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Health Surveillance in a Down Syndrome Specialty Clinic: Implementation of EHR-integrations during the COVID pandemic

Stephanie L. Santoro, MD[1,2]; Yamini Howe, MD[2,3]; Kavita Krell[1]; Brian G. Skotko, MD, MPP[1,2], John Patrick T. Co, MD, MPH[2]

Affiliations: [1]Down Syndrome Program, Division of Medical Genetics and Metabolism, Department of Pediatrics, Massachusetts General Hospital, Boston, MA

[2]Department of Pediatrics, Harvard Medical School, Boston, MA

[3]Lurie Center for Autism, Massachusetts General Hospital, Boston, MA

Address correspondence to: Stephanie Santoro, MD, 125 Nashua St, Suite 821, Boston, MA, 02114, [ssantoro3@mgh.harvard.edu], 617-643-3197

Short title: Down syndrome health surveillance

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BGS occasionally consults on the topic of Down syndrome through Gerson Lehrman Group. He receives remuneration from Down syndrome non-profit organizations for speaking engagements and associated travel expenses. Dr Skotko receives annual royalties from Woodbine House, Inc., for the publication of his book, Fasten Your Seatbelt: A Crash Course on Down Syndrome for Brothers and Sisters. Within the past two years, he has received research funding from F. Hoffmann-La Roche, Inc., AC Immune, and LuMind IDSC Down Syndrome Foundation to conduct clinical trials for people with Down syndrome. Dr Skotko is occasionally asked to serve as an expert witness for legal cases where Down syndrome is discussed. Dr Skotko serves in a non-paid capacity on the Honorary Board of Directors for the Massachusetts Down Syndrome Congress and the Professional Advisory Committee for the National Center for Prenatal and Postnatal Down Syndrome Resources. Dr Skotko has a sister with Down syndrome.

YJH has received education-related funding (Autism Speaks Autism Care Network for teaching in autism ECHO), internal funding, and philanthropic funding for clinical support (Nancy Lurie Marks Foundation). Her daughter has Down syndrome.

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Abbreviations: electronic health record (EHR), American Academy of Pediatrics (AAP), thyroid stimulating hormone (TSH), Massachusetts General Hospital Down Syndrome Program (MGH DSP), best practice advisory (BPA)

Abstract

Objective To address gaps in routine recommended care for children with Down syndrome, through quality improvement during the COVID-19 pandemic.

Study design A retrospective chart review of patients with Down syndrome was conducted. Records of visits to the Massachusetts General Hospital Down Syndrome Program were assessed for adherence to five components of the 2011 American Academy of Pediatrics (AAP) Clinical Report, "Health Supervision for Children with Down Syndrome." The impact of two major changes was analyzed using statistical process control charts: a planned intervention of integrations to the electronic health record (EHR) for routine health maintenance with age-based logic based on a diagnosis of Down syndrome, created and implemented in July 2020; and a natural disruption in care due to the COVID-19 pandemic, starting in March 2020.

Results From December 2018 to March 2022, 433 patients with Down syndrome had 940 visits. During the COVID-19 pandemic, adherence to the audiology component decreased (58% to 45%, $p < 0.001$); composite adherence decreased but later improved. Ophthalmology evaluation remained stable. Improvement in adherence to three components (TSH, hemoglobin, sleep study ever) in July 2020 coincided with EHR-integrations. Total adherence to the 5 AAP guideline components was higher for follow-up visits compared with new patient visits (69% and 61%, respectively; $p < 0.01$).

Conclusion The COVID-19 pandemic influenced adherence to components of the AAP Health supervision for children with Down syndrome but improvements in adherence coincided with implementation of our intervention, and re-opening after the COVID-19 pandemic.

As each primary care pediatrician cares for 1–2 patients with Down syndrome (1), for many children the current care model involves a primary care physician providing health supervision for children with Down syndrome following the American Academy of Pediatrics' (AAP) Clinical Report.(2–4)

Studies show wide variation in adherence to the various recommended care elements in the AAP's report. Annual blood work, including thyroid screening with thyroid stimulating hormone (TSH) is conducted in 56–92% of patients, and hemoglobin determination is completed in 48–67%(1,5–9) Hearing is screened at least annually in 18–85%, and vision is screened in 43–88%(1,6–9). Sleep studies are conducted in 4–70%(1,5,6,8,9).

The AAP guidelines are revised over time as new evidence emerges. In the past, sleep studies were recommended for symptomatic children, but in 2011 were recommended universally by age 4 years. Sleep study completion rates were lower prior to publication of the 2011 AAP document with subsequent increases(1,5,6,8,9). Two studies from single institutions in Ohio focused on adherence to the 2011 document(1,5). At baseline, 13-16.7% patients were fully up-to-date on components studied(1,9). Adherence improved with physician education, integration of components of the AAP guidelines directly into the electronic health record (EHR), and direct-to consumer tools(1,5,10).

We began this quality improvement initiative within our subspecialty clinic for Down syndrome, the Massachusetts General Hospital Down Syndrome Program (MGH DSP), to attempt to improve health supervision. We based our approach on our prior work in a different hospital system, which demonstrated that a combination of EHR tools using the same EHR system, Epic®, improved adherence for patients with Down syndrome(5).

Methods

The MGH DSP is affiliated with Partners Healthcare, now Mass General Brigham (MGB) in Boston, MA and is housed in the Genetics department. The MGH DSP is a multidisciplinary specialty program for individuals with Down syndrome, and medical visits include a physician, a social worker, a nutritionist, a self-advocate with Down syndrome, and a program coordinator. The location has phlebotomy available on-site; bloodwork is ordered during a visit and completed on the same day. In addition to the medical visit, patients may see audiology and/or ophthalmology at MGH-affiliated Mass Eye and Ear Institute (MEEI) the same day. Prior to a visit, parents complete an electronic intake form with parent-reported interval medical history and health surveillance.

Beginning in 2019, our team began a Quality Improvement (QI) initiative focused on adherence to 2011 AAP guideline components, based on previous work and the existing literature. A typical team-based approach was used to evaluate barriers, drivers, and study adherence and the EHR-integrations at MGH. The team consisted of an Epic® analyst, the Director of Quality Improvement Research for the MGH DSP (geneticist), the MGH DSP Director (geneticist), a parent of a child with Down syndrome (developmental-behavioral pediatrician), and a research coordinator. In prior work using EHR-integrations at another institution, process improvement methods were critical for successful implementation and adoption(5); we needed to follow the integrations closely to make sure that they were functioning appropriately, and not excessively, and to check in with locations where the intervention was functioning to determine if changes were needed(5). We included an Epic® analyst to monitor feedback about the EHR-integrations. The first author presented to the Clinical Committee for MGB, in October 2019 for approval to implement these pediatric integrations throughout the

MGB healthcare system. We included a parent to incorporate a parent's insight and perspective. Team interactions included e-mail communication, meetings in-person or through videoconferencing technology.

In April 2020, due to the COVID-19 pandemic, the MGH DSP transitioned from a fully in-person clinic model to a virtual visit model using videoconferencing(11). As we were conducting this planned QI project, we were able to capture the real-time impact of adherence due to the unplanned, natural disruption of the COVID-19 pandemic, and our ability to maintain adherence during use of the virtual visit model.

Baseline

Baseline data were collected in 2019, while developing the intervention, and prior to the COVID-19 pandemic. From this, our Specific, Measurable, Achievable, Relevant, and Time-Bound. (SMART) aim was: to increase adherence to components of the AAP Clinical Report for patients with Down syndrome to 90% by October 2020 and sustain improvement for 12 months. We created a Key Driver Diagram as we planned our initiative (Figure 1).

The Intervention

In 2019, our team developed an intervention to address gaps in adherence. Epic® analysts in the MGB system developed EHR-integrations, to replicate previous work that showed the benefit of specific EHR-integrations at a pediatric hospital in Ohio(5). The EHR-integrations at MGB we studied consisted of a listing of components in the Health Maintenance Record section of Epic®, for patients with the diagnosis of Down syndrome already added to their "problem list" in Epic®.

The goal of the intervention was to alert physicians in the MGH DSP of missing components of the 2011 AAP guidelines. The EHR-integrations consisted of the same approach used previously(5), with integration of reminders to key components which apply to all children with Down syndrome, of which we studied three: a sleep study once before age 4 years, a serum hemoglobin with complete blood count at age 0-6 months, then annual hemoglobin, and a TSH at 6 months of age, and then annually. These items were shown as text in the Health Maintenance Record of Epic®, and in our build were listed in red text as "Care Gaps" (Figure 2; available at www.jpeds.com).

Implementation

EHR-integrations began in July 2020. At implementation, an Epic® analyst reviewed responses from users. In August 2020, the responses in the best practice advisory were changed to include all Genetics departments in the MGB hospital system, and to combine Genetics department names to shorten the number of options listed for easier readability. Feedback from users continued to be followed. In January 2021, additional modifications were made to the BPA; to give users time to review the chart, the age range of sleep health maintenance was changed to allow time for users to order a sleep study before it was "overdue," and the hemoglobin healthcare maintenance was updated to include the common name "HGB" as completing the hemoglobin component.

When we began planning and developing the intervention, we did not foresee that our implementation would occur during a global pandemic with broad consequences at many levels: from our MGH DSP clinic operations, to our institutional procedures, and provision of health care state-wide.

Chart Review

Although our MGH DSP follows patients throughout the lifespan, we chose to study retrospectively patients aged 18 years old and younger to correspond with the MGB-approved EHR-integrations. Included for study were all completed clinic visits to the MGH DSP in December 2018 or after, regardless of visit format (e.g., telemedicine, phone only, or in-person). Scheduled but not completed visits, and encounters outside a clinic visit were excluded. We extracted data from finalized progress notes written and signed by the MGH Down Syndrome Program physicians, and included medical record information prior to, but not including, the clinic visit date; age, sex, race, ethnicity, and visit type. The MGB Institutional Review Board approved this study.

Outcome Measures

We studied adherence to five components of Health supervision for children with Down syndrome(3). We defined adherence to each component as completion of: thyroid stimulating hormone (TSH) measurement within the past 12 months, hemoglobin check within the past 12 months, sleep study any time for those age 4 and above, audiogram within the past 6 months for those age <5 and within the past 12 months for those age 5 and above, ophthalmology consultation within the past 12 months for those age 1 to 4, within the past 2 years for those age 5-12, and within the past 3 years for those age 13 and above.

We calculated adherence in reference to the date of clinic visit to the MGH DSP. Each of the five components was scored at each visit as either adherent or not adherent. Adherence was defined as the completion of a component as documented in a MGH DSP physician's progress note. The first three measures were included in the intervention, and the latter two were not included.

Our outcome measures were: three different composite measures of adherence, sleep study ever, adherence to each component and percentage fully up-to-date. First, we calculated a composite measure of total adherence at each visit, for each patient: [(the number of components that were adherent) / (the number of components recommended)] x 100. Then, a composite measure of total adherence each month was calculated as [(the number of components that were adherent for all patients with visits in month X) / (the number of components recommended for all patients with visits in month X) x 100. And, then calculated a composite measure of EHR-integration components (TSH, hemoglobin, Sleep Study ever) each month by dividing the number of EHR-integration components that were adherent for all patients with visits in month X by the number of EHR-integration components recommended for all patients with visits in month X and multiplied by 100.

Sleep study adherence for those 4 years of age and above each month, was calculated as [(the number of patients ≥4 who had a sleep study completed ever with visits in month X) / (the number of patients ≥4 with visits in month X) x 100. Adherence to each component (TSH / hemoglobin / Audiology / Ophthalmology) each month, was calculated by dividing the number of patients adherent with visits in month X by the number of patients with visits in month X and multiplying by 100. And, the percentage of patients fully up-to-date to 5 components each month, was calculated as: [(the number of patients with 100% adherence with visits in month X) / (the number of patients with visits in month X) x 100. To be 100% adherent, patients age 4 and older needed all five components, and patients less than 4 needed all four components except sleep study.

Analysis

We plotted p-charts using software from a local quality improvement course(12) to analyze monthly percentages of: composite adherence for all measures tracked, composite adherence for EHR-integration measures, sleep study adherence, adherence to TSH / hemoglobin / Audiology / Ophthalmology, and the percentage of patients fully up-to-date. We tracked the impact of the integration for more than twelve months. Centerline shifts were determined using standard statistical process control (SPC) chart rules.(13,14) We used the American Society for Quality (ASQ) rules to detect special cause variation on control charts.(15) Final charts were reviewed by quality improvement course faculty(12).

Given the general stability in charts, we conducted chi-square analysis to compare aggregate values (total adherence) by race / ethnicity (non-Hispanic White, Black, Hispanic, and Asian); by visit type (new patient visit and follow-up); and by Massachusetts residency (residents and non-MA residents). Determination of race was based on EHR documentation of race, generally obtained by patient report at time of registration. A "new" patient visit referred to those patients who were establishing care with the MGH DSP, and had never been seen previously in our clinic. Any patient with previous visits in the MGH DSP was considered a "follow-up" patient.

Results

From 2019 to 2022, there were 940 eligible visits to the MGH DSP, of which 109 were new patient visits and 831 were follow-up visits. These visits corresponded to 433 unique patients of mean age 7.7 years (range 1.0-18.9), who were most commonly Caucasian race and non-Hispanic ethnicity (Table I). Patients most often lived in Massachusetts and New England states, but some were from a variety of states and other countries.

Plotting measures over time, we considered four time periods: baseline (before April 2020 when our clinic was practicing in-person, prior to the COVID-19 pandemic), Virtual visits, pre-intervention (from April 2020 to June 2020, when our clinic transitioned to virtual visits but before our intervention was implemented), Virtual visits, post-intervention (from July 2020 to June 2021, when our clinic remained in virtual visits and after our intervention was implemented), and In-person, post-intervention (July 2021 and after, when our clinic returned to in-person clinic and our intervention remained active).

At baseline, we found 67% adherence to the five components of the 2011 version of the AAP Clinical Report from December 2018 to March 2022 (Figure 3; available at www.jpeds.com). From May 2020 to January 2021, adherence to the five components was below the baseline median (67%); based on the SPC rule of "7 or more consecutive points on one side of the average", these 9 points are special cause variation, do not coincide with the timing of our intervention, occurred before our intervention in July 2020, and occurred during the COVID pandemic and virtual visits. In later months, the adherence to five components returned to baseline range, with values both above and below the baseline median, and within control limits. At baseline 24% of patients each month were fully adherent to the five components from the AAP, from 4/2019 to 9/2019 showed variability during the COVID-19 pandemic and virtual visits, and was 34% from 7/2021 to 3/2022.

To study the impact of our EHR-integrations, at baseline there was 69.9% adherence to the three components included in the EHR-integrations (TSH, hemoglobin, sleep study ever) from January 2019 to March 2020 (Figure 4; available at www.jpeds.com). Special cause was

detected in July 2020, which coincided with implementation of our EHR-integrations; adherence was 72.2% from July 2020 to March 2022. Adherence to each individual component of the composite showed: 78% of patients age 4 and older from 2019-2022 had a sleep study in their life without special cause, 72% of TSH screens were done, and 62% were adherent to hemoglobin screening at baseline without special cause (Figure 5; available at www.jpeds.com). Adherence to audiograms (58%) was the lowest individual component and showed a downward shift with greater than 8 consecutive points below the centerline from 5/2020 to 6/2021 (corresponding to an average adherence of 43%), aligning with transition to virtual visits and the COVID-19 pandemic, but subsequently returned to baseline range (Figure 5; available at www.jpeds.com). Adherence to Ophthalmology was 70% at baseline and showed special cause from 8/2021 to 1/2022 with consecutively decreasing points (Figure 5).

The composite measure of monthly total adherence to the 5 components was plotted on p charts by demographic characteristics. Total adherence by visit type (new versus follow-up visits) demonstrated that on average follow-up visits had 69% adherence at baseline, compared with new patients with 60% adherence at baseline. Chi-square analysis by visit type was significant ($\chi^2 = 11.10$, $p < 0.01$) such that follow-up patient visits had higher adherence than new patient visits. On average, non-Hispanic White patients were 68% adherent, Black patients (of any ethnicity) were 69% adherent, Hispanic patients (of any race) were 63% adherent, and Asian patients were 72% adherent (Figure 6; available at www.jpeds.com). Total adherence by race did not show special cause due to either our EHR-integrations, or during the time of virtual visits due to the COVID pandemic. Chi-square analysis by race was not significant ($\chi^2 = 7.6$, $p = 0.06$). Analysis by location of residence (Massachusetts versus non-Massachusetts) showed an average

of 68% and 66% adherence to the 5 AAP guideline components, respectively, at baseline; chi-square analysis by location of residence was not significant ($\chi^2 = 0.11$, $p = 0.74$).

We summarized our results and existing studies on adherence to the 2001 and 2011 AAP documents (Table II; available at www.jpeds.com).

Discussion

In this quality improvement project, we aimed to improve adherence to 5 AAP guideline components for Down syndrome to 90% by October 2020 and sustain improvement for 12 months. By beginning our project in 2019, our quality improvement project unexpectedly overlapped with the COVID-19 pandemic and provided an unanticipated opportunity to study adherence in real-time during the natural disruption of the pandemic and our transition to a virtual visit model(11).

Assessing adherence in the MGH DSP for the first time, our median monthly adherence rate at baseline (67%) showed that many, but not all, of our patients were up to date on five components prior to their MGH DSP clinic date. At baseline, only 24% of patients had 100% adherence to the components demonstrating opportunity for improvement; previous studies report 10% adherence to all guidelines (9). Baseline monthly adherence rates were higher for follow-up (69%) than new patients (61%) which could be the result of interval completion of components at a Down syndrome specialty clinic(9), like the MGH DSP. From our baseline adherence, we created a SMART aim target of 90% adherence sustained for 12 months. In this project, we did not meet that aim, and considered that we may have set our target (90%) unrealistically high, that we had too many changes in our system to sustain change for 12 months, and that additional, different interventions may be needed to reach 90% adherence.

In comparison with published studies of adherence in Down syndrome at other sites, we found that our adherence rates to TSH and hemoglobin were similar to studies of the 2001 AAP statement(6–9) or the revised 2011 AAP statement(1,5,8). Our adherence to sleep study was higher than published adherence rates of 4.6-69.0%(1,5,6,8). Change in sleep study guidance may account for some difference; our sleep study adherence is higher than studies using the 2011 AAP statement (12-57% at baseline)(1,5). This could represent a selection bias; patients in the MGH DSP may not represent the national population with Down syndrome. For example, pediatricians may be more likely to refer complicated, "sicker" patients with Down syndrome to the MGH DSP, and those more complicated patients may have seen more specialists and been more likely recommended for sleep study. Additional regional differences such as distance to MGH, interval time to incorporate this new recommendation, stakeholder buy-in, or sleep laboratory availability could all impact adherence.

Adherence to audiology in the MGH DSP was our least adherent component. Audiology adherence decreased during the COVID pandemic, and our parent representative agreed that in-person visits were limited or delayed due to the pandemic in 2020. During the pandemic, as outpatient elective procedures were canceled, audiology testing might have been canceled; decreased availability or closing of in-person testing centers may explain our finding. However, the other components, such as TSH and hemoglobin blood tests, and an ophthalmology evaluation would also require an in-person encounter and adherence to those components did not decrease. Differences between laboratories and testing centers may have existed, for example, phlebotomy may have been more open and accessible during the pandemic than audiology testing. It is possible that the recommendation to conduct an audiological evaluation at higher

frequency led us to be able to detect a change in adherence during the 16 months when we were in virtual visits.

We began our quality improvement project to study the impact of EHR-integrations and demonstrated improvement in a composite measure of 3 EHR-integration components which coincided with the intervention in July 2020. We did not see a change in our other outcome measures: a composite measure of total adherence, sleep study adherence, adherence to TSH/hemoglobin/Audiology/Ophthalmology, or the percentage of patients fully up-to-date, which coincide with the implementation of these EHR-integrations in July 2020. We tracked adherence at four time frames to attempt to distinguish the impact of the COVID-19 pandemic, and the impact of the intervention. We selected the baseline (before 4/2020) to include only data before both the transition to virtual visits due to the COVID-19 pandemic and the intervention. We used standard, accepted QI methods of following data over time and using SPC rules defining shifts and trends, to determine special cause, and found special cause (Figure 4) which aligned with our intervention. Given the broad implications of the COVID-19 pandemic, we anticipated that the total adherence, or adherence to individual components might have worsen due to disruptions to medical care systems and saw decreased adherence to Audiology as outlined above. In the third time frame, adherence to the 3 EHR-integrations (Figure 4) might have improved regardless of our intervention due to reopening and return to in-person clinic after the COVID-19 pandemic. Our adherence to 5 measures (Figure 3), was highest in the fourth time frame giving hope that increased adherence in the future is possible.

EHR-integrations were effective in Ohio, but not in all measures in this study(5). In developing this quality improvement initiative, we replicated the methods of the EHR-integrations with many similarities, including EHR-integrations, EHR platform, outcomes

measured, the patient population, and the implementation. Yet, there are inherent differences between sites, and multi-site QI studies show variation between sites even when locations are using a cohesive, consistent approach(16). In other research, we have seen site differences in prevalence of iron deficiency and iron deficiency anemia(17). In our study, we relied on the clinical notes from physicians in the MGH DSP for documentation which included physician review of chart, and the Ohio study reviewed the full medical chart(5); it is possible that nuance allowed capture of additional components in the other study. Considering the two hospital systems, the MGH DSP is a subspecialty clinic for Down syndrome housed in the genetics department, and the integrations in Ohio were previously effective in the genetics department, neonatal intensive care units, and primary care clinics but did not study the Down syndrome specialty clinic housed in developmental pediatrics (5). The MGH DSP is associated with the pediatric component of Mass General for Children (MGfC), within MGH, and the MGB medicine system, and the hospital system in Ohio is a large, stand-alone pediatric hospital system(5). The two studies differed in time; the Ohio project was done in conjunction with larger outreach efforts to local neonatal intensive care units during a generally stable time (2015-2017)(5), although our project was started prior to the COVID-19 pandemic with all the changes that entailed when families may have had other priorities beyond routine healthcare maintenance for Down syndrome.

Overall, it is important to consider nuances in all aspects of a quality improvement project from the team, the aim, the intervention, the measures, and the broader context(14,18,19). We compared adherence among subgroups by race / ethnicity and location of residence and saw similar rates of adherence between groups; in the future, additional factors could be evaluated. If

we could identify any features which are common among patients with the lowest adherence rates, this could help us to choose interventions of greatest benefit.

Many aspects of preventive health care in primary care have been negatively affected by COVID(20–23). As we transitioned to a virtual visit model, we attribute our success with continued health care maintenance to our dedicated, multidisciplinary team which took on new roles and worked to maintain our clinic during the COVID pandemic(11).

Our MGH DSP may not generalize to other Down syndrome clinics which follow different care models, and may need to be updated as the AAP statement is revised(24). Studies to-date have also focused on single hospital systems or the use of Medicaid claims; in the future it would be useful to study adherence to the AAP statement for Down syndrome in other hospitals which have adopted the EHR-integrations(25), or in a population-based cohort, such as a national ambulatory pediatric database.

In conclusion, total adherence to components of the 2011 AAP Health supervision for children with Down syndrome was imperfect at baseline, decreased during the COVID-19 pandemic, and subsequently improved, especially once in-person visits resumed. Adherence to three EHR-integration components improved in July 2020 and coincided with the intervention.

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Figure Legends:

Figure 1: Graphic of Key Driver Diagram with drivers, interventions, and aims

Figure 2: Screenshots of integrations in the electronic health record

Figure 3: Total adherence rate to 5 select age-based AAP guidelines for individuals with Down syndrome in the MGH DSP from December 2018 to March 2022. Yellow lines denote the transition to virtual visits from April 2020 to June 2021 due to the COVID-19 pandemic, and the timing of EHR-integration intervention in July 2020. Gray lines indicate the process stage mean, which refers to the arithmetic mean for all points within that process stage; statistical rules indicate that there is 1 stable process stage. Red lines indicate the control limits (±3 SDs based on the process mean and number for that month).

Figure 4: Total adherence rate to 3 EHR-integration components of the AAP guidelines for individuals with Down syndrome in the MGH DSP from January 2019 to March 2022. Yellow lines denote the transition to virtual visits from April 2020 to June 2021 due to the COVID-19 pandemic, and the timing of EHR-integration intervention in July 2020. Gray lines indicate the process stage mean, which refers to the arithmetic mean for all points within that process stage; statistical rules indicate that there are 2 stable process stages, which are indicated by the shift in July 2020. Red lines indicate the control limits (±3 SDs based on the process mean and number for that month).

Figure 5: Adherence to Guideline Components (thyroid stimulating hormone (TSH), hemoglobin Audiology and Ophthalmology evaluation) from January 2019 to March 2022. Yellow lines denote the transition to virtual visits from April 2020 to June 2021 due to the COVID-19

pandemic, and the timing of EHR-integration intervention in July 2020. Gray lines indicate the process stage mean, which refers to the arithmetic mean for all points within that process stage; statistical rules indicate that there is 1 stable process stage. Red lines indicate the control limits (±3 SDs based on the process mean and number for that month).

Figure 6: Total adherence rate to 5 select age-based AAP guidelines for individuals with Down syndrome in the MGH DSP by race / ethnicity from January 2019 to March 2022. Yellow lines denote the transition to virtual visits from April 2020 to June 2021 due to the COVID-19 pandemic, and the timing of EHR-integration intervention in July 2020. Gray lines indicate the process stage mean, which refers to the arithmetic mean for all points within that process stage; statistical rules indicate that there is 1 stable process stage. Red lines indicate the control limits (±3 SDs based on the process mean and number for that month).

SQUIRE 2.0 TABLE FOR QUALITY REPORTS

Manuscript Section	Key Considerations for Authors	Reported on Page #
Title	Include the condition and key outcome	1
Abstract	Sections should include Background, Methods, Results, and Conclusion. The results should summarize findings in relation to key specific aims	3
Introduction	Summarizes problem description, available knowledge, rationale, and specific aims.	4-5
Methods		5-11
Context		5
Intervention		7
Study of the Intervention		7-11
Measures	• Each outcome, process, and balance measure must be described • If costs are included in the measures, the method of cost assessment and evaluation should be clear and rigorous.	9-10
Analysis	• The authors should include description about how any run/control charts were developed and analyzed (eg, rules governing changes in center lines and confidence intervals). • If run charts or statistical process control was not used, the authors should explain why an alternative analytic approach was selected.	11
Ethical Considerations	• Authors should review their institution's guidelines around quality improvement projects. • If the authors did not obtain IRB approval and/or formal IRB exemption after review, they must state how the project described in their submission met criteria for not being reviewed by their institution's IRB.	11
Results	• Describes the actual course of the intervention, including contextual elements. • Results should be described in relation to specific aims and be presented in the same order as in the Introduction and Methods. • Describes the actual course of the intervention, including contextual elements, as well as changes in process and outcomes (including balance measures and any cost assessment). • The results should include a description of and interpretation of any run/control chart findings, specifically whether special cause variation was noted or not.	11-14
Discussion		14-19
Summary	Summarize findings in relation to specific aims.	2, 14-15
Interpretation	• Were there specific intervention(s) related to improvement? • How do the findings compare to findings from other publications?	15-19

	• How were the findings compared to what authors expected, and why?	18-19 ↓
Limitations		
Conclusion		19
Figures	• Run and/or control charts are helpful for illustrating changes in measures over time. • Run and/or control charts should include annotations that show when interventions were implemented.	Attached

Table I. Demographic characteristics of 433 unique patients in the MGH DSP from 2018-2021

	N (%)
Sex	
Male	201 (46)
Race	
Caucasian	304 (70)
Black	16 (4)
Asian	20 (5)
Other	44 (10)
Multiple races	14 (3)
Unknown	35 (8)
Ethnicity	
Hispanic	64 (15)
Non-Hispanic	300 (69)
Other	13 (3)
Unknown	56 (13)
Residence	
State	
MA	284 (66)
NY	56 (13)
NH	33 (8)
CT	15 (3)
NJ	9 (2)
ME	8 (2)
RI	5 (1)
PA	4 (1)
MI	3 (1)
FL	2 (<1)
WA, MO, TX, MS	1 (<1)
International	4 (1)
Unknown	2 (<1)
Missing / blank	1 (<1)
	Mean (Std Dev, Range)
Age at first visit (years)	7.7 (5.2, 1.0-18.9)

Table 2: Summary of Adherence for Down Syndrome from Literature Review.

	Jensen[7]	Williams[8]	O'Neill[9]	Santoro[5]		Santoro[3]		Skotko[10]	This study	
Source	CO, CA, MI, PA Medicaid claims; 2006-2010	University of Wisconsin-Madison; 2001-2011	Lurie Children's Hospital of Chicago: two urban academic clinic sites; 2008-2012	Nationwide Children's Hospital system; 2015-2017		Cincinnati Children's Hospital: 22 pediatric care sites;		Boston Children's Hospital; 2009-2010	Massachusetts General Hospital Down Syndrome Program; 2018-2021	
Age	12+ years	0-21 years	0-17 years	0-32 years		pediatric		3-21 years	0-18 years	
Guideline version	2001	2001	2001	2011		2011		2001	2011	
				Baseline	Post-intervention	Baseline	Post-intervention		Baseline (before 4/2020)	4/2020 and after (included COVID, Post-COVID, and Post-intervention)
Thyroid	2517/3501 = 71.9% had annually	445/732 = 61% had at ages 6 and 12 months, yearly ages 2-21	55/60 = 92% had annually	72/118 = 61%	166/226 = 73%	48/82 = 59%	52/82 = 63%	58/103 = 56% had annually	216/333 = 65%	444/638 = 70%
Hearing	637/3500 = 18.2% had annually	265/794 = 33% had every 6 months ages 1 to 3 years, yearly ages 4-21	68/80 = 85% had Annually age 1–4, and 13+ years Once from age 5–12 years			52/82 = 63%	75/82 = 91%	49/104 = 47% had annually	174/299 = 58%	327/638 = 51%
Vision	1919/3502 = 54.8% had annually	285/661 = 43% had by age 6 months, every 2 years ages 1-5, then yearly ages 5-21	52/59 = 88% had – Annually age 1–4, and 13+ years As needed age 5–12 years			57/82 = 69%	68/82 = 83%	58/104 = 56% had annually	208/299 = 70%	438/638 = 69%
OSA / Sleep study	162/3521 = 4.6% if risk / symptoms		58/84 = 69% had if symptoms; 57% had by age 4 years	33/65 = 51%	78/119 = 66%	12%	43%		173/223 = 78%	410/465 = 88%
Complete Blood Count / Hemoglobin		114/206 = 55% had CBC yearly if ages 13-21years	10/15 = 67% had Hgb annually for 13+ years	88/167 = 51%	206/299 = 69%	39/82 = 48%	41/82 = 50%		185/333 = 56%	388/638 = 61%
Echocardiogram				62/66 = 94%	107/108 = 99%	35/82 = 43%	74/82 = 90%			
Genetics visit				37/66 = 56%	97/108 = 90%	25/82 = 31%	55/82 = 67%			

Key Driver Diagram: QI Mini-Grant Project

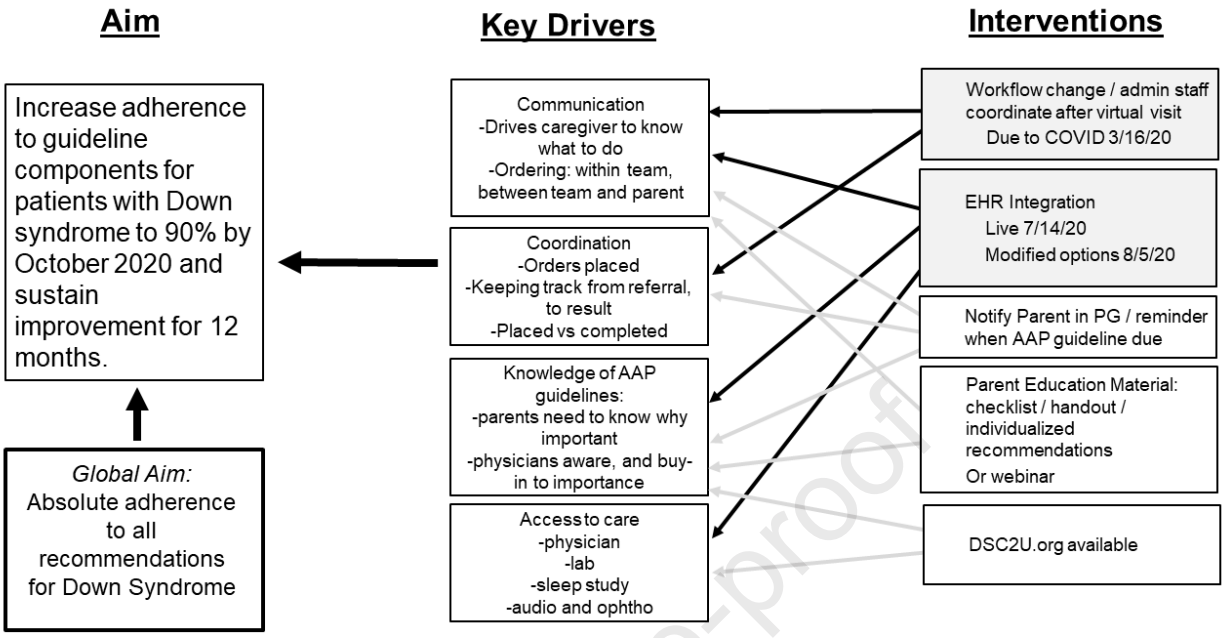

Figure 2

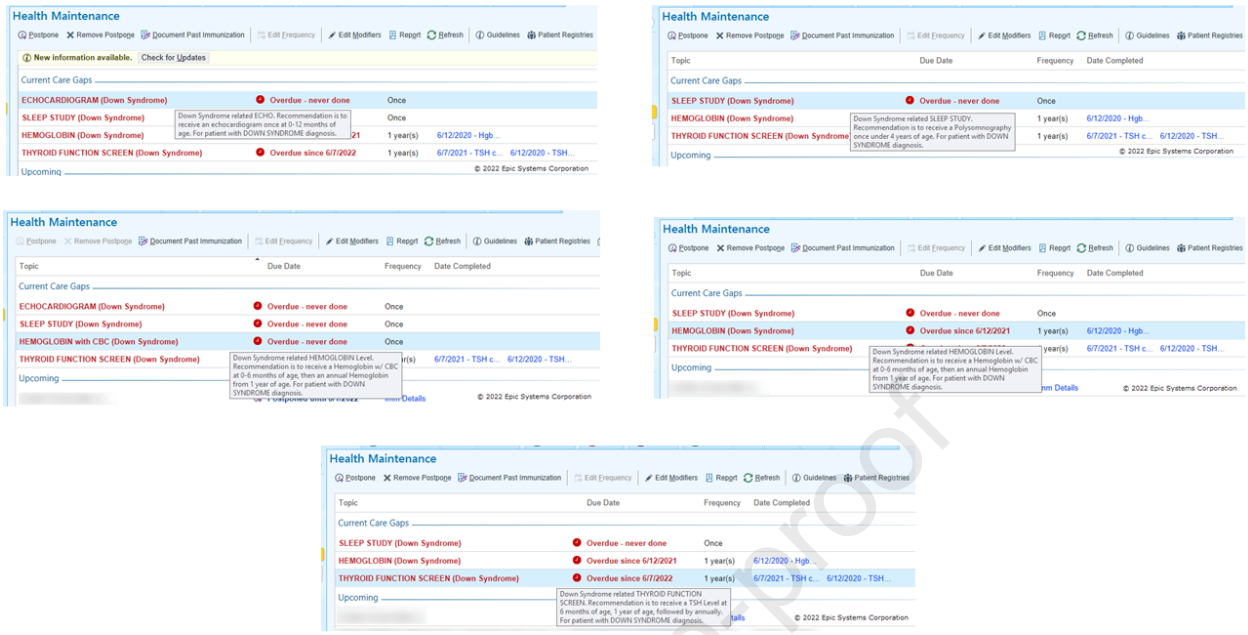

Figure 3: Adherence to all 5 Measures (TSH, Hgb, PSG, Audio, Ophtho), p Chart

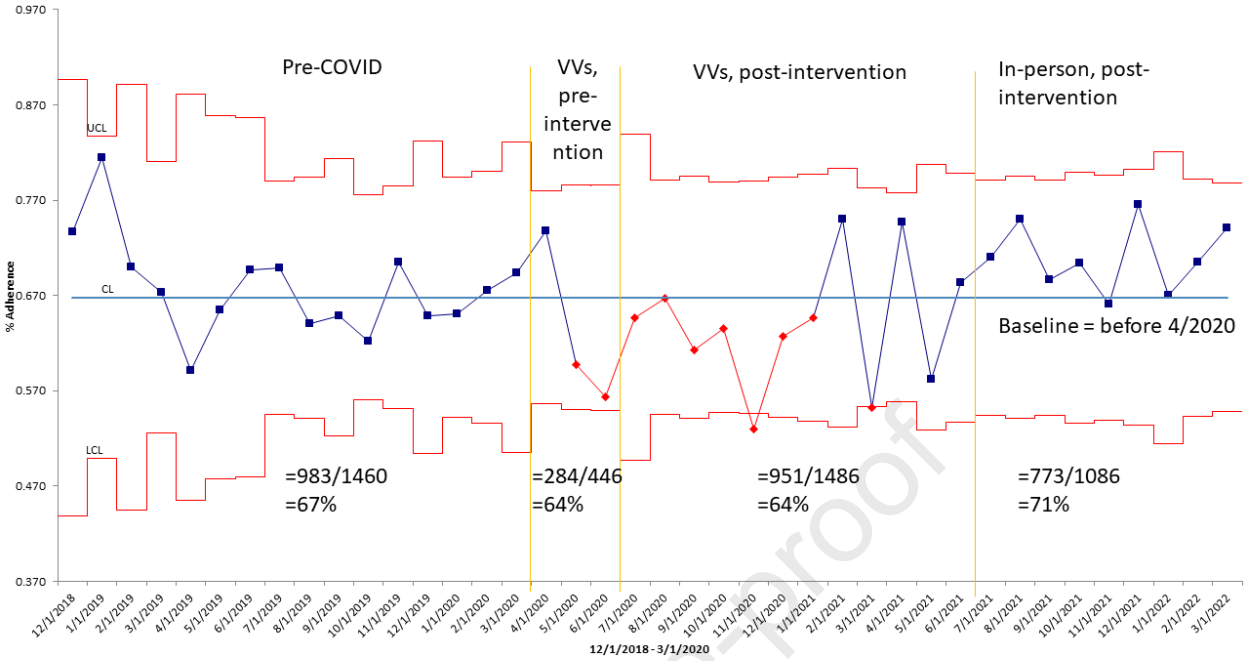

Figure 4: Adherence to EHR Integration (TSH, Hgb, PSG), p Chart

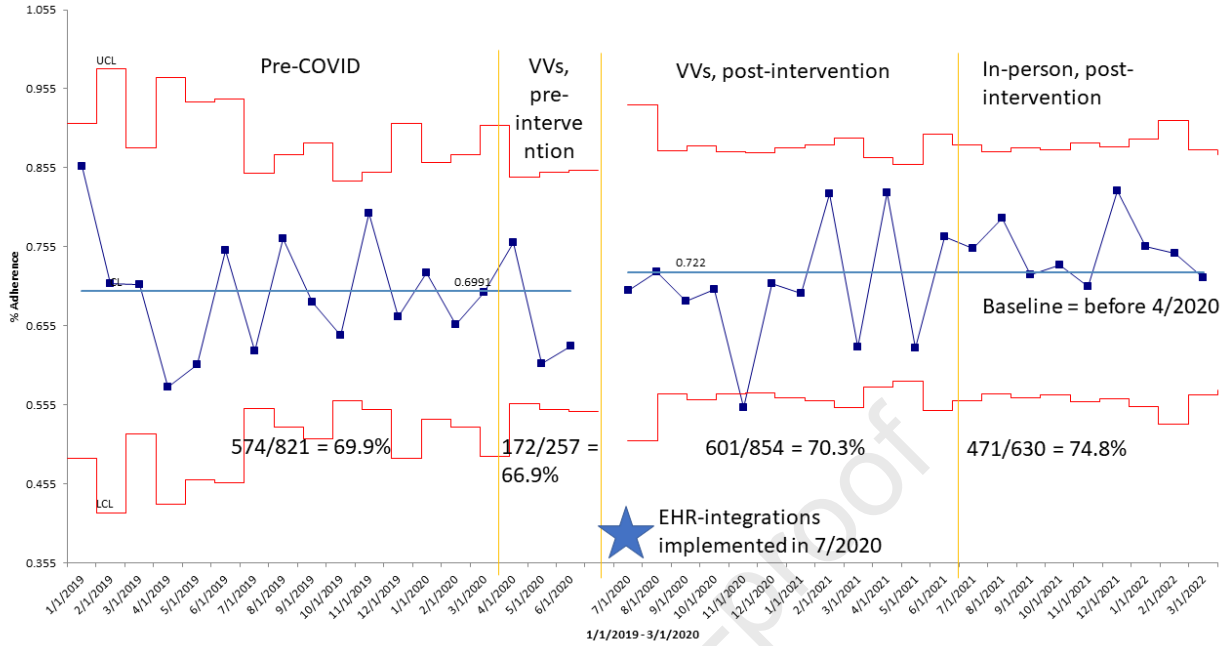

Figure 5: Adherence to Guideline Components, p Charts

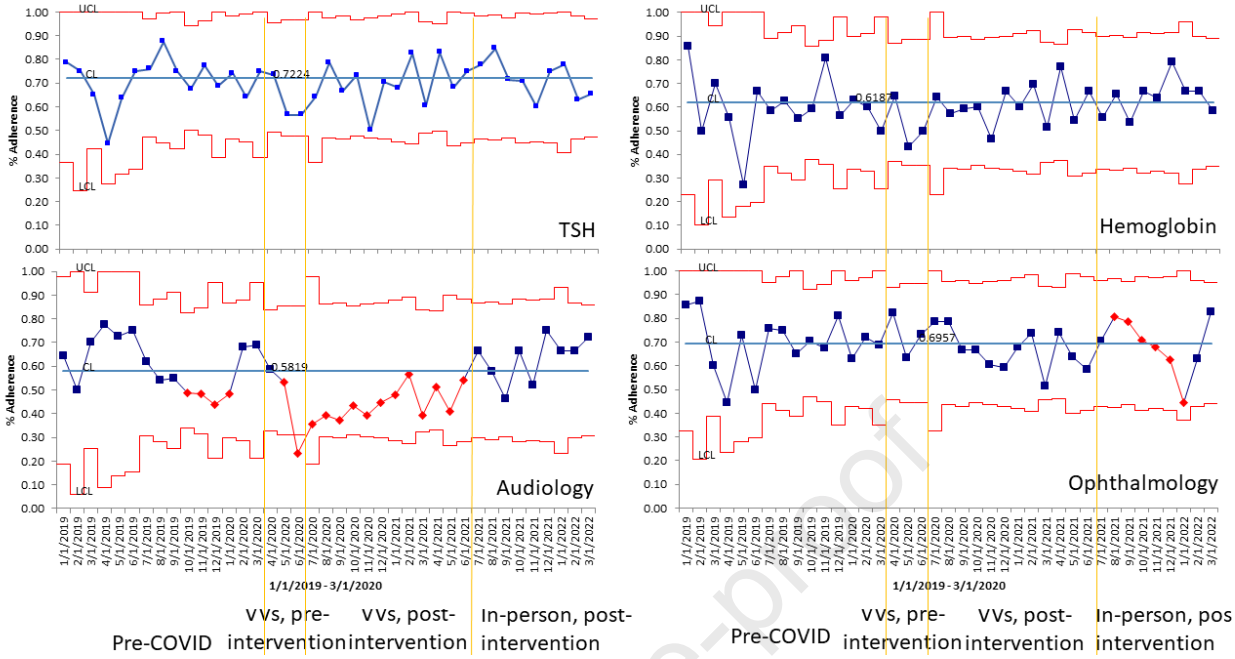

Figure 6: Adherence by Race and Ethnicity