REPORT OF VACCINE DAMAGE STEERING GROUP

June 2009

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REPORT OF VACCINE DAMAGE STEERING GROUP

June 2009

1. Introduction

The purpose of this document is to provide the Minister for Health and Children with a final report and recommendations from the Vaccine Damage Steering Group.

1.1 History of Immunisation in Ireland

In the first half of the 20th Century, Immunisation against Tuberculosis, Diphtheria and Tetanus became available, with immunisations against Whooping Cough and Polio added in the 1950s. Immunisation against Rubella was introduced in the 1970s for girls only, and during the 1980s, immunisation against Measles, Mumps and Rubella was added to the early childhood immunisation schedule. Immunisation against Haemophilus influenzae Type B (Hib) was added in 1992, and Meningococcal C disease in 2000. In July 2008 pneumococcal conjugate (PCV) and Hepatitis B vaccines were included in the primary childhood immunisation schedule.

Ireland's recommended immunisation programme is based on the guidelines of the National Immunisation Advisory Committee (NIAC) of the Royal College of Physicians of Ireland. The Committee was established in 1994, and reconvened in December 1997.These guidelines are prepared with the assistance of an active committee from associated disciplines in paediatrics, infectious diseases, general practice and public health. The current childhood schedule contains immunisations against twelve infectious diseases: Tuberculosis, Diphtheria, Tetanus, Whooping cough, Polio, Haemophilus Influenzae B (Hib) disease, Hepatitis B, Pneumococcal disease,Meningococcal Group C disease, Measles, Mumps and Rubella.

It has long been accepted that immunisation is a simple, safe and effective way to protect children against certain diseases. Immunisation against infectious disease has saved more lives than any other public health intervention, apart from providing clean water. When immunisation uptake rates are below 95%, outbreaks of infectious disease will continue to occur, and some children will suffer complications or die as a result. Although immunisation uptake rates in this country have not yet reached the target of 95% they continue to improve. The national uptake rate for children aged 24-months now stands at 94% for diphtheria, tetanus and pertussis and 90% for measles, mumps and rubella. The social benefits for the community in general of

achieving an uptake level of 95% thus providing population immunity cannot be emphasised enough.

1.2 Background

In its Report on Childhood Immunisation (July 2001), the Joint Oireachtas Committee on Health and Children recommended that legislation be drawn up to provide for a no-fault National Vaccine Injury Compensation Scheme. This scheme would not be the first of its kind in Ireland. A similar scheme operated during the late 1970's and early 1980's.

In November 1977 the then Minister for Health established the Expert Medical Group on Whooping Cough Vaccination to

- Examine persons who, it was claimed, had been permanently damaged by whooping cough vaccination,

- Review the medical information available in relation to them and

- Indicate whether, in its opinion, the damage was attributable to the vaccination.

Of the 93 cases presented to the Expert Group, the Group found that there was a reasonable probability that the vaccine was responsible for damage in 16 of the cases. Where there was a reasonable doubt in any case, the Group gave the benefit of that doubt to that person.

In 1982, an offer of an ex-gratia payment of £10,000 was made in 14 cases with a further 2 offers in 1984. There was no acceptance of liability on the part of the State or any public authority. Award of the ex-gratia payment was on condition that the persons concerned waived any further liability against the State or any public authority.

The Expert Group reviewed all the cases that came before it and is no longer sitting.

2. ***Establishment of Current Group***

The Vaccine Damage Steering Group was established by the Department of Health and Children in early 2007, on foot of the Joint Oireachtas Committee recommendations above and following commitments made by the Minister. The following were nominated as members of the Steering Group:

Organisation	Nominee	Position
DOHC	Mr Chris Fitzgerald (Chair)	Principal, Public Health Division
Health Service Executive	Dr Darina O'Flanagan,	Director of the HPSC
Health Service Executive	Dr Brenda Corcoran	Head of National Immunisation Office
Health Service Executive	Ms Cornelia Stuart	Quality and Risk Manager – Dublin North East
Irish Medicines Board	Ms Rita Purcell	Director of Finance and Corporate Affairs
State Claims Agency	Ms Susan Moriarty Ms Josephine Deasy	Solicitor/ Deputy Head of Claims Solicitor/Claims Manager (from Oct'07)
UCD	Professor Denis Cusack	Forensic and Legal Medicine, UCD School of Medicine and Medical Science
DOHC	Mr Brendan Phelan	Principal, Public Private Policy Issues and Health Insurance
DOHC	Dr Eibhlin Connolly	Deputy Chief Medical Officer
DOHC	Ms Caroline Sellars Mr Dave O Connor	Secretary to Group Secretary to Group (from Sept'07)

2.1 Terms of Reference

The Group had the following terms of reference:

1. To identify and define the adverse events following immunisation with certain vaccines.
2. To examine the feasibility of estimating from available documentation the number of recipients of vaccination programmes who experienced an adverse reaction and

the extent and severity of any resulting permanent damage.

3. To review the general details of vaccine damage compensation schemes operating in other countries and identify the most relevant models from a clinical, administrative and fairness point of view.
4. To consider the possible components of a payment or benefit package, including the degree of retrospection, if any.
5. To estimate the likely overall cost and the cost to the State of introducing a 'no-fault' scheme.
6. To ensure that there is no resultant damage to public confidence in the national immunisation programme.
7. To make such recommendations as the Group sees fit.

2.2 Meetings

The Group convened on eleven occasions:
13 March '07, 17 April '07, 21 May '07
3 July '07, 18 September '07, 7 November '07,
19 November '07, 30 January '08, 23 April '08, 21 May '08,
1 April '09
Members of the Group also travelled to the UK in June 2007 to meet with representatives of the UK Vaccine Damage Payments Scheme.

2.3 ***Preliminary Findings***

Before turning its attention to the details of any payment scheme the Group considered, in the first instance, whether it was appropriate to recommend the introduction of such a scheme. The State has a duty to the more vulnerable members of society to protect them as best it can and this includes encouraging parents to immunise their children against potentially life threatening diseases. It could, of course, be argued that all recipients do gain personal benefits from immunisation and that therefore they should accept the risks involved. However, while immunisation is not compulsory in Ireland, the State, through organised call and recall programmes, exerts considerable influence on families to immunise their children with a view to achieving the social benefits for the community in general referred to earlier. It is against this background that the very small number of cases of children who suffer serious adverse reactions to certain vaccines need to be considered. In circumstances where the State actively encourages all parents to participate in a national immunisation programme the Group concluded that there is an onus on the State to look sympathetically at the very rare number of cases where children suffer serious adverse reactions because of their participation.

The Group agreed that the State should acknowledge that notwithstanding the substantial and proven benefits of

vaccination programmes, individuals react differently to vaccines and there is no way to predict with certainty the reaction of a specific individual to a particular vaccine. It is therefore right to acknowledge that and make arrangements for a payment scheme in the small number of cases who have been adversely affected

The Group recommends that payment to any individual should not be regarded as compensation but rather a recognition that, in limited cases, an adverse event could take place following immunisation, and that on the balance of probability, damage occurred as a result. The Group also agreed it was essential that the integrity of the immunisation programme was maintained and that the establishment of such a payment scheme would enhance this objective.

In considering the issues the Group took into consideration the existence of a number of older cases, where there was still a strong belief among the families that there was vaccination related damage.

Research was also carried out by the Group as to who else might have an interest in such a scheme. The State Claims Agency was aware of 3 cases being taken, alleging vaccine damage, while Irish Public Bodies was aware of 2 cases. Consultations with the UK Unit revealed that after the initial high number of applications when the scheme was established

(which could be expected here) there are now about 100 – 120 applications per year of which approximately five are successful.

2.4 Examination of Other Schemes

A review of similar schemes in other countries was carried out by the Group. It found that similar schemes were in operation in other countries, including the United Kingdom (UK), United States of America (USA), New Zealand, Germany, France, Denmark, Sweden, Italy, Norway, Switzerland, Japan, Quebec and Taiwan. A summary table is at appendix 2.

In June 2007 a sub-group met with representatives of the UK Vaccine Damage Payments Scheme to discuss the UK Scheme and how it is operated.

3. Consultation

The Group agreed to consult with members of the public and interested parties as part of its background research into the issue of vaccine damage. It wrote to the following bodies and invited submissions from them:

- Irish Pharmaceutical Healthcare Association
- Irish Practice Nurses Association

- Faculty of Paediatrics, Royal College of Physicians of Ireland
- Faculty of Public Medicine, Royal College of Physicians of Ireland
- Irish College of General Practitioners

A copy of these submissions can be seen at Appendix 3.
In addition to this, a public notice was placed in the national press in July 2007, inviting submissions from members of the public. A total of 125 submissions were received from, or on behalf of individuals who had claimed to have experienced an adverse reaction following the administration of a vaccine. Submissions were also received from Deputy Denis Naughten TD and the Irish Vaccine Injury Campaign.

4. Vaccinations within the scope of the scheme

A clinical subgroup was established to consider and advise on what vaccines should be included in any such scheme and on what other relevant inclusion criteria should be recommended. The subgroup's recommendations were accepted by the Group and are set-out below.

The clinical subgroup considered that all vaccines provided as part of public immunisation programmes in line with NIAC guidance should be included in any proposed scheme. This

would include all vaccines provided as part of the Primary Childhood Immunisation Programme, the School Immunisation Programme and other vaccines provided by the public health system to defined at-risk categories of children and adults in line with NIAC recommendations.

The following vaccines are/have been recommended by NIAC:

- BCG
- Diphtheria, tetanus, pertussis (DTP, DTaP, Tdap, DT, Td, Tdap or TT)
- Haemophilus influenzae type b (Hib)
- Hepatitis A (HA V)
- Hepatitis B (HBV or as part of DTaP/IPV/Hib/Hep B)
- Influenza (TIV) [given each year during the flu season]
- Measles, mumps, rubella (MMR, MR, M, R)
- Meningococcal C (Men C, MPSV)
- Polio (OPV or IPV)
- Pneumococcal conjugate (PCV)
- Pneumococcal polysacharide vaccine (PPV)
- Varicella (VZV)

It is envisaged that any future vaccines recommended by NIAC for inclusion in the public immunisation programme, would be included in the proposed scheme.

5. Eligibility Criteria

The group recommends that the list of adverse events described in Appendix 1 would be recognised as adverse events specified for payment under the scheme.

The criteria for all adverse events specified should also include a requirement that the effects of the person's injury:

- Must occur within a specific period of time as detailed in the table;
  and have
- Lasted for more than 6 months after the vaccine was given; **or**
- Resulted in a hospital stay and surgery; **or**
- Resulted in death.

There is now medical evidence that certain children are at increased risk of encephalopathy and seizure disorders due to recently identified familial or sporadic gene mutations. Individuals with these mutations develop epilepsy and subsequent neurological deterioration whether or not they are immunised in the first year of life.

6. Recommendations

The group recommends that an ex-gratia payment scheme be established.

A three tiered structure depending on the severity of damage is recommended as follows:

Minor Damage - €15,000

Moderate Damage - €75,000

Severe Damage - €200,000

The Group recommends that the scheme should be administered by the Department of Social and Family Affairs.

The scheme should be established in a manner that will be client friendly. In that regard consideration should be given to easily read application forms and information leaflets.
The structure/layout of the application form will ensure that there is no ambiguity in the relation to the requirements that:-

(i) The adverse event being claimed for must be one recognised as an adverse event specified for payment under the scheme, and

(ii) The effects of the person's injury should:-

- occur within a specific period of time as detailed in the table; **and** have either
- Lasted for more than 6 months after the vaccine was given; **or**
- Resulted in a hospital stay and surgery; **or**
- Resulted in death.

Prior to submission of the application form the applicant will be required to have the form certified by their GP or treating consultant.

The applicant will be required to submit with the application form all medical records/reports/other evidence available to them in support of their application.

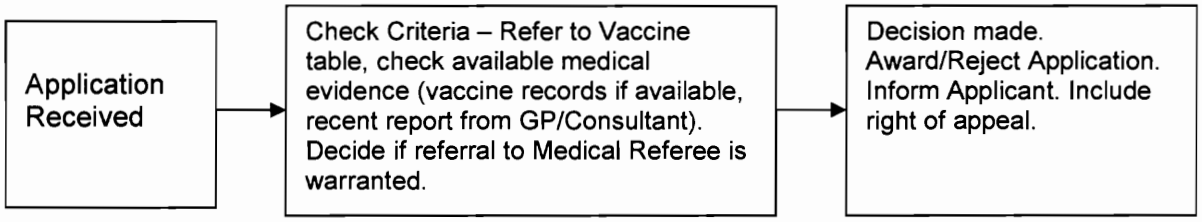
The Group recommends that medical and other professional fees should not be reimbursed to applicants. However, consideration should be given to funding vouched expenses to an agreed amount, this amount being subject to review periodically.

As part of its terms of reference the Group considered whether the scheme should be retrospective and concluded that in the interests of fairness and equity the scheme should apply to all cases of vaccination, whensoever they occurred, provided they meet the criteria set out in the eligibility criteria above.

The Group considered two possible models for the proposed scheme.

Model 1

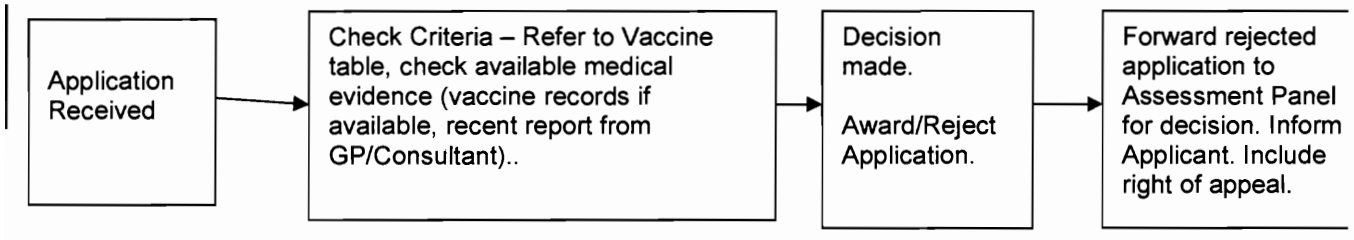
This model envisages a 3 person assessment panel comprising 2 medical and 1 administrative. The process would essentially be a desktop exercise. The process flow would be:



Model 2

This model would see all applications assessed by one person with a provision that any rejected applications would automatically be referred to a 2/3 member assessment panel of the same make-up as in Model 1.

The process flow would be:



The Group recommends Model 1.

7. Structure of the Scheme

Consideration should be given to establishing the Scheme on a statutory basis to include such matters as:

- The nature of the damage which qualifies for an award;
- Mode and standard of proof,
- The amount payable,
- The composition of the body that will award payments
- The process they will administer,
- The interaction of the ex gratia scheme with the legal system.
- The interaction of the ex gratia scheme with the earlier scheme.

7.1 Outline of the Scheme

- The scheme will be a no-fault scheme in that complainants will only be required to establish that, on balance of probabilities, the injuries were caused by the vaccine. They will not be required to show that the healthcare practitioner or some other person was negligent in administering the vaccine.

- Applicants will be required to prove their case on balance of probabilities. It will be a matter for them to supply all evidence of alleged vaccine damage at the start of the process.

- As a matter of law, the body may sit either in private or public. However, given that it will be required to hear medical evidence relating to individuals who may lack full capacity, it is recommended that hearings be held in private.

- The body must be independent in the exercise of its functions.

- The Department will liaise with other Departments/Agencies to discuss any proposed cross-departmental care packages or concessions. Legislation should detail how a scheme would affect Social Welfare Benefits, Medical Cards, Income Tax Liabilities, or other assistance provided by the Health Service Executive or Department of Education & Science.

- An appeal mechanism must be built into the scheme.

- It should be noted that, as a matter of law, citizens have a constitutional right of access to the Courts. The existence of the Scheme may not preclude any person who believes that their vaccine damage has been caused negligently from taking their case to court. However, it should be a condition of acceptance of an award that any claims against the State in relation to the alleged vaccine damage are waived.

8. Estimated Cost of the Scheme

It is difficult to assess with any degree of certainty the likely cost of establishing a payment scheme as recommended. This will entirely depend on the number of individuals who will be successful in their applications for payment under the scheme. The Group's assessment however, having examined the evidence base for known adverse events associated with vaccination, and having developed eligibility criteria to mirror that outcome, is that few cases are likely to satisfy the criteria which properly reflect the proven low incidence of vaccine damage.
In this regard it is worth noting that the UK authorities advise that approximately five new cases annually receive payment under their scheme.

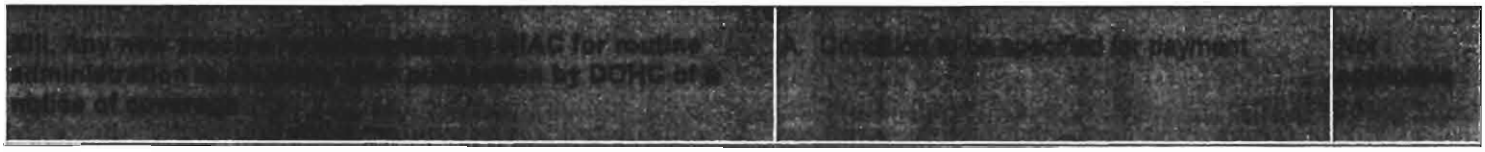
In attempting to assess the likely financial impact for the State of the Group's recommendations cognisance must also taken

of the potential savings to the health service of a higher uptake of vaccination programmes as a result of enhanced public and practitioner confidence in the safety and efficacy of national immunisation initiatives. Without predjudice ,therefore, to the outcome of any cases that might be taken under the proposed scheme the Group estimates the likely annual cost to be small.

Appendix 1: Table of adverse events that would be recognised for payment.

Vaccine	Adverse Event	Time Interval
I. Tetanus toxoid-containing vaccines (e.g., DTaP, Tdap, DTP-Hib, DTaP-Hib-IPV, DTaP-IPV, DT, Td, TT)	A. Anaphylaxis or anaphylactic shock [1]	0-4 hours
	B. Brachial neuritis [6]	2-28 days
	C. Any acute complication or sequela (including death) of above events [4]	Not applicable
II. Pertussis antigen-containing vaccines (e.g., DTaP, Tdap, DTP, P, DTP-Hib, DTaP-Hib-IPV, DtaP-IPV)	A. Anaphylaxis or anaphylactic shock [1]	0-4 hours
	B. Encephalopathy (or encephalitis) [2]	0-72 hours
	C. Any acute complication or sequela (including death) of above events [4]	Not applicable
III. Measles, mumps and rubella virus-containing vaccines in any combination (e.g., MMR, MR, M, R)	A. Anaphylaxis or anaphylactic shock [1]	0-4 hours
	B. Encephalopathy (or encephalitis) [2]	5-15 days
	C. Any acute complication or sequela (including death) of above events [4]	Not applicable
IV. Rubella virus-containing vaccines (e.g., MMR, MR, R)	A. Chronic arthritis [5]	7-42 days
	B. Any acute complication or sequela (including death) of above event [4]	Not applicable
V. Measles virus-containing vaccines (e.g., MMR, MR, M)	A. Thrombocytopenic purpura [7]	7-30 days
	B. Vaccine-Strain Measles Viral Infection in an immunodeficient recipient [8]	0-6 months
	C. Any acute complication or sequela (including death) of above events [4]	Not applicable
VI. Polio live virus-containing vaccines (OPV)	A. Paralytic polio	
	• in a non-immunodeficient recipient	0-30 days
	• in an immunodeficient recipient	0-6 months
	• in a vaccine associated community case	Not applicable
	B. Vaccine-strain polio viral infection [9]	

	• in a non-immunodeficient recipient	0-30 days
	• in an immunodeficient recipient	0-6 months
	• in a vaccine associated community case	Not applicable
	C. Any acute complication or sequela (including death) of above events [4]	Not applicable
VII. Polio inactivated-virus containing vaccines (e.g., IPV)	A **Anaphylaxis or anaphylactic shock** [1]	0-4 hours
	B. **Any acute complication or sequela (including death) of above event** [4]	Not applicable
VIII. Hepatitis B antigen-containing vaccines	A. Anaphylaxis or anaphylactic shock [1]	0-4 hours
	B. Any acute complication or sequela (including death) of above event [4]	Not applicable
IX. Haemophilus influenzae (type b polysaccharide conjugate vaccines)	A. **No condition specified for payment**	Not applicable
X. Meningococcal Group C conjugate and meningococcal polysaccharide vaccines	A. No condition specified for payment	Not applicable
XI. Pneumococcal conjugate vaccines	A. No condition specified for payment	Not applicable
XII. Hepatitis A antigen containing vaccines	A. No condition specified for payment	Not applicable
XIII. Trivalent influenza vaccines	A. **No condition specified for payment**	Not applicable
XIV. Varicella vaccines	A. **No condition specified for payment**	Not applicable
XV. BCG vaccine	A. Subcutaneous abscess requiring hospitalization and surgery B. Disseminated BCG infection with sequalae lasting over 6 months	



Adapted from National Vaccine Injury Compensation Program, US Department of Health and Human Services

Qualifications and Aids to Interpretation

(1) **Anaphylaxis and anaphylactic shock** mean an acute, severe, and potentially lethal systemic allergic reaction. Most cases resolve without sequelae. Signs and symptoms begin minutes to a few hours after exposure. Death, if it occurs, usually results from airway obstruction caused by laryngeal oedema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, oedema of the pharynx and/or trachea and/or larynx with stridor and dyspnoea. Autopsy findings may include acute emphysema which results from lower respiratory tract obstruction, oedema of the hypopharynx, epiglottis, larynx, or trachea and minimal findings of eosinophilia in the liver, spleen and lungs. When death occurs within minutes of exposure and without signs of respiratory distress, there may not be significant pathologic findings.

(2) **Encephalopathy.** For purposes of the Table, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An **acute encephalopathy** is one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).

(A) **For children less than 18 months of age** who present without an associated seizure event, an acute encephalopathy is indicated by a "significantly decreased level of consciousness" (see "D" below) lasting for at least 24 hours. Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

(B) **For adults and children 18 months of age or older**, an acute encephalopathy is one that persists for at least 24 hours and characterized by at least two of the following:
(1) A significant change in mental status that is not medication related; specifically a confusional state, or a delirium, or a psychosis;
(2) A significantly decreased level of consciousness, which is independent of a seizure and cannot be attributed to the effects of medication; and
(3) A seizure associated with loss of consciousness.

(C) Increased intracranial pressure may be a clinical feature of acute encephalopathy in any age group.

(D) A "significantly decreased level of consciousness" is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (2)(I)(A) and (2)(I)(B) of this section for applicable timeframes):
(1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
(2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

(ii) **Chronic encephalopathy** occurs when a change in mental or neurological status, first manifested during the applicable time period, persists for a period of at least 6 months from the date of vaccination. Individuals who return to a normal neurological state after the acute encephalopathy shall not be presumed to have suffered residual neurological damage from that event; any subsequent chronic encephalopathy shall not be presumed to be a sequela of the acute encephalopathy. If a preponderance of the evidence indicates that a child's chronic encephalopathy is secondary to genetic, prenatal or perinatal factors, that chronic encephalopathy shall not be considered to be a condition set forth in the Table.

(iii) An encephalopathy shall not be considered to be a condition set forth in the Table if in a proceeding on a petition, it is shown by a preponderance of the evidence that the encephalopathy was caused by an infection, a toxin, a metabolic disturbance, a structural lesion, a genetic disorder or trauma (without regard to whether the cause of the infection, toxin, trauma, metabolic disturbance, structural lesion or genetic disorder is known). If at the time a decision is made on a petition filed for a vaccine-related injury or death, it is not possible to determine the cause by a preponderance of the evidence of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the Table.

(iv) In determining whether or not an encephalopathy is a condition set forth in the Table, the review panel shall consider the entire medical record.

(3) **Seizure and convulsion. For** purposes of paragraphs (b)(2) of this section, the terms, "seizure" and "convulsion" include myoclonic, generalized tonic-clonic (grand mal), and simple and complex partial seizures. Absence (petit mal) seizures shall not be considered to be a condition set forth in the Table. Jerking movements or staring episodes alone are not necessarily an indication of seizure activity.

(4) **Sequela.** The term "sequela" means a condition or event which was actually caused by a condition listed in the Vaccine Injury Table.

(5) **Chronic Arthritis.** For purposes of the Vaccine Injury Table, chronic arthritis may be found in a person with no history in the 3 years prior to vaccination of arthropathy (joint disease) on the basis of:

(A) Medical documentation, recorded within 30 days after the onset, of objective signs of acute arthritis (joint swelling) that occurred between 7 and 42 days after a rubella vaccination;

(B) Medical documentation (recorded within 3 years after the onset of acute arthritis) of the persistence of objective signs of intermittent or continuous arthritis for more than 6 months following vaccination:

(C) Medical documentation of an antibody response to the rubella virus.

For purposes of the Vaccine Injury Table, the following shall not be considered as chronic arthritis: Musculoskeletal disorders such as diffuse connective tissue diseases (including but not limited to rheumatoid arthritis, juvenile rheumatoid arthritis, systemic lupus erythematosis, systemic sclerosis, mixed connective tissue disease, polymyositis/dermatomyositis, fibromyalgia, necrotizing vasculitis and vasculopathies and Sjogren's Syndrome), degenerative joint disease, infectious agents other than rubella (whether by direct invasion or as an immune reaction), metabolic and endocrine diseases, trauma, neoplasms, neuropathic disorders, bone and cartilage disorders and arthritis associated with ankylosing spondylitis, psoriasis, inflammatory bowel disease, Reiter's syndrome, or blood disorders.

Arthralgia (joint pain) or stiffness without joint swelling shall not be viewed as chronic arthritis for purposes of the Vaccine Injury Table.

(6) **Brachial neuritis** is defined as dysfunction limited to the upper extremity nerve plexus (i.e., its trunks, divisions, or cords) without involvement of other peripheral (e.g., nerve roots or a single peripheral nerve) or central (e.g., spinal cord) nervous system structures. A deep, steady, often severe aching pain in the shoulder and upper arm usually heralds onset of the condition. The pain is followed in days or weeks by weakness and atrophy in upper extremity muscle groups. Sensory loss may accompany the motor deficits, but is generally a less notable clinical feature. The neuritis, or plexopathy, may be present on the same side as or the opposite side of the injection; it is sometimes bilateral, affecting both upper extremities. Weakness is required before the diagnosis can be made. Motor, sensory, and reflex findings on physical examination and the results of nerve conduction and electromyographic studies must be consistent in confirming that dysfunction is attributable to the brachial plexus. The condition should thereby be distinguishable from conditions that may give rise to dysfunction of nerve roots (i.e., radiculopathies) and peripheral nerves (i.e., including

multiple mononeuropathies), as well as other peripheral and central nervous system structures (e.g., cranial neuropathies and myelopathies).

(7) **Thrombocytopenic purpura** is defined by a serum platelet count less than 50,000/mm^3. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with other causes such as hypersplenism, autoimmune disorders (including alloantibodies from previous transfusions) myelodysplasias, lymphoproliferative disorders, congenital thrombocytopenia or hemolytic uraemic syndrome. This does not include cases of immune (formerly called idiopathic) thrombocytopenic purpura (ITP) that are mediated, for example, by viral or fungal infections, toxins or drugs. Thrombocytopenic purpura does not include cases of thrombocytopenia associated with disseminated intravascular coagulation, as observed with bacterial and viral infections. Viral infections include, for example, those infections secondary to Epstein Barr virus, cytomegalovirus, hepatitis A and B, rhinovirus, human immunodeficiency virus (HIV), adenovirus, and dengue virus. An antecedent viral infection may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing. Bone marrow examination, if performed, must reveal a normal or an increased number of megakaryocytes in an otherwise normal marrow.

(8) **Vaccine-strain measles viral** infection is defined as a disease caused by the vaccine-strain that should be determined by vaccine-specific monoclonal antibody or polymerase chain reaction tests.

(9)**Vaccine-strain polio viral infection** is defined as a disease caused by poliovirus that is isolated from the affected tissue and should be determined to be the vaccine-strain by oligonucleotide or polymerase chain reaction. Isolation of poliovirus from the stool is not sufficient to establish a tissue specific infection or disease caused by vaccine-strain poliovirus.

Appendix 2 - Summary Table of schemes in other countries

Summary of Vaccine Injury Compensation Programs (adapted from Evans G. 1999) Table 1							
	Sweden	**Italy**	**Norway**	**Switzerland**	**Japan**	**Quebec**	**Taiwan**
Enacted	**1978**	**1992**	**1995**	**1970**	**1970&1977**	**1985**	**1988**
Administrative entity	Pharmaceutical Insurance(non-governmental)	Ministry of Health	Ministry of Health and Social Affairs	State (Canton) {Federal law guides outcome}	Ministry of Health and Welfare	Ministry of Health and Social Services	Department of Health
Vaccines Covered	All approved products marketed in Sweden	Compulsory	Routine Childhood	Recommended by canton	Recommended Vaccines	Voluntary (none are required)	Compulsory
Filing Deadlines	3 years after being made aware of first injury	Injury: 3 years Death: No limit	Not specified	None (individual Cantons may have limits)	No Limit	3 years after vaccination or death or onset of chronic illness,	1 year after vaccination
Compensable Injuries	Those noted as side effect in FASS (like US PDR) or in medical literature	Death or injury resulting in permanent physical or mental impairment	Not specified	Injury has to exceed abnormal post vaccine reaction.	Disability or death resulting from vaccination.	Any serious permanent damage including death.	Table of compensable injuries
Process and Decision Making	Claims manager with Zurich insurance makes decisions with medical consultation as needed.	Medical Hospital Board for eligibility; compensation based on levels of injury	Ministry of Health decides eligibility	Health Department reviews claim and seeks supporting information.	Committee on Public Health decides eligibility and damages.	Claims reviewed by 3 member Medical Evaluation Committee, final decision by Minister of Health.	Vaccine Injury Comfort Fund Working Group, Dept of Health
Proof Needed	Strong probability of cause & effect	Not specified	Balance of probabilities	Not specified	Not specified	Balance of probabilities	Balance of probabilities
Elements of Compensation	Un-reimbursed medical costs, lost wages, death benefits	Free medical care, medication, disability pension, death benefit	Lump sum	Medical costs, death benefits, disability pension, non-economic loss.	Medical costs, disability pension, death benefits.	Un-reimbursed medical costs, rehabilitation costs, death benefits.	Medical costs, health care expenses, burial expenses.
Funding service	Manufacturers pay premiums into fund	National Treasury	National Treasury, contribution from manufacturers	General revenues of the Canton	Treasury:50% Perfecture:25% Municipal:25%	National Treasury	Manufacturers And local society and community
Appeal rights	Yes	Yes	No	Yes	Yes	Yes	Yes
Litigation rights	No	Yes	Yes	Yes (with limits)	Yes	Yes	Yes

Summary of Vaccine Injury Compensation Programs (adapted from Evans G. 1999) Table 2						
	United Kingdom	**United States**	**New Zealand**	**Germany**	**France**	**Denmark**
Enacted	1979	1988	1974	1961	1964	1972&1978
Administrative Entity	Department for work Pensions	Department of Health and Human Services	Accident Compensation Corporation (ACC)	State (Lander) pension system-Federal Law guides outcome	Ministry of Solidarity, Health and Welfare	National Social Security Office (NSSO)
Vaccines Covered	Routine Childhood (DTP,MMR,Polio,BCG,Hib)	Routine Childhood (DTP, MMR, Polio, Hib, Hep B, Varicella, rotavirus, Pneumococcal conjugate, Hep A)	All that are administered	Recommended by German federal states (Lander) – most routine and specific use vaccines	Compulsory	Governmental provided (free)
Filing Deadlines	The later of the following dates: On or before the disabled person's 21st Birthday (or if deceased the date they would have reached 21) Within 6 years of the vaccination to which the claim refers.	For injuries or deaths resulting from a vaccine administered on or after 1/10/1988 Injury: within 36 months. Death: within 24 months/48 months after onset of vaccine related injury from which the death occurred.	1 year after being made first aware of injury	None	4 years after injury stabilisation	1 year after onset of symptoms
Compensable injuries	Severe disability to extent of 60% or more as a result of vaccination.	Injuries listed on the vaccine injury table or by providing causation.	Vaccine related injury that is rare and severe.	Injuries exceeding the extent of usual vaccine reactions		
Process and Decision Making	If claim is accepted the Vaccine Damage Payments Unit obtains medical evidence; if level of disability that can be attributed directly to the vaccination is at least 60& then claim is successful	HHS Physician reviews each claim and forwards recommendation to the court. A "Special Master"- attorney appointed by the judges of the court makes the decision for compensation under the VICP	Individuals files claims with the Medical Misadventure Advisory Committee of ACC	Claims are evaluated by the Landers office in charge of social services, utilizing medical expert advice.		
Proof Needed	Balance of probabilities	Balance of probabilities	Balance of probabilities	Probable cause		
Elements of Compensation	Lump sum payment of £100,000	Unreimbursed past and future medical expenses, lost wages, non-economic loss, attorney's fees.	Medical costs, disability pension, death benefits	Medical costs, disability pension, funeral costs		
Funding service	Consolidated fund provided by Parliament	National Treasury(pre enactment)excise tax on covered vaccine(post enactment)	Employers, wage earners, auto licensing, government investment, income	General revenues of the Lander		
Appeal rights	Yes	Yes	Yes	Yes	Yes	Yes
Litigation rights	Yes (with limits)	Yes (with limits)	No	Yes (with limits)	No	Yes (with limits)

Appendix 3 - Group submissions to Vaccine Damage Steering Group

- Irish Pharmaceutical Healthcare Association
- Irish Practice Nurses Association
- Faculty of Paediatrics, Royal College of Physicians of Ireland
- Faculty of Public Medicine, Royal College of Physicians of Ireland
- Irish College of General Practitioners

IRISH PHARMACEUTICAL HEALTHCARE ASSOCIATION

6th November 2007

Mr Chris Fitzgerald,
Chairman,
Vaccine Damage Steering Group,
Department of Health & Children
Hawkins House
Dublin 2

Dear Mr Fitzgerald,

Re Vaccine Damage Steering Group

The Irish Pharmaceutical Healthcare Association (IPHA) represents the interests of the international research-based pharmaceutical industry in Ireland. Amongst the members of IPHA are GlaxoSmithKline, Sanofi Pasteur MSD, Solvay Healthcare Limited and Wyeth Pharmaceuticals. These four companies form the Vaccine Manufacturers Group within the IPHA and between them supply various vaccines such as those for the childhood immunisation schedule and the influenza vaccine for the elderly and other at risk groups.

The Association welcomes the opportunity to make a contribution to the work of the Vaccine Damage Steering Group.

Public health benefits of vaccination

Vaccination is one of the safest medical interventions and is probably the most cost effective of all healthcare initiatives.[1] More lives have been saved through vaccination against infectious diseases than through any other public health intervention, apart from the provision of clean water. Vaccination has almost totally eliminated many serious and potentially fatal diseases like diphtheria, polio, tetanus, rubella and more recently hib meningitis with the introduction of a vaccine in 1993.

The World Health Organisation is of the view that the benefits from vaccines for an individual and for a community far outweigh the disadvantages and it is working *"to ensure that all people at risk [are] protected against vaccine-preventable disease"*.

In Ireland, vaccination is strongly recommended by the Department of Health and Children. This view is endorsed by the Royal College of Physicians in Ireland, the Faculty of Paediatrics, the Irish College of General Practitioners and the Health Protection Surveillance Centre.

Developing safe and effective vaccines

The pharmaceutical industry is committed to developing and manufacturing safe and effective vaccines. The manufacturing process for vaccines is lengthy and complex and subject to independent scrutiny by regulatory authorities throughout Europe, the Irish Medicines Board (IMB) is the relevant licensing authority in Ireland.

All vaccines must undergo clinical trials before they are licensed for use. Several batches of the one vaccine are tested in a trial to ensure batch-to-batch consistency in terms of clinical safety and efficacy. Vaccines can only be approved for use after a rigorous benefit/risk assessment by independent scientific experts in national regulatory authorities. Even after the vaccine is licensed by the IMB, every batch undergoes internal batch release testing and it must also be submitted for testing by an independent external body before use.

The safety of all vaccines is closely monitored after they are released on the market. In the EU, data on side effects or adverse reactions for all medicines, including vaccines, must be collected by the manufacturer and by regulatory authorities. Such data comes from reports of adverse reactions submitted by healthcare professionals and also from literature reports of adverse reactions. Doctors, nurses and pharmacists are encouraged to report adverse reactions even if they are not sure whether the vaccine caused the reaction.

The information collected is scientifically evaluated and appropriate action is taken where necessary by the regulatory authority. Systems have been established to ensure that reports of adverse drug reactions are exchanged between regulatory authorities worldwide. Therefore, the surveillance of vaccines in Ireland is not only based on experiences here and in other EU member states but also on additional data from outside the EU.

Safety of vaccines

As infectious diseases continue to decline, some people have become less aware of the consequences of illnesses like diphtheria and tetanus and more concerned about risks associated with vaccines. Since vaccination is a common and memorable event, any illness following immunisation may be attributed to the vaccine even though scientific evidence to support a link between the two may be weak or non-existent.

Vaccine manufacturers provide detailed information about their products in a patient information leaflet, which accompanies the vaccine. Included in the information are lists of the contraindications and side effects of each particular vaccine. The content of the leaflet must be consistent with the Summary of Product Characteristics and is approved by the IMB as part of the authorisation process for the vaccine. The industry wholeheartedly supports the provision of detailed information to parents prior to the vaccination of their child.

Although in general, vaccines are extremely safe, no vaccine is completely without adverse effects. Minor reactions to vaccinations are common and expected. Serious major reactions are extremely rare. To put in context the safety of vaccines, the risk of complications from vaccine-preventable diseases far outweighs the risk of adverse events following the use of the vaccines.[2] That is not of course to deny that proper provision has to be made for the small number of adverse events that may occur.

Background to the establishment of Vaccine Damage Schemes

Although vaccination is one of the safest health interventions, it is not without any risk. In a very small number of cases vaccination may be associated with long-term disability and in some countries, such as the United Kingdom, Vaccine Damage Payment Schemes have been established to provide support to the people affected in this way.

The UK Vaccine Damage Payment Scheme is paid as a disability benefit provided as part of the State welfare system. Its purpose is to ease the present and future burdens of those who are considered to be suffering from vaccine damage, and their families.[3] The scheme was introduced by the British Government in 1979 because it accepted that it had a special responsibility to those thought to have been injured by properly manufactured and administered vaccines that it had decided to use in it's public health immunisation programmes.

The scheme was reviewed during 2000 and 2001, resulting in the following changes:

- An increase in the maximum payment under the scheme from £40,000 to £100,000
- 'Top-up' payments for people who have previously received payments under the scheme
- Removal of the six-year time limit within which claims under the scheme had to be made
- A reduction in the 'disability threshold' for payment under the scheme from 80% disablement to 60%

The scheme allows for payments to be made using the standard of the 'balance of probabilities' when deciding on possible causation of the disability.

The industry is very sympathetic to the tragic plight of any person who is thought to have been damaged by vaccines. As ethical manufacturers, vaccine companies are responsible for any legal liabilities arising from the use of their products. They are answerable in court if it is proved that their products have caused damage to people who use them and they have not warned them of the possible side effect of using the vaccines or they have been negligent in some way. But this is not usually the case for claims made under the Vaccine Damage Payment Scheme. In these cases, there is no suggestion of undeclared, possible side effects or of any negligence. As such the issue of whether to establish such a Scheme here in Ireland is a matter for the Government to decide upon and in the event of its establishment to fund.

Conclusion

As outlined above vaccine companies are committed to the provision of comprehensively tested vaccines to the Irish public. The industry clearly acknowledges that, as well as the great benefits which vaccination can bring, they also can result in side effects. Information on these potential side effects is set out in independently approved patient information leaflets which accompany the vaccines.

The IPHA recognises that the State may wish to consider the introduction of a Vaccine Compensation Scheme. It could be argued that such a Scheme might assist the State in underpinning the public vaccination programmes which require 95% take-up to ensure herd immunity. The industry would see such an initiative as being purely a Government one aimed at underpinning its public health objective of encouraging vaccination because of its undoubted benefits. It would be a matter for the State itself to decide upon and fund. It would be neither appropriate nor fair to expect vaccine companies to help fund such a scheme. The industry will continue to provide funds for the extensive and exhaustive systems of checks in place concerning their products and will also pay compensation where it is proven that it is appropriate they should do so.

The Association would of course, be happy to comment further on any of the points made in this submission.

Yours sincerely,

Brian Murphy

Brian Murphy
Director of Commercial Affairs

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[1] The World Bank World Development Report – "Investing in Health" (Oxford University Press)

[2] Health Protection Surveillance Centre – *"Your child's immunisations: A guide for parents"*

[3] Department for Work and Pensions; vaccine damage payments website: http://www.dwp.gov.uk/lifeevent/benefits/vaccine_damage_payments.asp

IPNA SUBMISSION TO VACCINE DAMAGE STEERING GROUP AUGUST 2007

In the absence of any terms of reference or guidelines for submissions, the IPNA contacted its' Practice Nurse members via e-mail to ask for any relevant comments. The comments returned by IPNA members are listed under the headings below which are the main issues of concern.

MAINTENANCE OF THE COLD CHAIN

- One Practice Nurse made the point that delivery of vaccines should be at a time agreed by the surgery, so that a designated person can be available to receive the delivery and therefore responsible for maintaining the cold chain by refrigerating the vaccines immediately.
- One Practice Nurse expressed concern about the United Drug service, saying that the service was not of the same standard as the previous supply company.
- Another Practice Nurse reported requesting an unscheduled delivery because the surgery fridge had broken down over the weekend. Despite numerous phone calls, the new vaccines were not delivered and she was eventually informed that she would have to wait until the courier was in the area again. When the delivery of Priorix eventually came, the driver would not take the damaged vaccines away, so she disposed of them in the sharps bin rather than wait for the next scheduled delivery.

SAFETY AND EFFICACY OF VACCINES

- Another Practice Nurse reported that the GSK Hep B vaccine supplied by her HSE area, in her experience, does not give patients a good response. She had to re-vaccinate 4 patients, 2 of which were staff, who had initially been given the GSK vaccine, with the MSD alternative, which involved distress, inconvenience, and an unnecessarily increased danger of infection.
- Another Practice Nurse complained that Wyeth's Meningitis C vaccine is not available from the HSE. She felt that the CHIRON vaccine is not as easy to handle because of the bulky packaging in comparison with ampoule from Wyeth.
- Practice Nurses report that flu vaccines are not delivered early enough each Autumn, which wastes vital time in vaccinating the at-risk population.
- One Practice Nurse feels that extensive media campaigns should be undertaken each year to highlight the need for those at risk to get their flu vaccine.

SAFETY OF THOSE RECEIVING VACCINES

- Practice Nurses have expressed concern about being asked or expected to administer vaccines at times when there is no GP on the premises. The presence of a GP in the premises when a vaccine is being administered is vital for both patient safety and the Practice Nurse's professional registration. It is vital that all members of the Primary Care Team know and respect each other's Scope of Practice.

COMPETENCY OF PERSON ADMINISTERING VACCINES

- Practice Nurses take on the "delegated" task of administering vaccines from the officially delegated General Practitioner. Looking at the responsibilities of the Practice Nurse who has been delegated the role - from a Scope of Practice perspective - raises questions about competence, where and when the competencies were acquired and how they are maintained. Practice Nurses feel that they are wide open to litigation in the area of immunisation albeit vicariously, if they cannot trace back where they acquired this competency and how they maintain it.
- Education programmes and regular updating for all health professionals who administer vaccines would ensure that there is a full understanding of *what* is being administered and that any vaccine is a challenge to the recipient's immune system to induce immunity. There should also be more focus on possible adverse reactions and ways to ensure that means of resuscitation should be present and accessible in all surgeries.
- **With the vast majority of immunisations now being administered by Practice Nurses, a standardised immunisation training programme for Practice Nurses needs to be established as a matter of urgency and made available nationally.**

SUPPORT AND COMMUNICATIONS BETWEEN HSE AND SURGERIES

- The coding of the vaccinations given e.g. PC1, D. etc makes them difficult to cross reference.
- The HSE area that has made any payments should be clearly marked.
- The names of relevant personnel within the HSE and their telephone numbers should be provided to each surgery in case of any queries.
- Practice Nurses report that payments for vaccines are often delayed and the details of what the payment is for or which HSE office has made the payment are not clear and therefore time is wasted trying to follow them up.

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12 September 2007

Mr C Fitzgerald
Vaccine Damage Steering Group
Dept of Health and Children
Hawkins House Dublin 2

Dear Mr Fitzgerald

We are responding to the Vaccine Damage Steering group (VDSG) call for submissions on behalf of the Faculty of Paediatrics, Royal College of Physicians of Ireland. The Vaccine Damage Steering group (VDSG) should note that, due to unavoidable constraints relating to submission deadlines and our own collective availability to meet, it has not been possible to submit this document to Faculty for formal endorsement before submission to VDSG. We have included some illustrative references but would be happy to provide more if VDSG needs further input from RCPI Faculty of Paediatrics.

None of us is an epidemiologist or has specialist experience in Public Health or Vaccinology. However we are all experienced Consultant Paediatricians, whose individual and overlapping areas of interest and expertise lead us to encounter many patients and families with concerns about immunisations. Our joint deliberations have included email correspondence, a meeting and conference call on 7th September, 2007, and joint review and editing of the submission.

We wish to start our submission by stating our complete support for universal active immunisation programmes, which together have been described as one of the most important and cost-effective public health successes of the 20th century (MMWR, 1999). We also endorse the planned inclusion of new immunisations in the primary immunisation programme in Ireland in the first decade of the 21st century. We would expect the impact of the additional immunisations to be as compelling in an Irish setting as they are proving to be in other countries. In addition, like the VDSG, we are all too aware of the adverse consequences of misplaced public concern or loss of confidence in the national immunisation programme (Mc Brien, et al, 2000).

It is clear that any adverse consequences of immunisation, for which VDSG and others may consider compensating families, should be significant and long-lasting, leading to altered expectations of life experiences for the child involved.

It is not our intention to review concerns regarding every vaccine product that has been used in Ireland. We specifically wish VDSG to note that some public concerns regarding certain immunisations, prevalent at the time of the DOHC report on Childhood Immunisations in 2001, have been proved either to be unfounded, or to relate to vaccines that have been modified in the intervening 6 years. Examples include concerns regarding whole cell pertussis vaccine and neurological events

(Kuno Sakai & Kimura, 2004), MMR and pervasive developmental disorders (Fombonne et al., 2006) and enteropathy and Hepatitis B and thiomersal/mercury poisoning.

VDSG will be well aware that there is a considerable difference between two events having a causal association and merely being temporally associated. To even entertain the possibility of any perceived "damage" being causally associated there should be a strong actual or theoretical etiological/pathogenetic link between the ingredients of the vaccine product (immunologically active ingredient, excipients, stabilisers etc) and the perceived adverse reaction.

Certain risks relating to medical interventions are real and relate in part to the immunological effect that is sought to be induced by the immunisations. Minor local reaction at the injection site is a good example. Minor local reactions can be minimised by changing injection technique and needle size. Anaphylaxis due to allergic reactions to protein components of a vaccine is another example. We consider these recognised adverse outcomes from immunisation to be either of such a low frequency (anaphylaxis) or a short-lived physical inconvenience (local reactions) in most of the very rare proven cases. VDSG should not routinely include them in its considerations for compensation programmes.

At present the major proven medical risk from immunisation with live vaccines is induction of the target illness in the immunised host, who may be immunocompetent and suffer only a minor illness, or who may be immunodeficient and suffer severe disease. Examples include: disseminated disease with the vaccine strain following immunisation with MMR, BCG or oral polio in previously unrecognised immunocompromised hosts or localised infective complications following BCG immunisation. Primary immunodeficiency is very rare in Ireland, though with changing demographics and increasing immigrant populations, single gene disorders may become relatively more common in ethnic communities where consanguinity is not uncommon. Such populations are also those at highest risk of TB; routine BCG administration should be continued in such groups. Additionally antenatal screening for HIV infection limits maternal transmission, however isolated cases still occur.

In the last 5-10 years considerable progress has been made in the field of neurogenetics. It is now apparent that certain children are at increased risk of encephalopathy and seizure disorders due to recently identified familial or sporadic single gene mutations (Berkovic et al., 2006). The onset of clinical disease from such unsuspected disorders may in the past have been attributed to temporally-associated immunisations. It is unlikely that population screening for these conditions will ever be considered but a case could be made that children whose families are claiming vaccine damage may need evaluation for such familial neurogenetic disorders. VDSG should consider how such an evaluation system would be resourced.

Regarding VSDGs terms of reference:

1. *To identify and define the adverse events following immunisation with certain vaccines as recommended by the National Immunisation Advisory Committee (NIAC).*

And

2. *To examine the feasibility of estimating from available documentation the number of recipients of vaccination programmes who experienced an adverse reaction and the extent and severity of any resulting permanent damage.*

It will be critical for VDSG to ensure the completeness and verifiability of all adverse reactions to vaccines. There is extensive international experience in this field, in countries such as Finland, the UK and the US (see, for example, www.vaers.org).

3. *To consider the possible components of a payment or benefit package, including the degree of retrospection, if any.*

We do not know whether or not any mooted compensation scheme is to be considered a no-fault scheme. Such "no-fault " schemes in areas such as medical error etc. are felt to support both health professionals in their daily activities and individuals and families who otherwise have to "battle" the bureaucratic machinery of State to get recognition of their plight. We would consider it reasonable and compassionate that any payments agreed should be dated to the time of the immunisation that had been implicated. Starting otherwise would be to encourage administrative and legalistic obfuscation and delay. Such delays would add further to a family's distress, loss of earnings etc., thereby possibly impeding further the optimisation of an affected child's quality of life.

4. *To review the general details of vaccine damage compensation schemes operating in other countries and identify the most relevant models from a clinical, administrative and fairness point of view.*

We support this international benchmarking.

5. *To estimate the likely overall cost and the cost to the state of introducing a 'no-fault' scheme*

See 3 above for our view on this point.

6. *To ensure that there is no resultant damage to public confidence in the national immunisation programme.*

We think public confidence in the immunisation programme may actually be enhanced if there were a visible and accountable system in place to deal with concerns over immunisation policies and practice.

7. *To make such recommendations as the Group sees fit*

There is a converse side to public policy regarding universal immunisation. VDSG may need to consider compensation for children who have been infected with diseases preventable by immunisation, in areas of the country where routine immunisation has not or is not offered by the HSE. The starkest example of this is the 2007 outbreak of TB in South Cork city. Affected children may have lifelong health issues relating to HSE South's BCG policy in Cork that was at variance with national and international practice. Similarly parents who opt not to immunise their children must accept

responsibility for any complications of specific illnesses that their un-immunised children may experience.

We conclude our submission by stating the Faculty's full support for this initiative and Faculty's readiness to be involved further in VDSG's deliberations and any initiatives that may follow therefrom.

Yours sincerely

Professor Jonathan O'B Hourihane MB, DM, FRCPCH
Professor of Paediatrics and Child Health, UCC, Cork
Consultant Paediatric Allergy and Immunology, Cork University Hospital

on behalf of:

Dr Patrick Gavin, MB, MRCPI, DABMM, MD
Consultant Paediatric Infectious Diseases, Children's University Hospital, Temple St, and Our Ladys Hospital for Sick Children, Crumlin, Dublin

Dr Bryan Lynch
Consultant Neurologist, Children's University Hospital, Temple St, Dublin

Dr Edina Moylett,
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Consultant Paediatrician, University College Hospital, Galway

References

Berkovic SF, Harkin L, McMahon JM, Pelekanos JT, Zuberi SM, Wirrell EC, Gill DS, Iona X, Mulley JC, Scheffer IE De-novo mutations of the sodium channel gene SCN1A in alleged vaccine encephalopathy: a retrospective study. Lancet Neurology 2006; 5(6): 488-492.

Fombonne E, Zakarian R, Bennett A, Meng L, McLean-Heywood D. Pervasive developmental disorders in Montreal, Quebec, Canada: prevalence and links with immunizations. Pediatrics 2006;118(1):e139-50. PMID: 16818529

Kuno-Sakai H, Kimura M. Safety and efficacy of acellular pertussis vaccine in Japan, evaluated by 23 years of its use for routine immunization.Pediatr Int. 2004;46(6):650-5. PMID: 15660862

MMWR Morbidity and Mortality Weekly Report April 02, 1999 / 48(12);243-248 Achievements in Public Health, 1900-1999 Impact of Vaccines Universally Recommended for Children -- United States, 1990-1998

McBrien J, Murphy J, Gill D, Cronin M, O'Donovan C, Cafferkey MT. Measles outbreak in Dublin, 2000. Pediatric Infectious Diseases Journal. 2003;22: 580-4

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August 29th 2007

Mr. Chris Fitzgerald
Chairman
Vaccine Damage Steering Group
Hawkins House
Dublin 2

Subject: Submission for the Vaccine Damage Steering Group

Dear Mr. Fitzgerald,

Dr. Anna Clarke, Dean of the Faculty of Public Health Medicine of Ireland, asked me to make a submission on behalf of the Faculty.

1. Vaccines are safe, effective and administered through the national immunisation programme

Vaccines are safe and effective, have been used for decades with proven direct and indirect benefit to children and communities. Vaccines have been shown to be the most cost effective health intervention. Irish and international public health policy encourages and actively supports all children to be vaccinated. In some places, to protect the health of the population, vaccination is mandatory under national/regional legislation.

2. Rarely vaccines may damage the recipient, through no fault

Routine childhood immunisation is given and accepted in good faith. There are extremely rare occasions when vaccines may damage the recipient. In Ireland, litigation though the courts is the usual process for seeking compensation in such circumstances. However, such litigation has substantial sequelae and adverse effects on the individual and the community:
Litigation activities are daunting, tortuous and expensive to the individuals, their families, health professionals and governmental health services.
Litigation creates an adversarial approach and antagonism between vaccine companies, those administering vaccines, the public services and the government.
Litigation cases (whether finding in favour or not of the claimant) result in substantial media attention which damages public and professional confidence in the national immunisation programme.
Litigation cases have led to dramatic and sustained declines in immunisation uptake for years after the case is in court. This has resulted in vaccine preventable disease outbreaks in the communities (e.g. measles).

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3. Vaccine injury compensation schemes

A number of countries have already introduced vaccine injury compensation programmes. Introduction of a vaccine injury compensation scheme publicly acknowledges that occasionally adverse serious events may follow recommended and publicly funded vaccination.
The advantages of having such a programme are that it assures the public that there is governmental support and an acceptance of responsibility for the programme and any untoward events that may rarely occur (but only following rigorous assessment of claims).
Having such a system may reduce litigation, may improve consumer and provider confidence.
Having such a system can increase immunisation uptake.

4. International examples of vaccine injury compensation programmes
United States

In 1988 the United States established the National Vaccine Injury Compensation Program (VICP). This programme provides an accessible and efficient forum for vaccine injury claims and provides compensation to people found to be injured by certain vaccines, adopting a no-fault approach. The U. S. Court of Federal Claims decides who will be paid, and how much. Three government offices have a role in the VICP, the Department of Health and Human Resources, Department of Justice, Department of Federal Claims.
The Vaccine Injury Compensation Trust Fund funds this programme. The Trust Fund is funded by a $0.75 excise tax on each dose of vaccine purchased (i.e., each disease prevented in a dose of vaccine).
Vaccines covered under this system include all the vaccines provided routinely in the immunisation programme as recommended by the Advisory Committee on Immunisation Practices (ACIP).

3. Need for rigorous surveillance and investigation of adverse events following immunisation

Strengthening vaccine pharmocovigilance and establishing a rigorous adverse events following immunisation (AEFI) programme is necessary if Ireland is to have a national immunisation injury compensation programme.
I believe that a national vaccine injury compensation programme would assist the national immunization programme.

Yours sincerely,

Dr. Suzanne Cotter MRCPI MFRHMI MPH DTM&H DCH

Cc: Dr. Anna Clarke, Dean of the Faculty of Public Health Medicine, RCPI

Vaccine Damage Payment Scheme for Ireland?

Outline Position Paper from ICGP

Introduction

In 2004 Professor David Isaacs, (Department of Immunology and Infectious Diseases, Children's Hospital at Westmead, NSW 2145, Australia), wrote

'At least a dozen countries or states in the world have introduced vaccine injury compensation schemes. This paper argues that the Australian Government should introduce such a scheme, which may reduce litigation, and may improve consumer and provider confidence. The most important justification, however, is an ethical argument from justice and equity: introduction of a vaccine injury compensation scheme acknowledges the unique situation that routine childhood immunization is a public health measure, given and accepted in good faith, that may occasionally damage the recipient.'

'Should Australia introduce a vaccine injury compensation scheme? D Isaacs'
(Journal of Paediatrics and Child Health, Vol. 40 Issue 5-6 Page 247 May 2004)
(Fax: + 61 2 9845 3421; email: davidi@chw.edu.au)

In Ireland, most childhood vaccination takes place in General Practice, and is supported by Public Health colleagues. This has resulted in high levels of uptake in

most parts of the country. However national vaccination programmes can pose ethical problems.

In summary, national vaccination programmes protect almost everybody from the illnesses concerned. As a result many patients, who would otherwise have faced illness, or even death, are protected. With the exception of some local 'black spots' the vaccination programmes nationally are working well.

However the vaccines themselves also have side effects, some of which are capable of causing serious illness or even death. Fortunately these are relatively uncommon but still cannot be totally eliminated. Most importantly they are less frequent and less damaging than the illnesses they prevent. Thus in terms of the whole population the benefits of vaccination are obvious.

But for individual patients damaged by the vaccine these population benefits are of little consolation. From their individual point of view they would never have been affected had they not taken the vaccine. For them vaccination has resulted in serious lifelong disability for which a financial payment is little compensation.

Fortunately the chances of being affected are relatively small. Nevertheless GPs must explain to patients that there is a small risk associated with the vaccines.

In the unlikely event of a child being damaged by the vaccine, a programme should be in place to confirm vaccine damage and to provide standard compensation. Based on

Appendix 1.

Welcome at the EUROPEAN FORUM ON VACCINE VIGILANCE website

VACCINATION DAMAGE is the entire set of health derangements that may occur due to vaccination. For more details go to "general information".

The **European Forum on Vaccine Vigilance** is a forum of European organisations which are dedicated to the investigation and prevention of such health derangements, under the presidency of ALIS (France) and the LIGA (Spain).
In order to do so

- we want to inform all individuals about the possible risks and side effects of vaccines;
- we want to network people and organisations with an interest in this area;
- we want to make the vaccination issue one of public interest which can and must be discussed openly with all those concerned;
- we want to help the victims of vaccine damage to help them defend their just cause and their rights;
- we want to put more pressure upon politicians to increase freedom of choice and enhance balanced information on vaccinations.
- we demand financial compensation for those who are victims to the vaccination policy of their government

VACCINATIONS

Mandatory vaccines
Contra-indications
Efficacy
Side effects
What vaccine to give?
When to vaccinate?
Some more suggestions
Homeopathic treatment

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You can visit our site for questions concerning the vaccination of yourself or your child. Whether you have yourself vaccinated or not must be a deliberate and free choice. Vaccination is a full medical act and is not to be underestimated as to its

experience in other jurisdictions a 'once off' payment to compensate for the damage appears to be the preferred option. In Ireland this should be in the region of €200,000.

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possible consequences. It should, therefore, be considered with utmost care and full knowledge of its side effects.

Most vaccines only protect partially and temporarily, others do not protect at all. Moreover, every vaccine includes a number of risks, ranging from transient inconveniences to lifelong damage to health or death. This means that thorough information and reflection are necessary before a decision is being made. An attitude of "just acting normal, doing what everybody does" could turn out to be a serious mistake because different people react in different ways to a particular vaccine.

The basic idea of vaccination is to increase specific immunity to one particular disease before the patient catches it. We, on the opposite, are convinced that it is far more efficient to stimulate general, a-specific immunity instead, allowing our system to react promptly to ANY infection by bacteria, virusses, fungi etc.

MANDATORY VACCINES

Whether vaccines are mandatory or not depends on the national or state legislation. As far as we are aware, the following vaccines are mandatory: (please corrrect or complete if incorrect or incomplete).
BELGIUM: polio (IPV)
FRANCE: tetanus, diphtheria, polio (IPV)
GERMANY: none
ITALY: polio, diphteria, whooping cough, hepatitis B
NETHERLANDS: none
SPAIN: none
U.K.: none

CONTRA-INDICATIONS

These are the states in which vaccination is unacceptable on medical grounds.

• Any child which is not in perfect health should NEVER be vaccinated. Even a common cold or a slight fever increase the risk for complications.

• A severe reaction (see SIDE EFFECTS) to a former vaccination compels to stop using that vaccine, because every subsequent administration may lead to fatal reactions.

• An allergy for any of the components of a vaccine is also a compelling reason not to administer it.

There are two ways to know whether your child is allergic to a vaccine or not: 1° if it developed an allergic reaction to an earlier dose of the vaccine; 2° if it has a known allergy to any of the components of the vaccine.

Examples of substances which are often present in vaccines and regularly lead to allergic reactions are the antibiotic neomycin (polio, DPT, MMR), the mercury

derivate thiomersal (hepatitis B, tetanus, influenza) which is used also in solutions to keep contact lenses, and aluminumhydroxide.

• In case of a suppressed immune system (for example by cortisone or cancer drugs or HIV treatment) one should not be vaccinated.

• Likewise, people suffering from chronic fatigue should not have themselves vaccinated.

• Manifest irritability after birth should inspire us to utmost care and eventually to postpone or even abort all vaccination plans.

• Allergy in the patient himself OR in a sibling or close relative increases the risk for side effects. By "allergy" we mean, among other expressions, asthma, hay fever, food allergies (milk, eggs, sugar etc.).

• Serious affections of the nervous system (e.g. M.S., A.L.S.), AIDS, serious skin disorders, systemic affections (Lupus, reumatoid arthritis, erythema nodosum, insulin dependent diabetes), even in close relatives, are valid reasons to decline vaccination.

EFFICACY

No vaccine is 100% effective. With some people the vaccine will not protect at all; in almost every instance, if protection is offered, it will subside in the course of time. There are no clear rules to know whether one is protected or not. Even the presence of antibodies is no absolute guarantee for protection.

SIDE EFFECTS

General side effects which may occur after any vaccine are:

** local swelling with heat and redness at the site of inoculation. Also a pink, elevated rash (urticaria) or little red, dry spots (rash) may occur all over the body.

** Fever:a raise of temperature above 39°C is not a normal reaction, and must be reported to the doctor who administered the vaccine.

** The vaccinated person may vomit, become flatulent, or develop a diarrhoea.

** Within minutes after vaccination, the vaccinated person may become pale, cold, flabby and unconscious. This means he is going into a shock. This situation is life threatening. Immediate reanimation and admission into the nearest hospital are necessary.

** Also convulsions are possible, in which case the patient loses contact, or becomes stiff, or starts moving eyes, arms and legs in an uncontrolled way. In this case start to cool off the patient progressively and call a doctor. The patient must remain under close surveillance because of a risk for permanent brain damage.

** Some children start shrieking uncontrolably, most commonly high pitched, are inconsolable, and do not stop crying until they fall asleep from exhaustion. This kind of behaviour indicates brain involvement and certainly is an alarming symptom! A doctor must be called at once.

A child may become uncommonly sleepy, or sleepless, or develop a completely disturbed sleeping pattern.

** Cot death is a tragic complication which is statistically related to vaccination.

** A child may develop a chronic coryza, or manifest recurrent ear- and throat infections, bronchitis or asthma.

** An allergy develops more frequently after vaccination against whooping cough or measles.

** Diabetes increased 60% after hepatitis B- and Hib-vaccination in New Zealand.

** Different kinds of paralysis may occur, e.g. Guillain-Barré paralysis.

** Auto-immune diseases (rheumatoid arthritis, lupus, erythema nodosum, periarteritis nodosa, Goodpasture syndrome) have been diagnosed after different vaccines (tetanus, BCG, measles, Hepatitis B).

** In the long run vaccines can lead to hyperkinetic behaviour, learning disabilities, behaviour problems (aggression, autism) and changes in character.

** Sudden death may be the result of an acute complication like shock or encephalitis.

WHICH VACCINE TO GIVE ?

Every vaccine must be considered separately. Not ever should a vaccination be thought of as a routine matter. Every vaccine given must have a specific, individual indication. We cannot approve mass vaccination against ANY disease.

Some professions may justify the use of a certain vaccine, e.g. tetanus vaccine in metal workers, or hepatitis B vaccine in surgeons or personnel working in blood transfusion or haemodialysis units.

POLIO still is mandatory in some countries. The disease hardly occurs in the West anymore, except as the result of vaccination. There is hope vaccination can be abandoned world wide within the next few years.

DIPHTHERIA (croup) is a serious bacterial infection. The upper respiratory tract may swell to such an extent that the patient chokes. Also the heart is frequently affected. Vaccination only has a mediocre protective effect and produces a number of side effects. Fortunately the disease does not occur anymore in most countries. Some outbreaks have been reported in the former Soviet Union, which does not constitute a threat to western society. Vaccination, therefore, is unnecessary. In case of infection

one can still be treated.

TETANUS generally can be prevented by accurate treatment of the lesion. The most capital measures are: to have the wound bleeding, rinse it copiously with hydrogen peroxide and keep it open to the air. Grazes or wide, bleeding wounds do not produce tetanus. The only risk is when the tetanus germ is locked into the wound and cut off from oxygen, which allows it to multiply and produce the feared toxin. Tetanus remains a dangerous condition that may result in death. Whether to vaccinate or not will depend upon the risk for stitches with infected matter.

WHOOPING COUGH is a serious and annoying disease, lasting many weeks, with fatal outcome only in very rare cases. The traditional whole cell vaccine does not guarantee protection, and the side effects are numerous and severe. Not to be recommended. The new acellular vaccine causes fewer local side effects but still is responsible for serious neurological trouble.

MEASLES is one of the traditional childhood diseases. The course of the disease can differ from mild and short (about three days) to rather ill during a week. The patient should stay at home. The most feared complication, meningitis, is much more rare than commonly thought, and occurs almost with the same frequency after the disease as after vaccination against the disease. This observation makes us question the very reason for vaccinating. The quality and the duration of immunity are far better after going through the disease than after vaccination. All this makes the vaccine absolutely redundant.

MUMPS is a very benign childhood disease. Generally it does not have to be treated at all, and if occasionally it has to be treated, alternative medicine can take care of it very well. Orchitis (inflammation of the testicles) is rare, and generally one sided. Infertility as a result of mumps, therefore, is extremely rare and does not justify the use of a vaccine and it's risks (diabetes!).

RUBELLA also is a benign childhood disease. The only danger is infection of the foetus in pregnant women during the first trimester, because this could damage the foetus. The best way to prevent this is lifelong immunity. The only way to obtain lasting immunity is... by having the disease during childhood. After vaccination, immunity is either absent, or temporary, but never lasting and, therefore, unsuitable for the goal of a safe pregnancy. Women can have their antibodies determined before they decide to get pregnant. If antibodies are absent, they still have the occasion then to have themselves vaccinated.

These three childhood diseases have in common that immunity against them is better and longer lasting (life long) after the disease than after vaccination. Going through one of these diseases during childhood is the ideal prevention against infection in adult life, or taking the risk that a mother does not have sufficient antibodies to pass on to her newborn baby. Both those situations imply an increased risk for exactly those complications the vaccines were meant to prevent. Moreover, having these childhood diseases at a young age appears to protect against a number of chronic

diseases (rheumatism, allergies, skin affections and cancers) in later life. The ideal prevention, therefore, is to make sure a child has had the diseases before puberty. This does not imply exaggerated risks. So, the idea of 'rubella parties' is not too bad after all!

VARICELLA fits in with this group. The disease is trivial and perfectly curable if necessary. The only measure parents need to take is to keep the child at home for as long as the fever lasts, and to dry up the vesicles.

HIB is not a vaccine against meningitis in general; it's only target is one subtype of one of the many bacteria, not to mention the many virusses, that can cause meningitis. It does NOT, therefore, offer any protection against these many other forms of meningitis. Neither does it protect against other complications of the infection such as otitis media. Haemophilus influenzae, the bacterium targetted by this vaccine, is commonly present on the mucosae of the throat without doing any harm at all. Vaccination is not without a risk and cannot be recommended.

HEPATITIS B infection is caught, in a large majority of cases, by stitches with infected needles (intravenous drug abuse) or by unprotected sexual contact with an infected person. It is generally a problem in adult life. The vaccine is nothing less than dangerous because of the many severe side effects. Not to be recommended with babies or younger people, neither in adults who are not at severe risk profesionally. Of course the vaccine does not protect against other forms of hepatitis (A, C, G...).

INFLUENZA implies a whole lot of possible side effects. To be advised against! Patients at risk will profit more from general measures to enhance their situation (vitamins, echinacea, rest, holistic treatment...) than from vaccination.

BCG is the vaccine against tuberculosis. A study performed by the WHO itself proved it to be completely ineffective. To be forgotten.

WHEN TO VACCINATE? If parents decide to have their children vaccinated with a particular vaccine, it is also important to do so at an appropriate time.

Tetanus is not a problem in infants. Serious side effects are less frequent and more easy to detect at a later age. So, if one decides to vaccinate, it makes sense to postpone this vaccination until the age of 3 years. A booster at 16 and another one at 50 will cover the need for protection for the rest of that patient's life.

A FEW MORE SUGGESTIONS

** Relax and discuss your concerns with your partner, your best friends... before taking a decision. Never decide in a panic situation.
** In case of vaccination, make sure the name of the vaccine and the lot number are recorded in the medical file.

**If there is any suspicion of a vaccine reaction, do not hesitate to warn your doctor, remind him the child has been recently vaccinated, and make sure the symptoms and diagnosis are recorded in the medical record. Ask your doctor to pass on his observations to the medical authorities.
** Also mention your experiences to your local Informed Choice organisation.
** Antipyretic drugs such as tylenol suppress an appropriate reaction by the recipient of the vaccine and may cover up an adverse effect. So it is better not to give any, but treat the situation with more adequate measures if necessary.
** It is extremely dangerous to vaccinate during an incubation period (that is the time between infection and the outbreak of the symptoms). Never agree with a last minute vaccination during an epidemic!
** Sometimes adverse reactions are observed only after weeks. Even then one must not fail to make the link with the vaccination. The long term consequences can be quite serious. Never allow anyone to turn you down as an over-concerned parent!

HOMEOPATHIC TREATMENT

Homeopathic treatment is capable of reversing a good number of adverse effects from vaccination. Treatment can be based either upon the acute symptoms, or it can be constitutional. Sometimes nosodes (i.e. homeopathic dilutions of the vaccines) will have to be administered to achieve a breakthrough.

The fact that your homeopath will generally be able to reverse the vaccine damage is not a reason to run unnecessary risks! Never forget that preventing vaccine damage is better than curing it!

Systematic use of homeopathic nosodes to prevent side effects cannot be accepted. First of all it is your responsability to make an informed decision. Nosodes may disturb a constitutional homeopathic treatment. Besides, some children are strong enough to survive vaccination without serious side effects, so that they don't need nosodes or homeopathic treatment at all.
Briefly, nosodes are needed only when treatment is indicated and a traditional homeopathic approach does not confer a solution.

Vaccine Damage

BMJ Clinical Evidence
Measles Prevention
(Search Date July 2004)

"Measles Vaccine (Monovalent or MMR) reduced the incidence of measles and child mortality compared with placebo or no vaccine." (vol.13 June 2005)

1. Found no RCTs comparing the clinical effects of MMR, versus no vaccine, or placebo.
2. One large RCT, one quasi randomised trial, one large retrospective cohort study, and several observational studies found that monovalent vaccine reduced the incidence of measles.
3. Mass population cohort studies and other observational studies also consistently found important reductions in child mortality after measles vaccination.
4. Observational studies found that measles vaccination programmes were followed by a reduction in the incidence of sub-acute sclerosing panencephalitis.
5. Several features of measles infection occur or are suspected to occur after the vaccine, but we found no studies comparing rates of occurrence between people with naturally acquired measles and those who have been vaccinated.
6. Severe complications are rare with measles immunisation.
7. One non-systematic review found that, compared with placebo, measles vaccination increased the incidence of fever and febrile seizures, although febrile seizures are rare and do not progress into afebrile seizures.
8. Aseptic meningitis, a rare complication, increased after mass vaccination, in some viral strains.
9. Observational studies found that both measles vaccination and naturally acquired measles increased the incidence of Idiopathic Thrombocytopenic Purpura.
10. Observational studies found no association between the incidence of asthma in healthy children and MMR vaccination.
11. They also found no significant change in the incidence of Guillain-Barre syndrome, autism, diabetes, or inflammatory bowel disease as a result of measles vaccination. Anaphylaxis has been reported after vaccination with MMR, but this is extremely rare.
12. No RCTs compared clinical effects of MMR versus monovalent vaccines. Sero-conversion rates are similar.

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Nothing new under the sun!

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Sentenced to life!!!

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Notes on ***Vaccine Damage Payment*** System in the UK.

- The severely disabled only.
  - At least 60%; mental/physical; (e.g. total blindness = 100%)
- Single once-off payment
- Paid directly to patient or his/her trustees
- £120,000 tax free
- 12 named diseases
  - Diphtheria
  - Tetanus
  - Pertussis (whooping cough)
  - Poliomyelitis
  - Measles
  - Mumps
  - Rubella ('german measles').
  - Tuberculosis
  - Haemophilus influenzae type B
  - Meningitis C
  - Pneumococcal infection
  - Smallpox pre August 1st 1971.

- Some vaccinations were combined (DTP; MMR).
- Maternal vaccination while pregnant is included.
- Also close physical contact with someone vaccinated using oral polio.
- Vaccination must have been given in UK, Isle of Man, or Armed forces.
- Claims on behalf of children must be made within six years of the date of vaccination, when at least 2 yrs old, and no later than aged 21 or on the date of death if before 21 years.
- A single payment is made direct to the individual or to Trustees if under the age of 18. Parents can act as trustees.
- The Vaccine Damage Payment can affect other benefits and entitlements.
- Decisions on claims can be reviewed by the Vaccine Damage Payments Unit and appealed to an independent appeal tribunal.