

# Reducing clinical variations with clinical pathways: do pathways work?

M. PANELLA<sup>1</sup>, S. MARCHISIO<sup>1</sup> AND F. DI STANISLAO<sup>2</sup>

<sup>1</sup>Department of Medical Sciences, Section of Public Health, University of Eastern Piedmont 'A. Avogadro', Novara, <sup>2</sup>School of Hygiene and Public Health, University of Ancona, Italy

## Abstract

**Objective.** To test clinical pathways in a variety of Italian health care organizations in 2000–2002 to measure performance in decreasing process and outcome variations.

**Design.** Creation of indicators, specific for each clinical pathway, to measure variations in the care processes and outcomes. Pre- and post-analysis model to evaluate the possible effect of the clinical pathways on each indicator.

**Setting.** We tested the clinical pathways in six sites, each with different clinical pathways.

**Results.** Reductions in health care macro-variation phenomena (length of stay, patient pathways, etc.) and in performance micro-variation (variations in diagnostic and therapeutic prescriptions, protocol implementation, etc.) were shown in sites where pathways were implemented successfully. A significant improvement in outcome for patients who were treated according to the clinical pathway for heart failure was also demonstrated.

**Conclusions.** The overall purpose of clinical pathways is to improve outcome by providing a mechanism to coordinate care and to reduce fragmentation, and ultimately cost. Our results demonstrated that it is possible to achieve this goal. Although controversial elements still exist, we think that clinical pathways can have a positive impact on quality in health care.

**Keywords:** clinical pathways, clinical variation, continuous quality improvement, evidence-based medicine, health care processes, integrated care pathways

Variation is a critical element in health care systems. Many authors agree that the main determinant factors of variation are the different availabilities of health care services, the scarce use of medical evidence, and the phenomena of professional uncertainties [1–5]. In particular, professional uncertainty and the scarce use of medical evidence seem to be the key elements in many problems dealing with health care variations, due to their possible links with medical errors [6]. It has been estimated that between 44 000 and 98 000 people die each year from medical errors in the United States [7]. Even if it is difficult to establish a direct relationship between variations and errors, reducing variations by standardizing clinical processes is an effective tool to minimize the probability of medical errors [8].

Other than the ethical considerations, variation problems are especially critical today because the pressure to reduce health care costs without reducing quality in patient care has increased. The creation of clinical pathways has become a popular response to these concerns [9–14].

Clinical pathways (also known as critical pathways, care maps, integrated care pathways, etc.) are integrated management plans that display goals for patients, and provide the

sequence and timing of actions necessary to achieve such goals with optimal efficiency [15,16].

According to continuous quality improvement principles, clinical pathways stress the improvement of clinical processes in order to improve clinical effectiveness and efficiency. Thus, clinical paths are clinical management tools used by health care workers to define the best process in their organization, using the best procedures and timing, to treat patients with specific diagnoses or conditions according to evidence-based medicine (EBM) [17]. As a consequence, the introduction of clinical pathways could be an effective strategy for health care organizations to reduce or at least to control their processes and clinical performance variations [18].

Pathways are an evidence-based response, at both a structured and a local level, to specific problems and care needs, and for this reason they could have a higher level of compliance compared with other instruments such as practice guidelines, which are not based on local professional consensus [19]. They are also developed by multi-professional teams, composed of all types of physicians (from family practitioners to specialists), nurses, social workers, and administrators, who manage the disease processes and are responsible for patient

Address reprint requests to Massimiliano Panella, MD, Assistant Professor, University of Eastern Piedmont 'Amedeo Avogadro', Faculty of Medicine, Department of Medical Sciences (Section of Public Health), Via Solaroli 17, 28100 Novara, Italy. E-mail: panella@med.unipmn.it

care [20]. The benefits are clear: sharing information develops the learning processes within an organization, helps professionals to understand their roles and responsibilities better, and improves integration in all segments of the health care system. All of these are basic steps to reduce variations [21,22].

Finally, this coordinated and integrated use of multi-professional working teams could provide effective protection against the risk of developing a clinical pathway that is led by only one professional group, which seems to be the best way to protect against opinion-based variations [23–25].

Despite widespread enthusiasm for clinical pathways, rigorous evidence to support their benefits in health care is limited [26,27]. For this reason we tested clinical pathways in various Italian health care organizations during the period 2000–2002 in order to measure their performance in decreasing process and outcome variations.

## Methods

### Study design and statistical analysis

We constructed a pre- and post-analysis model to evaluate the effect of applying clinical pathways to process and outcome indicators, and to the costs sustained to assist patients using the activity-based costing (ABC) methodology [28]. ABC is a technique to measure quantitatively the cost and performance of activities, resources, and cost items. ABC captures organizational costs for the factors of production and applies them to the defined activity structure. Costs are allocated based on interviews with professionals about their activities. ABC is usually used in comparative analysis because it helps to clarify the relationship between activities and costs [29].

We set up an experimental period of 1 year for each setting: 6 months before and 6 months after the implementation of the clinical pathway. The samples included all the patients treated by staff during the experimental period.

The normality of the distribution for quantitative variables was verified using the Shapiro–Wilks test. We studied each quantitative variable using the Student's *t*-test or Wilcoxon test, and each qualitative variable using the  $\chi^2$  test or Fischer test [30]. We considered *P* values <0.05 significant, and *P* values <0.01 strongly significant. Statistical analysis was performed using Statistica software (STASOFT).

### Development of indicators

A set of indicators was developed to measure the variations in the care processes (the macro-variations are expressed by the average and standard deviation (SD) of the length of stay, and the micro-variations are expressed by the core-process variations and deviations from the clinical pathways) and in the outcomes (rates of clinical outcomes).

The clinicians were involved in developing the indicators, and were basically asked to propose to the research team a set of process and outcome indicators that were specific for each clinical pathway [31–41]. We evaluated each indicator according to the following dichotomous criteria: validity (evidence

based or not; the proposed indicator had to be supported by consistent literature); reliability and feasibility of data collection (easy or difficult; data available from current information systems or from ad hoc databases); comparability (low or high; internal tracking versus external comparisons of the results); and relevance (yes or no; according to the strength of the relationship between the improvement of the indicator and the improvement for patient/organization outcome or process).

A rank of priority, determined using the preceding variables, was assigned to each indicator. According to the rank, we selected the 10 best indicators for each clinical pathway. The ultimate set of indicators is reported in the Appendix.

Finally we defined the procedures for data collection and analysis. Data were collected by local staff (clinical path teams); the analysis was performed by the research team. We did not use incentives for the local staff.

### Clinical pathway development

To build the clinical pathways, we merged EBM tools with business process re-engineering techniques [42–47] as follows:

1. *Select the area of practice.* We chose the area with a selection matrix, including diagnoses, with higher costs, higher volumes, higher mortality, higher length of stay, or greater number of outcome variations.

2. *Build the multidisciplinary work-team.* We involved physicians (from family practitioners to specialists), nurses, therapists, social workers, and administrators providing care in the selected area.

3. *Define the diagnosis.* We identified clinical selection criteria for each diagnosis with explicit and shared disease-staging scales.

4. *Define the patients.* We identified other selection criteria as non-clinical, such as socio-economic factor, housing status, age of the patient, etc.

5. *Review practice and literature.* We analysed the care processes and researched the best evidence for the patients. The results of this phase came from all the members of the team.

6. *Develop the clinical path.* We started by defining the appropriate goals to satisfy the multidimensional needs of the patients (patient focus phase). Next we ‘translated’ the results from the review phase into elements of care detailed in local protocols and documentation, including the sequence of events and expected progress of the patients over time. The elements of care for each professional were defined according to the care categories (Figure 1).

7. *Pilot and implement the clinical pathway.* We educated the staff and monitored the use of the pathway. This last step was carried out by completing data record sheets that summarized the tasks of each professional during the care of the patients and the possible deviations from the path.

8. *Ongoing evaluation.* We assessed the level of completion of the data recording, investigated why there were any differences between the one in practice and the recommended one (deviations from the pathways), and measured patients’ outcomes.

9. *Implementation.* The last phase consisted of the daily utilization of the clinical path, its regular monitoring (every 3 months) and updating (yearly).

1. Evaluation of patients' multidimensional needs;
2. Education of patients and families;
3. Planning of patients' pathway (through the whole organisation);
4. Planning and execution of diagnostic exams;
5. Execution of interventions or procedures;
6. Activation of specialty consultancies;
7. Management of pharmacological therapy;
8. Management of nutrition;
9. Management of activities and patients' safety.

**Figure 1** Phase of the clinical pathway development: the care categories.

## Results

The overall results are summarized in Table 1. The results of each clinical pathway are reported below.

### The clinical pathway for inguinal hernia repair

The overall sample consisted of 243 patients. Of the 126 patients treated according to the clinical pathway, 71 underwent day surgery and 55 underwent a 3-day stay. We compared these data with the results of 117 patients treated before the implementation of the clinical pathway (Table 2).

After the implementation of the pathway we noticed a significant increase in day-surgery activity, demonstrating a more rational use of hospital stays in the unit. As a consequence, we measured a strong decline in both the average length of stay and its variation (SD decreased from 2.27 to 1.38 days).

The pathway core processes yielded noticeable benefits. The number of exams included in preoperative diagnostic routine decreased. Antibiotic prophylaxis with clarithromycin 500mg infusion, which was performed without discrimination prior to pathway implementation (even if not evidence

**Table 1** Testing the use of clinical pathways: overall results

Clinical pathway	Level of implementation	Length of stay decrease	Core processes improvement	Residual variations rate	Outcome improvement	Costs reduction
Inguinal hernia repair	Completed	Yes <sup>2</sup>	Yes <sup>2</sup>	2.22%	No	Yes <sup>1</sup>
Stroke	Interrupted	NC	NC	28.20%	NC	NC
Chronic renal failure	Interrupted	No	NC	15.18%	NC	NC
Chronic heart failure	Completed	Yes <sup>2</sup>	Yes <sup>1</sup>	5.90%	Yes <sup>2</sup>	No
Total hip replacement	Completed	No	Yes <sup>1</sup>	13.55%	No	Yes <sup>1</sup>

NC, not calculable.

<sup>1</sup>Significant ( $P < 0.05$ ).

<sup>2</sup>Strongly significant ( $P < 0.01$ ).

**Table 2** The clinical pathway for inguinal hernia repair: comparison of the process indicators before and after the implementation of the clinical pathway

Indicators	Before (117 cases)	After (126 cases)	<i>P</i> value
Rate of day surgery activity	38.46%	56.35%	<0.05
Average length of stay (days)	3.25	1.64	<0.01
Median number of preoperative exams (per patient)	22	7	<0.01
Proportion of patients with antibiotic prophylaxis (not consistent with current recommendations)	100.00%	0.00%	<0.01
Proportion of patients with correct hair removal	81.19%	100%	<0.01
Rate of completion of clinical records	62.39%	95.24%	<0.01
Proportion of patients with massive bleeding	0.00%	0.00%	NS
Proportion of patients with postoperative pain	NA	3.18%	NC
Proportion of patients with wound infections	3.42%	2.34%	NS
Proportion of patients with unscheduled return to operating room	1.71%	0.79%	NS

NA, not available; NS, not significant; NC, not calculable.

based), was no longer administered. Also, the rate of correct performance of preoperative hair removal increased significantly, as did the percentage of completion of clinical records.

From a strictly clinical perspective, however, we did not notice any significant differences in patient outcomes between pre- and post-pathway implementation, as measured using local or early complication rates, which are the only ones related to surgical or management error.

We next analysed the causes of the residual variations after the implementation of the pathway. An interesting reason for deviations from the pathways was incomplete hospital-discharge cards for patients. This was due to organizational problems such as the untimely arrival of the card, on average 3 days after patient admission, when the patient had already been discharged. Furthermore, the clinical record and the consent form for the intervention were not completed for some patients. This happened more frequently with day-surgery admissions, mostly due to the poor habit/lack of attention of physicians when filling out the clinical documentation, along with the provision of care.

With respect to variations in outcome, we noted 12 ordinary-stay cases that remained longer than the defined 3 days, and four conversions from day surgery to ordinary stay, all of which were due to very intense postoperative pain, patient request, or other organizational barriers to getting the patients home.

Finally, we measured a significant reduction in the average costs sustained to assist each patient, which dropped from US\$732.94 (approximately 790) to US\$445.52 (approximately 480).

### The clinical pathway for strokes

Study regarding the clinical pathway for strokes was stopped after 3 months, because only the two physicians who participated in the development of the clinical pathway accepted using it to manage patient care. Before implementation of the clinical pathway, patients were treated without a structured assessment of their conditions, whereas with the clinical pathway all patients had to be stratified according to the seriousness of the condition at admission and during the stay. Doctors refused to adopt the clinical pathway because they considered this process like a 'cookbook', i.e. too simple to treat the heterogeneity of the patients' conditions. This situation compromised the chance of implementing the pathway and evaluating its effectiveness and efficiency.

Due to resistance from doctors, staff were able to treat only nine of the 35 patients admitted during the period using the clinical path. Moreover, variance report grids for core processes showed a residual variation rate of 28.20% for the patients treated. Also, the documentation was not filled out properly (mostly because medical staff indicated reasons for the variances in performance in only 2.5% of cases). For this reason we could not measure any significant improvement in quality using the process and outcome indicators.

### The clinical pathway for chronic renal failure

During the experimentation period, 26 patients were admitted but only nine were treated using the clinical pathway. Because of the small sample we could not observe any significant changes in process and outcome indicators before and after the implementation of the pathway.

From a strictly organizational perspective, the main goal of the pathway was the implementation of a process of programmed early discharge that could integrate hospital care with long-term and home care. We defined protocols for this purpose but they were adopted for only two patients. We tried to find the reasons for this using the analysis of variation grids. Due to the low level of accuracy in completing and reading documents (52.75% of cases), we also interviewed staff.

We could not find any specific reasons for failing to discharge patients early: hospital nurses reported generic integration difficulties with the other levels of care; doctors complained of their difficulties in adapting the discharge protocols of the clinical path to the clinical seriousness of, or variations in, the patients' clinical conditions. We did not measure any reductions in costs.

### The clinical pathway for heart failure

The sample consisted of 246 patients (43.62% males, average age 78.9 years). We used New York Heart Association (NYHA) class scores to classify the severity of patients' conditions at admission in the emergency room (ER) and in the general medicine unit (GM), and also at discharge.

We measured a diagnostic agreement between ER and GM in 77.78% of cases (heart failure versus other diagnoses). After stratification according to the patients' NYHA scores, agreement dropped to 54.41% of cases; in the ER, 22.06% of subjects received a NYHA class of less seriousness than assigned in the GM (one patient with NYHA II, eight patients with NYHA III, and six patients with NYHA IV) and 5.88% were misclassified as too serious (four patients with NYHA III).

We should note that we planned hospital admissions for patients with NYHA III–IV scores only. Nevertheless, we also admitted patients with NYHA II scores because of their social conditions (old people alone in their houses, residences very far from the hospital, etc.).

After the implementation of the clinical path we observed a significant improvement in the quality of the clinical core processes (left ventricular assessment, smoking cessation counselling, discharge instructions, etc.). Results are shown in Table 3. Moreover, we observed a significant improvement in the outcomes: we reduced both total admissions (from 178 to 68 cases) and unscheduled readmissions. The most significant result was the reduction in in-patient mortality with respect to class of severity of patient condition, as determined at admission (Figure 2). As also shown in Figure 2, before the pathway, we observed a high outcome variation in all cases, independent of patient disease-staging. Outcome variation was reduced after implementation of the pathway. Costs, however, did not decrease after the implementation of the pathway.

**Table 3** The clinical pathway for heart failure: comparison of the process indicators before and after the implementation of the clinical pathway

Indicators	Before (178 cases)	After (68 cases)	<i>P</i> value
Rate of diagnostic agreement between emergency room and general medicine unit	NA	77.78%	NC
Average length of stay (days)	10.89	7.96	<0.01
Rate of completion of clinical records in emergency room	21.71%	26.29%	NS
Rate of completion of clinical records in general medicine unit	26.29%	62.86%	<0.01
Proportion of patients with left ventricular function assessment	44.94%	100.00%	<0.01
Proportion of smoker patients with advice/counselling for smoking cessation	NA	100.00%	NC
Proportion of patients with written discharge instructions (activity, diet, etc.)	0.00%	100.00%	<0.01
Proportion of patients with ACE inhibitor at discharge	12.36%	20.59%	NS
Rate of unscheduled readmissions within 31 days	6.74%	2.94%	NS
Total in-patient mortality	17.42%	4.41%	<0.01

NA, not available; NC, not calculable; NS, not significant; ACE, angiotensin-converting enzyme.

**Table 4** The clinical pathway for total hip replacement: comparison of the process indicators before and after the implementation of the clinical pathway

Indicators	Before (43 cases)	After (57 cases)	<i>P</i> value
Average length of stay (days)	13.07	12.81	NS
Average diagnostic accesses of the patients (No. per patient)	3.50	1.00	<0.05
Median of preoperative exams (No. per patient)	32	14	<0.05
Proportion of patients compliant with preoperative analgesic therapy	9.30%	42.11%	<0.01
Proportion of patients with preoperative administration of erythropoietin	30.23%	68.42%	<0.01
Proportion of patients with antibiotic prophylaxis consistent with current recommendations	20.93%	40.35%	<0.05
Proportion of patients with complete follow up	51.16%	100.00%	<0.01
Proportion of patients with early complications	0.00%	0.00%	NS
Proportion of patients with late complications	NA	NM	NC
Average level of residual disability at follow up (FIM scale)	NA	NM	NC

NS, not significant; NA, not available; NM, not measurable; NC, not calculable; FIM, functional independent measure.

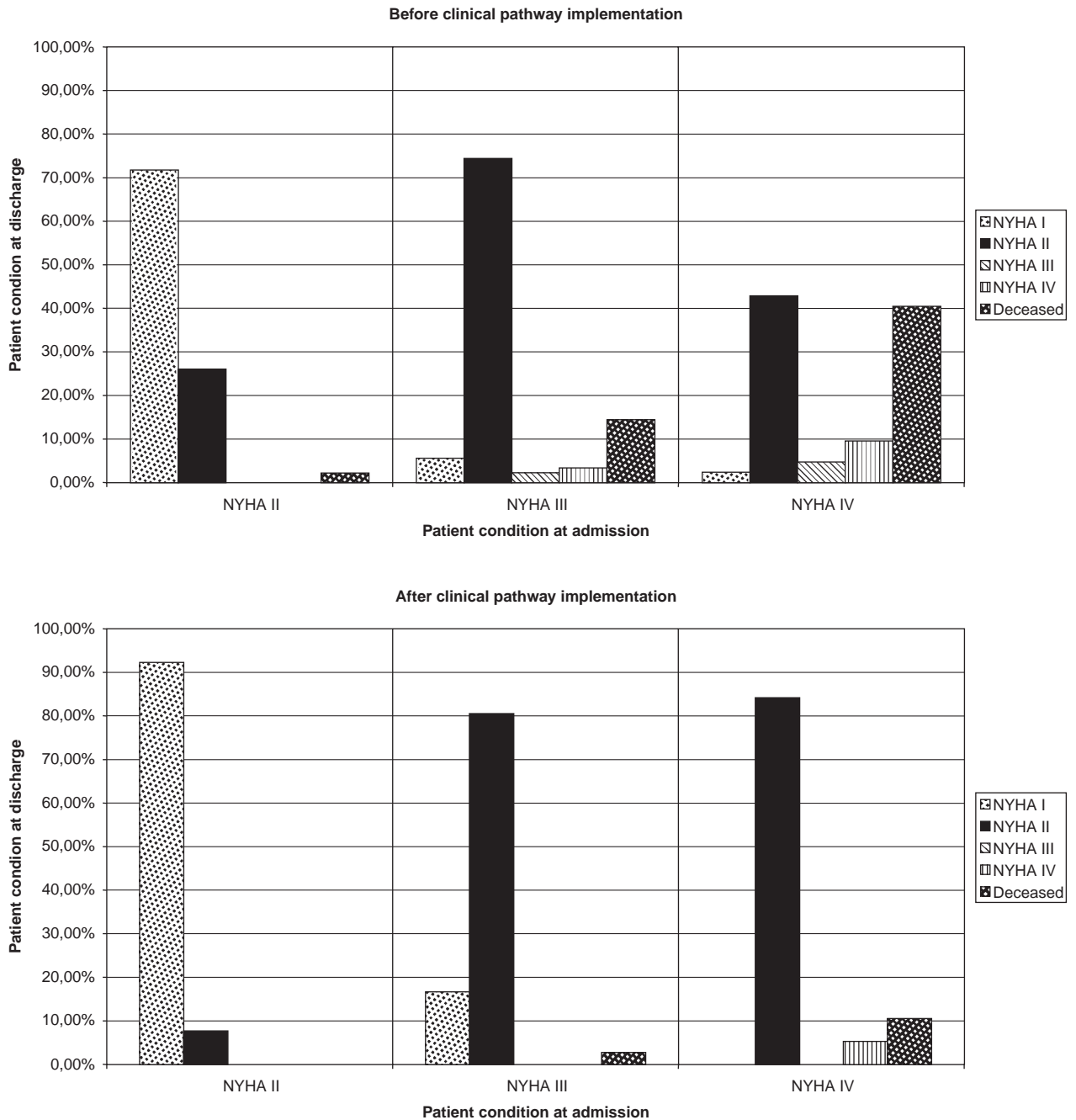
### The clinical pathway for total hip replacement

Results are reported in Table 4 and are based on a sample of 100 patients (43 patients before and 57 patients after implementation of the clinical pathway).

We did not observe any differences in the length of stay compared with the preceding situation. On the contrary, the most significant result was in the variation between pre- and post-admission patient paths. The pre-intervention diagnostic path was simplified into a single visit, whereas previously the pathway patients required four separate visits to three different facilities: an initial anaesthesiology visit, laboratory exams,

a cardiology visit, and a second anaesthesiology visit. The post-intervention path improved for all patients who received follow-up appointments periodically (follow-ups at 1 month, 3 months, 6 months, 1 year, and 2 years after the intervention).

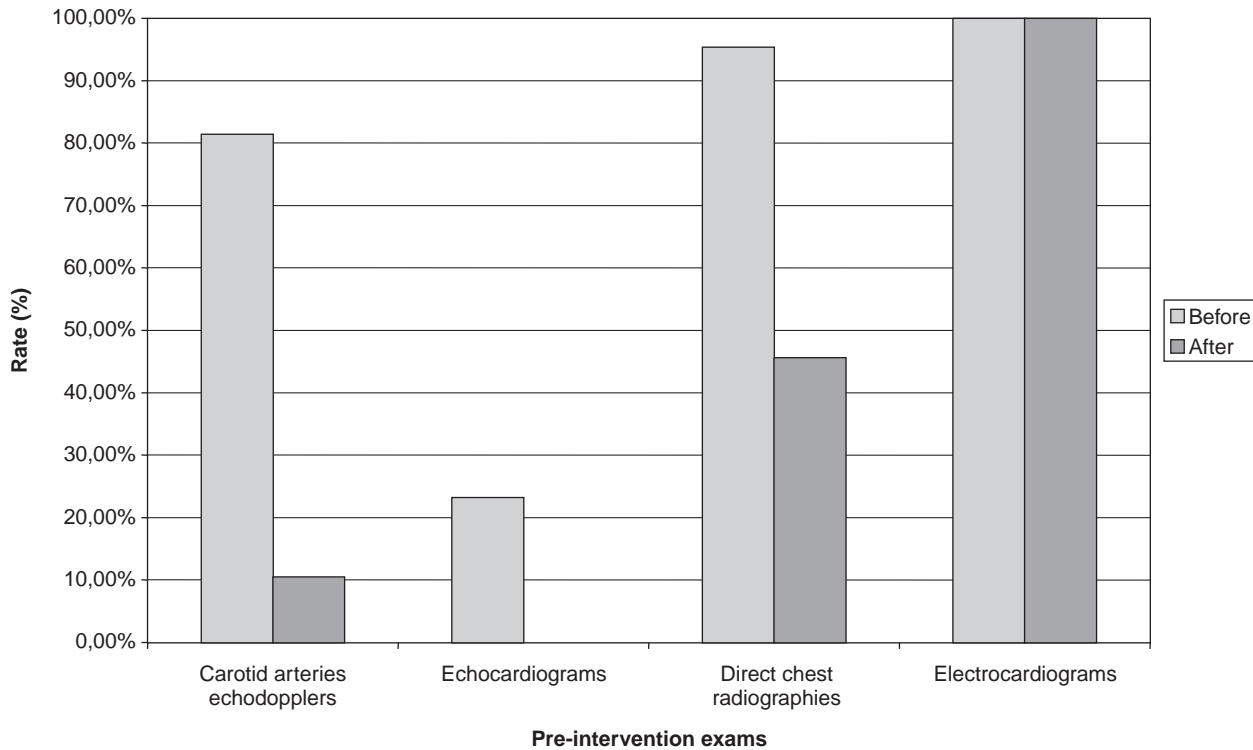
We measured similar improvement in the quality of the core processes after the implementation of the clinical pathway. The compliance with analgesic therapy increased, as well as the rate of erythropoietin administration. The number of laboratory exams included in the diagnostic routine decreased. Moreover, we measured a significant improvement in the appropriateness of the use of diagnostic technologies (Figure 3). We reduced the indiscriminate pre-intervention use of carotid arteries echodoppler and echocardiograms



**Figure 2** The clinical pathway for heart failure: comparison of patients' conditions at admission and discharge, before and after the implementation of the clinical pathway. The analysis was performed using the New York Heart Association scores (NYHA) attributed to the patients by the cardiologists in the General Medicine (GM) unit.

( $P < 0.01$ ), and direct chest radiography was limited to subjects who had not had an X-ray in the preceding 6 months. We did not change the rate of cardiology consultations and electrocardiograms, which were still performed on all subjects due to medical/legal concerns. In addition, radiological exams done on limbs to be operated on were reduced from 4.61 to 2.58 ( $P < 0.05$ ).

Variation grids showed that we were not successful in adopting the correct prophylaxis for surgical site infections. Basically, there was already a protocol in use, even though it differed from recommendations. For this reason, and considering that it was impossible to substitute this protocol immediately, which was deep-rooted in the physicians' habits, we decided to (i) back it up with a second one, which was



**Figure 3** The clinical pathway for total hip replacement: use of the pre-intervention exams before and after the implementation of the clinical pathway.

evidence based and less expensive, and (ii) to evaluate any differences in effectiveness (no infections were reported with either scheme).

Only short-term outcomes are currently available, and do not highlight any differences compared with the situation before the introduction of the clinical pathway. We observed a reduction in costs of ~25%.

## Discussion

Our primary finding was that the implementation of the clinical pathway for heart failure reduced in-patient mortality and outcome variations. We observed also a significant improvement in the quality of almost all clinical processes after the development of our clinical pathways: current practice was reviewed and the most recent evidence was incorporated. Pathways were helpful for clinical risk management. Our results also showed that this was possible without increasing costs; in fact, on the contrary, we observed a significant reduction in the costs of assisting patients treated according to the clinical pathways for inguinal hernia repair and total hip replacement. We also observed some major failures: the clinical pathways for strokes and chronic renal failure were not helpful, and their implementation was discontinued.

We tried to analyse the above results by addressing the main issue to arise from this research: were these results achieved through the pathways or through the way these tools were applied? Clinical pathways must be used as tools in an

overall quality improvement plan to meet specific patient population needs in all settings. Unfortunately, finding the proper balance between clinician autonomy and standardization has proved difficult. Many doctors still consider clinical pathways as ‘cookbook medicine’, even though they could change the pathway for a patient at any time [10]. On the contrary, they sometime refuse to change their routines even when they have been proved to be ineffective.

We tried to solve these problems by creating constant dialogue within the team, between clinicians and managers. A good tool suited to this purpose was the analysis of variance grids. When the team examined variance sheets regularly, it was possible to identify common reasons why the clinical path was not followed. According to other studies this can lead to discussion within the team, which then facilitates full implementation of the clinical pathway [20]. When it was impossible to create such a dialogue, the implementation of the pathways failed.

In our experience, quantification of outcomes can provide the key to an effective dialogue with clinical teams, because outcome assessment provides reports that are easy to use by health care professionals that will support clinical decision systems [48]. However, we encountered many difficulties as a result of current information systems.

A significant barrier to measuring and improving outcome indicators was found to be the method of documenting and collecting data from current sources (e.g. clinical records, hand-written abstraction tools, and variance grids). We think that with a more comprehensive information structure for

our pathways, implementation would be easier. In future programmes we intend to develop information systems that will provide automatic abstraction tools: this could increase the efficiency of reporting compliance with the indicators of the pathways. We believe that by saving hours of charting every day using computerized documentation and data collection, we can significantly improve physicians' attitudes towards clinical paths.

The incorporation of incentives for compliance with clinical pathways into staff performance appraisals and physician credentialing should have been explored. Even though good results were achieved with clinical paths in many areas, they probably could have been better had incentives been offered. Despite this, we observed in all the settings that the main determinant of success was the level of involvement of all health care providers in the development of the pathways. If clinicians are not the key players in this process, there is a real danger that the clinical path could be considered an administrative attempt to reduce costs, and therefore it would most likely fail [16]. This probably happened to the clinical pathways for strokes and renal failure.

The overall purpose of clinical pathways is to provide better care through a mechanism that is able to coordinate clinical processes and to reduce unjustified variations and, ultimately, costs. During this research it became apparent that teams should be educated more thoroughly with this purpose in mind, particularly physicians. The people involved in the implementation of the pathways are clinicians. They are less well educated about concepts such as 'the market', 'the organization', 'managed care' etc., and, following our research, we think that this type of education would have enhanced the implementation of our clinical pathways, resulting in greater success [49].

This study also has important limitations. The initial measurement occurred a year before the full implementation of the pathways. Thus, it is possible that some of the observed improvement represented a natural drift toward higher performance. Moreover, the comparison of the indicators before and after the adoption of the clinical pathways may have been distorted by the lack of attention while collecting data before pathway implementation. A longer implementation period and the adoption of a different study design, such as a randomized controlled trial, might have improved the strength of our findings. However, we observed significant improvements in different groups of patients, with different diagnoses, in different settings: this suggests that the implementation of the clinical pathways did have an impact on the quality of care.

Patient satisfaction was not measured, which is a serious study limitation. Combining clinical indicators with a satisfaction survey could have given a more accurate measure of the real level of quality achieved through clinical pathways [19]. Neither was the cost of the development and implementation of the pathways evaluated. Although some pathways reduced length of stay or cut costs for diagnostic exams, etc., we can not conclude that the implementation of a clinical path is a cost-effective process. This issue becomes critical for the clinical pathways that have not been shown to improve care, such as the paths for strokes and renal failure: how should health

care organizations respond to clinical paths when they fail? Further research is needed to answer this question [26].

Since many environmental factors may be determinants of the effectiveness of the clinical pathways, health care organizations should evaluate their institutional circumstances carefully before implementing them. In some instances the removal of other barriers to provision of care may be more effective, which would seem to be the basic goal before starting the development of clinical pathways [50].

Finally we implemented hospital-based clinical paths. Current trends suggest that pathways should be extended into primary care and community settings. The next step in our research will be the development of more highly integrated pathways that span the continuum of care for our patients.

In conclusion, this research provides further evidence of the value of clinical pathways. Some clinical pathways appeared to be effective in reducing unnecessary variations and in improving the outcomes and the quality of the care provided to patients. Also, the adoption of clinical pathways added permanent value to organizations as a whole: pathways supported and reinforced risk management, management by objectives, and utilization management, and also helped to promote EBM and the practice of evaluating. We believe that this is the real value that clinical pathways can add to the quality of modern medicine.

## Acknowledgements

We wish to thank all work-team members who participated in this study and Mrs Peggy Leung for her kind support during translation of the manuscript.

## References

1. Vayda E. A comparison of surgical rates in Canada and in England and Wales. *N Engl J Med* 1973; **23**: 1224–1236.
2. Birkmeyer JD, Sharp SM, Finlayson SRG, Fisher ES, Wenneber JE. Variation profiles of common surgical procedures. *Surgery* 1998; **5**: 917–923.
3. Conseil d'évaluation des technologies de la santé du Québec (Council for healthcare technology assessment of Quebec). *Variations in the frequency of surgical procedures by region in the Province of Quebec*. Canada: Conseil d'Évaluation des Technologies de la Santé du Québec, 1993.
4. Groff JY, Mullen PD, Byrd T, Shelton AJ, Lees E, Goode J. Decision making, beliefs, and attitudes toward hysterectomy: a focus group study with medically underserved women in Texas. *J Women's Health Gend Based Med* 2000; **9**: S39–S50.
5. Smith R. Where is the wisdom? The poverty of medical evidence. *Br Med J* 1991; **303**: 798–799.
6. Sanfilippo JS, Robinson CL. *The Risk Management Handbook for Healthcare Professionals*. London: The Parthenon Publishing Group Ltd, 2002.
7. Weingart SN, Wilson RM, Gibberd RW, Harrison B. Epidemiology of medical error. *Br Med J* 2000; **320**: 774–777.



8. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Washington, DC: Institute of Medicine, 2000.
9. Kitchiner D, Bundred PE. Clinical pathways. A practical tool for specifying, evaluating and improving the quality of clinical practice. *MJA* 1999; **170**: 54–55.
10. Pearson SD, Goulart-Fisher D, Lee TH. Critical pathways as a strategy for improving care: problems and potential. *Ann Intern Med* 1995; **12**: 941–948.
11. Wilson J. Integrated care management. *Br J Nurs* 1998; **4**: 201–202.
12. Archer SB, Burnett RJ, Flesch LV *et al*. Implementation of a clinical pathway decreases length of stay and hospital charges for patients undergoing total colectomy and ileal pouch/anal anastomosis. *Surgery* 1997; **4**: 699–705.
13. Wentworth DA, Atkinson RP. Implementation of an acute stroke program decreases hospitalization costs and length of stay. *Stroke* 1996; **6**: 1040–1043.
14. Willis B, Kim LT, Anthony T, Bergen PC, Nwariaku F, Turnage RH. A critical pathway for inguinal hernia repair reduces hospital admissions. *J Surg Res* 2000; **1**: 13–17.
15. Panella M, Moran N, Di Stanislao F. A methodology for the development of clinical pathways: the experience of TriHealth Inc (in Italian). *Qual Ass* 1997; **1**: 1–16.
16. Every NR, Hochman J, Becker R, Lopecky S, Cannon CP. Critical pathways. A review. *Circulation* 2000; **101**: 461–465.
17. Kitchiner D, Davidson C, Bundred P. Integrated care pathways: effective tools for continuous evaluation of clinical practice. *J Eval Clin Pract* 1996; **1**: 65–69.
18. Joint Commission on Accreditation of Healthcare Organizations. *An Integrated Approach To Medical Staff Performance Improvement*, 2nd edition. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations, 2000.
19. Weiland DE. Why use clinical pathways rather than practice guidelines? *Am J Surg* 1997; **174**: 592–594.
20. Campbell H, Hotchkiss R, Bradshaw N, Porteous M. Integrated care pathways. *Br Med J* 1998; **316**: 133–137.
21. Bradshaw MJ. Clinical pathways: a tool to evaluate clinical learning. *J Soc Pediatr Nurs* 1999; **1**: 37–40.
22. Gadacz TR, Adkins RB Jr, OLeary JP. General surgical clinical pathways: an introduction. *Am Surg* 1997; **63**: 107–110.
23. Wooster LD, Forthman MT. Establishing a proper perspective on clinical pathways before implementing a clinical improvement program. *Best Pract Benchmarking Healthcare* 1996; **2**: 84–88.
24. Bailey DA, Litaker DG, Mion LC. Developing better critical paths in healthcare: combining ‘best practice’ and the quantitative approach. *J Nurs Admin* 1998; **28**: 21–26.
25. Horne M. Involving physicians in clinical pathways: an example for perioperative knee arthroplasty. *Jt Comm J Qual Improv* 1996; **22**: 115–124.
26. Weingarten S. Critical pathways: what do you do when they do not seem to work? *Am J Med* 2001; **110**: 224–225.
27. Cappelletty DM. Critical pathways or treatment algorithms in infectious diseases: do they really work? *Pharmacotherapy* 1999; **19**: 672–674.
28. Asadi MJ, Baltz WA. Activity-based costing for clinical paths. An example to improve clinical cost and efficiency. *J Soc Health Syst* 1996; **5**: 1–7.
29. The Electronic College of Process Innovation. *ABC Guidebook*. Department of Defense, 1995. Available online at <http://www.c3i.osd.mil/bpr/bprcd/0201i.htm> (accessed February 2003).
30. Armitage P, Berry G. *Statistical Methods in Medical Research*. Oxford: Blackwell Scientific Publications Ltd, 1994.
31. Joint Commission on Accreditation of Healthcare Organizations. *National Library of Healthcare Indicators. Health Plan and Network Edition*. Oakbrook Terrace, IL: Joint Commission on Accreditation of Healthcare Organizations, 1997.
32. Joint Commission on Accreditation of Healthcare Organizations (JCAHO). *The ORIX Initiative. Quality Indicator Project. ORYX Approved Measures*. JCAHO, 1998. Available online at <http://www.jcaho.org/perfmeas/oryx/20pct.htm> (accessed October 2000).
33. Health Care Financing Administration (HCFA). *Heart Failure National Project Overview*. Baltimore, MD: HCFA, 1999, publication No. 10156, pp. 15–17.
34. Centers for Medicare and Medicaid Services. Quality Improvement Organization (QIO) Program. CMS National Surgical Infection Prevention (SIP) Project. Quality Indicators. Available online at [http://www.cmri-ca.org/healthcare\\_docs/7sowsummaries.pdf](http://www.cmri-ca.org/healthcare_docs/7sowsummaries.pdf) (accessed August 2002).
35. Albers GW, Easton JD, Sacco RL *et al*. Antithrombotic and thrombolytic therapy for ischemic stroke. *Chest* 1998; **114** (suppl.): 683S–698S.
36. Jencks SF, Cuedon T, Burwen DR *et al*. Quality of medical care delivered to Medicare beneficiaries. *J Am Med Assoc* 2000; **284**: 1670–1676.
37. The Association of Maryland Hospitals and Health Systems. *Maryland Hospital Association. Quality Indicator Project. List of Performance Measures. Acute Care Indicator Set*. MHA, 2000. Available online at <http://www.qiproject.org/Brochure/IndAcute.pdf> (accessed February 2001).
38. Taylor EW, Byrne DJ, Leaper DJ, Karran SJ, Browne MK, Mitche KJ. Antibiotic prophylaxis and open groin hernia repair. *World J Surg* 1997; **21**: 811–814.
39. The Quality Indicator Study Group. An approach to the evaluation of quality indicators of the outcome of care in hospitalized patients, with a focus on nosocomial infection indicators. *Infect Control Hosp Epidemiol* 1995; **16**: 308–316.
40. Bonucchi D, Ferramosca E, Ciuffreda A *et al*. Evaluation of dialysis access care by means of process quality indicators. *J Vasc Acc* 2000; **1**: 6–9.
41. Fonarow GC. Quality indicators for the management of heart failure in vulnerable elders. *Ann Intern Med* 2001; **135**: 694–702.
42. Panella M, Allochis G, Di Stanislao F. Clinical pathway for the management of patients with diabetes type I (in Italian). *Qual Ass* 1998; **9**: 274–275.
43. Di Stanislao F, Balzarro G, Panella M, Lombardo D, Zotti C. e Gruppo Collaboratore. Application of Business Process Re-engineering to daily care of the hospital ‘Amedeo di Savoia’ in Turin (in Italian). *L’Ospedale* 1998; **7/8**: 5–12.

44. Ross DT. *Structured Analysis: a Language for Communicating Ideas*. IEEE Transaction on Software Engineering, Volume 15, 1977.
45. Ellrodt G, Cook DJ, Lee J, Cho M, Hunt D, Weingarten S. Evidence-based disease management. *J Am Med Assoc* 1997; **278**: 1687–1692.
46. Hunter D, Farifield G. Managers' checklist: disease management. *Health Serv J* 1995; **106**: 11–12.
47. Panella M, Marchisio S, Kozel D et al. Building, experimenting and implanting clinical pathways in healthcare organisations: the instructions (in Italian). *Qual Ass* 2000; **11**: 251–262.
48. Flarey DL, Smith Blanchett S. *Cardiovascular Outcomes. Collaborative, Path-Based Approaches*. Gaithersburg, MD: Aspen Publishers, Inc., 1998.
49. Corbin CL, Kelley SW, Schwartz RW. Concepts in service marketing for healthcare professionals. *Am J Surg* 2001; **181**: 1–7.
50. Marrie TJ, Lau CY, Wheeler SL, Wong CJ, Vandervoort MK, Feagan BG. A controlled trial of a critical pathway for treatment of community-acquired pneumonia. *J Am Med Assoc* 2000; **283**: 749–755.

Accepted for publication 14 April 2003

## Appendix: the clinical pathways indicator set

Clinical pathway	Indicator	Typology	Criterion met/expected change	Measure	
Inguinal hernia repair	Average length of stay	Process	Significant reduction in pre–post comparison ( $P < 0.05$ )	No. of days	
	Rate of day surgery activity	Process	Significant improvement in pre–post comparison ( $P < 0.05$ )	Percentage	
	Median of preoperative exams	Process	Significant reduction in pre–post comparison ( $P < 0.05$ )	No. per patient	
	Proportion of patients with antibiotic prophylaxis consistent with current recommendations	Process	No patients given prophylactic antibiotics (prophylaxis is not recommended)	Percentage	
	Proportion of patients with correct hair removal	Process	Hair removal with disposable head shaver given to all the patients	Percentage	
	Rate of completion of clinical records	Process	At least 80% of clinical records must be fully filled up	Percentage	
	Proportion of patients with massive bleeding	Outcome	No patients with massive bleeding	Percentage	
	Proportion of patients with postoperative pain	Outcome	No patients with postoperative pain	Percentage	
	Proportion of patients with wound infections	Outcome	<3% of patients with wound infections	Percentage	
	Proportion of patients with unscheduled return to operating room	Outcome	No patients with unscheduled return to operating room	Percentage	
	Stroke	Proportion of patients with length of stay >2 hours in emergency room	Process	No patients with length of stay >2 hours in emergency room	Percentage
		Average length of stay	Process	Significant reduction in pre–post comparison ( $P < 0.05$ )	No. of days
		Proportion of patients with early rehabilitation (within 3 days from acute event)	Process	At least 90% of patients must receive early rehabilitation	Percentage
Proportion of patients treated with nifedipine		Process	Significant reduction in pre–post comparison ( $P < 0.05$ )	Percentage	
Proportion of patients with warfarin at discharge		Process	Significant improvement in pre–post comparison ( $P < 0.05$ )	Percentage	
Proportion of patients with antithrombotic at discharge		Process	Significant improvement in pre–post comparison ( $P < 0.05$ )	Percentage	
Rate of completion of clinical records		Process	At least 80% of clinical records must be fully filled up	Percentage	
Proportion of patients with unscheduled return to intensive care unit		Outcome	Significant reduction in pre–post comparison ( $P < 0.05$ )	Percentage	
Proportion of patients with improved Barthel Index at discharge		Outcome	Significant improvement in pre–post comparison ( $P < 0.05$ )	Percentage	
Total in-patient mortality		Outcome	Significant reduction in pre–post comparison ( $P < 0.05$ )	Percentage	

Clinical pathway	Indicator	Typology	Criterion met/expected change	Measure
Chronic renal failure	Average length of stay	Process	Significant reduction in pre–post comparison ( $P < 0.05$ )	No. of days
	Levels of appropriateness of the stay with AEP protocol	Process	Significant improvement in pre–post comparison ( $P < 0.05$ )	Percentage
	Proportion of patients with temporary access at the first dialysis	Process	Significant improvement in pre–post comparison ( $P < 0.05$ )	Percentage
	Proportion of patients with permanent catheters in dialysis population	Process	Significant improvement in pre–post comparison ( $P < 0.05$ )	Percentage
	Proportion of patients with infection to arteriovenous fistula	Process	Rate of infection must be $< 5\%$	Percentage
	Rate of completion of clinical records	Process	At least 80% of clinical records must be fully filled up	Percentage
	Proportion of patients with discharge instructions (activity, diet, etc.)	Process	Significant improvement in pre–post comparison ( $P < 0.05$ )	Percentage
	Proportion of patients with programmed discharge	Process	Programmed discharge given to all patients needing it	Percentage
	Minimum success rate (MSR) in dialysis patients	Outcome	Significant improvement in pre–post comparison ( $P < 0.05$ )	MSR score
	Total in-patient mortality	Outcome	Significant reduction in pre–post comparison ( $P < 0.05$ )	Percentage
Heart failure	Rate of diagnostic agreement between emergency room and general medicine unit	Process	Agreement good ( $60 < \kappa < 80$ )	Cohen's kappa
	Average length of stay	Process	Significant reduction in pre–post comparison ( $P < 0.05$ )	No. of days
	Rate of completion of clinical records in emergency room	Process	At least 80% of clinical records must be fully filled up	Percentage
	Rate of completion of clinical records in general medicine unit	Process	At least 80% of clinical records must be fully filled up	Percentage
	Proportion of patients with left ventricular function assessment (LVFA)	Process	LVFA given to all patients before arrival, during the stay or planned for after discharge	Percentage
	Proportion of smoker patients with advice/counselling for smoking cessation	Process	Advice or counselling during the stay given to all patients with a history of smoking	Percentage
	Proportion of patients with written discharge instructions addressing: activity level, diet, discharge medications, follow up, weight monitoring, and what to do if symptoms worsen	Process	Written discharge instructions/educational material given to all patients	Percentage

Appendix *continued*

Clinical pathway	Indicator	Typology	Criterion met/expected change	Measure
Total hip replacement	Proportion of patients with ACE inhibitor (ACEI) at discharge	Process	ACEI given to all patients (without contraindications) with left ventricular function <40%	Percentage
	Rate of unscheduled readmissions within 31 days	Outcome	Significant reduction in pre–post comparison ( $P < 0.05$ )	Percentage
	Total and specific in-patient mortality (stratification according to severity of patient’s condition at admission measured with New York Heart Association score)	Outcome	Significant reduction in pre–post comparison ( $P < 0.05$ )	Percentage
	Average length of stay	Process	Significant reduction in pre–post comparison ( $P < 0.05$ )	No. of days
	Average diagnostic accesses of the patients	Process	Significant reduction in pre–post comparison ( $P < 0.05$ )	No. per patient
	Median of preoperative exams	Process	Significant reduction in pre–post comparison ( $P < 0.05$ )	No. per patient
	Proportion of patients compliant with preoperative analgesic therapy	Process	Significant improvement in pre–post comparison ( $P < 0.05$ )	Percentage
	Proportion of patients with preoperative administration of erythropoietin	Process	Erythropoietin given to all patients with Hct <37	Percentage
	Proportion of patients with antibiotic prophylaxis consistent with current recommendations	Process	Antibiotic prophylaxis with cefazolin, cefuroxime, or vancomycin given to all patients	Percentage
	Proportion of patients with early complications	Outcome	Wound infections <3%, intraoperative fractures <3%, nervous-vascular lesions 0%	Percentage
Proportion of patients with late complications	Outcome	Prosthesis removal within 2 years from discharge <2%	Percentage	
Average level of residual disability at follow up	Outcome	Patient improvement at FIM	FIM scale	
Proportion of patients with complete follow up	Process	All patients must accomplish follow up process	Percentage	

FIM, functional independent measure; AEP, appropriateness evaluation protocol; Hct, hematocrit.

