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Neonatal Technology Development – using the delivery room as an example

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Professor of Neonatal Medicine & Technologies
University of Nottingham, UK

EPTRI Webinar 17/9/2024

Declarations/CoI:

- NIHR CYP MedTech Cooperative neonatal lead
- UK Neonatal Transport Group Research Lead
- Clinical Director & shareholder SurePulse Medical Ltd
- Number of patents relating to newborn monitoring
- Work with number of industry partners

Outline

- Barriers
- Technology readiness level
- Delivery room technologies
- Examples neonatal specific tech development
- Conclude

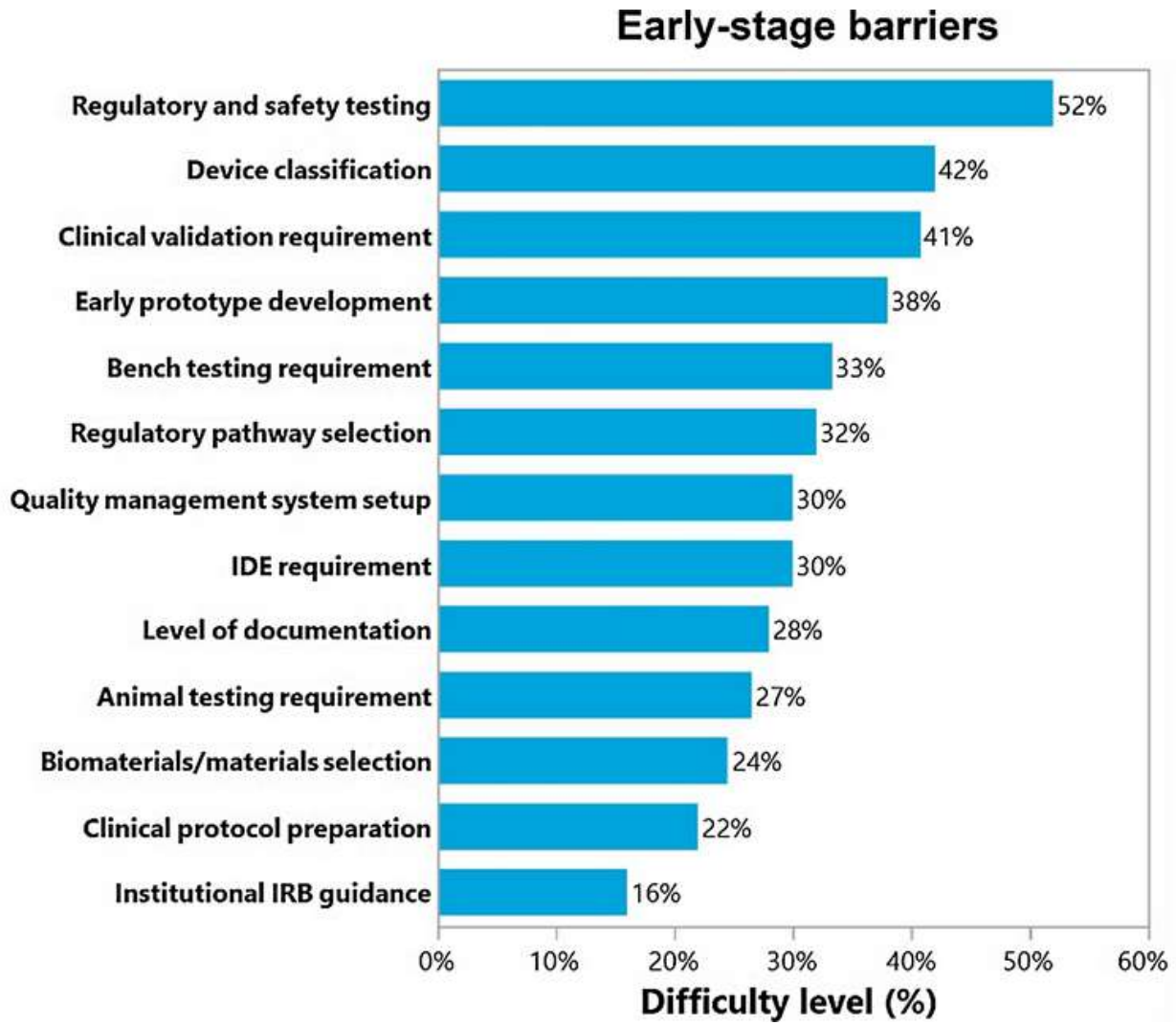
Barriers to paediatric device development

- Small pediatric disease population
- Difficulty in clinical trial enrollment
- Parental consent
- Liability concerns

- Translational Researchers
  - Academic recognition
  - Funding
  - Time (5-15 yrs device development)

Shah et al J Clin Tran Sci 2023

Barriers to paediatric device development



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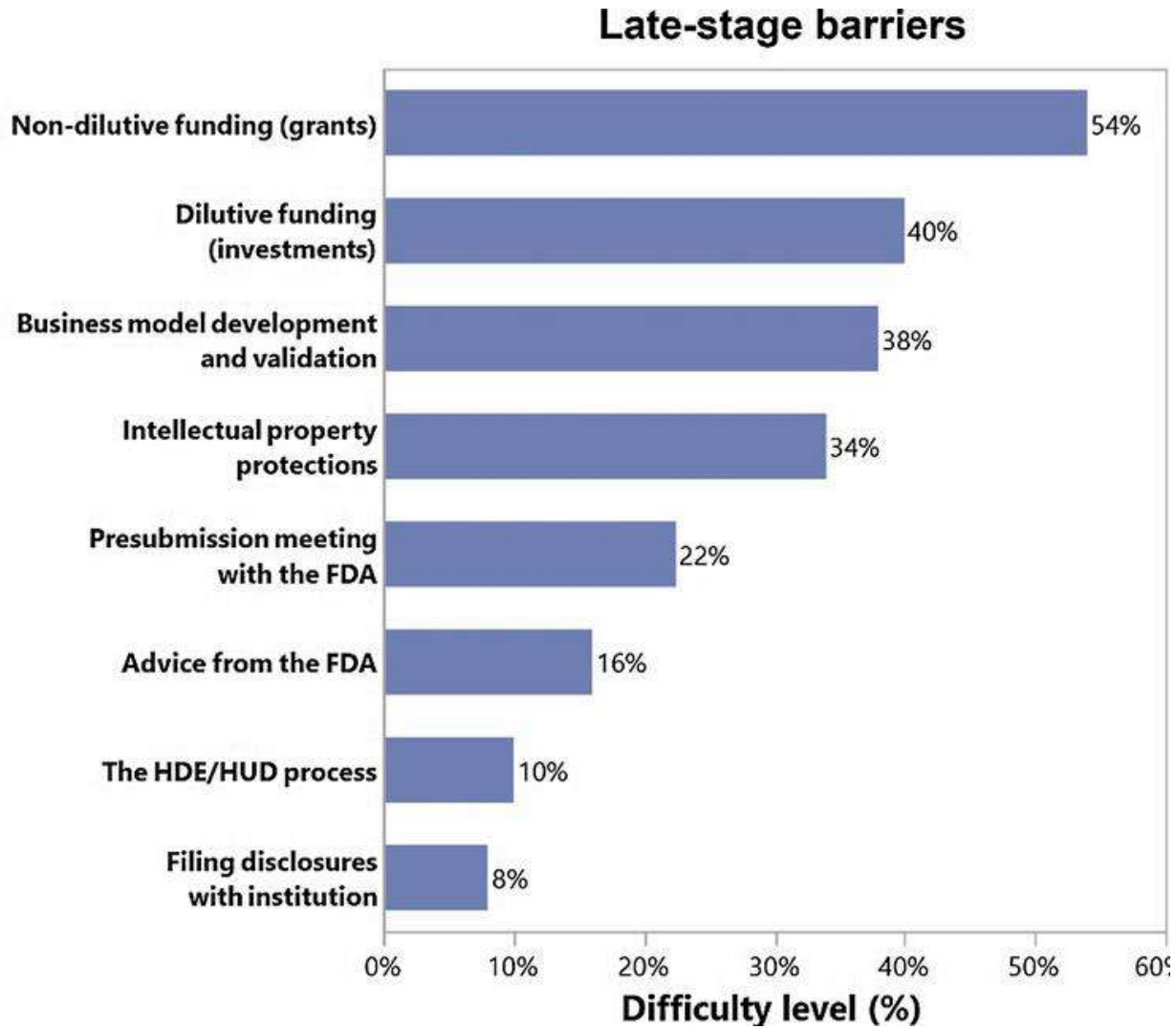
Barriers to paediatric device development



Shah et al J Clin Tran Sci 2023

Have you used…..

CE/FDA approved device not studied in infants/children?

“Off license” use of a medical device in neonates?

I have no idea if the devices I use have been studied in neonates prior to regulatory approval?

Impact of these barriers

- Class III medical devices approved for children
- Pre-marketing/Humanitarian exemption path
- 25 devices between 2008-2011
- 21 (84%) **not studied in patients <18yo**

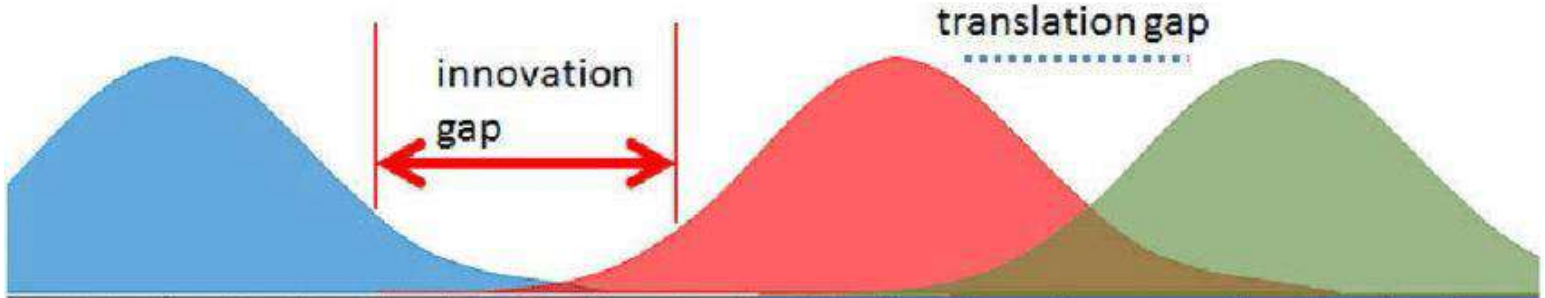
- Post-marketing studies mandated by FDA 3 required enrolment of paediatric patients

Bourgeois et al Peditrics 2014

Impact of these barriers

- Devices **NOT** studied in children (licensed to use!)
- Most devices ‘adapted’ adult devices, not designed for unique needs of population
- Neonatal devices
  - Niche
  - Small population
  - Challenging disease/anatomy/physiology
  - Commercial gains?
  - Argument ‘orphan’ recognition

Technology Readiness Level (TRL)



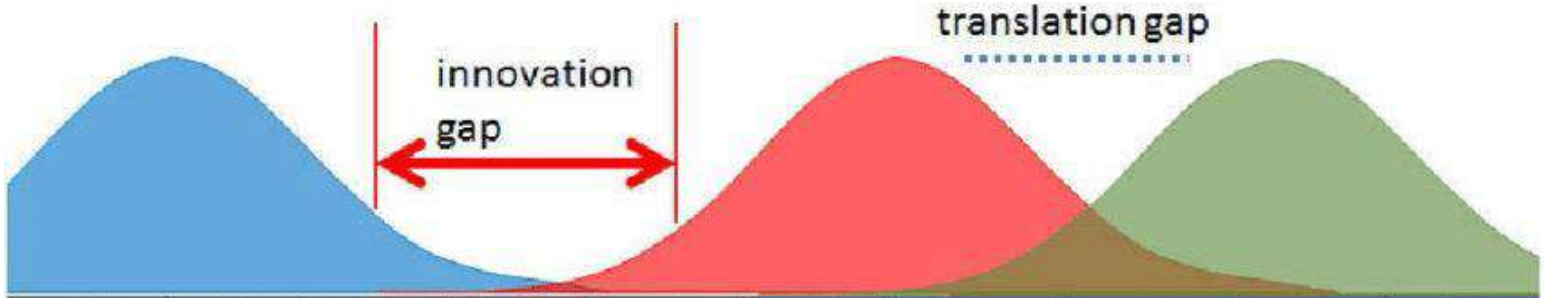
TRL	1	2	3	4	5	6	7	8	9
Activity	Discovery & Research		Innovation					Commercialisation	
Description	basic principles observed	application formulated	experimental proof of concept	lab validation	(system or component) validation in relevant environment	demonstrator in relevant environment	system prototype demonstrated in operational environment	system complete and qualified (test & demo) in operational environment	actual system proven in operational environment

Academia

Commercial

10-15 year pathway

Technology Readiness Level (TRL)



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Academia

Commercial

Technology focused researcher

Conceptualisation (TRL 1-2)

An unmet need is recognised, prompting an idea for a medical device to address a specific problem. "Proof of concept" is developed, determining feasibility and practicality. Market analysis conducted to determine which devices to support.

Prototype & pre-clinical testing (TRL 3-4)

Development, validation and design, followed by laboratory testing and refinement of prototype. Patient and Public Involvement and Engagement (PPI/E)

Clinical testing (TRL 5-6)

Clinical trials conducted following approval from sponsoring institution, ethics approval and regulatory notification. Device redesigned if required based on trial results.

Conformity assessment

Device checked for conformity to regulatory standards (e.g., CE or FDA) by a third-party organisation. Declaration of Conformity drawn up once certified.

Regulatory approval

Device registered with country-specific regulatory body (MHRA in the UK, FDA in USA).

Device production & launch (TRL 7-8)

Full manufacturing and market launch.

Post-market surveillance (TRL 9)

Manufacturer continuously monitors device performance and submits vigilance reports to the regulatory when incidents occur in the respective market.

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The critical role of technologies in neonatal care

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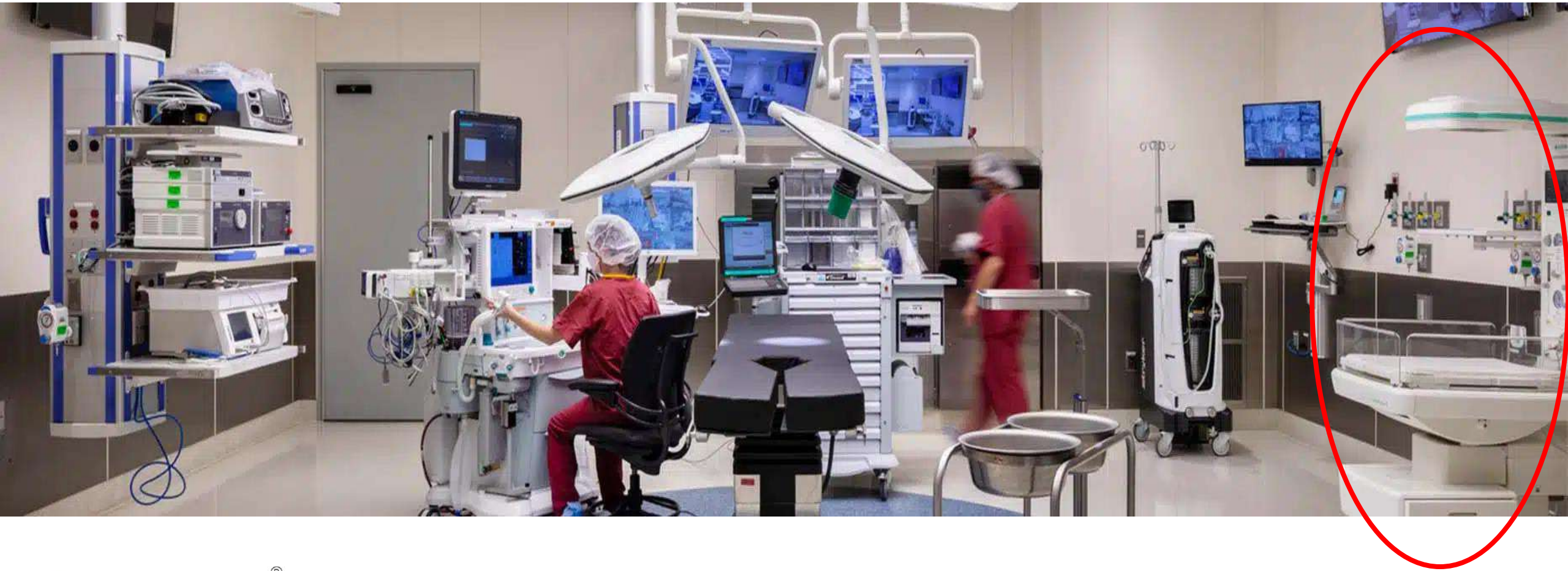
The Obstetric theatre (delivery room)



Delivery room – ILCOR guidance

Year	Key elements	Technologies
2000	• Suction for meconium • 100% O_2 for resuscitation	• Stethoscope • Exhaled CO_2
2005	• Less suction for meconium • Move to air for term resuscitation	• T-piece devices • Plastic bags
2010	• Monitor heart rate & SpO_2 • Consider CPAP	• Pulse oximeter
2015	• Delayed cord clamping • Monitor heart rate & oxygen saturations	• Pulse oximetry ± ECG • Humidified gases
2020	• Reducing invasive ventilation • Focus on monitoring again	• ECG for heart rate • Pulse oximetry for SpO_2

Batey et al Ped Res 2022

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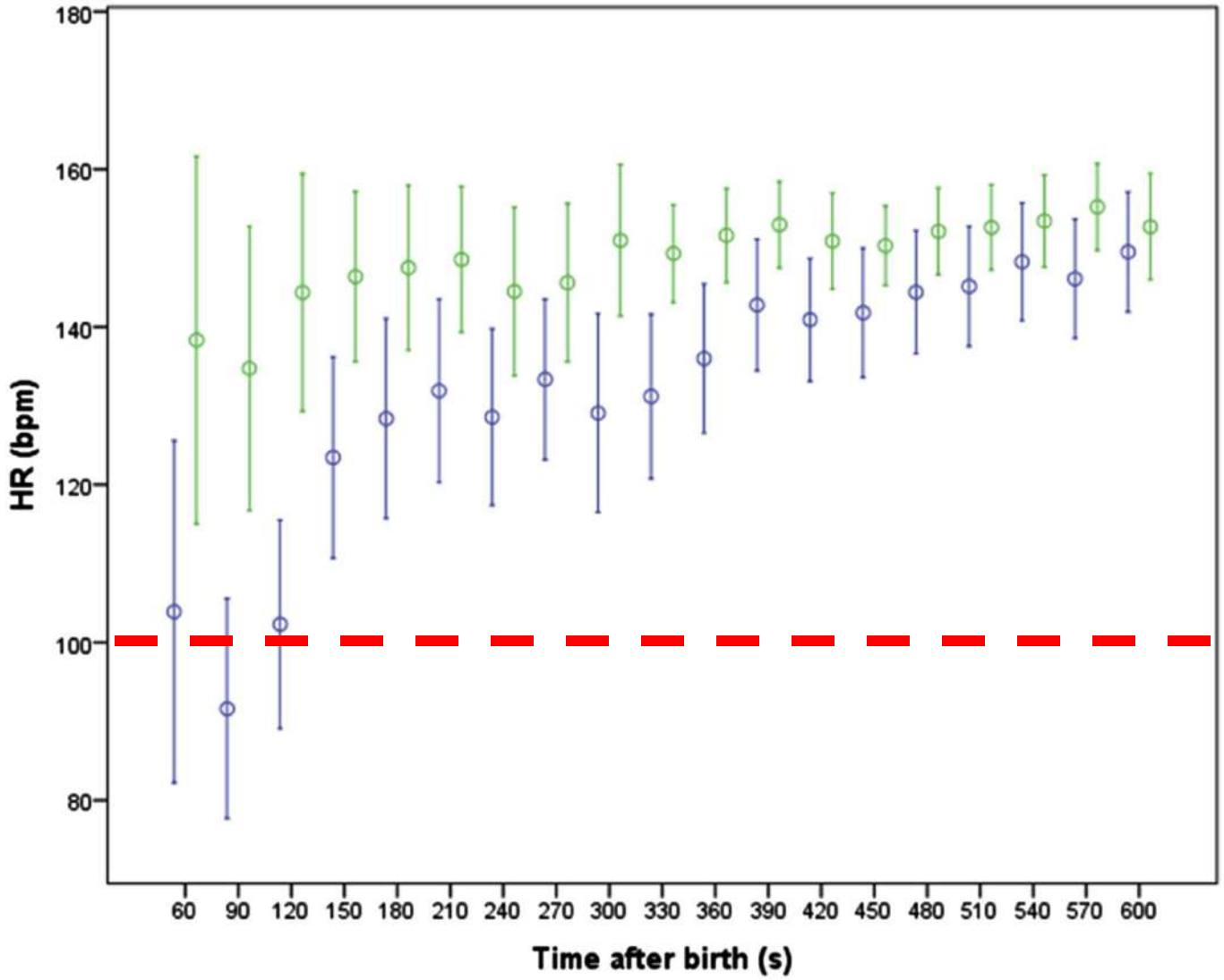
Batey et al Ped Res 2022

ECG vs Pulse Oximetry heart rate at birth



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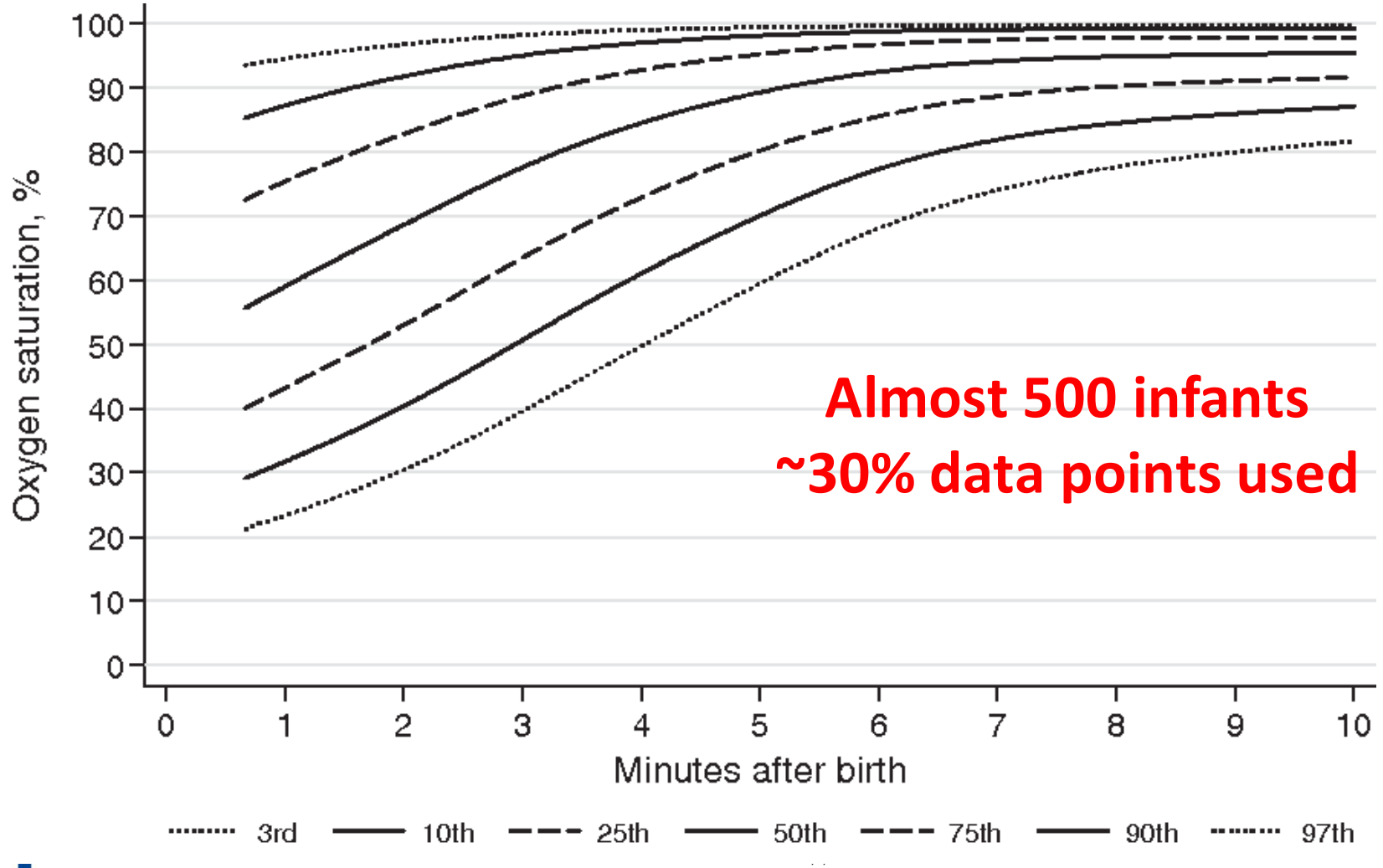
van Vonderen J Peds 2014

SpO_2 at birth – well newborns



Dawson Pediatrics 2010

‘Technology’ in the delivery room

- Remains relatively basic but evidence-based
- ILCOR guidance (Resuscitation 2023)
  - Plastic bags/wraps
  - Hat/cap
  - Humidified gas
  - ECG
  - Pulse Ox (for HR if no ECG)

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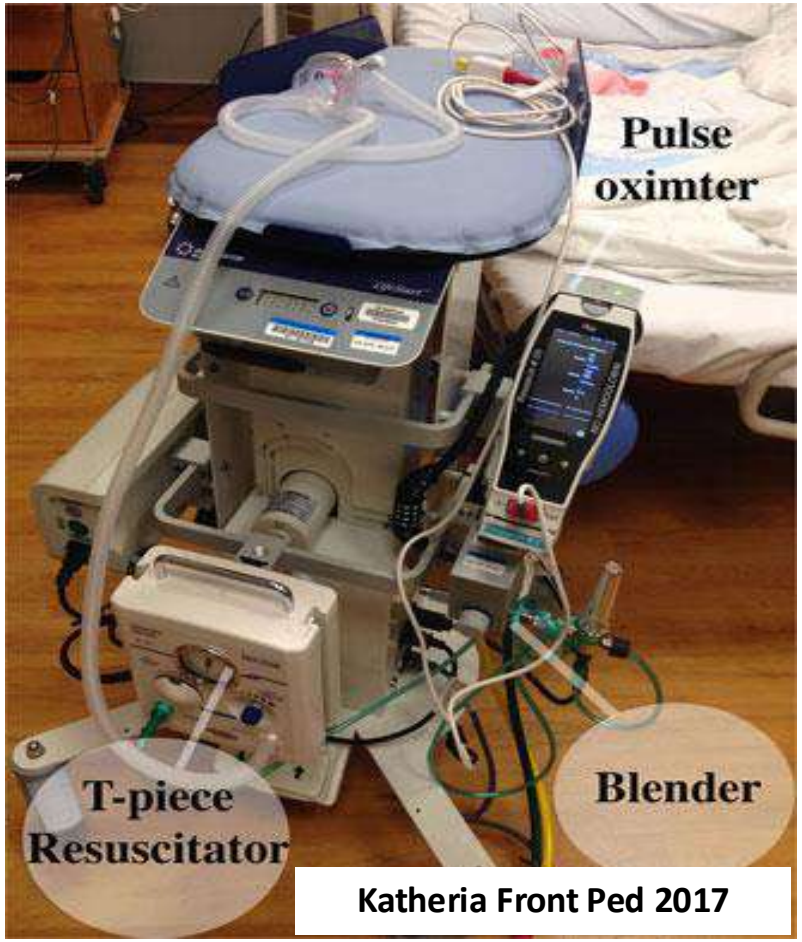
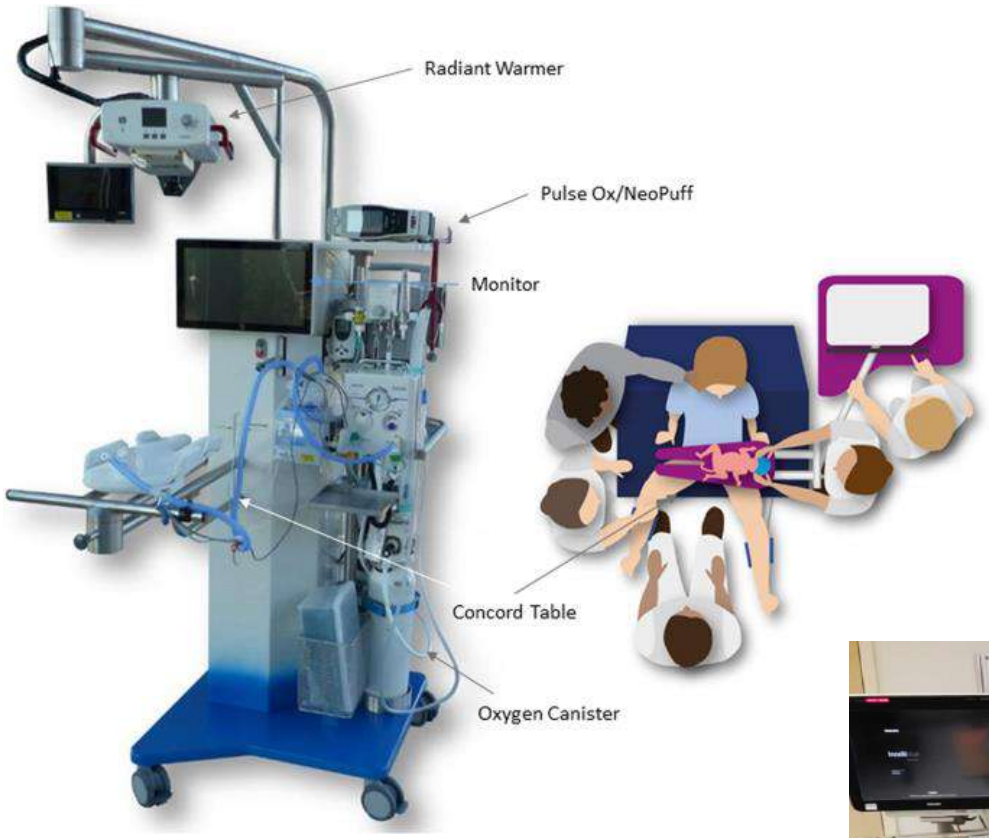
‘Technology’ in the delivery room



Katheria Front Ped 2017

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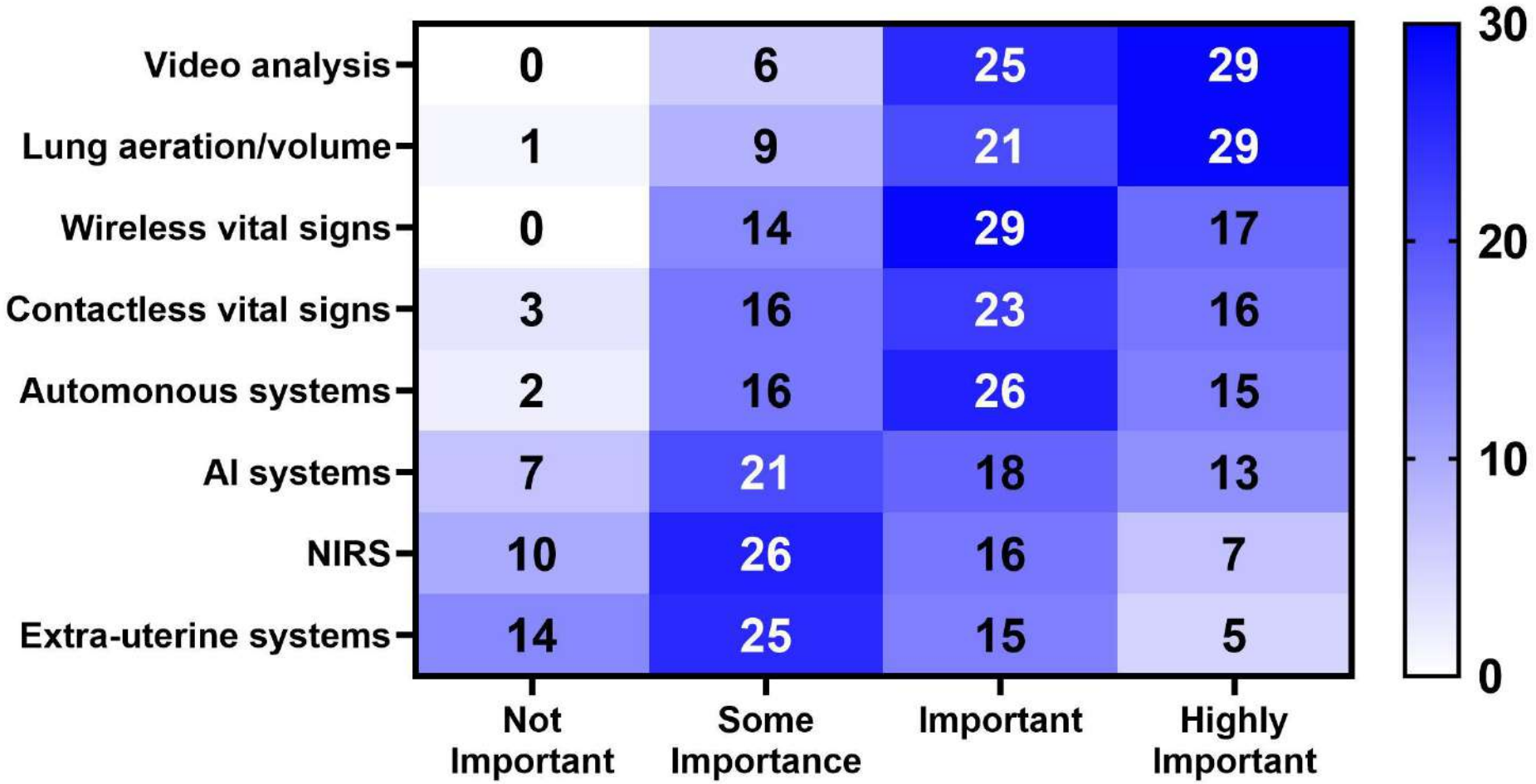
Other Tech in the delivery room

- Near infrared spectroscopy (NIRS)
- Multi-centre RCT, protocol driven
  - Cerebral regional tissue oxygen saturation to guide oxygen delivery in preterm neonates during immediate transition after birth (COSGOD III)
  - >600 infants, stopped 10% short sample size
  - **No difference in survival without cerebral injury**
  - **Similar findings in NICU**

What do leading clinicians want in DR?

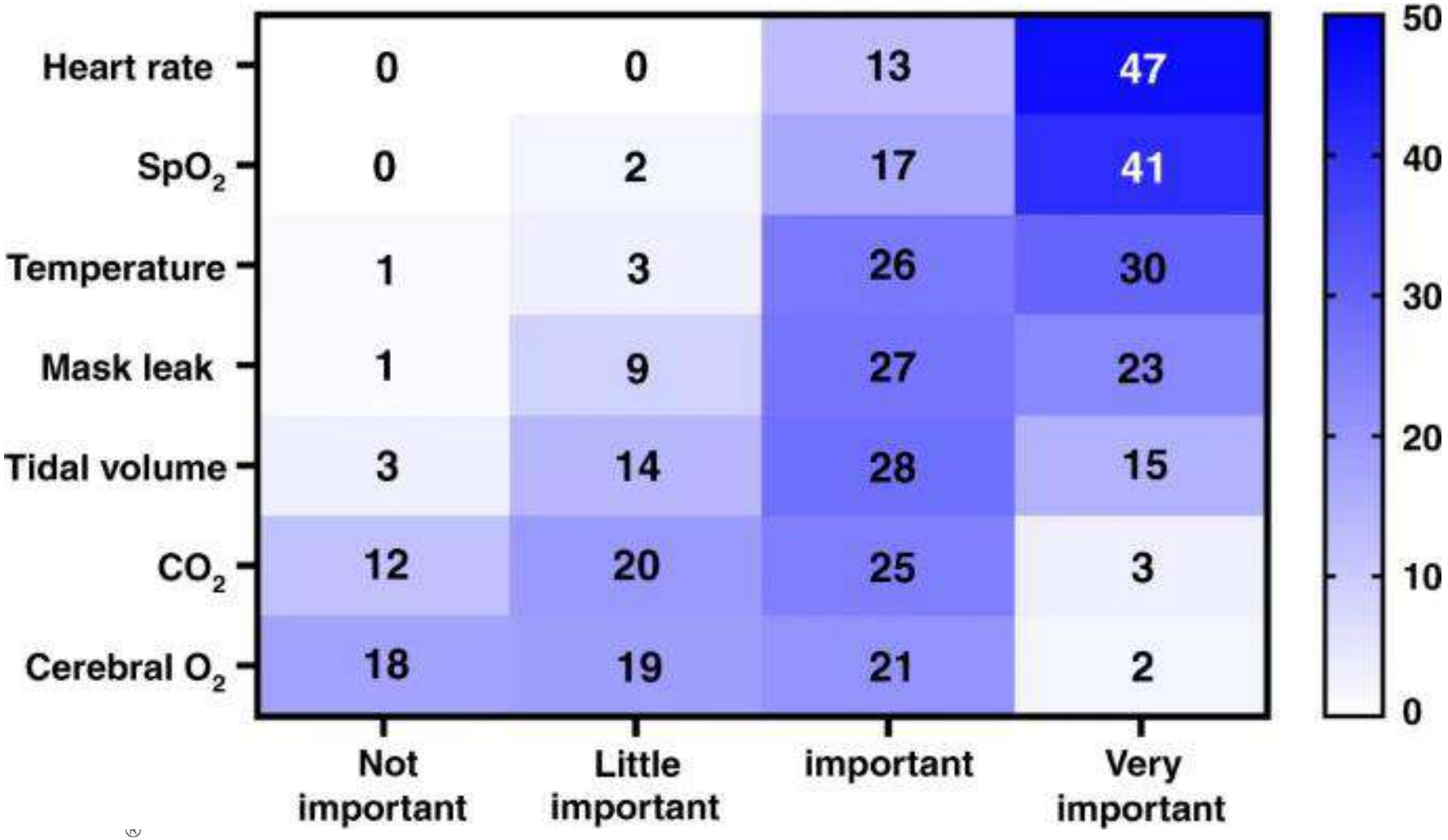


Batey et al Ped Res 2022

Better monitoring

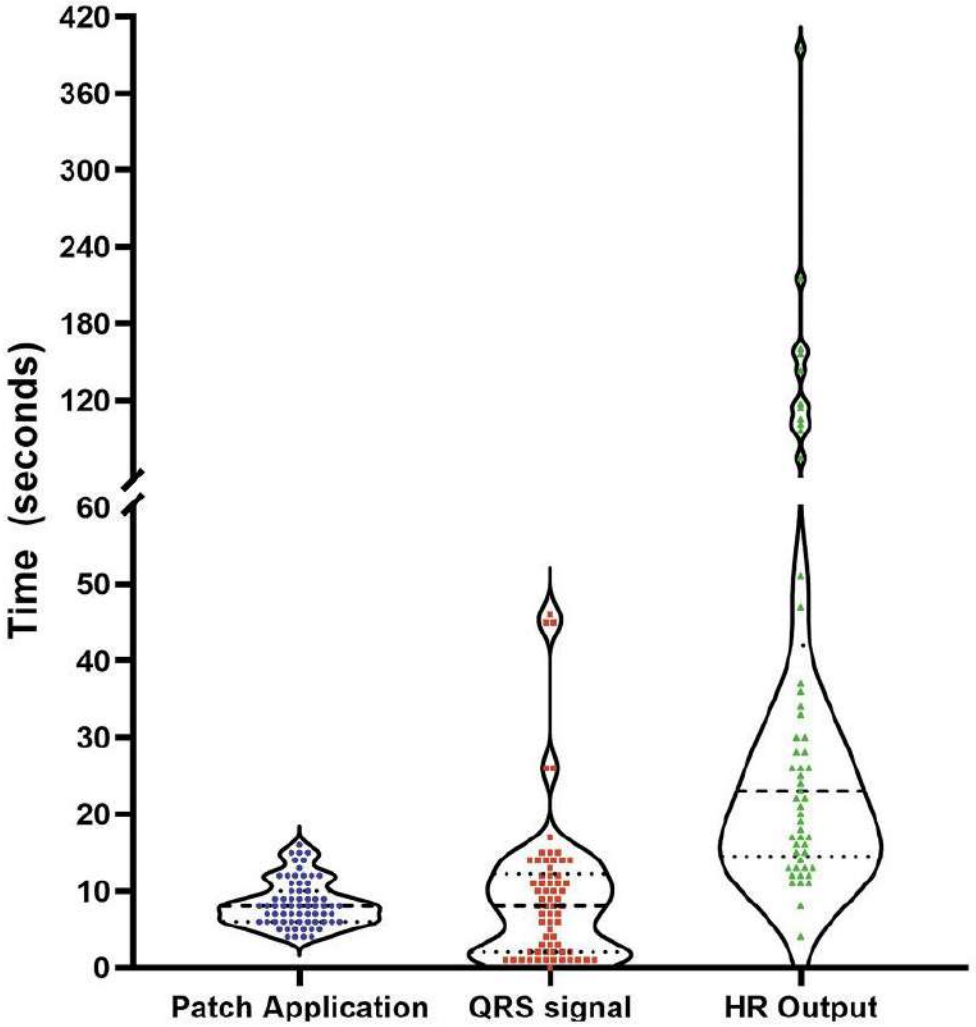
surepulse
Every second counts

Important monitoring measures?



Batey et al Ped Res 2022

Henry Neonatology 2022

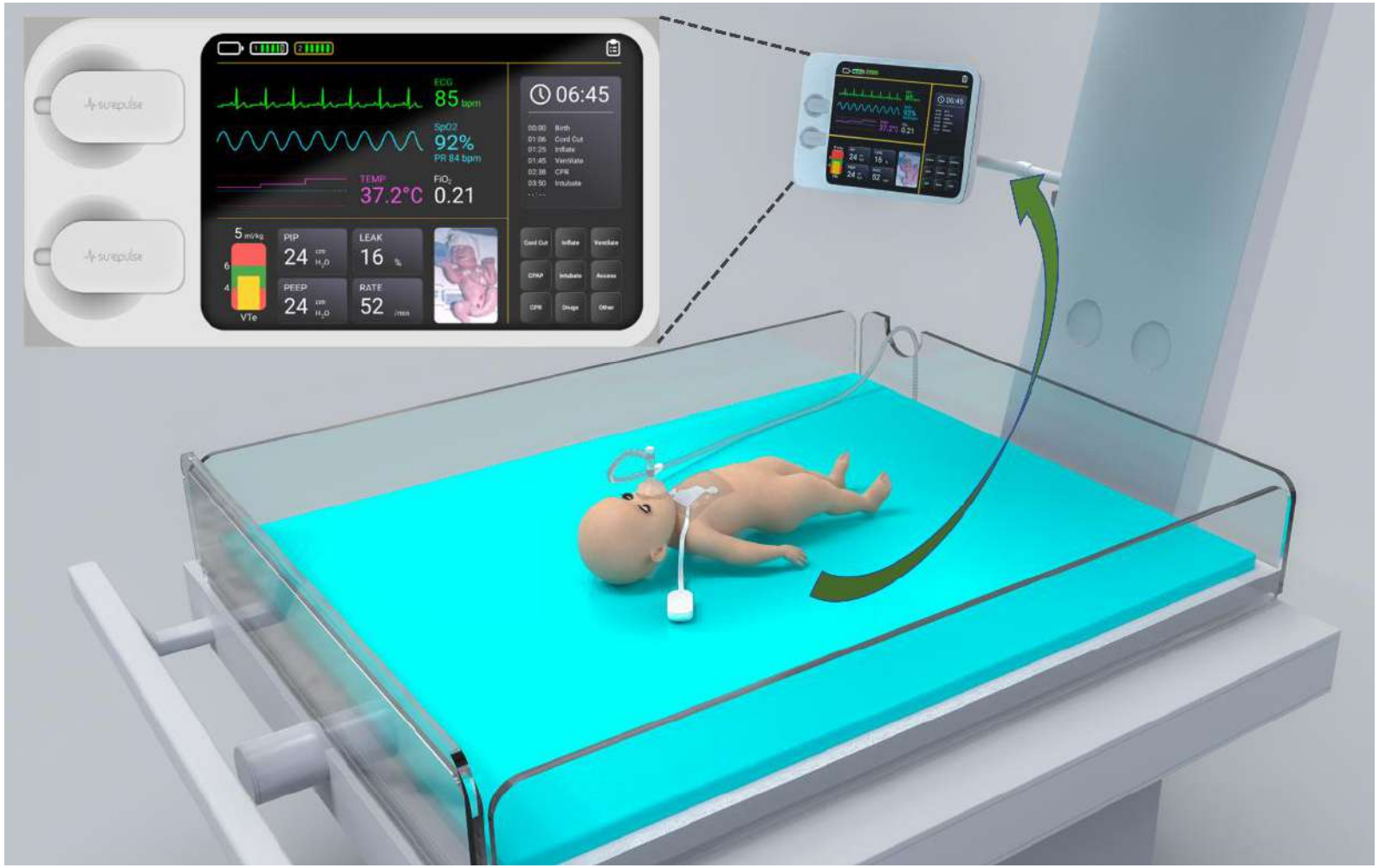

Time (seconds)
420
360
300
240
180
120
60
50
40
30
20
10
0
Patch Application
QRS signal
HR Output


>200 electrodes
NO detachments

Next generation neonatal monitor

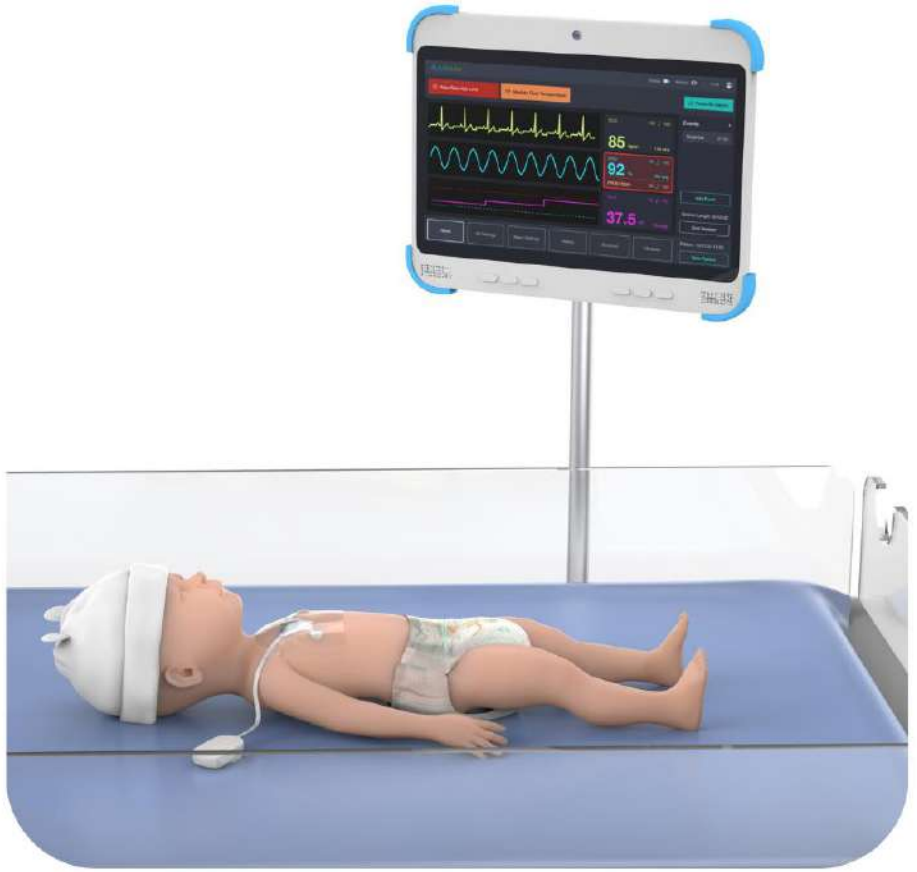
- Designed for newborns and unique environment
- Provide key vital signs
- Accurate and reliable measurements – within 1 minute
- Wireless
- Enhance optimal cord management, delivery room cuddles
- Potential to use video, RFM, artificial intelligence…..

Next generation neonatal monitor



SUPPORTED BY

Next generation neonatal monitor



NICU Kangaroo Care

Neonatal device development

- Small population
- Difficulty in clinical trial enrollment
- Parental consent
- Liability concerns
- **BUT**
  - Can be done – getting through maze
  - Potentially huge benefits

Neonatal device development

- In an ideal world
  - More funding (avoid valleys)
  - More industry engagement/resource
  - Smoother regulatory path
  - Designed for unique needs and unique environment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