

8166

MOTION NO. _____

A MOTION authorizing the county executive to make a grant application for funds in the approximate amount of \$50,569 for the period March 1, 1991 to February 29, 1992 to study the effectiveness of two HIV counseling strategies in reducing unsafe sex thereby decreasing the spread of HIV.

WHEREAS, the American Foundation for AIDS Research is authorized to make grants of funds to support AIDS related research; and

WHEREAS, the AIDS epidemic continues to impact those practicing unsafe sex in King County; and

WHEREAS, the Seattle King County Department of Public Health is positioned to evaluate how well two counseling strategies will a) motivate men who have sex with men to discontinue unsafe sex and b) prevent relapse among men who have sex with men who currently practice safe sex; and

WHEREAS, the results of this evaluation will provide invaluable information for agencies that fund or provide HIV counseling and testing services, and may help to prevent the further spread of HIV; and

WHEREAS, the council recognizes that the funds secured through an approval of the application by the American Foundation for AIDS Research will support the entire cost of the evaluation.

NOW, THEREFORE, BE IT MOVED by the Council of King County:

A. The King County executive is hereby authorized to make application for funds in the approximate amount of \$50,569 to the American Foundation for AIDS Research to support the evaluation of HIV counseling strategies.

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B. The King County executive is hereby authorized to file and execute such contracts as are required by the grantor:

PASSED this 28th day of January, 1991.

KING COUNTY COUNCIL
KING COUNTY, Washington

Lois North
Chairman

ATTEST:

Gerald A. Peters
Clerk of the Council

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8166

GRANT APPLICATION: INFORMATION AND REVIEW FORM

I. **GENERAL** DATE 12/5/90 County File No. ____

1. Program Title: Effectiveness of Two HIV Counseling Strategies
2. Department: Seattle-King County Dept of Public Health
3. Contact Person: Gary Goldbaum, M.D. Tel. No. 296-4891
4. Program Period: 3/1/91 to 2/29/92 Year 1 of Years 1
5. Number of Grant Funded Employees: 3 ; 1.25 FTE's.

II. **PURPOSE OF PROGRAM**

1. What need is addressed? We do not currently know how effectively counseling programs associated with HIV testing reduce unsafe sexual behaviors. This project evaluates two such counseling/testing programs.
2. When the project is completed what will be gained? We will better understand the extent that counseling reduces unsafe sexual behaviors, thereby decreasing the risk of transmitting HIV.
3. Why should the County engage in this activity? How does this activity relate to current programs and responsibilities? The County currently maintains HIV counseling/testing activities throughout the Department of Public Health with a variety of resources. This evaluation will guide the Health Department in developing more effective counseling/testing programs.

III. **PROGRAM ACTIVITY**

1. Target population: Men who have sex with other men (MSM).
 - a) Who or what will be affected? All MSM who register for HIV testing with the AIDS Prevention Project.
 - b) How many will be served? Approximately 750 annually.
2. Outline proposed work program and time scale.
 - 3/91 - 4/91: Develop and pilot "augmented" counseling procedure to compare with the current counseling procedure.
 - 5/91: Begin recruiting for the study. Randomly assign participants to current or augmented counseling. Participants complete questionnaire initially and every 6 months.
 - 11/91: Begin preliminary analyses of earliest follow-up questionnaires.
 - 2/92: Complete initial data collection and begin final analyses.
3. When the grant funds are expended will the program activity cease? Yes, although HIV counseling and testing will be maintained through regular funding channels.

IV. BUDGET (Amounts applied for)

1. What present and future funding is proposed:

Federal: N/A

State: N/A

Other: The requested award period is 3/1/91 to 2/29/92. The exact split of funds between years has not yet been determined.

Grants Total: \$50,569

County (Cash) N/A

County (In-Kind) N/A

Total \$50,569

2. Source of match: N/A

3. <u>Expenditures:</u>	Personnel	Contracts	Other	Total
Direct Costs	\$38,207	0	\$5,237	\$43,444
Indirect Costs; @ 16.4% of \$43,444				\$ 7,125
Program Total				\$50,569

4. When grant funding ends, what is the annual cost required to:

a) Continue the program? N/A or

b) for C.I.P. projects, operating and maintenance? N/A

V. EVALUATION

Explain how the project will be evaluated; what will be evaluated; who will do the evaluation?

The augmented intervention (to be developed) will be compared with the current standard counseling methods. Questionnaires completed by participants in both groups (augmented vs. standard) will be compared for a number of outcomes using a variety of statistical techniques. In particular, we will examine the extent to which unprotected anal and vaginal sex (approximately 10% of MSM also have sex with women) changes over time for these two groups. Department of Public Health staff (including Gary Goldbaum, the Principal Investigator) will analyze the data and complete all reports.



City of Seattle King County
Norman B. Rice, Mayor Tim Hill, Executive

Seattle-King County Department of Public Health

Bud Nicola, M.D., M.H.S.A., Director

December 4, 1990

Jay Theodore
Grants Officer
American Foundation for AIDS Research
Grants Department
5900 Wilshire Blvd.
Second Floor, East Satellite
Los Angeles, California 90036-5032

Dear Mr. Theodore:

Enclosed find our signed application for the grant "Effectiveness of Two HIV Counseling Strategies" for \$50,569 to examine the effectiveness of two low cost HIV counseling strategies. I am approving the application for these funds contingent upon the review and approval of the project by the county council. This process will take several weeks to complete.

Questions which you may have regarding this application may be directed to Gary Goldbaum, Sr. Staff Physician, Seattle King County Department of Public Health, at (206) 296-4649.

Thank you for the opportunity to submit this application for your consideration.

Sincerely,

Tim Hill
King County Executive

TH:tk:mm

enclosures

cc: Lois North, Chair, King County Council
ATTN: Shelly Sutton, Legislative Section Manager
Pat Steel, Chief Financial Officer
ATTN: Nick Carnevali
Bud Nicola, M.D., Director, Seattle King County Dept of Public Health
ATTN: Ethan Van Eck, Support Services Manager
Patricia McInturff, Regional Division Manager
Terri Kimball, Sr. Public Health Admin. Assistant
Gary Goldbaum, Sr. Staff Physician



AMERICAN FOUNDATION FOR AIDS RESEARCH
RESEARCH GRANT APPLICATION

001412

A. FACE SHEET

Effectiveness of Two HIV Counseling Strategies

1. TITLE OF APPLICATION: do not exceed 52 typewriter spaces

2. I Gary M. Goldbaum MD, MPH 524-62-3500
 P N name degree ss #
 R V Assistant Medical Director 206-296-4649
 I E position title Seattle-King County telephone #
 N S Dept. of Public Health 110 Prefontaine Place S., 6th floor
 C T department street, bldg., room
 I I Regional Health Services Seattle WA 98104
 P G subdivision city, state, zip
 A A
 L T
 O signature date
 R

3. HUMAN SUBJECTS: YES NO DHHS 596 ENCLOSED
 ANIMAL SUBJECTS: YES NO APPROVAL ENCLOSED
 BIOHAZARDS: YES NO APPROVAL ENCLOSED

4. PERIOD OF PERFORMANCE
 3/1/91 through 2/29/92

5. DIRECT COSTS REQUESTED \$ 43,444 INDIRECT COSTS REQUESTED \$ 7,125 TOTAL PROJECT COSTS \$ 50,569

6. PERFORMANCE SITE --> AIDS Prevention Project, 1116 Summit, Seattle WA 98101

Seattle-King County Department of Public Health

7. APPLICANT ORGANIZATION: full legal name

<p>8. I OFFICIAL SIGNING FOR ORGANIZATION: N S Tim Hill T name I King County Executive T title Department of U Executive Administration T dept. I Room 400 King County Courthouse O street, bldg., room N Seattle, WA 98104 city, state, zip (206) 296-3824 telephone # <i>[Signature]</i> 12/4/90 signature/date KING COUNTY EXECUTIVE</p>	<p>9. AWARD MADE PAYABLE TO: Seattle-King County Department of Public Health institution</p> <p>SEND ALL PAYMENTS TO: Mark Leaf financial officer Seattle-King County Department of Public Health department 110 Prefontaine Place S., 6th floor street, bldg., room Seattle, WA 98104 city, state, zip (206) 296-4810 telephone #</p>
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Title of Application: do not exceed 52 typewriter spaces

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	7. Letters of Agreement	<u>27</u>
	8. Consortium Agreements	<u>NA</u>
	9. Charts and Figures	<u>NA</u>
	10. Photographs	<u>NA</u>
	11. Literature Cited	<u>23</u>
J.	APPENDIX (FIVE SETS).	
	NUMBER OF MANUSCRIPTS:	<u>NA</u>
	NUMBER OF PUBLICATIONS:	<u>NA</u>

AMERICAN FOUNDATION FOR AIDS RESEARCH

RESEARCH GRANT APPLICATION

PEER-LANGUAGE ABSTRACT FORM

<u>Key Professional Personnel Engaged on Project:</u>		
<u>Name</u>	<u>Position Title</u>	<u>Dept. and Organization</u>
Gary M. Goldbaum, MD, MPH	Senior Physician/ Assistant Professor	Seattle-King County Dept. of Public Health
Robert W. Wood, MD	AIDS Control Officer	Seattle-King County Dept. of Public Health

1.

TITLE OF APPLICATION: do not exceed 52 typewriter spaces

2. ABSTRACT OF RESEARCH PLAN:

(please underline ten key words)

Since 1986, we have followed a cohort of men who have sex with men (MSMs). These men initially presented for HIV counseling and testing. They have completed questionnaires every six months to assess changes in sexual and drug-using behaviors. Data from this study suggest that there have been substantial changes in behavior over time, but that despite counseling some men continue to engage in high-risk sexual activities while other men relapse from safe to unsafe sexual behaviors. We propose to evaluate the effectiveness of two counseling strategies in 1) motivating MSMs to discontinue unsafe sexual behaviors and 2) preventing relapse among MSMs who currently practice safe sex. MSMs who register for HIV counseling and testing at a Health Department clinic will be randomly assigned to receive either usual counseling or augmented counseling (i.e., usual counseling plus additional strategies). To assure that the interventions will be practical for other publicly funded HIV counseling/testing sites, the interventions will be inexpensive, easy to use, brief, and require limited staff training. Participants will complete questionnaires before receiving counseling and again every six months for at least one year. Outcomes of interest are the stages-of-change in sexual behavior. The proposed research will provide invaluable information for agencies that fund or provide HIV counseling/testing services.

o Do not exceed space provided.

D. Principal Investigator's Name G. Goldbaum

AMERICAN FOUNDATION FOR AIDS RESEARCH
RESEARCH GRANT APPLICATION

PROJECT DESCRIPTION FORM

1.

PROJECT TITLE: do not exceed 52 typewriter spaces

2. LAY-LANGUAGE ABSTRACT OF RESEARCH PLAN:

Since 1986, we have studied a large group of men who have sex with men (MSMs). These men requested HIV counseling/testing services at a Health Department clinic. Responses to questions asked every six months have revealed important changes in sexual and drug-using behaviors over time. However, some men continue to practice unsafe sex while other men relapse from safe to unsafe sex. We want to evaluate how well two counseling strategies 1) motivate MSMs to discontinue unsafe sex and 2) prevent relapse among MSMs who currently practice safe sex. MSMs who register for HIV counseling/testing will be randomly assigned to receive either usual counseling or augmented counseling (i.e., usual counseling plus additional strategies). To assure that the augmented counseling will be practical for publicly funded HIV counseling/testing sites, the strategies will be inexpensive, easy to use, brief, and require limited staff training. Participants will complete questionnaires before receiving counseling and again every six months for at least one year. We will measure actual and intended changes in sexual behaviors. The proposed research will provide invaluable information for agencies that fund or provide HIV counseling/testing services.

3. ONE SENTENCE DESCRIPTION: This study examines how effective two low-cost HIV counseling strategies are in reducing unsafe sex among men who have sex with men.

- o Do not exceed space provided.
- o Single space type.
- o Use language accessible to persons not trained in the sciences.
- o This abstract is meant to serve as a public description of the proposed research and, should an award be made, it will be used as a press release and description in various AmFAR publications.

AMERICAN FOUNDATION FOR AIDS RESEARCH

RESEARCH GRANT APPLICATION

12-MONTH BUDGET

PERSONNEL		TIME		AMOUNT REQUESTED			
NAME	POSITION TITLE	%	HOURS PER WEEK	1. SALARY	2. FRINGE BENEFITS 26%	TOTALS	
Gary Goldbaum	PRINCIPAL INVESTIGATOR	5	2	--	--	--	
Robert Wood	Co-investigator	2	1	--	--	--	
Leigh Krueger	Statistician	5	2	--	--	--	
Ken Fowler	Programmer	8	10/4 mos	2318	603	2921	
Tsilke Pearlman	Analyst	16	10/8 mos	4365	1135	5500	
To be filled	Client clerk	100	40/12 mos	23,640	6146	29,786	
SUBTOTALS ====>				\$ 30,323	\$ 7884	\$ 38,207	
3. CONSULTANT COSTS							
Dr. Roger Roffman and associates will provide services gratis.						\$ 0	
4. EQUIPMENT (itemize)							
Printer: \$850						\$ 850	
5. SUPPLIES AND MATERIALS (itemize by category)							
Postcards 750 @.15 = \$112							
Condoms 8000 @.08 = 640							
Envelopes 3500 @.03 = 105						887	
Labels 4000 @ = 30							
6. TRAVEL							
DOMESTIC		None		subtotal		\$	
FOREIGN		None		subtotal		\$ 0	
7. OTHER DIRECT COSTS (itemize and explain)							
Printing tabloids 3500 @ .75 = 2625							
Postage for 3500 packages @ .25 = 875						3,500	
TOTAL DIRECT COSTS ====>							\$ 43,444
8. TOTAL INDIRECT COSTS							
(maximum 20% of Total Direct Costs) (16.4%)						\$ 7,125	
TOTAL AMOUNT REQUESTED ====>							\$ 50,569

E. 12-month budget

1,2. Personnel

Ken Fowler, programmer. (Request 10 hours/week for four months). The programmer is currently funded at half-time (20 hours/week) through a grant from the Centers for Disease Control. Programming for this project will be needed during the first four months, while the data collection instrument is refined, initial data entered, and reports for clinicians and patients are generated. A programmer is needed to permit modifications to software used for data entry and retrieval in the existing longitudinal study. This position is split with the analyst.

Tsilke Perlman, analyst. (Request 10 hours/week for eight months). The analyst is currently funded at 3/4 time (30 hours/week) through a grant from the Centers for Disease Control. Analysis for this project will commence in the fifth month, initially focusing on baseline data and ultimately including follow-up data. An analyst is needed to produce frequent reports on results, with an emphasis on reducing loss to follow-up. This position is split with the programmer.

To be filled, client coordinator. (Request 40 hours/week for 12 months). No such position currently exists. Request 100% funding for this clerical position to 1) provide orientation and intake services to clients entering the study (i.e., explaining the study and obtaining informed consent), 2) address client questions, 3) manage client scheduling, 4) mail or call appointment reminders, 5) review questionnaires for completeness, and 6) fill and mail intervention packages.

4. Equipment

Printer. Because clients will require individualized letters of introduction and reports, a dedicated high quality printer is needed.

5. Supplies and materials

Postcards needed to remind clients about followup appointments.

Condoms will be mailed to clients as part of the intervention.

Large envelopes will be used to mail intervention packages.

Labels needed to address mailings.

7. Other direct

Printing tabloids which form the basis for the mailed component of the augmented intervention.

Postage to mail intervention packages.

F.

PRINCIPAL INVESTIGATOR: GARY M. GOLDBAUM, MD

AMERICAN FOUNDATION FOR AIDS RESEARCH

RESEARCH GRANT APPLICATION

BIOGRAPHICAL SKETCH

Gary M. Goldbaum, MD, MPH

Assistant Medical Director,
AIDS Prevention Project

DOB: 3/20/52

EDUCATION

University of Colorado	BS	1973	Chemistry
University of Colorado	MD	1978	Medicine
University of Washington	MPH	1989	Epidemiology

RESEARCH AND PROFESSIONAL EXPERIENCE

Adjunct Assistant Professor, Department of Family Medicine, School of Medicine, University of Washington, Seattle WA

January 1990 to present

Assistant Professor, Department of Epidemiology, School of Public Health & Community Medicine, University of Washington, Seattle WA

November 1989 to present

Assistant Medical Director, AIDS Prevention Project, Seattle-King County Department of Public Health, Seattle WA

July 1989 to present

Health Officer, Thurston County Department of Public Health And Social Services, Olympia WA

January 1987 to July 1989

Medical epidemiologist, Epidemiology Program Office, Centers for Disease Control, (assigned to the Washington State Department of Social and Health Services), Olympia WA

August 1986 to July 1987

Medical epidemiologist, Center for Health Promotion and Education, Centers for Disease Control, Atlanta, GA

July 1984 to July 1986

Solo family practitioner, National Health Service Corps, Townshend, VT

August 1981 to June 1984

PUBLICATIONS

Goldbaum GM, Remington PL, Powell KE, Hogelin GC, Gentry EM: Failure to use seat belts in the United States: the Behavioral Risk Factor Surveys. JAMA 1986;255:2459-2462.

Goldbaum GM: Seat belt use--United States. Morbidity and Mortality Weekly Report 1986;35:301-304.

Goldbaum GM, ed. Focal Points (issue devoted to occupant restraints) 1986;3.

Goldbaum GM, Kendrick JS, Hogelin GC, Gentry EM, The Behavioral Risk Factor Surveys Group: The relative impact of smoking and oral contraceptive use on women in the United States. JAMA 1987;258:1339-1342.

Goldbaum GM, Ostroff S, Novotny T: The costs of smoking for Washington State. Washington Public Health 1989;7:37-38.

Chen RT, Goldbaum GM, Wassilak SGF, Markowitz LE, Orenstein WA: An explosive point-source measles outbreak in a highly vaccinated population: Modes of transmission and risk factors for disease. Am J Epidemiol 1989;129:173-182.

Goldbaum GM, Milham S, Jr, Daling JR: Risk factors for gastroschisis. Teratology 1990;42:397-403.

Goldbaum GM: AIDS in California medicine: Changing experiences, knowledge, and geographic distribution (Commentary). J Family Practice (In press).

BIOGRAPHICAL SKETCH

ROBERT WILLIAM WOOD, MD

**AIDS Control Officer, Seattle- DOB: 1/19/43
King Co. (WA) Dept. of Public Health**

EDUCATION

<u>Hamilton College</u> , Clinton, New York	BA	1965	Mathematics
<u>University of Rochester</u> , Rochester, NY	MD	1970	Medicine
<u>Strong Memorial Hospital</u> , Rochester, NY	Student Fellow	1968-9	Pathology Dept.
<u>Cambridge University</u> , Cambridge, England	Amer. Cancer Society Fellow	1969	Dept. of Medicine
<u>Dartmouth-Hitchcock Hospitals</u> , Dept. of Medicine, Hanover, New Hampshire	R1	1970-71	Internal Medicine
	R2	1971-72	Internal Medicine
	Fellow, PROMIS Lab	1974-75	Internal Medicine
<u>University of Washington</u> , Seattle, WA	Senior Fellow	1975-76	Dept. of Medicine

RESEARCH AND PROFESSIONAL EXPERIENCE

- Deputy Chief and Director of Research, Dept. of Health Services-Research, USPHS Hospital, Seattle, WA, 1975 to November 1981.
- Chief, Division of Health Services Research, Dept. of Medicine, Pacific Medical Center, November 1981 to February 1, 1986.
- Associate Medical Director for Quality Assurance/Utilization Review, Pacific Medical Center, January 1984 to February 1, 1986.
- Medical Staff, Dept. of Medicine, Pacific (formerly Public) Health Associates of Seattle, and Pacific Medical Center (formerly Seattle Public Health Hospital), November 1981-present.
- Attending Physician, AIDS Clinic and Associate Medical Staff, Harborview Medical Center, Seattle, WA March 1985 to present.
- Associate Professor of Medicine, School of Medicine; and Adjunct Associate Professor of Health Services, School of Public Health and Community Medicine, University of Washington, Seattle, WA July 1984 to present.
- AIDS Control Officer and Medical Director, AIDS Prevention Project, Seattle-King County Department of Public Health, February 1, 1986 to present.

AIDS RELATED RESEARCH (current)

AIDS Disease Prevention Demonstration Project II, Principal Investigator; September 1989 to present. This 5-year cooperative agreement with the CDC provides funds to develop and evaluate AIDS control interventions targeting three new hard-to-reach populations: men who have sex with men but do not identify as gay or bisexual, prostitutes, and street youth. Funding level of about \$900,000 yearly.

Control AIDS Through Community Health Outreach-Now (CATCH-ON), Principal Investigator; October 1988 to present. This National Institute of Drug Abuse (NIDA) project provides \$800,000 annually over 4 years to develop AIDS control interventions in two communities of intravenous drug users (IVDUs) and their sexual partners and to study their impacts. Funding to date \$1.7 million.

Bureau of Health Care Delivery and Assistance; Principal Investigator. This grant seeks to link primary medical care as delivered through a series of public health and community clinics with several drug treatment agencies. Funding at \$350,000 yearly for three years.

Epidemiology of Anal Dysplasia in Gay Men, Co-Investigator; 1989 to present.

AIDS Treatment/Evaluation Unit, Co-Investigator; July 1986 to present.

HONORS/AWARDS

Commendation Award, USPHS, Division of Hospitals and Clinics, 1980.

Fellowship, American College of Physicians, 1982.

Member (and Chair since 1989) of Governor's Advisory Council on HIV/AIDS; appointed 1987.

Represented US (Seattle-King County) at the World Health Organization's Special Programme on AIDS, July 1987, Geneva, Switzerland.

Founding Trustee, Second President, Northwest AIDS Foundation.

PUBLICATIONS (1980-90) IN CHRONOLOGICAL ORDER, MOST RECENT LAST

1. Wood RW, Tompkins RK, Wolcott BW; "An Efficient Strategy for Managing Acute Respiratory Illness in Adults," ANN INT MED, 93: 757-763, November 1980.
2. Christensen-Szalanski JJJ, Diehr PH, Bushyhead JB, Wood RW; "Two Studies of Good Clinical Judgement," JOUR MED DEC MAKING, 2: 275-283, 1982.
3. Bushyhead JB, Wood RW, Tompkins RK, Wolcott BW, Diehr PH; "The Effect of Physicians' Use of Chest Radiographs on the Management and Clinical Course of Patients with Acute Cough," MED CARE, 21: 661-673, July 1983.
4. Diehr PH, Wood RW, Bushyhead JB, Krueger L, Wolcott BW, Tompkins RK; "Statistical Prediction of Pneumonia in Outpatients with Acute Cough," JOUR CHR DIS, 37:215-225, 1984.
5. Berg AO, Heidrich FC, Fihn SD, Bergman JJ, Wood RW, Stamm WE, Holmes KK; "Establishing the Etiology of Genitourinary Symptoms in Women in Family Practice: Comparison of Clinical Examination and Comprehensive Microbiology," JAMA, 251: 620-625, 1984.
6. Wood RW, Collier AC; "The Acquired Immunodeficiency Syndrome." Chapter in Infectious Disease Clinics of North America, W.B. Saunders, Philadelphia, Vol. 1, No. 1, March 1987, pp. 145-163.
7. Wood RW; "The Public Health Response to AIDS." Chapter in UW Medicine, Vol. 13, No. 1, Winter, 1987.
8. Diehr PH, Highley R, Dehkordi F, Wood RW, Krueger L, Teitz C, Hermanson B; "Prediction of Fracture in Patients with Acute Musculo-skeletal Ankle Trauma," JOUR MED DEC MAKING, Vol. 8, No. 1, January-March 1988.
9. Melnick S, Engel D, Truelove E, DeRouen T, Morton T, Schubert M, Dunphy C, Wood RW; "Oral Mucosal Lesions: Association with the Presence of Antibodies to the Human Immunodeficiency Virus (HIV)," ORAL SURGERY, ORAL MEDICINE, AND ORAL PATHOLOGY, Vol. 68, No. 1, pp. 37-43, July 1989.
10. Wood RW, Celum C; "Screening, Counseling and Testing for HIV Infection." Chapter in AIDS DX/RX, 1989.
11. Wood RW, Krueger L, Kiehr P, Maxwell C; "Poverty and HIV Seropositivity." AIDS 4:8 811-814, Aug 1990.

F.

PRINCIPAL INVESTIGATOR: GARY M. GOLDBAUM, MD, MPH

AMERICAN FOUNDATION FOR AIDS RESEARCH

RESEARCH GRANT APPLICATION

BIOGRAPHICAL SKETCH

Leigh Ellen Krueger

Sr. Planning and Development
Specialist

DOB: 6/15/55

EDUCATION

University of Wisconsin

BS

1977

Experimental Psychology

University of Washington

MPH

1982

Biostatistics

RESEARCH AND PROFESSIONAL EXPERIENCE

1987-present Manager of Research and Analysis
AIDS Prevention Project
Seattle/King County Dept. of Public Health
Seattle, WA

1983-86 Manager of Planning and Analysis
Pacific Medical Center
Seattle, WA

1982-83 Research Specialist
Battelle Memorial Research Institute
Seattle, WA

1978-83 System Analyst/Programmer
School of Public Health
University of Washington
Seattle, WA

1978-79 Research Assistant
Child Development and Mental Retardation Center
University of Washington
Seattle, WA

1974-78 Research Assistant
Department of Psychology
University of Wisconsin
Green Bay, WI

1976-78 Teaching Assistant
Dept. of Computer Science
University of Wisconsin
Green Bay, WI

PUBLICATIONS

Referred Articles in Peer Reviewed Journals:

1. Diehr P, Wood R, Bushyhead J, Krueger L, Wolcott B, Tompkins R: Prediction of pneumonia in outpatients with acute cough. *Journal of Chronic Diseases* 37:215-25, 1984.
2. Diehr P, Martin D, Leickly R, Krueger L, Silberg N, Barchet S: Use of ambulatory health care services in a preferred provider organization. *Medical Care* 25:1033-1043, 1987.
3. Diehr P, Highley R, Dehkordi F, Wood R, Krueger L: Prediction of fracture in patients with acute musculo-skeletal ankle trauma. *Medical Decision Making* 8:40-47, 1988.
4. Diehr P, Leickly R, Tatarsky M, Hermanson B, Krueger L, Silberg N: Use of a preferred provider by employees of the preferred provider. *Health Services Research* 23:537-554, 1988.
5. Roffman R, Gilmore M, Gilchrist L, Mathias S, Krueger L: Continuing unsafe sex: assessing the needs for AIDS Prevention Counseling. *Public Health Reports* Jan-Feb 1990.
6. Krueger L, Wood R, Diehr P, Maxwell C: Poverty and HIV seropositivity. *AIDS* 4:8 811-814, Aug 1990.

AMERICAN FOUNDATION FOR AIDS RESEARCH

RESEARCH GRANT APPLICATION

OTHER SUPPORT

List in three categories all support that is current, pending or for which an application is contemplated in the near future. List the funding agency, agency I.D. number, the title of the project, project dates, the amount of the entire grant, amount of each sub-project, the percentage of effort on each project and the amount of salary support for the above named individual. See the application instructions for details. Other support listed will be closely scrutinized.

1. CURRENT

FEDERAL CENTERS FOR DISEASE CONTROL (CDC)
 COOPERATIVE AGREEMENT #U62/CCU001074
 "Community Based Demonstration Project for HIV Prevention and Risk Reduction Activities"

Current annual funding cycle: August 1, 1990 - July 30, 1991
Annual award amount: \$807,977
 Expected to be renewed annually through 1994
Amount of salary support for Dr. Robert Wood: (27%) \$31,000

LOCAL AIDS PREVENTION GRANT
 (City/County/State pooled revenues, Project 5688)

Current annual funding cycle: January 1 - December 31, 1991
Annual award amount: \$1,020,861
 Expected to be renewed annually
Amount of salary support for Dr. Gary Goldbaum: \$71,628
 (100%) (direct)
 19,340 (fringe)
 90,968 (total)

for Dr. Robert Wood: \$84,085
 (73%)

The AmFAR proposal seeks \$50,569 to add a demonstration study/project (comparing standard and augmented HIV counseling strategies) to the comprehensive AIDS prevention programs funded by the two sources listed above.

2. PENDING None.3. CONTEMPLATED None.

AMERICAN FOUNDATION FOR AIDS RESEARCH

RESEARCH GRANT APPLICATION

RESOURCES AND ENVIRONMENT FORM

Briefly describe the facilities to be used for this project, their nature, pertinent capabilities, relative proximity and extent of availability to the project. Use "OTHER" to describe the facilities at any other performance site or laboratory available to the project.

FACILITIES:

- LABORATORY HIV testing is provided by the Department of Public Health laboratory as part of usual prevention services.
- CLINICAL Space is already dedicated for counseling and testing activities. All clinical equipment and supplies are already provided as part of usual prevention activities.
- COMPUTER Seven IBM-compatible PC's are in use--4 are dedicated to specific individuals for word processing and data analysis, 1 is dedicated to data entry, 2 are shared for word processing and graphic design.
- ANIMAL
- OFFICE Work space is available for all staff working on the project. Space is also already dedicated for clients to complete questionnaires.
- OTHER

EQUIPMENT

- ADDITIONAL RESOURCES Staff at the University of Washington School of Social Work (Roger Roffman et al.) and the Centers for Disease Control Division of Sexually Transmitted Diseases (Kevin O'Reilly et al.) have committed their expertise and advice to this project.

use continuation page if necessary

Principal Investigator: Gary Goldbaum, MD

I. Research plan

Specific aims

We intend to evaluate the effectiveness of various counseling and other strategies in reducing high risk behaviors among men who have sex with men (MSM). By identifying optimal strategies, we expect to improve efficiency and maximize effectiveness for counseling/testing programs in this and other agencies. Given the substantial resources currently devoted to counseling/testing programming, our evaluation could have major implications for counseling/testing programming.

Background and rationale

With neither vaccine nor cure currently available, the spread of HIV can only be interrupted by public health measures aimed at preventing behaviors that increase risk of transmission. Foremost among these measures has been education. In particular, public health officials have encouraged counseling and testing of individuals in high risk populations. While counseling and testing have been associated with changes in behavior, there have been few attempts to clarify if either counseling or testing cause long-term changes. Nor have various counseling, testing, or other intervention strategies been carefully compared to evaluate relative effectiveness. Most studies to date have been

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too small or without comparison groups. Furthermore, most interventions and evaluations have lacked a theoretical framework for behavior change. Ajzen and Fishbein's (1980) Theory of Reasoned Action (emphasizing attitudes and norms) provides a basis for designing interventions, McAlister and colleagues (1989) suggest an approach to implementing such interventions, and Prochaska and DiClemente (1986) offer a model for assessing stages of behavior change (precontemplative, contemplative, intention, action, relapse).

Preliminary studies

The AIDS Prevention Project (APP) of the Seattle-King County Department of Public Health offers free anonymous and confidential HIV counseling and testing. All clients are interviewed about sexual and drug using behaviors. Since 1986, APP has also recruited men who have sex with men (MSM) for a longitudinal study of high risk behaviors. To date, more than 7100 clients have been counseled and tested at APP; 63% of these are men who have sex with men (MSM). In addition, more than 2200 men have enrolled in the longitudinal study. On follow-up visits, substantial numbers of MSM have reduced their risks, notably by decreasing number of partners and frequency of unprotected anal sex. These changes have been observed among men participating in the longitudinal study and among nonparticipating men who have simply returned for additional

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counseling or testing. However, approximately 5% of all men presented with and persisted in unsafe behaviors over one year. Furthermore, about 25% of men reducing risk relapse to unsafe practices within one year.

To identify potentially effective interventions to improve our current counseling/testing methods, we have conducted an ethnographic study of gay men seen at APP. In-depth interviews with APP staff and clients suggest several strategies addressing attitudes (drugs and alcohol increase risk by impairing judgement; safe sex can be gratifying sex), specific skills (heightening sensation with condom use; negotiating and correctly using condoms), subjective norms (matching clients to counselors by gender or sexual orientation; increasing opportunities for men to interact with other men who are trying to be safe; providing examples of how actual gay men have changed their attitudes and behaviors towards safer sex), and situational issues (providing periodic reminders to maintain safe behaviors; providing free lubricating jelly with all condoms).

In addition, APP staff have collaborated with Roger Roffman and colleagues to develop a comprehensive safer sex intervention package emphasizing group and individual therapy models. While this package is too complex and staff-intensive for routine use in the counseling/testing setting, an abbreviated version has been proposed. Such an abbreviated approach ("Individualized Assessment and Advice") has been developed for treating chronic

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marijuana abuse; it involves two individualized assessment and feedback sessions that employ motivational interviewing, marijuana education, and advice about strategies to end marijuana use and maintain a marijuana-free lifestyle. Dr. Roffman and colleagues have agreed to help develop a similar intervention package addressing unsafe sex.

Experimental design

We propose a clinical trials model in which men who have sex with men are randomly assigned to either a usual counseling (control) or augmented counseling (intervention) group. Augmented counseling will include all components of usual counseling, plus additional theoretically-based strategies to motivate clients to reduce sexual risks and help clients to maintain safer sexual behaviors. Participants will be followed up every six months to evaluate behaviors.

Procedures

Men will be recruited from clients registering for counseling/testing at the APP. All MSMs will be eligible (including men who are currently safe). All clients will be randomly assigned (by week enrolled) to either standard or augmented interventions. Health advisors (who provide the counseling/testing at APP) will explain the study to and obtain consent from clients. Those clients who agree to participate

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will receive the assigned intervention and active follow-up (e.g., mailed and phoned reminders for six month return visits); non-participants will receive standard counseling and usual follow-up (e.g., as needed). Health advisors will follow scripts as far as possible to assure that counseling is standardized. Augmented intervention subjects will receive an individualized report generated from responses to the initial questionnaire. In addition, the counselor will use motivational interviewing to strengthen commitment to change, recommend strategies for reducing sexual risks, and offer training in specific skills (such as heightening sensitivity when using condoms, negotiating condom use, and using condoms correctly). Each month, the client will be mailed printed maintenance materials (including reminders about condom use and real-life narratives about men who have already made changes to reduce risks) and three condoms. All participants will be asked to complete a questionnaire (at APP) every six months to evaluate stages of change for specific sexual behaviors. Seronegative participants will be encouraged to retest for HIV every six months. To improve response rates, participants will be asked to provide addresses and phone numbers which will be maintained in files separate from the clinical records (to assure security). Participants will be mailed three reminders prior to each six-month return visit. Participants who do not present within one month of their expected return will be contacted by phone.

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Outcomes of interest

Clients receiving the augmented or standard interventions will be compared on stages of change for anal, vaginal, and oral sex. Specifically, we are interested in the proportion of clients who shift from each stage of change (precontemplative, contemplative, intention, action, relapse) in abstaining from sex, maintaining monogamous relationships, substituting one type of sex for another that is potentially less risky (particularly substituting unprotected oral sex for any anal sex), or always using condoms.

Data analysis

Data will be stratified by variables such as initial risk status and age. Stratum-specific and Mantel-Haenszel summary outcome measures (plus confidence intervals) will be calculated to identify potentially confounding or modifying variables, including sex, race, age, income, education, and concurrent intervention activities (such as counseling or group therapy). Variables of interest and potential confounders will be evaluated by logistic regression to estimate the effect of the augmented intervention on stages of change over time. To assess the public health impact of any observed differences, we will also estimate the attributable benefit or risk of augmented intervention.

Sample size

Based on past experience recruiting for the current cohort study, we expect to enroll approximately 500 MSMs annually into

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the study, representing about half of all MSMs who present to APP for HIV counseling/testing. Currently, about 50% of current enrollees follow-up at six months. However, we have already implemented procedures to improve follow-up (obtaining phone numbers to contact participants in the current study); we expect to improve the follow-up rate to 90% by mailing reminders. Therefore, we estimate that at the end of one year, we will have six-month return data for at least 100 participants in each of the intervention groups. Reasonable estimates for power to detect difference in specific outcomes require information not currently available about current stages of change for this population.

Limitations

The many outcomes reduce the likelihood of identifying real differences between intervention groups for any specific outcome. However, it may be possible to aggregate certain outcomes (by creating a high risk/low risk index, for example).

Loss to follow-up would reduce power and could introduce bias, if the drop-outs differ substantially from participants who follow-up. However, heightened efforts to remind participants to follow-up should be effective in this generally motivated population.

Recall bias is always a concern. However, any bias is likely to be conservative (augmented intervention participants are

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probably more likely than standard intervention participants to
recall unsafe activities, since the augmented intervention
includes frequent reminders of the study). Thus, any differences
we detect will probably underestimate the real differences.

J. Appendix

References

Ajzen I, Fishbein M. Understanding Attitudes And Predicting Social Behavior. Englewood Cliffs, NJ: Prentice-Hall, Inc., 1980.

McAlister AL, Puska P, Orlandi M, Bye LL, Zbylot P: Behavior modification: Principles and illustrations. In Holland WW, Detels R, Knox EG (eds): Oxford Textbook of Public Health. London: Oxford Medical Publications, 1989.

Prochaska JO, DiClemente CC: Toward a comprehensive model of change. In Miller WR, Heather N (eds): Treating Addictive Behaviors: Processes of Change. New York: Plenum Press, 1986.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
 PROTECTION OF HUMAN SUBJECTS
 ASSURANCE/CERTIFICATION/DECLARATION

GRANT CONTRACT FELLOW OTHER
 New Competing continuation Noncompeting continuation Supplemental

ORIGINAL FOLLOWUP EXEMPTION
previously undesignated

APPLICATION IDENTIFICATION NO. (if known)
 U62/CCU001074

POLICY: A research activity involving human subjects that is not exempt from HHS regulations may not be funded unless an Institutional Review Board (IRB) has reviewed and approved the activity in accordance with Section 474 of the Public Health Service Act as implemented by Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46—as revised). The applicant institution must submit certification of IRB approval to HHS unless the applicant institution has designated a specific exemption under Section 46.101(b) which applies to the proposed research activity. Institutions with an assurance of compliance on file with HHS which covers the proposed activity should submit certification of IRB review and approval with each application. (In exceptional cases, certification may be accepted up to 60 days after the receipt date for which the application is submitted.) In the case of institutions which do not have an assurance of compliance on file with HHS covering the proposed activity, certification of IRB review and approval must be submitted within 30 days of the receipt of a written request from HHS for certification.

1. TITLE OF APPLICATION OR ACTIVITY
 Community-Based Demonstration Project for HIV Prevention and Risk Reduction

2. PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW
 Dr. Robert W. Wood

3. FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION (see reverse side)

4. HHS ASSURANCE STATUS

This institution has an approved assurance of compliance on file with HHS which covers this activity.
M1183 Assurance identification number 03XM IRB identification number

No assurance of compliance which applies to this activity has been established with HHS, but the applicant institution will provide written assurance of compliance and certification of IRB review and approval in accordance with 45 CFR 46 upon request.

5. CERTIFICATION OF IRB REVIEW OR DECLARATION OF EXEMPTION

This activity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. This certification fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device. (See reverse side of this form.)

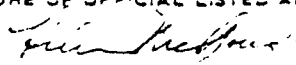
9-6-90 Date of IRB review and approval. (If approval is pending, write "pending." Followup certification is required.)
(month/day/year)

Full Board Review Expedited Review

This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by 45 CFR 46 will be reviewed and approved before they are initiated and that appropriate further certification (Form HHS 596) will be submitted.

Human subjects are involved, but this activity qualifies for exemption under 46.101(b) in accordance with paragraph of exemption in 46.101(b), 1 through 5i, but the institution did not designate that exemption on the application.

6. Each official signing below certifies that the information provided on this form is correct and that each institution assumes responsibility for assuring required future reviews, approvals, and submissions of certification.

APPLICANT INSTITUTION	COOPERATING INSTITUTION
NAME, ADDRESS, AND TELEPHONE NO. University of Washington Seattle, Washington 98195 206 543-0098	NAME, ADDRESS, AND TELEPHONE NO.
NAME AND TITLE OF OFFICIAL (print or type) Ms. Helen McGough Manager	NAME AND TITLE OF OFFICIAL (print or type)
SIGNATURE OF OFFICIAL LISTED ABOVE (and date) 9-10-90 	SIGNATURE OF OFFICIAL LISTED ABOVE (and date)

LONGITUDINAL COHORT STUDY CONSENT FORM

Seattle-King County Department of Public Health / AIDS Project

Background and Purpose

Acquired immune deficiency syndrome (AIDS) is a deadly syndrome caused by a virus known as HIV or simply "AIDS virus". HIV is spread only by the intimate exchange of body secretions or blood, through sexual contact, sharing of needles used for injection of drugs, blood transfusion, and birth to an infected mother. Sexual contact is the most common mode of transmission. At present, no medical treatment is known to prevent AIDS virus infection; therefore, control of AIDS depends mostly on behavioral change to reduce the risk of transmission of the virus.

The main purpose of the project is to help persons at risk for HIV to make changes that reduce their risk of getting an AIDS virus infection or, if infected, to reduce the chance of spreading the virus to other persons. Such changes may also slow the progression to AIDS itself. Another major purpose of the project is to learn about behaviors, attitudes, and other factors that foster spread of the virus; to determine how many persons have AIDS virus infection in various populations; to determine the level of knowledge about AIDS and its spread; and to examine ways to help persons make changes in risk-taking behavior.

Procedures

If you participate in this project, you will undergo a standard interview to assess your risk of catching or spreading the AIDS virus. You will also be asked to complete a questionnaire. The interview and questionnaire will include questions of a very personal nature, including a medical history and information about sexual practices and drug use. You are free to refuse to answer any question that you find uncomfortable or offensive.

You will then be randomly assigned to receive either our standard counseling or our "augmented" counseling sessions. The purpose of the "augmented" counseling is to include some new teaching techniques and reading materials and then to ask participants if they are helpful in reducing risky behavior. Sessions will last about one hour.

Participants are being asked to return every six months for up to five years for re-interview and follow-up counseling.

Benefits

Participation in this project may help to reduce your risk of acquiring an AIDS virus infection or overt AIDS, and may help some persons to prevent spread of the virus to others. The knowledge gained may contribute to the control of AIDS. All counseling, physical examinations, and diagnostic testing done as part of this project will be cost-free.

Risks

Participation in the project may be stressful for some individuals. Participation usually will require 1-2 hours for each clinic or counseling session that you attend, and each participant must bear any costs of transportation, parking, dependent care, loss of time from work, etc.

Privacy and Confidentiality

All information and data collected in this project will be held in the strictest confidence, and no identifying information of any kind will be released to any other person or agency. If you have chosen the anonymous registration path, your records will contain only your identifier code. If you have chosen the confidential registration path, your records will be filed under your mother's maiden last-name. Your records or test results

will not be released to any other person, agency, company, or government without your specific written permission, except as permitted by law. No publication or public discussion of the results of the project will contain information that could be used to identify any participant.

You are free to refuse to answer any interview question or to participate in the counseling session.

SUBJECT'S STATEMENT

I have read and I understand the above information and I voluntarily agree to participate in this project. I understand that I am free to decline to participate or to withdraw from the project at any time without penalty or loss of any benefits to which I would otherwise be entitled. I am aware of the risks and benefits of participating and am satisfied with the measures to protect my privacy and confidentiality. I have been given an opportunity to ask questions about the project, and any questions that I had were answered to my satisfaction; I understand that any additional questions that I may have about the project or about my rights as a participant will be answered by the project staff.

Name (Please Print)

Confidential path: your first initial and your mother's maiden last-name

Anonymous path: your identifier code

Signature

Date

(As above)

DEPARTMENT OF PUBLIC HEALTH CERTIFICATION

I certify that the person identified above has read the above information and that his/her decision to participate is voluntary and informed.

For the Seattle-King County Department of Public Health

Copies: Subject
Subject's clinic file

December 5, 1990

Gary Goldbaum, MD, MPH
AIDS Prevention Project
1116 Summit Avenue, Suite 200
Seattle, WA 98101

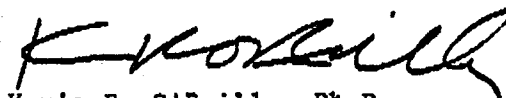
Dear Gary:

I have read your proposal with interest and it has our support. Although we cannot increase your funding level to cover the additional staff and materials needed to conduct the clinical trial, we enthusiastically offer our technical support. Specifically, we are willing to consult with you in modifying the data collection instruments, to assist you in developing the necessary interventions and in analyzing the complex Stages of Change outcomes.

Our team includes Donna Higgins, Christine Galavotti, Carolyn Beeker, Dan Schnell and myself. With her background in psychotherapy and her experience in AIDS research, Donna can offer a perspective that should be most valuable to your research. As a community psychologist, Christine has grappled with complex behavior change research for years. Carolyn Beeker, a sociologist, was herself the principle investigator on one of our Community Demonstration grants prior to coming to work with us; she has been involved in AIDS research for nearly six years, sexual behavior research for much longer. Dan Schnell, a mathematical statistician, has been invaluable to us in all our research, finding increasingly sophisticated ways to analyze complex behavior change data. As a medical anthropologist with over 13 years in public health and nearly seven years as an AIDS researcher, I bring a perspective to intervention trials that has been informed by the needs of public health and an understanding of the client's perspective. As a team, we represent a valuable resource and we are ready to commit that team to assisting you in your project.

Good luck with your proposal and let me know how we can assist you.

Sincerely yours,



Kevin R. O'Reilly, Ph.D.
Chief, Operational Research Section
Behavioral & Prevention Research Branch
Division of STD/HIV Prevention
Center for Prevention Services



4101 15th Avenue NE, JH-30
Seattle, Washington 98195
(206) 543-5640

December 5, 1990

Gary Goldbaum, MD
AIDS Prevention Project
1116 Summit Avenue
Seattle, WA. 98101

Dear Gary:

I am very pleased to offer the consultation and support of the University's Project ARIES staff as you plan to develop and evaluate the proposed AIDS risk reduction protocol. We join you in believing that the brief intensified relapse prevention focus of this intervention holds promise as an effective intervention that can be widely implemented in health education settings.

The therapeutic model that we have developed will readily lend itself to a brief intensive intervention. We'll be pleased to assist you in the development of assessment instruments, the intervention itself, and methods of evaluation. In addition to myself, the following clinical and research staff members will be available to you:

Blair Headnell, PhD. Blair is the director of Project ARIES telephone counseling program, and serves as Clinical Co-Director of the ARIES program.

Martin Stern, MPH. Marty serves as epidemiologist and statistical consultant in our group.

Judith Gordon, PhD. Judith serves as Clinical Co-Director, and has played a leadership role nationally in the development and assessment of the relapse prevention model.

Michael Sieyer, PhD. Michael is a senior therapist with Project ARIES, and has a wealth of experience in providing services to this population of AIDS-risk persons.

We wish you success in seeking funding, and hope to work with you in accomplishing this highly promising inquiry.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Roger'.

Roger A. Roffman PhD
Associate Professor
Principal Investigator,
Project ARIES