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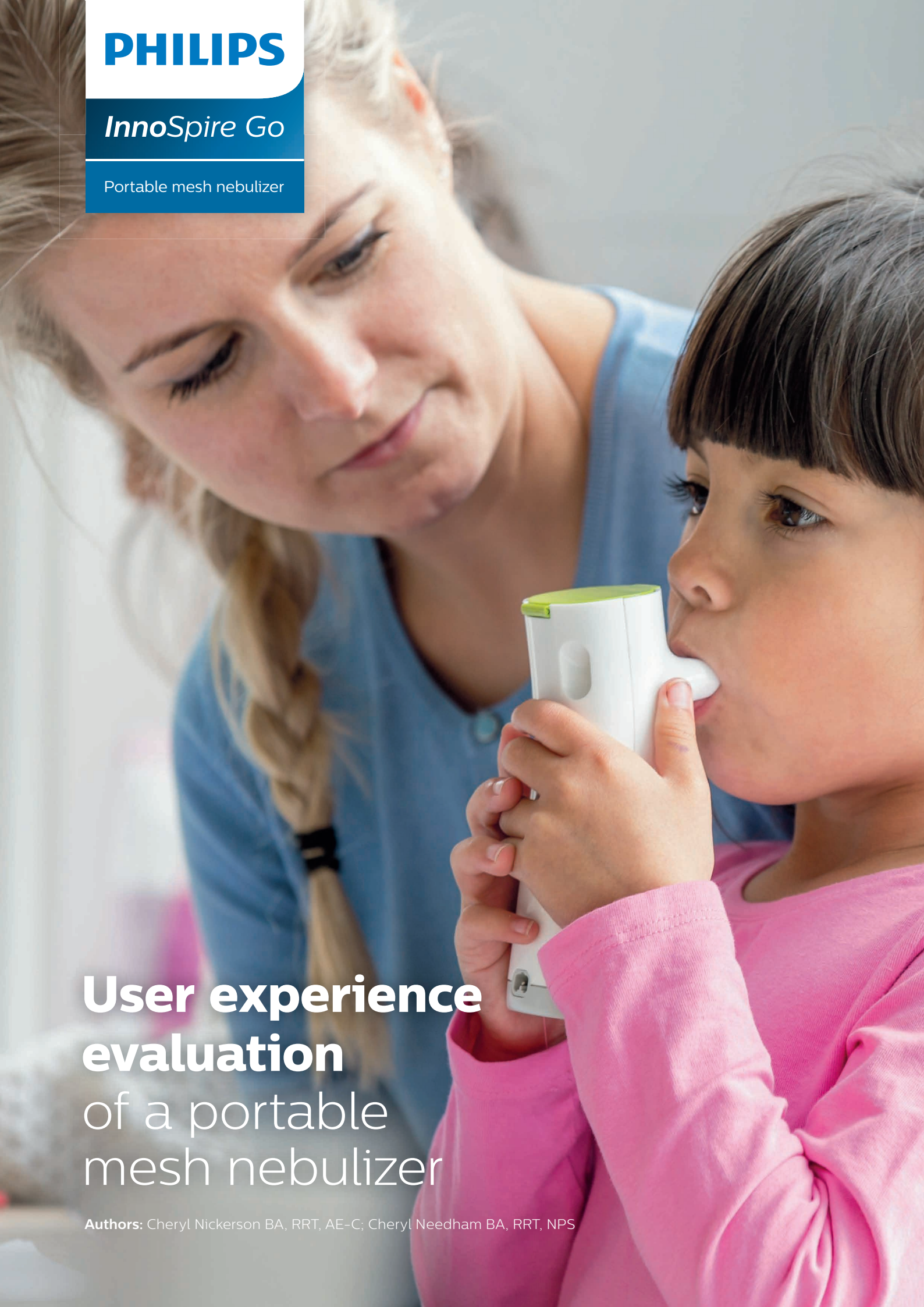
*Inno*Spire Go

Portable mesh nebulizer



User experience evaluation of a portable mesh nebulizer

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Background

Inhaled aerosolized medication is the cornerstone of asthma management. There are various aerosol delivery devices available for medication delivery to patients with asthma. Each method has advantages and disadvantages, and not all methods are available for delivery of every medication. Studies have demonstrated that performance of these devices are equivalent in patients who are willing to use the device and can use them correctly.[1] The selection of the medication delivery device ideally is dictated not only by what drug formulation is available in which delivery system, but also patient preference[2, 3] and capabilities.[1, 4, 5]

In asthma, non-adherence to the treatment regimen, range from 30 to 70 percent.[6] Poor adherence has been linked with greater symptoms, poor clinical outcomes and increased health service utilization.[7] Aerosol delivery devices that are a burden or difficult to use, may result in a higher incidence of mistakes during use, which may potentially result in lower drug delivery to the patient and reduced adherence to the prescribed treatment regimen.[8] Devices that are difficult for the patient to use may also require reinforcement of device training, which may add to the burden of the patient educator.

The World Health Organization describes five interacting dimensions that affect adherence:[9]

Social/economic related factors – finances (payor or insurance coverage and cost of treatment), low health literacy, lack of or no family or caregiver support, lack of transportation, distance to clinic or healthcare facility, wait times, and cultural beliefs.

Healthcare team and system related factors – inadequate discharge planning and lack of continuity of care, poor follow-up, poor provider patient relationship/communication, and inadequate communication (written and verbal), and inadequate time.

Condition related factors – inadequate understanding of disease, acute versus chronic nature of disease, severity of symptoms, and other chronic conditions or debilitating comorbidities.

Therapy related factors – complexity of treatment regimen, length of therapy, side effects, changes to prescription or delivery device, and burden on lifestyle.

Patient related factors – motivation, confidence, beliefs, experience, expectations (perceived benefit and risk), and stress.

Table 1 outlines elements of the aerosol medication delivery system, considerations that may improve use and potential impact on dimensions of adherence.

Delivery system elements	Considerations	Dimension of adherence
Complexity of system	Intuitiveness, ease of use, ability to breath without any special technique	Therapy-related Patient-related
Portability and ability to use discretely	Small, battery operated, quiet during operation	Therapy-related
Burden	Total treatment time (including - assembly, medication delivery, cleaning)	Therapy-related
User interface	Indicators for dose delivered	Patient-related
Durability	Robustness for transportation, cleaning and disinfectant	Therapy-related
Information for use and supplemental materials	Easy to understand user guide, supplemental user videos	Patient-related Healthcare team and System-related

Table 1 Delivery system impact on dimensions of adherence

Patient-centric approach

A patient-centric approach focuses on minimizing the burden of the medication delivery device by developing a product that is small, portable, easy to use, and incorporates design features to positively influence the aforementioned dimensions of adherence. This approach was used when designing the Philips InnoSpire Go portable nebulizer (Respironics Respiratory Drug Delivery [UK], Ltd, Chichester, UK). The goal was to balance two objectives. The first objective was the development of an aerosol delivery device for the delivery of safe therapeutic doses of commonly prescribed respiratory medications. Thus, a vibrating mesh was selected as the aerosol generator, because of the efficency of the technology (i.e., the ability to generate aerosol with a high, fine particle fraction, along with a minimal residual volume and delivery of the medication very quickly to the respiratory tract).[10] Previous studies by Slator et al, have demonstrated the InnoSpire Go's aerosol characteristics and the ability to deliver safe therapeutic doses of commonly prescribed respiratory medication for asthma and COPD.[11, 12] The second objective was to develop a system that would overcome the burden of traditional jet nebulizers and create a system that would provide an easier patient experience that patients would prefer to use.

The IHUT was conducted in the United Kingdom (UK) involving 81 children with asthma and their parents.

In-home User Testing (IHUT)

After launching the InnoSpire Go, an IHUT was completed to garner feedback regarding the user perception of the device. The aim of the study was two-fold; first, to evaluate satisfaction with and performance of the InnoSpire Go portable mesh nebulizer in relation to their current or previously prescribed nebulizer system, and second to evaluate the effect on quality of life amongst users after 30 days of using the product.

Methods

The test was conducted in the United Kingdom (UK) involving 81 children with asthma and their parents. Philips, as the sponsor of the study, collaborated with a third party, global market research agency to conduct the research. Recruitment of the participants was conducted in April of 2019 from a panel of consumers and the target population was identified by using an online screening survey. Eligible participants were required to be children aged 5-15 with a diagnosis of asthma, have a prescription for liquid medications and a history of nebulizer use for 6 months or longer. The research manager contacted each participant that opted-in to confirm personal details and eligibility. Qualifying participants provided informed consent, agreed to use the InnoSpire Go for 4 weeks, and complete a survey at the end of this period. During the study, the research manager kept in contact weekly with the participants to ensure that that they were actively using the nebulizer and preemptively resolve any questions or issues they may encounter with the nebulizer. Post thirty-day use surveys were conducted on-line. To validate the claims, the respondents were asked to what extent they agreed with statements related to use of the InnoSpire Go.

Sample size

One hundred and ten participants were enrolled in the study. Between May and June of 2019, eighty one respondents completed the study and filled in the evaluation questionnaire after 30 days of using the InnoSpire Go.

Data analysis

Prior to the test, a list of questions was developed to evaluate attributes associated with quality of life and preference with nebulizer therapy use. The third party research agency was the data processor for all data collected and evaluation of inconsistent and incorrect data. Upon completion of the test, anonymized questionnaire data was provided to Philips. A five point Likert scale was used that ranged in responses from 1 (strongly agree) to 5 (strongly disagree) to determine the extent in which the participants agreed with the statement. Statements were found to be validated when the top 2 boxes (agree and strongly agree) added up to 80% or more.

Results

Gender and age data for the children that participated are presented in figure 1. The gender breakdown among the participating parents was fifty-eight percent female vs. forty-two percent male. The majority of children that participated were children between the ages of five and ten. This is typical, because younger children are more apt to use nebulizers for delivery of aerosolized medications. Prepubescent boys have a higher incidence of asthma, therefore the majority of children that participated, fifty-five percent, were male. The participants reported that their predecessor device was a conventional jet compressor systems or mesh nebulizer system.

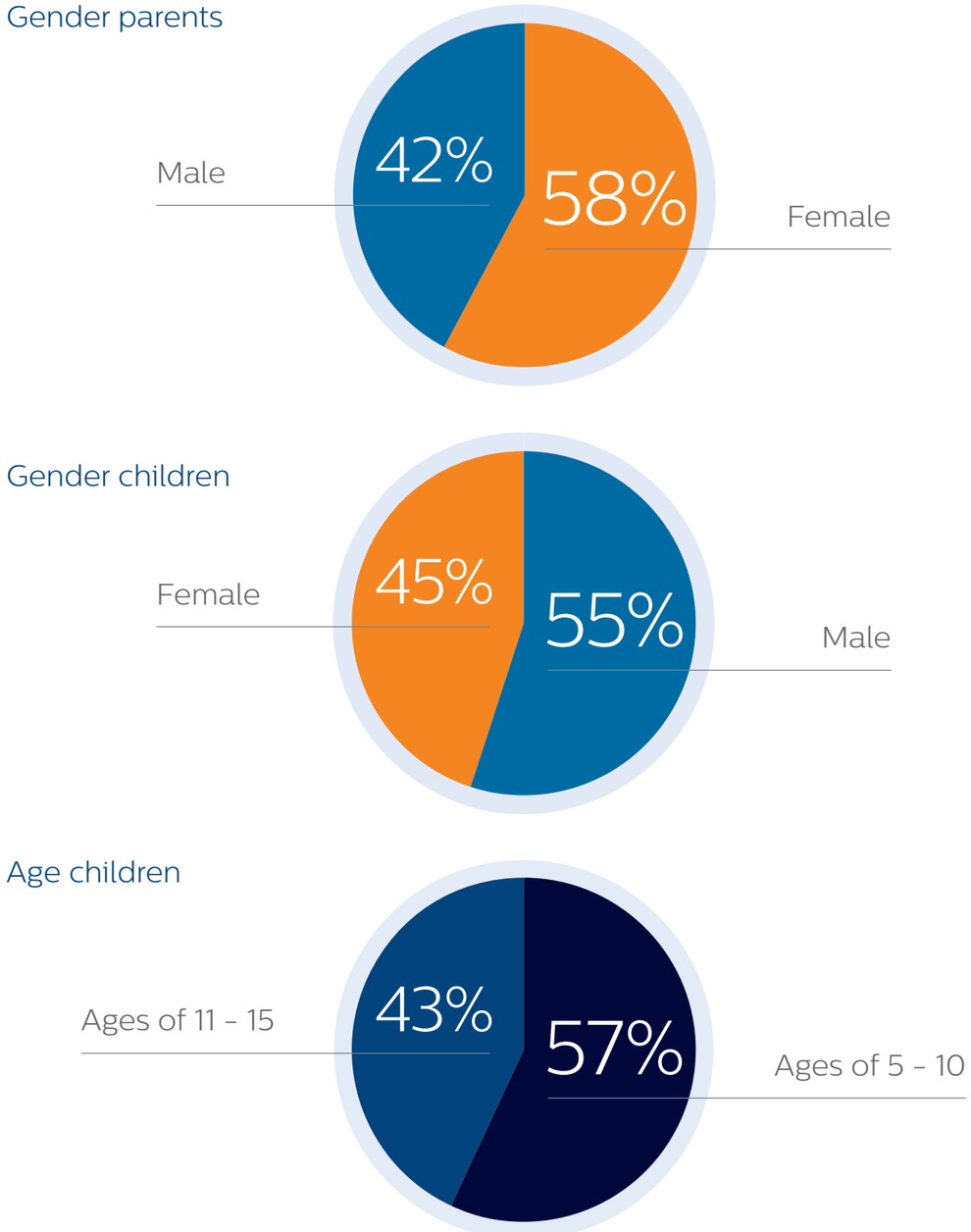

Figure 1 Age and gender characteristics of participants[13]

The survey results (Table 2) show that the participants rated the InnoSpire Go favorable in the following four categories:

Ease of use – it fit easily into the treatment regimen, and was easy to set up, use and clean.
Emotional – participant's children reported they felt good about using the InnoSpire Go.
Confidence – in use of the InnoSpire Go outside the home and while participating in activities.
Preference – for the InnoSpire Go over existing nebulizer.

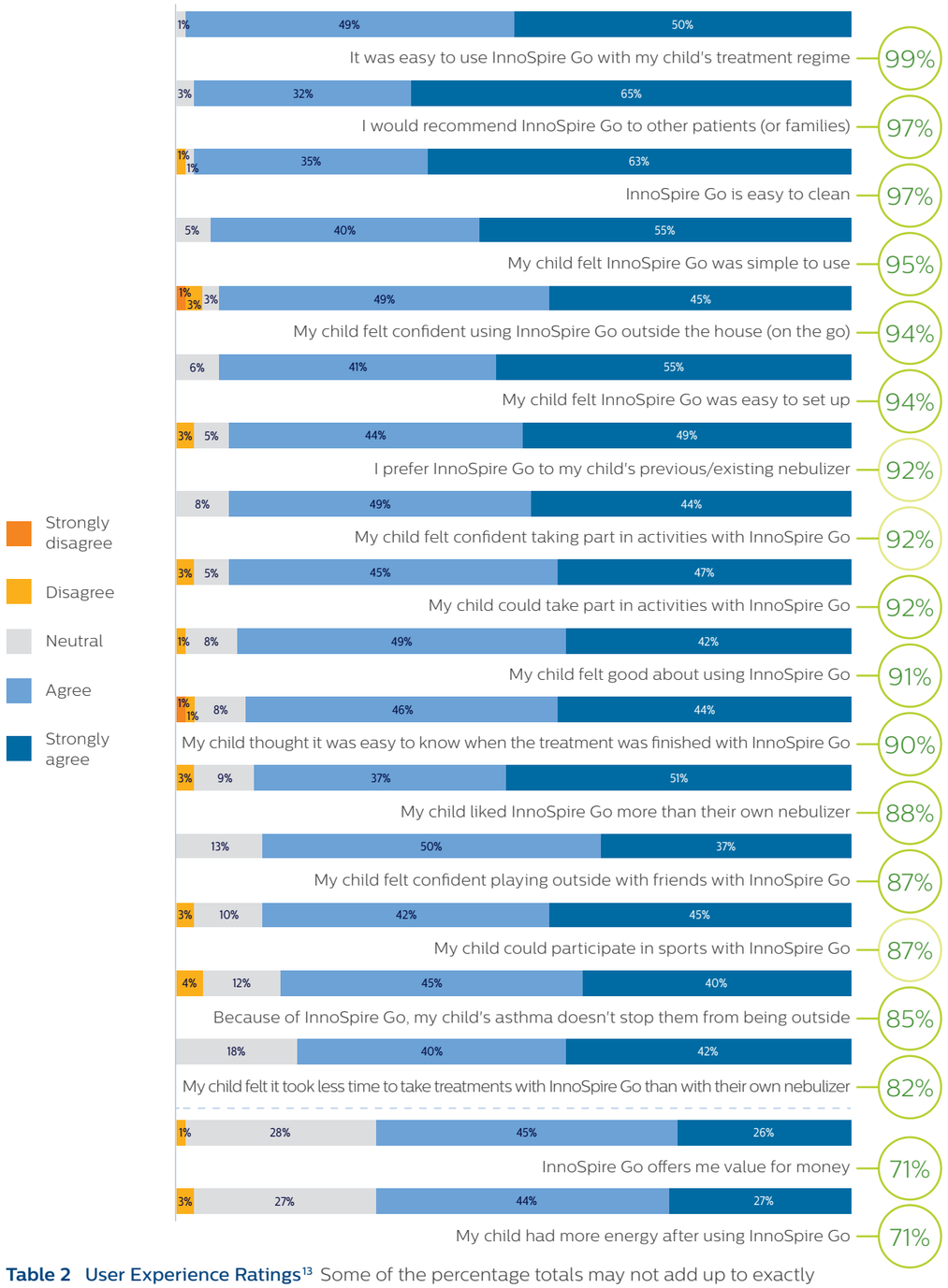

Table 2 **User Experience Ratings**[13] Some of the percentage totals may not add up to exactly 100% due to rounding to the nearest whole number.

Key performance indicators (KPIs)

KPIs associated with preference, ease of use, confidence and emotion, were reported on a 5 point scale and are reported in Table 3. The lower the mean, the more the respondents agreed with the statement.

KPI	Mean (95% CI)
I prefer InnoSpire Go to my child's previous nebulizer	1.62 (1.46-1.77)
It was easy to use my InnoSpire Go in my child's treatment regimen	1.51 (1.39-1.63)
My child felt confident taking part in activities	1.60 (1.46-1.74)
My child felt InnoSpire Go was simple to use	1.50 (1.37-1.63)
My child could take part in activities with InnoSpire Go	1.67 (1.51-1.82)
My child felt good about using InnoSpire Go	1.68 (1.58-1.83)

CI = confidence interval

Table 3 **KPI for preference, confidence, ease of use and emotion**[13]

Discussion

Survey results of the IHUT confirm that the InnoSpire Go portable mesh nebulizer was viewed more favorably than the participants' current nebulizer therapy, with respect to ease of use, confidence, preference and emotional benefit. The potential impact of the InnoSpire Go on four areas of WHO adherence dimensions are outlined in table 4. Devices that are easy to use and require minimal reinstruction may also make the task of the patient educator easier.

InnoSpire Go category	Dimension of adherence
Confidence and preference	Patient-related
Emotional	Patient-related
Ease of use	Therapy-related Patient-related Healthcare team-related

Table 4 **InnoSpire Go feedback potential impact on dimensions of adherence**

Previous research conducted in asthma has demonstrated that higher patient satisfaction with their medication delivery device has been linked to better clinical outcomes, and ease of use is one of the attributes associated with device satisfaction.[14] Thus, further clinical research would be required to confirm the impact of the InnoSpire Go on clinical outcomes.

Summary

The InnoSpire Go is a product that was developed to address the overall patient experience related to medication delivery, to simplify and reduce the burden of conventional jet nebulizer use, and to provide an option that would fit seamlessly into their existing lifestyle. The IHUT demonstrated that children with asthma and their parents adopted the new technology as a preferred option to meet the aforementioned needs.

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