

Centers for Disease Control
Key Contacts for AIDS

404-329
2091

<u>Subject Area</u>	<u>Contact</u>	<u>Extension</u>
General Medical Consultation	D. Peter Drotman, M.D.	(404) 329-2891
Case Reporting	Mary Cathrine Noa	3472
Number of Cases Reported	Surveillance	3472
Case Definition/Classification	Richard Selik, M.D.	3260
AIDS Reporting System (ARS)	James Williams	3775
Public-Use Data Tapes	Kathy Winter	3775
Seroprevalence Studies	Timothy Dondero, M.D.	3651
Serologic Testing	Charles Schable	3174
No Identified Risk (NIR) Follow-up	Carol White	2891
	Alan Lifson, M.D.	3162
Transfusion AIDS	Tom Peterman, M.D.	3162
Pediatric AIDS	Martha Rogers	3162
Hemophilia and AIDS	Jeanette Stehr-Green, M.D.	3410
	Janine Jason, M.D.	3711
Needlestick Protocol	Ruth Ann Marcus	3406
Disinfection/Sterilization	Martin Favero, Ph.D.	3821
Prevention and Control Activities/Policies	Tim Baker	2790
	Stephen Margolis, Ph.D.	2790
AIDS Education in Schools	Lloyd Colby, Ph.D.	2829
Epidemiologic Slide Set	Technical Services	1388
AIDS Hotline		1-800-342-AIDS
Cooperative Agreements:		
Programmatic Activities		
Surveillance	Dave Collie*	3651
	Kathy Rauch*	3651
	Harold VanPatten*	3651
Epidemiologic Studies	John Narkunas	3162
Health Ed/Risk Reduction	Pam Chin	2550
Counseling and Testing	Pam Chin	2550
Grants Management Office (Business Aspects)		
Surveillance	Marsha Driggans	(404) 262-6575
Epidemiologic Studies	Marsha Driggans	6575
Health Ed/Risk Reduction	Nancy Bridger	6575
Counseling and Testing	Nancy Bridger	6575

* Dave Collie - Primary responsibility for States in HHS Regions 2, 4, and 10.

* Kathy Rauch - Primary responsibility for States in HHS Regions 1, 5, 7 and 8.

* Harold VanPatten - Primary responsibility for States in HHS Regions 3, 6, 9.

AIDS PROGRAM
Center for Infectious Diseases

OFFICE OF DIRECTOR

(404) 329-2405

James W. Curran, M.D.
 Wilmon R. Rushing
 James R. Allen, M.D.
 Gerald Schochetman, Ph.D.

Director
Asst. Dir. for Operations
Asst. Dir. for Med. Science
Asst. Dir. for Lab. Science

Technical Information Activity

(404) 329-2891

D. Peter Drotman, M.D.

Chief

EPIDEMIOLOGY BRANCH

(404) 329-3162

Harold W. Jaffe, M.D.

Chief

Pediatric and Family Section

(404) 329-3162

Martha F. Rogers, M.D.

Chief

Special Studies Section

(404) 329-3472

Scott D. Holmberg, M.D.

Chief

SURVEILLANCE AND EVALUATION BRANCH

(404) 329-3651

Timothy J. Dondero, M.D.
 Lawrence D. Zyla

Chief
Assistant for Operations

Surveillance Section

(404) 329-3472

E. Thomas Starcher

Chief

Special Projects Section

(404) 329-3472

Timothy J. Dondero, M.D.

Acting Chief

Extramural Projects Section

(404) 329-3651

Lawrence D. Zyla
David F. Collie
Harold G. VanPatten
Kathryn J. Rauch

Acting Chief
Sr. Public Health Advisor
Sr. Public Health Advisor
Sr. Public Health Advisor

STATISTICS AND DATA MANAGEMENT BRANCH

(404) 329-3775

W. Meade Morgan, Ph.D.

Chief

LABORATORY BRANCH

(404) 329-3956

Gerald Schochetman, Ph.D.

Chief

For Your Information



Re attached - we have no record of this being cleared.

Attached is a copy of clearance procedures.
You can forward anything needing clearance
to Dr. Bowen or Technical Information Services.

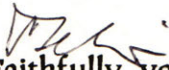
**From: Technical Information Services (E06)
Center for Prevention Services
Centers for Disease Control
Atlanta, Georgia 30333
(404-639-1819)**

Dear Sir,

I would greatly appreciate if you could send me
reprints of your paper(s) on ~~vet~~

Acquired Immunodeficiency Syndrome Vaccine. The
Continuing Challenge-Update on the Pursuit of a Vaccine
for AIDS

and other related papers
if available for distribution.


Faithfully yours,

RNDr. E. Štetinová
PSYCHIATRIC HOSPITAL

Research Department

902 01 Pezinok

Czechoslovakia

cytogenet. lab.

CP5
6D

M.D.



#07

D.P.FRANCIS

Ctr Dis Control,

ATLANTA, GA 730333

USA



DEPARTMENT OF HEALTH & HUMAN SERVICES

File
Public Health Service
Centers for Disease Control

Memorandum

Date December 4, 1984

From Assistant Director
Center for Prevention Services

Subject Revised Clearance Procedure

To See Below

Attached are several copies of the revised CPS Clearance Procedure which is in effect this date. Please have additional copies made so that all authors and support staff responsible for the clearance mechanism have a copy for reference.

Thank you for the many excellent comments and suggestions on the clearance draft. Most have been incorporated in this final document.

Windell R. Bradford
Windell R. Bradford

Enclosures

Director, Division of Diabetes Control
Director, Division of Immunization
Director, Division of Quarantine
Director, Division of Sexually Transmitted Diseases
Director, Division of Tuberculosis Control
Chief, Dental Disease Prevention Activity

Staff, Office of the Director, CPS - *Joyce Ayer*

CENTER FOR PREVENTION SERVICES CLEARANCE PROCEDURE
DECEMBER 1, 1984

The following clearance procedure is established for the Center for Prevention Services in accordance with CDC issuance No. CDC-18 (attached). This revision supersedes the CPS memorandum on clearance sent to you on September 2, 1983.

These guidelines do not cover pre-project clearance for public affairs materials, i.e., "Concept Review" (HHS-676), "Publication Plan Clearance" (HHS-615), and "Request for Audiovisual Materials" (HHS 524-A). Public affairs materials (materials going to more than 50 people outside of HHS) must be cleared at the concept and planning stage, i.e, prior to beginning actual work on the project. If approval is granted, the text of the publication goes through the CDC/CPS clearance procedures contained in this issuance.

Responsibility and Authority

The Directors of all Centers are responsible to the Director, CDC, for all scientific/technical materials originating in their Centers from the standpoint of scientific and technical accuracy, policy, editorial quality, propriety, and necessity.

The Center Director, CPS, has delegated to each Division Director and Activity Chief the responsibility for the technical and scientific accuracy, editorial quality, propriety, and necessity of materials prepared by their employees. Final approval in the Office of the Director, CPS, will be concerned primarily with conformance to CPS, CDC, PHS, and Departmental policy.

Material Which Requires CPS Clearance

1. Manuscripts of articles, book chapters, letters to the editor, etc., to be submitted for publication in medical journals.
2. Manuals, pamphlets, brochures, meeting announcements and agendas, meeting handouts, surveillance reports, newsletters, Dear Colleague letters, Epi II's, advisory memoranda, MMWR submissions. (CDC Staff Publications)
3. Abstracts of speeches to be submitted for consideration by program committees outside and within CDC (APHA, ICAAC, EIS Conference, etc.).
4. Complete text of speeches accepted for presentation to outside organizations and at CDC-sponsored meetings. If the speech is to be made from notes only and will not be published, an abstract or an outline of the presentation is adequate. Approval of an abstract or an outline in lieu of a complete speech which will be published will be considered on a case-by-case basis.

5. Complete text and illustrations for poster presentations. (See note below.)
6. Training materials for use inside and outside CDC. (See note below.)
7. Film scripts and texts of special audiovisual/slide productions. (See note below.)
8. Exhibits/displays. Any plans to exhibit must be coordinated with Technical Information Services (TIS). All 0.19's for services connected with an exhibit must be approved by the Chief, TIS, in addition to the usual administrative approvals.
9. Revisions of any of the above items.

NOTE: Text of materials described in items 5, 6, and 7 above which represent portions of previously cleared materials do not require re-submission to the Office of the Director, CPS, for clearance. Each Division Director and Activity Chief is responsible for insuring that the text of these materials has received prior clearance.

Clearance Procedure

Divisions and Activities should establish an internal system whereby manuscripts originating in that organization receive a thorough scientific/technical/editorial review. The review may be made by a publications board (e.g., a statistician, physician, public health advisor), by designated subject-matter specialists, supervisors of author, or any combination of these.

Technical Information Services will provide upon request editorial assistance to all CPS authors at any stage of the manuscript, but before the approval of the Division Director or Activity Chief.

Submit three copies of the manuscript and clearance form CDC 0.576 Publication/Presentation Clearance. (Submit additional copies if cross-clearance is needed - one copy for each Center/Program Office involved.) The clearance form should be initialed by all authors, approved through appropriate supervisory channels, and signed by the Division Director or Activity Chief. It should then be forwarded for policy review and signature of the Chief, Technical Information Services and the Director, Center for Prevention Services. A copy of a correctly filled out clearance form is attached.

As a rule, documents to be submitted to the OCD, CPS, for final policy review should be retyped to include all changes made during the clearance process; however, minor handwritten editing will be accepted.

If changes are made in the Office of the Director, CPS, the document will either be returned to the Division/Activity for correction and resubmission, or the clearance form will be signed with a notation that changes need to be addressed, depending on the extent of the changes. In the latter case, it is the responsibility of the Division Director or Activity Chief to insure that these changes are made prior to release from CPS and that a corrected copy is provided to TIS.

Cross-Clearance

Cross-clearance between Centers/Program Offices is mandatory if (1) authorship includes more than one Center, or (2) subject matter concerns more than one Center. Technical Information Services will obtain cross-clearance from other Centers before signature of the Director, CPS, but after the signature of the Division Director or Activity Chief.

Publication

After clearance by the Director, CPS, the manuscript may be submitted to a journal or printed at CDC.

If the paper is accepted by a journal and page charges for publication are required, a form CDC 0.602 Request for Approval of Payment of Publications Costs in Private Journals (copy attached) must be submitted to Publications Management for approval. See CDC Manual Guide - General Administration No. CDC-12.

If reprints are to be ordered at the time the galley proofs are returned to the journal, the informal order blank may be returned with the galleys but must be followed by an official purchase order. Failure to request a purchase order will constitute an unauthorized commitment. There is no longer a monetary limit on purchase of reprints from outside sources. (See attached letter dated March 19, 1984 from the Joint Committee on Printing to Secretary Heckler, and attached memo dated June 11, 1984 from Wilford J. Forbush to William E. Muldoon.)

After the paper is published, immediately send one copy (or written notification) to Technical Information Services so that this information can be entered into the CDC Bibliographic Retrieval System. Otherwise, your paper will appear as unpublished work.

Honoraria and Fees

An employee of the Department of Health and Human Services may not accept an honorarium or fee for participation in a professional meeting sponsored by a non-Government organization or for contribution of a paper or other writing prepared on official time for publication under non-Government auspices. (Refer to HHS Standards of Conduct.)

3/24/83

TRANSMITTAL NOTICE--GENERAL ADMINISTRATION

CDC TN-83.2

MATERIAL TRANSMITTED

Manual Guide--General Administration No. CDC-18, Clearance Procedures for Manuscripts

MATERIAL SUPERSEDED

Manual Guide--General Administration No. CDC-18, Clearance Procedures for CDC Informational Activities, dated 3/6/69

BACKGROUND

An ad hoc group, consisting of a representative from each of CDC's major components and chaired by the Assistant Director for Science, initiated the attached Guide to provide a uniform procedure for manuscript review/clearance for CDC.

The clearance procedures were developed in consultation with Center/Institute/Office officials and in recognition that CDC's image and credibility in the medical/scientific community and among the general public depend in a large part on the quality of CDC manuscripts published in journals. Considerable latitude is permitted within the framework of the Guide for each Center/Institute/Office to develop more detailed clearance procedures. Any additional procedures should serve to expedite clearance and further ensure the quality of CDC manuscripts.

FILING INSTRUCTIONS

Discard the superseded materials and file the attached Guide.

Change the title of the Guide in the CDC Contents to "Manual Guide--General Administration No. CDC-18, Clearance Procedures for Manuscripts---1."

Post receipt of this Transmittal Notice on the Checklist for CDC Transmittal Notices--General Administration.

William H. Foege

William H. Foege, M.D.
Assistant Surgeon General
Director, Centers for Disease Control

DISTRIBUTION: Mailing List No. 1, Code 2

CLEARANCE PROCEDURES FOR MANUSCRIPTS

- Section I. Purpose
 II. Coverage
 III. Definitions
 IV. Responsibilities and Procedures
 V. Retention of Manuscript

I. PURPOSE

The purpose of this Guide is to place responsibility and provide a uniform procedure for manuscript review/clearance for the Centers for Disease Control (CDC). The procedure has been developed to inform management of progress in scientific studies and to ensure manuscript quality by providing authors with editorial and technical assistance.

II. COVERAGE

This entire Guide applies to clearance of manuscripts for outside publication.

Although the procedures in the Guide are not mandatory for clearance of every manuscript (text) of proposed CDC publications, most of them are appropriate for adaptation by the Center¹ Directors for that purpose. Manual Guide--Public Affairs Management No. CDC-2 contains clearance procedures for publications. As stated in that Guide, Center Directors should establish guidelines and procedures for the Center components to follow for clearance of the text of CDC publications.

Form CDC 0.576, Publications/Presentation Clearance (Exhibit A), will be used CDC-wide for clearance of manuscripts (for CDC publication or for outside publication). (Copies of the form are available from the CDC Warehouse and the Self-Service Store at the Clifton Road Facility. Existing supplies of form CDC 0.576, CDC Information Clearance: Abstract or Manuscript for Outside Publication, will continue to be used until exhausted.)

¹ References to "Center" in this issuance also apply to Institute and Offices.

III. DEFINITIONS

"Author" means the first-listed CDC author; "coauthors" are all others. If a former CDC employee reports on work done with CDC, the manuscript must be cleared and the former employee considered a CDC author for clearance purposes.

"Manuscript" means the text (including any tables and illustrations) of any article, book chapter, letter to the editor, case report, clinical note, or written abstract of a presentation (to be given orally) that is to be submitted for publication or for consideration for publication or presentation. It also may include the complete text of an oral presentation.

"Outside publication" means publication by any organization other than the Centers for Disease Control.

"CDC publication" means a monograph, manual, periodical, pamphlet, etc., published by CDC.

IV. RESPONSIBILITIES AND PROCEDURES

A. General Responsibilities

The Directors of all Centers are responsible to the Director, CDC, for all scientific/technical materials originating in their Centers from the standpoint of scientific and technical accuracy, policy, editorial quality, propriety, and necessity.

Center Directors are responsible for providing written procedures and guidelines for the Center components to follow for manuscript clearance. Procedures may vary from Center to Center and even within Divisions of the same Center, but the functions described in this Section must be served by any clearance procedures for manuscripts.

B. Preliminary Work

The author:

1. Drafts the manuscript, completely (to include when applicable the title page, keywords, summary abstract, text, tables/graphs and other illustrations, acknowledgments, and references).
2. Obtains:
 - a. Coauthors' approval signified by a memorandum or initials on the clearance form CDC 0.576 or a letter if the coauthors are from other Government agencies or outside the Government.

IV. RESPONSIBILITIES AND PROCEDURES (Continued)

- b. Written permission from those listed in the acknowledgments to publish their names.
- c. Written permission to use copyrighted material.
- 3. Submits the manuscript with a completed clearance form CDC 0.576 to the author's immediate supervisor for technical/scientific clearance.

C. Technical/Scientific Review and Clearance

The author's immediate supervisor:

- 1. Reviews the manuscript for technical/scientific accuracy.
- 2. If necessary, returns to author to correct deficiencies and prepare manuscript for clearance.
- 3. Signifies approval of the manuscript on form CDC 0.576.
- 4. Follows the Center procedures for further clearance processing of the manuscript.

The author's Division Director (or designee) is responsible for technical/scientific clearance of the manuscript and should ensure that:

- 1. The manuscript contains information that has not already been published and that it is worth publishing in its present form.
- 2. The appropriate authors are included and that they are properly identified.
- 3. The information is correct.
- 4. The proper procedures were followed and that all procedures are described and/or cited correctly.
- 5. The numbers, percentages, rates, ratios, significance tests, and references are correctly presented.
- 6. The keyword list is complete and correct.
- 7. The article is appropriate for the journal chosen by the author.

IV. RESPONSIBILITIES AND PROCEDURES (Continued)

8. The tables and figures are necessary, concise, complete, and correct.
9. The conclusions drawn are valid and supported by reference to the facts.
10. The manuscript includes no information that might infringe on the privacy of or reflect unfairly on any person, institution, or agency.
11. The manuscript includes no information that is counter to the policies of CDC, the Public Health Service (PHS), or the Department of Health and Human Services (HHS). (NOTE: Questions of policy should be brought to the attention of the Center Director, who may request policy clearance from the Office of the Director, CDC.)

The reviewer may ask for advice from any others (statisticians, publications board, subject-matter specialists, etc.) deemed appropriate.

Any recommended substantive changes in the manuscript should be discussed with the author. If extensive revision is required before further review, the manuscript should be retyped, incorporating the necessary changes, and resubmitted for clearance.

The approval of the Division Director (or designee) should be signified on clearance form CDC 0.576.

D. Editorial Clearance

In the review of the manuscript, the editor should ensure that:

1. The manuscript is written clearly and concisely.
2. The grammar, sentence structure, and style are correct.
3. The parts of the manuscript are logically arranged.
4. The level of concepts, expression, and vocabulary are appropriate for the audience to which the material is directed.

Any recommended substantive changes in the manuscript should be discussed with the author. If extensive revision is required, the manuscript should be retyped, incorporating the necessary changes, and resubmitted for clearance.

Editorial clearance should be signified on form CDC 0.576.

IV. RESPONSIBILITIES AND PROCEDURES (Continued)

E. Cross-Clearance

To ensure that the manuscript reflects the policies of all Centers involved, it will be submitted for cross-clearance between Centers. The author's Center Director will ensure that cross-clearance is obtained from:

1. Directors of the coauthors' Centers.
2. Directors of other Centers specifically concerned with, or interested in, the subject matters.

The approval or disapproval should be communicated to the initiating Center within 10 workdays.

F. Final Clearance

The author's Center Director (or designee) is responsible for final approval or rejection of a manuscript on behalf of CDC. This action will be recorded on the clearance form CDC 0.576.

When approval/disapproval has been signified by all of the appropriate Center staff and by all concerned Centers, the author should be notified, and the manuscript and a copy of the clearance form CDC 0.576 should be sent to the author. The author is responsible for getting the concurrence of coauthors in any substantive modifications in the manuscript as a result of the review/clearance procedure.

Upon final clearance, the manuscript may be submitted for publication. (Refer to Manual Guide--Printing Management No. CDC-6 (on excess page changes) and Manual Guide--General Administration No. CDC-12 (on charges for reprints) on procurement considerations to be addressed in subsequent actions.)

An information copy of each approved manuscript for outside publication with a copy of the completed clearance form attached will be sent to the Office of Public Affairs, CDC.

V. RETENTION OF MANUSCRIPT

The author should keep his or her Center's office of record informed about subsequent revisions and the final disposition of the manuscript. The record copy of the manuscript and the record clearance form should be kept in the Center's designated "office of record" for at least 5 years. Then, the official manuscript should be transferred to the Federal Records Center for permanent storage. Supporting documents may be destroyed when 10 years old.

Publication / Presentation Clearance

Centers for Disease Control

Date required 9/9/83

Date submitted 9/1/83

Accession No. _____

Authors (initial to show approval) Alula Hadgu, M.A., Gladys H. Reynolds, Ph.D. and

Stephen J. Kraus, M.D.

Title of work Condyloma Acuminatum

FOR PUBLICATION

☒ Article, letter, etc. in (journal) Sexually Transmitted Diseases

☐ Chapter in _____
(book editor / title / publisher)

☐ CDC publication: ☐ Manual ☐ Pamphlet ☐ Report ☐ Other _____

☐ Other training material for _____

(course / location)

FOR PRESENTATION (oral or poster)

☐ Abstract ☐ Text for _____

(meeting / place / date)

AUDIOVISUAL

☐ Film (length / date)

☐ Slide series / film (place / date)

ABSTRACT (summary)

Condyloma acuminatum is one of the most common sexually transmitted diseases (STD's) in the United States. Morbidity and complications associated with this disease can be severe. More extensive training of physicians in the STD's has led to improved diagnosis and therapy of certain of these diseases, resulting in a favorable influence on their incidence. However, diagnostic and therapeutic practices have had less influence on the incidence of genital warts for which there are no laboratory tests to detect incubating disease, and for which therapy can be difficult and prolonged.

SAMPLE

KEYWORDS

APPROVAL (signature & title)

DATE

REMARKS

1. Chief, Evaluation & Statistical Services Branch
2. Assoc. Director for Operations, DVDC
3. Director, Division of Venereal Disease Control
4. Chief, Technical Information Services
5. Director, Center for Prevention Services

CDC cross-clearance ☐ Needed ☐ Obtained (date) _____
from (Ctr/Inst/Otc) _____

Approval to
author (date) _____

OD / CDC clearance ☐ Needed ☐ Obtained (date) _____
from (name & title) _____

Cleared MS & form
to OPA (date) _____

REQUEST FOR APPROVAL OF PAYMENT OF PUBLICATIONS
COSTS IN PRIVATE JOURNAL

TO: CHIEF, PUBLICATIONS MANAGEMENT

Date Submitted

Date Required

FROM CENTER/INSTITUTE/OFFICE/DIVISION

CENTER/INSTITUTE/OFFICE/DIVISION APPROVAL (Signature)

BRANCH / SECTION

BLDG. & ROOM NO.

TELEPHONE

Approval is requested for payment of publication costs of the article listed below. Explanatory information is presented as prescribed in HSM Circular No. 693, and CDC Manual Guide - General Administration No. CDC-12.

TITLE

AUTHOR(S)

SIGNIFICANCE OF PAPER

☐ Contains new information or original findings

☐ Is a significant contribution

☐ Is an extensive study

☐ Other

☐ Has practical application

BRIEF SUMMARY OF CONTENTS

JOURNAL

(a) Name

(b) Affiliation

ESTIMATED EXCESS COSTS INVOLVED

(a) Amount

(b) Explanation

APPROVAL IF CHARGES ARE \$1000 OR UNDER

APPROVAL IF CHARGES ARE OVER \$1000

Approved:

DIRECTOR, MANAGEMENT ANALYSIS AND SERVICES OFFICE

EXECUTIVE OFFICER, CDC

Date:

Date:

Congress of the United States

Joint Committee on Printing

83349

March 19, 1984

Waiver No. →
The Honorable Margaret M. Heckler
Secretary
Department of Health and Human Services
Washington, D.C. 20201

Dear Madam Secretary:

In response to the request dated October 12, 1983, from the Deputy Assistant Secretary for Management Analysis and Systems, the Joint Committee on Printing grants the Department of Health and Human Services (HHS) a waiver of paragraphs 38 and 46-1 of the Government Printing and Binding Regulations to permit the initial publication of articles written by employees of HHS in privately published journals, encyclopedias and textbooks. This includes permission to pay page charges and to purchase separates of the articles at the time of their publication, directly from the private publisher.

This authorization is granted with the following conditions:

1. Copyright will not be extended to the private publisher for the articles, even though the journal, encyclopedia or textbook may be copyrighted as a whole.
2. Royalty payments will not be paid to the Government.
3. An annual report, listing the articles and the journals in which they were published, and the amount of money expended for page charges and purchase of separates for each article will be submitted to the Joint Committee on Printing.

The Joint Committee would like your assistance in formulating a reasonable, cost-effective plan to make these articles available to the depository library program. Please assign a member of your staff to work with Bernadine Hoduski of the Joint Committee staff on this plan. She can be reached on 224-5953.

Sincerely,

Augustus F. Hawkins
Augustus F. Hawkins
Chairman

076

Date

JUN 11 1984

Memorandum

From

Deputy Assistant Secretary for Health Operations and
Director, Office of Management

Subject

Joint Committee on Printing Waiver to Publish Articles in Private Journals

To

Associate Commissioner for Management and Operations/FDA
Associate Administrator for Operations and Management/HRSA
Acting Director, Office of Program Support/CDC
Executive Officer/ADAMHA

Waiver No.

Attached is a copy of JCP letter No. 83349, which grants this Department a waiver to: (a) publish articles in private journals, encyclopedias, and textbooks; (b) pay page charges; and (c) purchase separates of such articles at the time of publication. This waiver supersedes all previous waivers on the subject.

Please note that application of the waiver is subject to three conditions, the first two of which are procedural. The third requires submission of an annual report listing each use of the waiver. Therefore, if your organization uses the waiver, as we expect it will, appropriate usage records will need to be maintained. These records should capture the following items of information each time the waiver is used:

- Name of journal or publisher.
- Date of issue.
- Title of article.
- Number of pages.
- Page charges (publication costs).
- Number of separates.
- Cost of separates.

The JCP did not provide a form or format for the report, so it may be prepared in a manner most convenient to your system of recordkeeping, i.e. computer printout, copy of each record, etc. Reports are to be submitted, in duplicate, to this office by November 15 of each year. Questions concerning the report should be referred to Mr. Richard L. Lutz, PHS Printing Officer, on FTS 443-6418.

Wilford J. Forbush
Wilford J. Forbush

6-18-84

Attachment

*No limit to cost of reprints,
per Linda Whipp to Reg Linden.*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date • May 4, 1987

From Chief, Technical Information Services, CPS

Subject CPS Manuscript Clearance

To Program Management Officers, CPS

Effective today, please add a signature line for the "Deputy Director (AIDS), CPS" on Publication/Presentation Clearance Form CDC 0.576 for all manuscripts related to AIDS. This signature line should follow that of Chief, Technical Information Services, CPS.


Joyce H. Ayers



Dateline: CDC

Centers for Disease Control Atlanta, Georgia 30333 Volume 22, No. 9

Oct 1989



Joseph Mountin, M.D.
Envisioned CDC

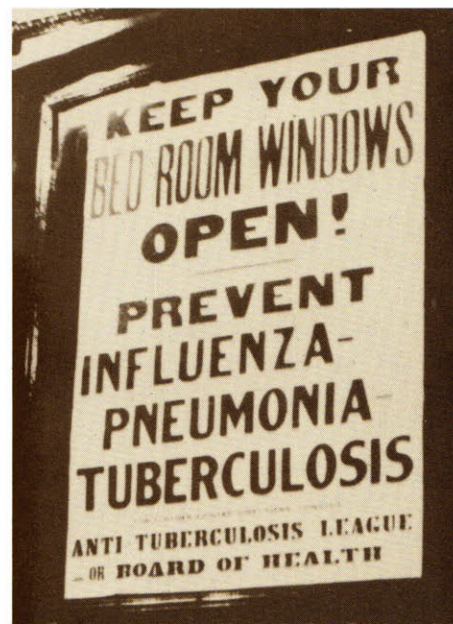
This Special Edition of *Dateline: CDC* Celebrates an Institution and an Individual.

The Commissioned Corps of the Public Health Service was established by Congress on Jan. 4, 1889, to prevent the interstate transmission of diseases. Today, Commissioned Corps officers work for all seven agencies of the Public Health Service.

Dr. Joseph Mountin, himself a Commissioned Corps officer, envisioned in 1946 the "Centers of Excellence" that turned a wartime malaria control effort into today's Centers for Disease Control which combines talents of the Commissioned Corps with those of its civilian employees. These stories illustrate some of their combined disease fighting efforts.



Early U.S. P.H.S. Officers



A 1918 poster in a Cincinnati trolley car during the Spanish influenza pandemic which killed millions worldwide.

ROUTING AND TRANSMITTAL SLIP

Date

7-23-87

TO: (Name, office symbol, room number, building, Agency/Post)

Initials

Date

1. *Jim Sullivan*

2. *Don Francis*

3.

4.

5.

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

FROM: (Name, org. symbol, Agency/Post)

Room No.—Bldg.

Karen L. Foster
Writer-Editor, Publications & Graphics

Phone No.

OD-618-1-6117 Ext. 3426

5041-102

★ U.S.GPO:1985-0-491-247/20036

OPTIONAL FORM 41 (Rev. 7-76)
Prescribed by GSA
FPMR (41 CFR) 101-11.206

Publication / Presentation Clearance

Centers for Disease Control

Date required ASAP

Date submitted 7-10-87

Accession No. 09870048

Authors (initial to show approval) CD Tempelis, RA Benjamin, DP Francis, G Shell, M Hoffman, A Chandler

Title of work HUMAN IMMUNODEFICIENCY VIRUS INFECTION OF WOMEN IN THE SAN FRANCISCO BAY AREA

☒ FOR PUBLICATION

☐ Article, letter, etc., in (journal) JAMA

☐ Chapter in _____
(book editor / title / publisher)

☐ CDC publication: ☐ Manual ☐ Pamphlet ☐ Report ☐ Other _____

☐ Other training material for _____
(course / location)

☐ FOR PRESENTATION (oral or poster)

☐ Abstract ☐ Text for _____
(meeting / place / date)

☐ AUDIOVISUAL

☐ Exhibit (place / date) _____

☐ Slide series / film (place / date) _____

ABSTRACT (summary)

SEE ATTACHED.

KEYWORDS

APPROVAL (signature & title)

DATE

REMARKS

1. James W. Curran, M.D., Director, AIDS Program

2. Publications and Graphics Ralph Foster

3. John V. Bennett

4.

5.

To WRD 7/23/87

CDC cross-clearance
from (Ctr/Inst/Ofc) _____

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(date) _____

Approval to
author (date) _____

OD / CDC clearance
from (name & title) _____

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(date) _____

Cleared MS & form
to OPA (date) _____

Publication / Presentation Clearance

Centers for Disease Control

Date required ASAP

Date submitted 7-10-87

Accession No. 8876048

Authors (initial to show approval) CD Tempelis, RA Benjamin, DP Francis, G Shell, M Hoffman, A Chandler

Title of work HUMAN IMMUNODEFICIENCY VIRUS INFECTION OF WOMEN IN THE SAN FRANCISCO BAY AREA

☒ FOR PUBLICATION

☐ Article, letter, etc., in (journal) JAMA

☐ Chapter in _____
(book editor / title / publisher)

☐ CDC publication: ☐ Manual ☐ Pamphlet ☐ Report ☐ Other _____

☐ Other training material for _____
(course / location)

☐ FOR PRESENTATION (oral or poster)

☐ Abstract ☐ Text for _____
(meeting / place / date)

☐ AUDIOVISUAL

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ABSTRACT (summary)

SEE ATTACHED.

KEYWORDS

APPROVAL (signature & title)	DATE	REMARKS
1. James W. Curran, M.D., Director, AIDS Program	7/17/87	To WRD 7/23/87
2. Publications and Graphics <i>Kaufman</i>	7/17/87	
3. John V. Bennett	7/17/87	
4.		
5.		

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Approval to
author (date) 7/23/87

Cleared MS & form
to OPA (date) 7/23/87

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☐ Obtained

(date) _____

HUMAN IMMUNODEFICIENCY VIRUS INFECTION OF WOMEN IN THE
SAN FRANCISCO BAY AREA

WHEN THIS MANUSCRIPT IS
REVISED, SEND 2 COPIES TO
CID PUBS & GRAPHICS, 1/6118

To the Editor:

The question of what heterosexually active people should do to avoid Human Immunodeficiency Virus (HIV) infection is becoming critical. Evidence is mounting that this virus, known to be spread by anal intercourse, may also be effectively spread by vaginal intercourse -- both from men to women and from women to men (1-4).

However, the number of AIDS cases in men (566) and women (545) classified as heterosexually acquired, remains relatively small when compared to homosexual/bisexual (21,371) or IV-drug-use-acquired (4,955) cases (Centers for Disease Control, National AIDS Statistics -- Cumulative, January 26, 1987). This relatively small number of cases has lead heterosexual men and women to consider themselves at low risk of infection.

To help estimate the risk of HIV infection for heterosexuals in the San Francisco Bay Area, we tested serum collected from women in Alameda County (eastern edge of the San Francisco Bay) which has had an intermediate incidence of AIDS (331 cumulative cases -- January 26, 1987). Women were exclusively selected to obviate biases incurred by inclusion of homosexual/bisexual men.

Sera from blood samples collected in sexually transmitted disease clinics (STD) and premarital testing sites were selected for this survey. The women attending county STD clinics were chosen to reflect individuals at elevated risk of infection, while the women attending premarital testing clinics were selected to more broadly reflect the general female population of child bearing age within the county. The overall composition of the client population seen in our clinics consists of approximately:

CLINICS	WHITE	BLACK	HISPANIC	OTHER
STD	18 %	69%	8%	5%
Premarital	52%	19%	10%	19%

Approximately 50% of the STD and premarital clients are between the ages of 20 through 29.

and
or 20-29? - check
a difference

Serum collected between November, 1985 and August, 1986 were stripped of personal identifiers and stored at 4 degrees centigrade. The specimens were tested for HIV antibody using commercially available enzyme-linked immunosorbent assay procedures (Abbott Laboratories, North Chicago, Illinois, and Genetic Systems, Seattle, Washington). The results were further confirmed by immunofluorescence assay (antigens from the California Department of Health Services Laboratories, Berkeley, California) and Western blot (antigens from the National Cancer Institute, Bethesda, Maryland, and Dupont, Wilmington, Delaware) tests.

A total of 377 premarital specimens were obtained. This represents approximately 12% of the ^{female} women marriage license applicants during the sampling period. Two ^{of 377} (0.53%) sera from the premarital sites (95% Confidence Interval: 0.15% to 1.91%) and 2 ^{of 299} (0.67%) from STD clinics (95% Confidence Interval: 0.18% to 2.41%) tested positive to the HIV antibody. By design, risk-factor information was unavailable for positive and negative specimens.

Our subsequent studies will attempt to identify demographic characteristics and risk factors of the seropositives.

These preliminary results are similar to those of female ^{recruit} military applicants, which showed seroprevalence rates as high as 0.6% from the San Francisco and the New York metropolitan areas (5, 6).

The message for ^{persons} individuals engaging in heterosexual intercourse outside of long-standing mutually monogamous relationships is clear. HIV infection is present in the heterosexual community. In Alameda County, one's chance of contacting a woman who is infected may approach 1 in 200. The chance of contacting an infected man would presumably be higher. Since prevalence has reached this level, it would behoove both women and men to protect themselves. Because infection with this virus carries a high probability of death (at least 30%) (7) within a few years, ^{persons} individuals should be highly motivated to avoid infection. ~~To be protected~~ we recommend that all sexual intercourse outside of long-standing (or known sero-negative) relationships should be protected by use of a condom (4,8) and a nonoxynol-9 containing spermicide (9).

^{Before} Prior to becoming pregnant, women who may have been exposed to infected ^{persons?} ~~individuals~~ ^{men?} should be serologically tested. Any women found ~~to be~~ positive should be advised against becoming pregnant at this time.

The prevalence of the HIV varies considerably in various geographic regions. Therefore, we encourage other areas to assess their own prevalence rates.

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AIDS Prog. CID, CDC, PHS, HHS

*What do you
mean by
"contacting"?*

*a bit
preachy*

alt-

1. Redfield RR, Markham PD, Salahuddin SZ, et al: Heterosexually acquired HTLV-III/LAV disease (AIDS-related complex and AIDS) epidemiologic evidence for female-to-male transmission. JAMA 1985; 254:2094-2096.
2. Luzi G, Ensoli B, Turbessi G, et al: Transmission of HTLV-III infection by heterosexual contact. Lancet 1985; 2: 1018.
3. Fischl MA, Dickinson GM, Scott GB, et al: Evaluation of Partners, Children and Household Contacts of Adults with AIDS. JAMA 1987; ~~Feb 6~~ 640-644.
Vol. no.
4. Whittington WL, Kraus SJ, Lee F, et al: The prevalence of HTLV-III/LAV antibodies in heterosexuals. JAMA 1986; 255: 1702-1703.
5. ~~CDC~~ Human T-Lymphotropic Virus type III/Lymphadenopathy-Associated Virus antibody prevalence in U.S. ~~Military~~ recruit applicants. MMWR 1986; 35:521-424.
Military
6. Barnes DM: AIDS research in new phase -- military statistics on AIDS in the U.S. Science 1986; 223:283.
7. Goedert JJ, Biggar RJ, Weiss SH, et al: Three-year incidence of AIDS in five cohorts of HTLV-III infected risk group members. Science 1986; 231:992-995.
8. Conant M, Hardy D, Sernatinger J, et al: Condoms prevent transmission of AIDS-associated retrovirus. JAMA 1986; 255:1706.
9. Hicks, DR, Martin LS, Getchell JP, et al: Inactivation of HTLV-III/LAV infected cultures of normal human lymphocytes by nonoxynol-9, in-vitro. Lancet 1985; 2:1422.

OFFICE MEMO

STD 100 (REV. 12/85)

86 38867

TO:

James Curran, MD
CDC

DATE

6/29/87

ROOM NUMBER

FROM:

Abbe HALBENS, Secretary to
Don FRANCIS, MD

PHONE NUMBER

415
540-2522

SUBJECT:

Letter submitted to JAMA
Dr. Curran.

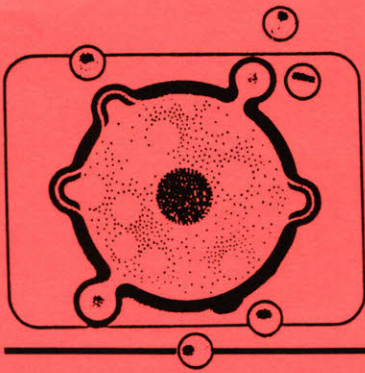
ATTACHED you will find a copy
of a letter written to JAMA for
publication

If you have any questions,
please call me.

Abbe

7/10/87

QUO - please
send through
clearance ASAP



Acquired Immunodeficiency Syndrome

AIDS

Recommendations and Guidelines

November 1982 - November 1986

Centers for Disease Control
Atlanta, Georgia 30333

PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Human Immunodeficiency Virus Infection in Transfusion Recipients and Their Family Members

CDC has received a report of human immunodeficiency virus (HIV) infection among multiply-transfused leukemia patients in New York City. In addition, there have been several reports that persons with transfusion-associated HIV infection have transmitted the virus to their sexual partners and newborn children. All infected transfusion recipients described in these reports had received blood or blood components before routine screening of donated blood for HIV antibody was begun in the spring of 1985.

Multiply-Transfused Leukemia Patients

During the past year, four long-term leukemia survivors at Memorial Sloan-Kettering Cancer Center in New York City developed unexplained fever, weight loss, diarrhea, or lymphadenopathy. They subsequently had positive serological tests for HIV antibody. A retrospective study of other multiply-transfused leukemia patients was conducted to determine how many had been infected with HIV. Informed consent was obtained from all living patients. Positive enzyme immunoassay (EIA) tests were confirmed by Western blot assay. Patients known to have other risk factors for HIV infection were excluded from the study.

Sera were located for 182 deceased and obtained from 22 surviving leukemia patients treated during the years 1978-1986. Sixteen of these transfusion recipients were seropositive for HIV antibody (Table 1). They had received a mean of 27 units of packed red blood cells (range 2-56) and 137 units of platelets (range 10-483). Forty-five percent of these 204 patients had acute myelogenous leukemia; 20% had acute lymphocytic leukemia; 13%, chronic myelogenous leukemia; 4%, chronic lymphocytic leukemia; 6%, myelodysplastic syndromes; and 12%, other or unclassified leukemias. There was no correlation between type of leukemia and the presence of HIV antibody. An additional 23 newly diagnosed, untreated, and untransfused leukemia patients were tested and all were seronegative.

Additional Case Reports From Other Areas

Case 1: An elderly man with no known risk for AIDS received multiple units of blood in early 1982, including one from a donor who subsequently tested positive for HIV antibody. The recipient developed *Pneumocystis carinii* pneumonia (PCP) in 1983 and died in 1984. His wife, who did not have any other risk factors for AIDS, had had vaginal intercourse with him until he became ill in late 1982. In late 1984, her HIV antibody test was positive and she was diagnosed as having a type of lymphoma indicative of AIDS (1).

Case 2: A pregnant woman with no other risk factors for AIDS received four units of blood in 1978, including one from a donor who later tested positive for HIV antibody. A son, born in 1980, had failure to thrive beginning at 13 months of age and died with PCP in 1986. The woman, her son, her husband, and the child born shortly after the transfusion all tested positive for HIV antibody.

Reported by DA Scheinberg, MD, PhD, GY Minamoto, MD, K Dietz, MS, JWM Gold, MD, T Gee, MD, D Armstrong, MD, J Gabrilove, MD, B Clarkson, MD, N Chein, MS, L Reich, MD, Memorial Sloan-Kettering Cancer Center, DL Morse, MD, State Epidemiologist, New York State Dept of Health; M Batt, MD, Luther-

TABLE 1. HIV serology results in leukemia patients, by year of specimen collection — Memorial Sloan-Kettering Cancer Center, New York City

Years	Total number of patients tested	Number with positive test	Estimated* risk per component
1978-80	86 (55M,31F) [†]	0 (0%)	0.00%
1981-83	77 (39M,38F)	9 (12%) (6M,3F)	0.07%
1984-86 [§]	41 (21M,20F)	7 (17%) (2M,5F)	0.10%
Total	204 (115M,89F)	16 (8%) (8M,8F)	0.05%

*Estimated risk based on an average of 164 components per recipient.

[†]M=males; F=females.

[§]These patients were treated before screening of blood products began in March 1985; 22 long-term survivors, four of whom were seropositive, are included.

an General Hospital, Park Ridge, HJ Miller, MD, Dept of Medicine, Evanston Hospital, Evanston, B Stevko, MD, Illinois Dept of Public Health; LA Chambers, MD, American Red Cross Blood Services—Northeast Region, Dedham, L Kunches, GF Grady, MD, State Epidemiologist, Massachusetts Dept of Public Health; Div of Blood and Blood Products, Center for Drugs and Biologics, FDA; AIDS Program, Center for Infectious Diseases, CDC.

Editorial Note: At present, prevention of HIV infection and AIDS is dependent upon deferral of blood or plasma donation by persons at increased risk for AIDS, testing of donated blood and plasma for HIV antibody, heat treatment of clotting factor concentrates, avoidance of unprotected sexual contact and needle sharing by persons infected with HIV, and prevention of perinatal transmission by infected women. Counseling and HIV antibody testing have been recommended for persons at risk for infection (including homosexual/bisexual men, intravenous drug abusers, hemophilia patients, prostitutes, and persons who have had sexual contact with members of these groups) (2). Routine counseling and antibody testing have not been recommended for blood transfusion recipients because, in general, their risk for infection is extremely low. However, as illustrated by this report and others (3), some multiply-transfused persons may be at a higher risk for HIV infection. In addition, some persons with transfusion-associated HIV infection have transmitted the virus to their sexual partners and, perinatally, to their infant children.

Although the number of infected transfusion recipients in the United States is unknown, it can be approximated using estimates of the prevalence of infection in donors, the efficiency of transmission, and the number of units transfused per year. In 1985, 0.04% of donations were positive for HIV antibody by Western blot assay (4). If 0.04% had been the seroprevalence among donors in the year prior to screening, if all seropositive units had transmitted infection (5), and if each seropositive unit had gone to a different recipient, then 7,200 of the approximately 18 million components transfused in 1984 (American Blood Commission, unpublished data) might have transmitted infection. If 60% of these recipients have died from their underlying disease (6), then approximately 2,900 living recipients who acquired a transfusion-associated HIV infection in 1984 would remain. Most of these would be asymptomatic. The number of infected donors was probably lower in earlier years. Mathematical projections from reported transfusion-associated AIDS cases estimate that approximately 12,000 people now living in the United States acquired a transfusion-associated HIV infection between 1978 and 1984 (7).

Blood banking organizations in the United States have begun "look-back" programs to identify previous recipients of blood from donors who tested positive for HIV antibody after screening began. In one region, 70% of recipients identified through such a program had HIV antibody (8). However, look-back programs cannot identify all infected transfusion recipients because many infected donors may have refrained from donating or become too ill to continue to donate after HIV serologic testing of donors began.

The risk of HIV transmission by transfusion was low, even before screening, and has been virtually eliminated by the routine screening of donated blood and plasma. However, since HIV-infected persons are at risk for developing AIDS or related conditions themselves and may transmit infection to others, physicians should consider offering HIV antibody testing to some patients who received transfusions between 1978 and late spring of 1985. This consideration should be based on the likelihood of infection in a recipient and the likelihood of transmission from that recipient. The risk of infection is greatest if the recipient received large numbers of transfusions and if the blood was collected during the few years before screening in an area with a high incidence of AIDS. (The leukemia patients in this report received many units of blood and blood components in an area with a higher prevalence of HIV than most parts of the United States, so their seropositivity rate is higher than would be expected in other patients. Conversely, persons who received a small number of units in a low prevalence area would have an extremely low risk of HIV infection.) Testing is particularly important if the patient is sexually active. Since the overall prevalence of infection in transfusion recipients is expected to be low, the positive predictive value of EIA screening tests for HIV antibody will be much lower than that seen when testing high-risk populations (9). Therefore, all transfusion recipients with a positive EIA should also have their serum tested by a second method (Western blot assay, immunofluorescence assay) before they are informed of their test result. Seropositive persons should be evaluated for signs and symptoms of AIDS or related conditions and counseled regarding the avoidance of HIV transmission to others.

References

1. Duncan ED, Miller HJ, McKeever WP. Non-Hodgkin's lymphoma, HTLV-III/LAV, and HTLV-III/LAV antibody in the wife of a man with transfusion-acquired AIDS. *Am J Med* 1986;81:898-900.
2. CDC. Additional recommendations to reduce sexual and drug abuse-related transmission of human T-lymphotropic virus type III/lymphadenopathy-associated virus. *MMWR* 1986;35:152-5.

3. Troy K, Cuttner J, Zaroulis C. Incidence of anti-HIV antibodies in patients with acute leukemia treated between 1978 and 1986 [Abstract]. *Blood* 1986;68:135a.
4. Schorr JB, Berkowitz A, Cumming PD, Katz AJ, Sandler SG. Prevalence of HTLV-III antibody in American blood donors [Letter]. *N Engl J Med* 1985;313:384-5.
5. Ward JW, Deppe DA, Samson S, et al. Risk of human immunodeficiency virus infection from blood donors who later developed the acquired immunodeficiency syndrome. *Ann Intern Med* 1987; 106:61-2.
6. Perkins HA, Samson S, Rosenschein S, et al. Risk of AIDS from blood donors who subsequently develop AIDS. Presented at the International Conference on Acquired Immunodeficiency Syndrome (AIDS), Atlanta, Georgia, April 16, 1985.
7. Peterman TA, Lui K, Lawrence DN, Allen JR. Estimating the risks of transfusion-associated AIDS and HIV infection. *Transfusion* (in press).
8. Menitove JE. Status of recipients of blood from donors subsequently found to have antibody to HIV [Letter]. *N Engl J Med* 1986;315:1095-6.
9. Ward JW, Grindon AJ, Feorino PM, Schable C, Parvin M, Allen JR. Laboratory and epidemiologic evaluation of an enzyme immunoassay for antibodies to HTLV-III. *JAMA* 1986;256:357-61.

AIDS PREVENTION
JAN 4, 1983 meeting

JAN 14 1983

Director
Centers for Disease Control
Summary Report on Workgroup to Identify Opportunities for Prevention of
Acquired Immune Deficiency Syndrome, January 4, 1983

The Assistant Secretary for Health
Through: RS/PBS _____

Attached is a report of the Workgroup to Identify Opportunities for Prevention
of Acquired Immune Deficiency Syndrome which was held on January 4, 1983, in
Atlanta, Georgia.

This report summarizes the deliberations of the meeting's participants.

William H. Foege
William H. Foege, M.D.
Assistant Surgeon General

Attachment

cc:

OD

CDCW

KS Task Force ✓

CDC:OD:JPROPLAN:rs(1/12/83)
DOC # 0029R (CDC)

- C. Guidelines for prevention of AIDS cases by person-to-person transmission were generally accepted by the workgroup (proposed guidelines are in Attachment 2).
- D. A consensus was reached that it would be desirable to exclude high risk donors to reduce the risk of AIDS transmission via blood and blood products. However, no consensus was reached as to the best method of doing this. The principal strategies are:
1. voluntary restriction by potential donors within high risk groups;
 2. exclusion of donors on the basis of history and/or physical examination at the time of donation, e.g., a positive response to questions such as, "Have you had sexual contact with another man?", "Are you a past or present intravenous drug user?", "Are you Haitian?" etc. On physical exam, patients with lymphadenopathy, etc. could be excluded.
 3. Use of a "surrogate" laboratory test; a test which when positive is associated with high risk groups for AIDS.
 4. A combination of these strategies.

All these strategies will be difficult to evaluate for effectiveness.

- E. Voluntary restriction has the advantage of enabling high risk groups to play a major and responsible role in protecting others in society. It is independent of the blood supply system. It is inexpensive, and is relatively easy to initiate. The disadvantages are that it has the limitations of not being able to influence less responsible persons and being unlikely to reach and motivate some proportion of those for whom it is intended.
- F. Questioning donors for their nationality, sexual orientation or personal habits has the advantages of being an easy extension of the screening history already used in blood donation, is inexpensive, can be directed toward high risk groups and causes little disruption in the blood collection and processing routine. It has the disadvantage of being potentially intrusive into personal matters, may be viewed as unethical, might institutionalize a stigma on groups already prone to prejudice and persecution, and may be ineffective in identifying persons in these high risk groups. Concerns about record privacy have been raised. A considerable proportion of practicing homosexual males may not consider themselves high-risk for AIDS and others may be reluctant to disclose their sexual orientation. Similarly, recently emigrated Haitians and drug users may be reluctant to identify themselves. Some commercial plasmaphoresis processors are already excluding by history some AIDS high risk groups.

Summary Report on Workgroup to Identify Opportunities for
Prevention of Acquired Immune Deficiency Syndrome
January 4, 1983

I. The Meeting

On January 4, 1983, from 8:30 a.m. to 4:30 p.m., a meeting was held in Atlanta to consider existing opportunities for prevention of Acquired Immune Deficiency Syndrome (AIDS), both by person-to-person transmission and by blood or blood products. This meeting was a follow-up to a meeting held July 27, 1982 in Washington, D.C. which considered the significance of the occurrence of AIDS in three patients with hemophilia.

Invited participants included representatives of the National Hemophilia Foundation, American National Red Cross, various blood banking organizations, National Gay Task Force, New York and San Francisco Health Departments, Conference of State and Territorial Epidemiologists and the Pharmaceutical Manufacturers Association as well as staff members of the CDC, FDA and NIH (Attachment 1).

The morning was devoted to reviewing recent information pertinent to AIDS, risk groups and the blood and plasma donation process: the epidemiology of AIDS, AIDS among persons with hemophilia and those receiving transfusions, potential laboratory screening tests, current recommendations and regulations for screening of blood and plasma donors, the demographics of blood donation and the separation and processing of blood and blood derivatives, including Factor VIII. Discussion was then held on various alternative opportunities for prevention.

II. Aspects of Discussion

- A. AIDS continues to be a major public health problem. In addition to the previously described high risk groups (homosexual men, intravenous drug users, recently arrived Haitians, etc.), persons with hemophilia are also at increased risk of developing AIDS presumably by introduction of a transmissible agent in Factor VIII concentrate. Five cases of AIDS have been reported in persons with hemophilia since the three described in July and two to three more are considered to be possible cases.
- B. One case of AIDS has occurred in an infant who received a platelet transfusion from a man who subsequently was diagnosed as an AIDS patient. Several other AIDS cases under investigation (five) have no risk factors but have received blood products within the past two years. Some participants were reluctant to accept the hypothesis that AIDS has been transmitted by whole blood in the absence of additional evidence.

- G. Surrogate laboratory tests have the advantages of being objective and can be done on specimens already being drawn for HBsAg. They respect donor privacy and may be most effective in eliminating potential transmitters of AIDS. They have the disadvantage of adding expense to the blood collection process, both through test cost, administrative overhead, and loss of blood units already collected. Further, they may stigmatize as unsatisfactory many "normal" donors for each potential AIDS transmitter that is rejected.

For example, if the presence of hepatitis B core antibody is used as a laboratory surrogate screening test:

1. In CDC's specimen file, 90 percent of known definite AIDS cases are positive for anti-Hb_c and would be excluded as blood donors.
2. Approximately five percent of the general population of voluntary donors are positive for anti-HB_c, though this figure may vary by blood center. These results would be determined after collection, and the collected units would have to be destroyed, unless they could be safely and practically processed into other blood products.
3. The costs of the test might add to the cost of processing. The loss of each destroyed unit represents further expense and there might be additional overhead costs. The costs of preventing an unknown number of AIDS cases (and possibly non-A, non-B hepatitis cases) are unknown, but each such case is very costly in direct and indirect costs and the intangible costs of grief and suffering.
4. Concern was expressed over availability of adequate anti-HB_c test materials. However, information suggests that some companies are already planning production of large quantities of anti-HB_c and that demand would provoke an adequate supply.
5. As the epidemiology of AIDS changes, high risk groups may have lower rates of positivity for anti-Hb_c.
6. This additional laboratory test will require new training and procedures for many laboratories.

- H. Alterations in blood processing could also reduce the risk of AIDS transmission. The FDA expects an improved Factor VIII concentrate to be available within 12 months. This product would be heat treated sufficiently to inactivate hepatitis B virus and presumably eliminate other transmissible agents from the finished product. Although preliminary data on such treated Factor VIII materials suggest that there is little loss in activity, detailed information on increased costs, product availability and likelihood of reducing AIDS risk are not yet available.

III. Conclusions and Recommendations

- A. The workgroup participants represented various organizations, governmental agencies and constituent groups concerned with and affected by AIDS and the blood and plasma donation process. They have differing perceptions of:
 - 1. The likelihood that AIDS is caused by a transmissible agent;
 - 2. The risk of AIDS from blood donation (both whole blood and pooled plasma); and
 - 3. The best approach for establishing altered guidelines for blood donation, donor screening or testing and donor restriction.
- B. The workgroup meeting was successful in presenting the most recent data on AIDS and blood/blood products and as a forum for differing views to be expressed. This enabled all participants to gain further insight and appreciation of an extraordinarily complex health problem.
- C. I recommend that each Public Health Service Agency (CDC, FDA, NIH) provide candidate sets of recommendations for the prevention of AIDS in patients with hemophilia and for the other recipients of blood and blood products to Dr. Jeffrey P. Koplan, Assistant Director for Public Health Practice, CDC. The three agencies should then develop a uniform set of recommendations on AIDS for your office.

ATTENDEESWorkgroup to Formulate Recommendations for
Prevention of Acquired Immune Deficiency SyndromeCenters for Disease Control, Auditorium A
Tuesday, January 4, 1982

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AMERICAN BLOOD COMMISSION	William Dolan, M.D.
AMERICAN BLOOD RESOURCES ASSOCIATION	Robert Riley James Cundall
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AMERICAN PUBLIC HEALTH ASSOCIATION	William McBeath, M.D.
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HEMOPHILIA EXPERTS	Oscar Ratnoff, M.D. Leon Hoyer, M.D.
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NATIONAL GAY TASK FORCE

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William Martin M.D.

SAN FRANCISCO HEALTH DEPARTMENT

Selma Dritz, M.D.

AIDS Prevention

PERSON-TO-PERSON TRANSMISSION:

The risk of transmission is likely to be reduced by the following:

- A. Homosexual Men
 - 1. Avoiding sexual contact with known or suspected AIDS cases;
 - 2. Minimizing number of sexual contacts, avoiding casual or anonymous contacts;
 - 3. Other?
- B. Intravenous Drug Users
 - 1. Avoiding illicit IV drug usage;
 - 2. Avoiding sharing needles, other apparatuses.
- C. Haitians
 - 1. Little is known about specific risk factors;
 - 2. Avoiding heterosexual contact with known or suspected AIDS cases.
- D. Others
 - 1. Generally, risk appears to be very low;
 - 2. Avoiding sexual contact with known or suspected AIDS cases;
 - 3. Precautions for health care, laboratory personnel -- similar to hepatitis B.
- E. AIDS patients can minimize their risk of transmission to others by:
 - 1. Avoiding intimate sexual contact;
 - 2. Restricting activities which may result in exposure of their blood to others (e.g., surgical procedures, phlebotomies, blood donation, etc.).

4777
MAY 16 1988
Department of Health
Berkeley

Memorandum

Date .February 22, 1984

From Director, AIDS Program
Center for Infectious Diseases

Subject Summary of the February 14, 1984, meeting on AIDS related to transfusions.

To Director, Center for Infectious Diseases

Attached is a summary of the meeting on future studies of Acquired Immunodeficiency Syndrome (AIDS) related to transfusions. The report is organized as follows:

1. Participants and their Affiliations.
2. Objectives and Implementation Steps.
3. Rated Objectives and Implementation Steps.
4. Summary of Individual Comments.
5. Summary.

James W. Curran, M.D.

Participants

Meeting on Acquired Immunodeficiency Syndrome (AIDS) Related to Transfusions

Ronald Altman, M.D.
Division of Epidemiology and
Disease Control
New Jersey State Department of Health

Joseph R. Bove, M.D.
Director, Blood Transfusion Service
Yale New Haven Hospital

*Mary E. Chamberland, M.D.
AIDS Program
New York City Health Department

Amoz I. Chernoff, M.D.
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and Resources
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Director, Division of Blood
and Blood Products
Office of Biologics Research
& Review, FDA

Robert J. Gerety, M.D.
Office of Biologics
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Alfred J. Grindon, M.D.
American Red Cross Blood Services

Harry Haverkos, M.D.
AIDS Program, CID, CDC

Martin S. Hirsch, M.D.
Associate Professor of Medicine
Harvard Medical School
Associate Physician
Massachusetts Gen Hospital

Paul McCurdy, M.D.
Director, American Red Cross
Washington, D.C. Regional
Blood Services Center
Representing the American Hematology
Society Public Education Committee

Jay E. Menitove, M.D.
Medical Director
Blood Center of
Southeastern Wisconsin

Mr. Larry Miike
Office of Technology Assessment
United States Congress

Herbert A. Perkins, M.D.
Scientific Director
Irwin Memorial Blood Bank

S. Gerald Sandler, M.D.
Associate Director
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Neil R. Schram, M.D.
President
American Association of Physicians
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David J. Sencer, M.D.
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*Rand Stoneburner, M.D.
AIDS Program
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Objectives and Implementation Steps

Meeting participants were asked to rank the following objectives and implementation steps:

- | <u>Objectives</u> | <u>Implementation Steps</u> |
|--|--|
| 1. To determine whether AIDS is transmitted through blood transfusion. | 1. Improve ascertainment of whether reported cases of AIDS have donated blood and/or plasma and develop a uniform notification system. |
| 2. To quantify and clarify the risk of AIDS from blood transfusion. | 2. Continue investigations of AIDS associated with transfusions, including identification and follow-up of possible "high-risk" donors. |
| 3. To prevent the inadvertent transfusion of blood components from patients known or suspected to have AIDS. | 3. Conduct a national cohort study of blood component recipients from:
a. patients with AIDS;
b. patients with lymphadenopathy;
c. "high-risk" donors;
d. comparison groups. |
| 4. To evaluate the effectiveness of current (or future) prevention recommendations. | 4. Compare donor characteristics before and after implementation of prevention recommendations in selected cities. |

Name and Affiliation

S.G. Sandler, ARC
P. McCurdy, ASHPEC
H. Perkins, Irwin B.B.
A. Grindon, ARC/AABB
J. Menitove BCS.E.WI
J. Bove, AABB/YALE
M. Hirsch, Mass Gen Hosp
N. Schram, AAPHR
A. Chernoff, NIH
R. Gerety, FDA
D. Donoghue, FDA
L. Miike., OTA, Cong.
R. Stoneburner, NYC (CDC)
M. Chamberland, NYC (CDC)
H. Haverkos, AIDS, CDC
TOTAL
RANK

Ratings

	Objectives				Implementation Steps			
	1	2	3	4	1	2	3	4
—	H	M	M	M	M	H	M	—
—	L	H	H	M	H	H	M	M
—	L	H	L	M	H	H	H	L
—	M	H	M	H	H	H	M	H
—	L	H	H	L	H	H	H	—
—	L	H	M	M	H	H	M	L
	L	H	H	M	H	H	H	L
	L	—	H	H	H	H	L	H
—	L	H	M	L	H	H	H	L
	L	H	H	H	H	H	L	—
	—	H	H	H	H	—	—	—
	L	H	H	H	H	H	L	—
	L	L	H	H	H	H	H	M
	L	H	H	L	H	M	H	L
	<u>L</u>	<u>H</u>	<u>H</u>	<u>M</u>	<u>H</u>	<u>H</u>	<u>—</u>	<u>—</u>
	17	39	39	33	44	41	29	17
	3	1	1	2	1	2	3	4

Key

— = ZERO = 0
L = LOW = 1
M = MEDIUM = 2
H = HIGH = 3

Summary of Comments by Objective

Objective 1. To determine whether AIDS is transmitted through blood transfusion.

- 1) Dr. S. Gerald Sandler of the American Red Cross ranked this high as a laboratory priority but low epidemiologically. The blood organizations are already responding as though AIDS is transmitted by blood.
- 2) Dr. Paul McCurdy, representing the American Society of Hematology Public Education Committee stated that objective 1 was "probably a given now." Solving objective 2 would further confirm this supposition.
- 3) Dr. Herbert A. Perkins of the Irwin Memorial Blood Bank also thinks that AIDS is probably transmitted by blood transfusion and that work on objective 2 will provide answers for objective 1.
- 4) Dr. Alfred J. Grindon of the American Red Cross suggests that questions about different types of components and whether "high-risk" groups are involved be answered.
- 5) Dr. Jay E. Menitove of the Blood Center of Southeastern Wisconsin requests that samples be saved from donors and patients to provide retrospective proof of the assumption that AIDS is transmitted through blood transfusion.
- 6) Dr. Joseph R. Bove of Yale New Haven Hospital does not favor putting much effort into objective 1, stating that work on objective 2 will provide answers to the first objective.
- 7) Dr. Martin Hirsch of Massachusetts General Hospital is reasonably convinced that transfusion AIDS is a reality.
- 8) Dr. Neil R. Schram of the American Association of Physicians for Human Rights accepts transfusion AIDS as likely and recommends continued surveillance.
- 9) Dr. Amoz I. Chernoff of the National Institutes of Health states there is little reason to doubt the transmissibility of AIDS via blood or blood products, although a cause and effect relationship has not been established.
- 10) Dr. Robert J. Gerety of the Food and Drug Administration states that mere transmissibility should have a low priority. However, determining what blood components are involved in transmission deserves a high priority.
- 11) Dr. Dennis M. Donohue of the Food and Drug Administration indicates that transmission by transfusion seems to be reasonably established. General surveillance and specific prospective studies are indicated.
- 12) Mr. Lawrence Miike of the United States Congress states that it is generally assumed to be a connection between blood transfusion and AIDS. Concentration on objective 2 will help to answer the question raised by objective 1.

- 13) Dr. Rand Stoneburner of the New York City Health Department (EIS Officer) feels there is sufficient evidence to assume a relationship between blood transfusion and AIDS.
- 14) Dr. Harry Haverkos of the AIDS Program states that the connection between blood transfusion and AIDS appears to be accepted.

Objective 2. To quantify and clarify the risk of AIDS from blood transfusion.

- 1) Dr. Sandler feels this will be a very big study. Cohort studies would have a positive effect if they showed we did something with the current guidelines. It will be important to determine which components are infective.
- 2) Dr. McCurdy states that it will be important to: determine what components are involved, how long they were stored, what is the incubation period, and amount of time passed between the donation and symptoms and diagnosis of AIDS in the donor.
- 3) Dr. Perkins thinks meeting this objective will assist the public in providing them needed information. It will clarify the relative risk between high risk and low risk blood donors. It will also be important to determine why one patient gets AIDS after exposure and many others with the same exposure do not.
- 4) Dr. Grindon considered this objective to be very important, but he feels the need of a case control study to ensure that the "high-risk" donor is the likely transmitter.
- 5) Dr. Menitove feels that a cohort study may identify protective factors, which makes objective 2 very important. He also feels that the subclinical and clinical expression of AIDS must be included in these studies.
- 6) Dr. Bove believes this objective is critical. Important issues include: recipient factors, identifying the high risk donor, and determining which blood components have the highest risk.
- 7) Dr. Hirsch feels this objective is of the utmost importance. The following need definition: the role of high risk versus low risk donors, the types of blood products involved, and recipient factors, for example, prematurity, underlying disease, and CMV-EBV-HTLV seropositivity.
- 8) Dr. Schram felt that clarification of risk factors is needed, but questions the need for quantification.
- 9) Dr. Chernoff felt recipient status may be the most important issue to study. It is important to determine what blood components or products are responsible for transmissibility. He believes that carriers may be a more important aspect of the problem than high risk donors.
- 10) Dr. Gerety believes that the role of the high risk donor will be determined; the natural history of AIDS and opportunistic infections will be clarified; and the differences between those exposed who do, and do not get AIDS may be defined.

- 11) Dr. Donohue believes this objective is highly desirable as a cohort study, but probably not achievable. He recommends a case-control study, but has reservations due to the complexity of interactions between doctors, patients, blood programs, and hospitals.
- 12) Mr. Miike questions whether one can accurately quantify the risk. Clarification is necessary. A case-control study may be the best method to test the hypotheses of the "high-risk" donor. A cohort study appears necessary to estimate the risk and follow the recipients of "high risk" blood. Mr. Miike suggests the cohort study be limited to recipients of components from a single "high risk" donor.
- 13) Dr. Stoneburner believes that further work on quantifying risks will have little benefit to public health. It is important to maintain surveillance of transfusion-associated AIDS cases to determine when the risks may be decreasing as a result of voluntary controls.
- 14) Dr. Chamberland favors a cohort study of "exposed" recipients versus "unexposed" recipients. This study could only answer the question of risk to recipients from a known AIDS donor. She doubts whether there will be enough recipients from such donors to provide the study adequate statistical power.
- 15) Dr. Haverkos believes that large numbers of patients will be necessary to do this study. He recommends a national cohort study of blood component recipients or following a definable group of patients such as coronary artery disease (CAD) patients with immunologic studies in New York City, Los Angeles, San Francisco, and Miami.

Objective 3. To prevent the inadvertent transfusion of blood components from patients known or suspected to have AIDS.

- 1) Dr. Sandler stated that good ideas are needed to increase ascertainment and improve notification.
- 2) Dr. McCurdy recommended that some way should be worked out to notify blood collecting agencies when a donor has been diagnosed with AIDS so that components can be withdrawn and followup of recipients can be carried out, as indicated.
- 3) Dr. Perkins called for a uniform policy for handling such donors. He doubts that people with AIDS would continue blood donations. High risk donors, including those with prodromes, should be investigated. Keeping them from donating blood is an FDA obligation.
- 4) Dr. Grindon feels it is important to recall any remaining components and to remove the AIDS patient from donor rolls. The lack of sufficient treatment and confidentiality issues may make it difficult to inform and follow recipients.
- 5) Dr. Menitove favors notification of blood centers about AIDS patients who have donated blood. He feels a national program should be developed rapidly.

- 6) Dr. Bove recommends that action be taken to be sure that the product is not used. He feels we have to identify the agent and develop a test to identify the agent and develop a test in order to determine who is a "carrier."
- 7) Dr. Hirsch feels that identification of AIDS donors is important and it is a Federal responsibility.
- 8) Dr. Schram believes this objective may be impossible to achieve without surrogate markers.
- 9) Dr. Chernoff suggests that most "high-risk" donors have probably eliminated themselves already. The identification of the carrier state is the problem.
- 10) Dr. Gerety states that this should be an FDA issue with notification of CDC. He proposes a separate meeting to work out mechanisms. Information should be made available to all involved including: manufacturers, blood banking establishments, hospitals, and physicians, etc.
- 11) Dr. Donohue believes the recall of fresh frozen plasma (FFP) and frozen red cells is the only major practical problem. He recommends a separate meeting to develop FDA and CDC policy with State and local health departments to construct a donor selection process. He feels that steps should be taken to enhance communications between physicians, blood centers, FDA, and CDC.
- 12) Mr. Miike felt this objective should be a top priority, but did not know if CDC should take the lead.
- 13) Dr. Stoneburner considered this objective extremely important and recommended removal of all products on the shelf. He suggested instituting an inverted T-cell (T4/T8) ratio screening program based on the Stanford model, which would be cost effective. The achievement of this objective may be difficult because of confidentiality issues.
- 14) Dr. Chamberland suggests that another meeting has to be arranged to consider the specifics of the notification process. She questions how a person suspected to have AIDS can be defined. Since they are in possession of the patient's name, the ultimate responsibility will fall on State and local health departments.
- 15) Dr. Haverkos ranked this objective as a high priority with complex factors involving the State and local health departments, CDC, FDA blood centers, attending physicians, and the patient recipients.

Objective 4. To evaluate the effectiveness of current (or future) prevention recommendations.

- 1) Dr. Sandler recommends the study of donors in high risk areas such as New York City, San Francisco, and Los Angeles. He feels that confidentiality is important and suggests that post-donation cancellations by telephone be adopted by blood centers as a step to address the problem.

- 2) Dr. McCurdy feels that this objective be given a high priority, but is hesitant to do so until it becomes feasible to achieve.
- 3) Dr. Perkins believes this objective to be important to be sure our procedures for eliminating high risk donors are effective, but he does not regard this as a CDC obligation.
- 4) Dr. Grindon feels this objective is necessary, for "high-risk" donors may be transmitting AIDS.
- 5) Dr. Menitove feels this objective is important, yet he has reservations about how it can be implemented.
- 6) Dr. Bove states this objective is absolutely essential to do if at all possible.
- 7) Dr. Hirsch suggests that, although a worthy goal, this objective will require a long time and its results will become evident eventually. He feels that short-term efforts to see whether fewer "high-risk" donors are currently in the pool are unlikely to yield much useful data.
- 8) Dr. Schram feels the AAPHR guidelines should help, if implemented. Little can be done at present except prevention. We need to know if we are being successful prospectively rather than retrospectively.
- 9) Dr. Chernoff believes this objective cannot be pursued, except retrospectively, until the completion of objective 2 provides the needed answers.
- 10) Dr. Gerety suggests that this objective is more properly the responsibility of the blood community and should be given a low priority at CDC.
- 11) Dr. Donohue suggests evaluating the spread of AIDS beyond the current groups to those at unknown risk to determine effectiveness. Prevention of donations by "risk" donors is most, since only the donor makes the personal qualification decision.
- 12) Mr. Miike felt this objective should be a top priority, but did not know if CDC should take the lead.
- 13) Dr. Stoneburner feels that it is always important to document whether a prevention measure is effective.
- 14) Dr. Chamberland gives this objective a low priority because it will be so difficult to implement and will not provide certain information for 2 or 3 years.
- 15) Dr. Haverkos questions whether resources will be available to carry out this objective if the other studies are done.

Summary of Comments by Implementation Step

Implementation Step 1: Improve ascertainment of whether reported cases of AIDS have donated blood and/or plasma and develop a uniform notification system.

- 1) Dr. Sandler gave this step a medium priority, but feels a uniform notification system is absolutely necessary, and that one can be developed through work with the American Red Cross and others.
- 2) Dr. McCurdy refers to his comments under objective 3 where he recommended that Blood Collecting Agencies be notified whenever an AIDS patient is diagnosed so that components can be withdrawn and followup of recipients carried out as appropriate.
- 3) Dr. Perkins favors collaboration between blood banks and local health departments so that donor files can be checked against lists of AIDS patients with CDC possibly serving as an intermediary.
- 4) Dr. Grindon believes this is a very important step, especially for recalling stored components. Notification of AIDS in a donor to blood centers may pose confidentiality problems. Physicians of patients who have received suspect blood should be informed.
- 5) Dr. Menitove favors a national registry and recommends a protocol be developed for notification of patients which includes informing the physician, hospital blood bank, and blood collecting agency. CDC should take a leadership role. A consensus on confidentiality should be developed through an ad hoc committee.
- 6) Dr. Bove sees this step as a relatively straightforward public health measure with links between CDC, health departments, blood banks, hospitals, patient's physician, and patient.
- 7) Dr. Hirsch feels that it is crucial that this information be obtained.
- 8) Dr. Schram recommends that this information not be reported to the physician and that AAPHR be consulted regarding confidentiality and reporting. He suggests that it be determined if the transfusion-associated AIDS case received blood from donors who had prior transfusions.
- 9) Dr. Chernoff feels this step will be difficult to do but it will provide important information to have. He feels that CDC and national blood bank organizations have a role in implementing this policy.
- 10) Dr. Gerety feels that the FDA can assist CDC, which should be responsible for lining up notification of blood banks and physicians to prevent distribution of products and have physicians notify their patients. He suggests a broad information sharing system modeled after the National Hemophilia Foundation's work with AIDS in persons with hemophilia.
- 11) Dr. Donohue believes that the issue of confidentiality intrinsic to this step needs to be clarified. CDC, the FDA, the ARC, CCBC, and State and local health departments, with a special role for the New York City Health Department should work on this policy.

- 12) Mr. Miike considers improved ascertainment to be a necessity with the FDA becoming the intermediary deciding who should get information and how it is to be disseminated.
- 13) Dr. Stoneburner recommends that a uniform notification system be done only by soundex or through the local health department where confidentiality can be assured. He feels that if voluntary self-exclusion works, most products will be off the shelves by the time this policy is implemented.
- 14) Dr. Chamberland maintains that notification of blood banks to withdraw products from shelves must be done. The physician should decide to inform the patient recipient. There is not enough information available to determine whether such recipients themselves should be excluded as donors. It will be a State and local health department's responsibility to work with blood banks.
- 15) Dr. Haverkos believes this will be a very complex policy to implement. It will require links between CDC or State and local health departments, the FDA, blood banks, the patient's attending physician, and the recipient.

Implementation Step 2: Continue investigations of AIDS associated with transfusions, including identification and follow-up of possible "high-risks" donors.

- 1) Dr. Sandler reconfirms the commitment of the ARC to assist CDC to study transfusion-associated AIDS.
- 2) Dr. McCurdy feels it will be particularly important to follow-up recipients of other components and temporally related donations from the same donor.
- 3) Dr. Perkins sees this step as extremely important, requiring follow-up of recipients of donors with AIDS and recipients with AIDS to donors. It will be important to follow co-recipients and use controls.
- 4) Dr. Grindon considers this step to be very important and should include case controls. He does not believe these investigations will be difficult to do.
- 5) Dr. Mentove supports the need to identify and investigate donors carefully and follow-up co-recipients. Major blood banking organizations must be involved in establishing a policy for members to follow.
- 6) Dr. Bove feels that there should be no real problems with this step and the the AABB and member banks will cooperate in every way.
- 7) Dr. Hirsh states that we do not currently know who is a high-risk donor. Comparison of those with presumed high-risk factors, e.g. inverted T₄/T₈ ratios, increased susceptibility, etc. with those without these factors, is important. He doubts whether a truly comparative study of high-risk versus low risk donors can be done, because of the infrequency

of transfusion-AIDS. Continued close monitoring of recipients of blood from high-risk donors may identify factors among recipients that are important in AIDS pathogenesis.

- 8) Dr. Schram feels it will be beneficial to determine if a "high-risk" donor has been a previously transfused individual. He does not support a co-recipient study, giving that a low priority. The AAPHR will help to implement this step in any way it can.
- 9) Dr. Chernoff ranked this step as a high priority, suggesting NHLBI support for any group with the expertise to implement it, i.e. CDC, Blood Banking Organizations etc.
- 10) Dr. Gerety suggested that step 3 be substituted for step 2, or that 2 and 3 should be combined.
- 11) Dr. Donohue recommended a case-control study with selected cases and a limited number of transfusions and donor exposures. He supports comparing "high-risk" with no known risk donors.
- 12) Mr. Miike linked implementation steps 1, 2, and 3. His comments on 2 and 3 can be found under step 3.
- 13) Dr. Stoneburner considers this very time consuming, but extremely important, particularly following the high-risk donor. He recommends consideration be given to conducting donor investigations more selectively.
- 14) Dr. Chamberland recommends continuing these investigations but feels there is no conclusive way to identify the transmitter without a laboratory test.
- 15) Dr. Haverkos considers this step a high priority and recommends obtaining laboratory specimens from donors and recipients to help identify the causative agent that might be discovered in these pairs.

Implementation Step 3: Conduct a national cohort study of blood component recipients from:

- a. patients with AIDS;
- b. patients with lymphadenopathy;
- c. "high-risks" donors;
- d. comparison groups.

- 1) Dr. Sandler supports the desirability of such a national study, although he considers it a difficult one to design. He suggests CDC as a likely coordinator with NHLBI funding. In order to be evaluated properly, a more specific proposal is needed.
- 2) Dr. McCurdy feels that follow-up of recipients for more than a year after their donor's AIDS diagnosis is a high priority. The other 3 parts to such a study will require time and great expense.

- 3) Dr. Perkins recommends a case-control study to investigate these points in high-risk areas through blood banks with assistance from CDC, local health departments, hospitals, and physicians.
- 4) Dr. Grindon recommends that a case-control study be done first on patients with and without AIDS to define the background. He feels the cohort study will be complex, but it is worth proceeding.
- 5) Dr. Menitove feels that CDC and NHLBI should design the study and assess patients through coordination with their physicians and blood collection agencies.
- 6) Dr. Bove recommend a statistical evaluation be done before committing resources to this study, for it may be difficult to do. If it is possible to carry out, this study will provide useful information.
- 7) Dr. Hirsch states that, although difficult, this study is extremely important to identify the true high-risk donor. This study should be a national study coordinated by CDC, with assistance from the NHLBI, Red Cross, and other blood organizations.
- 8) Dr. Schram gave this step a low priority, suggesting it would cause hysteria in people in each category. The AAPHR wishes to be involved, if the proposed study reaches the planning stage.
- 9) Dr. Gerety feels this is an important study which will provide information about the natural history of transfusion-acquired AIDS cases. He suggests the FDA coordinate contact with blood and plasma establishments and plasma derivatives manufacturers. The NHLBI might provide controls.
- 10) Dr. Donohue believes this investigation will be too complex as a national cohort study.
- 11) Mr. Miike combined his answers to steps 2 and 3, stating that it should be determined if AIDS patients gave blood and then follow that population of blood component recipients. "High-risk" donors should be followed to document whether in fact they do develop AIDS. Mr. Miike does not think a large cohort study is required and suggests that recipients be followed to learn if they do get AIDS and complement this investigation technique with a case-control study, which should reveal more in the short term.
- 12) Dr. Stoneburner believes this study has theoretical merit but has reservations about informing recipients and the worry that may provoke. This concern must be balanced against the possible need to notify them not to give blood.
- 13) Dr. Chamberland recommends doing a. and b. first with an appropriate control groups for for comparison. She suggests a statistical evaluation of the study to examine requirements to direct implementation plans.
- 14) Dr. Haverkos believes this is a good study to evaluate quantity of cases and clarify risk factors. Very large numbers will be necessary and notifying recipients may cause anxiety.

Implementation Step 4. Compare donor characteristics before and after implementation of prevention recommendations in selected cities.

- 1) Dr. Sandler believes this study is needed to assist blood collection organizations to get their story across.
- 2) Dr. Perkins favors the goal but wonders how much can be learned because blood donor groups vary so much and comparisons will be difficult.
- 3) Dr. Grindon is not sure of CDC's role in such a study, believing it would be done most appropriately at the local blood center level. He considers this study to be important.
- 4) Dr. Menitove feels this will be a difficult study to implement. High-risks donors from 1981 may not want to be identified as such in 1984.
- 5) Dr. Bove feels this study should probably be done by individual blood banks or area groups.
- 6) Dr. Hirsch does not believe quantifying the changes in the donor pool will be very useful. He recommends simple surveys, while watching for reductions in transfusion-associated AIDS cases.
- 7) Dr. Schram feels this study should have a very high priority, since the AAPHR continues to work to reduce the number of high-risks donors. The organization must know if it is successful, and if not, why not and what it can do.
- 8) Dr. Donohue supports this study and considers it possible if it is done soon.
- 9) Mr. Miike feels this should be done, but by regional groups, the Red Cross, or AABB.
- 10) Dr. Stoneburner feels the results of this study might provide some reassurance that the characteristics of the donor pool has changed since voluntary self-exclusion.
- 11) Dr. Chamberland is not sure what this study would accomplish and how to interpret its results.
- 12) Dr. Haverkos sees this study as worth doing, provided there are resources available, following other suggested studies, such as the recipient study; coronary artery diseases (CAD) study, and the follow-up of transfusion-associated AIDS cases and donors.

Summary of Written Comments

Objective 1 received one high mark and a single medium score. The remaining scores were low, which indicates the reviewers generally accepted the association between AIDS and blood transfusion. However, that assumption needs to be proven in the laboratory. Several writers indicated pursuit of objective 2 will help to answer the question raised in the first objective. One reviewer distinguished priorities, giving a low mark regarding transmission itself and a high priority to determining what blood components are involved in transmitting AIDS.

The second objective received a high score with a single low and one medium mark recorded. Virtually all reviewers considered this objective to be critically important. Its results should provide answers to questions regarding: the type of components or blood products involved in transmissibility; who transmits AIDS, the "high risk" donor, the "low-risk" donor, or the "carrier"; the natural history of AIDS and opportunistic infections; and recipient factors. Several writers noted the complexity of large cohort studies. A few suggested limiting the cohort or carrying out case-control studies. One commentator felt the objective highly desirable as a cohort study, but probably not achievable. Due to the complexity of interactions involved, a reviewer had reservations about controlling them in a case-control study.

Objective 3 received a high rating, tying with the second objective. Ten high marks, 4 medium, and 1 low score were given to this objective. The reviewers generally agreed on the importance of recalling remaining products and components and removing the AIDS patient from donor rolls. Certain reviewers felt that laboratory tests will be a necessary tool to determine who is capable of transmitting AIDS through donations. The opinions regarding the mechanics of carrying out this objective were diverse and reflected concern about the notification process, confidentiality which institutions are responsible, and lead agencies.

Objective 4 received 6 high, 6 medium, and 3 low scores. Several reviewers felt the objective to be important, but appeared to have reservations about its feasibility. These doubts included: difficulty to implement, availability of resources, the amount of time involved, and the value of what is to be learned after the effort. Suggestions were made that concentration on high risk cities, high-risk donors, objective 2, transmission beyond the current risks groups, and confidentiality may be productive. One reviewer recommended that a policy of post-donation cancellations by telephone be adopted at the blood center level as a start to address this need for confidentiality. The ratings of the implementation steps placed them in the order they appeared on the evaluation sheet, that is 1, 2, 3, and 4. The first step was supported by the reviewers. They recommended a national notification policy but they did not agree on how it was going to be done, who would do it, and who would be notified. Differences appeared concerning how difficult or straightforward it would be to implement this policy. Several reviewers suggested that confidentiality would be a concern and held that a consensus on it be obtained.

Implementation step 2 received support from the reviewers. Two suggestions advocated combining steps 2 and 3. Several comments reflected interest in following co-recipients of blood or components, although one reviewer did not agree. Certain reviewers recommended a case-control approach to studying this

issue. Most reviewers felt this study would present no problems and would not be difficult to accomplish. Three commentators indicated the study would be either time consuming, difficult without a laboratory test, or hard to do, because of the infrequency of transfusion-AIDS.

Step 3 received moderate support with several reviewers indicating how difficult such a national cohort study would be to design and accomplish. Certain reviewers suggested using a case-control approach on a limited basis to study these issues. Two reviewers recommended a sound statistical analysis be made before committing resources. Notification of recipients was viewed to be a problem by three reviewers.

Implementation step 4 received mixed reviews with some support for doing it, tempered with reservations about the validity of comparisons between groups of blood donors. There were differences of opinion recorded concerning who should do this study. On the other hand, certain reviewers felt this was a most important study, which should begin immediately to provide much needed information about the results of prevention activities to reduce the number of high-risk donors.

ATMS
MAY 16 1988
Department of Health
Berkeley

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Memorandum

Date August 23, 1983

From Director, AIDS Activity
Center for Infectious Diseases

Subject Report of Meeting of Consultants. - AIDS and Blood
and Blood Products, CDC, May 12, 1983

To Jeffrey P. Koplan, M.D.
Assistant Director for Public Health Practice
Office of the Director

Enclosed you will find: (1) Summary comments submitted by each of the consultants regarding the cases of AIDS possibly associated with blood transfusion; (2) A summary of cases of AIDS in patients with hemophilia; (3) A brief listing of cases of AIDS possibly associated with blood transfusions which have been reported since May 12, 1983.

After presentations by CID staff and review of possible AIDS related transfusions and hemophilia cases, the following summary of comments and recommendations were made by the group of consultants at the May 12, 1983 Meeting.

1. There was general recognition of the amount of effort required in investigating AIDS cases (with no risk factors that received blood products) and the difficulty in reaching definite conclusions about the relationship of transfusions and AIDS.
2. Although individual hemophilia cases were not discussed at length, the data in presentations provided convincing evidence about the relationship of concentrates and AIDS.
3. Four or five adult and one infant of the total AIDS cases reviewed (no risk factors - received blood products) provided, with available information, strong evidence that there was a relationship between AIDS and Blood and Blood Products in these cases.
4. Presently there appears to be a very small but finite risk in acquiring AIDS through transfusion.
5. CDC should continue investigating, documenting, and reviewing possible AIDS related transfusion cases.
6. Controlled information should be obtained by CDC to determine whether the proportion of "suspect donors" significantly exceeds the number expected.

7. Data available on possible AIDS related transfusion cases should be published soon in MMWR and/or a respected scientific journal to provide advice to physicians.
8. A perspective of transfusion-associated AIDS should be conveyed to the public, emphasizing the small risk and overall safety of blood and blood products.
9. Consultant group should continue and meet when needed and consideration be given to add experts from other disciplines.

A draft of the transfusion associated AIDS cases is in preparation by Dr. Curran. Current plans include submission to a refereed journal after rapid-turnaround review by the six consultants. CDC has been in contact with the New York City Health Department and the New York Blood Center regarding the rapid obtaining of control information from donor populations in New York City. A longer-term prospective case-control study is in the planning stage.

We believe it will be desirable to reconvene in the next few months. If you think that additional individuals should join us as consultants please let me know their names, fields of expertise, and the reason for their proposed inclusion. I hope that we can meet the objective of getting the desired input without enlarging the group beyond approximately 8-10 persons.

Thank you for your very valuable input. I look forward to hearing from you.



James W. Curran, M.D., M.P.H.

Attachment

CONSULTANTS SUMMARY COMMENTS

At this point there appears to be a small risk, overall, of AIDS transmitted by blood transfusion (larger for pooled plasma donors, specifically AHF).

Focus on donors associated with AIDS cases raises level of concern because of common following of donors in AIDS risk groups.

Most needed now is a study or studies to determine prevalence of donors in AIDS risk groups in areas where PTA-AIDS has occurred.

Continuing (at 1-6 month interval) depending on rate of new information accumulation) necessary in order to keep affected parties adequately informed and paired to take further steps when indicated).

Consider addition to this group of an NHLBI/BDR advisory group member or an AIDS physician; otherwise, I would keep this group more or less intact and convene then with CDC/NIH/FDA, all present and participating.

Barker

CONSULTANTS SUMMARY COMMENTS

The case review has been helpful and points up the great difficulty in reaching conclusions about the relationship between transfusion and AIDS. The best guess I can make is that there are a few cases where the relationship between transfusion and AIDS is strong. The number is small in adults and even smaller in children. The 2 children who are the most convincing had so much other disease that they are hard to evaluate.

I suggest that the data be reviewed and published - after careful editing - with an eye to helping doctors and patients make good discussions.

In several cases there are "suspect" donors. We need a control study to see how many similar "suspect" donors are in the group who gave to patients who didn't get AIDS.

Continued review is appropriate as is continued contact with the medical community. The CDC has the current data and needs to make it available to the medical community. MMWR would be ideal.

My analysis is in HH to 0 next to case numbers. HH means PT AIDS with high probability, ± very doubtful, 0 means I doubt it.

Bovie

CONSULTANTS SUMMARY COMMENTS

1. The review of data for PTA-AIDS has provided a much better overview of the likelihood that AIDS can be a consequence of blood transfusion. The aggregate of data clearly indicate a definite, though small-risk.
2. I would favor the adoption of a semi-quantitative scale for both donors and recipients. I have used the following:
 - D₁ - AIDS in a donor
 - D₂ - Donor from high risk group with signs/S_x or lab data
 - D₃ - Donor from high risk group
 - D₄ - No suspicious donor
 - R₁ - Definite AIDS in recipient - no other risk factors - except blood products
 - R₂ - Incomplete information to exclude other factors
 - R₃ - Confounding features or illness
 - R₄ - Definite additional risk factors for immunodeficiency.
3. A study is needed to determine if incidence of donors with risk factor is inordinate. This must compare other donors from centers equivalent to those which — cases. They should be matched by age/sex with the donors involved in PTA-AIDS cases. This should have high priority and should be undertaken in the near future - not held to "see if it is needed."
4. Continuing review of PTA- and Hemophilia-AIDS is needed and serves to provide an outside opinion on the grounds for categorization. This needs a group of physicians with broad expertise and that issue is probably more important than the "biases" of the individuals. I recognized today the great need for virologic counsel in the pediatric cases, especially - and agency affiliation, etc., is less critical. It would not be inappropriate for this group - with some augmentation with epidemiologists and immunologists - to meet 3 - 4 months.
5. The hemophilia data need to be evaluated in the same way - though I would expect the situation to be clearer to resolve. A mail review would be appropriate and I would very much like to participate in this effort.

Hoyer

CONSULTANTS SUMMARY COMMENTS

The data presented pointed out the need for careful evaluation of each purported case of transfusion-AIDS. Several cases were inadequately studied or reported. The result is that one pediatric case and 2-4 adult cases are reasonably convincing; the others are either unconvincing or have insufficient data to make decisions.

Studies on donor-recipient status, as outlined by Dr. Grady, are necessary. Control recipients and their donor status are essential missing data. Are the high risk donors selectively distributed with AIDS recipients or not? The two stage approach, i.e., (1) check donors, and if indicated, (2) check subsequent recipients, would be appropriate as a starter.

The CDC should update the AIDS epidemic in the N Engl J Med, as done in 1982, with particular emphasis on blood-related and pediatric cases. Appropriate cautionary advice should be provided to spell out what is known and what is speculation. Advice to both physicians and the public should be provided.

"Expert" review groups serve a useful function in bringing data together and offering suggestions. I believe such a group is essential in the pediatric AIDS group, with experts such as Good, Hughes,, Krugman, Katz, Alford, Nahmias, etc., to review the data.

I would be happy to continue to serve on this "committee" or as a consultant in this area, if you should so desire.

Hirsch

CONSULTANTS SUMMARY COMMENTS

1. The staff have done a remarkable job of assembling complex data into the best form possible.
2. The hemophilia-associated cases are convincing but the "etiology" issues leave me wondering about the theory of immune-alteration susceptibility factors - (Dr. Evatt's chart of the UNC lymphopenia was very impressive). Thus, it is important to decide whether a transfused agent (in AHF?) is causative, and that this phenomenological interpretation can be used to strengthen the "theory" of blood-transmitted AIDS (see below).
3. Blood Transfusion-Associated Cases -- I've rated each of these on the foregoing charts:
For adults - I would bet that at least 2-3 of these candidate donor-case reports will stand up,
For pediatrics - I agree that 1-2 donor-case sets will stand up.
4. Future Study Priorities - Donor clusters associated with ["dummy"] control recipients should be examined to see if:

A-1 Donor Study

- (A) Concealed drug use history if much rarer than is the current AIDS-recipient cases under review. If so, this strengthens the inferences that donor characteristics reported here can be used to strengthen the transmission-from-transfusions theory.

If these "random" donors, however, reveal as high a "suspect" frequency as for the "AIDS-recipients," then further study is necessary (see below) to help with interpretation.

A-2 Donor-Recipient study

If the (control) donor clusters were selected on a 5:1 match to the time of transfusion of AIDS cases - the high (5) number of control donor clusters would allow a reserve for recipient-donor followup when recipients have died (perhaps 1 or 2 of 5 would still be alive and traceable.) Then within the (control) donor clusters that had suspect members or not, there would be a chance to see if the donor clusters with no suspects gave rise to less "sub-clinical AIDS" (lymphadenopathy, T_H/T_S , etc.)

Study B

Intensive tracking of health recipients of blood from regular donors implicated in AIDS - [choose recipients bracketed on either side of the time of transfusion of the AIDS recipient.

CONSULTANTS SUMMARY COMMENTS

Of the 11 adult possible AIDS cases associated with prior transfusion, I would categorize 6 as unequivocal (837, 848, 1945, 2678, 2684, 1494), 1 probable (1524) and 4 as questionable (2494, 2649, 2510, 2632). Three of unequivocals also have a suspect donor.

The critical issues are whether the transfusion-association is in excess of expected and whether the rate of identifying suspected donors is in excess for the specific donor populations. Key information = 1) strength of data that these cases have no other known risk factors, 2) is the rate of transfusion prior to onset in cases without a known risk factor in excess of general transfusion rates?, 3) is the rate of finding suspect donors in excess for the donors in general.

Information useful to collect from the cases = Pre-transfusion immune status (i.e., lymphocyte counts).

Other people who ought to review these cases = pediatric and adult immunologists, CMV experts (especially pediatric), people experienced with AIDS.

Stevens

1775
MAY 16 1988
Department of Health
Berkeley

AUG 06 1982

Director
Centers for Disease Control

Open Meeting of the PES Committee on Opportunistic Infections in Patients with Hemophilia, June 27, 1982, Washington, D.C.

The Assistant Secretary for Health
Through: ES/PES _____

Attached is a report of the Open Meeting of the PES Committee on Opportunistic Infections in Patients with Hemophilia which was held on July 27, 1982, at your request.

This report summarizes the deliberations, conclusions, and recommendations of the meeting's participants and was compiled by the PES attendees, representatives of the CDC, FDA, and HHE.

/s/ Freddie Le Luyter
for William H. Foege, M.D.
Assistant Surgeon General

Attachment
Tab A: Summary Report with List of Invitees

cc:

OL

CDCW

KS Task Force ✓

CDC:OD:JPKOFLAN:rs(8/2/82)
CDC Doc 08485

OPEN MEETING OF PHS COMMITTEE ON OPPORTUNISTIC INFECTIONS
IN PATIENTS WITH HEMOPHILIA

List of Invitees

AMERICAN ASSOCIATION OF BLOOD BANKS

Paul Holland, M.D.
Chief, Clinical Center Blood Bank
National Institutes of Health
Bethesda, MD 20205

AMERICAN NATIONAL RED CROSS

Dr. Gerald Sandler, M.D.
Associate Director
Medical and Laboratory Services
American National Red Cross
8th E. Street, N.W.
Washington, DC 20006

AMERICAN BLOOD RESOURCES ASSOCIATION

Dr. Robert Riley
Executive Director
P.O. Box 3346
Annapolis, MD 21403

CENTERS FOR DISEASE CONTROL

Jeffrey P. Koplan, M.D.
Assistant Director for Public Health Practice
Office of the Director
Centers for Disease Control
Bldg. 1, Rm. 2035
Atlanta, GA 30333

James W. Curran, M.D.
Coordinator
Kaposi's Sarcoma Task Force
Centers for Disease Control
Building 3, Rm SB.
Atlanta, GA 30333

Bruce L. Evatt, M.D.
Director
Host Factors Division
Center for Infectious Diseases
Bldg. 1, Rm. 1323
Centers for Disease Control
Atlanta, GA 30333

Donald L. Francis, M.D.
Assistant Director for Medical Science
Hepatitis Laboratories Division
Center for Infectious Diseases, CDC
4402 N. 7th Street
Phoenix, AZ 85014

COUNCIL OF COMMUNITY BLOOD CENTERS

Dr. Jay E. Menitove
Medical Director
Blood Center of East Wisconsin
1701 W. Wisconsin Avenue
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Milwaukee, WI 53201

FOOD AND DRUG ADMINISTRATION

Harry M. Meyer, Jr., M.D.
Director
National Center for Drugs and Biologics
FDA
8800 Rockville Pike, HFB-200
Bethesda, MD 20205

Paul D. Parkman, M.D.
Scientific Director
National Center for Drugs and Biologics (NCDB)
FDA
(same address as above)

Hope E. Hopps
Acting Associate Director for Program Development
and Operations
NCDB
(same address as above)

Dennis Donohue, M.D.
Director, Division of Blood and Blood Products
NCDB
(same address)

Robert J. Garaty, M.D.
Director, Hepatitis Branch
Division of Blood and Blood Products
NCDB
(same address)

Gerald Quinnan, Jr., M.D.
Director, Division of Virology
NCDB
(same address)

HEMOPHILIA CENTERS

M. Elaine Eyster, M.D.
Chief, Hematology
Milton S. Hershey Medical Center
Hershey, PA 17033

NATIONAL GAY TASK FORCE

Dr. Roger Enlow
301 East 17th Street
New York, NY 10003

Dr. Bruce Voeller
P.O. Box 36B35
Los Angeles, CA 90036-1166

NATIONAL HEMOPHILIA FOUNDATION

Louis Aledort, M.D.
Co-Medical Director
National Hemophilia Foundation and
Vice Chairman of Medicine
Mt. Sinai Medical School
5th Avenue at 100th Street
New York, NY 10029

Charles Carman, M.D.
President
Hemophilia Foundation
19 West 34th Street
New York, NY 10001
or
1288 W. Arndale Road
Stow, OH 44224

NATIONAL INSTITUTES OF HEALTH

Robert S. Gordon, Jr., M.D.
Assistant to the Director
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Bldg. 1, Rm. 238
Bethesda, MD 20205

Kenneth Sell, M.D.
Scientific Director
National Institute of Allergy and Infectious Diseases
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Bethesda, MD 20205

Anthony Fauci, M.D.
Chief, Laboratory of Immunoregulation
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Bg. 10, Room 11B13
Bethesda, MD 20205

N. Raphael Shulman, M.D.
Chief, Clinical Hematology Branch
National Institute for Arthritis, Diabetes and Digestive and Kidney Diseases
NIH
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Environmental Epidemiology Branch
National Cancer Institute
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Bethesda, MD 20205

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Commissioner
New York City Department of Health
125 Worth Street, Room 606
New York, NY 10013

NEW YORK GROUP ON KSOI

Donald Armstrong, M.D.
Chairman, New York Group on KSOI and
Director, Microbiology Laboratory
Memorial Sloan Kettering Cancer Center
1275 York Avenue
New York, NY 10021

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

Lowell T. Harnison, Ph.D.
Science Advisor
Office of the Assistant Secretary for Health
9A55 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Michael B. Rodell, M.D.
Director
Regulatory Affairs and Clinical Development
Hyland Therapeutic Division
Travenol Laboratory, Inc.
444 W. Glenoaks Drive
Glendale, California 91202

Summary Report on Open Meeting of PHS Committee on Opportunistic
Infections in Patients with Hemophilia

I. The Meeting

On July 27, 1982, from 8:30 a.m. to 4:30 p.m. a meeting was held to consider the significance of the occurrence of opportunistic infections (OI) with Pneumocystis carinii pneumonia (PCP) in three patients with hemophilia.

Invited participants included representatives of the CDC, FDA, NIH, National Hemophilia Foundation, American National Red Cross, various blood banking organizations, National Gay Task Force, New York City Health Department, and the New York Inter-Hospital Study Group on the Acquired Immune Deficiency Syndrome (AIDS) and Kaposi's Sarcoma (KS) (Attachment 1).

The morning was spent reviewing the various contributory disciplines related to the problem: the epidemiology of AIDS/KS; immunosuppression associated with AIDS/KS; the course, complications, etc. of hemophilia; description of Factor VIII concentrate and other blood products; and a description of the three hemophilia patients with opportunistic infections.

The afternoon was spent discussing the significance of the finding and the appropriate course of action.

II. Aspects of Discussion

- A. AIDS (and the sequelae of KS and OI) are occurring in several populations--homosexual men, recent Haitian entrants and I.V. drug abusers. The possibility exists that it is occurring in patients with hemophilia.
- B. If the PCP observed in three patients with hemophilia represents the same process as seen in other groups with AIDS, then a possible mode of transmission is via blood products, in this case Factor VIII concentrate. This finding would strengthen the existing hypothesis that AIDS is caused by a transmissible agent.
- C. Other seemingly unusual disorders among hemophilia patients were mentioned at the meeting, including cases of Burkitt's Lymphoma, unexplained thrombocytopenia, and possibly other opportunistic infections; but these have not been studied sufficiently to establish their relationship to AIDS.
- D. There are 11,000 to 15,000 persons with hemophilia in the United States with varying severity of condition. The morbidity and mortality from hemophilia as well as the lifestyle of hemophilia

patients has changed considerably over the past 10 years. These patients are treated with either a product derived from fresh frozen plasma (cryoprecipitate) or a protein concentrate prepared from these precipitates called antihemophilic factor or Factor VIII. Such therapy has allowed the development of home treatment regimens which permit patients to live a more normal life, including sharing educational and vocational opportunities and pursuits with the rest of the population. The number of days of hospitalization annually has decreased markedly for hemophilia patients on home treatment programs. Hemorrhage (spontaneous and traumatic) remains the major cause of death in hemophilia patients.

- E. Almost all patients regularly receiving Factor VIII or cryoprecipitate develop hepatitis B and non-A--non-B (NANB) infections. These products have been shown to transmit these infections. Because of the freedom and reduction of suffering permitted hemophilia patients by Factor VIII concentrate, the product's benefits are perceived by patients to vastly outweigh currently known risks.
- F. The Factor VIII normally present in fresh plasma is heat labile and inactivated by many types of chemical or physical treatment. For this reason, the techniques developed for the production of Factor VIII concentrate from fresh plasma are known to have little effect on hepatitis viruses. There are five commercial producers of Factor VIII concentrate. Lots of Factor VIII concentrate are prepared from plasma pooled from 1,000 - 5,000 donors. Donors come from many parts of society. Most material is pooled from paid donors in plasmaphoresis centers. Hemophilia patients use large amounts of Factor VIII (40,000 to over 65,000 factor units per year) from multiple preparations with subsequent potential exposure to material derived from thousands of donors.
- G. The occurrence of PCP in three patients with hemophilia is disturbing, particularly since there is no previous evidence that this infection is common in hemophilia patients. The two patients who had immunologic studies performed demonstrated a T-cell abnormality similar to that among other patients in other high-risk groups with AIDS/KS. There is no known intrinsic immune disorder in hemophilia patients that would permit or promote such opportunistic infections.

III. Conclusions and Recommendations

There was general agreement among all participants on the following:

A. Conclusions

1. The pathologic process should be termed Acquired Immune Deficiency Syndrome (AIDS). Kaposi's Sarcoma and the various opportunistic infections are sequelae of the AIDS state.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

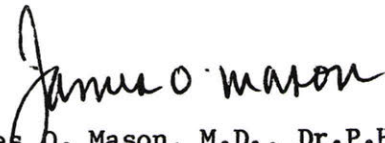
Date MAR 02 1988

From Director, CDC, and
Administrator, ATSDR

Subject CDC/ATSDR General Policy on Human Immunodeficiency Virus (HIV) Infections
and Acquired Immunodeficiency Syndrome (AIDS) in the Workplace

To All CDC and ATSDR Employees

The CDC/ATSDR general policy on HIV infections and AIDS in the workplace is attached. I encourage each employee to read this policy carefully and to contact his or her personnel generalist or employee counselor if there are questions or concerns.


James O. Mason, M.D., Dr.P.H.
Assistant Surgeon General

Attachment

CDC/ATSDR General Policy
on
Human Immunodeficiency Virus (HIV) Infections and
Acquired Immunodeficiency Syndrome (AIDS) in the Workplace

POLICY

Employees with AIDS or HIV infection will be treated as any other employee. They will be encouraged to continue to work as long as they are able to maintain acceptable performance.

BACKGROUND

PHS guidelines issued by CDC state that the kind of nonsexual person-to-person contact that generally occurs among workers and clients or consumers in the workplace does not pose a risk for transmission of HIV. Employees have no medically established basis for not wanting to work with fellow employees or agency clients who have been or are suspected of being infected with HIV. To allay unnecessary concerns, employees will be provided with appropriate information on HIV infection and AIDS, and how the virus is transmitted.

IMPLEMENTATION

Confidentiality

Any medical documentation submitted to an agency by an employee for the purposes of an employment decision becomes a record covered by the Privacy Act and must be treated confidentially. Officials who have a need to know the information for an appropriate management purpose must maintain the confidentiality of that information.

Leave

Accommodation of employees' AIDS-related illnesses will be considered in the same manner as for other employees whose medical conditions warrant such consideration. Employees with AIDS may be granted sick leave or leave without pay when they are incapable of performing their duties or when they have medical appointments.

Insurance

Employees infected with HIV can continue their coverages under the Federal Employee Health Benefits (FEHB) and/or the Federal Employees Group Life Insurance (FEGLI) program in the same manner as other employees. Their continued participation in either or both of these programs will not be jeopardized on the basis of their medical condition. Under the Federal health benefits plans, an individual's health-care status or a preexisting condition will not be used to exclude coverage for medically necessary health-care services.

Job Changes

CIO Directors and other personnel considering job restructuring, detail, reassignment, or other changes in position for employees whose health is affected by HIV-related illnesses or AIDS must do so as they would for other employees whose medical conditions affect job performance. General personnel policies (such as those governing qualifications and internal placement) must be observed and confidentiality must be maintained.

Any employee or supervisor who has concerns or questions about this policy regarding employees with HIV infection or AIDS should contact their personnel generalist or employee counselor.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date June 10, 1988

From Assistant to Deputy Director (AIDS)
Center for Prevention Services

Subject Topics - Friday AIDS Update Meeting

To See Below

Attached are topics discussed during the May 27, 1988, AIDS Update meeting. Please circulate to those who need to know.

Stephen Schneider
for Gary R. West

Attachment

Addressees:

Russ Alexander/Joe Lossick
Sevgi Aral
Joyce Ayers
Stu Berman
Stephen Bowen
Windell Bradford
Kathy Cahill
Ward Cates
Pam Chin
Dick Conlon
Don Francis ✓
Willis Forrester
Larry Furman
Jessica Gardom
Russ Havlak
Alan Hinman
Bob Johnson
Steve Jones
Jack Kirby
Martha Mayfield
Kevin O'Reilly
Walter Orenstein
Deborah Rugg
Tony Scardaci
Mark Schrader
Steve Schindler
Dixie Snider
Jack Spencer
Susan Toal
Charlie Watkins

AIDS UPDATE NOTES
MAY 27, 1988

Attendees: J. Allen, T. Baker, D. Berreth, C. Blackmore, S. Bowen, W. Bradford, W. Cates, H. Colvin, C. Fallis, P. Holman, H. Jaffe, F. Kroger, N. Lee, K. Malone, G. Matthews, B. Mullan, F. Murphy, G. Noble, G. West, J. Whitney

OD

A thank you celebration was held on May 26 in the sound stage area for all persons who worked on the national mailer, "Understanding AIDS."

Dr. Noble announced that Mr. Fred Kroger has been detailed from CHPE to serve as Acting Director, NAIEP.

Dr. Noble discussed the pending AIDS reorganizational structure. NAIEP will remain in the Office of the Director. The immediate office of the Deputy Director (AIDS) will be reorganized. (See attached chart)

Drs. Mason, Noble, Mr. Pickelsimer, Ms. Cowart, and Ms. Katz will meet with Dr. Windom on Wednesday, June 1, on the 1990 budget appeals.

Dr. Noble congratulated Dr. Murphy and CID for the outstanding "International Symposium: Viruses, Rickettsiae, and Severe Human Disease: Natural History and Prevention," which was held on May 24-25.

Mr. Bloom will be Acting Deputy Director (AIDS) while Dr. Noble is out of the country, June 10 to June 28.

CID

Dr. Allen thanked everyone for their assistance in developing responses for the Presidential Commission. Admiral Watkins will hold a press conference on June 2 to announce the Commission's report. We should be prepared for requests from PHS to review this report.

Thanks also to Jim Allen for doing an outstanding job coordinating CDC's requests from the Presidential Commission.

NIOSH

Dr. Mullan announced that WHO and ILO (International Labor Organization) are sponsoring a conference in Geneva, June 27-29. Bob has been asked to develop a background paper on the risk of HIV transmission to non-health care workers. If you have comments/information, please contact Bob.

RO

Mr. Whitney stated that the State health officers have received favorable comments on the national mailout. The State of Alabama is considering

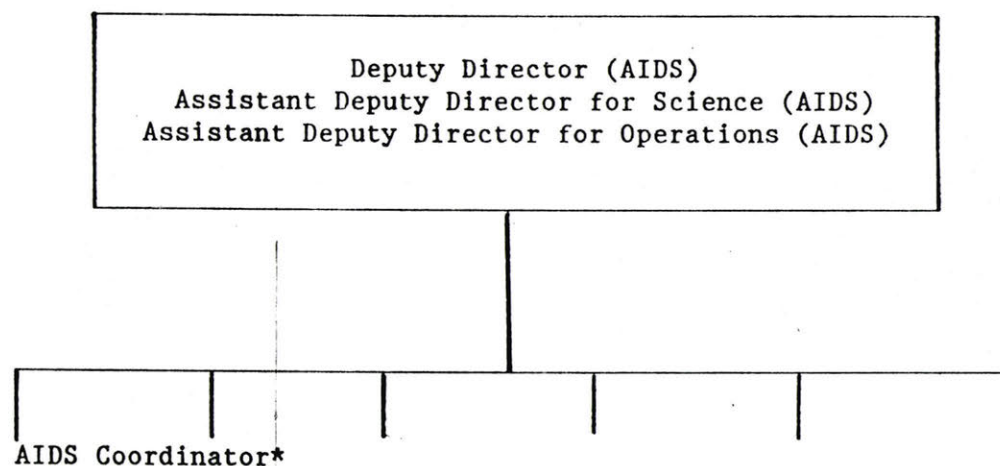
doing a follow-up attitude and behavior survey after their residents have received the brochure.

REMINDER: The AIDS Updates scheduled for June 3 and 17 have been cancelled.

NOTICE: An AIDS Update meeting will be held on June 10 at 10:30 a.m., room 207.

bw

OFFICE OF DEPUTY DIRECTOR (AIDS), CDC



*4 to 6 AIDS Coordinators for areas to be discussed, e.g. Epi/Lab/Surveillance;
Information/Education; Behavioral Research; Prevention; International



Memorandum

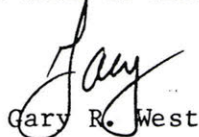
Date June 22, 1988

From Assistant to Deputy Director (AIDS)
Center for Prevention Services

Subject Topics - Friday AIDS Update Meeting

To See Below

Attached are topics discussed during the June 10, 1988, AIDS Update meeting. Please circulate to those who need to know.


Gary R. West

Attachment

Addressees:

Russ Alexander/Joe Lossick
Sevgi Aral
Joyce Ayers
Stu Berman
Stephen Bowen
Windell Bradford
Kathy Cahill
Ward Cates
Pam Chin
Dick Conlon
Don Francis
Willis Forrester
Larry Furman
Jessica Gardom
Russ Havlak
Alan Hinman
Bob Johnson
Steve Jones
Jack Kirby
Martha Mayfield
Kevin O'Reilly
Walter Orenstein
Deborah Rugg
Tony Scardaci
Mark Schrader
Steve Schindler
Dixie Snider
Jack Spencer
Susan Toal
Charlie Watkins

OFFICE OF

JUL 1 1988

AIDS - BERKELEY

AIDS UPDATE NOTES
JUNE 10, 1988

Attendees: C. Blackmore, G. Duhon, G. Hawkins, P. Holman, L. Kolbe, F. Kroger, A. Liang, J. Lococo, G. Matthews, V. Neslund, G. Noble, W. Rushing, A. Sims, D. Tolsma

OD

Dr. Noble stated that position announcements are posted for the Assistant Deputy Director for Science (AIDS), Assistant Deputy Director for Operations (AIDS), and the AIDS Coordinators. Please notify interested staff.

Dr. Marshall Kreuter will chair a search committee to identify a Director and other key staff for NAIEP. The committee will also review the NAIEP mission statement.

Dr. Noble met with CIO Directors on Thursday, June 9, to discuss formal and informal lines of authority and communication for AIDS activities.

Ms. Deena Koniver gave an overview and distributed copies of the PHS "Policy On Informing Those Tested About HIV Serostatus." Questions should be directed to Deena.

A summary response to the Presidential Commission report will be sent to Dr. Fischinger's office today. Comments for the detailed version are due to Mr. Bloom by c.o.b. June 16.

Dr. Noble announced that the Second PHS AIDS Prevention and Control Meeting, Charlottesville, Virginia, was a useful process. The reports from the Subgroups are due to Dr. Fischinger's office on June 13. Copies of the report from Dr. Noble's group entitled "Prevention: Information, Education, and Behavior Change" will be sent to the CIOs for their information. The final report from Charlottesville will be published in a supplement to the Public Health Reports.

Mr. Hawkins announced that the Quarterly Health Officers meeting will be held on July 7, Stafford-Emory. Please send agenda topics to Gil by c.o.b. Wednesday, June 15.

Ms. Holman gave an update on the national household mailout. For the most part, the response has been positive. Copies have also been sent to the military, prisons, shelters for the homeless, foreign service personnel and the Peace Corps. The brochure is also being translated into Chinese, Portuguese, Haitian, Viet Nameese, and Laotian.

W Ms. Blackmore distributed copies of the announcement for the "National Conference on the Prevention of HIV Infection and AIDS Among Racial and Ethnic Minorities in the United States."

Dr. Rosenberg announced that during the next month he will be developing a report on AIDS and behavioral science at CDC. He will distribute for review and comment.

Mr. Bloom alerted the staff that Congressman Waxman will be holding hearings on AIDS information and education in late June or early July.

CID

Mr. Rushing announced that the Karolinska Institute in Stockholm has organized a 1st AIDS Computer Conference that will allow remote participation using computer telecommunications during the AIDS conference, June 12-16. For more information contact Dr. Bruce Weniger, ext. 1780.

CHPE

Mr. Tolsma and Dr. Kolbe attended a meeting of the Executive Committee of the International Union for Health Education, Moscow, May 30 through June 3.

OGC

Mr. Matthews introduced Ms. Ginny Duhon, an Emory law student, who will be working in OGC for the summer. Welcome!

bw



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date July 28, 1988

From Assistant to Deputy Director (AIDS)
Center for Prevention Services

Subject Topics - Friday AIDS Update Meeting

To See Below

Attached are topics discussed during the July 22, 1988, AIDS Update meeting. Please circulate to those who need to know.


Gary R. West

Attachment

Addressees:

Russ Alexander/Joe Lossick
Sevgi Aral
Joyce Ayers
Stu Berman
Stephen Bowen
Windell Bradford
Kathy Cahill
Ward Cates
Carol Ciesielski
Dick Conlon
Don Francis ✓
Larry Furman
Jessica Gardom
Joel Greenspan
Russ Havlak
Alan Hinman
Bob Johnson
Laurie Johnson
Steve Jones
Jack Kirby
Martha Mayfield
Chuck McCance
Kevin O'Reilly
Walter Orenstein
Tom Peterman
Deborah Rugg
Tony Scardaci
Mark Schrader
Steve Schindler
Dixie Snider
Jack Spencer
Susan Toal
Kathleen Toomey
Charlie Watkins

OFFICE OF
AUG 2 1988
AIDS - BERKELEY

AIDS UPDATE NOTES
JULY 22, 1988

Attendees: G. Bales, C. Blackmore, J. Bloom, S. Bowen, W. Cates, S. Cort, G. Hawkins, A. Hinman, P. Holman, R. Jackson, R. Mullan, V. Neslund, G. Noble, B. Peterson, A. Sims, G. West, P. Wiesner, L. Zyla

OD

Dr. Noble distributed copies of a note that he had written to CDC staff on the issue of using alternative terms rather than "AIDS". For example, "Use of the terms "HIV/HIV infection/HIV epidemic" whenever appropriate, rather than "AIDS," should remind us that we are fighting an epidemic of HIV infection." Discussions followed and a consensus was reached to explore the possibility of developing this concept as CDC policy.

Dr. Noble thanked AIDS staff who assisted him this week in briefing Congressmen Hoyer, Early, Neal, and Roybal as well as Tom Hayden and other entertainers. The Congressmen and actors were attending the Democratic National Convention.

The subject of providing integrated health care was discussed. It was decided that Dr. Wiesner would explore this issue with Mr. Tolsma.

Ms. Blackmore gave an update on the minority conference. The resource book has been sent to the CIOs for review. Comments should be returned to Cheryl by c.o.b. July 27.

Mr. Hawkins distributed a listing of "action items" from the CDC/Health Officers Quarterly AIDS meeting, July 7. Comments should be sent to Gil by c.o.b. July 29. Dr. Noble reminded us that it is important that we meet our commitments to the health officers.

NAIEP

Ms. Holman reviewed the status of the minority funding package. August 1 is the target date for award announcements to be made. Over \$6 million will be awarded.

Ms. Holman conveyed appreciation to staff of CPS and CHPE for their help in reviewing the PSAs being prepared for the fall campaign. A preview is scheduled for Dr. Mason on Thursday, July 28.

CPS

Dr. Cates announced that 10 applications had been received for the perinatal prevention announcement. The panel is scheduled to meet on August 2.

Dr. Hinman will represent CDC in Mexico City on July 27 for their AIDS Awareness Day. The issue was discussed that CDC does not currently have any audiovisual materials available in Spanish. This issue will be explored further.

Dr. Bowen announced that a preapplication meeting for the cooperative agreements will be held on Sunday, August 28, 11:00 a.m. to 4:00 p.m. This meeting will be held in conjunction with the STD Conference.

One of the recommendations from the Report of the Presidential Commission on the HIV Epidemic was that CDC should reexam the issue of mandatory testing for illegal aliens. Dr. Bowen announced that the Division of Quarantine was working on this.

Dr. Bowen announced that CPS will hold monthly AIDS scientific seminars on prevention issues. Announcements will be distributed.

TLPO

Dr. Wiesner reported that staff from TLPO had been discussing with FDA the subject of recordkeeping and logistics within the bloodbanking system. We have offered to help FDA in any way we can.

CID

An audio tape from the AIDS Rounds on the Stockholm conference will be available from Dr. Drotman in approximately two weeks.

bw



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date July 20, 1988

From Assistant to Deputy Director (AIDS)
Center for Prevention Services

Subject Topics - Friday AIDS Update Meeting

To See Below

Attached are topics discussed during the July 15, 1988, AIDS Update meeting. Please circulate to those who need to know.


Gary R. West

Attachment

Addressees:

Russ Alexander/Joe Lossick
Sevgi Aral
Joyce Ayers
Stu Berman
Stephen Bowen
Windell Bradford
Kathy Cahill
Ward Cates
Dick Conlon
Don Francis
Willis Forrester
Larry Furman
Jessica Gardom
Russ Havlak
Alan Hinman
Bob Johnson
Laurie Johnson
Steve Jones
Jack Kirby
Martha Mayfield
Kevin O'Reilly
Walter Orenstein
Deborah Rugg
Tony Scardaci
Mark Schrader
Steve Schindler
Dixie Snider
Jack Spencer
Susan Toal
Kathleen Toomey
Charlie Watkins

AIDS UPDATE NOTES

JULY 15, 1988

Attendees: D. Berreth, J. Bloom, S. Bowen, W. Cates, H. Colvin, D. Harris, G. Hawkins, P. Holman, R. Jackson, H. Jaffe, L. Kolbe, F. Kroger, G. Matthews, B. McMichen, R. Mullan, V. Neslund, G. Noble, B. Peterson, M. Rosenberg, A. Sims

OD

Dr. Noble reminded everyone that CDC will have congressional visitors next week due to the Democratic National Convention. Good Morning America will film on Monday, July 18, and Dr. Mason will appear live on the Today show on Wednesday, July 20.

On Tuesday, July 19, Mr. Bloom will accompany Dr. Mason and other CDC staff to a 1990 budget meeting in Washington, D.C. with Secretary Bowen.

Dr. Noble and Mr. Matthews will go to Washington, D.C. on Wednesday, July 20, to meet with Dr. Koop, Mr. Robertson, and representatives of the Justice Department on the AIDS antidiscrimination policy.

Dr. Rosenberg announced that the position paper, "Preventing AIDS in Minorities," being prepared for the minority conference, will be sent to the CIOs for clearance early next week. Mark asked that comments be returned by July 28. The paper will be included in the resource handbook.

A briefing for the CIOs on the minority conference will be held on July 19, 9 to 10 a.m., classroom 3.

NAIEP

Mr. Kroger reported that the PSAs for the fall campaign will be previewed on Monday, July 18. If you are interested, please contact Fred for details.

Tim Baker and Fred Kroger will go to North Carolina next week to meet with representatives from the clearinghouse and hotline. The primary topic will be interaction between the clearinghouse and hotline.

Mr. Kroger stated that minority funds should be awarded to 31 national and regional organizations in early August.

An exhibit has been prepared for the Conference of State Legislators meeting being held in Reno, Nevada, July 24-27.

CHPE

Dr. Kolbe announced that he will attend a meeting of the urban superintendents of education in Washington, D.C. on July 18 and 19. The purpose of the meeting is to further collaborative efforts with the Department of Education.

The AIDS Research Committee, National Academy of Science, will meet in Washington, D.C. on July 22 and 23.

CID

Dr. Jaffe gave a briefing on a case in Miami of delayed HIV seroconversion in a woman over 60-years old. The case is being investigated by the Florida Department of Health.

Dr. Jaffe also reported on a meeting held this week with representatives from CID AIDS Program, Hospital Infections Program, and Division of Tuberculosis, CPS. The purpose of the meeting was to discuss the outbreak of skin test conversion to TB in a health center in Belle Glade, Florida. One of the questions raised was the issue of whether CDC should develop guidelines.

CPS

Dr. Bowen and other CPS staff were in Albany, New York, on July 11 to discuss New York State's plan to use the \$3 million awarded for counseling and testing in drug abuse treatment facilities.

Ms. Kathy Cahill has developed a standardized data collection process for reporting of counseling and testing in the States. The project has been very well received by the States.

bw

ROUTING AND TRANSMITTAL SLIP

Date 7/11/88

TO: (Name, office symbol, room number, building, Agency/Post)		Initials	Date
1.	<u>Don Francis</u>		
2.			
3.			
4.			
5.			

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	☒ For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

file

VID2 - BEKKELEY

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don

OFFICE OF

JUL 18 1988

AIDS - BERKELEY

6-00

X

don Francis

5/11/88



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date July 7, 1988

From Assistant to Deputy Director (AIDS)
Center for Prevention Services

Subject Topics - Friday AIDS Update Meeting

To See Below

Attached are topics discussed during the July 1, 1988, AIDS Update meeting. Please circulate to those who need to know.


Gary R. West

Attachment

Addressees:

- Russ Alexander/Joe Lossick
- Sevgi Aral
- Joyce Ayers
- Stu Berman
- Stephen Bowen
- Windell Bradford
- Kathy Cahill
- Ward Cates
- Dick Conlon
- Don Francis ✓
- Willis Forrester
- Larry Furman
- Jessica Gardom
- Russ Havlak
- Alan Hinman
- Bob Johnson
- Laurie Johnson
- Steve Jones
- Jack Kirby
- Martha Mayfield
- Kevin O'Reilly
- Walter Orenstein
- Deborah Rugg
- Tony Scardaci
- Mark Schrader
- Steve Schindler
- Dixie Snider
- Jack Spencer
- Susan Toal
- Charlie Watkins

AIDS UPDATE NOTES
July 1, 1988

Attendees: G. Bales, D. Berreth, J. Bloom, W. Cates, M. Cohen, H. Colvin, J. Curran, G. Hawkins, P. Holman, L. Kolbe, M. Kreuter, F. Kroger, K. Malone, G. Matthews, B. McMichen, G. Noble, B. Peterson, M. Rosenberg, G. West, J. Whitney

OD

Dr. Noble expressed his pleasure at listening to the AIDS Rounds tape which contained reports of the Stockholm conference. Anyone who is interested in listening to the tape can obtain a copy from Peter Drotman.

The Stockholm conference was well-organized and massive. The International Society was kicked off--now they will help plan future meetings. Next year's meeting will be held in Montreal in June, in San Francisco in 1990, and future years in Germany, Boston, Italy, and Japan.

The Charlottesville conference was useful. We are still reviewing drafts of the follow-up reports. Apologies for the short deadlines that Washington is giving us. The Charlottesville conference proceedings will be published in the Public Health Reports.

Dr. Windom may ask the Agency Heads to go to Washington next week to review the Presidential Commission report. There was a lot of work put into the Presidential Commission Interim Report and it is certainly appreciated. Dr. Macdonald has been asked by the President to provide a 30-day report on the Presidential Commission Report. Dr. Macdonald has asked us to give a status report of all recommendations by July 12, but we must provide our reports to NAPO/OASH by noon July 8.

Dr. Noble circulated a request from Molly Coye, State Commissioner of Health in New Jersey who is looking for a physician with requisite skills for a newly created division of AIDS. This new position will hold the title of Assistant Commissioner of Health. They are interested in attracting someone from CDC.

Dr. Noble discussed the upcoming Health Officers meeting which is scheduled for all day July 7. Gil Hawkins passed out the agenda and a list of members. The agenda was discussed, some changes were made, and Mr. Hawkins will finalize it. Dr. Noble stressed the importance of having the appropriate staff from each CIO attend. He also would like to have a pre-session meeting to discuss controversial issues.

OFFICE OF
OFFICE OF
JUL 1 1988
JUL 15 1988
AIDS - BERKELEY
AIDS - BERKELEY

There were some discussions of the request for information from Dr. Petricciani concerning the U.S. Health Summit on HIV Infection to be held in late November. Dr. Noble has asked for agenda items.

Dr. Kreuter is chairing a committee to search for the Director, National AIDS Information/Education Program. They have drafted the organizational structure and mission statement. It is informally being circulated. An announcement for the position vacancy has been posted and it will come off the board on July 7.

Dr. Kolbe passed out copies of the announcement of the First International Symposium on Information and Education on AIDS to be held October 16-20 in Mexico.

A preliminary analysis of the national adolescent and student survey has been done. A press conference will be held August 9.

CHPE is co-sponsoring with the U.S. Department of Education a meeting with school superintendents of 11 major cities on what can be done to most effectively prevent HIV transmission and other health problems.

NIOSH

Welcome to Dr. Murray Cohen on his first official day in Atlanta!

Dr. Cohen announced that OSHA is planning a conference next November in Washington—as a follow-up to the Joint Advisory Notice. At this point, do not know the CDC/NIOSH role.

The Firefighters are having 2 meetings later this month. NIOSH has been asked to participate.

CID

Lyle Peterson met with the IHS people to finalize the serosurvey on American Indian population.

Jim Buehler is joining the AIDS Program staff on July 6 as Chief of the Special Projects Section of the Surveillance Branch.

CID and TLPO have instituted a retrovirus medical surveillance program for CDC laboratory staff. Program will be voluntary. A later program will be open to all CDC employees on a voluntary basis.

A Domestic Policy Council meeting is scheduled for July 21 to discuss the quarterly report on serosurveillance and the Charlottesville meeting with a pre-meeting scheduled for July 11 with the Health Policy Working Group.

The Office of Science Technology and Policy has planned a national 5-day meeting on AIDS. It is supported by CDC and will be held in Fairfax, Virginia, on July 25-29.

CID has two MMWR articles coming out. One is on hepatitis surveillance.

CID is formalizing assignments of their staff to WHO. Details are planned for 2-3 months for specific tasks. There will be no FTE reimbursement. WHO will pay travel and per diem.

OPA

Mr. Berreth reminded everyone to be aware of potential imbroglios resulting from partisan political activities in the next several months.

CPS

Gary West reported on meeting with consultants from national minority organizations to look at proper funding through State and local health departments.

dh

HIV PREVENTION 1991 INITIATIVE PROPOSAL
CENTER FOR PREVENTION SERVICES

SBR
→ new file
CDC/Prep/Rx

Provision of Prevention-Related Services to Infected Individuals

I. Initiative Descriptions

Relative Strategies:

Prevention of transmission through management of the infected individual; prevention of transmission through sexual exposure and intravenous drug abuse; prevention of perinatal exposure.

A. Nature of the Problem

Since licensure of the HIV antibody test in 1985, an estimated 1,500,000 people have received counseling and testing through Federally supported service sites operated by State and local health departments. Of this number, more than 100,000 individuals have been found to be positive. Additional people have obtained counseling and testing services through private and other public sources and have been found to be infected. In many States more people receive counseling and testing through private than public providers.

The number of people who know that they are infected continues to increase. In some communities a high proportion of homosexual men and many IVDUs know their serostatus. Although most of the HIV infections detected through antibody testing are asymptomatic, personal knowledge of HIV infection can cause psychological distress. Infected individuals may have difficulty making or sustaining behavior changes to prevent HIV transmission through sex or needle sharing. They may also have difficulty obtaining needed counseling and other psychosocial support or drug treatment. Many infected women may not fully understand the implications for childbearing and they may not have access to appropriate counseling and contraceptive services.

B. Purpose/Impact Statement

The purpose of this initiative is to evaluate current prevention related services for infected persons and to develop and implement interventions to reduce or eliminate further transmission from infected people. Ways to reduce psychological and medical illness among persons with HIV infection will also be explored (with funds from other sources such as HRSA) to determine if through the provision of these services further transmission can be reduced or eliminated.

C. Relationship To Other CDC Priorities

Prevention of HIV infection is the highest priority of the CDC and the PHS. This initiative addresses strategies for management of the infected individual developed at the CDC Strategy Development Workshops to prevent the transmission of HIV by focusing on behavior modification for those who are already infected.

D. Activities to be Undertaken

This initiative is intended to accomplish the following in the 25 metropolitan statistical areas most heavily impacted by the HIV epidemic:

- 1) Systematically evaluate the extent, quality, and accessibility of local prevention-related services for HIV infected persons, including drug treatment services.
- 2) Determine the relative public health advantages of centralized and decentralized case management systems for providing long term prevention-related services.
- 3) Evaluate the effectiveness of prevention-related services such as peer group support, couples counseling, skill-building training, and extended counseling intended to help infected persons to make and sustain behavior changes and to adopt new behaviors and life skills that exclude the possibility of further HIV transmission.

E. Collaborative Relationships

Close collaboration will be required within CDC, the PHS and with State and local HIV prevention programs. Within CDC, CPS, CID, NAIEP, TLPO, and CCDDPH will need to jointly develop and evaluate various long term behavior modification strategies. At the PHS level, CDC will collaborate with HRSA in the best approaches for provision of comprehensive services for follow-up of HIV seropositive individuals.

F. Measurable Objectives for FY 1991

- By the end of 1991, conduct comprehensive HIV prevention program reviews in the 25 highest impacted HIV areas.
- Increase the availability of routine testing and counseling services in these areas (cross relates with initiative to fully implement counseling and testing programs).
- Develop, implement, and analyze a survey to evaluate the effectiveness of various prevention related services in motivating and sustaining behavior change by infected individuals that excludes the possibility of further HIV transmission.

II. Legislative Authority

This program would be authorized under Sections 301, 307, 311, 317 (42 U.S.C.), of the Public Health Service Act, as amended, and by Section 2411 "Demonstration Projects for Individuals with Positive Test Results" of the Health Omnibus Programs Extensions Act of 1988 (PL 100-607).

III. Resource Requirements

A. Projected Funds Required

	<u>1991</u>	<u>1992</u>	<u>1993</u>
Extramural	9.0 M	15.0 M	20.0 M
Direct Operations	.5 M	1.0 M	1.3 M
CDC Overhead (20%)	1.9 M	3.2 M	4.3 M
GPS Overhead (15%)	1.4 M	2.4 M	3.2 M
Total	12.8 M	21.6 M	28.8 M

B. Personnel Required

FTEs	5	7	7
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Steve Bowen - M.D.

Gary West - PHA

Steve Jones - M.D.

Jessica Gardom - PHA

Mary Willingham - writer/editor

Charles Rabkin - M.D.

Sandy Kerr - Staff Specialist

~~Imani~~ Imani Thompson - H.E. Specialist

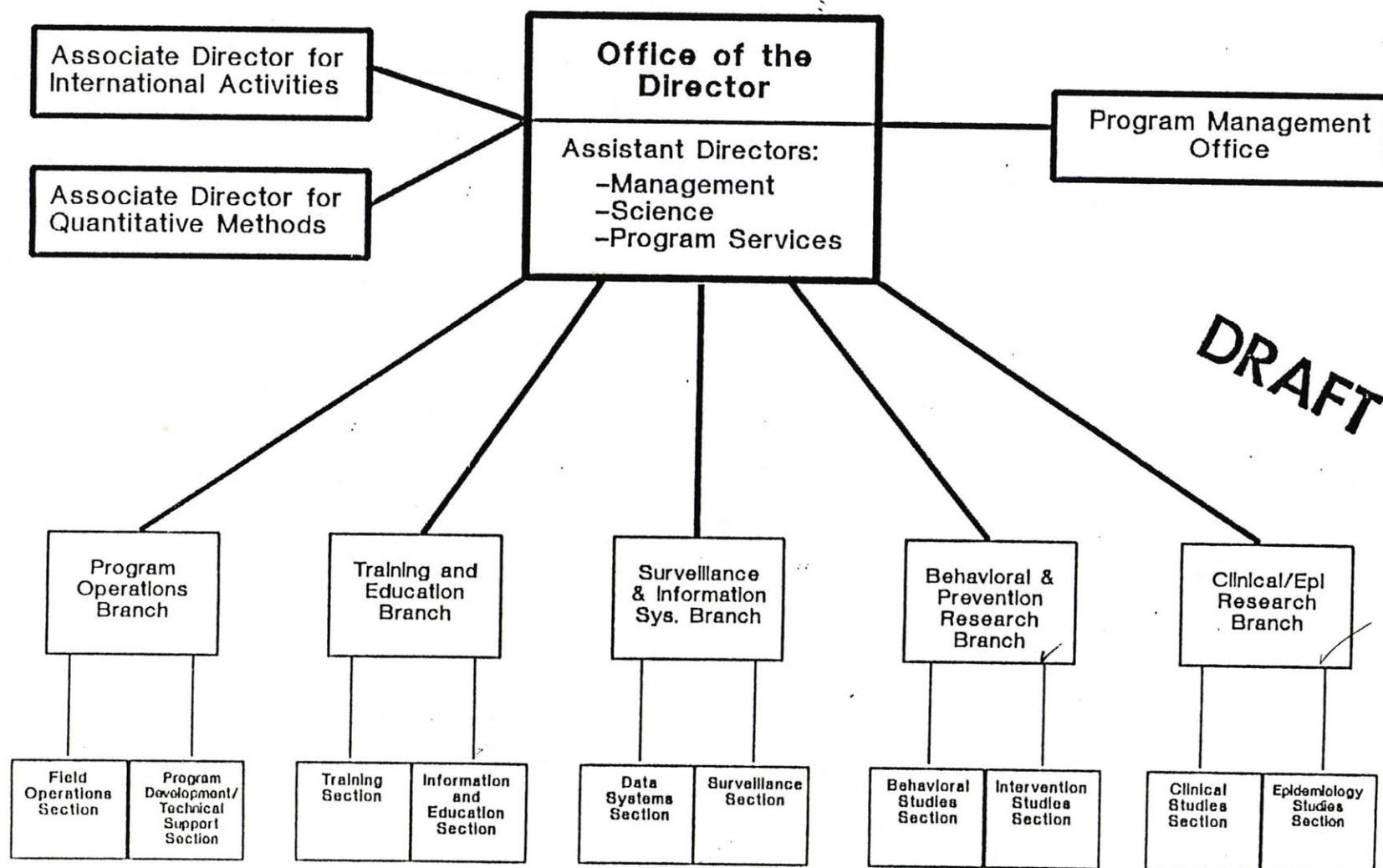
Mary Trebor - sect

Kaye Phillips - sect.

Barbara Johnson - sect.

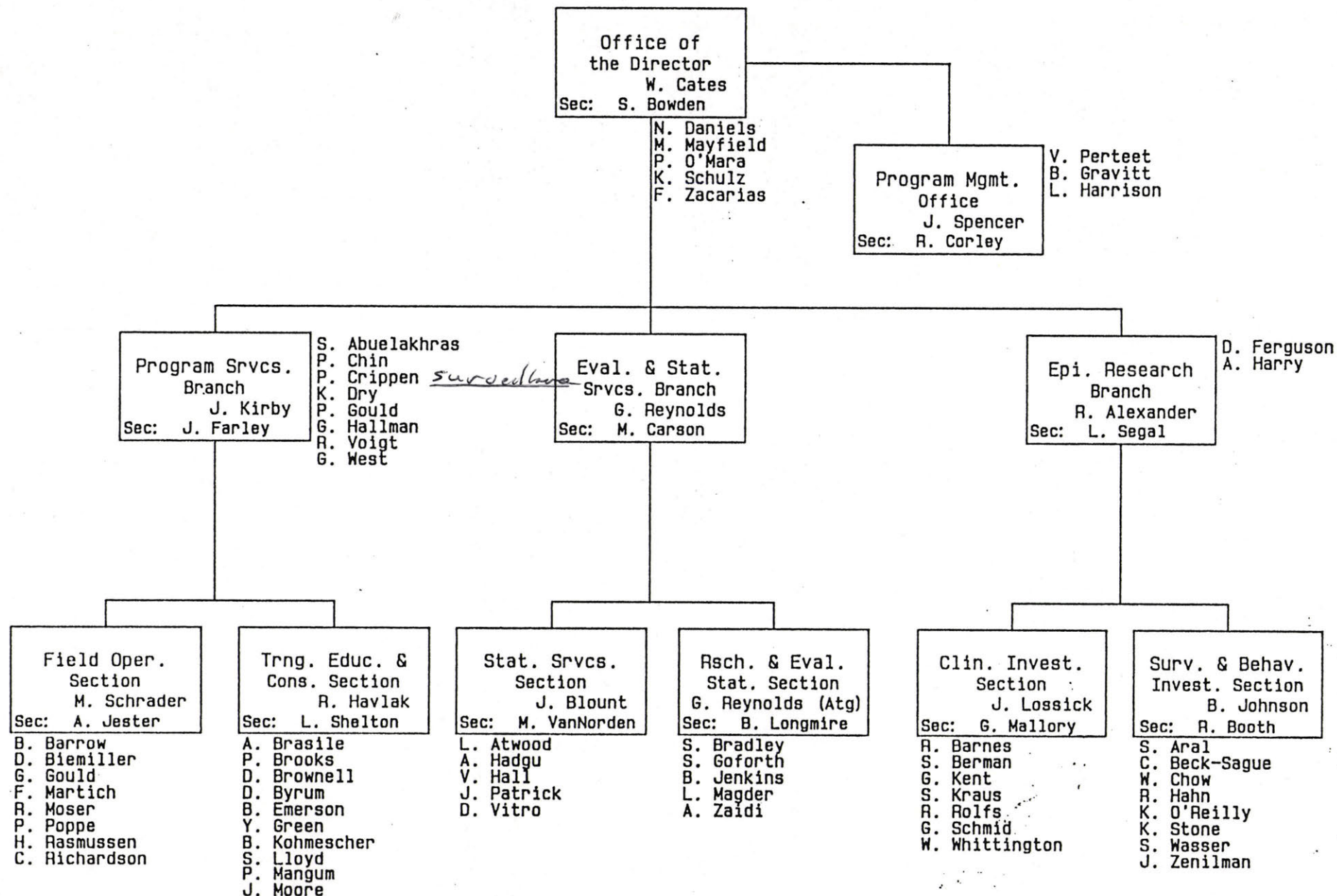
Steve Schindler - PHA

Suggested DSTD Reorganization



3/87

DIVISION OF SEXUALLY TRANSMITTED DISEASES CENTER FOR PREVENTION SERVICES



Memorandum

To : Alexander Kelter, M.D.
Deputy Director (Acting)
Public Health
OB 8/1253

Date : May 13, 1988

Subject: Press Conference
AIDS Budget Task Force


From : Donald P. Francis, M.D., D.Sc.
CDC AIDS Advisor
State of California
2151 Berkeley Way, Room 715
Berkeley, CA 94704
8-571-2522

Per the request of the Office of External Affairs, I am sending this memo to let you know that I plan to attend and participate in a press conference (called by Assemblyman John Vasconcellos). I will be attending this press conference as a representative of CDC, to provide medical and scientific information related to the AIDS Budget Task Force.

This press conference is being held at the State Capitol, Press Room, 1st Floor, Suite 1190, on May 18th. I will be participating from 1:20 to 2:00.

If you have any questions pertaining to the above, please give me a call.

cc: Thelma Frazier, Chief
Office of AIDS
Dan Heincy, Chief
External Affairs

Memorandum

To : Alexander Kelter, M.D.
Deputy Director (Acting)
Public Health
OB8/1253 X2927

Date : April 20, 1988

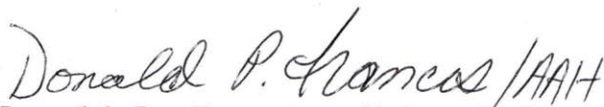
Subject: California Senate
Health and Human Services
Committee

From : Infectious Disease Branch
AIDS Health Education and
Risk Reduction
2151 Berkeley Way, Room 715
Berkeley, CA 94704
8-571-2522

Per the request of the Office of External Affairs, I am sending this memo to let you know that I plan to testify as a representative of CDC, to provide medical and scientific information related to Proposition 69 (AIDS initiative).

This hearing will be held on May 4, 1988, and I am scheduled to speak from 1:30 - 1:45 at the State Capitol, in room 4203. In addition, I will be answering questions from the Committee.

If you have any questions pertaining to the above, please give me a call.


Donald P. Francis, M.D., D.Sc.
CDC AIDS Advisor

DPF/ah

cc: Thelma Frazier, Chief
Office of AIDS
Dan Heincy, Chief
External Affairs

Memorandum

To : Alexander Kelter, M.D.
Deputy Director (Acting)
Public Health
OB8/1253 X2927

Date : October 21, 1987

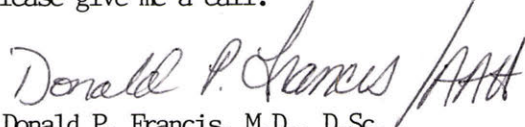
Subject: California State Senate Select
Committee on AIDS

From : Infectious Disease Branch
AIDS Health Education and Risk Reduction
2151 Berkeley Way, Room 715
Berkeley, CA 94704
8-571-2522

Per the request of the Office of External Affairs, I am sending this memo to let you know that I plan to testify as a representative of CDC, to provide medical and scientific information related to AIDS issues to the Senate Select Committee of AIDS.

The title of this presentation is "AIDS: Past, Present, and Future". The meeting will be held on October 26, 1987 and I am scheduled to present an overview of the history and epidemiology of AIDS; roles of the federal, state and local governments; current and future medical and policy issues. In addition, I will be giving the concluding remarks from 11:45 to noon.

If you have any questions pertaining to the above, please give me a call.


Donald P. Francis, M.D., D.Sc.
CDC AIDS Advisor

DPF/ah

cc: Donald O. Lyman, M.D., PMSD
Thelma Frazier, Chief, Office of AIDS
Dan Heincy, External Affairs
Teri Hodges, External Affairs

Assembly Health Committee

CURTIS R. TUCKER

CHAIRMAN

AGENDA

ASSEMBLY HEALTH COMMITTEE HEARING ON ACQUIRED IMMUNE DEFICIENCY (AIDS)

Monday, November 2, 1987

10:00 a.m. to 1:00 p.m.

Inglewood City Hall

10:00 a.m. Opening Statement

Assemblyman Curtis R. Tucker, Chairman
Assembly Health Committee

10:05 a.m. Overview

Donald Francis, M.D., Sc.D.
U.S. Center for Disease Control
AIDS Advisor to the California State Department
of Health Services

10:15 a.m. General Medical Care

Donald Francis, M.D., Sc.D.

Michael Asher, M.D.
Viral and Rickettsial Laboratory
California Department of Health Services

Martin Finn, M.D., Director
Los Angeles County Health Department

R.W. Burgoyne, M.D., Director
Los Angeles County Mental Health Department

Thomas M. Mundy, M.D.
Pediatric Rheumatology and Immunology Department
Cedars-Sinai Medical Center

Charles Gessert, M.D.
Assistant Project Director
California Area Health Education System

11:30 a.m. AIDS in the Minority Community

German Maisonet, M.D., F.A.A.P.
Medical Director
Consultant Minority AIDS Project

Hampton Deslonde, M.D., Director
Dr. Ruth Temple Health Center
Los Angeles County Department of Health Services

Eunice Diaz, Commissioner
Los Angeles County AIDS Commission

12:00 p.m. AIDS In The Workplace

Honorable John Heilman, Councilman West Hollywood

Co-Chairs, Human Relations Commission of West Hollywood
Bill Carey
Sandra Jacoby-Klein

12:30 p.m. Services and Financing

John Mortimer
Director of Governmental Affairs
AIDS Project Los Angeles

Carol Emmot, Ph.D., Executive Director
California Association of Public Hospitals

Diana M. Bonta, R.N., MPH
Deputy Executive Director
Los Angeles Family Planning Inc.

12:50 p.m. Discrimination and Law Enforcement

David Schulman, Esq.
AIDS Discrimination Unit
Los Angeles City Attorney's Office

LEON E. PANETTA, CALIFORNIA
CHAIRMAN

ONE HUNDRED FIRST CONGRESS

THOMAS S. FOLEY, WASHINGTON
MARTY RUSSO, ILLINOIS
ED JENKINS, GEORGIA
MARVIN LEATH, TEXAS
CHARLES E. SCHUMER, NEW YORK
BARBARA BOXER, CALIFORNIA
JIM SLATTERY, KANSAS
JAMES L. OBERSTAR, MINNESOTA
FRANK J. GUARINI, NEW JERSEY
RICHARD J. DURBIN, ILLINOIS
MIKE ESPY, MISSISSIPPI
DALE E. KILDEE, MICHIGAN
ANTHONY C. BEILSON, CALIFORNIA
JERRY HUCKABY, LOUISIANA
MARTIN SABO, MINNESOTA
BERNARD J. DWYER, NEW JERSEY
HOWARD L. BERMAN, CALIFORNIA
ROBERT E. WISE, JR., WEST VIRGINIA
MARCY KAPTUR, OHIO
JOHN BRYANT, TEXAS

U.S. House of Representatives

COMMITTEE ON THE BUDGET

Washington, DC 20515

February 24, 1989

file
BILL FRENZEL, MINNESOTA
RANKING REPUBLICAN MEMBER
WILLIS D. GRADISON, JR., OHIO
WILLIAM F. GOODLING, PENNSYLVANIA
DENNY SMITH, OREGON
WILLIAM M. THOMAS, CALIFORNIA
HAROLD ROGERS, KENTUCKY
RICHARD K. ARMEY, TEXAS
JACK BUECHNER, MISSOURI
AMO HOUGHTON, NEW YORK
JIM McCRERY, LOUISIANA
JOHN R. KASICH, OHIO
DEAN A. GALLO, NEW JERSEY
BILL SCHUETTE, MICHIGAN
HELEN DELICH BENTLEY, MARYLAND

MARTHA H. PHILLIPS,
REPUBLICAN STAFF DIRECTOR
226-7270

JOHN C. ANGELL,
CHIEF OF STAFF
226-7200

Dr. Donald Francis
Centers for Disease Control
2151 Berkeley Way
Room 715
Berkeley, California 94704

Dear Dr. Francis:

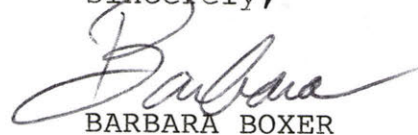
I am writing to confirm my invitation to you to testify before the House Budget Committee's Task Force on Human Resources on Tuesday, March 7, 1989, at 9:30 a.m. in Room 210 Cannon House Office Building.

The Task Force would like you to focus on your particular expertise with regard to the AIDS crisis. You will be part of a panel on "The Changing Face of AIDS" which will include an epidemiologist, a pediatric AIDS physician, a public health official, and other experts involved in education and prevention strategies.

The Joint Committee on Printing requires that all materials and statements submitted for the record be printed single-spaced on legal-size paper. The Task Force would appreciate receiving a copy of your testimony and a brief biographical sketch by March 3, 1989, so that Members can prepare for the hearing. Please send these materials to the House Budget Committee, Room 210 Annex #1, Washington, D.C. 20515 Attn: Lynne Richardson. In addition, it would be very helpful if you could provide at least 50 copies of your testimony at the hearing.

I sincerely appreciate your taking the time to appear before the Task Force. If you have any questions concerning your testimony, please contact Martha Grundmann of the Budget Committee staff at (202) 226-7130. I look forward to seeing you on March 7th.

Sincerely,



BARBARA BOXER

Chair

Task Force on Human Resources

Memorandum

To : Alexander Kelter, M.D.
Deputy Director (Acting)
Public Health
OB8/1253 X2927

Date : October 3, 1987

Subject: Assembly Committee on Health
Testimony

From : Infectious Disease Branch
AIDS Health Education and Risk Reduction
2151 Berkeley Way, Room 715
Berkeley, CA 94704
8-571-2522

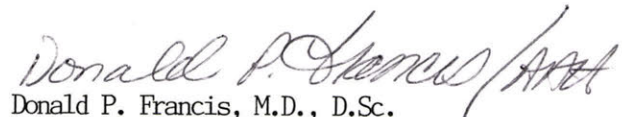
Per the request of the Office of External Affairs, I am sending this memo to let you know that I plan to testify as a representative of CDC, to provide medical and scientific information related to AIDS issues to the Assembly Committee on Health.

There will be two hearings:

October 9, 1987 - San Francisco Public Health Department
101 Grove Street
San Francisco
9:00 am

November 2, 1987 - Inglewood City Hall
1 Manchester Boulevard
Inglewood
10:00 am

If you have any questions pertaining to the above, please give me a call.


Donald P. Francis, M.D., D.Sc.
CDC AIDS Advisor

DPF/ah

cc: Dan Heincy, External Affairs
Thelma Frazier, Chief, Office of AIDS
Don Enderton, External Affairs

Memorandum

To : Alexander Kelter, M.D.
Deputy Director (Acting)
Public Health
OB8/1253 X2927

Date : October 7, 1987

Subject: Briefing on AIDS
Issues for Attorney General of CA

From : Infectious Disease Branch
AIDS Health Education and Risk Reduction
2151 Berkeley Way, Room 715
Berkeley, CA 94704
8-571-2522

Per the request of the Office of External Affairs, I am sending this memo to let you know that I plan to brief the Attorney General of California (as a representative of CDC) on scientific information related to AIDS issues. Among the participants of this briefing are: Leslie Cummings, Assembly Ways and Means Committee, Dr's. Marcus Conant of San Francisco and Michael Gottlieb of Los Angeles.

This briefing will be held on October 15, 1987, in the Attorney General's office, 350 McAllister Street, 6th floor, from 2:30 - 5:00 pm in San Francisco.

If you have any questions pertaining to the above, please give me a call.

Donald P. Francis/AH
Donald P. Francis, M.D., D.Sc.
CDC AIDS Advisor

DPF/ah

cc: Thelma Frazier, Chief, Office of AIDS
Dan Heincy, External Affairs
~~Don Ederton~~, External Affairs

TERI HODGES

Memorandum

To : Alexander Kelter, M.D.
Deputy Director (Acting)
Public Health
OB8/1253 X2927

Date : March 27, 1987

Subject: Assembly Testimony
March 31, 1987

From : Infectious Disease Branch
AIDS Risk Reduction and Education
2151 Berkeley Way, Room 715
Berkeley, CA 8-571-2522

Per the request of the Office of External Affairs, I am sending this memo to let you know that I plan to testify as a representative of CDC, to provide medical and scientific information related to SB 136 (Hart), on March 31, 1987 in Room 437, State Capitol.

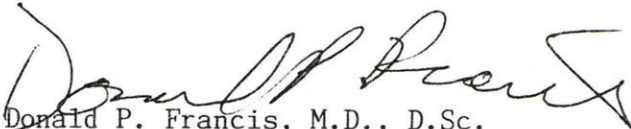
This testimony will cover the following:

AIDS Educational Video Tapes

AIDS Education in the Schools

Federal perspectives on AIDS Education.

If you have any questions pertaining to the above, please give me a call.


Donald P. Francis, M.D., D.Sc.
CDC AIDS Advisor

DPF/ah

cc: Dan Heincy, External Affairs
Donald Lyman, Office of AIDS

Don Engerton
Thelma Frazier, C, OA
Dan Heincy

Memorandum

Author Copy

To : Alexander Kelter, M.D.
Deputy Director (Acting)
Public Health
OB8/1253 X2927

Date : June 29, 1987

Subject: Assembly Testimony
July 8, 1987

From : Infectious Disease Branch
AIDS Risk Reduction and Education
2151 Berkeley Way, Room 715
Berkeley, CA 94704 8-571-2522

Per the request of the Office of External Affairs, I am sending this memo to let you know that I plan to testify as a representative of CDC, to provide medical and scientific information related to AB 563, on July 8, 1987.

My testimony will cover the scientific research aspects in relationship to the AIDS Research Tax Credit.

If you have any questions pertaining to the above, please give me a call.

Donald P. Francis /AH
Donald P. Francis, M.D., D.Sc.
CDC AIDS Advisor

DPF/ah

cc: Don Enderton, External Affairs
Thelma Frazier, Chief, Office of AIDS
Dan Heincy, External Affairs

file PHS policy

OPRR Reports

NIH PHS HHS

June 10, 1988

Dear Colleague:

The attached U.S. Public Health Service (PHS) Policy on Informing Those Tested About HIV Serostatus was signed by the Assistant Secretary for Health, Dr. Robert E. Windom, on May 9. The attached Policy refines and reiterates that which was set forth in the document "Guidelines for Institutional Review Boards for AIDS Studies," in OPRR Reports of December 26, 1984, (page 3).

The 1984 Guidance remains policy, but the discussion concerning notification of seropositives (page 3, Procedures and Documentation of Informed Consent) is made more explicit by the May 9 policy attached here. OPRR has had numerous discussions about HIV-related protocols since 1984 which contributed to the development of this document which was prepared by a Working Group of representatives of all the PHS Agencies.

This Policy applies to all intramural and extramural PHS activities, including both research and health services activities, domestic and foreign. It requires that where HIV testing is conducted or supported by PHS, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided the opportunity to receive appropriate counseling unless the situation calls for an exception under the special circumstances set forth in the Policy.

It will be important for Institutional Review Boards (IRBs) to adopt these provisions in their consideration of HIV-related protocols research. IRBs should address issues of obtaining informed consent, confidentiality, the notification process, the timeliness of informing individuals, and counseling of the individuals and others designated by the individual (e.g., sexual partners).

We hope this information will be helpful. Any comments you have are appreciated.

Yours sincerely,



Charles R. McCarthy, Ph.D.
Director, Office for Protection
from Research Risks
Office of the Director

OFFICE OF

APR 23 1990

Enclosure **AIDS - BERKELEY**



Memorandum

Date . MAY 9 1988

From Assistant Secretary for Health

Subject Policy on Informing Those Tested About HIV Serostatus

To PHS Agency Heads

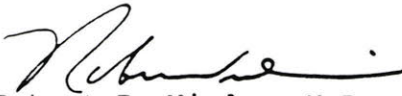
I am transmitting to you the attached "Policy on Informing Those Tested About HIV Serostatus," developed by the Working Group on Ethical and Legal Issues Related to AIDS, PHS Executive Task Force on AIDS. I fully concur with this policy and ask that you disseminate it to appropriate staff in your Agency.

The policy mandates that when HIV testing is conducted or supported by PHS, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided with the opportunity to receive appropriate counseling. This policy applies to all intramural and all extramural PHS activities, including both research and service activities, domestic and foreign.

In order to implement mandatory notification as defined in this policy, I ask that each Agency Head insure that both intramural and extramural Institutional Review Boards, adjudicating on HIV human subject studies, design protocols for informing participants in studies involving HIV testing of their positive antibody status.

The protocols should address: issues of confidentiality; the notification process; access to the information at hand; the specific timing between the initial positive test result and its confirmation; the timing between the test result and informing the individual; the structure for counseling of the seropositives; and provisions for transmitting this information to known sexual partners. I recognize that in some instances, specific agency needs should be addressed in developing the protocols.

I appreciate your cooperation as we move to include this policy in PHS AIDS activities.


Robert E. Windom, M.D.

Attachment

POLICY ON INFORMING THOSE TESTED ABOUT
HIV SEROSTATUS

Policy and Applicability

It is the policy of the Public Health Service (PHS) that when HIV testing is conducted or supported by PHS, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided with the opportunity to receive appropriate counseling. This policy applies to all intramural and to all extramural PHS activities, including both research and service activities, domestic and foreign. Individuals may not be given the option "not to know" the result, either at the time of consenting to be tested or thereafter. This policy does not apply to testing situations in which subjects consent to be tested but specimen results cannot be linked to individual subjects by anyone other than the subjects themselves. The PHS encourages testing facilities to advise test subjects to obtain test results and to abstain from risk behaviors.

Exceptions

1. Pertaining to an Individual

Where there are compelling and immediate reasons that justify not informing a particular individual that he or she is seropositive, e.g., indication that an individual would attempt suicide, the particular individual need not be informed of HIV test results. When this exception is made to the policy of informing individuals, the details of the exception shall be documented by the responsible individuals at the testing facility. If this exception is involved in the context of a research study, the principal investigator

shall promptly report the exception to the local Institutional Review Board (IRB) without identifying the individual.

2. Pertaining to Protocol Design

Because circumstances may exist in which extremely valuable knowledge might be gained from research involving subjects who would be expected to refuse to learn their HIV antibody results, an exception included in the protocol design may be proposed to the IRB reviewing the research proposal. The IRB shall consider the particular circumstances of the research study, the characteristics of the target research subjects, and other factors, and may approve a testing procedure that would allow research subjects to participate without being informed of their individual results. In proposing such an exception, the investigator must demonstrate to the satisfaction of the IRB that (a) research subjects will be informed of their risk of infection; (b) research subjects will receive risk reduction counseling whether or not they receive their test results; (c) there is good reason to believe that a requirement for test result notification would significantly impair collection of study information that could not be obtained by other means; and (d) the risk/benefit ratio to individuals, their partners, and society will be periodically reevaluated by the IRB so that the study might be revised or terminated if it is determined that it is no longer justifiable to allow subjects to continue to participate without receiving their HIV test results.

3. Pertaining to Foreign Sites

Activities conducted at foreign sites should be carefully evaluated to account for cultural norms, the health resource capabilities and

official health policies of the host country. If a research protocol review is involved, the reviewing IRB must consider if any modification to the policy is significantly justified by the risk/benefit evaluation of the research. The IRB might wish to seek expert advice, e.g., local public health experts, in evaluation of these projects.

Review of Exceptions

The Agency Head (or designee) must specifically approve any proposed exception described under 2 or 3 above that is to be funded or conducted by the PHS agency whether a research activity or a service activity and whether domestic or foreign.

For research activities under 2 or 3, IRB approval must be obtained before the approval of the Agency Head is sought. In addition, the Office for Protection from Research Risks (OPRR), NIH, is to be notified of the requested exception prior to or simultaneous with request for approval for an exception from the Agency Head.

Assessment of Current Activities

Any ongoing PHS activity that currently provides for an option "not to know" shall implement this policy for all persons tested hereafter. Individuals tested prior to the issuance of this policy, whose informed consent was given under the condition that they may choose not to learn their test results, may continue to decline to be informed. Every reasonable effort should be made to encourage such individuals to learn their results, however, and the individuals should be counseled about risk behaviors. The appropriate Agency Head, and OPRR if a research activity is involved, shall be informed of such ongoing activities.

Page 4

In ongoing HIV-related research studies, no additional research subjects may be entered as participants without being required to be informed of their results unless exceptions are approved by the IRB and Agency Head, as described above.

Counseling

Any person tested for HIV infection should receive the results of his or her tests and counseling in a timely fashion from an individual qualified to provide test counseling and partner notification services.

Guidance Concerning HIV/AIDS Research

The Office of Protection from Research Risks, The National Institutes of Health (NIH), has prepared a document entitled, Guidance for Institutional Review Boards for AIDS Studies. It is intended to provide guidance concerning studies involving HIV/AIDS which are subject to the Department of Health and Human Services (HHS) Regulations for the Protection of Human Subjects 45 CFR 46. The document deals with general conditions, procedures, and documentation of informed consent, along with special precautions to preserve confidentiality. The document clearly states that subjects are to be informed if tests confirm the presence of HIV antibodies in their blood. A copy of the AIDS Guidance is attached.

OPRR Reports

NIH PHS HHS

GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS FOR AIDS STUDIES

This document is intended to provide guidance concerning studies involving acquired immune deficiency syndrome (AIDS) which are subject to the Department of Health and Human Services (HHS) Regulations for the Protection of Human Subjects, 45 CFR 46. Subpart A of these regulations contains general provisions which apply to all research covered by the regulations. Subparts B, C and D, require additional protections for fetuses, pregnant women, prisoners and children. These additional protections must be observed whenever applicable.

Additionally, the Food and Drug Administration (FDA) regulations, 21 CFR 50 and 56, pertaining to informed consent and Institutional Review Boards (IRBs) and 21 CFR 312 regulations pertaining to new drugs for investigational use, must be observed whenever AIDS studies are subject to FDA jurisdiction. Insofar as the FDA regulations pertain to the membership requirements and functions of IRBs, FDA and HHS regulations are essentially congruent.

Because of the special sensitivity of AIDS research, IRBs are cautioned to exercise particular care in observing all applicable regulatory provisions. IRBs have a responsibility to see that risks to subjects are minimized consistent with sound research design. Whenever appropriate, procedures already being performed on subjects for diagnostic or treatment purposes should be used. IRBs should determine that risks to subjects are reasonable in relation to benefits and the importance of the knowledge that may reasonably be expected to result. The IRBs have primary responsibility for making certain that the informed consent process is properly designed for each research project and that accurate and complete information is provided to subjects.

For regulatory purposes [HHS at 45 CFR 46.102(f)] a human subject means a living individual, about whom an investigator conducting research obtains (1) data through intervention or interaction with the investigator, or (2) identifiable private information. Some research designs may involve only the study of existing data, documents, records, pathological specimens or diagnostic specimens, and in these types of designs, if information is recorded by investigators in such a manner that subjects cannot be identified directly or through identifiers, HHS regulations are not applicable. When reviewing studies based on such existing data, documents or specimens, it is sufficient for the IRB to determine that there is no link between the item under study and any living human being.

IRBs should exercise meticulous care in ensuring accurate and complete informed consent procedures and documentation essential to providing protection for the rights and welfare of human subjects. Special attention must be given to implementing the informed consent requirements of 45 CFR 46.116 and 46.117 and 21 CFR 50.25 and interpreting these requirements in a manner that is appropriate for AIDS research. These portions of the regulations are attached at Tab A.

To ensure adequate review of AIDS studies IRBs may wish to consult with persons who have special expertise and with persons who are qualified to represent the interests of the subject population.

The Assistant Secretary for Health has provided information to Public Health Service (PHS) officials reminding them of the importance of informed consent in AIDS research. This information is attached at Tab B.

GENERAL CONDITIONS OF INFORMED CONSENT

No investigator may engage in human subjects research until legally effective informed consent of the subjects (or the subjects' legally authorized representative) is obtained. Informed consent procedures are to be designed to provide subjects with ample opportunity to consider whether or not to participate. Subjects must be free from coercion and undue influence. The information given to subjects is to be in language understandable to them, and must not include exculpatory language that appears to make the subjects waive any legal rights or that appears to release the investigator, institution or sponsor conducting the research from liability.

IRBs should give careful consideration to the circumstances under which participants may be recontacted for follow-up studies. New informed consent procedures will be employed if additional studies not addressed by the first informed consent process are to be performed involving materials or data collected in the original study.

PROCEDURES AND DOCUMENTATION OF INFORMED CONSENT

IRBs are expected to see that each of the basic elements of informed consent, 45 CFR 46.116(a) and 21 CFR 50.25(a), is included in the informed consent process and that additional elements described in 45 CFR 46.116(b) and 21 CFR 50.25(b) are included whenever appropriate. Also an IRB may require that information, in addition to that required in these sections, be given to the subject as part of the informed consent process, when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

Ordinarily, informed consent is recorded by the use of a written informed consent document that is approved by the IRB and signed by the subject. The subject signing the document is to be given a copy. The informed consent document must contain all the basic elements of informed consent and the additional elements when appropriate. It may be read to the subject of the research, but there must always be a chance for the subject to read it before signing.

The informed consent document must identify persons to contact for answers to questions about the research and the research subjects' rights and whom to contact in the event of a research-related injury.

Informed consent information must include a statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. Investigators and the IRB must be certain that these conditions can actually be met before asking individuals to participate.

Subjects are to be informed if tests confirm the presence of HTLV-III antibodies in their blood. Careful attention is to be given to the methods employed to inform subjects of positive findings. Persons providing this information should be qualified to impart sensitive information, alert to privacy and confidentiality issues, and prepared to provide subjects with references for additional counseling.

IRBs must make sure that significant new findings developed during the course of the research which may relate to subjects' willingness to continue to participate are provided to subjects in a timely fashion.

CONFIDENTIALITY

Perhaps the most sensitive aspect of AIDS research from the perspective of the rights and welfare of the subjects is the matter of confidentiality. 45 CFR 46.116(a)(5) and 21 CFR 50.25(a)(5) require a statement of the extent to which confidentiality of records identifying the subject will be maintained.

Improper disclosure could have the most serious consequences for research participants, by threatening family relationships, job security, employability, or ability to obtain credit or insurance. In light of these risks, special precautions should be taken to preserve confidentiality, and potential subjects should be advised with care of the limits of that confidentiality, so they can make thoughtful, informed decisions, in light of their own circumstances, as to whether to participate.

Each study is to be designed with administrative, management and technical safeguards to control authorized use and disclosure of information and to protect against unauthorized disclosure. Where identifiers are not required by the design of the study, they are not to be recorded. If identifiers are recorded, they should be separated, if possible, from data and stored securely, with linkage restored only when necessary to conduct the research. No lists should be retained identifying those who elected not to participate. Participants must be given a fair, clear explanation of how information about them will be handled.

As a general principle, information is not to be disclosed without the subject's consent. The protocol must clearly state who is entitled to see records with identifiers, both within and outside the project. This statement must take account of the possibility of review of records by the funding agency, and by FDA officials if the research is subject to FDA regulations (21 CFR 50).

IRBs should consider what information will be recorded in the subjects' medical records, and may wish to minimize the recording of data from AIDS-related studies in the medical records. Some states or other jurisdictions may require AIDS to be reported and may require followup. Participation in research does not exempt compliance with those laws, but potential study participants must be fully informed of laws requiring disclosure of information before they volunteer for the studies.

IRBs should take account of the possibility of attempts under compulsory legal process to force disclosure of records, how such attempts will be responded to and whether individuals will be notified of such attempts. The IRB should consider and establish procedures for information disclosure in emergency situations involving the health either of research subjects or others. Whether and how to notify subjects' physicians of findings about a subject should be addressed.

The protocol should contain information setting forth how to respond to requests by third parties who have authorizations for disclosure of information signed by subjects. (Particular attention should be given to handling blanket authorizations that purport to authorize disclosure of all the data relating to a given person.)

The informed consent requirements set forth in the regulations are based on legal decisions, recommendations of national advisory bodies and years of experience and careful application by researchers and research institutional officials. The procedures have been designed to afford full opportunity for potential subjects to make informed decisions and for protection of the rights, welfare and dignity of those who agree to assist in obtaining important knowledge that will benefit society.

The Office for Protection from Research Risks will be pleased to assist investigators and IRBs in the development of informed consent documents. If you would like assistance pertaining to HHS regulations, please contact:

Office for Protection from Research Risks
Office of the Director
Building 31 - Room 4809
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20205

Telephone: 301 496-7005

If you would like assistance concerning biological investigational new drug research related to AIDS under FDA jurisdiction, please contact:

Division of Biological Investigational New Drugs (HFN 823)
Office of Biologics Research and Review
National Center for Drugs and Biologics
Food and Drug Administration
8800 Rockville Pike
Bethesda, MD 20205

Telephone 301 443-4864

12/26/84

§ 46.116 General requirements for informed consent.

Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) Any additional costs to the subject that may result from participation in the research;

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

(6) The approximate number of subjects involved in the study.

(c) An IRB may approve a consent procedure which does not include, which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) programs under the Social Security Act, or other public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible change in or alternatives to those program or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

(d) An IRB may approve a consent procedure which does not include, which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

(e) The informed consent requirements in these regulations are not intended to preempt any applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective.

(f) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law

§ 46.117 Documentation of informed consent.

(a) Except as provided in paragraph (c) of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in paragraph (c) of this section, the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(2) A "short form" written consent document stating that the elements of informed consent required by § 46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

(c) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

§ 50.25 Elements of informed consent.

(a) *Basic elements of informed consent.* In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) *Additional elements of informed consent.* When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.

(3) Any additional costs to the subject that may result from participation in the research.

(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

(6) The approximate number of subjects involved in the study.

(c) The informed consent requirements in these regulations are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed for informed consent to be legally effective.

(d) Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care to the extent the physician is permitted to do so under applicable Federal, State, or local law.

§ 50.27 Documentation of informed consent.

(a) Except as provided in § 58.109(c), informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

(b) Except as provided in § 58.109(c), the consent form may be either of the following:

(1) A written consent document that embodies the elements of informed consent required by § 50.25. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

(2) A "short form" written consent document stating that the elements of informed consent required by § 50.25 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative in addition to a copy of the short form.

INFORMATION PERTAINING TO AIDS RELATED RESEARCH

Because of the wide publicity and special sensitivity associated with AIDS, the following information is provided for research investigators, contractor institutions, Institutional Review Boards (IRBs) and others who share the responsibility for conducting this research in a fashion that is both scientifically rigorous and fully consistent with the rights and the welfare of the subjects involved in the research.

There are three ethical considerations that must be observed in the conduct of this AIDS related research.

1. THERE MUST BE FAIRNESS IN THE DISTRIBUTION OF BOTH RISKS AND BENEFITS OF RESEARCH.

Caution is needed to make sure that age, competence, experience, education, position, life style, etc., are not used to determine eligibility for entrance into a study unless these factors are necessary for the research design.

2. POSSIBLE BENEFITS OF THE RESEARCH MUST BE MAXIMIZED AND POSSIBLE HARMS MINIMIZED.

As the research develops these matters will have to be reviewed from time to time to clarify what benefits may accrue to society as a whole, what benefits may accrue to subjects, and what possible harms may come to subjects. Special care must be taken to establish safeguards to prevent accidental or careless disclosure of confidential information. Improper disclosure could threaten family relationships, job security, employability or ability to obtain credit or insurance.

Therefore, staff persons must be trained to handle information and data with due regard for the rights of subjects.

3. THE RIGHTS OF RESEARCH SUBJECTS TO MAKE CHOICES BASED ON INFORMED JUDGMENTS MUST BE RESPECTED.

These rights must be protected through a consent procedure which:

- (1) is legally effective;
- (2) is obtained in non-coercive circumstances with sufficient time and opportunity for subjects to make an informed decision;
- (3) does not attempt to waive the rights of subjects, or contain exculpatory language which is intended to limit the legal liability of the institution; and
- (4) is presented to subjects in language that is understandable to them--if necessary in language other than English.



Memorandum

Date November 17, 1989

From Director
Division of Commissioned Personnel

Subject Standards of Conduct

To Active Duty PHS Commissioned Officers

Federal employees must have high standards of integrity, honesty and impartiality in order to perform Government business properly and to earn and maintain the confidence of citizens. These standards are expressed in a variety of statutory and regulatory forms. As an active duty commissioned officer of the United States Public Health Service (PHS), you are expected to abide by all applicable standards at all times. Even the appearance of infraction may cause you to be held accountable -- as if there were an actual violation of the standards.

Violations, both apparent and real, have been the basis of administrative and disciplinary reviews. When substantiated, specific disciplinary action follows, its nature being determined in relation to the violation(s).

In actual experience, nothing suggests a widespread problem among Federal employees in general or PHS officers in particular. Apart from rare cases of willful violation of standards, most other situations appear to arise from unfamiliarity with ethical responsibilities. The purpose of this memorandum is to review many of these, providing you general instruction and guidance. However, since it cannot cover all situations, you must become familiar with other rules that apply to your specific employment or personal situation.

To Whom Does This Apply?

All PHS officers on active duty are covered by specific standards of conduct. These include regulations issued by the Department of Health and Human Services (DHHS) on Standards of Conduct, as provided by the Commissioned Corps Personnel Manual (CCPM), Subchapter CC26.1, INSTRUCTION 1. These responsibilities also apply to PHS officers assigned to billets outside of DHHS. If you are in that situation, you must also comply with all additional standards established by that organization.

General Conduct

PHS officers are health professionals. Beyond competence, your behavior must reflect the highest degree of integrity and impartiality. Officers must avoid conflicts of private interests with public duties and responsibilities and must not engage in any conduct prejudicial to the Government.

Compensation for Services Performed

PHS officers are Federal employees, and each is fully compensated for meeting his or her responsibilities. You may not accept other compensation or benefits in exchange for actions you take or agree to take on behalf of the Government. The law provides for fines and imprisonment when these principles are violated. (However, as discussed below, officers may sometime accept items of nominal value.)

Support of Federal Programs

PHS officers have a positive obligation to make Federal programs function as efficiently and economically as possible. You must support them as recognized public policy, be it expressed in law, Executive Order or regulation.

Use of Government Property

PHS officers must use Government property exclusively to advance public purposes. You have a positive duty to protect and conserve Government property, including equipment, supplies, and other property entrusted or issued to you and other Federal employees. You must not use or allow the use of Government property of any kind, including property leased to the Government, for other than officially approved activities.

Financial Interests

PHS officers may have private financial interests, but these may not conflict with your Government duties and responsibilities. It follows that you (1) may not engage in a financial transaction as a result of information obtained through your Government employment nor (2) participate in an official capacity in any matter in which you have, or your spouse or any minor child has, a financial interest. (See section 208 of Title 18, United States Code.)

Receipt of Meals, Favors of Nominal Value, and Travel Expenses

When attending a meeting or participating in an inspection tour on behalf of the Federal Government, PHS officers are permitted to accept food and refreshments of nominal value if offered in the ordinary course of the event and there is no reasonable opportunity to compensate the sponsor for this. You are also permitted to accept unsolicited advertising or promotional materials, such as pens, pencils, note pads, calendars, and other items of nominal intrinsic value.

When attending meetings or providing advisory services on behalf of the Federal Government, PHS officers may accept travel and subsistence from outside sources, but only if approved in advance in accordance with provisions of the Joint Federal Travel Regulations and the travel manual of this Department or the Department concerned.

Use of Information

PHS officers must use information received in the course of meeting their responsibilities to advance public purposes. You must not directly or indirectly make or allow use of official information that is not already available to the general public for the purpose of furthering private interests.

Outside Employment and Other Activity

PHS officers may engage in outside employment or other activity when this is compatible with the full and proper discharge of assigned duties and responsibilities. Your outside activities must not compromise your official functions in any way.

In general, PHS officers are encouraged to engage in professional teaching, lecturing, writing and publishing. It is critical, however, that all information on which the activity relies be in the public domain, not deriving from your Government employment. While these kinds of activities are encouraged, and other forms of professional activity are permitted, they require prior approval. Moreover, other limitations may be imposed by law, Executive Order, regulation, or the approving official.

Conditions for Outside Activities

- a. Prior Approval and Reporting. You must obtain prior approval (Form HHS 520) for outside professional activities and most other outside activities; you must also submit an annual report (Form HHS 521) of these activities by September 10 of each year. A copy of all outside work approvals must be forwarded to the Division of Commissioned Personnel (DCP) for inclusion in your official personnel file. For information pertaining to the need for advance approval, refer to the CCPM, Subchapter CC26.1, INSTRUCTION 1.
- b. Conflicts with Federal Assignments. You must ensure that outside activity does not conflict with current responsibilities or with any past responsibilities that would have provided you with information not in the public domain. For example, information acquired from your being a member of a group charged with technical evaluation of grant or contract proposals limits later "outside" employment while on active duty -- as well as your employment following separation.
- c. Use of Leave in Connection with Outside Activities. PHS officers may be granted leave to engage in outside activities. As with other requests for leave, the discretion to grant leave rests with the leave approving official -- you are not entitled to it. Within these and other limits, you may use station leave to participate in an outside activity for which you are NOT compensated; however, you must take annual leave to participate in an outside activity for which you are compensated if the outside activity takes place at a time that you would ordinarily be scheduled to be at your duty station, or enroute to or from it. (See CCPM, Subchapter CC29.1, INSTRUCTION 1.)
- d. No Other Federal Employment. While active duty PHS officers may receive permission to pursue outside professional activities, you may not be otherwise employed or compensated by the United States Government. Specifically, active duty PHS officers, like members of the military services, are not entitled to receive any additional pay for performing services for another component of the Federal Government. Moreover, the Comptroller General has further determined that active duty PHS officers who receive public funds for which they are not otherwise entitled acquire no right to those funds and are liable to make restitution to the Federal Government.

Holding Office in Professional Societies

PHS officers may join professional societies and be elected or appointed to offices in them. Activity in professional associations is generally mutually desirable from the point of view of DHHS, the association, and yourself. However, you must avoid any real or apparent conflict of interest in connection with such membership. In addition, certain office-holding activities in professional associations require advance administrative approval. (See Subpart F, 73.735-707 of the Department's Standards of Conduct).

Acceptance of Awards

PHS officers may accept an award for a meritorious public contribution or achievement given by a charitable, professional, social, nonprofit educational, recreational, public service, or civic organization. You may not accept a gift, present, decoration or other items from a foreign government except as authorized in the Standards of Conduct, Subpart F, 73.735-506. You must receive prior authorization from DCP before accepting gifts, presents, decorations or other items from a foreign government.

Personal Responsibilities

PHS officers must also meet a variety of personal obligations.

- a. Abuse of Alcohol and other Substances. A PHS officer's conduct must not be affected by the use of alcohol or other substances not used under the supervision of a physician. If such a situation arises, the officer is expected to take appropriate corrective action. Requests for assistance in gaining access to treatment programs will be handled confidentially and in accordance with applicable provisions of Federal statutes and regulations. However, failure to deal adequately with the problem causing unacceptable job performance and/or misconduct may subject the officer to appropriate administrative action as set forth in CCPM, Subchapter CC29.3, INSTRUCTION 8, and those referenced, below, in connection with disciplinary actions.
- b. Indebtedness. PHS officers must meet their personal financial obligations in a proper and timely manner, especially those imposed by law such as child support. Failure to do so violates DHHS policy and may be cause for official disciplinary action.

Other

There are various other statutory provisions in the DHHS Standards of Conduct governing the conduct of present and former employees relating to prohibited activities, e.g., sexual misconduct, bribery, graft, gambling on Government property, disloyalty, disclosure of classified material, or certain types of political participation. If you need a copy of this, refer to the CCPM, Subchapter CC26.1, INSTRUCTION 1, or consult with administrative officials at your duty station.

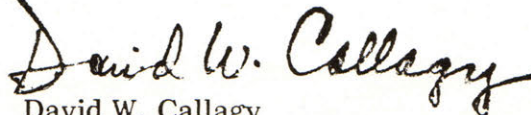
Disciplinary and Other Remedial Actions

PHS officers who violate, or appear to violate, the standards of conduct will be disciplined by their agency, the DCP, or the Surgeon General, as appropriate, in addition to any penalty prescribed by law. Some types of disciplinary action that may be imposed include issuing a letter of reproof or letter of reprimand (CCPM, Subchapter CC46.4, INSTRUCTION 1). More severe infractions could result in reduction in grade, forfeiture of eligibility for promotion, involuntary separation or retirement, possibly under less than honorable conditions following a review by a Board of Inquiry (CCPM, Subchapter CC23.7, INSTRUCTIONS 1, 4 and 6; Subchapter CC23.8, INSTRUCTIONS 3 and 4; and Subchapter CC46.4, INSTRUCTION 1). Remedial action to end real or apparent conflicts of interest may include changes in assignment, divestment of conflicting interest, or disqualification for particular assignment(s). This can further involve changes in pay and allowances that are associated with specific assignments and locations.

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The foregoing is provided, as stated at the outset, to provide you with general guidance. No single general instruction can cover all possible situations. If you need further clarification, we ask that you first contact officials in the program/agency to which you are assigned. We will work with you and them to resolve any uncertainties. If you need to contact the DCP, please do so either in writing or by phone (FTS/301 443-3067.)

Thank you for your diligence in reviewing this material -- and for your service as a commissioned officer in the United States Public Health Service.



David W. Callagy
Captain, USPHS

cc: Agency Representatives
Agency Liaisons