Care by Design

Fisher & Paykel Healthcare Investor Day
Sydney, October 2017
# Morning Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Speaker</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:00am</td>
<td>Welcome</td>
<td>Marcus Driller</td>
<td>General Manager Corporate</td>
</tr>
<tr>
<td>10:00am</td>
<td>Sustainable Profitable Growth</td>
<td>Lewis Gradon</td>
<td>Managing Director &amp; CEO</td>
</tr>
<tr>
<td>10:15am</td>
<td>Patient-focused R&amp;D</td>
<td>Andrew Somervell</td>
<td>VP - Products &amp; Technology</td>
</tr>
<tr>
<td>10:35am</td>
<td>Sales Approach: Enabling Clinical Change</td>
<td>Paul Shearer</td>
<td>Senior VP - Sales &amp; Marketing</td>
</tr>
<tr>
<td>10:55am</td>
<td>Airvo &amp; Optiflow: World-Leading Technology</td>
<td>Chris Crone</td>
<td>Airvo R&amp;D Manager</td>
</tr>
<tr>
<td>11:15am</td>
<td>Transforming Respiratory Therapy in Infant Care</td>
<td>Andy Niccol</td>
<td>General Manager - Infant Care</td>
</tr>
<tr>
<td>11:35am</td>
<td>Nasal High Flow The Brisbane (Paediatric) Experience</td>
<td>Dr Andreas Schibler</td>
<td>Lady Cilento Children's Hospital</td>
</tr>
</tbody>
</table>

12:00pm - 1:00pm  Lunch Break

Time will be made available at the end of each presentation specifically for questions and answers.
# Afternoon Agenda

<table>
<thead>
<tr>
<th>Time</th>
<th>Session Description</th>
<th>Presenter(s)</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>1:00pm</td>
<td>Building the body of clinical evidence for myAirvo and Optiflow in the home</td>
<td>Chris Crone</td>
<td>AIRVO R&amp;D Manager</td>
</tr>
<tr>
<td>1:10pm</td>
<td>Nasal high flow humidified air via hospital in the home</td>
<td>Dr Darren Mansfield</td>
<td>Monash Health</td>
</tr>
<tr>
<td>1:30pm</td>
<td>Driving Patient Success with OSA Therapy</td>
<td>Fiona Cresswell</td>
<td>General Manager Marketing</td>
</tr>
<tr>
<td>2:00pm</td>
<td>Management Team Q&amp;A</td>
<td>Lewis Gradon, Paul Shearer, Tony Barclay, Debra Lumsden, Andrew Somervell, Winston Fong</td>
<td>Managing Director &amp; CEO, Senior VP – Sales &amp; Marketing, Chief Financial Officer, VP – Human Resources, VP – Products &amp; Technology, VP – Surgical Technologies</td>
</tr>
<tr>
<td>2:25pm</td>
<td>Closing Comments</td>
<td>Lewis Gradon</td>
<td>Managing Director &amp; CEO</td>
</tr>
<tr>
<td>2:30pm</td>
<td>Product hands-on and further opportunity to speak with FPH team</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Time will be made available at the end of each presentation specifically for questions and answers.
Sustainable  
Profitable  
Growth

Lewis Gradon  
Managing Director & CEO
How long can you continue to grow at these kind of rates?

Operating Revenue (NZ$ Millions):
- 2013: 556.3
- 2014: 623.4
- 2015: 672.3
- 2016: 815.5
- 2017: 894.4

Net Profit After Tax (NZ$ Millions):
- 2013: 77.1
- 2014: 97.1
- 2015: 113.2
- 2016: 143.4
- 2017: 169.2

5 Year CAGR = 12% for Operating Revenue
5 Year CAGR = 21% for Net Profit After Tax
We’ve established an enviable track record for delivering SUSTAINABLE REVENUE GROWTH.
Where will sustainable growth come from in the SHORT-TERM?
Where will sustainable growth come from in the MEDIUM-TERM?
Where will sustainable growth come from in the LONGER-TERM?
OUR ASPIRATION: Sustainably DOUBLING our constant currency revenue every 5-6 years.
Characteristics of our business

Market opportunities
• Diverse, growing clinical data
• Underpinned by favourable demographics, aging populations and developing country healthcare spend

Valued customer benefits
• Improved patient outcomes
• Lower cost of care

Independence of economic cycles
• Revenue derived from treating a patient

Barriers to entry
• Regulated
• Patented IP
• Care Continuum: Throughout hospital to home
• Sales force investment
• Knowledge base

Relatively predictable cash generation
• Hardware placement drives per patient consumables
• Successful treatment resists change
• Change of clinical practice inertia

GROWTH PROFITABLY, SUSTAINABLY
Questions?
Patient-focused R&D

Andrew Somervell – Vice President
Products and Technology
Improving Clinical Practice: R&D approach

• Unique products with valued differentiation that:
  − Improve care and outcomes
  − Lower overall cost of treating patients
• Proven innovation history
• Original thought required
• Enabled through understanding unmet patient and caregivers’ needs
Patient Oriented R&D

• Philosophy of doing what’s best for the patient
  – Needs of all stakeholders align with patient needs
  – Encourages long term thinking
  – Ingrained in FPH culture

• Patient focused multi-disciplinary product teams
  – Specialist skills, broad knowledge
Patient Focused Teams: In-depth Knowledge

- Physiology
- Environment
- Users
- Adjacencies
- Key Opinion Leaders
- Clinical Research
- Technology
- Competitors

NEW IDEAS, ORIGINAL THOUGHT
Enabling our Product Teams

• Easy access to the user environment:
  − Strong relationships with local and offshore hospitals and homecare dealers
  − Patient knowledge, testing solutions

• Learning by creating
  − Prototype, test, learn
  − World-class prototyping and testing facilities

• Access to world-leading technology experts

• R&D access to manufacturing

• Proven ability to attract and grow top talent
F&P 950: Redefining Expectations

• F&P 850 current market leader
AirSpiral Inspiratory Limb

• Opportunity:
  − Optimal humidity, minimal condensation in difficult ambient conditions

• Benefits:
  − Reduce ventilation breaks
  − Reduce infection risk
  − Reduce clinician’s time dealing with condensate

• Idea:
  − Insulate delivered medical gas with pockets of air

• Result:
  − AirSpiral Tube

• Technical challenge
  − How to manufacture

• Conceived for 950, adapted for Airvo and SleepStyle
Sales approach: enabling clinical change

Paul Shearer
Senior VP - Sales & Marketing
Clinical change process

Process:
- Products
- Sales force knowledge
- Marketing
- Therapy/clinical
- Economics

PRODUCT DEVELOPMENT FEEDBACK

TRUSTED ADVISOR
- Evaluation
- Sales
- Adoption

LONG COMPLEX SALES CYCLE
Developing sales team effectiveness

- Product training
- Therapy understanding
- Expert domain knowledge
- Develop customer relationships
- Trusted advisor

Takes several years for a FPH sales rep to become fully effective
Role of marketing

- Condition market for sales organisation
- Patient group experts
- Develop messaging and approach
- Clinically-focused marketing
- Promote FPH brand
- Product approval and country registrations
Clinical and therapy validation

- Develop Key Opinion Leaders (KOL relationships)
- Pilot studies
- Physiological studies (Mechanisms)
- Outcome studies (RCT)
- Peer to peer education
Value-based economics

• Cost calculators
• Translation of clinical evidence to financial benefits
• User case studies
• External financial validation
• Reimbursement / payment pathways
Evaluation

- Customer preparedness
- Evaluation criteria
- Educating clinicians over multiple shifts
- Validating critical success factors
- Trust and confidence
Sales achievement

• Contract (GPO / IDN) formularies
• Win / meet tender specifications
• Capital acquisition (annual cycles)
• Lease / commitment programmes
• Installation / in-service support
• Customer success
Driving adoption

- Facilitate change management
- Customer commitment
- Standard of care
- Physician-generated protocol
- Product performance
- Ongoing review
Customer satisfaction

• Proven product performance ✓

• Improved care and outcomes based on unique FPH product ✓

• Strong relationships and trust ✓

• Product standardisation and continuum of care ✓

• Customer commitment ✓
Enabling clinical change - summary

• Clinical change is a disruptive, lengthy and complex process

• Clinicians: working with trusted products delivering improved outcomes to at risk patients are reluctant to change
Questions?
Airvo & Optiflow: World-Leading Technology

Chris Crone
Research & Development Manager - Airvo/Optiflow
What is Optiflow nasal high flow therapy?

CONVENTIONAL OXYGEN THERAPY

LOW FLOW NASAL PRONGS
SIMPLE FACE MASK
REBREATHER MASK

NON-INVASIVE VENTILATION
Interest accelerating in Nasal High Flow therapy

Nasal High Flow Clinical Papers Published Annually
2014-2015: Breakthrough publications

**Original Article**

**American Journal of Respiratory and Critical Care Medicine**

Nasal High-Flow versus Venturi Mask Oxygen Therapy after Extubation: Effects on Oxygenation, Comfort, and Clinical Outcome

**Original Article**

**The New England Journal of Medicine**

High-Flow Oxygen through Nasal Cannula in Acute Hypoxemic Respiratory Failure

**JAMA**

High-Flow Nasal Oxygen vs Noninvasive Positive Airway Pressure in Hypoxemic Patients After Cardiopulmonary Surgery: A Randomized Clinical Trial
2016: More evidence post-extubation

Summary
- 7 centres in Spain
- 527 patients at low risk of reintubation
- Optiflow significantly reduced reintubation rates vs O2

Summary
- 3 centres in Spain
- 604 patients at high risk of reintubation
- Optiflow was non-inferior to NIV

Reintubation is linked with poor outcomes
Emerging evidence in other areas

• Hypercapnic patients
  - Large randomised controlled trials (RCTs) in planning stages (French government support)

• Emergency department
  - Bell, et al. 2015. Emergency Medicine Australasia

• Wards
Emerging evidence in other areas

• Evolution in research
  − Different patient groups and settings
  − Larger trials

• Towards:
  − All spontaneously breathing patients requiring respiratory support
FPH technology advantage

For Optiflow Nasal High Flow:

- **Generating** with Airvo
- **Transporting** with AirSpiral
- **Delivering** with Optiflow
Generating with Airvo

Superiority in:

• Performance - humidification, flow, sensing
• Versatility – wide range of temperatures, flows and oxygen
• Mobility – throughout the hospital
Transporting with AirSpiral

- Superior protection against condensate
- Patents filed on technology and processes

AirSpiral tubes

Conventional breathing tubes
Delivering with Optiflow

• The only interface with Evaqua technology
• Reduces formation of mobile condensate
• Comfort for patients and confidence for clinicians
Exciting potential

• Huge clinical interest in Optiflow

• We are well-positioned with Airvo, AirSpiral and Optiflow technologies
Questions?
Transforming Respiratory Therapy in Infant Care

Andy Niccol
General Manager – Infant Care
Infant care continuum

- Resuscitation
- Invasive ventilation
- nCPAP
- Nasal high flow
- Oxygen therapy
Current evidence supporting the clinical applications of NHF

- **INVASIVE**
  - **NHF POST EXTUBATION**: STRONG SUPPORT FOR NHF
    - **PUBLISHED GUIDANCE**: COCHRANE REVIEW
  - **NHF AS AN ALTERNATIVE TO PROLONGED CPAP**: STRONG SUPPORT FOR NHF
    - **LEVEL OF EVIDENCE**: CONSSENSUS OF PUBLISHED EXPERT OPINION
  - **NHF AS PRIMARY SUPPORT**: GENERAL SUPPORT FOR NHF (some exceptions below)
    - **LEVEL OF EVIDENCE**: RANDOMISED CONTROLLED TRIAL DATA

**Exceptions**:
- Extreme prematurity
- Severe respiratory distress syndrome
- Untreated surfactant deficiency

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The next generation of care

Specifically designed for the delicate anatomy and flow requirements of your smallest patients.

F&P Optiflow™ Junior 2
Enhanced prong retention

- Improves prong stability in the nostrils
- Allows for natural facial movement when patient’s cheeks are compressed
- Easier readjustment and maintenance for caregivers

F&P Optiflow™ Junior 2

Waveflex™ TECHNOLOGY

Fisher & Paykel HEALTHCARE
Enhanced prong retention

Improves prong stability in the nostrils
Wider range of sizes

APPORXIMATE AGE AND WEIGHT

Age and weight information should only be used as a guide. Ensure clinical judgement is used when sizing.

<table>
<thead>
<tr>
<th>Size</th>
<th>XS</th>
<th>NEW</th>
<th>S</th>
<th>M</th>
<th>L</th>
<th>XL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (Kg)*</td>
<td>0.5</td>
<td>1</td>
<td>2</td>
<td>2.5</td>
<td>0.9</td>
<td>1</td>
</tr>
<tr>
<td>Correlated age**</td>
<td>21 wkGA</td>
<td>28 wkGA</td>
<td>32.5 wkGA</td>
<td>35 wkGA</td>
<td>27 wkGA</td>
<td>28 wkGA</td>
</tr>
<tr>
<td>Weight (Kg)*</td>
<td>3</td>
<td>3.5</td>
<td>18</td>
<td>20</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>Correlated age**</td>
<td>32.5 wkGA</td>
<td>40 wkGA</td>
<td>4.9</td>
<td>56 mth</td>
<td>4.7</td>
<td>4.7</td>
</tr>
</tbody>
</table>

wkGA = weeks of gestation; mth = months; yf = years
* Weight data is based on H&P product validation studies.
** Age data is a correlation to weight data based on a combination of Fenton, WHO and CDC growth charts.
Retains existing product benefits

- Sizes to fit a wider range of patients
- Enhanced prong retention with Waveflex™ technology
- Wide flow range (0.5 - 25 L/min)
- Soft, unobtrusive prongs facilitate kangaroo care
- Easy application and cares with Wigglepads™ 2
- Minimized condensate and kinking with FlexiTube™
Wigglepads
Tube Technology
Questions?
Nasal High Flow
The Brisbane (Paediatric) Experience

The Brisbane (Paediatric) Experience

The PCCRG receives an ongoing research grant from Fisher & Paykel Healthcare. Travel expenses associated with this presentation have been covered by Fisher & Paykel Healthcare.
Reduced intubation rates for infants after introduction of high-flow nasal prong oxygen delivery

Table 3 Infants with viral bronchiolitis listed by year

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

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
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?
Paediatric Acute Respiratory Intervention Studies
High Flow Trial
PARIS 1 Background

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

Inclusion Criteria
- Bronchiolitis
- SpO2 <92/94%%
- < 12mths

Primary Outcome

Responder

NHF 2L/kg/min

Non-Responder

Transfer

Control

Responder

Non-Responder

NHF 2L/kg/min

Responder

Non-Responder

Transfer

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

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

Children’s Health Queensland
<table>
<thead>
<tr>
<th>Primary Outcomes</th>
<th>Standard Oxygen</th>
<th>Nasal High Flow</th>
<th>P value</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Failure Rate</strong></td>
<td>N=731</td>
<td>N=745</td>
<td>#0.0001</td>
<td>2.20 (1.65-2.89)</td>
</tr>
<tr>
<td>% of patients</td>
<td>167</td>
<td>89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-responders/Responders</td>
<td>23%</td>
<td>12%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;3 month of age</td>
<td>55/130</td>
<td>28/179</td>
<td>#0.0001</td>
<td>2.71 (1.63-4.50)</td>
</tr>
<tr>
<td></td>
<td>112/434</td>
<td>61/477</td>
<td>#0.0001</td>
<td>2.02 (1.44-2.83)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-responders/Responders</th>
<th>3-12 months of age</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Length of O2 therapy (median)</strong></th>
<th>days (IQR)</th>
<th>days (IQR)</th>
<th>P value</th>
<th>Odds ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>All infants</td>
<td>1.23 (1.82)</td>
<td>1.24 (1.81)</td>
<td>*0.218</td>
<td></td>
</tr>
<tr>
<td>All infants without ICU admission</td>
<td>1.13 (1.54)</td>
<td>1.07 (1.51)</td>
<td>*0.025</td>
<td></td>
</tr>
</tbody>
</table>
PARIS II
Paediatric Acute Respiratory Intervention Studies

Acute Hypoxemic Respiratory Failure
AHRF Trial
• 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
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
Nasal High Flow - Acute vs. Chronic use

- Same therapy, different uses, different benefits
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
## Mechanisms research

<table>
<thead>
<tr>
<th>Author</th>
<th>Journal</th>
<th>n</th>
<th>Population</th>
<th>Comparison</th>
<th>F/up</th>
<th>Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hasani</td>
<td>Chron Resp Dis</td>
<td>10</td>
<td>Bronchiectasis</td>
<td>NHF vs no NHF</td>
<td>7d</td>
<td>↑ Increased Mucociliary clearance</td>
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<tr>
<td>Fraser</td>
<td>Thorax</td>
<td>10</td>
<td>COPD</td>
<td>NHF vs O₂</td>
<td>&lt;1d</td>
<td>↓ Reduced CO₂ (measured through skin) ↓ Reduced Respiratory Rate ↑ Increased Tidal Volume</td>
</tr>
<tr>
<td>Bräunlich</td>
<td>J COPD</td>
<td>48</td>
<td>COPD</td>
<td>NHF vs O₂</td>
<td>&lt;1d</td>
<td>↓ Reduced CO₂ (measured through skin) ↓ Reduced Respiratory Rate ↑ Increased Tidal Volume</td>
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<tr>
<td>Biselli</td>
<td>J Appl Physiol</td>
<td>18</td>
<td>COPD</td>
<td>NHF vs O₂</td>
<td>&lt;1d</td>
<td>↓ Reduced CO₂ (measured through skin) ↓ Reduced Work of Breathing ↓ Reduced Minute ventilation</td>
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<tr>
<td>Pisani</td>
<td>Thorax</td>
<td>14</td>
<td>Hypercapnic COPD</td>
<td>O₂ vs NHFO₂ and NIV</td>
<td>&lt;1d</td>
<td>↓ Reduced Respiratory Rate ↑ Increased Tidal Volume ↓ Reduced CO₂ (blood gas)</td>
</tr>
<tr>
<td>Pilcher</td>
<td>Respirology</td>
<td>24</td>
<td>AECOPD</td>
<td>NHF vs O₂</td>
<td>&lt;1d</td>
<td>↓ Reduced CO₂ (blood gas)</td>
</tr>
<tr>
<td>McKinstry</td>
<td>Respirology</td>
<td>48</td>
<td>COPD</td>
<td>NHF vs breathing</td>
<td>&lt;1d</td>
<td>↓ Reduced CO₂ (measured through skin) ↓ Reduced Respiratory Rate</td>
</tr>
</tbody>
</table>
## Outcomes research

<table>
<thead>
<tr>
<th>Author</th>
<th>Journal</th>
<th>Yr</th>
<th>Population</th>
<th>Comparison</th>
<th>F/up</th>
<th>Message</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rea</td>
<td>Resp Med 2010</td>
<td>2010</td>
<td>COPD &amp; Bronchiectasis</td>
<td>NHF (w and w/o O₂) vs SC</td>
<td>1y</td>
<td>Improved exacerbation days, time to 1st exacerbation, reduced antibiotic use</td>
</tr>
<tr>
<td>Cirio</td>
<td>Resp Med 2016</td>
<td>2016</td>
<td>COPD in Pulmonary Rehab</td>
<td>NHFO₂ vs Venturi O₂</td>
<td>&lt;1d</td>
<td>Improved exercise tolerance</td>
</tr>
<tr>
<td>Macann</td>
<td>Int J Radiation Oncol Biol Phys 2010</td>
<td>2010</td>
<td>Head &amp; Neck Cancer patients with mucositis</td>
<td>NHF vs Usual care</td>
<td>12w</td>
<td>Improved patient functioning, nutritional events, decreased number of inpatient days</td>
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<tr>
<td>McNamara</td>
<td>Resp Care 2014</td>
<td>2014</td>
<td>Tracheostomy</td>
<td>THF vs HME</td>
<td>10w</td>
<td>Long term: reduced adverse events</td>
</tr>
</tbody>
</table>
### COPD research underway

<table>
<thead>
<tr>
<th>PI, Country</th>
<th>n</th>
<th>Population</th>
<th>Comparison</th>
<th>F/up</th>
<th>Primary Outcome</th>
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</thead>
<tbody>
<tr>
<td>Weinreich, Denmark</td>
<td>200</td>
<td>COPD</td>
<td>NHFO₂ vs O₂</td>
<td>1y</td>
<td>Exacerbations &amp; hospital admissions</td>
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<tr>
<td>Mansfield, Australia</td>
<td>150</td>
<td>COPD</td>
<td>NHF vs no NHF</td>
<td>30d</td>
<td>Length of Stay, 30 d readmission</td>
</tr>
<tr>
<td>Bräunlich, Germany</td>
<td>100</td>
<td>COPD</td>
<td>NHF vs Bilevel</td>
<td>6w</td>
<td>Capillary CO₂</td>
</tr>
<tr>
<td>Nilius, Germany</td>
<td>40</td>
<td>COPD</td>
<td>NHFO₂ vs O₂</td>
<td>1y</td>
<td>Overnight trans. CO₂</td>
</tr>
<tr>
<td>Chihara, Japan</td>
<td>32</td>
<td>COPD w CRF</td>
<td>NHFO₂ vs O₂</td>
<td>4w</td>
<td>6 Min. Walk Distance</td>
</tr>
<tr>
<td>Tomii, Japan</td>
<td>30</td>
<td>COPD</td>
<td>NHFO₂ vs O₂</td>
<td>6w</td>
<td>Quality of Life (St Georges Resp. Quest.)</td>
</tr>
<tr>
<td>Allen, USA</td>
<td>30</td>
<td>COPD</td>
<td>NHF(O₂) vs Usual</td>
<td>3m</td>
<td>Quality of Life (Breathless, Cough Sputum Scale)</td>
</tr>
<tr>
<td>Fernandes, USA</td>
<td>30</td>
<td>COPD</td>
<td>NHFO₂ vs O₂</td>
<td>1y</td>
<td>Hospitalizations</td>
</tr>
<tr>
<td>Bräunlich, Germany</td>
<td>20</td>
<td>COPD</td>
<td>NHF Neb vs Neb</td>
<td>&lt; 1d</td>
<td>Lung Function (FEV₁)</td>
</tr>
<tr>
<td>Criner, USA</td>
<td>10</td>
<td>Unstable COPD</td>
<td>NHF</td>
<td>5 d</td>
<td>Ability to maintain SpO₂ &gt; 90%</td>
</tr>
<tr>
<td>Criner, USA</td>
<td>30</td>
<td>COPD</td>
<td>NHF</td>
<td>90 d</td>
<td>Compliance</td>
</tr>
</tbody>
</table>
A bright outlook

• There are challenges to home-based research

• Studies are underway with myAirvo and early results are promising
Questions?
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 CO₂ and depleted O₂

Unassisted breathing

Optiflow NHF

Alveolar volume

Alveolar volume

TIDAL VOLUME

TIDAL VOLUME

Dead space volume

Washout

Dead space volume

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
Unique and Personal
The Threat

• Up to 100M OSA sufferers\textsuperscript{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

Main Drivers of Non-Adherence

• Leaks¹
• Facial Abrasions¹
• Mask Discomfort¹,²
• Claustrophobia¹,²

Intimacy of the Mask

- Comfort
- Seal
- Ease of Use

= CONFIDENCE
User Experience Mask Design Philosophy

Perception | Fitting | Seal | Disassembly | Cleaning | Reassembly | Confident ongoing use

Patient

Perception | Fitting | Education | Part identification & Resupply

Equipment Provider

Eliminates need for support
Complex and Diverse Facial Anatomy
Our Leading-Edge Masks

F&P Simplus™

F&P Eson™ 2

F&P Brevida™
AirPillow Seal
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
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
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
Adjustable Headgear

Adjustable to offer personalised secure fit

Tactile Feedback and locks in place

Provides stability against dislodgement
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
Washable Exhaust Diffuser
We Quantify the Invisible

• Sound Testing
  - Target less than 25dBA

• Draft Testing

Anechoic Chamber
We Amplify Accuracy Using Technology

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

• Optical Gauge Smartscope
  - Accuracy of 1.4µm
The Benefit

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

- Blue Highlights incorporated into key components
- Supports mask education, orientation and reassembly
F&P SleepStyle
CPAP/Auto Therapy
Freedom in Simplicity

- Easy-access Chamber
- User-friendly menu & buttons
- Built-in connectivity options
- Quiet, integrated design

F&P SleepStyle
Powered by Technology

- Auto algorithm
- ThermoSmart™
- Expiratory relief
- SensAwake™
Empowering Clinicians
The Mask Matters Most
Questions?
Thank you

Fisher & Paykel Healthcare Investor Day
Sydney, October 2017