# Information about the Critically Appraised Topic (CAT) Series

The objective of the Doctor of Nursing Practice (DNP) program at George Mason University is to prepare graduates for the highest level of nursing practice. Emphasis is placed on evaluating and applying the evidence that supports practice, understanding and creating practice delivery systems based on patient outcomes, and assuming leadership roles in practice settings. Graduates of the program will be able to assume many roles in the health care system, including direct patient care, clinical nursing faculty, practice management, and policy development.

All DNP students take an evidence-based practice course titled Evidence Based Practice in Nursing and Healthcare (NURS 883). This hallmark course for the DNP program builds on knowledge of research methodologies to analyze the selection and evaluation of research underlying evidence based practice.  Emphasis is placed on the translation of research in practice, the evaluation of practice and the improvement of the reliability of health care practice and outcomes.

The first assignment students complete is a Critically Appraised Topic (CAT).  CATs are mini-systematic reviews and considered a snapshot of the literature on a topic of interest. Students critically appraise literature related to a focused clinical question and summarize the best available research evidence on the topic of interest. CATs conclude with clinical bottom lines for practitioners to quickly take away for consideration in practice.

The CATS published in MARS (Mason Archival Repository Service; mars.gmu.edu) are submitted by students after they have been reviewed, revised, and approved by their instructor. All CATs are current at the time of original publication but will not be updated over time.

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**TeleHealth Insulin Program for Uninsured Type 2 Diabetics**

**Purpose:** To assess the impact of a TeleHealth Insulin Program (TIP) on reducing Hemoglobin A1c (HgbA1c) levels in individuals with poorly controlled type 2 diabetes mellitus.

**Appraised by**: Mary June C. So

**Date of completion:** February 17, 2013.

**Date of Review:** February 10, 2013.

**Clinical Scenario:** Managing insulin therapy for individuals in an underserved community can be daunting as frequent follow-up visits and coordination to receive affordable care can be a challenge. Poorly controlled type 2 diabetes can lead to an increase in diabetes-related complications, diminished quality of life, and increased economic burden associated with the disease. Questions remain regarding the best approach to improve glycemic control in adults with type 2 diabetes.

**Question:** Can weekly telephone calls to titrate insulin by NPs and/or NP students reduce HgbA1c when compared to standard care in a low-income, ethnically diverse, and underserved adult population with insulin dependent type 2 diabetes?

**Search Strategies and Results:** EBSCO HOST search engine was used to search: a) CINAHL, b) MEDLINE databases. Terms used: "telehealth and diabetes" resulting in 97 articles from 2008 to 2013 of which, three studies with the best level of evidence and appropriateness were selected for critical appraisal. Only studies that focused on low-income and/or uninsured type 2 diabetics on insulin receiving telehealth interventions were considered for inclusion. As a result only one randomized controlled trial was found that fit the inclusion criteria. The other two studies reviewed consisted of a retrospective, matched, case-control design and a retrospective cohort study.

**Chosen Articles:**
1) Davis, R.M., Hitch, A.D., Salaam, M.M., Herman, W.H., Zimmer-Galler, I.E., & Mayer-Davis, E.J. (2010). TeleHealth improves diabetes self-management in an underserved community. *Diabetes Care, 33*(8), 1712-1717.
2) Pitlick, J.M., & Brooks, A.D. (2011). Glycemic control in pharmacist-managed insulin titration versus standard care in an indigent population. *Diabetes Spectrum, 24*(4), 211-217.
3) Salvo, M.C. & Brooks, A.M. (2012). Glycemic control and preventive care measures of indigent diabetes patients within a pharmacist-managed insulin titration program vs. standard care. *The Annals of Pharmacotherapy, 46*, 29-34.

**Evidence Retrieved:**

**Davis et al:** This randomized clinical trial evaluated Diabetes TeleCare, a 1-year, remote, evidence-based diabetes self-management education (DSME) intervention with adults with type 2 diabetes in rural and underserved areas. Telehealth strategies included interactive videoconferencing, telephone, fax, and telehealth-enabled retinal camera were used. Participants from three Federally Qualified Health Centers (FQHC) in South Carolina were recruited to yield a sample size of 165, which included those in the Diabetes TeleCare intervention (n=85) compared to those who received standard care (n=80). Primary outcome measure construct included glycated hemoglobin (GHb). Secondary outcome constructs

included LDL cholesterol and albumin-to-creatinine ratio. Mixed linear regression model results for repeated measures showed significant reduction in GHb in the Diabetes TeleCare group from baseline to 6 and 12 months ($9.4 \pm 0.3$, $8.3 \pm 0.3$, and $8.2 \pm 0.4$, respectively) compared with usual care ($8.8 \pm 0.3$, $8.6 \pm 0.3$, and $8.6 \pm 0.3$, respectively.) LDL cholesterol was reduced at 12 months in the Diabetes TeleCare group compared with usual care. GHb was reduced from baseline to 12 and 24 months in the Diabetes TeleCare group ($9.2 \pm 0.4$, $7.4 \pm 0.5$, and $7.6 \pm 0.5$, respectively) compared with the usual care ($8.7 \pm 0.4$, $8.1 \pm 0.4$, and $8.1 \pm 0.5$, respectively) in the post hoc analysis of a subset of the randomized sample that completed a 24-month follow-up visit.

*Strengths:* Participants were randomized to either Diabetes TeleCare or usual care. The duration of the Diabetes TeleCare was a 12-month, 13-session curriculum and appears to be sufficient. Analyses were conducted with SAS version 9.1. Linear mixed models for repeated measures tested for differences for each outcome. These models used intervention vs. usual care as the predictor of interest, controlling for potential confounders. *P* values <0.05 were regarded as significant. An adequate timeframe and duration for the study was utilized.

*Weakness:* Exclusion criteria of BMI < 25 kg/m2 was based on self-reported height and weight may decrease the generalizability of results. External validity with regards to generalizability of conditions is threatened by the researchers use of "interactive videoconferencing" between the self-management education team at the academic health center and participants at the primary-care clinic. Patients in the intervention group had a higher baseline A1c compared to the usual care group (9.4 and 8.8 respectively). It could be argued that it is not a valid comparison since their baseline A1c values differed so greatly. A potential threat to internal validity exists because control subjects were not matched to intervention subjects based on age and insulin regimen. Over 70% of the participants in both groups were female. The lack of male participants could affect the generalizability to other populations.

**Pitlick et al:** The authors assessed the impact of a pharmacist-managed insulin titration program in an underserved population with diabetes using a retrospective, matched, case-control design. The setting consisted of a community health center for uninsured or underinsured with limited income. The sample size was 70, which included a comparison of intervention (n=35) vs. control group with usual care (n=35). The primary outcome evaluated was change in A1C at 6 months between subjects in the intervention and control groups. Secondary outcomes included change in A1C within groups at 3, 6, 9, and 12 months, as well as the proportion of subjects attaining a goal A1C of < 7% and adhering to preventive care recommendations.

Within-group comparisons demonstrated significant A1C reduction from baseline at 6, 9, and 12 months in the pharmacist-managed group with no significant changes observed in the control group. The primary outcome of mean change in A1C at 6 months between groups demonstrated a significant difference favoring pharmacist management at 6 months (1.0%, 95% CI 0.2-1.6, $p = 0.009$). Within-group comparisons demonstrated significant A1C reduction from baseline at 6 months (-1.1%, 95% CI -1.7 to -0.4, $p = 0.002$), 9 months (-1.4%, 95% CI -2.0 to -0.7, $P<0.001$), and 12 months (-1.3%, 95%, CI -2.0 to -0.5, $p = 0.001$) in the pharmacist-managed group with no significant changes observed in the control group.

*Strengths:* External validity exists, as the evidence is transportable. Social validity regarding social importance or significance of the evidence also exists, as pharmacist-managed insulin titration programs are a feasible way to increase glycemic control in underserved populations. Control subjects were matched to intervention subjects based on age and insulin regimen.

*Weakness:* The retrospective, matched, case-control design is not as reliable as a randomized controlled

trial would have been. A potential threat to internal validity exists because, although control subjects were matched to intervention subjects based on age and insulin regimen, there was no match based on baseline A1C. Because more than 80% of the health center's patient population from which the sample group was drawn is African American, generalizability to other populations could be questionable. Intervention subjects were included if they interacted with the pharmacy service for initial education and at least two follow-up phone calls. Bias may exist towards people who are willing to interact with the pharmacy. The sample size calculated provided for an 80% power to detect a difference, as opposed to a 95% confidence interval.

**Salvo et al:** A retrospective cohort study compared pharmacist-managed insulin titration to standard care; St. Louis County Department of Health; sample size of 126; comparison of pharmacist-managed group (n=69) vs. control group (n=57). Primary outcome measured was the change in A1C between the 2 groups from index date to 3, 6, 9, 12, 18 months, and at study end. Secondary outcomes included frequency of preventive care measures, differences in total daily insulin dose at baseline and at study end, change in weight from baseline to study end, change in weight from baseline to study end, and attainment of ADA A1C goal at study end between groups.

Between group comparison demonstrated a significant difference in mean change in A1C favoring pharmacist management at all time points. Patients in the pharmacist-managed insulin titration program experienced an increase in total daily insulin dose by a mean of 33 units. The difference was statistically significant when compared to the standard-of-care group at study end ($p = 0.004$). Patients in the intervention group more often completed the ADA recommended preventive care measures with statistically significant differences demonstrated between the intervention and standard-of-care group.

*Strengths:* Baseline demographics between the two groups were very similar. The researchers included change in weight and total daily insulin dose from baseline to study end in their design.

*Weakness:* A standard-of-care match for each intervention patient was not identified. Patients in the intervention group had a higher baseline A1C ($p < 0.001$) than those in the standard of care group (10.4% and 8.9% respectively). Patients receiving the Medicare benefit were excluded because pharmacy claims data was used to identify control patients based on insulin prescriptions. This exclusion may have resulted in a patient population that was younger than the typical group that would be followed by a similar service and can yield limited generalizability. The retrospective design limits the ability to determine causation, as there are likely many confounding variable that can influence the changes observed.

**Conclusion/Clinical Bottom Line:** There appears to be sufficient evidence to support the premise that the use of telehealth to communicate with type 2 diabetic patients shows favorable outcomes in improving glycemic control. However, there is a lack of randomized controlled trials comparing usual care to the addition of telehealth interventions to standard care. The studies reviewed do confirm the use of telephone interventions as a cost-effective means to improve diabetes self-management in adults with type 2 diabetes. While these studies support the use of telephone intervention in underserved communities, more rigorous trials need to be conducted. In addition, empirical studies need to also examine what, if any, long-term effects exist after the intervention has been completed.