

Integration of Safety Technologies into Rheumatology and Orthopedics Practices

AQ:1

A Randomized, Controlled Trial

Gautam R. Moorjani, Edward J. Bedrick, Adrian A. Michael, Andres Peisajovich, Wilmer L. Sibbitt, Jr., and Arthur D. Bankhurst

AQ:2

Objective. To identify and integrate new safety technologies into outpatient musculoskeletal procedures and measure the effect on outcome, including pain.

Methods. Using national resources for patient safety and literature review, the following safety technologies were identified: a safety needle to reduce inadvertent needle sticks to health care workers, and the reciprocating procedure device (RPD) to improve patient safety and reduce pain. Five hundred sixty-six musculoskeletal procedures involving syringes or needles were randomized to either an RPD group or a conventional syringe group, and pain, quality, safety, and physician acceptance were measured.

Results. During 566 procedures, no accidental needle sticks occurred with safety needles. Use of the RPD resulted in a 35.4% reduction (95% confidence interval [95% CI] 24–46%) in patient-assessed pain (mean \pm SD scores on a visual analog pain scale [VAPS] 3.12 ± 2.23 for the RPD and 4.83 ± 3.22 for the conventional syringe; $P < 0.001$) and a 49.5% reduction (95% CI 34–64%) in patient-assessed significant pain (VAPS score ≥ 5) ($P < 0.001$). Physician acceptance of the RPD combined with a safety needle was excellent.

Conclusion. As mandated by the Joint Commission and the Occupational Safety and Health Administration, safety technologies and the use of pain scales can be successfully integrated into rheumatologic and orthopedic procedures. The combination of a safety needle to reduce needlestick injuries to health care workers and the RPD to improve safety and outcome of patients is effective and well accepted by physicians.

Presented in part at the 71st Annual Scientific Meeting of the American College of Rheumatology, Boston, MA, November 2007.

Gautam R. Moorjani, MD, Edward J. Bedrick, PhD, Adrian A. Michael, MD, Andres Peisajovich, MD, Wilmer L. Sibbitt, Jr., MD, Arthur D. Bankhurst, MD: University of New Mexico Health Sciences Center, Albuquerque.

Dr. Sibbitt is the inventor of the reciprocating procedure device (RPD), which is owned by the University of New Mexico and is commercially produced by Avanca Medical Devices, Inc., a company that Dr. Sibbitt founded and that is owned, in part, by the University of New Mexico. Dr. Sibbitt is presently the Scientific Director of Avanca Medical Devices and a full-time professor at the University of New Mexico, which owns the RPD technology and owns stock in Avanca Medical Devices, Inc. Drs. Bedrick and Sibbitt also own founder stock in AVANCA Medical Devices, Inc. There was no industry or grant support for this research or this publication. None of the other authors have any real or potential conflict of interest, and none of the authors have any relationship with Becton Dickinson or the BD safety needle.

Address correspondence and reprint requests to Wilmer L. Sibbitt, Jr., MD, Professor, Internal Medicine, Rheumatology, and Neurology, ACC 5th Floor, Department of Internal Medicine, Mail Stop MSC10–5550, University of New Mexico Health Sciences Center, Albuquerque, NM 87131. E-mail: wsibbitt@salud.unm.edu.

Submitted for publication November 25, 2007; accepted in revised form February 29, 2008.

Injuries to patients and health care workers during and after physician-performed procedures are considerable and are among the greatest risks to the safety of patients and health care workers yet are challenging to prevent, requiring changes in both behavior and medical technology (1–22). The Joint Commission on Accreditation of Healthcare Organizations, the Needlestick Safety and Prevention Act, and the Occupational Safety and Health Administration all direct health care entities, including rheumatology and orthopedics services, to develop formal mechanisms to improve patient and health care worker safety and outcomes, including but not limited to integration of new safety technologies and routine pain assessment (1–5). Improvement in the safety design of medical instruments through safety engineering is one of the most robust methods to



Figure 1. Safety needle in an intraarticular position. After being delivered with the reciprocating procedure device (RPD), the BD safety needle is in an intraarticular position. Note that the safety sheath does not interfere with interaction of the needle hub with the skin surface. This needle has another advantage in that it has both a usual Luer fitting and an external housing that can be used as a grip so that the Luer fitting is not contaminated during syringe exchanges. At this point, a syringe can be attached to aspirate further if more fluid is present in the joint. Alternatively, a syringe containing corticosteroids or hyaluronate can be attached to the hub of the intraarticular needle and the medication effectively injected into the joint.

improve patient safety and reduce iatrogenic injuries to patients and needle sticks to health care workers (1–4,9–12). To date, however, few rheumatology or orthopedics departments have formally integrated safety technologies and routine formal pain assessment into their procedures; moreover, there is a glaring lack of literature on studies of safety technologies and their effect on outcome in musculoskeletal procedures.

The identification, evaluation, validation, and introduction of a new safety technology are not always straightforward and require considerable research and validation that are challenging for an individual health care institution (1–12). To date, safety technologies are not standardized; thus, individual institutions and departments are granted considerable latitude regarding the choice of individual technologies (1–3). The identification of new safety technologies and methods can be

accelerated by utilizing the educational resources of regional or national centers of excellence for patient safety (22–25). Such centers continuously identify promising safety methods and new safety technologies that are used as examples to promote patient safety to interested health care workers and institutions (25). We describe the identification, trial introduction, measurement of outcomes, validation, and integration of needle and syringe–based safety technologies and pain assessment into routine musculoskeletal procedures in the practice of rheumatology and orthopedics.

AQ: 3

PATIENTS AND METHODS

AQ: 4

Selection of safety devices. Identification of the candidate safety technologies for musculoskeletal procedures occurred through literature review and through staff interaction



Figure 2. Reciprocating procedure device (RPD) being used in a one-handed manner for aspiration of the knee. As shown here, the accessory plunger is depressed with the thumb to aspirate, using only the extremely well controlled flexor muscles of the hand. The free hand is used to palpate anatomy, squeeze the joint, stabilize the RPD further, steady the patient, or operate other devices, such as an ultrasound probe. To inject, the thumb moves to the other plunger, while the fingers on the barrel and the finger flanges do not change position, and the well-controlled flexor muscles of the hand are used for injection.

with the educational resources of national centers of excellence for patient safety (22–25). Certain syringe-based needlestick-prevention devices were deemed unsuitable: barrel-based needle shields were too awkward and bulky and tended to rotate, and syringes that internalize the needle and/or needle fitting were actually dangerous if the safety mechanism was inadvertently activated during the procedure, while the needle was still in the patient's tissue. Thus, it was deemed that a needle-based safety system rather than a syringe-based system to prevent needle sticks would be most suitable for musculoskeletal procedures and other physician-performed syringe-related procedures.

Among the needle-based systems, safety needles with an elbow-like sheath were less desirable, because they increased the total length of the needle, resulting in the syringe and the operator's hands being farther away from the tissue target. A BD safety needle with an off-axis rotating safety sheath (25-gauge 1-inch [product no. 305761] and 22-gauge 1.5-inch [product no. 305783] BD Eclipse Needle; Becton Dickinson, Franklin Lakes, NJ) was chosen as the safety device to reduce needlestick injuries to health care workers. The BD needle comes with 2 sheaths, a conventional sheath that is removed to expose and then use the needle, and then a lateral

rotating sheath that is pushed with the finger and encloses and inactivates the used needle. Although the lateral sheath has a large profile, with proper education and physician practice, this safety needle permits close approximation to the skin surface, as is necessary for syringe and needle procedures (Figures 1 and 2). This class of safety devices has been shown to reduce needle sticks to health care workers by 70% (4). This needle has another advantage in that it has both a usual Luer fitting and an external housing that can be used as a grip so that the Luer fitting is not contaminated during syringe exchanges. Such exchanges are sometimes necessary during joint-related procedures involving effusion, when arthrocentesis is followed by injection of a pharmaceutical agent, or when several different medications are being injected (such as lidocaine followed by corticosteroids or hyaluronate).

In contrast, to improve quality of care and safety for patients during musculoskeletal procedures, safety technology in the form of the reciprocating procedure device (RPD-1, RPD-3, RPD-5, RPD-10; Avanca Medical Devices, Albuquerque, NM) was chosen (Figure 2). The RPD is a safety syringe technology that in randomized controlled trials has been shown to improve physician control of the needle and syringe, reduce procedure time, reduce the level of patient pain, and

F1,F2

AQ: 5

AQ: 6

Table 1. Characteristics of the patients*

Characteristic	Conventional syringe (n = 68)	RPD (n = 55)	Both (n = 18)	P
No. of procedures, mean \pm SD	3.2 \pm 1.6	3.6 \pm 2.3	8.2 \pm 4.5	<0.01
Patient age, mean \pm SD years	51.7 \pm 12.9	51.9 \pm 14.3	51.6 \pm 12.4	0.98
Female sex	66 (97.0)	44 (80.0)	14 (77.8)	0.01
Underlying diagnoses				
Rheumatoid arthritis	44 (64.7)	33 (60.0)	8 (44.4)	0.30
SLE	6 (8.8)	4 (7.3)	1 (5.6)	0.99
Osteoarthritis	5 (7.4)	4 (7.3)	4 (22.2)	0.15
Single other diagnosis	10 (14.7)	14 (25.5)	3 (16.7)	0.36
Multiple diagnoses	3 (4.4)	0 (0.0)	2 (11.1)	0.07
Location of procedure				
Knee	29 (42.7)	24 (43.6)	9 (50.0)	0.87
Shoulder	13 (19.1)	11 (20.0)	1 (5.6)	0.40
Wrist	6 (8.8)	3 (5.5)	2 (11.1)	0.69
Elbow	2 (2.9)	3 (5.5)	0 (0.0)	0.69
Ankle	8 (11.8)	2 (3.6)	0 (0.0)	0.10
Hip	4 (5.9)	8 (14.6)	0 (0.0)	0.11
Single other joint	2 (2.9)	0 (0)	1 (5.6)	0.30
Multiple joints	4 (5.9)	4 (7.3)	5 (27.8)	0.04

* Except where indicated otherwise, values are the number (%). Both the conventional syringe and the reciprocating procedure device (RPD) were fitted with the same BD safety needle, with an off-axis rotating safety sheath. SLE = systemic lupus erythematosus.

improve the outcomes of physician-performed syringe and needle procedures (13,14,27–30), and is accepted as being superior to and safer than the conventional syringe (31). The RPD is formed around the core of a conventional syringe barrel and plunger but has a parallel accessory plunger and an accessory barrel or track to control the motion of the accessory plunger (Figure 2). The 2 plungers are mechanically linked by a pulley in an opposing manner, resulting in a set of reciprocating plungers. Thus, when the accessory plunger is depressed with the thumb, the syringe aspirates, and when the dominant plunger is depressed with the thumb, the syringe injects. This permits the index and middle fingers to remain in one position during both aspiration and injection, while the thumb needs to move only in a horizontal plane to the alternative plunger in order to change the direction of aspiration or injection. The RPD can be fully operated with one hand, but physicians often use 2 hands for even greater control and hold the RPD in various ways depending on the procedure requirements. In randomized controlled trials, the RPD has been shown to be better controlled and superior to the conventional syringe, the 3-ring control syringe, syringe pistols, syringe handles, and other dedicated-procedure syringes (13,14). The RPD has also been shown to be safer than and superior to the conventional syringe for use in suction needle biopsy, arthrocentesis, intra-articular corticosteroid injection, intra-articular hyaluronate injection, and induction of musculoskeletal anesthesia (13,14, 27–31).

Subjects. This project was in compliance with the Helsinki Declaration and was approved by the institutional review board. Patient confidentiality and privacy were protected according to the Health Insurance Portability and Accountability Act. Thirty-seven physicians (2 attending physicians and 35 resident physicians) performed 566 procedures on 141 patients who required an outpatient syringe-and-needle

musculoskeletal procedure (arthrocentesis, intraarticular joint injection, or periarticular–intraarticular anesthesia) for their usual and customary medical care. The breakdown of individual joints and medical conditions is shown in Table 1, and the 3 groups of patients (those who underwent an RPD procedure only, those who underwent a conventional syringe procedure only, and those who underwent both procedures) were comparable in terms of age, sex, and type of joint procedures. In each case, patients individually consented to both the invasive musculoskeletal procedure and the institutional review board–approved research protocol. In each case, the procedures were randomized, patient-by-patient, to either the conventional syringe or the RPD, by flipping a coin. A total of 288 procedures were performed using the conventional syringe, and 278 procedures were performed using the RPD/safety needle. In each group, the proportion of procedures performed by attending physicians versus resident physicians was similar (~50:50).

Syringes. Depending on the joint or effusion size, the conventional syringe was a 1-ml, 3-ml, 5-ml, or 10-ml Luer-Lok syringe (product 309604; Becton Dickinson). Similarly, the appropriate size of the RPD (RPD-1, RPD-3, RPD-5, RPD-10; Avanca Medical Devices) was used. Both the conventional syringe and the RPD were fitted with the same BD safety needle, with an off-axis rotating safety sheath. If large effusions were present, the needle was left intraarticularly, and syringe exchanges were performed to fully drain the joint (Figure 2).

Outcome measures. A nonoperating observer queried the patient in real time regarding pain during the needle-and-syringe joint procedure and noted any needle sticks to the operator or assistants during or after the procedure, including cleanup after the procedure. Moreover, all needle sticks must mandatorily be reported to the attending physician and to the Employee Health Office. Directly after the procedure, the

T1

AQ:7,8

AQ: 9

Table 2. Outcomes of the syringe-and-needle procedures using the conventional syringe and the RPD*

	Conventional syringe (n = 288 procedures)	RPD (n = 278 procedures)	Difference, % (95% CI)	P
Needle sticks	0 (0)	0 (0)	0	>0.50
Immediate complications to patient	4 (1.4)	4 (1.4)	0	>0.50
Complications to patient at 2 weeks†	0 (0)	0 (0)	0	>0.50
Patient-assessed pain, mean ± SD score on VAPS	4.83 ± 3.22	3.12 ± 2.23	-35.4 (24-46)	<0.001
Patient pain as assessed by attending physicians	4.79 ± 3.21	2.62 ± 2.2	-45.3 (35-54)	<0.001
Patient pain as assessed by resident physicians	4.88 ± 3.24	3.53 ± 3.04	-27.7 (9-43)	0.032
Significant patient-assessed pain on VAPS (score ≥5)	154 (53.5)	75 (27.0)	-49.5 (34-64)	<0.001
Significant patient pain as assessed by attending physicians	91 (55.5)	25 (20.5)	-63.1 (46-78)	<0.001
Significant patient pain as assessed by resident physicians	63 (50.8)	50 (32.1)	-36.8 (4-61)	0.001
Physician satisfaction, mean ± SD score on VASS	5.91 ± 1.28	8.98 ± 0.77	+52.0 (43-62)	<0.001

* Except where indicated otherwise, values are the number (%). Both the conventional syringe and the RPD were fitted with the same BD safety needle, with an off-axis rotating safety sheath. Attending physicians performed 164 procedures with the conventional syringe and 122 procedures with the RPD; resident physicians performed 124 procedures with the conventional syringe and 156 procedures with the RPD. RPD = reciprocating procedure device; 95% CI = 95% confidence interval; VAPS = visual analog pain scale; VASS = visual analog satisfaction scale.

† All immediate complications to the patients were postinjection flares.

observer also queried the physician in terms of satisfaction with the conventional syringe or RPD. Patient pain was determined with the standardized and validated visual analog pain scale (VAPS), where 0 cm = no pain and 10 cm = unbearable pain (5,27-34). Operator satisfaction with the syringe devices after the procedure was determined with the visual analog satisfaction scale (VASS), where 0 cm = completely dissatisfied with the performance of the syringe used during the procedure and 10 cm = completely satisfied with the performance of the syringe (27-34).

Statistical analysis. Data were entered into Excel (version 5; Microsoft, Seattle, WA) and analyzed using SAS (SAS/STAT Software, release 9.1, Cary, NC). An initial sample size of 100 procedures for each treatment group was considered. With this sample size, a 2-tailed *t*-test at an alpha level of 0.05 has 80% power to detect a mean difference in pain levels of 1 unit on the VAPS, between procedures using the conventional syringe and the RPD-safety needle. In this calculation, the within-group SD is estimated to be 2.50, which corresponds with the range for VAPS scores divided by 4. If the SD is set at a more conservative value of 4, then 80% power is obtained for mean differences of ≥1.60. Ultimately, our study involved 566 procedures randomly assigned to the 2 treatment groups, resulting in 288 procedures using the conventional syringe and 278 procedures using the RPD. The slight imbalance in sample sizes for the 2 groups has little practical effect on the power, relative to a sample size of 100 per group.

Differences in characteristics of the 3 patient groups (RPD procedure only, conventional syringe procedure only, and both procedures) were determined using Fisher's exact test. Differences between the 2 treatment groups (i.e., conventional syringe versus RPD) were determined using a 2-sample test on the difference between group means or percentages, depending on whether the outcome measure was numeric or categorical. The standard error of the difference in mean values or percentages was obtained using generalized estimating equations to account for multiple responses in the same patient. A modification of Fieller's method to accommodate

multiple responses was used to calculate confidence intervals for relative differences in the mean values and percentages between treatment groups.

RESULTS

Physicians had to adjust to the larger profile of the BD safety needle caused by the shield (Figure 1) and found that they had to move more deliberately so that their fingers did not snag the shield. Thus, several physicians stated, at first, that the BD safety needle was somewhat clumsy. After training and practice, however, all of the physicians, including attending physicians and resident physicians, accommodated to the safety needle and performed well with it. Use of the RPD required instruction at first, to show how it functioned ("push-push" to aspirate-inject with the RPD rather than the usual "push-pull" with the conventional syringe), and the physicians were cautioned to be careful with the asymmetry of the device when rotating it off and on an intraarticularly residing needle (Figure 1). However, after 1 procedure, all physicians performed well and facilely with the RPD. Table 2 shows the outcomes of using the BD safety needle in musculoskeletal procedures. During 566 procedures, use of the safety needle resulted in no needle sticks of a health care worker. However, 1 resident physician broke the protocol and used a conventional needle on 1 patient and obtained a needle stick with the conventional needle.

The overall outcomes of the syringe-and-needle procedures with the conventional syringe and the RPD are shown in Table 2. The use of pain assessment (VAPS score) was well accepted by physicians and patients. Use

of the RPD resulted in a reduction in patient-assessed pain scores of 35.4% ($P < 0.001$). Use of the conventional syringe resulted in significant pain in 53.5% of procedures, while only 27.0% (75 of 278) of procedures with the RPD resulted in significant pain ($P < 0.001$). At 2 weeks, no major complication was observed with the use of either device, and outcomes were good (Table 2). Physician acceptance of the RPD was excellent, and physician satisfaction with the RPD was improved compared with satisfaction with the conventional syringe ($P < 0.001$).

Somewhat unexpectedly, the performance of attending physicians and resident physicians using the conventional syringe was almost identical, in terms of both pain scores and significant pain (Table 2). Both resident physicians and attending physicians performed significantly better with the RPD compared with the conventional syringe; however, the performance of attending physicians with the RPD was considerably better than that of resident physicians in terms of both reduced pain scores and a reduction in the number of patients experiencing significant pain (Table 2). This suggests that although use of the RPD combined with a safety needle markedly improves physician performance and patient safety regardless of the physician's experience, more experience with the RPD can further enhance performance and patient safety.

Based on the above-described positive results for the safety technologies and a review of the randomized controlled trials to date, the participating services recommended that the BD needle and RPD replace the conventional needle and syringe for physician-performed needle-and-syringe procedures within their departments, and that analog pain scales be used to assess preprocedure pain, anesthesia-related pain, procedure-related pain, and effectiveness of the procedure.

DISCUSSION

To date, few rheumatology or orthopedics departments have formally studied or integrated new safety technologies or the routine measurement of procedure-related pain into their outpatient musculoskeletal procedures, as encouraged by the relevant governing institutions (1–5). Moreover, there are very few, if any, studies or publications on the integration of safety technologies and these quality measures concerning outpatient procedures into rheumatology and orthopedics practices.

The present study demonstrates that safety tech-

nologies for musculoskeletal procedures and the use of pain scales can be successfully evaluated and introduced into rheumatology and orthopedics workplaces, resulting in not only improved patient and health care worker safety, but also improved patient outcomes and physician satisfaction. The candidate safety technologies, the safety needle and the RPD, were first identified by literature review, analysis of randomized controlled trials, and use of national patient safety resources (22–30). The safety technologies and the use of pain scales were then introduced, in a limited manner, into the clinic, and physicians were involved in determining the outcome measures during the introduction trials. Subsequently, the results of these trials were reported to the respective quality improvement committees and submitted to the product analysis group for general introduction.

Introduction of new safety technologies into rheumatology and orthopedics practice is challenging for an institution (6–46). Obstacles include identification of an appropriate candidate technology, physician acceptance of the new technology, and the ability of the institution to measure appropriate outcomes to demonstrate improved patient safety while maintaining a high quality of the procedure, within economic constraints. Moreover, the safety of the patient and the safety of the health care worker must be balanced; e.g., certain technologies such as safety needles generally improve safety for the health care worker with little benefit to the patient, and use of hundreds of thousands of devices may be required to measure a therapeutic effect (reduced rates of needle sticks) (4,40,44,45). In contrast, other technologies such as the RPD improve the safety and quality of care of the patient more than that of the health care worker, and use of fewer devices is required to demonstrate a therapeutic effect (27–31). As a general goal, the safety and quality of care of both parties—the patient and the health care worker—are important, and the safety needs of both should be addressed (1–5).

The present report describes a method of identification and introduction of new safety technologies, in this case a safety needle and the RPD, into rheumatology and orthopedics practices and the measurement of the effect on quality of care and health care worker safety. Although they are only a discrete piece of an overall safety and quality improvement program, judicious introduction and evaluation of new safety technologies may have a major effect on overall patient and health care worker safety within an institution (4,40–45). For example, the use of safety needles may reduce the incidence of occupational needle sticks in health care workers by 70% (from a rate of 20 needle sticks per

AQ: 10

AQ: 11

100,000 procedures to a rate of 6 needle sticks per 100,000 procedures) (4,45). Similarly, the RPD has been shown to reduce the rate of complications associated with syringe procedures by 30–50% (13,14,27–31). Based on the results of the present study, the combination of the 2 technologies would be anticipated to have a positive impact on both patient and health care worker safety and quality of care when integrated into all needle-and-syringe procedures performed by physicians within the entire health system.

The present report has several limitations. First, the effectiveness of the safety needle technology could not be statistically assessed in this study, because the rate of needle sticks is 6–20 occupational needle sticks per 100,000 devices; thus, the 566 procedures performed in this study could not supply adequate power to demonstrate a decrease in the rate of needle sticks (4,45). However, larger studies of these types of safety devices have shown considerable effectiveness in reducing the number of needle sticks (4,40–45). Moreover, one resident physician in this study broke the protocol and used a conventional needle on one patient and obtained a needle stick with the conventional needle, requiring further testing and medical care. Outcomes for the patients were primarily pain related to anesthesia and the procedures, rather than catastrophic complications, which would have required thousands of procedures to demonstrate a statistical effect. However, outcome studies are being performed, and early results suggest a significant decrease in the number of complications—not only pain, as shown in this study, but also hemorrhage (27).

In this study, syringes were used only for musculoskeletal procedures, which account for <10% of all the syringes used by physicians within the hospital. Moreover, syringes used for physician-performed procedures represent only 5% of the entire consumption of syringes within a hospital system; the majority of syringes are used by the nursing and pharmacy services (40–45). Thus, this study cannot address complications of syringe procedures performed by nurses or pharmacists or the effect of the safety intervention on these health care professions. However, physician-performed procedures account for the majority of serious needle-and-syringe-related injuries to patients and are responsible for the great bulk of patient-assessed procedural pain; thus, the design of this study as physician-focused is appropriate (15–32,46).

Beyond musculoskeletal procedures, complications of other physician-performed syringe-and-needle procedures are significant, with complication rates of 2–9% (22–34). Because the RPD/safety needle combi-

nation reduces complications, including pain by 35.4–49.5% (Table 2), and is likely to reduce the number of needle sticks by as much as 70% (4), the combined technology is likely to significantly improve the safety of both the patient and the health care worker during most needle-and-syringe procedures performed by physicians.

Health care entities, including rheumatology and orthopedics services, continue to develop formal mechanisms to improve patient and health care worker safety and quality of care, including integration of new safety technologies and the routine use of pain scales during the performance of procedures (1–5). New safety technologies such as the BD safety needle and the RPD can be successfully evaluated and introduced into rheumatology and orthopedics departments to improve patient and health care worker safety and quality of care. Keys to successful integration include review of randomized controlled trials, the utilization of national safety resource centers, timely identification of candidate safety technologies, early involvement of staff who would use the safety technology, identification of relevant quality measures (especially pain assessment), collection of outcome data, analysis by the quality improvement and new product evaluation committees, and final incorporation into the formal quality improvement and safety plans of the individual rheumatology and orthopedics practices.

ACKNOWLEDGMENTS

We wish to acknowledge Philip Mercurio, BA, RRT, Quality Consultant, Quality and Outcomes Management, University of New Mexico Hospitals, University of New Mexico Health Sciences Center, Albuquerque, for his contributions to the editing of this article, and to Ms Yvonne Tanuz-Trujillo, New Product Evaluation Committee, University of New Mexico Hospitals, University of New Mexico Health Sciences Center, Albuquerque, for her advice and knowledge concerning new product evaluation within hospital systems.

AUTHOR CONTRIBUTIONS

Dr. Sibbitt had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study design. Bedrick, Sibbitt.

Acquisition of data. Moorjani, Michael, Peisajovich, Sibbitt, Bankhurst.

Analysis and interpretation of data. Moorjani, Bedrick, Michael, Peisajovich, Sibbitt, Bankhurst.

Manuscript preparation. Bedrick, Michael, Peisajovich, Sibbitt, Bankhurst.

Statistical analysis. Bedrick.

REFERENCES

1. The Joint Commission. National patient safety goals. URL: <http://www.jointcommission.org/PatientSafety>.

2. Library of Congress. Needlestick Safety and Prevention Act. US Congress, 2000. URL: <http://thomas.loc.gov>.
3. Cuny EJ, Fredekind R, Budenz AW. Safety needles: new requirements of the Occupational Safety and Health Administration bloodborne pathogens rule. *J Calif Dent Assoc* 1999;27:525-30.
4. Adams D, Elliott TS. Impact of safety needle devices on occupationally acquired needlestick injuries: a four-year prospective study. *J Hosp Infect* 2006;64:50-5.
5. The Joint Commission. Nutritional, functional, and pain assessments and screens. URL: http://www.jointcommission.org/AccreditationPrograms/Hospitals/Standards/FAQs/Provision+of+Care/Assessment/nfp_assessments.htm.
6. Fisman DN, Harris AD, Rubin M, Sorock GS, Mittleman MA. Fatigue increases the risk of injury from sharp devices in medical trainees: results from a case-crossover study. *Infect Control Hosp Epidemiol* 2007;28:10-7.
7. Vincent C, Davy C, Esmail A, Neale G, Elstein M, Cozens JF, et al. Learning from litigation: the role of claims analysis in patient safety. *J Eval Clin Pract* 2006;12:665-74.
8. Berguer R, Forkey DL, Smith WD. Ergonomic problems associated with laparoscopic surgery. *Surg Endosc* 1999;13:466-8.
9. Berguer R. Surgical technology and the ergonomics of laparoscopic instruments. *Surg Endosc* 1998;12:458-62.
10. Lai F. Human factors engineering for designing the next in medicine. *Stud Health Technol Inform* 2007;125:262-4.
11. Kimberlin C. Device manufacturers: a partner in quality assurance. *Biomed Instrum Technol* 2006;40:435-6.
12. Williams DM. Engineering improvements in endovascular devices: design and validation. *Ann N Y Acad Sci* 2006;1085:213-23.
13. Sibbitt RR, Sibbitt WL Jr, Nunez SE, Kettwich LG, Kettwich SC, Bankhurst AD. Control and performance characteristics of eight different suction biopsy devices. *J Vasc Interv Radiol* 2006;17:1657-69.
14. Sibbitt W Jr, Sibbitt RR, Michael AA, Fu DI, Draeger HT, Twining JM, et al. Physician control of needle and syringe during aspiration-injection procedures with the new reciprocating syringe. *J Rheumatol* 2006;33:771-8.
15. Jones PW, Moyers JP, Rogers JT, Rodriguez RM, Lee YC, Light RW. Ultrasound-guided thoracentesis: is it a safer method? *Chest* 2003;123:418-23.
16. Alfirevic Z, Sundberg K, Brigham S. Amniocentesis and chorionic villus sampling for prenatal diagnosis. *Cochrane Database Syst Rev* 2003;CD003252.
17. Salem K, Mulji A, Lonn E. Echocardiographically guided pericardiocentesis: the gold standard for the management of pericardial effusion and cardiac tamponade. *Can J Cardiol* 1999;15:1251-5.
18. Tan KT, Kirby J, Rajan DK, Hayeems E, Beecroft JR, Simons ME. Percutaneous sodium tetradecyl sulfate sclerotherapy for peripheral venous vascular malformations: a single-center experience. *J Vasc Interv Radiol* 2007;18:343-51.
19. Derby R, Lee SH, Kim BJ, Chen Y, Seo KS. Complications following cervical epidural steroid injections by expert interventionalists in 2003. *Pain Physician* 2004;7:445-9.
20. Mallory A, Schaefer JW. Complications of diagnostic paracentesis in patients with liver disease. *JAMA* 1978;239:628-30.
21. Tomoda C, Takamura Y, Ito Y, Miya A, Miyauchi A. Transient vocal cord paralysis after fine-needle aspiration biopsy of thyroid tumor. *Thyroid* 2006;16:697-9.
22. Heget JR, Bagian JP, Lee CZ, Gosbee JW, John M. Eisenberg Patient Safety Awards. System innovation: Veterans Health Administration National Center for Patient Safety. *Jt Comm J Qual Improv* 2002;28:660-5.
23. Bagian JP, Gosbee J, Lee CZ, Williams L, McKnight SD, Mannos DM. The Veterans Affairs root cause analysis system in action. *Jt Comm J Qual Improv* 2002;28:531-45.
24. Stalhandske E, Bagian JP, Gosbee J. Department of Veterans Affairs patient safety program. *Am J Infect Control* 2002;30:296-302.
25. Williams L. Changing systems the hands-on way. The VA National Center for Patient Safety's Museum. *Md Med* 2005;6:16-8.
26. Food and Drug Administration. Substantial equivalence determination: 510 (K), summary. FDA document K042487.pdf; January 21, 2005.
27. Draeger HT, Twining JM, Johnson CR, Kettwich SC, Kettwich LG, Bankhurst AD. A randomised controlled trial of the reciprocating syringe in arthrocentesis. *Ann Rheum Dis* 2006;65:1084-7.
28. Bankhurst AD, Nunez SE, Draeger HT, Kettwich SC, Kettwich LG, Sibbitt WL Jr. A randomized controlled trial of the reciprocating procedure device for intraarticular injection of corticosteroid. *J Rheumatol* 2007;34:187-92.
29. Nunez SE, Draeger HT, Rivero DP, Kettwich LG, Sibbitt WL Jr, Bankhurst AD. Reduced pain of intraarticular hyaluronate injection with the reciprocating procedure device. *J Clin Rheumatol* 2007;13:16-9.
30. Nunez SE, Bedrick EJ, Kettwich SC, Kettwich LG, Bankhurst AD, Sibbitt WL Jr. A randomized, controlled trial of the reciprocating procedure device for local anesthesia. *J Emerg Med* 2008. E-pub ahead of print.
31. Sander O. Intra-articular corticosteroid injections with the reciprocating procedure device reduced procedural pain and duration more than the conventional syringe. *Evid Based Med* 2007;12:106.
32. Sutherland HJ, Lockwood GA, Minkin S, Tritchler DL, Till JE, Llewellyn-Thomas HA. Measuring satisfaction with health care: a comparison of single with paired rating strategies. *Soc Sci Med* 1989;28:53-8.
33. Miller MD, Ferris DG. Measurement of subjective phenomena in primary care research: the Visual Analogue Scale. *Fam Pract Res J* 1993;13:15-24.
34. Katz J, Melzack R. Measurement of pain [review]. *Surg Clin North Am* 1999;79:231-52.
35. Wakefield DS, Ward MM, Wakefield BJ. A 10-Rights framework for patient care quality and safety. *Am J Med Qual* 2007;22:103-11.
36. Metules T, Bauer J. JCAHO's patient safety goals: a practical guide. Part 1. *RN* 2006;69:21-6.
37. Conn J, DoBias M. Hospitals' dirty secret: new reports on hospital patient safety and infections reveal pattern of deadly and expensive, yet preventable, medical errors. *Mod Healthc* 2006;36:6-7.
38. David Y, Jahnke E, Blair C. Risk assessment: hospital view in selecting medical technology. *Conf Proc IEEE Eng Med Biol Soc* 2004;5:3504.
39. DePalma RG. Surgical quality programs in the Veterans Health Administration. *Am Surg* 2006;72:999-1004.
40. Ratzlaff JI. Needle safety technology [review]. *SCI Nurs* 2002;19:17-20.
41. Cook RI. Safety technology: solutions or experiments? *Nurs Econ* 2002;20:80-2.
42. Poon EG, Blumenthal D, Jaggi T, Honour MM, Bates DW, Kaushal R. Overcoming barriers to adopting and implementing computerized physician order entry systems in U.S. hospitals. *Health Aff (Millwood)* 2004;23:184-90.
43. Winston FK, Schwarz DF, Baker SP. Biomechanical epidemiology: a new approach to injury control research. *J Trauma* 1996;40:820-4.
44. Cleveland JL, Barker LK, Cuny EJ, Panlilio AL, for the National Surveillance System for Health Care Workers Group. Preventing percutaneous injuries among dental health care personnel. *J Am Dent Assoc* 2007;138:169-78.
45. Muntz JE, Hultburg R. Safety syringes can reduce the risk of needlestick injury in venous thromboembolism prophylaxis. *J Surg Orthop Adv* 2004;13:15-9.
46. Aviram G, Schwartz DS, Meirsdorf S. Transthoracic needle biopsy of lung masses: a survey of techniques. *Clin Radiol* 2005;60:370-4.