QBSAFE: A Randomized Trial of a Novel Intervention to Improve Care for People Living with Type 2 Diabetes

Kasia J Lipska, MD MHS[1]; Megan Branda, MS[2]; Anne Camp, MD[3]; Melissa Montosa, BS[3]; Rozalina McCoy, MD MS[4]; Victor Montori, BA[5]; Felipe Larios, MD[5] and Victor M Montori, MD MSc[5].

[1]Yale School of Medicine, New Haven, CT; [2]Mayo Clinic, Rochester, MN; [3]Fair Haven Community Health Center, New Haven, CT; [4]University of Maryland Institute for Health Computing, North Bethesda, MD; [5]Knowledge and Evaluation Research Unit, Rochester, MN

Background

- People living with type 2 diabetes are expected to manage complex daily routines, self-monitor and respond to metabolic parameters, and coordinate access to ongoing care.

- In busy or under-resourced clinical settings, clinicians may overlook the challenges of living with diabetes, despite their importance to patients' health and well-being.

- Effective interventions are critically needed to align the encounter agenda with the needs of each patient, and to enable the co-creation of diabetes care plans that are sensible, desirable and feasible, i.e., care that fits.

- The **QBSAFE agenda setting kit (ASK)** is a set of cards designed to help patients identify issues they would like to raise during the consultation pertaining to **Quality of Life, Burden of Treatment, Safety and Avoidance of Future Events.**

Objective

- To estimate the effect of adding QBSAFE ASK to usual primary care on patient-reported and clinical outcomes of patients living with type 2 diabetes.

Figure 1. QBSAFE ASK tool.

Methods

- **Study design:** Clinician-level cluster randomized trial.

- **Setting:** Federally qualified health center.

- **Participants:** 11 clinicians and 155 of their patients with type 2 diabetes and hemoglobin A1c >8% were randomly assigned to usual care either with or without the use of QBSAFE cards.

- **Primary outcomes:** Fit of care – measured by Illness Intrusiveness Ratings Scale (IIRS) at 6 months, and glycemic control – measured by hemoglobin A1c levels at 6 months.

- **Secondary outcomes:**
  Treatment burden – Treatment Burden Questionnaire (TBQ).
  Diabetes distress – Diabetes Distress Scale (DDS).

- **Other outcomes:**
  Quality of Life, patient and clinician satisfaction.

- A videographic analysis was performed to assess fidelity and the impact of QBSAFE on encounter discussions and care plans.
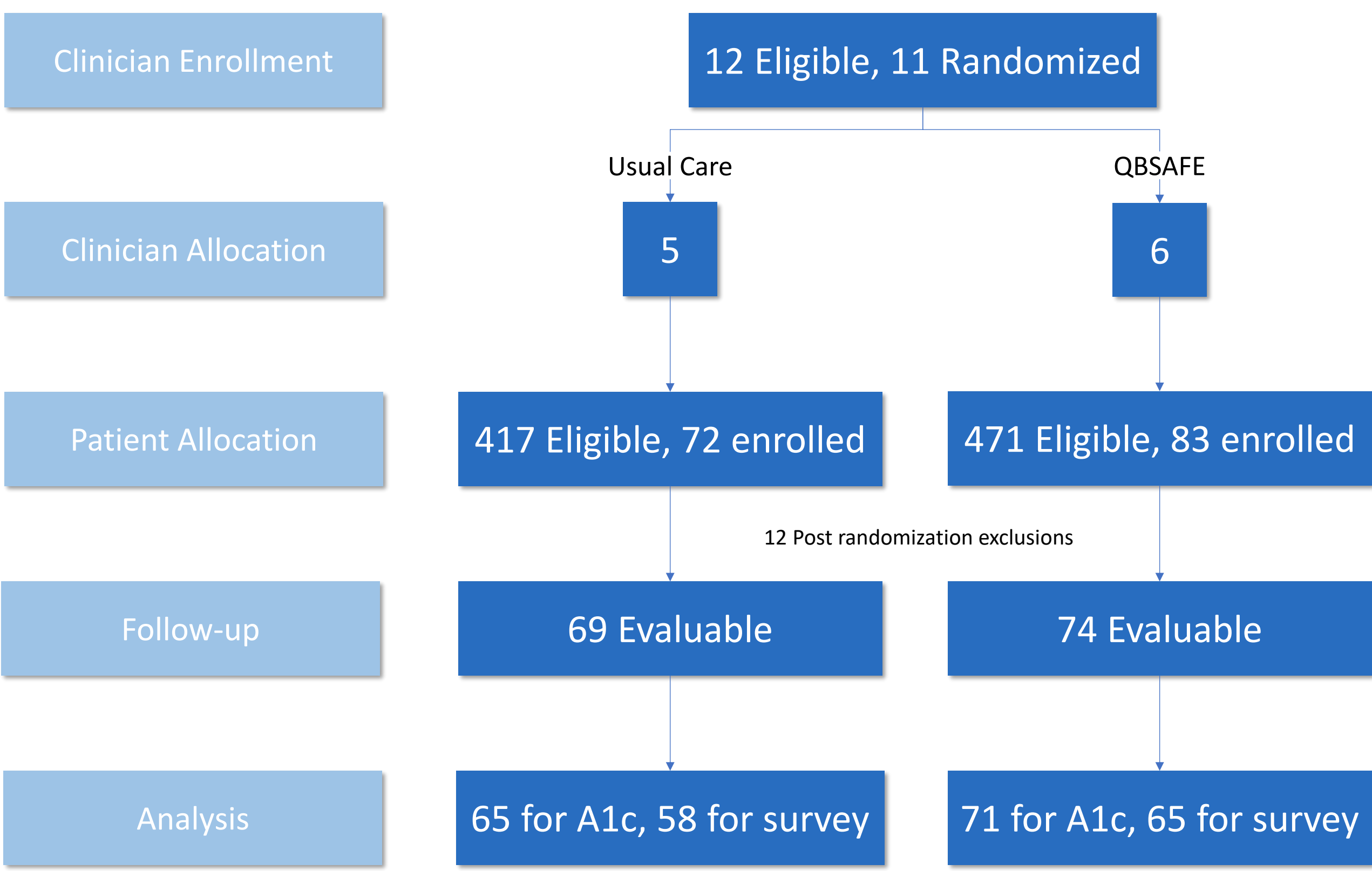
Figure 2. CONSORT diagram.

Clinician Enrollment	12 Eligible, 11 Randomized
Clinician Allocation	Usual Care: 5 / QBSAFE: 6
Patient Allocation	417 Eligible, 72 enrolled / 471 Eligible, 83 enrolled
	12 Post randomization exclusions
Follow-up	69 Evaluable / 74 Evaluable
Analysis	65 for A1c, 58 for survey / 71 for A1c, 65 for survey

Figure 3. Study measures timeline.

Initial visit → 6 months

A1c ... A1c

Results

Table 1: Characteristics of patient participants in the QBSAFE trial by study arm.

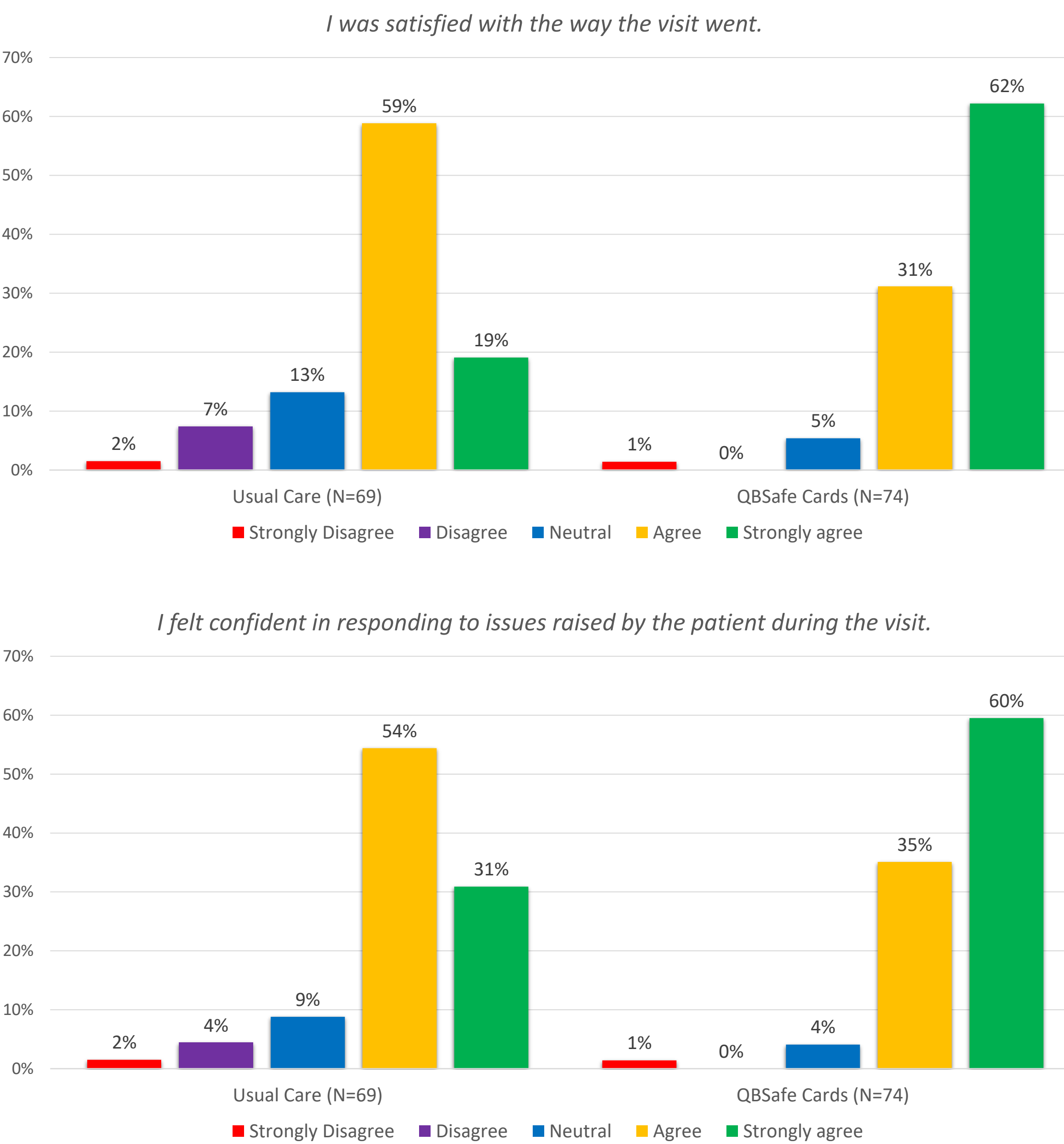|	Study Arm	
	Usual Care (N=69)	QBSAFE (N=74)
Age, Mean (SD)	53.8 (10.9)	58.4 (12.3)
Sex, n (%)		
Female	44 (64%)	43 (58%)
Race, n (%)		
White	19 (27%)	32 (43%)
Black	15 (22%)	13 (18%)
Other	29 (42%)	25 (34%)
Unknown	6 (9%)	4 (55%)
Ethnicity, n (%)		
Hispanic or Latino	53 (77%)	51 (69%)
Primary Language, n (%)		
English	21 (30%)	34 (46%)
Spanish	48 (70%)	40 (54%)
BMI, Mean (SD)	31.7 (5.12)	30.9 (5.63)
Medical Insurance, n (%)		
Commercial	9 (13%)	11 (15%)
Medicaid	27 (39%)	26 (35%)
Medicare	13 (19%)	22 (30%)
Self-Pay	20 (29%)	15 (20%)
Federal Poverty Level, n (%)		
0-150%	55 (90%)	61 (92%)
>150%	6 (10%)	5 (8%)
Missing	8	8

Table 2: QBSAFE trial patient-reported and clinical outcomes at 6 months by study arm.

	Study Arm			
	Usual Care (N=69)	QBSAFE (N=74)	DID (95% CI)	P-value
Illness Intrusiveness Score: Mean (SD)	37.1 (18.7)	32.1 (15.1)	-3.9 (-10.4, 2.6)	0.24[1]
Diabetes Distress Scale: Mean (SD)	2.3 (1.0)	2.0 (1.0)	-0.09 (-0.4, 0.2)	0.49[1]
< 2.0	24 (42%)	40 (61%)		
≥2.0 to <3.0	19 (33%)	14 (21%)		
≥ 3.0	14 (25%)	12 (18%)		
Treatment Burden Questionnaire	46.8 (44.4)	41.2 (44.8)	1.01 (-16.6, 18.6)	0.91[1]
<=59	40 (70%)	46 (70%)		
> 59	17 (30%)	20 (30%)		
HbA1c[3]	9.1 (1.8)	8.8 (1.8)	-0.2 (-0.9, 0.5)	0.59[1]
HbA1c categories1, n (%)				0.47[2]
<8.0	17 (26%)	26 (37%)		
8.0 to <9.0	14 (22%)	16 (22%)		
9.0 to < 10.0	14 (21%)	10 (14%)		
10.0+	20 (31%)	19 (27%)		

[1]Mixed generalized linear model adjusting for a fixed effect of arm and baseline score for the scale, and a random effect of clinician;
[2]Rao-Scott Chi-Square p-value – accounting for clustering of clinician, no baseline scale adjustment;
DID: Difference-in-Differences

- Encounter length did not differ between arms (22.2 vs. 22.1 minutes, p=0.95).

- QBSAFE encounters had significantly more discussions about burden of treatment, but not other domains (p=0.02).

- Patient satisfaction was overall high and did not vary between arms.

Figure 4. Clinician-reported satisfaction.

I was satisfied with the way the visit went.

Usual Care (N=69): Strongly Disagree 2%, Disagree 7%, Neutral 13%, Agree 59%, Strongly agree 19%
QBSafe Cards (N=74): Strongly Disagree 1%, Disagree 0%, Neutral 5%, Agree 31%, Strongly agree 62%

I felt confident in responding to issues raised by the patient during the visit.

Usual Care (N=69): Strongly Disagree 2%, Disagree 4%, Neutral 9%, Agree 54%, Strongly agree 31%
QBSafe Cards (N=74): Strongly Disagree 1%, Disagree 0%, Neutral 4%, Agree 35%, Strongly agree 60%

Conclusions

- While QBSAFE ASK did not improve specific patient-reported or clinical outcomes in this trial, the cards offer a low-cost, feasible strategy to prompt conversations about treatment burden in primary care.

- Given the high levels of illness intrusiveness and distress among patients in this underserved setting, efforts to personalize and de-burden diabetes care remain a priority.

- Future interventions should focus on both enhancing conversations about treatment burden and equipping clinicians to meaningfully respond to patient's situations, particularly in high-need populations where the stakes for care fit are greatest.

Research Partners

Fair Haven Community Health Care

MAYO CLINIC

KER UNIT — CARE THAT FITS