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Using a Clinical Surveillance System to Detect Drug-Associated Hypoglycemia in Nursing Home Residents

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Elements of Financial/Personal Conflicts	*CMC		SP		ZAM		SLKG		SMH	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
Employment or Affiliation		X		X		X		X		X
Grants/Funds		X		X		X		X		X
Honoraria		X		X		X		X		X
Speaker Forum		X		X		X		X		X
Consultant		X		X		X		X		X
Stocks		X		X		X		X		X
Royalties		X		X		X		X		X
Expert Testimony		X		X		X		X		X
Board Member		X		X		X		X		X
Patents		X		X		X		X		X
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Abstract

Background/Objectives—Hypoglycemia is a common adverse drug event (ADE) frequently associated with temporary harm in the nursing home (NH) setting. Reports from the Office of the Inspector General and the U.S. Department of Health and Human Services recommend the need for increased surveillance of drug-associated hypoglycemia events. The objective of this study was to test if a clinical surveillance system could be used to detect drug-associated hypoglycemia events and determine their incidence in NH residents

Design—Retrospective cohort

Setting—Four NHs in Western Pennsylvania

Participants—Computer-generated alerts detecting potential drug-associated hypoglycemia in residents with glucose ≤ 70 mg/dL and ordered a medication(s) associated with hypoglycemia over a 6-month period were included.

Measurements—Descriptive statistics were used to summarize all variables, including the frequency and distribution of alert type by glucose threshold. Analyses were conducted per numbers of alerts and per distinct residents. The frequency of medications associated with the alerts was determined. Additional calculations included the time to drug-associated hypoglycemic event alert from date of admission and frequency of events associated with post-acute/short-stay (≤ 35 days) admissions.

Results—Total of 772 alerts involving 141 unique residents were detected. Ninety (63.8%) residents had a glucose ≤ 55 mg/dL, and 42 (29.8%) had a glucose ≤ 40 mg/dL alert. Insulin orders were associated with 762 (98.7%) alerts. Overall incidence of drug-associated hypoglycemia events was 9.5 per 1000 resident-days.

Conclusion—Hypoglycemia can be detected using a clinical surveillance system. Our evaluation found a high incidence of drug-associated hypoglycemia in a general NH population. Future studies are needed to determine the potential benefits of use of a surveillance system in real-time detection and management of hypoglycemia in the NH.

Keywords

hypoglycemia; nursing home; clinical surveillance; adverse drug event detection

Hypoglycemia has been reported in as many as 70% of diabetic nursing home (NH) residents.[1,2] Effective detection and management of hypoglycemic episodes in NH residents is hampered by infrequent access and review of glycemic trend data, and lack of glucose management algorithms, including provider alerting and communication of events.[3] A recent Office of Inspector General (OIG) report stated that drug-associated hypoglycemia events were the most common cause of temporary harm related to medications (i.e., adverse drug events; ADEs) in U.S. NHs.[4] In another recent report, the U.S. Department of Health and Human Services' Office of Disease Prevention and Health Promotion released the National Action Plan for Adverse Drug Event Prevention (ADE Action Plan) highlighted three types of ADEs that were considered to be common, clinically significant, preventable

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and measurable.[5] The three initial target medication classes included anticoagulants (primary ADE of concern is bleeding), opioids (primary ADE of concern is overdose/oversedation) and diabetes agents (primary concern drug-associated hypoglycemia events).

The OIG report and the ADE Action Plan suggest that there needs to be improvements made to methods of surveillance, detection, management, and prevention of drug-associated hypoglycemic events.[4,5] As an initial response to these reports, the objectives of this study were to test a clinical surveillance system, primarily used in the hospital setting, to determine if a modified system could be used to detect drug-associated hypoglycemia events, and to determine the incidence of these events in NH residents.

Methods

Setting

The study was conducted in four nonprofit, academically-affiliated NHs that are part of an integrated healthcare delivery system located in Southwestern Pennsylvania. These facilities are dually certified as both skilled nursing facilities and NHs equipped to provide care for residents with a variety of medical conditions. Two NHs are in an urban setting and two are suburban. These four NHs range in bed size from 80 to 174 for a total of about 550 beds. There are a combined estimated 1900 admissions annually to these four facilities. Subjects included any resident from one of the four NHs whose stay was between 10/23/2012 and 04/22/2013 and were being treated for any condition. Subjects did not need to be treated for diabetes to be included in this study.

Data Source and Collection

The TheraDoc™ Clinical Surveillance System (Premier, Inc., Charlotte, NC), licensed by UPMC for use in acute care hospitals and NHs, was programmed by a study investigator (CC) with rule parameters to automate the detection of drug-associated hypoglycemia in NH residents for research purposes. To trigger a drug-associated hypoglycemia alert, a glucose result ≤ 70 mg/dL and ≥ 1 concurrent order for a medication reported in the literature to be associated with hypoglycemia were required.[3,6] Blood glucose readings from either venipuncture or fingerstick blood glucose (FSBG) were transmitted electronically to the surveillance system using HL7-compliant interfaces during routine care of the residents. The FSBG results were obtained by nursing using LifeScan SureStep® (LifeScan, Inc. Milpitas, CA) glucometers and entered manually into the Accu-Flo electronic medication administration record (Creative Strategies, Louisville, KY).

An expert panel of physicians and pharmacists developed the knowledge base of medications for the drug-associated hypoglycemia alert, as previously described.[7] The alert-triggering medications or medication classes included dipeptidyl pepitadase-4 inhibitors, disopyramide, insulins, levofloxacin, meglitinides, octreotide, pentamidine, quinidine, and sulfonylureas, as single ingredient or in combination product with other antidiabetic medications.

The alerts generated by the surveillance system were part of work related to the parent Agency for Healthcare Research and Quality (AHRQ)-funded study for ADE detection and

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management (NCT01531088). The computer generated these alerts prospectively during the routine care of the residents; however, these alerts were not received or reviewed by clinicians at that time. The alerts were retrospectively evaluated for the purposes of this evaluation.

Data Analysis

Data were evaluated for residents whose primary physician consented to participate in the parent AHRQ-funded study, as noted above. This study was approved by the University of Pittsburgh IRB.

In order to analyze hypoglycemia alerts from eligible NH residents, a series of steps were taken to exclude alerts that included nonparticipating physicians, erroneous nursing data entry of FSBG results of zero, glucose results collected during hospital visits/admissions at UPMC hospitals, and duplicate alerts prior to analysis. Duplicate alerts were defined as those with identical glucose readings based on the date and time of data collection, result (a known limitation of the laboratory information system), and medication(s) listed.

Descriptive statistics (means, standard deviations, frequencies) were used to summarize all variables, including the frequency and distribution of alert type by glucose threshold of ≤ 70 mg/dL, ≤ 55 mg/dL, and ≤ 40 mg/dL[5,6,8] and collection method (venipuncture or FSBG). We performed analyses both in terms of numbers of alerts and number of distinct residents for whom the alerts were generated. The medications associated with the drug-associated hypoglycemia alerts were identified and frequencies calculated. The time to drug-associated hypoglycemic event alert from date of admission was calculated. Similar to the OIG report, we also analyzed the frequency of events associated with post-acute/short-stay (≤ 35 days) admissions.[4] All analyses were conducted using SAS version 9.2 (SAS® Institute, Inc., Cary, NC).

Results

A total of 893 alerts were generated during the 6-month study period. After applying exclusion criteria, 772 drug-associated hypoglycemia alerts remained for 141 distinct residents with a mean (± SD) age of 76.3 ± 13.0 years.

Of these 141 residents, 90 (63.8%) residents had 221 (28.6%) alerts with a glucose level ≤ 55 mg/dL, and 42 residents (29.8%) triggered 61 alerts (7.9%) with ≤ 40 mg/dL. Most residents had one (n = 45; 31.9%) or two (n = 30; 21.3%) alerts fire during the study, while the remaining residents had between 3 and 50 alerts. The majority of alerts fired from FSBG (n = 695; 90.0%) data, while the rest were from venipuncture (n = 77; 10.0%). Concomitant medications captured by the drug-associated hypoglycemia alerts are listed in **Table 1**. An active order for insulin was detected in 98.7% (762 of 772) alerts. Of note, 623 alerts included at least one insulin order written as a sliding scale (80.7%).

During the study, there was at least one alert for 141 of the 1101 distinct residents representing a 12.8% incidence of drug-associated hypoglycemia events. This translates into an overall incidence of drug-associated hypoglycemia events of 9.5 per 1000 resident-days.

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In over half of the residents (n = 83; 58.9%) with a hypoglycemia alert, the first alert fired within 35 days of NH admission.

Discussion

Prior studies have found detection of hypoglycemia with glycemic control monitoring with computerized systems in hospital settings to be an efficient method of surveillance.[9-12] To the best of our knowledge, this is the first study to prospectively use a computerized clinical surveillance system to detect and determine the incidence of drug-associated hypoglycemia in NHs. Our study is responsive to the OIG's recommendation to raise awareness of ADEs in post-acute care and seeks to reduce harm to NH residents through mirroring methods used to promote medication safety and adverse event detection in the hospitals.[4]

Our results suggest that the overall incidence of drug-associated hypoglycemia was 9.5 per 1000 resident-days in a general NH population. Incidence rate has not been reported by other studies in the NH setting. The closest comparator is the overall incidence of all-cause temporary harm events of 11 per 1000 resident-days reported by the OIG.[4] The all-cause temporary harm events in the OIG report included medication-related events (e.g., hypoglycemia, fall or trauma, delirium or mental status change, allergic reactions), as well as events related to resident care (e.g., pressure ulcers, fall or trauma), and infections. The report does not provide an incidence for drug-associated hypoglycemia alone. When compared to the OIG incidence of temporary harm, our incidence of drug-associated hypoglycemia appears to be high. One explanation for the difference in incidence could be that the OIG report used a representative sample of all Medicare NH residents who had a NH length of stay of ≤ 35 days. Our study included residents regardless of length of stay and showed that drug-associated hypoglycemic events occurred in over 40% of residents who stayed beyond 35 days in the study facilities.

In 80.7% of all alerts, our system detected sliding scale insulin (SSI) as one of the medications associated with drug-associated hypoglycemia. Although SSI is not recommended for routine treatment of diabetes in the elderly due to the risk of hypoglycemia and lack of improvement in hyperglycemia management,[8,13,14] it was frequently associated with hypoglycemia alerts detected by our system and hypoglycemic events reported in the literature.[15] Newton et al[1] reported that 184 of 436 residents (42%) with type 2 diabetes experienced at one or more episode(s) of mild hypoglycemia (< 70 mg/dL) and 31 residents (7%) with serious hypoglycemia (< 40 mg/dL). Residents in this study received insulin 64.0% of the time and sulfonylureas 18.8% of the time. Of the 356 residents receiving SSI alone or in combination with basal or premixed insulins or oral hypoglycemics, 151 experienced a hypoglycemic event (42%). Pandya and colleagues[13] retrospectively assessed the use of SSI in a cohort of 2,096 residents from 117 NHs with type 2 diabetes receiving insulin over a one-year period. Glycemic control, indicated by HbA1c at or below the suggested treatment goals, was achieved for more residents receiving the non-SSI regimens compared with SSI-containing regimens. However, they found that hypoglycemic events (glucose ≤ 70 mg/dL) occurred in roughly the same frequency for those residents who received or did not receive SSI (14.9% and 15% respectively). These

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studies illustrate that SSI may be associated with a higher incidence of hypoglycemia and that its use may result in poor glycemic control with a higher FSBG burden.

Our study was also responsive to the *ADE Action Plan* in that we were able to link pharmacy and laboratory data from the NH in an electronic fashion. We did this without using a more integrated electronic medical record (EMR) as suggested in the report. The use of a stand-alone clinical surveillance system, as the one used in this study, may be particularly beneficial and more generalizable for ADE detection, since EMR penetration rates remain low in SNFs.[16] We believe that our system is feasible in other NHs since systems similar to what we describe in this study can be developed in conjunction with the NHs laboratory and/or pharmacy service providers. Even in those NHs where there are insufficient resources or health information technology expertise, NHs can implement more manual-based approach using trigger tools.[7] The trigger tool methodology, developed in part by the Institute of Healthcare Improvement (IHI), simplifies the chart review process by allowing rapid and systematic examination of charts to extract relevant data for the detection of potential ADEs.[17] We also agree with these reports' suggestions[4,5] that further research is needed to couple real-time detection of drug-associated hypoglycemic events with management in the NH setting and to assess its impact on outcomes, such as emergency department visits, falls, and/or hospitalizations, regardless of the surveillance system strategy used – computer or paper. It is important to note that admission to the hospital for hypoglycemia is considered a potentially avoidable hospitalization from the NH by the Centers for Medicare and Medicaid Services.[18]

Our study has several limitations that deserve mention. First, TheraDoc™ does not have an interface with medication administration records at our facilities; therefore, medications are identified by active orders in the pharmacy system. This means that medications associated with the hypoglycemia alerts may have been prescribed, but not administered or held in response to NH hypoglycemia treatment protocols. This could falsely elevate the incidence of drug-associated hypoglycemia. Second, no formal causality assessment tool was used to exclude competing factors for hypoglycemia for these residents, such as co-morbid disease and asymptomatic episodes not requiring management. Therefore, we were unable to determine the most likely medication(s) implicated in the hypoglycemia events when multiple medications were prescribed. Third, we did not assess the reliability of system or directly compare it to other clinical surveillance systems. However, the rules used to develop the clinical surveillance system have been using the trigger tool method in VA nursing homes.[7] Finally, this study included a limited number of NHs in a geographically-restricted area which may limit its generalizability.

Our results suggest that computerized clinical surveillance systems have the potential to detect hypoglycemic events in real-time – a current significant barrier to providing safe NH clinical care. However, regardless of the system used, *detection* of these events is not sufficient. We believe that innovative ways are needed to communicate hypoglycemic events that have been *detected* coupled with specific *recommendations* as to how to manage the current event, as well as prevent their future occurrence. To better understand how to improve communication of these events, our research group has surveyed nursing home physicians to learn about (1) the laboratory value thresholds that a clinical surveillance

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system should use to generate alerts about potential ADEs, (2) the specific information to be included in ADE alerts, and (3) the communication modality that should be used for delivering the alerts (e.g., pager, smartphone, email, fax).[19] Our results suggest that the majority of physicians want to be alerted when the glucose value is ≤ 70 mg/dL, that they should be provided with a complete active medication list, current vital signs, previous values of triggering labs, medication changes in the past 30 days and allergies, and that alerts should be communicated by direct phone conversations or by emails sent to mobile devices. We are currently evaluating the results of an AHRQ-funded RCT (NCT01531088) to determine if a pharmacist-led intervention using a computerized clinical surveillance system to automate the detection of potential ADEs coupled with SBAR (Situation, Background, Assessment, and Recommendation) formatted emails that provide specific recommendations to NH physicians can improve the detection and management of these events. If the results are positive, this may create a generalizable model that can significantly improve medication safety in NHs.

Conclusion

Hypoglycemia can be detected using a clinical surveillance system. Hypoglycemia is a common adverse drug event (ADE) frequently associated with temporary harm in the NH setting. Recent reports from the Office of the Inspector General and the U.S. Department of Health and Human Services targeting ADEs recommend the need for increased surveillance of drug-associated hypoglycemia events. Our evaluation found a high incidence of drug-associated hypoglycemia in a general NH population. Future studies are needed to determine the potential benefits of use of the automated surveillance system in real-time detection and management of hypoglycemia in the NH.

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Table 1

Frequency of medications in drug-associated hypoglycemia alerts

Medication Class	Generic (Brand) Medication Names	# Alerts	Totals
Sulfonylurea			188
	Glimepiride (Amaryl®)	61	
	Glipizide (Glucotrol®)	109	
	Glipizide extended-release (Glipizide XL®, Glucotrol XL®)	15	
	Glyburide (Diabeta®, Glynase®)	3	
Insulin; rapid-acting			599
	Insulin lispro (Humalog®)	111	
	Insulin lispro (Humalog® Sliding Scale	286	
	Insulin aspart (Novolog®)	80	
	Insulin aspart (Novolog®) Sliding Scale	122	
Insulin; short-acting			219
	Insulin regular (Humulin® R, Novolin® R)	9	
	Insulin regular (Humulin® R, Novolin® R) Sliding Scale	210	
Insulin; intermediate-acting			42
	Insulin NPH (Novolin® N, Humulin® N)	42	
Insulin; basal			528
	Insulin glargine (Lantus®)	461	
	Insulin detemir (Levemir®)	67	
Insulin; premixed			76
	Insulin lispro protamine/insulin lispro (Humalog® Mix 50/50™)	8	
	Insulin lispro protamine/insulin lispro (Humalog® Mix 75/25™)	20	
	Insulin NPH and insulin regular (Humulin® 70/30, Novolin® 70/30)	31	
	Insulin aspart protamine and insulin aspart (Novolog® Mix 70/30)	17	
Dipeptidyl peptidase-4 inhibitor	Sitagliptin (Januvia®)	17	17
Fluoroquinolone	Levofloxacin (Levaquin®)	32	32
Somatostatin analog	Octreotide (Sandostatin®)	3	3
Meglitinide derivative			105
	Nateglinide (Starlix®)	11	
	Repaglinide (Prandin®)	94	

Note: These will not add up to 772 due to multiple medications listed in alerts.