A Controlled Trial of a Critical Pathway for Treatment of Community-Acquired Pneumonia

Thomas J. Marrie, MD

Catherine Y. Lau, PhD

Susan L. Wheeler, RN

Cindy J. Wong, MSc

Margaret K. Vandervoort, MSc

Brian G. Feagan, MD

for the CAPITAL Study Investigators

C OMMUNITY-ACQUIRED PNEUMO-nia (CAP) is a common and serious illness. Each year in the United States, approximately 15% of the 600 000 affected people who are admitted to the hospital die of the disease.[1] Analyses of administrative data show that large variations exist in admission rates, length of hospital stay, and use of institutional resources.[2,3] Lack of a common approach to the diagnosis and treatment of CAP is often cited as an explanation for these findings.[4,5] Since the cost to society for the treatment of CAP is high,[6] interventions that increase the efficiency of care are desirable.

Critical pathways are management strategies that define the essential steps of complex processes.[7] These schemata may improve the quality and/or reduce the cost of a product or service by ensuring that the events necessary for occurrence of an optimal outcome take place in a timely fashion. Originally developed by industry, critical pathways are frequently used by health care organizations to ensure the delivery of high-quality care and control costs.[8-10] However, the widespread acceptance of these "care paths" is questionable because very little prospective controlled data are available demonstrating that they either

See also Patient Page.

Context Large variations exist among hospitals in the use of treatment resources for community-acquired pneumonia (CAP). Lack of a common approach to the diagnosis and treatment of CAP has been cited as an explanation for these variations.

Objective To determine if use of a critical pathway improves the efficiency of treatment for CAP without compromising the well-being of patients.

Design Multicenter controlled clinical trial with cluster randomization and up to 6 weeks of follow-up.

Setting Nineteen teaching and community hospitals in Canada.

Patients A total of 1743 patients with CAP presenting to the emergency department at 1 of the participating institutions between January 1 and July 31, 1998.

Intervention Hospitals were assigned to continue conventional management (n = 10) or implement the critical pathway (n = 9), which consisted of a clinical prediction rule to guide the admission decision, levofloxacin therapy, and practice guidelines.

Main Outcome Measures Effectiveness of the critical pathway, as measured by health-related quality of life on the Short-Form 36 Physical Component Summary (SF-36 PCS) scale at 6 weeks; and resource utilization, as measured by the number of bed days per patient managed (BDPM).

Results Quality of life and the occurrence of complications, readmission, and mortality were not different for the 2 strategies; the 1-sided 95% confidence limit of the between-group difference in the SF-36 PCS change score was 2.4 points, which was within a predefined 3-point boundary for equivalence. Pathway use was associated with a 1.7-day reduction in BDPM (4.4 vs 6.1 days; $P = .04$) and an 18% decrease in the admission of low-risk patients (31% vs 49%; $P = .01$). Although inpatients at critical pathway hospitals had more severe disease, they required 1.7 fewer days of intravenous therapy (4.6 vs 6.3 days; $P = .01$) and were more likely to receive treatment with a single class of antibiotic (64% vs 27%; $P<.001$).

Conclusion In this study, implementation of a critical pathway reduced the use of institutional resources without causing adverse effects on the well-being of patients.

JAMA. 2000;283:749-755 www.jama.com

improve the outcomes of patients or reduce the use of resources.[11,12] We evaluated the safety and effectiveness of a critical pathway for the management of CAP by means of a randomized controlled trial.

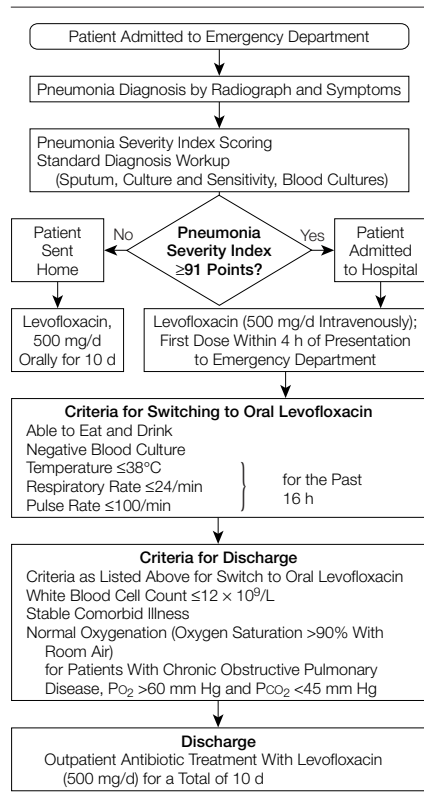## METHODS
Study Institutions and Randomization Procedure

Our primary hypothesis was that utilization of a critical pathway would reduce the use of institutional resources

Figure 1. Critical Pathway for the Treatment of Community-Acquired Pneumonia

without compromising the safety and efficacy of therapy. Since critical pathways are implemented at the institutional level, hospitals, rather than individual patients, were randomly assigned to either introduce the pathway or continue conventional management. The centers were Canadian teaching or community hospitals whose administrations (1) were willing to allow the institution to be allocated to either of the 2 strategies for a 6-month period and (2) agreed not to implement any of the components of the critical pathway if assigned to conventional management. The randomization procedure was stratified by type of institution (teaching or community hospital) and matched by the historical length of stay (obtained from a feasibility study). Random assignment was generated by a computer. The study was approved by the institutional review board at each center.

Study Patients

We collected data from all patients with CAP who presented to the emergency department (ED) between January 1 and July 31, 1998. Eligible patients were adults with at least 2 signs or symptoms of CAP (eg, temperature >38°C, productive cough, chest pain, shortness of breath, crackles on auscultation) and whose chest radiograph showed an opacity compatible with the presence of acute pneumonia.[13] Patients with an immune deficiency (eg, human immunodeficiency virus infection, use of >10 mg/d of prednisone or other immunosuppressive agents, active treatment for cancer, history of organ transplantation, active tuberculosis, cystic fibrosis) were ineligible. Individuals who experienced shock, those who required intubation or direct admission to the intensive care unit (ICU), women who were pregnant or nursing infants, persons with alcohol addiction, and patients with chronic renal failure (estimated creatinine clearance <20 mL/min [0.33 mL/s]) were not included. Informed consent was requested from all eligible patients for completion of quality-of-life and outpatient follow-up questionnaires. Admission status, length of hospital stay, and occurrence of complications or readmission to hospital were obtained from institutional records for every eligible patient.

Critical Pathway Sites

Prior to initiation of the study, 2 investigators (T.J.M. and C.Y.L.) met with personnel at each hospital and developed an educational plan designed to reinforce compliance with the pathway.

The critical pathway (**FIGURE 1**) has 3 components: use of a clinical prediction rule[14] to assist the admission decision, treatment with levofloxacin (Levaquin, Janssen-Ortho Inc, Toronto, Ontario),[15] and practice guidelines[16] for the care of inpatients. The guidelines consisted of criteria for switching from intravenous to oral antibiotics and discharge from hospital.

Patients having a suspected diagnosis of CAP were assessed in the ED and

treated by primary care physicians and/or specialists according to usual practice. Emergency department nurses were instructed on the use of the Pneumonia Severity Index (PSI), a clinical prediction rule that assigns a score based on 20 items that include demographic factors, coexisting illnesses, physical examination findings, and laboratory and radiographic findings.[17] Scores range from approximately 10 to 250; higher scores indicate more severe pneumonia. Five severity classes are defined; patients in classes I to III (scores ≤90 points) are at low risk for death or complications. For each subject, a PSI score was calculated by a nurse, who made this determination available to the ED physician. Patients with scores of 90 points or lower were recommended for discharge from the ED, whereas those with higher scores were recommended for admission. The PSI score was used only as a guide to the admission decision and did not supercede clinical judgment; we expected that the use of this instrument would result in the admission of fewer low-risk patients.

Levofloxacin, a fluoroquinolone antibiotic, has high bioavailability, a broad antimicrobial spectrum, and a cost similar to other antibiotics commonly used to treat CAP.[18] Patients treated as outpatients received 500 mg of oral levofloxacin once per day for 10 days. Those who were admitted to the hospital received a single 500-mg dose of parenteral drug and were subsequently treated according to the guidelines.[19,20] We expected that use of levofloxacin would increase the proportion of patients who were treated with a single class of antibiotic.

Patients who were admitted were assessed each day by a study nurse who placed a note on the patient's chart when the criteria for discontinuation of intravenous therapy or hospital discharge were fulfilled (Figure 1). We anticipated that practice guidelines would reduce the use of institutional resources by decreasing both the duration of parenteral antibiotic therapy and the length of stay. No direct incentives were provided to physicians to in-

crease compliance with these guidelines. Following discharge, patients continued taking oral levofloxacin for a maximum of 10 days.

Conventional Management Sites

At these hospitals, management of CAP was according to the usual practice of individual specialists or primary care physicians. Separate investigator meetings, study protocols, and correspondence were used to ensure that health care personnel at the conventional management sites remained unaware of critical pathway components. Levofloxacin was not available and no attempt was made to implement the PSI or the practice guidelines.

Follow-up Procedures

The hospital charts of admitted patients were reviewed each day by the study nurse, who recorded the occurrence of relevant outcomes and made recommendations according to the guidelines. At conventional sites, the nurse made no management recommendations. Patients who gave informed consent for the collection of follow-up data were contacted by telephone 2 and 6 weeks following the completion of the recommended 10-day course of antibiotics, at which time data on quality of life and clinical outcomes were collected.

Outcome Measures

The Short-Form 36 Physical Component Summary (SF-36 PCS) scale,[21] a generic quality-of-life measure, was selected as the primary measure of efficacy. This 36-question instrument has been previously validated in patients with CAP.[22] Scores range from 0 to 100; higher scores indicate better quality of life. Secondary outcome measures were pneumonia-related complications (respiratory failure, systemic sepsis, empyema, new onset of congestive heart failure, or atrial fibrillation), ICU admission, readmission to hospital, and death. All clinical outcomes were independently validated by 2 investigators (T.J.M. and B.G.F.) who were unaware of the treatment assignment and

who also evaluated antibiotic regimens and determined whether 1, 2, or more than 2 classes of antibiotics had been administered. Disagreement was resolved by consensus.

The primary measure of resource utilization was the number of bed days per patient managed (BDPM). This composite measure, which is the mathematical product of the institutional average length of stay and the admission rate, is sensitive to a change in either variable. Since approximately 89% to 96% of expenditures for CAP result from the provision of inpatient services,[23] the BDPM is a robust surrogate for the average (distinct from the typical or median) direct cost of care. The institutional rates of admission of low-risk (PSI classes I-III) patients, length of hospital stay, duration of intravenous antibiotic therapy, and proportion of patients who received a single class of antibiotic were also compared. The length of stay for patients who died in the hospital was calculated as time from admission to the day of death. Data from inpatients were arbitrarily censored at 42 days from the date of admission so that the results from patients with prolonged hospitalization would not strongly influence the estimates of the average length of stay and BDPM. The proportion of patients with length of stay longer than 42 days was similar in the 2 groups of institutions (3.6%).

Statistical Methods

Although the critical pathway was expected to reduce the use of institutional resources, for such savings to be meaningful, it was first necessary to demonstrate that the patients treated at these sites did not have a worse clinical outcome compared with those treated at the conventional management hospitals. To assess this issue, we predefined a lower limit for an acceptable equivalence range of no more than a 3-point worsening in the SF-36 PCS score.[21] The primary efficacy analysis was performed by constructing a 1-sided 95% confidence limit for the between-group difference in the change in institutional scores from baseline to the week 6 value. If the confidence limit

of the observed difference was entirely within this boundary, equivalence was judged to exist.[24] For secondary outcome measures, 2-sided 95% confidence intervals were constructed to describe the institutional rates of these outcomes within each treatment group. One-sided 95% confidence limits were also constructed to estimate the potential between-group difference in favor of conventional management.

Prior to the initiation of the trial, a feasibility study was performed to collect data from 782 patients with pneumonia at 18 of the participating institutions during November 1997 and January and March 1998. Estimates of the rates of admission for pneumonia were also available from 7 sites. From these data, the SD of the BDPM was estimated to be 1.6 days. We estimated that the critical pathway could decrease the admission rate by 10% to 15% and the length of hospital stay by 1 to 2 days, yielding a reduction in the BDPM of approximately 2 days. The randomization of 10 institutions per treatment arm was sufficient to detect a 2-day difference in BDPM with 80% power at the $\alpha = .05$ level of significance. Although the sample size was justified on the basis of a difference in BDPM, the randomization of 10 institutions per arm was also sufficient to define a 1-sided 95% confidence limit, which could demonstrate a 3-point difference in the SF-36 PCS change scores in favor of the conventional management strategy.

A nonparametric procedure, the Mann-Whitney test,[25] was used to compare the difference in BDPM between critical pathway and conventional management hospitals. A 2-sided test was performed at the $\alpha = .05$ level of significance. Since the BDPM is a proxy for the average cost, which is only meaningful at the institutional level, all statistical inferences were made using institutional data,[26] with the hospital as the unit of analysis. A similar approach was used to compare the rate of admission in low-risk patients, the duration of intravenous drug therapy, and the proportions of inpatients treated with a single class of antibiotic. All *P* values were 2-sided.

Although the institutions were matched, the matching was not considered in the analysis.[27] Since the distribution of the length of hospital stay is usually skewed with a few extreme values,[2] institutional median values were also compared. The effectiveness of the critical pathway was evaluated by applying the intention-to-treat principle using data from all eligible patients.

RESULTS

Twenty hospitals were randomized. However, 1 critical pathway institution withdrew prior to the initiation of the study at the site and was not replaced.

From January 1 to July 31, 1998, 1743 patients were evaluated. TABLE 1 shows the baseline characteristics of the institutions and patients. A greater number of patients per site were entered at conventional management institutions because 1 institution (Halifax) resulted from a merger that led to the inclusion of patients from 3 large hospitals. Mean PSI and SF-36 scores at the baseline assessment were similar at conventional management and critical pathway institutions.

Effects on Clinical Outcomes

FIGURE 2 shows the SF-36 PCS scores. Following treatment, patients' quality of life improved rapidly; 6 weeks after the discontinuation of oral antibiotic therapy, the scores in both groups were similar to those of age-matched, population-based controls. No important difference in quality of life was noted between conventional management and critical pathway sites. Since the lower boundary of the 1-sided 95% confidence limit of the between-group difference in the change scores at 6 weeks was 2.4 points in favor of the conventional management group, our prespecified criterion for therapeutic equivalence was satisfied. FIGURE 3 shows that the institutional incidence of adverse clinical outcomes was simi-

Table 1. Baseline Characteristics of the Institutions and Patients (N = 1743)*

| | Critical Pathway Institutions (n = 9) | | | | | | | | | |
	T1 (n = 87)	T2 (n = 55)	T3 (n = 135)	T4 (n = 37)	T5 (n = 85)	C1 (n = 62)	C2 (n = 58)	C3 (n = 66)	C4 (n = 131)	Overall Mean (SD)
Institution characteristics										
No. of beds	400	1200	544	288	1500	299	199	199	700	592 (465)
Historical length of stay, mean, d	9.3	8.4	7.7	8.5	9.8	12.2	8.4	6.8	8.7	8.9 (1.5)
Patient characteristics										
Age, mean, y	64.3	66.2	71.2	59.6	62.4	61.5	65.6	65.4	60.7	64.1 (3.5)
Sex, male, %	43.7	49.1	45.2	64.9	55.3	54.8	56.9	59.1	56.5	53.9 (6.8)
PSI score, mean†	93.5	82.0	101.5	76.3	79.2	80.9	85.8	80.8	77.1	84.1 (8.3)
PSI classes I-III, %†	54.0	61.1	39.4	70.3	65.9	64.5	53.4	59.1	64.6	59.2 (9.2)
SF-36 PCS score, mean‡	30.1	32.4	28.4	30.2	30.7	28.4	29.4	32.5	30.8	30.3 (1.5)
Chronic lung disease, %	22.4	13.5	41.7	24.3	20.2	27.3	32.8	26.2	24.6	25.9 (8.7)
Multilobar disease, %	20.7	32.7	21.8	19.4	36.5	19.4	19.0	7.6	15.3	21.4 (8.7)
Oxygen saturation with room air, %	90.8	93.9	92.0	91.4	92.7	92.6	90.9	93.5	93.3	92.3 (1.1)
	Conventional Management Institutions (n = 10)									
	T6 (n = 205)	T7 (n = 37)	T8 (n = 151)	T9 (n = 37)	T10 (n = 93)	C5 (n = 135)	C6 (n = 92)	C7 (n = 51)	C8 (n = 156)	C9 (n = 70)	Overall Mean (SD)
Institution characteristics											
No. of beds	1068	1000	500	600	353	500	199	200	600	500	552 (292)
Historical length of stay, mean, d	11.8	9.8	6.3	8.8	9.0	11.6	9.1	10.8	6.6	Not Done	9.3 (2.0)
Patient characteristics											
Age, mean, y	67.8	69.7	63.1	52.1	67.5	60.7	63.9	68.1	66.5	63.1	64.2 (5.1)
Sex, male, %	52.7	48.6	43.7	43.2	49.5	56.3	51.1	62.7	40.4	57.1	50.5 (7.0)
PSI score, mean†	99.3	92.4	87.0	62.2	97.0	84.1	81.1	88.5	89.7	86.2	86.8 (10.3)
PSI classes I-III, %†	45.6	54.1	63.9	83.8	52.7	67.2	68.2	62.7	63.4	65.7	62.7 (10.4)
SF-36 PCS score, mean‡	33.4	29.5	30.2	30.7	29.6	30.8	29.3	29.5	27.1	28.4	29.9 (1.6)
Chronic lung disease, %	38.9	29.7	23.3	13.5	27.1	25.2	45.8	73.3	29.4	26.1	33.2 (16.6)
Multilobar disease, %	22.0	27.0	24.5	16.2	21.5	19.7	42.4	12.2	16.7	15.7	21.8 (8.5)
Oxygen saturation with room air, %	91.1	89.4	93.2	93.3	91.6	93.5	91.1	93.4	91.5	92.2	92.0 (1.3)

*T indicates teaching hospital; C, community hospital; T1, St Joseph's Health Centre, London, Ontario; T2, Sunnybrook Health Sciences Centre, Toronto, Ontario; T3, Ottawa Civic Hospital, Ottawa, Ontario; T4, London Health Sciences Centre, University Campus, London, Ontario; T5, Vancouver Hospital and Health Sciences Centre, Vancouver, British Columbia; C1, Cape Breton Regional Hospital, Sydney, Nova Scotia; C2, Colchester Regional Hospital, Truro, Nova Scotia; C3, Valley Regional Hospital, Kentville, Nova Scotia; C4, Thunder Bay Regional Hospital, Port Arthur Site, Thunder Bay, Ontario; T6, Queen Elizabeth II Health Sciences Centre, Halifax, Nova Scotia; T7, University of Alberta Hospital, Edmonton; T8, Ottawa General Hospital, Ottawa, Ontario; T9, Health Sciences Center, St John's, Newfoundland; T10, McMaster University Medical Centre, Hamilton, Ontario; C5, The Moncton Hospital, Moncton, New Brunswick; C6, Western Regional Health Centre, Yarmouth, Nova Scotia; C7, Health Services Association of the South Shore, Bridgewater, Nova Scotia; C8, Oshawa General Hospital, Oshawa, Ontario; C9, Royal Columbian Hospital, New Westminster, British Columbia.
†PSI indicates Pneumonia Severity Index. Scores range from approximately 10 to 250; higher scores indicate more severe disease. Patients with PSI scores of 90 or fewer points are classified as classes I to III.
‡SF-36 PCS indicates Short-Form 36 Physical Component Summary; higher scores indicate better quality of life.

lar at the critical pathway and conventional management hospitals.

Effects on Resource Utilization

TABLE 2 shows the institutional resource utilization data. Significantly fewer low-risk patients (PSI classes I-III) were managed as inpatients at the critical pathway sites (31% vs 49% at conventional management sites; P = .01). Conversely, the admission rates of patients with PSI classes IV and V were similar in the 2 groups (87% at critical pathway vs 88% at conventional management sites; P = .70). Overall, a 10% absolute reduction was shown (53% at critical pathway vs 63% at conventional management sites; P = .11).

Although patients who were admitted at critical pathway institutions had more severe disease, defined by the mean institutional PSI score (103 vs 94 at conventional management sites; P = .05), their median length of hospital stay was lower (5.0 days vs 6.7 days at conventional management sites; P = .01), and they received 1.7 fewer days of intravenous antibiotic therapy (4.6 days vs 6.3 days at conventional management sites; P = .01). Patients at critical pathway hospitals were also more likely to be treated with a single class of antibiotic (64% vs 27% at conventional management sites; $P<.001$).

A 1.7-day decrease in BDPM was shown at critical pathway sites (4.4 days vs 6.1 days at conventional management sites; P = .04).

COMMENT

Our primary finding was that implementation of a critical pathway reduced the use of institutional resources for the treatment of CAP without causing harm to patients.

Hospitals assigned to the critical pathway had an 18% absolute reduction in the admission of low-risk patients (PSI classes I-III). In contrast, the rate of admission of high-risk patients (PSI classes IV and V) was similar in the 2 treatment groups. The most common explanation for the management of a minority of these severe cases as outpatients was patient or family preference, de-

spite, in most cases, a recommendation by a physician for admission to the hospital. Therefore, use of the PSI was discriminative because it identified individuals who could be safely treated in the community setting. We could not detect any negative effects of this intervention on the quality of life of patients or the occurrence of adverse clinical outcomes, including admission to the ICU, mortality, readmission to hospital, or complications. These observations support the use of the PSI as an adjunct to clinical judgment.

Because of the combined effects of a decrease in both the rate of admission and the average length of stay, the hospitals that implemented the critical pathway required an average of 1.7 fewer bed-days for each patient treated. We estimate that this reduction in the use of hospital resources has the potential of saving approximately US $1700 per patient treated.[6,23] While it is also possible that the use of the critical pathway might cause a shift of costs from the hospital to patients and/or outpatient caregivers, any such increase in expenditures will be relatively small compared with the savings realized from the reduced requirement for hospital resources. Thus, it is likely that the implementation of a critical pathway by an institution yields a net cost savings from a societal perspective. However, any definitive conclusions regarding the economic impact of the critical pathway should await the publication of a formal economic analysis, which we are preparing.

Although other randomized trials have shown that the use of a "respiratory" quinolone is an alternative to conventional antibiotic regimens,[28] our data confirm the safety and effectiveness of levofloxacin therapy in a large number of patients who were cared for at multiple sites by a diverse group of physicians. At critical pathway hospitals, patients were more likely to receive a single class of antibiotic. Since no important differences were observed between the 2 strategies for any clinical outcome, this advantage of fluroquinolone therapy should be given consideration when therapy for CAP is chosen.

Figure 2. Institutional Mean of Patients' Health-Related Quality of Life
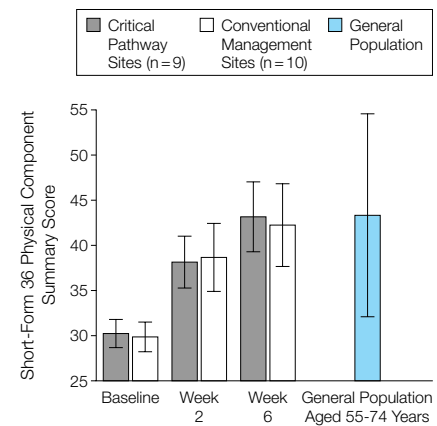
Health-related quality of life was measured by the Short-Form 36 Physical Component Summary scale. Error bars indicate SDs. The baseline value was obtained in the emergency department. The week 2 and week 6 assessments were carried out 2 and 6 weeks, respectively, after the completion of antibiotic therapy. The lower limit of the 1-sided 95% confidence limit of the between-group difference in the change from baseline to week 6 is −2.4. The age-specific mean (SD) estimates of the score for the US general population were obtained from published data.[21]

Figure 3. Percentage of Patients Experiencing the Specified Clinically Relevant Outcomes by Treatment Group
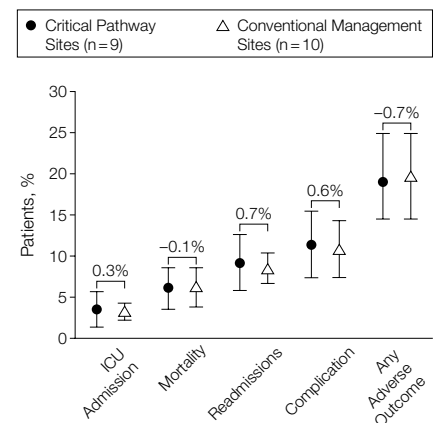
All estimates are based on institutional data displaying the mean (2-sided 95% confidence interval). Any adverse outcome is a composite of intensive care unit (ICU) admission, mortality, readmission, or occurrence of a complication. The absolute difference in rates between the experimental groups (critical pathway − conventional management) is shown above the brackets. The upper limit of the 1-sided 95% confidence limit of this value (for ICU admission, 2.0%; mortality, 2.5%; readmissions, 3.6%; complications, 4.6%; and any adverse outcome, 4.6%) gives an estimate of the outermost deleterious effect of the clinical pathway compared with conventional management.

Table 2. Measures of Institutional Resource Utilization*

	Critical Pathway Institutions (n = 9)									Overall Mean (SD)	P Value†
	T1 (n = 87)	T2 (n = 55)	T3 (n = 135)	T4 (n = 37)	T5 (n = 85)	C1 (n = 62)	C2 (n = 58)	C3 (n = 66)	C4 (n = 131)		
Admission rate, %‡											
PSI classes I-III	43	48	29	27	36	40	10	18	27	31 (12)	.01
PSI classes IV-V	95	76	75	100	93	100	85	81	78	87 (10)	.70
Overall	67	58	56	49	55	61	45	44	45	53 (8)	.11
Inpatient measures											
Length of stay, median, d	6.0	5.0	5.0	4.0	6.0	7.0	4.0	4.0	4.0	5.0 (1.1)	.01
Length of stay, average, d	8.3	8.3	8.4	7.2	7.6	12.0	7.0	5.2	9.8	8.2 (1.9)	.16
Duration of intravenous antibiotics, mean, d	5.3	5.5	3.5	3.6	4.9	6.0	4.8	3.6	4.3	4.6 (0.9)	.01
Receiving antibiotic monotherapy, %	69	53	82	39	41	63	89	76	63	64 (17)	<.001
BDPM	5.6	4.9	4.7	3.5	4.2	7.4	3.2	2.3	4.4	4.4 (1.5)	.04

	Conventional Management Institutions (n = 10)										Overall Mean (SD)
	T6 (n = 205)	T7 (n = 37)	T8 (n = 151)	T9 (n = 37)	T10 (n = 93)	C5 (n = 135)	C6 (n = 92)	C7 (n = 51)	C8 (n = 156)	C9 (n = 70)	
Admission rate, %‡											
PSI classes I-III	46	85	27	45	44	45	55	38	61	46	49 (16)
PSI classes IV-V	90	100	58	100	91	91	96	74	96	88	88 (13)
Overall	70	92	37	54	65	61	66	51	73	60	63 (15)
Inpatient measures											
Length of stay, median, d	8.0	6.5	4.0	6.5	4.5	7.0	7.0	8.5	8.0	6.5	6.7 (1.5)
Length of stay, average, d	11.9	9.5	5.1	7.9	10.1	8.3	8.9	11.6	10.4	12.0	9.6 (2.1)
Duration of intravenous antibiotics, mean, d	6.0	5.2	4.6	5.9	5.2	5.6	6.0	6.9	8.2	9.1	6.3 (1.4)
Receiving antibiotic monotherapy, %	23	18	41	25	40	13	25	23	14	45	27 (12)
BDPM	8.3	8.8	1.9	4.2	6.5	5.0	5.9	5.9	7.6	7.2	6.1 (2.1)

*T indicates teaching hospital; C, community hospital; and BDPM, average number of bed-days per patient managed. See footnote to Table 1 for institution identification.
†P values are for comparison of critical pathway with conventional management institutions by Mann-Whitney test.
‡PSI indicates Pneumonia Severity Index. Scores range from approximately 10 to 250; higher scores indicate more severe disease. Patients with PSI scores of 90 or fewer points are classified as classes I to III.

Some limitations to this study exist. First, the trial was not designed to evaluate the effectiveness of the separate components of the critical pathway. Although it is likely that the PSI accounted for the lower rate of admission at the critical pathway hospitals, it was not possible to determine the independent contributions of levofloxacin and the practice guidelines to the observed decrease in the length of hospital stay. Further studies are needed to examine the relative importance of these interventions.

Second, because the study was performed exclusively in Canada, the generalizability of our findings may be limited. Important differences exist among countries with respect to access to care,[29] prevalence of admission,[30] length of stay[31] and availability of community care and nursing home beds.[32] During the past decade, the emergence of managed care in the United States has been associated with a progressive decrease in the length of stay for most diseases. Accordingly, from 1990 to 1996 the average length of stay for CAP fell from 8.3 to 6.5 days.[33] Although the average length of stay in the United States in 1996 was even shorter than that observed at our intervention hospitals in Canada in 1998 (6.5 vs 8.2 days), 2 important points should be considered. First, considerable heterogeneity in length of stay exists among institutions in both countries. In 1994 (the most recent year for which national variance data are available), although the mean length of stay for US hospitals was 7.3 days, the 75th percentile of the distribution was 9.0 days.[33] Because of this large variability, we expect that many US institutions could benefit from use of the critical pathway. Second, efforts to reduce the length of stay cannot be examined in isolation; the effects of these initiatives on the quality of patient care and outcomes must also be assessed.

Our experimental data show that a critical pathway for CAP can reduce the use of hospital resources without compromising the well-being of patients. Whether the decrease in hospital use resulting from managed care has also met this essential standard is unknown. It is also possible that some proportion of the decrease in length of stay in the United States is the result of some of the interventions used in the critical pathway. In any event, since many environmental factors may be determinants of the effectiveness of a critical pathway, health care practitioners should carefully evaluate their institutional circumstances before implementing these systems. In some instances, the removal of barriers to the

provision of efficient outpatient care may be more effective than the development and promotion of a critical pathway.[34] The potential importance of confounding factors also underscores the need for performing randomized controlled trials. Although studies that randomize institutions, rather than individual patients, are complex to carry out, they are, in our opinion, the optimal method for assessing the effectiveness of interventions, such as critical pathways, that must be implemented and perceived at the level of the institution.[35]

In summary, we found a critical pathway for the treatment of CAP to be a safe and effective intervention that improved the efficiency of patient care.

CAPITAL Study Investigators: D. Gregson, J. Gibson, K. Woolfrey, C. Hammerberg (St Joseph's Health Centre, London, Ontario); A. McIvor, P. Hawkins, K. Johnson, K. Robinson (Sunnybrook Health Science Centre, Toronto, Ontario); R. Saginur, J. R. Worthington, K. Heney, G. Nichol (Ottawa Civic Hospital, Ottawa, Ontario); B. Feagan, E. Ralph, K. Theakston, C. McCabe (London Health Sciences Centre, University Campus, London, Ontario); G. Stiver, T. Lee, J. Buchanan, K. Sleigh, D. McKnight, A. Grunfeld, B. Kassen (Vancouver Hospital and Health Sciences Centre, Vancouver, British Columbia); S. Affias, A. Coakly, B. MacDonald, S. Butler (Cape Breton Regional Hospital, Sydney, Nova Scotia); M. Cook, D. Rowe, C. Bartlett, M. Howler (Colchester Regional Hospital, Truro, Nova Scotia); L. Harrigan, R. Doucet, K. Roddgues (Valley Regional Hospital, Kentville, Nova Scotia); A. Dhar, A. McGee, D. Martin (Thunder Bay Regional Hospital, Port Arthur Site, Thunder Bay, Ontario); W. Patrick, S. Campbell, D. Sinclair, C. Touchie, K. Forward, G. Patrick, D. Murray, T. Romard (Queen Elizabeth II Health Sciences Centre, Halifax, Nova Scotia); S. Houston, B. Rowe, A. Lindemulder, S. Roberts (University of Alberta Hospital, Edmonton); G. Victor, G. Dickinson, A. Cwinn, L. Radey, D. Rehel-Giordano, K. Fyke, D. Garber, I. Sèquin (Ottawa General Hospital, Ottawa, Ontario); J. Hutchinson, V. Patel, J. Watson, E. Condon (Health Sciences Centre, St John's, Newfoundland); F. Smaill, L. Kelleher, S. Brons, S. Savoy (McMaster University Medical Centre, Hamilton, Ontario); G. Dow, C. MacLoughlin, G. Pavlatos-Jones, M. Hanley, J. Thompson (The Moncton Hospital, Moncton, New Brunswick); G. Sullivan, P. Legere, M. Wheeler (Western Regional Health Centre, Yarmouth, Nova Scotia); A. Atkinson, L. Farrell, S. Atkinson (Health Services Association of the South Shore, Bridgewater, Nova Scotia); P. Whitsitt, R. Vandersluis, D. Taylor (Oshawa General Hospital, Oshawa, Ontario); A. Holmes, C. Metcalfe (Royal Columbian Hospital, New Westminster, British Columbia); L. Rance, R. Arshinoff, T. Smith, R. Anstey, U. Kuprath, J. Sigindere, J. Perkins, V. Holloway (Janssen-Ortho Inc, Toronto, Ontario); E. Liddiard, W. Johnson (London Clinical Trials Research Group, London, Ontario).

REFERENCES

1. Bartlett JG, Mundy LM. Community-acquired pneumonia. *N Engl J Med.* 1995;333:1618-1624.
2. Fine MJ, Singer DE, Phelps AL, Hanusa BH, Kapoor WN. Differences in length of hospital stay in patients with community-acquired pneumonia: a prospective four-hospital study. *Med Care.* 1993;31:371-380.
3. Gilbert K, Gleason PP, Singer DE, et al. Variations in antimicrobial use and cost in more than 2,000 patients with community-acquired pneumonia. *Am J Med.* 1998;104:17-27.
4. Weingarten SR, Riedinger MS, Hobson P, et al. Evaluation of a pneumonia practice guideline in an interventional trial. *Am J Respir Crit Care Med.* 1996;153:1110-1115.
5. Fine MJ, Smith MA, Carson CA, et al. Prognosis and outcomes of patients with community-acquired pneumonia: a meta-analysis. *JAMA.* 1996;275:134-141.
6. Niederman MS, McCombs J, Unger A, Kumar A, Popovian R. The cost of treating community-acquired pneumonia. *Clin Ther.* 1998;20:820-836.
7. Ellrodt G, Cook DJ, Lee J, et al. Evidence-based disease management. *JAMA.* 1997;278:1687-1692.
8. Weingarten SR, Riedinger MS, Varis G, et al. Identification of low-risk hospitalized patients with pneumonia. *Chest.* 1994;105:1109-1115.
9. Pearson SD, Lee TH, Goldhaber SZ. A critical pathway to treat proximal lower-extremity deep vein thrombosis. *Am J Med.* 1996;100:283-289.
10. Raschke RA, Reilly BM, Guidry JR, Fontana JR, Srinivas S. The weight-based heparin dosing nomogram compared with a "standard care" nomogram. *Ann Intern Med.* 1993;119:874-881.
11. Pearson SD, Goulart-Fisher D, Lee TH. Critical pathways as a strategy for improving care: problems and potential. *Ann Intern Med.* 1995;123:941-948.
12. Falconer JA, Roth EJ, Sutin JA, Strasser DC, Chang RW. The critical path method in stroke rehabilitation. *QRB Qual Rev Bull.* 1993;19:8-16.
13. Brown PD, Lerner SA. Community-acquired pneumonia. *Lancet.* 1998;352:1295-1302.
14. Laupacis A, Sekar N, Stiell IG. Clinical prediction rules. *JAMA.* 1997;277:488-494.
15. Isaacson DM, Fernandez JA, Frosco M, et al. Levofloxacin: a review of its antibacterial activity. *Recent Res Dev Antimicrob Agents Chemother.* 1996;1:391-439.
16. Grol R, Dalhuijsen J, Thomas S, Veld C, Rutten G, Mokkink H. Attributes of clinical guidelines that influence use of guidelines in general practice: an observational study. *BMJ.* 1998;317:858-861.
17. Fine M, Auble T, Yealy D, et al. A prediction rule to identify low-risk patients with community-acquired pneumonia. *N Engl J Med.* 1997;336:243-250.
18. File T, Segretti J, Dunbar L, et al. A multicenter, randomized study comparing the efficacy and safety of intravenous and/or oral levofloxacin versus ceftriaxone and/or cefuroxime axetil in treatment of adults with community-acquired pneumonia. *Antimicrob Agents Chemother.* 1997;41:1965-1972.
19. Meehan TP, Fine MJ, Krumholz HM, et al. Quality of care, process, and outcomes in elderly patients with pneumonia. *JAMA.* 1997;278:2080-2084.
20. Fine MJ, Medsger AR, Stone RA, et al. The hospital discharge decision for patients with community-acquired pneumonia. *Arch Intern Med.* 1997;157:47-56.
21. Ware JE, Kosinski M, Keller SD. *SF-36 Physical and Mental Health Summary Scales: A User's Manual.* Boston, Mass: Health Institute; 1994.
22. Metlay JP, Fine MJ, Schulz R, et al. Measuring symptomatic and functional recovery in patients with community-acquired pneumonia. *J Gen Intern Med.* 1997;12:423-430.
23. Guest JF, Morris A. Community-acquired pneumonia. *Eur Respir J.* 1997;10:1530-1534.
24. Ware JH, Antman EM. Equivalence trials. *N Engl J Med.* 1997;337:1159-1161.
25. Mann HB, Whitney DR. On a test whether one of two random variables is stochastically larger than the other. *Ann Math Stat.* 1947;18:50-60.
26. Donner A, Brown KS, Brasher P. A methodological review of non-therapeutic intervention trials employing cluster randomization, 1979-1989. *Int J Epidemiol.* 1990;19:795-800.
27. Diehr P, Martin DC, Koepsell T, Cheadle A. Breaking the matches in a paired t-test for community interventions when the number of pairs is small. *Stat Med.* 1995;14:1491-1504.
28. O'Doherty B, Dutchman DA, Pettit R, Maroli A. Randomized, double-blind, comparative study of grepafloxacin and amoxicillin in the treatment of patients with community-acquired pneumonia. *J Antimicrob Chemother.* 1997;40(suppl A):73-81.
29. Weinberger M, Oddone EZ, Henderson WG. Does increased access to primary care reduce hospital readmissions? *N Engl J Med.* 1996;334:1441-1447.
30. Philbin EF, DiSalvo TG. Managed care for congestive heart failure. *Am Heart J.* 1998;136:553-561.
31. Glick HA, Polsky D, Willke RJ, Alves WM, Kassell N, Schulman K. Comparison of the use of medical resources and outcomes in the treatment of aneurysmal subarachnoid hemorrhage between Canada and the United States. *Stroke.* 1998;29:351-358.
32. Townsend J, Piper M, Frank AO, Dyer S, North WRS, Meade TW. Reduction in hospital readmission stay of elderly patients by a community based hospital discharge scheme. *BMJ.* 1988;297:544-547.
33. *1994 National Hospital Discharge Survey* [CD-ROM]. Series 13, No. 12. Atlanta, Ga: Centers for Disease Control and Prevention; 1997.
34. Rich MW, Beckham V, Wittenberg C, et al. A multidisciplinary intervention to prevent the readmission of elderly patients with congestive heart failure. *N Engl J Med.* 1995;333:1190-1195.
35. Donner A, Klar N. Statistical considerations in the design and analysis of community intervention trials. *J Clin Epidemiol.* 1996;49:435-439.