SurfON Trial – Associate PI Webinar

5th May 2022

Delivered by Dr Ranveer Sanghera

Associate PI for SurfON Leicester, Neonatal Grid Trainee

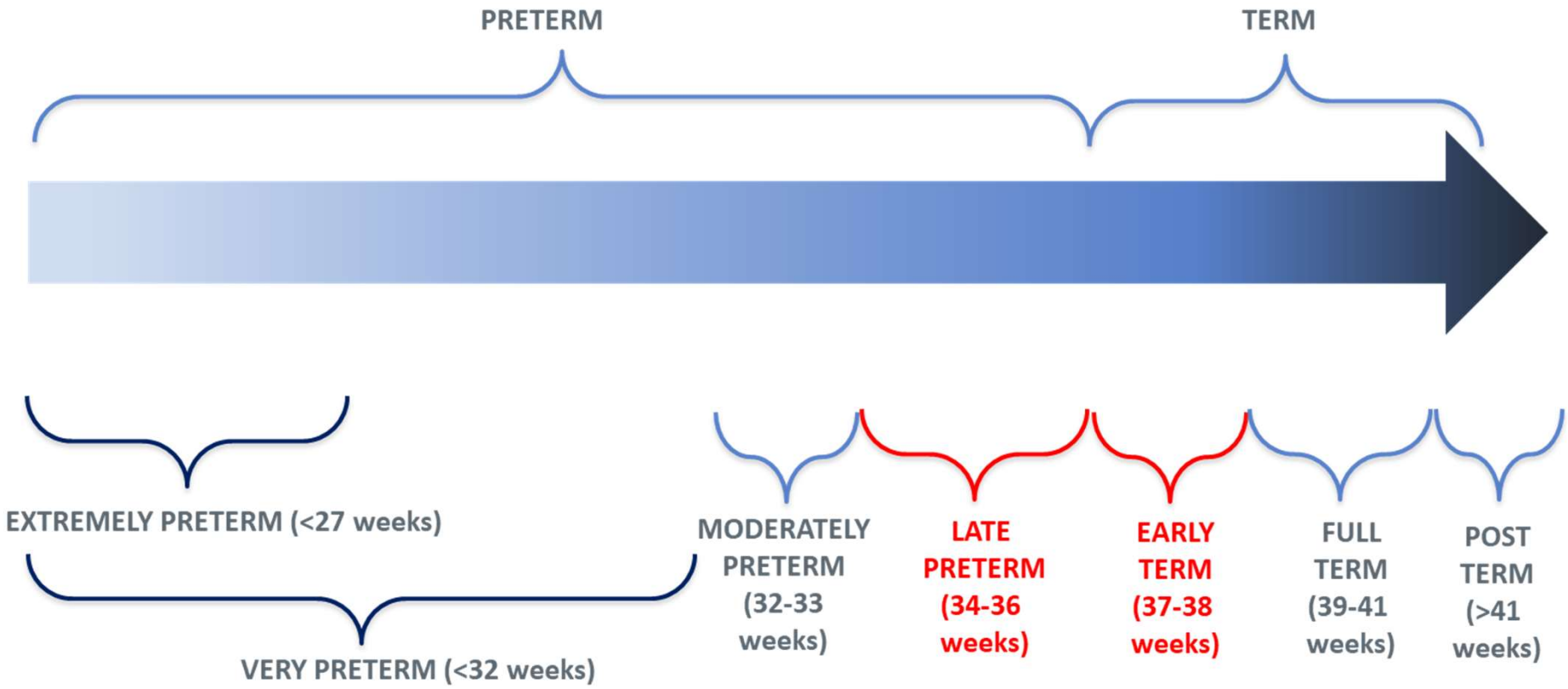
Presentation overview

- Brief overview of the background and rationale for the SurfON Study
- Brief overview of our Primary outcomes

- Why have we paused recruitment?
- How we can utilise the pause effectively

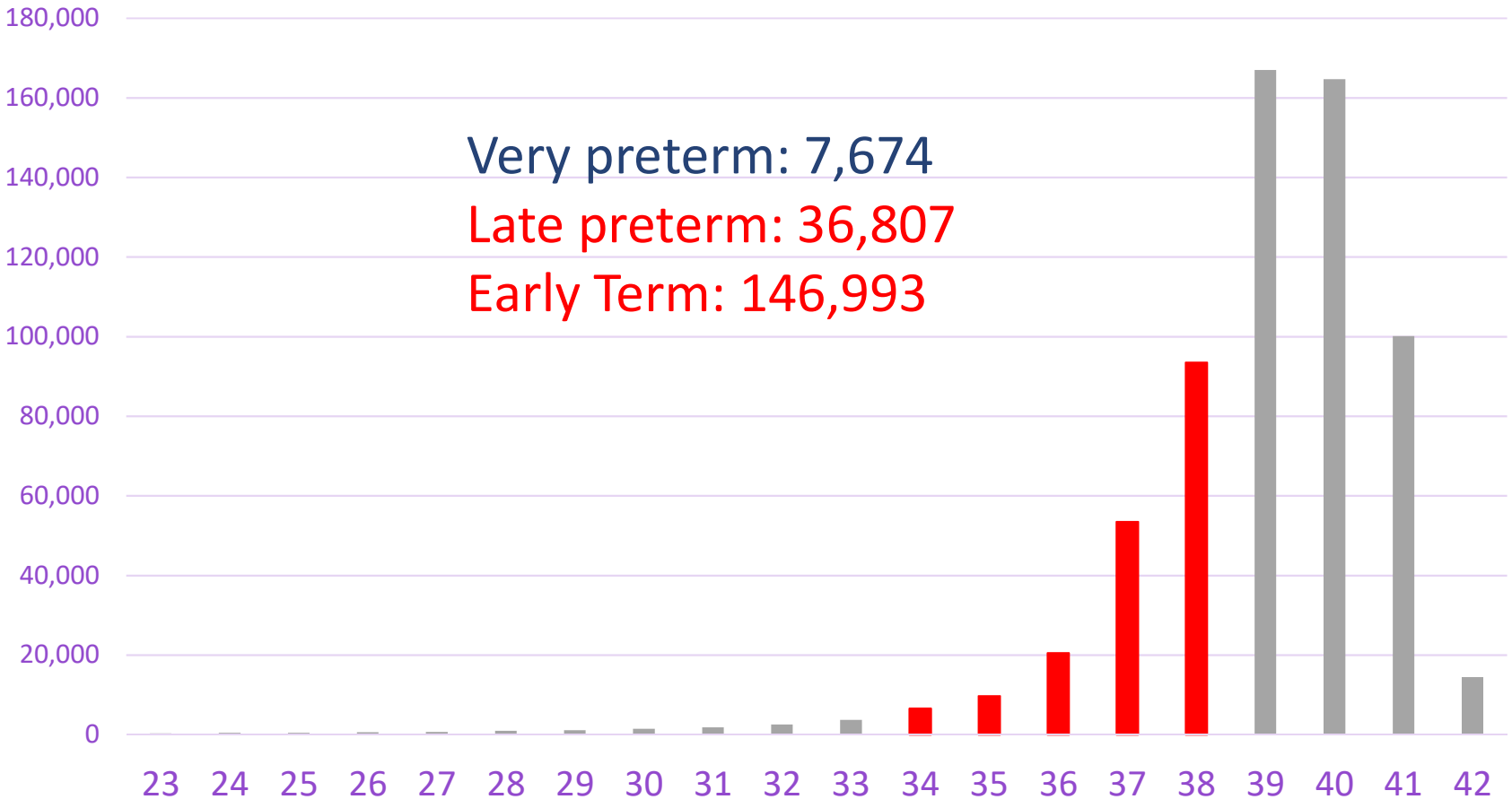
- What is means to be an Associate PI
- Why and how I became an API

Background & rationale for study



Gestational age

Live births by week of gestation
(England and Wales 2017)



SurfON
Surfactant Or Not

Current practice

- Variable between and within neonatal units
- Some clinicians treat early with surfactant to prevent deterioration
- Some prefer to adopt a ‘watch and wait’ approach
- No defined limits for intervention
- No evidence for either approach
- Both can be regarded as “standard care”
- No RCTs in this group of babies

SurfON
Surfactant Or Not

HYPOTHESIS

Early, proactive management of respiratory disease will

- reduce the progression to severe respiratory failure requiring mechanical ventilation
- reduce length of hospital stay
- reduce early hospital readmissions
- reduce costs of neonatal care

Study Objectives

- To compare **duration of neonatal hospital stay** in infants randomised to receive early surfactant versus those who received expectant management

- To compare **incidence of severe respiratory failure** in infants randomised to receive early surfactant therapy versus those who received expectant management

- To investigate the effects of early surfactant therapy versus expectant management on **perinatal secondary outcomes**

- To investigate the **cost-effectiveness** of early surfactant therapy versus expectant management

Primary outcomes

1. Length of infant's hospital stay after birth, defined as,
   the number of days from birth to discharge home from hospital

2. Incidence of severe respiratory failure, defined as,
   sustained (≥ 30 minutes) requirement for FiO_2 ≥ 0.45 to maintain SaO_2 ≥ 92%

Study Criteria

Inclusion criteria

1. Born at 34^{+0}–38^{+6} weeks of gestation
2. ≤ 24 hours old
3. Respiratory distress, defined as:
   - FiO_2 ≥ 0.3 and < 0.45 to maintain oxygen saturations SaO_2 ≥ 92%

   or

   - Clinically significant work of breathing, regardless of FiO_2
4. Clinical decision to provide non-invasive respiratory support
5. Written parental informed consent

Exclusion criteria

1. Major structural or chromosomal abnormality
2. No realistic prospect of survival
3. Prior intubation and/or surfactant administration
4. Known or suspected hypoxic ischaemic encephalopathy
5. Congenital abnormality of the respiratory tract
6. Known or suspected neuromuscular disorder

Why have we paused recruitment?

- Adverse effects of COVID-19 on all research
  - Focus on COVID-19 related studies
  - Late start and slow set-up
  - Fewer sites than anticipated
  - Fewer babies recruited
  - Omicron variant
  - Local capacity & capability issues

- NIHR – review of all studies after COVID-19
  - Recognise some will need to close
  - We do not want SurfON to be one of them

Utilising the pause effectively

- CI visit to all sites in person where possible
- Virtual visit where distance precludes F2F visit
- Set-up of new sites – aiming for 45 in total
- Explore methods of enhancing recruitment
  - Associate PI Scheme
  - SurfON Champions
- Explore any other factors that might be influencing recruitment
- Share tips

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SurfON

NIHR CRN Associate Principal Investigator Scheme

Associate PI Scheme – Structure

- Open to any doctor, nurses and AHPs willing to make a significant contribution to the conduct and delivery at a local level. The scheme is not open to those who are funded to work on research, such as Research Nurses.

- Participation in the Associate PI Scheme does not absolve local PIs of their responsibilities at site. Local PIs will act as mentors to their Associate PI.

- Commitment of at least 6 months will be required for gaining Associate PI status.

- Must register prospectively- retrospective recognition is not possible

Why did I become an Associate PI

Research

- The opportunity to be involved with a higher level of research
  - not just recruiting, consenting and randomising,
  - looking at the inner working of the research study

My development

- Good for your CV
- Good for consultant working
- Helps me understand research at a different level.

Liked the study

- I am a firm believer in increasing the awareness that late preterm and early term infants, as they don't do as well as their term counterparts.
- The management of these infants is different between clinicians.

Benefits of the Associate PI Scheme

For the Associate PI

- Experience of research - able to contribute to the conduct and delivery of a study at local level with the oversight of the local enthusiastic PI.
- Learns about the challenges and practicalities of delivering a portfolio study, understands the responsibilities associated with the PI role, and their participation is recognised through certification for their CPD portfolio.
- Associate PIs will be acknowledged in the primary publication(s) from the study, which will be defined upfront on an individual trial basis.

For the PIs

- Additional support with the delivery of the study
- Play a part in developing the PIs of the future

For CTUs

- Increased support for the trial at sites- managing delegation logs etc
- Speedier delivery

For the Patients

- Increased opportunities to be involved in high- quality research

How do I become an Associate PI?

- Create an account with NIHR
  - If you have done GCP you should already have an account
- Find the study you are interested in.
- Register your interest with study
- Form to fill out
- Must be GCP trained
- Research CV required
- Must be on delegation log already.
- You are then given your API status after 6 months after filling in a checklist.

Associate PI Scheme - How to Register

Go to the NIHR Associate PI Scheme Website :
https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040

To register yourself as an Associate PI, complete the Associate PI Scheme Applicant Registration Form


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Associate PI Scheme - Applicant Registration Form

This form should be completed by applicants wishing to register for the Associate PI scheme.

If you would like to apply for Covid-19 Urgent Public Health studies, please use the form at the following link:
https://docs.google.com/forms/d/e/1FAIpQLSc-y-Y_qgl42hFkznZk_eZLCNkCq7liUYZkiI4I0Kxy0nDykQ/viewform

The scheme has been endorsed by the NIHR Clinical Research Network and the following Royal Colleges:

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Please Note - Applicants need to download and save a copy of this checklist and edit your version, we cannot give you edit access to the live document.

Associate Principal Investigator (PI) Status Checklist

Associate PI Name:			
Study Name:			
Specialty:			
CPMS ref:			
Site/GP Practice:		**ODS Code** (If applicable):	

Clinical Trials Unit: Associate PIs should fulfill the criteria below. This form should be completed during the Associate PI time period. Towards the end of the rotation or time period, the Associate PI applicant should meet with the local PI (and research delivery team) in order to review the Checklist and if completed satisfactorily, the PI should sign it off. The Checklist should then be forwarded to the Study Coordinator/Trial Manager for final confirmation that the activities described have been undertaken.

Associate PIs MUST register prospectively via the NIHR website (https://www.nihr.ac.uk/documents/associate-principal-investigator-pi-scheme/25040). If applicants are not registered prospectively and submit a checklist of activities their application will be rejected.

Participation in the Associate PI Scheme does not absolve local PIs of their responsibilities at site. The Local PI remains responsible for the oversight of the trial/study at site, including the activities of the Associate PI.

All activities undertaken by the Associate PI must be undertaken in line with GCP and, for CTIMP trials, the Medicines for Human Use Clinical Trials Regulations.

We are looking for SurfON Champions to help us recruit at least

1-2 Babies Per Month at every site

Could YOU be our local Champion?

SurfON Study Team

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- Charles Roehr (Clinical Director, NPEU CTU)
- Christina Cole (Senior Trial Manager)
- Ann Kennedy (Assistant Trials Manager)
- Andy King (Head of Trials Programming)
- David Murray (Senior Trials Programmer)
- Kayleigh Stanbury (Head Of Operations)
- Joy Wiles (Quality Assurance Manager)
- Richard Welsh (Senior Software Developer)
- Madeleine Hurd (Data Manager)

Co-Investigators

- Marie Hubbard (Neonatal Research Nurse)
- Ed Juszczak (Medical Statistician)
- Oliver Rivero-Arias (Health Economist)
- Ben Stenson (Neonatologist)
- David Sweet (Neonatologist)
- Bliss Charity

NPEU Clinical Trials Unit

UNIVERSITY OF OXFORD

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The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Thank you for listening

Questions & feedback

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Systematic Review

Arch Dis Child Fetal Neonatal Ed. 2021 Oct 22;fetalneonatal-2021-322890.
doi: 10.1136/archdischild-2021-322890. Online ahead of print.

Surfactant therapy in late preterm and term neonates with respiratory distress syndrome: a systematic review and meta-analysis

Viraraghavan Vadakkencherry Ramaswamy [1], Thangaraj Abiramalatha [2], Tapas Bandyopadhyay [3], Elaine Boyle [4], Charles Christoph Roehr [5 6 7]

- 17 studies (16 observational studies ,1 randomised controlled trial)
- 46% (95% CI 40% to 51%) were treated with surfactant.

Conclusions: Current evidence base on surfactant therapy in LPT and term infants with RDS indicates a potentially decreased risk of mortality, air leak, PPHN and duration of respiratory support.

In view of the low to very low CoE and widely varying thresholds for deciding on surfactant replacement in the included studies, further trials are needed.