Executive summary

Health Council of the Netherlands. Committee on adverse reactions to vaccinations in the national immunization programme. Adverse reactions to vaccinations in the national immunization programme 1997-2001. The Hague: Health Council of the Netherlands, 2002; publication no. 2002/16.

The RIVM* Laboratory for Clinical Vaccine Research registers and evaluates reports of (suspected) adverse events following immunisations administered under the National Vaccination Programme (RVP). Since 1983 the Health Council's Committee on adverse reactions following immunisations under the National Vaccination Programme (henceforth referred to as "the Committee") has been reviewing this particular RIVM task by reassessing the adverse events reports. The purpose of this reassessment is to form as accurate an opinion as possible about reports of adverse events under the RVP.

As of 1996, the Committee has been reviewing only a selection of reports on serious adverse events. The selection of these reports is undertaken by RIVM in accordance with criteria formulated by the Committee. The Committee keeps track of the total number of reports submitted to the Institute by evaluating the Institute's annual report and by paying a working visit to RIVM at least once a year.

The current advisory report covers the period from 1997 to 2001. The Committee discusses the 142 selected reports which it has reassessed. For each report, it gives its opinion on the likelihood of there being a causal relation between morbidity or mortality and the preceding vaccination (the so-called causality assessment). The Committee judges such a causal relation to be either highly probable, probable, possible, unlikely or absent. If there is insufficient data, the Committee declares that it is unable to make a causality assessment (non-classifiable).

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Of the reports, 115 were related to morbidity. In 64 of these 115 reports, the Committee judges the inferred causal relation with the preceding vaccination to be unlikely or absent. The Committee regards such a relationship as possible in 40 reports, probable in ten reports and highly probable in one.

Twenty seven reports related to fatalities. In one case – a patient with a severe underlying disorder – the Committee considers it possible that it was not the vaccination itself but its possible sequelae (e.g. fever) that contributed to the patient's death. In six of the fatalities, the Committee finds a causal relation between vaccination and death unlikely and in ten cases it believes such a relation to be absent. The Committee is unable to fully evaluate the remaining ten fatalities, in most cases owing to a lack of data. It notes in this regard that the data which it was, in fact, able to examine do not suggest that death was causally related to preceding vaccination(s).

According to the Committee, it is therefore conceivable that a relationship exists between vaccinations performed under the RVP and the occurrence of (severe) morbidity in a total of 52 of the 142 reports selected, which were assembled over a period of five years. One child ultimately died of the underlying disease, and in four children serious residual neurological effects were noted. In the remaining reports, the Committee has found no evidence to suggest serious residual effects.

The Committee regrets these tragic events, which in some cases had extremely far-reaching and traumatic consequences for the individuals involved. However, it also emphasises that the number of cases in which there is at least a possible causal relation between vaccination and morbidity is relatively low and certainly does not outweigh the benefits of the RVP initiative – i.e. the large-scale prevention of serious disease and complications. Over the past five years, more than ten million vaccinations have protected an estimated two million children against serious childhood diseases.

In nine of the 27 fatalities reassessed by the Committee, the data required in order to establish the possibility of a causal relation between vaccination and death were unavailable. The Committee stresses the importance of a comprehensive post-mortem investigation, including autopsy, in the event of unexpected child deaths. The Committee finds it unsatisfactory that such a large number of fatalities have proved impossible to evaluate, not least because it believes that this may undermine confidence in the RVP.

Also nine fatalities concern children with serious congenital abnormalities or children whom the Committee suspects of having such abnormalities. The only fatality suspected by the Committee of having an (indirect) causal relation with vaccination belongs to this group. Also featured in the reports of morbidity are children with underlying health problems (e.g. the reports of apnoea in preterm infants). The Committee strongly advocates that these children should receive vaccination, though

this should not be performed without first weighing the risks very carefully and ensuring proper monitoring.

The Committee has evaluated the RIVM annual reports covering the period from 1995 to 1999 and applauds the thoroughness of the reporting and the clarity with which the results are presented. During its working visits, the Committee has observed the extremely meticulous manner in which the RIVM staff register and process the adverse events reports. This too is applauded by the Committee, not least because low staffing levels and a substantial turnover of personnel over the past few years have meant that much of the work has fallen on the shoulders of just a handful of individuals. The Committee reaches the conclusion that it has received all of the relevant reports, as agreed with RIVM.

The 1995 annual report marked the first time RIVM has reported ‘discoloured legs' as a separate category of adverse reactions. The Committee finds it extremely important that RIVM carries out the investigation of cause and risk factors that is outlined in its reports for this particular adverse reaction and that it should submit the results of that investigation to an international scientific journal for publication.

Based on the RIVM annual reports and on its own findings, the Committee concludes that no major shifts have occurred in recent years in the nature and the severity of the adverse events to vaccinations carried out under the RVP. It therefore also sees no reason to propose any changes to the RVP in the light of the reported adverse events.

The Committee does find, however, that the processing of the AR reports is taking longer than it should. In addition, it feels that too long a time elapses between the end of a given reporting year and the publication of the annual report. Without the RIVM annual report the Committee is unable to verify whether it has, in fact, received all of the requisite adverse events reports.

Thus, although the Committee declares its confidence in the data submitted, it nevertheless finds the present situation at RIVM undesirable, in view of the personnel problems and the lack of a properly equipped, automated data-processing system. The Committee judges the registration of the adverse events reports as very vulnerable.