National Reyes Syndrome Foundation UK

TRUSTEES REPORT
EXTRACTS – FOR THE PERIOD 22 NOVEMBER 1985 to 30 SEPTEMBER 1986

Significant events

1. Committee on Safety of Medicines: Recommendation that paediatric aspirin be withdrawn from sale

The most important event for the Foundation took place in June 1986, when as a result of the Risk Factor Study undertaken at the Communicable Disease Surveillance Centre, the Committee on Safety of Medicines decided to recommend that paediatric aspirin be withdrawn from sale. This was immediately followed by a press release from the Foundation commenting on certain aspects of the Committee's decision.

2. Meetings

The first annual meeting for parents and friends was held in November 1985 and the first medical conference organised by the Foundation – "Reye's Syndrome and Medication" – was held in July 1986.

Appendix One below – Aspirin ban – Hansard – 24th July 1986

Appendix Two below – BPSU First Annual Report 1985/86

National Reyes Syndrome Foundation UK

APPENDIX ONE

HANSARD – 24 JULY 1986

Aspirin (Ban)

6.43 am

Mr Archy Kirkwood (Roxburgh and Berwickshire)

I am grateful for the opportunity to raise some of the implications of the experience that Britain has had over the disease called Reye's syndrome and the recent ban that has been announced by Britain's health authorities as a result of some of the experience with that disease and the way in which aspirin has been involved with the disease.

It may be helpful if I spend a moment outlining some of the background. Reye's syndrome is a rare disease and the public may not be aware that it is a potentially lethal childhood illness. It was first described by Reye and his colleagues working in Sydney in 1963 and it affects all organs of the body, with especially devastating attacks on the liver and in the brain and muscle tissue. It usually appears soon after a viral infection such as influenza or chickenpox or gastro-enteritis. Early signs are continuous vomiting, loss of energy, drowsiness, aggressiveness and confusion and that usually leads to delirium, coma and in some cases subsequent death following brain inflammation.

The disease strikes children from infancy all the way through late adolescence. It is rare. Between three and seven cases per million children under 16 have been reported in Britain, but its main characteristic is its high mortality rate. In the United Kingdom, some 229 cases have occurred in the last four years. The figures available to me suggest that something like 80 children recovered completely, 20 survived with some evidence of permanent brain damage, and something of the order of 115 died. That is a high mortality rate of about 40 to 50 percent.

Reye's syndrome may be somewhat commoner than this. When Reye first described the condition only the most dramatically affected patients could be identified and 80 per cent. of those died. Mild cases are now known to occur. Mild Reye's syndrome may be a common cause of vomiting after chickenpox or influenza, and mortality rates in the United States are around 10 per cent. which suggests to me that doctors there may be diagnosing more mild cases than are diagnosed in Britain. The other factor about America is that the Americans have now probably slightly more experience in diagnosing and treating the disease than we have. Various studies in the United States show that about two thirds of cases can be detected by alert medical personnel before the coma stage sets in. Early treatment at that stage can halt progression of the disease and reduce fatalities to almost nil.

I should now like to turn to the link with aspirin. The basic cause of Reye's syndrome is still unknown, but it is still thought to be an abnormal reaction in a genetically susceptible person to a viral infection such as chickenpox or influenza, both of which are common viral infections in Britain. Studies of the disease began in the United States in 1974 and four epidemiological studies published between 1980 and 1982 linked aspirin given to treat viral illness with the onset of the syndrome. The first small epidemiological study reports appeared in 1980 and demonstrated an association with aspirin. They were followed by larger studies and on 6 June 1982 the American Academy of Pediatrics produced a special report called "Aspirin and Reye's syndrome".

That report said:

"the studies for each of the two years showed a strong association with aspirin……. Statistically, each of these studies considered independently of the others is significant; considering them together the significance is enormous…… As you are well aware, an epidemiological association does not prove causation. However, causation may be strongly indicated by association when no other explanation for the relationship is found……the consensus of the Committee is that there is a high probability that the administration of aspirin contributes to the causation of Reye's syndrome. In balancing this probability" -

in saying that the report is referring to the risk,

"with the benefits of aspirin, it is the opinion of the Committee that aspirin should not be prescribed under usual circumstances …….The Committee recognises that this recommendation is made with less than absolute proof…. until contradictory information is available, the present evidence is sufficient to warrant this recommendation."

The United States Food and Drug Administration had earlier established a working group to review the data. Its evaluation was discussed in an open public meeting on 24 May 1982, and after consideration of the available evidence, on 11 June 1982, the United States Surgeon-General advised against the use of salicylates, the chemical name for aspirin, and salicylate-containing medications for children with influenza and chickenpox.

These early studies were criticised for various reasons and in 1983 the United States public health services mounted a further study designed to eliminate possible sources of error in the earlier work. The pilot phase of that study provided evidence to support the association between the disease and aspirin use in feverish children. A total of 93 per cent. of children with Reye's syndrome had a history of aspirin ingestion compared with only 46 per cent. of the matched controls.

In the light of these findings, on 17 December 1985 the Food and Drug Administration and the manufacturers of aspirin-containing medicines launched a campaign against giving aspirin to children and teenagers.

It is significant that the number of cases of Reye's syndrome reported in the United States had already fallen from 204 in 1984 to 91 in 1985. I conclude that the fall was a direct result of public discussion following the Surgeon-General's warning in 1982. The decline seems to bear out the association between the disease and aspirin.

What about the reactions in Britain? I want to contrast what has happened here with what has happened in the United States. British reporting of Reye's syndrome started in August 1981. Between February 1984 and August 1985 the communicable diseases surveillance centre published three annual reports. After the first report, the October 1984 edition of Drugs and Therapeutics Bulletin, published by the Consumers Association warned:

"the possibility of an association between aspirin and Reye's syndrome has been raised and cannot be ignored…..while the issue remains unresolved it seems sensible to recommend paracetamol rather than aspirin as an antipyretic in infants and children."

Three years earlier, the National Reye's Syndrome Foundation had been started by a couple whose 11-year-old daughter, Katie Harrington, had just died after taking aspirin for flu. In October 1982, Mrs Harrington wrote to the DHSS about the possible link.

Two months later it replied:

"no causal link between aspirin and Reye's syndrome has been established by the present evidence, and that no warning is therefore needed in the United Kingdom."

Meanwhile, the CDSC conducted its own study of the association between aspirin and Reye's syndrome. The preliminary results of this study reached the Committee on Safety of Medicine in February 1986, and were discussed at its meeting in March. The CSM has not published the figures from the study, but a scientist at the CDSC who carried out the study, confirmed that of 106 victims studied in depth, 62 had been given aspirin in the three weeks preceding admission to hospital.

On 9 June, the chair of the CSM wrote to all doctors, dentists and pharmacists advising that aspirin should not be given to children under 12 except on medical advice – for instance, in cases of rheumatoid juvenile arthritis. The next day, the DHSS *chief medical officer,* Dr Donald Acheson, issued a statement repeating this advice.

The leading manufacturers of aspirin responded to the CSM's advice by halting the supply of junior aspirin products such as Junior Dispirin. Label warnings are to appear on new packs of all other aspirin preparations by early 1987, advising parents not to give aspirin to children unless a doctor tells them to. Announcements to this effect were placed in the national press over the following week. Posters were made available for GP's surgeries and child health clinics.

The warning was subsequently extended to a range of drugs containing salicylate. The manufacturers will place warnings on the packets, but whereas children's aspirin preparations will be withdrawn, childrens' salicylates in general will not. This includes most notably, Bonjela, a painkiller used very widely for babies with teething troubles. In fact, Reckitt and Coleman does not even intend to place a warning on packets of Bonjela, on the grounds that it is not supposed to be used for fevers anyway.

Alternatives to aspirin include paracetamol, and in fact the CMO has advised avoiding drugs altogether, using instead fluid intake, sponging, and so on.

Against this background I should like to raise several questions. As I hope I have demonstrated, I believe that there have been clear differences between what has happened in Britain and what has happened in the United States in the way in which the problem has been approached. In the United States, the issue was discussed in the open from the beginning, and with full public attention. I believe that that resulted in the fall in the incidence of the disease before the Food and Drug Administration finally issued its official warning.

In the United Kingdom, however, the issue was kept completely in the dark, despite the warnings from various quarters that I set out earlier. Secondly, the United Kingdom authorities waited until the results of the British study were clear before acting, despite the mounting evidence from the United States as to the association between aspirin and the disease.

In the United States, the Surgeon-General did not wait to be certain. He issued the warning, anyway. Since that happened in 1982, probably in the region of 200 children died in Britain from Reye's syndrome.

Thirdly, a possible reason for the delay – I hope that the Minister will say something about this – is the pressure from the pharmaceutical industry. The official report of the CSM's March 1985 meeting says that members "seemed to favour" a compulsory label on aspirin products. The drugs industry in the shape of the Aspirin Foundation worked hard to throw doubt on the research, criticising the methodology of the CDSC's study. Nevertheless, earlier this year the CSM reported that the evidence was overwhelming and a ban was eventually considered.

The industry, this time in the shape of the Proprietary Association of Great Britain – which includes all the main firms – came back offering to withdraw children's preparations and to place warnings on adult packets.

The CSM documents, which are confidential but which were leaked extensively to *The Guardian*, suggest that firms were primarily concerned with protecting their market. The firms told the CSM that an under–16ban – originally proposed by the CSM – would confuse people and there was

"a need to maintain public confidence in aspirin"

The junior aspirin market is worth about £3 million a year – a small proportion of the total aspirin market.

Fourthly, in the specialist medical journal *Pulse*, which was published this month, the warnings and the public education campaign undertaken by the Government have been extensively criticised. In fact, most children do not take junior aspirin products but simply take lower doses of adult preparations of aspirin – and the warnings are not yet included on the packets. There seems very little reason why labels could not have been stuck on the existing packets. Even more recently, I have come across some anecdotal evidence that some junior aspirin products are still on sale without warning labels and that some prescriptions are slipping through the pharmacists' and doctors' network. If that is true, and if it is substantiated on investigation, that would give me cause for great concern.

Fifthly, it is clear to me that a number of questions remain unanswered. One reason given by the DHSS for the delay in issuing warnings was the differences revealed in the United States and the United Kingdom studies. It is true that median age of onset is much lower here – starting at about 14 months compared with the eight to nine year age group that is affected in the United States. In the United States there are also marked seasonal peaks, possibly associated with the incidence and virulence of influenza B, but no such peaks have been recorded in Britain. Therefore, I accept that there are some differences in the way in which the disease occurs in Britain compared with America.

Reye's syndrome is much more common in some parts of the United Kingdom, which raises another unanswered question. The incidence of the disease in Northern Ireland is much higher than in the rest of the United Kingdom. Of the United Kingdom cases, 25 per cent. lived in rural areas compared with the national average for all under 15-year-olds living in the rural areas – 10 per cent. There is a higher incidence in rural areas. A surprisingly high number of those affected had apparently been exposed to pesticides from crop spraying. That needs careful investigation.

A likely explanation for the disease seems to be a combination of factors – a body infected with viruses, perhaps weakened by some genetic susceptibility, exposed to an environmental pollutant and finished off by aspirin. More research is needed but the Department of Education and Science – through the Medical Research Council – is not supporting any such research.

In conclusion I shall quote Clifford Harrington who is the co-founder of the National Reye's Syndrome Foundation:

"It's almost like Thalidomide all over again – complacency, secrecy, bureaucratic bungling, and a lack of care for innocent children".

I hope that the Minister will accept that in raising this issue I am not, in any way, looking for scapegoats or stating that heads should roll because no action has been taken. I believe that this is a matter of public concern which involves the lives of young children. On the evidence which is available to me I do not believe that the Government are doing enough. I hope that this debate will spur the Government into more activity to get to the root of the problem. I also hope that they will answer some of the questions that I have raised.

7.2 am

The Parliamentary Under-Secretary of State for Health and Social Security (Mr Ray Whitney): I am glad to have the opportunity to discuss this important and worrying phenomenon of Reye's syndrome and especially the relationship of Reye's syndrome with aspirin. The Committee on Safety of Medicines recommended that aspirin should not generally be given to children under 12, because of its possible association with Reye's syndrome. Reye's syndrome is a serious but fortunately very rare disease; there are about three to seven cases each year per million children under 16. As the hon. Member for Roxburgh and Berwickshire (Mr Kirkwood) said, the disease strikes suddenly, usually when a child seems to be recovering from a viral infection. The early symptoms are usually very severe vomiting, and the child then becomes confused, sleepy or aggressive, and may then progress to coma. About half the cases in this country have ended in death, and in some other cases there is brain damage. The children are very young, often only babies. Quite obviously, this disease is deeply distressing for families. I wish to extend my sympathy to the parents of all the children who have suffered from this condition particularly those who did not recover or who suffered brain damage.

Doctors have known of Reye's syndrome since 1963. There have been various attempts to investigate its nature, by clinical and biochemical investigations of the patients, and by looking at the epidemiology of the condition. The epidemiological approach showed some differences between different countries. In the United States, patients are noticeably older than they have been here. The median age of onset was about eight to nine years in the United States, but only 14 months in this country. In the United States there has been a very clear seasonal peak, as the hon. Member for Roxburgh and Berwickshire mentioned, in winter or early spring, just as there is for influenza, but in this country there is no seasonal peak. Perhaps this is linked to another finding, that most United States children had been ill with influenza or chickenpox before they developed Reye's syndrome, but a wider range of viral illnesses have been involved here. At present, I understand, there is no clear medical view about the reasons for these differences between countries, or about their implications. It is important, though, for us to keep them in mind throughout the discussion, just as the Committee on Safety of Medicines did during all its deliberations.

The committee considered the possibility of a causal link between Reye's syndrome and aspirin in 1982 and 1985 but decided that the available evidence did not establish that there was such a link. So what changed between April 1985 and June 1986, when the CSM gave a public warning that aspirin should not be given to children under 12 except on medical advice? Two new pieces of evidence became available. From the United States came figures showing that the number of reports of Reye's syndrome had fallen, in line with the fall in the use of aspirin. A statistical correlation in itself does not prove anything, but this was evidence of a different type which seemed to confirm the risk factor studies.

Secondly, the Committee was shown the preliminary findings of a risk factor study in the British Isles. This report will soon be ready for publication, but the committee saw the preliminary results in confidence. Its findings were consistent with the American ones, that aspirin seemed to be associated with Reye's syndrome. That is still not proof; there is no excepted explanation of how aspirin might cause Reye's syndrome. Many children who have developed Reye's syndrome had not taken aspirin. The best medical advice at present is that Reye's syndrome arises from a virus-host interaction in a constitutionally susceptible individual, possibly modified by an exogenous agent.

Given this new evidence, the committee concluded that aspirin may be a contributory factor in some cases of Reye's syndrome, and that action should be taken to reduce the use of aspirin in children. Aspirin should be avoided for children because it may, very occasionally, lead to Reye's syndrome, but there is always an alternative available. When a child really needs a medicine for fever or aches or pains, paracetamol is as effective as aspirin and is safer, with the very important proviso that the correct dosage should be given. The availability of the alternative was an important factor in determining the advice given about aspirin.

Whenever an expert body warns against a well established product which was previously thought to be safe, there are two accusations. Either the cry is "What an overreaction! How can there be anything wrong with something which has been used for years?" Or the other critics say, "If this warning is needed now, it should have been given a long time ago." Scientific truth is not so simple. The Committee on Safety of Medicines has to try to get the balance right, between the danger of overreacting and wrongly condemning a useful drug, and the opposite danger of letting a known hazard continue too long. The Committee is very experienced in performing this balancing act, and I have every confidence in its expertise and judgment.

Aspirin is, of course, a very old, extensively used and useful medicine. However, the special position of aspirin must, I believe, have given the Committee on Safety of Medicines a particular problem. In general, when the committee has to advise about the safety of a drug, it is giving advice to doctors about a medicine which is usually given on prescription, and perhaps may only be legally given on prescription, and perhaps may only be legally available on prescription. Advice to professions can be given in terms of cautions, qualified, technical guidance, subject to professional discretion in particular cases. Much more was needed for aspirin. Any advice had to be clear-cut and easy to convey to people in their homes and given in a way which would not cause unjustified anxiety about a well-used and valuable medicine.

The committee is independent and its proceedings are confidential, so I cannot say exactly what it thought at different times, but the main conclusions are already on public record. The right hon. Member for Stoke-on-Trent, South (Mr Ashley) asked a number of questions in the first half of 1985 about Reye's syndrome and the committee's deliberations, and he received replies which were full and informative. There was no

secret that a link between aspirin and Reye's syndrome had been postulated that the CSM had considered the possibility of a causal connection in 1982 and again in 1985, and that in the light of the available evidence had concluded that there was no adequate proof of a causal connection. That information was available in *Hansard* to any hon. Member or for the press.

The CSM considered, at different times, a wide range of information and opinion about the possibility of a link between aspirin and Reye's syndrome. Some sources have already been given in *Hansard*. I have a complete bibliography of printed references considered by the committee, which I would be happy to make available to any hon. Member. Much of the material was about the epidemiology of Reye's syndrome, looking particularly at the risk factors which seemed to have occurred more frequently in children who developed Reye's syndrome than in other children of the same age, who had the same viral illness. Four studies in the United States, published between 1980 and 1982, all suggested that aspirin was such a risk factor.

This is a difficult area of research. It means retrospective questioning about how ill children were and what medicines they took. M There are many ways in which the research can be flawed. Scientists must look hard at the research methods, not just at the overall statistics. There were criticisms of each research paper. In the United States, the Food and Drug Administration was so conscious of the criticisms that it commissioned yet more research, which would endeavour to overcome the design problems of the earlier work. The CSM decided, when it first looked at these reports in 1982, that they did not provide satisfactory evidence of a causal link between aspirin and Reye's syndrome.

In March and April 1985, the CSM again carefully considered the available evidence. That included the report of the pilot phase of the further study in the united States. That study again showed a high numerical link between aspirin and Reye's syndrome, but I understand that there are still some criticisms of the methodology. Again, after carefully weighting all the evidence the CSM decided that a causal link between aspirin and Reye's syndrome had not been established.

In reaching this conclusion, the Committee was aware of the label warnings and publicity in the United States, and we should be in no doubt of its concern to make the right decision, in the best interests of children in this country. Of course, although the evidence at that time did not convince the committee that there was a causal link, it could have said "To be on the safe side, let us advise that children could be at risk of Reye's syndrome if they take aspirin even though we ourselves do not see any reason to believe that." So far as the Committee could see in 1985, it would have been asking almost every family in the country to change its habits, just on a rumoured possibility that the Committee itself did not find scientifically convincing. In these circumstances such action could not be regarded as responsible by a Committee which, in my view, is rightly held in high esteem.

It has been suggested that the Committee should have published a full account of the issues and its conclusions about them in 1982 and 1985 and, in the light of the information, left the public to make its own decision on the use of aspirin for children. Although, superficially, that approach might seem to have its attractions, I do not think that it would have provided a practical solution. It is likely that a cautious solution by the CSM would have suffered from being summarised in reporting and that the message from such of the media would have suffered from the over-simplification or even distortion with a real risk of the story emerging as a largely unsubstantiated aspirin scare, without serious consideration of the facts.

In fact, the medical reports from the United States were available to the press, and they wished to write about them, I believe that there was some coverage. The CSM's opinion on the evidence it had seen was also publicly available. I do not accept that the Committee, or the Department, should at that time have done anything more.

I now wish to turn to the successful exercise carried out last month to publicise the CSM's recommendation about aspirin. Reye's syndrome is still, I am glad to say, a very rare disease, but many families are now aware of it. We have tried to make sure that all families know that it is best not to give aspirin to a sick child under 12 years, unless their doctor tells them to do so. First, there was an extensive publicity campaign in which a number of parties were involved. The chairman of the CSM wrote to all doctors, dentists and pharmacists, explaining why the committee was recommending that children should not be given aspirin, except in certain special medical circumstances.

The chief medical officers for England, Scotland, Wales and Northern Ireland announced this advice to the press, and the chief nursing officers wrote to nurses with a copy of the chairman's letter. There were also similar notifications to health authorities and family practitioner committees. Poster were provided by the pharmaceutical industry. The industry also paid for press advertisements, to follow up the extensive news coverage that the story attracted.

Secondly, the industry responded to the CSM's advice by making a voluntary decision immediately to take Junior Aspirin off the market.

I should like to emphasise that the decision to cease marketing Junior Aspirin was made voluntarily by the pharmaceutical industry. It was a prompt and constructive decision, which has made it much easier to carry out the CSM's recommendations. Manufacturers will also be following the CSM's recommendations by putting a warning on the labels of adult aspirin products, as soon as practicable.

I wish to put my appreciation of the industry's response on record, as my right hon. Friend the Minister of Health did at the time of the first announcement. I acknowledge also the part played by the Pharmaceutical Society of Great Britain, who gave clear, well-timed advice to their members to get junior aspirin off the shelves and about what they should tell their customers.

Another and most important reason why the committee's advice on aspirin made such an impact was simply because it was aspirin, one of the oldest and best known of modern medicines, used in treating a wide variety of aches and pains.

As I have said, the committee would not have been acting responsibly had it given premature advice on the basis of inadequate evidence that aspirin was suspected of causing an unnecessary hazard when used by children and babies. Once the CSM was convinced that aspirin might be a contributory factor in the causation of Reye's syndrome in some children ity acted very quickly and, I believe successfully. However, I acknowledge that the CSM will continue to monitor the situation very closely, and will give further prompt advice to the licensing authority if necessary.

I hope that my comments will reassure the hon. Member for Roxburgh and Berwickshire (Mr. Kirkwood) that the due processes were followed.

Mr. Kirkwood: I am grateful to the hon.. Gentleman for his useful comments, which I shall study carefully. Will he consider my point about continuing research into the

disease? My information is that overt and explicit research is being undertaken. Will the hon. Gentleman write to reassure me that something is being done in terms of research into the causes of the disease?

Mr. Whitney: I shall certainly write to the hon. Gentleman on that point. I hope that he accepts the reassurance which I have given on the basis of the way in which this extremely difficult and delicate issue was handled.

7.16 am

National Reyes Syndrome Foundation UK

APPENDIX TWO

BRITISH PAEDIATRIC SURVEILLANCE UNIT
FIRST ANNUAL REPORT – 1985/1986
EXTRACTS

Introduction:

The British Paediatric Surveillance Unit (BPSU) was established in 1985 with the aim of involving paediatricians nationally in the surveillance of rare childhood disorders, making possible the ascertainment of cases on the scale needed for both clinical and epidemiological study of such uncommon diseases as *Reye's syndrome*, neonatal herpes and subacute sclerosing panencephalitis (SSPE). The Unit is a joint venture of the British Paediatric Association (BPA), the Communicable Disease Surveillance Centre of the Public Health Laboratory Service, and the Department of Epidemiology at the University of London Institute of Child Health.

The basis of the BPSU reporting scheme is the mailing of a monthly report card to all consultant paediatrician members of the British and Irish Paediatric Associations. Respondents return the card to the BPSU office in London, marking the number of cases seen against of specific conditions or ticking a "nothing to report" box. For respondents in Scotland, the scheme operates via the Communicable Diseases (Scotland) Unit in Glasgow.

Notification of a case is forwarded to a research worker studying that particular condition, who sends a short questionnaire (which has been approved by the BPSU) to the reporting consultant or requests a loan of the case notes. The researcher subsequently notifies to the BPSU the number of confirmed cases, and for certain conditions gives basic epidemiological data.

The full implementation of the scheme was preceded by a pilot mailing to a sample of BPA members and a "pre-mailing" of information to all Ordinary Members. The first full mailing took place in July 1986.

Inclusion of studies

Studies included in the scheme to date

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Reye's syndrome
Kawasaki disease
Haemolytic uraemic syndrome (HUS)
Haemorrhagic shock encephalopathy syndrome (HSES)

Principal research worker: Dr S. Hall
Research base: BPSU/CDSC
Duration of studies: June 1986 for 3 years

National Reyes Syndrome Foundation UK

Cases reported – first quarter (1986)

Condition	*Confirmed cases*			
	June	July	August	Total
Reye's	6	1	2	9

(correct at 19/11/86)

British Paediatric Surveillance Unit: first quarterly summary report

The British Paediatric Surveillance Unit (BPSU), described in CDR 86/28, sent out the first of its monthly cards to all hospital; consultant paediatricians in the British Isles. In July (returns from Scottish paediatricians are received via the CD Scotland Unit). This report summaries the Unit's activities and results for the first 3 months' mailings. During this period the reportable conditions were: Aids in childhood; neonatal herpes; *Reye's syndrome*; Kawasaki disease; haemolytic uraemic syndrome; haemorrhagic shock encephalopathy syndrome; subacute sclerosing panencephalitis.

Response rate

Because paediatricians are asked not only to report cases but also to make a nil return if no patients with any of the reportable conditions have been seen in the past month, general compliance with the scheme can be measured from the proportion of total cards returned. The table below shows that this has been high, increasing to nearly 85% of respondents by the third month

Table 1 Overall response rate (at 5.11.86)

	Reporting month			
	June Number %	July Number %	August Number %	Total
Total cards sent*	824 (100)	821 (100)	820 (100)	-
Total cards returned*	603 (73.2)	680 (82.8)	698 (85.1)	-
Total cases reported+	49	22	37	108

* Includes those sent by, and returned to, Communicable Diseases (Scotland) Unit.
\+ All conditions as listed in *table 2*

The number of cases reported for June was greater than in succeeding months because the reporting instructions for that month for some of the conditions (see table 2), requested all cases who had been seen up to a year before. Small variations in the size of the mailing list result from new appointments, retirements and changes of post and address.

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Table 2 **Cases *reported* (at 14.11.86)**

Condition	Reporting month			
	June	July	August	Total
AIDS in childhood*++	12 (8)	- (-)	- (-)	12 (8)
Neonatal Herpes++	6 (-)	- (-)	1 (-)	7 (-)
Reye's syndrome	7 (4)	3 (1)	5 (1)	15 (6)
Kawasaki disease	8 (6)	9 (6)	15(12)	32(24)
Haemolytic uraemic syndrome#	3 (1)	9 (4)	8 (2)	20 (7)
Haemorrhagic shock encephalopathy syn.	1 (1)	1 (-)	- (-)	2 (1)
Subacute sclerosing panencephalitis++#	4 (3)	- (-)	3 (-)	7 (3)
X linked anhydrotic ectodermal dysplasia*#	8 (-)	-(-)	5 (3)	13 (3)
	49(23)	22(11)	37(18)	108(52)

Numbers refer to total reports received; those in brackets refer to cases followed up and confirmed by Investigators

* June figures included all cases ever seen by respondents
++ June figures included all cases seen in past 12 months
\# These conditions are also ascertained by other surveillance schemes whose data are not included

Of the paediatricians mailed there were 67 who did not return any of the first 3 cards. These non-respondents.....

14th November 1986 **CDR 86/46**

Table 2 summarises total reports of cases and those in which research workers have confirmed satisfactory follow up. Of cases reported to date, only 1 has been 'double reported' within the BPSU system and 9 have been 'parallel reported' with other methods of ascertainment.

New conditions and changes of menu

The XLARD .....

Comment

The BPSU is a new venture and has got off to a good start. Investigators have been pleased by the response.....

Reporting rates by region.....

Cases reported

The scheme has caused substantial improvement in ascertainment of some of the conditions for which there was an existing surveillance scheme, notably AIDS in childhood, Kawasaki disease and X-linked anhydrotic ectodermal dysplasia (XLAED).

National Reyes Syndrome Foundation UK

British Paediatric Surveillance Unit: second quarterly Summary Report

Not reproduced apart from the table for the second quarter.

Cases reported

Table **Cases *reported* to BPSU June-November 1986**

Condition	First Qtr.	Second quarter Reporting month				Total first six
	total	Sept	Oct	Nov	Total	months
AIDS in childhood	10 (10)	3 (2)	3 (-)	2 (-)	8 (2)	18 (12)
Neonatal herpes	7 (2)	- (-)	2 (-)	3 (1)	5(1)	12 (3)
Reye's syndrome	15 (10)	1 (1)	4 (3)	8 (1)	13 (5)	28 (15)
Kawasaki disease	31 (27)	11(10)	11 (8)	12 (7)	34(25)	65 (52)
Haemolytic uraemic syndrome	20 (10)	7 (5)	4 (2)	1 (1)	12(8)	32 (18)
Haemorrhagic shock encephalopathy syndrome	2 (1)	1 (1)	- (-)	1 (1)	2(2)	4 (3)
Subacute sclerosing panencephalitis	8 (8)	4 (1)	5 (5)	3 (2)	12(8)	20 (16)
X-linked anhydrotic ectodermal dysplasis	13 (2)	n/a	n/a	n/a	n/a	13 (2)
Diabetes	n/a	7 (7)	8 (8)	5 (4)	20(19)	20 (19)
All	106(70)	34(27)	37(26)	35(17)	106(70)	212(140)

The overall number of cases of the reportable conditions in the second quarter (106) was identical to that in the first. There was a slight decrease.....

Addendum to table 2: cases reported *(confirmed cases)*

Condition	Confirmed cases						
	June	July	Aug	Sept	Oct	Nov	Total
AIDS	10 [1]	-	-	2	-	-	12
Herpes	4 [2]	-	1	-	-	1	6
Reye's syndrome	5	1	3	1	2	2	14
Kawasaki	8	7	13	10	9	10	57
HUS	1	2	4	4	2	1	14
HSES	1	-	-	-	-	-	1
SSPE	4 [2]	-	1	1	3	2	11
X-LAED	8 [*1]	-	5 [*]	n/a	n/a	n/a	13 [*]
Diabetes [3]	n/a	n/a	n/a	7	8	4	19

(correct at 18/3/87)

[*] Includes unconfirmed cases
[1] Month 1 figures included all cases known to respondents
[2] Month 1 figures included cases seen in past 12 months
[3] Survey covering South Western Regional Health Authority only
n/a Study not in progress in this mnth