Original Paper

Caregiver-Informed Safety and System Requirements for Real-Time Feedback During Pediatric Inhaler Use: Qualitative Concept-Elicitation Study

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Abstract

Background: Correct use of a pressurized metered-dose inhaler (pMDI), usually with a valved holding chamber, depends on use-related conditions that caregivers may not observe directly, including inhalation pattern, actuation-inhalation timing, mask seal, and device orientation. Many digital inhaler systems emphasize actuation or adherence. Systems that infer technique-related conditions from proxy signals may add real-time feedback but also create false reassurance if a positive state is displayed when evidence is inadequate. Caregiver expectations for such feedback and its failure states remain poorly characterized before prototype development.

Objective: This study aimed to characterize caregivers' experiences of pediatric inhaler administration and translate responses to a proposed sensor concept into traceable candidate safety, system, and validation requirements.

Methods: We conducted 23 semistructured concept-elicitation sessions through Zoom videoconference with 27 caregivers of children who currently or previously used a pMDI. Interviews consisted of 19 individual and 4 dyadic sessions pairing 2 caregivers from different households. Sessions were conducted remotely between April and July 2026 from the University of Calgary, Alberta, Canada. Recruitment originated in Calgary and was not geographically restricted. A 6-phase guide examined current practices, difficulties, prior digital-tool use, and responses to a screen-shared clip-on concept incorporating airflow-, timing-, seal-, and orientation-related sensing; on-device feedback; an optional child-facing app; and a caregiver dashboard. No working prototype was evaluated. Approximately 86,000 transcript words underwent hybrid directed and conventional qualitative content analysis using an 18-category codebook. Two researchers independently coded the complete 27×18 matrix (486 paired decisions) across 2 rounds. Consensus categories were translated into candidate requirements and assigned an earliest verification or evaluation locus. Counts are descriptive caregiver-voice tallies, not prevalence estimates.

Results: Persistent uncertainty about whether administration conditions were adequate was the dominant lived experience (19/27); for 5 caregivers, existing passive cues had not resolved it. A simple, real-time on-device signal was endorsed by 25 caregivers, but willingness to consider the concept was conditional on reliability (9 caregivers named reasons for abandonment, notably a “false green”), low-friction operation during acute symptoms (12/27), minimal added bulk and technique change, and one or more of clinical validation, clinician recommendation, or a trial pathway (composite category; 23/27). Stances on gamification (20/27), dashboard cadence (18/27), aesthetics (24/27), and privacy (18/27) supported an optional, configurable software layer. Intercoder agreement was 94% (Cohen κ=0.88). The analytic synthesis yielded a conceptual architecture separating observable proxy signals, an inference and data-quality gate, and positive, corrective, or uncertain feedback states.

Conclusions: Participating caregivers prioritized immediate and interpretable feedback about use-related conditions. The findings support conservative state assignment, an explicit uncertain state for indeterminate signals, and app-independent acute-use

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feedback. These are candidate requirements rather than validated device specifications; subsequent work should proceed through bench verification, simulated-use human factors evaluation, and prospective clinical or field validation.

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KEYWORDS

asthma; metered-dose inhaler; child; caregivers; digital health; human factors; trust calibration; user-centered design; qualitative research; requirements engineering

Introduction

Pediatric Inhaler Use as a Feedback Problem

Asthma is the most common chronic respiratory disease in childhood [1]. It is characterized by chronic airway inflammation and narrowing of the small airways, which produce wheeze, cough, and chest tightness symptoms, which can escalate into requiring urgent care [2]. Management rests on inhaled corticosteroids, taken daily to suppress inflammation, and short-acting bronchodilators, taken as needed to relieve acute symptoms [3]. Both are delivered to the airways by inhalation, making their effectiveness contingent not only on adherence but on the physical technique of each administration.

The pressurized metered-dose inhaler (pMDI) is the most widely used delivery device and a cornerstone of pediatric management [1]. It consists of a small, pressurized canister that releases a dose of aerosolized medication each time it is actuated. Effective delivery requires the user to synchronize that actuation with a slow, deep inhalation and then hold the breath so that the aerosol can deposit into the lower airways [4]. In children, pMDIs are commonly paired with a valved holding chamber (VHC), a plastic chamber that retains the aerosol for several seconds [5]. For younger users, a face mask is also paired with the VHC [1].

Despite widespread use, correct administration remains difficult. Reviews spanning decades show persistently high rates of errors in inhaler use, particularly in actuation-inhalation coordination and postinhalation breath-holding [5,6]. Critical errors are also common among children hospitalized for asthma, and incorrect technique is associated with poor disease control and greater acute care use [7,8]. Guidelines recommend VHC use to reduce coordination demands and oropharyngeal deposition [3], but the chamber relocates rather than removes the technique burden. Correct administration remains affected by breathing patterns, mask seals, and chamber models—conditions that can be difficult for caregivers to assess directly [3,5].

Caregivers are central to pediatric inhaler administration: they prepare and deliver doses, judge whether the maneuver was successful, and sustain treatment routines. Yet, they receive little objective feedback during an individual administration. Existing research documents caregiver burden, knowledge gaps, data-sharing concerns, and caregiver-perceived determinants of asthma morbidity [9-12]. Collectively, this literature shows that home administration is shaped by emotion, routine, stigma, access, and equity as well as technique, but caregiver-informed requirements for real-time device feedback remain less developed.

Digital Inhalers, Proxy Signals, and False Reassurance

Digital inhaler technologies support adherence monitoring, education, and symptom management. Meta-analytic evidence suggests that electronic adherence-monitoring devices can improve adherence in children [13] and that patient-facing digital tools can improve asthma control and may reduce severe exacerbations across age groups [14,15]. Many systems emphasize actuation and adherence, although some newer devices capture technique-related proxies [1,14]. Practical human factors barriers, including battery burden, device incompatibility, notification fatigue, and device loss, also threaten continued use [14,16,17]. Gamified pediatric apps may support knowledge or engagement, but their value depends on age, design, and sustained participation [12,18,19].

Technique-related sensing and real-time feedback already exist in several forms. Some connected inhalers measure inspiratory flow rather than actuation alone: the Digihaler, a dry-powder inhaler, has an inbuilt inhalation flow sensor, and next-generation Hailie add-on sensors monitor inspiratory flow, shaking, and orientation, with results returned through a smartphone app [20]. CapMedic, a sensor attached to a pMDI, gives real-time audiovisual feedback on the device about critical errors, including the number of shakes, inhaler orientation during actuation, actuation-inhalation coordination, and inhalation duration [20]. Some spacers also give feedback on the device itself: the Flow-Vu indicator on a VHC provides visual feedback during inhalation, and parents of children aged 1 to 5 years preferred it to the same chamber without the indicator, although asthma control did not differ [21]. These products nonetheless leave 3 gaps. First, electronic pMDI monitors are usually not combined with a spacer or VHC, and the Smart AeroChamber, a digital chamber available as a research prototype, returns its data only to clinicians after download [20]; the chamber-and-mask configuration used with young children is therefore largely unserved. Second, electronic feedback in these systems is directed to the person using the inhaler, whereas a spacer indicator shows a single cue that the caregiver must watch and interpret; to our knowledge, none combines airflow, timing, mask seal, and orientation into one interpreted state for a caregiver. Third, to our knowledge, none has been described with an explicit state for inadequate evidence or with requirements for how a positive state should behave when the underlying signal is uncertain. This study is therefore positioned as novel not in sensing any single condition but in 3 respects: the intended user is a caregiver administering a dose to a child through a VHC rather than a person self-administering; the concept combines several use-related conditions into an interpreted on-device state that includes an explicit uncertain state; and caregiver accounts are translated into traceable

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candidate requirements with an assigned earliest verification locus rather than into design preferences alone.

A future system combining airflow, timing, mask-seal, and orientation signals could estimate whether prespecified use-related conditions were met during administration. These proxy signals cannot, by themselves, establish pulmonary deposition or confirm that a prescribed dose reached the lungs. A caregiver-facing positive state is therefore an interpretation of the measured conditions, and its safety depends on calibrated reliance, validated operating limits, and clear claim boundaries.

Human-automation research distinguishes appropriate reliance from misuse, in which a person relies on automation beyond its capability, and disuse, in which a potentially useful aid is rejected [22]. Trust is safest when calibrated to system performance and limitations rather than maximized [23]. In home medication use, an incorrect positive state may create false reassurance, whereas overly frequent or poorly explained corrective feedback may increase frustration, distress, or abandonment. Real-time feedback should therefore be treated as a safety-relevant information architecture, not only as an engagement feature.

From Caregiver Evidence to Risk-Informed Requirements

User-centered requirements analysis offers a means of converting stakeholder evidence into criteria that can be traced into design and evaluation [24]. Recent digital health studies have used qualitative workshops or interviews to derive actionable requirements for intervention components, workflow integration, and implementation [25,26]. However, few studies have examined caregiver-informed requirements for immediate on-device inhaler feedback, particularly the failure states that could undermine trust and the sequence of evidence needed before deployment.

This study addressed that gap by using caregiver interviews conducted before prototype testing. The proposed concept was an elicitation stimulus, not a validated product. The analysis therefore distinguishes participant evidence from analyst-derived requirements and limits conclusions to feedback about measured use-related conditions. It does not estimate lung deposition, sensor accuracy, usability, adoption, adherence effects, or clinical benefit.

Objectives

This study had 2 objectives: (1) to characterize caregivers' experiences of administering inhaled medication to children, including technique difficulties, adherence drivers, and prior digital-tool use; and (2) to translate caregiver responses to a proposed clip-on smart-sensor concept—including acceptance conditions, rejection triggers, privacy boundaries, and unprompted feature requests—into candidate requirements for prototype development and evaluation.

Methods

Ethical Considerations

The study, "Investigation on Human Factors Design Parameters for New Inhalers," was approved by the University of Calgary Conjoint Faculties Research Ethics Board (REB25-1436). Participation was voluntary, and all participants provided written informed consent, including consent to audio recording. Participants could withdraw at any time and request removal of their data for up to 2 weeks after the interview, after which the data were deidentified. Names and contact information were collected only for scheduling and reimbursement. Research data were deidentified, stored securely, and scheduled for permanent deletion after 5 years. Participants received a CAD $20 (US $14.10; US $1=CAD $1.4181 as of November 10, 2026) gift card. Interview topics could evoke mild distress related to caring for a child with respiratory symptoms; this risk was mitigated through a voluntary, caregiver-paced format.

Study Design and Reporting

This exploratory qualitative study combined a brief preinterview questionnaire with 23 semistructured concept-elicitation sessions: 19 individual and 4 dyadic interviews. The questionnaire captured participants' self-reported caregiving and device context before the interview. Questionnaire responses were used descriptively to characterize the sample and contextualize the qualitative findings, not for inferential analysis.

NM, a female MSc student in biomedical engineering with training in qualitative and human factors methods, conducted all the interviews. She helped develop the concept stimulus, had no prior relationship with the participants, was not a clinician, and approached the topic as an outsider to caregivers' lived experience. JP, the supervising investigator and second coder, observed 1 session without participating and was also involved in the project. These roles were considered in the reflexive procedures described below.

Transcripts were analyzed using hybrid qualitative content analysis, combining directed (deductive) and conventional (inductive) coding [27]. Deductive seed categories were drawn from 2 sources: the stable interview guide, including the concept components it presented (on-device light feedback, a child-facing gamification app, and a caregiver dashboard), and a prior structured gap analysis of pediatric inhaler human factors conducted for this project, which had identified caregiver-facing feedback, mask-seal quality, child emotional-state detection, and health-equity considerations as candidate problem areas. An inductive pass allowed findings outside that frame to emerge. Reporting follows COREQ (Consolidated Criteria for Reporting Qualitative Research) [28], with the completed checklist provided in Multimedia Appendix 1. Earlier project documents used the term "focus groups." As 19 sessions involved 1 caregiver and 4 involved 2 caregivers from different households attending the same session, the sessions are reported here as individual and dyadic interviews.

Recruitment and Participants

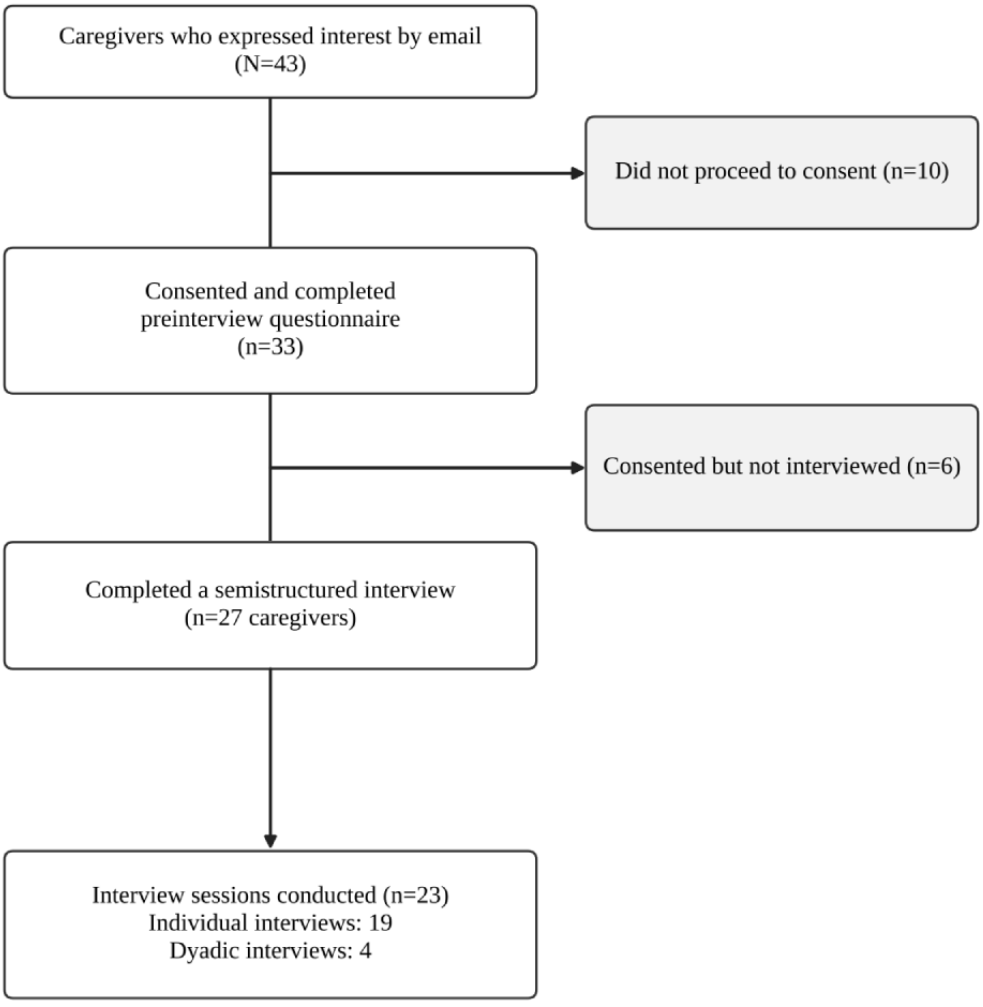
Eligible participants were adults aged 18 years or older who were fluent in English and self-identified as a caregiver of a child who currently or previously used medication delivered by inhaler. No additional exclusion criteria were applied. Recruitment notices were distributed through the University of Calgary Participate in Research website, digital notices posted on the Alberta SPOR SUPPORT Unit (AbSPORU) participant

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engagement platform, and social media advertisements placed through the Cumming School of Medicine Meta platforms. Notices were issued from Calgary, Alberta, Canada, and participation was not restricted geographically. Interested caregivers contacted the study team by email and were screened for eligibility. Of 43 caregivers who expressed interest, 33 provided consent and completed the preinterview questionnaire. Six consented but were not interviewed, leaving 27 caregivers who completed 23 sessions (Figure 1). Sessions were conducted remotely between April and July 2026.

All caregivers who responded to the recruitment notices and met the eligibility criteria were invited to participate; no selection was applied. Recruitment closed at the end of the planned data collection period rather than in response to a prespecified sample size. The research team observed that later sessions were largely repeating difficulties described in earlier ones, though this was not formalized as a stopping criterion. The dominant categories also recurred without new properties in the final sessions, which supports a bounded information-sufficiency claim for dose-use uncertainty, simple on-device feedback, and validation or clinician backing rather than exhaustive saturation across all categories. The study's analytic aim was to elicit the range of caregiver-reported difficulties and reactions to the concept rather than to estimate their prevalence, and the resulting sample of 27 caregivers is consistent with sizes reported for qualitative studies with a narrow aim, a specific population, and an established analytic framework [29,30]. As participants were not selected to achieve variation across characteristics, the sample composition reflects who volunteered; the implications of this are addressed in Limitations.

Figure 1. Participant recruitment, screening, and interview workflow. Each dyadic interview involved 2 caregivers from different households attending the same session.



Concept Stimulus and Analytic Scope

The stimulus was a screen-shared concept for a clip-on module intended to sense airflow pattern, breath timing, mask seal, and inhaler orientation (Multimedia Appendix 2). It included simple light-emitting diode feedback, an optional child-facing gamification app, and a caregiver dashboard. The concept brief did not include a functioning sensor, a validated algorithm, or a physical attachment. Participants therefore responded to an anticipated information service and product configuration rather than an operational device.

Several steps were taken to limit leading and framing effects. The concept was introduced as an early-stage idea under evaluation rather than as a planned product; the moderator made no claims of benefit, effectiveness, or safety; each element was first met with a neutral prompt before any targeted probe. As

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NM had helped develop the concept, the guide also deliberately solicited rejection triggers, abandonment conditions, privacy concerns, and redesigns, and criticism was probed neutrally. Phases 1 to 3 of the guide, covering current practice, difficulties, and prior digital-tool use, were completed before the concept was displayed; so, accounts of lived experience were elicited without reference to the proposed solution.

Throughout this manuscript, "positive feedback" refers to its meaning in the intended device: that predefined criteria for one or more measured use-related conditions, once validated, have been met; the concept evaluated in this study had no validated algorithm. It would not mean that medication reached the lungs, pulmonary deposition was adequate, or a clinically sufficient dose was delivered. "Anticipated acceptance" and "stated willingness to try" refer to interview responses; they are not measures of actual adoption or continued use. In reporting these responses, we distinguished 3 levels: problem recognition, in which a caregiver identified the targeted difficulty in their own routine; anticipated acceptance, in which a caregiver judged the concept desirable in principle; and stated willingness to try, in which a caregiver said they would trial the device, in most cases under stated conditions. These levels are a convention for reporting results; they are neither categories in the codebook nor a separate coding dimension, as the codebook recorded only whether each of its 18 categories was present for each caregiver. Intended sustained or routine use was neither elicited nor coded and is not reported. As participants had not handled or used a device, a statement about future regular use would have been a forecast about a product whose form, reliability, and cost were not yet defined; this level of acceptance is therefore deferred to simulated-use and field evaluation with a working prototype. Because the levels were not coded separately, each tally represents the level set by its category's coding rule and does not imply the levels above it: the lived-experience categories record problem recognition; the simple on-device feedback category records anticipated acceptance at most; and condition categories, such as conditions for distrust or abandonment, record the conditions caregivers attached to acceptance or to considering use, not stated willingness to try, which was not tallied.

Data Collection

Interviews were conducted from April to July 2026 using Zoom videoconferencing software (Zoom Communications, Inc). Participants were informed of NM's role and the study aim. JP observed session 5 without participating. Sessions occurred once and were audio-recorded; no contemporaneous field notes were taken. Transcripts were not returned to participants, and member checking was not conducted.

The 6-phase guide covered (1) a recent administration experience and technique confidence; (2) current challenges and pain points; (3) adherence, motivation, and prior digital-tool use; (4) responses to the sensor concept, including its on-device feedback, gamification app, and caregiver dashboard; (5) design, usability, and safety, including an 8-item physical-design checklist, a second question on prior digital-tool use, trust and adoption conditions, technique-change probes, and privacy probes; and (6) a closing redesign prompt and the single most important problem to solve. The checklist was the guide's only structured item: its 8 features served as prompts for discussion, selections were not tallied, and caregivers' spoken responses were coded with the rest of each transcript in the content analysis described below. The concept was introduced only after current experience had been explored to reduce anchoring of the initial accounts.

Sessions were scheduled for approximately 45 minutes. Recordings were transcribed using Zoom transcription and exported as time-stamped verbatim transcripts. Transcript-level accuracy was addressed by auditing the automated transcripts against the recordings. Transcripts were lightly cleaned by removing time stamps, merging consecutive turns from the same speaker, and correcting speech-recognition errors only when meaning was unambiguous. Ambiguous segments were not quoted and were excluded from tallies. The corpus contained approximately 86,000 words, including approximately 41,200 participant words.

Qualitative Content Analysis

Two researchers (NM and JP) independently coded the full corpus, each blinded to the other's coding. NM developed the codebook and coded all the transcripts; JP then applied the same codebook to all transcripts without access to NM's matrix or the drafted findings. Agreement between the 2 coders was calculated, a category rule was clarified, and the complete matrix was recoded, and the remaining disagreements were discussed until consensus was reached.

The unit of analysis was a meaning unit: a phrase, sentence, or short exchange conveying 1 idea about inhaler use, caregiver experience, or the concept stimulus [31]. Analysis followed the preparation, organization, and reporting sequence described by Elo and Kyngäs [32]. NM repeatedly read all transcripts, labeled meaning units close to participant language, added inductive codes alongside deductive seeds, grouped codes into subcategories and higher-order categories, and tested categories against disconfirming cases.

The final codebook contained 18 categories. Counts in the Results are consensus caregiver-voice tallies, not frequencies of mentions. A caregiver was counted once within a category when the transcript contained a clearly qualifying statement. Stance categories for gamification, dashboard cadence, aesthetics, and privacy count any clearly expressed position, regardless of direction; a high tally therefore indicates that many caregivers expressed a view, not that they agreed on a single option. Statements whose meaning remained unclear in the context of the surrounding exchange were not counted. As the unit of analysis was a meaning unit, a mixed statement was divided into its parts: the approving part was coded to the relevant concept category, such as simple on-device feedback; and the condition to the corresponding condition category, such as conditions for distrust or abandonment, simplicity and low friction, or validation and clinician backing. A caregiver could therefore be counted in both a concept category and a condition category, and endorsement tallies in the Results are reported with the conditions attached to them.

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In the 4 dyadic sessions, each caregiver was assigned a separate participant identifier at transcription, and all coding was performed at the level of the individual speaker. Participants are identified by session number (P1-P23), with the suffixes a and b distinguishing the 2 caregivers in each dyadic session. A category was credited to a caregiver only where that caregiver articulated it in their own turns; unelaborated agreement with a co-participant was not coded unless the caregiver described the experience or position themselves. The 2 caregivers in each dyad came from different households and therefore described separate children and separate routines because they were interviewed together and could hear one another; however, their accounts are not independent, as noted in Limitations.

Coding was managed in Microsoft Excel, with intercoder agreement calculated in a purpose-built workbook. Dedicated qualitative analysis software was not used because the analytic object was a 27×18 presence-or-absence matrix, which both coders could code identically while blinded and from which agreement could be computed directly.

Each coder's matrix comprised 27 caregiver voices by 18 categories (486 paired decisions). Round 1 produced 85.6% agreement and a pooled Cohen κ of 0.71. One category rule, training and onboarding experiences, had a κ of 0.27 because coders differed on whether descriptions of how families learned qualified without evidence of a training gap. The rule was clarified to include both, wording for 2 high-prevalence categories was reviewed, and JP recoded the complete matrix rather than only discrepant cells.

Round 2 produced 94% agreement and a pooled Cohen κ of 0.88, conventionally interpreted as almost perfect agreement [33]. Per-category κ values ranged from 0.52 to 1.00 (mean 0.84), and all categories exceeded the prespecified threshold of 0.40. The lowest values occurred for simple on-device feedback and validation or clinician backing, both of which had extreme positive base rates. Prevalence-adjusted bias-adjusted κ values were 0.78 and 0.85, respectively [34]. The remaining 29 disagreements were reviewed case by case and resolved by discussion-based consensus against the codebook rules. As JP was also involved in the project, disagreements were not adjudicated by an independent third researcher. In terms of the trustworthiness criteria of Lincoln and Guba [35], this independent double coding of the complete matrix, together with analysis of the complete transcript corpus, illustrative evidence for every category, and retention of disconfirming cases, supported credibility. The codebook, the 2 coding matrices, and the disagreement register, which document each coding decision and its resolution, supported dependability and confirmability.

Member checking and transcript return were not used because the analytic claims are aggregated statements about caregivers' initial responses to a concept, which returning transcripts after an interval could have revised post hoc; interpretive accuracy was instead addressed by the independent double coding and consensus procedure described above.

Requirements Translation

After consensus coding, each category was translated into a candidate requirement using a 3-step traceability procedure informed by user-centered requirements analysis [24,25]. First, the analysts stated the underlying information need, use-related difficulty, anticipated failure, or implementation constraint. Second, they drafted a candidate requirement without exceeding what the participant evidence supported. Third, they assigned the earliest applicable verification or evaluation locus: technical or bench, simulated-use human factors, clinical or field, or implementation or governance. Requirements spanning more than 1 locus were labeled accordingly and refined against coded excerpts and disconfirming cases.

This translation deliberately separates participant evidence from design inference. For example, participants directly emphasized that a false-positive signal would destroy trust. The explicit uncertain state was an analyst-derived risk control responding to that evidence; it was not a feature directly requested by all caregivers. Similarly, the staged validation sequence is a design and evaluation synthesis, not an outcome observed in the interviews.

Interpretation of the Descriptive Counts

All n/27 values are descriptive consensus tallies of caregiver voices. They are not prevalence estimates or inferential statistics. Equal weighting prevents more verbose speakers from dominating the tallies, but the counts do not represent the amount or intensity of discussion. As the concept was screen-shared rather than handled, reactions reflect responses to a described and depicted concept, not to use.

Results

Participant Characteristics

The cohort comprised 27 caregivers across 23 sessions. Participant demographics, child characteristics, and inhaler configurations are summarized in Table 1; participant-level detail is provided in Multimedia Appendix 3. Boundary cases included a toddler, self-managing adolescents, a nonspeaking autistic child, episodic-use households, and a household managing both a pMDI and a dry-powder inhaler. Caregiver race or ethnicity, educational attainment, household income, and geographic location were not captured in the preinterview questionnaire. The questionnaire also did not capture the clinical severity of the child's condition, such as asthma control, exacerbation history, or treatment step; the closest available indicators are duration of inhaler use and administration frequency, reported in Table 1. Prior use of digital tools for inhaler management, such as apps or connected devices, was asked about in every session and was reported by 2 caregivers. Caregivers who tracked doses did so on paper or in a spreadsheet (P13 and P19), P22 had never tried a digital tool ("I'm not really a tech person"), and P14's son had rejected an earlier app whose "animations were for babies."

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Table 1. Aggregate caregiver, child, and inhaler-use characteristics (n=27 caregiver voices across 23 sessions).[a]

Characteristic	Participants (n=27), n (%)
Caregiver age (years)	
26-34	11 (40.7)
35-44	14 (51.9)
45-54	2 (7.4)
Caregiver gender	
Woman	12 (44.4)
Man	12 (44.4)
Nonbinary or gender diverse	3 (11.1)
Relationship to child	
Parent	24 (88.9)
Aunt or uncle	2 (7.4)
Older sibling	1 (3.7)
Child age (years)	
<2	1 (3.7)
2-4	2 (7.4)
5-7	7 (25.9)
8-11	8 (29.6)
12-18	9 (33.3)
Child respiratory diagnosis	
Asthma	24 (88.9)
Allergies	1 (3.7)
No formal diagnosis	2 (7.4)
Duration of inhaler use	
<6 months	2 (7.4)
6-12 months	5 (18.5)
1-3 years	7 (25.9)
>3 years	13 (48.1)
Device interface	
pMDI[b] alone	9 (33.3)
pMDI with mouthpiece	1 (3.7)
pMDI with spacer and face mask	7 (25.9)
pMDI with spacer and mouthpiece	10 (37)
Administration frequency	
As needed	9 (33.3)
Every few days	1 (3.7)
Once daily	5 (18.5)
Multiple times daily	12 (44.4)

[a]Characteristics were self-reported. Percentages may not total 100 due to rounding. Counts are across 27 caregiver voices.

[b]pMDI: pressurized metered-dose inhaler.

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Analytic Overview

The 18 categories formed 4 domains: lived experience and acute-use context; core feedback and trust; the optional digital layer; and implementation, governance, and boundary conditions. Table 2 summarizes how the evidence domains were mapped to candidate requirements.

Table 3 provides the full traceability matrix, including an example quote for each category, intercoder reliability, and the earliest proposed verification or evaluation locus. Two findings organized the pattern. First, caregivers repeatedly described uncertainty about whether administration conditions were adequate. Second, they endorsed a simple on-device signal only under conditions of reliability, low friction, and use during difficult administration moments.

Table 2. Mapping of consensus caregiver evidence categories to analyst-derived candidate requirements.

Consensus category	Voices, n[a]	Derived candidate requirements[b]
Lived experience and acute-use context	• Dose-use uncertainty (n=19) • Forgetting, rushing, mood, or stigma (n=16) • Distress disrupted coordination (n=13) • Ergonomic mismatch or bulk (n=11) • Passive cues failed (n=5)	• R1: Prioritize difficult as well as routine use conditions. • R2: Keep acute-use operation low friction and immediately visible. • R3: Minimize bulk and avoid required technique change.
Core feedback and trust	• Simple on-device feedback endorsed (n=25) • Conditions for distrust or abandonment (n=9)	• R4: Use a small set of rapidly interpretable feedback states. • R5: Reserve positive feedback for validated criteria. • R6: Use issue-specific corrective feedback. • R7: Provide an uncertain state when evidence is insufficient.
Optional digital layer	• Aesthetic preferences (n=24) • Gamification stances (n=20) • Dashboard or alert stances (n=18)	• R8: Keep acute-use feedback independent of the app. • R9: Make gamification optional, age-tiered, and contingent on validated event criteria. • R10: Use a default-quiet dashboard and configurable appearance.
Implementation, governance, and boundary conditions	• Validation, clinician recommendation, or trial pathway (n=23) • Privacy positions (n=18) • Simplicity or low friction (n=12) • Built-in versus clip-on and technique change (n=10) • Unprompted features (n=10) • Training and onboarding experiences (n=9) • Age, device, and use-pattern boundaries (n=8) • Cost and access (n=6)	• R11: Require evidence and evaluate clinician-recommended or trial-based introduction pathways. • R12: Address affordability, access, and privacy. • R13: Provide brief, rewatchable training. • R14: Configure by age, device interface, and daily versus episodic use.

[a]Counts are consensus category tallies across 27 caregiver voices from 23 sessions (19 individual and 4 dyadic). Counts are descriptive and are not prevalence estimates; percentages are therefore not reported.

[b]Requirements (R) were derived by the analysts from the consensus categories; they were not stated verbatim by participants and are not validated specifications.

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Table 3. Traceability from consensus qualitative categories to candidate requirements and the earliest proposed verification or evaluation locus.

Consensus category and example quote[a]	n[b]	κ[c]	Candidate requirement[d]	Earliest locus[e]
Lived experience and acute-use context				
Dose-use uncertainty ("gray area") *"I think it worked … I think she got the dose"* [P4]	19	0.76	Provide immediate feedback about validated use-related conditions; do not present the state as proof of pulmonary deposition.	Bench and simulated use
Forgetting, rushing, mood, or stigma affected adherence *"keep it real for teenagers, don't make it feel like medical devices are something to be ashamed of"* [P21a]	16	0.85	Support reminders and technique coaching without adding acute-use friction or stigma.	Clinical or field
Distress disrupted coordination or calming *"technique actually slips when he panics"* [P21a]	13	0.85	Support difficult and distressed use conditions; feedback should remain visible without shaming or escalating distress.	Simulated use
Ergonomic mismatch, grip difficulty, or bulk *"press mechanism isn't really designed for [small hands]"* [P8]	11	0.92	Minimize bulk and grip interference and preserve the familiar use sequence.	Bench and simulated use
Existing passive cues failed *"that whistle don't work"* [P7]	5	0.79	Do not rely on a whistle or valve movement as the sole confirmation channel.	Bench and simulated use
Core feedback and trust				
Simple on-device feedback endorsed *"instantly recognizable, especially when sleep-deprived"* [P13]	25	0.52[f]	Use a rapidly interpretable on-device state; do not make acute-use feedback dependent on an app.	Simulated use
Conditions for distrust or abandonment *"false green light when [my] child didn't actually [inhale] properly"* [P8]	9	1.00	Assign a positive state only when validated criteria are met; use an explicit uncertain state when evidence is insufficient.	Bench and simulated use
Optional digital layer				
Aesthetic configuration stance *"look normal … not feel clinical"* [P23]	24	1.00	Offer age-appropriate, configurable, and discreet appearance options.	Simulated use
Gamification stance *"animations were for babies"* [P14]	20	0.91	Make gamification optional, age-tiered, resistant to unrelated reward-seeking interactions, and contingent on validated event criteria.	Simulated use
Dashboard and alert-cadence stance *"I don't need a ping for every single leak"* [P14]	18	0.76	Use a default-quiet dashboard with summaries, exception alerts, and user-set escalation.	Simulated use
Implementation, governance, and boundary conditions				
Validation, clinician recommendation, or a trial pathway (composite) *"if the doctor had prescribed one of these, and the app came with it, we would have just done that"* [P13]	23	0.63[f]	Match evidence to claim boundaries and evaluate clinician recommendation and low-commitment trial pathways separately before scale-up.	Clinical or field, and implementation
Privacy position *"I don't need the app to know where my child is*" [P21a]	18	1.00	Do not collect location or direct identifiers by default; minimize audio or video capture and retention.	Bench and governance
Simplicity and low friction *"if it's too complicated … there's no fun in it again"* [P20]	12	0.69	Enable low-setup acute use, avoid mandatory app pairing during a dose, and target multiweek battery life.	Bench and simulated use
Built-in versus clip-on architecture and technique-change resistance *"if it changes the core flow, like different breath timing, that's way different"* [P14]	10	0.83	Verify clip-on effects on airflow, internal volume, and aerosol-device performance; consider an integrated architecture as a later product state.	Bench

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Consensus category and example quote[a]	n[b]	κ[c]	Candidate requirement[d]	Earliest locus[e]
Unprompted feature demands *"there is no way to know if the contents are really finished"* [P16]	10	0.92	Evaluate counter, reminder, and locator functions as secondary features; subject any lockout to separate clinical risk analysis so access to rescue therapy is not impeded.	Simulated use and clinical governance
Training and onboarding experiences *"just picked it up—I don't even think the pharmacist went over it"* [P18]	9	0.83	Provide brief, rewatchable technique instruction that supports return demonstration.	Simulated use
Age, device, and use-pattern boundary conditions *"a poor parent trying to do it on a toddler"* [P13]	8	0.91	Configure by age, device interface, and daily versus episodic use.	Simulated use, and clinical or field
Cost and access *"available at the pharmacy" … "covered … for benefits"* [P1a]	6	1.00	Treat affordability and routine pharmacy or clinic access as implementation requirements.	Implementation and governance

[a]Example quotes are from caregivers coded to the category and are shown in lightly cleaned form, with clarifying insertions in square brackets. P refers to participant. Numbers are session numbers, and the suffixes a and b distinguish the 2 caregivers in a dyadic session (eg, P21a).

[b]Consensus category tallies across 27 caregiver voices from 23 sessions (19 individual and 4 dyadic); counts are descriptive and are not prevalence estimates.

[c]Per-category Cohen κ from round 2 of independent double coding of the complete 27×18 matrix (486 paired decisions).

[d]Candidate requirements are analytic products derived by the research team; they are not participant statements or validated specifications.

[e]Earliest proposed locus: bench, simulated-use human factors, clinical or field, or implementation or governance.

[f]Prevalence-adjusted bias-adjusted κ was 0.78 for simple on-device feedback and 0.85 for validation, clinician recommendation, or a trial pathway.

Persistent Uncertainty and Conditions for On-Device Feedback

Dose-use uncertainty was the dominant lived experience (19/27). Caregivers described a recurring inability to judge whether an individual maneuver was adequate rather than a single isolated error. P4 called each dose a "gray area," P8 wanted "real confidence it was delivered correctly," and P13 described the problem as "message sent, message received."

Existing passive cues did not reliably close that gap (5/27). Caregivers described flow whistles or valve movement as indirect, late, or easy for children to circumvent. In 1 household, unresolved uncertainty had contributed to mostly stopping administration because the caregiver did not know whether it was helping. This account does not establish causality, but it illustrates a possible behavioral consequence of unresolved uncertainty.

Simple, real-time on-device feedback was the most endorsed concept element (25/27). Several caregivers independently converged on a traffic-light metaphor. P13 said a yes-or-no signal would be "instantly recognizable, especially when sleep-deprived," whereas a gauge could invite second-guessing. The immediate on-device signal, rather than the app, was the center of the proposed value.

Willingness to consider the concept was nevertheless conditional on reliability: 9 caregivers named conditions under which they would distrust or abandon the device, most pointedly a false positive signal. P8 and P15 stated as follows:

> *…A false green light when [my] child didn't actually [inhale] properly would make me lose trust in the device completely.* [P8]

> *…I would abandon a device if it is signifying the use is good but actually there is a leak.* [P15]

In the requirements translation, these statements were mapped to 3 candidate states: positive only when validated criteria for measured conditions are satisfied, corrective when a specific actionable issue is detected, and uncertain when evidence or signal quality is insufficient (Figure 2). The 3-state vocabulary is an analyst-derived risk control; participants did not test or validate it.

Caregivers also warned that harsh or persistent negative feedback could add distress during respiratory symptoms:

> *…If it flashes red nonstop during a genuine attack, this could shame and further distress the child.* [P4]

Together, these accounts identified 2 opposing anticipated failure modes: false reassurance from an incorrect positive state and added distress or abandonment from harsh or persistent corrective feedback.

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Figure 2. Risk-informed architecture and validation sequence derived from the qualitative requirements analysis. The model is conceptual, noncausal, and not technically or clinically validated. Positive denotes that validated criteria for measured use-related conditions are met; corrective denotes a specific detected issue; and uncertain denotes insufficient evidence for reassurance. The 3-state architecture is an analytic synthesis and was not directly tested with participants. A. Observable signals; B. Inference and data-quality gate; C. Caregiver-facing state; D. Requirement domains; E. Staged validation sequence.



Acute-Use and Physical Design Constraints

Caregivers described coordination and calming difficulties during respiratory distress (13/27). They reported that timing actuation with a slow inhalation became harder when a child was frightened or panicking and that technique could deteriorate during the situations in which feedback would be most needed.

Physical ergonomics added friction (11/27). Reported barriers included pressing the canister with small hands, handling a long chamber, and transporting bulky equipment at school. Caregivers also resisted changes to established administration sequences.

> *…Six years of muscle memory...changing it mid-attack would be asking for trouble.* [P4]

Low-friction operation was an explicit condition (12/27). P8 rejected "fumbling with an app, pairing Bluetooth mid-attack." Battery dependence was also described as a failure point, particularly for school use. These accounts were translated into candidate requirements for app-independent acute-use feedback, no mandatory pairing during a dose, minimal grip interference, and bench testing of any clip-on effect on airflow resistance, internal volume, and aerosol-device performance. These requirements were not tested in this study.

Forgetting, rushing, mood, shortened inhalation maneuvers, and stigma affected routines or adherence (16/27). The combined evidence positioned reminders and coaching as secondary functions that should not increase acute-use friction or make an adolescent-facing device conspicuously childish or medical.

Optional and Configurable Digital Layer

Gamification stances were polarized and age-bounded (20/27). Some caregivers expected games to motivate younger children, whereas low-screen households would opt out and adolescents could reject age-inappropriate graphics. Caregivers also anticipated that children might manipulate an app to obtain rewards. The requirements synthesis therefore designated gamification as optional, age-tiered, and contingent on a validated sensed event rather than an unverified app interaction. This requirement does not imply that the event confirms pulmonary delivery or clinical benefit.

Dashboard and alert-cadence stances also varied (18/27). A dashboard was valued when a caregiver was absent or another person administered the dose, but it offered less value when the caregiver directly observed use. Participants who discussed cadence commonly preferred exception alerts or periodic summaries over frequent push notifications. Aesthetic stances (24/27) ranged from bright, character-based designs to discreet, unbranded options. Together, these findings supported an optional software layer with configurable alerting and appearance rather than a single mandatory interface.

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Evidence, Data Governance, Access, and Boundary Conditions

A composite category captured 1 or more of clinical validation, clinician recommendation, or a trial period as conditions for considering use (23/27). This tally should not be interpreted as 23 caregivers endorsing each component. The pattern indicated a preference for evidence or trusted introduction before use. Prescription bundling arose as 1 implementation suggestion and was retained as a hypothesis for future evaluation rather than a general caregiver mandate.

Cost and access concerns were raised by 6 of the 27 caregivers, including the possibility that a nonreimbursed direct-to-consumer add-on could widen disparities. Among the 18 caregivers who expressed a privacy position, sharing inhaler-use data with a clinician was generally acceptable, while location and child identity were recurring red lines. One caregiver additionally objected to audio or video capture. These data support candidate data-minimization requirements but do not establish a preferred technical architecture.

Nine caregivers described how they had learned the administration technique. Those who felt confident had been taught by demonstration and return demonstration, whereas others had received little instruction. Participants preferred brief, rewatchable guidance:

> *…A quick video from his asthma nurse built into the app, not a 200-page leaflet—something he can rewatch in 30 seconds.* [P21a]

Caregivers generated unprompted requests for secondary features (10/27), including a dose counter, reminders, a device locator, and an overuse lockout. Because a lockout could impede access to rescue medication, the analysts retained it only as a separate clinical hazard-analysis question; this was not a participant consensus or a recommended feature. Boundary cases (8/27) also challenged a single default configuration, including toddlers, adolescents, nonspeaking children, daily and episodic regimens, pMDI and dry-powder inhaler use, and transitions from face masks to mouthpieces. Age, device interface, and usage pattern were therefore treated as candidate configuration variables.

Discussion

Principal Findings

Drawing on a qualitative corpus of 27 caregiver voices across 23 sessions, analyzed in full using an 18-category codebook, this study identified a central caregiver information need and translated it into candidate safety and system requirements for real-time feedback during pediatric inhaler use. Most caregivers in this sample (19/27) framed uncertainty not merely as a missing adherence record but as an inability to judge whether important use-related conditions of an individual maneuver were met. Simple on-device feedback was the most frequently endorsed concept element (25/27), and 9 caregivers named conditions under which they would distrust or abandon the device, most pointedly an incorrect positive state; both findings reflect anticipated responses to a described concept rather than experience with a working device. The principal contribution is a traceable synthesis linking these caregiver accounts to candidate requirements, which are the authors' proposals and have not been tested.

The empirical findings capture anticipated responses and the conditions caregivers attached to considering use. They do not demonstrate that caregivers can correctly interpret the proposed states in real time, that a sensor array can capture proxy conditions reliably in the home, that a physical attachment preserves aerosol-device performance, or that sustained adoption or clinical benefit will occur. The traceability matrix, which maps each category to a candidate requirement and evaluation locus, and the staged validation sequence make those evidentiary gaps explicit.

Comparison With Prior Work

Systematic reviews of pediatric digital asthma interventions emphasize adherence tracking, reminders, education, symptom logs, and remote monitoring [1,13-15]. Many digital inhaler studies focus on actuation or adherence, although technique-related sensing is emerging and varies in capability and validation [1,14]. Our findings extend this literature by separating event logging from a caregiver-facing inference about an individual maneuver and by documenting the conditions under which caregivers in this sample anticipated distrusting or abandoning such feedback (9/27), most pointedly an incorrect positive state. Five of the 27 caregivers described existing passive cues, such as flow whistles and valve movement, as indirect, late, or easy for children to circumvent; for these caregivers, such cues had not resolved the uncertainty they described. Reported barriers such as battery burden, incompatibility, notification fatigue, device loss, cost, and workflow fragmentation are consistent with prior reviews [12,14,16,17].

Prior pediatric asthma studies have documented caregiver burden, knowledge gaps, conditional willingness to share health data, and the need for low-burden, age-appropriate digital tools [9-12,36]. Our findings localize these concerns to medication administration. Privacy preferences in this sample suggest data minimization and, where technically appropriate, on-device processing rather than dictating a specific architecture. Likewise, anticipated manipulation of gamification may support tying rewards to a validated sensed event, while preserving opt-out and age-appropriate design.

The method also aligns with recent JMIR studies that translate stakeholder evidence into digital health requirements [25,26]. The added contribution is an explicit chain from caregiver evidence to a use-related need or anticipated failure, a candidate requirement, and the earliest proposed evaluation locus. This structure is intended to keep early enthusiasm for a concept from being interpreted as evidence of safety, usability, adoption, or clinical readiness, although whether it does so has not been tested.

The 2 opposing failure modes identified in caregivers' accounts are consistent with human-automation research, in which overreliance (misuse) and rejection (disuse) can occur when system behavior, user expectations, and feedback are misaligned [22,23]. A "false green" corresponds to a plausible misuse

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scenario, in which a positive signal could encourage inappropriate reassurance or delayed corrective action, and harsh or persistent corrective feedback to a plausible route to disuse; neither consequence was observed in this study, and both remain hypotheses for use-related risk analysis.

Implications for Development and Evaluation

Interpreted in this context, the findings suggest several considerations for subsequent design, each of which requires testing. First, the uncertainty caregivers described concerned whether a dose had been delivered (19/27), whereas proxy signals can indicate only whether measured use-related conditions were met; feedback may therefore need to be framed around those conditions rather than around pulmonary deposition. Second, the conditions under which caregivers anticipated distrusting or abandoning the device (9/27), together with warnings that harsh or persistent negative feedback could distress a child, suggest that a binary green-red display may be insufficient when the evidence is indeterminate. The positive, corrective, and uncertain states proposed in response are the authors' risk-control hypothesis and were not tested with caregivers. Third, the endorsement of a simple on-device signal (25/27) and the low-friction conditions caregivers set for acute use (12/27) suggest that acute-use feedback may need to work without an app or active connectivity, whereas the varied stances on gamification (20/27) and dashboards (18/27) suggest that these features may be better offered as options. Fourth, the evidence and introduction pathways caregivers named (23/27), together with the cost and access concerns (6/27), privacy positions (18/27), and training experiences (9/27) they described, suggest that these factors may warrant evaluation alongside the device rather than after its development; as the composite category combined validation, clinician recommendation, and trial pathways, these routes would need to be evaluated separately.

Figure 2 summarizes these proposals as a conceptual, noncausal architecture in which observable signals pass through an inference and data-quality gate before a positive, corrective, or uncertain state is assigned, together with the stages of evidence that would be needed before use. The architecture is the authors' synthesis rather than a study finding. Any device developed from it would require technical and bench verification, including of any effect on aerosol delivery, followed by simulated-use human factors evaluation with representative caregivers and children and then clinical or field evaluation, consistent with human factors guidance [37], aerosol-device verification requirements [38], and risk management practice [39]. A positive state would be implemented only once the conditions it represents had been defined and validated.

Limitations

Several limitations apply. The sample was self-selected, English-speaking, and recruited through academic and social media channels, which likely favored engaged caregivers and limited transferability. The participant and device contexts reported in Table 1 and Multimedia Appendix 3 are intended to support readers' judgments of transferability to other settings. Diagnoses, inhaler configurations, and use patterns were self-reported without health-record verification. Pediatric patients, clinicians, respiratory therapists, pharmacists, and manufacturers were not interviewed in this phase. Four sessions were dyadic, pairing 2 caregivers from different households in the same interview; because these caregivers could hear one another, their accounts may have been mutually influenced and are not independent observations. As recruitment relied on university notices and social media, the sample is likely to overrepresent caregivers who are comfortable with research participation and with digital technology, so willingness to consider an instrumented device may be higher here than among caregivers generally. The preinterview questionnaire also did not capture caregiver race, ethnicity, or education, so sample diversity cannot be fully characterized and differences in requirements across these groups could not be examined; these have been specified as required intake variables for the planned simulated-use evaluation. Clinical severity was not captured, so we could not examine whether reactions to the concept differed by severity.

All sessions were remote and conducted by 1 moderator. Transcripts were generated using automated speech recognition and then audited; no field notes, transcript return, or member checking were used. The moderator and second coder were involved in the concept, creating potential confirmation bias despite neutral probing, explicit questions about rejection conditions and failure modes, independent double coding of the complete matrix (486 paired decisions) with high agreement (94%; Cohen κ=0.88), and retention of boundary cases and disconfirming positions rather than only favorable responses. Most importantly, participants evaluated a screen-shared concept rather than a working prototype. The study therefore cannot establish usability, sensing performance, aerosol-device compatibility, sustained adoption, adherence improvement, or clinical efficacy.

Conclusions

The caregivers in this study prioritized immediate, interpretable feedback about whether important use-related conditions were met. Feedback inferred from airflow, timing, seal, or orientation proxies must not be presented as proof of pulmonary drug delivery. An incorrect positive state could create false reassurance, while harsh or persistent corrective feedback could increase distress or abandonment.

The findings support candidate requirements for conservative state assignment, an explicit uncertain state, app-independent acute-use functionality, minimal physical and operational friction, evidence-matched introduction pathways, and privacy-preserving design. The requirements reported here are inputs to bench and simulated-use evaluation. They do not validate a device or predict adoption. Instead, they provide a traceable foundation for technical and bench verification, simulated-use human factors evaluation, and prospective clinical or field validation.

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Acknowledgments

The authors thank the caregivers who shared their time and experiences with the study team. The authors used generative AI for language editing, structural reorganization, consistency checks, and refinement of table and figure wordings [40]. Generative AI was used to produce the visual concept stimuli presented to participants during the screen-shared sessions provided in Multimedia Appendix 2. Both authors reviewed and verified the final manuscript and take responsibility for its content. The relevant generative AI use record is provided in Multimedia Appendix 4.

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Data Availability

Deidentified interview transcripts are not publicly available because participant consent and research ethics approval did not include public release, and the narratives may be reidentifiable. The semistructured interview guide is provided in Multimedia Appendix 5. The codebook and aggregate consensus matrix may be requested from the corresponding author; access is subject to University of Calgary and research ethics requirements.

Generative AI Use

The authors declare that after data collection, coding, and interpretation were completed, they used ChatGPT (GPT-5.6 Pro; OpenAI) and Claude for language editing, structural reorganization, consistency checks, and refinement of table and figure wording. Generative AI (ChatGPT, Claude) was used for proofreading, editing, or language polishing and for visualization or media generation. These tools were not used for recruitment, data collection, or intercoder agreement calculations. No generative AI was used for coding or determination of findings; transcription was performed by automated speech recognition and audited by NM. No raw transcripts or directly identifying participant information were entered. Generative AI was used to produce the visual concept stimuli presented to participants during the screen-shared sessions. The authors verified all outputs of the tool(s) used in the preparation of this manuscript and take full responsibility for the final content of the manuscript.

Authors' Contributions

Conceptualization: NM, JP
Data curation: NM
Formal analysis: NM (lead), JP (supporting)
Investigation: NM
Methodology: NM, JP
Project administration: JP
Supervision: JP
Validation: JP
Visualization: NM (lead), JP (supporting)
Writing – original draft: NM (lead), JP (supporting)
Writing – review & editing: NM, JP

Conflicts of Interest

None declared.

Multimedia Appendix 1

COREQ checklist.
[DOCX File , 32 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Screen-shared concept stimulus.
[PNG File , 668 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Detailed participant-level caregiver, child, and inhaler-use characteristics.
[DOCX File , 31 KB-Multimedia Appendix 3]

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Multimedia Appendix 4

Generative AI use record.
[DOCX File , 13 KB-Multimedia Appendix 4]

Multimedia Appendix 5

Semistructured interview guide.
[DOCX File , 20 KB-Multimedia Appendix 5]

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Abbreviations

COREQ: Consolidated Criteria for Reporting Qualitative Research
pMDI: pressurized metered-dose inhaler

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VHC: valved holding chamber

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