

Uptake of Newly Introduced Universal BCG Vaccination in Newborns

O Braima¹, A Rigney³, CA Ryan^{1,2}, C Murphy³

¹Department of Neonatology, Cork University Maternity Hospital, Wilton, Cork

²Paediatrics & Child Health, University College Cork, Cork

³Community Health Service, HSE South

Abstract

Universal neonatal BCG vaccination was discontinued in Cork in 1972. Following an outbreak of TB in 2 cr^aches in the HSE South, a universal BCG vaccination program was re-introduced in October 2008. The aim of this study was to determine the vaccination process (in-hospital and community) and the in-hospital uptake of the vaccine. Following informed parental consent, babies of birth weight > 2.5 Kg were eligible for in-hospital vaccination if they were not: febrile, jaundiced on phototherapy, on antibiotics and if not born to HIV- positive mothers. Parents of babies not vaccinated in-hospital were asked to book an appointment in either of the 2 Cork community clinics. The immunization nurse collected data on BCG vaccination, prospectively. This study examined vaccination uptakes in-hospital and community over a 6 month period (October 2008 to March 2009). There were 4018 deliveries during the study period. In-hospital consent was declined in only 16 babies (<1%) while the in-hospital vaccination uptake was 80% of total live births. Although 635 newborns were admitted to the NICU, only 46 (8%) were vaccinated while in the NICU. At least 48% of planned community vaccination has been achieved to date. In conclusion, in-hospital consent was almost universal and vaccination uptake was satisfactory. NICU exclusion criteria accounted for a significant proportion of non-vaccination in-hospital. These criteria need to be readdressed considering that all premature babies are given other routine newborn vaccines at 2 months of age, regardless of weight.

Introduction

The efficacy of BCG immunization in preventing serious extra-pulmonary tuberculous (TB) disease in infants is widely accepted. Recent data has also suggested a protective effect against pulmonary TB among young children¹. Although the efficacy of the vaccine in preventing the disease has varied in reported studies; its protection duration is said to be up to 15 years². Two meta-analyses of published clinical trials and case control studies have shown the vaccine to be 70-80% effective against the most severe forms of TB in children^{3,4}. More recent studies have shown unexpected benefits to BCG vaccination apart from decreasing the risk of TB. Systemic reviews of epidemiological studies suggest that exposure to the BCG vaccine in early life prevents asthma, possibly through a modulation of the immune maturation process⁵.

BCG is a live attenuated vaccine, which was developed by two French Scientists, Leon Calmette and Camille Guerin (between 1912 â 1924) and first used in Paris in 1921. More than 70 years ago, Dr Dorothy Price introduced the BCG vaccine to Ireland, vaccinating infants in St Ultan's Hospital, Dublin⁶. Subsequently, neonatal BCG vaccination has been in use through the country albeit, with significant regional variation^{7,8}. In the southern area, a universal neonatal BCG vaccination was offered in Cork up to 1972 when a decision was taken to discontinue the vaccine for a variety of reasons. This included a relatively low TB rate in the general population and concerns that BCG immunized children may subsequently have a positive mantoux test, confounding future diagnosis. Since then, the BCG has been given only following parental request or if there was a history of direct TB contact. However, following a recent outbreak of TB among children attending two cr^aches in the HSE south in 2007, the universal neonatal BCG program was re-introduced at Cork University Maternity Hospital (CUMH). The aim of this study was to examine vaccination uptake in-hospital and in the community over a 6 month period (October 08 - March 09) following the introduction of the BCG programme.

Methods

Information on BCG vaccination and its sequelae was given to parents in the postnatal wards prior to consenting to vaccination. An appointed team consisting of an area medical officer (AMO) and a public health nurse (PHN) administered the vaccination during week days only. Babies were eligible if they were > 2.5 Kg and were not pyrexial, jaundiced on phototherapy, on IV antibiotics and if not born to HIV positive mother. BCG was given by the intradermal route in the left arm. Written and verbal information regarding the care of injection site was also given to parents. Parents who refused BCG or had issues concerning the vaccination were offered the opportunity to discuss those concerns with either the vaccination nurse or the medical officer. Parents of babies not vaccinated in hospital were asked to make an appointment in one of the community clinics in the Southern HSE area, which was recommended within 6 weeks post discharge. Data on BCG vaccination were collected prospectively from CUMH and the 2 Cork City community clinics by the vaccination nurse. Birth statistics were collected from the CUMH HIPE office.

Results

There were 4368 deliveries over the 6 months study period. The in-hospital vaccination uptake was 80% (3204 babies) of total live births. Consent was declined in only 16 babies. Although less than 15% (635) of total live births newborns were admitted to the NICU, less than 8% (46) of them were vaccinated while in the NICU. The remaining number of babies was either vaccinated in the postnatal ward following discharged from the NICU, not eligible for vaccination or discharged home without being vaccinated. At least, 50% of the number planned for community vaccination has been achieved. The figure below summarizes the results.

Figure 1: Summary of Neonatal BCG Uptake

Discussion

Following the introduction of the neonatal BCG programme, In-hospital consent was almost universal and vaccination uptakes were satisfactory, with 80% of live births completed in hospital. Almost half of the projected community vaccination had taken place through the 2 community clinics in Cork City. Since parents had the opportunity to attend community clinics in other local areas such as Kerry, North and West Cork or even from other HSE areas, we do not have data for these other clinics and we cannot calculate the actual community uptake of the BCG. The national BCG vaccination uptake is higher than other similar childhood vaccines. Uptake of most vaccinations ranges between 80 to 88% whilst for BCG it was 87% to 95% throughout the years. For areas which data was available, there was no significant variation between HSE regions regarding BCG vaccination uptake.

Babies of Low Birth Weight (LBW < 2.5 Kg) were excluded from vaccination as per national guidelines. This exclusion criterion has led to a significant number of babies, who were otherwise well and not being vaccinated. One of the reasons suggested is that it may be technically more difficult to give an intra-dermal injection to smaller babies. However, studies from developing countries have shown that LBW infants tolerate the BCG vaccine very well with no difference to complications compared to bigger babies. These studies have also shown good immune response to BCG with no significant impact on Tuberculin Skin Test (TST) or scar formation¹⁰⁻¹². NICU exclusion criteria accounted for 15% of non vaccination cases in-hospital. These criteria, particularly the birth weight criteria, need to be readdressed by the National Immunization Committee, considering that all premature babies are given the remaining newborn vaccines at 2 months of age regardless of weight.

Most parents, who initially objected to vaccination, subsequently agreed after being approached by the vaccination staff. For the 16 parents who declined in-hospital vaccination, the commonest reason given was that they felt the child was too young and that they planned to attend the community clinics when the child was older. We do not have data to show how many of these parents subsequently attended for vaccination in the community clinics. Nor are we aware of how many of the NICU ineligible babies were subsequently immunized. When the BCG vaccination was discontinued in Cork in 1972, the rate of TB in the population was so low that it was believed it was possible to achieve the WHO criteria for discontinuation of the BCG vaccine. However, in the recent time, the TB rate in Ireland had increased considerably, perhaps due to more immigration and the diversity of the population in addition to concerns regarding multi-resistant strains. The media coverage for the recent TB outbreak in the Southern area precipitated a considerable public health evaluation and response. With the decision to re-introduce the neonatal BCG programme into the Southern area, the BCG vaccination is now available to most newborn infants born in Ireland.

Correspondence: CA Ryan
Department of Neonatology, Cork University Maternity Hospital, Wilton,
Cork
Email: tony.ryan@hse.ie

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Comments: