

HEALTH CARE

QUALITY IMPROVEMENT:

ETHICAL AND

REGULATORY ISSUES



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Health Care Organization Responsibility for Quality Improvement

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Do health-care organizations (HCOs) have a responsibility to improve the quality of the care they provide? This question is particularly pertinent today because of the dynamic changes caused by alterations in the system of reimbursement, medical practice patterns, the introduction of new technologies, and health-professional shortages. This chapter answers the question affirmatively, arguing that a consideration of the nature of health care, the role of HCOs in its delivery, and social and economic conditions of contemporary health-care delivery provide a firm foundation for concluding that improving patient-care quality is a fundamental responsibility of the HCO. This argument does not imply that the HCO is uniquely responsible. However, fully integrating—and perhaps reconciling—the HCO responsibility for quality improvement (QI) with the responsibility of others, e.g., health professionals, is beyond the scope of this discussion.

The Role of the Organization in the Delivery of Health Care

The term *health-care organization* applies to a wide range of organizations, including hospitals, provider organizations such as Preferred Provider Organizations (PPOs) and Health Maintenance Organizations (HMOs), physician group practices, visiting-nurse associations, nursing homes, and home-care agencies, as well as organizations that support the infrastructure wherein health care is delivered, e.g., claims processors. Addressing such a heterogeneous group of organizations complicates our question but does not invalidate it. Although HCOs have a variety of different organizational structures, operational processes, business models, and agendas, they share a family of normative commitments that ethically differentiate them from other social entities. In a similar way, although improving quality can serve a variety of purposes, such as increasing efficiency, reducing costs, or increasing market share, there are distinctively ethical reasons for improving the quality of care. These reasons derive from the pivotal, but often underappreciated, role that HCOs play in the delivery of health care.

While it is true that individual health-care professionals provide health care, it is a profound mistake to think that HCOs do not. Consider the delivery of surgical services. Contemporary surgery is inconceivable without anesthesia, intraoperative monitoring, post-surgery anesthesia recovery, the availability of appropriate operating facilities, sterilized spe-

cialized instruments and devices, immediate postoperative care, and recovery support, including rehabilitation. Although many individual health professionals provide these services, they are provided *in a coordinated fashion* that delivers more than the sum of the parts.

Surgical care is thus best understood not as a performance by virtuoso individuals, but as the product of the complex efforts of a surgical team. Just as there are team sports and individual sports, surgical care—and much of contemporary health care—is best thought of as a team rather than an individual sport. To press the sports analogy further, a group of talented players does not automatically make a successful team, as the performance of the U.S. basketball team in the 2004 Summer Olympics showed. The players must *play well together*. They have to perform *as a team*. They have to pursue a *team* goal, not just individual goals. Because contemporary health care involves the delivery of services that are produced by groups of individuals acting cooperatively and in a highly coordinated fashion, contemporary health care is a *social* enterprise.

For this reason, the HCO is a central player in the development and delivery of contemporary health care. Although improving health care can involve something as straightforward as improving the design of an instrument used in a particular procedure, even such improvements must be integrated within the operational environment. For example, a medical instrument must not only perform the specific task for which it was designed, it must be fabricated from a material that will not harm the patient, and it must be tested and approved for use. In addition, it must be available and ready for use when needed. A cascade of actions and adaptations by multiple individuals is entailed in the introduction of a new instrument. These actions are social in nature. Because coordination of services is integral to contemporary health care, it is natural to regard HCOs as agents or entities that have responsibility for improving the quality of care. Contemporary scientific health care is a *social* action that embodies a commitment to the ideal of a progressive improvement.

HCOs and Medical Ethics

Ethical analyses of health care have customarily focused on health-care professionals rather than organizations. Indeed, organizations, particularly Managed Care Organizations (MCOs), have been mainly regarded as agents obstructing the delivery of ethical health care, and they have been roundly criticized, for example, for providing financial incentives for reducing care, creating conflicts of interest for physicians, and breaking down the traditional trust in physician-patient relationships.¹ Relatively little attention has been given to the positive ethic of the HCO. In fact, organizational ethics is a relatively new field of interest that is only beginning to define the ethical responsibilities of the HCO.²

The continuing dominance of the traditional physician-patient relationship in the health-care ethics discussion continues to deflect attention not only from team-delivered care, nursing, and allied health-professional relationships with patients, but from the HCO as well. The driving ideal of contemporary scientific medicine, however, is inherently collaborative and progressivist. The production and delivery of contemporary care are driven by the hope that discoveries will improve patient care.³ The HCO provides and coordinates the capital, fiscal,

human, and information resources essential for this style of health care. For these reasons, HCOs are structurally and functionally central in contemporary health care, and they are the natural focus of responsibility for improving the quality of care.⁴

Responsibility of Organizations

Talk of HCO responsibility for improving the quality of health care might sound odd to the ears of those who are skeptical that organizations, much less HCOs, are the sorts of entities that can bear responsibility. At least since the work of Max Weber,⁵ a common view of formal or bureaucratic organizations is that they create a structure that stifles moral accountability.⁶ The alternative view that formal organizations are bearers of ethical responsibility is a distinctively recent development. It can be traced to work on the nature of accountability of corporate businesses in the 1970s and 1980s that argued that corporate moral responsibility is a valid concept.⁷ In the view of Peter French, agency is required for the attribution of responsibility. An organization has agency if it has an internal structure that organizes knowledge and the motivations of the individuals who constitute it.⁸ More recently, critics have focused on the way in which French derived metaphysical propositions about the nature of organizations from semantic propositions concerning the way we talk about organizations. While there is an extensive literature on the nature of agency that organizations manifest and the meaning and foundation of organizational responsibility,⁹ there is general agreement that the concept of organizational responsibility is meaningful. Many thinkers now simply accept that a distinctive responsibility devolves on organizations.¹⁰ Because the practice of attributing responsibility to an organization is reasonable,¹¹ we can accept that it is semantically sound to say that organizations can bear responsibility. This conclusion, however, does not directly answer a further set of questions that naturally arise, namely, Does HCO responsibility include improving the quality of care? If it does, what definition of quality should guide the HCO commitment to QI? or What is the relationship between HCO responsibility for improving the quality of care and other important organizational goals?

HCO Responsibility for QI

Because of their function in providing health care, HCOs have responsibility for QI. Contemporary health care is inherently unstable and dynamic. It functions on the cusp of change, driven as much by normative commitments to improving the quality of patient care and extending its effectiveness in the treatment of disease as by well-recognized financial, regulatory, scientific, social, and technical factors. Therefore, QI embodies the normative commitment at the heart of contemporary health care—a commitment to improve the well-being of patients, not just to increase scientific knowledge. This practical, normative commitment is essential to contemporary scientifically based health care. HCOs are the primary institutional agents that carry out this social ideal. Because the HCO is the essential agent in the progressivist enterprise of contemporary health care, QI is one of its essential responsibilities.

Even if improving the quality of care were viewed as an activity best carried out by health professionals, the management of QI would involve social processes that logically belong to

the organization. Providing the accepted standard of care may have been a justified ethical expectation for an individual physician in the conservative atmosphere of traditional medical practice or in the context of malpractice litigation, but it is an utterly inadequate norm for contemporary medicine that aims at the progressive improvement in care. It is especially important that this normative commitment provide a signpost in the dynamic environment of fiscal, regulatory, scientific, and technological change that dominates contemporary health care. A normative framework that links the commitment to the progressive improvement in the quality of patient care and the social nature of health care is needed. In this context, it is thus natural to look to the HCO, rather than the individual physician, as the primary locus for improving the quality of care.

A Definition of Quality

Grant E. Steffen has pointed out that *quality* has two different meanings: first, in a metaphysical sense, quality is identical with the properties of an object and does not imply preference or value; second, in a preferential sense, quality is identical with the capacity of the properties to achieve a specific goal.¹² Contemporary health care involves the pursuit of quality in both senses. The metaphysical sense underlies the idea of contemporary scientific medicine committed to the progressive application of technical and scientific knowledge to improve patient care. Commitment to the preferential sense of quality is implied, but in an unspecified way—Avedis Donabedian has insisted that “quality is a property that medical care can have in varying degrees.”¹³

Claiming that QI is an essential feature of contemporary scientific medicine does not imply that there is agreement regarding the definition of *quality* worthy of pursuit or the specific types of activities that constitute improvements in care. Our claim is simply that improving quality is built into the idea of medicine as a progressive enterprise founded on the application of scientific and technical knowledge. That this commitment is linked directly with the HCO, because contemporary health care is delivered in complex institutional and organizational settings. However, concluding that improving quality is a responsibility of the HCO is important, but it does not take us very far. We need to inquire how this responsibility can be discharged and what conditions complicate its enactment. These questions are important, because improving quality is but one of a complex range of responsibilities that fall to HCOs. Some prioritization of the responsibility for QI must be made among the many HCO responsibilities, and this responsibility must be assigned and evaluated within the HCO leadership.

It is important to put the question of HCO responsibility for QI in a positive light, because it is not primarily about calling HCOs to account for failing to achieve quality measures; rather, it is about the positive responsibility for improving the quality of care. Viewed in this way, quality of care is a normative ideal that is fixed only to the extent that the idea of quality involves distinctive normative elements that define the domains that contribute to the definition of ideal quality. The implication is that the term “quality improvement” admits a range of definitions in actual use which are dependent upon a variety of operational and value judgments made by HCOs. Even a cursory review of the literature on quality of care and QI shows that these concepts are plastic and depend on a shifting constellation of factors and values.¹⁴ Their definition relies on context-specific commitments that reflect interests and concerns that

vary over time and across practice and institutional settings. In defining the HCO responsibility for QI, we thus need to avoid platitudinous recommendations. Instead, it is important to identify the structural and procedural features that *in general* define that responsibility.

Toulmin's Negative Assessment

Stephen Toulmin provides an important but negative assessment of the health-care institution in the context of responsibility.¹⁵ Toulmin took the hospital as the paradigm HCO, arguing that a variety of forces have historically transformed it into an organization that tyrannically limits professional authority and discretion. Instead of encouraging professional judgment and moral commitment, which Toulmin regards as central ethical values in health care, HCOs are motivated to articulate rules to constrain professional action and discretion in deference to cost control and promotion of their economic agenda as businesses.

Toulmin articulated a Weberian view of the HCO as a bureaucratic entity that ultimately stifles individual health-professional responsibility. The upshot is that the activities of physicians and other health-care workers are demoralized, because the sphere of moral and personal commitment is inevitably corroded as it is placed under the control of bureaucratic structures and organization rules that are driven by market concerns. Stressing professional integrity as an important ethical value that is threatened by the bureaucratic (and profit-maximizing) functioning of health-care institutions, Toulmin laments that the responsibility of physicians in these organizations has been transmuted into delivering “the best medical goods that collectivity of medicine has yet devised.”¹⁶ In his view, this objective, which seems remarkably consonant with many of the objectives of QI, causes the physician to lose independent moral autonomy and professional authority. As a result, the traditional commitment to the well-being of the individual patient is sacrificed on the altar of business expediency; the physician becomes “more like a sales rep” for a large corporation than a true professional exercising independence of judgment.¹⁷

This assessment represents an important challenge to thinking that HCOs should be responsible for QI. Even under a more favorable view of HCOs, the inevitable potential for conflicts between organizational and professional concepts of quality of care and among the competing definitions of quality reflecting competing goals and interests, especially within complex organizations, needs to be considered. Even if these concerns are overblown, they suggest a critical question, namely, What normative ideals should constrain the pursuit of quality, and what degrees of control over these processes should rest with the HCO managers and health professionals?¹⁸

Normative Constraints

There are three main areas of substantive concern in the HCO responsibility for QI: respect for professional integrity, respect for patients, and respect for workers.¹⁹ As with all responsibilities, using these normative guides will require judgment.

Respect for Professional Integrity

Respecting professional integrity in QI involves the following elements:

- Respect for legitimate exercise of professional judgment and discretion;
- Support for interprofessional communication and respect; and
- Shared leadership.

Toulmin's concern that HCO decisions in pursuit of QI will efface or override professional discretion, especially when decisions are taken for economic reasons, is widely shared, as the literature on managed care and futility attests.²⁰ One way to avoid this problem would be to involve health professionals in the management and administration of the HCO, especially in the processes of QI.

Involving health professionals and allowing for professional judgment is a critical requirement for HCOs in carrying out QI initiatives. When health professionals are regarded as mere employees, they are likely to be given marching orders and forced to follow rules that constrain their professional judgment. This can be avoided by insisting that HCOs include health professionals in QI initiatives. Here, the issue is less one of control than one of leadership and the kind of judgment that should guide the QI process. Managers have a responsibility to focus on the fact that their business is health care; the concern for quality of care should be the prime driver of QI efforts.

Health professionals are trained to focus on the immediate clinical needs of individual patients. That focus can lead them to overlook the relation of their work to ultimate outcomes or to the organization as a whole. This tendency is compounded when HCO leadership fails to positively define a wide concept for the professional's QI responsibility. HCO leadership must articulate a clear expectation that health professionals will undertake and support improving patient care beyond their immediate professional concerns. We do not assume that health professionals are disinclined to participate in QI or that they lack a responsibility to do so, but establishing the conditions for health-professional involvement in QI is a responsibility of HCO leadership, which includes the leadership of the medical staff. Including *participation* in QI in performance evaluations could create positive incentives for health professionals to be so engaged. It does so, perhaps even more effectively than rewarding the achievement of quality *per se*, given the potential perverse incentives in so-called "pay-for-quality" schemes, e.g., the incentive to avoid caring for patients who are likely to have bad outcomes.²¹

Respect for Patients

The HCO responsibility to respect patients is an important ethical constraint on QI. This responsibility includes

- Respect for patient values and rights, such as informed consent, confidentiality, and privacy;
- Incorporation of patient values and preferences in the assessment of quality; and
- Transparency of process consistent with the organizational mission and structure of the HCO.

A corollary of the previous section is that the responsibility for preserving professional integrity is itself bound up with the value of promoting and pursuing patient welfare. Respecting patients is a separate normative consideration in QI even if one argues that the pursuit of patient welfare is primarily assured by maintaining professional integrity. HCOs cannot delegate the duty to respect patients to direct-care providers and allow organizational operations to function on the basis of cost containment or to be driven by other business values. Respecting patients is such a core value in health care that the HCO must itself assume this responsibility. The HCO must similarly accept this as a normative constraint in QI. It is well established that whenever health-care professionals fail to maintain or pursue patient welfare, HCOs can be assigned independent responsibility to assure patient welfare. Cases such as *Darling v. Charleston Hospital*²² have shown that both health-care organizations and individual health-care professionals have legal accountability for actions that harm patients.²³ In addition to responsibility in the negative sense of *liability*, organizational responsibility for QI has the important positive aspect that it is a component of the overall organizational ethic. Respect for patients is a key feature of this ethic and should be part of the organization's mission that guides its operational practices.

In QI, respect for patients has to involve more than respecting the universally acknowledged rights of patients, such as confidentiality, informed consent, and privacy. It must also include the responsibility to actively identify and accommodate patient assessments of designed changes in care. Ideally, improving patient care should involve achieving outcome objectives that are broadly in agreement with patients' values; but since this is an empirical issue, HCOs have a responsibility to incorporate patient values and preferences into QI.

Respect for Workers

Given the complexity of contemporary health care, even workers who are not, strictly speaking, health professionals have a stake and a role in QI. This role is often overlooked in discussions of the ethics of HCOs and QI, but it is an essential concern for responsible managers. Respect for workers in QI includes at least the following:

- Participation and buy-in of employees;
- Open and honest communication and trust; and
- Fair share in the benefits and burdens of process improvements.

Contemporary health care would not be possible without the services of multiple support personnel. These workers have an important but often overlooked role to play in improving quality of care. Resources and services must be available in the settings where need has been identified. Because hospitalized patients are increasingly transported to various departments for services, a complex transportation and distribution system that involves multiple non-health-professional workers is essential in contemporary HCOs. Effective QI within an HCO will thus impact operations, and some changes will most directly affect support personnel. Attention to the impact of these changes should be a key managerial concern. Failure to address them effectively will limit the organization's ability to carry out QI, particularly improvements that require coordination beyond the unit level.

Many health professionals occupy dual roles in HCOs. They are both health professionals and employees of the organization. In many instances, protection of professional integrity will assure protection of worker rights, but this is not always the case. Other health-care workers who are not health professionals are less well paid and more vulnerable, because they fill jobs that have low entry requirements, and they are thus more easily replaced. Custodial services, transport, materials-handling, clerical and secretarial support, data entry, food service, and so on are essential to the operation of HCOs, yet these functions are provided by the most vulnerable workers. Improving quality of patient services should ideally be conducted in ways that protect the rights and welfare of workers, not only those who provide direct patient care, but those who provide support services as well. Some improvements in patient-care quality entail alteration in scheduling or duties. These changes can cause worker dissatisfaction, contributing to overall decreases in productivity and morale that can have adverse effects on patient care. Even positive change that improves the quality of care is not necessarily less stressful or disruptive for workers than changes caused by economic exigencies. Keeping workers aware of and committed to the HCO mission and maintaining their commitment to QI within the framework of the mission is an important responsibility of HCO leadership. Educating health-care workers about the contribution that they can make to the overall mission of the institution and the connection between their functions and patient outcomes is critical for maintaining worker morale and commitment.

Pursuing Quality

How might these considerations be incorporated by HCOs in pursuing QI? First, the decisionmaking process for QI should be institutionalized in such a way that there is open participation. QI should include not only health professionals, but workers and patients as well. Accepting and adapting to the changes that result from QI require trust and transparency of process. The values and goals that drive the process should be clear to patients, workers, and health professionals. The HCO needs to accept the fact that health-care workers, health professionals, and patients are all stakeholders and that their involvement in QI should have institutional support.²⁴ Support involves providing resources, release time, and appropriate recognition in annual performance evaluations. As a managerial responsibility,²⁵ QI cannot be responsibly managed from the top down; rather, the commitment to quality needs to be part of all structures within the HCO culture, and it should permeate administration and support services as well as patient care. In this regard, HCO management has the overall responsibility to provide leadership in the commitment to quality and QI. Clearly, administrative styles and processes associated with QI will vary from one HCO to another, depending, in part, on institutional mission and culture. Despite the variety of ways that QI might be institutionalized, a common expectation for HCO leadership in QI is that it match actions and decisions to words. Fairness and openness of process are critical for the success of QI.

Although some QI involves small-scale, noncontroversial projects that are evolutionary solutions to unit-level operational difficulties, other improvements, such as implementing consensus guidelines for managing complex clinical problems, can have a revolutionary impact on

an organization. Such change can be achieved best in organizations in which the leadership exhibits high levels of trust, openness, and integrity.²⁶ The commitment to QI needs to be articulated and supported by the governing board of the institution and incorporated into the evaluation of personnel at all levels. Even when QI is not conducted as a delegated responsibility, such as within a defined department in the organization, e.g., a QI officer or office, a fully responsible leadership will accept accountability for improving quality and will carry this message throughout the organization. At all levels, QI has to be seen as *our* responsibility rather than *their* responsibility. From a management perspective, the quest for quality must be seen as a fundamental organizational goal accepted at the highest levels and institutionalized in ways that positively shape the daily operations of the organization.

These conclusions are consistent with the recommendations of the Institute of Medicine in *Crossing the Quality Chasm: A New Health System for the 21st Century*.²⁷ Ten rules are offered in this report:

1. Care based on continuous healing relationships.
2. Customization based on patient needs and values.
3. Patient is source of control.
4. Shared knowledge and the free flow of information.
5. Evidence-based decisionmaking.
6. Safety as assisted property.
7. The need for transparency.
8. Anticipation of needs.
9. Continuous decrease of waste.
10. Cooperation among clinicians.

These ten rules might be viewed as defining two thematic domains. The first theme includes the elements of relationship, knowledge and information, and patient welfare; the second includes the concerns of patient values and preferences, health-care-professional integrity, and worker rights. Rules 2, 3, and 7 clearly place the patient at the center of health-care delivery and at the center of efforts for improving quality of care. Permeating both thematic domains is a concern that services be provided effectively and efficiently. Rule 9 is best read as saying not simply that waste should be avoided for the financial benefit of the HCO, but that there is a positive and continuous responsibility to decrease waste of all sorts of resources, not only financial resources but even patients' time. This commitment is important, because one worry about organizational commitment to QI is that the underlying motive for management in pursuing QI is simply to reduce cost and increase efficiency without regard for preserving the integrity of the professional relationship, the well-being of employees, or the rights and welfare of patients, families, and communities. This criticism, however, needs to face up to the legitimate responsibility for managing resources that rightly falls to HCOs.²⁸ In acknowledging this responsibility, the Institute of Medicine re-balances the scale on which the pursuit of quality in health care will be weighed. The Institute of Medicine Report is an important document that comes to terms with both the complexities of QI in health care and the complex nature of pursuing quality in the contemporary environment.

Conclusion

This chapter has argued that improving quality of care is an important responsibility that falls to the HCO because of its historically distinctive place in the delivery of health care. Because complex contemporary health care often must be delivered in and through health-care institutions, the HCO is properly regarded as having responsibility for the quality of care. The concepts of quality of care and QI, however, are not fixed or static; rather, they reflect purposes and values that are, in part, context-dependent. It is thus to be expected that HCOs will pursue quality in a variety of ways. The differences are justified if they reflect differences in mission, community setting, resource base, and place in the health-care system, but they are not justified if they reflect managerial lack of interest or commitment. The HCO has affirmative responsibilities for quality, and management should be held accountable for the overall quality of the HCO. Worries like that of Toulmin that HCOs can structure health care in ways that erode professional values can be somewhat allayed by insisting that the commitment to quality of care and QI is not optional for HCOs; it is an essential responsibility not only for health professionals, but also for management. Health professionals and the institutions within which they practice should be partners. HCO leaders should seek out and join other stakeholders—patients, families, and the community at large—in the pursuit of quality and should work cooperatively with those regulatory agencies that oversee and measure patient care.

Our discussion of HCO responsibility for QI has focused on what might be termed the *internal responsibility of HCOs for QI*. We have not addressed the responsibility of HCOs in a competitive environment to avoid the diminution in the overall quality of care provided to communities as competitors are driven from markets, creating gaps in service and coverage. Such organizational-ethics issues are beyond the scope of this essay, but the corrosive effects that HCO decisions in competitive markets can have on the overall quality of care within a community need further analysis.

Acknowledgments

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Notes

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3. The view that scientific research and knowledge should have practical benefits for society is hardly new. It can be found as early as the 16th century in the work of Francis Bacon (F. Bacon, *Novum Organum*, 1620, in Peter Urbach and John Gibson, eds. (Peru, IL: Open Court Publishing Company, 1994)). The granting of licensure to physicians, beginning in the late 19th century, was based on medicine’s claim or commitment to the application of scientific methods and knowledge in the traditional physician-patient relationship. By the late 20th century, however, this commitment had evolved into a complex system of care featuring multiple, interdependent, and technology-mediated social relationships. The traditional solo-practice-based, dyadic physician-patient relationship was effectively replaced by group practices and team- and institution-based systems of care. Thus, HCOs emerged as the social structures within which health care is produced and delivered.

4. Although I have argued for the key role of HCOs in health-care delivery, one might object, citing the fact that scheduling, staffing, custodial services, maintenance, utilities, and continuing education are variably distributed across HCOs. Although it is clear that the management of these supportive services is essential to the provision of everyday health-care services, these services are not health care properly regarded. Just as the tailor, grocer, and buggy maker who helped clothe, feed, and transport the solo practitioner so idealized in traditional medical ethics cannot be said to be agents in the provision of health care, so, too, the objection goes, HCOs at most create and sustain the environment within which health care is produced, but individual health-care professionals provide that care. To say otherwise would involve a category mistake, confusing the actual delivery of health care, which essentially involves interpersonal relationships, with its supportive social structures.

This criticism must be taken seriously. It is true that health professionals are involved at all stages of patient care, but insofar as this care is technologically mediated and cooperatively delivered, it is a mistake to see the individual health professionals involved as the prime agents by which health care is delivered. Even if they were, they often function collaboratively to such a degree that the care in question is actually delivered by the collective and not by the individual agents.

A sports analogy might help to make this point. Although it is true that not all players score in team sports, it is a mistake to say that only the players who score win games. The team wins because the nature of the team sport requires their

collective action. Without collective action, there would be no football or baseball game. Similarly, without technology, training, and supplies, health care could not be delivered in its present form. A physician does not compound his own medications; he relies not only on pharmaceutical manufacturers, but also on distributors. More remotely, the physician relies on basic and clinical researchers to develop the medications and to test them and the subjects who participate in the clinical trials. Clearly, contemporary health care is a social, or collective, product.

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18. One can accept Toulmin's concern over the erosion of professional integrity and discretion caused by the intrusion of bureaucratic decisionmaking without agreeing that responsibility cannot be readily attributed to HCOs. Whether HCOs can be properly said to be moral agents is a separate issue that we have already pointed out is not addressed in this analysis. It is sufficient for present purposes to accept that HCOs as such produce and deliver health care. If they do, then it is sensible to speak of HCO responsibility for QI irrespective of whether or not this responsibility is moral in the strict sense.

19. These concerns derive broadly from stakeholder theory. Although a justification of these concerns is beyond the scope of the present discussion, recognition of the practical and ethical importance of stakeholder considerations in HCO and QI is growing (T.C. Beierle, "The Quality of Stakeholder-Based Decisions," *Risk Analysis* 22(4) (2002): 739–49; A.R. Benedetto, "Six Sigma: Not for the Faint of Heart," *Radiology Management* 25(2) (2003): 40–53; F. Crockett, "Revitalizing Executive Information Systems," *Sloan Management Review* 33(4) (1992): 39–47; E.J. Emanuel, "Choice and Representation in Health Care," *Medical Care Research Review* 56 Suppl 1 (1999): 113–40; J.S. Hagen, "Value Management: Decision Making Using the Value Paradigm," *Medical Group Management Journal* 43(6) (1996): 52–57, 76; P. Illingworth, "A Role for Stakeholder Ethics in Meeting the Ethical Challenges Posed by Managed-Care Organizations," *HEC Forum* 11(4) (1999): 306–22; K.R. Jones, R.W. Redman, T.M. VandenBosch, C. Holdwick, and F. Wolgin, "Evaluation of the Multifunctional Worker Role:

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21. This point was made to the author by an anonymous reviewer.

22. Supreme Court of Illinois, *Darling v. Charleston Community Memorial Hospital*, 33 Ill.2d 326, 211 N.E.2d 253 (1965).

23. Laws that protect HMOs from lawsuits for patient harms attributable to denial of noncovered services notwithstanding.

24. P.H. Werhane, "Business Ethics, Stakeholder Theory, and the Ethics of Healthcare Organizations," *Cambridge Quarterly of Healthcare Ethics* 9 (2000): 169–181.

25. This does not mean that the responsibility for QI belongs solely to management. However, exploration of the relationship of HCO responsibilities for QI and, for example, physicians is beyond the scope of this chapter.

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