SPECIAL ISSUE
COVID-19: a guide for neonatal staff

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infant

for neonatal and paediatric healthcare professionals

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References: 1. Agostoni C *et al. J Pediatr Gastroenterol Nutr.* 2010;50:1–9. **2.** Aggett PJ *et al. J Pediatr Gastroenterol Nutr.* 2006;42(5):596–603. **3.** Boehm G *et al. Arch Dis Child Fetal Neonatal Ed.* 200;86:F178–81. **4.** Knol J *et al. Acta Paediatr.* 2005;94(449):31–3. **5.** Mihatsch W *et al. Acta Paediatr.* 2006;95(7):843–8. **6.** Bar-Yoseph F *et al. Prostaglandins Leukot. Essent. Fatty Acids.* 2013;89(4):139–43. **7.** Carnielli *et al. Am J Clin Nutr.* 1995;61(5):1037–1042. **8.** Carnielli *et al. J Pediatr Gastroenterol Nutr.* 1996;23(5):553–560. **9.** Kennedy *et al. Am J Clin Nutr.* 1999;70(5):920–7. **10.** Quinlan *et al. Pediatr Gastroenterol Nutr.* 1995;20(1):81–90.

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for neonatal and paediatric healthcare professionals

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Infant is an independent, peer-reviewed bimonthly journal for the multidisciplinary team that cares for sick or premature babies in their first year of life. The journal contains authoritative articles written by experts in their field, covering a wide range of subjects that reflects the varied roles of the professionals working in this area. Practically and clinically based, *Infant* supports neonatal and infant paediatric nursing and medical practice and develops professional education and health promotion skills. All opinions expressed in the articles published in *Infant* are those of the authors and not necessarily those of the publishers.

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Nestlé Health Science

National research to understand and better manage neonatal COVID-19

The Neonatal Complications of COVID-19 Surveillance Group
(TABLE 1)

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The novel coronavirus SARS-CoV-2 was identified in late December 2019 and causes coronavirus disease (COVID-19). This disease has been declared a pandemic by the World Health Organization and is an international public health crisis. So far there is only relatively limited information describing the incidence, clinical course, treatments or outcomes of SARS-CoV-2 infection and COVID-19 in neonates up to 28 days old.

There are three main ways that neonates may be affected by SARS-CoV-2 infection:

1. Potential vertical transmission of SARS-CoV-2 from mother to infant during pregnancy, labour or birth which may lead to neonatal COVID-19.
2. Horizontal transmission of SARS-CoV-2 in the neonatal period; this may also lead to neonatal COVID-19 and can occur from close family contacts such as the mother, or from nosocomial transmission in places such as neonatal units.
3. Maternal COVID-19 that impacts pregnancy or labour and birth, leading to neonatal complications such as preterm birth. Such circumstances can be thought of as indirect neonatal effects of maternal COVID-19, and will include situations where the neonate does not contract SARS-CoV-2.

Understanding how common each of these different scenarios are is critical to prevent and control neonatal COVID-19, and to plan neonatal services to best cope with the pandemic. Understanding vertical and horizontal transmission will help protect neonatal staff and those attending births, as well as informing management of babies born to women with COVID-19. Accurate data describing the presentation and clinical course of neonatal COVID-19 are important to determine which infants might benefit from current supportive treatments, and to identify where potential disease modifying treatments might be tested in clinical trials. Data describing the direct and the indirect neonatal effects of COVID-19 are also needed to predict and plan neonatal care effectively, particularly as SARS-CoV-2 may lead to increased preterm birth or other birth-related complications, similar to previous pandemic respiratory viruses like 2009/H1N1 influenza.[1]

At time of writing there is no definitive evidence of vertical transmission of SARS-CoV-2; so far cases suggesting vertical transmission have been limited to a small number with increased IgM levels in umbilical cord samples,[2,3] but the validity of these tests is not certain.[4] Data describing how common COVID-19 is in the neonatal period come from single centre studies[5] or from healthcare systems like China,[6] which have taken a different approach to perinatal management of SARS-CoV-2 infection than that currently recommended in the UK.[7] These countries have implemented almost universal caesarean birth followed by strict and prolonged isolation of the newborn from the mother and other affected family members. Unfortunately, there is no good evidence to guide any current practice following birth to a mother with COVID-19. The clinical course of paediatric SARS-CoV-2 infection and COVID-19 in older babies and children is slightly better described and appears to be considerably less severe than in adults, but more recent data[6] suggest that up to 10% of neonates and infants with COVID-19 develop severe or critical disease. It is, however, unclear how generalisable these data are to UK paediatric and neonatal practice given the different perinatal and neonatal management practices.

The wider impact of maternal COVID-19 on babies is also not fully understood; while several hundred women with COVID-19 in pregnancy have been described worldwide, these are mainly in limited case series or single centre studies. The majority of reported newborn infants were asymptomatic for COVID-19 but several were born preterm, and at least one baby who died in

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TABLE 1 Members of the BPSU Neonatal Complications of COVID-19 Surveillance Group.

the neonatal period has been reported – suggesting that indirect impacts of maternal COVID-19 on neonatal services may be substantial in the context of sustained community transmission.

In the absence of reliable and relevant data we urgently need active population-based surveillance data to inform UK neonatal care. Such data differ from information collected through registries, which are commonly retrospective and may not achieve universal coverage, and as a result registry data cannot be guaranteed to provide robust or reliable information about incidence or complication rates at the population level. The British Paediatric Surveillance Unit (BPSU) has pioneered population-based active surveillance for rare diseases since 1985. The Orange Card system developed by the BPSU has been an exemplar for national surveillance systems in other specialties and internationally. Crucially, the BPSU emails paediatricians and neonatologists across the UK and Ireland every month and asks them to report whether they have managed a baby or child with any condition listed under active BPSU surveillance. Following each positive response, the paediatrician is sent a detailed questionnaire to complete. Active surveillance prompts a response even if no babies or children were managed by the reporting doctor; because more than 90% of paediatricians and neonatologists respond to the BPSU every month this ensures high case ascertainment and enables population incidence rates to be estimated.

A BPSU study entitled *Neonatal Complications of Coronavirus Disease (COVID-19)* started on 1 April 2020 to ascertain robust data on incidence, clinical course and management of any neonate affected by COVID-19 from 1 March 2020 onwards, and has been identified as an Urgent Public Health Priority study by the NIHR Clinical Research Network. Any baby or infant that meets the surveillance case definition (**TABLE 2**) should be reported to the BPSU. Because of the unprecedented nature of the COVID-19 pandemic, for the first time the BPSU is asking for notifications of affected babies to be reported weekly rather than monthly. To ensure that all affected babies are identified as completely as possible the study will also link with other related data sources including ongoing United Kingdom Obstetric Surveillance System (UKOSS) surveillance of COVID-19 in pregnancy for maternal cases, MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK) for neonatal deaths and stillbirths, and Public Health England (PHE), Health Protection Scotland, Public Health Wales and the Health and Social Care Public Health Agency in Northern Ireland. To limit the amount of information that neonatologists and paediatricians are asked to report and to further increase case ascertainment, surveillance will also link with routinely recorded neonatal and paediatric intensive care data held in the National Neonatal Research Database (NNRD) and Paediatric Intensive Care Audit Network (PICANet). The resulting data will be used to inform clinical care and service provision and to advise pregnant women. It will also be shared with global registries for international comparisons.

There are some limitations to the data that will be obtained from BPSU surveillance of COVID-19 as babies reported will only be those seen in secondary and tertiary care. It will therefore miss babies who are asymptomatic or with milder infections developing in the community. Because testing to date has been recommended for clinical indications only, it is unlikely to obtain the early antigen and serological samples needed to delineate fully between vertical and horizontal transmission. The most recent Royal College of Paediatrics and Child Health (RCPCH) guidance addresses this matter to some degree, in suggesting that early testing, if available, may have utility in helping to understand perinatal SARS-CoV-2 infection. We note that such testing is also commonly practised across the world.

Any baby or infant
1. That has a diagnosis of COVID-19 made on a sample taken before 29 days of age and receives inpatient care for COVID-19 (this includes postnatal ward, neonatal unit, paediatric inpatient wards, paediatric intensive care units)
OR
2. Where the mother had confirmed COVID-19 at the time of birth or suspected COVID-19 at the time of birth that has subsequently been confirmed, and the baby was admitted for neonatal care

TABLE 2 BPSU surveillance case definition for neonatal complications of COVID-19.

The periCOVID study (www.pericovid.com) recently established at St Georges Hospital in collaboration with PHE will help us to better understand perinatal SARS-CoV-2 transmission. To determine which treatments may improve outcomes in neonatal COVID-19 randomised trials of interventions have been rapidly developed, including the Randomised Evaluations of COVID-19 Therapy (RECOVERY) trial (www.recoverytrial.net), which can enrol pregnant women and children, including neonates.

Although neonates, infants and children appear more mildly affected by COVID-19 than adults, robust population level data are limited, and considerable uncertainty remains about the incidence, transmission, clinical course and outcomes of neonatal SARS-CoV-2 infection and COVID-19, and the impact of maternal COVID-19 on the newborn. National research and active surveillance through established national systems such as the BPSU are the simplest, quickest and most efficient way to obtain accurate data to inform optimal neonatal care in the context of the SARS-CoV-2 pandemic. Data from this surveillance project will be rapidly and regularly summarised and provided to key stakeholders, such as the British Association of Perinatal Medicine (BAPM) and the RCPCH, to provide updates on the impact of COVID-19 in the neonatal population, allowing timely review and dissemination of guidance during the emergence of this new disease.

References

1. **Pierce M, Kurinczuk JJ, Spark P, et al.** Perinatal outcomes after maternal 2009/H1N1 infection: national cohort study. BMJ 2011;342:d3214.
2. **Zeng H, Xu C, Fan J, et al.** Antibodies in infants born to mothers with COVID-19 pneumonia. JAMA 2020:E1-2.
3. **Dong L, Tian J, He S, et al.** Possible vertical transmission of SARS-CoV-2 from an infected mother to her newborn. JAMA 2020:26-28.
4. **Kimberlin DW, Stagno S.** Can SARS-CoV-2 infection be acquired in utero? More definitive evidence is needed. JAMA 2020 doi: 10.1001/jama.2020.4868.
5. **Zeng L, Xia S, Yuan W, et al.** Neonatal early-onset infection with SARS-CoV-2 in 33 neonates born to mothers with COVID-19 in Wuhan, China. JAMA Pediatr 2020 doi: 10.1001/jamapediatrics.2020.0878.
6. **Dong Y, Mo X, Hu Y, et al.** Epidemiology of COVID-19 among children in China. Pediatrics 2020: e20200702.
7. **RCOG**. Coronavirus (COVID-19) infection in pregnancy. In: Gynaecologists RCoOa, ed: RCOG; 2020 online at www.rcog.org.uk/en/guidelines-research-services/guidelines/coronavirus-pregnancy

Interruption of high flow nasal oxygen during transfer

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PATIENT SAFETY
Working together

A safety critical National Patient Safety Alert has been issued on the risk of harm from interruption of high flow nasal oxygen (HFNO) during transfer. This alert relates to the risk of harm caused by the interruption of HFNO to babies, children and adults in acute respiratory failure without hypercapnia during patient transfer.

Some HFNO delivery devices have a transport mode, but most require mains power and will not deliver oxygen during transfer unless attached to a compatible uninterruptible power supply (UPS) device. In the context of this alert, transfer means between wards, departments and rooms within a hospital; HFNO is not used for ambulance transfer between hospitals.

The alert asks providers to add clear labels to HFNO delivery devices to make staff aware that even brief interruptions to mains power supply could lead to respiratory and cardiac arrest; and that HFNO in any emergency department or short stay unit must not be started without a plan for how to transfer the patient onwards.

Where a UPS is used, action must be taken on the storage and maintenance of UPS devices to ensure they are ready for use and staff know where to locate them.

A review of patient safety incident data identified four deaths in a recent two-year period from interrupted HFNO during patient transfer. Further reports described hypoxia, cyanosis, collapse and respiratory arrest. Patients affected ranged from age one month to 85 years, but most incidents occurred in those aged one month to one year and 66-75 years. The review of these incidents suggests:

- some staff may assume devices have an internal battery
- staff do not realise how rapidly the patient is likely to deteriorate with even brief interruption of HFNO
- a misconception is that less intensive methods of oxygen delivery (eg reservoir masks with an oxygen cylinder on full flow) are an adequate substitute during transfer; however, most patients requiring HFNO need more intensive intervention such as intubation if HFNO is interrupted
- staff have no obvious visual cue to the criticality of HFNO and may confuse it with low-flow nasal oxygen
- emergency departments starting a patient on HFNO then find they have no access to a supplementary battery source or transport mode to move the patient safely out of the department.

A number of immediate actions are required to reduce the risk of harm:

1. Identify all devices used to provide HFNO that do not have an in-built transport mode
2. Add clear and visible labels to these HFNO delivery devices stating:
   a. even brief interruptions to mains power supply will lead to interruption of oxygen therapy and subsequent respiratory or cardiac arrest
   b. do not start HFNO in any emergency department or short stay unit without a plan for how to transfer the patient onwards.
3. If you already have UPS devices to use with HFNO:
   a. identify a storage place for your UPS that can be accessed 24/7
   b. label all HFNO devices with the location of a compatible UPS
   c. allocate responsibility for ensuring the UPS is returned, charged and prepared for next use.

In the long-term, purchase additional equipment supported by the manufacturer of the HFNO device, and redesign patient pathways, protocols and staff training to address the underlying causes.

For further information visit:
www.england.nhs.uk/publication/national-patient-safety-alert-interruption-of-high-flow-nasal-oxygen-during-transfer/

Join us to help improve patient safety

In collaboration with BAPM, *Infant* journal is keen to help improve patient safety and raise awareness of issues affecting neonatal patients, their families and staff by devoting a specific section to patient safety in each edition of the journal. Anyone can submit an article so if you have ideas for highlighting safety aspects to improve care, please do let us know.

British Association of Perinatal Medicine

If you would like to submit a patient safety article to *Infant*, please email lisa@infantjournal.co.uk
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Practical considerations for the emergency delivery of babies from mothers with confirmed or suspected COVID-19

Maternity and neonatal departments must be prepared for the delivery of babies from COVID-19 positive women. We describe a guideline developed at the North Middlesex University Hospital maternity unit, for multidisciplinary team members attending an emergency caesarean section of mothers with confirmed or suspected COVID-19. Anticipated staff actions and personal protective equipment were considered to optimise staff safety and reduce transmission of SARS-CoV-2. We recommend units generate individualised guidance suitable to their settings.

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Keywords

COVID-19; emergency caesarean section; vaginal delivery; personal protective equipment; infection control; aerosol generating procedure

Key points

Wells P, Taylor A, Battersby C, Singh C. Practical considerations for the emergency delivery of babies from mothers with confirmed or suspected COVID-19. *Infant* 2020; 16(3): 94-98.

1. Healthcare staff must be prepared for the delivery of babies from COVID-19 positive women.
2. Preparations should include planning of logistical steps to prevent transmission of the virus.

The SARS-CoV-2 virus global outbreak has resulted in a significant challenge to healthcare systems globally. Clinical presentation ranges from asymptomatic to severe coronavirus disease 2019 (COVID-19) pneumonia, respiratory failure and death.[1,2] More severe symptoms are widely described in those populations who have long-term conditions, are older and the immunocompromised.[1,2] The morbidity in children and neonates is currently believed to be very minimal.[3] Pregnancy alters the body's immune system and it is known from experience with other viruses that this can result in more severe symptoms, particularly towards the end of pregnancy.[4] As of the end of April 2020 the UK had 177,454 confirmed cases and 27,510 deaths.[5] Over 700,000 births are recorded each year in the UK.[6] It is likely that at least some of these deliveries will be affected by the SARS-CoV-2 virus.

Evidence relating to the effect of SARS-CoV-2 viral infection on the mother and fetus is currently evolving. In a recent rapid review by Mullins et al, of the 32 pregnant women affected with COVID-19, only two women (6%) required care in the intensive care unit; however, strikingly 47% (n=15) resulted in preterm delivery.[7] The question of vertical transmission remains unanswered. Evidence is lacking and although in a small cohort the SARS-CoV-2 virus was not detected in amniotic fluid, cord blood, breast milk and neonatal throat swabs,[8] there are some indications that vertical transmission may occur. In two separate reports from China, a total of three babies born to mothers affected by COVID-19 were found to have a raised SARS-CoV-2 IgM after delivery, despite a negative real-time reverse transcriptase-polymerase chain reaction (RT-PCR) nasal pharyngeal swab for SARS-CoV-2.[9-11]

	PPE requirement for maternity wards		High risk PPE
	Non AGP close contact PPE	Non AGP clinical area PPE	
Definition	Direct patient contact (within 2m) of a patient with confirmed/ possible COVID-19	Clinical area but no direct patient contact (within 2m)	Used when conducting an AGP or in an acute care area where AGP are being conducted
Required equipment	Disposable gloves Disposable plastic apron Fluid resistant (type IIR) surgical mask Eye protection	Fluid resistant (type IIR) surgical mask +/- Eye protection (risk assessment)	Disposable gloves Long sleeved disposable plastic gown Filtering face piece (class 3) Eye protection

TABLE 1 Recommended PPE, adapted from advice by Public Health England.[14,15]

- Intubation, extubation and related procedures
- Manual ventilation
- Open suctioning of the respiratory tract (including the upper respiratory tract)
- Less invasive administration of surfactant (LISA)
- Tracheotomy/tracheostomy procedures (insertion/open suctioning/removal)
- Non-invasive ventilation (NIV), eg bi-level positive airway pressure ventilation (BiPAP) and continuous positive airway pressure (CPAP)
- High frequency oscillatory ventilation (HFOV)
- High flow nasal oxygen (HFNO)

FIGURE 1 Aerosol generating procedures, compiled from RCPCH guidance.[3]

Furthermore there are reports of neonates testing RT-PCR nasal pharyngeal swab positive for SARS-CoV-2 within a week of delivery.[12]

Maternity and neonatal departments must be prepared for the delivery of babies from COVID-19 positive women. Healthcare staff looking after such patients are at risk of contracting SARS-CoV-2. It is therefore vital that preparations include the planning and adoption of management steps to prevent transmission of virus to healthcare workers present at the delivery and, potentially, to the baby.

The transmission of SARS-CoV-2 is thought to occur largely via respiratory droplets generated by coughing or sneezing or through contact with a contaminated surface.[13] The current guidance by Public Health England (PHE) indicates different personal protective equipment (PPE) should be worn by staff managing patients with suspected or confirmed COVID-19 in different settings (**TABLE 1**).[14] Endotracheal intubation for general anaesthesia (GA) at an emergency caesarean section (CS) as well as intubation of the newborn and positive pressure ventilation are considered aerosol generating procedures (AGP) and carry a higher risk of transmission of infection (**FIGURE 1**).[3,5,14]

Intrapartum care and the safe delivery of babies involves multiple teams and a large number of personnel. Maintaining stringent infection control procedures in such emergencies, to protect staff and patients, is a logistical challenge that requires prior consideration to minimise exposure. In addition to appropriate PPE, it is also important for 'contact' and 'non-contact' members of staff to be identified. These non-contact team members are important to facilitate actions outside of the delivery room to minimise movement to and from the delivery room, and reduce risk of transmission.

Department	Individual	Role	PPE required
Anaesthetics	Anaesthetic doctor 1	Intubation	High risk PPE
	Anaesthetic doctor 2	Assist if needed	Non-AGP clinical area PPE Might require high risk PPE
	Operating department practitioner	Assist	High risk PPE
	Runner	Runner outside theatre	Non-AGP clinical area PPE
Theatres	Scrub nurse	Prepare theatre Assist operation	High risk PPE + scrubbed
	Runner	Prepare donning/ doffing area Pass cord gases and placenta to dirty sluice/ Midwife 1	High risk PPE
Obstetrics	Obstetric doctor 1	Perform CS	High risk PPE + scrubbed
	Obstetric doctor 2	Assist CS Take cord gases	High risk PPE + scrubbed
Midwifery	Midwife 1	Transfer of patient Run cord gases Check placenta	Non-AGP close contact PPE
	Midwife 2	Prepare theatre checklist Assist Midwife 1	Non-AGP close contact PPE
	Runner	Transfer assist/back up	Non-AGP clinical area PPE
Neonatology	Neonatal doctor 1	Resuscitation and intubation	High risk PPE
	Neonatal doctor 2	Assist if needed	Non-AGP clinical area PPE Might require high risk PPE
	Neonatal doctor 3	Runner Transfer of patient	Non-AGP close contact PPE Might require high risk PPE
	Neonatal nurse 1	Assist resuscitation and intubation	High risk PPE
	Neonatal nurse 2	Transfer assist/back up	Non-AGP close contact PPE
Totals			
Staff required	**16**	**PPE required** **Minimum spare PPE**	X3 High risk PPE + scrubbed X5 High risk PPE X8 Non-AGP PPE X3 High risk PPE

TABLE 2 Staff required for emergency CS alongside anticipated role and required PPE. Contact team members (shaded) are those present within theatre during a CS. Non-contact team members (shaded) facilitate actions outside of the theatre. Other team members may be required to join the contact team where necessary (shaded).

Methods

The North Middlesex University Hospital recognised the need for a pathway for deliveries of COVID-19 positive mothers. We consulted the most up-to-date guidance published by PHE, the Royal

Timeline	Midwifery team	Obstetric team	Anaesthetic team	Theatre team	Neonatal team
Admission to maternity - suspected or confirmed COVID-19	Inform neonatal team	Clinical review of patient and individualised decision			Consider need to counsel
Decision to perform emergency CS					
1)	Locate PPE for all members of staff in CS Leave additional PPE outside theatre Complete theatre checklist Ensure patient catheterised	Consent patient Inform neonatal team, theatre staff and anaesthetic team			Discuss with nurse in-charge and on call consultant Identify isolation room available Identify contact and non-contact team members
2)	Move cot to theatre and set up with sterile sheet		Prepare anaesthetic plan	Prep theatre Set up donning areas Set up doffing area in dirty sluice	Set up resuscitaire and saturation monitor in prep room Bring in temporary grab bag Leave neonatal transport incubator and main grab bag outside prep room
3)		Scrub and don PPE Wait in corner of theatre	Don PPE	Don PPE +/- scrub Scrubbed: wait in corner of theatre Non-scrubbed: wait in prep room	Contact team: don PPE and wait in prep room Non-contact team: don PPE and assemble outside prep-room
Confirm ready for patient in theatre					
4)	Clear corridor and hold doors open Move patient to theatre Transfer mum to theatre bed				
5)	Clear corridor and hold doors open Return bed to patient's room		Assess patient		
6)	Ensure all non-contact team members present outside theatre	Prep room team return to theatre Plan where patient will recover + members of staff required			
WHO surgical checklist					
7)		Prep room team return to prep room			
8)			Anaesthesia		
9)		Prep room team (excluding neonatal team) return to theatre			
Perform CS					
10)		Deliver baby		Move baby in cot to prep room	Resuscitation as required
11)		Deliver placenta			
12)		Take cord gases		Pass placenta and cord gases to dirty sluice for midwife 1 waiting outside theatre	

TABLE 3 Timeline of anticipated team movements and decisions during an emergency CS. *Continues on the next page.*

Timeline	Midwifery team	Obstetric team	Anaesthetic team	Theatre team	Neonatal team
13)	Take placenta and run cord gases Consider sending placenta Pass cord gas result into prep room				Decide whether baby requires NNU admission If admitting, arrange transfer of baby to 'clean' non-contact outer neonatal team 'Dirty' saturation monitor to be placed in incubator
CS completed					
14)		Recovery plan as decided earlier Staff not required for recovery to doff in dirty sluice and leave If AGP took place must wait 20 minutes prior to transfer			
Patient safe for transfer back to room					
15)	Clear corridor and hold doors open Move patient's bed to theatre	Transfer patient to her bed			If admitting: clear corridor, hold doors open Move incubator to NNU Contact team to doff in dirty sluice and leave
16)	Clear corridor and hold doors open Return patient to her room - with baby if staying with mum	Doff PPE in dirty sluice Arrange urgent 'amber clean' (if AGP took place, wait 20 minutes post procedure before cleaning)			If admitting: NNU admitting nurse to be donned and ready to receive the baby in isolation room

College of Obstetricians and Gynaecologists (RCOG), the Royal College of Paediatrics and Child Health (RCPCH) and the British Association of Perinatal Medicine (BAPM).[3,4,13,14] The guidance was applied to a draft practical pathway for emergency CS. Revisions were made following feedback from simulations with the multidisciplinary team and consultation with our local infection control team. Further modifications were incorporated as guidance from PHE, RCOG, RCPCH and BAPM evolved and subsequent statements were released by the UK Resuscitation Council.[15]

Practical guidance

The required personnel from five different teams and appropriate PPE for each member of the team were considered. The obstetric theatre layout was considered (**FIGURE 2A**). Neonatal resuscitation was designated to occur in a sideroom, termed the prep room. This was agreed so that staff exposure to AGP completed on the mother or the baby would be minimised. The PPE 'donning' area was designated as inside theatre or the prep room prior to patient arrival. The PPE 'doffing' area was identified as the dirty sluice, given it was an anteroom containing a sink.

The emergency CS was divided into 16 key steps and key roles of team members were identified. High risk PPE and infection control measures are crucial and anticipated staff actions and location were designated to help minimise transmission (**FIGURE 2B, TABLES 2 and 3**). Individual emergency cards were produced for each staff member involved, documenting their responsibilities, considerations and anticipated PPE (**FIGURE 3**).

Similar guidance was generated for CS under spinal anaesthetic and vaginal delivery requiring neonatal presence (available on request from the authors).

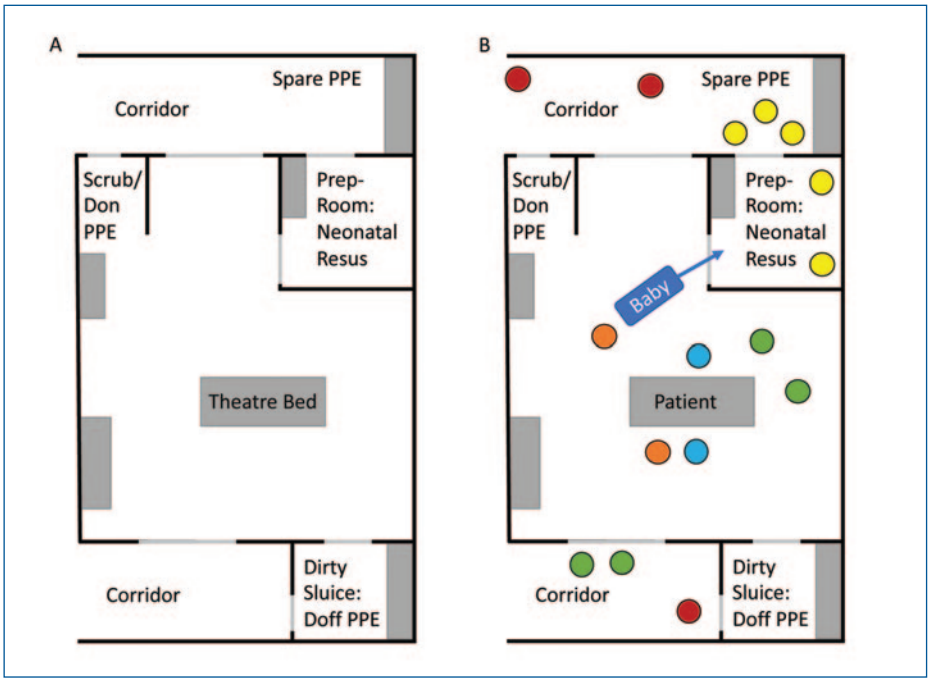

FIGURE 2 Theatre layout. A) Theatre layout and areas designated for donning PPE, doffing PPE, keeping spare PPE and neonatal resuscitation. B) Demonstration of team positions during emergency CS prior to delivery of baby. Key: red=midwifery, yellow=neonatology, green=anaesthetics, blue=obstetrics, orange=theatre staff.

Neonatal resuscitation and commonly used interventions such as suction, and endotracheal intubation are considered AGPs (**FIGURE 1**). Although evidence for vertical transmission is not currently conclusive, the recommendation is that the neonatal team should wear AGP PPE during neonatal resuscitation, or if within 2m of neonatal resuscitation to optimise staff safety and minimise interruption to the resuscitation.[3,15]

Conclusion

Maternity areas have a high flow of patients and more mothers with COVID-19 should be anticipated in light of the ongoing pandemic. Multiple professionals from various teams are involved in the safe delivery of babies from pregnant mothers. An emergency CS is a high intensity event with multiple clinical and practical considerations for reducing transmission of SARS-CoV-2, for patient and staff. This guidance was generated to provide a clear framework for multidisciplinary team members and has been useful at the North Middlesex University Hospital maternity unit. The authors recommend that all units should develop their own individualised guidance based on theatre and building layout, staffing, skill mix and PPE availability. The areas to be used for donning and doffing of PPE, neonatal resuscitation, and the number of staff required should be planned prior to the event. Simulations of different scenarios is crucial in ensuring local logistics are considered and to familiarise staff with additional PPE considerations.

Contributions and conflict of interest

PW, AT, CS: involved in development and implementation of guideline at North Middlesex University Hospital.
CB: critical review of article.
No conflicts of interest to declare.

Neonatal doctor 1 (most senior/confident neonatologist present)

Key roles

- Counsel mother
- Lead resuscitation/stabilisation – intubate if required
- Decide whether baby requires admission
- Assist transfer of baby into transport incubator

PPE required

High risk PPE

Don in prep room, doff in dirty sluice

Considerations

- Minimise staff exposure during resuscitation
- Minimise staff exposure post stabilisation, eg if baby required antibiotics but not NNU admission this should be done in theatre by staff already present

Neonatal nurse 1

Key roles

- Identify available isolation room on NNU
- Leave transport incubator and emergency bag outside prep room
- Assist resuscitation/stabilisation
- Assist transfer of baby into transport incubator

PPE required

High risk PPE

Don in prep room, doff in dirty sluice

Considerations

- Minimise staff exposure during resuscitation
- Equipment needed

FIGURE 3 An example of emergency personnel briefing cards.

References

1. **Huang C, Wang Y, Li X, et al.** Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet 2020;395:497-506.
2. **Guan W-J, Ni Z-Y, Hu Y, et al.** Clinical characteristics of coronavirus disease 2019 in China. N Engl J Med 2020;1-13.
3. **RCPCH.** COVID-19: guidance for paediatric services p26. 2020 online at: www.rcpch.ac.uk/resources/covid-19-guidance-paediatric-services [accessed 3 April 2020].
4. **RCOG.** Coronavirus (COVID-19) infection in pregnancy. Version 5 p43. 2020 online at www.rcog.org.uk/en/guidelines-research-services/guidelines/coronavirus-pregnancy/ [accessed 3 April 2020].
5. **Department of Health and Social Care, Public Health England.** Guidance: Number of coronavirus (COVID-19) cases and risk in the UK. 2020 online at: www.gov.uk/guidance/coronavirus-covid-19-information-for-the-public [accessed 1 May 2020].
6. **Office for National Statistics.** Vital statistics in the UK: births, deaths and marriages. 2019 online at: www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/datasets/vitalstatisticspopulationandhealthreferencetables [accessed 29 March 2020].
7. **Mullins E, Evans D, Viner RM, et al.** Coronavirus in pregnancy and delivery: rapid review. Ultrasound Obstet Gynecol 2020 doi: 10.1002/uog.22014.
8. **Chen H, Guo J, Wang C, et al.** Clinical characteristics and intrauterine vertical transmission potential of COVID-19 infection in nine pregnant women: a retrospective review of medical records. Lancet 2020;395:809-15.
9. **Zeng H, Xu C, Fan J, et al.** Antibodies in infants born to mothers with COVID-19 pneumonia. JAMA 2020:E1-2.
10. **Dong L, Tian J, He S, et al.** Possible vertical transmission of SARS-CoV-2 from an infected mother to her newborn. JAMA 2020:26-28.
11. **Kimberlin DW, Stagno S.** Can SARS-CoV-2 infection be acquired in utero? More definitive evidence is needed. JAMA 2020 doi: 10.1001/jama.2020.4868
12. **Dashraath P, Jing Lin Jeslyn W, Mei Xian Karen L, et al.** Coronavirus Disease 2019 (COVID-19) Pandemic and Pregnancy. Am J Obstet Gynecol 2020 doi.org/10.1016/j.ajog.2020.03.021
13. **Department of Health and Social care, Public Health Wales, Public Health Agency Northern Ireland, Health Protection Scotland, Public Health England.** COVID-19: Guidance for infection prevention and control in healthcare settings. Version 1.0 2020 online at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/874316/Infection_prevention_and_control_guidance_for_pandemic_coronavirus.pdf
14. **Public Health England.** Guidance COVID-19 personal protective equipment. Updated 2 April 2020. 2020 online at: www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control/covid-19-personal-protective-equipment-ppe [accessed 3 April 2020].
15. **Resuscitation Council (UK).** COVID-19 resources: newborn life support. 2020 online at: www.resus.org.uk/media/statements/resuscitation-council-uk-statements-on-covid-19-coronavirus-cpr-and-resuscitation/covid-19-resources-nls/?utm_source=tw_date=170420

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Twins Trust gives extra support to new families during the COVID-19 pandemic

New mums of twins, triplets and more face caring for their babies' first hours alone due to partners and close family no longer able to visit because of COVID-19.

Having more than one baby to care for in normal circumstances is difficult but in these uncertain times, the lack of support available due to lockdown restrictions is causing huge anxiety. The baby charity, Twins Trust, has adapted its family crisis support service to help women who may be feeling overwhelmed and isolated, by remotely supporting them in hospital or at home. The charity has recruited more volunteers to help parents of newborn twins or triplets who may not get the usual level of NHS support due to the COVID-19 outbreak.

With many postnatal services being cut as staff are diverted to help with the pandemic, the family support service will also help families when they return home from hospital with their new babies by providing remote support over the phone or a video call on feeding, bathing, sleeping, bonding, crying and other challenges faced by families with more than one baby to care for.

The charity has adapted many of its services in light of the pandemic, including offering antenatal and parenting classes by live webinars instead of face-to-face classes. Like many other charities, Twins Trust is facing a drop in income due to the pandemic as online classes bring in less income and fundraising activities are either postponed or cancelled.

To find out more about Twins Trust visit www.twinstrust.org

Each Baby Counts report makes recommendations to reduce stillbirths, baby deaths and brain injuries

The latest report from Each Baby Counts finds there are still too many avoidable stillbirths, baby deaths and brain injuries that occur during term labour in the UK. It makes new recommendations including how maternity care can be improved, and how to support maternity teams to escalate critical situations.

Launched in 2014 by the Royal College of Obstetricians and Gynaecologists (RCOG), Each Baby Counts is a national quality improvement programme that aims to reduce the number of babies who die or are left severely disabled as a result of incidents that happen during term labour. The programme brings together the results of local maternity investigations into stillbirths, neonatal deaths and brain injuries to understand the bigger picture and share the lessons learnt to prevent future cases. The latest report analysed 1,130 cases of babies who met the eligibility criteria, out of around 677,192 babies born at term in the UK in 2017. The findings show there were:

- 130 (12%) stillbirths
- 150 (13%) babies born alive following labour but who died within the first seven days after birth
- 850 (75%) babies who had severe brain injury (it is not known how many of these babies will have a significant long-term disability as a result of injuries sustained during birth).

These figures remain similar to the number of cases reported in 2015 and 2016. Other key findings include:

- the number of babies reviewed where different care might have led to a different outcome was slightly lower at 72% of babies (714 cases) in 2017, compared to 76% in 2015.
- parents being invited to contribute to the local review rose to 493 (50%) of cases in 2017, compared with 34% in 2015.
- the number of local reviews that contained sufficient information for analysis has grown year on year, 95% in 2017 from 75% in 2015.

The increasing number of parents involved in investigations and improvement in the quality of reviews helps understanding of how to prevent future deaths and injuries.

A further analysis found that there was an average of nine contributory factors for babies for whom different care might have led to a different outcome. The most commonly identified factors included a lack of timely recognition of women and babies at risk, communication problems, training and education issues, human factors and inadequacies related to the monitoring of the baby's wellbeing during labour. Detailed analysis of 986 fully completed local reviews revealed 358 (36%) cases of a failure to identify a high risk situation, escalate appropriately and transfer a woman and/or baby in a timely way. Successful clinical escalation of a woman and baby at risk of harm is essential. With the right medical intervention at the right time, maternity care can ensure the safest possible outcome for a mother and her baby.

Recommendations from the report focus on clinical and non-clinical factors that need to be improved, including better team working and behaviour, addressing workload and workforce challenges, and improving communication among maternity teams.

The report is published on the RCOG Each Baby Counts website: www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/each-baby-counts/reports-updates/2019-progress-report

COVID-19: reflections on childbirth and neonatal care in Italy

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I work in Seriate in the Province of Bergamo in the Italian region of Lombardy where, at the time of writing, there have been approximately 600 births since the beginning of the COVID-19 pandemic. In Italy, the spread of the SARS-CoV-2 infection has hit with an uneven distribution and, fortunately, in the neonatal setting the virus affects fewer patients and with less severity. Nevertheless, the moment of childbirth has turned into a more complex event for healthcare professionals as we have to work with visors, masks and gowns. The continuously increasing number of COVID-19 cases has also given rise to the need for specific protocols to protect pregnant women and newborn babies.

Precise and distinct pathways have been put in place for women giving birth depending on whether they are COVID-positive or COVID-free. In Lombardy, a network of six hubs for pregnant COVID-positive patients has been designed.

Our working practice has changed, marked by constantly updated rigid protocols. We have learnt the repetitive and exhausting process of donning and doffing personal protective equipment (PPE) in a rapid and controlled response to an emergency.

The moment of birth

For parents, childbirth is a time of bewilderment and the curiosity of facing something new, something that they may have never imagined before. Emotions mix with fear when they cuddle their baby for the first time. Now, in the time of COVID-19, the mother faces the pain of childbirth with the discomfort of wearing a mask on her face. The father, while present at the moment of birth, is only allowed a quick cuddle and then immediately leaves, only to return at the time of discharge.

The NICU is closed to parents but we send photos and videos to try and help keep them virtually close to their infant.

The identities of the doctors and nurses are hidden behind masks, glasses, gowns and gloves. The only visible part of their face is the eyes and it is with these that we embrace each other. The empathy and every encouraging word to the parents must overcome these barriers, where feelings are perceived only through a glance.

Babies born to asymptomatic COVID-positive mothers can room-in (mother and baby stay in the same room without any other patients in that room) but the infant is kept in a cot two metres away from the mother's bed. Breastfeeding is allowed, while taking precautions to avoid transmitting the virus to the infant by the use of PPE. In our unit, five COVID-positive mothers have given birth and we have not recorded vertical transmission of the virus.

Admission to the neonatal unit

It's a day like any other, as busy as ever. Suddenly the phone rings and I am asked to attend the preterm delivery of a COVID-positive woman. I stand at the door of the delivery room momentarily feeling lost. I have to resist my instinct to rush inside; first I must put on my armour to protect myself from the insidious and invisible enemy – mask, hat, gown, double gloves. I enter the delivery room where I find frightened, tired and unrecognisable faces whose voices are muffled through the masks that they wear.

There it is… the first cry. The midwife hands the baby to me and reality is distorted. The euphoria, emotions and the intensity of the moment is toned down by the parents' tears. Their cuddles are transmitted through loving looks aiming to seal the first bond with their new baby, the bond that will last forever. Instead the parents must let go of their baby; they must entrust his care to us in order to be able to hold him again only at the time of discharge, which may be weeks, sometimes months.

New admissions to the neonatal intensive care unit (NICU) are considered COVID-positive. We have closed the doors of the NICU, forbidding parents from entering. Any assistance given to the infants takes place with great caution. Invasive procedures, such as intubation, can only occur with the appropriate PPE.

At this time, those present on the unit are just the staff and our little patients who, unaware of the latest events, seek to cling on to life alone. Segregated and imprisoned in its incubator, the baby has us doctors and nurses to take care of him but the presence of his parents next to the incubator, their gaze and their touch, is missing. I wonder what will be the effect of this enormous absence on a premature infant.

Andra tutto bene – everything will be alright

COVID-19 has moved parents away from the neonatal unit, forcing them to imagine their child almost as if it were a dream. They can only experience the thrill of their new arrival with nervous anticipation of the result of a virus test on top of precarious prematurity. For neonatal staff there is the need to protect the life of this new infant but we must not forget its parents. Once a day there is telephone contact between the doctors and parents and to try to reduce the huge void we have found virtual ways to keep parents and infants together. We regularly send and receive photos, videos of their little ones, a virtual cuddle, a kiss from a distance – ways to stay close even if miles apart.

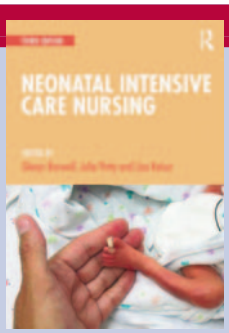
As healthcare professionals we all face our daily work, alternating between the joy of a negative COVID-19 swab in a newborn infant and the sadness of many deaths in adult intensive care units. We continue to fight for our babies until the great moment of their discharge arrives and they can be reunited with their parents. After hospital discharge, the neonatal clinical follow-up appointments, including repeat testing for COVID-19, are scheduled on days 7, 20 and 30.

We share in the hope that everything can return to normal soon while knowing that nothing will be the same as before – the coronavirus has highlighted what is indispensable, what is useful, what is not necessary. Today in the time of COVID-19, the world regards us as heroes, but we are not the real heroes. The real heroes are the little infant warriors who have landed prematurely in our open hands and the families who have had the joy of bringing their baby into this world dampened by the spread of the coronavirus.

Book review

Neonatal Intensive Care Nursing, third edition

Glenys Boxwell, Julia Petty, Lisa Kaiser (editors)
Routledge, 2020
ISBN: 9781138556843
£32.99, paperback, 658 pages



The third edition of *Neonatal Intensive Care Nursing* is a comprehensive book that delivers more than its title suggests. It is not just about intensive care nursing, but provides relevant and up-to-date evidence-based content that can be applied to all levels of neonatal dependency. A copy should be found in every neonatal unit (NNU). As a Senior Lecturer in Neonatal Nursing responsible for the four modules leading to neonatal nurses becoming Qualified in Specialty (QIS), I believe this new edition would serve well as a core text for those students undertaking QIS education. This book is also particularly well suited to the needs of any new recruit to the NNU and pre-registration child field students who have placements on the NNU.

This third edition has grown in size and organisation to reflect the changes that are taking place in delivery of the service and clinical advancements. The book is now organised into four sections. The first section, a new addition, provides the reader with the essential context or overview of neonatal care – care organisation and service provision, assessment of the newborn and a review of the preterm and low birth weight baby.

Another new section considers all aspects relating to the physical and emotional wellbeing of the neonate and family. This considers family supportive and developmentally focused care, management of pain and stress, neonatal bereavement, legal and ethical issues and a very welcome new chapter exploring neonatal palliative care. The family is a thread that runs through all chapters, as it should, to reflect the importance of the family in the delivery of neonatal care.

The third section of the book follows the content of the previous two editions and considers the clinical aspects of neonatal care. Using a systems approach, key topics are addressed and content updated. On the whole the updates are appropriate and result in clear and fluid explanations. Although not well articulated in the second edition, the fetal process of absorbing lung fluid prior to onset of labour and delivery in the term infant is sadly no longer included even though fetal adaptation to prepare for extrauterine life is important.

I found the fourth section, Practices and Procedures in Neonatal Care, a bit misleadingly titled in light of the content provided. The section reflects relevant content that just did not fit elsewhere, although not necessarily neonatal nursing procedures.

This edition continues to provide a table of contents at the outset of each chapter and guidance for the reader on how to get the most out of the chapter to enhance personal learning, such as the identification of key points, questions for reflection and implications for practice. In keeping with tradition in neonatal textbooks and as seen in one of my own ancient textbooks from 1976, each chapter ends with a case study. No textbook today seems complete without the use of educational technology and a really excellent and comprehensive companion website has been developed. The website provides possible case study answers, a variety of quizzes to test knowledge from the book and additional web-based resources for further reading for every single chapter. To make learning even easier, all resources are web-linked; learning could not be simpler.

A minor issue with the book is that photos are printed in a muddy mono-chrome or too small for viewing while some diagrams could benefit from the use of colour. Although this may be to keep costs down and make the book affordable, the impact of many of the photos would be improved if they were in colour, larger and/or better processed.

This new edition of a previously much-valued book and the companion website is a comprehensive resource that reflects neonatal care in the four countries of the UK and is very much welcomed.

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Parents are caregivers not visitors, even during a pandemic

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While in most ways, daily life has changed drastically over the last couple of months in response to the unprecedented COVID-19 crisis, some things remain the same. Babies are still being born, and around 300 of them will continue to be admitted to neonatal care every day in the UK. Neonatal services are part of the system-wide response to COVID-19 and have had to make changes to how they operate. But now is not the time to abandon family-centred care on neonatal units – indeed it is more important than ever.

As hospitals have severely limited entrants onto hospital sites to minimise the spread of the infection, the visiting regulations on neonatal units across the UK have also changed. The British Association of Perinatal Medicine (BAPM) and the Royal College of Paediatrics and Child Health (RCPCH) have developed specific guidance for neonatal settings, which states that only parents, and no wider family (including siblings) can enter a neonatal unit, and that only one parent should do so at any one time; meaning both parents can enter a unit, just not at the same time.[1]

Bliss recognises the need for these temporary restrictions in order to reduce the COVID-19 risk overall – particularly to already vulnerable babies and the dedicated staff who care for them. We know that this departure from usual practice is difficult for staff to implement, as well as painful for families with a baby currently in neonatal care. However, how this guidance is being interpreted and implemented appears to vary widely both across and within networks.

Delivering family-centred care, where parents are partners in their baby's care, should remain a priority.

In some, only one nominated parent is allowed onto the unit for the duration of the outbreak, and in certain cases, it has been specified that that parent should be the mother, fully excluding fathers and partners from caring and face-to-face decision-making opportunities, in some cases for many weeks or even months. Despite there being no guidance or evidence to justify restricting visiting times, Bliss is also aware that some units are limiting access to a maximum of two hours per visit. As a result, some parents, invariably fathers and partners, are unable to be with their baby and play an active role in their care at all.

It is essential that neonatal units avoid policies that routinely deny parents access to their baby, without clear evidence or rationale.[2] Delivering family-centred care, where parents are partners in their baby's care, should remain a priority even amid a pandemic because it is best for babies, best for parents, and potentially beneficial for healthcare professionals trying to limit the impact of COVID-19.

Parental involvement in their baby's care is proven to be best for babies' developmental outcomes. Evidence has shown that long periods of direct care lead to increased weight gain and improved breastfeeding rates, and skin-to-skin care has been linked to better infant reflexes at term and better gross motor development at 4-5 years.[3,4] More broadly, parental contact and involvement with their baby is vital for early attachment and bonding, which are critical to babies' long-term wellbeing and for the whole family. While increased access to video technology during the crisis is welcome, and is absolutely crucial for minimising the impact of separation, it is not a replacement for hands-on parental care. For babies to have these long-term benefits, both parents must still be supported to be hands-on partners in delivering their baby's care throughout their neonatal stay.

Inseparable from the benefits for babies, high levels of involvement also increase parental confidence, and reduce their scores of stress and anxiety.[3] Furthermore, parental involvement in care is critical for parents *feeling* like parents, which may be key for their own perceptions of

attachment to their baby, and physical and emotional closeness is crucial for forming strong parent-infant bonds.[5,6] It is always important for parents to feel confident at the point of discharge. But in these current circumstances, it is more vital than ever as many community outreach services have been temporarily suspended and families are facing lockdown at home, unable to access support from grandparents, other family members or friends, new parent classes or health visitors. In addition, services will be seeking to discharge babies as soon as it is safe to do so – again reducing the opportunity for parents to build their confidence and skills.[1]

Very sadly, some babies will die on neonatal units during the current weeks and months. For their parents in particular, involvement in care and memory-making is critical. It is imperative that services are actively considering unintended consequences of very restrictive policies that may make it difficult for both parents to be with their baby during their final hours, and putting in place measures to support both parents to be with their baby, together, during palliative and end-of-life care.

The impact of this pandemic will endure long after it is over. We know that a neonatal experience is often stressful and even traumatic – research by Bliss found that 80% of parents felt their mental health was negatively impacted by their experience.[7] If this is the case in comparatively normal times, how much more widespread and how much deeper will the impact be when parents cannot turn to their partners for support on the unit, have to socially distance from other parents there, and have the added anxiety of what COVID-19 might mean for their loved ones, including their baby, and their own financial situation? The long-term impact on families must be considered when developing parental access policies. Any restrictions should be proportionate and should seek to maximise opportunities for both parents to be present on the unit.

Finally, family-centred care could ease some of the pressure on healthcare professionals caused by COVID-19. Like all hospital departments, neonatal units may face increased staffing pressures as nurses and doctors have to self-isolate if they, or someone in their household, show symptoms of the virus, or through redeployment of staff to other services. Parents being supported to undertake tasks such as mouth care, changing nappies, giving oral medication and comfort holding may enable clinical staff to focus on specialist tasks – allowing them to make the most of their time when they are overstretched. In addition, far from increasing the risk of infection, allowing parents to provide a significant amount of their baby's care reduces the number of healthcare professionals who have to directly handle the baby, reducing the risk of infection from clinical staff.[8]

Caroline Lee-Davey, Chief Executive of Bliss, comments: "Ensuring the safety of vulnerable babies on neonatal units during the COVID-19 outbreak is paramount and we are incredibly grateful to all members of staff working in neonatal care across the UK for their dedication and hard work in such challenging circumstances. But we want to ensure the progress made towards implementing family-centred care in recent years is not lost as, while this pandemic is temporary, the impact on babies receiving neonatal care during this tumultuous period, and their families, will be long-lasting.

"At Bliss, we have reconfigured our services so that we can still help parents through this incredibly anxious and lonely time. While our Bliss Champion Volunteers are no longer able to go into neonatal units, some of them are now providing emotional support to parents remotely using video calls, which can be accessed by parents anywhere in the country. We have also been regularly updating our information about COVID-19 for parents of babies born premature and sick as soon as new guidance and information is issued.

"We are hearing the most heart-breaking stories from parents across the country as they tell us they're scared they will miss their baby's first smile, that they might forget what mummy and daddy look like, that they won't be able to cope on just maternity pay after they have lost a partner's income, and as they struggle on without the support of their own parents, wider family and friends.

"We are therefore urging neonatal units to ensure any limitations on parents' access and participation are proportionate and based on evidence, with a focus on maximising parental involvement in hands-on care as far as possible, and on keeping parents involved in decision-making and informed about their baby's progress if they aren't able to be on the unit. Babies' time on neonatal units may be relatively brief – days, weeks and, in some cases, months – but the effect of their care will be long-lasting, which is why it is so important that they are able to have their parents by their side during their difficult early days."

Information about COVID-19 for parents of babies born premature and sick can be found at:

bliss.org.uk/support

References

1. **RCPCH**. COVID-19: guidance for neonatal settings. April 2020 online at: www.rcpch.ac.uk/resources/covid-19-guidance-neonatal-settings
2. **Bliss**. Parental access and involvement during COVID-19. 2020 online at: www.bliss.org.uk/parental-access-and-involvement-during-covid-19
3. **O'Brien K, Robson K, Bracht M, et al.** Effectiveness of family integrated care in neonatal intensive care units on infant and parent outcomes: a multicentre, multinational, cluster-randomised controlled trial. Lancet Child Adolesc Health 2018;2:245-54.
4. **Pineda R, Bender J, Hall B, et al.** Parent participation in the neonatal intensive care unit: predictors and relationships to neurobehavior and developmental outcomes. Early Hum Dev 2017;117:32-38.
5. **Treherne SC, Feeley N, Charbonneau L, Axelin A.** Parents' perspectives of closeness and separation with their preterm infants in the NICU. J Obstet Gynecol Neonatal Nurs 2017;46:737-47.
6. **Flacking R, Lehtonen L, Thomson G, et al.** Closeness and separation in neonatal intensive care. Acta Paediatr 2012;101:1032-37.
7. **Bliss**. Bliss releases new research on mental health. 2018 online at: www.bliss.org.uk/news/bliss-releases-new-research-on-mental-health
8. **BAPM and Bliss.** Family integrated care for COVID-19 – frequently asked questions 2020 online at: https://hubble-live-assets.s3.amazonaws.com/bapm/redactor2_assets/files/422/FAQs_-_FIC_Covid19_-_version_2.docx.pdf

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Embrace® neonatal MRI system: mitigating infection risk in the NICU

The need to avoid healthcare-associated infections (HCAI) and their associated complications is well understood, especially when caring for the most fragile patients in neonatal intensive care units (NICU). Aggressive policies and procedures relying on clinical team members to thoroughly clean and disinfect equipment, and the adoption of visitation policies designed to limit the neonate's exposure to non-parental visitors and staff, are routinely employed in NICUs today.

Despite the vigilance applied to infection prevention, NICUs are forced to accept unnecessary risks and transport fragile infants out of the controlled environment of the NICU to the radiology department when an MRI is needed. In many cases, this is the only time a baby is moved from the NICU prior to discharge from the hospital.

An evaluation of outcomes during intra-hospital neonatal transport showed that 27% of patients transported for radiology services suffered complications.[1] In addition to the risk of clinical instability while transporting sick neonates through the hospital to the MRI suite, the transport exposes them to public and clinical areas that primarily serve other patient populations and increase their risk for exposure to infectious microorganisms and cross-contamination. In 2013, the American College of Radiology alerted hospitals to the importance of infection control in MRI facilities.[2] More recently, a paper in the *Journal of Medical Imaging* highlighted how deficiencies in infection prevention precautions exist in many radiology departments worldwide.[3]

"Any exposure to infection, even a simple sneeze or cough from a person in a hallway or elevator, can mean life or death for a baby who has been in the NICU since birth, is not immunised and may have respiratory issues," says Patricia G. Bondurant, DNP, RN, Co-founder and Chief Transformation and Quality Officer, TransForm Healthcare Consulting LLC. Dr Bondurant is a nationally recognised expert in healthcare management, neonatal and paediatric nursing, and quality improvement. Her work has resulted in improved care and outcomes for neonates and children and she was a key stakeholder and nursing lead in the development and implementation of the American Academy of Pediatrics NICU Levels of Care Verification Program.

The custom-designed infant bed provides a secure, temperature-controlled environment with quick access.

Transforming neonatal neuro imaging inside the NICU

Modern hospital design is based on providing the best possible care for patients. Faster access to services, improved patient experience, greater workflow efficiency – all of these goals are considered when designing clinical areas in the hospital. NICUs now include many services within their department: pharmacy, respiratory, laboratory, even surgical suites, to provide care to critically ill neonates in the unit without transport. While initially driven by the need to increase timely access to services, the benefit of keeping babies in the NICU is no longer strictly a convenience or a way to increase workflow efficiency. It is more critical than ever to keep babies, and those services they require, within the protected environment of the NICU and avoid the added risk of intra-hospital transport for any reason.

"The most important point is to not move the baby," adds Dr Bondurant. "In the US, higher level NICUs have dedicated ultrasound and X-ray machines to prevent infection transmission because we know that when a machine travels around a hospital it could be a vector for infections. So why should we change our practice when it comes to MRI, and not have it as contained as the rest of the NICU? It draws a natural conclusion that we should have a dedicated MRI in the NICU."

Today, that risk to move a baby from the NICU to an MRI in the radiology department is magnified with the heightened concern of COVID-19, a novel coronavirus causing widespread infection, especially with MRI equipment in most hospitals being located a great distance from the NICU, requiring long transport of babies through the hospital.[4] According to Dr Bondurant, she's hearing from colleagues who report they are more reluctant to order MRI scans and, in some cases, postponing the exam until after discharge during the COVID-19 healthcare crisis.

Yet, delaying an MRI for a NICU patient can impact not only their diagnosis, but also their development. It's important, Dr Bondurant says, that parents have access to habilitative services for their child as soon as possible, especially when long-term

The Embrace system's small footprint and unique design allows NICU equipment, staff and parents to remain close.

services are needed to maximise a baby's development. The extent of an injury may not be known unless the infant has an MRI, which is more specific than an ultrasound or X-ray and is a standard of care for diagnosing brain and spinal injuries.[5]

As concern for minimising infection risks to the most fragile patients increases, the option of providing care to neonates without leaving the NICU has transitioned from a nice-to-have approach, to a must-have approach to mitigate the risk of infection for patients at the highest risk of complications.

That's where Aspect Imaging's Embrace, the only FDA 510(k) and CE approved dedicated neonatal MRI system, can make a world of difference for the health and development of critically ill infants. Uniquely designed to be placed within the NICU, the Embrace offers the critically valuable, timely diagnostic information only available from MRI, without the acknowledged risk of taking the baby out of the NICU.

"The Embrace Neonatal MRI allows us to do things we couldn't do before because of the risks of moving a baby down to the MRI suite," says Dr Bondurant. "It gives us timely information that will allow us to provide habilitative, early intervention services when needed. Without the Embrace we are forced to compromise our practice and transport the baby from the safe, sterile environment of the NICU to get their MRI. We shouldn't be breaking the practices that we so heartedly put into place to protect these babies in every way possible when there is another option."

References

1. **Bastug O, Gunes T, Korkmaz L, et al.** An evaluation of intra-hospital transport outcomes from tertiary neonatal intensive care unit. J Matern Fetal Neonatal Med 2016;29:1993-98. Doi: 10.3109/14767058.2015.1072158.
2. **Expert Panel on MR Safety, Kanal E, Barkovich AJ, et al.** ACR guidance document on MR safe practices: 2013. J Magn Reson Imaging 2013;37:501-30. Doi: 10.1002/jmri.24011.
3. **Ilyas F, Burbridge B, Babyn P.** Health care-associated infections and the radiology department. J Med Imaging Radiat Sci 2019;50:596-606.e1. Doi: 10.1016/j.jmir.2019.07.011.
4. **Wu TW, McLean C, Friedlich P, et al.** Maintenance of whole-body therapeutic hypothermia during patient transport and magnetic resonance imaging. Pediatr Radiol 2014;44:613-17. Doi: 10.1007/s00247-013-2863-2.
5. **Rademaker KJ, Uiterwaal CS, Beek FJ, et al.** Neonatal cranial ultrasound versus MRI and neurodevelopmental outcome at school age in children born preterm. Arch Dis Child Fetal Neonatal Ed 2005;90:F489-93. Doi: 10.1136/adc.2005.073908.

The role of simulation in preparing a response to the COVID-19 pandemic

In response to COVID-19, simulation has been used to embed practical skills such as donning and doffing of personal protective equipment and scenario-based logistics of proposed COVID-19 patient flows. We have developed small staff group training sessions, alongside larger scale multidisciplinary team sessions and used simulation to guide the development of our standard operating procedure. We have also created online training resources to reach a larger number of staff within the neonatal unit (NNU). In this article we share our experiences to help others develop their own ideas on the plethora of ways that simulation can aid a response to the COVID-19 outbreak and any other future advances within the NNU.

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Keywords

COVID-19; personal protective equipment; infection control

Key points

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1. The current COVID-19 outbreak has raised concern about providing high quality neonatal care while minimising risk to staff.
2. Simulation can help address these challenges by promoting teamwork and testing logistics in novel situations.

Emergence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, COVID-19) has caused a worldwide pandemic. The response to this health crisis needs to be rapid and involve multidisciplinary team (MDT) working. The advice from the government and regulatory bodies can fluctuate and is ever-evolving. The challenges are numerous as departments and staff members may have clashing priorities, there are staff shortages and an even more variable staff rota than usual, unease with new working practices, unfamiliarity with personal protective equipment (PPE), and reduced time for staff training and dissemination of information.

Health care needs to implement complex training at ground level – fast and flexible solutions to practically implement COVID-19 prevention strategies and procedures. Our experience at St Mary's Hospital, Manchester, has shown that simulation can help address these challenges through problem solving, logistical testing and building familiarisation of MDT working in novel circumstances.

COVID-19 and newborn services

At the time of writing, there is little evidence available regarding the impact of COVID-19 on newborn infants. The evidence to date would suggest little risk of vertical transmission (no evidence of virus RNA on placental swabs, amniotic fluid, cord blood) nor in breast milk.[1,2] However, due to the rapid spread of COVID-19 and the novel nature of the virus, there is paucity of research in this area. In addition, the risks of transmission of COVID-19 to infants have to be balanced against the detriment of separation after birth.[3] While leaving a newborn infant with its COVID-19 positive mother may increase the risk of postnatal virus transmission, there is also potential harm in terms of bonding and breastfeeding if the infant is completely isolated from its mother for a sustained period after birth. Based on this, our department has decided that infants born to COVID-19 suspected/positive mothers who are well will remain with their parents and we will only admit infants to the neonatal intensive care unit (NICU) if they require support.

Simulation at St Mary's Hospital

The newborn service at St Mary's Hospital is a large tertiary level medical and surgical neonatal unit that regularly uses simulation in a variety of ways to familiarise and improve technical and human factors skills in multiple contexts. The unit has a pre-existing positive simulation culture – simulation is embedded into the functioning of the unit with MDT *in situ* simulations occurring twice a week, alongside additional regular joint simulation sessions with obstetrics, midwifery and anaesthetics.

Simulation can be used in simple and very effective ways to ensure safe and robust patient care and staff safety. Ideally, the first time a system or flow process is tested should not be with a real patient. Use of simulation helps to promote patient

Learning need	Type of simulation	Benefit from simulation learning
1. Skills training in use of PPE	Small group sessions utilising video and practical skills in donning and doffing	Familiarity with PPE requirements in different contexts (**TABLE 2**) Practical experience of donning and doffing Set-up habit of checking each other's PPE
2. Scenario and systems testing	Small group sessions and clinical scenario simulations	Identification of latent safety threats in the SOP Familiarisation with the SOP for staff
3.Simulation scenario to develop SOP	Clinical scenario simulations (walk-through and second phase testing)	Identification of latent safety threats – ensure these are addressed in updated versions of the SOP Development of video showing the SOP being used in a simulated scenario to illustrate to the wider team
4. MDT simulation	Second and third phase testing Video-based resources	Identify key concerns and requirements for each team involved Ensure each team is aware of major requirements/working needs of the other teams Ensure these major requirements are acknowledged in the MDT SOP Video resources to allow sharing of SOP between teams
5. Creating accessible learning in difficult circumstances	Online video-based resources to demonstrate key skills and to improve understanding of processes and physiology	Continued staff development despite formal courses and mandatory training cancellations Staff remain up-to-date with key life-support skills to ensure they provide high quality care

TABLE 1 Different applications of simulation in the context of COVID-19. Key: PPE= personal protective equipment, SOP=standard operating procedure, MDT=multidisciplinary team.

Neonatal team at delivery		**Neonatal team on NICU**		**Neonatal team on PNW**
Contact team (in the delivery room)	**Non-contact team**	**Contact team** (in the NICU)	**Non-contact team**	
Standard PPE	**Basic PPE**	**Standard PPE**	**Basic PPE**	**Basic PPE**
FFP3 mask	Surgical mask	FFP3 mask if AGP likely Surgical mask if in the room/basic cares	Surgical mask	Surgical mask
Blue long-sleeved apron	Blue long-sleeved apron	Blue long-sleeved apron	Plastic apron	Plastic apron
Non-sterile gloves	Non-sterile gloves	Non-sterile gloves	Non-sterile gloves	Non-sterile gloves
Scrubs/uniform	Scrubs/uniform as may be called into the delivery room to assist contact team if additional staff are needed for full resus. If this happens, switch surgical to FFP3 mask before entering the delivery room	Scrubs/uniform		
Visor/goggles	Visor/goggles	Visor/goggles		

TABLE 2 PPE recommendations for neonatal teams (taken from our SOP version 3.10, 3 April 2020). Key: PNW=postnatal ward, FFP3= filtering face-piece particles mask type 3, AGP=aerosol generating procedures (include intubation, suctioning, continuous positive airway pressure, high-flow therapy).

safety without exposing a patient to risk. **TABLE 1** shows the different applications of simulation in the context of COVID-19, which will be discussed in this article.

1. Skills training in use of PPE

PPE is utilised to varying extents on a daily basis and is familiar to the majority of healthcare workers; for example, aprons and gloves should be worn for blood taking. However, in the midst of a pandemic, risks may be more significant and staff may experience higher levels of anxiety regarding PPE including uncertainty over which type of PPE to wear and when. Familiarity does not equate to good practice and staff may not have sufficiently robust personal habits, in terms of applying/removing their usual PPE, to ensure they can do so correctly in the context of a pandemic pathogen. To further compound the issue, there have been numerous updates regarding the level of PPE to be worn in various situations with potential for confusion and/or misinterpretation.

Videos of donning and doffing

procedures have been developed by numerous hospitals and trusts across the country. These videos are a helpful introduction; however, they should not be the only form of training that staff are able to access. Our experience of using these videos was that staff had often watched them prior to the session but when questioned, they struggled to remember the sequence of donning and doffing or would confidently proceed but with errors that could lead to self-contamination with a COVID-19 positive patient.

Over a one-week period, simulation sessions were run utilising pre-existing teaching slots on the unit. Staff watched the donning and doffing videos on the trust intranet and then had to physically don and doff PPE themselves. Two participants donned then doffed at a time. This ensured facilitators could monitor the process and check it was performed safely and correctly. The other participating staff members watched multiple times and acted as checkers for each other. This repetition meant each person had numerous encounters with the donning and doffing sequence, thus embedding the skills.

Over the initial one-week training period, 40 staff members were trained, including 80% of junior doctors (the 20% that were missed were self-isolating and not present at work) and reaching members of the 250+ neonatal nursing team. The sessions will continue throughout the COVID-19 outbreak. **TABLE 2** and **FIGURE 1** show the different PPE recommendations for neonatal teams in the context of COVID-19.

2. Scenario and systems testing

The neonatal infection control lead, departmental lead and nursing leads met to discuss how to manage the delivery and potential resuscitation of infants born to COVID-19 suspected/positive mothers, and how to manage infants who require admission to the NICU. Advice from available research and guidance from relevant professional bodies (eg Royal College of Obstetricians and Gynaecologists and the British Association of Perinatal Medicine) was used to create a standard operating procedure (SOP).

The SOP was then tested using our own phase-structured simulation approach:

i. **First phase testing:** The initial SOP was used while performing a walk-through (members of the SOP development team physically walked through the delivery and admission areas to ensure the proposed SOP would be practical). This process is simple, easy to perform and allows identification of more obvious and immediate issues.
ii. **Second phase testing:** The SOP is tested in a full simulation scenario using a low-fidelity infant manikin and physically performing each stage of the SOP. This involved senior members of the SOP development team (neonatal consultants and neonatal matrons).
iii. **Third phase testing:** Scenarios were run with NICU staff members to allow the SOP to be used in simulated clinical scenarios. This gave the SOP development team an opportunity to get feedback and make updates to ensure it is as clear as possible for users. This type of simulation will be ongoing throughout the COVID-19 pandemic.

3. Using simulation to develop a neonatal SOP: lessons learnt

Resuscitation at birth of an infant delivered to a COVID-19 suspected/positive mother

An SOP was developed for a variety of neonatal resuscitation scenarios, which attempted to minimise risks to staff through the creation of a contact and a non-contact team. The contact team would don PPE, including an FFP3 mask (**TABLE 2**), would be present in the delivery room and provide hands-on resuscitation if required. The non-contact team would don PPE involving a surgical face mask, as they would remain outside the room providing equipment and assistance as needed to the contact team. This ensured clear task allocation, minimisation of the number of staff members potentially exposed and minimal contamination of emergency equipment.

In the usual full neonatal resuscitation situation, a yellow emergency trolley laid out in an 'ABCD' structure is used. Through the simulated walk-through process we recognised that any equipment taken into a COVID-positive environment has to be discarded at the end of the resuscitation. Our labour ward has two emergency trolleys servicing 20 delivery rooms, in addition to one in the obstetric theatres. Therefore, concern was that if an emergency trolley was taken into a delivery room and used for an infant born to a COVID-19 positive mother, the destruction of the remaining contents of that trolley and the decontamination and restocking process would be extensive, and the trolley would be unavailable for other possible resuscitations in the meantime. By creating the contact and non-contact teams it was clear that in the event of a full resuscitation the non-contact team could usefully gather necessary equipment and draw up emergency medications outside the room. When simulating various scenarios using the contact and non-contact team approach, it was clear that a runner was needed within the room to pass requests from the contact team to the non-contact team. It was recognised that the midwife already in the delivery room would be in the most appropriate position to do this.

FIGURE 1 The different COVID-19 PPE recommendations for neonatal staff. Left: Non-contact staff remain outside the delivery room (or theatre or designated NICU room) and assist with equipment and medications for the contact team. Non-contact staff wear an apron, gloves, visor/goggles and a surgical mask. Right: Contact staff remain inside the delivery room and wear an FFP3 mask because of the risk of AGPs.

Transport to the neonatal intensive care isolation room

It was identified that if the usual transport incubator was used to move an infant born to a COVID-19 suspected/positive mother from the delivery suite to the NICU, again the extensive decontamination process could mean this incubator would be

unavailable for some time for subsequent infants. This was highlighted through simulation and our SOP development team worked with NICU equipment technicians to create a specific COVID-19 transport incubator (**FIGURE 2**). Over the course of subsequent simulations the equipment that might be needed on this COVID transport incubator was refined. This included identification that the COVID incubator needed a dedicated thermometer as the newly designated dedicated COVID obstetric theatres were previous gynaecology theatres and did not have neonatal equipment.

In addition, simulation scenarios with the full MDT in theatres identified issues with PPE provision. When attending a delivery, the NICU team had been expecting PPE to be available at the MDT donning station by the theatres. Whereas, the theatre team was expecting the NICU team to bring its own supplies of PPE. We therefore modified our transport incubator to include provision of PPE for the entire NICU team, while agreeing with theatres that initial responders (the contact team) could utilise theatre PPE and be ready earlier.

Admission to NICU

We used a walk-through simulation on the admission process to the NICU for infants born to COVID-19 mothers, where members of the SOP development team physically walked through the delivery and admission areas to ensure the proposed SOP would be practical. We updated the SOP following the walk-through and then ran full simulated clinical scenarios using team members to test the logistics and practicalities. This process raised issues (such as the lack of a specific airway trolley for our COVID-19 isolation room), which were addressed by the SOP development team. Simulated scenarios were then repeated with our clinical medical and nursing teams.

4. MDT simulation

MDT working has been pivotal in the development of our neonatal SOP; neonatal care is inextricably linked to maternal care. Therefore, through each stage of the SOP development the neonatal SOP development team worked closely with the obstetric, midwifery and anaesthetic SOP development teams. A series of simulated clinical delivery scenarios were run with the entire MDT, allowing potential issues to be addressed, for example, when to call the neonatal team. Due to the process of donning before entering the room, the neonatal team requires additional advance warning time; having an MDT approach allowed the other teams to recognise and build this into their department's SOP.

FIGURE 2 Through simulation we discovered that we needed a specific COVID-19 transport incubator.

FIGURE 3 Simulating the admission process to the NICU.

5. Creating accessible learning in difficult circumstances

To avoid spread of the COVID-19 virus many face-to-face mandatory and educational courses and conferences have been cancelled for the coming months. This includes Newborn Life Support (NLS) courses and in-house mandatory training courses, raising concern that staff are not being given the opportunity to have crucial skills reviewed and refreshed.

This is of particular concern in the current COVID-19 outbreak. For example, a midwife attending a COVID-19 positive mother may be left to initiate NLS alone for a longer period than usual while the neonatal resuscitation team dons PPE – donning PPE can take 3-5 minutes when done properly.

There is an ethical obligation to ensure that as many midwifery and neonatal staff as possible have the most up-to-date NLS skills and our simulation team created video-based resources to provide the same content as the cancelled face-to-face mandatory training. These videos allow staff to access NLS refresher sessions either remotely or in a one-to-one session with the midwifery or neonatal education team. The videos ensure content is consistently delivered by an expert NLS certified

professional instructor. They contain a lecture-style overview of the physiology guiding newborn resuscitation and practical demonstrations of key NLS skills. The videos can be accessed via the staff intranet or staff email and can be downloaded onto education team computers/tablets to allow staff to easily watch and then practise on a manikin.

The videos were filmed using iPhones and then edited into the final teaching video using the freely available iMovie software, which is user-friendly and has easily accessible support via the Apple website.

Tips for successful simulation

Simulation does not require extensive experience to yield useful results. As illustrated in this article, simulation can be used effectively in systems and safety testing, and development and modification of a SOP. This type of simulation does not require prior experience, however, simulation of clinical scenarios should always be run by someone with experience of debriefing in order to manage the learning and psychological safety of the staff participating in the simulation.

In our experience, staff are enthusiastic and insightful following simulations to aid systems testing. However, it is vital to make it clear to participating staff that the key aim of the simulation is to test the system – not to covertly test the staff.

It is important to include a pre-brief; a conversation before the simulation begins between facilitators and participants outlining the set-up, scenario and providing reassurance that participants are helping test the proposed system/SOP.

It needs to be made clear to participants that any major concerns about aspects of observed care would be addressed privately afterwards. The focus of the debrief will be on gathering feedback about positive and negative aspects of the system tested, rather than commenting on an individual participant's skills or performance.

Conclusion

Simulation has played an important role in developing a COVID-19 specific neonatal SOP for safe and effective care at St Mary's Hospital. **TABLE 3** summarises the learning points contributing to this. Our SOP and training videos are available for others to use – please direct any questions or comments to the corresponding author.

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References

1. **Chen H, Guo J, Wang C, et al.** Clinical characteristics and intrauterine vertical transmission potential of COVID-19 infection in nine pregnant women: a retrospective review of medical records. Lancet 2020;395:809-15.
2. **Zhu H, Wang L, Fang C, et al.** Clinical analysis of 10 neonates born to mothers with 2019-nCoV 377 pneumonia. Transl Pediatr 2020;9:51-60.
3. **Unicef UK Baby Friendly Initiative.** Baby Friendly Initiative statement on infant feeding during the COVID-19 outbreak. 2020 online at: www.unicef.org.uk/babyfriendly/wp-content/uploads/sites/2/2020/03/Unicef-UK-Baby-Friendly-Initiative-statement-on-infant-feeding-during-the-Covid-19-outbreak-4.pdf

Area of SOP development	Type of simulation	Learning points
Designation and equipping of COVID-19 transport incubator	Walk-through and second phase testing	- Need for a dedicated COVID-19 incubator stocked with additional equipment, eg PPE, thermometer, transwarmer, plastic bag for preterms - MDT working with equipment technicians
Development of contact and non-contact teams	Second and third phase testing	- Minimises staff exposure to COVID-19 while still ensuring good clinical care - Allows clear job allocation inside and outside the delivery room
Taking the neonatal emergency trolley into a COVID-19 positive room meant that remaining equipment would be destroyed after the resuscitation	Walk-through and second phase testing	- Through recognition of this latent safety threat, wastage of potentially contaminated equipment was avoided and the role of the non-contact team was cemented
Appropriate positioning of neonatal team and neonatal equipment in theatres	Walk-through, second and third phase testing	- MDT working ensured all teams involved in a delivery are only exposed to the minimum risk - MDT working identified an appropriate set-up that allows all teams to work effectively
Development of the COVID-19 emergency trolley for the isolation room within NICU	Second phase testing	- Our newly designated COVID isolation room within the NICU is a recently renovated clinical room, which usually functions as a special care nursery. It has functionality for ICU if required, however, is not routinely stocked as such - Simulation identified a lack of an emergency airway trolley in this room - Creation of a new COVID emergency trolley in conjunction with the NICU stock team
Development of a training video for staff regarding management of an infant born to a COVID-19 suspected/positive mother	Second phase testing	- Development of a video showing the SOP in action. An efficient method of disseminating the content of the SOP to the wider clinical team.

TABLE 3 The role of simulation in development of a COVID-19 specific neonatal SOP for safe and effective care.

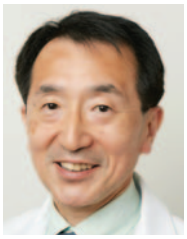
Advancing the science of human milk to benefit more infants

Human Milk Science and Innovation

Earlier this year the International Conference on Human Milk Science and Innovation (ICHMSI) took place in Barcelona, Spain. Founded by Prolacta Bioscience, ICHMSI brings together renowned scientists, clinicians and parent advocates from around the world to discuss developments in human milk nutrition, thus ensuring that the latest clinical research will benefit critically ill and premature babies. Although attendees came from 18 different countries, four words were on everyone's lips: exclusive human milk diet (EHMD).

What is an EHMD, how can it be applied in clinical practice and what impact does it have on critically ill and premature babies? Unfortunately breast milk alone does not provide enough nutrition for preterm and very low birthweight (VLBW) infants and this is why clinicians add fortifiers to their feeds. Traditional cows' milk-derived fortifiers have been associated with enteral feeding intolerance, onset of milk allergy and fatty acid calcium stone formation. An EHMD is achieved when 100% of the protein, fat and carbohydrates in an infant's diet are derived from human milk. This diet includes a human milk-based human milk fortifier. No substances derived from cows' milk are added.

Infant asked four of the speakers at ICHMSI for their insights on achieving healthy growth using an EHMD.



Professor Katsumi Mizuno of Showa University School of Medicine, Tokyo, Japan, works on standardisation of enteral nutrition for very preterm infants and co-authored the recently published Japan Pediatric Society policy statement for enteral nutrition.

Can you tell us about the new policy statement for enteral nutrition in preterm and VLBW infants?

"Mother's own milk (MOM) is best for very preterm infants and if MOM is not available, donor human milk (DHM) is second best. In Japan, we now have human milk banks and so therefore the time is right to issue a policy statement that sets out how we will create a system to supply an EHMD to preterm and VLBW infants consisting of human milk with the addition of a human milk-based fortifier.

"An EHMD has been shown to reduce the complications of babies born at <1,500g. There is evidence that early nutrition is important to prevent bronchopulmonary dysplasia and retinopathy of prematurity in preterm infants. We have not experienced any cases of necrotising enterocolitis (NEC) with MOM or DHM."

How have you standardised enteral nutrition for very preterm infants?

"We do not wait for MOM to come in – we aim to start enteral feeding as soon as possible. We use DHM as a 'bridge' before MOM is available and we start enteral feeds at 12 hours of age. As soon as we get the mother's milk we switch to her supply."

What effects do you hope the new policy for enteral nutrition will have on care standards in Japan?

"Neonatologists are very good at dealing with respiratory support and neuroprotection and these are essential, but nutrition is not regarded as a crisis and often gets overlooked. I hope that the policy will increase awareness of the importance of nutrition for preterm infants."

Professor Roy Philip is Adjunct Clinical Professor of Neonatology and Consultant Paediatrician and Neonatologist at UL Hospitals, Limerick, Ireland. His neonatal unit is the first in Ireland to introduce an EHMD.

What prompted you to implement an EHMD in your unit?

"Unfortunately in Ireland the breastfeeding uptake for term babies is not great and consequently in the past we had a significant number of preterm and VLBW infants who were exposed to cows' milk-based products. With extreme prematurity and very low birth weight we usually fortify the breast milk, which means whatever we add becomes part of the feed. We wanted to establish ourselves as a breast milk-based unit to reduce morbidity and mortality."

How did you begin to implement the diet and did you face any challenges along the way?

"It began as a quality improvement project 10 years ago when we had relatively low breast milk uptake in the neonatal unit. We improved upon this year-on-year. There were two phases to the

task; firstly, we wanted to go from being a formula-based unit to a breast milk-based unit. Implementing a human milk diet in any unit is challenging and requires clinical leadership and a dedicated team. However, if we can achieve this goal, any unit can.

"Having established ourselves as a breast milk-based unit we then wanted to use fortifier that was made from only human milk products. Using a combination of fresh maternal breast milk (supplemented by DHM if needed) with the addition of human milk-based fortifier is the best intervention to optimise a baby's nutrition."

What favourable outcomes have you seen with your approach?

"We have reduced morbidity and mortality. The babies grow faster, the NEC rate has come down – we have created a NEC-free neonatal unit. A consistently low NEC rate, however, is just the top of the pyramid; look below this and we see low sepsis rates, shorter durations of long-lines, less total parenteral nutrition (PN), less antibiotic use, etc."

Your unit now uses an EHMD for some subsets of premature infants. Which babies do you select and why?

"For over five years all of our extremely low birthweight infants have received breast milk and in early 2019 we started using human milk-based fortification. To date, 12 VLBW infants on our unit have been offered an EHMD. When it comes to breast milk for vulnerable premature infants, my approach would be the three Es: early, enterally and entirely."

Professor Christoph Fusch from Nuremberg General Hospital, Germany, works on lactoengineering and postnatal growth in VLBW infants.

What is lactoengineering and why did you choose lactoengineering-based fortification rather than standard fortification?

"Human breast milk is highly variable in composition in terms of carbohydrate, protein, fats and energy. It is therefore hard to know what we need to 'put in' to adequately fortify the breast milk. Preterm infants have high growth rates and high nutritional needs. Some preterm babies do not achieve optimal growth with standard fortification, they are undernourished and current feeding practices are not sufficient to meet the nutritional needs of these infants. We analyse the breast milk and measure these macronutrients and from this we can individualise the fortification of breast milk. This is called lactoengineering."

This sounds complicated; does it require a lot of special equipment?

"No, we have a sonicator to homogenise and a small tablet-like device to analyse. It takes 1-3 minutes. It's comparable to performing blood gas analysis to guide ventilation strategies. All units perform blood gas analysis, so why not individualised target fortification?"

What experience have you had with an EHMD?

"I was lucky to gain experience with an EHMD 10 years ago in North America where I saw the benefit of this on gut health and NEC prevention. Babies tolerate this type of feeding better and they have fewer line days and consequently less sepsis. When I came back to Germany we had relatively high NEC rates in the unit. We worked very hard to bring down our sepsis rates by starting to feed earlier, having fewer line days and putting infection prevention measures in place. The sepsis rates came down and our NEC rates came down but we didn't get down to zero. We decided that the next step was to introduce an EHMD for our high-risk babies. It's too soon to say for sure if this has worked, but last year we did not see any NEC cases."

How do you define and measure growth for VLBW infants on an EHMD?

"We use weight charts, classic intrauterine growth charts and we have also developed the concept of individualised growth trajectories, which take into account the preterm baby's weight loss after birth. For each baby we have an individualised trajectory to work out how best it can achieve its target weight. We compare our weight gains against these trajectories, which we have validated in eight cohorts of 14,000 subjects with known outcomes. This concept helps us to monitor growth and guide nutrition."

Dr Amy Hair is Program Director of the NICU Intestinal Rehabilitation Team at Texas Children's Hospital, USA. She successfully manages the nutrition of infants with short bowel syndrome using an EHMD.

Can you tell us about the challenges that babies with short bowel syndrome face?

"Depending on how much bowel they lose, babies with short bowel syndrome can be on long-term PN. They can have developmental delays, they have lots of hospitalisations. It's a lifelong condition. Most can eat when they are older but usually not a normal diet.

"Nowadays we have more survivors. Eight years ago if a baby had 10cm of bowel, the clinicians would tell the parents there was nothing they could do, they wouldn't save the baby, but now these babies are running around at three years of age and off PN.

"The biggest cause of short bowel syndrome is NEC and if we can prevent NEC with an EHMD then we don't have to worry about long-term outcomes."

When did Texas Children's Hospital implement an EHMD?

"We have been using an EHMD at Texas Children's Hospital for 11 years and we have been able to prevent NEC. We started using DHM and Prolacta's human milk-based fortifiers in 2009. Our NEC rate went from 16% to a consistent 2-3%. We have spent a lot of time optimising our feeding."

What outcomes or morbidity data have you tracked and what were your findings?

"We noticed that the babies who were on an EHMD were simply doing better than those that were not. The neonatal journey is often described as a 'rollercoaster ride' but these babies had less bumps in the road – they didn't have a lot of complications. We did a before (bovine diet) and after (EHMD) study and found that we had less NEC, less infection, less retinopathy of prematurity, less lung disease and less death. Not only did these babies survive prematurity but they also had less morbidity."

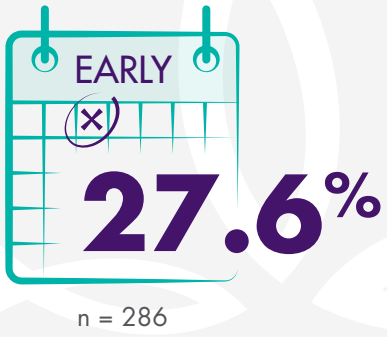
What advice about an EHMD can you offer to those working with premature babies?

"In the US, we have been using an EHMD for several years now but the human milk-based fortifier has only been available in Europe for the last year. As someone with lots of experience with an EHMD I'd say it's good for the babies; it's one of those products that really improves outcomes – you should try it."

For healthcare professional use only

Early enteral fortification with Prolacta's fortifiers as part of an Exclusive Human Milk Diet (EHMD) reduced the risk of bronchopulmonary dysplasia (BPD) by 15%.[1]

A recent multicenter, retrospective, cohort study showed significant reduction ($P = 0.008$) in the risk of developing BPD in extremely premature infants when feeding Prolacta's fortifiers in the first days of life as a part of an EHMD.[1]



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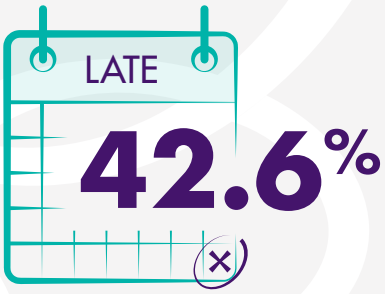

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Development of premature infants' lungs,[1] gut,[2] and brain[3] are all impaired without the necessary enteral nutrition. With Prolacta's products as a part of an EHMD, you can safely fortify within the first week of life to provide the necessary nutrition.[1]

Neonatal intensive care units throughout Europe and the United States are using human milk–based products for premature infants under 1500 g. To date, this includes more than 63,000 premature infants globally.[4]

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1 Huston RK, Lee ML, Rider ED, et al. Early fortification of enteral feedings for infants <1250 grams birth weight receiving a human milk diet including human milk-based fortifier. *J Neonatal Perinatal Med.* 2019. [Epub ahead of print]. doi:10.3233/NPM-190300 **2** Brune KD, Donn SM. Enteral feeding of the preterm infant. *NeoReviews.* 2018;19(11):e645-e653. doi:10.1542/neo.19-11-e645 **3** Schneider J, Fischer Fumeaux CJ, Duerden EG, et al. Nutrient intake in the first two weeks of life and brain growth in preterm neonates. *Pediatrics.* 2018;141(3):e20172169. doi:10.1542/peds.2017-2169 **4** Data on file.

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COVID-19: the importance of healthcare professionals in protecting human milk and breastfeeding

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It is clear that the world will never be the same since the onset of the COVID-19 pandemic. Our daily routines and the healthcare system will be forever changed. Nonetheless, families will continue to conceive and bring new lives into the world. Now more than ever, families need access to evidence-based lactation care and support. With social distancing there are both opportunities and risks: opportunities to improve breastfeeding outcomes; risks that families may not be able to access much-needed lactation care or lactation technology.

Guidance from the Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Midwives (RCM) supports the use of human milk and breastfeeding.[1] The Royal Colleges report that, to date, the virus has not been found in human milk and that the main risk for COVID-19 transmission is the close contact of the mother and child – an infected mother could transmit the virus via infective droplets. In light of the current evidence, RCOG and RCM state that the benefits of breastfeeding outweigh any potential risks of transmission of the virus through human milk and recommend the following precautions to limit viral spread to the baby:[1]

1) wash hands before touching the infant, breast pump or bottles
2) avoid coughing or sneezing on the infant during breastfeeding
3) consider wearing a fluid-resistant surgical face mask, if available, while feeding or caring for the baby
4) consider asking someone who is not infected to feed expressed milk to the infant
5) if the mother is expressing milk in a hospital, a dedicated breast pump is recommended and the mother should be given explicit instructions for hand washing and pump cleaning/disinfection.

The Spatz 10-step model
1. Informed decision
2. Establishment and maintenance of milk supply
3. Human milk management
4. Oral care and feeding of human milk
5. Skin-to-skin care
6. Non-nutritive sucking at the breast
7. Transition to breast
8. Measuring milk transfer
9. Preparation for discharge
10. Appropriate follow up

TABLE 1 Ten steps to promote and protect human milk and breastfeeding in vulnerable infants.

What can healthcare professionals do?

Given the guidance to protect human milk and breastfeeding during the COVID-19 pandemic, the model that I developed to promote and protect human milk and breastfeeding in vulnerable infants is highly applicable (**TABLE 1**).[2-4] In particular, the first three steps will be discussed in relation to the COVID-19 pandemic.

Step 1: Informed decision

Not all families in the UK and globally have the opportunity to make informed feeding decisions. Many families do not initiate breastfeeding due to a lack of family support, culture and/or lack of education. During this current pandemic, we have the opportunity to change the prenatal care paradigm to ensure that all families make an informed feeding choice.[5] Breastfeeding should be a point of discussion at every single prenatal visit.[5] At the first point of contact we should assess the family's exposure and experience with breastfeeding, as well as any positive or negative views. We should provide data and resources to help families understand how and why human milk and breastfeeding are important for their personal situation. In particular, during this pandemic, we can provide information about how human milk protects against other viral infections. Liang and colleagues found that multiple human viruses were more abundant in stool samples from infants who were exclusively formula fed compared to those that received either partial or exclusive human milk diets.[6]

Step 2: Establishment and maintenance of milk supply

During pregnancy, the family should be instructed on the physiology of lactation so that they can

have the best opportunity to effectively establish and maintain a milk supply.[2-5] The mother begins to secrete milk in the second trimester of pregnancy so regardless of whether she has a preterm or term delivery, her breasts are prepared to make milk for her child. In addition, we should proactively empower the partner/support person so that the mother's main focus after delivery is to eat, sleep and make milk for the infant.

With the COVID-19 pandemic, some hospitals are separating COVID-positive mothers from their infants immediately at birth. If this is the practice, the mother must be supported to pump early and pump often with a hospital-grade pump.[7] Research demonstrates that the sooner the mother expresses after birth (within six hours but ideally within the first hour), the more likely she is to come to volume and have a higher milk supply at three weeks postpartum.[8,9] It is particularly important to note that personal-use pumps are not designed to initiate lactation.[10] Mothers who are separated from their infants at birth for any reason should have access to a hospital-grade pump with 'initiation technology'.[10,11]

There is a critical window of opportunity for the establishment of milk supply and therefore the role of the paediatric healthcare provider is of paramount importance.[11] Some hospitals discharge mothers and their infants early (within 24 hours of vaginal birth and 48 hours of caesarean birth) so it is essential that at the newborn visit the provider determines if the mother has effectively converted from lactogenesis I to lactogenesis II. Mothers may continue to need in-person technical assistance for breastfeeding but should also be referred to virtual support groups and 'tele-lactation' visits.

Step 3: Human milk management

Step 3 of my model is of critical importance during the pandemic for several reasons. First, if mother and child are separated and the mother is expressing milk, she and her family need specific instructions on daily cleaning and disinfection of the pump, the pump pieces and the pump kit.[1] The family will also need instructions on correct storage of the milk, with an emphasis on the use of freshly expressed milk.[2,3] Human milk contains live white blood cells (WBCs), stem cells, lactoferrin, antioxidants, antibodies, and other immune, growth, and developmental factors.[5] When milk is frozen, WBCs and stem cells are destroyed and many of the other immune components become less potent. Fresh milk matters now more than ever.

So many unknowns...

With the COVID-19 pandemic, there are many things that we are unable to predict and control. We don't know when this pandemic will end or when social distancing guidelines will relax but what we can embrace is human milk and breastfeeding as a life-saving medical intervention. **FIGURE 1** demonstrates just how vital human milk is. Baby Charlotte was born with a giant omphalocele (exomphalos) that had been prenatally diagnosed. I met with her mother while she was pregnant and provided her with a personalised 1:1 consultation.[5] Her mother followed the Spatz 10-step model exactly as instructed. She produced over a litre of milk per day and had not only enough milk for her daughter, but was able to donate milk to a non-profit milk bank. Charlotte will be 10 this year and has no health concerns. Her photos are a testimonial to the life-saving power of human milk as a medical intervention.

FIGURE 1
The life-saving power of human milk: first time at the breast for baby Charlotte (left) who will be 10 years old this year (below).

References

1. **RCOG and RCM**. Coronavirus (COVID-19) infection in pregnancy: information for healthcare professionals. Version 8; 17 April 2020 online at: www.rcog.org.uk/globalassets/documents/guidelines/2020-04-17-coronavirus-covid-19-infection-in-pregnancy.pdf
2. **Spatz DL**. Ten steps for promoting and protecting breastfeeding in vulnerable populations. J Perinatal Neonatal Nurs 2004;18:385-96.
3. **Spatz DL.** Beyond BFHI: The Spatz 10-step and breastfeeding resource nurse models to improve human milk and breastfeeding outcomes. J Perinatal Neonatal Nurs 2018;32:164-74.
4. **Spatz DL.** Increasing capacity for the provision of evidence-based human milk and breastfeeding support. Infant 2018;14:54-57.
5. **Spatz DL.** Changing the prenatal care paradigm to improve breastfeeding outcomes. Am J Matern Child Nurs 2020;45:186.
6. **Liang G, Zhao C, Zhang H, et al.** The stepwise assembly of the neonatal virome is modulated by breastfeeding. Nature 2020; doi.org/10.1038/s41586-020-2192-1.
7. **Spatz DL, Froh EB, Schwarz J, et al.** Pump early, pump often: a continuous quality improvement project. J Perinatal Educ 2015;24:160-70.
8. **Parker LA, Sullivan S, Krueger C, et al.** Effect of early expression on milk volume and timing of lactogenesis stage II among mothers of very low birth weight infants: a pilot study. J Perinatol 2012;32:205-09.
9. **Parker LA, Sullivan S, Krueger C, Mueller M.** Association of timing of initiation of breast milk expression on milk volume and timing of lactogenesis stage II among mothers of very low-birth-weight infants. Breastfeeding Med 2015;10:84-91.
10. **Meier PP, Patel AL, Hoban R, Engstrom JL.** Which breast pump for which mother: an evidence-based approach to individualizing breast pump technology. J Perinatol 2016;36:493-99.
11. **Spatz DL**. Getting it right – the critical window to effectively establish lactation. Infant 2020;16:58-60.

Response of UK milk banks to ensure the safety and supply of donor human milk in the COVID-19 pandemic and beyond

The COVID-19 pandemic is presenting several challenges to human milk banks and has highlighted a number of vulnerabilities in service provision that have been long known by those who work in the sector. In recent weeks, milk banks across the UK have worked together to understand any risks posed to infants, milk bank staff and volunteers by COVID-19, and to put in place mitigation strategies to ensure the safeguarded provision and safety of donor human milk. The authors call on policymakers to better support these essential services for vulnerable neonates during the COVID-19 pandemic and minimise the impact of future challenges through greater investment in milk bank infrastructure, research and innovation.

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Keywords

infant feeding; breastfeeding; prematurity; nutrition; donor human milk; milk bank

Key points

Shenker N., Hughes J., Barnett D., Weaver G. Response of UK milk banks to ensure the safety and supply of donor human milk in the COVID-19 pandemic and beyond. *Infant* 2020; 16(3): 118-21.

1. This article outlines the challenges facing provision of DHM during the COVID-19 pandemic.
2. Mitigation strategies to ensure safety and provision of DHM have been developed by group consensus.
3. There is a high probability that SARS-CoV-2 is not transmitted through human milk – the latest data are reported.

If mother's own milk (MOM) is not available for low birth weight or otherwise vulnerable infants, donor human milk (DHM) from a human milk bank (HMB) is recommended as the first alternative.[1-6] In February 2020, the World Health Organization (WHO) issued specific advice for breastfeeding during the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2; COVID-19) outbreak stating that women who become too unwell to breastfeed or express should have the option of DHM, depending on the cultural context and availability, with the option of re-lactation support for women when they recover.[7]

The UK's HMBs

It is estimated that more than 800,000 babies annually receive donor milk in the 66 countries with active milk banks,[8] including up to 6,000 in the UK. There are currently 14 active HMBs operating in the UK. Scotland has a single national service located in Glasgow that supports all 15 neonatal units (NNUs) in the country. Northern Ireland's HMB provides milk to NNUs north and south of the border, making it a unique part of the health service. England has 12 HMBs ranging in size – two produce over 2,000 litres each year and support several NNUs (North West and Hearts), while some support only their own Trust's NNU. There are currently no milk banks in Wales.

DHM provision

The primary role of HMBs is to protect, promote, and support breastfeeding. With appropriate use in the context of optimal support for lactation, a short period of DHM provision can support mothers to establish their milk supply without the need for supplementation with infant formula milk.

DHM is used primarily for premature and low birthweight babies being cared for in a hospital NNU; each unit has its own protocol. Several UK HMBs also supply DHM to families who meet specific clinical criteria in the community if surplus DHM is available. These include families where breastfeeding is not possible as a result of maternal ill-health (eg maternal cancer, anti-psychotic medication use) or maternal absence (eg death, fostering, adoption).

The COVID-19 response

The COVID-19 pandemic brings additional considerations and challenges for the mother-infant dyad, newborn nutrition and HMB operations. Increased separation of mothers and infants limiting access to maternal milk (as is happening in some settings despite WHO guidance),[7] together with reduced availability of DHM could lead to an increase in morbidity and mortality related to prematurity and other health conditions.[9-11]

The potential for increased demand

from NNUs raises questions as to which clinical situations should be prioritised, and the capacity of HMB infrastructures to respond. During this critical COVID-19 response period, UK HMBs are facing challenges in terms of maintaining adequate staffing, donor recruitment, safe handling/transportation of DHM, and increased demand. It is essential that systems that provide DHM for vulnerable infants are not inadvertently impacted by efforts to contain COVID-19.

As the COVID-19 pandemic has developed, some individual milk banks initially published their own guidance for the recruitment of donors. The first advice by the Hearts Milk Bank to donors was published online on 23 January 2020, under the guidance of Dr Jim Gray, Clinical Microbiologist and Lead Advisor for Screening. In the absence of global safety standards, HMB associations and individual HMB programmes have since developed their own specific guidance relating to DHM in the context of COVID-19.[12,13] Additionally, the Human Milk Foundation has been instrumental in supporting the creation of a Global Alliance of Milk Banks and Associations, which will facilitate the development of globally appropriate minimum standards and regulatory recommendations.[8]

A virtual communication network for UK HMBs

On 16 March 2020, the Hearts Milk Bank initiated a virtual communication network (VCN) via WhatsApp for UK milk bank leads, which has rapidly facilitated the sharing of information, discussion of evidence, and development of consensus views of best practice related to local circumstances. The group now includes over 19 members from 12 of the UK milk banks. Furthermore, the authors developed a 'preparedness tool' that aimed to ensure milk banks had recognised potential challenges that may occur throughout the course of the COVID-19 pandemic. Critically, it asked group members to consider which milk banks would have sufficient capacity and suitable geographical location to maintain a continuous provision of donor milk to hospital NNUs in the event of staff shortages or other issue causing the temporary closure or cessation of pasteurisation within a milk bank (**TABLE 1**). Further collation of data, such as that reported in the preparedness tool, can highlight trends such as the efficiency of larger milk banks. This type of data collection, preparedness and facilitation of communication will be instrumental in supporting the development of a future national milk bank service.

Staffing	How many staff members do you have? Are any staff self-isolating? Do you have sufficient staff to maintain core service?
NNU supply	What volume do you issue weekly? How many weeks of pasteurised stock do you have?
Processing	What volume do you pasteurise weekly? What are your pre-pasteurisation stock volumes?
Donors	How many litres are donated each week? Do you need to recruit donors? Can donors access phlebotomy services?
Stock supplies	Is your supply chain intact? Are you quarantining milk? Do you have sufficient cleaning materials?
Transportation	Are there issues with incoming milk? Are there issues with outgoing milk?
Contingency	Do you have alternative milk bank support? Are you in the COVID-19 WhatsApp group?
PPE	Is PPE required? Is PPE available?
Finances	Do you face additional costs? Are costs planned for?

TABLE 1 Some of the questions addressed by the preparedness tool to assess UK milk banking during the COVID-19 pandemic. Key: PPE=personal protective equipment.

Challenges and mitigation strategies

In recent weeks, milk banks have worked together to understand the risk posed to infants, milk bank staff and volunteers by COVID-19. By group consensus a number of mitigation strategies have been put in place to overcome the challenges and ensure safe provision of DHM (**TABLE 2**).

Ensuring safety between mother and infant during suspected or confirmed COVID-19 infection is complex and has resulted in mixed messages and confusion. Currently, global policy leaders now agree that mothers and infants should remain together and safe breastfeeding and access to human milk should be supported. The virtual group unanimously supports the WHO's recommendations not to separate the mother and infant and to support breastfeeding, thereby decreasing the demand for DHM and improving outcomes for the mother and her infant. However, in the context of separation of a symptomatic mother and infant, DHM use may be a critical bridge for the infant, assuming that systems will simultaneously provide lactation support to ensure the mother can initiate and maintain lactation during separation.

Reduced access to MOM through reduced availability of face-to-face breastfeeding support and, in some areas, problems with the supply of infant formula, initially led to increased demand for DHM from hospitals as well as from families in the community. Increased demand placed further pressure on DHM supply and current HMB infrastructure, particularly in March during the earliest phase of the pandemic when there was greater uncertainty about the continuation of transportation and other logistics.

The consensus from the VCN is that a comprehensive approach should be implemented to maintain contact between mothers and babies, with skin-to-skin and breastfeeding support. If DHM is provided during separation, this should be for as short a time as possible as a bridge to receiving MOM. This approach increases the chances that these infants will leave the

NNU exclusively breastfeeding, which is critical for the longer-term health of mother and baby.

SARS-CoV-2 transmission through human milk

Based on best available evidence, there is a high probability that SARS-CoV-2 is not transmitted through human milk. Viral transmission through breast milk has been described for a range of viruses, including HIV and cytomegalovirus.[14,15] Coronaviruses (CoV) are enveloped, single-stranded RNA viruses that are primarily spread via droplet and contact transmission. CoVs have not been detected in breast milk, and transmission of CoVs via breast milk has not been reported, although it is likely that mothers could infect infants via the respiratory route while breastfeeding.[16]

No peer-reviewed published studies have found the presence of SARS-CoV-2 in milk samples from COVID-19 positive mothers. It is highly unusual for a CoV or other respiratory virus to cross into breast milk.[17] Neither direct breastfeeding nor feeding of expressed human milk has been shown to be a route to vertical transmission. For the limited data available, where breast milk has been analysed from mothers infected in the third trimester of pregnancy, evidence of viral particles in samples of expressed milk is lacking (though little information has been given regarding sample collection).[18]

To date, vertical transmission has been reported *in utero* in two infants, with IgM and IgG antibodies present two hours after birth,[19] and in one single infant at three months of age exposed to their COVID-19 positive grandmother.[20] Typically, serum antibodies appear several days after symptom development, with specific IgM antibodies appearing at 10 days and IgG

Challenge	Mitigation
Maintenance of donor engagement	Traditional media (radio, print, TV) and social media calls have been successfully employed to ensure supply of donor milk continues.
Additional screening of milk donors	HMBs now use a set of pre-screening questions on symptoms, test results and exposure to COVID-19. Donors should delay donation or expressing and storing milk for donation until asymptomatic, or may be deferred permanently. The exclusion also applies if the donor is a known contact of someone with symptoms or a COVID-19 diagnosis within 14 days after contact.
Serological screening	Potential milk donors are finding it increasingly difficult to access phlebotomy services for their compulsory screening tests. HMBs have responded by working with volunteer phlebotomists, travelling to donor homes and working with the NHSBT to access phlebotomy at donor centres. Donor recruitment has also focussed on mothers of inpatient infants who could get bloods taken in the hospital.
Communication	HMBs have improved communication with each other and with donors and community-based recipient families. Regular communication with NNUs is essential to determine levels of demand and changes to infant-feeding policies and to inform units about potential interruption of DHM supply.
Collection and transportation of donor milk	Non-contact collection and delivery processes have been implemented while adhering to all aspects of screening and quality control. Donors should be screened before face-to-face contact (as above). Social distancing, no contact and appropriate PPE should be observed where appropriate by donors, staff, volunteers and couriers. A standard operating procedure developed by the Hearts Milk Bank team has now been adopted nationally.
Donor milk handling	SARS-CoV-2 can maintain infectivity on plasticware, stainless steel, and cardboard for several hours/days.[25,29] Although not a major transmission route, there is a risk of accidental transmission during container handling if standard protocols for DHM handling are breached. Typically, hygiene and handwashing are highly stringent in HMBs. There is no evidence to support the use of disinfection of containers, and this approach may introduce a secondary risk of feed contamination. HMB staff should: (i) practice regular handwashing (ii) wear gloves whenever handling containers/bags (iii) avoid touching their faces/spectacles (iv) protect their skin from repeated exposure to soap, alcohol gel and water (v) allow only limited access to their premises (vi) practice social distancing where possible (vii) self-isolate for 14 days if in contact with a symptomatic individual. Safe solitary working procedures should also be considered if feasible.
Milk quarantine	Some HMBs are instituting milk quarantine, whereby pre-pasteurised milk is kept separately from other stocks for 14 days after the last expression. Before milk is removed from the freezer, donors are contacted to ensure they have been symptom-free for the previous 14 days. However, this is guidance only and should not compromise stocks if DHM supplies are insufficient.
Contingency planning	HMBs are generally under-resourced, minimally staffed, operate without a large DHM surplus, and risk closure due to self-isolation. Each HMB is now considering contingency plans for which HMBs could cooperate to safeguard supplies.
Safety of HMB staff	Staff who are in contact with donors should wear situation appropriate PPE.

TABLE 2 Challenges and mitigations for the continuation of DHM provision. Key: NHSBT= NHS Blood and Transplant.

antibodies developing by 14 days.[21] Profiling of human milk for IgG or IgM antibodies against SARS-CoV-2 is ongoing in several centres worldwide, and in the UK the Hearts Milk Bank, established among other reasons to facilitate wide-ranging research into human milk composition, is now actively recruiting mothers who have recovered from COVID-19 as part of an Imperial College-led research study that seeks to determine the presence and functionality of anti-SARS-CoV-2 antibodies. Batches of donor milk with antibodies could be clinically useful in the care of infants of symptomatic mothers unable to express their own milk.

The persistence of antibodies after SARS-CoV-2 infection is not known. A case report from the SARS outbreak in 2003 showed that a pregnant woman infected at seven days of gestation was antibody-positive at 28 days and 64 days post-illness, and at birth at 36 weeks, but milk samples were negative for SARS-CoV antibodies. Another woman who developed symptoms at 19 weeks of gestation and delivered at 36 weeks had SARS-CoV antibodies detected in serum, umbilical-cord blood, and breast milk by enzyme immunoassays and indirect immunofluorescence assays 130 days after infection.[22-24] Research is urgently needed to understand true viral presence in breast milk across gestation and lactation during COVID-19 infection in order to inform guidelines for infant feeding worldwide for the general population, as well as hospital settings.

HMB practices to mitigate the risk of SARS-CoV-2 transmission

Practices that are common to HMB services are likely to mitigate the risk of SARS-CoV-2 transmission. HMB services operate according to guidelines set by national bodies or local organisations. Donors are screened using interviews and questionnaires based on health and lifestyle. These aim to reduce the risk of microbial or other contamination of donated milk and are usually employed in addition to serological screening for common blood-borne infections. Human milk is collected and pasteurised via Holder pasteurisation (milk heated to 62.5°C for 30 min). Recent work has shown that SARS-CoV-2 is inactivated by heating in a dose-dependent manner, with viral inactivation at 10-30 min at 56°C, or 5 min at 70°C,[25] although no specific studies have yet investigated viral inactivation in human milk under Holder pasteurisation conditions. Research on similar coronaviruses, SARS-CoV and MERS-CoV has shown complete heat inactivation by treatment at 60°C for 15-30 min.[26-28]

Conclusions

Many milk banks initially struggled to respond to the COVID-19 pandemic, with issues deepened by the lack of agreed safety guidelines on HMBs, no mechanism for rapid communications among HMBs, and limited data gathering and infrastructure to ensure responsiveness during a crisis. With increased communication and strategic planning, the system has already strengthened.

Milk banks offer a unique opportunity to support research into human milk, and a number of studies have started during the course of the pandemic. Other work is starting in terms of disaster-preparedness, including the provision of freeze-dried milk that can offer longer storage durations and simplified postal delivery, without the need for couriering. Further investment is required into innovation, research, training and infrastructure to ensure that provision of safe DHM remains an essential component of routine early newborn care, as well as emergency situations.

References

1. **WHO/UNICEF**. Meeting on infant and young child feeding. J Nurse Midwifery 1980;25:31-39.
2. **WHO**. Guidelines on Optimal Feeding of Low Birth-Weight Infants in Low- and Middle-Income Countries. 2011.
3. **Israel-Ballard K, Cohen J, Mansen K, et al.** Call to action for equitable access to human milk for vulnerable infants. Lancet Glob Health 2019;7:e1484-86.
4. **Section on Breastfeeding.** Breastfeeding and the use of human milk. Pediatrics. 2012;129(3):e827-41.
5. **Arslanoglu S, Corpeleijn W, Moro G, et al.** Donor human milk for preterm infants: current evidence and research directions. J Pediatr Gastroenterol Nutr 2013;57:535-42.
6. **Mizuno K, Shimizu T, Ida S, et al.** Policy statement of enteral nutrition for preterm and very low birthweight infants. Pediatr Int 2020;62:124-27.
7. **WHO**. Breastfeeding advice during the COVID-19 outbreak. 2020 online at: www.emro.who.int/nutrition/nutrition-infocus/breastfeeding-advice-during-covid-19-outbreak.html
8. **Shenker N**. Maintaining safety and service provision in human milk banking: a call to action in response to the COVID-19 pandemic. Lancet Child and Adolesc Health 2020 Doi: 10.1016/S2352-4642(20)30134-6.
9. **El-Khuffash A, Jain A, Lewandowski AJ, Levy PT.** Preventing disease in the 21st century: early breast milk exposure and later cardiovascular health in premature infants. Pediatr Res 2020;87:385-90.
10. **Tully MR, Lockhart-Borman L, Updegrove K.** Stories of success: the use of donor milk is increasing in North America. J Hum Lact 2004;20:75-77.
11. **Hoban R, Khatri S, Patel A, Unger SL.** Supplementation of mother's own milk with donor milk in infants with gastroschisis or intestinal atresia: a retrospective study. Nutrients 2020;12:e589.
12. **Human Milk Banking Association of North America.** Milk Banking and COVID-19. 2020 online at: www.hmbana.org/news/covid-19.html
13. **European Milk Bank Association.** COVID-19: EMBA Position Statement. 2020 online at: https://europeanmilkbanking.com/covid-19-emba-position-statement
14. **Moland KM, de Paoli MM, Sellen DW, et al.** Breastfeeding and HIV: experiences from a decade of prevention of postnatal HIV transmission in sub-Saharan Africa. Int Breastfeed J 2010;5:10.
15. **Hamprecht K, Goelz R.** Postnatal cytomegalovirus infection through human milk in preterm infants: transmission, clinical presentation, and prevention. Clin Perinatol 2017;44:121-30.
16. **Chang L, Yan Y, Wang L.** Coronavirus disease 2019: coronaviruses and blood safety. Transfus Med Rev 2020 Doi: 10.1016/j.tmrv.2020.02.003.
17. **Schwartz DA, Graham AL.** Potential maternal and infant outcomes from (Wuhan) coronavirus 2019-nCoV infecting pregnant women. Viruses 2020;12:E194. Doi: 10.3390/v12020194.
18. **Chen H, Guo J, Wang C, et al.** Clinical characteristics and intrauterine vertical transmission potential of COVID-19 infection in nine pregnant women. Lancet 2020;395:809-15.
19. **Zeng H, Xu C, Fan J, et al.** Antibodies in infants born to mothers with COVID-19 pneumonia. JAMA 2020 Doi: 10.1001/jama.2020.4861.
20. **Le HT, Nguyen LV, Tran DM, et al.** The first infant case of COVID-19 acquired from a secondary transmission in Vietnam. Lancet Child Adolesc Health 2020;4:405-06.
21. **Chen Y, Li L.** SARS-CoV-2: virus dynamics and host response. Lancet Infect Dis 2020;20:515-16.
22. **Robertson CA, Lowther SA, Birch T, et al.** SARS and pregnancy: a case report. Emerg Infect Dis 2004;10:345-48.
23. **Schneider E, Duncan D, Reiken M, et al.** SARS in pregnancy. AWHONN Lifelines 2004;8:122-28.
24. **Stockman LJ, Lowther SA, Coy K, et al.** SARS during pregnancy, United States. Emerg Infect Dis 2004;10:1689-90.
25. **Chin AWH, Chu JTS, Perera MRA, et al.** Stability of SARS-CoV-2 in different environmental conditions. Lancet Microbe 2020 Doi: 10.1016/S2666-5247(20)30003-3.
26. **Darnell ME, Taylor DR.** Evaluation of inactivation methods for severe acute respiratory syndrome coronavirus in noncellular blood products. Transfusion 2006;46:1770-77.
27. **Rabenau HF, Cinatl J, Morgenstern B, et al.** Stability and inactivation of SARS coronavirus. Med Microbiol Immunol 2005;194:1-6.
28. **van Doremalen N, Bushmaker T, Karesh WB, Munster VJ.** Stability of Middle East respiratory syndrome coronavirus in milk. Emerg Infect Dis. 2014;20(7):1263-4.
29. **Kampf G, Todt D, Pfaender S, Steinmann E.** Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents. J Hosp Infect. 2020;104(3):246-51.

Simultaneous epidermolysis bullosa, pyloric atresia and imperforate anus in a newborn

The coexistence of congenital pyloric atresia (PA) and epidermolysis bullosa (EB) is rare but has been previously described. Here, we present the case of a newborn infant with EB-PA and an imperforate anus (IA). To our knowledge, the combination of EB-PA-IA has not been previously reported in the literature. We discuss the diagnosis and therapeutic measures in this unusual case.

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Keywords

epidermolysis bullosa; pyloric atresia; imperforate anus; newborn infant

Key points

Tabatabaei F-S , Hosseininejad S-M, Tabatabaei S-S, Alaee E. Simultaneous epidermolysis bullosa, pyloric atresia and imperforate anus in a newborn. *Infant* 2020; 16(3): 122-24.

1. The case of a newborn baby with EB, PA and IA is described. This association has not been reported elsewhere.
2. The course of EB-PA is usually severe; coexistence of IA may lead to faster deterioration of the condition.

The case

A 24-hour-old male infant presented to Taleghani Pediatric Hospital in Gorgan, Northern Iran, with non-bilious vomiting, failure of meconium defaecation and abdominal distension.

He was born at term (38 weeks' gestation) weighing 3,400g by vaginal delivery to a 31-year-old gravida 5 female. The pregnancy and delivery were uncomplicated with no history of polyhydramnios. Antenatal karyotyping was not carried out. His parents were non-consanguineous Turkmen with no family history of bullous disease or congenital anomalies.

At birth his Apgar scores were 8 and 9 at one and five minutes, respectively. A physical examination revealed well-defined erythematous areas of peeled skin over the left forearm, left lower foot and scalp (**FIGURE 1**), and a membranous layer covering the anus, indicative of IA (**FIGURE 2**). Some very small blistering lesions were noted in the oral mucosa. A systemic physical examination showed no other abnormality except for a wide sagittal skull suture but with a normal head circumference of 34cm.

It was noted that the baby could not tolerate feeding. After initiating oral supplements through an orogastric tube, non-bilious, straw-coloured, gastric fluid was evident. Following this, the patient developed recurrent vomiting, he did not defaecate and his abdomen became distended.

Investigations

Laboratory blood tests were unremarkable. Abdominal X-rays illustrated gastric dilation with absent distal bowel gas and the duodenum was free of any air (**FIGURE 3**). Upper gastrointestinal barium meals showed a thickened and distended stomach (**FIGURE 4**); contrast failed to pass the pylorus to reach the duodenum. A distal colostogram depicted a dead-end lumen and no fistula of the rectum to the urinary tract or genitalia (**FIGURE 5**). Ultrasound of the abdomen did not reveal any renal or other organ abnormalities.

Histopathology of the skin biopsies obtained on the first and second days were compatible with a diagnosis of EB, ie dermal-epidermal cleavage and cell-poor subepidermal blisters.

FIGURE 1 Well-defined erythematous areas of peeled skin indicative of EB.

FIGURE 2 Imperforate anus: a membranous layer covering the anus.

Treatment

Parenteral nutrition with amino acids, dextrose, lipid emulsion, nutritional supplements and electrolytes was provided. Following stabilising measures, a laparotomy was performed on day 3, which confirmed the existence of atresia of the pylorus, pouch colon and imperforate anus. The child underwent surgical procedures to correct the PA and IA – a gastrojejunostomy, direct percutaneous jejunostomy, a colostomy and a mucus fistula.

Skin care included lancing of blisters using a sterile needle, regular skin cleanings, dressing with topical antiseptics and antibiotics (ampicillin, amikacin and metronidazole). The dressings on broken skin were changed two to three times a week. All tapes on the skin were removed by waterlogging and liquid paraffin.

Postoperatively, the baby appeared more comfortable; his symptoms gradually subsided and he was discharged in a generally stable condition. At the one-year follow-up appointment his condition was stable.

Discussion

The association of congenital EB-PA is very rare and, with few cases found in the literature, the exact prevalence remains unknown. Lestringant et al[1] analysed 42 cases of EB-PA reported up until 1992. Worldwide, over 100 cases of EB-PA have been reported,[2-6] however association of PA, EB and IA has not been reported to date as far as we are aware.

EB-PA

The clinical features of EB may be apparent at birth or may appear later. The skin may show localised or extensive areas of peeling or blistering with little or no trauma. Oral and mucous membrane involvement is common, as in the case described here. Congenital absence of skin (aplasia cutis congenita) is present in approximately 20% of cases[7] but this was not seen in our case. Extensive EB lesions can have a fatal outcome in the neonatal period due to sepsis and fluid loss.[8]

PA is usually suspected when neonates develop recurrent non-bilious vomiting and abdominal distension; the distention is even more severe if IA coexists. Additional features of EB-PA may include fusion of the skin between the fingers and toes, nail dystrophy, scarring alopecia, contractures and dilated cardiomyopathy. Extracutaneous manifestations include involvement of genitourinary, respiratory and gastrointestinal tracts, in particular, genitourinary malformations such as dysplastic/multicystic kidneys, hydronephrosis/hydroureter, ureterocoele, duplicated renal collecting systems and an absent bladder,[9] although such abnormalities were not detected in this case. Regular follow-up is needed in monitoring urinary symptoms because ureterovesical obstruction can occur after the neonatal period. Atresia involving multiple regions of the gastrointestinal tract may occur simultaneously.[10,11] Polyhydramnios, secondary to PA, is usually evident by the third trimester in pregnancies with an affected fetus. In this case polyhydramnios was not reported.

The course of EB-PA is usually severe and often fatal in the neonatal period; coexistence of IA may lead to faster deterioration of the condition.

FIGURE 3 An X-ray showing gastric dilation with absent distal bowel gas.

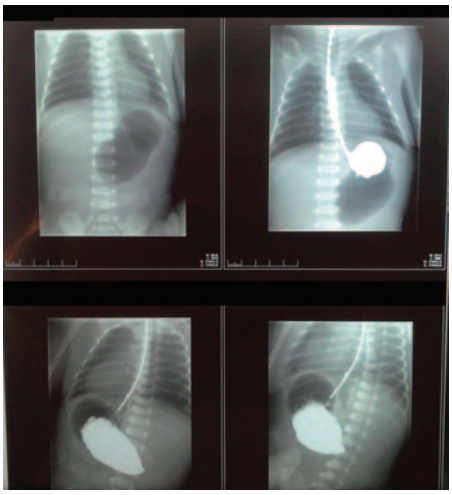

FIGURE 4 The contrast agent failed to pass the pylorus and did not reach the duodenum.

FIGURE 5 A distal colostogram depicting a dead-end lumen and no rectal fistula.

IA

The signs of IA include: no anal opening; an anal opening in the wrong place; no stool in the first 24-48 hours of life; stool passing through the wrong place, such as the urethra, vagina, scrotum, or the base of the penis; swollen abdomen; and an abnormal connection (fistula) between the baby's rectum and reproductive system or urinary tract.[7,12,13] The latter sign was not seen in our case.

Inheritance

EB-PA is inherited as an autosomal recessive disorder and is associated with mutations in three genes:[11,14-16]

- *ITGB4* (integrin-β-4) – accounts for 80% of EB-PA patients
- *ITGA6* (integrin-α-6) – 5% of patients
- *PLEC1* (plectin) – 15% of patients.

In most cases the cause of an anorectal malformation is not known; the genetic basis of these anomalies is very complex because of their anatomical variability. In 8% of patients genetic factors are clearly associated and the gene *HLXB9* may be involved.[1,12,16]

Diagnosis

EB can be diagnosed by skin biopsy using transmission electron microscopy and/or immunofluorescent antibody/antigen studies. Molecular genetic testing is available but not necessary to confirm the diagnosis. PA is diagnosed by the manifestation of a single gastric gas bubble on plain abdominal X-ray representing pyloric obstruction.[17] IA should be picked up in a physical examination shortly after birth. A number of diagnostic investigations including X-rays, ultrasound and MRI will help to further evaluate the problem and determine whether other abnormalities such as spinal cord

disorders are present.[13]

For at-risk pregnancies, prenatal diagnosis of EB-PA can be established by examining DNA or by using monoclonal antibodies.[18,19] With the routine use of prenatal ultrasound scan, polyhydramnios and fetal gastric dilation may be detected long before the time of delivery.

If a prenatal diagnosis is established, a caesarean section should be planned to reduce trauma during delivery.

Genetic counselling is essential for families with a strong history of EB and/or PA and/or IA. Molecular genetic testing of the parents can establish heterozygous carrier status. Preimplantation genetic diagnosis for pregnancies at increased risk of EB-PA is possible once the gene mutations have been identified.

Management

Treatment of such disorders is mostly symptomatic and supportive. Surgical intervention is needed to correct PA and IA. Parents need education and training to better handle their infant. Skin care is of vital importance; protection of skin from poorly fitting clothing and use of atraumatic sterile dressings may avoid further skin peeling. Supportive measures improve outcomes, including antibiotics and antiseptics to prevent wound infections, fluid and electrolyte balance and nutritional support. Prevention of secondary complications such as growth delay, anaemia, zinc deficiency, osteopenia/osteoporosis and scarring of skin and mucosal surfaces should be considered. Psychological support for parents and caregivers is essential.

Prognosis

In most cases, the course of EB-PA is relentless and usually fatal despite surgical correction of PA. The prognosis is poor due to prematurity (although not in this case), extensive skin blistering with fluid and electrolyte imbalance, respiratory distress syndrome, malnutrition, sepsis, persistent vomiting and diarrhoea, and possible associated genitourinary disease.

In those cases who survive, the condition may improve with time. Some affected individuals may have little or no blistering later in life. Conversely, many affected individuals living past infancy experience blistering and formation of granulation tissue around the mouth, nose, fingers and toes, and infrequently in the trachea yielding stridor.

Conclusion

PA should be considered in neonates born with vesico-bullous lesions on the skin. Genetic counselling should be provided to families who are at risk for developing EB-PA. Adequate and timely medical and psychosocial care must be provided to reduce morbidity and improve the prognosis and quality of life. The course of EB-PA is usually severe and often fatal in the neonatal period; it is uncertain how the coexistence of IA may impact but it is possible that it may lead to faster deterioration of the condition.

Parental consent

The authors obtained written informed consent from the child's parents for publication of the case history and images.

References

1. **Lestringant GG, Akel SR, Qayed KI**. The pyloric atresia-junctional epidermolysis bullosa syndrome. Report of a case and review of the literature. Arch Dermatol 1992;128:1083-86.
2. **Egan N, Ward R, Olmstead M, Marks JG, Jr.** Junctional epidermolysis bullosa and pyloric atresia in two siblings. Arch Dermatol 1985;121:1186-88.
3. **Nawaz A, Matta H, Jacobsz A, Al-Salem A.** Congenital pyloric atresia and junctional epidermolysis bullosa: a report of two cases. Pediatr Surg Int 2000;16:206-08.
4. **Rosenbloom MS, Ratner M.** Congenital pyloric atresia and epidermolysis bullosa letalis in premature siblings. J Pediatr Surg 1987;22:374-76.
5. **Sahebpor AA, Ghafari V, Shokohi L**. Pyloric atresia associated with epidermolysis bullosa. Indian pediatr 2008;45:849-51.
6. **Samad L, Siddiqui EF, Arain MA, et al.** Pyloric atresia associated with epidermolysis bullosa-three cases presenting in three months. J Pediatr Surg 2004;39:1267-69.
7. **Fine JD, Johnson LB, Weiner M, et al.** Epidermolysis bullosa and the risk of life-threatening cancers: the National EB Registry experience, 1986-2006. J Am Acad Dermatol 2009;60:203-11.
8. **Mithwani AA, Hashmi A, Adil S.** Epidermolysis bullosa and congenital pyloric atresia. BMJ Case Rep 2013;2013.
9. **Berger TG, Detlefs RL, Donatucci CF.** Junctional epidermolysis bullosa, pyloric atresia, and genitourinary disease. Pediatr Dermatol 1986;3:130-34.
10. **Cetinkursun S, Ozturk H, Celasun B, et al.** Epidermolysis bullosa associated with pyloric, esophageal and anal atresia: a case report. J Pediatr Surg 1995;30:1477-78.
11. **Ruzzi L, Gagnoux-Palacios L, Pinola M, et al.** A homozygous mutation in the integrin alpha6 gene in junctional epidermolysis bullosa with pyloric atresia. J Clin Invest 1997;99:2826-31.
12. **Fine JD, Eady RA, Bauer EA, et al.** The classification of inherited epidermolysis bullosa (EB): Report of the Third International Consensus Meeting on Diagnosis and Classification of EB. J Am Acad Dermatol 2008;58:931-50.
13. **El-Asmar KM, Abdel-Latif M, El-Kassaby AA, et al.** Colonic atresia: association with other anomalies. J Neonatal Surg 2016;5:47.
14. **Pereira MP, Pogatzki-Zahn E, Snels C, et al.** There is no functional small-fiber neuropathy in prurigo nodularis despite neuroanatomical alterations. Exper Dermatol 2017;26:969-71.
15. **Stoevesandt J, Borozdin W, Girschick G, et al.** Lethal junctional epidermolysis bullosa with pyloric atresia due to compound heterozygosity for two novel mutations in the integrin beta4 gene. Klinische Padiatrie 2012;224:8-11.
16. **Tzu J, Marinkovich MP.** Bridging structure with function: structural, regulatory, and developmental role of laminins. Int J Biochem Cell Biol 2008;40:199-214.
17. **Kadian YS, Rattan KN.** Congenital pyloric atresia with distal duodenal atresia- role of CT scan. J Neonatal Surg 2014;3:37.
18. **Nazzaro V, Nicolini U, De Luca L, et al.** Prenatal diagnosis of junctional epidermolysis bullosa associated with pyloric atresia. J Med Genet 1990;27:244-48.
19. **Heagerty AH, Eady RA, Kennedy AR, et al.** Rapid prenatal diagnosis of epidermolysis bullosa letalis using GB3 monoclonal antibody. Brit J Dermatol 1987;117:271-75.

Working with parents with seriously ill children and understanding the impact on their mental health

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A new report from Rainbow Trust Children's Charity examining the mental wellbeing of parents caring for a seriously ill baby or child has highlighted that they can often feel traumatised and hopeless.

Parents Matter – The Impact on Parents' Mental Health When a Child has a Life Threatening Illness calls for better access to support for this neglected group of parents, warning that unless it is provided at the right time and in the right way, their feelings of depression, stress and anxiety could escalate into more significant and severe mental health problems.

A survey commissioned by the charity, coinciding with the report, found that 51% of parents believe the greatest impact on their mental health would be their child dying or being diagnosed with a terminal or life-threatening illness.

Families supported by Rainbow Trust, such as Mum Ella-Mae Michalski whose premature twins survived against the odds, tell us that early intervention is crucial in improving their mental wellbeing.

Ella-Mae's is one of many families featuring in *Parents Matter* who are backing the report, keen to raise awareness and eradicate mental health taboos when struggling to cope with caring for a life threatened child.

The report recommends that health and social care commissioners urgently review local respite care funding to include practical and emotional support to families with seriously ill babies and children. It also seeks to raise awareness of how communities can help and includes a checklist for health and social care professionals to follow when working with parents of a seriously ill child, whether this is in hospital, at home or in the community.

A premature birth or admission to a neonatal unit can have a great impact on a family and it is recognised that parents whose baby is admitted are at increased risk of postnatal depression and post-traumatic stress disorder. This risk can be mitigated if support mechanisms are made available to parents. Many hospitals offer parent support groups that may be facilitated by the unit social worker or psychologist and can offer a safe arena for parents to explore their feelings. However, not all parents will choose to access such a group, with some feeling uncomfortable hearing other parents' stories, which may increase anxiety and stress. Others might not wish to leave their baby's bedside, particularly if they live a distance from the hospital and are visiting for short periods.

Rainbow Trust provides practical and emotional support to families caring for a seriously ill child in certain areas across England. This can include transport to and from hospital, enabling parents to visit without the additional pressures of negotiating traffic and parking. The journey to and from hospital can also provide an opportunity for a parent to sit quietly and have a break or chat to the family support worker. Support can be offered in the hospital and at home following discharge, offering a bridge between the neonatal unit and home. Should a baby die, then the dedicated family support worker can offer ongoing bereavement support for as long as the family needs it.

Rainbow Trust's family support workers offer non-judgemental support to help a parent to manage their feelings more effectively. They can provide rest and respite so that a parent has a chance to do something for themselves, reduce the worry about siblings by giving brothers and sisters quality time with an adult who is there just for them, or reduce practical burdens by helping with transport or helping around the house.

The financial cost of having a seriously ill child in hospital can also be a great strain on parental mental health. Where possible, parents should be given a permit that allows for free or reduced cost

- Do you feel confident that you could spot the signs of a parent or carer struggling with their mental health?
- Do you regularly offer access to psychological support or counselling?
- Is the offer of support repeated at different stages, rather than being a one-off?
- Is support offered in a sensitive and discrete manner, so parents do not feel singled out?
- When parents are interested in accessing psychological support or counselling, do you discuss with them whether there are practical barriers that need to be addressed, such as transport or childcare needs?
- Do you include all relevant professionals in discussions about how families are managing, to ensure that all-round support is provided?
- Have you considered how you can ensure that information is shared effectively between professionals involved with a family?
- Are you able to signpost parents to relevant charities or support groups that offer emotional and practical support?

FIGURE 1 Rainbow Trust's checklist for healthcare professionals working with parents with a seriously ill child.

Bella born at 26 weeks' gestation.

parking when visiting. Parents should be shown options for making drinks and light meals on the unit – most will have a small parents' room that might contain a fridge, microwave and kettle – this should be made explicit to families on admission so they are able to plan accordingly.

Many parents say that they put on a brave face in front of professionals and their children. It may not be obvious how much a parent is struggling. Rainbow Trust recommends that healthcare professionals follow the checklist in **FIGURE 1**.

Case study: A parent's perspective

At her 20-week scan Ella-Mae was told she was 3cm dilated and that she should immediately prepare to lose her twin babies. Following medical intervention and almost seven weeks of bed rest, Ella-Mae and her husband Giovanni's non-identical girls, Bella and Ruby, were born 14 weeks early weighing 910g and 900g respectively.

The twins had chronic lung disease and required oxygen. They were kept in the neonatal intensive care unit from October 2018 until mid-January 2019, during which time they collectively had 10 blood transfusions and experienced several complications. Ella-Mae says: "When I thought the girls may not make it, I felt my world had crashed down around me. I was in a very difficult emotional place. I felt really isolated and alone. It was as if I was fighting a long and lonely battle, despite having people all around me in the hospital. I fell into a really, really deep depression. I can't explain how dark that place was. It was so bad that I could barely get up even to wash. I was never suicidal but I was definitely hopeless."

Ella-Mae and Giovanni had to ring the hospital each day to check if the girls had made it through the night. "There was such a level of fear, a level of depression. It is categorically the worst feeling to be a parent in that situation. My immediate feeling was to run. I tried to detach myself. I didn't want to bond with them, I was so scared they might die and then it wouldn't be so bad."

She began to make excuses for not visiting them, and Giovanni would visit alone. Embarrassed about her poor mental health, Ella-Mae put on a brave face in front of medical staff. The situation worsened when one daughter improved and was moved to a second hospital, so they needed to split their visits between two locations. Ella-Mae would visit to deliver expressed milk for nurses to give to her daughters but one day she didn't feel strong enough to see them at all. A nurse asked her if she was OK and

Ella-Mae at home with Bella and Ruby.

Ella-Mae said no. She was introduced to a psychologist on the ward but did not find it very helpful. Ella-Mae says: "She asked me how the babies were. She didn't see me as a person. They saw me as a mum. They didn't see the fear."

Once the twins left hospital and returned to their home, they still required round the clock care and oxygen for another eight months. At this point the family was referred to Rainbow Trust's Family Support Worker Fiona. "There was no judgment. Fiona would say to me, if you want to cry, cry. If you feel bad, it's OK to feel bad. If you want to swear, go ahead. Saying it's OK to feel bad is so powerful in helping someone."

Fiona helped the couple to adapt to moving the girls back home, taking them to outpatient appointments, assisting the girls with their oxygen and giving Ella-Mae and Giovanni a break. Bella and Ruby are now well, with no long-term health problems.

"I couldn't have done it without my family support worker and Rainbow Trust," Ella-Mae says. "Having her visit for a couple of hours was like coming out of deep water and being able to breathe again. Having someone to talk to and who is good with the girls was amazing.

"Fiona gave us emotional support during the hardest time of our lives. We had no certainty the girls would make it and this support made the world of difference to us. The magnitude of difficulty and the overwhelming rollercoaster that comes with having two sick children is unimaginably hard. We are eternally grateful to Rainbow Trust for helping us get through."

Rainbow Trust's full report and a downloadable checklist for healthcare professionals can be found at:
rainbowtrust.org.uk/parentsmatter

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Additional doses of 100mg/kg (1.25ml/kg) each at about 12 hourly intervals may also be administered if RDS is considered to be the cause of persisting or deteriorating respiratory status of the infants (max total dose of 300-400 mg/kg). **Prophylaxis:** single dose of 100-200mg/kg administered as soon as possible after birth (preferably within 15 mins). Further doses of 100mg/kg can be given 6-12 hours after first dose and then 12 hours later for persistent signs of RDS and ventilator-dependency (max total dose of 300-400mg/kg). Curosurf should only be administered by those trained and experienced in the care, resuscitation and stabilisation of preterm infants. Warm vial to room temp (e.g. holding in the hand for a few mins) and gently turn upside down a few times without shaking to obtain a uniform suspension. Withdraw suspension using sterile needle and syringe. A suitable catheter or tube should be used to instil Curosurf into the lungs. Doses are administered either by: **1) Disconnecting the baby momentarily from the ventilator,** administer 1.25 to 2.5ml/kg of suspension, as a single bolus directly into lower trachea via endotracheal tube. Perform one min of hand-bagging and then reconnect baby to the ventilator at original settings. Further doses (1.25ml/kg) that may be required can be administered in the same manner; ***OR* 2) Without disconnecting the baby from the ventilator,** administer 1.25 to 2.5ml/kg of the suspension, as a single bolus, directly into the lower trachea by passing a catheter through the suction port and into the endotracheal tube. Further doses (1.25ml/kg) that may be required can be administered in the same manner. After administration, pulmonary compliance can improve rapidly, requiring prompt adjustment of ventilator settings. Rapid adjustments of the inspired oxygen concentration should also be made to avoid hyperoxia. Continuous monitoring of transcutaneous PaO_2 or oxygen saturation advisable; ***OR* 3) Administer through an endotracheal tube in the delivery room before mechanical ventilation has been started** – a bagging technique is used and extubation to CPAP is an option either in the delivery room or later after admission to neonatal unit (INtubation SURfactant Extubation – INSURE); ***OR* 4) Less Invasive Surfactant Administration with a thin catheter (LISA).** Doses are same as indicated for modalities 1) 2) and 3). Small diameter catheter is placed into the trachea of infants on CPAP ensuring continuous spontaneous breathing with direct visualisation of the vocal cords by laryngoscopy. Instilled by single bolus over 0.5-3 mins. After instillation, tube is immediately removed. CPAP treatment should be continued during the whole procedure. Thin catheters CE marked for this intended use should be used for administration. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** Prior to commencing Curosurf, the infant's general condition should be stabilised. Correction of acidosis, hypertension, anaemia, hypoglycaemia and hypothermia is also recommended. If ventilation becomes impaired shortly after dosing check the endotracheal tube for mucus plugs. Administration to preterm infants with severe hypotension has not been studied. In the event of episodes of bradycardia, hypotension and reduced oxygen saturation, administration of Curosurf should be stopped and suitable measures to normalise heart rate should be taken. After administration of Curosurf, pulmonary compliance (chest expansion) and oxygenation can improve rapidly requiring prompt adjustment of ventilator settings. With LISA an increase in frequency of bradycardia, apnoea and reduced oxygen saturation was seen. Events were of brief duration without consequences and easily managed. If events become serious, stop treatment and treat complications. **Side effects:** *Uncommon* sepsis, haemorrhage intracranial, pneumothorax. *Rare* bradycardia, hypotension, bronchopulmonary dysplasia, pulmonary haemorrhage, oxygen saturation decreased. *Frequency not known* hyperoxia, cyanosis neonatal, apnoea, electroencephalogram abnormal, endotracheal intubation complication. Slight tendency towards increased incidence of patent ductus arteriosus reported in clinical studies. In LISA clinical studies, events of frothing at mouth, coughing, choking and sneezing were noted. Increased events of necrotizing enterocolitis and focal interstitial perforation were seen in LISA clinical study but were not statistically significant. See SPC for full details. **Legal category:** POM. **Prices and Packs:** £281.64 1 x 120mg/1.5ml single use vial, £547.40 1 x 240mg/3ml single use vial. **Marketing authorisation (MA) no:** PL 08829/0137. **MA holder:** Chiesi Limited, 333 Styal Road, Manchester, M22 5LG, UK. **Date of Preparation**: June 2018.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Chiesi Limited on 0800 0092329 (UK), 1800 817459 (IE) or PV.UK@Chiesi.com.

For further information visit – www.curosurf.co.uk

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