Medical Surveillance Programs for Workers Exposed to Hazardous Medications

A Survey of Current Practices in Health Care Institutions

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Objective: To assess current medical surveillance monitoring practices for health care workers who prepare, handle, or administer hazardous medications. **Methods:** A cross-sectional survey was distributed to members of the American College of Occupational and Environmental Medicine and the National Comprehensive Cancer Network. **Results:** Forty-six of the 91 survey respondents indicated that their institution had a hazardous medication surveillance program. We identified the most frequent laboratory (complete blood count) and physical (skin) examination components. A health history was frequently used. Statistical analysis did not suggest an association between institutions with greater resources and presence of a surveillance program. **Conclusions:** A consensus standard for medical monitoring was not reported by the respondents. We recommend using a standardized surveillance questionnaire and applying uniform laboratory testing across institutions, in addition to establishing a national repository for surveillance data.

Keywords: antineoplastics, chemotherapy, occupational disease, surveillance toxicology

Health care workers who handle hazardous medications such as chemotherapeutic drugs potentially have increased risk of adverse health outcomes.[1–7] This risk has been a subject of increasing interest and concern for health care workers,[8] medical centers, and organizations that provide guidance to the health care industry.

Most health care institutions are aware of the hazardous drug list developed by the National Institute for Occupational Safety and Health (NIOSH),[9,10] but questions remain regarding best practices for monitoring programs for medical workers exposed to chemotherapeutics and other hazardous pharmaceutical agents. Existing guidelines do not include specific recommendations such as how frequently workers should be monitored, what screening laboratory tests should be used, or whether the program should be mandatory. Additionally, some recommendations by NIOSH, such as periodic physical examinations, may not be conducted routinely,[10] and organizations may vary in their interpretation of periodicity and question the usefulness of the recommended practices. Individuals responsible for employee safety and surveillance can reasonably question, given the limited existing guidance, whether their hazardous medication surveillance program (HMSP) is sufficiently protecting employees.

Prior research[11] has shown that leaders from major medical institutions question the validity and benefits of hazardous medication surveillance. Many institutions lack formal surveillance programs for employees who prepare or administer hazardous medications, in part due to these concerns.[10] Other institutions have discontinued surveillance programs because health outcomes were not correlated with workplace exposures.

For patients with a specific health problem, the health benefits of hazardous medications are generally believed to outweigh the risks. However, health care workers may have frequent, recurrent exposure to these drugs without any offsetting personal health benefit. Associations have been observed between workplace exposure to hazardous medications and adverse health outcomes, including increased rates of cancers[1,3,4] and infertility,[4,7] but the frequency of these health outcomes in the general population makes it difficult to attribute an individual's specific adverse health outcome (eg, spontaneous abortion) to a workplace exposure to hazardous medications. Health effects and changes in chromosome structure in health care workers have been documented previously[4,6,12–14] and remain a source of concern.

Use of personal protective equipment and environmental controls such as closed-system devices and wipe sampling[15] have led some institutions to conclude that medical monitoring is not necessary.[11] However, new guidelines anticipated from the USPharmacopeia, general chapter <800> (USP 800) have renewed interest in this topic because the USP 800 addresses safety for nurses, physicians, and other health care professionals outside of the pharmacy.[16] This study seeks to describe current practices for medical surveillance of health care workers exposed to hazardous medications.

METHODS

This research project was exempted by the Mayo Clinic Institutional Review Board.

We performed a cross-sectional survey of health care employees with experience in developing or administering HMSPs. The purpose of the survey was to gain information on current medical surveillance monitoring practices for health care workers who prepare, handle, or administer hazardous medications such as chemotherapeutic agents. The survey was distributed through an online linked invitation (via SurveyMonkey) and sent to members of the American College of Occupational and Environmental Medicine (ACOEM) and the National Comprehensive Cancer Network (NCCN). Two special-interest sections of the ACOEM were selected to receive the survey: the Medical Center Occupational Health section (MCOH) and the Pharmaceutical Industry section. In addition, the survey was sent to the 28 member institutions of the

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NCCN. Surveys sent to the NCCN were distributed according to the group's standard practice, with the NCCN best practices program manager identifying a single expert at each member institution who would receive and respond to the survey.

Completion of the survey was voluntary, and no individually identifying information was collected. All members of MCOH and the Pharmaceutical Industry sections of the ACOEM, plus the 29 member-institution experts at NCCN received an initial email invitation to complete the survey, which was sent by a representative of their member organization (ACOEM or NCCN). Two additional reminder emails were sent before the close of the survey. The survey (see Appendix, Supplemental Digital Content 1, http://links.lww.com/JOM/A491) had 31 questions that were designated as mandatory for the MCOH respondents and 32 questions were mandatory for the NCCN representatives. NCCN leadership requested that all respondents answer questions about personal protective equipment and practices for reassigning pregnant workers.

Descriptive statistics and response frequencies are provided for survey responses. Chi-squared tests were used to determine difference between work locations and presence of surveillance programs. P values <0.05 were considered significant. Analyses were performed using STATA (version 15; StataCorp LLC, College Station, TX).

RESULTS

We obtained responses from 76 individuals (24% response rate) from the ACOEM MCOH section and 15 responses (51% response rate) from NCCN. The ACOEM Pharmaceutical Industry section returned four responses, with none of the respondents reporting an HMSP at their institution; their data were excluded from the analysis because of the low response rate (6%).

Respondents had considerable experience and knowledge of their current institutional practices. The average duration of employment at the current employer was 13.9 years, and the average time spent in the current role was 12 years. Thirty-five respondents (38%) were older than 60 years. Most respondents ($n = 73$ [80%]) identified their work area as Employee or Occupational Health, and 11 individuals (12%) worked primarily in a pharmacy. Consistent with the membership profile of MCOH, 73 respondents (80%) identified as medical providers (65 were physicians, eight were nurse practitioners or physician assistants). Most respondents worked in large hospitals ($n = 23$ [25%]) or academic medical centers ($n = 30$ [33%]), and only seven (8%) identified as primarily working in a cancer center. Table 1 shows the characteristics of all individuals who responded to the survey. Table 2 shows characteristics for the subset of respondents whose institutions had an HMSP.

TABLE 1. Characteristics of Survey Respondents ($N = 91$)

Characteristic	Value
Surveyed organization	
Medical center occupational health, no. (%)	76 (84)
National comprehensive cancer network, no. (%)	15 (16)
Work area, no. (%)	
Employee or occupational health	73 (80)
Pharmacy	11 (12)
Nursing administration	3 (3)
Oncology	1 (1)
Other (please specify)	3 (3)
Pharmacy administration	1 (1)
Consultant	1 (1)
Private occupational medical clinic	1 (1)
Age, yr, no. (%)	
No response	15 (16)
30–44	8 (9)
45–59	33 (36)
>60	35 (38)
Highest level of education, no. (%)	
MD/DO	65 (71)
RN/LPN	3 (3)
NP/PA	8 (9)
CNS	1 (1)
PharmD	8 (9)
PhD	1 (1)
Work location, no. (%)	
Academic medical center	30 (33)
Cancer center	7 (8)
Community hospital	11 (12)
Large hospital	23 (25)
Outpatient clinic	10 (11)
Other (please specify)	10 (11)
Hospital health system	1 (1)
Hospital system	1 (1)
Large hospital system	1 (1)
Multicenter health care system	1 (1)
Regional health care system	1 (1)
Combined outpatient clinic, community hospital, and large hospital	1 (1)
Executive health clinic	1 (1)
VA healthcare system	1 (1)
Consultant	1 (1)
Free-standing pediatric cancer hospital	1 (1)
Years at current employer, mean (SD)	13.89 (10.28)
Years in current role, mean (SD)	12.04 (9.28)

Although all respondents reported that hazardous medications were prepared or administered in their facility, only 43 MCOH respondents (56%) and three NCCN respondents (20%) reported having an HMSP at their institution. Among those respondents whose institutions had a surveillance program, eight (17%) believed that they had clear guidance about what should be included in a monitoring program for hazardous medications. Of those with surveillance programs, 31 (67%) indicated "appropriate labs should be better defined," 24 (52%) reported that "recommended frequency of surveillance should be specified," and 23 (50%) reported that "guidance on action to take due to surveillance results should be provided." Individual respondents provided free-text comments such as "endpoints of monitoring should be defined" and "participation is voluntary and underutilized," and one noted that recommended activities for surveillance "have not been validated or studied."

In most cases, Employee or Occupational Health was identified as making most decisions regarding the HMSP at the institution. Of the respondents from institutions with surveillance programs, 16 (35%) indicated having "responsibility for overseeing the program," 13 (28%) had "responsibility for developing and updating the program as needed," and 8 (17%) said they were not responsible for the program but were "involved in the program." Seven respondents (15%) indicated that they advised colleagues on the design of their institution's HMSP. The majority of institutions with HMSPs monitored only employees exposed to chemotherapeutics ($n = 24$ [52%]), whereas 21 individuals (46%) reported including employees exposed to other hazardous medications. One individual was unsure of the scope of their institution's surveillance program.

Almost all institutions that performed surveillance (45/46 [98%]) monitored nurses; in addition, 42 institutions (91%) included pharmacists, and 36 (78%) included pharmacy technicians. Sixteen respondents (35% of those with an HMSP) reported providing surveillance to physicians and 17 programs (37%) included environmental or janitorial staff. Five programs (11%) included physical therapists and occupational therapists in the surveillance.

Greater than half the programs had voluntary participation, with 17 (37%) inviting employees to "opt-in," and 10 (22%) including applicable employees but allowing them to "opt-out," if desired. Seven respondents (15% of those with a HMSP) reported

TABLE 2. Characteristics of the Subset of Respondents From Institutions With Hazardous Medication Surveillance Program ($n = 46$)

Characteristic	Value
Surveyed organization	
Medical center occupational health, no. (%)	43 (93)
National comprehensive cancer network, no. (%)	3 (7)
Work area, no. (%)	
Employee or occupational health	43 (93)
Pharmacy	2 (4)
Other (please specify)	
Pharmacy administration	1 (2)
Age, y, no. (%)	
No response	3 (7)
30–44	4 (9)
45–59	15 (33)
>60	24 (52)
Highest level of education, no. (%)	
MD/DO	34 (74)
RN/LPN	1 (2)
NP/PA	6 (13)
PharmD	1 (2)
PhD	1 (2)
Work location, no. (%)	
Academic medical center	12 (26)
Cancer center	1 (2)
Community hospital	9 (20)
Large hospital	14 (30)
Outpatient clinic	5 (11)
Other (please specify)	5 (11)
Hospital health system	1 (2)
Hospital system	1 (2)
Large hospital system	1 (2)
Multicenter health care system	1 (2)
Regional health care system	1 (2)
Years at current employer, mean (SD)	14.15 (10.72)
Years in current role, mean (SD)	12.76 (9.26)

mandatory programs with a declination option and six (13%) reported mandatory programs without a declination option. Of the 13 respondents who indicated a mandatory program (with or without a declination option), four (31%) reported consequences for employees who were not compliant with surveillance. Consequences included withholding merit-based pay increases, removal from work, disciplinary action, and work restrictions that removed the employee from exposure. A summary of responses to questions about existing HSMPs is shown in the Appendix (see Appendix, Supplemental Digital Content 1, http://links.lww.com/JOM/A491).

Thirty-five of the 46 surveillance programs (76%) required chemotherapy-rated gloves and 29 programs (63%) required chemotherapy-rated gowns for personal protective equipment. However, not all employees were subject to these requirements; additional personal protective equipment requirements are noted in Fig. 1.

Of the surveillance programs reported, 19 programs (41%) performed laboratory testing if an exposure occurred, 24 (52%) performed laboratory testing at baseline only, and 22 (48%) performed periodic laboratory testing for surveillance. Four respondents (9%) reported no laboratory testing as part of their surveillance program. Although laboratory testing was common, we noted wide variation in the specific tests used. Complete blood count, aspartate transaminase or alanine aminotransferase, and urinalysis were reported by the majority of respondents (33 [72%], 23 [50%], and 24 [52%], respectively) (Fig. 2).

Fourteen respondents (30% of respondents with HMSPs) reported that physical examinations were not part of their program. Among the remaining 32 respondents, physical examination components varied (Fig. 3). Musculoskeletal examinations were performed least frequently (13 programs [28%]); skin examinations were performed most frequently (24 programs [52%]).

The most common element of surveillance programs was a health history, with 36 respondents (78%) reporting that it was part of their HMSP. Within the health history, the most commonly included element was reproductive history; six programs (13%) obtained reproductive history at baseline and 27 programs (59%) obtained reproductive history at baseline and during follow-up screening. Comprehensive medical histories (13 respondents

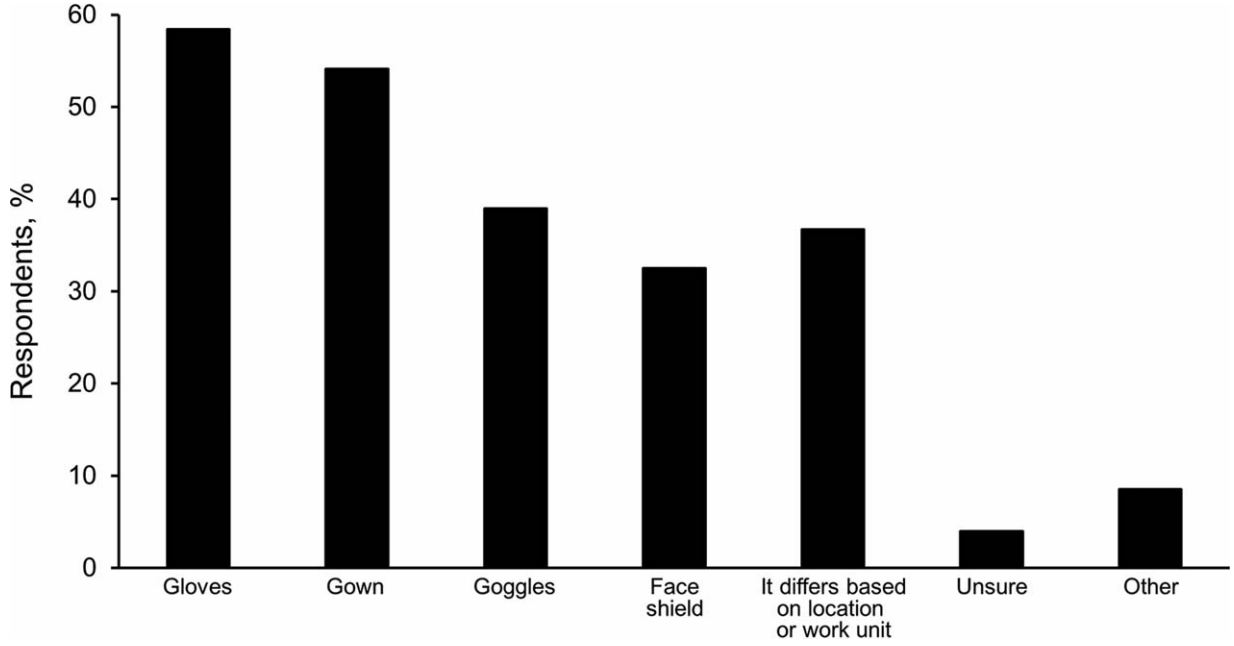

FIGURE 1. Personal protective equipment required for employees handling chemotherapeutic medications.

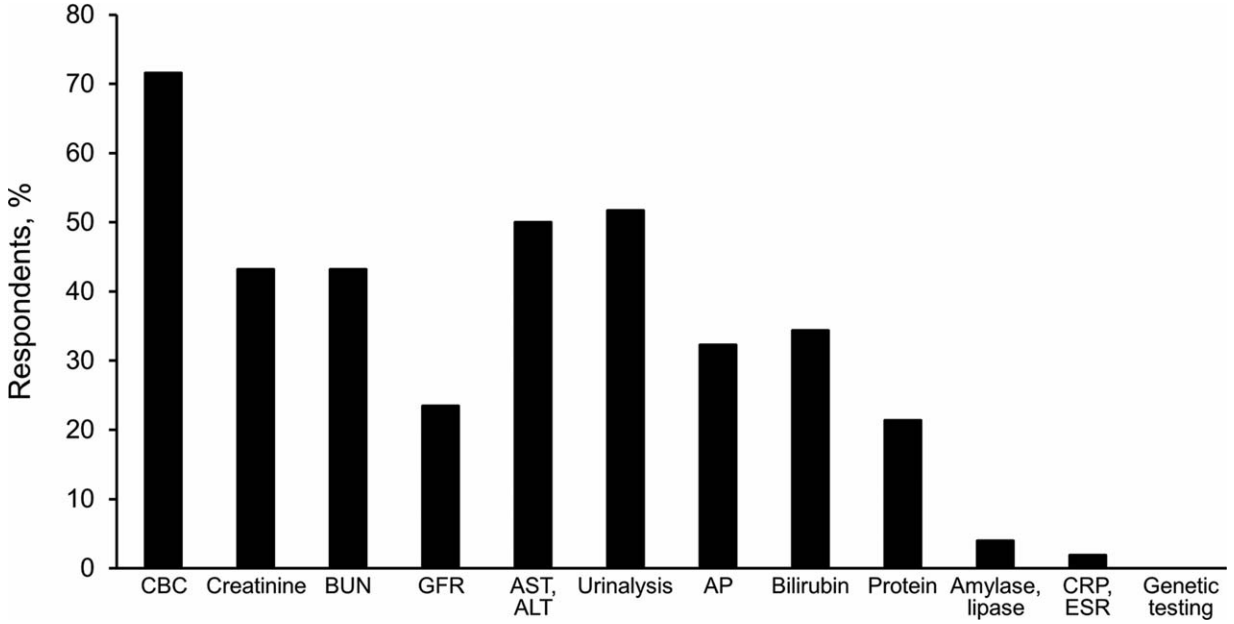

FIGURE 2. Common laboratory tests used in surveillance programs. ALT, alanine aminotransferase; AP, alkaline phosphatase; AST, aspartate transaminase; BUN, blood urea nitrogen; CBC, complete blood count; CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; GFR, glomerular filtration rate.

[28%]) and complete reviews of systems (10 respondents [22%]) were obtained least often.

We sought to determine whether the presence (or absence) of a HMSP correlated with the estimated resources available to the organization. Self-reported work location information was used as a surrogate for the presumed resources available to the institution. In general, multisite institutions (eg, academic medical centers, large hospital systems, multicenter health care systems) were considered to have a high level of available resources, outpatient settings (eg, where surgical procedures would not be performed) were categorized as low-resource settings, and the remaining institutions were categorized as having medium or average financial resources. Although we had anticipated that higher-resource institutions would be more likely to have a surveillance program, there was no correlation between hospital resources and presence of a surveillance program (Table 3).

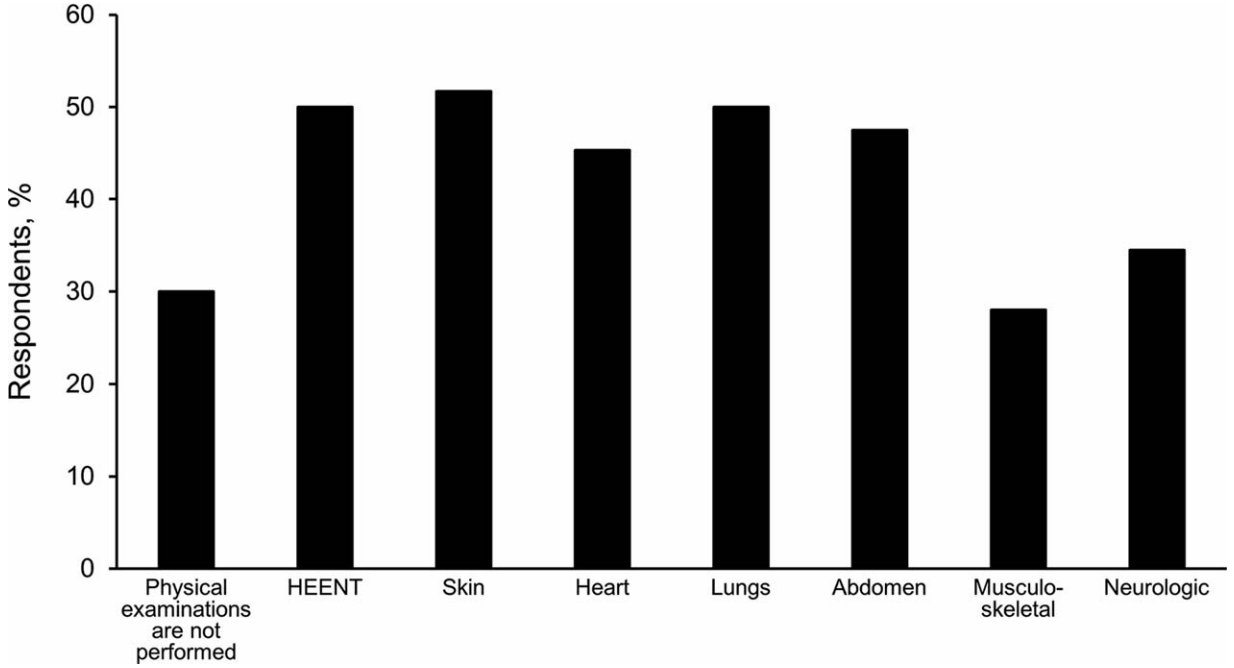

FIGURE 3. Elements of physical examinations performed. HEENT, head, ears, eyes, nose, and throat.

TABLE 3. Resource Level and Medical Surveillance Presence

Resource Level	Surveillance Program Present, No. (%)*
Low ($n = 12$)†	5 (41.7)
Medium ($n = 42$)‡	24 (57.1)
High ($n = 37$)§	17 (45.9)

*Pearson χ^2 (2) = 1.4229; $P = 0.491$.
†Outpatient clinic, executive health clinic, or consultant.
‡Community hospital, large hospital, free-standing pediatric cancer hospital, or cancer center.
§Academic medical center, hospital health system, hospital system, large hospital system, multicenter health care system, regional health care system, VA health care system, or combined outpatient clinic, community hospital, and large hospital.

DISCUSSION

The USP 800 includes criteria for HMSPs and has renewed interest in exposure prevention for employees who administer, prepare, and handle hazardous medications. As indicated in the Appendix (see Appendix, Supplemental Digital Content 1, http://links.lww.com/JOM/A491), respondents to our survey consistently indicated concern for nursing safety ($n = 34$ [74% of respondents with HMSPs]), pharmacy staff safety ($n = 33$ [72%]), and regulatory compliance ($n = 34$ [74%]) as primary factors driving the intent of the monitoring program. However, the responses to components of individual surveillance programs showed marked variability. Although we noted some trends in surveillance program components (eg, the most common laboratory tests were complete blood counts, liver function tests, and urinalyses), no consensus or criterion standard currently exists regarding what tests, questionnaires, or physical examination components to use, the frequency of assessment, or when interventions are necessary.

One of the most common practical issues with surveillance programs for health care workers who handle or administer hazardous medications is the inability to clearly connect workplace exposure to adverse health effects, given that many potential effects (eg, spontaneous abortion) are common. Many respondents indicated that a proactive approach that used environmental controls (eg, wipe sampling, closed systems, etc) was preferable to medical surveillance for reducing risk of exposure or ensuring that no exposure occurs. Wipe sampling is a well-established and useful component of an environmental control program, and environmental contamination correlates with the presence of pharmaceutical metabolites in urine[15]; however, in the absence of standards for acceptable or allowable surface concentrations, low limits of detection may make interpretation and communication of results to employees challenging. Furthermore, because nursing workload (number of patients per day) can notably affect the use of precautions when working with hazardous medications,[17] a wipe-sampling program must be performed in a carefully standardized manner to reliably verify the adequacy of environmental control practices and trends.

Biological monitoring for metabolic byproducts of chemotherapeutics[18] or for genotoxic effects[19] can be used to confirm exposure; however, the prognostic significance of observed changes is uncertain, and testing employees for genetic mutations has inherent ethical concerns. Furthermore, with limited exceptions, genetic testing by employers is prohibited under the Genetic Information Nondiscrimination Act of 2008.[20]

Ongoing research is needed to determine whether the environmental and administrative controls implemented in response to the USP 800 mitigate the risk of exposure to employees. For example, do closed systems for medication administration reduce risk to the extent that monitoring these employees for end-organ effects becomes unnecessary? At present, given the USP 800 guideline for a surveillance program without specific screening tools, health care facilities may opt to enact focused surveillance. A reasonable approach could be a focused health history with limited laboratory testing only for the organ system(s) most likely to be affected by the relevant hazardous medication(s). Monitoring employees with the highest risk of adverse effects (ie, those handling chemotherapeutics or teratogenic medications) should be prioritized.

To ensure capture of relevant trends, the surveillance program should include all employees who meet exposure criteria (with an option for employees to decline surveillance) plus any employee who experiences an acute exposure event. Among the tools utilized for surveillance, a well-designed questionnaire may identify trends among employees that could be missed with only physical examinations or laboratory testing. The value of laboratory tests for health care workers preparing or handling hazardous medications is limited by the prevalence of abnormal test results[21] in diverse populations that include individuals without potential occupational exposure to hazardous medications. For example, the frequency of abnormal results in a general patient cohort has been reported to be as high as 36%, with therapeutic yield of less than 1% for an abnormal result.[22] Without data from a control group and criteria for when to act on abnormal results, institutions should be cautious in performing broad laboratory testing as part of an HMSP. Responding to abnormal test results in isolation risks harm to employees by potentially exposing them to psychological stress and more invasive testing. Use of a standard questionnaire for HMSPs, similar to questionnaires used for other mandated surveillance programs (eg, respiratory protection, asbestos, etc) would capture data suitable for comparisons, benchmarking, and detection of trends over time.[23,24]

The main strength of this study is that it provides detailed data to those looking to understand current practices of HMSPs throughout the United States because it included a large number of respondents representing a broad cross-section of practice settings. The demographics of respondents with HMSPs suggest that they are knowledgeable and experienced with the benefits and limitations of HMSPs.

The main weakness of the study is the low survey response rate (24% for MCOH members, 51% for NCCN representatives). Respondents from institutions with HMSPs may have been more likely to respond, given the recent interest in this topic resulting from USP 800. Another factor that could affect the results from MCOH respondents is the possibility that multiple MCOH members from the same institution responded to the survey. To maintain privacy and encourage disclosure of institutional practices, respondents were not asked to identify their specific employer but were instead asked demographic information about their work area. However, the lack of duplicate or identical responses to the questions suggests that it was unlikely that multiple individuals from one institution responded to the survey. Although the relatively low response rate may have contributed to the lack of a statistically significant correlation between hospital resources and presence of a surveillance program, we believe it is unlikely to be the cause of the observations. Table 3 shows that fewer cancer centers had HMSPs compared with other work locations, despite frequent use of chemotherapeutic medications. Although cancer centers handle hazardous medications frequently, the lower prevalence of surveillance programs could be due to a focus on controlling or preventing exposure.

CONCLUSIONS

A consensus standard for medical monitoring was not reported by the respondents. However, because respondents indicated that it is extremely difficult to associate an adverse health

effect with a subacute exposure, consideration should be given to focusing HMSPs on the highest-risk populations, systematically monitoring employees with a known exposure event, and frequently monitoring all employees with potential exposure to hazardous medications for compliance with preventive measures.

The high baseline rate of positive findings on health questionnaires and routine laboratory tests and the relative rarity of adverse health effects attributable to low-level occupational exposure to hazardous medications suggest that individual facilities are unlikely to generate surveillance data with sufficient power to detect trends and statistically significant associations. A national repository or registry of de-identified answers to health-screening questionnaires is needed to identify trends in health effects for this occupational population that differ from outcomes expected in the general population. Such a system would require a standardized questionnaire and some uniformity of laboratory testing across institutions.

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