Health Effects Associated With Medical Glove Use

Natural rubber latex allergy is recognized as an important public health issue and continues to be addressed in both the public and private sectors through rule making, educational efforts, and research.[1] Coincident with the increased recognition of glove reactions in the late 1980s and clinical natural rubber latex allergy in the early 1990s, the US Food and Drug Administration (FDA) began to receive reports describing various health effects, such as contact dermatitis and allergic reactions, that were associated by the reporters with the use of medical gloves.[2] The term *medical glove,* from the FDA's regulatory perspective, refers to a wide variety of glove products with specific barrier claims that are labeled and marketed for medical use as either surgeon's gloves or patient examination gloves.[3] Currently, medical gloves are required to receive FDA premarket clearance under section 510(k) of the Food, Drug, and Cosmetic Act before they can be marketed legally in the United States. They also are subject to mandatory reporting requirements outlined under the FDA's Medical Device Reporting (MDR) regulations.[4] Gloves that are not labeled for medical use, such as cleaning gloves, painter's gloves, and hobby gloves, are not covered under the FDA's jurisdiction. The FDA's reporting system does not capture problems directly associated with the use of consumer glove products. The aim of this study was to provide a descriptive analysis and summary of health effects reported to the FDA in association with the use of medical gloves made from either natural rubber latex formulations or synthetic materials.

A B S T R A C T

Adverse reactions to medical gloves represent an important public health issue. Accordingly, there is increasing interest in understanding the information reported to the US Food and Drug Administration (FDA) describing health effects associated with the use of medical gloves. This article provides a retrospective analysis and summary of health effects associated with medical glove use reported to the FDA. The FDA's medical device adverse event databases were searched via computer using keywords to identify reports of reactions associated with any type of medical glove. Demographic and clinical information abstracted from these reports was used to perform frequency and trend analyses. The reported medical glove-related events, including the noted trends in reporting, suggest the need for further study and continued monitoring of such reports. ***AORN J*** **76 (July 2002) 88-96.**

THE FDA'S REPORTING SYSTEM

Since 1973, the FDA has maintained a nationwide voluntary reporting program for adverse events associated with medical devices. Currently administered as part of the FDA's MedWatch program, the program accepts information voluntarily submitted to the FDA by health care providers and consumers. Beginning in 1984, the FDA's MDR regulations require device manufacturers and importers to submit reports to the FDA concerning medical device-related deaths, serious injuries, and device malfunctions. Since 1991, facilities that use medical devices also have been required to report device-related deaths and serious injuries to either the manufacturer or the FDA. Facilities that use medical devices subject to mandatory reporting include hospitals, nursing homes, outpatient diagnostic and treatment facilities, ambulatory surgery centers,

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ambulance services, and home health care service providers. Private offices of physicians, dentists, or other health care professionals are exempt from the FDA's mandatory reporting requirements, but practitioners can report problems voluntarily to the FDA. From 1990 to 1996, medical device distributors also were required to report certain types of events. Both the mandatory and voluntary reporting systems continue to capture information about medical device-related adverse events, and the FDA's adverse event databases currently contain more than one million reports. The FDA uses the information reported through these programs to assist in the early identification and characterization of emerging medical device problems and related public health issues.

METHODS

The FDA's medical device adverse event databases were searched via computer using text search criteria (eg, red, rash, allergic, anaphylaxis, asthma, wheezing, reaction, swollen, swell, itch, passed out) developed to identify reports describing local or systemic reactions associated with the use of any type of medical glove. The search covered information submitted from the inception of the database in 1973 through March 31, 1999. Duplicate reports describing the same event were identified and merged into a single adverse event report, yielding a total of 2,639 candidate reports. A secondary manual review of the candidate reports resulted in the identification of a subset of 2,396 unique reports of glove-associated reactions that served as the subject of the study.

Certain prescribed information (eg, patient age, gender, location of event) must be included in mandatory adverse event reports submitted to the FDA unless it cannot be obtained by the reporter. Since 1993, voluntary reporters have been asked to supply basic data elements as part of a standard adverse event report format developed by the FDA, but voluntary reports are accepted regardless of whether the minimal requested information is provided by the reporter. Narrative information is requested for all adverse event reports; however, the FDA's adverse event databases are not designed to capture and code detailed clinical information associated with an individual device-related event, and there are no specific content requirements for the narrative sections of the report form. When supplied, the quality of narrative information varies substantially between reports.

This study required the use of a secondary database and the development of a unique coding scheme that allowed for manual abstraction and organization of the coded narrative and information of interest. The coding system entailed the creation of dichotomous and nominal variables to represent the information of interest in the reports for entry into the secondary database. The computerized database was created with checks to assume the correct entry of values for the variables. The manual abstraction was intended to identify, categorize, and record demographic and clinical information contained in the selected reports, particularly when such information was provided exclusively in the narrative sections of a report. Clinical information included symptoms, physical findings, or diagnostic terms that were reported in association with a specific glove reaction. This information then was used to assign each report to one or more of the following clinical response categories:

- asthma,
- anaphylaxis,
- immediate hypersensitivity,
- dermatological response, and
- nondermatological response.

Frequency analysis and chi-square tests for statistical significance were performed using Statistical Analysis System software. The Cox-Stuart test was used to analyze trends. Some reports describe events involving multiple people or an unspecified number of people. In this study, all analyses were based on the total number of reports, not the number of affected people or the number of distinct health events described in a specific report.

RESULTS

No reports associating the use of medical gloves with a local or systemic reaction were received by the FDA from the inception of the reporting system through 1984. From Jan 1, 1985, through March 31, 1999, the FDA received 2,396 reports describing either local or systemic reactions associated with the use of medical gloves. Sixty-five (3%) of these reports were received before 1990. Although the FDA first received reports associating local or systemic reactions with medical glove use in 1985, the actual dates of reported reactions were between 1976 and 1999. Both the date the reactions occurred and the date the report was received by the FDA were recorded in 1,113 (46%) of the reports. Intervals ranged from zero to 7,703 days (ie, approximately 21 years) with a median of 254 days.

The annual number of medical glove-associated event reports received by the FDA increased during the period 1985 through 1998 (Figure 1). This positive trend was highly significant ($P = .008$), and it remained significant after conducting an additional analysis that excluded 249 event reports for which the interval between date of receipt and date of reaction was two years or more. A total of 2,309 (96%) of the subject reports describe reactions associated with exposure to medical gloves that contained natural

rubber latex, and 87 (4%) describe reactions associated with the use of medical gloves made from synthetic materials.

A total of 1,516 (63%) of the 2,396 reports analyzed were submitted as mandatory reports, including 1,432 submitted by medical glove manufacturers. Eight hundred and eight reports (37%) were submitted through the FDA's voluntary system. Health care workers submitted 727 (83%) of the voluntary reports. The reaction of a single individual was described in 2,084 (87%) of the reports. The remaining 312 (13%) reports either did not indicate the number of people who experienced the reported reaction or indicated that more than one person experienced a reaction. Reported demographic and occupational characteristics of affected people and event locations are shown in Table 1.

The most frequently reported clinical signs, symptoms, and diagnostic terms describing affected people are shown in Table 2. The term *allergy* was mentioned in 1,728 (72%) of the reports. Dermatological signs and symptoms were recorded in 1,917 (81%) of the reports, and nondermatological signs and symptoms were described in 863 (36%) reports. Rash, the most frequently reported dermatological term, was included in 560 (23%) of the reports. Dyspnea, the most frequently reported nondermatological term, was recorded in 517 (22%) of the reports.

Table 3 summarizes the natural rubber latex hypersensitivity diagnostic test results and the clinical response categories assigned to affected people based on the information provided in the reports. A total of 205 (9%) of the 2,396 reports could not be included because only broad diagnostic terms such as allergy or reaction were recorded. From the raw data,

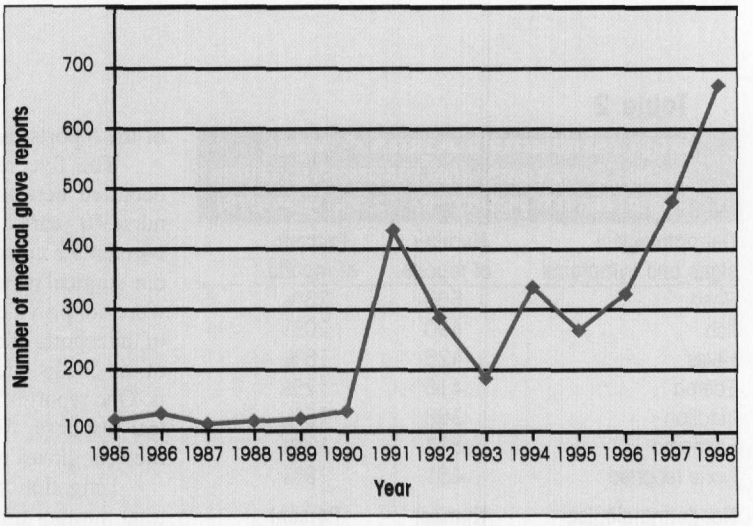

Figure 1 • Reports to the US Food and Drug Administration associating reactions with medical glove use, 1985 to 1998 (N = 2,396 reports).

Table 1

REPORTED CHARACTERISTICS OF AFFECTED PEOPLE AND EVENT LOCATIONS (N = 2,396 REPORTS)

Gender*	Number of reports	Percent of reports
Female	1,468	61%
Male	232	10%
Not reported	696	29%
Occupation	**Number of reports**	**Percent of reports**
Unspecified health professional	752	31%
Nurse	527	22%
Physician	137	6%
Dental professional	131	5%
Other†	162	7%
Not reported‡	687	29%
Location of event	**Number of reports**	**Percent of reports**
Hospital inpatient care facility	674	28%
Dental office	103	4%
Medical clinic or office	96	4%
Other§	119	5%
Not reported	1,404	59%

* Median age = 37 years (range 1-91). Age indicated in 470 (20%) reports.
† Includes phlebotomists, respiratory therapists, medical technologists, pharmacists, and laboratorians; also includes food servers and housekeeping/janitorial staff members identified in 9 reports. There also were 49 reports of people in the "other" category who were patients undergoing an examination or a procedure.
‡ Of these 687 reports, 160 (23%) described reactions of patients undergoing a medical, surgical, or dental examination or procedure.
§ Includes nursing homes, ambulatory surgery facilities, restaurants/public buildings, and private residences.

Table 2

MOST FREQUENTLY REPORTED CLINICAL SIGNS, SYMPTOMS, AND DIAGNOSTIC TERMS FOR AFFECTED PEOPLE* (N = 2,396 REPORTS)

Dermatological signs and symptoms	Number of reports	Percent of reports
Rash	560	23%
Itch	490	20%
Hives	426	18%
Edema	416	17%
Irritation	366	15%
Erythema	317	13%
None reported	461	19%
Nondermatological signs and symptoms	**Number of reports**	**Percent of reports**
Dyspnea	517	22%
Eye irritation	293	12%
Nasal irritation	231	10%
Wheezing	210	9%
Headache	52	2%
None reported	1,532	64%
Diagnostic terms	**Number of reports**	**Percent of reports**
Allergy	1,728	72%
Anaphylaxis	341	14%
Asthma	201	8%
Contact dermatitis	133	6%
Rhinitis	114	5%
Irritant dermatitis	79	3%
Urticaria	67	3%
None reported	533	22%

* The signs, symptoms, and diagnostic terms are not mutually exclusive; that is, reports in many cases recorded multiple signs, symptoms, and diagnostic terms.

diagnostic testing for natural rubber latex allergy was indicated in 340 (14%) of the 2,396 subject reports. These 340 reports indicated the performance of a total of 395 tests; 317 tests were reported as positive for natural rubber latex hypersensitivity, 28 tests were negative, and 50 did not provide test results.

Reported treatments and outcomes for affected people are shown in Table 4. For the 462 reports describing the use of medication therapy, the use of corticosteroids was reported most frequently (38%) followed by use of antihistamines (34%). The proportion of reports indicating disability was greater in mandatory reports (21%) than voluntary reports (8%) ($P < .001$). Anaphylaxis was recorded in 109 (27%) of the reports that indicated disability as an outcome.

The five reports of death included events that occurred between 1994 and 1998 involving a male nurse 40 years of age; a female nurse 39 years of age; two female nurses whose ages were not provided; and one surgical patient whose occupation, gender, and age were not provided. Anaphylaxis was recorded in three of the reports of death, and asthma was recorded in two of the deaths, including one also involving anaphylaxis. One report of death did not indicate a specific clinical response. All death reports were associated with medical gloves made from natural rubber latex.

Litigation was mentioned in 874 (36%) of the total number of reports and in 325 (82%) of the 398 reports indicating disability. In addition, the proportion of reports that indicated litigation was higher for mandatory reports (56%) than for voluntary reports (3%) ($P < .001$).

DISCUSSION

Within the study time frame, 2,396 unique reports were identified that contained information describing local or systemic reactions associated with the use of medical gloves. Medical gloves made from natural rubber latex formulations were implicated in 96% of these reports. This is, at least in part, a reflection of the dominance of natural rubber latex as a medical glove raw material. It also documents that clinical information suggesting nonallergic irritant contact dermatitis and type I and type IV hypersensitivity reactions, including anaphylaxis, are recognized and reported to the FDA primarily in association with the use of medical gloves containing natural rubber latex. The reports originate from a variety of health care settings, but inpatient facilities were predominant among identified locations. This may be a reflection of the impact of the FDA's mandatory reporting requirements on these facilities versus the voluntary nature of reports received from physician or dental offices. Other factors that may affect the distribution of reports include patterns of glove use, adherence with reporting requirements, institutional risk management policies, and employee awareness of and access to natural rubber latex allergy-related educational efforts.

The reports identify reactions in a diverse group of health professionals who use gloves during the provision of health care, including physicians, nurses, dentists, radiological technologists, pharmacists, dental hygienists, laboratory personnel, and respiratory therapists. In general, the adverse events reported through this system are consistent with the findings of

Table 3

CLINICAL RESPONSES OF AFFECTED PEOPLE INDICATED BY REPORT* (N = 2,191 REPORTS)

Frequency	Asthma†	Anaphylaxis‡	Immediate hypersensitivity§	Dermatological responseII	Nondermatological response¶
Number of reports	444 (20%)	375 (17%)	929 (42%)	1,917 (87%)	1,030 (47%)
Diagnostic testing#	**Asthma**	**Anaphylaxis**	**Immediate hypersensitivity**	**Dermatological response**	**Nondermatological response**
Number of reports indicating testing	135	85	205	284	253
Number of tests performed (% of 395 total tests)	166 (42%)	96 (24%)	247 (63%)	332 (84%)	294 (74%)
Reported number of					
positive tests	121	82	197	269	230
negative tests	12	6	15	26	20
results not reported	33	8	35	37	44

* Clinical responses are not mutually exclusive; 2,191 (91%) of the total number of reports (ie, 2,396) could be placed in one or more of the clinical response categories.
† Indicated by wheezing, chest tightness, bronchospasm, and asthma.
‡ Indicated by hypotension, shock, and anaphylaxis.
§ Indicated by hives, angioedema, edema, urticaria, anaphylaxis, hypotension, and shock.
II Included variables for all dermatological signs, symptoms, and diagnostic terms.
¶ Included variables for all nondermatological signs, symptoms, and diagnostic terms.
# The diagnostic tests performed were not mutually exclusive (ie, some reports indicated the performance of more than one test; they included natural rubber latex serology and natural rubber latex skin tests that were reported as positive or negative for natural rubber latex sensitivity).

many published studies that indicate hypersensitivity reactions to medical gloves containing natural rubber latex are not limited to any identifiable subsets of health care occupations.[5] It is noteworthy that reactions also were reported among food handlers, janitorial and housekeeping service providers, and health care facility patients. This diversity continues to make the management of natural rubber latex allergy and glove-related chemical sensitivities in the perioperative setting a substantial challenge for perioperative nurses and other caregivers. For example, perioperative nurses need to ensure that adequate documentation is obtained preoperatively about prior allergy symptoms or diagnosis of natural rubber latex or synthetic glove-related allergy. This is particularly true among high risk individuals such as health care workers; dental workers; people with preexisting allergies or asthma; and those with previous multiple surgeries, especially children with multiple deformities. Appropriate diagnosis and follow-up of any perioperative anaphylactic event is important to communicate with future caregivers and to ensure safe medical and dental care.

No reports describing dermatitis or allergic-type reactions associated with medical glove use were submitted to the FDA's reporting system until 1985. The frequency of reports describing glove-associated health effects increased significantly between 1985 and 1999. During this time, there was increasing concern and awareness of occupational hazards for health care workers, particularly in relation to the occupational transmission of bloodborne pathogens. Reflecting these concerns, universal precautions were widely adopted, and the use of medical gloves increased from approximately two billion pairs per year in the United States in 1986 to approximately 22 billion pairs by 1997.[6] The year 1990 marked the beginning of considerable educational efforts; media attention; and regulatory, medical, and scientific activity directed specifically at the problem of natural rubber latex allergy. The significant trend for increasing reports of glove-associated reactions, therefore, may be occurring for one or more of the following reasons:

- increased awareness, recognition, and reporting of natural rubber latex allergies;

Table 4

REPORTED TREATMENTS AND OUTCOMES FOR AFFECTED PEOPLE (N = 2,396 REPORTS)

Treatment*	Number of reports	Percent of reports
Physician visit	488	20%
Medication therapy	462	19%
Emergency room visit	114	5%
Hospitalization	75	3%
Pharmacist visit	3	0%
Nurse visit	1	0%
Not reported	1,560	65%

Outcome†	Number of reports	Percent of reports
Disability	398	17%
Need to avoid natural rubber latex	127	5%
Necessary to change job	54	2%
Sick leave from work	38	2%
Death	5	0%
Not reported	1,820	76%

* Treatments are not mutually exclusive; 836 (35%) of the total number of reports indicated one or more treatments.
† Outcomes are not mutually exclusive; 576 (24%) of the total number of reports indicated one or more outcomes.

- increased recognition of other potential causes of glove-related sensitivities; or
- an increase in the actual incidence of such reactions.

For example, the marked increase in reporting in 1991 may be associated, in part, with the March 29, 1991, release of an FDA medical alert titled "Allergic reactions to latex-containing medical devices."[7]

It is important to recognize that there are a number of limitations to the data used in this report. First, information reported to the FDA concerning adverse device-related events is not verified by an independent source so information provided in the reports may be incomplete or inaccurate. Second, data in the individual reports do not provide information that definitively establishes a causal link between the reported adverse event and glove use. Third, substantial under-reporting is a recognized characteristic of all passive-reporting systems, such as the FDA systems. Finally, the information reported is influenced by various reporting biases. For example, awareness of the FDA's medical device reporting system, publicity, FDA medical alerts, educational initiatives, advocacy programs, litigation-related issues and concerns, and severity of the adverse events may influence reporting patterns substantially.

CONCLUSION

In spite of recognized limitations, the voluntary and mandatory adverse event reports received by the FDA represent unique surveillance tools. They continue to comprise an important national system for surveillance of adverse events related to medical devices and a powerful early signaling function for emerging problems in marketed medical devices. As with issues related to natural rubber latex allergy, these surveillance data have demonstrated repeated utility in the initial recognition of medical device-related health effects; in understanding their scope, distribution, and determinants; and in guiding further investigative and preventive actions.[8] The reactions reported to the FDA in association with the use of medical gloves, including the noted trends in reporting, suggest the need for further study and continued monitoring of reports. ▲

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NOTES

1. "Natural rubber-containing medical devices; User labeling; Final rule," *Federal Register* 62 (Sept 30, 1997) 51021-51030; "Surgeon's and patient examination gloves; Reclassification and medical glove guidance manual availability; Proposed rule and notice," *Federal Register* 64 (July 30, 1999) 41709-41743; National Institute for Occupational Safety and Health, *Preventing Allergic Reactions to Natural Rubber Latex in the Workplace,* publ no 97-135 (Cincinnati: National Institute for Occupational Safety and Health, 1997); K J Kelly et al, "The diagnosis of natural rubber latex allergy," *The Journal of Allergy and Clinical Immunology* 93 (May 1994) 813-816; L C Granady, J E Slater, "The history and diagnosis of latex allergy," *Immunology and Allergy Clinics of North America* 15 no 1 (1995) 21-29; O Vandenplas et al, "Prevalence of occupational asthma due to latex among hospital personnel," *American Journal of Respiratory and Critical Care Medicine* 151 (January 1995) 54-60; D K Heilman et al, "A prospective, controlled study showing that rubber gloves are the major contributor to latex aeroallergen levels in the operating room," *The Journal of Allergy and Clinical Immunology* 98 (August 1996) 325-330; J S Taylor, P Praditsuwan, "Latex allergy. Review of 44 cases including outcome and frequent association with allergic hand eczema," *Archives of Dermatology* 132 (March 1996) 265-271; M H Lebenbom-Mansour, "The incidence of latex sensitivity in ambulatory surgical patients: A correlation of historical factors with positive serum immunoglobin E levels," *Anesthesia and Analgesia* 85 (July 1997) 44-49; American College of Allergy, Asthma, and Immunology, American Academy of Allergy, Asthma, and Immunology, "ACAAI statement concerning the use of powdered and non-powdered natural rubber latex gloves," http://allergy.mcg.edu/physicians/joint.html (accessed 6 June 2002); R H Brown, J F Schauble, R G Hamilton, "Prevalence of latex allergy among anesthesiologists: Identification of sensitized but asymptomatic individuals," *Anesthesiology* 89 (August 1998) 292-299.

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3. "Surgeon's and patient examination gloves; Reclassification and medical glove guidance manual availability; Proposed rule and notice," 41709-41743

4. US Food and Drug Administration, "Federal Food, Drug, and Cosmetic Act," http://www.fda.gov/opacom/laws/fdcact/fdctoc.htm (accessed 6 June 2002); "Medical device reporting," in *Code of Federal Regulations CFR: 21: Food and Drugs, Part 803* (Washington, DC: US Government Printing Office, 2000).

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7. US Food and Drug Administration, *FDA Medical Alert: Allergic Reactions to Latex-Containing Medical Devices,* MDA91-1

8. "Natural rubber-containing medical devices; User labeling; Final rule," 51021-51030; "Surgeon's and patient examination gloves; Reclassification and medical glove guidance manual availability; Proposed rule and notice," 41709-41743; National Institute for Occupational Safety and Health, *Preventing Allergic Reactions to Natural Rubber Latex in the Workplace,* publ no 97-135; US Food and Drug Administration, *FDA Medical Alert: Allergic Reactions to Latex-Containing Medical Devices,* MDA91-1.

Blood Donation Reminder Crucial to Avert Shortage

Only 5% of Americans who are eligible to give blood actually do, according to a May 13, 2002, news release from the College of American Pathologists. Of this percentage, not all donate on a regular basis. Those eligible to donate can do so every eight weeks.

Summer, as well as the winter holidays, is a crucial time for blood donations because donations decrease and shortages increase. Shortages can be prevented by encouraging those eligible to donate to do so regularly.

The College has launched a blood donation reminder web site, http://www.myhealthtest reminder.com. Users can register with this site and choose a date to receive an e-mail reminder to donate blood. They also can send e-mail reminders to encourage family members and friends to use the service. Information on the site is presented in both English and Spanish.

Regular Donations are Key to Preventing Serious Blood Bank Shortages *(news release, Northfield, Ill: College of American Pathologists, May 13, 2002) http://www.cap .org/html/public/donations.html (accessed 29 May 2002).*

Changes Improve *AORN Journal* Home Study Programs

Beginning in this issue of the *AORN Journal,* some changes have been made to the Home Study Programs, in accordance with revised American Nurses Credentialing Center's Commission on Accreditation criteria. The revised criteria allows for more creativity in the development of Home Studies, participant interactivity, and evaluation. This flexibility will not impact the number of contact hours AORN typically offers for Home Studies. Also, more learner input is being sought via the learner evaluation. We hope to use this information to improve the Home Study Programs and bring you articles that are relevant to your practice. We would like your feedback on these changes. Please send any comments to Editorial Assistant, *AORN Journal,* 2170 S Parker Rd, Suite 300, Denver, CO 80231-5711, or send via fax to (303) 750-3441.

Also, all currently valid Home Studies now are available on AORN Online http://www.aorn .org/journal/homestudy. After printing the Home Study you wish to take, complete the examination and mail the answer sheet, learner evaluation, and payment to AORN Customer Service, c/o Home Study Program, 2170 S Parker Rd, Suite 300, Denver, CO 80231-5711, or send via fax to (303) 750-3212.