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Diabetes Rescue, Engagement and Management (D-REM): rationale and design of a pragmatic clinical trial of a community paramedicine programme to improve diabetes care

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ABSTRACT

Introduction Diabetes is one of the most common serious chronic health conditions in the USA. People living with diabetes face multiple barriers to optimal diabetes care, including gaps in access to medical care and self-management education, diabetes distress, and high burden of treatment. Community paramedics (CPs) are uniquely positioned to support multidisciplinary care for patients with diabetes by delivering focused diabetes self-management education and support and bridging the gaps between patients and the clinical and community resources they need to live well with their disease.

Methods and analysis We will conduct a pragmatic single-arm prospective trial of a CP-led Diabetes Rescue, Engagement and Management (D-REM) programme that seeks to reduce diabetes distress. We will enrol 70 adults (≥18 years) with diabetes who have haemoglobin A1c (HbA1c)≥9.0%, experienced an emergency department (ED) visit or hospitalisation for any cause within the prior 6 months, and reside in areas with available CP support in Southeast Minnesota (Olmsted, Freeborn and Mower counties) and Northwest Wisconsin (Barron, Rusk and Dunn counties). Participants will be identified using Mayo Clinic electronic health records, contacted for consent and enrolled into the D-REM programme. Visit frequency will be individualised for each patient, but will be an average of four CP visits over the course of approximately 1 month. Outcomes will be change in diabetes distress (primary outcome), confidence in diabetes self-management, health-related quality of life, self-reported hypoglycaemia and hyperglycaemia, HbA1c, ED visits and hospitalisations. Outcomes will be assessed on enrolment, programme completion and 3 months after programme completion.

Ethics and dissemination The study was approved by Mayo Clinic Institutional Review Board. Findings will be disseminated through peer-reviewed publications and presentations. If demonstrated to be successful, this model of care can be implemented across diverse settings and populations to support patients living with diabetes.

Trial registration number NCT04385758.

Strengths and limitations of this study

- ► This prospective pragmatic clinical trial is the first, to our knowledge, to evaluate the effectiveness of a community paramedic intervention in patients with uncontrolled diabetes.
- ► Strengths of this study include its pragmatic design and evaluation of a scalable, generalisable intervention.
- ► By including patients living in urban, rural and highly rural areas, this study will examine the feasibility and effectiveness of a community-based intervention across settings with a wide range of access to healthcare resources.
- ► Limitations include a relatively small sample size, location in the upper Midwest and limited prevalence of racial/ethnic minorities in the included geography.

INTRODUCTION

More than one in seven American adults, or 37.1 million people, are living with diabetes,[1] making it a leading cause of morbidity, disability, impaired quality of life, mortality and high healthcare costs in the USA.[1–6] The goals of glucose-lowering therapy are to prevent acute and chronic complications of diabetes by controlling hyperglycaemia, avoiding hypoglycaemia and minimising burdens of treatment and disease.[7–12] Despite advances in the science of diabetes management, rates of acute and chronic diabetes complications remain unacceptably high, particularly in racial/ethnic minorities, low income individuals and rural residents[13–17] who often have limited access to comprehensive diabetes care. Recent data suggests that control of hyperglycaemia and key cardiovascular disease risk factors, particularly

hypertension and hyperlipidaemia, has worsened since 2010.[18] Thus, there is great need for innovative care delivery models that can support patient-centred, accessible and affordable diabetes care.

Community paramedicine has emerged across the USA and in other countries around the world as an effective and efficient care delivery model to improve healthcare access for underserved communities and populations.[19–26] Community paramedics (CPs) are uniquely positioned to provide multidisciplinary, interprofessional care for patients with both medical and socioeconomic complexities with the goals of improving access to care, health outcomes and reducing costs.[27–29] CPs are experienced paramedics with advanced training in the management of low acuity and chronic health conditions, primary/preventive care and social determinant of health. They practice under the supervision of a physician medical director to provide a wide range of services tailored to each patient's medical, educational and social needs. In contrast to traditional emergency medical services (EMS), which focuses on high acuity medical care, CPs deliver longitudinal low and intermediate acuity care with emphasis on primary care, education, social support and wellness.[21 24–28 30–41] In the US fee-for-service healthcare system, financial sustainability is one of the biggest challenges facing CP programmes as a novel care delivery model. Minnesota is currently the only state to legislatively require Medicaid to reimburse for CP services as professional services. Additionally, and not limited to Minnesota, CP services can be billed to Medicare as 'incident-to' to other physician services. Finally, CP services can be funded under the umbrella of Accountable Care Organisations, Medicaid Integrated Health Partnerships and other value-based care models.[42] For this study, CP services will be supported by institutional grant funding seeking to improve diabetes care in rural and underserved communities, with plans for broader implementation and dissemination using established funding streams once programme effectiveness is established.

Thus far, most CP programmes have primarily focused on specific high-risk patient populations, most often those with history of frequent hospital, emergency department (ED) and/or EMS utilisation, multimorbidity and frailty.[21 26 36 38 43–46] While, to our knowledge, there has been no diabetes-specific CP programme, community paramedicine is uniquely suited to meet the multifaceted needs of patients with diabetes living in rural and underserved communities.[27 47 48] Our objective in this prospective single-arm pragmatic trial is therefore to evaluate the effectiveness of a CP-led intervention—Diabetes Rescue, Engagement and Management (D-REM)—on reducing diabetes distress and improving diabetes self-efficacy, glycaemic control and quality of life. Our ultimate goal is to bring care to the communities and homes where people live, and thereby improve health outcomes and quality of life for people living with this serious, progressive, chronic disease.

METHODS AND ANALYSIS

Study design

Prospective pragmatic single-arm clinical trial that began on 13 July 2020, has an estimated primary completion date 30 June 2022, and a final completion date of 30 June 2023.

Setting

Patients residing in six counties of southeast Minnesota (Olmsted, Freeborn and Mower counties) and northwest Wisconsin (Barron, Rusk and Dunn counties) will be eligible for enrolment if they are panelled to a Mayo Clinic Rochester or Mayo Clinic Health System (MCHS) primary care provider (PCP). These specific locations were chosen because they have available CP services and to ensure a diverse patient population in terms race/ethnicity, socioeconomic status, rurality and access to primary and diabetes-specific care.

Mayo Clinic is an integrated healthcare delivery system serving local, regional, national and international patients with a central hub in Rochester, Minnesota (Olmsted County). Mayo Clinic Rochester primary care practices (internal medicine, geriatrics, family medicine and paediatrics specialties) care for Mayo Clinic employees, their dependents, and local area residents. MCHS is a network of community-based clinics, hospitals, and healthcare facilities serving communities in southeast and southwest Minnesota and in northwest and southwest Wisconsin, delivering primary and specialty care to empaneled patient populations.

Mayo Clinic Ambulance carries multiple accreditations including the Commission on Accreditation of Ambulance Services (ground ambulance), Commission on Accreditation of Medical Transport Systems (ground and air ambulance) and Accredited Centre of Excellence (emergency communications centre). It serves as the primary advanced life support provider for 14 locations throughout eastern and central Minnesota and western Wisconsin, covering 6894 square miles of urban, suburban and rural areas. Mayo Clinic Ambulance is staffed by emergency medical technicians, paramedics, and registered nurses, and responds to approximately 100 000 requests for service, including 75 000 911 calls, each year. The Mayo Clinic Ambulance Community Paramedic Service has two hubs: a small hub in Barron county, WI (with 1.0 CP full-time equivalent (FTE) CP staffing, working Monday through Friday, 8:00–17:00 hour) and a larger hub in Olmsted county, MN (3.0 FTE, working 7 days per week, 7:00–19:00 hour). All CPs will be involved in this work.

Participants

Eligible participants will be patients with an established diagnosis of type 1 or type 2 diabetes, ≥18 years old, and a most recent haemoglobin A1c (HbA1c)≥9.0% obtained within the last 2 years. Patients will be required to be panelled to a PCP in Mayo Clinic Rochester or MCHS, be able to provide informed consent, have conversational

English, live independently in a private residence (ie, not in a skilled nursing facility or another congregate living setting where they receive medication management), and live in Mower, Freeborn or Olmsted counties of Minnesota or Barron, Rusk and Dunn counties of Wisconsin.

Potential participants will be identified by using Mayo Clinic electronic health records (EHR) to identify all patients meeting eligibility criteria. An initial data pull identified 233 potential participants. A report will be run monthly by an analyst within Mayo Clinic Ambulance (MCR) to identify potential participants, with new eligible patients to be identified during each data pull. Their charts will be reviewed by the study coordinator (there will be one study coordinator (AKM) supporting this study at 0.2 FTE) to confirm that inclusion criteria are met and to further exclude individuals if they have (1) cognitive impairment precluding informed consent, (2) lack of conversational English skills, (3) are a resident of a long-term care facility, (4) are enrolled in hospice, (5) are enrolled in a care coordination or disease management programme, or (6) have advanced or terminal illness. Once eligibility is confirmed, the study coordinator will call potential participants to introduce them to the D-REM programme and offer participation in the study. On receipt of oral consent (see online supplemental file), the study coordinator will mail patients (via postal mail or email, per participant preference) a HIPAA release form and (via postal mail only) the baseline study survey.

Trial enrolment will be by invitation only and contingent on CP programme availability. If a clinician was to contact the study team to request enrolment of their patient, that patient will be reviewed for eligibility criteria and offered study enrolment only if all eligibility criteria are met and the CP programme has capacity to accept new patients.

Intervention

After the signed HIPAA release form is received by the study coordinator, she will notify three CPs (two from Olmsted county and one from Barron county) that the participant is ready to be scheduled for their first visit. Scheduling will be done by the CPs for their respective region. The CP will call the participant and schedule an intake visit for a mutually agreeable time and place (if not at the participant's home). For southeast Minnesota, the participant will be assigned to be seen by the CP scheduled to work the day the participant selects as most convenient for their first visit. Subsequent visits, whether in person or phone, will be scheduled by the CP caring for them in consultation with the participant. Only one CP is available in northwest Wisconsin and will complete all scheduling and visits herself.

Trial procedures are detailed in figure 1, while the care processes and guidelines for CPs are detailed in figure 2 and the online supplemental appendix During the first (intake) visit, CPs will clarify the roles and responsibilities of the CP as compared with other members of the participant's healthcare team and answer any questions the participant may have about the intervention. CPs will obtain a full history, review and reconcile medications, obtain vital signs, perform a physical exam and review and validate the information found in the EHR as pertinent to the patient's diabetes management and overall health. Review of systems and physical exam will pay specific attention to diabetes-related complications, including skin problems (eg, lower extremity ulcers, rashes and/or injection site reactions), nervous system problems (eg, central, autonomic and/or peripheral neuropathy), cardiovascular problems (eg, dyspnoea, angina, claudication), vision and/or hearing impairment, cognitive/memory concerns and mood concerns (eg, depression, anxiety, diabetes distress, burn-out). As part of medication review, CPs will assess medication adherence and how participants store, administer and dispose of their medications. To identify potential barriers to optimal diabetes management and elicit clinical and non-clinical needs, CPs will assess the participant's socioeconomic challenges, including food insecurity, housing insecurity and cost-related non-adherence to medications and/or care plan.

Following the general assessment portion, diabetes-specific evaluations will include concerns or questions that the participant has related to their diabetes; self-reported hypoglycaemia, hyperglycaemia and impaired hypoglycaemia awareness; and factors potentially contributing to hypoglycaemia and hyperglycaemia. CPs may conduct a variety of assessments and educational interventions including: observe a blood glucose check to make sure it is done correctly and confirm that the participant's glucose meter is functioning properly; review glucose log with the participant or, if the participant does not keep a log, teach them how to maintain and interpret one; discuss the signs and symptoms of hypoglycaemia and how to manage them; review the negative health consequences associated with hypoglycaemia and hyperglycaemia; discuss the risk factors for and causes of hypoglycaemia and hyperglycaemia; review the participant's daily routine as it related to diabetes management; ensure an optimal supply of and access to insulin/other medications and testing/administration supplies through local or regional supply chains; and review needle/syringe safe disposal. What items will be covered, and the order in which they are covered, will be guided by the clinical context and participant's needs.

The CPs will use this information to identify areas in need of intervention and education. They will work with the participant to set ≥3 SMART (Specific, Measurable, Achievable, Relevant and Time-Bound) goals for the 1-month intervention. Depending on the needs identified by the CP and the participant, the CP will recommend referrals to primary care, social services and/or community resources. If the participant agrees, the CP will execute these referrals after each visit is completed. CPs will also introduce the participant to the patient online services portal, a free online resource, as a means of efficient and secure asynchronous communication with the healthcare team, if not already set up.

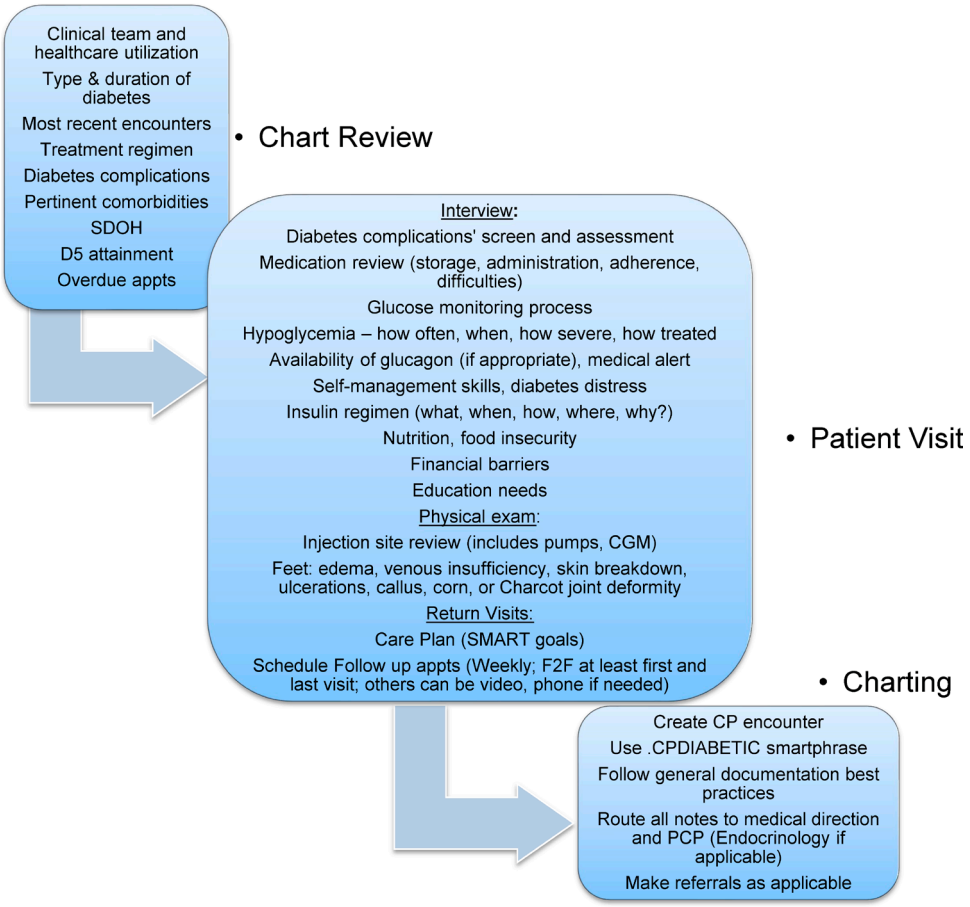

Figure 1 Schematic of the intervention. CPs, community paramedics; DM, diabetes mellitus; F/U, follow-up; ED, emergency department; EHR, electronic health record; HbA1c, haemoglobin A1c; SDOH, social determinants of health.

This information will be charted in the Mayo Clinic EHR. Following completion of the intake visit, the CP will forward a copy of the patient's care summary, via the EHR, to the CP Medical Director (RGM), who is also the study principal investigator, and the participant's PCP within 24 hours. If the participant already has established

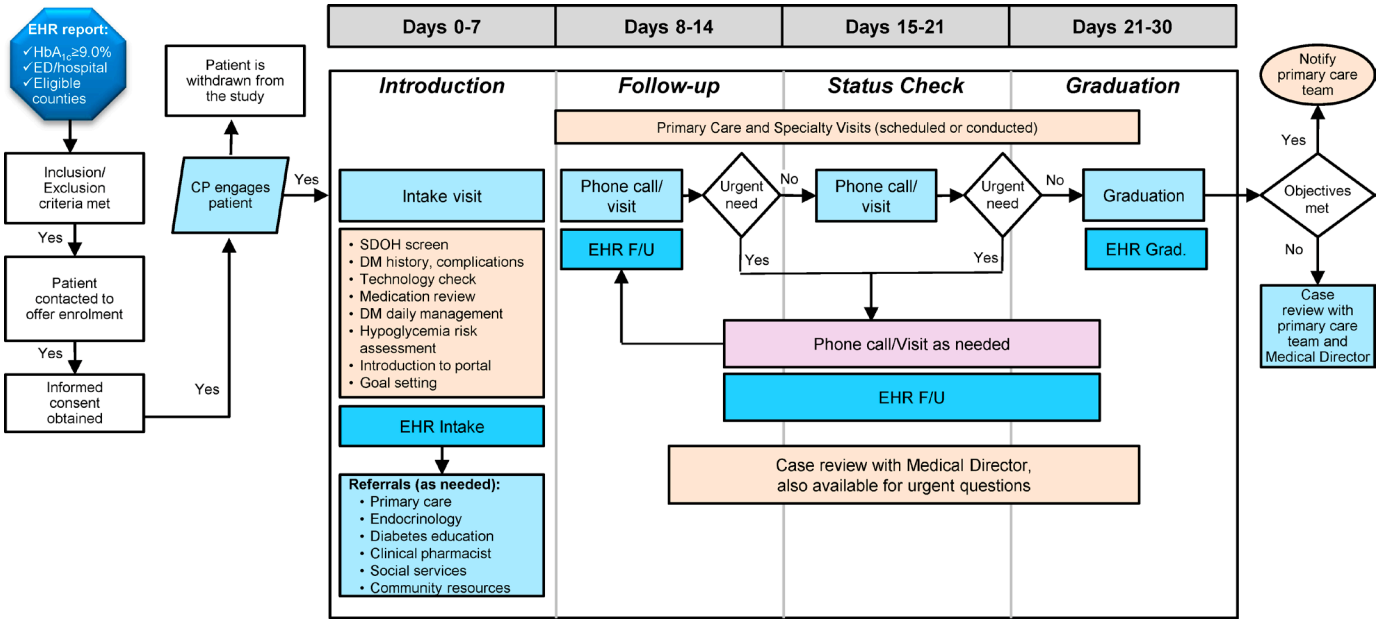

Figure 2 Care processes for community paramedic (CP) diabetes visits. CGM, continuous glucose monitor; F2F, face-to-face; PCP, primary care provider; SDOH, social determinants of health.

care with an endocrinologist, certified diabetes care and education specialist and/or clinical pharmacist, they will be included in the communication as well. This correspondence will include the participant's care report; the participant's set goals, concerns and questions; any needs for the participant identified by the CP; and any referrals to clinical providers or external agencies that the CP deems to be potentially necessary. The PCP will be responsible for ordering any clinical referrals as dictated by their judgement and within the scope of usual practice. Discussion with the PCP related to care planning can occur prior to subsequent visits. Medical issues requiring immediate or urgent attention will be forwarded to the PCP and/or CP Medical Director via the message feature imbedded in the EHR or by telephone, as the acuity of the issue dictates.

Frequency, timing, and modality (ie, in person or telephone) of follow-up visits will be determined by the participant and the CP during the intake visit and will be reassessed at each subsequent encounter. An average of two in-person visits and two phone visits over the 1-month period is anticipated; however, an alternate schedule will be accommodated depending on clinical need. At each visit, CPs will obtain an interval history and deliver education and other services as dictated by participant's needs and circumstances.

Primary outcome

The primary outcome will be change in diabetes distress, measured by the validated Diabetes Distress Scale (DDS)[49 50] and ascertained using mailed survey, from baseline to end of the intervention (1-month survey). Time frame of outcome collection is shown in figure 3. Each participant will receive up to three mailings of each survey with reminder phone calls to complete the survey if not received within a 3-week period.

Secondary outcomes

Multiple secondary outcomes will be examined, measuring the change from baseline to 1 month (approximately at D-REM completion) to assess programme effectiveness and 4 months (approximately 3 months after D-REM completion) to assess programme durability. Outcomes collected via mailed survey will include (1) confidence in diabetes-self management (measured by the Diabetes Self-Management Questionnaire (DSMQ))[51]; (2) health-related quality of life (measured by the EQ-5D)[52 53]; (3) frequency of self-reported hypoglycaemia (blood glucose <70 mg/dL and <54 mg/dL) and hyperglycaemia (blood glucose ≥250 mg/dL); (4) open-ended questions regarding concerns/challenges with diabetes management and perceptions of the CP programme. The EHR will be used to assess for (1) HbA1c before and within 3–6 months after enrolment; (2) attainment of the D5 composite measure[54] of diabetes care quality (includes indicators of HbA1c, blood pressure and low density lipoprotein cholesterol control, tobacco use and aspirin use) before and 4 months after enrolment and (3) number of ED visits and hospitalisations during the 6 and 12 months before, and 6 and 12 months after, enrolment. EHR-derived outcomes will be collected for all study participants, including those who do not respond to the surveys.

During the final phase of the research, we will conduct interviews with CPs engaged in the programme to examine barriers to implementation, opportunities for improvement and potential gaps in knowledge, training andresources. All CPs delivering the intervention will be invited to participate and share their experiences related to the programme via teleconference technology at a time that is convenient for them. Participation will be voluntary. Interviews will last 45–60 min and be conducted by a qualitative researcher unaffiliated with the CP Service. All interviews will be audiorecorded and transcribed for analysis.

Independent variables

The EHR will be used to ascertain participant age, gender, race/ethnicity, rurality, glucose-lowering medications, comorbidities and prior ED/hospital utilisation for hypoglycaemia and hyperglycaemia. Comorbidities of interest will be ascertained using validated code sets and include retinopathy, neuropathy, coronary artery disease, cerebrovascular disease, peripheral arterial disease, heart failure, chronic kidney disease, chronic obstructive pulmonary disease, asthma, depression, other mental health disorders, hypertension and substance use. Survey will ascertain diabetes type and duration. Survey will also assess baseline diabetes distress (DDS,[49 50] DSMQ,[51] self-reported hypoglycaemia (glucose <54 mg/dL or need for third party assistance), hyperglycaemia (glucose ≥250 mg/dL) and quality of life (EQ-5D).[52 53]

Baseline		Enrollment	Intervention	Follow-Up		
-12 months	-6 months	0	+1 month	+4 months	+6 months	+12 months
EHR (comorbidities, HbA_{1c}, D5, ED and hospital use)	**EHR** (comorbidities, HbA_{1c}, D5, ED and hospital use)	Identify patients in EHR Oral consent, written HIPAA **Baseline survey**	*D-REM Program* *CP home visits & calls* **1-month survey**	**4-months survey** **EHR** (HbA_{1c}, D5, ED/hospital use)	**EHR** (HbA_{1c}, D5, ED and hospital use)	**EHR** (HbA_{1c}, D5, ED and hospital use)

Figure 3 Study timeline. CP, community paramedic; D5, composite indicator of diabetes care quality; D-REM, Diabetes Rescue, Engagement and Management; ED, emergency department; EHR, electronic health recor; HbA1c, haemoglobin A1c.

Power analysis

There has been no prior study examining impact of CP on diabetes management. However, we anticipate that our programme will be as or more effective than other limited diabetes self-management education/support interventions. Based on a previous study,[50] patients with diabetes who were administered an educational intervention showed a decrease in DDS score of 0.24±0.89 over a 4-month period, corresponding to a decline of approximately 0.27 SD. If the change from baseline to end of study has a similar effect size, a sample size of N=64 (one tailed, alpha=0.1) will provide statistical power of 80%. To accommodate sample attrition of up to 10%, a total sample size of 70 is proposed. Participants will be recruited sequentially until target accrual is reached.

Analysis plan

The primary outcome of the study will be the change in DDS score from baseline to 1 month. DDS scores from baseline to 4, and 1 month to 4 months will be analysed to see the lasting impact of the intervention. Secondary outcomes of HbA1c, D5 and ED visits/hospitalisations are exploratory due to the short duration of the intervention. Descriptive statistics will be summarised using mean and SD for continuous variables and frequency percentages for categorical variables. Data will be analysed using a one-tailed paired t-test with 90% CIs.

Qualitative data gathered through free-text responses to the participant surveys and CP interview transcripts will be analysed separately using a content analysis approach.[55] Data will be uploaded into NVivo qualitative management software for coding and analysis. A code structure will be developed for each using an integrated deductive and inductive approach informed by survey/interview questions and content that emerges from the data. An iterative process involving multiple members of the research team will be used to develop and refine the analysis and interpretation. An analysis audit trail will document decisions made during the analyses. Cross-cutting themes will be identified among the participant groups and compared within and across key subgroups, and presented through aggregate description.

Patient and public involvement

This work was motivated by the need for accessible patient-centred care delivery models for patients with diabetes, though not explicitly informed by individual patients' experience and preference. Patients were not directly involved in the design or conduct of this study.

ETHICS AND DISSEMINATION

The study protocol, consent form, survey instruments and all communication materials have been reviewed and approved by the Mayo Clinic Institutional Review Board (IRB). Any protocol modifications that will occur during the course of the study will be reported to the IRB. Participants will be consented using verbal consent but will need to sign a HIPAA release form (either mailed or electronic) prior to enrolment in the study. At the time potential participants provide verbal consent, they will be asked, for follow-up purposes, to provide their name, address, phone number and email address. They will be informed that study records will be kept as confidential as possible. No individual identities will be used on any reports or publications resulting from the study. Study information will be coded and stored in secured files. Only authorised study personnel will have access to the files. Individuals with cognitive impairment, which precludes them from providing informed consent, will not be included in the study per inclusion/exclusion criteria.

The potential risks associated with participation in this study are low, and the involved activities are considered minimal risk to subjects. Participants may be uncomfortable being identified as having uncontrolled diabetes, revealing personal information to the CPs, revealing their home living situation or providing responses to certain questions included in the questionnaires. They will have the option to refuse to provide any information they are not comfortable providing and to schedule appointments outside of their home in a convenient, mutually agreed on location. Safety and COVID-19 infection control precautions will be implemented and followed according to contemporaneous Mayo Clinic and Mayo Clinic Ambulance standard protocols.

CP participation in the interviews will be voluntary. Members of the CP leadership team, including the Medical Director, will not know if a CP declined participation and will not have access to identifiable interview transcripts. CPs will be advised that their decision whether to participate, and any information they provide during the interview, will have no impact on their employment or standing in Mayo Clinic Ambulance.

Dissemination of research findings will be a collaborative, multimodal effort by the study investigators and Mayo Clinic Ambulance as a critical partner. Dissemination will occur at academic conferences, peer-reviewed publications and institutional meetings. We further anticipate that results of this study will inform clinical practice and allow for D-REM to be a standard offering to patients with uncontrolled diabetes.

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Contributors MBJ oversees the community paramedic intervention and reviewed/revised the manuscript. CPL cocreated the diabetes clinical practice guidelines and reviewed/revised the manuscript. PNC codesigned the community paramedic intervention and reviewed/revised the manuscript. LAM participated in study design and reviewed/revised the manuscript. ZRS supported the study coordinator and reviewed/revised the manuscript. JARS supported the study coordinator and reviewed/revised the manuscript. AKM is the lead study coordinator on the study and reviewed/revised the manuscript. EB supported the study coordinator, participated in study design and reviewed/revised the manuscript. MAL participated in study design, will oversee qualitative analyses and reviewed/revised the manuscript. MCR conducted analyses and reviewed/revised the manuscript. KMF participated in study design, will be conducting analyses and reviewed/revised the manuscript. RGM secured funding, designed the study, prepared the protocol and drafted the manuscript. All authors approved the final version of the manuscript. All authors will have access to study data.

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Disclaimer The study sponsors have had no role, and will not have a role, in the study design; collection, management, analysis, or interpretation of data; writing of the report; or the decision to submit the report for publication. Study contents are the sole responsibility of the authors and do not necessarily represent the official views of NIH.

Competing interests In the last 36 months, RGM received support from NIDDK, PCORI and AARP. She also serves as a consultant to Emmi (Wolters Kluwer) on developing patient education materials related to diabetes.

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 Not applicable.

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Background

Screening and Monitoring Parameters

1. Hemoglobin A1c (HbA1c) should be checked every 3 months if not at goal, every 6 months if at goal
2. Lipid panel should be checked annually
3. Kidney function (creatinine, urine albumin/creatinine ratio, potassium if treated with an ACE inhibitor or an angiotensin receptor blocker, sodium if treated with a diuretic) should be checked at least annually. More frequent monitoring required if patients have kidney disease.
4. Annual eye exam
5. Annual foot exam
6. Hypoglycemia: every patient treated with medications that place them at risk for hypoglycemia (insulin, sulfonylurea) should be screened for hypoglycemia at each visit

Optimal Diabetes Care (D5)

This is what the primary care team will consider to be "goal" for most patients with diabetes (both type 1 and type 2), as this measure is calculated and reported for all adults ages 18 through 75 years (exceptions: pregnancy, skilled nursing facility resident, enrolled in hospice). Importantly, these hemoglobin A1c (HbA1c) and blood pressure targets are the upper limits of what is acceptable and is not necessarily the evidence-based goal of therapy. Diabetes management is about a lot more than just blood sugars. It is also about blood pressure, taking a cholesterol medication, not smoking, and taking aspirin if they have heart disease. *We need to be asking patients about all these things doing our visit.*

1. HbA1c <8%
    - Evidence-based goals: <7% for most adults; <8% for adults with multiple or advanced comorbidities; goals lower than 7% may be appropriate for select patients if achieved without hypoglycemia or treatment burden.
2. BP <140/90 mmHg
    - BP <130/80 may be appropriate for patients at high risk for cardiovascular disease, if achieved without hypotension or treatment burden
3. Statin therapy for patients ≥40 years old, unless LDL-C <70 mg/dL (without history of cardiovascular disease) or LDL-C <40 mg/dL (with history of cardiovascular disease) or patient has an allergy or contraindication to a statin.
4. Nonsmoker (no tobacco use of any kind, including no chewed or vaped tobacco)
5. Aspirin use required only for patients who have existing vascular disease (cardiovascular, cerebrovascular, or peripheral vascular), unless they have an allergy or contraindication to aspirin (such as history of significant bleed).

Initial Chart Review

☐ Review most recent notes from primary care, endocrinology, pharmacy, certified diabetes care and education specialist (CDCES), dietician, and social worker as available.

- ☐ Get a sense of their healthcare utilization: emergency department visits, hospitalizations, no show rates to appointments, engagement with primary care, specialists seen.
- ☐ Diabetes history
    - Diabetes type: type 1, type 2, post-pancreatectomy or post-pancreatitis, steroid-induced, other
    - Year first diagnosed with diabetes
    - Diabetes control (most recent and trends in HbA1c over time)
- ☐ Current treatment regimen:
    - Glucose-lowering medications
    - Glucagon: yes/no, what type (injection, nasal)
        - Glucagon should be prescribed to all patients with type 1 diabetes, most patients with type 2 diabetes treated with intensive insulin therapy (multiple daily insulin injections or insulin pump).
    - Diabetes testing supplies: see what is listed in the medication list, if anything
    - Cholesterol-lowering medications
    - Blood pressure medications
    - Aspirin
- ☐ Diabetes complications (review problem list, prior hospital notes, most recent primary care H&P, most recent endocrine note if present)
    - Retinopathy or visual impairment
    - Neuropathy
    - Kidney disease
    - History of amputation, lower extremity ulcers, other lower extremity complications; note if there is an alert for an overdue foot exam
    - Heart disease (history of MI, stenting, CABG)
    - Cerebrovascular disease (history of stroke or TIA)
    - Peripheral vascular disease (mention of claudication, prior lower extremity stenting procedures, carotid artery stenting)
    - History of severe hypoglycemia (ED visit or hospitalization)
    - History of severe hyperglycemia (ED visit or hospitalization for DKA or hyperglycemic hyperosmolar state)
- ☐ Pertinent comorbidities
    - Depression
    - Anxiety
    - Substance use
    - Smoking
    - Serious mental illness (schizophrenia, bipolar disorder, etc)
    - Sleep apnea (note CPAP or BiPAP use)
    - Obesity (note BMI)
    - Dementia or other cognitive impairment
- ☐ Review the social determinants of health section for any concerns
- ☐ What are they overdue for? (review BPAs and HM module) – if overdue, would be helpful to tell them that their PCP may be contacting them to schedule these and they should do it
    - A1c should be checked every 3 months if 8% or higher, otherwise every 6 months
    - Creatinine, Cholesterol, and urine microalbumin should be checked every 12 months
    - Eye exam every year (either dilated eye exam or retinopathy photo screen)

First Visit

- ☐ Verify diabetes type and duration
- ☐ Ask about diabetes complications and their symptoms – heart disease (chest pain, shortness of breath), eye disease (blurry vision), kidney disease (verify awareness of kidney disease if present), amputation (screen for ambulation concerns and fall risk), lower extremity pain/numbness/tingling/ulcers/corn/callus (symptom screen, foot exam)
- ☐ Medication review, including screen for adherence, side effects, cost concerns, storage
- ☐ Glucose monitoring: how, how often, and when; what are the values
    - I typically ask the patient to walk me through their day to understand how diabetes fits into their life and what challenges they face
- ☐ Hypoglycemia – how often, when, how severe (level 1: glucose <70, level 2: glucose <54, level 3/severe: any glucose when another person had to help the patient be treated). Ask about the circumstances these happened in, how the patient treated them, what they learned for the future to avoid having future hypoglycemia
- ☐ If they endorse severe hypoglycemia (hypo that required another person to help treat), have type 1 diabetes, or are treated with an insulin pump or 4 injections of insulin per day, they should have glucagon. Glucagon expires after 1-2 years, depending on the specific type, so check the expiration date.
- ☐ If treated with insulin, ask if they take the same doses of insulin every time or if they vary it based on either their blood sugar or their meal or some other factor. If they have a correction scale or sliding scale, ask to see it and make sure they are doing what it says. If they vary the insulin dose without specific instructions to do so, note that it may be dangerous and they should talk to their PCP/endocrinologist about it. Document what they are actually doing to discuss with PCP/endocrinologist after the visit.
- ☐ Ask about meals – who cooks them, what kinds of food, how often, food insecurity
- ☐ Make sure they have a fridge to store their insulin (if insulin treated) and food
- ☐ Ask about financial barriers to medications, testing supplies, insulin administration supplies; rationing of insulin or medications or food.
- ☐ Physical activity and exercise

On physical exam, key areas to look at are:

1. Sites of insulin/GLP-1 receptor agonist (the non-insulin injectable diabetes medication) administration to see if there are many bruises or hardened areas where they keep injecting the insulin; counsel to inject in a different site every time (M or W method)
2. If they have a device (pump or CGM), look at the site where it is inserted and assess for irritation or other problems at the insertion site
3. Feet: edema, venous insufficiency, skin breakdown, ulcerations, callus formation, or Charcot joint deformity. Microfilament exam (if not done within the last year per).
4. Comorbidity-specific: lung exam with heart failure and lung disease; heart exam with any cardiovascular disease.
5. Screen for depression with PHQ-2:

Return Visits

- Create care plan during the first visit together with the patient (SMART goals)
- Cadence and type (in person, video, or phone) to be determined based on patient's need

- At each visit, set at least one goal to be achieved prior to the next visit
- Expectation of at least 4 visits with the patient over the course of the month

Charting

1. Create a community paramedic external outreach encounter
2. Use the CPDIABETIC smart phrase and follow general documentation best practices
3. Route each note to medical director, primary care physician, and any other diabetes provider (endocrinology, CDCES, pharmacist, dietician) as appropriate. Note should include details on glucose levels, barriers to care, recommendations to patient, requests/recommendations to the clinical team.

Patient Resources

- Use relevant patient education materials from Mayo Clinic Patient Education
- Medication cost assistance resources (savings cards, patient assistance programs)
- Community resources: Aunt Bertha, county social services

Oral Consent Script IRB 10138.003 Effective Date 12/19/2016

Mayo Clinic: Office for Human Research Protection
Oral Consent Script

Protocol Title: Community Paramedicine Program to Improve Diabetes Care Quality, Equity, and Outcomes
IRB #: 20-001011
Principal Investigator: Rozalina McCoy, MD, MS

You are being asked to participate in a research study about a home-based diabetes management and support program offered to patients with diabetes. You are being invited to participate in this study because you have diabetes with elevated hemoglobin A1c, and have had an emergency department visit or hospitalization within the last six months.

The goal of this research study is to learn about how our patients manage their diabetes, what challenges they face as they live with diabetes, and how community paramedics can help patients like you manage their diabetes.

If you agree to participate, you will be connected with a community paramedic to enroll in a program designed to support patients with diabetes. As part of this program, a community paramedic will follow-up with you in person and/or by phone over the course of the next month. We estimate an average of two one-hour in-person visits and two 30-minute phone visits; however, you may receive more or less depending on your individual desire and need. The community paramedic will work with you to help manage your diabetes, improve your health, and connect you with any additional resources that may be needed. The community paramedics will document these clinical encounters in your medical record.

Additionally, you will be asked to complete three questionnaires over the course of four months: (1) right now, (2) at the time that you complete the program, and (3) in about four months. We anticipate these will take about 15 minutes of your time to complete. Your medical record will be accessed to collect information regarding your history with diabetes and basic demographic information (age, sex, etc.). All information that is collected during this study will be stored in a locked file cabinet and on a secure, password-protected computer. You and/or your insurance will be responsible for covering the cost of any tests or procedures that are ordered as part of your clinical care through your participation in this program. You will not receive remuneration for your participation, but the in-person and phone visit portions of this program will be offered at no cost to you.

If you decide to participate, you will need to read and sign the Authorization to Use and Disclose Protected Health Information (HIPAA) form and return it with the first questionnaire. You may choose to have the HIPAA sent to you electronically or by mail for review and signature. We are not allowed to use the answers without your signature on the HIPAA form. An extra copy will be included for your records. Once your signed authorization (HIPAA) form has been signed and returned, a member of our study team will forward your information to a community paramedic to start your enrollment into the program.

The risks associated with the research study are minimal, which means that we do not believe that they will be any different than what you would experience at a routine clinical visit or during your daily life. You may choose not to answer any questions that make you feel uncomfortable.

Oral Consent Script IRB 10138.003 Effective Date 12/19/2016

This study will not make your health better. It is for the benefit of research. Information we will learn from this study will help us further develop the community paramedicine program and make it available to more patients across Minnesota.

Your information collected as a part of this research could be used for future research or distributed to another investigator for future research without additional informed consent from you, only after information that identifies you is removed.

Please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty. Specifically, your current or future medical care at the Mayo Clinic or Mayo Clinic Health System will not be jeopardized if you choose not to participate.

If you have any questions about this research study you can contact Danielle Bostrom at 507-538-6911. If you have any concerns, complaints, or general questions about research or your rights as a participant, please contact the Mayo Institutional Review Board (IRB) to speak to someone independent of the research team at 507-266-4000 or toll free at 866-273-4681.