AGENDA ITEM NUMBER 14

PAPER NUMBER JCVI(04)38

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NOT FOR PUBLICATION

JOINT COMMITTEE ON VACCINATION AND IMMUNISATION

TITLE OF PAPER Annual Vaccine Damage update

REASON FOR INCLUSION (please say whether this is a discussion paper or for information).

For information

ACTION REQUIRED BY THE COMMITTEE

None

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LIST OF PAPERS/ARTICLES ATTACHED (if applicable)

ANY OTHER COMMENTS

Update on reports received through the Vaccine Damage PaymentScheme (October 2002 to March 2004)June 2004

Key points of note

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- From April 1996 to March 2004, a total of 1430 claims were submitted to the VDPU, of which 1137 claims proceeded to medical evaluation.
- From October 2002 to March 2004, the DH received information on a total of 370 claims.
- A total of seven claims were awarded during this period.
- MMR (37%) and DTP (35%), alone or in combination, were the most commonly cited vaccines.
- The majority of claims was for males and related to neurological conditions such as autistic spectrum disease, developmental delay, seizures and paralysis. This is similar to previous findings.
- The number of reports received relating to bowel disease was fewer during this period than previously.
- The key change has been an increase in the number of claims relating to DTP vaccine, the majority of which related to neurological conditions such as developmental delay and seizures. This may be a reflection of the recent media interest in thiomersal in DTP and neurodevelopment problems.

Update on reports received through the Vaccine Damage PaymentUnit (October 2002 to March 2004)June 2004

Background

The Vaccine Damage Payment Scheme was set up in 1978 to provide individuals seriously damaged following vaccination with a single, tax-free payment to help ease the burden. This scheme was set up following the conclusions of the Royal Commission on Civil Liberty and Compensation for Personal Injury Report published in 1978. Background information on the Vaccine Damage Payment Scheme is attached at Annex 1.

Process of reviewing vaccine damage claims

All vaccine damage claims submitted to the Vaccine Damage Payment Unit (VDPU) are reviewed to see whether they fulfil the criteria set out in Annex 1. Claims may be rejected without undergoing medical assessment (referred to as lay rejections) if they do not fulfil these criteria. The majority of claims undergo medical assessment and are awarded or rejected on the basis of the level of disablement and whether it is the result of the immunisation. When a claim is reviewed it may take some months to undergo evaluation before it proceeds to medical assessment.

Number of claims submitted to VDPU

Table 1 summarises (a) the total number of claims received by the VDPU; (b) the total number of claims which proceed to medical assessment; and (c) the total number of lay rejections, from 1 April 1996 to 31 March 2004 (six-monthly intervals).

From April 1996 to March 2004, a total of 1430 claims were submitted to the VDPU. During this period 1137 claims proceeded to medical evaluation and 318 claims were rejected because they did not fulfil the necessary criteria.

The number of claims received by the VDPU in each six-month period was variable. The maximum number of claims received in any one six-month period (with the exception of Apr 02-Sept 02) has been around 100. The dramatic rise in number of claims received in April – Sept 02 was a result of the legislative changes in the disability thresholds and time limits for submitting a claim for vaccine damage (point 3 of Annex 1). This change has meant that a large number of claims that were originally rejected could be re-submitted for reassessment.

<u>Table 1 – (a) Total number of claims received by the VDPU; (b) the total number of claims which proceed to medical assessment; and (c) the total number of lay rejections, from 1 April 1996 to 31 March 2004 (six-monthly intervals)</u>

Time period	(a) Total no. of claims received	(b) Total no. of claims which undergo medical assessment	(c) Total no. of lay rejections
Apr 96 – Sept 96	36	32	13
Oct 96 – Mar 97	33	30	. 15
Apr 97 – Sept 97	90	52	15
Oct 97 – Mar 98	112	98	16
Apr 98 – Sept 98	87	114	19
Oct 98 – Mar 99	48	57	17
Apr 99 - Sept 99	27	22	7
Oct 99 - Mar 00	63	25	24
Apr 00 - Sept 00	100	49	43
Oct 00 - Mar 01	102	50	39

Total	1430	1137	318
Oct 03 – Mar 04	84	77	8
Apr 03 – Sept 03	81	73	15
Oct 02 – Mar 03	102	239	18
Apr 02 – Sept 02	319	99	13
Oct 01 – Mar 02	71	42	26
Apr 01 – Sept 01	75	78	30

Information provided to Department of Health

Since 1 April 1996, information on claims submitted to the VDPU that proceed to medical evaluation (where claimant has given consent) has been forwarded to the Department of Health (DH). The DH does not receive information on claims rejected at the initial stage ('lay rejections'). Approximately 85% of claims, which undergo medical assessment, are forwarded to DH. As these reports relate to individuals who have been seriously damaged as a result of vaccination, these reports may be viewed as a marker of the chronic conditions parents believe are associated with vaccines.

From April 1996 to March 2004, the DH received information on a total of 959 claims. A breakdown (six-monthly intervals) of the number of claims received by the DH is shown in Figure 1 (Annex 2). As there is a lag period between the claim being submitted the VDPU and undergoing evaluation for eligibility, the DH may receive details of claims up to six months after the claim was originally made.

A detailed paper on the claims received from April 1996 to September 2002 was provided at the Feb 2003 JCVI meeting. This paper updates the committee on the claims received from October 2002 to March 2004.

Vaccines implicated in claims

When submitting a claim, claimants do not have to specify a particular vaccine as a causal factor in the disability. The majority of reports (72%) cited only one vaccine as the suspected vaccine. In a small number of cases the suspected vaccine(s) (4%) was not stated or was unknown.

During October 2002 and March 2004, the most commonly cited vaccines, alone or in combination, were MMR (37%) and DTP (35%). Of the remaining reports, the most common vaccines cited were OPV (17%), measles/measles rubella (6%), and pertussis (7%). In six reports (2%) all routine childhood vaccines were implicated in the claimant's illness by the parents. An increase in number of claims citing DTP (35%) is a key change as only 11% of previous claims cited DTP. This is likely due to the recent media interest in thiomersal in DTP and neurodevelopment problems.

Chronic illness described in vaccine damage claims

During October 2002 to March 2004, the majority of conditions cited in the vaccine damage claims related to neurological conditions such as developmental problems, autistic spectrum disease, paralysis, palsy, and seizures. There were also a large number of reports of bowel disease and deafness. The majority of claims were for males: 651 out of 959 (68%).

Table 2 shows the main types of conditions reported for the most commonly cited vaccines. These were autism/autistic spectrum disease, seizures, developmental delay, and chronic bowel problems.

In some cases recognised reactions were also reported to have occurred after vaccination, such as pyrexia, rash, or febrile convulsion prior to the development of the chronic condition.

The predominance of neurological conditions is in keeping with previous data.

Type of diagnosis	MMR	DTP	OPV	Pertussis*	Measles/ MR	Total (by condition)
Chronic joint problems (arthritis)	1	2	0	0	0	3
Atopy (asthma, eczema)	10	4	0	0	0	14
Autistic spectrum disorder/Autism	94	16	- 3	1	3	117 ·
Chronic bowel problems	15	3	0	1	0	19
Diagnosed with a congenital disorder	1	2	0	0	0	3
Deafness/ hearing impairment	5	2	1	1	2	11
Death						
*Developmental/speech/l earning/ behavioural problems	80	75	27	12	13	207
Encephalitis/ encephalopathy leading to chronic problems	1	0	0	- 1	1	3
Eye problems/ visual impairment	2	13	6	0	2	23
IDDM	3	0	0	0	0	3
ME/ Chronic fatigue syndrome	0	0	0	0	1	1
Other	11	12	8	4	2	37
Palsy	2	14	5	3	0	24
Paralysis (including poliomyelitis/paraparesis /transverse myelitis)	2	21	18	3	3	47
Psychiatric symptoms	0	3	2	1	3	9
Seizures	10	63	24	8	9	114
Total (vaccine)	236	230	94	35	39	

Table 2: Summary of types of conditions for the most commonly cited vaccines in claims

Reports with a fatal outcome

From October 2002 to March 2004, there was a small number of claims (6) that stated that the individual had died. Five out of six of these reports related to deaths a number of years following immunisation (range 5-40 years) due to conditions (epilepsy, SLE, heart condition, encephalitis) which were alleged to have been caused by immunisation. The other report related to a child who developed meningitis and encephalitis three weeks after MMR immunisation and died within two days of becoming ill.

Successful claims

The VDPU advise the Department of claims that have been successful after review by their medical assessors. Claims can also be successful after appeal but the VDPU does not hold this information and there can be substantial delays. From October 2002 to March 2004, there have been a total of seven awards were paid out. The DH received information on six of these reports. The vaccines cited in these claims were DTP (3), polio (1), Hib (1), measles (1), smallpox (1) and BCG (1).

Annex 1

1. What is the Vaccine Damage Payment Scheme ?

• The Vaccine Damage Payment Scheme provides a single, tax-free payment to people who have suffered severe mental and/or physical disablement of 60 per cent or more, as a result of immunisation against one or a group of the diseases listed below:

diphtheria, rubella, tetanus, poliomyelitis, pertussis, meningitis C, measles, tuberculosis (TB), smallpox (up to 01/08/1971), mumps and *Haemophilus influenzae* type B (Hib)

• Claims can also be made by a person who is thought to be severely disabled because their mother was immunised against any of the diseases above while she was pregnant or if someone is thought to be severely disabled because they have been in close contact with a person who has been immunised against polio (using orally administered vaccine).

2. Requirements for submitting a claim

- The disabled person must be two or more years old and must have been immunised in the UK or the Isle of Man unless they, or someone in their family, were in the armed forces and the immunisation was given as part of the armed services medical forces.
- The individual must have been immunised before their eighteenth birthday, unless the immunisation was against polio, rubella or meningitis C or given during an outbreak within the UK or the Isle of Man.
- The claim must be made within six years of the date of immunisation or of the child reaching the age of 21 whichever is the later.
- Payments are made direct to disabled persons aged 18 or over that are capable of managing their own affairs. In other cases payment can be made to trustees, such as the disabled person's parents.
- The payment is **not compensation** but is designed to ease the present and future burdens of those suffering from vaccine damage and their families. The amount payable is £100,000 for claims made on or after 22 July 2000.

3. Recent changes which have been made to the VDPU Scheme

Following a review of the VDP scheme the following changes were made to the disability thresholds and time limits for claiming by a Regulatory Reform Order. The key changes came into force June/July 2002 and were as follows:

- reduction of the disability threshold from 80 to 60 per cent;
- increasing the time limits for claiming for children to age 21 or within six6 years of the immunisation the claim is for, whichever is the later; and
- allow for the consideration of further claims in cases previously disallowed under either time limit or disability threshold rules.

4. The decision-making process

Decisions on claims are made by the Secretary of State for Work and Pensions on the basis of a medical officer's assessment of the percentage level of disablement and whether it is the result of the immunisation. If a claim is medically disallowed the claimant may, at any time, seek a review of the medical officer's assessments by an independent Vaccine Damage Tribunal.

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Number of claims (which have proceeded to medical evaluation) forwarded to DH by the VDPU

ANNEX 2