



DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

3 JUN 2016

MEMORANDUM FOR SGQA
ATTN: ELLEN COBB

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Glucagon Kits: Are Your Parents Prepared for a Hypoglycemic Emergency** presented at/published to **AADE in Practice** with MDWI 41-108, and has been assigned local file #**16206**.
2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

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NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

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PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

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5. PROTOCOL TITLE: **(NOTE: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)**
QA/QI study

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:
Glucagon Kits: Are Your Patients Prepared for a Hypoglycemic Emergency?

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13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email) Cobb, Ellen, C., ellen.cobb@us.af.mil	14. DUTY PHONE/PAGER NUMBER 210-292-2818
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15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

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f.			

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

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26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: NO YES If yes, give date. _____ N/A

27. COMMENTS APPROVED DISAPPROVED
 -Originally submitted 5/9/2016. Missing Supervisors Signature/DoD Disclaimer. Sent back on 5/11/2016. Resubmitted 5/12/2016 with corrections. MEW
 - Form 3039 received for review on 31 May. The article is approved.

28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER Rocky Calcote, PhD, Clinical Research Administrator	29. REVIEWER SIGNATURE CALCOTE ROCKY.D.1178245844 <small>Digitally signed by CALCOTE ROCKY D 1178245844 DN: cn=Rocky D. Calcote, email=rocky.d@us.af.mil, o=USAF Date: 2016.05.11 11:28:03 -0500</small>	30. DATE
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Glucagon Kits

Are Your Patients Prepared for a Hypoglycemic Emergency?

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Keywords: Glucagon kits, severe hypoglycemia

Hypoglycemia is responsible for approximately 100,000 emergency room visits per year in the United States at a cost of about \$120,000,000.¹ The American Diabetes Association (ADA) recommends people with diabetes have an immediate source of glucose to treat mild or moderate hypoglycemic episodes and a prescription glucagon kit for the treatment of severe hypoglycemic episodes. Instructing patients on the risk, avoidance, and treatment of hypoglycemia is a core component of Diabetes Self-Management Education.

The ADA defines hypoglycemia as a condition characterized by abnormally low blood glucose levels, usually less than 70 mg/dl. While all hypoglycemia is of concern, mild to moderate hypoglycemia typically does not constitute an emergency and can be treated by the individual with the ingestion of 15 grams of a quick acting simple carbohydrate, such as glucose tablets or gel, regular juice or soda, sugar, honey, or candy such as gummy bears or jellybeans. Treatment of severe hypoglycemia requires assistance from others and is considered a medical emergency. If unconsciousness or the inability to eat or drink occurs, glucagon may be administered by injection to raise the glucose levels to normal. A hypoglycemia emergency plan should be established, including training a caregiver to correctly assess the situation, knowing the location of the kit, and proper administration of the life-saving medication.

Glucagon, a hormone produced by the pancreas, stimulates the liver to produce and release stored glucose into the bloodstream. Injectable glucagon kits are available as a medication to treat severe hypoglycemia. While the safety of glucagon administered by trained non-medical personnel is well established, the treatment has been reported as underutilized.²

Risk factors for severe hypoglycemia include length of time living with diabetes and previous episodes of severe hypoglycemia. Individuals with type 1 diabetes are at increased risk,

especially if they are trying to obtain tight glucose management. Approximately 25% of people with type 1 diabetes have impaired hypoglycemia awareness and are more likely to experience severe hypoglycemia requiring assistance from a third party.³ When assessing the care and resources of insulin pump patients, Meade and Rushton found the lack of an in-date glucagon kit was a common area of deficiency.⁴ The glucagon kit should not be used past its expiration date to ensure proper action of and response to glucagon.

Our team at the Diabetes Center of Excellence (DCOE) at Joint Base San Antonio-Lackland chose to assess if our patients had an emergency plan in place consisting of a current prescription for glucagon, availability of the glucagon, and someone trained to administer it in the time of need.

A Quality Improvement Project to Investigate Glucagon Access and Utilization

A quality improvement project was developed to investigate the accessibility and use of glucagon for patients in our clinic. This process was projected to continue for 12 months. The patients targeted were all type 1 patients (insulin pump or multiple daily injections) and type 2 patients using insulin pumps. The patients were identified each day prior to their clinic appointments and were provided with a short questionnaire during the screening process. This form was then given to the providers for review and, if needed, glucagon was ordered and verbal and written instructions were given to the patients. The clinical staff recorded answers to the following questions:

- Do you have glucagon in your home? Yes or No
- Is it expired? Yes, No, or Don't know
- Have you had a hypoglycemic event that required assistance? Yes or No
- Who was taught to use glucagon? You, Family member, Other, No one

Initial data was primarily collected during 2013. The providers were required to complete the bottom of the questionnaire answering the following questions:

- Did you review this form?
- Did you order glucagon?

This process was repeated in 2015 for 7 months to determine if the improvements made as a result of our project were sustained. The same target population was used.

Results

A total of 218 patients were surveyed in 2013 and 200 patients in 2015. Approximately two-thirds (67.4%) of the patients in 2013 and 57% in 2015 utilized insulin pump therapy with the remaining patients using multiple daily injections (MDI) to administer insulin. There were 132 patients who participated in both surveys.

Figure 1 compares the patient response to the 2013 and 2015 surveys. There was a significant increase from 2013 to 2015 in the presence of glucagon kits in the home. However, there was no significant difference in the percentage of patients that either have expired glucagon at home or do not know whether it is expired or not. A smaller percentage of patients affirmed the presence of in-date glucagon.

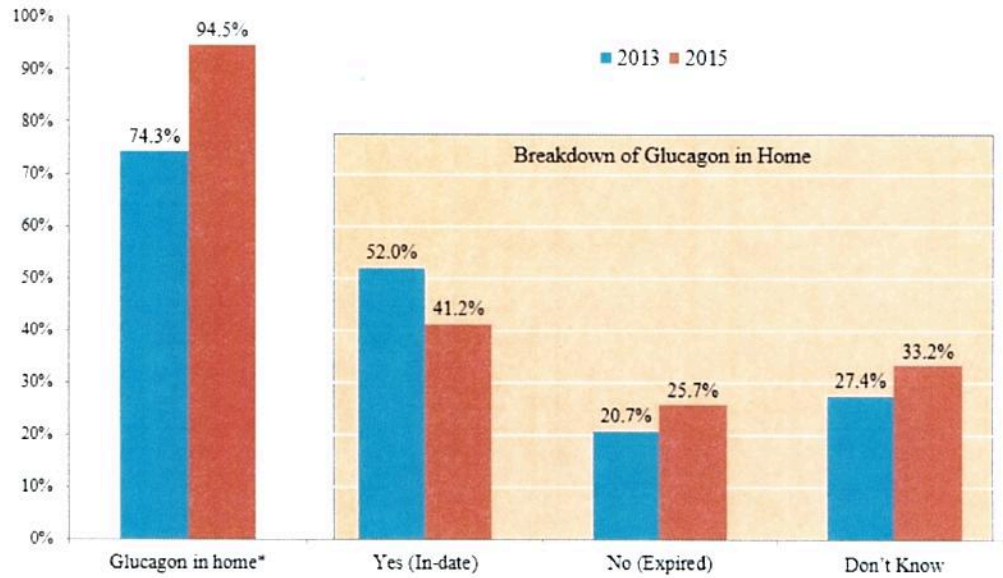


Figure 1. Comparison of Patient Reported Glucagon in the Home in 2013 and 2015

The percentage of family members trained to administer glucagon increased significantly from 50.8% in 2013 to 79.7% in 2015 (Figure 2). The percentage of patients educated in glucagon administration also significantly increased from 66.2% to 83.2%. Only 1.5% of patients in 2015 reported that no one knew how to use glucagon.

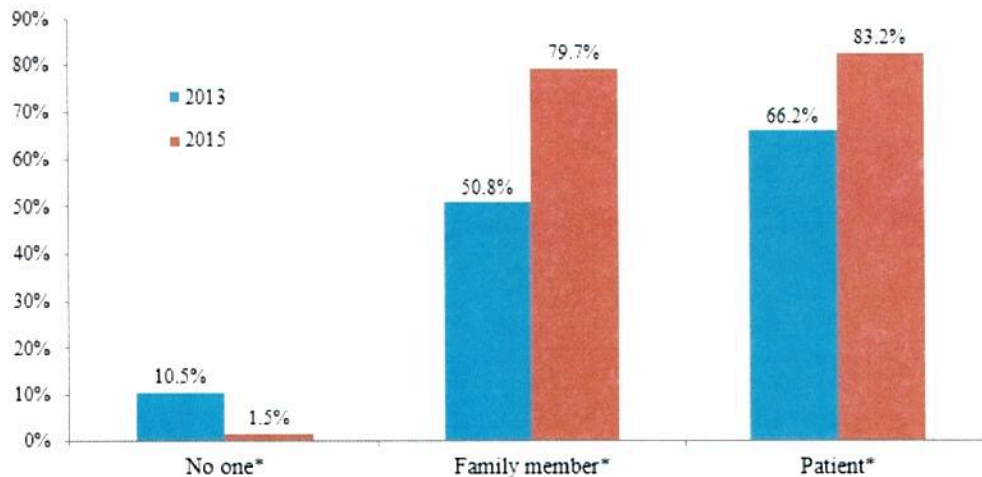


Figure 2. Comparison of Glucagon Trained People in 2013 and 2015

Since our population in the Department of Defense (DoD) tends to be transient, we looked at subgroups including the 132 individuals who participated in both surveys and those who only participated 2013 or 2015 to see if the data reflected a change as a result of the intervention or of other confounding factors associated with the improvement. Results were very similar to the overall population; thus, we infer the improvement observed was the result of our intervention.

Discussion

As this project progressed, we realized assumptions were being made by our providers that our insulin pump patients and patients with type 1 diabetes had glucagon readily available and a plan in place to receive it in the event of a severe hypoglycemic reaction. It was also assumed the patients would contact us when they needed a new prescription. As a result of the 2013 survey, we investigated ways to increase staff awareness and to incorporate an ongoing assessment for addressing hypoglycemia and the need for glucagon in our patient population. An addition to the patient convenience files now tracks all patients identified as using an intensive insulin regimen which places them at risk for severe hypoglycemia. A note in the convenience file alerts staff to address the need for initiating or renewing the glucagon prescription, generating or updating the emergency plan, and educating the patient's friends or family members on how to administer glucagon in the event of a severe hypoglycemic reaction.

Additionally, a patient handout was developed to facilitate training for home reference. Glucagon training kits were obtained from both Lilly and Novo Nordisk for training in the clinic. We share a free phone app created by Lilly that provides virtual training on how to administer glucagon and a reminder system for an approaching expiration date of the glucagon kit.

During the individual training sessions, it was noted that many identified support people had a fear of needles and of giving shots. This challenge was addressed by offering in-clinic training for the support person. We also recommend the patient teach the individual how to check blood glucose levels and assist in administering insulin. Familiarization with the diabetes equipment and the injection technique during a non-stressful time was felt to increase the confidence needed during an emergency.

Many of our patients stated that there were only children in the home and most underestimated the abilities of a young person to recognize hypoglycemia symptoms and administer emergency glucagon if needed. We have instructed children as young as seven years of age to administer glucagon and to call 911. The administration of glucagon may ordinarily omit the need for EMS assistance, but this step was included in the instruction for children. Thirteen minutes is the average response time for glucagon⁵ and seemingly is a long time to wait, so children are instructed to call EMS and unlock the front door, so they will not be alone.

Adult learners and children are instructed on the proper storage, preparation and the injection of the glucagon. We teach that glucagon may be administered almost anywhere on the body and we emphasize that it may be injected through the clothes if needed.

We encountered a small group of patients that lived alone and had no friends or family to administer the glucagon. We provided these patients with contacts to local companies that provided emergency home monitoring systems. We encouraged these patients to identify and consider other options of support (e.g. neighbors, church members, coworkers) as potential participants in their emergency plan.

Upon implementation of the project, we realized we did not consider some of the cost related issues. Within the DoD, medications are predominantly provided by the Military

Treatment Facility (MTF) pharmacy. The pharmacies maintain an inventory based on past and present utilization, and budget accordingly. We neglected to inform the pharmacy of our project and as a result, the supply of glucagon was quickly depleted which brought about an unexpected increase in costs to the facility.

DoD beneficiaries receive medications at little or no co-pay, but the cost of glucagon to non-DoD beneficiaries could be prohibitive for some patients. An online cost comparison suggests the estimated cash price is about \$244 to \$271. Even with insurance, a patient may have a substantial co-pay; many patients report paying about \$100 out-of-pocket. For patients experiencing financial hardship, the manufacturer of glucagon have a patient assistance program.

Manufacturers of glucagon state that the medication has a shelf life of twenty-four months; however, that does not mean the patient is receiving a kit that will not expire before two years. Often, the kits have been in pharmacy storage for some time before the patient fills the prescription. Therefore, it is important for patients and family members to be aware of the expiration date on their glucagon kit and request a new one before it expires. The phone app, previously mentioned, has a place to record the expiration date and receive a reminder to get a new kit.

There are some interesting new delivery systems for glucagon on the horizon. For example, in trials, a nasal spray containing powdered glucagon was shown to be highly effective in treating severe hypoglycemia.⁵ Since it does not require mixing and needles are not involved, it may be easier for a third party to administer. Even though it took longer to take effect (16 minutes versus 13 minutes for the Glucagon injection), it took less time to administer (16 to 26 seconds versus 1.9 to 2.4 minutes for the injection).⁵

Tracking glucagon availability and training may be an important intervention to increase safety for those at risk for severe hypoglycemia. This simple project can be replicated in other clinics to ascertain glucagon access and utilization in patients at risk for severe hypoglycemia. Patients with type 2 diabetes on intensive insulin therapy may also be included as they may be at increased risk for severe hypoglycemia.

References

1. Kedia, N. Treatment of severe diabetic hypoglycemia with glucagon: An underutilized therapeutic approach. *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*. 2011; 4:337.
2. Meade, LT., Rushton, WE. Optimizing Insulin Pump Therapy A Quality Improvement Project. *The Diabetes Educator*. 2013; 39(6):841-847.
3. Mitchell, BD, He, X, Sturdy, IM, Cagle, AP, Settles, JA. Glucagon prescription patterns in patients with either type 1 or type 2 diabetes newly prescribed insulin. *Endocrine Practice*. 2015. In press.
4. Otway, D. Glucagon for the treatment and prevention of severe hypoglycemia in people with diabetes. *Diabetic Hypoglycemia*. 2014; 6(3):18-22.
5. Rickels, M. R., Ruedy, K. J., Foster, N. C., Piché, C. A., Dulude, H., Sherr, J. L., ... & Ahmann, A. J. (2016). Intranasal Glucagon for treatment of insulin-induced hypoglycemia in adults with type 1 diabetes: a randomized crossover noninferiority study. *Diabetes Care*, 39(2), 264-270.

List of Figures:

Figure 1. Comparison of Patient Reported Glucagon in the Home in 2013 and 2015

Figure 2. Comparison of Glucagon Trained People in 2013 and 2015

All authors declare that neither members of the clinical team nor any relatives have any financial arrangements or affiliation with a commercial organization which would relate to content presented or to commercial support of the activities.

“The views expressed are those of the {author(s)} [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components.”

Acknowledgements: Tammy Swigert, MSN, RN, CDE Aurora CO