Miller, Diane M. (CDC/NIOSH/EID)

From: Hodson, Laura (CDC/NIOSH/EID) (CTR)
Sent: Friday, November 09, 2007 10:55 AM
To: Miller, Diane M. (CDC/NIOSH/EID)
Subject: FW: Opportunity to assist NIOSH with Home Health Care Workers document
Follow Up Flag: Follow up
Flag Status: Blue
Attachments: Latex Allergens in Pharmaceutic Vial Closures.pdf; Qualitative study of the working conditions of home health workers.pdf

For Docket NIOSH-114

Laura

From:
Sent: Friday, November 09, 2007 10:53 AM
To: Hodson, Laura (CDC/NIOSH/EID) (CTR)
Subject: RE: Opportunity to assist NIOSH with Home Health Care Workers document

I have only 2 comments to make about the comprehensive and well researched document

1. In the Chapter 2 Latex Allergy in Home Care there was not emphasis on latex allergy related to immunization or pharmaceutical vial stoppers. Immunization for influenza is now required for some hospital and nursing home workers, and in NYS home care workers could be also required in the future. Latex free vaccine is available and Human Resourse departments should be advised to make it available in any employee health immunization processes. Attached is a reference: *Natural rubber pharmaceutical vial closures release latex allergens that produce skin reactions*
2. In Chapter 6 Other Hazards in the Home the hygiene issues and dangers around insects (e.g. lice), rodents, and fomites was not emphasized, and this is a significant problem for health care workers, especially those caring for the low income or home bound individuals who do not have the means or the physical ability to adequatly address these problems in their environment. Health care workers with asthmatic conditions can also be adversly affected. Reference Attached: *There's No Place Like Home: A Qualitative Study of the Working Conditions of Home Health Care Providers*

Than you for allowing me to participate in the review of this publication. A scanned copy of my Peer Review Conflict of Interest Form is attached.

-----Original Message-----
From: Hodson, Laura (CDC/NIOSH/EID) (CTR) [mailto:gey7@cdc.gov]
Sent: Thursday, November 08, 2007 9:59 AM
To:
Subject: RE: Opportunity to assist NIOSH with Home Health Care Workers document

Thank you for volunteering to review the NIOSH Hazard Review: Occupational Hazards in Home Health Care. This is a friendly reminder that the reviews were requested by October 31 and we still have not heard from you. It would be greatly appreciated if you could review the document for content and let us know if we are on target. I am especially eager to learn if there are any errors of omission, such as are there any overlooked hazards or solutions that we failed to identify? Are the solutions to the identified hazards accurate?

Please try to get your comments back to NIOSH within the next two weeks so that we can move forward with getting this document published. You can send an email with NIOSH Docket -114 in the subject line to DMMiller@cdc.gov, or if it is easier for you, just mail any comments you may have written in the draft document to the NIOSH Docket Office, 4676 Columbia Parkway, MS C-32, Cincinnati, Ohio 45226. We will need the conflict of interest form mailed back or scanned in and sent as an attachment.

Of course if your review is in the mail, you can ignore this reminder.

Respectfully,
Laura Hodson, MSPH, CIH
Document Manager

From:
Sent: Thursday, September 06, 2007 3:47 PM
To: Hodson, Laura (CDC/NIOSH/EID) (CTR)
Subject: RE: Opportunity to assist NIOSH with Home Health Care Workers document

I would be glad to review it, what is the turn-around time?

Please Note the Change in Address and Fax #

the employees or agents responsible for delivering the message to the intended recipient (s), please note that any dissemination, distribution, copying or other use of this communication is strictly prohibited. If you received this communication in error, please notify us immediately by return e-mail and delete the original message from your system.

-----Original Message-----
From: Hodson, Laura (CDC/NIOSH/EID) (CTR) [mailto:gey7@cdc.gov]
Sent: Thursday, September 06, 2007 3:29 PM
To:

Greetings, The National Institute for Occupational Safety and Health (NIOSH), part of the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Service, is in the process of preparing a safety and occupational health guidance document for employers and workers in home healthcare. I am writing today to ask for your assistance. As part of our intensive document preparation process we like to have our documents reviewed by external reviewers who are considered knowledgeable and experts in their profession. I am hopeful that you will be willing to provide a review of a 90 page document titled "Occupational Hazards in Home Healthcare". The reward to you is that you will have the opportunity to participate in a program designed to make the home health care environment a better place to work. You will also be acknowledged as a reviewer in the published document.

The document will be mailed out in the very near future as this document has already gone through our intensive internal review and has received approval for the external review. We usually request a 6 week turn around. A letter explaining the charge to the reviews will accompany the document. We don't expect editorial review but content review. Are you available and willing to provide a technical review of this document? If so, please respond to this email within the next week and I will prepare a paper copy package for your review.

We need your insight to make this the best document it can be. You may notice that this email has gone out to mostly academics and union representatives. I have already gotten commitments from home health care workers "in the field" with the assistance of the editor of Home Healthcare Nurse.

Respectfully yours,

Laura Hodson, MSPH, CIH

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Natural rubber pharmaceutical vial closures release latex allergens that produce skin reactions

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Rapid publications

Natural rubber pharmaceutical vial closures release latex allergens that produce skin reactions

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Key words

Natural rubber

latex allergy

pharmaceutical vial closures

skin testing

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Baltimore, Md

Background: The release of allergenic proteins from natural rubber vial closures (stoppers) into aqueous pharmaceuticals may induce allergic reactions in individuals with latex allergy (LA) receiving medications from such vials.
Objective: The goal of this study was to determine whether solutions stored in vials containing natural rubber closures release allergenic proteins detectable by skin testing of subjects with LA.
Methods: Five pharmaceutical vial closures (2 natural rubber and 3 synthetic) were coded, inserted onto vials containing phenol-saline-human serum albumin, and stored in an inverted position before use. Twelve volunteers with and 11 volunteers without LA underwent skin testing with solutions from each of the 5 vials, either those not punctured (0P) or those punctured 40 times with a 21-gauge needle 12 to 24 hours before testing (40P).

Results: All intradermal skin test responses in the group without LA were negative. Two and 5 of the 12 subjects with LA had positive intradermal skin reactions to 0P and 40P solutions, respectively, from vials containing rubber closures. Two subjects with LA had inexplicable, positive, nonreproducible intradermal skin test reactions to solutions from vials containing bromobutyl but not vials with isoprene synthetic closures. In vitro inhibition analysis detected 6 to 7 AU/g latex allergen in extracts of cut natural rubber containing closures but not in extracts of synthetic closures.

Conclusion: Natural rubber vial closures released allergenic latex proteins into the tested solutions in direct contact during storage in sufficient quantities to elicit positive intradermal skin reactions in some individuals with LA. These data support a recommendation to eliminate natural rubber from closures of pharmaceutical vials. (J Allergy Clin Immunol 2001;107:958-62.)

Abbreviations used

FDA:
Food and Drug Administration
LA:
Latex allergy

Allergy to natural rubber latex is an established health problem, with a prevalence of 1% to 6% in the general population, [1] [4] 8% to 16% in health care workers, [5] [6] and up to 50% in children with spina bifida. [7] The symptoms range from mild local cutaneous reactions to generalized urticaria, angioedema, allergic rhinitis, respiratory symptoms, and life-threatening or fatal anaphylaxis. The severity of symptoms is dependent on an individual's susceptibility but also on the mode and route of latex allergen exposure, with mucosa, visceral, and parenteral exposure being associated with the greatest risk for the development of severe systemic reactions. [8]

Avoidance of exposure to natural rubber latex products is the primary method for preventing allergic reactions. Latex products can be classified into 2 types on the basis of their manufacturing processes. Dipped latex products refer to those manufactured by means of dipping a porcelain form into liquid latex. Exposure to dipped products (eg, gloves, balloons, and condoms) causes most of the observed immediate-type reactions. Dry or natural rubber refers to products that are made from hardened sheets of *Hevea* latex. They generally release less latex proteins on extraction than dipped products. [9] Vial stoppers (hereafter called closures) are natural rubber products. There has been widespread concern that latex allergen may leach from natural rubber closures into medications, with potential for causing a life-threatening allergic reaction if injected into an individual with latex allergy (LA).

In this study the release of latex proteins into solutions stored in vials containing natural rubber and synthetic closures was investigated by using intradermal skin testing of individuals with documented LA and control subjects without LA, as well as by using in vitro inhibition analysis.

Methods

Subjects

Two groups of subjects 18 years of age or older (18 with LA and 11 without LA) were recruited from the Johns Hopkins and University of Maryland Allergy Clinics by means of advertisements and direct invitations. At the screening visit, a clinical history and blood samples were collected. Subjects were recruited into the LA group if they had a positive history for IgE-mediated LA and a positive latex-specific IgE serology (>1 kIUa/L, Pharmacia CAP System). Control subjects were recruited with a negative LA history and a negative latex-specific IgE serology (<0.35 kIUa/L). Subjects were not qualified by means of skin testing because of the unavailability of a Food and Drug Administration (FDA)–approved latex extract.

Study vials

Five 13-mm pharmaceutical vial closures were manufactured for this study by American Stelmi (n = 1), West Pharmaceutical Services (n = 2), and Tompkins Rubber Company (n = 2) by using natural rubber (n = 2) or synthetic (n = 3) formulations (Table I).

Table I. Properties of the five 13-mm vial closures evaluated in the study

Parameter*	Closure A	Closure B	Closure C	Closure D	Closure E
Closure formulation† (natural rubber or synthetic)	Synthetic (bromobutyl)	Natural rubber (gum/crepe)	Natural rubber (crepe)	Synthetic (isoprene)	Synthetic (gum/isoprene)
Lot number† and color of closure	G802/1433 (gray)	PD8301-002 (brown)	390-98 (gray)	393-98 (gray)	PD8301-001 (tan)
Percentage weight of natural rubber content reported in formulation†	0	95.3	66	0	0
Latex allergen content in 0P and 40P solutions (AU/mL)	<0.5	<0.5	<0.5	<0.5	<0.5
Latex allergen content extracted from cut closures (AU/g)	<0.5	7.4	6.7	<0.5	<0.5

A * †

AU, Allergen units assigned by RAST inhibition analysis with natural rubber latex (E8-FDA) as a standard, with 100,000 AU/mL undiluted.

*Closure designation code (A-E) arbitrarily specified by the Parenteral Drug Association before insertion into vials for use in study.

†Defined by manufacturer.

All closures were sent by the manufacturers to the Parenteral Drug Association (Washington, DC), where they were randomized and coded from A to E. The coded closures were then sent to the Chesapeake Biological Laboratories (Baltimore, Md), where good manufacturing practices were used to wash, sterilize, and insert the closures into washed and sterilized 3-mL borosilicate pharmaceutical-grade vials containing 1 mL of saline-0.03% human serum albumin-0.4% phenol (FDA-licensed intradermal skin testing diluent from Greer Laboratories, hereafter called saline). All vials were capped, inverted after manufacturing, and quarantined for at least a month before being released as sterile. They were stored inverted at room temperature until their use within a 9-month period.

Study protocol

Twelve to 24 hours before each study visit, a set of 5 vials (A-E) was punctured 40 times with a 21-gauge needle while inverted and denoted as 40P. Saline removed from the nonpunctured vials after removing their closure was referred to as the 0-puncture (0P) solution. All solutions (saline negative control, histamine positive control, and 0P and 40P solutions from vials A-E) were drawn up into their own labeled 27-gauge needle–equipped tuberculin syringe containing synthetic plunger seals (Becton-Dickinson) 30 to 60 minutes before use.

For safety reasons, a puncture skin test was initially performed, as previously described.[10] If the reaction was negative, single intradermal skin tests were then performed[10] with all 0P solutions and repeated in duplicate if positive at 15 minutes. Next, intradermal skin tests were performed with all 40P solutions in duplicate and read at 15 minutes. The Norman grading criteria[10] were used to define

positive or negative results. Individuals with positive (>5-mm wheal or >10-mm erythema) skin reactions to the diluent negative control were excluded from further study. If the initial duplicate intradermal skin tests produced discrepant results, the same solution was retested in duplicate until an unequivocal result was obtained. The project was approved by the Johns Hopkins Bayview Institutional Review Board.

Laboratory analyses

Whole blood was collected from all subjects for measurement of latex-specific IgE levels, total serum IgE levels, and a multiaeroallergen screen (Phadiatop[11]) by using the CAP System (Pharmacia). The 5 closure types (A-E) were evaluated for the presence of extractable latex allergen by means of CAP inhibition analysis. Five grams of each vial closure (each cut in half) were extracted in duplicate overnight at room temperature with rotation by using 5 mL of PBS containing 1% BSA and 0.01% thimerosal. All closure extracts were centrifuged, sterile filtered, and, together with the 0P and 40P solutions from all 5 vials types, analyzed by means of CAP inhibition analysis. The assay used nonammoniated latex (E8) from the FDA (CBER; neat = 100,000 AU/mL) as the reference and an IgE anti-latex containing a human serum pool known to contain Hev b 1 to Hev b 7–specific IgE antibody. The analytic detection limit of the CAP inhibition assay was 0.5 AU/mL.

Statistical analyses

Qualitative differences in the frequency of positive skin test responses between the LA and non-LA groups with solutions from natural rubber (B0P, B40P, C0P, and C40P) and synthetic (A0P, A40P, D0P, D40P, E0P, and E40P) closure–containing vials were assessed by using χ^2 Pearson correlation analysis with SPSS software. Differences in the quantitative mean value (in millimeters) of wheal and erythema responses between the non-LA and LA groups for each of the test solutions (0P and 40P from vials A-E) were evaluated by using ANOVA, with the 2-tailed *t* test for equality of mean (SPSS). Significance was considered at a *P* value of less than .05.

Results

Study population characteristics

Six of 18 subjects with LA were excluded from participation because of a positive intradermal skin test response to the negative control diluent. The remaining 12 subjects with LA (10 female and 2 male subjects) and 11 subjects without LA (10 female and 1 male subject) underwent skin testing with 0P and 40P solutions from each of the 5 test vials. IgE anti-latex levels ranged from 1.0 to 31.9 kIUa/L in the sera of the subjects in the LA group (Table II).

Table II. Intradermal skin test reactivity in subjects with solutions from vials A-E

Subject code	Latex-specific IgE (kIUa/L)	S	H	Closure A Synthetic		Closure B Natural Rubber		Closure C Natural Rubber		Closure D Synthetic		Closure E Synthetic	
				0P	40P	0P	40P	0P	40P	0P	40P	0P	40P
LA-1	1.0	0 × 0	14 × 32	–	–	–	–	–	–	–	–	–	–
LA-2	1.1	1 × 6	10 × 53	–	–	–	5 × 29	–	–	–	–	–	–
LA-3	1.2	0 × 0	13 × 43	–	–	–	–	–	–	–	–	–	–
LA-4	1.6	0 × 0	11 × 48	–	–	–	–	–	–	–	–	–	–
LA-5	1.8	0 × 0	9 × 34	–	–	–	–	–	–	–	–	–	–
LA-6	3.0	0 × 0	12 × 37	–	–	–	8 × 15	–	–	–	–	–	–
LA-7	3.2	0 × 0	10 × 58	6 × 31	–	–	–	–	6 × 39	–	–	–	–

LA-8	4.9	0 × 0	15 × 50	–	–	–	–	–	–	–	–	–	–	
LA-9	5.7	0 × 0	11 × 41	–	–	10 × 37	12 × 36	9 × 29	9 × 46	–	–	–	–	
LA-10	25.7	0 × 0	19 × 53	–	7 × 25	9 × 37	10 × 28	–	6 × 44	–	–	–	–	
LA-11	3.8	0 × 0	12 × 49	–	–	–	–	–	–	–	–	–	–	
LA-12	31.9	0 × 0	13 × 13	–	–	–	–	–	–	–	–	–	–	
Reactivity of 11 subjects without LA	<0.35	0 × 0†	10 × 37†	–	–	–	–	–	–	–	–	–	–	

S * †

S, Saline; *H*, histamine; –, Negative intradermal skin test defined as a wheal of less than 5 mm and erythema of less than 10 mm.

*Mean (millimeters) wheal × erythema of positive intradermal skin test reactions.

†Mean results for 11 subjects without LA.

There were no significant differences in the levels of latex-specific IgE antibody or total serum IgE between the 12 subjects with LA included and the 6 individuals with LA excluded from further testing.

In vivo analyses

All puncture skin test reactions to solutions from vials A to E were negative in both the LA and non-LA groups. Fig 1 illustrates skin reactions produced by intradermal skin testing with solutions from study vials A to E in a representative subject with LA.

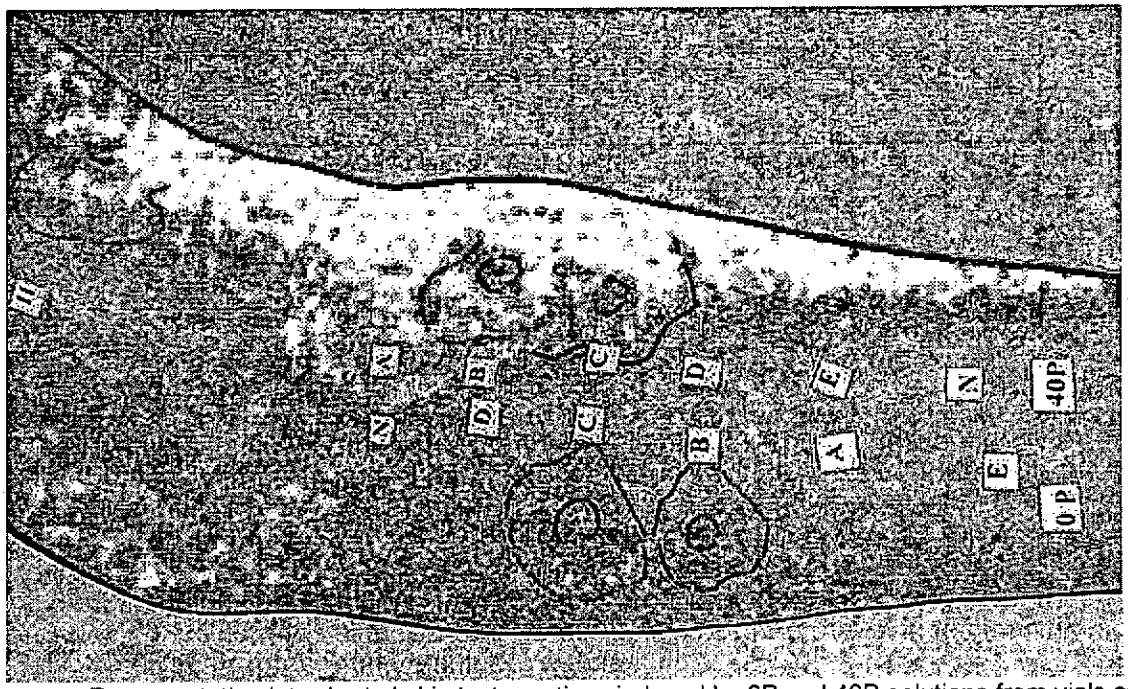

Fig. 1. Representative intradermal skin test reactions induced by 0P and 40P solutions from vials containing natural rubber closures B and C on the forearm of subject LA-9. *Ink lines* demarcate the wheal-and-flare perimeters observed at 15

minutes. *H*, Histamine positive control; *N*, saline negative control.

Table II summarizes the results of intradermal skin testing to the 0P and 40P solutions in the 12 subjects with LA and the 11 subjects without LA. Intradermal skin test reactions with 0P and 40P solutions from test vials A to E were all negative in the 11 subjects without LA. Two subjects with LA had positive skin reactions to solutions from unpunctured (0P) natural rubber closure–containing vials. Five subjects with LA experienced positive intradermal skin test reactions to 40P solutions stored in vials B, C, or both containing a natural rubber closure. The frequency of skin test positivity with solutions from natural rubber closure–containing vials was significantly higher in the LA group than in the non-LA group ($P = .003$). Moreover, the mean diameter of the wheal and erythema produced by solutions from vial B40P was significantly larger in the subjects with LA than in those without LA ($P = .007$ and .03, respectively; range for the group with LA, 5- to 12-mm wheal and 4- to 29-mm erythema). Wheal skin reactions produced by solutions from the other natural rubber closure–containing vials tended to be larger in the LA group than in the non-LA group, but the difference was not statistically significant (B0P, $P = .07$; C0P, $P = .3$; C40P, $P = .1$). Surprisingly, 2 subjects with LA exhibited a positive intradermal skin test reaction to solutions from vial A but not from vials D and E, all of which contained synthetic closures. In subject LA-7, retesting on the same day with a 0P solution withdrawn from a different A-vial caused negative results (data not shown). Subject LA-10 was also retested on a different day with an A40P solution and had a negative reaction (data not shown).

In vitro analysis

After decoding by the Parenteral Drug Association, 3 vial closures were identified as 100% synthetic (A, D, and E), and 2 were reported to contain 95.3% (B) and 66% (C) natural rubber (Table I). RAST inhibition analysis detected 6 and 7 AU of latex allergen per gram in the extracts from closures B and C, confirming that they contained natural rubber. No allergen (<0.5 AU/g) was detected in extracts from synthetic closures A, D, and E or any of the solutions stored in the 0P or 40P vials A to E (<0.5 AU/mL, Table I).

Discussion

Since the medical alert[12] on LA that was issued in 1991 by the FDA, physicians and patients with LA have expressed concerns about the potential for latex allergen exposure from natural rubber closures in pharmaceutical vials and the possibility of allergic reactions after parenteral drug administration. The US Pharmacopeia was prepared in 1996 to ban natural rubber in pharmaceutical vial closures[13] because satisfactory synthetic butyl and isoprene rubber stoppers were available that contained no latex allergen. This ban was, however, resisted by FDA staff, who believed there was insufficient data to show that natural rubber closures contribute to a significant risk for reactions in individuals with LA (personal communication from Yana Ruth Mille, FDA, to Joseph Valentino, JD, The United States Pharmacopeial Convention, Rockville, Md, February 19, 1997 [Ref. 2-97-001-T]). Their decision was based on the fact that natural rubber vial closures are manufactured from dry rubber that is known to release lower amounts of latex protein than dipped rubber products, such as latex gloves. Total protein tests performed on natural rubber vial closures by the FDA with the insensitive Lowry test failed to detect leached protein. Second, the FDA could only identify 2 reports of allergic reactions presumed to be due to natural rubber vial closures.[14] [15] In both cases further FDA investigation revealed that the vial closures implicated in these studies were in fact synthetic butyl rubber and not natural rubber, as had been previously reported by the authors.

Out of concern for the potential risk for latex allergen exposure from vial closures, hospital staff began removing pharmaceutical vial closures at the bedside of patients with LA and drawing medications into glass or latex-free plastic syringes. Infection control officers were concerned about this practice because it increased the potential for infections. Several hospitals, including our own, adopted a one-stick policy,[16] in which a single puncture was permitted through any vial closure before drug administration to an individual with LA. This practice minimized the risk of leaching from multiple punctures but did not eliminate the possibility that latex proteins may leach slowly from nonpunctured closures into pharmaceuticals during shipping and storage.

In this study we have demonstrated that latex allergens are released into physiologic solutions in contact with natural rubber vial closures. Two individuals with LA had positive intradermal skin test reactions to solutions from nonpunctured natural rubber closure–containing vials. Five subjects with LA reacted to the solution from punctured natural rubber closure–containing vials. Forty punctures was adopted as a worse-case condition for a multidose pharmaceutical vial (eg, insulin).

Seven of the 12 individuals with LA in the study failed to display positive skin reactions to solutions from vials with natural rubber closures, including the subject with LA with the highest latex-specific IgE levels in the serum. A likely explanation for this is the heterogeneity of IgE antibody responses to the spectrum of known latex allergens[17] [18] coupled with the possibility of differential leaching of various latex allergens from the natural rubber closures. Noteworthy are the negative skin test results in 4 of 5 subjects with LA with serum latex-specific IgE levels of less than 3 kIUa/L. It is unclear why 2 of the 5 individuals with LA with positive skin reactions to solutions stored in vials containing natural rubber closures also exhibited skin reactions to solutions from vials containing synthetic bromobutyl but not isoprene closures (Table II). Although these skin reactions were not reproducible, they warrant further study and suggest that accelerator chemicals or other ingredients in bromobutyl rubber may induce immediate-type hypersensitivity reactions in the skin. This hypothesis is, however, not supported by any data in the literature.

Two different natural rubber closure sources (B and C) were evaluated in this study. Closure B had a higher latex content as a percentage of weight, and we found higher intradermal skin test reaction rates with solutions from vial B than with those from vial C. One subject with LA reacted to solution from vial C but not from vial B. This suggests that the latex proteins released from the 2 rubber closures may differ.

Other investigators have analyzed solutions stored in vials containing natural rubber closures and syringe plungers for latex allergen content. Thomsen and Burke[19] evaluated 20 solutions from 16% rubber closure–containing vials punctured once and were unable to detect latex allergen with an inhibition immunoassay with a reported analytic sensitivity of 250 ng/mL. Their results are concordant with those from the present study, in which only extracted closures, and not solutions stored in punctured vials, contained detectable latex allergen, as measured by a comparable CAP inhibition assay (Table I). In another study, Jones et al[20] evaluated 3 bovine collagen preparations stored for 0, 3, and 45 months in contact with the rubber plungers of syringes for latex allergen content by skin prick testing. They observed that only 1 of 39 subjects with LA and 0 of 31 control subjects without LA had positive skin prick test responses to the collagen solutions stored for 3 and 45 months. This indicates that these injectable collagen syringes may contain low levels of latex allergen. The higher rate of observed positive skin test responses in the present study is attributed to greater sensitivity of the intradermal skin test technique to detect latex allergen in nanogram per milliliter levels while also maintaining diagnostic specificity.[21] We previously have shown that intradermal skin testing is at least a thousand times more sensitive than puncture skin testing and 100-fold more sensitive than RAST inhibition analysis for the detection of latex allergens.[21]

The percentage of the total number of pharmaceutical vial closures that contain natural rubber has declined in the recent years. Some closures manufactured today contain a mix of natural rubber and synthetic butyl rubber, with a ratio that can be as low as 13.4%.[19] The 2 closures containing 66% and 93.5% natural rubber and 3 synthetic closures used in this study were produced by using standard formulations by 3 companies who make the majority of closures used in commercial pharmaceutical vials. The problem remains that practitioners have no easy method for determining which products or lots of closures contain natural rubber. This information is often not readily available, even from the pharmaceutical manufacturers themselves.

Data from our study confirm that latex allergen can be released into pharmaceutical solutions simply by direct contact during storage in vials with natural rubber closures. We therefore conclude that both the pop-off and one-stick rule approaches for delivering medications from natural rubber–stoppered vials do not provide adequate protection for patients with LA. Although such contamination may not be hazardous for all individuals with LA, prudence dictates the removal of this allergen source from pharmaceutical closures because suitable latex-free substitutes are readily available. More immediately, however, uniform labeling of the natural rubber content of pharmaceutical closures would serve as a practical interim solution for minimizing risks to patients with LA.

We thank Chesapeake Biological Laboratories, Inc, Baltimore, Md, for providing the borosilicate vials and performing the filling, closure insertion, and capping of the test vials by using good manufacturing practice procedures. We also thank Dr Mary Elizabeth Bollinger for facilitating patient participation.

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There's No Place Like Home: A Qualitative Study of the Working Conditions of Home Health Care Providers

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Objective: *Home health care (HHC) is one of the fastest growing US industries. Its working conditions have been challenging to evaluate, because the work environments are highly variable and geographically dispersed. This study aims to characterize qualitatively the work experience and hazards of HHC clinicians, with a focus on risk factors for bloodborne pathogen exposures.* ***Methods:*** *The researchers conducted five focus group discussions with HHC clinicians and ten in-depth interviews with HHC agency managers and trade union representatives in Massachusetts.* ***Results:*** *HHC clinicians face serious occupational hazards, including violence in neighborhoods and homes, lack of workstations, heavy patient lifting, improper disposal of dressings or sharp medical devices, and high productivity demands.* ***Conclusions:*** *The social context of the home-work environment challenges the implementation of preventive interventions to reduce occupational hazards in HHC.* (J Occup Environ Med. *2007;49:327–337*)

I was recently asked . . . to place a midline in somebody's arm and the situation was just horrific. The living situation of the patient. Very cluttery, no place, we didn't have one, not even a table to use. (a focus group participant)

Health care is one of the largest US industries, constituting 13.5 million jobs.[1] The home health care (HHC) sector represents 5.8% of overall US health care employment and is one of the fastest growing parts of the economy.[1] For example, 56% growth in the home health aide occupation is predicted between 2004 and 2014.[2] Reasons for the HHC industry expansion include the increasing elderly population, availability of medical monitoring and advanced treatment technologies in the home, overall health care cost savings, and patients' preference for receiving care at home.[1] In Massachusetts, senior home health care has gained legislative support: a new law on long-term care choice,[3] adopted in August 2006, strengthens the ability of Massachusetts citizens to use Medicaid funds to compensate health services in private settings, rather than in nursing homes.[4]

This growing demand for HHC is placing pressure on agencies to hire more nurses and aides. Internationally, a study by Maybud and Wiskow revealed that the global health care professional shortage has fostered fierce competition, sometimes with aggressive recruitment campaigns.[5] A literature review by Janiszewski Goodin explored factors for the severe shortage of registered nurses in the United States and concluded that facilitation of the immigration of foreign health care professionals is a

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critical solution.[6] Unless the current trends change, a 20% deficit in the registered nurse workforce is forecast in the United States by 2020.[5,6] Consequently, it is not surprising that immigrant HHC clinicians increased by 114% from 1990 to 2000, compared with a 31% growth of US-born clinicians.[7] A review of direct care workers in long-term care revealed that half of home health aides were nonwhite and 89% of them were female.[8]

A significant occupational hazard in health care is exposure to bloodborne pathogens through sharp injuries and other routes. It is estimated that about 385,000 needlestick and other percutaneous sharp injuries are sustained annually by hospital-based health care clinicians—an average of 1000 sharp injuries a day.[9,10] In addition to the physical and mental toll on injured workers and their families, sharp injuries carry a high monetary cost. It is estimated that short-term follow-up medical treatments range from $50 to $3800 in the United States, and long-term treatment associated with HIV, HBV, or HCV seroconversion can reach hundreds of thousands of US dollars.[11] Unreported sharp injuries and blood/body fluid exposures, estimated to range from 40% to 80%,[9,11,12] present a 2-fold dilemma according to Wilburn[12]: 1) Injured health care workers often do not receive timely post-HIV exposure prophylaxis that may be up to 80% effective against HIV infection; and 2) the magnitude of the problem remains unknown and challenges the implementation of appropriate interventions, such as the implementation of safe work practices and the development of improved medical devices with features of sharp injury prevention.

To date, most documented information about health care hazards originates from hospitals. Only a few studies have evaluated health and safety in HHC. Perry et al examined sharp injuries in homecare and inpatient settings by analyzing EPINet data (Exposure Prevention Information Network, International Health Care Worker Safety Center, University of Virginia) of 84 hospitals from 1993 through 1998 and HHC agencies affiliated with these hospitals.[13] Their analysis revealed that 40% of reported sharp injuries in homes were associated with blood drawing or intravenous access procedures, compared with 34% for the same procedures in hospital patient rooms. In the home setting, 48% of percutaneous injuries occurred either after the use of a sharp medical device (sharp) or during sharp disposal, compared with 38% for the same injury mechanism in hospital patient rooms.[13]

Haiduven and Ferrol noted that in the United States, more HIV patients are being cared for in the home setting than in other health care settings and that patients who are hepatitis C positive, who may not be aware of their HCV status, are receiving home care for other conditions.[14] Homecare patients infected with HIV require more injections or intravenous administrations than those with noninfectious conditions,[15,16] making blood exposures all the more dangerous for HHC clinicians caring for HIV-positive patients. More research is needed to collect information from home settings systematically, where clinicians are vulnerable to bloodborne pathogen exposures as well as other workplace hazards so that effective occupational health interventions can be implemented.

Project SHARRP

To investigate the risks associated with blood and body fluid exposures in HHC, the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) awarded a 4-year grant (2004–2008) to the School of Health and Environment at the University of Massachusetts Lowell (UMass Lowell). This research undertaking was named Project SHARRP, which stands for Safe Homecare and Risk Reduction for Providers. In addition to UMass Lowell, the SHARRP research team includes the Occupational Health Surveillance Program of the Massachusetts Department of Public Health. A structured working relationship was established with several industry and union partners that agreed to provide access to their staff or constituency for conducting the research.

Objectives

This paper examines findings of the initial qualitative research phase of Project SHARRP. The qualitative assessment, composed of five focus group discussions and ten in-depth interviews, had the following objectives: 1) to investigate and describe the nature of HHC work and its associated occupational health risk factors, circumstances surrounding sharp injuries and other blood exposures, as well as availability and efficacy of safety medical devices; and 2) to compare the two methodologies used in order to evaluate the type of information they yielded.

Materials and Methods

Two types of qualitative research methods were employed: clinician focus groups and specialist/manager in-depth interviews. The intent of the focus groups was to elucidate the general nature of work as well as risk factors regarding exposures to bloodborne pathogens in HHC from the perspective of clinicians in nonsupervisory positions delivering homecare services. The specialist interviews sought to complement the focus groups by providing insights into bloodborne pathogen exposures and other workplace hazards, safety policies, medical device procurement practices, and other topics from the perspective of agency managers, supervisors, specialists, and health care union representatives. Study materials and protocols were approved by the Institutional Review Board (IRB) of UMass Lowell. Agency and union representatives critiqued and assisted

in developing study participant recruitment materials.

Study Population

In the United States, major occupations that provide HHC services include: nurses, therapists, home health aides, and personal and homecare aides.[1] This study focuses on nurses and home health aides, the occupations most likely to encounter sharp medical devices (sharps) and blood and body fluid exposures.

Recruitment of Study Subjects

We engaged each partner agency and union in recruiting participants for a focus group of their workers or members to be held in a private room at their site. At one large agency, focus groups were planned at two offices: a larger city office and a small suburban office. Two criteria were required for participation: 1) minimum age of 18 years, and 2) experience in handling sharps in homes or working in homes where there is a likelihood of exposure to blood and body fluids. With the assistance of our agency/union contact, HHC aides and nurses received packets containing an informational brochure, a letter of invitation, and reply materials for participating in a focus group. These were distributed through work mailboxes (for agency staff) or by mail (for union members). Interested candidates completed the reply form and returned it in the attached prepaid envelope by mail or to a secure collection box in the workplace. The group size limit was set at ten participants, with the intention of randomly selecting ten names from the group of volunteers. Seventeen nurses and seven home health aides (24 total) were recruited from all agencies and unions.

For the specialist/manager interviews, our agency and union contacts were invited by phone and follow-up letter to participate in an in-depth interview. They were also asked to identify additional interview candidates belonging to any of these categories: 1) infection control practitioners, 2) health care union leaders, 3) occupational health nurses, and 4) managers or program coordinators of any clinical HHC units where sharp instruments are used. Ten agency managers and union representatives were recruited from all agencies and unions. Their health care experience ranged from 10 to 45 years.

Conduct of Focus Groups and Interviews

Focus groups and interviews were conducted at agency or union offices. A stipend of $50 per participant was paid to the individual at the time of the session if the session was outside work hours. If the session took place during work hours, the individuals were compensated by their agency at their regular rate, and the stipend per participant was paid to the agency.

All focus groups were moderated by the same researcher, supported by assistants who took handwritten notes, oversaw tape recording, and performed other functional tasks. Interviews were conducted by investigators with professional experience matching that of the interviewees, such as nursing, management, or trade unions. After obtaining a signed consent, a tape recorder was activated and the discussion commenced, following a standard script. A few minutes before the end of the allotted time (90 minutes for a focus group or 60 minutes for an interview), the tape recorder was stopped and participants were offered a few minutes to add unrecorded comments. The session closed with the distribution of anonymous participant evaluation forms.

Follow-up

After each focus group and interview, recording tapes were copied and sent to a transcription service. The research team verified all typed transcripts and analyzed them thematically using NVivo qualitative research software, version 2.0 (QSR International Pty Ltd, Doncaster, Victoria 3108, Australia). All participants received a cover letter thanking them for their participation, a summary of the aggregate findings of all focus groups, and a voluntary feedback form with a prepaid mailback envelope. Interview participants received a transcript of their own interview session.

Results

Nature of HHC Work: Advantages, Challenges, and General Work Hazards

Tables 1 and 2 show the main advantages and challenges of working in HHC as well as examples of potential hazards, as reported by the interviewees and focus group participants. Many study subjects had work experience in the hospital setting prior to working in HHC. The chief advantages were identified as flexibility, independence, and autonomy, especially for clinicians who have childcare responsibilities. The home-work environment is diverse and constantly changing with patients' ages ranging from newborn to 100 years old, different disease diagnoses and patient personalities, as well as various housing environments. HHC clinicians often bond with patients and families, witness patients' health progress, and/or receive gestures of appreciation and gratitude—all of which create a strong sense of meaning for their work. One focus group participant described:

> *She [the hospice patient] took this big bag out, and she [had] hand knitted an afghan for me. She said, "I wanted you to have this . . . I wanted to hand it to you personally before I go . . ." . . . I wrapped up in that the other night, and I just [thought] about her, you know. The hands, here's a person that's in hospice, they knitted a blanket . . . That's what makes this job worthwhile, not the gift, the love.*

Another participant in the same focus group expressed sadness when describing the loss of two patients after long-lasting care relationships:

> *I had two people. One I worked for nine years and eight months, until she died. She was 99. And the other one I worked with 10 years. She was almost 90. I don't think I ever want to work that long with one person again, because they get so attached.*

TABLE 1
Advantages and Challenges of Home Health Care Described in Focus Groups and Interviews

		Cited in: Focus Groups	Interviews
Advantages			
Flexibility, independence	• Accommodates family responsibilities	✓	✓
	• Work not restricted within four walls	✓	✓
Long-term patient relationships	• See patients' health progress	✓	
	• Learn to know patients and families	✓	✓
Acts of appreciation and gratitude by the patients		✓	
Diversity of nursing	• Diversity of patients, diagnoses, and environments	✓	✓
	• Teach and support patients to improve their lives (eg, teach a teenage girl how to draw blood off IV line)	✓	✓
	• Multitasked work duties		✓
Informality of work		✓	
Supervisor support		✓	
Patient's choice bears importance	• Patient chooses to stay and be cared for at home		✓
	• Patient has position of power at home (vs facility-based care setting)		✓
	• Choosing to die comfortably either at home or in hospice		✓
Cost-effectiveness of healthcare			✓
Challenges			
Detailed paperwork	• Medicare billing, insurances, payment reimbursements	✓	✓
	• Paperwork often continues at home	✓	
Long-distance travel	• Long-distance driving	✓	✓
	• Waiting for public transportation (eg, in the city areas, especially in the dark)	✓	
Emotional attachment	• Patient dies	✓	
Insensitive, cranky, or moody patients/family members		✓	
High patient workload		✓	
Lack of information about patient's health condition	• Concern of health aides	✓	
Culture shock	• Extreme poverty in some neighborhoods	✓	
Isolation	• Some situations where a nurse does not have skills or lacks needed medical supplies		✓
	• No timely backup, or help may not be available		✓
Time constrains and productivity pressures			✓
Communication boundaries	• Difficulty reaching physicians in the field		✓
	• Provider-patient language differences		
Less salary than in the hospital setting			✓
Possibility of a sentinel event	• Sudden health deterioration of a patient		✓

As the biggest challenge, both the focus group participants and interviewees described detailed paperwork for medical care insurance, billing, and reimbursement. Moreover, the workday often does not end when the last patient is seen because paperwork may need to be completed at home:

> *I love taking care of the patients but spending hours every night on the computer is very daunting and it's very hard to do it day in and day out which is what you have to do. And it eats into your family time and I think that's very difficult.*

All focus groups described long-distance driving as exhausting and time-consuming. One interviewee pinpointed a challenge which clinicians may encounter when being out in the field alone: as difficulties or uncontrollable situations arise (eg, security and safety concerns, lack of supplies, or needing specific clinical skills that a nurse or home health aide may lack), backup support may not be nearby and a physician may not be available by phone on a short notice. All study subjects were concerned about the threat of violence in a patient's neighborhood or inside a patient's home. In addition, clinicians care for patients who live in poverty. Thus, they encountering hazardous conditions that their patients face every day, such as neighborhoods where drug use is widespread, guns in homes, pest infestations, unsanitary conditions, indoor air-quality concerns (eg, due to deteriorating buildings and cigarette smoking), clutter, rickety stairs, inadequate lighting, and unshoveled walkways. Other hazards include ag-

TABLE 2
General Work Hazards Described in Focus Groups and Interviews

Work Hazards		Cited in: Focus Groups	Cited in: Interviews
General security/personal safety concerns	• Unsafe neighborhoods (eg, drugs, guns, robbery, violence)	✓	✓
	• Violent or unstable patients/family members	✓	✓
	• Clinician out in the field alone		✓
	• Working during after-dark hours		✓
	• Snowy/slippery walkways, clutter, rickety or unsafe stairs, inadequate lighting, fire hazards	✓	✓
	• Entering an unknown place, not knowing the person who lives in the house	✓	
	• Pets (dogs [can bite when sensitive to sick master], birds, cats)	✓	
Rapid work pace	• Clinicians may feel rushed to complete an assignment, even a risky procedure		✓
	• Dealing with uncontrollable situations in a hurry and alone		✓
Long-distance driving	• Accidents	✓	
Hygiene issues	• Insects, rodents, hot indoor air, and other indoor air-quality concerns (smoking)	✓	
Lack of workstations	• Carrying out risky sharps use procedures	✓	
Heavy lifting and moving	• Heavy lifting and moving of patients or other items	✓	✓
Lack of supplies		✓	
Allergies/irritations	• Cleaning chemicals, latex gloves	✓	
Exposures to bloodborne pathogens (see Table 3)		✓	✓

gressive animals and heavy patient lifting. In-depth interviewees identified underlying reasons for hazardous incidents. In addition to being out in the field alone, other root-causes included time constraints, rapid work pace, and productivity pressures—all of which may trigger clinicians to conduct even risky medical procedures in haste. In one focus group, the participants described the unpredictable nature of hazards. Often clinicians must enter a house where they do not know its residents, relationship dynamics between family members and friends of the residents, and the living environment inside.

Sharp Injuries and Blood Exposures: Circumstances and Underreporting

Table 3 summarizes circumstances related to sharp injuries, blood exposures, and near-exposures sustained by or familiar to study participants. The focus group discussants attributed sharp injury and blood contact risks to syringes and lancets left uncovered in various places in the house, lack of proper sharp disposal containers, inadequate training for using the variety of medical devices encountered in the home, lack of proper workstations for procedures using sharps, sharp devices without safety features, diabetic and cancer patient treatment care tasks, dangerous distractions during a medical procedure (eg, pets, children), episodes of sudden profuse bleeding (eg, bleeding tumors and amputations), and wound care tasks. Patient-related risk factors included violent, confused, or uncooperative behaviors; sudden movements by patients or family members during procedures involving the use of a sharp device; improper dressing disposal practices; and unsafe sharp disposal habits.

The study subjects raised various reasons for not reporting sharp injuries and blood contacts, many of which correspond to those previously cited: time-consuming post-injury process; frightening possibility of infection and the anxiety surrounding the post-exposure process; fear of being blamed as careless or perceived as a "bad nurse" by the employer; disease history of a patient (eg, an elderly patient thought not to be an infection risk); nonsevere exposure (scratch vs deep puncture); possible consequences on health insurance coverage (eg, increasing fees, future difficulties getting insurance); fear of implications for present or future job prospects; and lack of health insurance. "The big deal factor" and "the fear factor" were brought up repeatedly in both focus groups and interviews. "The big deal factor" combines reporting taking too much time, dedicated clinicians not wanting to disrupt the workday, unclear reporting procedures, and not having a health care facility in the immediate vicinity when the injury occurs. "The fear factor" comprises worries about developing an illness and not wanting to face it, being regarded as a careless clinician, and fear that the incident would adversely impact employment status. "The health

TABLE 3
Factors Related to Blood and Body Fluid Exposures, Sharp Injuries, or Near-Exposures as Expressed in Focus Groups and Interviews

Factor		Cited in: Focus Groups	Cited in: Interviews
Sharp disposal or management	• Injuring others through trash, lack of disposal containers, overfilled containers, poor container design (too small or too big, no leakproof cover)	✓	✓
	• Poor disposal technique either by patient or clinician (eg, handing over a syringe in a Styrofoam cup to a coworker)		✓
	• Patients leaving sharps around in the house	✓	
Patient moving when clinician uses a needle or sharp item		✓	✓
Wound care	• Dressing change/disposal, treating bed sores, irrigation/ forceful irrigation, dressing a deep wound, dressing comes off, debridement	✓	✓
Certain medical conditions/treatments	• Lancets, pens, blood-draw, IV lines, insulin syringes (eg, used multiple times and left out unshielded)	✓	✓
	Examples:		
	• Incidents with blood-drawing equipment (eg, injuries with butterfly needles when patient flinches, Vacutainer explodes in the hand, blood-draw needle that extends through a Vacutainer adapter sticks, splashes if syringes used for blood drawing)		✓
	• Incidents with IV equipment (eg, Huber needle bounces [de-accessing and accessing a Port-A-Cath], "piggyback tubing")		✓
	• Pulling needle out from a vein when the tourniquet is tight	✓	
	• Amputations, bleeding tumors	✓	
Patient falls and bleeds			✓
Malfunctioning/ineffective safety sharp device		✓	✓
Clutter/lack of workspace		✓	✓
Recapping habits		✓	✓
Exposure of health aides	• Bathing a patient, encountering sharps when housekeeping (eg, in linen)		✓
Incidents in hospice	• Patient may bleed out before dying; not enough time to put gloves on		✓
Glove issues	• No glove use during blood work, slippery gloves		✓
Carrying sharp supplies in nursing bag	• Traveling with sharps (eg, disposal container opened and syringe fell out)	✓	✓
Different sharps supply vendors	• Educating clinicians on all existing safety sharp products		✓
	• With a same agency, different products may be used for a same medical procedure		✓

insurance factor"(ie, complete lack of health insurance, inadequate health insurance, or possible negative consequences affecting personal health insurance) also emerged as an underreporting theme.

Preventive Measures, Safety Sharps, and Purchasing Practices

Study participants provided views and recommendations for preventing exposures to bloodborne pathogens (Table 4). Both research methods highlighted the importance of providing properly designed medical devices with sharp injury prevention features and sharp disposal containers. Interviewees stressed the need for medical device designers to communicate with users and incorporate their feedback into improved product design.

In a focus group representing one HHC agency, more than 90% of medical devices used were reported to be devices with sharp injury prevention features. In another group, participants described circumstances in which safety features on devices were entirely absent, for example, in lancets used by diabetic patients. When sharps with safety features were available, many focus group discussants thought that safety was improved (eg, retractable needles and syringes were repeatedly cited as protective). In addition to retractable needles, butterfly needles with a "stiff section" that minimized unexpected movement of the device, needleless IV systems, blood-draw-

TABLE 4
Advice on Prevention of Blood Exposures and Sharps Injuries and Improving Exposure Reporting as Expressed in Focus Groups and Interviews

		Cited in:	
		Focus Groups	Interviews
Safety sharps design	• Easy to use	✓	
	• Needleless systems	✓	✓
	• Designers collaborate with sharps users		✓
	• Improving retractable needle design; no splashbacks or pain to patients		✓
	• Device fully tested before market introduction		✓
	• Reduced cost for safety devices		✓
Sharp disposal containers and practices	• Being prepared with a container ready	✓	
	• Improved container design		
	• Safe sharp containers for patients (eg, diabetics)		
	• One disposal container for one sharp		
	• Have two sharp disposal containers ready		✓
	• Disposal containers provided by patients		
	• Leakproof cover for disposal container		
Training of clinicians	• Not punished when reporting injuries	✓	
	• Pre-event planning for an injury (patient care plan)		✓
	• Educational intervention after sharps injury/blood exposure		
	• Reporting is the right thing to do		
Safe work area	• Setting up a clean, safe work area for sharps use	✓	
	• Work area that is clear of distractions	✓	
Work posture	• Heavy patients should recline before sharp insertion	✓	
	• IV or blood draw procedure, set the patient in a position you are comfortable with		✓
Dressing disposal	• Improving current awkward practice		✓
Patient education		✓	
Safe butterfly needle use	• When a needle is in the patient, keep your hand on the needle in case the patient flinches		✓
Consistency among manufacturers and vendors	• Standardizing sharps for improved safety	✓	
Compensated involvement of clinicians	• Participating in committees/meetings on bloodborne pathogen prevention		✓
Injury and exposure reports	• Using reports as lessons learned from staff safety and patient safety perspective one agency reporting form for all workplace injuries		✓
Home health aides/personal care attendants (PCAs)	• Aides need better information about patient health status	✓	
Standard precautions	• Consistent use of personal protective equipment (gloves, gown, face protection)	✓	
	• Using gloves when drawing blood		✓

ing equipment with sliding sheaths, and safety Huber needles (with a self-blunting tip, activated when removing the needle from an IV port) helped make their work safer. However, sometimes safety mechanisms did not activate properly or otherwise failed to protect nurses. For effective use of a device with sharp injury protection features, adequate training and practice are necessary, especially when first introduced and implemented. In addition, patients can become agitated if the device use seems complicated. The lack of consistency and lack of standardization across device manufacturers were identified as risk factors. Numerous styles of a single medical device (eg, IV equipment and Glucometers) pose training challenges. Lack of standard design is a problem especially when an insurance agency arranges for medical products to be delivered to the home, often selecting devices different than those provided by or familiar to the homecare agency clinicians.

All in-depth interviews elucidated incentives and barriers to the purchase and selection of medical devices. A representative of one private HHC agency described her agency's practice of procuring medical devices through a national distributor of medical supplies. If the agency's preferred medical devices are not carried by the distributor, the distributor tries to acquire them elsewhere. If unsuccessful, the agency can purchase them someplace else. In a hospital-affiliated HHC agency, medical

devices are often ordered through the hospital's purchasing department. A patient's health insurance may also influence the medical device used in the home. One manager explained that insurance companies have purchasing contracts with certain device vendors; the lowest price is often the determining factor for treatments and devices; hence, many homecare patients do not necessarily receive the safest or the easiest-to-use product.

Discussion

Comparison of Two Methodologies

McDonald and colleagues have highlighted the effectiveness of qualitative methods for understanding job tasks and estimating occupational exposures, particularly for autonomous workers who tend to be dispersed with no fixed workplace.[17] Our study supports this assertion. The data gathered for this study, using open-ended questions in focus groups and interviews, permit a detailed, complex, and structured analysis of the hazards of work in HHC. The picture that emerges is much fuller than if we had first imposed close-ended survey questions on the study population. These qualitative methods also produced more balanced data that may lead to better interventions. For example, in addition to the hazards, we learned about the many positive aspects of HHC. The best interventions should eliminate or minimize the hazards, without eroding the benefits.

The focus group narratives reflected clinicians' personal experiences encountered at homes when caring for patients; details were often vivid and emotionally powerful. The interviews with managers and union representatives provided an overview of HHC work, rather than specific personal clinical experiences. They provided factual examples on incidents, practices, and policies either at the workplace or in a larger health care community. The in-depth interview narratives illustrated underlying causes of sharp injuries and hazardous exposures (eg, time constraints, productivity pressures, isolation) as well as broader health policy concerns. For example, the following is an opinion by a HHC agency interviewee:

> *I'm actually a big advocate in universal health care . . . and even though there are drawbacks to universal health care, I really think that it takes away that middle insurance huge issues [sic] that complicate our mission tremendously. So it's the paperwork part.*

In particular, Table 3, which depicts blood contact, sharp injury, and near-exposure risk factors, demonstrates how the two study methods generated diverse data perspectives. Of 20 examples, only 8 were reported similarly in both the focus groups and in-depth interviews. Together, the data collected by these two methods provide a more informed evaluation of HHC work than would be obtained with either method alone. In focus groups, "the memory work effect" and experience sharing are significant research methodology advantages. One individual's narrative may awaken "dormant" memories in other focus group discussants to enrich the conversation, or when someone initiates sharing a sensitive experience (eg, blood exposure), others are likely to talk openly about their own experiences. Because the focus groups were limited to frontline clinicians, it was not possible to obtain detailed information on topics occurring at the agency level, such as device purchasing and safety policies. Therefore, in-depth interviews with specialists were necessary. If possible, it is better to conduct focus groups and interviews during working hours, provided there are no adverse consequences to the participants. Although we provided a $50 incentive for focus group participation, many clinicians said that this was not necessarily a strong motivator to participate after working hours, especially if anyone had childcare responsibilities or long travel to the interview venue.

Dedication Versus Dangers

The clinicians who participated in the focus groups uniformly reflected commitment to their profession, satisfaction in forming meaningful relationships with patients, sensitivity to the patient's suffering, and awareness of personal safety concerns in the field. A home visit requires circumstances that are not necessarily encountered in facility-based care job settings: for example, frequent long-distance driving, lack of workstations, housekeeping (clutter) and hygiene issues, sudden disruptions (pets, kids, family members), and most of all being alone in the field without support when an unexpected, difficult situation arises. HHC nurses and home health aides face a wide range of physical and psychosocial hazards. Violence emerged as an important occupational hazard, especially in neighborhoods of pervasive drug use. Although clinicians are advised to leave an unsafe situation, it must first be assessed as "dangerous." Furthermore, they face a range of serious ergonomic risk factors, namely lifting and moving patients as well as awkward and static postures. For 2004, the Bureau of Labor Statistics reported an incidence rate of 5.3 nonfatal occupational injury and illness cases per 100 workers for home health care services. The overall private industry incidence rate is 4.8 similar cases.[18] Based on 1995 to 1996 West Virginia workers' compensation data, Myer and Muntaner analyzed the types of 386 total injuries recorded for HHC workers: overexertion injuries and falls accounted for 63% of total injuries, while motor vehicle accidents accounted for 13.5% of injuries.[19] In many HHC settings, equipment and assistance for lifting and moving or for responding to a patient's fall may be nonexistent or minimal.[19]

Clinicians' dedication to their profession and patients emerged clearly as they provided views on preventing

sharp injuries and blood exposures (Table 4). While highlighting the importance of availability of properly designed devices with engineered sharp injury prevention features and sharp disposal containers, they also stressed personal responsibility for safe work practices (eg, setting up a clean and safe work area where procedures utilizing sharp devices are performed, and eliminating extraneous distractions). In one focus group discussion, the sense of personal responsibility and accountability became intense. An "our-own-fault" type of self-blame emerged several times, for example:

> *An overfilled sharps container is nobody's fault but our own for not checking on them . . . Because we keep them in the car. So it's not often that we use them. We don't use them every day. So you get your assignment in the morning and you're thinking OK, I've got my sharps and you get the laboratory stuff you need but then when you go to use it and you're already at the patient's home, [my colleague] is smart, she has a backup [disposal container], I don't.*

> *Maybe [a reason for] under-reporting is because most of the time it is our fault from carelessness or something like that. So maybe we're feeling oh, God, you know . . .*

In any industry, both the self-blame and "worker-error" mindset create a challenge for implementing effective occupational health interventions. When safety systems function well, they should "design out" or minimize the potential for incidents, regardless of whether the incident is caused by the user, patient, or work environment. In the health care industry context, medical devices, including those for blood drawing and medication administration, should be designed in such a way that sharp injury risks are minimized.

Beltrami et al[20] assessed risk factors for blood exposures among HHC nurses and identified 14,744 home visits that included at least one sharp use procedure. During these visits, gloves were worn during 52% of the time; masks, 5%; gowns, 3%; and goggles or other eye protection, 2%.[20] Their findings raise concerns about the application of standard precautions that require using these personal protective items. Linkages with improved workplace infection control practices and management commitment for occupational health interventions have been identified. Green-McKenzie et al have found strong associations among infection control practices and 1) the availability of personal protective equipment, 2) the presence of engineering controls, and 3) organizational commitment to safety.[21] Gershon et al introduced a safety climate scale to measure hospitals' safety culture with respect to management of bloodborne pathogens. It was significantly associated with both employees' compliance with safe work practices and the number of exposure incidents.[22]

Underreporting Dilemma

Many clinicians in our study reported personal experiences with sharp injuries and blood exposures. They also described many barriers to reporting an injury or exposure. In a study of 1163 nurses employed in a variety of health care settings, Brown and colleagues found that reporting of work-related injuries was reduced when nurses felt that their work culture fostered a climate of blame.[23] Nurses were also less inclined to report work-related injuries when working in nonstandard work arrangements.[23]

Our study found that reporting a blood exposure can be a time-consuming and frightening "big deal" and that these factors also can influence reporting. Factors related to the health condition of the patients, such as infection status, also influence reporting. These findings are consistent with Backinger and Koustenis, who determined that HHC clinicians may be more likely to report needlestick injuries when a patient is known to be infectious; when the fear of infection is low, the commitment to report remains low.[15] Haiduven identified the following reasons for not reporting exposures: lack of knowledge regarding the need to report, time constraints, dissatisfaction with reporting and follow-up procedures, and confidentiality concerns.[24] Gershon et al report that most hospital-based clinicians found their follow-up care after bloodborne pathogen exposure to be excellent.[22] Our focus group discussants also noted that hospitals have more supportive reporting of bloodborne pathogen exposure and follow-up system than the HHC setting. Post-exposure follow-up and treatment can be initiated quickly in hospitals, whereas clinicians providing home-care might be miles away from the nearest health care facility. In another study, Gershon and colleagues determined that low reporting rates among workers in correctional health care facilities may reflect the difficulty of receiving post-exposure care; consequently, only serious bloodborne pathogen exposures are reported.[25]

Both the focus groups and interviews raised "the health insurance factor" as an underreporting issue. One of our interviewees highlighted that many home health aides stand at the margins of the workforce and their jobs can be very temporary. Because steady employment is paramount, it is unlikely that they would choose to report a needlestick or blood exposure. The "health insurance factor" also indicates that there is a lack of understanding about workers' compensation insurance coverage. This lack of understanding highlights the need for better education by employers of both the reporting procedures and workers' compensation coverage.

Social Context of Home as a Workplace

Clarke et al suggest that needlestick injuries can serve as a proxy for a range of safety and quality issues; hence, it is vital to understand the organizational context in which they occur.[26] For hospital settings, such organizational problems as understaffing, inadequate administrative support, and poor morale were identified as risk factors. As in hospital

settings, sharp injuries and blood exposures can serve a proxy for safety and quality practices in homecare settings. Regrettably, home as a work environment is too often assumed to be "comfortable" and not a priority for occupational health interventions. However, many HHC tasks are similar to those performed in hospitals, including blood drawing, administering medication through injection or intravenous therapy, and wound care with bloody dressings. Each of these presents risks of infection from bloodborne pathogens.

It is vital to acknowledge the importance of gender and race or ethnicity in the homecare work environment. The vast majority of HHC practitioners are women,[8] and the number of foreign-born HHC clinicians has been increasing.[7] Results from Duke University's Health and Safety Surveillance System show an elevated risk of blood and body fluid exposure among Hispanic employees.[27] Through her study of HHC workers in Montreal, Cognet determined that a HHC provider's job is not only associated with heavy physical risk factors and emotional burdens, but also with invisibility of HHC providers' skills that the society has molded into an easily quantifiable task list with little value.[28] Despite the problems, the study notes that HHC providers often contribute more than what is required, declare a love of their labor, and feel a strong sense of accomplishment.[28] Our study identified similar findings. Despite the hazards, most HHC clinicians found their work profoundly meaningful, citing rewarding relationships with patients and their families, flexibility and independent work (compared with the hospital setting), and regular confirmation that they make positive impacts on people's lives.

Conclusions and Recommendations

The Massachusetts legislation to support health care of the elderly population in private settings rather than nursing homes[3,4] indicates that the HHC industry will continue to grow. Despite its social and economic importance, hazardous job exposures are still poorly characterized in HHC. We hypothesize that this is because the social context of the caregivers and their work environment makes them invisible. The home is not recognized as a workplace, the workers are predominantly female, and many are immigrants. Our qualitative study has demonstrated that HHC clinicians face regularly social and physical hazards, including those associated with bloodborne infection. Research is needed to quantify occupational risks and identify effective interventions. Health and safety interventions should be aimed at reducing harmful exposures while preserving or enhancing the meaningful aspects of the job.

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