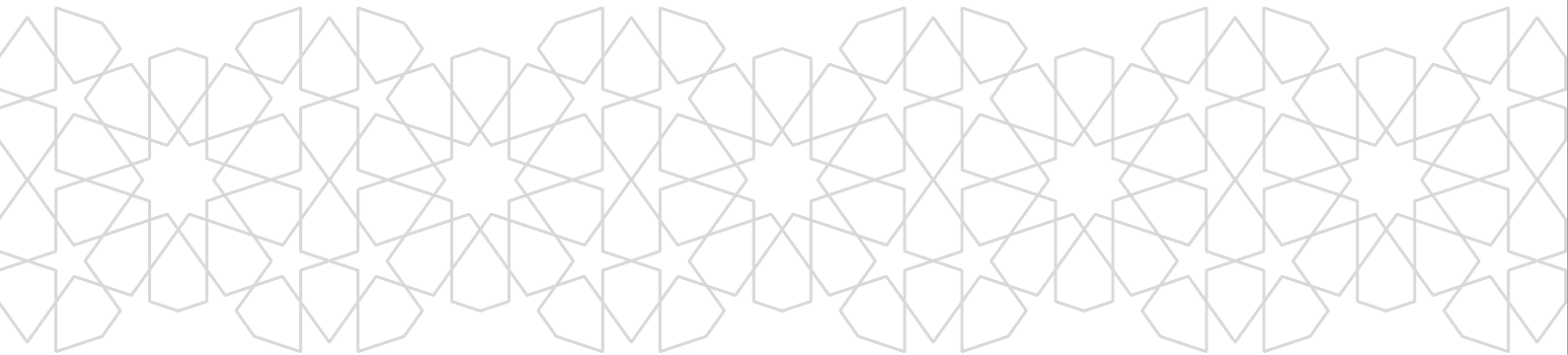


The contents of this guideline are informed by review of national and international medical ethics guidelines, input from subject matter experts, and participatory workshops.





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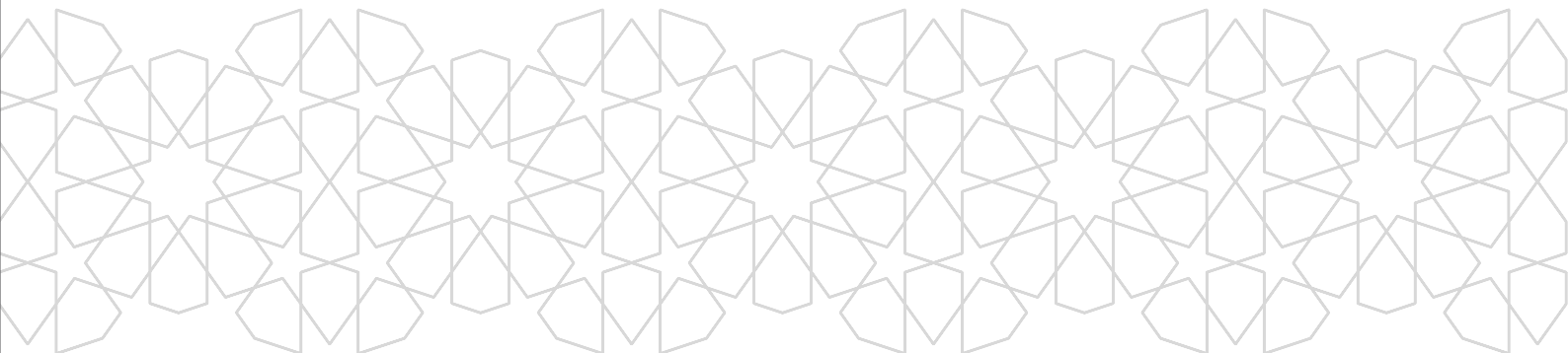
وزارة الصحة ووقاية المجتمع
MINISTRY OF HEALTH & PREVENTION



دائرة الصحة
DEPARTMENT OF HEALTH

Healthcare Workforce Bioethics Guidelines

ISSUE 2024





صاحب السمو الشيخ محمد بن زايد آل نهيان

رئيس دولة الإمارات العربية المتحدة

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PRESIDENT OF THE UNITED ARAB EMIRATES



المغفور له بإذن الله الشيخ زايد بن سلطان آل نهيان

تغمده الله بواسع رحمته

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Preface

The Healthcare Workforce Bioethics Guidelines were developed in line with the UAE's efforts to enhance the quality of health services provided to the community, and as one of its strategic initiatives and objectives toward a sustainable agile and competent healthcare workforce. The contents of the guidelines are informed by review of national and international medical ethics guidelines, input from national and international subject matter experts, and a series of interactive workshops that included more than 120 national and international experts and leaders in bioethics. The guidelines have been adopted by the UAE Ministry of Health and Prevention (MOHAP), and the Sharjah Health Authority (SHA). For the purpose of this document, these Healthcare regulatory authorities in the UAE shall be referred to as the local Regulating Bodies.

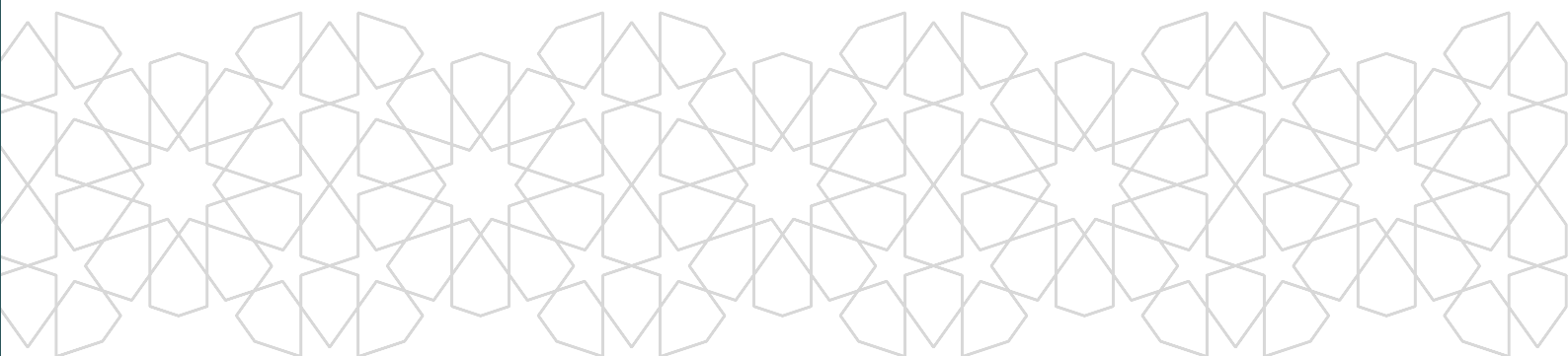
The guidelines are an important milestone in ensuring medical ethics and principles of ethical practices in healthcare are defined, disseminated & maintained. Sincere gratitude and appreciation go to the national and international subject matter experts and delegates from participating committees, and from all involved stakeholders for their cooperation and participation in finalizing the Healthcare Workforce Bioethics Guidelines.



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1 Introduction



Purpose of the Guidelines

The UAE health regulators play a crucial role in the development and implementation of healthcare policies, strategies, and guidelines to ensure the delivery of high-quality and safe healthcare services to all patients, including residents and visitors. As the UAE strives to achieve excellence in healthcare provision, it is crucial for healthcare professionals (HCPs) to build a shared understanding of and language for medical ethics guidance in clinical practice.

Competence, professionalism, honesty, integrity, compassion, collegiality, and a commitment to equity and justice are among the key virtues that guide the practice of medicine. Ethically and professionally, HCPs are obligated to promote the health of individuals and the public, ensure a safe environment for patients and colleagues, and foster trust and confidence in the healthcare system. Healthcare institutions in the UAE embrace advanced medical technologies and attract medical professionals and patients from around the world; as such, HCPs must care for patients in the context of diverse cultural backgrounds, values, and norms. HCPs should aim to provide collaborative, respectful, and up-to-date care in emergency, short-term, and longitudinal interactions with patients.

This document aims to highlight key guidelines to direct ethical conduct within the healthcare system. These guidelines are built upon a combination of international standards and principles of bioethics, as well as expert input on local practice and culture, reflecting insights from a variety of disciplines and healthcare settings. Each chapter is organized by topic and accompanied by sample teaching cases providing examples of practical applications of the guidelines. Some concepts are pertinent to multiple areas of practice and additional relevant chapters are referenced to direct the reader accordingly.

Clinical scenarios that raise ethical concerns and considerations are rarely identical – each has its own set of details and tensions influenced by different perspectives. While there may be disagreement about how to resolve a given case, creating consistent and transparent assessment and deliberation processes, within and across institutions, will help foster a healthy and agile medical ethics ecosystem. While this document is meant to provide guidance, it is not a comprehensive list of ethical dilemmas

that might arise. Rather, the guidance is meant to help HCPs navigate dilemmas by balancing multiple principles, interests, and perspectives in pursuit of ethically sound solutions that uphold a high level of care. Importantly, practice must always adhere to UAE laws and policies; HCPs should seek dedicated legal guidance separate from this document in any scenario requiring clarification of the law.

Principles of Medical Ethics

The guidance in this document is grounded in a set of core principles that shape the ethical provision of healthcare services. These principles guide the way healthcare professionals provide care, while considering the facts specific to each scenario, religious beliefs and cultural views of patients, available resources, and the need to maintain professional boundaries.

1. **Respect for autonomy:** Respecting patients' rights to make informed decisions about their own healthcare and ensuring their involvement in treatment choices, including accepting or refusing care, with the necessary information and without undue coercion.
2. **Beneficence:** Acting in the best interest of patients, striving to maximize benefits while minimizing harm, and promoting the overall well-being of individuals and communities.
3. **Non-maleficence:** Avoiding harm to patients, ensuring that medical interventions do not cause unnecessary suffering or adverse effects.
4. **Justice:** Ensuring fairness and equity in the distribution of healthcare resources, and promoting access to healthcare services for all individuals, irrespective of their background or position.

Balancing these principles in the context of diverse opinions and interests will require institutional resources, such as ethics committees, available to assist with and provide guidance for complex ethical issues in clinical practice. Ethics committees are multidisciplinary, often comprised of clinicians, ethicists, social workers, risk managers, hospital administrators, legal counsel, spiritual care providers, and others.

General Duties of Healthcare Professionals in Providing Ethical Clinical Care

All patients must be treated with respect and dignity regardless of their race, ethnicity, religion, gender, age, or socioeconomic status; discrimination of any kind is unethical and unprofessional. According to the principle of respect for autonomy, all patients have the right to direct choices in their care, including decisions whether to accept or refuse care. HCPs and healthcare institutions should promote a culture of patient safety and transparent systems of practice.

1. HCPs should provide information regarding diagnosis and prognosis in a clear and transparent manner, allowing time for questions and clarifications to promote patients' understanding of their clinical status.
2. HCPs should provide patients with all the necessary information about testing, treatment, or other interventions—including the risks, benefits, and alternatives—to facilitate informed decision-making free of undue pressures.
3. HCPs should promote community measures for healthier environments and provide patient education on preventative healthcare, including screening tests, vaccinations, and information on lifestyle changes for modifiable clinical risk factors.
4. HCPs should engage in shared decision-making by offering patients, their families, and alternative decision-makers professional medical judgment relating to healthcare decisions. Professional guidance provided by HCPs should be evidence-based and grounded in up-to-date clinical information.
5. HCPs should promote a safe and hospitable care environment for all patients and their family members, ensuring they are protected from any form of harassment, abuse, or discrimination.



2 Autonomy, Decisional Capacity, and Informed Consent



Introduction

In accordance with the principle of respect for autonomy, and to foster trust in medical practice, patients have the right to make decisions about their own clinical care and to be provided with the information necessary to make informed and uncoerced choices. An individual's capacity to make medical decisions – based on a demonstrated ability to comprehend and appreciate pertinent information, reason through a decision, and communicate a choice – should be assessed by the clinical team, with iterative reassessments as the patient's clinical status evolves. Patients who have decision-making capacity may communicate their informed decisions in real time or assign alternative decision-maker(s) to make decisions on their behalf.

If patients lack decision-making capacity and do not have prior documentation of their wishes, decisions about their clinical care should be discussed with and made by their alternative decision-makers. Alternative decision-makers should be supported in making choices based on substituted judgment, which are those most aligned with what patients would have chosen for themselves based on their known values and preferences. When a person lacks decision-making capacity and does not have an alternative decision-maker, clinicians should provide care according to the best interest standard: care that clinicians believe is in the best interests of the patient to maximize well-being and reduce pain and suffering.

Assessing Medical Decision-Making Capacity

In accordance with respect for autonomy, patients who demonstrate capacity to make medical decisions have the right to make their own decisions about their medical care. Decisional capacity is specific to time, able to fluctuate as a patient's clinical status changes (e.g., temporary loss of capacity due to delirium or effect of a medication). It is also specific to individual decisions; a patient who may be able to make more simple decisions, such as consenting to a non-invasive diagnostic procedure, may not demonstrate the comprehension or reasoning to make higher stakes decisions, such as providing consent for a high-risk surgical procedure.

1. Physicians should assess patients' decisional capacity by evaluating their ability to:
 - Understand the information relevant to the decision at hand, such as the purpose of the intervention and its risks, benefits, and alternatives;
 - Appreciate how the intervention being considered will impact their own specific medical courses and lives;
 - Demonstrate rational reasoning in considering the intervention and its alternatives; and
 - Provide clear communication of their choice.
2. HCPs should approach patients with the presumption that they have decisional capacity and are therefore able to make their own choices. However, HCPs should consider limitations of patients' capacity when potentially impairing circumstances and diseases are present.

Alternative Decision Making

Alternative decision-makers participate in care discussions and make healthcare choices, including the provision of informed consent for specific interventions, for patients who lack decisional capacity or have otherwise decided that they would like another individual to make decisions on their behalf.

1. HCPs should encourage patients to notify them if they have legally identified an alternative decision-maker(s).
2. Per legal guidance, in the event that an incapacitated patient did not legally designate an alternative decision-maker while capacitated and does not have a court appointed guardian, HCPs should seek consent and choices about care from a relative of the patient in the following order of priority: father, mother, husband, wife, son, daughter, grandfather, grandmother, son's children, daughter's children, paternal aunt, maternal

uncle, maternal aunt, paternal uncle's children and maternal aunt's children.

3. HCPs should support and guide patients' alternative decision-makers to make decisions in accordance with substituted judgement, meaning decisions that are based in knowledge of the patient's own wishes and values, preferences, and attitudes towards illness and medical interventions.
4. When patients' wishes or preferences are not known, HCPs should support and guide alternative decision-makers in making care choices using the best interest standard, meaning decisions that will promote patients' well-being and quality of life, with consideration of potential suffering or impairments that could result from clinical interventions.
5. If there is disagreement among multiple alternative decision-makers or between alternative decision-makers and the clinical care team regarding healthcare choices most aligned with the patient's wishes and interests, HCPs should attempt to resolve these disagreements through multidisciplinary family meetings and/or timely consultation with their institutional ethics committee.

Informed Consent

Informed consent is the process by which patients with decision-making capacity or their alternative decision-makers are provided the information necessary to freely give authorization for a clinical intervention.

1. In informed consent discussions, HCPs should provide information including but not limited to: known details of the patient's diagnosis and prognosis; description and purpose of the medical intervention that is proposed; the risks and benefits of accepting or declining the intervention; alternatives to undergoing the intervention, including declining treatment.

2. In providing the necessary information for a patient to make decisions about undergoing medical interventions, HCPs should communicate their clinical judgement in a clear and transparent manner that is sensitive to the patient's values.
3. HCPs should approach informed consent as a process, allowing time for questions and clarifications to promote patients' understanding of their clinical status and the proposed medical intervention.
4. HCPs should encourage a model of shared decision-making, by which care choices are informed by a patient's values and preferences, in addition to medical evidence and clinical judgment.
5. HCPs should document informed consent discussions and the patient's decision in the patient's medical record.
6. If the patient lacks decision-making capacity and the clinical team is unable to locate an alternative decision-maker in an emergent situation where an urgent clinical intervention is deemed necessary, HCPs may proceed with the intervention without obtaining informed consent. Under such circumstances, the clinical team should inform patients or their alternative decision-makers of the situation as soon as it is feasible to do so. Informed consent should then be obtained for ongoing clinical care.

Refusal of Treatment

In accordance with respect for autonomy, a patient who demonstrates decisional capacity may refuse any healthcare intervention, including evidenced-based therapies or the initiation of life-sustaining treatment.

1. Clinicians should thoroughly assess patients' capacity to make decisions of treatment refusal and document this assessment in patients' medical charts.

2. If there is disagreement among patients and their family members or between patients and the clinical care team regarding adequate decision-making capacity to refuse care, clinicians should seek timely consultation with appropriate specialties, including psychiatry and/or the institutional ethics committee.

Protective Stabilization and Patient Restraint

All individuals possess an inherent right to bodily autonomy and to avoid unjustifiable physical confinement. However, certain clinical scenarios may lead to behaviors that put patients at risk of self-harm or causing harm to others. In such cases, under very limited circumstances, it may be ethically acceptable for HCPs to authorize the use of pharmacologic (i.e., sedation) or physical restraint to safeguard the patient or other individuals under active and imminent threat of harm. Restraints must never be utilized punitively, for convenience, or as a substitute for appropriate staffing.

1. HCPs should only employ pharmacologic or physical restraint when no other options are available to protect patients from harming themselves or others.
2. If restraints are employed, HCPs should try to explain the reasoning for use of restraints to patients and to obtain patients' or their alternative decision-makers' consent for their use, if possible.
3. Pharmacologic or physical restraints should be maintained for the shortest time possible, with the decision to employ restraints continually reevaluated to allow for prompt discontinuation at the earliest time that it is safe for the patient.
4. In situations where patient restraint is deemed necessary, HCPs should choose the least restrictive form of restraint.
5. HCPs should clearly document the reason for employing patient restraints, as well as the

choice of restraint and its duration, in the patient's medical record.

6. Institutions should have formal procedures for conditions under which patient restraints may be used and HCPs should be familiar with and act in accordance with these protocols.
7. HCPs should be aware that, even when employed under justifiable circumstances, the use of restraints may lead patients to experience trauma, frustration, and/or mistrust. HCPs should offer support and ancillary resources to the patient to help mitigate these reactions and negative effects.

Appendix 1:

Sample teaching cases

Case 1

Your patient, Mrs. M, is a 72-year-old woman admitted to the hospital yesterday with a left foot infection complicated by sepsis. When you first spoke to and examined her, she was in pain from her foot wound, but was able to discuss her care with you calmly and rationally. When you go to see her today, she seems confused about where she is and who you are. She adamantly exclaims that she wants you to stop treating her and to leave her alone, and that she plans to leave the hospital immediately. How should you proceed?

Your patient seems to have demonstrated decisional capacity to make choices in her own care when she was first admitted to the hospital. Since she now seems confused, it would be fair and prudent to reassess her capacity, which may be limited by her clinical status or effect of medications. You should again explain her diagnosis, prognosis, and treatment options and assess her ability to understand and appreciate this information, reason through her options, and communicate a clear choice. If your assessment reveals that her decision-making capacity is currently limited, you should locate an alternative decision-maker to make decisions on her behalf. You should also continue to reassess the patient as her clinical status changes and she returns to her baseline, as she may regain the capacity to make her own healthcare decisions.

Case 2

You are treating a critically ill patient in the intensive care unit whose designated alternative decision-maker is her adult son. The patient is currently unconscious, but before she was incapacitated, she specified that her son should make medical decisions on her behalf. However, other family members notify you and the care team that they believe the patient's son is making decisions based on his own values and beliefs, rather than those of the patient. How should you proceed?

It is important to guide alternative decision-makers to employ substituted judgement when making decisions on a patient's behalf. Your patient's son should make

healthcare choices guided by the patient's own known values, beliefs, and preferences. If you have reason to believe this is not the case, you should discuss this with the patient's son, attempting to resolve any misunderstandings or disagreement. If, despite this discussion, you continue to believe that her son is not acting in the patient's best interest, you should involve your institution's ethics committee for guidance in resolving the situation and identifying an alternate decision-maker.

Case 3

Mr. C is a 62-year-old man who presented to your outpatient clinic with pain in his right knee from longstanding osteoarthritis. The patient was evaluated by your colleague last week and referred to you for a follow-up appointment to receive an intra-articular corticosteroid injection. Your colleague tells you the patient has signed an informed consent form authorizing the intervention and you reviewed the signed form. However, when you begin speaking to the patient at the current appointment, he does not seem to fully understand the risks and benefits of the injection. How should you proceed?

Informed consent is crucial to providing healthcare that maintains respect for patient autonomy, or the right of every patient to direct his own care. Informed consent should be regarded as a process that is meant to ensure patients are making decisions with all the necessary information and without undue coercion. Even though your patient signed an authorization form, he does not seem to truly understand the risks and benefits of the proposed intervention, and therefore cannot provide true informed consent. You should review the necessary information with your patient again, allowing him to ask questions and seek clarifications, and only proceed with the injection if he provides his consent after this process.



3 Resource Allocation, Equity, and Access to Care



Introduction

Equity in medicine, including access to care and resource allocation, is most typically managed on a policy, or structural level. The actions of individual healthcare professionals (HCPs) must align with institutional, local, and federal policies. Importantly, HCPs are often their patients' chief advocates in the healthcare setting especially in cases of scarce resource allocation challenges, such as transplantation of organs, mass casualty events, and drug shortages. The principle of justice is the broad requirement that equals be treated equally; practically, in medicine, justice refers to fairness in access to resources and the humane, equitable treatment of patients. This does not mean that inequality is automatically unjust, but it does mean that when something overrules the norm of equality, there must be an acceptable explanation.

Although most resource allocation decisions are made at the institutional or governmental level, HCPs will still face decisions relating to access to care and equality, for instance when dealing with drug shortages. Such decisions are often difficult and may cause moral distress for HCPs as they carry the dual responsibility of being equitable and just stewards of scarce resources, while also being the best placed advocates for their patients. HCPs also have an important role to play in witnessing the impact of institutional and governmental policies and therefore have a responsibility to inform policymakers as to how policies could be improved. Additionally, HCPs have a moral obligation to help increase awareness of health care disparities, both to policymakers and to the public.

Treating All Patients Without Discrimination

1. HCPs must treat all patients in a similar manner regarding access to safe, effective, patient-centered, evidence-based care.
2. HCPs may not discriminate against patients based on their religion, race, gender, sexual orientation, or other personal or social characteristics that are not clinically relevant to the patient's care.

3. HCPs (and the institutions for which they work) must be transparent about treatment decisions, such as how similar patients may be treated differently, and why. Patients cannot be deprived of appropriate medical care on the grounds of individual clinician conscience (see discussion of "Conscientious Objection in Clinical Practice" in "Professionalism in Clinical Practice" chapter).
4. HCPs must provide culturally competent care and must work, individually and in conjunction with their institution, to be sensitive and accommodating to cultural differences that may impose communication barriers or affect the HCP-patient relationship.

Justice as it Pertains to Resource Allocation

In medical settings, there are multiple ways to allocate resources. For example, you could prioritize helping those who are worst off; alternatively, you could prioritize those who are best off and thus likely to recover the quickest or derive the longest-term benefit from a clinical intervention; you could prioritize the youngest, or you could prioritize those who are considered to have the highest social value; you could randomly allocate supplies through a lottery. Which of these approaches is most ethical in specific settings is hotly debated. If you are unable to select a principle-based notion of justice, as listed above, you can instead choose to rely on procedural justice, in which all the same factors were taken into consideration, in the same way as they were considered every other time.

Responsible Use of Resources

Justice requires that HCPs must treat patients similarly unless there is good cause not to do so and the relevant policy for this disparate treatment has been shared and justified publicly. Patients with connections, fame, or wealth may not receive medical goods that come at the expense of other patients (for example, a donor organ or a drug that otherwise would have gone to another patient in that institution). Medical goods must be distributed

solely on the grounds of medical need. HCPs also have professional and ethical obligations to be prudent stewards of healthcare resources.

1. HCPs should help patients articulate their health care goals and help patients and their families form realistic expectations about whether a particular intervention or use of a particular resource is likely to achieve those goals.
2. HCPs should be transparent about treatment alternatives, including disclosing when resource constraints play a role in decision making.
3. HCPs are responsible for basing recommendations and decisions on patients' medical needs and scientifically grounded evidence, adhering to interventions that meet the standard of care and are allocated on the grounds of medical need.
4. HCPs should follow institutional, local, and/or governmental policies concerning the use of limited healthcare resources. When exceptional occasions arise, these should be reviewed (when possible, in real time; when not, retrospectively) to see if there were any issues of preferential treatment or bias at play in decision making.
5. HCPs should endorse recommendations that offer reasonable likelihood of achieving the patient's goals. When possible, courses of action offer similar likelihood and degree of anticipated benefit compared to anticipated harm for the patient, HCPs should choose those that requires fewer resources.
6. As HCPs should be engaged in shared decision-making with patients or their alternative decision-makers, they may be met with opposition if the patient, the patient's family, or other stakeholders prefer a more costly intervention than that recommended by the HCP. In this case, it is essential to reaffirm that the proposed treatment plan is based

on standards of practice and professional judgment. Another HCP can be asked to provide a second opinion and, if there remains a disagreement about what treatment to pursue, the case should be referred to an institutional clinical ethics committee.

7. HCPs should participate in efforts to resolve persistent disagreement about whether a costly intervention is worthwhile, which may include consulting other experts.
8. When there are questions about the appropriate use of healthcare resources in a particular situation, HCPs must: (1) reflect whether they would ask this question of a similar patient or if the patient is being treated differently; (2) seek consultation with an experienced colleague, an ethics committee, and/or legal counsel; and (3) if the situation has revealed a scenario that would benefit from an individualized policy, inform relevant policymakers.
9. HCPs should acknowledge that disagreements about resource allocation can cause moral distress in themselves and their colleagues and seek to find ways to voice this distress productively (e.g., by taking concerns to relevant policymakers and institutional bodies).
10. HCPs have a moral obligation to advocate for patients. When HCPs witness concerns related to resource allocation, equity, and access to care, they have a responsibility to inform their supervisors, patient advocates, and/or relevant policymakers of these concerns.

Appendix 1:

Sample teaching cases

Case 1

You are a cardiologist whose long-time patient is now in acute heart failure. His son, a local official, demands that his father receive the next donor heart for which he is a biological match. However, there are five people listed ahead of your patient on the heart transplant recipient list. You have always been taught that medical need should be the rationale for resource allocation, but you know that powerful people often seek special treatment. You are worried that the institution may support the official's demand, which would mean that your patient would be given priority access to a donor heart over those whose medical need for it is more acute than is his. Do you have reason to be concerned?

Institutions may not prioritize certain patients in ways that would be injurious to other patients, for example, by moving this official's father to the top of the transplant list. Because medical resource allocation is driven only by medical need, the institution should not meet the official's demand to move his father up the transplant list. If you are concerned the institution is not adhering to these standards, you should raise your concern to hospital administrators or, if left unaddressed, to the local regulatory body.

Case 2

You are an orthopedic nurse. A morbidly obese patient is scheduled for his fourth hip replacement. While the first hip replacement, several years ago, was successful, his second and two hip replacements involved long hospitalizations and protracted recovery time, in part because of the patient's inability to handle the pain of rehabilitation. While the attending surgeon is willing to do the hip replacement, others, including you, ask if this is a good use of the institution's limited resources, specifically a bed and rehabilitation and nursing personnel and services. What should you do?

Unless there is a policy or law limiting the number of times a patient may receive a hip replacement, the decision should be made in accordance with what would be in this patient's best interests, not what results in the least strain on institutional resources. Allocation of medical resources should always hinge on medical need.



4

Professionalism in Clinical Practice



Introduction

Healthcare professionals (HCPs) are charged with delivering high-quality care to all patients without discrimination. To accomplish this objective, medical professionals must maintain an up-to-date fund of knowledge through ongoing education, incorporate evidence-based innovations into their practice in a timely manner, and provide efficient healthcare with transparency and compassion. As another measure of high-quality practice, healthcare should be provided in collaboration with colleagues, with appropriate referrals to alternate clinicians and/or specialists when clinical evaluations or interventions are outside an individual HCP's scope of practice.

To maximally respect individuals and promote trust in the medical system, measures should be in place to ensure healthcare settings are safe for patients and HCPs. Healthcare institutions and individual HCPs are responsible for safeguarding an environment free of harassment or prejudice throughout the care continuum, including upon transfer of care or discharge from a care facility. HCPs and healthcare institutions should promote a culture of patient safety and systems of practice that aim to report, analyze, and prevent medical errors. HCPs should be truthful in documentation of medical errors and, although institutions may have policies or offer guidance regarding what HCPs may say to patients in situations involving medical error, HCPs are nonetheless ethically required to treat patients with compassion. Finally, to maintain a healthcare workforce that can provide the best possible care, HCPs must support their own health and wellness, encouraging the same of their colleagues.

Obligations to Maintain Healthcare Professional Competence in High-Quality Care

In accordance with professional, legal, and institutional requirements, clinicians should remain up to date on medical knowledge. HCPs should also remain informed of cultural sensitivities important to providing patient-focused care.

1. HCPs should maintain their competence in standard-of-care practice by participating in self-assessment and continuing medical education initiatives.
2. HCPs should adopt proven novel medical innovations into their practice.
3. HCPs should be aware of the limitations of their own knowledge, declining to deliver care that is outside the scope of their competence. In these cases, clinicians should refer patients to colleagues able to provide appropriate care.

Potential Patients

Under certain circumstances, HCPs may have justifiable reason to decline to provide care to patients. These include a need for care outside the clinician's scope of practice, a request for scientifically invalid or otherwise not medically indicated care, a lack of available resources and inability to provide an acceptable alternative of care, an abusive patient, or a valid conscientious objection to the intervention required. Institutional ethics committees should be consulted in cases where HCPs feel they have justifiable reasons to decline provision of care to a patient.

1. HCPs may not decline to provide care to patients for discriminatory reasons.
2. HCPs who decide they cannot provide care or must terminate a relationship with a patient should attempt to ensure that the patient has access to alternate means of care and to maintain any continuity of care possible (see "Ending a Professional Relationship with a Patient" below). HCPs should be aware of the limitations of their own knowledge, declining to deliver care that is outside the scope of their competence. In these cases, clinicians should refer patients to colleagues able to provide appropriate care.

Conscientious Objection in Clinical Practice

If HCPs feel that providing certain medical services conflicts with their beliefs and values, they may express conscientious objections to delivering this care. For a conscientious objection to be considered potentially valid, the beliefs and values on which it is based must be sincerely held and not motivated by discrimination or self-interest. As the HCP's professional and ethical duty is to practice in the interest of the patient's well-being, circumstances under which conscientious objections are considered acceptable should be very rare and should involve consultation with institutional ethics committees, legal counsel, and any other necessary administrative body. HCPs should also employ necessary measures to minimize the burden their objections have on the patients they treat and on their colleagues' workload.

1. When possible, HCPs should make their conscientious objection to provision of specific care clear to patients before a patient-clinician relationship is initiated.
2. In cases of valid conscientious objections, HCPs are ethically required to ensure that patients can receive the care they need from other clinicians or institutions, and to maintain any continuity of care possible (see below, "Ending a Professional Relationship with a Patient"). provide appropriate care.
3. Claims to conscientious objection are significantly limited in emergency care situations, in which HCPs must treat patients in accordance with their medical needs.

Ending a Professional Relationship with a Patient

When possible, HCPs and medical institutions should attempt to prevent the termination of a viable clinician-patient relationship by supporting mediation of disagreements and employing any additional clinical and psychosocial support required. A professional relationship between HCPs and patients should be terminated only in

rare circumstances and for specific, justifiable reasons (see "Potential Patients" above).

1. HCPs who decide to terminate a clinical relationship should give the patient timely notification and facilitate exploration of alternative avenues to care, including consultation with other clinicians or care facilities.
2. When a clinician-patient relationship is justifiably terminated, HCPs and medical institutions should make efforts to facilitate transfer and continuity of care by making the patient's medical records available as needed, as well as geographical transport of the patient where appropriate.

Providing Safe Discharge

Ethically and professionally, HCPs' obligations of care for patients include the arrangement of safe discharge. Planning should account for patient-specific factors required for transition to ongoing high-quality medical care after discharge; these may include access to medication, consistent access to food, stable housing, and feasibility of transport to medical appointments.

1. HCPs should only discharge patients from a healthcare facility when it is medically indicated and there is a safe discharge plan in place.
2. When necessary, HCPs should coordinate with institutional and community organizations and resources to establish safe discharge plans for patients.

Obligations to Maintain Healthcare Professional Health and Well-being

HCPs must maintain their own health and wellness to best perform their obligations to patient care. As safeguarding patient well-being is primary to the ethical and professional obligations of HCPs, a clinician who is impaired in the ability

to provide safe and competent care should not practice medicine and should seek and be offered help. Institutions should have policies to guide identification, appropriate intervention, provision of supportive resources, and reporting in cases of clinician impairment. Both clinicians who seek help for impairing conditions and other HCPs who may report them to their institutions should be protected from punitive consequences.

1. HCPs should seek timely and appropriate support resources for their own health complications, substance use disorders, or other personal problems that may impact their ability to provide appropriate patient care.
2. HCPs should not continue to practice medicine if facing impairment, including that due to physical impairment, psychiatric illness, substance use, or acute stressors or life events.
3. HCPs should create a supportive environment for colleagues. This includes working collaboratively and encouraging openness in discussing personal hardships or the need for help.
4. HCPs should be alert to signs of impairment among colleagues, facilitating appropriate interventions and helping to coordinate support resources. HCPs must be aware of and closely follow institutional guidelines and mechanisms for reporting potentially impaired colleagues.

Appendix 1:

Sample teaching cases

Case 1

Mr. V is a 32-year-old man who is admitted to the hospital for treatment of bacterial endocarditis as a complication of intravenous heroin use. You see in his medical chart that he has been admitted for similar infections at least twice before, each time leaving the hospital before completing a full course of antibiotics. Dr. L, a medical resident on

your team, voices her reluctance to care for Mr. V, citing her moral objection to the patient's ongoing drug use and noncompliance with prior treatments. Dr. L requests not to be involved in Mr. V's care. What should you tell Dr. L?

The patient deserves dedicated and compassionate care; refusing to provide this care would be discriminatory and in violation of ethical and professional duties. While it is a sensitive topic, this can be an important teaching moment with Dr. L to discuss how the presence of personal biases may impact patient care. You should counsel Dr. L that, in addition to his acute infection, the patient's substance use disorder is a clinical diagnosis that requires medical attention and that her obligation to care for Mr. V may not be affected by her feelings about his substance use.

Case 2

Your patient, Mrs. B, is a 72-year-old woman who was admitted to the hospital for treatment of a myocardial infarction one week ago. She has received the necessary clinical care and is now medically stable to leave the hospital. However, in discussion with the patient and the hospital social worker, you have come to understand that she lives on the fifth floor of a building without an elevator, and her current physical condition is too limiting to allow her to descend and climb so many stories when she needs to leave the house for routine purposes such as purchasing food or refilling her medications. How should you proceed in coordinating her hospital discharge?

Discharging the patient from the hospital to her current home environment will create an unsafe situation. A safe discharge should be coordinated by involving the patient's family, who may be able to assist her with everyday activities, as well as social services in the community. If these measures will not suffice in ensuring the patient receives a safe discharge from the hospital, the clinical team should consider an alternate discharge plan, including the possibility of transferring the patient to an assisted care facility while she receives the physical rehabilitation necessary to return to living in her home.

Case 3

Your colleague, Dr. S, has been exhibiting abnormal behavior at work for the last month. He is frequently late and often appears confused, forgetful, and disorganized. There have been two occasions where you noticed that he did not appropriately follow up on important patient lab results. When you gently confront him about this, he shares that he is facing a personal crisis, but assures you that it is under control. However, later that week, other members of the clinical team ask for your help, reporting that Dr. S has not been responsive to acute alerts about his patient's clinical status. What should you do?

It is ethically and professionally necessary to intervene when a patient's care is potentially jeopardized. You should be attentive to a colleague's behavior that has the potential to compromise safe and appropriate patient care. Clinicians may be impaired in their ability to adequately care for patients due to several reasons, including physical or mental health concerns and substance use. When you have such concerns, it is often appropriate to speak to your colleague, trying to help identify supportive resources. You should be aware of and follow your institution's reporting policy for clinicians exhibiting impairment in their ability to practice safely. Institutions should have mechanisms for assisting impaired clinicians and systems intended on intervening appropriately in these situations, rather than creating punitive consequences for impaired clinicians or those who report them.



5

Patient Privacy & Confidentiality



Introduction

Trust between patients and healthcare professionals (HCPs) is the foundation of good patient care. Preserving confidentiality fosters trust and a willingness to share sensitive personal information, both critical to effective care. In addition to institutional and legal requirements, HCPs have an ethical obligation to maintain and protect all patients' personal health information. Certain patients or populations require safeguards. Obligations to maintain privacy and protect confidentiality, however, are not absolute, and HCPs must understand the scope and limits of confidentiality and communicate to patients' circumstances when information may be shared.

All entities involved in patient care shall establish privacy policies covering the management of patient information and policies on how they collect, use, retain, and disclose information and identify and mitigate privacy risks. HCPs should understand and act in accordance with these policies.

Exceptions to the Duty of Confidentiality

There may be times when HCPs must breach patient confidentiality. These instances must be explained clearly and sensitively to patients, and information that will be shared must be stated explicitly; these instances should also be documented in the medical health record.

1. HCPs should understand and follow their institutions' policies for protecting and/or disclosing patient information.
2. HCPs are morally required to describe limits to confidentiality to patients when the context warrants it, assure patients that only the amount of information to fulfill their ethical or legal obligations will be shared, and that legal and health authorities work to protect patient privacy to the extent practicable.
3. Health information may be shared if patients give consent; HCPs must ensure that patients understand which specific information will be shared and with whom it will be shared.

4. HCPs may disclose confidential information of patients who lack decision-making capacity to healthcare personnel when it is in the patients' best interest to do so. The disclosure must be documented in patients' health records.
5. Confidentiality must be breached if HCPs believe patients pose an imminent threat of serious harm to themselves or others.
6. HCPs are obligated to notify authorities if they suspect that a patient's illness or injury may be the result of criminal activity.
7. HCPs must comply with laws regarding subpoenas for access to confidential information.
8. HCPs are legally and ethically required to report cases of certain communicable diseases to health authorities to help prevent harm to the public, even over the objection of patients.

Maintaining Privacy During Physical Examination

1. Ethically, legally, and professionally, HCPs are required to obtain informed consent before any clinical examination. Consent must be obtained in front of a chaperone for intimate examinations, and it must be documented in the patient's health record.
2. HCPs should ensure that patients have appropriate private space for undressing and are provided with gowns and/or draping prior to physical examination.
3. HCPs should explain to patients their reasons for conducting a physical examination and what to expect during the examination in a way patients will understand. They should provide time for patients to ask questions before and after the examination.

4. HCPs should ask whether patients would like an authorized chaperone present during examination. Examination of patients of the opposite gender should be performed with the accompaniment of a chaperone. By law, female patients must have chaperones.
5. HCPs should reconfirm consent before beginning an intimate physical examination, including examining the genitalia, rectum, or female breasts, in front of a chaperone, if present.
6. During a physical examination, clinicians should expose only the parts of the body that are required for the clinical assessment.
7. HCPs should record patients' permission to involve medical students or trainees during physical examinations and expose only parts of the body required for clinical assessment and educational objectives. Patients must be informed that they can refuse such requests.

Intimate Examinations of Female Patients

In addition to the above guidelines for maintaining privacy and respect modesty, HCPs should be sensitive to the fact that female patients may require special considerations or sensitivity during physical exams in general and during intimate exams specifically.

1. In accordance with respect for persons, HCPs should explain what will take place during the examination and alert patients to what to expect as the examination continues.
2. HCPs should advise patients that they may ask the HCP to stop the examination at any time.
3. HCPs should ensure that a chaperone is readily available; chaperones can be other healthcare staff or a family member if the patient provides consent.

4. Patient requests for a family member, in addition to the required chaperone, should be honored if it will not interfere with the care of the patient.
5. Consent must be obtained in front of a chaperone for intimate examinations, and it must be documented in the patient's health record.

Confidentiality for Minors

Parents usually make decisions about the care of their children, although there are instances when children may legally make decisions regarding care for themselves. Confidentiality and privacy must be maintained to the greatest extent possible.

1. HCPs may withhold information from parents or guardians if it is in the best interest of the patient, and if the law allows. Under such circumstances, HCPs should design a care plan with which minors can comply and HCPs should monitor the plan's implementation.
2. HCPs should understand and follow their institutions' policies and professional codes regarding confidentiality of minors.
3. Legally, clinicians must notify health authorities if they suspect a patient has certain communicable diseases. Ethically, clinicians should not disclose identifying information when feasible, and disclose only as much information as is needed to assist public health measures.

Confidentiality for Vulnerable Patients

All patients are vulnerable—to death, disease, chronic conditions, suffering—but some patients are vulnerable in additional ways, such as those with cognitive disabilities, the elderly, poor, those with limited educational background or limited access to health services, those who cannot care for themselves, those who do not understand the

HCPs' language, and others. HCPs should afford vulnerable patients, to the extent practicable, the same privacy and confidentiality protections as they do other patients; however, the obligations of privacy and confidentiality may require expanding the scope of information-sharing to alternative decision-makers or other HCPs.

1. HCPs should be attentive to vulnerable populations' increased risk of physical, mental, emotional, or sexual abuse or neglect and report suspected or documented cases to the appropriate authorities.
2. HCPs are ethically obligated to secure interpreters for patient who cannot speak, hear, or understand the HCPs' language and assure patients that confidentiality will be maintained.
3. HCPs should refer patients who are unable to care for themselves to social or other services and share information as is necessary to ensure proper care.

Patient Privacy during Transfers

Patient privacy may be at heightened risk during transfers, such as within a healthcare facility or between facilities, to an ambulance or aircraft, or between wards and care sections. HCPs should be alert to patient privacy during transfers and act to ensure it.

1. HCPs should ensure that patients' bodies are not unnecessarily exposed during transfer.
2. HCPs should ask whether patients would like additional coverings or precautionary steps regarding privacy during transfer.
3. HCPs should avoid discussing or otherwise revealing patient information during transfer.

Disclosing Patient Information to a Family Member

Patients are the owners of their health information. The ethical principle of beneficence requires that the safety and well-being of the patient guide decisions regarding disclosure, except in specific circumstances (see "Exceptions to the Duty of Confidentiality" above). Those who request access to patient information must have valid and compelling reasons to do so.

1. HCPs should not share adult patients' information with family members without explicit permission. Exceptions include when patient welfare is at stake; the patient is incapable of consenting and the information is necessary for alternative decision-making; or there is imminent risk of serious harm to the patient or others. The minimum amount of information to mitigate harm should be provided.
2. Patients' family members may request or even demand patients' health information without their permission. In such cases, HCPs must be prepared to explain why they cannot provide this information without the patient's direct permission or instructions.

Protecting Patient Information

Hospital systems or individual institutions are required to have security measures in place to protect all facets of clinician-patient interactions. Access should be password-protected and strictly monitored. Institutions should disseminate policies about information security and require annual courses for all employees and vendors.

1. HCPs should ensure confidentiality of patients' physical or electronic records in accordance with their institutions' policies.

2. HCPs should avoid discussing patient information in public areas, such as elevators or hallways.
3. HCPs should be aware that the use of third-party apps and communication channels (e.g., text messaging or personal email) jeopardizes patient privacy and confidentiality and should be familiar with their institutions' policy regarding such communication.
4. HCPs may use social media to support their ongoing education, expand their networks, and educate the public about health issues. While engaging online, HCPs must uphold the ethical guidelines of the patient-clinician relationship, just as they would in any other situation. No personal patient information should be disclosed on social media; doing so poses risks to the professionalism and trust in a patient's HCP. Patients may, however, consent to the sharing of agreed upon and de-identified information for professional purposes.
5. HCPs must always safeguard their access code to patients' files and not share it with anyone to ensure security of patient records.
6. HCPs should not share a patient's personal health information with their employer. Exceptions include instances in which the patient's physical or mental health poses a direct risk of serious harm to their employer or institution. In such cases, HCPs should contact the appropriate authorities.

Maintaining Confidentiality in Telemedicine

1. HCPs should practice telemedicine only through approved and secure platforms and in offices or spaces that afford privacy.
2. HCPs conducting virtual consultation should inform patients about safeguards in place to protect confidentiality and cyber threats

unique to the electronic transmission of information as well as limitations of virtual consultation.

3. HCPs must ensure that patients, or their alternative decision-makers when applicable, have consented to the teleconsultation when they are fully aware of limitations of the service and the process of providing the service through telemedicine. If recording is involved during the delivery of this service, HCPs must obtain patient authorization and abide with the guidelines in "Audio/Visual Patient Recording" below.
4. Guidelines for confidentiality for in-person consultations apply to virtual consultations.
5. Intimate assessment involving genitalia, rectum, or female breast via telemedicine is not permitted and must not be performed.

Maintaining Confidentiality in Audio / Visual Patient Recording

1. HCPs must secure the consent of patients or alternative decision-makers before photographing or audio- or video-recording patients. The consent discussion must explain the purpose of the photographing/recording and potential benefits and risks, including concerns related to privacy as well as the potential for additional uses. This consent should be documented.
2. HCPs should clearly inform patients that they are free to stop the recording at any time, for any reason, and prevent it from being shared.
3. Recordings/photographs are part of patients' medical records and are subject to the same privacy and confidentiality rules, as well as to relevant laws and regulations.

4. Patient information should be de-identified if recordings are used for educational or training purposes.
5. Patients must give explicit consent for photographs or recordings to be used in their healthcare institution's advertisements. HCPs must protect patients by de-identifying information unless the patient has given permission to be identified. Advertisements must adhere to laws and regulations regarding patient privacy and confidentiality.
6. HCPs must obtain patient consent regarding audio/visual recording during intra-operative or laparoscopic procedures. They should explain the purposes of the recording and its potential uses (e.g., educational sessions). HCPs must adhere to institutional policies regarding the protection, management, and erasure of any recorded surgical procedures.
7. For deceased patients, HCPs must seek consent from the alternative decision-maker to make any sort of recordings for educational or research purposes and ensure that the identity of the patient is protected.

Preserving Patient Privacy and Confidentiality During Educational Sessions

1. HCPs must receive permission from the patient to allow trainees to observe the clinician-patient encounter.
2. All trainees should be familiar with their institutional privacy and confidentiality policies.
3. Where the use of audio/visual recording is involved for educational purposes, HCPs must abide by the guidelines listed under "Maintaining Confidentiality in Audio/Visual Patient Recording."

4. All patient information used for educational purposes is considered part of the patient's medical record and is subject to applicable laws and regulations.
5. Accepting payments to permit trainees or an observer to witness a patient-physician encounter is prohibited and is considered in breach of the law.

Maintaining Confidentiality in Research

1. HCPs conducting or assisting research should secure the confidentiality of participants' information from research teams and/or research sponsors in accordance with laws and regulations, including governmental policies on human research subjects' protections. Appropriate safeguards should be used with all identifiable electronic data and access protections.
2. Researchers should abide by legal standards on human research subjects for the storage, maintenance, use, and security requirements for all research, including genomic research.
3. Researchers, including clinician-researchers, must inform patients of the privacy and confidentiality risks posed by their participation in a study.

Maintaining Confidentiality in Legal Proceedings

There may be instances when HCPs must divulge confidential patient information during legal proceedings. HCPs should follow applicable laws, with the patients' interests in mind.

1. HCPs should consult their institution's legal department before participating in legal proceedings.

2. HCPs may be asked to serve as experts in legal cases. Patient information must be kept confidential to the extent possible, and clinicians should follow expert legal guidance.
3. HCPs may be involved in the care of incarcerated people; these patients should be afforded the same privacy and confidentiality as other patients, according to applicable laws and regulations.

Post-Mortem Privacy and Confidentiality

HCPs obligations to protect patient confidentiality continue after patients die. Records remain confidential and should be managed in accordance with laws and regulations. Family members or others may request information about deceased patients. To ensure that a requester is authorized to receive such information, HCPs should consult and comply with relevant guidelines, laws, and regulations.

1. HCPs must continue to respect and protect the confidentiality and privacy of a deceased patient as per their known wishes or those of their alternative decision-makers if the deceased patient's wishes are unknown.
2. The deceased patients' medical records should remain confidential and must be managed in accordance with the relevant laws and regulations.
3. If a deceased patient has given clear instructions to maintain confidentiality, the HCP must not disclose their information.
4. Limited disclosure of a deceased patient's information may be permitted if an authorized family member requests access, if their purpose is verifiable, and if it does not cause harm to the deceased person's family.
5. HCPs may disclose deceased patients' information if compelled to do so by a legal authority or if doing so is considered necessary to prevent imminent or severe harm to others.

Appendix 1:

Sample teaching cases

Case 1

You are an emergency room physician. A 42-year-old man is brought in with chest pain. He is awake and alert. A woman comes to you demanding information about the patient, saying that she is his wife and presenting her identification card verifying this. What should you tell her?

Legally and ethically, you cannot release a patient's medical information to anyone unless the patient gives consent for you to do so. You should explain to the wife that you understand her concern, but that you are unable to share medical information with her without her husband's consent. You may let her know that her husband will be informed of her presence and concern.

Case 2

You're an oncologist, and your female patient is awaiting the results of a biopsy to determine if a tumor is malignant. Her son calls you and asks you to tell him about the results instead of his mother, because her family is concerned that the bad news will depress her. The son is sincere and genuine in his concern, and you believe that he has his mother's best interests at heart. What do you tell him?

Ethically, professionally, and legally, medical information, including test results, should first be reported to the patient. Without explicit instruction from the patient which should be documented in her health record—the son should not receive the patient's confidential medical information. It may be that the patient would prefer her test results be told to her son, but that is her decision to make. Note that there are exceptions to this requirement; see "Limits of Confidentiality" above.



6 Digital Health and Virtual Care



Introduction

The scope of digital health in medicine is broad, encompassing technologies such as mobile health apps and platforms, health information technology, wearable devices and remote monitoring, telehealth and telemedicine, and personalized medicine. The rise in digital health and virtual care stands to improve the efficiency of and access to healthcare delivery, increase the cost-effectiveness of care, and integrate/automate technologies that ease healthcare burdens on a globalized population. However, technological advances also fundamentally alter the clinician-patient relationship and pose new ethical risks, particularly to confidentiality and privacy, as well as trust in medicine. As such, healthcare professionals (HCPs) must adhere to the standards issued by Shafafiya and governed within the centralized Malaffi database and should strive to uphold the highest ethical standards when implementing digital and telehealth measures.

Digital health tools may be used advantageously in a variety of ways. For instance, electronic records increase the transferability of and access to personal health information, providing patients and their families with greater autonomy over their health. Additionally, remote monitoring can facilitate the delivery of healthcare in ways that save time, effort, and money, expanding access to more patients. On the other hand, digital health has the potential to cause harm, including incursions on privacy and consent.

The cornerstone of successfully integrating digital health into clinical care will be the extent to which HCPs embrace it as an enhancement of their abilities and expertise rather than as their replacement. Certain aspects of in-person care must be maintained. For instance, performing regular physical examinations ensures that current and ongoing needs of a patient are identified. Similarly, all HCPs who participate in telehealth/telemedicine must maintain confidentiality and must ensure that proper protections are in place. To prevent unauthorized access to patient information, all digital technologies used in telehealth and digital medicine must be approved and legally regulated.

Telehealth

HCPs may engage in telehealth services by responding to individual health queries or offering personalized health advice electronically.

1. HCPs should communicate the limitations of the professional relationship and the services provided to patients and those seeking care, ensuring they understand the boundaries and scope of the telehealth modality as compared to in-person encounters.
2. HCPs should guide site users on how to arrange follow-up care when it is deemed necessary, providing clear instructions and recommendations for seeking further medical attention, including in-person appointments, if required. HCPs should also themselves maintain vigilance in escalating care from video to in-person when clinically warranted.
3. HCPs should follow the local regulatory body's Standard on Tele-medicine, including always using private locations for telehealth services. Patients should not receive telehealth services in public or semi-public settings, absent patient consent or exigent circumstances. HCPs should pause consultation if/when another individual enters the virtual room to ensure privacy and should seek permission from the patient before continuing the visit. Likewise, clinicians should take note of who is physically present with the patient during the virtual encounter and secure patient permission and consent.
4. HCPs should encourage telehealth users to inform their primary healthcare providers, and/or any other clinicians relevant to their care, about the online health consultation, emphasizing the importance of maintaining open communication and continuity of care, even if immediate in-person care is not required.

Ethical Consideration for Patients' Access to Data and Devices

Electronic medical records can be accessible from private and government hospitals to ease the patient experience and improve patient satisfaction.

1. Healthcare Institutions should develop policies for which types of health information may be held as classified and policies for cases in which an individual's wishes regarding privacy may be over-ridden.
2. Decisions to opt out of having one's information in Malaffi should be made in consultation with the relevant ethics committee or regulatory liaison.
3. The cross-border transfer of patient data may be permissible in some cases per legal guidance.

Patient Autonomy and Informed Consent

Patient autonomy should be respected in the realm of digital health and virtual care.

1. HCPs must adequately inform patients about the nature, purpose, benefits, and risks of using digital health technologies and virtual care services.
2. HCPs should obtain informed consent in a clear and understandable manner, ensuring patients are aware of the limitations, security measures, and potential privacy risks associated with digital health platforms or virtual care encounters.
3. HCPs should disclose any financial stakes, investments, or other conflicts of interest in any telehealth/telemedicine application or service and should eliminate such conflicts of interest to the most reasonable extent possible.

4. Patients have the right to opt out or withdraw their consent for digital health services or virtual care at any time without compromising their access to appropriate healthcare.
5. Healthcare institutions should take every measure possible to ensure the safety and confidentiality of patient data. Even so, there is still a risk that patients may be identified. HCPs should inform all patients of these potential breaches of privacy.
6. To achieve informed consent for research using patient data, there should be a multi-model process in place to ensure patients understand, to the greatest extent possible, what data is being recorded and how it will be used, analyzed, and protected in any study. Patients should also be informed of any risks the research poses to the confidentiality of their data before consenting to participate.

Appendix 1: Sample teaching cases

Case 1

One of your patients, Mr. R, has just been referred to you by a colleague at a different institution. This colleague sends you a text message about the patient's condition along with an X-ray and a photo of his medical chart. You find this information helpful but worry about Mr. R's privacy. What should you do in this situation?

According to the UAE's "Health Data Law," the transfer of patient data is permitted in specified circumstances. In this case, while there may be good reason for the HCPs to share information about the patient's condition, it is required that the associated data must be securely encrypted prior to transfer. For this reason, HCPs should ensure that when communicating about patients, they are doing so using approved and regulated systems. HCPs should not store any personal health information of their patients on their personal devices. Additionally, Mr. R's former HCP must obtain permission from the patient to share his medical information with another institution.

Case 2

An HCP-researcher wishes to analyze data on all the cases of childbirth at their institution in the last year to explore the potential correlation of time of day on the rate of C-section births. The HCP-researcher is also interested in including data on their patients' ethnic backgrounds in his study. He plans to de-identify the data to maintain the patients' privacy but is not sure if and how he should proceed with his research. What should he do?

While digital health data creates opportunities to use patient data for research, researchers must still seek patient consent to use their information for research given the fact that it is almost impossible to anonymize patient data. The HCP-researcher should obtain the approval of a research oversight committee, as well as guidance on consent that needs to be obtained. HCPs should explain to their patients how their data will be used in research, who else will have access to it, and the safeguards in place to protect their privacy. They should also emphasize to patients that even in anonymous research with safeguards in place, there is always a risk of being re-identified.

Case 3

Mr. A, a 35-year-old man who works as a taxi driver, presents to you with abdominal pain. Upon examination, there are no abnormal findings, but you would like him to follow up via telemedicine. Mr. A points out that he doesn't have regular access to a computer and has limited use of his cell phone. How should follow-up care be coordinated in this case?

Not all patients will have equal access to digital health technologies and systems. It is critical to recognize that for some patients in-person visits will still be their primary and preferred method of receiving healthcare. It is possible for some healthcare institutions to offer patients remote monitoring devices; in such cases, it is still important to maintain contact in person or via telephone to ensure continuity of care for patients for whom telehealth is less accessible.

7 Conflict of Interest



Introduction

Conflict of interest (COI) arises when the judgment or actions of healthcare professionals (HCPs) regarding their patients is influenced, or appears to be influenced, by another interest. COI can happen at any stage and with any aspect of medical care, from clinical research to adjudicating patient and colleague complaints. Relationships between industry, HCPs, and organizations can also raise COI.

The primary interest of HCPs is always the patient. Ethical principles of beneficence, nonmaleficence, and respect for persons require HCPs to act always in the best interest of patients, in accordance with their values and preferences. Even the appearance of COI can damage the trust that patients and the public place in HCPs and the field of medicine—trust that is essential to effective and ethical patient care.

Prescribing

HCPs with the authority to prescribe medications must prescribe products or treatments based only on patient needs and scientific evidence, according to current standards of care, and the expectation of optimal benefit for the patient.

1. HCPs must decline all offers of payment or compensation from sponsors or drug companies for prescribing, using, or recommending their products (see “Inducements and Kickbacks,” below).
2. HCPs should not recommend pharmacies in which they have a financial interest.
3. HCPs serving on committees, including formulary and policy-setting boards, must disclose all potential COIs to fellow committee members and supervisors.

Referrals

Referrals are important to medical practice, but HCPs must be alert to potential COI. Institutions should freely allow HCPs to refer patients to external entities and establish policies for overseeing referrals.

1. Referrals should be objective, medically indicated, and intended to enhance patient care.
2. Professional codes of conduct and the ethical principle of beneficence require HCPs to refer a patient to another HCP who might be better able to treat the patient when clinical circumstances require it.
3. HCPs should refer patients to specialists if such collaboration will enhance patient care.
4. HCPs are legally and ethically barred from receiving remuneration of any type for any referral.
5. Word-of-mouth referrals are common practice and are ethically appropriate, so long as HCPs do not encourage or in any way incentivize patients for such referrals.
6. HCPs may refer patients to facilities or practices in which they have financial relationships if it is in the best interest of patients. HCPs must disclose these relationship(s) to patients.
7. Ethical principles of respect for persons and beneficence require clinicians to offer alternative arrangements for care if requested and resume care of the patient if an HCP referral is rejected or is not able to be completed.

Financial Interests in Companies

COI arises if HCPs have financial interest in businesses seeking to provide products or services to them or their institutions. These guidelines apply to businesses in which HCPs' family members or friends have a financial interest, or businesses that employ them.

1. HCPs should not be involved in their institutions' purchasing decisions involving companies in which they have a financial interest. They should recuse themselves from committees that make purchases from or decisions involving companies in which they have a financial interest.
2. HCPs must disclose financial interest in any business or company that provides, or seeks to provide, products or services to their organizations.
3. On occasions when CME content is developed or offered by companies in which HCPs have a financial interest, institutions and HCPs must act to mitigate COI to maintain trust in medical education. CME educators and content providers should be selected by professionals unaffiliated with industry funders.

Telemedicine

1. In terms of potential COIs, HCPs should treat virtual patient relationships and consultations as they would if they were in person.
2. HCPs must disclose financial interests in telemedicine products, applications, or services and use those products only if they best serve the needs of patients.

Inducements, Incentives, and Kickbacks

An inducement, or bribe, is cash, a gift, or other incentive given in exchange for favorable treatment or provision of a service. Kickbacks are "commissions" in exchange for service. Unlike other types of gifts, inducements are intended to influence HCP behavior. Accepting them is ethically impermissible. Kickbacks are illegal, unethical, and violate professional codes of conduct. Institutions should establish protocols to monitor kickbacks and inducements.

1. Ethically, professionally, and legally, HCPs should never accept gifts, in any form, in exchange for providing, prescribing, trading, or otherwise using any product or service.
2. Not all incentives create COI, but in the field of medicine incentives can be like inducements and raise serious COI concerns. Incentives for prescribing medical products, admitting patients, referrals, and performing procedures/surgeries should be declined.
3. HCPs should not provide unnecessary treatment that may cause needless expense solely to benefit themselves or their practices or institutions.
4. Insurers often provide incentives to HCPs to accept their plans. HCPs must carefully evaluate insurance plans and base acceptance solely on whether they are in the best interests of patients.
5. HCPs should report all offers of inducements and kickbacks to the appropriate person or committee in their institutions. Similarly, they should report colleagues who offer or accept them.

Industry Funding, Support, and Honoraria

Collaborations between industry and HCPs spur innovation and contribute to local and national economies. However, such collaborations must be conducted ethically and transparently so as not to damage trust in HCPs, organizations, or the practice of medicine. Local regulatory bodies' regulations require institutional support from industry to be managed at the corporate/organizational level, not by individual HCPs

1. Industry may offer to fund HCPs or institutions by supporting training or awards for trainees. HCPs and/or their institutions should select such trainees according to their own independent criteria; funders should not have input into the selection of trainees receiving awards.
2. HCPs who receive funding to speak at conferences should present material that is evidence based, reliable, accurate, valid, balanced, and up to date; they should not in any way commercially advance the interests of funders. HCPs should disclose the receipt of funding to speak at conferences to the audience verbally and within the presented material.
3. All honoraria, funding, and grants should be disclosed to appropriate offices or personnel.

Intimate Relationships

Intimate relationships between HCPs and patients, whether romantic or sexual, are ethically fraught and always create COI. The power imbalance has significant potential to affect 'patient care and damage trust in HCPs, institutions, and the practice of medicine. HCPs objectivity may be jeopardized, potentially compromising care of patients. HCPs must comply with laws governing sexual relationships, including consensual relationships, in instances when one person is in a position of authority over the other. Further, intimate relationships could have legal consequences for HCPs and/or their practices or institutions and could jeopardize their licenses

1. Romantic or sexual relationships between HCPs and their current patients are unethical.
2. HCPs who wish to engage in personal relationships with patients must end professional relationships first. Patient well-being remains paramount, and HCPs must refer patients to qualified colleagues.
3. Romantic or sexual relationships with former patients are ethically problematic and thus ill-advised, as the power imbalance may remain even if a patient is no longer under an HCP's care.
4. HCPs who do pursue relationships with former patients must never exploit the trust that was established in the former professional relationships or exploit medical knowledge about or influence over patients to their advantage.
5. HCPs who provide mental or emotional healthcare to patients should be especially sensitive to the potential harm personal relationships may cause former patients.

Intimate Relationships with Third Parties associated with Patients

Spouses, parents, adult children, guardians, or others who accompany patients to medical care are there to guide, comfort, or represent patients and should not be distracted from that role; nor should HCPs' attention be diverted from the patient, raising COI as well as the potential for harm. Thus, intimate relationships with third parties should be avoided.

1. HCPs must not enter relationships that could compromise patient care.
2. HCPs must not enter relationships that take advantage of a third party's trust or emotional state. HCPs must be cognizant of the emotional state of the third party.

3. Intimate relationships between HCPs and caregivers can damage trust in the HCP-patient relationship and can place the HCP and institution at legal risk. They should be avoided.

Treating Family, Friends, Associates, VIPs, Senior Personnel

HCPs should not treat members of their immediate families, including themselves, except in emergency situations or for very minor conditions, and they should avoid treating patients with whom they have personal relationships. These relationships can affect HCPs' objectivity, judgment, communication, and patient care. Patients may be reluctant or embarrassed to discuss sensitive symptoms or disagree with recommendations, affecting physical exams, sharing of pertinent information, and discussions of treatment plans. HCPs may be uncomfortable discussing sensitive information with famous patients or those in supervisory positions, or they feel pressured to yield to requests for prescriptions, treatments, or referrals when not medically indicated.

1. HCPs should not give preferential treatment to any patient at the expense of patients with more urgent medical needs; nor should family, friends, the famous, or the powerful influence HCPs' care of or divert attention from other patients.
2. Patients may feel entitled to pressure clinicians with whom they have close relationships to prescribe products or treatments that are not medically indicated. Although HCPs may be hesitant to decline such requests, they should prescribe products or treatments based only on fully assessed patient needs, according to medical expertise and the expectation of benefit to the patient.
3. HCPs should refer family, friends, associates, and personnel who are in a supervisory role to qualified clinicians for treatment, when possible. Referrals should be in the best interest of the patient and should not involve special or preferential treatment for the patient.

4. Fame, wealth, social influence, or employment status of patients should not "purchase" medical care otherwise unavailable or not medically indicated.
5. HCPs may ethically advise or advocate for patients with whom they have relationships, such as by acting as interpreter (of language or medical terms) or accompanying them to appointments.
6. In emergencies, HCPs must treat patients with whom they have close relationships until another qualified clinician is available. Patients' medical information must be shared with the patients' primary care clinicians or others who assume their care.
7. Privacy and confidentiality should be strictly maintained. HCPs should be sensitive to media or other interests in celebrity patients. Trainees should understand their similar duties to protect privacy.

Physicians as Researchers

HCPs frequently pursue research interests while caring for patients, and patients may participate in clinical research conducted by their HCPs. Despite this dual role of clinician-researcher, the healthcare of the patient is paramount and supersedes research goals. (See chapter titled "Clinical Research" for further discussion.)

1. HCPs who conduct research involving patients are required to follow ethical, legal, and institutional guidelines regarding COI.
2. To avoid the appearance of COI, clinician-researchers must explicitly inform patient-subjects of their dual roles and assure them that patient well-being is their primary concern. Transparency is essential to maintain trust in the HCP-patient relationship.
3. HCPs who find themselves prioritizing research should refer patients to qualified colleagues.

4. HCPs and physician-researchers must ensure that patients' consent is voluntary and that patients do not feel pressured to participate or remain in a research study.

4. Industry funding of trainee education and related activities is permissible under certain circumstances. See "Industry Funding, Support, and Honoraria" above.

Gifts:

Gift from patients

Professional and ethics codes bar HCPs from accepting gifts from patients.

1. HCPs should not request or encourage gifts, donations, or bequests from patients.
2. HCPs should not ask, encourage, or make patients feel pressured to donate to other practices, institutions, businesses, people, or organizations, as such donations raise COI.

Gifts from industry

HCPs may be offered gifts from industry, research sponsors, and other entities, especially pharmaceutical companies, which rely on HCPs and institutions use or prescription of their products. Industry support for travel, lodging, registration, entertainment, event tickets, or meals are also forms of gifts. Institutions should establish policies regarding gifts and make them known to all staff.

1. HCPs must not request or encourage gifts from anyone with whom they have a business relationship; nor should they ask for donations or bequests to their institutions.
2. HCPs must refuse gifts from any entity that expects quid pro quo consideration, such as by prescribing or recommending a product or service (see "Inducements and Kickbacks" above).
3. HCPs may accept in-kind gifts only of minimal value or that benefit patients directly.

Selling Medical Products:

Health-related products

HCPs may ethically sell non-prescription health-related products in which they have a financial interest, yet it creates conditions for COI and can threaten patient trust in the HCP and the practice of medicine.

1. HCPs should only sell products that address immediate, medically indicated needs of patients.
2. HCPs should base their judgments of expected benefit on peer-reviewed studies or reputable, unbiased scientific review. HCPs must explain the evidence supporting recommendation of the product plainly and clearly.
3. HCPs must disclose financial interests in products they sell or recommend to patients and their institutions. Transparency about financial interests can mitigate the appearance of COI.
4. HCPs must avoid being sole distributors of products, as the risk of COI is too great.
5. Patients must never be pressured, or feel pressured, to purchase anything from their HCPs.

Non-health-related products

Non-health-related products do not confer health benefits on patients, yet there are limited circumstances when such sales may be ethical, such as if proceeds will benefit a charity or community.

1. HCPs who sell non-health-related products to patients may not profit from the sales.

Advertising/Publicity

HCPs may ethically promote themselves or their practices if promotions are truthful, not misleading, and materials are straightforward (for example, feature HCPs' education background, information regarding fees, forms of payment and insurance accepted, and the like).

1. HCPs' claims of ability and experience must be truthful and provable.
2. Claims of the ability to treat or cure certain serious conditions may raise false expectations in prospective patients and should be avoided.
3. Patient testimonials must accurately represent general patient experience.
4. Truthful claims can be misleading if they are made in medical "jargon" or technical wording; HCPs' advertising or publicity materials must be easily understandable by laypeople.
5. HCPs should avoid aggressive advertising tactics or other methods that could pressure current or prospective patients to use their services.
6. HCPs who believe that an advertiser is unfairly targeting or attempting to manipulate prospective patients or otherwise acts in ways that may harm patients or violate laws regarding direct-to-consumer advertising should report the advertisers to the proper medical and business authorities.

7. Advertising in any form must be authorized by the pertinent authorities.

Appendix 1:

Sample teaching cases

Case 1

You are an orthopedic surgeon. After successful knee replacement surgery for a patient, you wish to send him to a physical therapy facility that you co-own. The facility is widely recognized as a leader in post-surgical rehabilitation, but you are concerned that referring the patient raises a conflict of interest because of your financial interest. Should you refer the patient to your facility or another?

Clinicians are ethically required to refer patients to facilities that will offer them the best care for their conditions, so you may refer the patient to the facility you co-own if you believe it will provide the best care for your patient. However, you must disclose this financial stake to the patient; if the patient is hesitant to be treated at the facility, you must recommend another clinician or facility.

Case 2

A cousin has asked you, an internist, for a prescription for antibiotics for a sinus infection. She is leaving for a conference and needs to feel better soon. She cannot come in for an examination, but she assures you she has had many sinus infections and knows this is one. Should you provide the prescription?

You should not write prescriptions (or recommend other forms of treatment) for patients you have not examined. This could jeopardize the health of the patient if her "self-diagnosis" is inaccurate, as well as potentially leave another condition untreated. You may also be missing crucial information pertaining to other medications she is taking or her medical history. Although it is understandable to want to help family members, ethically and professionally they should be treated as you would non-family members.

Case 3

You are an oncologist who has successfully treated a patient. The patient's family present you with a new car to show their gratitude. You assure them that it is unnecessary, but they insist, telling you that they would feel terrible if did not thank you for saving their family member's life. Should you accept it?

These kinds of situations are tricky because you do not want to quash the family's impulse for kindness; nor do you want to seem arrogant or ungrateful by declining their gift. However, you should check with appropriate organization or facility personnel to discuss the best course of action: your decision should be made in conjunction with your healthcare institution. Explain to the family the sensitive appearance of conflict that their generous gift raises and discuss the option of a charitable donation in your honor instead of a physical gift.



8

Responsibility towards Community
and Public Health



Introduction

While many of the duties and responsibilities of healthcare professionals (HCPs) are discharged to the individual patients that they treat, HCPs also have duties to populations, be those all patients, all individuals in a certain jurisdiction, or other specified populations (e.g., conducting occupational health screening for specific workers). Some of these duties and responsibilities fall in the category of public health activities focused on preventing harm and improving the well-being of the population. As such, clinicians may sometimes override their duties to individual patients in the service of public health, such as when responsibility toward protecting a patient's confidentiality is superseded by the need to report a communicable disease to public health officials who can take actions to try to prevent spread of the disease. HCPs' additional duties to populations include making the most effective use of person-power and other medical goods, disseminating accurate medical information, and combatting medical disinformation.

Duties to Public Health

HCPs must at times shift their mindsets from that of placing the utmost emphasis on the welfare of the patient that they are treating to placing the utmost emphasis on the welfare of a population of people. In this situation, the individual patient does not lose all rights; for example, a patient who has a contagious disease requiring isolation but is unwilling to voluntarily restrict movements may be detained to prevent transmission of that disease to others. Public health is controlled by government, which can, in times of need, extend its power into a variety of institutions to address the situation, whether it is to control a communicable disease or manage a disaster response. In these situations, HCPs are typically asked to follow policies that value utility over individual rights. Still, public health policies ideally restrict individuals to the least possible degree.

1. HCPs must report communicable diseases to health authorities in accordance with legal requirements, even when patients may not want their diseases reported. While confidentiality should be protected to the greatest extent possible, the reporting of communicable diseases may trigger contract tracing, in which public health officials contact

those who were exposed to the patient and may ask highly personal questions, advising them to seek testing or treatment.

2. Beyond reporting, public health rules may require HCPs to quarantine or isolate persons, impound goods, impose travel and funerary rite restrictions, shutter businesses, and prevent gatherings, among other things.
3. In situations of communicable disease and disaster response, HCPs are expected to shift to utilitarian practices that may devalue individual patients' autonomy and/or wellbeing, which may lead to moral distress.

Duties to Contribute to Best Possible Outcomes from Healthcare Efforts and Expenditures

While HCPs are trained to focus on the wellbeing of the patient in front of them, treatment decisions are made in the context of resource constraints. Thus, HCPs are urged to make the most effective use of person-power and other medical goods. Likewise, it is laudable for HCPs to use their knowledge to assist their communities through engagement in health-oriented advocacy efforts.

1. HCPs should not overprescribe or carry out unnecessary procedures that will not benefit the patient or needlessly create increased healthcare expenditures.
2. HCPs should disseminate accurate medical information and combat medical disinformation when encountered.

Role of the Clinician in the Community

To the extent that HCPs have special abilities and social standing, they are urged to use these for the wellbeing of the community.

1. HCPs should report communicable diseases and epidemics per legal requirements and preserve public safety through the reporting or certain criminal incidents.
2. HCPs should use their skills, knowledge, and expertise to improve the standards and quality of health services available in the community.
3. HCPs should consider engaging in health education programs related to their area of influence.
4. HCPs should be truthful when providing documentation, such as certification of sick leave.
5. HCPs should provide correct information to the community, including when interacting with the media.

Reporting Abuse

HCPs have an obligation to ensure their patients' safety from preventable harm, including harm from other people, in addition to illness or accidents. Questions about intimate partner harm should be a routine part of medical visits, including telemedicine visits, and clinicians should integrate best practices about how to ask these questions into their care.

1. Per legal requirements, those entrusted with the protection, care, or education of the child under the age of majority are mandatory reporters to child protection specialists or child protection units of anything that threatens a child's mental integrity or health.

2. An HCP's legal requirement to report abuse outweighs any request on behalf of the victim to prevent disclosure of the information, either to protect the abuser or the victim.

Medical Procedures Provided for Religious or Cultural Reasons

Medical procedures ought to only be performed when their benefits outweigh their harms to the patient. While there are active and polarized debates on whether procedures conducted for religious or cultural reasons (for example, male circumcision or cosmetic procedures) offer more social benefits or medical harms to the recipients, where there are relevant laws in place, the HCP must follow these. Where there are no relevant laws, it would be ideal to delay the procedure until the individual upon whom the procedure would be performed would be able to make their own decision. However, no matter what age the individual is, there may well be community or familial pressure on them that constitutes undue inducement and constrains voluntary decision-making. Furthermore, pressure may be exerted on the individual to have the procedure done earlier than later. At the very least, the individual or, if not of age, their alternative decision-maker must provide voluntary informed consent acknowledging the possible risks of the intervention and the existence of other alternatives. In some cases, it may be possible to take an approach that minimizes harm.

1. For procedures not covered by relevant laws, medical institutions should create their own policies and have processes for referring such cases to the ethics committee or assigning minors a patient advocate to speak for their interests.

Practicing Health Equity

HCPs provide an essential community service: to help all patients, no matter who they are or the problem they face. Every person has the right to the protection of his health as is best possible without consideration based on religion, gender, race, age, ability, or socio-economic status.

1. HCPs should not discriminate between patients and avoid stereotyping to provide each patient with the best quality care possible and to treat each patient based on medical need.
2. HCPs should help increase awareness of health care disparities, both to policymakers and to the public.

While it is unfortunate and understandable that your patient is stressed about the time constraint to get the necessary travel visa, you cannot complete a medical form with false information. This is both a derogation of the clinician's duty as a medical professional and of the duty to protect the community and public health.

Appendix 1:

Sample teaching cases

Case 1

Your patient is diagnosed with measles but asks you not to report her case to public health authorities. She says she is worried that she will lose her job if her communicable disease is reported and that she will remain at home and can easily avoid interactions with any other individuals. What should you do regarding the report of this case of measles to public health authorities?

Measles is a highly transmissible, reportable disease, so you will need to explain to your patient that it is required by law to report her diagnosis. However, you should also explain how her privacy and confidentiality will be maintained to the greatest extent possible. You should also explore your patient's plans for returning home and isolating there to best ensure there will not be unacceptable exposure to another person.

Case 2

Your patient needs a visa to travel to another country for his brother's wedding. You complete the medical exam and require laboratory work, and your patient's test for tuberculosis returns inconclusive. When you call the patient to tell him he needs to return to the office for repeat tuberculosis testing, he expresses concern saying that he is running out of time to get the visa. The patient asks you to complete the visa medical exam certifying that there are no issues while awaiting the results of the repeat testing, and he promises that if the second test is positive, he will not travel or attend his brother's wedding. What should you do?

9



Emergency Care



Introduction

Emergencies are extraordinary situations that often require suspension or alteration of normal procedures, as well as immediate actions to avoid the worst possible outcomes, which can impose significant ethical demands on medical institutions and healthcare professionals (HCPs). The ethics of emergencies have two extraordinary features: (1) More is permissible (e.g., breaking speed limits for the sake of rescue); and (2) More is required (e.g., taking on risks, burdens, or costs for the sake of rescue). Medical emergencies require that HCPs reaffirm their commitments to their ethical and professional obligations in situations where they are both permitted and required to do more.

In emergency circumstances, HCPs are obligated to provide urgent care even when normal prerequisites are not satisfied. For example, in truly emergent situations, HCPs should provide urgent care even when the patient's informed consent is lacking, even when no alternative decision-maker is available, and even when the patient is someone with whom the clinician has a personal relationship. HCPs should provide emergency care to any individual in need regardless of that person's age, sex, religion, nationality, citizenship, insurance coverage, ability to pay, or any other medically irrelevant status. Emergencies should also prompt removal or reduction of the social, economic, and political obstacles that normally prevent some individuals or populations from accessing care.

Patient Privacy and Confidentiality in Emergencies

Normally, HCPs should not share an adult patient's information with family members without the patient's explicit permission. But in emergencies, commitments to privacy and confidentiality might be subordinate to the need to protect patients from death or other imminent serious harm.

1. HCPs may share or access a patient's information without their permission when the patient's welfare is at stake and when sharing or accessing information would mitigate risks of death or serious harm.

2. HCPs should share or access only the minimum amount of information needed to mitigate imminent serious harm. HCPs should also share such information minimally (i.e., with the least number of people needed to mitigate the harm).
3. HCPs may disclose patient information without the patient's consent when there is a public health emergency, and such disclosure would mitigate serious risk or is required by the law or the relevant authorities.
4. In emergencies, HCPs may examine patients in places that are not prepared or intended for this purpose. In such cases, HCPs should take steps to protect patient privacy to the greatest extent possible without interfering with the provision of emergency care.

Consent in Emergencies

Normally, HCPs cannot provide care without the informed consent of patients or their alternative decision-makers. But in emergencies, the obligation to obtain informed consent can be waived provided that the patient is at risk of death or imminent serious harm.

1. If a medical decision in an emergency must be made urgently and neither the patient nor an alternative decision-maker can participate in decision-making, HCPs can initiate treatment without the patient's consent when it is deemed necessary and in the patient's best interest.
2. If acting without patient or surrogate consent, HCPs should only provide medically appropriate interventions aimed at meeting the patient's immediate clinical needs.
3. If a patient regains decisional capacity or an alternative decision-maker becomes available after HCPs initiate emergency treatment, HCPs ought to inform them of the care provided thus far and obtain at the earliest opportunity their consent to continue treatment.

4. HCPs may initiate certain treatments or measures of containment without a patient's consent if the patient has a disease or infection that poses serious threat to public health and safety.

Patient's Best Interest in Emergencies

Normally, HCPs are discouraged from treating themselves or their family members. Typically, HCPs may refuse to provide care given that they are afforded the liberty to practice conscientious objection. But in emergencies, HCPs should prioritize the patient's best interest—namely, meeting the patient's immediate medical need and thereby preventing gross complications or the loss of life or limb. The urgency and severity of that medical need means that many of the normal prohibitions and requirements are suspended.

1. HCPs should not hesitate to treat themselves, their family, their friends, or their peers when in emergencies and no other qualified clinician is available. If care was initiated for a family member, friend, or peer during an emergency, the patient should be transferred to another clinician when another clinician becomes available or when the patient is stabilized, whichever occurs sooner.
2. HCPs must give emergency patients the proper treatment until it is no longer needed (e.g., once the patient is stable), until it is refused by patients with decisional capacity or by appropriate alternative decision-makers, or until care for the patient is taken over by another clinician.
3. HCPs should provide care in emergencies that is in the best interest of patients in accordance with standards of clinical care, even care to which they conscientiously object and refuse to provide in normal circumstances.
4. HCPs can and should provide immediate and necessary emergency surgeries without meeting the usual requirements, such as informed consent.

Post-Emergency Communication and Decision Making

HCPs should act immediately when necessary to provide emergency care to patients, even, as outlined above, when that means acting without the informed consent of patients or their alternative decision-makers. However, HCPs should disclose what transpired during the emergency as soon as is appropriate. For example, when the state of emergency is over and the stabilized patient is to be discharged or transferred, HCPs ought to have already informed the patient of the emergency care provided.

1. HCPs ought to document all emergency care they provide in patients' medical records.
2. HCPs ought to inform patients and/or their alternative decision-makers of all relevant information at the earliest opportunity.
3. HCPs ought to communicate in ways that are consistent with their normal practices of protecting privacy and confidentiality in their post-emergency communications.

Responsibilities in Disaster Response and Preparedness

In addition to their responsibilities to provide care to individual patients experiencing medical emergencies, HCPs occupy pivotal roles in responding to—and being prepared for—disasters and public health emergencies.

1. During disasters and community-wide emergencies, HCPs must respond and provide emergency care despite potential risks.
2. To enhance disaster preparedness, HCPs and health facilities should advocate for and provide resources for research, training, regular risk assessments, and equipment so that HCP and systems can respond to disasters efficiently.

3. HCPs should be trustworthy stewards of resources when responding to large-scale emergency situations and disasters, which requires that they commit to and implement triage with the goal of avoiding the most deaths or harms (i.e., avoiding the worst outcome).
4. HCPs and health facilities ought to explain their disaster response-related policies and goals to the public prior to, throughout, and after disasters and public health emergencies.

decision-maker readily available.

Because the patient is at risk of death or imminent serious harm, you can initiate treatment without his consent or that of an alternative decision-maker. When such emergencies occur, two physicians will need to sign the consent on behalf of the patient. All care decisions should be documented and communicated to the patient, or his alternative decision-maker as soon as is possible. When the patient regains decisional capacity or an alternative decision-maker becomes available, you should obtain consent to continue all care.

Appendix 1:

Sample teaching cases

Case 1

You are an emergency physician, and your patient is a 54-year-old male migrant worker from Nepal. The patient arrived at the Emergency Department after suffering a stroke and injuries at his construction job site. Your team's interventions have stabilized him, and the emergency is now over. You want to transfer the patient to another facility for monitoring and specialized care. However, you cannot find a facility that will accept the patient since he lacks insurance coverage for his non-emergency care, and he is unable to afford to pay out of pocket for the care. You are especially worried that his hypertension will continue to go unmanaged, and this will lead to another stroke and further health complications. What should you do?

You should continue to provide care to the patient. Even though the emergency is over, the patient remains under your care and will remain your responsibility until his care is safely transferred or he is safely discharged from your facility.

Case 2

Your patient is a 35-year-old Emirati man who presents via ambulance to the Emergency Department following a road traffic accident in his sports car. He has difficulty breathing, severe bleeding, and low blood pressure. To stabilize the patient, you must provide urgent and necessary care. However, the patient cannot provide consent since he is incapacitated due to his injuries and there is no alternative

Case 3

Your patient is a 27-year-old woman who recently moved to UAE from the U.K. for her work in finance. She presents to the Emergency Department with a forehead laceration after falling down some stairs at a club on Yas Island. She appears highly intoxicated and cannot provide additional historical information because of her altered mental status. She demands to leave the Emergency Department and repeatedly attempts to walk out untreated.

While this patient is clearly intoxicated, you should assess her decisional capacity with respect to your concern of potential head trauma and your intention to suture the laceration. Remember that alcohol intoxication is a transient state, and decisional capacity is dynamic, changing over time and in relation to specific decisions. Given the seriousness and urgency of potential head trauma, you should perform that assessment even without the consent of the patient. If significant head trauma is ruled out and the patient has sufficient decisional capacity, she may refuse sutures. You may also allow the patient to leave the Emergency Department provided she has decisional capacity, has made an informed decision to decline treatment, and can walk and navigate her way home safely. For care refusal and discharge against medical advice, you should document your actions and discussion, and the patient's decision of refusal. References.

10



Palliative and End-of-Life Care



Introduction

While preserving and improving health are among the primary goals of the practice of medicine, critical illness and death are inevitable parts of the human life cycle. Healthcare professionals (HCPs) must therefore be adept at offering and delivering therapeutic and supportive measures during serious illness or near the end of life, recognizing these circumstances raise unique ethical, emotional, and practical considerations. Palliative care is aimed at improving quality of life through the relief of symptoms and suffering. As with all clinical care, practice in these settings should be compassionate, nondiscriminatory, and transparent, involving effective communication and clear documentation. Healthcare decisions should be made in the interest of patients and in accordance with their values, preferences, beliefs, and goals. However, practice must also be based on scientific evidence, accounting for potential risks and benefits to the individual, as well as resource availability.

In accordance with the principle of respect for autonomy, patients have the right to direct their own medical care by communicating their informed decisions or by assigning alternative decision-maker(s) to make decisions on their behalf. Alternative decision-makers should be supported in making choices based on substituted judgment, which are those most aligned with what patients would have chosen for themselves. End-of-life and palliative care are often guided by iterative, complex, and difficult discussions with patients and their alternative decision-makers, and it is appropriate for clinicians to involve psychosocial and spiritual support for patients and their families, as well as to seek guidance from institutional ethics committees.

Breaking Bad News

HCPs have ethical and professional obligations to communicate honestly with patients and their families to achieve informed consent, respect patient autonomy, promote trust, and allow patients to conduct their lives according to their own values and to make plans that express those values. Patients who are informed benefit by choosing more appropriate care (e.g., palliative rather than curative) and recalibrating their hopes, expectations, and plans. Patients also need clinical information to inform their choices and decisions outside of their care. (For communication tools relating to breaking bad news, see “Communication Toolbox” chapter.)

1. HCPs should disclose bad news in a truthful manner to patients or alternative decision-makers, utilizing the support of psychologists, social workers, spiritual care providers, and others.
2. Patients may not want to be informed and may explicitly request non-disclosure or limited disclosure to themselves, even when allowing disclosure to family members or alternative decision-makers. HCPs should document and honor this request when made by a capacitated patient.
3. A patient’s family may request or demand that clinicians withhold bad news from a capacitated patient with the aim of protecting the patient from psychological stress, preserving hope, or promoting recovery. However, in keeping with respect for autonomy, HCPs should not honor such a request unless in keeping with the patient’s wishes; HCPs should ask all patients with decisional capacity about their preferences pertaining to being told their medical information.
4. HCPs should be sensitive to the possibility that patients may not understand relevant information and that delivering bad news in these situations may require the use of additional time, resources, and communication strategies (e.g., interpreters, age-appropriate language).

5. HCPs may withhold clinical information from a patient only if non-disclosure or delayed disclosure is in the patient's best interest. HCPs should know that such situations are rare and that the bar for invoking therapeutic exceptions to justify non-disclosure to patients with decisional capacity is remarkably high. They must understand that their judgments about what is in the best interest of the patient are subjective, corrigible, and may be subject to scrutiny by colleagues, patients, patients' representatives, and courts of law.

Issues surrounding Palliative and Hospice Care

Palliative care should involve a multidisciplinary approach, including timely referral to and consultation with specialists in palliative care, pain management, psychiatry, nutrition, social work, and spiritual care. Palliative and hospice care decisions should be made by the patient or by the patient's alternative decision-maker in accordance with the patient's known wishes and preferences

1. Clinicians should educate patients and their families or alternative decision-makers on palliative care measures using clear, honest, and open communication.
2. Clinicians should communicate clinical uncertainty pertaining to prognosis or treatment efficacy honestly and straightforwardly.
3. Decisions pertaining to palliative and end-of-life care should be guided by patients' preferences and values. HCPs should be aware of the potential for personal biases stemming from their own preferences or values, and these biases should not impact their practice or recommendations.
4. HCPs should encourage patients to consider their goals of care including those pertaining to curative treatments, measures of symptom control, and end-of-life preferences. HCPs should further encourage patients to discuss

these considerations with loved ones when helpful, and to set specific goals for their treatment plans.

5. If patients lack decision-making capacity and there is no alternative decision-maker, clinicians should provide care according to the best interest standard: care that clinicians believe is in the best interests of the patient to maximize well-being and reduce pain and suffering.
6. HCPs should not recommend or agree to provide therapies or other interventions that are not rooted in evidence-based practice. Patients receiving palliative care have the right to request the use of investigational medical products or devices; HCPs should consider the use of investigational medical therapies in accordance with medical indication, directives of local regulatory bodies, and institutional guidelines.
7. HCPs may consider offering sedation to unconsciousness to patients in the very terminal stages of their diseases to alleviate suffering, but never with the intention to hasten or precipitate death. Sedation to unconsciousness should only be offered and undertaken by clinicians with expertise in the practice after extensive discussion with, and explicit consent from, the patient or their alternative decision-maker. This discussion and consent should be documented in the patient's medical record.
8. HCPs should be aware of institutional standards regarding potentially inappropriate or futile care concerning interventions that are not resuscitative or life-sustaining sustaining (see "Do Not Resuscitate (DNR) Orders" and "Termination of Life-Sustaining Treatment" below). For treatments that are not life-sustaining, determining whether a requested therapy is medically inappropriate may require consultation with other members of the clinical team and/or an ethics committee. If, after such consultation, a requested

intervention is determined to be medically inappropriate or futile, it should not be provided.

9. HCPs should keep in mind the stressful and vulnerable positions of patients facing serious or terminal illness and their families. HCPs should strive to provide social, psychological, and spiritual support and additional resources wherever possible.

Do Not Resuscitate (DNR) Orders

Legally, a patient may be allowed to die by natural means (i.e., without attempted resuscitation) if all the following criteria are met: the patient is diagnosed with an incurable disease; all medications with potential efficacy have been tried; the attending physician recommends against performing cardiopulmonary resuscitation (CPR); and at least three other consultant clinicians concur that it is in the patient's best interest to withhold CPR. According to UAE law, if a patient express wishes to receive CPR, these wishes must be followed regardless of the clinician's judgment regarding the appropriateness of an DNR order.

1. HCPs' decisions to place a DNR order may cause distress among the patient's loved ones or members of the clinical team. These scenarios should prompt clinicians to consult an institutional ethics committee, with every attempt to mediate disagreement or confusion about the care plan and to support the patient's family.
2. HCPs should support families of patients who are critically ill and have DNR orders with clear and transparent communication, as well as emotional support. Institutional ethics committees should be consulted as needed in making decisions to apply DNR orders and explaining such orders to patients' families.
3. HCPs should be aware that DNR orders apply only to resuscitative measures and that other therapeutic and palliative measures should

be continued in accordance with the patient's preferences, interests, and well-being.

4. HCPs should clearly document discussions and decisions pertaining to DNR orders.

Termination of Life Sustaining Treatment

Per legal guidance, withdrawing or terminating life-sustaining treatment that would result in the death of a patient is not permitted. Cardiopulmonary support such as mechanical ventilation or vasopressor medications may be removed or stopped only if the patient has been declared dead by accurate legal medical criteria, including complete cardiopulmonary arrest or the irreversible cessation of all functions of the entire brain including brainstem determined in accordance with the legal definition of death by neurologic criteria

1. HCPs should discuss the legal prohibition against terminating life-sustaining treatments with patients and/or their families before a decision is made to initiate such treatment.
2. Requests for termination of life-sustaining treatment should prompt transparent discussions with patient families, with the aid of psychosocial or religious support, to explain why such interventions cannot be accommodated.
3. Disagreements or misunderstandings pertaining to termination of life-sustaining treatment, among clinical team members or between HCPs and patients' families, should prompt consultation with institutional ethics committees.

Rights of Capacitated Patients to Refuse Life Sustaining Treatments

In accordance with respect for autonomy, a patient who demonstrates decisional capacity may refuse any healthcare intervention, including the initiation of life-sustaining treatment.

1. Clinicians should thoroughly assess patients' capacity to make decisions of treatment refusal and document this assessment in patients' medical charts.
2. If there is disagreement among patients and their family members or between patients and the clinical care team regarding adequate decision-making capacity to refuse care, clinicians should seek timely consultation with appropriate specialties, including psychiatry and/or the institutional ethics committee.
3. HCPs should remain with the family after informing them of the patient's death unless the family indicates they prefer to be left alone. HCPs should facilitate their grief reaction, encouraging them to express it, empathizing with them, and sharing in their loss.
4. If possible, and if the family desires, HCPs should arrange for a viewing of the body. Before viewing, the body should be made presentable, including being covered or clothed appropriately, disconnected from machines, having blood and other secretions wiped clean, and other preparations as possible and as culturally appropriate.
5. HCPs should be aware of and utilize their facility's resources and staff to assist the families in completing official formalities relating to patient death.

Informing Families of a Patient's Death in a Timely Manner

Informing a patient's family that the patient has died may be difficult and stressful. Still, HCPs should communicate about patients' death directly yet compassionately, placing the family's emotional needs at the center of their attention throughout the encounter. In addition, HCPs should be well-prepared for the moment of disclosure and set aside adequate time for this interaction with the patient's family.

1. HCPs should disclose the patient's death to the family in a timely manner. Although no treatment decisions are at stake, many other decisions and activities are time-sensitive (e.g., organ donation, autopsy, preparation for funeral services).
2. HCPs should use plain, direct language, and avoid euphemisms when reporting the death.

Appendix 1:

Sample teaching cases

Case 1

Your patient, Mrs. G, is a 76-year-old woman with end-stage metastatic breast cancer admitted to the intensive care unit overnight with tachycardia and hypotension. She has demonstrated symptoms of delirium, and her son has been making medical decisions on her behalf since admission. After a long family discussion involving the patient's longtime outpatient oncologist, who is very well-trusted by her family, her son has agreed to focus on palliative measures in accordance with his mother's wishes. Her son asks how the clinical team intends to proceed with his mother's care and whether he can take her home since she will not be receiving medical or surgical intervention to cure her metastatic disease. How should you advise Mrs. G's son about her care?

The patient should receive treatment for symptom alleviation, which may include medication for pain and intravenous fluids. She should be discharged from the hospital only when there is a safe plan for her to continue palliative care at home or an alternative care setting. Prompt consultation with the pain management and palliative care services is appropriate to ensure that Mrs. G receives care in accordance with her needs. Psychosocial and spiritual support resources should also be offered to her family members.

Case 2

You are caring for Mr. K, a 48-year-old man who suffered a cardiac arrest 12 days ago while vacationing in UAE from his home country of France. Mr. K was successfully resuscitated in the emergency room but remains dependent on life-sustaining treatments including a mechanical respirator and two vasopressors, without signs of improving. He has remained unconscious since admission to the hospital but does not meet diagnostic conditions for death by neurologic criteria. His wife shares with you that she and her husband have discussed his not wanting to be maintained on life-sustaining treatments indefinitely if there is no meaningful chance of recovery. She would like to withdraw care, which she believes is in accordance with his wishes. How should you proceed?

While this is an emotionally and ethically difficult scenario, per legal guidance, life-sustaining treatment for any patient in the United Arab Emirates may not be withdrawn. This should be explained to the patient's wife with patience and compassion, and supportive resources such as referrals to spiritual care and social work should be offered. The patient's wife should be informed of the possibility of transferring the patient's care to another medical facility, outside of the United Arab Emirates, where his wishes may be honored if withdrawal of life-sustaining treatment is deemed clinically appropriate.

Case 3

Your patient is a 64-year-old woman who just completed a evaluation and imaging after presenting with several troubling symptoms. Based on her assessment, you suspect that she has advanced lung cancer that has spread to other parts of the body. As you order additional diagnostic tests, her adult sons approach you and demand that you not disclose any bad news to their mother. They say that she will not be able to deal with the stress and she needs a positive mental attitude to fight her illness and to recover. They also say that this is how they do things in their culture. What should you do?

Because your patient has decisional capacity, you must respect her autonomy. To do so, you should find an appropriate time and place to discuss her understanding of her situation and her information-sharing and decision-making preferences. If the patient declines information sharing—if she prefers not to hear her diagnosis and prognosis and defers to her sons then nondisclosure is a way of respecting her autonomy. If your patient requests information sharing, however, then telling her the truth is the way to respect her autonomy. Throughout all of this, it is important that you take the measures available to maintain a healthy relationship with the family despite their disagreement about disclosure of information to the patient. For communication tools to help in this process, see the chapter titled “Communication Toolbox.”

11



Care of Children and Adolescents



Introduction

The clinical care of children (individuals under the age of 18) presents unique ethical concerns for healthcare professionals (HCPs). Children’s ability to contribute to their own treatment decisions varies as they mature; thus, they require special protections in accordance with their individual physical, psychosocial, communication, and cultural needs. HCPs (and pediatric researchers) are obligated to act as advocates for their patients and to make decisions based on consideration of the children’s interests.

In these guidelines, a “parent/guardian” refers to the person, usually parent(s) but sometimes another alternative decision-maker, who makes decisions and gives consent for the child’s treatment. While parent/guardians are generally assumed to act in the child’s best interests, disagreements about what is best for a child may occur. These cases require sensitivity to children’s developmental stage and ongoing, age-appropriate assessments of their capacity to make decisions. HCPs also have a duty to assess the parent/guardian’s decision-making capacity and willingness and ability to act in the patient’s best interests. If HCPs believe a parent/guardian lacks decision-making capacity, they should bring the case to their institution’s ethics committee or other relevant oversight bodies. If they believe a parent/guardian is making decisions that may harm the child, they must alert relevant authorities in accordance with laws and institutional policies. Providing good care to children involves building a relationship of respect and trust among HCPs, patients, and parent/guardians. These guidelines aim to help HCPs identify and weigh the various medical, cultural, social, and ethical issues that must be considered when treating children and interacting with those who care for them.

Shared Decision-making and Complex Decisions

Decision-making for children should occur through a collaborative process between patients, their parents/guardians, and HCPs in a mutually respectful alliance aimed at building trust between them. In this model, decisions about treatment incorporate evidence-based guidance, as well as the patient’s and parent/guardian’s preferences, values, and religious and cultural beliefs. HCPs should explore these values—while respecting the limits of parental authority and children’s autonomy—to better communicate medical information and recommend a treatment course in alignment with the patient’s and family’s priorities.

1. HCPs should always provide care based on their best clinical judgment. They should not deviate from medically appropriate or evidence-based standards of practice at the request or insistence of pediatric patient’s parent/guardians.
2. The principle of respect for persons requires HCPs to communicate with children (when appropriate) and families in clear, comprehensible language. Interpreters should be provided if necessary, including signers for hearing-impaired patients or family members.
3. HCPs should present all potential treatment options to the parents/guardians and when possible, translate the same information into developmentally appropriate language for the minor patient. If there are multiple treatment options, HCPs should discuss the benefits and risks of each, and should explain what each intervention would entail (i.e., length of hospital stay, testing, course of medications and potential side-effects, follow-up visits, etc.) to help families reach a decision that is right for them. Additional resources such as pictures, infographics, videos, or patient testimony may be supplied when available to help guide decision-making.

4. HCPs should answer any questions patients or families may have and ensure that they have an adequate understanding of care options, avoiding medical terminology and enlisting interpreters if necessary.
5. HCPs are legally required to report suspicions of harm, abuse, or neglect to appropriate authorities.
6. If there is disagreement between HCPs and parent/guardians that cannot be resolved through provision of further information or exploration of values and preferences, HCPs should consult with colleagues, ethics committees, or the legal department, depending on institutional policies.
7. HCPs are ethically and professionally obligated to treat children in emergency situations in accordance with their acute clinical needs even if they are unable to obtain parent/guardians' consent.
2. HCPs should involve pediatric patients in healthcare discussions when feasible. They should avoid condescending or overtly complicated language, make space for them to ask questions and voice their thoughts, and seek to understand their values, as well as their emotional, social, and informational needs.
3. Because an effective assent process should deliver information in a developmentally appropriate way, HCPs should assess the amount and quality of information to disclose to children and their families, with the best interest of the child in mind.
4. When seeking assent, HCPs should be responsive to the cultural and religious needs/preferences of patients and, when feasible, provide the option of seeking support from other HCPs with whom the family has a longitudinal relationship, religious counselors, or other trusted advisers.

Assent for Treatment in Adolescent Patients

Children are not legally able to give consent for medical treatment or research participation. However, they can still express their assent, or agreement, to care. Assent is based on children's decision-making capacity, which is evaluated by a member of their healthcare team. Adolescents, for example, may have the cognitive and emotional maturity to participate in certain medical decisions, and involving them in the decision-making process is a way for HCPs to show respect for the patient and promote their autonomy. Adolescents have the capacity to participate in decision discussions when they can understand and weigh the risks and benefits of a given option. HCPs should assess this capacity on a case-by-case basis.

1. HCPs who assess adolescent capacity should be experienced in such discussions and skilled at eliciting patients' views. They should respect opinions and answer questions honestly.

Adolescent Refusal of Care

When an adolescent refuses non-emergency care, it is challenging for the HCP to balance relevant principles such as autonomy and non-maleficence. Further, ethical calculations in these cases will vary depending on the severity of the patient's condition, developmental capacity, and the relationship between adolescents and their parents/guardians.

1. HCPs must balance an adolescent's dissent for treatment choices with the duty to provide medical care and respect for the parent/guardian's consent. HCPs should explore adolescents' rationale for dissent to try to mediate disagreement, correct any misunderstandings, and encourage their willingness to participate in care that is in their best interest.
2. While the parents/guardians ultimately can make decisions on their behalf, HCPs a duty to foster the autonomy of the adolescent and should involve them in discussions about their health and the decision-making process.

3. Factors such as age, cognitive ability, and understanding of consequences should be considered when assessing the adolescent's capacity to participate in informed decisions.
4. HCPs should explain the potential benefits, risks, and consequences of refusing care. Collaborative decision-making, involving all parties, can help find a resolution that respects adolescents' autonomy while ensuring their well-being.
5. HCPs must evaluate the urgency and severity of the adolescent's condition. If the refusal poses an immediate risk to the adolescent's life or health, medical intervention may be necessary to protect their well-being. In such cases, legal and ethical mechanisms may be considered.
6. If an adolescent refuses treatment, their decision may be overruled by an alternative decision-maker (e.g., parent/guardian). Before seeking unilateral consent from a parent/guardian, HCPs should consider the potential harms and benefits of the treatment, its necessity, the availability of less invasive options, and the possibility of allowing more time for discussion with the patient.
7. It is essential to thoroughly document all discussions, assessments, and decisions made regarding the adolescent's refusal of care if the parents/guardians do not intervene. This documentation should include the reasons for refusal, the assessment of capacity, alternative options considered, and steps taken to address the refusal.
8. If an adolescent persists in refusing care, HCPs should ensure that they receive appropriate follow-up care. If necessary, HCPs can consider referral to other providers who may be better suited to establish rapport and address the adolescent's concerns.

Babies Born at the Borderline of Viability (Periviability)

Borderline viability, also referred to as periviability, is defined as the earliest stage of fetal maturity when there is a reasonable chance, although not a high likelihood, of extrauterine survival. According to internationally accepted standards, periviability is defined as deliveries at 22+0 to 23+6 weeks gestation. The clinical team should recognize the enormous stress that decision-making in this setting causes parents/guardians and work closely with them to reach management decisions together, based primarily on an assessment of the perceived benefits and burdens to the infant of treatments under consideration. Institutions should review local and published outcomes data, as well as societal and national guidelines, when developing a consensus institutional approach to define management categories for periviability. Institutional policies should also use a framework that addresses the obligations of the clinical team to safeguard and promote the welfare of the patient as the main goal of treatment, respects the interests of the infant and parents/guardians, and ensures just and equitable treatment for perivable infants with similar prognoses

1. The prognostic uncertainty of perivable infants requires assessment on a case-specific basis, as the precise gestational age will differ in different clinical settings and depends in part on available medical resources.
2. Infants should receive treatment that has a reasonable chance of saving their lives.
3. HCPs should not subject infants to painful procedures that are unlikely to provide benefit (i.e., improve survival and/or decrease morbidity).
4. As part of shared decision-making, HCPs must present parents/guardians with the relevant information, such as morbidity and mortality data (as well as the limitations of those data or the presence of clinical uncertainty) and

should offer their clinical judgment to help them with the profoundly difficult decisions for the care of newborn infants. An honest presentation of the relevant information and the available options (including, if feasible, transfer to another institution with a different institutional policy) is critical.

5. In rare circumstances, the clinical team may determine that parents/guardians' preferences are clearly opposed to the child's best interests; in these instances, HCPs may need to override parent/guardians' preferences, via proper procedural channels as time allows.
6. HCPs should refer a patient's parents/guardians to other clinicians, social workers, ethicists, and religious counselors, as needed for support in decision-making.

Treatment Without Medical Benefit

Parents/guardians making medical decisions on behalf of their child often experience feelings of distress, guilt, mistrust, denial, and being overwhelmed. This emotionally fraught and traumatic experience may lead to demands for care and an inability to cope with or accommodate the situation at hand, leading to the pursuit of interventions that may not be beneficial (commonly referred to as "non-beneficial care") or medically appropriate.

1. In situations of uncertain medical benefit, HCPs should discuss all possible options with parents/guardians, including obtaining second or third opinions. While the parents/guardians ultimately can make decisions on their behalf, HCPs
2. HCPs should communicate to families in a straightforward manner to ensure sufficient comprehension of the potential impact caused by treatment that may be non-beneficial or medically inappropriate.

3. If parents/guardians wish to pursue treatment that the HCP believes to be non-beneficial, HCPs may provide support to the family to get other consultations.
4. HCPs should offer genuine expressions of kindness and compassion and take time to explore the parents/guardians' emotions and cultural, religious, and social factors influencing their treatment approach.
5. HCPs should encourage parents/guardians to seek religious or spiritual counsel when appropriate. Spiritual advisers may ease the burden of difficult decisions such as discontinuing non-beneficial treatment or other interventions that prolong the dying process.
6. HCPs are neither ethically nor professionally obligated to provide interventions that they consider to be clearly harmful to patients. When there is disagreement about such decisions, HCPs should facilitate consultation with others at their facility or at other institutions to see if another clinical team can and will assume care for the patient. When there is ongoing disagreement about a child's best interests or treatment recommendations, HCPs should continue to manage the patient in accordance with standards of care and seek consultation with an ethics committee, legal counsel, or other institutional resources.

Research Involving Children

HCPs may recommend enrollment in a clinical trial as part of a child's care. Unlike adult participants, research in children must offer at least the prospect of direct benefit, and HCPs should approach processes of informed consent, risk/benefit calculation, and communication in accordance with ethical and institutional research participant protections and regulations, and with utmost concern for the child's well-being. In rare situations, the obligation to obtain informed consent may be waived in research involving emergency interventions; any deviation from research protocol must be reported to the relevant Institutional Review Board (IRB) or Research Ethics Committee following the applicable standards.

1. HCPs and researchers must balance the duty to develop safe and effective interventions for pediatric patients with the duty to minimize risks posed by study involvement. All research on children must have the prospect of direct benefit to the child participant or be of only minimal risk (defined as no more than the risk of everyday life.) Participation in research by children or other individuals who lack decision-making capacity is permissible in limited circumstances provided that:
 - The parents/guardians provide consent under circumstances in which informed and prudent adults would reasonably be expected to volunteer themselves or their children in research.
 - The child has been included in the consent discussion in a developmentally appropriate way and has provided assent.
 - There is potential for the individual to benefit from the study.
 - The research entails only minimal risk.
2. Although research may have the prospect of direct benefit, HCPs should make it clear to parents/guardians that research outcomes are uncertain to a varying degree and may not benefit the participant. HCPs should also be transparent about all known risks.
3. HCPs should offer to include social workers, religious counselors, or other family members in the decision about whether to enroll children in a research study. Such advisers can also provide support during the informed consent process and help participants and parents/guardians understand the proposed research and weigh potential risks and benefits.

End-of-Life Care for Children

HCPs should discuss end-of-life care with parents/guardians, including preferences regarding life-supporting interventions. They should also discuss whether to shift the goals of treatment from maximal life-prolongation to minimizing pain, discomfort, and burdens of treatment. Such issues are complex; all stakeholders in end-of-life decisions have their own unique emotions, experiences, cultural beliefs, and medical insight. Fostering strong partnerships and early involvement from subspecialty HCPs who are trained in palliative and end-of-life care, as well as psychosocial support, offers the best chance at providing high-quality care for children with terminal illnesses.

1. HCPs should recognize that preferences about end-of-life care are often deeply rooted in family and community experiences of illness and death. Iterative conversations with families facilitate delivery of care that is aligned with the goals of all parties, as does palliative care engagement, shared decision making, and formal advance care planning.
2. HCPs should provide parents/guardians with information about psychological support services or grief counseling when appropriate, recognizing that discussion of such options might trigger emotional responses by signaling the end of curative treatment.

Genetic Testing of Children

Genetic testing in pediatric patients raises significant concerns regarding the child's autonomy and best interests both now and in the future. The decision to proceed with testing requires careful consideration of various factors, such as the potential benefits, the risks associated with knowing the genetic status (which may prevent the child from making an autonomous decision in adulthood), specific characteristics of the condition being tested (e.g., age of onset), and the availability of effective preventive, therapeutic, or palliative treatments.

1. Diagnostic testing may be offered when the child is at risk for a condition for which effective measures to prevent, treat, or ameliorate it are available.
2. When obtaining consent, HCPs should seek informed consent from the parents/guardians of the minor patient, involving the patient in decision-making as developmentally appropriate.
3. HCPs should respect the decision of the patient's parents/guardians if they seek testing for risk of a pediatric onset condition even if there are no effective measures to prevent, treat, or ameliorate the condition.
4. Regardless of the testing source, HCPs should assist the patient and parents/guardians in accessing appropriate counseling services.
5. HCPs should encourage parents/guardians to share genetic information with their child in a developmentally appropriate manner.
6. HCPs should ensure that parents/guardians are made aware of findings that are not immediately relevant but will need to be communicated later, so that the information can be shared with the child when it becomes relevant.
7. HCPs should not offer, provide, or recommend a genetic test in the following situations:
 - When parents/guardians request testing for a child at risk for a condition with adult onset and no effective measures to prevent, treat, or ameliorate the condition exist. HCPs should inform the parents/guardians about the test and explain why it is not recommended.
 - When parents/guardians request testing solely to determine the child's carrier status for a recessive genetic condition with no other health implications for the child. However, HCPs may consider providing testing if reproductive decisions need to be made on behalf of or by a minor patient, following ethical guidelines.
 - When testing is conducted solely for the benefit of a family member unless testing would prevent substantial harm to that individual.
 - When testing would not serve the child's health interests.
8. HCPs should seek consultation from an ethics committee or other institutional resources when disagreements regarding genetic testing persist. If parents/guardians unreasonably request or refuse testing for their child, HCPs should take appropriate steps to address or, if necessary, use legal means to override the parents' decision.

Gender-affirming Surgery

Gender-affirming surgery (GAS) is severely restricted to limited circumstances which are highly regulated. These circumstances must be confirmed by medical records and have the approval of a special board of the Health Authority.

Appendix 1:

Sample teaching cases

Case 1

You are a pediatric oncologist and your patient, a 16-year-old girl, has cancer and is refusing life-saving chemotherapy treatment. The chemotherapy will cause some discomfort but is relatively low risk when compared to not receiving chemotherapy. Her parents/guardians want her to receive the treatment. How should you proceed? What if the parents/guardians support her refusal?

HCPs should make every attempt to understand the reasons for refusal. Although the process of pediatric assent fosters respect for patient autonomy, it is not legally required, and the decision of whether to undergo medical treatment is ultimately up to the patient's parents/guardians. In most cases, HCPs can reach a resolution by listening to the patient and parents/guardians and offering evidence-based explanations for the recommended treatment in simple language. If necessary, HCPs can involve secondary consultants such as experienced colleagues, ethicists, psychologists, spiritual care providers, or palliative care specialists in the discussion. Multidisciplinary meetings often clarify misunderstandings and help everyone reach consensus. In cases where parents/guardians support their child's refusal, HCPs have a legal and ethical responsibility to question and, if necessary, contest parental medical decisions that might put the patient at significant risk of serious harm. In extreme cases, HCPs may need to involve relevant legal authorities to resolve disputes over medical interventions for children.

Case 2

A woman gives birth to a child on the borderline of viability, with severe medical complications. The HCP has determined that the newborn has a very low likelihood of survival and recommends withholding life support, in accordance with standards of care. The parents are angry and accuse the HCP of giving up on their child. They insist on continued medical intervention despite the lack of potential benefit and the possibility of causing undue distress and suffering to the child. The nurses feel that further treatment would be painful and inappropriate.

HCPs should address the family with patience and compassion, allowing a safe space for grief and other emotions. They should explain how and why they arrived at their decision, affirm the devastating difficulty of making such decisions, and assure the parents/guardians that they are acting in the child's best interest by limiting unnecessary harms to or further struggle by the child. Sometimes, even the act of seeking second or third opinions helps cultivate trust between the family and the HCP. HCPs may offer to consult with others at their facility or other institutions to see if another HCP will take over, in which case care is transferred. If not, HCPs may ethically and professionally decline to participate further in the interventions that they deem to be against a patient's interests. HCPs may refer parent/guardians to religious or spiritual counsel; shifting decision-making responsibility can sometimes help ease the burden on parents/guardians.

Case 3

You are a pediatrician and your patient, a 12-year-old child, requests a Covid vaccine without his parent's consent/approval.

By law, children cannot receive non-emergency medical care without the consent of a parent/guardian, which you should explain to the child. There are ethical obligations to protect the public's health, which you should explain to the parents/guardians. You should also offer to discuss the vaccine with the parents/guardians to address questions and concerns they may have. If the parents/guardians still do not give their consent for the child to receive the vaccine, you should respect their decision and not administer the vaccine to the child. It is important for HCPs to respect the rights and autonomy of both children and their parents/guardians when making decisions about medical treatment, while also acknowledging and educating them about public health interests.



12

Women's Health and Reproductive Medicine



Introduction

In addition to the multifaceted issues faced by all patients, women's health and reproductive care require dedicated consideration of additional ethical, legal, and practical concerns. Women are at greater risk of physical, mental, and emotional abuse than men. Clinical care of female patients raises unique concerns relating to privacy, and women's care is also governed by laws and religious and cultural practices in unique ways. Pregnant women are further differently affected by laws, policies, ethics, culture, and religious guidance. Healthcare professionals (HCPs) should be cognizant of these variations, as well as the resources available to support pregnant women and families. These guidelines review ethical issues that may arise for HCPs when treating adult female patients, including in considerations related to reproductive planning or pregnancy, and offer guidance for managing their care ethically.

Ethical Considerations pertaining to Women's Health

Women have needs and considerations regarding medical examinations and care, privacy, consent, and research. Their mental health issues differ from men's and children's, as do risks for and presentations of cardiovascular events, certain types of cancer, and other conditions. Women are at greater risk of physical, psychological, and sexual abuses. HCPs who care for any female patients must be up to date on best practices and guidelines for women's health.

1. HCPs must be alert to signs of domestic violence and other types of abuse, and must enlist specialists with relevant expertise for assistance when necessary. HCPs may be female patients' only avenues to protection and well-being and should be ready to refer victims of abuse to counselors as well as to information about orders of protection, legal representation, and the like, all of which they are entitled to under the law.
2. HCPs should refer female patients to age-appropriate gynecological care in a respectful and affirming manner.

3. Any patient may request a chaperone be present during exams, but chaperones must be present during intimate examinations and when an HCP examines a patient of the opposite sex. See the chapter on "Patient Privacy and Confidentiality" for more information.
4. Informed consent is essential to ethical medical care and is a foundation of patient autonomy. Consent requirements for female patients may vary according to type of examination, with intimate exams requiring more explicit, documented consent.

Ethical Considerations pertaining to Reproductive Health Issues

Women should be informed of and supported in their options surrounding reproductive healthcare and a woman's decisions about her reproductive care should be respected.

1. HCPs who treat or specialize in the care of women are professionally and morally obligated to be up to date on treatment guidelines regarding contraception, reproductive planning, pregnancy, peri-natal care, and post-partum care.
2. HCPs who care for women should freely discuss various methods of contraception with patients who inquire about it. They should instruct patients on correct use of contraceptives and review the types of contraception to determine which one best fits a patient's goals.
3. HCPs should discuss the risks of pregnancy with patients, being sensitive to cultural and religious considerations.

Termination of Pregnancy

Medically assisted abortion of a viable pregnancy is illegal except when the woman's life is in danger or medical evidence indicates that the baby will be born with certain fatal abnormalities and will not survive. In cases of legally permissible medical or surgical abortion, the terminal nature of the abnormalities must be independently confirmed by an authorized medical board, and the abortion must be performed before the fetus is 120 days old.

Medically Assisted Reproduction (MAR)

HCPs who practice MAR, including in vitro fertilization (IVF), should understand laws and regulations governing the practice. Federal law describes consent and other requirements for MAR, along with such matters as licensing requirements, stipulations for couples who wish to pursue MAR, transfer of zygotes or gametes, cycle limits, and others. Legally, MAR and/or IVF are only permissible when provided to a couple that can verify that they are husband and wife. The law also reviews practices to ensure safe, ethical practice of MAR.

1. MAR should be attempted by specialists with expertise in the practice; HCPs who treat women should have referrals on hand should patients wish to pursue MAR.
2. The ethical principle of autonomy requires fully informed consent from women who plan to pursue MAR; legally, husbands are also required to consent.
3. HCPs should thoroughly review benefits and risks, including potential negative outcomes; likelihood of success; costs; limits on the number of attempts; and opportunities for future pregnancies, both natural and assisted. Laws governing gamete or embryo preservation must be explained during the informed consent discussion.

4. HCPs should counsel patients in accordance with evidence-based standards of practice and provide guidance that fosters realistic expectations about the likelihood of MAR interventions to successfully achieve their intended outcomes.
5. HCPs should inform patients about genetic counseling and refer patients upon request.
6. Oncologists should also be familiar with the ethical, legal, and professional obligations of MAR in case female patients wish to explore fertility preservation prior to certain cancer treatments.
7. Laws and regulations change as technology and patient needs evolve; HCPs must remain up to date on these to ensure safe and effective treatment of patients.

Genetic Testing of Fertilized Eggs

Genetic diagnosis of fertilized eggs prior to implantation is permissible only with couples' written request. Non-therapeutic genetic modifications of embryos are illegal.

1. HCPs should communicate risks, benefits, and unknowns of genetic testing; appropriate and comprehensive discussions will often require assistance from a genetic counselor.
2. HCPs must obtain the couple's informed consent for specific test(s) that will be performed.
3. HCPs should refer patients to qualified genetic counselors when it is in the best interests of the patient or upon request.
4. HCPs must clearly and patiently explain abnormal findings and the potential severity of the disease or condition, when it expected

to manifest in the child, and other relevant factors. Genetic counselors, social workers, and/or spiritual care providers may provide valuable assistance with this.

5. Before initiating testing, HCPs must ask if couples wish to be informed of incidental findings.

Ownership, Preservation, and Destruction of Fertilized and Unfertilized Gametes

Federal laws regulate implantation of fertilized eggs; preserving and destroying fertilized eggs; prohibited uses of gametes; and more. The selling or transferring of embryos to another patient is illegal. HCPs who practice in relevant fields should explain these regulations to couples during the informed consent process.

1. HCPs should raise fertility-preserving options with women, with special consideration for female patients who face treatment that may impair their ability to conceive, such as chemotherapy. Risks and benefits to both patients and gametes, as well as risks from retrieval procedures, potential mental and emotional repercussions, and considerations of cost should be part of the informed consent discussion. Genetic counselors or social workers should be available as needed or if requested.

Ethical Considerations pertaining to Pregnancy

The ethical principles of respect for patients, beneficence, non-maleficence, and justice that govern all medical practice governs care of pregnant women and their fetuses.

1. HCPs must be up to date on practice and treatment guidelines to ensure healthy pregnancies and deliveries.
2. HCPs must be appropriately trained in prescribing medicines for pregnant women, or consult with pharmacists or other specialists, to ensure that the pregnant patient and fetus are not harmed by a medication.
3. In addition to physical risks during pregnancy, HCPs should be alert to mental health issues in pregnant and post-partum patients and counsel or refer to specialists accordingly.
4. HCPs should understand that pregnant patients may have concerns in addition to medical care, such as fear of the birth process, concerns about caring for a newborn, and many more and allow adequate time during appointments to counsel patients.
5. HCPs should openly discuss the risks of pregnancy when appropriate, such as the role the age of the mother and father may play in conception, gestation, and health of the child.
6. Surgical procedures during pregnancy, including intrauterine fetal surgery, require detailed informed consent discussions. Clinicians involved should be mindful of unique considerations and potential familial and cultural pressures that may impact a pregnant patient's decisions regarding surgery during her pregnancy.

Research Involving Pregnant Women

Ethical principles of justice and autonomy support involving pregnant women in clinical research. Women should be able to benefit from medicines being developed, and for serious communicable diseases, research including pregnant women is a moral and public health imperative. Nevertheless, pregnant women are at heightened risk both because of pregnancy and because medical products being tested may pass to the fetus.

1. HCPs must ensure that informed consent protocols for research participation are followed, and both the pregnant woman and her husband give consent. The consent discussion should include specific considerations of the risks and other potential effects of the proposed research on the patient and the fetus.
2. HCPs should ensure that preclinical studies on pregnant animals and research including nonpregnant women establish a favorable risk-benefit profile for pregnant women participants.
3. The medical product being investigated must be intended to provide direct benefit to the woman or fetus, involve only minimal risk to the fetus, and the research cannot be achieved by other means.
4. To avoid the appearance of conflict of interest, clinician-researchers must explicitly inform patient-subjects of their dual roles and assure them that patient well-being is their primary concern. HCPs who function in the dual role of clinician and research should always prioritize their patients' health over their research goals.
5. HCPs and physician-researchers must ensure that informed consent is voluntary. Particularly when the life of the fetus is in danger, the mother may discount risks of research or be pressured by family members to consent to research.

Novel and Evolving Clinical Interventions

New issues will continue to emerge in the treatment of women as technology advances, and HCPs may be confronted with novel cases. Novel and rare circumstances naturally raise ethical questions, but in the context of healthcare, resolutions should follow the law and cultural practices while serving the interest of patients. Until federal or local law is established, questions regarding such novel practices in women's health as uterine transplant, ovarian tissue preservation, medically indicated puberty blocking hormones for adolescents, elective hysterectomy/sterilization under limited circumstances, and the like should be discussed with hospital ethics committees and administrators, as often such cases require individualized consideration. In many of these cases, ethicists, social workers, and religious counselors should be consulted.

Appendix 1:

Sample teaching cases

Case 1

You are an oncologist about to begin chemotherapy for a female patient with an aggressive form of breast cancer. However, she tells you that she just learned she is pregnant. You tell her that chemotherapy could harm the fetus and suggest she and her husband discuss the option of terminating this pregnancy and freezing eggs or embryos so they can attempt another pregnancy after treatment ends if they choose to do so. She is adamant that she will not end this pregnancy, even though you tell her that beginning chemotherapy as soon as possible is her best chance at a cure. She refuses to consider it. What do you do?

You should try to keep the dialogue ongoing, as the patient is no doubt reeling from the shock of the diagnosis and the news of the pregnancy. Assure her that her well-being is your chief concern, and plainly and patiently explain how egg preservation works and its success rates in other patients in her situation. Her husband or other family members may be helpful here, as might a social worker or a spiritual care provider. However, the ethical principles of respect for persons/autonomy require you to honor whatever decision the patient makes and continue to treat her compassionately.

Case 2

You are an obstetrician and a specialist in fetal abnormalities whose institution has received a large grant to study a diagnostic test that would detect a fatal condition in fetuses that usually affects babies beginning at about three months old—a groundbreaking treatment that would prevent infants from developing the condition. You begin to recruit participants from pregnant patients under your care. Although some patients are not interested in joining the trial, your administrator urges you to try to convince them, noting that research will not only help future babies but will improve the medical center’s standing and lead to improved services for all patients. What should you do?

When clinicians are also researchers, conditions are ripe for conflict of interest. Even the best-intentioned clinicians may be understandably pulled toward research that could

result in beneficial treatments for many future patients. Nevertheless, HCPs are ethically and professionally required to put the interests of current patients first—they must treat patients as patients, not as potential research participants. Pressuring or otherwise trying to convince reticent patients to join a study violates professional codes of conduct as well as ethical principles of non-maleficence and autonomy.

Case 3

You are an internist, and a female patient comes to you complaining of a persistent cough. While examining her, you see bruises on her back, and faint bruising on her face. She tells you she and her children play physically on the floor. You do not find the bruising to be consistent with her explanation, and she becomes visibly upset when you press her on her injuries. What do you do?

After addressing her complaint of a cough with appropriate examination, testing, and treatment plan, you should attempt to readdress your concern about her bruising. If you suspect domestic violence, it is important to make your patient feel safe and supported and to try to keep her engaged with you as her ally in her healthcare. Explain that abuse, including physical abuse, is never justified and that you are always available if she needs someone to listen or guide her. You can offer to put her in touch with a social worker, spiritual care provider, or counselor. You must take care not to seem condescending or judgmental.

13



Mental Health Care



Introduction

Provision of mental healthcare poses unique ethical challenges as some patients facing mental illnesses can experience masked perceptions of reality or exhibit a lack of insight into their diseases while otherwise remaining functional in their daily activities. Thus, mental health poses complex and challenging questions about patient autonomy and its limits, as well as questions about when patients have the right to refuse treatment. A psychiatric diagnosis does not dictate a lack of decisional capacity and healthcare professionals (HCPs) thus have a moral obligation to iteratively assess each patient's capacity to direct their own care and make their own medical decisions, recognizing capacity is time- and decision-specific, and may be fluctuating. HCPs must also maintain patient confidentiality to the greatest extent possible, with exceptions including circumstances where there is risk of imminent harm to the patient or to others. Finally, HCPs must work to ensure mental healthcare is accessible to all patients and to minimize the stigma concerning mental illnesses.

Decision-Making Capacity and Informed Consent

Scenarios involving patients with psychiatric diagnoses and those receiving mental healthcare may raise particularly complicated questions concerning decision-making capacity and when a patient's autonomy may be ethically limited. For a fuller discussion of decision-making capacity and its clinical assessment, see chapter titled "Autonomy, Decisional Capacity, and Informed Consent."

1. Per law, HCPs must obtain informed consent for treatment from patients with decisional capacity except in the cases of routine, diagnostic, or non-invasive procedures where presumed consent is inferred (for example, a blood draw).
2. A patient with a psychiatric diagnosis should be afforded the same confidentiality protections as any other patient and disclosure of protected health information should not occur without the patient's consent. In the situation where patients pose an imminent risk of serious harm

to themselves or others, HCPs have a duty to report the risk to security personnel or to warn individuals directly. When a justifiable breach of confidentiality of this nature occurs, HCPs should record details of the circumstances and their rationale in the patient's medical record and should report the case to their institution's legal counsel.

Medication Refusal: Preventive and Reactive Ethical Considerations

Patients with decision-making capacity retain the right to refuse treatment, even when members of the clinical team believe treatment would be in the patients' best interests. However, such a right to refuse treatment may be restricted when there is potential of serious harm to others, such as in cases involving communicable diseases.

1. If a patient demonstrates decision-making capacity, HCPs must respect their choice to refuse or forgo treatment. This remains true regardless of whether a patient has a psychiatric diagnosis or is receiving psychiatric care.
2. If patients do not have capacity to make their own decisions, designated alternative decision-makers may make medical decisions on the patient's behalf—including continuing any wishes to refuse medical care that the patient communicated while capacitated.
3. For patients with diagnoses or diseases that may contribute to potentially fluctuating decisional capacity (e.g., episodes of psychosis or mania), HCPs should consider proactively discussing with the patient what their treatment wishes would be if they lose capacity. This "psychiatric advance directive" should be noted in the patient's chart and the patient's alternative decision-maker should be involved in the discussion surrounding the creation of the directive to decrease the likelihood of conflict in the future.

4. Institutions can seek legal rulings to overrule patient or alternative refusals of treatment. However, such cases should remain exceptional to minimize violations of a patient's autonomy.

Use of Protective Stabilization/Restraining Patients

1. In the rare occasions when a patient's autonomy must be violated by restraints employed for the patient's own protection or the protection of others, the patient should always be treated with the least restrictive alternative possible and HCPs should ensure that the welfare of the patient remains a primary concern.
2. Initiating medical intervention (e.g., sedation or emergency administration of drugs) without the informed consent of the patient or alternative decision-maker is acceptable only when there is serious risk of imminent death or severe harm to the patient or others.
3. When a patient is being restrained or involuntarily medicated and/or hospitalized, HCPs should ensure this is done in a way that will minimize the chance of resultant trauma or humiliation in the patient and instead help the patient to build rapport with the treating clinicians.
4. After the decision is made to employ restraints of any kind, HCPs should engage in frequent and ongoing evaluations to determine the earliest point at which the restraint may be removed or deescalated.
5. Institutions should have formal procedures for conditions under which patient restraints may be used and HCPs should be familiar with and act in accordance with these protocols.

Covert Administration of Medication

Covert administration of medicine denies a patient agency, either by deceiving them about what they are receiving or by willful omission. As such it either deprives patients of the opportunity to exercise their autonomy (because they are not aware treatment is happening) or overrules their autonomy (because they are covertly receiving the treatment they previously refused). Covert administration of medicine poses numerous potentially long-term risks, including loss of patient trust and, in the case of covert administration in food, an aversion to eating. Covert administration of medication should only occur when deemed necessary for the care of a patient without decision-making capacity and should not be done simply because it makes treatment easier or faster for clinicians

1. Incapacitated patients may receive covert medication—administration of medication without the patient's knowledge—only when the following conditions have been met:
 - Last resort: The covert administration of medication is the only remaining option available for delivering emergently necessary treatment to the patient.
 - Time-limited: The covert administration is employed for as short a time as possible.
 - Frequent review: HCPs should continually reassess the necessity of covert medication and the patient's ability to be informed of and/or provide consent for the treatment.
 - Transparency: The practice of and justification for covert administration of medication should be clearly documented in the patient's chart.
 - Inclusivity: The decision to covertly administer medication should be made by a multidisciplinary team and people closest to the patient, including alternative decision-makers, should be involved in the decision.
 - Best interests: All decisions regarding covert medications should be made in the patient's best interests, having undertaken a holistic assessment of the impact of the decision on the patient.

Perinatal Mental Health Disorders

Perinatal mental health disorders are particularly complex in that they require consideration of the well-being of the pregnant patient, who is experiencing the mental health condition, and the fetus. For ethical reasons, research on the impact of psychotropic medications on the developing fetus has been constrained; however, it appears that many commonly used psychotropic medications do not need to be discontinued in all circumstances. Therefore, these decisions should be individualized, weighing the benefits to the pregnant patient against the possibility of risk to the fetus. Furthermore, having a mentally and emotionally healthy patient during both a pregnancy and the post-partum period is a benefit to the fetus/child as well.

1. HCPs have an obligation to remain up to date about the risks and benefits of psychiatric medications and their appropriate usages.
2. Pregnant patients or new parents who are identified as being at risk of or having a psychiatric disorder through screening programs must be referred appropriately for treatment; other than such referral, the result of the screening must be kept confidential unless there is reason to believe a pregnant patient or new parent poses an imminent and serious danger to themselves or others.
3. So long as they have capacity, pregnant patients retain their autonomous right to refuse treatment for themselves. If a patient lacks decision-making capacity, an alternative decision-maker is charged with making the decision that they believe is best aligned with the pregnant patient's values and preferences or, if these are unknown, the decision that would be in the patient's best interests. In this situation, the alternative decision-maker may take the best interests of the fetus or child into account as well.

Telepsychotherapy

For further discussion, see chapter titled "Digital Health and Virtual Care."

1. Concerning the assessment of a patient to determine if telepsychotherapy is appropriate, trained and licensed HCPs should only provide opinions about individuals after conducting an examination adequate to support their statements or conclusions. The examination can be via telemedicine (including both audio and visual components) if the clinician has assurances that the individual is able to speak freely and privately.
2. Whether providing assessment, therapy, counseling, or consulting services via electronic transmission, clinicians must obtain the informed consent of the patient using language that is understandable to that person and document that verbal, electronic, and/or written consent in the patient's medical record.
3. As with all telemedicine services, consent should be obtained voluntarily from the patient or alternative decision-maker before beginning the use of telepsychotherapy.
4. Prior to consultation, the clinician must verify and document in the patient's medical record:
 - The identity of the person giving consent.
 - The patient who is the subject of the intervention (e.g., assessment, counseling).
 - The planned intervention and/or treatment.
 - That the patient and/or alternative decision-maker acknowledge that adequate information about the intervention and alternatives have been provided.
 - That the patient or alternative decision-maker give consent voluntarily.

5. For patients who are legally incapable of providing informed consent, HCPs should still: (1) provide an explanation of what will happen, (2) seek the individual's assent, (3) consider the patient's preferences and best interests, and (4) obtain appropriate permission from a legally authorized alternative decision-maker.
6. HCPs should inform the patient or alternative decision-maker of the risks to privacy and limits of confidentiality incurred when using a telemedicine service. The patient or alternative decision-maker should be made aware if recording devices will be used and the release of recording data shall require written authorization from the patient or an alternative decision-maker.
7. Patient photographs and audio or video recording should not be used without the patient's or alternative decision-maker's consent. HCPs and institutions should have policies concerning the creation, maintaining, storing, accessing, transferring, and disposing of records, whether these are written, automated, or in any other medium.
3. HCPs who prescribe digital tools to patients or use them in their practice have an ethical obligation to vet digital mental health tools for sufficient privacy and confidentiality practices, as well as transparency about data collection and usage.
4. Not all patients will have access to robust internet services or to private spaces from which to use such tools confidentially. As a professional duty, mental health care providers must evaluate which patients are unable to use these tools and design alternate ways to provide access to mental healthcare.

Ethical Considerations in Psychiatric Research

For further discussion, see the chapter titled "Clinical Research."

1. When research is conducted on patients with psychiatric diagnoses or impairment due to mental health concerns, it is essential to assess whether the potential research participants have capacity. If not, investigators should conduct the consent conversation with a designated alternative decision-maker, and, if possible, assent should be sought from the patient.
2. Investigators should ensure the consent giver understands the proposed research, the role of the participant in the research, and the option not to participate or to withdraw from participation at any time.
3. As with all human subjects' research, researchers seeking to obtain the informed consent of a potential research subject or an alternative decision-maker must use language that is understandable to the consent giver.
4. In obtaining this informed consent, researchers must inform potential participants or their alternative decision-makers about:

Ethical Challenges in the Adoption of Digital Mental Health Tools

All new tools, such as telemedicine platforms and mental health apps, pose unforeseen challenges to privacy, fairness, transparency, and accountability. These tools are being increasingly adopted and many challenges have yet to be identified; however, privacy of sensitive patient information must be a central concern.

1. Medical institutions and those designing digital mental health tools need to have transparent policies and accountability structures in place.
2. It must be clear to users/patients who will have access to their information and in what form (e.g., aggregate or individual, identifiable or deidentified).

- The purpose of the research, its expected duration, and the procedures involved;
 - The potential participant's right to decline to participate and to withdraw from the research once participation has begun;
 - The foreseeable consequences of declining or withdrawing;
 - Foreseeable factors that may be expected to influence a potential participant's willingness to participate, such as potential risks, discomfort, or adverse effects;
 - Any prospective research benefits and available alternatives to participating in the research study;
 - Limits of confidentiality;
 - Incentives for participation; and
 - Whom to contact for questions about the research and research participants' rights.
5. The prospective participants and/or alternative decision-makers must have opportunities to ask questions and receive answers.
 6. Potential participants and/or alternative decision-makers must clearly understand that the research is not intended as treatment, although there may be a possibility that a patient could benefit from participating in the research.

Appendix 1:

Sample teaching cases

Case 1

The mother of a 6-month-old baby boy is identified as having moderate to severe depression through a postnatal depression screening program and is referred to a psychiatrist. She says she does not feel depressed and does not think she requires counseling or any other services. Should this patient be allowed to forego counseling, potentially placing herself and her baby at risk of harm?

The HCP should assess the patient's decisional capacity. If she demonstrates the capacity to make medical decisions then the patient has the right to make her own treatment choices, including foregoing counseling services. HCPs must evaluate patients thoroughly and to the greatest extent possible engage in shared decision-making with them. The HCP should also ensure that this patient is not the sole caregiver of the baby and that there are others on hand to care for him if she is unable or unwilling.

Case 2

Mary is a tourist in the UAE. She arrives at the hospital with no medical record or companions but in an agitated state, convinced that people are trying to harm her. While she is a petite woman, in her agitation, she has slightly injured several medical personnel by kicking and hitting them. The emergency physician wants to take blood samples to test for illicit substances or diseases that may be affecting her cognition, but Mary is unwilling to allow the blood to be drawn. Does the physician require consent from Mary? Is it acceptable to restrain Mary to draw the blood?

Blood may be drawn from Mary without her consent for diagnostic purposes if it is deemed emergently necessary for her treatment. Such a decision may require consultation with colleagues, or even an institutional ethics committee. Blood draws, or other procedures, should be pursued in the minimum amount necessary for the purpose of her emergent stabilization and treatment. If Mary poses a risk of harm to herself or others (e.g., the person drawing the blood), she may be restrained during the blood draw, but this should be undertaken only if deemed truly necessary

with no other safe alternative course of action. She should be restrained in the least threatening manner possible, with the understanding that doing so is likely to exacerbate her perception that people are trying to harm her. She should be freed from the restraint as soon as safely possible after the blood draw; however, if it is deemed necessary to prevent further harm to herself or others (and not likely to pose a risk by cross-reacting with possible drugs in her system, etc.) she may be given a sedative while restrained. Efforts should be made throughout to try to identify an alternative decision-maker for this patient to assist in directing her current care and with the consideration that her agitation and lack of capacity could persist.

Case 3

A clinician-researcher would like to conduct research on generalized anxiety disorder. He sees several patients with this disorder in his telemedicine clinic and has noticed that they have distinct patterns of speech; thus, he would like to analyze all his therapy session audio recordings to determine if there is an association between patterns of speech and generalized anxiety disorder. He plans to de-identify the recordings and only report aggregate data. Does he need to seek consent from his patients?

The clinician-researcher needs to consult an appropriate research ethics body and those in charge of his institution's confidentiality policy. When patients join his clinical practice, are they informed that their sessions are audio recorded and that they may be used for research purposes? If not, this clinician-researcher would need to seek consent from each patient, after receiving the approval of the research ethics body. If patients were told that their sessions would be audio recorded and that the recordings may be used in a deidentified, aggregated manner, he may not need to seek consent. However, he still needs approval from the research ethics body and his institution before he conducts his desired research.

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Organ Donation and Transplantation



Introduction

Organ and tissue transplantation—the surgical removal of organs or tissues from one individual and their surgical implantation in another individual—can be a life-saving procedure. Donors can be deceased individuals who wished to donate their tissues or organs to others after their death, or donors can be living individuals who have made the altruistic decision to donate tissues or organs without which they can continue to live healthy lives. However, many patients across the globe die annually due to the critical human organ shortage: the number of patients with organ failure in need of a healthy organ far exceeds the number of donated organs that are available for transplantation.

Transplantation medicine therefore raises a host of unique ethical concerns, including those pertaining to autonomy and informed consent, distributive justice in allocation of a scarce resource, and beneficence and nonmaleficence towards organ donors and recipients. These include, for example, deliberations of which factors should determine how potential recipients receive priority for available organs and tissues, and how to make sure all patients in need of organ or tissue donation have equitable access to them. Additionally, allowing living donation requires thorough evaluations and safeguards that can ethically permit healthy individuals to assume the risks of surgery for altruistic purposes and ensure these choices are informed and voluntary.

Transplantation centers and individual healthcare professionals (HCPs) participating in tissue transplantation procedures and care must be licensed by appropriate health authorities. Institutions must abide by governmental and legal provisions outlining the proper resources, infrastructure, personnel, and training/expertise required for safe transplantation services.

Organ Procurement from a Living Donor

Living donors choose to assume the risks of organ and tissue recovery, including diagnostic evaluations and surgical procedures, for the altruistic purpose of helping another individual in need. Per legal guidance, prospective living donors in UAE are permitted to donate their organs or tissues to relatives up to the fourth degree, a spouse to

which the donor has been married for at least two years, or individuals who are up to fourth degree relatives of their spouse. Reciprocal, or paired, donation allows two prospective living donors who are incompatible with their intended recipients to trade recipients with each other, if medically compatible; for reciprocal transplantation to occur, each donor must meet the kinship criteria listed above for their respective intended recipients.

1. HCPs must assess the decision-making capacity of a prospective living donor to ensure the decision to donate is fully informed and voluntary, without undue influence from family, community, or other sources.
2. HCPs must ensure that living donors receive the proper clinical assessment for and counseling on the risks of living tissue donation, including those relating to mental health and psychosocial matters. Prospective living donors should also be counseled on the risks to the organ recipient.
3. HCPs should ensure that individuals considering living donation are aware of and given the opportunity to withdraw from donation at any time, with their reasoning kept confidential.
4. HCPs must obtain informed consent from the prospective living donor for each and all procedures required in the procurement of the donated tissue or organ.
5. HCPs must ensure that living donors' wellbeing is considered independent of that of the intended organ recipient. To the greatest degree possible, HCPs involved in care and counseling of living donors should be separate from those caring for the intended recipient.
6. Living donation from an individual below the age of majority should only be considered and pursued under very select circumstances, often those in which the prospective donor has a familial or otherwise close connection to the intended recipient. In such cases, the prospective donor should receive thorough evaluation and support services, at times

requiring corroborating assessment from an independent body and/or input from an institutional ethics committee. The minor's alternative decision-maker (often a parent or guardian) must provide informed consent for the donation and the minor should provide assent for the procedure as well. (See "Assent for Treatment in Adolescent Patients" in the "Care for Children and Adolescents" chapter.)

7. It is prudent for transplant institutions to facilitate the presence of patient advocates individuals independent of the clinical team who are knowledgeable in the organ recovery and transplantation processes—to support prospective living donors in their consideration of and decisions about donation of tissues or organs.
8. HCPs should counsel prospective living donors that, while they may receive compensation of expenses relating to their donation (e.g., travel fees), it is legally impermissible to receive payment in exchange for agreeing to donate organs; receipt of such payment is punishable by imprisonment and monetary fines.

Organ Procurement from a Deceased Donor

Deceased donors are those from whom organs are recovered after their death. Legally, death is defined as complete cardiopulmonary arrest or the irreversible cessation of all functions of the entire brain including the brainstem.

1. HCPs must be familiar with processes by which organ donation after death is authorized:
 - First-person authorization: Individuals who wish to be donors after death can register these wishes through the Ministry of Health and Prevention or the government-sponsored "Hayat" app, confirm them on their identity cards, or state them in written and witnessed wills; documented desire to be a deceased donor can be revoked at any time before an

individual's death. Individuals may similarly document their wishes not to be deceased donors.

- Authorization by relative(s): If a decedent's wishes pertaining to organ donation were not previously documented or are unknown, authorization for organ donation may be obtained from an alternative decision-maker. Per legal guidance, if a decedent did not identify an alternative decision-maker before death, HCPs should seek authorization from a relative of the patient in the following order of priority: father, mother, husband, wife, son, daughter, grandfather, grandmother, son's children, daughter's children, paternal uncle, paternal aunt, maternal uncle, maternal aunt, paternal uncle's children and maternal aunt's children.
2. Institutions should have clear policies regarding deceased organ donation, including which personnel will discuss donation with the family; how the clinical team caring for the patient before death will be separate to the greatest degree possible from clinicians involved in organ procurement; and procedures for organ recovery after the declaration of death. HCPs should be aware of and abide by these policies.
 3. HCPs should ensure that consideration of organ donation after death does not compromise end-of-life care or palliative care measures in any way.
 4. HCPs should ensure the families of deceased donors are supported, with the help of social workers, spiritual care providers, and psychology services, as needed.
 5. HCPs must ensure that procedures required for organ procurement are completed in a manner that is as respectful of the deceased donor's body as is possible.
 6. HCPs should protect the confidentiality and privacy of deceased donors in the same manner as that of any other patient post-mortem. Organ recipients should not be informed of deceased

donors' identities; likewise, the families of deceased donors should not be informed of the identity of recipients.

7. HCPs should educate all patients on the option of deceased donation, the general procedures or organ recovery after death, the potential benefit to organ recipients, and how donation wishes may be registered.

Recipient-Related Considerations

1. Only those HCPs who have the medical knowledge and technical expertise needed should participate in transplantation procedures and transplant-related care. Similarly, transplant-related care should only be offered in medical facilities that have the equipment, infrastructure, and personnel required.
2. HCPs should discuss all necessary information for potential organ recipients, or their alternative decision-makers, to provide informed and voluntary consent. This includes risks and benefits of accepting transplantation; details of procedures required and their risks and benefits; realistic expectations of the process before, during, and following transplantation; the anticipated recovery from the transplantation procedure(s); and the need for long-term follow-up care and medication adherence. This will require dedicated time, allowing patients to ask questions and receive clarifications, as well as support services such as social workers, palliative care specialists, and patient advocates.
3. HCPs should inform patients and their families of the physical, emotional, and social support the patient will likely need from caretakers at home. HCPs should ensure that the recipients have individuals in their life with close relationships who can provide such support.

Ethical Allocation of Organs and Tissues

All patients in need of transplantation should undergo the same processes of evaluation and have equal access to transplantation waiting lists, with prioritization of recipients based on predetermined and medically grounded criteria that do not allow discrimination.

1. HCPs should promote policymaking that treats organs as a precious resource to be allocated based on fair mechanisms.
2. HCPs should promote policymaking that allows for organized central registries that are subject to continual oversight and updating.
3. HCPs should provide equitable access to organ transplantation by ensuring all patients with (or anticipated to develop) organ failure are referred for necessary evaluations per evidence-based standards and in a timely manner, and that eligible patients are equitably listed for transplantation.
4. HCPs should ensure that organs for transplantation are allocated to recipients based on clinically and ethically grounded criteria, which include but are not limited to how urgently the patient needs transplantation, as well as the degree to which and for what duration the patient is likely to benefit from transplantation.
5. HCPs are ethically and legally prohibited from participating in any selling or buying of transplantable tissues or organs, punishable by imprisonment and monetary fines.

Emerging Technologies in Transplantation Medicine

HCPs who participate in transplant-related care should remain abreast of emerging technologies and promising advances that could help reduce the morbidity and mortality of organ failure and the human organ shortage. For example, avid research is underway exploring the prospect of xenotransplantation, the use of organs and tissues from nonhuman animals for transplantation into humans. HCPs should be aware of the novel concerns such research raises, including the risk of zoonoses, infections that could be transferred from nonhuman animals into humans through transplantation. In the future, other innovations with potential for clinical translation include bioengineered or synthetically derived organs.

Appendix 1:

Sample teaching cases

Case 1

You are a member of the transplant clinical team involved in evaluating Mr. B, a potential living kidney donor who is considering donating a kidney to his cousin. Mr. B is a 42-year-old man who is married with two young children; he works as a cook at a restaurant and is the sole provider for his family. During the evaluation process, Mr. B cautiously voices to you that he is incredibly nervous about the donation, especially about the surgical procedures required since he has never undergone surgery. He is also extremely anxious about the anticipated recovery process, the potential limitations he'll face in returning to work quickly, and how this will impact the household income his entire family relies on. However, he says, he feels obligated to proceed with the organ donation since his entire extended family is counting on him to help save his cousin's life. How should you proceed?

The decision to make a living organ donation is an admirable and altruistic one, but should always be made with complete information and voluntariness. It is important that Mr. B does not proceed with organ donation because he feels significantly pressured rather than it being a decision he has come to freely. Familial pressure can be a difficult issue to balance in considerations of living donation as many

individuals considering donation care a great deal for the loved one hoping to be the recipient of their organ. Mr. B should be assured that if he were to decline to proceed with organ donation, his reasoning would remain confidential and his relative would simply be told that Mr. B was not a compatible match. He should also be supported in taking the time he needs, as well as receiving and reviewing all pertinent information, to make a decision with which he feels truly comfortable. Achieving this may require a patient advocate: a person knowledgeable in organ donation who is independent of the clinical team and can help Mr. B reason through his decision, realistically consider what the process will entail, and scrutinize the internal and external pressures he is feeling.

Case 2

You are a hepatologist specializing in peri-transplant care. One of your patients is Mrs. N, a 65-year-old woman who is awaiting liver transplant. After one of her appointments, her son approaches you privately and offers a large sum of money in exchange for your help in getting his mother higher priority for the next available donated liver. He says he wishes he didn't have to make this request and is only doing so because of how worried he is for his mother and how much she means to his entire family. How should you proceed?

You should explain to the patient's son that it is ethically and legally impermissible to accept money for the buying or selling of organs and tissues for transplantation, or for circumventing normal waiting list procedures. You can compassionately discuss your understanding of his deep care and concern for his mother but reiterate that transplant waiting list priorities are determined by clinical criteria based on urgency of need and likelihood of benefit. You should also reassure Mrs. N's son that you will do everything you can to provide the care she needs, including transplantation as soon as it becomes a viable option.

Case 3

You are a primary care physician seeing a 72-year-old patient in clinic. During the visit, your patient mentions that he has seen informational pamphlets about organ donation after death, but that he is nervous to register as an organ donor. He explains that he is concerned that if he were to become critically ill or have a medical emergency and the

clinical team in the hospital knew that he had registered his wishes to be deceased donor, they may not take as good care of him or may forgo resuscitation efforts so that he could be declared dead and then his organs could be procured for transplantation to save someone else's life. How should you counsel the patient?

This is an opportunity to educate the patient on deceased organ donation. You should assure the patient that the decision to become an organ donor after death does not and will not impact any of the healthcare he receives. You should explain that patient care is always a clinician's primary concern and that he will receive the care that is in his best interest, including resuscitation, curative treatment, adequate palliation, or end-of-life care. You should also take the time to explain the general procedures of donation after death and how other patients could benefit from donated organs and tissues. Finally, regardless of whether he decides to be a deceased organ donor, you should encourage the patient to register his decision with appropriate registries, and to discuss his wishes with family members.

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Medical Tourism



Introduction

Medical tourist is defined as an individual “who has no residence visa in UAE or travelling from abroad into the UAE for the purpose of receiving clinical treatment services and non-emergency healthcare services, excluding patients whose medical care is funded by the by the UAE government or who are insured by health insurance policies issued by UAE licensed health insurance companies.” More simply, a medical tourist is a person who travels abroad for healthcare, which can refer to treatment for a disease, organ transplant or other surgery (including cosmetic procedures), dental care, wellness care, and more.

Although people travel abroad for healthcare for many reasons, it is generally because they are not able to obtain the required or desired care in their home countries. Importantly, although this care may be available in the patient’s home country, it may be inaccessible to the individual patient because of cost, the quality not being to their standards, wait times that are too long, or due to legal, cultural, or other barriers to access. A medical tourist may also wish to combine healthcare with a planned vacation.

Morally and professionally, medical tourists should be treated the same as any other patient. Although medical tourism may frustrate efforts to afford patients the same quality and ethical care provided to domestic patients, ethical principles of respect for persons, beneficence, nonmaleficence, and justice nevertheless require healthcare professionals (HCPs) to act in the best interest of medical tourists, in accordance with patients’ values and preferences. These guidelines review ethical issues that may arise for HCPs when treating medical tourists, both visiting and returning.

Justice Concerns

Medical tourism raises unique concerns about equity of access to quality medical care. Locations that are popular medical tourism destinations may serve a population of travelers that are able to pay out of pocket for their care.

1. HCPs should ensure that all patients get the same high-quality care; in accordance with the principles of justice and beneficence, care should not be prioritized for better resourced foreign patients at the expense of local patients.

2. HCPs should be familiar with and abide by the local regulatory body’s policies that ensure that medical tourism does not negatively affect existing care for the UAE population, as well as policies ensuring quality and continuity of care for medical tourists.

Informed Consent

Informed consent is the foundation of ethical care. A sound consent process relies on patients’ understanding of what care comprises, its potential risks and benefits, and alternative treatment options. Medical tourism presents challenges to informed consent that HCPs should be aware of and work to address, including that international patients may be unfamiliar with local language, culture, religion, and medical systems. Similarly, HCPs may be unfamiliar with these aspects of international patients’ backgrounds and experiences.

1. HCPs must provide information in a way that patients can comprehend and with the same detail as is provided to all patients.
2. HCPs should provide, or arrange for, interpreters and/or translators, as well as culturally competent assistance if patients request it, including chaperones and social workers.
3. HCPs should understand that patients from under-resourced countries or communities may not be familiar with medical practices of more technologically advanced countries or health systems. Also, there may be cultural practices or norms surrounding medical care in other regions of which HCPs should be aware. HCPs must therefore take the time and use the resources necessary to ensure patients understand discussions of care options.
4. HCPs must ensure that all patients give consent voluntarily.

Medical Tourists Traveling to the UAE

Local Regulating Bodies' standards describe guiding principles for medical tourism, as well as requirements for HCPs regarding international accreditation. Although the standard is designed for HCPs in the UAE Medical Tourism Network, all HCPs should be familiar with these recommendations and requirements, as they may find themselves caring for international patients

1. HCPs are ethically and professionally required to offer international patients the same high-quality, compassionate care that they provide local patients.
2. HCPs should arrange for culturally competent assistance as needed, including provision of interpreters and/or translators, chaperones, and social workers.
3. HCPs should ensure that patients leave their care with complete, easy-to-understand records of treatment, prescriptions, and follow-up care requirements, as well as clear contact information.
4. HCPs are required to report medical tourism patient data through Shafafiya within 24 hours after the patient encounter ends.
5. HCPs are required to maintain patient confidentiality in accordance with the ethical principles of respect for persons as well as professional, legal, and institutional guidelines. See the chapter on "Patient Privacy and Confidentiality" for more information.

Medically Assisted Reproduction (MAR)

The UAE offers medically assisted reproduction (MAR) to international patients. See "Medically Assisted Reproduction" in "Women's Health and Reproductive Medicine" chapter for further discussion.

1. The ethical principle of autonomy requires fully informed consent from women who plan to pursue MAR; legally, husbands are also required to consent. HCPs should allow sufficient time during the informed consent process to adequately inform couples of benefits and risks, including potentially negative outcomes such as failure to conceive or adverse events; evidence-based counseling on likelihood of success; costs; limits on the number of attempts; and opportunities for future pregnancies.
2. HCPs must obtain written permission and informed consent from couples before screening embryos for genetic abnormalities prior to implantation. HCPs must obtain the couple's informed consent for specific test(s) that will be performed.
3. HCPs must discuss abnormal findings of preimplantation or prenatal genetic testing and clearly explain the potential severity of the disease or condition, when it is expected to manifest in the child, and other relevant factors. Genetic counselors should be available before testing and during and following disclosure of results.
4. HCPs must ask before preimplantation or prenatal genetic testing whether the couple wishes to be informed of incidental findings.

Telemedicine

HCPs might provide virtual healthcare consultations with foreign patients who have traveled to the UAE, especially for treatments that require longer-term care, such as MAR, or for post-surgical and other types of follow-up care. Telehealth care entails unique privacy considerations for patients, but respect for persons requires that the same privacy and confidentiality guidelines for in-person care be applied to virtual care.

1. HCPs conducting virtual appointments should inform patients about safeguards in place to protect confidentiality and cyber threats unique to the electronic transmission of

information as well as limitations of virtual appointments. This is especially important for medical tourists who have come to UAE for treatment that is prohibited or limited in their home countries.

2. HCPs should conduct/practice telemedicine only through approved and secure platforms and in offices or spaces that afford privacy.
3. Patients must expressly acknowledge the security limitations of tele-appointments and consent to recordings. HCPs should abide by the guidelines outlined in “Maintaining Confidentiality in Audio/Visual Patient Recording” in the Patient Privacy and Confidentiality” chapter.
4. For minors or patients who lack capacity, guidelines apply to alternative decision-makers.

Medical Tourists Traveling from the UAE Before the Patient Travels

1. HCPs should actively promote relationships of trust and openness to encourage patients to be forthcoming about medical travel abroad.
2. HCPs have an ethical obligation to express concerns to patients if they believe they may be placing themselves at undue risk, would be pursuing unnecessary care, or forgoing care at home that may be in their best interests, such as hospice care for end-stage diseases.
3. HCPs should ensure that patients considering medical tourism have considered comparable options at home and should refer them to appropriate colleagues.
4. HCPs should offer candid opinions about the expected quality of care a patient may receive abroad and when such care may or may not be in a patient’s best interests.

5. HCPs should urge patients who will travel abroad to provide foreign HCPs with comprehensive medical records, in accordance with local regulatory bodies and institutional requirements.
6. HCPs should encourage patients to familiarize themselves with local laws regarding legal recourse for adverse events, substandard care, or even malpractice, including the fact that there may be limited or no recourse, especially after a patient has left the country.
7. HCPs should strongly recommend that patients return as much detailed information about the care they receive abroad as is possible. At minimum, patients should record the name of and contact information for the HCP abroad; they should also be strongly encouraged to obtain information regarding care provided, prescriptions, after-care recommendations, and the like.
8. HCPs should inform patients about care they will or will not be able to provide when patients return from their medical travel.
9. HCPs should assure patients that all information about healthcare, no matter where it was provided, will be held in confidence according to country, state, local, and institutional regulations, as well as professional codes of conduct.

Risks and Benefits

1. HCPs should provide, to the extent possible, information about what patients may expect during care abroad so that patients can assess the benefits and risks, and can make informed decisions.
2. HCPs should plainly discuss the possibility of inadequate infection control practices abroad, such as for HIV, hepatitis, and other bloodborne infections that may not be prevalent at home.
3. All experimental/unapproved treatments come with risk, and benefit may be limited or even unlikely in certain circumstances. HCPs should stress this with patients and encourage them to enroll in clinical trials for experimental treatments when practicable.
4. HCPs should discuss the effects of long-distance travel on recovery; the possibility of separate, treatment-unrelated travel risks; and that engaging in vacation activities, such as physical activities and consuming alcohol, may affect recovery, especially following surgery.
5. Patients with chronic pain or life-threatening conditions comprise a vulnerable population who may be incentivized to seek alternative or experimental treatment abroad and may be more likely to try riskier medicines or procedures while discounting the potential for complications or poor outcomes. HCPs should be especially sensitive to this vulnerability and take special care to help patients understand risks and benefits.

Appendix 1:

Sample teaching cases

Case 1

You are an oncologist with a young patient who has end-stage pancreatic cancer, has exhausted all approved treatments, and is unable to enroll in a clinical trial due to the advanced stage of his disease. The patient has a wife and two young children, and he cares for his elderly mother. He informs you of his plans to travel to another country for experimental immunotherapy. You believe the therapy will not help and may well hasten the patient's death, but he insists that he must try. What should you do?

While respect for persons and patient autonomy require that you honor the patient's decision about his own care, you should attempt to provide sufficient information to make a truly informed choice more feasible. You should explain the potential harms of the therapy he is seeking and his small chance of success. You should also encourage the patient to consider associated costs—physical, emotional, and financial. Importantly, you should discuss the benefits of palliative and/or hospice care to improve his quality of life and allow him to spend his remaining time with his family. A palliative care specialist should be enlisted to assist in this discussion. Since the decision is your patient's to make, if he decides to travel to pursue the treatment, you should encourage him to return with information about the clinician, treatment provided, recommended follow-up treatment, and possible adverse events. You must treat him compassionately, and he must not feel abandoned by you because of his decision.

Case 2

You are a cosmetic surgeon with a busy practice. A colleague in London asks you to see their patient for a procedure the next day, as the patient is in the UAE on vacation and hopes to have the procedure done before returning home. The patient is very wealthy and would pay a premium to be able to be seen by you. The extra funds would benefit your clinic greatly. Should you see the patient?

The principle of justice prevents you from contributing to an unequal healthcare system, whereby wealthy medical tourists receive preferential treatment at the expense of your local patients. This can create a two-tier unjust medical system. Even though the treatment may be elective, and non-emergent, respect for patients requires you to honor your appointments and responsibilities to local patients and to only see this patient if care of other patients will not be compromised in any meaningful way.

16



Clinical Research



Introduction

Clinical research is the testing of new medical products (drugs, biologics, devices), medical practices, and clinical teaching methodologies. Research subjects may be patients or colleagues, in addition to healthy volunteers. Patients typically participate in research in hopes of personal benefit, although they may have altruistic reasons too, hoping their participation will benefit other patients, science, or society. Non-patient research participants may also hope for personal benefit (including financial benefit), but generally volunteer for the advancement of science. In all cases, it is essential that prospective research subjects have a realistic understanding of the research experience, including potential benefits and harms. All individuals participating in research must do so voluntarily; for those unable to consent to participate, an alternative decision-maker must consent on their behalf. This emphasis on voluntariness is based on the ethical principle of respect for persons, whereby capacitated individuals are understood to have the moral authority to make decisions for themselves.

This chapter reviews ethical concerns entailed by human subjects research in the clinical setting and offers guidelines to help researchers and healthcare professionals (HCPs) act in the best interests of individuals who are research subjects. Some individuals and communities view human research with suspicion and believe that it is exploitative; because such research establishes the evidence on which good medical care is based, HCPs have an ethical obligation to explain the vital importance of human subjects research and the role that ethical and legal oversight entities play in preventing exploitation.

Oversight and Transparency

Researchers may also be HCPs and sometimes they may interact with patients in both roles. In such cases, HCP-researchers have an ethical obligation to be transparent and forthcoming with patients about their dual roles and to always practice in the best interest of the patient.

1. HCP-researchers should refer patients who are uncomfortable with the HCP's dual role to colleagues for their clinical care. Patients are free to decline to participate in the HCP's research (or to withdraw at any time) without

damaging their relationship with the HCP or losing access to the clinical care they receive from that HCP.

2. In the UAE, to conduct research on humans, a researcher is required to receive approval of a research protocol from either an institutional Research Ethics Committee or, where this does not exist, the local regulatory body's Research Ethics Committee. Other approvals may be required from legal or institutional bodies.
3. Researchers must disclose to funders, oversight bodies, and potential subjects any possible conflicts of interest, as these may result in biased data and undermine social trust in research. For further discussion, see "Conflict of Interest" chapter.
 - A conflict of interest can be financial (such as having a stake in a company sponsoring a study or funding that is dependent on study outcomes) or non-financial (such as a researcher motivated by ideology or academic prestige).
 - Researchers are typically required to disclose conflicts of interest during the grant application process, when publishing articles, when presenting their research (such as at professional conferences), and at other times.
4. Human subjects research must be:
 - Justifiable by its potential benefits, including (but not limited to) its contribution to knowledge, improving social welfare and individual wellbeing;
 - Based on a thorough study of the literature and, where appropriate, preceded by adequate laboratory and/or animal studies;
 - Undertaken with a commitment to disseminating and communicating results, whether favorable or unfavorable, in ways that permit scrutiny and contribute to public knowledge and understanding;

- Just, in that the selection, exclusion, and inclusion of categories of research participants and recruitment and distribution of benefits of participation is fair; the process is accurately described in its methods and results; and there is no exploitation of participants;
 - Respectful of the privacy, confidentiality, and cultural sensitivities of the research participants and, where relevant, their communities;
 - Respectful of the right of research participants to make their own decisions; and
 - Able to offer potential benefits that outweigh its risks.
5. Researchers are responsible for ensuring the integrity of the data collection and storage.
 6. Researchers should be aware that research can be terminated if an oversight entity determines that there are ethical or safety reasons for doing so, or if the medical product under study is shown to lack efficacy.

Voluntary Informed Consent

1. Informed consent for participation in research should be an ongoing process. While informed consent is sought to enroll an individual into research, investigators must be alert throughout the course of research for any signs that the study subject did not clearly understand the study purpose or procedures and/or their rights as a study subject. If there is a question of the validity of a subject's consent, care must be taken to re-explain everything to the study participant and reaffirm their consent.
 2. Researchers must obtain informed consent from each potential research participant or their alternative decision-maker and have this informed consent documented by obtaining their signature on a consent form approved by a research ethics committee.
3. Informed consent entails two equally important aspects: information and voluntariness.

A Information:

 - Researchers should ensure that the consent discussion is conducted in an age- and comprehension-appropriate way, free from technical terminology or jargon. Interpreters, including signers, must be provided for patients who request them. Consent forms must be written in terms that can be readily understood by potential subjects.
 - Researchers must inform potential subjects of the purpose of the study, how it will be conducted, its duration, the probability of random assignment, potential benefits and risks, and what/if compensation for harm will be provided. "Opportunity costs" such as lost time from work, the possibility of having to hire childcare, and the like should also be explained. Research oversight bodies may require that potential subjects undergo additional steps such as taking a quiz or answering questions to ensure comprehension.
 - Potential subjects should be given time to review materials and information, ask questions, and discuss participation with family, friends, HCPs, or others.
 - Researchers must inform potential participants of any alternatives to participation in research that are available, as well as the potential outcomes of choosing the various options.
 - Researchers must ensure that participants receive a copy of their signed and dated consent form and urge them to share it with their HCPs.

B Voluntariness:

 - All potential research participants must be deemed to have capacity to make the participation decision. If there is a question as to an individual's decision-making capacity, researchers must obtain a capacity assessment, conducted by a qualified clinician who is not involved in the research.

- Participants must understand that their participation is voluntary and that they may withdraw their consent at any time, for any reason, with no negative consequences.
 - Policies should be in place that define research participation incentives permissible per research ethics committee; these incentives must not be so enticing as to be considered undue inducement, meaning incentives that are so great that they compromise the participant's ability to make a rational consideration about enrolling in a research study.
4. Some research may require modifying the informed consent process by actively deceiving participants for the purposes of the study, such as behavioral studies. Some people maintain that active deception is never permissible, while others would permit it in certain circumstances.
- Deception is not permissible in cases in which the study exposes participants to more than minimal risk.
 - When deception is deemed indispensable for obtaining valid results in a study, researchers must demonstrate to the research ethics committee that no other method could obtain valid and reliable data; that the research has significant social value; and that no information has been withheld that, if divulged, would cause a reasonable person to refuse to participate.
 - Researchers and research ethics committees must be aware that deceiving research participants may wrong or harm them; participants may resent not having been informed when they learn that they have participated in a study under false pretenses. Furthermore, knowledge of research involving deception may undermine public trust in researchers and research institutions.
 - Whenever deception is necessary to maintain the scientific validity of the research, potential participants must be asked to agree to receiving incomplete or inaccurate information during

the informed consent process (meaning that researchers obtain consent in advance for the deception). The research ethics committee must determine how participants must be informed of the deception upon completion of the research. Such informing, commonly called "debriefing", ordinarily entails explaining the reasons for the deception. Debriefing is an essential part of trying to rectify the wrong of deception.

- Participants who disapprove of having been deceived for research purposes must be offered an opportunity to refuse to allow the researcher to use their data obtained through deception. In exceptional cases, a research ethics committee may approve the retention of non-identifiable information. For example, an option to withdraw data may not be offered in cases where research is evaluating quality of services or competence of providers.

Special Populations

Researchers have an obligation to protect all participants in clinical research. Certain populations may need special considerations or protections. Often referred to as "vulnerable" populations, the chief concern regarding these populations is that because of external (for example, imprisonment) or internal (for example, developmental disability) factors, certain individuals who are potential research subjects may not fully understand to what they are being asked to consent or they may not feel empowered to decline participation.

1. For children under 18 years of age, researchers must obtain consent from a parent or legal guardian; researchers should also obtain assent from children 8 years of age and older.
2. Because communication is essential to the researcher-subject relationship and the ethical conduct of research, researchers are ethically obligated to secure professional interpreters for potential subjects who cannot speak, hear, or understand the language spoken by researchers or others involved in the study.

3. Researchers must ensure that written, visual, audio, or other materials are presented in formats and language that potential participants and participants can understand.
 4. Researchers must ensure that potential participants who are patients or otherwise in dependent relationships on the HCPs conducting the research (e.g., medical students) fully understand that they do not need to participate in the research and can withdraw at any time with no loss of care or other detrimental impacts.
 5. Research populations should be chosen because they provide suitable subjects for testing a hypothesis or observing an outcome of interest, not because they are merely convenient or easy to conduct research on. Researchers must be able to justify why they wish to study a particular population of subjects and how the knowledge gained will benefit that population as well as any other populations.
2. The study coordinator must make arrangements for someone on the research team to be able to be unblinded quickly at any point, if needed, for urgent patient care. For example, if a subject has a medical emergency and/or is hospitalized, the unblinded member of the study needs to be able to report if the patient was receiving the active drug or the placebo.
 3. At the end of the trial, if the active drug was deemed safe and effective, all subjects who received the placebo must be offered the opportunity to receive the active drug for the same amount of time as the subjects who were assigned to the active drug.
 4. The public may have a negative view of placebo controls, seeing them as undesirable. However, if a placebo is known to be less effective than an experimental agent, then a comparative trial between the two cannot be held, and once it is determined that one is better than another the trial ends. Thus, being randomly assigned to a placebo is not a bad outcome and, in fact, it may be the preferential outcome if the experimental drug has unacceptable side effects. HCPs and researchers should help to educate patients, their families, and the public about the important role of placebos and help make placebo-controlled trials more acceptable.

Ethical Use of Placebo Controls

In placebo-controlled research studies, participants may be randomized to receive a placebo, an inert substance resembling the active test agent. Humans may develop physiological responses, good or bad, simply from anticipating effects; to understand the true effects of an experimental agent, one needs to be able to account for these effects of a placebo. In a blinded study, the subject does not know if they are receiving the active drug or the placebo; in a double-blinded study, neither the subject nor the researcher knows what the subject is receiving to minimize bias in the researcher's recording or interpretation of results. In some studies, the subjects "cross-over," receiving both the active drug and the placebo during the study, without knowing when.

1. Ethically, a study may not include a placebo once there is a standard-of-care treatment available. In this case, the experimental treatment would be compared to the standard of care.

Obligation to Promote Knowledge

The primary objective of human subjects' research is to advance knowledge. Before a study begins, the methodological/preclinical work underlying the protocol must be deemed sound and must indicate that beginning human studies is warranted. Independent bodies should be tasked with reviewing and prioritizing research protocols to maximize the utility of the research endeavor and prevent duplicative or unimportant research from using limited personnel and resources. In accordance with laws and regulations governing the protection of human subjects' research, institutions should develop policies for the reporting of incidental findings during research, as well as the need to revisit discussions of privacy and confidentiality when primary data is reanalyzed or reused. There should also be a commitment to disseminating results, both positive and negative, in effective ways.

1. Researchers should halt enrollment for studies that have no chance of being fully enrolled or for research that cannot be completed in a timely manner.
2. The ethical principles of respect for persons and justice require researchers to share research findings publicly, such as by publishing manuscripts, presenting at conferences, or other means. The advancement of science relies on such sharing.
3. Researchers should make concerted efforts to locate participants of completed studies to share the findings.

Maintaining Social Confidence in Research

The research community must make efforts to demonstrate to the public the benefits of human subjects' research and explain what protections are in place to prevent unethical research. Monitoring and auditing research involving human subjects and public disclosure of research misconduct are essential to preserving social trust in such research. These may entail the development of new oversight bodies and/or increased funding of existing ones. The research community should also make every effort to ensure that research is designed to be of maximal utility to those who would seek to use its findings. Being fit for purpose is an essential ethical precursor for any research on humans. Furthermore, as physical or emotional harm may be a foreseeable outcome of human subjects research, the research community should be at the vanguard of developing policies for ameliorating such harms and/or compensating the victim(s).

1. Researchers should ensure that participants know that they may withdraw from the research at any point, without penalty. However, subjects may or may not be able to have data and/or specimens already collected from them destroyed and they may or may not receive the full incentive or reimbursement that they would have received had they completed the entire study. Researchers should emphasize provisions in the consent documents that may be of special interest to participants, such as those regarding data maintenance and confidentiality, conditions that could affect reimbursement or incentive, and the like.
2. Researchers must secure the confidentiality of participants' information in accordance with relevant laws and regulations. This should be detailed in the consent form and emphasized to participants.
3. In accordance with the local regulatory body policies, researchers must ensure appropriate safeguards are used with all identifiable electronic data, including encryption, de-identification, and access protections.

4. Researchers should abide by the storage, maintenance, use, and security requirements of the local regulatory body's standards on human subjects research for all research, including genomic research."
5. Researchers, including clinician-researchers, must inform patients of the privacy and confidentiality risks posed by their participation in a study.

Research Misconduct

There are a variety of forms of research misconduct. Fabrication is making up data or results and recording or reporting them. Falsification is changing or omitting data or manipulating research materials, equipment, or processes such that the research is not accurately represented in the record. Plagiarism is the appropriation of another's ideas, processes, results, or words without attribution. All of these can lead to financial harm by wasting resources and personnel time and can lead to a lack of trust in science and medicine.

1. HCPs with research oversight responsibilities should facilitate timely and fair investigation of reports of scientific misconduct.

Publication/Citation of Findings from Unethical Research

HCPs who hold positions in medical journals may occasionally have to decide if it is ethical to publish a study describing unethical research that produced novel, potentially valuable, findings. Opinion has been, and remains, divided on this topic, with some saying unethical research should never be published and others saying if subjects were treated unethically, the least that can be done is to honor their mistreatment by learning from them. The debate extends to citations, with some saying citing an unethical study validates it, while others say if material was relied upon in any way, then it should be cited. Still others suggest that if the findings from the unethical study are used, it must be accompanied by a text disclaimer explaining the source of the material and why it was unethical.

1. HCPs must never engage in unethical research.
2. When publishing or citing, HCPs should use only ethical sources in all but exceptional situations.
 - When there is no ethical source available and it is not possible to replicate the study in an ethical manner, the unethical source may be published/cited if the author or journal pays honor to those who were harmed by the unethical experimentation, considers the research methodologically sound, considers the findings valuable for the advancement of patient welfare or some other socially beneficial purpose, discloses the source of the content, and explains why it is unethical and why it is being published anyway.

Appendix 1:

Sample teaching cases

Case 1

You are an oncologist, and your patient has been diagnosed with metastatic breast cancer. You inform her that there is a phase III clinical trial of an investigational agent currently recruiting participants at your hospital. She and her family react negatively, saying that she will not be experimented upon. What should you do?

You should emphasize that participation in a clinical trial is voluntary on the part of participants and declining to participate will not affect her standing as a patient at your hospital in any way. But you should also explain that clinical trials are an essential part of testing potential new treatments and procedures, and that phase III is the final stage of this testing. You should explain that in this study patients are randomly assigned to receive either the standard of care anti-cancer drug that she is currently taking or a new drug that is not approved but seems promising. If she is assigned to receive the standard of care drug, nothing will change in her treatment. If she is assigned to receive the new drug, it may benefit her and, if it does not, she can come out of the trial and return to the drug she is on currently. Clinical research is overseen by scientific, legal, and ethical experts to ensure that participants are not exploited and to try to ensure that the trade-off of risks and benefits of participating in research is in participants' favor. Finally, if she were to choose to participate in clinical research, she could change her mind and withdraw at any point, without penalty.

Case 2

You are designing a research study to test a hypothesis using blood routinely collected from patients in your clinic. No extra blood would be drawn; rather, the blood left over after routine blood draws would be used. Since the blood being used is being collected from routine medical care, you do not believe you need to seek research ethics approval. A colleague disagrees, and says you need both research ethics approval and, even if consent is waived, a plan for handling de-identification and data security. How should you proceed?

When in doubt, you should always presume you need human subject research review and approval; the appropriate reviewers will inform you if your research is exempt from oversight or if it qualifies for lessened oversight, as in the case of a waiver of consent. In this case, you should take your colleague's advice and seek review and approval of your research protocol.

Case 3

To gauge the impact of racist beliefs in medical students, you propose a study where medical students interact with a standardized medical patient (actor playing the role of patient) who provides all the same information from student to student except self-identified race. The medical students recruited for the study would be told the purpose of the study is to examine the role of standardized patients in medical education, while the true purpose of the study would be to examine the role of self-reported race in the students' assessments of the standardized patients. Thus, the recruitment would involve deception, with the idea that if the students were told the true purpose of the study, they would alter their behaviors and not behave naturally, undercutting the utility of the study. Is this study permissible?

Even though it involves deception, this study may well be permissible, if it is deemed: (1) likely to yield important findings that would not be otherwise findable; (2) of no more than minimal risk in terms of possible harms to subjects; and (3) subjects can be debriefed about the true purpose of the study right away. However, studies that involve deception run the risk of souring public opinion on research and researchers, so they must be carefully reviewed and only used when deemed worthwhile and when there is no option that does not involve deception.

17



Use of Innovative Medicine



Introduction

Medical innovation is crucial in advancing healthcare and improving patient outcomes. As medical advancements and technological innovations emerge, clinicians must ensure that ethical principles are upheld to protect the well-being and rights of patients. Innovation in medicine could be: (1) a non-standard treatment or approach solely aimed at enhancing the well-being of an individual patient; (2) a scientific change from currently accepted medical practice based on scientific observations and explicit rationale; or (3) a modification of the accepted standard of care in small incremental steps. Innovation and research both aim to explore paths beyond currently accepted practice and standard of care; but the aim of innovation is to provide clinical benefit to a current individual patient, while research aims to provide generalizable knowledge for future patients.

There need to be collaborative efforts within healthcare institutions to answer questions such as: Where is the line between innovative practice and clinical research? What should healthcare professionals (HCPs) do when they want to pursue an innovative intervention for their patient? How can HCPs assess whether proposed innovative interventions are ethically and scientifically sound? Within the local regulatory body, what is the legal and ethical process for adopting innovative treatments as the new standard of care?

HCPs should be educated about their institution's policies for engaging in innovative practice and the processes by which an innovative practice transitions into clinical research and, if supported by data, the new standard of care. While guidance may vary depending on whether an innovation is a drug, device, procedure, test, or technology, this chapter aims to provide HCPs with a framework for ethical considerations in the context of innovation in medicine. The ethical framework takes into consideration both diverse patient populations and cultural, religious, and genetic factors.

Informed Consent for Innovative Interventions

1. Patients or alternative decision-makers must be fully informed about the nature, purpose, risks, benefits, alternatives, and potential outcomes of any innovative medical intervention, allowing them to make informed decisions. These decisions also need to be voluntary and made without undue pressure from family members, communities, clinicians, researchers, or medical institutions.
2. HCPs should be sensitive during the informed consent process to the notion that innovative interventions may be particularly complicated or entirely novel to a patient, and allow time for questions and clarifications as needed.
3. Informed consent should be obtained in a culturally appropriate manner, considering language, religious beliefs, educational background, and the health literacy of patients or alternative decision-makers.
4. Patients or alternative decision-makers have the right to refuse receipt of non-evidence based innovative treatments or participation in research without compromising their access to standard, traditional medical care.
5. Special effort should be made in educating patients and alternative decision-makers about the difference between medical errors and potential side effects of adverse reactions to interventions or procedures.

Risk and Benefit Assessment

1. The potential benefits and risks of an innovative practice should be carefully evaluated by HCPs and explained in detail to patients.
2. Innovative interventions should prioritize patient welfare, aiming to provide clear, or at least acceptable, benefits and/or minimizing harm.
3. The potential risks and benefits of innovative treatments should be carefully evaluated, considering the available evidence and the expertise of HCPs.
4. The use of innovative interventions should be based on a reasonable expectation of efficacy and safety, supported by scientific research or well-founded theoretical justification.

Equity and Accessibility

1. Innovative practices should be equitably accessible to all patients. Efforts should be made to ensure equitable distribution and affordability of innovative treatments, tests, procedures, and technologies.
2. The potential impact of innovative interventions on healthcare disparities should be considered; HCPs and healthcare institutions should take steps to minimize or address any unintended consequences that may exacerbate existing inequities.

Confidentiality and Privacy

While there is a social obligation to report the outcomes of innovative practice—so that if there were harms these be avoided in future patients—the confidentiality of patient information must be safeguarded. Healthcare providers and researchers must adhere to local data protection laws and regulations.

1. Patient data collected during innovative interventions should be de-identified whenever possible to protect privacy and maintain confidentiality upon reporting of findings or outcomes.
2. Transparent procedures for data storage, sharing, and access should be established, ensuring the protection of patient privacy and maintaining the highest standards of data security.
3. HCPs should provide patients who utilize innovation in medicine with education and appropriate tools to protect their data.

Research and Professional Development

HCPs have an ethical obligation to initiate clinical trials for innovative practices that show promise of efficacy. Anecdotal evidence, in the case of innovation, does not suffice, and HCPs should consult with their ethics and local regulatory committees to initiate, design, and oversee research protocols which empirically test new methods and technologies. (See “Clinical Research” chapter for further discussion.)

1. Innovation in medicine often involves research activities. Researchers must adhere to ethical guidelines and obtain appropriate institutional review board (or comparable research oversight committee) approvals for research involving human subjects.
2. Researchers should disseminate their findings transparently, contributing to collective knowledge and fostering a culture of continuous learning and evidence-based clinical practice.
3. Every step should be taken to reduce the therapeutic misconception of research and manage therapeutic hope of patients.

Professional Competence and Accountability

1. HCPs involved in innovative interventions should possess the necessary knowledge, skills, and experience to ensure patient safety and optimal outcomes.
2. HCPs must be educated about their institution's policies for engaging in innovative practice and the process by which an innovative practice transitions into clinical research and, if supported by clinical data, the new standard of care.
3. Adequate training and education should be provided to HCPs engaged in innovative practices, allowing them to stay up to date with the latest advancements and ethical considerations.
4. Professional accountability should be maintained, with clear mechanisms for reporting adverse events, errors, and unexpected outcomes associated with innovative interventions.

Appendix 1: Sample teaching cases

Case 1

A surgeon has invested a small amount of money in an augmented reality company that designs software for facilitating and improving the accuracy of surgery. She thinks this software would benefit her practice and wishes to bring the technology to her own institution. How should she proceed?

The HCP should approach the local regulatory body's Research and Innovation Center to apply for approval of the use of any new health technology. If the software is approved and incorporated into her institution's practice, the HCP must disclose all financial ties she has to the company to her institution and to any patient on whom it will be used. She should be aware that there may be a conflict of interest, being particularly vigilant in ensuring that the patient stands to benefit from the technology and that risks are still minimized.

Case 2

An HCP decides that it is necessary to use an innovative surgical method to save his patient's life. There is no time to consult with another HCP or his institution's legal counsel. Can he proceed with the surgery in this case, despite the lack of clinical evidence of efficacy?

The use of this innovative treatment may be ethically permissible in this case since it involves a life-threatening situation and the HCP has deemed the intervention to be the only option available. After the surgery has been completed, the HCP must report his decision-making process and actions to the local regulatory body and explain it to the patient and the patient's family. Furthermore, the HCP is encouraged to publish or otherwise disseminate findings from the application of this novel intervention to maximize learning from and proper use of this innovation on future patients.

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Medical Education



Introduction

It is critically important to train the next generation of healthcare professionals (HCPs) with the necessary clinical, collegial, and interpersonal skills. These skills are often best learned through interaction with patients and other members of the clinical team. However, medical education and the involvement of medical and clinical trainees (e.g., medical and nursing students, resident physicians, physicians in fellowships) in patient care also raise unique ethical concerns by potentially introducing challenges to patient autonomy, confidentiality, and quality of care. Even in educational settings, patient care must always be the primary concern and high-quality healthcare should never be compromised by teaching and/or learning exercises.

Medical supervisors should foster a learning environment that is safe and encouraging of open inquiry, acquisition of up-to-date knowledge and skills, and a pursuit of ongoing education. HCPs in educational and supervisory roles should remain aware of and mitigate the negative impacts of the power dynamics with students and trainees. Supervisors must also strive to demonstrate proper role modeling of professional and respectful conduct that is always in the patient's interest and emphasizes humility, empathy, honesty, and collaboration. Training institutions should maintain policies to support trainees, educators, and supervisors, maintaining the standards set by accreditation bodies.

Trainee Involvement in Patient Care

Interaction with patients, as well as observation and collaboration with more experienced clinicians, is imperative for students and trainees to learn and master technical skills, clinical reasoning, and bedside manner. But high-quality care, respect for patients, and protections of patient autonomy and confidentiality should never be compromised for educational purposes. Patients should always be informed of and have a choice in whether trainees are involved in their care; some patients may find value in, and derive benefit from, their role in contributing to medical training.

1. HCPs should inform patients (and/or their alternative decision-makers) of, and obtain consent for, trainee involvement in care of any kind including examinations, care discussions, and procedures during which the patient is awake or sedated.
2. Patients should be informed of the identity and training level of all clinical team members involved in their care using unambiguous terms (e.g., "junior doctor" should not be used to refer to a medical student). HCPs should either introduce trainees or instruct trainees to properly introduce themselves and disclose their training level.
3. If a trainee is going to perform or participate in a procedure, the trainee or their supervisor should inform the patient of the trainee's level of experience with the specific procedure.
4. HCPs should ensure trainees receive the appropriate level of supervision and that trainees are only allowed to participate in the parts of a patient's care with which they have adequate experience so as not to create unjustifiable risk.
5. HCPs should ensure trainees are aware of and follow all necessary protections for patient confidentiality and privacy.
6. Patient care in educational environments must remain just and fair. HCPs should not disproportionately assign students to assist in the care of patients of certain demographics, such as those who are socioeconomically or otherwise disadvantaged.

Practice of Clinical Skills on Fellow Students

Medical students and other trainees may sometimes practice a variety of clinical skills on their fellow trainees. Such teaching exercises should not involve examinations or procedures that are invasive or intimate.

1. HCPs and educators should ensure that students have consented to participation in any teaching exercise and are aware that they may freely decline to participate without the need to provide a reason and without penalty.
2. HCPs and educators should ensure that students in teaching exercises are afforded protection of their privacy and confidentiality.
3. Should a teaching exercise reveal a diagnosis or condition requiring further medical attention, educators and HCPs should ensure students are provided with resources for appropriate follow-up.

Practicing Procedures on the Newly Deceased

The bodies of newly deceased patients are sometimes used for teaching purposes, especially in practicing life-saving procedures such as pericardiocentesis or endotracheal intubation. While the newly deceased may offer trainees unique and useful educational opportunities, respect is still owed to the bodies of these patients and to their families.

1. Trainees and their supervisors should practice procedures on the bodies of newly deceased patients only if this is in accordance with the known wishes of the decedent or if permission has been obtained from the patient's family or alternative decision-maker.
2. HCPs who plan to supervise a procedure on the newly deceased must ensure that the practice does not create risk of infectious exposure to the trainee or cause unnecessary harm to the decedent's family.

3. Trainees and their supervisors should ensure the privacy and confidentiality of the newly deceased are maintained to the greatest extent possible.
4. If a procedure is practiced on the body of a newly deceased patient, HCPs should document this clearly in the medical chart.
5. Healthcare institutions should have clear policies about the practicing of procedures on the newly deceased and trainees and their supervisors should adhere to these policies.
6. When possible, HCPs serving as educators or supervisors should consider or find an alternative way to effectively teach the procedures that would have been practiced on the newly deceased, such as through simulations.

The Trainee-Supervisor Relationship

Medical education and training aiming to produce competent, compassionate, and professional HCPs relies on a positive learning environment. Institutions of medical education should ensure there are clear policies and appropriate institutional committees in place to oversee and enforce proper standards of trainee education, remediation, and conflict resolution.

1. Educators and supervisors should create a safe and encouraging environment that allows students to ask questions and raise concerns without fear of exploitation, discrimination, or punitive measures.
2. Educators and supervisors must be mindful of their positions as role models, demonstrating and reinforcing professional behavior, effective communication, and respectful interpersonal skills.

3. Educators and supervisors should encourage trainees to consider and curb their own biases, working to become culturally sensitive and competent to diverse patients.
4. Educators and supervisors should intervene if they observe students or trainees exhibiting impairment or participating in inappropriate behavior or negligence, dishonesty, or discrimination towards patients. HCPs in supervisory roles should be aware of institutional mechanisms for reporting and remediating such behavior but should aim to intervene in a way that is least harmful to students and does not involve discrimination or unwarranted punitive measures.

Appendix 1:

Sample teaching cases

Case 1

You are an attending physician leading your team in morning rounds. Upon entering a patient's hospital room, the resident physician on the team appropriately introduces herself and her training position. However, while referring to the medical student on the team, she tells the patient, "My colleague will now examine you." The patient subsequently consents to undergoing physical examination. How should you proceed?

Patients have the right to be notified of who is participating in their care so that they may provide consent that is informed and voluntary and, as the attending physician, it is your responsibility to ensure patients are afforded this right. You should interject, calmly and kindly making it clear that the person who is going to perform the exam is a medical student. If needed, you can provide your assurance to the patient that the medical student's physical exam will be fully supervised and will provide useful information to the clinical team, without compromising the patient's care. Still, it is the patient's decision whether to consent to the examination. After rounds, you should also approach the resident physician privately and educate her on the importance of informing patients truthfully of who is involved in their care.

Case 2

You are a physician-educator and are leading a class of first-year medical students in an educational exercise aimed at teaching them how to properly conduct a cardiovascular exam. You suggest all the medical students pair up and listen to each other's hearts with their stethoscopes. However, you realize that one student appears uncomfortable as other students approach him and ask to be his partner for the teaching exercise. How should you proceed?

It is important that medical students do not feel obligated or pressured to allow fellow trainees to practice skills on them. Before any teaching exercise in which students will practice skills on each other, including the one in this case, the instructor/supervisor should make it clear to students that they have the option to consent to or withdraw from the exercise without penalty. The instructor should also review the low-risk nature of the exercise and assure students that confidentiality and privacy will be protected.

Case 3

You are an attending physician at a teaching hospital and your team is receiving hand-off from the overnight attending of a 32-year-old patient he just admitted to the hospital. The patient was given a new diagnosis of breast cancer last week and presented to the hospital with uncontrolled pain. The overnight Attending mentions how hard it has been to discuss pain management and cancer treatment options because the patient and her husband have been so emotional about the diagnosis. The medical student on your team asks whether it may be worth involving a psychologist or social worker to help support them, but the overnight attending interjects in a frustrated tone and says, "that's a really silly suggestion, they've been such a waste of our time, it's impossible to get them to talk to us calmly." How should you proceed?

Clinicians in educational or supervisory positions have the responsibility to role model professional, compassionate, and collegial behavior. In this instance, you should encourage your team to approach the patient holistically and with an understanding for the vulnerable and extremely difficult position they are in after receiving a life-changing diagnosis. You should also encourage your medical student to continue sharing suggestions to improve patient care, fostering such behavior.

القيود
• الخطب النحوي
• العلاج بالأدوية
• علاج الأورام

الطابق الأرضي
 • مركز رعاية
 • عيادة الحوادث
 • عيادة الأُف
 • عيادة أمراض
 • عيادة الأُورام
 • الأقسام الخدمية

الطباق الأول

- عيادة العدد
- عيادة طب الأسنان
- عيادة أمراض النساء
- عيادة جراحات النسائية
- عيادة أمراض الأطفال
- قسم الأشعة
- عيادة الجلدية
- عيادة الأمراض المعدية
- عيادة جراحات المسالك البولية
- عيادة أمراض الكلى
- عيادة المخ والأعصاب
- طب الأطفال
- عيادة طب العيون
- عيادة أمراض القلب

- وحدة العناية
- العناية المزدوجة
- وحدة العناية

- الطابق الثاني
- المعهد
- طابق الأرض
- مرادف إلى



SPIKES: A Strategy for Breaking Bad News

When communicating bad news, HCPs should consider employing the SPIKES strategy. “SPIKES” is an acronym for: Setting, Perception, Invitation, Knowledge, Empathy, and Summary.

1. **Setting.** Clinicians should identify and prepare an appropriate place and time for the delivery of bad news, and invite people important to the patient (e.g., family members) given that the patient consents to their presence. In general, clinicians should not disclose bad news to others without the patient’s permission.
2. **Perception.** Clinicians should identify what patients already know about their situation by asking them to share their understanding of their illness or condition.
3. **Invitation.** Clinicians should identify patients’ information-sharing preferences by asking, for example, “Would it be okay for me to discuss the results of your tests with you now?” Or, “How do you prefer to discuss medical information in your family?”
4. **Knowledge.** Clinicians should deliver the information in a simple and straightforward manner, avoiding medical jargon and unnecessary technical details. It is recommended to give a “warning shot” (e.g., “I have something serious we need to discuss”) before delivering the bad news, which prepares recipients to receive it.
5. **Empathy.** After delivering the bad news, clinicians should wait quietly, giving patients/families adequate time to process it and to express their emotional reactions to it. Clinicians should also respond empathically (e.g., “I know this is very difficult news”). For more on communicating with empathy, see the NURSE-related guidance below.

6. **Summary.** Clinicians should discuss the next steps and the follow-up plan by inviting patients/families to communicate their understanding of the new information; correcting misconceptions or misunderstandings about their condition or treatment options; and working with patients/families to plan follow-up appointments and next steps.

Throughout the process of breaking bad news, clinicians should reassure patients and their families that they remain committed to their welfare, that they stand by them, and that they will continue caring for them. Following the delivery of bad news, clinicians should continue to alleviate the patient’s physical and psychological suffering and to provide required care.

NURSE: A Strategy for Responding to Emotions

Patients and their families will react to bad news with a wide range of emotions. When empathizing with patients and their families, HCPs should consider employing one or a combination of NURSE statements. “NURSE” is an acronym for: Naming, Understanding, Respecting, Supporting, Exploring.

1. **Naming.** Clinicians might identify, describe, or name the emotion(s) the patient/family is expressing (e.g., “It sounds like you are frustrated”).
2. **Understanding.** Clinicians might acknowledge what patients/families are thinking (e.g., “This helps me understand what you are thinking”).
3. **Respecting.** Clinicians might acknowledge and praise what patients/families are doing or have done (e.g., “I can see you really have been trying to follow our instructions”).
4. **Supporting.** Clinicians should make commitments to provide support and care (e.g., “I will do my best to make sure you have what you need”).

5. Exploring. Clinicians should ask focused questions that help patients/families explore their mental lives (e.g., “Can you say more about what you mean when you say that?”).

When Families Request Nondisclosure

As members of multi-value societies, HCPs and their patients belong to and represent a diverse set of cultures. With this cultural diversity, there comes diversity in values, commitments, and practices. Clinicians often encounter the challenge of fulfilling their truth-telling obligations, on the one hand, and respecting the values, commitments, and practices of the peoples they serve, on the other. In some cases, a patient’s family requests or demands that clinicians withhold bad news from the capacitated patient to protect the patient from psychological stress, to preserve hope, and to promote recovery. In such cases, HCPs should consider managing the dilemma by employing the ARCHES model. “ARCHES” is an acronym for: Acknowledge, Relationship, Common Ground, Honor, Support.

1. Acknowledge. Clinicians should acknowledge the request for nondisclosure.
2. Relationship. Clinicians should build and maintain their relationships with the patient and the family, clarifying the values involved and achieving mutual understanding.
3. Common Ground. Clinicians should find common ground by identifying shared goals and values, typically those related to optimizing the patient’s wellbeing and relationships within the family.
4. Honor. Clinicians should honor the patient’s information preferences and outline the harm(s) of nondisclosure. Patients have the authority, by virtue of their autonomy, to decide matters of disclosure and nondisclosure. In addition, patients are harmed or wronged by the concealment and deception involved in nondisclosures for which they do not volunteer. HCPs should communicate this to the family and assure them that they will deliver

bad news sensitively. autonomy, to decide matters of disclosure and nondisclosure. In addition, patients are harmed or wronged by the concealment and deception involved in nondisclosures for which they do not volunteer. HCPs should communicate this to the family and assure them that they will deliver bad news sensitively.

5. Support. Clinicians should devise supportive solutions, including plans for what to do if the family continues to insist on nondisclosure. The solutions can be flexible and must be in accordance with laws and policies.

As a supplement to the ARCHES model, HCPs should consider the following approach to managing requests for nondisclosure:

6. Stay calm. These situations can be confusing and emotional for clinicians. The calmer one remains, the more information one will gain from the family as to why they do not want their loved one to be informed of the bad news. Demonstrating frustration or implying that the request is inappropriate can break trust and derail efforts to resolve the situation.
7. Try to understand the family’s viewpoint. The family knows the patient best and can provide insight into the cause of the request. HCPs should politely ask questions to understand the nature of the request. For example: “Can you tell me more about why you feel this way? How does your family typically handle difficult information? How are important decisions made by your family?” HCPs can ask about how the patient has responded in the past to bad news and if they have made specific statements about what they want to know. The family may be more worried about how the information is given rather than the information itself (e.g., given to the patient when alone, use of “death” or “dying,” the disclosure of specific prognostic timeframes).
8. Clarify what the patient already knows. HCPs should politely ask questions to understand

what the family believes the patient already knows. Does the family think the patient already knows or strongly suspects what is going on and would rather not talk further about it, or is the patient completely in the dark? Have other clinicians already told or implied to the patient what is going on? How did the patient respond to that? Is the patient talking with the family about their concerns? A patient's reluctance to talk with family may represent an attempt to protect them.

9. Respond empathically. A family's request to withhold information from their loved ones usually comes from a kind and loving place; they are often frightened for themselves and the patient. When HCPs respond empathically, this allows families to recognize that they care about them. It may allow them to see HCPs' ability to give information to their loved ones compassionately.
10. State your views openly, but as your own views. HCPs should disclose any discomfort they have with the family's request; they should explain their professional obligation to ensure the patient is able to make informed decisions in the manner they prefer. HCPs should disclose this specifically in the context of wanting what is best for the patient, including respecting how the patient would like to hear information.
11. Be willing to brainstorm possible solutions. Rigidly informing the family that the clinician must disclose all information to a patient breaks trust and is inaccurate. There is no "one-size-fits-all" solution to these scenarios. Often, there are solutions neither party has thought about that will meet everyone's goals. In other cases, families may not have considered the implications of a request (e.g., requesting their mother receive chemotherapy, but not telling her she has cancer).
12. Negotiate a solution. HCPs may recommend to the family that they, in their presence, share with the patient a limited amount of information, and then the HCP may specifically

ask the patient if they would like to hear more. HCPs should tell the family what they plan on saying; for example, "You came to the hospital because you were not eating well and became dehydrated. We have been trying to figure out what is going on. Some people want to know everything about their medical condition, others prefer the doctors speak with family members about what is happening and the best way to help a patient. What would you prefer?" HCPs can contract with the family that all will respect the patient's decision.

Glossary

Advance care planning: Learning about the types of decisions that might need to be made, considering those decisions ahead of time, and then letting others know both family members and health care providers about preferences, goals, and wishes in written or verbal directives.

Alternative decision-maker: An individual designated to make healthcare decisions for a patient who lacks decision-making capacity or who has otherwise decided that they would like another individual to make decisions on their behalf. The alternative decision-maker should be an individual identified and specified by the patient or a court appointed guardian. If no such individuals were previously identified to make decisions for an incapacitated patient, HCPs should seek consent and choices about care from a relative of the patient in the following order of priority: father, mother, husband, wife, son, daughter, grandfather, grandmother, son's children, daughter's children, paternal uncle, paternal aunt, maternal uncle, maternal aunt, paternal's uncle children and maternal aunt's children.

Assent: The expression of approval or agreement; the agreement of a child to treatment or research participation when they are not able to provide a legally valid informed consent.

Best interest standard: Standard for healthcare decision-making guided by choices that will promote a patient's well-being and quality of life.

Chaperone: A third party who is present during a medical examination. A chaperone of the same sex as the patient must be present when the HCP is of the opposite sex. Intimate exams require the presence of a chaperone. Institutions should have policies regarding access to chaperones.

Clinician impairment: The presence of physical or mental illness, substance use, or other condition that impairs a clinician's ability to provide safe and competent care to patients.

Confidentiality: Preventing the release of patient health data and information to unauthorized persons and allowing information sharing only in ethically, legally, or professionally indicated instances.

Conflict of interest: A situation or set of circumstances that could impair professional judgment and objectivity regarding the primary interests and goals of medicine.

Conscientious objection: A moral objection to providing medically indicated and legal care due to conflict with a clinician's sincerely held beliefs and values. Conscientious objection to providing care should never be rooted in discrimination.

Covert administration of medication: The administration of medication without the patient's knowledge. This should only be undertaken when it is deemed the only option to provide emergently necessary care. The decision to covertly administer medication should be time-limited, done in the patient's best interests, continually reevaluated for earliest discontinuation, and transparently documented in the patient's medical record.

Deception: Actively telling someone a mistruth or withholding information from someone so that they make an untrue assumption due to lack of full knowledge.

Decision-making capacity: A patient's assessed ability to make healthcare decisions by demonstrating comprehension and appreciation of information, rational reasoning through pertinent considerations, and the ability to clearly communicate a choice.

Disaster: A natural or manmade event that significantly disrupts the environment, causes widespread distress, death, illness or injury, and suspension of usual activities; normal conditions of life are disrupted and the level of suffering exceeds the short-term adaptive capacities of the affected community.

Disclosure: A statement, usually written, of financial or non-financial relationships with a business or person that might be perceived as a conflict of interest; disclosures encourage transparency.

Emergency: A serious situation in which normal procedures are suspended or altered for the sake of taking immediate action aimed at avoiding the worst possible outcomes.

Futile care: Clinical interventions that do not have any chance of achieving their intended effect.

Healthcare resources: Materials, facilities, supplies, personnel, and equipment (including pharmaceutical, blood collecting and dispensing supplies, and emergency surgical instruments and supplies) required to prevent the impairment of, improve, or restore the physical and mental health conditions of the population.

Honoraria: Payments in recognition of service for which payment is not required.

Hospice: Palliative care provided to patients with terminal diagnosis and poor prognosis, often defined as an estimated life expectancy of six or fewer months.

Human subject: A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information, including a subject's opinion on a given topic.

Incentive: Something of value (e.g., money, gifts, tickets, meals) offered to someone in hopes of influencing behavior.

Inducement: Incentive paid to someone (cash or in-kind) to encourage a service.

Informed consent: Process in which HCPs explains a proposed intervention or care plan, and patients or their alternative decision-maker agrees or declines to undergo the treatment or procedure. The patient must be fully informed about risks, benefits, and alternatives to the proposed treatment or procedure and how the treatment has helped or been tolerated by other patients; consent discussions should also include the consequences of declining treatment. Patients and/or their parents/guardians must provide their consent voluntarily without coercion.

In-kind gift: Nonmonetary (such as cash or securities) gifts, such as services, equipment, supplies, and other tangible items.

Innovation: Innovative practice occurs when a clinician provides something new, untested, or nonstandard to a patient during clinical care, rather than as part of a research study. This can include using an existing medical product for new purposes or in a novel clinical context.

Kickback: An agreed-upon bribe, like a commission, paid to a healthcare professional in exchange for service.

Life-sustaining treatment: Medical interventions that aim to prolong life without reversing the primary clinical condition. Such treatment may include mechanical ventilation, renal dialysis, and artificial nutrition and hydration.

Malaffi: The region's first Health Information Exchange platform that safely and securely connects public and private HCPs in the Emirate of Abu Dhabi. Malaffi enables the meaningful, real-time exchange of important patient health information between the healthcare providers, creating a centralized database of unified patient records, improving healthcare quality and patient outcomes.

Medical emergency: An emergency involving illness or injury and requiring immediate action by HCPs, often involving threats of serious harm or death to patients.

Medical supervisor: A clinician providing supervision to any medical trainee.

Medical tourist: A person who travels abroad for the purpose of receiving healthcare.

Medical trainee: An individual undergoing training in the provision of medical care under the supervision of more experienced clinicians within medical institutions. Trainees can be at the level of students, resident physicians, or physicians in fellowships.

Medically assisted reproduction: Medical or technological assistance with conception of a child. Examples include in vitro fertilization, ovarian stimulation, and other procedures.

Minimal risk: Risk where the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life, or during the performance of standard-of-care treatment or routine physical or psychological examinations or tests.

Moral distress: In the healthcare context, the physical, mental, or emotional discomfort that results when ethical beliefs conflict with patients' preferences or institutional policies.

Organ/tissue donor: An individual from whom tissues or solid organs have been surgically removed for the purpose of transplantation.

Organ/tissue recipient: An individual who has undergone surgical placement into their body of tissues or solid organs from another source (typically from another human; however, emerging technologies and medical advancements may allow tissue sources in the future to include animals or bioengineered materials).

Palliative care: Clinical interventions that may be provided at any point in a patient's care and are aimed at improving quality of life through relief of symptoms and suffering, regardless of their curative impact.

Parent/guardian: A child's primary legal guardian or alternative decision-maker, most often a parent.

Periviability: Earliest stage of fetal maturity when there is a reasonable chance, although not a high likelihood, of extrauterine survival.

Potentially inappropriate care: Clinical interventions that may have a very small chance of achieving the patient's goal but are deemed inappropriate by HCPs due to competing ethical considerations.

Privacy: Patients' right to control access to their personal or healthcare data.

Protected health information: Identifiable patient information, including past, present, and future information regarding the physical or mental health of a patient as well as care and financial information about the patient.

Public health emergency: A situation that threatens life, personal health, population health, safety, infrastructure, and habitats; typically related to a sudden-onset social, political, or environmental change, but may develop gradually.

Reimbursement: Compensation for time spent or expenses incurred.

Research: The systematic investigation into and study of medical treatments and interventions to gather data on safety, efficacy, and appropriate dosages, and to contribute knowledge to the broader medical field.

Resource stewardship: Using medical supplies wisely to delay or prevent shortages of resources.

Scarce resources: Healthcare resources available in finite amounts, often with demand for the resource being higher than the available supply.

Shafafiya: Clearing house for insurance that contains claims and clinical data, and only sends data to the DoH. Shafafiya contains the key standards which govern how healthcare information is exchanged and used in accordance with the Regulator Policy Manual and hosts the information exchange.

Shared decision-making: Model of healthcare decision-making between HCPs and patients (or their alternative decision-makers), by which care choices are informed by a patient's values and preferences, in addition to medical evidence and clinical judgment.

Substituted judgment: Standard for healthcare decision-making guided by familiarity with a patient's values, preferences, and goals of care. This serves as a guide for decision-making on behalf of patients who lack decisional capacity or cannot otherwise communicate their choices.

Telehealth: Telehealth refers to a broader scope of remote healthcare services than telemedicine. While telemedicine refers specifically to remote clinical services, telehealth can refer to remote non-clinical services, such as provider training, administrative meetings, and continuing medical education, in addition to clinical services.

Telemedicine: The provision of healthcare services remotely, using telecommunications technology. Telemedicine involves the use of digital communication tools, such as video calls, phone calls, messaging apps, and other online platforms to connect HCPs with patients who are not physically present in the same location. Telemedicine can include a wide range of healthcare activities, including virtual consultations, diagnosis, treatment, monitoring of patients' health conditions, and follow-up appointments. It can be utilized across various medical specialties, such as primary care, mental health, and care from a specialist.

Therapeutic exception to disclosure: The authority of HCPs to withhold information from patients because it is

feared that disclosure would cause immediate and serious harm to the patient. This power is invoked rarely and only under extraordinary circumstances, requiring that HCPs be prepared to justify their decision

Triage: A system that prioritizes treatment and allocates resources based on evaluating and categorizing patients according to the severity and urgency of needs related to their injuries or illnesses. In emergencies or disasters, triage aims to maximize the number of lives saved and to minimize harms.

Utilitarianism: Moral framework that holds that ethical decisions should be made based on which action will maximize well-being overall.

Vulnerable patients: Patients who are likely to have their interests unjustly considered or discounted. Vulnerable patients are at heightened risk of neglect, abuse, or suboptimal care.

Xenotransplantation: The transplantation into humans of organs or tissues from nonhuman animals.

Guidance

This section is dedicated to guiding the frequently asked questions related to the Healthcare Workforce Bioethics Guidelines received during finalization of guidelines. These answers aim to help better understand the utilization of the Healthcare Workforce Bioethics Guidelines.

1. What is the purpose of the Healthcare Workforce Bioethics Guidelines?

Healthcare institutions in the UAE embrace advanced medical technologies and attract medical professionals and patients from around the world; as such, healthcare professionals must care for patients in the context of diverse cultural backgrounds, values, and norms. Healthcare professionals should aim to provide collaborative, respectful, and up-to-date care in emergency, short-term, and longitudinal interactions with patients. This document aims to highlight key guidelines to direct ethical conduct within the healthcare system.

2. Why was it important to publish these guidelines?

To achieve excellence in healthcare provision, it is crucial for healthcare professionals to build a shared understanding of and language for medical ethics guidance in clinical practice for a sustainable and agile healthcare workforce.

3. How were these guidelines developed? What informs these guidelines?

These guidelines are built upon a combination of international standards and principles of bioethics, as well as expert input on local practice and culture, reflecting insights from a variety of disciplines and healthcare settings.

4. How should I use these guidelines? Will I be able to look up a direct answer to my ethical question or case?

Clinical scenarios that raise ethical concerns and considerations are rarely identical – each has its own set of details and tensions influenced by different perspectives. While there may be disagreement about how to resolve a given case, creating consistent and transparent assessment and deliberation processes, within and across institutions, will help foster a healthy and agile medical ethics ecosystem. While this document is meant to provide guidance, it is not a comprehensive list of ethical dilemmas that might

arise. Rather, the guidance is meant to help HCPs navigate dilemmas by balancing multiple principles, interests, and perspectives in pursuit of ethically sound solutions that uphold a high level of care. This may require the support of institutional resources, such as ethics committees, available to assist with and provide guidance for complex ethical issues in clinical practice. Ethics committees are multidisciplinary, often comprised of clinicians, ethicists, social workers, risk managers, hospital administrators, legal counsel, spiritual care providers, and others.

5. Can I treat these guidelines as legal guidance? What should I do if I am concerned about legal matters pertaining to clinical care?

Clinical practice must always adhere to the UAE laws and policies, and regulations of the local regulatory body. The Medical Ethics Guidelines for Healthcare Professionals is not a legal document. Healthcare professionals should seek dedicated legal guidance through their institution or by contacting the local healthcare regulatory body in any scenario requiring clarification of the law.

6. Who can I contact if I have further questions or need support regarding ethical decision-making in healthcare or the assistance of an ethics committee?

While this document is meant to provide guidance, it is not a comprehensive list of ethical dilemmas that might arise. Practice must always adhere to UAE laws and regulations; and HCPs should seek dedicated guidance from their local ethics committee and legal team separate from this document for further support regarding ethical decision-making.

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