Health technology assessment

of a selective BCG vaccination programme

For public consultation

Consultation Feedback Form

September 2015

Your feedback is very important to us. We welcome responses to all questions as well as any additional comments you would like to make.

When commenting on a specific section of a document, it would help if you can identify which element you are commenting on and the relevant page number.

The closing date for consultation is 5pm on Wednesday 21 October 2015

You may email or post a completed form to us.

About you

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Date	21st October 2015

General Information and Questions

You may provide us with feedback on the specific questions (see questions that follow), or alternatively you may provide us with general comments.

Part 1

Are you replying in a personal capacity or on behalf of an institution or organisation?

☐ Personal capacity

☐ On behalf of an institution

☐ On behalf of an organisation Pavee Point Traveller and Roma Centre

Part 2

Please outline any general or specific feedback on the documents. In your response, where applicable, please specify the section to which you are referring.

Please comment

1. Section 7.6 does not clarify that in the absence of mainstream ethnic identifier, how the high-risk groups are going to be identified, especially, the Travellers. If that mechanism is absent, the high-risk groups may fall through the net and this could lead to a partial failure of the programme. Reliable and consistent use of ethnic identifiers across the health service is essential to avoid mistaken classification of infants as low or high TB risk. Ethnic identification is also vital to ensure accurate recording of BCG vaccine uptake rates in addition to TB incidence and prevalence in Irish Travellers. Measures of data completeness specifically with regard to Irish Travellers will be need to be contained within the surveillance information collected.

2. The consultation document acknowledges the role of improved **socioeconomic conditions (through better housing and reduced overcrowding) and nutrition** in the reduction of TB. According to section 2.1, "in Ireland, improvements in socioeconomic conditions (through better housing and reduced overcrowding) and nutrition as well as introduction of effective treatment in the 1940s led to a rapid decrease in the incidence and mortality rate from TB" (p.5). However, the document does not explain how this selective BCG vaccination **alone** will bring down the number of new cases of TB without concomitant improvements in the social determinants of health in the high risk group.

3. High risk groups are already being vaccinated through the Universal BCG Vaccination Programme. Therefore, it is not what clear in any of the sections what additional health outcomes will be achieved for the high risk group following a switch to Selective BCG vaccination.

4. There could be some reluctance from the high risk groups to participate in the selective programme as they may believe that the government is trying to blame them for TB in the

country. Consequently, some people may not participate, fearing stigmatisation as outlined in section 7.8. Exactly how this fear will be overcome will need to be addressed.

5. As section 7.8 notes, if vaccinated, high-risk groups may be subjected to possible side effects and scarring where those in the general population are not. This will need to be highlighted to the high risk group. Furthermore, visible scarring could potentially become an idenitifiable and associated mark with high-risk groups and may further stigmatise individuals belongining to those groups.

6. Following the switch from Universal to Selective BCG vaccination in Sweden, a drop in vaccine coverage to a level that was considered "too low to cover the risk group" was reported[1] (Romanus, 2006). It is not clear from the consultation document how a potential drop in vaccine coverage in the high risk group with the introduction of selective vaccination in Ireland would be measured or rectified. Sections 6.1.3-6.1.5 outline practices in other jurisdictions in addition to respective advantages and disadvantages (p.105-108). However, the consultation document is tentative in terms of setting out which preferred strategies will be employed in the selective BCG vaccination of Irish Travellers. More detailed information should be provided such that it is apparent that the selective BCG vaccination programme will, in all probability, lead to enhanced delivery of the BCG vaccine to Irish Traveller children.

7. Section 7.4 states that "it is likely that there will be an increase in TB cases as a result of changing from universal to selective vaccination in Ireland" (p.120). This will need to be communicated very clearly to the general population.

8. Section 7.7 states, "**in the event that a child whose parents have refused vaccination later becomes infectious with TB, protection and detention measures may be necessary in order to prevent spread of the disease"** (p.123). Detention measures are legislated for to manage situations where a "person is a probable source of infection with an infectious disease and that his isolation is necessary as a safeguard against the spread of infection" rather than vaccine refusals. The main grounds for detention, or the threat of detention, in Ireland are **"non-compliance with anti-infective therapy"**[2] (Duffy, 2009). Detention measures, albeit rare, would be applicable to individuals from both low TB risk and high TB risk groups but it is not clear from the consultation document whether the detention provision would also be made known to individuals who, due to belonging to a low TB risk category, are not receiving the BCG vaccine. Hence, it appears inappropriate to make the connection between vaccine refusal and possible detention in relation to parental consent. This connection should not form part of the proposed selective BCG vaccination programme.

[1] http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=606
[2] http://www.ncbi.nlm.nih.gov/pubmed/19091360

Thank you for taking the time to give us your views.

After the closing date, we will assess all feedback and use it to finalise our documents. The final documents and the Statement of Outcomes (a summary of the responses) will be published on http://www.hiqa.ie.

If you wish to do so, you can request that your name and/or organisation be kept confidential and excluded from the published summary of responses. Please note that we may use your details to contact you about your responses. We do not intend to send responses to each individual respondent.

Please return your form to us either by email or post:

consultation@hiqa.ie

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Please return your form to us either by email or post before 5pm on Wednesday 21 October 2015

Please note that the Authority is subject to the Freedom of Information Acts and the statutory Code of Practice regarding FOI.

For that reason, it would be helpful if you could explain to us if you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.