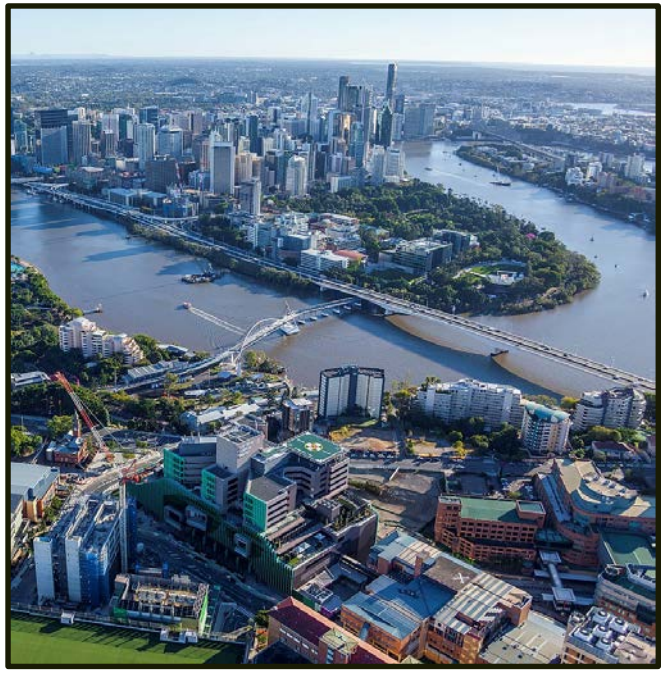
Nasal High Flow
The Brisbane (Paediatric) Experience



Associate Professor Andreas Schibler

Paediatric Intensive Care Staff Specialist FCICM - PICU
Medical Lead of Paediatric Critical Care Research Group (PCCRG)
Lady Cilento Children's Hospital and The University of Queensland

The PCCRG receives an ongoing research grant from Fisher & Paykel Healthcare. Travel expenses associated with this presentation have been covered by Fisher & Paykel Healthcare

Children's Health Queensland

Intensive Care Med
DOI 10.1007/s00134-011-2177-5

PEDIATRIC ORIGINAL

A. Schibler
T. M. T. Pham
K. R. Dunster
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K. Gibbons
J. L. Hough

Reduced intubation rates for infants after introduction of high-flow nasal prong oxygen delivery

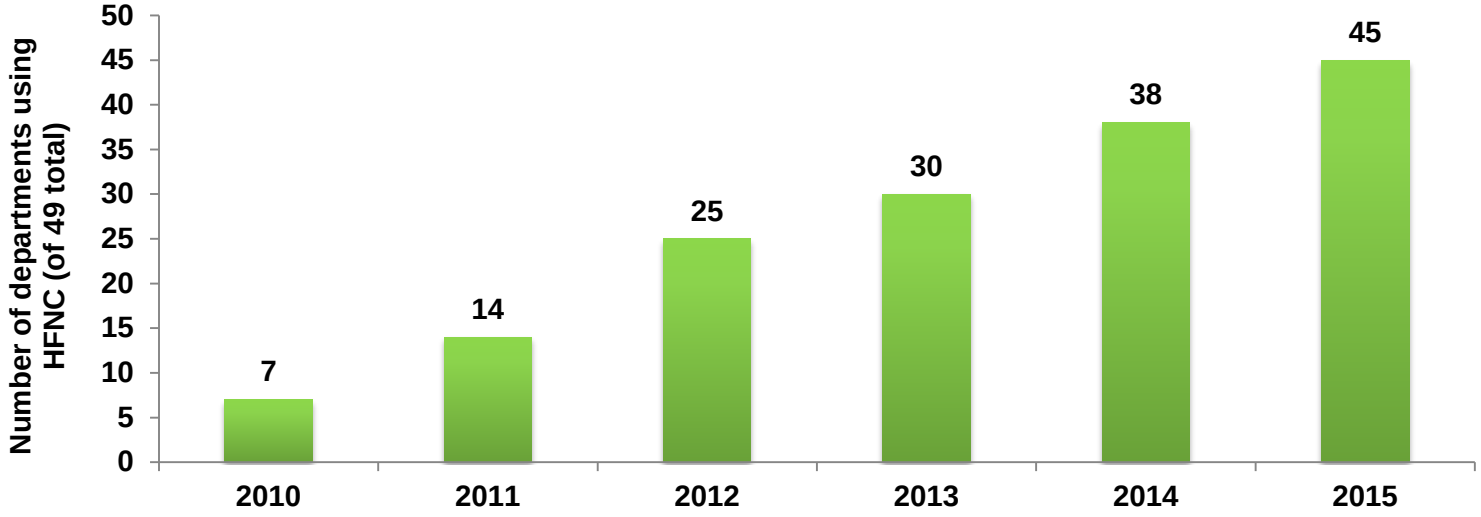
Table 3 Infants with viral bronchiolitis listed by year

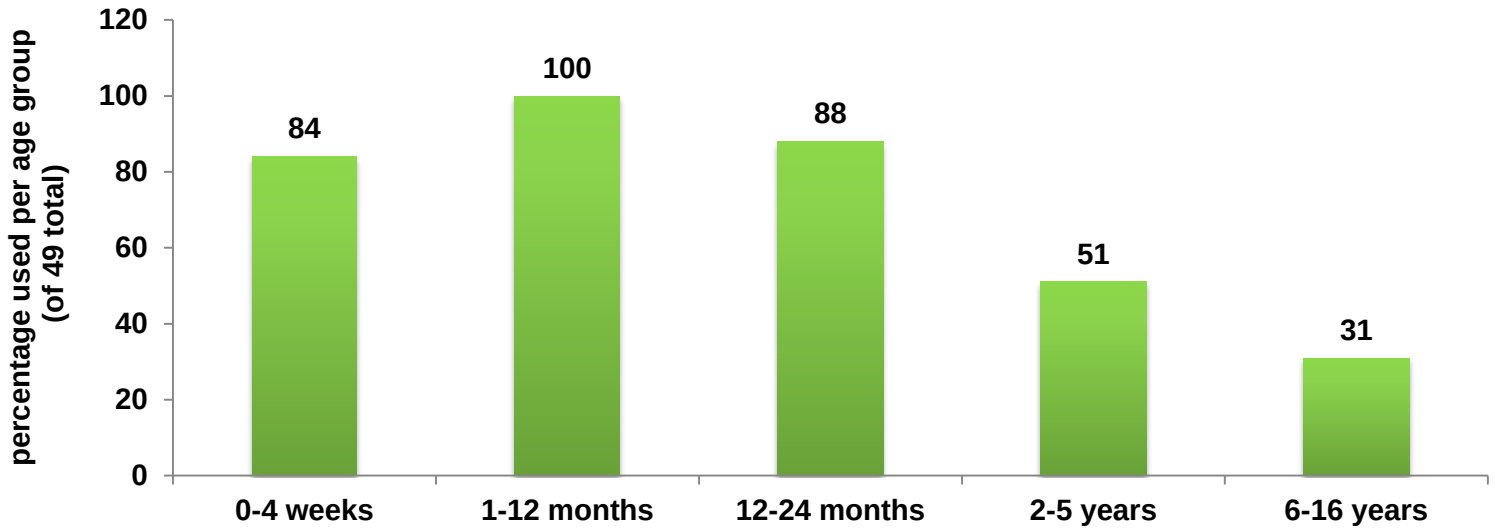
Year	Total BRONCH	HF and HF + N	Total intubated
2005	52	7 (13%)	19 (37%)
2006	72	32 (44%)	21 (29%)
2007	49	23 (46%)	15 (31%)
2008	90	56 (62%)	12 (13%)
2009	67	44 (66%)	5 (7%)
Total	330	161 (49%)	72 (22%)

2016: Current intubation rate <3%

Survey of NHF therapy use in Australia

- 83 general paediatric departments (peripheral/secondary/tertiary)
- 7/8 tertiary, 5/6 secondary and 38/69 peripheral response





Survey of NHF therapy use in Australia

Diagnostic groups

- 100% of departments use it for bronchiolitis
- 82% in pneumonia
- 55% in reactive airways (asthma)
- 40% in other respiratory disease

Other benefits of NHF therapy

- Can be applied very early in the disease process
- Greater patient tolerance
- Ease of application
- Clinical effectiveness

What are the trials we need to do?

- RCT in infants with bronchiolitis
- RCT in infants and children with Acute Hypoxic Respiratory Failure:
  - Pneumonia
  - Pneumonitis
  - Reactive Airway Disease (Asthma)

When, Where and How?

- Start in ED ? Early ?
- Start only if admitted ?
- Start only if certain severity threshold is achieved?

PARIS

Paediatric Acute Respiratory Intervention Studies

High Flow Trial

Children's Health Queensland

PARIS 1 Background

PARIS
Paediatric Acute Respiratory Intervention Study
High Flow Trial

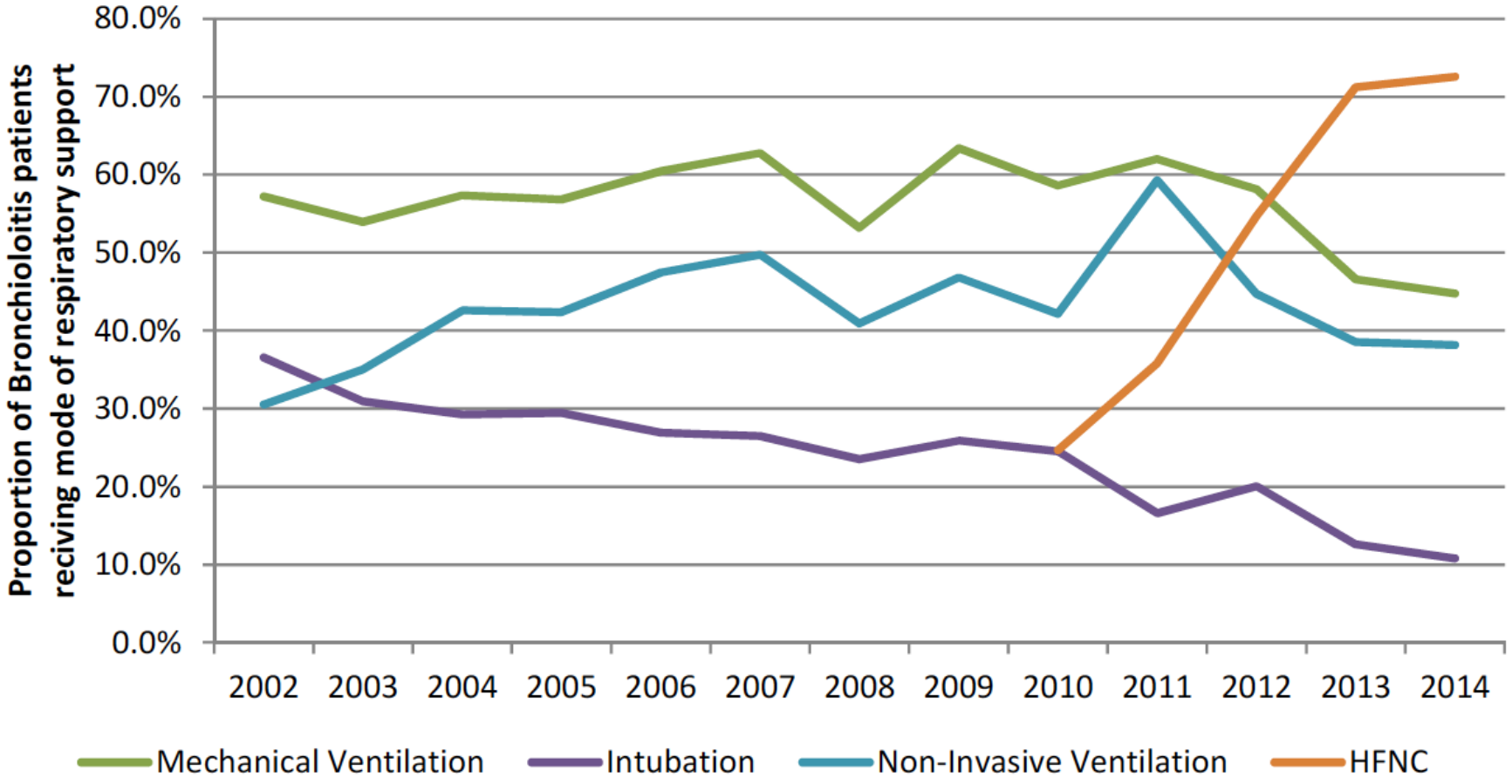
Burden of Bronchiolitis

- Highest number of non-elective PICU admissions in 2015 (19%).
- Low mortality (~0%)
- Median PICU LOS 3.08 days
- Currently ANZPIC data registry showing higher figures for bronchiolitis admitted to ICU. Compatible with USA data which is also increasing. Is this due to NHF being used in some centres in ICU only?
- USA cost burden – US$1.7B/annum (Hagaswasa)

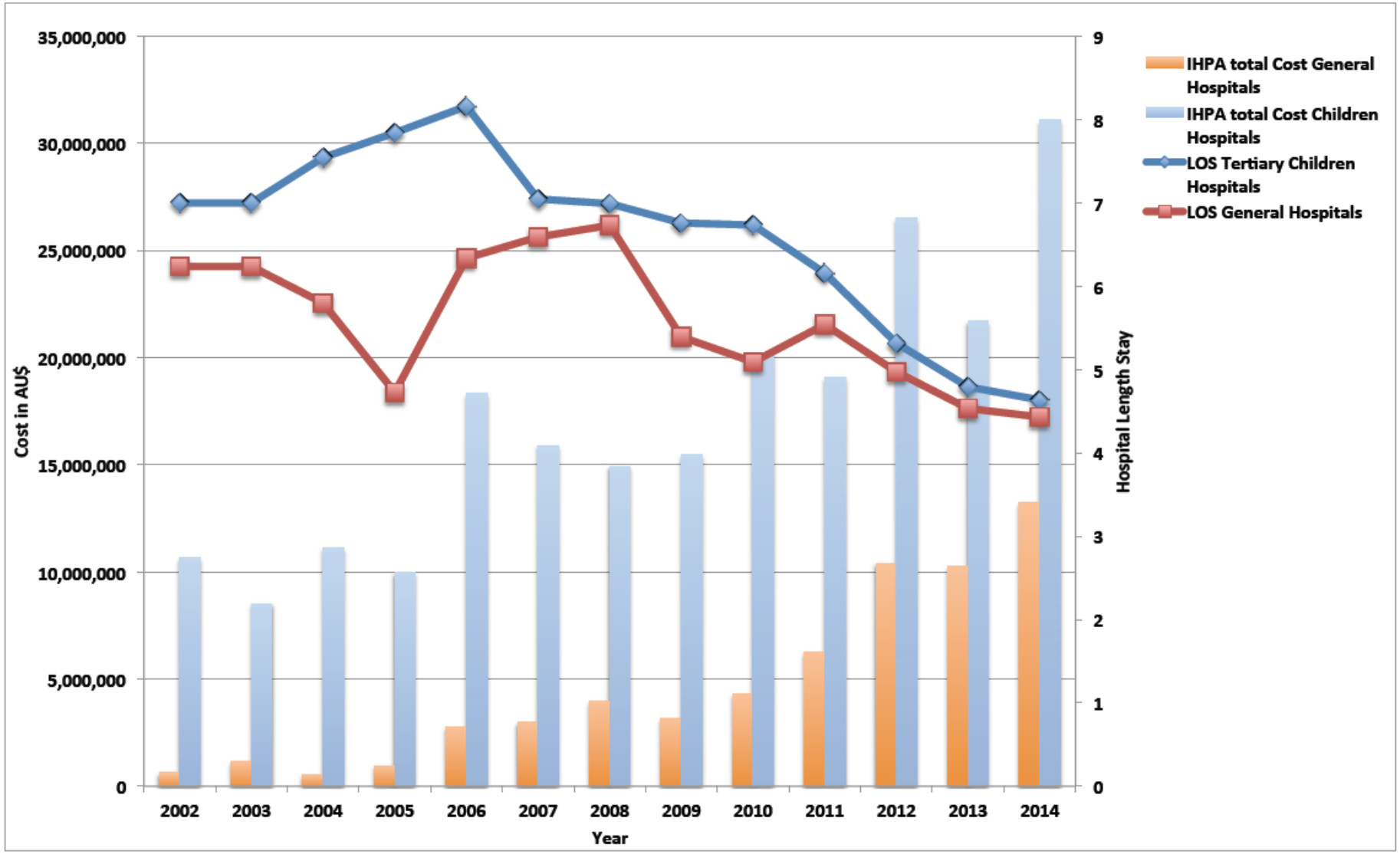
Should NHF therapy be used outside of ICU??

Year	Mechanical Ventilation	Intubation	Non-Invasive Ventilation	NHF therapy
2002	57.2%	36.6%	30.5%	
2003	53.9%	30.9%	35.0%	
2004	57.4%	29.2%	42.6%	
2005	56.8%	29.5%	42.4%	
2006	60.5%	26.9%	47.5%	
2007	62.8%	26.5%	49.7%	
2008	53.2%	23.5%	40.9%	
2009	63.4%	25.9%	46.8%	
2010	58.6%	24.5%	42.2%	24.7%
2011	62.0%	16.6%	59.3%	35.8%
2012	58.1%	20.1%	44.7%	54.7%
2013	46.6%	12.6%	38.5%	71.2%
2014	44.8%	10.8%	38.2%	72.6%

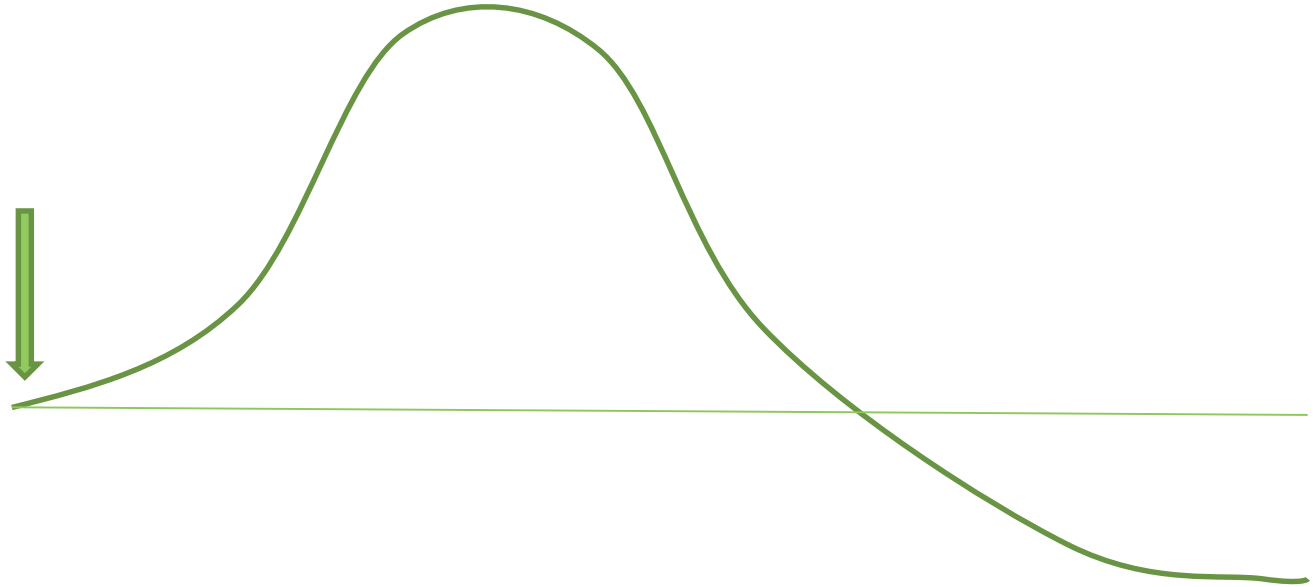
Modes of Respiratory Support in PICU for Bronchiolitis



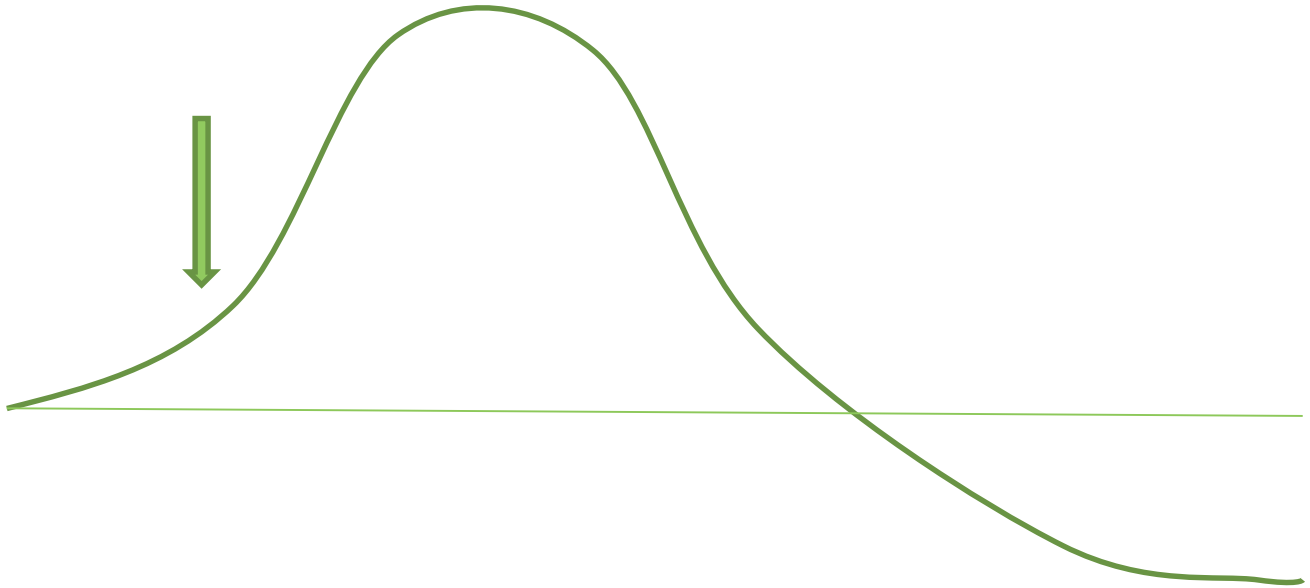
Health care costs associated with Bronchiolitis infants admitted to ICU



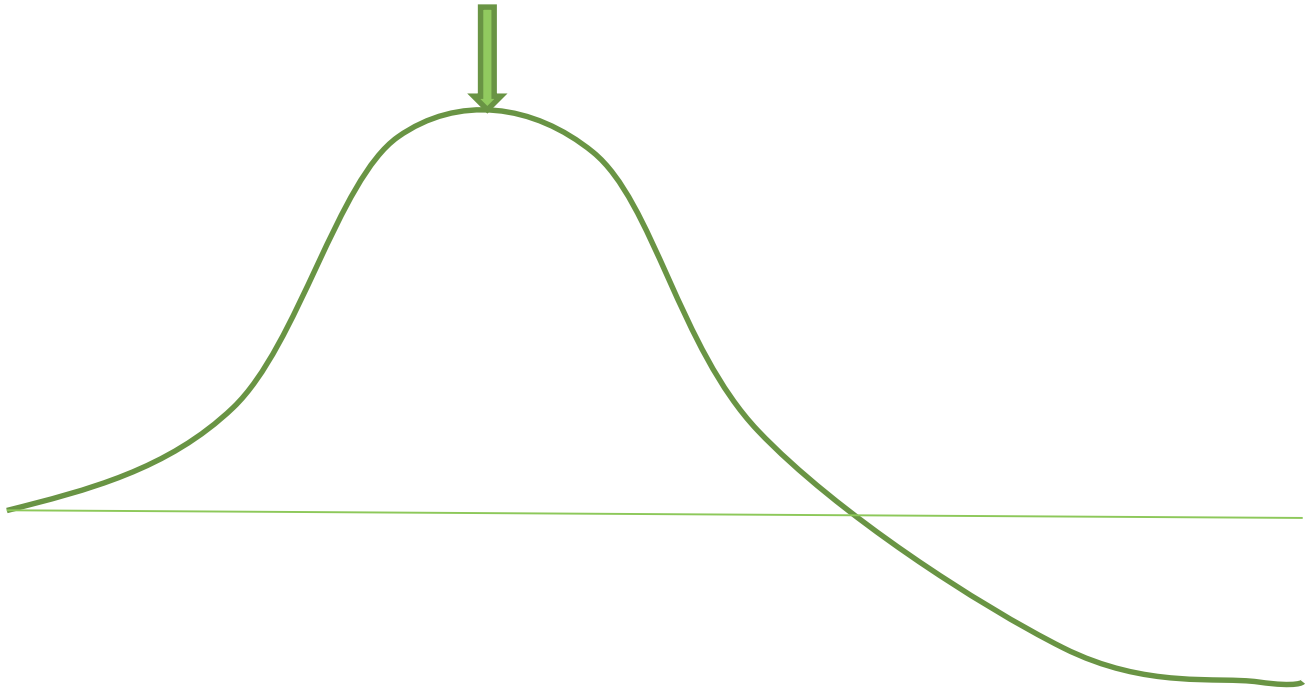
NHF introduction

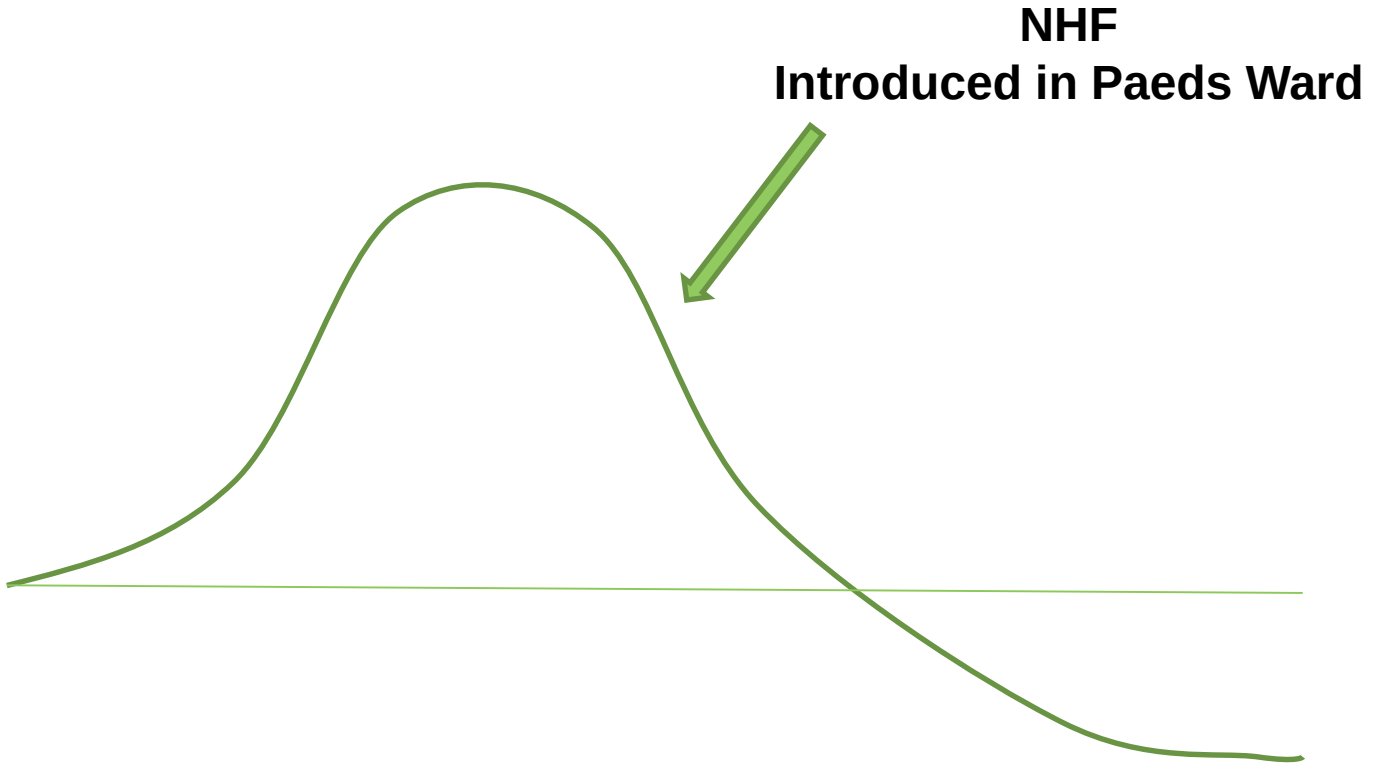


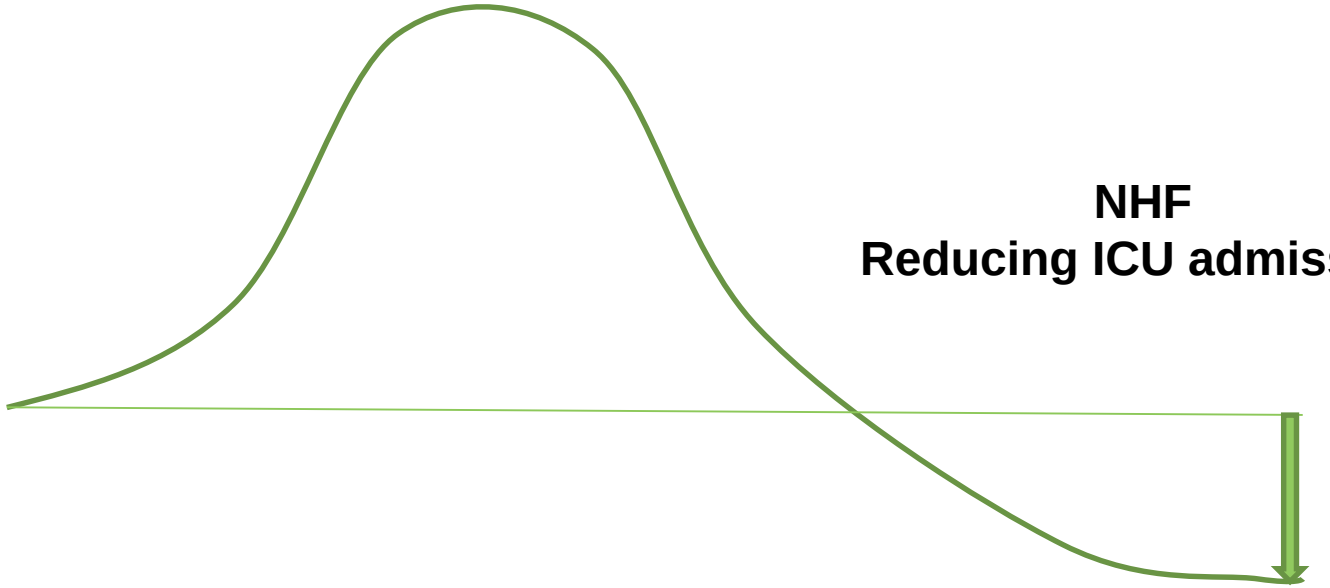
NHF = Everybody Loves it



NHF
Everybody
is over it




NHF
Introduced in Paeds Ward



NHF
Reducing ICU admission

PARIS I – Nasal High Flow therapy in infants with bronchiolitis – a Randomised Controlled Trial

AIM

To compare in a Randomised Controlled Trial, Nasal High Flow therapy to standard oxygen delivery in infants with bronchiolitis, presenting to regional, metropolitan and tertiary centres.

PRIMARY OUTCOME

Defined as treatment failure of NHF therapy or standard oxygen therapy.

INCLUSION CRITERIA

- Infants < 12 months of age
- Diagnosis of bronchiolitis
- Oxygen requirement (SpO2 <92% in room air)

SAMPLE SIZE: 1400

Children's Health Queensland

Secondary Outcomes

To measure:

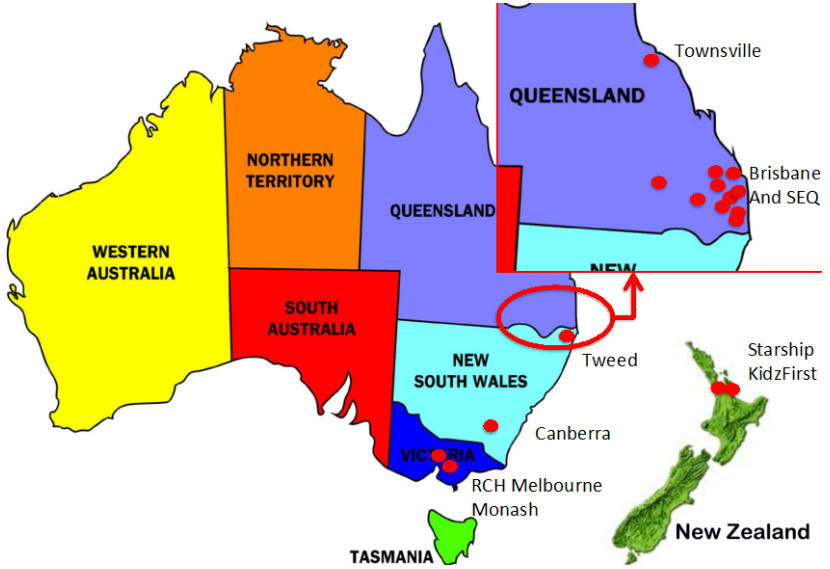
- reduction in the need for retrievals/ICU admission
- reduction in intubation rate
- reduction in LOS
- length of oxygen therapy
- adverse effects
- health care costs
- study effect of room air only?

Recruitment over 3 years – 1400 patients

- **Nine Regional Hospitals**
- Ipswich Hospital
- TPCH
- Redcliffe Hospital
- Redland Hospital
- Caboolture Hospital
- Logan Hospital
- Nambour Hospital
- Toowoomba Hospital
- The Tweed Hospital

Additional PREDICT sites with NHMRC funding

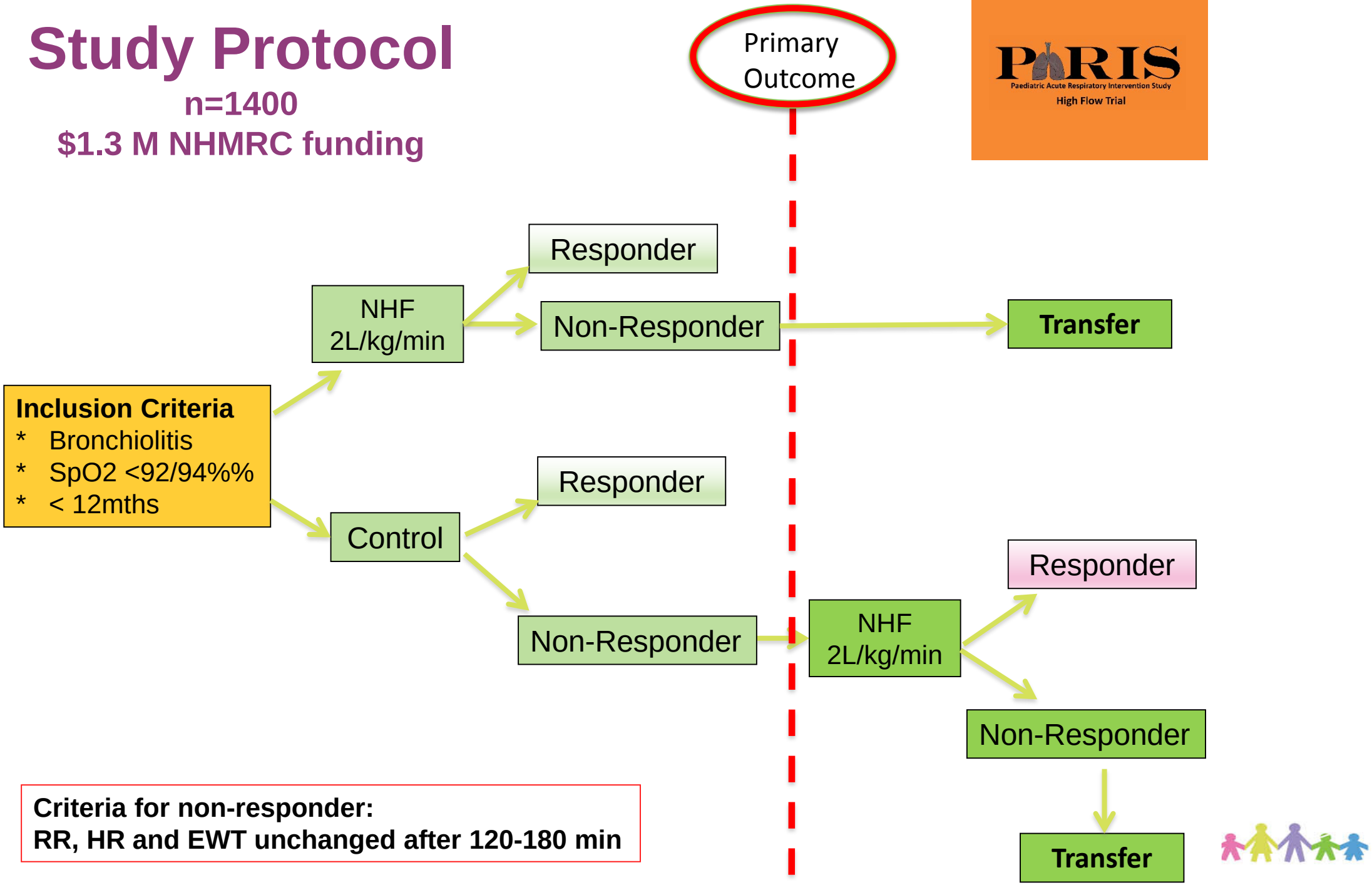
- LCCH
- GCUH
- RCH – Melbourne
- Monash – Melbourne
- Canberra Hospital
- Townsville Hospital
- Starship – Auckland NZ
- KidzFirst, Middlemore – NZ



Study Protocol

n=1400

$1.3 M NHMRC funding



Criteria for non-responder:
RR, HR and EWT unchanged after 120-180 min

Baseline Characteristics

	Standard Oxygen	Nasal High Flow
Sex	N=731	N=745
Male	469 (64%)	455 (61%)
female	261 (36%)	287 (39%)
Median age	months (IQR)	months (IQR)
	6.1 (3.4)	5.8 (3.5)
Age		
≤3 month	185 (25%)	207 (28%)
3-12 months	546 (75%)	538 (72%)
Prematurity	107 (15%)	127 (17%)
Weight (kg) (SD)	7.6 (2.2)	7.3 (2.3)
Virus detected		
RSV positive	321 (44%)	335 (45%)

Primary Outcomes

	Standard Oxygen	Nasal High Flow	P value	Odds ratio
	N=731	N=745		
Failure Rate	167	89	#0.0001	2.20 (1.65-2.89)
% of patients	23%	12%		
Non-responders/Responders <3month of age	55/130	28/179	#0.0001	2.71 (1.63-4.50)
Non-responders/Responders 3-12 months of age	112/434	61/477	#0.0001	2.02 (1.44-2.83)
Length of O2 therapy (median)	days (IQR)	days (IQR)		
All infants	1.23 (1.82)	1.24 (1.81)	*0.218	
All infants without ICU admission	1.13 (1.54)	1.07 (1.51)	*0.025	

PARIS II

Paediatric Acute Respiratory Intervention Studies

Acute Hypoxemic Respiratory Failure

AHRF Trial

Children's Health Queensland

AHRF BACKGROUND

- 6.3 million children < 5yrs died worldwide in 2013 (WHO)
  - ✧ 1 million of these deaths - caused by resp infections
- AHRF - most frequent reason for paeds admission
  - ✧ Most common initial treatment is to offer 02
- Approx 20% of children with AHRF rapidly deteriorate and require assisted breathing with positive pressure or mechanical ventilation (PICU)
- Very little evidence in children with AHRF

PARIS II

Nasal High Flow therapy in children with Acute Respiratory Failure – a Randomised Controlled Trial

AIM

To compare in a Randomised Controlled Trial, Nasal High Flow therapy to standard oxygen delivery in infants and children with Acute Hypoxemic Respiratory Failure (AHRF), presenting to regional, metropolitan and tertiary centres.

PRIMARY OUTCOME

Defined as treatment failure of NHF therapy or standard oxygen therapy.

INCLUSION CRITERIA

- Infants and children 0-16 yrs of age
- Diagnosis of AHRF and admitted to hospital
- Oxygen requirement (SpO2 <92% in room air)

SAMPLE SIZE: 610

Children's Health Queensland

Secondary Outcomes

- To determine if use of NHF therapy reduces the need for hospital transfer to a tertiary centre
- To determine if there is an age dependent efficacy of NHF therapy
- To perform Subgroup Analysis for children with:
  eg. RAD (asthma), Bronchiolitis 12-24mths, Acute Lower Resp. Tract Infection

CHALLENGES PARIS 1 & 2 – Study specific

- Bias (creep in effect)
- If NHF therapy has been used prior in a centre (stronger bias present)
- Adherence to protocol by medical staff – change in diagnosis to place child on NHF (bias) Consent Research culture present or not
- Study Fatigue (PARIS 2 with dual trials)

THANK YOU

myAirvo Research Update

Chris Crone
Research & Development Manager – Airvo/Optiflow

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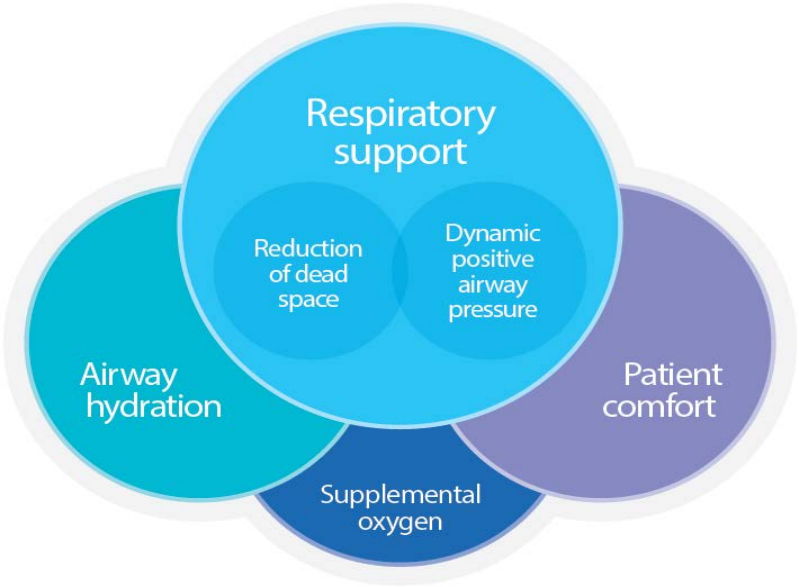
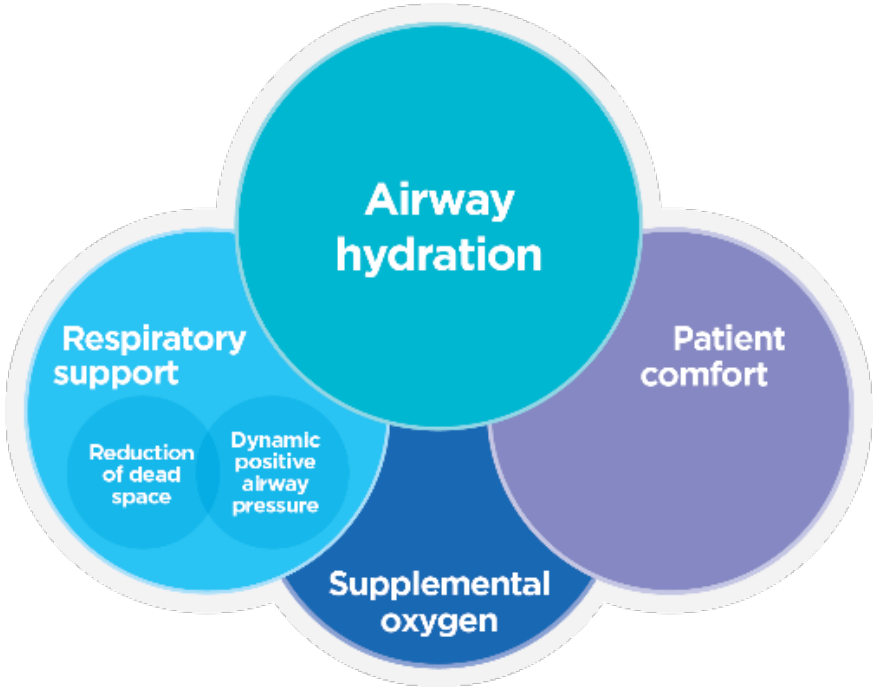
Nasal High Flow - Acute vs. Chronic use

- Same therapy, different uses, different benefits

Acute



Chronic



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Home-based clinical research

- More research being carried out in the home
- Challenges
  - Patient group – age, care needs
  - Logistics
  - Compliance monitoring
  - Longer treatment times (1 year : 5 years)
  - Higher costs

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Mechanisms research

Author *Journal* Yr	n	Population	Comparison	F/up	Effects
Hasani Chron Resp Dis **2008**	10	Bronchiectasis	NHF vs no NHF	7d	↑ Increased Mucociliary clearance
Fraser *Thorax* **2016**	10	COPD	NHF vs O_2	<1d	↓ Reduced CO_2 (measured through skin) ↓ Reduced Respiratory Rate ↑ Increased Tidal Volume
Bräunlich *J COPD* **2016**	48	COPD	NHF vs O_2	<1d	↓ Reduced CO_2 (measured through skin) ↓ Reduced Respiratory Rate ↑ Increased Tidal Volume
Biselli *J Appl Physiol* **2016**	18	COPD	NHF vs O_2	<1d	↓ Reduced CO_2 (measured through skin) ↓ Reduced Work of Breathing ↓ Reduced Minute ventilation
Pisani *Thorax* **2017**	14	Hypercapnic COPD	O_2 vs $NHFO_2$ and NIV	<1d	↓ Reduced Respiratory Rate ↑ Increased Tidal Volume ↓Reduced CO_2(blood gas)
Pilcher *Respirology* **2017**	24	AECOPD	NHF vs O_2	<1d	↓ Reduced CO_2 (blood gas)
McKinstry *Respirology* **2017**	48	COPD	NHF vs breathing	<1d	↓ Reduced CO_2 (measured through skin) ↓ Reduced Respiratory Rate

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Outcomes research

Author *Journal* Yr	n	Population	Comparison	F/up	Message
Rea *Resp Med* 2010	108	COPD & Bronchiectasis	NHF (w and w/o O_2) vs SC	1y	Improved exacerbation days, time to 1st exacerbation, reduced antibiotic use
Cirio *Resp Med* 2016	12	COPD in Pulmonary Rehab	$NHFO_2$ vs Venturi O_2	<1d	Improved exercise tolerance
Macann Int J Radiation Oncol Biol Phys 2010	210	Head & Neck Cancer patients with mucositis	NHF vs Usual care	12w	Improved patient functioning, nutritional events, decreased number of inpatient days
McNamara Resp Care 2014	15	Tracheostomy	THF vs HME	10w	Long term: reduced adverse events

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COPD research underway

PI, Country	n	Population	Comparison	F/up	Primary Outcome
Weinreich, Denmark	200	COPD	$NHFO_2$ vs O_2	1y	Exacerbations & hospital admissions
Mansfield, Australia	150	COPD	NHF vs no NHF	30d	Length of Stay, 30 d readmission
Bräunlich, Germany	100	COPD	NHF vs Bilevel	6w	Capillary CO_2
Nilius, Germany	40	COPD	$NHFO_2$ vs O_2	1y	Overnight trans. CO_2
Chihara, Japan	32	COPD w CRF	$NHFO_2$ vs O_2	4w	6 Min. Walk Distance
Tomii, Japan	30	COPD	$NHFO_2$ vs O_2	6w	Quality of Life (St Georges Resp. Quest.)
Allen, USA	30	COPD	$NHF(O_2)$ vs Usual	3m	Quality of Life (Breathless, Cough Sputum Scale)
Fernandes, USA	30	COPD	$NHFO_2$ vs O_2	1y	Hospitalizations
Bräunlich, Germany	20	COPD	NHF Neb vs Neb	< 1d	Lung Function (FEV_1)
Criner, USA	10	Unstable COPD	NHF	5 d	Ability to maintain SpO_2 > 90%
Criner, USA	30	COPD	NHF	90 d	Compliance

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A bright outlook

- There are challenges to home-based research

- Studies are underway with myAirvo and early results are promising

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Questions?

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HOSPITALIZED COPD EXACERBATIONS:

NASAL HIGH FLOW HUMIDIFIED AIR VIA HOSPITAL IN THE HOME

A/PROF DARREN MANSFIELD
MONASH HEALTH

DISCLOSURE

- A/Prof Mansfield has received research funding from Fisher & Paykel Healthcare.

- Fisher &Paykel Healthcare will make a donation to the Monash Lung and Sleep Institute and Assoc Prof Mansfield will be reimbursed for any expenses incurred in connection with his participation in today's event.

THE BURDEN OF DISEASE ON THE ACUTE FACILITY

- COPD exacerbations Dandenong Hospital
- 90% are admitted to hospital
  - No/yr
  - LOS 5.9 days
  - 60 day readmission rate 22%

Large numbers due to *comorbidities and social circumstances* rather than severe acute exacerbations

CHARACTERISTICS

FLOW RATES -60L/MIN

TEMPERATURES 37 DEGREES

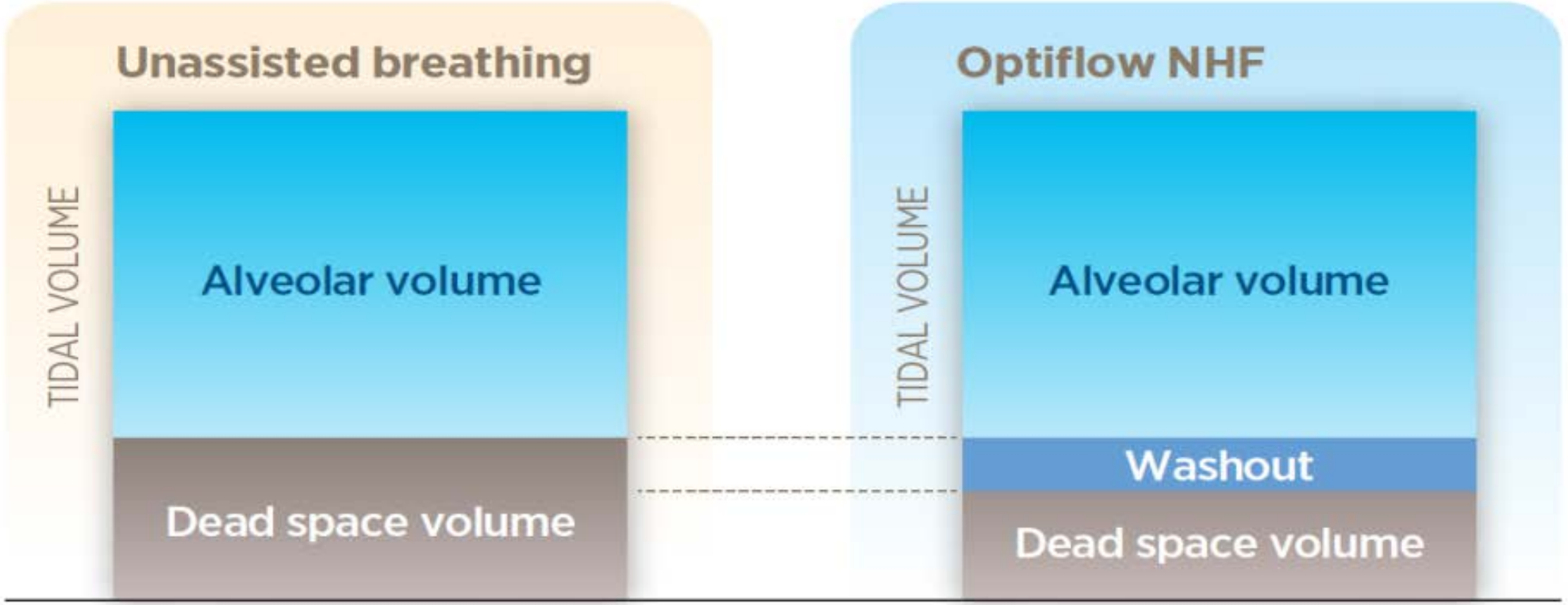
LOOSE FITTING CANNULA

POSTULATED BENEFITS

- Facilitative effects
  - Staff
  - Patients
- Clinical/Physiological Effects

Reduction of dead space

Reduces rebreathing of gas with high CO_2 and depleted O_2



1. Mündel T. et al. *J Appl Physiol.* 2013.
2. Möller W. et al. *Am J Respir Care Med.* 2012.

PRELIMINARY NUMBERS

- Admissions under Hospital In The Home (HITH) = 20
- Readmissions post discharge from HITH = 1
- Patients who purchased AIRVO system privately = 2
- Good outcomes in patient satisfaction with care & symptom improvement while on NHF

SUMMARY

- Can realistically be incorporated into an acute clinical management setting
- Reduces hospital length of stay, inpatient complications and recurrent admissions
- Beneficial not only to patients
- Can assist in unloading the healthcare system

Thank you

Driving Patient Success with OSA Therapy

Fiona Cresswell
General Manager Marketing

Fisher & Paykel HEALTHCARE

Unique and Personal

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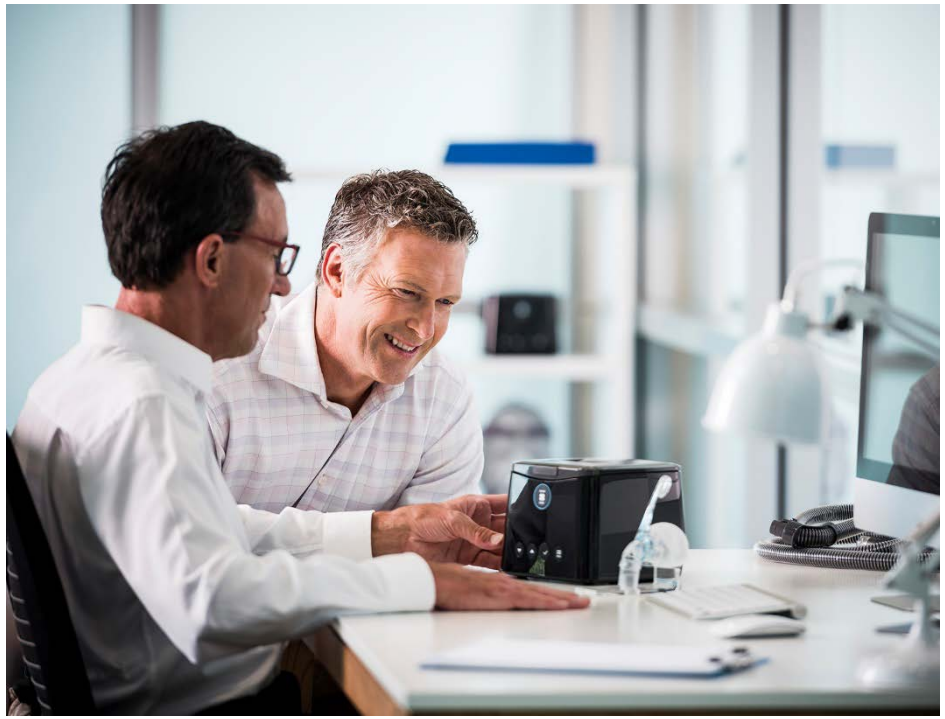
The Threat

- Up to 100M OSA sufferers[1,2]
- CPAP therapy is the gold standard of treatment
- Up to 50% will abandon therapy, many within first 2 weeks
- Untreated sleep apnea has many life threatening consequences



1. Chronic disease epidemics. World Health Organization website. May 23, 2012. 2. Peppard, PE et al, American Journal of Epidemiology (2013): National Center for Biotechnology Information. U.S. National Library of Medicine

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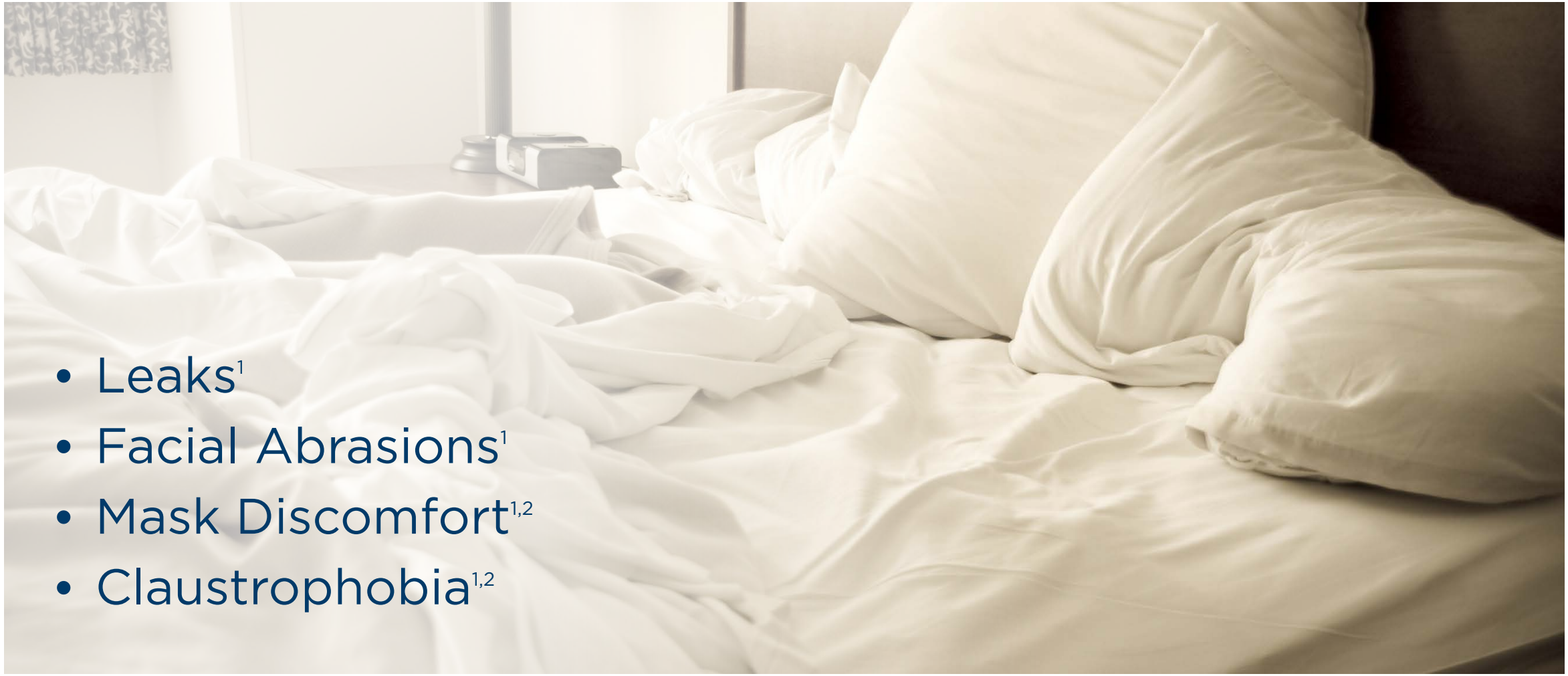
Main Drivers of Non-Adherence



- Leaks[1]
- Facial Abrasions[1]
- Mask Discomfort[1,2]
- Claustrophobia[1,2]

1. Bollig, S.M. Respir Care, 2010. 55(9): pp. 1230-9 2. Aljasmi, M., et al. J Sleep Med Disord, 2016. 3(2): 1044

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Intimacy of the Mask

- Comfort
- Seal
- Ease of Use

= CONFIDENCE

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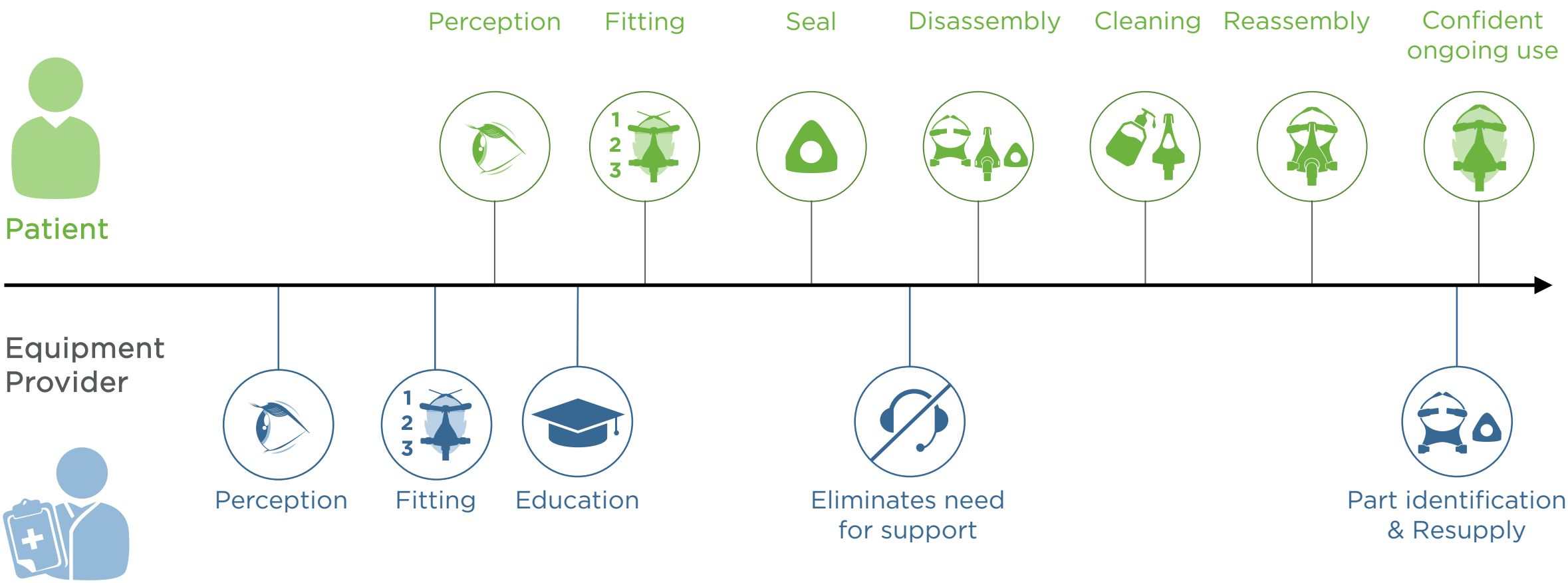
User Experience Mask Design Philosophy



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Complex and Diverse Facial Anatomy

Fisher & Paykel HEALTHCARE

Our Leading-Edge Masks

HME B New Product Award 2014

Purple. Best Design Awards Best of Discipline 2014

Gold. Best Design Awards Winner 2013

F&P Simplus™

F&P Eson™ 2

iF DESIGN AWARD 2017

reddot award 2017 winner

F&P Brevida™

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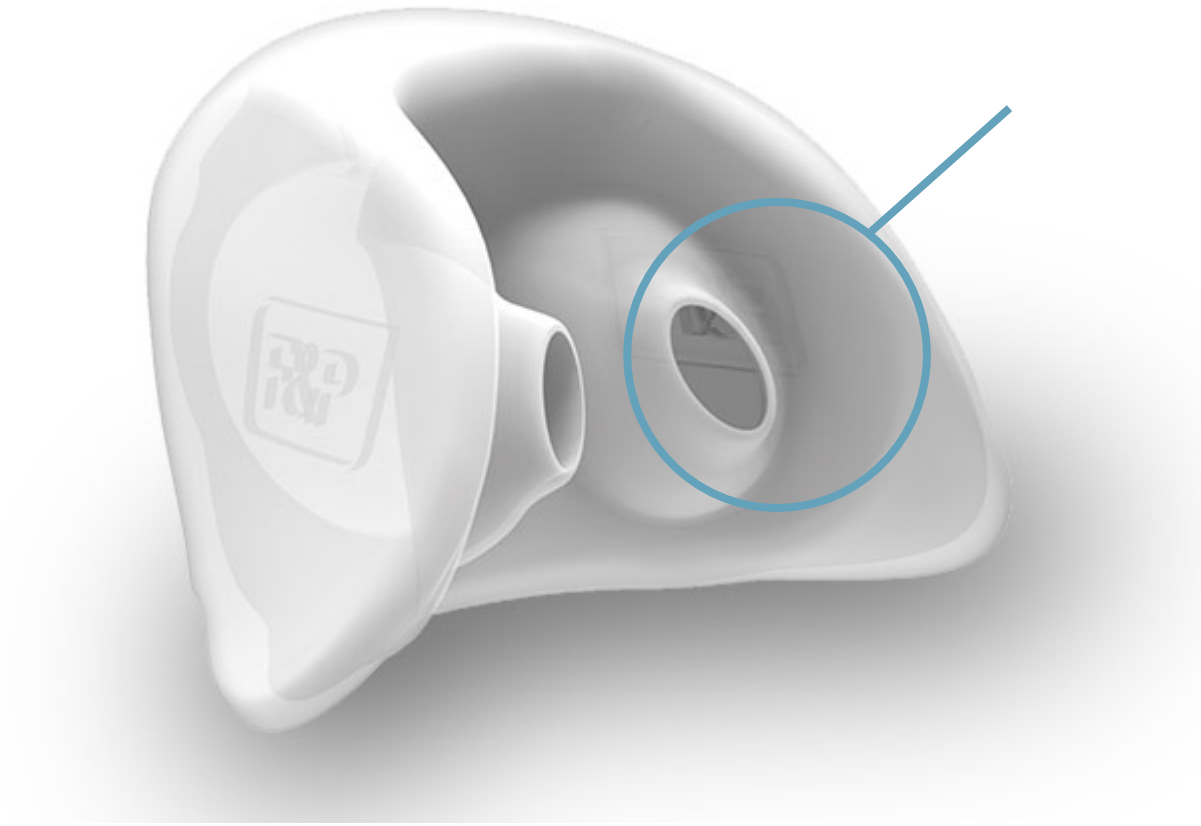
AirPillow Seal



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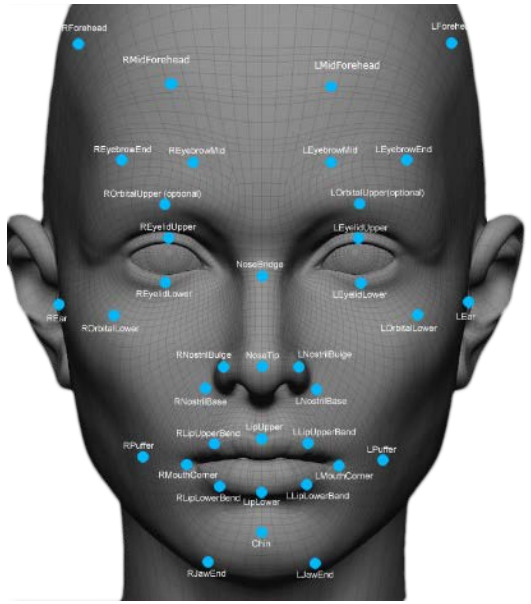
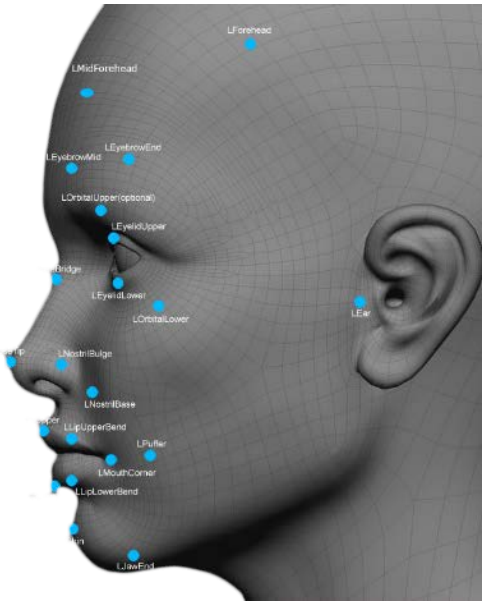
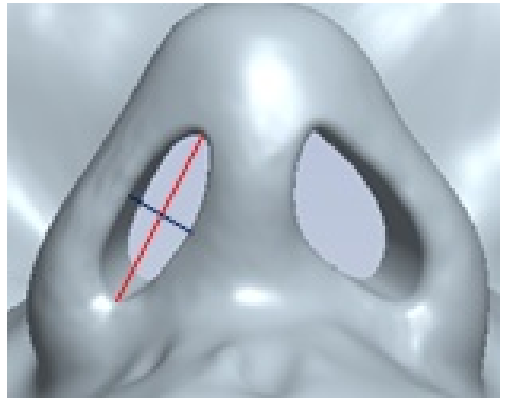
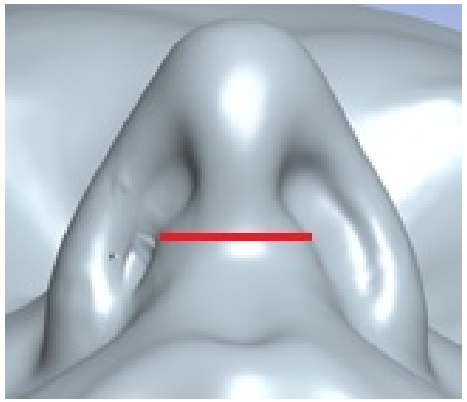
We Measure What Nature Created

- Facial Scanning
  - Many hundreds of real OSA participants
  - 200,000+ points captured
- Anthropometric Database
  - 42 key facial dimensions
  - Statistically analysed
  - Numerically driven seal design









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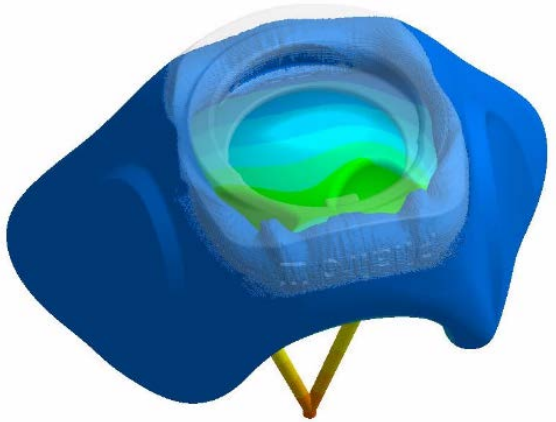
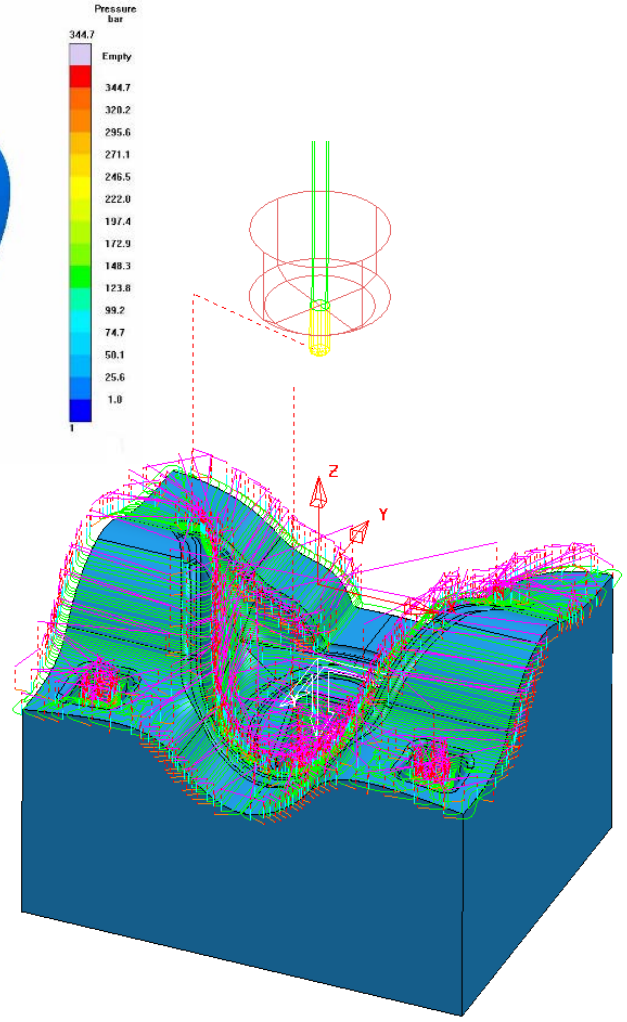
We Use Technology to Optimise Design

- 3D CAD Modelling
  - Gradient transitions
  - Integrated mask stabilizers
- Massive Variable Thickness Molding
  - 1200% range in single molded part
  - Satin surface finish





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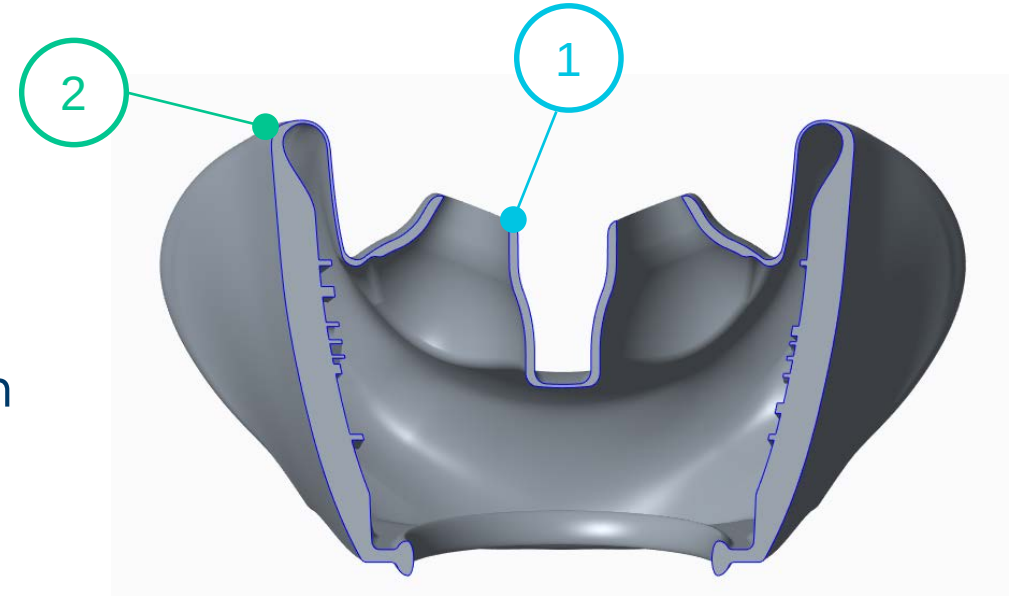
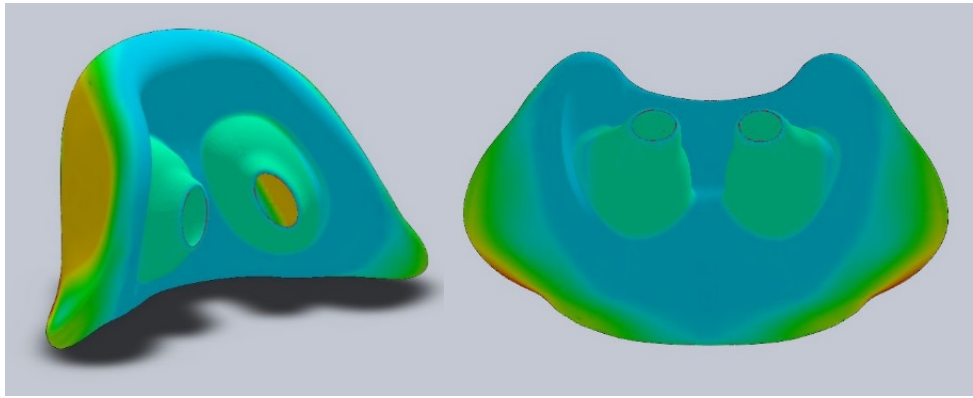
The Benefit

- Soft Nasal Prongs
  - 1/33 inch (0.75mm) thickness (1)
  - Gently contours to nostril shape
  - Significantly less pressure on the septum
- Super Thin Silicone Seal Membrane
  - Prongs surrounded by thin silicone
  - 1/100 inch (0.25mm) thickness (2)
  - Allows prong rotation in any direction





Fisher&Paykel HEALTHCARE

Adjustable Headgear

Adjustable to offer personalised secure fit

Tactile Feedback and locks in place

Provides stability against dislodgement

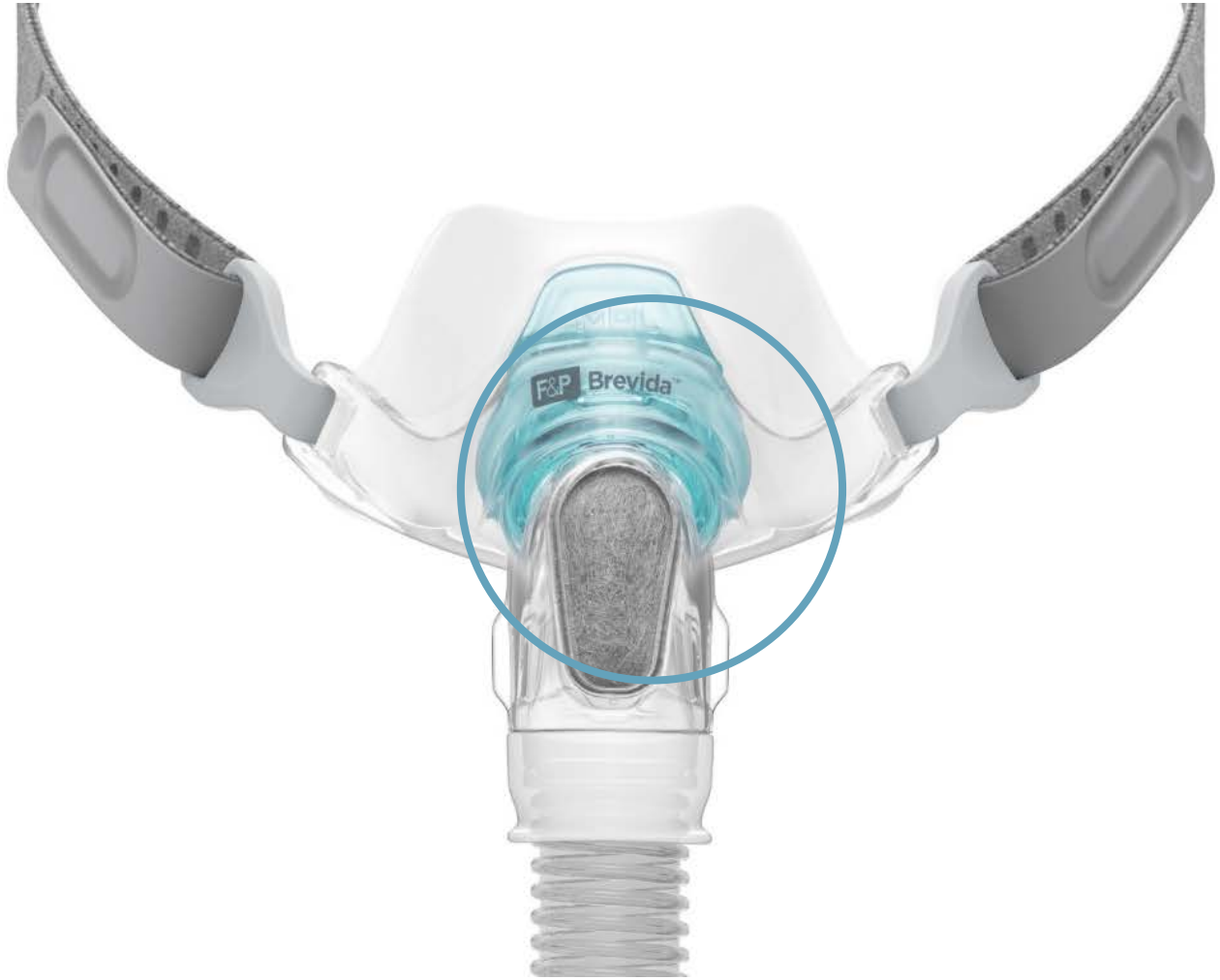
Fisher & Paykel HEALTHCARE

We Consider Real World Use

- Lifecycle Testing
  - Soaked in sweat solution
  - Cleaned over 50 times
  - Stretched 2800 times
- Destruction Testing
  - Pulled until broken
  - Target = 30N Force

Fisher&Paykel HEALTHCARE

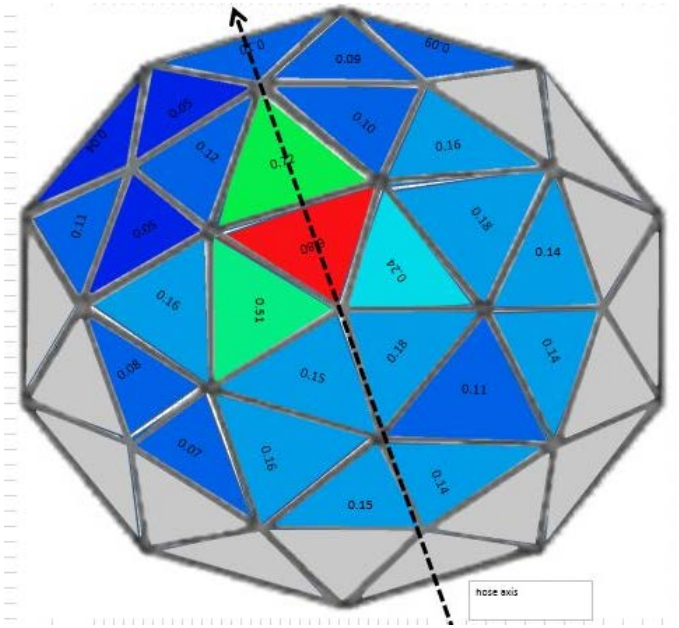
Washable Exhaust Diffuser



Fisher & Paykel HEALTHCARE

We Quantify the Invisible

- Sound Testing
  - Target less than 25dBA
- Draft Testing

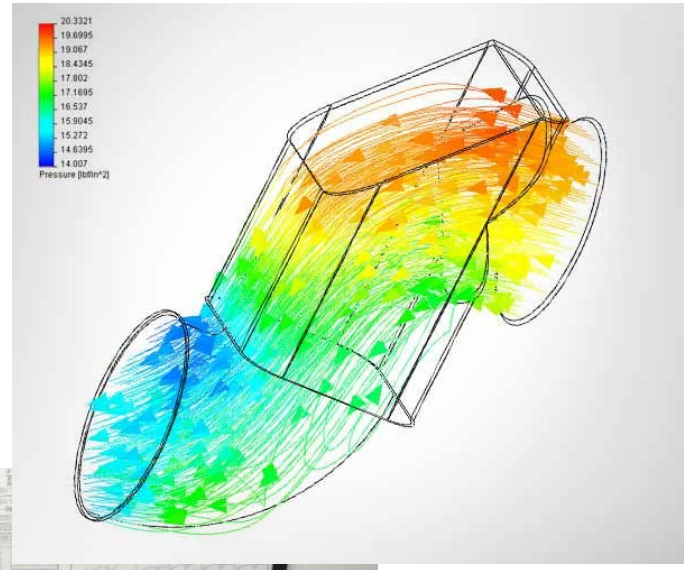


Anechoic Chamber

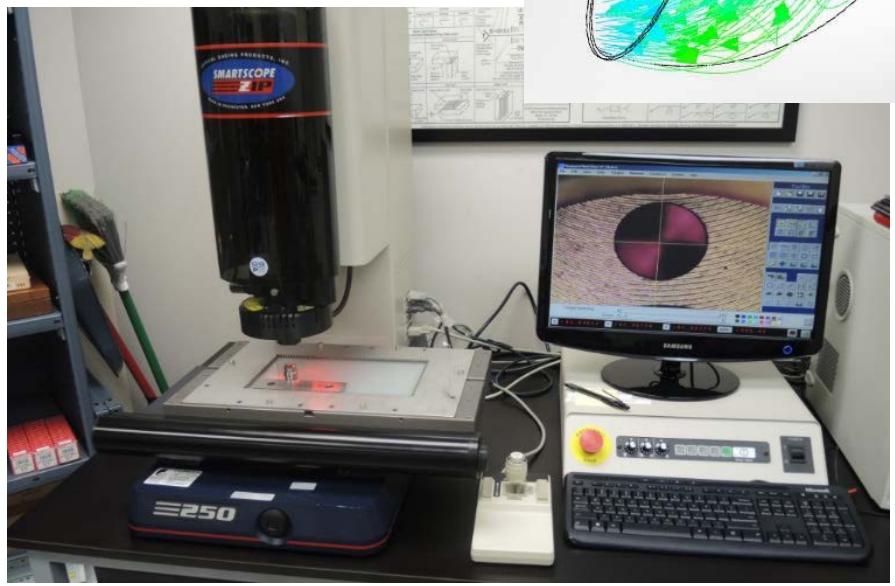
Fisher&Paykel HEALTHCARE

We Amplify Accuracy Using Technology

- Computational Fluid Dynamics
  - Map airflow
  - Highlight turbulence
  - Optimise design



- Optical Gauge Smartscope
  - Accuracy of 1.4µm



Fisher&Paykel HEALTHCARE

The Benefit

- Reduced air flow disruption
- Sound reduction - 17.5dB
  - similar to a ticking watch

Fisher&Paykel HEALTHCARE

Visiblue

- Blue Highlights incorporated into key components
- Supports mask education, orientation and reassembly

F&P SleepStyle

CPAP/Auto Therapy

Fisher & Paykel HEALTHCARE

Freedom in Simplicity

Easy-access Chamber

Built-in connectivity options

User-friendly menu & buttons

Quiet, integrated design

Fisher&Paykel HEALTHCARE

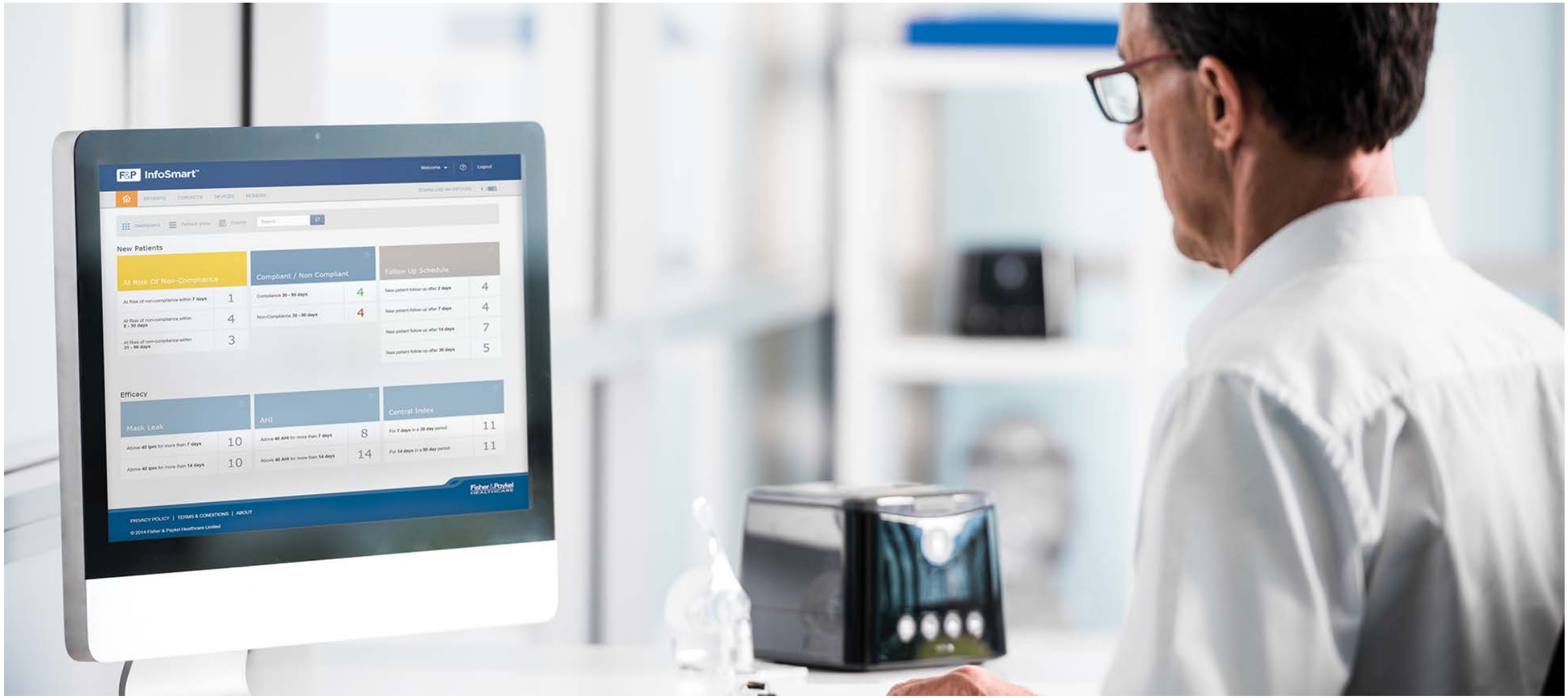
Powered by Technology

Fisher & Paykel HEALTHCARE

Engaging Patients

Fisher & Paykel HEALTHCARE

Empowering Clinicians



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The Mask Matters Most

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Questions?

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Thank you

Fisher & Paykel Healthcare Investor Day
Sydney, October 2017

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