Thursday Afternoon Abstracts

Physiology / Sleep / NIV

Abstract ID = 13525

CTN-Lung Clearance Index Core Facility: Quality Assessment

Clare Saunders

imperial College

Fiona Dunlevy
Mary Abkir
Sophie Pinnell
Chris Short
Jane Davies

Introduction & Objectives

Introduction: The ECFS Clinical Trials Network (CTN) LCI Core Facility trains operators in the Multiple Breath Washout (MBW) test, providing a pool of certified sites available to sponsors. Certified MBW operators (n>200) across Europe come from a number of professional backgrounds with varying levels of physiology experience. Our training is ideally conducted face-to-face but can also be provided virtually with ongoing support during trials. Centralised over-reading systems are in place to evaluate MBW trial data. We have supported 13 trials to date; success rates are good overall, although some sites require additional support.

Objectives: A quality improvement exercise was initiated to 1) understand correlates with varying performance; 2) implement quality improvement initiatives; 3) provide recommendations to sites.

Methods

Methods: Success rates from 3 recent commercial trials of CFTR modulators were calculated (success rate of >80% acceptable). A survey sent to 48 MBW certified ECFS-CTN sites assessed the operators' professional background, testing environment and any training needs.

Results

Results: From 25 trial participating sites, n=74 operators were medical (32%), physiology/ lung function (8%), nursing/ research co-ordinator (34%), other/ NA (26%). 18 (72%) sites achieved acceptable MBW quality, whereas scores were lower for 7 (28%). Operator background differed significantly in these two groups (Chi^2, $p<0.01$), success being associated with a greater proportion of medical or physiology staff performing MBW. Of the 42 sites which responded, 36% did not follow advice on a suitable testing environment and 75% requested annual refresher training.

Conclusions

Conclusions: This initiative has identified that our training may need to be enhanced for operators with less experience in respiratory physiology; a foundation level training module could

be beneficial. We will also initiate annual refresher training in order to maintain operators' skills. A summary of individual site success rates will be provided to each site with personalised training plans implemented. Some sites not partaking in commercial trials still perform MBW, therefore, we are considering a service where sites can submit practice traces for quality control once a year.

References

Cystic Fibrosis / Suppurative lung disease

Abstract ID = 13524

The Lung Clearance Index Core Facility

Sophie Pinnell

Royal Brompton & Harefield Hospital

Clare Saunders
Mary Abkir
Christopher Short
Jane Davies

Introduction & Objectives

Historically, spirometry has been used in many cystic fibrosis clinical trials to obtain FEV^1 for use as a well-established outcome measure[1]. However, FEV^1 is not able to detect early disease changes which occur in the smaller, peripheral airways. The multiple breath washout test (MBW), with lung clearance index (LCI) as its primary outcome, can provide an overall indication of ventilation inhomogeneity and is now used in cystic fibrosis clinical trials as a key outcome measure. The LCI Core Facility was created in 2014 to assist with standardisation of testing by certifying operators across Europe and providing an overreading service for clinical trials[2]

Methods

Our team at the Royal Brompton/Imperial College have aided the standardisation of testing by working with other specialist centres to create a standard operating procedure. Training is provided to sites using a combination of online and face-to-face sessions. Operators can then submit traces for analysis whereby a well-defined set of quality criteria is applied to determine whether they pass or fail the certification. In collaboration with the cystic fibrosis clinical trials network, a log of all certified sites and operators is maintained. This allows sponsors to access a pool of suitable sites for clinical trials.

Results

To date, we have certified 175 operators; on average 78% of operators pass certification first time. We provide further training and support to those who need to re-submit. Since the core facility was

established, we have overread a total of 4403 MBW traces for clinical trials; this ensures high quality testing data is used in CF research.

Summary of operator pass rate

Year	Number of operators certified	First time pass rate (%)	Total number of traces submitted
2014	12	75	38
2015	45	73	270
2016	21	67	123
2017	18	83	95
2018	23	83	140
2019	15	73	85
2020	19	74	111
2021	15	87	88
2022	7	86	44

Conclusions

The LCI Core Facility has helped to enable standardisation of MBW testing, resulting in a higher quality outcome measure for CF research. Following our success, we have been approached by other disease group networks for which LCI could be a useful outcome measure.

References

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2. Saunders, C., Jensen, R., Robinson, P.D., Stanojevic, S., Klingel, M., Short, C., Davies, J.C. and Ratjen, F., 2020. Integrating the multiple breath washout test into international multicentre trials. Journal of Cystic Fibrosis, 19(4), pp.602-607.

Physiology / Sleep / NIV

Abstract ID = 13546

Determining cut-off values for respiratory indices that predict night-to-night variability in pulse oximetry screening of children with trisomy 21

Jonathan Ong

Southampton Children's Hospital

Anne Marie Walker
Paula Lowe
Hazel Evans

Introduction & Objectives

Home pulse oximetry (HPO) can be used as a screening tool for obstructive sleep apnoea in children with trisomy 21. Previous studies[1,2] have demonstrated significant night-to-night variability. We aimed to determine cut-off values to predict the likelihood that respiratory indices on night one would change over subsequent nights.

Methods

Children with trisomy 21 over the age of 12 months were recruited between April 2020 and March 2022 to attend HPO over three consecutive nights. Studies containing night recordings with less than 4 hours artefact-free recording time (AFRT) were excluded from the analysis. Pre-determined clinically relevant cut-off (CRCO) values - mean oxygen saturations (SpO2) <94%, Oxygen Desaturation Index 4% (ODI4%) >4 and delta 12s index (D12) >0.55 - were used to identify cases of change (COC), defined as: values that fluctuated above and below the CRCO values across nights one to three. Receiver-Operator Curve (ROC) analysis was used to determine cut-off values with the optimum sensitivity and specificity to predict likelihood of becoming COC over subsequent nights.

Results

47 children aged 1.6 to 15.7 years (median 5.5 years) underwent 60 HPO studies over the study period. 13 studies were excluded due to insufficient AFRT on at least one night and 11 failed to complete three nights due to equipment failure or user error, leaving 36 complete studies for analysis. The median SpO2 for the cohort was 95.7% (91.5–98.8). The proportion of COC across nights one to three were as follows: mean SpO2 =17% (6/36), ODI4% =47% (17/36), D12 =36% (13/36).

Table 1: Cut-off values predicting COC for each index
AUC: area under the curve; NPV: negative predictive value; PPV: positive predictive value

	Below CRCO on night one						Above CRCO on night one					
Index	Lower Limit	AUC	Sensitivity	Specificity	NPV	PPV	Upper Limit	AUC	Sensitivity	Specificity	NPV	PPV
ODI4%	2.74	0.833	75%	83%	83%	75%	4.74	0.683	56%	100%	64%	100%
D12	0.475	0.816	100%	74%	100%	55%	n/a	n/a	n/a	n/a	n/a	n/a

A meaningful upper limit for D12 could not be determined due to large variability. There were no COC for studies with mean SpO2>94% on night one (NPV 100%).

Conclusions

The high proportion of COC within the respiratory indices corroborates existing reports of night-to-night variability in these children. NPVs for ODI4%<2.74, D12<0.475 and mean SpO2>94% were 83%, 100% and 100% respectively, suggesting these values are unlikely to cross these cut-offs over subsequent nights. When obtaining complete three-night HPO studies is challenging, predicting COC after a single night of HPO may help inform whether further investigation via cardiorespiratory sleep study is warranted.

References

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2. Galway NC, Maxwell B, Shields M, et al. Use of oximetry to screen for paediatric obstructive sleep apnoea: is one night enough and is 6 hours too much? Archives of Disease in Childhood 2021;106:58-61

Neonatal pulmonology, bronchoscopy, congenital malformations, respiratory intensive care and airways

Abstract ID = 13523

Tracheostomy as a management option in Cardiothoracic Paediatric Intensive Care: a single centre experience

Deborah Cross

Newcastle upon Tyne Hospitals NHS Foundation Trust

Caroline Harris

Introduction & Objectives

Patients managed in the cardiothoracic Paediatric Intensive Care Unit (PICU) include those with congenital heart disease, cardiac failure, airway and respiratory disorders. There are few recent studies which represent this subgroup of patients. We describe experience from a quaternary cardiothoracic centre to better understand characteristics, indications for and outcomes of patients undergoing tracheostomy.

Methods

Single centre retrospective cohort study of patients undergoing tracheostomy during admission to cardiothoracic PICU between 2017 and 2022. The Freeman Hospital is one of two UK centres which provides a quaternary paediatric cardiothoracic transplant service and mechanical support to those awaiting heart transplant. Electronic records were reviewed and data recorded included demographics, diagnosis, co-morbidities and outcome.

Results

During the study period there were 1420 admissions. 40 (2.8%) patients underwent tracheostomy. Median age at tracheostomy was 560 days [IQR 152 – 2982]. 43% of patients were under 1 year of age at time of tracheostomy. 60% of the cohort had a diagnosis of congenital heart disease, 32% had cardiomyopathy and 8% had primary respiratory disease.

36 patients (90%) underwent a procedure prior to tracheostomy. 29 patients (73%) received mechanical cardiac support during their admission (Extracorporeal Membrane Oxygenation (ECMO) or Ventricular Assist Device (VAD).

Indications for tracheostomy were multifactorial in 40% of patients. These included cardiac failure (60%), airway anomalies (40%), lung pathology (including diaphragmatic lesion) (27.5%), and critical illness myopathy (27.5%).

24 patients (60%) survived until hospital discharge. At time of follow up, 6 patients (15%) were surviving with tracheostomy, 19 (48%) were surviving decannulated, 15 (37%) died with tracheostomy in situ. There were no patients who died following decannulation and there were no tracheostomy related deaths. Median duration of tracheostomy was 152 days [IQR 55 – 546].

Conclusions

In cardiothoracic PICU tracheostomy is most often indicated to support longterm ventilation for children with cardiac failure and is required more often than in non-cardiothoracic centres (1). Many patients have multiple factors necessitating its use and it is difficult to identify predictive factors to determine insertion or duration. Despite high mortality rates in this subgroup nationally, the majority of patients who survive until discharge are later decannulated (2).

References

1. Powell J, Buckley HL, Agbeko R, Brodlie M, Powell S. Tracheostomy trends in paediatric intensive care. Arch Dis Child. 2021 Jul;106(7):712–4.

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Cystic Fibrosis / Suppurative lung disease

Abstract ID = 13555

Are we failing in the respiratory management of children with neurodisabilities and complex respiratory diseases?

Zoe Johnstone

Royal Hospital for Children and young people Edinburgh

Stefan Unger

Introduction & Objectives

Background:

Children and Young People (CYP) with neurodisabilities and complex respiratory disease are considered “orphan respiratory diseases” with respiratory illness being a significant cause of morbidity and mortality, resulting in frequent hospital admissions and poor quality of life. The importance of airway clearance techniques (ACT) has been documented, with recommendations for daily use of adjuncts to reduce respiratory morbidity.

Aims and objectives

- Audit physiotherapy care in CYP with neurodisability and chronic respiratory morbidity
- Investigate bacteria isolated and audit treatment received

Methods

Methods and inclusion criteria: Retrospective audit of CYP receiving regular community respiratory physiotherapy input (2011 -2021) at a tertiary paediatric centre. Primary comorbidities included Cerebral Palsy (GMFCS 4 or 5), and undiagnosed neurological conditions.

Results

Results: All identified 39 (44%Female) patients received physiotherapy input with a variety of ACT techniques (positive expiratory pressure (PEP) devices, autogenic drainage, manual techniques and cough assist) often used in conjunction. Documented physiotherapy annual review occurred in 62% (24/39), however children were reviewed at least twice a year, some weekly.

All 39 patients had respiratory samples sent for standard culture. 247 positive samples out of a total of 283 sent were analysed. 51% (20/39) of patients isolated *Pseudomonas aeruginosa* (PA) (90% (18/20) with repeat isolates), 24 (62%) patients isolated *Staphylococcus aureus* (60% (18/24) with repeated isolates), and 16 (41%) *Haemophillus influenza* (60% (10/16) with repeat isolates*).* None had eradication therapy for 1st PA isolate. 35% (7/20) of CYP with chronic PA were on nebulised Colistimethate, none receiving nebulised tobramycin despite frequent chronic co-infection with PA and *S. aureus*. 31% (33/39) received prophylactic Azithromycin.

Conclusions

Discussion:

Physiotherapy input in this population is high with care throughout childhood. All patients received some form of daily airway clearance with regular assessments but a lack of documented annual reviews. Despite frequent microbiology surveillance, less than a third received prophylactic antibiotics, none had PA eradication and only few received nebulised treatment for chronic PA.

Conclusions:

A wide variety of evidence-based ACT to treat children with neurodisabilities and chronic respiratory morbidity is used. Bacterial isolation is highly prevalent in this population and further research is required to ascertain best treatment strategies.

References

Physiology / Sleep / NIV

Abstract ID = 13553

Transition to adult care of children with severe disabilities under a tertiary paediatric respiratory service: gaps and challenges

Laura Lowndes

Addenbrookes Hospital

Theofilos Polychronakis
Miriam Murlis

Introduction & Objectives

Over the past decade there has been an increase in the prevalence of children with life limiting conditions and complex needs (1). Inequalities and poor standards of care of individuals with disabilities have been highlighted in various reports. The number of patients under follow up with our paediatric respiratory multidisciplinary team (MDT) for children with severe neurodisability has increased in the past 3 years with a significant rise in those reaching transition age. We established a transition clinic jointly with adult respiratory services in 2018 in a large, tertiary hospital.

Our aim was to identify gaps and areas of improvement in our transition process of children with complex needs under the care of our MDT clinic.

Methods

This was done by a retrospective notes audit pulling data out of the hospitals computerised notes system.

Results

19 patients reached transition age between 2018 and 2021. The majority of patients had a diagnosis of cerebral palsy (61.5%). All patients had severe motor function impairment, required feeding via enterostomy and had a high number of co-morbidities. Burden of respiratory care was high, all patients were on nebulised medication, had regular respiratory physiotherapy, the majority were using suction at home (77%). All patients had input from community paediatrician.

Conclusions

We identified a number of gaps with transition process which include no access to respiratory physiotherapy or specialist nurses, lack of pathways for equipment provision and maintenance. Greater reliance on general practitioners (GP) posed a challenge to both the GP and families. Highlighted areas for improvement were earlier involvement of GPs in transition process and increasing local clinical commissioning group engagement

References

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Cystic Fibrosis / Suppurative lung disease

ePoster

Abstract ID = 13539

Non-cystic fibrosis bronchiectasis in children: a cross sectional analysis.

Luisa Moraes Teixeira

Children's Clinical Research Facility, Royal London Hospital, Bart's Health NHS Trust

Kushalinii Hillson
Abigail Whitehouse
Jonathan Grigg
Sarah Brown

Introduction & Objectives

Paediatric non-cystic fibrosis bronchiectasis (NCFB) can present with a multitude of symptoms and underlying disorders (1, 2). This study aims to identify potential clinical phenotypes and risk factors for NCFB in children presenting to one tertiary respiratory hospital in London.

Methods

Children diagnosed with NCFB in a tertiary respiratory hospital were reviewed in terms of their demographics, microbiological profile, lung function and hospital admissions. Patients with primary ciliary dyskinesia were excluded. Statistical analysis was conducted using SPSS.

Results

We evaluated 24 paediatric NCFB patients [(16 male, 67%) with mean age: 11.7, Standard Error of Mean (SEM) 0.8], from eight ethnic groups. The most commonly associated conditions included: gastroesophageal reflux (GORD) (n=14, 58%), atopy (n=9, 38%), dysphagia (n=8, 33%), airway malacia (n=5, 21%), immunodeficiency (n=5, 21%) and post tuberculosis (TB) infection (n=3, 12.5%). Hospital admissions were used as a marker of severity of exacerbations, and only 10 patients (41.6%) required an inpatient stay between 2021-2022.

Overall, our cohort of patients maintained good lung function [FEV1% of predicted normal value: mean 89.1, SEM 4.4 – two patients excluded from analysis as they were unable to perform spirometry]. *Staphylococcus aureus* was the most common pathogen isolated in sputum cultures (n=8, 33%) and 21 patients (88%) were on prophylactic azithromycin. No statistically significant association was found between FEV1% or number of hospital admissions in the last year and age, gender, ethnicity, or any of the most common comorbidities (Table 1).

Table 1: Statistical analysis

Potential Risk Factors	FEV 1 %	Number of Hospital Admissions
Gender	U = 61.5, p = .714	U = 58.5, P = .742
Age	r= 0.122, p = .590, N= 22	r= -.491, p =.015, N=24
Ethnicity	H (7) = 8.61, p = .282	H (7) = 6.63, p =.468
GORD	U = 55.5, p = .845	U= 61.0, p = .625
Atopy	U = 41.0, p = .262	U = 58.0, p = .599
Dysphagia	U = 33.5, p = .185	U= 49.5, p=.383
Airway Malacia	U = 36.5, p = .649	U= 61.5, p = .331
Post tuberculosis	U = 39.5, p = .308	U= 26.5, p = .622
Immunodeficiency	U = 63, p = .120	U= 32.5, p = .297

U= Mann Whitney U test; p= p value, H= Kruskal – Wallis ANOVA test; r= Spearman's Correlation, N= degrees of freedom

Conclusions

The population analysed represents a heterogeneous group of children, with overall good lung function. None of the potential risk factors analysed were statistically associated to FEV1% or the number of hospital admissions. Most patients had co-morbidities commonly described for NCFB, including post-TB (1, 2). Limitations of this study include the small sample size and the imposition of COVID restrictions during the analysis period, which may have reduced these children's exposure to the usual pathogens which contribute to infective exacerbations. Future analysis will be useful to compare the difference in hospital admissions post COVID restrictions, success rate of rescue antibiotics at home in preventing hospital admissions, and adherence to physiotherapy regimes in maintaining good lung function.

References

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Asthma / Allergy

Abstract ID = 13549

How do we identify dysfunctional breathing (DB) in children and young people - a UK delphi consensus

Ruth Stewart

NHS Lothian

Kenny MacLeod
Ann McMurray
Kirstin Unger

Introduction & Objectives

Dysfunctional breathing (DB) is a commonly recognised condition in adults. Due to a lack of a clear definition to accurately distinguish from other conditions (e.g. asthma), prevalence in Children and Young People (CYP) remains unclear (de Groot 2013). Currently diagnosis is made following exclusion of other causes, however symptoms and outcome measures are generally based only on adult data. The literature also highlights a lack of confidence in clinicians to diagnose DB (Pedersen et al 2021) and consequently the time from symptoms occurring to treatment can be protracted. Obtaining a better understanding of which criteria experienced clinicians consider most accurate in identifying DB in CYP may reduce misdiagnosis, reduce the use of unnecessary medication and improve quality of life.

Objective: To achieve an agreed definition of dysfunctional breathing & symptoms specific to CYP.

Methods

An e-Delphi survey was conducted with paediatric respiratory experts across the UK: medical, nursing & physiotherapy with >5 yrs experience. A structured questionnaire based on current literature findings was used to identify the relative importance of main clinical features and descriptions to reach an agreement on the definition of this combination of symptoms. Consensus was defined in advance at 75% and 3 rounds were undertaken to achieve improving consensus at each round.

Results

39 participants were recruited and 30 respondents completed all 3 rounds. ‘Dysfunctional breathing’ continues to be most commonly used as an over-arching term encompassing breathing pattern disorder, inducible laryngeal obstruction & vocal cord dysfunction. Agreed key clinical features were breathlessness, chest or throat tightness, difficulty breathing in, anxiety and a sensation of air hunger. Interestingly subsequent analysis highlighted that physiotherapists also scored frequent yawning and frequent sighing as important or very important indicators although this was not the case across all clinicians.

Conclusions

A multidisciplinary Delphi panel delivered a high level of agreement on the definition & clinical features specific to CYP with DB. We anticipate this will better inform clinicians in the diagnosis of DB and will support the development of an accurate screening tool to enable more timely intervention in future.

References

De Groot, E., Duiverman, E. & Brand, P. (2013) Dysfunctional breathing in children with asthma: a rare but relevant comorbidity. Eur Respir J. 41 (5): 1068-73.

Pedersen, E., Ardura-Garcia, C., de Jong, C., Jochmann, A., Moeller, A., Mueller-Suter, D., Regamey, N., Singer, F., Goutaki, M. & Kuehni, C. (2021) Diagnosis in children with exercise-induced respiratory symptoms: Pediatric Pulmonology. 56:217–225.

Asthma / Allergy

Abstract ID = 13530

Making Asthma Greener, Puff by Puff

Andy Brookes

Leeds Teaching Hospitals NHS Trust

Alex Olney
Matthew Hick
Hannah Robertshaw

Introduction & Objectives

The impact that the NHS has on the environment is huge. The carbon dioxide emissions from the NHS account for more than all flights leaving Heathrow each year.[1] One of the biggest contributors of carbon emissions are medicines, which account for 25% of the overall carbon footprint. Inhalers make up 3.1% of this.[2] It is the hydrofluorocarbon propellants in inhalers which produce carbon dioxide. By switching from metered dose inhalers (MDIs) to dry powdered inhalers (DPIs), the amount of CO_2 released into the atmosphere can be reduce by 25 times per actuation.[3]

This study aimed to highlight the impact that our prescribing practices for children with asthma at Leeds Children's Hospital (LCH) have on the environment. Our primary objective was to increase the number of children in our tertiary asthma clinics who were prescribed DPIs as their preventer inhaler. Our secondary objective was to highlight how we dispose of inhalers and encourage the use of one puff over two puffs to achieve the same dose.

Methods

All patients aged 8-16 years who attend the tertiary asthma clinic at Leeds Children's Hospital were included in the study. Those who had an alternative diagnosis, poor lung function (FEV1 <75%) or significant co-morbidities which would make them unable to co-ordinate a forceful inhalation were excluded.

We planned a training programme for staff and families, displayed posters and added a section to the asthma clinic proforma to encourage switching to DPIs.

Results

224 patients were identified, of these 26 were excluded based on the exclusion criteria. Of the 198 included, 122 were suitable to switch to a DPI, 45 were already on a DPI and 31 were not appropriate based on their clinical condition. With respect to acute Salbutamol prescribing, 2,973 Salbutamol MDIs were prescribed in LCH in 2021 (Paediatric A&E and inpatient paediatric wards). This is the equivalent carbon dioxide emissions of 520,275 miles of driving.

Conclusions

There is a huge scope for reducing the carbon footprint asthma inhalers have on the environment by changing our prescribing practices, disposing of inhalers effectively and encouraging families to only replace their inhalers when they need to.

References

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Asthma / Allergy

Abstract ID = 13535

Medicines optimisation across care boundaries: Experience from a tertiary paediatric asthma clinic

Sukeshi Makhecha

Royal Brompton and Evelina Hospitals

Sukeshi Makhecha
Molly Smith
Samatha Sonnappa
Andrew Bush

Introduction & Objectives

Introduction: Regular reviews of children with asthma are essential to ensure adherence to medication and correct use of delivery devices. Any medication changes made in hospital clinics should be continued in primary care. Transfer of information about medications across care boundaries can be challenging; between 30 and 70% of patients have either an error or an unintentional change to their medicines when their care is transferred [1].

Objectives: i) To determine whether medication changes made in a tertiary hospital paediatric asthma out-patient clinics are continued in primary care and ii) to explore parents/carers experience on medicines optimisation across care boundaries.

Methods

Mixed-methods service evaluation using qualitative and quantitative methods. Electronic patient records were used to identify children who had medication changes made in clinic between September-November 2020 and to see if this change was reflected on GP summary care records (SCR) three months later.

Telephone interviews using semi-structured questionnaires were conducted with parents/carers of children in whom medication changes had been made in an out-patient clinic in a tertiary paediatric asthma centre, exploring their experiences and categorized into themes.

Results

See **fig 1 - consort flow diagram of patients below**.

52% (12/23) of changes were accurate on SCR records, 35% (8/23) of changes were inaccurate and in 13% (3/23) no changes appeared on SCR.

Patient's responses in the interviews were grouped into themes:

1. Medication supply issues:

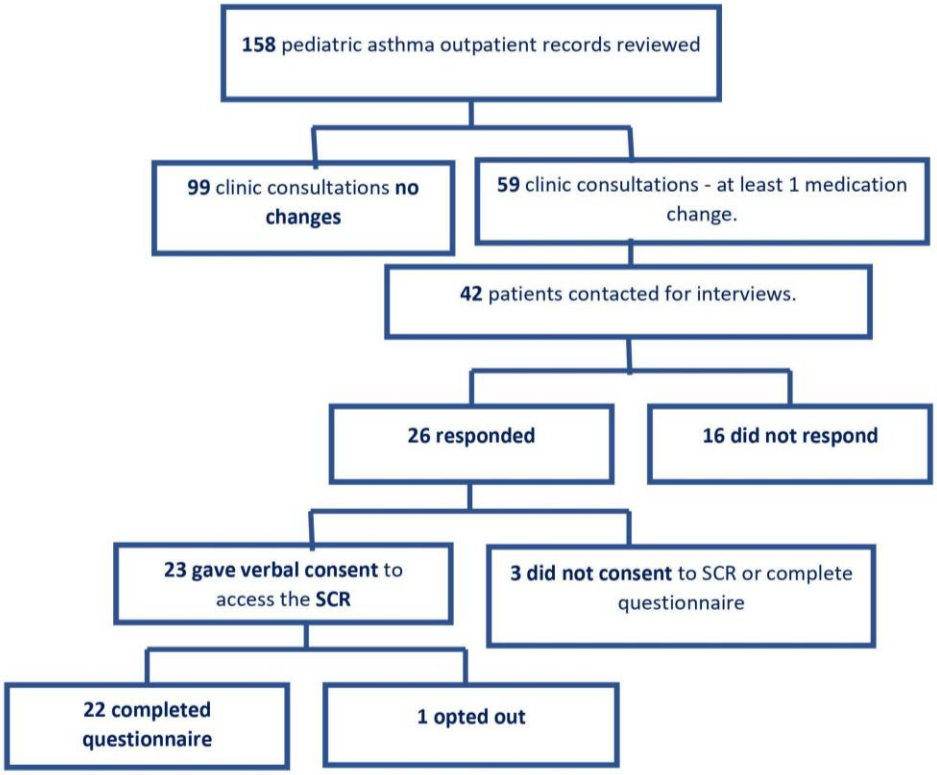
"The GP surgery couldn't find the clinic letter that had been sent to them, so he missed a couple of days of his inhalers whilst we sorted out the issue"

2. Improvements in transfer of care:

"You can never have too much communication"

"It would be useful to have someone else looking out for the medication changes just in case the GP misses it. I don't always remember correctly either."

Fig 1: Consort flow diagram of patients.



Conclusions

Medication changes made in hospital out-patient clinics are either not transferred accurately or no changes appear in primary care records nearly 50% of the time. Better communication between care providers is required for more effective care.

References

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Asthma / Allergy

Abstract ID = 13536

Race and Ethnicity Related Bias in Paediatric Asthma Research

Adam Lawton

North Middlesex Hospital

Alexander Stephenson-Allen
Abigail Whitehouse
Atul Gupta

Introduction & Objectives

Children from ethnic minority backgrounds often receive poorer asthma care than their White peers, and in some cases experience a threefold higher hospitalisation rate.[1] Epidemiological data from the US suggests that Black patients suffer more frequent asthma attacks, and are more likely to die from asthma.[2]

One of the factors contributing to divergent asthma outcomes between White and non-White children is that many pharmacological studies of asthma drugs have been studied in cohorts that over-represent White children.[3] Lack of participation of Black and non-White children in registered clinical trials is a matter of concern, as emerging data leading to licensing of asthma drugs may have limited external validity.

Methods

We sought to determine the proportion of participants in registered clinical trials relating to paediatric or adolescent asthma over the last decade that were from White and non-White backgrounds. We searched the ClinicalTrials.gov database for all completed interventional studies between the dates 01/01/2011 and 01/01/2021 that were on the topic of asthma, and included participants below 18 years of age. Of the 500 studies returned, 208 had results available on the ClinicalTrials.gov website.

Studies were excluded studies that did not include patients under the age of 18. We then reviewed the published tables of baseline characteristics to determine if data on the race and/or ethnicity of the participants was available.

Results

In total, of the 112,327 patients studied, almost 69% (77,333) of the patients were described as White or Caucasian, and fewer than 13% (14,189) were described as Black, African, or African-American. Overall - just over 30% of study participants - some 34,207 children - were from non-White backgrounds.

Conclusions

There is a significant difference between the numbers of White and non-White children recruited to paediatric asthma trials. This may introduce biases in our understanding of the efficacy of pharmacological treatments for asthma.

Targeted strategies to recruit children to clinical trials from non-White backgrounds may ensure that treatment recommendations are more robust and are more broadly applicable.

References

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Asthma / Allergy

Abstract ID = 13540

Does Omalizumab lead to sustained improvement in Asthma Control

Elizabeth Gregson

Sheffield Children's Hospital NHS Foundation Trust

Angela Tang
Sarah Brookman
James Tarr
Azim Amin
Anil Shenoy
Sonal Kansra
Clare Murray
Atul Gupta

Introduction & Objectives

Background: Omalizumab binds to IgE, blocking IgE binding to it’s receptor, preventing an inflammatory response. It has shown good safety and tolerability profile in children with severe asthma. Little is known on its long-term effectiveness in children, or factors predicting response.

Aims: To investigate if omalizumab provides long-term, sustained effectiveness by maintaining good asthma control defined as ≤2 oral steroid (OCS) courses in one year and/or an ACT≥ 20 and whether any markers reliably predict effectiveness.

Methods

A multi-centre case note review of children (<18 years) on omalizumab for severe allergic asthma. Demographic, ACT, total and specific IgE, eosinophils, FEV1, FeNO, and exacerbation history were collected at baseline and 4 monthly intervals (excluding IgE and eosinophils).

Results

79 patients, 42% male, with a mean age of 11.6 years (5-17 years) were included. At baseline, the median IgE was 1000 (57-1300), the total mean daily ICS dose equivalent to fluticasone propionate was 617mcg (400-1000), 47% of patients were receiving daily oral steroids and mean ACT was 12. The follow up ranged from 4-84 months. In 12 months, 14 patients discontinued: 9 (poor efficacy), 1 (needle phobia), 3 (unclear reasons) and 1 (urticaria). One was lost to follow up and 3 moved to different centres.

Table 1 shows asthma control at baseline and 12 months. By 12 months, 46% of patients reached our definition of "well controlled". No factors predicted "well controlled" asthma, overall or when adjusted for ICS dose.

	Baseline (N= 79)	**12 months (N=58)**
Lung Function		
FeNO- ppb (mean)	7-247 (54.2)	6-214 (46)
FEV1 % predicted (mean)	26-142 (80)	37-140 (85)
Asthma control		
ACT (mean)	1-25 (12.5)	5-27 (18.3)
Steroid courses (mean)[1]	0-24 (6.2)	0- 5 (1)
Hospitalisations(mean)	0-37 (3)	0-2 (0.3)
Asthma Medications		
Total daily ICS (mean)[2]	400-1000 (671)	200-2000 (657)
Daily OCS (%)	37 (47%)	17 (29%)
FEV1: Forced expiratory volume in 1 second, ACT: Asthma control test, ICS: inhaled corticosteroids, 1: ≥3 days of oral prednisolone, 2Total daily dose equivalent to fluticasone		

Table 1

Conclusions

Omalizumab improved asthma control in 46% of patients and most on OCS were able to stop over time, but many remained sub optimally controlled. Other variables are likely to influence asthma control.

References

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Asthma / Allergy

Abstract ID = 13550

Dupilumab Impact on Lung Function in Children With Uncontrolled, Moderate-To-Severe Asthma and Elevated Type 2 Biomarkers

Theresa W Guilbert

Cincinnati Children's Hospital

Leonard B. Bacharier
Constance H. Katelaris
Antoine Deschildre
Wanda Phipatanakul
Arman Altincatal
Leda P. Mannent
Nikhil Amin
Elizabeth Laws
Bolanle Akinlade
Xavier Soler
Juby A. Jacob-Nara
Yamo Deniz
Paul J. Rowe
David J. Lederer
Megan Hardin

Introduction & Objectives

Asthma is the most prevalent chronic disease in children, and type 2 inflammation is the most common driver of asthma in children. Low pre-bronchodilator forced expiratory volume in 1 second (FEV_1) is associated with increased exacerbation rates, lung function decline and increased mortality in patients with asthma. Dupilumab, a fully human monoclonal antibody, blocks the shared receptor component for interleukin-4 and interleukin-13, key and central drivers of type 2 inflammation. In the phase 3 VOYAGE study (NCT02948959), add-on dupilumab vs placebo demonstrated significant improvements in percent predicted (% predicted) pre-bronchodilator FEV_1 at Week 12 in children aged 6 to <12 years with uncontrolled, moderate-to-severe asthma, a type 2 inflammatory phenotype (baseline blood eosinophils ≥150 cells/μL or fractional exhaled nitric oxide [FeNO] ≥20 parts per billion [ppb]). This analysis evaluated dupilumab efficacy in improving lung function by assessing the proportion of patients that achieve FEV_1 % predicted ≥80% and ≥95%, in the type 2 population and in patients with ≥300 eosinophils/μL at baseline.

Methods

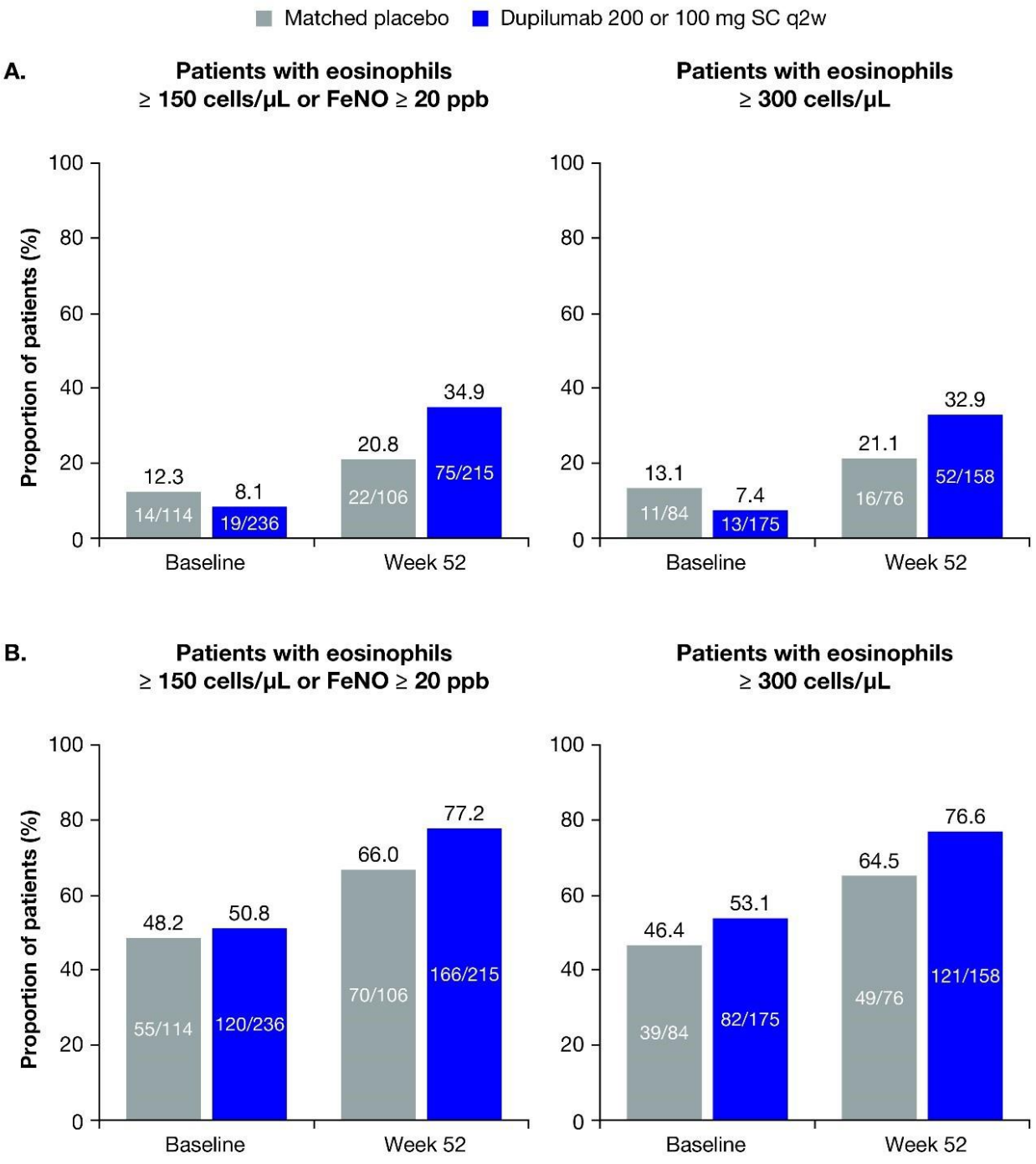
Patients were randomized 2:1 to receive add-on subcutaneous dupilumab 200/100 mg every 2 weeks (q2w) based on body weight, or matched placebo q2w for 52 weeks. Proportion of patients with % predicted pre-bronchodilator FEV_1 <80%, ≥80% and ≥95% at baseline and Week 52 were analysed.

Results

In type 2 patients who received dupilumab (n=236) vs placebo (n=114), 8.1% vs 12.3% had % predicted FEV_1 ≥ 95% at baseline, and 50.8% vs 48.2%, had % predicted FEV_1 ≥80% at baseline. At Week 52 these proportions increased in dupilumab vs placebo patients to 34.9% vs 20.8% with % predicted FEV_1 ≥ 95%

and 77.2% vs 66.0% with % predicted $FEV_1 \geq 80\%$ (**Figure**). 22.8% vs 34.0% of dupilumab vs placebo patients continued to have % predicted FEV_1 <80% at Week 52 (49.2% vs 51.8% at baseline). Similar results were observed in the Eos ≥300 subpopulation.

Figure. Proportion of patients with % predicted pre-bronchodilator $FEV_1 \geq 95\%$ (A) and $\geq 80\%$ (B) at baseline and at Week 52 – ITT population.



SC, subcutaneous.

Conclusions

Dupilumab increased the proportion of paediatric patients with improved lung function, in both the type 2 population as well as the Eos ≥300 subpopulation.

Asthma / Allergy

Abstract ID = 13544

Dupilumab Improves Asthma Control and Health-Related Quality of Life in Children With Uncontrolled Persistent Asthma: VOYAGE Study

Alessandro Fiocchi

Pediatric Hospital Bambino Gesù IRCCS, Rome

Wanda Phipatanakul
Sandy R. Durrani
Jeremy Cole
Dongfang Liu
Jérôme Msihid
David J. Lederer
Megan Hardin
Yi Zhang
Asif H. Khan

Introduction & Objectives

Asthma is the most common chronic respiratory condition in children. Patients with uncontrolled disease experience reduced health-related quality of life (HRQoL) despite controller medication. Type 2 (T2) inflammation (blood eosinophils ≥150 cells/μL or fractional exhaled nitric oxide (FeNO) ≥20 parts per billion) underlies most pediatric asthma cases. Dupilumab (DPL), a fully human monoclonal antibody, blocks the shared receptor component for interleukin (IL)-4/IL-13, key and central drivers of T2 inflammation in multiple diseases. VOYAGE, a 52-week, randomized, double-blind, placebo (PBO)-controlled, phase 3 study (NCT02948959), evaluated DPL efficacy/safety in children aged 6–11 years with uncontrolled persistent asthma. We assessed the impact of DPL on asthma control (Interviewer-Administered 7-Item Asthma Control Questionnaire [ACQ-7-IA] score) and HRQoL (Interviewer-Administered Pediatric Asthma Quality of Life Questionnaire with standardized activities [PAQLQ[S]-IA] score) in children with a T2 inflammatory asthma phenotype.

Methods

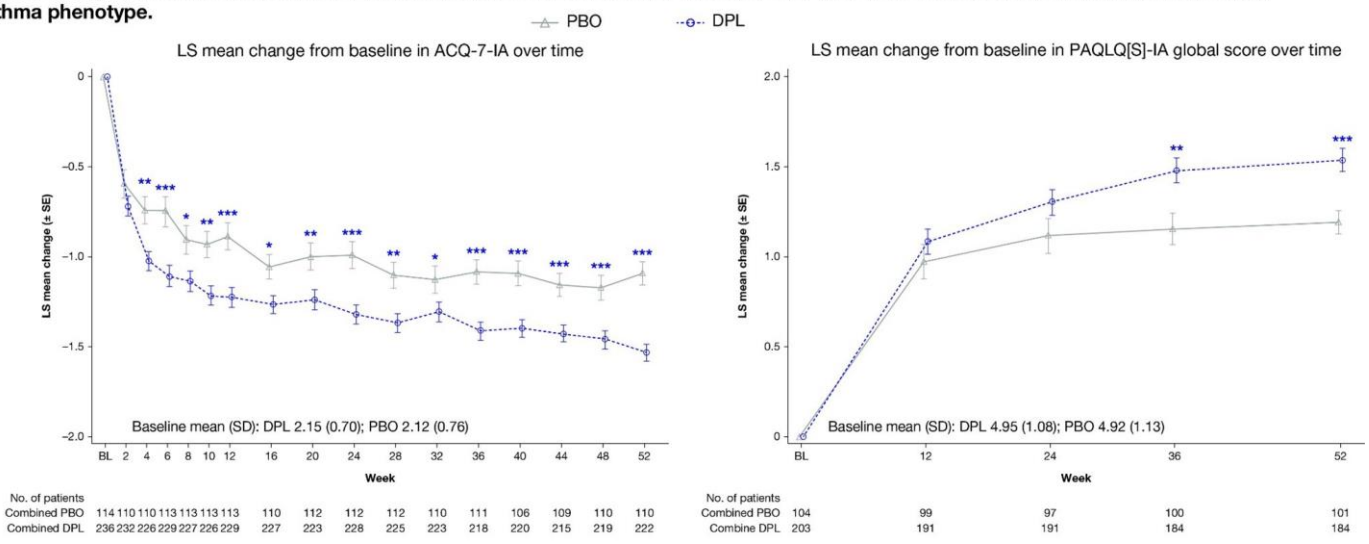
Patients were treated with DPL (100/200mg by body weight at randomization) or matched PBO every 2 weeks. We assessed change from baseline in ACQ-7-IA total and individual item scores, PAQLQ[S]-IA total and domain (symptoms, activity limitation, emotional) scores (patients aged 7–11 years); percentage of ACQ-7-IA and PAQLQ[S]-IA responders (improvement from baseline ≥0.5); and percentage with well-controlled asthma (ACQ-7-IA score ≤0.75).

Results

DPL vs PBO rapidly improved total ACQ-7-IA score by Week 4 (P<0.01); improvements were sustained until Week 52 (P<0.0001; **Figure**). By Week 24, more patients on DPL (79%) vs PBO (69%) were ACQ-7-IA responders (odds ratio [OR]: 1.82 [95% confidence interval (CI): 1.02, 3.24]; P<0.05), and more DPL (61%) vs PBO (43%) patients achieved well-controlled asthma (OR: 2.23 [95% CI: 1.38, 3.61]; P=0.01). From Week 36, DPL vs PBO significantly improved PAQLQ[S]-IA total (P<0.01) and domain scores (P<0.05). By Week 52, a greater proportion of patients on DPL vs PBO were PAQLQ[S]-IA responders

(*P*<0.05; **Figure**). All differences were sustained at Week 52 (*P*<0.05).

Figure. Change in asthma control (ACQ-7-IA score) and HRQoL (PAQLQ[S]-IA score) over time in VOYAGE patients with a T2 inflammatory asthma phenotype.



ACQ-7-IA	Responder (improvement from baseline ≥ 0.5)		Well controlled asthma (ACQ-7-IA ≤ 0.75)	
	Week 24	Week 52	Week 24	Week 52
PBO (n=114)	79/114 (69.3%)	85/114 (74.6%)	49/114 (43.0%)	52/114 (45.6%)
DPL (n=236)	187/236 (79.2%)	204/236 (86.4%)	144/236 (61.0%)	164/236 (69.5%)
OR vs PBO (95% CI) *P* value	1.82 (1.02, 3.24) *P*=0.0411	2.57 (1.33, 4.98) *P*=0.0051	2.23 (1.38, 3.61) *P*=0.0011	3.00 (1.79, 5.01) *P*<0.0001

PAQLQ[S]-IA	Responder (improvement from baseline ≥ 0.5)	
	Week 24	Week 52
PBO (n=107)	70/107 (65.4%)	73/107 (68.2%)
DPL (n=211)	154/211 (73.0%)	161/211 (76.3%)
OR vs PBO (95% CI) *P* value	1.57 (0.87, 2.84) *P*=0.1370	1.89 (1.02, 3.52) *P*=0.0428

Changes from baseline (BL) in ACQ-7-IA and PAQLQ[S]-IA scores were analyzed using MMRM models; percent responders (improvement ≥0.5) and percentage of patients who achieved well-controlled asthma (ACQ-7-IA score ≤0.75) were analyzed using logistic regression models. For PAQLQ(S)-IA, only patients aged ≥7 years at randomization were included in the analysis.The *P* values presented in the figures and tables are nominal *P* values, except for that of LS mean change from BL in ACQ-7-IA at Week 24. **P*<0.05; ***P*<0.01; ****P*<0.001. ACQ-7-IA, Interviewer-Administered 7-item Asthma Control Questionnaire; CI, confidence interval; LS, least squares; MMRM, mixed-effect model with repeated measures; OR, odds ratio; PAQLQ[S]-IA, Interviewer-administered Pediatric Asthma Quality of Life Questionnaire with standardized activities; q2w, every 2 weeks; SD, standard deviation; SE, standard error.

Conclusions

In children with uncontrolled persistent asthma and a T2 phenotype, DPL rapidly improved asthma control and resulted in sustained improvements in asthma control and HRQoL; majority of patients achieved well-controlled asthma.

References

Lung health / Public Health / COVID-19 Pandemic

Abstract ID = 13559

Parent/carer feedback on paediatric homecare administration of biologics for severe asthma patients

Angela Jamalzadeh

Royal Brompton Hospital

Louise Fleming
Sukeshi Makhecha
Pippa Hall
Laura Baynton

Rachael Moore-Crouch
Claire Jackman

Introduction & Objectives

Prior to the COVID-19 pandemic, paediatric severe asthma patients at the Royal Brompton Hospital requiring biologic treatment, attended hospital 2-4 weekly for injections. Due to the national lockdown in March 2020, an alternative initiative was explored. Parents/caregivers of children suitable for homecare were trained to administer biologic injections initially face to face by Clinical Nurse Specialists (CNSs) in hospital, followed by video calls from the CNS at the time of all injections to support administration and complete clinical reviews. Children were issued a home spirometer to mimic hospital appointments.

The aim of this study was to obtain parent/carer/patient feedback to evaluate the service and make improvements adapting to service needs.

Methods

Parents/carers were sent a link to a structured questionnaire by email or text message using Google surveys in March 2020. The questions were designed to gain feedback on support and training, impact on home life balance, asthma management and the delivery service. Free text box at the end of the questionnaire allowed feedback on service improvements.

Children and young people were sent a separate questionnaire.

Results

The questionnaire was sent to 14/16 families on homecare. The response rate was poor; 6/14 parent/carers (43%) and 2/14 patients (14%).

6/6 parents felt they had sufficient training on administration, found the video calls supportive and helpful and felt a 4-6 monthly appointment with the clinician was sufficient. They also felt that the use of the spirometer to measure lung function at home very helpful. 5/6 respondents found the flexibility of timings outside of school very helpful.

Specific feedback was themed as follows:

Table 1: parent/ patient feedback

	Parent/Patient feedback
Flexibility of timings	‘This is much better as I don’t have to book a day off work and my child doesn’t miss any school’ ‘No time off school’ ‘It fits in better with our busy lives’ ‘ It's great as we can fit around the school timetable’

Reduction in travelling	‘Much easier don't need to travel’ ‘Makes life so much easier not having to travel up to the hospital monthly.
Training and support	‘Very helpful and always to hand if any questions need answering’ ‘The support and care that we receive is amazing.’

Conclusions

- The feedback from patients/carers has been overwhelmingly positive indicating the service set up has been successful and will continue to be offered to eligible patients as part of standard care.
- Homecare reduces hospital visits for families, in turn saving families time and money, carbon footprint in travelling, offers a perceived improved quality of life in view of parent/carer feedback. In addition, video calls are scheduled 5 days a week around the family work/education commitments and not within clinic time, freeing up healthcare professional time.

References

Lung health / Public Health / COVID-19 Pandemic

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Paediatric Respiratory CNS service: being agile during COVID-19

Pippa Hall

Royal Brompton Hospital

Laura Baynton
Nicola Collins
Caroline Devon
Angela Jamalazedeh
Sukeshi Makhecha
Sarah Moledina
Sarah Ollosson

Sam Sonnappa
Siobhán Carr

Introduction & Objectives

In March 2020, the way in which Respiratory Paediatric Clinical Nurse Specialists (CNS), supported by the wider MDT, were able to deliver and provide care for patients was dramatically curtailed due the COVID-19 pandemic. Our CNS team needed to adapt quickly away from the normal face to face care model whilst ensuring minimal compromise to patient care. There are several specialist CNS teams covering Cystic fibrosis (CF), Primary Ciliary Dyskinesia (PCD), Complex care, Non-Invasive Ventilation (NIV) and Difficult Asthma. Our objectives were i) to deliver care by resourcing and implementing a range of service adaptions and innovations ii) to collect patient feedback on these innovations.

Methods

Service adaptions and innovations implemented by the CNS team alongside the wider MDT are summarised in the table. A range of qualitative patient questionnaires utilising online platforms such as data collection tools were used to obtain feedback.

Results

Feedback from parents / carers using a range of surveys focusing on specific innovations amongst different patient groups has shown a positive response to service adaptations. Less time missed off school, reduced travel times to attend appointments and improved convenience for families were common themes. Patients reported the home spirometry service and sampling services useful. Overall, most patients did not feel their respiratory care was compromised and a hybrid solution of face to face and virtual monitoring would be their preference going forward. Most of these changes have been adopted into our continued routine practice including home spirometers still being used for clinics. The postal sampling for microbiology and other tests has been rolled out across the hospital.

Conclusions

Adaptions developed in response to the COVID-19 pandemic have been shown to be positive for patient experience. A hybrid approach is likely to be the on-going future of Respiratory CNS service delivery. Two years since the onset of the pandemic many of the changes to our services and innovations are still in place. Follow-up questionnaires would be useful in determining ongoing satisfaction. However, further work needs to be done to look at long-term outcomes of our patients to confirm adequacy of this model of care.