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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Office of Disease Prevention and Health Promotion
Washington DC 20201

- let Patsy Fleming know Dr. following up on this —

- Send to Jim Cellucci with note "what's going on to clarify these issues?" —

Spoke w/ Dorinda in Mr. Fleming's office on 7/6/93.

Bob —

① DRAFT MEMO FROM KLE TO J. CELLUCCI ASKING FOR INPUT/COMMENT/STATUS BY COB TUES.

AIDS Action foundation

MEMORANDUM

To: Jim Buehler

From: Jeff Levi jl

Re: Program Announcement 343 "Evaluation of Human Immunodeficiency Virus (HIV) Infection Reporting Systems"

Date: June 28, 1993

cc: Jim Curran, Kristine Gebbie, Patsy Fleming

This memo is pursuant to our telephone conversation on June 23rd regarding my concerns about the draft program announcement for evaluating reporting systems. I apologize for the delay in getting written comments to you but I have been out of town since our conversation.

I am pleased that the CDC has moved forward with an evaluation of reporting systems. This was a major recommendation of the Foundation's report on named reporting. However, as we have discussed on numerous occasions, how the evaluation is conducted is critical to its moving the policy debate forward.

There are three elements that I believe need to be corrected in the program announcement for this to be a valuable use of taxpayer dollars. I was glad that, in our conversation last week, you agreed to pull the announcement from the review process at PHS to assure that it reflected the original intent of this undertaking.

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First, and most importantly, *the program announcement does not make clear that the CDC and its academic collaborator will develop a standard protocol for evaluating different named reporting systems.* As currently written, it appears that each state will develop its own protocol. Unless the same questions are asked across state lines and across systems of reporting, we will not have comparable data with which to evaluate the various systems. And unless non-participants are developing the protocol, the objectivity of the process may be called into question. It clearly would be of value for states to identify additional questions they may wish to evaluate according to their own needs, but the centerpiece of this study must be a standard protocol.

Second, the questions asked regarding named reporting and epidemiologic monitoring on page 4 are not the right ones. As you say on page 2, "as a surveillance tool, HIV infection reporting should provide a minimum estimate of the number of known HIV-infected persons and can be used to monitor trends in particular populations...for public health planning." The relevant questions to

ask, then, are whether named reporting provides this information as well or better than other forms of reporting *or other surveillance tools* such as seroprevalence data. The criteria on page 4 -- completeness and timeliness of reporting, elimination of duplicate reports, etc. -- are not the relevant measures of the value of named reporting for epidemiologic monitoring.

Third, the question associated with referral to therapy and services is also misstated. Determining the proportion of persons who were referred and received care as a result of follow-up to a positive HIV infection report assumes that referral is a goal of reporting. It seems more appropriate to ask each state to describe its case management system for people with HIV infection, regardless of how they are identified, and to determine the impact of named reporting on the success of that case management system. It might also be interesting to see if there is any correlation between named reporting and successful case management programs.

As you know, I believe these concerns are central to the validity of this evaluation. I certainly hope that we can address them expeditiously.

DRAFT

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[PROGRAM ANNOUNCEMENT NUMBER 343]

EVALUATION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION REPORTING SYSTEMS

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DRAFT

Department of Health and Human Services

Centers for Disease Control and Prevention

[PROGRAM ANNOUNCEMENT 343]

EVALUATION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION REPORTING SYSTEMS

Introduction

The Centers for Disease Control and Prevention (CDC) announces the availability of fiscal year (FY) 1993 funds for a competitive cooperative agreement program to evaluate the uses of HIV infection reporting systems for epidemiologic monitoring and to evaluate their public health impact on programs that provide HIV prevention, medical, and social services for HIV infected children, adolescents, and adults.

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of *Healthy People 2000*, a PHS-led national activity to reduce morbidity and mortality and improve the quality of life. This announcement is related to the priority of HIV Infection. (For ordering a copy of *Healthy People 2000*, see the section WHERE TO OBTAIN ADDITIONAL INFORMATION.)

Authority

These cooperative agreements are authorized under Sections 301(a) and 311 of the Public Health Service Act (42 U.S.C. 241[a] and 243), as amended. Applicable program regulations are found in 42 CFR Part 52, Grants for Research Projects.

Eligible Applicants

Assistance will be provided only to official public health agencies of states and their bona fide agents or instrumentalities. This includes the District of Columbia, American Samoa, the Commonwealth of Puerto Rico, the Virgin Islands; the Federated States of Micronesia, the Northern Mariana Islands, the Republic of the Marshall Islands, the Republic of Palau; and the following cities and county only: the cities of Chicago, Houston, Philadelphia, New York, San Francisco, and the County of Los Angeles.

Availability of Funds

Approximately $1,300,000 is available in (FY) 1993 to fund four to six awards. It is expected that the average award will be $250,000, ranging from $100,000 to $300,000. It is expected that the awards will begin on or about September 30, 1993, and will be for a 12-month budget period within a project period of up to 3 years. Funding estimates may vary and are subject to change. Continuation awards within a project period will be based on satisfactory progress and the availability of funds.

Background

Since 1981, CDC has collected case reports of acquired immunodeficiency syndrome (AIDS). AIDS is reportable in all 50 states, the District of Columbia, and U.S. territories and trusts. The AIDS case surveillance data base has been a vital public health resource in monitoring the course of the epidemic and in projecting the future impact of the disease. However, AIDS surveillance provides information only on severe HIV disesse and because of HIV's long latency period, provides limited information on recent changes in HIV transmission.

To improve public health planning and to allow interventions to be offered earlier in the course of the disease (i.e., before the onset of AIDS), numerous states have passed statutes mandating the reporting of persons infected with HIV. As of March 1, 1993, 25 states had instituted confidential named reporting of persons with HIV infection (subsequently referred to as named reporting). In addition, some states have adopted alternatives to named reporting. The most common alternative is anonymous reporting, with no unique identifier or other system to eliminate duplicates in reporting. Other alternatives to named reporting use a unique identifier or other system to eliminate duplicates. However, little information is available on the use and effectiveness of these reporting systems to monitor the HIV epidemic and prevent transmission.

In evaluating HIV infection reporting systems in adult/adolescent and pediatric populations the following three aspects must be considered:

<u>Epidemiologic Monitoring</u>

As a surveillance tool, HIV infection reporting should provide a minimum estimate of the number of known HIV-infected persons and can be used to monitor trends in particular populations (e.g., children, adolescents, women of child-bearing age) for public health planning.

Referrals for therapy and services

While surveillance cannot provide case management, early diagnosis and treatment is an important outcome of public health surveillance systems. This aspect involves the effectiveness of the surveillance systems in linking persons reported with HIV infection to prevention and treatment services.

Impact on persons' willingness to access testing and other services

Perceptions and attitudes concerning reporting requirements and confidentiality of information reported to surveillance programs may affect an individual's decision to be tested. Fear of potential discrimination and other motives may deter individuals from seeking HIV testing and thus limit the public health usefulness of HIV infection reporting systems. This aspect involves the impact of testing policies and options and reporting requirements (i.e., named, anonymous, or other alternative) on the willingness of persons to seek testing.

Purpose

The purpose of these awards is to assist state/local health departments in evaluating HIV infection reporting systems (named, anonymous, or other alternatives) for 1) their usefulness in epidemiologic monitoring, 2) their ability to link HIV-infected individuals to prevention, medical, and social support services, and 3) the impact of HIV testing and reporting policies and options on the willingness of persons to seek testing services. Named reporting systems are those which require HIV infection reporting by name. Anonymous reporting does not require a name or unique identifier which would allow the elimination of duplicate reports. Other alternatives to named or anonymous reporting use a unique identifier or other system to eliminate duplicate reports.

Program Requirements

In conducting activities to achieve the purpose of this program, recipient shall be responsible for the activities under A, below, and CDC shall be responsible for conducting activities under B, below:

A. Recipient Activities

1. Implement methods for evaluating the three aspects of HIV infection reporting systems listed above. This evaluation should include the impact of the surveillance system on persons in all demographic (age,

race/ethnicity and sex) and transmission categories. Applicants may evaluate either named or alternative systems alone or may compare named and alternative systems. Examples of activities for each aspect include:

Epidemiologic monitoring

- Assess the completeness and timeliness of reporting, the system's ability to eliminate duplicate reports, the validity of HIV infection report information, the system's ability to facilitate follow-up investigations, and the impact of the reporting system on AIDS surveillance (e.g., does HIV reporting affect the timeliness and completeness of AIDS case reporting?).

Referrals to therapy and services

- Determine the proportion of persons who were referred and received care as a result of health department follow-up initiated by a positive HIV infection report, by source of report (e.g., physician, counseling and testing site, laboratory, community-based organization).

- Monitor persons and families (in the case of HIV infected children) to determine if family members and other close contacts have been offered counseling and testing and medical/social support services.

Impact on persons' willingness to access testing and other services

- Assess perceptions and attitudes of health care providers and persons seeking HIV testing and related medical services concerning testing options (e.g. named, anonymous, or other alternatives) and reporting requirements.

- Monitor trends in HIV counseling and testing and reporting by type (confidential, anonymous, or other alternative) and by test site, (e.g., public, private, out-of-state testing services,), in relation to changes in policy, especially in areas that have recently adopted named HIV infection reporting.

2. Involve established community groups that have the trust of the affected populations in developing the

study protocol and in implementing and evaluating the study. Their participation can improve study planning and implementation, and increase community acceptance of the study outcomes.

3. Participate in CDC-sponsored national planning and implementation meetings related to HIV surveillance and evaluation. Participation will be supported through travel funds awarded in the cooperative agreement.

4. Participants using named HIV infection reporting will be required to report HIV infection cases (without identifiers) to CDC using the CDC software and HIV/AIDS report forms (or facsimiles that include all data elements in the CDC standardized report form). Those with alternatives to named reporting systems are encouraged to use the CDC software and forms whenever possible. Otherwise, data should be submitted to CDC in a compatible form. Additional data collection procedures and forms may be developed to supplement data collected by the HIV/AIDS surveillance report form. In addition, participants may collect information specific to local needs.

5. Develop and share with CDC a data base tailored to the individual project. Access to this data base must be limited to ensure confidentiality of persons with HIV infection or AIDS. This data base must be protected from involuntary disclosure by state law or regulation.

6. Analyze data and present results.

B. CDC Activities

1. Assist in designing and conducting the projects, including providing technical guidance in developing study protocols and data collection forms, training and pretesting as necessary, and designing of data management systems.

2. Identify a co-collaborator from a private, academic, or other non-governmental organization to assist with protocol development and oversight of the project, especially with activities related to evaluating the impact of HIV testing policies and reporting systems on persons' willingness to access testing and other services.

3. Compile and analyze data from recipients and present aggregate results.

Technical Reporting Requirement

Progress reports are requested semiannually. The first report must be submitted with the noncompeting continuation application. The second report must be submitted on or before March 31 of each year of Federal support. The final progress and financial status reports are required 90 days after the end of the project period.

Application Content

Application Narrative

Applications must include a narrative that details the background and need for project support. The narrative must be limited to 10 pages excluding addenda items.

Applicants should provide a description of how their current (or proposed) HIV infection reporting systems can address the three major aspects of HIV infection reporting described in the Background section. For example, applicants may propose to address these aspects evaluating named reporting systems only, alternative systems only, or by comparing named and alternative systems. Regardless of the type of reporting system, all applicants are required to address all three aspects of evaluating HIV infection reporting systems, and their impact on all demographic (age, race/ethnicity, and sex) and transmission categories. In addition, the following should be included in the application:

1. Provide numbers and characteristics of persons with AIDS and HIV infection identified through AIDS case surveillance and HIV infection reporting (by source of report, e.g., physicians, counseling and testing sites, laboratories) through December 31, 1992; for sites not implementing HIV infection reporting until after 12/31/92, substitute available serosurvey and other appropriate data. In addition, if available, provide estimates of numbers of HIV-infected persons.

2. Describe the HIV infection reporting system and how HIV infection reports are (or will be) used to monitor the epidemic and to provide referrals to medical and social services, including the availability/accessibility of programs to provide such services.

3. Provide a description of HIV testing policies, availability of testing, sources of HIV reports (e.g. counseling and testing sites, physicians, STD clinics), referral policies, and other factors affecting the completeness of HIV reporting.

4. Provide an estimate of the accuracy of reporting of

demographic and exposure category information on HIV-infected persons by source of report, including attempts to verify the accuracy of reports.

5. Describe previous and planned efforts to characterize community perceptions and attitudes regarding HIV testing and reporting options and policies.

6. Provide the current reporting laws/regulations for the applicant's jurisdiction related to reporting of HIV infection, HIV disease, and AIDS. Provide copies of regulations protecting confidentiality of HIV/AIDS reports and related laboratory tests as well as policies regarding release of data, if not contained in the reporting laws.

7. Document and describe the proposed involvement of community groups in the planning, implementation, and evaluation of the project. Include the names and descriptions of the organizations and describe the planned collaboration. Letters of support from all participating organizations should be included.

8. Provide specific, time-framed, and measurable objectives that are consistent with the purpose of the cooperative agreement.

9. Describe the methods that will be used to accomplish the proposed objectives and evaluate progress in meeting the objectives.

10. Describe the proposed staffing for the project including job descriptions for existing and proposed personnel and resumes for each current staff member who will work in the program.

11. Submit a detailed budget and line-item justification that is consistent with the purpose of the program and proposed project objectives.

12. Provide any other information that supports the request for assistance.

Format

Pages must be clearly numbered, and a complete index to the application and its appendices must be included. The original and each copy of the application set must be submitted UNSTAPLED AND UNBOUND. All material must be typewritten with unreduced type on 8 1/2" by 11" paper, with at least 1" margins, and printed on one side only.

Evaluation Criteria

Applications will be reviewed and evaluated on the following criteria:

A. The quality of plans to develop and implement the evaluation project, including how potential surveillance data (e.g., HIV test results, clinical and demographic information) will be identified, accessed, and used, and how the confidentiality of all surveillance data will be protected. The applicant should demonstrate the ability to examine the impact of the reporting system on all demographic and transmission categories. (15 points)

B. Evidence of the applicant's ability to use the HIV infection reporting system for epidemiologic monitoring, including plans to evaluate completeness of reporting, validity of data, and impact on AIDS surveillance. (15 points)

C. Evidence of the applicant's ability to evaluate the use of the HIV infection reporting system to link HIV-infected persons with prevention, medical, and support services, including a source of client-level data (e.g. HRSA's Uniform Reporting System) describing people who are receiving health and social support services and a plan to provide such referrals. (15 points)

D. Evidence of the applicant's ability to evaluate the impact of perceptions and attitudes about testing, confidentiality, and discrimination on the effectiveness of the reporting system for public health monitoring, including how the applicant will avoid biases in sampling persons when assessing perceptions and attitudes about testing options and reporting requirements. (15 points)

E. The extent to which affected communities are to be involved in planning, implementing, and evaluating program objectives, including letters of support from community organizations. (10 points)

F. The applicant's understanding of the objectives of the evaluation and the applicant's ability, willingness, and/or need to cooperate in a study with CDC and other participants, including willingness to use standard data collection forms and software developed by CDC or compatible forms. (10 points)

G. The applicant's current activities in HIV reporting and AIDS surveillance and how they will be applied to achieving the objectives of the evaluation study. Applicant must demonstrate adequate sample size to carry out the activities described above in B, C, and D and provide examples of

hypotheses to be tested (with statistical power associated with sample sizes). (10 points)

H. How the project will be administered, including the size, qualifications, and time allocation of the proposed staff; and the facilities to be used during the evaluation study and a schedule for accomplishing the activities of the evaluation study. (10 points)

I. The extent to which the budget is reasonable, clearly justified, and consistent with the intended use of the funds. (not scored)

Funding Priorities

Sites that reported more than 500 AIDS cases in 1992 (as reported in the CDC HIV/AIDS Surveillance Report, Year-End Edition, published in February 1992) will be given priority for funding. In addition, priority will be given to sites that, as a group, represent at least two of the following categories: 1) sites that implemented a named HIV infection reporting system prior to January 1, 1993 by law or regulation; 2) sites that have recently (since January 1, 1993) implemented named HIV infection reporting by law or regulation; and 3) sites that have implemented or proposed an anonymous or alternative reporting system (which may be in addition to a named reporting system) that can be evaluated for its ability to eliminate duplicate reports.

Executive Order 12372

Applications are subject to Intergovernmental Review of Federal Programs as governed by Executive Order 12372. E.O. 12372 sets up a system for state and local government review of proposed Federal assistance applications. Applicants should contact their state Single Point of Contact (SPOC) as early as possible to alert them to the prospective applications and receive any necessary instructions on the state process. For proposed projects serving more than one state, the applicant is advised to contact the SPOC for each affected state. A current list of SPOCs is included in the application kit. If SPOCs have any state process recommendations on applications submitted to CDC, they should forward them to Edwin L. Dixon, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention (CDC), 255 East Paces Ferry Road, NE., Room 314, Mail Stop E-18, Atlanta, GA 30305, no later than 60 days after the application deadline. All correspondence should reference this Announcement by title or number. The granting agency does not guarantee to "accommodate or explain" state process recommendations it receives after that date.

Public Health System Reporting Requirement

This program is not subject to the Public Health System Reporting Requirements.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 93.944.

Other Requirements

Paperwork Reduction Act

Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

Human Subjects

If the proposed project involves research on human subjects, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR Part 46) regarding the protection of human subjects. Assurance must be provided to demonstrate that the project will be subject to initial and continuing review by an appropriate institutional review committee. The applicant will be responsible for providing assurance in accordance with the appropriate guidelines and form provided in the application kit.

HIV/AIDS Requirements

Recipients must comply with the document entitled "Content of HIV/AIDS-related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions," June 1992, a copy of which is included in the application kit. In complying with the requirements for a program review panel, recipients are encouraged to use an existing program review panel, such as the one created by the state health department's HIV/AIDS prevention program. If the recipient forms its own program review panel, at least one member must be an employee (or a designated representative) of a governmental health department consistent with the Content guidelines. The names of the review panel members must be listed on the Assurance of Compliance Form CDC 0.1113, which is also included in the application kit. The recipient must submit the program review panel's report that indicates all materials have been reviewed and approved.

Application Submission and Deadline

The original and two copies of the application PHS Form 5161-1 (Rev. 7/92) must be submitted to Edwin L. Dixon, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control and Prevention, 255 East Paces Ferry Road, NE., Room 314, Mail Stop E-18, Atlanta, Georgia 30305 on or before July 27, 1993.

1. Deadline: Applications shall be considered as meeting the deadline if they are either:

   (a) received on or before the deadline date; or

   (b) sent on or before the deadline date and received in time for submission to the objective review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

2. Late Applications: Applications that do not meet the criteria in either 1(a) or 1(b) above are considered late applications. late applications will not be considered in the current competition and will be returned to the applicant.

Where to Obtain Additional Information

A complete program description and information on application procedures are contained in the application package. Business management technical assistant may be obtained from Nealean K. Austin, Grants Management Specialist, Grants Management Branch, Centers for Disease Control and Prevention (CDC), Procurement and Grants Office, 255 East Paces Ferry Road, N.E., Room 314, Mail Stop E-18, Atlanta, Georgia, 30305, (404) 842-6508. Programmatic Technical assistance may be obtained from Dale Hu, M.D., M.P.H., Division of HIV/AIDS, National Center for Infectious Diseases, Centers for Disease Control and Prevention, 1600 Clifton Road, Mail Stop E-47, Atlanta, Georgia 30333, (404) 639-2050.

Please refer to Announcement Number 343 when requesting information and submitting an application.

Potential applicants may obtain a copy of *Healthy People 2000* (Full Report; stock No., 017-001-00474-0) or *Healthy People 2000* (Summary Report; Stock No. 017-0001-00473-1) referenced in the Introduction through the Superintendent of Documents, Government Printing Office, Washington, DC. 20402-9325, (202) 783-3238.

AIDS Action foundation

MEMORANDUM

To: John Ward and Jim Buehler

From: Jeff Levi JL

Re: Evaluation of names reporting

Date: April 21, 1993

cc: Jim Curran

I want to follow up on our conversation yesterday regarding the CDC's plans to issue an RFP funding evaluation of mandatory names reporting and alternatives. While we do not agree at this point, I want to thank you for your willingness to talk through these issues.

As I understand your proposal, you would be *increasing funding to states under their cooperative agreements* to examine three areas: (1) to evaluate named HIV reporting systems in terms of their ability to link people with services, to evaluate the epidemiologic usefulness of the data collected, and to evaluate the completeness of the data; (2) to evaluate the impact of the introduction of named reporting on willingness to seek testing in a state(s) that has (have) recently implemented reporting; and (3) to evaluate alternatives to name reporting.

While I completely agree with the objectives of these evaluations, I still believe that these evaluations should be conducted by *independent third parties* such as academic institutions. We are all biased toward wanting to prove that policies we have adopted are valid and effective; asking states to evaluate themselves -- whether they have chosen name reporting or an anonymous system -- will include just such a bias. The area where funding to states is appropriate would be to allow a state to undertake a demonstration program of an alternative to HIV name reporting, but the evaluation should be conducted by a third party.

As an alternative, I propose that the CDC issue an RFP for objective evaluation of reporting programs, asking essentially the same questions posed above that you had planned to be done under the cooperative agreements. In addition, a few states could be funded to implement a demonstration program as an alternative to name reporting, with the CDC or the state contracting with an outside party to do an evaluation. Finally, as part of the contract, the recipient would be required to meet with a representative group of concerned groups and health departments to agree on the specific questions that will be asked. As I mentioned to you, unless there is prior agreement about the general questions that need to be answered, any data -- no matter how valid -- may be subject to the criticism that you did not examine the right questions.

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I think we share the same goal here: getting sound data on which to make good public policy decisions. For there to be trust in the data, there needs to be the reality *and* the perception of objectivity, which can only occur if a neutral party does the evaluation, and there needs to be the some general consensus on the objectives of the data collection, which requires more upfront discussion with many of the people who attended the last meeting in Atlanta.

I hope we can come to agreement on this and move this issue forward. I look forward to hearing from you.