

Core outcomes and factors influencing the experience of care for children with severe acute exacerbations of asthma: a qualitative study

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ABSTRACT

Objective To identify the outcomes considered important, and factors influencing the patient experience, for parents and caregivers of children presenting to hospital with a severe acute exacerbation of asthma. This work contributes to the outcome-identification process in developing a core outcome set (COS) for future clinical trials in children with severe acute asthma.

Design A qualitative study involving semistructured interviews with parents and caregivers of children who presented to hospital with a severe acute exacerbation of asthma.

Setting Hospitals in 12 countries associated with the global Pediatric Emergency Research Networks, including high-income and middle-income countries. Interviews were conducted face-to-face, by teleconference/video-call, or by phone.

Findings Overall, there were 54 interviews with parents and caregivers; 2 interviews also involved the child. Hospital length of stay, intensive care unit or high-dependency unit (HDU) admission, and treatment costs were highlighted as important outcomes influencing the patient and family experience. Other potential clinical trial outcomes included work of breathing, speed of recovery and side effects. In addition, the patient and family experience was impacted by decision-making leading up to seeking hospital care, transit to hospital, waiting times and the use of intravenous treatment. Satisfaction of care was related to communication with clinicians and frequent reassessment.

Conclusions This study provides insight into the outcomes that parents and caregivers believe to be the most important to be considered in the process of developing a COS for the treatment of acute severe exacerbations of asthma.

INTRODUCTION

Management of acute severe asthma exacerbations in children in the emergency

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Management of acute severe asthma in children is based on weak evidence and inconsistent outcome measures. There is a need to develop a globally relevant core outcome set (COS) to ensure robust future research.
- ⇒ Qualitative interviews are increasingly used as part of COS development, however, often concentrate on participants from high-income countries.

WHAT THIS STUDY ADDS

- ⇒ This study highlights the outcomes that parents and caregivers of children with acute severe exacerbations of asthma from a broad range of countries consider important to include in a COS.
- ⇒ The study also provides information about the factors which influence the patient and family experience in children with an acute exacerbation of asthma.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ This study was part of the process of developing a COS for use in trials and other studies for the treatment of acute severe exacerbations of asthma in children worldwide.

department (ED) is complicated by a variety of possible treatment options,¹ significant variation in practice,^{2,3} and little evidence to support the use of one particular medication over another.¹ The Paediatric Emergency Research Networks (PERN) asthma working group was formed in 2017. It aims to gather the input of patients, families and clinicians



to develop a global consensus on outcome measures and create international guidelines for the conduct and reporting of clinical trials of therapies for acute asthma exacerbations in children.⁴

The currently available asthma literature does not include outcomes prioritised by patients and families,⁵ and little is known about what is important to them. Further, although asthma affects children across the globe, most research has been conducted in high-income countries. We conducted an international qualitative study to address this gap.

Qualitative methods are recommended to identify outcomes important to stakeholders, help understand why these outcomes are important and identify appropriate language to use when presenting these outcomes in later surveys.⁶ Our findings will inform the development of a planned Delphi survey,⁴ which aims to achieve consensus on a core outcome set (COS) of clinical trial measures for these patients.

The specific objectives of this study were to determine parent and caregiver opinions on: (1) the patient and family experience of treatment of an acute asthma exacerbation; (2) and which clinical outcomes are the most important to patients and families.

METHODS

This was a qualitative study conducted using inductive thematic analysis of semistructured interviews with parents and caregivers whose children had presented to a participating ED due to an acute exacerbation of asthma. The project is reported according to the Standards for Reporting Qualitative Research⁷ and the Consolidated Criteria for Reporting Qualitative Studies checklist.⁸

Selection of participating hospitals

To ensure global representation and maximum diversity, we used a purposive sampling strategy,⁹ aiming to select families of children with recent experience of acute severe asthma exacerbations managed in a variety of hospitals, in diverse healthcare systems.

Emails inviting physicians and hospitals to participate were distributed via the seven partner networks that contribute to PERN,¹⁰ and to clinicians associated with the PERN asthma working group.⁴ Hospitals were asked to register with the study steering committee, which then determined participation on the basis of each hospital's ability to conduct the patient interviews, and overall diversity (geographic, health system and sociodemographic differences) of hospitals selected.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of our research.

Patient selection

Investigators at each participating hospital were initially asked to arrange at least two interviews. The patient was also able to participate alongside the parent/carer if deemed mature enough by their parent/carer. Participation required that the child had recently (within the preceding week) attended the ED and had been admitted to hospital with an acute exacerbation of asthma and was considered clinically stable by their treating team. We did not explicitly define asthma within the study protocol, nor did we prespecify a particular severity of illness.

Participants were excluded if they were deemed clinically unstable by the treating team, if they did not have an appropriate next of kin to provide consent, or if there was a language barrier between the patient/family and the interviewer that could not be readily overcome with the use of a qualified interpreter.

Once eligible patients/families were identified by the treating clinical team, they were provided with written information about the study. They were then approached by a member of the research team to seek verbal consent to participate in the interview.

It was planned to conduct semistructured face-to-face interviews, as these are likely to allow flexibility, while still enabling coverage of important aspects of the patient's care.⁶ All interviews were planned to be conducted in a convenient private setting, either at the patient's bedside or in an interview room within the ward setting. However, the COVID-19 pandemic led to recorded video calls and/or telephone calls being additional options.

Interview conduct and further data collection from medical records

Prior to any interviews commencing, all interviewers were oriented to the project and familiarised with the study protocol and interview guide (online supplemental appendix 1). This occurred by email and with an optional additional videoconference with the lead investigator (SC). Interviewers comprised a mixture of clinician-researchers (eg, study investigators at some hospitals) or research staff (usually nursing staff employed as research assistants). Most interviews occurred without any non-interview participants; one father arrived towards the end of an interview with the patient's mother, and two interviews were briefly interrupted by nurses recording vital signs.

Interviews were audio recorded. No field notes were taken. All transcription and translation to English (where needed) were conducted by a central secure academic transcription service (www.gotranscript.com). Due to the relatively short hospital stays of most patients, we did not have transcripts checked by participants. However, transcripts were available for interviewers to review and correct. These corrections usually resulted in minor changes to grammar or emphasis.

A focused review of the relevant medical records for each patient extracted patient's age, gender, previous

asthma history, as well as treatment administered during the index hospitalisation (online supplemental appendix 2).

Participant sample size

Due to the qualitative nature of the study, we did not predetermine the number of participants. We aimed to obtain representative views from diverse populations around the world, so originally anticipated the involvement of at least ten hospitals.

After recoding and analysis of two interviews from five participating sites (a total of ten interviews), the project steering group reviewed the content of the themes obtained and assessed participant demographic and clinical characteristics. At that point, we recognised that there were gaps in recruitment from the Middle East, Africa and Asia. Additional hospitals were therefore approached through personal contacts of two investigators (SC and YX); this resulted in further recruitment outside the PERN networks: from Qatar, China and Nigeria. At the same time (after ten interviews), the interview schedule was expanded and revised in response to preliminary analysis, with the addition of prompts to encourage participants to expand on their answers (eg, ‘what was your main concern?’)

A reassessment of emergent themes and the patient population was planned to occur every 5 interviews after the initial 10 until it was determined that thematic saturation had been reached and that a representative sample of all major geographic regions had been achieved. Interviews occurred from May 2019 until September 2022. Due to disruptions caused by the COVID-19 pandemic, interviews proceeded at a more rapid rate in some hospitals than in others, and overall recruitment varied considerably. Notably, 1 hospital submitted 21 interviews at a single time.

Data analysis

The core research team included an Australian paediatric emergency physician (SC) undertaking a PhD in outcome measures related to acute severe asthma in children, a bicultural (Chinese/Australian) PhD-qualified researcher with 10 years of experience in triangulation research combining quantitative and qualitative methods (YX), and a final-year medical student (KR) who received specific training from SC and YX for the purpose of this project.

Data were analysed using inductive thematic analysis. Thematic analysis is a method commonly used in analysing qualitative data by searching, identifying, analysing and reporting repeated patterns found across a data set.¹¹ Three investigators (SC/YX/KR) independently reviewed the transcriptions and open-coded free-text responses using NVivo V.12 software (March 2020; QSR International, Melbourne, Australia). Coding was discussed after the first three interviews to ensure consistency among investigators. Any discrepancies were

Table 1 Overview of interview setting

	Number (%)
Country where interview was conducted	
Paraguay	21 (39)
Argentina	6 (11)
Costa Rica	5 (9)
China	4 (7)
USA	4 (7)
Australia	3 (6)
Singapore	3 (6)
Canada	2 (4)
Nigeria	2 (4)
UK	2 (4)
Spain	1 (2)
Qatar	1 (2)
Language interview conducted	
Spanish	23 (43)
English	17 (32)
Spanish/Guarani	8 (15)
Mandarin	4 (7)
Guarani	2 (4)
Interview participant(s)	
Mother	49 (91)
Father	3 (6)
Grandmother and child	1 (2)
Mother and child	1 (2)
Interview setting	
Hospital ward	38 (70)
Emergency department	9 (17)
Intensive care/high-dependency unit	3 (6)
Outpatients	4 (7)

identified and discussed, and consensus was reached. Saliency analysis identified themes which were frequently mentioned by participants, or those which were identified as important by respondents.¹²

Thematic saturation was determined by five consecutive interviews (including interviews from at least two different settings) being completed with no new themes emerging. Data collection was considered complete when (1) thematic saturation was reached (determined by agreement between the three investigators performing analysis), and (2) all participating regions had submitted at least one interview.

RESULTS

A total of 54 interviews were obtained from 12 countries. Two children participated alongside their parent/caregiver. Most participants were from South and Central America. [Table 1](#) presents a summary of interview

**Table 2** Clinical characteristics of children with asthma

Clinical characteristic	Value, n (%) or median (IQR)
Age in years	6(4–8)
Number of previous ED attendances with asthma	3.5(2–5)
Number of previous hospital admissions	1.5(1–3)
Number of children with previous intensive care unit admission	9 (17)
Family history of asthma in first degree relative	30 (56)
Usual treatment for asthma	
Inhaled short-acting beta-agonist	23 (43)
Inhaled corticosteroid	21 (39)
Montelukast	8 (15)
Long-acting beta-agonist/steroid combined inhaler	6 (11)
No usual medications for asthma	18 (33)
Arrived by ambulance	2 (4)
Length of stay in hospital (hours)	38(16–85)
Treatment while in hospital	
Intravenous corticosteroids	41 (76)
Intravenous bronchodilator	37 (69)
Magnesium	25 (46)
Aminophylline	9 (17)
Salbutamol	35 (65)
Ipratropium bromide	27 (50)
High-flow oxygen therapy	5 (9)
Intravenous antibiotics	4 (7)
Non-invasive ventilation	4 (7)
Nebulised magnesium	1 (2)
Intensive care unit/high-dependency unit admission	3 (6)

ED, emergency department.

characteristics, while [table 2](#) presents the clinical details of the children whose parents/carers participated in the study. Online supplemental appendix 3 provides a breakdown of clinical details by country. Most interviews were conducted in English or Spanish, and interviews lasted for a median of 9:32 min (IQR 6:16 to 14:09 min).

Major themes relating to the patient and family experience ([table 3](#)) included the decision to seek hospital care, transit to hospital, healthcare costs, waiting times, readiness for discharge and length of stay, intravenous treatment, intensive care unit (ICU)/HDU admission and satisfaction with care (relating to efficiency, communication and frequent reassessment). Notably, more than two-thirds of children had received intravenous bronchodilators.

Important outcomes ([table 4](#)) included work of breathing, ICU admission, length of stay and speed of recovery, side effects, costs and satisfaction with treatment.

A summary of major themes relating to both patient and family experience, and potential outcomes for future clinical trials is presented in [figure 1](#). Notably, length of stay, ICU admission and costs were prominent themes for both patient experience and clinical trial outcomes.

PATIENT AND FAMILY EXPERIENCE OF TREATMENT OF AN ACUTE ASTHMA EXACERBATION

Decision to seek hospital care

Symptoms prompting the decision to seek hospital care ranged from typical asthma symptoms (difficulty breathing, wheeze, coughing, chest tightness), to those consistent with more severe disease (vomiting, low oxygen levels, agitation, altered conscious state). Parents/caregivers who had seen their child have an exacerbation previously were more concerned when there were unexpected new symptoms (eg, vomiting or agitation) and/or poor response to management at home. Some were keen to avoid a presentation as severe as a previous exacerbation which had been complicated by critical illness ([table 3](#)).

Parents/caregivers who had not previously been exposed to an asthma exacerbation were often prompted to attend the hospital due to worsening respiratory symptoms, although some were concerned about the possibility of their child dying.

Some participants mentioned uncertainty about whether symptoms had been severe enough to prompt hospital attendance, or how long they should persist with home management. However, others demonstrated a clear understanding of when they should seek medical assistance.

Transit to hospital

Some parents/caregivers reported difficulties accessing prehospital care, particularly if living in a region without an ambulance service. Transporting a sick child to hospital was a stressful experience, with worries regarding potential deterioration *en route*, compounded by difficulties finding a safe place to park a vehicle. Other participants who received prehospital treatment by ambulance paramedics felt reassured and were able to focus on their child.

Cost of care

Cost of care was highlighted by some parents/caregivers as a significant factor, with concerns relating to affordability of hospital treatment, as well as their ability to comply with ongoing treatment at home.

Waiting times

Prolonged waiting in the ED was a recurring theme. Significant delays between arrival and the commencement

Table 3 Representative quotes relating to patient/family experience of a child with an acute asthma exacerbation

Decision to seek hospital care	<p><i>"She felt bad, her chest and back hurt a lot, she couldn't breathe, and when we brought her in, she was breathing directly into her stomach"</i> – Mother of 10 year-old, Argentina</p> <p><i>"...when I came to the emergency room, I feel very scared. Not only scared but very worried for him because asthma is not something that is to be taken lightly actually because ... the airways block. So very worried. Very scared."</i> – Mother of 4 year-old, Singapore</p> <p><i>"For this time, because she coughed occasionally a few days ago, I did not pay attention to it. Then her cough suddenly worsened, and then followed by asthma."</i> – Mother of 3 year-old, China</p> <p><i>"...because when he was previously hospitalized, I'd brought him to the hospital unconscious and without air."</i> – Mother of 14 year-old, Argentina</p> <p><i>"He seems to be quite responsive to Redipred [Prednisolone] previously and he finally can get better within like 12 hours or 10–12 hours of the first dose, but this time he obviously didn't. That's why we're in here."</i> – Mother of 4 year-old, Australia</p>
Transit to hospital	<p><i>"Every time we've rung for an ambulance... we've not been able to get one. Then having to drive here and trying to find somewhere to park to bring him in, every time I've just left my car out in the road, which obviously isn't safe but if they're not going to let me park underneath in an emergency, what can I do? I can't park down the road and carry him. I think that's the most worrying bit is being able to get here."</i> – Mother of 6 year-old, UK</p> <p><i>"I didn't have the means to get him [child] to the hospital. My husband was at work, and I didn't have money to get a taxi, so I called my neighbour, and thank God, he brought us to the hospital on his bike."</i> – Mother of 1 year old, Paraguay</p> <p><i>"Everyone in the ambulance were quite reassuring to me. They told me we're going to arrive in a moment, to be calm. They put the mask on him [child]... It's better to be in the ambulance, because you don't need to pay attention to the road and you can be there reassuring him."</i> – Mother of 9 year-old, Spain</p>
Costs of care	<p><i>"What worries me the most is that I will spend a lot of money again this time... my family is poor and the bills issued to me every day are very painful for me.... Because of my poor economic condition and overwhelming medical bills, it's very difficult for me to offer the best treatment to my child according to the doctor's advice."</i> – Mother of 4 year-old, China</p>
Waiting times	<p><i>"It was really busy in emergency. We would just sit in a little cubicle for several hours before they actually found her a bed to start off with."</i> – Mother of 8 year-old, Australia</p> <p><i>"When I told them she was out of breath, they made me wait a long time."</i> – Mother of 11 year-old, Argentina</p> <p><i>"I don't think you need to improve anything... When you see the red card, they will see the asthma thing, they quickly send him to observation ward and get his treatment first before we get to see the doctor."</i> – Mother of 3 year-old, Singapore</p>
Readiness for discharge and length of stay	<p><i>"...as frustrating as it is, we want to get home, but what I am liking is that they won't send him home unless they're very comfortable that he is well enough... It's important for me to get him home, but at the same time it's good to know that they're not going to let him home unless they're happy."</i> – Mother of 4 year-old, Australia</p> <p><i>"I brought him in and they sent me home saturating 89% after three nebulizations."</i> – Parent of 10 year-old, Costa Rica</p>
Intravenous treatment is a 'step up' but is also a distressing experience	<p><i>"100% of the time XXXXXX is going to want to do whatever treatment there is that has no needles, no pinpricks... [when using IV] The first doctor didn't get it in properly and was pushing and poking around and it didn't go in and she was screaming. It was all a bit dramatic."</i> – Parent of 8 year-old, Australia</p> <p><i>"Among the treatment methods I know, I prefer the inhaled aerosol therapy. I'm very resistant to intravenous injection, because I think the side effects of injection is great. In addition, it costs a lot."</i> – Mother of 4 year-old, China</p> <p><i>"I'm quite happy for them to try anything so we can get home quickly because he hates being in, but I know he is very reluctant to have the cannula again, so his opinion will be different to mine. I think he would prefer just nebulizers and oral medicine, not IV."</i> – Mother of 10 year-old, UK</p> <p><i>"I really didn't like doing the IV thing. I'd rather do something else."</i> 10 year-old, UK.</p>
Intensive care unit/high-dependency unit admission	<p><i>"...in that moment when they told me that she was going to go there (ICU), I imagined that she was very ill. Yes, a little uncomfortable, the uncertainty of now knowing, "Why is she going there?"... when they said it was intensive care, it was like saying, "This is serious"."</i> – Parent of 5 year-old, Costa Rica</p> <p><i>"I guess the previous experience would help because you know what it is, but you also don't know how it's going to evolve, the uncertainty and worry are always there (in ICU)."</i> – Mother of 9 year-old, Spain</p> <p><i>"They explained that to us very well the first time he was in the ICU. We didn't realise the seriousness of the situation. They immediately made it clear to us that something was wrong and that we had to act quickly. When the critical moment passed, they told us we were at another point. It's important to stay informed at all times."</i> – Father of 9 year-old, Spain</p>

Continued

Table 3 Continued

Satisfaction with care is associated with effective communication and frequent reassessment.	<p><i>“I find that a lot of the time it’s between parent and doctor when he’s actually old enough to discuss his care as well.” – Mother of 10 year-old, UK</i></p> <p><i>“We were treated very quickly and very well. They asked XXXXXX questions all the time, how he was doing and explained what they were going to do to him... The fact that they explained what was going to be done to him reassured him: “It’s difficult for you to breathe”, “Don’t worry”, “We’re going to put on the oxygen mask so you can breathe better”, “I know you don’t want to”... They took good care of him and were very careful about the fact that he is a child and needs his time.” – Mother of 9 year-old, Spain</i></p> <p><i>“I think consistency ... I think there should be a universal—if it’s for severe chronic asthma, a clear plan when you’re going across the board for treatment and aftercare because I find that it’s different advice from different consultants, different opinions.” – Mother of 10 year-old, UK</i></p>
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of medical treatment were associated with negative emotions: ‘anxious’, ‘scared’, ‘stressful’, ‘worried’, ‘devastated’, ‘helplessness’ and ‘sheer torture’. Shorter waiting times or nurse-initiated treatment according to clinical protocols were viewed positively. Some parents believed that medical staff did not recognise the severity of their child’s illness, and others were concerned about the risks of cross-infection in the waiting room.

Readiness for discharge and length of stay

Children who made a rapid recovery usually received care in the ED and/or short stay unit. Those who were more unwell (eg, requiring admission to ICU/HDU or ward-based care) had much longer length of stay. Regardless of duration of hospitalisation, patients and families were consistently in favour of making a safe recovery and getting back home. Discharge home without adequate symptom resolution was felt to be sub-optimal care.

Intravenous treatment is a ‘step up’ but is also a distressing experience

Inhospital treatment ranged from inhaled bronchodilators (delivered through a nebuliser or a spacer), corticosteroids, oxygen therapy and intravenous medications. Participants felt that their child’s condition was taken more seriously when the interventions included administering intravenous medication. However, nearly all participants strongly expressed their dislike of needles.

ICU/HDU admission

Admission to ICU and HDU was a significant stressor for some participants, including seeing their children connected to machines and monitoring equipment. Nevertheless, others reported feeling reassured due to clinical staff comforting children during interventions and communicating with child and caregivers at an appropriate level.

ICUs were perceived as ‘safer’ than ward-based care, where there were more frequent mentions of difficulties with the delivery of medical care including late administration of medication, poor handover between staff and poor communication of discharge plans.

Effective communication and frequent reassessment are associated with satisfaction with care

The most frequent comments that related to a positive experience included efficiency (‘quick and good response to treatment’), frequent reassessment (‘frequent checking’, ‘attentive’) and ‘open communication’ from medical staff. Parents and caregivers expressed a desire for clear explanations of their child’s clinical status and treatment. They further emphasised the importance of including children in communication with clinicians.

Negative experiences included delays in the administration of medications, being asked repetitive questions on admission and when staff changed, no communication of the anticipated discharge date, visitor restrictions and environmental disruptions (eg, noise, light). Some participants also commented on the inconsistencies of treatment plans their children received.

WHICH CLINICAL OUTCOMES ARE MOST IMPORTANT, AND WHY?

Intensive care admissions, costs and hospital length of stay were highlighted as important clinical outcomes relevant to patients and families; these also featured prominently as determinants of the patient and family experience (table 4).

Work of breathing

Work of breathing was highlighted as a visible sign of the severity of their child’s illness. Dyspnoea is an unpleasant sensation to experience, or observe in a loved one, and many participants mentioned relief as work of breathing improved following treatment.

Side effects

Some parents were very concerned about potential side effects, particularly if a clinical trial introduced a new treatment. Specific side effects (such as tremor or nausea) were rarely mentioned; concerns were more often related to non-specific medication toxicity, intravenous access and administration, and the potential for a treatment to cause pain.

Table 4 Representative quotes relating to potential clinical trial outcomes for children with an acute asthma exacerbation

Work of breathing	<p><i>"You have to see his face. The way you do your research for me is all right, shortness of breath, all that, they're able to see it instantly"</i> – Mother of 14 year-old, Argentina</p> <p><i>"He needed oxygen because he couldn't breathe. He was short of breath.... We wanted [him] to feel better."</i> – Mother of 4 year-old, Argentina</p> <p><i>"At that point, what is most important is to see the child breathing better because it's the fast breathing and the fact that your child cannot make a complete sentence that really scares you. Like, is he going to suddenly stop breathing? The most reassuring part is to see that the child is breathing better."</i> – Mother of 3 year-old, Nigeria</p> <p><i>"Just get his breathing under control is what I want."</i> – Grandmother of 12 year-old, USA</p> <p><i>"The worst I probably been, is that I didn't get no air, at all. I couldn't breathe, at all. There was no hard, intense wheezing. I could not breathe, at all."</i> – 12 year old (patient), USA</p> <p><i>"If she had gotten better at that hospital, I don't think we would have come here... You guys did an amazing job. I remember coming here, I was literally crying, and in six or seven hours, she was close to stable."</i> – Mother of 2 year-old, Nigeria</p>
Intensive care admission	<p><i>"For me, it wasn't really important that he went to ICU because I know there's other sick kids in ICU, and so I didn't really care where he went just as long as he was getting the monitoring that he was needing."</i> – Mother of 6 year-old, Australia</p> <p><i>"...When they said it was intensive care, it was like saying, "This is serious"."</i> – Mother of 5 year-old, Costa Rica</p> <p><i>"It's preferable if they don't end up in intensive care because they spend a lot of time alone there, and they put a mask on their face, and they become desperate. It's much better here, in the emergency room ... and I'm with him."</i> – Mother of 6 year-old, Paraguay</p> <p><i>"[Going to intensive care] would be terrible... It would be very horrible."</i> – Mother of 5 year-old, Qatar.</p>
Length of stay and speed of recovery	<p><i>"What worries me the most is that he will have a long stay in the hospital again this time. Because I'm busy with my work, I have no time to take care of my child.... It's a sheer torture for me to stay with my child in the hospital, because I have to give up too many opportunities to make money. For me, time is money."</i> – Father of 5 year-old, China</p> <p><i>"What he says is he has to stay longer. Then my husband has to take [unpaid leave], this kind of thing."</i> Mother of 3 year-old, Singapore</p> <p><i>"No one likes to come to hospital. I hate coming to hospital whether I'm a patient or visiting or bringing your child in. I don't like it. I never have...."</i> - Mother of 8 year-old, Australia</p> <p><i>"I suppose how quickly the patients respond and getting them back to health quickly and staying healthy.... He's a four and half year-old boy. He wants to get out there and play. That's what's important to me, having a healthy little boy."</i> – Mother of 4 year-old, Australia</p> <p><i>"It is important to know what to expect when your child receives treatment and how long it's going to take for them to get better so that we, as parents, can have peace of mind and accompany our children in the process."</i> – Parent of 9 year-old, Paraguay</p> <p><i>"I would prefer a drug that saves days of hospitalization."</i> – Mother of 9 year-old, Spain</p>
Side effects of treatment	<p><i>"If a new treatment method is introduced, I am most concerned about its efficacy and side effects. If it works well and has little side effects, I can accept it."</i> – Father of 8 year-old, China</p> <p><i>"I'm very resistant to intravenous injection, because I think the side-effects of injection is great.... I prefer to accept the method that is the least harmful and safest to the patient's body."</i> – Mother of 5 year-old, China</p> <p><i>"We should be careful not to irritate children with treatment, that the treatment doesn't cause them pain..."</i> – Mother of 6 year-old, Paraguay</p>
Costs	<p><i>"I am most concerned about ... cost. Even if its treatment effect is good..., if the cost is too high, I cannot afford it."</i> Mother of 4 year-old, China.</p>
Satisfaction with treatment	<p><i>"It's better to have not only quantitative study, qualitative to see the patient experience and if they are satisfied with it, and also with a couple of follow-ups to see if there is any improvement."</i> – Mother of 5 year-old, Qatar.</p>

Satisfaction with treatment

Overall satisfaction with treatment and seeking opinions directly from patients and families was also suggested as an important outcome measure. It was recommended that this be measured not only at the time treatment was administered, but also later in the child's treatment.

Due to the greater than anticipated number of interviews from a single country (Paraguay), we compared themes identified in interviews from Paraguay to those from all other participating countries (online supplemental appendix 3). All themes mentioned by those interviewed in Paraguay were also mentioned by participants

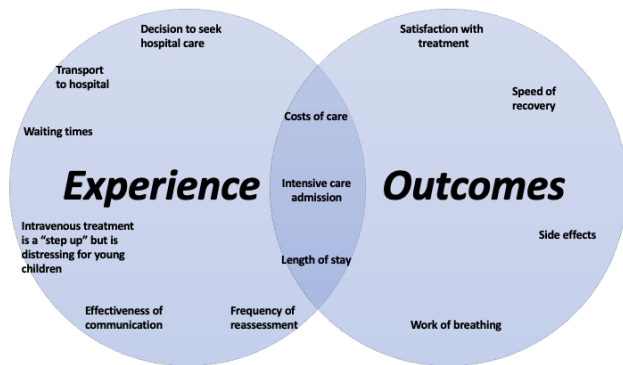


Figure 1 Summary of major themes relating to acute asthma in children presenting to the emergency department.

from other countries. Two themes identified in other countries were not mentioned by those from Paraguay: ‘readiness for discharge and length of stay’ and ‘satisfaction with treatment’.

DISCUSSION

Our qualitative study resulted in a list of factors which influence the patient and family experience and a list of important outcomes which can be measured in future clinical trials for children with acute exacerbations of asthma. Including patients and families in this stage ensures that they inform outcomes presented in the planned further work on COS development. A Delphi survey is planned⁴ to be conducted across the global PERN network, with input from clinicians, researchers, patients and families. The first round will present clinical outcomes identified in this study, a related study of clinicians,¹³ and a recent systematic review¹ conducted by our group. Further rounds are planned to achieve consensus on a COS, which will then inform the design of future multicentre randomised clinical trials.

The patient and family experience for a child with an acute exacerbation of asthma is not only determined by care within the ED. Significant prehospital considerations include knowledge about asthma (experience of previous episodes, initiation of treatment at home, decision to seek hospital care), availability of prehospital care (ambulance transport and treatment) and means to get to hospital. Once in hospital, waiting times, communication between health professionals and patients/families and frequency of reassessment are important considerations. The use of intravenous therapy is recognised as a clear escalation of care; however, it is associated with pain and distress, and concerns about a greater risk of side effects. Concerns about risk of acquiring infection while waiting are likely to have been made more prominent by the COVID-19 pandemic.

Parental and caregiver health literacy is associated with child health outcomes,¹⁴ and has been found to influence asthma control and healthcare associated quality of life.¹⁵ If patients and families are supported

to understand and effectively manage asthma, there is a lower risk of subsequent exacerbations requiring hospital attendance.¹⁶ Innovative ways of improving condition-specific health literacy within the time-pressured ED environment include video discharge instructions,¹⁷ while the use of audio recorded¹⁸ or pictorial asthma management plans¹⁹ have been found to be helpful in settings where there is low literacy, language barriers or difficulty accessing traditional written plans.

Hospital length of stay, admission to an ICU or HDU, and treatment costs were highlighted as important clinical trial outcomes. These three measures also directly influenced the patient and family experience. Countries with an universal healthcare funding model are likely to have much lower costs for individual patients and families than those with a copayment system, and copayment disadvantages those with lower incomes.^{20,21} Costs should therefore be assessed from both the patient perspective and the healthcare system perspective. Other potential clinical trial outcomes included work of breathing, speed of recovery, side effects and satisfaction with treatment. All of these outcomes were identified in a recent systematic review⁵ of outcomes in previous clinical trials of children with severe asthma, except satisfaction with treatment.

Previous asthma trials have used various length of stay measures including hospital length of stay, ED length of stay and length of stay in ICU.⁵ Patients and families wish to leave hospital and return home as soon as safely possible. Therefore, the most appropriate measure of length of stay should reflect total time in hospital, rather than time in a particular location (such as ED or ICU). Although this measure may also reflect aspects of care not related to the underlying disease process (eg, discharge may not be possible prior to a ward round, or if a pharmacist is not available), this would likely be balanced out by randomisation within a clinical trial.

A recent retrospective review of 14 029 children from New Zealand and Australia presenting to hospital with acute wheeze found that severe outcomes were rare, with only 243 (1.7%) children admitted to ICU, 22 receiving non-invasive ventilation and 4 being intubated.² Although relatively rare, the inclusion of ICU or HDU admission is likely to be appropriate, as this is a marker of severe illness which has not responded to initial treatment.²²

Work of breathing and speed of recovery were noted as prominent outcomes. Although clinical assessment of dyspnoea in children is subject to considerable interobserver variation,²³ measures of clinical improvement and/or work of breathing are commonly used in clinical trials.⁵ The use of scoring systems, where points are allocated for various clinical findings, is common in some settings (North America, Spain), while rarely used in others (UK, Australia, New Zealand).²⁴ However, a systematic review and subsequent validation study suggests that commonly used asthma scores show insufficient validity and reliability to be used in routine clinical practice without caution.^{25,26} This suggests that further research

is required to determine the most accurate and globally acceptable measure of dyspnoea for use in clinical trials for children with asthma.

Health economic analysis alongside clinical trials has gained increasing prominence in recent years.²⁷ Measures of costs from both the patient and the healthcare system are important considerations. Most asthma medications used during hospitalisation are relatively cheap and established (such as beta-agonists, aminophylline, or epinephrine). Costs within a clinical trial are expected to be more closely linked to overall hospital length of stay and whether a child was admitted to an ICU/HDU rather than the medications administered to the patient.

Limitations

Prolonged recruitment occurred due to clinical and research challenges posed by the COVID-19 pandemic, and delays in approval for data-sharing agreements in some jurisdictions. Despite this, there have been no major changes in asthma treatment protocols in recent years, so the experiences and outcomes reported are likely to remain valid.

We hoped to obtain views of patients and families, but, due to the young age of included patients (median age of 6 years), only two patients participated in the interviews. It is therefore difficult to understand whether views of children differ from those of their caregivers. Further, due to most participants being mothers of young children, outcomes and perspectives of older children and other family members may not be fully represented. We did not assess caregiver health literacy, socioeconomic circumstances or insurance status, nor did we involve patients and families in the design of the study. These factors may have impacted on the patient experience and/or reported clinical outcomes of importance.

Although we aimed for a globally representative sample and for at least two interviews from each hospital, we recruited more than one-third of our interview participants from a single country, Paraguay. In addition, a number of sites only provided a single interview. However, there were minimal differences in the themes identified from participants from Paraguay and those from other countries.

No interviews were conducted in low-income countries and only two interviews in a low-middle income country (Nigeria). Further, we did not collect data on how the health system was organised in each participating country. This information could have provided additional context to the responses. It is possible that including patients and families from additional settings would generate additional outcomes. However, we recruited participants from all constituent networks of PERN,¹⁰ and data saturation was reached.

We did not specify a particular definition of asthma, nor did we specify a particular degree of severity of illness for inclusion. However, the conduct of the study within an international emergency medicine research network

working group focused on severe asthma may have biased our inclusion of children with more severe exacerbations, and/or a history of severe illness. Although this is in keeping with our overall work,⁴ experiences and outcomes may be different had we included more children with milder illness or a first presentation to hospital.

Multiple interviewers were used across the various participating countries to ensure that each interviewee was able to interact in their preferred language with someone familiar with local conversational norms. Although this may have reduced the consistency of interview conduct, we attempted to ameliorate this with a targeted interview guide focused on experience and clinical trial outcomes, orientation of each interviewer to the project and provision of an interview guide.

CONCLUSION

Hospital length of stay, ICU or HDU admission, and treatment costs were highlighted as important outcomes and influence the patient and family experience for a child with an acute exacerbation of asthma. Other potential clinical trial outcomes included work of breathing, speed of recovery and side effects. Patient and family experience was also impacted by decision-making leading up to seeking hospital care, transit to hospital, waiting times and the use of intravenous treatment. Satisfaction of care was related to communication with clinicians and frequent reassessment.

Our findings will be used to inform the design of a planned Delphi consensus exercise involving clinicians, patients, families and researchers to develop a COS for clinical trials in acute asthma in children.

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