Development and pilot testing of a mobile health solution for asthma self-management: Asthma action plan smartphone application pilot study

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BACKGROUND: Collaborative self-management is a core recommendation of national asthma guidelines; the written action plan is the knowledge tool that supports this objective. Mobile health technologies have the potential to enhance the effectiveness of the action plan as a knowledge translation tool.

OBJECTIVE: To design, develop and pilot a mobile health system to support asthma self-management.

METHODS: The present study was a prospective, single-centre, nonrandomized, pilot preintervention-postintervention analysis. System design and development were guided by an expert steering committee. The network included an agnostic web browser-based asthma action plan smartphone application (SPA). Subjects securely transmitted symptoms and peak flow data daily, and received automated control assessment, treatment advice and environmental alerts.

RESULTS: Twenty-two adult subjects (mean age 47 years, 82% women) completed the study. Biophysical data were received on 84% of subject days (subject day = 1 subject × 1 day). Subjects viewed their action plan current zone of control on 54% and current air quality on 61% of subject days, 86% followed self-management advice and 50% acted to reduce exposure risks. A large majority affirmed ease of use, clarity and timeliness, and 95% desired SPA use after the study. At baseline, 91% had at least one symptom criterion for uncontrolled asthma and 64% had \geq 2, compared with 45% (P=0.006) and 27% (P=0.022) at study close. Mean Asthma Quality of Life Questionnaire score improved from 4.3 to 4.8 (P=0.047).

CONCLUSIONS: A dynamic, real-time, interactive, mobile health system with an integrated asthma action plan SPA can support knowledge translation at the patient and provider levels.

Key Words: Asthma; Cellular phone; Guideline adherence; Implementation; Knowledge translation; Patient education as topic; Primary care

A sthma is the most common pediatric disease and the third most common adult chronic disease in Canada, with a prevalence of 12% in children ≤ 12 years of age and 8.4% in individuals ≥ 12 years of age (1-4). Although asthma care based on guideline recommendations leads to well-controlled asthma in the majority of patients, studies have demonstrated that 50% of patients with asthma in Canada experience disease that is uncontrolled (1,5). There are nearly 150,000 resultant emergency room visits and 60,000 hospital admissions in Canada each year (1). The economic burden of asthma in Canada is substantial: the estimated direct and indirect costs in 2011 totalled more than \$1.8 billion (6).

Collaborative self-management and engaging patients as active participants in their care can reduce this morbidity by 40% to 60% (7-9), is a key element in the Wagner chronic disease management model (10) and is a core recommendation of national asthma guidelines including the Canadian Asthma Consensus Guidelines (CACG) L'élaboration et le projet pilote d'une solution mobile pour l'autogestion de l'asthme : projet pilote d'une application pour téléphone intelligent d'un plan d'action de l'asthme

HISTORIQUE : L'autogestion coopérative est une recommandation clef des lignes directrices nationales sur l'asthme. Quant au plan d'action écrit, c'est l'outil de connaissance qui appuie cet objectif. Les technologies mobiles dans le secteur de la santé peuvent accroître l'efficacité du plan d'action à titre d'outil de transfert du savoir.

OBJECTIF : Concevoir, élaborer et faire l'essai pilote d'un système mobile dans le secteur de la santé pour soutenir l'autogestion de l'asthme.

MÉTHODOLOGIE : La présente étude était une analyse monocentrique prospective et non aléatoire d'un projet pilote avant et après l'intervention. La conception et l'élaboration du système ont été orientées par un comité d'experts. Le réseau se composait de l'application pour téléphone intelligent (ATI) d'un plan d'action sur l'asthme fondé sur un fureteur Web agnostique. En toute sécurité, les sujets transmettaient quotidiennement leurs symptômes et leur débit de pointe et recevaient des évaluations du contrôle, des conseils thérapeutiques et des alertes environnementales automatisés.

RÉSULTATS : Vingt-deux sujets adultes (âge moyen de 47 ans, 82 % de femmes) ont effectué l'étude. Les données biophysiques ont été transmises dans 84 % des jours-sujets (jour-sujet = 1 sujet × 1 journée). Dans 54 % des jours-sujets, les sujets ont vérifié la zone de contrôle de leur plan d'action et dans 61 % des jours-sujets, la qualité de l'air courante. De plus, 86 % respectaient les conseils d'autogestion et 50 % prenaient des mesures pour réduire leurs risques d'exposition. Une grande majorité soulignait la facilité d'utilisation, la clarté et la rapidité, et 95 % désiraient continuer d'utiliser l'ATI après l'étude. Au départ, 91 % présentaient au moins un critère d'asthme non contrôlé et 64 % en présentaient au moins deux, par rapport à 45 % (P=0,026) et à 27 % (P=0,022) à la fin de l'étude. L'indice moyen du questionnaire sur la qualité de vie avec l'asthme est passé de 4,3 à 4,8 (P=0,047).

CONCLUSIONS : Un système mobile dans le secteur de la santé, à la fois dynamique, interactif et en temps réel, muni d'une ATI intégrée du plan d'action sur l'asthme, peut soutenir le transfert du savoir pour le patient et le dispensateur.

(11,12). The written action plan is a patient-focused knowledge tool that facilitates knowledge translation, specifically by supporting patient-initiated evidenced-based clinical decision making. It is a communication tool that supports patients in the assessment of asthma control and directs management decisions that occur between regular clinic visits. In the context of regular clinical review, the written asthma action plan has been demonstrated to be efficacious in multiple randomized controlled trials and demonstrated to be effective as a component of care in community asthma programs (7-9).

However, outside of specialized asthma programming, there is a significant knowledge-to-action gap, with as few as 2% of asthmatic patients having a written action plan (13). An action plan delivered as a wireless mobile health application has the potential to be a more effective community knowledge translation tool. eHealth technologies can improve access to care and improve communication between patients and providers; they have been demonstrated to increase

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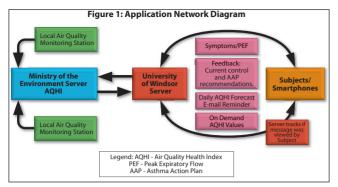


Figure 1) Application network diagram

adherence with practice guidelines and improve health outcomes (14,15). Furthermore, there is a consumer demand for eHealth self-care technology from individuals who seek answers to questions about their chronic disease (16). Importantly, virtually all Canadian households now have access to broadband Internet services via computers and/or mobile phones, making mobile health systems highly accessible (17).

An asthma action plan smartphone application (SPA) has the following advantages over a written action plan: decision support for the creation of an evidence-based plan; increased accessibility, portability 24 h per day, seven days per week; real-time and standardized assessment of asthma control with interactive feedback on clinical actions; automated medication adherence reminders; improved patient engagement and self-efficacy by capitalizing on teachable moments; and permitting real-time and forecast environmental inputs, such as air quality conditions, that support risk reduction/trigger avoidance behaviours. Health Canada and Environment Canada have developed and implemented the Air Quality Health Index (AQHI) nationally. The AQHI is a simple air quality and health risk scale ranging from 1 to 10, best air quality/ lowest health risk to poorest air quality/highest health risk (18). With its clear risk reduction messaging, the AQHI can provide real-time asthmatic trigger avoidance advice as a component of the asthma action plan.

The Canadian Institutes of Health Research defines knowledge translation conceptually as the process that connects the researcher to the knowledge user, converts knowledge into actions and links research outputs to clinical practice (19). Nationally, there remains a significant knowledge-to-practice gap with respect to asthma collaborative self-management; we hypothesized that access to an asthma action plan SPA would reduce that gap by intervening at two levels: by implementing an asthma action plan in patients who may not otherwise have received one (provider level); and/or by facilitating utilization of the action plan (patient level). In the present study, we sought to design, develop and pilot test a mobile asthma self-management system within the Canadian context.

METHODS

Study design and participants

The present analysis was a prospective, single-centre, nonrandomized pilot study. Asthma-related health outcomes are reported comparing preintervention with postintervention data. A convenience sample of subjects recruited from the Primary Care Asthma Program in Windsor, Ontario, was used. This population has been described previously (8). Adults (>18 years of age) with a physician diagnosis of asthma who reported symptom worsening with exposure to air pollution were enrolled. Patients with respiratory disease other than asthma were excluded. There were no specific technology-based inclusion or exclusion criteria. All subjects received care within the asthma program including self-management education and a written action plan before enrollment. On enrollment, subjects were provided with a BlackBerry Storm 2 (BlackBerry, Canada) smartphone and a data plan using TELUS as the carrier at no cost. Certified asthma/respiratory educators instructed subjects on how to use the smartphone and the asthma action

plan SPA. Subjects were educated about the AQHI scale and health-risk messages and provided with a Health Canada AQHI brochure.

Mobile health network and communication infrastructure

The SPA used standard 3DES encryption and secure sockets layer network transmission security protocols in an IBM Domino enterprise application server architecture, with an integrated lightweight directory access protocol for authentication according to user name and encrypted passwords. The SPA-based platform used bidirectional wireless communication. The system server acquired forecast and real-time AQHI data from the Ontario Ministry of Environment through a direct secure server-to-server connection (Figure 1).

SPA design

The SPA was developed and beta tested in collaboration with expertise at the Centre for Smart Community Innovation. An interdisciplinary expert steering committee provided clinical advice on the content and format of the SPA. The design process was iterative and informal, and no users were engaged during this phase. The CACG were the evidence-based guidelines selected as the foundational knowledge tool (12). The written action plan of the Ontario Lung Association was adapted. This plan has a traffic light configuration.

SPA description

The SPA was a web browser-based application functional on any Internet-enabled device, presented to fit the screen size of a smartphone. Adaptive design technology was not used. After launching the application, the user was directed to a splash screen where they entered their username and password. After authentication, the user was presented with all of the functional components of the application in a tab-accessible format. Accessible tabs were as follows: AQHI, which opened current AQHI information; AQHI Forecast for Tomorrow; Breathing Test (for entering peak flow data); Today's Symptoms (for entering current symptoms); Your Current Zone (calculated based on the subjects symptoms and peak expiratory flow inputs); Your Asthma Action Plan (a view of their complete action plan); and Breathing Test Graphs (a summary plot of their peak expiratory flow values). The peak expiratory flow meters were not 'Bluetooth' linked; subjects entered numerical data using the SPA device keypad. Symptoms, β_2 -agonist use and adherence to asthma control medication were entered daily using on-screen radio buttons for symptoms/adherence and the numerical keypad for the number of β_2 -agonist puffs. Adherence was self-reported based on a 'yes or no' response to a question personalized with their controller medication, dose and frequency. This functioned as a medication adherence reminder system. Subjects received e-mail reminder prompts if their data were not entered within a predefined time range.

Bidirectional secure communication was established consisting of information sent by the subject to the server and from the server to the subject.

Subject to server: Daily symptoms, β_2 -agonist use, peak expiratory airflow and controller medication use, daily self-reported risk reduction behaviour in response to the AQHI and weekly self-reported health care utilization. The server analyzed biophysical inputs, determined the subjects' level of asthma control, and instantly presented a green, yellow or red screen on the smartphone identifying current zone of control along with the self-management recommendations. Asthma control was assessed continuously based on the benchmark criteria for control described in the CACG and calculated using a rolling sevenday average (12).

Server to subject: Daily AQHI forecast for the next day was sent at 15:00 with corresponding risk reduction message; real-time notification was sent if the AQHI forecast differed significantly from current conditions; e-mail alerts were sent for moderate and high-risk days; and asthma control assessment displayed as green, yellow or red zone with the corresponding asthma management advice (Figure 1). The server was able to track whether system messages were viewed by the subject.

Outcome measures

System outcomes: The primary outcome was the volume of data transferred between the subject and the server; the secondary outcome measures were the effective message delivery/contact rate (how frequently information sent by the server was reviewed by the subject) and subject satisfaction.

Patient outcomes: The primary health outcome measure was the change in mini-Asthma Quality of Life Questionnaire (AQLQ) administered by paper questionnaire at the enrollment and withdrawal visits, respectively. Secondary outcomes included subject self-reported adherence to risk reduction messaging (recorded by radio button daily on the SPA) and self-management recommendations (evaluated by questionnaire at study close), subject understanding of the action plan and the AQHI (by paper questionnaire at the enrollment and withdrawal visits respectively), asthma symptom control (baseline by questionnaire averaging symptoms over the preceding four weeks by recall and postintervention based on the last week of symptoms recorded by radio button on the SPA), and health care utilization (baseline over the preceding three months by recall and intervention self-reported weekly by radio button on the SPA). There is no validated knowledge assessment tool for the action plan or the AQHI; therefore, a simple knowledge questionnaire was created. A satisfaction survey was created: subjects used a five-point Likert scale ranging from 'strongly disagree' to 'strongly agree' to rate statements.

Statistical analysis

Descriptive: Contact rates, subject satisfaction and self-reported risk reduction behaviours, and knowledge outcomes are presented descriptively.

Comparative: Pre-post intervention, mini-AQLQ, symptoms and health care utilization were compared using McNemar's χ^2 test.

Ethics review

The present study was approved by the Research Ethics Board at Western University, London, Ontario (REB 17197E). Informed consent was obtained from all subjects.

RESULTS

In the comparative analysis, P values were included where statistically significant differences were identified.

Subject characteristics

Twenty-four subjects from the Primary Care Asthma Program operating in seven sites with nine primary care physicians were recruited over an eight-day period. Twenty-two subjects completed the study between July 12 and September 30, 2010 (81 days), 82% women, 82% on controller therapy, mean (\pm SD) age 47 \pm 12 years (Table 1).

Bidirectional communication

The total volume of data transfers between server and subject were 4135 including: subject-to-server clinical (ie, symptoms) 2773; and server-to-subject forecasts 409, AQHI real-time values 953.

Message delivery/contact rates

Contact rate data are presented as 'subject-days', in which 1 subject day = 1 subject \times 1 day (or, for example, 10 subjects \times 20 days = 200 subject days). The AQHI forecast was viewed by the subject on 24% (409 of 1694) and AQHI real-time values on 61% (953 of 1573) of subject days. Clinical data were received from subjects on 84% (1433 of 1716) of subject days. The action plan current zone of control with self-management advice was viewed on 54% (846 of 1562) of subject days.

Satisfaction

A majority (82% to 100%) of subjects agreed or strongly agreed with seven positive statements about the ease-of-use, timeliness, simplicity and clarity of the SPA, mobile health system and the associated AQHI advisories. Subjects agreed or strongly agreed that the system "improved

TABLE 1 Subject characteristics (n=22)

Characteristic	
Female sex	18 (82)
Age, years, mean ± SD	47±12
Smoking status	
Current	4 (18)
Previous	5 (23)
Expose to second-hand smoke	4 (18)
Own and use a cellular telephone	17 (77)
Own a smartphone	14 (64)
Skill level* with using the web browser and e-mail	
Very good	4 (18)
Average	6 (27)
Below average	2 (9)
Poor	3 (14)
Mean FEV ₁ , % predicted ± SD	87±24
Mean PEF, % predicted ± SD	73±21
Patient taking any controller medication	18 (82)
ICS alone	3 (14)
Combination therapy (ICS+LABA)	15 (68)
Patients taking rescue medication (past two weeks)	15 (68)
Rescue medication dose/day, mean ±SD	0.92±1.53

Data presented as n (%) unless otherwise indicated. *Skill level is self-reported. FEV₁ Forced expiratory volume in 1 s; ICS Inhaled corticosteroid; LABA-Long-acting beta agonist; PEF Peak expiratory flow

my ability to control my asthma" (82%) and that the system "is ready for use by people with asthma" (95%). Almost all subjects indicated that they would continue to use the SPA if it was available after the study.

Knowledge

Subjects had no knowledge of the AQHI before enrollment. The baseline knowledge questionnaire (three questions) was administered after initial AQHI education. At baseline, 50% and 68% correctly identified the high and moderate risk reduction messages, 68% correctly identified that the AQHI was reported on a scale from 1 to 10 versus 86%, 100% and 95% at study close.

All subjects had a written action plan before enrollment in the study. An 11-question action plan knowledge questionnaire that included questions about the number of zones on the action plan, the benchmark symptom profile for each zone, the name of the controller medication to be taken in each zone, the role of preventer medication, the role of rescue medication, and the dose and frequency of controller medications in each zone was administered. In nine of 11 questions, the proportion of subjects that answered correctly improved from baseline to study close. The average increase in the proportion of individuals answering correctly was 18%.

Adherence to self-management and risk reduction recommendations

All subjects indicated that they used the SPA to determine whether their asthma was controlled. Sixty-eight per cent were surprised to be notified by the SPA that their asthma was not controlled, and 86% reported following action plan recommendations to improve control. Fifty per cent of subjects changed their behaviour at least once in response to a moderate risk AQHI health message that read "consider reducing or rescheduling strenuous activities outdoors if you are experiencing symptoms" and 32% changed their behaviour at least six times. There were no high-risk air quality days during the study interval.

Quality of life

Subjects demonstrated an improved asthma-related quality of life; the mean mini-AQLQ score improved by 0.5, from 4.3 at baseline to 4.8 (P=0.047).

No App name	Description	Daily Share Gr. journal info or c	Share Graph info or chart	Graph Peak or chart flow	ak Zones w (R,G,Y)	۲ ۵	Participate in Research	te in Inhale ch Location* puffs [†]	Inhale * puffs [†]	FEV,	Excel data	Google Health	GINA	EA	Action plan	KF Sx
Current study mHEALTH Sys	ic: iPhone, BlackBerry and Andro	d comp	atible		1											
 AQHI – Asthma Action Plan Smartphone Application 		>		>	>	>	>			>	>		>	>	>	>
BlackBerry, Waterloo, Ontario	0															
1 Asthma Tracker	Track asthma level	>	>	>												
2 Peak Flow Calculator	Track peak flow			>	>											
iPhone, Apple Inc, USA																
1 STAT Asthma NHLBI Guidelines	Navigate the complex NHLBI guidelines on the Treatment of Asthma															
2 Asthma-Charter	Peak flow and medication recording			>												
3 Asthma Journal Free	Keep daily journal	>	>													
4 Asthma Journal Pro	Keep daily journal	>	>													
5 AsthmaMD	Track asthma and help research	>	>	`	>	>	>									
6 iAsthma GPS Tracker HD Lite	Record of the location of the asthma attacks, temperature, time of the year, and other relevant information	>						>								
7 Asthma Tracker by healthycloud.com			·	>	>				>	>	>					
8 Asthma journal (iAsthma)	Diary to track triggers, medication	>				>						>				
9 iAsthma GPS Tracker HD	Record of the location of the asthma attacks, temperature, time of the year, and other relevant information	>						>								
10 AsthmaCheck	Medication planner, notification, Symptom check	>	>	>		>							>			
11 Asthma-Charter MMC	Peak flow and medication recording			>												
12 AsthmaPulse		>	>	>	>	>						>		>	>	
13 Peak Flow	Provided by NAEPP			>												
14 asthmaTrack	Record symptoms, treatments, vital signs and environmental conditions using our pre-loaded templates	>	>												>	>
15 Abriiz	Record information and receive reminders to take medication	>	>													>
16 iAsthma in Control	Manage daily medications	>		>												>
Android																
1 Asthma Tracker & Log	Frequency of attacks with the length of attack		ŗ	>	>	>		>								
2 Asthma Tracker & Log Free	Frequency of attacks with the length of attack		r	` `	>	>		>								
3 My Asthma Log Pro	Manage: Attacks, medications, triggers, loca- tions, symptoms						>		>							>
4 Peakflow	Peak flow readings o	>	>	>												
5 SymptomTracker Pro	Track any symptoms/triggers/ conditions for several disease included asthma	>				>										
6 AsthmaTracker Pro	Track a variety of triggers related to asthma		`			`										

There were improvements in all four domains: symptoms, activity limitation, emotional function and environmental stimuli; however, only improvements in the activity domain were statistically significant. Thirty-two per cent of subjects demonstrated an increase of at least 0.5 (minimum clinically important difference).

Symptoms

The CACG symptom benchmarks of asthma control were better at study end than at enrollment. In the week before enrollment, 91% of subjects had >1 symptom outside of benchmark criteria and 64% had >2, compared with 45% (P=0.006) and 27% (P=0.022), respectively, in the final week of the study.

Health services utilization

There were fewer total urgent health care visits (unscheduled physician visits, emergency department visits, hospitalizations) and a smaller proportion of subjects requiring visits during the study (approximately three months) compared with the three-month interval before enrollment (21 versus 15 visits, and 46% versus 32%, respectively). The results, however, did not reach statistical significance.

DISCUSSION

We designed, developed and pilot tested a mobile eHealth application for asthma self-management that embedded a web browser-based asthma action plan SPA in a telecommunication network that delivered realtime environmental (air quality) information with risk-reduction advice; received and analyzed biophysical inputs; and provided immediate asthma self-management instructions back to the subject. Subjects accepted the SPA, were satisfied with its functionality and most wanted to continue using it after the pilot study. Our cohort was highly engaged in the management of their asthma: they used the SPA system almost daily; viewed their action plan approximately every other day; followed risk reduction and asthma management recommendations; and learned about their asthma action plan and about the AQHI. An evaluation of health outcomes demonstrated improvements in symptom control and in asthma-related quality of life.

Despite a proliferation in the use of eHealth technologies, and despite the pervasiveness of smartphones, there are relatively few studies that have evaluated the role of mobile health technologies in the management of chronic respiratory disease (14,15). We identified seven studies that focused on a qualitative description of a SPA, patient acceptance and satisfaction, but without health outcomes or system performance measures (20-26). Two randomized controlled trials examined the health impacts of a mobile asthma self-management system (27,28). Ryan et al (27) compared a mobile phone-based monitoring system with paper-based monitoring in 288 adolescents and adults in the United Kingdom, and concluded that the mobile phone-based system was not more effective. In contrast, in a study from Taiwan, Liu et al (28) randomly assigned 89 patients to a mobile phone-based system or usual care and found significant improvements in lung function, quality of life and reduced health services utilization.

A commercial search of the three major online App stores, BlackBerry App World (http://appworld.BlackBerry.com/webstore/ product/1?lang=en); App Store (iPhone, Apple Inc, USA) (www. apple.com/ca/itunes/); and Android Market (https://market.android. com/) using the search term "Asthma" identified 180 Apps. Of this initial group, 133 did not directly relate to asthma, leaving 47 asthma Apps. Of these 47 Apps, only 24 (two for BlackBerry, 16 for iPhone and six for Android) were functionally related to the system in the present project. A majority of these Apps had limited functionality, were primarily electronic diaries and, to our knowledge, none have been evaluated in a clinical trial or developed using the CACG. Selected criteria of the functionality of the 'best' 24 Apps are compared with the SPA developed for the present project in Table 2.

In the present study, the SPA transformed a static written action plan into a real-time interactive plan that was 'always' accessible, responded to current symptoms, lung function measurements and environmental exposures, and provided physician-directed

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management recommendations based on the current level of asthma control. There is a strong consumer demand for eHealth information that creates the environment within which eHealth self-care technologies, such as SPA, can be developed and implemented (16). This demand is mirrored by increasing access to mobile health technology in Canada. In 2011, there were more than 27 million wireless subscribers, and almost one-half were smartphone users (16,17). Thus, a national infrastructure to support mobile health self-care exists, there is a perceived demand for these technologies, and our study suggests that an asthma action plan SPA would be accepted and used. Future development of eHealth tools needs to consider societal disparities in access to wireless resources (16). Paradoxically, asthma patients of low socioeconomic status - who have the lowest rates of access to wireless service - may have the greatest need for enhanced self-management tools (16). A tiered implementation approach that ensures access to eHealth tools on any Internet-enabled device would mitigate this disparity.

The present analysis was designed as a feasibility/pilot study and our primary objective was to design, develop and pilot test a mobile health self-management system for asthma; there was no expectation that we would show an improvement in health outcomes. However, we demonstrated improvements in asthma-related quality of life and in symptom control. We acknowledge that without a randomly assigned control group, we cannot exclude the possibility of bias in our health outcomes evaluation. These results also have limited generalizability because of the small sample size and because this population self-identified air pollution as a trigger, was in poor baseline control and did not all own a smartphone. Additionally, we used two methods for recording asthma symptoms that may have influenced these results. The sample size and pre-post design do not permit conclusions regarding causation. Whereas there is a seasonal influence on asthma, the present study was conducted over the summer months only - a future trial will need to test the effect of the application over a full year. An additional limitation of the present study was the absence of end-user involvement in the design phase. Acknowledging these important limitations, the lessons learned from the present study can be applied to a definitive future trial.

It is feasible to implement a mobile eHealth solution in support of asthma self-management based on the CACGs that is accepted by individuals with asthma, measures subject and system performance and has the potential to improve asthma-related health outcomes. Future development will include a more robust design phase using user-centred design philosophy, adaptive design technology to enhance access, enhanced functionality including a formally developed interactive medication adherence reminder system, and a randomized controlled evaluative design with a statistically determined sample size.

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