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# Safety of Patients Isolated for Infection Control

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**P**ATIENT SAFETY HAS EMERGED AS an important health care issue because of the consequences of iatrogenic injuries.<sup>1</sup> Preventable injuries result largely from system failures, not from individual inadequacy.<sup>2-5</sup> Human factors research in nonmedical settings (eg, aviation) suggests that people tend to take the path of least effort; hence, demanding greater vigilance from providers of medical care may not result in meaningful safety improvement.<sup>2,3</sup> Instead, redesigning faulty systems appears to be a more promising way to reduce human error.<sup>1</sup>

The infection control technique of patient isolation may be a system change that predisposes patients to errors and adverse events.<sup>6-8</sup> Such strategies, sometimes referred to as transmission-based precautions, are intended to prevent the spread of pathogens by airborne, droplet, or contact transmission. The recommended precautions depend on the infectious agent but typically involve placing the patient in a private room, requiring visitors to wear protective apparel (eg, gloves, gowns, and masks), and restricting the movement of the patient outside of the room.<sup>9</sup> Infection control authorities view patient isolation as an important tool for management of selected established (eg, vancomycin-resistant enterococcus) and emerging (eg, severe acute respiratory syndrome) infectious diseases.<sup>9-14</sup>

Critics of isolation policies have raised questions about quality of care

**Context** Hospital infection control policies that use patient isolation prevent nosocomial transmission of infectious diseases, but may inadvertently lead to patient neglect and errors.

**Objective** To examine the quality of medical care received by patients isolated for infection control.

**Design, Setting, and Patients** We identified consecutive adults who were isolated for methicillin-resistant *Staphylococcus aureus* colonization or infection at 2 large North American teaching hospitals: a general cohort (patients admitted with all diagnoses between January 1, 1999, and January 1, 2000; n=78); and a disease-specific cohort (patients admitted with a diagnosis of congestive heart failure between January 1, 1999, and July 1, 2002; n=72). Two matched controls were selected for each isolated patient (n=156 general cohort controls and n=144 disease-specific cohort controls).

**Main Outcome Measures** Quality-of-care measures encompassing processes, outcomes, and satisfaction. Adjustments for study cohort and patient demographic, hospital, and clinical characteristics were conducted using multivariable regression.

**Results** Isolated and control patients generally had similar baseline characteristics; however, isolated patients were twice as likely as control patients to experience adverse events during their hospitalization (31 vs 15 adverse events per 1000 days;  $P<.001$ ). This difference in adverse events reflected preventable events (20 vs 3 adverse events per 1000 days;  $P<.001$ ) as opposed to nonpreventable events (11 vs 12 adverse events per 1000 days;  $P=.98$ ). Isolated patients were also more likely to formally complain to the hospital about their care than control patients (8% vs 1%;  $P<.001$ ), to have their vital signs not recorded as ordered (51% vs 31%;  $P<.001$ ), and more likely to have days with no physician progress note (26% vs 13%;  $P<.001$ ). No differences in hospital mortality were observed for the 2 groups (17% vs 10%;  $P=.16$ ).

**Conclusion** Compared with controls, patients isolated for infection control precautions experience more preventable adverse events, express greater dissatisfaction with their treatment, and have less documented care.

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and whether isolated patients receive less attention.<sup>6-8,15,16</sup> In 1 medical intensive care unit, isolated patients had half as many hourly contacts with clinicians as control patients.<sup>15</sup> In another study, isolated patients were less likely than other patients to be examined by physicians during rounds.<sup>16</sup> Inevitably, isolation policies place physical barriers between clinicians and patients, are time consuming, and impede visitors. However, less contact is not an indication of inadequate care, and data are lacking regarding the quality of care received by isolated pa-

tients. To examine the safety of isolating patients for infection control, we conducted a study at 2 teaching hos-

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pitals, 1 in Canada and 1 in the United States.

## METHODS

### Study Cohorts

We identified consecutive adults admitted to Sunnybrook and Women's College Health Sciences Centre (Toronto, Ontario) between January 1, 1999, and January 1, 2000, who were isolated for at least 2 days because of methicillin-resistant *Staphylococcus aureus* (MRSA) colonization or infection. Control patients were selected by identifying the 2 patients who occupied each isolated patient's hospital bed immediately before and after his/her admission. Isolated patients are typically treated in regular single-bed rooms at this hospital. Matching by hospital bed ensured that isolated and control patients were treated by similar clinicians, located within similar proximity to the nursing station, and cared for at similar times of the year. This cohort of patients was selected to evaluate isolation policies in a general teaching hospital.

We also selected a second, disease-specific cohort of patients by identifying consecutive adults admitted to Brigham and Women's Hospital (Boston, Mass) between January 1, 1999, and July 1, 2002, who had a principal admitting diagnosis of congestive heart failure, a previously recorded isolate of MRSA, and an admission order for isolation. Control patients were selected by identifying the 2 patients who were admitted with a diagnosis of congestive heart failure immediately before and after the isolated patient. Matching by primary diagnosis ensured that isolated and control patients had similar indications for admission, were treated by similar clinicians, and were cared for at similar times of the year. This cohort of patients was selected to evaluate isolation policies in patients admitted with a common cardiac disorder for which established standards of care are available.

### Isolation Policies

Isolation precaution policies for MRSA (contact precautions) at both study in-

stitutions are based on the most recent recommendations from the Centers for Disease Control and Prevention.<sup>9</sup> The precautions are designed to prevent transmission through both direct (person-to-person) contact and indirect (via environmental surface) contact. Patients are cared for in private rooms, visitors are required to wear gloves and gowns, patient movement from the room is limited to essential purposes, and dedicated equipment (eg, stethoscope and blood pressure cuff) is used for each patient.

### Patient Characteristics

Each patient's chart was reviewed for demographic, hospital, and clinical data. Median household income was imputed on the basis of principal residence using geocoding (postal codes and ZIP codes) and census data (1996 Canadian Census and 2000 US Census).<sup>17</sup> Patient comorbidities were summarized using the Charlson comorbidity index<sup>18</sup> and illness severity was measured by Acute Physiology and Chronic Health Evaluation (APACHE) II scores.<sup>19</sup> Treatment preferences were summarized by recording do-not-resuscitate orders issued within the first 2 days of admission. The most recent ejection fraction was recorded for patients admitted with congestive heart failure.

### Process of Care

Documentation of patient vital signs and clinicians' narrative notes were recorded as general process-of-care measures and markers for thoroughness of care.<sup>20-22</sup> These measures were selected because they are appropriate for patients with a broad range of diagnoses. The following disease-specific inpatient process-of-care measures were recorded for patients with congestive heart failure: inpatient evaluation of left ventricular function, inpatient ischemia evaluation (eg, stress test or coronary angiogram), documentation of daily weight, efforts toward heart failure education, timely (within 4 weeks) follow-up appointment scheduled at discharge, and admission and discharge cardiovascular medications.<sup>23,24</sup>

### Outcomes of Care

Adverse events were defined as injuries caused by medical management. We included injuries that prolonged the hospital stay or produced disability (the definition used for the Harvard Medical Practice Study),<sup>25</sup> as well as injuries that resulted in transient disability or abnormal laboratory value measurements (which would not have met those criteria). We applied this more inclusive definition to capture events that would be clinically significant yet might not have met the standard for malpractice.

A trained medical record analyst abstracted each patient's hospitalization into a 1-page summary (excluding mention of MRSA or isolation procedures). Two independent physicians, blinded to isolation status, reviewed each summary for adverse events.<sup>25</sup> Clinical reviewers were also asked to grade the severity of any injury (on a 6-point scale ranging from a single day of symptoms to death) and rate their confidence in the preventability of the adverse event (on a 6-point scale ranging from no evidence to virtual certain evidence of preventability). A third reviewer resolved discrepancies. The adequacy of reviewer blinding was not tested.

### Patient Satisfaction

Evidence of dissatisfaction with hospital care was ascertained from 2 sources. First, a structured implicit review of each medical record was performed using the method of Nettleman and Nelson.<sup>26</sup> Documented evidence of dissatisfaction included patients leaving against medical advice, recorded complaints about medical care, attempted suicide, and altercations. Second, files from the public relations offices at both institutions were reviewed for unsolicited complaints. Narratives were coded for specific complaints using a standardized set of codes comprising 6 categories: perceptions of treatment, access to staff, communication, humaneness of staff, environmental cleanliness, and billing.<sup>27-29</sup>

### Statistical Analyses

The primary analysis tested associations between patients' isolation status and all of the quality-of-care measures. Baseline patient characteristics were compared using *t* tests and  $\chi^2$  tests and the Fisher exact test for outcomes with rare events. A team of 6 medical record reviewers tested the reliability of the measurement instruments. All medical records were reviewed and abstracted by a trained medical record analyst using a standard data abstraction tool. One other reviewer independently evaluated a 10% random sample of all medical records. Four physician-reviewers provided judgments on adverse events. Agreement was assessed with Cohen  $\kappa$  reliability coefficients.<sup>30</sup>

Linear, logistic, and Poisson regression analyses were used to test for differences between isolated and control patients after adjustment for study cohort and patient demographic characteristics (age, sex, race/ethnicity, primary language, household income), hospital characteristics (mode of hospital arrival, admitting service, ward, admission day), and clinical characteristics (health habits, institutional status, individual comorbidities, Charlson comorbidity index score, admitting diagnosis, APACHE II score, do-not-resuscitate status). The data for our general process-of-care measures were longitudinal in nature, with repeat daily hospital observations clustered within each patient. In analyzing these data, we adjusted for day-level variables (day of hospital stay, hospital ward, day of week) in addition to patient-level variables. To account for the interdependence of these observations, we used robust estimates of variance (generalized estimating equation).<sup>31</sup> Cardiovascular medications were examined using paired analyses that compared changes in medications from admission to discharge for isolated and control patients. Statistical analyses were performed using Stata (version 8.0; Stata Corp, College Station, Tex), with 2-tailed significance levels of .05.

The ethics committee of Sunnybrook and Women's College Health Sciences Centre and the institutional re-

view board of Brigham and Women's Hospital approved the study.

### RESULTS

We identified 78 isolated patients and 156 control patients in our general cohort. In addition, we identified 72 isolated patients and 144 control patients in our congestive heart failure cohort. The matching process was straightforward and complete. Four patients had missing nursing notes (1 isolated patient and 3 control patients) while 1 isolated patient had missing physician notes. Medical records were available for the remaining 445 patients (99%). The interrater reliabilities for our measurement instruments ranged from 0.78 to 0.97, and the  $\kappa$  coefficients for the presence and preventability of adverse events were 0.72 and 0.40, respectively.

The baseline characteristics of the study groups were similar, with a few notable exceptions (TABLE 1). In the general cohort, there were fewer noninstitutionalized patients in the isolated group than the control group ( $P < .001$ ). In the congestive heart failure cohort there were more cases of diabetes ( $P = .048$ ), more arrivals by ambulance ( $P = .03$ ), and generally higher baseline ejection fractions ( $P = .009$ ) for isolated patients than for controls. All of the isolated patients in both cohorts were isolated for MRSA during their hospital stay (144 [96%] colonizations and 6 [4%] infections), while 4 control patients were temporarily isolated for other infectious disorders (2 vancomycin-resistant enterococcus infections, 1 *Acinobacter* infection, and 1 for infectious diarrhea).

### Process of Care

Isolated and control patients had similar numbers of daily vital sign recordings (TABLE 2). However, isolated patients were more likely to have their vital signs incompletely recorded (14% vs 9%;  $P < .001$ ) and to have days with no vital sign recordings (5% vs 1%;  $P = .02$ ) at all. A third of the respiratory rates were recorded as exactly 20/min for both groups. Isolated patients were almost twice as likely to have their

vital signs not recorded as ordered (51% vs 31%;  $P < .001$ ), and they were also more likely to have days with no nursing narrative notes (14% vs 10%;  $P < .001$ ) or physician progress notes (26% vs 13%;  $P < .001$ ) recorded.

Among the patients admitted with congestive heart failure, isolated and control patients received similar care in the emergency department. They were equally likely to have an electrocardiogram (85% vs 94%;  $P = .22$ ), chest radiograph (93% vs 88%;  $P = .49$ ), general blood work (100% vs 99%;  $P = .72$ ), and cardiac enzyme measurement (69% vs 66%;  $P = .50$ ) on arrival. Once admitted to the ward, however, isolated patients were far less likely to have a stress test or angiogram if they had angina (8/59 [14%] vs 42/93 [45%];  $P < .001$ ), to have their weight recorded on at least half of the days of the hospitalization (58% vs 87%;  $P = .01$ ), or to have an evaluation of left ventricular function while in the hospital (57% vs 69%;  $P = .049$ ).

Overall, 199 patients with a diagnosis of congestive heart failure were discharged from the hospital alive. Among these, isolated patients were less likely to have documentation of congestive heart failure education (18/63 [29%] vs 69/136 [51%];  $P = .004$ ) and timely (within 4 weeks) follow-up appointments scheduled (15/63 [24%] vs 63/136 [46%];  $P = .001$ ). When cardiovascular medications on admission (mean number of medications, 4.4 vs 4.2;  $P = .38$ ) and discharge (mean number of medications, 4.6 vs 5.0;  $P = .09$ ) were compared, isolated patients were found to have a smaller increase in the mean number of medications prescribed than control patients (+0.2 vs +0.8;  $P = .02$ ). Specifically, admission-to-discharge changes in the proportion of patients prescribed angiotensin-converting enzyme inhibitors (-9% vs +8%;  $P = .009$ ), digoxin (-6% vs +7%;  $P = .045$ ), and diuretics (+3% vs +11%;  $P = .03$ ) favored control patients. No significant differences in medication changes were noted for angiotensin II receptor antagonists, hydralazine,  $\beta$ -blockers, spironolactone, antiplatelet agents, anticoagu-

lants, lipid-lowering medications, nitrates, amiodarone, or calcium channel blockers.

### Outcomes and Satisfaction

Isolated patients had longer hospitalizations and higher rates of adverse events

compared with control patients (TABLE 3). Overall, there were 161 independent adverse events experienced by

**Table 1.** Demographic, Hospital, and Clinical Characteristics of Patients\*

Characteristics	General Cohort		Congestive Heart Failure Cohort	
	Isolated Patients (n = 78)	Control Patients (n = 156)	Isolated Patients (n = 72)	Control Patients (n = 144)
<b>Demographic</b>				
Age, mean (SD), y	69.6 (17.1)	65.4 (18.2)	66.9 (14.7)	66.0 (14.5)
Female	43 (55)	77 (49)	30 (42)	66 (46)
Nonwhite race	5 (6)	14 (9)	16 (22)	34 (24)
English not primary language	7 (9)	9 (6)	7 (10)	9 (6)
Household income, median (IQR), \$†	43 585 (35 352-55 162)	47 040 (37 809-58 921)	51 843 (42 567-62 586)	46 592 (36 025-57 838)
<b>Hospital</b>				
Ambulance hospital arrival‡	40 (51)	66 (42)	41 (57)	59 (41)
Admitting service				
Medicine	53 (68)	101 (65)	69 (96)	139 (96)
Surgery	25 (32)	55 (35)	3 (4)	5 (3)
Critical care unit admission	17 (22)	32 (20)	8 (11)	9 (6)
Weekend or holiday admission	17 (22)	26 (17)	10 (14)	34 (24)
<b>Clinical</b>				
Smoking history	23 (29)	50 (32)	35 (49)	84 (58)
Alcohol use history	16 (20)	28 (18)	19 (26)	45 (31)
Noninstitutionalized‡	62 (79)	149 (95)	67 (93)	136 (94)
Comorbidities				
Congestive heart failure	11 (14)	29 (19)	54 (75)	110 (76)
Coronary artery disease	26 (33)	38 (24)	45 (62)	83 (58)
Chronic lung disease	10 (13)	30 (19)	23 (32)	42 (29)
Diabetes‡	12 (15)	28 (18)	40 (56)	58 (40)
Liver disease	3 (4)	0	1 (1)	3 (2)
History of malignancy	21 (27)	28 (18)	17 (24)	22 (15)
Human immunodeficiency virus infection	0	4 (3)	0	0
Neurological disease	25 (32)	34 (22)	7 (10)	26 (18)
Renal insufficiency	7 (9)	19 (12)	26 (36)	41 (28)
Charlson comorbidity index score, mean (SD)§	2.3 (1.6)	2.1 (1.9)	4.1 (1.9)	3.7 (1.9)
Admitting diagnosis				
Medical condition	52 (67)	98 (63)	72 (100)	144 (100)
Congestive heart failure	5 (6)	6 (4)	72 (100)	144 (100)
Pneumonia	7 (9)	16 (10)	0	0
Malignancy	8 (10)	13 (8)	0	0
Other	32 (41)	63 (40)	0	0
Surgical condition	26 (33)	58 (37)	0	0
Elective	15 (19)	26 (17)	0	0
Nonelective	11 (14)	32 (20)	0	0
APACHE II score, mean (SD)	12.4 (6.4)	11.8 (6.6)	12.1 (5.1)	11.1 (5.2)
Ejection fraction, %‡				
>60	NA	NA	7 (10)	9 (6)
41-60	NA	NA	32 (44)	44 (31)
21-40	NA	NA	26 (36)	47 (33)
≤20	NA	NA	7 (10)	42 (29)
DNR within 48 h of admission	4 (5)	12 (8)	11 (15)	17 (12)

Abbreviations: APACHE, Acute Physiology and Chronic Health Evaluation; DNR, do-not-resuscitate order; IQR, interquartile range; NA, not applicable.

\*Data are expressed as number (percentage) unless otherwise indicated.

†Household income is reported in Canadian dollars (1996 Canadian Census) for the general cohort and US dollars (2000 US Census) for the congestive heart failure cohort.

‡There were statistically significant differences in the general cohort for noninstitutionalized ( $P < .001$ ) and in the congestive heart failure cohort for ambulance hospital arrival ( $P = .03$ ), diabetes ( $P = .048$ ), and ejection fraction ( $P = .009$ ).

§The range of scores for the Charlson comorbidity index was 1 through 10, with higher scores indicating greater comorbidity.

121 patients; 88 patients with a single adverse event (45 isolated patients vs 43 control patients), 27 patients with 2 adverse events (22 isolated patients vs 5 control patients), and 6 patients with 3 or more adverse events (6 isolated patients vs 0 control patients) ( $P = .002$  for test of proportions). Isolated patients were twice as likely as control patients to experience adverse events (31 vs 15 adverse events per 1000 days;  $P < .001$ ) during their hospital stay. This difference reflected preventable (20 vs 3 adverse events per 1000 days;  $P < .001$ ) as opposed to nonpreventable (11 vs 12 adverse events per 1000 days;  $P = .98$ ) adverse events. Specifically, isolated patients were 8 times more likely than control patients to experience supportive care failures such as falls, pressure ulcers, and fluid or electrolyte disorders; in contrast, no significant differences in diagnostic, operative, anesthesia, medical procedure, or adverse drug events were noted. The overall severity of patient injuries from adverse events was

similar for both groups (Table 3), and no differences in total hospital mortality were observed (26 isolated patients [17%] vs 30 control patients [10%]; odds ratio, 1.69; 95% confidence interval, 0.49-3.21;  $P = .16$ ).

**Table 2.** Common Process-of-Care Measures

Measures	General Cohort		Congestive Heart Failure Cohort		Isolated Patients vs Control Patients*	
	Isolated Patients (n = 78)	Control Patients (n = 156)	Isolated Patients (n = 72)	Control Patients (n = 144)	Test Statistic (95% CI)†	P Value
No. of daily vital signs expected	3.2	3.1	4.7	4.2	0.32 (0.11 to 0.53)	.003
No. of daily vital signs recorded	2.6	3.0	6.2	6.3	-0.21 (-0.54 to 0.12)	.21
Vital signs incompletely recorded, %	10	8	19	10	1.92 (1.61 to 2.30)	<.001
Days with no vital signs recorded, %	6	1	5	1	2.55 (1.14 to 5.69)	.02
Vital signs with respiratory rate of 20/min, %	41	39	43	36	1.07 (0.93 to 1.23)	.34
Days with vital signs not recorded as ordered, %	58	41	43	21	2.76 (2.17 to 3.51)	<.001
Days with no nursing narrative notes, %	11	11	17	9	1.77 (1.40 to 2.24)	<.001
Days with no physician progress notes, %	43	24	7	2	2.91 (1.90 to 4.47)	<.001

Abbreviation: CI, confidence interval.

\*Comparisons between isolated and control patients are adjusted for study cohort and patient demographic, hospital, and clinical characteristics.

† $\beta$  Coefficients are reported for absolute differences in vital signs expected and recorded; odds ratios are reported for the remaining measures.

**Table 3.** General Nature and Severity of Adverse Events

Measures	General Cohort		Congestive Heart Failure Cohort		Isolated Patients vs Control Patients*	
	Isolated Patients (n = 78)	Control Patients (n = 156)	Isolated Patients (n = 72)	Control Patients (n = 144)	Rate Ratio (95% CI)	P Value
Length of stay, median (IQR), d	31 (10-69)	12 (7-24)	8 (4-13)	6 (4-9)	NA	<.001†
Adverse events, No. (rate per 1000 d)						
Any	70 (17.0)	25 (7.0)	38 (47.3)	28 (24.5)	2.20 (1.47-3.30)	<.001
Nonpreventable	19 (4.6)	16 (4.5)	15 (18.7)	23 (20.1)	0.99 (0.54-1.81)	.98
Preventable	51 (12.4)	9 (2.5)	23 (28.6)	5 (4.4)	6.96 (3.38-14.3)	<.001
Nature of adverse events, No. (rate per 1000 d)						
Operative	13 (3.2)	12 (3.4)	4 (5.0)	8 (7.0)	0.79 (0.37-1.68)	.55
Medical procedure-related	10 (2.4)	3 (0.8)	3 (3.7)	4 (3.5)	1.80 (0.64-5.06)	.27
Drug-related	10 (2.4)	7 (2.0)	16 (19.9)	12 (10.5)	1.47 (0.78-2.78)	.23
Supportive care failure	25 (6.1)	3 (0.8)	13 (16.2)	2 (1.8)	8.27 (3.09-22.1)	<.001
Diagnostic error	7 (1.7)	0	2 (2.5)	2 (1.7)	NA	.06‡
Anesthesia-related	1 (0.2)	0	0	0	NA	.51‡
Miscellaneous	4 (1.0)	0	0	0	NA	.07‡
Overall injury severity due to adverse events, No. (%) of patients					NA	.51§
Symptoms¶	15 (33)	7 (32)	11 (39)	14 (54)		
Disability	18 (40)	11 (50)	11 (39)	8 (31)		
Death	12 (27)	4 (18)	6 (21)	4 (15)		

Abbreviations: CI, confidence interval; IQR, interquartile range; NA, not applicable.

\*Comparisons between isolated and control patients are adjusted for study cohort and patient demographic, hospital, and clinical characteristics.

†P value calculated by Wilcoxon rank-sum test.

‡Unadjusted P values calculated by Fisher exact test due to small number of events.

§A single P value for a test of proportions comparing isolated and control patients is reported for overall injury severity.

||Data do not necessarily sum to 100 (rounding error).

¶Includes asymptomatic patients with laboratory abnormalities.

**Table 4.** Measures of Patient Dissatisfaction\*

Measures	General Cohort		Congestive Heart Failure Cohort		Isolated Patients vs Control Patients†	
	Isolated Patients (n = 78)	Control Patients (n = 156)	Isolated Patients (n = 72)	Control Patients (n = 144)	Odds Ratio (95% CI)	P Value
Any complaint‡	30 (38)	8 (5)	12 (17)	5 (3)	23.5 (8.20-66.4)	<.001
Informal complaint	28 (36)	6 (4)	9 (12)	4 (3)	17.0 (6.11-47.6)	<.001
Formal complaint	8 (10)	2 (1)	4 (6)	1 (1)	14.8 (3.07-71.3)	<.001

Abbreviation: CI, confidence interval.

\*Data are expressed as number (percentage) of patients.

†Comparisons between isolated and control patients are adjusted for study cohort and patient demographic, hospital, and clinical characteristics.

‡Subtotals of patient complaints do not sum because some patients had both informal and formal complaints.

Isolated patients expressed greater dissatisfaction with their treatment than control patients (TABLE 4). These differences were reflected by both informal and formal complaints. Twelve isolated patients (8%) submitted unsolicited complaints to the hospital compared with only 3 control patients (1%). Complaints were associated with negative perceptions of treatment (5 isolated patients vs 0 control patients), access to staff (3 isolated patients vs 0 control patients), communication (3 isolated patients vs 0 control patients), humanness of staff (0 isolated patients vs 1 control patient), cleanliness of the environment (1 isolated patient vs 1 control patient), and billing and payment (0 isolated patients vs 1 control patient). Only 2 unsolicited compliments were identified, both from control patients.

## COMMENT

Our study examined the quality of medical care received by patients isolated for infection control during hospitalization. The results demonstrate a strong association between patient isolation and shortfalls of processes, outcomes, and satisfaction. Isolated patients were less likely than control patients to have their vital signs accurately recorded, to have daily physician progress notes documented, and to achieve selected disease-specific standards of care for heart failure management. Isolated patients also were more likely to experience a preventable adverse event and to express dissatisfaction with their care. Hospital mortality rates were similar for both groups.

Patient safety has become an increasingly prominent issue.<sup>1</sup> Much of the attention has focused on medications<sup>32</sup> and surgery,<sup>33</sup> yet any medical intervention can have adverse consequences. Isolation represents one such intervention. A large body of observational studies supports the effectiveness of isolation policies in preventing nosocomial infections.<sup>10-11</sup> Furthermore, prominent authorities endorse such procedures for selected patients.<sup>9,12,13</sup> However, persistent concerns remain about the safety of isolation policies because infection control is only one component of patient safety.<sup>6-8,14-16</sup>

Our study provides some of the strongest data to date on how a systems change can result in frequent, systematic, and predictable medical errors. It is unlikely that the lapses in processes, outcomes, and satisfaction documented in this study were deliberate; hence, our results underscore the importance of examining any intervention (eg, isolation precautions) for unintended consequences. In addition, multicomponent interventions (eg, barriers, restricted access, reduced mobility) should have their individual parts examined to determine whether all elements are essential. For example, it may be possible to disentangle which isolation policy components are most important for infection control and which may be most deleterious to the isolated patient. Finally, the need for individualization is highlighted because the patients who experienced the most negative effects from isolation strategies might not necessarily be those who

presented the highest risk of disease transmission. The interdependence of individual patient characteristics, clinician factors, environmental constraints, and organizational climate is likely to significantly influence safety.

Our study also underscores some of the challenges of improving patient safety. First, adverse consequences are not always easily detected; furthermore, rigorous clinical trials may minimize adverse events because special attention by research assistants provides an extra layer of safeguard and error interception. Second, difficult trade-offs may emerge, such as the tension between preventing injury to other patients (such as reducing nosocomial transmission of pathogens) and maximizing the well-being of an individual patient (by avoiding barrier restrictions). Third, because most medical interventions are well intentioned, faulty systems often arise when a focus on one priority detracts from other unrelated clinical concerns. Interventions that simplify tasks (such as minimizing barriers between patients and clinicians) and minimize distractions are likely to improve safety.<sup>2,5</sup> Fourth, while educational or regulatory policies that update clinicians with new information on an intervention's risks and benefits (such as unintentional discrepancies in the care of isolated patients) have intuitive appeal, they are unlikely to have a significant effect on safety.<sup>34</sup> Rather, creative solutions that recognize the limitations of clinicians are badly needed. Ultimately, the only foolproof way to eliminate medical errors is by eliminating disease—for example, effective eradication techniques might allow patients with multidrug-resistant pathogen colonization to avoid isolation altogether.

Our study also highlights the limitations of science applied to medical errors. Similar to most research in this field, our data are quasi-experimental in nature and raise the question of whether the differences between the 2 study groups are simply a function of illness severity. This concern seems less worrisome in our study because the patient characteristics of our groups were

remarkably similar. Nevertheless, unmeasured differences in illness severity in our study may cause our results to underestimate quality-of-care differences if isolated patients were inherently sicker than control patients because the standard of care for isolated patients should therefore have been higher. In addition, our data were obtained through retrospective chart review, as with most articles on patient safety. Chart review is problematic because it tends to miss subtle lapses in care.<sup>35,36</sup> Finally, our results are based on patients with MRSA at 2 major North American teaching hospitals. Patients isolated because of other infectious agents or treated in smaller hospitals may have different experiences.

In summary, hospital infection control policies may prevent the spread of communicable infections but may also inadvertently lead to poorer quality of care and adverse events. Our results illustrate the importance of balancing the risks and benefits of an intervention while highlighting that mandatory policies may not always be appropriate. In addition, our findings provide greater incentives for the eradication of chronic disease states and promote the use of human factors research to develop safer medical policies. The complexities of health care are likely to increase in the future, making the detection of unintended adverse consequences even more difficult. Well-designed, carefully evaluated, and appropriately implemented interventions will be essential in ensuring the safety of all patients.

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Acquisition of data: Stelfox.

Analysis and interpretation of data: Stelfox, Redelmeier.

Drafting of manuscript: Stelfox, Redelmeier.

Critical revision of manuscript for important intellectual content: Stelfox, Bates, Redelmeier.

Statistical expertise: Stelfox, Redelmeier.

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Supervision: Bates, Redelmeier.

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Medicalis Corp. He holds a minority equity position in the privately held company Medicalis, which develops Web-based decision support for radiology test ordering, and serves as a consultant to Medicalis. He is also a consultant and serves on the advisory board for McKesson MedManagement, a company that assists hospitals in preventing adverse drug events. He has received honoraria for speaking from Automated Healthcare, which makes robots that dispense medications. He is on the clinical advisory board for Zynx Inc, which develops evidence-based algorithms; Clineguides, which develops clinical knowledge; and Voltage Inc, which compiles information on compliance for drug companies. He is a consultant for Alanis, which makes intravenous drug delivery systems.

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## REFERENCES

- Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: National Academy Press; 2000.
- Reason JT. *Human Error*. Cambridge, England: Cambridge University Press; 1990.
- Reason JT. *Managing the Risks of Organizational Accidents*. Aldershot, England: Ashgate; 1997.
- Weick KE. Organizational culture as a source of high reliability. *Calif Manage Rev*. 1987;29:112-127.
- Pew C. Normal Accidents: Living With High-Risk Technologies. New York, NY: Basic Books; 1984.
- Peel RK, Stolarek I, Elder AT. Isolating patients with MRSA can have long term implications. *BMJ*. 1997;315:58.
- Teare EL, Barrett SP. Stop the ritual of tracing colonised people. *BMJ*. 1997;314:665-666.
- Knowles HE. The experience of infectious patients in isolation. *Nursing Times*. 1993;89:53-56.
- Garner JS. Guideline for isolation precautions in hospitals. *Infect Control Hosp Epidemiol*. 1996;17:54-80.
- Ostrowsky BE, Trick WE, Sohn AH, et al. Control of vancomycin-resistant enterococcus in health care facilities in a region. *N Engl J Med*. 2001;344:1427-1433.
- Montecalvo MA, Jarvis WR, Uman J, et al. Infection-control measures reduce transmission of vancomycin-resistant enterococci in an endemic setting. *Ann Intern Med*. 1999;131:269-272.
- World Health Organization. Hospital infection control guidance for severe acute respiratory syndrome (SARS). Available at: <http://www.who.int/csr/sars/infectioncontrol/en>. Accessed April 22, 2003.
- Centers for Disease Control and Prevention. Severe acute respiratory syndrome (SARS). Available at:

<http://www.cdc.gov/ncidod/sars/>. Accessed April 22, 2003.

- Burke JP. Infection control—a problem for patient safety. *N Engl J Med*. 2003;348:651-656.
- Kirkland K, Weinstein J. Adverse effects of contact isolation. *Lancet*. 1999;354:1177-1178.
- Higgins L, Saint S, Nallamothu B, Chenoweth C. Do physicians examine patients under contact precautions less frequently? *J Gen Intern Med*. 2001;16 (suppl 1):200.
- Krieger N. Overcoming the absence of socioeconomic data in records: validation and application of a census-based methodology. *Am J Public Health*. 1992;82:703-710.
- Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis*. 1987;40:373-383.
- Knaus W, Draper E, Wagner D, et al. APACHE II: a severity of disease classification system. *Crit Care Med*. 1985;13:818-829.
- Brown LH, Prasad NH. Effect of vital signs on advanced life support interventions for prehospital patients. *Prehosp Emerg Care*. 1997;1:145-148.
- Sobie JM, Gaves D, Tringali A. ED "hold" patients: is their care also being held? *J Emerg Nurs*. 2000;26:549-553.
- Rosenberg AL, Watts C. Patients readmitted to ICUs: a systematic review of risk factors and outcomes. *Chest*. 2000;118:492-502.
- Quality of care and outcomes research in CVD and stroke working groups: measuring and improving quality of care. *Circulation*. 2000;101:1483-1493.
- Krumholz HM, Baker DW, Ashton CM, et al. Evaluating quality of care for patients with heart failure. *Circulation*. 2000;101:E122-E140.
- Harvard Medical Practice Study. *Patients, Doctors and Lawyers: Studies of Medical Injury in New York*. Boston, Mass: Harvard University; 1990.
- Nettleman MD, Nelson AP. Adverse occurrences during hospitalization on a general medicine service. *Clin Perform Qual Health Care*. 1994;2:67-72.
- Hickson G, Pichert JW, Federspiel CF, Clayton EW. Development of an early identification and response model of malpractice prevention. *Law Contemp Problems*. 1997;27:8-29.
- Pichert JW, Federspiel CF, Hickson GB, Miller CS, Gauld-Jaeger J, Gray CL. Identifying medical center units with disproportionate shares of patient complaints. *Jt Comm J Qual Improv*. 1999;25:288-299.
- Hickson GB, Federspiel CF, Pichert JW, Miller CS, Gauld-Jaeger J, Bost P. Patient complaints and malpractice risk. *JAMA*. 2002;287:2951-2957.
- Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics*. 1977;33:159-174.
- Zeger SL, Liang K-Y. Longitudinal data analysis for discrete and continuous outcomes. *Biometrics*. 1986;42:121-130.
- Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. *JAMA*. 1995;274:29-34.
- Gawande AA, Studdert DM, Orav EJ, Brennan TA, Zinner MJ. Risk factors for retained instruments and sponges after surgery. *N Engl J Med*. 2003;348:229-235.
- Smalley W, Shatin D, Wysowski D, et al. Contradicted use of cisapride: impact of food and drug administration regulatory action. *JAMA*. 2000;284:3036-3039.
- O'Neil A, Petersen LA, Cook F, Bates DW, Lee TH, Brennan TA. Physician reporting compared with medical-record review to identify adverse medical events. *Ann Intern Med*. 1993;119:370-376.
- Andrews LB, Stocking C, Krizek T, et al. An alternative strategy for studying adverse events in medical care. *Lancet*. 1997;349:309-313.