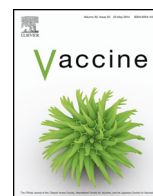




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## Neonatal death: Case definition & guidelines for data collection, analysis, and presentation of immunization safety data

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### ABSTRACT

More than 40% of all deaths in children under 5 years of age occur during the neonatal period: the first month of life. Immunization of pregnant women has proven beneficial to both mother and infant by decreasing morbidity and mortality. With an increasing number of immunization trials being conducted in pregnant women, as well as roll-out of recommended vaccines to pregnant women, there is a need to clarify details of a neonatal death. This manuscript defines levels of certainty of a neonatal death, related to the viability of the neonate, who confirmed the death, and the timing of the death during the neonatal period and in relation to immunization of the mother.

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### 1. Preamble

#### 1.1. Need for developing case definitions and guidelines for data collection, analysis, and presentation for neonatal death as an adverse event following immunization

Classification of a child's life into well-defined periods has become an important standardization to determine the care and interventions necessary to increase the chances of child survival. The neonatal period, which is globally accepted as beginning at birth and ending at 28 completed days of life [1], is recognized as the most vulnerable time in an infant's life. Neonatal death has been defined by the World Health Organization (WHO) as "deaths among

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live births during the first 28 completed days of life” [1] which can be further sub-divided into early neonatal deaths (deaths between 0 and 7 completed days of birth) and late neonatal deaths (deaths after 7 days to 28 completed days of birth) [2].

Although global neonatal mortality rates have declined, from 31.9 (95% confidence interval [CI] 31.9–32.8) deaths per 1000 live births in 1990 to 18.4 (95% CI 17.6–19.2) deaths per 1000 live births in 2013 [3], this rate of decline (40%) lags the progress made in decreasing mortality in children aged 1–59 months (56%) [2]. The contribution of neonatal deaths (2.8 million in 2013) to the under-5 deaths has increased from 37.4% in 1990 to 41.6% in 2013 [2,3]. This trend has been projected to continue with anticipated further rapid declines in under-5 mortality. The first week of life is the most critical for a neonate with 36% of neonatal deaths occurring (1 million) in the first 24 h of life, 37% (1 million) occurring between days 1 and 7 of life and 27% (0.8 million) occurring between day 7 and day 27 of life in 2013 [2,4].

The leading causes of neonatal death in 2013 globally were (i) preterm birth complications (742,400), (ii) intrapartum related complications (neonatal encephalopathy from birth asphyxia/trauma, 643,800), and (iii) neonatal sepsis (346,400) and other neonatal infections [3] including pneumonia, tetanus and diarrhoea [2]. These global estimates mask the variations between countries and regions. For instance, only 7% of neonatal deaths in high-income countries are caused by infectious diseases, compared with 27% in Sub-Saharan Africa and 23% in Southern Asia [2] (Figs. 1 and 2).

Immunization of pregnant women has been proven to be beneficial to the mother as well as the infant by decreasing morbidity and

mortality during this vulnerable period [5,6]. With the huge success of maternal tetanus vaccination for the prevention of neonatal tetanus [7], there has been significant resource allocation to vaccine research and development for pregnant women. Currently immunization of pregnant women with tetanus and influenza vaccines is widely recommended, with several countries also recommending pertussis vaccination [8,9]. Other vaccines specifically targeting use during pregnancy are in various stages of development and include vaccines against Group B Streptococcus (GBS), Respiratory Syncytial Virus (RSV) and Cytomegalovirus (CMV).

The association between receipt of a vaccine during pregnancy and the subsequent death of the neonate requires documentation and investigation to assess if there are potential vaccine safety concerns which could have been associated with neonatal death. Adverse pregnancy outcomes, including neonatal death, can coincide temporally with immunization of pregnant women, and are therefore reported as adverse events in clinical trials. Clinical trials involving immunization of pregnant women have not, to date, shown any increase in incidence of neonatal deaths in infants of vaccine recipients compared to placebo recipients, or any increase above local incidence rate [10–12].

Despite a WHO definition of neonatal death being well accepted globally, an established, detailed definition for use in maternal immunization trials and surveillance following widespread implementation of maternal vaccinations does not currently exist. This is a missed opportunity, as data comparability across trials or surveillance systems would facilitate data interpretation and promote the scientific understanding of the event. The focus of vaccine safety monitoring in currently licensed vaccines has been on foetal death,

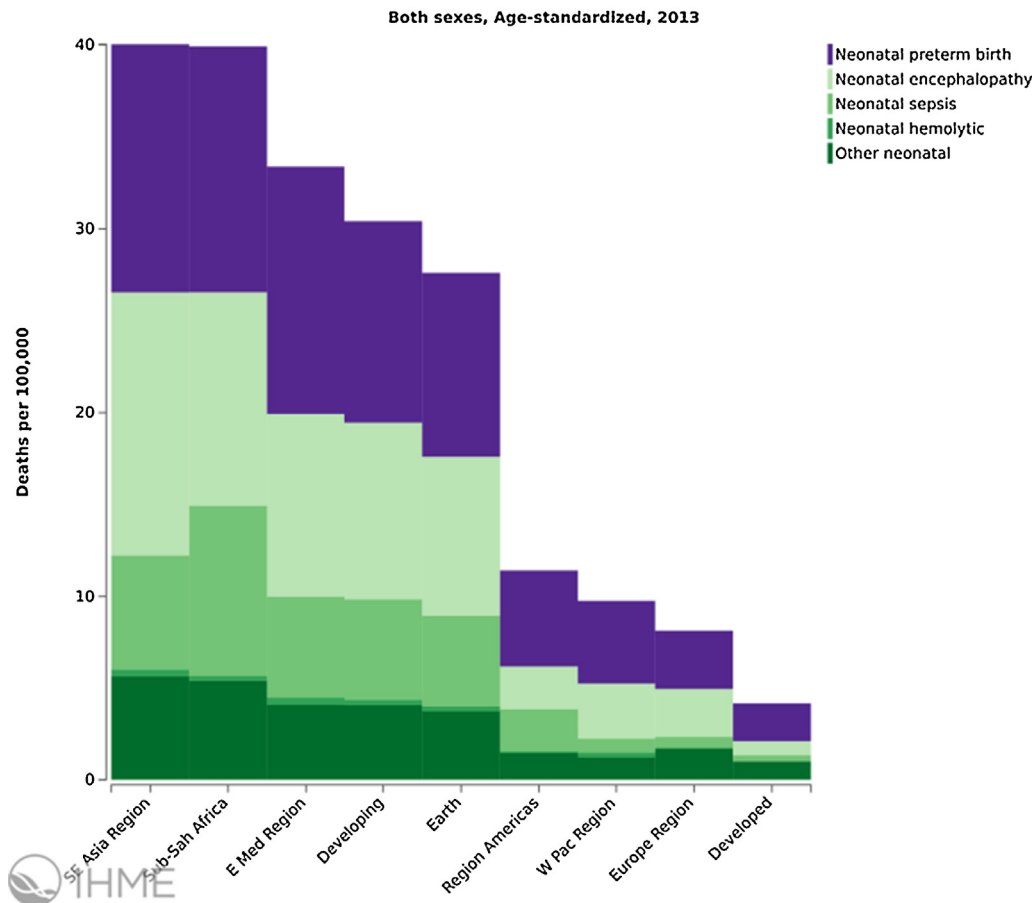


Fig. 1. Neonatal mortality rate in 100,000, age-standardized, both sexes, World Health Organization regions, 2013/Institute for Health Metrics and Evaluation (IHME). GBD Compare. Seattle, WA: IHME, University of Washington, 2015. Available from <http://ihmeuw.org/3qjx> (accessed 21.12.15).

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