



BY EMAIL ONLY

4th July 2023

Deputy John Brady
Dáil Éireann
Leinster House
Kildare Street
Dublin 2

PQ 29404/23 Deputy John Brady - To ask the Minister for Health when parents in Ireland can expect to have their babies screened for severe combined immunodeficiency disease as part of the heelprick test, given his announcement that it is to be included in January of this year; the other diseases that use the same T-cell receptor excision circle screening and may be added to the newborn screening programme easily as a result; the resources that the HSE has requested from his Department in order to implement this new screening methodology; and if he will make a statement on the matter

Dear Deputy Brady

This PQ has a number of components and the response has been compiled accordingly.

a) when parents in Ireland can expect to have their babies screened for severe combined immunodeficiency disease as part of the heelprick test, given his announcement that it is to be included in January of this year

The addition of any new condition to the National Newborn Bloodspot Screening Programme (NNBSP) requires a substantial amount of programme planning and technical laboratory validation and verification before screening can commence. A large number of considerations are required including, but not limited to:

- the operational and clinical complexities around the screening method for SCID (TREC) - this is not currently a methodology employed within the NNBSP
- the programme expansion capacity (additional medical scientists and other support staff) and the physical ability to facilitate this expansion in the context of significant space compromise at the current site at CHI Temple Street

- the complex preparations required for the move of the Newborn Screening Laboratory to the new National Children's Hospital site at St James, with maintained service delivery. This process is due to commence during 2024

Screening for SCID will not commence until after the relocation to the new National Children's Hospital has been completed.

b) the other diseases that use the same T-cell receptor excision circle screening and may be added to the newborn screening programme easily as a result;

As noted in part A of this response, the addition of any new condition to the NNBSPP is an extremely complex and time consuming process. Every condition proposed for addition to the NNBSPP must go through the National Screening Advisory Committee (NSAC) assessment process which includes a detailed Health Technology Assessment (HTA) carried out by HIQA and they provide a recommendation to the Minister.

Implementation must be carried out carefully to ensure that the screening methodology used by the Laboratory is verified and validated to the highest international standards. It must also be undertaken in line with clinical integration and capacity to provide wrap around supports for families who are determined ultimately to have a case or a 'false positive'. Previous experience of adding MCADD, GA1 and most recently ADA-SCID to the NNBSPP is that the implementation timeline can be between 18 and 24 months if all goes to plan (Covid and the cyber attack severely impacted on the commencement of ADA-SCID screening).

With regard to other conditions that use the same T-cell receptor excision circle screening, the NSAC and HIQA HTA processes are where screening recommendations are made. Once a recommendation is made, the laboratory verification and validation aspects specific to that condition, still need to be carried out. Alignment and integration with clinical services and their need to support screening services must also be undertaken, before screening can commence.

c) the resources that the HSE has requested from his Department in order to implement this new screening methodology

Advice from the Department of Health to the HSE regarding the resources required for the implementation of SCID screening was to submit the funding request through the annual HSE National Service Plan estimates process for 2024 which subsequently goes into the Department of Health for consideration. The HSE will make a submission for the requisite funding for the equipment and

staffing. The resources will then hopefully be realised in 2024 to enable the HSE to commence the implementation plan to commence screening for SCID.

Your sincerely

John Cuddihy.

Dr John Cuddihy

National Director Public health

