

Report 02/03



Report on Childhood Immunisation

**Dr. Marie Laffoy
Director of Public Health
January 2003**

TABLE OF CONTENTS

ABBREVIATIONS:	3
EXECUTIVE SUMMARY	4
1. INTRODUCTION	12
1.1 TERMS OF REFERENCE	13
1.2 MEMBERSHIP OF THE REGIONAL IMMUNISATION COMMITTEE.....	13
2. CHILDHOOD IMMUNISATION IN IRELAND	14
2.1 VACCINE PREVENTABLE DISEASES	15
2.2 OUTBREAKS OF MEASLES	17
2.3 RISKS OF ILLNESS VERSUS THE RISKS OF IMMUNISATION	19
2.4 COST EFFECTIVENESS OF IMMUNISATION PROGRAMMES	22
2.5 IMMUNISATION UPTAKE RATES IN THE EASTERN REGION	24
2.5.1 <i>Primary Immunisations</i>	24
2.5.2 <i>Booster Immunisations</i>	26
2.6 BARRIERS TO IMMUNISATION.....	30
2.7 SPECIFIC VACCINE ISSUES	30
3. MANAGEMENT OF IMMUNISATION PROGRAMMES	34
3.1 PLANNING AND ORGANISATION OF IMMUNISATION PROGRAMMES	34
3.2 IMMUNISATION CONTRACT BETWEEN HEALTH BOARDS AND GENERAL PRACTITIONERS	38
3.3 INFORMATION SYSTEMS FOR IMMUNISATION SURVEILLANCE	38
3.4 MATERIALS MANAGEMENT.....	41
3.5 COMMUNICATIONS	47
3.6 DISADVANTAGED GROUPS.....	48
4. CONCLUSIONS:	50
5. RECOMMENDATIONS:	52
6. COSTS	59
7. REFERENCES	63
8. APPENDICES	65
APPENDIX 1: UPTAKE RATES	65
APPENDIX 2: IMMUNISATION UPTAKE RATES IN EASTERN REGION BY DED.....	68
APPENDIX 3: MAINTAINING COLD CHAIN DURING COURIER TRANSPORT OF MENINGOCOCCAL C VACCINE TO GENERAL PRACTITIONERS AND SCHOOLS 2000 TO 2002.....	74
APPENDIX 4: PROTOCOL FOR RESEARCH STUDY	77
APPENDIX 5: POLICY DOCUMENT FOR HEPATITIS B VACCINATION IN INTELLECTUAL DISABILITY SERVICES IN THE ERHA.....	78

Abbreviations

ADR: Accord Dangereux Routier (European Agreement concerning the international carriage of dangerous goods by road)
AHB: Area Health Board
AMO: Area Medical Officer
ASD: Autism Spectrum Disorder
BCG: Bacille Calmette Guerin vaccine
CSA: Community Services Area
DTaP: Diphtheria, Tetanus and Acellular Pertussis Combination Vaccine
ECAHB: East Coast Area Health Board
EHSS: Eastern Health Shared Services
ERHA: Eastern Regional Health Authority
Hib: *Haemophilus influenzae* type b Vaccine
ICU: Intensive Care Unit
IMB: Irish Medicines Board
IMO: Irish Medical Organisation
IPV: Inactivated Polio Vaccine
JCVI: Joint Committee of Vaccination and Immunisation
Men C: Meningococcal C Vaccine
MMR: Measles, Mumps and Rubella Combination Vaccine
NAHB: Northern Area Health Board
PHN: Public Health Nurse
PPD: Purified Protein Derivative
RCPI: Royal College of Physicians of Ireland
RICHS: Regional Interactive Child Health System
SAMO: Senior Area Medical Officer
SOP: Standard Operating Procedures
SSPE: Sub-acute Sclerosing Panencephalitis
SWAHB: South Western Area Health Board
Td: Adsorbed Tetanus Toxoid plus Adult Diphtheria Toxoid
WHO: World Health Organisation

Executive Summary

In 2000, there was a measles outbreak in the Eastern Region, which led to 1,253 cases, three deaths and just over 350 hospital admissions. In 2001, there was a decline in the uptake rates at 12 and 24 months for all primary immunisations. This decrease was most marked for the Measles, Mumps and Rubella Vaccine (MMR) uptake rates at 24 months where a drop of 21% was noted. This reflected a national trend and was also influenced by negative media coverage of MMR vaccine. A Regional Immunisation Committee was convened in February 2002, which resulted in this report.

The issues considered by the Regional Committee were:

1. Planning and organisation of immunisation programmes including structures, processes, staffing and the immunisation contract between Area Health Boards and General Practitioners
2. Information systems for immunisation surveillance
3. Materials management
4. Communication strategies

The deficits identified in the four areas outlined above were as follows:

Planning and Organisation

1. A standard practice does not exist in the Region for provision of lists to general practitioners (GP) of cohorts of children requiring primary immunisation. This limits calculation of an important performance indicator within practice populations i.e. uptake rates of primary childhood immunisations and estimation of targets for bonus payments.
2. Problems exist in relation to the timeliness of receipt of immunisation returns by Area Health Boards (AHBs) from GPs and also in the timeliness of payment of GPs for primary childhood immunisations.
3. There is no regional policy for identifying and following up defaulters.
4. Use of parent-held records is not standard practice across the Region.
5. Difficulties in recruiting and retaining staff to run school immunisation programmes have impacted negatively on the uptake of booster vaccination in the 4 to 6 year age group in some Community Services Areas (CSAs).

Information Systems

1. Substantial delays in entering immunisation data onto the information system occurred up to recently, in some CSAs in the Region. This impacted on the timeliness and accuracy of the uptake data available.
2. The current information system does not have the facility to record neonatal BCG and booster immunisations i.e. 4-in-1 and MMR. These records are all paper-based, which is problematic when look back exercises, are required e.g. recent incident relating to subpotent BCG vaccine.
3. The system does not record all demographic details on clients e.g. socio-economic class and ethnic group. Hence, it is difficult to calculate uptake rates in specific groups and this impacts on targeting health promotion programmes.
4. There is no standard procedure in the Region to ensure that GPs and Public Health Nurses (PHN) receive lists of defaulters on a regular basis.
5. Lack of a unique patient identifier is problematic.
6. Difficulties exist in eliminating duplicates from the system in particular when children move between CSAs. This leads to an artificially inflated denominator, which falsely lowers the uptake rate.
7. The current information system does not easily facilitate policy changes in the immunisation programmes; hence difficulties arise in recording the uptake of new vaccine schedules.
8. Birth notifications from maternity hospitals constitute the register by which children are identified for primary immunisation. There have been delays in receiving birth notifications on occasion. There has also been failure to incorporate all relevant information from the birth notification form onto the system e.g. incomplete addresses, child's GP.
9. Direct electronic transfer of immunisation data between GPs and CSAs is not standard practice in the Region. This would facilitate the generation of more timely and complete immunisation data.

Materials Management

1. There is no standard operating procedure or practice for stock control, maintaining a verifiable cold chain, vaccine transport, distribution and disposal in the Region. This needs to be addressed nationally also.
2. There are no dedicated staff in AHBs who specifically deal with vaccine distribution. Staff who deal with this area are of varying seniority and in addition, are responsible for other areas of work.

3. There is no delivery system for transporting vaccines to GPs and schools.
4. No regional policy exists for the management of vaccine shortages.
5. No alert system exists for informing health professionals (GPs and CSAs) of impending vaccine shortages.

Communications

1. Provision of timely information to health professionals and the public on changes in immunisation schedules has been deficient in the past.
2. The risks of illness and the benefits from vaccination are not clearly communicated to the public and to health professionals.
3. Information leaflets on 4-in-1 and 5-in-1 vaccines need to be updated at both regional and national levels. There are no information leaflets available on Td booster regionally or nationally.
4. There is insufficient consumer involvement in compiling information materials.
5. Educational sessions for professionals are communicated in an ad-hoc manner.

Summary of Recommendations

The recommendations are summarised as follows:

Planning and Organisation

1. The ERHA Immunisation Committee should continue to advise on planning, implementation and evaluation of all current and new immunisation programmes in the Region.
2. A Specialist in Public Health Medicine with special responsibility for immunisation should be appointed in the Department of Public Health in the Region to ensure that all aspects of the immunisation services are implemented.
3. Multidisciplinary immunisation committees already established in each AHB should continue to ensure that all efforts are made for optimal functioning of immunisation programmes in their AHB.
4. Each AHB/CSA should prioritise immunisation at both planning and operational level. In this context, all efforts should be employed to make staff available for this function.
5. An immunisation co-ordinator should be appointed to each AHB as recommended in the National Review of Immunisation/Vaccination Programmes.

6. Each CSA should prioritise timely delivery of school booster immunisation programmes to 5-6 year olds i.e. DTaP/IPV, MMR and to 12-14 year olds i.e. Td. This may involve staff redeployment. The Meningitis C programme was perceived as a successful model. Consideration should be given to using a similar model for school booster programmes.
7. A regional policy should be developed and implemented for follow-up of defaulters and for areas with low immunisation uptake rates. Particular attention should be given to ensuring maximum uptake.
8. Each GP in the Region should be furnished with a list of his/her cohort of children for primary immunisation by the relevant AHB/CSA in order to facilitate the administration of the primary immunisation programme and to accurately estimate the uptake rates for the Region and for each practice. This has currently commenced in the Region through the co-operation of PHNs but must be given ongoing prioritisation. Consideration should be given to obtaining this information in hospital at time of birth registration.
9. Each AHB/CSA should ensure that all information returned by GPs in relation to immunisations is promptly inputted onto the information system and that the relevant payments and information are disseminated in an efficient and timely manner.
10. A review of the immunisation contract between the Department of Health and Children (DoHC) and General Practitioners in respect of providing Primary Immunisation should be expedited in order to address ongoing issues in relation to immunisation programmes. This would assist in resolving some of the problems, which currently impede attainment of optimal childhood immunisation uptake rates.

Information Systems

1. The development and implementation of a new information system must be a priority for 2003. In the interim, the number of administration staff working on the current information system i.e. Regional Interactive Child Health System (RICHS) should be increased to ensure that:
 - Inputs to the immunisation surveillance system are accurate and timely.
 - Returns and payments to GPs are accurate and timely.
 - Tracking and follow-up of defaulters or those who move residence is monitored.
 - 4-in-1 and 5-in-1 input forms are used for recording primary immunisation.

2. The new immunisation surveillance system should incorporate the facility to record uptake rates for neonatal BCG and school booster vaccinations. This should be given high priority, as currently these uptake rates are not computerised in the Region.
3. Processing of all birth notifications should be standardised, regardless of mother's marital status.
4. All maternity hospitals and GPs should be electronically linked to the health board headquarters both at AHB and regional level.
5. GPs should be encouraged to return accurate and complete data on immunisation uptake.
6. Updated figures must be produced on a regular basis with dissemination of the information to all involved in the immunisation scheme especially the GPs.
7. Quality assurance protocols should be implemented immediately to ensure that the information provided by RICHs is accurate and timely.
8. Information on migrant and ethnic populations should be available.
9. Local analysis by small area (DED) should be available in order to target "blackspots".
10. Ongoing training of staff working on the immunisation surveillance system should be prioritised.
11. Every effort should be made to provide each child with a unique identifier.
12. Parent held records should be introduced as soon as possible. The use of electronic parent held records should be considered which conforms to the requirements of the forthcoming National Health Information Strategy and harmonises with the Primary Care Strategy.
13. Details of all children immunised in the hospital setting should be reported to the Senior Area Medical Officer (SAMO) of the CSA where the child resides so that they can be recorded on RICHs and be included in the uptake statistics for the Region.

Materials Management

1. All vaccines should be distributed, received and stored with a verifiable cold chain to the end user.
2. The options for distributing vaccine to end users are as follows:
 - 1) Each AHB to establish its own distribution system.
 - 2) A central depot located at Materials Management Department, EHSS, that controls the distribution system in the entire Region.

- 3) Contracting the procurement and distribution of vaccines to a private company, which would deliver directly to the end user.
- 4) The manufacturers/agents delivering the vaccine directly to the end user.

Serious consideration should be given to the benefits of Options 3 and 4.

3. A computerised process for stock distribution and control is needed regionally and locally.
4. A Regional expert group should develop Standard Operating Procedures (SOPs) for vaccine distribution and disposal based on best practice in order to ensure ongoing quality assurance.
5. This quality assurance system should systematically verify continuous maintenance of the cold chain for all vaccines at all stages during transportation and storage. Distribution and storage should comply with WHO standards.

Communication

1. Information on immunisation for the public should be available on the ERHA web site, in health centres (print and visual), during antenatal classes, in hospitals, in GP surgeries and in non-health care facilities e.g. libraries etc. This information should be:
 - a) Balanced, complete and in multiple formats
 - b) Updated at regular intervals
 - c) Readily accessible in particular to those with most need
 - d) User friendly
 - e) Misinformation should be quickly addressed.
2. Information on childhood immunisation should be circulated on a regular basis to all crèches and schools in the Region.
3. Information materials should be customised to meet the needs of those with language difficulties and poor literacy skills. They should be made available in print, audio, video and electronic format. Consumer representatives should be involved in compiling these materials.
4. The promotion of immunisation through one-to-one communication with parents should take place in all relevant health care settings.
5. A cascade system of information for health professionals should be implemented especially in relation to changes in the immunisation schedule and any controversial immunisation issues.
6. Back to school campaigns should be launched to promote the benefits of childhood immunisation, both primary and booster programmes.

7. Ongoing frequent training should be provided to all relevant health professionals including:
 - a) Lectures on the benefits, risks, policy of immunisation
 - b) Skills maintenance
 - c) On-going continuing professional development
 - d) Media training.
8. A strategy for media management of immunisation issues should be developed and implemented at both AHB and Regional levels. This strategy should aim to counter misinformation and highlight the benefits of immunisation in preventing disease.
9. Encourage all staff including midwives, Public Health Nurses, GPs, Public Health doctors and community pharmacists to act as advocates for immunisation.
10. Ensure that all relevant health board staff are aware of and implement health board policy in relation to immunisation and its benefits. In addition, staff should be supported in maintaining their knowledge base and provided with up to date scientific evidence based information on immunisation matters.
11. Research should be undertaken on the strengths and weaknesses of current communication strategies. Annual surveys and focus group research with parents of young children should take place to assist in identifying the beliefs and attitudes of parents towards childhood immunisations, their knowledge of immunisations, their experiences and preferred information sources.
12. Communication between health boards, service providers and the Irish Medicines Board (IMB) in relation to vaccine licensing, safety and reporting adverse events should be improved.

Disadvantaged Groups

1. PHNs and GPs should target these groups as priority for primary immunisation.
2. Information on vaccine preventable diseases should be provided to this group taking into consideration language and cultural differences.
3. Back to school campaigns should be launched to promote the benefits of childhood immunisation, both primary and booster programmes.

Recommendations in relation to MMR Vaccine

The committee strongly recommends the administration of MMR vaccine at 12 to 15 months with a booster at 4 to 5 years as recommended by the National Immunisation Advisory Committee and best international practice.

Parents should receive regular information on the risks associated with measles mumps and rubella infection and on the benefits from immunisation.

Chapter 1

Introduction

The prevention of serious childhood illness through immunisation is a major public health action that protects the health of children in Ireland and throughout the world. In order to prevent outbreaks of communicable diseases such as measles and mumps, the uptake of primary childhood immunisation should be 95%. At levels lower than this the risk of outbreaks occurring increases significantly.

In 2001, immunisation uptake rates at 12 and 24 months of age for primary childhood immunisation dropped in the Eastern Region. The uptake rate at 12 months of age for diphtheria, tetanus, pertussis, polio and Hib vaccines dropped by 10% from 70% in the final quarter of 2000 to 60% for the same quarter of 2001. The uptake rate of these vaccines at 24 months of age remained relatively stable at 77%, although it represented a drop of 4% from the previous year (uptake rate in 2000 was 81%).

The most worrying observation occurred in relation to MMR immunisation as the uptake rate at 24 months of age dropped by 21% from 80.5% at the end of 2000 to 59% at the end of 2001. Some Community Services Areas (CSA) displayed uptake rates of between 45% and 50%. These low uptake rates greatly increase the risk of an outbreak of measles or mumps. Although the decline in MMR immunisation was noted nationally, it was much more marked in the Eastern Region. (Appendix 1). The recent negative media publicity surrounding MMR vaccine contributed to this decline in immunisation uptake rate.

Of those who contract measles, one in 15 will develop complications such as otitis media, pneumonia, and encephalitis. Complications of mumps include meningitis, encephalitis and sensorineuronal deafness. Rubella is generally a mild illness. However, if acquired by mothers in early pregnancy, it can have devastating effects on unborn children as it causes congenital rubella syndrome, which includes learning difficulties, deafness and cardiac defects.

An outbreak of measles occurred in the Eastern Region in 2000, which led to 1,230 cases, three deaths and just over 350 hospital admissions in children. A recent outbreak of measles in the Western Health Board Region involving 24 children highlights the need to continually strive for improved primary childhood immunisation uptake rates until the optimal target of 95% is reached.

In this context an Eastern Regional Health Authority (ERHA) immunisation committee was convened in February 2002 to address immunisation issues in the Region and to examine both short-term and long-term strategies to improve the uptake of primary childhood immunisation. The aim of the committee is to increase the primary immunisation uptake rate in the Eastern Region to 95% and to maintain it at this level.

1.1 Terms of Reference

1. To investigate current immunisation arrangements and make recommendations on management structures and individual roles and responsibilities in relation to all aspects of childhood immunisation within the Eastern Region.
2. To ensure that there is an information system, which provides accurate, reliable, timely and accessible data on primary childhood immunisation at regional, health board and local level.
3. To prepare:
 - Short-term strategies based on best practice to immediately improve the low immunisation uptake rates in the Eastern Region.
 - Long-term strategies based on best practice with the ultimate aim of achieving and sustaining a primary immunisation uptake rate of 95% in the Eastern Region.
4. To develop a strategy to identify and target “black-spots” and marginalised groups, including travellers and asylum seekers who may have low immunisation uptake rates.
5. To develop strategies for informing the public and healthcare professionals on the benefits of primary immunisation and the risks of vaccine preventable diseases.

1.2 Membership of the Regional Immunisation Committee

1. Dr. Marie Laffoy, Director of Public Health, ERHA (Chair)
2. Ms. Patricia Garry, Immunisation Co-ordinator, South Western Area Health Board
3. Ms. Breda Matthews, RICHS, South Western Area Health Board
4. Dr. Deirdre Mulholland, Department of Public Health, ERHA.
5. Dr. Joan O Donnell, Specialist in Public Health Medicine, ERHA
6. Ms. Sheila O Malley, Director of Nursing, ERHA
7. Dr. Brian Redahan, General Manager, CSA10, East Coast Area Health Board
8. Mr. John Swords, Director of Materials Management, EHSS
9. Dr. Ray Walley, Primary Care Unit, Northern Area Health Board
10. Mr. Michael Walsh, Assistant Chief Executive, Northern Area Health Board

Consultation occurred with Professor Denis Gill, Children’s Hospital, Temple Street, NAHB. Dr. Emer Feely, Specialist Registrar in Public Health Medicine assisted the committee.

Chapter 2

2.0 Childhood Immunisation in Ireland

Routine immunisation programmes were introduced in Ireland for diphtheria in 1932, for pertussis (whooping cough) in 1948 and for polio in 1956. Tetanus toxoid was introduced to make a triple vaccine (DPT) in 1959. Measles vaccine was introduced in 1985 and MMR was then introduced in 1988. *Haemophilis Influenza* vaccine (Hib) was introduced in 1992 and immunisation against meningococcal type C disease in 2000. The introduction of a booster dose of MMR at 4-5 years occurred in 1999. Primary immunisation with MMR combined with a booster dose confers 99% immunity in the population against measles, mumps and rubella.

The Immunisation Advisory Committee of the Royal College Physicians of Ireland (RCPI) makes recommendations to the Department of Health and Children (DoHC) regarding the National Immunisation Schedule. The DoHC considers these recommendations and decides whether or not to endorse them. The National Vaccine User Group of the DoHC is responsible for procuring vaccine supplies for the country based on birth cohorts.

In 2001, inactivated polio vaccine (IPV) was introduced to replace oral polio vaccine because of the risks of vaccine associated paralytic polio (1 in 2.4 million doses of oral polio vaccine). This occurred as part of the World Health Organisation (WHO) action plan to eradicate polio virus by 2005. There has been no case of wild polio virus reported in Ireland since 1984. IPV was introduced as it is a safe effective vaccine and available in combination preparations, namely 5-in-1 (DTaP/IPV/Hib) and 4-in-1 (DTaP/IPV).

The current primary childhood immunisation schedule in operation in Ireland is outlined in Table 1.⁽¹⁾

Table 1. Primary Childhood Immunisation in Ireland

Age	Immunisation
Birth-1 month	BCG
2 months	DTaP/IPV/Hib +Men C*
4 months	DTaP/IPV/Hib +Men C
6 months	DTaP/IPV/Hib +Men C
12-15months	MMR, Hib [∇]
4-5 years	DTaP/IPV +MMR
11-12 years	MMR (Omit if 2 previous doses were given)
10-14 years	BCG (ensure interval of 3 weeks post MMR) [⌘]
12-14 years	Td [⌘]

*=It is recommended that any person between 12 months and 23 years who has not had Meningococcal C vaccine should have a single dose.

[∇]=A single dose of Hib is also recommended if the child presents after age 13 months and has had no previous Hib Vaccine. Immunisation with Hib is not normally required over four years of age.

[⌘]=Only for those who are known to be tuberculin negative and have had no previous BCG.

[⌘]=It is proposed that each child should have received five doses of tetanus and diphtheria at school leaving age.

2.1 Vaccine Preventable Diseases

Under the Infectious Diseases Regulations 1981, the following vaccine preventable diseases are statutorily notifiable by clinicians:

- Bacterial Meningitis (including meningococcal septicaemia-applies to Meningococcal C disease and *H. influenza* b disease).
- Diphtheria
- Measles
- Mumps
- Pertussis
- Rubella
- Tetanus
- Polio
- Tuberculosis

Table 2 outlines the numbers of and notification rates for vaccine preventable diseases notified to the Department of Public Health, ERHA, by year since 1999. It should be noted that the figures shown may not offer a true representation of the burden of disease due to the significant under reporting of these statutorily notifiable diseases.

**Table 2. Notification Rates for Vaccine Preventable Disease Notified to the
Department of Public Health, Eastern Region 1998-2001**

YEAR	DISEASE TYPE	Number	Denominator	Rate per 100,000
1998	HIB MENINGITIS-HAEMOPHILIS INFLUENZAE	1	1316225	0.1
	HIB DISEASE-INFLUENZAL PNEUMONIA	0	1316225	0.0
	MEASLES	129	1316225	9.8
	MUMPS	21	1316225	1.6
	MENINGOCOCCAL DISEASE-MENINGITIS	38	1316225	2.9
	MENINGOCOCCAL DISEASE-SEPTICAEMIA	89	1316225	6.8
	MENINGOCOCCAL DISEASE-MENINGITIS & SEPTICAEMIA	0	1316225	0.0
	DIPHTHERIA	0	1316225	0.0
	POLIO	0	1316225	0.0
	RUBELLA	31	1316225	2.4
	TETANUS	1	1316225	0.1
	PERTUSSIS-WHOOPING COUGH	66	1316225	5.0
	TUBERCULOSIS	154	1316225	11.7
1998 TOTAL	TOTAL	530	1316225	40.3
1999	HIB MENINGITIS-HAEMOPHILIS INFLUENZAE	3	1326367	0.2
	HIB DISEASE-INFLUENZAL PNEUMONIA	2	1326367	0.2
	MEASLES	108	1326367	8.1
	MUMPS	23	1326367	1.7
	MENINGOCOCCAL DISEASE-MENINGITIS	49	1326367	3.7
	MENINGOCOCCAL DISEASE-SEPTICAEMIA	159	1326367	12.0
	MENINGOCOCCAL DISEASE-MENINGITIS & SEPTICAEMIA	3	1326367	0.2
	DIPHTHERIA	0	1326367	0.0
	POLIO	0	1326367	0.0
	RUBELLA	34	1326367	2.6
	TETANUS	0	1326367	0.0
	PERTUSSIS-WHOOPING COUGH	77	1326367	5.8
	TUBERCULOSIS	180	1326367	13.6
1999 TOTAL	TOTAL	638	1326367	48.1
2000	HIB MENINGITIS-HAEMOPHILIS INFLUENZAE	2	1336510	0.1
	HIB DISEASE-INFLUENZAL PNEUMONIA	6	1336510	0.4
	MEASLES	1230	1336510	92.0
	MUMPS	26	1336510	1.9
	MENINGOCOCCAL DISEASE-MENINGITIS	69	1336510	5.2
	MENINGOCOCCAL DISEASE-SEPTICAEMIA	123	1336510	9.2
	MENINGOCOCCAL DISEASE-MENINGITIS & SEPTICAEMIA	0	1336510	0.0
	DIPHTHERIA	0	1336510	0.0
	POLIO	0	1336510	0.0
	RUBELLA	51	1336510	3.8
	TETANUS	0	1336510	0.0
	PERTUSSIS-WHOOPING COUGH	58	1336510	4.3
	TUBERCULOSIS	143	1336510	10.7
2000 TOTAL	TOTAL	1708	1336510	127.8
2001	HIB MENINGITIS-HAEMOPHILIS INFLUENZAE	2	1346653	0.1
	HIB DISEASE-INFLUENZAL PNEUMONIA	1	1346653	0.1
	MEASLES	182	1346653	13.5
	MUMPS	22	1346653	1.6
	MENINGOCOCCAL DISEASE-MENINGITIS	74	1346653	5.5
	MENINGOCOCCAL DISEASE-SEPTICAEMIA	45	1346653	3.3
	MENINGOCOCCAL DISEASE-MENINGITIS & SEPTICAEMIA	0	1346653	0.0
	DIPHTHERIA	0	1346653	0.0
	POLIO	0	1346653	0.0
	RUBELLA	45	1346653	3.3
	TETANUS	1	1346653	0.1
	PERTUSSIS-WHOOPING COUGH	73	1346653	5.4
	TUBERCULOSIS	180	1346653	13.4
2001 TOTAL	TOTAL	625	1346653	46.4
1998-2001	Grand Total	3501	5325755	65.7

Rates based on extrapolations of 1996 census data

2.2 Outbreaks of Measles

Outbreaks of measles tend to be of a cyclical nature. There have been several recent outbreaks of measles in Europe with fatalities. The Netherlands reported an outbreak in 2000, which resulted in three deaths and 2,961 cases (1 in 1,000.⁽²⁾ During the same year, an outbreak of measles in the Eastern Region, resulted in 1,230 cases (of whom approximately 30% were under 15 months of age) and three deaths. In addition, just over 350 children required hospitalisation and 13 were admitted to intensive care units (ICU) of whom six required ventilation. The commonest causes for admission were dehydration, pneumonia and tracheitis. Prior to that in the Eastern Region, there was an outbreak in 1993 with over 2,500 measles cases notified.

In order to prevent outbreaks of measles by ensuring herd immunity* an MMR vaccine uptake of 95% is required. The mean uptake of MMR vaccine for children reaching 24 months of age in 2000 in the Eastern Region was 75%, with areas where the uptake was as low as 64%.

During the ERHA measles outbreak of 2000, an outbreak team met every two to three weeks to review the epidemiological data and to institute and review control measures. The following control measures were implemented:

1. A media campaign highlighting that measles can be a serious illness and that MMR is a safe effective vaccine.
2. Parents of all children under five years of age for whom there was no MMR record were contacted by post and advised to contact their GP for immunisation.
3. Managers of pre-school facilities in the Eastern Region were contacted by post, to alert them of the outbreak and asking that they encourage parents to have the children in their care vaccinated. It was also requested that they alert the Senior Area Medical Officer (SAMO) in their local health board offices, if a case occurred in their facility so that specific control measures could be put in place to prevent secondary cases among other children attending the facility.
4. A policy for prevention of secondary cases was drawn up for pre-schools as follows:

* Herd immunity means that if someone incubating measles has contact with others in the community the disease will not spread if immunisation rates are high as the chance of being in contact with someone who is not immune is so small if most people have immunity. Children who cannot be immunised depend on high population levels for their personal protection, as do children under one year of age.

- General reduction in the recommended age of MMR immunisation to six months (Northern Area Health Board) and 12 months (South Western / East Coast Area Health Boards).
- It was recommended that when a case of measles was notified in a child attending a pre-school facility, attendees aged over 12 months of age should receive two injections of MMR vaccine at least 28 days apart.
- Attendees aged between 6 and 12 months should receive one dose of MMR vaccine (children vaccinated before their first birthday should receive a second dose of MMR vaccine at 15 months and a third dose at school entry).

2.3 Risks of Illness versus the Risks of Immunisation

Table 3 describes the vaccine preventable diseases.⁽³⁾ It also compares the complications of these diseases with the side effects of the vaccines, which are used to combat the diseases.

Table 3. Comparison of Effects of Diseases and Vaccines

Disease	Complications of disease	Side effects of vaccine
Polio Spread by faeces and saliva. Incubation Period: 1-2 weeks. Infection may lead to fever, headache, nausea and vomiting, muscle weakness and paralysis.	1% of infections have clinical symptoms but about 1 in 20 hospitalised patients dies and 50% of survivors remain paralysed	IPV used so vaccine associated polio, is no longer a risk. Local discomfort or inflammation in 5% of recipients
Diphtheria Spread by nasal droplets. Incubation Period: 2-5 days. Infection may lead to severe pharyngitis and cervical adenopathy. Patient is infectious for up to 2 weeks.	Case fatality rate 5-10%. Toxin may lead to myocardial and neurological complications	DTaP vaccine-about 20% have local discomfort or inflammation. 5% have fever. A transient nodule may develop at the injection site lasting a few weeks. Up to 70% at the 4-6 yr booster develop redness and swelling
Tetanus Bacteria present in soil and animal faeces. Incubation Period: 3-21 days. Causes painful muscular contractions and convulsions.	Case fatality about 10%. Risk is greatest for the very young or old	See above – side effects of DTaP vaccine. Local erythema and swelling not uncommon with adult boosters, and increasing with age. Peripheral neuropathies have been rarely reported
Pertussis Spread by cough and nasal droplets. Incubation Period: 7-10 days	About 5% case fatality in patients under 6 months, from pneumonia or fatal encephalopathy	See above – side effects of DTaP vaccine. Rate of reactions to acellular pertussis vaccine is less than with whole cell
<i>Haemophilus influenzae b</i> Spread by nasal droplets. Incubation Period: 2-4 days. Presents as an acute illness with fever, vomiting and lethargy in 55-65%. In the remainder it can also cause epiglottitis, pneumonia, bacteraemia and other complications	Case fatality of meningitis is 5%. 10-15% of survivors have permanent neurologic sequelae and 15-20% have deafness.	5% have discomfort or local inflammation, 2% have fever. Usually given in combination with DTaP

Measles Spread by cough and droplets. Incubation Period: 1-2 weeks. Symptoms include fever, sore throat, cough and rash	Complications such as bronchopneumonia and otitis media in about 10%. 1/1000 encephalitis (case fatality 10%, permanent sequelae 25%). 1/8,000 children under 2 years develop SSPE. Death in 1 in 2,500 to 1 in 5,000 depending on age	5-10% have discomfort, local inflammation or fever with or without a non-infectious rash. 1/million recipients develop encephalitis. About 1/24,000 develop transient thrombocytopenia.
Mumps Spread by saliva. Incubation Period: 2-3 weeks. Symptoms include fever and parotitis	1/200 children develops encephalitis. 20-30% of post-pubertal males develop orchitis, 5% of females develop oophoritis. Occasionally mumps causes infertility or deafness.	Fever and a mild skin rash occasionally occur. 1% of recipients may develop parotitis. 1 in 3 million recipients may develop aseptic meningitis.
Rubella Spread by nasal droplets. Incubation Period: 2-3 weeks. Symptoms include fever, headache, itchy eyes and rash	50% develop a rash and adenopathy; 50% of adolescents and adults have acute arthralgias or arthritis; 1/6,000 develops an encephalopathy. Infections in the first 10 weeks of pregnancy have a 85% risk of CRS	10% have discomfort, local inflammation or fever. 5% have swollen glands, stiff neck or joint pains. About 1% develop a non-infectious rash. Transient arthralgias or arthritis may occur, usually in post-pubertal females. About 10% have discomfort, local inflammation or fever.
Meningococcal C Disease Meningococcal C disease is spread by saliva and nasal droplets. Incubation Period: 2-10 days. May cause meningitis or septicaemia	Mortality of 20% for septicaemia and 7% for meningitis. About 25% of survivors have some disability. Main long term effects include skin scars, deafness, seizures, limb amputation and brain damage	One third have a local reaction. Headaches, nausea and fever occur in 1-2%. The Men C vaccine gives ~ 95% protection against Meningococcal C disease. The vaccine DOES NOT protect against other types of meningococcal disease

Example of a Successful Immunisation Programme in Ireland: Meningococcal C Campaign in Ireland, 2000-2001

One example of a successful immunisation campaign was the meningococcal C campaign which was recently carried out in Ireland. In 1999, Ireland had the highest rate of meningococcal disease in Europe at almost 15 per 100,000 population.

The meningococcal C immunisation campaign was introduced into the primary immunisation programme in October 2000, with a catch-up programme for all those aged less than 23 years. The first phase comprised of offering immunisation to all children aged under five years and to adolescents aged between 15 and 18 years as the largest burden of disease occurs in these age groups. The remaining age groups under 23 years were immunised in phases 2 and 3 of the Programme, which were completed in February 2002.

Meningococcal C vaccine is now given as part of the primary immunisation programme at 2, 4 and 6 months. For children aged over 1 year, who receive the vaccine for the first time, one dose only is required. The uptake rates for Phase 1 of the Meningococcal C campaign for the Eastern Region were as follows:

- 60% in the 1-4 year old
- 79% in 15-18 year olds –School
- 57% in 15-18 year olds –College
- 53% at 12 months ^{*}
- 70% at 24 months [∅]

The immunisation campaign has impacted favourably on morbidity and mortality from Meningococcal C disease in Ireland. There has been a 76% reduction in cases of meningococcal C disease and the number of deaths has decreased from 11 in 2000 to three in 2001 (Verbal communication- AHBs and National Disease Surveillance Centre (NDSC)).

^{*} = *These uptake rates relate to those who received three doses of meningococcal C vaccine*

[∅] = *These uptake rates relate to those who received one dose of meningococcal C vaccine only*

2.4 Cost Effectiveness of Immunisation Programmes

It is well established that immunisation programmes can lead to a reduction in disease prevalence and its associated complications. Vaccines are a popular preventive intervention worldwide; they save lives and are socially useful interventions. The World Health Organisation states that immunisation is more cost-effective than other health interventions saving individuals and governments money. Immunisation is seen as the most cost-effective intervention in driving forward the delivery of a health package to the poorest children in the world and it is recognised that it is the right of every child to be protected against infectious disease.⁽⁴⁾

The economic importance of immunisation programmes is due in part to the burden of disease that can be avoided and partly to the competition for resources between vaccines and other interventions. There is a wide array of methods to measure the economic performance of a vaccine, including studies of the cost of illness, the cost-benefit, the cost-effectiveness and the cost-utility. Research in all aspects of immunisation has been increasing and one of the areas of growth is in the area of economic evaluation.⁽⁵⁾ Many of these studies have shown that immunisation is highly cost-effective and in fact many show that immunisation is cost saving. It is important to look at combination vaccines as they can confer large economic advantages because they reduce the number of immunisation visits required, reduce the costs of administration (nurse and physician time, equipment and vaccine storage) and ensure better acceptance (improved coverage and reduced risk of disease).⁽⁶⁾

The burden in the Eastern Region of the measles outbreak of 2000 can be highlighted by the cost of measles related hospital admissions in that year. According to the HIPE data for the Region, there were just over 350 cases admitted to hospital where measles was recorded as any of the 6 possible diagnoses at the approx cost of €144,000.⁽⁷⁾ These costs do not include the cost of days of work missed for parents, travel expenses, GP attendances and stress and anxiety for the families. The potential complications and the subsequent management and treatment of these complications can also be a significant cost to the families and government. Some of the sequelae may not present for many years e.g. subacute sclerosing panencephalitis and so it may not be possible to fully calculate the long-term cost of this disease to individuals and government in the short term. The cost of hospital admissions do not account for more than 850 ill children who were treated at home. In addition, the cost of three preventable deaths cannot be quantified.

The cost-effectiveness of measles outbreak intervention strategies were analysed in Australia in 1998.⁽⁸⁾ They attempted to determine the cost-effectiveness of six measles outbreak interventions compared with no intervention in Australia. The introduction of the immunisation programmes led to a reduction in measles outbreaks by 67–81%. The average cost per case prevented including hospital savings ranged from Aus\$ 375-546.

In 1992, the Canadian National Advisory Committee on Immunisation (NACI) recommended the introduction of a two-dose measles immunisation programme, due to the limitations of the one-dose measles immunisation programme. A cost benefit

analysis was carried out at the introduction of this immunisation programme, with and without a mass catch up campaign, comparing it with the previous one-dose campaign.⁽⁹⁾ They found that the benefits of a second dose immunisation campaign against measles far outweighed the costs of such a programme under both scenarios.

In 1997 in the United States an economic evaluation of the use of diphtheria, tetanus and acellular pertussis vaccine was carried out. Using a simulated cohort of 4.1 million it was estimated that without an immunisation programme diphtheria, tetanus and pertussis disease caused more than 3 million cases and more than 28,000 deaths at a cost of \$23.6 billion. From a societal perspective net savings from the use of DTaP was \$22.5 million. Therefore compared with no programme immunisation with DTaP resulted in substantial savings.⁽¹⁰⁾

An economic evaluation was performed of universal acellular pertussis immunisation in Italy.⁽¹¹⁾ The results indicate that a 50% coverage rate of pertussis immunisation in Italy was not optimal on the basis of cost-effectiveness and cost benefit considerations. Additional increases in coverage were found to yield extra health gains at modest net costs or even potential net savings to the health care sector. For example, an increase in coverage to 90% would yield direct net savings of US\$42 per extra vaccinee in comparison to a situation of 50% coverage.

In Spain the cost-effectiveness of a universal programme of Hib immunisation for children less than 1 year of age was compared to a selective immunisation programme targeted at children between 2 months and 5 years with risk factors for Hib disease.⁽¹²⁾ The study concluded that universal immunisation against Hib in Spain would represent a cost saving where the annual incidence rates were above 20 cases of invasive disease per 100,000 children under 5 years of age, while for lower rates of invasive disease, a net economic benefit would depend on the price of the vaccine dose.

Although the type of immunisation programme, the disease it targets and the conditions under which it is delivered may vary the evidence in support of the cost effectiveness of such programmes is strong. It is important to remember that cost – effectiveness does not always equate with cost savings. However in contrast to other healthcare programmes many immunisation programmes do achieve cost savings and even immunisation programmes that do not achieve a net cost saving are cost-effective. There is strong evidence to support these programmes in terms of cost-effectiveness but it is also important to remember the improved quality of life issues that arise due to such programmes and which cannot always be quantified.

2.5 Immunisation Uptake Rates in the Eastern Region

2.5.1 Primary Immunisations

Tables 1-6 in Appendix 1 show the immunisation uptake rates in all CSAs for children aged 12 and 24 months in all four quarters of 2001 and in the first and second quarters of 2002.

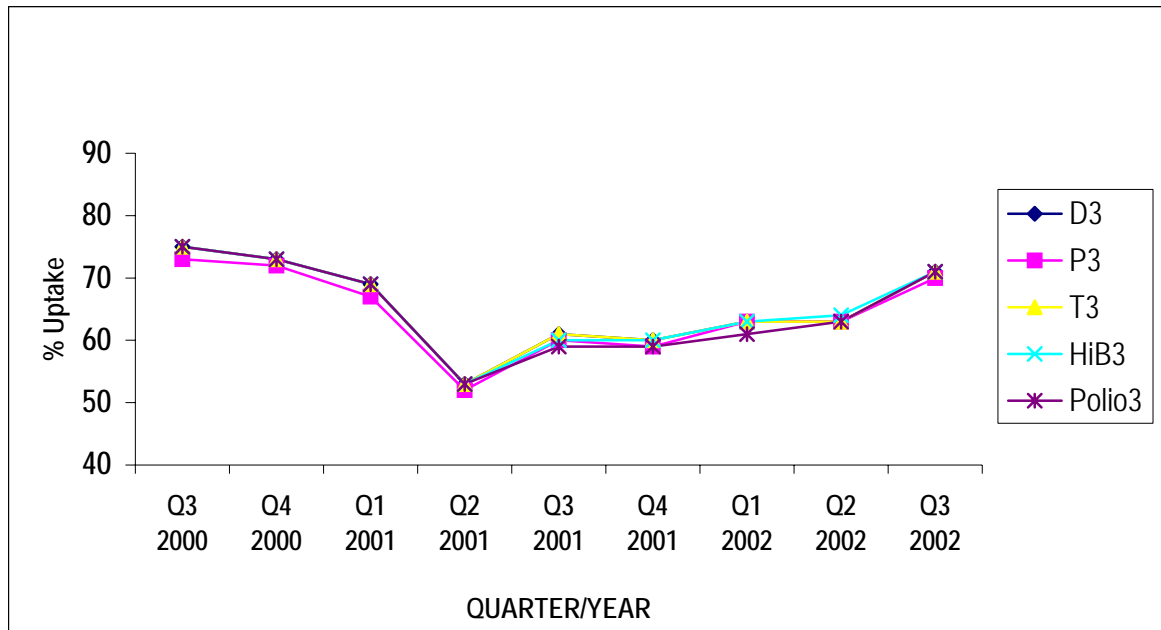
The key points to be noted from these tables are:

1. By the fourth quarter of 2001 MMR uptake at 24 months decreased by almost 20% from 77% to 59.7%. In some areas, MMR uptake fell to under 50% (CSA 3 and 7) by the fourth quarter of 2001. The decline in immunisation uptake was most marked between the first and second quarters of 2001, this slowed by the third quarter and there was a marginal increase in uptake by the fourth quarter (Figures 1,2). For the first quarter of 2002 there was another small increase in MMR uptake, and a further increase of 4% was noted for Q2 2002, bringing the uptake rate in the Region to 63%. These low uptake rates greatly increase the risk of an outbreak of measles or mumps).
2. The uptake of DTaP/Polio/Hib at 12 months also dropped by approximately 10% over 2001.
3. Inner city areas (CSA 3 and 7) have the lowest uptake rates.
4. It is notable that the uptake rates at 12 and 24 months for all childhood immunisations and in particular MMR was lowest in the Eastern Region for the fourth quarter of 2001 compared to those recorded in the rest of the country.

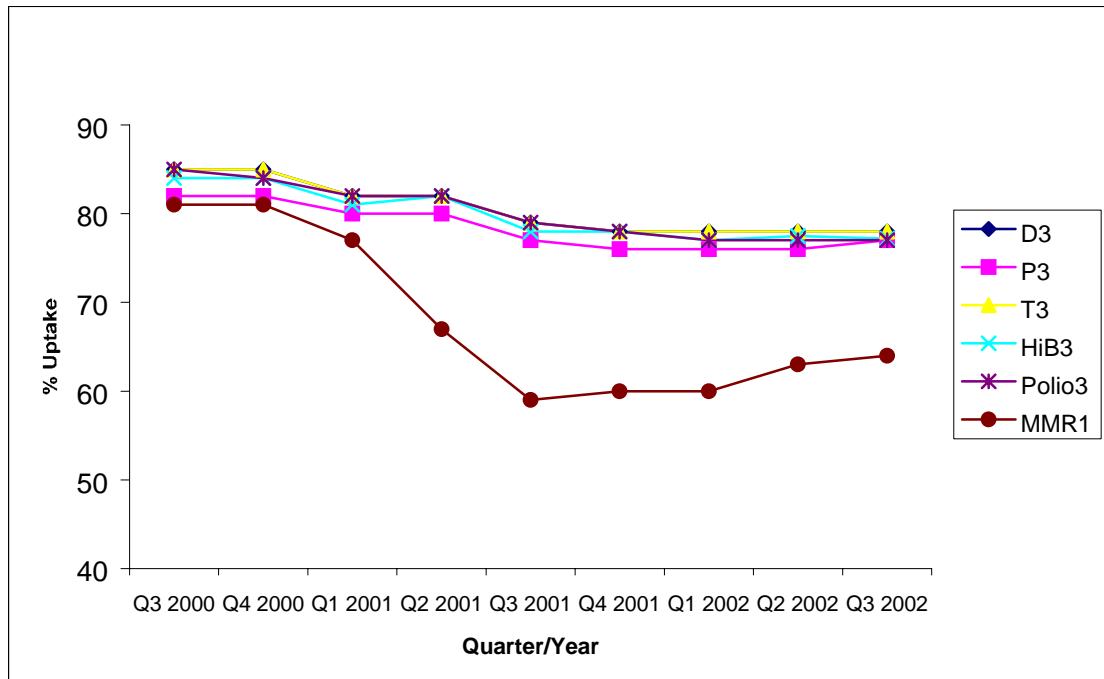
Maps of uptake rates were produced (Appendix 2). The lowest uptake areas include:

- North inner city
- South inner city
- Swords
- Tallaght
- Crumlin
- Ballyfermot
- Clondalkin
- Neilstown
- Coolock
- Darndale
- Ballymun
- Inchicore
- Bray

**Figure 1. ERHA Quarterly Immunisation Update Rates at 12 Months:
Q3 2000-Q3 2002**



**Figure 2. ERHA Quarterly Immunisation Update Rates at 24 Months:
Q3 2000-Q3 2002**



2.5.2. Booster Immunisations

The booster immunisation scheme is carried out in schools by teams of area medical officers (AMOs), PHNs and administration staff in each AHB. Administration of booster immunisation in the school setting has proven very effective, as it provides a “captive audience” of vaccinees and can achieve uptake rates of between 80 to 95%. The uptake rates for school booster immunisations in the Eastern Region for 2000/2001 are outlined in Table 4. The uptake figures for 2001/2002 will be compiled in October 2002 as some returns are still awaited. However, verbal communication with some CSAs indicates that the backlog of children for immunisations has been cleared.

Following recommendations from the National Immunisation Advisory Committee (RCPI), there have been changes to the school immunisation schedule over the last few years leading to an increase in the number of immunisations recommended for children at school going age. In addition, the Meningococcal C vaccination programme was carried out in primary schools during 2001 in conjunction with the school booster programme. Verbal communication with CSAs indicates that the introduction of these changes caused a great deal of confusion and upset among parents. This presented some problems for school immunisation teams, however, these have now been overcome.

Difficulties in recruiting and retaining staff have hampered the operation of optimal booster immunisation programmes in some CSAs in the Region. In one CSA, administration of booster immunisations by GPs was introduced as a pilot scheme in 2001. The outcome of this pilot scheme will be evaluated in 2003. Another CSA introduced a similar scheme in Autumn 2002. In addition administering the booster tetanus and diphtheria (Td) vaccine to 12-14 year olds has been recommended by the National Immunisation Advisory Committee. This will be implemented nationally in the near future. CSA medical teams should prioritise immunisations as they are an effective proven health intervention (See 2.3:Meningococcal C Campaign).

Views were sought from Senior Area Medical Officers (SAMOs) in CSAs in relation to perceived barriers/obstacles to optimal operation of school immunisation services, which are outlined as follows:

1. Difficulties in recruiting and retaining manpower
2. Lack of a computerised information system for booster immunisation uptake
3. Insufficient notice of imminent vaccine shortages which impact on programme planning
4. Lack of parent held record
5. No media campaign to promote school booster immunisation
6. Frequent changes in immunisation programmes

**Table 4. School Immunisation Programme Statistics for Eastern Region
(September 2000 –June 2001)**

Community Services Area	1*	2*	3	4**	5**	6	7	8	9	10	Total
No of schools	60	45	41	46	47	71	57	81	114	68	630
No of schools where immunisation programme undertaken	12-J* 28-S	4-J* 28-S	41 S only	46	47	67	None	81	114	68	536
No of children (4-6 year) target population for DT/Polio booster	3,435	2,773		1863	1825	2163		2848	2524	1369	18,800
No of Children who received DT/Polio booster	640	272		1339	1327	1323		2488	2337	1162	10,880
Uptake % DT/Polio	18.6	9.8		71.8	72.7	61.0		87.4	92.8	84.8	62.4%
No of Children (4-6 year) in target population for MMR booster	3,435	2,773		1863	1825	2163			2524	1369	15,952
No of Children who received MMR booster	602	252		1217	1403	1373			2327	1128	8,543
Uptake %	17.5	9.0		65.3	76.9	63.0			92.2	82.4	58.0
No of Children (10-11 year) in target population for “catch-up” MMR booster	1,967	1,459	2050	1909	1725	2236		2884	2575	1541	18,346
No of Children who received MMR booster (11yrs)	972	774	1434	1561	1389	1883		2644	2465	1246	14,368
Uptake %	49.0	53.0	70.0	89.0	80.5	84.0		91.7	95.7	80.8	77.0

* J=Age Group 5 to 8 years

* S=Age Group 10 to 12 years

* CSA 1 plans and co-ordinates the school immunisation programme for both CSA 1 and CSA 2

* * CSA 4 plans and co-ordinates the school immunisation programme for both CSA 5 and CSA 5

Note:

1. CSA1 and CSA 2 (ECAHB) have a large backlog in relation to school booster immunisations due to difficulties with recruitment and retention of AMOs, PHNs and administration staff. In these CSAs, immunisation must receive greater priority
2. CSA 7 (NAHB) was unable to undertake the booster immunisation programme for DT/OPV and MMR in the junior school age group for the year 2000/2001 due to difficulties in recruiting AMOs, PHNs and administration staff. School booster immunisations are currently being undertaken by GPs in the area as a pilot initiative. CSA8 –MMR booster is not given to 5 to 6 year age group due to difficulties in recruiting and retaining AMOs, PHNs and administration staff. Immunisations should be prioritised in these CSAs, in the context of evaluating all other public health work currently being done and redeploying staff if necessary.

Total Number of Schools in Eastern Region =630
Total Number of Schools targeted for booster immunisation in Eastern Region))
in 2000/2001= 536
% Schools targeted in Region= 85%

SCHOOL YEAR 2001/2002: SCHOOL BOOSTER IMMUNISATION PROGRAMMES ARE CURRENTLY UP TO DATE IN CSA 3.

In CSA 8, THE DIFFICULTY IN RELATION TO ADMINISTRATION OF MMR VACCINE TO THE 5-6 YEAR AGE GROUP DUE TO DIFFICULTY IN RECRUITING STAFF, WILL BE ADDRESSED IN 2002/2003 WITH THE IMPLEMENTATION OF A PILOT SCHEME WITH GPS IN THE AREA TO UNDERTAKE THESE IMMUNISATIONS

THE SCHOOL BOOSTER PROGRAMMES IN CSA 9 AND 10 ARE EXAMPLES OF VACCINE UPTAKE “SUCCESS STORIES”. THE TEMPLATE USED FOR DELIVERY OF THESE PROGRAMMES SHOULD BE CONSIDERED BY ALL CSAs WHO UNDERTAKE SCHOOL BOOSTER PROGRAMMES.

Table 5 outlines the additional resources required by CSAs to operated effective school immunisation programmes.

Table 5. Manpower Requirements by CSA for Effective Operation of School Booster Programme

CSA	Current Manpower	Additional Manpower Required for Effective Operation	Cost of Additional Manpower (Excluding PRSI)
1	1.5 WTE AMO 1.5 WTE PHN 1 WTE Clerical Officer (Grade III)	1.5 WTE AMO 1.5 WTE PHN 3 WTE Clerical Officer (Gr III)	€76,527.12 €54,407.01 €59,267.55
2	Undertaken by CSA1	Undertaken by CSA1	
3	0.5 WTE AMO 0.5 WTE PHN 1 WTE Clerical Officer (Gr III)	1 WTE AMO 0.5 WTE PHN 2 WTE Clerical Officer (Gr III)	€51,018.08 €18,135.67 €39,511.70
4	1.5 WTE AMO 1.0 WTE PHN 2 WTE Clerical Officer (Gr III)	1.5 WTE AMO 1.5 WTE PHN 2 WTE Clerical Officers (Gr III)	€76,527.12 €54,407.01 €39,511.70
5	Undertaken by CSA 4	Undertaken by CSA 4	
6	0.5 WTE AMO 1 WTE PHN 1 WTE Clerical Officer (Gr III)	0.5 WTE AMO 0.5 WTE PHN 0.5 WTE Clerical Officer (Gr III)	€25,509.04 €18,135.67 €9,877.93
7	GP Pilot Evaluation in 2003	0.5 WTE AMO to liaise with GPs and evaluate programme 0.25 WTE PHN to liaise with vaccinees 1 WTE Clerical Officer (Gr III)	€25,509.04 €9,067.84 €19,755.85
8	0.5 WTE AMO 0.5 WTE PHN 1 WTE Clerical Officer (Gr III)	2 WTE AMO 2 WTE PHN 1 WTE Clerical Officer (Gr III)	€102,036.16 €72,542.68 €19,755.85
9	1 WTE AMO 0.5 WTE PHN 2 WTE Clerical Officers (Gr III)	1 WTE AMO 1 WTE PHN 1 WTE Clerical Officer (Gr III)	€51,018.08 €36,271.34 €19,755.85
10	1 WTE AMO 0.5 WTE PHN 1.5 WTE clerical officer (Gr III)	0.5 WTE AMO 1 WTE PHN 0.5 WTE Clerical Officer (Gr III)	€25,509.04 €36,271.34 €9,877.93
Total	6.5 AMO 5.5 PHN 9.5 Clerical Officers (Gr III)	8.5 AMO 8.25 PHN 9 Clerical Officers (Gr III)	€50,206.60

Measures to ensure optimal operation of the school immunisation scheme need to be urgently implemented as it has been shown to be an effective intervention with proven health gain. The main requirement is to ensure recruitment and retention of staff.

2.6 Barriers to immunisation

Many factors contribute to the low immunisation uptake rates recorded in the Eastern Region as in other areas. These include:

- Adverse negative publicity about immunisation has created doubt and fear among some parents regarding vaccine safety.
- Wariness of health professionals adds to the reluctance of some parents to have their children immunised.
- The once common vaccine preventable diseases have become uncommon, which can lead to incorrect assumptions that immunisation against these diseases, is no longer important.
- Many parents are poorly informed about vaccine preventable diseases and of the benefits of vaccination.
- Competing priorities in particular for those in deprived areas with young children,
- Research has shown that many health professionals feel poorly equipped to answer parents' questions.⁽¹³⁾

Some more specific reasons for low uptake include the following:

- The Regional Interactive Child Health System (RICHS) database in the Eastern Region contains many duplicate names. This creates a falsely elevated denominator with the result that actual uptake may be higher than recorded.
- Delays in full implementation of the 1995 agreement between the health boards and GPs.
- Timely return of birth notifications to health boards has been a problem with regard to single mothers whose babies are born in certain maternity hospitals.

2.7 Vaccine Specific Issues-MMR

In recent times, there has been much controversy in relation to the alleged association between the MMR vaccine and autism or inflammatory bowel disease (Crohn's Disease) but the body of scientific evidence does not support this suggestion. The following expert groups have assessed all the scientific evidence and they have all concluded that there is no link between the MMR vaccine and autism or bowel disease:

In Ireland

- Department of Health and Children
- National Immunisation Committee, Royal College of Physicians of Ireland
- National Disease Surveillance Centre
- Irish Medicines Board
- Irish College of General Practitioners
- Faculty of Paediatrics, RCPI
- Irish Medical Organisation

The Oireachtas Joint Committee on Health and Children in their Report on Childhood Immunisation ⁽¹⁴⁾ concluded that:

- There is no evidence of a proven link between MMR and autism
- There is no evidence to show that separate vaccines are any safer than combined vaccines.
- Babies are very susceptible to measles, mumps and rubella, diseases that can cause death and serious morbidity so they must be protected as soon as possible and this can only be done with the MMR vaccine.
- Giving separate measles, mumps and rubella vaccines would leave children unnecessarily exposed and vulnerable.

Internationally, the World Health Organisation (WHO) and the following professional organisations also endorse MMR immunisation:

- UK Committee on Safety of Medicines
- UK Joint Committee on Vaccination and Immunisation
- Medical Research Council Expert Group
- United States Institute of Medicine
- American Academy of Paediatrics

A Report of the MMR Expert Group published by the Scottish Executive in April 2002 ⁽¹⁵⁾ made the following recommendations:

- More research is needed into the aetiology of autism and inflammatory bowel disease.
- Services provided for persons with Autism Spectrum Disorder (ASD) should be improved.
- The Joint Committee on Vaccination and Immunisation (JCVI) should be assisted in developing future immunisation policy and ongoing research.
- The level and quality of information available to parents of children due to be immunised should be improved.

In relation to MMR vaccine this group considered the following options:

<p style="text-align: center;"><u>RECOMMENDED OPTION</u></p>

<p><i>Administration of MMR vaccine at between 12 and 15 months with a booster at 4-5 years (in line with current national policy and international best evidence).</i></p>

**Other options considered by the committee of which NONE WERE
RECOMMENDED include:**

i) Single Antigen Vaccines

This option cannot be recommended on the basis of current scientific evidence as:

- MMR vaccine is as effective against measles, mumps and rubella as when each component is given on its own.
- The component viruses do not interfere with each other and there is no advantage in receiving the vaccines separately.
- The time between getting the different vaccines would expose the child to infection risk. There could be an increased default rate and lower uptake.
- Single vaccines are not licensed in Ireland.
- The use of separate vaccines for measles, mumps and rubella has never been used in any country in the world. There are no studies done to determine whether or not this approach is safe or effective. Likewise there is no experience in using this approach.
- MMR vaccine has been in use for 30 years and underwent rigorous studies to ensure that it is safe and effective.

ii) Compulsory Immunisation Policy

This is similar to the US model and implementation would have wide societal implications. Parental choice in relation to immunisation is important. This option is not currently recommended in Ireland.

iii) No Immunisation

This option is not recommended due the evidence of the harm that can be caused by measles, mumps and rubella infections. A “no immunisation” policy is not tenable.

iv) Deferral of Immunisation

This option is not recommended and is not in keeping with the key elements of the principles of immunisation policy. It is not supported in the scientific literature. It leaves children unprotected and at greater risk of infection for longer than is necessary.

Immunisation uptake rates for primary immunisations declined in the Region in 2001. This reflects a national trend. Negative media communication regarding MMR vaccine compounded by recent vaccine crises influenced this. Outbreaks of measles have been reported in Ireland and internationally in the past 24 months reflecting the risk associated with low immunisation uptake rates. Immunisation prevents disease and the success of the recent Meningococcal C vaccine programme is evidence of this.

The type of immunisation programme, the disease it targets and the conditions under which it is delivered may vary but the evidence in support of the cost effectiveness of such programmes is strong.

In recent years, difficulties in the recruitment and retention of staff have impacted negatively on school booster immunisation programmes. This needs to be addressed as a matter of urgency.

Following a review of the evidence and the option appraisal, (pages 31-32), the committee strongly recommend the administration of MMR vaccine at 12 –15 months with a booster at 4-5 years as recommended by the National Immunisation Advisory Committee and international best practice.

Chapter 3

Management of Immunisation Programmes in the Eastern Region

The issues considered by the Regional Committee regarding immunisation were:

1. Planning and organisation, including structures and staffing at both ERHA and AHB level.
2. Immunisation contract between AHBs and GPs for the delivery of the primary childhood immunisation programme.
3. Information Systems for immunisation surveillance.
4. Materials Management.
5. Communication Strategies /Education.
6. Disadvantaged Groups.

3.1 Planning and Organisation of Immunisation Programmes

Primary Immunisation

Since 1996, General Practitioners carry out primary childhood immunisation. In addition, AMOs undertake neonatal BCG, which is part of this programme. The uptake rates for BCG are not recorded on the RICHs system but are held manually in each CSA.

General practitioners are paid a fixed amount per child immunised. They are also paid a bonus payment if an uptake of 95% is reached in children of 24 months in their target population. However, due to difficulties experienced by AHBs in validating records and calculating bonus payments, the Department of Health and Children agreed with the Irish Medical Organisation (IMO) that bonus payments be made to GPs who achieved the average uptake level in their health board region in respect of children born between 1997 and 1999 inclusive. In the Eastern Region, this average was 63%, which is over 30% less than the WHO target of 95%.

School Booster Immunisation Programmes

The school booster immunisation programmes are currently co-ordinated and organised by SAMOs in the CSA in which the schools are located. These programmes are targeted at 1st and 2nd Class and in some instances at 11-12 year olds (MMR if not obtained at age 4 to 5 years). This programme is administered during the school year and is undertaken by teams comprising AMOs, PHNs and administration staff. The delivery of this service involves provision of class lists, transportation of vaccine and emergency equipment from CSAs by AMOs or PHNs, and collation of uptake rates. In recent years, difficulties in recruiting and retaining staff have impacted on the delivery of these programmes in the Region. In light of this and as immunisation is a proven health intervention, it is now important that it is prioritised by area medical teams.

3.1.1 Deficits with the Current Operation of Immunisation Programmes

1. The lack of an agreed general practice register poses difficulties in terms of providing practices with cohorts of children who require primary immunisation. This limits GPs' capacity in targeting their practice population requiring primary immunisation. It also impacts on the accuracy of uptake rates in each practice and estimation of bonus payments.
2. The current payment system for GPs is complex and is a disincentive to maximising uptake rates. In addition there is insufficient consideration given to GPs in deprived areas where additional input is required in encouraging parents of children to attend for immunisation, which is not always reflected in the uptake rates. However, these small incremental improvements are important and need encouragement.
3. Lists of defaulters are now being circulated to GPs by AHBs but not in a standardised manner across the Region. In addition, this practice has only been recently implemented. This practice needs to be standardised across the Region so that contingency plans can be appropriately implemented to ensure maximum vaccine coverage.
4. Proposed or planned changes to the immunisation schedules are not always circulated to health care professionals in advance.
5. No alert system exists to notify end users of vaccine shortages. They may become aware of a problem when a practice team member unsuccessfully attends to collect vaccines from the health board office. When a shortage of vaccine occurs there is often limited advice on contingency plans to be undertaken by GPs and immunisation teams in CSAs.
6. The school booster immunisation programmes have also been affected by difficulties in recruitment and retention of manpower. In one CSA in the Region, boosters are undertaken by GPs as a pilot project. This will require evaluation in the future. This pilot scheme should be used opportunistically to track those who may not have received any or incomplete primary immunisation. Presently there are difficulties in providing primary immunisation status when booster immunisation invitations are issued. These difficulties should be addressed when developing a new immunisation surveillance programme. As mentioned previously, it is now imperative that immunisation is prioritised by area medical teams.
7. Furthermore, MMR was not given in school to 4-5 year olds in one CSA. This is being addressed by the introduction of a pilot project with GPs who will undertake MMR. In addition, there are large backlogs in the school immunisation programme in other CSAs.
8. There is no regional policy in relation to follow-up of persistent defaulters

3.2 Immunisation Contract between Health Boards and General Practitioners

The immunisation contract between the health boards and General Practitioners was agreed in 1995. The Meningococcal C immunisation schedule was incorporated into the contract in October 2000. There have been no substantial changes to the contract since 1995 but there is a commitment by the DoHC for a workload review, being undertaken at presents by an independent consultant, and subsequent to this a review of payments.

There have been several problems with the GP contract including:

1. The Contract specifies that the each Health Board will compile an immunisation register from birth notification forms. There were problems in the past with the efficient transfer of this information to the health boards from maternity hospitals but this has generally been addressed and the information is being disseminated more promptly.
2. Some GPs do not return completed immunisation forms in a timely fashion. It has now been agreed that each AHB examine ways to facilitate GPs in completing forms and returning the information promptly. AHB immunisation committees are currently working on this issue. This will include the timely entering of data onto the RICHs system, the provision of up-to-date information and feedback to GPs and the efficient payment of immunisation fees to them.
3. It has been highlighted that there have been problems in relation to GPs not being paid the agreed immunisation fees in a timely fashion and this is having a negative impact on the relationship between health boards and GPs. In addition, it has also been highlighted that payment methods are complicated and inefficient with 35% of the immunisation fee taken up by the bonus payment. It is notable that GPs, particularly in areas of deprivation, are not able to reach the bonus payment for 95% coverage of their target population. This is often related to social and economic factors, which are outside the GPs' control. Hence, the uptake rates achieved in these areas do not truly reflect the work involved to reach even these lower levels. Current difficulties surrounding identification of agreed target populations because of registration problems compounds the situation especially for GPs in deprived areas.

Immunisation teams need to be strengthened at CSA level with particular emphasis placed on staff recruitment and retention and redeployment of staff if necessary.

School booster programmes must be prioritised at CSA level.

Liaison between GPs, CSAs and the Department of Public Health needs to be strengthened in particular in relation to provision of vaccinee cohorts, feedback of uptake rates, payments, training and communication regarding vaccine supplies.

A standardised policy on the follow-up of defaulters needs to be implemented across the Region.

Ongoing training for staff on immunisation issues and the importance of best practice and quality assurance needs to be prioritised. Information channels in relation to vaccine shortage, changes in immunisation programmes and new developments need to be strengthened.

3.3 Information Systems for Immunisation Surveillance

Since 1989, information on the uptake of primary childhood immunisation in the Region is held on RICHs. This was developed by the North Eastern Thames Regional Health Authority and was adopted by the Eastern Health Board (EHB) in 1989. RICHs is a DOS based system and as such has limited technological capability.

The system currently has three different components:

1. Birth Notification Module
2. Immunisation Module
3. Child Development Module

The current immunisation module was developed and incorporated into the system by the EHB. This module was piloted in CSA 9 in 1994 and implemented in 1996. A sub-module on Registration Payments was implemented in May 1996 and a sub-module on Fee Payments in October 1996.

The uptake levels for immunisation in the Region are monitored through the RICHs system and so are dependent on accurate and timely inputting of information at all stages. RICHs provides detailed analysis of immunisation uptake for the Region by antigen i.e. DTaP/IPV, Hib, Men C and MMR, birth cohort, AHB and CSA. This data is available at Regional, AHB and local level through a Vax menu and a geographical information system is used by the Health Information Unit of the ERHA to reveal uptake patterns by small area (DED). However, there is concern that the information is not being entered in an accurate and timely fashion and this needs to be addressed by each AHB. Accurate figures for immunisation uptake are very important and inputting of data should be prioritised.

An evaluation of RICHs was undertaken in 1999 ⁽¹⁶⁾ by the Department of Public Health, EHB and deficiencies were identified with the system as follows:

1. The objectives of RICHs are non-specific and difficult to evaluate.
2. There is lack of involvement of nursing and medical personnel (including GPs) in keeping the data up-to-date and accurate.
3. Notifications of births to RICHs do not contain information on the infant's GP. Information on the mother's GP, which is obtained at the first antenatal visit, is only available. While the mother's GP will most likely be that of the infant this is not always the case. In light of this, it is currently not possible to obtain lists of GP cohorts for primary immunisation from RICHs.
4. There has been a failure to incorporate all relevant information collected from the birth notification onto RICHs.

5. There is no network to facilitate the direct electronic transfer of immunisation data from GPs to central RICHs administration. Transfer of data is currently a paper-based manual system.
6. Valuable information on adverse reactions to immunisation although collected on the GP return forms is not transferred to RICHs.
7. Data transfer is slow and prone to error due to inaccuracies and incompleteness of return forms.
8. RICHs is location specific, designated by CSA. This makes it inflexible and labour intensive to operate. There is access to each of the ten CSAs individually for information purposes only. Alteration of data can only take place in the CSA where the child is resident. Given the mobility of families in the Eastern Region, there are many duplicates on RICHs and it is difficult to validate cohorts.
9. RICHs does not have a facility to record ethnic or migrant populations and socio-economic group. However, DED is recorded which allows for socio-economic differences to be assessed by area of residence.
10. RICHs does not have the facility to record BCG or school booster immunisation uptake rates. These records are all paper-based and not centralised. Consequently, analysis of this information proves difficult to compile. This was highlighted in the recent episode in relation to subpotent BCG vaccine where retrieval of records had to be undertaken manually. This had substantial resource implications and yet did not provide timely data.
11. When changes to immunisation schedules are introduced, the information system does not change in a timely manner, which impacts negatively on the timeliness and accuracy of the information produced.
12. There is no unique patient identifier to facilitate opportunistic immunisation of defaulters.
13. Use of parent-held records is not standard practice in the Region.

Since 1999, a number of these issues were addressed in particular:

1. A person was appointed with overall responsibility for RICHs in the Region.
2. In 2002, each CSA is endeavouring to put a system in place in order to produce cohorts of primary vaccinees for GPs. This involves collaboration between PHNs, SAMOs, Clerical staff Immunisation Co-ordinator and senior immunisation PHN. It is hoped to have this system in place by 2003.

3. Default lists are being issued to all GPs in the Region. However, this needs to be standardised regionally.
4. A new child health information system (CHIS) with an immunisation module is being developed for the Region

However, the aforementioned deficits (1 to 13) outlined above need to be addressed urgently. The Report from the National Review of Immunisation /Vaccination Programmes ⁽¹⁷⁾ recommends the development of a National Immunisation Information System based on either of the following options:

1. A national database directly accessible by health boards and GPs.
2. A national database linked to local databases maintained by health boards.

Until such time as a new information system is in place ongoing audit of RICHs should be prioritised and undertaken to ensure high quality, accurate data on immunisation uptake rates.

This new immunisation information system will assist in addressing issues related to:

- Electronic transfer of data between health boards, GPs and hospitals.
- Tracking of defaulters within and outside the Region by using the unique identifier.
- Improving information on demographic details e.g. ethnicity.
- Recording of BCG and booster vaccination uptake rates.
- Providing more accurate and timely data on immunisation uptake rates.

Quality assurance programmes should be implemented and data validated at regular intervals. These programmes should comprise of both internal and external quality assurance programmes.

A new information system for immunisation uptake surveillance needs to be developed and implemented as a matter of urgency.

The development of the unique patient identifier must also be prioritised.

A quality assurance system must be an integral part of the new system.

3.4 Materials Management

3.4.1 Background

Materials management in the context of immunisation relates to vaccine procurement, and supply, cold chain standards and quality control. The potency of vaccines and therefore the protection they give against disease decreases over time; this is indicated by the expiry date on the vaccine. Vaccines are also sensitive to temperature changes and manufacturers recommend storage within defined temperature range of +2°C to +8°C to ensure maximum potency until expiry date, this process is called maintaining the “cold chain”. Freezing can cause deterioration in the potency of a vaccine and may also lead to hairline cracks in the vial/pre-filled syringe allowing the potential contamination of the vaccine. Vaccine exposed to temperatures above +8°C may also lose potency or may shorten its expiry date. The effect of repeated exposures is cumulative and specific advice should be obtained from the vaccine manufacturer in the event of the recommended temperature not being maintained even for short periods. Where vaccine is exposed to temperatures outside the cold chain manufacturers may advise that the vaccine is stable +/- a shortened shelf life or that the vaccine potency can no longer be guaranteed.

3.4.2 Procurement

The Materials Management Function of the Eastern Health Shared Services (EHSS) acts as an agent of the DoHC for the purchase of vaccines for all immunisation programmes in Ireland. It seeks and collates the vaccine requirements of the 10 health boards, commences the tendering process in interfacing with the industry and signs off vaccine contracts with health boards. Presently this is a part-time function of the Central Purchasing Section and it was established at a time when the workload was considerably less than it is now.

3.4.3 Distribution

The introduction in 2001 of regulations regarding the carriage of dangerous goods by road (CDGRR) in response to the EU ADR Framework Directive has implications for the distribution of vaccines by road. In view of this, clarification is currently being sought on its application to the transport of vaccines.

Vaccine companies deliver vaccines to the country from abroad. Vaccines are then stored by the vaccine company's agent(s) in Ireland until they are ready for distribution. The ten health boards place orders for stock with the vaccine company's agent(s) and vaccine is then distributed to them by van. The storage and distribution of vaccines by such agents is regulated by the IMB, which grants a license to the agents and has the power of inspection.

In the Eastern Region, the materials management section of the EHSS based in Cherry Orchard Hospital is a licensed holder for vaccine storage for all products and distribution of some products e.g. purified protein derivative (PPD) for Mantoux tests. In addition, there are a number of depots for the storage and distribution of vaccine in

the Eastern Region i.e. health centres. Vaccines are then collected from the health board depots by or on behalf of GPs. Vaccines are also transported by immunisation teams from the health board depots to health centres, maternity hospitals and during school term on a daily basis for school immunisation programmes. Despite this, there is no agreed distribution system regionally. Clerical officers, of differing seniority and knowledge of vaccines, have responsibility for stock management at health centres. However, there is no standardised approach to this function.

A document was produced in Eastern Region in 1997 in relation to vaccine distribution in the Region. This has not been updated since. Currently, there are no national standard operating procedures (SOP) for vaccine distribution and disposal. In light of this, there is a potential gap in quality control and it needs to be addressed by the three AHBs and the ERHA. An obvious solution is to establish a delivery system based on international best practice to deliver vaccine to GPs and schools under cold chain conditions. There is no service for delivering vaccines to end users e.g. GPs and school immunisation teams for booster immunisation service.

The options for distributing vaccine include:

1. Each AHB to establish its own distribution system.
2. A central depot located in Materials Management Department, EHSS which controls the distribution system providing a service for GPs and schools in the entire Region.
3. Contracting the procurement and distribution of all vaccines to a private company which would deliver directly to the end user, or
4. The manufacturers/agents delivering the vaccine directly to the end user.

The advantages and disadvantages of the above options are outlined in Table 6.

Table 6. Option Appraisal for Vaccine Distribution System

Option	Advantages	Disadvantages
<u>Option 1</u> AHB establish own vaccine distribution system	<ul style="list-style-type: none"> • Customised for specific needs of AHB in terms of demography of Region , end users etc. • More end user friendly and accessible • More participation from end user 	<ul style="list-style-type: none"> • Varying distribution systems • Fragmented as spread over three depots • Lack of standardisation in Protocols/Quality Assurance • Less economical • Difficult to monitor vaccine use and needs across Region • Difficult to collate surveillance data for Region • Difficulty in recruiting and retaining staff • Inadequate infrastructure to maintain skill base at AHB level
<u>Option 2</u> Materials Management Department, EHSS provide distribution system for the Region	<ul style="list-style-type: none"> • Standardised protocols and quality assurance system across the Region • Fulltime dedicated Team with expertise • Ongoing training facilitated as all team on one site • More economical in terms of structural costs • Easier to mount and monitor response in emergencies • Monitoring of vaccine stock and use easier • Collation of Regional data easier 	<ul style="list-style-type: none"> • May not meet individual AHB needs as effectively • May be more difficult to implement due to many stake holders with different needs
<u>Option 3</u> Contract to Private Company	<ul style="list-style-type: none"> • Dedicated service • Standardised uniform system • Delivery to end user ensured and eliminates unnecessary tiers • Easier to monitor vaccine use • Audit by IMB 	<ul style="list-style-type: none"> • Third part involved • More expensive-needs economic analysis • Deskill HB staff • Monopoly
<u>Option 4</u> Contract to Manufacturers	<ul style="list-style-type: none"> • Dedicated service • Standardised uniform system • Delivery to end user more efficient • Regular Audit 	<ul style="list-style-type: none"> • Third party involved • Cost analysis needed • De-skill health board staff • Monopoly

A regional multidisciplinary group comprising a specialist in public health medicine, a pharmacist, a health economist and representatives from senior management should be convened to define the gold standard for a vaccine distribution system in the Region following appraisal of the options outline in Table 6. It is imperative that a regional system is agreed and that whichever option is chosen meets quality standards and is based on best practice. Strong consideration should be given to Options 3 and 4.

3.4.4 Stock Management and Control

At regional level there are ad hoc arrangements in place in relation to stock control. In addition, stock management systems are not adequate in health centres in the Region. The problems associated with the distribution system in the Region are outlined as follows:

1. The current system of vaccine collection from health board depots (health centres) by end users may not always conform to cold chain standards. It's not always possible to verify if best practice takes place as the cold chain, batch numbers and expiry dates are not always recorded.
2. Current practices at CSAs do not always correlate with best practice in relation to ordering, invoicing and certification processes.
3. There are no designated trained individuals solely responsible for vaccine management and distribution. Staff ordering vaccine and managing stock are of varying seniority.
4. Current procedures do not ensure that every unit of vaccine is always readily traceable and verifiable by batch number at every stage of the supply chain from the manufacturers agent to the end user.
5. Emergency stock (contingency supplies) is kept at the central depot. An early warning system urgently needs to be put in place to ensure this stock is always maintained and that end users are alerted of vaccine shortages.
6. There is no reliable collect information system for stock management.
7. In addition, as current arrangements allow GPs to collect vaccines from AHB depots at specified intervals only, it is likely that excessive numbers of vaccine are collected which do not get used by the expiry date. This will lead to wastage.

3.4.5 Cold Chain Standards

Attention to maintaining correct temperatures during storage and transportation of vaccine is a major task for health workers.

There are three major elements in the cold chain system.

I) Personnel:

- Education and training

- a. Staff should understand the importance of the cold chain.
- b. Management of stock including ordering, rotation, recording batch numbers, monitoring expiry dates, ensuring sufficiency, managing unused vaccine and developing early warning systems regarding shortages is needed.
- c. Obtaining and acting on the feedback from end users.
- d. Ensuring clear lines of accountability and responsibility.

ii) Equipment:

- a. Ensuring quality of the vaccine to the end user.
- b. Ensuring correct temperatures during storage and distribution.
- c. Refrigerators, cool boxes, icepacks and temperature gauges.
- d. Transport requirements.

iii) Procedures:

- a. Implementation of SOP systems.
- b. Delivery and cold chain maintenance.
- c. Stock control policy.
- d. Stock ordering policy.
- e. Stock Requisitions.

Appendix 3 outlines the mechanism and cost for maintaining the cold chain during transport of Meningococcal C vaccine for the Meningococcal C Immunisation Programme in the Northern Area Health Board (NAHB).

3.4.6 Deficiencies in the Cold Chain

The main deficiencies in the cold chain system are:

1. Repeated opening of fridges.
2. Over packing of fridges which reduces the circulation of cold air.
3. Inadequate contingency plans when power cuts arise.
4. High temperatures during storage and transport.
5. Exposure of vaccine to freezing temperatures.
6. Refrigerators without thermometers.

7. Failure to take and record refrigerator temperatures regularly.
8. Storage of drugs, food and specimens with vaccines.
9. Failure to discard unused vaccine after sessions at ambient temperature (requirements as indicated for specific vaccines).

A multidisciplinary team should be convened to appraise the options outlined in Section 3.4.3 prior to choosing the most effective and efficient vaccine distribution system. A regional system is required and strong consideration should be given to Options 3 and 4.

SOPs should be developed and implemented across the Region to ensure standardisation of practice in relation to vaccine distribution and disposal.

In order to ensure that all three elements of the cold chain reach best practice standards, a quality assurance system should be implemented. This will involve risk management protocols together with internal and external audit procedures. Regular systematic quality checks will be critical to ensuring and maintaining an effective vaccine delivery system.

3.5 Communication

Communication of accurate, reliable and positive information on the benefits and risks of immunisation is critical to achieving and maintaining high immunisation uptake rates. This requires a multifaceted approach as several information providers must supply consistent information to many different groups i.e. parents/guardians, healthcare professionals, the public and the media. It is important that the benefits of vaccines in preventing a range of infectious diseases and their potential serious complications are communicated effectively.

A survey undertaken by the National Review Group of Immunisation/vaccination Programmes¹⁷ indicates that provision of accurate and reliable information is key to generating maximum confidence in immunisation programmes. Other contributory factors included the mode of communication, the media perspective, and professional's involvement in imparting information, well planned and organised communication strategies and adequate IT networks for dissemination of information.

Information is best relayed to professionals through efficient IT networks and well-organised educational sessions. This should be done in advance of changes to the immunisation schedule or in relation to any controversial immunisation issues.

The media plays a major role in determining public perception in relation to immunisation programmes. Well-organised media campaigns will provide information on immunisation, highlight the issues and counter negative/false information. Currently, the majority of media publicity focuses on the risks from vaccines in particular the MMR vaccine. Sustained action needs to be taken by health professionals to counterbalance this and to highlight the benefits of the vaccine in providing protection against infectious diseases. In this context an immunisation communications strategy should:

1. Promote the benefits of immunisation in a pro-active manner.
2. Give information on the vaccine preventable diseases–risk communication.
3. Address negative publicity regarding immunisation–using an evidence based approach.
4. Provide accurate, reliable, timely and positive information about immunisation to the public, the media, health professionals, and statutory and voluntary organisations.

Information and its dissemination must be uniform to all professional disciplines and consistent with that supplied to parents and the public. This information should be:

- a. User friendly.
- b. Clear and concise.
- c. Evidence based.
- d. Regularly updated.
- e. Address negative publicity.
- f. Address worries and explains risks.

Research in the Eastern Region is being undertaken to inform communication strategies, track immunisation interventions and produce information materials. Focus groups will also provide insight into parental knowledge of and beliefs and attitudes towards childhood immunisation (Appendix 4).

3.5.1 Deficiencies in Current Immunisation Communication Mechanism in Eastern Region include:

1. Poor co-ordination of communication of vaccine issues to both the public and professionals.
2. Information on benefits of vaccine, risks from diseases and changes in immunisation schedules is not disseminated to parents in a standard manner across the Region.
3. The mechanism for communicating vaccine shortages, changes in immunisation schedule and controversial issues regarding vaccines is not satisfactory and does not meet the needs of professionals and the public
4. Information leaflets on 4-in-1, 5-in-1 need to be updated at both regional and national levels. There are no information leaflets available on Td, booster both regionally and nationally.
5. More innovative approaches are needed to meet the needs of those with poor English and poor literacy skills.
6. Media especially local radio and newspapers is not optimised to communicate the benefits of immunisation and the risks from vaccine preventable diseases.
7. Educational sessions for professionals are infrequent, on an ad-hoc basis and not proactive.

Information on the risks of disease, benefits of immunisation and changes in immunisation schedules is not disseminated to the public in a standard manner in the Region. The media is not optimised as a communication channel.

One-to-one consultations with healthcare professionals must be optimised to promote immunisation.

Ongoing training of relevant healthcare staff on immunisation issues needs to be prioritised.

3.6. Disadvantaged Groups

GPs vaccinate traveller children as with all other children and their immunisation records are documented in the RICHs system. In addition, in the Region, there is a mobile traveller's unit, which offers primary childhood immunisation to traveller children. Information from the mobile clinic indicates that 72% of the target population completed primary immunisation (5-in-1) and MMR and a further 23 % are in the process of completing primary immunisation. No information is available on the remaining 5%. There are 1, 400 families in the Region and 4,000 children under the age of 16 years (Verbal Communication with Traveller's Mobile Unit).

General Practitioners undertake immunisation of asylum seekers. Anecdotally, from speaking with GPs it is felt that the majority of asylum seekers are proactive in seeking immunisation. However, immunisation uptake rates in this group cannot be quantified, for though they are recorded on RICHs, data on ethnicity is not. However, a new child health information system/national immunisation information system is being developed for the Region, which will address this issue.

It is notable that the vast majority of “black spot” areas are areas of social and economic deprivation, where competing priorities impact on the uptake rates. It is vital that primary care and community services in these areas are resourced sufficiently with regard to the provision of immunisation programmes. It is evident that the traveller’s mobile unit obtains positive outcomes in relation to immunisation uptake levels. Similar models should be applied to these areas and groups who are difficult to access with regard to immunisation programmes. In addition, the importance of providing Hepatitis B vaccine to children with intellectual disability needs to be prioritised (Appendix 5).

Chapter 4

4.1 Conclusions

The importance of immunisation as a public health issue is beyond question. However at both regional and national levels there are a number of areas that need to be addressed to ensure the smooth operation of immunisation programmes. The low immunisation uptake rates in the Eastern Region are of particular concern and need to be addressed as a matter of priority.

In the Eastern Region, manpower issues have meant that children in certain CSAs have not received their MMR boosters in junior school. In other CSAs the uptake rates are as high as 95.7% showing how successful the captive audience in the school setting can be. We need to ensure that all children in the region are offered age-appropriate immunisation as recommended by the National Immunisation Advisory Committee. Immunisation should be prioritised in areas with staff shortages so that staff are deployed from other areas of work to ensure that no geographical barriers to immunisation exist within the Eastern Region. Another issue is the Td booster, which, although recommended nationally for all 12-14 year olds, is not being given in the region. This issue needs to be addressed as a priority.

A review of the RICHs system, which is currently used in the Eastern Region, has revealed a number of deficits in this system, which leads us to query the accuracy of the immunisation rates which it produces. Duplication of names in the database means that the accuracy of the denominator used in the calculation of uptake rates is falsely elevated. This leads to an underestimation in uptake rates. In addition, RICHs does not have the facility to record BCG and booster vaccination uptake rates resulting in difficulties with relation to estimation of accurate uptake rates. The development and implementation of high quality information system for immunisation is critical to the success of the immunisation programme in the Region. The National Immunisation Steering Committee has recommended the introduction of a National Immunisation Database. The development of the CHIS in the Region should link in with this development.

In relation to the distribution system for vaccines to end users within the Eastern Region, it is not always possible to verify if best practice in relation to the cold chain takes place. In light of this, it is recommended that SOPs for vaccine distribution and disposal are developed and implemented across the Region. It is important to ensure that practices with regard to the cold chain conform to best practice standards laid down internationally. Current procedures do not ensure that every unit of vaccine is always readily traceable and verifiable by batch number at every stage of the supply chain from the manufacturers agent to the end user. Health boards do not always flag vaccine shortages to the end user. A regional vaccine distribution system should be implemented following an appraisal of all the options by an expert group. Strong consideration should be given to options 3 and 4 as outlined previously (p. 43).

The role of communication is an essential one where immunisation is concerned. Information must be provided for parents to ensure that they can make informed decisions about whether or not to immunise their children. Staff working in the area

of immunisation must be kept up-to-date about vaccine developments so that they can answer parents' queries about immunisation. A pro-active approach to the benefits of immunisation should be encouraged in all those involved in this area. The Department of Public in the Eastern Region and the AHBs will work with other agencies such as the Health Boards Executive (HEBE) in areas such as health education and health promotion regarding immunisation.

Improving immunisation uptake rates must be a priority for the Region and must be resourced accordingly.

There is some overlap between the following recommendations and the recommendations of the National Immunisation Steering Committee. The regional immunisation committee has considered the best ways to support and endorse the recommendations of the National Immunisation Steering Committee within the Region.

Chapter 5

5.0 Recommendations

The following are the recommendations of the Regional Immunisation Committee of the ERHA. The WHO recommends immunity levels of around 95% to prevent outbreaks of infectious disease. While it is the aim of the committee to attain such levels, a realistic approach must be adopted in light of the current drop in MMR uptake. The uptake of MMR vaccine decreased in the Region in 2001 following publicity about speculation that the MMR vaccine might be linked with autism and Crohn's disease. These concerns have been investigated by the WHO, the National Immunisation Advisory Committee and others, and have been firmly refuted.

5.1 Planning and Organisation of Immunisation Programmes

Recommendations

1. The ERHA Immunisation Committee should continue to advise on planning, implementation and evaluation of all current and new immunisation programmes in the Region.
2. A Specialist in Public Health Medicine with special responsibility for immunisation should be appointed in the Department of Public Health in the Region to ensure that all aspects of the immunisation services are implemented.
3. Multidisciplinary immunisation committees already established in each AHB should continue to ensure that all efforts are made for optimal functioning of immunisation programmes in their AHB.
4. Each AHB/CSA should prioritise immunisation at planning and operational level. In this context, all efforts should be employed to make staff available for this function.
5. An immunisation co-ordinator should be appointed to each AHB as recommended in the National Review of Immunisation/Vaccination Programmes
6. Each CSA should prioritise timely delivery of school booster immunisation programmes to 5-6 year olds i.e. DTaP/IPV, MMR and 12-14 year old i.e. Td. This may involve staff redeployment. The Meningitis C programme was perceived as a successful model. Consideration should be given to using a similar model for school booster programmes.
7. A regional policy should be developed and implemented for follow-up of defaulters and for areas with low immunisation uptake rates. Particular attention should be given to ensuring maximum uptake.

8. Each GP in the Region should be furnished with a list of his/her cohort of children for primary immunisation by the relevant AHB/CSA in order to facilitate the administration of the primary immunisation programme and to accurately estimate the uptake rates for the Region and for each practice, This has currently commenced in the Region through the co-operation of PHNs but must be given ongoing prioritisation. Consideration should be given to obtaining this information in hospital at time of birth registration.
9. Each AHB/CSA should ensure that all information returned by GPs in relation to immunisations is promptly inputted onto the information system and that the relevant payments and information are disseminated in an efficient and timely manner.
10. A regional policy should be developed and implemented for follow-up of defaulters and for areas with low immunisation uptake rates. Effective operation of such a policy would not be possible without having the following structures in place:
 - Facility to provide GPs with cohorts for primary vaccination through collaboration with PHNs and improved information systems.
 - Facility to provide GPs with monthly defaulter list in a timely manner.
 - Timely return of forms by GPs and timely payments for same
 - Improved information system with more rigorous quality control measures in place to ensure elimination of duplicates and more reliable, timely and accurate data.
 - Sufficient resources in particular manpower and effective distribution system.
 - Provision of primary immunisation status to GPs when booster immunisation invitations are issued in order to use the opportunity to target those who have not completed primary immunisation.
 - When these structures are in place, all efforts to follow-up should be made by the GP, PHN and SAMO. In situations, where these efforts fail, mop-up clinics and mobile units should be considered. The role of nurse practitioners in administering vaccines in these situations should also be considered.
11. Secondary Immunisation clinics should be established in Children's Hospitals in the Region where children who have contraindications, can be referred for immunisation in the hospital setting.
12. Ongoing evaluation and review should be undertaken following implementation of recommendations in order to monitor impact.

5.2 Immunisation Contract between Health Boards and General Practitioners

Recommendations

1. A review of the immunisation contract between DoHC and GPs in respect of providing Primary Immunisation should be expedited in order to address ongoing issues in relation to immunisation programmes. This would assist in resolving some of the problems, which currently impede attainment of optimal childhood immunisation uptake rates.
2. Each AHB/CSA should review the list of GPs participating in the immunisation contract in their board and develop systems and work practices to optimise relationships between the AHBs/CSAs and GPs. A mechanism, which is agreeable to both parties, should be developed and implemented to monitor compliance with the terms of the contract.

5.3 Information Systems for Immunisation Surveillance

Recommendations

1. The development and implementation of a new information system must be a priority for 2003. In the interim the number of administration staff working on the current system (RICHS) should be increased to ensure that:
 - Inputs to the immunisation surveillance system are accurate and timely.
 - Returns and payments to GPs are accurate and timely.
 - Tracking and follow-up of defaulters or those who move residence is monitored.
 - 4-in-1 and 5-in-1 input forms are used for recording primary immunisation.

The system should facilitate the provision of defaulter lists to GPs and should be evaluated on an ongoing basis.

2. This new system should incorporate the facility to record uptake rates for neonatal BCG and school booster vaccinations. This should be given high priority, as currently these uptake rates are not computerised in the Region.
3. Processing of all birth notifications should be standardised, regardless of mother's marital status.
4. All maternity hospitals and GPs should be electronically linked to the health board headquarters both at AHB and regional level.

5. GPs should be encouraged to return accurate and complete data on immunisation uptake.
6. Updated figures must be produced on a regular basis with dissemination of the information to all involved in the immunisation scheme especially the GPs.
7. Quality assurance protocols should be implemented immediately to ensure that the information provided by RICHs is accurate and timely.
8. Information on migrant and ethnic populations should be available
9. Local analysis by small area (DED) should be available in order to target “blackspots”.
10. Ongoing training of staff working on the immunisation surveillance system should be prioritised.
11. Every effort should be made to provide each child with a unique identifier.
12. Parent held records should be introduced as soon as possible. The use of electronic parent held records should be considered which conforms to the requirements of the forthcoming National Health Information Strategy and harmonises with the Primary Care Strategy.
13. Standardised surveillance documentation should be developed and agreed centrally. Change of address and surname forms should be available and used in all areas. This would reduce the number of inaccuracies of name, address and date of birth on the system.
14. Details of all children immunised in the hospital setting should be reported to the SAMO of the CSA where the child resides so that they can be recorded on RICHs and be included in the uptake statistics for the Region.

5.4 Materials Management

Recommendations

1. All vaccines should be distributed, received and stored to the end user with a verifiable cold chain.
2. The options for distributing vaccine to end users are as follows:
 - a) Each AHB to establish its own distribution system.
 - b) A central depot located at Materials Management Department, EHSS that controls the distribution system in the entire Region.

- c) Contracting the procurement and distribution of vaccines to a private company, which would deliver directly to the end user.
- d) The manufacturers/agents delivering the vaccine directly to the end user.

Serious consideration should be given to the benefits of Options 3 and 4.

- 3. A computerised process for stock distribution and control is needed regionally and locally.
- 4. A Regional expert group should develop Standard Operating Procedures (SOPs) for vaccine distribution and disposal based on best practice in order to ensure ongoing quality assurance.
- 5. This quality assurance system should systematically verify continuous maintenance of the cold chain for all vaccines at all stages during transportation and storage. Distribution and storage should comply with WHO standards.
- 6. Transport of vaccines and emergency equipment in particular oxygen should meet the ADR standard.
- 7. A computerised process for stock distribution and control is needed regionally and locally. This would enable the management of vaccine stock at local level to be enhanced. At health board level records should be maintained to provide evidence of compliance with the labelled storage recommendations.
- 8. National Vaccine Users Group to liaise with end users in relation to issues encountered with vaccine products.
- 9. GPs and CSA immunisation teams should forecast vaccine needs and inform the relevant person in a timely manner of their needs. All end users including GPs and school immunisation teams should provide details of their vaccine needs in a timely manner.

5.5 Communication

Recommendations

- 1. Information on immunisation for the public should be available on the ERHA web site, in health centres (print and visual), during antenatal classes, in hospitals, in GP surgeries and in non-health care facilities e.g. libraries etc. This information should be:
 - a. Balanced, complete and in multiple formats.
 - b. Updated at regular intervals.
 - c. Readily accessible in particular to those with most need.
 - d. User friendly.
 - e. Misinformation should be quickly addressed.

2. Information on childhood immunisation should be circulated on a regular basis to all crèches and schools in the Region.
3. Information materials should be customised to meet the needs of those with language difficulties and poor literacy skills. They should be made available in print, audio, video and electronic format. Consumer representatives should be involved in compiling these materials.
4. The promotion of immunisation through one-to-one communication with parents should take place in all relevant health care settings.
5. A cascade system of information for health professionals should be implemented especially in relation to changes in the immunisation schedule and any controversial immunisation issues.
6. Back to school campaigns should be launched to promote the benefits of childhood immunisation, both primary and booster programmes.
7. Ongoing frequent training should be provided to all relevant health professionals including:
 - Lectures on the benefits, risks, policy of immunisation.
 - Skills maintenance.
 - On-going continuing professional development.
 - Media training.
8. A strategy for media management of immunisation issues should be developed and implemented at both AHB and Regional levels. This strategy should aim to counter misinformation and highlight the benefits of immunisation in preventing disease. The regional immunisation committee and each AHB committee should work with their respective communication departments to ensure all opportunities to promote immunisation are fully used.
9. Encourage all staff including midwives, PHNs, GPs, Public Health doctors and community pharmacists to act as advocates for immunisation.
10. Ensure that all relevant health board staff are aware of and implement health board policy in relation to immunisation and its benefits. In addition, staff should be supported in maintaining their knowledge base and provided with up to date scientific evidence based information on immunisation matters.
11. Research should be undertaken on the strengths and weaknesses of current communication strategies. Annual surveys and focus group research with parents of young children should take place to assist in identifying the beliefs and attitudes of parents towards childhood immunisations, their knowledge of immunisations, their experiences and preferred information sources.

12. Communication between health boards, service providers and the IMB in relation vaccine licensing, safety and reporting adverse events should be improved.

5.6 Disadvantaged Groups

Recommendations

1. PHNs and GPs should target these groups as priority for primary immunisation.
2. Information on vaccine preventable diseases should be provided to this group taking into consideration language and cultural differences.
3. Back to school campaigns should be launched to promote the benefits of childhood immunisation, both primary and booster programmes.

5.7 Recommendations in relation to MMR

1. The committee strongly recommends the administration of MMR vaccine at 12 to 15 months with a booster at 4-5 years as recommended by the National Immunisation Advisory Committee and best international practice.
2. Parents should receive regular information on the problems associated with measles mumps and rubella infection in comparison with the risks of immunisation.
3. Negative media coverage of MMR should continuously be counteracted with evidence-based information in relation to the benefits.
4. The recently completed ERHA report on autism, which recommends ongoing research, improving services and involving parents of children with Autism Spectrum Disorder (ASD) in such activities should be implemented.
5. A database of people with ASD in the Eastern Region should be established.
6. It is apparent that doubt has been planted in parents' minds in relation to the safety of MMR vaccine. Research needs to be undertaken to explore the psychological impact of such messages and how to overcome this.

Chapter 6

Costs of Recommendations

The cost of implementing the above recommendations in the Eastern Region are outlined as follows:

The following is the funding required by the ERHA and the AHBs in order to meet the recommendations of the National Review of Immunisation/Vaccination Programmes. While, the estimated costs are large, it must be considered that the ERHA covers approximately one third of the Irish population and that in order to reach uptake levels equivalent to other European countries, this level of investment will be required. This plan covers requirements for the ERHA and three AHBs i.e. East Coast Area Health Board (ECAHB), Northern Area Health Board (NAHB) and South Western Area Health Board (SWAHB).

Planning, Organisation & Delivery of Vaccine Programmes

Department of Public Health, ERHA

• 1 WTE Specialist in Public Health Medicine	Pay	€79,492.50
	Non-Pay	€5,897.50
• 1 WTE surveillance scientist	Pay	€37,679.00
	Non-Pay	€4,246.60
	Total	€127,315.60

Area Health Boards

• 1 fulltime immunisation co-ordinator for each AHB (3 Senior Area Medical Officer Salaries)	Pay	€189,988.80
	Non Pay	€ 47,497.20
	Total	€237,486.00

(This is the cost if the post is filled by a SAMO, it is acknowledged that this post may be filled by other disciplines)

• 1 WTE Senior Pharmacist (ERHA) to monitor vaccine/cold chain requirements	Total	€55,000
---	-------	---------

Support to Immunisation Co-ordinators Post and Regional Implementation Team

1 Grade III per AHB	Pay	€76,164.60
	Non-Pay	€19,041.15
	Total	€95,205.75

Clerical Support for Health Professionals in Community Services Areas (CSAs)

East Coast Area Health Board

3x Grade IV for each CCA

Pay	€91,094.19
Non-pay	<u>€22,775.64</u>
Total	€113,869.83

Northern Area Health Board

3x Grade IV for each CCA

Pay	€91,094.19
Non-pay	<u>€22,775.64</u>
Total	€113,869.83

South Western Area Health Board

4x Grade IV for each CCA

Pay	€121,458.92
Non-pay	<u>€30,367.52</u>
Total	€151,826.44

Cost for School Immunisation Programme (P. 27) €950,206.60

Black spot initiative (Mechanism to be developed at local level)

This will be needed to improve uptake of primary childhood immunisation uptake rates in areas identified as “blackspots”, mainly focused around the north and south inner city areas.

NAHB	€120,000
ECAHB	€100,000
SWAHB	<u>€50,000</u>
Total Cost, ERHA	€370,000

This funding would cover the cost of extra multidisciplinary immunisation teams, mobile units, accommodation costs, medical practitioners fees and communication materials.

Information Systems

Department of Public Health Funding Requirements

Funding for programming in order to export data from (RICHS/CHIS) to the Eastern Regional Health Atlas to allow routine and ongoing monitoring of immunisation uptake rates by AHB, CCA and DED €10,000

Area Health Boards

IT maintenance €35,000 per AHB	Total	€105,000
--------------------------------	-------	----------

GP Registration

IT interim measures to initiate GP registration to provide GP cohorts for primary immunisation €15,000 per AHB

Total	€ 45,000
-------	----------

<i>Total IT Costs</i>	€160,000
------------------------------	-----------------

Communication Strategy

Staff Training and Media	Eastern Region	€200,000
--------------------------	----------------	----------

Promotional Material/Leaflets/Videos	AHB (€10,000)	<u>€ 30,000</u>
--------------------------------------	---------------	-----------------

<i>Total</i>	€230,000
---------------------	-----------------

Materials Management

Cold chain management, transport and staffing for 3 AHBs	€750,000
--	----------

Research

Funding for a qualitative research project on parental attitudes and issues relating to primary childhood immunisation for the entire Eastern Region. The aim of this in-depth project is to highlight positive factors associated with the current system and also to identify barriers to uptake of primary childhood immunisation. The methodology is designed to be flexible and repeatable, so as to identify emerging trends in parental attitudes and behaviour.

Costings

- | | |
|--|----------------|
| • Ongoing Research | €20,000 |
| • Focus Group Expenses (Accommodation & Equipment) | € 6,000 |
| • Transcribing | <u>€ 4,000</u> |
| Total | €30,000 |

Other Development Costs

Risk Management systems/quality assurance per AHB	<u>€ 30,000</u>
Total	€ 90,000

This would include funding for evaluation of current systems by external auditors, expert advice on improvement, manpower, materials, technology and training.

**Summary of Costs for New Developments relating to the National Review of
Immunisation/Vaccination Programmes in the ERHA.**

No.	Item	Total Cost €
1	1 WTE Public Health Specialists	85,390.00
2	3 WTE Immunisation Co-ordinators	237,486.00
3	1 WTE Surveillance Scientist	41,925.60
4.	1 WTE Senior Pharmacist	55,000
5.	Clerical Staff <i>(as per document above)</i>	474, 771.85
6.	School Immunisation Pgme (P.27)	950,206.60
7	Blackspot Initiative	370,000.00
8.	IT Requirements	160,000.00
9	Communication Requirements	230,000.00
10.	Materials Management	750,000.00
11.	Research Project	30,000.00
12.	Risk Management Systems	90,000.00
	Total	3,474,780.05

Costings were prepared by:

Dr. Joan O'Donnell, Specialist in Public Health Medicine in consultation with Dr. Marie Laffoy, Director of Public Health, ERHA, Dr. Diana Kiely, A/Immunisation Co-ordinator, East Coast Area Health Board, Mr. Gerry Hanley, Operations Manager, Northern Area Health Board and Ms. Patricia Garry, A/Immunisation Co-ordinator, South Western Area Health Board, Mr. Jim Breslin, Senior Commissioner, ERHA and Ms. Karen Burke, Service Planner, ERHA.

Chapter 7

References

1. National Immunisation Committee of the Royal College of Physicians of Ireland. Immunisation Guidelines for Ireland, 2002. Dublin, RCPI.
2. National Immunisation Committee of the Royal College of Physicians of Ireland. Measles, Mumps and Rubella: Frequently Asked Questions. 2002. Dublin, RCPI.
3. Canadian Immunisation Guide, Fifth edition 1998, Health Canada
4. World Health Organisation.
[URL:http://www.vaccinealliance.org/press/press_econ.html](http://www.vaccinealliance.org/press/press_econ.html)
5. Demicheli V, Jefferson T. Economic aspects of vaccination Vaccine 1996; 14(10): 941-943.
6. Szucs T. Cost-benefits of vaccination programmes. Vaccine 2000; S49-S51.
7. HIPE/Casemix 2000.
8. Shiell A, Jorm L R, Carruthers R, Fitzsimons G J. Cost-effectiveness of measles outbreak intervention strategies. Australian & New Zealand Journal of Public Health 1998; 22(1): 126-132
9. Pelletier L, Chung P, Duclos P, Manga P, Scott J. A benefit-cost analysis of two-dose measles immunisation in Canada. Vaccine 1998; 16(9/10) 989-9967.
10. Ekwueme DU, Strebel PM, Hadler SC, Meltzer MI, Allen JW, Livengood JR. Economic evaluation of use of diphtheria, tetanus, and acellular pertussis vaccine or diphtheria, tetanus, and whole-cell pertussis vaccine in the United States, 1997. Arch Pediatr Adolesc Med 2000; 154(8) 797-803.
11. Jefferson T. Do vaccines make best use of available resources? (In other words are they cost-effective?). Vaccine 1999; S69-S73.
12. Jimenez FJ, Guallar-Castillon P, Terres CR, Guallar E. Cost - benefit analysis of Haemophilis influenza type b vaccination in children in Spain. Pharmacoeconomics, 1999; 15 (1) 75-83.
13. Cotter S, Ryan F, Hegarty H, Mc Cabe T, Keane E. Immunisation: The views of parents and health professionals. Department of Public Health, May 2002.
14. Oireachtas Joint Committee on Health and Children. Report on Childhood Immunisation, 2001.

- 15. Scottish Executive. Report of MMR Expert Group. April 2002.**
- 16. Department of Public Health. Evaluation of RICHs System. Report, Eastern Health Board, 1999.**
- 17. National Review Group of Immunisation/ vaccination Programmes. Report of National Steering Committee. Dublin: The Office for Health Gain. 2002.**
- 18. Centre for Communicable Disease Control and Prevention. Updated Guidelines for Evaluating Public Health Surveillance Systems. Recommendations from the Guidelines Working Group. MMWR 200; 50:No. RR-13.**

Chapter 8

Appendices

Appendix 1: Immunisation Uptake Rates in Children 12 and 24 months in the Eastern Region, 2001 and Q1, 2 2002.

The following tables outline immunisation uptake rates for the Eastern Region in 2001 and for quarters 1 and 2, 2002.

**Table 1: Quarter 1 2001-Immunisation Uptake Rates in Children:
12 and 24 months**

CSA	% Uptake at 12 months Cohort born 01/01/2000-31/03/2000					% Uptake at 24 months Cohort born 01/01/1999-31/03/1999				
	No. in Cohort	DTaP ₃	Hib ₃	OPV ₃		No. in Cohort	DTaP ₃	Hib ₃	OPV ₃	MMR ₁
1	368	70.9	72.3	72.8		379	79.9	83.1	83.6	83.6
2	371	58.8	59.0	58.8		357	77.6	78.2	78.2	72.8
3	367	58.9	65.8	59.1		300	74.0	75.7	75.3	66.0
4	561	62.7	65.8	65.1		559	75.7	78.5	79.1	76.7
5	546	62.8	63.0	63.0		560	80.5	81.8	82.3	75.5
6	593	69.8	70.3	70.3		649	77.8	77.8	79.5	72.1
7	393	58.3	59.3	59.3		412	75.5	75.0	75.5	73.8
8	741	76.5	78.4	77.7		723	85.5	87.8	87.8	85.3
9	736	71.7	73.0	73.2		682	81.8	83.1	83.3	79.5
10	436	73.6	68.8	68.7		446	81.2	84.5	84.5	82.3
Total	5,112	67.5	68.8	68.7		5,067	79.5	81.1	81.5	77.0

**Table 2: Quarter 2, 2001,-Immunisation Uptake Rates in Children:
12 and 24 months**

CSA	% Uptake at 12 months Cohort born 01/04/2000-30/06/2000					% Uptake at 24 months Cohort born 01/04/1999-30/06/1999				
	No. in Cohort	DTaP ₃	Hib ₃	OPV ₃		No. in Cohort	DTaP ₃	Hib ₃	OPV ₃	MMR ₁
1	411	60.6	61.3	60.3		410	82.0	84.6	84.9	79.8
2	413	45.5	45.8	45.5		409	79.2	79.2	79.0	67.2
3	333	38.7	38.7	38.4		323	78.0	78.6	78.6	64.4
4	540	30.4	31.7	31.1		508	76.4	79.5	80.5	68.9
5	618	48.1	49.0	47.7		586	79.4	79.9	80.2	66.4
6	650	57.8	59.9	59.2		718	77.6	77.4	78.1	61.0
7	448	49.1	49.1	49.1		411	74.2	74.0	74.5	47.9
8	744	64.5	65.1	64.1		795	86.3	87.9	88.2	64.4
9	774	58.9	59.9	58.9		661	83.2	85.6	86.1	74.9
10	449	57.2	59.2	59.2		438	82.9	86.5	87.4	76.3
Total	5,380	52.3	53.3	52.6		5,259	80.4	81.8	82.2	67.0

**Table 3: Quarter 3, 2001,-Immunisation Uptake Rates in Children:
12 and 24 months**

	% Uptake at 12 months Cohort born 01/07/2000-30/09/2000					% Uptake at 24 months Cohort born 01/07/1999-30/09/1999				
CSA	No. in Cohort	DTaP ₃	Hib ₃	OPV ₃ / IPV ₃		No. in Cohort	DTaP ₃	Hib ₃	OPV ₃ / IPV ₃	MMR ₁
1	397	64.5	66.0	65.0		414	84.3	85.7	86.0	73.4
2	367	45.5	45.8	44.1		391	73.9	74.9	74.9	59.6
3	496	42.7	42.5	41.9		435	64.6	66.2	66.0	43.4
4	614	51.6	51.6	50.7		618	74.9	77.5	77.5	63.1
5	620	58.5	59.5	56.9		613	75.4	75.9	76.7	59.7
6	679	63.6	63.9	63.5		683	72.6	71.7	73.2	55.3
7	442	49.3	50.2	47.3		411	73.7	71.8	74.2	43.3
8	810	70.1	71.4	69.3		826	83.7	85.0	84.9	55.9
9	825	68.6	69.7	69.2		772	80.4	82.9	82.9	66.2
10	423	68.8	69.0	69.0		388	83.0	86.3	87.1	72.9
Total	5,673	59.8	60.4	59.2		5,551	77.0	78.2	78.7	59.3

**Table 4. Quarter 4, 2001,-Immunisation Uptake Rates in Children:
12 and 24 months**

	% Uptake at 12 months Cohort born 01/10/2000-31/12/2000					% Uptake at 24 months Cohort born 01/10/1999-31/12/1999				
CSA	No. in Cohort	DTaP ₃	Hib ₃	IPV ₃		No. in Cohort	DTaP ₃	Hib ₃	OPV ₃ / IPV ₃	MMR ₁
1	372	68.8	69.1	68.8		441	83.2	83.9	84.4	73.7
2	341	51.3	51.6	51.3		350	71.1	72.0	72.6	54.0
3	437	36.6	36.6	36.6		409	70.4	70.9	71.6	47.2
4	589	51.1	51.8	51.1		572	76.2	78.3	78.0	58.7
5	592	55.6	56.9	55.6		577	76.1	77.1	76.9	61.0
6	678	64.9	65.5	64.9		660	75.2	76.2	76.2	58.3
7	400	52.8	53.5	52.8		419	67.3	67.3	68.0	43.2
8	785	72.9	74.0	72.9		737	80.9	83.2	82.4	60.7
9	798	60.7	62.4	60.7		817	78.1	80.5	80.8	65.7
10	377	70.6	71.9	70.6		417	78.4	82.0	82.7	66.7
Total	5,369	59.5	60.4	59.5		5,399	76.3	77.8	78.0	59.7

**Table 5. Quarter 1, 2002,-Immunisation Uptake Rates in Children:
12 and 24 months**

	% Uptake at 12 months Cohort born 01/10/2001-31/3/2001							% Uptake at 24 months Cohort born 01/01/2000-31/3/2000						
CSA	No. in Cohort	DT ₃	P ₃	Hib ₃	IPV ₃	Men C		No. in Cohort	DT ₃	P ₃	Hib ₃	Polio	Men C	MMR ₁
1	363	73.5	71.9	72.7	73.3	71.9		398	75.8	74.1	75.6	75.9	74.6	66.8
2	274	65.4	65.4	65.7	65.3	64.2		320	73.1	73.1	72.8	73.8	69.1	55.9
3	461	26.0	26.0	25.6	18.7	24.9		459	65.0	65.0	64.9	64.3	70.2	36.6
4	602	62.2	62.0	62.5	57.6	62.0		605	75.0	73.6	76.2	76.2	75.0	58.3
5	605	64.0	62.6	64.0	62.0	61.0		582	74.0	73.2	74.1	74.2	74.1	57.2
6	601	70.7	70.2	70.4	69.9	63.2		589	75.0	75.0	75.4	75.4	67.6	61.8
7	395	61.3	61.3	61.3	60.5	55.4		397	72.0	71.5	71.3	72.3	67.5	50.1
8	771	67.4	67.1	67.2	66.8	62.4		765	85.2	83.0	84.7	84.7	77.3	72.3
9	812	64.6	64.3	64.2	64.2	63.2		807	83.0	80.4	82.5	82.8	79.8	63.2
10	397	73.0	73.0	74.3	74.3	70.8		382	86.0	82.2	85.1	85.3	84.0	72.8
Total	5281	63	62.6	62.9	61.4	60.0		5304	77.6	75.8	77.1	77.3	74.4	60.4

**Table 6. Quarter 2, 2002,-Immunisation Uptake Rates in Children:
12 and 24 Months**

	% Uptake at 12 months Cohort born 01/04/2001-30/06/2001						% Uptake at 24 months Cohort born 01/04/2000-30/06/2000						
CCA	No. in Cohort	DT %	P %	Polio %	Hib %	Men C %	No. in Cohort	DT %	P %	Polio %	Hib %	Men C %	MMR %
1	400	71.5	70.8	71.5	72.5	75.8	396	84.0	82.3	82.6	83.8	87.6	73.0
2	309	59.5	58.6	59.2	61.5	67.6	373	75.1	74.3	75.1	74.5	80.7	60.1
3	451	35.5	35.5	34.8	41.0	60.5	431	69.1	69.1	67.7	69.1	75.6	46.9
4	564	55.3	55.3	55.0	56.4	59.4	569	72.8	71.2	72.1	72.1	78.2	55.2
5	575	64.3	63.5	64.0	64.3	66.6	639	73.3	71.7	72.3	73.4	78.2	56.8
6	666	70.0	70.0	70.1	70.1	71.5	641	75.9	74.3	76.1	76.1	79.6	63.5
7	403	58.1	58.1	57.1	58.1	59.1	427	70.8	70.3	69.8	70.5	76.3	52.5
8	765	72.8	72.5	72.7	72.8	71.1	761	83.2	82.0	82.4	82.8	80.2	72.9
9	843	63.1	62.8	62.9	63.7	67.9	870	82.4	81.0	82.0	82.1	85.6	67.6
10	371	76.2	74.7	76.0	75.7	77.4	375	87.2	84.5	87.7	86.9	87.5	74.9
Total	5,347	63.3	62.9	63.0	64.1	67.7	5,482	77.7	76.4	77.1	77.5	81.0	62.9

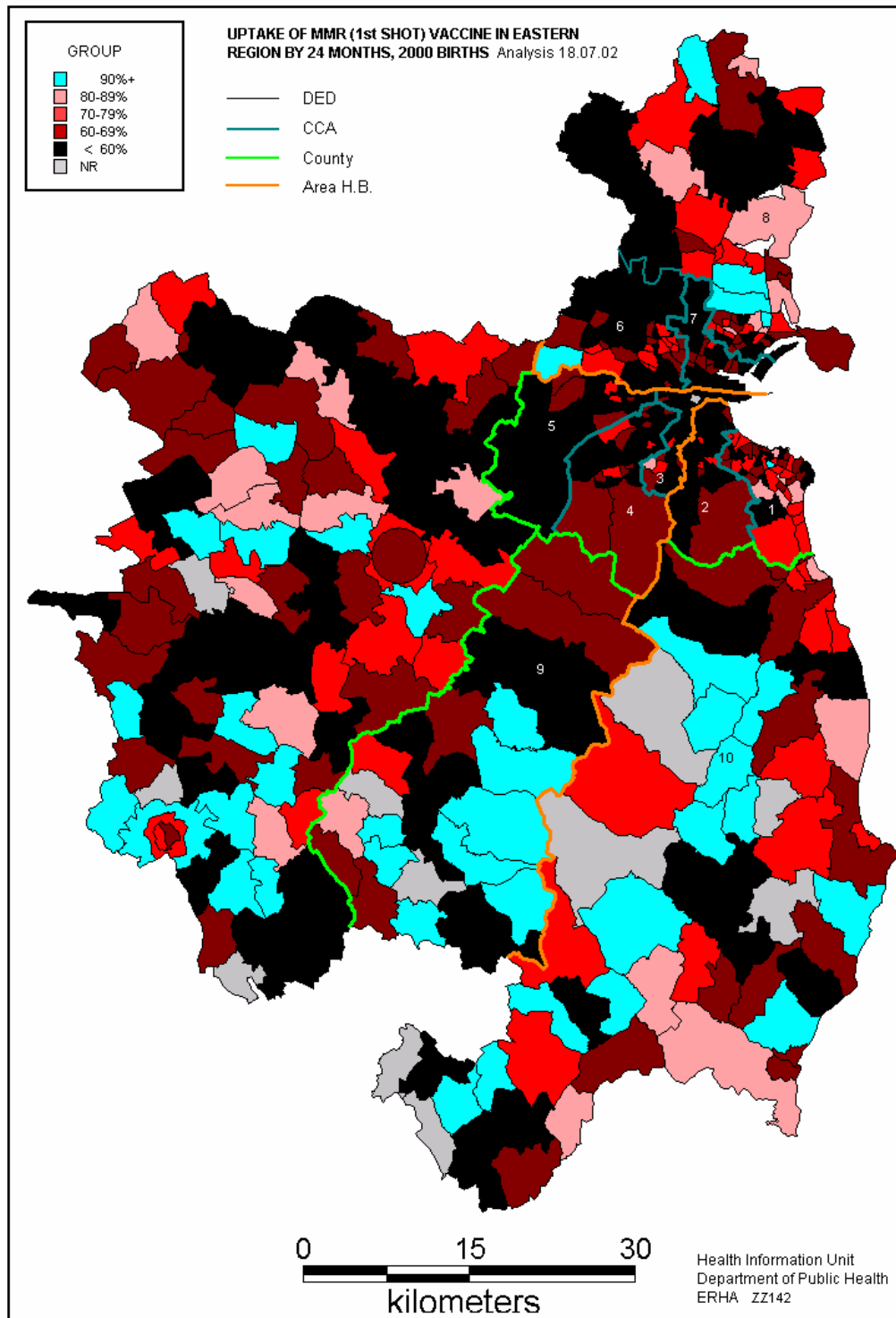
Note:

- **DT**=Completed course of 3 diphtheria and tetanus vaccinations
- **P**=Completed course of 3 Pertussis vaccination
- **Polio**=Completed course of 3 polio vaccinations
- **Hib**=Completed course of 3 Hib vaccinations
- **Men C**=At 12 months: Completed course of 3 meningococcal C vaccinations. In relation to 24 months relates to obtaining single shot of meningococcal C vaccine only.
- **MMR**=Relates to single shot of MMR at 15 months

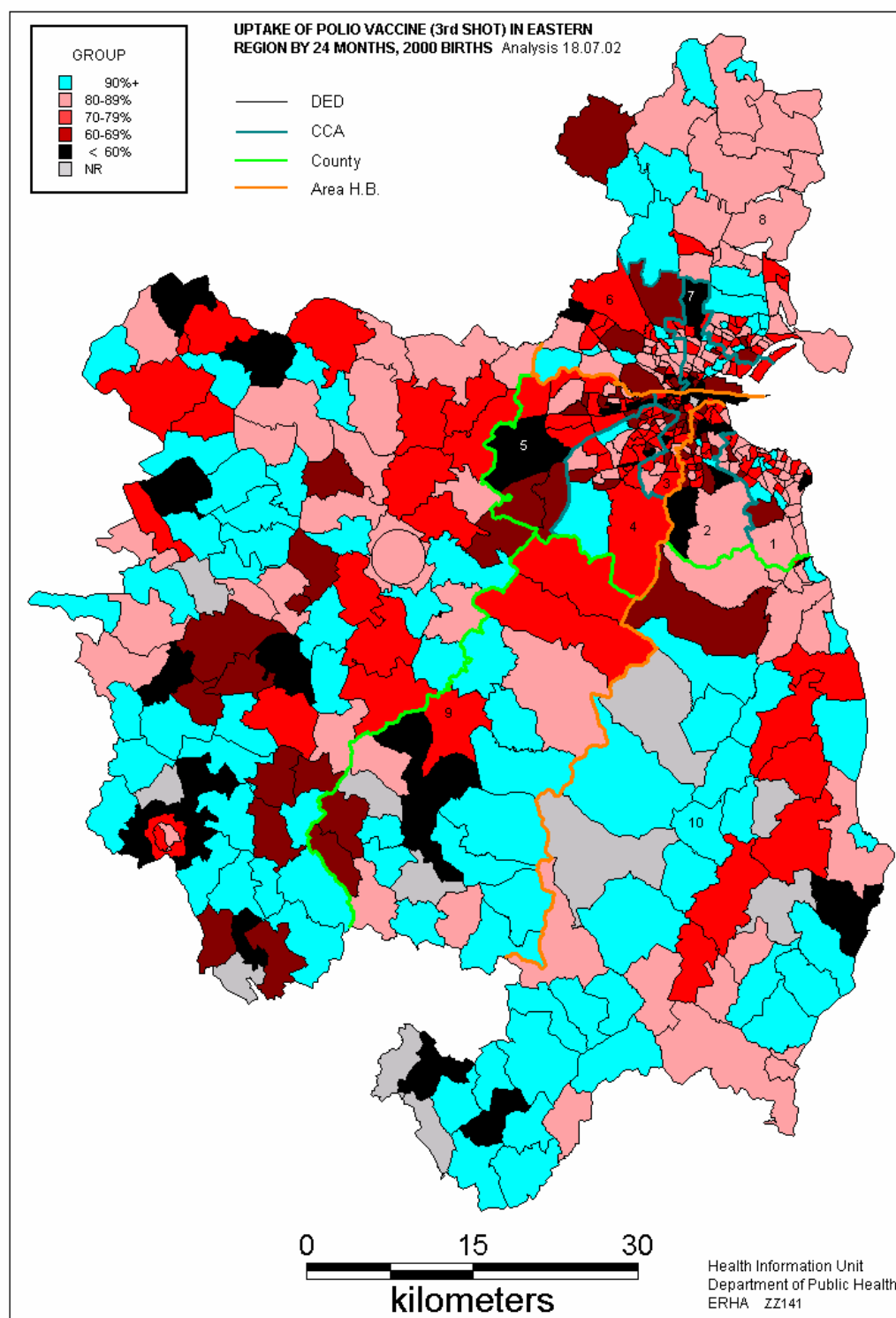
Information from ERHA Health Information Unit based on RICHs database. VAX 11 for DTaP/Hib/Polio, Meningococcal C and MMR.

Appendix 2: Maps of Immunisation Uptake Rates by DED for all Primary Vaccinations in birth cohorts 01/01/2000 to 30/06/2000- Eastern Region

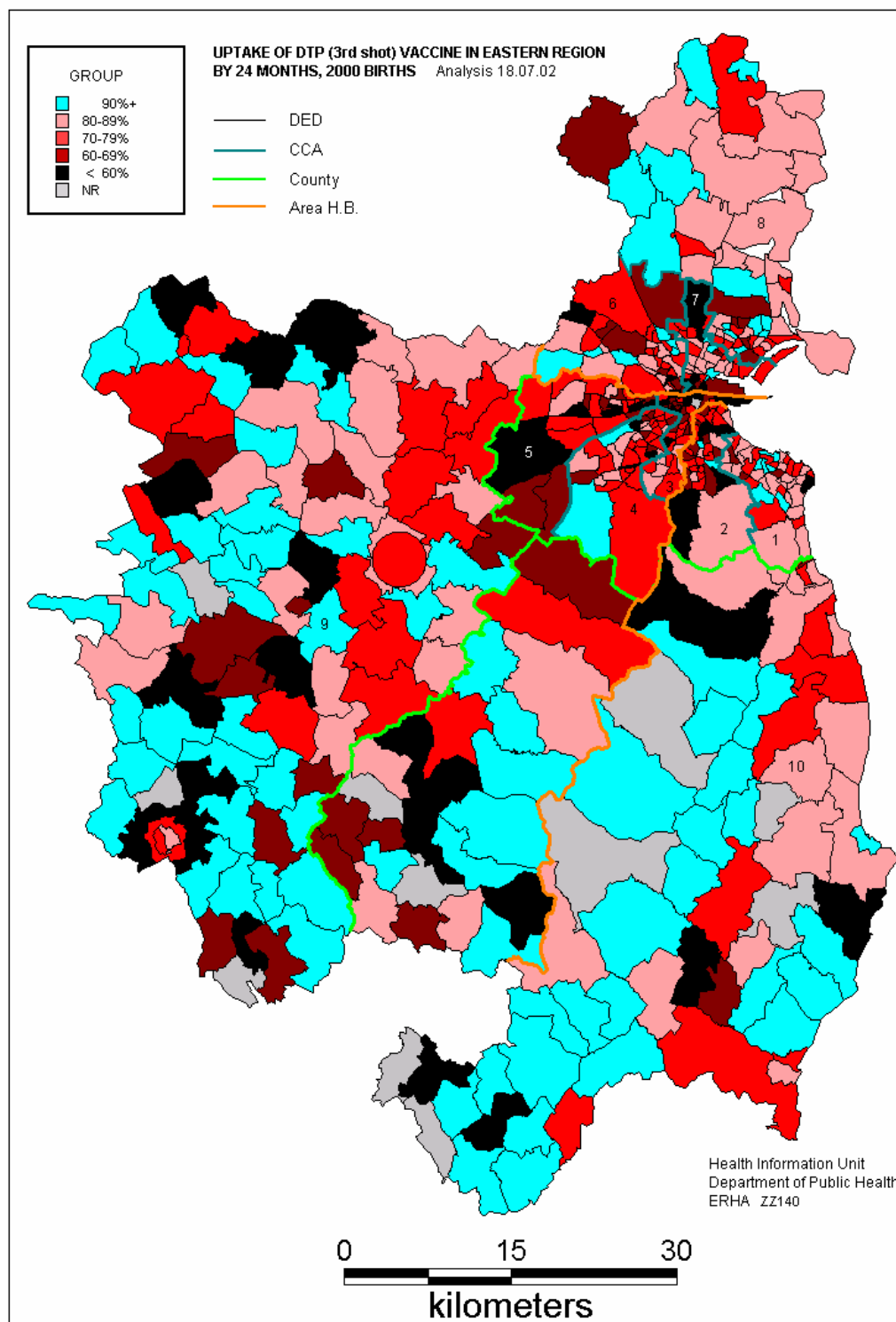
Map 1: Uptake of MMR Vaccine in the Eastern Region at 24 months for birth cohorts 01/01/2000 to 30/06/2000



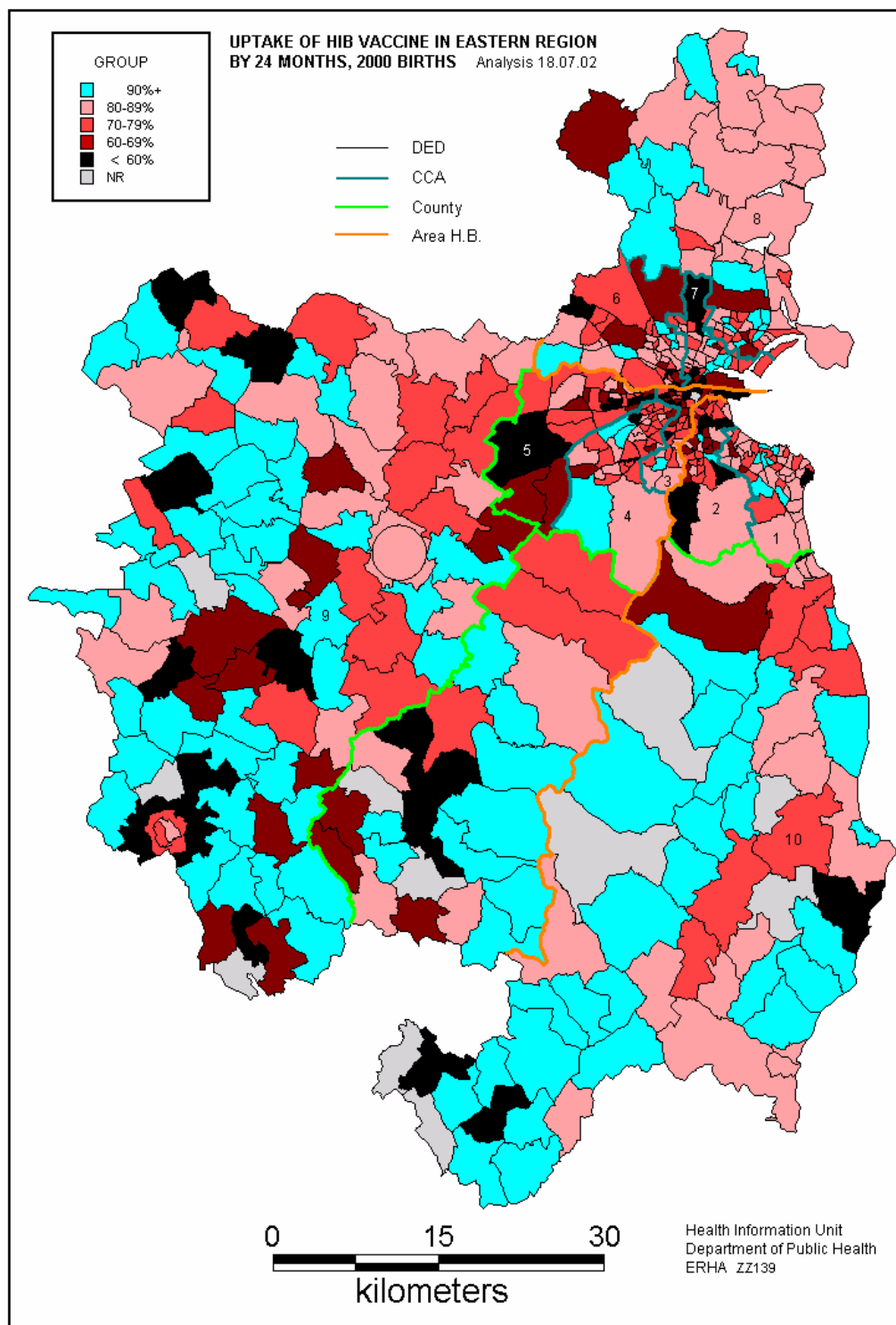
Map 2: Uptake of Polio Vaccine in the Eastern Region at 24 months for birth cohorts 01/01/2000 to 30/06/2000



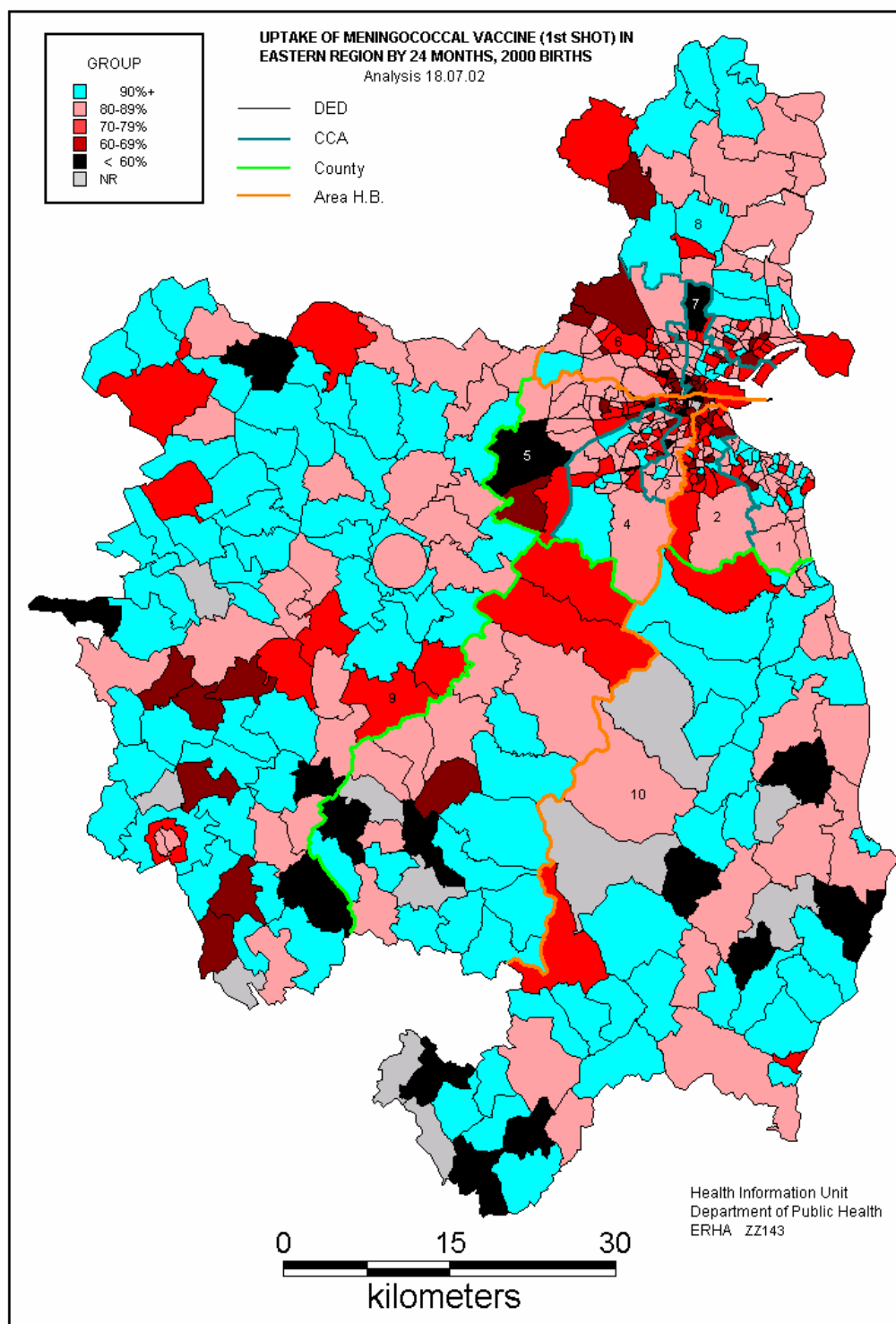
Map 3: Uptake of DTP (3rd shot) Vaccine in the Eastern Region at 24 months for birth cohorts 01/01/2000 to 30/06/2000



Map 4: Uptake of Hib Vaccine in the Eastern Region at 24 months for birth cohorts 01/01/2000 to 30/06/2000



Map 5. Uptake of Meningococcal Vaccine in the Eastern Region at 24 months for birth cohorts 01/01/2000 to 30/06/2000



Commentary on Maps

To provide a geographical picture of vaccine uptake throughout the Eastern Region, vaccine uptake by 24 months of age on a recent cohort (children born in 2000 and vaccinated by 24 months of age) was analysed (essentially for the first 6 months of 2002). The analysis is based on the most recent data export from the RICHS system and it refers to children who are current residents and where records are geo-coded by district electoral division (DED). The analysis refers to a single snapshot in time and the following results should be interpreted with these points in mind, and in light of the fact that the national target for vaccine uptake is 95%.

The overall vaccine uptake for the birth cohort is as follows:

Meningococcal	82.3% (first shot)
Hib	78.6% (third shot)
Polio	77.8% (third shot)
DTP	77.4% (third shot)
MMR	61.1% (first shot)

The accompanying maps illustrate vaccine uptake by district electoral division (DED) in five broad bands ranging from 90% or higher (blue) to 60% or lower (black).

With regard to DTP, polio, and Hib, the overall impression is that the uptake patterns are very similar (see maps 2, 3, 4). There are relatively few DEDs where vaccine uptake is in excess of 90%, and these are generally found in rural and sparsely populated areas. Areas with uptake less than 70% include north and south inner city areas, and the more disadvantaged suburban and densely populated areas of Dublin. Similar patterns are also seen in the more populous parts of Kildare and Wicklow.

The uptake for meningococcal vaccine shows a somewhat better picture than that described above. However, the results should be interpreted in light of the analysis being carried out for the first shot of this vaccine due to the varied vaccine programme that applied to children in this birth cohort when the programme was first introduced during 2001.

However, the geographical pattern for MMR shows a broadly similar pattern of uptake, but the overall 'colour' of the map is dramatically different from that for the other primary vaccines in line with the approximately 20% lower uptake of MMR vaccine for the Eastern Region as a whole (see map 1). As shown, a great many areas throughout the Eastern Region have an uptake of MMR vaccine less than 60% and there are very few DEDs having an uptake in excess of 90%.

Appendix 3:

Maintaining cold chain during courier transport of Meningococcal C vaccine to General Practitioners and schools in the Northern Area Health Board 2000 to 2002.

Background

It is widely accepted that maintaining the “cold chain” during storage and transport of vaccine is essential to ensure maximum potency of the vaccine within its stated shelf-life [Ref 1].

The Meningococcal C vaccines used in Ireland at the commencement of the Meningococcal C vaccination programme were manufactured by Chiron and Wyeth. Both companies gave guidelines for stability outside the cold chain. For both Chiron and Wyeth Meningococcal C vaccine, exposure to freezing inactivated the vaccine; for Chiron vaccine the advice was that the vaccine would be stable for up to 2 hours at room temperature $<+25^{\circ}\text{C}$; for the Wyeth vaccine the advice was that the vaccine would be stable for up to 24 hours at room temperature $<+25^{\circ}\text{C}$. Both companies recommended seeking specific advice for exposure to other temperatures or for other durations.

Meningococcal C Vaccination Programme in Northern Area Health Board

Phase 1 of Meningococcal C Vaccination Programme required the distribution 90,500 doses of vaccine over six months. The existing vaccine storage and distribution system within the Northern Area Health Board (October 2000) had a potential requirement to distribute approximately 100,000 doses of vaccine per year. *(Estimate was based on demographic data and requirement for 3 doses DTP/DT, Hib + OPV and 1 dose of MMR for approx. 8,000 children born in NAHB each year; and 1 dose DT/DTP + OPV + MMR for the cohort of approx. 6,500 five year olds in NAHB, each year, in the school vaccination programme).*

There was a requirement for additional vaccine storage refrigerators (10) and storage space (a new property was rented) and a new courier service was promised to General Practitioners. In the set up stages an air-conditioning system was installed in the storage depot, as the refrigerators were generating such heat that ambient temperature rose to 28°C .

GP vaccine courier system

Using cool-boxes the same as those already in use in the Northern Area Health Board for GP's collecting vaccine it was not possible to deliver the vaccines within the cold chain. The cold chain was maintained for only 4/17(23%) cool-boxes during deliveries to 16 GPs. The courier service was therefore suspended and a new cool-box system specifically for vaccine distribution was sought.

A UK insulated shipping company, Laminar Medica, was requested to provide validation of a suitable isothermic box for the transport of a low mass product, within the temperature range of $+2^{\circ}\text{C}$ to $+8^{\circ}\text{C}$ for periods of up to 12 hours in Irish weather conditions all year round. The company was also requested to validate the box for multiple openings and repeated removal of product in a process simulating school vaccination sessions. The validation process involved the attachment of temperature probes to glass vials containing 0.5mg mass, which were then placed in the isothermic box along with 3 cool-packs and 2 ice-packs. The cool-packs need conditioning for 24 hours at $+5^{\circ}\text{C}$, storage in a vaccine fridge meets this criteria. The ice packs require an initial conditioning for 72 hours at -18°C and if returned after less than 12 hours use, require storage for 24 hours before being used again. Before use the ice packs are left at ambient temperature for 30 minutes. During the validation process readings from the temperature probes, attached to product vials, were recorded every minute for 12 hours while the external temperature of the laboratory, containing the isothermic box, was altered to simulate Irish summer and winter temperatures.

The validation process guarantees maintenance of the cold chain as long as there is no loss of integrity of the isothermic box; the ice packs and cool-packs are correctly conditioned; the ice-packs are separated from the vaccine by the appropriate insulating spacer and the box is properly closed. There is no requirement for monitoring temperature during transport. As the isothermic boxes are made of polystyrene they may become damaged during repeated use and need replacement.

This system for courier delivery of Meningococcal C vaccine was introduced in April 2001 on a pilot basis and was extended to all GPs in the Northern Area Health Board by early June. The system has proved very satisfactory but ceased in March 2002 as Meningococcal C vaccine distribution was relocated to each CSA HQ where GPs call to collect all other vaccines required.

Table of courier delivery of Meningococcal C vaccine to GPs.

47 weeks of deliveries from 2 nd April 2001 to 15 th March 2002.	Total no. of deliveries	Total no. of vaccines delivered	Average no. of deliveries per week	Range of deliveries per week	Average no. of vaccines per delivery.	Range of vaccines per delivery.
Total	421	28,758	9	3-17	68	20-400

Cost of GP vaccine courier system

The material costs for validated isothermic boxes system was **€2,783.42** and total GP courier transport costs were **€17,690.10** hence cost per GP delivery was **€48.63** and cost per vaccine delivered was **€0.71**.

Protocols

Protocols were developed for the staff with regard to receiving vaccine, storage of vaccine and issuing vaccine. Within the school vaccination programme a system was set up such that vaccine which was returned from a school (unused) was marked and had to be used or discarded when next issued to a school. Vaccine marked as having had an excursion to a school vaccination session was not issued to GP's. Protocols were updated when use of the new Laminar Medica cool-boxes commenced.

School vaccine courier system

Cool-boxes the same as those already in use in the Northern Area Health Board for GP's collecting vaccine and in the existing school vaccination programme were initially used for the Meningococcal C school vaccination programme. When the validated cool-boxes became available they were also used in the school vaccination programme. The cool-boxes were subject to multiple openings during the school vaccination sessions and therefore the temperature was monitored continuously using a Min Max thermometer. The table below gives details of the results of this monitoring.

Maintaining cold chain during Meningococcal C school vaccination Programme 2000/2002

	Existing NAHB cool-boxes		Laminar Medica Meditherm 8.5	
	Number (vaccine)	% Boxes	Number (vaccine)	% Boxes
Cool-boxes issued to schools	426(39,740)	100%	487(54,853)	100%
Cool-boxes returned from schools				
Boxes returned empty	233(Nil)	54.7%	172(Nil)	35.3%
Boxes returned < +2°C	9 (634)	2.1%	2 (114)	0.4%
Boxes returned 2-8°C	29 (1,688)	6.8%	175(9,996)	36.2%
Boxes returned >+8°C	155(5,138)	36.4%	138(5,053)	28.3%
Details of boxes returned at >+8°C				
Boxes returned +9°C	22 (1,121)	5.2%	48 (1,829)	9.9%
Boxes returned +10°C	31 (1,332)	7.3%	32 (1,107)	6.6%
Boxes returned +11°C	28 (1,169)	6.6%	23 (803)	4.7%
Boxes returned +12°C	32 (1,157)	7.5%	19 (746)	3.9%
Boxes returned +13°C	16 (690)	3.8%	5 (209)	1.0%
Boxes returned +14°C	9 (296)	2.1%	6 (195)	1.2%
Boxes returned >+15°C**	17 (542)	4.0%	5 (164)	1.0%
	Vaccine - no.	%	Vaccine - no.	%
Men C vaccine issued to schools	39,740	100%	54,853	100%
Men C vaccine returned at <+2°C	634	1.6%	114	0.2%
Men C vaccine returned at >+8°C	5,138	12.9%	5,053	9.2%

** Existing NAHB boxes >+15°C = 17 [12=+15°C; 3=+16°C; 2=+18°C; containing 542 vaccines]

** Meditherm 8.5 >+15°C = 5 [1=+15°C; 1=+16°C; 1=+17°C; 1=+19°C; containing 164 vaccines]

Conclusion

Maintaining the cold chain is extremely important for any vaccination programme. In the event of vaccine failure the integrity of the cold chain is reviewed. This has already occurred in Wales in relation to the UK Meningococcal C vaccination programme. An investigation following two cases of Meningococcal C disease in vaccinated students at the same school suggested that the vaccine was stored at too low a temperature rendering it less effective and 25,000 students were being revaccinated from December 2001 [Ref 2]. The validated system introduced in the Northern Area Health Board for delivery of Meningococcal C vaccine to GPs and schools has worked very well and would be suitable for extension for delivery of other vaccines.

In relation to setting up the courier delivery system, validation of the cool boxes and developing protocols the input of Ms. Claire Kerr, Community Pharmacist, Eastern Regional Health Authority was invaluable.

References

1. Cold Chain Equipment. http://www.who.int/vaccines-access/Vaccine_Cold_Chain/cold_chain_equipment
2. Meningitis revaccination begins. http://news.bbc.co.uk/1/hi/english/uk/wales/newsid_1715000/1715193.stm

Report prepared by: Dr. Helena Murray, Project Manager, Meningococcal C Vaccination Programme, Northern Area Health Board. June 2002.

Appendix 4:

Protocol for Qualitative Study on Parental Knowledge and Attitudes to Primary Immunisation

Working Title: Exploration of parental issues surrounding childhood immunisations

Aim: To increase the uptake of childhood immunisation in the Eastern Regional Health Authority

Objectives: To understand parental issues surrounding childhood immunisations in order to address any negative issues that inhibit the uptake of immunisations and to identify and build on areas of strength.

Methodology: Qualitative research techniques including focus groups, one on one interviewing and snowball sampling.

Population: parents of children under five

Sample: 4-6 focus groups, 10 parents/group. Possible groups for study; family resource centres, mother and toddler group, breastfeeding support group, workplace group. Snowball interviewing through clinics and public health nurses.

Instrument: topic guide for focus groups, open-ended questions and discussion themes, issues generated by research team and parents

Analysis: identification of the emergence of key motifs and themes.

TimeLine;

July: protocol, design, ethical approval, and form working group, training in qualitative methodology.

August: consult with public health personnel in potential study locations; determine groups and locations for study. contact with sample groups and key personnel on the ground, design of instrument.

September: focus groups

October: focus groups, analysis

November: write-up and report

December: draft paper, identify journal and send for publication

Results: report themes emerging from research and recommendations following on from results

Dissemination;

- Report to working group on immunisation
- Report to Eastern Regional Health Authority
- Publication in appropriate peer reviewed journal
- Presentation at appropriate conferences

Research Team

Deirdre Mulholland, Area Medical Officer, Department of Public Health, ERHA

Louise Mullen, Research Officer, Department of Public Health, ERHA,

Virginia Delaney, Research Officer, ERHA

Sheila Reaper-Reynolds, Department of Health Promotion, SWAHB

Appendix 5

Policy document for Hepatitis B vaccination in Intellectual Disability services in the Eastern Regional Health Authority.

Dr Catherine Hayes, Specialist in Public Health Medicine; Dr Mary Condon, Specialist Registrar in Public Health Medicine, Department of Public Health, ERHA, August 2002

Introduction

Hepatitis B is an important cause of serious liver disease including acute and chronic hepatitis, cirrhosis and primary liver cancer. While it is not a common disease in Ireland, certain groups are at higher risk of contracting it. These groups include patients and health care staff in institutions for people with intellectual disability. Transmission occurs principally through blood and body fluids e.g. saliva. Clients who are chronic carriers of the virus can transfer the Hepatitis B virus to other clients, carers and staff. Health care personnel as well as being at risk themselves can also transfer Hepatitis B to patients if they are chronic carriers of the virus.

Hepatitis B is endemic in institutions for people with intellectual disability in Ireland with prevalence rates for markers of previous infection ranging from 41-60% and carrier rates (chronic carriage) of HbsAg of 9-10% in the residential population (Scanlon and Khan, 1989; Fitzgerald, 1998). Devlin et al (1993) studied the non-residential population in 1987/88 and found a prevalence rate for markers of previous infection with Hepatitis B of 11% and 4% for carriage of HbsAg. The immediate family of patients were also found to be at higher risk with one in five showing evidence of a previous infection. O'Connell (2000) found that in the general population in Ireland, the prevalence of past infection with Hepatitis B was 0.5%.

Hepatitis B can be prevented by good hygiene practices and vaccination against Hepatitis B.

The National Immunisation Guidelines (Royal College of Physicians of Ireland, 2002) recommend vaccination against Hepatitis B for health care personnel and for "patients and carers in institutions for those with intellectual disability (including day care facilities)".

Objectives

This document:

1. Sets out the background to efforts to implement Hepatitis B vaccination in services for people with an intellectual disability.
2. States ERHA policy on Hepatitis B vaccination in services for people with an intellectual disability by means of a protocol for Hepatitis B immunisation.
3. Identifies unresolved issues, which appear to be hampering implementation of the policy.
4. Makes recommendations as to how the policy can be implemented.

1. Background to implementation of Hepatitis B

The relevant policy statements over the past number of years are:

- 1988 Department of Health: circular.
Recommended that all healthcare staff should be vaccinated against Hepatitis B. This included staff of "agencies for the mentally handicapped".
Vaccine to be provided free of charge to all "approved" staff. Funding made available for it in budgetary allocation.
- 1990 Department of Health: circular.

- Reminder of 1988 circular. Stressed the importance of vaccinating all staff including student, trainee and temporary staff.
- 1995 Department of Health: letter of allocation for services to persons with a mental handicap in EHB area.
Funding (£107,000) provided for the provision of Hepatitis B vaccination “for staff working in mental handicap services and for client groups who are considered to be at risk”.
 - 1997 Department of Health: letter from the Chief Medical Officer and head of Disability section, entitled “Review of vaccination of health care staff and clients in the mental handicap services against Hepatitis B”. It referred to the 1996 National Immunisation Guidelines, which recommended vaccination for health care personnel and also for patients and carers in institutions for those with intellectual disability (including day care facilities). The target set was to have “all existing at-risk clients vaccinated as soon as practicable”. The letter also stated that “Vaccination is to be provided free of charge to approved groups”.
 - 1998 (July) Department of Health letter to EHB.
DOH expressed concern at the vulnerability of people in the mental handicap client group and requested a progress report from the EHB.
 - 1998 “Review of Hepatitis B Vaccination Programme in Mental Handicap Institutions in the Eastern Health Board Region 1998”. Report by Dr Margaret Fitzgerald, Department of Public Health.
This review included a survey of the Hepatitis B vaccination uptake among staff and clients in MH institutions. It found that 82% of all staff and approximately 14% of clients were vaccinated against Hepatitis B. The review also contained a protocol for Hepatitis B immunisation of clients and staff of institutions for intellectual disability. Included in the review were:
 - Recommendations to the Programme Manager for Disabilities,
 - Options for Improved Implementation and
 - An outline of the role for Medical Advisor or medical catch-up team.
 - 2000 (March) “Hepatitis B Infection: Surveillance and Control in the Eastern Health Board, From Policy to Practice”. Report from the Department of Public Health, EHB. Dr Lelia Thornton et al.
Recommended the implementation of Margaret Fitzgerald’s review.
 - 2000 (March to September). Mr David Dunne, Director of Mental Handicap Services, ERHA, in consultation with agencies, attempts to draw up and implement a policy for Hepatitis B vaccination.
 - May 2000: Central Planning Committee (CPC) meeting. Mr Dunne presents a short report on the Hepatitis B vaccination programme.
Issues, which emerged, were:
 - reluctance by some agencies to be responsible for providing vaccine to day attendees,
 - funding for the programme,
 - policy for new entrants to services,
 - consent,
 - information leaflets,
 - recording of information on Hepatitis B immunisation of staff and clients by each agency,
 - whether to give Hepatitis A vaccine in addition to Hepatitis B vaccine (It was subsequently decided to give Hepatitis B vaccination alone as there is not enough evidence to recommend Hepatitis A vaccine also in this client group at present).
 - July 2000. Draft Information leaflet was drawn up by subgroup of CPC.
Draft vaccine return form was also drawn up

- September 2000. Letter from Mr Dunne to CEOs of agencies requesting commencement of the Hepatitis B vaccination programme. Letter also included the information leaflet and a return form to record uptake of the vaccine.
- 2001 Ms Regina Buckley, Director of Disability Services in SWAHB works to implement the programme in the SWAHB area. Residents, day attendees and staff are targeted for vaccination. Information leaflets and returns forms have been sent to all agencies. The clients own GPs or GPs who deliver services on behalf of the agency carry out the programme. Those who have GMS medical cards get the vaccine free (collected from local community care area) and GPs are reimbursed according to a national agreement (£75 per course, paid by the GMS Payments Board). Non-GMS clients also receive the vaccine free, however they must pay the GP to administer it. The vaccine is provided free of charge to all staff members. In most cases, the agency organises administration of the vaccine and this is done free of charge. For a small number of staff, the vaccine is administered by their own GP and the staff member pays the GP to administer the vaccine.

The agencies record vaccination of residents and staff, and send return forms to Ms Buckley. The agencies do not record any information on day-attendees.

Ms Buckley pays for the vaccines and the blood tests

Parents have complained about having to pay an administration fee for non-GMS clients.

Directors of Disability Services in the ECAHB and NAHB are examining Ms Buckley's system with a view to implementation.

- December 2001. Hepatitis B vaccination discussed at Regional Provider Forum Meeting. Dr Catherine Hayes agrees to assess the situation and draw up a policy document.
- 2002 Uptake of Hepatitis B vaccination among clients and staff in residential services for people with an intellectual disability becomes a national performance indicator, and a performance indicator for the ERHA service plan for 2002.

2 ERHA policy for Hepatitis B vaccination in services for people with intellectual disability

Protocol for Hepatitis B immunisation programme

(Adapted from Review of Hepatitis B vaccination Programme in Mental Handicap Institutions in the Eastern Health Board Region (Fitzgerald 1998)).

Aim of the programme

The aim of the programme is to ensure that clients and staff in services for people with an intellectual disability are protected against Hepatitis B.

Specifically, the programme aims to ensure that all non-immune clients, both residential and day attendees, and all staff are fully vaccinated against Hepatitis B i.e. a 100% uptake level of the vaccine. It is also important to be able to demonstrate that a satisfactory immune response to the vaccine has been achieved by means of a satisfactory antibody titre level (blood test).

The vaccine schedule

The primary course of Hepatitis B vaccine consists of 3 doses of vaccine; given at 0, 1 month and 6 months. The vaccine is given intramuscularly in the deltoid region of the arm. In the case of infants the vaccine may be given in the antero-lateral thigh. The gluteal region should not be used as the vaccine efficacy may be reduced at this site.

A blood test (titre level) should be taken 2-4 months after the primary course to ensure that satisfactory anti-body levels have been achieved. The result of this blood test will determine whether further doses of the vaccine are required. See **Table 1** for this information.

Booster doses

To date there are no data to support the need for booster doses of hepatitis B vaccine in immunocompetent individuals who have responded to a primary course (Immunisation Guidelines for Ireland (2002)).

Vaccine dosage

There are currently two licensed Hepatitis B vaccines available. The two products contain different concentrations of antigen per ml.

Engerix B (SmithKline Beecham)

Age 0-12 years: 10mcg (0.5ml)
Adults and children >12 years: 20mcg (1ml)

HB-Vax II (Aventis Pasteur MSD)*

Age 0-15 years: HB-Vax II Paediatric: 5mcg (0.5ml)
Adults and children > 15 years: HB-Vax II: 10mcg (1ml)

*New product, HBvaxPRO was launched recently.

Contraindications

Immunisation should not be carried out in individuals who have had a previous serious reaction to a dose of this vaccine.

Precaution

Acute febrile illness is a reason for deferral of vaccination.

The response may be impaired in those who are immunocompromised, and a further dose of vaccine may be necessary.

Blood tests

i) Antibody titre following primary course or booster

The blood test, a titre level for antibody to hepatitis B (anti-HBs), is required to determine whether the vaccine has been effective. The level of antibody as outlined in Table 1 determines the need for further doses of vaccine. Approximately 10-15% of those vaccinated fail to respond to hepatitis B vaccines in practice.

ii) Blood tests to exclude past infection or chronic carriage

If blood tests are indicated to exclude past infection (approximately 1% of cases) or chronic carriage (test for core antibody (anti-HB core) or surface antigen (HbsAg) in a staff member or client, it is essential that pre-test counselling is carried out. If a staff member or client is found to be a chronic carrier of Hepatitis B, this may have significant implications for their personal and working lives.

***Table 1 Actions required following post-vaccination testing**

Anti-HBs Level	Result	Action required
0 or < 10 miu/ml	Non responder	Exclude past infection or chronic carriage by testing for anti-HBc and HBsAg (following counselling). Repeat three-dose course of Hepatitis B vaccine (a different brand of vaccine may be considered). Double dosing should also be considered. Recheck Anti-HBs at 2-4 months post completion.
10-99 miu/ml	Poor responder	Immediate booster and retest at 2-4 months using two assays; if both assays are >10 miu/ml, this indicates an adequate response. The results should be discussed with the reference laboratory.
100 miu/ml or greater	Adequate response	No further action required.

*Source: Immunisation Guidelines for Ireland (2002).

Policy for Clients

The following recommendations apply to both residential and non-residential clients equally. All clients of mental handicap institutions should be offered hepatitis B immunisation unless shown to be immune. Ideally immunisation should take place prior to entry to the institution.

Children

Many clients (especially those with Down Syndrome) enter the service before their first birthday and would best be offered a service through their family doctor. Although children with Down syndrome are more likely to live at home and to attend normal schools than in the past they are still likely to spend part of their lives in an institutional setting. Children should be immunised against HBV before they start pre-school.

It is recommended that institutions should ensure that new entrants to their service, who are offered a residential or day place, are vaccinated prior to entry to the service.

Adults

All adults, whether residents or day attendees, should be offered the vaccine. If the client lives at home or in sheltered accommodation and has little clinical involvement with the agency, it is still the agency's responsibility to ensure that the client is immunised whether by his/her GP or organized directly by the institution.

New entrants (adults and children):

Immunise and check antibody titre (anti-HBs) after 2-4 months. Follow **Table 1**.

Existing clients (adults and children):

If record of previous completed immunisation course, with satisfactory antibody response, no further action.

If previously immunised but no record of antibody response, give a booster dose then check anti-HBs and follow **Table 1**.

If not previously immunised, there are two options: (1) immunise directly, or (2) screen first (anti-HBc and HBsAg), then immunise if non-immune. Check antibody titre after 2-4 months. Follow **Table 1**.

Pre-immunisation screening

The decision to carry out pre-immunisation screening of potential recipients to detect prior HBV infection will be influenced by the following factors: prevalence of prior infection, financial cost, inconvenience to clients, and the benefit of the epidemiological data which would be obtained. It is essential that clients and their carers receive counselling prior to being tested for HBV infection.

As the major objective of the Hepatitis B vaccination programme is protection through immunisation, pre-immunisation screening should not be allowed to be a barrier to vaccination. It is therefore preferable to vaccinate first and test for response afterwards, unless there is good evidence to suggest that the person may have had HBV infection in the past.

Policy for Staff

All non-immune at-risk staff working with intellectually disabled people should receive hepatitis B immunisation, ideally prior to commencing work.

Staff members who are at risk of contracting hepatitis B and for whom hepatitis B vaccine is recommended are outlined in the National Immunisation Guidelines for Ireland (2002).

They are:

- Carers in institutions for those with intellectual disability (including day care facilities)
- Health care personnel. Doctors, nurses, dentists, midwives, laboratory staff, mortuary technicians, ambulance personnel, cleaning staff, porters, medical and dental students, health care professionals and anyone who is at particular risk through contact with blood or body fluids.

It is recommended that all staff receive ongoing education regarding the risk of hepatitis B. Staff should make an informed choice and be vaccinated if they consent. Those who refuse should be asked to sign indemnity. Compulsory vaccination for staff is not recommended.

Previously immunized staff

If record of a previous completed immunisation course, with satisfactory antibody response, no further action is needed.

If previously immunised but no record of antibody response exists, give a booster dose then check anti-HBs and follow **Table 1**.

Not previously immunized

If not previously immunised, carry out immunisation, with or without pre-immunisation screening. Check antibody titre after 2-4 months. Follow **Table 1**.

Pre-immunisation screening

Pre-immunisation screening for Hepatitis B infection may be indicated in a small number of staff. This might include staff who come from areas where the prevalence

of Hepatitis B is high or staff who are concerned that they may have had Hepatitis B infection in the past. It is essential that staff undergoing tests for Hepatitis B infection receive counselling prior to being tested.

3 Unresolved issues

Having examined the background to the implementation of the Hepatitis B vaccination programme in people with an intellectual disability and having spoken to several people working in or with services for people with an intellectual disability, a number of barriers to implementing the Hepatitis B programme have been identified. These are general issues relating to the programme, issues in relation to immunisation of staff, and issues in relation to immunisation of clients. The issues are outlined below:

General issues

1. Responsibility for the Hepatitis B vaccination programme for all staff and all clients needs to be clearly assigned and explicitly accepted by the CEOs of all agencies providing services for people with an intellectual disability.
2. A Hepatitis B vaccination co-ordinator needs to be appointed by each agency. This could possibly be done as part of the duties of an Infection Control Nurse.
3. Return forms which give accurate information on uptake of the vaccine and hence the level of protection within the service need to be designed, discussed, completed and updated.
4. Refusal of vaccine:
 - A written record of refusal by a staff member or client to accept the vaccine should be kept by the agency.
 - The proportion of refusals needs to be determined
 - Reasons for refusal need to be investigated. A pilot study of “refusals” may be useful to address this.
5. The national performance indicators for Hepatitis B vaccination in services for people with an intellectual disability (Department of Health and Children, 2001) are unsatisfactory, as they do not currently include the uptake in day attendees. Immunisation of day attendees is part of the national immunisation policy as stated in the Immunisation Guidelines for Ireland (1999). Hence the indicators need to be modified to reflect this policy.
6. Ideally, the Hepatitis B programme should be maintained on a computerized database. Software packages, developed by the Hepatitis B vaccine manufacturers, are available to record such information.
7. Clerical support is essential to maintain a Hepatitis B programme.
8. Education about prevention of Hepatitis B, including standard precautions and vaccination, is an essential part of a Hepatitis B programme for staff, clients and their carers.
9. A clear policy for administration of other vaccines is needed. These vaccines include: routine childhood vaccines (booster DPT, Hib and polio, meningococcal C, MMR), influenza vaccine, and pneumococcal vaccine.

Staff

1. Vaccination of staff is an occupational health function. This is a specialized area and needs to be recognized as such. In-house medical staff may not be trained to provide such a service and issues may arise in relation to confidentiality.
2. If staff are vaccinated by an outside agency e.g. a private company, information on who has been vaccinated and satisfactory titre levels needs to be made known to the intellectual disability agency.

3. Testing for Hepatitis B infection requires counselling beforehand. Some private companies do not provide pre-test counselling. This is clearly unsatisfactory and needs to be examined.
4. New staff may be non-nationals who come from areas where Hepatitis B is more prevalent. There may be a case for testing for Hepatitis B infection (screening for Hepatitis B) prior to commencement of their employment depending on the nature of their work.

Clients

1. Some agencies are reluctant to accept responsibility for ensuring that day attendees are vaccinated against Hepatitis B as vaccination is carried out by the GP. Information is maintained by the GP and receiving confirmation of vaccination and of titre levels may be difficult.
2. If the clients own GP is giving the vaccine, the problem for non-GMS clients of payment of a vaccine administration fee is an issue.
3. Some clients may have great difficulty in attending their GP because of a concomitant physical disability or behavioural problem. These clients are highly dependent on relatives who are frequently elderly and it is questionable as to whether it is appropriate to ask such clients to arrange Hepatitis B vaccination with their GPs themselves. In these cases, responsibility for ensuring that the client is vaccinated should lie with the institution the client is attending.
4. When discussing consent it may be necessary to explain to relatives or guardians that a client may need to be sedated or restrained while the vaccine is being given.

4 Recommendations to aid implementation of the Hepatitis B vaccination programme

1. Each agency to aim for 100% uptake by all non-immune staff and all non-immune clients.
2. A Hepatitis B vaccination co-ordinator is required in each agency. This could possibly be done as part of the duties of an Infection Control Nurse.
3. Each agency needs to develop a business plan to decide on how they are going to deliver the programme.
4. A policy for a catch-up programme needs to be in place if required. It is possible that a community care team could be organized in each AHB, along the lines of the Meningococcal C programme, to carry out this function.
5. Each agency must be able to produce regular, timely information on uptake levels of the vaccine and the current level of protection within the agency. This information should be gathered twice yearly on a return form and returned to the Director of Disability Services in the relevant area health board.
6. ERHA performance indicators should include uptake in both residential clients and day attendees.

References

Department of Health and Children. Health Services National Performances Indicators 2002. Final Draft. 7th Dec 2001. Department of Health and Children

Devlin JB, Mulcahy M, Corcoran R, Ramsay L, Tyndall P, Shattock A. Hepatitis B in the non-residential mentally handicapped population. *Journal of Intellectual Disability Research*, 1993; 37: 553-560.

European Consensus Group on Hepatitis B Immunity. Are booster immunisations needed for lifelong hepatitis B immunity? *Lancet*, 2000; 355: 561-565.

Fitzgerald M (1998). Review of Hepatitis B Vaccination Programme in Mental Handicap Institutions in the Eastern Health Board Region 1998. Confidential report. Dublin: Department of Public Health, Eastern Health Board.

O'Connell T, Thornton L, O'Flanagan D, Staines A, Connell J, Dooley S, McCormack G. Prevalence of hepatitis B anti-core antibody in the Republic of Ireland. *Epidemiol Infect*, 2000; 125: 701-704.

Royal College of Physicians of Ireland, Immunisation Advisory Committee (2002). Immunisation Guidelines for Ireland. Dublin: Royal College of Physicians of Ireland

Scanlon S, Khan SA. Hepatitis B in a residential population with a mental handicap. *Irish Medical Journal*, 1989; 82: 80-82.

Thornton L, O'Sullivan P, Barry J, Fitzgerald M, Hickey L, O'Connor A, Scully M (2000). Hepatitis B Infection: Surveillance and Control in the Eastern Health Board. *From Policy to Practice*. Dublin: Eastern Health Board.