Research Findings

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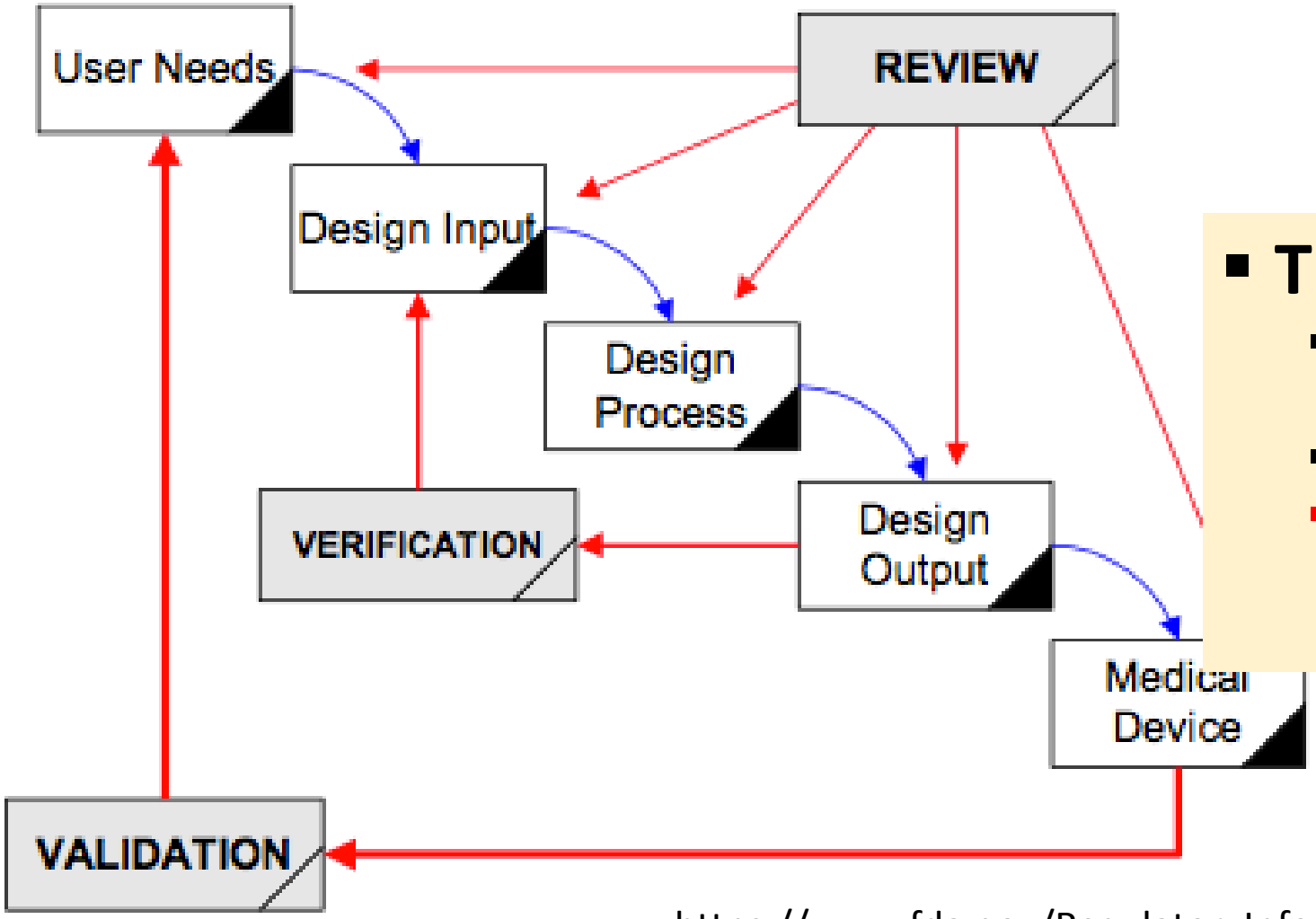
Medilink Yorkshire & Humber Ltd.

Patient/clinical needs assessment - Why?



- **The design process**
  - Required for requlatory approval (e.g. FDA)
  - Reduces technical and commercial risk
  - AN ASSESSMEN OF USER NEEDS IS CRITICAL

https://www.fda.gov/RegulatoryInformation/Guidances/ucm070627.htm

Focus on Patients and Clinical Needs

Patient

- Patients' needs

Clinical

- Health care professional need

Definition of problem to be solved

The device meets user needs

Customer pull approach to innovation

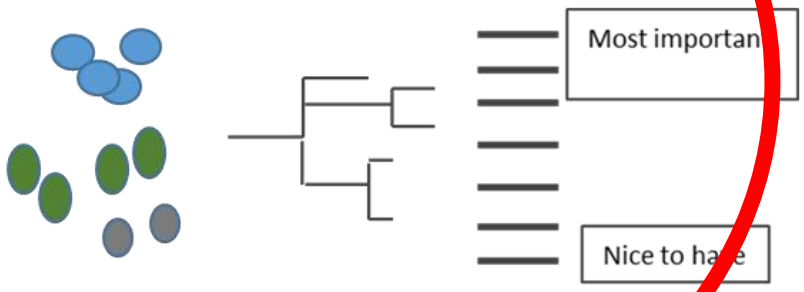
Reduce risk

Identification of user requirements

User and technical requirements → Design Inputs → Idea generation → Concept selection

FOCUS GROUPS x 2

Team R&D activities



Soft prototyping

Matrix prioritisation

Focus group

Wireless or cable

OUTPUT
FINALISED CONCEPT TO MOVE TO PHASE II CLINICAL STUDY

Clinician Interview Research

Conducted 27th February - 10th March 2017

Rationale

- Interview clinicians & health professionals in several different ‘parts’ of the care pathway
- Objective was to understand:
  - Current practice – and the way the machines are used to monitor patients
  - Attitudes towards the technology
  - Identify unmet needs – What works well, what doesn’t work, and what could be improved upon in a future device

- **Outcome:** A clear picture of the technical requirements for a new device, driven by the clinical understanding of the issues surrounding pulse oximetry monitoring

Clinical & Health Professional participants

- Consultant in Respiratory and Sleep Medicine
- Well Child Clinical Nurse Specialist in Ventilation
- Team Leader, Helena Homecare Specialist Nursing Team
- Respiratory Nurse
- Lead Sleep Physiologist
- Medical Student (Respiratory Interest)
- Consultant in Respiratory Medicine
- Consultant Paediatrician
- Specialist Sleep Clinical Physiologist
- Team Leader/Clinical Educator Paediatric Palliative Care
- Staff Nurse

Clinical & Health Professional participants

Children aged **3 months – 4 yrs**
With a variety of respiratory conditions

Children aged **0 – 18 months and 10 yrs to 18 yrs**
With ventilation required

Children aged **18 months – 10 yrs**
With chronic respiratory conditions but well most of the time

Children aged **3 months – 10 yrs**
With long-term conditions requiring periodic hospital care

Children aged **3 months – 10 yrs**
With suspected OSA/sleep disorder

Children aged **3 months – 4 yrs**
With suspected OSA/sleep disorder

Children aged **3 – 18 months**
With chronic conditions requiring oxygen in the home

Children aged **0 months – 4 yrs**
With chronic conditions requiring outpatient/inpatient care

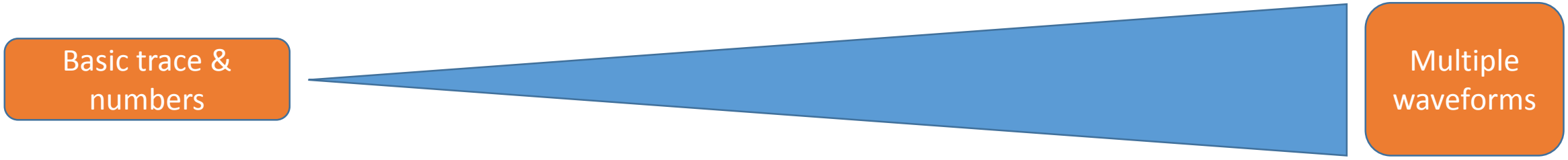
Children aged **3 months – 10 yrs**
With suspected OSA/sleep disorder

Children aged **18 months – 18 yrs**
With chronic life limiting conditions requiring palliative care

Children aged **18 months – 18 yrs**
With chronic conditions requiring outpatient/inpatient care

Clinical & Health Professional participants

Richness of data required (from pulse oximeter)



Team Leader/Clinical Educator Paediatric Palliative Care

Well Child Clinical Nurse Specialist in Ventilation

Team Leader, Helena Homecare Specialist Nursing Team

Medical Student (Respiratory Interest)

Respiratory Nurse

Consultant in Respiratory Medicine

Lead Sleep Physiologist

Staff Nurse

Consultant Paediatrician

Consultant in Respiratory and Sleep Medicine

Specialist Sleep Clinical Physiologist

Current Practice

Section 1

Favourite machine & why?

Home Monitoring

Machines
Konica Minolta 300i

Advantages
- Given to parents to take home
- Smaller than other units

Disadvantages
- Not good at filtering movement artefact

Home & Hospital monitoring

Machines
Masimo Radical 7
Masimo Radical 7 Touch
Masimo Radical 8

Advantages
- Portable
- Superior artefact filtering
- Gold standard for monitoring
- Visual Pleth Data

Disadvantages
- Difficult for parents/carers to use
- Device can fail to record data at times

Hospital monitoring

Machines
Nellcor 500/5
Nellcor Oximax

Advantages
- Large machines
- Mains operated
- Easier to use than alternatives
- All nurses trained on this machine
- Best for inpatient care
- Durable and easy to use

Disadvantages
- Not as good at Masimo devices for artefact rejection

Favourite machine & why?

Masimo units
favoured by respondents

Machines
Konica Minol

Advantages
- Given to p
- Smaller th

Disadvantage
- Not good
  artefact

- Device can fail to record data at times

Disadvantages
- Not as good at Masimo devices for artefact rejection

Favourite sensor & why?

Reusable

Sensors
With Elastoplast style fixings
Crocodile clips

Advantages
- Crocodile clips ones are easier than adhesives to use – something which clips straight on
- Easier to use for lay-people and nurses than disposable
- Better for spot checking

Disadvantages
- Expensive to replace
- Get damaged and replaced too often in home care (by carers)
- Crocodile clips do not fit on small fingers

Disposable

Sensors
Adhesive kits in packet

Advantages
- Single use downloads quicker
- Cheaper to replace – home care go through probes very quickly
- Better for long term monitoring
- Easier to put on a child

Disadvantages
- Can lead to poor placement on child fingers – difficult to use for lay people

Favourite sensor & why?

Reusable

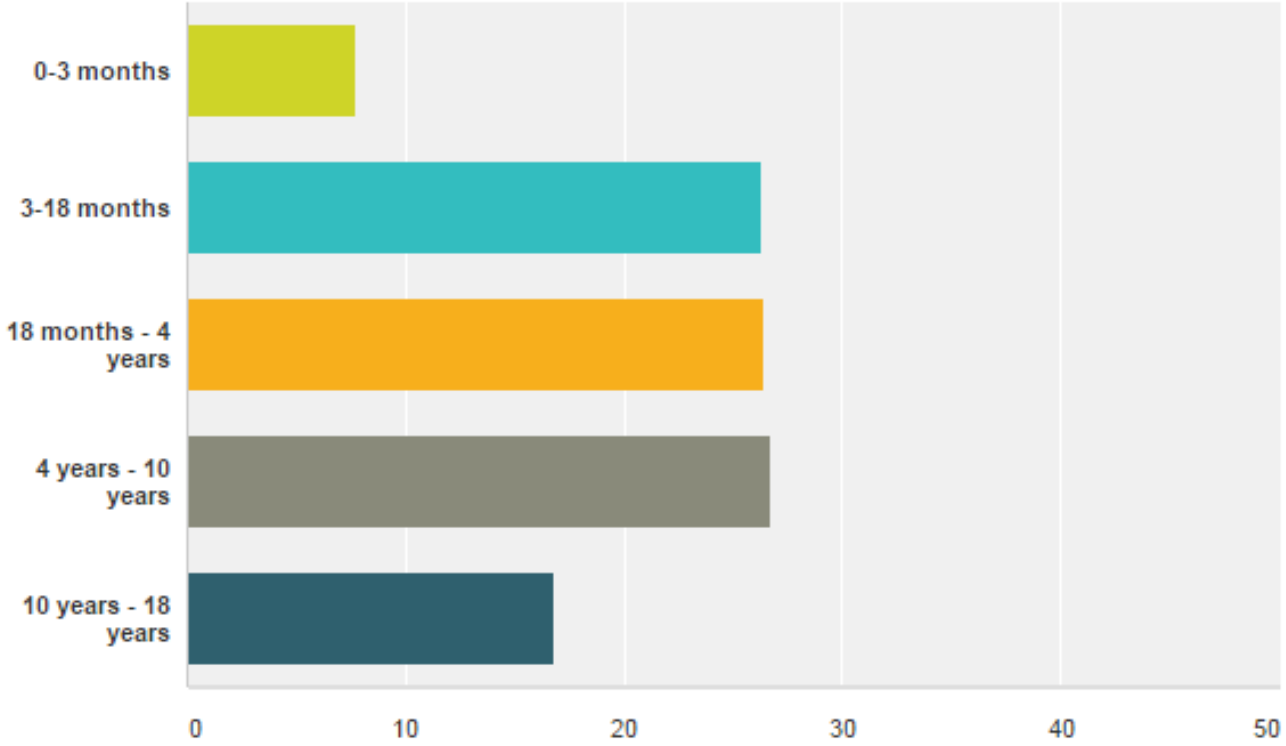
- Get damaged and replaced too often in home care (by carers)
- Crocodile clips do not fit on small fingers

Disposable

Reusable probes in the sleep lab, some hospital scenarios, for machines sent for short studies

Disposable sensors
For continuous home care (cost pressure), and small babies

How much of your time is taken up caring for patients in the following age categories?



- Average of 11 responses
- Over 75% of all time taken by 3 months – 10 years age group
- Neonates and >10 years relatively small proportion

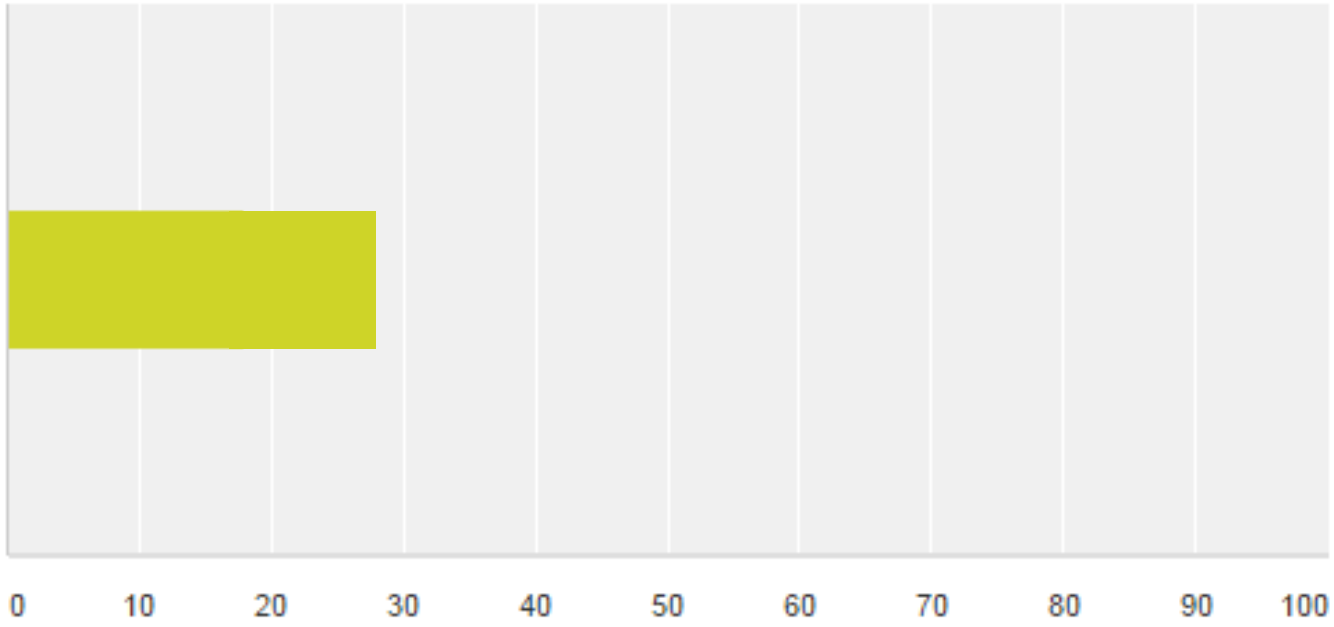
Forms of information collected during monitoring

- Carbon Dioxide
- FEV1 and FVC ratio (obstructive lung disease)
- Oxygen requirement
- Colour (complexion of child)
- Parental observations – sleep/wake, body positions, snoring
- Ventilation settings
- Secretions – colour and consistency
- Humidifier temperature
- Work of breath
- Peak Expiratory Flow Rate
- Spirometry examination
- Amount of suction required
- Breathing
- Heart rate
- Respiratory Rate & effort
- Chest deformity

Forms of information NOT currently collected (but which would be useful)

- Activity
- Carbon Dioxide
- Respiratory rate
- Video
- Audio
- Integrated Diary Card
- Sats and Respiratory Rate combined
- Body position

By your estimation, what percentage of A&E admissions for children with chronic respiratory problems could be avoided by improvements in home monitoring technology?

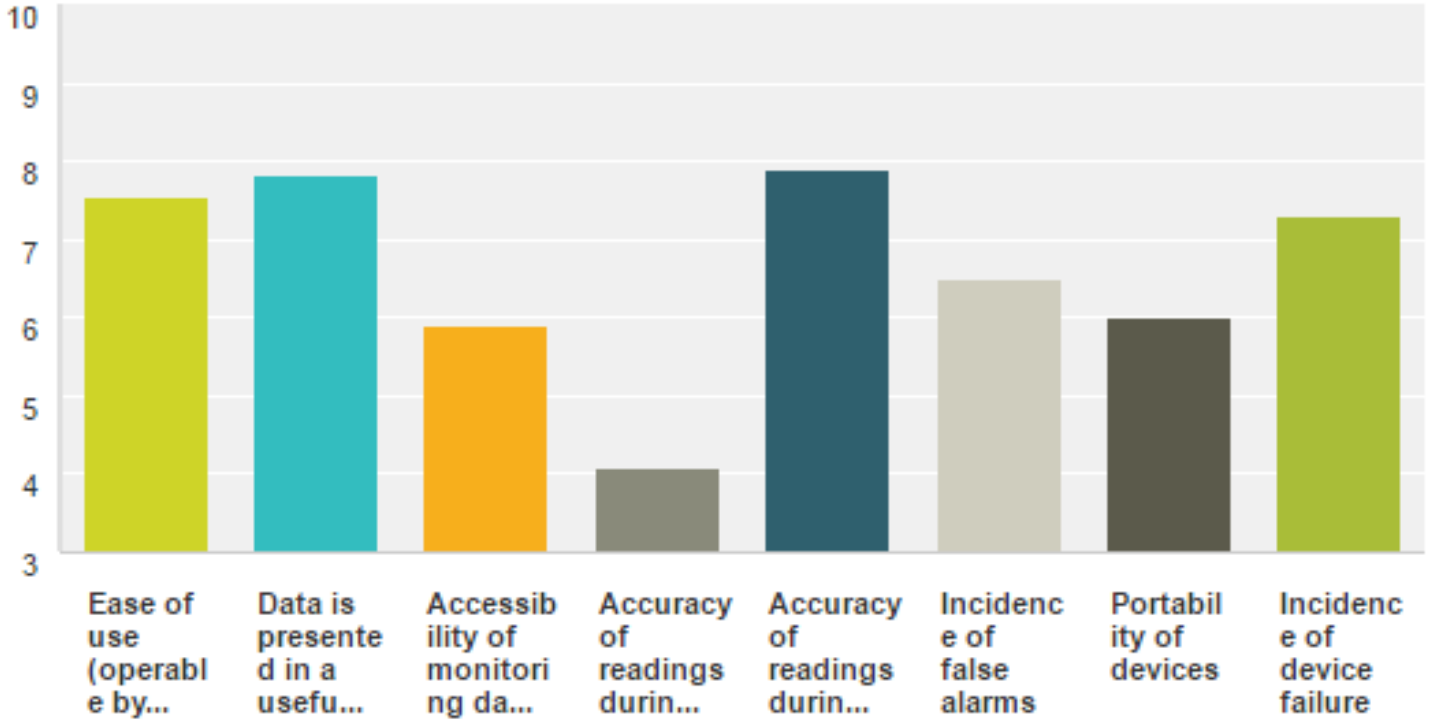


- An average score of 27%
- Responses ranged from 10 (Respiratory Consultant) to 60 (Team leader/Clinical Educator Paediatric Palliative Care)
- Examples of potential benefits included allowing bronchiolitic babies to remain under remote monitoring supervision at home instead of being admitted during outbreaks of RSV – reducing infection transmission

Attitudes towards the technology

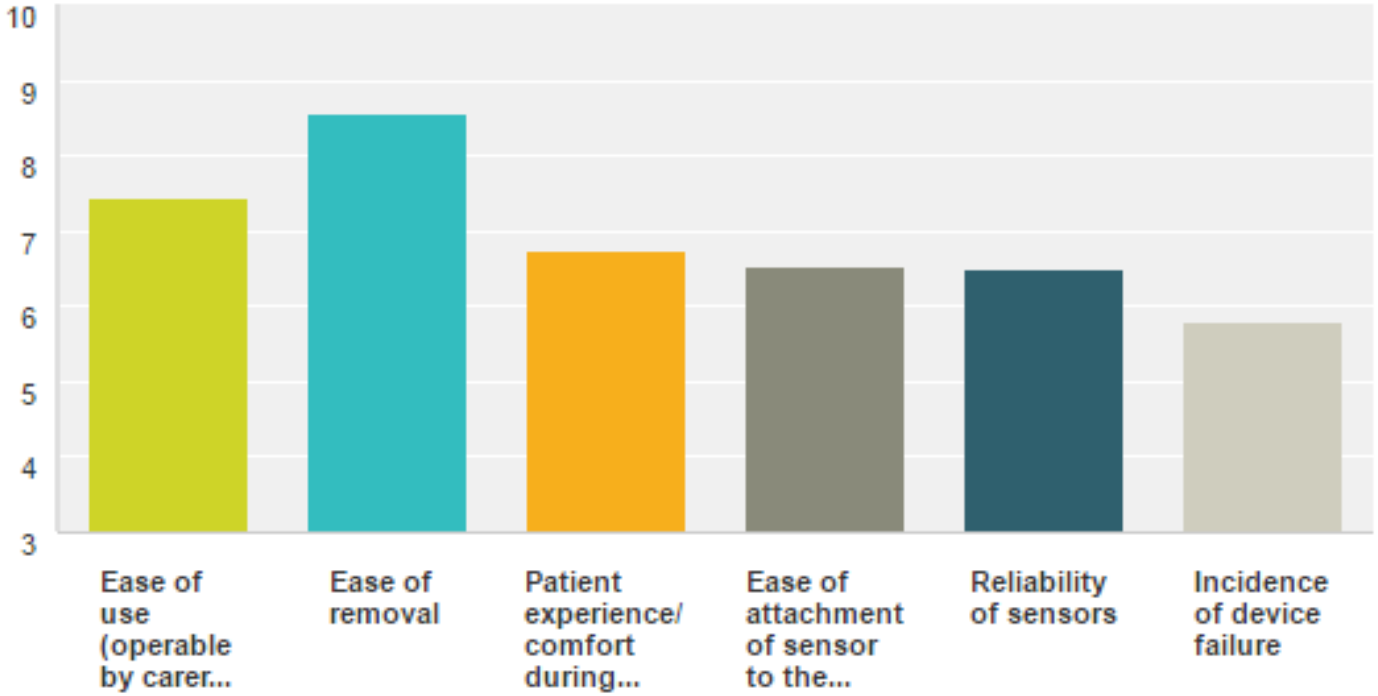
Section 2

In your opinion, how well does your preferred pulse oximeter unit perform in the following areas? Please assign each area a score of between 1 and 10



- Results show respondents judge accuracy of readings during sleep/restfulness to be very good, however, during movement they are judged to be poor
- Accessibility of data, device portability and incidence of false alarms are rated poorly

In your opinion, how well does this pulse oximeter sensor perform in the following areas? Please assign each area a score of between 1 and 10



- Sensors do not perform as well as pulse oximeter units in the same analysis
- They are easy to remove, but poorer at reliability, patient comfort and ease of attachment

Are there any particular limitations with the current technology not covered already?

Movement artefacts cannot be filtered easily

Unable to assess underlying reason for desaturations i.e central/obstructive events

Inability to transmit data remotely

Probes can be difficult to place correctly for inexperienced carers/nurses

Portable models can give false readings in sunlight

Sensor probes aren't always the right size for the patient – leads to poor placement and patient discomfort

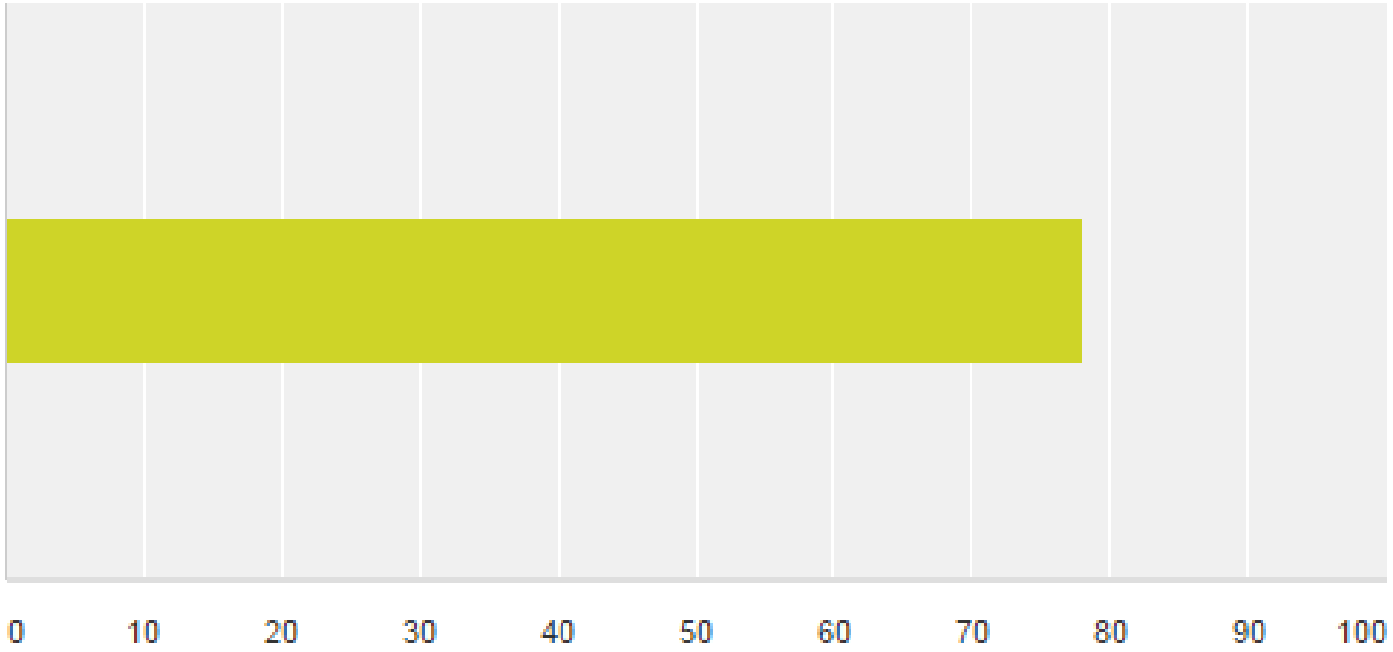
Getting good traces at home can be difficult – if it (the data) could be transmitted back to hospital automatically as it is created then we could guarantee it will be collected

Sensors can be fragile – re-usable "Y" sensors can break at the cable relatively easily - £150 each approx.

Analysis software for Masimo machines is not very good – crashes computers when downloading data, and download can take up to half an hour

Docking station for Masimo units fails occasionally – doesn't collect and store the data so study must be repeated

Overall, how much confidence do you have in readings taken from your preferred pulse oximeter?

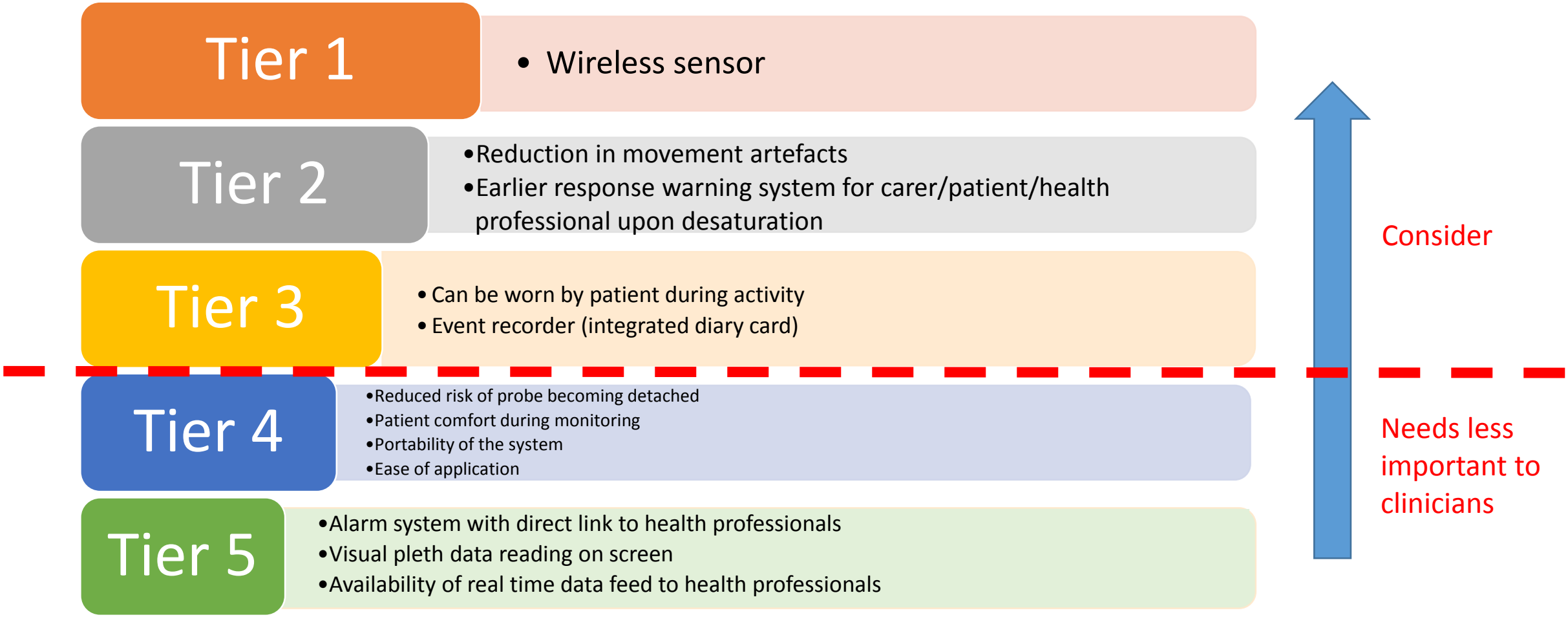


- An average score of 78 from 11 respondents
- Responses ranged from 52% for the Well child clinical nurse specialist ventilation, to 95% for the Respiratory Nurse
- Overall, respondents had a good level of confidence in the readings they were obtaining form their pulse oximeters

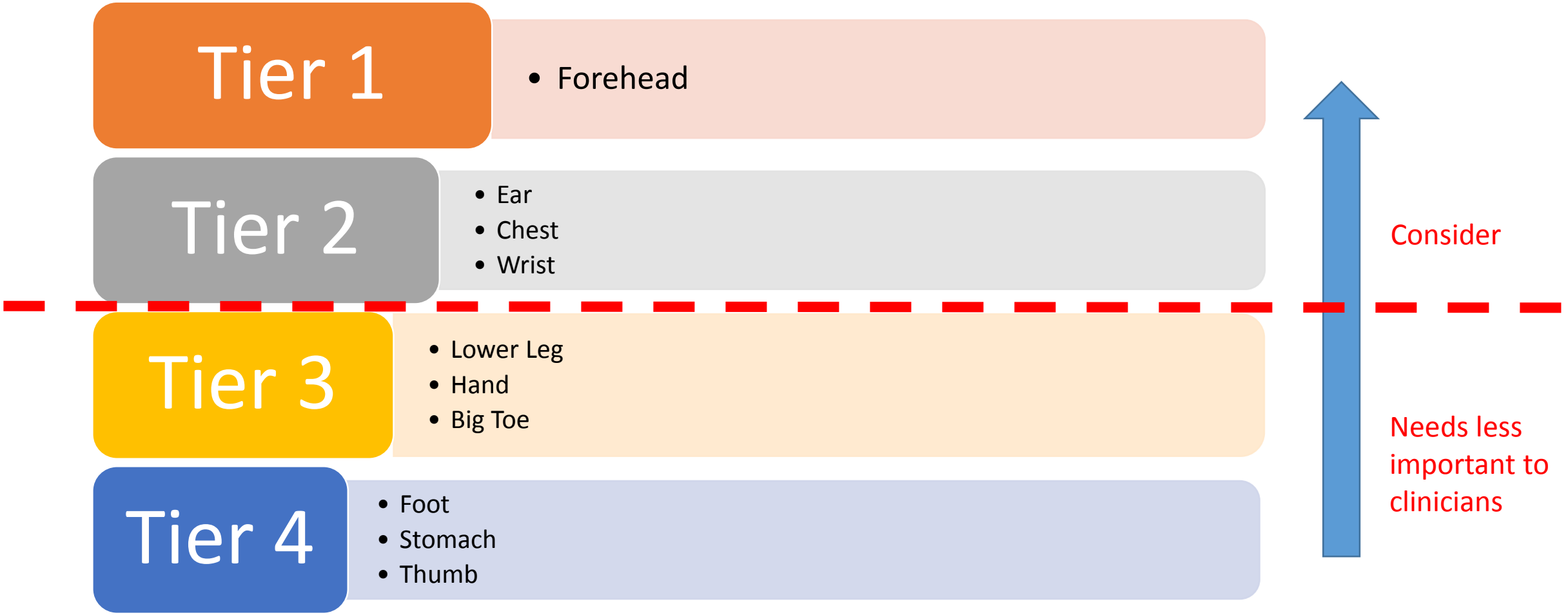
Identify unmet needs

Section 3

Future needs: List of prioritised features



Sensor probe placement: list of prioritised locations



Patient focus group

Report

10th March 2017

Background

- Objective
  - Patient focus group to identify unmet needs around oximetry and to use these in the new product design process
- 7 parents and 1 child (12 yr old)
- Location and time
  - Sheffield Children's Hospital
  - 10am, 9th March 2017

Patient participants

Mum of 18 month old with achondroplasia (on a ventilator)

Foster Mum of 5 year old on a ventilator due to cervical spine injury following a road traffic accident

Mother of child with down syndrome

12 year old with chronic lung disease secondary to congenital diaphragmatic hernia and his Mum

Mother of 12 yr old with chronic lung disease secondary to congenital diaphragmatic hernia

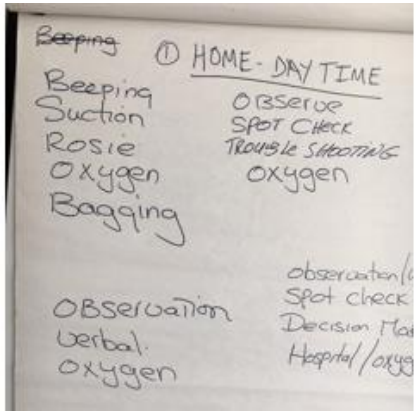
Mother of child with downs syndrome

Foster Mum of 3 year old with chronic lung disease and neurodisability secondary to prematurity

The patient focus group process

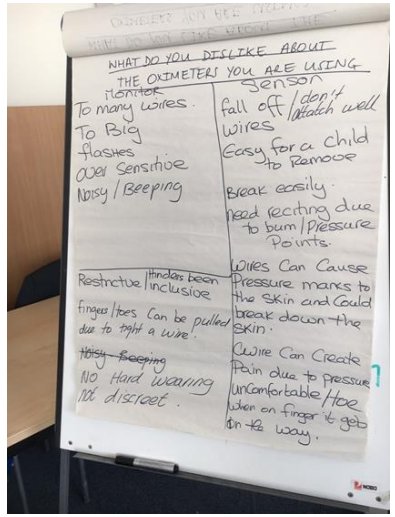
Baseline line

How is information used

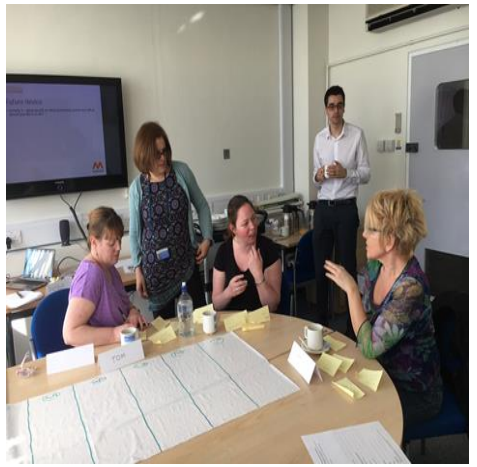


Current devices

Likes/dislike



Needs for future device



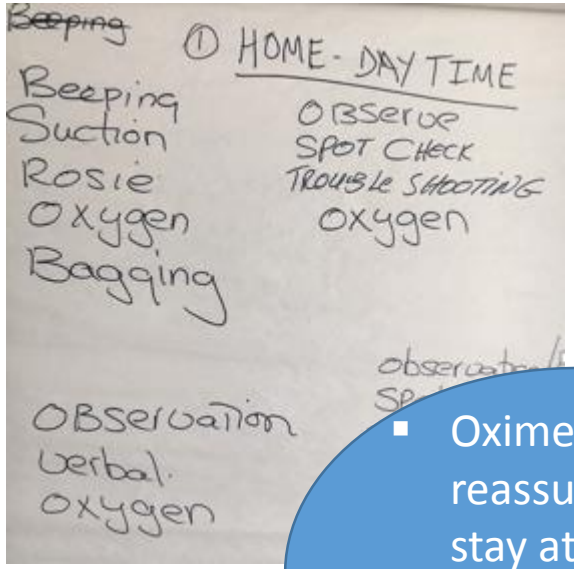
Placement of sensor

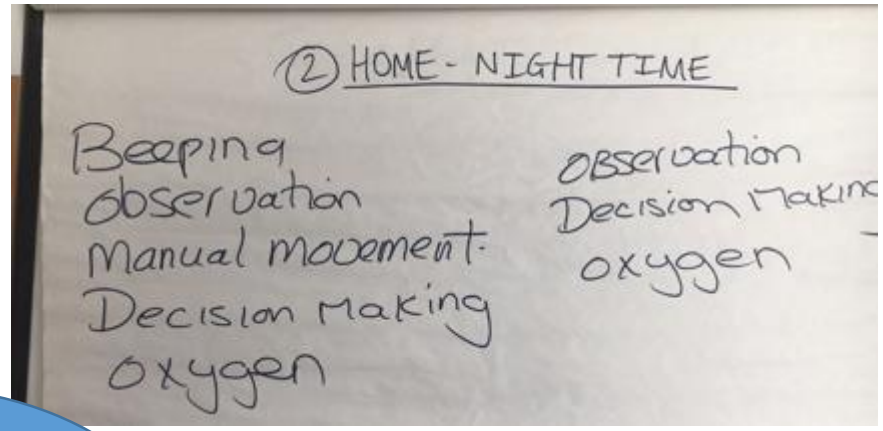
Baseline understanding

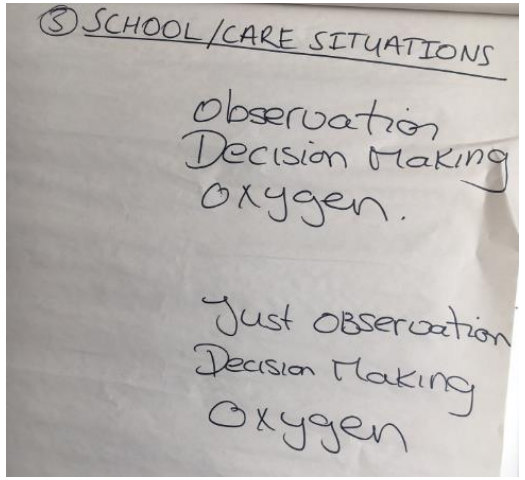
- Mixture of patients using continuous monitoring and periodic measurements
- Common to have two or more devices
  - Tendency to use a smaller unit during the day (but still considered to large
- Battery life highlighted as current frustrations
- Wires on current devices considered negative
  - Safety risk
  - Comfort (area connected to sensor highlighted as particularly problematic)
  - Reduced level of independence
- Durability of sensors
  - Even of reusable sensors considered poor
- Babycam system
  - would be nice to observe data remotely (e.g. in another room)

At this stage needs and frustrations with existing devices were unsolicited

How is information used







- Oximeter reassures me to stay at home and not bring my child to hospital

- False positives frustrating, particularly at night
- Reassurance was a recurring theme/ benefit
- One parent was monitored by sleep unit for 3 nights- no dip. On 4th night child had dipped four times by 11pm.

Current oximeters: Likes

- Reassurance
- Monitoring+ less hospitalisation
- One make is relatively small and can be personalised (pink or blue)
- Bright numbers

The group struggled to identify any specific elements that they liked regarding existing devices

Current oximeters: Dislikes

MONITOR

- Even portable ones are too big
- Too many wires (get tangled worried about
  - Strangled, caught (e.g. in doors), easy to dislodge)
- Over sensitive (too many false alarms)

The presence of wires was the causative factor of many dislikes

SENSOR

- Falls off/ doesn't attach well
- Wires make it easy for child to remove
- Break easily (even reusable ones)
- Need resiting due to burn pressure points/
- Wires can cause pressure marks and skin breakdown
- Wire can create pain due to pressure on toe (causes pain at point of sensor)
- It hurts when lying on the wire (from child)
- Need to unplug when visiting toilet (trails behind child and can get damaged

Future device (unsolicited wants)

Individual recorded needs

Affinity analysis

Prioritisation

Tier 1

- Wireless probes (overcome dislikes and increase patient independence)
- Reduce pressure/ burning on sensor
- Access data remotely (via an app)

Tier 2

- Better sensor that is more comfortable (e.g. soft materials)
- robust
- Easier to attach / does not fall off

Tier 3

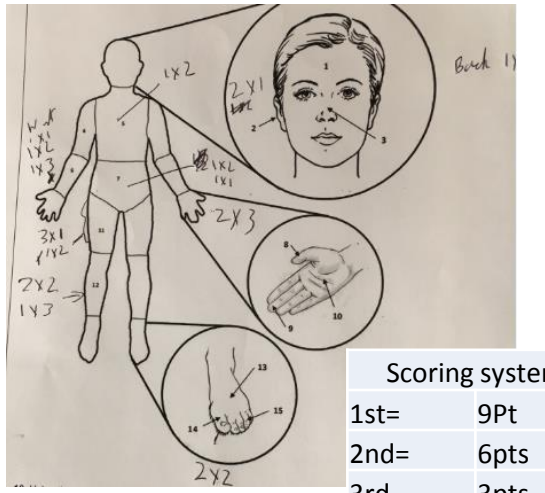
- More reliable/ less false positives
- Record data (e.g. on SD card or alternative)

Tier 4

- Smaller
- Non visible probe
- Less clinical looking (e.g. more colourful)
- Chargeable monitor or longer battery

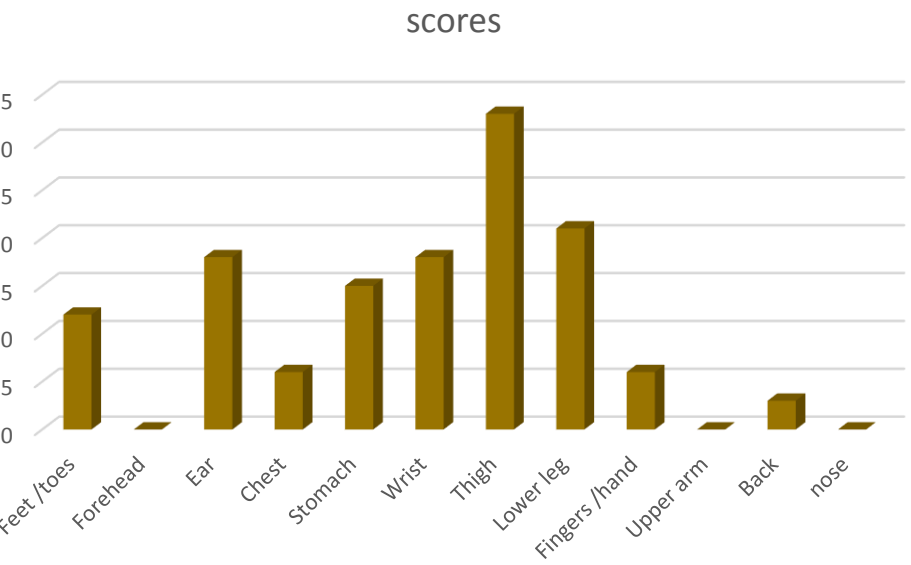
Preferred placement of sensor

- 3 choices Per person 1st, 2nd and 3rd
- Attach to mannequin



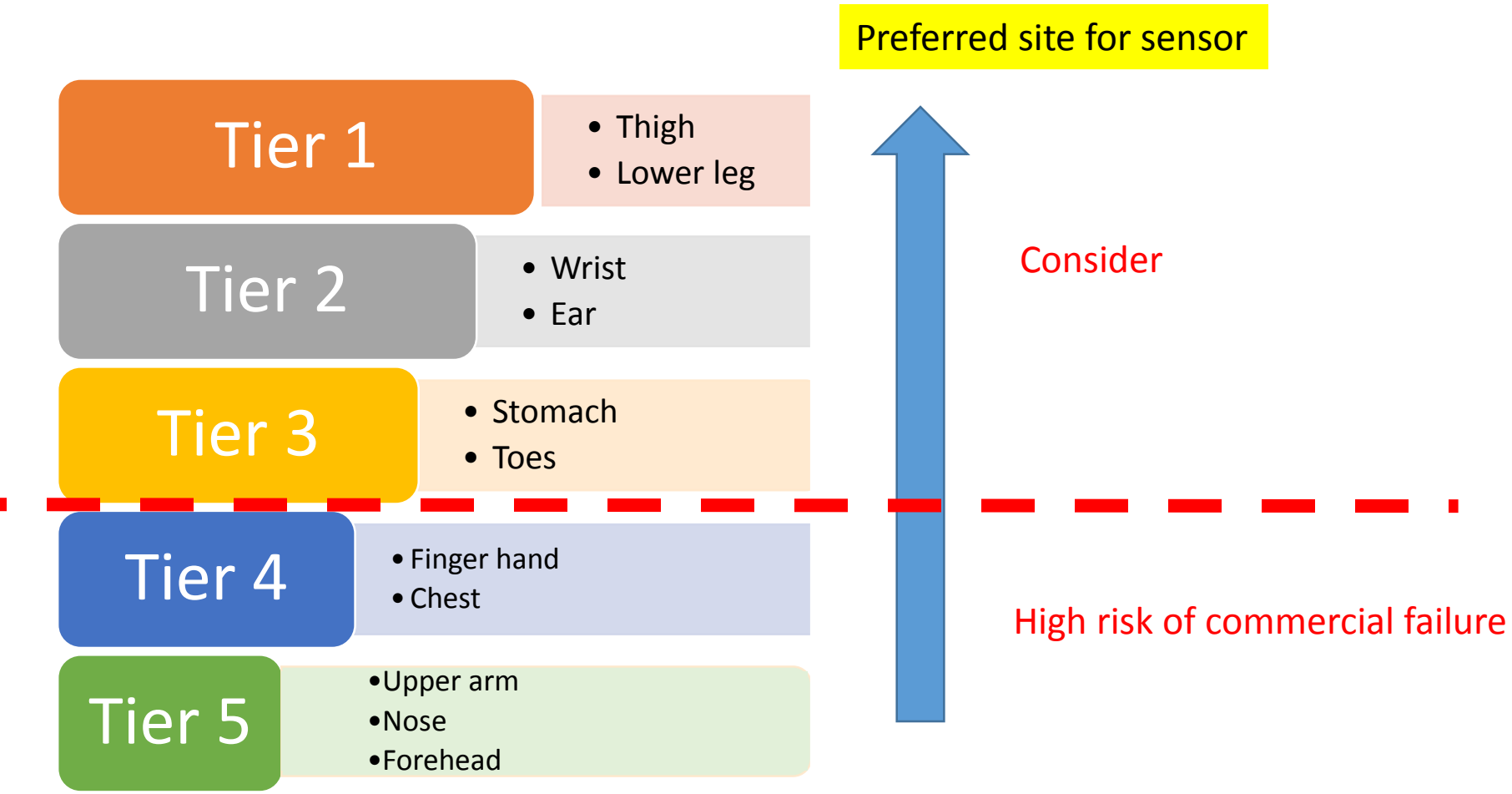
Scoring system	
1st=	9Pt
2nd=	6pts
3rd	3pts

Location	Total scores
Feet /toes	12
Forehead	0
Ear	18
Chest	6
Stomach	15
Wrist	18
Thigh	33
Lower leg	21
Fingers /hand	6
Upper arm	0
Back	3
nose	0



Tier 1	• Thigh • Lower leg
Tier 2	• Wrist • Ear
Tier 3	• Stomach • Toes
Tier 4	• Finger hand • Chest • Forehead

Preferred placement of sensor



Information form patient diary cards

Gender	Age	PMH	Comments
M	3	Respiratory Chest Issues	02:00 - woke up crying as did not want it on foot, refusing to have sensor back on, 04:30am - still refusing to have sensor on and kicking it off, does not want the machine on his toe
M	10	Duchennes Muscular Dystrophy	not the best night's sleep due to the wires and the machine buzzing
M	1	Down Syndrome	probe detached from toe after 1.5 hours
M	14	Epilepsy	2 nights - probe off 3 times first night, 2 times second night
M	0.88	Parental reports of breathing pauses	Night 1 - 10:15 woke after 2 hours as monitor off foot.11:45pm - finally reattached to toe; 03:15am - turned off machine as patient woke up and machine fell off foot. Would not let me put it back on. Night 2 - 09:30pm attached; 09:44pm woke up - put it back on as wasn't on toe properly; 12:30 - turned off as patient fully awake and won't let parent put it back on. 01:00 am reattachedm working ok. 01:45am - turned off for the night as won't keep it on foot and distressed
F	3	Sleep related breathing disorder	Night 1 - 20:42 bedtime; 20:47 - asleep; 01:15 - came off toe ?exact time; 07:52- awake Night 2 - 18:30-asleep; 20:33 - came off toe; 07:15 - awake
F	3	Wheeze	Overnight - woke up several times taking off the wire and falling back to sleep. Had to reattach the wire using up most of the stickers
F	2	Choking, ?asthma	Moved wire and probe cauing machine to alarm. Probe kept falling off causing machine to alarm.
M	7	?sleep disordered breathing. Autism	Tried with machine at home for 2 nights - failed, no data

Confirms findings from focus group.

- Patients do not like it on foot
- Wires and buzzing result in poor nights sleep
- Sensor not remaining attached was a problem in a number of patients
- False alarm due to moved wire

➢ This non solicited opinion validates data and conclusions from the focus groups

Summary sensor placement

Clinician	Patient	Acceptable to both
• Forehead • Ear • Chest • Wrist • Lower Leg • Hand • Big Toe	• Thigh • Lower leg • Wrist • Ear • Stomach • Toes	• Lower leg /thigh? • Wrist • Ear • ?

Summary -Future needs

Clinician

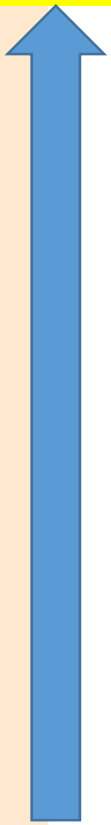
- Wireless sensor
- Reduction in motion artefacts
- Earlier response warning system for carer/patient
- Can be worn during activity
- Event recorder
- Reduced risk of probe becoming detached
- Patient comfort
- Portability of system
- Ease of application

Patient

- Wireless sensor
- Reduce pressure/ burning on sensor
- Access data remotely (via an app)
- Better sensor that is more comfortable (e.g. soft materials)
- robust
- Easier to attach / does not fall off
- More reliable/ less false positives
- Record data (e.g. on SD card or alternative)
- Smaller
- Non visible probe
- Less clinical looking (e.g. more colourful)
- Chargeable monitor or longer battery

Potential design inputs

Most important



- Wireless sensor
- Reduced pressure on sensor
- Access data remotely
- Reduction in motion artefacts
- Can be worn during activity
- Event recorder
- More comfortable sensor
- Robust
- Easy to attach/ doesn't fall off
- Earlier warning system