Recommended Guideline for Uniform Reporting of Neonatal Resuscitation: The Neonatal Utstein Style

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Clinical research on neonatal resuscitation has accelerated over recent decades. However, an important methodologic limitation is that there are no standardized definitions or reporting guidelines for neonatal resuscitation clinical studies. To address this, the International Liaison Committee on Resuscitation Neonatal Life Support Task Force established a working group to develop the first Utstein-style reporting guideline for neonatal resuscitation. The working group modeled this approach on previous Utstein-style guidelines for other populations. This reporting guideline focuses on resuscitation of newborns immediately after birth for respiratory failure, bradycardia, severe bradycardia, or cardiac arrest. We identified 7 relevant domains: setting, patient, antepartum, birth/preresuscitation, resuscitation process, postresuscitation process, and outcomes. Within each domain, relevant data elements were identified as core versus supplemental. Core data elements should be collected and reported for all neonatal resuscitation studies, while supplemental data elements may be collected and reported using standard definitions when possible. The Neonatal Utstein template includes both core and supplemental elements across the 7 domains, and the associated Data Table provides detailed information and reporting standards for each data element. The Neonatal Utstein reporting guideline is anticipated to assist investigators engaged in neonatal resuscitation research by standardizing data definitions. The guideline will facilitate data pooling in meta-analyses, enhancing the strength of neonatal resuscitation treatment recommendations and subsequent guidelines.

Approximately 10% of all newborns receive resuscitation interventions to successfully transition at birth.[1] Clinical research in the field of neonatal resuscitation has accelerated over recent decades.[2] This evidence base informs the International Liaison Committee on Resuscitation Neonatal Life Support (ILCOR NLS) Task Force consensus on science with treatment recommendations and subsequent neonatal resuscitation algorithms.[3,4] However, an important methodologic limitation is that there are no standardized definitions or reporting guidelines for clinical studies of neonatal resuscitation. This makes interpretation of individual studies difficult and limits efforts to synthesize data across studies and registries.[5]

In 1990, a conference was held at the Utstein Abbey, which led to published standard reporting guidelines for out-of-hospital cardiac arrest.[6] These guidelines represented an important milestone for resuscitation research and subsequently contributed to significant advances in improving

abstract

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cardiac arrest survival outcomes.[7] Since then, 30 Utstein-style reports and updates for emergency care across distinct settings and populations have been published.[7] Given the unique physiology of postnatal transition, these guidelines exclude neonatal resuscitation. In 2020, the ILCOR NLS Task Force convened a working group to establish an Utstein-style reporting guideline for neonatal resuscitation. Our objective was to generate a reporting guideline with standard definitions for clinical studies of neonatal resuscitation immediately after birth.

METHODS

We based our approach on previous Utstein-style guidelines, in particular the pediatric Utstein style published in 1995[8] and the 2019 update for in-hospital cardiac arrest.[9] We started with key domains identified in previous Utstein-style guidelines: setting, patient, preevent, resuscitation process, postresuscitation process, and outcomes.[9] The preevent domain provoked much discussion, because the event could be construed to start at the time of birth or at the initiation of resuscitation interventions. Therefore, this domain was replaced with 2 separate domains: antepartum and birth/preresuscitation. The antepartum domain includes relevant factors during pregnancy up to the time of birth, and birth/preresuscitation includes factors from the time of birth until the initiation of resuscitation, defined here as initiation of positive pressure ventilation (PPV). Neonatal interventions typically characterized as "initial steps" are included in the birth/preresuscitation domain.

The group identified candidate data elements within each domain from Utstein-style guidelines for other populations,[8,9] previous NLS systematic reviews, and the published ILCOR NLS consensus outcome rating.[10] These candidate elements were subsequently endorsed, modified, or rejected on the basis of open discussion within the Neonatal Utstein Working Group. Additional data elements were included on the basis of open group discussion. When consensus was not achieved for a given data element, a vote was held with majority rule.

All data elements were classified as core versus supplemental. Core data elements should be collected and reported for all neonatal resuscitation studies. These elements were felt to be both important for comparative analyses and likely to be routinely and reliably captured. Supplemental data elements may be collected and reported using standard definitions when possible. These data elements were those thought to be important for more detailed analyses but may not be routinely available or reliable in all settings.

The Neonatal Utstein Working Group met virtually approximately every 3 weeks over a 14-month period and employed an iterative consensus-based process similar to that used for development of other Utstein-style guidelines.[6,8] The draft guideline was presented to a joint meeting of the ILCOR NLS Task Force and an invited group of neonatal content experts on December 3, 2021. In addition, because the Neonatal Utstein Working Group members work in highly resourced settings, the draft guideline was circulated to providers and investigators working in lower resource settings to ensure its relevance in a global setting. The Neonatal Utstein Working Group revised the guideline to reflect solicited feedback. The ILCOR NLS Task Force approved the final reporting guideline, and the ILCOR board endorsed the guideline as an ILCOR statement.

RESULTS

The Neonatal Utstein template (Fig 1) displays core and supplemental data elements across all 7 domains. The Data Table (Table 1) provides detailed information for each data element, including the recommended format for collecting each data field for individual patients. In the following text, we provide the rationale for selecting specific data elements, expand on data definitions as applicable, and provide recommendations for reporting data elements in aggregate.

Eligible Resuscitation Events

This reporting guideline focuses solely on resuscitation of newborns immediately after birth, regardless of gestational age or birth location. This is because the physiology, techniques, and outcomes of resuscitation for newborns immediately after birth differ from newborns in other settings (ie, NICU) who have already transitioned to the extrauterine environment. Because neonatal resuscitation almost always indicates an inability to establish effective ventilation,[11] the group considered it important to include events related to both respiratory failure and cardiac failure. Therefore, these reporting standards pertain to the following delivery room resuscitative events:

1. Respiratory failure: apnea or insufficient respirations from any cause leading to a clinical decision to provide PPV
2. Bradycardia: heart rate <100 beats per minute leading to a clinical decision to provide PPV
3. Severe bradycardia: heart rate <60 beats per minute not responding to PPV leading to a

	Setting	Patient	Antepartum	Birth/ Preresuscitation	Resuscitation Process	Postresuscitation Process	Outcomes

CORE	• Country
	• Location
		• Gestational Age
		• Multiple GA
		• Birth weight
		• Sex
		• Major congenital anomaly/ genetic syndrome
		• Prenatal care
			• ANCS exposure
			• Meconium-stained fluid
			• Cesarean delivery
				• Umbilical cord clamping timing
				• Umbilical cord milking
				• Heart rate at 1 minute
				• Respiratory effort at 1 minute
				• Apgar score at 1 minute
				• Apgar score at 5 minutes
					• CPAP
					• PPV
					• Respiratory interface(s)
					• Supplemental oxygen
					• Cardiac compressions
					• Epinephrine (adrenaline)
						• Immediate disposition
						• TH
						• Temperature at one hour:
						  • Temperature monitored
						  • Measured value
							• Death in initial resuscitation area
							• Death before hospital discharge
							• Duration of hospital stay
							• Air leak
							• Moderate to severe HIE (if ≥35 weeks' GA at birth)
							Preterm only (≤32 weeks' GA)
							• ROP
							• Respiratory support at 36 weeks PMA
							• NEC
							• Surgical NEC/intestinal perforation
							• Severe IVH
							• Cystic PVL

SUPPLEMENTAL	• Out-of-hospital: planned out-of-hospital birth
	• In-hospital: high-risk pregnancy center
		• Maternal conditions:
		  • Age
		  • Education
		  • Hypertension
		  • Diabetes
		  • Smoking
		• Anomaly/syndrome: specify type
		• Any prenatal limit to resuscitation
			• Assisted delivery
			• Cesarean delivery:
			  • Labor before cesarean
			  • Emergency cesarean
			• Complete ANCS
			• Antepartum hemorrhage
				• Date of birth
				• Time of birth
				• Umbilical cord pH
				• Time between birth and cord clamping
				• Cord milking:
				  • Intact cord
				  • Number of times milked
				• Initial steps: stimulation
				• Initial steps: suction
				• Initial steps: thermoregulation
					• Number of providers
					• Timing of PPV, intubation, chest compressions
					• Duration of PPV, chest compressions
					• PPV device
					• Respiratory settings
					• Support, FiO_2 at completion of resuscitation
					• Epinephrine:
					  • Number of doses
					  • Route
					  • Dose
					  • Timing
					• Fluid boluses:
					  • Administered
					  • Total dose
					• Other interventions
						• Transfer to higher level of care
						• TH mode
						• TH control mode
						• Glucose measured
						• Lowest glucose
							• Death before last follow up
							• NDI at 18–24 months' corrected age
							• Components of NDI at 18–24 months' corrected age
							• Brain injury on neuroimaging (if chest compressions performed)
							• Meconium aspiration syndrome (if born through MSAF)

FIGURE 1

Neonatal Utstein template. Core data should be reported for all patients. Supplemental data variables may be reported. ANCS, antenatal corticosteroids; FiO_2, fraction of inspired oxygen; GA, gestational age; HIE, hypoxic ischemic encephalopathy; IVH, intraventricular hemorrhage; MSAF, meconium-stained amniotic fluid; NEC, necrotizing enterocolitis; PEEP, positive end expiratory pressure; PIP, peak inflation pressure; PMA, postmenstrual age; PVL, periventricular leukomalacia; ROP, retinopathy of prematurity; TH, therapeutic hypothermia.

clinical decision to provide chest compressions

4. Cardiac arrest: cessation of cardiac mechanical activity, determined by absent heart sounds and a pulseless state, leading to a clinical decision to provide chest compressions

We did not specify a minimum duration of time an intervention should be performed to classify an event as eligible. Resuscitation events with even brief episodes of PPV or chest compressions should be included. Newborns with apnea, insufficient respirations, or bradycardia who respond to stimulation or other initial steps and do not receive PPV or chest compressions should not be included. If a newborn receives continuous positive airway pressure (CPAP) without PPV or chest compressions, that resuscitation would not be considered an event per this reporting guideline. However, for newborns who receive CPAP in addition to PPV and/or chest compressions, core data will include information regarding the use of CPAP during resuscitation.

Setting

Two core elements relate to setting. The first is country, which is important to contextualize available resources and policies around the limits of viability. The second core element is in-hospital or out-of-hospital birth, with hospital defined as any licensed health facility that provides care for newborns at birth. Births that occur within the walls of hospitals that provide maternity and newborn care are considered in-hospital, regardless of where in the hospital the birth occurs.

There are 2 supplemental elements in the setting domain. For out-of-hospital births, an indicator for whether out-of-hospital birth was planned is meant to distinguish between unexpected births and births planned in homes or other nonhealth care settings. The second variable pertains to in-hospital births and refers to the definition of the hospital as a high-risk pregnancy center. The characteristics and resources of a high-risk pregnancy center are likely to differ widely by location, so reporting of this variable should be relevant to the local context. Finally, the Neonatal Utstein Working Group recognizes that resuscitation training for providers is an important aspect of the resuscitation

TABLE 1 Neonatal Utstein Data Table

Neonatal Utstein Element	Definition	Data Options
Setting (core)		
Country(ies)	Country(ies) of birth	Free text
Location	A hospital is considered as any licensed health facility that provides care for newborns at birth	In hospital versus out of hospital
Setting (supplemental)		
Planned out-of-hospital birth	Only pertains to out-of-hospital locations	Y/N/unknown
High-risk pregnancy center	Only pertains to in-hospital locations: indicate if the hospital is a center for high-risk pregnancies	Y/N/unknown
Patient (core)		
Gestational age	Completed wks' gestation at time of birth	Numerical
Multiple gestation	Multiple gestation pregnancy	Y/N/unknown
Birth weight	Birth weight in g	Numerical
Sex	Newborn biological sex; unknown pertains to ambiguous genitalia or biological sex not assigned	M/F/unknown
Major congenital anomaly or genetic syndrome	Indicate if a major congenital anomaly or genetic syndrome was diagnosed before or at the time of birth	Y/N/unknown
Prenatal care	Any prenatal care during pregnancy	Y/N/unknown
Patient (supplemental)		
Maternal age	Age in yr	Numerical
Maternal education	Cumulative yr of education	Numerical
Maternal hypertension	Pregestational hypertension or any hypertensive disease of pregnancy	Y/N/unknown
Maternal diabetes	Pregestational or gestational diabetes	Y/N/unknown
Maternal smoking	Indicate if the mother smoked tobacco during pregnancy	Y/N/unknown
Type of congenital anomaly or genetic syndrome	Only pertains to newborns designated as having a congenital anomaly or genetic syndrome diagnosed before or at the time of birth	Free text
Any prenatal limit to resuscitation	Indicate if there was any plan before birth to limit or curtail resuscitative efforts	Y/N/unknown
Antepartum (core)		
Exposure to antenatal corticosteroids	Any antenatal corticosteroid exposure at any point in pregnancy	Y/N/unknown
Meconium-stained fluid	Indicate if the amniotic fluid was meconium stained	Y/N/unknown
Cesarean delivery	Indicate if the mode of delivery was cesarean	Y/N/unknown
Antepartum (supplemental)		
Assisted delivery	Indicate if forceps or vacuum were used during delivery (regardless of mode of delivery)	Y/N/unknown
Labor before delivery	Only pertains to cesarean deliveries	Y/N/unknown
Emergency cesarean delivery	Only pertains to cesarean deliveries	Y/N/unknown
Complete antenatal corticosteroids	Only pertains if antenatal corticosteroids were administered: indicate if at least 48 h of fetal corticosteroid exposure	Y/N/unknown
Antepartum hemorrhage	Indicate if an antepartum hemorrhage or abruption was present after 20 wk' gestation	Y/N/unknown
Birth and preresuscitation process (core)[a]		
Umbilical cord clamping timing	Indicate timing of umbilical cord clamping	Immediate (<30 s) versus later or delayed (≥30 s)
Umbilical cord milking	Indicate if any cord milking was performed	Y/N
Heart rate at 1 min	Heart rate as assessed by any means by providers 1 min after birth, with birth defined as time the infant's body is fully exteriorized from the mother	≥100 beats per min, <100 beats per min, 0 (no detectable heart rate)
Respiratory effort at 1 min	Respiratory effort assessed by providers at 1 min after birth, with birth defined as time the infant's body is fully exteriorized from the mother	Adequate, inadequate, apneic (no effort)
Apgar score at 1 min	Summary of the assigned Apgar score at 1 min	Numerical
Apgar score at 5 min	Summary of the assigned Apgar score at 1 min	Numerical
Birth and preresuscitation process (supplemental)[a]		
Date of birth	Mo and yr of birth	Mo and yr
Time of birth	Time of birth; expressed as completed h (0–23 h)	Time

TABLE 1 Continued

Neonatal Utstein Element	Definition	Data Options
Umbilical cord pH	Umbilical cord blood gas sample	Numerical
Time between birth and cord clamping	Interval of time (in s) between birth and umbilical cord clamping, with birth defined as time the infant's body is fully exteriorized from the mother	Numerical (s)
Intact cord milking	Only pertains if umbilical cord milking was performed: indicate if the umbilical cord was intact when milking was performed	Y/N
Number of times umbilical cord milked	Only pertains if umbilical cord milking was performed: indicate the number of times the umbilical cord was milked	Numerical (count)
Initial steps: stimulation	Indicate if any stimulation was performed by the neonatal resuscitation providers	Y/N
Initial steps: suction	Indicate if the newborn's oropharynx or nasopharynx was suctioned by the neonatal resuscitation providers	Y/N
Initial steps: thermoregulation	Indicate if any interventions were performed to provide thermoregulation; includes drying, skin-to-skin contact, and/or use of adjunctive agents (occlusive wrap, exothermic mattress, hat)	Y/N
Resuscitation process (core)[a]		
CPAP	Indicate if CPAP was provided through any interface at any point during resuscitation process; excludes high-flow nasal cannula	Y/N
PPV	Indicate if PPV was provided through any interface at any point during the resuscitation process	Y/N
Respiratory interfaces	Indicate all interfaces used during the resuscitation process	Facemask, binasal prongs, oropharyngeal tube, supraglottic airway, endotracheal tube, other (specify)
Supplemental oxygen	Indicate if FiO_2 >0.21 was provided through any interface at any point during the resuscitation process	Y/N
Cardiac compressions	Indicate if cardiac compressions were performed at any point during the resuscitation process	Y/N
Epinephrine (adrenaline)	Indicate if epinephrine was provided through any route at any point during the resuscitation process	Y/N
Resuscitation process (supplemental)[a]		
Number of providers caring for newborn	Count of providers caring for newborn during resuscitation; indicate highest number present on team at a single time	Numerical (count)
Time PPV started	Only pertains if PPV was performed: indicate time (relative to birth) PPV through any interface was started	Time (min:s)
Duration of PPV	Only pertains if PPV was performed: indicate the interval of time from when PPV was first commenced to last performed during resuscitation (or until resuscitation ended, if PPV is ongoing at completion of resuscitation)	Whole min, with duration <1 min reported as 1 min
Time endotracheal tube placed	Only pertains if endotracheal intubation performed: indicate the time (relative to birth) endotracheal tube was successfully placed	Time (min:s)
Time chest compressions started	Only pertains if chest compressions were performed: indicate the time (relative to birth) chest compressions were started	Time (min:s)
Duration of chest compressions	Only pertains if chest compressions were performed: indicate the interval of time from when chest compressions were first commenced to last performed during resuscitation	Whole min, with duration <1 min reported as 1 min
PPV device	Indicate the device used to provide PPV	Self-inflating bag, flow-inflating bag, T-piece device, other (specify)
Respiratory settings: CPAP	Only pertains if CPAP was provided: indicate highest CPAP level provided through any interface (cm H_2O)	Numerical

TABLE 1 Continued

Neonatal Utstein Element	Definition	Data Options
Respiratory settings: PEEP	Indicate highest PEEP level provided during PPV through any interface (cm H_2O)	Numerical
Respiratory settings: PIP	Indicate highest PIP level provided during PPV through any interface (cm H_2O)	Numerical
Respiratory settings: FiO_2	Indicate highest FiO_2 provided through any interface	Numerical (0.21–1.0)
Support at completion of resuscitation	Indicate the mode of respiratory support in place at the completion of resuscitation; supplemental oxygen includes nasal cannula ≤2L per min, cot or headbox/oxyhood, or blow by oxygen	None (room air); supplemental oxygen, high-flow nasal cannula (>2 L per min), CPAP, PPV
FiO_2 at completion of resuscitation	Indicate the concentration of oxygen administered at the completion of resuscitation	Numerical (0.21–1.0)
Epinephrine number of doses	Only pertains if epinephrine was administered: indicate the total number of doses administered	Numerical count
Epinephrine route	Only pertains if epinephrine was administered: indicate the route of each dose	Umbilical vein, peripheral vein, intraosseous, endotracheal tube, other (specify)
Epinephrine dose	Only pertains if epinephrine was administered: indicate each dose	Numerical (mg/kg)
Epinephrine timing	Only pertains if epinephrine was administered: indicate the timing of each dose relative to time of birth	Time (min:s)
Fluid administration	Indicate if any bolus fluids (crystal, colloid, blood products) were administered for volume expansion or fluid resuscitation; excludes intravenous infusions and dextrose boluses administered for hypoglycemia.	Y/N
Total fluids administered	Only pertains if any bolus fluids (crystal, colloid, blood products) were administered for volume expansion: indicate the cumulative amount of bolus fluids administered during resuscitation, including crystal, colloid, and blood products	Numerical (mL/kg)
Other interventions	Indicate any other procedures or interventions performed during resuscitation	Pleurocentesis, defibrillation, other
Postresuscitation process (core)[a]		
Immediate disposition	Indicate the immediate disposition for the newborn after delivery	Routine care, NICU, died, other
Therapeutic hypothermia	Indicate if therapeutic hypothermia using a standardized protocol was initiated	Y/N
Temperature measured at 1 h	Indicate if the newborn's temperature was measured in the first h after birth	Y/N
Temperature at 1 h	Only pertains if temperature within the first h after birth: indicate the newborn's temperature measured as close to 1 h after birth	Numerical (Celsius)
Postresuscitation process (supplemental)[a]		
Transfer to higher level of care	Only applies to newborns born in hospital: indicate if the newborn was transferred to another facility for higher level of care before discharge	Y/N
Therapeutic hypothermia mode	Only pertains if therapeutic hypothermia was performed: indicate the mode of therapeutic hypothermia	Full body, head cooling, other (specify)
Therapeutic hypothermia control mode	Only pertains if therapeutic hypothermia was performed: indicate the control mode of therapeutic hypothermia	Servo, manual
Glucose measured	Indicate if the newborn's glucose level was measured at any point in the first 90 min after birth	Y/N
Lowest glucose	Only pertains if glucose was measured within the first 90 min after birth: indicate lowest glucose value measured within 90 min after birth	Numerical (recommended unit mmol/L)
Outcomes (core)		
Death in initial resuscitation area	Death in initial resuscitation area, defined as location where resuscitative efforts were initially performed	Y/N

TABLE 1 Continued

Neonatal Utstein Element	Definition	Data Options
Death before hospital discharge	Death before hospital discharge or transfer; only reported for newborns who are admitted to a hospital location and die before their first hospital transfer or discharge Does not include deaths in initial resuscitation area	Y/N
Duration of hospital stay	Interval between birth and hospital death, discharge, or transfer (whole calendar d); d of birth is considered d 1	Numerical
Air leak	Indicate if any air leaks (eg, pneumothorax) were diagnosed in first 7 d after birth	Y/N/unknown
Moderate-to-severe encephalopathy	Only pertains to newborns born ≥35 wk' gestation: indicate if moderate or severe encephalopathy was diagnosed on the basis of standard assessments (eg, NICHD,[27] BAPM,[28] SIBEN,[29] or the Thompson[30] scoring system)	Y/N/unknown
Outcomes (core for newborns born ≤32 wk' gestation)		
Retinopathy of prematurity	International classification of retinopathy of prematurity stage ≥3[31] or retinopathy of prematurity treatment	Y/N/no screening
Respiratory support at 36 wk' postmenstrual age	Indicate highest level of respiratory support provided on the date of the newborn's 36 wk' postmenstrual age	None (no support), low-flow nasal cannula (≤2 L per min), high-flow nasal cannula (>2 L per min), noninvasive positive pressure support, invasive ventilation
Necrotizing enterocolitis	Bell stage 2 or higher necrotizing enterocolitis[32]	Y/N/unknown
Surgical necrotizing enterocolitis or intestinal perforation	Laparotomy or surgical drain placement performed for suspected necrotizing enterocolitis or intestinal perforation at any time	Y/N/unknown
Severe intraventricular hemorrhage	Papile grade 3 or 4 on worst head imaging obtained during hospital stay[33]	Y/N/no imaging
Cystic periventricular leukomalacia	Cystic periventricular leukomalacia on worst head imaging obtained during hospital stay	Y/N/no imaging
Outcomes (supplemental)		
Death before last follow-up	Death after hospital discharge before last follow-up	Y/N/unknown
NDI	Moderate or severe NDI at 18–24 mo' corrected age among survivors	Y/N/unknown
Neurodevelopment: motor	Standardized motor assessment at 18–24 mo' corrected age among survivors	Numerical
Neurodevelopment: cognition	Cognitive assessment at 18–24 mo' corrected age among survivors	Numerical
Neurodevelopment: language	Language assessment at 18–24 mo' age corrected for gestation among survivors	Numerical
Visual impairment	Visual acuity <6 of 12 (<20 of 40) or logMAR >0.3 in the best corrected eye	Y/N/unknown
Hearing assessment	Unilateral or bilateral sensorineural hearing loss requiring hearing aids or implants	Y/N/unknown
Brain injury on neuroimaging	Only pertains to patients who received chest compressions	Y/N/no imaging
Meconium aspiration syndrome	Only pertains to patients born through meconium-stained amniotic fluid	Y/N/unknown

The Data Table defines the core and supplemental data elements for each Neonatal Utstein domain. Data options provide the suggested format to collect each data element. BAPM, British Association of Perinatal Medicine; F, female; FiO_2, fraction of inspired oxygen; H_20, water; logMAR, log of minimum angle of resolution; M, male; N, no; NICHD, Eunice Kennedy Shriver National Institute of Child Health and Human Development; PEEP, positive end expiratory pressure; PIP, peak inflation pressure; SIBEN, Ibero-American Society of Neonatology; Y, yes.

[a] For interventions in the birth/preresuscitation, resuscitation, and postresuscitation domains, elements should reflect documentation of the given intervention. If an intervention is not documented as having been performed, the element is expected to be coded as no. Therefore, unknown response options are not provided.

setting. Given that there is no standard classification for resuscitation training, this element is not included in the neonatal Utstein template. Instead, the nature and frequency of resuscitation training for providers in the setting should be described by authors in the Methods of neonatal resuscitation publications.

Patient

This domain includes demographic information about the newborn and the mother. Most important is the gestational age at birth, defined as completed weeks of gestation using the best obstetrical estimate available. To facilitate subgroup analyses across studies, consistent gestational age subgroups should be reported, following World Health Organization definitions[12]: extremely preterm (<28 weeks), very preterm (28 to <32 weeks), moderate preterm (32 to <34 weeks), late preterm (34 to <37 weeks), and term (≥37 weeks). Additional core patient elements include presence of multiple gestation (regardless of birth order), birth weight, biological sex, and presence of major congenital anomalies or syndromes that were known prenatally or at the time of birth. Finally, the core element "prenatal care" indicates whether any prenatal care was provided at any point during the pregnancy.

Maternal characteristics identified as supplemental elements in the patient domain are specified in the Data Table. These include maternal age at delivery, cumulative years of education, hypertensive disease, diabetes, and tobacco smoking. In addition, for newborns with a major anomaly or syndrome indicated in the core patient domain, the supplemental element should include a description or listing of the specific anomalies and/or syndrome. Finally, we included 1 supplemental element to indicate whether there were any prenatal plans to limit the intensity or duration of resuscitation to better contextualize the resuscitation process and outcome.

Antepartum

Antepartum factors thought to impact the resuscitation process or outcomes were included. We did not include a comprehensive set of data elements that might increase the risk of resuscitation because the Neonatal Utstein reporting guideline only pertains to patients who receive resuscitation. Thus, information on process and outcomes of newborns who do not receive resuscitation will not be available. Three core elements in this domain are any maternal exposure to antenatal corticosteroids (regardless of type of corticosteroid or timing of exposure), presence of meconium-stained amniotic fluid, and mode of delivery.

Supplemental elements considered to impact the newborn's physiologic status at the time of birth were included. Three of these pertain to the delivery. Assisted delivery should be indicated if any forceps, vacuum, or any other assistive devices were used at any time in the delivery (regardless of final mode of delivery). Two elements pertain to newborns born via cesarean delivery. The first is whether any labor occurred before delivery, because this may trigger fetal lung fluid absorption and affect pulmonary function.[13] The second is whether the cesarean delivery was considered an emergency. Because definitions for emergency cesarean delivery vary,[14] local classifications should be defined and used. If there was fetal exposure to antenatal corticosteroids, a supplemental element indicates whether at least 1 course was complete (defined as at least 48 hours of fetal exposure before delivery). Antepartum hemorrhage should be indicated as "yes" if there was any report of antepartum hemorrhage, regardless of amount or acuity, or if a placental abruption was diagnosed after 20 weeks' gestation.

Birth/Preresuscitation Process

This category describes the newborn's status and interventions performed between birth (defined as the time the infant's body is fully exteriorized from the mother)[15] and initiation of PPV or chest compressions. For interventions in the birth/preresuscitation, resuscitation, and postresuscitation domains, elements should reflect documentation of the given intervention. If an intervention is not documented as having been performed, the element is expected to be coded as "no." Therefore, "unknown" response options are not provided in the Data Table.

Because cord management is associated with neonatal outcomes, core data include the timing of umbilical cord clamping and performance of umbilical cord milking. Consistent with previous ILCOR NLS systematic reviews, cord clamping is categorized as immediate (<30 seconds) versus later or delayed (≥30 seconds).[16,17] The core cord milking element includes any milking or stripping of the cord, regardless of whether the cord is intact or cut at the time of milking. Additional core elements include the newborn's condition (heart rate and respiratory efforts at 1 minute after birth) and Apgar scores at 1 and 5 minutes. Respiratory effort is reported as adequate, inadequate, or absent. A practical guide for scoring this element is to use the Apgar score classification (strong cry, weak cry/hypoventilation, absent).[18]

Supplemental elements include the date of birth (month and year) and time of birth (in completed hours).

Recording month and year of birth is necessary to assess temporal trends in resuscitation practice. Time of birth may be important to contextualize resuscitation performance and outcomes.[19] Therefore, although the actual time of birth is collected for each patient, we recommend this element should be reported as a dichotomous indicator for overnight birth, with the hours constituting overnight defined in the Methods section by each investigator. Additional supplemental elements include umbilical cord pH (ideally from an arterial sample), more granular information around cord management, and the individual initial steps (stimulation, suction, thermoregulation) performed by the neonatal resuscitation team.

Resuscitation Process

This domain captures key interventions performed during neonatal resuscitation. Resuscitation is considered to start when PPV or chest compressions is initiated. The Neonatal Utstein Working Group was unable to develop 1 single approach to define the end of neonatal resuscitation. This has been variably defined across studies using location (eg, all interventions in the delivery room), patient physiologic status (eg, heart rate >100 beats per minute), or a prespecified duration (eg, first 20 minutes after birth). Conceptually, the resuscitation process should capture interventions intended to support immediate neonatal transition and not interventions for infants who require ongoing support at the completion of resuscitation (such as continuous PPV during transfer to NICU). As such, investigators should define in the Methods section how the end of resuscitation is defined for the particular setting.

Respiratory support is key to the process of neonatal resuscitation.[11] Core data therefore capture the modes of respiratory support provided (CPAP and PPV) and the interface through which support is delivered (mask, prongs, supraglottic airway, endotracheal tube). Most current guidelines suggest commencing resuscitation of term newborns with air with addition and titration of supplemental oxygen under specific circumstances.[20,21] The provision of supplemental oxygen is therefore a core element. Cardiac compressions and epinephrine (adrenaline) are rarely required and indicate severe compromise[22–24]; occurrence of these should be captured as core elements.

The number, professional group, and experience of resuscitation providers likely have an important impact on the resuscitation process. However, staffing models vary considerably across settings. For the first iteration of this consensus statement, the highest number of providers present and caring for the newborn at a single time during the resuscitation process is captured as a supplemental element. Devices to generate inflating pressure vary and may impact the quality of ventilation; the respiratory device is a supplemental element. The highest-pressure settings for each mode of respiratory support used throughout resuscitation (CPAP, positive end expiratory pressure, and peak inflation pressure) are also included as supplemental elements. The type of respiratory support (if any) in place at the completion of resuscitation is a further supplemental element.

Information on the timing and duration of resuscitative interventions was of high interest, but these are not consistently captured for all resuscitative interventions. Thus, limited data regarding initiation of key interventions (PPV through any interface, chest compressions, and intubation) are recorded as supplemental elements. These should be reported in minutes relative to time of birth. Duration of each intervention is defined as the interval from when the intervention was first initiated to last performed. If the intervention is ongoing at the end of resuscitation (such as ongoing PPV during transfer to the NICU), the endpoint for duration of the intervention is defined as the end of resuscitation. We discussed collecting data on whether chest compressions were coordinated with ventilation and the ratio used, but we ultimately decided this level of detail was too burdensome for most settings. However, these details should be collected and reported when human studies of cardiac compressions are conducted.

Finally, information about rare but important interventions will be captured as supplemental elements. These include the administration route, timing, dose, and total number of doses of epinephrine; the use and cumulative dose of fluid boluses (crystalloid, colloid, and blood products) for volume expansion; and other important procedures such as pleurocentesis and defibrillation.

Postresuscitation Process

Core elements in the care of the newborn after resuscitation include therapeutic hypothermia, the immediate disposition for the newborn after delivery, and temperature at 1 hour after birth. Regarding disposition, NICU refers to any area providing higher-level care (including a special care nursery), whereas routine care includes staying with parents and/or admission to newborn nursery. Therapeutic hypothermia is defined as a protocol-driven, time-limited controlled lowering of head or body temperature to mitigate the

neurologic effects of hypoxic ischemic encephalopathy. This includes either selective head cooling or whole-body cooling and excludes processes related to "passive cooling." Of note, therapeutic hypothermia performed with low-cost devices such as ice packs or phase-changing material is considered as "active cooling," provided these devices are used in a protocol-driven method.[25]

Supplemental elements include more details around therapeutic hypothermia (if performed) and transfer to a facility with higher level of care. Two elements related to glucose monitoring (action of monitoring and lowest measured value) were also included. Although need for resuscitative interventions may increase the risk of impaired glycemic control, there are insufficient data to identify the optimal timing for glucose monitoring or the correct targets that should prompt intervention.[20] Thus, these elements were included as supplemental variables and may help inform future studies.

Further elements considered but not included at this time were timing of therapeutic hypothermia initiation and intubation/invasive mechanical ventilation after resuscitation. These were excluded after discussion to maintain a parsimonious and clinically relevant core data set. Notably, information about respiratory interventions during and at the completion of resuscitation are captured within the resuscitation process domain.

Outcomes

The Neonatal Utstein Working Group recognizes that relevant outcomes vary for different populations of newborns on the basis of gestational age or other risk factors. In addition, resources to diagnose all important neonatal outcomes are not available globally. Thus, a discrete number of core outcome elements should be reported for all newborns. Outcomes that are gestational-age specific or specific to discrete populations based on risk factors are labeled as such in the Data Table.

For all outcomes, investigators should report whether outcome assessors were masked to relevant exposures and treatment protocols. For outcomes that require radiographic imaging or other diagnostic testing, the investigators should provide information on what method(s) were used to identify the outcome of interest, who was responsible for interpreting the results, and when the test or screening exam was performed. For outcomes that rely on standardized assessments, investigators should describe which standardized assessments were used and how outcome assessors were trained. For outcomes that require active screening, imaging, or standardized assessment, the data element should be coded unknown if no diagnostic examination or exam was performed. Similarly, outcome elements should be coded unknown if the patient was transferred or died before assessment. Summary results of these outcomes should be reported as the number of affected newborns among the number of newborns who were assessed with the relevant diagnostic or screening examination.

Clarification or justification for specific elements is provided below:

- Death in initial resuscitation area: For newborns who are transferred during ongoing resuscitation, this outcome should be recorded as yes if the resuscitative interventions are initiated in the location of birth, continued uninterrupted during transport, and the newborn subsequently dies during ongoing resuscitation. This does not pertain to ongoing interventions in place once the initial resuscitation is complete (such as continuous PPV during transfer to NICU).
- Death before last follow-up: This categorical data element is intended to document if the newborn died during the interval between the last point of contact (hospital discharge or last outpatient visit) and the last planned follow-up. This item should be scored unknown if the patient is lost to follow-up and survival status is unknown. Age at last follow-up should be reported in the methods of the paper.
- Neurodevelopmental impairment (NDI) at 18 to 24 months' age corrected for gestation: The Neonatal Utstein Working Group recognizes that comprehensive neurodevelopmental follow-up is difficult and expensive, and tools used to assess NDI vary on the basis of language and local resources. As a result, this critical outcome was considered supplemental. The criteria for defining NDI should be clearly stated. This item should be scored unknown if the patient is lost to follow-up and records are insufficient to assign a category. In addition, individual components of the criteria used to define NDI should be reported. Where feasible, appropriate descriptive statistics (mean and SD, or median and interquartile range) should be reported for each measure.
- Brain injury on neuroimaging: This outcome was considered important to fully understand the pathophysiology of long-term NDI. However, because neuroimaging is not routinely collected on most newborns who receive resuscitation, particularly for newborns who receive PPV alone, this supplemental outcome is indicated for newborns who

receive chest compressions during resuscitation at birth.
- Meconium aspiration syndrome: This should be reported for newborns born through meconium-stained amniotic fluid. The criteria used to define meconium aspiration syndrome should be described; a suggested practical definition is that used in Vain et al.[26]

DISCUSSION

We employed a consensus-based approach to develop the first Utstein-style reporting guideline applicable to neonatal resuscitation. Given the global burden of neonatal resuscitation and the growing volume of clinical studies focused on the neonatal population, the lack of standardized reporting guidelines poses an important methodologic limitation to the field. A consistent reporting framework is anticipated to provide significant value for individual investigators and networks engaged in neonatal resuscitation research. In addition, this will facilitate data pooling in meta-analyses, ultimately enhancing the strength of treatment recommendations and neonatal resuscitation guidelines.

The Neonatal Utstein Working Group confronted multiple challenges in this process, and some issues remain unresolved. Foremost was the tension between what was desirable versus feasible to include. Neonatal resuscitation is performed in both high- and low-resource settings. In addition, resuscitation teams and resources available for high-risk patients, such as extremely preterm newborns or newborns with major anomalies, often differ from lower-risk patients who unexpectedly require resuscitation. In resuscitations with fewer resources, personnel are not typically available for real-time documentation, and physiologic monitor data (if used) are not typically stored or downloaded. Finally, many variables of potential interest before and after resuscitation are variably defined across settings. Thus, core data elements were those felt to be clinically relevant and most reliably captured for all newborns.

One important difference between this guideline and reporting guidelines for other resuscitation settings relates to defining the event of interest. For example, cardiac arrest is a clearly defined event with a distinct onset and endpoint (return of spontaneous circulation). In contrast, there is a continuum between stabilization and resuscitation after birth. Many newborns require support to successfully transition to the postnatal environment because of immaturity or congenital anomalies, whereas others require resuscitation for perinatal depression or asphyxia. This reporting guideline was designed to focus on resuscitation events, not stabilization events. However, there is no standard definition or method to distinguish between these. Thus, we employed a pragmatic approach of defining eligible events on the basis of the resuscitative interventions received (PPV or chest compressions), rather than defining resuscitation events on the basis of patients' physiologic status, or need, for resuscitation. We acknowledge that it is often difficult to determine appropriateness of an intervention during newborn resuscitation on the basis of review of medical records. It is possible that some patients receive interventions such as PPV or chest compressions when they are not indicated. Likewise, some patients who need such interventions may not receive them.

Anticipated Use of the Neonatal Utstein Reporting Guideline

The Neonatal Utstein reporting guideline provides a framework to standardize reporting key data elements in publications of neonatal clinical resuscitation. The guideline applies to both clinical trials and observational studies. Although we defined a parsimonious list of core data elements across 7 domains, these are not exclusive. This guideline is not meant to replace investigators' autonomy and discretion when designing clinical studies and trials. Investigators are expected to identify and collect additional data that are appropriately informed by the intervention and study question of interest. However, it is the hope of the Neonatal Utstein Working Group that, at minimum, all specified core data elements will be reported using the standardized definitions provided here.

This first version of the Neonatal Utstein reporting guideline reflects the views and expertise of the ILCOR NLS; we acknowledge this methodologic limitation. We anticipate feedback from the neonatal resuscitation community will inform subsequent updates to this guideline. In addition, ongoing research will likely identify important clinical resuscitation data elements that are not included here. Future iterations of the Neonatal Utstein reporting guideline should account for emerging evidence to remain a useful resource for the neonatal resuscitation scientific community.

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ABBREVIATIONS

CPAP: continuous positive airway pressure
ILCOR: international liaison committee on resuscitation
NDI: neurodevelopmental impairment
NLS: neonatal life support
PPV: positive pressure ventilation

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