

Effect of a Clinical Pathway to Reduce Hospitalizations in Nursing Home Residents With Pneumonia

A Randomized Controlled Trial

Mark Loeb, MD, MSc

Soo Chan Carusone, MSc

Ron Goeree, MA

Stephen D. Walter, PhD

Kevin Brazil, PhD

Paul Krueger, PhD

Andrew Simor, MD

Lorraine Moss, BSc

Thomas Marrie, MD

PNEUMONIA AND OTHER LOWER respiratory tract infections are common among residents of nursing homes.¹⁻³ These infections are one of the most frequent reasons for transferring residents to hospital.⁴⁻⁷ Hospitalization may be associated with a reduction in quality of life, a decline in functional status, falls, and other hazards.⁸⁻¹¹ The economic costs associated with such hospital transfers are substantial.¹²

Given the potential hazards to residents and the burden on the acute care health system, a strategy for treating residents with pneumonia on-site in the nursing home may be beneficial. However, the effectiveness of providing care for residents with pneumonia and other lower respiratory tract infections on-site in the nursing home is uncertain.

We developed a clinical pathway, or algorithm, for treating nursing home residents with pneumonia and other lower respiratory tract infections on-site in the nursing home. We conducted a cluster randomized con-

Context Nursing home residents with pneumonia are frequently hospitalized. Such transfers may be associated with multiple hazards of hospitalization as well as economic costs.

Objective To assess whether using a clinical pathway for on-site treatment of pneumonia and other lower respiratory tract infections in nursing homes could reduce hospital admissions, related complications, and costs.

Design, Setting, and Participants A cluster randomized controlled trial of 680 residents aged 65 years or older in 22 nursing homes in Hamilton, Ontario, Canada. Nursing homes began enrollment between January 2, 2001, and April 18, 2002, with the last resident follow-up occurring July 4, 2005. Residents were eligible if they met a standardized definition of lower respiratory tract infection.

Interventions Treatment in nursing homes according to a clinical pathway, which included use of oral antimicrobials, portable chest radiographs, oxygen saturation monitoring, rehydration, and close monitoring by a research nurse, or usual care.

Main Outcome Measures Hospital admissions, length of hospital stay, mortality, health-related quality of life, functional status, and cost.

Results Thirty-four (10%) of 327 residents in the clinical pathway group were hospitalized compared with 76 (22%) of 353 residents in the usual care group. Adjusting for clustering of residents in nursing homes, the weighted mean reduction in hospitalizations was 12% (95% confidence interval [CI], 5%-18%; $P=.001$). The mean number of hospital days per resident was 0.79 in the clinical pathway group vs 1.74 in the usual care group, with a weighted mean difference of 0.95 days per resident (95% CI, 0.34-1.55 days; $P=.004$). The mortality rate was 8% (24 deaths) in the clinical pathway group vs 9% (32 deaths) in the usual care group, with a weighted mean difference of 2.9% (95% CI, -2.0% to 7.9%; $P=.23$). There were no significant differences between the groups in health-related quality of life or functional status. The clinical pathway resulted in an overall cost savings of US \$1016 per resident (95% CI, \$207-\$1824) treated.

Conclusion Treating residents of nursing homes with pneumonia and other lower respiratory tract infections with a clinical pathway can result in comparable clinical outcomes, while reducing hospitalizations and health care costs.

Trial Registration clinicaltrials.gov Identifier: NCT00157612

JAMA. 2006;295:2503-2510

www.jama.com

Author Affiliations: Departments of Pathology and Molecular Medicine (Dr Loeb and Ms Moss), Clinical Epidemiology and Biostatistics (Drs Loeb, Walter, Brazil, and Krueger, and Ms Carusone and Mr Goeree), McMaster University, Hamilton, Ontario; Department of Microbiology, Sunnybrook and Women's College Health Sciences Centre, Toronto, Ontario (Dr

Simor); and Department of Medicine, University of Alberta, Edmonton (Dr Marrie).

Corresponding Author: Mark Loeb, MD, MSc, Departments of Pathology and Molecular Medicine, McMaster University, 1200 Main St W, MDCL 3200, Hamilton, Ontario, L8N 3Z5 Canada (loebm@mcmaster.ca).

trolled trial to test the hypothesis that a clinical pathway would reduce hospitalizations. The effect of the pathway on clinical outcomes and health care costs was also assessed.

METHODS

Design

Nursing homes were paired by the number of occupied beds to help ensure similar rates of pneumonia and other lower respiratory tract infections between study groups. One member of each pair was randomized to a clinical pathway and the other member to usual care by a statistician independent of the study team using a random numbers table. Outcomes were measured in individual residents but the

nursing homes served as the unit of allocation, intervention, and analysis.

Study Nursing Homes

A research coordinator (L.M.) contacted potentially eligible nursing homes in the Hamilton region of southern Ontario, Canada. Nursing homes in Ontario provide medical, nursing, and personal care to residents. To reside in these facilities, individuals must require 24-hour nursing services, daily personal assistance, or be at risk of harm in their current home. Most residents are admitted from home or hospital and spend the rest of their lives in the nursing home. To be eligible for the study, nursing homes had to have at least 100 residents and have no stated policies for

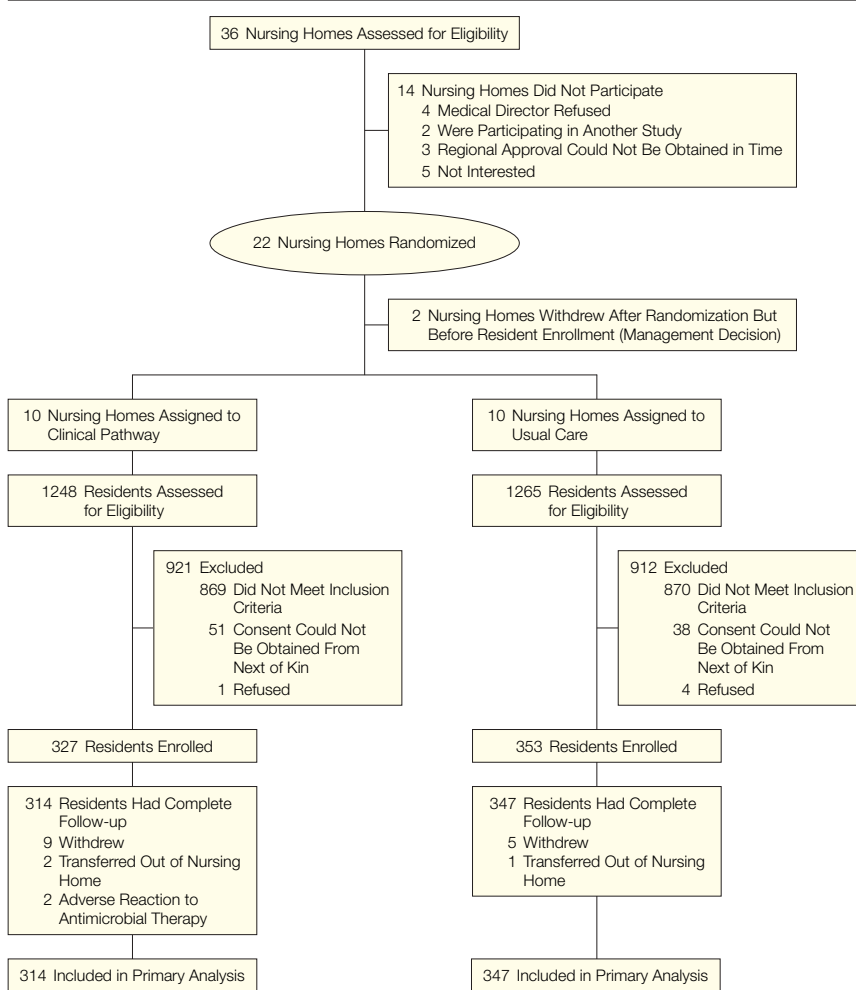
pneumonia treatment. Typically 1 registered nurse provided care for residents on each unit, which ranged in size from 30 to 50 beds. Personal care was provided by health care aides, with an average ratio of 1 registered nurse for every 7 health care aides in the nursing home. Nursing homes located on the campus of tertiary care centers were excluded.

Thirty-six potentially eligible nursing homes were contacted and 22 were randomized (FIGURE 1). Two of the 22 nursing homes withdrew after randomization but before resident enrollment based on a decision by the nursing home management. The mean (SD) bed size of the 10 nursing homes assigned to the clinical pathway group was 192 (59) and the mean (SD) bed size for the 10 nursing homes assigned to the usual care group was 175 (89). Nursing homes began enrollment between January 2, 2001, and April 18, 2002, with the last resident follow-up occurring July 4, 2005.

Study Participants

Residents aged 65 years or older were eligible if they met a standardized definition of lower respiratory tract infection,¹³ which consisted of having at least 2 of the following: new or increased cough, new or increased sputum production, temperature of more than 38°C, pleuritic chest pain, or new or increased findings on chest examination. Pneumonia was defined by the presence of 2 or more symptoms or signs of lower respiratory tract infection along with a new or increased infiltrate on chest radiograph.¹³ Residents who were not expected to live more than 30 days from the date of enrollment (as judged by their attending physician and nurse), those residents with a history of anaphylactic or serious allergic reaction to fluoroquinolones, or those residents with advance directives precluding transfer to hospital were excluded. The research protocol was approved by St Joseph’s Healthcare Hamilton Research Ethics Review Board. All participants or their designated surrogate decision makers gave informed consent.

Figure 1. Flow Diagram of the Clinical Trial



Interventions

Nurses in both study groups were asked to contact the study nurse if residents were potentially eligible. Study nurses made routine visits to the nursing home to assess resident eligibility, discuss the trial, obtain informed consent, and enroll residents. Residents' physicians were not involved in recruitment or in the consent process.

Clinical Pathway. Residents were assessed clinically by study nurses according to the study protocol (FIGURE 2). The study nurse measured vital signs and assessed whether the resident was eating and drinking. Care was provided in the nursing home if residents met all of the following criteria: pulse of 100/min or less, respiratory rate of less than 30/min, systolic blood pressure of at least 90 mm Hg, oxygen saturation of at least 92% (or $\geq 90\%$ if the resident had chronic obstructive pulmonary disease), and ability to eat and drink. If any 1 of these criteria was not met, the resident was transferred to the hospital. The nurse determined oxygen saturation by using a portable pulse oximeter initially without supplemental oxygen. If oxygen saturation was below the cutoff level, the nurse would administer oxygen and wait for 30 minutes. If upon remeasurement oxygen saturation was above the cutoff level, criterion for on-site treatment in the nursing home was met.

Chest radiographs were performed in the nursing home by a mobile unit within 12 hours of enrollment. However, presence of an infiltrate compatible with pneumonia was not a criterion with respect to site of care. The research nurse administered hypodermoclysis in the nursing home to residents who were dehydrated.¹⁴ This was performed by inserting a 21-gauge butterfly needle subcutaneously infusing saline at a rate of 30 mL per hour initially; if tolerated, it was increased to 60 mL per hour. The insertion site was checked hourly for the first 2 hours, then every 2 hours thereafter. Levofloxacin, administered as one 500-mg tablet orally once daily for 10 days, an antibiotic on the Ontario Drug Benefit

Formulary and therefore paid for by the provincial government, was prescribed empirically as recommended in the Canadian pneumonia treatment guidelines.¹⁵ The dose was reduced to 250 mg for residents with known renal insufficiency. Residents who were initially treated in the nursing home but subsequently deteriorated such that they no longer met criteria for nursing home treatment were transferred to hospital (Figure 2). For residents who were transferred to hospital, the pathway specified that they be transferred back to the nursing home once criteria for nursing home treatment were met. The research nurse informed the physician that the resident had been enrolled and informed him/her of any major change in the resident's clinical status. However, physicians were not involved in the implementation of the various components of the clinical pathway. For residents taking warfarin, international normalized ratios were ordered and monitored by the resident's primary care

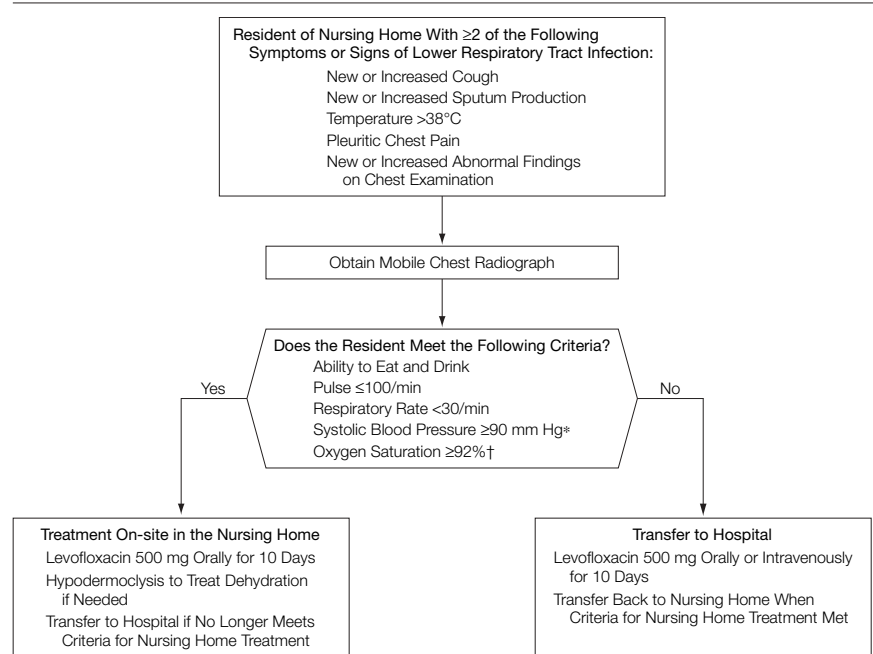
physician who was made aware that the resident was taking levofloxacin administered by the study nurse.

Usual Care. Care for residents allocated to usual care treatment was left up to the resident's physician (the physician and nursing home staff made treatment decisions, including antimicrobial use and transfer to hospital). A chest radiograph was requested within 48 hours of enrollment to assess the number of residents with radiological infiltrates compatible with pneumonia in both study groups. Study nurses recorded vital signs, oxygenation, and ability of the resident to eat and drink at each visit to assess comparability with the intervention group but did not implement any interventions.

Outcome Measures

Primary. The primary outcome measure was hospital admission. Hospital admission rates and resident lengths of stay per nursing home were assessed. These were used to calculate the mean

Figure 2. Clinical Pathway for Treating Residents of Nursing Homes With Lower Respiratory Tract Infection and Pneumonia



*For residents with baseline blood pressure of less than 100 mm Hg, a decrease of 20 mm Hg from baseline was used as a cutoff for hospitalization.

†If the resident had chronic obstructive pulmonary disease, oxygenation level was set at 90% or more.

resident hospital length of stay per nursing home.¹⁶ Emergency department visits with no hospital admission per nursing home were also assessed.

Secondary. The Minimum Data Set Health Status Index, based on the components of the Minimum Data Set version 2, was used to measure health-related quality of life.¹⁷ The scale presents a preference score of a particular health state, with scores ranging from 0 (dead) to 1 (full health), and has been tested for validity and reliability in residents of nursing homes. A modification of the Barthel Index was used to measure functional status, in which the minimum is 0 and the maximum is 20, representing full independence.¹⁸ Health-related quality of life and functional status were established for resident's premorbid state and then assessed 4 weeks after enrollment. These outcomes were considered as mean change scores per nursing home. Days to normalization of vital signs were measured in study residents and were considered as mean days per nursing home.¹⁹ Standardized definitions were used to assess residents for skin and soft tissue infections and catheter-related urinary tract infections.^{13,20} Adverse reactions to antimicrobials, defined as onset of nausea, vomiting, or rash while taking the antimicrobial, were measured and compared between residents in the 2 study groups.

Outcomes were assessed by a trained study nurse on a daily basis for the first 10 days of enrollment, then twice weekly for up to 30 days following enrollment. Data were also abstracted by the trained study nurse from nursing home and hospital charts. Baseline data collection included severity of illness, measured by a pneumonia severity index validated for residents of nursing homes.²¹ Although allocation was concealed, blinding of the study nurse and participating residents was not feasible because of the nature of the intervention. Microbiological and other laboratory investigations were performed in both intervention and usual care groups at the discretion of the resident's physician.

Statistical Analysis

To compare mean differences in outcomes between clinical pathway and usual care nursing homes, we used an analysis appropriate for cluster randomized trials; namely, a *t* test weighted by an inverse binomial variance weight for binary outcomes and a *t* test weighted by an inverse variance for continuous outcomes.²² These weights were proportional to the inverse of the variances of the cluster (nursing home) means or proportions. A weighted analysis of covariance, using a minimum variance weight, was used to evaluate changes in health-related quality of life and functional status, in which we assessed whether mean resident changes from baseline in nursing homes were significantly different between study groups. All outcomes were analyzed on an intention-to-treat basis. A subgroup analysis using data from residents with radiologically confirmed pneumonia was planned a priori. SAS version 9.1.3 (SAS Institute, Cary, NC) was used for all analyses and all *P* values were 2-sided with *P* < .05 considered statistically significant.

We also collected and valued health care resource utilization for residents from both the clinical pathway and usual care nursing home groups. The perspective taken for the economic analysis was that of a third-party payer. Included in the analysis were assessment costs and additional diagnosis and treatment resources, such as nursing time and portable chest radiographs, required by residents receiving the clinical pathway. In addition to the cost of hospital admissions and emergency department visits, our analysis also included costs related to stays in intensive care units and medical wards, resident transport via ambulance, oxygen therapy, hydration therapy, diagnostic imaging, and professional fees. Unit costs for services provided in nursing homes were based on those costs incurred during the trial. Costs for resident transport and hospitalizations were obtained from a large hospital participating in a case-costing project²³ and professional fees were derived from a

standard professional fee schedule.²⁴ Costs were calculated on the basis of 2005 Canadian dollars and were converted to US currency at the rate of \$1 US to \$1.20 Canadian; amounts are given in US dollars. We also repeated the analysis using US costs of hospitalization, therapy, consultations, diagnostic imaging, and professional fees.^{25,26}

Sample Size

The method of Hsieh²⁷ was used to estimate the number of clusters (nursing homes) needed. Based on a mean (SD) number of admission days of 4.5 (3.6) per resident enrolled, within-cluster variance of 12.9 days, and between-cluster variance of 8.4 days (all derived from Ontario long-term care facility data),^{28,29} to detect a relative reduction in mean hospital days per resident of 40% (1.8 days), assuming an annual average of 32 pneumonia episodes per nursing home, for a 1-sided significance level of .05 and a power of 80%, 20 nursing homes would be required with an enrollment of 640 residents. We increased the sample size to 22 nursing homes to allow for possible dropouts.

RESULTS

Participant Characteristics

A total of 680 residents were enrolled (327 in the clinical pathway group and 353 in the usual care group) (Figure 1). Characteristics of participants in the 2 groups were similar (TABLE 1). There was complete data at follow-up of hospitalization for 661 participants (97%), with 14 withdrawals (9 in the clinical pathway group and 5 in the usual care group) due to palliative care or a change in advance directives, 3 transfers from the nursing home (2 in the clinical pathway group and 1 in the usual care group), or adverse reactions to antimicrobial therapy (2 in the clinical pathway group). No residents met eligibility criteria for enrollment in 1 usual care nursing home. One of 77 blood cultures yielded *Streptococcus pneumoniae*.

Primary Outcome Measure

Thirty-four residents (10%) in the clinical pathway group were hospitalized compared with 76 (22%) in the usual care group. Adjusting for the clustering of residents in nursing homes, the weighted mean admission rate was 8% in the clinical pathway group vs 20% in the usual care group, with a weighted mean difference of 12% (95% confidence interval [CI], 5%-18%; *P* = .001) (TABLE 2). The weighted mean number of hospital days per resident was 0.79 in the clinical pathway group vs 1.74 in the usual care group, with a weighted mean difference of 0.95 days per resident (95% CI, 0.34-1.55 days; *P* = .004).

Of the residents in the clinical pathway group who were hospitalized, 4 were admitted for reasons other than pneumonia or lower respiratory tract infection, 1 for each of the following: elective surgery, fecal impaction, vertigo (at the family's insistence), and high international normalized ratio. In the usual care group, 2 residents were transferred for reasons other than pneumonia (1 due to stroke and 1 due to gastrointestinal bleed). None of the 31 residents hospitalized for pneumonia and other lower respiratory tract infections in the clinical pathway group were stable based on our criteria. In contrast, 18 (24%) of the 74 residents in the usual care group hospitalized for

these indications would have been considered stable (*P* = .003).

The results were similar when the analysis was restricted to residents with radiographically confirmed pneumonia. Eighteen (18%) of 98 residents in the clinical pathway group vs 43 (30%) of 142 residents in the usual care group

with pneumonia were hospitalized. The weighted mean admission rate was 9% for the clinical pathway group vs 29% for the usual care group, with a weighted mean difference of 19% (95% CI, 7%-32%; *P* = .005).

Seven residents (2%) in homes randomized to the clinical pathway group

Table 1. Characteristics of 680 Nursing Home Residents in the Clinical Pathway and Usual Care Study Groups*

Characteristics	Clinical Pathway (n = 327)	Usual Care (n = 353)
Age, y		
Mean (SD)	85.1 (7.69)	84.9 (7.47)
Range	65-101	65-100
Female	230/327 (70)	246/353 (70)
Radiologically confirmed pneumonia	105/323 (33)	142/341 (42)
Influenza vaccine	310/321 (97)	333/348 (96)
Pneumococcal vaccine	301/321 (94)	278/336 (83)
Coexisting diseases		
Cancer	68/321 (21)	57/347 (16)
Liver disease	7/320 (2)	6/346 (2)
Heart failure	62/318 (20)	68/345 (20)
Cerebrovascular disease	82/321 (26)	109/349 (31)
Renal disease	19/319 (6)	29/345 (8)
Severity of illness score, mean (SD)†	0.63 (0.83)	0.79 (0.88)
Clinical pathway criteria on enrollment		
Ability to eat and drink	317/327 (97)	327/353 (93)
Respiratory rate, <30/min	299/327 (91)	298/353 (84)
Oxygen saturation, ≥92% room air‡	284/327 (87)	271/353 (77)
Systolic blood pressure, ≥90 mm Hg§	324/327 (99)	338/353 (96)
Pulse, ≤100/min	304/327 (93)	306/353 (87)

*Data are presented as number/total number of residents (percentage) unless otherwise specified.

†Measured at enrollment and based on a scale that ranged from 0 to 5, which included the following: respiratory rate of more than 30/min (2 points), pulse of more than 125/min (1 point), altered mental status (1 point), and a history of dementia (1 point).²¹

‡For residents with chronic obstructive pulmonary disease, oxygen saturation cutoff was at least 90% room air.

§For residents with baseline blood pressure of less than 100 mm Hg, a decrease of 20 mm Hg from baseline was used as a cutoff for hospitalization.

Table 2. Summary of Weighted Outcome Variables and the Differences in 10 Clinical Pathway and 9 Usual Care Nursing Homes*

Outcomes	Weighted Mean (95% CI)			<i>P</i> Value
	Clinical Pathway (n = 314)	Usual Care (n = 347)	Difference	
Hospitalizations, %†	8 (4 to 12)	20 (15 to 26)	12 (5 to 18)	.001
Hospital days per resident	0.79 (0.45 to 1.13)	1.74 (1.17 to 2.3)	0.95 (0.34 to 1.55)	.004
Visits to emergency department without admission, %	1.2 (-0.2 to 2.5)	1.6 (-0.6 to 3.8)	0.4 (-1.9 to 2.8)	.72
Death, %	3.1 (-0.2 to 6.4)	6.0 (1.8 to 10.3)	2.9 (-2.0 to 7.9)	.23
Change in quality of life from baseline	-0.032 (-0.044 to -0.019)	-0.037 (-0.050 to 0.023)	-0.005 (-0.022 to 0.012)	.055
Change in functional status from baseline	-0.105 (-0.188 to -0.022)	-0.175 (-0.389 to 0.040)	-0.069 (-0.263 to 0.124)	.23
Falls, %	10.9 (6.4 to 15.3)	9.5 (5.9 to 1.3)	-1.3 (-6.6 to 3.9)	.60
Time to normalization of vital signs, d‡	2.55 (1.60 to 3.48)	2.66 (2.24 to 3.08)	0.12 (-0.78 to 1.02)	.79

Abbreviation: CI, confidence interval.

*No residents met eligibility criteria for enrollment in 1 usual care nursing home. Differences may not be exact due to rounding.

†Based on residents in whom complete 30-day follow-up was obtained (314 [96%] of the 327 residents in the clinical pathway group and 347 [98%] of the 353 residents in the usual care group). Rates of hospitalization in the clinical pathway group were 6 of 43 (14%), 4 of 26 (15%), 6 of 50 (12%), 1 of 21 (5%), 3 of 20 (15%), 1 of 33 (3%), 2 of 5 (40%), 6 of 37 (16%), 2 of 43 (5%), and 3 of 36 (8%) for residents in each of the 10 nursing homes; and in the usual care group, rates were 6 of 43 (14%), 14 of 43 (33%), 11 of 43 (26%), 7 of 36 (19%), 10 of 53 (19%), 2 of 24 (8%), 7 of 23 (30%), 8 of 30 (27%), and 11 of 52 (21%) for residents in each of the 9 nursing homes.

‡Defined as heart rate of 100/min or less, systolic blood pressure of at least 90 mm Hg, respiratory rate of 24/min or less, and temperature of 37.2°C or less.

made an emergency department visit with no admission compared with 14 residents (4%) in the usual care group. All such visits were for pneumonia or lower respiratory tract infection. The weighted mean visit rate was 1.2% in the clinical pathway group and 1.6% in the usual care group, with a weighted mean difference of 0.4% (95% CI, -1.9% to 2.8%; $P = .72$).

Secondary Outcome Measures

The mortality rates in both study groups were similar. There were 24 deaths (8%) among residents enrolled in the clinical pathway group and 32 (9%) among residents in the usual care group. Adjusting for clustering of residents in nursing homes, the weighted mean mortality rate in the clinical pathway group was 3.1% and in the usual care group was 6.0%, with a weighed mean difference of 2.9% (95% CI, -2.0% to 7.9%; $P = .23$). Mortality rates and other secondary outcome measures are shown in Table 2. There were no significant differences between study homes in change in scores in health-related quality of life or functional status. Similarly, there were no dif-

ferences in time to stabilization of vital signs, urinary or skin and soft-tissue infections, or falls. There were no catheter-related urinary infections in the clinical pathway group and only 1 (0.3%) in the usual care group (mean difference, 0.3%; 95% CI, -0.94% to 1.61%; $P > .99$). There were 8 skin and soft tissue infections (2.5%) in the clinical pathway group and 5 (1.4%) in the usual care group (mean difference, -1.1%; 95% CI, -1.2% to 3.8%; $P = .30$).

Adverse Events

Between clinical pathway and usual care groups, there were no significant differences in residents who experienced nausea (6 [2%] vs 11 [3%]; $P = .33$), vomiting (13 [4%] vs 22 [6%]; $P = .23$), diarrhea (13 [4%] vs 16 [5%]; $P = .85$), or rash (2 [0.6%] vs 2 [0.6%]; $P = .93$). One resident in a clinical pathway nursing home developed tendinitis and another resident developed hives, both leading to early discontinuation of levofloxacin.

Resource Utilization and Cost

Mean utilization and costs of health care resources consumed by residents from

both the clinical pathway and usual care groups are presented in TABLE 3. The initial up-front cost of oxygen and hydration therapy, mobile radiographs, and clinical pathway administration was higher for residents in the clinical pathway group by \$87 per resident (95% CI, \$83-\$91). However, these up-front costs were more than offset by reduced professional billings, resident transport, and hospitalization costs (\$1103), resulting in an overall cost savings, on average, of \$1016 per resident (95% CI, \$207-\$1824). When US costs of hospitalization, therapy, consultations, diagnostic imaging, and professional fees were used, the resulting savings were even larger, with an overall cost saving for clinical pathway residents of \$1517 (95% CI, \$601-\$2433).

COMMENT

We found that a clinical pathway to treat residents of nursing homes with pneumonia and other lower respiratory tract infections reduced hospitalizations by more than half compared with usual care, resulting in substan-

Table 3. Resource Utilization and Cost in Clinical Pathway and Usual Care Nursing Homes*

	Costs per Million, \$					
	Clinical Pathway		Usual Care		Clinical Pathway and Usual Care	
	Mean Utilization	Mean Cost	Mean Utilization	Mean Cost	Mean Utilization	Mean Cost (95% CI)
Initial assessment treatment costs						
Nurse administration of components of the clinical pathway	2.17	78	0	0	2.17	78
Oxygen	0.12	4	0.12	4	0	0
Hydration	0.04	2	0.03	1	0.01	1
Chest radiograph	0.96	80	0.86	72	0.1	8
Total initial assessment and treatment costs per resident		165		77	0	87 (83 to 91)
Hospitalization costs						
Intensive care unit length of stay	0.08	232	0.09	244	-0.01	-12
Non-intensive care unit length of stay	0.86	692	2.08	1680	-1.22	-988
Emergency department visit	0.02	5	0.05	11	-0.03	-6
Physician fees	1.15	43	2.53	92	-1.38	-49
Diagnostic imaging	0.34	24	0.6	49	-0.26	-25
Ambulance transport	0.13	22	0.28	45	-0.15	-23
Total hospitalization costs per resident		1018		2122		-1103 (-295 to -1912)
Total administration and inpatient costs per resident		1183		2199		-1016 (-207 to -1824)

Abbreviation: CI, confidence interval.

*Costs are all Canadian costs presented in US dollars. Costs per million may not add up to total costs due to rounding. Mean utilization numbers refer to average use of each resource (eg, mean number of chest radiographs).

tial cost savings, on average, of \$1016 per resident.

Mortality rates between residents in the clinical pathway and usual care groups of the study were similar, 8% vs 9%, respectively. These figures, which include residents with lower respiratory tract infection as well as radiologically confirmed pneumonia, are within the 5% to 40% range of case fatality rates reported for nursing home-acquired pneumonia.³⁰ These results confirm observational studies in which rates of death did not differ between residents with pneumonia who were transferred and those who remained on-site in the nursing home.³¹⁻³⁴ Our data suggest that hospitalization of residents of nursing homes for pneumonia and other lower respiratory tract infections has little impact on mortality.

No differences in health-related quality of life or functional status between the study groups were observed. Possible explanations are that the instruments used to measure health-related quality of life and functional status may not have been sufficiently sensitive enough to measure the observed changes, the 30-day length of follow-up may have been inadequate to detect changes, or the infection itself may have been the predominant effect on health-related quality of life and functional status vs hospitalization.

These data have important implications for the delivery of health care services for both long-term care facilities and acute care hospitals. Treating nursing home residents with pneumonia with the clinical pathway approach can reduce the burden to emergency departments and inpatient hospital units, particularly during influenza season, when many nursing home residents with pneumonia are frequently sent to the hospital.³⁵

Based on an incidence of pneumonia in nursing homes of 1 per 1000 resident-days³⁰ and an estimated 189 000 residents in nursing homes in Canada,³⁶ the implementation of clinical pathways could result in savings to the Canadian health care system of \$70 million annually. Based on an estimated 1.5

million elderly residents in nursing homes in the United States and using US costs,^{25,26,37} the cost savings of implementing clinical pathways in the United States could approximate \$831 million per year.

We acknowledge that the organization and funding of health care in the United States could pose a barrier to implementation of the clinical pathway. The incentive for implementing the clinical pathway will be different for a single-payer third-party system, as exists in Canada, in which costs of the pathway and offsetting hospital costs are realized by the same payer, than for a multiple payer system as exists in the United States, in which hospital cost offsets will be realized by the hospital and not the nursing home payer. Prospective payment and flat-rate systems of Medicaid reimbursement to nursing homes represent financial disincentives to have residents treated on-site in the nursing home.³⁸ Therefore, nursing homes would need to receive supplemental funding to implement the pathway. This could be used to hire appropriately trained nurses, such as nurse practitioners. We believe that acceptance of the pathway by physicians would be similar as in Canada. Although concern over litigation generally plays a more important role in medical decisions in the United States than in Canada,³⁹ the clinical pathway is conservative in that nursing home treatment is limited to residents with stable vital signs, such that severely ill residents would still initially be transferred to the hospital. However, buy-in from regulatory agencies that monitor nursing homes would be needed.

A limitation of our study is that we enrolled nursing homes with 100 or more beds, such that the results may not be generalizable to smaller nursing homes. Although the study was not blinded, the clinical pathway was a standardized protocol in that the nurses or members of the investigative team played no role in the decision to admit residents to hospital or obtain chest radiographs.

In conclusion, a clinical pathway for treating residents of nursing homes with

pneumonia and other lower respiratory tract infections results in similar clinical outcomes to usual care, reduces hospitalizations, and results in an overall reduction of health care costs.

Author Contributions: Dr Loeb 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 concept and design: Loeb, Walter, Krueger, Simor, Marrie.

Acquisition of data: Loeb, Goeree, Brazil, Moss.

Analysis and interpretation of data: Loeb, Carusone, Goeree, Walter, Brazil.

Drafting of the manuscript: Loeb, Carusone, Goeree, Walter, Brazil.

Critical revision of the manuscript for important intellectual content: Loeb, Carusone, Goeree, Walter, Brazil, Krueger, Simor, Moss, Marrie.

Statistical analysis: Loeb, Carusone, Goeree, Walter.

Obtained funding: Loeb, Brazil, Krueger, Simor.

Administrative, technical, or material support: Simor, Moss.

Study supervision: Loeb, Moss.

Financial Disclosures: Dr Loeb reported serving on an advisory board for Bayer Canada. Dr Simor reported serving on advisory boards and speaking for Bayer Canada. Dr Marrie reported receiving research funding from Janssen Ortho, Pfizer, and Bristol-Myers Squibb. No other authors reported financial disclosures.

Funding/Support: This study was supported by a Canadian Institutes of Health Research Interdisciplinary Health Research Team grant and by the Physicians' Services Incorporated Foundation of Ontario. Dr Loeb was supported by a Canadian Institutes of Health Research New Investigator Award, a Premier's Research Excellence Award (Ontario Ministry of Health and Long-term Care), and an Arthur Bond Scholarship.

Role of the Sponsors: The funding agencies played no role in the design and conduct of the study, in the collection, management, analysis, and interpretation of the data, or in the preparation, review, or approval of the manuscript.

Acknowledgment: We thank Allan Detsky, MD, PhD, Department of Medicine, University of Toronto, Toronto, Ontario, and Brian Haynes, MD, PhD, Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario, for their helpful comments about the manuscript. Drs Detsky and Haynes did not receive any compensation for their reviews. We are indebted to the research study nurses and nursing home staff who participated in this study.

REFERENCES

1. Jackson MM, Fierer J, Barrett-Connor E, et al. Intensive surveillance for infections in a three-year study of nursing home patients. *Am J Epidemiol.* 1992;135:685-696.
2. Muder RR, Brennen C, Swenson DL, Wagener M. Pneumonia in a long-term care facility: a prospective study of outcome. *Arch Intern Med.* 1996;156:2365-2370.
3. Marrie TJ. Pneumonia in the long-term-care facility. *Infect Control Hosp Epidemiol.* 2002;23:159-164.
4. Kerr HD, Byrd JC. Nursing home patients transferred by ambulance to the emergency department. *J Am Geriatr Soc.* 1991;39:132-136.
5. Teresi JA, Holmes D, Bloom HG, et al. Factors differentiating hospital transfers from long-term care facilities with high and low transfer rates. *Gerontologist.* 1991;31:795-806.
6. Bergman H, Clarfield AM. Appropriateness of patient transfer from a nursing home to an acute-care

- hospital: a study of emergency room visits and hospital admissions. *J Am Geriatr Soc*. 1991;39:1164-1168.
7. Loeb M, McGeer A, McArthur M, Walter S, Simor A. Risk factors for pneumonia and other lower respiratory tract infections in elderly residents of long-term care facilities. *Arch Intern Med*. 1999;159:2058-2064.
 8. Dempsey CL. Nursing home pneumonia: outcomes from a clinical process improvement program. *Pharmacotherapy*. 1995;15:335-385.
 9. Creditor MC. Hazards of hospitalization of the elderly. *Ann Intern Med*. 1993;118:219-223.
 10. Gill TM, Allore HG, Holford TR, Guo Z. Hospitalization, restricted activity, and the development of disability among older persons. *JAMA*. 2004;292:2115-2124.
 11. Wiener J, Quinn JP, Bradford PA, et al. Multiple antibiotic-resistant *Klebsiella* and *Escherichia coli* in nursing homes. *JAMA*. 1999;281:517-523.
 12. Kayser-Jones JS, Wiener CL, Barbaccia JC. Factors contributing to the hospitalization of nursing home residents. *Gerontologist*. 1989;29:502-510.
 13. McGeer A, Cambell B, Emori TG, et al. Definitions of infection for surveillance in long-term care facilities. *Am J Infect Control*. 1991;19:1-7.
 14. Dasgupta M, Binns MA, Rochon PA. Subcutaneous fluid infusion in a long-term care setting. *J Am Geriatr Soc*. 2000;48:795-799.
 15. Mandell LA, Marrie TJ, Grossman RF, Chow AW, Hyland RH; Canadian Infectious Disease Society; Canadian Thoracic Society. Summary of Canadian guidelines for the initial management of community-acquired pneumonia: an evidence-based update by the Canadian Infectious Disease Society and the Canadian Thoracic Society. *Can Respir J*. 2000;7:371-382.
 16. Marrie TJ, Lau CY, Wong CJ, Vandervoort MK, Feagon B. A controlled trial of a critical pathway for treatment of community-acquired pneumonia: CAPITAL study investigators: Community-Acquired Pneumonia Intervention Trial Assessing Levofloxacin. *JAMA*. 2000;283:749-755.
 17. Wodchis WP, Hirdes JP, Feeny DH. Health-related quality of life measure based on the minimum data set. *Int J Technol Assess Health Care*. 2003;19:490-506.
 18. Collin C, Wade DT, Davies S, Horne V. The Barthel ADL Index: a reliability study. *Int Disabil Stud*. 1988;10:61-63.
 19. Halm EA, Fine MJ, Marrie TJ, et al. Time to clinical stability in patients hospitalized with community-acquired pneumonia: implications for practice guidelines. *JAMA*. 1998;279:1452-1457.
 20. Garner JS, Jarvis WR, Emori TG, Horan TC, Hughes JM. CDC definitions for nosocomial infections, 1988. *Am J Infect Control*. 1988;16:128-140.
 21. Naughton BJ, Mylotte JM, Tayara A. Outcome of nursing home-acquired pneumonia: derivation and application of a practical model to predict 30 day mortality. *J Am Geriatr Soc*. 2000;48:1292-1299.
 22. Kerry SM, Bland JM. Unequal cluster sizes for trials in English and Welsh general practice: implications for sample size calculations. *Stat Med*. 2001;20:377-390.
 23. OCCI: Ontario Case Costing Initiative Web site. Ontario Case Costing Project (OCCP). <http://www.occp.com>. Accessed November 25, 2005.
 24. Schedule of Benefits for Physician Services Under the Health Insurance Act. Ontario Ministry of Health and Long-term Care Web site. http://www.health.gov.on.ca/english/public/program/ohip/ohip_mn.html. Accessed November 25, 2005.
 25. Samsa GP, Matchar DB, Harnett J, Wilson J. A cost-minimization analysis comparing azithromycin-based and levofloxacin-based protocols for the treatment of patients hospitalized with community-acquired pneumonia: results from the CAP-IN trial. *Chest*. 2005;128:3246-3254.
 26. Centers for Medicare & Medicaid Services. Physician Fee Schedule. US Department of Health and Human Services Web site. <http://www.cms.hhs.gov/PhysicianFeeSched/>. Accessed December 16, 2005.
 27. Hsieh FY. Sample size formulae for intervention studies with the cluster as unit of randomization. *Stat Med*. 1988;7:1195-1201.
 28. Loeb M, Simor A, Landry L, et al. Antibiotic use in facilities which provide chronic care. *J Gen Intern Med*. 2001;16:376-383.
 29. Allard JP, Aghdassi E, McArthur M, et al. Nutrition risk factors for survival in the elderly living in Canadian long-term care facilities. *J Am Geriatr Soc*. 2004;52:59-65.
 30. Muder RR. Pneumonia in residents of long-term care facilities: epidemiology, etiology, management, and prevention. *Am J Med*. 1998;105:319-330.
 31. Fried TR, Gillick MR, Lipsitz LA. Short-term functional outcomes of long-term care residents with pneumonia treated with and without hospital transfer. *J Am Geriatr Soc*. 1997;45:302-306.
 32. Thompson RS, Hall NK, Szpiech M, Reisenberg LA. Treatments and outcomes of nursing-home acquired pneumonia. *J Am Board Fam Pract*. 1997;10:82-87.
 33. Kruse RL, Mehr DR, Boles KE, et al. Does hospitalization impact survival after lower respiratory infection in nursing home residents? *Med Care*. 2004;42:860-870.
 34. Boockvar KS, Gruber-Baldini AL, Burton L, et al. Outcomes of infection in nursing home residents with and without early hospital transfer. *J Am Geriatr Soc*. 2005;53:590-596.
 35. Ellis SE, Coffey CS, Mitchel EF Jr, Dittus RS, Griffin MR. Influenza- and respiratory syncytial virus-associated morbidity and mortality in the nursing home population. *J Am Geriatr Soc*. 2003;51:761-767.
 36. Statistics Canada. Residential Care Facilities Survey. <http://www.statcan.ca/cgiin/imdb/p2SV.pl?Function=getSurvey&SDDS=3210&lang=en&db=IMDB&dbg=f&adm=8&dis=2>. Accessed November 25, 2005.
 37. Jones A. The National Nursing Home Survey: 1999 summary. *Vital Health Stat* 13. 2002(152):1-116.
 38. Wunderlich GS, Kohler PO, eds. *Improving the Quality of Long-term Care*. Washington, DC: National Academy Press; 2000.
 39. Scanlan A, Zyzanski SJ, Flocke SA, Stange KC, Grava-Gubins I. A comparison of US and Canadian family physician attitudes toward their respective health-care systems. *Med Care*. 1996;34:837-844.