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Maud Meulstee

Yale University, mmeuls@gmail.com

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DEVELOPMENT OF AN EDUCATIONAL PROGRAM ON PREVENTION OF
HYPOGLYCEMIC EVENTS AMONG ELDERLY VETERANS WITH TYPE 2 DIABETES

Submitted to the Faculty
Yale University School of Nursing

In Partial Fulfillment
of the Requirements for the Degree
Doctor of Nursing Practice

Maud Meulstee

May 15, 2015

The capstone is accepted in partial fulfillment of the requirements for the degree Doctor of Nursing Practice.

Ruth McCorkle, PhD, FAAN

May 18, 2015

Jessica Coviello, DNP, APRN, ANP-BC

May 18, 2015

Robin Whittemore, PhD, APRN, FAAN

May 15, 2015

Sharon Watts

May 15, 2015

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Signed: Maud Meulstee

May 15, 2015

**Development of an Educational Program on
Prevention of Hypoglycemic Events
among Elderly Veterans with Type 2 Diabetes**

Maud Meulstee, MSN, RN, CNP

Robin Whittemore, PhD, APRN, FAAN

Sharon A. Watts, DNP, FNP-BC, CDE

Yale University School of Nursing, New Haven, CT (Dr. R. Whittemore)

Veterans Healthcare Administration Cleveland, OH (Dr. S. Watts)

Veterans Healthcare Administration Boston, MA (Maud Meulstee)

940 Belmont Street, Brockton, MA 02301 □ Tel. 508-583-4500 | 800-865-3384.

maud.meulstee@yale.edu.

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Abstract

Purpose

The purpose of this project was to develop an evidence-based educational program to reduce *hypoglycemic* events in elderly veterans with type 2 diabetes mellitus (T2DM) enrolled in the Veterans Healthcare Administration system. US elderly persons are especially affected by T2DM and at great risk for complications. Until recently, tight glycaemic control has been advocated to avoid *hyperglycemic* events. However, this approach has been shown to have no major benefit but instead has resulted in increased *hypoglycemic* events, morbidity, and mortality.

Hypoglycemia is now seen to be the most serious complication in the treatment of T2DM in all adults, and is especially dangerous in elderly persons. Updated guidelines have emphasized the importance of *hypoglycemia* prevention and recommend individualized and less stringent glycaemic control.

Methods

We conducted a comprehensive literature review, which led to the development of evidence-based content for an educational program. Several categories and sub-categories of content were identified and subsequently evaluated by a panel of experts in the field of diabetes management. Expert evaluations were summarized and informed program development.

Results

Experts were unanimous on the importance and relevance of the categories and provided insight into the priority of sub-categories of content.

Conclusions

Developing an evidence-based educational program for health care providers on prevention of *hypoglycemia* has important clinical implications. The rigorous process used in this project can

serve as a model for developing educational programs on other topics.

Key Words: *hypoglycemia*, type 2 diabetes, educational program, veterans, elderly.

“Education is the most powerful weapon which you can use to change the world.”

Nelson Mandela¹

Diabetes Mellitus (DM) continues to be on the increase in the U.S and worldwide, and elderly persons and veterans are especially affected. ^{2, 3, 4, 5} DM management is not an easy task as “the paradox of balancing cost-effective and evidence-based diabetes guidelines with the outcomes-effective trend of individualizing patient care could be like walking a tightrope “. ⁶ DM management, especially in the in-patient setting, has emphasized tight glycemic control [hemoglobin A1C (A1C) of <7%] in order to avoid *hyperglycemic* events and improve hospital outcomes. ^{7, 8} Several large randomized control trials demonstrated that this approach, while providing microvascular benefit in adults with both type 1 and type 2 DM, had no major macrovascular benefit in adults with T2DM but resulted in significantly higher numbers of *hypoglycemic* events and increased mortality. ^{9, 10, 11, 12, 13} Hence, major professional organizations such as the American Diabetes Association, the American Association of Clinical Endocrinologists, the US Department of Veterans Affairs, and the European Association for the Study of Diabetes have issued statements emphasizing the need for *hypoglycemia* prevention and recommending more individualized and less stringent glycemic control (Table 1). ^{14, 15, 16, 17}

Translating these important recommendations into clinical practice is paramount, however a known gap exists between research and clinical practice. ^{18, 19} In a retrospective cohort study of 15,880 elderly veterans with T2DM and dementia, 52% of veterans had tight glycemic control and were at high risk of *hypoglycemia*. ²⁰

The purpose of this project was to develop an evidence-based educational program to reduce *hypoglycemic* events in elderly veterans with T2DM enrolled in the federal Veterans Healthcare Administration system.

Background

Intense glyceemic control [A1C < 7% or plasma blood glucose level (PG) between 80 and 110 mg/dl] has been advocated to decrease cardiovascular (CV) complications²¹ but recent research reveals inconsistent results.²² Several large clinical trials such as the ACCORD, ADVANCE, VADT and NICE-SUGAR investigated the relation between intense glucose control and improved CV outcomes, but failed to demonstrate a positive correlation except for decreased microvascular complications.^{23, 24, 25, 26}

Alarminglly, participants randomized to the intensive glucose control arm in the ACCORD study with an A1C target of less than 6.0%, had 22% higher mortality (predominantly due to CV complications) than those randomized to the standard glucose control arm with an A1C target of 7.1–7.9%, and the trial was stopped prematurely.²⁷ The NICE-SUGAR study, a large British multi-site randomized clinical trial of 6,104 intensive care unit patients with T2DM, showed similar results with significantly increased rates of *hypoglycemic* and CV events, as well as a 10 percent increase in mortality in patients in the intensive control group (non-fasting PG target range of 81 and 108 mg/dl) compared to the conventional control group (non-fasting PG target of < 180mg/dl).²⁸ In a nested case-control study (part of a retrospective cohort study of > 5000 medical and surgical critically ill patients), a PG of <40 mg/dl was an independent risk factor for death after adjustment for severity of illness, age, mechanical ventilation, renal failure, sepsis, and DM.²⁹

Hypoglycemia

The clinical syndrome of *hypoglycemia* is defined in the classic Whipple's triad as 1) symptoms consistent with *hypoglycemia*, 2) low PG and 3) relief of symptoms after the PG concentration has been raised.^{30, 31} Reflecting recent research, the ADA and Endocrine Society

have redefined *hypoglycemia* /to include all episodes of abnormally low PG (Table 2).^{32, 33} Hence, it is not only the numerical PG and the duration of *hypoglycemia* that may be dangerous; but frequent *hypoglycemic* events can interfere with daily living such as driving and, even if asymptomatic, lead to defective glucose counter-regulation and *hypoglycemia* unawareness. Risk factors for hypoglycemic events for hospitalized patients include continued anti-hyperglycemic therapy when caloric intake is reduced or stopped; history of MI, neuropathy, micro-albuminuria, chronic kidney disease, sepsis or liver disease; use of a standard insulin "sliding scale" without consideration of the individual patient; acute renal failure; interruption of continuous renal replacement; attempts to provide "tight" glycemic control intra-operatively; and implementation of intensive insulin protocols in critically ill patients.^{34, 35, 36}

Hypoglycemia is associated with acute CV events and increased risk of death in patients with T2DM.^{37, 38} The reasons for increased mortality after hypoglycemic events are somewhat unclear, but contributing factors may include comorbidities, CV events, falls, seizures, and coma.³⁹ *Hypoglycemic* events have been shown to have serious CV consequences such as tachycardia, bradyarrhythmias, frequent ventricular ectopic beats, ST depression, T-wave flattening and QT prolongation.⁴⁰ Proposed pathways include sympatho-adrenal activation leading to abnormal cardiac repolarization, QT prolongation, and hypokalemia.⁴¹

Recurrent prior *hypoglycemic* events can lead to the development of *hypoglycemia*-associated autonomic failure, which includes defective glucose counter regulation and *hypoglycemia* unawareness. If PG level is allowed to fall below 50 mg/dl, transient cognitive deficits may ensue with resulting falls or aspiration, high risk factors for morbidity and mortality in elderly persons. If PG level falls even further, to <40 mg/dl, seizure or coma may ensue.⁴²

Population

Elderly persons

As previously stated, elderly persons are disproportionately affected by T2DM, with one in four suffering from the disease. Admission rates for *hypoglycemic* events among elderly persons now outnumber those for *hyperglycemic* events.⁴³ The Diabetes and Aging study followed a cohort of 72,310 older (>60 years of age) adults with T2DM from 2004-2010.⁴⁴ Among older adults with T2DM with short duration (0-9 years), CV complications, followed by *hypoglycemia* were the most common, non-fatal complications with higher incidence rates than End Stage Renal Disease, amputations and acute *hyperglycemic* events. For a given age group, rates of complications, particularly *hypoglycemia* and microvascular complications, increased dramatically with longer duration (10+ years). Also, for a given duration of T2DM, rates of *hypoglycemia*, CV complications and mortality increased considerably with advancing age, while rates of microvascular complications remained stable or declined. The authors concluded that “as long-term survivorship with diabetes increases and the population ages, more research and public health efforts to reduce *hypoglycemia* will be needed, to complement ongoing efforts to reduce cardiovascular and microvascular complications”.⁴⁵

Veterans

Nearly 25 percent of adult veterans cared for by the Veterans Healthcare Administration have DM, significantly higher than the national average of 9.3%.^{46, 47} A variety of factors have been implicated: older age, lower socioeconomic status, lower self-reported health status, large proportion of minorities, significant smoking and drinking history, and significant co-morbidities which makes this demographic a particularly disadvantaged population.^{48, 49} Thus, it is critical that health care providers at the Veterans Healthcare Administration are aware of best practices

for DM management, including individualizing A1C goals and preventing *hypoglycemic* events.

Translating research into clinical practice

Unfortunately, successful, effective practices, programs, and policies resulting from research do not consistently affect the delivery of health care services resulting in a serious “quality chasm”.⁵⁰ A known gap exists between evidence-based guidelines and clinical practice with new research findings taking several years to disseminate to the clinical arena.^{51, 52} This research/practice gap is of considerable concern as lack of timely dissemination could potentially harm patients. Knowledge deficiencies about DM management have been identified in the healthcare setting.^{53, 54, 55, 56} As staff nurses spend a lot of time with patients, they have a major impact on patient experiences and are ideally positioned to provide key aspects of self-management education to a large majority of people with DM.^{57, 58}

Methodology

Process

A two-step process was used to develop an evidence-based educational program to reduce *hypoglycemic* events in elderly veterans with T2DM enrolled in the federal Veterans Healthcare Administration system. Initially, a literature review was completed to identify content, followed by independent validation of proposed content by a panel of experts.

A systematic literature review was performed to ensure that the content of the educational program was evidence-based and reflected current research. Search engines included PubMed, CINAHL, Scopus, Ovid, Cochrane Library and National Guidelines Clearing house. Search terms included: diabetes and the elderly, diabetes and veterans, *hypoglycemia*, *hypoglycemic* complications, *hypoglycemia* and the elderly. MeSH headings included *Hypoglycemia*, Aged, and Veterans. Publicly available information was retrieved from the American Diabetes

Association and the Centers for Disease Control (CDC). Veteran specific data were retrieved from the Veterans Healthcare Administration, Veterans Affairs, Veterans' Affairs/Department of Defense, and veterans' organizations.

The first author developed a detailed outline of the content for the educational program from data extracted from the literature review. Categories and sub-categories of content were identified. The content of the educational program was reviewed by a five-member expert panel, according to the Yale School of Nursing Doctor of Nursing Practice program guidelines for expert panel methodology.⁵⁹ The expert panel was selected based on education, experience and published journal articles in the subject matter of T2DM in elderly veterans (preferable) or T2DM in the elderly (secondary). Professionals from varied backgrounds (medicine/nursing) were included, including a doctoral prepared professor of nursing education (Table 3). Experts were approached individually and invited to review and evaluate educational categories and sub-categories on relevance and importance and to suggest missing content. Then, a summary report of the relevance and importance of each topic across reviewers was completed. Based on established methods of content validity in questionnaire development, a consensus of 90% was required to retain a category topic of content (Content Validity Index of 0.90) and 78% to retain a sub-category topic of content (Content Validity Index of .78).⁶⁰

Approvals

Institutional Review Board exemption for this educational project was obtained from Yale University and the VHA Research and Development. VHA policies were respected.

Results

Content topics were identified as a result of the literature review. Six overarching categories and 24 sub-categories were identified as important content to include. Categories

included: The Importance of T2DM (5 sub-categories); Introduction to Hypoglycemia (5 sub-categories); Adverse Consequences of Hypoglycemia (3 sub-categories); Prevention of *Hypoglycemia* (no sub-categories); ADA Updated Guidelines (3 sub-categories); and Special Considerations in Managing T2DM in the Elderly” (8 sub-categories). For reasons of scope of the educational program, the important category of T2DM medication management, identified in the literature, was purposefully excluded.

All six categories received 100% expert agreement on relevance and importance (Table 4). Category I: the Importance of T2DM, was considered a relevant topic, but expert advice was to limit this content and focus on *hypoglycemia*. For reasons of focus, category I was renamed: Introduction.

The majority of sub-categories received > 80% expert agreement on both relevance and importance. Twenty-four sub-categories were considered *relevant* to the educational program (80-100% agreement), but several sub-categories were considered less *important*. Sub-categories considered *relevant but less important* were eliminated (Prevalence of T2DM; Marker of Frailty in Elders, and Healthy eating). The two experts employed at the Veterans Healthcare Administration and three experts outside this system differed in opinion on including the sub-category of Veterans with T2DM. As stated previously, the veteran elderly population is especially disadvantaged compared to non-veterans. It was thus decided to eliminate this topic for general use but to include it for use at the Veterans Healthcare Administration. The two Veterans Healthcare Administration experts commented on ADA guidelines,” better to use Veterans Affairs/Department of Defense (VA/DoD) Guidelines” and “of note the Veterans Affairs/Department of Defense Guidelines have stressed risk stratifying since their inception”. The authors decided to include both the ADA and VA/DoD guidelines. The sub-categories

Morbidity and Mortality of T2DM and *Hypoglycemia* were scored of low importance by one expert, who commented that they would be rated high importance “if related to older adults”. As the educational program focuses on elderly persons, the sub-categories were counted as high importance and the topics were retained.

Additional content was recommended by the expert panel. This included: 1) Medications 2) Landmark Studies like ACCORD, ADVANCE , VADT and NICE-SUGAR ^{61, 62, 63, 64, 65} 3) Risk Factors for *Hypoglycemia*; 4) Geriatric Syndromes and Interaction with DM management, (e.g., polypharmacy, functional decline, syncope, delirium, falls, urinary incontinence); 5) BP and Lipid Targets as they are part of the ABCs of diabetes self-management; 6) Role of New Technology (e.g., continuous glucose monitoring) ; 7) Impact of “transition of care” in Frail Elderly with DM; 8) *Hypoglycemia* in Different Settings (e.g., ICU); and 9) organizing categories and sub-categories in a different way. After careful consideration, several topics were determined to be relevant and were added to the educational content (Items 2, 3, 4). Other topics were determined to be outside the scope of this educational program (Items 5, 6, 7, 8). Item 9 was considered in the final Topical Outline of the Educational Program (Table 5).

Discussion

The dangers of *hypoglycemia* and the importance of prevention cannot be underestimated. Hospital admissions for severe *hypoglycemia* now appear to have more serious consequences than those for *hyperglycemia*. ⁶⁶ *Hypoglycemia* is considered the most dangerous complication of DM management, especially for the elderly. ⁶⁷ *Hypoglycemic* events have been linked to increased length of stay and increased risk of morbidity and mortality in hospitalized patients. ⁶⁸ In a retrospective analysis of the ACCORD trial, adults who had experienced symptomatic, severe *hypoglycemia* were at greater risk of death than those who had not

experienced any hypoglycemic event.⁶⁹ Severe *hypoglycemia* itself may be seen as a marker of frailty and can be used as a prognostic tool to identify patients at increased risk of CV events and death.⁷⁰

The development and implementation of an evidence-based educational program on the prevention of *hypoglycemia*, can be of great value, especially if as in this case, it has been validated by renowned experts in the field of diabetes. After implementation of the educational program, the healthcare providers in turn can educate patients, families and caregivers on *hypoglycemia* episode prevention, recognition or awareness, and treatment.⁷¹ The family must be included since autonomic failure or certain medications may mask symptoms contributing to long-term neurologic changes more commonly seen in elderly persons.⁷² In this way, a *hypoglycemia* prevention safety net can be developed around the elderly person, consisting of health care providers, staff nurses, caregivers, and the family.

Limitations of the project are the scope of the topic, which focuses on T2DM management for elderly persons, specifically prevention of *hypoglycemia* and does not include medication management or other valuable topics, which may be addressed at a later date.

Conclusion

The process undertaken to systematically develop and validate the content for an educational program has the potential to decrease the research/practice gap. Educating healthcare providers in a timely manner has the potential to significantly reduce *hypoglycemic* events and its consequences of increased morbidity and mortality of elderly persons/veterans with T2DM. This educational program will be further developed and disseminated at a federal Veterans Healthcare Administration site.

Implications/relevance for diabetes educators

The benefits of this project are directly related to increased knowledge of best practices of T2DM among healthcare practitioners. Diabetes educators can play an important role in this process. The rigorous process used to identify educational content and the use of an expert panel, can serve as a powerful model for educators interested in developing similar evidence-based programs.

Recommendations

It is difficult for clinical practitioners to stay current with the enormous daily increase in research findings, and constant changes in clinical practice guidelines and recommendations. The process for developing an educational program as described in this article, can serve as a model for others eager to develop educational programs. The authors recommend that practitioners and educators familiarize themselves with this process in order to help decrease the gap between current research and safe clinical practice.

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