The National Institute for Occupational Safety and Health (NIOSH) requested public comment on the content and conduct of two separate but related national surveys, one of healthcare workers' health and safety practices and the other of employer health and safety practices. We would like to thank everyone for taking time to submit comments to NIOSH. Obtaining stakeholder input on our proposed data collection effort in healthcare is an important part of our open process to gather valuable information on important health and safety issues and concerns.

The NIOSH Docket Office received 39 sets of comments, with nearly two-thirds from professional associations. The sources are categorized as follows:

- 16 from professional associations who represent hospitals and healthcare system employers;
- 9 from professional associations who represent healthcare workers;
- 8 from healthcare employers;
- 2 from academic institutions;
- 2 from healthcare equipment manufacturers; and
- 2 from private persons.

All of the comments will be taken into consideration. They bring into light new information and insight that will result in revisions to the management and worker surveys. Our responses do not include specific revisions. We are in the process of evaluating all of the comments received from stakeholders in order to make targeted revisions to improve both survey questionnaires.

Because many of the comments address the same issues, our responses to these issues contain the same text as a means of both individually addressing each respondent and maintaining consistency. Also, comments from many of the state hospital associations closely reflect comments of the American Hospital Association (AHA); we referenced our response to the AHA in our response to the state hospital associations.

Each set of comments and the NIOSH response are presented in order of receipt below.

1. Comment

Names

Arnold J. Berry and Jonathan D. Katz

Organization

American Society of Anesthesiologists

Email

aberry@emory.edu Jonathan.katz@yale.edu

Comments:

Thank you for the opportunity to comment on the proposed Hazard Surveillance Survey of Health Care Workers. We are submitting this response on behalf of the American Society of Anesthesiologists (ASA), a medical specialty organization representing over 40,000 physicians practicing anesthesiology in the U.S. In preparing these comments we have solicited input from many colleagues who have conducted

research and are experts in the areas of waste anesthetic gases, infection control, and prevention of sharps injuries.

Because of the relevance to the health and safety of ASA members, we have concentrated our comments on the Employee Core Module, the Management Survey, and the 4 modules that most directly address the practice of anesthesiologists. Each of these recommended edits should get careful consideration. There is a strong feeling among the content experts in anesthesiology who reviewed the proposed study that these changes are crucial to avoid questions that will yield biased, incomplete, or inaccurate data. Each of the numbers below refers to questions in the latest published version of the proposed survey modules.

Employee Core Module

Question 6): This question requests information on the "department or specialty area" where the work takes place. Is the purpose of question 6 to identify the location of work within the facility or the administrative unit of the worker? One choice is "Anesthesiology" but anesthesiologists work in the operating room (Surgery) and labor and deliver suite (Obstetrics/Gynecology). Anesthesiologists also provide anesthesia services (general anesthesia) in other places such as radiology department (Radiology), cardiac cath lab (Cardiology), radiation therapy, or GI endoscopy suites. Some anesthesiologists work in ambulatory surgery centers (freestanding without a relationship to a hospital) or in physician or dentist's offices. It is very possible that a significant hazard would be present in one location but totally absent in others. This information would not be captured with the current format of the question.

Question 7): Anesthesiologists often are partners or work for their own group which is contracted by the hospital or facility. Which of the categories would this fall under?

Question 12): It is important to separate weekend versus weekday shifts since staffing, level of emergency cases, and duty hours may impact on exposures.

Question 13): Anesthesiologists frequently rotate among several locations during the week. How would they respond to this question and is it important to capture the information from their entire 7 day exposure?

Question 21) We question the relevance of many of the questions under "Job Demands". "My job requires me to be creative" or "People I work with are friendly" does not pertain to the stated goals of the survey-"....to collect information describing hazards, exposures, safety and health practices." (ajb comment: Some of the questions are designed to assess anger or rage in the workplace which is becoming a significant issue in healthcare. NIOSH added these kinds of questions to begin to look at workplace violence.)

Question 21b) The term "repetitive work" is used but not defined. Anesthesiologists do repetitive work in that each patient gets an intravenous, each gets ECGs placed, etc. This is likely not the kind of repetitive work that you are interested in so a definition of the term is necessary.

Many of these questions have implied value judgments built into the question which should be changed. For example:

- 21) e) "I get to do...." Change to "I do...." --- "get to" adds a value judgment
 - f) "I have an opportunity..." Change to "I can..." "Opportunity"= value judgment
 - g) "My job allows me to"..... Change to "I can....."

Question 29): This asks if the individual handles "syringes". Syringes are not sharps unless they have a needle on them. Many anesthesiologists now use needleless systems for injections into intravenous tubing and so they would handle syringes but there would be no risk of needle stick injury. The use of needles on syringes needs to be specifically noted.

Question 31, 32, 33): These ask if safe needle devices are used "for injections, IV insertions, or phlebotomy." Anesthesiologists are likely to use the safety devices for injections into IV lines but not for IV insertions. How would they answer this question since the various procedures/devices are grouped together? For question 33, there should be another option: No commercially available device is acceptable for use in my practice.

Question 37): Contaminated "equipment" should be added to this list.

Question 54) This question is a bit confusing and potentially misleading. Required-sometimes? all of the time? These will elicit different answers.

Management Survey:

Question A33: 2nd response): "Number of lost work-days" should be revised to "Number of lost work-hours" - not all work days are of the same length. Anesthesiologists' work hours often vary by day depending on the setting (hospital operating room, outpatient center, or on-call duties).

Question C6, D7, E7, F7): The questions that deal with air sampling require revision. The answers will not be interpretable without specifics about the type(s) of sampling as well as how many samples over what time frame

Question E9) Requires a possible response of "Not Used",

Module F: Surgical Smoke

Question 11): In some institutions, smoke evacuation devices are routinely used during laser surgery but not when electrosurgical devices are used. This question should be divided into two parts to permit the data to correctly capture the above situation.

Question 15-17) These questions need to be rewritten to be more specific or alternatively they should be eliminated. They do not account for differences in type of procedure and distance that the individual was located from the plume, both of which would have impact on the level of protection that is appropriate.

Module G: Anesthetic Gases (Those who administer)

Question 2) Either eliminate or rewrite this question. "When have you received formal training at this facility....." Since this education is a standard part of the residency curriculum, all anesthesiologists receive training on the safe use of anesthetics during their residency. Unless there is new information to be presented, there would be no need to repeat training in the safe handling of anesthetic gases and volatile liquids at each facility that anesthesiologists worked. Any on-site education would be limited to the particular information related to the specific procedures of the facility.

Also, most of the commonly used anesthetics are volatile liquids that are put into a vaporizer before administering to patients. If the term "anesthetic gases" is used, you may not capture information regarding how the liquid forms of the anesthetic are handled.

Question 6-10) These questions need to be more specific or eliminated. They appear to seek a measurement of "exposure" to anesthetic gases, but time administering anesthesia may be poorly correlated with true exposure. There are too many confounding variables since these questions make no assessment of the use of low flow anesthetic administration techniques, use of waste gas scavenging, and the proportion of time that mask anesthetics are administered. Without measurement of waste gas concentrations in the breathing space of the anesthesiologist, reliance only on time of anesthetic administration will likely lead to incorrect exposure information.

Question 10): Anesthesiologists work in many other locations such as radiology suite, cath lab, MRI, labor and deliver. These "off site" (non-operating room) locations may pose a greater risk of exposures. These other sites must be listed to create a more complete picture.

Question 27) – 29) These questions should be eliminated. We are unaware of any practice standards that mandate wearing "respirators" while administering anesthetic gases. Furthermore, we are unaware of any literature that recommends that anesthesiologists routinely use respirators during administration of anesthetic gases or of any facility where this practice occurs.

Module H: Anesthetic Gases (Bystanders who do not administer)

Questions 11 and 12): These questions should be eliminated. Most surgeons or operating room nurses would not know the answer to these questions since they have no involvement in the anesthetic management of patients. Also, this "recall data" would likely be very inaccurate.

Question 19-21) These questions should be eliminated. As in Questions G 27-29 (see comments above), these questions assume that respiratory protection is required during the routine administration of anesthetic gases.

Module I: Waste Anesthetic Gases (Post Anesthesia Care and Surgical Recovery)

General Comments:

One of the major factors determining the level of waste anesthetic gases in the Post Anesthesia Care Unit (PACU) is the adequacy of room ventilation, i.e. airflow, air exchanges per hour, and proportion of recirculated air in the HVAC system. A question regarding this information would provide important information regarding conditions in PACU that related to ambient level of waste anesthetic gases. Another factor that is likely to affect ambient level of anesthetic gas is the specific anesthetic practice at the institution. Many anesthesiologists extubate patients in the operating room as they awaken and therefore, the exhaled concentration of volatile anesthetic coming from these patients would be very low when they reached the Post Anesthesia Care Unit. In contrast, other anesthesiologists choose to bring the patients to the Post Anesthesia Care Unit while they are still anesthetized and intubated and then let them wake up in the Post Anesthesia Care Unit. Under the latter circumstance it would be expected that the exhaled concentration of anesthetic would be higher leading to greater ambient levels of waste anesthetic gases. If valid information is to be obtained from this module, questions regarding the clinical practice at the institution would be necessary.

In some ambulatory surgical practices, most of the cases are done without general anesthesia (local anesthesia with sedation would be used) and therefore, nursing personnel in the Post Anesthesia Care Unit would have less or no exposure to waste anesthetic gases. If valid information regarding exposures is to be obtained from this module, questions regarding the clinical practice would be necessary. In many facilities, periodic monitoring of the ambient air in the Post Anesthesia Care Unit is performed. Data on the routine use of monitoring, either air sampling or use of dosimeters, appears warranted to assess true exposure to anesthetic gases.

Question 10-13) These questions should be eliminated. As in Questions G 27-29 and H 19-21, there is an unwarranted implication that "respiratory protection" is recommended in the PACU to prevent exposure to anesthetic gases coming from patients awakening from general anesthetics. We are unaware of literature to support such an assumption or any such recommendation.

Additional comments:

ASA is anxious to continue in assisting NIOSH as they refine the survey questionnaire. Please feel free to contact Dr. Berry or Dr. Katz directly if we can be of help.

Finally, as we discussed when we were considering participation, it will be extremely helpful for ASA if we can gain access to the unanalyzed data that specifically pertains to our specialty. That information will be important to allow us to move from data collection to meaningful improvements in our daily work habits and routines.

Response:

Dear Drs. Berry and Katz:

We would like to thank ASA for the interest in the proposed management and worker surveys and the general and question-specific comments in your submissions dated March 3, May 3 and June, 2008. We are in the process of evaluating all of the comments received from stakeholders in order to make improvements in both survey questionnaires. Because ASA's comments from the June submission included comments from the March and May submissions, we are responding to all three submissions with this correspondence.

We should be able to provide each of the partnering organizations with a scrubbed flat file of the data. Even though we will not be collecting any personal identifying information as part of the survey, there is the potential that some of the respondents may be able to be identified by the organization (e.g., respondent works for a small employer in a small town). In this case, the data would be presented in a manner so that the identity of the respondent is protected. Another option is to have participating organizations who request raw data sign an agreement stating that they will not attempt to identify respondents who are members of their organization.

We look forward to continuing our collaboration with ASA on the surveys and welcome the opportunity of including ASA members in our worker survey. Thank you again for providing valuable comments on the worker survey.

2. Comment

Name

Marian Swinker

Organization

American College of Occupational and Environmental Medicine Representative

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East Carolina University

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Comments:

Thanks again for the opportunity for input. After the meeting, I contacted ACOEM. Per a recent survey, about 64% of the membership are primarily in patient care/clinical practice, and 22 % are in administrative roles. There are about 5000 members.

I attended the Management group for the breakout sessions, and did express my opinion there. At the wrap-up, it sounded like there were similar comments in the Individual's group; I will repeat some of my comments to you, just to be sure.

Some Management Survey questions, e.g. Anti-neoplastic Agents Module B.11 and B.13 (and comparable questions in other modules) seemed somewhat challenging in tone, implying that such services be should offered or else justify why not. The problem with medical surveillance in this setting is that the sensitivity and specificity of testing or exam is very low; positive predictive value is very low. There are no accepted biomarkers for exposure or effect that are valid or useful across the various classes of anti-neoplastics exposures. (If there are such markers, they are still considered research tools, and are not widely available outside of research settings.)

At the meeting, we discussed the introductory material that should necessarily accompany the survey, to explain that the purpose is research /information gathering, and to explicitly disclaim re any regulatory or enforcement agenda ---or link to OSHA. This discussion helped mitigate the implication/ perception that such measures *should* be in place, just because they were included in the survey.

Please consider whether there is a way to modify or soften the language of the questions; to clarify that the various measures presented are "possible approaches", not to be construed as "requirements" or "evidence-based best practice" (when that is the actual case). For several of these chemical exposures the risk from the hazard is potential or theoretical, not well-quantified or quantifiable. Even the effectiveness of PPE is not well-defined for some, although prevention of exposures is undeniably the prudent course.

Such an approach might help increase your participation rates---by relieving Management concern or reluctance to participate in reporting their practices---if their initial reaction is similar to mine.

Again we appreciate being part of the process and wish you the best as you proceed.

Response:

Dear Dr. Swinker:

Thank you for your comments and your interest in the surveys. We are interested in a wide range of employer health and safety practices including those that are considered best practices and requirements as well as those that are not. Although we are planning to clearly state the purpose of the survey in presurvey announcements, we are also planning to provide introductory information in the survey questionnaires to clarify that not all of the practices covered in the survey are considered requirements or evidence-based best practice, as you suggested. It was not our intent to imply that all of the practices included in the survey are requirements or best practices. Rather, the purpose of these types of questions is to characterize current practices relative to the use of exposure controls whether or not they are

requirements. Again, we thank you for bring this important issue to our attention and for contributing to this process.

3. Comment

Name

Richard Branson

Organization

American Association for Respiratory Care Representative

Email

bransord@ucmail.iuc.edu

Address University of Cincinnati 231 Albert Sabin Way Cincinnati, OH 45267-0558

Comments:

Thank you for inviting me and AARC to be part of the meeting at CVG. I ran a couple of issues by the AARC and have these comments.

Core Survey

The AARC does not recognize the job title Respiratory Technician any more. All individuals working are considered Respiratory Therapists. The AARC would prefer to see the technician classification removed. If you mean to include people who perhaps work in a respiratory therapy department who might set up equipment or clean equipment - this may be alright.

Aerosol survey

Tobramycin is in fact the most commonly used aerosolized antibiotic. However, amikacin and colistin are also frequently used. Do you want to change the question about Tobi to any aerosolized antibiotic and perhaps list these three as examples?

If NIOSH wanted to exhibit at the AARC national meeting Kathy Blackmon at AARC (blackmon@arc.org) would be the person to contact.

I believe the AARC is interested in helping and has the ability to select a random sample of the membership to include adult and pediatric therapists working in the hospital, long term care, and home care.

Response:

Dear Mr. Branson:

We would like to thank AARC for the comments and interest in the proposed surveys. We look forward to continuing our collaboration with AARC and welcome the opportunity of including its members in our worker survey.

4. Comment

Name Margrethe May

Organization Association of Surgical Technologists

Email mmay@delta.edu

Comments:

Modification to the Worker Questionnaire - Targeted Hazards and Occupations by Modules:

Module E - High Level Disinfectants

add: Surgical Technologists, Medical Assistants, and Housekeeping/

Environmental Services

Module F - Surgical Smoke

add: Surgical Technologists, Surgical Assistants, and Perfusionists

Module G - Waste Anesthetic Gases

add: Anesthesiologist Assistants

delete: Surgeons

Module H - Waste Anesthetic Gases, bystander

add: Surgeons, Surgical Technologists, Surgical Assistants, Perfusionists,

Radiologic Technologists, and Sonographers

Module J - Housekeeping Hazards

add: Surgical Technologists, Operating Room Nurses, and Medical Assistants (note: page 25 of the Employee Core Module, question # 79 says "primary duties", while none of the other questions specify that -while all of the above personnel may be involved in cleaning or spill response, those are not their primary duties)

On the Employee Core Module:

page 2-3, question #2 - I would add methylmethacrylate (the "bone cement" used in total joint surgery), which requires a closed container for mixing the powder and liquid components at the field

page 2 - question #2.d., High Level Disinfectants, only lists glutaraldehyde as an example - Since the Steris peracetic acid system became available, I have not seen glutaraldehyde used in hospitals, and when I gave a talk to the Michigan state group of Medical Assistants last Fall, they indicated that they were only using the Steris system in offices and endoscopy units. I think that glutaraldehyde is outdated, even in small facilities.

page 2 - question #2.f. asks about ionizing radiation (X-rays, fluoroscopy, gamma rays), but there are no follow-up questions or follow-up module -

In addition to Radiologic Technologists, obviously, Surgical Technologists, Surgical Assistants, Operating Room Nurses, and Dental Assistants are all exposed to X-rays and/or fluoroscopy. page 3 - number "j" should add infectious disease agents other than TB, such as MRSA, VRE, etc.

page 4 - under Special Practitioners, add Anesthesiologist Assistant, Perfusionist, and Surgical Assistant under Technologists and Technicians, add Dialysis Technicians under Cleaning, Maintenance, and Food, add Surgical Services Associate/Assistant -I don't know if you are aware that in many Operating Rooms, special housekeeping personnel (usually called SSA's), help lift

and transport patients, are trained to chemically sterilize or disinfect instruments and endoscopes, and may even open sterile supplies or scrub in and hold retractors during surgery, in addition to cleaning OR's between cases. Therefore, such personnel should fill out Modules E, F, H, and J.

If you are going to include a Student category, the exposures would be different for Interns/Residents, Medical Students, Nursing Students, and students in all the other listed Allied Health disciplines.

page 6 - add: Acute Care Mental Health, Correctional Facility, Dialysis Unit,
Radiation Therapy (separate from Nuclear Medicine), and some category that would include the
growing number of freestanding Ambulatory Surgery Centers, clinic-based surgery, and single
physician/office-based surgery
I would suggest changing number 11 to "Anesthesia Provider", which would
include CRNA's (Nurse Anesthetists) and Anesthesiologist Assistants,
rather than limiting the category to Anesthesiologists number 61 just says "Surgery" - Was that
meant to include all other surgical specialties that are not otherwise listed (e.g. Neurosurgery,
Cardiothoracic and Peripheral Vascular Surgery, Plastic Surgery, etc.) and everyone who works

page 13 - Please differentiate hollow-bore hypodermic or biopsy needles from a solid surgeon's sewing/suture needle or scalpel. The risks from blood-borne pathogens are very different.

in the Operating Room? Or should that be split to say "All other surgical specialties" and then

On Module D: (and probably in the Core Module under #2.d and 2.e on page 2 and under #73 on page 24), I suggest that you list examples of trade names in the introduction, as was done for Module E -- namely, ethylene oxide (ETO or EO) and hydrogen peroxide gas (Sterrad system). I think that many workers who would recognize trade names may not be aware of the generic names.

I think Module E should just be named "High Level Disinfectants" because, as I said before, my sense is that the use of glutaraldehyde is outdated. Also, are you interested in some of the newer chemical sterilants such as ozone gas and vapor phase hydrogen peroxide/VPHP? Are you interested in Low Level Disinfectants, such as phenolic compounds and quaternary ammonium compounds?

On Module F:

list "Operating Room" separately?

page F-4 - Just an aside: I don't know if you are aware that there has been a move in some hospitals over recent years to require personnel to take scrub suits home for laundering (which involves blood and body fluids, not just ESU/laser smoke).

page F-3, question #11 - I think you need to differentiate between using the regular/surgical suction apparatus and using one of the special closed evacuation/filtering devices that are designed for smoke.

page F-6 - After the questions about wearing respiratory protection "not including a surgical mask", you need to add a question about whether the person wore a surgical mask. Furthermore, I would suggest differentiating a regular surgical mask from a high-filtration "laser" mask.

On Module H, I agree with the Nurse Anesthetist who commented that the people in the room other than the anesthesia provider probably would not be knowledgeable about the methods or agents used (questions 11, 12, 13, 15, 16, and 17), other than possibly being aware of the mask-induction of a Pediatric patient. On pages H-4 and H-5, add "wore a surgical mask".

I forgot to ask at the meeting, do you care about antiseptic agents used for the preoperative skin wash of patients and for surgical scrubbing by sterile team members? That might include: providone-iodine/iodophorschlorhexidine/CHG quaternary ammonium compounds, such as benzalkonium chloride (Zephiran) chloroxylenol/PCMX triclosan (especially since safety issues were raised during the October 2005 testimony from the University of Michigan School of Public Health and in the March 2007 article in Environmental Science and Technology)

Response:

Dear Ms. May:

Thank you for your comments and interest in the worker survey. Also, we are very appreciative of the detailed comments that were provided on specific questions in the worker questionnaire. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements in both survey questionnaires.

We look forward to continuing our collaboration with AST and welcome the opportunity of including its members in the worker survey.

5. Comment

Name George Byrns

Organization Illinois State University

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Address Campus Box 5220 Normal, IL 61790

Comments:

Thank you for this long overdue initiative! My major concern is the length of the core questionnaire. It may be very difficult to get cooperation from understaffed health care workers because of the time commitment to complete the entire form. You may achieve a higher yield if the core document were administered in smaller chunks, such as demographics, safety climate, psychological strain profile, violence assessment, etc.

One minor comment: While most nurses still use the term universal precautions, it is being gradually phased-out in favor of the term standard precautions. I would use both terms to avoid confusion.

Response:

Dear Dr. Byrns:

Thank you for your comments and interest in the worker survey. We have received several comments regarding the length of this survey indicating that it too long. Prior to our pilot tests, we convened focus groups/cognitive testing; most participants indicated that they would complete a 30 minute survey, especially if they could complete the survey in more than one session (which is an option for respondents

of our web survey). Findings from our pilot tests show that the average time to complete the core module was about 20 minutes, and about 7 minutes for each hazard module. Response rates were fairly good, averaging 45% at two pilot test sites. While there appears to be no single guideline for questionnaire length, one literature review of the effect of questionnaire length on response rates stated that "results are still confusing and contradictory, conclusions are still not clear, and questionnaire designers still aim for shorter questionnaires with little more justification than the assumption that longer interviews will result in higher nonresponse" (Bogen K, 1996 Proceedings of the Section on Survey Research Methods, American Statistical Association, pgs 1020-1025). Although we feel that the length of the worker survey of reasonable length, we are planning to evaluate options for reducing the completion time.

6. Comment

Name Andrew Varner

Organization University of Pittsburgh Medical Center

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Comments:

Most of the questions on the core form are applicable questions but the survey is way too long. The time required to complete a 25 page questionnaire is way more than our staff will devote without being held at gun point.

There is a significant portion of our staff that are technologically challenged and would not be able to complete an electronic form without instruction. And though I feel we are a technologically advanced hospital, many of our Housekeeping, Nursing and Maintenance staff do not have prolonged access to computers during work hours. The survey would probably have to be completed as a hard copy then faxed or mailed in.

A few of the questions on the core form are somewhat leading. Data from this form may accurately measure perceptions but provide a false impression of true safety conditions in the hospital. In past questionnaires of our hospital staff we have found that staff are unlikely to record that their personal habits/practices are not safe. Rarely do our staff view their own work practices as presenting a significant hazard to their coworkers or themselves. This may cause the questions to be subjectively answered.

Response:

Dear Mr. Varner:

Thank you for your comments and interest in our survey. We have received several comments regarding the length of the worker survey indicating that it too long. Prior to our pilot tests, we convened focus groups/cognitive testing; most participants indicated that they would complete a 30 minute survey, especially if they could complete the survey in more than one session (which is an option for respondents

of our web survey). Findings from our pilot tests show that the average time to complete the core module was about 20 minutes, and about 7 minutes for each hazard module. Response rates were fairly good, averaging 45% at two pilot test sites. While there appears to be no single guideline for questionnaire length, one literature review of the effect of questionnaire length on response rates stated that "results are still confusing and contradictory, conclusions are still not clear, and questionnaire designers still aim for shorter questionnaires with little more justification than the assumption that longer interviews will result in higher nonresponse" (Bogen K, 1996 Proceedings of the Section on Survey Research Methods, American Statistical Association, pgs 1020-1025). Although we feel that the length of the worker survey is of reasonable length, we are planning to evaluate options for reducing the completion time.

To address your concerns regarding potential respondents who are technologically challenged, we plan to provide clear instructions on how to complete the web survey in our pre-survey correspondence. Respondents will have the option of completing the web survey anywhere there is access to the Internet, not just at work.

Stakeholders expressed interest in including perception questions in the worker survey as they allow for respondents to express their opinions on a number of important health and safety issues. Perception questions are very common in surveys conducted by others and have shown to provide valid information.

7. Comment

Name Susan Kent

Organization Empire Health Services

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Address 800 W. 5th Avenue Spokane, WA 99210 USA

Comments:

On the Employee Core Module, question #50 - b. There should not be use of brand names. Mechanical lifting devices can be described as ceiling lifts, floor lifts, sit-to-stand devices.

Also add another category - air-assisted lateral transfer device

Response:

Dear Ms. Kent:

Thank you for your comments and interest in the worker survey. This is important information. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements to the worker questionnaire.

8. Comment

Name Bruce Cunha

Organization Marshfield Clinic

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Address 1000 N Oak Ave GD2 Marshfield, WI 54449

Comments:

I am concerned in that the employee surveys will be distributed to healthcare organizations, but the survey for healthcare facilities will only be distributed to selected facilities? Why not open this up to all healthcare facilities and distribute it through healthcare organizations and groups that support the Health and Safety professionals in these facilities. This would give a larger picture of the issues asked about.

I also do not care for self observed studies. They lack scientific clarification and can be used as a political tool. This is especially true if you are relying on union organizations to distribute the survey.

Response:

Dear Mr. Cunha:

Thank you for your comments. Although we would have preferred to include all types of healthcare establishments in the management survey, the sample would include hospitals and ambulatory healthcare services. Through the employee survey, we should gain valuable insights into the different types of work settings in which respondents work. Such data will be useful in determining future surveillance efforts.

Regarding the collection of self-reported information, in our pilot tests we found that the data collected from the worker and management surveys were fairly accurate based on post survey interviews, observations of work areas and work practices, and review of documents.

Stakeholders expressed interest in the inclusion of perception questions in the worker survey as they allow for respondents to express their opinions on a number of important health and safety issues. Perception questions are very common in worker surveys conducted by others and have shown to provide valid information. Although labor organizations expressed interest in participating in the worker survey, a web survey of their members was considered impractical primarily because member email addresses are not readily accessible at a national level. As a result, the worker survey will be implemented exclusively through professional associations. The worker survey will be revised to include questions on professional association and labor union affiliations, as well as type, size and location of employer, in order to characterize responses by these variables and to assess whether the results are nationally representative.

9. Comment

Name Eileen McNeely

Organization

Harvard School of Public Health Department of Environmental Health Occupational Health Program

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Comments:

I commend this effort to look at the health care industry.

Based on five years of effort trying to collect data from 500 acute care facilities we have learned a lot about what type of data is available and who is able to provide it.

We had a multi-method strategy of collecting management surveys, management interviews, employee surveys, union surveys, OSHA logs and workers' compensation records. In addition, we collected organizational and staffing information from the American Hospital Association. Each of these methods had pluses and minuses. The most insight was gained came from the quality of data available.

We are happy to discuss the learnings from this vast canvassing effort as well as the areas of most need going forward in our opinion.

My caution to NIOSH is to avoid a substance-by substance or exposure- by-exposure approach. The organization of health care facilities is so fragmented that collecting this knowledge from any one or two individuals is impossible.

This realization speaks to our greatest learning from our undertaking---that OH&S systems are not integrated, comprehensive, effectual, or even understood. In addition, the focus seems to be on treatment versus prevention.

I am happy to discuss these results with you further.

Response:

Dear Dr. McNeely:

Thank you for your comments and your willingness to share your experiences conducting employee and management surveys in the healthcare industry and provide us with information on areas of greatest need. We are particularly interested in knowing how to improve our management survey given the fact that the information we are collecting are not typically available from one source (i.e., health and safety manager). We will contact you as we move forward with the surveys.

10. Comment

Name Jeff Pajot

Organization

Ontario Safety Association for Community and Healthcare

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Comments:

I commend you on your efforts to discover best practices in OHS for healthcare. Our clients will benefit greatly. A few comments:

- Since Musculoskeletal Disorders (MSD) are the most common injury in healthcare I think more effort should be placed in determining best practices. I see that you cover ergonomics issues in the core module and management questionnaires but not in hazard module J.
- 2) Perhaps an entire "hazard module" could be devoted to MSD or ergonomics.
- 3) In the management questionnaire, under 'ergonomics' I recommend that you ask: Has a formal ergonomics risk assessment been conducted on high risk jobs? This is different than question A39- Job Analysis. Perhaps you can ask them to list the name of the MSD risk assessment tools that they used.
- 4) In the management questionnaire, under 'ergonomics' question A41- Back Belts. I wonder why this question is asked. It suggests that back belts are a "best practice". But they are definitely NOT a best practice to reduce MSD. It's also mentioned in question 54 of the core module questionnaire.

I look forward to seeing the results.

Response:

Dear Mr. Pajot:

Thank you for your comments and interest in our surveys. Regarding comments 1 and 2, questions addressing MSDs were not included in hazard module J because the focus of the hazard modules is on chemical agents. The hazard modules were developed to focus on selected classes of chemical agents of concern to stakeholders.

Because we recognize that MSDs represent a significant and well-recognized problem in healthcare, we decided to address MSDs in the core module of the worker survey, along with other cross-cutting health and safety hazards and issues affecting most healthcare workers.

Regarding comments 3 and 4, we are in the process of evaluating all of the comments received regarding specific questions and will make revisions as necessary.

11. Comment

Name James Dunn

Organization
Dornoch Medical Systems, Inc.

Email JDunn@Dornoch.com Address 3018 SW Boswell Ave Topeka, KS 66611

Comments:

I did not notice concern addressing the aerosolization generated from liquid infectious waste. Areas of concern from flushing a toilet or hopper after emptying infectious fluids or splashing and splattering of infectious fluids caused by mishandling of the fluids. These concerns in hospitals are growing as the sharps issues have grown nation wide. Technologies are being developed to address these issues. There are at least seven different technologies developed over the past ten plus years to meet the demands by hospitals and surgery centers. Improper autoclaving of these infectious fluids in an effort to "treat" can generate significant healthcare issues.

Improper handling of the liquid infectious wastes is addressed by OSHA, DOT, EPA, and most of the State DOH. You have addressed smoke plume as an issue. I applaud you for focusing on this issue. Liquid infectious waste can be as much as 50% of the total infectious waste generated by ORs, L&Ds, and other hospital departments. Please give this issue equal time.

Thank you,

Response:

Dear Mr. Dunn:

Thank you for your comments and bringing to our attention the issues of aerosolization from liquid infectious waste and improper handling of the same. We will evaluate these issues along with other issues that have been raised during the public comment period, and assess whether question(s) should to be added to the worker survey.

12. Comment

Name Beth McKinney

Organization Montgomery County HHS Maternal and Child Dental Program

Email

Beth.McKinney@montgomerycountymd.gov

Comments:

A request to review and comment on your training modules was posted on the American Dental Hygiene Association's website. As a public health dental hygienist with responsibilities in the area of infection control, I was very interested in looking at your surveys. I am sending the following comments for use as you see fit. I reviewed only Module A for Core Workers.

I found the module to be comprehensive, well-designed and easily understood. The module flowed well and was easy to complete. It is long and did take me about a half an hour to finish. I have the following suggestions, most of which are small typos in the document.

Question 34: if the answer is zero, it should say "skip TO question 37". You omitted the word "to" making it sound as if you want people to skip answering question 37.

Question 37: This question is worded poorly for those of us in the dental field. After reading the first few items on the list, "bed pans, sheets, clothing" we are tempted not to read the rest of the question and answer no, when the correct answer for dental personnel is yes. Could you reword the question to say something like, "...do you handle contaminated materials (e.g. gauze, sheets, etc) that are visibly soiled with blood..."? I would also suggest adding the word "saliva" to the end of the question, i.e. "blood, saliva, urine,..." In dentistry saliva is still considered an infectious body fluid.

Question 50: answer f needs a parenthesis at the end.

Question 69: Since this question immediately follows the ones about ethnicity, does it apply to education in other countries? If so, does it apply only to high school or to professional programs as well? There are many foreign trained dentists and physicians who cannot practice in the U.S. and are working in lesser capacities. You not get the data you want if they are misinterpreting this question.

I would really like to see a Module K for Dental Personnel. I believe that, while the core module is very comprehensive, it does not do adequate justice to the unique environment in which dental personnel work. We encounter a variety of potential hazards in our daily work settings including, x-ray chemicals, ionizing radiation, mid-level disinfectant chemicals, phosphoric acid, mercury, moving heavy dental equipment, extracted teeth containing amalgam fillings, lead containing crowns made in China, lack of a functional safer dental needle, aerosolized sprays containing pathogens and medicaments, nitrous oxide gas, electrosurgery devices, lasers, and wet floors. I think developing a separate module for dentistry would be a prudent endeavor on your part. I urge you to consider it.

I hope these comments have not been too cumbersome. I appreciate being given the opportunity to review your materials; and I believe the core module is excellent. If I can be of any assistance in the development of a module for dental personnel, please feel free to contact me.

Response:

Dear Ms. McKinney:

Thank you for your comments and interest in our surveys. In reference to your detailed comments, we are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements in both survey questionnaires.

We believe that the hazard modules (which you had not reviewed), as well as the core module, already address many of the important health hazards encountered by dentists, dental hygienists, and dental assistants. We will review them with your comments in mind.

13. Comment

Name:

Private person

Comments:

OSHA's Hospital eTool covers more work areas than NIOSH's proposed survey. What about these work areas? Administration, Central Supply, Dietary, Engineering, Laboratories, Laundry, Biomedical Services, and Pharmacy. Why are these work areas not being surveyed.

OSHA's Hospital eTool covers more hazards than NIOSH's proposed survey.

What about these hazards? Electrical, Legionnaires' Disease, Noise, Mercury, Slips/Trips/Falls,
Tuberculosis, Asbestos Exposure, Burns/Cuts, Carbonless Paper, Foodborne Disease, Lockout/Tagout,
and Radiation Exposure. Why are these hazards not being included in the survey.

Response:

Thank you for your comments and interest in our surveys. We recognize that there are other important exposures and would like to include more. However, the hazards covered in our proposed surveys were selected because they were described by stakeholders as some of the top issues facing healthcare workers.

Please note that Questions 2 and 6 of the worker core module collect information on a wide range of safety and health hazards and work areas, respectively. Because it was not practical to include an exhaustive list of hazards and work areas, respondents are provided an opportunity to identify other hazards and work areas that are not specifically listed in the survey. Because we are recruiting healthcare workers through their membership in professional associations, it is very likely that respondents will represent many types of healthcare workplaces, in addition to hospitals.

14. Comment

Name Michael McNally

Organization United Health Services Hospitals

Comments:

I have reviewed this survey with my colleagues here at United Health Services Hospitals and we believe this survey should NOT be used. The reasons for our concerns are as follows:

- Workers will be paid \$10 to complete the survey and NIOSH plans to use organized labor groups like Service Employees International Union and professional groups to market the survey to health care workers. With NIOSH reaching out to other groups to market the survey, there is concern about NIOSH's ability to ensure that the survey process is not used to advance other advocacy or political agendas.
- Both the management and the employee surveys are lengthy and will take far longer than NIOSH
 estimates to complete. Completing the management survey is more complicated a task than
 completing the worker survey. The survey should be user-friendly to managers as well as to
 workers to ensure the best possible response rate.
- The worker survey is largely based on workers' perception (subjective) while the management survey is based on concrete management practices (objective). The worker survey contains several "factual" statements that the worker is asked either to agree or disagree with. Some of the statements may not have a solid scientific basis and, in fact, may directly contradict agency recommendations. While NIOSH intends to "validate" the management survey through site-visits of either a sample or all of the responding hospitals, there is no intention to "validate" the workers' survey results.

Dear Mr. McNally:

Thank you for your comments and interest in our surveys. Since preparing the project proposal and receiving estimated costs from our contractor to implement the surveys we decided not to offer a monetary incentive to respondents of the worker survey. We believe that receiving a strong commitment of support for the worker survey from the leadership of all participating professional associations will be more worthwhile and effective than any type of financial incentive for respondents.

Although labor organizations expressed interest in participating in the worker survey, a web survey of their members was considered impractical primarily because member email addresses are not readily accessible at a national level. As a result, the worker survey will be implemented exclusively through professional associations. The worker survey will be revised to include questions on professional association and labor union affiliations, as well as type, size and location of employer, in order to characterize responses by these variables and to assess whether the results are nationally representative.

We received several comments regarding the length of both the worker and management surveys indicating that they are too long. In regards to the worker questionnaire, prior to our pilot tests we convened focus groups/cognitive testing; most participants indicated that they would complete a 30 minute survey, especially if they could complete the survey in more than one session (which is an option for respondents of our web survey). Findings from our pilot tests show that the average time to complete the core module was about 20 minutes, and about 7 minutes for each hazard module. Response rates were fairly good, averaging 45% at two pilot test sites. While there appears to be no single guideline for questionnaire length, one literature review of the effect of questionnaire length on response rates stated that "results are still confusing and contradictory, conclusions are still not clear, and questionnaire designers still aim for shorter questionnaires with little more justification than the assumption that longer interviews will result in higher nonresponse" (Bogen K, 1996 Proceedings of the Section on Survey Research Methods, American Statistical Association, pgs 1020-1025). Although we feel that the length of the worker survey is of reasonable length, we are planning to evaluate options for reducing the completion time.

Stakeholders expressed interest in the inclusion of perception questions in the worker survey as they allow for respondents to express their opinions on a number of important health and safety issues. Perception questions are very common in worker surveys conducted by others and have shown to provide valid information. We plan to revisit these questions to assess whether all of them need to be included in the survey.

In our pilot tests we found that the data collected from the worker and management surveys were fairly accurate based on post survey interviews, observations of work areas and work practices, and review of documents

We considered including a validation component to the worker survey effort; however, the anonymous nature of the worker survey does not lend itself to validation. Current plans do not include validation of management responses primarily due to lack of project funds.

15. Comment

Name Kathleen Coughlin

Organization

Catholic Health System Kenmore Mercy Hospital

Email kkc1114@chsbuffalo.org

Comments:

It is **much** too long. When would a worker be expected to complete? at work? Would it be expected to be done on line? If so would it only be available to those with computers? Some workers have poor reading abilities and would not be able to complete. The S reimbursement would then make it discriminatory.

Which managers? collecting the info about practices and P&P would be extremely time consuming for most managers who would have to gather info. I would not take the time to complete it and I would be very concerned about how the info would be used. I agree with the other objections points made in your correspondence.

Response:

Dear Ms. Coughlin:

Thank you for your comments and interest in the proposed surveys. We received several comments regarding the length of the worker survey indicating that it too long. Prior to our pilot tests, we convened focus groups/cognitive testing; most participants indicated that they would complete a 30 minute survey, especially if they could complete the survey in more than one session (which is an option for respondents of our web survey). Findings from our pilot tests show that the average time to complete the core module was about 20 minutes, and about 7 minutes for each hazard module. Response rates were fairly good, averaging 45% at two pilot test sites. While there appears to be no single guideline for questionnaire length, one literature review of the effect of questionnaire length on response rates stated that "results are still confusing and contradictory, conclusions are still not clear, and questionnaire designers still aim for shorter questionnaires with little more justification than the assumption that longer interviews will result in higher nonresponse" (Bogen K, 1996 Proceedings of the Section on Survey Research Methods, American Statistical Association, pgs 1020-1025). Although we feel that the length of the worker survey is reasonable, we are planning to evaluate options for reducing the completion time.

In regards to the management questionnaire, the fact that the requested information would need to be collected by persons other than the primary recipient of the questionnaire (especially in medium to large sized facilities) adds complexity and time to complete the survey. We are planning to evaluate options for streamlining the management survey.

Because contractor costs exceeded our project proposal budget, it is unlikely that we will be able to offer respondents of the worker survey with a monetary incentive. We believe that receiving a strong commitment of support for the worker survey from the leadership of all participating professional associations will be more worthwhile and effective than any type of financial incentive for respondents.

Recruiting healthcare workers who are members of professional associations rather than by place of employment should increase the likelihood that sampled individuals would complete the web survey as they have the option of completing the survey anywhere there is access to the Internet, not just at work.

16. Comment

Name

Sandra Domeracki Prickitt

Organization

Association of Occupational Health Professionals in Healthcare (AOHP)

Email

domeras@sutterhealth.org

Address 109 VIP Drive, Suite 220 Wexford, PA 15090

Comments:

AOHP welcomes the opportunity to comment on the proposed healthcare worker and management safety surveys. We support NIOSH's efforts to research both front line and management in this high hazard industry. In addition we are ready to partner with NIOSH as an association in the conduct of the surveys. Denise Knoublach was our representative at the meeting in Cincinnati where she and other stakeholders had the opportunity to discuss the survey and share comments about the content and conduct of the survey.

Both surveys are comprehensive and it is clear that it was a significant effort to develop them. As a result the surveys are lengthy and require considerable time to complete. The front-line healthcare worker (HCW) survey:

- would be difficult to administer to employees who are not represented by an association. For example, there would most likely only be one AOHP member at a healthcare facility who may or may not be the contact person for employee safety. Nurses may be represented by a variety of nursing associations based on their specialty.
- does not address groups of workers such as environmental service workers and dietary workers who
 usually do not belong to professional associations. It would be important to gather data from these groups
 of workers. The question then becomes, how do we engage these employees participation?
- requires completing the main module of the survey and then a second module which would require
 additional time. The estimated time of 30 minutes to complete this survey is a considerable time
 commitment for facilities with scarce resources and demands to maintain productivity.

With regard to the content of the survey:

- question #38 in the core module states "universal precautions" rather than "standard precautions" which
 is now used by infection control practitioners when training staff.
- the demographics section does not include an age breakdown. Age information would be valuable in
 determining safety behaviors based on age. One is example is that in the literature there has been some
 data suggesting that younger nurses have not report sharps injuries. The ability to make this type of
 correlation can lead to changes in education, training methods and ultimately improved safety for the
 employee but more specific data is needed.

The management survey would require input from various individuals within the organization - human resources, safety, occupational health, risk management, pharmacy, etc. It would require a team effort and many hours to complete the 50 page survey. As a result the survey return may not be as high as anticipated. It may be worthwhile to reconsider the conducting the survey in modules sent out at certain time intervals and focusing on one or two hazards.

Given the time commitment for both frontline staff and management, employers would want to know up front, "what is in it for them?" to participate in both surveys. The benefits of participation including the return on investment in participating in the survey would need to be clearly stated to obtain "buy-in" from senior management. Senior management support would increase the likelihood of optimal participation in the survey process.

AOHP is a national organization with over 1100 occupational health professionals who work in healthcare settings, primarily hospitals. AOHP's vision is to be the defining resource and leading advocate for occupational health and safety in healthcare. Our mission is dedicated to promoting the health and safety of workers in healthcare. This is accomplished through:

- Advocating for employee health and safety
- Occupational health education and networking opportunities
- · Health and safety advancement through best practice and research
- Partnering with employers, regulatory agencies and related associations.

Again, thank you for the opportunity to provide comments on this document. Please contact MaryAnn Gruden, our Association Community Liaison, if additional information or questions arise. She can be reached at 412/578-6792 or by email at magaohp@yahoo.com.

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Response:

Dear Ms. Prickett:

We would like to thank AOHP for the comments and interest in the proposed management and worker surveys. Also, we are very appreciative of the detailed comments that were provided on specific questions in the management and worker questionnaires. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements in both survey questionnaires.

We have received several comments regarding the length of both the worker survey and the management indicating that they are too long. Regarding the worker survey, we convened focus groups prior to our pilot tests and most participants indicated that they would complete a 30 minute survey, especially if they could complete the survey in more than one session (which is an option for respondents of our web survey). Findings from our pilot tests show that the average time to complete the core module was about 20 minutes, and about 7 minutes for each hazard module. Response rates were fairly good, averaging 45% at two pilot test sites. While there appears to be no single guideline for questionnaire length, one literature review of the effect of questionnaire length on response rates stated that "results are still confusing and contradictory, conclusions are still not clear, and questionnaire designers still aim for shorter questionnaires with little more justification than the assumption that longer interviews will result in higher nonresponse" (Bogen K, 1996 Proceedings of the Section on Survey Research Methods, American Statistical Association, pgs 1020-1025). Although we feel that the length of the worker survey is of reasonable length, we are planning to evaluate options for reducing the completion time.

In regards to the management questionnaire, the fact that the requested information would need to be collected by persons other than the primary recipient of the questionnaire (especially in medium to large sized facilities) adds complexity and time to complete the survey. We are planning to evaluate options for streamlining the management survey.

Please note that we are working with numerous professional associations to implement the worker survey because in our pilot tests we found that an establishment-based approach required significant resources. Therefore, we will not be relying on a facility point of contact to recruit front-line healthcare workers to complete the web survey.

We share your concern about the challenges associated with gaining access to environmental services workers (covered by Module J of the worker survey) as they are not represented by an association. Although we believe that this is an important group of workers to survey, this group may not be included in our survey because there is no easy means to gain access to them. We had not specifically targeted dietary workers for our survey due to lack of concerns from stakeholders.

Question 59 of the core module asks for the year the respondent was born and our analysis will include age distribution of respondents.

Due to the fact that the worker survey is to be implemented through professional associations whose members represent a wide range of workplaces, and due to the fact that the management survey is to be implemented in a random sample of about 500 hospitals and ambulatory health care services establishments, employer burden would primarily be associated with the completion of the management survey as it is unlikely that the workers in these sampled establishments would complete the worker survey.

We are aware of the importance of developing appropriate recruitment materials that clearly state the purpose of the survey, reasons for participation, and examples of how the information can be used as a means to maximize response rates. We also recognize that for the worker and management surveys to be successful, we need the support of each participating organization (worker survey) and the American Hospital Association (management survey).

We look forward to working with AOHP as we move forward with the surveys.

17. Comment

Name

Patricia Anderson

Organization

Kindred Healthcare

Email

trish.anderson@kindredhealthcare.com

Address

1412 County Hospital Road Nashville, TN 37218

Comments

Survey was easy to complete; diverse information to be obtained which will be an asset to promoting safety in the hospital environment.

Response:

Dear Ms. Anderson:

Thank you for your comments and interest in the surveys. We are in the process of reviewing all of the comments and will be making necessary improvements in the questionnaires.

18. Comment

Name Private person

Comments:

I really like the idea of this survey and hope the results can be utilized to make positive changes so that those that work with these agents understand the potential risks, along with the benefits of adequately protecting themselves. I also hope that organizations receive this information & are held to the recommendations & work towards supporting their employees to uphold the recommendations.

One comment...the 2004 alert from you all at NIOSH spoke to Hazardous Drugs, not just antineoplastic agents. We worked very hard at this institution to create our hazardous drug list (per your recommendations) and while the majority of agents are antineoplastic or chemotherapy drugs, there were a few that fell outside of that definition. Is there a way to survey for Hazardous Agents in the broader sense & not just chemotherapy agents? I realize that each institution may have a different list of what they have determined to be hazardous, but I do feel by not including the larger group we could perpetuate the idea that chemo drugs are the only hazardous drug out there that staff need to protect themselves.

| Thanks. | | |
|-----------|--|--|
| Response: | | |
| Dear: | | |

Thank you for your comments and interest in the surveys. Use of the term *hazardous drugs* may be problematic because respondents would not necessarily know the specific agents as they may differ from one institution to another and may change over time. In Question 2.c of the worker core module, respondents are asked to rate level of risk to "hazardous drugs (including antineoplastic agents)" a statement which conveys that hazardous drugs represent more than antineoplastic agents. Although ribavirin and pentamidine aerosols (hazard module a) and antineoplastic agents (hazard modules b and c) meet the ASHP definition of hazardous drugs, the specialized methods in which these agents are used necessitated that we address them separately rather than collectively as hazardous drugs.

19. Comment

Name P. Richard Warburton

Organization ChemDAQ Inc.

Email rwarburton@chemdaq.com www.chemdaq.com

| Address 135 Industry Drive | | |
|---|--|--|
| Comments: | | |
| I am writing this letter in response to your solicitation for comments on the Survey of Healthcare Employer Safety and Health Practices, docket # NIOSH-135. | | |
| I am the Chief Technology Officer and General Counsel for ChemDAQ Inc. ChemDAQ is a leading manufacturer of gas monitoring equipment, focusing primarily on monitoring sterilant gases in healthcare for occupational safety. | | |
| Comments are offered for modules D (chemical Sterilants) and E (High Level Disinfectants) and Module G (Anesthetic Gases – administration). Overall, I fully support NIOSH developing this survey. It will provide very valuable information that is not currently available. | | |
| Module D: Chemical Sterilants | | |
| A) New Question after Q. 26, intended to assess frequency of employee exposure to sterilant gases | | |
| During the past 7 calendar days have you experienced any symptoms of exposure to ethylene oxide? Check all that apply: | | |
| Headache, nausea Smell Eyes stinging Irritation of respiratory tract Skin irritation, burn or blister Other; (Please specify): | | |
| B) New Question after Q 26, intended to assess level employee protection from sterilant gases. What methods are employed in the facility to monitor employee exposure to ethylene oxide? Check all that apply: | | |
| Badges occasionally Badges continually Continuous monitor that displays the EtO concentration in the room air. | | |
| Gross leak detector, provides an alert in the case of a major leak. | | |

Other (please specify): _

| C) | New Question after 33 (similar to Q. 26, but for hydrogen peroxide gas plasma) |
|----|---|
| | In regards to that same sterilizer, was a visual display of the hydrogen peroxide level (i.e., concentration of hydrogen peroxide in the room) present in the work area? Yes No Don't know |
| D) | New Question after 33, (Repeat exposure question for hydrogen peroxide) During the past 7 calendar days have you experienced any symptoms of exposure to hydrogen peroxide? Check all that apply: |
| | Headache, nausea Smell Eyes stinging Irritation of respiratory tract Skin irritation, burn or blisters Other; (Please specify): |
| E) | New Question after Q 33, intended to assess level employee protection from sterilant gases. |
| | What methods are employed in the facility to monitor employee exposure to hydrogen peroxide? Check all that apply: Badges occasionally Badges continually Continuous monitor that displays the EtO concentration in the room air. Gross leak detector, provides an alert in the case of a major leak. Other (please specify): |
| F) | New Question after Q. 26 (analogous to Q. 4, but related to hydrogen peroxide) |
| | Do you know the OSHA permissible exposure limit (PEL) value for hydrogen peroxide and the NIOSH Immediately dangerous to life and health limit (IDLH) value? |

| | | Yes, I know the OSHA PEL for hydrogen peroxide No, I don't know the OSHA PEL for hydrogen peroxide Yes, I know the NIOSH IDLH for hydrogen peroxide No, I don't know the NIOSH IDLH for hydrogen peroxide |
|-------|-------------------------|--|
| F) | there ozone is another | ited to ethylene oxide (EtO) and hydrogen Peroxide gas plasma; however chemical sterilant that was recently approved by the FDA and so should be a very even though there not many ozone sterilizers in service yet. |
| Modul | e E: High Level Disin | fectants |
| A) | After question 12 | |
| | _ | that same disinfectant system, was a visual display of the disinfectant vapor incentration of disinfectant vapors in the room) present in the work area? Yes No Don't know |
| B) | After question 17 | |
| | | 7 calendar days have you experienced any symptoms of exposure to ution? Check all that apply: |
| | | Headache, nausea Smell Eyes stinging Irritation of respiratory tract Skin irritation, burn or blisters Other; (Please specify): |
| Modul | e G (Anesthetic Gase | s – administration) |
| New Q | uestion, after Question | 19, or 19(b). |
| | level (i.e., conc | ministration of the anesthetic, was a visual display of the anesthetic agent entration of anesthetic gas in the room) present in the work area (not the eing delivered to the patient)? Yes |
| | | No |

| ш | Don't | know |
|---|-------|------|

Thank-you for the opportunity to comment on the NIOSH survey. Please let me know if there is any thing I can do to further its success.

Yours sincerely

Response:

Dear Mr. Warburton:

Thank you for your comments and suggestions for questions to include in the worker survey. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements to both survey questionnaires.

20. Comment

Name Justine Coffey

Organization American Society of Health-System Pharmacists

Email jcoffey@ashp.org Address 7272 Wisconsin Avenue Bethesda, MD 20814

Comments:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to the proposed National Institute for Occupational Safety and Health (NIOSH) Survey of Healthcare Workers' Safety and Health. For more than 60 years, ASHP has helped pharmacists who practice in hospitals and health systems improve medication use and enhance patient safety. The Society's 35,000 members include pharmacists and pharmacy technicians who practice in inpatient, outpatient, home-care, and long-term-care settings, as well as pharmacy students.

General Comments

ASHP is pleased that NIOSH is developing the health care workers' survey since the Society believes the survey will identify trends and areas for improving the processes health care workers are required to follow when handling hazardous materials and drug products. Although the information that NIOSH proposes to gather through the survey will be useful, ASHP is concerned that the complexity and length of the survey may limit participation. The Society recommends that NIOSH consult with survey experts to determine appropriate survey length and appropriate use and timing of reminders to obtain the best response rate.

Where possible, NIOSH should prioritize information requests to encourage broader survey participation. ASHP also suggests that NIOSH ask respondents to complete the survey in stages, and that administrator and worker surveys be staggered to alleviate the burden imposed at each site.

Additionally, each module in the survey lists the health care workers toward whom the module is directed. However, this proscriptive approach may preclude the possibility of obtaining data from other relevant practitioners. For example, many health care facilities have established an operating room pharmacy, but NIOSH does not identify pharmacists and pharmacy technicians who practice in these settings and post surgical care areas as practitioners who should respond to Modules H and I.

Furthermore, the instructions for Module B indicate that pharmacists and pharmacy technicians are the primary respondents to the survey. However, nursing personnel also prepare hazardous drug products in outpatient clinics. ASHP therefore recommends the following alternative wording for Module B: "This module is directed toward individuals such as pharmacists, pharmacy technicians or nurses who prepare, mix, or compound hazardous drugs or antineoplastic agents."

<u>Project Aim 3</u>: Project Aim 3 of the Background information states: "Describe prevalence and distribution of worker exposures, health and safety perceptions and practices, and use of exposure controls and barriers to their use." ASHP recommends comparing employee reports of exposure with the number of incidents reported to employee health departments at those same institutions. This comparison should identify the extent to which incidents are under- or over-reported.

Hazardous Drug and Antineoplastic: The terms "hazardous drug" and "antineoplastic" are interchanged throughout the modules. ASHP recommends providing a comprehensive definition of these terms at the beginning of the survey, and maintaining consistent terminology throughout the modules. The Society is concerned that, without this consistency, specific mention of "antineoplastic agents" to the exclusion of other hazardous drugs (e.g., monoclonal antibodies, immunosuppressants, etc.) may result in respondents answering from a more limited perspective. ASHP recommends the following broader terminology: "Hazardous drugs (including oral, topical or injectable forms of cytotoxic or antineoplastic agents)." This is a critical change for the Core Module question 71, where respondents will self-select additional modules to complete.

<u>Disposal of Hazardous Drugs</u>: NIOSH should consider adding questions to the current survey, or developing a separate survey, to assess the disposal of hazardous drugs and materials. There has been significant recent coverage in the trade and lay press about the environmental impact of pharmaceutical waste, and wastes from hazardous drugs present an occupational hazard while they remain in the health care setting.

Worker Core Module

General comment: In several places tobramycin is provided as an example, however it is unclear why this drug is listed since it is not defined as a hazardous drug product.

Question 1R: Following Question 1R, which assesses adequate staffing, ASHP recommends asking whether workers believe the construction or layout of their facilities is adequate to minimize hazardous exposures. For example, personally protective equipment located far away from the area where it is needed would discourage use.

Question 2J: It is unclear whether the intent of Question 2J is to assess exposure to infectious diseases. The use of the term "infectious diseases agents" could be misinterpreted as exposure to drugs used to

treat infectious diseases. ASHP recommends revising this question to read: "Infectious diseases (e.g., tuberculosis)." Gene therapy could also be included as an example.

Question 20: ASHP recommends changing the wording to "Excessive noise level."

Question 3: ASHP recommends breaking out "Special Practitioners" into a distinct category, and naming that category "Other Health Care Professionals," since pharmacists, dieticians, nutritionists, and others are unlikely to identify themselves as "Special Practitioners." This new category could follow the "Nurses and Nursing Support Staff" category.

Questions 29-33: Questions 34 and 35 assesses whether workers experienced a sharps injury from a non-sterile needle or device, meaning one not contaminated with drugs or biohazards. ASHP recommends making this same distinction for questions 29-33.

Question 41: ASHP recommends assessing the use of protective eyewear.

Question 54: Various levels of personal protective equipment may be worn during the day or week depending on the types of tasks performed. ASHP therefore suggests changing Question 54 to read: "During the past 7 calendar days, which of the following personal protective devices or equipment were you required to wear while performing specific tasks for your job?"

In Question 54, and throughout all modules, the term "respirators" is used. Health care professionals commonly refer to the respirator as an "N95 mask." Therefore, ASHP recommends using more specific terminology, such as "Respirators or N95 mask (does not include surgical mask)," rather than simply using the term "respirators."

Question 57: ASHP recommends adding a question after Question 57 that assesses the use of chemotherapy or nitrile gloves. Adherence to double gloving should also be assessed.

Questions 58 – 60: "Medical Surveillance" is commonly used for the testing defined in questions 58 through 60. This terminology should replace or supplement the current section title, "Medical Evaluation."

Question 69: ASHP recommends adding Pharm.D as an example of a professional degree.

Question 71: Nurses sometimes prepare hazardous drugs in a clinic setting, which may not be perceived as "pharmacies." ASHP recommends rewording this question as follows: "In your current job, do you prepare or mix oral, topical or injectable hazardous drugs or antineoplastic agents in a pharmacy, outpatient clinic, or pharmacy-like setting?"

Module B: Antineoplastic Agents (Pharmacists, Pharmacy Technicians)

ASHP recommends that Module B be expanded to include questions that assess proper practices for staging, preparation, labeling, and decontamination (including spills and exposures). The following are examples of questions that should be addressed in the survey, and include areas where exposure and contamination may occur:

- Are drug vials wiped before placement in the biological safety cabinet?
- · Are final products surfaces decontaminated prior to placement of labeling?
- Are gloves worn when moving vials to the product preparation area?
- Are gloves changed at least every 30 minutes during compounding procedures or when damaged or contaminated?

Are gowns worn for no longer than 3 hours?

ASHP recommends developing these questions based on the practices described in <u>ASHP Guidelines on Handling Hazardous Drugs</u>, Appendices B, C, D, E, H, I (http://www.ashp.org/s_ashp/docs/files/BP07/Prep_Gdl_HazDrugs.pdf). ASHP would be pleased to assist NIOSH in the development of these questions.

Several questions in this module ask respondents why they do not use personal protective equipment. It would be useful to add the following answer option: "Not recommended or required by the Food and Drug Administration (FDA) or manufacturer."

Question 2: Following this question, ASHP recommends adding a question to assess whether respondents have received training on the principles and proper use of the biological safety cabinets and/or isolators.

Question 3: ASHP recommends deleting this question. While individual practice settings may "certify" their employee in product preparation and handling, there is no nationally recognized certification program for preparation of these products. At a minimum, option two should be deleted since the Pharmacy Technician Certification Exam is a knowledge-based exam that cannot assess the ability of personnel to <u>demonstrate</u> proper handling precautions for hazardous drugs.

<u>Question 5</u>: ASHP recommends assessing whether workers believe the facility's policies and procedures are consistent with nationally recognized standards, including the ASHP Guidelines on Handling Hazardous Drugs and NIOSH's Hazardous Drug Alert.

Question 6: ASHP recommends modifying "street clothing" to "unprotected street clothing."

Question 8: ASHP recommends that the respondent not be limited to two write-in drugs.

Question 13: ASHP recommends adding option (d) "biologic safety cabinet" and option (e) "barrier isolator."

Question 20: ASHP recommends adding an additional question following Question 20 assessing the number of spills that occurred inside the compounding area (biological safety cabinet or barrier isolator).

Question 24: ASHP recommends adding an additional question following Question 24 to assess adherence to recommendations to use inner and outer gloves.

Question 30: This question asks about the use of a respirator for product preparation. However, the question does not acknowledge that most hazardous drugs are prepared in a biological safety cabinet, which is ventilated and therefore does not require use of a respirator. This question may provide results that falsely indicate low use of respirators, when in fact respirators are not needed for this most common setting of product preparation.

The Society appreciates this opportunity to present its written comments on the proposed survey. Feel free to contact Cynthia Reilly, R.Ph., Director, Clinical Standards and Quality, Practice Standards and Quality Division, if you have any questions regarding our comments. She can be reached by telephone at 301-664-8664, or by e-mail at creilly@ashp.org.

Sincerely,

Response:

Dear Mr. Coffey:

We would like to thank ASHP for their interest in the worker survey. Also, we are very appreciative of the detailed comments that were provided on specific questions in the worker core module and module B. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements to both survey questionnaires.

We have received several comments regarding the length of the worker and management surveys indicating that they are too long. Relative to the worker survey, focus group participants indicated that they would complete a 30 minute survey, especially if they could complete the survey in more than one session (which is an option for respondents of our survey). Findings from our pilot tests show that the average time to complete the web version of the core module was about 20 minutes, and about 7 minutes for each hazard module. Response rates were fairly good, averaging 45% at two pilot test sites. While there appears to be no single guideline for questionnaire length, one literature review of the effect of questionnaire length on response rates stated that "results are still confusing and contradictory, conclusions are still not clear, and questionnaire designers still aim for shorter questionnaires with little more justification than the assumption that longer interviews will result in higher nonresponse" (Bogen K, 1996 Proceedings of the Section on Survey Research Methods, American Statistical Association, pgs 1020-1025). Although we feel that the length of the worker survey of reasonable length, we are planning to evaluate options for reducing the completion time.

Regarding the management survey, our pilot tests showed that the survey itself could be completed in about 45-50 minutes. However, in many cases, the health and safety manager needed to contact managers of other departments (human resources, oncology ward, pharmacy, sterile processing, etc) to complete the survey, a process which was estimated to take up to 3-4 hours in large hospitals. We are working with consultants with expertise in survey design and implementation to improve the management survey.

Unlike in the pilot tests, the proposed surveys will be conducted independently of one another (the worker survey is to be implemented through professional associations; the management survey is to be implemented in hospitals) and no link will exist between the two surveys. Therefore, it will not be possible to compare employee reports of exposure with the number of incidents reported to employee health departments at those same institutions.

Regarding hazardous drugs and anti-neoplastic agents, we did not intend to use these terms interchangeably as we are aware that hazardous drugs encompass more than antineoplastic agents. We plan to review the questionnaires to ensure that this is clear. Although ribavirin and pentamidine aerosols (hazard module A) and antineoplastic agents (hazard modules B and C) meet the ASHP definition of hazardous drugs, the specialized methods in which these agents are used necessitated that we address them separately rather than collectively as hazardous drugs. Although an important issue, this survey will not address disposal of hazardous drugs and related materials since disposal of hazardous materials is under the regulatory purview of the EPA.

Thank you for bringing the issue of identifying specific healthcare occupations to our attention. We agree that this may unintentionally preclude other affected occupations from responding to the survey. Please note that this was not an issue in the web survey as the hazard modules did not specify occupations of healthcare workers. Respondents of the web survey were directed to hazard modules based on responses to the same gateway questions in the paper version, which did not specify any occupations. We will review the content of the web survey to ensure that this is not a problem.

We look forward to continuing our collaboration with ASHP on the surveys and welcome the opportunity of including ASHP members in the worker survey. Thank you again for providing valuable comments on the worker survey.

21. Comment

Name Rick Pollack

Organization American Hospital Association

Email rpollack@aha.org

Address 325 7th St. NW, Suite 700 Washington, DC 20004

Comments:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 37,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the National Institute for Occupational Safety and Health's (NIOSH) proposed national surveys of health care workers' safety and employer safety and health practices.

As employers and as providers of health care, hospitals and health systems are committed to the health and safety of our caregivers and patients. Hospitals have long had in place policies, programs and resources that are designed to protect employees, and they strive to ensure that these protections are updated and kept relevant as new hazards emerge and best practices are defined.

NIOSH states that the overall objective of this project is to "describe the prevalence and distribution of important health and safety hazards and perceptions, work practices, and use of exposure controls from a health care worker perspective, and to describe institution-based health and safety management policies, programs and resources of health care establishments, from the perspective of the person responsible for employee health and safety." We agree that it is critical to have current and accurate data on the top health and safety issues facing caregivers. However, we have serious concerns about these surveys and the methodology that NIOSH proposes to use to obtain these data.

Problems with the pilot-testing of the questionnaires. NIOSH reports that it conducted a pilot-test of the surveys at two large medical centers to evaluate the establishment-based approach for implementing the employee survey, the preference for mode of response, response rates, and to validate the worker and management questionnaires. NIOSH further reports that the management questionnaire was validated at four hospitals that completed the surveys and permitted site visits to assess the accuracy of their response. However, no detail is provided in the background materials as to the type, location or size of these hospitals or whether they included the two large medical centers that also participated in the employee survey pilot test. Given the lack of detail in the background materials provided to the public, it is impossible to determine whether the pilot-testing was adequate and, therefore, whether the conclusions drawn from the pilot test can be used to support the content and conduct of the NIOSH surveys. Certainly, using just two large medical centers to validate the questionnaires would not lead to results that were representative of the different types of hospitals in the nation. In order to support the validity of the management survey in particular, it would be important to include several types of hospitals, such as a small rural or critical access hospital, and a medium-sized community hospital.

Problems with the length and complexity of the surveys. The management and health care worker surveys are extremely long, with complex questions, many of which contain multiple parts. We believe that completing them will take far longer than the time NIOSH estimates. NIOSH estimates that it will take 20 minutes to complete the core module of the worker survey, which is 25 pages long and contains 79 questions; and that the hazard modules, which include up to 42 questions, will take an average of seven minutes to complete. The agency estimates that it would take 45 to 50 minutes to complete the management survey, which is 50 pages long and contains 63 core questions, with 140 questions in the hazard modules. Further, many of the questions in the management survey would require significant research to determine the appropriate response.

Clearly, NIOSH has significantly underestimated the time it will take to complete the surveys. We are concerned that this level of burden will reduce the survey response rate, particularly in the management survey, and result in an inadequate and non-representative sample of respondents completing the survey. A significant response burden would fall on larger hospitals, which, because they generally offer a full range of services, would need to complete not only the core questions but most or all of the hazard modules.

Completing the management survey is a far more complicated task than completing the worker survey. Within a single hospital there will likely be a number of individuals, such as infection control, occupational health and safety/facility officers, who will be called on to complete various sections of the survey. Also, while many hospitals have on-site occupational health offices, health systems with multiple hospitals may not have such offices within each of their facilities. They would have to provide access to data to complete the survey from within their centralized occupational health departments. Still other facilities contract out the occupational health functions to a third party.

Also, there are many variations in the types of positions responsible for the areas being addressed in the survey, making it more difficult to identify those to whom the survey should be targeted. These factors will make it difficult to ensure that the survey gets to the right individual(s) within hospitals and increase the likelihood that surveys could be lost in the system, hurting the response rate and jeopardizing accuracy for the management survey.

Problems with survey questions. While NIOSH claims to be seeking comments on the content of the survey questionnaires, its background materials note that the survey questionnaires have already been pilot tested in two large medical centers. The agency states that "the content of the questionnaires has been fairly well-defined" and "minor revisions will be made...prior to use in this study." The AHA has serious concerns about many of the questions in the survey, which we describe in attached detailed comments. However, NIOSH implies that it does not intend to correct or remove the problems; errors and inconsistencies in the survey instruments and instead is seeking input only in an attempt to identify other issues for possible inclusion in these already long and burdensome questionnaires. We urge NIOSH to reconsider this decision and be open to making substantive changes to the content of the surveys.

Our greatest concerns relate to statements, especially those to which the worker is asked to respond, that are presented as factual or imply a best practice, but which do not have solid supporting evidence. In our attached detailed comments, we identify those questions that do not have a proper basis in evidence and recommend that they be removed or changed. Additionally we are concerned that many questions, especially those referring to the use of personal protective equipment, have inadequate response options. As a result, respondents cannot answer in a way that accurately describes their health and safety practices. Our detailed comments also address these concerns. Unless NIOSH ensures that its questions describe practices that are truly supported by scientific evidence and allow responses that reflect actual health and safety practices, the survey results will be misleading and identify gaps that are not relevant to worker health and safety.

Concerns about the methodology for conducting the surveys. For the worker survey, NIOSH indicates that it will use a "population-based" approach to gather hazard surveillance data from health care workers by partnering with various labor unions and professional associations that will send survey information to their membership. These organizations will either directly e-mail their members with a link to the survey or promote the survey to members via various avenues of communication and direct them to a Web site where they can complete the survey. This results in a "convenience" survey sample of workers who are members of the partnering labor unions and professional associations and who have access to the Internet. To maximize response rates, NIOSH proposes to award workers who complete the survey with a \$10 on-line gift certificate.

The AHA has serious concerns about this approach. As stated in NIOSH's background materials, the disadvantages associated with the use of a convenience sampling approach include the problem of a non-representative sample of the total population of workers and sampling bias. The use of labor unions to market the survey further magnifies this problem because within health care, labor unions are concentrated in certain areas of the country and therefore the workers that unions such as the Service Employee's International Union (SEIU) will be able to reach will skew the sample and move it further away from being nationally representative. We recommend that NIOSH continue to reach out to other organizations that may have a more appropriate balance of geography among their membership to help ensure a more nationally representative health care worker survey sample. We also support NIOSH's intention to modify the survey to include questions regarding characteristics of the worker's place of employment (i.e., type and size) and professional association or labor union affiliation; this will help researchers determine whether the survey results are nationally representative.

For the management questionnaire, NIOSH proposes to use an "establishment-based" approach from which a size-stratified random sample of hospitals will be drawn. Contact will be made with each hospital to obtain the name and e-mail address of the person primarily responsible for employee occupational health and a series of survey related e-mails will be sent. While we believe that this approach has a better chance of resulting in a nationally representative sample of respondents, we have a number of concerns and questions about how NIOSH proposes to conduct the management survey.

First, NIOSH indicates that the sample of hospitals it will draw will be size-stratified by the number of employees (1-19; 20-449; 500+). The AHA recommends that NIOSH not finalize this sampling framework, but instead use the more typical hospital research sampling framework that is based on bed size, geographic region and type of facility.

We also are concerned that the stark differences in the approaches used to conduct the two surveys will make it appear, incorrectly, that hospitals are indifferent to the health and safety of their workers. As noted above, due to the lengthy and complex management questionnaire, we believe that there will be a low response rate, resulting in an inadequate and non-representative respondent population. While the worker questionnaire is also lengthy, workers will be provided with a financial incentive, a \$10 gift certificate, to complete the survey.

Further, the worker questionnaire, being primarily based on worker's perceptions and opinions, and being loaded with questions that are not evidence-based, is far more subjective than the management questionnaire, which is largely based on concrete management practices.

There is no way to validate the results of the worker questionnaire because it includes no information that could link a worker to his or her place of employment. By contrast, NIOSH has indicated that it will validate some samples of the management questionnaire responses via site visits.

For these reasons, we recommend that NIOSH reconsider its methodology for administering the health care worker survey. Instead of utilizing a convenience sample, NIOSH should evaluate how it could

develop a statistical sampling approach that would more accurately represent the populations of workers it would like to survey. NIOSH also should consider developing a methodology to validate the worker questionnaire results, perhaps by linking the responses from workers within a single institution and/or through comparing the worker responses to the responses from a validated management questionnaire from the health care facilities in which they are employed.

If such changes are not made, and if the responses to the worker and management surveys are determined not to be nationally representative (as NIOSH notes it expects will be the case with housekeeping staff), NIOSH should place the caveat in its public release that the results should not be used to make generalizations about entire populations, and that any associated conclusions run the risk of being false.

Our detailed comments are attached. If you have any questions, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

This letter included two attachments, as follows:

Attachment 1

AMERICAN HOSPITAL ASSOCIATION DETAILED COMMENTS

OVERARCHING AREAS OF CONCERN

The American Hospital Association (AHA) has identified a number of issues and problems that are repeated throughout the health care worker and the management questionnaires. Revisions should be made throughout the survey in a consistent manner. These issues:

Use of personal protective equipment (PPE) excludes masks. The questions in the core questionnaires and modules consistently exclude masks from the definition of PPE. This is a major flaw in these surveys and the absence of questions regarding the use of masks prevents the collection of important information. Surgical masks remain important in health care settings for managing patients and facilities cannot always separate protection of patients or equipment from protection of the worker when care is being provided. There are circumstances where the use of masks is perfectly acceptable and consistent with Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA) guidance. This would be the case, in locations involving biological agents, such as isolation rooms or around patients in "contact precautions;" when a worker preparing antineoplastic drugs uses a biological safety hood; where the sterility of equipment must be protected; and many other circumstances. The survey's consistent misrepresentation of what is acceptable PPE will undermine health care worker confidence that masks have value. By maintaining this position throughout the questionnaire, a systematic bias is introduced and valuable information on standard and appropriate practices is lost. The survey language's implication is that a respirator is required to protect the worker from any potential exposure. The questionnaires should be revised to list masks as an appropriate type of PPE.

Routine medical surveillance for workers. The management questionnaire consistently, and inaccurately, implies that routine medical surveillance of workers in the absence of a specific problem is a standard of practice. In fact, with the exception of skin testing for occupational exposure to tuberculosis and a very few other circumstances, most health care facilities do not routinely conduct medical surveillance. Instead, they have occupational health programs in place to which an employee would be referred if there

is evidence of a problem related to perceived exposures in the workplace, such as a worker with shortness of breath or an allergic reaction. This concern about the assumption that routine medical surveillance is taking place applies to questions regarding exposure to antineoplastic agents (page 16, questions B10-B13A); ribavirin, pentamidine and tobramycin (pages 23-24, questions C8-C12); glutaraldehyde (page 28, questions D9-12A); ethylene oxide (page 35 and 36, questions E10-13A); and waste anesthetic gases (page 44, questions F9-F12A). These questions should be restated to inquire whether testing is being conducted when problems are identified (e.g., worker with shortness of breath or allergic reaction.). For instance, they could ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to the chemical in the workplace.

Use of back belts not supported by evidence. (See attached citations for back belts.) Several of the questions in the worker core questionnaire refer to the use of back belts. The implication throughout is that this is expected behavior or policy, or standard of practice. Yet the literature is clear that back belts are not recommended. The National Institute for Occupational Safety and Health's (NIOSH) own major study published in the Journal of the American Medical Association in 1996 states, "There is a lack of scientific evidence that back belts work. Workers wearing back belts may attempt to lift more weight than they would have without a belt. A false sense of security may subject workers to greater risk of injury." Back or gait belts are referred to within the health care worker core questionnaire in questions 50, 52, 54 and 55 on pages 17-20. In the management survey, back belts are referred to on page 9, question A41 (Musculoskeletal Injury). These references to back belts should be removed from the questionnaires.

Natural rubber latex products. All references to powder-free natural rubber latex gloves and other natural rubber latex products should be changed to reflect the current availability of Food and Drug Administration (FDA) approved powder-free, low protein/allergen latex products. Powder-free, low protein/allergen natural rubber latex gloves are already widely used within health care facilities, and we expect that there will be other products on the market by the time these surveys are administered. Therefore, to avoid confusion among respondents, all such references should be cited as "powder-free and low protein/allergen" natural rubber latex gloves or products.

Within the health care worker questionnaire, the references to natural rubber latex gloves and other products that need to be changed are in:

- Core Module, page 20, question 57;
- Module B (Antineoplastics (Pharmacists, Pharmacy Techs)) pages B-6 through B8, questions 24 and 27; and
- Module C (Antineoplastics Agents Administration (Oncology Nurses)) page C-6 and C7, questions 24 and 26.

Within the management questionnaire, the references to natural latex rubber gloves and other products that need to be changed are in:

- Section A, Core Questions, Pages 10-11, Question 54-59; and
- Section B, Antineoplastic Agents, Page 20, Question B28, option (f).

HEALTH CARE WORKER QUESTIONNAIRE

CORE MODULE

Health & Safety Hazards Concerns

<u>Page 3 Question 2 (j)</u>. In its example of an infectious agent, NIOSH selects only the airborne agent tuberculosis. We believe that contact transmission of infectious diseases is of equal, if not greater concern to health care workers. However, this would require that NIOSH include questions referring to masks as part of PPE, not just respirators. This is an issue that surfaces repeatedly in the management and worker (both core and individual hazard) modules and results in a built-in bias that will not permit collection of information on actual safe practices.

<u>Page 12, Question 29: Safe Needle Devices – Universal Precautions.</u> The term "Universal Precautions" should be replaced with "Standard Precautions," the current terminology. Also, as there is increasing usage of non-needled syringes with luer locks to IV lines, which do not involve sharps at all. Please replace the word "syringes" with "syringes with needles" in the question, "do you handle syringes, scalpels or other sharp instruments..."

<u>Page 14 Questions 39-40</u>. This question asks about the frequency of handling soiled sheets, bedpans, etc. The follow-up Question 41 asks *only* if water-resistant gowns/gloves are always worn. There is no choice for responding that water-resistant gowns/gloves are worn most or some of the time, as is offered for other questions. Further, handling a soiled sheet or bedpan may not require a water-resistant gown and no option is given for any other types of protective or isolation gowns. The wording permits no other response.

Medical Evaluation

<u>Page 21, Question 58</u>. The question indicates that an evaluation "may include blood tests, and/or urine test." Mentioning these sets an expectation that blood and urine testing are required without any reason and implies a standard of practice that does not exist.

MODULE A: AEROSOLIZED MEDICATIONS (RESPIRATORY THERAPISTS)

(See attached citations for aerosolized medication.)

Issue: Engineering controls versus personal protective equipment (PPE) in handling aerosolized medications. Research studies detail the progress on the use of sealed or scavenger type systems that minimize risk and indicate that engineering controls and work practices are primary over respiratory protection. There also are options such as booths, enclosed hoods or negative pressure rooms, especially since pentamidine may be used on patients infected with tuberculosis. However the questions in the survey do not recognize improved sealed delivery systems that offer more options and less reliance on PPE. This issue, raised below for ribavirin, also applies to the questions on pentamidine (pages A-4 and A-5, questions 20 and 21; page A-3, question 16) and tobramycin (page A-6, questions 28 and 29; page A-5, question 24).

- Page A-3, Question 12. This question offers only three options: sealed booth, partially enclosed hood/tent or no enclosure. There is no option related to a negative pressure room (possibly an isolation room). This option should be added to question 12.
- Page A-3, Question 13. In this question, use of a negative pressure room option should not be limited to an isolation room.
- Page A-2, Question 8 and Page A-3, Question 13. These questions begin to address the fact
 that the type of equipment used is a critical engineering control to minimize aerosols and deliver
 drug directly to a patient's lungs, but they do not address this directly or clearly. Distance from
 patient (within five feet) is made to appear to be more important than the seal of the medical

device being used. There should be a statement added indicating that the best engineering control is a well-sealed drug delivery device.

<u>Page A-10 Questions 38-41</u>. Although respirators may be "reasonable" according to cited current studies, studies have not shown that masks or respirators are effective. Rather, engineering controls are critical, from the type of sealed device to the use of scavenging systems. The survey should make it clearer that cited study data supporting engineering controls take precedence over PPE. Exclusion of masks prevents a response that masks may be worn to protect the patient.

<u>Page A-11, Question 41.</u> "Did you wear **booties** to administer any of the above?" again puts more emphasis on PPE at the expense of other more effective controls. Further, there are no recommendations for booties to be used within the current OSHA Technical Manual nor in the "Guidelines for Controlling Occupational Exposure to Hazardous Drugs." (www.osha.gov/dts/osta/otm/otm_vi_2.html)

MODULE B: ANTINEOPLASTICS (PHARMACISTS, PHARMACY TECHS)

<u>Page B-9, Questions 30-32A</u>. These questions do not allow a response for masks, implying that they are not protective. However, the OSHA Technical Manual is clear that, as long as the worker uses a biological safety hood (an engineering control), a respirator is not required. Further, we recommend that the questions be modified to refer to the "appropriate use of respiratory protection," since many of these listed drugs are not aerosolized but rather they are liquids or tablets.

<u>Page B-10 Question 33—Use of booties</u>. We echo the comment identified under module A, question 41 for respiratory therapists. There are no OSHA recommendations for use of booties.

MODULE C: ANTINEOPLASTICS AGENTS ADMINISTRATION (ONCOLOGY NURSES)

This module contains no questions about respiratory protection or booties, yet many oncology nurses in clinics prepare these drugs in medication rooms and hoods and administer them directly to the patient. This again raises the question of why booties are included in other modules.

MODULE D: CHEMICAL STERILANTS

<u>Page D-6</u>, <u>Question 27</u>. STERRAD is mentioned here and used as an example of hydrogen peroxide but is not listed or used as an example in the management questionnaire or in the worker questionnaire module E. The questionnaire should be consistent regarding whether or not STERRAD is mentioned.

<u>Page D-7</u>, <u>Questions 33 and 34</u>. This question does not permit a response involving the appropriate use of a mask. The implication is that respiratory protection of the worker is routinely required. However there are other protocols that require workers to wear masks; for example, in protocols for protecting sterile equipment. The inability to choose a mask as a response makes this question difficult to answer.

MODULE E: HIGH LEVEL DISINFECTANTS

<u>Page E-1 and E-3 (Question 9)</u>. Why is STERRAD not listed here and used as an example of hydrogen peroxide, although it is listed in Worker Survey D? The questionnaire should be consistent regarding whether or not STERRAD is mentioned.

<u>Page E-3, Question 11</u>. We recommend the addition of a third option as follows: "3. No local exhaust, but in a room with either good air dilution (six, 10, 12 air changes per hour) AND/OR a negative pressured room, in which the air is exhausted out of the room."

<u>Pages E-7 and E-8, Questions 24-26A</u>. These questions relate to the use of respiratory protection and do not permit a response involving the appropriate use of a mask. The implication is that a respirator is required to protect the worker from any of these chemicals, regardless of room ventilation or the use of local exhaust.

MODULE F: SURGICAL SMOKE (FROM LASERS OR ELECTROSURGERY DEVICES)

MODULE G: ANESTHETIC GASES (ADMINISTRATION)

MODULE H: ANESTHETIC GASES (BYSTANDERS WHO DO NOT ADMINISTER)

MODULE I: WASTE ANESTHETIC GASES (POST ANESTHESIA & SURGICAL RECOVERY)

(See attached citations for anesthetic gases, surgical smoke and laser plume.)

Pages F-6 to F-8, Questions 20-22A; Pages G-5 and G-6, Questions 27-29A; Pages H-4 and H-5, Questions 19-21A; and Pages I-2 and I-3, Questions 10-12A. The questions are misleading in that they do not reference any need for verifying functioning scavenger systems or ensuring they are in good working order. While engineering controls are far more critical to worker protection, all the emphasis in this module is on respiratory protection. The questions imply that a respirator is required to protect workers from surgical/laser smoke, regardless of room ventilation or use of local exhaust. But the surgical suite is an area in which personnel would be wearing FDA-approved sterile surgical masks, worn to protect the patient, and appropriately relying on engineering controls such as scavenging system and use of filters to protect workers. OSHA, the agency that sets out regulations and guidance for worker safety, has made it clear that engineering controls and administrative/work practices are effective, and the data do not demonstrate the usefulness of respirators at this time.

MODULE J: HOUSEKEEPING OR ENVIRONMENTAL SERVICES STAFF

Page J-2, Questions 5 and 6; Page J-4, Question 12; Page J-4, Question 15. The manner in which these questions are presented is misleading. Question 5b (Safe clean-up procedures for spills of anti-cancer drugs) may be addressed in policies and procedures, but policies are likely to indicate that a spill team will do the initial clean-up and environmental services/housekeeping will only do the final clean-up. So the task in question 5b is not usually the responsibility of environmental services. For clarity, question 6 should be applied to each practice listed under question 5, since only choices (a) and (c) may apply. Policies and procedures are usually are covered under training but often it indicates that a trained registered nurse, pharmacist or spill team will handle (b). We recommend that anti-cancer drugs should be included as a separate question. For question 12, we recommend that it first ask whether spills are precleaned by a specialist for (a), (b), and (c). Then there should be questions asking whether they do the final cleanup after a spill of (a), (b) and (c). In question 15, we recommend that the question be asked separately for anti-cancer drugs, chemicals and bodily fluids.

<u>Page J-3, Question 8</u>. With regard to the list of quaternary ammonium compounds and phenols, the questionnaire should list all common brands if brand names are going to be used. Also, "oxidizers" is not a familiar term. We recommend using "low level disinfectants."

<u>Pages J-4 and J-5, Questions 17-18</u>. The questionnaire never asks about cleaning in locations involving biological agents, such as isolation rooms, or around patients in "contact precautions" where, in most cases, the use of masks is perfectly appropriate. This undermines confidence that masks have any value. By maintaining this position throughout the questionnaire so consistently, a systematic bias is introduced and valuable information on standard and appropriate practices is lost. The theme and implication for all modules is also that a respirator is required to protect the worker from any chemical, regardless of its concentration.

SECTION A. CORE QUESTIONS

<u>Page 1, Question A4</u>. The question should reference accreditation by the American Osteopathic Association (AOA) and any other organizations that have deemed status from the Centers for Medicare & Medicaid Services. Further, the question should be reworded to use the current name of The Joint Commission (TJC) and the parenthetically note "formerly known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)."

<u>Page 3, Question A14.</u> The question should include options if the respondent is answering as a corporate headquarters for a multiple hospital system.

<u>Page 12, Question A60, Respiratory Protection</u>. In this question, masks are erroneously eliminated from consideration of respiratory protection.

SECTION B. ANTINEOPLASTIC AGENTS

<u>Pages 15-16, Questions B8-B9A, Exposure Monitoring</u>. These questions should be clarified as to whether the sampling/monitoring is done routinely versus as a result of spills. This blurs the difference between a standard of practice versus emphasis on prevention.

<u>Page 16</u>, <u>Questions B10-B13A</u>, <u>Medical Surveillance</u>. These questions should be clarified as to whether the medical surveillance is done routinely versus as a result of known exposures. For instance, they should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to the chemical in the workplace (e.g., worker with shortness of breath or allergic reaction.)

<u>Page 19, Question B27, Policies for Designated Spill Clean-Up Teams</u>. This question appropriately refers to a spill team. This reinforces the problem in the Worker Questionnaire modules J (environmental services/housekeeping) in questions that do not ask if these staff perform a final cleanup after a spill team is engaged, resulting in a biased question for environmental services/housekeeping</u>.

<u>Page 20, Question B28</u>. With regard to option (n), as in all other PPE questions, the option of surgical masks is not allowed, erroneously implying that respirators should always be used for antineoplastic agents. If NIOSH wishes to collect information on actual practice, then questions should be included regarding surgical masks.

SECTION C. AEROSOLIZED MEDICATIONS

(See attached citations on aerosolized medications)

<u>Pages 22-23, Questions C6 and C7, Exposure Monitoring</u>. These questions should be clarified as to whether the sampling/monitoring is done routinely versus as a result of spills. This blurs the difference between a standard of practice versus emphasis on prevention.

<u>Pages 23-24</u>, <u>Questions C8-C12</u>, <u>Medical Surveillance</u>. These questions imply that medical monitoring, including blood, urine and pulmonary function tests, should be done routinely for these medications. The data do not support these non-specific tests as a standard of practice for any one of these drugs. Studies have been done to determine risk but they do not include recommendations for routine medical surveillance.

<u>Page 26, Question C14</u>. In this question, masks are erroneously eliminated from consideration of respiratory protection.

SECTION D. GLUTARALDEHYDE AND OTHER HIGH LEVEL DISINFECTANTS (HLD)

STERRAD is not listed as an example of hydrogen peroxide in this section, although it is listed elsewhere in the Worker Survey D. The questionnaire should be consistent regarding whether or not STERRAD is mentioned.

<u>Page 27, Question D7</u>. This question implies an expectation that air sampling should be done for all HLDs, whether or not engineering controls are in place (e.g., local exhaust). In addition, there are no questions on ensuring whether engineering controls are functioning properly.

<u>Page 28, Questions D9-12A, Medical Surveillance</u>. This question inaccurately implies that routine medical surveillance of workers, including pulmonary function or allergy sensitization testing, is a standard of practice. For instance, they should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to glutaraldehyde in the workplace (e.g., worker with shortness of breath or allergic reaction).

<u>Page 32, Question D27(h)</u>, <u>Policies for PPE</u>. We reiterate our concern here that masks are not considered as PPE. This does not permit a response for practices that could legitimately involve the use of a mask. The implication is that respiratory protection of the worker is routinely required versus the wearing of a mask by the worker to protect the sterile equipment, as required by other protocols. This makes a response to this question difficult.

SECTION E. CHEMICAL STERILANTS

<u>Pages 35 and 36, Questions E10-13A, Medical Surveillance</u>. These questions inaccurately imply that routine medical surveillance is a standard of practice. Also, we do not understand why non-specific "blood tests" are listed. Instead, the question should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to ethylene oxide in the workplace.

<u>Page 38, Question E21, PPE</u>. We are concerned that, in this question, masks are not considered as PPE for exposure to any sterilants, posing potential confusion for respondents. Standard practice is mandatory and rigid engineering controls (e.g., for ethylene oxide) are required. Workers in these areas wear surgical masks to protect sterile equipment being processed, and this question makes it impossible to reflect actual practice, even if for other purposes.

SECTION F. ANESTHETIC GASES

(See attached citations for anesthetic gases, surgical smoke, laser plume.)

<u>Page 42, Question F7 – F8A, Air Sampling.</u> This question implies that routine air sampling should be conducted even though engineering controls are expected to be in place per other rules and regulations. The questionnaire never asks about whether engineering controls are working. Questions could address whether sampling is done to maintain environmental quality control with indirect impact on patients as well as workers.

<u>Page 44, Questions F9-F12A, Medical Surveillance</u>. This question inaccurately implies that routine medical surveillance is a standard of practice. Instead, it should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to the chemical in the workplace.

<u>Page 45, Question F14, PPE</u>. We are concerned that masks are not considered part of PPE for exposure to any anesthetic, regardless of scavenging system. Further, with regard to OSHA recommendations for

Waste Anesthetic gases, the only time respirators are considered is for spills. There are no questions in this questionnaire regarding PPE, including respiratory protection, during spills.

SECTION G. SURGICAL SMOKE

(See attached citations on anesthetic gases, surgical smoke, laser plume.)

<u>Pages 46-47, Questions G4-G5A and G7, Air Sampling</u>. This question implies that routine air sampling should be conducted even though engineering controls are expected to be in place per other rules and regulations. However, we are pleased that at least one engineering control is addressed; in question G7, where the question is whether smoke evacuation systems are inspected to prevent leaks.

<u>Page 48, Question G9, PPE.</u> We are concerned that in this question masks are not considered as PPE for exposure to smoke, posing potential confusion for respondents. Given the importance of scavenger system and use of FDA-approved sterile surgical masks for surgical procedures, this does not permit response that reflects actual practice in surgical procedures.

SECTION H. SPILL RESPONSE TEAM AND HOUSEKEEPING

<u>Page 49, Questions H2-H5</u>. We support the use of these questions, as we do in Section B, Antineoplastics. This appropriately refers to a spill team, but again this reinforces the problem in the Worker Questionnaire modules J (environmental services/housekeeping) in questions that do not ask if these staff perform a final cleanup after a spill team is engaged, resulting in a biased question for environmental services/housekeeping.

<u>Page 50, Question H7, PPE</u>. This question does not ask about cleaning in locations involving biological agents, such as isolation rooms or around patients in "contact precautions" where, in most cases, the use of masks is perfectly appropriate. This undermines confidence that masks have any value. This introduces a systematic bias and the loss of valuable information on standard and appropriate practices. The theme and implication here, as elsewhere in these surveys, is that a respirator is required to protect the worker from any chemical, regardless of its concentration.

Attachment 2

ANNOTATED CITATIONS

Back Belt

- 1. Martimo, KP, Verbeek J, Karppinen J, Furlan AD, Takala EP, Paul P, Kuijer FM, Jauhiainen M, Viikari-Juntura E. Effect of training and lifting equipment for preventing back pain in lifting and handling: systematic review <u>BMJ 2008</u>; 336;429-431; originally published online 31 Jan 2008. Conclusion: There is no evidence to support use of advice or training in working techniques with or without lifting equipment for preventing back pain or consequent disability. The findings challenge current widespread practice of advising workers on correct lifting technique.
- Martimo KP, Verbeek J, Karppinen J, Furlan AD, Kuijer PP, Viikari-Juntura E, Takala EP, Jauhiainen M. Manual material handling advice and assistive devices for preventing and treating back pain in workers Cochrane Database Syst Rev. 2007 Jul 18;(3):CD005958.

Conclusion: There is no evidence available from RCTs for the effectiveness of manual material handling advice and training or manual material handling assistive devices for treating back pain.

 Ammendolia C, Kerr MS, Bombardier C. Back belt use for prevention of occupational low back pain: a systematic review. J Manipulative Physiol Ther. 2005 Feb;28(2):128-34. **Conclusion:** Currently, because of conflicting evidence and the absence of high-quality trials, there is no conclusive evidence to support back belt use to prevent or reduce lost time from occupational low back pain.

- 4. Anon, Recommendation statement from the Canadian Task Force on Preventive Health Care: Use of back belts to prevent occupational low-back pain, <u>CMAJ</u>, 2003, Aug. 5, 2003; 169 (3). Recommendation: The Canadian Task Force on Preventive Health Care concludes that the existing evidence is conflicting and does not allow the task force to make a recommendation for or against the use of back belts to either prevent occupational low-back pain or to reduce lost work time due to occupational low-back pain (Grade C recommendation).
- Wassell JT, Gardner LI; Douglas, Landsittel P; et al. A Prospective Study of Back Belts for Prevention of Back Pain and Injury JAMA. 2000; 84(21):2727-2732

Conclusion: In the largest prospective cohort study of back belt use, adjusted for multiple individual risk factors, neither frequent back belt use nor a store policy that required belt use was associated with reduced incidence of back injury claims or low back pain.

6. NIOSH Press Release - JAMA 2000 study.

Conclusion: In the largest study of its kind ever conducted, the CDC's NIOSH found no evidence that back belts reduce back injury or back pain for retail workers who lift or move merchandise, according to results published today in the *Journal of the American Medical Association (JAMA)* Dec. 6 **2000** issue.

7. NIOSH- Back Belts Do They Prevent Injury? 1996 (online reviewed 1997) Pamphlet.
Conclusion: There is a lack of scientific evidence that back belts work. Workers wearing back belts may attempt to lift more weight than they would have without a belt. A false sense of security may subject workers to greater risk of injury.

Aerosolized Medication

 Dimich-Ward H, Wymer ML, Chan-Yeung M. Respiratory health survey of respiratory therapists. <u>Chest 2004</u>;126:1048–1053 (full document).

Conclusion: The lowest ribavirin levels were measured when an additional aerosol containment tent was used or when ribavirin was administered through a ventilator, which is a closed system. On the other hand, reporting the use of a small particle aerosol delivery or ribavirin unit, which is exclusively used for ribavirin, was not associated with reported asthma or respiratory symptoms. If the ribavirin units had aerosol containment systems, this would be effective in reducing occupational exposures.

 Prober CG, MD; Walson PD, MD; Jones J. and the Committee on Infectious Diseases and Committee on Drugs Technical Report: Precautions Regarding the Use of Aerosolized Antibiotics December. PEDIATRICS 2000 Vol. 106 No. 6 December 2000.

Recommendation 8: To minimize microbial contamination of nebulizer equipment, centers should develop policies for aerosolized antibiotic use in the home, clinic, and inpatient facility. Such a policy should address barrier techniques, filters, exhaust, environmental contamination, disposal of unused product, and cleaning of nebulizers.

 Shults RA, Baron S, Decker J, Deitchman SD, Connor JD. Health care worker exposure to aerosolized ribavirin: biological and air monitoring. <u>Occup Environ Med. 1996</u> Mar;38(3):257-63. NIOSH.

Recommendation: Ventilators and other administration units that were enclosed by an aerosol containment tent produced significantly lower airborne ribayirin exposures than administration

units without a containment tent did (range, < 2.5 to 78 micrograms/m3). On the basis of this and other evaluations of airborne ribavirin concentrations, we recommend using aerosol containment systems with all types of ribavirin administration units except mechanical ventilators.

Mueller BA, Waldon VK. Use of an in-house-built ribavirin aerosol evacuation system to control
incidental employee exposure to ribavirin aerosol. <u>J Clin Eng. 1996 Jan</u>-Feb;21(1):46-50.

Conclusion: Ongoing controversy regarding the hazards of exposure of healthcare workers to ribavirin aerosol led to the design and evaluation of a ribavirin aerosol evacuation system that scavenges the excess ribavirin. The results suggest that the system evaluated is an efficient and inexpensive means of reducing incidental employee exposure to ribavirin aerosol.

 Balmes JR, Estacio PL, Quinlan P, Kelly T, Corkery K, Blanc P. Respiratory effects of occupational exposure to aerosolized pentamidine. <u>J Occup Environ Med. 1995</u> Feb;37(2):145-50.

Conclusion: Pentamidine was not detected in the urine of any of the subjects. There were no significant increases in symptoms on days when AP was administered. There was no statistically significant difference in mean diurnal variation of peak expiratory flow rate on days when AP was administered. Methacholine inhalation challenge testing did not show a statistically significant mean change in airway responsiveness across the workweek. The ambient concentrations of pentamidine that we measured document that detectable occupational exposure to AP can occur in poorly ventilated treatment rooms. We recommend that steps be taken to minimize health care worker exposure to AP.

 AARC Clinical Practice Guideline-Selection of a Device for Delivery of Aerosol to the Lung Parenchyma <u>Respir Care 1994</u>; 41(7):647–653.

Protocol Because the data regarding adverse health effects on the health-care worker and on those casually exposed are incomplete, the prudent course is to minimize exposure in all situations.(26).

Measures to reduce aerosol contamination of room air include:

- **6.5.2.1.1** discontinuing nebulization of medication while patient is not breathing the aerosol;
- **6.5.2.1.2** ensuring that staff who administer medications understand risks inherent with the medication and procedures for safely disposing of hazardous wastes;
- 6.5.2.1.3 screening of staff for adverse effects of exposure to aerosol medication;
- **6.5.2.1.4** providing alternative assignments for those staff who are at high risk of adverse effects from exposure (eg, pregnant women or those with demonstrated sensitivity to the specific agent). 6.5.2.2 Engineering controls:
- 6.5.2.2.1 Filters or filtered scavenger systems to remove aerosols that cannot be contained.
- 6.5.2.2.2 Frequent air exchanges to dilute concentration of aerosol in room to eliminate
- 99% of aerosol before the next patient enters/receives treatment in area.
- **6.5.2.2.3** Booths or stalls for sputum induction and aerosolized medication administration in areas in which multiple patients are treated. Booths or stalls should be designed to provide adequate air flow to draw aerosol and droplet nuclei from the patient and into an appropriate filtration system, with exhaust directed to an appropriate outside vent.
- **6.5.2.2.4** Handling of filters, nebulizers, and other contaminated components of the aerosol delivery system used with suspect agents (such as pentamidine and ribavirin) as hazardous waste. **6.5.2.3** *Personal protection devices:*
- 6.5.2.3.1 Personal protection devices should be used to reduce exposure when engineering alternatives are not in place or are not adequate. Use properly fitted respirators with adequate filtration when exhaust flow cannot adequately remove aerosol particles. (28)
- **6.5.2.3.2** Goggles, gloves, and gowns should be used as splatter shields and to reduce exposure to medication residues and body substances.

 Kacmarek RM, Kratohvil J. Evaluation of a double-enclosure double-vacuum unit scavenging system for ribavirin administration. <u>Respir Care</u>, 1992 Jan;37(1):37-45.

Conclusions: Use of a double-enclosure, double-pump scavenging system and implementation of entry protocols ensure reduction of environmental ribavirin levels below recommended maximum levels during administration to spontaneously breathing patients. Use of expiratory filters adequately controls environmental ribavirin levels during mechanical ventilation.

 Kacmarek RM Care-giver protection from exposure to aerosolized pharmacologic agents Is it necessary? <u>Chest 1991</u>;100;1104-1105 (full publication).

Conclusion: Pentamidine should be administered in a negative-pressure HFPA-filtered room with at least six exchanges per hour or with use of a booth or hood designed for scavenging the drug. Nebulizers should incorporate a hand control for aerosol production and exhalation filters.

 Torres A Jr, Krilov LR, Jacobson JM, Kelly KJ, Havens PL. Reduced environmental exposure to aerosolized ribavirin using a simple containment system. <u>Pediatr Infect Dis J. 1991</u> Mar; 10(3):217-21.

Conclusion: To minimize the exposure of health care workers to aerosolized ribavirin, we designed a double tent containment system with circulating mist and suction applied between the tents and we evaluated the ability of this system to contain and evacuate aerosolized ribavirin. Though the risk to exposed health care workers is unknown, this system offers a simple way to decrease significantly occupational exposure to ribavirin.

 Bradley JS Connor JD, Compogiannis LS, Eiger LL, Exposure of Health Care Workers to Ribavirin during Therapy for Respiratory Syncytial Virus Infections, <u>Antimicrobial Agents and</u> Chemotherapy, Apr. 1990, p. 668-670 Vol. 34, No. 4 (Full publication).

Conclusion: These data confirm, in a clinical setting, that ribavirin concentrations in room air can be substantially lowered when the delivery of aerosol is accompanied by a system designed to remove and filter the aerosol during treatment. However, such devices may prove to be more effective if education for HCW includes specific instructions to stop the nebulizing airflow prior to opening the hood.

 Montgomery AB, Corkery KJ, Brunette ER, Leoung GS, Waskin H, Debs RJ Occupational exposure to aerosolized pentamidine. <u>Chest. 1990</u> Aug;98(2):386-8.

Conclusion: The greater risk to health care workers is probably transmission of tuberculosis from undiagnosed cases, especially in populations with an increased incidence of tuberculosis.

 Rodriguez WJ, Dang Bui RH, Connor JD, Kim HW, Brandt CD, Parrott RH, Burch B, Mace J. Environmental Exposure of Primary Care Personnel to Ribavirin Aerosol When Supervising Treatment of Infants with Respiratory Syncytial Virus Infections ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, *July 1987*, Vol. 31, No. 7 p. 1143-1146 (full publication).

Conclusion: The absence of detectable ribavirin in the erythrocytes of nurses participating in the study is reassuring. However, these negative data must be interpreted within their limitations. Finding neither detectable levels nor side effects with the sample size provides an approximate 84% probability of deriving the right conclusion. These data rule out any long-run risk rate higher than 16%, with 95% confidence or 5% limit of credibility (8). We should also note that the air exchange rates at the two institutions studied could have contributed to optimal environmental conditions. These factors should also be considered by those engaged in administering aerosol therapy.

13. OSHA Technical Manual for "Controlling Occupational Exposure to Hazardous Drugs. (www.osha.gov/dts/osta/otm/otm_vi_2.html?

Anesthetic Gases; Surgical Smoke; Laser Plume (laser or electro-surgical unit).

Alp E, Bijl D, Bleichrodt R, Hansson B, A, Voss. Surgical smoke and infection control. <u>Journal of Hospital Infection</u>, 2006 Volume 62, Issue 1, Pages 1 - 5 E. (Full publication).

Conclusion: While higher quality filter masks and/or double masking may increase the filtration capability, a smoke evacuation device or filter placed near (2–5cm) the electrocautery blade or on endoscope valves offers additional (and necessary) safety for operating personnel and patients. Various studies demonstrated that specially designed masks (respirators) are still insufficient barriers. Furthermore, leakage of the mask's seal to the face is another source of possible penetration. No studies have measured the effectiveness of these respirators. The degree to which they protect individuals from surgical smoke is not known and varies depending on the filtering efficiency of the different respirators.

 OSHA Directorate for Technical Support; Office of Science and Technical Assessment Anesthetic Gases: Guidelines for Workplace Exposures, 2000 Revised May 18, 2000.

Engineering controls such as an appropriate anesthetic gas scavenging system are the first line of defense and the preferred method of control to protect employees from exposure to anesthetic gases. An effective anesthetic gas scavenging system traps waste gases at the site of overflow from the breathing circuit and disposes of these gases to the outside atmosphere. HVAC system also contributes to the dilution and removal of waste gases not collected by the scavenging system or from other sources such as leaks in the anesthetic apparatus or improper work practices.

Administrative controls represent another approach for reducing worker exposure to waste gases other than through the use of engineering controls, work practices, or personal protective equipment.

Personal protective equipment should not be used as a substitute for engineering, work practice, and/or administrative controls in anesthetizing locations and PACUs During clean-up and containment of spills of liquid anesthetic agents, personal protective equipment should be used in conjunction with engineering, work practice, and/or administrative controls Respirators, where needed, should be selected based on the anticipated contamination level.

Operating Room. As a result of using appropriate anesthetic gas scavenging in ORs, the levels of contamination have been decreased.

PACU. A properly designed and operating dilution ventilation system should be relied upon to minimize waste anesthetic gas concentrations.

OSHA Hospital eTool-Surgical Suite Module, www.osha.gov/SLTC/etools/hospital/index.html.

Anesthetic Gases: Recommendations Use appropriate anesthetic gas scavenging systems in Operating Rooms. Appropriate waste gas evacuation involves collecting and removing waste gases, detecting and correcting leaks, considering work practices, and effectively ventilating the room (Dorsch and Dorsch 1994).

- 4. OSHA Hospital eTool-Surgical Suite Module, www.osha.gov/SLTC/etools/hospital/index.html.
- Laser smoke: During surgical procedures that use a laser or electro-surgical unit, the thermal
 destruction of tissue creates a smoke byproduct Although there has been no documented transmission

of infectious disease through surgical smoke, the potential for generating infectious viral fragments, particularly following treatment of venereal warts, may exist.

Recommendation engineering controls and work practices: Use portable smoke evacuators and
room suction systems. Install new filters and tubing before each procedure. Inspect smoke
evacuator systems regularly to prevent possible leaks. Use <u>Universal Precautions</u> as required by the
OSHA Bloodborne Pathogens Standard [1910.1030(d)(1)].

Response:

Dear Mr. Pollack:

We would like to thank AHA for the comments and interest in the proposed management and worker surveys, and for concurring that it is critical to have current and accurate data on the top health and safety issues facing healthcare workers. We welcome the opportunity of working more closely with AHA on this data collection effort to begin addressing the needs of healthcare stakeholders. Data gathered by the management survey will provide valuable baseline data on the prevalence and distribution of facility-based health and safety management policies, programs and resources which can be used by healthcare stakeholders, including AHA, to improve worker health and patient safety.

We appreciate the detailed comments that were provided on specific questions in the management and worker questionnaires. We are in the process of evaluating all of the comments we received from stakeholders in order to make the necessary improvements to both survey questionnaires. Our response to AHA's comments primarily addresses the general and overarching concerns outlined in your June 26, 2008 letter. We are still in the process of evaluating the comments on specific questions and any revisions to these questions will be made in the near future.

General Concerns

Problems with pilot-testing of the questionnaires -- The pilot tests were conducted at two VHA medical centers located in the Pacific Northwest. The management questionnaires were validated at four hospitals, not including the two hospitals who participated in the pilot tests as validation efforts at the two VHA facilities focused on the worker survey. These four hospitals were located in Washington State and included a large private sector urban (acute care) hospital, a large public sector rural community hospital, a large public sector rural community hospital. Validation results are provided in our contractor's final report.

Problems with the length and complexity of the surveys -- We received comments from several respondents regarding the length of the worker and management surveys indicating that they are too long. Regarding the worker survey, we convened focus groups/cognitive testing; most participants indicated that they would complete a 20-30 minute survey, especially if they could complete the survey in more than one session (which is an option for respondents of our web survey). Findings from our pilot tests show that the average time to complete the core module was about 20 minutes, and about 7 minutes for each hazard module. Response rates were fairly good, averaging 45% at two pilot test sites. While there appears to be no single guideline for questionnaire length, one literature review of the effect of questionnaire length on response rates stated that "results are still confusing and contradictory, conclusions are still not clear, and questionnaire designers still aim for shorter questionnaires with little more justification than the assumption that longer interviews will result in higher nonresponse" (Bogen K, 1996 Proceedings of the Section on Survey Research Methods, American Statistical Association, pgs 1020-1025) Although we feel that the length of the worker survey is reasonable, we are planning to evaluate options for reducing the completion time.

Regarding the management survey, our pilot tests showed that the survey itself could be completed in about 45-50 minutes. However, in many cases, the health and safety manager needed to contact managers of other departments (human resources, oncology ward, pharmacy, sterile processing, etc) to complete the survey, a process which was estimated to take up to 3-4 hours in large hospitals. Given the concern raised over the potential of low response rates if the current management questionnaire is used in a national survey, we are planning to evaluate options for streamlining the management survey.

Problems with survey questions – As noted above, we are in the process of evaluating all of the comments we received from stakeholders in order to make the necessary changes to improve both survey questionnaires. Comments from AHA and others bring into light new information and insight that will result in targeted revisions to the management and worker surveys.

Concerns about the methodology for conducting the surveys – A number of professional associations representing health care workers stated that they are willing to collaborate with NIOSH on the worker survey. Most indicated that they prefer a statistical sampling approach to a convenience sampling approach; it is our intention to employ a statistical sampling approach. Although labor organizations expressed interest in participating in the worker survey, a web survey of their members was considered impractical primarily because member email addresses are not readily accessible at a national level. As a result, the worker survey will be implemented primarily through professional associations. The worker survey will be revised to include questions on professional association and labor union affiliations, as well as type, size and location (but not name) of employer, in order to characterize responses by these variables and to assess whether the results are nationally representative.

The additional criteria provided by AHA for development of hospital sampling frames will be considered. We plan to share this information with our contractor and will rely on their expertise in developing a comprehensive sampling frame for hospitals. Any information that AHA has on its hospital members that could be used in developing the sample frame would be of interest to NIOSH.

We appreciate your concern that the different approaches proposed for the worker and management surveys may result in lower response rates for the management survey and the appearance that hospitals are indifferent to occupational health and safety issues. As noted above, we are planning to evaluate options for streamlining the management survey as a means of reducing response time and maximizing response rates and welcome the opportunity of working with AHA in this process.

We do not plan to offer respondents of the worker survey with a monetary incentive. We believe that receiving a strong commitment of support for the worker survey from the leadership of all participating professional associations will be more worthwhile and effective than any type of financial incentive for respondents. We also believe that a strong commitment of support from the leadership of AHA is equally valuable for successful implementation of the management survey.

Although both surveys gather information on health and safety practices, the worker survey also gathers information on health and safety perceptions. Stakeholders expressed interest in the inclusion of these types of questions in the worker survey as they allow for respondents to express their opinions on a number of important health and safety issues. Perception questions are very common in worker surveys conducted by others and have shown to provide valid information in other studies. We plan to revisit these questions to assess whether all of them need to be included in the survey.

In our pilot tests, workers were able to provide fairly accurate responses for questions concerning health and safety practices, including use of exposure controls such as engineering controls and use of personal protective equipment. We considered including a validation component to the worker survey effort; however, the anonymous nature of the worker survey does not lend itself to validation. Furthermore, we do not intend to ask respondents to provide specific information on their employer (name, address, etc)

because of breach of anonymity concerns and the potential for lowering response rates. Rather, we will be collecting general information on the employer including type, size and location of facility. Current plans do not include validation of management responses due to lack of funds of the survey.

Overarching Concerns

Use of personal protective equipment (PPE) excludes masks

We agree with AHA that gathering information on work practices related to the use of surgical masks is relevant and we plan to revise the questionnaires to gather this information. However, as you are aware, NIOSH does not approve surgical masks as respiratory protection as they lack adequate filtering and fitting attributes to protect the wearer from airborne contaminants such as particulates, gases and vapors. Rather, surgical masks are designed to help prevent large droplets (spit, mucous, etc) expelled by the wearer from reaching patients and/or sterile work areas, although some (those with fluid resistant properties) may help reduce sprays/splashes of bodily fluids from reaching the wearer's mouth and nose.

Routine medical surveillance for workers

The questions addressing medical surveillance are included to describe current practices regardless of whether or not they are requirements or best practices. We plan to include introductory information in the survey to clarify this issue, as well as other practices/approaches. AHA's suggestion that these questions be restated to assess whether testing is conducted when problems are identified may also be an acceptable way to address this issue.

Use of back belts not supported by evidence

We did not receive any comments on back belts from management respondents during the pilot tests or from stakeholders other than AHA. For the same reason stated above for medical surveillance, the purpose of these questions is to describe current practices regardless of whether or not they are requirements or best practices. We are considering either rephrasing the questions or eliminating them entirely.

Natural rubber latex products

We plan to revise the questions regarding natural latex rubber to include the most current terminology.

In closing, we are very appreciative of the insightful comments offered by AHA on the survey instruments. We would appreciate the opportunity of working collaboratively with AHA as we move forward with the management survey to ensure its successful implementation. We would like to propose a face-to-face meeting at your offices in Washington, DC, preferably within the next several weeks, to introduce ourselves and further discuss the surveys. Please let me know whether you are receptive to such a meeting and, if so, provide me with several dates in mid October that would be good for you and your staff.

We look forward to hearing from you soon.

Respectfully submitted,

22. Comment

Craig Becker

Organization Tennessee Hospital Association

Email cbecker@tha.com

Comments:



Ruid 111108

Tennessee Hospital Association

June 27, 2008

NIOSH Docket Office Robert A. Taft Laboratories MS-C34 4676 Columbia Parkway Cincinnati, OH 45226

RE: NIOSH docket number 135, notice of public meeting and availability for public comment (Vol. 73, No. 64), April 2, 2008.

To Whom It May Concern:

On behalf of our member hospitals and health systems, the Tennessee Hospital Association (THA) appreciates the opportunity to comment on the National Institute for Occupational Safety and Health's (NIOSH) proposed national surveys of health care workers' safety and employer safety and health practices. THA is the premiere organization in Tennessee that promotes and represents the interests of all hospitals, health systems and other healthcare organizations and the patients they serve. Established in 1938, it also provides education and information for its members.

As employers and providers of health care, hospitals and health systems are committed to the health and safety of our caregivers and patients. THA and its member hospitals have been extremely proactive in developing programs and resources that are designed to protect employees and patients as new hazards emerge and best practices are developed.

As an example of the efforts that are underway in Tennessee, THA launched the Tennessee Center for Patient Safety (TCPS) to support and accelerate hospital patient safety and quality improvement efforts. The primary purpose of the center is to channel education, resources and support services to help hospitals in the state to accelerate adoption of evidence-based strategies that improve the reliability, safety and quality of care received by patients.

The center's first two statewide initiatives, operating under the banner of "Safe Patients. Healthy Patients," are a hospital collaborative on reducing healthcare-acquired infections, and a nursing collaborative to integrate nurse staffing, work environment and patient safety. These projects are expected to have a broad impact on the quality and reliability of care delivered to patients across Tennessee in the future.

TCPS and the Tennessee Chapter of the American College of Surgeons (TnACS) have received a \$2.5 million grant from the Blue Cross-Blue Shield of Tennessee Health Foundation to develop the Tennessee NSQIP Surgical Quality Consortium, which is designed to evaluate and improve surgical care delivered by general and vascular surgeons in the state of Tennessee.

Serving Team user Houlth Core Source 1938. S80 Intervitie Houleyand, South + Nashville, Teamsisee 37210-4634 + 615-256-8240 + Tol. Free 800-258-9541 + EAX 615-242-4803 This collaboration between hospitals and surgeons represents an innovative partnership and will significantly enhance the TCPS' current initiatives on surgical care and reducing infections. It also will involve the collection of additional quality data that has been proven to be effective in driving improvement in surgical outcomes. Hospitals will use aggregate reports to identify improvement opportunities, identify areas that have better than average results, evaluate and identify difference in practice between the hospitals in the state, and ascertain and disseminate best practices in Tennessee

In addition, THA developed the Tennessee Rural Hospital Patient Safety Demonstration Project, which was a collaborative effort to improve patient safety in small, rural facilities by strengthening their ability to implement priority patient safety interventions, including the assessment of patient safety culture and implementation of a safety culture plan.

It is important to demonstrate that each state respectively has initiated the appropriate steps to protect the safety and well-being of their hospitals' staff and patients.

NIOSH states that the overall objective of this project is to "describe the prevalence and distribution of important health and safety hazards and perceptions, work practices, and use of exposure controls from a healthcare worker perspective, and to describe institution-based health and safety management policies, programs and resources of healthcare establishments, from the perspective of the person responsible for employee health and safety." THA, along with the American Hospital Association (AHA), agree it is critical to have current and accurate data on the top health and safety issues facing caregivers. However, we have serious concerns about these surveys and the methodology that NIOSH proposes to use to obtain this data.

Problems with the pilot-testing of the questionnaires. NIOSH reports it conducted a pilot-test of the surveys at two large medical centers to evaluate the establishment-based approach for implementing the employee survey, the preference for mode of response, response rates, and to validate the worker and management questionnaires. NIOSH further reports the management questionnaire was validated at four hospitals that completed the surveys and permitted site visits to assess the accuracy of their response. However, no detail is provided in the background materials as to the type, location or size of these hospitals or whether they included the two large medical centers that also participated in the employee survey pilot test.

Given the lack of detail in the background materials provided to the public, it is impossible to determine whether the pilot-testing was adequate and, therefore, whether the conclusions drawn from the pilot test can be used to support the content and conduct of the NIOSH surveys. Certainly, using just two large medical centers to validate the questionnaires would not lead to results that were representative of the different types of hospitals in the nation. In order to support the validity of the management survey in particular, it would be important to include several types of hospitals, such as a small rural or critical access hospital, and a medium-sized community hospital.

Problems with the length and complexity of the surveys. The management and healthcare worker surveys are extremely long, with complex questions, many of which contain multiple parts. We believe completing them will take far longer than the time NIOSH estimates. NIOSH estimates it will take 20 minutes to complete the core module of the worker survey, which is 25 pages long and contains 79 questions; and that the hazard modules, which include up to 42 questions, will take an average of seven minutes to complete. The

agency estimates it would take 45 to 50 minutes to complete the management survey, which is 50 pages long and contains 63 core questions, with 140 questions in the hazard modules. Further, many of the questions in the management survey would require significant research to determine the appropriate response.

Clearly, NIOSH has significantly underestimated the time it will take to complete the surveys. We are concerned this level of burder will reduce the survey response rate, particularly in the management survey, and result in an inadequate and non-representative sample of respondents completing the survey. A significant response burden would fall on larger hospitals, which, because they generally offer a full range of services would need to complete not only the core questions but most or all of the hazard modules.

Completing the management survey is a far more complicated task than completing the worker survey. Within a single hospital, there will likely be a number of individuals, such as infection control, occupational health and safety/facility officer, who will be called on to complete various sections of the survey. While many hospitals have onsite occupational health offices, health systems with multiple hospitals may not have such offices within each of their facilities. They would have to provide access to data to complete the survey from within their centralized occupational health departments. Still other facilities contract out the occupational health functions to a third party.

There also are many variations in the types of positions responsible for the areas being addressed in the survey, making it more difficult to identify those to whom the survey should be targeted. These factors will make it difficult to ensure the survey gets to the right individual(s) within hospitals and increase the likelihood that surveys could be lost in the system, hurting the response rate and jeopardizing accuracy for the management survey.

Problems with survey questions. While NIOSH claims to be seeking comments on the content of the survey questionnaires, its background materials note that the survey questionnaires already have been pilot-tested in two large medical centers. The agency states "the content of the questionnaires has been fairly well-defined" and "minor revisions will be made...prior to use in this study." THA has serious concerns about many of the questions in the survey, which we describe in attached detailed comments. However, NIOSH implies that it does not intend to correct or remove the problems, errors and inconsistencies in the survey instruments and instead is seeking input only in an attempt to identify other issues for possible inclusion in these already long and burdensome questionnaires. We urge NIOSH to reconsider this decision and be open to making substantive changes to the content of the surveys.

Our greatest concerns relate to statements, especially those to which the worker is asked to respond, that are presented as factual or imply a best practice, but which do not have solid supporting evidence. Additionally, we are concerned that many questions, especially those referring to the use of personal protective equipment, have inadequate response options. As a result, respondents cannot answer in a way that accurately describes their health and safety practices.

Unless NIOSH ensures that its questions describe practices that are truly supported by scientific evidence and allow responses that reflect actual health and safety practices, the survey results will be misleading and identify gaps that are not relevant to worker health and safety. Detailed comments related to specific questions and concerns are being provided by AHA.

Concerns about the methodology for conducting the surveys. For the worker survey, NIOSH indicates it will use a "population-based" approach to gather hazard surveillance data from healthcare workers by partnering with various labor unions and professional associations that will send survey information to their membership. These organizations will either directly e-mail their members with a link to the survey or promote the survey to members via various avenues of communication and direct them to a web site where they can complete the survey. This results in a "convenience" survey sample of workers who are members of the partnering labor unions and professional associations and who have access to the Internet. To maximize response rates, NIOSH proposes to award workers who complete the survey with a \$10 online gift certificate.

THA has serious concerns about this approach. As stated in NIOSH's background materials, the disadvantages associated with the use of a convenience sampling approach include the problem of a non-representative sample of the total population of workers and sampling bias. The use of labor unions to market the survey further magnifies this problem because within healthcare, labor unions are concentrated in certain areas of the country and, therefore, the workers that belong to unions, such as the Service Employee's International Union (SEIU), will be able to reach will skew the sample and move it further away from being nationally representative.

We recommend that NIOSH continue to reach out to other organizations that may have a more appropriate balance of geography among their membership to help ensure a more nationally representative healthcare worker survey sample. We also support NIOSH's intention to modify the survey to include questions regarding characteristics of the worker's place of employment (i.e. type and size) and professional association or labor union affiliation. This change will help researchers determine whether the survey results are nationally representative.

For the management questionnaire, NIOSH proposes to use an "establishment-based" approach from which a size-stratified random sample of hospitals will be drawn. Contact will be made with each hospital to obtain the name and email address of the person primarily responsible for employee occupational hoalth and a series of survey related emails will be sent. While we believe this approach has a better chance of resulting in a nationally representative sample of respondents, we have a number of concerns and questions about how NIOSH is proposing to conduct the management survey.

First, NIOSH indicates the sample of hospitals it will draw will be size-stratified by the number of employees (1-19; 20-449; 500+). THA recommends that NIOSH not finalize this sampling framework, but instead use the more typical hospital research sampling framework that is based on bed size, geographic region and type of facility.

We also are concerned the stark differences in the approaches used to conduct the two surveys will make it appear, incorrectly, that hospitals are indifferent to the health and safety of their workers. As noted above, due to the lengthy and complex management questionnaire, we believe there will be a low response rate, resulting in an inadequate and nonrepresentative respondent population. While the worker questionnaire also is lengthy, workers will be provided with a financial incentive, a \$10 gift certificate, to complete the survey.

In addition, the worker questionnaire, being primarily based on workers' perceptions and opinions, and loaded with questions that are not evidence-based, is far more subjective than the management questionnaire, which is largely based on concrete management practices.

There is no way to validate the results of the worker questionnaire because it includes no information that could link a worker to his or her place of employment. By contrast, NIOSH has indicated it will validate some samples of the management questionnaire responses via site visits.

For these reasons, we recommend that NIOSH reconsider its methodology for administering the healthcare worker survey. Instead of utilizing a convenience sample, NIOSH should evaluate how it could develop a statistical sampling approach that would more accurately represent the populations of workers it would like to survey. NIOSH also should consider developing a methodology to validate the worker questionnaire results, perhaps by linking the responses from workers within a single institution and/or through comparing the worker responses to the responses from a validated management questionnaire from the healthcare facilities in which they are employed.

If such changes are not made and the responses to the worker and management surveys are determined not to be nationally representative (as NIOSH notes it expects will be the case with housekeeping staff), NIOSH should place the caveat in its public release that the results should not be used to make generalizations about entire populations, and any associated conclusions run the risk of being false.

If you have any questions, please Chris Clarke, cclarke@tha.com, or Bill Jolley, bjolley@tha.com, at THA, 615-256-8240.

Singerely

Craig A Becker, FACHE

President

Tennessee Hospital Association

Response:

Thank you for your comments and interest in the proposed management and worker surveys. Because the THA shares the same concerns as the AHA, please refer to our response to the AHA (Comment #22)

23. Comment

Name

Ann R. Cox

Organization

American Association of Occupational Health Nurses, Inc.

Email ann@aaohn.org

Address 2029 Brandywine Rd., Suite 100 Atlanta, Georgia 30341

Comments:

The American Association of Occupational Health Nurses, Inc. (AAOHN) has conducted web surveys using non-probability or convenience samples and statistical samples. The advantages of web surveys are 1) easier to respond in most cases, 2) cost effective and 3) quick results. The disadvantages include 1) if too complex and/or lengthy increases difficulty for responders, 2) limited to type of questions that may be asked, and 3) some individuals still experience challenges with technology. AAOHN will not provide email list of members. The association will provide links to members so they can respond and coordinate communication and promotion.

AAOHN has staff that can manage/coordinate sample selection. Sample selection can be targeted (e.g., educational level, business sector, membership classification, etc.) based on audiences to be targeted. AAOHN 's experience has shown that short and less complex questionnaires receive a better response, higher percentage of members respond earlier in the process than close to the deadline, several communications (e.g., emails, electronic newsletters) increase participation, and the significance/importance of the topic increases participation. AAOHN's response rate is approximately 20-30 percent of the sample. Rarely does the association use incentives. We do post an executive summary on the association web site and in some cases; participants can obtain a copy of the survey results.

AAOHN communications vehicles used to promote participation can include 1) letter from the association President, 2) weekly electronic newsletter, 3) monthly printed newsletter, 4) targeted audiences' emails, and 5) email blasts. The association does not specifically identified IRB review as it relates to study protocols; however, the association's policy is as follows:

- Participation is strictly voluntary,
- Data is reported as an aggregate,
- Responses are anonymous,
- Data are used for no other purpose and
- Only data that is required for the purposes of the project is asked.

As for reporting we recommend electronic and printed formats, links, presentations (e.g., face to face, web casts, etc). We prefer reading a summary/executive summary so that we can immediately see the results and implications. Details can be made available.

Worker Survey

AAOHN feedback is as follows:

Recommend using the term "health" instead of "medical" surveillance.

- Health is a broader term encompassing healthy workers as well as those affected workers. It also reflects the diverse group of health care providers responsible for health surveillance.
- Regarding emerging hazards or issues, what about musculoskeletal issues(e.g., lifting), blood and body fluid and latex exposure, and exposure to infectious diseases.

Management Survey

AAOHN feedback is as follows:

- Recommend that the participants know in advance that they may have to secure data from other departments/units. Our experience has been that having to secure additional data increases the complexity and decreases the participation rate. This audience may be less inclined to take the time to gather additional data. The root issue is finding the right person to complete the survey.
- Recommend a short time line.
- Recommend multiple approaches to reporting results including an executive summary that provides the information one would want to know right up front.
- 4) Regarding core modules, wondering why Bloodborne Pathogens program was not included?
- 5) Recommend the emerging hazards or issues we identified under worker survey be asked about on the management survey—blood and body fluids, latex exposure, and infectious diseases.

Response:

Dear Ms. Cox:

We would like to thank AAOHN for the comments and interest in the proposed management and worker surveys, and for sharing AAOHN's practices relative to conducting surveys of its members. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements to both survey questionnaires.

We plan to have the management survey completed by personnel who are responsible for employee health; these individuals will be identified from a random sample of hospitals. Consideration was given to accessing these individuals through the various professional associations such as AAOHN; however, we opted for an establishment-based approach since most of the data we are collecting in the management survey resides with the employer.

Again, thank you for the valuable comments.

24. Comment

Name Bruce Yarwood

American Health Care Association (AHCA) and the National Center for Assisted Living (NCAL)

Comments:

The American Health Care Association (AHCA) and the National Center for Assisted Living (NCAL) welcome the opportunity to provide comments to the National Institute for Occupational Safety and Health (NIOSH) on the proposed Survey of Healthcare Workers' Safety and Health, and the proposed Survey of Healthcare Employer Safety and Health Practices.

AHCA and NCAL represent more than 10,000 non-profit and for-profit providers dedicated to

continuous improvement in the delivery of professional and compassionate care for our nation's frail, elderly and disabled citizens who live in long term care (LTC) facilities, including nursing facilities, assisted living residences, sub-acute centers and homes for individuals with developmental disabilities. Our member facilities employ nearly one million workers, the majority of whom are front-line caregivers. AHCA/NCAL also represents LTC to the Department of Labor, the Centers for Disease Control and Prevention; the Department of Health and Human Services Centers for Medicare & Medicaid Services; the Institute of Medicine; and other agencies and organizations in various worker safety initiatives.

Executive Summary

NIOSH is requesting public comment on the content and conduct of a survey of healthcare workers' safety and health and a survey of healthcare employers' safety and health practices. The goal of the healthcare worker survey is to collect information describing hazards, exposures, safety and health practices, and use of exposure controls by occupation, type and size of establishments.

The goal of the management survey is to collect information by type and size of establishment by: describing facility-based health and safety resources, safety and health management programs, and policies and practices for the health and safety hazards covered in the worker survey. Information collected from these hazard surveillance surveys will be useful in identifying gaps relative to the use of best practices and define future research and intervention priorities.

AHCA/NCAL Comments and Recommendations

This draft guidance has been well thought out and is comprehensive, but AHCA/NCAL has some concerns and recommendations relating to LTC facilities as follows:

NIOSH states that the surveys were pilot-tested at two large medical centers to evaluate response rates, validate the management and worker questionnaires, etc. In addition, NIOSH states that the management questionnaire was validated at four hospitals that completed the surveys and permitted NIOSH on-site visits to assess the accuracy of the hospitals' responses. As LTC facilities operate quite differently from medical centers and hospitals, these pilot tests would not accurately reflect the appropriateness of these surveys for LTC. Therefore, AHCA/NCAL recommends that NIOSH pilot test these surveys in LTC facilities and revise them as appropriate.

The surveys are lengthy and complex, and it will take much longer for employees and managers to complete the surveys than NIOSH estimates; especially as many of the questions in the management survey would require additional significant research and staff coordination to obtain a response. In addition, LTC facility staff are too busy caring for their residents to take the time needed to accurately complete these lengthy surveys. An additional stumbling block is the requirement that the surveys be completed by computer as computer use is restricted and limited in LTC facilities.. The resultant low response rate would render a non-representative sample of employees and managers completing the survey.

Therefore, AHCA/NCAL requests that NIOSH revise the surveys to be less lengthy and establish a mail-in option for management and employees to complete the surveys.

Management Questionnaire:

- a. Routine medical surveillance for workers: The management questionnaire consistently and inaccurately implies that routine medical surveillance of workers, without apparent clinical problems, is a best practice standard to promote safety. Although LTC facilities do perform skin testing for occupational exposure to tuberculosis and have occupational health programs for employee referral in cases of injury, etc., there is little rationale for general health surveillance. Therefore, AHCA/NCAL recommends that NIOSH remove the implication throughout the management questionnaire that broad medical surveillance of workers is routinely appropriate beyond that for tuberculosis exposure.
- b. Questions A15 and A18: These questions ask whether there is an individual at the facility whose primary [emphasis supplied by NIOSH] responsibility is to manage the occupational safety program, or an individual to manage the occupational or employee health program. The "yes" or "no" response options to these questions are inappropriate as, in LTC, coordinating these programs would not be the primary function of the manager, who is probably a member of the maintenance staff, is the director of nursing, etc. Therefore, AHCA recommends that NIOSH add an alternative response option that is more appropriate for LTC as our staff perform numerous functions in their roles, only one of which may be management of facility safety programs.
- c. Question A 26: This question inquires about the facility's emergency preparedness plan. LTC facilities are not equipped for isolation beds (e.g., having extensive ventilation systems,) or for systems to decontaminate victims/facility personnel affected by contaminants, as are listed in this question. These equipment and systems would be inappropriate as LTC facilities do not admit patients with tuberculosis or they discharge them upon diagnosis in order to protect the much larger numbers of rehabilitation and long-term stay patients. However, LTC facilities correctly have programs in place to prepare employees for emergencies, such as shelter in place and evacuation plans, employee vaccination programs, etc. Therefore, AHCA/NCAL recommends that NIOSH add an additional alternative response to the survey which is appropriate to evaluate LTC emergency preparedness.

Worker Core Module:

a. NIOSH's "population based" approach to gather hazard surveillance data from health care workers by partnering with various labor unions and professional associations (that will in turn send surveys out to their members) likely will render an unrepresentative sample of the total population of workers nationwide. In LTC, labor unions such as the Service Employee's International Union (SEIU,) are concentrated only in certain areas of the country, so union member responses could skew survey results and make them unrepresentative of healthcare workers nationwide. Therefore, AHCA/NCAL recommends that NIOSH evaluate the geographic membership of the organizations it partners with to promote obtainment of more nationally representative health care worker data.

- b. Unlike the management questionnaire, there is no way to validate the results of the worker questionnaire because it includes no information that could link a worker to his or her place of employment. This is in contrast to NIOSH indicating that it will validate some samples of management questionnaire responses via healthcare facility site visits. AHCA/NCAL recommends that NIOSH establish a validation process for the worker questionnaire; if this is not feasible, NIOSH needs to note in its conclusion reports and press releases that survey results should not be used to make generalizations about entire employee populations.
- c. Question 21: Some of the questions in this "Job Demands" section appear unnecessary and add length to an already inappropriately long survey. Examples are when employees are asked for their level of agreement with item c, "My job requires me to be creative," and item f, "I have an opportunity to develop my own special abilities." These inquiries have no bearing on employee safety programs. Therefore, AHCA/NCAL recommends that NIOSH pare down survey questions to those applicable to employee safety issues.
- The questions in the employee core questionnaire and modules consistently exclude masks from the definitions of personal protective equipment (PPE.) However, surgical masks do remain important and are effective in healthcare settings for preventing many nosocomial infections. Therefore, AHCA/NCAL recommends that surveys list masks as an appropriate type of PPE.

AHCA/NCAL appreciates the opportunity to submit comments on the NIOSH Survey of Healthcare Workers' Safety and Health and the NIOSH Survey of Healthcare Employer Safety and Health Practices, and how they affect LTC providers. We encourage NIOSH to contact us at any time for additional information.

Sincerely,

Response:

Dear Mr. Yarwood:

We would like to thank AHCA and NCAL for the comments and interest in the proposed management and worker surveys. Also, we are very appreciative of the detailed comments that were provided on specific questions in the management and worker questionnaires. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements to both survey questionnaires.

Although we would have preferred to include all types of healthcare establishments in the management survey, we are only planning to target general medical and surgical hospitals because of limited resources and the fact that we pilot tested the management survey at hospitals. We appreciate your concerns

regarding the inappropriateness of using the existing survey instruments in LTC facilities. If these types of facilities are included in future surveys, we will make sure to address your comments to ensure that the survey instruments are appropriately refined and pilot tested in LTC facilities.

25. Comment

Name Paul Speidell

Organization Virginia Hospital and Healthcare Association

Email pspeidell@vhha.com

Comments:

The Virginia Hospital & Healthcare Association (VHHA) is strongly concerned about the National Institute for Occupational Safety and Health's (NIOSH's) proposed Survey of Healthcare Workers' Safety and Survey of Health and Healthcare Employer Safety and Health Practices. VHHA has 49 member health systems and hospitals, representing 112 community, psychiatric, rehabilitation and specialty hospitals throughout Virginia. We care deeply about the safety and health of the workers, patients, and visitors in these facilities. We appreciate and support NIOSH's interest in measuring and working to improve worker safety. However, both the content of the surveys and their administration will need significant changes to be objective and accurate.

Virginia's hospitals and health systems believe there is always room for improvement in health care and health. That includes constantly working to improve the environments in which we care for patients – for both those receiving and administering care. We remain committed to improving the care environments in our member facilities, including through NIOSH surveys as appropriate. However, we have significant concerns with both the content and administration of the employer and worker surveys as currently proposed.

CONTENT

Burdensome

The surveys are very long. NIOSH has grossly underestimated the time that will be required to complete them. While VHHA recognizes NIOSH's desire for more data, **the proposed approach is overly burdensome and needs to be streamlined.**

The core management survey is 50 pages long, with additional hazard modules for some respondents. There are some basic questions, such as whether the facility is not-for-profit or part of a managed care organization. However, the majority of questions will require detailed knowledge of and research into facility-specific information, such as the number of doses given in the past week for about <u>80</u> specific antineoplastic agents. Likewise, it asks how many workers at the facility use high level disinfectants on medical instruments and devices.

These are not simple questions. They will require research by numerous individuals, including infection control, occupational health, and safety officers. Also, while many hospitals have on-site occupational health offices, health systems with multiple hospitals may not have such offices within each of their facilities. Respondents would have to access data from within their systems' centralized occupational health departments to complete the survey. Moreover, smaller rural hospitals may have less staff to research and collect data – making the survey completion a large burden on a smaller staff.

NIOSH suggests this core employer survey will take 50 minutes to complete, and the hazard modules only a few minutes longer. VHHA believes it may take nearly that long simply to farm out the questions to the appropriate responder in the hospital. This represents a significantly greater burden on the facility than suggested in the proposal.

While not as long as the management survey, the worker survey is also burdensome, complex, and will take well more than the estimated 20 minutes to complete. There also are hazard modules for certain employees in addition to the core module. Workers will be offered a \$10 payment for their completed survey, so that financial incentive may be enough to encourage a broader response at the worker level than at the facility level. That could skew results and make it appear that hospitals are less concerned with worker safety than their individual caregivers.

To increase participation and level response rates between the two surveys, NIOSH should more realistically assess how long the survey will take to complete, and work to reduce that burden to a more manageable level for both the facility management and workers.

Objective or Subjective?

The types of questions posed suggest an inappropriate disconnect between the styles and therefore likely outcomes of the two surveys. This will almost certainly confound attempts to comparatively analyze responses to the two surveys. The management survey is based on objective measures while the worker survey is largely opinion-based and subjective. For example, the management survey poses questions like:

Is there a policy for taking rest breaks at this facility?

Does this facility have a formal emergency preparedness plan?

These questions seek specific, concrete responses to help assess the circumstances at a facility. They stand in sharp contrast to the employee survey, which asks respondents to rate on a scale whether they:

Feel safe from work-related injury or illness in my current work environment.

The safety procedures and practices in this organization are useful and effective.

These are not concrete and the responses "strongly agree, agree..." are not specific. VHHA recognizes that some differences will exist in the types of data available to management and workers. But the gap in objectivity and specificity should be much smaller than the proposal. The subjective, immeasurable nature of the worker survey especially opens the door to biased responses. NIOSH needs to strive to ensure the worker survey is as objective and specific as the facility survey.

ADMINISTRATION

Validated or Not?

NIOSH has indicated that it intends to validate the management surveys via site visits. Such site visits immediately escalate the burden associated with this process. It appears that NIOSH has not adequately accounted for this added burden in its assessment of how challenging the survey administration will be for facilities.

Moreover, NIOSH has given no indication of validating the worker survey responses. In fact, it does not appear that NIOSH will know which worker completed which survey. Of course, one might say the subjective nature of the questions in the worker survey does not lend itself to validation. That should raise concern about the subjectivity of the questions, as discussed above. It also raises the question of whether such subjective questions present an even greater need for validation despite the difficulty of that process.

For example, the worker survey asks "during the past seven calendar days, how many times did you lift or move objects, other than patients, weighing 50 lbs or more?" If workers did not know beforehand that question would be posed in a survey, it is highly unlikely they would be able to provide a reliable, accurate answer to this question. Did they count and record each time they lifted a heavy object in the last seven days? Did they weigh each object? Workers at an airline ticket counter have scales to tell them how much each piece of luggage weighs. Health care facility workers do not operate in that sort of environment and are unlikely to know how much objects weigh with such specificity. The question is subject to faulty memory, inaccurate judgment of weights, and other problems. This question and others like it beg validation.

VHHA believes that the subjectivity of the worker survey questions needs to be eliminated to the greatest extent possible. If responses to either survey are to be validated then both sets of surveys should have appropriate validation.

Neutral or Biased?

NIOSH has indicated it will use labor groups and professional associations to help distribute the worker surveys. These organizations may e-mail their members with a link to the survey or otherwise promote the survey to members. VHHA is concerned that this administration methodology will result in a slanted sample of respondents overpopulated with members of these organizations. Moreover, given the subjective nature of the worker survey, there is inappropriate room for these advocacy organizations to promote advocacy agendas via worker responses, resulting in even less objective and more biased responses. The lack of any planned validation of the worker survey responses makes using organized labor advocacy groups to distribute the surveys (and encourage responses) particularly alarming.

NIOSH should not permit organized labor to be formally involved in distributing these surveys. There is nothing NIOSH can do to prevent organized labor from holding educational sessions or producing educational materials related to the survey – nor should there be. Those may be appropriate roles for a union. However, to formally enlist them as points-of-contact for the survey in distribution or collection represents a clear conflict of interest.

Labor unions should not distribute the surveys for NIOSH. A more statistically accurate methodology of survey administration should better reflect the health care workforce population. If labor unions are used, NIOSH should reach out to a wide variety of other organizations to help distribute the surveys. Additionally, NIOSH should add a demographic question to the worker survey to determine how much of the survey sample holds membership in a union.

Moreover, NIOSH indicates that its sample of hospitals will be stratified by the number of employees (1-19; 20-449; 500+). However, due to multiple variations among hospital types as well as among the communities that hospitals serve, typical hospital research sampling is based on bed size, geographic region, and type of facility. **NIOSH should consider adjusting its sampling strategy to most effectively capture the broad variety of hospitals and health systems in its sample.**

Thank you for the opportunity to comment on the proposed surveys. Virginia's hospitals and health systems are committed to the safety of our workers, patients, and visitors and support the need for

specific information on hazards exposure. We also are committed to good governance. VHHA is strongly concerned that although the proposed surveys strive after the former, they over reach the latter. We would be pleased to work with NIOSH to revise and streamline the surveys in a way that will help to measure workplace safety more objectively and in the least burdensome fashion.

Sincerely,

Response:

Dear Mr. Speidell:

We would like to thank VHHA for the comments and interest in the proposed management and worker surveys. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements to both survey questionnaires. Because some of your comments are similar to those provided to NIOSH from the American Hospital Association (AHA), please refer to our response to the AHA (Comment #21), as well.

We received several comments regarding the length of the worker and management surveys indicating that they are too long. Our pilot tests showed that the management survey itself could be completed in about 45-50 minutes. However, in many cases, the health and safety manager needed to contact managers of other departments (human resources, oncology ward, pharmacy, sterile processing, etc) to complete the survey, a process which was estimated to take up to 3-4 hours in large hospitals. Given the concern raised over the potential of low response rates if the current management questionnaire is used in a national survey, we are planning to evaluate options for streamlining the management survey.

Regarding the worker survey, we convened focus groups/cognitive testing; most participants indicated that they would complete a 20-30 minute survey, especially if they could complete the survey in more than one session (which is an option for respondents of our web survey). Findings from our pilot tests show that the average time to complete the core module was about 20 minutes, and about 7 minutes for each hazard module. Response rates were fairly good, averaging 45% at two pilot test sites. While there appears to be no single guideline for questionnaire length, one literature review of the effect of questionnaire length on response rates stated that "results are still confusing and contradictory, conclusions are still not clear, and questionnaire designers still aim for shorter questionnaires with little more justification than the assumption that longer interviews will result in higher nonresponse" (Bogen K, 1996 Proceedings of the Section on Survey Research Methods, American Statistical Association, pgs 1020-1025) Although we feel that the length of the worker survey is reasonable, we are planning to evaluate options for reducing the completion time. Because contractor costs exceeded our project proposal budget, it is unlikely that we will be able to offer respondents of the worker survey with a monetary incentive. We believe that receiving a strong commitment of support for the worker survey from the leadership of all participating professional associations will be more worthwhile and effective than any type of financial incentive for respondents.

Although both surveys gather information on health and safety practices, the worker survey also gathers information on health and safety perceptions. Stakeholders expressed interest in the inclusion of these types of questions in the worker survey as they allow for respondents to express their opinions on a number of important health and safety issues. Perception questions are very common in worker surveys conducted by others and will be a part of our worker survey, though we are planning to reduce the number of these questions.

In our pilot tests, workers were able to provide fairly accurate responses for questions concerning health and safety practices, including use of exposure controls such as engineering controls and use of personal protective equipment. We considered including a validation component to the worker survey effort; however, the anonymous nature of the worker survey does not lend itself to validation. Furthermore, we do not intend to ask respondents to provide specific information on their employer (name, address, etc) because of breach of anonymity concerns and the potential for lowering response rates. Rather, we will be collecting general information on the employer including type, size and location of facility. Current plans do not include validation of management responses due to lack of funds of the survey.

A number of professional associations representing health care workers stated are collaborating with NIOSH on the worker survey. Most indicated that they prefer a statistical sampling approach to a convenience sampling approach; it is our intention to employ a statistical sampling approach. Although labor organizations expressed interest in participating in the worker survey, a web survey of their members was considered impractical primarily because member email addresses are not readily accessible at a national level. As a result, the worker survey will be implemented exclusively through professional associations. The worker survey will be revised to include questions on professional association and labor union affiliations, as well as type, size and location of employer, in order to characterize responses by these variables and to assess whether the results are nationally representative.

Relative to the proposed sampling strategy, we welcome the additional criteria to consider for evaluation of hospital sampling frames. We plan to share this information with our contractor and will rely on their expertise in developing a comprehensive sampling frame for hospitals.

We are very appreciative of the thoughtful input from the VHHA and we look forward to working with VHHA as we move forward with our surveys.

26. Comment

Name Raymond D. Sweeney

Organization Healthcare Association of New York State

Email rsweeney@hanys.org

Comments:

On behalf of our more than 550 member hospitals, health systems, and continuing care providers, the Healthcare Association of New York State (HANYS) appreciates the opportunity to comment on the National Institute for Occupational Safety and Health's (NIOSH) proposed national surveys of health care workers' safety and employer safety and health practices.

New York's hospitals, health systems, and continuing care members, as part of their not-for-profit mission, are committed to the health and safety of caregivers and patients. Nationwide, health care facilities have long had in place policies, programs, and resources designed to protect employees, and these facilities strive to ensure that these protections are updated and kept relevant as new hazards emerge and best practices are defined.

NIOSH states that the project's objective is to "describe the prevalence and distribution of important health and safety hazards and perceptions, work practices, and use of exposure controls from a health care worker perspective, and to describe institution-based health and safety management policies, programs and resources of health care establishments, from the perspective of the person responsible for employee health and safety." We agree that it is critical to have current and accurate data on the top health and safety issues facing caregivers. However, we have serious concerns about these surveys and the methodology that NIOSH proposes to use to obtain these data.

Length and Complexity of the Survey Instruments

The management and health care worker survey instruments are extremely long, with complex questions, many of which contain multiple parts. We believe that completing them will take far longer than the time NIOSH estimates. We are concerned that this burden will reduce the survey response rate, particularly in the management survey, and result in an inadequate and non-representative sample of respondents. A significant response burden would fall on larger hospitals, which, because they generally offer a full range of services, would need to complete not only the core questions but also most or all of the hazard modules.

NIOSH estimates that it will take 20 minutes to complete the core module of the worker survey, which is 25 pages long and contains 79 questions; and that the hazard modules, which include up to 42 questions, will each take an average of seven minutes to complete. The agency estimates that it would take 45 to 50 minutes to complete the management survey, which is 50 pages long and contains 63 core questions, with 140 questions in the hazard modules.

Completing the management survey is a far more complicated task than completing the worker survey. Many of the questions in the management survey would require significant research to determine the appropriate response. Within a single hospital, there will likely be a number of individuals, such as the infection control, occupational health, and safety/facility officers, who would be involved in completing various sections of the survey. In addition, while many hospitals have on-site occupational health offices, health systems with multiple hospitals may not have such offices within each of their facilities; therefore, individuals completing the management survey would need to take steps to access the appropriate data sources. Still other facilities contract out the occupational health functions to a third party.

In addition, the variations in the types of positions responsible for the areas addressed in the management survey make it more difficult to identify those to whom the survey should be targeted. This will make it difficult to ensure that the survey gets to the right individual(s) within hospitals and increase the likelihood that surveys could be lost in the system, hurting the response rate and jeopardizing accuracy.

HANYS requests that NIOSH consider streamlining its surveys in regard to length and complexity.

Content of the Survey Questions

HANYS has serious concerns about many of the questions in the worker survey. The worker survey is more subjective than the management questionnaire. The management survey is largely based on concrete management practices. The worker survey is primarily based on workers' perceptions and opinions, and contains questions that are not evidence-based. For example, several statements on the worker survey are presented as factual or imply a best practice, but which do not have solid supporting evidence. We ask that those questions that do not have a proper basis in evidence be removed or changed. Additionally, we are concerned that many questions, especially those referring to the use of personal protective equipment, have inadequate response options. As a result, respondents cannot answer in a way that accurately describes their health and safety practices.

HANYS requests that NIOSH use questions that describe practices that are truly supported by scientific evidence and allow responses that reflect actual health and safety practices. If NIOSH does not, the survey results will be misleading and could identify gaps that are not relevant to worker health and safety.

Methodology for Conducting the Surveys

For the worker survey, NIOSH indicates that it will use a "population-based" approach to gather hazard surveillance data from health care workers by collaborating with various labor unions and professional associations that will send survey information to their membership. These organizations will either directly e-mail their members with a link to the survey or promote the survey to members via various avenues of communication and direct them to a Web site where they can complete the survey. This results in a "convenience" survey sample of workers who are members of the partnering labor unions and professional associations and who have access to the Internet. To maximize response rates, NIOSH proposes to award workers who complete the survey with a \$10 online gift certificate.

HANYS has serious concerns about this approach. As stated in NIOSH's background materials, the disadvantages associated with the use of a convenience sampling approach include the problem of a non-representative sample of the total population of workers and sampling bias. The use of labor unions to market the survey further magnifies this problem because within health care, labor unions are concentrated in certain areas of the country and therefore the workers that unions, such as the Service Employee's International Union, will be able to reach will skew the sample and move it further away from being nationally representative.

HANYS recommends that NIOSH continue to reach out to other organizations that may have a more appropriate balance of geography among their membership to help ensure a more nationally representative health care worker survey sample. We support NIOSH's intention to modify the survey to include questions regarding characteristics of the worker's place of employment (i.e., type and size) and professional association or labor union affiliation; this will help researchers determine whether the survey results are nationally representative.

For the management questionnaire, NIOSH proposes to use an "establishment-based" approach from which a size-stratified (by the number of employees) random sample of hospitals will be drawn. Contact will be made with each hospital to obtain the name and e-mail address of the person primarily responsible for employee occupational health and a series of survey related e-mail messages will be sent.

While we believe that this approach has a better chance of resulting in a nationally representative sample of respondents, HANYS recommends that NIOSH instead use the more typical hospital research sampling framework that is based on bed size, geographic region, and type of facility.

We are also concerned that the stark differences in the approaches used to conduct the two surveys will make it appear, incorrectly, that hospitals are indifferent to the health and safety of their workers. As noted above, due to the lengthy and complex management questionnaire, we believe that there will be a low response rate, resulting in an inadequate and non-representative respondent population. While the worker questionnaire is also lengthy, workers will be provided with a financial incentive, a \$10 gift certificate, to complete it.

There is no way to validate the results of the worker questionnaire because it includes no information that could link a worker to his or her place of employment. By contrast, NIOSH has indicated that it will validate some samples of the management questionnaire responses via site visits.

HANYS recommends that NIOSH reconsider its methodology for administering the health care worker survey. Instead of utilizing a convenience sample, NIOSH should evaluate how it could develop a statistical sampling approach that would more accurately represent the populations of workers it would like to survey. NIOSH should also consider developing a methodology to validate the worker questionnaire results, perhaps by linking the responses from workers within a single institution and/or

through comparing the worker responses to the responses from a validated management questionnaire from the health care facilities in which they are employed.

We request that absent the above requested changes, if the responses to the worker and management surveys are determined not to be nationally representative (as NIOSH notes it expects will be the case with housekeeping staff), NIOSH should place a caveat in its public release that the results should not be used to make generalizations about entire populations, and that any associated conclusions run the risk of inaccuracy.

If you have any questions, please contact me at (518) 431-7729 or at rsweeney@hanys.org, or Cindy Levernois, Director of Behavioral Health and Workforce, at (518) 431-7744 or cleverno@hanys.org.

Sincerely,

Response:

Thank you for your comments and interest in the proposed management and worker surveys. Because the HANYS shares the same concerns as the AHA, please refer to our response to the AHA (Comment #21)

27. Comment

Name Gail M. Blanchard-Saiger

Organization California Hospital Association

Email gblanchard@calhospital.org

Address 1215 K Street, Suite 800 Sacramento, CA 95814

Comments:

The California Hospital Association (CHA), representing over 400 California hospitals and health systems, appreciates the opportunity to submit comments on the National Institute for Occupational Safety and Health (NIOSH) proposed national surveys of health care workers' safety and employer safety and health practices. These written comments are supplemental to the comments I made on behalf of CHA at the April 30, 2008, public meeting.

CHA has also had the opportunity to review the comments submitted by the American Hospital Association and we incorporate that discussion by reference here. We do wish, however, to elaborate on several issues that are of particular concern to hospitals and health systems in California.

California hospitals and health systems are committed to the health and safety of our workforce as well as our patients. In addition to instituting a variety of voluntary safety policies and practices, California hospitals and health systems are subject to a variety to state statutes and regulations relating to health and

safety practices. For example, the California Division of Occupational Safety and Health issues standards related to toxic materials and harmful physical agents (California Labor Code § 144.6; 8 Cal. Code Reg. § 5144), blood borne pathogens (California Labor Code § 144.7; 8 Cal. Code Reg. § 5193) as well as other health and safety issues that frequently arise in the health care environment. Given the substantial difference among the states on the regulation of these issues, we believe it is important to take such regulation into consideration when reporting the survey results.

Additionally, we believe it is important to underscore several concerns raised by AHA. First, the purpose of the proposed survey has not been adequately developed. According to NIOSH,

the objective of this project is to describe the prevalence and distribution of important health and safety hazards and perceptions, work practices, and use of exposure controls from a worker perspective, and to describe institution-based health and safety management policies, programs and resources.

However, as acknowledged during the public meeting, the choice of "hazards" included in the survey was not evidence based. Including agents that have not been proven "hazards" may raise unfounded concerns among employers and workers regarding exposure to particular agents that may not, in fact, be harmful.

While NIOSH indicates that "information collected form these hazard surveillance surveys will be useful in identifying gaps relative to the use of best practice and define future research and intervention priorities," we do not believe the proposed surveys serve that purpose. As NIOSH acknowledged during the public meeting, the surveys do not incorporate a method for collecting information regarding outcomes. Without this information, the survey results have little practical value. The results may provide data on whether a particular practice is common but will not inform regarding development of "best practices." Thus, there is a question as to whether the survey results will assist in adoption of evidence based health and safety practices.

Additionally, CHA has concerns about the proposed method of distributing the worker and management surveys. The proposal to distribute the worker survey through professional associations and labor unions will not result in a representative sampling of California's health care workforce. A substantial number of California's professional and technical workforce is neither represented by a labor union nor a member of a professional association.

Our concern regarding the management survey derives from the recognition that California hospitals are currently subject to numerous mandatory surveys and other regulatory requirements. It is unlikely that either small, rural hospitals or large health systems have the resources to complete the proposed voluntary NIOSH survey containing over 200 questions covering a range of issues, particularly where workforce shortages and the impact of Medi-Cal cuts are pressing concerns. As a result, it is very likely that the management response rate will be low. This, in turn, may be unfairly perceived as a lack of interest in worker health and safety by hospitals.

We appreciate NIOSH's interest in attempting to gather information to improve health care worker health and safety. However, we have serious concerns as to the design and methodology of the currently proposed surveys. If you would like to discuss CHA's comments in more detail, please feel free to contact me at gblanchard@calhospital.org or (916)552-7620.

Sincerely,

Response:

Thank you for your comments and interest in the proposed management and worker surveys. Because the CHA shares the same concerns as the AHA, please refer to our response to the AHA (Comment #21)

28. Comment

Name Wayne Smith

Organization
Delaware Healthcare Association

Email wayne@deha.org

Address 1280 South Governors Avenue Dover, Delaware 19904-4802

Comments:



Delaware Healthcare Association

Wayne A. Smith President & CEO

June 30, 2008

Sent via E-mail and U.S. Mail

NIOSH Mail Stop C-34 Robert A. Taft Laboratory 4676 Columbia Parkway Cincinnati, OH 45226

RE: NIOSH Docket number 135

To Whom It May Concern:

On behalf of our member hospitals and health systems, the Delaware Healthcare Association (DHA) appreciates the opportunity to comment on the National Institute for Occupational Safety and Health's (NIOSH) proposed national surveys of health care workers' safety and employer safety and health practices.

As employers and as providers of health care, hospitals and health systems are committed to the health and safety of our caregivers and patients. Hospitals have long had in place policies, programs and resources that are designed to protect employees, and they strive to ensure these protections are updated and kept relevant as new hazards emerge and best practices are defined.

NIOSH states the overall objective of this project is to "describe the prevalence and distribution of important health and safety hazards and perceptions, work practices, and use of exposure controls from a health care worker perspective, and to describe institution-based health and safety management policies, programs, and resources of health care establishments, from the perspective of the person responsible for employee health and safety." We agree it is critical to have current and accurate data on the top health and safety issues facing caregivers. However, we have serious concerns about these surveys and the methodology NIOSH proposes to use to obtain these data.

Problems with the pilot-testing of the questionnaires. NIOSH reports it conducted a pilot-test of the surveys at two large medical centers to evaluate the establishment-based approach for implementing the employee survey, the preference for mode of response, response rates, and to validate the worker and management questionnaires. NIOSH further reports the management questionnaire was validated at four hospitals that completed the surveys and permitted site visits to assess the accuracy of their response. However, no detail is provided in the background materials as to the type, location, or size of these hospitals or whether they included the two large medical centers that also participated in the employee survey pilot test.

Given the lack of detail in the background materials provided to the public, it is impossible to determine whether the pilot-testing was adequate and; therefore, whether the conclusions drawn from the pilot test can be used to support the content and conduct of the NIOSH surveys. Certainly, using just two large medical centers to validate the questionnaires would not lead to results that were representative of the different types of hospitals in the nation. In order to support the validity of the management survey in particular, it would be important to include several types of hospitals, such as a small rural or critical access hospital, and a medium-sized community hospital.

1280 South Governors Avenue Dover, Delaware 19904-4802 302-674-2853 Fax 302-734-2731 www.deha.org Problems with the length and complexity of the surveys. The management and health care worker surveys are extremely long, with complex questions, many of which contain multiple parts. We believe that completing them will take far longer than the time NIOSH estimates. NIOSH estimates it will take 20 minutes to complete the core module of the worker survey, which is 25 pages long and contains 79 questions; and the hazard modules, which include up to 42 questions, will take an average of seven minutes to complete. The agency estimates it would take 45 to 50 minutes to complete the management survey, which is 50 pages long and contains 63 core questions, with 140 questions in the hazard modules. Further, many of the questions in the management survey would require significant research to determine the appropriate response.

NIOSH has significantly underestimated the time it will take to complete the surveys. We are concerned that this level of burden will reduce the survey response rate, particularly in the management survey, and result in an inadequate and non-representative sample of respondents completing the survey. A significant response burden would fall on larger hospitals, which, because they generally offer a full range of services, would need to complete not only the core questions, but most or all of the hazard modules.

Completing the management survey is a far more complicated task than completing the worker survey. Within a single hospital there will likely be a number of individuals, such as infection control, occupational health and safety/facility officers, who will be called on to complete various sections of the survey. Also, while many hospitals have on-site occupational health offices, health systems with multiple hospitals may not have such offices within each of their facilities. They would have to provide access to data to complete the survey from within their centralized occupational health departments. Still other facilities contract out the occupational health functions to a third party.

Also, there are many variations in the types of positions responsible for the areas being addressed in the survey, making it more difficult to identify those to whom the survey should be targeted. These factors will make it difficult to ensure the survey gets to the right individual(s) within hospitals and increase the likelihood that surveys could be lost in the system, hurting the response rate and jeopardizing accuracy for the management survey.

Problems with survey questions. While NIOSH claims to be seeking comments on the content of the survey questionnaires, its background materials note the survey questionnaires have already been pilot tested in two large medical centers. The agency states "the content of the questionnaires has been fairly well-defined" and "minor revisions will be made... prior to use in this study." The DHA has serious concerns about many of the questions in the survey, which we describe in attached detailed comments. However, NIOSH implies that it does not intend to correct or remove the problems, errors, and inconsistencies in the survey instruments and instead is seeking input only in an attempt to identify other issues for possible inclusion in these already long and burdensome questionnaires. We urge NIOSH to reconsider this decision and be open to making substantive changes to the content of the surveys.

Our greatest concerns relate to statements, especially those to which the worker is asked to respond, that are presented as factual or imply a best practice, but which do not have solid supporting evidence. In our attached detailed comments, we identify those questions that do not have a proper basis in evidence and recommend they be removed or changed. Additionally we are concerned that many questions, especially those referring to the use of personal protective equipment, have inadequate response options. As a result, respondents cannot answer in a way that accurately describes their health and safety practices. Our detailed comments also address these concerns. Unless NIOSH ensures its questions describe practices that are NIOSH Docket # 135 June 30, 2008 Page 3

truly supported by scientific evidence and allow responses that reflect actual health and safety practices, the survey results will be misleading and identify gaps that are not relevant to worker health and safety.

Concerns about the methodology for conducting the surveys. For the worker survey, NIOSH indicates it will use a "population-based" approach to gather hazard surveillance data from health care workers by partnering with various labor unions and professional associations that will send survey information to their membership. These organizations will either directly email their members with a link to the survey or promote the survey to members via various avenues of communication and direct them to a Web site where they can complete the survey. This results in a "convenience" survey sample of workers who are members of the partnering labor unions and professional associations and who have access to the Internet. To maximize response rates, NIOSH proposes to award workers who complete the survey with a \$10 online gift certificate.

The DHA has serious concerns about this approach. As stated in NIOSH's background materials, the disadvantages associated with the use of a convenience sampling approach include the problem of a non-representative sample of the total population of workers and sampling bias. The use of labor unions to market the survey further magnifies this problem because within health care, labor unions are concentrated in certain areas of the country and therefore the workers that unions such as the Service Employee's International Union (SEIU) will be able to reach will skew the sample and move it further away from being nationally representative. We recommend NIOSH continue to reach out to other organizations that may have a more appropriate balance of geography among their membership to help ensure a more nationally representative health care worker survey sample. We also support NIOSH's intention to modify the survey to include questions regarding characteristics of the worker's place of employment (i.e., type and size) and professional association or labor union affiliation; this will help researchers determine whether the survey results are nationally representative.

For the management questionnaire, NIOSH proposes to use an "establishment-based" approach from which a size-stratified random sample of hospitals will be drawn. Contact will be made with each hospital to obtain the name and e-mail address of the person primarily responsible for employee occupational health and a series of survey related e-mails will be sent. While we believe this approach has a better chance of resulting in a nationally representative sample of respondents, we have a number of concerns and questions about how NIOSH proposes to conduct the management survey.

First, NIOSH indicates the sample of hospitals it will draw will be size-stratified by the number of employees (1-19; 20-449; 500+). The DHA recommends NIOSH not finalize this sampling framework, but instead use the more typical hospital research sampling framework that is based on bed size, geographic region, and type of facility.

We also are concerned that the stark differences in the approaches used to conduct the two surveys will make it appear, incorrectly, that hospitals are indifferent to the health and safety of their workers. As noted above, due to the lengthy and complex management questionnaire, we believe there will be a low response rate, resulting in an inadequate and non-representative respondent population. While the worker questionnaire is also lengthy, workers will be provided with a financial incentive, a \$10 gift certificate, to complete the survey.

Further, the worker questionnaire, being primarily based on worker's perceptions and opinions, and being loaded with questions that are not evidence-based, is far more subjective than the management questionnaire, which is largely based on concrete management practices.

There is no way to validate the results of the worker questionnaire because it includes no information that could link a worker to his or her place of employment. By contrast, NIOSH has indicated it will

validate some samples of the management questionnaire responses via site visits.

For these reasons, we recommend NIOSH reconsider its methodology for administering the health care worker survey. Instead of utilizing a convenience sample, NIOSH should evaluate how it could develop a statistical sampling approach that would more accurately represent the populations of workers it would like to survey. NIOSH also should consider developing a methodology to validate the worker questionnaire results, perhaps by linking the responses from workers within a single institution and/or through comparing the worker responses to the responses from a validated management questionnaire from the health care facilities in which they are employed. If such changes are not made, and if the responses to the worker and management surveys are determined not to be nationally representative (as NIOSH notes it expects will be the case with housekeeping staff), NIOSH should place the caveat in its public release that the results should not be used to make generalizations about entire populations, and that any associated conclusions run the risk of being false.

Our detailed comments are attached. If you have any questions, please feel free to contact me or at (302) 674-2853 or Wayne@deha.org.

Attachments (2)

Attachment 1 DELAWARE HEALTHCARE ASSOCIATIONDETAILED COMMENTS AREAS OF CONCERN

The Delaware Healthcare Association (DHA) has identified a number of issues and problems that are repeated throughout the health care worker and the management questionnaires. Revisions should be made throughout the survey in a consistent manner. These issues:

Contractor Questions. The management questionnaire (Question 7, last two items listed) asked if there are policies "to provide site-specific health and safety information for contractors' employees prior to their beginning work at this facility" and "Evaluation of contractors' health and safety training provided to their employees prior to their assignment at this facility." These items should be modified to include more information and/or examples of the type of contractors and where they would be working so these questions could be answered correctly.

Use of personal protective equipment (PPE) excludes masks. The questions in the core questionnaires and modules consistently exclude masks from the definition of PPE. This is a major flaw in these surveys and the absence of questions regarding the use of masks prevents the collection of important information. Surgical masks remain important in health care settings for managing patients and facilities cannot always separate protection of patients or equipment from protection of the worker when care is being provided. There are circumstances where the use of masks is perfectly acceptable and consistent with Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health

Administration (OSHA) guidance. This would be the case, in locations involving biological agents, such as isolation rooms or around patients in "contact precautions;" when a worker preparing antineoplastic drugs uses a biological safety hood; where the sterility of equipment must be protected; and many other circumstances. The survey's consistent misrepresentation of what is acceptable PPE will undermine health care worker confidence that masks have value. By maintaining this position throughout the questionnaire, a systematic bias is introduced and valuable information on standard and appropriate practices is lost. The survey language's implication is that a respirator is required to protect the worker from any potential exposure. The questionnaires should be revised to list masks as an appropriate type of PPE.

<u>PPE policy questions</u>. In addition, after an employee responds "No" to wearing health care industry standard PPE, NIOSH follows-up with asking why the employee did not wear PPE; however, NIOSH does not then follow-up with asking if not wearing the PPE is against hospital policy. The management questionnaire asks about such PPE policies in place, but does not then ask the employee about the policy. This is not consistent.

Routine medical surveillance for workers. The management questionnaire consistently, and inaccurately, implies routine medical surveillance of workers in the absence of a specific problem is a standard of practice. In fact, with the exception of skin testing for occupational exposure to tuberculosis and a very few other circumstances, most health care facilities do not routinely conduct medical surveillance. Instead, they have occupational health programs in place to which an employee would be referred if there is evidence of a problem related to perceived exposures in the workplace, such as a worker with shortness of breath or an allergic reaction. This concern about the assumption that routine medical surveillance is taking place applies to questions regarding exposure to antineoplastic agents (page 16, questions B10-B13A); ribavirin, pentamidine and tobramycin (pages 23-24, questions C8-C12); glutaraldehyde (page 28, questions D9- 12A); ethylene oxide (page 35 and 36, questions E10-13A); and waste anesthetic gases (page 44, questions F9-F12A). These questions should be restated to inquire whether testing is being conducted when problems are identified (e.g., worker with shortness of breath or allergic reaction.). For instance, they could ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to the chemical in the workplace.

Use of back belts not supported by evidence. (See citations below for back belts.) Several of the questions in the worker core questionnaire refer to the use of back belts. It is implied this is expected behavior or policy, or standard of practice. Yet the literature is clear that back belts are not recommended. The National Institute for Occupational Safety and Health's (NIOSH) own major study published in the Journal of the American Medical Association in 1996 states, "There is a lack of scientific evidence that back belts work. Workers wearing back belts may attempt to lift more weight than they would have without a belt. A false sense of security may subject workers to greater risk of injury." Back or gait belts are referred to within the health care worker core questionnaire in questions 50, 52, 54 and 55 on pages 17-20. In the management survey, back belts are referred to on page 9, question A41 (Musculoskeletal Injury). These references to back belts should be removed from the questionnaires.

<u>Job hazard analysis</u>. The management questionnaire (question 9) asks "Has a job hazard analysis been conducted?" The answers should be modified to include an answer which states review of job hazards are continuously conducted for health and safety.

Natural rubber latex products. All references to powder-free natural rubber latex gloves and other natural rubber latex products should be changed to reflect the current availability of Food and Drug Administration (FDA) approved powder-free, low protein/allergen latex products. Powder-free, low protein/allergen natural rubber latex gloves are already widely used within health care facilities, and we expect there will be other products on the market by the time these surveys are administered. Therefore,

to avoid confusion among respondents, all such references should be cited as "powder-free and low protein/allergen" natural rubber latex gloves or products.

Within the health care worker questionnaire, the references to natural rubber latex gloves and other products that need to be changed are in:

Core Module, page 20, question 57;

Module B (Antineoplastics (Pharmacists, Pharmacy Techs)) pages B-6 through B8, questions 24 and 27; and

Module C (Antineoplastics Agents Administration (Oncology Nurses)) page C-6 and C7, questions 24 and 26.

Within the management questionnaire, the references to natural latex rubber gloves and other products that need to be changed are in:

Section A, Core Questions, Pages 10-11, Question 54-59; and

Section B, Antineoplastic Agents, Page 20, Question B28, option (f).

Questions which ask "How many employees" perform a specific task and a breakdown by male and female employees. Dependant upon the types of Human Resources systems in place, this could require a count be conducted by specific task and by the sex of the employee.

Questions which ask "How many doses" of specific drugs were mixed or administered in the last 7 days. Since this asks for several specific drugs, by brand name; and dependent upon the pharmacy system in place, this could require a specific report be written to obtain these numbers. Some facilities may not have reports in place for weekly usage of all drugs.

HEALTH CARE WORKER QUESTIONNAIRE

CORE MODULE

Health & Safety Hazards Concerns

<u>Page 3 Question 2 (j)</u>. In its example of an infectious agent, NIOSH selects only the airborne agent tuberculosis. We believe contact transmission of infectious diseases is of equal, if not greater concern to health care workers. However, this would require that NIOSH include questions referring to masks as part of PPE, not just respirators. This is an issue that surfaces repeatedly in the management and worker (both core and individual hazard) modules and results in a built-in bias which will not permit collection of information on actual safe practices.

Page 12, Question 29: Safe Needle Devices – Universal Precautions. The term "Universal Precautions" should be replaced with "Standard Precautions," the current terminology. Also, as there is increasing usage of non-needled syringes with luer locks to IV lines, which do not involve sharps at all. Please replace the word "syringes" with "syringes with needles" in the question, "do you handle syringes, scalpels or other sharp instruments..."

Page 14 Questions 3 9-40. This question asks about the frequency of handling soiled sheets, bedpans, etc. The follow-up Question 41 asks only if water-resistant gowns/gloves are always worn. There is no choice for responding that water-resistant gowns/gloves are worn most or some of the time, as is offered for other questions. Further, handling a soiled sheet or bedpan may not require a water-resistant gown and no option is given for any other types of protective or isolation gowns. The wording permits no other response. These questions should be revised to allow for other types of protective or isolation gowns.

<u>Page 9 Question 21, Item n.</u> "Some demands I face at work are in conflict with other demands at work." This should be revised to provide an example to clarify what NIOSH is asking the employee.

Medical Evaluation

<u>Page 21, Question 58</u>. The question indicates an evaluation "may include blood tests, and/or urine test." Mentioning these sets an expectation that blood and urine testing are required without any reason and implies a standard of practice which does not exist.

Overtime, Work Shifts, and Vacation

<u>Page 10 Question 22</u>. The question asks about overtime, work shifts, and vacation. The overtime portion of this question does not ask if the employee is/was eligible for overtime, and if there was an outside factor why an employee may have been needed to work overtime (e.g. large flu outbreak, severe weather event, etc.).

The portions of this question which ask about the employee's shift do not ask if the employee is new to this facility. New employees are hired for a specific shift and are not eligible to transfer to another shift for a certain number of months. There also may be factors, such as employees who wish to work a shorted schedule (e.g. two or three workdays); they may be limited to certain days of the week and shifts.

New employees are also not eligible for vacation time for a certain number of months; unless something has been pre-arranged at the time of hire (e.g. the new employee notified the facility at the time of hire of a pre-planned vacation at the time of hire and received approval for the time off). There are also some facilities which have a tourist season and/or large event (e.g. two NASCAR race weekends – three races in three days in Delaware) and may request their employees not to take their vacation during this time to have maximum staffing levels to accommodate the enlarged population of the area due to the tourists.

We recommend these questions to be broken out and allow for answers which include new employees and outside factors (e.g. area illness outbreak, severe weather event, tourist events, etc.) which affect the answers to these questions.

Concerns in all Employee Modules:

Questions asking "How many times did you ..."perform a task. If these tasks are part of the employee's normal work, they would not necessarily know how many times they performed a certain task. This will either initiate a count of how many times they perform a specific task and/or guessing how many times they performed the task.

Questions asking "How much time did you spend ..." performing a task during the last 7 calendar days. If these tasks are part of the employee's normal work, they would not necessarily know how many times they performed a certain task or the length of time that specific task takes each time it is performed. This will either initiate a count of how much time spent performing a specific task and/or guessing how much time is spent performing the task.

Questions asking if the employee has taken home any clothing, sheets, etc. which have been exposed to certain substances. These questions should be followed-up by asking if this is against hospital policy. The management questionnaire asks if the facility has policies in place for this, but does not ask the employee and is not consistent.

MODULE A: AEROSOLIZED MEDICATIONS (RESPIRATORY THERAPISTS)

(See attached citations for aerosolized medication.)

Issue: Engineering controls versus personal protective equipment (PPE) in handling aerosolized medications. Research studies detail the progress on the use of sealed or scavenger type systems that minimize risk and indicate engineering controls and work practices are primary over respiratory protection. There also are options such as booths, enclosed hoods or negative pressure rooms, especially since pentamidine may be used on patients infected with tuberculosis. However, the questions in the survey do not recognize improved sealed delivery systems that offer more options and less reliance on PPE. This issue, raised below for ribavirin, also applies to the questions on pentamidine (pages A-4 and A-5, questions 20 and 21; page A-3, question 16) and tobramycin (page A-6, questions 28 and 29; page A-5, question 24).

Page A-2, Question 8 and Page A-3, Question 13. These questions begin to address the type of equipment used is a critical engineering control to minimize aerosols and deliver drug directly to a patient's lungs, but they do not address this directly or clearly. Distance from patient (within five feet) is made to appear to be more important than the seal of the medical device being used. There should be a statement added indicating the best engineering control is a well-sealed drug delivery device.

Page A-3, Question 12. This question offers only three options: sealed booth, partially enclosed hood/tent or no enclosure. There is no option related to a negative pressure room (possibly an isolation room). This option should be added to question 12.

Page A-3, Question 13. In this question, use of a negative pressure room option should not be limited to an isolation room.

<u>Page A-10 Questions 38-41</u>. Although respirators may be "reasonable" according to cited current studies, studies have not shown that masks or respirators are effective. Rather, engineering controls are critical, from the type of sealed device to the use of scavenging systems. The survey should make it clearer that cited study data supporting engineering controls take precedence over PPE. Exclusion of masks prevents a response that masks may be worn to protect the patient.

Page A-11, Question 41. "Did you wear booties to administer any of the above?" again puts more emphasis on PPE at the expense of other more effective controls. Further, there are no recommendations for booties to be used within the current OSHA Technical Manual nor in the "Guidelines for Controlling Occupational Exposure to Hazardous Drugs."

(www.osha.gov/dts/osta/otm/otm_vi_2.html)

MODULE B: ANTINEOPLASTICS (PHARMACISTS, PHARMACY TECHS)

Page B-9, Questions 30-32A. These questions do not allow a response for masks, implying that they are not protective. However, the OSHA Technical Manual is clear, as long as the worker uses a biological safety hood (an engineering control), a respirator is not required. Further, we recommend the questions be modified to refer to the "appropriate use of respiratory protection," since many of these listed drugs are not aerosolized, but rather they are liquids or tablets.

<u>Page B-10 Question 33—Use of booties</u>. We echo the comment identified under module A, question 41 for respiratory therapists. There are no OSHA recommendations for use of booties.

MODULE C: ANTINEOPLASTICS AGENTS ADMINISTRATION (ONCOLOGY NURSES)

This module contains no questions about respiratory protection or booties, yet many oncology nurses in clinics prepare these drugs in medication rooms and hoods and administer them directly to the patient. This again raises the question of why booties are included in other modules.

MODULE D: CHEMICAL STERILANTS

<u>Page D-6</u>, <u>Question 27</u>. STERRAD is mentioned here and used as an example of hydrogen peroxide, but is not listed or used as an example in the management questionnaire or in the worker questionnaire module E. The questionnaire should be consistent regarding whether or not STERRAD is mentioned.

<u>Page D-7</u>, <u>Questions 33 and 34</u>. These questions do not permit a response involving the appropriate use of a mask. The implication is that respiratory protection of the worker is routinely required. However, there are other protocols that require workers to wear masks; for example, in protocols for protecting sterile equipment. The inability to choose a mask as a response makes these questions difficult to answer.

MODULE E: HIGH LEVEL DISINFECTANTS

<u>Page E-1 and E-3 (Question 9)</u>. Why is STERRAD not listed here and used as an example of hydrogen peroxide, although it is listed in Worker Survey D? The questionnaire should be consistent regarding whether or not STERRAD is mentioned.

<u>Page E-3, Question 11</u>. We recommend the addition of a third option as follows: "3. No local exhaust, but in a room with either good air dilution (six, 10, 12 air changes per hour) AND/OR a negative pressured room, in which the air is exhausted out of the room."

<u>Pages E-7 and E-8, Questions 24-26A</u>. These questions relate to the use of respiratory protection and do not permit a response involving the appropriate use of a mask. The implication is that a respirator is required to protect the worker from any of these chemicals, regardless of room ventilation or the use of local exhaust.

MODULE F: SURGICAL SMOKE (FROM LASERS OR ELECTROSURGERY DEVICES) MODULE G: ANESTHETIC GASES (ADMINISTRATION)

MODULE H: ANESTHETIC GASES (BYSTANDERS WHO DO NOT ADMINISTER)

MODULE I: WASTE ANESTHETIC GASES (POST ANESTHESIA & SURGICAL RECOVERY)

(See attached citations for anesthetic gases, surgical smoke and laser plume.)

Pages F-6 to F-8, Questions 20-22A; Pages G-5 and G-6, Questions 27-29A; Pages H-4 and H-5, Questions 19-21A; and Pages I-2 and I-3, Questions 10-12A. The questions are misleading since they do not reference any need for verifying functioning scavenger systems or ensuring they are in good working order. While engineering controls are far more critical to worker protection, all the emphasis in this module is on respiratory protection. The questions imply that a respirator is required to protect workers from surgical/laser smoke, regardless of room ventilation or use of local exhaust. But the surgical suite is an area in which personnel would be wearing FDA-approved sterile surgical masks, worn to protect the patient, and appropriately relying on engineering controls such as scavenging system and use of filters to protect workers. OSHA, the agency that sets out regulations and guidance for worker safety, has made it clear that engineering controls and administrative/work practices are effective, and the data does not

demonstrate the usefulness of respirators at this time.

MODULE J: HOUSEKEEPING OR ENVIRONMENTAL SERVICES STAFF

Page J-2, Questions 5 and 6; Page J-4, Question 12; Page J-4, Question 15. The manner in which these questions are presented is misleading. Question 5b (Safe clean-up procedures for spills of anti-cancer drugs) may be addressed in policies and procedures, but policies are likely to indicate that a spill team will do the initial clean-up and environmental services/housekeeping will only do the final clean-up. So the task in question 5b is not usually the responsibility of environmental services. For clarity, question 6 should be applied to each practice listed under question 5, since only choices (a) and (c) may apply. Policies and procedures are usually covered under training, but often it indicates a trained registered nurse, pharmacist, or spill team will handle (b).

We recommend anti-cancer drugs should be included as a separate question. For question 12, we recommend it first ask whether spills are pre-cleaned by a specialist for (a), (b), and (c). Then there should be questions asking whether they do the final cleanup after a spill of (a), (b) and (c). In question 15, we recommend the question be asked separately for anti-cancer drugs, chemicals, and bodily fluids.

<u>Page J-3, Question 8</u>. With regard to the list of quaternary ammonium compounds and phenols, the questionnaire should list all common brands if brand names are going to be used. Also, "oxidizers" is not a familiar term. We recommend using "low level disinfectants."

Pages J-4 and J-5, Questions 17-18. The questionnaire never asks about cleaning in locations involving biological agents, such as isolation rooms, or around patients in "contact precautions" where, in most cases, the use of masks is perfectly appropriate. This undermines confidence that masks have any value. By maintaining this position throughout the questionnaire so consistently, a systematic bias is introduced and valuable information on standard and appropriate practices is lost. The theme and implication for all modules is also that a respirator is required to protect the worker from any chemical, regardless of its concentration.

MANAGEMENT QUESTIONNAIRE

SECTION A. CORE QUESTIONS

<u>Page 1, Question A4</u>. The question should reference accreditation by the American Osteopathic Association (AOA) and any other organizations that have deemed status from the Centers for Medicare & Medicaid Services (CMS). Further, the question should be reworded to use the current

name of The Joint Commission (TJC) and the parenthetically note "formerly known as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)."

<u>Page 3, Question A14</u>. The question should include options if the respondent is answering as a corporate headquarters for a multiple hospital system.

<u>Page 12</u>, <u>Question A60</u>, <u>Respiratory Protection</u>. In this question, masks are erroneously eliminated from consideration of respiratory protection.

SECTION B. ANTINEOPLASTIC AGENTS

<u>Pages 15-16</u>, <u>Questions B8-B9A</u>, <u>Exposure Monitoring</u>. These questions should be clarified as to whether the sampling/monitoring is done routinely versus as a result of spills. This blurs the difference between a standard of practice versus emphasis on prevention.

<u>Page 16, Questions B 10-B 1 3A, Medical Surveillance</u>. These questions should be clarified as to whether the medical surveillance is done routinely versus as a result of known exposures. For instance, they should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to the chemical in the workplace (e.g., worker with shortness of breath or allergic reaction.)

<u>Page 19, Question B27, Policies for Designated Spill Clean-Up Teams.</u> This question appropriately refers to a spill team. This reinforces the problem in the Worker Questionnaire modules J (environmental services/housekeeping) in questions that do not ask if these staff perform a final cleanup after a spill team is engaged, resulting in a biased question for environmental services/housekeeping.

<u>Page 20</u>, <u>Question B28</u>. With regard to option (n), as in all other PPE questions, the option of surgical masks is not allowed, erroneously implying respirators should always be used for antineoplastic agents. If NIOSH wishes to collect information on actual practice, then questions should be included regarding surgical masks.

SECTION C. AEROSOLIZED MEDICATIONS

(See attached citations on aerosolized medications)

<u>Pages 22-23</u>, <u>Questions C6 and C7</u>, <u>Exposure Monitoring</u>. These questions should be clarified as to whether the sampling/monitoring is done routinely versus as a result of spills. This blurs the difference between a standard of practice versus emphasis on prevention.

<u>Pages 23-24</u>, <u>Questions C8-C12</u>, <u>Medical Surveillance</u>. These questions imply that medical monitoring, including blood, urine and pulmonary function tests, should be done routinely for

these medications. The data do not support these non-specific tests as a standard of practice for any one of these drugs. Studies have been done to determine risk, but they do not include recommendations for routine medical surveillance.

<u>Page 26, Question C14</u>. In this question, masks are erroneously eliminated from consideration of respiratory protection.

SECTION D. GLUTARALDEHYDE AND OTHER HIGH LEVEL DISINFECTANTS (HLD)

STERRAD is not listed as an example of hydrogen peroxide in this section, although it is listed elsewhere in the Worker Survey D. The questionnaire should be consistent regarding whether or not STERRAD is mentioned.

<u>Page 27</u>, <u>Question D7</u>. This question implies an expectation that air sampling should be done for all HLDs, whether or not engineering controls are in place (e.g., local exhaust). In addition, there are no questions on ensuring whether engineering controls are functioning properly.

Page 28, Questions D9-12A, Medical Surveillance. This question inaccurately implies routine medical surveillance of workers, including pulmonary function or allergy sensitization testing, is a standard of practice. For instance, they should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to glutaraldehyde in the workplace (e.g., worker with shortness of breath or allergic reaction).

<u>Page 32</u>, <u>Question D27(h)</u>, <u>Policies for PPE</u>. We reiterate our concern here that masks are not considered as PPE. This does not permit a response for practices that could legitimately involve the use of a mask. The implication is that respiratory protection of the worker is routinely required versus the wearing of a mask by the worker to protect the sterile equipment, as required by other protocols. This makes a response to this question difficult.

SECTION E. CHEMICAL STERILANTS

<u>Pages 35 and 36, Questions E10-13A, Medical Surveillance</u>. These questions inaccurately imply routine medical surveillance is a standard of practice. Also, we do not understand why non-specific "blood tests" are listed. Instead, the question should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to ethylene oxide in the workplace.

<u>Page 38, Question E21, PPE.</u> We are concerned that, in this question, masks are not considered as PPE for exposure to any sterilants, posing potential confusion for respondents. Standard practice is mandatory and rigid engineering controls (e.g., for ethylene oxide) are required. Workers in these areas wear surgical masks to protect sterile equipment being processed, and this question makes it impossible to reflect actual practice, even if for other purposes.

SECTION F. ANESTHETIC GASES

(See attached citations for anesthetic gases, surgical smoke, and laser plume.)

<u>Page 42</u>, <u>Question F7 –F8A</u>, <u>Air Sampling</u>. This question implies routine air sampling should be conducted even though engineering controls are expected to be in place per other rules and regulations. The questionnaire never asks about whether engineering controls are working. Questions could address whether sampling is done to maintain environmental quality control with indirect impact on patients as well as workers.

<u>Page 44, Questions F9-F12A, Medical Surveillance</u>. This question inaccurately implies routine medical surveillance is a standard of practice. Instead, it should ask whether there is an occupational health program to which an employee is referred if there is evidence of a problem related to a perceived exposure to the chemical in the workplace.

<u>Page 45, Question F14, PPE.</u> We are concerned that masks are not considered part of PPE for exposure to any anesthetic, regardless of scavenging system. Further, with regard to OSHA recommendations for Waste Anesthetic gases, the only time respirators are considered is for spills. There are no questions in this questionnaire regarding PPE, including respiratory protection, during spills.

SECTION G. SURGICAL SMOKE

(See attached citations on anesthetic gases, surgical smoke, and laser plume.)

Pages 46-47, Questions G4-G5A and G7, Air Sampling. This question implies routine air sampling should be conducted even though engineering controls are expected to be in place per other rules and regulations. However, we are pleased at least one engineering control is addressed; in question G7, where the question is whether smoke evacuation systems are inspected to prevent leaks.

<u>Page 48, Question G9, PPE</u>. We are concerned that masks are not considered as PPE for exposure to smoke, posing potential confusion for respondents. Given the importance of scavenger system and use of FDA-approved sterile surgical masks for surgical procedures, this does not permit response that reflects actual practice in surgical procedures.

SECTION H. SPILL RESPONSE TEAM AND HOUSEKEEPING

<u>Page 49</u>, <u>Questions 112-115</u>. We support the use of these questions, as we do in Section B, Antineoplastics. This appropriately refers to a spill team, but again this reinforces the problem in the

Worker Questionnaire modules J (environmental services/housekeeping) in questions that do not ask if these staff perform a final cleanup after a spill team is engaged, resulting in a biased question for environmental services/housekeeping.

<u>Page 50, Question 117, PPE</u>. This question does not ask about cleaning in locations involving biological agents, such as isolation rooms or around patients in "contact precautions" where, in most cases, the use of masks is perfectly appropriate. This undermines confidence that masks have any value. This introduces a systematic bias and the loss of valuable information on standard and appropriate practices. The theme and implication here, as elsewhere in these surveys, is that a respirator is required to protect the worker from any chemical, regardless of its concentration.

Attachment 2

ANNOTATED CITATIONS

Back Belt

1. Martimo, KP, Verbeek J, Karppinen J, Furlan AD, Takala EP, Paul P, Kuijer FM, Jauhiainen M, Viikari-Juntura E. Effect of training and lifting equipment for preventing back pain in lifting and handling: systematic review <u>BMJ 2008</u>; 336;429-431; originally published online 31 Jan 2008.

Conclusion: There is no evidence to support use of advice or training in working techniques with or without lifting equipment for preventing back pain or consequent disability. The findings challenge current widespread practice of advising workers on correct lifting technique.

2. Martimo KP, Verbeek J, Karppinen J, Furlan AD, Kuijer PP, Viikari-Juntura E, Takala EP, Jauhiainen M. Manual material handling advice and assistive devices for preventing and treating back pain in workers <u>Cochrane Database Syst Rev.</u> 2007 Jul 1 8;(3):CD005958.

Conclusion: There is no evidence available from RCTs for the effectiveness of manual material handling advice and training or manual material handling assistive devices for treating back pain.

Ammendolia C, Kerr MS, Bombardier C. Back belt use for prevention of occupational low back pain: a systematic review. **J Manipulative Physiol Ther**. 2005 Feb;28(2): 128-34.

Conclusion: Currently, because of conflicting evidence and the absence of highquality trials, there is no conclusive evidence to support back belt use to prevent or reduce lost time from occupational low back pain.

 Anon, Recommendation statement from the Canadian Task Force on Preventive Health Care: Use of back belts to prevent occupational low-back pain, CMAJ, 2003, Aug. 5, 2003; 169 (3).

Recommendation: The Canadian Task Force on Preventive Health Care concludes the existing evidence is conflicting and does not allow the task force to make a recommendation for or against the use of back belts to either prevent occupational low-back pain or to reduce lost work time due to occupational low-back pain (Grade C recommendation).

- 5. Wassell JT, Gardner LI; Douglas, Landsittel P; et al. A Prospective Study of Back Belts for Prevention of Back Pain and Injury JAMA. 2000; 84(21):2727-2732 Conclusion: In the largest prospective cohort study of back belt use, adjusted for multiple individual risk factors, neither frequent back belt use nor a store policy that required belt use was associated with reduced incidence of back injury claims or low back pain.
 - 6. NIOSH Press Release JAMA 2000 study.

Conclusion: In the largest study of its kind ever conducted, the CDC's NIOSH found no evidence that back belts reduce back injury or back pain for retail workers who lift or move merchandise, according to results published today in the Journal of the American Medical Association (JAMA) Dec. 6 2000 issue.

 NIOSH- Back Belts Do They Prevent Injury? 1996 (online reviewed 1997) Pamphlet.

Conclusion: There is a lack of scientific evidence that back belts work. Workers wearing back belts may attempt to lift more weight than they would have without a belt. A false sense of security may subject workers to greater risk of injury.

Aerosolized Medication

- Dimich-Ward H, Wymer ML, Chan-Yeung M. Respiratory health survey of respiratory therapists. <u>Chest</u> 2004;126:1048–1053 (full document). Conclusion: The lowest ribavirin levels were measured when an additional aerosol containment tent was used or when ribavirin was administered through a ventilator, which is a closed system. On the other hand, reporting the use of a small particle aerosol delivery or ribavirin unit, which is exclusively used for ribavirin, was not associated with reported asthma or respiratory symptoms. If the ribavirin units had aerosol containment systems, this would be effective in reducing occupational exposures.
- 2 Prober CG, MD; Walson PD, MD; Jones J. and the Committee on Infectious Diseases and Committee on Drugs Technical Report: Precautions Regarding the Use of Aerosolized Antibiotics December. PEDIATRICS 2000 Vol. 106 No. 6 December 2000.

Recommendation 8: To minimize microbial contamination of nebulizer equipment, centers should develop policies for aerosolized antibiotic use in the home, clinic, and inpatient facility. Such a policy should address barrier techniques, filters, exhaust, environmental contamination, disposal of unused product, and cleaning of nebulizers.

 Shults RA, Baron S, Decker J, Deitchman SD, Connor JD. Health care worker exposure to aerosolized ribavirin: biological and air monitoring. <u>Occup Environ Med. 1996</u> Mar;38(3):257-63. NIOSH.

Recommendation: Ventilators and other administration units that were enclosed by an aerosol containment tent produced significantly lower airborne ribavirin exposures than administration units without a containment tent did (range, < 2.5 to 78 micrograms/m3).

On the basis of this and other evaluations of airborne ribavirin concentrations, we recommend using aerosol containment systems with all types of ribavirin administration units except mechanical ventilators.

 Mueller BA, Waldon VK. Use of an in-house-built ribavirin aerosol evacuation system to control incidental employee exposure to ribavirin aerosol. <u>J Clin</u> Eng. 1996 Jan-Feb;21(1):46-50.

Conclusion: Ongoing controversy regarding the hazards of exposure of healthcare workers to ribavirin aerosol led to the design and evaluation of a ribavirin aerosol evacuation system that scavenges the excess ribavirin. The results suggest the system evaluated is an efficient and inexpensive means of reducing incidental employee exposure to ribavirin aerosol.

 Balmes JR, Estacio PL, Quinlan P, Kelly T, Corkery K, Blanc P. Respiratory effects of occupational exposure to aerosolized pentamidine. <u>J Occup Environ Med. 1995</u> Feb;37(2): 145-50. Conclusion: Pentamidine was not detected in the urine of any of the subjects. There were no significant increases in symptoms on days when AP was administered. There was no statistically significant difference in mean diurnal variation of peak expiratory flow rate on days when AP was administered. Methacholine inhalation challenge testing did not show a statistically significant mean change in airway responsiveness across the workweek. The ambient concentrations of pentamidine that we measured document that detectable occupational exposure to AP can occur in poorly ventilated treatment rooms.

We recommend that steps be taken to minimize health care worker exposure to AP.

 AARC Clinical Practice Guideline-Selection of a Device for Delivery of Aerosol to the Lung Parenchyma <u>Respir Care 1994</u>; 41(7):647–653.

Protocol Because the data regarding adverse health effects on the health-care worker and on those casually exposed are incomplete, the prudent course is to minimize exposure in all situations. (26).

Measures to reduce aerosol contamination of room air include:

discontinuing nebulization of medication while patient is not breathing the aerosol;

ensuring staff who administer medications understand risks inherent with the medication and procedures for safely disposing of hazardous wastes;

screening of staff for adverse effects of exposure to aerosol medication;

providing alternative assignments for those staff who are at high risk of adverse effects from exposure (eg, pregnant women or those with demonstrated sensitivity to the specific agent).

- 6.5.2.2.1 Engineering controls:
- 6.5.2.2.1 Filters or filtered scavenger systems to remove aerosols that cannot be contained.
- 6.5.2.2.2 Frequent air exchanges to dilute concentration of aerosol in room to eliminate 99% of aerosol before the next patient enters/receives treatment in area.
- 6.5.2.2.3 Booths or stalls for sputum induction and aerosolized medication administration in areas in which multiple patients are treated. Booths or stalls should be designed to provide adequate air flow to draw aerosol and droplet nuclei from the patient and into an appropriate filtration system, with exhaust directed to an appropriate outside vent.
- 6.5.2.2.4 Handling of filters, nebulizers, and other contaminated components of the aerosol delivery system used with suspect agents (such as pentamidine and ribavirin) as hazardous waste.
- 6.5.2.3 Personal protection devices:
- 6.5.2.3.1 Personal protection devices should be used to reduce exposure when

engineering alternatives are not in place or are not adequate. Use properly fitted respirators with adequate filtration when exhaust flow cannot adequately remove aerosol particles. (28)

- 6.5.2.3.2 Goggles, gloves, and gowns should be used as splatter shields and to reduce exposure to medication residues and body substances.
- Kacmarek RM, Kratohvil J. Evaluation of a double-enclosure double-vacuum unit scavenging system for ribavirin administration. <u>Respir Care. 1992</u> Jan;37(1):37-

45.

Conclusions: Use of a double-enclosure, double-pump scavenging system and implementation of entry protocols ensure reduction of environmental ribavirin levels below recommended maximum levels during administration to spontaneously breathing patients. Use of expiratory filters adequately controls environmental ribavirin levels during mechanical ventilation.

 Kacmarek RM Care-giver protection from exposure to aerosolized pharmacologic agents Is it necessary? <u>Chest</u> 1991;100;1 104-1105 (full publication).

Conclusion: Pentamidine should be administered in a negative-pressure HFPAfiltered room with at least six exchanges per hour or with use of a booth or hood designed for scavenging the drug. Nebulizers should incorporate a hand control for aerosol production and exhalation filters.

 Torres A Jr, Krilov LR, Jacobson JM, Kelly KJ, Havens PL. Reduced environmental exposure to aerosolized ribavirin using a simple containment system. Pediatr Infect Dis J. 1991 Mar;10(3):217-21.

Conclusion: To minimize the exposure of health care workers to aerosolized ribavirin, we designed a double tent containment system with circulating mist and suction applied between the tents and we evaluated the ability of this system to contain and evacuate aerosolized ribavirin. Though the risk to exposed health care workers is unknown, this system offers a simple way to decrease significantly occupational exposure to ribavirin.

 Bradley JS Connor JD, Compogiannis LS, Eiger LL, Exposure of Health Care Workers to Ribavirin during Therapy for Respiratory Syncytial Virus Infections, <u>Antimicrobial Agents and Chemotherapy</u>, <u>Apr. 1990</u>, p. 668-670 Vol. 34, No. 4 (Full publication).

Conclusion: These data confirm, in a clinical setting, that ribavirin concentrations in room air can be substantially lowered when the delivery of aerosol is accompanied by a system designed to remove and filter the aerosol during treatment. However, such devices may prove to be more effective if education for HCW includes specific instructions to stop the nebulizing airflow prior to opening the hood.

Montgomery AB, Corkery KJ, Brunette ER, Leoung GS, Waskin H, Debs RJ
 Occupational exposure to aerosolized pentamidine. <u>Chest. 1990</u> Aug;98(2):386-8.
 Conclusion: The greater risk to health care workers is probably transmission of

tuberculosis from undiagnosed cases, especially in populations with an increased incidence of tuberculosis.

12 Rodriguez WJ, Dang Bui RH, Connor JD, Kim HW, Brandt CD, Parrott RH, Burch B, Mace J. Environmental Exposure of Primary Care Personnel to Ribavirin Aerosol

When Supervising Treatment of Infants with Respiratory Syncytial Virus Infections ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, July 1987, Vol. 31, No. 7 p. 1143-1 146 (full publication).

Conclusion: The absence of detectable ribavirin in the erythrocytes of nurses participating in the study is reassuring. However, these negative data must be interpreted within their limitations. Finding neither detectable levels nor side effects with the sample size provides an approximate 84% probability of deriving the right conclusion. The data rule out any long-run risk rate higher than 16%, with 95% confidence or 5% limit of credibility (8). We should also note the air exchange rates at the two institutions studied could have contributed to optimal environmental conditions. These factors should also be considered by those engaged in administering aerosol therapy.

13. OSHA Technical Manual for "Controlling Occupational Exposure to Hazardous Drugs. (www.osha.gov/dts/osta/otm/otm_vi_2.html?

Anesthetic Gases; Surgical Smoke; Laser Plume (laser or electro-surgical unit).

Alp E, Bijl D, Bleichrodt R, Hansson B, A, Voss. Surgical smoke and infection control. <u>Journal of Hospital Infection</u>, 2006 Volume 62, Issue 1, Pages 1 - 5 E. (Full publication).

Conclusion: While higher quality filter masks and/or double masking may increase the filtration capability, a smoke evacuation device or filter placed near (2–5cm) the electrocautery blade or on endoscope valves offers additional (and necessary) safety for operating personnel and patients. Various studies demonstrated specially designed masks (respirators) are still insufficient barriers. Furthermore, leakage of the mask's seal to the face is another source of possible penetration. No studies have measured the effectiveness of these respirators. The degree to which they protect individuals from surgical smoke is not known and varies depending on the filtering efficiency of the different respirators.

OSHA Directorate for Technical Support; Office of Science and Technical Assessment Anesthetic Gases: Guidelines for Workplace Exposures, 2000 Revised May 18, 2000.

Engineering controls such as an appropriate anesthetic gas scavenging system are the first line of defense and the preferred method of control to protect employees from exposure to anesthetic gases. An effective anesthetic gas scavenging system traps waste gases at the site of overflow from the breathing circuit and disposes of these gases to the outside atmosphere. HVAC system also contributes to the dilution and removal of waste gases not collected by the scavenging system or from other sources such as leaks in the anesthetic apparatus or improper work practices.

Administrative controls represent another approach for reducing worker exposure to waste gases other than through the use of engineering controls, work practices, or personal protective equipment.

Personal protective equipment should not be used as a substitute for engineering, work practice, and/or administrative controls in anesthetizing locations and PACUs During clean-up and containment of spills of liquid anesthetic agents, personal protective equipment should be used in conjunction with engineering, work practice, and/or administrative controls Respirators, where needed, should be selected based on the anticipated contamination level.

Operating Room. As a result of using appropriate anesthetic gas scavenging in ORs, the levels of contamination have been decreased.

PACU. A properly designed and operating dilution ventilation system should be relied upon to minimize waste anesthetic gas concentrations.

 OSHA Hospital eTool-Surgical Suite Module, www.osha.gov/SLTC/etools/hospital/index.html.

Anesthetic Gases: Recommendations Use appropriate anesthetic gas scavenging systems in Operating Rooms. Appropriate waste gas evacuation involves collecting and removing waste gases, detecting and correcting leaks, considering work practices, and effectively ventilating the room (Dorsch and Dorsch 1994).

 OSHA Hospital eTool-Surgical Suite Module, www.osha.gov/SLTC/etools/hospital/index.html.

Laser smoke: During surgical procedures that use a laser or electro-surgical unit, the thermal destruction of tissue creates a smoke byproduct Although there has been no documented transmission of infectious disease through surgical smoke, the potential for generating infectious viral fragments, particularly following treatment of venereal warts, may exist.

Recommendation engineering controls and work practices: Use portable smoke evacuators and room suction systems. Install new filters and tubing before each procedure. Inspect smoke evacuator systems regularly to prevent possible leaks. Use <u>Universal</u>

Precautions as required by the OSHA Bloodborne Pathogens Standard [1910.1 030(d)(1)].

Response:

Dear Mr. Smith:

Thank you for your comments and interest in the proposed management and worker surveys. Also, thank you for the detailed comments (most of which are identical to those submitted by the AHA) on specific questions in the management and worker questionnaires. We are in the process of evaluating all of the comments received on specific questions and plan to make necessary improvements to both survey questionnaires. Because the DHA shares the same general concerns as the AHA, please refer to our response to the AHA (Comment #21)

29. Comment

Name Karin Reuter-Rice Suzette Harper Organization

National Association of Pediatric Nurse Practitioners (NAPNAP)

Email

sharper@napnap.org

Address

20 Brace Road, Suite 200 Cherry Hill, NJ 08034-1600

Comments:

I have been asked by the National Association of Pediatric Nurse Practitioners (NAPNAP) to review the modules that a Pediatric Nurse Practitioner may have some experience or exposure to. I am a practicing critical care NP and have reviewed modules E & I.

Module E: Overall, very well written and with good flow. I would suggest for more accurate data I would incorporate questions 35, 36, 37, & 37A under each section for Ribavirin, Pentamidine, and Tobramycin. This way you would have information about clothing, masking, boots for each aerolized medication.

Module I: Well written and thorough. Perhaps the role for question 7 might be best asked as "administrative role with possible contact" that would then allow for question 8 to sound less repetitive and prevent survey skip as the two questions are so similar. Also, I would suggest reversing question 8 & 9's order to keep flow of answering.

Thank you for including NAPNAP and their representatives in this important survey instrument development and review.

Karin Reuter-Rice, PhD, CPNP

Response:

Dear Dr. Reuter-Rice:

Thank you for your comments and interest in the worker survey. We are in the process of evaluating all of the detailed comments received on specific questions and plan to make necessary improvements to the worker questionnaire.

We look forward to continuing our collaboration with NAPNAP and welcome the opportunity of including NAPNAP members in the worker survey.

30. Comment

Name

Everett Liddell

Organization

Saint Francis Hospital-Memphis

Email

Liddell@tenethealth.com Human Resources Officer, Memphis Market

Address

5959 Park Ave, Memphis TN 38119

Comments:

This is in response to the request for comments concerning the Subject survey.

- Being sensitive to Union organization, using organized unions like the SEIU and marketing groups to market the survey will allow such organizations to promote their agenda or cause directly or indirectly...objectivity and factual response will be lost.
- People will take the survey for the \$10 without giving considered answers.
- Both surveys are overly lengthy and will take considerable time to complete...people will lose focus and just try to get thru it.
- The workers' survey is very subjective and many of the questions are not clear, well defined, or left open for interpretation.

Thanks for the opportunity to comment.

Response:

Dear Mr. Liddell:

Thank you for your comments and interest in our proposed surveys. We are in the process of evaluating all of the general and detailed comments received on the survey and plan to make necessary improvements to both survey questionnaires.

31. Comment

Name

Lisa Thiemann

Organization

American Association of Nurse Anesthetists

Email

lthiemann@aana.com

Address

222 S. Prospect Ave.

Park Ridge, IL 60068-4001

Comments:

The American Association of Nurse Anesthetists (AANA) is the national professional organization for more than 36,000 nurse anesthetists and student nurse anesthetists dedicated to providing quality anesthesia care in the United States. Nurse anesthetists provide approximately 27 million anesthetics each year in this country, and are the sole anesthesia providers in approximately two-thirds of all rural hospitals in the United States.

Executive Summary

The AANA appreciates this opportunity to comment regarding the National Institute for Occupational Safety and Health's (NIOSH) proposed surveys of healthcare workers and management health and safety practices. Our comments predominantly concern issues of clarity surrounding certain items within the following modules:

Employee Core Module;

Worker Core Module;

Module F: Surgical Smoke (from Lasers or Electrosurgery Devices);

Module G: Anesthetic Gases (Administration); and,

Module H: Anesthetic Gases (Bystanders who do NOT Administer).

We do not have comments regarding the remaining proposed survey modules associated with this project (i.e., modules A, B, C, D, E, I, or J).

General Comments:

In several of the modules (i.e., Employee Core, F, G, and H) the term "respirator" is used; however, the term is not clearly defined within the proposed surveys. For example, in question 54 on page 19 of the Employee Core Module, surgical masks are clearly listed to not be an example of a respirator; however, in question 56 on page 20 of the same module surgical masks are listed as an example of a respirator. This may lead to respondent confusion in completing the survey. We request NIOSH define this term more clearly in order to facilitate respondent understanding.

Contained within several of the modules (i.e., F, G, and H) there appears to be a consistent typographical error. Towards the end of each module an instruction box directs respondents to "skip to question XX." In each of these modules, the question number referenced does not exist. This situation may lead to confusion or frustration on the part of survey respondents.

Worker Core Module

Certified registered nurse anesthetists (CRNAs) have a long standing history of delivering high quality anesthesia services, and as such are proud of the credential CRNA. In the subheading titled "Nurses and Nursing Support" within section "Job and Facility Description" on page four of the proposed Worker Core Module, CRNAs are listed as "Nurse Anesthetist." We respectively request NIOSH use the complete credential (i.e., Certified Registered Nurse Anesthetist) when listing nurse anesthetists in this module.

Module G: Anesthetic Gases (Administration)

Anesthesia services which require the administration of anesthetic gases may be delivered under

a variety of different staffing models. For example, certified registered nurse anesthetists may personally deliver anesthetic gases without the participation of another anesthesia professional, such as an anesthesiologist. In a similar fashion, an anesthesiologist may personally deliver anesthetic gases without the participation of other anesthesia professionals. In yet another care delivery model, CRNAs and anesthesiologists may work collaboratively in order to provide anesthesia services. In this collaborative model of care, the CRNA often is personally administering the anesthetic gases and the anesthesiologist is not. We have concerns that Module G's proposed language may not accurately capture these care model differences, and lead to discrepancies in data collection.

In order to maximize the accuracy of data collected, we suggest the following change to Module G's title:

Module G: Anesthetic Gases (Personally Administer)

Module H: Anesthetic Gases (Bystanders who do NOT Administer)

In order to accurately answer many of the questions contained within Module H, a thorough understanding of the anesthesia process is required by the "bystander." "Bystanders" without knowledge of the anesthesia process may misinterpret or misunderstand anesthetic gas-related activities, and may not be able to identify whether inhalation anesthetic gases are actually being administered or whether oxygen is the only gas being administered. For example, it is possible for an anesthesia professional to induce and maintain general anesthesia without the use of inhalational anesthetic gases. In this situation, a patient would still receive oxygen using the same delivery apparatus as that used during an inhalational general anesthetic. A bystander may not be aware of this anesthetic technique because it appears very similar to one using inhaled anesthetic gases. This lack of knowledge may lead to inadvertent inaccurate responses to question numbers 11 thru 17 in Module H.

We suggest further clarifying "anesthetic gases" in order to highlight these possible care differences for respondents by inserting the following language into the module's title section:

This module is directed toward individuals who work in area(s) while anesthetic gases (i.e., gases in addition to oxygen) are being administered, <u>but who are not administering</u> <u>the gases themselves</u>. You are considered to be in the area if you are in the same room and within five (5) feet of where anesthetic gases are being administered.

Note: Do <u>not</u> complete this section if you actually administer the anesthetic gases.

The AANA appreciates this opportunity to express our concerns to NIOSH regarding the proposed survey modules. If NIOSH has any questions or comments that it would like to discuss with the AANA regarding our comments, please contact Lisa J. Thiemann, CRNA, MNA, the AANA's Acting Senior Director, Professional Practice at (847) 655-1136 or lthiemann@aana.com.

Response:

Dear Ms. Thiemann:

Thank you for your comments and interest in the worker survey. We are in the process of evaluating all of the detailed comments received on specific questions and plan to make necessary improvements to the worker questionnaire.

We look forward to continuing our collaboration with AANA on the surveys and welcome the opportunity of including AANA members in the worker survey.

32. Comment

Name Helen Ristic

Organization American Dental Association

Email ristich@ada.org

Address 211 East Chicago Ave Chicago, IL 60611

Comments:

On behalf of the American Dental Association, I would like to take this opportunity to respond to the request published in the Federal Register (FR 17983 Notice) for public comments on National Survey of Healthcare Worker's Safety and Health NIOSH Docket number 135.

The Association respectfully submits the following comments for your consideration, which we believe will make the survey more relevant to dental healthcare workers.

Employee Core Module

In general, the length of the employee core module may negatively affect the response rate. The survey could be shortened by tailoring the surveys to specific health services groups.

When respondents estimate their level of risk from workplace exposures, is this with or without proper protection?

Add a separate heading in the Health Services section for dental professionals that includes the following occupations:

General Dentist Endodontist Periodontist Prosthodontist Oral and Maxillofacial Radiologist Oral and Maxillofacial Pathologist
Oral and Maxillofacial Surgeon
Orthodontist
Pediatric Dentist
Public Health Dentist
Dental Assistant
Dental Hygienist
Dental Technician

Add "Private practice" to the options for employment status.

Add "Device not effective or practical" to the reasons for not always using safe needle devices. Also, when referring to needlestick injuries consider that in dental practice most sharps injuries are the result of contact with dental burs.

Add "also known as standard precautions" after mention of "universal precautions" in question 38. Also delete "formally" in the first sentence.

Under the violence in the workplace section including "bitten" may result in positive responses from dental professionals that do not represent violent situations.

Module G

Delete "formal" in front of "training" in question 2. This may be interpreted differently among respondents.

Thank you for the opportunity to provide these comments on the healthcare worker survey. We also appreciated the opportunity to share other comments and discuss the survey with Mr. Jim Boiano and other NIOSH representatives at the April 30th meeting held at the Sheraton Cincinnati Airport Hotel. The ADA looks forward to participating in this project in the future.

Response:

Dear Dr. Ristic:

Thank you for your comments and interest in the worker survey. We are in the process of evaluating all of the detailed comments received on specific questions and plan to make necessary improvements to this questionnaire.

We look forward to continuing our collaboration with ADA on the surveys and welcome the opportunity of including ADA members in our worker survey.

33. Comment

Name

Daniel Landon

Organization Missouri Hospital Association Address P.O. Box 60 Jefferson City, MO 65102-0060

Comments:



MISSOURI HOSPITAL ASSOCIATION
Marc D. Smith. Ph.D., President

June 30, 2008

NIOSH Docket Office Robert A. Taft Laboratories MS-C34 4676 Columbia Parkway Cincinnati, OII 45226

RE: NIOSH Docket Number 135, Notice of Public Meeting and Availability for Public Comment (Vol. 73, No. 64), April 2, 2008

To Whom It May Concern:

On behalf of our 151 member hospitals and health systems, the Missouri Hospital Association submits the following comments and concerns about the National Institute for Occupational Safety and Health's (NIOSH) proposed national survey of health care workers' safety and employer safety and health practices. Although we agree with the overall objective of this project, we have the following specific concerns about length, format and collection methodology of the surveys.

We believe using labor unions and professional associations to identify respondents promotes sampling bias because of the inability of workers and facilities who are not members of these organizations to participate in the survey. If NIOSH intends to use organized labor and professional groups to market the survey, these organizations should be required to use standardized text in any communication used to solicit participation in the survey. Without this standardization, these organizations could knowingly or unknowingly influence responses. To protect the integrity of the survey results, we also believe that these organizations should only have access to the survey responses data or results that is provided to the public. We also are concerned that there is no way to verify that the workers completing the survey are actually employed in health care. We also oppose the convenience sampling approach NIOSH is proposing for the worker survey because it may result in sampling bias and skewed data. To preserve the quality of the data, we strongly feel NIOSH must ensure the surveys are administered and conducted according to the highest research standards and procedures, and we recommend using a random sampling approach.

In regards to the health care worker survey, we are concerned about the survey's length. A staff member, who is a registered nurse, took the survey to assess the ease of completion and clarity. She found the survey was far too long, and it was impossible to complete the core survey questions in NIOSH's estimated time frame of 20 minutes. We also believe that workers with limited English proficiency would have difficulty understanding and appropriately answering the questions. Many of the questions are not written at the reading comprehension level of some workers in support staff positions. The lack of clear definitions and examples also could affect responses. In addition, offering payment for survey completion also could affect the validity of the responses. There also is no category under "Job Description" to describe middle management positions such as directors, managers and supervisors.

P.O. Box 60 • Jefferson City, MO 65102-0060 • Phone: 573/893-37(0 • Fax: 573/893-2809 • www.mbanet.com

NIOSH Docket Office June 30, 2008 Page 2

In regards to the management survey, we believe NIOSH has grossly underestimated the time required for completing the survey. This survey would require input from personnel in different departments, satellite locations, offices and contracted services. Many of the questions would not be applicable to all health care settings. Compiling the number of different doses of antineoplastic drugs would require a significant amount of time. Rather than addressing each of these drugs individually, we recommend that only the total number of antineoplastic doses be recorded. Although some of the drugs listed also are available in oral form, the instructions for completing this section do not differentiate between oral and intravenous doses. Yet, the questions related to preparation and administration appear to only refer to intravenous agent preparation and administration.

We appreciate the opportunity to comment and hope they are useful in supporting NIOSH's efforts to ensure workplace safety. If you have questions, please contact me at 573/893-3700, ext. 1349 or dlandon@mail.mhanet.com or Sharon Burnett, vice president of licensure, regulation and accreditation, at ext. 1304 or sburnett@mail.mhanet.com.

Sincerely,

Daniel Landon

Senior Vice President of Governmental Relations

dl/cml

Response:

Dear Mr. Landon:

We would like to thank MHA for the comments and interest in the proposed management and worker surveys. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements to both survey questionnaires. Because some of your comments are similar to those provide to NIOSH from the American Hospital Association (AHA), please refer to our response to the AHA (Comment #21), as well.

A number of professional associations representing health care workers stated that they are willing to collaborate with NIOSH on the worker survey. Most indicated that they prefer a statistical sampling approach to a convenience sampling approach; it is our intention to employ a statistical sampling approach. Although labor organizations also expressed interest in participating in the worker survey, a web survey of their members was considered impractical primarily because member email addresses are not readily accessible at a national level. As a result, the worker survey will be implemented exclusively through professional associations. The worker survey will be revised to include questions on professional association and labor union affiliations, as well as type, size and location of employer, in order to characterize responses by these variables and to assess whether the results are nationally representative. NIOSH will be developing all survey communication materials pre-survey announcements, recruitment and reminder letters, etc., to ensure that the same text is presented to members of all participating organizations.

We received several comments regarding the length of the worker and management surveys indicating that they are too long. Our pilot tests showed that the management survey itself could be completed in about 45-50 minutes. However, in many cases, the health and safety manager needed to contact managers of other departments (human resources, oncology ward, pharmacy, sterile processing, etc) to gather information to complete the survey, a process which was estimated to take up to 3-4 hours in large hospitals. Given the concern raised over the potential of low response rates if the current management questionnaire is used in a national survey, we are planning to evaluate options for streamlining the management survey.

Regarding the worker survey, we convened focus groups/cognitive testing; most participants indicated that they would complete a 20-30 minute survey, especially if they could complete the survey in more than one session (which is an option for respondents of our web survey). Findings from our pilot tests show that the average time to complete the core module was about 20 minutes, and about 7 minutes for each hazard module. Response rates were fairly good, averaging 45% at two pilot test sites. While there appears to be no single guideline for questionnaire length, one literature review of the effect of questionnaire length on response rates stated that "results are still confusing and contradictory, conclusions are still not clear, and questionnaire designers still aim for shorter questionnaires with little more justification than the assumption that longer interviews will result in higher nonresponse" (Bogen K, 1996 Proceedings of the Section on Survey Research Methods, American Statistical Association, pgs 1020-1025) Although we feel that the length of the worker survey is reasonable, we are planning to evaluate options for reducing the completion time. Because contractor costs exceeded our project proposal budget, it is unlikely that we will be able to offer respondents of the worker survey with a monetary incentive. We believe that receiving a strong commitment of support for the worker

survey from the leadership of all participating professional associations will be more worthwhile and effective than any type of financial incentive for respondents.

Thank you for providing recommendations on how to reduce the burden associated with collecting information on anti-neoplastic doses and for pointing out that we need to clarify dose types.

Again, we are very appreciative of the thoughtful input from the MHA.

34. Comment

Gail Mallory

Organization Oncology Nursing Society

Email gmallory@ons.org

Address 125 Enterprise Drive Pittsburgh, PA 15275-1214

Comments:

Worker Core Module, Draft Page 4, Question 3 (Job and Faculty Description):

 Under Nurses and Nursing Support Staff, add choices for: Advanced Practice Nurse, Nurse Educator and Clinical Nurse Specialist

Module B: Antineoplastic Agents (Pharmacists, Pharmacy technicians) - Draft Page B-1

- COMMENT: A large number of nurses are still mixing chemo, please add nurses to the title of this section after pharmacy technicians
- Add to the text box: This module is directed towards individuals, such as pharmacists or pharmacy technicians or nurses...
- Same page, Add to choices for question 3: Hospital-Based Chemotherapy and Biotherapy Course, and Oncology Nursing Society (ONS) Chemotherapy and Biotherapy Course
- Question 3 ONS is not sure if other professional societies offer courses...

Module B: Antineoplastic Agents (Pharmacists, Pharmacy technicians) - Draft Page B-2

- Question 8: Include biotherapy agents and update chemotherapy list
- Recommend using for both biotherapy and chemotherapy separate questions
- Who is preparing oral medications same precautions and same preparation as for IV antineoplastic agents?

Module B: Antineoplastic Agents (Pharmacists, Pharmacy technicians) - Draft Page B-4

Question 17: Type of Hood

Hood in community-based practices – how maintaining and cleaning directions (e.g. hood should stay "on" all the time). Maintenance protocol (who is cleaning).

Module B: Antineoplastic Agents (Pharmacists, Pharmacy technicians) - Draft Page B-6

- Question 24 and others relating to gloves: perception of accuracy of this item latex and chemo gloves are different – NIOSH (2004) recommends Double gloving with chemo gloves (both pair) – this should be reflected in ALL questions – as the questions are written it implies that latex and chemo gloves are the same or interchangeable.
- Add, Do you weargloves? Yes No
- Add, If you don't weargloves, why not?

Module B: Antineoplastic Agents (Pharmacists, Pharmacy technicians) - Draft Page B-10

- · After Question 34A: Transportation of drug from pharmacy to admin unit
- Need procedure questions such as Prime tubing, no needle, type of container, double bagged, leak proof, steps to transport, where stored in unit, who can transport, med room or chemo only area or remain in container, and what if it leaks?

Module C: Antineoplastic Agents (Oncology Nurses) - Draft Page C-1

- Question 3: Revise to, "Have you received any <u>formal (classroom) education</u> for handling antineoplastic agents? Change answer options to:
 - o Yes, employer based
 - Yes, ONS chemotherapy and Biotherapy Course
 - Yes, other (please specify) ____
- Question 9 draft page C-2
 - Add new drugs
 - Add biotherapy
 - Suggest making two questions one with chemotherapy drugs and one for biotherapy drugs

Module C: Antineoplastic Agents (Oncology Nurses) - Draft Page C-4

- Ouestion 13: Add for answer options:
 - E. Phaseal system, closed system
- Add after Question 18 a new question 19: Cleaning surfaces of administration area (maintenance before spill), general wipedown.
- Add questions from above regarding latex and chemo gloves and double gloving from C-6 on

Module C: Antineoplastic Agents (Oncology Nurses) - Draft Page C-7

- Question 26: add "or chewing gun" to option "d".
- Add an option "f. apply cosmetics (eg. Lip balm) to Question 26.

Module C: Antineoplastic Agents (Oncology Nurses) - Draft Page C-8

 Need questions about: Patient education for call at home, incontinent at home, prewash, double wash clothes/diapers, separate wash, stay away from kids, especially aged and pediatrics.

Module C: Antineoplastic Agents (Oncology Nurses) - Draft Page C-1

- End of page need questions about disposal:
 - Lid down

- Double flush
- Chemo gowns
- o Chux pad disposal
- Radioactive
- Disposal of output
 - Urine
 - Stool
 - Irrigation returns
- Need questions about face protection
- Survey ends abruptly may want to add an open ended question

Management Questionnaire - Draft Page 7

- For the option:
 - Routine worker notification of medical surveillance results does it capture chemotherapy adm?

Management Questionnaire - Draft Page 13

Check spellings for: Metho-trexate, pegaspar-gase, and procarba-zine

Management Questionnaire – Draft Page 18 Policies for Preparing Antineoplastic Agents

- Incorporated into mixing and administration of chemotherapy B 15 through B 27
- Policies in institution at end of preparer and administration
- These questions should be in the "Mixing" section also

Response:

Dear Dr. Mallory:

Thank you for your interest in the proposed surveys. Also, thank you for reviewing the questionnaires and providing detailed comments on components of both survey questionnaires addressing antineoplastic agents. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements to both survey questionnaires.

We look forward to working with ONS and welcome the opportunity of including ONS members in our worker survey.

35. Comment

Name

Lynn Gurski-Leighton

Organization

The Hospital and Healthsystem Association of PA (HAP)

Email

lgleighton@haponline.org

Address 4750 Lindle Road Harrisburg, PA 17105

Gentlemen:

The Hospital & Healthsystem Association of Pennsylvania (HAP), on behalf of its members, more than 250 acute and specialty hospitals and health systems, appreciates the opportunity to provide comments on the National Institute for Occupational Safety and Health's (NIOSH) proposed national surveys of health care workers' safety and employer safety and health practices.

HAP appreciates NIOSH's efforts to collect information about facility-based health and safety resources as well as workers' perceptions of safety and health practices, however, HAP has concerns about the surveys and the methodology proposed for the collection of the data.

Specifically, HAP questions the validity of the pilot-testing of the questionnaires. Pennsylvania is a very diverse state whose health care population is represented by various sizes and types of hospitals, including large health care systems, small rural hospitals, and community-based hospitals. NIOSH indicated that it used two large medical centers to validate the questionnaires, however, HAP does not believe that this validation truly represents Pennsylvania's total health care community.

Furthermore, HAP is concerned about the methodology for conducting the surveys, particularly as it relates to the worker survey. HAP questions whether the use of various labor unions and professional associations will present a bias to the survey results. And because the worker survey is based on workers' perceptions and opinions, HAP is concerned that this survey is too subjective and the data may be skewed as a result.

HAP fully supports the comments submitted by the American Hospital Association on June 26, 2008, and echoes the same concerns outlined in their detailed technical comments included as Attachments 1 and 2 of their comment letter.

HAP urges NIOSH to delay implementation of their survey tools until the content of the surveys and the methodology for the collection of the data can be appropriately revised to address the concerns and comments received during this public comment period.

If you have any questions about HAP's comments, please feel free to contact me at (717) 561-5308 or by email at lgleighton@haponline.org or Mary Marshall at (717) 561-5312 or by email at mmarshall@haponline.org.

Response:

Dear Ms. Gurski-Leighton:

Thank you for your comments and interest in the proposed management and worker surveys. Because the HAP shares the same concerns as the AHA, please refer to our response to the AHA (Comment #21).

36. Comment

Name Teresa Cain

Organization
Association for Professionals in Infection Control & Epidemiology (APIC)

Email tcain@apic.org

Address 1275 K Street, NW Suite 1000 Washington, DC 20005-4106

Comments:



1275 K Street, NW, Suite 1000 Washington, DC 20005-4006

Phone: 202/789-1890 Fax: 202/789-1899 apicinfo@apic.org www.apic.org

July 1, 2008

Dr. John Howard, Director National Institute for Occupational Safety and Health NIOSH Mailstop: C-34 Robert A. Taft Lab. 4676 Columbia Parkway Cincinnati, Ohio 45226

RE: Docket # NIOSH-135, Survey of Healthcare Workers' Safety and Health and NIOSH Survey of Healthcare Employer Safety and Health Practices

Dear Dr. Howard,

The Association for Professionals in Infection Control and Epidemiology (APIC), an international association of 12,000 infection preventionists, appreciates the opportunity to comment on the proposed surveys of healthcare workers and management.

First, allow us to address several specific issues within the survey itself that we wish to comment on:

- A) In the core module, question 38. The term "universal precautions" is not the current terminology. We recommend changing the term to "standard precautions" to coincide with currently used terminology.
- B) In the core module, masks are excluded from the definition of personal protective equipment (PPE). There are circumstances where the use of masks is acceptable and consistent with Centers for Disease Control and Prevention (CDC) and Occupational Safety and Health Administration (OSHA) guidance such as in specific types of isolation rooms or where the sterility of equipment must be protected. The questionnaires should list masks as an appropriate PPE.
- C) In the core module, question 54 (and several subsequent questions found in the survey) use the term "respirators" without definintion. This is not consistent with current terminology used with healthcare workers. We would recommend providing examples of respirators (such as N95, PAPR) to define the term most clearly.

These surveys have important goals: to collect information describing hazards, exposures, safety and health practices, use of exposure controls and to collect information describing facility-based health and safety resources, safety and health management programs, policies and practices for the same health and safety hazards. Therefore, we would like to offer some suggestions for improving the survey process, in order to maximize the collection of valid and actionable information.

Our initial concern is that the sampling bias will be difficult to identify. The use of a web-based survey for cost effectiveness purposes selects for the better educated and motivated employees who are familiar with and/or have access to the internet. While NIOSH indicated the membership of labor unions and professional organizations would be the target audience, this would limit the pool of respondents significantly, eliminating the average environmental service worker from the database. Also, based on the length of survey and complexity of the questions we feel the time for completion has been underestimated and may lead to poor responses on a limited number of questions.

Currently observations are available to document unsafe working conditions in the nation's health care facilities and offices. Per OSHA regulations, logs must be kept documenting occupational injuries, such as those that occur from contaminated sharps. We fear the completed surveys will represent the employee who has issues with their employer, rather than the vast majority of workers.

Finally, we are concerned the current survey design will fail to provide actionable data which will be useful in helping us improve worker safety in a meaningful fashion. However, infection preventionists applaud efforts to increase occupational safety for all workers and stand ready to assist NIOSH with developing a survey instrument which would improve worker safety and encourage our members to participate in such a survey.

Sincerely.

Theresa Cain

Chair, Public Policy Committee

Sherera Cain

Response:

Dear Ms. Cain:

We would like to thank APIC for the comments and interest in the proposed management and worker surveys. We are very appreciative of the detailed comments that were provided on specific questions in the worker questionnaire. We are in the process of evaluating all of the comments received from stakeholders in order to make the necessary improvements in both survey questionnaires.

We appreciate your concerns regarding our sampling approach for the worker survey and that limiting the survey to a web mode administration would limit responses to those individuals with access to the Internet, particularly for environmental services workers. Although we believe that this is an important group to survey, this group may not be included in our survey because there is no easy means to collectively gain access to them.

We received several comments regarding the length of the worker and management surveys indicating that they are too long. Regarding the worker survey, focus group participants indicated that they would complete a 30 minute survey, especially if they could complete the survey in more than one session (which is an option for respondents of our web survey). Findings from our pilot tests show that the average time to complete the core module was about 20 minutes, and about 7 minutes for each hazard module. Response rates were fairly good, averaging 45% at two pilot test sites. While there appears to be no single guideline for questionnaire length, one literature review of the effect of questionnaire length on response rates stated that "results are still confusing and contradictory, conclusions are still not clear, and questionnaire designers still aim for shorter questionnaires with little more justification than the assumption that longer interviews will result in higher nonresponse" (Bogen K, 1996 Proceedings of the Section on Survey Research Methods, American Statistical Association, pgs 1020-1025). Although we feel that the length of the worker survey is reasonable, we are planning to evaluate options for reducing the completion time.

In regards to the management questionnaire, the fact that the requested information would need to be collected by persons other than the primary recipient of the questionnaire (especially in medium to large sized facilities) adds complexity and time to complete the survey. We are planning to evaluate options for streamlining the management survey.

37. Comment

Name Jean Scholz

Organization Ohio Hospital Association

Email jeans@ohanet.org

Address 155 East Broad St., FL 15 Columbus, OH 43215

Comments:

On behalf of Ohio's hospitals and their employees and medical staff, we reiterate the concerns already expressed to you by the American Hospital Association (AHA) on NIOSH proposed national surveys of health care workers' safety and employer safety and health practices. A copy of the letter sent to you by AHA is attached for your reference.

Ohio hospitals employ over 250,000 health care workers and in Ohio, the health care workforce makes up about 10 percent of the total Ohio workforce. Therefore, the health and safety of Ohio's health care workforce is significant to our state and we share your intent to study the issues associated with their work. However, AHA's concerns are valid and their comprehensive comments should be carefully considered prior to embarking on any national survey. OHA requests your reconsideration of the strategy NIOSH will use to study and investigate workplace safety in hospitals.

OHA is committed to helping hospitals create environments that attract and retain employees. Safe workplaces are environments that attract and retain staff. OHA and the Industrial Commission of Ohio created the hospital Safety Campaign in January 1953. Ohio hospitals continue to have a strong commitment to reducing workplace injuries. OHA's Safety Campaign is a positive, win-win approach to the design of institution-based health and safety management policies, programs and resources. We would be happy to share more details about the Safety Campaign with you, and would be happy to help you redesign your efforts to advance any work place safety needs of healthcare professionals. We look forward to hearing from you.

Sincerely,

Response

Dear Ms. Scholz:

Thank you for your comments and interest in the proposed management and worker surveys. Because the OHA shares the same concerns as the AHA, please refer to our response to the AHA (Comment #21)

38. Comment

Name Aline Holmes

Organization
New Jersey Hospital Association

Email aholmes@njha.com

Address 760 Alexander Road, PO Box 1 Princeton, NJ 08543-001

Comments:



July 1, 2008

NIOSH Docket Office Robert A. Taft Laboratories MS-C34 4676 Columbia Parkway Cincinnati, OH 45226

RE: NIOSH Docket number 135, Notice of public meeting and availability for public comment (Vol. 73, No. 64), April 2, 2008

To Whom It May Concern:

On behalf of all of our members, including hospitals, health systems, nursing homes and other healthcare organizations, the New Jersey Hospital Association (NJHA) appreciates the opportunity to comment on the National Institute for Occupational Safety and Health's (NIOSH) proposed national surveys of healthcare workers' safety and employer safety and health practices.

While we agree with the overall objective of the project to have current and accurate data on health and safety hazards and perceptions, work practices and use of exposure controls, NJHA has serious concerns with the methodology that NIOSH is proposing to use. The survey tools are very long and complex and we believe that NIOSH has significantly under-estimated the time and resources that will be needed by healthcare organizations to complete them. We concur with the American Hospital Association's comments that many of the statements in the survey suggest best practices which are not evidence-based, e.g., the use of back belts.

Of great concern is the proposed methodology to gather hazard surveillance data from healthcare workers by partnering with various labor unions and professional associations. As noted by NIOSH, this will result in a biased non-representative sample of employees, especially with the addition of a \$10 gift certificate. The use of labor unions to gather this information is problematic to many of our members who have employees who are organized. NJHA recommends that NIOSH develop a statistical sampling approach with a method of validating the results of the worker questionnaire to ensure that the results accurately reflect work practices and perceptions of our employees.

NJHA asks that NIOSH change the survey tools to make them shorter, less resource intensive and more objective, and change the methodology of collecting this data to one that is more statistically appropriate so that the results are more generalizable to the healthcare worker population.

If you have any questions regarding this letter, please do not hesitate to contact me at 609-275-4157, aholmes@njha.com.

Sincerely.

Aline M. Holmes

Senior Vice President, Clinical Affairs

760 Alexander Road ≈ PO Box 1 ≈ Princeton, New Jersey, 08543-0001 Tet 609-275-4000

Response:

Dear Ms. Holmes:

Thank you for your comments and interest in the proposed management and worker surveys. Because the NJHA shares the same general concerns as the AHA, please refer to our response to the AHA (Comment #21)

39. Comment

Name

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Comments:



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NIOSH Docket Office Robert A. Taft Laboratories MS-C34 4676 Columbia Parkway Cincinnati, OH 45226-1998

RE: Survey of Health Care Workers' Safety and Health and Survey of Health Care Employer Safety and Health Practices - Docket # NIOSH-135

To Whom It May Concern:

I am writing on behalf of the Greater New York Hospital Association (GNYHA) to provide comments on the National Institute for Occupational Safety and Health's (NIOSH's) proposed national surveys of health care workers' safety and health as well as management health and safety practices. In general, GNYHA strongly recommends that NIOSH revise the proposed approach to its survey process in order to ensure the collection of valid and meaningful information. As outlined below, GNYHA believes that the process should be more streamlined, the questions should be more evidence-based, and the methodology should result in a more nationally representative sample.

GNYHA represents approximately 250 hospitals and continuing care facilities, both voluntary and public, in New York State, as well as New Jersey, Connecticut, and Rhode Island. GNYHA members share a common mission to serve patients, support caregivers, and promote high-quality health care. To that end, the health care industry has long been committed to reducing work-related injuries as demonstrated by policies, programs, and resources designed to protect employees.

NIOSH states that the overall objective of this project is to "describe the prevalence and distribution of important health and safety hazards and perceptions, work practices, and use of exposure controls from a health care worker perspective, and to describe institution-based health and safety management policies, programs and resources of health care establishments, from the perspective of the person responsible for employee health and safety" Further, "information collected will be useful in identifying gaps relative to the use of best practices and define future research and intervention priorities."

GNYHA agrees that it is critical to have current and accurate data on the top health and safety issues facing caregivers. However, we have serious concerns about these surveys and the methodology that NIOSH proposes to use to obtain these data.

Length and Complexity of Survey Instruments

The health care worker and management surveys are extremely long, with many complex questions GNYHA believes that the survey length and complexity will negatively affect the response rate and, ultimately, the results. In this regard, GNYHA believes NISOH has significantly underestimated the length of time needed for both health care workers and management to complete their respective portions of the survey.

Health Care Worker Survey

Health care workers are required to complete a 25-page core survey that contains 79 questions. In addition, health care works are required to complete hazard-specific modules that are up to 11 pages long and contain up to 42 questions. While NIOSH estimates it will take health care workers 20 minutes to complete the core module and an average of 7 minutes for the hazard-specific modules, GNYHA believes that health care workers will need significantly more time to accurately complete their sections of the survey.

Management Survey

The management portion of the survey is 50 pages long and contains 63 core questions in addition to 140 hazard-specific questions. NIOSH estimates it will take 45 to 50 minutes to complete the management section of the survey. In many institutions, multiple people will be responsible for questions based on subject matter. Again, GNYHA believes NIOSH has significantly underestimated the time needed to complete the management section of the survey.

GNYHA recommends NIOSH consider streamlining the surveys in regard to length and complexity.

Content of Survey Questions

NIOSH background materials related to the proposed surveys note that the questionnaires have already been pilot-tested in two large medical centers. The Agency states that "the content of the questionnaires has been fairly well-defined" and "minor revisions will be made...prior to use in this study." GNYHA has serious concerns about many of the questions in the survey and requests NIOSH to consider substantive changes to the surveys based on stakeholder feedback.

In particular, GNYHA has serious concerns related to statements, especially those to which the worker is asked to respond, that are presented as factual or imply a best practice, but that do not have solid supporting evidence. Additionally, we are concerned that many questions, especially those referring to the use of personal protective equipment, have inadequate response options. As a result, respondents cannot answer in a way that accurately describes their health and safety practices. Unless NiOSH ensures that its questions describe practices that are truly supported by scientific evidence and allow responses that reflect actual health and safety practices, the survey results will be misleading and will identify gaps that are not relevant to worker health and safety.

GNYHA has coordinated with the American Hospital Association (AHA) and other state hospital association representatives to construct comments that will be useful when revising the health care workers' safety and health and management health and safety practices surveys. To that end, I reference the AHA's attachment to its comment letter, which contains detailed comments and suggestions regarding the construct of certain questions. GNYHA concurs completely with concerns identified in the AHA's detailed comments (Attachment 1) and requests that NIOSH consider all of the recommended changes.

GNYHA recommends NIOSH consider substantive changes to the surveys based on stakeholder comments

Methodology for Conducting the Surveys

Health Care Worker Survey

NIOSH indicates that it will use a "population-based" approach to gather data from health care workers by partnering with labor unions and professional associations that will send survey information to their membership. These organizations will either directly e-mail their members with a link to the survey or promote the survey to members via various avenues of communication and direct them to a Web site where members can complete the survey. To maximize response rates, NIOSH proposes to award workers who complete the survey with a \$10 on-line gift certificate. GNYHA has serious concerns about this approach. As stated in NIOSH's background materials, the disadvantages associated with the use of this approach include the problem of a non-representative sample of the total population of workers and sampling bias.

Further, the health care worker survey modules request worker perceptions and opinions and are very subjective, in contrast to the management questionnaire, which is largely based on concrete management practices. In addition, there is no way to validate the results of the worker survey responses because there is no information linking a worker to his or her place of employment.

Management Survey

While NIOSH indicates that the sample of hospitals it will draw will be size-stratified by the number of employees (1-19; 20-449; 500+), GNYHA recommends that NIOSH use the more typical hospital research sampling framework that is based on bed size, geographic region, and type of facility.

Due to the length and complexity of the management questionnaire, we believe that there will be a low response rate, resulting in an inadequate and non-representative respondent population. Correspondingly, we also are concerned that a low response rate will make it appear that hospitals are indifferent to the health and safety of their workers.

GNYHA recommends that NIOSH reconsider its methodology for administering the surveys and develop a sampling approach that will result in nationally representative responses. In addition, NIOSH needs to consider how to validate workers' responses as management responses will be validated through random site visits.

GNYHA and its members are committed to employee safety and evidence-based employee safety and health programs. As a result, GNYHA respectfully requests that NIOSH consider GNYHA's recommendations for improving upon NIOSH's intended survey process and instruments. If you have any questions, please contact me or Alison Burke, Associate Vice President of Regulatory and Professional Affairs, at (212) 506-5526 or Aburke@gnyha.org.

Sincerely.

Kenneth E. Raske

President

Response:

Dear Mr. Raske:

Thank you for your comments and interest in the proposed management and worker surveys. Because the GNYHA shares the same general concerns as the AHA, please refer to our response to the AHA (Comment #21)