BCG Vaccination: Policies and Pitfalls

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One of the articles published in this edition of the Portuguese Journal of Pediatrics highlights the relevance of monitoring the implementation of public health policies.[1]

Countries with declining rates of tuberculosis are encouraged by the World Health Organization (WHO) to periodically evaluate this disease epidemiology and consider whether a switch from universal vaccination to selective risk group vaccination would be appropriate.[2]

The decision to stop universal newborn vaccination was made in 2016 and it was based on the WHO recommendations,[2] and a theoretical model adapted to countries with low to intermediate tuberculosis prevalence.[3] In fact we already had:

- A well-established surveillance system that gives confidence on the results and future monitoring;
- Continuous and sustained reduction on tuberculosis incidence and particularly on smear positive pulmonary tuberculosis cases which are the responsible for transmission;
- More than 50% of the cases occurring in well-defined risk groups.

Also, the number of disseminated mycobacterial infections due to bacillus Calmette-Guérin (BCG) strains was not inferior to that caused by *Mycobacterium tuberculosis* in children less than 5 years-old in the previous five years (data not shown of a national inquiry to pediatric hospitals).

Bacillus Calmette-Guérin is a live vaccine which may lead to relatively frequent non severe side effects, such as lymphadenopathy, and very rarely to disseminated disease in severely immunosuppressed children. However, their significance rises when the impact of tuberculosis decreases in the same population. Also the newborn vaccination, that aims to confer an early protection against disease, does not allow the diagnosis of a possible immunodeficiency that would prevent vaccination.

What happened after 2016? The national tuberculosis report published on 2020 showed a 3.9% reduction in the annual incidence of the disease in the last five years (2015-2019).[4] In 2019 we had the lowest incidence rate ever registered, 18 cases per 100 000 habitants, and only 53.8% of pulmonary tuberculosis cases were smear positive.[4]

Since we have achieved a low tuberculosis incidence in our population there are few cases in children below 6 years-old which implies that any small variation may impact in the analysis of that particular year. Tuberculosis incidence in infants seems to be rising in the last three years but looking backwards it is still lower than that observed in 2012 and 2014, whereas BCG was offered to all newborns.[4]

Data relative to tuberculosis cases in children below 6 years-old in 2018, presented by the coordinator of the national program on tuberculosis (personal communication) showed that out of 20 administrative districts, including Madeira and Azores, 12 had no cases, and only two had more than three cases per year.

However, if we look at tuberculosis meningitis, a major form of disease that BCG is expected to protect against, we had more cases than the previous years. In 2018 we had three cases, none of them were vaccinated, and in 2019 two out of four cases had been vaccinated.[4]

The impact of BCG vaccination on transmission of *Mycobacterium tuberculosis* is limited. The more relevant tools in reducing tuberculosis prevalence in children are the prompt diagnosis and treatment of infected people and the screening and preventive treatment of their contacts. Most of all, this must not fail. That is why the national authorities are worried with the longer time for diagnosis of tuberculosis that has been registered in the last years and are the origin of severe cases in children.[4]

Bacillus Calmette-Guérin vaccination is a complementary strategy, and the selective approach that has started in 2016 may not be validated if it is not fully implemented. The published study,[1] although with a small sample that may not reflect the nation profile, is worrisome as it reveals that 45.7% of eligible children were missed. And it rises the relevant questions in order to improve the implementation of the risk group vaccination strategy: the prompt identification of eligible children, the

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possibility of BCG newborn vaccination at the maternity hospital, vaccination within a week of selection, re-assessment of eligibility for vaccination and adequate information of health care workers.

The national health authority had already identified all these problems and made a reinforcement for a more effective application of the BCG vaccination policy.[5] But these data clearly show that it was not enough.

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