased array of treatment options available to improve healthcare outcomes. This is especially pertinent in diabetes

# WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Conventionally, shared decisionmaking (SDM) is often defined as a stepwise, collaborative process in which the pros and cons of multiple options are weighed. However, in clinical practice, patients and clinicians need to respond in a sensible way to a broad range of situations, going beyond selecting one alternative from a set of prespecified options.

#### WHAT THIS STUDY ADDS

⇒ SDM is highly prevalent in primary diabetes care after considering collaborative decision-making processes other than weighing alternatives only. Most consultations contained multiple forms of SDM, with SDM focused on solving problematic situations being most prevalent.

# HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Allowing for the range of SDM forms that occur in practice beyond weighing alternatives expands the practice relevance of SDM and changes the problem researchers and policymakers need to solve: from nonoccurrence to quality improvement.

care, where the development of e.g. novel pharmacological agents (such as GLP-1 (glucose-like peptide 1) receptor agonists <sup>12</sup> and sodium-glucose cotransporter-2 (SGLT2) inhibitors <sup>12</sup>) and technological innovations (such as flash glucose monitoring, <sup>3-6</sup> smart insulin pens <sup>67</sup> and pumps <sup>68</sup> and the artificial pancreas <sup>89</sup>) are rapidly changing the field. To form sensible plans of care that respond well to and advance the situation of the individual patient, that is, to make care fit, patients and clinicians must collaborate to determine what to do, work often referred to as shared decision-making (SDM). <sup>10-13</sup> SDM is crucial for the practice of evidence-based medicine. <sup>14</sup>

Forms of purposeful SDM	Type of decision sought	Example
1. Weighing alternatives	A determination that pros, cons and preferences are optimally balanced in the selected option	Emma, a 52-year-old woman, has had type 2 diabetes for over 10 years. Her HbA1c has been rising for over 9 months. She is increasingly fatigued and would like to feel better soon. With her clinician, she decided that it is time to change her diabetes medication regime. After considering the different medications available and their respective pros and cons, they decided to start basal insulin.
2. Negotiating conflicting desires	An agreement reconciling conflicting positions or desires within or between parties to decisionmaking	Emma has been on insulin for a few years now. Her fear of complications has led to a programme of care with which she has frequent and dangerous severe hypoglycaemic events. These are scary to her and her family, who is pushing Emma to stop or cut back on her medicines. Emma feels torn between easing her glycaemic control to reduce the incidence of hypoglycaemia, but potentially also increasing the risk of complications due to hyperglycaemia. Together with her clinician she develops a compromise by which she will reduce the intensity of her programme, discontinuing insulin, and switches to a non-hypoglycemic agent.
3. Solving problematic situations	The conclusion that different potential ways of understanding and advancing the problematic situation have been sufficiently uncovered, evaluated and coordinated.	With the oral medication in combination with diet and regular exercise, Emma's diabetes has been regulated well over time. Over the last few months, however, she has become the primary caregiver of her spouse, who was diagnosed with cancer. With caring for him taking up most of her time, she struggles with sticking to her diet and regular exercise. Together Emma and the clinician try to find ways to stay healthy physically and emotionally, that will fit with the demands and limitations of her new situation. They come up with a plan to try out and refine over the upcoming months.
4. Developing existential insight	The existential insight into what ultimately matters that has developed sufficiently that what to do becomes obvious and meaning is found in the splintered elements of a person's life.	At 81, Emma has been receiving dialysis for end-stage diabetes-related kidney disease for 3 years. As they talk, it tearfully emerges how life-diminishing dialysis is becoming for her and how she feels that her life is breaking apart. Together Emma and her clinician develop an understanding that it might be time to step away from dialysis and to implement a palliative care approach.

To ensure that evidence-based diabetes care is personalised, international diabetes guidelines emphasise the importance of SDM. 15 In theory, SDM is frequently considered a process for decisions in care which are subjected to patient preferences ('preference-sensitive') and in which a stepwise approach can be used of fostering choice awareness, discussing options, discussing preferences and making a final decision. 16-18 It is often focused on 'taking the right steps, in the correct sequence, at the right time. 19 Although it may seem useful to circumscribe SDM to this particular practice, SDM, defined in this way, is reported as rare in practice, even as clinicians report 'doing SDM' routinely.<sup>20</sup> In practice, however, patients and clinicians must respond to a broad range of situations collaboratively. The problems they face may call for different manners of making decisions together other than selecting from a set of established alternatives as they form plans of care that make sense as possible ways to respond to the problematic situation of each patient.21 22 Hargraves et al have proposed that there may be different forms of SDM depending on the situation that needs to be resolved.<sup>23</sup> This 'purposeful SDM framework' proposes that the situation the patient is facing determines the way in which patients and clinicians interact and collaborate in the decision-making process. Purposeful SDM identifies at least four forms of SDM appropriate for different situations: (1) weighing treatment alternatives, (2) negotiating conflicting desires, (3) solving problematic situations and (4) developing existential insight<sup>23</sup> (table 1). The framework, thus, suggests that in addition to the canonical form of SDM in which alternatives are weighed, there are at least three other SDM forms in which patients and clinicians jointly and deliberately engage in conversations to decide how to address the patient's situation. Hargraves et al do not consider these forms to be separate entities but rather a spectrum of collaborative decision-making processes.

To date, it is unknown how the different problem-based forms of SDM manifest in daily clinical encounters. The primary aims of our study were to assess (1) which forms of SDM are used in clinical diabetes care, (2) how these forms of SDM relate to the final treatment decision, and (3) how they correlate with scores on clinicians' efforts to involve patients in decision-making. Secondarily, we also aimed to assess the extent to which within-encounter conversation aids promoting SDM affect the prevalence and distribution of the different forms of SDM. In SDM, decisions

are to be made based on patients' informed preferences or desires, and these desires—focusing on desires towards an option, a personal want or disposition, a situation or integrity of self—may be an important driver for the most appropriate way for patients and clinicians to collaborate. Therefore, the other secondary aim of our study was to assess what kind of desires patients and clinicians voiced during the consultation and how these desires are associated to the forms of SDM used during the clinical encounter.

#### Methods

#### Data source

This is a secondary analysis of the TRICEP study ("Test Use of a Decision Aid in a Clinical Visit to Help Patients Choose a Diabetes Medication" registration #NCT01293578 ClinicalTrials.gov), a multicentre randomised trial (n=350 patients), which compared primary care as usual with and without using a within-encounter SDM conversation aid.<sup>24</sup> This conversation aid presents general considerations and adverse effects of diabetes medication, organised by topics that matter to patients, such as weight change, daily routine, 'blood sugar' levels (haemoglobin A1c (HbA1c)), daily 'blood sugar' testing, hypoglycaemia and cost. The latest version of the tool is freely available at https://diabetesdecisionaid.mayoclinic.org/.<sup>24</sup> The study took place between July 2010 and May 2014 across 20 rural, suburban and inner-city primary care practices from six health systems in the Midwest (Minnesota, Wisconsin), USA. The video recordings of the patient-clinician encounters were used in this secondary analysis. The Mayo Clinic Institutional Review Board approved the original study and this secondary analysis (IRB #10-006952 and #19-011553). All participating patients and clinicians provided written informed consent.

#### Sample size and study design

This is an observational, cross-sectional retrospective study using video recordings. Using a random number generator, we selected a random convenience sample of 100 video-recorded clinical encounters, irrespective of the TRICEP trial arm. We judged that 100 encounters would be sufficient to address the descriptive primary aims (aims 1-3). We selected 20 encounters from TRICEP as a training set to practice the self-designed coding scheme

Patient demographics	N=100
Study arm (n)	
Primary care (control)	31
Primary care using a within-encounter conversation aid (intervention)	69
Age, years (mean, SD)	60.0 (9.7)
Women (n)	41
Body mass index, kg/m <sup>2</sup> (mean, SD)	36.7 (9.1)
Race (n)	
White	85
Black	9
Other	6
Education* (n)	
High school or less	29
Vocational/4-year college degree	46
Graduate degree	9
HbA1c, % (mean, SD)	8.9 (1.3)
Years with diabetes* (n)	
<b>(5</b>	27
5 to<10	32
>10	30
Literacy* (n)	
Inadequate	9
Adequate	81
Clinician demographics	N=89
Age, years (mean, SD)	45.2 (11.3)
Women (n, %)	45 (50.6)
Years in practice (mean, SD)	12.0 (10.4)
Number of encounters included (mean, SD)	3.8 (3.3)

and subsequently coded the remaining 80 selected encounters. Patients and members of the public were not involved in the design, conduct, reporting or dissemination plans of this research,

#### Measures

Given the novelty of coding various forms of SDM, we used a self-developed coding scheme to count, characterise and time-stamp the forms of SDM used and desires stated by patients and clinicians (online supplemental material 1). Two team members (MMR and MK) drafted the coding scheme based on theories presented in a previous publication on SDM forms<sup>23</sup> and discussed it with the rest of the team. In the coding scheme, SDM forms were categorised as (1) weighing treatment alternatives, (2) negotiating conflicting desires, (3) solving problematic situations and (4) developing existential insight. We pilot tested the coding scheme on encounters until we felt no further changes to the scheme were needed (after n=14 encounters). The encounters in this pilot were not included in our final sample.

Pilot testing showed that multiple forms of SDM could be used in the same encounter and that it was difficult to determine when a form of SDM finished—other than when another form of SDM started. We, therefore, allowed multiple SDM forms per encounter and coded only the start of the form of SDM. In addition, we also collected and coded voiced desires of both patients and clinicians and characterised them into desires towards (1) an option, (2) a personal want/disposition, (3) a situation or (4) integrity of self, in line with the classification used by Hargraves *et al.*<sup>23</sup> We used 20 video-recorded encounters to practice the coding scheme. These video-recorded encounters were included in the analyses. Two investigators (MMR, a medical doctor, and MK, a clinical linguist

and decision scientist) coded all encounters in duplicate and independently. All codings were discussed in regular meetings and disagreements were resolved by discussion and consensus.

#### **Data extracted**

We extracted patient and clinician characteristics along with the assigned study arm from the TRICEP database. In addition, from the database we extracted scores from the 12-item Observing Patient Involvement in Decision Making (OPTION12) scale for each encounter, a validated observer-based scale used to quantify the extent to which clinicians involve patients in the decision-making process. Researchers scored the encounters with the OPTION12-scale in the original trial, prior to this secondary analysis, and, thus, blinded to our research questions. Scores are reported on a 0–100 scale, with higher scores implying more behaviours to involve patients. The reviewers of this secondary analysis were blinded to the OPTION12 scores while coding.

#### Statistical analyses

We used descriptive statistics to report on participant characteristics and numerical estimates, mean and SD for continuous variables and counts and frequencies for categorical variables. To compare study arms, we used a Kruskal-Wallis test for continuous and a  $\chi^2$  test for categorical variables. To assess SDM instances, an Analysis of Variance (ANOVA) was conducted, where the number of instances was categorised into groups, adjusted by whether a medication change occurred as well as the intervention arm. We used an alluvial plot to represent the instances and forms of SDM used and the order they occurred within the encounter. We used a boxplot to show the distribution of the OPTION12 score for encounters focused on weighing alternatives, either as the only form of SDM used or as part of multiple forms used or encounters that were not focused towards weighing alternatives. We collected data in REDCap (Grant UL1TR002377) and conducted our analysis in SAS V.9.4 (SAS Institute, Cary, North Carolina).

#### **Results**

#### **Participants**

In total, we included and coded 100 video-recorded clinical encounters (intervention arm: n=69, control arm: n=31). Of the 100 participating patients, 59 were men. Patients had a mean age of 60 years (range: 41–85 years) and a mean Body Mass Index (BMI) of 36.7 (SD 9.14) kg/m². The average HbA1c was 8.9% (SD 1.26%) and most patients (54%) had an HbA1c >8.5%. A third of the patients had lived with diabetes for over 10 years (table 2). Patients in the intervention arm were younger compared with those in the control arm (59 vs 63, p<0.03). Otherwise, all patient characteristics were comparable between arms (online supplemental table 1).

The clinical encounters involved 89 clinicians, of which 44 (49%) were men. On average, clinicians had been working in practice for 12 years (SD 10.4) and 79% of clinicians had completed their medical training (table 2). The average length of the clinical encounter was 17.0 min (range: 4.0–43.6 min).

#### Forms of SDM used

In 86 of 100 clinical encounters, we identified at least one form of SDM. In 31 (36%) of these 86 encounters, we identified one single form of SDM, two forms in 25 (29%), and three or more instances in 30 (35%) encounters. Figure 1 depicts the instances in which patients and clinicians switched to a different form of SDM during the clinical encounter.

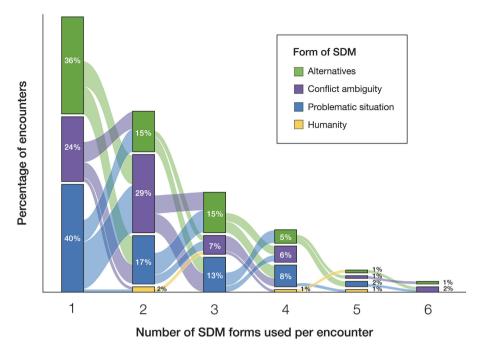


Figure 1 Switches in forms of SDM used during clinical encounters. Light coloured waves reflect changes from one SDM form to another. Percentages reflect the frequency of SDM form used. X-axis represents the instances of SDM used within the encounter. Only consultations in which at least one form of SDM was used were included in this figure (n=86). SDM, shared decision-making.

Of the observed total of 196 instances of SDM, 70 (36%) were focused on solving a problematic situation, 64 (33%) on weighing treatment alternatives and 59 (30%) on negotiating conflicting desires. Three (1%) of the instances sought to develop existential insight.

#### **Treatment decisions**

Patients and clinicians decided in 27 of the 100 encounters to change the medication of the patient, with no differences between study arms. A change in medication was related to more instances of SDM used during the encounter (no change: 1.8 instances of SDM (SD 1.46); change: 2.4 instances of SDM (SD 1.48), p=0.050). This effect was maintained after adjusting for the use of a conversation tool.

#### Patient involvement in decision-making

When patients and clinicians used SDM focused on weighing different treatment alternatives, either as the only form of SDM used or as one of multiple forms of SDM used during the encounter, this was related to a higher OPTION12 score compared with when they used other forms of SDM (26.4 (SD 9.6) vs 20.5 (SD 8.9), p=0.0056), even when adjusted for the use of a within-encounter conversation aid (online supplemental figure 1). In the 14 of 100 encounters, in which we identified no form of SDM, the scores on OPTION12 were lower (mean: 17.3 (SD 16.3)), irrespective of the use of a conversation aid (figure 2 and online supplemental figure 1).

#### **Conversation aid intervention**

The use of a conversation aid during the consultation did not affect the amount of forms of SDM used (use of within-conversation aid: mean: 2.08; 95% CI (1.88 to 2.27), without use of within conversation aid: mean: 1.88; 95% CI (1.55 to 2.21), p=0.32). or type of forms of SDM used during the consultation (p=0.51, table 3).

#### Secondary aim: desires

In 83 of the 100 encounters, we identified at least one voiced desire, resulting in a total of 247 voiced desires with a mean of 2.5 (95% CI 2.07 to 2.87) desires per encounter. Most encounters contained one (n=23, 28%), two (n=14, 17%), three (n=19, 23%) or four (n=12, 15%) desires (online supplemental table 2). Desires were more often stated by patients than by clinicians (N=157, 64% vs N=90, 36%, p<0.001) (online supplemental table 3). Voiced desires were directed towards a personal want or disposition (n=132/247, 53%), a type of medication or lifestyle (n=81/247, 33%), a situation (n=27/247, 11%) or about the integrity of self (n=7/247, 3%).

We found that the use of a conversation aid did not significantly affect the number of desires voiced during the clinical encounter (2.6 desires (95% CI 2.1 to 3.1) with the use of the conversation aid versus 2.2 (95% CI 1.5 to 2.9) without the conversation aid, p=0.42) or the type of desire voiced.

#### The correlation between forms of SDM and voiced desires

In the 55 encounters in which we identified multiple instances of SDM, we observed 107 switches between forms of SDM, of which half (N=53 switches) were directly preceded by a desire voiced by either the patient or the clinician. Of these 53 switches, 39 (64%) preceding desires were in line with the form of SDM used, for example, an SDM conversation focused on solving a problematic situation following a desire voiced towards a situation (online supplemental figure 2).

#### **Discussion**

Here, we show that in diabetes care, patients and clinicians use a variety of SDM forms during clinical encounters. SDM focused on solving a problematic situation was the form of SDM most often used, exceeding the use of SDM focused on weighing treatment alternatives. Thus, restricting SDM to deliberative conversations focused on matching patient preferences to treatment options

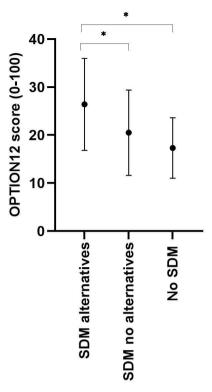


Figure 2 Association between OPTION12 score and SDM for weighing alternatives versus other forms of SDM. Dots represent means, bars represent SD. OPTION12 score quantifies efforts clinicians make to involve patients in SDM. Scores range from 0 to 100, with higher scores indicating more observed clinician behaviours of involving patients in decision-making. SDM alternatives: encounters in which SDM was present and focused on weighing alternatives solely or as part of other forms of SDM used (n=52). Other forms of SDM: encounters in which SDM was present but not focused on weighing alternatives (n=33). No SDM: encounters in which no SDM was observed (n=14). \*P value<0.05. SDM, shared decision-making.

will underestimate the prevalence of SDM in practice. This leaves efforts of patients and clinicians unacknowledged and hampers the successful, flexible and meaningful implementation of SDM in clinical practice.

Scores on clinician's efforts to involve patients in decision-making, measured by OPTION12, were associated with SDM focused on weighing treatment alternatives. This finding is in line with our hypothesis, based on a paper recently published by Hartasanchez, *et al*,<sup>26</sup> that showed SDM measures to predominantly measure collaborative processes focused on decision-making when weighing multiple options, only one form of SDM used during patient–clinician collaborations.

We found that patients and clinicians often switched between different forms of SDM during their encounter. In half of the cases,

SDM, shared decision-making.

a desire—voiced by a patient or clinician—preceded a switch in the SDM form used and, usually, the focus of the voiced desire was in line with the form of SDM that followed its utterance. While the exact meaning of these switches remains a topic to be investigated further, we propose that these switches reflect a change in the purpose of the collaborative deliberation, that is, patients and clinicians alter their deliberative approach to better respond to the situation as it becomes clearer during the conversation. In this way, a voiced desire may flag a change in needs and therefore may be the starting point of a different form of SDM.

There is substantial debate as to SDM's nature and boundaries. Nearly 30 years ago, SDM stood between the paternalistic form of decision-making and so-called informed decision-making, in which the responsibility of the decision lied with the patient.<sup>27</sup> <sup>28</sup> Over the last decades, SDM has evolved with the identification of steps and 'talks', 18 29 the development of conversation tools 30 and their implementation through policy and practice.<sup>31</sup> Throughout this evolution, SDM has referred narrowly to situations in which the fundamental process is to rationally match the patient's preferences to the pros and cons of the available options. 29 32 33 At the same time, research indicates that SDM is rare in practice, even as clinicians insist that they 'do SDM all the time'. 20 34 35 This may be explained in part by what actions have counted as 'doing SDM'. Assuming that a single method should be used to address the broad range of problematic situations, patients and clinicians collaborate to advance may have hindered the study and optimal practice of SDM.21 22

In 2019, Hargraves et al expanded the remit of SDM by proposing that the nature of the problem that the patient and clinician are trying to solve determines the form of SDM they adopt to address it.23 This was supported by Shoesmith et al in 2022, when trying to develop a scale to measure patient-collaboration, carercollaboration and clinician-collaboration in clinical care. They found that shared problemsolving was an important component of collaboration, together with SDM.<sup>36</sup> To acknowledge the range of forms of SDM used in response to the problem that needs to be solved, Hargraves et al proposed a framework of 'purposeful SDM'. Purposeful SDM states that each form of SDM involves the use of form-specific and general elements, such as communication, information sharing and collaborative deliberation, with different emphases and roles depending on the situation.<sup>37</sup> Adding to the knowledge about purposeful SDM, Hartasanchez et al recently showed that the current available observer-based SDM measures all describe behaviours that are pertinent to all forms of SDM but fail to distinguish between them.<sup>26</sup> Our study now adds to this knowledge with evidence from real-life clinical practice on the prevalence and use of different forms of SDM in primary diabetes care, further emphasising the need to move away from an overly narrow definition of SDM (that ultimately describes only one of the forms of SDM observed in practice, and not the most common

Form of SDM	Not using a within-encounter conversation aid (n=31)	Using a within-encounter conversation aid (n=69)	Total
Weighing alternatives	12 (24%)	51 (35%)	63 (32%)
Negotiating conflicting desires	17 (34%)	43 (29%)	60 (31%)
Solving problematic situations	20 (40%)	49 (34%)	69 (35%)
Developing existential insight	1 (2%)	3 (2%)	4 (2%)
Total	50 (100%)	146 (100%)	196 (100%)

one) and expand its remit from the preference-sensitive selection among alternatives to a method of care that practically contributes to the work patients and clinicians do together to address problems of care. How these problem-based forms of SDM relate to the conventional steps of SDM will be discussed in a different manuscript.<sup>38</sup>

There are some limitations to be considered. First, we used video-recorded clinical encounters of the TRICEP trial. a study implementing a within-encounter conversation aid in primary diabetes care.24 Our study was a secondary analysis making use of videos of encounters with and without the conversation aid. Our analysis did not show any statistically significant differences in the amount and type of SDM forms used, nor in the amount and types of desires voiced between the study arms. Second, with this study being conducted in primary diabetes care in the Midwest of the USA, it remains unclear whether our findings are generalisable to other healthcare settings and patient populations. Diabetes care visits may involve problemsolving SDM more often than preventive care visits in which deciding whether to participate in cancer screening programmes may require weighing options SDM. SDM focused on developing existential insight is particularly appropriate in situations where the patient is troubled by issues of existential fracture or transition. Studies in oncology or the intensive care unit, particularly at the end of life, may involve this form of SDM frequently, while a rare finding in the diabetes care setting. Finally, with no validated coding scheme available regarding this subject, we self-developed a coding scheme based on the available literature on forms of purposeful SDM. This coding scheme was not externally validated, but we aimed to optimise the reliability of our data by coding all encounters independently and in duplicate, by two researchers with different backgrounds, and resolving all disagreements through consensus. Strengths of this study are the large sample size and the use of a random selection of video-recordings from the TRICEP database.

Notably, this study provides evidence of the presence of multiple forms of SDM within diabetes care encounters. It does not evaluate the quality of the SDM form used, for example, the appropriateness, effectiveness, grace or adequacy with which a form of SDM was used or moved away from. Furthermore, we did not assess the ability of SDM to form care plans that fully make sense for the patient and their situation<sup>24</sup> or the effects of SDM on clinical or quality of life outcomes or treatment adherence. These gaps should be addressed to identify any needs or opportunities for further supporting, improving and promoting the use of multiple forms of SDM and to develop and evaluate interventions that will enable their optimal use in care.

Clinicians that are able to flexibly dance across the different forms of SDM with their patient to find out the one that better helps advance the patient's situation may increase the chance that the resulting care plans will respond to the patient's situation and fit within their life and living. <sup>39 40</sup> In this manner, investments in purposeful SDM can contribute to improved patient-centred care and outcomes, in line with the recommendations of the American Diabetes Association and the European Association for the Study of Diabetes<sup>15</sup> and will provide new insights for training and teaching healthcare professionals.

#### Conclusion

This study shows that SDM occurs often in diabetes care, particularly when deliberative approaches beyond weighing treatment alternatives are considered. We found SDM focused on solving problematic situations together account for over a third of the SDM forms observed in primary diabetes care. Weighing alternatives, the only form of SDM usually considered in the literature, and negotiating conflicting desires each accounted for approximately another third of the instances of SDM. Furthermore, patients and clinicians often switched from one form of SDM to another, a behaviour that was even more pronounced when a change in medication was warranted.

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Contributors MMR, VM and MK conceived and designed this study. MMR and MK coded all video-recorded clinical encounters in duplicate. MEB performed all data analyses. MMR, VM, IH, MEB, MLG, EJPdK and MK helped to interpret the study results, drafted and revised the manuscript and approved the final version. MMR and MK are the guarantors of this work and, as such, had full access to all the data in the study and take responsibility for the integrity and accuracy of the data and data analyses.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained directly from patient(s)

Ethics approval The Mayo Clinic Institutional Review Board approved the original study and this secondary analysis (IRB #10-006952 and #19-011553). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed

Data availability statement Data are available upon reasonable request. Deidentified data from the video recordings used in this study are available upon reasonable request at the 'Knowledge and Evaluation Research Unit, Mayo Clinic, Rochester'.

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#### References

- 1 Brown E, Heerspink HJL, Cuthbertson DJ, et al. SGLT2 inhibitors and GLP-1 receptor agonists: established and emerging indications. Lancet 2021;398:262-76.
- 2 American Diabetes Association. Pharmacologic approaches to glycemic treatment: standards of medical care in diabetes-2021. *Diabetes Care* 2021;44:S111-24.
- 3 Yaron M, Roitman E, Aharon-Hananel G, et al. Effect of flash glucose monitoring technology on glycemic control and treatment satisfaction in patients with type 2 diabetes. *Diabetes Care* 2019;42:1178–84.
- 4 Evans M, Welsh Z, Ells S, *et al.* The impact of flash glucose monitoring on glycaemic control as measured by HbA1c: a meta-analysis of clinical trials and real-world observational studies. *Diabetes Ther* 2020:11:83–95.
- 5 Deshmukh H, Wilmot EG, Gregory R, et al. Effect of flash glucose monitoring on glycemic control, hypoglycemia, diabetes-related distress, and resource utilization in the association of British clinical diabetologists (ABCD) nationwide audit. *Diabetes Care* 2020;43:2153–60.
- 6 Marks BE, Williams KM, Sherwood JS, et al. Practical aspects of diabetes technology use: continuous glucose monitors, insulin pumps, and automated insulin delivery systems. J Clin Transl Endocrinol 2022;27:100282.
- 7 Heinemann L, Schnell O, Gehr B, et al. Digital diabetes management: a literature review of smart insulin pens. J Diabetes Sci Technol 2022;16:587–95.
- 8 Zeng B, Jia H, Gao L, et al. Dual-hormone artificial pancreas for glucose control in type 1 diabetes: a meta-analysis. *Diabetes Obes Metab* 2022;24:1967–75.
- 9 Ware J, Hovorka R. Recent advances in closed-loop insulin delivery. <u>Metabolism</u> 2022;127:154953.
- 10 Davies MJ, D'Alessio DA, Fradkin J, et al. Management of hyperglycemia in type 2 diabetes, 2018. A consensus report by the American diabetes association (ADA) and the European association for the study of diabetes (EASD). *Diabetes Care* 2018;41:2669–701.
- 11 Young-Hyman D, de Groot M, Hill-Briggs F, *et al.* Psychosocial care for people with diabetes: a position statement of the American diabetes association. *Diabetes Care* 2016;39:2126–40.
- 12 Tamhane S, Rodriguez-Gutierrez R, Hargraves I, et al. Shared decision-making in diabetes care. Curr Diab Rep 2015;15:12.
- 13 Kunneman M, Griffioen IPM, Labrie NHM, et al. Making care fit manifesto. BMJ Evid Based Med 2023;28:5–6.
- 14 Tikkinen KAO, Guyatt GH. Understanding of research results, evidence summaries and their applicability-not critical appraisal-are core skills of medical curriculum. BMJ Evid Based Med 2021;26:231–3.
- 15 Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach: position statement of the

- American diabetes association (ADA) and the European association for the study of diabetes (EASD). *Diabetes Care* 2012;35:1364–79.
- 16 Stiggelbout AM, Van der Weijden T, De Wit MPT, et al. Shared decision making: really putting patients at the centre of healthcare. BMJ 2012;344:e256.
- 17 Kunneman M, Montori VM, Castaneda-Guarderas A, et al. What is shared decision making? (and what it is not). Acad Emerg Med 2016;23:1320-4.
- 18 Elwyn G, Durand MA, Song J, et al. A three-talk model for shared decision making: multistage consultation process. BMJ 2017;359:j4891.
- 19 Kunneman M, Gionfriddo MR, Toloza FJK, et al. Humanistic communication in the evaluation of shared decision making: a systematic review. Patient Educ Couns 2019;102:452–66.
- 20 Kasper J, Hoffmann F, Heesen C, et al. MAPPIN'SDM -- the multifocal approach to sharing in shared decision making. PLoS One 2012;7:e34849.
- 21 Légaré F, Witteman HO. Shared decision making: examining key elements and barriers to adoption into routine clinical practice. *Health Aff* (Millwood) 2013;32:276–84.
- 22 Holmes-Rovner M, Valade D, Orlowski C, et al. Implementing shared decision-making in routine practice: barriers and opportunities. Health Expect 2000;3:182-91.
- 23 Hargraves IG, Montori VM, Brito JP, et al. Purposeful SDM: a problem-based approach to caring for patients with shared decision making. Patient Educ Couns 2019;102:1786–92.
- 24 Kunneman M, Branda ME, Ridgeway JL, et al. Making sense of diabetes medication decisions: a mixed methods cluster randomized trial using a conversation aid intervention. *Endocrine* 2022;75:377–91.
- 25 Elwyn G, Hutchings H, Edwards A, et al. The option scale: measuring the extent that clinicians involve patients in decision-making tasks. Health Expect 2005;8:34–42.
- 26 Hartasanchez SA, Grande SW, Montori VM, et al. Shared decision making process measures and patient problems. Patient Educ Couns 2022;105:2457–65.
- 27 Charles C, Gafni A, Whelan T. Shared decision-making in the medical encounter: what does it mean? (or it takes at least two to tango). Soc Sci Med 1997;44:681–92.
- 28 Towle A, Godolphin W. Framework for teaching and learning informed shared decision making. BMJ 1999;319:766–71.
- 29 Stiggelbout AM, Pieterse AH, De Haes J. Shared decision making: concepts, evidence, and practice. Patient Educ Couns 2015;98:1172–9.
- 30 Stacey D, Légaré F, Lewis K, et al. Decision AIDS for people facing health treatment or screening decisions. Cochrane Database Syst Rev 2017:4:CD001431.
- 31 Rabi DM, Kunneman M, Montori VM. When guidelines recommend shared decision-making. JAMA 2020;323:1345-6.
- 32 Charles C, Whelan T, Gafni A. What do we mean by partnership in making decisions about treatment? BMJ 1999;319:780-2.
- 33 Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. J Gen Intern Med 2012;27:1361–7.
- 34 Couët N, Desroches S, Robitaille H, et al. Assessments of the extent to which health-care providers involve patients in decision making: a systematic review of studies using the option instrument. Health Expect 2015;18:542-61
- 35 Légaré F, Thompson-Leduc P. Twelve myths about shared decision making. Patient Educ Couns 2014:96:281-6.
- 36 Shoesmith WD, Abdullah AC, Tan BY, et al. Development of a scale to measure shared problem-solving and decision-making in mental healthcare. Patient Educ Couns 2022;105:2480-8.
- 37 Hargraves IG, Fournier AK, Montori VM, et al. Generalized shared decision making approaches and patient problems. adapting AHRQ's SHARE approach for purposeful SDM. Patient Educ Couns 2020;103:2192–9.
- 38 Montori VM, Ruissen MM, Branda ME, et al. Problem-based shared decision making: the role of conventional SDM steps under consideration; 2022.
- 39 Kunneman MB. Montori VM making diabetes care fit. Diabetes update. NEJM Group; 2020.
- 40 Ruissen MM, Rodriguez-Gutierrez R, Montori VM, et al. Making diabetes care fit—are we making progress? Front Clin Diabetes Healthc 2021;2.

### Supplementary material

#### Supplement 1. Coding scheme and manual

## General notes:

- Only code utterances made when both patient and clinician were present in the room
- Code utterances of patient's significant other as the patient's, unless the patient explicitly disagrees/contradicts. Desires stated by next of kind will be coded as desire of the patient itself
- Sometimes there is a logical healthcare choice, for example if things are going well and no
  adjustment is needed. This is coded as an obvious next step. If there is an obvious next step
  during the consultation, SDM steps and/or forms of SDM may still be coded, since clinicians
  and patients may not be on the same line of thought.
- Every type of desire, even when stated in one sentence, will be coded as a separate desire.
- Increasing dose of medication should be coded as 'to start medication'.

### **Definitions:**

**Desire:** Any vocalized desire or utterance with a valuative element for a certain treatment option or strategy towards the patients' diabetes care. Code as 'yes' if you experience even the smallest 'maybe' during the consultation.

**Providing information:** Information provided by the care provider concerning various treatment options and strategies and potential harms and benefits.

	General				
Stu	ıdy ID:		Coder:		
Da	te:	(r	mm/dd/yyyy)		
1.	Was the pa	tient accompanied b	y a caregiver?		
		No <sub>0</sub>	(do not see, hear, or positively ID someone else in the room)		
		Yes <sub>1</sub>	(partner, relative, friend or significant other)		
2.	Was there a	an obvious next step	concerning future treatment?		
		No <sub>0</sub>			
		Yes <sub>1</sub>	(no decision making on treatment, because of logical next step)		
3.	What was t	he total time of the c	consultation (patient and clinician together in consultation		

Utterance (entire quote): \_\_

	Desires		
4.	. Number of desire:		
5.			
6.		patient/clinician	
	•		
7.	Who initiat	ted the comment on desires?	
		Patient <sub>1</sub>	
		Clinian	
		Clinician <sub>2</sub>	
Exp	olain:	(write in text)	
8.	What was	the desire about? (more than one may apply)	
		An option <sub>1</sub>	
		(medication or lifestyle)	
	☐ A personal want/disposition₂  (e.g. I don't like needles, I'm not giving up my glass of wine )		
	(e.g. r don't like needles, r m not giving up my glass of wine )		
	☐ A situation <sub>3</sub>		
	(e.g. we've got to do something about all the hypos you've been having)		
		Intervity of solf	
		Integrity of self₄ (e.g. I wish I wasn't like this, It's good—I'm figuring this out)	
		(a.g	
		Other <sub>5</sub> (write in text)	

(write in text)

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9. State which steps of SDM you encountered during the consultation video in chronological order. Choose from: choice awareness (1), providing information (2), deciding on final treatment (3)

Step of SDM	Starting time	Citation

10. Which forms of SDM did you see? (see table 1 and 2 listed below) Multiple forms of SDM are possible during one consultation. Please enter forms in chronological order during the conversation. Choose from no form of SDM to be defined (0), weighing treatment alternatives (1), negotiating conflicting desires (2), solving problematic situations (3) and developing existential insight (4).

Form of SDM	Starting time	Citation

### Supplementary table 1. Patient characteristics per study arm.

Patient demographics	Intervention (n=69)	Control (n=31)	p-value
Age, years (mean, SD)	59 (9)	63 (10)	0.03
Gender, female (n, %)	25 (36)	16 (52)	0.15
BMI (mean, SD)	36.3 (9.6)	37.5 (8.3)	0.30
Race (n, %)			0.83
White	58 (84)	27 (87)	
Black	7 (10)	2 (6.5)	
Other	4 (6)	2 (6.5)	
Education (n, %)			0.87
High School or less	20 (36)	9 (31)	
Vocational/4 year	29 (53)	17 (59)	
college degree			
Graduate degree	6 (11)	3 (10)	
HbA1c, % (mean, SD)	8.9 (1.3)	9.0 (1.2)	0.53
Years with diabetes (n,			0.30
%)			
<5	20 (33)	7 (24)	
5 to <10	23 (38)	9 (31)	
>10	17 (28)	13 (45)	
Literacy (n, %)			0.17
Inadequate	8 (13)	1 (4)	
Adequate	54 (87)	27 (96)	

BMI: body mass index; HbA1c: glycated hemoglobin; SD: standard deviation. The intervention consisted of the use of a within-encounter conversation aid. P-value < 0.05 is considered statistically significant.

# Supplementary table 2. Number of desires voiced per study arm.

Number of desires voiced	Study arm		
	Intervention	Control	Total
0	11 (15.94)	6 (19.35)	17
1	14 (20.29)	9 (29.03)	23
2	12 (17.39)	2 (6.45)	14
3	11 (15.94)	8 (25.81)	19
4	11 (15.94)	1 (3.23)	12
5	3 (4.35)	2 (6.45)	5
6	2 (2.90)	3 (9.68)	5
7	4 (5.80)	0 (0.00)	4
8	1 (1.45)	0 (0.00)	1
Total	69	31	100

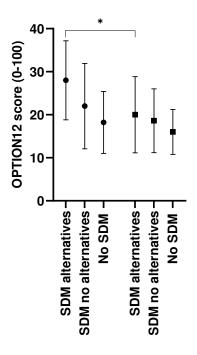
The intervention consisted of the use of a within-encounter conversation aid.

Supplementary table 3. Type of desire stated by patient or clinician per study arm.

	Study		
Desire	Intervention	Control	p-value
Overall			0.07
Patient	107 (60%)	50 (72%)	
Clinician	71(40%)	19 (28%)	
Medication/Lifestyle			0.03
Patient	18 (29%)	10 (56%)	
Clinician	45 (71%)	8 (44%)	
Personal want			0.89
Patient	65 (74%)	33 (75%)	
Clinician	23 (26%)	11 (25%)	
Problematic situation			>0.99
Patient	20 (87%)	4 (100%)	
Clinician	3 (13%)	0 (0%)	
Integrity of self			~
Patient	4 (100%)	3 (100%)	
Clinician	0 (0%)	0 (0%)	

The intervention consisted of the use of a within-encounter conversation aid. P-value <0.05 is considered statistically significant.

Supplementary figure 1. Association OPTION12 score and weighing of alternatives per study arm.



- Conversation aid used
- No conversation aid used

CA: conversation aid; SDM: shared decision making. Figures represent means, bars represent standard deviations. Dots: consultations in which a within-conversation aid was used. Squares: consultations in which no within-conversation aid was used. SDM alternatives; consultations in which SDM was present and focused on weighing alternatives solely or as part of multiple forms of SDM used (CA: n=42, no CA: n=10). SDM no alternatives; consultations in which SDM was present but not focused on weighing alternatives (CA: n=18, no CA: n=15). No SDM; consultations in which no form of SDM was observed (CA: n=8, no CA: n=6). OPTION12 score: score measuring the clinician's efforts to involve a patient within a consultation. Scores range from 0 to 100, with higher scores indicating more aspects of SDM present.\*p-value<0.05.

# Supplementary figure 2. Overview of forms of SDM used and desires voiced by patients and clinicians per consultation.

X-axis represents the percentage of time of the encounter. Consultations are ordered by the amount of SDM instances observed during the encounter, with no instance of SDM at the top to six instances of SDM at the bottom. Colors represent the different forms of SDM. Only the start of an SDM instance was coded, since a clear end could often not be distinguished. Desires voiced during the encounter are indicated by a P for desires voiced by the patient or C for a desire voiced by the clinician and further characterized as focused towards 1) an option, 2) a personal want/disposition, 3) a situation or 4) integrity of self.

