DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) and the Acting Assistant Secretary for Health have taken final action in the following case:

Justin Radolf, M.D., University of Connecticut Health Center: Based on the report of an investigation conducted by the University of Connecticut Health Center (UCHC Report), Dr. Radolf's admissions, and additional analysis conducted by ORI in its oversight review, the U.S. Public Health Service (PHS) found that Dr. Radolf, Professor at UCHC's Center of Microbial Pathogenesis, engaged in scientific misconduct in research supported by National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), grant R01 AI29735–11 and incorporated false claims into a grant application entitled ''Tick Inhibitors of Hemostatis: Novel Therapeutic Agents and an Anti-Tick Vaccine'' to the United States Department of Agriculture (USDA). Dr. Radolf falsified and fabricated preliminary research data to falsely claim that the genes that he proposed to characterize were specifically expressed in the tick salivary gland. Dr. Radolf represented the products of control samples as positive tests for mRNA expression from different genes and presented data as positive for genes that had not been tested.

Specifically, PHS finds that Dr. Radolf falsified and fabricated data in January 2000 by altering the labeling of a figure included in a USDA grant application and by falsifying the text in both the USDA application and in an overlapping application to a state-sponsored program.

This incident of falsification and fabrication is significant because the data was the first direct evidence that the isolated clones represented genes expressed in tick salivary gland, and therefore represented proteins that could be targets of vaccine development to protect the hosts from tick-transmitted microbial diseases. The misinformation of the extent of the progress in this project had the potential to mislead grant reviewers and the scientific community about an area of research that could have led to the prevention of Rocky Mountain Spotted Fever and other tick-transmitted diseases.

The Respondent submitted the following admission to ORI: In January of 2000, I engaged in scientific misconduct involving research supported by the National Institutes of Health. The misconduct occurred during the preparation of grant proposals submitted to the United States Department of Agriculture and Connecticut Innovations, Inc. More specifically, I falsified and fabricated preliminary data by intentionally altering the labeling of an ethidium bromide-stained agarose gel purporting to demonstrate the expression of genes in the salivary glands of feeding Dermacentor andersoni ticks. In so doing, I misrepresented the products of control samples as positive tests for the presence of mRNAs derived from unrelated genes, and I fabricated data to show the expression of genes that, in fact, were not tested. The texts of the two proposals also contained inaccurate statements relating to these falsified and fabricated data. By inaccurately portraying the extent of our progress in characterizing salivary gland proteins that might interfere with tick feeding, my actions would have misled the reviewers of the proposals into thinking that we were closer to the development of an anti-tick vaccine than we actually were.

Truthfulness in the recording, presentation, and reporting of data—the accuracy and reliability of the research record—is the foundation of all scientific research. By intentionally misrepresenting preliminary findings in the two grant proposals, my actions violated this basic precept, compromised my scientific integrity, and placed my 20-year career as a biomedical researcher in jeopardy. My actions also could have compromised the integrity and careers of individuals with whom I work, individuals who place their trust in me and who look to me for scientific leadership. I take full and complete responsibility for this misconduct. I committed this wrongful act without prompting by other individuals and without the consent or knowledge of others. I am deeply remorseful for my behavior and offer my strongest assurance to the Office of Research Integrity that it will never recur.

Dr. Radolf has entered into a Voluntary Exclusion Agreement in which he has voluntarily agreed for a period of five (5) years, beginning on March 10, 2003:

(1) To exclude himself from serving in any advisory capacity to PHS including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant;

(2) That any institution which submits an application for PHS support for a research project on which Dr. Radolf's participation is proposed or which uses Dr. Radolf in any capacity on PHS-supported research, or that submits a report of PHS-funded research in which Dr. Radolf is involved, must concurrently submit a plan for supervision of Dr. Radolf's duties to the funding agency for approval; the supervisory plan must be designed to ensure the scientific integrity of Dr. Radolf's research contribution; a copy of the supervisory plan must also be submitted to ORI by the institution; Dr. Radolf agrees that he will not participate in any PHS-supported research until such a supervision plan is submitted to ORI; and

(3) To ensure that any institution employing him submits, in conjunction with each application for PHS funds or report, manuscript, or abstract of PHS funded research in which Dr. Radolf is involved, a certification that the data provided by Dr. Radolf are based on actual experiments or are otherwise legitimately derived, and that the data, procedures, and methodology are accurately reported in the application or report. Dr. Radolf must ensure that the institution sends the certification to ORI.

FOR FURTHER INFORMATION CONTACT: Director, Division of Investigative Oversight, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Director, Office of Research Integrity.

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BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Preliminary Measure Set for Home Health in the National Healthcare Quality Report—Request for Comments

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Request for comments.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) announces a request for public comment on the Preliminary Measure Set on home health to be used in preparing the National Healthcare Quality Report (NHQR). The NHQR is a congressionally

mandated annual report (*see* 42 U.S.C. 299b–2(b)(2)) on national trends with respect to health care quality. The legislation mandated that AHRQ submit this report on an annual basis beginning in 2003. The preliminary Measure Set for the NHQR was generated through a call for health care quality measures to Federal agencies and private organizations.

DATES: Written comments on this notice must be received by April 23, 2003.

ADDRESSES: Written comments should be submitted to: Judith Sangl, Sc.D., Center for Quality Improvement and Patient Safety, Agency for Healthcare Research and Quality, 6011 Executive Boulevard, Suite 200, Rockville, MD 20852, Fax: (301) 594–2155, E-mail: *jsangl@ahrq.gov.*

Public Review of Comments

Comments and responses received will be available for public inspection at AHRQ's Information Resource Center (IRC) public reading room between the hours of 8:30 a.m. and 5 p.m. on regular business days at 2101 East Jefferson Street, Suite 500, Rockville, MD 20852. Arrangements for viewing public comments may be made by calling (301) 594–6394. Responses may also be accessed through AHRQ's Electronic Freedom of Information Reading Room on AHRQ's Web site at *http://www.ahrg.gov/news/foiaindx.htm.*

Availability of Technical Expert Panel (TEP) Meeting Transcript and Background Materials

Copies of the transcript from the TEP meeting are available from the AHRQ Web site at: *http://www.ahrg.gov/qual/nhrq02/hhmtep.htm.* For organizations without access to the Internet, AHRQ will make a paper version available either through overnight mail or by fax upon written request. Requests for paper versions of the preliminary measure set should be faxed to the above fax number. The background materials will be available in the IRC (see address above).

FOR FURTHER INFORMATION CONTACT: Judith Sangl, Sc.D. (*See* information under **ADDRESSES**).

SUPPLEMENTARY INFORMATION:

1. Background

This request follows up on an earlier request for public comments on the preliminary measure set dated August 19, 2002. At that time, no home health measures were proposed for the preliminary measure set because AHRQ was working together with the Centers for Medicare & Medicaid Services (CMS) to determine as appropriate set of measures for the CMS public reporting initiative on home health as well as the NHQR. AHRQ and CMS decided that, in the short term, the Outcome and Assessment Information (OASIS) measures would be used as the initial measure set because there is more standardization around these measures than any other in home health care. This view was reiterated in the one comment received in response to the August request, *i.e.,* that OASIS measures were the best currently available to measure the quality of home health care.

OASIS is a uniform set of patient assessment items developed for monitoring and measuring outcomes of care, adjusted for patient factors that might affect those outcomes. The OASIS data set is the only national, standardized data source on adult home health care delivery. The OASIS instrument was created over a 14-year period to measure functional outcomes for the purpose of improving quality of home health care. It was developed through a scientific process, using input from the home healthcare industry, and has been tested for validity and reliability. All Medicare certified home health agencies (HHAs) implemented the OASIS instrument nationwide for collection and reporting of comprehensive patient assessments in October 1999. There are 41 measures derived from OASIS data covering (1) functional outcomes; (2) physiologic outcome; (3) emotional/behavioral/cognitive outcomes; and (4) utilization outcome measures. When one includes the additional 13 low-frequency adverse patient outcomes identified from OASIS data, there are a total of 54 measures. The Web site at *www.cms.hhs.gov/providers/hha/* contains extensive detail on the development of OASIS, a copy of the OASIS data collection form (OASIS B1) and measure definitions.

Because CMS currently wanted to select a subset of OASIS measures for its home health public quality reporting initiative, AHRQ decided to convene a technical expert panel (TEP) to review the set of OASIS home health quality measures as candidates for both the NHQR and the CMS home health care public reporting initiative. Accordingly, AHRQ convened a TEP on October 21–22, 2002 with the purpose of addressing these two independent but overlapping efforts being planned by CMS and AHRQ.

2. TEP Composition and Meeting Process

The TEP was composed of 18 members representing a wide range of disciplines and interests: home health agency representatives, clinicians (both physicians and nurses), an epidemiologist, consumer reporting experts and a consumer groups organization, quality improvement organizations, State survey agencies, and home health services researchers. The panelist list is included in the meeting transcript on the AHRQ site at *http://www.ahrq.gov/qual/nhrq02/hhmtep.htm.*

AHRQ and CMS staff gave introductory remarks and overviews of the two parallel purposes and goals of the meeting. Speakers gave background presentations on: (1) Development of the OASIS measures, their statistical properties, and their use in quality improvement and (2) results of testing OASIS measures (in plain language) in focus group with consumers and interviews with physicians and discharge planners, who would be users of such quality measure information. Results of these focus groups are also on the above referenced AHRQ Web site.

After presentation of the introductory background material, the meeting facilitator described how the remainder of the meeting would proceed. Since this technical expert panel was not established as a formal Federal advisory committee, AHRQ would not seek any formal votes from the panel nor consensus from the panel members. Instead, the emphasis would be on viewpoints of the individual panel members as each of the existing OASIS measures was discussed according to pre-established criteria (*see* Attachment A in the meeting transcript on the AHRQ Web site), derived from criteria for quality measures developed by the Institute of Medicine for the NHQR. Panelists were given a workbook with criteria worksheets and statistical properties for each of the measures. The presenters stayed during the entire meeting for technical support and clarifications.

At the end of the second day, all of the panel members were asked to bring together their values, insights and assessments to provide input to AHRQ on which of the 41 OASIS measures should be priority items for the two purposes: (1) AHRQ's NHQR and (2) CMS's home health public reporting initiative. It was acknowledged that these two priority measure lists might be different.

The meeting was open to the public and representatives from the home health industry trade associations, industry consultants, agencies and journalists attended.

3. OASIS Measures Reviewed by Panel

The Panel was charged with focusing on 41 OASIS measures, a subset of the

54 measures in OASIS. To facilitate discussion, these 41 measures were put into 13 categories (used in consumer testing) and three domains (adapted from the Foundation for Accountability framework) as follows:

• Domain: Getting Better

Category 1: Physical Health

Improvements in: Dyspnea, status of surgical wounds, number of surgical wounds, urinary tract infection, urinary incontinence, bowel incontinence.

Category 2: Mental Health

Improvements in: Behavior problem frequency, cognitive functioning, confusion frequency, anxiety level.

Category 3: Meeting Basic Daily Needs

Improvements in: Eating, upper body dressing, lower body dressing, in bathing, grooming, management of oral medications.

Category 4: Getting Around

Improvements in: Ambulation/locomotion, toileting, transferring, pain interfering with activity.

Category 5: Meeting Household Needs

Improvements in: Light meal preparation, laundry, shopping, housekeeping.

Category 6: Talking With People

Improvements in: Speech and language, phone use.

Category 7: Staying at Home Without Home Care

Discharged to community.

• Domain: Living With Illness or Disability

Category 8: Meeting Basic Daily Needs

Stabilization in: Bathing, grooming, management of oral medications.

Category 9: Meeting Household Needs

Stabilization in: Light meal preparation, laundry, shopping, housekeeping.

Category 10: Mental Health

Stabilization in: Cognitive functioning, anxiety level.

Category 11: Getting Around

Stabilization in: Transferring.

Category 12: Talking With People

Stabilization in: Speech and language, phone use.

• Domain: Staying Healthy/Avoiding Injury or Harm

Category 13: Medical Emergencies

Any emergency care provided, acute care hospitalization.

CMS and AHRQ focused panel attention on just these 41 measures because they assess long-term quality improvement issues that every home health agency should address. These OASIS measures are not specific to particular diagnoses but the functional outcomes they measure apply to many diagnoses. There are an additional 13 adverse event outcome OASIS measures that were not considered by the panel because they cover events that occur infrequently.

4. AHRQ Proposed Recommendations for Home Health Care Measures for the NHQR

Based on the Home Health Quality Measures Technical Expert Panel input, including: the individual panelist prioritization lists (*i.e.,* a significant proportion of panelists listed particular measures as priority items for inclusion), their written comments and the meeting discussion, AHRQ proposes using results collected on the following 12 OASIS measures for reporting on the quality of home health care in the NHQR:

—Improvement in dyspnea (physical health category);
—Improvement in urinary incontinence (physical health category);
—Improvement in upper body dressing (basic daily needs category);
—Improvement in management of oral medications dressing (basic daily needs category);
—Improvement in ambulation/locomotion (getting around category);
—Improvement in toileting (getting around category);
—Improvement in transferring (getting around category);
—Improvement in pain interfering with activity (getting around category);
—Improvement in bathing (basic daily needs category);
—Stabilization in bathing (basic daily needs category);
—Improvement in confusion frequency (mental health);
—Acute care hospitalization (medical emergencies category).

AHRQ is soliciting public comment on this proposed set of 12 home health care measures selected from the 41 OASIS measures considered. Ten of these measures are the same as CMS has announced for use in its initial home health public reporting effort. Based on panel input regarding the NHQR, AHRQ is recommending two additional measures, ''Improvement in dyspnea'' and ''Improvement in urinary incontinence.'' Finally, although CMS is using the measure, ''Any Emergency Care,'' (one of the OASIS measures listed above in Category 13), AHRQ is not recommending this measure for the NHQR at this time because we believe that this measure raises some significant issues that warrant further investigation. AHRQ would like to hear comments on the advantages and disadvantages of this measure in particular.

Carolyn M. Clancy,

Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–53]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: The National Violent Death Reporting System—New—National Center for Injury prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Violence is an important public health problem. In the United States, homicide and suicide are the second