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Active Surveillance Cultures and Contact Precautions for Control of Multidrug-Resistant Organisms: Ethical Considerations

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Infection control personnel are required to develop institutional guidelines for prevention of transmission of multidrug-resistant organisms, especially methicillin-resistant *Staphylococcus aureus,* within health care settings. Such guidelines include performance of active surveillance cultures for patients after admission to health care facilities or to high-risk–patient care units, to detect colonization with target multidrug-resistant organisms. Patients who are colonized with these potential pathogens are placed under contact precautions to prevent transmission to other patients. Such screening programs are labor and resource intensive and raise the following ethical considerations: (1) autonomy versus communitarianism, (2) indication for informed consent for obtainment of active surveillance cultures, and (3) identification of the appropriate payer. Relevant infection control, public health, and ethical principles are reviewed in an effort to provide guidance for ethical decision making when designing a multidrug-resistant organism control program that includes active surveillance cultures and contact precautions. We conclude that a program of active surveillance cultures and contact precautions is part of standard medical care that requires patient education but not a specific informed consent and that the cost for such programs should be assigned to the health care institution, not the individual patient.

Infection control is an integral component of daily activities in health care settings and is closely related to our unbridled passion as physicians "to cure sometimes, to relieve often, to comfort always" [1, p. 5] and, above all, to "do no harm" [2, p. 119]. An infection control program is required in health care institutions as a condition of participation in Medicare and/or Medicaid programs [3]; one goal is to decrease the incidence of health care–associated infections (HAIs) to an irreducible minimum, working toward zero [4]. Because HAIs caused by multidrug-resistant (MDR) organisms in the United States are a growing and serious problem [5], the medical community has been called to action to prevent these infections via implementation of a combination of practices to enhance antimicrobial stewardship and infection control practices, to prevent transmission in health care settings [6, 7]. Many infection control, public health, and quality-improvement practices described in recent years (e.g., prioritization of individuals for receipt of influenza vaccine or antiviral agents when faced with shortages [8, 9], rationing of scarce resources during pandemic influenza [8–12], quarantine for those with severe acute respiratory syndrome [13], and the duty to work even in the face of an associated personal risk [14]) have required balancing the individual's rights (autonomy) with the protection of the population (communitarianism). MDR organism control programs introduced into health care facilities in recent years raise similar ethics questions [4].

The rationale for MDR organism control programs that include routine active surveillance cultures (ASCs) and contact precautions and the relevant ethical principles are reviewed here. We use methicillin-resistant *Staphylococcus aureus* (MRSA) as the prototype in this review, but it is important to recognize that the same principles and practices apply to vancomycin-resistant *Enterococcus* species and MDR gram-negative

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bacilli, including extended-spectrum β-lactamase (ESBL)–producing organisms, when those pathogens are the most problematic within a specific patient care unit or health care facility. For the purposes of this discussion, the following operational definitions are used:

Quality improvement practices—systematic, data-guided activities designed to bring about immediate improvements in health care delivery in particular settings.

Autonomy—the right of a rational individual to make an informed, uncoerced decision.

Communitarianism—decisions made for the common good on the basis of virtuous values and thought to benefit the members of a specific group overall.

Justice (distributive)—normative principles to guide fair allocation of benefits, burdens, resources, information, and so forth in the community.

MDR ORGANISMS: EMERGENCE AND CONTROL

One of the great contributions in medicine is the discovery of antibiotics. Since the discovery of the penicillin nucleus (6-aminopenicillanic acid) from *Penicillium chrysogenum* 50 years ago, other structurally related agents and several unrelated classes of antimicrobial agents have been developed [15]. The introduction of each new class of antibiotics has been followed by the emergence of resistance to that class over time and often to other classes of agents, rendering hospitalized patients vulnerable to infection that is not treated effectively by routinely used agents or by any available agent. Even the newest classes of antimicrobial agents, with more potent and broader activity against MDR organisms and the greatest promise of not encouraging resistance (e.g., fluoroquinolones, carbapenems, lipopeptides, and oxazolidinones), have been associated with varying degrees of resistance [5, 6].

MDR organisms are microorganisms that have resistance to >1 class of antimicrobial agents. These include, but are not limited to, MRSA; vancomycin-resistant *Enterococcus;* certain gram-negative bacilli, including ESBL-producing organisms; and MRSA with varying degrees of resistance to vancomycin. The clinical importance of resistant organisms in health care settings is the associated increases in morbidity and mortality, length of hospitalization, and cost of health care [5–7, 16–19] and the limited therapeutic options [6, 20]; therefore, prevention of transmission to other patients is an important patient-safety activity.

Infection control personnel are under increased pressure from the public and regulatory agencies to implement programs for prevention of transmission of MDR organisms, especially MRSA, within health care facilities. In the past 5 years, 2 guidelines for prevention of transmission of MDR organisms were published [6, 21]. There is a consensus that ASCs [18] should be performed for patients who are transferred from other hospitals, for patients who are related by proximity to an index patient, if there is evidence of transmission of an MDR organism within a patient care unit, or if a pathogen with a new resistance pattern that threatens the ability to treat infection with it has been identified (e.g., vancomycin-resistant *S. aureus*). Whether to perform ASCs for MRSA routinely for all patients at the time of admission to a health care facility or to a high-risk–patient care unit remains controversial. Recent publications suggest that risk factors for MRSA colonization at the time of hospital admission may be identified within a population and may reduce the number of required screening cultures at admission by 50% [22, 23]. Because the contact route is the most important route for MDR organism transmission, patients colonized or infected with MDR organisms are placed under contact precautions (table 1) [6], either preemptively at the time the culture specimens are obtained and continued until culture results are negative for the target organism or after an MDR organism is identified, depending on the anticipated delay in obtaining the culture or antigen-detection results (e.g., 24 h vs. 3 days) and the severity of the transmission problem.

Widespread ASC programs have focused on MRSA and, to a lesser extent, vancomycin-resistant *Enterococcus,* without much direction with regard to MDR gram-negative bacilli. In December 2006, the Institute for Healthcare Improvement posted a bundle of practices for reduction of health care–associated MRSA infections [24], and in January 2007, the Veterans Health Administration issued a mandate to all its member hospitals to develop a standardized initiative to reduce health care–associated MRSA infections in the population served by the Veterans Health Administration [25]. Both initiatives include widespread use of ASCs and contact precautions. Although mandates for performance of ASCs for control of MRSA have been issued by some states and are under consideration in several others, there is insufficient evidence to justify mandatory application of this strategy to all hospitalized patients. Individual hospitals must retain the flexibility to conduct risk assessment and to determine resource allocation. The rationale for not legislating this component of an infection control program and for allowing each health care organization to develop its own program based on local conditions has been summarized elsewhere [26].

ASC screening programs are labor and resource intensive. Broad institution of ASCs for MRSA could quadruple the number of patients placed under contact precautions [27]. Consequently, the freedom of a substantial number of patients would be limited by restricting them to the confines of their rooms, to protect other patients from potential exposure to MRSA [6, 28]. Some unintended consequences of contact precautions that have been reported include social isolation [29],

Table 1. Components of a program of active surveillance cultures and contact precautions for control of multidrug-resistant (MDR) organisms.

Active surveillance cultures
Identify target organism, target population, and frequency of surveillance
Consult with microbiology laboratory
Determine what sites to culture
Determine what methods to use
Communicate results to frontline providers
Monitor consistency with which culture specimens are being obtained
Contact precautions
Room placement
Single-patient room when available
Cohort the patients colonized and/or infected with the same MDR organisms when a single-patient room is not available (after consultation with infection control), but observe contact precautions between each patient in that room
Don the following upon entry into the room:
Clean nonsterile gloves
Clean nonsterile gowns
Remove and discard gown and gloves before leaving the patient room to contain MDR organisms, especially those that are transmitted by environmental contamination (e.g., *Clostridium difficile,* noroviruses, respiratory syncitial virus, and vancomycin-resistant *Enterococcus*)
Perform hand hygiene after glove and gown removal
If transmission is continuing, assign separate caregivers to colonized or infected patients and separate caregivers to uninfected patients
Monitor adherence to contact precautions
Outcome measures
Colonization rates: admission, conversion during hospital stay, and reaquisition rates
Rates of health care–associated infections caused by target organism and other organisms
Adverse effects of contact precautions
Delay in room placement
Reduced frequency of contact with health care providers
Noninfectious adverse events
Feelings of depression and isolation
Patient dissatisfaction

feelings of depression [30], less frequent examinations with health care providers [31], and an increased number of noninfectious adverse effects [32]. Health care facilities must prevent these unintended consequences for patients on contact precautions whether or not ASC is performed within an institution.

ETHICAL CONSIDERATIONS

Infringement on individual patient's rights. The primary benefit of an ASC program is for the population of patients and health care providers, not for the individual patient whose colonization state is identified. Patients who would not have been identified and placed under contact precautions in the absence of ASCs may feel that their individual rights have been compromised unfairly. Benefits of ASCs for the individual patient are fewer than those for others but may include the optimization of antimicrobial choices when the patient develops signs of HAI and the potential for MRSA decolonization. Exposure to broad-spectrum antimicrobial agents suppresses the patient's normal flora and provides an environment favorable for an MDR organism to persist [6, 7, 21], especially in immunocompromised patients who become colonized with an MDR organism. Therefore, improvement of antimicrobial stewardship will create a milieu that could prevent proliferation of MDR organisms [7]. Because the long-term success and value of decolonization programs for MRSA, especially for individuals returning to the home environment, remain uncertain and because there are no proven effective regimens for decolonization for other MDR organisms, we have little to offer the individual patient as a definite end point to the imposed contact precautions.

Principles of informed consent. Ethical issues in the application of infection control measures in health care settings are reminiscent of the medical aphorism from Hippocrates "Ars longa, vita brevis, occasio praeceps, experimentum periculosum, iudicium difficile…" ("art is long, life is short, oppor-

tunity fleeting, experiment treacherous, judgment difficult…" [33]). In the pursuit of medical knowledge through clinical research, our patient care can be filled with problems and our management of choice may be perilous and may be fraught with uncertainties and difficult decisions [2, 33]. One of those ethical concerns is whether an ASC program for the prevention of MDR organism transmission is research that requires specific informed consent, is quality improvement for which consent would not be required, or is standard medical care that would be covered by the general consent form signed at admission.

Clinical research. There are several documents that have been created to protect the rights of human subjects. In 1949, the Nuremberg Code [34] was published in response to the atrocities committed by the Nazi scientists during World War II that were exposed during the Doctors Trial at Nuremberg. This code consists of 10 principles to protect human volunteers participating in research. The first of the precepts states that "the voluntary consent of the human subject is essential" to uphold the ethical, legal, and moral standards of the clinical research [2, 35, p. 1662]. Then, in 1964, the World Medical Association developed the Declaration of Helsinki, which describes additional standards required to protect patients who are also research subjects. Several amendments have been added since then, to encompass the growing diversity in clinical research. The same document also declares that, when appropriate, new information should be documented and published [2, 36].

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created when the National Research Act was signed into law on 12 July 1974. It identified the basic ethical principles (general prescriptive judgments) relevant in guiding investigators in the conduct of research involving humans. These principles—respect for persons, beneficence, and justice—are contained in the Belmont report that was published in February 1976. The commission also provided the framework for "the nature and definition of informed consent" in the various genres of research [2, 37, p. 128].

In university medical settings, all research subjects are protected by the conditions provided in Title 45 Code of Federal Regulations (CFR) Part 46, regardless of the source of funding. This is also known as the "common rule," which defines who the human subject is and allows informed consent to be waived if the interventions and/or procedures involve no more than minimal risk [38, 39]. Minimal risk, as established in Title 45 CFR Part 46 [39], means that the probability and magnitude of harm or discomfort anticipated in research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. These principles do not apply to programs involving ASCs and contact precautions, because the routine implementation of these practices is not considered human-subject research and the process of obtaining ASCs has no more than minimal risk. Furthermore, the specimen obtained for ASC does not in itself constitute identifiable private information, and the culture result is a part of the medical record and, therefore, is privacy protected.

Quality improvement. Health care providers are obligated to improve the quality of patient care through clinical and managerial changes in the processes of care. An ASC program for MDR organism control may be considered to be quality improvement, because it involves evidence-based and data-guided activities that are designed to bring about prompt improvement in the quality of health care delivered in specific settings [40]. A review of the ethics of using quality-improvement methods in health care concluded that most quality-improvement activities are not human subject research and should not undergo review by an institutional review board [40, 41]. However, the authors called for accountability for the ethical conduct of quality-improvement projects, to ensure that inadvertent harm does not occur to patients and that scarce resources are not wasted. The optimal procedure for that accountability has yet to be established, but it should be distinct from the institutional review board. Furthermore, a recent statement from the Office for Human Research Protections supports not requiring informed consent for quality-improvement activities and is supported by bioethicists [42].

Medical care. Every patient (or parent/guardian in the case of minors, *explicitly*) signs a general consent form that allows his or her physicians to perform diagnostic procedures and/or therapeutic management once he or she is admitted to the hospital. Although subject to challenge [43] if they are too broad or ambiguous, such consent forms are valid insofar as they apply to a wide array of procedures that are often routine or that a patient reasonably could expect a hospital to perform during his or her stay. Beyond the general consent form, a hospital (or, more accurately, a physician) may have a duty to obtain a patient's specific informed consent before providing a therapeutic or diagnostic procedure that is not routine. This duty is established and defined by a complex web of federal and state statutes, regulations, and case law; accreditation standards; and national specialty groups [44]. Despite significant differences among these various sources, there is agreement that the argument for obtaining informed consent becomes more compelling as the risks to the patient increase. Significant risks are associated with procedures that are invasive, that have serious adverse effects, and that pose a threat to the patient's privacy. The conditions under which specific informed consent may be waived are summarized in table 2 [38, 39, 45].

Assessment of ASCs and contact precautions in the framework of informed consent principles. Individual institutional screening programs involving ASCs may be considered standard

Table 2. Conditions under which informed consent may be waived.

Procedure involves no more than minimal risk to the patient
Procedure will not adversely affect the rights and welfare of the subject
Procedure could not be practicably performed without the waiver
Whenever appropriate, the subject will be provided with additional pertinent information after participation

NOTE. All 4 conditions must be met. Data from [38, 39, 45].

of medical care as defined in an institution's infection control policies, which may vary among hospitals; thus, the signed informed consent form at admission *implicitly* [46] encompasses the screening for MDR organisms. The specific plan for performance of ASCs and management of colonization and/or infection of patients should be stated in an institutional infection control policy, to ensure transparency. Such a policy requires approval from a group of representative institutional administrative and clinical leaders. By including in this process the individual(s) who oversees the institution's quality-improvement program, ethical accountability is ensured. In the presence of continued transmission of MRSA or other MDR organisms, fiscal and human resources must be made available for implementation of an effective infection control program [7]. If the local infection control committee chooses not to adhere to published guidelines for MDR organism screening, because there is not an MDR organism problem present and because ASC is not a standard of medical care for that facility, it is important to demonstrate that an assessment of MDR organism transmission has been made, that there is no indication for additional interventions, and that there is a plan for ongoing reassessment [6]. Education and clear communication with patients concerning the institution's program of ASCs and contact precautions is essential, independent of a requirement for informed consent.

Responsibility for the cost of an ASC-based program for MDR organism control. Ultimately, the patients in a health care facility are the collective beneficiaries of a reduction in transmission of MDR organisms, because their risk of morbidity and mortality associated with HAI is reduced. However, the institution itself is also a beneficiary. The hospital infection control officer is held accountable for prevention, investigation, and control of clusters of HAIs, including those caused by MDR organisms and those associated with adverse outcomes [28]. Preventive actions will protect the hospital from costly interventions required to curtail an infectious disease outbreak and from medicolegal actions taken by patients who become infected [6]. Further accountability is being imposed through "pay for performance" or "quality-based purchasing" programs that provide monetary incentives from insurance companies and Medicare and/or Medicaid to top performers, by use of standardized measures [47, 48]. In the case of MDR organisms, the top performers would be those whose institutions have the lowest rates of HAI caused by MDR organisms. In some instances, a program of ASCs and contact precautions will contribute to the reduction of HAIs caused by MDR organisms. Public reporting of selected HAI rates and denial of payment for health care incurred for preventable conditions (e.g., HAI or injury from accidental falls) serve as additional incentives for prevention of HAI. Furthermore, the monitoring of adherence to the recommended practices of standard and to transmission-based isolation precautions to avoid transmission among patients and health care providers is the responsibility of the infection control officer [6]. Lastly, charging for a hospital activity that is of minimal-to-no benefit to the patient who is screened and that is undertaken primarily for the benefit of other patients and the institution fails the tests of proportionality and basic fairness. Therefore, the cost of the MDR organism control program developed by the hospital epidemiologist should be borne by those responsible for development, implementation, and outcome of the program and by those who are likely to benefit monetarily from those interventions (i.e., the hospital).

Publication of unanticipated results of ASC programs. ASCs and contact precautions are performed for the purposes of improving the quality of care, without the intention of publication of results. However, if the screening program yields new information about unexpected benefits or adverse effects that would benefit the infection control community and patients (e.g., identification of isolates with novel antimicrobial resistance that have not been reported previously, a new resistant strain with the potential to reach epidemic proportions, specific risk factors identified that could streamline ASCs and save costs, or innovative methods of preventing transmission of a specific MDR organism), it would be important to publish such results on the basis of the principle of justice [38, 46, 49]. In such instances, institutional review board approval may be sought to analyze de-identified data (i.e., data not linked to a particular individual so that they are no longer protected health information) retrospectively.

CONCLUSIONS

Infection control personnel in each health care facility must develop a program for prevention of transmission of MRSA and other MDR organisms that may include performance of ASCs to screen for a target MDR organism on the basis of an assessment of the local epidemiology. The principles and arguments provided suggest that such programs are quality improvement and not human research; therefore, specific informed consent for obtainment of culture specimens for MDR organism screening programs that are considered to be no more than minimal risk to the patients is not needed. However, ed-

ucation and clear communication with patients about the ASC program and the impact it may have on them is essential. Considering the public health model and the principle of communitarianism and given the beneficiaries of a successful program, it is appropriate to shift the financial burden from the patients to the responsible health care institution. The most important priority is to protect the health and life of each patient while upholding the dignity and privacy of every patient.

An in-depth analysis and open discussion with the hospital administrators and patient advocate groups are required when there is a shift of financial burden from patients to the hospital. We believe that sound ethical principles can provide support for the solution of ethical dilemmas in infection control. As the Hippocratic oath says, "I swear… to keep according to my ability and my judgment… the good of my patients…" [50, p. 2028].

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