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RESEARCH ARTICLE

Do Clinical Standards for Diabetes Care Address Excess Risk for Hypoglycemia in Vulnerable Patients? A Systematic Review

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Objective. To determine whether diabetes clinical standards consider increased hypoglycemia risk in vulnerable patients.

Data Sources. MEDLINE, the National Guidelines Clearinghouse, the National Quality Measures Clearinghouse, and supplemental sources.

Study Design. Systematic review of clinical standards (guidelines, quality metrics, or pay-for-performance programs) for glycemic control in adult diabetes patients. The primary outcome was discussion of increased risk for hypoglycemia in vulnerable populations.

Data Collection/Extraction Methods. Manuscripts identified were abstracted by two independent reviewers using prespecified inclusion/exclusion criteria and a standardized abstraction form.

Principal Findings. We screened 1,166 titles, and reviewed 220 manuscripts in full text. Forty-four guidelines, 17 quality metrics, and 8 pay-for-performance programs were included. Five (11 percent) guidelines and no quality metrics or pay-for-performance programs met the primary outcome.

Conclusions. Clinical standards do not substantively incorporate evidence about increased risk for hypoglycemia in vulnerable populations.

Key Words. Diabetes mellitus, quality and safety, health disparities, vulnerable populations, clinical guidelines

Diabetes is a common condition (Rodbard et al. 2007), and preventable diabetes complications constitute a worldwide public health problem. Clinical standards for diabetes care, such as clinical practice guidelines, quality metrics, and incentive-based pay-for-performance, all share the goal of influencing clinician behavior to achieve particular diabetes outcomes.

Glycemic control targets, as indicated by Hemoglobin A1c (HbA1c) level, are meant to delineate a point at which the prevention of future complications, such as microvascular disease (ADA 2011) offsets the risk of harms of treatment such as increased hypoglycemia risk (Gerstein et al. 2008; Duckworth et al. 2009), weight gain, and decreased quality of life. These are often adjusted depending on a patient's particular expectation of benefit or harms from treatment. For example, higher HbA1c targets are often suggested for diabetic patients with chronic kidney disease (CKD) due to the increased risk of hypoglycemia, or coronary heart disease (CHD) due to the increased adverse events associated with the occurrence of hypoglycemia in this group (ADA 2011).

Social vulnerabilities, such as low socioeconomic status (Miller et al. 2010), low health literacy (Sarkar et al. 2010), and food insecurity (Seligman et al. 2011), have been shown to be independent risk factors for hypoglycemia, even when controlling for age, gender, and clinical characteristics such as insulin use, renal function, HbA1c level, and duration of diabetes. These large, well-controlled studies are consistent with other work that demonstrates the association between social vulnerability and hypoglycemia (Muhlhauser et al. 1998; Leese et al. 2003; Duran-Nah et al. 2008; Ginde, Espinola, and Camargo 2008; Wild et al. 2010), low health literacy (Sotiropoulos et al. 2005), and food insecurity (Nelson, Brown, and Lurie 1998; Nelson et al. 2001; Seligman et al. 2010). In fact, vulnerabilities such as low SES can confer a risk of hypoglycemia that is as great as that conferred by insulin use (Miller et al. 2010). Because vulnerable populations may comprise up to half of patients with diabetes (Kumari, Head, and Marmot 2004; Dalstra et al. 2005; Rabi et al. 2006; Seligman et al. 2007; Maty, James, and Kaplan 2010; Agardh et al. 2011; CHIS 2009), the public health implications of this increased risk are large.

To better understand this complex issue, we performed a systematic review to determine whether, and to what extent, clinical standards (comprising guidelines, quality metrics, and pay-for-performance programs) for adults with type 2 diabetes in primary care consider evidence about the specific risk of hypoglycemia in vulnerable populations.

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METHODS

Data Sources and Searches

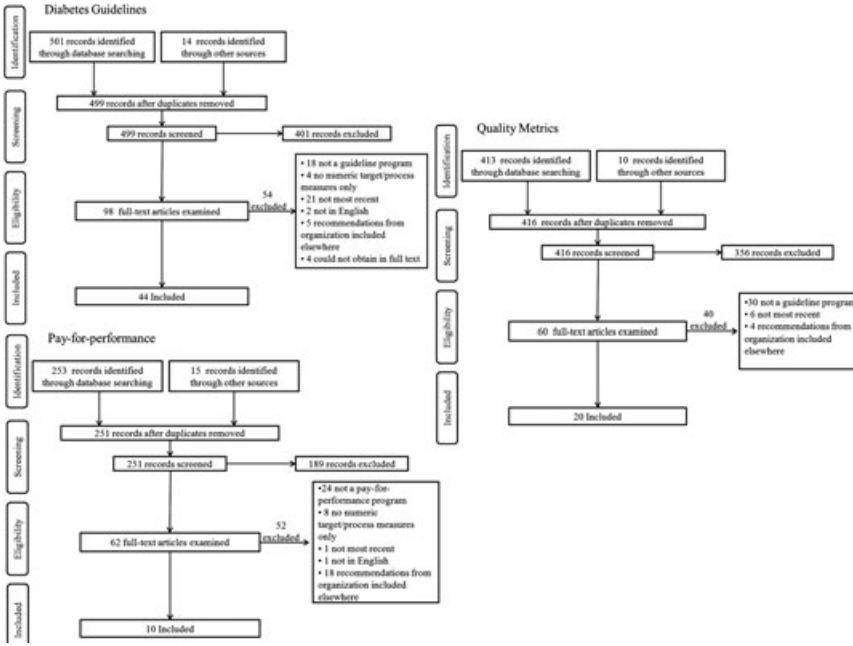
We conducted a systematic review of clinical standards for glycemic control in adult diabetic patients, including guidelines, quality metrics, and pay-for-performance programs. Our method was similar to previously published reviews of guidelines (Qaseem et al. 2007), and in accord with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (Liberati et al. 2009) recommendations.

We defined a guideline as a "systematically developed statement to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (IOM 1990). We defined a Quality Metric as "a mechanism to assign a quantity to quality of care by comparison to a criterion" (AHRQ). Finally, we defined a pay-for-performance program as the combination of performance measurement with "financial incentives to bring about clinician and systems change" (Snyder and Neubauer 2007). Working with a medical librarian, we developed search strategies and searched MEDLINE on November 30, 2010, including all dates up to then. The search strategies are available in the appendix and a flow sheet of the search is presented as Figure 1. In addition, we searched the National Guidelines Clearinghouse (www.guideline.gov), the National Quality Measures Clearinghouse (www.qualitymeasures.arhq.gov), the CMS Physician Reporting Quality Initiative 2010 Measures list (www.cms.gov/PQRI), and the National Committee for Quality Assurance (www.ncqa.org) websites with the search term "diabetes." Because many pay-for-performance programs are not traditionally published, we supplemented our search by utilizing the Cochrane Collaboration's Effective Practice and Organization of Care Registry of Interventions (http://epoc.cochrane.org/), and the Leapfrog Group Compendium (http://www.leapfroggroup.org/compendium2), a database of pay-for-performance programs. We included additional clinical standards uncovered by searching the reference section of reviewed articles, and from experts in the field.

Study Selection

We included all clinical standards (guideline, quality metric, or pay-for-performance program) that set a numeric HbA1c target for glycemic control applicable to an adult diabetes population. Standards specific to gestational diabetes, or not specifically dealing with glycemic control, such as preventing foot infections, were excluded. We chose to include standards that were issued by one

Figure 1: Search Flow Diagram



body, but adapted from another (e.g., a state guideline adapted from an ADA guideline), because adapting a standard to suit a specific situation could provide an opportunity to add information about vulnerable populations. All standards were initially reviewed in abstract. Those not excluded were then evaluated in full text by two independent reviewers using a standardized inclusion/exclusion form (S. A. B. and K. A. or J. H.). Disagreements over inclusion or abstraction were resolved by discussion between the two reviewers and a third party (US), who reached consensus.

We obtained the full text of the clinical standards from the website of the issuing organization to ensure we reviewed the most up-to-date version. Full versions, rather than summaries, were used. Recommendations issued jointly by multiple organizations were included if they were the most recent recommendations for at least one of the organizations.

Quality metrics and pay-for-performance programs are not uniformly presented in the scientific literature. Our intent was to understand the population to which these standards were meant be applied; more technically, we wanted to see who the authors thought should comprise the denominator. We

preferentially included documents giving the technical specifications of the measure, but if these were unavailable we included other documents as long as they described how the denominator population was defined.

Data Extraction

All included clinical standards were abstracted using a standardized form by two independent abstractors (S. A. B. and K. A. or J. H.). Our outcome of interest was whether each clinical standard provided clinicians with guidance around increased risk for hypoglycemia in vulnerable populations. Vulnerable populations were defined as those who have low socioeconomic status (as measured by individual or area income/wealth, educational attainment, or occupation), food insecurity, housing insecurity, or low health literacy. Because we were focused on socioeconomic circumstances, we did not include race/ethnicity, advanced age, or depression as criteria for being considered a member of a vulnerable group in this study. We also abstracted whether any other groups were discussed as being at high risk for hypoglycemia, and whether clinicians were encouraged to individualize care, or allowed to exempt patients for whom a particular standard was inappropriate.

Data Synthesis and Analysis

Included standards were tabulated. We present descriptive statistics summarizing the extent to which diabetes clinical standards make reference to vulnerable and other populations.

RESULTS

We screened 1,166 titles and reviewed 220 manuscripts in full text. Of these, 44 guidelines, 17 quality metrics, and 8 pay-for-performance programs met criteria for inclusion. A flow sheet of these results is presented as Figure 1.

Table 1 presents the results of our data extraction. For guidelines, 5 of 44 guidelines (11 percent) mentioned that vulnerable populations may be at greater risk for hypoglycemia or may require a different HbA1c target than the general population. This is in contrast to over 50 percent of guidelines mentioning other factors (such as CKD, and older age) that may increase the risk for hypoglycemia. While most guidelines did suggest individualization of glycemic targets, 6 (14 percent), did not. We found no quality metrics or pay-for-performance programs that mentioned vulnerable populations.

Table 1: Results Summary

	Total Included	*Call for/Allow Individualization, N (%)*	*Mention Any Group at Increased Risk for Hypoglycemia or for Whom a Different HbA1c Target Could Be Considered (or Exempted from Metric/P4P Program) (%)*	*Mention Vulnerable Populations Increased Risk for Hypoglycemia (%)*
All standards	69	48 (70)	34 (49)	5 (7)
Guidelines	44	38 (86)	25 (57)	5 (11)
Metrics	17	6 (35)	6 (35)	0 (0)
P4P	8	4 (50)	3 (38)	0 (0)

For guidelines that do mention vulnerable populations, the passages are often not detailed and are not always explicit about the increased risk of hypoglycemia. No clinical standard quantified the increased risk with odds ratios or another measure of association.

Certain factors that increase the likelihood of hypoglycemia or seriousness of its complications are taken into account in guidelines, quality metrics, and pay-for-performance programs. These often include microvascular complications of diabetes, particularly CKD, macrovascular complications such as CHD, and age. Table 2 presents commonly discussed conditions.

DISCUSSION

Our review demonstrates that few clinical standards incorporate evidence about the increased risk of hypoglycemia in vulnerable diabetes patients even in the subset of guidelines meant to help clinicians individualize glycemic targets (Akalin et al. 2009; Cheung et al. 2009; Skyler et al. 2009; Del Prato et al. 2010) or specifically about treatment-induced hypoglycemia (Cryer et al. 2009). In addition, although a majority of guidelines state that targets should be individualized, no guideline reviewed provided clinicians with evidence or instruction about individualizing treatment targets in vulnerable patients. When vulnerabilities are discussed, it is often as barriers to achieving glycemic control or medication adherence, rather than as risk factors for adverse treatment outcomes.

Vulnerable patients represent a unique group at high risk for both complications of diabetes and harms from diabetes care. Clinical standards meant to be applied to vulnerable populations must offer clinicians guidance about

Table 2: Factors Mentioned as Increasing Risk of Severe Hypoglycemia or to Consider When Setting an HbA1c Target Due to Increased Complications from Hypoglycemia

	Frequency Mentioned			
Risk Factor	*Overall (%)*	*Guidelines (%)*	*Quality Metrics (%)*	*P4P (%)*
CKD/microvascular complications	18/69 (26)	16/44 (36)	1/17 (6)	1/8 (13)
Age	18/69 (26)	13/44 (30)	3/17 (18)	2/8 (25)
Limited life expectancy	17/69 (25)	13/44 (30)	3/17 (18)	1/8 (13)
History of severe hypoglycemia/ hypoglycemia unawareness	12/69 (17)	12/44 (27)	0/17 (0)	0/8 (0)
CAD/macrovascular complications	12/69 (17)	10/44 (23)	1/17 (6)	1/8 (13)
"Co-morbidities" not further specified	8/69 (12)	8/44 (18)	0/17 (0)	0/8 (0)
Long duration of DM	7/69 (10)	7/44 (16)	0/17 (0)	0/8 (0)
Frailty	4/69 (6)	2/44 (5)	1/17 (6)	1/8 (13)
Dementia/cognitive impairment	4/69 (6)	2/44 (5)	1/17 (6)	1/8 (13)
Polypharmacy	3/69 (4)	3/44 (7)	0/17 (0)	0/8 (0)

their unique risks and offer the flexibility to recognize appropriately individualized care as being "high quality."

To our knowledge, no review of this kind has been conducted for vulnerable populations. However, similar work has been done with regard to older adults (Boyd et al. 2005). Our findings, that subgroups may require explicit consideration due to different risk profiles, are consistent with that review. Our methodology builds on prior reviews of guidelines for diabetes care (Qaseem et al. 2007), by searching in not only traditional databases such as MEDLINE but also adjunctive sources such as the National Quality Metrics Clearinghouse and the Leapfrog Compendium.

Because of the large number of patients from vulnerable populations with diabetes, our work has important implications for diabetes care. Glycemic targets seek to provide a balance point for the benefits and burdens of glycemic control. While clinicians' effect on HbA1c lowering may be modest (Hofer et al. 1999), aggressive treatment can lead to serious harms, such as increased mortality seen in the intensive treatment arm of the ACCORD trial (Gerstein et al. 2008).

This study has several limitations. A causal mechanism for the association between vulnerability and hypoglycemia is not yet fully known. However, because hypoglycemia is a serious iatrogenic harm, clinicians should be aware of the strong association that exists. Next, protocols of pay-for-performance programs are less likely to be published than other clinical standards,

and this limits our ability to comprehensively evaluate them. While the search strategy did augment our ability to identify these programs by using alternative data sources, it is likely that many still were not available for review. However, as no published programs discussed vulnerable populations, it is unlikely that a high proportion of unpublished programs did. In addition, we recognize that it is possible that the excess risk faced by vulnerable populations was considered in deliberations creating these standards, but not included in the final product.

Excess risk of hypoglycemia among vulnerable patients does not mandate that all such patients have higher HbA1c targets. Indeed, tailoring diabetes care to the needs of vulnerable populations, such as Project Dulce (Philis-Tsimikas et al. 2004, 2011) has done, can significantly improve patient outcomes. Because this kind of program is founded on the identification of the specific needs of vulnerable patients, however, it is imperative that clinical standards explicitly recognize these needs.

Having considered this issue, we offer the following recommendations. First, the existing data on risk of hypoglycemia and vulnerable populations should be disseminated along with clinical standards. Next, the ability to individualize HbA1c targets in quality metrics, as some methodologies (Pogach, Rajan, and Aron 2006) already allow, must become more common. An inability to do this increases both the risk of harm from therapy and the risk that vulnerable patients may be 'deselected' from panels that undergo quality assessment. Finally, an HbA1c target is a starting point. A vulnerable patient who safely achieves a recommended level could have hers lowered if additional benefits were expected, as may be the case early in her disease course; one who experiences recurrent severe hypoglycemia might have her target increased.

We hope this work will spur future research that directly addresses the needs of vulnerable populations. Incorporating these needs is important, not only because these populations bear a disproportionate burden of diabetes worldwide, but also because clinical standards that do so are better able to support individualized care for all diabetes patients.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of this article:

Appendix SA1: Author Matrix.
Appendix SA2: Guidelines Results.
Appendix SA3: Metrics Results.
Appendix SA4: P4P Results.
Appendix SA5: MEDLINE Search Strategy.