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The crucial role of definition in perinatal epidemiology

Studies and interpretation of perinatal statistics have traditionally been the concern of politicians, demographers, epidemiologists, pathologist, obstetricians, pediatricians and neonatologists (this list is not in order of importance). As the question asked by each of these disciplines varies, it is understandably difficult to reach a consensus in establishing criteria for optimal birth registration. I am very glad, I have not been asked to discuss this complex problem today, so I will limit my analysis to a few of the outstanding questions: the definition of the term “liveborn” in contrast to that of “stillborn”, and I will illustrate the effect of imprecise and/or that of the change of definitions over the years on perinatal mortality rate. I am not an expert in perinatal statistics. I am only a consumer of the data produced by epidemiologists. But as a consumer I have a legitimate right to judge the quality of the goods. My interest in the definition of live birth and stillbirth started last year when I noticed, by chance, that the definition published in our national statistics data book (*Mouvement de la population suisse; Bevölkerungsbewegung in der Schweiz*) has changed. Until 1988 the definition of live birth was restricted to a newborn of more than 30 cm in

crown to heel length. Later the definition no longer specifies a limit of viability.

– Does this change mean that every product of delivery showing signs of life, irrespective of birth weight and gestational age, must be registered, for example, a fetus of 200 g with movements of voluntary muscle at birth? Does this mean that our perinatal statistics have included this new group of “babies” since 1988? If this is true, are these “so called” babies now uniformly registered in Switzerland? What is the effect of including this new population on our perinatal mortality rates?

Very disturbing questions! Particularly because this change was carried out without discussion and a consensus with obstetricians and neonatologists who are responsible for each registration.

We are all aware that perinatal mortality rates are very crude and questionable monitors of the quality of perinatal care, particularly when they are used as indicators to evaluate the progress achieved over time within a specific country or for international comparison. Nevertheless, perinatal mortality rate dominates the debates about obstetrical practice (for example, home versus hospital deliveries)

and about the organization of perinatal care (regionalization versus decentralisation of high risk deliveries).

Knowledge of the yearly trend of perinatal mortality rate in a given country remains an important item of information, particularly when striking changes occur. This is illustrated on figure 1. Without precise neonatal mortality data, in this case, death rates on the day-of-birth in the USA and Wales increase in mortality associated with reduced use of oxygen in the fifties would never have been noticed¹.

The change in definition of “live birth” and “stillbirth” over the years is not only a Swiss phenomenon. The history of the poor application of WHO recommendations by national authorities illustrates the difficulties in trying to establish comparable international statistics². Even in 1853, at the first international statistical conference held in Brussels, attempts were made to formulate recommendations that would allow international comparisons. In 1925, the League of Nations recommended the registration of “live birth”, “stillbirth” and “death” using the following definition: “Live birth” is defined by the presence of breathing at birth irrespective of gestational age and duration of life. “Stillbirth” is

defined by the absence of breathing independent of other vital signs; whether they are present or not. "Death" is the permanent disappearance of any signs of life, following a live birth. This last definition was easily accepted (death is the clearest diagnosis in medicine, although we cannot be absolutely sure when the duration of the absence of signs of life is not defined). The definition of "live birth" was more controversial and it remains so today. In fact, in the fifties the majority of the countries in Europe did not use the WHO criteria, but used instead as the criterion for live birth, "the presence of any signs of life". In 1950 WHO adopted the definition used by the majority and live birth was defined as the presence of any signs of life such as breathing, beating of the heart, pulsation of the umbilical cord, movements of voluntary muscles; all independent of other viability criteria such as birthweight or gestational age³. This definition was quoted again by WHO in 1975⁴; in 1993, and remains valid today. For defining stillbirth, the absence of any signs of life appears to be insufficient; it was made complete by adding a viability criteria, defined as "the capacity of the fetus to survive independently of its mother. "The last definition was completed by a comment that restricted viability to a minimum duration of gestation of 28 weeks. The committee was aware of the difficulty in trying to assess the exact duration of gestation around 28 weeks; but it did not choose birth weight because of its dependence on too many factors. But here again, independent of the WHO recommendations, the birth weight limit was chosen by most of the countries as viability criterion because it is easier to measure. Once again, WHO was forced to follow the majority and defined birth weight limits in 1975 for registration of a "stillbirth".

The last WHO recommendations of 1993⁵ are the following:

"*Live birth* is the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles, whether or not the umbilical cord has been cut or the placenta is attached; each product of such a birth is considered liveborn".

"*Fetal death* is death prior to the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such a separation the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles".

The definitions of "live birth" and "stillbirth" do not contain any dimensional limitation of viability such as weight and gestational age. This does not mean that every product of conception should be registered. The recommendations for reporting are clear. For national perinatal statistics the limits for registration of "live birth" and "stillbirth" are 500 g or 22 completed weeks or crown-heel length of 25 cm. For international comparisons standardized perinatal mortality statistics should only include babies of more than 1000 g, 28 weeks gestation and a minimum of 35 cm length. Evidently this last definition fails to include a group of infants with increasing chances of survival, but it is the only way to allow an international comparison of like with like. The grey zone of viability will always be difficult to define and the applicability of any definition will be influenced very much by personal opinions, reli-

gious attitudes, legal and national traditions.

As an example of the differences in doctors opinions in countries, where criteria of registration are clearly defined, let me summarize a study conducted in Holland and the Flemish part of Belgium⁶. A questionnaire was sent to all members of the Dutch and Flemish Society of Obstetrics and Gynecology, a total of 1004 doctors. They were asked which of the following deaths should be registered, "1. a normally formed girl weighing 590 g born at 23 weeks, of gestation who died some minutes after birth; 2. an anencephalic infant weighing 600 g, born at 24 weeks, who died a few minutes after birth; and 3. an anencephalic infant weighing 600 g, stillborn at 24 weeks. Inserted among questions on the management of each of these cases was one on whether the obstetrician would provide a death certificate. In both countries, two of these cases (the normally formed and the anencephalic liveborn babies) require such certificates". In both countries the official recommendations indicate that the first two babies must be reported but not the last one⁶.

Of the respondents 69% admitted that they would report none of these cases and 13% would report all of them. Overreporting occurred twice as often and underreporting ten times as often as correct reporting. Only 6% applied the national regulation. Thus in two apparently well organized European Countries, more than 90% of the obstetricians do not comply with their country's regulation. Moreover, although the statutory regulations with regards to these cases were similar in the two countries, there were important differences in opinion between Belgian and Dutch doctors. This demonstrates that perinatal mortality statistics do not measure the same thing in each of these countries since this difference of opinion is only important for the

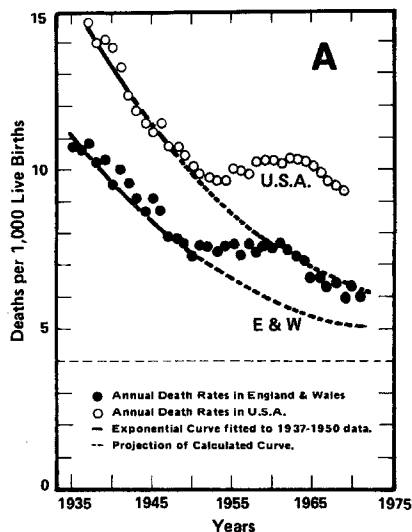


Figure 1. Day-of-birth death rate in the USA, England and Wales, 1935 to 1970. The death rate line depart from the projected exponential curve (dashed line) in the 1950's (Ref. 1).

babies at limit of viability. It can be argued that cases with such low birth weight represent only a small minority in the perinatal mortality statistics of any country. However, in the 1970 British birth survey⁷ babies of less than 1000 g already accounted for 15% of the first-week deaths in singletons and for 50% of deaths in twins. In the Swiss data, combining 1982 and 1985⁸, 25% of the neonatal deaths were accounted for by babies below 1000 g.

We have seen that WHO has tried to formulate applicable definitions of "live birth" and "stillbirth", definitions that have not been changed since 1975. What do we know about the actual application of these recommendations? Two interesting reviews have approached this question. The first of Miranda Mugford⁹ and the second of Catherine Gourbin and Godelieve Masuy-Strooband². This second study contains very informative tables of comparison between different countries and they still

show important discrepancies. In general, comparing 1983 with 1991 there appears to be a tendency toward the adoption of the WHO definition. For example from 27 European countries, 20 have adopted the WHO definition, and 7 have not; these are Austria, France, Germany (East and West), Iceland, Switzerland, and in the past, USSR. Particularly interesting in the Leuven report² was the impact of changing criteria over the years on perinatal mortality rate, a situation we are facing today in Switzerland.

In Finland (Fig. 2) changes in definitions in stillbirth explain some of the trend in this curve. From 1938 to 1954 all stillbirths had to be declared. From 1955 to 1963 only stillbirths of at least 25 cm had to be declared, notice the parallel decrease in the stillbirth rates. From 1964 to 1986 stillbirth was declared if gestation had lasted for a minimum of 185 days, this corresponds to 26 weeks and 3 days. The stillbirth rates seem to be stabilized by this new definition. Since 1987, the WHO recommendations have been adopted. All births with a minimum gestational age of 22 weeks or a birth weight of at least 500 g are eligible for registration and you see a little hump. The new political situation in the Baltic Republics has allowed the adoption of the WHO recommendations (Fig. 3). Consequently you see here the increase in the trend of infant mortality and early neonatal mortality.

What is the effect for our country of the changing definition of "live birth" as indicated since 1988 in our annual report? If it is true that since 1988 products of delivery showing signs of life, independent of gestational age and birth weight, are annually registered, we can expect a negative effect on our reported rate of survival. Is this change in definition responsible, at least in part for the flatness of our

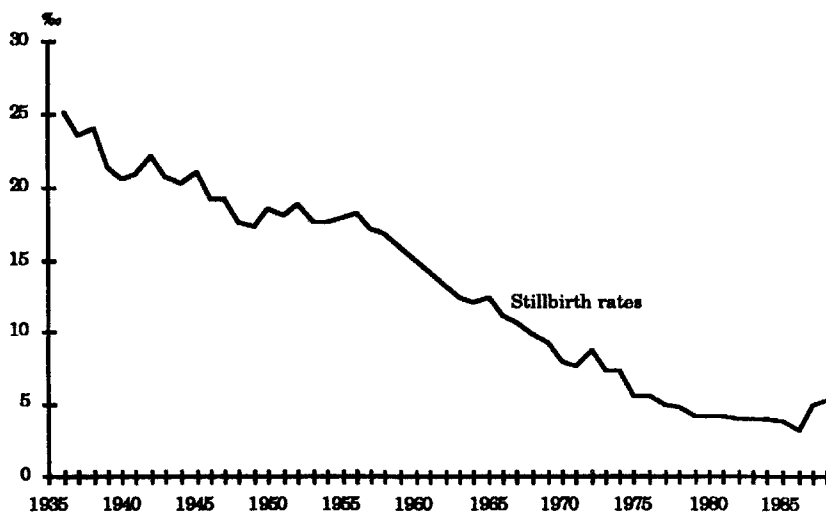


Figure 2. Stillbirth rates in Finland 1935–1990. Effect of periodical changes in legal criteria for registration, each of them having an impact on the published figures. 1938–1954: no explicit lower threshold. 1955–1963: declaration only if body length of at least 25 cm. 1964–1986: declaration only if gestation duration of at least 185 days. From 1987 onward: WHO recommendations (Ref. 2).
Source: Vital Registration

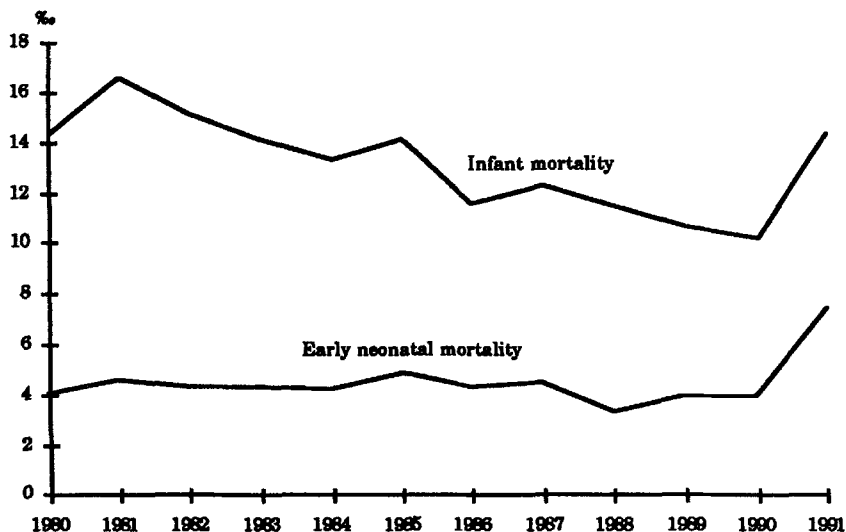


Figure 3. Early neonatal mortality and infant mortality in the Baltic Republics 1980-1991. Effect of adoption of WHO recommendations since 1991 (Ref. 2). Source: Vital Registration

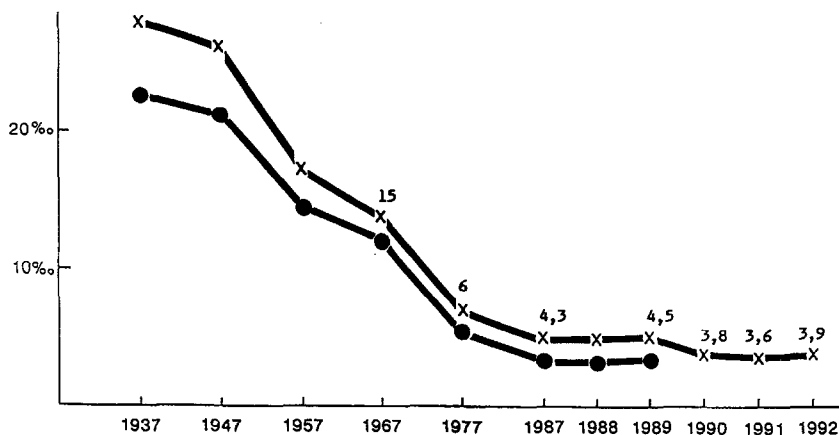


Figure 4. Neonatal (x) and early neonatal mortality (●) in Switzerland, 1937-1992 (Ref. 8).

neonatal mortality curve since 1987 (Fig. 4)? I am sure that our Federal Office for Statistics can answer this question, as birth weight is mandatory in our registration. This would be an interesting bit of information, but I don't think it is the most important part of the question. As long as we have not clearly defined what we want to register and clear-

ly inform doctors, midwives and nurses, as well as civil officers, telling them which baby must be registered, we will not generate acceptable national perinatal mortality statistics that will allow obstetricians and neonatologists to analyse trends. On the other hand, as long as we don't accept the WHO mortality recommendations, we will not produce data for inter-

national comparison. It is time for this conference to ask our Federal Office for Statistics to create a working group including epidemiologists, obstetricians and neonatologists to solve this "impasse".

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