

White Paper

# It's Time to Play


*Can Recruitment and Retention of Children on Clinical Trials be Significantly Improved by Using Qualified Health Play Specialists?*

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# Introduction

For the majority of parents, a trip to see the doctor with a child or teen is often cause for stress and anxiety. In many cases, the distress begins even before they have left home, and for those affected by chronic conditions this can often start at the conclusion of the last visit in anticipation of the next appointment.

Any health interaction with a child may be interpreted as invasive and stressful. Parents have to prepare for a multitude of behavioral outcomes and the possible failure of the objectives of the visit. These same challenges in interaction also apply to clinical research, and with the number of pediatric trials increasing, there needs to be better understanding and solutions to mitigate the hurdles involved.<sup>1,2</sup>

Is there more that can be done to alleviate the stress associated with healthcare appointments and procedures for both the child and the parent? By doing more, are we better able to achieve successful outcomes for all involved in pediatric clinical research?

# Background and Key Challenges

Whether a clinical trial is a success is significantly dependent on addressing the unique pediatric challenges at all stages, including regulatory approval, trial design, awareness and hospital support. It is clear from the limited literature and our experience that ensuring family engagement with the pediatric recruitment and retention challenges play an important role. Difficulties in recruitment jeopardize the development progress of vital medicines that could improve lives. Despite a growing interest in, and commitment in implementing pediatric clinical trials, approximately **one in every five trials** fails because of inappropriate study design, suboptimal experiment planning, or inadequate participant enrollment.<sup>3</sup>

This article will focus on some of the important considerations for the family at the consent stage and issues that may arise during the trial itself. These interactions can also have wider ramifications for the research team, sponsor and regulatory bodies. Importantly, it cannot be assumed that the hospital research team will be best qualified and equipped to support these pediatric interactions.

We then review the role that Health Play Specialists (hereafter known as Play Specialists) can play as an existing resource that can make a difference to recruitment, retention and high-quality data collection. This will be supported by insights collected from a wide scale parent survey as well as expert opinion.

## CHALLENGES IN PEDIATRIC TRIAL RECRUITMENT

### 1. Consent

The common theme, that re-occurs in the limited literature for the family approaching consent, is the anticipated burden.<sup>4,5,6,7</sup> Those participating in trials are seen more frequently at hospitals and tend to have more invasive assessments, with concurrent implications on family life. In research, the justification for anxiety and distress becomes even more difficult, as the primary aim is for the collective good rather than the need of

the individual child. Wider research highlights that detailed informative communication from the health professionals is also important. Whether a family and child are willing to consent in the first instance will depend on perceived benefit vs burden, how well informed they are, the enthusiasm and trust in the lead physician and wider research team, and what steps have been taken proactively to minimize the burden.

### 2. Patient Burden and Retention

There is little good quality data on attrition rate, especially in pediatric interventional trials. Reported dropout rates for pediatric trials range widely from 5-70%. Most studies involving childhood retention factors have concentrated on psychiatric disorders, where hospitals found a general loss of 20-30% of participants from the first follow-up.<sup>8</sup>

A key factor is to maintain family engagement with communication and positive experiences. During the visit, the hospital team often focuses on data collection, such as administering blood tests and collecting information for the research form; this is sometimes to the detriment of interaction with the family. These interactions, or lack thereof, can lead to anxiety, non-compliance, and will inevitably impact the overall family experience increasing the likelihood of trial drop out.

Wider authority bodies have also recognized the need to address the child burden regarding participation in trials and how the risk benefit ratio needs to be justified.<sup>9</sup> Anything that may reduce distress and add to the positive experience has been shown to gain favor from the ethics and regulatory committees.<sup>6,10,11</sup>

### 3. Research Team Efficiency and Study Validity

For the research team it is often a challenge to ensure adequate data collection during pediatric assessments, or when attempting to administer investigational medication. What may take five minutes in an adult could take two hours in the resistant or preverbal child. These appointments may overrun, potentially impacting the care of other hospital patients. Furthermore, the validity of studies could be eroded by missed appointments,

resulting in protocol deviations, inadequate samples, or patients lost to follow up. A large drop-out rate may also lead to trial discontinuation at huge expense to the sponsor, while potentially negatively impacting future treatment. **A recent report** indicates that 19% of pediatric trials were discontinued early from 2008-2010, with an estimated 8,369 children enrolled in trials that were never completed, with many (37%) discontinued due to poor patient accrual.<sup>12</sup>

With all the above in mind, there is a clear need to take a proactive approach to designing recruitment and retention strategies for pediatric trials.

There are an increasing number of innovative ideas and digital solutions when it comes to engaging children. However, as a first step, it seemed logical to look at successful existing hospital resources to establish whether those resources could be better utilized to support clinical trials in the same way they support standard of care (SOC) patients, leading us to look at the professional role of Health Play Specialists.

## Role of Play Specialists

Many hospitals with specialist pediatric facilities seek to improve the experience and success of the medical consultation by employing professionals dedicated to supporting the children and their families.

Wider professional healthcare bodies advocate for the use of qualified Play Specialists.<sup>13</sup> They are trained to work with specific age groups, with specific emotional and physical and behavioral needs, which are more commonly found in the chronic disease population.

In the UK the qualified individuals are Health Play Specialists, a qualification that comes under the registration body is HPSET-Healthcare Play Specialist Education Trust (HPSET). Qualified professionals known as Child Life Specialists also exist in US healthcare settings, where they may be part of the professional body "The Association of Child Life Professionals."<sup>14</sup> They

are trained in a variety of communication techniques that can be employed to help children feel at ease in a clinical setting.<sup>15</sup> Their deployment has proven to reduce stress and aid compliance.<sup>16,17,18,19,20</sup>

Other countries with equivalent roles exist across Europe and Asia with their own umbrella organizations. Each organization has varying definitions for the role, but there is a clear emphasis on professional standards and pertinent qualifications. Another distinct professional specialist with overlap functions can be found as part of "Hospital Clowning Programs" deployed across Americas, Africa, Asia and Europe.

It is our belief, that in order to offer the best level of care to children participating in research, there should be a requirement that any Play Specialists dedicated to support families on research studies are educated to the standards set out by the local professional body.

*"Child life services are associated with improved quality, outcomes, and patient and family experiences as well as decreased costs in pediatric care. There is evidence that child life services help to contain costs by reducing the length of stay, decreasing the need for sedation and analgesics, and increasing patient satisfaction ratings"<sup>13</sup>*

## Using Play Specialists in Research

The effectiveness of Play Specialists in the clinical setting suggests their involvement in research would be an obvious extension of their remit.

Allocating a Play Specialist to support study patients and their families will provide an advocate for the child to facilitate productive communication. This support can be offered at all stages of the trial journey; for example, specialists may conduct a brief tour of the research unit at the time of enrollment which can be very reassuring for a child/family.<sup>22</sup> They are also trained to advocate during the consent process, provide feedback once the trial is over, and maintain long term engagement. Play Specialists are also successfully deployed when assisting with research procedures by offering age appropriate, interactive distraction for all patients.

Beyond a shorter and more successful consultation, a trial dedicated Play Specialist has the potential to introduce greater efficiency into the trial design itself. For instance, the Play Specialist can result in decreased use of sedation for assessment procedures.<sup>23</sup> This has proven to be successful in the healthcare setting and has led to improved cost savings.<sup>13,24</sup>

In addition to the patient interaction, the physical environment of the facility where research is conducted can also be supported by the Play Specialist. The look, feel, and function of the pediatric research facility must be inviting and safe, and has been shown to have a beneficial role in the consent procedure itself.<sup>25</sup> The current COVID pandemic and the limitations on physical touch and shared equipment mean that ensuring the environment is tailored to engage a child is difficult.

Deploying a qualified and experienced Play Specialist on pediatric research studies, where they can build a relationship with the child and their family, may

be the difference between a child that shows up for every appointment and one that drops out after their first interaction. However, Play Specialists are often not involved. This may be due to a combination of lack of awareness amongst the hospital team, the wider research team and local hospital governance around their role. Yet, the biggest factor by far is the lack of resources allocated to this role, both in the clinical setting and in research.

Our aim is to raise awareness and continue discussion regarding this resource.

To explore the potential and gather further insights, IQVIA conducted a detailed survey and series of interviews.



## Interview Process

Our team conducted in-depth questionnaires with experts in key fields to ascertain their experience of the Play Specialist role, its impact on family and child health outcomes and its potential for improving patient recruitment and retention in pediatric clinical research. Individuals were identified through the team's own contacts and with the help of the Cambridge Rare Disease Network.<sup>26</sup> The interviews were conducted over email and phone. The questionnaire, for the experts, consisted of 5 questions with responses collected over the period June 2020 – June 2021.

### PARTICIPANTS

- Pediatric Consultant (PC) Dr Omi Narayan. Pediatric Respiratory Consultant, Honorary Senior lecturer. Experienced Principal Investigator. **Royal Manchester Children's Hospital, UK. IQVIA PRIME Site**
- Advanced Clinical Practitioner (ACP) MS Becky Platt. Senior Advanced Nurse Practitioner (Autonomous health care professional trained to manage common pediatric conditions) and Research Nurse with experience in pediatric clinical research trials. **Barts Health NHS Trust, UK. IQVIA PRIME Site**
- Lucy Wootton. Health Play Specialist (HPS) CCLS, Clinical Lead. Play Department. **Barts Health NHS Trust, UK. IQVIA PRIME Site**
- Expert Care Giver (ECG). Celia Enderle. Mother of child with chronic disease. Higher qualifications in child wellbeing (MSc in Applied Positive Psychology), member of **Cambridge Rare Disease Research Network** and Patient Advocacy Group **Unique Feet**

## Expert Insights: Key Findings

### BARRIERS TO CLINICAL INTERACTION AND ROLE OF PLAY SPECIALIST IN CLINICAL CARE

The Pediatric Consultant (PC) felt Play Specialists had a key role in clinical care. As part of a team approach "...Play Specialists dedicated for better engagement, using child friendly explanations and techniques..." make a difference. This included having a "...child friendly environment..." Her child had "never had any bad experience" when using Play Specialists and has seen benefit in both the Face to Face and virtual environment.

The ACP highlighted that there are a multitude of factors that impact the success of a child's interaction in the clinical setting and that even "with the best will in the world..." things do not always go "smoothly." This anxiety can occur in any procedure ranging from "being weighed" to "cannulation". Even the thought or "potential for something to hurt" can cause barriers. Key enablers highlighted were having dedicated time and a dedicated individual to explain the process to a child can make "all the difference." The ACP explained that in the clinical team (which also includes parents), the Play Specialists are "the only person who is going to focus completely on the child and their experience." It was also articulated that beyond the Face to Face contact, Play Specialists "...spend a lot of time...preparing resources that improve child and family experience," including the environment.

Powerful testimony from the ECG highlights that the professional pediatric care setting cannot be relied on to provide adequate care for a child's mental well-being.

As a "... mother to a child with a rare disease, I have had plenty of experience in medical settings – both for treatment and to participate in research. For the first six years, I had a child that loved going to the hospital – he loved the attention, the children's play areas and even the cafeteria. After eight years, it became apparent that my child was suffering from anxiety and CPTSD (complex post-traumatic stress disorder) from his medical experiences, which consequently affected his everyday life."

“For the child, a medical appointment is often where they are exposed to boredom, isolation, fear, and pain. Their parents are often preoccupied and exhibiting apprehension or stress.”

It is all summarized by the experience of the HPS. Families and children come to health appointments with a host of negative perceptions. Even before they arrive, it is common to have “anxiety and fear...” based on “past traumatic...experiences...” compounded by “lack of understanding” from families and patients.

It is not a given that a healthcare setting will automatically mean a well-prepared child supportive clinical team, even at pediatric centers of excellence. The HPS observes how some staff are not always comfortable interacting with children and the hospital settings are not always child-friendly. Even more worryingly, some children/adolescents are not involved in their healthcare decision making or plans and have a lack of understanding.

The ECG states how “The child is powerless, often ignored, not part of the conversation. The professional’s dialogue is understandably directed to the parent...the child is often left sat beside the parent, with nothing to do but listen to often-difficult conversations about... their weaknesses and problems.” Whilst in “... deliverance of any medical procedure in a typical busy clinic, the child can feel rushed and pressured to have the medical procedure.” The procedure itself is “... often rushed – the professionals are busy. For the parent, it is so hard to hold their screaming child whilst blood is drawn, to hold an anesthetic mask on their child’s face, or to help strap the child to the shelf of an MRI scanner. The children will witness their parent’s stress and be upset. The medical procedures maybe perceived as a physical attack.” There is “...little positivity.”

Proactive measures are required to avoid these scenarios. The ECG is clear that “Relationships are essential for the family...children need therapeutically trained professionals...to learn coping skills, and...be

resilient to medical experiences.” Also that the “...parent needs support, and to be enabled to give the medical professionals their utmost attention, without being torn to manage their restless child.” The ECG has experienced positive Play Specialist support and described their experiences. “...In the waiting room...tables set up with the correct resources...allowed the child to be kept occupied whilst waiting 50 minutes for an appointment .” During consultations the young “...child was protected from listening to talk that was not child-centered or trauma-informed.” A child undergoing an emergency procedure “... was supported and distracted by a health play specialist.”

The HPS role is designed to meet this demand, they “...work to support patients and their families attending hospital... are qualified members of the health care team and work to promote effective coping mechanisms through play, procedural preparation, procedural support, distraction therapy, education, and self-expression activities.”

In the F2F setting, they can utilize specific tools and resources available to their team, to ensure the success of a procedure or consultation of the child and family. Beyond the F2F their actions can help build “long term trust and rapport.”

One example given by the HPS was how “during the pandemic we have also been running virtual clinics for our referral service to offer preparation and play sessions prior to attending the hospital for required procedures.”

### **BARRIERS TO CLINICAL TRIALS AND POTENTIAL ROLE OF PLAY SPECIALISTS.**

The PC described that in his experience, the main barriers preventing trial participation included “reluctance by children, poor understanding...” and “anxiety” over procedures.

They felt there is a role for “...early engagement in enrollment from Play Specialists who can spend more time with the child and will get a better engagement from child and family...” Importantly, he said it would also make the hospital team feel more “...positive about a better recruitment rate if the hospital has Play Specialists.”



However, he felt the main hurdles for their involvement are, "...no funding, not enough Play Specialists available, poor recognition of contribution."

The ACP felt that having Play Specialists actively involved in a clinical trial "would allow children to be better prepared which would improve their ability to give informed consent and take part in a more comfortable, less stressful way." They also felt that the "procedures would be more likely to succeed."

The HSP suggested significant schemes such as "...individualized coping plans/reward systems with families to encourage patient adherence and retention... delivered by staff dedicated to providing support...(which) may enhance participants trust." This "slight separation" from the main research team is "often very helpful for families."

The ECG was also able to speak powerfully about pediatric clinical trials and the role of Play Specialists. "When approached to participate in medical research, there are two main considerations... One of them is the impact of the study on their child... Parenting a child with a medical condition is both physically and emotionally exhausting, with little rest. Both the parents and the child will need support. This is the role of the health play specialist." Regarding the clinical team, the ECG felt "...professionals are often embarrassed of the little time they can give. This feeling would be alleviated by the presence of a Health Play Specialist."

The ECG understood that the main challenge in their deployment is "...availability and employment of Play Specialists, particularly as this would be for ad hoc employment." However, the ECG feels if there is access to "...organizations who have banks of play Specialists ... there would be an opportunity for collaboration with research hospitals."

**The HPS is clear as to the main barrier:** "lack of funding and acknowledgment of the role is a key factor in the reason behind Play Specialists not being involved in clinical trials."

## Patient Survey

To further examine awareness and the impact of the role of Play Specialists in the healthcare setting, our team developed a detailed survey to assess parental interactions with Play Specialists, their understanding of the role and their perceptions of the positive / negative impact on their child's healthcare experience.

The survey was conducted using an IQVIA online community platform and was also open to those outside the IQVIA registered patient community. Participation in a study was not a prerequisite for completion.

### PARENT SURVEY; DEMOGRAPHY

We received 165 responses from parents of children across the age spectrum, from infants under one and up to and including 17-year-old adolescents.

The response came from a wide demography representative of different health experience backgrounds. Key variables represented were age of care givers (Figure 1), age of child (Figure 2), whether the child had a chronic condition (Figure 3), and what health care setting encounters took place (Figure 4).

The majority of parents identified as white, but there was also representation from Black, Hispanic, Native American and Asian families from the UK, USA, UAE and others.

Figure 1: Age of caregiver

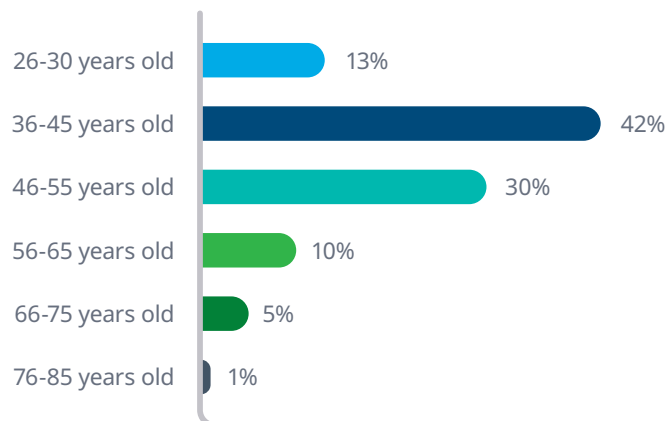


Figure 2: Age of child

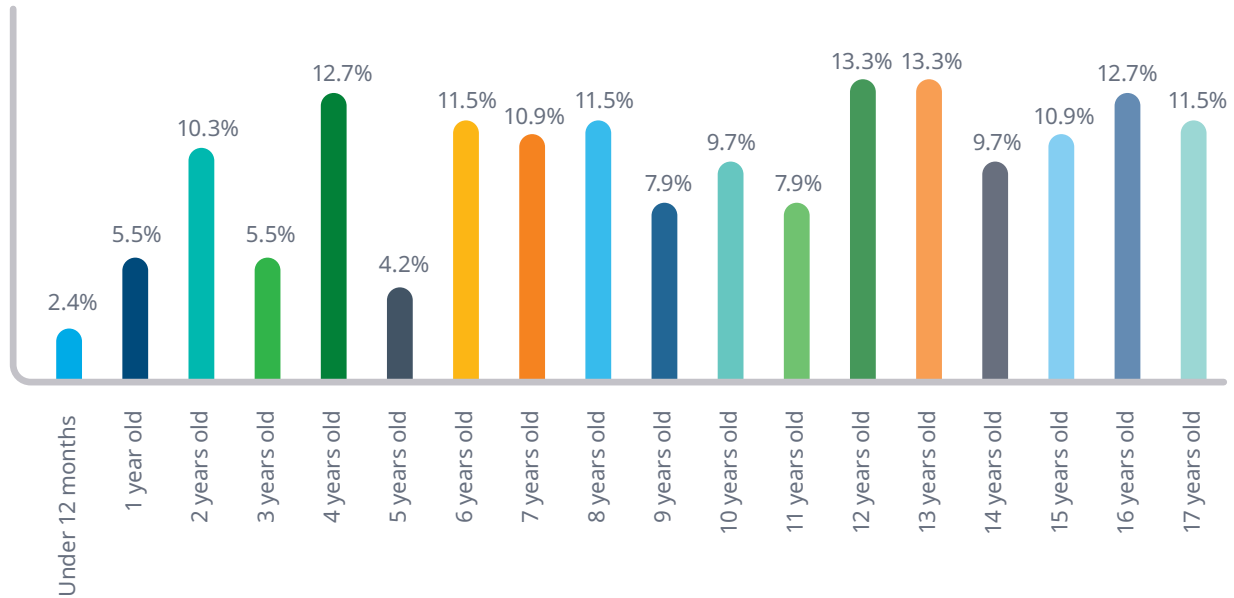
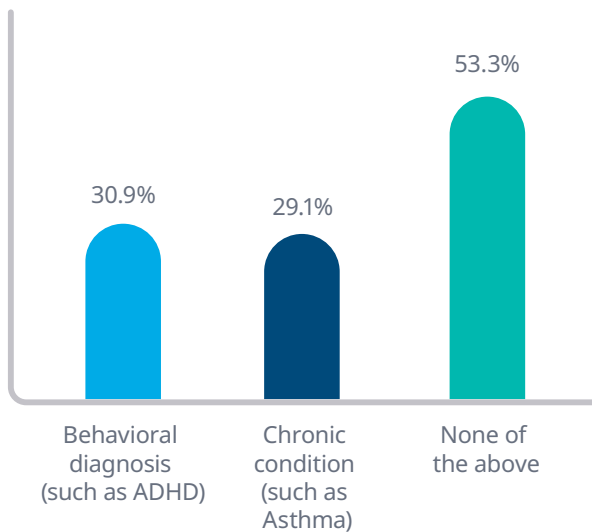


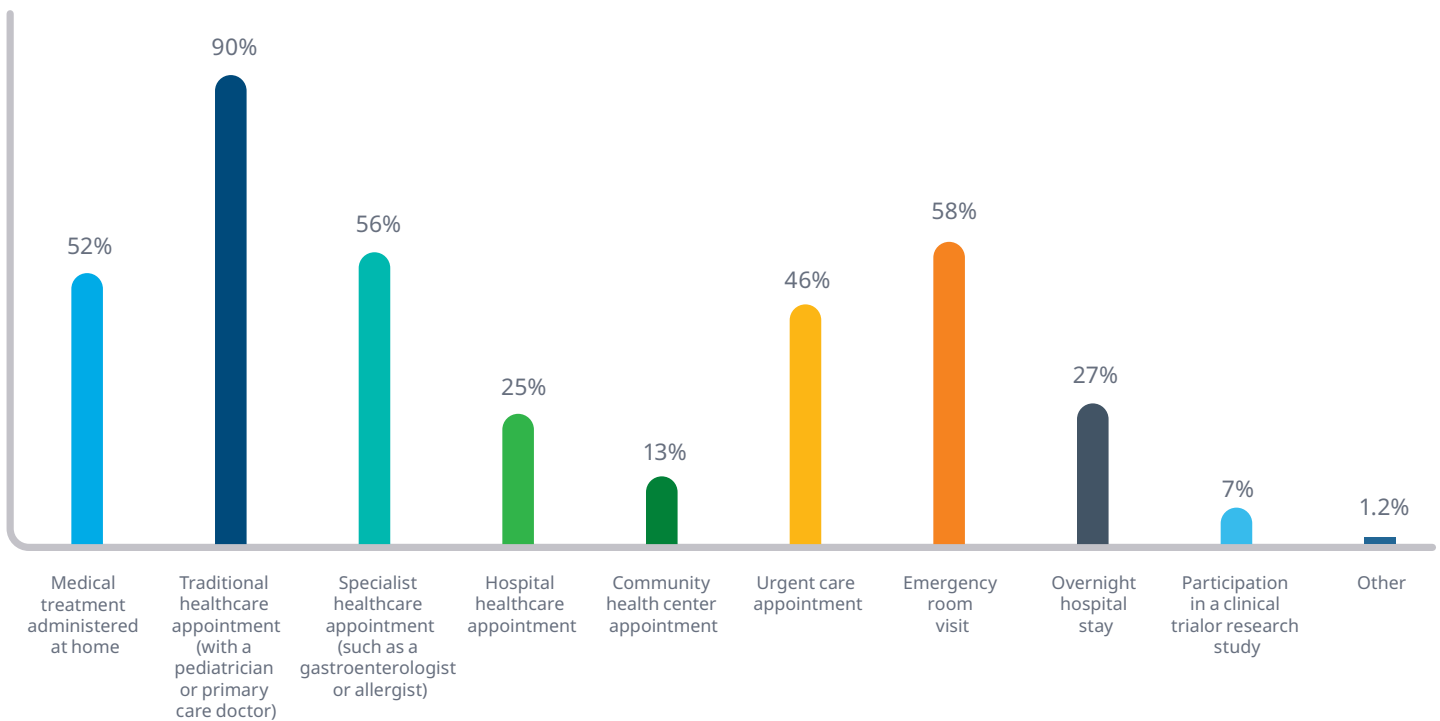
Figure 3: Coexisting chronic condition



## Patient Survey: Key Findings

Our most compelling finding, which highlighted the importance of reducing distress and ensuring child cooperation, was that **20% of caregivers had an experience where the objectives of the medical appointment had not been achieved due to the stress, anxiety, and/or behavior of their child.** If this percentage was to be taken across to a trials schedule of events, the disruption to a trials overall aims is significant. This negative child behavior can manifest in a number of ways that need a tailored response. **17% of caregivers noted that children often or always refused instructions from the clinical team.** Even if the aims were achieved, a positive experience is not guaranteed; **65% of children made the encounter more difficult for all involved through; active verbal disruption and distress, becoming physically aggressive or running away.**

**Figure 4: Existing family experience with healthcare settings**



**PARENT COMMENTS INCLUDED:**

- “It was a blood draw and the technician kept sticking him unsuccessfully. Maybe 3 times and I said no more it was just too much stress on him. I requested to reschedule.”
- “The doctor was so very unprepared for a child with anxiety and became cross with my 5yr old. This made him shut down and become upset and scared. I chose to end the appointment and leave.”
- “There has also been a time where I couldn’t get my oldest daughter to get a flu shot - she whined and cried and became combative to the point where I gave up”

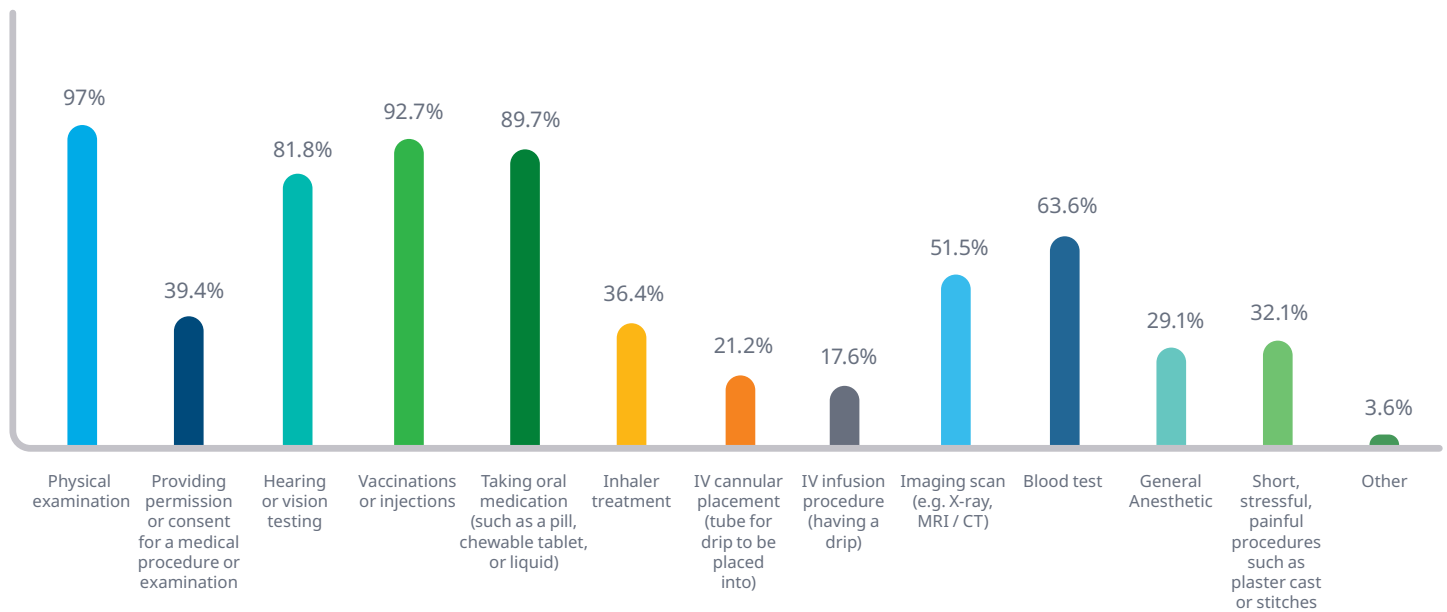
Importantly, this outcome should not be taken as unavoidable and it is our belief that a child’s behavior is modifiable. Children do not have to be stressed during these encounters and preparation, staff and setting will play an important role. **Only 18% of children are stressed/very stressed during medical procedures/medication at home.** Which is comparable to the level of stress experienced by children during medical

procedures/medication at their local GP/Paediatrician who are likely well known to them. This is in stark contrast to the **hospital appointment where 40% of caregivers responded their child became stressed/very stressed during medical procedures/medication.** A selection of parent / caregiver comments included:

- “Quiet, reserved, won’t respond vocally or with gestures.
- “They kick the nurse or doctor. They yell, “NO!” They spit.”
- “Worried, asking lots of questions.”
- “Hard to breath or hyperventilating. Clinging behaviors, impatience and ready to leave.”

We asked parents whether their children had experienced a series of procedures including hearing and vision tests, physical exams, injections, blood tests and taking medication (whether oral liquid or tablet).

Figure 5



We then asked the parents to rate the level of stress or anxiety caused by each of these procedures. **Unsurprisingly, blood tests and vaccinations were the procedures that caused either “high” or “very high” levels of stress or anxiety experienced by the child at 46% and 51% respectively.** However, the responses also highlighted how all interactions can potentially cause stress and need to be proactively managed to minimize data gaps and trial drop out. Our survey results showed a clear correlation between **child related anxiety and medical procedures, with even basic physical exams causing some children distress (13%). 7% of children were stressed/very stressed during taking a pill. 13% of children become stressed/very stressed whilst taking an inhaler.** Even traditional “passive” processes can give negative experiences with **14% of parents saying children became stressed/very stressed during the consent process.**

### CAREGIVER AND CLINICAL TEAM INTERVENTIONS

We were then keen to explore how parents seek to manage these behaviors when it comes to necessary medical appointments and procedures.

**Effective communication was a key resource, with 93% of parents saying they took time to explain what was going on.**

Physical contact also played a key role to lowering child anxiety. **80% said they supported through physical contact such as hand holding and 81% said they continued to talk to their child throughout the procedure. We also saw that 47% brought distraction items such as toys and 45% incentivized their children.**

When we asked parents what their healthcare providers did to support their children through appointments similar tactics were mentioned. **79% said healthcare professionals explained to the child what was going on, 72% said they talked to the child throughout the appointment or procedure and 62% provided a “child-friendly” environment through decor to help reduce stress.** There was also, however, a common thread in the use of personnel to support children. **30% said healthcare providers offered consistency of staff interacting with the child while 19% said they were supported by staff that were specifically trained.**

## INSIGHTS REGARDING PLAY SPECIALISTS

Parents completing the survey were then given a description of a Play Specialist<sup>26</sup> and asked to confirm whether they felt they had been supported by such an individual during a healthcare appointment or procedure. Nine percent of respondents could confirm they had been supported by a dedicated Play Specialist. We then asked those that had experience of Play Specialists whether they agreed or disagreed with a number of key statements.

**85% agreed that the Play Specialist reduced their child's anxiety and stress. 85% of parents agreed that the Play Specialist also reduced their anxiety and stress during the appointment or procedure and 92% stated their child had a positive experience engaging with a Play Specialist.**

- "When my son was getting prepared for surgery, he had to have a lot of tests done because he was obese, a play Specialist came and talked to my child with puppets."
- "My son's tantrums are reduced drastically."
- "My son went in for a few hearing tests and they had fantastic Play Specialists who interacted well with him and made him feel distracted and reassured."

## CAREGIVER CONSIDERATIONS REGARDING CLINICAL TRIAL PARTICIPATION

Finally, we asked the parents what factors would influence their decision to enroll their child into a clinical trial. Aside from the opportunity to improve their child's health, parents were interested in factors that reduced their study burden, such as being able to update study doctors digitally through a website or mobile app, ensuring their child would receive study related medical care at no extra cost and there would be a minimum of in-person appointments. **49% of all the parents in our survey also stated that they would be more likely or much more likely to have their child participate in a trial if Play Specialists were provided, with the remainder stating it would make them no more or less likely to participate.**

## Summary

The clear message from the parent's survey is that more support is required for parents and their children during visits to hospital. This support should be offered for all interactions, not just invasive procedures as the anxiety around any contact can impact whether a family decides to engage with a trial and see it through. Another key point was the need for effective communication that is age appropriate and offered to both the child and caregivers.

The parental survey results regarding the potential role of "Play Specialists" are more ambiguous, **with 49% saying it would play a decisive role in engagement** with a clinical trial. However, a lack of awareness and understanding as well as international variations in the definition of a Play Specialist will almost certainly impact this global assessment.

The expert interviews offer greater insights regarding the potential benefit of a professional. All our experts speak powerfully about how Play Specialists and their equivalent could support clinical trials.

Qualified Play Specialists are an extremely valuable, yet under-utilized resource in both healthcare settings. Involving these trained individuals effectively is not only recommended by health regulatory bodies but would address an existing need amongst parents and children for further physical and emotional expert support during routine appointments and procedures. By offering time and support when hospital staff are stretched and providing a friendly, familiar face would reduce study related barriers and anxieties that may lead to improvements in pediatric clinical trial recruitment, retention and data quality.

## Recommended Next Steps

Our recommendation is that all pediatric trials should be supported as much as possible by qualified Play Specialists. However, many specialists are overloaded with their standard caseload and are therefore unable to dedicate time to supporting research participants. There is a further need to understand what Play Specialist resources exist at a local level, their qualifications and availability to support a pediatric clinical trial. There also needs to be a greater awareness amongst caregivers and professionals of the support they can bring to reduce the burden involved in taking part in a study.

This is an area where a large scale CRO can add tangible benefit to both pediatric trial success and the patient experience. CROs have the ability to audit local hospital resources and help address the lack of awareness around Play Specialists and the potentially powerful role they have, not just amongst health professionals but also parents. CROs potentially also have the global resources to support the research teams' use of Play Specialists. Where the professionals already exist within a hospital, IQVIA is already seeking to ensure they are able to dedicate time to support upcoming trials. Many teams will unlikely have capacity in their existing role to support with this, and it is clear additional staff time will be required. For those hospitals where Play Specialists are not in residence, IQVIA is seeking to support the identification of qualified, appropriate specialists to provide the critical support that could be the difference between trial completion and patient drop out.

In conclusion, as leaders in pediatric clinical research, it is our role to think creatively and listen to the struggles faced by families and experts. We can then offer support they find valuable. Whether a child is 5 or 15, they need to be a willing and active participant in clinical research. For the future of pediatric clinical research, this means making children a part of the conversation and giving them the opportunity to play.



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26. Description of Play Specialist: A play specialist is a specifically qualified individual whose sole responsibility is to provide emotional support to the child through their procedure or treatment. They may employ different techniques such as the use of toys, bubbles, talking therapies, drawing etc.



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