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ORIGINAL RESEARCH

The Diabetes Staging System (DSS): A Pilot Study Assessing Feasibility, Provider Engagement and Implementation Challenges of a Novel Staging System for Type 2 Diabetes

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Introduction and Objective: Type 2 diabetes (DM2) currently lacks a standardized staging system that can be used to predict survival and guide providers towards guideline concordant care much like TNM staging does for cancer. We conducted a pilot study to assess the feasibility, provider engagement and implementation challenges of the DSS and examined if guideline concordant care improved especially SGLT2i/GLP-1a use in Veterans DM2 patients with cardiorenal disease.

Methods: A 6-month pilot study implemented DSS in VA primary care clinics between December 2023–September 2024. Study visits were at baseline and 6 months. Primary outcome: the initiation of SGLT2i/GLP-1a in Veteran DM2 patients with CVD/CKD compared to baseline. Secondary outcomes: weight, blood pressure, hemoglobin A1C, glomerular filtration rate (GFR), and medication adherence compared to baseline. Inclusion criteria: Male or female Veterans between the ages of 18–75 years with DM2 and ≥1 CV event and/or CKD and not on SGLT2i/GLP-1a. Exclusion criteria: Veterans with contraindications to SGLT2i/GLP-1 and/or a serious mental health disorder.

Results: After baseline visit, all providers prescribed to 14/14 patients at least one of the medications with 12/14 prescribed SGLT2i and 2/14 prescribed GLP-1a. We found 13/14 (93%) patients to still be on at least one of the medications at 6 months. At 6 months compared to baseline, weight (216 lbs. ± 41 → 213 lbs. ± 39), blood pressure (141/76 ± 20/10 → 132/73 ± 17/10), A1C (7.7% ± 1.5% → 7.4% ± 0.8%) modestly decreased but GFR remained stable (64 mL/min ± 17 → 64 mL/min ± 19). Medication adherence was continued for all 13 patients (Medication possession ratio was ≥80%).

Conclusion: DSS use was associated with increased SGLT2i/GLP-1a prescribing by VA primary care providers and medication adherence in Veterans DM2 patients with CVD/CKD. The DSS could help improve cardiorenal outcomes and guideline concordant in their DM2 patients in the future if larger studies can validate these findings.

Clinical Trials Registration Number: NCT06142006.

Keywords: type 2 diabetes, healthcare delivery, SGLT2i, GLP-1a

Introduction

Type 2 diabetes (DM2) affects more than 800 million people worldwide and is a leading cause of both cardiovascular disease (CVD) and chronic kidney disease (CKD), with approximately 177 million patients developing CVD and many progressing to end-stage renal disease (ESRD).[1] Evidence shows that sodium-glucose cotransporter-2 inhibitors (SGLT2i) and glucagon-like peptide-1 receptor agonists (GLP-1a) significantly reduce these cardiorenal complications yet despite strong guideline recommendations, fewer than 25% of eligible patients receive these therapies.[1–5] This

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underuse reflects persistent clinical inertia, often stemming from the absence of a standardized framework that helps clinicians conceptualize and manage DM2 as a progressive, multi-system disease.

In oncology, the Tumor Node Metastasis (TNM) staging system transformed cancer care by organizing disease severity into discrete stages that guide treatment, predict survival, and create a shared language among stakeholders—including patients, providers, insurers, and pharmaceutical companies. No comparable system exists for DM2, even though it shares similar complexity and global burden. Previous attempts to stage diabetes lacked training components to support provider adoption and were not integrated into clinical workflows to improve adherence to SGLT2i, GLP-1a, and other evidence-based therapies.[6–8]

To address this gap, we developed the Diabetes Staging System (DSS) to organize disease severity into discrete stages that guide treatment, predict survival and create a shared language among DM2 stakeholders. The DSS stage is based on each patient's macrovascular and microvascular complications and DSS substage is based on estimated glomerular filtration rate (eGFR), and hemoglobin A1C (HbA1C). DSS stage predicts survival and steers providers towards SGLT2i and GLP-1a use in patients with cardiorenal complications and other guideline concordant known to improve/treat microvascular complications.[9] DSS substage is used to guide providers towards specific DM2 treatment strategies that can safely improve glycemic control. Modeled after TNM, the DSS aims to provide a clear, stepwise framework for risk communication, treatment decision-making, and stakeholder alignment across clinical care, insurance, and research.

In collaboration with Boehringer-Ingelheim, we previously demonstrated that DSS stage predicts survival using pooled data from three major cardiovascular outcomes trials (EMPA-REG, CAROLINA, and CARMELINA).[10] Building on that work, we herein report the results of a 6-month pilot study in Department of Veterans Affairs (VA) primary care clinics that tested the DSS's feasibility in real-world settings—specifically, whether it is acceptable to providers and can increase the use of SGLT2i and GLP-1a among Veterans with DM2 and established CVD and/or renal disease.

Research Design and Methods

Trial Design

A prospective 6-month pilot study was conducted at the Greenville VA Healthcare Center and primary and secondary outcomes measured at baseline and 6 months. Qualitative interviews of study providers were completed at study conclusion.

Study Population

Study Providers

Study providers defined as medical doctor or physician assistant were recruited from primary care clinics at the Greenville VA Healthcare Center to participate in the study using Microsoft VA TEAMS messaging and Outlook emails. We recruited 10 primary care providers to participate in the study.

Patients

Eligible male or female Veterans between the ages of 18–75 years, not on SGLT2i/GLP-1a with DM2 with ≥1 CVD event and/or CKD, were included. Based upon the American Diabetes Association (ADA) 2025 standards of care, SGLT2i/GLP-1a is recommended for people with DM2 who have established cardiovascular or kidney disease.[11] Veterans with glomerular filtration rate (GFR) <20, chronic indwelling catheter, uncircumcised males, recurrent balanitis, multiple endocrine neoplasia (MEN) 1 or 2, medullary thyroid cancer, history of pancreatitis, gastroparesis and/or serious mental health disorder were excluded. Microsoft Power BI was used to identify 10 eligible patients from each provider's patient panel who met inclusion/exclusion criteria. The study provider's RN care manager then determined DM2 stage, generated a DM2 staging note in the VA computerized patient record system (CPRS) and assisted the provider in scheduling study visits.

Cohort Transparency

This is a real-world study that integrated the DSS into the normal clinical workflow of VA primary care providers and nurses. Nurses assigned to work with study providers determined DSS stage between December 20, 2023–March 5, 2024. A patient flow diagram (CONSORT style) in Figure 1 shows how we arrived at the final analytic cohort of 14 patients. Initially, 59 patients who were identified as being eligible for the study, but 13 patients were not assigned a DSS stage due to nurse staffing shortages. Therefore, 46 patients were assigned to a DSS stage at baseline and scheduled for a

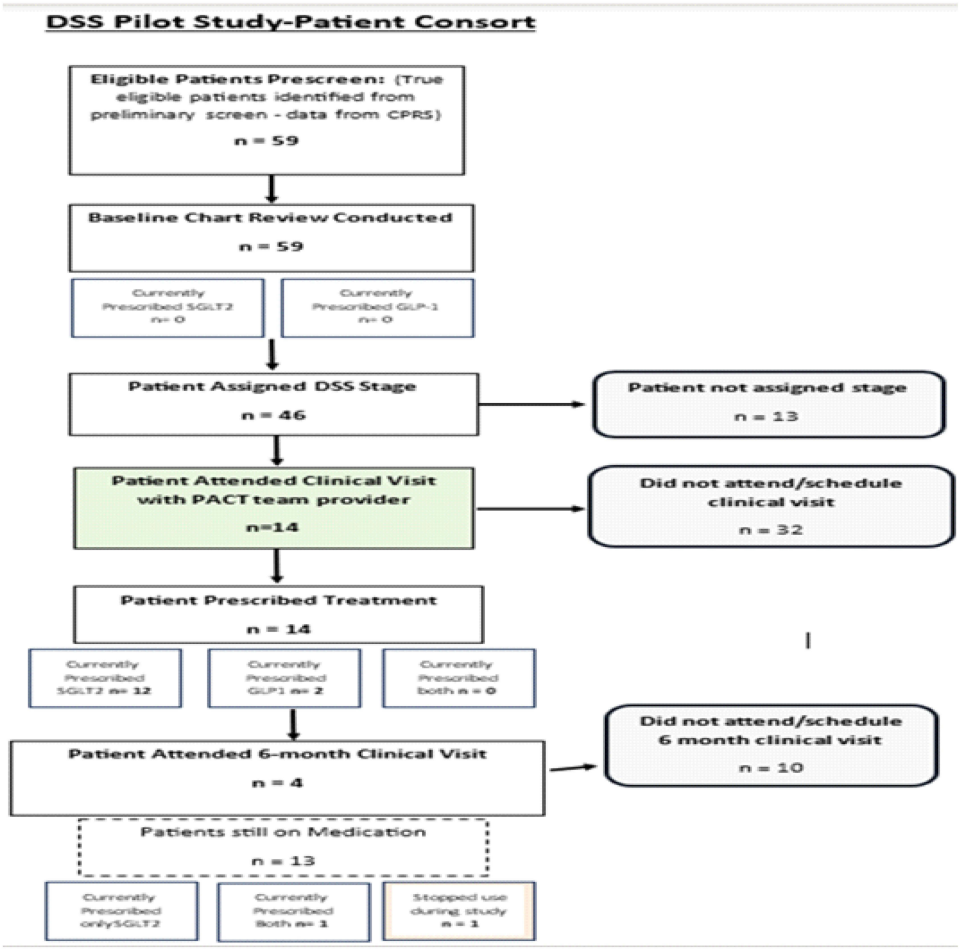

Figure 1 DSS Pilot Study Patient Cohort.

study visit but 32 patients never completed a study visit. This left a final analytic cohort of 14 patients that were staged and attended at least one study visit and 32 patients that were staged but never attended a study visit.

Study Intervention

DSS Training-Nursing Support Staff

A certified diabetes educator (CDE) who works at the Greenville VA specialty clinic and is also a registered nurse (RN) assisted us in adapting the DSS provider training program for nurses. The DSS nurse training program was then delivered in person by the CDE/RN to RN care managers assigned to each study provider in three parts: 1) power point slides, 2) cases to practice DM2 staging, and 3) time for questions. The total length of the DSS nurse training was ~30–60 minutes. At the conclusion of the training, RN care managers were able to determine DSS stage, generate a DM2 staging note in computerized patient registration system (CPRS) prior to study visit using a "point and click" DSS template. The DSS template incorporated feedback from the VA Office of Primary Care and was created with the assistance of Durham VA informatics team.

DSS Training-Providers

DSS provider training consisting of two 30-minute PowerPoint presentations was given 1–2 months prior to baseline visit and then reinforced at 3 months. Part 1 focused on the importance of cardiorenal complications, and rationale for the DSS. Part 2 focused on how to use the DSS stage and substage to make clinical decisions and provided educational reinforcement on SGLT2i/GLP-1a, insulin, oral and/or injectable DM2 meds and continuous glucose monitoring. DSS

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training was delivered in-person to maximize opportunities to observe provider engagement, enthusiasm and to receive feedback so that training material could be improved and developed into an e-learning module in the future. We also completed a mid-study fidelity session at 3 months with study provider to allow them an opportunity to ask any questions about how to DSS and to ensure that they were using the DSS properly. We did not conduct audits on the DSS stages assigned to patients during the study because we felt that sufficient time had been devoted to properly training providers and nurses on how to use the DSS.

It was demonstrated to study providers how the DSS uses each patient's macrovascular/microvascular complications, GFR and hemoglobin A1C (A1C) (Figure 2) to develop a personalized treatment plan that aligns with current DM2 treatment guidelines (Figure 3). The RN care manager-generated DM2 staging note in CPRS was used by study providers to quickly reference the DSS STAGE "cheat sheet" to determine if DSS stage recommended SGLT2i/GLP-1a (Figure 3) and other evidence-based treatments to minimize diabetic retinopathy, nephropathy and neuropathy were indicated. The DSS SUBSTAGE "cheat sheet" (Figure 3) was then referenced to determine what oral and/or injectable agents could safely be used to improve glycemic control (Figure 3).

Dx		Diabetes status is unknown			
Stage 0		Prediabetes			
Stage		Stage		Substage	
		Macrovascular events	Microvascular complications	GFR	AIC
Stage I	1A	None	None	1. Normal or high (GFR ≥90) 2. Mildly decreased (GFR 60–89) 3. Moderately to severely decreased (GFR 30–59)	a. <7% b. 7%–8.5% c. 8.6%–10% d. >10%
	1B	None	1		
	1C	None	2		
	1D	None	3		
Stage II	2A	1	None		
	2B	1	1		
	2C	1	2		
	2D	1	3		
Stage III	3A	2	None		
	3B	2	1		
	3C	2	2		
	3D	2	3		
Stage IV	4A	≥3	None		
	4B	≥3	1		
	4C	≥3	2		
	4D	≥3	3		
Stage V	5A	Any	Any	4. Severely decreased (GFR 15–29) 5. Kidney failure (GFR <15)	

Figure 2 Diabetes Staging System. The Diabetes Staging System (DSS) consists of DSS stage and DSS substage. DSS stage uses the number of discrete macrovascular complications to determine DSS stage number and the number of discrete microvascular complications to determine DSS stage letter. Macrovascular complications: myocardial infarction, coronary artery bypass, cardiac stent, stroke, femoral-popliteal bypass, carotid endarterectomy, amputation, amputation, amputation. Microvascular complications: EYE (retinopathy, macular edema, VEG-F injection, laser surgery, legal blindness), NERVE (loss of sensation to pinprick, vibration, light, proprioception, neuropathic pain, amputation), KIDNEY (urine albumin creatinine ratio >30 mg/g, GFR < 90, proteinuria on urinalysis). **DSS substage** uses GFR to determine DSS substage number and Hemoglobin A1C to determine DSS substage letter. Example: DSS 2A, 2b means 1 macro complication (2), no micro complication (A), GFR 60–89 (2), A1C 7–8.5% (b).

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Study Outcomes

Primary outcome was the initiation of SGLT2i/GLP-1a at 6 months in Veteran DM2 with CVD/CKD compared to baseline.

Secondary outcomes were weight (pounds), blood pressure (mmHg), hemoglobin A1C, glomerular filtration rate (mL/min), and medication adherence (medication possession ratio). The medication possession ratio (MPR) is a formula used to determine patient adherence by comparing the amount of drug received (numerator) to the amount needed for continuous therapy over a given period (denominator).[12] An MPR ≥80% indicates that patient is "adherent" to medication. *Exploratory outcomes* were percentage of eye care referrals, hospitalization, and death.

DSS STAGE "cheat sheet"

DSS STAGE NUMBER	Start SGLT2i and/or GLP1 agonist?	Dose?
1	OPTIONAL	N/A
2	YES	EMPAGLIFLOZIN 10 MG QD//OZEMPIC 0.25 MG per WEEK x 4 wk then 0.5 MG per wk
3	YES	
4	YES	
5A	EMPA preferred if GFR > 20 because of ability to delay progression to ESRD; avoid GLP-1a	

DSS stage letter	Recommendation (see below)
A	Nothing needed
B (eye)	Eye
B (kidney)	Kidney
B (nerve)	Nerve
C (eye, kidney)	Eye, Kidney
C (eye, nerve)	Eye, Nerve
C (kidney, nerve)	Kidney, nerve
D (eye, kidney, nerve)	Eye, Kidney, Nerve

Diabetic Retinopathy (Eye): ensure annual dilated eye exam; consider VEG-F injections for macular edema, diabetic retinopathy

Diabetic Nephropathy (Kidney): consider ACE or ARB, and/or EMPA; consider NEPHRO referral for GFR<40 or urine microalbumin/cr ratio >300 mg/g

Diabetic Neuropathy (Nerve): consider Cymbalta, Neurontin, Lyrica or Elavil for neuropathic pain; consider Podiatry referral for Charcot foot, foot ulcer or h/o amputation

SGLT2i → Empagliflozin is VA's preferred SGLT2i (no consult needed); can start if GFR>20; starting dose 10 MG QD and can increase to 25 MG QD; use SGLT2i with caution in uncircumcised males or if there is a history of indwelling catheter or need to self-cath in order to void; effectiveness of SGLT2i to lower glucose diminishes when GFR is <30 but the cardiovascular, renal and mortality benefits still persist

GLP-1 agonist → Semaglutide is VA's preferred GLP-1 agonist (Pharmacy consult needed); recommended starting dose 0.25 MG per WEEK x 1 month then 0.5 MG per WEEK and can titrate as tolerated to 1 MG per WEEK after 1 month and then 2MG per WEEK after 1 month; Liraglutide is 2nd option in case of severe diabetic retinopathy or macular edema but not as potent; avoid GLP-1 agonist if the patient has a history of pancreatitis, thyroid cancer or thyroid nodules, severe diabetic retinopathy, macular edema or severe swallowing disorder (i.e. dysphagia, esophageal strictures); insulin doses may need to be adjusted once GLP-1 agonist are started

Figure 3 Continued.

DSS SUBSTAGE "cheat sheet"

DSS substage	Therapeutic Suggestions
1A, 2A, 3A	Start Oral DM2 agents (METFORMIN, GLIPIZIDE, EMPAGLIFLOZIN) +/- injectable DM2 agent (LANTUS, OZEMPC, VICTOZA); if already on DM2 therapy and A1C 7% or less then continue; recurrent hypoglycemia and anemia can artifactually lower A1C
4A, 5A	Fingerstick blood sugars (FSBS) more reliable than A1C in advanced CKD (GFR<30) if ANEMIC; consider DPP-4 (ALOGLIPTIN) or LANTUS +/- NOVOLOG; EMPAGLIFLOZIN should be started as long as GFR >20 and no contraindications. GLP-1 is an alternative if GFR >30 avoid if GFR <20; need to be extra cautious with INSULIN as it does not clear as well when GFR<30; see RENAL DOSING RECOMMENDATIONS
1B, 2B, 3B	POST-PRANDIAL HYPERGLYCEMIA a bigger cause of A1C elevation; consider adding NOVOLOG or OZEMPIC or VICTOZA to base regimen of LANTUS + METFORMIN +/- EMPA to improve POST-PRANDIAL HYPERGLYCEMIA
4B, 5B	Fingerstick blood sugars (FSBS) more reliable than A1C in advanced CKD (GFR<30) if ANEMIC; consider DPP-4 (ALOGLIPTIN) or LANTUS +/- NOVOLOG; EMPAGLIFLOZIN should be started as long as GFR >20 and no contraindications. GLP-1 is an alternative; need to be extra cautious with INSULIN as it does not clear as well when GFR <30; see RENAL DOSING RECOMMENDATIONS
1C, 2C, 3C	POST-PRANDIAL and FASTING HYPERGLYCEMIA likely at play; LANTUS + NOVOLOG or OZEMPC or VICTOZA + METFORMIN +/- EMPAGLIFLOZIN; refer to CDE and DIETICIAN
4C, 5C	Fingerstick blood sugars (FSBS) more reliable than A1C in advanced CKD (GFR<30) if ANEMIC; consider DPP-4 (ALOGLIPTIN) or LANTUS +/- NOVOLOG; EMPAGLIFLOZIN should be started as long as GFR >20 and no contraindications. GLP-1 is an alternative; need to be extra cautious. with INSULIN as it does not clear as well when GFR <30; see RENAL DOSING RECOMMENDATIONS; request FREESTYLE LIBRE 2 and refer to CDE and DIETICIAN
1D, 2D, 3D	Intensify LANTUS + NOVOLOG + METFORMIN + EMPA + OZEMPIC; request FREESTYLE LIBRE 2; refer to CDE and DIETICIAN and consider referral to ENDOCRINOLOGY
4D, 5D	Fingerstick blood sugars (FSBS) more reliable than A1C in advanced CKD (GFR<30) if ANEMIC; consider DPP-4 (ALOGLIPTIN) or LANTUS +/- NOVOLOG; EMPAGLIFLOZIN should be started as long as GFR >20 and no contraindications. GLP-1 is an alternative; need to be extra cautious with INSULIN as it does not clear as well when GFR <30; see RENAL DOSING RECOMMENDATIONS; request FREESTYLE LIBRE 2; refer to CDE and DIETICIAN

Figure 3 DSS STAGE and SUBSTAGE "cheat sheet".

Statistical Analysis Plan

The pilot study was not powered for statistical significance, so we calculated descriptive statistics with mean and standard deviation.

Qualitative PACT Provider Feedback

Qualitative feedback was obtained through the completion of a survey and interview that focused on seven broad areas: 1) utility of the DSS for medical decision making; 2) impact on understanding of diabetes severity; 3) influence on chronic kidney disease management; 4) time constraints and workflow integration; 5) communication with other providers; 6) training and educational materials; and 7) impact on patient care and compliance. All 6 primary care providers participating in the study were invited to give feedback but only 3 providers completed a survey, and 1 provider completed an interview. High clinical workload and limited time were the main reasons that prevented the other providers from participating.

Results

Study Provider/Patient Participation

Of the 10 primary care providers, 1 provider left the VA, 1 provider's role transitioned from primary care to home based primary care, 2 primary care providers had recently joined the VA and were not actively seeing patients. These 4 providers completed the training but did not contribute to the study. The remaining 6 primary care providers participated in the study and 59 of their paneled patients were identified during the screening process to be eligible for the study, 46 patients were assigned to a DSS stage, but 13 patients were not assigned a DSS stage due to nursing staffing shortages. We identified 14 patients who attended at least 1 study visit but 32 patients did not attend/schedule clinic visits (Figure 1) because of limited clinic appointment slot availability which made it difficult to schedule patient at the start of the study. Therefore, we focused our analysis on these 14 patients because there was confirmation that clinical interaction between the study provider and patient had occurred.

Primary Outcome

Baseline visit: After baseline PACT visit, 14/14 patients were prescribed at least one of the medications with 12/14 prescribed SGLT2i and 2/14 prescribed GLP-1a. 6-Month visit: We found 13/14 patients to still be on at least one of the medications at 6 months. This group of 14 patients includes 1 patient in whom a second agent was added (SGLT2i + GLP-1), 1 patient in whom medications were switched during the study (GLP-1a → SGLT2i) and 1 patient on neither medication (no SGLT2i nor GLP-1a).

Secondary Outcomes

At 6 months compared to baseline, weight (216 lbs. ± 41► 213 lbs. ± 39), blood pressure (141/76 mmHg ± 20/10 ►132/73 mmHg ± 17/10), A1C (7.7% ± 1.5% ►7.4% ± 0.8%) modestly decreased while GFR remained stable (64 mL/min ± 17 ►64 ± 19). Medication possession ratio was ≥80% in all 13 patients indicating medication adherence. *Exploratory outcomes* showed an improvement in the rate of eye care referrals (0%►79%), low rates of hospitalization (0%►7%) and no deaths (0%►0%).

Combined Summary of Themes: Interview and Survey Data

The feedback gathered from both the interview (n = 1) and survey (n = 3) data highlights several common themes and areas of divergence regarding the Diabetes Staging System (DSS) implemented in the 6-month pilot study at the Greenville VA Health Care Center. These insights provided a comprehensive understanding of how healthcare providers experienced the DSS and its impact on their practice. Analytical methodology was not employed due to the small sample size.

Feedback from both the interview and survey data on the Diabetes Staging System (DSS) pilot at the Greenville VA Health Care Center revealed that providers generally found the DSS helpful in guiding medication

decisions—especially regarding SGLT2 inhibitors and GLP-1 analogs—and in improving awareness of diabetes severity and related complications. The system also supported more informed management of chronic kidney disease by emphasizing medication adjustments for renal protection. However, some providers perceived limited impact due to time constraints, inconsistent use, and minimal integration into existing workflows. While DSS training and educational materials were viewed as beneficial, particularly for enhancing confidence and patient education—opinions were mixed on the usefulness of the PowerPoint presentation, handouts, and CPRS templates. Overall, the DSS showed promise for improving communication among providers and patient care decisions, though greater efficiency and adoption are needed for sustained use.

SGLT2i/GLP-1a Prescribing Behavior

We also examined if there was a residual impact of DSS training on study providers prescribing behavior during usual care of DM2 patients with CVD/CKD not involved in the study. Using power BI, we calculated % of SGLT2i/GLP-1a use in DM2 patients with CVD/CKD from fiscal year 2024 (FY 24) quarter 1 (Q1) → quarter 4 (Q4) for all study providers except one as they had 0% in Q1 and this would bias the computed % change (Table 1). This timeframe allowed us to compare the before (Q1) and after (Q4) effects of DSS training on provider prescribing behavior. We noted a 4.8% overall increase in SGLT2i/GLP-1a use from FY 24 Q1 ► FY 24 Q4 in all DM2 Veterans with CVD/CKD who comprised the patient panels of 8 study providers but were not involved in the pilot study.

Analytic Cohort vs Non-Analytic Cohort

We have included a brief comparison of baseline characteristics (age, race, gender) and DSS stage of the 14 patients who attended 1 study visit (analytic cohort) and the 32 patients who were staged but did not attend a study visit (non-analytic cohort) to strengthen confidence in the representativeness of the analytic sample. Table 2 compares the analytic vs non-analytic cohort by age (70 ± 8 vs 68 ± 9 yrs), gender (100% male vs 94% male) and race (50% black/36% white vs 50% black/50% white), respectively. Table 3 compares the analytic vs non-analytic group by DSS stage (Stage 1–21% vs 31%, Stage 2–50% vs 28%, Stage 3–14% vs 19%, Stage 4–14% vs 19%, Stage 5–0% vs 3%), respectively. Overall, baseline characteristics and DSS stage composition were similar between the analytic and non-analytic cohort.

Table 1 Percentage of SGLT2i/GLP-1a Use in Veteran DM2 Patients with CVD and/or CKD

	FY 24 Q1	FY 24 Q4
Study Provider 1	50.3	56.8
Study Provider 2	21.1	24.4
Study Provider 3	26.5	32.1
Study Provider 4	47.8	50
Study Provider 5	36.9	41.8
Study Provider 6	40.2	50
Study Provider 7	38.6	37.7
Study Provider 8	40.4	47.6
Avg %	37.725	42.55
% Change Q1-Q4	4.825	

Table 2 Baseline Characteristics (Analytic Cohort vs Non-Analytic Cohort)

		Analytic Cohort (n = 14)	
Age (at Staging)	**Gender**	**Race**	**DSS Stage Number/Letter**
67	M	Black/African American	3B (kidney)
61	M	White	1A
73	M	Black/African American	2A
73	M	Black/African American	2A
75	M	White	3B (eye)
76	M	Black/African American	1B (nerve)
57	M	Native Hawaiian/Pacific Islander	1B (kidney)
76	M	White	4B (kidney)
55	M	Asian	2B (kidney)
75	M	White	2C (eye, kidney)
76	M	Black/African American	4B (kidney)
62	M	Black/African American	2C (eye, nerve)
76	M	White	2C (kidney, nerve)
79	M	Black/African American	2B (kidney)
Mean Age (yrs)	70.07143		
SD (yrs	8.042811		
		Non-analytic cohort (n = 32)	
Age (at staging)	**Gender**	**Race**	**DSS Stage number/letter**
78	M	Black/African American	1D (eye, kidney, nerve)
77	M	Black/African American	4B (kidney)
65	M	Black/African American	1B (kidney)
73	M	White	1B (kidney)
76	M	White	1B (kidney)
76	M	White	3A
76	M	Black/African American	2A
76	M	White	4A
71	M	White	2A
68	M	Black/African American	1A
65	M	Black/African American	1A
78	M	White	4A
78	M	White	2C (eye, nerve)
68	M	Black/African American	2A

(*Continued*)

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Table 2 (Continued).

59	M	White	2A
75	M	White	3C (eye, kidney)
69	M	White	3C (kidney, nerve)
49	M	Black/African American	3B (kidney)
55	M	White	1B (eye)
47	F	Black/African American	1B (nerve)
65	M	Black/African American	3C (kidney, nerve)
55	M	White	4B (kidney)
64	F	Black/African American	4A
78	M	White	3B (kidney)
78	M	Black/African American	2A
68	M	White	4A
56	M	Black/African American	2B (kidney)
68	M	Black/African American	2C (kidney, nerve)
71	M	Black/African American	5A
75	M	White	2C (kidney, nerve)
58	M	Black/African American	1A
74	M	White	1C (kidney, nerve)
Mean (yrs)	68.40625		
SD (yrs	9.012033		

Table 3 DSS Stage Percentage (Analytic Cohort vs Non-Analytic Cohort)

Analytic Cohort (n = 14)		
Stage	**# of pts**	**% pts by Stage**
1	3	21%
2	7	50%
3	2	14%
4	2	14%
5	0	0%
Total	14	100%

(*Continued*)

Table 3 (Continued).

Non-analytic cohort (n = 32)		
Stage	**# of pts**	**% pts by stage**
1	10	31%
2	9	28%
3	6	19%
4	6	19%
5	1	3%
Total	32	100%

Discussion

Our pilot study demonstrated that implementing the DSS in the VA primary care clinic workflow is feasible and generally well accepted by providers. Statistical analysis was not performed due to the small sample size of the analytic cohort (n = 14) and the lack of a control group. However, there was a trend of increased prescribing of SGLT2i/GLP-1a in Veteran DM2 patients with CVD/CKD compared to baseline. We also observed a 4.8% overall increase in SGLT2i/GLP-1a use in Veterans DM2 patients with CVD and/or CKD who were not involved in the study but were seen by study providers during routine care at one VA Healthcare Center from FY 24 Q1 and FY 24 Q4. We are not aware of any changes in clinical guidelines or broader VA initiatives aimed at improving SGLT2i/GLP-1a use in Veteran DM2 patients with CVD/CKD that took place during study timeframe but cannot completely exclude this possibility. This suggests that DSS training may have had residual effects that improved SGLT2i/GLP-1 prescribing behavior in VA primary care providers and could serve as a metric for system level change in future VA studies.

We received generally positive qualitative feedback on the impact of the DSS on seven broad areas: 1) utility of the DSS for medical decision-making; 2) impact on understand of diabetes severity; 3) influence on chronic kidney disease management; 4) time constraints and workflow integration; 5) communication with other providers; 6) training and educational materials; and 7) impact on patient care and compliance. However, lack of time, impact of workflow integration, engagement with the DSS, quality and ease of the DSS educational material and CPRS template were identified as areas for future improvement.

There were clear challenges regarding the time required to implement the DSS, especially for providers with high caseloads or those who already feel confident in managing diabetes without additional staging. It was felt that workflow integration could be smoother, and widespread adoption across the healthcare team was likely necessary for maximum effectiveness. Additionally, providers felt that a more streamlined training program and improved patient-facing materials might enhance the overall experience for both providers and patients. While it was felt that the DSS system provided valuable tools for diabetes management, its effectiveness was contingent on how well it is integrated into the daily workflow of healthcare providers and how actively it is engaged with the team.

Limitations

We acknowledge the need for a larger randomized control trial since our study lacked a control arm. Patient attrition reduced our original 59 patients to 46 patients who received a DSS stage. Of those 46 patients, only 14 patients completed 1 study visit while 32 patients did not complete a study visit. This reduced our analytic cohort to 14 patients but as noted in the results section baseline characteristics (age, race and gender) and DSS stage between the analytic and non-analytic cohorts were similar which argues against selection bias. The attrition was due to real world challenges in implementing the DSS into existing VA clinic workflow that is impacted by multiple operational factors (ie. clinic capacity, scheduling constraints, missed appointments, nursing staff shortage) that are difficult to predict a priori. For example, VA primary care providers are full-time clinical and are not afforded protected time if they choose to participate

in research. Furthermore, their clinics are often heavily booked with a 6 month wait for appointments, making it very challenging to schedule study visits. The Greenville VA clinic serves a mostly rural patient population that sometimes has difficulty traveling to the clinic for their appointments. Finally, ongoing nursing staffing shortages limited the time some nurse had to determine DSS stage because it was perceived as "extra work". All these operational factors reflect real-world implementation challenges rather than methodological limitations or selection bias.

We believe that the inclusion of clinical pharmacists in future studies of the DSS will help overcome many of the real-world challenges to implementation that we confronted in the pilot study because of their targeted clinical focus on chronic disease management of limited conditions like type 2 diabetes, their training in medication management and their existing integration into VA primary care teams across the entire VA system. This makes them ideally suited to stage patients and medically manage them in concert with the primary care provider. We also noted improvements in A1C and referrals for eye care during the pilot study which highlight that DSS does not seek to just improve SGLT2i/GLP-1a use but also improves glycemic control and minimizes microvascular complications through implementation of guideline concordant care.

Conclusion

The DSS appears to be feasible and was well-accepted by most study providers despite real world implementation challenges that contributed to patient attrition. Although the analytic cohort was small, modest improvement in guideline concordant DM2 care was noted. If future studies of the DSS overcome implementation challenges and improve scientific rigor in study design, there is potential to make a significant impact on guideline concordant DM2 care.

Data Sharing Statement

Data will be made available on reasonable request and the corresponding author should be contacted via email (moahad.dar@va.gov). Data will only be shared if it is ethically correct to do so, where this does not violate the protection of human subjects, or other valid ethical, privacy, or security concerns.

Ethics

The Durham VAHCS IRB Committee provided ethical approval for this study (IRBnet ID # 1746160-7). All research studies on humans were performed in accordance with the principles stated in the Declaration of Helsinki.

Informed Consent

We obtained a waiver of informed consent for patients from the Durham VAHCS IRB because the aim of the study was to use an intervention (DSS) to increase use of SGLT2i and GLP-1a agents in Veterans DM2 patients with cardiorenal complications by teaching VA primary care providers how to use the diabetes staging system (DSS). Using sodium glucose cotransporter 2 inhibitor (SGLT2-i) and glucagon-like-peptide-1 agonist (GLP-1a) medicines to treat existing cardiorenal complications in DM2 patients is the current standard of care and both medicines are FDA-approved for this indication. These are routine clinical care decisions that don't involve procedures. VA primary care providers were considered the "subjects" for this study and confirmation of their voluntary participation was obtained prior to the start of the study via email.

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Author Contributions

M. Dar is the guarantor of this work and, as such, has full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. M Dar – Conceptualization, funding acquisition, investigation, methodology, supervision, writing original draft, review and editing. H Bosworth – methodology,

resources, supervision, validation, writing – review and editing. J Zhang and A Ashline – investigation, writing – review and editing. S. Kota and S. Woolson – formal analysis, software, validation, writing – review and editing. N Majette – data curation, software, project administration, writing – review and editing. All authors gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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