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

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4

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,

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

Data Extraction

We used the PROGRESS-Plus framework,[9] to consider the range of factors that may increase the risk for a population subgroup to be disadvantaged, including participants' Place of residence, Race/ethnicity/culture/language, Occupational status, Gender/sexual identity, religious affiliations, Education level, Socioeconomic status, Social capital, plus age, disability, sexual preferences, and relationships.[9] Specifically, we interpreted these risk factors in the context of a patient's ability to access health care and effectively manage their diabetes. For example, it may be more difficult for patients living in rural or geographically isolated areas to access dependable primary care, leading to negative implications for their ability to achieve diabetes-related targets. Supplemental Table 1 outlines our full interpretation of PROGRESS-Plus factors in considering how these factors might lead to inequity in diabetes management across sub-populations, developed based on previous literature,[6] the PROGRESS framework,[9] and in collaboration with PROGRESS-authors (VW).

We extracted PROGRESS-Plus factors identified in the baseline patient characteristics for all studies. Additionally, for equity-relevant studies, we extracted PROGRESS-Plus factors identified in the study objective, study design (e.g., patient eligibility criteria and patient recruitment techniques), and analysis of results. Two reviewers independently abstracted the relevant data for each RCT. We only coded instances when authors were explicit in their mention of PROGRESS-Plus factors. Discrepancies were resolved by discussion.

Data Synthesis and Analysis

As we had no *a priori* hypothesis about the differences or similarities that would be found among trials regarding issues of equity or efforts to address areas of disadvantage, we provide here descriptive analyses only. We describe the proportion of trials that focused on equity-relevant factors and types of factors considered in these trials. In addition, to explore for time-trends in 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 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.

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

CONCLUSIONS

Among 278 diabetes QI trials, only 34.2% provided equity-relevant findings. These studies provide insight into the effectiveness of various diabetes management strategies among racial and ethnic minorities, among patients with low income or low socioeconomic status, as well as in remote medically underserved populations. A few trials looked at age, gender/sex, education status, and disability as potential factors that contribute to disparities in diabetes care. However, we know little about the effects of other factors that may play a role in determining how patients experience and respond to health interventions. There is a need for better data collection, reporting, and analysis on the social determinants of health that may influence the health outcomes of patients with diabetes.

While the majority of diabetes QI trials did not have an equity focus, the vast majority collected some form of equity-relevant data to assess balance between study arms in RCTs, suggesting that many opportunities to explore equity-relevant analyses are missed.

In this systematic review, only 22 trials (7.9%) directed interventions toward a population that was impacted by two or more risk factors for health disparities. The limited foci of diabetes QI trials stand in contrast to the harsh reality experienced by many patients, for whom multiple social and economic determinants of health intersect in complex ways. In fact, the risk for health disparities often increases in populations where multiple PROGRESS-Plus factors are concerned.[9] Given that these populations tend to bear a disproportionate burden of disease,[2,3] it is a further injustice that interventions and analyses inclusive to these patients be absent from present research enquiry.

Interventions tailored toward socially disadvantaged populations show promising results in reducing health disparities in diabetes care. In a review of 17 QI trials, Glazier et al. (2006) found that interventions worked best when they were adapted to the local community to fit local circumstances.[2] Similarly, in a study of 42 QI trials, Peek et al. (2007) found evidence to suggest that culturally tailored programming and community-based partnerships led to improvements in health outcomes for racial/ethnic minorities and successfully contributed to reductions in health disparities in the population.[3] In 2013, Clarke et al. reported that interventions to improve care in ethnic minorities predominantly focussed on patient-level strategies, placing the burden of change on patients without addressing equally relevant factors at the level of health providers, health care organizations, and health systems.[11] Here, we show that there is increasing data from trials testing health system interventions, such as case management and team changes, to consider when developing QI interventions to either address or prevent worsening health inequities across several PROGRESS-Plus characteristics.

This study has several limitations. First, we included only English language publications as translation of non-English studies was not feasible. Second, due the large number of included studies we focused our review of equity factors in the primary publication of trials. It is possible that authors did additional equity-relevant analyses in secondary publications, which were not captured in this review. This may result in an underestimate of the number of general studies that analyzed effects in disadvantaged groups. However, by focusing on primary publication, we have identified studies in which equity concerns were prioritized by authors, either through targeted interventions or subsequent analyses, to warrant discussion in a primary paper. Finally, our ability to capture the full breadth of issues that may disadvantage patients was restricted by limitations in reporting these variables within each study and by the lack of a standardized terminology in the literature. As our objective was to assess the extent to which researchers considered equity-relevant factors, we did not analyze the effect of equity-relevant factors on study outcomes. This represents another important area for future research.

In conclusion, findings of this secondary study of a systematic review of diabetes QI trials indicate substantial room for improvement in the proportion of studies that address equity and the range of equity factors that could be reported and analyzed.

Table 1. Study characteristics

Study Characteristics	Non-Equity Studies, n = 183	Equity-Relevant Studies		
		All, n = 95	**Targeted**, n = 64	**General**, n = 31
Sample Size	904.9 (17 - 23740)	733.5 (35 - 7557)	490.7 (35 - 7557)	1226.8 (46 - 7009)
Duration of Follow-Up (months)	13.8 (3 - 159.6)	13.2 (3 - 72)	12.5 (3 - 60)	14.6 (3 - 72)
Types of Diabetes				
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)
Mean Baseline HbA1c				
< 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)
Primary Focus				
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)
Intervention Methods				
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.

Each trial is counted once under each column. Columns on the left of the table reflect the number of trials that contained PROGRESS-Plus factors in the objectives (O), baseline characteristics (B), or analysis (A). Trials that assessed for PROGRESS-Plus factors in two 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 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 of the table (columns 4 and 5).

Targeted trials with an objective (O) defined by PROGRESS-Plus factors were further scrutinized for different PROGRESS-Plus factors in their baseline characteristics (B) or analysis (A) – the inclusion of a PROGRESS-Plus factor different from that targeted by the intervention objective (O) would warrant the trial to be counted under headings B and A in their respective PROGRESS-Plus categories.

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)	11 (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)	7 (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)	2 (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)	2 (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)	3 (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

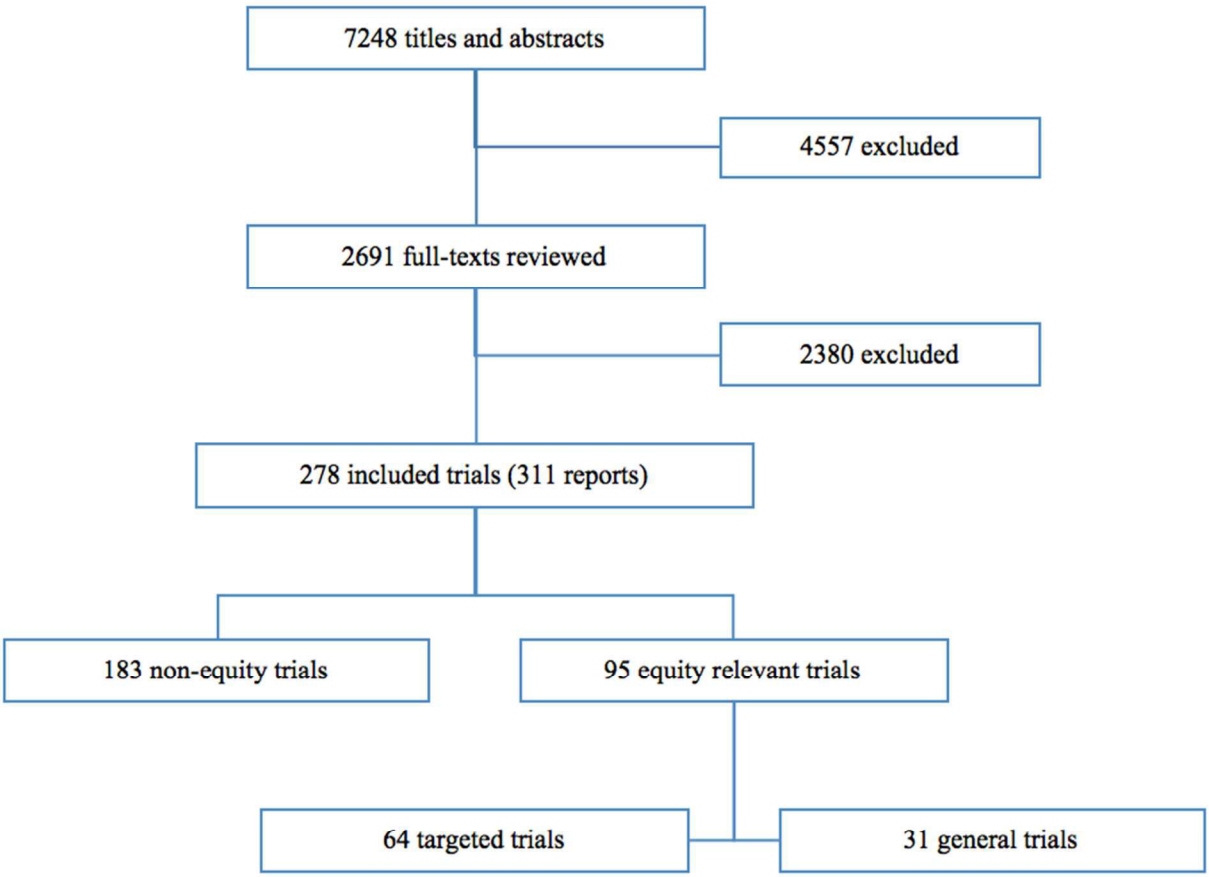
The dataset generated and analyzed during the current study are available from the corresponding author on request.

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-

related complications in urban African Americans. *Prev Med* 2003;37:23-32.
16. 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 Poland. *Telemedicine J E Health* 2011;17(3):153-163. doi:10.1089/tmj.2010.0113
17. DePue JD et al. Nurse-community health worker team improves diabetes care in American Samoa. *Diabetes Care* 2013;36(7):1947-1953. doi:10.2337/dc12-1969
18. Shea S et al. A randomized trial comparing telemedicine case management with usual care in older, ethnically diverse, medically underserved patients with diabetes mellitus: 5 year results of the IDEATel study. *J Am Med Inform Assoc* 2009;16(4):446-456. doi:10.1197/jamia.M3157

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.

PROGRESS-Plus Factor	Definition
Place of residence	Residence in a medically underserved area where it is difficult to physically access care *Example: rural, remote, inner city*
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 *Example: full-time, part-time, retired, disability leave, temporary worker, migrant worker*
Gender, sex	Gender roles and sexual identities *Example: men, women, cisgender, transgender, intersex*
Religion	Religious affiliations
Education	Education level and circumstances *Example: highest level of education completed, education status of family members*
Socioeconomic status	Income levels and availability of health insurance *Example: low income, lack of health insurance, state-sponsored insurance*
Social capital	Social relationships and availability of social support networks *Example: marital status, community networks, professional networks*
Plus 1. Age	Ages that may be associated with an increased risk of bias or discrimination in care. *Example: elderly or young*
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 *Example: mental health issues, intellectual disabilities, chronic pain, blindness, end-stage renal disease, symptomatic heart disease*
Plus 1. Sexual preference	Sexual orientation *Example: homosexual, heterosexual, bisexual*
Plus 2. Features of relationships	Relationships that impact an individual's ability to assert their autonomy and self-manage *Example: social hierarchies at school, work, or home*
Plus 3. Time-dependent relationships	Times of transition where an individual may face increased risks for poor health management *Example: discharge from hospital, release from prison, students on the move, practice guideline changes*

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
ADMINISTRATIVE INFORMATION			
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
INTRODUCTION			
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
METHODS			
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 τ)	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 (Ete 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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Do quality improvement initiatives for diabetes care address social inequities? Secondary analysis of a systematic review.

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

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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.

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,

diastolic and systolic blood pressure; proportion of patients with controlled hypertension or who quit smoking).

For this secondary review, we developed a data extraction form using the PROGRESS-Plus framework,[9] to consider the range of factors that may increase the risk for a population subgroup to be disadvantaged, including participants' Place of residence, Race/ethnicity/culture/language, Occupational status, Gender/sexual identity, Religious affiliations, Education level, Socioeconomic status, Social capital, plus age, disability, sexual preferences, and relationships.[9] Specifically, we interpreted these risk factors in the context of a patient's ability to access health care and effectively manage their diabetes. For example, it may be more difficult for patients living in rural or geographically isolated areas to access dependable primary care, leading to negative implications for their ability to achieve diabetes-related targets. Supplemental Table 1 outlines our full interpretation of PROGRESS-Plus factors in considering how these factors might lead to inequity in diabetes management across sub-populations, developed based on previous literature,[6] the PROGRESS framework,[9] and in collaboration with PROGRESS-authors (VW).

Two reviewers independently extracted data based on a thorough reading of the full text for all included studies. This allowed us to identify a cohort of *equity-relevant trials* that targeted or assessed equity factors as defined by the PROGRESS-Plus framework.[9] Within this cohort, trials were classified as either Targeted or General. *Targeted equity-relevant trial*s were defined as a trial focussed on a population with an identified disadvantage in health in order to improve the health status of that population or to reduce the health gradient. *General equity-relevant trials* were defined as a trial involved a broad participant population but made comparisons of effects in disadvantaged subgroups to assess the extent to which interventions may have differential impacts. For example, a trial testing a primary care-based culturally sensitive behavioural intervention in a population of urban African Americans with type 2 diabetes [14] would be classified as a *targeted* equity-relevant trial because it purposefully directed interventions towards a disadvantaged population. In contrast, a trial testing a tele-homecare monitoring system for patients with type 2 diabetes that explored the benefit of the intervention in female patients and those with lower education levels,[15] would be classified as a *general* equity-relevant trial.

The reviewers extracted PROGRESS-Plus factors identified in the baseline patient characteristics for all studies. Additionally, for equity-relevant studies, the reviewers extracted PROGRESS-Plus factors identified in the study objective, study design (e.g., patient eligibility criteria and patient recruitment techniques), and analysis of results. We only coded instances when authors were explicit in their mention of PROGRESS-Plus factors. Discrepancies were resolved by discussion or the involvement of authors NMI and KJD.

Data Synthesis and Analysis

As we had no *a priori* hypothesis about the differences or similarities that would be found among trials regarding issues of equity or efforts to address areas of disadvantage, we provide here descriptive analyses only. We describe the proportion of trials that focused on equity-relevant factors and types of factors considered in these trials. In addition, to explore for time-trends in

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.,

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.[16,17] 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. 12 trials found differential effects among disadvantaged subgroups when intervention outcomes were further analyzed. Notably, 6 trials found differences in outcomes based on the sex of participants, 5 trials found differences based on age, and 4 trials found differences based on race/ethnicity group.

Table 3 examines the extent of equity-relevance in diabetes QI trials over time. Prior to 2007, there were 41 equity-relevant trials out of 126 diabetes QI studies. In the period from 2007 to 2014, there were 54 equity-relevant trials out of 146 diabetes QI studies. Targeted trials were responsible for 56.1% of equity-relevant trials prior to 2007. This number increased to 75.9% of equity-relevant trials in the period from 2007 to 2014. The most notable increases in the absolute number of targeted studies occurred with occupation, education, and disability.

CONCLUSIONS

Among 278 diabetes QI trials, only 34.9% provided equity-relevant findings. These studies provide insight into the effectiveness of various diabetes management strategies among racial and ethnic minorities, among patients with low income or low socioeconomic status, as well as in remote medically underserved populations. A few trials looked at age, gender/sex, education status, and disability as potential factors that contribute to disparities in diabetes care. However, we know little about the effects of other factors that may play a role in determining how patients experience and respond to health interventions.

Trials designed for the general population which then conducted stratified analyses point to the importance of considering PROGRESS-Plus factors when designing and examining interventions. In fact, 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. For example, a general trial looking at telehome monitoring systems as an affordable and efficient means to monitor patients with diabetes showed greater efficacy in patients who were male, elderly, and/or more educated.[15] Another study examining the efficacy of telephone-based weight loss programs to improve glycemic control found the intervention outcomes differed between Caucasians and non-Caucasians.[18]. Alternatively, adding care guides to the primary care team was more likely to have benefits for patients on Medicaid rather than patients with other forms of health insurance in the United States.[19] These findings emphasize the need for better data collection, reporting, and analysis on the social determinants of health that may influence the health outcomes of patients with diabetes.

While the majority of diabetes QI trials did not have an equity focus, the vast majority collected some form of equity-relevant data to assess balance between study arms in RCTs. This collection of stratified data presents a missed opportunity for researchers to further explore equity-relevant analyses.

In this systematic review, only 22 trials (8.1%) directed interventions toward a population that was impacted by two or more risk factors for health disparities. The limited foci of diabetes QI trials stand in contrast to the harsh reality of many patients, for whom multiple social and economic determinants of health intersect in complex ways. The risk for health disparities often increases in populations where multiple PROGRESS-Plus factors are concerned.[9] For example, there is a paucity of research targeting elderly racial and ethnic minorities despite this being one of the fastest growing demographic for diabetes diagnoses and diabetes-related complications.[3] Given that these populations tend to bear a disproportionate burden of disease,[2,3] it is even more important that interventions and analyses relevant to these patients be represented in the current body of research.

Interventions tailored toward socially disadvantaged populations show promising results in reducing health disparities in diabetes care. In a review of 17 QI trials, Glazier et al. (2006) found that interventions worked best when they were adapted to the local community to fit local circumstances.[2] Similarly, in a study of 42 QI trials, Peek et al. (2007) found evidence to suggest that culturally tailored programming and community-based partnerships led to improvements in health outcomes for racial/ethnic minorities and successfully contributed to reductions in health disparities in the population.[3] Fisher et al. (2007) showed narrowing of racial disparities in health care with culturally specific programming and health care messaging. Culturally sensitive strategies can help strengthen connections between patients and health care organizations, thereby facilitating a more effective exchange of health information and improved adherence to treatment plans for ethnic and racial minorities.[20]

In 2013, Clarke et al. reported that interventions to improve care in ethnic minorities predominantly focussed on patient-level strategies, placing the burden of change on patients without addressing equally relevant factors at the level of health providers, health care organizations, and health systems.[11] Here, we show that there is increasing data from trials testing health system interventions, such as case management and team changes, to consider when developing QI interventions to either address or prevent worsening health inequities across several PROGRESS-Plus characteristics.

This study has several limitations. First, we included only English language publications as translation of non-English studies was not feasible. Second, due the large number of included studies we focused our review of equity factors in the primary publication of trials. It is possible that authors did additional equity-relevant analyses in secondary publications, which were not captured in this review. This may result in an underestimate of the number of general studies that analyzed effects in disadvantaged groups. However, by focusing on primary publication, we have identified studies in which equity concerns were prioritized by authors, either through targeted interventions or subsequent analyses, to warrant discussion in a primary paper. Finally, our ability to capture the full breadth of issues that may disadvantage patients was restricted by

limitations in reporting these variables within each study and by the lack of a standardized terminology in the literature.

As our objective was to assess the extent to which researchers considered equity-relevant factors, we did not analyze the effect of equity-relevant factors on study outcomes. We believe the effectiveness of interventions may vary based on the participant population and the existing health system. Based on the limited primary data that we have from targeted and general trials, it is difficult to make definitive conclusions about which interventions or QI strategies are effective or ineffective in reducing health disparities and/or improving health outcomes for disadvantaged groups without oversimplifying the issue and potentially misleading future enquiry. What ultimately works in one health care setting may not work in another. However, this represents an important area for future research.

In conclusion, the findings in this secondary study of a systematic review of diabetes QI trials indicate substantial room for improvement in the proportion of studies that address equity and the range of equity factors that can be reported and analyzed.

Table 1. Study characteristics

Study Characteristics	Non-Equity Studies, n = 177	Equity-Relevant Studies		
		All, n = 95	**Targeted**, n = 64	**General**, n = 31
Sample Size	931.6 (17 - 23740)	733.5 (35 - 7557)	490.7 (35 - 7557)	1226.8 (46 - 7009)
Duration of Follow-Up (months)	14 (3 - 159.6)	13.2 (3 - 72)	12.5 (3 - 60)	14.6 (3 - 72)
Types of Diabetes				
Types I	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)
Mean Baseline HbA1c				
< 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)
Primary Focus				
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)
Country of Study by Health System				
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)
Intervention Methods				
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;

FR=facilitated relay; PE=patient education; PSM=promotion of self-management; PR=patient reminders; CQI=continuous quality improvement; FI=financial incentives.

Countries with universal health care include: Argentina, Australia, Austria, Belgium, Brazil, Canada, Denmark, Finland, France, Germany, Greece, Hong Kong, Iceland, Ireland, Israel, Italy, Japan, Luxembourg, New Zealand, Norway, Portugal, Singapore, South Korea, Spain, Switzerland, The Netherlands, UAE, and UK. Countries with privatized health insurance include: China, India, Iran, Jordan, Mexico, Oman, Poland, South Africa, Thailand, Turkey, and USA. Two trials were conducted over multiple countries, in which case each country was counted as a discrete entity.

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.

Each trial is counted once under each column. Columns on the left of the table reflect the number of trials that contained PROGRESS-Plus factors in the objectives (O), baseline characteristics (B), or analysis (A). Trials that assessed for PROGRESS-Plus factors in two 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 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 of the table (columns 4 and 5).

Targeted trials with an objective (O) defined by PROGRESS-Plus factors were further scrutinized for different PROGRESS-Plus factors in their baseline characteristics (B) or analysis (A) – the inclusion of a PROGRESS-Plus factor different from that targeted by the intervention objective (O) would warrant the trial to be counted under headings B and A in their respective PROGRESS-Plus categories.

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)	11 (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)	7 (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)	2 (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)	2 (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)	3 (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

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

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.

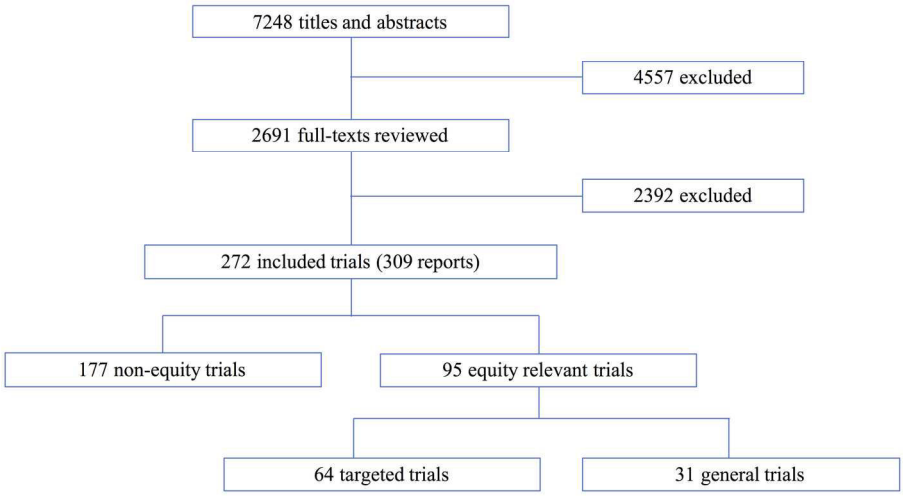

Figure 1. PRISMA flow diagram
Figure 1 summarizes the flow of literature in the QI review. The initial search identified a total of 7248 citations; review of 2,691 full text articles resulted in a final sample of 309 reports, representing 272 unique trials.

173x95mm (300 x 300 DPI)

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
Place of residence	Residence in a medically underserved area where it is difficult to access care. *Example: rural, remote, inner city*
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	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. *Example: part-time, disability leave, temporary worker, migrant worker*
Gender, sex	Gender roles that may define differential access to health services and differential exposure to health risks, sexual identities that face violence and discrimination. *Example: men, women, cisgender, transgender, intersex*
Religion	Religious beliefs may limit a patient's ability to choose certain medical therapies, religious affiliations may lead to discrimination and bias from service providers.
Education	Education level and education opportunities correlate with income status as well as knowledge about health and access to preventative health practices. *Example: highest level of education completed, education status of family members*
Socioeconomic status	Income levels that allow or prohibit participation in preventative health behaviours, ability to access health insurance in times of illness. *Example: low income, private health insurance, state-sponsored insurance*
Social capital	Social relationships and availability of social support networks to provide support and build resilience in times of distress. *Example: marital status, community networks, professional networks*
Plus 1. Age	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. *Example: elderly or young*
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. *Example: mental health issues, intellectual disabilities, chronic pain, blindness, end-stage renal disease, symptomatic heart disease*
Plus 1. Sexual preference	Sexual orientations that may lead to discrimination and bias from service providers. *Example: homosexual, heterosexual, bisexual*

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

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
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
INTRODUCTION			
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
METHODS			
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

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
RESULTS			
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 measures 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
DISCUSSION			
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
FUNDING			
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.

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Secondary Subject Heading:	Evidence based practice, Qualitative research
Keywords:	Quality improvement, Social determinants of health, Equity

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

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2614

Tables and figures
4

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.

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,

diastolic and systolic blood pressure; proportion of patients with controlled hypertension or who quit smoking).

For this secondary review, we developed a data extraction form using the PROGRESS-Plus framework,[9] to consider the range of factors that may increase the risk for a population subgroup to be disadvantaged, including participants' Place of residence, Race/ethnicity/culture/language, Occupational status, Gender/sexual identity, Religious affiliations, Education level, Socioeconomic status, Social capital, plus age, disability, sexual preferences, and relationships.[9] Specifically, we interpreted these risk factors in the context of a patient's ability to access health care and effectively manage their diabetes. For example, it may be more difficult for patients living in rural or geographically isolated areas to access dependable primary care, leading to negative implications for their ability to achieve diabetes-related targets. Supplemental Table 1 outlines our full interpretation of PROGRESS-Plus factors in considering how these factors might lead to inequity in diabetes management across sub-populations, developed based on previous literature,[6] the PROGRESS framework,[9] and in collaboration with PROGRESS-authors (VW).

Two reviewers independently extracted data based on a thorough reading of the full text for all included studies. This allowed us to identify a cohort of *equity-relevant trials* that targeted or assessed equity factors as defined by the PROGRESS-Plus framework.[9] Within this cohort, trials were classified as either Targeted or General. *Targeted equity-relevant trial*s were defined as a trial focussed on a population with an identified disadvantage in health in order to improve the health status of that population or to reduce the health gradient. *General equity-relevant trials* were defined as a trial involved a broad participant population but made comparisons of effects in disadvantaged subgroups to assess the extent to which interventions may have differential impacts. For example, a trial testing a primary care-based culturally sensitive behavioural intervention in a population of urban African Americans with type 2 diabetes [14] would be classified as a *targeted* equity-relevant trial because it purposefully directed interventions towards a disadvantaged population. In contrast, a trial testing a tele-homecare monitoring system for patients with type 2 diabetes that explored the benefit of the intervention in female patients and those with lower education levels,[15] would be classified as a *general* equity-relevant trial.

The reviewers extracted PROGRESS-Plus factors identified in the baseline patient characteristics for all studies. Additionally, for equity-relevant studies, the reviewers extracted PROGRESS-Plus factors identified in the study objective, study design (e.g., patient eligibility criteria and patient recruitment techniques), and analysis of results. We only coded instances when authors were explicit in their mention of PROGRESS-Plus factors. Discrepancies were resolved by discussion or the involvement of authors NMI and KJD.

Data Synthesis and Analysis

As we had no *a priori* hypothesis about the differences or similarities that would be found among trials regarding issues of equity or efforts to address areas of disadvantage, we provide here descriptive analyses only. We describe the proportion of trials that focused on equity-relevant factors and types of factors considered in these trials. In addition, to explore for time-trends in

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.,

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.[16,17] 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. 12 trials found differential effects among disadvantaged subgroups when intervention outcomes were further analyzed. Notably, 6 trials found differences in outcomes based on the sex of participants, 5 trials found differences based on age, and 4 trials found differences based on race/ethnicity group.

Table 3 examines the extent of equity-relevance in diabetes QI trials over time. Prior to 2007, there were 41 equity-relevant trials out of 126 diabetes QI studies. In the period from 2007 to 2014, there were 54 equity-relevant trials out of 146 diabetes QI studies. Targeted trials were responsible for 56.1% of equity-relevant trials prior to 2007. This number increased to 75.9% of equity-relevant trials in the period from 2007 to 2014. The most notable increases in the absolute number of targeted studies occurred with occupation, education, and disability.

CONCLUSIONS

Among 278 diabetes QI trials, only 34.9% provided equity-relevant findings. These studies provide insight into the effectiveness of various diabetes management strategies among racial and ethnic minorities, among patients with low income or low socioeconomic status, as well as in remote medically underserved populations. A few trials looked at age, gender/sex, education status, and disability as potential factors that contribute to disparities in diabetes care. However, we know little about the effects of other factors that may play a role in determining how patients experience and respond to health interventions.

Trials designed for the general population which then conducted stratified analyses point to the importance of considering PROGRESS-Plus factors when designing and examining interventions. In fact, 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. For example, a general trial looking at telehome monitoring systems as an affordable and efficient means to monitor patients with diabetes showed greater efficacy in patients who were male, elderly, and/or more educated.[15] Another study examining the efficacy of telephone-based weight loss programs to improve glycemic control found the intervention outcomes differed between Caucasians and non-Caucasians.[18]. Alternatively, adding care guides to the primary care team was more likely to have benefits for patients on Medicaid rather than patients with other forms of health insurance in the United States.[19] These findings emphasize the need for better data collection, reporting, and analysis on the social determinants of health that may influence the health outcomes of patients with diabetes.

While the majority of diabetes QI trials did not have an equity focus, the vast majority collected some form of equity-relevant data to assess balance between study arms in RCTs. This collection of stratified data presents a missed opportunity for researchers to further explore equity-relevant analyses.

In this systematic review, only 22 trials (8.1%) directed interventions toward a population that was impacted by two or more risk factors for health disparities. The limited foci of diabetes QI trials stand in contrast to the harsh reality of many patients, for whom multiple social and economic determinants of health intersect in complex ways. The risk for health disparities often increases in populations where multiple PROGRESS-Plus factors are concerned.[9] For example, there is a paucity of research targeting elderly racial and ethnic minorities despite this being one of the fastest growing demographic for diabetes diagnoses and diabetes-related complications.[3] Given that these populations tend to bear a disproportionate burden of disease,[2,3] it is even more important that interventions and analyses relevant to these patients be represented in the current body of research.

Interventions tailored toward socially disadvantaged populations show promising results in reducing health disparities in diabetes care. In a review of 17 QI trials, Glazier et al. (2006) found that interventions worked best when they were adapted to the local community to fit local circumstances.[2] Similarly, in a study of 42 QI trials, Peek et al. (2007) found evidence to suggest that culturally tailored programming and community-based partnerships led to improvements in health outcomes for racial/ethnic minorities and successfully contributed to reductions in health disparities in the population.[3] Fisher et al. (2007) showed narrowing of racial disparities in health care with culturally specific programming and health care messaging. Culturally sensitive strategies can help strengthen connections between patients and health care organizations, thereby facilitating a more effective exchange of health information and improved adherence to treatment plans for ethnic and racial minorities.[20]

In 2013, Clarke et al. reported that interventions to improve care in ethnic minorities predominantly focussed on patient-level strategies, placing the burden of change on patients without addressing equally relevant factors at the level of health providers, health care organizations, and health systems.[11] Here, we show that there is increasing data from trials testing health system interventions, such as case management and team changes, to consider when developing QI interventions to either address or prevent worsening health inequities across several PROGRESS-Plus characteristics.

This study has several limitations. First, we included only English language publications as translation of non-English studies was not feasible. Second, due the large number of included studies we focused our review of equity factors in the primary publication of trials. It is possible that authors did additional equity-relevant analyses in secondary publications, which were not captured in this review. This may result in an underestimate of the number of general studies that analyzed effects in disadvantaged groups. However, by focusing on primary publication, we have identified studies in which equity concerns were prioritized by authors, either through targeted interventions or subsequent analyses, to warrant discussion in a primary paper. Finally, our ability to capture the full breadth of issues that may disadvantage patients was restricted by

limitations in reporting these variables within each study and by the lack of a standardized terminology in the literature.

As our objective was to assess the extent to which researchers considered equity-relevant factors, we did not analyze the effect of equity-relevant factors on study outcomes. The effectiveness of interventions often varies based on the participant population and the existing health system. Based on the limited primary data that we have from targeted and general trials, it is difficult to make definitive conclusions about which interventions or QI strategies are effective or ineffective in reducing health disparities and/or improving health outcomes for disadvantaged groups without oversimplifying the issue and potentially misleading future enquiry. What ultimately works in one health care setting may not work in another. However, this represents an important area for future research.

In conclusion, the findings in this secondary study of a systematic review of diabetes QI trials indicate substantial room for improvement in the proportion of studies that address equity and the range of equity factors that can be reported and analyzed.

Table 1. Study characteristics

Study Characteristics	Non-Equity Studies, n = 177	Equity-Relevant Studies		
		All, n = 95	**Targeted**, n = 64	**General**, n = 31
Sample Size	931.6 (17 - 23740)	733.5 (35 - 7557)	490.7 (35 - 7557)	1226.8 (46 - 7009)
Duration of Follow-Up (months)	14 (3 - 159.6)	13.2 (3 - 72)	12.5 (3 - 60)	14.6 (3 - 72)
Types of Diabetes				
Types I	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)
Mean Baseline HbA1c				
< 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)
Primary Focus				
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)
Country of Study by Health System				
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)
Intervention Methods				
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;

FR=facilitated relay; PE=patient education; PSM=promotion of self-management; PR=patient reminders; CQI=continuous quality improvement; FI=financial incentives.

Countries with universal health care include: Argentina, Australia, Austria, Belgium, Brazil, Canada, Denmark, Finland, France, Germany, Greece, Hong Kong, Iceland, Ireland, Israel, Italy, Japan, Luxembourg, New Zealand, Norway, Portugal, Singapore, South Korea, Spain, Switzerland, The Netherlands, UAE, and UK. Countries with privatized health insurance include: China, India, Iran, Jordan, Mexico, Oman, Poland, South Africa, Thailand, Turkey, and USA. Two trials were conducted over multiple countries, in which case each country was counted as a discrete entity.

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.

Each trial is counted once under each column. Columns on the left of the table reflect the number of trials that contained PROGRESS-Plus factors in the objectives (O), baseline characteristics (B), or analysis (A). Trials that assessed for PROGRESS-Plus factors in two 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 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 of the table (columns 4 and 5).

Targeted trials with an objective (O) defined by PROGRESS-Plus factors were further scrutinized for different PROGRESS-Plus factors in their baseline characteristics (B) or analysis (A) – the inclusion of a PROGRESS-Plus factor different from that targeted by the intervention objective (O) would warrant the trial to be counted under headings B and A in their respective PROGRESS-Plus categories.

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)	11 (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)	7 (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)	2 (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)	2 (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)	3 (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

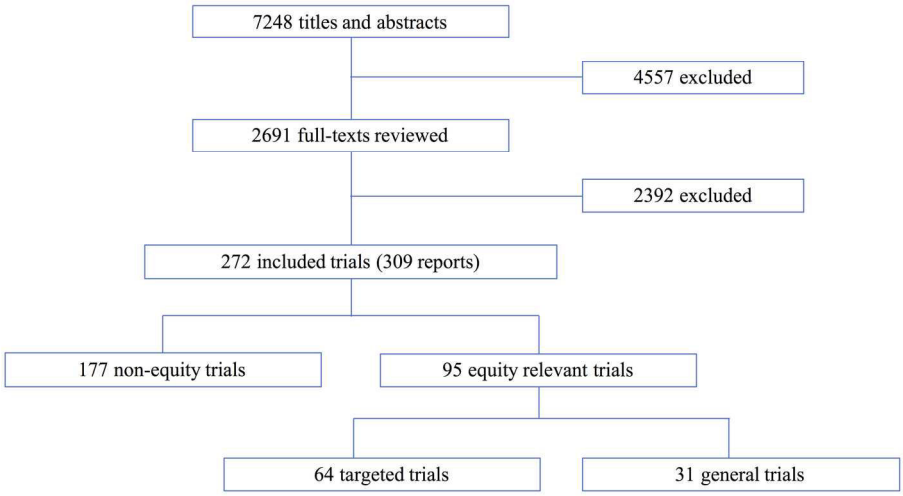
1. World Health Organization. Global report on diabetes. France: World Health Organization; 2016.
2. Glazier RH, Bajcar J, Kennie NR, et al. A systematic review of interventions to improve diabetes care in socially disadvantaged populations. *Diabetes Care* 2006;29:1675-1688. doi:10.2337/dc05-1942
3. 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

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

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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173x95mm (300 x 300 DPI)

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
Place of residence	Residence in a medically underserved area where it is difficult to access care. *Example: rural, remote, inner city*
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	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. *Example: part-time, disability leave, temporary worker, migrant worker*
Gender, sex	Gender roles that may define differential access to health services and differential exposure to health risks, sexual identities that face violence and discrimination. *Example: men, women, cisgender, transgender, intersex*
Religion	Religious beliefs may limit a patient's ability to choose certain medical therapies, religious affiliations may lead to discrimination and bias from service providers.
Education	Education level and education opportunities correlate with income status as well as knowledge about health and access to preventative health practices. *Example: highest level of education completed, education status of family members*
Socioeconomic status	Income levels that allow or prohibit participation in preventative health behaviours, ability to access health insurance in times of illness. *Example: low income, private health insurance, state-sponsored insurance*
Social capital	Social relationships and availability of social support networks to provide support and build resilience in times of distress. *Example: marital status, community networks, professional networks*
Plus 1. Age	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. *Example: elderly or young*
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. *Example: mental health issues, intellectual disabilities, chronic pain, blindness, end-stage renal disease, symptomatic heart disease*
Plus 1. Sexual preference	Sexual orientations that may lead to discrimination and bias from service providers. *Example: homosexual, heterosexual, bisexual*

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

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
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
INTRODUCTION			
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
METHODS			
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

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
RESULTS			
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 measures 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
DISCUSSION			
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
FUNDING			
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

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