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### Review

# Evidence-Informed Guidelines for Treating Frail Older Adults With Type 2 Diabetes: From the Diabetes Care Program of Nova Scotia (DCPNS) and the Palliative and Therapeutic Harmonization (PATH) Program

Laurie Herzig Mallery MD, FRCPC <sup>a,\*</sup>, Tom Ransom MD, FRCPC <sup>b</sup>, Brian Steeves MD <sup>c</sup>, Brenda Cook MAdEd, PDt, CDE <sup>d</sup>, Peggy Dunbar MEd, PDt, CDE <sup>d</sup>, Paige Moorhouse MD, MPH, FRCPC <sup>a</sup>

#### ABSTRACT

Keywords: Clinical practice guidelines diabetes frailty glycosylated hemoglobin (HbA1c) random blood glucose Clinical practice guidelines specific to the medical care of frail older adults have yet to be widely disseminated. Because of the complex conditions associated with frailty, guidelines for frail older patients should be based on careful consideration of the characteristics of this population, balanced against the benefits and harms associated with treatment. In response to this need, the Diabetes Care Program of Nova Scotia (DCPNS) collaborated with the Palliative and Therapeutic Harmonization (PATH) program to develop and disseminate guidelines for the treatment of frail older adults with type 2 diabetes. The DCPNS/PATH guidelines are unique in that they recommend the following:

- 1. Maintain HbA1c at or above 8% rather than below a specific level, in keeping with the conclusion that lower HbA1c levels are associated with increased hypoglycemic events without accruing meaningful benefit for frail older adults with type 2 diabetes. The guideline supports a wide range of acceptable HbA1c targets so that treatment decisions can focus on whether to aim for HbA1c levels between 8% and 9% or within a higher range (ie, >9% and <12%) based on individual circumstances and symptoms.
- Simplify treatment by administering basal insulin alone and avoiding administration of regular and rapid-acting insulin when feasible. This recommendation takes into account the variations in oral intake that are commonly associated with frailty.
- 3. Use neutral protamine Hagedorn (NPH) insulin instead of long-acting insulin analogues, such as insulin glargine (Lantus) or insulin detemir (Levemir), as insulin analogues do not appear to provide clinically meaningful benefit but are significantly more costly.
- 4. With acceptance of more liberalized blood glucose targets, there is no need for routine blood glucose testing when oral hypoglycemic medications or well-established doses of basal insulin (used alone) are not routinely changed as a result of blood glucose testing.

Although these recommendations may appear radical, they are based on careful review of research findings.

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There are not many treatment guidelines that are specific to the population of physically frail older adults. In their absence, "evidence-based" clinical practice guidelines (CPGs), originally developed for healthy individuals based on studies that exclude frail

older adults,<sup>2</sup> are often indiscriminately applied to frail patients. Moreover, most CPGs focus on a single illness without addressing the vulnerability of older adults with multiple complex conditions.<sup>3,4</sup> Such limitations in the current treatment of the frail can only be

TR has been involved in clinical trials run by Merck & Co., Novartis, Boehringer Ingelheim, Bristol-Myers Squibb, AstraZeneca, Eli Lilly, GlaxoSmithKline, Novo Nordisk, and Sanofi-Aventis and has received speaking honoraria from Merck & Co., Boehringer Ingelheim, Eli Lilly, Novo Nordisk, and Sanofi-Aventis. TR has attended advisory meetings for Merck & Co., Boehringer Ingelheim, AstraZeneca, and Novo

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\* Address correspondence to Laurie Herzig Mallery, MD, FRCPC, Camp Hill Veterans' Memorial Building, 5955 Veterans' Memorial Lane, Suite 2650, Halifax, Nova Scotia B3H 2E1, Canada.

E-mail address: laurie.mallery@cdha.nshealth.ca (L.H. Mallery).

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<sup>&</sup>lt;sup>a</sup> Division of Geriatric Medicine, Department of Medicine, Dalhousie University, Halifax, Nova Scotia

<sup>&</sup>lt;sup>b</sup> Division of Endocrinology, Department of Medicine, Dalhousie University, Halifax, Nova Scotia

CDistrict Medical Director of Continuing Care, Guysborough Antigonish Strait Health Authority and RK MacDonald Nursing Home, Antigonish, Nova Scotia

<sup>&</sup>lt;sup>d</sup> Diabetes Care Program of Nova Scotia, Nova Scotia Department of Health and Wellness, Halifax, Nova Scotia

overcome by developing distinct therapeutic strategies that carefully balance the characteristics of frailty against the potential for benefit and harm from treatment.<sup>5,6</sup>

In April 2010, the Diabetes Care Program of Nova Scotia (DCPNS) released *Diabetes Guidelines for Elderly Residents in Long Term Facilities*, a set of recommendations specific to the population of frail older adults. The guideline initiative is a result of an important collaboration between the DCPNS and the Palliative and Therapeutic Harmonization (PATH) program, <sup>8,9</sup> and is congruent with the larger methodological PATH strategy to create novel, practical treatment recommendations that highlight the clinical implications of and limited life expectancy associated with frailty. The goal of this endeavor is to advance a system-wide acceptance of a more appropriate standard of care—a "new normal" regimen—for frail patients. <sup>10</sup>

#### **Need for Treatment Guidelines Specific to Frail Older Adults**

Physical frailty is characterized by diminished strength, endurance, and physiologic function and is associated with increased dependency on others for performing activities of daily living (ADLs) as well as an increased risk for mortality. 11,12 Frail older adults commonly have multiple coexisting medical problems and dementia that can cause geriatric syndromes such as falls, impaired mobility, adverse effects of medication, prolonged hospital stay, functional/cognitive decline, and reduced life expectancy, 11–18 all of which impact the risk-benefit tradeoff of medical treatments.

A number of validated models have been developed to identify frailty. 11 The Fried frailty phenotype defines frailty as a clinical syndrome in which 3 or more of the following criteria are present: unintentional weight loss, self-reported exhaustion, weakness in grip strength, slow walking speed, and low physical activity/energy expenditure.<sup>19</sup> Similarly, frailty can be identified with the 5-item FRAIL questionnaire, which measures Fatigue, Resistance (inability to climb stairs), Ambulation (inability to walk 1 city block), Illnesses (more than 5 major illnesses), and Loss of weight. The FRAIL scale defines frailty as the presence of at least 3 of the 5 measured variables and a prefrail state as deficiencies in 2 domains.<sup>20–22</sup> Several items in the Fried frailty phenotype and other frailty measures evaluate clinical features associated with sarcopenia, a condition characterized by loss of skeletal muscle mass, impaired muscle function, and slow gait, 23,24 which may not only be a precipitant but also a consequence of type 2 diabetes

Frailty can also be measured using the 9-item Clinical Frailty Scale (CFS), which categorizes frailty based on limitations in function, cognition, and mobility. The DCPNS/PATH guidelines have been developed for individuals who are severely frail, defined as those with a CFS score of seven or higher and who require assistance performing basic ADLs, such as bathing or dressing.

## Description of the PATH Program and the Diabetes Care Program of Nova Scotia

Recognized as a leading program by Accreditation Canada, <sup>8,9</sup> the PATH program aims to optimize decision making and resource utilization across the health care continuum. The program uses a standardized approach to help health professionals, patients, and families consider frailty when making treatment decisions through a 3-step process that consists of (1) assembling the story of frailty by synergizing efforts across different health care disciplines, (2) communicating information about frailty, and (3) empowering all stakeholders to make decisions that consider frailty prognosis and aimed at preservation of quality of life. Use of the PATH process improves appropriateness of care, with one study demonstrating that its

application resulted in a 75% reduction in the demand for interventional treatments for the significantly frail.<sup>8</sup>

Implemented in 1991, the DCPNS is 1 of 8 provincial programs funded by the Nova Scotia Department of Health and Wellness. In pursuit of its aim of improving the care of persons with or at risk of developing diabetes,<sup>27</sup> the DCPNS advises the Department of Health and Wellness on service delivery models; establishes, promotes, and monitors adherence to diabetes guidelines; provides support and resources to health care providers; and collects, analyzes, and disseminates diabetes-related information for and throughout Nova Scotia.

#### Methods

Guideline Development Process

In 2004, the DCPNS convened a long term care subcommittee to develop consensus guidelines for the care of older adults with diabetes who reside in nursing homes, influence policy decisions for this population, and address the continuing education needs of health care professionals. The committee mandate was driven in part by the findings of a needs-assessment survey, sent to all licensed long term care facilities in Nova Scotia, in which 80% of respondent facilities reported that they lacked a diabetes protocol and 84% indicated that a standardized provincial approach would be helpful.

The guideline committee had diverse professional membership, including an endocrinologist, a geriatrician, a family physician/ medical director of a long term care facility, long term care nurses, nutrition staff, diabetes educators, and a representative from the Department of Health Continuing Care Branch. In developing the guidelines, which was neither funded by industry nor dominated by a specialist perspective, the committee members reviewed and discussed the findings of treatment trials for T2DM,<sup>28–33</sup> the conclusions of meta-analyses/reviews of these trials,<sup>34–38</sup> and relevant guidelines/ recommendations.<sup>39–52</sup> Other publications on this topic were identified using reference lists from pertinent studies, reviews, and guidelines, which were supplemented by relevant articles obtained from a PUBMED search.

Although the committee adhered as much as possible to the guidelines established by the Appraisal of Guidelines Research and Evaluation (AGREE) collaboration,<sup>53</sup> it failed to meet 2 of the 23 criteria: (1) seek the views and preferences of the target population and (2) employ experts for external review of the guidelines prior to publication. Despite failing to meet these criteria, the guideline-development process had several strengths. Acceptance of each recommendation required consensus from all committee members and solicitation of feedback on draft recommendations was requested from directors of long term care facilities, the DCPNS Advisory Council, and diabetes educators, which resulted in modification.

Continuous work over several years culminated in the development of 2 specific guidelines, one regarding glycemic targets and one for the treatment and prevention of hypoglycemia. These guidelines became the Phase 1 guidelines, which were released within a pocket reference that describes recommended blood glucose targets. Publication of these guidelines was followed by the development of Phase 2 guidelines, <sup>27</sup> which focused on laboratory hemoglobin A1c (HbA1c) testing and bedside capillary testing, <sup>54</sup> both at the time of admission and routinely thereafter.

#### Results

Since the 1998 publication of the UK Prospective Diabetes Study (UKPDS), a trial of individuals newly diagnosed with T2DM, <sup>28</sup> tight glycemic control has been a dominant objective for the management

of T2DM. Achieving this objective was incentivized by practice guidelines that aggressively advocated strict HbA1c targets to reduce the risk of microvascular complications.<sup>39</sup> However, recent studies call into question the benefit of intensive glycemic control for T2DM,<sup>29–31</sup> with some meta-analyses concluding that the findings of clinical trials neither sufficiently supports nor refutes the benefit of intensive glycemic control.<sup>36,37</sup> This conclusion is particularly relevant to the treatment of frail older adults with T2DM, who have shortened life expectancy and face greater risk from hypoglycemia.<sup>55</sup> Nonetheless, tailored CPGs for frail older adults with T2DM have yet to be widely disseminated. In their absence, conventional guidelines and superficial endorsements, which do not communicate the full complexity of the evidence, have disproportionately swayed the practices of health care practitioners. Summary statements, such as "glycemic control improves microvascular outcomes [with T2DM],"51 oversimplifies complex findings from studies. Indeed, careful evaluation of the data reveals the tenuous association between stringent glycemic control and any reduction in the risks of clinically relevant micro- and macrovascular disease. The following aspects of pertinent research draw attention to the unresolved relationship between glucose lowering and clinical benefit for the frail:

- Available studies do not include frail participants. None of the randomized controlled trials that examine the benefit of decreasing HbA1c levels enrolled frail older subjects.<sup>28–31</sup>
- 2. The time needed to achieve benefit is not relevant for those who are frail. Because frailty shortens life expectancy, <sup>12,13</sup> frail older adults will not benefit from therapies that only accrue benefit after an extended treatment period. Indeed, a decrease in the risk of microvascular disease was only realized after 6.0 to 7.5 years of intensive glycemic control in the UKPDS<sup>28</sup> and after 5 years in the Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified-Release Controlled Evaluation (ADVANCE)<sup>29</sup> trial, whereas mortality increased after 2 years in the Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial.<sup>30</sup> The only study to show a reduction in macrovascular outcomes after decreasing HbA1c levels was a 10-year follow-up study of the UKPDS.<sup>32</sup> This benefit was only achieved after more than a decade of glycemic control, which is an irrelevant time frame for the frail.
- 3. **Reported microvascular outcomes are inconsequential with frailty.**The claim that decreasing HbA1c levels reduces microvascular complications is based on achieved outcomes that would not improve quality of life for the frail. For instance, in the UKPDS, <sup>28</sup> tight blood glucose control reduced microvascular complications largely due to decreased laser photocoagulation without evidence of improved visual acuity. Although urinary albuminuria levels decreased, there were no significant differences in the rates of renal failure with dialysis or plasma creatinine level above 250 mmol/L (2.8 mg/dL). Likewise, the conclusion that intensive therapy reduces the risk of neuropathy was based on a composite outcome that measured change in reflexes, biothesiometer readings at the great toe and lateral malleolus, R-R intervals on electrocardiogram, lying and standing blood pressure, and self-reported erectile dysfunction. This composite is not a true measure of neuropathy and is unlikely to be clinically meaningful.
- 4. The importance of achieving tight glycemic control for older patients with longstanding diabetes is uncertain. In contrast to the UKPDS, <sup>28</sup> which enrolled relatively young individuals newly diagnosed with diabetes, more recent studies, such as the ADVANCE study, <sup>29</sup> ACCORD study, <sup>30</sup> and the Veterans Affairs Diabetes Trial (VADT), <sup>31</sup> enrolled older individuals (mean age, 60–66 years) with well-established T2DM and at higher cardiovascular risk than the subjects in the UKPDS, but who were not frail. These studies showed that either harm or limited to no benefit was associated with tight glucose control, and challenges the conventional wisdom that intensive lowering of the HbA1c concentration is beneficial for older adults with T2DM.

Based on these 4 considerations, the committee concluded that maintaining tight glycemic control is unlikely to prevent clinically meaningful micro- or macrovascular disease in frail older adults with T2DM.

#### Risks Associated With Hypoglycemia

The most consistent finding from randomized controlled trials of intensive blood glucose lowering has been an increased risk of hypoglycemia, <sup>28–31</sup> which is particularly problematic for the elderly. Older adults are not only at higher risk of developing hypoglycemia but also less equipped to perceive and respond to hypoglycemic episodes when they occur, especially when there is a diagnosis of dementia.<sup>55</sup> Inconsistent oral intake, which is common among the frail population, makes the response to diabetic therapies less predictable. Further, the effects of hypoglycemia in the frail, including falls, fracture, hospitalization, confusion, and coma, can be more serious. Finally, there is preliminary evidence that severe hypoglycemia may increase the risk of developing dementia and that individuals diagnosed with dementia are approximately 3 times more likely to experience hypoglycemia that requires hospitalization.<sup>56</sup>

## Risks Associated With Hyperglycemia

The committee also considered the potential adverse effects of hyperglycemia, such as polyuria, incontinence, blurred vision, dehydration, infection, impaired cognition, and hyperglycemic hyperosmolar state. Although many publications describe these harms, most fail to cite<sup>42,43</sup> or properly evaluate<sup>52</sup> the evidence. For instance, the California Healthcare Foundation/American Geriatrics Society Panel for improving diabetes care for the elderly<sup>42</sup> report that "it is likely that there is an association between moderate glycemic control and enhancement of wound healing, reduction of polyuria and fatigue, and possibly maximization of cognitive function" without citing the sources on which this statement is based. In fact, the effects of hyperglycemia have been poorly studied in the elderly population and symptoms related to hyperglycemia may be difficult to differentiate from the physical manifestations of frailty. Moreover, there is some evidence suggesting that older adults may be able to tolerate HbA1c levels beyond those suggested by clinical practice guidelines. For example, despite significant differences in median glycated hemoglobin levels recorded at the end of the VADT,<sup>31</sup> 6.9% in the intensive-therapy group versus 8.4% in the standard-therapy group, no significant differences were found between groups in the incidence of serious hyperglycemic adverse events or blurred vision. Similarly, a longitudinal cohort study of nursing home residents with diabetes found that at 2 years, those with higher HbA1c levels experienced less (8.0%-8.9%) or similar (>9.0%) "functional decline or death" compared to those with HbA1c levels between 7.0% and 7.9%. Other studies found either no<sup>58,59</sup> or marginal relationships<sup>60,61</sup> between glycemic control and symptoms, whereas two studies observed an increase in the incidence of falls when the HbA1c level decreased to 7% or lower<sup>62</sup> or 6% or lower<sup>63</sup> while on insulin therapy. A recent study examined the effect of providing clinician education to achieve HbA1c levels below 8% in nursing home eligible individuals, of whom more than 30% had HbA1c levels above 8% at the beginning of the study.<sup>48</sup> The study found that implementation of this guideline led to greater use of antihyperglycemic medications, a decrease in HbA1c values, and fewer episodes of hyperglycemia, but at greater risk of severe hypoglycemic episodes requiring emergency department visits, although this risk receded over time.

In contrast, 2 studies observed benefit with better glycemic control. Based on the results obtained using the Short Physical Performance Battery (SPPB) measure, the San Antonio Longitudinal Study of Aging<sup>64</sup> reported that subjects with median HbA1c levels below 7% had better maintenance of lower-extremity function compared to those with

HbA1c levels above 7%. Likewise, a retrospective study of 71,000 subjects with T2DM older than 60 years<sup>65</sup> reported decreased mortality risk with HbA1c levels between 6% and 9%, increased risk when HbA1c values were above 11%, and increased risk of any end point (complications or death) with HbA1c values above 8%, including for those older than 80 years. Notably, this was a retrospective study in which subjects with higher glycated hemoglobin levels were more likely to have had diabetes for a longer duration.

Another notable finding is that high baseline HbA1c levels may be relatively common. For example, the median baseline HbA1c value in the VADT was  $9.4\% \pm 2.0\%$ , <sup>31</sup> whereas the HbA1c values in a study of nursing home residents were 8.9% among those using oral medications and 9.6% among those using insulin therapy. <sup>66</sup> In another study of nursing home residents with diabetes, 17.0% had baseline HbA1c values above 8.5%. <sup>67</sup> The common occurrence of high HbA1c levels suggests tolerability, at least for some individuals.

#### **Blood Glucose Monitoring**

The benefits of blood glucose monitoring should be weighed against its costs, including the human resources associated with its performance in the nursing home. Several guidelines and reviews recommend regular self-monitoring of blood glucose (SMBG), even for adults who exclusively use oral antidiabetic agents. <sup>43,50</sup> However, the effectiveness of SMBG is unclear, with several studies showing either no or insignificant changes in HbA1c values using SMBG when individuals with type 2 diabetes are treated with oral agents without insulin. <sup>68</sup> A recent Cochrane review concluded that any benefit of SMBG for patients with T2DM who are not using insulin subsides after 1 year. <sup>69</sup>

#### Diabetes Care in Nursing Homes

Diabetes is highly prevalent in nursing homes, affecting up to 25% of residents older than 65 years. A review of Nova Scotia Department of Health and Wellness long term care data indicates that in fiscal year 2010/11, residents had an average age of 79.8 years and remained in long term care for an average of 2.5 years. On admission to long term care, 27% had diabetes and more than 75% of individuals with diabetes were taking more than 9 medications.

Older adults living in nursing homes are typically severely frail (defined by the Clinical Frailty Scale as needing assistance with basic ADLs<sup>72</sup>) and commonly have multiple interacting chronic illnesses, shortened life expectancy, trouble communicating the symptoms of hypoglycemia, and erratic eating habits. Accordingly, achieving HbA1c levels below 8% would have little clinical benefit, but could increase complexity of care, drug burden, cost, human resource demand, and possible harm. Informal evaluation of diabetes treatment in one Nova Scotia nursing home indicated that many residents were being overtreated to lower blood glucose levels and that among those treated for diabetes with antihyperglycemic medications, 29 of 36 (81%) commonly had blood glucose measures below 7 mmol/L (126 mg/dL) (Bustin R, written communication, November 2012).

#### Clinical Recommendations: DCPNS/PATH Guidelines

A review of the evidence justifies an endorsement of higher glycemic targets than are commonly recommended, while avoiding extreme and prolonged hyperglycemia. In contrast to most other guidelines that recommend lower targets for the frail, such as glycated hemoglobin levels between 7.5% and 8.0% or slightly higher, 40 this committee concluded that stringent targets should be avoided altogether, and explicitly specified termination of any drug treatments that result in blood glucose levels below 7.0 mmol/dL (126 mg/dL) or HbA1c values below 8%.

**Table 1**Guidelines for Random Blood Glucose Level

Random Blood Glucose Level, mmol/L (mg/dL)	Action
Below 7 (126)	Decrease diabetes treatment
7.0–9.9 (126–179)	May be acceptable, but consider risk of hypoglycemia; if hypoglycemia occurs, decrease treatment
10-20 (180-360)	Acceptable in the absence of reversible symptoms
Frequently above 20 (360)	Increase treatment

Source: Diabetes Care Program of Nova Scotia. Diabetes Guidelines for Elderly Residents in Long Term Care Facilities (Pocket Reference). April 2010.<sup>7</sup>

#### Recommendations Regarding Random Blood Glucose

The following are recommendations regarding random blood glucose (Table 1):

- 1. A blood glucose level below 7.0 mmol/L (126 mg/dL), which may be desirable for healthy individuals, is too low for the frail. A blood glucose level of 6.9 mmol/L (124 mg/dL) correlates with an HbA1c value of 6.0%. 73 Results from the ACCORD trial 30 showed that a median glycated hemoglobin level value of 6.4%, which was achieved in the intensive-treatment group, was associated with increased mortality compared with a value of 7.5%, achieved in the standard-treatment group. This finding indicates that blood glucose levels below 7.0 mmol/L (126 mg/dL) increases the risk of hypoglycemia without accruing benefit. As such, diabetes treatment should be decreased when blood glucose levels fall below 7.0 mmol/L (126 mg/dL).
- 2. A blood glucose level between 7.0 and 9.9 mmol/L (126 to 179 mg/dL) is generally safe but poses a risk of hypoglycemia, and thus, reduction of treatment should be considered. Notably, blood glucose levels consistently below 10 mmol/L (180 mg/dL) correlates with an HbA1c value below 7.9%. Thowever, the VADT showed that similar benefits were accrued and similar hyperglycemic symptoms were experienced with median glycated hemoglobin values of 6.9% compared with 8.4%. As there is no objective evidence to justify these low blood glucose targets, it seems reasonable to decrease diabetic treatment when the blood glucose level is between 7.0 and 9.9 mmol/L (126 to 179 mg/dL) to avoid hypoglycemia and the adverse effects of unnecessary medications.
- 3. A blood glucose level between 10.0 and 14.9 mmol/L (180 to 269 mg/dL) or between 15.0 and 20.0 mmol/L (270 to 360 mg/dL) is acceptable in the absence of reversible symptoms. Permitting a wide range of blood glucose levels, as long as they are not associated with bothersome hyperglycemic symptoms, provides clinicians with treatment flexibility. In some situations, high blood glucose levels are acceptable based on consideration of the shortened life expectancy associated with severe frailty; the lack of clinically meaningful benefit of blood glucose lowering observed in relevant clinical trials; the high prevalence of poor glucose control that suggests tolerability 31.66.67; inconclusive evidence regarding the harm of hyperglycemia; and the fact that many individuals with long-standing diabetes may have lived with high blood glucose levels for some time and may therefore not need adjustment of blood glucose levels at the end of life.

## Recommendations Regarding HbA1c

Using the same logic, the committee concluded that HbA1c levels of frail patients should be maintained at or *above* 8% but *below* 12% (Table 2). Based on the VADT<sup>31</sup> finding of no benefit when the median HbA1c value was 6.9% compared with 8.4%, the committee concluded that it is unnecessary to maintain HbA1c levels below 8% and endorsed a wide range of acceptable HbA1c targets. In this way, treatment decisions can be based on the level of frailty and tolerability of hyperglycemia. Individualized treatment decisions can be made, such as whether to aim for HbA1c values between 8% or 9% or higher (ie, >9% to <12%). Although acceptance of high HbA1c levels near 12% may be the

**Table 2**Guidelines for HbA1c Level

HbA1c Level	Action
Below 8%*	Decrease or discontinue diabetes treatment
≥8% to <12%	Acceptable if asymptomatic
Above 12% <sup>†</sup>	Consider increasing diabetes treatment

\*8% is equal to an average blood glucose level of  $\sim$  10 mmol/L ( $\sim$  180 mg/dL). <sup>54,73</sup> †12% is equal to an average blood glucose level of  $\sim$  16.5 mmol/L (298 mg/dL). <sup>54,73</sup> Source: Diabetes Care Program of Nova Scotia. Diabetes Guidelines for Elderly Residents in Long-Term Care Facilities. June 2013. <sup>27</sup>

exception, the committee concluded that it is unnecessary to alter therapy if an individual has tolerated high HbA1c levels for many years, has limited life expectancy, and is not experiencing hyperglycemicassociated symptoms.

#### Recommendations Regarding Antihyperglycemic Treatment

Although some guidelines recommend caution when using sulfonylurea therapy in the elderly, <sup>43,45,46</sup> the committee concluded that sulfonylurea therapy is relatively safe if the goal of treatment is to achieve higher HbA1c values. The committee also recommended the use of basal insulin alone, if possible, to avoid the hypoglycemia associated with the use of regular or rapid-acting insulin, <sup>74</sup> as many frail older adults have unpredictable oral intake. In addition, the committee recommended the use of intermediate or long-acting human insulins, such as neutral protamine Hagedorn (NPH) or ultralente, while avoiding the use of long-acting insulin analogues, such as insulin glargine (Lantus) or insulin detemir (Levemir), as the insulin analogues do not appear to provide clinically meaningful benefit compared with NPH insulin but are more expensive. <sup>75,76</sup>

#### Recommendations Regarding HbA1c and Blood Glucose Monitoring

The committee concluded that there is no need for routine blood glucose testing for patients who have either remained stable on oral hypoglycemic medications or on well-established doses of basal

**Table 3**Guidelines for HbA1c Monitoring

Should HbA1c be Tested on Admission to the Nursing Home?				
Treatment Type	Action	Rationale		
Lifestyle modification only Noninsulin agents* Insulin	Possibly Yes Yes	To determine the need to adjust treatment		
How Often Shoul>d HbA1c Testing be Conducted?				
Treatment Type	Action	Rationale		
Lifestyle modification only Noninsulin agents and/or basal insulin only Basal insulin and meal time insulin	No more than once a y 1–2 times per year 1–2 times per year	ear To determine the need to adjust treatment		

<sup>\*</sup>Noninsulin agents = oral agents and injectable incretin-based therapies.

insulin alone that are not routinely altered based on the results of blood glucose testing (Tables 3 and 4).

Other recommendations and considerations

- Most oral medications decrease the HbA1c concentration by approximately 1% or less; this is an important consideration when deciding whether and which medications can be stopped.
- Dietary management of diabetes in nursing home settings does not appear to meaningfully improve glycemic control and is therefore not needed.<sup>77</sup>
- Basal insulin therapy should never be discontinued for residents with true type 1 DM.

## Discussion

The DCPNS/PATH guidelines are unique in that they recommend an HbA1c level above, rather than below, a specific target to clearly

**Table 4**Guidelines for Capillary Blood Glucose Testing

Should Capillary Blood Glucose Be Tested on Admission to Long Term Care Facility?					
Treatment Type	Recommendation	Frequency		Rationale/Notes	
None (no known diabetes) Lifestyle modification only Noninsulin agents	No Possibly Yes	2 times per day for 1—2 weeks using alternate testing times: Day 1: ac bkft and evening meal; Day 2: ac noon meal and HS Same as for noninsulin agents		To establish the baseline with which to determine the need to adjust treatment (as per recommended glycemic targets) due to the following:  • Change in environment (from home to long term care)  • Change in oral intake  • Change in treatment regimen	
Should Capillary Blood Glucose Testing Be Routinely Tested and, if so, How Often?					
Treatment Type	Routine Te	sting	Frequency	Rationale/Notes	
Lifestyle modification only Noninsulin agents* and/or basal† insulin only Basal insulin and mealtime (bolus)† insulin  Yes Note: Meal-time insu administration can fr be terminated and basal insulin administration only (1–2 times per day) i		nd if stable  al-time insulin  ration can frequently  lated  insulin  ration only	If unstable, use clinical judgment If stable, once a day (alternate times)	Conduct testing with major changes in health status  More frequent blood glucose monitoring may be needed with the following:  • Acute illness  • Major change in health status  • Significant change in oral intake  • Suspicion of marked dysglycemia (high or low)  • Adjustment in diabetes treatment  • Initiation or change in oral steroid use	

ac, before; bkft, breakfast; HS, bedtime.

Source: Diabetes Care Program of Nova Scotia. Diabetes Guidelines for Elderly Residents in Long-Term Care Facilities. June 2013.<sup>27</sup>

<sup>&</sup>lt;sup>†</sup>Basal insulin = background insulin (ie, N/NPH), usually taken 1–2 times per day. Source: Diabetes Care Program of Nova Scotia. Diabetes Guidelines for Elderly Residents in Long-Term Care Facilities. June 2013.<sup>27</sup>

<sup>\*</sup>Noninsulin agents = oral agents and injectable incretin-based therapies.

 $<sup>^{\</sup>dagger}$ basal = background insulin (ie, N/neutral protamine Hagedorn).

bolus insulin = insulin taken to cover specific meals.

**Table 5** Other Guidelines

Organization(s)	Recommendations for Frail Patients
American Diabetic Association/European Association for the Study of Diabetes <sup>40</sup>	<ul> <li>Glycemic targets and glucose-lowering therapies must be individualized.</li> <li>All treatment decisions, where possible, should be made in conjunction with the patient, focusing on his/her preferences, needs, and values.</li> </ul>
	<ul> <li>Less stringent targets (eg, 7.5% to 8.0% or even slightly higher) are appropriate for patients with limited life expectancy and an extensive number of comorbid conditions.</li> </ul>
American College of Physicians <sup>41</sup>	<ul> <li>To prevent microvascular complications of diabetes, the goal for glycemic control should be maintaining a blood glucose level as low as feasible without posing undue risk of adverse events or placing an unacceptable burden on patients.</li> </ul>
	<ul> <li>Treatment goals should be based on a discussion of the benefits and harms of maintaining specific levels of glycemic control with the patient.</li> </ul>
	<ul> <li>An HbA1c level below 7%, based on individualized assessment, is a reasonable goal for many, but not all, patients.</li> </ul>
	<ul> <li>The HbA1c target should be based on individualized assessment of risk for complications from diabetes and other comorbidities, life expectancy, and patient preferences.</li> </ul>
California Health Care Foundation/American Geriatric Society Panel <sup>42</sup>	<ul> <li>For frail older adults, persons with life expectancy of less than 5 years, and for others in whom the risks of intensive glycemic control appear to outweigh the benefits, a less stringent target such as 8% is appropriate.</li> </ul>
Canadian Diabetes Association <sup>43</sup>	Sulfonylurea therapy should be used with caution.
	<ul> <li>Glycemic targets should be HbA1c levels ≤8.5% and fasting plasma glucose or preprandial plasma glucose levels of 5.0−12.0 mmol/L, depending on the level of frailty.</li> </ul>
	Detemir and glargine may be used instead of neutral protamine Hagedorn or human 30/70 insulin to decrease  the foreup of the polynomia synthese.
Veterans Affairs and Department of Defense <sup>44</sup>	the frequency of hypoglycemic events.  • All patients with diabetes should maintain an HbA1c level <9% to reduce symptoms of hyperglycemia.
vecerans i mans and Department of Belense	Patients with advanced microvascular complications, major comorbid illnesses, and/or a life expectancy of less
	than 5 years are unlikely to benefit from aggressive glucose-lowering management and should aim to maintain HbA1c levels between $8\%$ and $9\%$ . A lower target (HbA1c $<8\%$ ) can be established on an individual basis.
International Association of Gerontology	When making treatment decisions for patients over the age of 70,
and Geriatrics (IAGG), the European Diabetes Working Party for Older People	<ul> <li>Consider comorbidities and cognitive/functional status when developing glucose goals with the patient and/or caregiver.</li> </ul>
(EDWPOP) <sup>45</sup>	<ul> <li>Initiate treatment only when fasting blood glucose level is consistently 7 mmol/L or higher.</li> </ul>
(EDWI OI)	Prevent fasting blood glucose levels from decreasing below 6.0 mmol/L and strictly avoid a decrease in blood glucose levels below 5.0 mmol/L.
	<ul> <li>Prevent random blood glucose level from increasing above 11.0 mmol/L to minimize symptoms and reduce the risk of diabetes-related complications.</li> </ul>
	• Aim to maintain the HbA1c level between 7.0%—7.5%.
	• Individualize treatment for those in care homes to (1) prevent hypoglycemia, (2) avoid metabolic complications, (3) decrease risk of infection, and (4) prevent hospitalization.
	<ul> <li>In cases of functional dependence, care home residency, dementia, end-of-life care, and other high-dependency states, adjust treatment to reduce risk of hypoglycemia and enhance patient safety.</li> </ul>
	Avoid use of restrictive diets.  Avoid to If and the state of the
	<ul> <li>Avoid sulfonylurea therapy for those at higher risk of hypoglycemia.</li> <li>Consider that basal insulin therapy may be safer than basal/bolus or premixed insulin therapy in preventing hypoglycemia.</li> </ul>
Report from the American Diabetes Association	<ul> <li>Consider that hypoglycemic risk associated with sulfonylurea therapy may be problematic for the elderly.</li> </ul>
Consensus Development Conference*.46	<ul> <li>Consider that consistently maintaining a blood glucose level above 180–200 mg/dL increases the risk of dehydration, electrolyte abnormalities, urinary incontinence, dizziness, falls, and hyperglycemic hyperosmolar</li> </ul>
	syndrome (no reference provided).  • Aim for an HbA1C value of <8.0% for patients with 2 or more instrumental ADL impairments or mild to
	<ul> <li>Aim for an HbA1c level of &lt;8.5% for patients in long term care or with end-stage chronic illnesses, moderate to severe cognitive impairment, or 2+ ADL impairments.</li> </ul>
UpTodate <sup>50</sup>	• Aim for an HbA1c level of $\leq 8.0\%$ for frail older adults with medical and functional comorbidities and/or
	with life expectancy less than 10 years.
	<ul> <li>HbA1c targets for the very elderly may be even higher and should include efforts to preserve quality of life and avoid hypoglycemia and related complications.</li> </ul>
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ADL, activities of daily living.

\*The recommendations in this report are those of the authors only and do not represent the official opinion of the American Diabetes Association.

communicate the benefit of avoiding hypoglycemia and unnecessary medications (Figure 1). Although other guidelines and reviews now indicate the need to adjust glycemic targets for frail older adults or individuals with limited life expectancy (Table 5), 40–46.50 they typically have 2 limitations. First, guidelines for frail individuals often lack specificity, encouraging "individualized" targets and calling for "understanding of patient or caregiver preferences, "40.41,44,45.50 rather than making more definitive recommendations. This approach is problematic because the significance of frailty and its relationship to treatment outcomes may not be understood by patients and families. The Providing specific guidelines for frailty would improve the health care professionals' understanding of the issues

and facilitate navigated decision making with patients or their caregivers. Second, some published guidelines aim to achieve unnecessarily stringent glycemic control for the frail. 40–42,45,46,50 For example, the American Diabetes Association recommends an HbA1c level of 7.5% to 8.0% or higher for frail patients, <sup>40</sup> even though the VADT<sup>31</sup> reported no increase in the risk of hyperglycemic events with a median HbA1c value of 8.4% compared to 6.9%, <sup>31</sup> which suggests that a target of 7.5% is unnecessarily low with frailty. In this regard, the DCPNS/PATH guidelines are most similar to the Veterans Affairs and Department of Defense guidelines, <sup>44</sup> which recommend achieving HbA1c levels between 8% and 9% when there is limited life expectancy.



Fig. 1. Image of cake.

#### Effects of the Guidelines to Date

The Phase 1 guidelines were widely distributed by direct mail to long term care facilities, diabetes centers, academic centers, and provincial professional nursing organizations within a pocket reference that detailed the recommended blood glucose targets. The guidelines were also supported by written resources that described the rationale for the guidelines, telehealth sessions, and standardized PowerPoint slide presentations. A survey of 93 Nova Scotia nursing homes in 2012 generated a response rate of 56% and found that of the 82% of facilities that implemented the guidelines, 58% reported a decrease in blood glucose testing and 50% reported decreased calls to physicians/nurse practitioners and fewer episodes of hypoglycemia. Most facilities (66%) also reported that the number of episodes of blood glucose measures reaching a level of over 20 mmol/L (360 mg/dL) did not decrease or increase. Regarding the qualitative impact, the staff described gaining a better understanding of the goals of care for the frail elderly with diabetes, and spending less time performing bedside monitoring and more time on patient quality-of-life activities. Overall, implementation of the guidelines appears to shift resources away from intensive glucose monitoring, reduced episodes of hypoglycemia, and reduced medication administration.

## Conclusion

In conclusion, the stringent glycemic targets advocated by conventional practice guidelines are based on weak evidence that is mostly extraneous to the frail population. As such, new guidelines of equal import must be developed to assist health care practitioners in making treatment decisions for frail elderly patients. The DCPNS/PATH guidelines recommend maintaining HbA1c values higher than those recommended by previous guidelines—at or above 8%—and stress the importance of re-educating health professionals who may be unduly influenced by unsupported claims about the benefit of stringent glycemic targets.

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