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HEALTH POLICY

High Quality Care and Ethical Pay-for-Performance: A Society of General Internal Medicine Policy Analysis

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BACKGROUND: Pay-for-performance is proliferating, yet its impact on key stakeholders remains uncertain.

OBJECTIVE: The Society of General Internal Medicine systematically evaluated ethical issues raised by performance-based physician compensation.

RESULTS: We conclude that current arrangements are based on fundamentally acceptable ethical principles, but are guided by an incomplete understanding of health-care quality. Furthermore, their implementation without evidence of safety and efficacy is ethically precarious because of potential risks to stakeholders, especially vulnerable patients.

CONCLUSION: We propose four major strategies to transition from risky pay-for-performance systems to ethical performance-based physician compensation. These include implementing safeguards within current pay-for-performance systems, reaching consensus regarding the obligations of key stakeholders in improving health-care quality, developing valid and comprehensive measures of health-care quality, and utilizing a cautious evaluative approach in creating the next generation of compensation systems that reward genuine quality.

KEY WORDS: ethics; health policy; pay-for-performance; quality improvement; physician reimbursement.

Pay-for-performance systems seek to improve health-care quality by providing bonus dollars to physicians, practice groups, or hospitals whose patients achieve certain health goals. These arrangements are proliferating, yet their impact on key stakeholders remains uncertain. The Society of General Internal Medicine (SGIM), through its Ethics Committee, systematically evaluated ethical issues raised by performance-based physician compensation. Investigations included literature review, in-depth interviews with key informants, focus groups among SGIM members, open forums at national SGIM meetings, and discussions among SGIM committees and leadership. A comprehensive report of the Ethics Committee’s findings and recommendations is available at http://www.sgim.org/index.cfm?pageId=806.

This position paper begins by examining the fundamental principles of pay-for-performance and setting forth our organization’s definition of health-care quality. Based on this exploration, we present our conclusions regarding the manner of implementation of pay-for-performance and its potential effects on key stakeholders. We propose four major strategies for moving toward more ethical and effective performance-based physician compensation, emphasizing the need to implement immediate safeguards to protect vulnerable populations.

FUNDAMENTAL PRINCIPLES OF PAY-FOR-PERFORMANCE; UNDERSTANDING HEALTH-CARE QUALITY

The fundamental principles of pay-for-performance include rewarding quality health care and aligning physicians’ financial incentives with the best interests of patients. Although this inherent appeal to physician self-interest might be in tension with professional ideals of altruism and beneficence, the principles that inform pay-for-performance are not inherently unethical. It seems just, for example, to financially reward physicians who demonstrate outstanding levels of patient-centered and evidence-based care. Nevertheless, systems intending to improve medical care must be guided by evidence and a precise definition of health-care quality to ensure that they are effective, valid, and fair. We define health-care quality in a manner that prioritizes patient-
centered care while recognizing the importance of population-level health improvement:

Health-care quality is the degree to which physicians and health-care institutions fulfill their care obligations to individual patients and the degree to which patients, physicians, and health-care institutions enable these obligations to be fulfilled justly across the population.

This understanding of health-care quality informs our criticisms of current pay-for-performance arrangements and provides a roadmap to high quality care and ethical performance-based physician compensation.

Potential Ethical Problems in the Implementation of Pay-for-Performance

In light of these principles, we see the following potential ethical problems in the implementation of pay-for-performance systems.

1. **Lack of proven safety and benefit for patients**: Studies of performance-based physician compensation have generally shown scant evidence of quality improvement. Implementation without proof of safety and effectiveness is ethically problematic. It is unclear, for instance, why a new drug to be used by several dozen individuals requires proof of safety and efficacy, while policy changes affecting millions do not. From an ethical perspective, pay-for-performance is a potentially risky experiment in health-care delivery. Further, current pay-for-performance systems generally lack key safeguards against readily anticipated adverse effects (discussed below), and we are concerned that negative outcomes may already be unfolding.

2. **Inadequate definitions of quality**: Although commentators have proposed many definitions of health-care quality, none are universally accepted, and they provide little guidance regarding accountability or how quality can be validly measured. Furthermore, current pay-for-performance arrangements are guided by a highly incomplete understanding of quality that does not resemble any published or well-reasoned definition. This understanding typically equates quality with the achievement of non-individualized, pre-determined health goals for broad populations and fails to consider contributions from stakeholders other than physician entities (such as health plans) that also have partial responsibility for ensuring quality. This approach has severely limited our ability to capture the myriad of elements comprising quality care, let alone the most complex but essential feature of a praxis like medicine—the exercise of correct judgment—which is only readily assessed by peers.

3. **Inadequate measures of quality**: Because they are based on inadequate definitions, existing pay-for-performance measures lack validity and comprehensiveness in assessing health-care quality. Measures typically cover only isolated and readily quantifiable aspects of physician clinical performance and fail to assess crucial realms such as judgment, compassion, and communication skills.

Quantifying health-care quality is notoriously difficult, and basing payment incentives upon inadequate measures and definitions of quality will make consequences difficult to control. Unfortunately, this approach is often used to make judgments about individual practitioners when variability in case mix and patient preferences precludes making valid judgments. For example, in a patient with difficult-to-control diabetes, a decline in hemoglobin A1C from 10.0 to 8.0 might be a remarkable achievement and more validly represent high quality care than a decline from 7.3 to 6.9 in another patient.

4. **Misallocating the locus of accountability for quality improvement**: Many pay-for-performance measures hold physicians accountable for aspects of quality beyond their control, such as health-care delivery problems, lack of incentives for coordinated care, and even social determinants of health. Some may hold physicians accountable for the care of patients with whom they have not had a continuous relationship.

5. **Potential for adverse effects on patients and vulnerable populations**: Performance targets used today may have detrimental effects on quality. For example, it may seem reasonable to require that diabetic patients achieve hemoglobin A1C levels below 7.0. In patients with previous hypoglycemic episodes, however, this target might be life-threatening.

Or, consider a patient with a hemoglobin A1C of 7.5 who frequently skips preventive visits but happens to present with back pain. If bonuses are provided for reducing glucose levels, a physician might prefer to discuss diabetes control rather than ruling out life-threatening causes of back pain. Such “treating the measure” might worsen outcomes.

Pre-determined population-centered measures might also induce physicians to avoid patients who are less likely to meet targets. Such patients are often society’s most vulnerable members—those with multiple chronic conditions, the poor, the educationally disadvantaged, those with limited English proficiency, and members of racial minority groups.

Because physicians serving disadvantaged patients might receive lower compensation, less well-off practices would be left with fewer resources to improve care. This could create a vicious cycle of worsening quality for the most vulnerable patients.

Poorly designed pay-for-performance systems could therefore limit access to care for vulnerable populations, worsen health-care quality, and erode patient trust.

6. **Potential for adverse effects on physicians**: In systems using a limited set of population-level measures, physician professionalism and morale could decline. Some clinicians might “treat the measure” or select the “best” patients to enhance income. Others might provide optimal care despite reduced income, but grow frustrated. Pay-for-performance is also likely to increase the complexity of the reimbursement system, and metrics might be used against physicians for legal, credentialing, or recertification purposes. Such changes would decrease physician job satisfaction, with detrimental effects on patient care and the attractiveness of medicine (especially primary care) as a profession.

7. **Potential for adverse effects on society**: The potential detrimental effects above would have broader implications for society. A decreasing supply of primary care physicians would exacerbate problems in access and quality. Truly valid and comprehensive measurements might require overly burdensome or expensive systems, and could make...
the marginal value of performance-based compensation negligible. Deteriorating value could also result if physicians drive up expenses by ordering unnecessary tests or referrals to specialists.36

Ultimately, insurers could face a backlash by patients and physicians against an effort that might be viewed cynically as another cost-containment attempt, offered disingenuously as quality improvement.

8. Lack of structured monitoring for adverse outcomes: A substantial literature advocates structured oversight of any risky intervention not meant to directly benefit individuals.39–53 Although pay-for-performance is intended to improve patient care, some would argue that it is primarily a population-centered cost control measure with unclear effectiveness and a substantial risk-benefit ratio for certain populations.53 We believe the risks from pay-for-performance outlined above are serious enough and have a high enough probability of occurring to engender an ethical obligation for structured monitoring of key outcomes (discussed below).

POLICY RECOMMENDATIONS

SGIM supports evidence-based, ethical, and comprehensive efforts to improve health-care quality and physician compensation. While carefully designed pay-for-performance systems could be a component of such an approach, current iterations fail to reach acceptable ethical standards for the reasons above. We therefore advocate the following four major strategies to achieve high quality health care and ethical performance-based physician compensation (Tables 1, 2, 3).

Current Pay-for-Performance Systems should Rapidly Adopt Safeguards to Protect Vulnerable Populations

Until researchers develop valid and comprehensive quality measures, pay-for-performance systems must prioritize the protection of vulnerable populations and minimize readily anticipated adverse consequences (Table 3). Pay-for-performance leaders should institute the following safeguards to achieve these aims:

1. Balance current population-level measurements with the best available measures of quality from the patient perspective.

2. Reduce or stabilize the percentage of physicians’ salaries at stake. Policy makers should limit bonus amounts to reduce temptations to “game” the system, especially in arrangements that do not adjust for case mix. Current levels of approximately 5% of physicians’ salaries seem reasonable in systems that adjust for case mix, while lower levels would be appropriate for those that do not.

3. Provide adequate offsetting compensation to physicians serving vulnerable patients. For example, the Consumer Assessment of Healthcare Providers Ratings54 places a strong emphasis on measuring how well health-care providers communicate with patients. A growing body of research55,56 could inform the development of valid measures in the outpatient setting.

4. Population-level measures should:
   a. Be evidence-based and clearly linked to valued patient outcomes
   b. Assess domains clearly within the influence of the physician or physician group, especially for complex patients
   c. Assess quality at the level of large physician practices rather than individual physicians
   d. Assess improvement toward goals in addition to achievement of cut-points

Table 1. Potential Ethical Problems in the Implementation of Pay-for-Performance

| I. Lack of proven safety and benefit for patients |
| II. Inadequate definitions of quality |
| III. Inadequate measures of quality |
| IV. Misallocating the locus of accountability for quality improvement |
| V. Potential for adverse effects on patients and vulnerable populations |
| VI. Potential for adverse effects on physicians |
| VII. Potential for adverse effects on society |
| VIII. Lack of structured monitoring for adverse outcomes |

Table 2. Major Strategies to Achieve High Quality Health Care and Ethical Performance-Based Physician Compensation

| I. Current pay-for-performance systems should rapidly adopt safeguards to protect vulnerable populations (see Table 3) |
| II. Key stakeholders should develop consensus regarding their responsibilities in improving health-care quality |
| III. Researchers and policy makers should develop valid and comprehensive quality measures for use in the next generation of compensation systems that reward genuine quality |
| IV. Researchers and policy makers should use a cautious evaluative approach to long-term development of compensation systems that reward quality |

Table 3. Recommended Safeguards to Protect Vulnerable Populations and Prevent Unintended Consequences Within Current Pay-for-Performance Systems

| I. Balance current population-level measurements with the best available measures of quality from the patient perspective |
| 2. Reduce or stabilize the percentage of physicians’ salaries at stake (except as in point 3 below) |
| 3. Provide adequate offsetting compensation for physicians serving vulnerable patients |
| 4. Population-level measures should:
   a. Be evidence-based and clearly linked to valued patient outcomes
   b. Assess domains clearly within the influence of the physician or physician group, especially for complex patients
   c. Assess quality at the level of large physician practices rather than individual physicians
   d. Assess improvement toward goals in addition to achievement of cut-points |
| 5. If systems utilize population-level outcomes measures, they should:
   a. Explicitly assess patient complexity and vulnerability
   b. Carefully adjust for case-mix based on relevant patient factors
   c. Carefully adjust for the manner in which responsibility for patient outcomes is shared between physicians, patients, health plans, and other health-care institutions |
| 6. Initiate monitoring before and after implementing the above changes. Monitoring should assess:
   a. Patient satisfaction, access, continuity, and coordination of care; effects on vulnerable patients as a particularly important focus
   b. Physician satisfaction and professionalism, administrative burden, effects on the patient-physician relationship (see Table 3) |
   c. Effects on disparities between physician practices serving vulnerable and non-vulnerable populations |
   d. Payer satisfaction and value for health-care expenditures |
4. Recommendations regarding population-level measures. Pre-determined population-level measures of quality must be instituted carefully because they are inherently non-patient-centered. Because such measures are pervasive in modern pay-for-performance systems, we recommend several strategies to maximize the protection of vulnerable patients:

4.a. Utilize population-level measures that are evidence-based and clearly linked to valued patient outcomes. For example, pneumonia and influenza immunizations have been proven to prevent potentially debilitating illnesses while having minimal adverse effects. Other commonly utilized measures may fail to reach these standards; hemoglobin A1C targets are based on evidence from randomized control trials, but the applicability to individual patients on real-life physician panels is often unclear.

4.b. Population-level measures should assess domains clearly within the influence of the physician or physician group, especially for complex patients. Basic process measures, such as vaccination rates and the frequency of diabetic eye exams, are imperfect measures of quality, but are more within the influence of physicians and practice groups than outcomes measures. Process measures seem less likely than outcomes measures to cause avoidance of vulnerable patients and physician frustration.

4.c. Measures should assess quality at the level of large physician practices rather than individual physicians. Experts skilled in statistical analysis should determine minimum patient population sizes for each measure to provide optimal data and avoid statistical error. Only practice groups with sufficient numbers of patients should initially be measured.

4.d. Measures should assess improvement toward goals in addition to achievement of cut-points. This could apply to both process and outcomes measures. For example, physician groups could be rewarded both for achieving vaccination rates at a pre-determined level as well as for annual improvements toward the target.

5. Recommendations regarding population-level outcomes measures. Population-level outcomes measures are methodologically complex, and the validity of current measures is uncertain. This will likely preclude their use in an ethically defensible manner in the short-term unless provisions that maximize validity are closely followed, including:

5.a. Explicitly assess patient complexity and vulnerability. This would require integrating patient survey data and medical record data regarding sociodemographic characteristics and medical comorbidities.

5.b. Carefully adjust for case-mix based on relevant patient factors. For example, it would be inappropriate to reduce systolic blood pressure levels below 140 mmHg in an 85-year-old diabetic patient with multiple co-morbidities taking three antihypertensive medications. Proper case-mix adjustment might allow this patient’s physician to prioritize other care, while a lack of adjustment could induce either dangerous efforts to lower blood pressure or substantial physician frustration.

5.c. Carefully adjust for the manner in which responsibility for patient outcomes is shared between physicians, patients, health plans, and other health care institutions. For example, consider two physicians who must eventually prescribe three hypoglycemic medications to similar diabetic patients whose initial hemoglobin A1C levels were 9.5. The first patient has generous health insurance, enabling him to purchase all three medications and lower his hemoglobin A1C to 6.5. The second patient must pay the full cost of medications, and she can only afford two. She only lowers her hemoglobin A1C to 7.5. A proper system would adjust for health insurance status.

6. Pay-for-performance leaders should initiate monitoring before and after implementing the above changes. Monitoring should assess important patient outcomes not often included in pay-for-performance studies, such as satisfaction, access, continuity, and coordination of care. Effects on vulnerable patients should be a particularly important focus. Studies should also assess physician satisfaction and professionalism, administrative burden, effects on the patient-physician relationship, and the impact on disparities between physician practices serving more vulnerable and less vulnerable populations. Monitoring should examine payer satisfaction and value for health-care expenditures.

Key Stakeholders should Develop Consensus Regarding their Responsibilities in Improving Health Care Quality

A crucial first step in achieving ethically defensible health-care quality improvement will be for key stakeholders to develop consensus regarding their shared and unique obligations to individual patients and patient populations. For example, to improve blood glucose control among diabetic patients, physicians must recommend evidence-based, patient-centered management strategies, practice groups must provide access to testing facilities, health insurers must facilitate receipt of affordable medications and testing, and patients must adhere to therapeutic plans.

Bringing health insurers, patients, employers, and physicians to the table would highlight opportunities to improve coordination and continuity of care; new paradigms for quality improvement that integrate assessment at the individual physician level and institution level could emerge.
Researchers and Policy Makers should Develop Valid and Comprehensive Quality Measures for Use in the Next Generation of Compensation Systems that Reward Genuine Quality

A long-term strategy for quality improvement will be guided by a framework of accountability in which physicians, practice groups, health plans, and public payers are measured based on how well they fulfill well-defined obligations to individual patients and populations.

For example, measures of physician quality should assess multiple domains, such as accessibility, adherence to evidence-based but patient-centered care, and communication skills. Appropriate measures would account for individualized patient-physician goals, be based on the best available evidence, and minimize administrative burden and expense.

Measures of health-care institution quality (e.g., physician groups, hospitals, and public and private payers) should assess domains such as how well these groups foster teamwork, facilitate achievement of patient goals, strengthen the doctor-patient relationship, and improve access, coordination, and continuity of care for individual patients.

Equally important will be development of valid population-level health-care quality measures. In addition to measuring how well physicians and health-care institutions fulfill obligations to individual patients, comprehensive quality measures would assess the degree to which patients, physicians, and health-care institutions maximize health-care resources available to the population, distribute them fairly, and fulfill their obligations justly.

Measures should be developed under strict principles of transparency. For example, all persons involved in creating new measures should, at minimum, be required to state potential conflicts of interest.

Researchers and Policy Makers Should Use a Cautious Evaluative Approach to Long-Term Development of Compensation Systems that Reward Quality

After developing evidence-based measures of physician, health-care institution, and population-level quality, policy makers should implement carefully planned, small-scale pilot programs that reward physician and health-care institution quality. Benefits and adverse effects should be monitored. Those entities implementing innovations in payment and quality improvement should take the lead in funding these studies.

Even with results from well-designed studies, judgments about the ethics of pay-for-performance will remain challenging. One approach might be to give preferential consideration to outcomes among vulnerable patients.

We base our suggestion to begin with pilot programs upon an ethical principle of precaution. However, efforts should be scaled up if benefits prove sufficient, health disparities are reduced and adverse outcomes are minimized.

THE ROLE OF SGIM

In order to aid in the above processes, SGIM is committed to having general internists participate in articulating the quality-related obligations that physicians and health-care institutions have to patients and the population. SGIM encourages its members to take the following actions: (1) help develop measures of physician, health-care institution, and population-level health-care quality, (2) evaluate pay-for-performance measures and programs, and (3) participate in the ongoing monitoring of effects of pay-for-performance on vulnerable populations and physicians. SGIM will continue to develop collaborative alliances with other key national organizations to ensure fair, valid, and comprehensive measures and to promote ethical compensation reform.

CONCLUSIONS

Performance-based physician compensation, if carefully guided by a comprehensive understanding of health-care quality and evidence-based evaluations, might improve patient care, narrow health disparities, and promote fair physician compensation while increasing health-care value. If research and monitoring determine that improved payment systems can benefit patients, physicians, and payers while minimizing risks, they could be ethical arrangements. However, until such data are available, widespread expansion of untested pay-for-performance systems poses substantive ethical issues associated with potential harm to patients, clinicians, and organizations.

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REFERENCES
1. Rosenthal MB, Landon BE, Normand SL, Frank RG, Epstein AM. Pay for performance in commercial HMOs. N Engl J Med. 2006; 355:1895–1902.
2. Rosenthal MB, Frank RG. What is the empirical basis for paying for quality in health care? Med Care Res Rev. 2006; 63:155–157.
3. Petersen LA, Woodard LD, Urech T, Daw C, Sookanan S. Does pay-for-performance improve the quality of health care? Ann Intern Med. 2006; 145:265–272.
4. Amundson G, Solberg LI, Reed M, Martini EM, Carlson R. Paying for quality improvement: compliance with tobacco cessation guidelines. Jt Comm J Qual Saf. 2003; 292: 59-65.

5. Fairbrother G, Hanson KL, Friedman S, Butts GC. The impact of physician bonuses, enhanced fees, and feedback on childhood immunization coverage rates. Am J Public Health. 1999; 892: 171-175.

6. Koudes RW, Bennett NM, Lewis B, Cappuccio JD, Barker WH, LaForce FM. Performance-based physician reimbursement and influenza immunization rates in the elderly. The Primary-Care Physicians of Monroe County. Am J Prev Med. 1998; 142: 89-95.

7. Roski J, Jeddeloh R, An L, et al. The impact of financial incentives and a patient registry on preventive care quality: increasing provider adherence to evidence-based smoking cessation practice guidelines. Prev Med. 2003; 363: 291-299.

8. Wharam JP, Farber NJ, Paasche-Orlow MR, Sinsky C, Rask KJ, Rucker L, Figaro MK, Braddock C, Barry M, Sulmasy D. Can Pay-for-Performance be Ethical? An Analysis by the Society of General Internal Medicine Ethics Committee. Available at: http://www.sgim.org/index.cfm?pageid=806.

9. Epstein AM, Lee TH, Hamel MB. Paying physicians for high-quality care. N Engl J Med. 2004; 3504: 406-410.

10. Blumenthal D. The vital role of professionalism in health care reform. Health Aff (Millwood). 1994; 131: 252-256.

11. Swick HM. Toward a normative definition of medical professionalism. Acad Med. 2000; 756: 612-616.

12. Wynia MK, Latham SR, Kao AC, Berg JW, Emanuel LL. Medical professionalism in society. N Engl J Med. 1999; 34121: 1612-1616.

13. Beauchamp TL, Childress JF. Principles of biomedical ethics. 5th ed. New York, NY: Oxford University Press; 2001.

14. Davis K, Schoenbaum SC, Audet AM. A 2020 vision of patient-centered primary care. J Gen Intern Med. 2005; 2010: 953-957.

15. Povar GJ, Blumen H, Daniel J, et al. Ethics in practice: manager and the changing health care environment: medicine as a profession managed care ethics working group statement. Ann Intern Med. 2004; 141: 131-136.

16. Wharam JP, Paasche-Orlow MK, Farber NJ, Sinsky C, Rucker L, Rask KJ, Figaro MK, Braddock C, Barry M, Sulmasy DP. High Quality Care and Ethical Pay-for-Performance: A Position Statement of the Society of General Internal Medicine. Available at: http://www.sgim.org/index.cfm?section=site&pageId=806. Accessed December 10, 2008.

17. Wharam JP, Daniels N. Toward evidence-based policy making and standardized assessment of health policy reform. Jama. 2007; 2986: 667-679.

18. Committee on Quality of Health Care in America IoM. Crossing the Quality Chasm: A New Health System for the 21st Century. Available at: http://www.qualitychasm.com. Accessed November 24, 2008.

19. Lohr KN, Donaldson MS, Harris-Wehling J. General internists’ views on pay-for-performance and public reporting of quality scores: a national survey. Health Aff (Millwood). 2007; 262: 492-499.

20. Casalino LP, Elster A, Eisenberg A, Lewis E, Montgomery J, Ramos D. Will pay-for-performance affect health care disparities? Health Aff (Millwood). 2007; 263: w405-414.

21. Fisher ES. Paying for performance–risks and recommendations. N Engl J Med. 2006; 35518: 1845-1847.

22. Hayward RA. All-or-nothing treatment targets make bad performance measures. Am J Manag Care. 2007; 133: 126-128.

23. Hayward RA. Performance measurement in search of a path. N Engl J Med. 2007; 3569: 951-953.

24. Wodchis WP, Ross JS, Detsky AS. Is P4P really FFS? Jama. 2007; 29815: 1797-1799.

25. Wachter RM, Shojanagi KG. The unintended consequences of measuring quality on the quality of medical care. N Engl J Med. 2000; 3427: 520.

26. Volandes AE, Paasche-Orlow MK. Health literacy, health inequality and a just healthcare system. Am J Bioeth. 2007; 711: 5-10.

27. Lo B, Gromman M. Oversight of quality improvement: focusing on benefits and risks. Arch Intern Med. 2003; 16312: 1418-1486.

28. Bellin E, Dubler NN. The quality improvement research divide and the need for external oversight. Am J Public Health. 2001; 919: 1512-1517.

29. Casarett D, Karlstevich JH, Sugarman J. Determining when quality improvement initiatives should be considered research: proposed criteria and potential implications. Jama. 2000; 2837: 2275-2280.

30. Kofke WA, Rie MA. Research ethics and law of healthcare system quality improvement: the conflict of cost containment and quality. Crit Care Med. 2003; 313 Suppl: S143-152.

31. Frommelt TP. Why would we need an ethical oversight of quality improvement projects. Int J Qual Health Care. 2004; 165: 343-344.

32. Nerenz DR, Stoltz PK, Jordan J. Quality improvement and the need for IRB review. Qual Manag Health Care. 2003; 123: 159-170.

33. Lynn J, Baily MA, Bottrell M, et al. The ethics of using quality improvement methods in health care. Ann Intern Med. 2007; 14699: 647-673.

34. Strasberg SM, Ludbrook PA. Who oversees innovative practice? Is there a structure that meets the monitoring needs of new techniques? J Am Coll Surg. 2003; 1966: 938-948.

35. Marron JM, Siegler M. Ethical issues in innovative colorectal surgery. Dis Colon Rectum. 2005; 486: 1109-1113.

36. Bunker JP, Hinkley D, McDermott WV. Surgical innovation and its evaluation. Science. 1978; 2004344: 937-941.

37. Cronin DC 2nd, Mills JM, Siegler M. Transplantation of liver grafts from living donors into adults–too much, too soon. N Engl J Med. 2001; 34241: 1633-1637.

38. Reitman AM, Moreno JD. Ethical regulations for innovative surgery: the last frontier? J Am Coll Surg. 2002; 1946: 792-801.

39. Reitman AM, Moreno JD. Ethics of innovative surgery: US surgeons’ definitions, knowledge, and attitudes. Jama. 2005; 2001: 103-110.

40. Margo CE. When is surgery research? Towards an operational definition of human research. J Med Ethics. 2001; 271: 40-43.

41. Amoroso PJ, Maddiugh JP. Research vs. public health practice: when does a study require IRB review? Prev Med. 2003; 362: 250-253.

42. Wharam et al.: Quality Care and Ethical Pay-for-Performance