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Diabetes outcomes before and during telehealth advancements surrounding COVID-19

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Abstract

Background: Pharmacists can optimize outcomes related to type-2 diabetes (T2D) by taking advantage of telehealth opportunities despite the coronavirus 2019 (COVID-19) Public Health Emergency (PHE).

Objective: Identify and compare changes in T2D outcomes before (August 2019 through February 2020) and during (March 2020 through October 2020) the COVID-19 PHE. Secondary objectives were to identify and compare pay-for-performance metrics and additional fee-for-service submitted in these patients.

Methods: This study examined changes in T2D outcomes at one primary care office within a community health system. Pharmacists started regularly using Remote Patient Monitoring (RPM) services during the COVID-19 PHE to reduce in-person visits. Patients with an initial glycosylated hemoglobin (A1C) greater than or equal to 8% were included. Data collected included comorbidities, change in A1C, and diabetes and statin medication therapy adherence. Percentage of Healthcare Effectiveness Data and Information Set (HEDIS) and Merit-Based Incentive Payment System (MIPS) measures were met, and billing code frequencies were also assessed.

Results: In the pre-COVID-19 PHE group (N = 30), the average 3- and 6-month A1C reductions were 1.3% and 1.2%, respectively, and the reductions were 2.0% and 2.2% in the during-COVID-19 PHE group (N = 61). The percentage of patients appropriately initiated or maintained on statins was 96.2% in the pre-COVID-19 PHE group versus 82.6% in the during-COVID-19 PHE group. Related to HEDIS, statin adherence was 95.2% in the pre-COVID-19 PHE group and 84.2% in the during-COVID-19 PHE group, and A1C control was 41.7% versus 54%, respectively. A1C control related to MIPS was 60% before COVID-19 PHE versus 73.8% during the COVID-19 PHE. Diabetes medication adherence related to HEDIS and medication reconciliation related to MIPS was 100% for both groups.

Conclusion: Data demonstrate the opportunity for pharmacists to maintain and improve clinical outcomes related to T2D despite the ongoing COVID-19 PHE through implementation of telephonic monitoring.

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outcomes. The data surrounding T2D outcomes when pharmacists are integrated into the primary care setting are less robust. Furthermore, the gap in the literature includes a lack of analysis of valuable benchmark quality measures for providers, including medication adherence and optimization of therapy.

Pharmacists have been integrated into primary care offices within St. Joseph’s/Candler (SJ/C) and collaborating with supervising providers to optimize chronic disease state management since 2017. Before the coronavirus 2019 (COVID-19) PHE, this collaboration was mainly carried out through in-person visits conducted by the pharmacist under the provider’s order and supervision. The COVID-19 PHE created various barriers to effective patient care delivery, some of which were satisfied with the promotion of telemedicine or telehealth not previously used. Although the COVID-19 PHE did allow for SJ/C pharmacists to take advantage of the relaxed supervision requirements for some pharmacy driven services, audio-visual telemedicine appointments were still reserved for Medicare providers. Subsequently, other opportunities were explored for pharmacists to provide telephonic care. These efforts led to further examination of other care opportunities such as Remote Patient Monitoring (RPM) and Chronic Care Management (CCM). Although pharmacist involvement in RPM was possible previously, the COVID-19 PHE presented a need to provide patient care through previously unexplored care avenues. RPM allows for the management of chronic disease states through audio-only telecommunication. Pharmacists are able to provide RPM services telephonically within their state-defined scope of practice and under the indirect supervision of the provider. Given the lack of federal provider status and inconsistency in state provider status and scopes of practice, there is a current need to assess the benefit and application of pharmacist collaboration in T2D management within the federal telehealth platform of RPM and CCM under indirect supervision of a Medicare provider. The purpose of this study was to identify and compare the overall change in T2D outcomes before and after the COVID-19 PHE versus during the COVID-19 PHE with the application of telehealth opportunities.

Objectives

The primary objective of this study was to determine the overall change in pharmacist-managed A1C before and after implementation of pharmacist-driven telehealth services during the COVID-19 PHE. Secondary objectives were to determine the percentage of patients with T2D on appropriate statin therapy, adherence to statin and T2D medications as it relates to meeting Healthcare Effectiveness Data and Information Set (HEDIS) and Merit-Based Incentive Payment System (MIPS) measures, and additional billing codes generated because of pharmacist-conducted visits.

Methods

This retrospective, observational study evaluated adult patients with T2D managed by a pharmacist between August 2019 and October 2020. Data obtained during this time period allowed for analysis of outcomes both before and during the COVID-19 PHE. Patients with pharmacist interaction from August 2019 through February 2020 were considered part of the pre—COVID-19 PHE group. Patients who had an interaction with a pharmacist from March 2020 through October 2020 were included in the during—COVID-19 PHE group. Although patients were occasionally contacted by phone before the COVID-19 PHE, these interactions were not as robust or comprehensive until changes were made to the pharmacists’ workflow to accommodate the COVID-19 PHE using telehealth.

Two pharmacists work a combined total of 40 hours a week in this particular primary care office collaborating with physicians through annual wellness visits and the management of chronic disease states such as T2D, hypertension, hyperlipidemia, and osteoporosis. The pharmacists managed T2D for patients referred to the pharmacist by their primary care provider within the office. The pharmacists have Collaborative Drug Therapy Modification protocols on file with the Georgia Board of Pharmacy. Two postgraduate year 2 (PGY-2) pharmacy residents also assisted with the visits during the study period. The pharmacists manually added a nonbillable code to all patient interactions to demonstrate pharmacist involvement. A retrospective report was generated to identify all patients who had this code added to their chart during the study period. The patients on this report were assessed to identify whether the interaction was related to T2D management. Subjects were included if they were aged 18 years or older with T2D managed by pharmacists at least once in the aforementioned time frame and had an initial A1C value of at least 8%. Patients were excluded if they had type-1 diabetes, were pregnant, or had an initial A1C value of less than 8%. Although the majority of patients are treated to an A1C goal of less than 7%, for the purposes of this study and pharmacist resources to provide increased telehealth services, data collection was restricted to A1C greater than or equal to 8%.

Information gathered for study subjects included their history of T2D, A1C values, and medication therapy adherence. Demographic data collected included age, sex, and comorbidities such as hyperlipidemia, hypertension, and history of atherosclerotic cardiovascular disease (ASCVD) (Table 1). Patients who did not have A1C values for a certain time period were excluded from that calculation. For example, if a patient did not have an A1C value obtained 6 months after their initial A1C, they would have been excluded from the average change in 6-month A1C. The average change in A1C data included patients who had a value for that time frame in addition to the initial A1C value.

Incidence of MIPS and HEDIS measures pertaining to T2D outcomes were analyzed. MIPS collects quality data from the entire patient population and applies the future payment adjustment to Medicare payments only. HEDIS collects quality data from only the managed commercial population and applies future payment to only the managed commercial population. MIPS A1C control is reported to the Centers for Medicare and Medicaid (CMS) through the Quality Payment Program as A1C control greater than 9% in the entire diabetes population age 18–75 years. This is an inverse measure because higher numerators mean less population control of A1C. HEDIS A1C control is reported as A1C less than 8% and only in the managed care insured population under quality payment models. All quality reporting is submitted under physician National Provider Identification as a Medicare provider. For the purposes of consistency for this retrospective review, our data...
reported A1C control of less than 9% (MIPS) and less than 8% (HEDIS).

The percentage of patients appropriately on statin therapy and statin use in persons with diabetes was defined as patients with T2D between the ages of 40 and 75 years who are prescribed statin therapy. Medication adherence for T2D and statin medications was confirmed at PBM claim review or at the time of medication reconciliation. Only 1 payer of managed care provided PBM claim review at the close of data collection. Billing codes generated because of pharmacist visits were also assessed. A 99457 code was billed for visits in which RPM was utilized (Table 2). For a 99457 code to be billed, telephonic interaction had to take place for at least 20 minutes during that month. Specific templates were utilized to ensure appropriate documentation and record keeping. This study was approved by the SJ/C Institutional Review Board.

Statistical analysis was performed using a z test for both primary and secondary outcomes to compare data in the pre–COVID-19 PHE group with that in the during-COVID-19 PHE group. All outcomes are described in detail in Table 2.

Table 1
Patient demographics

| Characteristic               | Pre–COVID-19 PHE n (%) | During COVID-19 PHE n (%) |
|------------------------------|------------------------|--------------------------|
| Age in y, mean (SD)          | 60.8 (13.03)           | 62.1 (10.77)             |
| Male sex                     | 11 (37)                | 27 (44)                  |
| Female sex                   | 19 (63)                | 34 (56)                  |
| Patients with hyperlipidemia | 24 (80)                | 45 (74)                  |
| Patients with hypertension   | 24 (80)                | 47 (77)                  |
| Patients with ASCVD history  | 6 (20)                 | 14 (23)                  |

Abbreviations used: PHE, public health emergency; ASCVD, Atherosclerotic cardiovascular disease.

Table 2
Primary and secondary outcomes

| Measure                        | Pre–COVID-19 PHE % (SD) | During COVID-19 PHE % (SD) | P value |
|--------------------------------|--------------------------|----------------------------|---------|
| A1C reduction                   |                          |                            |         |
| 3-month A1C mean reduction     | −1.3 (1.80)              | −2 (2.34)                  | .305    |
| 6-month A1C mean reduction     | −1.2 (1.98)              | −2.2 (3.03)                | .249    |

| Measure                        | Pre–COVID-19 PHE n (%) | During COVID-19 PHE n (%) | P value |
|--------------------------------|------------------------|--------------------------|---------|
| Appropriately on statin        | N = 26                 | N = 46                   | .19     |
| HEDIS measure: SUDD           | 25 (96.2)              | 38 (82.6)                | .3      |
| HEDIS measure: Statin adherence | 20 (95.2)              | 32 (84.2)                | .34     |
| HEDIS measure: Diabetic medication adherence | 24 (100) | 50 (100) | 1.00 |
| HEDIS Measure: A1C control (<8%) | 10 (41.7)              | 27 (54)                  | .345    |
| MIPS Measure: Med reconciliation | 30 (100)              | 61 (100)                 | 1.00    |
| MIPS Measure: A1C control (<9%) | 18 (60)                | 45 (73.8)                | .337    |

| Billing code                  | Pre–COVID-19 PHE n (%) | During COVID-19 PHE n (%) | P value |
|--------------------------------|------------------------|--------------------------|---------|
| Total codes                   | 47 (100)               | 105 (100)                | <.0001  |
| 99211 (in person)             | 32 (68)                | 34 (62.4)                | <.0001  |
| 99212 (in person)             | 1 (2.1)                | 5 (4.8)                  | .226    |
| 99213 (in person)             | 6 (12.8)               | 17 (16.2)                | .317    |
| 99214 (in person)             | 8 (17)                 | 11 (10.5)                | .165    |
| 99457 (virtual)               | 0 (0)                  | 38 (36.2)                | <.0001  |

Abbreviations used: PHE, public health emergency; HEDIS, Healthcare Effectiveness Data and Information Set; MIPS, Merit-Based Incentive Payment System.

a Includes all patients aged 40 to 75 years on statin therapy.
b Statin use in persons with diabetes: Includes patients with commercial insurance only who are aged 40 to 75 years on statin therapy.
c Includes all patients with commercial insurance with diabetic medications documented in their electronic medical record.
d Includes all patients with commercial insurance.
e Includes all patients regardless of insurance type.

Results

A total of 91 patients had their T2D managed by pharmacists during the study period and met the inclusion criteria. Thirty of these patients were included in the pre–COVID-19 PHE group, and 61 patients were included in the during-COVID-19 PHE group. There was a total of 13 patients who overlapped between the 2 groups. Patient demographics and comorbidities are detailed in Table 1. The average 3- and 6-month A1C reduction in the pre–COVID-19 PHE group was 1.3% and 1.2%, respectively. A greater A1C reduction was seen at both 3 months (2%) and 6 months (2.2%) in the during-COVID-19 PHE group where patients were being followed...
telephonically (Table 2). There were more patients deemed as appropriately on statin therapy in the pre—COVID-19 PHE group (96.2%) than in the during—COVID-19 PHE group (82.6%). Of note, there were more patients in the during—COVID-19 PHE group who were not on statin therapy owing to statin allergy or intolerance, influencing the lower percentage.

The final secondary objectives are related to HEDIS and MIPS quality measures and billing outcomes. The percentage of patients appropriately initiated or maintained on a statin was 95.2% in the pre—COVID-19 PHE group and 84.2% in the during—COVID-19 PHE group as it relates to HEDIS. T2D medication adherence was 100% in both study groups. In the pre—COVID-19 PHE group, 41.7% of patients were considered to have A1C control as defined by HEDIS, whereas 54% met this measure in the during—COVID-19 PHE group. Medication reconciliation as it relates to MIPS was met 100% of the time in both study groups. In the pre—COVID-19 PHE group, 60% of patients had A1C less than 9% versus the 73.8% in the during—COVID-19 PHE group. There was an increase in total billing opportunities for the during—COVID-19 PHE group. In addition, in-person visits were reduced through the utilization of RPM services in the during—COVID-19 PHE group. All results are detailed in Table 2.

Discussion

Despite its availability before the COVID—19 PHE, RPM services were not utilized until the COVID—19 PHE presented the need to reduce in-person visits while sustaining both clinical and fiscal outcomes related to pharmacist—provided care. Implementation of these services also allowed pharmacists in this setting to maintain the same quality of direct patient care experiences for pharmacy students and residents during a time of reduced in-person visits. While there were more total in-person visits during the COVID—19 PHE, this group included twice as many patients, therefore increasing the total number of patients reached and expanding patient access. RPM allowed for this reduction of in-person visits while maintaining the same standard of patient care. A potential explanation for higher visit numbers during the COVID—19 PHE is that RPM services allowed more frequent contact with patients as it was often more convenient for them, therefore increasing engagement and rapport. Increased outcomes may be a result of this increased patient interaction.

During the study period, RPM was able to be used via telephonic systems, including audio-only, that incorporated patient—reported physiological data (i.e., self—reported blood glucose or blood pressure).3 After the study period, the release of the 2021 Physician Fee Schedule final rule changed the policies and requirements for RPM. Rather than allowing patient—reported physiological data, CMS now specifies that devices must meet the Food and Drug Administration’s definition of a medical device, and the device must automatically upload patient data.8 Although this does not change the scope or ability of pharmacist involvement as described in this article, it does mean that additional resources may be necessary to continue successful and compliant RPM programs. Currently, the patient population described in this study is being evaluated for eligibility in other similar services, such as CCM. Enrolling eligible patients in CCM would allow for continued pharmacist collaboration in patient care without the need to purchase and integrate additional monitoring devices.

There were many limitations to this research. Insurance claim data were not available to allow for a recognized assessment of statin and T2D medication adherence. However, we think that it is valuable to incorporate these metrics into our model. Patients were said to have been adherent if these medications were reconciled as taken on their electronic medical record by a pharmacist during the specified time period. There were also limitations related to MIPS and HEDIS measures reporting. HEDIS and MIPS benchmark A1C control differently; however, they are both stakeholders in pay-for-performance, so their data points are worth assessing. Of note, HEDIS measures do not account for statin intolerance or allergy resulting in a reduction in the percentage of patients with T2D on statin therapy. The final limitations involve A1C obtainment. Some of the 3—month A1C values were not drawn in a timely manner; all A1C values drawn at less than 6 months were counted as 3—month A1C values to account for this. There were also some patients who did not have an A1C value drawn at both 3 and 6 months after their initial A1C value was obtained.

Conclusion

In conclusion, data demonstrate the opportunity for pharmacists, as part of a care team, to maintain and improve clinical outcomes related to T2D, given relaxed supervision requirements and payment for telehealth services.

References

1. CDC. Prevalence of both diagnosed and undiagnosed diabetes. Available at: www.cdc.gov/diabetes/data/statistics-report/diagnosed-undiagnosed-diabetes.html. Accessed June 1, 2021.
2. American Diabetes Association. 6. Glycemic Targets: Standards of Medical Care in Diabetes—2021. Dia Care. 2021;44(Suppl 1):S73—S84 (suppl 1).
3. American Diabetes Association. 10. Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes—2021. Dia Care. 2021;44(Suppl 1):S125—S150 (suppl 1).
4. American Diabetes Association. 2. Classification and diagnosis of diabetes: standards of medical care in diabetes—2021. Dia Care. 2021;44(Suppl 1): S15—S33 (suppl 1).
5. Pousinho S, Morgado M, Falcão A, Alves G. Pharmacist interventions in the management of type 2 diabetes mellitus: a systematic review of randomized controlled trials. J. Manag. Care Spec. Pharm. 2016;22(5):493—515.
6. CMS. Medicare telemedicine health care provider fact sheet. 2020. Available at: Telehealth-CMS.gov. Accessed June 1, 2021.
7. CMS. A rule by the Centers for Medicare & Medicaid Services; revisions to payment policies under the physician fee schedule CV 2019. Available at: https://www.federalregister.gov/documents/2018/11/23/2018-24170/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-and-other-revisions. Accessed June 1, 2021.
8. CMS. Final policy, payment, and quality provisions changes to the medicare physician fee schedule for calendar year 2021. Available at: https://www.cms.gov/newsroom/fact-sheets/ finalized-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calender. Accessed June 1, 2021.

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