The National Newborn Bloodspot Screening Programme (NNBSP) Process Review 2010

Abstract

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Abstract

The National Newborn Bloodspot Screening Programme (NNBSP) incorporates screening for several conditions where early identification helps prevent serious disability or mortality. A national group was established (2009) to plan for the introduction of screening for cystic fibrosis (CF), as part of this process a review of the existing NBS was undertaken. Information was obtained through consultation with the Director of the National Newborn Bloodspot Screening Laboratory (NNBSL), local midwives, maternity units (20), Directors Public Health Nursing (DPHN) in LHO areas (32) and Practicing Midwives (16). Data were analysed using SPSS version 17.0.

Introduction

The National Newborn Bloodspot Screening Programme (NNBSP) in Ireland commenced in 1966 with screening for phenylketonuria (PKU). The programme developed to accommodate screening for homocystinuria (HCU), classical galactosaemia, maple syrup urine disease (MSUD) and congenital hypothyroidism. These conditions may result in serious disability or death if treatment is delayed. Laboratory testing is carried out by the National Newborn Bloodspot Screening Laboratory (NNBSL) while sample taking occurs in both hospital and community settings. The birth rate in Ireland has increased steadily from 14.4 per 1000 population (53,924) in 1999 to 16.7 per 1000 population (73,724) in 2010. Newborn screening for cystic fibrosis (CF) had been recommended in several reports multidisciplinary group established by the HSE, including the Cystic Fibrosis Association of Ireland (CFAI), also recommended this as soon as services and infrastructure are in place to meet newly identified need.

Methods

A National Steering Group was set up by the HSE in 2009 to design and oversee the implementation of a Newborn Cystic Fibrosis Screening Programme which meets the appropriate governance and quality assurance standards. The review included the NNBSL which coordinated the programme nationally and the hospitals, LHO areas and domiciliary midwives who were involved in providing the newborn screening service at local level. The NNBSL data were gathered through interviews and consultation with the Director of the NNBSL. A questionnaire was designed for the previous review4 by identifying several critical points in the system. This was further developed for use in the current review. The questionnaire, together with a letter explaining the review, were issued in November 2009 to Directors of Nursing and/or Midwifery in maternity hospitals (20), Directors of Public Health Nursing (DPHN) in LHO areas (32) and Practicing Midwives (16). Data were analysed using SPSS version 17.0.

Results

Information from the NNBSL was reported by its Director. Response rate (after follow up) was 100% from maternity units (LHO areas and domiciliary midwives). The response rate in hospital and LHO areas were 100% and 56% respectively. There were several points along the screening pathway where quality assurance controls may be strengthened and these are classified mainly under governance and tracking (Figure 1).

Goverance

Responsibility for screening in the hospital was held by a variety of management, medical or midwifery personnel while responsibility clearly lay with the DPHN in the community. Quality management initiatives had been implemented by the NNBSL. However there was no overall national quality assurance and audit including the non-laboratory elements. The position in relation to availability of written protocols at local level had improved considerably since the 2004 review. A need was identified for local written protocols to cover recording of information in relation to newborn screening and recording and checking of results. While the NNBSL guidelines were quite specific in this regard, the detailed procedure was not being applied in all areas.

Tracking and documentation

At birth, not all babies are allocated a chart number and the lack of a standardised unique identification number to record on the screening card of each infant was identified. While there was generally timely notification of the request for screening to the DPHN or to Paediatrics /Special Care Baby Units, there was a lack of standardisation of procedures for checking results. Recommendations, many of which have since been implemented, included: Overall governance structure, liaison officer, quality assurance programme, ring-fenced funding, standardised unique identifier, dedicated laboratory IT system, secure web-based transmission of results and fail-safe method of tracking samples.

Discussion

The Department of Health (DoH) is responsible for policy issues in relation to the National Newborn Bloodspot Screening Programme (NNBSP). The implementation of a nationally consistent screening programme requires a national governance structure supported by national policy and quality standards. This should ensure that each element of the screening programme is reaching internationally accepted screening criteria on an on-going basis, through audit, monitoring and evaluation. The need for a defined and ring-fenced budget was identified as in other reviews recommendation need to be implemented.

The day-to-day co-ordination of the NNBSP is undertaken by the NNBSL. The Department of Health report ultimate responsibility for ensuring that all infants are offered screening rests with the HSE and maternity units hold responsibility for ensuring that all children born in hospital are offered screening. The maternity units are also responsible for ensuring that the DPHN is notified of all children discharged before screening has taken place. However, the lack of clarity on terms of overall responsibility noted in the 2004 review. The management lead is required within each of the four HSE areas with operational responsibility and accountability for newborn screening. The hospital and LHO leads should have a reporting relationship to this individual in relation to the screening programme. Domiciliary midwives hold responsibility for newborn screening for domiciliary births in accordance with HSE Clinical Governance.

Timely sample taking facilitates early diagnosis. According to current guidelines, samples should be collected between 72 hours and 120 hours from birth. Where babies are discharged from hospital more than 72 hours after birth the sample taking and recording is completed in the hospital. Where this time span is less than 72 hours, the hospital advises the DPHN that sample taking and recording needs to be completed in the community. Discharges in this category have almost doubled over the past 10 years and reached 53% of births in 2010. Not all babies are allocated a chart number so it is essential to generate a standardised unique ID for each infant. A comprehensive, single screening register...
is essential to facilitate uniform recording of sample taking in all areas, timely identification of missed babies, and programme audit. The request for screening to DPHN and paediatric or special care baby units requires standardised electronic notification. A lack of failsafe method of sample tracking within the laboratory identified in 2007 continues to present a clinical risk to the programme. A dedicated laboratory screening IT system is required to ensure specimen identification throughout the laboratory process.

The co-ordination of the clinical pathway for the positive infant is managed effectively by the Director of the NNBSL. This includes organising appropriate referral of the screened positive baby to the clinical services. However, at local level, responsibility for checking to ensure a result is returned for every infant is not standardised. While there are some excellent practices and procedures in place, this needs to be comprehensive in all hospitals and LHO areas. Secure web-based transmission of all results is required to ensure timely return of results. This coupled with timely and standardised checking of results is essential to avoid implications for a baby who is not screened or for whom the sample is mislaid. Real time issuing of results should be the target. A high quality screening programme is required to ensure that it does more good than harm. The PAC review recommended annual audit of the national newborn screening programme together with establishment of a national IT system to facilitate it.

A number of quality management measures have been implemented by the NNBSL and it is accredited by Clinical Pathology Accreditation, UK. The NNBSL regularly undertakes audit as part of the quality management system. However, audit of the non-laboratory aspects of the programme to date is a very rare occurrence, not surprisingly given the various methods of recording and storing data and the lack of IT systems to facilitate it. For routine audit of the screening programme it is important that key performance indicators are accessible in an efficient manner. The NNBSL has standard operating procedures for all laboratory testing procedures and reporting. The NNBSL also provides and regularly updates guidelines for screening for use by staff in hospitals, LHO areas and domiciliary midwives. Considerable work has been undertaken in several hospital and LHO areas in relation to developing protocols. Some of these, in conjunction with national guidelines, could be used to provide a basic national protocol with provision for amendments by individual hospital or LHO areas to accommodate specific local issues. This would provide a national standard which would facilitate future audit of the programme.

This review aimed to describe the process of newborn screening in the various settings rather than to audit practice in this area. It is subject to the usual limitations of self-reported data. However the maximum response rate achieved in hospitals and LHO areas is a major strength. The lack of a national standardised process did create difficulties, particularly in relation to the wide variety of procedures for recording data and checking results. Since the review was undertaken the findings were progressed by the National Steering Group for Cystic Fibrosis Screening. The structures for the governance and management of the NNBSP have been agreed and are specified in NNBSL (2011) standard operating procedures for programme performance assessment. Pending availability of a unique HSE identifier (expected 2013) an interim Unique Perinatal Identifier (UPI) is being issued to all babies born. This is formed by the Hospital HIPE code of the birth hospital followed by the Healthcare Record Number of the baby. Babies who are not born in Irish hospitals are issued with an identification number by the DPHN in the area in which their birth is registered. Advances have been made in relation to provision of a single screening register through modification of the existing immunisations registers and child health IT systems. A dedicated laboratory IT system is being developed. This will provide failsafe tracking, transmission of results and will have capability to interface with HSE systems. A liaison person has been appointed to the laboratory. These developments will help to enhance the quality of the NNBSP.

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