FOR FURTHER INFORMATION CONTACT: Nominations of assays should be submitted online at *http://iccvam.niehs.nih.gov/contact/Tox21-nomination.htm* (preferred means) or to Dr. Warren Casey, Deputy Director, NICEATM, NIEHS, P.O. Box 12233, Mail Stop: K2–16, Research Triangle Park, NC 27709, (telephone) 919–541–2384, (fax) 919–541–0947, (email) *niceatm@niehs.nih.gov.* Courier address: NICEATM, NIEHS, Room 2034, 530 Davis Drive, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

The Tox21 Consortium is a collaboration of the NIH Center for Translational Therapeutics (NCTT),[1] NIEHS/NTP,[2] U.S. Environmental Protection Agency (EPA),[3] and U.S. Food and Drug Administration (FDA).[4] The goal of Tox21 is to develop, validate, and translate innovative HTS methods to characterize the impact of chemicals on key steps in toxicity pathways and ultimately to provide tools to risk assessors to protect human health and the environment.

The Tox21 HTS Initiative aims to prioritize substances for in-depth toxicological evaluation, identify mechanisms of action for further investigation, and develop predictive models for *in vivo* biological responses using efficient, high throughput *in vitro* assays. Tox21 also aims to expand the ability to screen environmental compounds for organ-specific toxicity, focusing in particular on the liver, kidney, and nervous system.

The current Tox21 inventory of 10,000 chemicals covers a variety of classifications, including consumer products, food additives, human and veterinary drugs, manufacturing intermediates, and pesticides. These 10,000 chemicals are being profiled using HTS assays designed to estimate toxicity potential and identify the specific perturbations they induce in biological pathways.

Request for Nominations of HTS Assays

NICEATM requests nominations of *in vitro* HTS toxicity assays that might be used in the Tox21 testing program. Tox21 intends to develop a systematic view of how chemicals interact with and affect biological systems using its collection of 10,000 chemicals. To achieve this goal, assays, which target all pathways relevant to toxicity, are needed to assess chemicals' effects. Nominated assays will be assessed for their overall applicability to the Tox21 HTS program in terms of biological relevance, cost, and potential for adaption to a HTS format. Suitable assays will then be prioritized for use by the NCTT. Protocol information and test data submitted in response to this notice may be incorporated into future NCTT and NICEATM reports and publications as appropriate.

Nominations should consider the following general criteria: (1) Relevance to the goals of the Tox21 Initiative (*http://nctt.nih.gov/27543703*), (2) high throughput capability of the assay (96-well format or higher, with no obvious impediments to miniaturization to a 1536-well format), (3) evaluation of preliminary assay performance using appropriate reference compounds, (4) validation status of the assay, (5) availability of complete detailed protocols, and (6) efficiency and cost of the assay. A list of compatibility criteria for 1536-well biochemical and cell-based assays is available at *http://nctt.nih.gov/27545107.*

Assay nominations should be submitted electronically using the online form (*http://iccvam.niehs.nih.gov/contact/Tox21-nomination.htm*). When submitting HTS assay nominations and protocol information, please reference this **Federal Register** notice and provide appropriate contact information (name, affiliation, mailing address, phone, fax, email, and sponsoring organization as applicable). NICEATM prefers submission of the nominations via the Web site identified above; however, submissions by mail, fax, or email are acceptable. Questions about the submission process should be directed to Dr. Warren Casey (see **FOR FURTHER INFORMATION CONTACT**).

Background Information on NICEATM

NICEATM was established in 1998 to administer and provide scientific support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), which is composed of 15 member Federal agencies and includes the EPA, FDA, NIEHS, and NIH. The ICCVAM Authorization Act of 2000 (42 U.S.C. 285*l*–2, 285*l*-5, available at *http://iccvam.niehs.nih.gov/about/PL106545.htm*) established ICCVAM as a permanent interagency committee of the NIEHS under NICEATM. NICEATM and ICCVAM conduct technical evaluations of new, revised, and alternative safety testing methods with regulatory applicability and promote the scientific validation and regulatory acceptance of safety-testing methods that more accurately assess the safety and hazards of chemicals and products and that will reduce, refine (enhance animal well-being and decrease or eliminate pain and distress), or replace animal use. NICEATM also conducts independent validation studies to assess the usefulness and limitations of new, revised, and alternative test methods and strategies applicable to the safety-testing needs of Federal agencies. In 2012, NICEATM began providing support to Tox21 regarding HTS assay nomination and review.

NICEATM and ICCVAM welcome the public nomination of new, revised, and alternative test methods and strategies applicable to the needs of Federal agencies. Additional information about NICEATM can be found on the NICEATM–ICCVAM Web site (*http://iccvam.niehs.nih.gov*).

Dated: April 5, 2012.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2012–8942 Filed 4–12–12; 8:45 am]

BILLING CODE 4140–01–P

[1] *http://nctt.nih.gov/27543703.*

[2] *http://ntp.niehs.nih.gov/go/28213.*

[3] *http://www.epa.gov/ncct/Tox21/.*

[4] *http://www.fda.gov/.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Patient Safety Data Collection and Event Reporting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Availability—New Common Format.

SUMMARY: As authorized by the Secretary of HHS, AHRQ coordinates the development of a set of common definitions and reporting formats (Common Formats) for reporting patient safety events to Patient Safety Organizations (PS0s). The purpose of this notice is to announce the availability of new Common Formats—Hospital Version 1.2 for public review and comment.

DATES: Ongoing public input.

ADDRESSES: The new Common Formats—Hospital Version 1.2, version dated April 2012, and the remaining Common Formats can be accessed electronically at the following HHS Web site: *http://www.PSO.AHRQ.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Cathryn Niane, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403–3697;

Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *PSO.AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) provides for the formation of PS0s, which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. The Patient Safety Act (at 42 U.S.C. 299b–23) authorizes healthcare providers to voluntarily collect and submit in a standardized manner, as explained in the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008: 73 FR 70731–70814. The collection of patient safety work product allows the aggregation of sufficient data to identify and address underlying causal factors of patient safety problems.

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, skilled nursing facilities, and other healthcare providers may assemble information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs—called ''patient safety work product''—is privileged and confidential. Patient safety work product is used to identify events, patterns of care, and unsafe conditions that increase risks and hazards to patients. Definitions and other details about PSOs and patient safety work product are included in the Patient Safety Act and Patient Safety Rule which can be accessed electronically at: *http://www.PSO.AHRQ.gov/REGULATIONS/REGULATIONS.htm.*

Definition of Common Formats

The term ''Common Formats'' refers to the common definitions and reporting formats, specified by AHRQ, that allow health care providers to collect and submit standardized information regarding patient safety events. The Common Formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/recording system; rather the formats are intended to enhance the ability of health care providers to report information that is standardized both clinically and electronically.

In collaboration with the interagency Federal Patient Safety Workgroup (PSWG), the National Quality Forum (NQF) and the public, AHRQ has developed Common Formats for two settings of care—acute care hospitals and skilled nursing facilities—in order to facilitate standardized data collection. The scope of Common Formats applies to all patient safety concerns including: Incidents—patient safety events that reached the patient, whether or not there was harm; near misses or close calls—patient safety events that did not reach the patient; and unsafe conditions—circumstances that increase the probability of a patient safety event.

AHRQ's Common Formats include:

- Event descriptions (descriptions of patient safety events and unsafe conditions to be reported);
- Specifications for patient safety aggregate reports and individual event summaries;
- Delineation of data elements to be collected for different types of events to populate the reports;
- A user's guide and quick guide, and
- Technical specifications for electronic data collection and reporting.

The technical specifications promote standardization of collected patient safety event information by specifying rules for data collection and submission, as well 'as by providing guidance for how and when to create data elements, their valid values, conditional and go-to logic, and reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning. They also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PS0s, so that the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PPC) for data de-identification and transmission to the Network of Patient Safety Databases (NPSD).

The Common Formats include two general types of formats, generic and event-specific. The generic Common Formats pertain to all patient safety concerns. The three generic formats are: Healthcare Event Reporting Form, Patient Information Form, and Summary of Initial Report. The event-specific Common Formats pertain to frequently-occurring and/or serious patient safety events.

Since the initial release of the Common Formats in August 2008, AHRQ regularly revises the formats based upon public comment. The Common Formats—Hospital Version 1.2 features new content to incorporate the event specific formats entitled Venous Thromboembolism (VTE) and Device or Medical/Surgical Supply including Health Information Technology (HIT) Device. Common Formats—Hospital Version 1.2, which also includes minor changes to existing modules and technical specifications, is available at the PSO PPC Web site: *https://www.PSOPPC.ORG/web/patientsafety.*

Common Formats Development

In anticipation of the need for Common Formats, AHRQ began their development by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provides an evidence base that informs construction of the Common Formats. The inventory includes many systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (e.g., from the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems are included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has convened the PSWG to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within HHS—CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration—as well as the DoD and VA.

When developing Common Formats, AHRQ first reviews existing patient safety event reporting systems from a variety of health care organizations. In collaboration with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment. The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues. To the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, framework, and definitions

contained in their draft International Classification for Patient Safety (ICPS).

Commenting on Common Formats Hospital 1.2

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the NQF, a non-profit organization focused on health care quality, to solicit comments and advice to guide the further refinement of the Common Formats. The NQF then convenes an expert panel to review the comments received and provide feedback. The NQF began this process with feedback on AHRQ's 0.1 Beta release of the Common Formats in 2008. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, revises and refines the Common Formats.

The Agency is specifically interested in obtaining feedback from both the private and public sectors on the new Common Formats—Hospital Version 1.2 to guide the improvement of the formats. Information on how to comment and provide feedback on the Common Formats—Hospital Version 1.2, is available at the NQF Web site for Common Formats: *http://www.Quality.forum.ORG/projects/commonformats.aspx.*

The process for updating and refining the formats will continue to be an iterative one. Future versions of the Common Formats will be developed for ambulatory settings, such as ambulatory surgery centers and physician and practitioner offices. More information on the Common Formats can be obtained through AHRQ's PSO Web site: *http://www.PSO.AHRQ.gov/index.html.*

Dated: April 5, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–8743 Filed 4–12–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Correction—Solicitation for Nominations for Members of the U.S. Preventive Services Task Force (USPSTF)

The original date of publication for this **Federal Register** notice was March 28, 2012, Volume 77, Number 60, pages 18823–18825. On this publication, Gloria Washington's email address is incorrect in two places of page 18824 under subheadings **ADDRESSES:** and **FOR FURTHER INFORMATION CONTACT:**. The correct email address for Gloria Washington is: *USPSTFmember nominations@AHRQ.HHS.GOV*

Dated: April 4, 2012.

Carolyn M. Clancy,

Director.

[FR Doc. 2012–8737 Filed 4–12–12; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Treatment of Tinnitus

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for scientific information submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from manufacturers of cochlear implants, sound masking devices, hearing aids, and transcranial magnetic stimulation medical devices. Scientific information is being solicited to inform our Comparative Effectiveness Review of Evaluation and Treatment of Tinnitus, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on this device will improve the quality of this comparative effectiveness review. AHRQ is requesting this scientific information and conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173.

DATES: Submission Deadline on or before May 14, 2012.

ADDRESSES: *Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submitscientific-information-packets/.* Please select the study for which you are submitting information from the list of current studies and complete the form to upload your documents.

Email submissions: ehcsrc@ohsu.edu (please do not send zipped files—they are automatically deleted for security reasons).

Print submissions: Robin Paynter, Oregon Health and Science University, Oregon Evidence-based Practice Center, 3181 SW Sam Jackson Park Road, Mail Code: BICC, Portland, OR 97239–3098.

FOR FURTHER INFORMATION CONTACT: Robin Paynter, Research Librarian, Telephone: 503–494–0147 or Email: *ehcsrc@ohsu.edu.*

SUPPLEMENTARY INFORMATION: In accordance with Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, the Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a comparative effectiveness review of the evidence for evaluation and treatment of tinnitus.

The EHC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by systematically requesting information (e.g., details of studies conducted) from medical device industry stakeholders through public information requests, including via the **Federal Register** and direct postal and/or online solicitations. We are looking for studies that report on treatment of tinnitus, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=811#4755.*

This notice is a request for industry stakeholders to submit the following:

- A current product label, if applicable (preferably an electronic PDF file).
- Information identifying published randomized controlled trials and observational studies relevant to the clinical outcomes. Please provide both a list of citations and reprints if possible.
- Information identifying unpublished randomized controlled trials and observational studies relevant to the clinical outcomes. If possible, please provide a summary that includes the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to withdrawn/follow-up/analyzed, and effectiveness/efficacy and safety results.
- Registered *ClinicalTrials.gov* studies. Please provide a list including the *ClinicalTrials.gov* identifier, condition, and intervention.

Your contribution is very beneficial to this program. AHRQ is not requesting