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# BMJ Open

## Do quality improvement initiatives for diabetes care address social inequities? Secondary analysis of a systematic review.

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## ABSTRACT

### Objective

To examine the extent of equity considerations in diabetes quality improvement (QI) studies.

### Research Design and Methods

This is a secondary analysis of a systematic review assessing the effectiveness of QI interventions. Studies were identified using Medline, HealthStar, and the Cochrane EPOC database. Randomized controlled trials assessing twelve QI strategies targeting health systems, healthcare professionals, and/or patients for the management of adult outpatients with diabetes were eligible. The PROGRESS-Plus framework was used to identify trials that focused on disadvantaged patient populations, to examine the types of equity-relevant factors that are being considered, and to explore temporal trends in equity-relevant diabetes QI trials.

### Results

Of the 278 trials that met the inclusion criteria, 95 trials were identified to have equity-relevant considerations. These include 64 *targeted trials* that focus on a disadvantaged population with the aim to improve the health status of that population and 31 *general trials* that undertook subgroup analyses to assess the extent to which interventions may have had differential impacts on disadvantaged subgroups. Trials predominantly focused on race/ethnicity, socioeconomic status, and place of residence as potential factors for disadvantage in patients receiving diabetes care.

### Conclusions

This systematic review of diabetes QI studies identifies a substantial gap in equity-relevant considerations. To ensure that good medical care is accessible and effective for those who need it the most, further research is needed to evaluate the effects of socioeconomic determinants of health in determining how patients with diabetes experience and respond to health interventions.

### Word Count

245

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- The use of the PROGRESS-Plus framework provides an objective and standardized approach for identifying and analyzing equity relevant information within research publications.
- The inclusion of only English language publications was a practical limitation on the scope of this study.
- The focus on only primary publications of trials meant any equity relevant analyses in subsequent publications of the same trial were not captured in this review.
- The lack of standardized terminology for equity relevant information in the general literature restricted our ability to fully capture all the various issues that may lead to disadvantages in medical care.

## INTRODUCTION

Diabetes affects approximately 8.5% of the adult population; the increasing prevalence of physical inactivity, obesity, and an aging population means that this number will increase over time.[1,2] The burden of diabetes is not evenly spread through the population. Racial and ethnic minorities, as well as people of lower socioeconomic status are more likely to develop diabetes.[2,3] Such individuals are also more likely to experience delayed diagnosis and lower quality of care, leading to greater risk for diabetes-related complications.[2,3]

Patients with diabetes require lifelong medications, routine follow-up with healthcare professionals, and regular preventative screening exams to reduce the likelihood of morbidity and mortality.[4,5] Socially disadvantaged groups may experience multiple barriers to high quality care due to factors such as differences in language or culture, inadequate financial resources, or prohibitive distances from care centres. [2,6–8] To ensure that innovations and standards of care in healthcare reach the most disadvantaged segments of the population, interventions must recognize and address these equity-based considerations.[2,7–9]

Quality improvement (QI) in the care of patients with diabetes is a rapidly expanding field of interest.[10] However, while many QI strategies are effective in improving diabetes care in general populations,[10] it is unclear whether they improve or worsen health disparities among disadvantaged subgroups.[11] QI strategies designed for the general population may not be accessible to disadvantaged groups or may not have the same efficacy in disadvantaged populations and may inadvertently lead to an increase in diabetes related health disparities.[2,7,9,11,12]

Recently, we updated a systematic review of trials of QI strategies for diabetes care.[13] In this secondary analysis of that review, we examine the extent to which health equity concerns were considered in diabetes QI studies. Specifically, we assessed the ways in which QI studies targeted interventions toward disadvantaged populations, looked at risk factors for disadvantage in the patient population, and analyzed the impact of interventions on disadvantaged subgroups.

## RESEARCH DESIGN AND METHODS

Our goal was to examine the extent of focus in the literature on understanding the effects of diabetes QI for disadvantaged populations. A detailed description of methods used for searching and screening the relevant data for the underlying systematic review has been published.[13]

### Study Selection

RCTs examining one of the twelve predefined QI strategies targeting health systems, healthcare professionals, and/or patients for the management of adult outpatients with diabetes were included. Studies had to report at least one process of care measure (e.g., proportion of patients taking acetylsalicylic acid, statins, or antihypertensive medication; screened for retinopathy or foot abnormalities and monitored for renal function) or intermediate outcomes (e.g., glycosylated haemoglobin levels [HbA1c], low-density lipoprotein cholesterol levels, diastolic and systolic blood pressure; proportion of patients with controlled hypertension or who quit smoking).

For this secondary analysis, we further identified a cohort of *equity-relevant trials* that targeted or assessed equity factors as defined by the PROGRESS-Plus framework.[9] Within this cohort,

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3 trials were classified as either Targeted or General. *Targeted equity-relevant trials* were defined  
4 as a trial focussed on a population with an identified disadvantage in health in order to improve  
5 the health status of that population or to reduce the health gradient. *General equity-relevant trials*  
6 were defined as a trial involved a broad participant population but made comparisons of effects  
7 in disadvantaged subgroups to assess the extent to which interventions may have differential  
8 impacts. For example, a trial testing a primary care-based culturally sensitive behavioural  
9 interventions in a population of urban African Americans with type 2 diabetes [15] would be  
10 classified as a *targeted* equity-relevant trial because it purposefully directed interventions  
11 towards a disadvantaged population. In contrast, a trial testing a tele-homecare monitoring  
12 system for patients with type 2 diabetes that then specifically explored the benefit of the  
13 intervention in female patients and those with lower education levels,[16] would be included as a  
14 *general* equity-relevant trial.  
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### 18 **Data Extraction**

19 We used the PROGRESS-Plus framework,[9] to consider the range of factors that may increase  
20 the risk for a population subgroup to be disadvantaged, including participants' Place of residence,  
21 Race/ethnicity/culture/language, Occupational status, Gender/sexual identity, religious  
22 affiliations, Education level, Socioeconomic status, Social capital, plus age, disability, sexual  
23 preferences, and relationships.[9] Specifically, we interpreted these risk factors in the context of  
24 a patient's ability to access health care and effectively manage their diabetes. For example, it  
25 may be more difficult for patients living in rural or geographically isolated areas to access  
26 dependable primary care, leading to negative implications for their ability to achieve diabetes-  
27 related targets. Supplemental Table 1 outlines our full interpretation of PROGRESS-Plus factors  
28 in considering how these factors might lead to inequity in diabetes management across sub-  
29 populations, developed based on previous literature,[6] the PROGRESS framework,[9] and in  
30 collaboration with PROGRESS-authors (VW).  
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34 We extracted PROGRESS-Plus factors identified in the baseline patient characteristics for all  
35 studies. Additionally, for equity-relevant studies, we extracted PROGRESS-Plus factors  
36 identified in the study objective, study design (e.g., patient eligibility criteria and patient  
37 recruitment techniques), and analysis of results. Two reviewers independently abstracted the  
38 relevant data for each RCT. We only coded instances when authors were explicit in their mention  
39 of PROGRESS-Plus factors. Discrepancies were resolved by discussion.  
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### 43 **Data Synthesis and Analysis**

44 As we had no *a priori* hypothesis about the differences or similarities that would be found among  
45 trials regarding issues of equity or efforts to address areas of disadvantage, we provide here  
46 descriptive analyses only. We describe the proportion of trials that focused on equity-relevant  
47 factors and types of factors considered in these trials. In addition, to explore for time-trends in  
48 the consideration of equity-relevant factors in diabetes QI trials, we split our analyses by median  
49 date of study conduct.  
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## 51 **RESULTS**

### 52 **Literature search and review process**

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Figure 1 summarizes the flow of literature in the QI review. The initial search identified a total of 7248 citations; review of 2,691 full text articles resulted in a final sample of 311 reports, representing 278 unique trials.

### Study characteristics

Ninety-five trials (34.2%) were identified as equity-relevant; 64 of these were classified as targeted and 31 as general. Characteristics were similar between non-equity studies and equity-relevant studies (Table 1). Most trials focused on patients with type 2 diabetes, and looked at glycemic control combined with cardiovascular status or other health benchmarks (aspirin use, statin use, hypertensive drug use, screening for retinopathy/nephropathy/neuropathy, smoking cessation) as the primary outcomes of interest. Mean baseline HbA1c was comparable between non-equity and equity-relevant trials, but targeted trials reported the inclusion of a greater proportion of patients with HbA1c greater or equal to 8% compared to general trials.

The relative frequency of individual QI strategies assessed in the studies were also comparable across non-equity and equity-relevant trials with a few exceptions. Overall, patient education, promotion of self-management, and case management were the most frequently used QI interventions across all studies. Among equity-relevant trials, case management, team changes, and patient education were evaluated more frequently in targeted trials compared to general trials.

Table 2 describes the frequency of PROGRESS-Plus factors examined in all studies. Among 183 non-equity studies, 94.5% reported data on the age of participants, 90.7% reported data on gender/sex, 35.0% reported data on race/ethnicity/culture/language, 31.7% reported data on education levels, and 30.1% reported data on disability status. Overall, age and gender/sex were the most frequently documented PROGRESS-Plus factors, appearing equally in both equity-relevant studies and non-equity studies. In comparison, race/ethnicity/culture/language, socioeconomic status, education, social capital, occupation, and place of residence appeared significantly more frequently in equity-relevant trials than in non-equity trials. The PROGRESS-Plus factors of sexual preference, features of relationships, and time-dependent relationships were not identified in any of the studies.

The targeted trials were most commonly directed toward race/ethnicity/language/culture (53.1% of targeted trials), place of residence (29.7%), and socioeconomic status (28.1%); occupation, gender/sex, religion, or social capital were rarely addressed in the objective of target trials. Most targeted trials (n=42; 66) used a single PROGRESS-Plus factor to define its patient population (e.g., interventions targeted people in rural communities *or* patients belonging to a particular ethnic minority). Twenty trials looked at population subgroups with two PROGRESS-Plus factors. Only two trials simultaneously targeted three factors.[17,18] Fifteen targeted trials (23%) conducted sub-analyses to understand whether their intervention varied in its effectiveness across additional PROGRESS-Plus factors distinct from those used to define their intervention and their target patient populations.

Of the 31 general trials that did not contain an equity-specific objective but conducted stratified analyses across PROGRESS-Plus factors, gender/sex (71.0% of general trials), age (71.0%), race/ethnicity/culture/language (25.8%), and education (29.0%) were the most commonly stratified factors.



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4 Table 3 examines over time in the extent of equity-relevance in diabetes QI trials. Prior to 2007,  
5 32.0% of all diabetes QI studies were equity-relevant trials. In the period from 2007 to 2014,  
6 36.0% were equity-relevant trials. Targeted trials were responsible for 56.1% of equity-relevant  
7 trials prior to 2007. This number increased to 75.9% of equity-relevant trials in the period from  
8 2007 to 2014. The most notable increases in the absolute number of targeted studies occurred  
9 with occupation, education, and disability.  
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## 12 CONCLUSIONS

13 Among 278 diabetes QI trials, only 34.2% provided equity-relevant findings. These studies  
14 provide insight into the effectiveness of various diabetes management strategies among racial  
15 and ethnic minorities, among patients with low income or low socioeconomic status, as well as  
16 in remote medically underserved populations. A few trials looked at age, gender/sex, education  
17 status, and disability as potential factors that contribute to disparities in diabetes care. However,  
18 we know little about the effects of other factors that may play a role in determining how patients  
19 experience and respond to health interventions. There is a need for better data collection,  
20 reporting, and analysis on the social determinants of health that may influence the health  
21 outcomes of patients with diabetes.  
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25 While the majority of diabetes QI trials did not have an equity focus, the vast majority collected  
26 some form of equity-relevant data to assess balance between study arms in RCTs, suggesting that  
27 many opportunities to explore equity-relevant analyses are missed.  
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30 In this systematic review, only 22 trials (7.9%) directed interventions toward a population that  
31 was impacted by two or more risk factors for health disparities. The limited foci of diabetes QI  
32 trials stand in contrast to the harsh reality experienced by many patients, for whom multiple  
33 social and economic determinants of health intersect in complex ways. In fact, the risk for health  
34 disparities often increases in populations where multiple PROGRESS-Plus factors are  
35 concerned.[9] Given that these populations tend to bear a disproportionate burden of disease,[2,3]  
36 it is a further injustice that interventions and analyses inclusive to these patients be absent from  
37 present research enquiry.  
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40 Interventions tailored toward socially disadvantaged populations show promising results in  
41 reducing health disparities in diabetes care. In a review of 17 QI trials, Glazier et al. (2006)  
42 found that interventions worked best when they were adapted to the local community to fit local  
43 circumstances.[2] Similarly, in a study of 42 QI trials, Peek et al. (2007) found evidence to  
44 suggest that culturally tailored programming and community-based partnerships led to  
45 improvements in health outcomes for racial/ethnic minorities and successfully contributed to  
46 reductions in health disparities in the population.[3] In 2013, Clarke et al. reported that  
47 interventions to improve care in ethnic minorities predominantly focussed on patient-level  
48 strategies, placing the burden of change on patients without addressing equally relevant factors at  
49 the level of health providers, health care organizations, and health systems.[11] Here, we show  
50 that there is increasing data from trials testing health system interventions, such as case  
51 management and team changes, to consider when developing QI interventions to either address  
52 or prevent worsening health inequities across several PROGRESS-Plus characteristics.  
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3 This study has several limitations. First, we included only English language publications as  
4 translation of non-English studies was not feasible. Second, due the large number of included  
5 studies we focused our review of equity factors in the primary publication of trials. It is possible  
6 that authors did additional equity-relevant analyses in secondary publications, which were not  
7 captured in this review. This may result in an underestimate of the number of general studies that  
8 analyzed effects in disadvantaged groups. However, by focusing on primary publication, we  
9 have identified studies in which equity concerns were prioritized by authors, either through  
10 targeted interventions or subsequent analyses, to warrant discussion in a primary paper. Finally,  
11 our ability to capture the full breadth of issues that may disadvantage patients was restricted by  
12 limitations in reporting these variables within each study and by the lack of a standardized  
13 terminology in the literature. As our objective was to assess the extent to which researchers  
14 considered equity-relevant factors, we did not analyze the effect of equity-relevant factors on  
15 study outcomes. This represents another important area for future research.  
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19 In conclusion, findings of this secondary study of a systematic review of diabetes QI trials  
20 indicate substantial room for improvement in the proportion of studies that address equity and  
21 the range of equity factors that could be reported and analyzed.  
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**Table 1. Study characteristics**

Study Characteristics	Non-Equity Studies, n = 183	Equity-Relevant Studies		
		All, n = 95	Targeted, n = 64	General, n = 31
<b>Sample Size</b>	904.9 (17 - 23740)	733.5 (35 - 7557)	490.7 (35 - 7557)	1226.8 (46 - 7009)
<b>Duration of Follow-Up (months)</b>	13.8 (3 - 159.6)	13.2 (3 - 72)	12.5 (3 - 60)	14.6 (3 - 72)
<b>Types of Diabetes</b>				
Types I	10 (5.5)	5 (5.3)	1 (1.6)	4 (12.9)
Type 2	117 (63.9)	51 (53.7)	37 (57.8)	14 (45.2)
Types 1 and 2	35 (19.1)	17 (17.9)	9 (14.1)	8 (25.8)
Type unclear or not reported	20 (10.9)	22 (23.2)	17 (26.6)	5 (16.1)
<b>Mean Baseline HbA1c</b>				
< 8% or 64 mmol/mol	62 (33.9)	33 (34.7)	19 (29.7)	14 (45.2)
≥ 8% or 63 mmol/mol	90 (49.2)	45 (47.4)	34 (53.1)	11 (35.5)
Not reported	31 (16.9)	17 (17.9)	11 (17.2)	6 (19.4)
<b>Primary Focus</b>				
Glycemic only	50 (27.3)	19 (20)	8 (12.5)	11 (35.5)
Glycemic and CVD	45 (24.6)	30 (31.6)	21 (32.8)	9 (29)
Glycemic and other	64 (35)	33 (34.7)	25 (39.1)	8 (25.8)
CVD only	16 (8.7)	6 (6.3)	4 (6.3)	2 (6.5)
Other or unclear	8 (4.4)	7 (7.4)	6 (9.4)	1 (3.2)
<b>Intervention Methods</b>				
AF	21 (11.5)	10 (10.5)	5 (7.8)	5 (16.1)
CM	94 (51.4)	61 (64.2)	46 (71.9)	15 (48.4)
TC	70 (38.3)	44 (46.3)	33 (51.6)	11 (35.5)
EPR	38 (20.8)	18 (18.9)	8 (12.5)	10 (32.3)
CE	52 (28.4)	19 (20)	13 (20.3)	6 (19.4)
CR	30 (16.4)	23 (24.2)	9 (14.1)	14 (45.2)
FR	61 (33.3)	21 (22.1)	10 (15.6)	11 (35.5)
PE	115 (62.8)	68 (71.6)	51 (79.7)	17 (54.8)
PSM	113 (61.7)	63 (66.3)	44 (68.8)	19 (61.3)
PR	30 (16.4)	19 (20)	11 (17.2)	8 (25.8)
CQI	6 (3.3)	1 (1.1)	1 (1.6)	0 (0)
FI	4 (2.2)	6 (6.3)	4 (6.3)	2 (6.5)

**Table 1. Study characteristics.** Sample Size and Duration of Follow-Up reported as *mean* (range). All other categories reported as *n (%)*. Under primary focus, other refers to aspirin use, statin use, hypertensive drug use, smoking cessation, as well as screening for retinopathy, nephropathy, or neuropathy. DM=diabetes mellitus; CVD = cardiovascular disease; HbA1c=glycated hemoglobin; AF=audit and feedback. CM=case management; TC=team changes; EPR=electronic patient registry; CE=clinician education; CR=clinician reminders; FR=facilitated relay; PE=patient education; PSM=promotion of self-management; PR=patient reminders; CQI=continuous quality improvement; FI=financial incentives.

**Table 2. PROGRESS-Plus factors by trial type**

PROGRESS-Plus Factors	Non-Equity Studies, n = 183	Equity-Relevant Studies			Equity-Relevant Studies, n = 95					
		All, n = 95	Targeted, n = 64	General, n = 31	Targeted, n = 64			General, n = 31		
					O	B	A	O	B	A
Place of Residence	4 (2.2)	19 (20)	19 (29.7)	0 (0)	19 (29.7)	1 (1.6)	0 (0)	0 (0)	0 (0)	0 (0)
Race/Ethnicity/ Culture/Language	64 (35)	75 (78.9)	57 (89.1)	18 (58.1)	34 (53.1)	41 (64.1)	7 (10.9)	0 (0)	18 (58.1)	8 (25.8)
Occupation	18 (9.8)	24 (25.3)	18 (28.1)	6 (19.4)	1 (1.6)	17 (26.6)	1 (1.6)	0 (0)	6 (19.4)	2 (6.5)
Gender/Sex	166 (90.7)	91 (95.8)	60 (93.8)	31 (100)	0 (0)	60 (93.8)	9 (14.1)	0 (0)	31 (100)	22 (71)
Religion	0 (0)	1 (1.1)	1 (1.6)	0 (0)	1 (1.6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Education	58 (31.7)	57 (60)	42 (65.6)	15 (48.4)	1 (1.6)	42 (65.6)	5 (7.8)	0 (0)	14 (45.2)	9 (29)
Socioeconomic Status	27 (14.8)	51 (53.7)	45 (70.3)	6 (19.4)	18 (28.1)	40 (62.5)	2 (3.1)	0 (0)	5 (16.1)	2 (6.5)
Social Capital	31 (16.9)	33 (34.7)	30 (46.9)	3 (9.7)	0 (0)	30 (46.9)	1 (1.6)	0 (0)	3 (9.7)	0 (0)
Plus 1. Age	173 (94.5)	92 (96.8)	61 (95.3)	31 (100)	8 (12.5)	61 (95.3)	7 (10.9)	0 (0)	31 (100)	22 (71)
Plus 1. Disability	55 (30.1)	32 (33.7)	23 (35.9)	9 (29)	7 (10.9)	22 (34.4)	3 (4.7)	0 (0)	9 (29)	1 (3.2)

**Table 2. PROGRESS-Plus factors by trial type.** All values are expressed as *n* (%). O=study objective; B=baseline patient characteristics; A=study analysis. The PROGRESS-Plus factors of sexual preference, features of relationships, and time-dependent relationships were omitted from this table as we did not find any studies which looked at these characteristics as a potential risk factor for being disadvantaged.

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3 Each trial is counted once under each column. Columns on the left of the table reflect the number of trials that contained PROGRESS-  
4 Plus factors in the objectives (O), baseline characteristics (B), or analysis (A). Trials that assessed for PROGRESS-Plus factors in two  
5 or more categories of O, B, and A were still counted as one trial. As such, the sum of trials under headings O, B, and A within targeted  
6 and general trials (columns 6-8 and 9-11) are not equal to the corresponding number of trials under targeted and general in the left side  
7 of the table (columns 4 and 5).  
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10 Targeted trials with an objective (O) defined by PROGRESS-Plus factors were further scrutinized for different PROGRESS-Plus  
11 factors in their baseline characteristics (B) or analysis (A) – the inclusion of a PROGRESS-Plus factor different from that targeted by  
12 the intervention objective (O) would warrant the trial to be counted under headings B and A in their respective PROGRESS-Plus  
13 categories.  
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**Table 3. Frequency of PROGRESS-Plus factors stratified by year of study conduct**

PROGRESS-Plus Factors	Non-Equity Studies, n = 183		Equity-Relevant Studies, n = 95					
			All, n = 95		Targeted, n = 64		General, n = 31	
Year of Study Conduct	Pre-2007 n = 87	2007-2014 n = 96	Pre-2007 n = 41	2007-2014 n = 54	Pre-2007 n = 23	2007-2014 n = 41	Pre-2007 n = 18	2007-2014 n = 13
Place of Residence	2 (2.3)	2 (2.1)	10 (24.4)	9 (16.7)	10 (43.5)	9 (22)	0 (0)	0 (0)
Race/Ethnicity/ Culture/Language	28 (32.2)	36 (37.5)	31 (75.6)	44 (81.5)	20 (87)	37 (90.2)	1 (61.1)	7 (53.8)
Occupation	5 (5.7)	13 (13.5)	6 (14.6)	18 (33.3)	5 (21.7)	13 (31.7)	1 (5.6)	5 (38.5)
Gender/Sex	74 (85.1)	92 (95.8)	39 (95.1)	52 (96.3)	21 (91.3)	39 (95.1)	18 (100)	13 (100)
Religion	0 (0)	0 (0)	1 (2.4)	0 (0)	1 (4.3)	0 (0)	0 (0)	0 (0)
Education	21 (24.1)	37 (38.5)	18 (43.9)	39 (72.2)	11 (47.8)	31 (75.6)	1 (38.9)	8 (61.5)
Socioeconomic Status	13 (14.9)	14 (14.6)	18 (43.9)	33 (61.1)	16 (69.6)	29 (70.7)	1 (11.1)	4 (30.8)
Social Capital	10 (11.5)	21 (21.9)	11 (26.8)	22 (40.7)	9 (39.1)	21 (51.2)	1 (11.1)	1 (7.7)
Plus 1. Age	80 (92)	93 (96.9)	40 (97.6)	52 (96.3)	22 (95.7)	39 (95.1)	18 (100)	13 (100)
Plus 1. Disability	24 (27.6)	31 (32.3)	6 (14.6)	26 (48.1)	3 (13)	20 (48.8)	1 (16.7)	6 (46.2)

**Table 3. Frequency of PROGRESS-Plus factors stratified by year of study conduct.** Year of publication where the last year of study conduct was not reported. All values are expressed as *n* (%).

## ABBREVIATIONS

QI: quality improvement; RCT: randomized control trial

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NMI and KJD conceived the study. All authors participated in the design of the study. KJD managed and coordinated the source data. JBL and MDE coded the source data with input from NMI and KJD to resolve discrepancies between coders. All authors contributed to the interpretation of the findings. Writing of the paper was led by JBL, KJD, and NMI with all authors commenting on drafts and approving the final manuscript.

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## COMPETING INTERESTS

No potential conflicts of interest relevant to this article were reported.

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## DATA SHARING STATEMENT

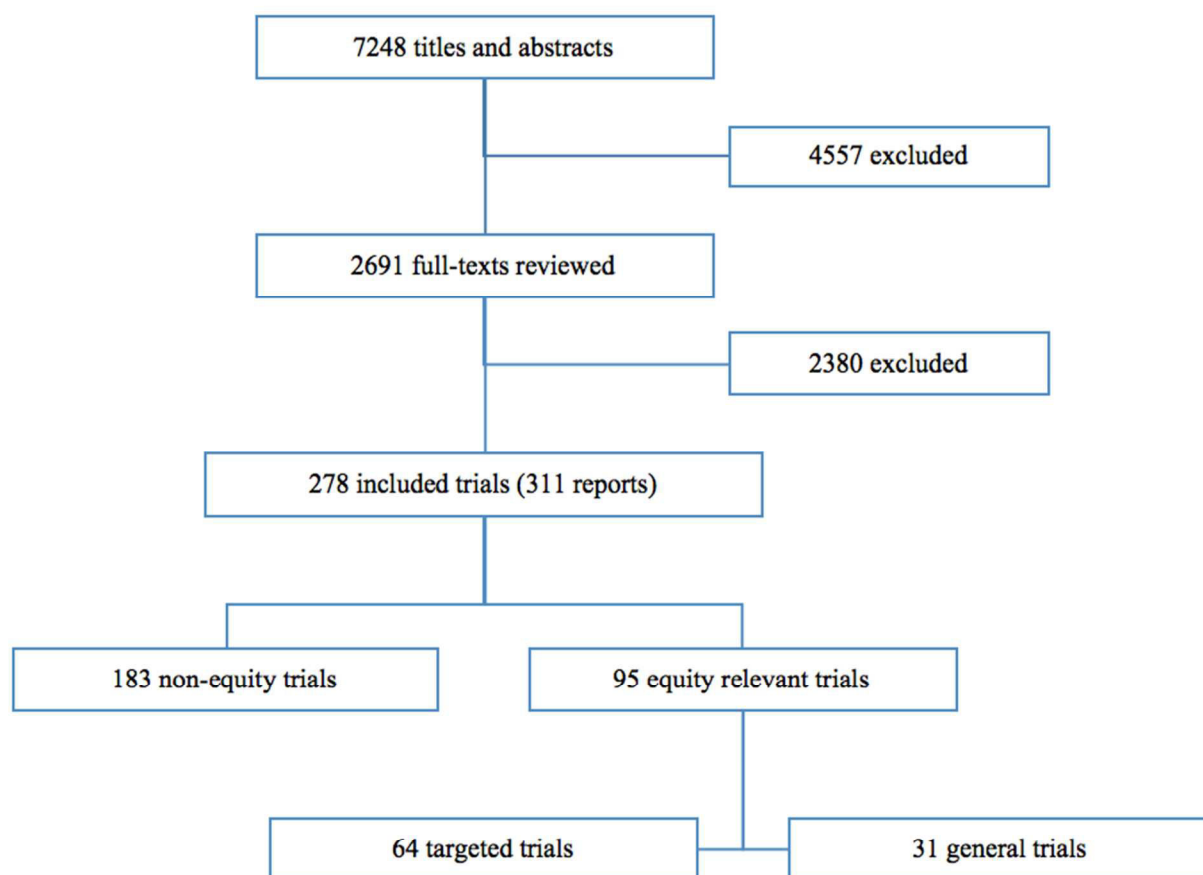
The dataset generated and analyzed during the current study are available from the corresponding author on request.

## REFERENCES

1. World Health Organization. Global report on diabetes. France: World Health Organization; 2016.
2. Glazier RH, Bajcar J, Kennie NR, et al. A systematic review of interventions to improve diabetes care in socially disadvantaged populations. *Diabetes Care* 2006;29:1675-1688. doi:10.2337/dc05-1942
3. Peek ME, Cargill A, Huang ES. Diabetes health disparities: A systematic review of health care interventions. *Med Care Res Rev* 2007;64(5):101S-156S. doi:10.1177/1077558707305409
4. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. *Can J Diabetes* 2013;37(suppl 1):S1-S212.
5. American Diabetes Association. Foundations of care and comprehensive medical evaluation. *Diabetes Care* 2016;39(Suppl. 1):S23-S35. doi:10.2337/dc16-S006.
6. Borkhoff CM, Wieland ML, Myasoedova E, et al. Reaching those most in need: A scoping review of interventions to improve health care quality for disadvantaged populations with osteoarthritis. *Arthritis Care Res* 2011;63(1):39-52. doi:10.1002/acr.20349
7. Chin MH, Parrillo R. Advancing equity in healthcare: Lessons from Massachusetts and beyond. *BMJ* 2015;350:h1617. doi:10.1136/bmj.h1617
8. Chin MH, Goddu AP, Ferguson MJ, et al. Expanding and sustaining integrated health care: Community efforts to reduce diabetes disparities. *Health Promot Pract* 2014;15(2):29S-39S. doi:10.1177/1524839914532649
9. O'Neill J, Tabish H, Welch V, et al. Applying an equity lens to interventions: Using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. *J Clin Epidemiol* 2014;67(1):56-64. doi:10.1016/j.jclinepi.2013.08.005
10. Tricco AC, Ivers NM, Grimshaw JM, et al. Effectiveness of quality improvement strategies on the management of diabetes: A systematic review and meta-analysis. *Lancet* 2012;379(9833):2252-2261. doi:10.1016/S0140-6736(12)60480-2
11. Clarke AR, Goddu AP, Nocon RS, et al. Thirty years of disparities intervention research: What are we doing to close racial and ethnic gaps in health care? *Med Care* 2013;51(11):1020-1026. doi:10.1097/MLR.0b013e3182a97ba3
12. Lorenc T, Petticrew M, Welch V, et al. What type of interventions generate inequalities? Evidence from systematic reviews. *J Epidemiol Community Health* 2013;67(2):190-193. doi:10.1136/jech-2012-201257
13. Ivers NM, Tricco AC, Trikalinos TA, et al. Seeing the forests and the trees – innovative approaches to exploring heterogeneity in systematic reviews of complex interventions to enhance health system decision-making: A protocol. *Syst Rev* 2014;3:88. doi:10.1186/2046-4053-3-88
14. Shojania KG, Ranji SR, McDonald KM, et al. Effects of quality improvement strategies for type 2 diabetes on glycemic control: A meta-regression analysis. *JAMA* 2006;296(4):427-440. doi:10.1001/jama.296.4.427
15. Gary TL, Bone LR, Hill MN, et al. Randomized controlled trial of the effects of nurse case manager and community health worker interventions on risk factors for diabetes-



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3 related complications in urban African Americans. *Prev Med* 2003;37:23-32.
- 4 16. Bujnowska-Fedak MM, Puchala E, Steciwko A. The impact of telehome care on health  
5 status and quality of life among patients with diabetes in a primary care setting in  
6 Poland. *Telemedicine J E Health* 2011;17(3):153-163. doi:10.1089/tmj.2010.0113
- 7 17. DePue JD et al. Nurse-community health worker team improves diabetes care in  
8 American Samoa. *Diabetes Care* 2013;36(7):1947-1953. doi:10.2337/dc12-1969
- 9 18. Shea S et al. A randomized trial comparing telemedicine case management with usual  
10 care in older, ethnically diverse, medically underserved patients with diabetes mellitus:  
11 5 year results of the IDEATel study. *J Am Med Inform Assoc* 2009;16(4):446-456.  
12 doi:10.1197/jamia.M3157  
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**Figure 1. PRISMA flow diagram**

## Supplemental Table 1. PROGRESS-Plus definitions

We defined *disadvantage* according to the PROGRESS-Plus framework as outlined by O'Neill *et al.* (9). The table below outlines our interpretation of these risk factors associated with disadvantage in the context of patients with diabetes.

<b>PROGRESS-Plus Factor</b>	<b>Definition</b>
Place of residence	Residence in a medically underserved area where it is difficult to physically access care <i>Example: rural, remote, inner city</i>
Race, ethnicity, culture, language	Ethnic and racial minorities, patients who do not speak the dominant language of the region or who do not identify with the dominant culture of the area
Occupation	Employment status <i>Example: full-time, part-time, retired, disability leave, temporary worker, migrant worker</i>
Gender, sex	Gender roles and sexual identities <i>Example: men, women, cisgender, transgender, intersex</i>
Religion	Religious affiliations
Education	Education level and circumstances <i>Example: highest level of education completed, education status of family members</i>
Socioeconomic status	Income levels and availability of health insurance <i>Example: low income, lack of health insurance, state-sponsored insurance</i>
Social capital	Social relationships and availability of social support networks <i>Example: marital status, community networks, professional networks</i>
Plus 1. Age	Ages that may be associated with an increased risk of bias or discrimination in care. <i>Example: elderly or young</i>
Plus 1. Disability	Any mental health assessment, any quality of life or functional assessment, as well as any comorbid condition that is explicitly severe enough for us to reasonably believe that it impacts the ability to self-manage <i>Example: mental health issues, intellectual disabilities, chronic pain, blindness, end-stage renal disease, symptomatic heart disease</i>
Plus 1. Sexual preference	Sexual orientation <i>Example: homosexual, heterosexual, bisexual</i>
Plus 2. Features of relationships	Relationships that impact an individual's ability to assert their autonomy and self-manage <i>Example: social hierarchies at school, work, or home</i>
Plus 3. Time-dependent relationships	Times of transition where an individual may face increased risks for poor health management <i>Example: discharge from hospital, release from prison, students on the move, practice guideline changes</i>

**PRISMA-P (Preferred Reporting Items for Systematic review and Meta-Analysis Protocols) 2015 checklist: recommended items to address in a systematic review protocol\***

Section and topic	Item No	Checklist item	Page No
<b>ADMINISTRATIVE INFORMATION</b>			
Title:			
Identification	1a	Identify the report as a protocol of a systematic review	1
Update	1b	If the protocol is for an update of a previous systematic review, identify as such	1
Registration	2	If registered, provide the name of the registry (such as PROSPERO) and registration number	1
Authors:			
Contact	3a	Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contributions	3b	Describe contributions of protocol authors and identify the guarantor of the review	13
Amendments	4	If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	4
Support:			
Sources	5a	Indicate sources of financial or other support for the review	13
Sponsor	5b	Provide name for the review funder and/or sponsor	13
Role of sponsor or funder	5c	Describe roles of funder(s), sponsor(s), and/or institution(s), if any, in developing the protocol	13
<b>INTRODUCTION</b>			
Rationale	6	Describe the rationale for the review in the context of what is already known	4
Objectives	7	Provide an explicit statement of the question(s) the review will address with reference to participants, interventions, comparators, and outcomes (PICO)	4
<b>METHODS</b>			
Eligibility criteria	8	Specify the study characteristics (such as PICO, study design, setting, time frame) and report characteristics (such as years considered, language, publication status) to be used as criteria for eligibility for the review	4
Information sources	9	Describe all intended information sources (such as electronic databases, contact with study authors, trial registers or other grey literature sources) with planned dates of coverage	4
Search strategy	10	Present draft of search strategy to be used for at least one electronic database, including planned limits, such that it could be repeated	4
Study records:			
Data	11a	Describe the mechanism(s) that will be used to manage records and data throughout the review	5

management				
Selection process	11b	State the process that will be used for selecting studies (such as two independent reviewers) through each phase of the review (that is, screening, eligibility and inclusion in meta-analysis)		5
Data collection process	11c	Describe planned method of extracting data from reports (such as piloting forms, done independently, in duplicate), any processes for obtaining and confirming data from investigators		5
Data items	12	List and define all variables for which data will be sought (such as PICO items, funding sources), any pre-planned data assumptions and simplifications		5
Outcomes and prioritization	13	List and define all outcomes for which data will be sought, including prioritization of main and additional outcomes, with rationale		5
Risk of bias in individual studies	14	Describe anticipated methods for assessing risk of bias of individual studies, including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis		5
Data synthesis	15a	Describe criteria under which study data will be quantitatively synthesised		5
	15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as $I^2$ , Kendall's $\tau$ )		5
	15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)		5
	15d	If quantitative synthesis is not appropriate, describe the type of summary planned		5
Meta-bias(es)	16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)		5
Confidence in cumulative evidence	17	Describe how the strength of the body of evidence will be assessed (such as GRADE)		5

**\* It is strongly recommended that this checklist be read in conjunction with the PRISMA-P Explanation and Elaboration (cite when available) for important clarification on the items. Amendments to a review protocol should be tracked and dated. The copyright for PRISMA-P (including checklist) is held by the PRISMA-P Group and is distributed under a Creative Commons Attribution Licence 4.0.**

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# BMJ Open

## Do quality improvement initiatives for diabetes care address social inequities? Secondary analysis of a systematic review.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-018826.R1
Article Type:	Research
Date Submitted by the Author:	04-Nov-2017
Complete List of Authors:	Lu, Jacquie Boyang; Queen's University Faculty of Health Sciences, School of Medicine Danko, Kristin; Ottawa Hospital Research Institute, Clinical Epidemiology Program; University of Ottawa Faculty of Medicine, School of Epidemiology, Public Health, and Preventive Medicine Elfassy, Michael; University of Toronto Faculty of Medicine Welch, Vivian; University of Ottawa Faculty of Medicine, School of Epidemiology, Public Health, and Preventive Medicine; Elisabeth Bruyere Research Institute Grimshaw, Jeremy; Ottawa Hospital Research Institute, Clinical Epidemiology Program; University of Ottawa Faculty of Medicine, Department of Medicine and School of Epidemiology, Public Health, and Preventive Medicine Ivers, Noah; Women's College Hospital, Family Practice Health Centre, Women's College Research Institute, and Institute for Health Systems Solutions and Virtual Care; University of Toronto Dalla Lana School of Public Health, Department of Family and Community Medicine, and Institute of Health Policy Management and Evaluation
<b>Primary Subject Heading</b>:	Diabetes and endocrinology
Secondary Subject Heading:	Evidence based practice, Qualitative research
Keywords:	Quality improvement, Social determinants of health, Equity

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3 Do quality improvement initiatives for diabetes care address social inequities? Secondary  
4 analysis of a systematic review  
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43 **Word count**

44 2618  
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46 **Tables and figures**

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## ABSTRACT

### Background

Socially disadvantaged populations carry a disproportionate burden of diabetes-related morbidity and mortality. There is an emerging interest in quality improvement (QI) strategies in the care of patients with diabetes, however, the effect of these interventions on disadvantaged groups remains unclear.

### Objective

This is a secondary analysis of a systematic review that seeks to examine the extent of equity considerations in diabetes QI studies, specifically quantifying the proportion of studies that target interventions toward disadvantaged populations and conduct analyses on the impact of interventions on disadvantaged groups.

### Research Design and Methods

Studies were identified using Medline, HealthStar, and the Cochrane EPOC database. Randomized controlled trials assessing twelve QI strategies targeting health systems, healthcare professionals, and/or patients for the management of adult outpatients with diabetes were eligible. The PROGRESS-Plus framework was used to identify trials that focused on disadvantaged patient populations, to examine the types of equity-relevant factors that are being considered, and to explore temporal trends in equity-relevant diabetes QI trials.

### Results

Of the 278 trials that met the inclusion criteria, 95 trials had equity-relevant considerations. These include 64 *targeted trials* that focussed on a disadvantaged population with the aim to improve the health status of that population and 31 *general trials* that undertook subgroup analyses to assess the extent to which their interventions may have had differential impacts on disadvantaged subgroups. Trials predominantly focused on race/ethnicity, socioeconomic status, and place of residence as potential factors for disadvantage in patients receiving diabetes care.

### Conclusions

Less than a third of diabetes QI trials included equity-relevant considerations, limiting the relevance and applicability of their data to disadvantaged populations. There is a need for better data collection, reporting, analysis, and interventions on the social determinants of health that may influence the health outcomes of patients with diabetes.

### Word Count

294



### STRENGTHS AND LIMITATIONS OF THIS STUDY

- The use of the PROGRESS-Plus framework provides a standardized approach for identifying and analyzing equity relevant information within research publications. The focus on only primary publications of trials meant any equity relevant analyses in subsequent publications of the same trial were not captured in this review.
- The lack of standardized terminology for equity relevant information in the general literature restricted our ability to fully capture all the various issues that may lead to disadvantages in medical care.
- The inclusion of only English language publications was a practical limitation on the scope of this study.

For peer review only

## INTRODUCTION

Diabetes affects approximately 8.5% of the adult population; the increasing prevalence of physical inactivity, obesity, and an aging population means that this number will increase over time.[1,2] The burden of diabetes is not evenly spread through the population. Racial and ethnic minorities, as well as people of lower socioeconomic status are more likely to develop diabetes.[2,3] Such individuals are also more likely to experience delayed diagnosis and lower quality of care, leading to greater risk for diabetes-related complications.[2,3]

Patients with diabetes require lifelong medications, routine follow-up with healthcare professionals, and regular preventative screening exams to reduce the likelihood of morbidity and mortality.[4,5] Socially disadvantaged groups may experience multiple barriers to high quality care due to factors such as differences in language or culture, inadequate financial resources, or prohibitive distances from care centres.[2,6–8] To ensure that innovations and standards of care in healthcare reach the most disadvantaged segments of the population, interventions must recognize and address these equity-based considerations.[2,7–9]

Quality improvement (QI) in the care of patients with diabetes is a rapidly expanding field of interest.[10] However, while many QI strategies are effective in improving diabetes care in general populations,[10] it is unclear whether they improve or worsen health disparities among disadvantaged subgroups.[11] QI strategies designed for the general population may not be accessible to disadvantaged groups or may not have the same efficacy in disadvantaged populations and may inadvertently lead to an increase in diabetes related health disparities.[2,7,9,11,12]

Recently, we updated a systematic review of trials of QI strategies for diabetes care.[13] In this secondary analysis of that review, we examine the extent to which health equity concerns were considered in diabetes QI studies. Specifically, we quantified the proportion of QI studies that targeted interventions toward disadvantaged populations, looked at risk factors for disadvantage in the patient population, and analyzed the impact of interventions on disadvantaged subgroups.

## RESEARCH DESIGN AND METHODS

Our goal was to examine the extent of focus in the literature on understanding the effects of diabetes QI for disadvantaged populations. A detailed description of methods used for searching and screening the relevant data for the underlying systematic review has been published.[13]

### Study Selection and Data Extraction

An experienced librarian developed the search strategy, which was peer reviewed independently by another information specialist. Studies were identified using Medline, HealthStar, and the Cochrane Effective Practice and Organization of Care (EPOC) database. Randomized controlled trials (RCTs) assessing one of twelve predefined QI strategies targeting health systems, healthcare professionals, and/or patients for the management of adult outpatients with diabetes were eligible. Studies had to report at least one process of care measure (e.g., proportion of patients taking acetylsalicylic acid, statins, or antihypertensive medication; screened for retinopathy or foot abnormalities and monitored for renal function) or intermediate outcomes (e.g., glycosylated haemoglobin levels [HbA1c], low-density lipoprotein cholesterol levels,

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3 diastolic and systolic blood pressure; proportion of patients with controlled hypertension or who  
4 quit smoking).  
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7 For this secondary review, we developed a data extraction form using the PROGRESS-Plus  
8 framework,[9] to consider the range of factors that may increase the risk for a population  
9 subgroup to be disadvantaged, including participants' Place of residence,  
10 Race/ethnicity/culture/language, Occupational status, Gender/sexual identity, Religious  
11 affiliations, Education level, Socioeconomic status, Social capital, plus age, disability, sexual  
12 preferences, and relationships.[9] Specifically, we interpreted these risk factors in the context of  
13 a patient's ability to access health care and effectively manage their diabetes. For example, it  
14 may be more difficult for patients living in rural or geographically isolated areas to access  
15 dependable primary care, leading to negative implications for their ability to achieve diabetes-  
16 related targets. Supplemental Table 1 outlines our full interpretation of PROGRESS-Plus factors  
17 in considering how these factors might lead to inequity in diabetes management across sub-  
18 populations, developed based on previous literature,[6] the PROGRESS framework,[9] and in  
19 collaboration with PROGRESS-authors (VW).  
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23 Two reviewers independently extracted data based on a thorough reading of the full text for all  
24 included studies. This allowed us to identify a cohort of *equity-relevant trials* that targeted or  
25 assessed equity factors as defined by the PROGRESS-Plus framework.[9] Within this cohort,  
26 trials were classified as either Targeted or General. *Targeted equity-relevant trials* were defined  
27 as a trial focussed on a population with an identified disadvantage in health in order to improve  
28 the health status of that population or to reduce the health gradient. *General equity-relevant trials*  
29 were defined as a trial involved a broad participant population but made comparisons of effects  
30 in disadvantaged subgroups to assess the extent to which interventions may have differential  
31 impacts. For example, a trial testing a primary care-based culturally sensitive behavioural  
32 intervention in a population of urban African Americans with type 2 diabetes [14] would be  
33 classified as a *targeted* equity-relevant trial because it purposefully directed interventions  
34 towards a disadvantaged population. In contrast, a trial testing a tele-homecare monitoring  
35 system for patients with type 2 diabetes that explored the benefit of the intervention in female  
36 patients and those with lower education levels,[15] would be classified as a *general* equity-  
37 relevant trial.  
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41 The reviewers extracted PROGRESS-Plus factors identified in the baseline patient characteristics  
42 for all studies. Additionally, for equity-relevant studies, the reviewers extracted PROGRESS-  
43 Plus factors identified in the study objective, study design (e.g., patient eligibility criteria and  
44 patient recruitment techniques), and analysis of results. We only coded instances when authors  
45 were explicit in their mention of PROGRESS-Plus factors. Discrepancies were resolved by  
46 discussion or the involvement of authors NMI and KJD.  
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48

### 49 **Data Synthesis and Analysis**

50 As we had no *a priori* hypothesis about the differences or similarities that would be found among  
51 trials regarding issues of equity or efforts to address areas of disadvantage, we provide here  
52 descriptive analyses only. We describe the proportion of trials that focused on equity-relevant  
53 factors and types of factors considered in these trials. In addition, to explore for time-trends in  
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the consideration of equity-relevant factors in diabetes QI trials, we split our analyses by median date of study conduct.

## RESULTS

### Literature search and review process

Figure 1 summarizes the flow of literature in the QI review. The initial search identified a total of 7248 citations; review of 2,691 full text articles resulted in a final sample of 309 reports, representing 272 unique trials.

### Study characteristics

Ninety-five trials (34.9%) were identified as equity-relevant; 64 of these were classified as targeted and 31 as general. Characteristics were similar between non-equity studies and equity-relevant studies (Table 1). Most trials focused on patients with type 2 diabetes, and looked at glycemic control combined with cardiovascular status or other health benchmarks (aspirin use, statin use, hypertensive drug use, screening for retinopathy/nephropathy/neuropathy, smoking cessation) as the primary outcomes of interest. Mean baseline HbA1c was comparable between non-equity and equity-relevant trials, but targeted trials reported the inclusion of a greater proportion of patients with HbA1c greater or equal to 8% compared to general trials.

Interestingly, 73.7% of equity-relevant trials were based in countries with private health insurance systems, whereas 32.6% of equity-relevant trials were based in countries with universal health insurance. However, this finding may simply reflect the predominance of publications from the United States included within this review, contributing 65 of 177 non-equity studies and 63 of 95 equity-relevant studies.

The relative frequency of individual QI strategies assessed in the studies were also comparable across non-equity and equity-relevant trials with a few exceptions. Overall, patient education, promotion of self-management, and case management were the most frequently used QI interventions across all studies. Among equity-relevant trials, case management, team changes, and patient education were evaluated more frequently in targeted trials compared to general trials.

Table 2 describes the frequency of PROGRESS-Plus factors examined in all studies. Among 177 non-equity studies, 94.4% reported data on the age of participants, 90.4% reported data on gender/sex, 35.0% reported data on race/ethnicity/culture/language, 32.2% reported data on education levels, and 29.9% reported data on disability status. Overall, age and gender/sex were the most frequently documented PROGRESS-Plus factors, appearing equally in both equity-relevant studies and non-equity studies. In comparison, race/ethnicity/culture/language, socioeconomic status, education, social capital, occupation, and place of residence appeared significantly more frequently in equity-relevant trials than in non-equity trials. The PROGRESS-Plus factors of sexual preference, features of relationships, and time-dependent relationships were not identified in any of the studies.

The targeted trials were most commonly directed toward race/ethnicity/language/culture (53.1% of targeted trials), place of residence (29.7%), and socioeconomic status (28.1%); occupation, gender/sex, religion, or social capital were rarely addressed in the objectives of target trials. Most targeted trials used a single PROGRESS-Plus factor to define its patient population (e.g.,

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3 interventions targeted people in rural communities *or* patients belonging to a particular ethnic  
4 minority). Twenty trials looked at population subgroups with two PROGRESS-Plus factors.  
5 Only two trials simultaneously targeted three factors.[16,17] Fifteen targeted trials (23%)  
6 conducted sub-analyses to understand whether their intervention varied in its effectiveness across  
7 additional PROGRESS-Plus factors distinct from those used to define their intervention and their  
8 target patient populations.  
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11 Of the 31 general trials that did not contain an equity-specific objective but conducted stratified  
12 analyses across PROGRESS-Plus factors, gender/sex (71.0% of general trials), age (71.0%),  
13 race/ethnicity/culture/language (25.8%), and education (29.0%) were the most commonly  
14 stratified factors. 12 trials found differential effects among disadvantaged subgroups when  
15 intervention outcomes were further analyzed. Notably, 6 trials found differences in outcomes  
16 based on the sex of participants, 5 trials found differences based on age, and 4 trials found  
17 differences based on race/ethnicity group.  
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19  
20 Table 3 examines the extent of equity-relevance in diabetes QI trials over time. Prior to 2007,  
21 there were 41 equity-relevant trials out of 126 diabetes QI studies. In the period from 2007 to  
22 2014, there were 54 equity-relevant trials out of 146 diabetes QI studies. Targeted trials were  
23 responsible for 56.1% of equity-relevant trials prior to 2007. This number increased to 75.9% of  
24 equity-relevant trials in the period from 2007 to 2014. The most notable increases in the absolute  
25 number of targeted studies occurred with occupation, education, and disability.  
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## 28 CONCLUSIONS

29 Among 278 diabetes QI trials, only 34.9% provided equity-relevant findings. These studies  
30 provide insight into the effectiveness of various diabetes management strategies among racial  
31 and ethnic minorities, among patients with low income or low socioeconomic status, as well as  
32 in remote medically underserved populations. A few trials looked at age, gender/sex, education  
33 status, and disability as potential factors that contribute to disparities in diabetes care. However,  
34 we know little about the effects of other factors that may play a role in determining how patients  
35 experience and respond to health interventions.  
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39 Trials designed for the general population which then conducted stratified analyses point to the  
40 importance of considering PROGRESS-Plus factors when designing and examining  
41 interventions. In fact, QI strategies designed for the general population may not be accessible to  
42 disadvantaged groups or may not have the same efficacy in disadvantaged populations and may  
43 inadvertently lead to an increase in diabetes related health disparities. For example, a general  
44 trial looking at telehome monitoring systems as an affordable and efficient means to monitor  
45 patients with diabetes showed greater efficacy in patients who were male, elderly, and/or more  
46 educated.[15] Another study examining the efficacy of telephone-based weight loss programs to  
47 improve glycemic control found the intervention outcomes differed between Caucasians and  
48 non-Caucasians.[18]. Alternatively, adding care guides to the primary care team was more likely  
49 to have benefits for patients on Medicaid rather than patients with other forms of health  
50 insurance in the United States.[19] These findings emphasize the need for better data collection,  
51 reporting, and analysis on the social determinants of health that may influence the health  
52 outcomes of patients with diabetes.  
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3 While the majority of diabetes QI trials did not have an equity focus, the vast majority collected  
4 some form of equity-relevant data to assess balance between study arms in RCTs. This collection  
5 of stratified data presents a missed opportunity for researchers to further explore equity-relevant  
6 analyses.  
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9 In this systematic review, only 22 trials (8.1%) directed interventions toward a population that  
10 was impacted by two or more risk factors for health disparities. The limited foci of diabetes QI  
11 trials stand in contrast to the harsh reality of many patients, for whom multiple social and  
12 economic determinants of health intersect in complex ways. The risk for health disparities often  
13 increases in populations where multiple PROGRESS-Plus factors are concerned.[9] For example,  
14 there is a paucity of research targeting elderly racial and ethnic minorities despite this being one  
15 of the fastest growing demographic for diabetes diagnoses and diabetes-related complications.[3]  
16 Given that these populations tend to bear a disproportionate burden of disease,[2,3] it is even  
17 more important that interventions and analyses relevant to these patients be represented in the  
18 current body of research.  
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22 Interventions tailored toward socially disadvantaged populations show promising results in  
23 reducing health disparities in diabetes care. In a review of 17 QI trials, Glazier et al. (2006)  
24 found that interventions worked best when they were adapted to the local community to fit local  
25 circumstances.[2] Similarly, in a study of 42 QI trials, Peek et al. (2007) found evidence to  
26 suggest that culturally tailored programming and community-based partnerships led to  
27 improvements in health outcomes for racial/ethnic minorities and successfully contributed to  
28 reductions in health disparities in the population.[3] Fisher et al. (2007) showed narrowing of  
29 racial disparities in health care with culturally specific programming and health care messaging.  
30 Culturally sensitive strategies can help strengthen connections between patients and health care  
31 organizations, thereby facilitating a more effective exchange of health information and improved  
32 adherence to treatment plans for ethnic and racial minorities.[20]  
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36 In 2013, Clarke et al. reported that interventions to improve care in ethnic minorities  
37 predominantly focussed on patient-level strategies, placing the burden of change on patients  
38 without addressing equally relevant factors at the level of health providers, health care  
39 organizations, and health systems.[11] Here, we show that there is increasing data from trials  
40 testing health system interventions, such as case management and team changes, to consider  
41 when developing QI interventions to either address or prevent worsening health inequities across  
42 several PROGRESS-Plus characteristics.  
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46 This study has several limitations. First, we included only English language publications as  
47 translation of non-English studies was not feasible. Second, due the large number of included  
48 studies we focused our review of equity factors in the primary publication of trials. It is possible  
49 that authors did additional equity-relevant analyses in secondary publications, which were not  
50 captured in this review. This may result in an underestimate of the number of general studies that  
51 analyzed effects in disadvantaged groups. However, by focusing on primary publication, we  
52 have identified studies in which equity concerns were prioritized by authors, either through  
53 targeted interventions or subsequent analyses, to warrant discussion in a primary paper. Finally,  
54 our ability to capture the full breadth of issues that may disadvantage patients was restricted by  
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3 limitations in reporting these variables within each study and by the lack of a standardized  
4 terminology in the literature.  
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7 As our objective was to assess the extent to which researchers considered equity-relevant factors,  
8 we did not analyze the effect of equity-relevant factors on study outcomes. We believe the  
9 effectiveness of interventions may vary based on the participant population and the existing  
10 health system. Based on the limited primary data that we have from targeted and general trials, it  
11 is difficult to make definitive conclusions about which interventions or QI strategies are effective  
12 or ineffective in reducing health disparities and/or improving health outcomes for disadvantaged  
13 groups without oversimplifying the issue and potentially misleading future enquiry. What  
14 ultimately works in one health care setting may not work in another. However, this represents an  
15 important area for future research.  
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18 In conclusion, the findings in this secondary study of a systematic review of diabetes QI trials  
19 indicate substantial room for improvement in the proportion of studies that address equity and  
20 the range of equity factors that can be reported and analyzed.  
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**Table 1. Study characteristics**

Study Characteristics	Non-Equity Studies, n = 177	Equity-Relevant Studies		
		All, n = 95	Targeted, n = 64	General, n = 31
<b>Sample Size</b>	931.6 (17 - 23740)	733.5 (35 - 7557)	490.7 (35 - 7557)	1226.8 (46 - 7009)
<b>Duration of Follow-Up (months)</b>	14 (3 - 159.6)	13.2 (3 - 72)	12.5 (3 - 60)	14.6 (3 - 72)
<b>Types of Diabetes</b>				
Types 1	9 (5.1)	5 (5.3)	1 (1.6)	4 (12.9)
Type 2	116 (65.5)	51 (53.7)	37 (57.8)	14 (45.2)
Types 1 and 2	0 (0)	17 (17.9)	9 (14.1)	8 (25.8)
Type unclear or not reported	19 (10.7)	22 (23.2)	17 (26.6)	5 (16.1)
<b>Mean Baseline HbA1c</b>				
< 8% or 64 mmol/mol	56 (31.6)	33 (34.7)	19 (29.7)	14 (45.2)
≥ 8% or 63 mmol/mol	90 (50.8)	45 (47.4)	34 (53.1)	11 (35.5)
Not reported	31 (17.5)	17 (17.9)	11 (17.2)	6 (19.4)
<b>Primary Focus</b>				
Glycemic only	44 (24.9)	19 (20)	8 (12.5)	11 (35.5)
Glycemic and CVD	45 (25.4)	30 (31.6)	21 (32.8)	9 (29)
Glycemic and other	0 (0)	33 (34.7)	25 (39.1)	8 (25.8)
CVD only	16 (9)	6 (6.3)	4 (6.3)	2 (6.5)
Other or unclear	8 (4.5)	7 (7.4)	6 (9.4)	1 (3.2)
<b>Country of Study by Health System</b>				
Universal health care	96 (54.2)	31 (32.6)	12 (18.8)	19 (61.3)
Private health insurance	79 (44.6)	70 (73.7)	52 (81.2)	18 (58.1)
<b>Intervention Methods</b>				
AF	29 (16.4)	17 (9.6)	10 (5.6)	7 (4)
CM	110 (62.1)	71 (40.1)	53 (29.9)	18 (10.2)
TC	74 (41.8)	49 (27.7)	35 (19.8)	14 (7.9)
EPR	48 (27.1)	24 (13.6)	10 (5.6)	14 (7.9)
CE	72 (40.7)	31 (17.5)	23 (13)	8 (4.5)
CR	35 (19.8)	29 (16.4)	10 (5.6)	19 (10.7)
FR	73 (41.2)	30 (16.9)	12 (6.8)	18 (10.2)
PE	165 (93.2)	98 (55.4)	74 (41.8)	24 (13.6)
PSM	153 (86.4)	81 (45.8)	54 (30.5)	27 (15.3)
PR	35 (19.8)	25 (14.1)	13 (7.3)	12 (6.8)
CQI	9 (5.1)	1 (0.6)	1 (0.6)	0 (0)
FI	6 (3.4)	6 (3.4)	4 (2.3)	2 (1.1)

**Table 1. Study characteristics.** Sample Size and Duration of Follow-Up reported as *mean* (range). All other categories reported as *n* (%). Under primary focus, other refers to aspirin use, statin use, hypertensive drug use, smoking cessation, as well as screening for retinopathy, nephropathy, or neuropathy. DM=diabetes mellitus; CVD = cardiovascular disease; HbA1c=glycated hemoglobin; AF=audit and feedback. CM=case management; TC=team changes; EPR=electronic patient registry; CE=clinician education; CR=clinician reminders;



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3 FR=facilitated relay; PE=patient education; PSM=promotion of self-management; PR=patient  
4 reminders; CQI=continuous quality improvement; FI=financial incentives.  
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7 Countries with universal health care include: Argentina, Australia, Austria, Belgium, Brazil,  
8 Canada, Denmark, Finland, France, Germany, Greece, Hong Kong, Iceland, Ireland, Israel, Italy,  
9 Japan, Luxembourg, New Zealand, Norway, Portugal, Singapore, South Korea, Spain,  
10 Switzerland, The Netherlands, UAE, and UK. Countries with privatized health insurance include:  
11 China, India, Iran, Jordan, Mexico, Oman, Poland, South Africa, Thailand, Turkey, and USA.  
12 Two trials were conducted over multiple countries, in which case each country was counted as a  
13 discrete entity.  
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**Table 2. PROGRESS-Plus factors by trial type**

PROGRESS-Plus Factors	Non-Equity Studies, n = 177	Equity-Relevant Studies			Equity-Relevant Studies, n = 95					
		All, n = 95	Targeted, n = 64	General, n = 31	Targeted, n = 64			General, n = 31		
					O	B	A	O	B	A
Place of Residence	4 (2.3)	19 (20)	19 (29.7)	0 (0)	19 (29.7)	1 (1.6)	0 (0)	0 (0)	0 (0)	0 (0)
Race/Ethnicity/ Culture/Language	62 (35)	75 (78.9)	57 (89.1)	18 (58.1)	34 (53.1)	41 (64.1)	7 (10.9)	0 (0)	18 (58.1)	8 (25.8)
Occupation	17 (9.6)	24 (25.3)	18 (28.1)	6 (19.4)	1 (1.6)	17 (26.6)	1 (1.6)	0 (0)	6 (19.4)	2 (6.5)
Gender/Sex	160 (90.4)	91 (95.8)	60 (93.8)	31 (100)	0 (0)	60 (93.8)	9 (14.1)	0 (0)	31 (100)	22 (71)
Religion	0 (0)	1 (1.1)	1 (1.6)	0 (0)	1 (1.6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Education	57 (32.2)	57 (60)	42 (65.6)	15 (48.4)	1 (1.6)	42 (65.6)	5 (7.8)	0 (0)	14 (45.2)	9 (29)
Socioeconomic Status	27 (15.3)	51 (53.7)	45 (70.3)	6 (19.4)	18 (28.1)	40 (62.5)	2 (3.1)	0 (0)	5 (16.1)	2 (6.5)
Social Capital	30 (16.9)	33 (34.7)	30 (46.9)	3 (9.7)	0 (0)	30 (46.9)	1 (1.6)	0 (0)	3 (9.7)	0 (0)
Plus 1. Age	167 (94.4)	92 (96.8)	61 (95.3)	31 (100)	8 (12.5)	61 (95.3)	7 (10.9)	0 (0)	31 (100)	22 (71)
Plus 1. Disability	53 (29.9)	32 (33.7)	23 (35.9)	9 (29)	7 (10.9)	22 (34.4)	3 (4.7)	0 (0)	9 (29)	1 (3.2)

**Table 2. PROGRESS-Plus factors by trial type.** All values are expressed as *n* (%). O=study objective; B=baseline patient characteristics; A=study analysis. The PROGRESS-Plus factors of sexual preference, features of relationships, and time-dependent relationships were omitted from this table as we did not find any studies which looked at these characteristics as a potential risk factor for being disadvantaged.

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3 Each trial is counted once under each column. Columns on the left of the table reflect the number of trials that contained PROGRESS-  
4 Plus factors in the objectives (O), baseline characteristics (B), or analysis (A). Trials that assessed for PROGRESS-Plus factors in two  
5 or more categories of O, B, and A were still counted as one trial. As such, the sum of trials under headings O, B, and A within targeted  
6 and general trials (columns 6-8 and 9-11) are not equal to the corresponding number of trials under targeted and general in the left side  
7 of the table (columns 4 and 5).  
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10 Targeted trials with an objective (O) defined by PROGRESS-Plus factors were further scrutinized for different PROGRESS-Plus  
11 factors in their baseline characteristics (B) or analysis (A) – the inclusion of a PROGRESS-Plus factor different from that targeted by  
12 the intervention objective (O) would warrant the trial to be counted under headings B and A in their respective PROGRESS-Plus  
13 categories.  
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**Table 3. Frequency of PROGRESS-Plus factors stratified by year of study conduct**

PROGRESS-Plus Factors	Non-Equity Studies, n = 177		Equity-Relevant Studies, n = 95					
			All, n = 95		Targeted, n = 64		General, n = 31	
Year of Study Conduct	Pre-2007 n = 85	2007-2014 n = 92	Pre-2007 n = 41	2007-2014 n = 54	Pre-2007 n = 23	2007-2014 n = 41	Pre-2007 n = 18	2007-2014 n = 13
Place of Residence	2 (2.4)	2 (2.2)	10 (24.4)	9 (16.7)	10 (43.5)	9 (22)	0 (0)	0 (0)
Race/Ethnicity/ Culture/Language	28 (32.9)	34 (37)	31 (75.6)	44 (81.5)	20 (87)	37 (90.2)	1 (61.1)	7 (53.8)
Occupation	5 (5.9)	12 (13)	6 (14.6)	18 (33.3)	5 (21.7)	13 (31.7)	1 (5.6)	5 (38.5)
Gender/Sex	72 (84.7)	88 (95.7)	39 (95.1)	52 (96.3)	21 (91.3)	39 (95.1)	18 (100)	13 (100)
Religion	0 (0)	0 (0)	1 (2.4)	0 (0)	1 (4.3)	0 (0)	0 (0)	0 (0)
Education	21 (24.7)	36 (39.1)	18 (43.9)	39 (72.2)	11 (47.8)	31 (75.6)	1 (38.9)	8 (61.5)
Socioeconomic Status	13 (15.3)	14 (15.2)	18 (43.9)	33 (61.1)	16 (69.6)	29 (70.7)	1 (11.1)	4 (30.8)
Social Capital	10 (11.8)	20 (21.7)	11 (26.8)	22 (40.7)	9 (39.1)	21 (51.2)	1 (11.1)	1 (7.7)
Plus 1. Age	78 (91.8)	89 (96.7)	40 (97.6)	52 (96.3)	22 (95.7)	39 (95.1)	18 (100)	13 (100)
Plus 1. Disability	24 (28.2)	29 (31.5)	6 (14.6)	26 (48.1)	3 (13)	20 (48.8)	1 (16.7)	6 (46.2)

**Table 3. Frequency of PROGRESS-Plus factors stratified by year of study conduct.** Year of publication where the last year of study conduct was not reported. All values are expressed as *n* (%).

## ABBREVIATIONS

QI: quality improvement; RCT: randomized control trial

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NMI and KJD conceived the study. All authors (JBL, KJD, MDE, VW, JMG, NMI) participated in the design of the study. KJD managed and coordinated the source data. JBL and MDE coded the source data with input from NMI and KJD to resolve discrepancies between coders. All authors contributed to the interpretation of the findings. Writing of the paper was led by JBL, KJD, and NMI with MDE, VW, and JMG commenting on drafts. All authors approved the final manuscript.

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## COMPETING INTERESTS

No potential conflicts of interest relevant to this article were reported.

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## DATA SHARING STATEMENT

The dataset generated and analyzed during the current study are available from the corresponding author on request.

## REFERENCES

1. World Health Organization. Global report on diabetes. France: World Health Organization; 2016.
2. Glazier RH, Bajcar J, Kennie NR, et al. A systematic review of interventions to improve diabetes care in socially disadvantaged populations. *Diabetes Care* 2006;29:1675-1688. doi:10.2337/dc05-1942
3. Peek ME, Cargill A, Huang ES. Diabetes health disparities: A systematic review of health care interventions. *Med Care Res Rev* 2007;64(5):101S-156S. doi:10.1177/1077558707305409
4. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. *Can J Diabetes* 2013;37(suppl 1):S1-S212.
5. American Diabetes Association. Foundations of care and comprehensive medical evaluation. *Diabetes Care* 2016;39(Suppl. 1):S23-S35. doi:10.2337/dc16-S006.
6. Borkhoff CM, Wieland ML, Myasoedova E, et al. Reaching those most in need: A scoping review of interventions to improve health care quality for disadvantaged populations with osteoarthritis. *Arthritis Care Res* 2011;63(1):39-52. doi:10.1002/acr.20349
7. Chin MH, Parrillo R. Advancing equity in healthcare: Lessons from Massachusetts and beyond. *BMJ* 2015;350:h1617. doi:10.1136/bmj.h1617
8. Chin MH, Goddu AP, Ferguson MJ, et al. Expanding and sustaining integrated health care: Community efforts to reduce diabetes disparities. *Health Promot Pract* 2014;15(2):29S-39S. doi:10.1177/1524839914532649
9. O'Neill J, Tabish H, Welch V, et al. Applying an equity lens to interventions: Using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. *J Clin Epidemiol* 2014;67(1):56-64. doi:10.1016/j.jclinepi.2013.08.005
10. Tricco AC, Ivers NM, Grimshaw JM, et al. Effectiveness of quality improvement strategies on the management of diabetes: A systematic review and meta-analysis. *Lancet* 2012;379(9833):2252-2261. doi:10.1016/S0140-6736(12)60480-2
11. Clarke AR, Goddu AP, Nocon RS, et al. Thirty years of disparities intervention research: What are we doing to close racial and ethnic gaps in health care? *Med Care* 2013;51(11):1020-1026. doi:10.1097/MLR.0b013e3182a97ba3
12. Lorenc T, Petticrew M, Welch V, et al. What type of interventions generate inequalities? Evidence from systematic reviews. *J Epidemiol Community Health* 2013;67(2):190-193. doi:10.1136/jech-2012-201257
13. Ivers NM, Tricco AC, Trikalinos TA, et al. Seeing the forests and the trees – innovative approaches to exploring heterogeneity in systematic reviews of complex interventions to enhance health system decision-making: A protocol. *Syst Rev* 2014;3:88. doi:10.1186/2046-4053-3-88
14. Gary TL, Bone LR, Hill MN, et al. Randomized controlled trial of the effects of nurse case manager and community health worker interventions on risk factors for diabetes-related complications in urban African Americans. *Prev Med* 2003;37:23-32.
15. Bujnowska-Fedak MM, Puchala E, Steciwko A. The impact of telehome care on health status and quality of life among patients with diabetes in a primary care setting in

- 1  
2  
3 Poland. *Telemedicine J E Health* 2011;17(3):153-163. doi:10.1089/tmj.2010.0113  
4 16. DePue JD et al. Nurse-community health worker team improves diabetes care in  
5 American Samoa. *Diabetes Care* 2013;36(7):1947-1953. doi:10.2337/dc12-1969  
6 17. Shea S et al. A randomized trial comparing telemedicine case management with usual  
7 care in older, ethnically diverse, medically underserved patients with diabetes mellitus:  
8 5 year results of the IDEATel study. *J Am Med Inform Assoc* 2009;16(4):446-456.  
9 doi:10.1197/jamia.M3157  
10 18. Eakin EG, Reeves MM, Winkler E, et al. Six-month outcomes from living well with  
11 diabetes: A randomized trial of telephone-delivered weight loss and physical activity  
12 intervention to improve glycemic control. *Ann Behav Med* 2013;46:193-203. Doi:  
13 doi:10.1007/s12160-013-9498-2  
14 19. Adair R, Wholey DR, Christianson J, et al. Improving chronic disease care by adding  
15 laypersons to the primary care team: A parallel randomized trial. *Ann Intern Med*  
16 2013;159:176-184.  
17 20. Fisher TL, Burnet DL, Huang ES, et al. Cultural leverage : Interventions using culture  
18 to narrow racial disparities in health care. *Medical Care Research and Review*  
19 2007;64(5):243S-282S. doi: 10.1177/1077558707305414  
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## FIGURE LEGEND

### Figure 1. PRISMA flow diagram

Figure 1 summarizes the flow of literature in the QI review. The initial search identified a total of 7248 citations; review of 2,691 full text articles resulted in a final sample of 309 reports, representing 272 unique trials.

For peer review only



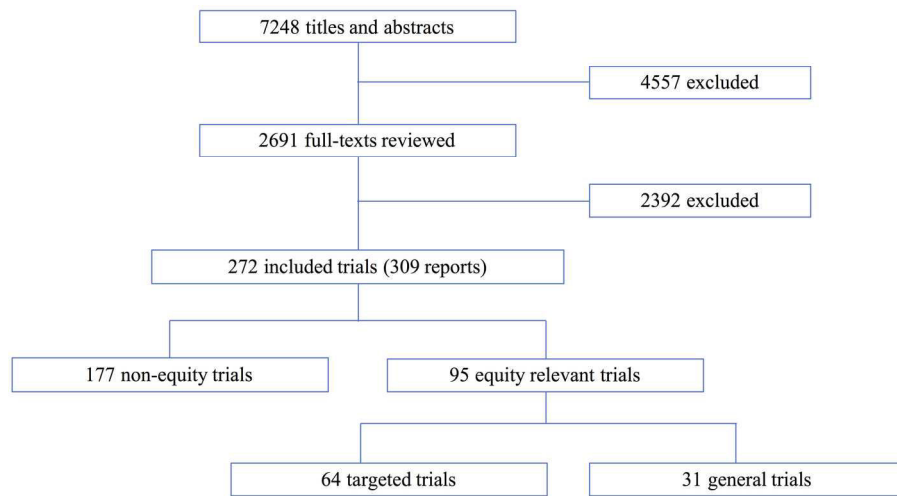


Figure 1. PRISMA flow diagram

Figure 1 summarizes the flow of literature in the QI review. The initial search identified a total of 7248 citations; review of 2,691 full text articles resulted in a final sample of 309 reports, representing 272 unique trials.

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## Supplemental Table 1. PROGRESS-Plus definitions

We defined *disadvantage* according to the PROGRESS-Plus framework as outlined by O'Neill *et al.* (9). The table below outlines our interpretation of these risk factors associated with disadvantage in the context of patients with diabetes.

PROGRESS-Plus FACTOR	DEFINITION
<b>Place of residence</b>	Residence in a medically underserved area where it is difficult to access care. <i>Example: rural, remote, inner city</i>
<b>Race, ethnicity, culture, language</b>	Ethnic and racial minorities, patients who do not speak the dominant language of the region or who do not identify with the dominant culture of the area.
<b>Occupation</b>	Occupations that involve high risk exposures or unsafe working environments, instability in employment status, lack of access to employee benefits or employer-funded insurance systems. <i>Example: part-time, disability leave, temporary worker, migrant worker</i>
<b>Gender, sex</b>	Gender roles that may define differential access to health services and differential exposure to health risks, sexual identities that face violence and discrimination. <i>Example: men, women, cisgender, transgender, intersex</i>
<b>Religion</b>	Religious beliefs may limit a patient's ability to choose certain medical therapies, religious affiliations may lead to discrimination and bias from service providers.
<b>Education</b>	Education level and education opportunities correlate with income status as well as knowledge about health and access to preventative health practices. <i>Example: highest level of education completed, education status of family members</i>
<b>Socioeconomic status</b>	Income levels that allow or prohibit participation in preventative health behaviours, ability to access health insurance in times of illness. <i>Example: low income, private health insurance, state-sponsored insurance</i>
<b>Social capital</b>	Social relationships and availability of social support networks to provide support and build resilience in times of distress. <i>Example: marital status, community networks, professional networks</i>
<b>Plus 1. Age</b>	Old age and frailty may be associated with decreased independence, decreased social capital, and increased health comorbidities; young age may be associated with decreased decision-making power. <i>Example: elderly or young</i>
<b>Plus 1. Disability</b>	Any mental health assessment, any quality of life or functional assessment, as well as any comorbid condition that is explicitly severe enough for us to reasonably believe that it impacts the ability to self-manage. <i>Example: mental health issues, intellectual disabilities, chronic pain, blindness, end-stage renal disease, symptomatic heart disease</i>
<b>Plus 1. Sexual preference</b>	Sexual orientations that may lead to discrimination and bias from service providers. <i>Example: homosexual, heterosexual, bisexual</i>

<b>Plus 2. Features of relationships</b>	Relationships that impact an individual's ability to assert their autonomy and self-manage. <i>Example: social hierarchies at school, work, or home</i>
<b>Plus 3. Time-dependent relationships</b>	Times of transition where an individual may face increased risks for poor health management. <i>Example: discharge from hospital, release from prison, students on the move, practice guideline changes</i>

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# PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
<b>TITLE</b>			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
<b>ABSTRACT</b>			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
<b>METHODS</b>			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	4
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	4
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	5
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ ) for each meta-analysis.	5



# PRISMA 2009 Checklist

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
<b>RESULTS</b>			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measure of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
<b>DISCUSSION</b>			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	7-8
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	8
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	8
<b>FUNDING</b>			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	13

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: the PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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# BMJ Open

## Do quality improvement initiatives for diabetes care address social inequities? Secondary analysis of a systematic review.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-018826.R2
Article Type:	Research
Date Submitted by the Author:	20-Dec-2017
Complete List of Authors:	Lu, Jacquie Boyang; Queen's University Faculty of Health Sciences, School of Medicine Danko, Kristin; Ottawa Hospital Research Institute, Clinical Epidemiology Program; University of Ottawa Faculty of Medicine, School of Epidemiology, Public Health, and Preventive Medicine Elfassy, Michael; University of Toronto Faculty of Medicine Welch, Vivian; University of Ottawa Faculty of Medicine, School of Epidemiology, Public Health, and Preventive Medicine; Elisabeth Bruyere Research Institute Grimshaw, Jeremy; Ottawa Hospital Research Institute, Clinical Epidemiology Program; University of Ottawa Faculty of Medicine, Department of Medicine and School of Epidemiology, Public Health, and Preventive Medicine Ivers, Noah; Women's College Hospital, Family Practice Health Centre, Women's College Research Institute, and Institute for Health Systems Solutions and Virtual Care; University of Toronto Dalla Lana School of Public Health, Department of Family and Community Medicine, and Institute of Health Policy Management and Evaluation
<b>Primary Subject Heading</b>:	Diabetes and endocrinology
Secondary Subject Heading:	Evidence based practice, Qualitative research
Keywords:	Quality improvement, Social determinants of health, Equity

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3 Do quality improvement initiatives for diabetes care address social inequities? Secondary  
4 analysis of a systematic review  
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7 PROSPERO 2013: CRD42013005165  
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### 43 **Word count**

44 2614  
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### 46 **Tables and figures**

47 4  
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## ABSTRACT

### Background

Socially disadvantaged populations carry a disproportionate burden of diabetes-related morbidity and mortality. There is an emerging interest in quality improvement (QI) strategies in the care of patients with diabetes, however, the effect of these interventions on disadvantaged groups remains unclear.

### Objective

This is a secondary analysis of a systematic review that seeks to examine the extent of equity considerations in diabetes QI studies, specifically quantifying the proportion of studies that target interventions toward disadvantaged populations and conduct analyses on the impact of interventions on disadvantaged groups.

### Research Design and Methods

Studies were identified using Medline, HealthStar, and the Cochrane EPOC database. Randomized controlled trials assessing twelve QI strategies targeting health systems, healthcare professionals, and/or patients for the management of adult outpatients with diabetes were eligible. The PROGRESS-Plus framework was used to identify trials that focused on disadvantaged patient populations, to examine the types of equity-relevant factors that are being considered, and to explore temporal trends in equity-relevant diabetes QI trials.

### Results

Of the 278 trials that met the inclusion criteria, 95 trials had equity-relevant considerations. These include 64 *targeted trials* that focussed on a disadvantaged population with the aim to improve the health status of that population and 31 *general trials* that undertook subgroup analyses to assess the extent to which their interventions may have had differential impacts on disadvantaged subgroups. Trials predominantly focused on race/ethnicity, socioeconomic status, and place of residence as potential factors for disadvantage in patients receiving diabetes care.

### Conclusions

Less than a third of diabetes QI trials included equity-relevant considerations, limiting the relevance and applicability of their data to disadvantaged populations. There is a need for better data collection, reporting, analysis, and interventions on the social determinants of health that may influence the health outcomes of patients with diabetes.

### Word Count

294



### STRENGTHS AND LIMITATIONS OF THIS STUDY

- The use of the PROGRESS-Plus framework provides a standardized approach for identifying and analyzing equity relevant information within research publications. The focus on only primary publications of trials meant any equity relevant analyses in subsequent publications of the same trial were not captured in this review.
- The lack of standardized terminology for equity relevant information in the general literature restricted our ability to fully capture all the various issues that may lead to disadvantages in medical care.
- The inclusion of only English language publications was a practical limitation on the scope of this study.

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## INTRODUCTION

Diabetes affects approximately 8.5% of the adult population; the increasing prevalence of physical inactivity, obesity, and an aging population means that this number will increase over time.[1,2] The burden of diabetes is not evenly spread through the population. Racial and ethnic minorities, as well as people of lower socioeconomic status are more likely to develop diabetes.[2,3] Such individuals are also more likely to experience delayed diagnosis and lower quality of care, leading to greater risk for diabetes-related complications.[2,3]

Patients with diabetes require lifelong medications, routine follow-up with healthcare professionals, and regular preventative screening exams to reduce the likelihood of morbidity and mortality.[4,5] Socially disadvantaged groups may experience multiple barriers to high quality care due to factors such as differences in language or culture, inadequate financial resources, or prohibitive distances from care centres.[2,6–8] To ensure that innovations and standards of care in healthcare reach the most disadvantaged segments of the population, interventions must recognize and address these equity-based considerations.[2,7–9]

Quality improvement (QI) in the care of patients with diabetes is a rapidly expanding field of interest.[10] However, while many QI strategies are effective in improving diabetes care in general populations,[10] it is unclear whether they improve or worsen health disparities among disadvantaged subgroups.[11] QI strategies designed for the general population may not be accessible to disadvantaged groups or may not have the same efficacy in disadvantaged populations and may inadvertently lead to an increase in diabetes related health disparities.[2,7,9,11,12]

Recently, we updated a systematic review of trials of QI strategies for diabetes care.[13] In this secondary analysis of that review, we examine the extent to which health equity concerns were considered in diabetes QI studies. Specifically, we quantified the proportion of QI studies that targeted interventions toward disadvantaged populations, looked at risk factors for disadvantage in the patient population, and analyzed the impact of interventions on disadvantaged subgroups.

## RESEARCH DESIGN AND METHODS

Our goal was to examine the extent of focus in the literature on understanding the effects of diabetes QI for disadvantaged populations. A detailed description of methods used for searching and screening the relevant data for the underlying systematic review has been published.[13]

### Study Selection and Data Extraction

An experienced librarian developed the search strategy, which was peer reviewed independently by another information specialist. Studies were identified using Medline, HealthStar, and the Cochrane Effective Practice and Organization of Care (EPOC) database. Randomized controlled trials (RCTs) assessing one of twelve predefined QI strategies targeting health systems, healthcare professionals, and/or patients for the management of adult outpatients with diabetes were eligible. Studies had to report at least one process of care measure (e.g., proportion of patients taking acetylsalicylic acid, statins, or antihypertensive medication; screened for retinopathy or foot abnormalities and monitored for renal function) or intermediate outcomes (e.g., glycosylated haemoglobin levels [HbA1c], low-density lipoprotein cholesterol levels,

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3 diastolic and systolic blood pressure; proportion of patients with controlled hypertension or who  
4 quit smoking).  
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7 For this secondary review, we developed a data extraction form using the PROGRESS-Plus  
8 framework,[9] to consider the range of factors that may increase the risk for a population  
9 subgroup to be disadvantaged, including participants' Place of residence,  
10 Race/ethnicity/culture/language, Occupational status, Gender/sexual identity, Religious  
11 affiliations, Education level, Socioeconomic status, Social capital, plus age, disability, sexual  
12 preferences, and relationships.[9] Specifically, we interpreted these risk factors in the context of  
13 a patient's ability to access health care and effectively manage their diabetes. For example, it  
14 may be more difficult for patients living in rural or geographically isolated areas to access  
15 dependable primary care, leading to negative implications for their ability to achieve diabetes-  
16 related targets. Supplemental Table 1 outlines our full interpretation of PROGRESS-Plus factors  
17 in considering how these factors might lead to inequity in diabetes management across sub-  
18 populations, developed based on previous literature,[6] the PROGRESS framework,[9] and in  
19 collaboration with PROGRESS-authors (VW).  
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23 Two reviewers independently extracted data based on a thorough reading of the full text for all  
24 included studies. This allowed us to identify a cohort of *equity-relevant trials* that targeted or  
25 assessed equity factors as defined by the PROGRESS-Plus framework.[9] Within this cohort,  
26 trials were classified as either Targeted or General. *Targeted equity-relevant trials* were defined  
27 as a trial focussed on a population with an identified disadvantage in health in order to improve  
28 the health status of that population or to reduce the health gradient. *General equity-relevant trials*  
29 were defined as a trial involved a broad participant population but made comparisons of effects  
30 in disadvantaged subgroups to assess the extent to which interventions may have differential  
31 impacts. For example, a trial testing a primary care-based culturally sensitive behavioural  
32 intervention in a population of urban African Americans with type 2 diabetes [14] would be  
33 classified as a *targeted* equity-relevant trial because it purposefully directed interventions  
34 towards a disadvantaged population. In contrast, a trial testing a tele-homecare monitoring  
35 system for patients with type 2 diabetes that explored the benefit of the intervention in female  
36 patients and those with lower education levels,[15] would be classified as a *general* equity-  
37 relevant trial.  
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41 The reviewers extracted PROGRESS-Plus factors identified in the baseline patient characteristics  
42 for all studies. Additionally, for equity-relevant studies, the reviewers extracted PROGRESS-  
43 Plus factors identified in the study objective, study design (e.g., patient eligibility criteria and  
44 patient recruitment techniques), and analysis of results. We only coded instances when authors  
45 were explicit in their mention of PROGRESS-Plus factors. Discrepancies were resolved by  
46 discussion or the involvement of authors NMI and KJD.  
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### 49 **Data Synthesis and Analysis**

50 As we had no *a priori* hypothesis about the differences or similarities that would be found among  
51 trials regarding issues of equity or efforts to address areas of disadvantage, we provide here  
52 descriptive analyses only. We describe the proportion of trials that focused on equity-relevant  
53 factors and types of factors considered in these trials. In addition, to explore for time-trends in  
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3 the consideration of equity-relevant factors in diabetes QI trials, we split our analyses by median  
4 date of study conduct.  
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## 6 **RESULTS**

### 7 **Literature search and review process**

8 Figure 1 summarizes the flow of literature in the QI review. The initial search identified a total of  
9 7248 citations; review of 2,691 full text articles resulted in a final sample of 309 reports,  
10 representing 272 unique trials.  
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### 13 **Study characteristics**

14 Ninety-five trials (34.9%) were identified as equity-relevant; 64 of these were classified as  
15 targeted and 31 as general. Characteristics were similar between non-equity studies and equity-  
16 relevant studies (Table 1). Most trials focused on patients with type 2 diabetes, and looked at  
17 glycemic control combined with cardiovascular status or other health benchmarks (aspirin use,  
18 statin use, hypertensive drug use, screening for retinopathy/nephropathy/neuropathy, smoking  
19 cessation) as the primary outcomes of interest. Mean baseline HbA1c was comparable between  
20 non-equity and equity-relevant trials, but targeted trials reported the inclusion of a greater  
21 proportion of patients with HbA1c greater or equal to 8% compared to general trials.  
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24  
25 Interestingly, 73.7% of equity-relevant trials were based in countries with private health  
26 insurance systems, whereas 32.6% of equity-relevant trials were based in countries with  
27 universal health insurance. However, this finding may simply reflect the predominance of  
28 publications from the United States included within this review, contributing 65 of 177 non-  
29 equity studies and 63 of 95 equity-relevant studies.  
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32 The relative frequency of individual QI strategies assessed in the studies were also comparable  
33 across non-equity and equity-relevant trials with a few exceptions. Overall, patient education,  
34 promotion of self-management, and case management were the most frequently used QI  
35 interventions across all studies. Among equity-relevant trials, case management, team changes,  
36 and patient education were evaluated more frequently in targeted trials compared to general trials.  
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39 Table 2 describes the frequency of PROGRESS-Plus factors examined in all studies. Among 177  
40 non-equity studies, 94.4% reported data on the age of participants, 90.4% reported data on  
41 gender/sex, 35.0% reported data on race/ethnicity/culture/language, 32.2% reported data on  
42 education levels, and 29.9% reported data on disability status. Overall, age and gender/sex were  
43 the most frequently documented PROGRESS-Plus factors, appearing equally in both equity-  
44 relevant studies and non-equity studies. In comparison, race/ethnicity/culture/language,  
45 socioeconomic status, education, social capital, occupation, and place of residence appeared  
46 significantly more frequently in equity-relevant trials than in non-equity trials. The PROGRESS-  
47 Plus factors of sexual preference, features of relationships, and time-dependent relationships  
48 were not identified in any of the studies.  
49  
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51 The targeted trials were most commonly directed toward race/ethnicity/language/culture (53.1%  
52 of targeted trials), place of residence (29.7%), and socioeconomic status (28.1%); occupation,  
53 gender/sex, religion, or social capital were rarely addressed in the objectives of target trials. Most  
54 targeted trials used a single PROGRESS-Plus factor to define its patient population (e.g.,  
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3 interventions targeted people in rural communities *or* patients belonging to a particular ethnic  
4 minority). Twenty trials looked at population subgroups with two PROGRESS-Plus factors.  
5 Only two trials simultaneously targeted three factors.[16,17] Fifteen targeted trials (23%)  
6 conducted sub-analyses to understand whether their intervention varied in its effectiveness across  
7 additional PROGRESS-Plus factors distinct from those used to define their intervention and their  
8 target patient populations.  
9

10  
11 Of the 31 general trials that did not contain an equity-specific objective but conducted stratified  
12 analyses across PROGRESS-Plus factors, gender/sex (71.0% of general trials), age (71.0%),  
13 race/ethnicity/culture/language (25.8%), and education (29.0%) were the most commonly  
14 stratified factors. 12 trials found differential effects among disadvantaged subgroups when  
15 intervention outcomes were further analyzed. Notably, 6 trials found differences in outcomes  
16 based on the sex of participants, 5 trials found differences based on age, and 4 trials found  
17 differences based on race/ethnicity group.  
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21 Table 3 examines the extent of equity-relevance in diabetes QI trials over time. Prior to 2007,  
22 there were 41 equity-relevant trials out of 126 diabetes QI studies. In the period from 2007 to  
23 2014, there were 54 equity-relevant trials out of 146 diabetes QI studies. Targeted trials were  
24 responsible for 56.1% of equity-relevant trials prior to 2007. This number increased to 75.9% of  
25 equity-relevant trials in the period from 2007 to 2014. The most notable increases in the absolute  
26 number of targeted studies occurred with occupation, education, and disability.  
27

## 28 CONCLUSIONS

29 Among 278 diabetes QI trials, only 34.9% provided equity-relevant findings. These studies  
30 provide insight into the effectiveness of various diabetes management strategies among racial  
31 and ethnic minorities, among patients with low income or low socioeconomic status, as well as  
32 in remote medically underserved populations. A few trials looked at age, gender/sex, education  
33 status, and disability as potential factors that contribute to disparities in diabetes care. However,  
34 we know little about the effects of other factors that may play a role in determining how patients  
35 experience and respond to health interventions.  
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39 Trials designed for the general population which then conducted stratified analyses point to the  
40 importance of considering PROGRESS-Plus factors when designing and examining  
41 interventions. In fact, QI strategies designed for the general population may not be accessible to  
42 disadvantaged groups or may not have the same efficacy in disadvantaged populations and may  
43 inadvertently lead to an increase in diabetes related health disparities. For example, a general  
44 trial looking at telehome monitoring systems as an affordable and efficient means to monitor  
45 patients with diabetes showed greater efficacy in patients who were male, elderly, and/or more  
46 educated.[15] Another study examining the efficacy of telephone-based weight loss programs to  
47 improve glycemic control found the intervention outcomes differed between Caucasians and  
48 non-Caucasians.[18]. Alternatively, adding care guides to the primary care team was more likely  
49 to have benefits for patients on Medicaid rather than patients with other forms of health  
50 insurance in the United States.[19] These findings emphasize the need for better data collection,  
51 reporting, and analysis on the social determinants of health that may influence the health  
52 outcomes of patients with diabetes.  
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3 While the majority of diabetes QI trials did not have an equity focus, the vast majority collected  
4 some form of equity-relevant data to assess balance between study arms in RCTs. This collection  
5 of stratified data presents a missed opportunity for researchers to further explore equity-relevant  
6 analyses.  
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9 In this systematic review, only 22 trials (8.1%) directed interventions toward a population that  
10 was impacted by two or more risk factors for health disparities. The limited foci of diabetes QI  
11 trials stand in contrast to the harsh reality of many patients, for whom multiple social and  
12 economic determinants of health intersect in complex ways. The risk for health disparities often  
13 increases in populations where multiple PROGRESS-Plus factors are concerned.[9] For example,  
14 there is a paucity of research targeting elderly racial and ethnic minorities despite this being one  
15 of the fastest growing demographic for diabetes diagnoses and diabetes-related complications.[3]  
16 Given that these populations tend to bear a disproportionate burden of disease,[2,3] it is even  
17 more important that interventions and analyses relevant to these patients be represented in the  
18 current body of research.  
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22 Interventions tailored toward socially disadvantaged populations show promising results in  
23 reducing health disparities in diabetes care. In a review of 17 QI trials, Glazier et al. (2006)  
24 found that interventions worked best when they were adapted to the local community to fit local  
25 circumstances.[2] Similarly, in a study of 42 QI trials, Peek et al. (2007) found evidence to  
26 suggest that culturally tailored programming and community-based partnerships led to  
27 improvements in health outcomes for racial/ethnic minorities and successfully contributed to  
28 reductions in health disparities in the population.[3] Fisher et al. (2007) showed narrowing of  
29 racial disparities in health care with culturally specific programming and health care messaging.  
30 Culturally sensitive strategies can help strengthen connections between patients and health care  
31 organizations, thereby facilitating a more effective exchange of health information and improved  
32 adherence to treatment plans for ethnic and racial minorities.[20]  
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36 In 2013, Clarke et al. reported that interventions to improve care in ethnic minorities  
37 predominantly focussed on patient-level strategies, placing the burden of change on patients  
38 without addressing equally relevant factors at the level of health providers, health care  
39 organizations, and health systems.[11] Here, we show that there is increasing data from trials  
40 testing health system interventions, such as case management and team changes, to consider  
41 when developing QI interventions to either address or prevent worsening health inequities across  
42 several PROGRESS-Plus characteristics.  
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46 This study has several limitations. First, we included only English language publications as  
47 translation of non-English studies was not feasible. Second, due the large number of included  
48 studies we focused our review of equity factors in the primary publication of trials. It is possible  
49 that authors did additional equity-relevant analyses in secondary publications, which were not  
50 captured in this review. This may result in an underestimate of the number of general studies that  
51 analyzed effects in disadvantaged groups. However, by focusing on primary publication, we  
52 have identified studies in which equity concerns were prioritized by authors, either through  
53 targeted interventions or subsequent analyses, to warrant discussion in a primary paper. Finally,  
54 our ability to capture the full breadth of issues that may disadvantage patients was restricted by  
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3 limitations in reporting these variables within each study and by the lack of a standardized  
4 terminology in the literature.  
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7 As our objective was to assess the extent to which researchers considered equity-relevant factors,  
8 we did not analyze the effect of equity-relevant factors on study outcomes. The effectiveness of  
9 interventions often varies based on the participant population and the existing health system.  
10 Based on the limited primary data that we have from targeted and general trials, it is difficult to  
11 make definitive conclusions about which interventions or QI strategies are effective or  
12 ineffective in reducing health disparities and/or improving health outcomes for disadvantaged  
13 groups without oversimplifying the issue and potentially misleading future enquiry. What  
14 ultimately works in one health care setting may not work in another. However, this represents an  
15 important area for future research.  
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18 In conclusion, the findings in this secondary study of a systematic review of diabetes QI trials  
19 indicate substantial room for improvement in the proportion of studies that address equity and  
20 the range of equity factors that can be reported and analyzed.  
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**Table 1. Study characteristics**

Study Characteristics	Non-Equity Studies, n = 177	Equity-Relevant Studies		
		All, n = 95	Targeted, n = 64	General, n = 31
<b>Sample Size</b>	931.6 (17 - 23740)	733.5 (35 - 7557)	490.7 (35 - 7557)	1226.8 (46 - 7009)
<b>Duration of Follow-Up (months)</b>	14 (3 - 159.6)	13.2 (3 - 72)	12.5 (3 - 60)	14.6 (3 - 72)
<b>Types of Diabetes</b>				
Types 1	9 (5.1)	5 (5.3)	1 (1.6)	4 (12.9)
Type 2	116 (65.5)	51 (53.7)	37 (57.8)	14 (45.2)
Types 1 and 2	0 (0)	17 (17.9)	9 (14.1)	8 (25.8)
Type unclear or not reported	19 (10.7)	22 (23.2)	17 (26.6)	5 (16.1)
<b>Mean Baseline HbA1c</b>				
< 8% or 64 mmol/mol	56 (31.6)	33 (34.7)	19 (29.7)	14 (45.2)
≥ 8% or 63 mmol/mol	90 (50.8)	45 (47.4)	34 (53.1)	11 (35.5)
Not reported	31 (17.5)	17 (17.9)	11 (17.2)	6 (19.4)
<b>Primary Focus</b>				
Glycemic only	44 (24.9)	19 (20)	8 (12.5)	11 (35.5)
Glycemic and CVD	45 (25.4)	30 (31.6)	21 (32.8)	9 (29)
Glycemic and other	0 (0)	33 (34.7)	25 (39.1)	8 (25.8)
CVD only	16 (9)	6 (6.3)	4 (6.3)	2 (6.5)
Other or unclear	8 (4.5)	7 (7.4)	6 (9.4)	1 (3.2)
<b>Country of Study by Health System</b>				
Universal health care	96 (54.2)	31 (32.6)	12 (18.8)	19 (61.3)
Private health insurance	79 (44.6)	70 (73.7)	52 (81.2)	18 (58.1)
<b>Intervention Methods</b>				
AF	29 (16.4)	17 (9.6)	10 (5.6)	7 (4)
CM	110 (62.1)	71 (40.1)	53 (29.9)	18 (10.2)
TC	74 (41.8)	49 (27.7)	35 (19.8)	14 (7.9)
EPR	48 (27.1)	24 (13.6)	10 (5.6)	14 (7.9)
CE	72 (40.7)	31 (17.5)	23 (13)	8 (4.5)
CR	35 (19.8)	29 (16.4)	10 (5.6)	19 (10.7)
FR	73 (41.2)	30 (16.9)	12 (6.8)	18 (10.2)
PE	165 (93.2)	98 (55.4)	74 (41.8)	24 (13.6)
PSM	153 (86.4)	81 (45.8)	54 (30.5)	27 (15.3)
PR	35 (19.8)	25 (14.1)	13 (7.3)	12 (6.8)
CQI	9 (5.1)	1 (0.6)	1 (0.6)	0 (0)
FI	6 (3.4)	6 (3.4)	4 (2.3)	2 (1.1)

**Table 1. Study characteristics.** Sample Size and Duration of Follow-Up reported as *mean* (range). All other categories reported as *n* (%). Under primary focus, other refers to aspirin use, statin use, hypertensive drug use, smoking cessation, as well as screening for retinopathy, nephropathy, or neuropathy. DM=diabetes mellitus; CVD = cardiovascular disease; HbA1c=glycated hemoglobin; AF=audit and feedback. CM=case management; TC=team changes; EPR=electronic patient registry; CE=clinician education; CR=clinician reminders;



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3 FR=facilitated relay; PE=patient education; PSM=promotion of self-management; PR=patient  
4 reminders; CQI=continuous quality improvement; FI=financial incentives.  
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7 Countries with universal health care include: Argentina, Australia, Austria, Belgium, Brazil,  
8 Canada, Denmark, Finland, France, Germany, Greece, Hong Kong, Iceland, Ireland, Israel, Italy,  
9 Japan, Luxembourg, New Zealand, Norway, Portugal, Singapore, South Korea, Spain,  
10 Switzerland, The Netherlands, UAE, and UK. Countries with privatized health insurance include:  
11 China, India, Iran, Jordan, Mexico, Oman, Poland, South Africa, Thailand, Turkey, and USA.  
12 Two trials were conducted over multiple countries, in which case each country was counted as a  
13 discrete entity.  
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**Table 2. PROGRESS-Plus factors by trial type**

PROGRESS-Plus Factors	Non-Equity Studies, n = 177	Equity-Relevant Studies			Equity-Relevant Studies, n = 95					
		All, n = 95	Targeted, n = 64	General, n = 31	Targeted, n = 64			General, n = 31		
					O	B	A	O	B	A
Place of Residence	4 (2.3)	19 (20)	19 (29.7)	0 (0)	19 (29.7)	1 (1.6)	0 (0)	0 (0)	0 (0)	0 (0)
Race/Ethnicity/ Culture/Language	62 (35)	75 (78.9)	57 (89.1)	18 (58.1)	34 (53.1)	41 (64.1)	7 (10.9)	0 (0)	18 (58.1)	8 (25.8)
Occupation	17 (9.6)	24 (25.3)	18 (28.1)	6 (19.4)	1 (1.6)	17 (26.6)	1 (1.6)	0 (0)	6 (19.4)	2 (6.5)
Gender/Sex	160 (90.4)	91 (95.8)	60 (93.8)	31 (100)	0 (0)	60 (93.8)	9 (14.1)	0 (0)	31 (100)	22 (71)
Religion	0 (0)	1 (1.1)	1 (1.6)	0 (0)	1 (1.6)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Education	57 (32.2)	57 (60)	42 (65.6)	15 (48.4)	1 (1.6)	42 (65.6)	5 (7.8)	0 (0)	14 (45.2)	9 (29)
Socioeconomic Status	27 (15.3)	51 (53.7)	45 (70.3)	6 (19.4)	18 (28.1)	40 (62.5)	2 (3.1)	0 (0)	5 (16.1)	2 (6.5)
Social Capital	30 (16.9)	33 (34.7)	30 (46.9)	3 (9.7)	0 (0)	30 (46.9)	1 (1.6)	0 (0)	3 (9.7)	0 (0)
Plus 1. Age	167 (94.4)	92 (96.8)	61 (95.3)	31 (100)	8 (12.5)	61 (95.3)	7 (10.9)	0 (0)	31 (100)	22 (71)
Plus 1. Disability	53 (29.9)	32 (33.7)	23 (35.9)	9 (29)	7 (10.9)	22 (34.4)	3 (4.7)	0 (0)	9 (29)	1 (3.2)

**Table 2. PROGRESS-Plus factors by trial type.** All values are expressed as *n* (%). O=study objective; B=baseline patient characteristics; A=study analysis. The PROGRESS-Plus factors of sexual preference, features of relationships, and time-dependent relationships were omitted from this table as we did not find any studies which looked at these characteristics as a potential risk factor for being disadvantaged.

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3 Each trial is counted once under each column. Columns on the left of the table reflect the number of trials that contained PROGRESS-  
4 Plus factors in the objectives (O), baseline characteristics (B), or analysis (A). Trials that assessed for PROGRESS-Plus factors in two  
5 or more categories of O, B, and A were still counted as one trial. As such, the sum of trials under headings O, B, and A within targeted  
6 and general trials (columns 6-8 and 9-11) are not equal to the corresponding number of trials under targeted and general in the left side  
7 of the table (columns 4 and 5).  
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10 Targeted trials with an objective (O) defined by PROGRESS-Plus factors were further scrutinized for different PROGRESS-Plus  
11 factors in their baseline characteristics (B) or analysis (A) – the inclusion of a PROGRESS-Plus factor different from that targeted by  
12 the intervention objective (O) would warrant the trial to be counted under headings B and A in their respective PROGRESS-Plus  
13 categories.  
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**Table 3. Frequency of PROGRESS-Plus factors stratified by year of study conduct**

PROGRESS-Plus Factors	Non-Equity Studies, n = 177		Equity-Relevant Studies, n = 95					
			All, n = 95		Targeted, n = 64		General, n = 31	
Year of Study Conduct	Pre-2007 n = 85	2007-2014 n = 92	Pre-2007 n = 41	2007-2014 n = 54	Pre-2007 n = 23	2007-2014 n = 41	Pre-2007 n = 18	2007-2014 n = 13
Place of Residence	2 (2.4)	2 (2.2)	10 (24.4)	9 (16.7)	10 (43.5)	9 (22)	0 (0)	0 (0)
Race/Ethnicity/ Culture/Language	28 (32.9)	34 (37)	31 (75.6)	44 (81.5)	20 (87)	37 (90.2)	1 (61.1)	7 (53.8)
Occupation	5 (5.9)	12 (13)	6 (14.6)	18 (33.3)	5 (21.7)	13 (31.7)	1 (5.6)	5 (38.5)
Gender/Sex	72 (84.7)	88 (95.7)	39 (95.1)	52 (96.3)	21 (91.3)	39 (95.1)	18 (100)	13 (100)
Religion	0 (0)	0 (0)	1 (2.4)	0 (0)	1 (4.3)	0 (0)	0 (0)	0 (0)
Education	21 (24.7)	36 (39.1)	18 (43.9)	39 (72.2)	11 (47.8)	31 (75.6)	1 (38.9)	8 (61.5)
Socioeconomic Status	13 (15.3)	14 (15.2)	18 (43.9)	33 (61.1)	16 (69.6)	29 (70.7)	1 (11.1)	4 (30.8)
Social Capital	10 (11.8)	20 (21.7)	11 (26.8)	22 (40.7)	9 (39.1)	21 (51.2)	1 (11.1)	1 (7.7)
Plus 1. Age	78 (91.8)	89 (96.7)	40 (97.6)	52 (96.3)	22 (95.7)	39 (95.1)	18 (100)	13 (100)
Plus 1. Disability	24 (28.2)	29 (31.5)	6 (14.6)	26 (48.1)	3 (13)	20 (48.8)	1 (16.7)	6 (46.2)

**Table 3. Frequency of PROGRESS-Plus factors stratified by year of study conduct.** Year of publication where the last year of study conduct was not reported. All values are expressed as *n* (%).

## ABBREVIATIONS

QI: quality improvement; RCT: randomized control trial

## ACKNOWLEDGEMENTS

NMI and KJD conceived the study. All authors (JBL, KJD, MDE, VW, JMG, NMI) participated in the design of the study. KJD managed and coordinated the source data. JBL and MDE coded the source data with input from NMI and KJD to resolve discrepancies between coders. All authors contributed to the interpretation of the findings. Writing of the paper was led by JBL, KJD, and NMI with MDE, VW, and JMG commenting on drafts. All authors approved the final manuscript.

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## COMPETING INTERESTS

No potential conflicts of interest relevant to this article were reported.

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## DATA SHARING STATEMENT

The dataset generated and analyzed during the current study are available from the corresponding author on request.

## REFERENCES

1. World Health Organization. Global report on diabetes. France: World Health Organization; 2016.
2. Glazier RH, Bajcar J, Kennie NR, et al. A systematic review of interventions to improve diabetes care in socially disadvantaged populations. *Diabetes Care* 2006;29:1675-1688. doi:10.2337/dc05-1942
3. Peek ME, Cargill A, Huang ES. Diabetes health disparities: A systematic review of health care interventions. *Med Care Res Rev* 2007;64(5):101S-156S. doi:10.1177/1077558707305409
4. Canadian Diabetes Association Clinical Practice Guidelines Expert Committee. Canadian Diabetes Association 2013 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. *Can J Diabetes* 2013;37(suppl 1):S1-S212.
5. American Diabetes Association. Foundations of care and comprehensive medical evaluation. *Diabetes Care* 2016;39(Suppl. 1):S23-S35. doi:10.2337/dc16-S006.
6. Borkhoff CM, Wieland ML, Myasoedova E, et al. Reaching those most in need: A scoping review of interventions to improve health care quality for disadvantaged populations with osteoarthritis. *Arthritis Care Res* 2011;63(1):39-52. doi:10.1002/acr.20349
7. Chin MH, Parrillo R. Advancing equity in healthcare: Lessons from Massachusetts and beyond. *BMJ* 2015;350:h1617. doi:10.1136/bmj.h1617
8. Chin MH, Goddu AP, Ferguson MJ, et al. Expanding and sustaining integrated health care: Community efforts to reduce diabetes disparities. *Health Promot Pract* 2014;15(2):29S-39S. doi:10.1177/1524839914532649
9. O'Neill J, Tabish H, Welch V, et al. Applying an equity lens to interventions: Using PROGRESS ensures consideration of socially stratifying factors to illuminate inequities in health. *J Clin Epidemiol* 2014;67(1):56-64. doi:10.1016/j.jclinepi.2013.08.005
10. Tricco AC, Ivers NM, Grimshaw JM, et al. Effectiveness of quality improvement strategies on the management of diabetes: A systematic review and meta-analysis. *Lancet* 2012;379(9833):2252-2261. doi:10.1016/S0140-6736(12)60480-2
11. Clarke AR, Goddu AP, Nocon RS, et al. Thirty years of disparities intervention research: What are we doing to close racial and ethnic gaps in health care? *Med Care* 2013;51(11):1020-1026. doi:10.1097/MLR.0b013e3182a97ba3
12. Lorenc T, Petticrew M, Welch V, et al. What type of interventions generate inequalities? Evidence from systematic reviews. *J Epidemiol Community Health* 2013;67(2):190-193. doi:10.1136/jech-2012-201257
13. Ivers NM, Tricco AC, Trikalinos TA, et al. Seeing the forests and the trees – innovative approaches to exploring heterogeneity in systematic reviews of complex interventions to enhance health system decision-making: A protocol. *Syst Rev* 2014;3:88. doi:10.1186/2046-4053-3-88
14. Gary TL, Bone LR, Hill MN, et al. Randomized controlled trial of the effects of nurse case manager and community health worker interventions on risk factors for diabetes-related complications in urban African Americans. *Prev Med* 2003;37:23-32.
15. Bujnowska-Fedak MM, Puchala E, Steciwko A. The impact of telehome care on health status and quality of life among patients with diabetes in a primary care setting in

- 1  
2  
3 Poland. *Telemedicine J E Health* 2011;17(3):153-163. doi:10.1089/tmj.2010.0113
- 4 16. DePue JD et al. Nurse-community health worker team improves diabetes care in  
5 American Samoa. *Diabetes Care* 2013;36(7):1947-1953. doi:10.2337/dc12-1969
- 6 17. Shea S et al. A randomized trial comparing telemedicine case management with usual  
7 care in older, ethnically diverse, medically underserved patients with diabetes mellitus:  
8 5 year results of the IDEATel study. *J Am Med Inform Assoc* 2009;16(4):446-456.  
9 doi:10.1197/jamia.M3157
- 10 18. Eakin EG, Reeves MM, Winkler E, et al. Six-month outcomes from living well with  
11 diabetes: A randomized trial of telephone-delivered weight loss and physical activity  
12 intervention to improve glycemic control. *Ann Behav Med* 2013;46:193-203. Doi:  
13 doi:10.1007/s12160-013-9498-2
- 14 19. Adair R, Wholey DR, Christianson J, et al. Improving chronic disease care by adding  
15 laypersons to the primary care team: A parallel randomized trial. *Ann Intern Med*  
16 2013;159:176-184.
- 17 20. Fisher TL, Burnet DL, Huang ES, et al. Cultural leverage : Interventions using culture  
18 to narrow racial disparities in health care. *Medical Care Research and Review*  
19 2007;64(5):243S-282S. doi: 10.1177/1077558707305414
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## FIGURE LEGEND

### Figure 1. PRISMA flow diagram

Figure 1 summarizes the flow of literature in the QI review. The initial search identified a total of 7248 citations; review of 2,691 full text articles resulted in a final sample of 309 reports, representing 272 unique trials.

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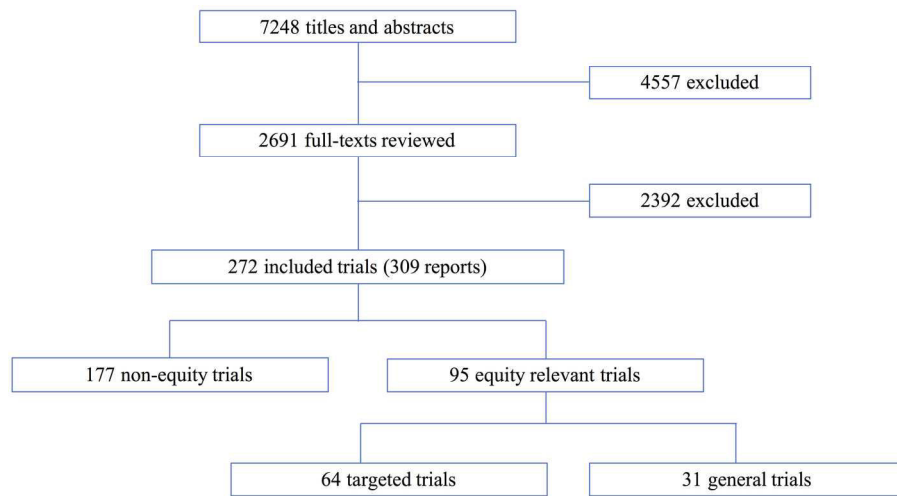


Figure 1. PRISMA flow diagram

Figure 1 summarizes the flow of literature in the QI review. The initial search identified a total of 7248 citations; review of 2,691 full text articles resulted in a final sample of 309 reports, representing 272 unique trials.

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## Supplemental Table 1. PROGRESS-Plus definitions

We defined *disadvantage* according to the PROGRESS-Plus framework as outlined by O'Neill *et al.* (9). The table below outlines our interpretation of these risk factors associated with disadvantage in the context of patients with diabetes.

PROGRESS-Plus FACTOR	DEFINITION
<b>Place of residence</b>	Residence in a medically underserved area where it is difficult to access care. <i>Example: rural, remote, inner city</i>
<b>Race, ethnicity, culture, language</b>	Ethnic and racial minorities, patients who do not speak the dominant language of the region or who do not identify with the dominant culture of the area.
<b>Occupation</b>	Occupations that involve high risk exposures or unsafe working environments, instability in employment status, lack of access to employee benefits or employer-funded insurance systems. <i>Example: part-time, disability leave, temporary worker, migrant worker</i>
<b>Gender, sex</b>	Gender roles that may define differential access to health services and differential exposure to health risks, sexual identities that face violence and discrimination. <i>Example: men, women, cisgender, transgender, intersex</i>
<b>Religion</b>	Religious beliefs may limit a patient's ability to choose certain medical therapies, religious affiliations may lead to discrimination and bias from service providers.
<b>Education</b>	Education level and education opportunities correlate with income status as well as knowledge about health and access to preventative health practices. <i>Example: highest level of education completed, education status of family members</i>
<b>Socioeconomic status</b>	Income levels that allow or prohibit participation in preventative health behaviours, ability to access health insurance in times of illness. <i>Example: low income, private health insurance, state-sponsored insurance</i>
<b>Social capital</b>	Social relationships and availability of social support networks to provide support and build resilience in times of distress. <i>Example: marital status, community networks, professional networks</i>
<b>Plus 1. Age</b>	Old age and frailty may be associated with decreased independence, decreased social capital, and increased health comorbidities; young age may be associated with decreased decision-making power. <i>Example: elderly or young</i>
<b>Plus 1. Disability</b>	Any mental health assessment, any quality of life or functional assessment, as well as any comorbid condition that is explicitly severe enough for us to reasonably believe that it impacts the ability to self-manage. <i>Example: mental health issues, intellectual disabilities, chronic pain, blindness, end-stage renal disease, symptomatic heart disease</i>
<b>Plus 1. Sexual preference</b>	Sexual orientations that may lead to discrimination and bias from service providers. <i>Example: homosexual, heterosexual, bisexual</i>

<b>Plus 2. Features of relationships</b>	Relationships that impact an individual's ability to assert their autonomy and self-manage. <i>Example: social hierarchies at school, work, or home</i>
<b>Plus 3. Time-dependent relationships</b>	Times of transition where an individual may face increased risks for poor health management. <i>Example: discharge from hospital, release from prison, students on the move, practice guideline changes</i>

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# PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
<b>TITLE</b>			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
<b>ABSTRACT</b>			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2
<b>INTRODUCTION</b>			
Rationale	3	Describe the rationale for the review in the context of what is already known.	4
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4
<b>METHODS</b>			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	4
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	4
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	4
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	5
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$ ) for each meta-analysis.	5



# PRISMA 2009 Checklist

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
<b>RESULTS</b>			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	6
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	6
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	N/A
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measure of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	N/A
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
<b>DISCUSSION</b>			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	7-8
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	8
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	8
<b>FUNDING</b>			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	13

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: the PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: [www.prisma-statement.org](http://www.prisma-statement.org).

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