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Incidence of severe adverse neonatal outcomes: Use of a composite indicator in a population cohort

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Short title*:* Composite Neonatal Adverse Outcome Indicator

Abbreviations: PPV = Positive Predictive Value, RR = Relative Risk, LOS = length of stay, SD = Standard deviation; NAOI= neonatal adverse outcome indicator; ICD-10-AM=International Statistical Classification of Diseases and Related Health Problems, Australian Modification; ACHI =Australian Classification of Health Interventions; MDC= Midwives Data Collection; APDC=Admitted Patient Data Collection

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Contributor's Statement page

Samantha Lain was the main author of the manuscript. Charles Algert conducted the analysis and drafted the methods and results. Drs Christine Roberts and Natasha Nassar developed the concept and design of the study and contributed to the drafting of the manuscript. Dr Jennifer Bowen revised the manuscript for important intellectual content. All authors contributed to the interpretation of data and had final approval of the manuscript to be published.

What's Known?

Composite outcomes have frequently been used in perinatal research studies to measure neonatal morbidity. Although the use of routinely collected data for research is increasing, there has not been a validated composite neonatal outcome measure available for use in population datasets.

What's New?

The Neonatal Adverse Outcome Indicator described is a reliable composite indicator suitable for measuring severe neonatal morbidity amongst both term and pre-term infants in population health databases. The indicator also identifies infants who are at increased risk of readmission or infant death.

ABSTRACT

Objectives

The aim was to develop a composite outcome indicator to identify infants with severe adverse neonatal morbidity and mortality in routinely collected population health datasets, and assess the indicator's association with readmission and infant mortality rates.

Methods

A comprehensive list of diagnoses and procedures indicative of serious neonatal morbidity was compiled based on literature review, validation studies and expert consultation. Relevant diagnoses and procedures indicative of severe morbidity that are reliably reported were analysed and reviewed, and the neonatal adverse outcome indicator (NAOI) was refined. Data were obtained from linked birth and hospital data for 516,843 liveborn infants ≥24 weeks gestation, in New South Wales, Australia from 2001-2006. Face validity of the indicator was examined by calculating the relative risks (and 95% CI) of hospital readmission or death in the first year of life of those infants identified by the NAOI.

Results

Overall 4.6% of all infants had one or more conditions included in the NAOI; 35.5% of preterm infants and 2.4% of term infants. Infants identified by the composite indicator were over 9 times more likely to die in the first year of life or almost twice as likely to be readmitted to hospital in the first year of life, than those infants not identified by the NAOI.

Conclusion

The NAOI can reliably identify infants with a severe adverse neonatal outcome and can be used to monitor trends, assess obstetric and neonatal interventions and the quality of perinatal care in a uniform and cost-effective way.

INTRODUCTION

Neonatal mortality has been a commonly used outcome measure for research into obstetric and neonatal interventions and the quality of perinatal care. However as the neonatal mortality rate has been decreasing, especially amongst infants born after 27 weeks gestation(1), severe morbidity has been suggested as a more relevant outcome(2). The five minute Apgar score has been used as an outcome measure of neonatal morbidity(3), however the Apgar score was designed to be a quick and convenient method to report on the status of the newborn infant immediately after birth(4) not an indicator of morbidity.

Individual conditions (outcome measures), such as seizures or intraventricular haemorrhage, require large study samples to detect often subtle clinical differences between groups of infants at risk. To overcome this, composite neonatal outcomes have been used in randomised controlled trials(5), prospective(6) and retrospective cohort studies(7-9) where the incidence of individual outcomes are low.

Routinely collected or population health datasets (PHDS) such as birth registries and hospital discharge data, are an easily accessible resource to assess neonatal morbidity. Compared to prospective studies or retrospective chart review(10, 11) PHDS potentially provide a less resource-intensive and costly method of research. However for PHDS to be used to monitor neonatal morbidity its reliability and validity has to be assured(12, 13).

Studies validating the reporting of neonatal outcomes in PHDS report high positive predictive values (generally greater than 85%) which is important as a high PPV

ensures that the majority of neonates identified truly have the condition or procedure. Neonatal outcomes collected in PHDS also generally report moderate to high sensitivities (>75%), indicating good ascertainment of neonatal conditions(14-16), although some individual conditions have been reported to have lower ascertainment. These include pulmonary hypertension (64%)(15), necrotising enterocolitis (62%)(15), respiratory distress (range 50% to 94%)(14-16), intraventricular haemorrhage (range 52% to 100%)(14-16), pneumonia (48%)(15), and bacterial sepsis (38%),although the sensitivity of sepsis was increased to 67% when adult sepsis codes were also included(14). Furthermore, procedures are generally reported better than conditions(17), especially surgical procedures, for example major neonatal surgery has a sensitivity of 91% and a PPV of 95%(15).

The use of a composite indicator helps overcome the under-ascertainment of individual conditions and procedures. Severely ill neonates may have co-morbidities and multiple procedures, so a composite indicator that includes any morbid event increases the chance of identifying those infants with major morbidity(18). A validated indicator for maternal morbidity using PHDS identified almost 80% of women with a severe maternal morbidity with a positive predictive value of 95%(18).

The aims of this study were: (1) to develop a neonatal adverse outcome indicator (NAOI) to measure severe adverse neonatal morbidity and mortality in population health datasets by using previously validated diagnoses and procedure codes; and (2) to assess the face validity of the outcome indicator by examining its association with readmission and infant mortality rates.

METHODS

Development of Neonatal Adverse Outcome Indicator (NAOI)

The composite outcome indicator, the NAOI, was initially developed based on review of the literature (including studies validating the reporting of infant outcomes in PHDS) and consultation with neonatologists. A comprehensive list of reliably reported diagnoses and procedures indicative of serious adverse neonatal outcomes was compiled(14-16, 19-21). The components of the morbidity indicator were reviewed, discussed with neonatologists and refined in an iterative process. For example, less severe transitional neonatal conditions; such as transient tachypnoea of the newborn, jaundice, low blood sugar and feeding difficulties were considered for inclusion. Ultimately, these were not included unless they were already associated with comorbidities or the need for intensive care support (eg continuous ventilation, exchange transfusion, or intravenous fluids). This was decided because the diagnosis, management and service provision for these problems varies between hospitals and their associated rates of readmission were lower than for the included conditions and procedures. The final list of the components of the indicator are reported in Appendix A.

Study population and datasets

All livebirths with a gestational age of 24 weeks or greater to women residing in New South Wales (NSW), Australia from January 2001 through December 2006 were included in the cohort. NSW is the most populous state in Australia, and with around 90,000 births per year, comprising 34% of all Australian births(22). Data from the Midwives Data Collection (MDC), a population-based surveillance system of all births in New South Wales (NSW), Australia, and the Admitted Patient Data Collection (APDC), an administrative database of all hospital admissions in NSW,

were used. These databases have been described previously(23). The APDC hospital discharge summaries can include more than twenty diagnoses and procedures that are coded for each admission from the medical records according to the 10th revision of the International Classification of Diseases and Related Health Problems, Australian Modification (ICD-10-AM) and the affiliated Australian Classification of Health Interventions (ACHI), respectively. The two databases have been linked, using probabilistic linkage. This linkage enables the infant's MDC birth data to be linked to their hospital birth admission, and longitudinally linked to subsequent hospital admissions. These data are also linked to Australian Bureau of Statistics (ABS) mortality data, so that all deaths in the first year of life could be identified. Only anonymized data are available to researchers.

Maternal factors available on the databases included age, parity, patient in a private or public hospital and smoking status. Socio-economic status was available and categorised into quintiles based upon the ABS's SEIFA (Socio-Economic Indexes for Areas) 2006 index of relative disadvantage by postcode. Infant birthweight, sex, gestational age, Apgar score (1 and 5 minute) and level of resuscitation at birth were available on the MDC; other conditions were determined by searching both the ICD-10 diagnosis and procedure fields on each admission record. Size-for-gestational-age was determined using standard birthweight percentile charts. Small-for-gestational-age (SGA) and large-for-gestational-age (LGA) were defined as $<10^{th}$ percentile and $>90^{th}$ percentile birthweight for gestational age respectively.

From 2001 to 2006 there were 516,843 infants of at least 24 weeks gestational age, born alive to women residing in NSW with an MDC birth record. However, 9,166 (1.8%) births did not link to any hospital admission record, and 814 (0.2%) births

only linked to a post-delivery admission. Homebirths were over-represented in these non-linked records: 5.4% were planned homebirths versus 0.1% of births that did link to a hospital record. Any neonatal morbidity identified among the unlinked records was only established by gestational age, birthweight, resuscitation or mortality criteria. The proportion of missing data for variables from the MDC that were incorporated into the NAOI was small: birthweight 0.01%, gestational age 0.01%, resuscitation 0.09%.

Data analysis

The frequency and relative risks of the NAOI were calculated for a range of maternal and infant characteristics. In addition, incidence rates were calculated for each condition or procedure included in the composite outcome indicator for preterm (< 37 weeks gestation) and term (≥ 37 weeks gestation) infants before first discharge home. Denominators were based on all livebirths and sourced from the MDC.

Longer term neonatal outcomes, including infant mortality and readmission to hospital following the first discharge after birth, were also assessed. Deaths after 28 days postpartum but, where the infant never left hospital, were counted as neonatal deaths but not as infant deaths. Readmissions included day-only stays as well as overnight admissions. Readmissions for certain elective procedures (eg circumcision, vaccination) were not included in the calculation of readmission rates. The rate of hospital readmission or death after the first discharge and before one year of age was calculated for each component of the NAOI.

To investigate the face validity of the NAOI the association between neonatal morbidity and subsequent infant mortality and hospital readmission were examined.

Relative risk (RR) (and 95% confidence intervals (CI)) for hospital readmission or infant death in the first year of life were calculated for infants identified by the NAOI compared to those without the indicator. This analysis was performed on all infants and then on a subgroup which excluded infants with severe congenital abnormalities. For comparative purposes, we also investigated the mortality rate in infants with 5 minute Apgar score <7.

RESULTS

Of the 516,843 infants of at least 24 weeks gestational age, 23,998 infants (4.64%) had one or more conditions indicative of neonatal morbidity or mortality. The frequency of infants identified by the NAOI fell sharply by week of gestation. At 32 weeks the morbidity rate was 71.4%, but this fell to 5.2% at 37 weeks (Figure 1). Morbidity was lowest at 39 weeks (2.0%) and 40 weeks gestation (2.0%), but increased to 2.5% at 41 weeks and 3.1% for gestations of 42 weeks and greater.

The distribution of maternal and infant characteristics by NAOI is shown in Table 1. Nulliparous mothers, smokers and mothers in the lowest quintile for socioeconomic status were associated with increased risk of an infant with an adverse outcome. The median length of stay (LOS) (including any transfer admissions) for infants with an adverse outcome was 7 days (IQR 4-18 days), while infants who did not have a record of morbidity had a median LOS of 3 days (IQR 2-5). The LOS for preterm infants identified by the NAOI was typically much longer than for term infants identified by the NAOI: 15 days (IQR 7-30) versus 5 days (IQR 3-7) for term infants with an adverse outcome.

The frequency of conditions included in the NAOI is shown in Table 2, for preterm and term births. The incidence of an adverse outcome was much higher in preterm (35.5 per 100 births) compared to term births (2.4 per 100 births), so that the absolute number with an adverse outcome in this group exceeded that in the term births. The most common indications of an adverse outcome were ventilatory support, intravenous fluids and respiratory distress syndrome. Respiratory distress syndrome and ventilatory support were highly correlated: 65.4% of infants with a diagnosis of

respiratory distress syndrome required resuscitation with intubation and/or subsequent continuous ventilation.

Table 2 also shows the rate of readmission/infant death associated with conditions included in the NAOI. A diagnosis of bronchopulmonary dysplasia had the highest rate of readmission/death (57.9%) along with neonatal surgery (57.6%). All term infants with a diagnosis of bronchopulmonary dysplasia had received over 95 hours of ventilation. The rate of readmission/death in infants without any neonatal condition was 16.2%.

The composite neonatal adverse outcome indicator was strongly associated with death subsequent to discharge home (RR=9.79; 95% CI 8.02-11.9). The NAOI identified 32% of deaths in the first year after discharge home, compared with only 6% of infants identified with a 5 minute Apgar < 7. The strong association between the NAOI and subsequent infant death persisted even when infants with serious malformations were excluded (RR=7.98; 95% CI 6.34-10.1). With regards to readmissions during the first year of life, there was also a strong association with the composite neonatal outcome indicator (RR=2.02; 95% CI 1.98-2.06). The readmission rate among all infants was substantial (17.0%) as it included day-only admissions, with respiratory or other infections and sleeping and feeding problems being the most common reasons for admission to hospital.

DISCUSSION

The neonatal adverse outcome indicator outlined in this study can be used with population health data to identify infants with serious morbidity at birth and at increased risk of longer term morbidity. In the past, studies have used various measures such as gestational age, birth weight and/or Apgar scores to represent neonatal morbidity(3, 6, 24, 25), however these measures are often not sensitive enough to differentiate infants with severe neonatal morbidity. To our knowledge this is the first outcome indicator to capture overall severe neonatal morbidity in both term and preterm infants using PHDS. Other validated neonatal outcome indicators use a scale to score newborns that rely on data collected from clinical and laboratory records(10, 11).

Recent studies using population health data have applied composite outcomes to measure neonatal morbidity amongst term and low risk babies(7, 8). These studies report higher incidence of composite morbidity in their population of term babies than our study (9.5%(8) and 11.9%(7) compared to 2.4%). This is likely to be due to the inclusion of transient tachypnea and hypoglycaemia. Both of these conditions are common but infrequently lead to admission into a neonatal intensive care unit (NICU). Infants with these less severe conditions and without other morbidity had lower hospital readmission rates than those with conditions and procedures included in the NAOI (21.9% for those with transient tachypnea, 23.4% with hypoglycaemia, 22.1% with jaundice and 23.4% for infants receiving enteral nutrition). This suggests a lesser degree of morbidity. Including these conditions in the NAOI would only slightly increase the sensitivity of indentifying infants with serious morbidity at the expense of including many infants with a less severe spectrum of morbidity, decreasing specificity. As an example, if transient tachypnea had been included, the

overall incidence of morbidity would have been 6.81% instead of 4.64%, and proportionately greater for term infants (4.35% instead of 2.39%). For infants with hypoglycaemia, although these were not included, those neonates who received intravenous fluids were included in the NAOI, so infants with more severe forms of hypoglycaemia that required invasive treatment were identified. We also found that although longitudinally linking databases to obtain all transfers identified more newborns with severe morbidity, data from the birth admission alone identified the majority of infants included in the NAOI.

Despite other neonatal morbidity indicators including neonates with a hospital stay of five days or greater or those admitted to a NICU(8), we did not include these factors in our NAOI as we considered them to be related to service provision. Given we plan to use the NAOI to compare outcomes across hospitals, rates may be biased by the fact that some small hospitals do not have a NICU and length of hospital stay may be affected by local health policy, mother's mode of delivery or bed availability.

Readmission to hospital and death in the first year of life was used as a measure of longer term morbidity to test the face validity of the NAOI. Although neither of these outcomes are perfect measures to validate the indicator they have been widely used as proxies for longer term neonatal morbidity(26-29). Hospital readmission has been identified as a significant outcome indicator as sicker or more complicated patients have higher rates of readmission(30), however this may be an unreliable variable as we found a high proportion (16.2%) of infants without a severe morbidity in the neonatal period were also readmitted to hospital in the first year of life. Infant death in the first year of life is also an outcome of severe neonatal morbidity however, many infant deaths do not relate to morbidity in the neonatal period. From 1997 to 2001 the

leading causes of death of infants in the postnatal period in Australia were sudden infant death syndrome (28%) followed by unspecified congenital malformation of the heart (3.1%)(31). Although the five minute Apgar score is associated with neonatal mortality, some experts suggest that it should not be used to predict long-term outcomes such as neurological sequalae(32). Our results show that the NAOI had a higher association with hospital readmission or death in the first year of life than a five minute Apgar score of less than seven. Face validity was further demonstrated by the significant decrease in the proportion of infants with the NAOI by gestational age.

A strength of this study is the use of diagnoses and procedures that have been validated in population health data across numerous jurisdictions(14-16, 32-34). As reported in the validation studies, population health data have few false positives but under-ascertainment of conditions and procedures, consequently the incidence of individual conditions and procedures reported in this study need to be interpreted with caution. However the use of a composite indicator helps overcome this under-ascertainment. Published incidence rates from retrospective chart reviews or cohort studies highlight the potential under-enumeration of particular conditions in our study; such as respiratory distress syndrome (2.85%(16) versus 1.69%) and grade 3 or 4 intraventricular haemorrhage in preterm infants (1.8%(33) versus 0.8%). However published incidence rates of 0.18% for seizures, and 0.66% for intubation in term infants(33) were comparable to incidence rates of 0.20% (seizures) and 0.73% (ventilatory support) in our study. The inclusion of procedure codes can also improve identification of morbidity as procedures are generally reported more accurately than diagnoses(15), and the use of adult codes can improve ascertainment without

increasing false negatives(14). We have included adult codes for seizures, pneumonia and sepsis to improve sensitivity of these conditions.

CONCLUSION

The composite neonatal adverse outcome indicator is a reliable population measure of severe neonatal morbidity utilizing routinely collected data that can easily be applied by other users of population health databases which is an important feature of an indicator(34). The NAOI, along with the maternal morbidity outcome indicator(18), can also be used to monitor the quality of obstetric and neonatal care in a uniform and cost-effective way. Because it is based on coded hospital data, it can also be used to determine the direct health system costs of severe neonatal morbidity. Finally, with increasing longitudinal linkage of administrative health data, the NAOI can identify infants for follow-up studies of longer term outcomes.

Figure 1: Rate of neonatal morbidity by gestational age at delivery

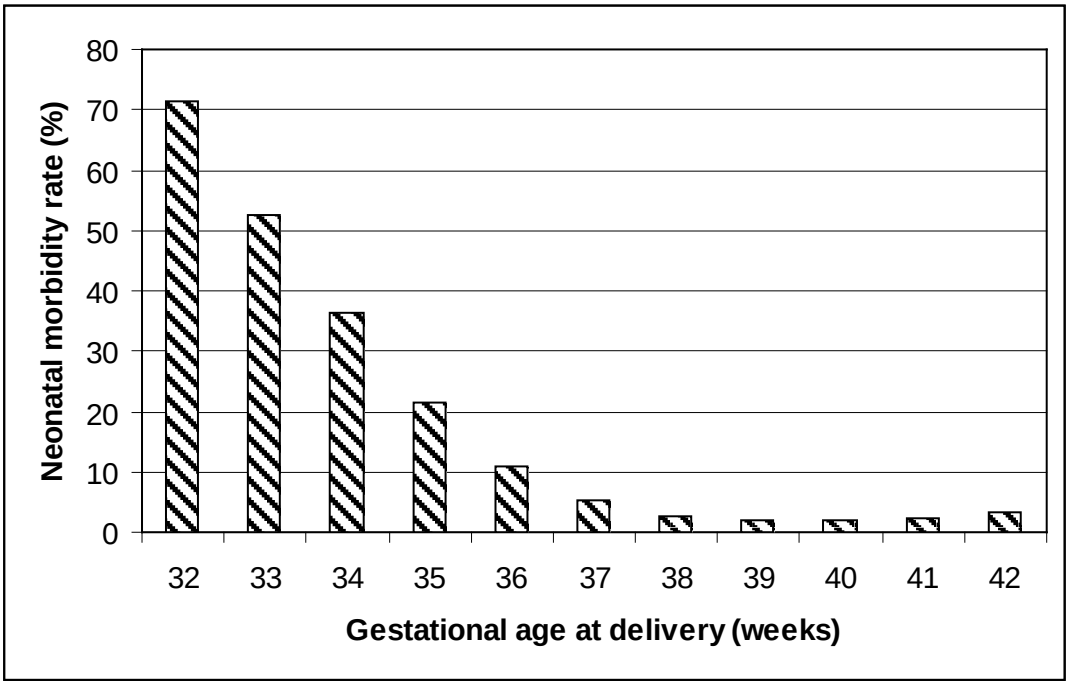

Table 1: Frequency of infants with NAOI and association of NAOI with maternal and infant characteristics

Maternal and infant characteristics	Infants identified by NAOI n=23,998 (%)	Infants not identified by NAOI n=492,845 (%)	Relative risk of neonatal morbidity (95% CI)
Maternal characteristics			
Age <20 years	4.5	4.0	1.13 (1.06, 1.21)
Age 20-34 years	74.1	76.2	Ref
Age ≥ 35 years	21.4	19.8	1.10 (1.07, 1.14)
Nulliparous	47.4	41.5	1.25 (1.22, 1.29)
Lowest quintile SES score	20.9	19.5	1.08 (1.05, 1.12)
Private hospital patient	24.9	26.0	0.95 (0.92, 0.97)
Smoker	18.2	14.9	1.26 (1.22, 1.30)
Infant characteristics			
Mean birthweight (SD)	2620 (1039)	3421 (513)	not applicable
Male	58.2	51.3	1.31 (1.27, 1.34)
Preterm (<37 weeks)	50.8	4.5	14.5 (14.2, 14.9)
Small for gestational age	14.2	9.7	1.51 (1.46, 1.56)
Large for gestational age	12.2	10.3	1.19 (1.15, 1.24)

Table 2: Incidence (per 100 births) before discharge home, and rates of hospital readmission or death after discharge home, for conditions and procedures indicative of neonatal morbidity

Neonatal condition or procedure	Incidence before discharge home n (per 100 births)		Rate of readmission or infant death in first year %
	<37 weeks	≥ 37 weeks	
All livebirths	*34,354*	*482,489*	
NAOI	12,190 (35.48)	11,808 (2.39)	32.9
Neonatal death*	853 (2.48)	439 (0.09)	not applicable
Resuscitation with intubation or CPR	2348 (6.85)	2252 (0.47)	30.7
Birthweight <1500 grams	4322 (12.59)	32 (0.01)	41.8
Respiratory distress syndrome	6305 (18.79)	2382 (0.50)	36.1
Hypoxic ischemic encephalopathy	77 (0.23)	328 (0.07)	34.1
Intraventricular haemorrhage (grade ≥2)	259 (0.77)	18 (0.00)	44.8
Injury due to birth trauma†	41 (0.12)	125 (0.03)	25.3
Ventilatory support††	7175 (21.32)	3448 (0.73)	41.4
Sepsis	1330 (3.96)	1162 (0.25)	37.6
Seizure	235 (0.70)	775 (0.16)	41.8
Pneumothorax with intercostal catheter	256 (0.76)	172 (0.04)	41.8
Pneumonia	220 (0.65)	402 (0.08)	27.2
Surgical procedure	682 (2.03)	1012 (0.21)	57.6
Central line (incl. umbilical vein or artery)	3169 (9.45)	1035 (0.22)	44.4
Transfusion	1810 (5.38)	415 (0.09)	48.5
Necrotising enterocolitis	305 (0.91)	29 (0.01)	42.2
Any intravenous fluids	6486 (19.27)	4649 (0.98)	35.5
Broncho-pulmonary dysplasia	569 (1.70)	11 (0.0)	57.9

* includes deaths ≥ 28 days if the infant was never discharged home
† intracranial haemorrhage, brachial plexus, skull or longer bone fracture
†† mechanical ventilation and/or CPAP

Appendix A: Components of composite outcome indicator identified from a birth record or in any hospital transfer admission prior to the first discharge home

Diagnosis	Data source	ICD10 diagnosis code
Gestational age <32 weeks	Birth and hospital data	
Birthweight <1500 grams	Birth and hospital data	
Neonatal death (defined as any death within 28 days of birth or before a discharge home from hospital)	Birth, hospital and ABS mortality data	
Respiratory distress syndrome	Hospital data	P22.0
Seizure	Hospital data	P90, R56
Intraventricular haemorrhage (grades 2, 3 and 4)	Hospital data	P52.1, P52.2
Birth trauma (intracranial haemorrhage paralysis due to brachial plexus, skull or longer bone fracture)	Hospital data	P10.0 to P10.3, P13.0, P13.2, P13.3, P14.0, P14.1
Hypoxic ischemic encephalopathy	Hospital data	P91.5, P91.81, P91.6
Necrotising enterocolitis	Hospital data	P77
Broncho-pulmonary dysplasia	Hospital data	P27.1
Sepsis/septicaemia (streptococcus, staphylococcus, E. coli, unspecified Gram-negative)	Hospital data	P36, A40, A41.5, A41.9, B95.1, B96.2
Pneumonia	Hospital data	P23, J12 to J18
Other respiratory: primary atelectasis, respiratory failure, birth asphyxia	Hospital data	P28.0, P28.5, P21.0

Procedure	Data source	ACHI ICD10 procedure codes
Resuscitation	Hospital data and birth data	92052, 92053, 92042-00, 90225
Ventilatory support (including continuous positive airways pressure)	Hospital data and birth data	13882, 13857-00, 13879-00, 22007, 90179, 92038, 92039
Central venous or arterial catheter	Hospital data	38206, 13303-00, 34524-00, 34530-01, 13300-00 to 02, 13319-00, 13815
Transfusion of blood or blood products	Hospital data	13706-01 to 04, 92206-00, 13306-00
Pneumothorax requiring an intercostal catheter	Hospital data	38409-00
Any body cavity surgical procedure	Hospital data	30373, 30375, 30378-00, 30562, 30564 to 30566, 30571, 30601, 30615-00, 30617-00, 32123-00, 36516, 36537, 36564, 36579, 38403-00, 38600-00, all codes start with 387, 39015, 39640-00, 40003, 40100-00, 40103-00, 41883, 43801-00, 43807-00,

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Any intravenous fluids	Hospital data	96199

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