

Guideline-Based Standardized Care Is Associated With Substantially Lower Mortality in Medicare Patients With Acute Myocardial Infarction

The American College of Cardiology's Guidelines Applied in Practice (GAP) Projects in Michigan

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OBJECTIVES	We sought to assess the impact of the American College of Cardiology's Guidelines Applied in Practice (GAP) project for acute myocardial infarction (AMI) care, encompassing 33 acute-care hospitals in southeastern Michigan, on rates of mortality in Medicare patients treated in Michigan.
BACKGROUND	The GAP project increases the use of evidence-based therapies in patients with AMI. It is unknown whether GAP also can reduce the rate of mortality in patients with AMI.
METHODS	Using a before (n = 1,368) and after GAP implementation (n = 1,489) cohort study, 2,857 Medicare patients with AMI were studied to assess the influence of the GAP program on mortality. Multivariate models tested the independent impact of GAP after controlling for other conditions on in-hospital, 30-day, and one-year mortality.
RESULTS	Average patient age was 76 years, 48% were women, and 16% represented non-white minorities. The rate of mortality decreased after GAP for each interval studied: hospital, 10.4% versus 13.6%; 30-day, 16.7% versus 21.6%; and one-year, 33.2% versus 38.3%; all p < 0.02. After multivariate adjustment, GAP correlated with a 21% to 26% reduction in mortality, particularly at 30 days (odds ratio of GAP to baseline 0.74; 95% confidence interval [CI] 0.59 to 0.94; p = 0.012) and one year (odds ratio 0.78; 95% CI 0.64 to 0.95; p = 0.013), particularly in the patients for whom a standard discharge tool was used (1-year mortality, odds ratio 0.53; 95% CI 0.36 to 0.76; p = 0.0006).
CONCLUSIONS	Embedding AMI guidelines into practice was associated with improved 30-day and one-year mortality. This benefit is most marked when patients are cared for using standardized, evidence-based clinical care tools. (J Am Coll Cardiol 2005;46:1242-8) © 2005 by the American College of Cardiology Foundation

Although the knowledge base for the management of acute myocardial infarction (AMI) has grown substantially in recent decades, numerous studies have suggested that therapies known to be effective are omitted in a surprising percentage of patients (1-5). The opportunity to improve AMI care is particularly large for our nation's elderly, in

whom the rate of morbidity and mortality is high and the gap between evidence-based guidelines' recommended care and the care actually provided is large (6-8).

The American College of Cardiology (ACC), in partnership with the Michigan quality improvement organization (i.e., Michigan Peer Review Organization) and the Greater

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Greater Detroit Area Health Council, the Greater Flint Health Coalition, the Mardigian Foundation, and the University of Michigan. The analyses on which this publication is based were performed under contract number 500-02-MI-02, "Utilization and Quality Control Quality Improvement Organization for the state of Michigan" and sponsored by the Centers for Medicare & Medicaid Services, Department of Health and Human Services. The content of this article does not necessarily reflect the views or policies of the Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. government. The authors assume full responsibility for the accuracy and completeness of the ideas presented. The article is a result of the Health Care Quality Improvement Program initiated by the Centers for Medicare & Medicaid Services, which has encouraged identification of quality improvement projects derived from analysis of patterns of care, and therefore required no special funding on the part of this contractor. Ideas and contributions to the authors concerning experience in engaging with the issues presented here are welcomed.

Manuscript received October 19, 2004; revised manuscript received November 23, 2004, accepted December 6, 2004.

Abbreviations and Acronyms

ACC	= American College of Cardiology
AMI	= acute myocardial infarction
BCBSM	= Blue Cross Blue Shield of Michigan
CMS	= Centers for Medicare and Medicaid Services
GAP	= Guidelines Applied in Practice

Detroit Area Health Council, initiated a pilot program in Michigan in 1999 to test the hypothesis that by embedding the key priorities of the national guidelines into AMI care itself, quality could be improved (9,10). Three AMI Guidelines Applied in Practice (GAP) projects, involving 33 hospitals, have suggested that rapid-cycle quality improvement could be achieved (11). Improvement in key indicators was optimized when caregivers adopted a systems approach, driven by routine use of standard, admission orders, a standard discharge contract, and with strong physician, nurse, and administrative leadership (12). Although the GAP projects have shown improvement in key quality indicators, a favorable impact on patient outcomes is the real goal of GAP. In this study, we examined the impact of guideline-based-standard AMI care on in-hospital, 30-day, and one-year mortality in the Medicare beneficiaries who participated in the three Michigan GAP AMI projects.

METHODS

The GAP projects. After their initial development at the University of Michigan Health System (13), the ACC AMI (GAP) projects included a 10-hospital study in Southeast Michigan in 1999 (10), a 5-hospital project in Flint and Saginaw in 2001 (11), and an 18-hospital project in Southeast Michigan in 2002 (14). Each project built upon lessons learned previously. A rapid-cycle quality improvement model was created, emphasizing a collaborative culture of learning, sharing, and problem-solving among hospitals and by designing care processes to assure clinical tool use (11). The GAP project fosters systems-based care from admission to discharge, incorporating evidence-based tools into practice and targeting patients, physicians, and nurses. The methods used in the ACC GAP projects have been described previously (9-12,15). The clinical care tool templates, including standardized orders, a pocket guideline, and a standardized discharge tool, are available elsewhere (16).

The Medicare sample. We examined the impact of GAP on Medicare beneficiaries by studying patients treated in each hospital before and after the implementation of GAP. Baseline samples were created using a 50% random sample with at least 20 cases per hospital of Medicare AMI patients (principal diagnosis code: 410.xx) from patients treated in the year preceding GAP implementation. The post-GAP sample included a 95% to 100% sampling of all Medicare AMI patients in the four months immediately after GAP implementation at each hospital. Hospital records for each patient were copied and forwarded to DynKePRO's Centers

for Medicare & Medicaid Services (CMS) Clinical Data Abstraction Center. Each record was screened to ensure that AMI was the principal diagnosis. Then, data regarding patient history, presenting symptoms and signs, rates of comorbidity, diagnostic studies, therapies, outcomes, and use of standard orders and/or the discharge tool were extracted. For quality of care indicators, only ideal cases were included in the denominator. Patients with contraindications were excluded. To assure quality, data were re-abstracted for a random sample of baseline and post-GAP records by the CMS Clinical Data Abstraction Center. Reliability (94%) and accuracy (97%) were high. To assess for 30-day and one-year mortality, Medicare claims were screened using each patient's unique identifier.

Statistical methods. We compared patients treated before (baseline) and immediately after the implementation of GAP (post-GAP). Using standard statistics, demographics, presentation variables, rates of comorbidity, diagnostic tests, treatments, and outcomes were analyzed in the two cohorts, including the use of evidence-based therapies and use of AMI standard admission and discharge tools. We examined in-hospital, 30-day, and one-year mortality in baseline compared with post-GAP patients. To assess the potential independent benefit of GAP on mortality, separate multivariate logistic regression models for in-hospital, 30-day, and one-year mortality were developed. Age, troponin levels, and heart rate were included as continuous variables. Each hospital was included in the model as an independent variable to account for practice variation between facilities. Candidate variables included age (continuous), gender, history of MI, previous heart failure, previous chronic obstructive pulmonary disorder, history of stroke, previous percutaneous coronary intervention, left ventricular ejection fraction, chest pain, hematocrit <30%, heart rate (continuous), anterior MI, inferior MI, atrial fibrillation, percutaneous coronary intervention during the index hospitalization, coronary artery bypass grafting during the index hospitalization, elevated troponin (continuous), in-hospital heart failure, hypertension, elevated creatinine, renal failure, stroke, cardiac arrest, and cardiogenic shock. To assess whether the GAP effect was primarily driven by use of standardized tools, we added their use to the multivariable models to see whether they supplanted the apparent GAP effect. For in-hospital mortality, the independent effect of using standardized orders at admission was analyzed. To assess the influence of clinical care tool use on long-term outcomes, we studied the independent effect of standardized discharge document on 30-day and one-year mortality, after excluding patients with in-hospital death.

RESULTS

Among 2,857 patients studied, 1,368 were in the baseline cohort and 1,489 in the post-GAP cohort. Average age was 76 years. When comparing demographics, previous cardiovascular disease (Table 1), comorbid conditions, presenting

Table 1. Patient Characteristics

Variable	Baseline (%) (n = 1,368)	Post-GAP (%) (n = 1,489)	p Value
Demographics			
Mean age (yrs)	76.4	76.2	0.57
Females	656 (47.9)	717 (48.1)	0.91
Non-white	211 (15.5)	245 (16.5)	0.31
Impaired functional status			
Immobility	60 (6.0)	67 (5.8)	0.86
Dementia	158 (11.5)	172 (11.5)	NS
Admission from care facility	114 (8.5)	98 (6.7)	0.08
Previous cardiovascular disease			
MI	572 (41.8)	675 (45.3)	0.06
CABG	270 (19.7)	294 (19.7)	NS
PCI	216 (15.8)	262 (17.6)	0.19
Heart failure	482 (35.2)	533 (35.8)	0.75
Stroke	280 (20.5)	331 (22.2)	0.25
Hypertension	1,024 (74.8)	1,175 (78.9)	0.01
Comorbidities			
Diabetes	507 (37.1)	549 (36.9)	0.91
Current smoker	255 (18.6)	286 (19.2)	0.70
COPD	357 (26.1)	425 (28.5)	0.14
Terminal illness	1 (0.07)	1 (0.07)	NS

CABG = coronary artery bypass graft surgery; COPD = chronic obstructive pulmonary disease; MI = myocardial infarction; PCI = percutaneous coronary intervention.

symptoms, and test results (Table 2), the two cohorts were similar with rare exceptions. On average, post-GAP patients a higher rate of hypertension (78.9% vs. 74.8%; $p = 0.01$), more anterior AMIs as diagnosed by electrocardiogram (33.8% vs. 29.8%; $p = 0.02$), and slightly greater likelihood of normal or only mildly depressed left ventricular function (50.8% vs. 46.6%; $p = 0.03$).

Table 3 lists the diagnostic and treatment approaches. After GAP implementation, eligible patients were more likely to receive aspirin in the first 24 h of admission (87.3%

vs. 84.8%; $p = 0.05$), have standardized admission orders used (45.5% vs. 19.8%; $p < 0.001$), and have the discharge tool used (30.8% vs. 1.8%; $p < 0.001$). Among ideal candidates, post-GAP patients were more likely to receive aspirin (90.0% vs. 81.6%, $p < 0.001$), beta-blockers (91.6% vs. 84.2%; $p < 0.001$), a lipid-lowering drug (78.2% vs. 73.1%; $p = 0.001$) and an angiotensin-converting enzyme inhibitor (81.0% vs. 77.1%; $p = 0.01$) at discharge.

Table 4 lists in-hospital complications and mortality data. Mortality in-hospital (10.4% vs. 13.6%; $p = 0.017$), at 30 days (16.7% vs. 21.6%; $p = 0.001$), and at one year (33.2% vs. 38.3%; $p = 0.04$) was significantly lower in the post-GAP patients. Table 5 illustrates the potential independent effect of GAP on hospital, 30-day, and one-year mortality. After adjustment for clinical findings, tests, and treatments, patients cared for post-GAP were less likely to die at 30 days and one year, and there was a trend for better hospital survival as well (Table 5).

When we compared the impact of standardized care tools versus the overall impact of GAP, 30-day mortality was significantly less likely among patients receiving the standardized discharge tool (odds ratio 0.52; 95% confidence interval 0.27 to 0.98; $p = 0.042$; Table 6). This variable resulted in elimination of the GAP effect from the model, although GAP drove the use of the standard discharge tool from less than 2% pre-GAP to nearly 31% after GAP. Use of the discharge tool was associated with a significant reduction in one-year mortality (odds ratio 0.53; 95% confidence interval 0.36 to 0.76; $p = 0.0006$).

DISCUSSION

Previous studies have suggested that adherence to guideline-based therapeutic goals may have a benefit in lowering acute and long-term outcomes after patients suffer an AMI (17).

Table 2. Clinical Characteristics

Variable	Baseline (%) (n = 1,368)	Post-GAP (%) (n = 1,489)	p Value
Patient characteristics at presentation			
Chest pain	970 (72.3)	1,068 (73.9)	0.31
Pain <6 h	28 (2.4)	31 (2.5)	0.43
Heart rate >100 beats/min	361 (26.6)	396 (26.7)	0.94
Heart failure	265 (17.8)	265 (17.8)	0.28
Electrocardiogram at presentation			
LBBB	77 (6.2)	96 (7.1)	0.30
Atrial fibrillation	284 (20.8)	308 (20.7)	0.94
Paced rhythm	130 (10.8)	147 (11.4)	0.62
Anterior MI	408 (29.8)	504 (33.8)	0.02
Inferior MI	439 (32.1)	502 (33.7)	0.36
Test results			
Creatine kinase $\geq 5 \times$ normal	220 (20.0)	197 (17.2)	0.06
Hematocrit <30 g/dl	154 (11.4)	185 (12.7)	0.30
Cardiomegaly on CXR ⁺	598 (50.5)	625 (49.0)	0.44
LVEF $\geq 40\%$ (normal or mild ↓)	638 (46.6)	756 (50.8)	0.03
LVEF 25%–39% (moderately ↓)	336 (24.6)	343 (23.0)	0.34
LVEF <25% (severely ↓)	167 (12.2)	156 (10.5)	0.15
LVEF not assessed	227 (16.6)	234 (15.7)	0.52

CXR = chest X-ray; LBBB = left bundle branch block; LVEF = left ventricular ejection fraction; MI = myocardial infarction.

Table 3. In-Hospital Treatment

Test or Treatment	Baseline (%) (n = 1,368)	Post-GAP (%) (n = 1,489)	p Value
Noninvasive tests			
Echocardiogram	846 (61.8)	893 (59.9)	0.31
Gated blood pool scan	57 (4.2)	98 (6.6)	0.004
Stress test	112 (8.2)	163 (10.9)	0.12
Invasive procedures			
Admission to facility with cardiac surgery capability	768 (56.1)	902 (60.6)	0.02
Cardiac catheterization	618 (45.2)	713 (47.9)	0.15
PCI	261 (19.1)	344 (23.1)	0.008
CABG	110 (8.0)	138 (9.3)	0.24
In-hospital medical therapy*			
Aspirin	873 (84.8)	896 (87.3)	0.05
Beta-blocker	509 (70.7)	520 (73.1)	0.15
Standard orders used	271 (19.8)	677 (45.5)	<0.001
Discharge medical therapy*			
Aspirin	694 (81.6)	819 (90.0)	<0.001
Beta-blocker	247 (84.2)	285 (91.6)	<0.001
Lipid-lowering agent	364 (73.1)	510 (78.2)	0.001
ACE inhibitor	327 (77.1)	331 (81.0)	0.01
Standard discharge tool used	21 (1.8)	409 (30.8)	<0.001

*Data provided reflect rates of therapy among ideal patients for each treatment, that is, without any contraindication (relative or absolute).
 ACE = angiotensin-converting enzyme; CABG = coronary artery bypass graft surgery; PCI = percutaneous coronary intervention.

Because the guidelines reflect a scientific basis for treatment emphasizing strategies that have been studied in large randomized clinical trials (1,3), it makes sense that the actual clinical use of these strategies through guideline implementation would lead to improved patient outcomes. However, most such studies have struggled to demonstrate improvement in process measures, let alone clinical outcomes (18). Part of this failure has been due to only mild uptake of guideline tools, and much has been attributable to issues of sample size where, unlike large clinical trials, the numbers of patients studied have been modest (13,19). Some reports have represented single-center initiatives over the course of long periods of time (19) and have been criticized as reflecting natural diffusion of knowledge into care, not a direct benefit of a labor-intensive guideline implementation effort. Other reports have included voluntary data entry so that assuring similar “before and after” samples was impos-

sible (20). The failure of guideline implementation efforts to demonstrate improved outcomes has served to fuel nihilism among many care providers regarding the importance of guidelines and their use in practice (21).

The ACC AMI GAP initiatives in Michigan provided a unique opportunity to assess the effect of an active guideline implementation program on outcomes after AMI. We were able to assess the effects of GAP on not only in-hospital quality indicators but also immediate and downstream mortality using data gathered the preceding year as each hospital's control. The results suggest that across 33 hospitals, a rapid-cycle quality improvement effort is associated with a lower 30-day and one-year mortality among Medicare beneficiaries hospitalized for an AMI. The size of this effect appears to be a 21% to 26% reduction in death.

Because our study was not a randomized trial, is it really possible to state that GAP lowered the rate of mortality after an AMI in elderly patients? Although, “before and after” observational studies can “suggest” such effects, uncertainty remains. However, in the case of GAP in Michigan, the accumulated evidence is consistent with this conclusion. First, patients were selected randomly for inclusion and their charts were copied and sent to a data abstraction organization for data extraction. This procedure should mitigate selection bias that can cloud any observational study. Second, the degree of improvement in many of the quality indicators after GAP correlated strongly with increased use of standardized orders and discharge documents. Third, in the GAP pilot project, performance in 11 control hospitals that wanted to participate in GAP but were not selected were compared with 10 GAP hospitals, demonstrating that “wanting to improve” did not achieve the degree of change observed in the participating hospitals (10). Fourth, mortality reduction noted after GAP persisted

Table 4. Complications and Outcomes

Complications/Outcomes	Baseline (%) (n = 1,368)	Post-GAP (%) (n = 1,489)	p Value
In hospital			
Hypotension	419 (30.6)	492 (33.0)	0.17
Shock	16 (1.2)	18 (1.2)	0.92
Heart failure/pulmonary edema	652 (47.7)	660 (44.3)	0.07
Stroke	68 (4.9)	78 (5.2)	0.74
Renal failure	340 (25.0)	357 (24.2)	0.61
Hemorrhage/bleeding	338 (24.7)	381 (25.6)	0.59
Transfusion	278 (20.3)	364 (24.4)	0.008
Discharge to acute care hospital	174 (12.7)	162 (10.9)	0.13
In-hospital mortality	186 (13.6)	159 (10.4)	0.017
Later outcomes			
30-day mortality	295 (21.6)	249 (16.7)	0.001
1-year mortality	524 (38.3)	494 (33.2)	0.004

Table 6. Independent Predictors of Mortality—Influence of Standard Care Tools and GAP

Variable	In-Hospital Mortality				30-Day Mortality				1-Year Mortality			
	Odds Ratio	95% CI	p Value	Variable	Odds Ratio	95% CI	p Value	Variable	Odds Ratio	95% CI	p Value	
Age*	1.04	1.02-1.06	<0.0001	Age*	1.04	1.02-1.06	0.0004	Age	1.05	1.03-1.06	<0.0001	
No prior MI	0.69	0.51-0.94	0.019	History of stroke	1.75	1.23-2.50	0.002	Prior HF	1.61	1.26-2.05	0.0001	
Chest pain	0.41	0.31-0.56	<0.0001	History of PCI	0.41	0.32-0.52	<0.0001	Prior COPD	1.55	1.22-1.98	0.0004	
Heart rate*	1.006	1.001-1.012	0.03	Chest pain	0.47	0.33-0.66	<0.0001	Chest pain	0.51	0.40-0.65	<0.0001	
Ant. MI	1.55	1.16-2.07	0.003	LVEF	1.40	1.10-1.79	0.006	Anemia	1.74	1.27-2.37	0.0005	
Inf. MI	1.84	1.37-2.48	<0.0001	PCI	0.22	0.09-0.54	0.001	LVEF	1.46	1.16-1.85	0.0014	
PCI	0.41	0.25-0.67	0.0004	CABG	0.15	0.03-0.62	0.009	PCI	0.34	0.23-0.51	<0.0001	
CABG	0.53	0.28-0.99	0.05	Heart failure	0.59	0.39-0.91	0.017	CABG	0.22	0.12-0.42	<0.0001	
Troponin ↑*	1.001	1.001-1.002	0.0002	GAP	0.84	0.59-1.20	0.339	GAP	0.95	0.75-1.21	0.687	
GAP	0.81	0.59-1.13	0.21	Discharge tool	0.52	0.27-0.98	0.042	Discharge tool	0.53	0.36-0.76	0.0006	
Standard orders	0.92	0.63-1.35	0.68									
C-statistic = 0.767				C-statistic = 0.800				C-statistic = 0.774				

*Continuous variable.

Abbreviations as in Table 5.

physicians and nurses, with support from the subspecialty's premier professional society, the ACC, and its leaders. Professional leadership and physician engagement are essential to achieving improvement (25-27). Second, energy for change was fueled by involvement of community stakeholders involved with caring for, insuring, and employing patients and their families. General Motors, Ford Motor Company, Daimler-Chrysler, The United Auto Workers, Blue Cross Blue Shield of Michigan (BCBSM), CMS, and many others supported GAP through the Greater Detroit Area Health Council and the Greater Flint Health Coalition. Third, CMS and Michigan Peer Review Organization were strong collaborators for assistance in cardiovascular care measurement and improvement in local hospitals, which was critical for the ability to initiate rapid cycle change. Fourth, hospitals were ready for improvement given the current focus of CMS, BCBSM, Joint Commission for Accreditation of Hospital Organizations, and others on AMI quality. Fifth, the intervention focused on the patient-doctor-nurse triangle of care, trying to assure that a short list of key care priorities was emphasized in a consistent way and with systems which supported these priorities during the care itself. Sixth, assuring late benefit of treatments after hospital discharge was enhanced through use of an AMI discharge form. This simple, one-page check-list guarantees that key pharmaceutical and lifestyle goals, their rationale, and their duration of use are understood both by the care provider and the patient. Initiation of secondary prevention treatment, in-hospital, improves the likelihood that patient's will be on treatment 3 to 12 months later (28-30). Finally, the willingness of physicians and nurses in Michigan to work together reflects an appreciation that more than 40% of the state's citizens currently die of cardiovascular disease and that by learning from each other, care can improve in each institution (31).

We believe that further improvement is possible. Only 32% of the post-GAP patient charts contained a discharge contract, and <50% had initial care directed by standardized orders. One GAP hospital has moved from a culture where use of the standardized order sets and discharge document is "encouraged," to a system where it is "guaranteed" for heart failure or acute coronary syndromes. Patients must have orders provided in standard sets, and use of the discharge contract is required. Patients' charts are coded on the floor, in real time, and deficiencies in use of standard care tools and in documentation or adherence to quality indicators are promptly identified and fed back to the care team and the patient. Fundamentally, this approach likens a missed quality of care opportunity to a medical error. This has resulted in adherence to key quality indicators among eligible patients of nearly 100% (20).

Study limitations. The cost-effectiveness of the GAP intervention has not been studied. We do not know whether GAP is more or less cost-effective than other current medical strategies. Regardless of its cost-effectiveness, efforts such as GAP are being adopted because AMI quality indicators are now a key performance measure for hospital accreditation by the Joint Commission for Accreditation of

Hospital Organizations, care reimbursement in Michigan by BCBSM, and will become targets of incentive-based reimbursement by CMS in 2005. Thus, hospitals must invest in certain quality initiatives to maintain excellence in care, their accreditation, and to maximize clinical revenues. Given these pressures, both hospitals and caregivers are searching for practical methods to measure and improve performance. The GAP and the American Heart Association's Get With the Guidelines (32) represent the most well-publicized methods to do this for acute coronary care.

Conclusions. Medicine based on memory is unreliable. Guidelines, when embedded into care systems which remind patients, doctors, and nurses of care priorities, can improve the degree to which current medical knowledge is directly applied to patient care. In doing so, indirect process measures of care improve but, more importantly, they translate into improved patient outcomes. Through collaboration, a systems-based approach and a professional commitment to never-ending improvement, patients can get better care.

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