News from The EpiCenter

Northwest Tribal Epidemiology Center - Northwest Portland Area Indian Health Board

Spring 2003

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If you have questions, comments, or would like to be placed on the mailing list for News from *The EpiCenter*, please contact Sayaka Kanade, Technical Writer, at (503) 228-4185 or email skanade@npaihb.org.

EpiCenters for the New Millenium

IHS funding could position EpiCenters to receive innovative categorical grants

In the FY 2003 IHS Budget, $2.95 million was allocated for tribal EpiCenters nationwide, more than double from the previous year. As tribal epidemiology centers continue to grow and provide advanced research and surveillance for their respective tribes, we should take the opportunity to examine the original intent of the EpiCenters, their current capacity, and in what ways their scope could be expanded.

EpiCenters were developed in 1996 to act as a central mechanism for providing advanced technical support to area tribes. With the increase in data collection at tribal clinics, additional resources to analyze and interpret the data became crucial. Automatic computer generated reports are invaluable for day-to-day production and tracking, but expert interpretation is necessary to reveal more subtle health information. EpiCenters were designed to fill this gap by employing trained epidemiologists to provide high-level data analysis that would be impossible for most tribal clinics to support on their own.

The NPAIHB EpiCenter currently uses two types of funding to provide this service: categorical grant funding from outside agencies, and IHS funding that allows much more flexibility.

With non-categorical IHS funding, the NPAIHB EpiCenter tracks overall health issues through the comprehensive health status report. This report is unlike others in that it analyzes a myriad of national, regional, and local data sources for the most complete, up-to-date, and accurate information on Northwest American Indian and Alaska Natives. The NPAIHB EpiCenter also provides technical assistance support for tracking health status objectives through the tribal Resource and Patient Management System (RPMS). Almost all of the Northwest tribes use RPMS and submit clinical data to the RPMS project for compilation and analysis.

National IHS funding for tribal epidemiology centers has increased more than four-fold since 1996. Beginning with four centers being funded at around $155,000 each, by FY 2002, there were six centers funded at around $250,000. In FY 2003, funding will increase by $1.5 million and 2 new centers will be developed; a total of eight centers will be funded at around $380,000 each.

All six of the tribal EpiCenters are also funded by categorical grants. Since categorical funding is applied for through grant proposals, the number of grants organizations can be awarded is technically unlimited, as long as agencies such CDC, NIH, and other

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The HIPAA Privacy Rule and Research:

The basics and where to go for more information

There's been recent hubbub over the new federal regulations that people often confuse with a particularly massive and misunderstood swamp animal. The compliance date- April 14, 2003 – is upon us, and still, how the new "HIPAA" regulations will affect research in tribal communities and beyond may seem murky.

Gaining access to individual health information for research purposes is critical to the testing of new drugs and treatment methods and to the shaping of health care policies and services. But in the electronic age, when private health information can be transmitted instantly from one computer to another, more stringent safeguards are needed than those enacted in the past for paper files.

To improve the efficiency and effectiveness of the health care system, the Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) was put into effect April 14, 2001 as a component under the Health Insurance Portability and Accountability Act (HIPAA) of 1996. The HIPAA Privacy Rule addresses the electronic portability of information and establishes for the first time national standards to ensure the privacy of individuals' health information.

This brief article is not intended to provide detailed information about the requirements, but rather provide an overview and point to specific sections of the Rule.

Overall, the Privacy Rule provides patients with more control over their own health records and holds those entities that collect and maintain protected health information (health plans, health care clearinghouses, and health care providers) responsible for safeguarding the information. The Privacy Rule has wide-reaching effects including how health information can be accessed by the government or used for marketing and public health practice. Researchers are one of the parties affected indirectly by the Privacy Rule, as the health information they may be seeking for their studies are safeguarded by the covered entities.

Currently the guiding principles for human subjects research, including the informed consent process, are contained in the Common Rule[1] and/or the Food and

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NARCH Fellowship Opportunity

The Northwest Tribal Health Research Center (NTHRC) is looking for AI/AN undergraduate, graduate, and post-doctoral students who are interested in a two year fellowship position at Oregon Health Sciences University or the University of Washington.

For information on the NTHRC AI/AN Fellowship Program, please contact Luella Azule, NTHRC Coordinator, at (503) 228-4185 X 275 or email lazule@npaihb.org. NTHRC applications are also available on our website at www.npaihb.org/NTHRC/index.html under Training Program.

Drug Administration's (FDA) human subject protections regulations[2]. While the Common Rule and related FDA regulations address the ethical practice of research as a whole, the Privacy Act and its research authorization processes are solely concerned with the use and disclosure of personal health information in a particular research study. Thus a research project, for example, to survey patients on their perception of the health care they receive may not be affected by the Privacy Act. The requirements for the Privacy Act are meant to work with the existing regulations for humans subject research. The Privacy Act does not replace nor modify the Common Rule or the FDA's human subject protection laws.

Health information consists of any diagnosis regarding an individual's health status; past, present, or future condition. This includes any information that can ultimately reveal the treatment or care that a patient received, such as payment information and the provisions under which health care was administered. Privacy becomes an issue when health information can be traced back to an individual, and the Rule identifies specific elements that could potentially enable a person to link a piece of health information to the individual. Thus health information is protected under the Privacy Rule if it contains any of the following 18 identifiers: 1) names, 2) address, 3) dates, such as date of birth, 4) telephone numbers, 5) fax numbers, 6) email addresses, 7) social security number, 8) medical record numbers, 9) health plan beneficiary numbers, 10) account numbers, 11) certificate and license numbers, 12) vehicle identifiers and serial numbers, 13) device identifiers and serial numbers, 14) website addresses (or URLs), 15) numeric Internet addresses (or IP addresses), 16) biometric identifiers, such as finger prints, 17) full face photos, and 18) any other unique identifying number, characteristic, or code. In effect, any unique number or characteristic that could lead to individual identification is an identifier. There is more detail in the Rule regarding addresses and dates. The complete list of the 18 identifiers and their specifics are available in Section 164.514 of the Privacy Rule[3] at www.hhs.gov/ocr/combinedregtext.pdf.

If a research protocol requires use of protected health information (PHI), the researcher must first obtain authorization from each individual participant. There are specific required elements that constitute a valid authorization form, which are listed in Section §164.508 (c) *Implementation specifications: Core elements and requirements*. A valid authorization must be written in plain language and include a description of the PHI that is requested, a description of how the PHI will be used, the names of the authorized people of the covered entity that will disclose the said PHI, and the names of the researchers or people that intend to use the PHI. It must also include an expiration date for the authorization, which can be "until the end of research" or "none." The signed authorization may be a condition for participants to enroll in the research study, as stated in §164.508 (b)(4), and if so, this eligibility requirement must be stated in the form. The form must also include a statement on the individual's right to revoke the authorization at any time and identify any possible circumstances under which PHI may be redisclosed by the researcher. The authorization form must be signed and dated by the participant and a copy be given to the participant.

However, there are 4 circumstances under which research can be conducted without participant authorization. The circumstances are: 1) documented IRB or Privacy Board approval, where the IRB or the Privacy Board must follow certain guidelines to ascertain whether a waiver is permissible, 2) preparatory to research, where information is used solely to prepare a protocol or to identify potential participants for recruitment, and the PHI is not removed from the covered entity site, 3) research on protected health information of the deceased, or 4) limited data sets with a data use agreement, where only particular identifiers, dates and the city, state, and zip codes, can be contained in the data set. Circumstances 1-3 are referenced in §164.512 (i) *Standard: uses and disclosures for research purposes*. Circumstance 4 is referenced as a part of legitimate uses of de-identified PHI in §164.514 (e) on limited data sets and data use agreements.

Finally, the Privacy Rule does not supplant state or local laws that afford patients greater protection. Laws and policies followed by individual tribes that protect their patients more rigorously still need to be observed. Under HIPAA, each covered entity must assign a privacy officer to oversee the administration of the Rule at their facility. When conducting research at a tribal site, it is necessary to contact the designated Privacy Officer to ensure compliance with their local regulations as well as the federal regulations.

HIPAA laws and regulations are intended to further protect individuals and tribes from unethical use or negligent disclosure of protected health information. Covered entities are more accountable for the health information they house, and researchers that need to access that information must follow stringent national standards in justifying the collection and use for research purposes.

For information on how the Privacy Rule affects research, the best source for guidelines is from the Office of Civil Rights, the department that oversees the administration of the Rule itself. Visit www.hhs.gov/ocr/hippa/privacy.html and go to the research section. In addition to the guidelines and combined text of the regulations, the Office of Civil Rights www.hhs.gov/ocr/ has posted a variety of resources related to the HIPAA Privacy Rule including a searchable catalogue of Frequently Asked Questions. For additional resources, contact Sayaka Kanade at 503-228-4185 x284 or email skanade@npaihb.org.

(Endnotes)
For official rules, go to http://www.access.gpo.gov/nara/cfr
1 Common Rule (Title 45 CFR Part 26, Subpart A)
2 FDA Protection of Human Subjects (Title 21 CFR Part 50) and FDA Institutional Review Boards (Title 21 CFR Part 56)
3 Official version of the HIPAA Privacy Rule (45 CFR Part 164)

EpiCenter New Staff Profiles:

Some new, some familiar, but all with the Western Tribal Diabetes Project

Kerri Lopez, Project Director for the Western Tribal Diabetes Project

Kerri Lopez, an enrolled member of the Tolowa Tribe of Northern California, began as the Director of the Western Tribal Diabetes Project in October of 2002. Since joining WTDP, Kerri has been working with her staff making site visits to various tribal communities and working with the Diabetes Screening Toolkit (DST) Committee on finalizing the DST for publication.

Kerri graduated from San Francisco State University with a Bachelors degree from the Native American Social Work Program. Kerri has worked previously for NPAIHB as the Tribal Tobacco Policy Project Director and Health Resource Coordinator. Most recently, Kerri worked for the Native American Rehabilitation Association Indian Health Clinic, National Breast and Cervical Cancer Screening Program, the Legacy Tobacco Cessation Grant, State of Oregon American Indian Tobacco Project and the Diabetes Program. To contact Kerri, call 503-228-4185 x301 or email klopez@npaihb.org.

Angela Mendez, National Lead Diabetes Specialist for the Western Tribal Diabetes Project

Angela Mendez began in November 2002 as the National Lead Diabetes Specialist for the Western Tribal Diabetes Project.

Since beginning, Angela has made site visits with the Diabetes Specialists to assist tribal communities in using the diabetes management system (DMS). She also collaborating with the EpiCenters at United South and Eastern Tribes (USET) and the Great Lakes Intertribal Council (GLITC) to increase the number of people trained in using the DMS at the local level. Angela is also working on the Diabetes Screening Toolkit.

Angela has a Bachelor of Science from the University of Portland, and a Master of Education from Idaho State University. Angela is a member of the Shoshone-Bannock Tribes in Fort Hall, Idaho. She has worked 28 years for the tribes. Previous to coming to the NPAIHB, Angela was the Shoshone-Bannock Tribal Health Director. To contact Angela, call 503-228-4185 x316 or email amendez@npaihb.org.

First Annual Northwest Area Diabetes Program Gathering
May 7-8, 2003
Portland, OR

The theme of the Gathering is sharing knowledge and experiences amongst the tribal diabetes programs. There will be interactive roundtable sessions and workshops led by local Diabetes Teams and staff. Registration packets were mailed out to clinics in late March. If you would like more information and additional registration packets, or would like to contribute or present at the Gathering, please contact Rachel Plummer, WTDP Administrative Assistant, at 1-800-862-5497 or email rplummer@npaihb.org.

Crystal Gust, Northwest/National Project Specialist for the Western Tribal Diabetes Project

Crystal Gust has been with NPAIHB since June 2002 and has recently moved from the National Tribal Tobacco Prevention Network to the Western Tribal Diabetes Project as the Northwest/National Project Specialist. She will be working on-site with diabetes programs to set up and implement the RPMS Diabetes Register, as well as provide trainings on other project specific tools.

Crystal is originally from Montana and is an enrolled Chippewa-Cree from the Rocky Boy Reservation. She graduated from Montana State University, located in Bozeman, MT, in 1996 and has lived on and off in the Portland area since then. She enjoys spending time outdoors with her horses and dogs. To contact Crystal, call 503-228-4185 x293 or email cgust@npaihb.org.

Rachel Plummer, Administrative Assistant for the Western Tribal Diabetes Project

Rachel Plummer is the new Administrative Assistant for the Western Tribal Diabetes Project. Prior to NPAIHB, Rachel was the Tobacco Cessation Coordinator & Counselor at the Native American Rehabilitation Association where she helped patients quit smoking through the Tobacco Cessation Program and provided support to the diabetic patients during Diabetes Clinic Days.

Rachel is an enrolled member of the Northern Cheyenne Tribe from Lame Deer, Montana. She is married and has two daughters, which she schooled at home until two years ago. In her spare time, Rachel enjoys beading, reading, and attending both of her daughter's various extra curricular activities. To contact Rachel, call 503-228-4185 x291 or email rplummer@npaihb.org.

Reminder: IHS Diabetes Audit

The time to complete the annual IHS Diabetes Audit is almost here, and WTDP staff is ready to assist sites, through site visits and telephone calls, with the completion, use, and interpretation of their audit.

The annual IHS Diabetes Audit is an important measure of clinical performance. The Audit parallels the IHS Standards of Care for Patients With Diabetes, measuring 87 different items that reflect both the process of diabetes care and health outcomes. For example, the Audit shows how many of your patients received nutrition counseling, how many are prescribed lipid-lowering drugs, and how many have "ideal" blood pressure control.

The Audit will be due sometime late summer for review period April 1, 2002 - March 31, 2003. Currently, the Diabetes Audit can be completed either electronically or manually; each method has its strengths and limitations. WTDP Project Specialists are available to answer questions you may have, including troubleshooting or developing strategies to complete the Audit. For assistance or more information, please contact one of our WTDP Specialists, Penny Schumacher, Jen Olson, or Crystal Gust, at 1-800-862-5497.

Projects of *The EpiCenter*

Fetal Alcohol Syndrome Surveillance Project

Indian Community Health Profile Project

Northwest RPMS Cancer Assessment Project

Northwest Tribal Behavioral Risk Factor Surveillance System Project

Northwest Tribal Dental Support Center

Northwest Tribal Elder Diet & Nutrition Project

Northwest Tribal Health Research Center

Northwest Tribal Infant Mortality Project

Northwest Tribal Registry Project

Stop Chlamydia! Project

Western Tribal Diabetes Project

EpiCenters continued

organizations such as the Robert Wood Johnson Foundation have monies to give. For the NPAIHB EpiCenter, categorical funding supports projects in priority areas such as diabetes, fetal alcohol syndrome, and sexually transmitted diseases.

However categorical funding, by definition, has its limitations. Categorical funding is typically the type of grant offered to address a specific health topic or to conduct a focused research project, where certain measurable outcomes and tangible products are expected at the conclusion of the project. It is harder to propose a project that intends to explore overall community health or investigate relationships between diseases without clearer focus. The NPAIHB EpiCenter does currently receive categorical funding to address overall health status, for example, the Indian Community Health Profile Project, the Behavioral Risk Factor Surveillance System (BRFSS) Project, and the Northwest Tribal Registry. However, their scope is clearly defined and constrained by their research focus and methodologies.

Investigating topic areas that have not yet entered general public health consciousness would only be possible through flexible, non-categorical funding. While the increase in IHS funding is a testament to the worth of the programs and the progress they have made over the years, are EpiCenters funded at a level to truly realize their potential of being a "centralized mechanism" of epidemiological support for area tribes? Currently, the IHS funding for the NPAIHB EpiCenter supports the director, support staff, and 2 part-time epidemiologists. However, in order to adequately assist tribes area-wide, the NPAIHB EpiCenter requires more epidemiologists. To function at full capacity, an EpiCenter would require a doctoral-level epidemiologist, two master-level epidemiologists, and a statistician. With additional staff and incidental costs, IHS non-categorical funding would have to be increased to $500,000 per center to meet this level.

With full time epidemiologists working directly for the EpiCenter and not limited by categorical funding, EpiCenters could increase the level of meaningful support to tribes and track significant regional trends. Categorical funding limits the format and level of technical assistance available to tribes, as such support may not fall within the scope of a project. These projects have to justify the support to their funding agency or even tailor the TA to fit within the scope of their project.

EpiCenter staff would also have the expertise and the access to combine resources and information gathered through categorically funded projects and find links through in-depth analysis that might otherwise be impossible. Relationships between various diseases and their risk factors could be tracked and analyzed without confinement to specific topic areas. EpiCenters could examine region-wide trends that may lead to identifying potential problems before they become epidemics. Ultimately, the additional non-categorical funding would allow EpiCenters to gather the evidence necessary to obtain future categorical funding for health issues that do not fit within the current public health paradigm.

Northwest Tribal Epidemiology Center

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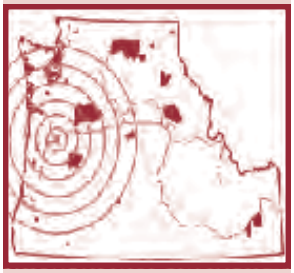

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