WORLD HEALTH ORGANIZATION
ORGANISATION MONDIALE DE LA SANTÉ

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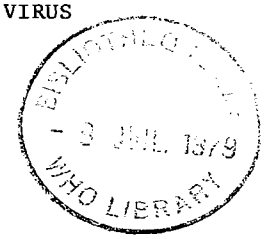
ENGLISH ONLY

Smallpox-Virus - Cant.

REPORT OF MEETING OF OFFICIALS FROM LABORATORIES RETAINING VARIOLA VIRUS AND NATIONAL CONTROL AUTHORITIES CONCERNED

Geneva, (23-24 April 1979)



1. INTRODUCTION

1.1 Background

Eighteen months have passed since the last case of smallpox was detected in October 1977 in Somalia. Certification of global smallpox eradication is expected before the end of 1979. Realizing the potential danger posed by variola virus stocks in laboratories, the World Health Assembly, in 1976, requested the Organization to consider "the need for retention of variola virus in laboratories and, if necessary, to make recommendations on the number and distribution of such laboratories and on the precise precautions which should be taken to prevent accidental infection" (WHA29.54). The Organization has complied with this request. Expert groups have considered the justification for the retention and use of variola virus (WHO/SE/79.135) and guidelines have been established to assure maximum security in laboratories retaining this virus (SME/77.2 Revision 1, Annex 1).

In December 1978, the Global Commission for the Certification of Smallpox Eradication recommended that "WHO should continue its efforts to reduce the number of laboratories retaining stocks of variola virus with the objective that by 1980 not more than four laboratories should retain stocks. These laboratories should be WHO collaborating centres with maximum containment facilities" (WHO/SE/78.132). The recommendations of this report were endorsed by the Executive Board in January 1979 (EB63.R5). Public concern about this issue was accentuated following the laboratory-associated cases of smallpox which occurred in the United Kingdom in 1973 and 1978.

Since 1976 WHO has developed a register of laboratories retaining variola virus. As a result of cooperation with governments and laboratories, this number has decreased from 76 such institutions in 1976 to eight by 23 April 1979 (Annex 1), four of which are WHO smallpox reference or collaborating centres.

1.2 Objectives

With the above in mind, WHO convened representatives from national control authorities and from laboratories where variola virus was being retained (Annex 2). The objective of the meeting was to assist in assuring the permanence of smallpox eradication by:

1.2.1 Review of WHO policies regarding retention of variola virus including the revised safety measures (Annex 1).

1.2.2 Discussion of national and laboratory policies pertaining to safety measures in facilities where variola virus is retained.

1.2.3 Discussion of plans for retention, destruction or transfer of strains in individual laboratories.

1.2.4 Making recommendations to minimize the risks posed by variola virus stocks while meeting diagnostic and research requirements.

1.3 Meeting procedure

Dr I.D. Ladnyi, Assistant Director-General, opened the meeting on behalf of Dr H. Mahler, Director-General. Dr Ladnyi briefly reviewed the evolution of the programme and the concern of WHO about variola virus in laboratories now that global eradication appears to have been achieved.

Dr H. Mahler attended the meeting on the second day and stressed the international nature both of the programme and of the role of the WHO collaborating centres.

Dr J. Kostrzewski was elected chairman, Dr H.H. Cohen, vice-chairman, and Dr K. Dumbell and Dr J. Richardson were appointed co-rapporteurs and an agenda was adopted.

2. TOPICS CONSIDERED

The group considered the following topics, supported by the working papers, listed in Annex 3:

2.1 The justification for continuing to retain variola virus in a few laboratories for research projects in support of the general activities of the eradication programme;

2.2 The safety standards and control measures which should be adopted by any laboratory holding variola virus stocks, and the relation of such measures to the equivalent measures for safe handling of other dangerous organisms;

2.3 Current research and diagnostic activities related to the eradication programme and the organization of such activities in the future;

2.4 The role of the national governments in maintaining safety standards in those laboratories which remain custodians of variola virus stocks; and,

2.5 The current status and future plans of the participating laboratories. This topic was introduced by the Chairman who quoted the following resolutions of the World Health Assembly:

"REQUESTS governments and laboratories to continue to cooperate in preparing the international register of laboratories retaining stocks of variola virus or specimens from smallpox cases, and to ensure that, in accordance with the recommendation of the Committee on International Surveillance of Communicable Diseases endorsed by the Executive Board in resolution EB59.R28, these stocks and specimens be retained only by WHO collaborating centres under conditions ensuring maximum safety;" (WHA30.52, 1977)

"REQUESTS all laboratories except WHO collaborating centres to destroy or transfer remaining stocks of variola virus to a collaborating centre;" (WHA31.54, 1978)

"URGES all institutions still retaining stocks of variola virus to destroy or transfer them to WHO collaborating centres with adequate safety facilities;"(EB63.R5, 1979).

Following this, national control procedures (Annex 4) were presented and individual laboratories were discussed. Statements from them are summarized in Annex 5.

3. CONCLUSIONS

3.1 The group applauded the success achieved by WHO in association with Member States in bringing about a reduction in the number of laboratories holding variola virus from 76 in 1976 to eight at the present time; the group anticipated that the number of such laboratories will be further reduced to a total of five or six by 1980.

3.2 The group supported the revised recommendations for safety in laboratories holding and working with variola virus (Annex 1, section 4). The group noted that such a laboratory would require the maximum degree of secondary containment and a somewhat lesser degree of primary containment. Those engaged in constructing or modifying a laboratory to meet these standards might consider whether design features should be incorporated, which, though not required for work with variola, might subsequently facilitate up-grading to a maximum degree of primary containment; in particular this might be by provision for the later incorporation of a positive pressure personnel suit system.

3.3 All participating laboratories stated that variola virus stocks were kept under strict security and would only be handled in a maximum containment laboratory. Of the eight laboratories still retaining variola virus, four are WHO collaborating centres, two of which already have maximum containment laboratories and two are initiating construction of maximum containment laboratories. Of the remaining four laboratories, which are not WHO collaborating centres, one, with a maximum containment laboratory, is prepared to transfer the virus, one has postponed the decision and the last two indicated their wish to retain the virus stock for diagnostic and research purposes in the future. One of the latter three laboratories has built a maximum containment laboratory and the others are planning to build such a facility. All participating laboratories and control authorities accept the importance of safe procedures, visits by WHO inspection teams and further consultation with WHO.

3.4 The group endorsed the recommendations related to research made in the report of the Informal Consultation on Monkeypox, Whitepox and Related Poxviruses (SME/78.20), and in the report of the Consultation on the Justification for Retention and Use of Variola Virus in the Post-eradication Era (WHO/SE/79.135).

3.5 The group considered that, where a laboratory has transferred its stocks of variola virus to a collaborating centre in another country, the national government of that country should not obstruct the return of such stocks, on request, to a properly constituted laboratory meeting the requirements described in Annex 1. It is to be expected that any such transfers would be made with the prior approval of WHO. Representatives of the USA Government and the UK Government were able to confirm that their respective authorities would allow any such transfers to be made.

4. RECOMMENDATIONS

4.1 In supporting the revised WHO recommendations for safety in laboratories holding and working with variola virus, described in section 4 of SME/77.2 Revision 1 (Annex 1), the group recommends that such laboratories should, if necessary, up-grade their facilities as rapidly as possible to conform with these recommendations.

4.2 The group endorses the WHO recommendation that those laboratories which do not meet the WHO safety recommendations (SME/77.2 Revision 1, section 4; Annex 1) and which still have stocks of variola virus should destroy these stocks or transfer them to a WHO collaborating centre which meets these safety standards. Those laboratories which do not at the moment meet the WHO safety standards, but which are in the process of up-grading or constructing new facilities should evaluate the relative risks of transfer or storage within existing facilities and take appropriate action, after consultation with WHO.

4.3 The group recommends that, in the very unlikely event that smallpox should once again threaten any country, WHO should collaborate in every aspect of the required epidemiological and laboratory investigation, including the return of reference variola virus strains to a suitably equipped laboratory in that country in order to expedite diagnostic and other related activities.

4.4 The group recommends that any laboratory retaining variola virus stocks should be subject to a site visit by WHO staff and consultants at intervals of not more than two years. Any laboratories which have not yet been visited should, in consultation with their national authorities, request such a visit as soon as possible.

4.5 The group recommends that all proposed research with variola virus should be reported to the national control authority and to WHO, and each project should be reviewed by an expert sub-group reporting directly to the Global Commission.

ANNEX 1
SME/77.2
Revision 1

WHO RECOMMENDED SAFETY MEASURES IN LABORATORIES RETAINING VARIOLA VIRUS[1]

1. Introduction

With the interruption of smallpox transmission expected to be certified in the near future, the only known source of variola virus and potential for smallpox epidemics will be in laboratories maintaining the virus. Following the recommendation of the 30th World Health Assembly (1977) that variola virus be retained only by World Health Organization (WHO) collaborating centres under conditions ensuring maximum safety, WHO convened a group of experts to consider the safety standards for the maintenance and use of variola virus in laboratories. The group recognized the need to retain a minimum number of such laboratories for archival, diagnostic and research purposes and this view has been endorsed by the Global Commission for the Certification of Smallpox Eradication at its first meeting.

1.1 Objectives

The objectives of the meeting were to define physical containment standards for maintaining the virus, establish requirements to ensure the safety of personnel and propose administrative control measures. The group formulated recommendations addressed to these objectives and, with WHO, strongly urges that national safety measures for containing variola virus in laboratories embody these recommendations.

2. Agents subject to safety recommendations

2.1 Variola and whitepox viruses

Among the orthopoxviruses only variola virus is recognized as a highly dangerous pathogen but because there is no consistent laboratory difference between whitepox viruses and variola virus, whitepox viruses must also be subject to these safety measures, although, at present, whitepox viruses are not known to infect humans.

2.2 Monkeypox and vaccinia viruses

Monkeypox and vaccinia viruses pose no major public health danger. Although suitable precautions, including vaccination, should be taken by personnel working with these and other orthopoxviruses, they need not be subject to the same stringent safety measures as variola viruses.

3. Numbers and functions of laboratories

Risk is directly related to the number of laboratories maintaining variola virus stocks. It was recommended that variola virus should only be held in WHO collaborating centres which have full containment as described in 4, and that the number of these should be subject to periodic review. WHO collaborating centres which do not retain variola virus will be encouraged to continue research on orthopoxviruses other than variola virus. Further recommendations were:

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[1] The safety measures described herein are based on the "Report of a Workshop Meeting in Laboratories Retaining Variola Virus, Geneva 1-4 August 1977", (WHO document SME/77.2) as revised in March 1979.

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3.1 Archival

The responsibility for maintaining a representative collection of variola viruses for archival purposes should rest on the WHO collaborating centres.

3.2 Diagnostic

The laboratories at the Viral Exanthems Branch, CDC, Atlanta, and the Laboratory of Smallpox Prophylaxis, Research Institute of Virus Preparations, Moscow, should continue as the principal WHO centres for diagnosis of suspect human smallpox cases.

3.3 Research

3.3.1 Variola virus should not be used for research purposes in laboratories which are not WHO collaborating centres, and these latter should, by 1980, not exceed four in number.

However, should national authorities deem variola virus necessary in their institutions, the WHO should be notified and be assured that the physical containment system of the laboratory and the personnel safety measures meet the standard safety requirements. However, it is urged that national authorities and their institutions follow the procedures presented in section 3.3.2.

3.3.2 It is strongly recommended that all other institutions maintaining variola virus destroy these stocks or transfer them to one of the above-mentioned WHO centres; they should be informed that the WHO centres would accept visiting investigators who wish to work with variola if the research protocol fell within the general policy of WHO and there was no substitute for variola for the research in question.

4. Recommended safety procedures pertaining to physical construction and administration of laboratories with variola virus

4.1 Physical containment

Because, even for archival purposes, it is necessary from time to time to handle the stock viruses, all holding of variola virus whether or not research is undertaken, should be in laboratories meeting all the following requirements.

A place authorized to hold, or work with variola viruses, including infecting animals (hereinafter called the laboratory) must be constructed and operated in such manner to prevent dissemination of variola virus. Experiments involving smallpox virus shall be confined to work areas in a laboratory of the type designed to contain microorganisms that are extremely hazardous to man or may cause serious epidemic disease. The laboratory is either a separate building or it is a controlled area, within a building, which is isolated from all other areas of the building. Access to the laboratory is under strict control, excluding entry of unauthorized persons. Requirements for laboratories holding and working with variola are:

4.1.1 Imperviously sealed walls, floors and ceilings in which all penetrations (such as for air ducts, electrical conduits, and utility pipes) are sealed to assure the physical isolation of the work area and to facilitate housekeeping and space decontamination.

4.1.2 If air locks are provided through which supplies and material can be brought into the laboratory, a system for gaseous fumigation must also be available to prevent breach of containment.

4.1.3 Contiguous clothing change and shower rooms through which personnel enter into and exit from the laboratory.

4.1.4 Double-door autoclaves, sealed to the laboratory barrier wall, to decontaminate and safely remove wastes and other materials from the laboratory.

4.1.5 If laboratory drains are installed, a biowaste treatment system to decontaminate liquid effluents, including autoclave chamber condensates, prior to discharge.

4.1.6 A separate ventilation system which maintains negative air pressures and directional air flow into the laboratory, whenever diagnostic or experimental work is in progress.

4.1.7 Passage of supply air through a prefilter and high efficiency particulate air (HEPA) filter before entering the laboratory. Exhaust air should be decontaminated by passage through two HEPA filters connected in series before discharge to the atmosphere. The HEPA filters should be pretested to retain 99.97% of 0.3 micron particles. A post-installation test should be done to exclude accidental damage to the filters and to ensure adequate sealing of filters has been achieved.

4.1.8 All primary doors leading into the laboratory are always locked except for entry and exit to prevent entry of unauthorized persons. Any windows should also be secured against intruders. The laboratory director controls access to the laboratory.

4.1.9 A biohazard warning sign on all primary doors of the laboratory and a list of authorized personnel posted on the entries.

4.1.10 Appropriate primary safety devices (such as biological safety cabinets and sealed centrifuge buckets) to prevent or minimize release of virus into the air of the laboratory.

4.1.11 Provisions for maintaining visual or voice contact (view windows intercom system) with colleagues outside of the laboratory.

4.1.12 Appropriate design and operational measures employed to prevent introduction of Insects, rodents and other pests.

4.1.13 A laboratory operations manual should be prepared which describes function and operation of the laboratory.

4.1.14 A contingency plan which provides for special guarding in the event of pending or potential threat to the facility.

4.2 Administrative control

4.2.1 Responsibility, authority and compliance

An effective safety system defines clear lines of responsibility and authority. The day-to-day safety in the laboratory is the responsibility of the laboratory director, who is responsible to national health authorities. It is appreciated that different countries have different methods for ensuring safety. WHO should be informed of the safety measures adopted in each country and will be available to consult on such matters. WHO will keep the appropriate national authorities informed of all exchanges relating to safety measures which they have with collaborating centres. Laboratories will be requested to submit a safety report, through national authorities, at least yearly.

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4.2.2 The authorization to possess, receive, maintain and use variola virus shall be issued by national authorities and only to WHO centres. This authorization should be obtained in writing and WHO should be kept informed of all such authorizations issued.

4.2.3 Personnel

Only personnel authorized by the director shall enter the laboratory and these persons shall be indicated on a list posted on entries to the laboratory. This list shall be updated as necessary. All such persons must have been satisfactorily trained, briefed and immunized as judged by the director. Persons can be added to the list only on authorization of the director.

4.2.3.1 Prerequisites for authorization to enter the laboratory:

i) Vaccination at yearly intervals with potent WHO approved vaccine and proper technique and measurement of detectable antibodies at least every three years. This information must be recorded.

ii) All such persons must have been given a written copy of the safety instructions and must have signed a statement that they have been read and understood.

4.2.3.2 All untoward incidents and accidents, even minor ones, involving personnel, containment devices, and laboratory support systems must be reported to the director and immediately recorded.

4.2.3.3 All entries of personnel and visitors into the laboratory should be documented in a permanent record.

4.2.3.4 Any absence must be reported to the director who should verify cause of absence.

4.2.3.5 The personal physician of each worker should receive notification for his files that that individual works with variola virus. The physician should be provided with the telephone number of the director.

4.2.4 Special situations

Action in case of major accidents and other emergencies will be detailed in the laboratory operations manual.

5. Packaging and shipping

Diagnostic specimens and cultures should be packaged and shipped in accordance with national regulations and those of the International Air Transportation Association (IATA) and Universal Postal Union (UPU). Shipments should be sent by the most expeditious available method of transport to prevent loss. The shipment and arrival details should be cabled to the receiving laboratory prior to shipment of the specimens.

ANNEX 2

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ANNEX 3

LIST OF WORKING PAPERS

1. Report of the Global Commission for the Certification of Smallpox Eradication - First Meeting (WHO/SE/78.132)

2. Report of Consultation on the Justification for Retention and Use of Variola Virus in the Post-eradication Era (WHO/SE/79.135)

3. Post-eradication Strategy: Virological Aspects (Global Commission WP/78.51)

4. Report of Informal Consultation on Monkeypox, Whitepox and Related Poxviruses (SME/78.20)

5. Laboratory aspects of the Monkeypox Virus/Whitepox Virus problem (SME/78.19)

6. Laboratory-associated Infections: Summary and Analysis of 3921 Cases. Robert M. Pike, Health Laboratory Science, Vol. 13, No.2, April 1976.

7. Principles of Biosafety by Dr J. Richardson

8. Report of a Workshop Meeting on Safety Measures in Laboratories retaining Variola Virus, held August 1977, revised March 1979 (SME/77.2 Revision 1)

9. Review of World Health Assembly and Executive Board Recommendations on retention of Variola Virus by Laboratories

10. Laboratories with variola virus stocks

11. Comments on the future of variola laboratories

NATIONAL CONTROL PROCEDURES FOR LABORATORIES RETAINING VARIOLA VIRUS

Laboratory	National Control Authority	Control Procedure	Site Visit and Review
1. Center for Disease Control, Atlanta	Dept. of Health, Education and Welfare. Public Health Service. Center for Disease Control	Permit to import and work with variola	Special Pathogens Advisory Committee (local)
2. Institute for Control of Pharmaceutical and Biological Products	Ministry of Public Health	Letter of permit	Institute safety inspectorate
3. Institut für Schiffs- und Tropenkrankheiten, Hamburg	Federal and State Ministries of Health	Letter of authorization	Institute safety officer
4. National Institute for Virology, Sandringham	Department of Health	Permit to import and use pathogenic agents	Biological safety committee of Institute. Dept. of Health has right to visit and inspect at any time
5. Rijks Instituut voor de Volksgezondheid, Bilthoven	Chief Medical Officer of Health	-	Safety committee of the Institute
6. Research Institute of Virus Preparations, Moscow	Ministry of Health	Site and project subject to licence by Ministry of Health	Regular inspection by Institute, city and Ministry of Health
7. St Mary's Hospital Medical School, London	Dept. of Health and Social Security	DHSS approval of notice of intent to work with variola following site visit	Local safety committee and DHSS yearly inspection
8. US Army Medical Research Institute for Infectious Diseases	Dept. of Defense/Dept. of Health, Education and Welfare	Permit	Local control
9. National Institute of Health, Tokyo*	Ministry of Health and Welfare	Licence	Safety committee

*Virus has been temporarily transferred to the Center for Disease Control

ANNEX 5

SUMMARY OF STATEMENTS ON CURRENT STATUS AND FUTURE PLANS
BY REPRESENTATIVES OF LABORATORIES RETAINING VARIOLA VIRUS

WHO Collaborating Centres

1. The CENTER FOR DISEASE CONTROL, Atlanta, USA, will continue indefinitely with its diagnostic, research and archival functions in support of the eradication programme. The present laboratory meets the safety requirements and was inspected by WHO in March 1979. A new laboratory is planned and construction will begin in 1979. The laboratory will consider requests for visiting workers with relevant projects.

2. The RESEARCH INSTITUTE OF VIRUS PREPARATIONS, Moscow, USSR, is continuing its diagnostic activity. No research work with variola virus is presently being undertaken, pending the completion of a new laboratory designed to meet the requirements of SME/77.2 Revision 1. Stocks of variola viruses are being kept in a locked refrigerator under appropriate physical security. This laboratory has not been inspected by WHO.

3. The NATIONAL INSTITUTE OF HEALTH, Tokyo, Japan, has not been inspected by WHO and no active research with variola virus has been done there since 1978. A new maximum containment laboratory will be completed during 1980/81. Stocks of variola virus have been temporarily transferred to CDC, Atlanta.

4. The RIJKS INSTITUUT VOOR DE VOLKSGEZONDHEID, Utrecht, Netherlands, has not done active research with variola virus since the autumn of 1975. This centre was inspected by WHO in January 1979. Stocks of variola virus are kept under conditions of appropriate physical security. The laboratory has contributed to the eradication programme over many years and, should maximum containment facilities become available, will be in a position to resume its studies of variola virus.

5. ST MARY'S HOSPITAL MEDICAL SCHOOL, London, UK, is currently not undertaking active research using variola virus, pending the relocation of the laboratory in accordance with the recommendations of the Shooter Report to the Department of Health and Social Security. Stocks of variola virus are kept under conditions of maximum containment in a laboratory which was approved by a WHO inspection in May 1978. It is planned to resume research activities.

Other Laboratories

1. The laboratory at the United States Army Medical Research Institute of Infectious Diseases, Frederick, USA, meets the safety requirements of SME/77.2 Revision 1, as determined by a WHO inspection team in March 1979. USAMRIID has agreed to transfer its variola stocks to CDC before the end of 1979, in compliance with WHO recommendations.

2. The laboratory at the American Type Culture Collection, Rockville, USA, which maintained an archival collection of variola virus stocks under appropriate physical security, transferred all stocks to CDC in March 1979 in compliance with WHO recommendations. This laboratory had not been inspected by WHO.

3. In the INSTITUT FÜR SCHIFFS- UND TROPENKRANKHEITEN, Hamburg, Federal Republic of Germany, variola virus stocks are maintained in a laboratory which meets the requirements of SME/77.2 Revision 1, and was inspected in May 1978. No research with variola virus is presently being undertaken. Future plans for disposition or use of variola stocks are not yet decided.

Annex 5

4. The NATIONAL INSTITUTE FOR THE CONTROL OF PHARMACEUTICAL AND BIOLOGICAL PRODUCTS, Peking, People's Republic of China, maintains variola virus stocks under conditions of physical security in a laboratory which has not yet been inspected by WHO. No active work with variola virus has been undertaken since 1967. There are plans to provide a laboratory meeting the requirements of SME/77.2 Revision 1. After completion, and in consultation with WHO, it is possible that research work with variola virus will be undertaken.

5. In the NATIONAL INSTITUTE OF VIROLOGY, Sandringham, Republic of South Africa, no active work with variola virus is in progress or authorized. Variola stocks are kept under conditions of strict physical security in a laboratory which has not been inspected by WHO. They will be transferred to a new maximum containment laboratory as soon as this is commissioned during 1979. This laboratory is willing to assist with health problems on the African continent. It would also be willing to assist the programme activities at the request of WHO.

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