

JOINT SUB-COMMITTEE ON ADVERSE REACTIONS TO VACCINATION AND
IMMUNISATION

Minutes of the meeting held on Tuesday 8 March 1988 at 10.30am in
Room 1612, Market Towers

Present Professor J Collee (Chairman)
Professor J E Banatvala
Dr N Cavanagh
Dr J Cameron Bowie
Dr P E M Fine
Professor D Hull
Professor D G McDevitt
Dr B W McGuinness
Professor S R Meadow
Professor D L Miller
Dr E Miller
Dr D Reid

DHSS Dr D M Salisbury - Assessor
Mr K Fowler - Secretary
Dr R Mann
Dr F Rotblat

1. Confidentiality and Announcements

1.1 The Chairman reminded members that the proceedings, papers and information before them were confidential and should not be disclosed.

1.2 The Chairman announced that this was the last meeting of the Sub-Committee which would be attended by Dr Mann, the Medical Assessor of the CSM's Adverse Drug Reaction Section, because he would be retiring at the end of the month. The Chairman and members extended their thanks to Dr Mann for the work and advice he had given the Sub-Committee and wished him well in his retirement.

2. Apologies for Absence

Apologies had been received from Professor Breckenbridge, Sir John Badenoch and Dr Wallace.

3. Minutes of the last meeting

The minutes of the meeting held on Friday 2 October 1987 were signed by the Chairman as a true record of the meeting after adding Professor McDevitt's name to the list of apologies for absence.

4. Matters arising from the Minutes

4.1 Item 6.2 of the minutes of the July 1987 meeting - redraft of this paragraph (ARVI/88/1) was agreed by members and replaces the previous draft.

4.2 Item 7 (October 1987 minutes), paragraph 2 - reported about the CSM proposal for a pilot study to involve community pharmacists in the reporting of adverse drug reactions, which he thought would pick up information of the kind required.

4.3 Item 11 - the Chairman brought the attention of members to the date of the next meeting which will be Friday 2 September 1988.

5. Treatment of Anaphylaxis

The section on Anaphylaxis from the forthcoming edition of the Memorandum "Immunisation against Infectious Disease" had been made available to the Committee. The Anaphylaxis Section had been written to incorporate the recommendations of

The Committee recommended that this section should be made available to the British National Formulary who may wish to include it in subsequent editions.

6. Report of Yellow Card Data

There was considerable discussion of the information on reactions to vaccines during 1987.

X commented that this format of ^e~~the~~ data was more appropriate for the Committee's needs, provided that the Committee's attention could be drawn to any important or unusual reactions. The frequency of adverse reactions to influenza vaccine was noted, perhaps reflecting the age and ill-health of the target recipients and JCVI may wish to consider the specificity of recommendations for appropriate groups.

asked if information could be made available on the timing of convulsions in relation to immunisation.

asked for information to be available in the future on reactions to plasma derived or recombinant hepatitis B vaccine.

cautioned the Committee on interpretations or comparisons when there was a

significant degree of under-reporting. The figures were accepted as being useful for alerting ARVI ^{to} of evolving problems. X

7. Adverse Reactions Surveillance

introduced his paper on adverse reaction surveillance as a spontaneously generated contribution which was not a criticism of present policies. He expressed anxieties that since the loss of public confidence in pertussis vaccine, the public had become far more critical of all vaccines. He recommended consideration of a monitoring system for vaccine reactions which would cope with any vaccine related adverse publicity. There was considerable discussion of this paper which received the widespread support of ARVI. The Committee agreed the following recommendations:-

- (a) There was a need for good and adequate reporting of adverse drug reactions with control data where available.
- (b) The Committee had reservations about patient generated data often involving event reporting, endorsed the need for doctor generated reporting and noted the resource implications of any new scheme. Existing facilities were acknowledged such as the Red Alert Scheme.
- (c) The Committee suggested that a Working Group should be convened involving Dr Cameron Bowie, Dr Salisbury and the

ARVI secretariat who could co-opt other expert advisers to then provide advice for JCVI and CSM.

(d) The District Health Authority Immunisation Co-ordinators were identified as individuals who may have an important role in adverse reaction surveillance at district level and the possible involvement of CDSC/CDC was identified.

(e) paper will be submitted to JCVI as soon as possible.

8. Measles, Mumps, Rubella (MMR) Vaccines

(a) reported to the Committee on the steps which had been undertaken and were to be implemented in the near future for the introduction of MMR. The District Immunisation Co-ordinators had been identified as essential links in the dissemination of information to all those professionals involved in immunisation in each District. The Co-ordinators were all due to attend a meeting at DHSS on 15 March to discuss the implementation of MMR.

(b) spoke on the MMR trials which had been carried out using Health diaries on approximately 5,000 children in Fife, Somerset and North Hertfordshire. There had been no problem ⁱⁿ introducing MMR into these districts and there had been a 90 per cent response from patients to

take part. The rate of convulsions in Somerset was two per 1,000, similar to the rate of convulsions after measles vaccine in the original MRC trial. Parotid swelling was noted ⁱⁿ at approximately one per 100 children. The peak incidence of fever occurred eight to ten days after immunisation. Professor Hull spoke on the MMR trial in Nottingham and noted local concerns ^{about} of the potential infectivity of the mumps component of MMR to susceptible contacts. He was assured that the mumps vaccine virus is not transmissible.

(c) Five cases of mumps encephalitis following MMR have been reported from Canada. Four of these cases definitely followed the use of Urabex 9 mumps virus vaccine containing ~~containing vaccine~~, and the fifth probably did. This corresponded to a frequency of one per 100,000 doses and no sequelae had been reported in the sufferers.

had discussed the incidence of mumps related complications from MMR with the Communicable Disease Center, Atlanta, whose data ^{were} ~~was~~ unfortunately only superficial on this issue. In the United States, Jeryl Lynn mumps virus is included in MMR but no data ^{were} ~~was~~ available on parotitis following MMR and many of the reported neurological complications were clearly related to the measles component. Two manufacturers have applied for Product Licenses ⁱⁿ for the United Kingdom and both their vaccines contain Urabex 9 mumps virus. One manufacturer already had a Product Licence for vaccine containing Jeryl

Lynn mumps virus. After discussion, the Committee felt that the rate of adverse reactions to the mumps component of MMR from Canada was in keeping with that expected from live virus vaccine and endorsed the view that a study of the Jeryl Lynn containing vaccine should be carried out using the same health diaries as the present trial.

9. JCVI Memorandum

The rewriting of the 1988 edition of the Memorandum "Immunisation against Infectious Disease" had been completed and the material submitted to the printers. The publication was expected for mid-April. The Committee recommended that the Memorandum should have the widest possible distribution.

10. MMWR 36 Number 18 "Pertussis Immunisation"

This MMWR article had been distributed to Committee members for information. The ACIP had stated that a family history of convulsions should not be a contra-indication to vaccination with diphtheria and tetanus toxoids and pertussis (DTP) vaccine. In addition, the ACIP believed that antipyretic use in conjunction with DTP vaccination may be reasonable in children with personal or family history of convulsions.

11. Code of Conduct Disclosure of Interests

introduced this paper and explained the relevance of the proposed Code to Sub-Committee members. He briefly outlined the changes in the redrafted Code which members were being asked to consider, and which would be re-submitted to Ministers in due course. Some concern was expressed about the proposal to publish members' declared interests in the Committee's Annual Reports, and it was explained that this was the specific request of Ministers. invited any members who might have uncertainty about what they should personally declare to contact him or , the Secretary to the CSM.

1988

MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS AS FOLLOWS:

MEMBER	PERSONAL INTERESTS		NON PERSONAL INTERESTS		WHETHER CURRENT
	NAME OF COMPANY	NATURE OF INTEREST	NAME OF COMPANY	NATURE OF INTEREST	
MR B D HOSKIN	COOPERS ANIMAL HEALTH LTD PITMAN MOORE EUROPE WELLCOME PLC ICI PLC OXFORD VIROLOGY LTD	SALARIED UNTIL 31.8.89 CONSULTANCY FROM 1.11.89 SHARE HOLDER SHARE HOLDER CONSULTANCY (NOW COMPLETED)	NONE		
MR C N HUDSON	NONE		NONE		
PROFESSOR J M JONES	WELLCOME PLC	DIRECTOR	NONE		
PROFESSOR I KENNEDY	NONE		NONE		
DR M J LINNETT	ICI	SHARE HOLDER	NONE		
PROFESSOR D G MCDEVITT	DRUG DEVELOPMENT SCOTLAND LTD ICI WARNER-LAMBERT	DIRECTOR (EX-OFFICIO) ADVISORY GROUP MEDICAL REFEREE	ASTRA BAYER BEECHAM BOOTS GLAXO ICI LEDERLE JANSSEN PARKE-DAVIS G D SEARLE SMITH KLINE AND FRENCH SQUIBB	RESEARCH GRANT RESEARCH GRANTS RESEARCH GRANT RESEARCH GRANT SUPPORT FOR RESEARCH FELLOW RESEARCH GRANTS RESEARCH GRANT RESEARCH GRANT RESEARCH GRANT RESEARCH GRANTS SUPPORT FOR RESEARCH FELLOW RESEARCH GRANTS	NO YES YES YES YES YES YES YES YES YES YES YES

Professor Denis Gordon McDevitt MD FRCP

Qualifications: MB BCh Belf 1963; MD Belf 1968; M 1965, FRCP Irel 1977, M 1966
FRCP Lond 1978; FRCP Ed 1985; FFPM 1990; DSc Belf 1978; FRSE 1996

Appointed by: The Universities of Aberdeen, Dundee, Edinburgh and Glasgow

Date of birth: 17/11/37

Date of 70th birthday: 17/11/07

Current principal appointment: Head of Department of Clinical Pharmacology and Therapeutics, University of Dundee and Honorary Consultant Physician, Tayside University Hospitals NHS Trust.

Date of first appointment: 01/11/96

Professor McDevitt served as a member appointed by the other bodies not otherwise represented on the Council until 31 October 2001.

Current Council service:

PCC
Registration
Finance

Past Council service:

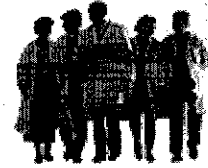
PCC 1997-00
Overseas 1997-98
Finance 1996-00
Registration 1998-00

Personal Statement:

As a member of the Finance and Establishment Committee since 1997, I am familiar with its business and aware of the fiscal pressures caused by Fitness to Practise issues. The enforced increases in registration fees require that we continue to exercise prudent management and, wherever possible, keep the profession informed.



University of Dundee



Clinical Pharmacology & Therapeutics

Professor Denis G. McDevitt, DSc, MD, FRCP, FFPM, FRSE



Professor of Clinical Pharmacology & Therapeutics, University of Dundee

Other Positions:

- **Consultant Physician, Ninewells Teaching Hospital, Dundee**
- **Director, Medicines Monitoring Unit, Dundee**
- **Civil Consultant in Experimental Medicine, The Royal Air Force**
- **Member of the General Medical Council**

Professor McDevitt is the physician-in-charge of Wards 5 & 6, Ninewells Hospital. His primary research interests are:

- Pharmacoepidemiology
- The clinical pharmacology of β -adrenoceptors
- Cardiovascular clinical pharmacology
- Adverse drug reaction monitoring

He holds appointments on a number of GMC consultative committees, including the Professional Conduct Committee, and is Vice-Chairman of the Ethics Committee of the Centre for Human Sciences. He is the Managing Editor of the *European Journal of Clinical Pharmacology*, and a member of the editorial board of *Pharmacoepidemiology and Drug Safety*.

Previous Positions:

- Dean of the *Faculty of Medicine and Dentistry*, University of Dundee
- President of the *Association of Physicians of Great Britain and Northern Ireland*
- Chairman of the Clinical Pharmacology Section of the *British Pharmacological Society*.
- Chairman of the Specialist Advisory Committee in Clinical Pharmacology and Therapeutics, *Joint Committee on Higher Medical Training*
- Chairman of the Association of Professors of Clinical Pharmacology
- Chairman of the UK Drug Utilisation Research Group

Details of his publications and other senior appointments can be obtained from:

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