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How Can Medical Training and Informed Consent Be Reconciled with Volume-Outcome Data?

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Data from hundreds of studies indicate that, for a broad range of procedures, treatment by inexperienced physicians is associated with worse medical outcomes.[1] Because inexperienced physicians often work in low-volume institutions, previous studies did not indicate whether the worse outcomes were a function of the institutions, the clinicians, or some combination of both. More recent data, which separately analyze the impact of inexperienced physicians and low-volume institutions, provide compelling evidence that inexperienced physicians pose increased risks, independent of the institutions in which they happen to practice.[2] One study found that "performance of primary angioplasty by a physician who performed > 10 procedures annually resulted in a savings of 33 lives per 1000 patients treated," a dramatic benefit in regduced mortality that "persisted after risk adjustment."[3] Another study identified "an inverse association between the increasing number of palate repairs undertaken by a surgeon and poor speech outcome."[4]

The impact of physicians' experience on medical outcomes is so great in some cases that inexperienced physicians represent an important risk factor compared to receiving care from an experienced physician. Indeed, some commentators argue that the experience level of the physician is sufficiently important that it should be disclosed to patients.[5] This approach has been adopted in several states, including New York, California, and New Jersey, which now publish medical outcomes by physician for Coronary Artery Bypass Graft (CABG) surgery.[6]

Volume-outcome data also has led numerous commentators to encourage patients to avoid inexperienced physicians: "patients could significantly increase their chances of survival by selecting surgeons who perform the operations [cardiovascular procedures and cancer resections] frequently, regardless of the number of such operations performed at their hospitals."[7] The same editorial argues, "the sum of evidence should compel purchasers and health plans to adopt a default position of selective avoidance of very-low-volume providers."[8] The Leap Frog Group, a coalition of purchasers of over $60 billion of health insurance annually, encourages patients to avoid low-volume surgeons.[9] Recommendations that patients avoid inexperienced physicians have the potential to improve patient outcomes and decrease costs. These recommendations also have the potential to inadvertently disrupt medical training.

Numerous commentators, as well as American Medical Association policy, argue that medical trainees should disclose their level of experience to patients.[10] Patients who are informed that they are being treated by an inexperienced physician, and recognize that inexperienced physicians pose increased risks, may insist on an experienced physician, thereby precluding care by a trainee. Similarly, it is not hard to imagine that parents, once informed that surgery by an inexperienced physician is associated with significantly poorer speech outcomes in their children, will insist on an experienced surgeon. Indeed, widely held standards that parents should act in the best interests of their children would seem to require that they respond in this way. Recognizing these possibilities, it is vital to consider steps to ensure that new physicians can be trained in a context of increasing recommendations that patients avoid inexperienced physicians.

IS THE STATUS QUO TENABLE?

What are the policy options for reconciling medical training and informed consent with data that inexperienced physicians pose increased risks? First, one might hope simply that no policy changes will be necessary. Data collected to date focus on inexperienced physicians as a group; they do not show that medical trainees in particular pose increased risks to patients. Hence, current data might seem consistent with informing patients of trainees' experience level without suggesting that trainees pose increased risks to patients. This approach could be supplemented by information that trainees, unlike other inexperienced physicians, often are supervised by more experienced physicians, and typically are limited to relatively uncomplicated cases until their skills improve. These steps may be sufficient to reassure patients and, thereby, ensure the medical profession's long-term capacity to develop experienced physicians.

At the same time, there are reasons to be concerned about the long-term tenability of the status quo. Many recommendations to avoid inexperienced clinicians are aimed at purchasers of healthcare, not individual patients.[11] And these groups, especially for-profit purchasers of healthcare, may not be inclined to give trainees the benefit of the doubt. To save money, they may advise their patients to avoid all inexperienced physicians.

Patients also may not wait until complete evidence is in concerning the relevance of these data to trainees in particular. Would most parents, informed that inexperienced physicians in general have dramatically worse speech outcomes for cleft palate surgery in children, knowingly allow their child to be operated on by an inexperienced trainee? Or will those parents who have a choice insist on the best care possible for their children?[12] The intuition that many parents and adult patients will insist on experienced physicians is supported by a number of studies. One study found that approximately one-third of patients surveyed "did not want learning to take place on themselves by physicians-in-training."[13] Another found that "only a minority of patients would allow medical students to perform their first procedure on them" and "many patients prefer that medical students never perform a procedure on them."[14]

The prospect that many patients may avoid trainees does not preclude the possibility that other patients may continue to agree to be treated by trainees. And other patients, for instance, those at public clinics, may have few options. As a result, society may be able to continue to train physicians by relying on the good will of some patients and the constrained options of others. Yet the importance of ensuring a steady supply of trained physicians underscores the potential costs of simply hoping the status quo will hold, and failing to consider potential alternatives. Reliance on the good will of some patients and the constrained options of others to train new physicians also raises the potential for exploitation.

Exploitation occurs when some individuals receive an unfair level of benefits as the result of a given interaction. Whether the benefits that individuals receive are fair depends on the risks and burdens they bear as part of the interaction, and the extent to which others benefit from their participation in the interaction.[15] If I employ you in my factory and pay you a paltry wage relative to how hard you work and how much I profit from your efforts, I have provided you with an unfair level of benefits and, thereby, exploited you.

The status quo, which provides the benefit of trained physicians to all by relying on the efforts of some, involves a similar unfair balance of risks and benefits. This approach allows all patients to enjoy the benefits

of experienced physicians because a subset of patients agrees to be treated by trainees.[16] This potential for exploitation is especially worrisome, given that it likely falls disproportionately on certain groups.

Influential and highly educated patients are more likely to be aware of the correlation between experience and medical outcomes, and avoid trainees, leaving the burdens of training new physicians to the less educated and less well-connected. It is not hard to imagine, for example, that educated patients are more likely to access, understand, and act on a report entitled *The California Report on Coronary Artery Bypass Surgery: 1997-1998 Hospital Summary Data: Summary Report.* Even prior to publication of physicians' experience, the data reveal that less-educated patients are significantly less aware of the fact that training physicians requires that physicians-in-training learn their skills by practicing on patients.[17]

WHAT ABOUT INEXPERIENCED NON-TRAINEES?

Increasing promulgation of volume-outcome data also has the potential to result in patients avoiding inexperienced physicians who are not trainees, such as those working in rural areas. In these cases, only those who live in rural areas and are unwilling or unable to travel to urban centers may end up being treated by inexperienced physicians. This possibility ultimately may result in a situation in which some physicians are not able to treat sufficient numbers of patients to keep their skills current. Indeed, one study found that physicians who have been in practice for many years "may be at risk for providing lower-quality care."[18]

While this situation raises concern and deserves serious attention, it does not raise the same concerns of societal exploitation that arise in the case of medical trainees. Physicians working in rural areas benefit the individuals living there. In contrast, the system of training physicians benefits everyone in society, raising the potential for exploitation, if physicians receive their training by performing procedures on the poor and uneducated so that everyone in society can enjoy the benefits of experienced physicians. For this reason, we shall leave to the side the issue of inexperienced physicians in general, and focus on the question of how to reconcile physicians' training in particular with the volume-outcome data.

IS NON-DISCLOSURE ACCEPTABLE?

Disclosure and medical training may not be consistent, in the long term, with increasing data on the correlation between outcomes and experience. On these grounds, one might argue that it would be better to adopt a policy of non-disclosure. Medical training benefits everyone. Thus, it makes sense to argue that everyone should be willing to accept the possible risks associated with training physicians, by adopting regulations that either withhold information from patients on the experience level of their physicians, or preclude patients from choosing their own physician based on level of experience.

This solution might be defended on the grounds that everyone in society benefits from trained physicians; hence, everyone has an obligation to participate in the process of training them. While this looks, in theory, like the beginnings of a promising argument, in practice, in the U.S. at least, it seems a non-starter. Individuals in the U.S. tend to be very skeptical and resistant to programs that restrict their autonomy for the benefit of society in general. Continued accumulation of data on the correlation between experience and medical outcomes may pressure courts to support this approach by acknowledging that physicians' experience level is relevant to informed consent.

In the 1996 case of *Johnson v. Kokemoor*, the court wrote,

> While there may be a general risk of ten percent that a particular surgical procedure will result in paralysis or death, that risk may climb to forty percent when the procedure is performed by a relatively inexperienced surgeon. It defies logic to interpret this statute [of informed consent] as requiring that the first, almost meaningless statistic be divulged to a patient while the second, far more relevant statistic should not be.[19]

As more data are collected, more courts are likely to agree, and some may assume that data on inexperienced physicians applies to inexperienced trainees. Hence, non-disclosure may place medical trainees and their institutions in legal jeopardy. In March 1996, the Wisconsin Supreme Court upheld the jury verdict in *Johnson v. Kokemoor*, and the parties settled for $6.2 million in damages.[20]

Finally, a number of organizations are making concerted efforts to inform patients that less-experienced physicians pose increased risks for many procedures.[21] These efforts, in a context in which medical trainees do not disclose their lack of experience, may lead patients to question whether their physicians are being honest with them. Eventually, non-disclosure may undercut the public's trust in medical professionals.

ARE TRAINEES DIFFERENT THAN INEXPERIENCED PHYSICIANS?

Defenders of the status quo might point out that trainees are unlike other inexperienced physicians in several relevant respects, and these differences imply that trainees' involvement in patient care may not alter the risk-benefit ratio of some procedures. Most importantly, trainees typically are supervised by more-experienced physicians. Moreover, the intense nature of the training period sometimes provides trainees a good deal of experience in a short period of time. Senior residents at busy hospitals, with more experience placing central lines, may be more likely to succeed with the first insertion, and avoid the increased risks of repeated attempts.

In other cases, however, the process of learning by doing that is at the heart of medical training likely poses increased risks to patients. Medical trainees are likely to pose increased risk of pain and infection, despite careful supervision by a trained physician, the first time they attempt placement of a central line. One study found that first-year residents are significantly more likely to have unsuccessful outcomes for a range of procedures, including epidural anesthesia and tracheal intubation, despite careful supervision, including verbal comments and suggestions by an experienced physician.[22] Similarly, supervision of trainees' medication orders does not always occur in real time, leaving patients at increased risk of mistakes. And, in the often busy and confusing world of real-life medicine, supervision of trainees does not always take place as planned. Data from the United Kingdom suggest that "a fifth of all operations performed during weekday evenings and 7% during the day were done by apparently unsupervised senior house officers."[23]

COLLECTING DATA AND DISCLOSING IT TO PATIENTS

Patients should be informed when trainees pose significantly increased likelihood of minor harms, such as temporary pain, or somewhat increased likelihood of serious harm. Although judgment will be required to determine when these thresholds have been exceeded in individual cases, the necessary judgments are no different in principle from the kinds of judgments that are made routinely in clinical practice; for instance, deciding which risks of a particular procedure or medication are sufficiently worrisome that they should be disclosed to patients.

Data will be needed to determine when the risks posed by trainees exceed these thresholds. Because increased risks typically are defined in comparison to the common background or average, data collection should focus on whether medical trainees pose increased risks relative to physicians with the average level of experience for the procedure in question. To collect the data, ongoing assessments of medical outcomes based on physicians' experience could capture whether the practitioner is a trainee. For example, the Alliance for Quality Health Care currently ranks every hospital in New York State based on outcomes, and similar efforts are underway in California, New Jersey, and Pennsylvania.[24]

Systematically identifying when trainees pose significantly increased risks to patients will be a complex task. Patients' outcomes are influenced by a host of interacting factors. Isolating the impact of physicians' training on medical outcomes from these many other factors will be complicated, and will require multiple studies. Granting the difficulty of collecting these data systematically, it is worth noting that, in principle, this assessment is no different from numerous other examples in medicine in which the impact of a single

factor is assessed in the context of multiple factors that influence a single outcome. For example, it is clear that numerous environmental, dietary, lifestyle, and genetic factors influence individuals' risk of mortality. Nonetheless, systematic analysis has established that the single factor of smoking increases one's risk of dying.

WHAT TO DO IN THE INTERIM?

It will take decades, at least, to develop complete data on the outcomes for trainees. To take a complicated example, surgery to remove a glioma from the visual cortex might involve medical trainees at numerous steps in the process, from prepping the patient, to making the initial incision, to actually removing the tumor, to closing the incision, to writing orders for follow-up medications. It will take a good deal of data to determine when and to what extent trainees' involvement in these various steps introduces increased risks. To determine how to proceed in the interim, until complete data have been collected, consider an analogous example.

The U.S. Food and Drug Administration (FDA) often faces the question of whether the patients who take a particular drug should be informed of side-effects found in a related drug. To make this assessment, the FDA first attempts to determine precisely what characteristic of the drug causes the side-effects, and whether this characteristic is shared by the related drug. Is a common mechanism of action implicated, or perhaps a moiety not shared with the related drug?

When it remains unclear, after further investigation, why a class of drugs poses a particular risk, the FDA makes a simple assumption. It assumes that the risk applies to all members of the class. For instance, based on data that nucleoside analogs pose risks of lactic acidosis and severe hepatomegaly with steatosis, the FDA required a black box warning for tenovir disoproxil fumate, even though there were no data showing the risks in this specific member of the class of nucleoside analogs.

Standard medical practice suggests, then, that potential risks found in a class are assumed to apply to all the members of the class, absent convincing evidence to the contrary. This standard practice suggests that data on risks posed by inexperienced physicians as a group should be considered relevant and disclosed, in the absence of convincing evidence that trainees do not pose a particular risk found in inexperienced physicians: "If superior outcomes cannot be demonstrated directly, then high volume can, at least for the time being, be used as a proxy for better outcomes."[25]

Presumably, data that inexperienced radiologists pose increased risks of misdiagnoses do not apply to trainees who work in settings where all scans are reviewed by an experienced radiologist before treatment decisions are made. Conversely, as individuals perform challenging tasks repeatedly, they become better at them; the tasks become more familiar, and the quality of the results improves. Hence, data that inexperienced physicians pose increased risks for invasive procedures should be considered relevant to trainees, unless it is clear that the presence of a supervising physician eliminates the otherwise increased risk to the patient.

This same conclusion casts further doubt on the status quo of informing patients of trainees' experience level without informing patients that trainees may pose increased risks. In the absence of compelling evidence to the contrary, the fact that trainees belong to a class that is known to pose increased risks implies that patients should be informed that trainees themselves may also pose increased risks. The fact that this approach seems most consistent with current standards of informed consent provides even more reason to begin considering alternative approaches to reconciling informed consent, physicians' training, and volume-outcome data.

COMPENSATION

How might the training of physicians be reconciled with informed consent when convincing evidence shows that trainees pose significantly increased risks to patients? Notice that disclosure has the potential to undermine medical training, because patients may not accept the increased risks sometimes posed by medi-

cal trainees, without compensating benefits. Similarly, non-disclosure has the potential to exploit some patients by placing them at increased risk, without compensating benefits, for the good of society. The important point is that both concerns trace to a lack of compensating benefits, suggesting that it may be worth considering the feasibility of reconciling disclosure with the training of new physicians by findings ways to equalize the risk/benefit profiles presented by medical trainees and experienced physicians.

To the extent possible, it will be important first to minimize the risks posed by medical trainees. Existing supervision of medical trainees by experienced physicians likely reduces the risk-gap for many procedures, and eliminates it for some procedures. Future data on the ways in which trainees pose increased risks may identify other methods to reduce risks.

Supervision and other targeted measures are unlikely to reduce the increased risks posed by medical trainees to a minimal level for all procedures, especially invasive and complicated ones. This suggests that equalizing the risk/benefit profiles of medical trainees and physicians with the average level of experience may require offering compensatory benefits in some cases. To avoid exploitation, patients who undergo procedures that pose significantly increased risks at the hands of trainees should be informed of these risks, and offered compensatory benefits. The benefits offered by teaching hospitals — more experienced senior staff, cutting-edge technology — may compensate for the increased risks medical trainees pose for some procedures.[2]6 In these cases, it should be sufficient to inform patients of the increased benefits offered by teaching hospitals when informing them of the increased risks posed by medical trainees.

This approach will not yield enough trained physicians if patients are able to receive the benefits of teaching hospitals, yet opt out of being treated by medical trainees. In addition, relying on some patients to agree to be seen by trainees, while others enjoy the benefits of teaching hospital without running the risk of being seen by a trainee, seems unfair. To address these concerns, teaching hospitals might adopt an explicit policy of assigning physicians to patients, precluding patients from insisting on a particular physician based on experience level. This approach would ensure that all those who enjoy the benefits of teaching hospitals also accept the possibility of being seen by a trainee. Prospective patients could then be informed of this practice and offered the option of either accepting it or finding a different hospital.

Future data may indicate that the benefits available at teaching hospitals do not compensate fully for the increased risks that medical trainees pose for more invasive or complicated procedures, such as cardiac surgery. In these cases, additional compensatory benefits could be provided at the level of the units where such procedures are performed. Alternatively, these benefits, or others measures such as reduced insurance rates or free future medical care, could be offered at the individual level to patients who are treated by a medical trainee.

With respect to compensatory benefits that translate into decreased morbidity or mortality, compensatory benefits could be added to directly compensate for these risks. For example, a recent study suggests that each additional patient per nurse is associated with a 7 percent increase in 30-day mortality for surgical patients.[27] Such data, together with data on the increased mortality posed by medical trainees for various procedures, could be used to provide patients with sufficient increases in nursing coverage to ensure an equivalent overall risk/benefit profile.

It is impossible to specify a priori what level of benefits that do not translate directly into decreased morbidity or mortality, such as free future medical care or private suites, will be needed to protect patients from exploitation and ensure a steady supply of trained physicians. If used, these benefits will have to be fine-tuned, with specific benefits added until patients regard the risk/benefit profile of being treated by a medical trainee as comparable to the risk/benefit profile of being treated by a physician with the average level of experience. Focus groups may offer one way to estimate what benefits should be offered initially.

Finally, the choice of compensatory benefits will have to be made in concert with insurance and reimbursement mechanisms. Since society benefits from a steady supply of new physicians, it seems reasonable to expect society to pay for the benefits needed to ensure that new physicians can be trained in a way that respects patients and is non-exploitative.

CONCLUSION

Physicians' experience is now recognized as an important factor in medical outcomes. Based on these data, some commentators argue that physicians' experience level should be disclosed to patients. Other commentators have argued that patients should avoid inexperienced physicians. Taken together, these recommendations may, in the long run, inadvertently undermine the medical profession's ability to train new physicians. One response would be to require that all patients share these risks by agreeing to the possibility of being seen by a medical trainee. Although this approach is supported by the fact that all patients enjoy the benefits of trained physicians, it seems unlikely to be adopted in the U.S., raising the need to consider alternative approaches. One possibility would be to develop and assess a system of providing compensating benefits to patients who agree to be seen by trainees, based on the extent to which trainees pose increased risks for the procedure in question. This approach has the potential to ensure society's long-term capacity to train new physicians; it also has the potential to ensure that society does not exploit some patients in the process of providing the benefit of trained physicians for all patients.

DISCLAIMER

The opinions expressed are the authors' own. They do not represent any position or policy of the National Institutes of Health, Public Health Service, or Department of Health and Human Services.

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