Targeting IA-2 and GAD65 as a Cost-Saving Approach for Antibody Testing in Children With New-Onset Diabetes

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IN BRIEF "Quality Improvement Success Stories" are published by the American Diabetes Association in collaboration with the American College of Physicians, Inc., and the National Diabetes Education Program. This series is intended to highlight best practices and strategies from programs and clinics that have successfully improved the quality of care for people with diabetes or related conditions. Each article in the series is reviewed and follows a standard format developed by the editors of *Clinical Diabetes*. The following article describes an initiative to decrease costs associated with diagnosing type 1 diabetes through the use of selective antibody testing.

Describe your practice setting and location.

This is a multidisciplinary pediatric diabetes team within an academic center in Madison, Wisc., with both inpatient and outpatient services serving a relatively diverse population (75.3% Caucasian, 8.3% Black/African-American, 5.4% Hispanic, 5.1% Asian, 1.3% American Indian/Native Alaskan, and 0.3% Native Hawaiian or other Pacific Islander) throughout Wisconsin. All of our new-onset diabetes teaching is performed on an inpatient basis with frequent outpatient follow-up visits.

Describe the specific quality gap addressed through the initiative.

This project focused on applying the American Diabetes Association's definition of type 1 diabetes (presence of autoimmune antibodies) in new-onset pediatric patients while decreasing costs. Our goal was to decrease costs by 30% without affecting diagnosis or care through the use of selective antibody testing.

How did you identify this quality gap? In other words, where did you get your baseline data?

We identified this area of excess health care spending via a retrospective chart review covering 2 years of all patients <18 years of age presenting with new-onset diabetes. Data included results of four antibody tests that are known markers for autoimmune diabetes: tyrosine phosphatase–related islet antigen 2 (IA-2), glutamic acid decarboxylase 65 (GAD65), islet cell antibody (ICA), and zinc transporter 8 (ZnT8) and a cost analysis.

Summarize the initial data for your practice (before the improvement initiative).

Of 91 patients (mean age 10 years, range 11 months to 17 years; 93.4% Caucasian, 6.6% Hispanic, 2.2% African-American, 2.2% Native American, and 0% Asian) presenting over 24 months, 14 (15.4%) had just one positive antibody test (five were positive for IA-2, five for ZnT8 antibody, four for GAD65, and none for ICA) (Supplementary Tables 1 and 2). Eighty of the 91 patients (88%) had positive test results for either one or both of the IA-2 or GAD65 tests (Supplementary Figure 1).

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Eighteen patients (19.8%) were <6 years of age, with equal distribution of either a positive IA-2 or a positive GAD65. Interestingly, in this younger age-group, there were no cases in which ZnT8 was the only positive test. Six of all new-onset patients (6.5%) were antibody negative for all four antibodies, of which four (4.4%) were ultimately diagnosed with type 2 diabetes.

Total charges to patients for testing for four autoantibodies at our institution was $1,189 per patient, of which $528 was for the ZnT8 antibody test alone, and the direct costs to the institution for the tests were $358 per patient with ZnT8 again being the most expensive. During this time period, with an average of 52 new-onset pediatric patients per year at our institution, the total annual calculated charges to patients was $61,828 per year or $118,900 per 100 patients and cost to the institution of $18,720 per year or $36,000 per 100 patients (Supplementary Figure 2).

What was the timeframe from initiation of your quality improvement (QI) initiative to its completion?

This was a 12-month QI project with two PDSA (Plan-Do-Study-Act) cycles completed between 1 January 2017 and 31 December 2017.

Describe your core QI team. Who served as project leader, and why was this person selected? Who else served on the team?

The director of the pediatric diabetes service and the pediatric endocrinology senior fellow acted as project co-leaders. It was important to have the head of the diabetes team as a project leader to provide experience and knowledge of the culture and the rationale behind our screening practices. It was also important to have a fellow, who was invested in this project, lead and champion the efforts to implement changes in ordering practices and educating pediatric residents and the inpatient diabetes team. This QI project also included five other attending physicians, two pediatric endocrinology fellows, two nurse practitioners, and four diabetes nurses and involved the cooperation of inpatient nurses and pediatric residents.

Describe the *structural* changes you made to your practice through this initiative.

We instituted a tiered protocol for antibody testing (GAD65 and IA-2) at initial assessment, to be followed by ZnT8 if both were negative. With the ZnT8 test ordered reflexively for the estimated 12% of patients negative for IA-2 and GAD65, the average charges to patients was calculated to be $594 per patient (down from $1,189) and average costs to the institution were $180 per patient versus $358 before the project.

Describe the most important changes you made to your *process* of care delivery.

Our initial rollout included educating the diabetes staff and residents on ordering practices to avoid excess antibody ordering. This was achieved through presentations at the multidisciplinary diabetes team monthly meeting that included communication about the initial findings and the new tiered antibody protocol. Similar education was provided to the inpatient pediatric resident team, with written instructions sent via email to all residents and pediatric intensive care unit (PICU) fellows. The inpatient diabetes nurses received verbal education on the new tiered protocol by the pediatric endocrinology fellow, and the charge nurses were asked to verbally sign out this information to fellow nurses as well.

After the 6-month interval review demonstrating ongoing inadvertent additional testing of both ZnT8 and ICA, we revised the diabetes inpatient order set in the electronic medical record, EPIC, to preselect only the GAD65 and IA-2 antibody tests. This order set is used for all newly diagnosed patients with diabetes, is named "New Onset Diabetes Pediatric Order Set," and includes autoantibody, thyroid function, and celiac screening laboratory tests in addition to insulin orders, hypoglycemia protocol, nursing orders for vital sign and blood glucose monitoring, and diet orders.

The change in the order set would require an additional action by the ordering physician based on a patient's specific clinical indications if further autoantibody tests other than IA-2 and GAD65 were to be ordered. All orders would still be placed as part of the inpatient admission, including being able to add the ZnT8 test order on to the inpatient orders even after discharge by using the extra blood available in the reference laboratory from a patient's other autoantibody tests.

Education was provided again via email and by speaking to the diabetes team and residents in person to inform them of these changes. No further education was provided to the nursing staff except for verbally explaining that the order set would be changed to facilitate correct antibody ordering and asking for the charge nurses to relay this information to the nurses not on duty at that time.

Optional: If you used the PDSA change model, provide details for one example in the following sections:

Plan

A tiered protocol was implemented for antibody testing (GAD65 and IA-2) at initial assessment, to be followed by ZnT8 testing if both were negative. With the ZnT8 ordered reflexively for the estimated 12% of patients who were negative for IA-2 and GAD65, the goal was to decrease costs without affecting diagnosis and care.

Do

Initial rollout included education of the diabetes staff, nurses, and residents, as described above. Similar education was provided to the inpatient pediatric resident team and PICU fellows, inpatient diabetes nurses, and charge nurses.

Study

Data for first 6 months: Of 34 patients (mean age 11.3 years, range 3–17 years; 85.3% Caucasian, 14.7% African-American, 0% Hispanic, and 0% Asian), 33 were positive for IA-2 or GAD65. ZnT8 testing was ordered according to protocol one time, but there were 11 instances in which all four antibody tests were ordered at initial diagnosis; thus, in 11 of 34 instances (32%), protocol was not followed. The ideal charges would have been $18,548 for the tiered protocol ($530 per person for 34 people for the IA-2 and GAD65 tests plus $528 for one per-protocol ZnT8 test), or $546 per patient; costs to the institution would have been $5,621 for all patients, or $165 per patient. Due to the extra laboratory tests ordered, the actual total charges were $25,797, or $759 per patient, and costs to the institution were $7,818, or $230 per patient.

Act

In response to ongoing inadvertent additional testing of the ZnT8 and ICA, the diabetes order set was revised to preselect the GAD65 and IA-2 and not have the ZnT8 or ICA selected. Thus, an additional action would be required by the ordering physician to order these tests. Additional verbal and written education was provided, as described above.

Data for the second 6 months (months 6–12) were as follows: Of 48 patients (mean age 10.8 years, range 11 months to 21 years; 83.3% Caucasian, 16.7% African-American, 4.2% Hispanic, and 4.2% Asian), 39 tested positive for IA-2 or GAD65. There were seven instances (15%) in which additional tests (four for ZnT8 and three for ICA) were ordered against protocol. The additional tests (ZnT8 and ICA) were purposefully added based on clinical judgment six times, which added to adjusted costs. Ideally, total charges would have been $30,288 for all patients, or $631 per patient; institutional costs would have been $9,150, or $191 per patient. However, calculated charges came to $36,747 for all patients, or $766 per patient, and institutional costs were $11,108, or $232 per patient.

Summarize your final outcome data (at the end of the improvement initiative) and how it compared to your baseline data.

We evaluated our practice of work-up for pediatric patients newly diagnosed with diabetes in terms of tests for autoimmune markers and their related costs. In our institution, the majority of those presenting have either a positive GAD65 or a positive IA-2 antibody result at diagnosis, making further studies with the more expensive ZnT8 or ICA testing unnecessary. After 12 months of our QI initiative, our charges to patients for autoantibody testing decreased from $1,189 to $763 per patient and institutional costs decreased from $358 to $231 per patient. This represents a cost savings of 42–44% with inconsistent application of the tiered protocol.

What are your next steps?

We hope to continue to improve this process by removing the ICA test from the diabetes order set (it is never contributory) and continuing to educate the admitting team, including incoming pediatric residents and inpatient nurses. It is important that both the residents and nurses receive the education on the autoantibody ordering protocol, since the nurses have been trained for the diabetes floor and work specifically with the new-onset diabetes population. They are familiar with anticipated laboratory orders and can offer guidance to rotating residents. We also believe that our findings and the application of a tiered test protocol may be generalized to other practices with similar, predominantly Caucasian patient populations.

What lessons did you learn through your QI process that you would like to share with others?

Approaching the QI initiative from multiple avenues (in our case, educating personnel and changing our diabetes order set) can lead to a more rapid and complete change in clinical practice.

Duality of Interest

No potential conflicts of interest relevant to this article were reported.