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Statistical Analysis

Statistical analysis conducted by Dr. Jennifer R. Mammen, PhD, NP-C, University of Rhode Island College of Nursing, University of Rochester, Rochester, NY, and by Dr. James J. Java, PhD, Department of Biostatistics and Computational Biology, University of Rochester, Rochester, NY.

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Figure legends

Figure 1. Illustration of the TEAMS CDSS tool used by nurse for data entry and guideline based assessments during telemedicine visits (left), including built-in patient educational modules from the Let's Talk About Asthma series for smartphone (right)

Online supplemental materials legend

Figure E2. Sample progress note auto-generated by the TEAMS CDSS tool

List of abbreviations used in the manuscript:

- COPD Chronic obstructive pulmonary disease
- CDSS Clinical decision support software
- EMR Electronic Medical Record
- EPR3 Expert Panel Report 3
- FEV1 Forced expiratory volume in 1 second
- MID Minimum important difference
- PCP Primary care provider
- PEF Peak expiratory flow
- PFM Peak flow meter

TEAMS - Technology Enabled Asthma Management System

Abstract

Background: Technology-based interventions that can function within real-world practice and improve outcomes *without* increasing provider burden are needed, yet few successfully cross the research-to-practice divide. This paper describes the process of developing a clinically-integrated smartphone-telemedicine program for adults with asthma and results from proof-of-concept testing.

Methods: To ensure integration with practice, we used a contextually-grounded intervention development approach and May's implementation theory to design the intervention, with emphasis on systems capabilities and stakeholder needs. The intervention incorporated symptom monitoring by smart phone, smartphone telemedicine visits and self-management training with a nurse, and clinical decision support software, which provided automated calculations of asthma severity, control, and step-wise therapy. Seven adults (aged 18-40) engaged in a 3-month beta-test. Asthma outcomes (control, quality of life, FEV1) and healthcare utilization patterns were measured at baseline and end-of-study.

Results: Each participant received an average of 4 telemedicine visits with 94% patient satisfaction. All participants had uncontrolled asthma at baseline; by end-of-study 5/7 classified as well controlled. Mean asthma control improved 1.55 points (CI=0.59-2.51); quality of life improved 1.91 points CI=0.50-3.31), and FEV1 percent predicted increased 14.86% (CI=-3.09-32.80) with effect sizes of d=1.16, 1.09, and 0.96, respectively. Preventive healthcare utilization increased significantly (1.86 visits/year vs. 0.28/year prior, CI 0.67-2.47) as did prescriptions for controller medications (9.29 refills/year vs. 1.57 refills/year, CI 4.85-10.58).

Conclusion: Smartphone telemedicine may be an effective means to improve outcomes and deliver asthma care remotely. However, careful attention to systems capabilities and stakeholder acceptability is needed to ensure successful integration with practice.

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Introduction

Asthma remains one of the most common chronic health conditions, affecting 8.2% of adults, of which approximately 63% have persistent symptoms.^{1, 2} Typically, correct use of controller medication and effective self-management can alleviate symptoms, prevent exacerbations, and reduce risk of long-term lung damage.³ Yet while morbidity and mortality due to asthma are preventable, nearly 62% of adults with asthma remain uncontrolled, and implementation of potentially effective new interventions within real-world contexts has been limited.⁴

There is no doubt that careful assessment, close follow-up, medication reminders, and self-management training all improve adherence and outcomes.⁴ However, these approaches require personnel and time resources that may not exist within over-burdened healthcare systems. With the growing shortage of primary care providers (PCP) and the increasing complexity of clinical care, it is unlikely that PCPs can carve out additional time to focus on asthma management.⁵ For this reason, interventions that can function effectively within existing systems' constraints and improve patient outcomes *without* increasing provider burden are urgently needed.

There is growing evidence that use of e-health technology (e.g. smartphones, electronic medical record, and computer decision-support software "CDSS") can address common asthma management issues.^{6, 7} However, most technology-based interventions do not integrate with the electronic medical record (EMR), and are thus not currently clinically sustainable. While researchers may be optimistic about the ability to integrate *ex post facto*, few tech-based interventions cross the research to practice divide, typically due to unforeseen systems implementation issues or incompatibility with existing clinical workflow.

Thus, in designing a new technology-based intervention for asthma management, we adopted a contextually grounded intervention development approach that allowed for consideration of implementation issues during the development process ⁸. Specifically, we sought to develop a smartphone-based telemedicine program that could address common asthma management problems (e.g. patient non-adherence, ⁹⁻¹¹ inaccurate symptom reporting, ^{12, 13} poor self-management, ^{14, 15} access to care, ¹⁶⁻¹⁸ and provider nonadherence to asthma guidelines¹⁹⁻²¹) and integrate with the EMR and existing clinical practice. The goal in developing the intervention was to increase the accuracy, effectiveness, and convenience of care for patients, while avoiding increased clinician burden and promoting adherence to guidelines.²²⁻²⁶ In this manuscript, we describe the process of contextually grounded intervention development, the resulting technology, and proof of concept testing in a small, real-world sample of adult patients in a large urban medical center. We hypothesized that the intervention would show preliminary evidence of feasibility and acceptability and potential to improve asthma outcomes in younger adults with asthma.

Methods

Intervention Development

As shown in **Table 1**, we navigated an extensive two-year planning and development process aligning with May's implementation theory,²⁷ including identifying problems and solutions, target environments, system capabilities, key stakeholders, practice policies, and credentialing processes. Development required establishing key relationships; assembling a representative team, creating and testing the technology, obtaining approval to launch, and proof-of-concept testing with patients in the clinical setting.

Technology Enabled Asthma Management System (TEAMS) is a fully integrated EMRbased intervention designed for use in primary care. Based on the process described above, three technological components were selected to augment routine asthma care: (a) remote smartphone symptom monitoring, (b) synchronous smartphone telemedicine follow-up and self-management training with a nurse, and (c) computer-guided EMR assessments using built-in clinical decisionsupport software (CDSS). Patients recorded home-entered symptoms using their smartphones and a patient portal app (Mychart; Epic Systems Corporation, Wisconsin USA), which uploaded symptom data directly to the Epic EMR. One nurse (JRM) conducted telemedicine visits using Zoom's HIPAA-compliant secure video-conferencing platform (Zoom Inc. California USA). The nurse reviewed home-entered symptoms and entered a detailed asthma assessment into the TEAMS CDSS flowsheet (see Figure 1), which is a complex clinical documentation and decision-making tool embedded in the EMR. Guideline-based algorithms in the CDSS tool instantaneously calculated asthma severity, control, and provided a comparison of recommended versus prescribed step-wise therapy. The CDSS tool was designed to improve assessment accuracy, guide step-wise medication management,⁴ inform providers, and help patients achieve

better asthma control. Results of the analyses were shared with the participant and evidencebased self-management training was provided using the free online resource *Let's Talk About Asthma!* e-series for smartphone developed in our prior work.^{28, 29} A detailed progress note autogenerated by the CDSS tool (see **Figure E1**, online supplement) was filed in the EMR for each telemedicine visit. Per protocol, an EMR InBasket message with a visit summary was sent to the PCP team if the patient had uncontrolled asthma and needed medication adjustments or office follow-up, with a back-up phone call for urgent issues. To ensure safety and monitor for correct functioning of EMR algorithms, all telemedicine visits in this phase were conducted by an advanced practice nurse with IT training (JRM), and each calculated output was verified for accuracy.

CDSS calculations used National Asthma Education Prevention Program guidelines⁴ but are adaptable to other guidelines. Program components are likely compatible with other EMRs. **Approach (Proof-of-concept testing)**

This study was approved by the University of Rochester Internal Review Board (RSRB67900). A mixed methods approach was used. The quantitative portion consisted of a single-arm pilot study with pre-post and longitudinal collection of outcomes over 3 months (asthma control, quality-of-life, Forced Expiratory Volume (FEV₁), ED visits, hospitalizations, feasibility/acceptability surveys). The qualitative portion used descriptive methodology and open-ended interviews to capture patients' experiences and perceptions of TEAMS, to explore acceptability and perceived impact. Staggered enrollment was used to account for seasonal variation in symptoms.

Setting and sample

Participants were randomly selected from clinic rosters in an urban safety-net residentrun primary care clinic in Western NY. Eligibility criteria were: ages 18-40, with any diagnosis of current asthma, English speaking, and having a smartphone. Age range was restricted to younger adults (18-40 years) on the basis of smartphone prevalence and technology uptake. Patients with confounding comorbidities (e.g. heart failure COPD, Cystic fibrosis) and pregnant patients were excluded. Patients with psychiatric diagnoses were not excluded. Ten patients, randomly selected from clinic rosters, were screened; all had smartphones. One was ineligible on the basis of heart failure and two who were eligible could not be re-contacted after screening. The remaining seven consented and completed the beta-test (3-month duration).

Intervention delivery

Written informed consent and all study procedures were performed by a trained nonmedical research assistant in patients' homes due to high office-visit no-show rates. Technology set up and training occurred at the baseline visit. Participants were asked to record symptoms, medication use, and Peak Expiratory Flow (PEF) using a Microlife³⁰ digital peak flow meter (Microlife, USA) via smartphone, daily, for 3 months. A nurse (JRM) initiated follow up smartphone telemedicine visits with patients every 2-weeks until asthma control was achieved, as calculated by the TEAMS CDSS tool. All visits were scheduled by text messaging and text message reminders were sent the day prior to or the day of appointment. Following each visit, if the CDSS tool indicated that the patient's asthma was uncontrolled, a brief synopsis was sent to PCP via EMR InBasket messaging with urgent messages also conveyed via phone call. The PCP then initiated medication adjustments via e-prescribing, if warranted, and determined medically appropriate follow-up. The TEAMS nurse then helped to coordinate care and ensure follow up. Once the patient achieved good asthma control, follow up frequency decreased to once a month. There was no minimum requirement for participation in self-monitoring or telemedicine visits and patients participated in each activity as often as they were motivated to. Intervention dose for each participant was tracked and correlated with outcomes.

Outcome Measures

Feasibility was measured by: (a) frequency of participation in symptom monitoring, (b) number of visits needed to achieve/maintain asthma control, (c) duration of visits, and (d) no show and reschedule rates. Similar to clinical practice, length of visit was driven by the time it took to complete the asthma assessment, teach participants specific self-management skills, and relay follow up documentation to PCP/clinic. Thresholds for minimum or maximum intervention dose were not predefined, as the goal was not to deliver a standard intervention dose, but to assess dose needed to achieve good control or dose tolerated (e.g. frequency of voluntary participation), and relationship between intervention dose, asthma control, and quality of life.

Efficacy. Primary outcomes (asthma control, quality of life, and FEV₁ percent predicted) were collected at baseline and end of study. Asthma control and quality of life were measured using the Asthma Control Questionnaire (ACQ)³¹ and Asthma Quality of Life Questionnaire (AQLQ), respectively.³²

ACQ. The ACQ is a well-established 7-item questionnaire with a score range of 0-6 (lower scores represent better control). A score of ≤ 0.75 has a positive predictive value of 0.85 for controlled asthma, and a score of ≥ 1.5 has a positive predictive value of 0.88 for uncontrolled asthma.³¹ Minimum important difference is a change score of 0.5.³³

AQLQ. The AQLQ measures physical and emotional impact of disease with high testretest reliability (>0.90).³² Averaged total scale and subscale scores range from 1-7, with higher scores representing better quality of life. Minimum important difference is 0.5 per domain and overall quality of life.³⁴

FEV¹ was measured using Microlife digital PFMs.³⁰ FEV₁ percent predicted was calculated using NHANES III criteria.^{35, 36} Number of prescriptions written by providers for asthma medications were obtained through EMR review for the year pre and post intervention. Actual refills by patients could not be accurately determined due to external pharmacies data storage procedures.

Acceptability was assessed at the end of the study through 1:1 interview and the Usability Satisfaction and Ease of Use Questionnaire (USE-Q). The USE-Q³⁷ is a validated 21-item instrument with a 7-point Likert scale format (1=strongly disagree to 7=strongly agree). Higher scores represent more positive perceptions, with 7 being the most positive possible score and 1 representing the most negative possible score. Minimum acceptability thresholds were a score \geq 5=somewhat agree on at least 70% of USE-Q items. Exit interviews were conducted to qualitatively explore acceptability.

Demographics were collected via survey and the EMR.

Data analysis

Descriptive statistics were computed for demographics, feasibility, and USE-Q data. Paired t-tests were used to compare baseline and end of study scores for ACQ, AQLQ, and FEV₁ percent predicted, and effect sizes (Cohen's d) were calculated. Unadjusted bivariate correlation was used to explore associations between asthma control and quality of life (ACQ, AQLQ) and intervention dose (frequency of self-monitoring and telemedicine visits). Audio-recorded interviews were transcribed and qualitative content analysis techniques³⁸ were used to explore participants' perceptions of the program.

Results

Baseline asthma and demographic data are presented in Table 2.

Feasibility. Of 42 scheduled telemedicine visits, 7 were no-shows (16%; involving 4/7 patients), 7 rescheduled (16%; involving 4/7 patients), and 28 were conducted as expected (68%). Participants averaged 4 telemedicine visits (range 3-5), for a grand mean of 114 minutes spent with the asthma telemedicine nurse (range 88-160 minutes; SD 25.07; average 61 minutes self-management training and 53 minutes nursing-assessment per participant). Participants logged symptoms remotely an average of 32 days over 3 months (range 15 to 64; SD 15.56). Participants were asked to set a daily reminder on their smartphone; no external reminders were provided for self-monitoring. Average telemedicine visit duration was 29 minutes (range 20-45 minutes), and the majority of visits (17/28; 61%) were delivered after 5pm or on weekends to accommodate participants' work schedules.

Efficacy. At baseline, all participants had uncontrolled asthma. At 3-months, 6/7 participants had marked reduction in symptoms with 5/7 classifying as well-controlled ³⁹. Effect sizes were large for improvements in control, quality of life, and FEV₁ percent predicted (d=0.96 to 1.16). **Table 3** shows pre-post scores for asthma outcomes with effect sizes and confidence intervals. On average, asthma control improved 1.55 points—more than 3 times the clinical MID. Significant improvements were seen in morning symptoms, night time wakening, activity limitations and shortness of breath, with greatest effects on reductions in wheezing (d=1.48). Quality of life improved an average of 1.91 points, nearly 4 times the minimum important

difference (MID). Improvements were evenly distributed across all domains (symptoms, activity limitations, emotional functioning, and environmental stimuli. There was also an average increase of approximately 15% in FEV₁ percent predicted.

Table 4 shows individual peak flow graphs (extracted from the EMR) with a noticeable upward trend in PEF for most participants. Graphs for the first two participants showed downward or neutral trends. Association between number of days participants performed home self-monitoring, length of visit, and improvement in asthma control was moderate (r= 0.67 and p=0.10).

An average of 2 (range 1-4; SD 1.29) InBasket messages per participant were sent by the TEAMS nurse to the participants' PCP (n=4) over 3 months, to coordinate follow-up care and medication adjustments, with 100% PCP response. As seen in **Table 3**, there were significant and clinically meaningful increases in use of preventive health services and written prescriptions for controller medications, and a corresponding decrease in prescriptions for oral corticosteroids in the year following intervention.

Acceptability. As shown in **Table 5**, acceptability and satisfaction was high (93.9%). At exit interviews, six of seven participants reported that the intervention "changed my life" and enabled them to take control of their asthma for the first time. Qualitative data on the perceived impact of the intervention are presented in **Table 4**.

Discussion

Data from this proof-of-concept study suggest that use of an integrated smartphone and EMR/practice-based intervention might be an effective means to supplement primary asthma care and improve outcomes. The underlying importance of this approach lies in the ability to reduce barriers to accessing primary care.¹⁸ Telemedicine is inherently more flexible than office care, and does not require that patients travel to a given location. Extending telemedicine into patients' homes via ubiquitously available smartphones could make communities the front-line for primary care. Because of ability to supersede geographic boundaries, smartphone technology could increase clinical reach, and may thus be the key to delivering care to underserved populations locally and globally.

Prior studies have demonstrated that use of remote monitoring, self-management training, telemedicine, smartphones, and CDSS tools, individually, can improve outcomes.⁴⁰⁻⁴² To our knowledge, however, this is the first intervention to combine these components into a single technological package that effectively integrates with real-world medical practice and the live EMR.

In contrast to studies that have sought to isolate and quantify the impact of individual factors,^{43, 44} this study adopted a broad-spectrum approach with simultaneous intervention across multiple patient, provider and systems levels, as we theorized that the impact of a multifaceted program would likely be different from the impact of individual components in isolation ^{45, 46}. The marked improvement in outcomes, as evidenced by large effect sizes on key outcomes (d=0.96 to 2.62), supports this holistic approach. On average, participants achieved a 15% increase in FEV1, crossing the critical clinical threshold of >80%.³⁹ Additionally, improvements in asthma control and quality of life that were 3-4 times the minimum important difference.^{31, 34}

Patients' perceptions of acceptability and feasibility were high, and while participants only recorded symptoms only 33% of the time on average, greater engagement was associated with improved asthma control. Lastly, the significant increase in written prescriptions for controller medications and in-office PCP follow up suggest that the intervention can promote provider adherence to guideline-based care, in addition to improving patient specific outcomes.^{20, 47}

From a systems standpoint, clinical feasibility and affordability has yet to be determined. In this small sample, no-show and reschedule rates for telemedicine visits was only slightly better than office visit attendance rates (66%), with 68% of telemedicine visits conducted as expected ⁴⁸. Further research is needed to determine cost-effectiveness and institutional capability to run a program that operates heavily during evening and weekend hours. Furthermore, given that participants required an average of 114 minutes of individualized asthma education with a nurse to achieve and maintain control, the TEAMS approach is likely to require greater upfront investment by insurers and the medical community to achieve long-term societal gain. Yet, it is abundantly clear that current approaches to "feasible and affordable care" are not effective, as the majority of patients with asthma remain chronically uncontrolled. Thus, it may be necessary to stretch healthcare boundaries and explore ways to make *effective* care *affordable*, rather than perpetuating systems that are *affordable* but largely *ineffective*. In short, moving towards an aggressively proactive rather than reactive approaches to asthma management is essential to changing long-term health trajectories.⁴⁶

Limitations. This proof-of-concept study used a small sample. Patients were predominantly younger, minority, lower SES, lower health-literacy, with moderate/severe uncontrolled asthma, and the intervention was delivered by a single nurse. Further research in a larger and more representative population, with diverse interventionists is needed to replicate

findings, evaluate who the intervention is most effective for, and determine if all intervention components are necessary to achieve similar outcomes.

Despite limitations, we believe these data are compelling, and the processes delineated herein will be useful to those seeking to develop and implement technology-based clinical interventions. Several important lessons were learned: First, the technology took nearly two years to conceptualize, build, and integrate into practice, which was longer than anticipated. The majority of this time was spent navigating systems level barriers, gaining access to EMR build/programming environments, and getting healthcare provider buy-in. It is well-known that many potentially effective interventions are never integrated into clinical practice or the EMR. Our experience suggests that this may be partly due to failure to account for powerful real-world constraints. As seen throughout the development process (Table 1), we found that wherever the intervention disrupted existing practice (even by small amounts), it was met with resistance. Conversely, by avoiding workflow changes and carefully incorporating stakeholder feedback, we were able to minimize resistance and increase support for the intervention. It is also worth noting that even with using a contextually-grounded intervention development approach, where the intervention was crafted to the clinical context, there was still need for additional on-theground customization to account for unanticipated barriers (e.g. trouble engaging patients in office settings; preference of clinic providers to delegate use of the CDSS tool to nursing care). Thus, the final intervention that was implemented was noticeably different than originally conceptualized. Use of focus groups, interviews, community engagement studios, and close collaboration with key stakeholders are important precursors to developing a clinically sustainable intervention.²⁷ Additionally, careful negotiation of institutional practices for new EMR build and IT and administrative support will be essential, as there are substantial barriers to

new technology within the EMR due to potential for far-reaching negative systems impact. Based on these experiences, we conclude that use of advanced EMR, CDSS, and smartphone technology has strong potential to improve asthma care, but premature intervention development without sufficient groundwork could be detrimental to long-term success.

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TABLE 1. Process of contextually grounded intervention development

	Key components of process	Examples
PLANNING S	TAGE	
Problems and potential solutions	 Identify target population and specific problems Assess population capabilities, barriers, facilitators Define approaches that might work for problem and population using prior evidence and theory 	 Population: Adults at risk for uncontrolled asthma (urban, minority, underserved, low SES, low health literacy) Problems: Poor access to care; No show and transportation issues, Nonadherence; Poor follow-up; Poor self-management. Opportunity: 85% adults < 40 years use smartphones regularly
Target	 Identify environments with access to target population 	Environment: Urban primary care "safety-net" practice
environment	 Assess clinical capability, preparedness, and willingness to adopt a new intervention 	 Practice willing to support a tech-based asthma intervention <u>if no negative</u> <u>impact on workflow</u>
	 Identify current clinical structure (physical resources, ways of operating, workflow and scheduling patterns) 	 EMR/smartphone intervention run by nurses would be acceptable and integrate with practice
	 Develop awareness of general and specific barriers (staff, provider, or clinic resource limitations) 	 Modification to work flow/documentation patterns would not be supported by providers due to increased work burden
	 Determine approaches that might work for clinical 	 Limited availability of clinic appointments = delayed follow up.
	context, patient population, and identified problems	 Hours of operation: Weekdays until 4:30pm, conflicts with patient needs for afterhours and weekend care
System capabilities	 Identify system capabilities (technological, programmatic, IT resources, supports/barriers) 	Capabilities : Symptoms can be monitored remotely with smartphones via patient portal to EMR interface
	Identify implementation barriers (e.g. moratorium on new EMR build, anticipated build time and available build	 Guideline-based algorithms and decision support tools in EMR can minimize inaccuracies in clinical care
	resources (personnel and systems access issues), willingness to support novel research-based build)	 Home-based telemedicine can improve access to care Barriers: institutional cap on EMR build > 10 hours - requires formal review for priority and funding; research considered lower priority than clinical applications; limited funding available; initial plan to have clinic nurses do telemedicine visit was found to be non-viable due to patient need for evening and weekend visits, resulting in use of dedicated nurse interventionist
Key stakeholders	 Define potential impact of intervention (development and implementation) on patient, staff, and systems revenue or resources to identify stakeholders 	 Interviews and community engagement studios to engage: Admin: (support for hybrid clinical/research program) Madical faculty (support for program w/ Decident participation)
	 Recognize and respect needs and perspectives of stakeholders who may impact intervention uptake (e.g. patient, community, support staff, nursing, provider, administrative, IT and data security, research, reporting, insurers) 	 Medical faculty (support for program w/ Resident participation) Residents: (support shared patient management; in-basket notification of nursing assessments; <u>not supportive</u> of any workflow change/disruption; low interest in using CDSS) Nursing: (gatekeeper for clinical communication pathways; open to workflow changes if practicable, interested in maximizing scope of practice, including use of CDSS and telemedicine follow up) IT department (gatekeepers for new build; review/approve build)

			 Research community (requires rigorous science/data) Patient and community (feedback on design, problems)
Practice policies	٠	Identify practice policies and incorporate into design	 Factor for established communication pathways, scheduling procedures, usual follow up protocols Identify internal "champions" who can facilitate implementation
Credentialing and approval	•	Determine what certifications may be necessary to obtain approval or facilitate development of the intervention (e.g. specific build or reporting certifications) Identify needed permissions (e.g. IRB, clinical administration, provider/staff approvals or "buy-in")	 (Urgent) Epic builder certification of researcher needed due to limited build resources; EMR build had to be performed by researcher, and administrative approval was needed at multiple levels to support this (Delayed) Asthma educator certification necessary for eventual insurance billing
Funding sources	•	Identify immediate funding sources and potential for long-term sustainable funding	 Immediate: departmental and research funding Eventual: foundation funding → insurer reimbursement Current insurer policy does not reimburse for site to home telemedicine by nursing for asthma care; however demonstration of long-term cost savings could be used to drive policy changes
DEVELOPME	NT	STAGE	
Establishing relationships, Assembling the team	•	Representative of key internal stakeholders	 Relationships: Faculty/staff, patient and community, administrative, clinical research, and information technology Team members: clinical, research, IT, administration, pharmacy, community liaison
Developing technology – a systems approach	•	Translate guidelines to algorithms conceptually Draft (code), revise and test technology Build for compatibility with existing workflow Minimize disturbances to current clinical patterns Seek additional feedback from key stakeholders Modify algorithms and output based on feedback	 Determine quantity, granularity, and specificity of data capture (categorical interval, or narrative) Determine approach to data entry (e.g. smartform, flowsheet) Assess if data capture approach is well situated for reporting and statistica analyses and impact on workflow of data entry method Identify evidence-based guidelines and write code for CDSS Obtain expert review of CDSS (clinician, pharmacist, nursing) Test program comprehensively for analytic functioning—200 unique clinical scenarios evaluated across multiple iterations Design + test CDSS auto-generated progress note, obtain clinician review of note content and format
IMPLEMENTA	TIC	ON STAGE	
Final approvals and Launch		Review of the final product by stakeholders	 Clinic permission to launch IRB approvals Beta testing with patient feedback and revision as indicated

Notes: CDSS=Clinical decision support software; EMR=Electronic medical record; IT=Information technology; SES=Socioeconomic status

Variable	N (%)
Single (% Yes)	6 (86)
Low income ^a (% Yes)	5 (71)
Employed full time (% Yes)	5 (71)
Public insurance (% Yes)	4 (57)
High School Graduate (% Yes)	5 (71)
Sex (% Female)	6 (86)
Comorbid mental illness (% Yes) ^b	5 (71)
Comorbid substance use disorder (% Yes) ^c	4 (57)
Ethnicity (%)	
African American	4 (57)
Hispanic/Latino	2 (29)
Caucasian	1 (14)
Any Controller Medication Use Past Month (% Yes)	3 (43)
Asthma Control (%)	
Well-controlled	0
Not-well-controlled	2 (29)
Very-poorly-controlled	5 (71)
Asthma Severity (%)	
Mild persistent	0
Moderate persistent	2 (29)
Severe persistent	5 (71)
	Mean (SD)
Age	29.5 (5.22)
Years diagnosed with asthma	16.57 (8.33)

TABLE 2. Sample Baseline Characteristics (n=7)

^a Low income: < 200% US Federal poverty level (\$12,140 individual; \$25,100 for a family of four)⁴⁹ ^bMental illness: bipolar, PTSD, panic disorder, anxiety/depression ^cSubstance use disorders: marijuana, tobacco, alcohol

	Baseline Mean (SD)	End Mean (SD)	Change Mean (SD)	Effect (d)	P-value	CI
ACQª	2.75 (1.27)	1.20 (1.35)	-1.55 (1.02)	1.16	0.007	0.59-2.51
Morning symptoms	2.00 (0.82)	1.00 (1.00)	1.00 (1.00)	1.09	0.045	0.075-1.93
Nighttime wakening	2.43 (1.71)	0.57 (1.13)	1.86 (1.95)	1.28	0.038	0.052-3.66
Activity limitations	3.00 (1.92)	1.73 (1.90)	1.57 (1.27)	0.66	0.017	0.40-2.75
Shortness of breath	4.00 (1.52)	2.00 (2.00)	2.00 (1.00)	1.13	0.002	1.08-2.93
Wheezing	2.86 (1.22)	1.00 (1.29)	1.87 (1.34)	1.48	0.011	0.61-3.10
SABA use	2.14 (2.04)	1.29 (1.60)	0.86 (1.57)	0.46	0.20	-0.60-2.31
AQLQ ^a	3.69 (1.27)	5.60 (2.13)	1.91 (1.53)	1.09	0.016	0.50-3.31
Symptom domain	3.49 (1.60)	5.69 (2.13)	2.20 (1.52)	1.17	0.009	0.79-3.61
Activity domain	4.12 (1.15)	5.57 (2.21)	1.45 (1.44)	0.82	0.037	0.12-2.79
Emotional domain	3.49 (1.59)	5.77 (1.99)	2.29 (2.17)	1.27	0.032	0.28-4.29
Environmental domain	3.39 (1.18)	5.18 (2.29)	1.79 (1.86)	0.98	0.044	0.06-3.51
FEV _{1%Pred}	76.14% (17.79)	91.00% (12.99)	14.86% (19.4)	0.96	0.089	-3.09-32.80
	Year prior (SD)	Year post (SD)	Change (SD)	Effect (d)	P-value	CI
Emergency visits	0.28 (0.76)	0 (.00)	0.28 (0.76)	0.52	0.356	-0.41-0.98
Preventive office visits	0.29 (0.49)	1.86 (0.69)	1.57 (0.96)	2.62	0.005	0.67-2.47
Prescriptions - controller medication	1.57 (2.70)	9.29 (3.50)	7.71 (3.09)	2.47	0.001	4.85-10.58
Prescriptions - SABA	4.29 (3.30)	10.57 (7.02)	6.29 (6.55)	1.14	0.044	0.22-12.34
Prescriptions - OCS	0.43 (0.79)	0.14 (0.38)	0.28 (0.95)	0.47	0.457	-0.59-1.17

TABLE 3. Change pre to post intervention for key clinical asthma outcomes

Abbreviations. ACQ=Asthma Control Questionnaire; AQLQ=Asthma Quality of Life Questionnaire; OCS=oral corticosteroid; SABA=short acting beta agonist

^aMinimum important difference = 0.5 per domain and total score; Large effect size (d) is considered >0.80;

TECHNOLOGY ENABLED ASTHMA MANAGEMENT SYSTEM (TEAMS) TABLE 4. Key outcomes and qualitative data by case for patients participating in TEAMS Beta test

P# (Sex) Race Age	Graph of daily PEF (extracted from EMR) Baseline → End	Measure	Pre	Post	Perceived impact of intervention (Exit interviews)
P#1		ACQ	4	4	[Before] I didn't realize my asthma wasn't controlled, I was
	-	AQLQ	2.43	1.19	wheezing but I just thought I had a cold all the time I thought I was doing pretty good even though I be out of
(F) AA	Mar	FEV _{1%pred}	67	68	breath. But when I started using [the peak flow] I saw the
40		# Televisits		3	numbers and realized I couldn't breathe, and that made me want to get my lungs healthy I'll be honest, I didn't used to
	The second secon	# Entries ^a		29	take my pump, but now I use it every day.
		ACQ	2.14	1.29	The program helped me recognize the symptoms of my
P#2		AQLQ	3.97	5.84	asthmaI learned if you don't take your control medicine you can scar your lungs—that got me to pay attention! Now that
(F) AA		FEV _{1%pred}	85	84	I'm daily taking my medicine—it's given me a whole 'nother
32		# Televisits		4	breathI thought I didn't need it, 'til I found out how to use it and what it does for your body. I'm recommending this to my
	and a set of the set o	# Entries		15	family and friends—I'm spreading the word!
	1 1	ACQ	5	1.71	I realized I have the right to control my asthma. First time we
P#3	- WW	AQLQ	1.88	4.59	met I was crying cause all I wanted to do is breathe, but I felt powerless. This changed my life—I'm like 100% better.
(F) HL/AA	MMM	FEV _{1%pred}	46	100	[Before] I didn't use my inhalers cause of how I was raised.
29		# Televisits		5	Now I take my [control inhaler] every day I had a medication that could've been helping me the whole time, but I
		# Entries		64	didn't know what it was for, so I'm not gonna take it!
		ACQ	2.29	0.43	I used to have symptoms for hours every day, and now I
P#4 (F) AA 24		AQLQ	4.41	6.94	almost never do. I take my control inhaler every day and I work out—and I couldn't do that before. And before, if I had an
		FEV _{1%pred}	102	103	asthma attack, I wouldn't take my inhaler, I would've just
		# Televisits		4	called the ambulance and gone to the hospital. But [now] I take it and it works! I have the knowledge and confidence that
		# Entries		24	I can take care of myself—This changed my life!
		ACQ	2.43	0.43	I'm not really having symptoms anymore, maybe once a week. Before I was wheezing all the time, and I didn't have any
P#5		AQLQ	3.28	6.88	medication, and I didn't know what was causing it. I was
(M) AA		FEV _{1%pred}	85	95	suffering. Now, I take my control medication every day. It takes a load off a person when you get the education and you
29		# Televisits		3	can monitor it and control itit changed my life dramatically. I
		# Entries		24	can breathe, and I can control it. I feel like a regular person. It's amazing. I recommend <i>anyone</i> do this.
		ACQ	1.57	0.29	I'm more aware and more educated about my symptoms now,
P#6		AQLQ	5.50	6.81	and I take my control meds every day. I used to wait out my symptoms, thinking "it'll go away, it's OK." I'm less accepting
(F) C		$FEV_{1\%pred}$	80	103	of symptoms now because I know I'm doing damage—I was
24		# Televisits		5	never taught that. It's kind of embarrassing …I'm a nurse and I should've known these things. Now I can better educate my
		# Entries		34	patients and even my doctors.
	MMM	ACQ	1.71	0.29	(Crying) Six months ago I was scared. I was out of work for a
P#7		AQLQ	4.47	6.94	month because of asthma. Now I'm not scared and I know what to do to prevent something small from getting big.
(F) HL		FEV _{1%pred}	68	84	Before, I never paid for my control inhaler because it was
24		# Televisits		4	expensive and I didn't know why I should get it when I could use the cheap one. I don't freak out now if I leave home
	The graph shows for data is means characteristic (2020) 522001 (2020)	# Entries		36	without my rescue inhaler because I almost never need it.

Notes. ^aEntries = home entered symptoms. AA=African American; ACQ=Asthma Control Questionnaire (Range 0-6; Lower scores represent better asthma control; < 1.5 is predictive of controlled asthma); AQLQ=Asthma Quality of Life Questionnaire (Range 1-7; Higher scores represent better quality of life); C=Caucasian; HL= Hispanic/Latino; F=Female; M=Male; P#=Participant(#); Visits=Telemedicine visits with a Nurse; Recordings=daily home symptom and peak flow recordings via smartphone patient portal. (PEF graph images extracted from the EMR show peak flow over time and have been flipped to display data in left to right chronological order. PEF images © 2019 Epic Systems Corporation. Used with permission.

		Range	0.5
	Mean	(1-7)	SD
It helps me be more effective.	7	7	0
It helps me be more productive.	6.86	6-7	0.378
It is useful.	6.71	6-7	0.488
It gives me more control over the activities in my life.	6.71	6-7	0.488
It makes the things I want to accomplish easier to get done.	6.43	4-7	1.134
It saves me time when I use it.	6.14	4-7	1.215
It does everything I would expect it to do.	6.43	4-7	1.134
It is easy to use.	6.29	5-7	0.951
It is easy to use. It is simple to use.	6.86	6-7	0.378
It is user friendly.	6.86	6-7	0.378
It requires the fewest steps possible to accomplish what I want to do with it.	6.57	5-7	0.787
I learned to use it quickly.	6.57	5-7	0.787
I easily remember how to use it.	6.57	6-7	0.535
It is easy to learn to use it.	6.71	6-7	0.488
I am satisfied with it.	6.86	6-7	0.378
I would recommend it to a friend.	6.57	5-7	0.787
It is fun to use.	6.43	4-7	1.134
It works the way I want it to work.	6.43	4-7	1.134
It is wonderful.	6.43	5-7	0.976
I feel I need to have it.	6.14	3-7	1.574
It is pleasant to use.	6.43	4-7	1.134
Average score for survey	6.57	5.6-7	0.654

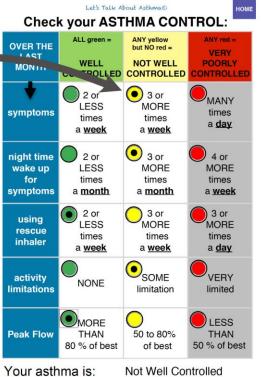
TABLE 5. Item scores for the Usability, Satisfaction and Ease of Use Questionnaire

Notes: Likert scale range 7=Very satisfied to 1=Very dissatisfied

Nurse (computer) side - TEAMS CDSS tool:

Patient (smartphone) side - LTAA series:

SUBJECTIVE	(Quick tab #) = (Narrative text)
Patient perceived asthma control	1 = Not well controlled
Days per week with asthma symptoms	5 = Five days per week (!)
Wake up due to asthma per week	3 = Three nights per week (!)
Rescue inhaler for active symptoms per week	1 = One day per week
Rescue inhaler use BEFORE exercise	0 = Rarely using
Activity limitations due to asthma	1 = Some limitation (!)
Current respiratory illness	0 = No respiratory illness
Any smoking in the past 6 months	No
NOTES	Symptoms are worse at night than daytime
OBJECTIVE	
Patient appearance	0 = Appears well
Respiratory effort	0 = Normal respiratory effort
Peak Flow	350
PFM personal best	450
PFM % of personal best	78% (calculated)
FEV1 (today)	2.06
FEV1 Predicted	2.46
FEV1 % of predicted	84% (calculated)
FEV1 or PFM Zone	Green (calculated, FEV1 preferred)
NOTES	
NURSING ASSESSMENT	
ICS formulation details (Rx)	Eluticasone MDI 220 mcg
Remaining inhalations (# on back of ICS inhaler)	Fluticasone MDI 220 mcg 85
Maximum prescribed puffs per day (AM + PM)	2
Actual puffs ICS (AM)	1
Actual puffs ICS (PM)	0
Other asthma control medications	0 = None
Current rescue medication	Albuterol (Proair)
Actual puffs rescue inhaler (describe)	Rarely using - rationing/holding off
Any symptoms of life-threatening asthma	N = None
Asthma safety assessment	N = No Safety concerns
NOTES	Having trouble remembering nighttime dose
ANALYSIS + RECOMMENDATIONS (Calculate	ed)
Asthma control	Not Well Controlled
	Moderate Persistent asthma
Asthma severity (EPR3)	
Guideline based assessment of controller therapy	Insufficient control medication
Guideline based assessment of controller therapy • Guideline recommended stepwise therapy	Step 3-4
Guideline based assessment of controller therapy Guideline recommended stepwise therapy Provider prescribed stepwise therapy level 	
Guideline based assessment of controller therapy • Guideline recommended stepwise therapy • Provider prescribed stepwise therapy level • Patient using stepwise therapy level	Step 3-4 Step 3 Step 2
Guideline based assessment of controller therapy • Guideline recommended stepwise therapy • Provider prescribed stepwise therapy level • Patient using stepwise therapy level • Can still increase ICS by (#) puffs/day	Step 3-4 Step 3
Guideline based assessment of controller therapy • Guideline recommended stepwise therapy • Provider prescribed stepwise therapy level • Patient using stepwise therapy level • Can still increase ICS by (#) puffs/day • Recommended ICS adjustments	Step 3-4 Step 3 Step 2
Guideline based assessment of controller therapy • Guideline recommended stepwise therapy • Provider prescribed stepwise therapy level • Patient using stepwise therapy level • Can still increase ICS by (#) puffs/day	Step 3-4 Step 3 Step 2 1
Guideline based assessment of controller therapy • Guideline recommended stepwise therapy • Provider prescribed stepwise therapy level • Patient using stepwise therapy level • Can still increase ICS by (#) puffs/day • Recommended ICS adjustments	Step 3-4 Step 3 Step 2 1 Increase to full prescribed dose
Guideline based assessment of controller therapy • Guideline recommended stepwise therapy • Provider prescribed stepwise therapy level • Patient using stepwise therapy level • Can still increase ICS by (#) puffs/day • Recommended ICS adjustments • Recommended follow up	Step 3-4 Step 3 Step 2 1 Increase to full prescribed dose Telemedicine follow up
Guideline based assessment of controller therapy • Guideline recommended stepwise therapy • Provider prescribed stepwise therapy level • Patient using stepwise therapy level • Can still increase ICS by (#) puffs/day • Recommended ICS adjustments • Recommended follow up NURSING PLAN	Step 3-4 Step 3 Step 2 1 Increase to full prescribed dose Telemedicine follow up 2 = Follow up in 2 weeks
Guideline based assessment of controller therapy Guideline recommended stepwise therapy Provider prescribed stepwise therapy level Patient using stepwise therapy level Can still increase ICS by (#) puffs/day Recommended ICS adjustments Recommended follow up NURSING PLAN Follow up plan	Step 3-4 Step 3 Step 2 1 Increase to full prescribed dose Telemedicine follow up
Guideline based assessment of controller therapy Guideline recommended stepwise therapy Provider prescribed stepwise therapy level Can still increase ICS by (#) puffs/day Recommended ICS adjustments Recommended follow up NURSING PLAN Follow up plan Medication refill NOTES	Step 3-4 Step 3 Step 2 1 Increase to full prescribed dose Telemedicine follow up 2 = Follow up in 2 weeks 0 = No refills needed
Guideline based assessment of controller therapy Guideline recommended stepwise therapy Provider prescribed stepwise therapy level Can still increase ICS by (#) puffs/day Recommended ICS adjustments Recommended follow up NURSING PLAN Follow up plan Medication refill NOTES PLAN: Education	Step 3-4 Step 3 Step 2 1 Increase to full prescribed dose Telemedicine follow up 2 = Follow up in 2 weeks 0 = No refills needed Continue to work on adherence, strategies to
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adapted from the National Guidelines (2007) Figure 3-4c

Space

Don't forget to use a Spacer!

Spacers help more medicine get in your lungs. When you use your inhaler with out a spacer a lot of the medicine gets lost.

- 1. Shake the inhaler and attach it to the spacer
- 2. Breathe OUT
- 3. Put the spacer mouth piece in your mouth, squirt in one puff into the chamber, and then inhale slowly through your mouth
- 4. Hold for 10 seconds
- 5. Wait 1 minute and repeat as directed
- 6. Clean your spacer as directed



Figure 1. Illustration of the TEAMS CDSS tool used by nurse for data entry and guideline based assessments during telemedicine visits (left), including built-in patient educational modules from the Let's Talk About Asthma series for smartphone (right) Copy right J Mammen, used with permission

Figure E1. Sample progress note auto-generated by the TEAMS CDSS tool

Progress note

TECHNOLOGY ENABLED ASTHMA MANAGEMENT SYSTEM (TEAMS)

Asthma telemedicine visit summary xx/xx/xxxx:

- Assessment: Very Poorly Controlled, likely Severe persistent asthma based on prescribed medications and symptom pattern.
- Prescribed: SYMBICORT 160-4.5 mcg (Budesonide-Formoterol MDI) at a MEDIUM dose (640 mcg daily) and is currently taking 2 puffs in the morning and 2 puffs at night (640 mcg daily - MEDIUM dose)
- Other asthma control medications: NONE (taking cetirizine for allergy)
- Recommended stepwise therapy is Step 5.
- The patient is currently taking Step 4 Insufficient control medication
- Plan: Schedule office visit with PCP, Follow up virtual visit in 2 weeks

DETAILED NOTE BELOW

SUBJECTIVE

XXX was seen via Zoom (telemedicine) for nursing follow up of Asthma.

The patient reports the following:

Daytime symptoms	Every day, throughout the day (maybe 2-3x day,			
Well controlled <= 2 x week	mostly morning or evening). Notes recurrent chest			
	discomfort which resolves with albuterol			
Night time wake up from asthma	Wakes three nights a week			
Well controlled <= 2 x month				
Use of rescue inhaler for symptoms	Using inhaler many times a day			
Well controlled <= 2 x week				
Activity limitations	Some limitation			
Well controlled = none				

Patient perceived asthma control: **Very poorly controlled** Current respiratory illness: Feels fine Any smoking in the past 6 months: **Yes** Any symptoms of life-threatening asthma: No

NOTES: noticing chest discomfort all day, a pain with deep breathing, pain resolved with taking albuterol and stays away for 3 to 4 hours then returns.

MEDICATION USE:

Prescribed: SYMBICORT 160-4.5 mcg (Budesonide-Formoterol MDI) and is currently taking 2 puffs in the morning and 2 puffs at night (MEDIUM dose)—fully adherent. Low dose is equal or less than 540mcg; High dose is greater than 1080mcg

Taking any additional long acting beta agonist or leukotriene inhibitor: NONE (taking cetirizine for allergy) Rescue medication: Albuterol inhaler - used about 4-5 times a day - takes prior to AM/PM Symbicort as recommended, and then a couple of times during the day

Most recent patient self-reported data (MyChart smartphone monitoring) shows:

	4/16/2019	4/15/2019	4/14/2019	4/5/2019	4/3/2019	4/1/2019
Time	6:00 AM	7:01 AM	9:22 AM	7:52 AM	5:44 AM	2:23 PM
Did you have ANY	I had SOME					
SYMPTOMS of	asthma	asthma	asthma	asthma	asthma	asthma
asthma in the	symptoms	symptoms	symptoms	symptoms	symptoms	symptoms
past 24 hours?						
What was your	358	357	352	401	318	533

today?

OBJECTIVE

Appears well - Normal effort with respiration

Peak flow today via digital PEF meter is 481 L/min, which is 100% of personal best (481) FEV1 (today): 3.35 FEV1 Predicted: 4.15

• FEV1 % of predicted: 81

• FEV1 or PFM Zone: Green

ASSESSMENT

No current safety concerns: Symptoms have decreased over all, but noticing regular chest discomfort - needs to follow up in office ASAP and may need stepwise increase to bring symptoms under control faster. Should follow up ASAP for chest pain.

EPR-3 calculated asthma assessment:

Asthma control: Very poorly controlled Asthma severity (EPR3): Severe persistent asthma Guideline based assessment of controller therapy: Insufficient control medication

- Guideline recommended stepwise therapy: Step 5
- Provider prescribed stepwise therapy level: 4
- Patient using stepwise therapy level: 4
- · Recommended ICS adjustments: Taking maximum dose prescribed by provider
- · Recommended follow up: Follow up with PCP ASAP

Based on DHHS. National Heart Lung & Blood Institute. Asthma Care Quick Reference: Diagnosing and Managing Asthma

PLAN

Asthma Education covered this visit:	
What is asthma + what causes symptoms	
What happens when asthma is uncontrolled	Demonstrates understanding
How do you know if your asthma is controlled?	Demonstrates understanding
Control vs. rescue medications	Demonstrates understanding
Recognizing symptoms of asthma	Demonstrates understanding
What to do during an asthma attack	Demonstrates understanding
Life threatening asthma symptoms	Demonstrates understanding
How to take inhalers correctly	Demonstrates understanding
How and why you should use a spacer	Demonstrates understanding
How to use a peak flow meter	Demonstrates understanding
Asthma triggers and how to handle them	Demonstrates understanding
Managing exercise induced asthma	Demonstrates understanding
Keeping track of symptoms	
Using an asthma action plan	

Personal goals for asthma management: Wants to get rid of chest discomfort; Total minutes asthma education: 35 Follow up plan: Schedule office visit with PCP ASAP, Follow up virtual visit in 2 weeks. Reinforced need to follow up in office ASAP; given # to call clinic since he did not have it.