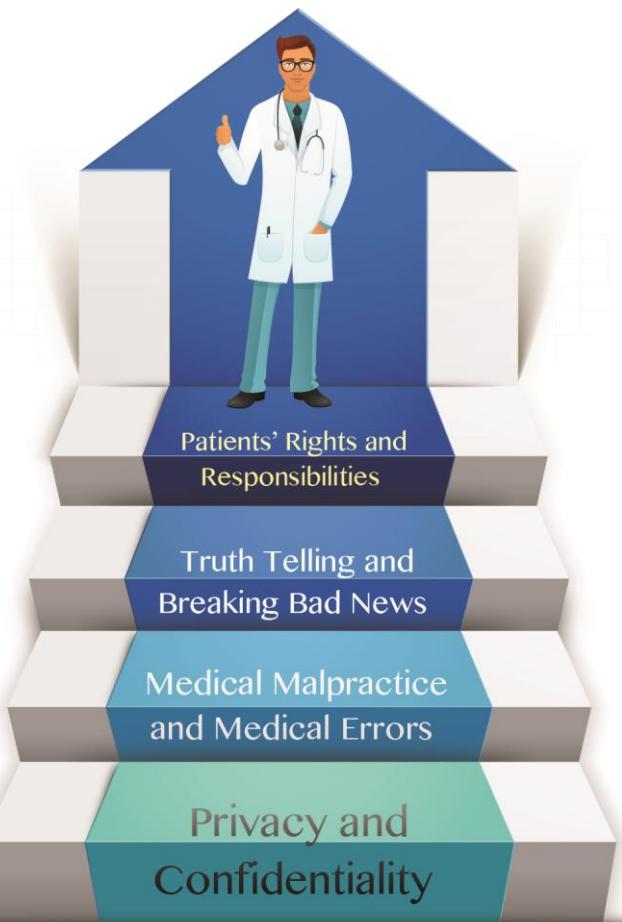


Professionalism and Ethics Handbook for Residents

A Practical Guide



Saudi Commission for Health Specialties
Department of Medical Education & Postgraduate Studies

2015

EDITOR

Professor James Ware, MA, MB, FRCS, DMSc
Director of Medical Education and Postgraduate Studies
Department of Medical Education and Postgraduate Studies
Saudi Commission for Health Specialties
Riyadh, Saudi Arabia

CONTRIBUTORS

Dr. Abdulaziz Fahad Al Kaabba, MBBS, JMHPE, MHSc, DCH, ABFM
Family Physician Consultant
Associate Professor of Family Medicine & Bioethics
College of Medicine
Al-Imam Muhammad Ibn Saud Islamic University
Riyadh, Saudi Arabia

Dr. Ghaiath MA Hussein, MBBS, MHSc (Bioethics)
Doctoral Researcher
Ethics, Society & History (MESH)
School of Health & Population Sciences
University of Birmingham
United Kingdom

Professor Dr. Omar Hasan Kasule, Sr., MBChB (MUK), MPH & DrPH (Harvard)
Head of Knowledge Exchange and International Collaboration
Chairman, KFMC Ethics Committee and the Institutional Review Board (IRB)
Faculty of Medicine
King Fahad Medical City
Riyadh, Saudi Arabia

FORMATTER & LAYOUT DESIGNER

Ms. Vittoriana Crisera
Journal Manager, Journal of Health Specialties
Saudi Commission for Health Specialties
Riyadh, Saudi Arabia

© Saudi Commission for Health Specialties, 2015
King Fahd National Library Cataloging-in-Publication Data

Saudi Commission for Health Specialties, Riyadh - 2015
Professionalism and Ethics Handbook for Residents

232p; 14.8cm x 21cm

ISBN: 978-603-90608-2-6

1-Medical ethics 2-Professional ethics I-Title

174.2 dc 1436/2924

L.D. no. 1436/2924

ISBN: 978-603-90608-2-6





© 2015 by the Saudi Commission for Health Specialties

All rights are reserved. You must have prior written permission for any reproduction, storage in a retrieval system, or transmission, in any form or by any means. Requests for permission should be directed to

The Saudi Commission for Health Specialties (SCHS), Diplomatic Quarter, next to the Egyptian Embassy, PO Box: 94656, Postal Code: 11614.

It is also possible to contact SCHS through the Consolidated Communication Centre (from within KSA): 920019393, and through International Contact Call +966114179900.

This Manual is a publication of the Department of Medical Education and Postgraduate Studies, The Saudi Commission for Health Specialties (SCHS). It was written and edited by a group of experts in the field of medical education and medical ethics. Its contents do not necessarily reflect the policies of the SCHS, except where this is clearly and explicitly indicated.

Production and Concept

The Saudi Commission for Health Specialties, KSA.

For further information and suggestions, please contact **Ms. Laila Al-Yousef**, l.alyousef@scfhs.org

Disclaimer: Every effort has been made in preparing this Handbook to provide accurate and up-to-date information that is in accord with accepted standards and practice. Nevertheless, the editors and authors can make no warranties that the information contained herein is totally free from error, not least because clinical standards are constantly changing through research and regulation. The editors and authors therefore disclaim all liability for direct or consequential damages resulting from the use of material contained in this book.

Although many of the case studies contained in this Handbook are drawn from actual events, every effort has been made to mask the identities and the organizations involved.

Citation:

Hussein GM, Alkabba AF, Kasule OH. **Professionalism and Ethics Handbook for Residents (PEHR): A Practical Guide.** Ware J, Kattan T (eds). 1st Edition. Riyadh, Saudi Arabia: Saudi Commission for Health Specialties, 2015.

**PROFESSIONALISM AND ETHICS
HANDBOOK FOR RESIDENTS**
A Practical Guide

FOREWORD	XVI
ACKNOWLEDGMENTS	XVII
MODULE 1 - INTRODUCTION TO MEDICAL ETHICS	1
1.1 Objectives of the Module	3
1.2 Case (Ethical Scenario)	3
1.3 What is the PEHR of Health Care Ethics?	3
1.4 Why is the PEHR Needed?	4
1.5 How is the PEHR Structured?	5
1.6 How to use the PEHR in Practice	5
1.7 Definitions of Terminology and Concepts	6
Ethics	6
Bioethics	7
Clinical (medical) ethics	7
Research ethics	7
Public health ethics	7
Islamic bioethics	7
Why is it important to know about bioethics?	8
1.8 Case Discussion	8
1.9 Conclusion and Summary	8
1.10 References and Suggested Readings	9
MODULE 2 - PRINCIPLES OF WESTERN & ISLAMIC APPROACHES TO BIOETHICS	11
2.1 Objectives of the Module	13
2.2 Case (Ethical Scenario)	13
2.3 Introduction	13
The global/Western approach to bioethics	13
The Islamic approach to bioethics and how it differs from Western approaches	15
How do Muslims tell right from wrong?	15
The purpose of Islamic laws and rulings	16
The major principles that guide Islamic judgment on ethical issues and their sub-principles	17
2.4 Ethical, Fiqhi, Legal, and Policy Implications of Bioethics in Health care	19
2.5 How to Improve Your Practice by Knowing About Western and Islamic Ethics	20
2.6 Case Discussion	20
2.7 Conclusion and Summary	22
2.8 References and Suggested Readings	22
MODULE 3 - DOCTORS' PROFESSIONAL RELATIONSHIPS AND DUTIES	25
3.1 Objectives of the Module	27
3.2 Case (Ethical Scenario)	27
3.3 Why is Knowing About Doctors' Duties and Relationships Important?	27
3.4 Where Are You? What Do You Do?	28
3.5 Interprofessional Relationships and Duties	31
Duties of a doctor and his/her profession	32

Duties towards patients and their families	33
Duties towards colleagues	35
Duties towards community	36
3.6 Ethical, Legal, and Policy Implications	37
3.7 Islamic Rulings and Fatwas on the Topic	37
3.8 How to Improve Your Practice by Using Consideration and Empathy	39
3.9 Case Discussion	40
3.10 Conclusion and Summary	40
3.11 References and Suggested Readings	41
MODULE 4 - TRUTH TELLING AND BREAKING BAD NEWS 43	
4.1 Objectives of the Module	45
4.2 Case (Ethical Scenario)	45
4.3 Introduction	45
The ethical issues related to truth telling	45
Disclosing unfavorable information	47
How to break bad news to patients?	48
4.4 Are there Ethically Acceptable Conditions that Allow Us Not to Tell Our Patients the Truth About their Conditions?	50
4.5 Why is Truth Telling and Breaking Bad News Important to Your Practice	51
4.6 Ethical, Legal, and Policy Implications of Truth Telling and Breaking Bad News	52
4.7 Case Discussion	52
4.8 Conclusion and Summary	53
4.9 References and Suggested Readings	54
MODULE 5 - PATIENTS' RIGHTS AND RESPONSIBILITIES 55	
5.1 Objectives of the Module	57
5.2 Case (Ethical Scenarios)	57
Case scenario 1	57
Case scenario 2	57
5.3 Introduction	57
5.4 Why are Patients' Rights Important?	58
5.5 Ethical, Legal, and Policy Issues	59
5.6 Patients' Responsibilities:	60
5.7 Rulings and Fatwas on the Topic:	60
5.8 How to Improve Your Practice by Knowing About Patients' Rights	61
5.9 Case Discussion	61
Case 1	61
Case 2	62
5.9 Conclusion and Summary	62
5.10 References and Suggested Readings	62
MODULE 6 - MEDICAL MALPRACTICE AND MEDICAL ERRORS 65	
6.1 Objectives of the Module	67
6.2 Cases (Ethical Scenarios)	67
Case scenario 1	67
Case scenario 2	67

6.3	Introduction	67
6.4	Why is this Subject Important?	68
6.5	Ethical Issues Related to Malpractice	69
6.6	Islamic Issues Related to Medical Errors and Malpractice	69
6.7	How to Improve our Practice by Knowing About Medical Negligence	70
6.8	Case Discussion	71
	Case 1	71
	Case 2	71
6.9	Conclusion and Summary	71
6.10	References and Suggested Readings	72

MODULE 7 - PATIENT AUTONOMY AND CONSENT TO TREATMENT		73
7.1	Objectives of the Module	75
7.2	Case (Ethical Scenarios)	75
	Case scenario 1: Autonomy as the basis of informed consent	75
	Case scenario 2: Scope and limitations of consent	75
	Case scenario 3: Consent and protection of the patient	75
	Case scenario 4: Consent and the protection of the physician	76
	Case scenario 5: The process of informed consent	76
	Case scenario 6: Capacity/competence to consent	76
	Case scenario 7: Proxy consent/substitute decision maker	76
	Case scenario 8: Prospective consent/advance directives	77
	Case scenario 9: Consent for children	77
	Case scenario 10: Consent for the mentally impaired	77
	Case scenario 11: Consent for the unconscious	77
7.3	Introduction: Terminology and Concepts	77
7.4	Why is it Important To Know About Autonomy and Consent?	79
7.5	Ethical, Legal, and Policy Issues	79
	Autonomy as the basis of informed consent	79
	Scope and limitations of consent	79
	Consent and protection of the patient	80
	Consent and the protection of the physician	80
	The process of informed consent	80
	Capacity/competence to consent	81
	Proxy consent and substitute decision maker	81
	Prospective consent and advance directives	81
	Consent for children	82
	Consent for the mentally impaired	82
	Consent for the unconscious	83
7.6	How to Improve Your Practice	83
7.7	Case Discussion	83
	Case 1: Autonomy as the basis of informed consent	83
	Case 2: Scope and limitations of consent	83
	Case 3: Consent and protection of the patient	83
	Case 4: Consent and the protection of the physician	84
	Case 5: The process of informed consent	84
	Case 6: Capacity and competence to consent	84

Case 7: Proxy consent and substitute decision maker	84
Case 8: Prospective consent and advance directives	84
Case 9: Consent for children	84
Case 10: Consent for the mentally impaired	84
Case 11: Consent for the unconscious	84
7.8 Conclusion and Summary	84
7.9 References and Suggested Readings	85
 MODULE 8 - PRIVACY AND CONFIDENTIALITY	
8.1 Objectives of the Module	89
8.2 Case (Ethical Scenario)	89
8.3 Introduction	90
How privacy and confidentiality differ	90
Measures to protect patients' privacy	90
Measures to protect the confidentiality of your patients' information	91
Conditions to disclose identifiable medical information	92
8.4 Why is Learning About Privacy and Confidentiality Important?	93
8.5 Ethical, Legal, and Policy Implications of Privacy and Confidentiality	94
8.6 Rulings and Fatwas on the Topic	94
8.7 How to use Privacy and Confidentiality in Your Practice	96
8.8 Case Discussion	96
8.9 Conclusion and Summary	97
8.10 References and Suggested Readings	98
 MODULE 9 - TERMINALLY INCURABLE DISEASES AND END-OF-LIFE DECISIONS	
99	
9.1 Objectives of the Module	101
9.2 Case (Ethical Scenarios)	101
Case scenario 1: Palliative vs. curative care	101
Case scenario 2: Capacity for decision making	101
Case scenario 3: Advance directive proxy vs. father	101
Case scenario 4: Advance directive: anticipated vs. real circumstances	102
Case scenario 5: DNR physicians vs. family	102
Case scenario 6: Euthanasia	102
Case scenario 7: Withholding futile life support	102
Case scenario 8: Life support with brain stem death	102
Case scenario 9: Ventilation for purposes of organ harvesting	103
Case scenario 10: Post-mortem family vs. police	103
9.3 Introduction	103
Terminology and concepts	103
9.4 Why is it Important to Know About End-of-Life Issues?	104
9.5 Ethical, Legal, and Policy issues	104
The continuum of care	104
Ethical issues in geriatric care	105
Ethical issues in palliative care	105

Ethical issues in disability care	105
Ethical issues in care for the terminally ill	105
Decisions for the terminally ill	106
Capacity for decision making	107
Substitute/proxy decision makers	107
Advance directives	108
Withholding artificial life support	108
Withdrawing artificial life support	108
Organ donation, harvesting, and transplantation	109
DNR and DNT orders	109
Euthanasia	109
Post-mortem issues, autopsy, and embalmment	110
9.6 How to Improve Your Practice	110
9.7 Case Discussion	110
Case 1: Palliative vs. curative care	110
Case 2: Capacity for decision making	110
Case 3: Advance directive proxy vs. father	111
Case 4: Advance directive: anticipated vs. real circumstances	111
Case 5: DNR physicians vs. family	111
Case 6: Euthanasia	111
Case 7: Withholding futile life support	111
Case 8: Life support with brain stem death	112
Case 9: Ventilation for purposes of organ harvesting	112
Case 10: Post-mortem family vs. police	112
9.8 Conclusion and Summary	112
9.9 References and Suggested Readings	113
Medical futility palliative and terminal care	113
Substitute/proxy decision makers	114
Advance directives	115
Do Not Resuscitate (DNR) orders	115
Euthanasia	115
Withdrawing artificial life support	116
Organ donation, harvesting, and transplantation	116
Autopsy and post-mortem examination	116
MODULE 10 - HEALTH PRACTITIONER RELATIONSHIPS WITH PHARMACEUTICAL INDUSTRY: PRACTICE AND CONFLICT OF INTEREST 119	
10.1 Objectives of the Module	121
10.2 Introduction	121
10.3 Cases (Ethical Scenarios)	123
Case scenario 1	123
Case scenario 2	123
10.4 Why is Knowing About Conflict of Interests Important?	124
10.5 Ethical, Legal, and Policy Issues	124
10.6 Rulings and Fatwas on the Topic	125
10.7 How to Improve Your Practice	125

10.8	Case Discussion	126
	Case 1	126
	Case 2	126
10.9	Conclusion and Summary	127
10.10	References and Suggested Readings	127
MODULE 11 - ETHICAL ISSUES IN RESEARCH		129
11.1	Objectives of the Module	131
11.2	Case (Ethical Scenarios)	131
	Case scenario 1	131
	Case scenario 2	131
	Case scenario 3	131
	Case scenario 4	132
	Case scenario 5	132
	Case scenario 6	132
	Case scenario 7	132
	Case scenario 8	132
	Case scenario 9	133
	Case scenario 10	133
11.3	Introduction	133
11.4	Why are Research Ethics Important?	134
11.5	Ethical, Legal, and Policy issues	134
	Background: terminology and history	134
	Informed consent for research	135
	Patient safety: Benefit vs. risk considerations	135
	Privacy and confidentiality	136
	Rights and obligations: Investigator, sponsor, and patient	136
	The balance between clinical care and clinical research	136
	The research protocol and related documents	137
	Review governance: IRB/REC, GCP, Saudi research regulations	137
	Ethics of research publication	138
	Conflict of Interest (COI) issues	138
11.6	How do Research Ethics Improve Your Practice	138
11.7	Case Discussion	138
	Case 1	138
	Case 2	139
	Case 3	139
	Case 4	139
	Case 5	139
	Case 6	139
	Case 7	140
	Case 8	140
	Case 9	140
	Case 10	140
11.8	Conclusion and Summary	141
11.9	References and Suggested Readings	141
	Background: terminology and history	141

Informed consent for research	141
Patient safety: Benefit vs. risk considerations	142
Privacy and confidentiality	142
Rights and obligations: Investigator, sponsor, and patient	142
The balance between clinical care and clinical research	142
The research protocol and related documents	143
Ethics of research publication	144
Conflict of interest issues	144
Others	144
MODULE 12 - RESOURCE ALLOCATION IN HEALTH CARE	145
12.1 Objectives of the Module	147
12.2 Introduction	147
What are the ethical issues and principles in resource allocation?	147
Different approaches to allocation of resources in health care	148
12.3 Why is Resource Allocation Important to Your Practice	149
12.4 Ethical, Legal, and Policy Implications of Resource Allocation	150
12.5 Rulings and Fatwas on the Topic	151
12.6 How to use Resource Allocation in Your Practice: Examples of Frameworks	151
The American College of Healthcare Executives (ACHE) framework	151
The Hamilton Health Sciences (ISSUES) framework	151
12.7 Conclusion and Summary	152
12.8 References and Suggested Readings	152
MODULE 13 - ETHICS OF PUBLIC HEALTH AND HEALTH PROMOTION	155
13.1 Objectives of the Module	157
13.2 Case (Ethical Scenarios)	157
Case scenario 1: The body-mind duality	157
Case scenario 2: Disease versus illness	157
Case scenario 3: Mental basis of disease	157
Case scenario 4: Mental and social basis of physical disease	157
Case scenario 5: Preventive versus curative medicine	158
Case scenario 6: Health promotion	158
Case scenario 7: Controversy about childhood immunization	158
Case scenario 8: Autonomy versus benefit	158
Case scenario 9: Benefits of early disease screening versus suffering from false negative results	158
Case scenario 10: Public versus individual interests and autonomy	158
Case scenario 11: Disclosure to protect others versus patients' right to privacy and confidentiality	159
Case scenario 12: Public interest versus individual autonomy	159
Case scenario 13: Prioritization of services in an emergency: Vulnerability versus social utility	159
Case scenario 14: Payment for unhealthy disease-causing lifestyles	159
13.3 Introduction: Basic Concepts	159
The concept of health	159

The concept of illness	160
The concept of family health	160
The concept of community health	160
The concept of preventive medicine	161
The concept of health promotion	161
13.4 Why are Public Health Ethics Important?	161
13.5 Ethical, Legal, and Policy Issues	162
Disease prevention versus disease treatment	162
Concepts of equality and equity in health care	162
Ethical issues in priority setting in health resource allocation	163
Ethical issues in epidemiological research	163
Ethics of disease screening	163
Ethics of contagious disease control	164
Smoking and drug addiction control	164
Ethical issues in vaccination	164
Ethical issues in disasters	164
13.6 Rulings and Fatwas on the Topic	165
13.7 How to Improve Your Practice	165
13.8 Case Discussion	165
Case 1: The body-mind duality	165
Case 2: Disease versus illness	165
Case 3: Mental basis of disease	166
Case 4: Mental and social basis of physical disease	166
Case 5: Preventive versus curative medicine	166
Case 6: Health promotion	166
Case 7: Controversy about childhood immunization	167
Case 8: Autonomy versus benefit	167
Case 9: Benefits of early disease screening versus suffering from false negative results	167
Case 10: Public versus individual interests and autonomy	168
Case 11: Disclosure to protect others versus patients' right to privacy and confidentiality	168
Case 12: Public interest versus individual autonomy	168
Case 13: Prioritization of services in an emergency: Vulnerability versus social utility	168
Case 14: Payment for unhealthy disease-causing lifestyles	169
13.9 Conclusion and Summary	169
13.10 References and Suggested Readings	169
Theories of ethics for public health	169
Concepts of holistic health	169
Public versus private interest	169
Disease prevention versus disease treatment	169
Concepts of equality and equity in health care	170
Priority setting in health resource allocation	170
Epidemiological research	170
Disease screening	170

Contagious disease control	170
Smoking and drug addiction control	170
Vaccination	170
Disasters	170
MODULE 14 - ETHICS OF EMERGENCY MEDICINE	171
14.1 Objectives of the Module	173
14.2 Introduction	173
14.3 Why is Ethics Important for Emergency Medicine?	174
14.4 Ethical and Legal Issues	174
14.5 Islamic Views on this Topic	175
14.6 Why Emergency Cases are Different	176
14.7 Case (Ethical Scenarios)	176
Case scenario 1	176
Case scenario 2	176
14.8 The Ethical Issues Related to Emergency: How to Improve Your Practice	176
Professionalism	176
Emergency staff relations with patients	177
Privacy of the patients	177
Triage in ER cases	177
Confidentiality of information and files	177
Honesty	178
Truth telling	178
Equal resource distribution	178
How to break bad news	178
Examinations of opposite gender (male to female patient or female to male patient)	178
14.9 Case Discussion	179
Case 1	179
Case 2	179
14.10 Conclusion and Summary	180
14.11 References and Suggested Readings	180
MODULE 15 - HOW TO RESOLVE ETHICAL ISSUES IN CLINICAL PRACTICE	183
15.1 Objectives of the Module	185
15.2 Case (Ethical Scenario)	185
15.3 Introduction	185
The Clinical Ethics Committees (CECs)	186
The four boxes(quadrants) model	187
The CLEO approach	188
A principle-based framework/Process for ethical decision making	188
A structured approach to case consultation	190
15.4 An Islamic Principle-Based Approach	191
Stages of rational systematic problem solving	191
Authoritative sources	191

Solutions using the goals of Sharia (Maqasid Al-Sharia - مقاصد الشريعة)	192
Solutions from principles of the law, Qawaids Al Fiqh (قواعد الفقه)	193
15.5 Why is Utilizing Ethical Frameworks Important to Your Practice	195
15.6 Ethical, Legal, and Policy Implications	195
15.7 How do you use Ethical Analysis Tools and Frameworks in Your Practice	196
15.8 Case Discussion	197
What are the goals of Sharia involved?	197
15.9 Conclusion and Summary	199
15.10 References and Suggested Readings	200
MODULE 16 - ETHICAL ISSUES IN REPRODUCTIVE HEALTH	
16.1 Objectives of the Module	203
16.2 Case (Ethical Scenarios)	203
Case scenario 1	203
Case scenario 2	203
Case scenario 3	203
Case scenario 4	203
Case scenario 5	203
Case scenario 6	204
Case scenario 7	204
16.3 Introduction of Basic Concepts	204
Infertility	204
Assisted reproduction	204
Contraception	204
Reproductive cloning	204
Abortion or pregnancy termination	205
Gender selection	205
Gender change	205
Menopause	205
16.4 Why is Knowing About the Ethical Issues in Assisted Reproduction Important?	205
16.5 Ethical, Legal, and Policy Issues	205
Assisted reproduction	205
Contraception	206
Human reproductive cloning	207
Abortion	208
Gender selection	209
Gender correction/change operations	209
Menopause	209
Onco-fertility	210
16.6 Case Discussion	210
Case 1	210
Case 2	210
Case 3	210
Case 4	210
Case 5	210

Case 6	211
Case 7	211
16.7 References and Suggested Readings	211
Assisted reproduction	211
Contraception	211
Reproductive cloning	212
Abortion	212
Gender selection	213
Gender change	213
Menopause	213
Onco-fertility	214
MODULE 17 - ORGAN TRANSPLANT AND DONATION	215
17.1 Objectives of the Module	217
17.2 Introduction	217
17.3 Why is Organ Transplantation Important?	219
Ethics	219
Policy	220
How should we approach organ transplantation in practice	222
17.4 Cases (Ethical Scenarios)	223
Scenario 1	223
Scenario 2	223
17.5 Consequences of Selling Organs	224
17.6 Islamic Declarations and Other Bioethical Guidelines	225
17.7 Conclusion and Summary	227
17.8 References and Suggested Readings	227
INDEX	229

FOREWORD

One of the great pleasures of being in academics is to participate in the training of the next generation in the practice. The Saudi Commission for Health Specialties (SCHS) has been striving to provide Residents the knowledge and training needed to practice efficiently as well as safely. Taking this into account, the SCHS has motivated the contributors of this book to prepare one which would best fit practice in Saudi Arabia based on Islamic moral and legislative sources (Quran, Sunnah and Ijtihad).

As health care practitioners professionalism and ethics are obligatory for the success of our careers in order to meet professional standards, not only clinical guidelines.

The authors of this book are to be commended on their perspicacity in professionalism and ethics. It is a good source for information that will guide Residents and/or any healthcare practitioners, understand their duties and responsibilities pertaining to their profession and patients, and vice-versa. The various topics regarding ethics have been well covered in this book with different sample scenarios and discussions on how to handle them.

I hope all health care practitioners will benefit from this book and make its practice part of their profession. Ethics and professionalism go hand-in-hand and it is important to understand ethics to practice professionally.

Prof. Abdulaziz Al Saigh
Secretary General
Saudi Commission for Health Specialties

ACKNOWLEDGMENTS

The editors and authors of this handbook would like to acknowledge the very supportive role that **Prof. Sulaiman Al-Emran**, BDS, MSc, PhD, the Assistant Secretary General for the Saudi Commission for Health Specialties has played in providing the initiative to develop the Professionalism and Ethics Handbook for Residents (PEHR). He has continuously followed the development progress of this handbook.

We would like to thank **Dr. Thuraya Kattan** and **Ms. Laila Al-Yousef** for their relentless efforts to keep track of the progress of the video series and the complementary handbook. It would not have been possible to finalize this handbook in its current form without their efficient organization and communication skills.

Last, but not least, we would like to thank **Mr. Muammar B. Amanollah**, the secretary for the dean of medical college, King Fahad Medical City, Riyadh for his role as a researcher and communication facilitator for the various authors of this handbook.

On behalf of the editors and authors,
Dr. Ghaiath Hussein, MBBS, MHSc (Bioethics)

MODULE 1 - INTRODUCTION TO MEDICAL ETHICS

Ghaiath MA Hussein, MBBS, MHS_c (Bioethics)

1.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. Understand the structure and goals of this handbook
2. Utilize the cases and discussion points in each module
3. Define the basic terminology related to ethics of health care

1.2 CASE (ETHICAL SCENARIO)

A resident in her obstetrics and gynecology rotation was faced with a case of a 28-year-old pregnant woman of 13 weeks gestational age, who is already a mother of three healthy children. The woman was diagnosed with ovarian cancer stage 2. The oncologists made a recommendation to the obstetric team to terminate the pregnancy to initiate chemotherapy.

The resident was not sure whether it was lawful, from an Islamic perspective, to terminate the pregnancy. She found no clear guidance from an Islamic perspective in the medical textbooks that she had found in the library, which were all written and published from a Western perspective. She asked her colleagues in the hospital's religious affairs department if they had written a Fatwa-based policy or statements on the issue. She did not find a clear answer, so she started to search the Internet and finally found a few Arabic written Fatwas that allowed similar acts in similar types of patients. However, the resident was not fully satisfied, and was quite frustrated from the time and effort that she had to exert to find an answer to the condition she had faced. Moreover, what she had found was not clear to her, as the Fatwa was full of Fiqhi terminology that she was not familiar with.

1.3 WHAT IS THE PEHR OF HEALTH CARE ETHICS?

PEHR stands for Professionalism and Ethics Handbook for Residents program that was developed and launched by the Saudi Commission for Health Specialties (SCHS). The idea of the handbook came from the feedback that SCHS had received from the residents after distributing the first series of the educational DVDs on Introduction to Biostatistics and Research Methodology (<http://www.youtube.com/user/scfhs2012>). Many residents wished to have some “hand-outs” to accompany the DVDs, to increase their value and usability; also, residents are now using portable devices that do not have DVD readers.

The idea was taken further with the second part of the series, which was on Medical and Research Ethics, and which developed into the PEHR. Along with the video-recorded lectures, and the PowerPoint presentations, this handbook provides an easy-to-use text that residents can refer to, similar to any other bedside book for a clinical specialty.

It should be emphasized that this is a handbook and *not* a textbook. We have tried to make it as concise and user-friendly as possible. Therefore, the contributors were asked to avoid elaborate explanations, though we have tried to set the stage with an introductory module with the basic common philosophical, ethical, legal, and Fiqhi grounds that will be applicable to almost any branch of health care ethics.

It is also important to note that this handbook is not intended to be a substitute for currently available textbooks, or those in the pipeline. It is also worth emphasizing that we have tried to summarize the main and relevant Fatwas in each module, yet the referencing in Fatwas should still be to the authenticated sources authorized by Fatwa in Saudi Arabia, namely the High Scholars Commission, The General Presidency of Scholarly Research and Ifta, and the Permanent Fatwa Issuing Committee, which we have used for the Fatwas described in this handbook.

1.4 WHY IS THE PEHR NEEDED?

The literature on the education of ethics in Saudi Arabia, among other countries in the region, reflects the gaps in our undergraduate and postgraduate medical education on ethics education (Bajammal et al., 2008).

Most of the available references considering and discussing ethical issues are either written and/or published by Western authors and publishing houses. This is not necessarily a bad thing; however, it is a situation that needs to be addressed and rectified. It is well-known that ethics are deeply rooted in Islamic teachings and heritage, mainly in the Quran and Sunnah. Moreover, the Islamic rulings give clear guidance that should be followed by Muslim doctors who treat Muslim patients, which is mostly the case in Saudi Arabia and most of the countries in the region.

In addition, the available Islamic resources mainly address students of Islamic jurisprudence (Fiqh - فقہ) or consultants who have asked trusted scholars on religious opinion about a specific situation they have faced in clinical practice. There are usually a lot of details and Fiqhi terminologies (مصطلحات فقهیة) that may not be clear to clinicians who are not “experts” in Islamic studies, and do not usually explain the grounds on which the Fatwas were issued, at least not in a way that allows bedside clinicians to utilize them in the cases they encounter.

The main goal of this handbook is to provide residents with the foundation knowledge to identify, analyze, and manage the most common ethical issues.

1.5 HOW IS THE PEHR STRUCTURED?

To ensure the greatest use for this handbook, its modules have been divided into the main foundation and the practical aspects of ethics and professionalism. Reference can be made to the table of contents for detailed descriptions of each module.

Each module is itself designed to be concise, simple, and practical. Each module starts with clearly stated learning objectives, so that the reader is aware whether this module has what he or she is looking for. Then, the module presents a real case scenario that is usually encountered in real practice. After that, the module goes on to describe the basic concepts and definitions of the themes and issues it covers. Finally, the module ends with a discussion of the scenario previously presented using the knowledge given within the module. There is also a summary box that summarizes the most important points from a practical point of view.

This handbook is designed as an integrated, yet independent set of modules, so that the reader does not have to read the whole handbook to make use of one of its modules. That being said, it is advisable to read it as a whole, with special emphasis on the foundation modules that explain the philosophical and Fiqhi basis of ethical analysis, moral reasoning, and practical approaches to the resolution of the ethical issues in health care practice.

1.6 HOW TO USE THE PEHR IN PRACTICE

In practice, residents (and practitioners in general) usually look for fast and reliable answers for the cases they face. This is as important for an ethical issue as it is for a clinical case. In practice, this division is imaginary, as one could argue that any aspect of health care has professionalism and ethics components attached to it. It is our duty as practitioners to look for the answers that help us provide the best possible care to our patients and the community in general.

The way that you use this handbook may vary according to the case's complexity and urgency. You could be using it as a resource for the exam (the Saudi or the Arab Board).

The approach we advise is to read it well, and completely. This applies for the whole handbook, or just the module you choose to read. We advise you to read the objectives first, as they tell you whether the module has what you are looking for. Reading the case is also helpful in identifying the module's theme and contents.

It is not advisable to jump from the case to the discussion. This may allow you to gain some time, but nothing else. The content of the module is perhaps more important to you than the case discussion, as you may be able to understand the discussion of the case on your own by reading the content, but never the opposite. With a limit of 4,000 words per module, this should be an easy book to read and, hopefully, benefit from.

1.7 DEFINITIONS OF TERMINOLOGY AND CONCEPTS¹

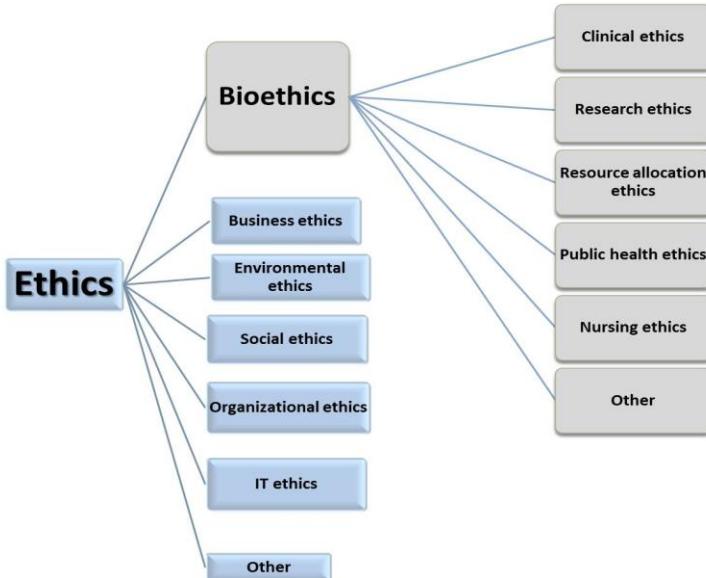


Figure 1.1 An overview of the branches of applied ethics and bioethics.

Ethics

Ethics can be defined as the system of moral principles that govern the conduct of an individual or a group of individuals and according to which human actions are judged as right or wrong, good or bad.

¹ The definitions given here are selected for practical reasons. Other sources may have different definitions. The list of concepts mentioned here is not exhaustive. It was summarized to the extent appropriate to the handbook's goal and audience.

It is generally divided into:

- **Meta-ethics** that seek to understand the nature of ethical properties, statements, attitudes, and judgments (the philosophical study of morality);
- **Normative ethics** investigate the set of questions that arise when considering how one ought to act, morally speaking. Normative ethics are distinct from meta-ethics because they examine standards for the rightness and wrongness of actions; and
- **Applied ethics** that define how to apply moral standards in various practical fields like health care (bioethics), business (business ethics), environment (environmental ethics), etc. (Wikipedia, 2012)

Bioethics

This is the division of applied ethics that helps in defining, analyzing, and resolving ethical issues that arise from the provision of health care or the conduct of health-related research.

Clinical (medical) ethics

This is the branch of bioethics that is related to the identification, analysis, and resolution of moral issues that arise in the health care of *individual* patients.

Research ethics

This is the branch of bioethics that is related to the identification, analysis, and resolution of ethical issues that are encountered before, during, and/or after the conduct of health-related research, specifically on humans (or animals). This is especially important for research that involves the collection and further processing of human tissues, biological materials, or identifiable information.

Public health ethics

This is the branch of ethics that is related to the identification, analysis, and resolution of ethical issues that are encountered in the conduct of public health interventions and/or research on a large-scale population.

Islamic bioethics

It is:

- the methodology of defining, analyzing, and resolving ethical issues that arise in health care practice or research;
- based on the Islamic moral and legislative sources (Quran, Sunnah, and Ijtihad; القرآن، السنة والاجتهاد); and
- aimed at achieving the goals of Islamic morality (i.e., preservation of human religion, soul, mind, wealth, and progeny)

Why is it important to know about bioethics?

Basically, bioethics helps us in answering three main questions that are usually encountered in health care provision, which are as follows:

- Deciding **what we should do** (what decisions are morally right or acceptable),
- Explaining **why we should do it** (how do we justify our decision in moral terms), and
- Describing **how we should do it** (the method or manner of our response when we act on our decision).

(Secker, 2007)

1.8 CASE DISCUSSION

For any clinical aspect related to the care of patients, the clinical team, including residents, should make sure they offer the patient the care that is compatible with the patient's moral values and religious beliefs. In many instances, the patients themselves may ask the doctor about the religious ruling (Fatwa) related to their condition. These questions may be simple, like how to perform *Tayamoum* (تيمموم), or which drugs can interfere with fasting in Ramadan. This is particularly important when it comes to a very sensitive issue like termination of pregnancy, whose ethical and religious bases are also explained in the module on end-of-life decisions (Module 9).

Although it is the role of the hospital to provide guidance for clinicians to standardize practice, there are other sources to which clinicians can refer to resolve ethical and religious issues. These include the ethics committee in the hospital, if present, the religious affairs department, and the Fatwas collected in books that answer similar questions. It is important to note that Saudi Arabia has adopted a policy that makes only the members of the Higher Scholars Commission eligible to give Fatwas, to avoid multiple sources that lead to more confusion than clarification. Some of the resources are mentioned in the suggested readings (see below).

1.9 CONCLUSION AND SUMMARY

1. This handbook is intended to provide comprehensive and clear guidance on how to manage ethical issues in health care.
 2. Although this handbook can be a good source for your board exams, or even undergraduate medical education, it is not intended to be a textbook for academic purposes.
 3. You need to keep a ready-to-use list of trustworthy resources relating to the main ethical and religious aspects of your specialty.
-

1.10 REFERENCES AND SUGGESTED READINGS

1. Abdel-Halim RE, AlKattan KM. Introducing medical humanities in the medical curriculum in Saudi Arabia: A pedagogical experiment. *Urology Annals* 2012;4(2):73.
2. Adkoli BV, Al-Umran KU, Al-Sheikh M, Deepak KK, Al-Rubaish AM. Medical students' perception of professionalism: a qualitative study from Saudi Arabia. *Medical Teacher* 2011;33(10):840-845.
3. Al-Gindan YM, Al-Sulaiman AA, Al-Faraidy A. Undergraduate curriculum reform in Saudi medical schools. Which direction to go? *Saudi Med J* 2000;21(4):324-326.
4. Al-Shehri AM, Al-Ghamdi AS. Is there anything wrong with undergraduate medical education in Saudi Arabia. *Saudi Medical Journal* 1999;20(3):215-218.
5. Alshehri MY. Medical curriculum in Saudi medical colleges: current and future perspectives. *Annals of Saudi Medicine* 2001;21(5/6):320-323.
6. Bajammal S, Zaini R, Abuznadah W, Al-Rukban M, Aly SM, Boker A, et al. The need for national medical licensing examination in Saudi Arabia. *BMC Medical Education* 2008;8(53).
7. Secker B. PHL2146Y-Topics in Bioethics: Course Outline. 2007.

MODULE 2 - PRINCIPLES OF WESTERN & ISLAMIC APPROACHES TO BIOETHICS

Ghaiath MA Hussein, MBBS, MHSc (Bioethics)

2.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. Differentiate between Western and Islamic approaches to bioethics.
2. Appreciate the ethical, religious, legal, and policy importance of knowing about the standards of ethics and professionalism in the health care setting, and be able to follow them.

2.2 CASE (ETHICAL SCENARIO)

Dr. Huda is a Muslim Saudi resident who is doing her rotation in one of the largest women's hospitals in Toronto, Canada. Her consultant asked her to see a patient in the outpatient clinic who was 16 years old, unmarried, and living with her boyfriend. The patient asked Dr. Huda about the best contraception method she could use to avoid getting pregnant. She also asked her for advice on the safest way, and the safest place, to arrange an abortion, in case the contraception failed.

Dr. Huda felt very uncomfortable and confused about how to deal with this patient, as her religious beliefs do not allow for sexual relations before or outside of marriage. Moreover, the kind of abortion requested by her client is prohibited in Islam. She told the patient that she could not provide her with the advice she wanted and kindly asked her to set another appointment where she could see the consultant.

2.3 INTRODUCTION

The global/Western approach to bioethics

As mentioned in the introduction, one of the main roles of the field of bioethics is to help us justify our choices ethically. Any individual refers to some “moral reference” to justify what he/she did (or did not). For example, you do not cheat in your exams because cheating is against your religion; while some may see this as wrong because they think it is against the ethical principle of justice, others would say it is against the university’s policy to cheat. In summary, different people have different reasons why they would do or would not do things.

To understand how people think about ethical issues, how they tell right from wrong, it is important to establish the idea of “ethical schools of thought.” The following diagram shows a brief “taxonomy of ethics.”

Main Western Philosophies	Other philosophies	Abrahamic religions	Oriental philosophies
Utilitarianism	African, Asian, etc.	Islamic	Buddhist
Deontology	Human Rights	Jewish	Confucius
Feminist ethics		Catholic	Indian
Casuistry			
Virtue ethics	Christian Ethics	Protestant	Persian
Principlism		Jehovah Witnesses	

© SCHS/Medical Education and Postgraduate Studies

**Figure 2.1** A brief taxonomy of the main ethical theories and schools

Table 2.1 briefly describes the main ethical theories that people, including academicians and clinicians, tend to refer to when providing an ethical argument. This is used to defend an ethical stand that they believe to be right.

Table 2.1 Summary and examples of the main philosophical theories used in bioethical arguments

Theory	Main ethical points	Acts are ethically right when...	Examples from practice
Utilitarianism (Consequentialism)	Actions <i>not</i> morally right in themselves—they become morally right <i>if</i> they produce certain consequences	They achieve overall amount of good (or the least overall harm) for the greatest number	Patients with public health-threatening disease are quarantined for the sake of the good of the general public
Deontology (Duty-based)	Consequences are morally irrelevant, i.e., they don't determine the ethical nature of action by themselves	They follow a set of duties and rules that are applicable to anyone in the community without exceptions	Doctors are bound to "the <i>duty</i> to serve" their patients, even if there is risk attached to this duty. Doctors have the "duty to do good" for their patients
Virtue-based Ethics	Emphasizes moral character—not just moral action	The acts are done by a moral person, not just simply to be done morally	Smoking doctors cannot advise their patients not to smoke. If smoking is morally wrong, then the moral person should not do it

Theory	Main ethical points	Acts are ethically right when...	Examples from practice
Casuistry	Case comparison/analogy used toward ethical consensus; it is the theory of adopting no theory	There is a practical judgment in <i>that</i> particular case where appeal to precedent ("paradigm cases") is possible	This approach is very similar to that of Fatwa issuance. For example, we cannot generalize a Fatwa that permitted abortion for one patient to all patients with the same condition
Principleism	A framework that includes four clusters of moral principles for identifying and reflecting on moral problems	They respect the four main principles of autonomy, beneficence (do good), non-maleficence (do no harm), and justice	Taking consent from patients before surgery respects the patients' autonomy
Feminist Ethics	Oppression (of all people, in all its forms) is morally and politically unjust and must be addressed. Autonomy should be a relational (rather than an individualistic) notion; fair relationships among social groups	They consider one's self as essentially a "self-in-relation"	Giving the female patient the right to consult and consider her family before giving consent. Doctors should not insist on her taking her decisions alone (to avoid the potential undue influence of the family on her)

Source: Modified from a lecture by Prof. Barbara Secker on ethical theories given in the University of Toronto Joint Center for Bioethics Master's program of bioethics (October 2007).

The Islamic approach to bioethics and how it differs from Western approaches

Islamic bioethics fall under what is known as "Divine Command Theories," or religious ethics, which refer to the commands of God (Allah) as a reference for telling right from wrong.

How do Muslims tell right from wrong?

Though this question may seem naïve to any Muslim doctor, we believe that framing the answer in an actionable and organized manner would further help in analyzing and deciding about certain ethical issues that we may encounter.

Muslims (including Muslim doctors) have two main categories of sources to guide them on what to do and what not to do. They are 1) the main (primary)

sources, namely the Quran and the Sunnah; and 2) the secondary sources that can collectively be called “Ijtihad,” which refers to the deduction of decisions about issues that are not specifically stated in the Quran or Sunnah. This is achieved through a methodology used by the knowledgeable and trusted scholars in the field to issue the “Fatwas” related to contemporary health-related issues.

Table 2.2 summarizes the main components of the **Ijtihad** process with related examples from clinical practice. For a more detailed account, you can find a list of informative and simple readings. (For example: Kamali 1991; Kamali 2000; Karim 2010; Kasule Sr. 2008; Kasule 2004; Kasule Sr. 1999; Hussein, 2012).

Table 2.2 The main components of the Ijtihad process with related examples from clinical practice.

Ijtihad Constitutes(الاجتہاد)	Example
Ijmaa (الجماع): Unanimous agreement among trusted scholars on a ruling	Tobacco smoking is unanimously considered as prohibited (<i>haram</i> - حرام)
Rayul Jomhour (رأي الجمهور): The opinions of the majority of trusted scholars	Medically-indicated abortion is permissible by most of the trusted scholars before 40 days if it fulfills given conditions (see Module 16 on abortion by Prof. Kasule).
Qiyas (قياس): refers to likening (comparing) a new case in question without textual evidence to an original ruling that is supported by explicit legal text if they share the same cause	The prohibition of smoking Hashish was made based on likening/comparing its effects to those of other illegal drugs
Maslaha Morsala (مصلحة مرسلة): Allowing an act for the sake of public interest that no holy text from the main sources prohibits	The health authorities have the right to restrict the movement of a patient with serious contagious disease to prevent its spread to the general public
Istishab (استصحاب): is continuation of an existing ruling until there is evidence to the contrary	A patient who is terminally ill but has not started the active process of dying is considered alive, until there is clear clinical evidence that he or she is dead
Sadd al dhari'at (سد الذرائع): is prohibition of an act that is otherwise permissible (<i>mubaah</i> - مباح) because it has a high probability of leading to a prohibited act (<i>haram</i>)	Male doctors should not casually examine female patients without a chaperone to avoid the possibility of inappropriate physical contact between them

The purpose of Islamic laws and rulings

Like other ethical theories, Islam sets certain purposes or standards that human actions should meet or fulfil to be considered ethically acceptable.

These purposes are known as the “Purposes of the Islamic Law,” or Maqasid Al-Sharia (مقاصد الشريعة). There are five purposes that human actions are judged against and these are summarized in Table 2.3.

Table 2.3 Summary and examples of the main purposes of the Islamic laws (Sharia)

The Sharia Purpose	Example of application in health care
Preservation of Soul/Self/Life (Hifz An-Nafs - حفظ النفس)	The main purpose of the practice of medicine is to achieve this Sharia goal. (الهدف الشرعي) Islam has prohibited abortion, in part because it contradicts this purpose.
Preservation of Religion/Faith (Hifz Ad-deen - حفظ الدين)	Doctors help in keeping healthy people healthy and minimize the disability associated with illness so that Muslims can practice their worship fully. ¹
Preservation of Mind/Intellect (Hifz Al-Aql - حفظ العقل)	Islam prohibits the consumption of drugs and any substance that could affect a person's mental capacity, e.g., alcohol.
Preservation of Wealth (Hifz Al-Mal - حفظ المال)	Muslim doctors should abstain from requesting unnecessary investigations or interventions, especially surgical, to avoid causing additional financial burden on the patient, along with the physical complications and side effects of the intervention.
Preservation of Progeny/Lineage (Hifz Al-Nasl/Nasab - حفظ النسل/النسب)	Islam prohibits any reproductive gametes (ova and sperms) donation or exchange. This explains why many of the scholars were reluctant to accept IVF amid the fear of having the gametes messed up mistakenly or on purpose.

The major principles that guide Islamic judgment on ethical issues and their sub-principles

Though the “Purposes of Sharia” (Maqasid Al-Sharia- مقاصد الشريعة) provide a generally acceptable framework for determining what could be right or wrong, there should be some practical methodology that could be followed to reach ethically and religiously acceptable decisions. This is particularly important when the purposes conflict; for example, when managing terminally ill patients with incurable diseases in the intensive care unit (ICU) where other patients need the bed and the costs are mounting up for the patient’s family. On one hand, some would argue that a DNR (Do Not Resuscitate) order should be

¹ Most Islamic duties are either minimized or completely dropped from the disabled or incompetent person until his/her capacity to do them is restored.

considered to achieve the goal of preserving wealth (of the family). On the other hand, another may counter-argue that preservation of life is prior to the preservation of money. A third may advocate preserving the lives of the patients who are waiting for the needed medical intervention(s) to achieve the goal of preserving life.

There are five major principles derived to help in reaching ethical and religious decisions (Table 2.4). Under each of these major principles, there are sub-principles that explain the major principle in further details. The following diagram summarizes the major and sub-principles:

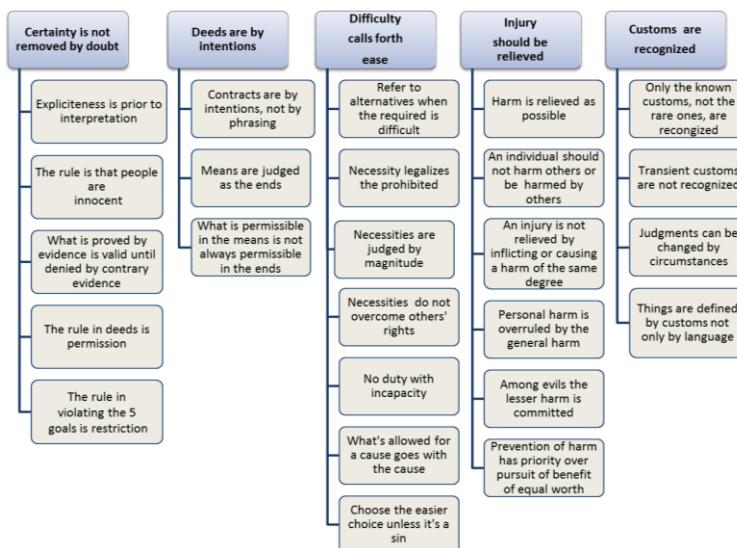


Figure 2.2 A diagram summarizing the major Fiqhi principles and examples of their main sub-principles.

Table 2.4 The major Fiqhi principles and examples of their application in healthcare practice

Major Fiqhi Principles	Example of its sub-principles	Application in practice
The principle of Intention (Qasd - قصد)	Acts are judged by the intentions behind them	Removal of an organ from a patient cannot be judged as good or bad, per se, unless the intentions of the doctor are known. For example, if the organ is removed with the intention to protect the rest of the body, then this is good, while if it is removed with the intention to be sold by the doctor to another patient then this is wrong.

The principle of Harm (Dharar) ضرر	No harm and no return of harm	Doctors should abstain from carrying out any intervention that is known to harm the patient.
The principle of Certainty (Yaqeen) ثقين	Certainty cannot be removed by doubt	Even terminally ill patients with incurable diseases should be considered alive, until there is evidence that makes it more certain than doubtful that they are dead.
The principle of Hardship (Mashaqqat - مشقة)	Difficulty calls forth ease	A surgeon who is expected to have a long surgery is allowed to perform his prayers (which would be due to happen while he is in the OR) before the start of the surgery.
The principle of Custom (Urf - عرف)	Custom is recognized as a source of law	It is left to the custom of the (lay and professional) community to decide whether the doctors' fees are acceptable or not.

2.4 ETHICAL, FIQHI, LEGAL, AND POLICY IMPLICATIONS OF BIOETHICS IN HEALTH CARE

Providing ethical health care at all levels is no longer a matter of choice, depending on how virtuous the doctor is. There are many factors that make it obligatory to provide responsible health care systems that meet professional standards, not only clinical guidelines.

Ethically speaking, all those with whom you have contact in your practicing career have rights. This includes not only your patients and their families but also your colleagues in all the other disciplines at all learning levels (junior and senior) as well as your community in general. You too have rights, but it is the public's expectation that doctors should be asked (rather than themselves asking) for rights. This attitude is usually referred to as "altruism," which is one of the major elements of professionalism (see Module 3 on professionalism).

As a Muslim doctor, you have additional responsibilities, or more precisely, other intentions with your responsibilities. By acting in an Islamic moral manner, you are fulfilling many objectives and duties at the same time. You will be fulfilling the requirement of excellence that was clearly stated by The Prophet Mohamed (Peace Be Upon Him), "Allah loves that whenever any of you does something, he should excel in it" (reported by Al-Bayhaqi). The intentions of the Muslim doctor should always be devoted and clarified to Allah, as He Subhanahu WaTa'alaa mentioned in The Quran,

فَلَمَّا صَلَّيْتِ وَسُكِّيْ وَمَحْنَيْ وَمَمَّيْ لِلَّهِ رَبِّ الْعَالَمِينَ (162) لَا شَرِيكَ لَهُ وَيَدْلِكَ أَمْرَتْ وَاتَّا أَوْلَى الْمُسْلِمِينَ (163)

Say: "Truly, my prayer and my service of sacrifice, my life and my death are

(all) for Allah, the Cherisher of the Worlds: (162) No partner hath He: this am I commanded, and I am the first of those who bow to His Will (163)" (Surat Al-Anaam:162-163).

2.5 HOW TO IMPROVE YOUR PRACTICE BY KNOWING ABOUT WESTERN AND ISLAMIC ETHICS

As Muslim practitioners, Islam provides us with clear guidance on how to treat each other with fairness and altruism. It is essential for us to understand the morals of Islam and learn how to apply them in practice. Nowadays, most of our Saudi residents may spend a lot of their training years in non-Muslim countries, particularly in the regions of North America and Western Europe. The mind-set, the culture, the way of thinking about right and wrong and how all of these apply in practice differs from how they are set here in Saudi Arabia. Our residents are asked to apply the same "Western" ethical standards as when they are being trained, and this could be problematic for them if they are not aware of Western mind-sets and how Westerners justify their moral judgments.

It is true that Western approaches to health care are not solely guided by the philosophical approaches that we mentioned earlier. There are many other historical, demographical, and economical factors that come into play when we try to understand how Western doctors or patients see things related to their health care.

Fortunately, Western approaches generally match the Islamic teachings, apart from some controversial issues, such as abortion. For example, the four principles of autonomy, beneficence, non-maleficence, and justice are well established in the Islamic morals. It is important to know that these issues are also controversial among Western people themselves, depending on their personal or religious standpoints. As a Muslim doctor, you should be confident in what you receive and what you provide. This module aims, in part, to provide you with a common language with which you can deliver your ideas to non-Muslim colleagues and patients.

By doing this, you are serving your faith, improving your communication, minimizing the potential cultural/religious tensions and opening your mind to hearing from others and learning from them.

2.6 CASE DISCUSSION

It is not uncommon for Muslim residents to face situations in which they are uncertain about what to do, in terms of whether what they should be doing is permissible or not in Islam. This is not only unique when working in Western

settings, but also in the context of their national hospitals. This uncertainty is usually the result of lack of knowledge about the Islamic guidance on health-related issues. Moreover, in a Western setting, there is also the duty to follow policies that were not developed on a religious basis-at least not an Islamic one. Then what should one do?

1. Do your duty to care.

Dr. Huda has a duty of care to her patient and a duty to explain her standpoint to her colleagues and consultant(s). This does not mean that she should provide a medical intervention against her beliefs.

2. Refer. Be honest.

Generally, the doctor has the right and sometimes the duty to refer his/her patients to another provider who can deliver a better and more specialized service, if he/she feels incompetent to manage the case. This does not apply to emergency situations, or when there is no provider available that the patient can have access to. In addition, he/she has to be honest to his/her patient in case the patient wants to know why he/she can't provide such a service directly, i.e., why he/she needs to refer the patient to another provider.

3. Explain Islam, but don't advocate.

Using the brief summary mentioned in this module, as well as other resources, try to explain to your patients and colleagues why you as a Muslim cannot, for example, help in abortion. Tell them that Islam has a set of certain goals that include preservation of life, and that there are some guiding principles that you follow. Use the principles that are relevant.

Generally, be precise and do not elaborate on what Islam states about other issues, unless you are directly asked. It is good to call for Islam, but the casual doctor-patient setting is not the best place to do so. If you are interested in calling people (including your colleagues) you can invite them to some activity in the nearest mosque or Islamic center.

4. Know the system, and follow it.

It is crucial that you are aware of how your health institution works and what the policies in place are. Most of the time, you will find them clear and consistent with your roles as a Muslim doctor. If this is not the case, consult other Muslim colleagues, or ask your consultant on how to manage situations in which the health care service asked by the patient is not permissible in Islam. Please refer to the module on "Doctors' roles and duties" to obtain a clearer view of the concept of "conscientious objection."

2.7 CONCLUSION AND SUMMARY

One of the most unique features of being human is the ability to choose among alternatives. This is referred to in philosophy as being a "moral agent," and is what is known in Islam as "*Amana* - أمانة"-the Trust, as mentioned in the Quran.

إِنَّا عَرَضْنَا الْأُمَانَةَ عَلَى السَّمَاوَاتِ وَالْأَرْضِ وَالْجَبَالِ فَأَبَيْنَ أَن يَخْمَلُهَا وَأَشْفَقُنَّ مِنْهَا وَخَلَلُهَا إِنْسَانٌ ۝
كَانَ ظُلُومًا جَهُولًا (الأحزاب:72)

"We did indeed offer the Trust to the Heavens and the Earth and the Mountains; but they refused to undertake it, being afraid thereof: but man undertook it; - he was indeed unjust and ignorant" (Quran 33:72)

In making decisions, different people refer to different sets of guidance to decide which action to take or not. In this module, we have tried to summarize how the Western schools of thoughts (philosophies) tried to provide some guidance on how to make decisions on what is ethically acceptable.

1. Islam provides us with robust guidance on how to make decisions about what is ethically acceptable, based on the preservation of the five main goals of Sharia (شريعة; religion, soul/body, wealth, mind, and progeny/lineage).
2. The guidance on how to achieve these goals are either found in the main sources of legislation (The Quran and Sunnah), or deducted from the secondary sources collectively known as "Ijtihad."
3. The Islamic approach is more robust. It has priority in application over the Western approach when the conclusions of Western approaches to ethical analysis are contradictory to the Islamic teachings and rulings (Fatwas).

2.8 REFERENCES AND SUGGESTED READINGS

1. Methodologies in Shariah Decision-making. In: Shariah Resolutions in Islamic Finance, Shariah Advisory Council of Bank Negara Malaysia, ed. Bank Negara Malaysia 2010;pp. 2-11.
2. Hussein G. An Islamic Approach to Ethical Analysis of Stem Cell Research. In: Third Regional Conference on Stem Cell Research: Current Controversies 2012.
3. Kamali MH. Al-Qawa'id Al-Fiqh: The Legal Maxims of Islamic Law. The Association of Muslim Lawyers 2000.
4. Kamali MH. Principles of Islamic Jurisprudence. Nature Publishing Group 1991;283-296.

5. Karim MF. 2010. Shariah Maxims and Their Implication on Modern Financial Transactions. *Journal of Islamic Economics, Banking, and Finance* 2010;6(3):75-102
6. Kasule OH Sr. Medical Ethico-Legal-Fiqhi Basis of Medical Practice: An Islamic Perspective. In: Scientific and Islamic Medicine Seminar, Timur Indonesia: The Students' Executive Board Faculty of Medicine Deponegoro University.
7. Kasule OH. Medical Ethics From Maqasid Al Shari'at. *Arab Journal Of Psychiatry* 2004;15(2):75
8. Kasule OH Sr. Medical Ethico-Legal-Fiqhi Issues: An Islamic Perspective. In: Training Workshop on the Islamic Input in the Medical Curriculum held at the Faculty of Medicine UNISSULA 2008.
9. Kasule OH Sr. Principles of the Law (Qawasid Al Shariat). Lecture to 3rd year students at the Kulliyah of Medicine, International Islamic University, Kuantan 4-12-1999. Kuantan, International Islamic University, Kuantan 21-12-2008.
10. Bajammal S, et al. The need for national medical licensing examination in Saudi Arabia. *BMC Medical Education* 2008;8(53).

MODULE 3 - DOCTORS' PROFESSIONAL RELATIONSHIPS AND DUTIES

Ghaiath MA Hussein, MBBS, MHSc (Bioethics)

3.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. Define the doctor's duties towards self, colleagues, patients (and families), the profession, and the community in general.
2. Describe the relationships that the doctor has with others during the provision of health care.
3. Appreciate the significance of maintaining professional relationships with colleagues in achieving the best health care.

3.2 CASE (ETHICAL SCENARIO)

On his round, the well-known surgeon Mr. Butcher was always keen to have all the residents and interns on his unit in attendance, in addition to other health care team members (dietician, physiotherapist, nurses, and others) to whom he always referred as the "paramedics." During the round, he asked one of his unit's female interns to examine a 65-year-old male patient who had had his prostate removed two days before. He asked her in a loud voice. Both the intern and the patient felt embarrassed. The surgeon stopped her when she tried to pull the curtains, as there were few other patients next to this patient who would see him being examined if the curtains were not pulled. He said, "Nothing to be ashamed of. He is a patient in a teaching hospital so he expects that you will all examine him," then, "isn't that right Mr. X?" talking to the patient. The intern asked the patient's permission then examined him, and the operation site. The surgeon then asked her and the other "doctors" some questions. As usual in his round, the wrong answers were ridiculed, and the "paramedics" were never given a chance to answer. "Paramedics are to take the instructions doctors give them," he would always say.

3.3 WHY IS KNOWING ABOUT DOCTORS' DUTIES AND RELATIONSHIPS IMPORTANT?

Classically, doctors have been educated to be clinicians, i.e., doctors in a clinical specialty who manage patients in hospitals. In addition, traditional medical education has produced medical doctors who think that they are the most important component in the health care system. This is inflated by the fact that it is the doctors who give instructions and lead the health care team in clinical settings. This is not necessarily a bad thing. However, it is crucial to remember that a doctor is a member of a team. He or she needs to be an effective team member and leader in order to have an effective team. As doctors, we should give patient-centered care. This means that the main focus and priority is what is in the best interest of the patient, at the physical, socio-cultural, and psychological levels. A doctor manages other humans, who need his or her help to restore their lives to the best possible quality, not just to

treat their sick bodies. This should be reflected in respectful attitudes and behavior towards oneself, our colleagues, our patients, the profession, and the whole community.

This module will help you expand your understanding of your profession as a doctor in its broader sense. It also aims to help you to be a more effective health care team member, which will be reflected in less problematic relationships with your non-doctor colleagues and more focus on the patient.

“... The physician should be modest, virtuous and merciful... He should wear clean clothes, be dignified, and have well-groomed hair and beard. He should select his company to be persons of good reputation. He should be careful of what he says and should not hesitate to ask forgiveness if he has made an error...”

He should be punctual and reliable. He should not wrangle about his fees. He should not give drugs to a pregnant woman for an abortion unless necessary for the mother's health. He should be decent towards women and should not divulge the secrets of his patients. He should speak well of his colleagues. He should not honour himself by shaming others.”

Al-Tabari, 970 A.D., Fardous Al Hikma

3.4 WHERE ARE YOU? WHAT DO YOU DO?

It is crucially important to know your roles and to learn how to fulfill them. These roles depend on where you are. The following figure summarizes the possible locations where doctors could find themselves working, and what their roles would be in such settings.



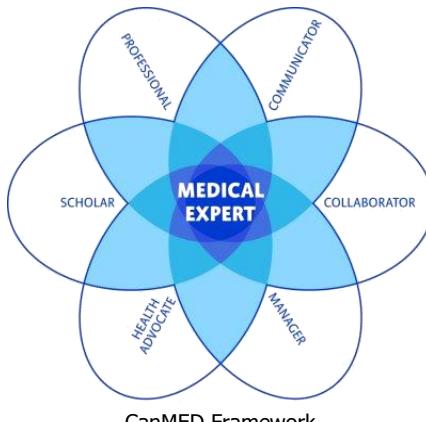
Figure 3.1 summarizes the places where doctors are usually found and the professional roles they play in each of them.

The following table (modified from the CanMEDS model; Jason R. Frank, 2005) briefly introduces the main focus of each of the professional roles and the main competencies that a doctor should be able to play his/her role efficiently in.

Table 3.1 Summary of the CanMEDS framework for medical expert competencies

CanMEDS framework	Definition	Key Competencies: Physicians are able to...
Healer/ Medical Expert	As Medical Experts, physicians integrate all of the doctor's roles, applying medical knowledge, clinical skills, and professional attitudes in their provision of patient-centered care.	<ol style="list-style-type: none"> Function effectively as consultants, integrating all of their roles to provide optimal, ethical, and patient-centered care; Establish and maintain clinical knowledge, skills, and attitudes appropriate to their practice; Perform a complete and appropriate assessment of a patient; Use preventive and therapeutic interventions effectively; Demonstrate proficient and appropriate use of procedural skills, both diagnostic and therapeutic; Seek appropriate consultation from other health professionals, recognizing the limits of their expertise.
Collaborator	As Collaborators, physicians effectively work within a health care team to achieve optimal patient care.	<ol style="list-style-type: none"> Participate effectively and appropriately in an interprofessional health care team; Effectively work with other health professionals to prevent, negotiate, and resolve interprofessional conflict.
Health Educator	As Health Educators, physicians share their medical knowledge with their patients in a language they understand and a way that is culturally acceptable to the patients; the aim is to keep them healthy in the future, not just to cure them from their current illness.	<ol style="list-style-type: none"> Communicate effectively with their patients to convey medically relevant information in an appropriate way; Effectively work with other health care team members who specialize in communication to help educate the patient; Develop their personal communication skills through attending training and through self-development and practice.

Manager/ Planner	As Managers, physicians are integral participants in health care organizations, organizing sustainable practices, making decisions about allocating resources, and contributing to the effectiveness of the health care system.	<ol style="list-style-type: none"> Participate in activities that contribute to the effectiveness of their health care organizations and systems; Manage their practice and career effectively; Allocate finite health care resources appropriately; Serve in administration and leadership roles, as appropriate.
Researcher/ Scholar	As Scholars, physicians demonstrate a lifelong commitment to reflective learning, as well as the creation, dissemination, application, and translation of medical knowledge.	<ol style="list-style-type: none"> Maintain and enhance professional activities through ongoing learning; Critically evaluate information and its sources, and apply this appropriately to practice decisions; Facilitate the learning of patients, families, students, residents, other health professionals, the public, and others, as appropriate; Contribute to the creation, dissemination, application, and translation of new medical knowledge and practices.
Communicator	As Communicators, physicians effectively facilitate the doctor-patient relationship and the dynamic exchanges that occur before, during, and after the medical encounter.	<ol style="list-style-type: none"> Develop rapport, trust, and ethical and therapeutic relationships with patients and families; Accurately elicit and synthesize relevant information, and the perspectives of patients and families, colleagues, and other professionals; Accurately convey relevant information and explanations to patients and families, colleagues, and other professionals; Develop a common understanding of issues, problems, and plans with patients and families, colleagues, and other professionals to develop a shared plan of care; Convey effective oral and written information about a medical encounter.
Health Advocate	As Health Advocates, physicians responsibly use their expertise and influence to advance the health and well-being of individual patients, communities, and populations.	<ol style="list-style-type: none"> Respond to individual patient health needs and issues as part of patient care; Respond to the health needs of the communities that they serve; Identify the determinants of health of the populations that they serve; Promote the health of individual patients, communities, and populations



CanMED Framework

(<http://www.rcpsc.edu/canmeds/CanMEDS2005/index.php>)

3.5 INTERPROFESSIONAL RELATIONSHIPS AND DUTIES

It is important to remember that the roles of a doctor have different levels, depending on where he/she serves. This begins with himself, and extends to those surrounding him while serving his individual patients (patients, patients' families, colleagues), as well as the whole community. At all levels, he has commitments to the progress of the profession.

Who is the FOCUS of healthcare?



Doctors Are NOT the focus of the healthcare

The following section shows the main duties a doctor is expected to commit himself to, as part of his overall role as a doctor.

Duties of a doctor and his/her profession

Table 3.2 Summary and examples of a doctor's duties

Duty	Good (professional) example (What to do) ☑	Bad (unprofessional) example (What not to do) ✗
Respect the honor of the profession	✓ Look good, neat, and tidy	✗ Wild haircuts & weird fashion
Develop him/herself to develop the profession	✓ Attend continuous medical education (CME) activities, conduct research, and publish results	✗ Sign the attendance sheet, take the certificate, and go without attending the activity
Adhere to the standards of practice	✓ Follow the GCP, EBM, clinical guidelines, etc.	✗ Do whatever comes to mind. Patient won't know anyway!
Abstain from any behavior/action that would question his/her credibility, or establish dishonest affairs with patients or their families	✓ Examine patients of different gender with chaperone, after receiving permission	✗ Using your female patients' information to add them to your Facebook friends
Avoid the request of fame on account of professional ethics and standards	✓ "Dr. Surgeon, MD, FRCS" on your clinic's door-	✗ "Dr. Butcher, MD, FRCS, Best Plastic Surgeon in the Middle East"
Provide a role model for his colleagues and patients	✓ Greet your patients and ask for help from any other discipline, when needed	✗ Shout and insult your juniors as a sign of authority and "knowledge"
Reflect sincere devotion and dedication to the medical profession	✓ Perhaps seeing your patients outside of duty hours.	✗ Write what keeps you safe in the record, never see your patient, and switch your phone off
Avoid any action that could lead to contempt of the medical profession and maintain the standards of the medical profession	✓ Avoid unnecessary eye/physical contact with patients of opposite gender	✗ Calling your patients' phone numbers, which you took from their records for no treatment-related reason
The physician should not take advantage of his professional position for obtaining any material or moral gains, which are not in conformity with, or violate, the laws and tradition	✓ As the medical director, you help in providing service faster to those who need it	✗ As the medical director, you help your friends and family to have faster, better service, regardless of their condition

Take the appropriate action upon becoming aware that one of the members of the health team is sick, ignorant, or negligent of his duties, in order to protect the patient in the first place and the medical profession next	<ul style="list-style-type: none"> ✓ If your colleague doesn't perform as well as he/she usually does, talk to him/her and provide advice 	<ul style="list-style-type: none"> ⊗ Tell everyone that your colleague may be having drug or drinking problems
The physician should refrain, when dealing with the patient, from any act or conduct that would infringe his honesty and integrity	<ul style="list-style-type: none"> ✓ Make sure someone else (chaperone) is attending ✓ Ask for permission, expose the needed part only 	<ul style="list-style-type: none"> ⊗ Perform a clinical examination on your female patient without having someone with you

Duties towards patients and their families

Table 3.3 Summary and examples of a doctor's duties towards his/her patients and their families

Duty	Good (professional) example (What to do) ⊗	Bad (unprofessional) example (What not to do) ⊗
Treat your patient as a person, not just a body.	<ul style="list-style-type: none"> ✓ Listen carefully to the patient's complaint, sympathizing with him in his suffering, treat him well, and be gentle while examining him 	<ul style="list-style-type: none"> ⊗ Interrupt your patient, asking him to do these investigations and have these treatments
Respect your patient's autonomy	<ul style="list-style-type: none"> ✓ Listen to your patient's opinion, but that should not keep you from giving the appropriate instructions 	<ul style="list-style-type: none"> ⊗ Tell your patients what you think should be done and leave without listening to them ("You're the doctor, not them")
Treat all patients equally, without discrimination	<ul style="list-style-type: none"> ✓ Disregard (forget) your patients' prestige, social or moral status, your own feelings towards them, their religious or racial background, their political orientation, or their gender, nationality, or color. 	<ul style="list-style-type: none"> ⊗ VIP patients should receive VIP treatment (fast access to premium service). Simple people should wait
Fear God when dealing with your patients; show respect for their beliefs, religions, and traditions	<ul style="list-style-type: none"> ✓ If you think your patient is not following the right faith, you may ask the Religious Affairs in your hospital to talk to him/her without disturbing their religious practices 	<ul style="list-style-type: none"> ⊗ With a patient of a different faith or sect (of Islam), call security to remove his chaplain.

<p>Ask only for the tests needed for the patient without adding any tests not justified by the patient's case. A doctor should base his whole diagnosis and treatment on the best available evidence and data</p>	<p>✓ If the patient says, "Please doctor, check everything you can," tell her that you will do only what needs to be done</p>	<p>⊗ The self-paying patient asks, "Which of these investigations do I need?" The doctor shouts, "All of them. Do you want to teach me my job?!"</p>
<p>Explain honestly to the patient or anyone representing him/her the type, causes, and complications of the illness, and of the usefulness of diagnostic and therapeutic procedures</p>	<p>✓ Tell the patients what they want to know in simple language about their illness, diagnosis, and treatment</p>	<p>⊗ The patient asks, "What's wrong with my kidney?" The doctor answers, "I'm the doctor not you."</p>
<p>DO NOT hesitate to refer the patient to a more experienced doctor or to a doctor who has more effective equipment whenever the patient's case calls for such a referral, nor to refer him to a doctor whom the patient wishes to consult</p>	<p>✓ If your patient develops some complications beyond your specialty, don't hesitate to refer him</p>	<p>⊗ If your patient develops some complications beyond your specialty, keep him as long as he is paying</p>
<p>Continue to give an emergency patient the proper treatment until it is no longer needed or until care for the patient is taken over by another doctor</p>	<p>✓ A patient enters the Emergency Department at 08.05 a.m. Your shift ends at 08.00, but the new shift doctor didn't show up yet. See the patient and stabilize his/her condition</p>	<p>⊗ "I won't see her. My time is over already. If you want to blame someone, blame my colleague who came late"</p>
<p>Continue to extend proper care to patients with incurable, terminal, or fatal diseases and to console them and give them hope to the last minutes of their lives</p>	<p>✓ See your terminally-ill patients, greet them, and raise their morale with a smile and encouragement</p>	<p>⊗ A doctor says to the nurse "Don't waste my time with such patients. They are dying anyway."</p>
<p>Relieve the patient's pain and give him the feeling that the physician is eager to give him proper care and attention</p>	<p>✓ Discuss with your patient the pain-management options</p>	<p>⊗ "I'm in pain, Doctor; I couldn't sleep last night." The doctor replied coldly, "Sorry, I can't give you stronger pain killers. You may become addicted to them."</p>
<p>Respect for Privacy</p>	<p>✓ Ask for your patient's permission before examining them. Make sure that only those who</p>	<p>⊗ The consultant says to his resident, "This is an interesting patient. Make sure all the students I</p>

	are needed are attending, and other patients cannot see him/her	teach examine her."
Respect for patient's autonomy	✓ Take informed consent from your patient whenever a decision about his/her health is needed	⊗ "Don't waste my time with ignorant patients. Just let them sign the paper!"
Inform the patient about his/her condition	✓ Encourage your patient to ask you about his/her condition. Answer honestly to the best of your knowledge	⊗ The doctor interrupts his patient, "This is what I think is good for you. You have to be compliant with my treatment plan."
Keep the patient's secrets (confidentiality)	✓ Keep your patient's medical records safe (whether on paper or on the computer)	⊗ Don't hand the record to anyone just because he/she wears a white coat

Duties towards colleagues

Table 3.4 Summary and examples of a doctor's duties towards his/her colleagues

Duty	Good (professional) example (What to do) ⊗	Bad (unprofessional) example (What not to do) ⊗
To deal with, and act towards his/her colleagues in a good manner and in the same way he/she would prefer to be treated	✓ Acknowledge them, praise them, and thank them	⊗ "Who does she think she is? She has to stop showing up in the round answering all the questions."
To avoid direct criticism to his/her colleague in front of patients	✓ "I think I know another way to do this examination."	⊗ "What do you think you're doing? This examination is completely wrong."
Not to indulge in defaming the honor of his/her colleagues	✓ A patient was referred to you from another doctor. You don't agree with his/her diagnosis/treatment. Tell the patient that there are different ways of investigating and treating his case, and then call the first doctor to discuss.	⊗ A doctor tells his patient, "How on earth did such an ignorant doctor give you such treatment? You are lucky you didn't continue with him."
To exert every possible effort to educate colleagues	✓ Read an interesting article? Bought an important book? Share it with them	⊗ Hiding the important notes or questions that your senior colleagues gave you
Respect the differences among colleagues (gender, culture, belief...)	✓ Your colleague is from a peripheral part of the country; tell him "It's amazing that you could	⊗ Telling jokes about your colleague's nationality or tribe in front of everyone

	have gained all these achievements being from there."	
The physician should respect other non-physician medical professional colleagues, and appreciate their roles in the health care of the patient	✓ You learned something from a nurse or midwife? "Thanks. I'm so grateful you showed me that."	⊗ A doctor says to a midwife, "This is a doctor's job. Please give way!"
He/she must report incidents in which a colleague's actions would be dangerous could be dangerous to the authority concerned	✓ Your surgery consultant made a mistake during surgery; write it down in the surgery sheet.	⊗ "Why should I cause myself trouble? Nobody was hurt anyway."

Source: Saudi Commission for Health Specialties Manual of Ethics of the Medical Profession

Duties towards community

Table 3.5 Summary and examples of doctor's duties towards his/her community

Duty	Good (professional) example (What to do) ⊗	Bad (unprofessional) example (What not to do)
Positive interaction with the community's affairs	✓ Volunteer for an NGO in case of disaster	⊗ "It's the government's work, why should I care?"
Protect the community by reporting reportable/epidemic diseases	✓ Acquaint yourself with the reporting system and forms	⊗ "I won't report. Someone else will. It'll cause me a headache later."
Improve health in the community through advocacy and health education, and involvement in community health activities	✓ Prepare advocacy material ✓ Give a public talk about a health issue	⊗ An NGO invited you to their camp for a disaster. "How much will you compensate me for my time?"
Rational use of the health care institution's resources	✓ Use hi-tech expensive investigations only when needed	⊗ Request MRI or CT scan for every patient. "The machines are already there. It could be something serious anyway."
Effective contribution to the development of policies and health systems that respond to community needs and facilitate easier access to health care	✓ Respond to quality control questionnaires ✓ Join committees of interest	⊗ Doing what everybody else does, and constantly complaining about the failure of the system

As far as possible, to be an ideal example in his attitude and religion	<input checked="" type="checkbox"/> Make sure there is another qualified person looking after your patient while you go to pray	⊗ "Why should I care? No one would dare to blame me. I was praying."
Promotion of health equity among the society's members	<input checked="" type="checkbox"/> Your patient is diabetic or hypertensive? Discuss lifestyle options and refer them to other departments, as needed	⊗ Writing a prescription without giving any more advice.
Use his/her skills, knowledge, and expertise to improve the standards and quality of health services rendered to the society	<input checked="" type="checkbox"/> Have an idea to improve the work? Do it if you can, or share it with your colleagues and department	⊗ "Who cares? The whole situation is hopeless. Let me keep my ideas to myself."

3.6 ETHICAL, LEGAL, AND POLICY IMPLICATIONS

From a very humane viewpoint, all people like to be treated kindly. Your colleagues and your patients are not an exception. Ethically, you are obliged to fulfill certain duties: not to harm, to do only good, not to interfere with others' lives/bodies without their voluntary informed acceptance, and to be fair to them. More specifically, there are duties and boundaries that you need to know and to act on accordingly. Being too close to, or too distant from, others may be not only annoying, but also harmful to you and to the health provision. Therefore, the relations you have to develop with others need to be clear to you.

Legally, these relations have to be clear to you so that you know what your rights, and what the rights of others, are. Otherwise, you may face legal implications if you do not respect the rights of others for privacy, confidentiality, etc. Indeed, laws don't ask doctors to be polite, but to be polite and attentive is a moral, religious, and professional obligation. In addition, it makes you more liked among your colleagues and your patients. This means that your reputation as a "good doctor" will be better; more patients will want to be seen by you, and more colleagues will be interested in working in your unit or hospital.

In conclusion, when you map your relationships at their different levels, you will not only avoid unnecessary professional and legal troubles, but also contribute to the overall good of the profession and the community.

3.7 ISLAMIC RULINGS AND FATWAS ON THE TOPIC

There are a lot of Fatwas and Islamic guidance related to these topics. Islam places great importance and emphasis on people's duties and rights. More Fatwas are mentioned in detail in different modules; for example, privacy is

associated with many Fatwas related to "Awra" (عوره; the part of the body that should not be exposed to strangers), and confidentiality is associated with Fatwas related to witnessing "Shahada" (شهادة) to decide when to disclose a patient's secret.

However, it is worth mentioning that these general good manners, "Adab" (أدب), were emphasized very much, and are at the very core of Islam, the practice of medicine, and health care in general. The following are only examples of what the Prophet Mohammed (Peace Be Upon Him) said about these *Adab*:

قال أبو ذر لما بلغه منبعث النبي صلى الله عليه وسلم قال لأخيه ازكب إلى هذا الوادي فاسمع من قوله فرجع فقال رأيته يأمر بمتکايم الأخلاق (حديث صحيح متفق عليه)

Abu Dharr said that when he heard about the coming of the Prophet (Peace Be Upon Him) he said to his brother, "Go to this valley and hear his words." He returned and said to him, "I saw him commanding people about the noblest morals and manners" (An authentic hadith Narrated by Al-Bukhari and Muslim).

The Prophet also said, as narrated by Abu Huraira,

عن أبي هريرة قال: قال رسول الله صلى الله عليه وسلم أكمل المؤمنين إيماناً أحسنتهم خلقاً وخيالكم خيالكم لنسائهم خلقاً (رواه الترمذى والسيوطى وصححه الابانى)

"The most perfect believer in faith is the one who is best in moral character. The best of you are those who are the best to their spouses in manners." (Narrated by Al-Tirmidhi and authenticated by Al-Albani)

عن عائشة قالت سمعت النبي صلى الله عليه وسلم يقول إن المؤمن يدرك بحسن خلقه درجات قائم الليل صائم النهار (مسند أحمد)

"Aishah -may Allah be pleased with her- said, 'I heard the Prophet -Peace Be Upon Him- say, "Indeed the believer by his good morals reaches the ranks of those who spend the whole night in prayer and whole day in fasting." (Musnad Ahmad, 23219)

عن أبي الدرداء قال سمعت النبي صلى الله عليه وسلم يقول ما من شيء يوضع في الميزان أثقل من حسن الخلق وإن صاحب حسن الخلق ليبلغ به درجة صاحب الصوم والمصلحة (الترمذى)

Abu Al-Darda' reports that "I heard the Prophet -Peace Be Upon Him- say, 'There is nothing in the Balance heavier than the good morals. Indeed the person of good morals will reach by them the rank of the person of fasts and prayers.'" (Al-Tirmidhi 1926)

3.8 HOW TO IMPROVE YOUR PRACTICE BY USING CONSIDERATION AND EMPATHY

One could argue that, "I'm not a smiling person," "I'm not into social activities very much," "I'm not into sharing my thoughts very much, or even speaking a lot." These are some of the arguments that could be made by any doctor to justify why he/she is not "nice to colleagues and patients."

Indeed, we are humans above all, before being doctors. This means that we have different personalities and different levels of ability to interact with others, whether colleagues or patients. Therefore, it is important to emphasize that we are not asking you to be someone else or to always be perfect. This is far from attainable. Nevertheless, here are some tips and tricks to deal with some of the common problems that you may have, which may prevent you from being a "nicer doctor."

Table 3.6 Tips and tricks for common problems

Common problems	Suggested tips	Which resources to look for
• Coming late to lectures, theatre, shifts, etc.	Use email planners, mobile reminders, alarms, to-do lists	Time management, self-motivation
• "ill-tempered" and easily agitated	Know your signs of intolerance, i.e., what happens when you start to become angry? Fast breath, increased heartbeats, closed fists, tense parts of your body, etc. Use time-outs and breathing exercises	Anger management, communication skills, breaking bad news techniques
• Not into socialization	Befriend a sociable colleague, join activities without a lot of interaction with people (e.g., review literature, write manuscripts)	Communication skills, fear management
• Forgets a lot (from a patient's name, to the medication he takes)	Use sticky notes, pocket guides (paper or electronic), keep near to the flowcharts, link names to things you'd remember easily	Memory enhancement resources (sites, books, or even games)

There are many other problems that negatively affect your professionalism. This doesn't mean that you're a bad doctor. It only means that you have problems like all of us, and we need help to sort these problems out. What we suggest initially is an Internet search, where a lot of free materials are available, and the reading of relevant books. You are strongly advised to seek some psychological/psychiatric help, if needed. There is nothing to be ashamed of at all in doing this.

3.9 CASE DISCUSSION

We have outlined the professional values that our profession of doctor involves. It is crucial to understand that these values imply respective duties towards ourselves, our colleagues, our profession, and our communities in general. So let's go back to Mr. Butcher, the well-known surgeon. We can easily demonstrate many unprofessional behaviors that he engaged in. Here are some of them:

- Referring to non-doctor health care providers as paramedics is not acceptable, at least in the way he uses the term. It is more respectful to your colleagues to call them by their job titles.
- An old patient, especially a man in our community, feels quite depressed-if not abused-to be put in a situation where a female of his daughter's age examines his private areas.
- By not pulling the curtains, the doctor deprives his/her patient of his/her least level of privacy.
- Not asking for the permission of the patient to be examined is never acceptable, unless it is an emergency or the patient is unable to give permission. This is applicable even in teaching university hospitals.
- Again, humiliating your colleagues, especially the junior ones, is completely unethical. It is abusive, and totally inappropriate as a role model in front of junior practitioners. Even worse, it widens the gap between the health care team members, without which not even the most skilled doctor can achieve the management goals.
- All health care team members are of equal value and should be given the chance to share the knowledge they have. You can learn a lot from them, as much from your physician colleagues.

3.10 CONCLUSION AND SUMMARY

In conclusion, you need to remember that you do not work in a vacuum. Your work as a doctor means that you are connected to a network of people with whom you have to deal in a professional manner. Though your patient is your primary focus, you still have strong obligations to your colleagues, your profession, yourself, and your community. We have outlined the main duties you have to each of them.

1. Being a doctor is about being part of a team. You have rights and duties as part of this team.
2. Central to your care is your patient (not your ego and not your bank account).
3. Many of the positive attitudes and skills can be developed through training, and self-development.
4. Developing and adhering to these standards develops you, improves health care, and enhances public trust in the health system.

5. By respecting your patients, colleagues, and the community in general, you build better relations and a better reputation for being a faithful model doctor.

3.11 REFERENCES AND SUGGESTED READINGS

1. The Islamic Charter of Medical and Health Ethics: www.emro.who.int/PDF/IslamicCharter_MedicalHealthEthics.pdf
2. The CanMEDS 2005 Physician Competency Framework: http://www.ub.edu/medicina_unitedadecaciomedica/documentos/CanMeds.pdf
3. WMA International Code of Medical Ethics: <http://www.wma.net/en/30publications/10policies/c8>

MODULE 4 - TRUTH TELLING AND BREAKING BAD NEWS

Ghaiath MA Hussein, MBBS, MHSc (Bioethics)

4.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. Discuss the ethical issues related to truth telling
2. Identify the situations in which truth telling to the patient needs to be approached with greater caution
3. Describe a systematic approach to breaking bad news using the 6-step protocol for delivering bad news

4.2 CASE (ETHICAL SCENARIO)

A very famous 90-year-old businessman has been repeatedly admitted to the ICU after suffering from an end-stage lung cancer. In his last admission, you were the doctor in charge. He was accompanied by one of his 14 sons who told you that they have been hiding from him (and other family members) the fact that he has got cancer, and they have told him that he has a chronic chest infection that will be treated by rest and antibiotics. They asked you not to tell him, otherwise he may die of shock, and his market competitors may abuse this information to damage his financial status. This could then lead to the loss of most of his fortune, most of which is being spent on charity to help the needy. Later, another son of the patient, from a different wife to that of the elder son, approached you and asked you about the diagnosis of his father. Luckily, the father called him when you were about to talk to him. What would you do?

4.3 INTRODUCTION

The ethical issues related to truth telling

People need information to help them take appropriate decisions in their lives. Information related to health care is not an exception. Patients need information that they can understand to be able to make the appropriate decisions about their health and bodies. Any form of barrier to such information getting to the patient is usually considered an act of misconduct. This is especially the case when it includes intentional fabrication, falsification, or misrepresentation of the information you give to the patient in order to make the patient decide in favor of what you think is in his/her best interests.

This "right to know" has many ethical principles and duties related to it. We will demonstrate a few of them in the following paragraphs.

1. Informed decision and respect for autonomy

We have discussed in an earlier module the main ethical principle on which the informed consent process relies, which is the respect for autonomy. Briefly, this principle states that any competent person should be given the freedom to decide on any decision that is related to his/her body and/or health. We

have also demonstrated that this right is justified and even sometimes required by the Islamic law of Sharia. (Refer to Module 2)

For an informed consent to be ethically acceptable, there are conditions that it should fulfill. These conditions are capacity, disclosure, and voluntariness.

Capacity usually refers to the mental competencies that are needed for a human to make rational decisions, which includes the ability to understand the information about an intended intervention (or medical condition), appreciate the risks associated with the proposed intervention (medical condition, or research) and be able to recall this information later on.

Disclosure. This condition emphasizes that the information given to the patient, who is supposed to take a decision, is given in a thorough, yet simple and understandable way and that the person is given the chance to have his/her questions answered in a satisfactory way.

Lastly, **voluntariness** refers to the importance of having the freedom to take these decisions without any pressure or coercion, including the emotional and social pressure conveyed by other family members or the health care team.

Obviously, the right to know is attached to the informed consent process, especially the disclosure condition. In other words, patients will not be able to take the appropriate decisions about their health without being told the "truth" about their conditions. Those who know less, or are less able to understand (for example, those who are illiterate or of a lower educational level) are usually less able to take appropriate decisions.

2. Non-maleficence

One of the most crucial duties of a health care provider is not to harm the patient, i.e., if the provider cannot be part of the solution, then at least he/she should not be part of the problem.

The concept of harm is a wide and contested one. Many commentators have different views on it, but what matters is what the patient (the person concerned) believes to be harmful. There are many risks/harms that we, as providers, may not be aware of or even consider at all, but they mean a lot to the affected person-our patient. Again, people need to know about their conditions in order to make an adequate assessment of harm. How can patients tell what the potential harm of this investigation or that treatment is, if they do not know the "truth"?

Hiding, manipulating, or falsifying information given (or not) to the patient could affect their ability to make a decision, which in turn may cause them

direct harm if they make a misguided decision, or cause harm that could have been avoided if they knew the “truth.”

3. Beneficence

This principle is linked in part to both of the earlier principles, as well as others. Harm is usually measured in comparison to benefits and not in absolute terms. Thus, many interventions include a “justifiable” degree of harm because they bring much greater benefit. For example, almost all drugs have side effects, ranging from mild (e.g., nausea or abdominal upset) to severe (e.g., atrial fibrillation or bleeding). However, this doesn’t usually stop people from taking drugs because they compare the risk of these side effects with the ultimate benefit they get from the drug, which is hopefully a cure for their condition. That being said, without the “truth,” such informed decisions about the benefit of the intervention can never be reached. This means that the state of being “uninformed” (or misinformed) might lead people to miss a true benefit, or to have illusions about a false one.

4. Justice

The concept of justice is usually used synonymously with fairness, which in turn refers to the ethical duty to provide fair access to the service or the benefit of an intervention. Again, it may not be easy to decide what is a fair distribution (as we will discuss in a later module), just as it is difficult to decide the nature of the benefit that people should have fair access to. In its broader sense, telling our patients the truth about their conditions would make their decisions more informed, and will help them to be “fair” to others as well. It is important to emphasize that justice here is not only related to being fair to our patients, but also involves making our patients fair to others. We will give one example, and then elaborate more in the case discussion towards the end of this module. If a patient has been misled about her condition by, for example, being told that her condition has a very good prognosis, while in fact most of the previous experiences from our practice and literature suggest the opposite, she might delay her daughter’s wedding until she gets better. She expects to recover within weeks, but if she does not, then eventually the marriage may never take place. In this situation, the mother has been unintentionally unfair to her daughter because she was not told the truth. More extreme examples can be, and are, seen in practice, as we will discuss in the case scenario later.

Disclosing unfavorable information

To summarize the last section, we can conclude that the rule is that patients should be told the truth. Why then, in reality, do some physicians fail to do this? In this section, we will demonstrate the main reasons why doctors may not tell their patients the truth about their conditions (usually referred to as

telling them the “bad news”) and then present the SPIKES model to help in “breaking bad news.”

Examples of unfavorable information include disease recurrence, spread of disease or failure of treatment to affect disease progression, the presence of irreversible side effects, revealing positive results of genetic tests and raising the issue of hospice care and resuscitation when no further treatment options exist (Baile et al., 2000).

The main reasons that doctors may not deliver unfavorable information to their patients include, but are not limited to, the following:

1. Uncertainty about many aspects of the conditions, especially those related to terminal illnesses
2. Lack of proper communication skills
3. Fear (worry) about the patient’s reaction to the information disclosed
4. A belief that it is “in the patient’s best interest”
5. Lack of adequate time to properly explain to the patient
6. Language barrier: either by speaking a different language than that of the patient or failure to communicate with the patient in a language he/she can understand

How to break bad news to patients?

The following is a summary of the 6-step protocol, referred to as the SPIKES Protocol for Delivering Bad News that has been adapted from the EPEC project (Education for Physicians on End-of-life Care) and *How to Break Bad News: A Guide for Health Care Professionals* by Robert Buckman.

Step 1. S - SETTING UP the interview includes

- Creating a conducive environment
- Allotting adequate time
- Determining who else the patient would like present

Step 2. P - Assessing the patient’s PERCEPTION

- Start the discussion by establishing what the patient and family know about the patient’s health
- With this information, ascertain if the patient and family will be able to comprehend the bad news

Step 3. I - Obtaining the patient’s INVITATION

- Each patient has the right to
 - i. Decline voluntarily to receive information
 - ii. Designate someone to communicate on his or her behalf
 - Ask the patient and family how they would like to receive information
-

- If the patient prefers not to receive critical information, establish to whom information should be given

Step 4. K - Giving KNOWLEDGE and information to the patient

- Deliver the information in a sensitive but straightforward manner. Say it as it is, then stop
- Avoid delivering all of the information in a single, steady monologue
- Use simple language that is easy to understand
- Avoid technical jargon or euphemisms
- Pause frequently, check for understanding
- Use silence and body language as tools to facilitate the discussion
- Do not minimize the severity of the situation-Well-intentioned efforts to "soften the blow" may lead to vagueness and confusion

Step 5. E - Addressing the patient's EMOTIONS with empathetic responses

- Patients and families respond to bad news in a variety of ways, including affective, cognitive, and psychophysiological responses:

Affective responses	Cognitive responses	Basic psychophysiological responses
<ul style="list-style-type: none"> • Tears • Anger • Sadness • Love • Anxiety • Relief 	<ul style="list-style-type: none"> • Denial • Blame • Guilt • Disbelief • Fear • Loss • Shame • Intellectualization 	<ul style="list-style-type: none"> • "Fight or flight" • Leaving the room • Withdrawal

Step 6. S - STRATEGY AND SUMMARY

- ✓ Establish a plan for the next steps, which may include:
 - Gathering additional information
 - Performing further tests
 - Treating current symptoms
 - Helping parents to tell their child about their illness and what their treatment will be like for them
 - Arranging for appropriate referrals
 - Explaining plans for additional treatment
- ✓ Assess support by discussing potential sources of emotional and practical support, including:
 - Family
 - Friends
 - Social worker

- Spiritual counselor
 - Peer support group
 - Professional therapist
 - Home health agency
- ✓ **Provide reassurance**
- ✓ **Ensure patient safety**
- ✓ **Plan future visits**

4.4 ARE THERE ETHICALLY ACCEPTABLE CONDITIONS THAT ALLOW US NOT TO TELL OUR PATIENTS THE TRUTH ABOUT THEIR CONDITIONS?¹

First, we need to make an important clarification. It is conceptually and practically important to understand that the patient's right to know the truth does not mean forcing him/her to know. The patient has the right not to know, if he/she is competent to make such a choice. However, this is not always a safe strategy to adopt as a doctor. It may happen that the patient's condition has changed over time, and is now different from when he/she initially made their first choice. Moreover, you need to ensure that even when the patient does not want to know, there is at least someone else with whom you can share the patient's information. Normally, however, you will share the information with the patient if he/she is competent. Alternatively, he/she should be the one to delegate one of his/her family members to be the substitute decision maker. If the patient is incompetent, then the doctor should follow the policy of the hospital in which he/she works.

That being said, some may argue that there are situations in which it is better not to inform the patient, or at least not to tell them all the unfavorable facts about their condition. These arguments are usually based on the claim that this would cause deterioration in the psychological and physical condition of the patient. This claim is often hard to define and even harder to be certain about. It has its ethical, professional, and perhaps legal implications, which we will elaborate later. It is safer to improve one's skills in communicating unfavorable information, than to base such a grave decision on assumptions that may never be true. The only exceptions to this may be if the patient had decided that he/she does not want to know, or if the patient is incompetent to receive the information. These incompetencies may include unconsciousness, dementia, severe mental illness, or other conditions that would indicate the

¹ The author needs to make a disclaimer that this view is only his view, and many commentators or even hospital polices may state different opinions that need to be respected and followed professionally.

patient's inability to receive the medical information or to act on it in an appropriate way. The doctor should make such a decision based on his/her clinical judgment, or based on a documented request from the delegated substitute decision maker.

Another, perhaps more valid, argument is based on the potential harm to the patient from other members of the family or community as a result of disclosing such information. An example would be if a doctor discovers that a single woman is pregnant. This would be considered a major sin by the local community, and according to religious tenets. The Islamic approach advocates a step-wise approach that unfortunately is not usually followed by the community, leading to the possibility that some male members of the family may try to harm the pregnant woman and/or the fetus. Such a scenario might lead her to take irrational and potentially risky decisions, such as seeking non-medical termination of her pregnancy, or even to commit suicide. This scenario is quite unlikely, thus no rule can be based on it. In addition, pregnancy is not something anyone can hide. Therefore, hiding the information from this woman would make things worse; it would be much better to inform her earlier, in accord with the SPIKES model, so that she may find some support or other non-harmful alternatives.

4.5 WHY IS TRUTH TELLING AND BREAKING BAD NEWS IMPORTANT TO YOUR PRACTICE

There is plenty of evidence in the literature to show that many practitioners in different settings face situations in which they have to disclose unfavorable information to their patients. This is part of your job of being a doctor. That said, the best way is to deal with it the way you deal with any other clinical skill that is needed to perform your job: learn it and practice it.

From the patients' perspective, there is a noticeable shift in patients' attitudes towards knowledge and practice of their rights. This is reflected in the substantial media coverage of the health services, and of medical errors and allegations. As people become better educated and have better access to medical information, mainly through the Internet, it is to be expected that they ask more questions. It is your duty to answer these questions, even when the answers may not be favorable to the patients when measured against their expectations.

Moreover, there is increasing literature on the effect of doctors' methods of breaking bad news on clinical outcomes. This includes the patient's satisfaction with the health care service, which is key to your reputation as a "good" doctor. Physicians who fail to communicate bad news to their patients were

found to subject their patients to unnecessary treatments that sometimes worsen, rather than help, the patient's condition.

4.6 ETHICAL, LEGAL, AND POLICY IMPLICATIONS OF TRUTH TELLING AND BREAKING BAD NEWS

We discussed earlier some of the ethical principles that would be affected by your decision to tell or not to tell your patients about their conditions. By hiding, falsifying, or manipulating the information you may be giving to your patients, you might be acting in an unprofessional way. Even worse, you may face allegations of professional misconduct.

If, by any chance, the patients knew that they had been lied to, this would negatively affect the key element of trust that is needed to prompt people to seek medical help from official health care (public and private) sources. Otherwise, people may seek medical help from other sources, like herbal healers or other alternative medical services. This could, in turn, mask the true health profile of the country if we lose our patients to places where they may receive more harm than good, and if they disappear from the health statistics, which rely on the public and private sector facilities as their main sources of data.

Finally, it is important to understand the legal imperative to keep your patient or their substitute decision maker informed with the information they need to make appropriate decisions. Further legal and ethics issues are discussed in the case discussion. A doctor is unlikely to escape conviction of professional misconduct if it is proven that he/she has intentionally hidden information from his/her patient.

4.7 CASE DISCUSSION

In principle, the patient has the right to know his condition for many reasons. First, if he is competent (refer to early sections on competence), then he has the right to be told about his condition, including its diagnosis, treatment, and prognosis. This could improve his compliance, which may improve or at least maintain his condition. This is to respect his autonomy. Second, with such a big family and a lot of people expecting to inherit from him, he should be given the chance to arrange his priorities himself. He is the most knowledgeable of whom among his children needs more and who is better off. Lastly, as a businessman, it is reasonable to expect that he could have many pending financial issues, including debts he owes or has owing. Not telling him about his condition deprives him of the chance to give others their (financial) rights. He could be willing to set aside some of his money for charity. Not telling him of his true condition might harm him and others as well. The argument that the market stocks will be affected is not a valid one. Basically,

you are not disclosing his condition to the press; it is only the patient who would be informed.

Something that should be discussed with the patient early on is which of his sons (or other family members) has the right to know about his condition. You should discuss openly with any patient for whom you expect his/her condition to deteriorate which of his/her family members should be consulted and informed about the health condition. In this particular case, if the patient is competent, then he should be asked directly, whom does he wish to know about his condition? If he is not, then check if the consent he has signed mentions a proxy decision maker. If no name were found, then it would be wise to refer the case to the ethics committee in the hospital, who will most likely call for a family meeting to discuss the condition of the patient. The bottom line is that the doctor should not make assumptions about what is in the best interests of the patient or the family.

When the family says, "Don't Tell." Professional responsibility, family preferences, and patient rights

Often, family members will ask the physician not to tell the patient the diagnosis or other important information.

- In these cases, physicians may feel caught between:
 - i. A legal obligation to obtain informed consent from the patient, and
 - ii. Maintaining a congenial alliance with the family in order to ensure a successful therapeutic relationship.
- Rather than confronting their request with "I have to tell the patient," ask them:
 - i. "Why do you feel that I shouldn't tell?"
 - ii. "What are you afraid I will say?"
 - iii. "What are your previous experiences with bad news?"
 - iv. "Is there a personal, cultural, or religious context to your concern that I should try to understand?"
- Suggest:
 - i. "Why don't we go to the patient together to ask how much he or she wants to know about his or her health and what questions there might be."

4.8 CONCLUSION AND SUMMARY

1. People need information to help them take appropriate health-related decisions
 2. This information should be presented in a way they can understand
 3. The "right to know" has many ethical principles and duties related to it
-

4. The patient's right to know the truth does not mean forcing him/her to know
5. The patient should be the one to delegate one of his/her family members to be the substitute decision maker
6. If the patient is incompetent, then the doctor should follow the policy of the hospital in which he/she works
7. Disclosing unfavorable information has more than one approach; we presented the SPIKES Protocol for Delivering Bad News

4.9 REFERENCES AND SUGGESTED READINGS

1. Baile WF, Buckman R, et al. SPIKES: A Six-Step Protocol for Delivering Bad News: Application to the Patient with Cancer. *The Oncologist* 2000;5(4):302-311.
2. Buckman R. Communication skills in palliative care: a practical guide. *Neurologic clinics* 2001;19(4):989-1004.
3. Buckman R. How to break bad news: a guide for health care professionals. JHU Press 1992.

MODULE 5 - PATIENTS' RIGHTS AND RESPONSIBILITIES

*Abdulaziz Fahad Al Kaabba, MBBS, JMHPE,
MHS_c, DCH, ABFM*

The issue of patients' rights is one of the most important ethical issues dealt with in a health care system. It is the top major public ethical issue in KSA (Alkabba et al., 2012).

5.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. Understand and protect patients' rights and responsibilities
2. Identify patients' values and beliefs
3. Understand the ethical issues related to patients' rights

5.2 CASE (ETHICAL SCENARIOS)

Case scenario 1

Noura is 35 years old and 10 weeks pregnant. She comes to the Emergency Department with severe bleeding per vaginum. A doctor asks her husband to sign for a termination of the pregnancy. The patient is unable to accept the way she is being treated, without any consultation. How can the patient's rights be dealt with in this case?

Case scenario 2

Hosa is 80 years old and lives alone in her apartment. She is fully independent and has never had a serious illness. She prefers not to see doctors. Now she is admitted to the hospital after falling on the stairs and suffering a fracture of the femoral neck. A consultant in internal medicine diagnoses critical aortic stenosis, which is confirmed by echocardiography. The anesthetist visits Hosa to discuss the scheduled surgery and anesthesia. When he says that serious risks are associated with the surgery, Hosa says she does not want to know about them. She wants her fracture fixed because she simply cannot live with reduced mobility. The anesthetist feels that he has a duty to disclose the risks of anesthesia.

5.3 INTRODUCTION

Patients' rights are one of the most important ethical issues related to the patient, his/her relatives, and the community. There have been many studies that have discussed patients' rights. One such study was reported by a group of Toronto ethicists in Canada, and entitled *Top ten health care ethics challenges facing the public*. They revealed the importance of many ethical issues in the community and issues related to patients' rights. Patients' rights are the fifth leading ethical issue in Canada.

There are many ethical issues related to patients' rights and disagreements between patients, families, and health care professionals about treatment

decisions, informed consent, and refusal of treatment, as well as disclosure of medical information and easy access to health care resources.

Waiting lists and prolonged waiting times for patients to receive treatment and be admitted to hospital beds are some of the most pressing ethical issues related to patients' rights in many community.

Another study carried out in Saudi Arabia, and reported in April 2012, focused on major ethical challenges facing the public and health care providers in Saudi Arabia. The results showed that patients' rights are identified as the top major ethical issue facing the public. The second most important ethical issue is the equitable access of resources; third, patient confidentiality; fourth, patient safety; and fifth, informed consent. All these issues are related to patients' rights.

Therefore, patients' rights are important and should be supported in numerous ways. It is essential to explain to patients their rights and responsibilities, and the way these rights are supported, e.g., informed consent, signed consent, treatment decisions, refusal of treatment, personal safety, security and protection, transfer of rights, provision of a bed in a hospital, patient compliance, and process resolution. All of these are actually related to patients' rights.

So, what is meant by patients' rights?

They are the moral and legal entitlements of an eligible patient while being treated at any health care institution.

5.4 WHY ARE PATIENTS' RIGHTS IMPORTANT?

This topic is important because

1. Patients' rights are one of the most important ethical issues related to patients, their family, and the community.
2. Patients' rights include many important ethical issues, e.g., autonomy, informed consent, privacy, confidentiality, risk information, refusal of treatment, personal safety and protection, and the process of resolution for patients' complaints; all these are related to patients' rights. When these problems are solved, many ethical issues will be solved in our communities.
3. Supporting these rights will improve health care systems and safety.
4. Supporting these rights will improve trust between patient and community.

5.5 ETHICAL, LEGAL, AND POLICY ISSUES

There are many policies related to patients' rights all over the world, including Saudi Arabia. These ethical guidelines pertaining to patients' rights are usually related to the patient's informed consent, the patient's safety, risks and benefits, practice and confidentiality, the patient's rights, and obligation and responsibility. The aim is to achieve a balance between clinical care and clinical research, the patient's decision, and the ethics of research publication. Therefore, all of these are actually dealing with the policies of patients' rights.

1. Patients' rights and research
2. Informed consent
3. Patient safety: Benefit versus risk considerations
4. Privacy and confidentiality
5. Patients' rights and responsibilities
6. Disclosure of medical errors.

It is always important to present the Islamic approach to the ethical issues in summary.

Patients have the following rights, to the extent allowed by law:

- Receive the health care needed regardless of race, creed, age, color, beliefs, national origin, gender, gender identity, religion, or disability.
- Be treated with dignity and respect in a safe environment free of threat and harm.
- Have an interpreter present if unable to understand or speak the language used, e.g. English.
- Request assistance if having visual and/or hearing impairment.
- Express personal religious and cultural beliefs as long as the exercise of these beliefs does not harm others or interfere with the medical treatment or the rights of others.
- Sign an advance directive so providers know what care is desired in the event of near death and inability to communicate personal wishes.
- Decide who can make decisions about care and treatment in the event one isn't able to communicate personal wishes.
- File a dispute or grievance for any issues, like care or access, that haven't been resolved with doctor or nurse by calling the Patient Assistance Coordinator or the Department of Health.
- Speak to a member of the Ethics Committee when there are ethical issues about care.
- Have a family member, representative, or physician notified when admitted to the hospital.
- Know the members of the health care team providing care.

- Get information needed to understand what is thought to be the health concern, as well as the risks, benefits, and choices of treatment.
- Participate with the treatment team in making decisions about care and treatment.
- Refuse treatment to the extent permitted by law.
- Get a second opinion.

5.6 PATIENTS' RESPONSIBILITIES:

Just as a patient has certain rights, a patient also has certain responsibilities.

Patients' responsibilities:

- Treat other patients, hospital staff, and the property of others with respect.
- Give correct and complete information to the treatment team.
- Ask questions or request more information when unable to understand information or instructions.
- Follow treatment plan, or tell health care team member inability to follow it.
- Tell doctor about any changes in health.
- Cancel appointments that cannot be kept.
- Follow hospital rules and regulations.
- Meet financial obligations.
- Express opinions and concerns in a helpful way to the right people, including doctor, nurse, or the Patient Assistance Coordinator.
- Keeping appointments and informing hospital when unable to attend for any reason.

5.7 RULINGS AND FATWAS ON THE TOPIC:

Islam supports patients' responsibilities and rights, as well as informed consent, signed consent, and patients' right to refuse treatment. There are many Fatwas to support these decisions; if the patient is an adult and able to think clearly, these Fatwas also support his/her power of attorney. Therefore, all of these rights are clearly supported by Islamic Fatwas and laws.

The Islamic Fiqh Assembly stated the following in its resolution (No. 7/5/67, and dated May 1992) about informed consent:

- The informed consent is required from the competent patient. If the patient has reduced or absent competence, then his legal substitute decision maker's consent is considered, only within what is in the patient's best interests. Therefore, the substitute decision maker's consent is not valid if there is clear harm on the patient; hence the

- right to substitute in the decision making is shifted to other guardians. If no guardian is found, then the right [to decide on behalf of the patient] is shifted to the governor.
- In cases of emergency, the medical interventions are not dependent on the informed consent (i.e. the doctors should not wait for an informed consent to start lifesaving medical interventions)
 - In cases of medical research, the informed consent should be given by the competent persons without coercion (like prisoners), or financial temptations (like the needy); given that there will be no harm on them.

5.8 HOW TO IMPROVE YOUR PRACTICE BY KNOWING ABOUT PATIENTS' RIGHTS

Health care professionals should support patients' rights in many ways:

1. Educate the patient about his/her rights and responsibilities.
2. Educate physicians, nurses, and health care providers about the patients' rights and responsibilities.
3. Educate medical students and residents about these important issues through the teaching process, such as CME, videos, TV, radio, courses, workshops, etc. All of these will increase the media and public awareness of the importance of patients' rights and responsibilities.

5.9 CASE DISCUSSION

Case 1

This case includes many ethical issues:

1. A woman is pregnant but is still in the first trimester. She comes with severe bleeding per vaginum. Her husband wants to sign the consent form in place of his wife but she refuses. What conclusions can be drawn?
2. The patient is mentally sound and it is her right to sign an informed consent for any procedure related to her own body.
3. If she is not aware of the safety and risk benefits associated with her consent, the health care workers have a duty to educate her, and in case of an emergency take the decision to protect her. Refusal of treatment is one of the patient's rights, and she should be allowed to sign the informed consent form by herself. However, in the case of a real emergency, her opinion should be listened to; if she refuses to sign the informed consent form, her husband or another near relative may sign. In these cases, an Emergency Medicine doctor can sign the form to protect a patient's life.

Case 2

Ms. Hosa has asked the anesthetist not to further disclose the risks associated with hip surgery. She says that her goal is to be able to walk and that further suffering from pain and immobility is not acceptable. She tells the anesthetist that any further discussion of the risks will not change her mind, but might upset her. The anesthetist respects Ms. Hosa's request but tells her that she can change her mind regarding the discussion of risks at any time. He also asks her if there are any family members whom Ms. Hosa would like to involve in the decision-making process. Ms. Hosa wants her daughters to participate in the decision, and so the scheduled surgery and its possible risks are disclosed to them. The entire discussion is documented, including Ms. Hosa's reasons for waiving (refusal of) further disclosure of the risks of surgery. Ms. Hosa undergoes an uncomplicated repair of her hip fracture and returns home to live independently. This case includes many ethical issues, such as patient safety, informed consent, patients' rights, and the decision-making process.

5.9 CONCLUSION AND SUMMARY

1. Patients' rights are one of the most important ethical issues related to the patient and community.
2. Patients' rights include many issues, such as autonomy, information disclosure, privacy, confidentiality, informed consent, refusal of treatment, protection of patient safety, and the right to seek a second opinion.
3. Support should always be provided to educate our communities and health care providers about patients' rights and responsibilities.
4. Patients' rights should be taught to our undergraduate and postgraduate students as ethical issues.

5.10 REFERENCES AND SUGGESTED READINGS

1. Al-Jarallah J, AlMazrou B. Ethics of the medical professional: Manual guide for medical practitioners. Edition II 2003.
2. AlKabba AF, Hussein GM, Albar AA, et al. The major medical ethical challenges facing the public and healthcare providers in Saudi Arabia. *J Family Community Med* 2012;19(1):1-6.
3. AlKabba AF, Hussein GM, Kasule O, Jarallah J, Alrukban M, Alrashid A. Teaching and evaluation methods of medical ethics in the Saudi public medical colleges: cross-sectional questionnaire study. *BMC Medical Education* 2013;13(1):122 available from: <http://www.biomedcentral.com/1472-6920/13/122>
4. Breslin J, MacRae S, Bell J, Singer P, The University of Toronto Joint Centre for Bioethics Clinical Ethics Group. Top 10 health care ethics

- challenges facing the public: views of Toronto bioethicists. BMC Medical Ethics 2005;6(1):5.
- 5. Patient Rights and Responsibilities - Riyadh Care Hospital www.care.med.sa
 - 6. Singer P, Finnis AM. The Cambridge Textbook of Bioethics. 1st Edition 2008.
 - 7. رضا المريض عن الأعمال الطبية والجراحية، د. مأمون عبد الكريم، دار المطبوعات الجامعية الإسكندرية 2006م.
 - 8. مجلس مجمع الفقه الإسلامي الدولي المنعقد في دوره مؤتمره السابع بجدة في المملكة العربية السعودية من 7-12 ذي القعده 1421 الموافق 9-14 أيار (مايو) 1992م.

MODULE 6 - MEDICAL MALPRACTICE AND MEDICAL ERRORS

*Abdulaziz Fahad Al Kaabba, MBBS, JMHPE,
MHS_c, DCH, ABFM*

6.1 OBJECTIVES OF THE MODULE

By the end of this module, residents will be able to understand:

1. How to define medical errors and malpractice
2. How often medical errors happen
3. The different types of medical errors
4. How we should disclose and solve medical errors and malpractice
5. The important ethical issues related to medical errors

6.2 CASES (ETHICAL SCENARIOS)

Case scenario 1

A 23-year-old medical student was in his last year of medical school. He was asked to perform a procedure he hadn't done before. His mentor was called away from the operating room about an urgent matter and the young student made a mistake, which led to a complication that caused the woman patient to lose her life.

Case scenario 2

A 30-year-old female patient went through an aggressive chemotherapy session and hysterectomy after she was diagnosed with a rare form of cancer. Later, her oncologist told her she had been mistakenly diagnosed.

6.3 INTRODUCTION

In health care, it is not uncommon that patients are exposed to harmful risks. Some risks are predictable, at least at a level of probability, and informed consent is obtained. Other risks, such as those occurring because of medical errors (ME) are in a sense unpredictable, and an informed consent cannot be obtained. By definition, an ME is defined as the failure of a planned action to be completed as intended. It is also defined as a preventable adverse medical offense.

An ME is also defined as an act or omission that would have been judged wrong by knowledgeable peers at the time it occurred (Kohn et al., 2000). Some MEs may not cause any harm; a near miss is an event that under slightly different circumstances could have been an accident, either because the error was detected and corrected in time or because the patient was just lucky (Murphy & McEvoy, 2008). When an ME occurs, two actions should be considered: reporting it to the health care system (and hence, via this channel, to potential future patients) and disclosing it to the patient involved. Reporting an ME is paramount for quality and safety improvement and the incident should be labeled a "near miss ME" (Kohn et al., 2000; Hammami et al., 2010); compared to the reporting of harmful MEs, the reporting of near miss MEs occurs with greater frequency and fewer barriers to data collection

(Hammami et al., 2010). Errors are considered "preventable" and not primarily a result of the disease process. One definition states that an error occurs when there is "failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim" (Leape, 1994).

Medical errors are an important topic in medicine because they are related to many issues. They are related ethically to patients' rights, to issues of regulation, trust, and finance for the patient and for medical hospitals. Medical error is a big problem for every country. In many studies, the overall frequency of medical error is similar to the reported rate in North America of 7.5%; in European countries, the rate has been estimated to be between 5 - 10%. The list below shows the most frequent types of medical errors.

Common types of medical errors are as follows:

- Surgery-related as in obstetrics and gynecology, general surgery, orthopedic, cardiac and plastic surgery.
- Medication-related like mismanagement and possibly incorrect medication, wrong prescription or dosage, and inadequate instructions to patient.
- Body-fluid-related error, e.g. blood transfusion administered too quickly, which resulted in congestive heart failure and death.
- Diagnostic error, such as misdiagnosis leading to an incorrect choice of therapy.
- Failure to order necessary diagnostic test, misinterpretation of test results, and failure to act on abnormal results.
- Equipment failure, for instance defibrillators with dead batteries or intravenous pumps whose valves are easily dislodged or bumped which cause increased doses of medication over too short a period.
- Others, including medical reports, file errors. (*Baker et al., 2004*)

6.4 WHY IS THIS SUBJECT IMPORTANT?

This subject is very relevant because it is important to patients, the public, and physicians. Medical errors should be disclosed in order to

1. promote public trust
2. prevent further harm to a patient and to other patients
3. respect personal autonomy
4. support principle of justice
5. improve the safety of medical practice
6. be able to trust the physicians and the system

Therefore, all these ethical issues are important for the patient and the community.

6.5 ETHICAL ISSUES RELATED TO MALPRACTICE

Many ethical issues are related to the subject of ME disclosure. According to the principle of justice (fairness) for patients or their families, when harmed, they should be able to seek appropriate restitution. The main ethical issues involved are as follows:

1. Patient autonomy
2. The beneficence of the patient and non-beneficence also
3. Justice: Patients need their rights and right to compensation
4. Truth telling
5. Confidentiality
6. Informed consent
7. The relationship between a physician when he makes a disclosure and the patient, who must be supported, must be transparent

Finally, non-disclosure of error may undermine efforts to improve the safety of medical practice in general (Lansky, 2002). If practitioners are unable to be honest with patients or families regarding the harmful event, they are unlikely to be entirely straightforward in the reporting of an incident to the appropriate authorities within a health care setting. This will block efforts to identify the faults and weaknesses in the health care processes and procedures.

All these ethical issues are important, and legally we should have an efficient system for disclosures of our own medical mistakes, and those of higher authorities, as well as written policies and procedures that fully support patients and their rights.

6.6 ISLAMIC ISSUES RELATED TO MEDICAL ERRORS AND MALPRACTICE

It is always important to present the Islamic approach to ethical issues in summary. A full chapter will be devoted solely to the Islamic approach to ethical analysis, so all you need to do is to give a summary from Fatwas that you are aware of.

There are many issues addressed in Islam that address the subject of the disclosure of medical errors. There is a hadith by the Prophet Muhammad (Peace Be Upon Him) رواه ابن ماجه والدارقطني، "لا ضرر ولا ضرار", and its translation is "There should be no harm or return of harm" (Narrated by Ibn-Majah and Al-Daraqotni) which means that we should not harm others (including patients, indeed).

There is another hadith by the Prophet Muhammad (Peace Be Upon Him):

"من تنبأ ولم يعلم منه طب فهو ضامن." (رواه أبو داود، وصححه الحاكم والذهبي)

"Whoever practices medicine when he is not known for that, he is liable."
(Narrated by Abu-Dawood and authenticated by Al-Hakim and Al-Zahaby)

Islam should be referred to in order to address patient rights in relation to the three types of medical error.

1. There is a mistake, error, or negligence
2. There should be complications
3. There is a relation between these complications and the mistakes or error

6.7 HOW TO IMPROVE OUR PRACTICE BY KNOWING ABOUT MEDICAL NEGLIGENCE

We should openly disclose our medical errors because, as stated earlier, this will promote public trust as well as justice and will also prevent further harm. Moreover, disclosure respects the patient and his/her autonomy. Medical professionals have high expectations placed upon them, and, not surprisingly, find it difficult to acknowledge their errors openly before patients and colleagues (Finkelstein et al., 1997). Clinicians who have observed a colleague disclosing an error to a patient are more likely to do so themselves (Hobgood et al., 2006).

So, how do we practically disclose medical errors?

Patients want full disclosures of all the errors that result in harm, and they need to know what has happened and why. It is also important to determine how the problem occurred, any implications, and how to prevent it happening again. One approach to the practical prevention of errors is called the "practical disclosure approach." Disclosure should take place at the right time, when the patient is medically stable enough to absorb the information, and in the right setting. A physician should take the lead in disclosing error(s) to patients and their families (Levinson et al., 1997). They should try to avoid being defensive or evasive, but rather explain what happened in an objective and narrative way, trying to avoid reacting to the charged response that such disclosure might generate. A physician may say, "I'm sorry this has happened." Patients may appreciate this form of acknowledgement and empathy. This may strengthen, rather than undermine, the physician-patient relationship.

The physician himself, or the person who makes the disclosure to the patient (usually the physician), should explain the error in a simple way, immediately, or as soon as possible after he has discussed the problem or error with his senior. He should disclose the error privately, with empathy, and with offers of support. In addition, he should explain what has happened, and if possible

state that it will not happen again; he should also support the patient's right to receive fair compensation. Whatever supports the needs of the patient and his/her family psychologically and physically shall be offered. This practical approach will help to support patients' rights.

6.8 CASE DISCUSSION

Case 1

For the first case, which is about Barack, the student who made a mistake:

1. The senior should not have left the student alone and he should have told him to wait for him to return.
2. The student should have not have continued by himself; he should have called another senior.
3. We should educate our students to know their limitations, in both knowledge and skills.
4. We should disclose any case immediately to the higher authorities for compensation.
5. The family of a patient should be informed immediately and according to law they should be compensated.

Case 2

For the second case, which was the woman who had a hysterectomy by mistake and was misdiagnosed:

1. We should support the patient's right for compensation and an apology.
2. We should explain comprehensively what happened.
3. There was a problem with the diagnosis, so the physician and the lab specialist should re-check the result again and again before they take any action with the patient.
4. According to the law, the physician should be questioned about this case.

6.9 CONCLUSION AND SUMMARY

1. Medical errors or mistakes are not uncommon, and more common in surgical, obstetrics and gynecological, and surgically-related specialties. Drugs also represent an important type of error; others are fluid-related, such as blood transfusions or IV fluids.
 2. Patients want a full disclosure of all the errors that result in harm, and they need to know what happened and why, what the implications are, how the problem occurred, and how to prevent it.
 3. Disclosure should take place at the right time, when the patient is medically stable enough to absorb the information, and in the right setting. A physician should take the lead in disclosing error(s) to patients and their families.
-

4. We should disclose our medical error(s) quickly, or as soon as possible, with full disclosure to the patient. We should then offer physical or psychological support, after discussion with our senior colleagues in a calm setting.

6.10 REFERENCES AND SUGGESTED READINGS

1. Baker GR, Norton PG, Flintcroft V, et al. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. *CMAJ* 2004;170.
2. Barach P, Small SD. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. *BMJ* 2000;320(7237):759-763.
3. Finkelstein D, Wu AW, Holtzman N, et al. When a physician harms a patient by a medical error; ethical, legal, and risk-management considerations. *J Clin Ethics* 1997;8(4):330-5.
4. Hammami M, Attalah S, Al Qadire M. Which medical error to disclose to patients and by whom? Public preference and perceptions of norm and current practice. *BMC Medical Ethics* 2010;11(1):17 available from: <http://www.biomedcentral.com/1472-6939/11/17>.
5. Hobgood C, Weiner B, Tamayo-Sarver JH. Medical error identification, disclosure, and reporting: do emergency medicine provider groups differ? *Acad Emerg Med* 2006;13:443-51.
6. Kohn LT, Corrigan JM, Donaldson MS. To err is human: building a safer health system. In: *A report of the Committee on Health Care in America, Institute of Medicine*. Washington, DC: National Academy Press; 2000.
7. Lansky D. Improving quality through public disclosure of performance information. *Health Aff* 2002;21(4):52-62.
8. Leape LL. Error in medicine. *JAMA* 1994;272:1851-7.
9. Levinson W, Roter DL, Mullooly JP, et al. Physician-patient communication. The relationship with malpractice claims among primary care physicians and surgeons. *JAMA* 1997;277:553-9.
10. Murphy JG, McEvoy MT. Revealing medical errors to your patients. *Chest* 2008;133:759-63.
11. Singer P, Finnis AM: The Cambridge textbook of bioethics. 1st Edition, 2008.

MODULE 7 - PATIENT AUTONOMY AND CONSENT TO TREATMENT

*Omar Hasan Kasule Sr. MBChB (MUK),
MPH (Harvard), DrPH (Harvard)*

7.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. Define the concept of autonomy and appreciate that it is the basis for consent.
2. Define informed consent and list its components.
3. Describe the scope of consent in terms of coverage and time, and what to do in an emergency situation necessitating life-saving procedures beyond the original consent.
4. Understand how consent protects the interests of both the patient and the physician.
5. Describe in detail the process of obtaining consent from a patient.
6. Define the concepts of competence and capacity and how they are assessed in the patient.
7. Describe the consent process for the incompetent using proxy or substitute decision makers and advance directives
8. Describe ethico-legal procedures in consenting for children, the mentally impaired, and the unconscious.
9. Describe consent procedures in emergency situations in which it is not possible to get consent from the patient and there are no substitute decision makers.

7.2 CASE (ETHICAL SCENARIOS)

Case scenario 1: Autonomy as the basis of informed consent

An 80-year-old, fully conscious, and competent man with advanced incurable cancer needed palliative chemotherapy. The family objected when the doctor wanted to obtain informed consent from the patient because that would involve disclosing the diagnosis, which would make the patient very sad and depressed. The family wanted to make the decision without informing the patient. What should the doctor do? Provide your moral reasoning.

Case scenario 2: Scope and limitations of consent

A 30-year-old woman presented with classical signs of acute appendicitis. She consented to an operation to open the abdomen and remove the inflamed appendix. The surgeon found a previously undiagnosed ovarian cyst and decided to remove it. The removal was a simple and safe procedure that would not have increased the duration of the operation. The head nurse refused because the patient had not given consent. What should the surgeon do? Provide your moral reasoning.

Case scenario 3: Consent and protection of the patient

An 80-year-old diabetic man, whose son had died last year from a transfusion of mismatched blood, was admitted to the same hospital for observation after falling at home. He insisted that no procedure be carried out without written

approval by his physician son, whom he wanted to sit by his bedside all the time. Nurses were inconvenienced by having to get written permission for routine monitoring of vital signs and insulin injections. The nurses refused to comply with his wishes and he refused to cooperate, leading to a standoff. What should the doctor in charge do? Provide your moral reasoning.

Case scenario 4: Consent and the protection of the physician

A young neurosurgeon planned to operate on a patient with lumbar spinal injury that had a 5 - 10% chance of success. He felt uncertain about taking informed consent. If he informed the patient that the operation could go wrong and result in paraplegia, there was a 90% chance the patient would refuse the operation. If the operation was not carried out, there was a 95% chance of further deterioration, leading to paraplegia after a few months. What should the neurosurgeon do? Provide your moral reasoning.

Case scenario 5: The process of informed consent

A complex brain operation had a 3-page risk disclosure sheet. The surgeon determined that his poorly educated patient could not understand the information even with the best of translations, and might even refuse the life-saving operation. The operation was necessary to release a hematoma and a fractured bone fragment putting pressure on the cerebrum, which would soon lead to loss of consciousness due to increased intracranial pressure. He gave the patient simple information that the operation would help him recover from the effects of trauma and that it had some risks, which he did not mention. What should the surgeon do? Provide your moral reasoning.

Case scenario 6: Capacity/competence to consent

A university professor admitted for stroke refused life-saving treatment even after a thorough explanation by his son, who was a neurosurgeon. While in the hospital, he seemed to forget essential information about his illness, forgot his age and his wife's name, and was confused about the day of the week. However, he was in continuous telephone contact with his laboratory at the university, guiding the young researchers. What should the doctor do? Provide your moral reasoning.

Case scenario 7: Proxy consent/substitute decision maker

A 30-year-old victim of a road traffic accident was in a deep coma, with some signs of brain stem function, and was put on life support in the ICU. He had told his wife before the accident that he would like to be left to die in dignity rather than live with the aid of machines. He had also authorized his wife, in writing, to make decisions about his treatment if he fell unconscious. Led by his father, his family refused this and insisted that life support continue until recovery. What should the doctor do? Provide your moral reasoning.

Case scenario 8: Prospective consent/advance directives

A 40-year-old victim of multiple sclerosis, aware of the final stages of his illness, signed an advance directive authorizing doctors not to initiate life support if he stopped breathing on his own. He developed acute pneumonia a short while after writing the directive, and experienced severe respiratory distress. The doctors were not sure what to do. Members of the family were divided in their views. What should the doctors do? Provide your moral reasoning.

Case scenario 9: Consent for children

A 14-year-old boy with bone cancer confined to the tibia refused amputation that would prevent spread of the cancer to other parts of the body. He understood the adverse consequences of his decision. His father and mother opposed his decision and authorized the surgeons to carry out the amputation. What should the doctor do? Provide your moral reasoning.

Case scenario 10: Consent for the mentally impaired

A 14-year-old mentally impaired girl used to wander from her home, and her parents feared that she might be raped and become pregnant. They took her to the hospital and asked the doctors to sterilize her. The doctors talked to her and she opposed the operation vehemently. What should the doctor do? Provide your moral reasoning.

Case scenario 11: Consent for the unconscious

A 60-year-old diabetic was admitted to the hospital in a coma due to diabetic keto-acidosis and a gangrenous foot. The doctors decided to amputate the foot as soon as the general condition had stabilized enough to withstand anesthesia. The patient's sons and daughters refused the operation, even after explanations that the gangrene would spread and result in fatal septicemia. They reasoned that it was better for him to die and be buried with all parts of his body than to live with an amputated limb. What should the doctor do? Provide your moral reasoning.

7.3 INTRODUCTION: TERMINOLOGY AND CONCEPTS

Autonomy is the innate human right of a patient to control access to his/her body and what is done to him or her. It involves the right to choose who treats him/her, where he/she is treated, and what treatment is used. It also involves authorization of the treatment. It is not enough for the patient to consent to a course of treatment; he must actually authorize the physician to go ahead with the chosen treatment.

Consent is a decision of a competent patient to accept the medical procedures proposed. The patient has the right to refuse the proposed

treatment. Both consent and refusal must be informed, i.e., based on full disclosure of the details of the proposed treatment, including its benefits and risks. Children with some degree of competence can **assent** to treatment, which signifies their agreement with what their parents, their legal decision makers, have decided. Parents may assent to the decision of a fully competent post-pubertal child who is below the age of majority, currently 18 years in Saudi Arabia.

The age of majority is the age above which a patient is considered to be an individual and responsible for all medical decisions if fully competent. According to existing regulations in Saudi Arabia, this age is 18 years for both males and females. The age of 7 is considered the age of discrimination, *sinn al tamyiz* (سن التمييز), after which a child can make some decisions. At puberty, a person becomes *mukallaf* (مكلف), fully responsible for fulfilling all religious obligations.

Competence, *ahliyyat* (أهلية), is the intellectual capacity to understand, analyze, and judge information. The main component of competence is intellectual competence, but other factors-such as emotional and psychological factors-make their contribution. Children and adults may reach this ability at different ages and some never become fully competent intellectually. A consensus was therefore reached about the average age at which most people should be considered competent. At the beginning, attaining puberty was used as a mark of competence. Later, it was realized that many post-pubertal children were not competent decision makers and the age of 18 was adopted. Another term used for competence is capacity.

Paternalism is a negative attitude that was common among physicians and has now almost disappeared. The paternalistic physician assumes that he knows what is best for the patient and should make treatment decisions without reference to the patient. Paternalism is a violation of the patient's autonomy rights.

Medical decision making is a joint process involving the physicians and the patient regarding treatment choice. It should be a rational process based on a consideration of the facts, but in the end, the final word is with the patient. The patient's decision will stand even if it is considered irrational by the physicians.

Advance treatment directives are instructions on treatment or its withdrawal made by a competent patient, to be applied when competence is lost. Such directives are best made in writing and with witnesses.

Substitute or proxy decision makers are the persons who are authorized to make decisions on behalf of a patient who does not have the intellectual competence to decide for him or herself.

Best interest standard is the criterion used to judge decisions by physicians and decisions of substitute decision makers. These decisions must be in the best interests of the patient.

7.4 WHY IS IT IMPORTANT TO KNOW ABOUT AUTONOMY AND CONSENT?

Medical practice has undergone much change from earlier times, when physicians were paternalistic and made benevolent decisions for the patient. Today, we recognize and respect the autonomy of the patient and his or her right to decide on medical interventions. Patients are now aware of their autonomy rights, which are protected by law. It is therefore very important for medical practitioners to know the process, scope, and uses of consent. Failure to respect patient autonomy rights is a major ethical violation and can lead to prosecution of the physician under malpractice laws. The good intentions of the doctor will not protect him from this prosecution, but may be considered in awarding punishment.

7.5 ETHICAL, LEGAL, AND POLICY ISSUES

Autonomy as the basis of informed consent

People have the basic human right to control their lives and their bodies. This includes decisions about what they do or what others can do to them. The right of autonomy has restrictions clearly demarcated by the law. The first legal restriction on the right of autonomy is based on age. Children below the age of majority, normally 15 or 18 years, do not have full autonomy rights, and many decisions that affect them are made by their parents. The second restriction is based on a person's mental state and ability to make decisions. The mentally incapacitated and those who are unconscious are not able to make their own decisions because of lack of intellectual capacity. The right of autonomy has to be respected and cannot be denied by any other human being.

Scope and limitations of consent

A patient has a right to make autonomous decisions regarding any medical procedures on his or her body. This includes decisions to allow health professionals to take a history, to carry out physical examinations, and to undertake any curative or preventive medical procedures. Any permission to undertake medical procedures has to specify the part of the body to be treated and the type of procedure to be carried out within a specified time

period. The medical professional can go beyond these limits only by getting new permission from the patient. In addition, it is part of the patient's autonomous right to decide which profession can treat him. The patient has a right to reject any professional procedure without having to give a reason. The patient also retains the right to withdraw the permission at any time without being required to explain why. Consent has a limited time period. Consent given in one admission will have to be repeated on re-admission. If a long time elapses, consent needs to be repeated because circumstances might have changed.

Consent and protection of the patient

The requirement that the patient has an autonomous right to consent or reject medical interventions ensures that the patient retains the ultimate right to protect his interests. Of all persons involved in a medical setting, the patient is the only one who has his best interests at heart and cannot deliberately or knowingly hurt himself. Others may be driven in their decisions by personal or professional considerations that are not in the best interests of the patient.

Consent and the protection of the physician

The requirement that no medical procedure be carried out without prior consent by the patient protects the medical practitioner in case of error or side effects. This is because the medical intervention was legal, and carried out after consent and authorization by the patient. The legal protection for the medical practitioner is, however, limited. Consent does not protect a physician from prosecution in the event of professional errors and malpractice. In case of patient injury, the practitioner will be under less legal liability if proper consent was given, but cannot be totally free of blame. Consent prior to medical intervention also protects the hospital in which the practitioner works from certain forms of litigation, but does not remove all liability.

The process of informed consent

Informed consent is consent following full disclosure of all medical facts related to the disease and the intervention, such that the patient makes a decision based on a full understanding of all the facts. The disclosure should include explanation of the diagnosis as much as possible to a lay patient, explanation of the intended procedure in non-technical terms, disclosure of all known side effects, and benefits of the procedure. To enable the patient to make an informed decision, alternative procedures and treatments, and their benefits and side effects, should also be disclosed. The financial cost of the procedure should also be disclosed, but preferably at a later stage because it could unduly influence a patient's decision.

Capacity/competence to consent

For informed consent to be legally valid, the patient making the decision must be judged to be legally competent; in other words, to have the capacity for decision making. Competence is judged by intellectual ability to understand, retain, and judge information. Children below the age of majority are considered not competent. A normal adult is judged legally competent unless there is a reason to suspect otherwise. If there is such a suspicion, or if the nature of the disease affects mental ability, specific tests of competence should be carried out. In simple cases, a physician caring for the patient can test for competence by asking simple questions about, for instance, the patient's name and address, orientation in time and place, the patient's ability to understand and retain information, and making judgments. In more complicated cases, a clinical psychologist may be invited to test for competence in a formal way. The testing for competence should be recorded clearly in the patient's chart. The record should preferably include the items used for testing.

Proxy consent and substitute decision maker

A patient who is judged legally incompetent cannot make decisions regarding his or her treatment. A proxy or substitute decision maker must be found. The proxy or substitute is usually a member of the family. If family members are not available, other proxies may be found. The problem that usually confronts practitioners is when several members of the family are present and one of them has to be the decision maker. In some cases, the patient might have designated one of them as decision maker, which makes the process very easy. If the patient did not designate a decision maker but there is a unanimous agreement among family members about who should decide, the matter is again easy to handle; usually the father or the most senior member of the family takes the responsibility. Problems arise when there is disagreement among family members and the physicians do not know who to listen to. If the patient indicates at the time of admission which family member should represent him, then we follow the patient's wishes. If the patient does not nominate anyone, according to Saudi customs the father has the right to decide. In some cases, the father acts as the decision maker even if the patient has designated someone else.

Prospective consent and advance directives

As part of the patient's prospective autonomy, decisions made in advance of loss of competence are respected. The patient may make an advance directive on how he wants to be treated in case of the loss of competence. The directive may be about withdrawing life support in futile circumstances, or about any other medical procedure. An advance directive is a relief to all involved. Members of the family are relieved from the difficult and stressful

duty of making a decision. The physicians also are relieved because they know that they have advance consent for their treatment of the patient. The advance directive could be challenged if the conditions of the patient have changed substantially from when they made the directive.

Consent for children

Parents have the overall right to decide for children below the age of majority, which is 18 years in Saudi Arabia. If both parents refuse, the physician can go ahead and give emergency life-saving treatment with no consent in the interests of saving life. If the two parents disagree, the physician can go ahead and give life-saving treatment based on the consent of one parent. Refusal by one or both parents of non-urgent treatment that the physician considers necessary for saving life can be resolved by reference to the law courts. Children below the age of discrimination, *sinn al tamyiz* (سن التمييز), which is seven years, have no say at all in decisions regarding treatment; everything is in the hands of the parents. Children above the age of seven, but below puberty, have increasing intellectual capacity to understand and participate in decision making. It is prudent to listen to them and consider their views in the full knowledge that it is the parents who will consent; the children can only assent. Children above puberty are virtually adults and unless there is evidence for their incompetence, they should be allowed to make decisions about their treatment. However, since the age of majority is 18 years, parents should assent to these decisions before they are carried out.

Consent for the mentally impaired

Patients with mental illness have varying degrees of capacity. Some have total impairment of intellectual capacity, and are not able to understand, retain, analyze, and make judgments about their disease condition. Some have selective impairment and are able to make some decisions. We therefore have a spectrum from total impairment to partial or selective impairment of capacity. In cases of total loss of mental capacity—and where a risk exists for the patient and the public—the patients are admitted, restrained, and treated involuntarily according to the stipulations of mental health legislation that gives the physicians the right to make decisions within the safeguards set by the law, which include regular reviews by courts of law. The measures taken by physicians should be in the interests of protecting the welfare of the patient and the welfare of the public. Some patients with mental health problems enter treatment voluntarily or are brought by their families. In the latter case, those with selective or partial impairment should be allowed to make some relevant decisions, while members of the family can make decisions for those with complete loss of intellectual capacity.

Consent for the unconscious

Patients with complete loss of consciousness are considered incompetent, and decisions about treatment are made by their next of kin. If the next of kin is not available, the physician will undertake urgent treatment that is considered in the best interest of the patient. If the patient left an advance directive, it should be respected unless it is irrelevant to the actual clinical conditions that the patient had not anticipated at the time of making the directive. Any decisions made by a proxy decision maker or the physician, have to be confirmed or even reversed when the patient recovers consciousness. If the treatment considered is not urgently needed to save life, the matter should be referred to a court of law for a decision if the procedure is a major one, like amputation or transplantation. If the procedure is minor, a designated official in the hospital can be the decision maker.

7.6 HOW TO IMPROVE YOUR PRACTICE

- Learn to avoid paternalism and consider the patient a full partner in medical decision making
- Follow the procedures of informed consent rigorously
- Seek a second opinion when not sure

7.7 CASE DISCUSSION

Case 1: Autonomy as the basis of informed consent

The doctor should respect the patient's autonomy. He should first ask the patient whether he personally wanted to receive information about his condition in order to make decisions on his treatment, or whether he would prefer that the information be disclosed to his family, and the family authorized to make decisions on his behalf. If he insists on making decisions for himself, he must receive full disclosure and exercise his autonomous right to informed consent. If he chooses to leave everything to the family, the doctor can deal with the family accordingly.

Case 2: Scope and limitations of consent

The doctor should not go ahead with the removal of the cyst because that would be outside the scope of the informed consent obtained. In this case, there is no emergency life-saving need to operate without consent.

Case 3: Consent and protection of the patient

The doctors should respect the patient's autonomy and accommodate his needs as much as possible. If, however, they find that complying with the patient's wishes is not possible without disrupting the work of the ward, they can follow the procedures for refusal of treatment by the patient, which may

later lead to discharge to another institution with the capacity to handle the patient's needs.

Case 4: Consent and the protection of the physician

The patient has a right to full disclosure even if that will result in refusal of treatment. Fear of refusal of necessary treatment is not a justification for violating the patient's autonomy.

Case 5: The process of informed consent

The patient is entitled to full disclosure, but a summary will suffice if it excludes technical details but covers the major benefits, and especially the risks, of the operation in simple language. This is justified because it maintains respect for the right of the patient to know.

Case 6: Capacity and competence to consent

A formal testing of competence by a physician or psychologist is necessary in this case. If the professor is found competent, his refusal of treatment should be upheld.

Case 7: Proxy consent and substitute decision maker

The decision of the wife based on the desires of the patient is respected. However, it is possible for the father to override her based on considerations of the Sharia.

Case 8: Prospective consent and advance directives

The advance directive was related to respiratory failure due to multiple sclerosis and cannot be applied to respiratory failure due to acute pneumonia.

Case 9: Consent for children

A 14-year-old cannot make a decision to refuse treatment, so in this case the parents' decision is the one upheld.

Case 10: Consent for the mentally impaired

The 14-year-old is not competent to decide. In view of the irreversible nature of the operation, advice of a court of law should be sought.

Case 11: Consent for the unconscious

The decision of the family is upheld in this case because they are the valid substitute decision makers.

7.8 CONCLUSION AND SUMMARY

1. Informed consent ensures respect for patient autonomy.
2. The decisions of a competent patient are final regarding his treatment.

3. Children below the age of majority, the mentally ill, and the unconscious are considered incompetent to decide on their treatment.
4. Proxy and substitute decision makers decide for incompetent patients.
5. Prospective autonomy of the patient in the form of an advance directive must be respected.

7.9 REFERENCES AND SUGGESTED READINGS

1. Appelbaum PS. Consent in impaired populations. *Curr Neurol Neurosci Rep* 2010;10(5):367-73.
2. Birchley G. What limits, if any, should be placed on a parent's right to consent and or refuse to consent to medical treatment for their child? *Nurs Philos* 2010;11(4):280-5.
3. Broaddus BM, Chandrasekhar S. Informed consent in obstetric anesthesia. *Anesth Analg* 2011;112(4):912-5.
4. Kaushik JS, Narang M, Agarwal N. Informed consent in pediatric practice. *Indian Pediatr* 2010;47(12):1039-46.
5. Leclercq WK, Keulers BJ, Scheltinga MR, Spaewen PH, van der Wilt GJ. A review of surgical informed consent: past, present, and future. A quest to help patients make better decisions. *World J Surg* 2010;34(7):1406-15.
6. Magauran BG Jr. Risk management for the emergency physician: competency and decision-making capacity, informed consent, and refusal of care against medical advice. *Emerg Med Clin North Am* 2009;27(4):605-14, viii.
7. Neff MJ. Informed consent: what is it? Who can give it? How do we improve it? *Respir Care* 2008;53(10):1337-41.
8. Paterick TJ, Carson GV, Allen MC, Paterick TE. Medical informed consent: general considerations for physicians. *Mayo Clin Proc* 2008;83(3):313-9.
9. Simpson O. Consent and assessment of capacity to decide or refuse treatment. *Br J Nurs* 2011;20(8):510-3.
10. Ursin LO. Personal autonomy. *Med Health Care Philos* 2009;12(1):17-24. Epub 2008 Jun 10.
11. van Staden WC. Acceptance and insight: incapacity to give informed consent. *Curr Opin Psychiatry* 2009;22(6):554-8.

MODULE 8 - PRIVACY AND CONFIDENTIALITY

Ghaiath MA Hussein, MBBS, MHSc (Bioethics)

8.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. Identify the measures that the health care team should guard against to protect the patient's privacy
2. Identify the measures that the health care team should guard against to protect confidentiality of the patient's medical information
3. Identify the conditions in which the confidential medical information may be shared beyond the patient

8.2 CASE (ETHICAL SCENARIO)

Dr. Man is an obstetrician who has recently finished his training in Canada. Upon his return to Saudi Arabia, he preferred to practice in a peripheral region near his home town. In his first week, an 18-year-old prima gravida woman came to his clinic in her full veil (Khimar) above her Abaya accompanied by her mother. The pregnant woman was in her first trimester, and complained of lower abdominal pain and vaginal bleeding. The doctor took a short history from the mother, and then wanted to start his examination. The mother asked him to have her daughter seen by a female doctor, and said that he should wait for the husband before touching her daughter. The doctor was very worried that the condition might be serious and he might not have the time to wait for the husband. The only available female doctor was a resident (R3) under his training. He told the mother that he was the only specialized doctor available. He then asked the pregnant woman to uncover her face and asked her permission to do a "private examination." She was in pain and said something in the local dialect to her mother that he didn't understand well. He asked the mother to call the nurse from the nurses' office, as he was busy stopping the bleeding. The mother left the clinic and came back five minutes later with the nurse. The doctor managed to maintain the vital signs and stop the bleeding.

A few minutes later, the husband arrived and was very upset that his wife had been examined by a male doctor; he started shouting, and threatened the medical director that he would "file a complaint against the hospital." Fortunately, the hospital security stopped him before he gained access to the clinic, where he might have physically harmed the doctor.

8.3 INTRODUCTION

How privacy and confidentiality differ¹

The terms “privacy” and “confidentiality” have been used together in much of the teaching we have received; thus, many may think they are synonymous. In fact, they are not. Theoretically, privacy is about the right or expectation not to be interfered with, to be free from surveillance, or more generally, a moral right to be left alone. On the other hand, confidentiality is about the right of an individual to have personal, identifiable medical information kept out of reach of others. In more practical terms, privacy is concerned with the setting within which the patient’s medical information is taken (i.e., the patient’s body), while confidentiality is concerned with the information collected from/about the patient (i.e., the patient’s information).

Confidentiality includes all identifiable patient information. Whether written, computerized, visual or audio, recorded, or simply held in the memory of health professionals, this information is subject to the duty of confidentiality.

It covers:

- The individual’s past, present, or future physical or mental health or condition;
- Any clinical information about an individual’s diagnosis or treatment;
- Pictures, photographs, videos, audiotapes, or other materials of the patient;
- Who the patient’s doctor is and what clinics patients attend and when;
- Anything else that may be used to identify patients directly or indirectly;
- The past, present, or future payment for the provision of health care to the individual.

Measures to protect patients’ privacy

It is important to understand the different measures needed to protect the privacy of patients. The following represent a summary of the measures that health care providers need to follow in order to protect their patients’ privacy:

- Make sure all physical examinations take place in isolation from other patients, unauthorized family members, and/or staff
- Provide gender-sensitive waiting and examination rooms
- Provide proper clothing for inpatients
- Make sure patients are well covered when transferred from one place to another in the hospital

¹ The author acknowledges that other commentators may disagree with such distinction.

- Make sure your patient's body is exposed ONLY as much as needed by the examination or investigation
- Patients should have separate lifts and be given priority
- Make sure there is another person (nurse) of the same gender as the patient present throughout any examination
- Always take permission from the patient before starting any examination
- Ensure privacy when taking information from patients
- Avoid keeping patients for periods more than required by the procedure
- It is prohibited to examine the patient in the corridors or waiting areas
- During an examination, no unrelated non-hospital person should be allowed to be present
- Give patients enough time to expose the part with pain
- Only relevant personnel are allowed to enter the examination room at any time during an examination

Measures to protect the confidentiality of your patients' information

You need to be clear about what constitutes your patients' confidential information. The Proficiency (Medical) Secret includes any information that the doctor (or treatment team) knows about the patient (alive or dead), directly or indirectly by the privilege of their professional status, the disclosure of which a patient may deem undesirable or harmful to his/her health, reputation, financial, social, or professional status. It includes any information about the patient's identity, condition, diagnosis, investigations, results, treatment, and/or prognosis (whether chances of cure, disability, or death).

The following are some of the main measures that you (with the help of your institution) need to follow when dealing with patients' information:

Email and fax	<ul style="list-style-type: none">• Whenever possible, clinical details should be separated from demographic data;• All data transmitted by email should be encrypted.
Electronic records	<ul style="list-style-type: none">• Always log out of any computer system or application when work is finished;• Do not leave a terminal unattended and logged in;• Do not share Smartcards or passwords with others;• Change passwords at regular intervals to prevent others using them;• Always clear the screen of a previous patient's information before seeing another.

Manual records	<ul style="list-style-type: none"> • Hold in secure storage; • Tracked if transferred, with a note of their current location within the filing system; • Return to the filing system as soon as possible after use; • Stored closed when not in use so that the contents are not seen by others; • Kept on site unless removal is essential.
All records	<ul style="list-style-type: none"> • Never inappropriately access records; • Shut/lock doors, offices, and filing cabinets; • Query the status of visitors/strangers; • Advise senior personnel if anything suspicious or worrying is noted.
General measures	<ul style="list-style-type: none"> • Limit the accessibility to the medical records; • Do not discuss the patient's medical information with unauthorized family members; • Do not disclose patient's information without his/her consent, or in established exceptions (below); • Do NOT collect information not related to the provision of care; • Set policies that regulate access to medical information and address how any breach to confidentiality is managed; • Limit sharing of information with other staff, unless in cases of consultations and second opinion.

Conditions to disclose identifiable medical information

The Saudi guidelines, which are quite similar to the guidelines of many other Arab and Muslim countries, have set some conditions by which it is permissible to disclose confidential information about your patient, even against his/her will. The following are the main conditions; they will be explored and discussed further in a later section of this module:

1. Approval from the patient or his/her substitute decision maker, within the limit given in the approval
2. If the information is required by judiciary
3. Consultation or second opinion
4. Notification of events of public health interest/threats (birth, death, notifiable diseases, etc.)
5. To prevent individual/personal threats (e.g., crimes, sexually transmitted infections (STIs), etc.)
6. If needed by the doctor to defend him/herself before judges, or a discipline committee
7. "For the doctor to disclose some or the entire secret if she/he deems this necessary to cure the patient" (Saudi Council for Health Specialties 2003), or in a way that is in the patient's best interest.

8.4 WHY IS LEARNING ABOUT PRIVACY AND CONFIDENTIALITY IMPORTANT?

People do not usually like to have their bodies exposed, especially in front of strangers. You need to remember that common sense must be used, as unfortunately some practitioners may get so used to examining patients' bodies that somehow they expect this exposure to be the norm, even for the patients themselves. In fact, it is quite the opposite. Therefore, practitioners should always make sure that their patients' bodies are covered and protected from irrelevant eyes, including other practitioners or patients in the same ward, or those that share the same room.

Confidentiality is the other side of this same coin. A very important basis of health care practice is trust. People usually seek medical advice because of their "trust" in the health care system. They come and talk openly to their doctors. Married men or women may tell their doctors some "secrets" that their spouses do not know. This reflects a huge burden of trust on the system and the practitioners they talk to.

A health care system is based on this trust. Therefore, if it becomes known that patients may not be well protected with respect to their bodily exposure and/or medical information, then they may hesitate to seek medical advice. They may prefer to remedy themselves, seek alternative (pseudo) medical choices, or even ignore their illness. This will lead to more undisclosed illness among the population; illness that the national statistics cannot record. This will, in turn, cause unreliable information to be used for health care planning.



Figure 8.1 Illustration of the significance of confidentiality in the provision of healthcare service

At a very personal level, a health care provider depends largely on his or her reputation as a good doctor. There are many criteria the public use to judge who is a "good doctor." These criteria may vary, but integrity is almost always one of the most important traits that your patients expect from you. You can probably easily remember a patient or relative telling you about a decent, honest, and polite doctor who cared about his/her patients' bodies and kept their secrets.

8.5 ETHICAL, LEGAL, AND POLICY IMPLICATIONS OF PRIVACY AND CONFIDENTIALITY

We outlined earlier the main ethical, legal, and policy implications of privacy and confidentiality. They can now be summarized as follows:

- **Ethically**, there are issues related to the duty of doctors not to harm their patients and to strive to do good for them. Breaching people's privacy and disclosing their medical information irresponsibly is considered to be professional misconduct, which might cause psychological, social, and sometimes physical harm to the patient. This harm may extend to their families, colleagues, and even tribe.
- **Legally**, you are required to keep your patient's body and medical information private and confidential. Sharing them with the press, or with friends (even if those friends are doctors) may make you legally liable for your actions. You may face unnecessary legal troubles if the patient and/or his or her family decide to sue you or your hospital and claim damages. By the way, the health insurance may not cover such claims, as they are not technically medical errors, which most policies usually cover.
- Finally, there are major **policy implications** if the trust between the community and the health care system is breached or broken. This trust is very hard to heal. You can easily see the public's annoyance with the Ministry of Health and the doctors involved when a "medical error" is leaked to the media. Ultimately, if people's trust in health care workers is lost, they will seek other alternatives like "alternative medical choices," which are not commonly based on scientific evidence. Moreover, this area of medicine does not have registers that feed into the national health statistical system. This practice would eventually lead, not only to broken trust, but also to a broken planning cycle; patients who seek medical care outside the official public and private sectors are not included in health care estimates, making it difficult for policy makers.

8.6 RULINGS AND FATWAS ON THE TOPIC

The holy Quran is full of advice for believers to keep the secrets, and to build trust among themselves. For example, Allah Subhanahu WaTa'ala said:

يَا أَيُّهَا الَّذِينَ آمَنُوا اجْتَبِرُوا كَثِيرًا مِّنَ الظُّنُونَ إِنَّ بَعْضَ الظُّنُونَ إِثْمٌ وَلَا تَجْسِسُوا وَلَا يُغْتَبْ بَعْضُكُمْ بَعْضًا أَيُّوبُ أَخْكَمَ
أَن يَأْكُلْ لَحْمَ أَخِيهِ مَيْتًا فَكَرْهَهُمُوهُ وَانفَقُوا اللَّهَ إِنَّ اللَّهَ تَوَابُ رَحِيمٌ (الْحُجَّاجَاتُ الآية 12)

"O you who believe! Avoid much suspicion, indeed some suspicions are sins. And spy not, neither backbite one another. Would one of you like to eat the flesh of his dead brother? You would hate it (so hate backbiting). And fear Allah. Verily, Allah is the One Who forgives and accepts repentance, Most Merciful." (49:12)

More specifically, there is a strong mandate for Muslim men and women to cover their bodies, especially the Awra (عوره), which was defined as follows:

"It also refers to everything that causes shame when exposed, thus, the Awra of an individual is the area of the body which (normally) causes embarrassment if exposed." (Ibn Manzur, Lisan Al-Arab, 9/370). In more strict Fiqhi terms, every Muslim should have his/her Awra covered, unless there is a need for its exposure, or if it is exposed to those permitted to see it.

Doctors, especially male doctors examining female patients or vice versa, are working within this excused "need". This means that the extent and duration of exposure of Awra is limited in terms of what is necessary. Your role as a doctor authorizes you to look at or touch areas of your patient's body, but not to do so beyond the needs of this role. For example, you should not expose the patient's private areas unless this is necessary for the examination, and only for the time needed to have this examination performed.

The general rule is that male doctors should examine male patients. It is only when there are no qualified female doctors available to examine a female patient that a male doctor may be allowed to carry out the examination, but only in the presence of a matron (a *mahram* محرم) male member of the patient's family or a female nurse).

Again, the rule also covers that which the patient asks us to keep secret. However, there are exceptions that are stated in the Quran and Sunnah. For example, Allah Suhanahu wta'ala has said that the witnesses should not refuse to give their witness:

وَلَا يَأْبُ الشُّهْدَاءِ إِذَا مَا دُعُوا (البقرة الآية 282)

"And let not the witnesses refuse when they are called upon," (2:282), and described those who hide the truth (that is crucial to expose the truth needed to settle a fair judgment) as sinful:

... وَلَا تَنْكِحُ شَهَادَةَ اللَّهِ إِنَّمَا لَئِنَ الظَّمِينِ (المائدَةِ الآية 106)

"...and we will not withhold the testimony of Allah. Indeed, we would then be of the sinful." (5:106)

8.7 HOW TO USE PRIVACY AND CONFIDENTIALITY IN YOUR PRACTICE

We have given examples of measures that may help you to approach privacy and confidentiality in your practice (see above, section 8.3). However, to consistently protect your patients' privacy and confidentiality, you need to follow some basic steps before starting to see patients in any hospital, particularly Saudi Arabian hospitals. These steps include

1. Different regions have different cultural structures, norms, and taboos. Learn about them through senior colleagues and by talking to the local people. For example, a simple request like asking a woman about her health condition in front of her husband may be an offensive act that might cause unnecessary problems and distress.
2. Become fully familiar with the health information management system in your institution. Do not assume the records and archiving systems are confidential. Different hospitals have different practices. Some systems are manual and some are electronic.
3. Refer to the relevant policies in the hospital, including the departments (or persons) you may need to talk to if you face a problem related to confidentiality. This may well include talking to the legal department, if present and if needed. You don't want to end up facing a legal case alone without your institution behind you.
4. Renew your medical practice insurance policy in a timely manner. Determine whether or not it protects you from allegations of breach of confidentiality.

8.8 CASE DISCUSSION

The case of Dr. Man is not uncommon. There are not only ethical, but also cultural, religious and legal issues related to the scenario. First, apparently the doctor has good intentions to help the patient as well as protect her from harm. However, this is not usually enough to justify further interventions without clear consent, or at least permission, from the patient or her substitute decision maker. The doctor failed to obtain this permission, probably because he gave priority to saving the patient's life rather than obtaining consent. This may be justifiable in life-threatening conditions where there is no one who is easily and quickly reached to take the decision on behalf of the unconscious patient. The patient was apparently competent; therefore, the doctor could have waited a reasonable time after stabilizing the general condition before pursuing further non-life-saving interventions.

The doctor should not have started any physical examination, especially a "private" one, without the matron or the mother being present. This is legally, religiously, and culturally problematic. Legally, he exposed himself to

allegations of abuse or harassment, as no witness was there in the room. He also misrepresented the information related to the presence of another female doctor, since there was one available who was qualified enough to manage the case, even if under his supervision. Religiously speaking, in Islam this condition would not provide an absolute excuse for a male doctor to stay alone with a female patient unattended, given that exposing the Awra in question is considered a major breach of trust. The excuse of need does not seem to help him here. Finally, what he did was insensitive to the culture and the norms of the community in which he works.

This behavior would not only affect his reputation as an individual doctor, but might also cause rumors to flourish that the hospital forces women to be examined by men. This could affect the element of trust; thus, many husbands may prohibit their wives from going to the hospital or seeking medical advice, even for their antenatal care visits or vaccinations. The public health implications of such attitudes are not easily or quickly remedied, and need to be considered before engaging in any such behaviors.

8.9 CONCLUSION AND SUMMARY

In conclusion, you need to remember that the patients you are treating are your mothers, fathers, and sisters. Treat them just as you would like your mother, sister, or father to be treated. Respect the patients' bodies. Don't make your repeated exposure of people's bodies a habit. This has been, and will always be, an issue of integrity and trust. The guidelines contain reasonable and feasible measures to address this issue. Do not make excuses by saying that the hospital you work in does not have policies for these matters; many—if not most—of the measures are manageable and doable even by individual doctors.

Not abiding by these measures is morally wrong because part of your duties is to first and foremost do good by your patients, and to protect them from harm. In addition, it puts you at risk of being in legal trouble.

1. Privacy is about respecting your patient's body, while confidentiality is about protecting your patient's medical information.
 2. You need to know and practice according to a code that helps you protect your patient's privacy and confidentiality.
 3. Abiding by these measures will help in building society's trust of the health care system and its ethical, religious, and legal obligations.
 4. There are exceptional cases in which, within limits, you can disclose some or all of the confidential medical information.
 5. Be acquainted with the relevant policies and procedures in the health care institution you work in, as well as the cultural considerations.
-

8.10 REFERENCES AND SUGGESTED READINGS

1. Alahmad G, Dierickx K. What do Islamic institutional Fatwas say about medical and research confidentiality and breach of confidentiality? *Dev World Bioeth* 2012;12(2):104-112.
2. Liegeois A, Haekens A, Eneman M. 2006. Sharing information among carers involved in mental health care: ethical advice. *Tijdschr Psychiatr* 2006;48(10):787-95.
3. Saudi Council for Health Specialties 2003. Ethics of the Medical Profession, A manual guide for medical practitioners Riyadh, Saudi Arabia, Saudi Council for Health Specialties.

MODULE 9 - TERMINALLY INCURABLE DISEASES AND END-OF-LIFE DECISIONS

*Omar Hasan Kasule Sr. MBChB (MUK),
MPH (Harvard), DrPH (Harvard)*

9.1 OBJECTIVES OF THE MODULE

1. Define terminal illness, terminal care, palliative care, and medical futility
2. Define capacity for decision making
3. Understand the roles of substitute/proxy decision makers
4. Understand the use of advance directives
5. Appreciate ethico-legal issues relating to Do Not Resuscitate (DNR) orders
6. Understand the definition of euthanasia and related ethical issues
7. Understand conditions of withholding artificial life support
8. Understand conditions of withdrawing artificial life support
9. Understand ethical issues of organ donation, harvesting, and transplantation in terminal illness
10. Appreciate ethico-legal issues relating to post-mortem autopsy

9.2 CASE (ETHICAL SCENARIOS)

Case scenario 1: Palliative vs. curative care

A 90-year-old in ICU with stage 4 widely metastasized cancer and multi-organ failure was told by the doctors that there was nothing they could do to reverse the course of the disease, and that they could only provide symptomatic treatment. He asked to be discharged to die at home. His children objected, saying that he needed complex nursing that they could not provide at home. He was finally admitted to a private hospice that provided palliative care at great expense.

Case scenario 2: Capacity for decision making

A thoracic surgeon wanted to carry out a de-bulking operation to decrease lung cancer mass to enable the patient to breathe easier; he told the patient of the high risk of death from hemorrhage. The 85-year-old patient was drowsy because of medication and was suspected of suffering from dementia. The doctor was not sure whether the patient was capable of understanding the explanations given and making serious decisions about the operation, and the patient had no relatives nearby.

Case scenario 3: Advance directive proxy vs. father

A 30-year-old patient with multiple sclerosis had 5 years of good health, and designated her husband as the decision maker. When she lost consciousness, the doctors needed a decision whether to put her on life support. The husband, who had remarried by then and lived in a separate house, decided against life support because it would prolong her suffering. Her father intervened and decided for life support because that would be in her best interests.

Case scenario 4: Advance directive: anticipated vs. real circumstances

A university professor with previous episodes of transient stroke had written a directive and had it witnessed that if he lost consciousness he would not like to be resuscitated. Years later, he was brought to the hospital unconscious from head injuries sustained in a car accident. The doctors reading his directive, which had been in his shirt pocket, decided not to resuscitate him, but his wife insisted that he be resuscitated.

Case scenario 5: DNR physicians vs. family

Doctors wrote a Do Not Resuscitate (DNR) order for an 80-year-old grandmother with disseminated untreatable ovarian cancer. Her family objected vehemently when told of this decision and sought its reversal. Before the dispute was resolved, the patient collapsed after an episode of acute pneumonia unrelated to her original condition. The nurses followed the DNR order and did not call the resuscitation team.

Case scenario 6: Euthanasia

A 70-year-old man with advanced cancer with severe pain was not responsive to morphine, and asked the doctor to kill him and save him from suffering. The doctor refused, claiming that he could not commit illegal homicide. The doctor also refused to give the patient any advice about suicide. On the patient's insistence, the doctor agreed to stop hydration and nutrition to enable slow death.

Case scenario 7: Withholding futile life support

A car accident victim in severe shock was wheeled into the Emergency Room with unrecordable blood pressure or pulse. ECG showed low amplitude slow waves. The doctor did not declare death, but-against the insistence of family members-refused to institute life support because he reasoned there was no hope. The patient was declared dead one hour later. The family threatened to sue the doctor.

Case scenario 8: Life support with brain stem death

A 90-year-old man with multi-organ failure and clinical signs of brain stem death was on life support. He was occupying the last available bed in the ICU because the doctors were afraid to disclose death to the family, which had many vocal and angry members. However, when 50 survivors from an air crash site were brought in, the doctors decided to withdraw life support from the old man to free up at least one ICU bed.

Case scenario 9: Ventilation for purposes of organ harvesting

An ICU doctor kept a brain-stem-dead patient on artificial life support to maintain the vitality of his organs until the arrival of the transplant team; they intended to harvest the heart and lungs donated by the patient while still conscious in favor of his cousin, who was born with severe congenital abnormalities and would die without the transplantation.

Case scenario 10: Post-mortem family vs. police

A policeman died suddenly during a fight with criminals, who were later arrested. The police authorities wanted to carry out a post-mortem to determine the cause of death in order to charge and punish the criminals with homicide. Some members of the family objected to the post-mortem on the grounds that it was against the Sharia. Other members supported the post-mortem because of insurance compensation purposes.

9.3 INTRODUCTION

Terminology and concepts

Terminal illness, also called *maradh al maut* (مرض الموت), is an illness from which recovery is not expected. Death is not an ON/OFF event. It is a process that has a timeline, and can be quite lengthy. There reaches a z-point in the timeline that is called the point of no return, and the illness is then called terminal because it is expected to soon end in death. Some illnesses can be called terminal way before the z-point because they have a predictable course; a good example is multiple sclerosis. The definition of terminal illness is not always accurate; some patients who were told they were going to die have lived for years, but such anecdotal cases are few in actual practice.

Palliation consists of measures taken to make the remaining life of a terminal patient as comfortable as possible and includes pain relief, support (psychological, social, and spiritual), nutrition, hydration, etc. Palliative care starts when the hope for cure of the disease disappears.

Do Not Resuscitate (DNR) is an advance medical decision not to undertake extreme artificial life support measures like intubation for patients in terminal illness who develop cardiopulmonary arrest. Do Not Treat (DNT) is an advance medical decision to withhold futile therapeutic intervention from a terminally ill patient; however, palliative and symptomatic treatments can continue.

Euthanasia, also called mercy killing, *qatl al rahmah* (قتل الرحمة), consists of measures that lead to the death of a terminal patient to spare him or her from further pain and suffering. If acts of commission deliberately bring about death, it is called active euthanasia. If acts of omission lead to death, it is called passive euthanasia.

Withholding of life support is not instituting futile artificial life support measures in a terminal or critically ill patient.

Withdrawal of life support is terminating futile artificial life support measures in a terminally or critically ill patient, or in some cases in patients who are clinically or brain-dead, but still on life support.

Brain death is cessation of all functions, including blood circulation in the brain. Brain death is diagnosed based on clinical criteria, and laboratory and radiological confirmatory tests. Brain death can be total brain death if it involves the whole brain, or can be brain stem death if it affects the vital centers of the brain stem. By consensus, brain stem death is considered clinical death; this is also a legal definition of death.

Autopsy examination is the dissection of a dead body to determine the cause of death. The dissection could cover the whole body or could be selective. Specimens for further analysis are usually taken during a post-mortem. Post-mortem examination can be carried out for legal forensic purposes to obtain evidence needed for criminal prosecution, or may be carried out for educational purposes, to enable doctors to make better diagnoses in the future.

Organ harvesting is surgically removing organs such as the heart, lungs, and the kidneys for subsequent transplantation into another patient. It can be carried out after death of the patient, but in this case, the organs could have already deteriorated. In most cases, it is carried out in patients who are brain-dead but still have blood circulation to keep the organs alive. Artificial life support for circulation and aeration may be carried out in clinically dead people to keep the organs alive until the arrival of the surgical team that will do the harvesting.

9.4 WHY IS IT IMPORTANT TO KNOW ABOUT END-OF-LIFE ISSUES?

Physicians encounter dying patients daily and need to know the ethico-legal guidelines in dealing with the period before and after death. Physicians need to understand the problems of terminal care from the patient's and family's points of view. Modern technology that prolongs physiological functions beyond "death" has created more moral and practical problems.

9.5 ETHICAL, LEGAL, AND POLICY ISSUES

The continuum of care

Young people in the prime of their life usually enjoy good health. As old age sets in, new problems appear that require geriatric care, a new discipline that caters for the elderly. A healthy person can fall sick and need medical care. A

reversible disease is cured quickly, while a chronic disease cannot be reversed, although its adverse effects can be mitigated. If the disease is not contained, the patient enters a terminal phase that usually has intense technological intervention; however, without a good outcome, death usually ensues. In a prolonged terminal phase, active disease treatment may be determined to be medically futile and patients are transferred to palliative care where they receive nutrition, hydration, and pain control, as well as social and psychological support.

Ethical issues in geriatric care

Geriatric specialists face many problems. The most serious is the mental deterioration that impairs the ability to make informed decisions. If an elderly patient makes no advance statement, a proxy decision maker has to be used. It is best if the patient designates the proxy decision maker at an earlier point in time, when he/she has full mental capacity. If a proxy decision maker has not been designated, a family member can be the decision maker. In the extreme situation in which no relative is found, the health care workers will decide according to what they think is in the best interests of the patient.

Ethical issues in palliative care

Palliative care patients share with geriatric patients the problem of deficient decision making capacity. Ethical issues arise with regard to what interventions can be made. These may be confined to nutrition, hydration, and pain control. They may also include treatment for infections that arise. Pain control is problematic because some analgesics such as morphine may cause respiratory depression. Questions also arise regarding the level of anesthesia. On one extreme, pain may be eliminated altogether, but the patient is left semi-conscious and unable to interact with the family. Less analgesia will leave the patient socially active, but with some level of pain.

Ethical issues in disability care

Patients with disabilities may be discriminated against if they are not provided with special services to enable them to live as normally as possible. Several jurisdictions have enacted special laws to protect the rights and interests of the handicapped. These laws require provision of special services for handicapped patients in hospitals and their homes. Health care workers receive training on sensitivity in dealing with the handicapped and their needs.

Ethical issues in care for the terminally ill

The terminally ill need physical, psychosocial, and spiritual support. Before reaching the stage of medical futility, they should receive treatment for their original disease, taking care to strike the right equilibrium between benefits and side effects. Less aggressive treatment may be advised if the benefits in

terms of overall health outcome are not worth the side effects. Beyond the stage of medical futility, only palliative care and symptomatic treatments are given. The core of palliative care is pain control, but it can include palliative surgery and palliative radiotherapy that are not expected to cure the disease but to control symptoms and improve the quality of life. Symptomatic treatment can be aggressive; for example, pneumonia is treated with first-line antibiotics. Terminal patients continue receiving nutrition, hydration, and general supportive care without discrimination. They also require psychosocial and spiritual support to allay their anxiety. Health care workers can tactfully start discussing legal issues, such as advance directives and organ donation. Terminal patients should also be reminded about their religious duties, such as paying zakat, and their liabilities, such as settling debts. Health care workers may remind them about concluding their wills.

Decisions for the terminally ill

Serious decisions with irreversible consequences might have taken by or on behalf of terminal patients. The first and most important is the decision to withhold or withdraw aggressive treatment that has no *net* benefit that would last for a reasonable time.

The second is the decision to withhold resuscitation in case of cardio-respiratory arrest for patients who cannot get a net benefit from CPR and who would succumb again and have to undergo resuscitation. Such repeated resuscitation is useless and should be withheld by a physician order, indicating that in case of collapse, specified resuscitation measures shall not be taken. This so-called Do Not Resuscitate order is a physician decision, but the family must be informed (without seeking their involvement in the decision).

For patients on artificial life support, a decision must be made about when to withdraw support. If brain stem death can be ascertained, the decision to withdraw life support is easy because brain stem death is accepted as a definition of legal death. If the patient is in an irreversible coma with intact brain stem function, the decision to withdraw life support is more complicated. Withdrawal on the basis of low quality of life and the continuing expense of intensive care are not usually ethically acceptable reasons because of the overriding concern of preserving life, *hifdh al nafs* (حفظ النفس). Life support could be withdrawn in cases that are definitely futile, but this is not an easy decision and is usually a cause of dispute between the family and the health care workers.

The families of terminal patients may be approached for consent to harvest their organs as soon as clinical death is ascertained. A prior decision taken by the terminal patient while still competent will make the work of the organ transplant team easier.

Capacity for decision making

A competent terminal patient must make all decisions regarding his care in fulfilment of the principle of autonomy. The effects of the disease or the treatment may affect the decision-making capacity of the patient to varying degrees. The health care workers will have to make a decision about whether the patient has the intellectual/cognitive capacity to understand and act on the information he/she is given. In most cases, the situation is clear, but in other cases, special tests for competence may have to be carried out by a psychologist. For example, the terminal patient may be competent in some matters, but not in others. A patient with intellectual capacity may have poor memory without the ability to retain a lot of information for decision making.

If the patient is competent, he/she will sign a statement of what should be done after loss of consciousness. It is preferable for the health care workers to sit with the patient and have a lengthy discussion, during which they probe the patient's mind to discover what the he or she believes and desires. The health care workers can then write the necessary instructions, which will have the advantage of being couched in medical terminology.

Substitute/proxy decision makers

When the terminal patient is deemed to lack capacity for decision making, he/she loses the right to autonomy. A substitute decision maker will have to make the necessary decisions. This decision maker might have been designated in advance by the patient.

If no substitute decision maker was previously designated, a member of the family can be the decision maker. A practical problem arises when there are several family members with different points of view. In general, the doctors should not be involved in family disputes; the family should be told to discuss among themselves and come back with one unanimous decision. If family consensus fails, some order of precedence among family members can be used based on their respective strengths as inheritors. For example, the decision of the son takes precedence over the decision of the brother.

The proxy decision maker decides in two ways, based on (a) what he thinks the patient would have decided if competent, and (b) the best interests of the patient.

When members of the family are not available, we proceed in two ways. For emergency decisions, the doctor decides what he thinks is in the best interests of the patient. For non-emergency situations involving surgery, the decision of a court of law may be sought. If a court is not readily available, the hospital senior administrator can make decisions for patients as the representative of governmental authority.

Advance directives

Advance directives are documents written during the period in which the patient is competent, and are part of prospective autonomy. They enable the patient to control what is done to him after losing consciousness, or even after death. The common term "living will" is often used to refer to an advance statement. The advance statement has benefits for the patient, the physicians, and the family. The patient is assured of his prospective autonomy, since his care is carried out according to his/her wishes. The physicians are relieved of the burden of looking for a decision maker, and of making the decision themselves in the absence of a decision maker. The family is relieved from the tension of looking for consensus and making difficult decisions when their state of mind is not at its best because of the patient's illness.

The advance directive can cover any aspect of care that the patient is entitled to decide on during terminal illness and after death. The patient's decisions are respected even if not logical, but they must not contradict the *Sharia*. The advance directive deals with major decisions like DNR.

An advance directive must preferably be written and witnessed. It is best that each institution develops a specific format to make sure that all legal requirements are fulfilled. An oral directive properly witnessed is effective, but should be avoided because doubts could arise about its authenticity.

Withholding artificial life support

The decision to withhold life support is made when the patient is found already brain-dead or when there is clear evidence that such support will be medically futile. However, this is easier said than done because practical realities condition the behavior of attending doctors. Faced with a critically ill patient with anxious family members looking to the doctor to save the patient, the doctor will find it emotionally difficult to withhold life support that in his better judgment is futile. In addition, it is difficult for doctors to take such a serious and irreversible decision because of uncertainty in clinical assessment and lack of enough time to absorb the facts. Many doctors therefore play safe by starting life support; however, this creates the new problem of when to terminate it, another emotion laden decision that families normally resist.

Withdrawing artificial life support

Life support theoretically should be stopped as soon as the patient is brain-dead, or when it is clearly futile. Clinical signs of brain death are reliable in this matter and confirmation can be by brain encephalography and imaging, as well as laboratory tests. To make sure, the testing for brain stem death should be repeated after 6-12 hours for confirmation. Withdrawal of life support is immediately followed by death in many cases, and the doctor is seen as "pulling the plug." Often, families oppose pulling the plug and doctors

sometimes acquiesce and wait for some time to give the family time to come to terms with the reality and finality of death. Withdrawal decisions can be affected by bed availability in the intensive care unit. In cases of bed shortage, there are more aggressive and frequent efforts to test for brain stem death.

Organ donation, harvesting, and transplantation

The decision to donate organs can be made by a competent patient before or during terminal illness. Sale of organs is forbidden. Hospitals train their staff to have the necessary sensitivity to broach this difficult subject with the patients. Most patients are realistic and can face the reality of their impending death and its consequences. They are ready to discuss these consequences, including decisions about donating their organs and tissues for research or for transplantation. A few patients may find the discussion of impending death very frightening, especially if they suspect that the health care workers are more interested in taking their organs than in their treatment. To avoid confusions and misunderstandings, the health care workers treating the terminal patient should not be involved in discussions of organ donation or the actual harvesting. Special teams from specialized organ donation organizations should be contacted to come to the hospital and take over the whole process. Even the surgeons who harvest the organs should not be from the hospital. It is acceptable to continue ventilation for some time after brain death to give time for the organ harvesting team to arrive.

DNR and DNT orders

A Do Not Resuscitate (DNR) order is a decision made by three physicians, including a disease specialist and the patient's primary doctor. The family must be informed of the decision, but they cannot intervene in the decision. The DNR order is made essentially for situations in which resuscitation is futile and not necessarily for terminal disease per se. The order should specify which procedures are included: intubation and ventilation, chest compressions, ionotropic drugs, gas mask, etc. A Do Not Treat (DNT) order relates to treatment of the primary disease condition, such as cancer, when that treatment is considered futile. A DNT order is sometimes misunderstood to mean that resuscitation is not carried out for cases of reversible cardio-respiratory arrest. Resuscitation with a net benefit lasting for a reasonable time should be carried out for terminal patients irrespective of the severity of their disease.

Euthanasia

Euthanasia, literally "good death," is causing the death of a terminal patient to save him/her from further pain and suffering. Active euthanasia is an act of commission in which the physician takes an action that results in the death of the patient. Passive euthanasia is an act of omission in which the physician fails to take action necessary to sustain the life of the terminal patient. Both

active and passive euthanasia are illegal and health care workers who engage in them can be sued for homicide. Euthanasia at the request of the patient and with his informed consent is still considered illegal. The distinguishing feature of euthanasia is the intention behind the action, which is to spare the patient further suffering. An action that is considered euthanasia can be deemed legal if the intention behind it is different. Withholding a treatment because it is futile is acceptable, but withholding it to hasten the death of the patient to avoid further suffering is passive euthanasia.

Post-mortem issues, autopsy, and embalmment

In the course of terminal illness, decisions may have to be made about postmortem actions. A competent patient can make their wishes about postmortem examination known and these will be respected with few exceptions (e.g., in cases of execution of justice). The normal and accepted practice is immediate burial, but if a patient dies in a foreign country where burial processes according to Islamic Sharia cannot be assured, the body can be embalmed for transport to a Muslim country. Family proxy decision makers can make decisions about autopsy and embalmment.

9.6 HOW TO IMPROVE YOUR PRACTICE

Knowledge of the ethical issues discussed above is necessary to be able to make the right decisions in terminal cases.

9.7 CASE DISCUSSION

Case 1: Palliative vs. curative care

Scenario: A 90-year-old in ICU with stage 4 widely metastasized cancer and multi-organ failure was told by the doctors that there was nothing they could do to reverse the course of the disease, and that they could only provide symptomatic treatment. He asked to be discharged to die at home. His children objected, saying that he needed complex nursing that they could not provide at home. He was finally admitted to a private hospice that provided palliative care at great expense.

Hint: importance of palliation.

Case 2: Capacity for decision making

Scenario: The thoracic surgeon wanted to carry out a de-bulking operation to decrease lung cancer mass to enable the patient to breathe easier. He told the patient about the high risk of death from hemorrhage. The 85-year-old patient was drowsy because of medication and was suspected of suffering from dementia. The doctor was not sure whether the patient was capable of understanding the explanations given and making serious decisions about the operation, and he had no relatives nearby.

Hint: impaired decision-making capacity requiring competence testing.

Case 3: Advance directive proxy vs. father

Scenario: A 30-year-old patient with multiple sclerosis had 5 years of good health, and designated her husband as the decision maker. When she lost consciousness, the doctors needed a decision whether to put her on life support. The husband, who had by that time remarried and lived in a separate house, decided against life support because it would prolong her suffering. Her father intervened and decided for life support because that would be in her best interests.

Hint: need for a policy to select the family proxy decision maker.

Case 4: Advance directive: anticipated vs. real circumstances

Scenario: A university professor with previous episodes of transient stroke had written a directive and had it witnessed that if he lost consciousness he would not like to be resuscitated. Years later, he was brought to the hospital unconscious from head injuries sustained in a car accident. The doctors reading his directive decided not to resuscitate him, but his wife insisted that he be resuscitated.

Hint: problem of advance directives being applied to unanticipated situations.

Case 5: DNR physicians vs. family

Scenario: Doctors wrote a Do Not Resuscitate (DNR) order for an 80-year-old grandmother with disseminated untreatable ovarian cancer. Her family objected vehemently when told of this decision and sought its reversal. Before the dispute was resolved, the patient collapsed after an episode of acute pneumonia unrelated to her original condition. The nurses following the DNR order did not call the resuscitation team.

Hint: DNR is a physician, not a family, decision.

Case 6: Euthanasia

Scenario: A 70-year-old man, who had advanced cancer with severe pain not responsive to morphine, asked the doctor to kill him and save him from suffering. The doctor refused, claiming that he could not commit illegal homicide. The doctor also refused to give the patient any advice about suicide. On the patient's insistence, the doctor agreed to stop hydration and nutrition to enable slow death.

Hint: passive euthanasia by withholding food and hydration is illegal.

Case 7: Withholding futile life support

Scenario: A car accident victim in severe shock was wheeled into the emergency room with unrecordable blood pressure or pulse. ECG showed low amplitude slow waves. The doctor did not declare death, but refused to institute life support- against the insistence of family members-because he

reasoned there was no hope. The patient was declared dead 1 hour later. The family threatened to sue the doctor.

Hint: doctor judgment vs. family emotions.

Case 8: Life support with brain stem death

Scenario: A 90-year-old with multi-organ failure and clinical signs of brain stem death was on life support. He was occupying the last available bed in the ICU because the doctors were afraid to disclose death to the family, which had many vocal and angry members. However, when 50 survivors from an air crash site were brought in, the doctors decided to withdraw life support from the old man to free up at least one ICU bed.

Hint: Unnecessary life support at family's insistence.

Case 9: Ventilation for purposes of organ harvesting

Scenario: An ICU doctor kept a brain-stem-dead patient on artificial life support to maintain the vitality of his organs until the arrival of the transplant team; they intended to harvest the heart and lungs donated by the patient while still conscious in favor of his cousin, who was born with severe congenital abnormalities and would die without the transplantation.

Hint: Delay of death determination for other interests.

Case 10: Post-mortem family vs. police

Scenario: A policeman died suddenly during a fight with criminals, who were later arrested. The police authorities wanted to carry out a post-mortem to determine the cause of death in order to charge and punish the criminals with homicide. Some members of the family objected to the post-mortem on the grounds that it was against the *Sharia*. Other members supported the post-mortem because of insurance compensation purposes.

Hint: balance of benefits and harms of post-mortem exam.

9.8 CONCLUSION AND SUMMARY

Most ethical issues in terminal care have no clear solutions; the right solution depends on the circumstances.

1. Terminal patients are entitled to palliative care.
2. They can make decisions about their care if competent, or by advance directives made before losing their competence.
3. In cases of incompetence, decisions are made by proxies.
4. Futile resuscitation and artificial life support should be withheld, and if started, should be stopped.
5. Organ harvesting with proper consent can be carried out in patients with brain stem death.

9.9 REFERENCES AND SUGGESTED READINGS

Medical futility palliative and terminal care

1. Abdulhameed HE, Hammami MM, Mohamed EA. Disclosure of terminal illness. *J Med Ethics.* 2011;37(8):472-5.
 2. Agrimson LB, Taft LB. Spiritual crisis: a concept analysis. *J Adv Nurs.* 2009;65(2):454-61.
 3. Amoah CF. The central importance of spirituality in palliative care. *Int J Palliat Nurs.* 2011;17(7):353-8.
 4. Candy B, Jones L, Drake R, Leurent B, King M. Interventions for supporting informal caregivers of patients in the terminal phase of a disease. *Cochrane Database Syst Rev.* 2011;15(6):CD007617.
 5. Clayton JM, Hancock K, Parker S, Butow PN, Walder S, Carrick S, Currow D, Ghersi D, Glare P, Hagerty R, Olver IN, Tattersall MH. Sustaining hope when communicating with terminally ill patients and their families: a systematic review. *Psychooncology.* 2008;17(7):641-59.
 6. Cobb M, Dowrick C, Lloyd-Williams M. What can we learn about the spiritual needs of palliativecare patients from the research literature? *J Pain Symptom Manage.* 2012;43(6):1105-19.
 7. Correia FR, De Carlo MM. Evaluation of quality of life in a palliativecare context: an integrative literature review. [Article in English, Portuguese, Spanish] *Rev Lat Am Enfermagem.* 2012;20(2):401-10.
 8. Dunn GP. Surgical palliative care: recent trends and developments. *Anesthesiol Clin.* 2012;30(1):13-28.
 9. El Nawawi NM, Balboni MJ, Balboni TA. Palliativecare and spiritual care: the crucial role of spiritual care in the care of patients with advanced illness. *Curr Opin Support Palliat Care.* 2012;6(2):269-74.
 10. Gadsby R, Barker P, Sinclair A. People living with diabetes resident in nursing homes--assessing levels of disability and nursing needs. *Diabet Med.* 2011;28(7):778-80.
 11. García-Pérez L, Linertová R, Martín-Olivera R, Serrano-Aguilar P, Benítez-Rosario MA. A systematic review of specialised palliative care for terminal patients: which model is better. *Palliat Med.* 2009;23(1):17-22.
 12. Glare P, Miller J, Nikolova T, Tickoo R. Treating nausea and vomiting in palliativecare: a review. *Clin Interv Aging.* 2011;6:243-59.
 13. Gómez-Batiste X, Martínez-Muñoz M, Blay C, Espinosa J, Contel JC, Ledesma A. Identifying needs and improving palliativecare of chronically ill patients: a community-oriented, population-based, public-health approach. *Curr Opin Support Palliat Care.* 2012;6(3):371-8.
 14. Kreuter M, Herth FJ. Supportive and palliative care of advanced nonmalignant lung disease. *Respiration.* 2011;82(4):307-16.
-

15. Litrivis E, Smith CB. Palliative care: a primer. Mt Sinai J Med 2011;78(4):627-31.
16. Long CO. Cultural and spiritual considerations in palliative care. J Pediatr Hematol Oncol 2011;33(Suppl 2):S96-101.
17. Maltoni M, Scarpi E, Rosati M, Derni S, Fabbri L, Martini F, Amadori D, Nanni O. Palliative sedation in end-of-life care and survival: a systematic review. J Clin Oncol 2012;30(12):1378-83.
18. Miner TJ. Communication as a core skill of palliative surgical care. Anesthesiol Clin 2012;30(1):47-58.
19. Schneiderman LJ, Jecker NS, Jonsen AR. Medical futility: its meaning and ethical implications. Ann Intern Med 1990;112(12):949-54.
20. Simoens S, Kuttin B, Keirse E, Berghe PV, Beguin C, Desmedt M, Deveugele M, Léonard C, Paulus D, Menten J. The costs of treating terminalpatients. J Pain Symptom Manage 2010;40(3):436-48.
21. Smith TJ, Coyne PJ, Cassel JB. Practical guidelines for developing new palliativecare services: resource management. Ann Oncol 2012;Suppl 3:70-5.
22. Toevs CC. Palliative medicine in the surgical intensive care unit and trauma. Anesthesiol Clin 2012;30(1):29-35.
23. von Gunten CF. Evolution and effectiveness of palliative care. Am J Geriatr Psychiatry 2012;20(4):291-7.
24. Wilkinson DJ, Savulescu J. Medical futility: Knowing when to stop: futility. Curr Opin Anaesthesiol 2011;24(2):160-5.

Substitute/proxy decision makers

1. Adelman EE, Zahuranec DB. Surrogate decision making in neurocritical care. CONTINUUM: Lifelong Learning in Neurology 2012; 18(3 Critical Care Neurology):655.
 2. Arnold RM, Kellum J. Moral justifications for surrogate decision making in the intensive care unit: implications and limitations. Crit Care Med 2003;31(5 Suppl):S347-53.
 3. Black PG, Derse AR, Derrington S, Lantos JD. Can a patient designate his doctor as his proxy decision maker? Pediatrics 2013;131(5):986-90.
 4. High DM. Surrogate decision making. Who will make decisions for me when I can't? Clin Geriatr Med 1994;10(3):445-62.
 5. Lautrette A, Peigne V, Watts J, Souweine B, Azoulay E. Surrogate decision makers for incompetent ICU patients: a European perspective. Current Opinion in Critical Care 2008;14(6):714-719.
 6. McCormick AJ. Self-determination, the right to die, and culture: a literature review. Soc Work 2011;56(2):119-28.
-

7. Shalowitz DI, Garrett-Mayer E, Wendler D. The accuracy of surrogate decision makers: a systematic review. *Arch Intern Med* 2006;13;166(5):493-7.

Advance directives

1. Bomba PA, Kemp M, Black JS. POLST: An improvement over traditional advance directives. *Cleve Clin J Med* 2012;79(7):457-64
2. Bravo G, Dubois MF, Wagneur B. Assessing the effectiveness of interventions to promote advance directives: a systematic review and multi-level analysis. *Soc Sci Med* 2008;67(7):1122-32.
3. Campbell LA, Kisely SR. Advance treatment directives for people with severe mental illness. *Cochrane Database Syst Rev* 2009;21(1):CD005963.
4. Evans N, Bausewein C, Meñaca A, Andrew EV, Higginson IJ, Harding R, Pool R, Gysels M; project PRISMA. A critical review of advance directives. *Patient Educ Couns* 2012;87(3):277-88.
5. Messinger-Rapport BJ, Baum EE, Smith ML. Advance care planning: Beyond the livingwill. *Cleve Clin J Med* 2009;76(5):276-85.
6. Olick RS. Defining features of advance directives in law and clinical practice. *Chest* 2012;141(1):232-8.
7. Zager BS, Yancy M. A call to improve practice concerning cultural sensitivity in a review of the literature. *Worldviews Evid Based Nurs* 2011;8(4):202-11.

Do Not Resuscitate (DNR) orders

1. Cherniack EP. Increasing use of DNR orders in the elderly worldwide: whose choice is it? *J Med Ethics*. 2002;28(5):303-7.
2. Costante CC. Managing DNR requests in the school setting. *J Sch Nurs* 1998;14(4):49-55.
3. Koehler S, Ramadan R, Salter M. Do not resuscitate: analysis of the DNR act. *J Okla State Med Assoc* 1999;92(7):316-9.
4. Layon AJ, Dirk L. Resuscitation and DNR: ethical aspects for anaesthetists. *Can J Anaesth* 1995;42(2):134-40.
5. Lederberg MS. Doctors in limbo: the United States 'DNR' debate. *Psychooncology* 1997;6(4):321-8.
6. Santonocito C, Ristagno G, Gullo A, Weil MH. Do-not-resuscitate order: a view throughout the world. *J Crit Care* 2013;28(1):14-21.
7. Tungpalan L, Tan SY. DNR orders in the OR. *Hawaii Med J* 2001;60(3):64-7.

Euthanasia

1. Aladangady N, de Rooy L. Withholding or withdrawal of life sustaining treatment for newborn infants. *Early Hum Dev* 2012;88(2):65-9.

2. Gielen J, van den Branden S, Broeckaert B. Religion and nurses' attitudes to euthanasia. *Nurs Ethics.* 2009;16(3):303-18.
3. Kon AA. Neonatal euthanasia. *Semin Perinatol.* 2009;Dec;33(6):377-83.
4. Neuhaus SJ. Battlefield euthanasia. *Med J Aust* 2011;194(6):307-9.
5. Schwartz KD, Lutfiyya ZM. "In pain waiting to die": everyday understandings of suffering. *Palliat Support Care* 2012;10(1):27-36.
6. Schwarz JK. Stopping eating and drinking. *Am J Nurs* 2009;109(9):52-61.
7. Wellesley H, Jenkins IA. Withholding and withdrawing life-sustaining treatment in children. *Paediatr Anaesth* 2009;19(10):972-8.

Withdrawing artificial life support

1. Goggin M. Parents perceptions of withdrawal of lifesupport treatment to newborn infants. *Early Hum Dev* 2012;88(2):79-82.
2. Mueller PS. The Terri Schiavo saga: ethical and legal aspects and implications for clinicians. *Pol Arch Med Wewn* 2009;119(9):574-81
3. Varelas PN, Abdelhak T, Hacein-Bey L. Withdrawal of life-sustaining therapies and brain death in the intensive care unit. *Semin Neurol* 2008;28(5):726-35.

Organ donation, harvesting, and transplantation

1. Berry PA, Thomson SJ, Rahman TM, Ala A. Review article: towards a considered and ethical approach to organ support in critically-ill patients with cirrhosis. *Aliment Pharmacol Ther* 2013;37(2):174-82.
2. Brierley J, Larcher V. Organ donation from children: time for legal, ethical and cultural change. *Acta Paediatr* 2011;100(9):1175-9.
3. Farsides B. Respecting wishes and avoiding conflict: understanding the ethical basis for organ donation and retrieval. *Br J Anaesth* 2012;108(Suppl 1):i73-9.
4. Freeman RB, Bernat JL. Ethical issues in organ transplantation. *Prog Cardiovasc Dis* 2012;55(3):282-9.
5. Lavee J, Brock DW. Prioritizing registered donors in organ allocation: an ethical appraisal of the Israeli organ transplant law. *Curr Opin Crit Care* 2012;18(6):707-11.
6. Petroni C. Ethical models in bioethics: theory and application in organ allocation policies. *Minerva Med* 2010;101(6):445-56.
7. Rady MY, Verheijde JL, McGregor JL. Scientific, legal, and ethical challenges of end-of-life organ procurement in emergency medicine. *Resuscitation* 2010;81(9):1069-78.

Autopsy and post-mortem examination

1. Henry J, Nicholas N. Dead in the water--are we killing the hospital autopsy with poor consent practices? *J R Soc Med* 2012;105(7):288-95.

2. Maeda H, Ishikawa T, Michiue T. Forensic biochemistry for functional investigation of death: concept and practical application. *Leg Med (Tokyo)* 2011;13(2):55-67.
3. Xiao J, Krueger GR, Buja LM, Covinsky M. The impact of declining clinical autopsy: need for revised healthcare policy. *Am J Med Sci* 2009;337(1):41-6.

MODULE 10 - HEALTH PRACTITIONER RELATIONSHIPS WITH PHARMACEUTICAL INDUSTRY: PRACTICE AND CONFLICT OF INTEREST

*Abdulaziz Fahad Al Kaabba, MBBS, JMHPE,
MHS_c, DCH, ABFM*

10.1 OBJECTIVES OF THE MODULE

By the end of this module, the health practitioner will be able to:

1. Explain the importance of a conflict of interest in the field of medicine.
2. Understand and explain some regulations and policies in the community related to these issues.
3. Explain the meaning of transparency in the relation between a health practitioner and pharmaceutical and medical equipment companies.
4. State some important ethical rules in this area.

10.2 INTRODUCTION

A conflict of interest has been described as “a set of conditions in which professional judgment concerning a primary interest tends to be unduly influenced by a secondary interest” (Thompson, 1993). According to the Institute of Medicine (IOM), conflict of interest policies should “protect the integrity of professional judgment” and “preserve public trust” instead of leaving physicians and institutions “scrambling ‘to remediate problems with bias and mistrust after they occur.’” (Steinbrook, 2012).

In the past few decades, the relationship between physicians and the pharmaceutical industry has become one of the most controversial issues in medicine. Many studies show that most physicians report some type of relationship with the pharmaceutical industry. Most of these relationships involve receiving food in the workplace, receiving drug samples, reimbursement for costs associated with professional meetings or continuing medical education, and receiving payments for consulting, giving lectures, or enrolling patients in trials. The provision of a free lunch and drug samples have been reported as the most frequent promotional activities to be practiced by pharmaceutical representatives (Sade, 2007).

In fact, the number of meetings with pharmaceutical representatives varies between physicians according to their specialties and job position. It was found that family practitioners met more frequently with industry representatives than did physicians in other specialties. In addition, physicians in solo, two person, or group practices met more frequently with industry representatives than did physicians practicing in hospitals and clinics. Furthermore, it was found that cardiologists were more than twice as likely as family practitioners to receive payments (Mohapatra, 2008).

In general, physicians (residents and faculty alike) meet with pharmaceutical representatives up to four times a month. As a result of these interactions, residents are often provided with drug-sponsored meals and samples, whereas faculty is given more honoraria, conference travel, and research funding (Wazana, 2000).

Many physicians, however, believe that representatives provide accurate information about their products; but at the same time, they also think that representatives prioritize sales over the general welfare of the patients. They do not believe that gifts can influence their behavior, yet also agree that without such incentives, there would not be as many meetings with pharmaceutical representatives (Coleman et al., 2006).

For instance, a study conducted on faculty and trainee physicians from all clinical departments showed that more than 65% found educational materials and sponsored lunches appropriate, whereas fewer than 25% considered vacations or large gifts appropriate (Korenstein et al., 2010). In addition, residents hold generally positive attitudes toward gifts from industry, believing they are not influenced by them; however, they also report behaviors that are often inconsistent with these attitudes (Steinman et al., 2001).

Other studies show that 85% of medical students believe it is not acceptable for a politician to accept a gift, but only 46% think that it is inappropriate for themselves to accept a comparable gift from a pharmaceutical company (Wazana, 2000).

Unfortunately, sales representatives present only selective-usually positive-information about their products. Therefore, physicians who choose to continue to see representatives must critically compare the information they get from them with that contained in scientific publications (Lexchin, 1997).

Furthermore, most physicians do not realize that pharmaceutical representatives receive lists of the prescriptions written by every doctor visited, which they then use to perfect their sales pitches (Iserson et al., 2007).

Thus, it appears that most physicians suffer from a lack of awareness regarding the dynamics of their relationship with pharmaceutical representatives. However, they do not purposely conspire with pharmaceutical companies to gain access to material benefits in exchange for customers (Iserson et al., 2007). On the other hand, compared to the physicians treating them, patients themselves feel that pharmaceutical gifts do have influence, and are less likely to see them as appropriate. In fact, physicians may want to consider their patients' opinions before deciding whether to accept particular gifts (Gibbons et al., 1998).

Despite physicians' claims that they are not influenced by pharmaceutical promotions and activities, many studies show that receiving drug samples and using information provided by pharmaceutical representatives appear to affect

physicians' prescribing and professional behavior (Adair & Holmgren, 2005; Chew et al., 2000; Chren & Landefeld, 1994; Caudill et al., 1996).

Although physicians most often report using drug samples to avoid cost to the patient, the availability of drug samples does lead physicians to dispense and subsequently prescribe drugs that differ from their preferred drug choice.^[9]

In addition, physicians' requests to add certain drugs to hospital formularies tend to be based strongly and specifically on their interactions with the companies manufacturing the drugs (Chren & Landefeld, 1994).

Another study claims that the frequency of use of information provided by pharmaceutical representatives, and group practice, non-academic, and non-hospital settings may be associated with increased primary care physician prescribing costs (Caudill et al., 1996).

In recent years, there has been a dramatic increase in the interaction between doctors and the pharmaceutical industry, which is likely to threaten fundamental professional responsibility and undermine public trust. The influence of the pharmaceutical industry on physicians, medical education, and patients' treatment is much greater than we realize (Mohapatra, 2008). However, broader dissemination of guidelines may be one means of changing physician behavior. At the same time, future guidelines should further consider the potentially different viewpoints of patients and physicians (Adair & Holmgren, 2005).

10.3 CASES (ETHICAL SCENARIOS)

Case scenario 1

A company producing drugs for the management of hypertension has offered to pay the part-time salary of a nurse in a doctor's practice. The nurse's role is to audit patients' records, ensuring that those with hypertension are regularly examined and receive up-to-date medicine. The doctor thinks this enhances patient care. The nurse provides anonymous patient data to the company, but is barred from promoting its products. Information about the company's drugs is regularly provided by a sales team, which visits the practice and pays for working lunches with the doctor. A good relationship exists, and the company provides occasional gifts and invites the doctor's staff for dinner.

Case scenario 2

Dr. Ahmad is a 46-year-old gastroenterologist consultant working in a hospital in Riyadh. He has been working happily in the same hospital for the past 13 years, and has never had any problems.

One day, he is approached by a representative named Saleh from a major pharmaceutical company. Saleh tells Dr. Ahmad about a new drug that the company has made that can effectively treat diarrhea, and Ahmad is invited to see a presentation on the drug in Dubai. The company pays all the costs for a three-day trip for Ahmad, even though the presentation was only going to be on one day. Ahmad accepts the invitation, and after attending the presentation, he enjoys the rest of the three days in Dubai as a vacation.

When he returns, Saleh visits him again, and says that the company was grateful that he attended the presentation, and as a show of their gratitude, they are willing to offer him 10 riyals every time he prescribes their drug to a patient.

10.4 WHY IS KNOWING ABOUT CONFLICT OF INTERESTS IMPORTANT?

While there is nothing inherently unethical in the occurrence of conflicts of interest in medicine, the manner in which they are addressed may well be unethical. It is important to have relations with companies, but this relationship should be according to the regulations and the law. Most physicians suffer from a lack of awareness regarding the dynamics of their relationships with pharmaceutical representatives, so it is important for them to become more aware of this relationship. For this reason, it would be preferable for drug requests to be made solely through scientific and therapeutic committees.

Public confidence is also compromised if it appears that decisions about prescribing and treatment are substantially influenced by pharmaceutical promotional materials, so public trust on this issue is important. Professional and regulatory bodies acknowledge that even the unfounded perception of undue influence can be as damaging to public trust as corrupt practice.

10.5 ETHICAL, LEGAL, AND POLICY ISSUES

One of the classic examples of conflict of interest in medical practice is the approach by a pharmaceutical company to physicians requesting them to prescribe a medication to patients which compromises the health care given to the patients. This serious matter puts a huge pressure on every medical institution and on the community as well.

Laws in the Kingdom of Saudi Arabia against bribery match the Sharia law in this aspect; Saudi Arabia's **Law for Combating Bribery** was issued in 1992 and it covers public-to-public and public-to-private bribery. It is against

multiple aspects of corruption, including abuse of authority and office for personal interest in addition to bribery.

10.6 RULINGS AND FATWAS ON THE TOPIC

A good practitioner should seek only legal, rather than illegal, ways of providing an income. Accepting incentives for work purposes would be considered an unlawful means of acquiring extra income. Yet opinion is divided about whether the acceptance of such "gifts" by doctors is acceptable or not from an Islamic perspective. There have been many Fatwas regarding this issue. The Standing Committee for Scientific Research, and Ifta, said that *it is forbidden for a doctor to accept gifts from pharmaceutical companies, because that would be considered as a bribe, which is haram (illegal) in Islam.* Their ruling is inferred from the Prophet Mohammad's, *Peace be Upon Him*, words: "May the Curse of Allah be upon the briber and the bribe recipient." Despite being called "gifts," or similar such terms, these still constitute bribes, and wordplay and paraphrasing doesn't change that.

Moving on to the Islamic perspective on bribery, there are some Fatwas that are relevant. First, Sheikh Abulaziz bin Baz, *may Allah have mercy on him*, stated that bribery in Islam is prohibited, and is one of the gravest sins a Muslim can commit in his life. Sheikh bin Baz also proved what he said by a Hadith that our Prophet Mohammed, *Peace be Upon Him*, had said:

(لعن الله الراشي والمرتشي) رواه أبو داود وأحمد وابن ماجه والتزمي

The meaning of the Hadith is "The one who bribes and the one who is being bribed are all being cursed by Allah." (Narrated by Abu-Dawood, Ahmad, Ibn-Majah, and Al-Tirmidhi)

In conclusion, the acceptance of such incentives must adhere to a list of guidelines, as it should not interfere with the doctor's decision of which drug to prescribe for the patient. In his interactions with pharmaceutical companies, his intentions should be in the patients' best interests.

10.7 HOW TO IMPROVE YOUR PRACTICE

A number of strategies for individual and collective action have been identified. The most basic are as follows:

- All health professionals have a duty to recognize the potential for *conflicting interests*, and to deal with this important ethical issue.
- Consider Allah (GOD) in all issues in your life and your work.
- There are many ethical issues in this field that need clearer regulations, especially in our countries.

- Relations with companies are important in the medical field, but these relations should be through our institutions.
- Locally, it is important that we have strong policies and regulations in this field.

Professional organizations must also strive to help doctors working in pharmaceutical companies to exercise rigorous control over marketing information.

10.8 CASE DISCUSSION

Case 1

These cases have been chosen because they are common and represent the borderline between what is clearly prohibited and what is deemed ethically acceptable. In the first case, it is unwise of the doctor to accept gifts or expensive meals. The services of the audit nurse represent a significant gift and, although it is not clearly prohibited, any strings attached to it need to be carefully reviewed, if a local public register exists. Although company-sponsored nurses do not promote drugs, the data they research are used by the company sales team to assess the practice's potential market. Nurses may also receive bonuses by identifying patients who could be transferred to costly new drug schemes, and so pressure to transfer them builds up on the doctor. Any form of company-sponsored service must be handled with care, and with a keen eye on the perceptions of patients and the public. Doctors' awareness of their own and colleagues' prescribing patterns needs to be high and in line with peer practice, and reviewed if patterns change as a result of accepting the service.

Case 2

This case scenario provides a perfect example of bribery. In this situation, the pharmaceutical company appealed to Dr. Ahmad, who is in a position of trust, by sending him on a luxurious trip to Dubai; they then offered him money for every prescription of their drug, to try to influence his judgment and behavior for their own benefit. Of course, while both the doctor and the pharmaceutical company benefit, the patients are the ones who may be getting harmed, as Dr. Ahmad was trusted to do his duty, which is to pick the best medication for each patient according to his or her situation and need.

From an Islamic point of view, the actions of Dr. Ahmad, Saleh, and the pharmaceutical company were haram, and all of them will be punished for such actions.

Ethically, we know that bribery is considered incorrect. Dr. Ahmad in this scenario didn't follow the medical ethics of beneficence and non-maleficence,

and may have harmed his patients for his own personal benefit. In addition, from a utilitarian perspective, the actions of the doctor and the pharmaceutical company cannot be justified, for while they both benefited, the consequences of their actions may have brought pain and harm to many people.

From a legal standpoint, this form of bribery is banned in most countries in the world. In the review of literature, we discussed various news reports of pharmaceutical companies and medical personnel being apprehended for their involvement in bribery. Saudi Arabian laws, particularly the law for combating bribery, do not allow such a deed, and Dr. Ahmad could have been punished by imprisonment and a fine. The pharmaceutical company could also have been fined for its actions.

10.9 CONCLUSION AND SUMMARY

It is important for all health professionals to be able to recognize the potential for conflicting interests. To help you do this, you can use the information and views provided here to analyze and resolve the cases outlined in the beginning of the module.

1. Conflict of interest is a major ethical issue that challenges health care providers, and we must deal with this ethical issue in a professional way.
2. Health care institutions should develop policies and regulations, and provide education to health care providers about this area.
3. However, prescription patterns are still often influenced by drug companies through the provision of gifts, dinners, funding, and financial assistance, as well as travel for prescribing doctors and nurses, or accommodation at scientific meetings.
4. Inexpensive gifts, limited hospitality, and travel sponsorship are acceptable, and our professional associations set out clear criteria.
5. Professional codes of practice ban lavish gifts or inducements from pharmaceutical companies, and prohibit company representatives from offering them. Therefore, we should be aware of the Saudi professional codes of practice that require prescribers to put the patient's interest first.

10.10 REFERENCES AND SUGGESTED READINGS

- 1 Adair RF, Holmgren LR. Do drug samples influence resident prescribing behaviour? *Am J Med* 2005;118(8):881-4.
- 2 Caudill TS, Johnson MS, Rich EC, McKinney WP. Physicians, pharmaceutical sales representatives, and the cost of prescribing. *Arch Fam Med* 1996;5(4):201-6.
- 3 Chew LD, O'Young TS, Hazlet TK, Bradley KA, Maynard C, Lessler DS. A physician survey of the effect of drug sample availability on physicians' behavior. *J Gen Intern Med* 2000;15(7):478-83.

- 4 Chren MM, Landefeld CS. Physicians' behaviour and their interactions with drug companies. *JAMA* 1994;271(9):684-9.
- 5 Coleman DL, Kazdin AE, Miller LA, Morrow JS, Udelesman R. Guidelines for Interactions Between Clinical Faculty and the Pharmaceutical Industry: One Medical School's Approach. *Aca Med* 2006;81:154-160.
- 6 Gibbons RV, Landry FJ, Blouch DL, Jones DL, Williams FK, Lucey CR, Kroenke K. A comparison of physicians' and patients' attitudes toward pharmaceutical industry gifts. *JGIM* 1998;13:151-154.
- 7 Iserson KV, Cerfolio RJ, Sade RM. Politely Refuse the Pen and the Note Pad: Gifts From Industry to Physicians Harm Patients. *Ann Thorac Surg* 2007;84:1077-1084.
- 8 Korenstein D, Keyhani S, Ross JS. Physician attitudes toward industry: a view across the specialties." *Arch Surg* 2010;145(6):570-7.
- 9 Lexchin J. What information do physicians receive from pharmaceutical representatives? *Can Fam Physician* 1997;43:941-5.
- 10 Mohapatra PR. Interaction between medical practitioners & pharmaceutical industry. *Indian J Med Res* 2008;127(1):93-94.
- 11 Sade RM. A national survey of physician-industry relationships. *N Engl J Med* 2007;357(5):507.
- 12 Steinman MA, Shlipak MG, McPhee SJ. Of principles and pens: attitudes and practices of medicine housestaff toward pharmaceutical industry promotions. *Am J Med* 2001;110(7):551-7.
- 13 Wazana A. Physicians and the Pharmaceutical Industry: Is a Gift Ever Just a Gift? *JAMA* 2000;283:373-380.

MODULE 11 - ETHICAL ISSUES IN RESEARCH

*Omar Hasan Kasule Sr. MBChB (MUK),
MPH (Harvard), DrPH (Harvard)*

11.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. Understand modern research ethics: terminology and historical background
2. Describe the principles and processes of informed consent for research
3. Understand patient safety in research and benefit vs. risk considerations
4. Understand the importance of privacy and confidentiality in research and methods of their assurance
5. Describe the rights and obligations of the investigator, the sponsor, and the patient
6. Appreciate the delicate balance between clinical care and clinical research
7. Describe the contents of the research protocol and related documents
8. Understand issues of research governance: Institutional Review Board/Research Ethics Committee (IRB/REC), Nuremberg, Helsinki, good clinical practice (GCP), and Saudi research regulations
9. Describe the ethics of research publication and how to prevent violations
10. Describe the types, and the prevention, of conflict of interest in research and publication.

11.2 CASE (ETHICAL SCENARIOS)

Case scenario 1

The commander of an army brigade asked the brigade physician to undertake research on causes of very high sick leave. The physician took blood from all soldiers to look for their immune profiles. When some soldiers protested that they were not asked for consent, he told them he was following military orders.

Case scenario 2

A physician was recruiting patients for a large multi-center study of myocardial infarction. The informed consent sheet was 10 pages long because there were many procedural details and adverse effects to disclose. Most of the subjects grew bored reading through or listening to the details, and were ready to sign because they trusted the physicians doing the study.

Case scenario 3

A new drug that had proved effective against leukemia in animal, in vitro, and phase 2 trials was submitted for human trials. Its risk profile was not well understood from earlier studies. It was to be tested against a placebo. There was no known effective treatment for this disease.

Case scenario 4

A physician in a local hospital agreed to be an investigator of a multi-center international trial sponsored by a pharmaceutical company. He regularly completed and sent Case Report Forms (CRFs) to the sponsor overseas. On one occasion the sponsor questioned the data submitted and insisted that the original patient's chart be shipped to him for inspection and verification.

Case scenario 5

A multi-center trial of a new medication was carried out at a local hospital; the hospital was among the last to join the 5-year trial. Local results showed that the drug was effective and patients were satisfied. Interim analysis of the data by the sponsor showed the superiority of the new drug. The sponsor also noticed that if the results of the local hospital were eliminated, the sample size of the remaining sites would be adequate. He therefore decided to terminate the study at the hospital prematurely and cut off the supply of the drug.

Case scenario 6

A hospital received a big grant from a pharmaceutical company to do a post-marketing survey on a new analgesic. After trial initiation, it was discovered that the physicians in the hospital rarely prescribed the drug. The principal investigator called a meeting of all physicians in the outpatient clinic and asked them to start prescribing the drug so that the hospital would not lose the grant. He explained that the drug was safe, and had already been found to be effective.

Case scenario 7

A physician was given a fat grant to study a new drug. The sponsor provided a well-written and detailed protocol. Implementation of the protocol was difficult in the local circumstances: the subjects found the informed consent information overlong, and they could not adhere to the visit dates fixed in the protocol. The physician made alterations in the protocol that he thought were simple and did not affect study validity or patient safety, and saw no reason to inform IRB/REC. The sponsor sent monitors, who discovered the discrepancy. The physician ignored their observations and continued the study without documenting the changes he had made.

Case scenario 8

A very experienced professor of surgery wanted to undertake research comparing two surgical approaches that he had been using alternately over the past 15 years. He reviewed the Nuremberg and Helsinki declarations, as well as the ICH-GCP guidelines, and the Saudi regulations on research. He made sure he fulfilled all stipulations of these documents in his research, and saw no reason to seek the approval of the local IRB, which in his view

consisted of young, inexperienced members, most of whom had been his students.

Case scenario 9

A professor of cardiology conducted a well-designed, post-marketing survey of a drug that had been marketed recently in Saudi Arabia, but had been marketed for over 10 years in the US and EU. Preliminary results were against what many researchers had published, and even seemed illogical to him. He told the team of researchers to keep this information secret until the study was completed. Analysis of the complete data confirmed the preliminary analysis. The professor decided not to submit the results for publication for fear of his reputation, and to avoid disturbing other cardiologists in the country who were satisfied with the drug.

Case scenario 10

The IRB of a major hospital sat to consider a proposal sponsored by a multi-national pharmaceutical firm, and 5 of the 6 members declared their interests. The Chairman had been engaged as a temporary consultant for the firm over the past 5 years, mainly to give lectures on drug development processes to potential researchers. The son-in-law of the deputy chairman had shares worth SAR 1,000 in the firm. One member was the brother-in-law of the principal investigator. The principal investigator, a member for 6 years, had not attended the meeting. Only one member had no interests to declare. The committee proceeded to consider the proposal because everybody's interests were now known.

11.3 INTRODUCTION

The following terminology is used widely, and it is important that researchers become familiar with it. A **clinical trial** is an investigation of the pharmacological properties, adverse effects, safety, and efficacy of a product. An **investigational product** is a pharmaceutical form of an active ingredient being tested in a clinical trial. An **Institutional Review Board (IRB)** is an independent body responsible for review, approval, and monitoring of ongoing research projects, in order to protect patient safety and rights, and assure the public of human subject protection. An **investigator** is a qualified person who is responsible for conducting research. **Sub-investigators** assist the investigator in all aspects of the study. A **sponsor** is the company (usually pharmaceutical) that will fund the study. **Review** is a rigorous and systematic process of assessing a research project regarding its scientific merit, its validity, the reliability of the research methodology, qualification of the investigators, research subject rights and safety, and other ethical considerations. A **reviewer** is a person with specialist knowledge in a field of

medicine, health care, and research methodology asked to review a research project and recommend to IRB its approval, modification, or rejection. **Exempt review** is for research that has no interventions and carries no risk to humans. **Expedited review** is for research that has minimal risk for humans. **Full review** is for research that involves human intervention and carries potential risk. It has to be reviewed and approved by the full IRB. **Informed consent form (ICF)** refers to background information and signature forms used to obtain informed consent. An **Investigator Brochure (IB)** contains scientific information about the investigational product. An **adverse event** is an untoward symptom or sign after use of the investigational product. It may be described as adverse or as serious.

11.4 WHY ARE RESEARCH ETHICS IMPORTANT?

Modern medical practice is evidence-based. Evidence is derived from research, either within the institution or carried out at other institutions and accessed through publications. A practitioner who engages in research tends to practice better medicine, not only because of the new evidence that is available to him/her, but because of the intellectual stimulation provided by research activities. Even clinicians who are not engaged in research cannot escape being affected because there are usually many active research protocols in their hospital, some of which their patients may be involved with. Reading and understanding medical textbooks and research papers requires knowledge and understanding of research terminology and research techniques. In all these instances, it is impossible to escape research ethics, and every practitioner is expected to know at least some of the fundamentals.

11.5 ETHICAL, LEGAL, AND POLICY ISSUES

Background: terminology and history

Modern research ethics owes its origins to horrifying violations committed by the Germans and the Japanese in the Second World War (1939-1945), when they carried out cruel experiments on prisoners of war and other victims without consent. The Japanese crimes were not publicized as much as the German ones. The Nazi doctors involved in the cruel experiments were tried at Nuremberg in Germany, and at the conclusion of the trials the Nuremberg declaration set out 10 principles to be followed in human research, the most important of these being informed and free consent. These principles were updated in the Helsinki declaration of 1964 and its subsequent amendments. In the US, the Belmont Report of 1979 restated similar principles. In 1996, the International Conference on Harmonization published Good Clinical Practice (GCP) guidelines that are followed by clinical researchers worldwide. The GCP guidelines are based on the Helsinki declaration and its amendments, and have two main objectives: (a) protect the subject/patient, (b) ensure credible

and accurate data. Patient protection is assured by informed consent, as well as independent review and approval of the research protocol.

Informed consent for research

Following full disclosure of the study details to enable the subject to make an informed decision, he or she must voluntarily and freely agree to participate in the study. The information given to the subject must be in writing and must have been approved by the IRB/REC. The subject must be given time to ask questions. The consent form must be signed by the subject, dated, and witnessed. The subject must be given a copy of the consent form.

The following information must be included in the consent information: purpose of the trial, that the treatments/procedures are for research, the procedures involved, expected benefits, expected risks/inconveniences, alternative treatments and procedures, compensation for trial injury, freedom of the subject to withdraw from the study without having to give reasons, confidentiality, subject's permission for direct access to his/her records, a person to contact in case of injury or questions, duration of the study, and number of subjects involved.

Special precautions have to be taken to make sure that interests of vulnerable subjects are protected because they may not be able to exercise their full autonomy due to certain constraints. Vulnerable subjects include minors, mental patients, and incapacitated persons for whom consent is by their legal representative. Students and junior employees are also vulnerable because they may consent to research under duress.

In exceptional circumstances, research can be carried out without consent. This can happen, for example, in the emergency room, when the patient is incapable of giving consent and the research is necessary for improving service delivery. In some types of psychological research, seeking consent may bias the respondent. IRB/RECs examine the situation very carefully before approving research without consent.

Patient safety: Benefit vs. risk considerations

Approval of a study is based on a careful consideration of the benefits and risks. Subjects participating in the study may benefit from the new treatment, and can improve after failure of traditional treatments. Some subjects in the control arm may receive no benefits; in these cases, we have to consider the study's benefit to the community. The benefits of the study, whether individual or communal, have to be considered against the risk that the study subject faces. All studies plan to minimize this risk. It is, however, not possible to envisage all risks in advance, so we need systems of ensuring patient safety.

Patient safety is ensured by monitoring and reporting adverse events. Potential adverse events are defined in the protocol and are reported on the CRF. An adverse drug reaction is any bad and unintended response to the investigational product. Serious adverse events have to be reported to IRB/REC and the sponsor. Death and life-threatening conditions are reported within 7 days. Others have to be reported within 15 days. IRB/REC will investigate the report, and may make decisions on suspending or stopping the study.

The consideration of benefit vs. risk is undertaken by IRBs/RECs but it seems that this is not done in a systematic way. It may be necessary to use techniques used in other disciplines, such as decision-making sciences.

Privacy and confidentiality

The study subject has rights to privacy and confidentiality. Study data should not be disclosed to any third parties. Even within the study team, data should be disclosed on a need-to-know basis. To protect confidentiality, study documents should be locked up or should be saved on password-protected computers. The sponsor has no right to access patient notes; only anonymized data from CRFs can be submitted.

Rights and obligations: Investigator, sponsor, and patient

The investigator must be qualified to undertake the study by education, training, and experience. The main responsibilities are commanding adequate human and other resources for the study, providing medical care for the study subjects, dealing with the IRB/REC, making sure that all study procedures conform to the protocol, assuring that all study subjects gave free and voluntary informed consent, keeping all the study records, accounting for the investigational product, and providing progress and final reports.

The main responsibilities of the sponsor are to provide the investigational product, funding of the study, and follow-up and monitoring.

The patient has the responsibility to comply with study procedures and to report any adverse events promptly.

The balance between clinical care and clinical research

The clinician investigator faces the dilemma of prioritizing between research and patient care, which is a difficult task. On one hand, the investigator may violate the doctor's duty to treat in pursuit of science. On the other hand, lack of good research may lead to poor clinical care. This dilemma may manifest as the conflict between the role of the doctor (to ensure the best interests of the

patient) and the role of the researcher (to produce knowledge that may not immediately benefit the patient).

The primary role of the doctor is to treat the patient. Research is a secondary role, and should never be allowed to interfere with patient care and patient safety. However, sometimes these may be violated; for example, when study subjects are not given full disclosure in the eagerness to obtain their consent.

The research protocol and related documents

The main document in research is the protocol. It must be a comprehensive and detailed guide to conducting the research. It must contain the research background (based on a literature review); general and specific objectives of the research; eligibility criteria; outcome measures; sampling and randomization details, including whether the sample size is adequate to detect a difference with sufficient power; and the intervention proposed.

The case report form (CRF) is an important study document. It must be constructed in such a way that it captures data correctly. Special precautions are needed to ensure the security of electronic CRFs.

Review governance: IRB/REC, GCP, Saudi research regulations

IRB/REC is an independent body, whose main function is to protect the safety, welfare, and rights of the patient. It reviews and approves the research protocol and all trial documents, making sure that the investigators are qualified and that the risk-benefit ratio is favorable. It also has to monitor the way that the study is conducted, to make sure that it adheres to the protocol. Its members must be drawn from a range of disciplines, and there must be some members who are non-scientists and some not affiliated to the institution. The members must not have any relation to the investigator or the sponsor; any members with a potential conflict of interest in a particular study must withdraw from the meeting. The IRB/REC must also review financial arrangements to make sure there are no unethical payments and conflicts of interests. IRB/REC also monitors and investigates safety reports and reports of adverse events. It can suspend or stop a study if it feels that patient safety is compromised.

A regulatory body is usually a governmental entity that carries out inspections to make sure that the study follows the guidelines. In Saudi Arabia, the Monitoring/Compliance Office of the National Bioethics Commission undertakes this function.

IRB/REC and regulatory bodies follow specific ethical and legal guidelines and regulations in their work. The regulations in Saudi Arabia were published in

the Umm al Qura Gazette as (a) Research Ethics Regulations No 4402 of 1420, (b) Research ethics bylaws No 4403 of 1433. The Helsinki Declaration and its amendments, and the ICH-GCP regulations are also followed.

The main principles of ICH-GCP focus on patient protection; a favorable risk-benefit ratio, and the safety and welfare of the patient are placed before scientific interests. The study must be carried out according to a protocol approved by an ethical committee, the researchers must be qualified, informed consent must be obtained, patient safety must be assured, patient confidentiality must be obtained, there must be compensation for study-related injury, products used must conform to Good Manufacturing Principles (GMP), and systems must exist to ensure quality.

Ethics of research publication

Several ethical violations can occur regarding publication of research results. Researchers tend to submit positive findings for publication and suppress negative ones. In a few cases, these decisions may involve a conflict of interest when the researcher succumbs to pressure from the sponsor. Other problems involve authorship and plagiarism, but these are common to all other types of scientific publication.

Conflict of Interest (COI) issues

COI situations occur when the sponsor of the study influences reported outcomes to make them favorable to the new investigational product. The investigator, consciously or unconsciously, may produce results favorable to the sponsor, and receive financial or other rewards for this. In some cases, the investigator may not seek material rewards, but may want promotion and recognition. COI issues also arise in the peer review process, when research reports are submitted for publication. Many institutions have developed detailed COI guidelines, which are constantly updated as new loopholes are found. The best protection against COI is full disclosure of such interests at all levels of the research process: IRB/REC must disclose their interests, and authors must disclose their interests when they submit work for publication.

11.6 HOW DO RESEARCH ETHICS IMPROVE YOUR PRACTICE

Knowledge of research ethics guidelines will help the clinician investigator undertake ethical research.

11.7 CASE DISCUSSION

Case 1

The commander of an army brigade asked the brigade physician to undertake research on causes of very high sick leave. The physician took blood from all soldiers to look for their immune profiles. When some soldiers protested that

they were not asked for consent, he told them he was following military orders.

Hint: voluntary consent.

Case 2

A physician was recruiting patients for a large multi-center study of myocardial infarction. The informed consent sheet was 10 pages long because there were many procedural details and adverse effects to disclose. Most of the subjects grew bored reading through or listening to the details, and were ready to sign because they trusted the physicians doing the study.

Hint: informed consent after full disclosure.

Case 3

A new drug that had proved effective against leukemia in animal, in vitro, and phase 2 trials was submitted for human trials. Its risk profile was not well understood from earlier studies. It was to be tested against a placebo. There was no known effective treatment for this disease.

Hint: high potential benefit.

Case 4

A physician in a local hospital agreed to be an investigator of a multi-center international trial sponsored by a pharmaceutical company. He regularly completed and sent CRFs to the sponsor overseas. On one occasion, the sponsor questioned the data submitted and insisted that the original patient's chart be shipped to him for inspection and verification.

Hint: confidentiality.

Case 5

A multi-center trial of a new medication was carried out at a local hospital; the hospital was among the last to join the 5-year trial. Local results showed that the drug was effective and that patients were satisfied. Interim analysis of the data by the sponsor showed the superiority of the new drug. The sponsor also noticed that if the results of the local hospital were eliminated, the sample size of the remaining sites would be adequate. He therefore decided to terminate the study at the hospital prematurely and cut off the supply of the drug.

Hint: investigator responsibility.

Case 6

A hospital received a big grant from a pharmaceutical company to do a post-marketing survey on a new analgesic. After trial initiation, it was discovered that the physicians in the hospital rarely prescribed the drug. The principal investigator called a meeting of all physicians in the outpatient clinic, and asked them to start prescribing the drug so that the hospital would not lose

the grant. He explained that the drug was safe, and had already been found to be effective.

Hint: clinical care vs. clinical research.

Case 7

A physician was given a fat grant to study a new drug. The sponsor provided a well-written and detailed protocol. Implementation of the protocol was difficult in the local circumstances: the subjects found the informed consent information overlong, and they could not adhere to the visit dates fixed in the protocol. The physician made alterations in the protocol that he thought were simple and did not affect study validity or patient safety, and saw no reason to inform IRB/REC. The sponsor sent monitors, who discovered the discrepancy. The physician ignored their observations and continued the study without documenting the changes he had made.

Hint: adherence to the protocol.

Case 8

A very experienced professor of surgery wanted to undertake research comparing two surgical approaches that he had been using alternately over the past 15 years. He reviewed the Nuremberg and Helsinki declarations, as well as the ICH-GCP guidelines and the Saudi regulations on research. He made sure he fulfilled all stipulations of these documents in his research, and saw no reason to seek the approval of the local IRB, which in his view consisted of young inexperienced members, most of whom had been his students.

Hint: research governance.

Case 9

A professor of cardiology conducted a well-designed, post-marketing survey of a drug that had been marketed recently in Saudi Arabia, but had been marketed for over 10 years in the US and EU. Preliminary results were against what many researchers had published, and even seemed illogical to him. He told the team of researchers to keep this information secret until the study was completed. Analysis of the complete data confirmed the preliminary analysis. The professor decided not to submit the results for publication for fear of his reputation, and to avoid disturbing other cardiologists in the country who were satisfied with the drug.

Hint: ethics of research publication.

Case 10

The IRB of a major hospital sat to consider a proposal sponsored by a multi-national pharmaceutical firm, and all 5 of 6 members declared their interests. The Chairman had been engaged as a temporary consultant for the firm over the past 5 years, mainly to give lectures on drug development processes to

potential researchers. The son-in-law of the deputy chairman had shares worth SAR 1,000 in the firm. One member was the brother-in-law of the principal investigator. The principal investigator, a member for 6 years, had not attended the meeting. Only one member had no interests to declare. The committee proceeded to consider the proposal because everybody's interests were now known.

Hint: conflict of interest.

11.8 CONCLUSION AND SUMMARY

1. The most important consideration in research is patient safety and rights. Research should pose minimal risk, and should be carried out after obtaining informed consent following a full disclosure.
2. IRB/REC ensures patient safety by reviewing research protocols and making sure that the researchers are qualified. They also monitor for adverse effects.
3. Conflict of interest situations occur in research and publications. The best protection is full disclosure of any personal interests of the researcher.

11.9 REFERENCES AND SUGGESTED READINGS

Background: terminology and history

1. Eckart WU, Vondra H. Malaria and World War II: German malaria experiments 1939-45. *Parassitologia* 2000;42(1-2):53-8.
2. Girdwood RH. Experimentation on prisoners by the Japanese during World War II. *Br Med J (Clin Res Ed)* 1985;291(6494):530-1.
3. Katz J. The Nuremberg Code and the Nuremberg Trial. A reappraisal. *JAMA* 1996;276(20):1662-6.
4. Lefor AT. Scientific misconduct and unethical human experimentation: historic parallels and moral implications. *Nutrition* 2005;21(7-8):878-82.
5. Nie JB. The United States cover-up of Japanese wartime medical atrocities: complicity committed in the national interest and two proposals for contemporary action. *Am J Bioeth* 2006;6(3):W21-33.
6. Shrestha BM. The Declaration of Helsinki in relation to medical research: historical and current perspectives. *J Nepal Health Res Counc* 2012;10(22):254-7.
7. White RM. Unravelling the Tuskegee Study of Untreated Syphilis. *Arch Intern Med* 2000;160(5):585-98.

Informed consent for research

1. Britz R, le Roux-Kemp A. Voluntary informed consent and good clinical practice for clinical research in South Africa: ethical and legal perspectives. *S Afr Med J* 2012;102(9):746-8.
2. Faden R, Kass N, Whicher D, Stewart W, Tunis S. Ethics and informed

- consent for comparative effectiveness research with prospective electronic clinical data. *Med Care* 2013;51(8 Suppl 3):S53-7.
3. Ghandour L, Yasmine R, El-Kak F. Giving consent without getting informed: a cross-cultural issue in research ethics. *J Empir Res Hum Res Ethics* 2013;8(3):12-21.
 4. Padhy BM, Gupta P, Gupta YK. Analysis of the compliance of informed consent documents with good clinical practice guideline. *Contemp Clin Trials* 2011;32(5):662-6.
 5. Ripley E, Ramsey C, Prorock-Ernest A, Foco R, Luckett S Jr, Ornato JP. EMS providers and exception from informed consent research: benefits, ethics and community consultation. *Prehosp Emerg Care* 2012;16(4):425-33.

Patient safety: Benefit vs. risk considerations

1. Bernabe RD, van Thiel GJ, Raaijmakers JA, van Delden JJ. The risk-benefit task of research ethics committees: an evaluation of current approaches and the need to incorporate decision studies methods. *BMC Med Ethics* 2012;20:13:6.
2. Rid A, Wendler D. A framework for risk-benefit evaluations in biomedical research. *Kennedy Inst Ethics J* 2011;21(2):141-79.

Privacy and confidentiality

1. Adinoff B, Conley RR, Taylor SF, Chezem LL. Protecting confidentiality in human research. *Am J Psychiatry* 2013;170(5):466-70.
2. Alahmad G, Diericky K. 2012. What Do Islamic Institutional Fatwas Say about Medical and Research Confidentiality and Breach of Confidentiality? *Developing World Bioethics* 2012;12(2):104-112 available from: <http://dx.doi.org/10.1111/j.1471-8847.2012.00329.x>.

Rights and obligations: Investigator, sponsor, and patient

1. Baer AR, Devine S, Beardmore CD, Catalano R. Clinical investigator responsibilities. *J Oncol Pract* 2011;7(2):124-8.
2. Kee AN. Investigator responsibilities for clinical research studies: proper staffing can ensure an investigator is compliant. *J Med Pract Manage* 2011;26(4):245-7.
3. Stobie M, Slack C. Treatment needs in HIV prevention trials: using beneficence to clarify sponsor-investigator responsibilities. *Dev World Bioeth* 2010;10(3):150-7.

The balance between clinical care and clinical research

1. Denson LA. How does knowledge from translational research impact our clinical care of pediatric inflammatory bowel disease patients? *Curr Gastroenterol Rep* 2012;14(3):275-81.
2. Haire BG. Ethics of medical care and clinical research: a qualitative

- study of principal investigators in biomedical HIV prevention research. *J Med Ethics* 2013;39(4):231-5.
3. Laman M, Pomat W, Siba P, Betuela I. Ethical challenges in integrating patient-care with clinical research in a resource-limited setting: perspectives from Papua New Guinea. *BMC Med Ethics* 2013;26;14:29.
 4. Patil S. Ethical acumen: the dexterity to balance clinical care, research and publication. *J Contemp Dent Pract* 2012;13(5):I.
 5. Zimbrick G, Srivastava R. Research in pediatric hospital medicine: how research will impact clinical care. *Curr Probl Pediatr Adolesc Health Care* 2012;42(5):127-30.

The research protocol and related documents

1. Adams P, Wongwit W, Pengsaa K, Khusmith S, Fungladda W, Chaiyaphan W, Limphattharacharoen C, Prakobtham S, Kaewkungwal J. Ethical issues in research involving minority populations: the process and outcomes of protocol review by the Ethics Committee of the Faculty of Tropical Medicine, Mahidol University, Thailand. *BMC Med Ethics* 2013;14(1):33.
2. Bernabe RD, van Thiel GJ, Raaijmakers JA, van Delden JJ. The risk-benefit task of research ethics committees: an evaluation of current approaches and the need to incorporate decision studies methods. *BMC Med Ethics* 2012;20;13:6.
3. Clark T, Berger U, Mansmann U. Sample size determinations in original research protocols for randomised clinical trials submitted to UK research ethics committees: review. *BMJ* 2013; 346:f1135.
4. Guillemin M, Gillam L, Rosenthal D, Bolitho A. Human research ethics committees: examining their roles and practices. *J Empir Res Hum Res Ethics* 2012;7(3):38-49.
5. Kaur S, Choy CY. Ethical Considerations in Clinical Trials: a Critique of the ICH-GCP Guideline. *Dev World Bioeth* 2014;14(1):20-8.
6. Lee DC, Peak DA, Jones JS, Domeier RM, Hendry PL, Rathlev NK, Swor RA, McLean SA. Variations in institutional review board reviews of a multi-center, Emergency Department (ED)-based genetic research protocol. *Am J Emerg Med* 2013;31(6):967-9.
7. Matar A, Silverman H. Perspectives of Egyptian research ethics committees regarding their effective functioning. *J Empir Res Hum Res Ethics* 2013;8(1):32-44.
8. Otte A, Maier-Lenz H, Dierckx RA. Good clinical practice: historical background and key aspects. *Nucl Med Commun* 2005;26(7):563-74.
9. Review governance: GCP, IRB/REC, Saudi research regulations.
10. Velentgas P, Dreyer NA, Nourjah P, Smith SR, Torchia MM, Eds. *Developing a Protocol for Observational Comparative Effectiveness Research: A User's Guide*. Rockville (MD): Agency for Healthcare

Research and Quality (US); 2013 Jan.

Ethics of research publication

1. Edwards AS. Research ethics committees have the power to enforce publication of drug trial results. *BMJ* 2013;346:f1201. doi: 10.1136/bmj.f1201.
2. Wager E, Kleinert S. Cooperation between research institutions and journals on research integrity cases: guidance from the committee on publication ethics (COPE). *Acta Inform Med* 2012;20(3):136-40.

Conflict of interest issues

1. Bariani GM, de Celis Ferrari AC, Hoff PM, Krzyzanowska MK, Riechelmann RP. Self-reported conflicts of interest of authors, trial sponsorship and the interpretation of editorials and related phase III trials in oncology. *J Clin Oncol* 2013;31(18):2289-95. Epub 2013 Apr 29.
2. Bero L. Industry sponsorship and research outcome: a Cochrane review. *JAMA Intern Med* 2013;173(7):580-1.
3. Binns CW, Low WY. Publications from clinical trials: process, conflict of interest and the evidence base. *Prev Med* 2013;57 Suppl:S3-4.
4. Freedman RS, McKinney R Jr. Is conflict of interest becoming a challenge for institution-based institutional review boards? *Clin Cancer Res* 2013;19(15):4034-9.
5. Isaacs D. Industry sponsorship of scientific meetings: peaks and troughs. *J Paediatr Child Health* 2012;48(7):547.
6. Johnson DH. Financial disclosure, industry sponsorship and integrity in cancer research reporting. *J Clin Oncol* 2013;31(18):2243-5.
7. Kang BH, Moon JY, Chang Y, Koo YM, Koh Y. Current levels of conflict of interest disclosure in medical publications from Korea. *J Korean Med Sci* 2013;28(7):978-82.
8. Lexchin J. Sponsorship bias in clinical research. *Int J Risk Saf Med* 2012;24(4):233-42.
9. Lundh A, Sismondo S, Lexchin J, Busuioc OA, Bero L. Industry sponsorship and research outcome. *Cochrane Database Syst Rev* 2012; Dec 12;12:MR000033.
10. Qureshi J, Sud A, Vakil N. Funding source and conflict of interest disclosures by authors and editors in gastroenterology specialty journals revisited. *Aliment Pharmacol Ther* 2012;35(6):690-5.

Others

1. Pieper I, Thomson C. Justice in Human Research Ethics. *Monash Bioethics Review* 2013;31(1):99-116 available from: <http://dx.doi.org/10.1007/BF03351345>
-

MODULE 12 - RESOURCE ALLOCATION IN HEALTH CARE

Ghaiath MA Hussein, MBBS, MHSc (Bioethics)

12.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. Identify the ethical issues related to resource allocation in public health
2. Present at least one ethical framework for resource allocation
3. Utilize an ethical framework to outline an approach to allocate resources

12.2 INTRODUCTION

What are the ethical issues and principles in resource allocation?

It is almost a fact in health care that there are never enough resources for everyone. This is true even in the richest countries. There are always health needs; some health care needs are basic, while other needs can be considered secondary or tertiary. For example, there is a growing need for body organs, which makes waiting lists longer and longer for patients with liver or kidney failure, and for patients who may even need lungs or hearts. Resource allocation is not only about money; it also includes time allocation to patients, and allocation of beds or drugs.

Issues related to allocation of resources are faced at both the higher level of policy setting (the Ministry of Health) and at the bedside level. We will mainly focus on the latter.

The following are examples of the main ethical principles that are relevant to this issue:

The principle of (distributive) justice

Patients and the community in general expect the health care system, represented mainly by clinicians, to be fair. However, the standard of fairness is usually measured against the patient's expectations of the system, which might be idiosyncratic, rather than realistic. In addition, the health care service should be provided regardless of gender, race, socioeconomic status, or any other non-clinical factors.

The principles of non-maleficence and beneficence

Doctors should not do anything that would harm their patients. This includes providing them with the care needed to avoid this harm (non-maleficence) and extending their well-being (beneficence). However, these principles do not tell doctors which patients' interests should be given priority when there is more than one patient in need of a resource.

The patient's autonomy

The principle of autonomy indicates that individuals have a right to make decisions that are related to their own health and bodies, though this right is

bound by similar limits given to other individual members of the community. It could logically be expected that patients (or their families) might want to "have everything done" to cure their disease.

Different approaches to allocation of resources in health care

There have been many attempts to decide who should get what, i.e., how to allocate health care resources. These approaches may not (and will not) arrive at the same conclusions, or the expected "right" answer. Some of these approaches are presented here, to help you decide which ones to utilize when facing similar problems related to allocation of scarce resources.

Consequentialist and utility principle approach

The utility principle is about acting to produce the greatest good. Consequentialism (utilitarianism) considers the right action to be that which produces the greatest sum of pleasure in the relevant population. This suggests that the resources available in a health care setting should be used to provide the greatest good for the greatest number.

Deontological (duty-based) approach

Deontology is duty-based, and suggests that people should act to fulfill their duties to others, and that acts should always follow a set of maxims (e.g., "Do not lie"). This approach focuses less on the act's consequences.

Cost-effectiveness, quality-adjusted life-years (QALYs) and disability-adjusted life-years (DALYs)

In addition to being just (fair), distribution of resources needs to be cost-effective. This means that the allocation maximizes health benefits for the population served. A cost-effectiveness analysis (CEA) compares the respective costs and benefits of alternative health intervention measures to determine their relative efficiency in the production of health. Costs are measured in monetary terms; benefits are measured in health improvements. By dividing costs by benefits, one can obtain a cost-to-effectiveness ratio for each health intervention, and interventions can be ranked by these ratios.

Quality-adjusted life-years (QALYs) are used to combine the two main benefits of health care: (a) protecting or improving health or health-related quality of life, and (b) preserving life. Disability-adjusted life-years (DALYs) are a variant of QALYs in that they measure the losses from disability or premature death; a CEA will determine which interventions will maximize QALYs or minimize DALYs (Brock & Wikler, 2006).

Principle-based approach (Principlism)

Principlism is one way of approaching professional deontology. Put simply, it is based on stating one or more principles from which stem duties. Some

examples of these principles include Hippocrates' oath ("First, do no harm" or "Primum non nocere"), the Belmont Report, produced in 1978 (three principles) and the four principles of beneficence, non-maleficence, respect for persons, and justice by Beauchamp and Childress. (Beauchamp & Childress, 2008)

Fair process approach (Accountability for reasonableness)

This approach is focused more on the process of allocating resources, rather than the principles used. In other words, if we cannot agree on what is a fair distribution, let us at least agree on procedural justice (fair process). For a "fair process" of resource allocation, Norman Daniels suggested a set of principles that should be followed in decision making:

- **Transparency/publicity:** information about the processes and bases of decisions should be made available to the affected population.
- **Participation:** the stakeholders should be involved in the processes of formulating the objectives and adopting the policies.
- **Effectiveness/Relevance:** states that there must be ways to translate the other principles into practice relevant to meeting population health needs fairly.
- **Appeal:** Stakeholders should have a way to appeal policies after they have been adopted, and processes should be in place that allow policies and plans to be reviewed and revised.

12.3 WHY IS RESOURCE ALLOCATION IMPORTANT TO YOUR PRACTICE

Resources are not only about medications or equipment, but also include aspects of time and care. Their importance is tied in with the difficulty of reaching a definite decision on who should be given what. In turn, this may lead to a level of dissatisfaction among patients and medical staff. Therefore, there should be an ethical basis on which you can base your decision about who should receive what.

There are many ways to achieve a fair allocation of resources, which are based on a number of ethical considerations, summarized in the following list:

1. **CEA: (Effectiveness)** - priority given to those most likely to achieve a good outcome, i.e., medical success
 2. **Medical Need** - priority given to those most in need of medical intervention, or those considered most helpless or generally neediest in society (vulnerable groups)
 3. **Utility** - achieving the least morbidity/mortality possible, given the resources available (maximizing good health/survival with the available resources)
-

4. **Immediate Usefulness** - priority given to those with special skills that could be used to serve the common good in the immediate circumstance
5. **General Social Value** - priority given to those who are considered by society to have the greatest social worth (past or future)
6. **Principle of Conservation** - priority given to those who use proportionally less resources
7. **Responsibility for Dependents** - priority given to those who have primary responsibilities to dependents (parents, nursing home attendants, etc.)
8. **None if not all** - no one should be saved if all cannot be saved
9. **Queue** - priority given on a first-come, first-served basis
10. **Random Selection** - allocation determined by chance (a lottery, for example)
11. **Ability to Pay** - priority given to those who can pay for the resources
12. **Merit based** - priority given to those who have earned it due to past actions

The main goal of this module is to help you approach such issues; it provides different approaches and references that will help you reach decisions on these issues, and justify those decisions to your colleagues and patients, if needed. This is an important issue because some clinical staff may experience moral reservations and frustration. This can happen if they feel they have failed, and let a patient down by allocating an intervention to a different patient.

12.4 ETHICAL, LEGAL, AND POLICY IMPLICATIONS OF RESOURCE ALLOCATION

Ethically, we have moral obligations of fairness, utility, and beneficence towards our patients, who expect us to work in their best interests.

In addition, the resource decisions that sectors make might negatively affect some patients by delaying or denying their access to a given medication or intervention. Therefore, it is important to find a way by which clinicians and other health care providers can justify these decisions, at least ethically.

At the policy level, we might expect significant differences between institutions that have guidance on how their resources should be allocated and those who do not. This includes policies related to, for example, organ donation, admission to ICU, and end-of-life care.

12.5 RULINGS AND FATWAS ON THE TOPIC

The Islamic approach to these issues is similar to the Islamic approach to other ethical issues. It aims at achieving the five main goals of the Sharia, which is to preserve people's religion/faith, souls/bodies, mind, wealth, and progeny. See Module 2 for more details.

12.6 HOW TO USE RESOURCE ALLOCATION IN YOUR PRACTICE: EXAMPLES OF FRAMEWORKS

As a clinician or member of an ethics committee, you can use more than one framework. These frameworks are based on a set of questions that, when answered, will hopefully help you take the most suitable decisions about allocating a given resource.

We will present two examples:

The American College of Healthcare Executives (ACHE) framework

It has suggested an 8-step approach:

- **Step One:** Clarify the ethical conflict
- **Step Two:** Identify all of the affected stakeholders and their values
- **Step Three:** Understand the circumstances surrounding the ethical conflict
- **Step Four:** Identify the ethical perspectives relevant to the conflict
- **Step Five:** Identify different options for action
- **Step Six:** Select among the options
- **Step Seven:** Share and implement the decision
- **Step Eight:** Review the decision to ensure it achieved the desired goal

The Hamilton Health Sciences (ISSUES) framework

1. **Identify** issue and decision-making process
 2. **Study** the facts
 3. **Select** reasonable options
 4. **Understand** values & duties
 5. **Evaluate** and justify options
 6. **Sustain** and review the plan
-

Ethical Decision Making: ISSUES

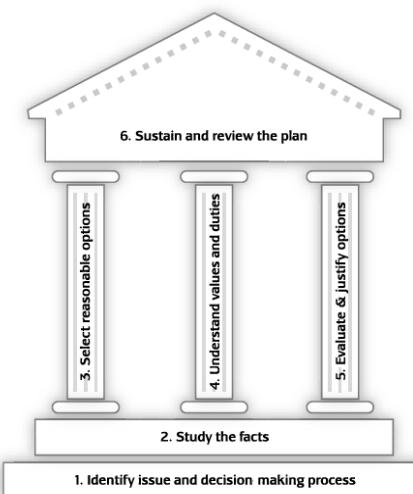


Figure 0.1 ISSUES Framework

(http://hamiltonhealthsciences.ca/workfiles/CLINICAL_ETHICS/HHSEthicsFramework.pdf)

12.7 CONCLUSION AND SUMMARY

There are rarely enough health care resources for everyone. At some point, there will be a need to prioritize the beneficiaries of the service that you provide in a fair way that fulfills your professional commitments.

1. Different people have different expectations of what the health care system ought to provide, thus it is hard to make decisions that satisfy everyone.
2. There are moral and professional commitments related to these decisions.
3. There are ethical frameworks and tools based on ethical principles that, if used in a transparent way, may help clinicians and ethics committees to provide fair resource allocation.

12.8 REFERENCES AND SUGGESTED READINGS

1. Beauchamp TL, Childress JF. Principles of Biomedical Ethics, 6th edition. 2008
 2. Brock D, Wikler D. Ethical Issues in Resource Allocation, Research, and New Products Development. In: Disease Control Priorities in Developing Countries. 2nd edition. Jamison D, Breman J, Measham A,
-

- et al., (eds). Washington (DC): World Bank; 2006. Chapter 14. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK11739/?report=reader>
3. Crippen D, Whetstine L. ICU resource allocation: life in the fast lane. Critical Care 1999;3(4):R47-R51 available from: <http://ccforum.com>
 4. Lasry A, Carter M, Zaric G. S4HARA: System for HIV/AIDS resource allocation. Cost Effectiveness and Resource Allocation 2008;6(1):7 available from: <http://www.resource-allocation.com/content/6/1/7>
 5. Lippert-Rasmussen K, Lauridsen S. Justice and the allocation of healthcare resources: should indirect, non-health effects count? Medicine, Health Care and Philosophy 2010;13(3):237-246 available from: <http://dx.doi.org/10.1007/s11019-010-9240-9>

MODULE 13 - ETHICS OF PUBLIC HEALTH AND HEALTH PROMOTION

*Omar Hasan Kasule Sr. MBChB (MUK),
MPH (Harvard), DPH (Harvard)*

13.1 OBJECTIVES OF THE MODULE

1. Concepts of good health, illness, family health, community health, public health, preventive medicine, and health promotion
2. Ethical issues in disease prevention versus disease treatment: Serious ethical, political, and economic issues
3. Concepts of equality and equity in health care
4. Ethical issues in priority setting in health care resource allocation
5. Ethical issues in epidemiological research
6. Ethics of disease screening
7. Ethics of contagious disease control
8. Ethics of smoking and drug addiction control
9. Ethical issues in vaccination
10. Ethical issues in disasters

13.2 CASE (ETHICAL SCENARIOS)

Case scenario 1: The body-mind duality

A patient presented to the clinic with vague abdominal complaints and worries about cancer. Physical examination and investigations revealed no pathology. The doctor was angry with the patient for wasting clinic time when he was in good health. As the patient was leaving, he told the doctor that his uncle had died the week before of stomach cancer. The doctor did not respond.

Case scenario 2: Disease versus illness

A young man who had been sent for a pre-employment examination filled out a health questionnaire and mentioned no health problems at all. Physical examination revealed a severely dislocated shoulder and an unhealed acromial fracture. When asked about them, he admitted that they caused him pain from time to time but that he was patient, and did not worry too much about these problems.

Case scenario 3: Mental basis of disease

A teenager was forcibly brought by her father to the clinic for severe anorexia. She was agitated and refused to talk to the doctor. She later opened up to the social worker and revealed that she was distressed, and that she had lost her appetite because of multiple conflicts in the family between her parents and among her three sisters.

Case scenario 4: Mental and social basis of physical disease

A suburban community of wealthy businessmen with good housing, health care, and educational and recreational facilities had the highest rates of suicide and illicit drug use in the whole district. A survey by the health department revealed no other health problems, but confirmed suicidal tendencies and illicit drug use.

Case scenario 5: Preventive versus curative medicine

A heated argument in the city council occurred between the Public Health Officer, who wanted to get funding for a community heart disease education program costing SAR 50,000 a year, and members of the council who wanted to allocate a higher budget to set up a coronary care unit costing SAR 5 million. Eventually the decision was made to set up the coronary care unit because of the votes of a majority of council members who were elderly, some of who had heart disease.

Case scenario 6: Health promotion

A large number of citizens who wanted to undertake physical exercise by walking and cycling convinced the city to allocate a large budget for construction of paths for cyclists and walkers. Some citizens were not happy with the huge budget allocation, saying that the benefit was not clear.

Case scenario 7: Controversy about childhood immunization

In a wealthy neighborhood of the city, professionals (including doctors) refused to take their children for measles vaccination, arguing that the side effects of the vaccine—though low overall—were much higher than the risk of measles, which had not been diagnosed in their community for the past 10 years. They also argued that their children went to neighborhood schools, and did not mix with children from areas where measles was endemic.

Case scenario 8: Autonomy versus benefit

Noticing a threefold increase in the diagnosis of late stage colon cancer that was fatal within a year, the city council passed a resolution requiring all men and women above 40 to undergo colonoscopic screening once every 5 years, with the warning that those who refused screening would not be treated for free if they got cancer.

Case scenario 9: Benefits of early disease screening versus suffering from false negative results

The city council introduced universal compulsory Pap smear screening for all women aged 20 and above. During the year, a false positive rate of 20% was found (i.e., women who were positive on Pap smear but negative on confirmatory biopsy). The mass media led a campaign to stop the screening program because cervical biopsy was found to be associated with many other problems.

Case scenario 10: Public versus individual interests and autonomy

The Ministry of Health ordered mass vaccination in a new flu virus epidemic that had just spread from a neighboring country. Citizens objected to vaccination without their consent.

Case scenario 11: Disclosure to protect others versus patients' right to privacy and confidentiality

A doctor examining a citizen returning from overseas found him positive for HIV. The doctor immediately looked up the man's home phone number in the telephone directory and informed the wife to take measures to avoid infection. The wife went to court and filed for divorce.

Case scenario 12: Public interest versus individual autonomy

A university research center developed a vaccine that, if given to teenagers, would prevent addiction to cigarettes by generating antibodies that would prevent the nicotine from crossing the blood-brain barrier. Realizing the potential benefit, The Ministry of Health passed a law making vaccination compulsory for all boys, but not for girls.

Case scenario 13: Prioritization of services in an emergency: Vulnerability versus social utility

A poisonous gas escaped from a factory in the city and only limited amounts of antidote were available. The city council held a meeting to decide priority targets for the antidote. The decision was taken to give the available doses only to emergency health workers.

Case scenario 14: Payment for unhealthy disease-causing lifestyles

The government introduced free universal health insurance for all citizens. Anti-smoking advocates objected to coverage of smoking-related diseases, saying that the smokers should pay for their health care since they deliberately exposed themselves to a risky lifestyle.

13.3 INTRODUCTION: BASIC CONCEPTS

The concept of health

Health is a positive state of being, not just the absence of disease. Individuals who are disease-free may not be healthy. The components of good health are spiritual health, physical, psychological, mental, and social health. These components have to be seen in a holistic way because Islam looks at health and all other aspects of life from a comprehensive and integrative perspective that derives from *tauhid* (توحيد). This holistic outlook can be described in several ways. First, the physical, social, spiritual, and mental aspects of each disease or illness must be recognized and dealt with accordingly. The disease of an organ or system must not be looked at in isolation; it must be seen as part of the whole body because the Prophet Mohammed (Peace Be Upon Him) taught that if any part of the body is sick, then the whole body is sick and suffering from insomnia or fever. An individual's disease must be seen from a family perspective because it impacts all members of the family. If a member of a family is sick, the rest of the family is emotionally and psychologically

affected. Illness in a family will impact on the community. Any sickness in the community will sooner or later have some negative impact on all its members.

The concept of illness

The definition of disease incorporates several dimensions that may operate singly or in combination: moral or spiritual, biological or pathological, and psychosocial or normative statistical. In general, disease is a state of disequilibrium, *khuruuj al badan 'an al i'tidaal* (خروج البدن عن الاعتدال). A distinction must be made between a disease as a pathological manifestation, and illness that is a subjective feeling. There is a two-way interaction between diseases of the heart, *amradh al qalb* (أمراض القلب), and diseases of the body, *amradh al badan* (أمراض البدن). The Islamic position is to approach most diseases empirically and to be guided by experimental science. Islam rejects superstitious beliefs and practices in all their various forms and manifestations.

The concept of family health

A healthy family promotes the health of all its members. There is no alternative to the family for bringing up children. The family teaches trust, loyalty, a sense of belonging, and rights and responsibilities. It is an economic unit and the main source of primary health care. It is a source of calmness and tranquility. Threats to the family include extra-marital sexual relations, neglect of family duties in pursuit of material goods, extreme individualism and self-interest, and bad socioeconomic circumstances. Dysfunctional families are not physically or psychologically healthy and have a long-term impact on the children. The causes of family dysfunction are multiple: economic pressures, a hedonistic lifestyle, and a decline of moral and religious values in society.

The concept of community health

The term community health covers private and public efforts of individuals, groups, and organizations to promote, protect, and preserve the health of those in the community. It involves community development, organization, participation, and diagnosis. Community health is affected by physical factors, such as geography, the environment, community size, industrial development, socio-cultural factors and beliefs, traditions, prejudices, economic status, politics, religion, social norms, individual behavior, and community organization. Whereas public health is government-driven, community health is community-driven. In both pre-history and the historical era, communities have undertaken measures to protect health. Before the 1980s, the emphasis was on public health. Later, the importance of community health and community participation were recognized. The Quran describes good and bad communities in the past. It describes communities that were punished or destroyed by Allah because of moral deviations. No community is destroyed or is punished until it receives a warning from Allah. Community diagnosis

consists of identifying and describing health problems in a community with a view to initiating public health interventions. Many communities are physically, socially, or mentally unhealthy. The underlying causes of poor community health are social and moral, such as social injustice, immorality, sexual promiscuity, overnutrition, and addiction to alcohol and drugs. Community health can be improved by having healthy individuals in the community, fulfilling communally obligatory functions, and establishing mutual cooperation and mutual complementation.

The concept of preventive medicine

Preventive medicine, *tibb wiqa'i* (الطب الوقائي), is covered under the Quranic concept of *wiqayat* (وقاية). Prevention is therefore one of the fixed laws of Allah in the universe and its application to medicine becomes obvious. The concept of prevention, *wiqayat*, does not involve claiming to know the future or the unseen, *ghaib* (غيب), or even trying to reverse fate, *qadar* (قدر). Using limited human knowledge, people attempt to extrapolate from the present situation and anticipate certain diseases for which preventive measures can be taken. Only Allah knows for sure whether the diseases will occur or not. Human beings use the knowledge of empirically established risk factors for particular diseases to predict disease risk. Preventive action usually involves alleviation or reversal of those risk factors.

The concept of health promotion

Most diseases can be prevented using spiritual approaches. These involve *aqidat* (عقيدات), *ibadat* (عبادات), avoiding *haram* (حرام) and promoting *halal* (حلال). Spiritual promotion at the community level involves enjoining the good and forbidding the evil. Physical health promotion at the individual level includes immunization, good nutrition, personal hygiene, and disinfection. Physical promotion at the community level involves environmental sanitation. Health promotion involves proactive measures that make health better, such as exercise, good nutrition, adequate rest, mental calmness, tranquility of family life, *iman* (إيمان), and spiritual calmness.

13.4 WHY ARE PUBLIC HEALTH ETHICS IMPORTANT?

Public health involves measures against disease and illness at a community level, in contrast to clinical medicine, which deals with disease and illness at an individual level. Its strategies and interventions have great ethical implications because they impact the whole community and many individuals can be affected and need protection. No intervention is purely beneficial, as there are always risks and side effects. Ethics requires maximizing benefits and minimizing risks. There are other ethical issues related to public health interventions that are important, such as autonomy and confidentiality. In

normal circumstances, public health interventions should not be carried out without informed consent, a basic right of autonomy. However, this may not be practical because it is not feasible to design individual-informed community-level interventions. A lot of private information is collected from individuals during public health interventions; this has to be kept secret, and should not be revealed to third parties without permission.

13.5 ETHICAL, LEGAL, AND POLICY ISSUES

Disease prevention versus disease treatment

A serious ethical, political, and economic debate surrounds the prioritization of resource allocation to preventive as opposed to curative care. The debate is not centered on the scientific evidence, which proves beyond a reasonable doubt that prevention of disease has better outcomes and is more cost-effective than cure. Primary prevention of disease by immunization will stop its occurrence altogether. Early detection and treatment of disease may result in complete cure or less complications. Preventive interventions are much cheaper than curative ones. For example, a measles immunization requires less than 10 minutes of a health worker's time and the vaccine costs less than SR50. This is minuscule compared to the cost of caring for a child with measles, who may stay in a hospital for several days to have pulmonary and other complications treated, some of which may have permanent consequences. The theory is that prevention should be given priority, but the practice does not reflect this. The health care systems of most countries are curative-oriented, with high technology hospitals consuming a high proportion of the health budget. The high expenditure on curative care has had less impact on the burden of disease than simple preventive measures, such as immunization, clean water, and sanitation.

Concepts of equality and equity in health care

The ideal of equality would be to provide the most advanced care available to every citizen. However, this is not possible for various practical reasons. Health care resources are limited, and some form of rationing must be put in place. Logistics do not allow for the provision of particular services in some places; for example, the facilities available in urban areas cannot be provided in rural areas for lack of the necessary infrastructure. Since public health resources are limited, citizens have to pay for some services. Those who are richer are able to enjoy a higher level of health care than the poor; these are the realities of life that health care providers cannot control. We therefore reach the inevitable but painful conclusion that perfect equality in health care is not possible. The only feasible alternative is to aim at equity, which is providing for each person the appropriate health care for his/her time, place, and social circumstances. Of course, this does not solve the problem because what is equitable is difficult to define and consensus is difficult to reach.

Ethical issues in priority setting in health resource allocation

Health care resources are limited, and some form of rationing and prioritization cannot be avoided. The practical problem is that it is not easy to reach agreement on the criteria of prioritization. Two issues relating to prioritizing allocation have been discussed above: preventive vs. curative care, and equality vs. equity. Other issues that arise are the rural vs. urban prioritization, prioritization of primary vs. tertiary care, and prioritization of the most vulnerable (children and women) versus the rest of society. Priorities are also considered for different disease or illness conditions. More resources tend to be allocated to acute conditions, such as trauma, rather than to chronic and endemic widespread conditions like headache. No rules on prioritization can be made to fit all situations. The best approach is to deal with each situation on its own merits, with the overall objective of maximizing benefit.

Ethical issues in epidemiological research

Many may think that epidemiological research based on questionnaires and records has no major ethical issues. This is far from the truth. Like all other forms of research, epidemiological research requires informed consent if personal data with identifiers are collected. The data must be kept confidential and should be reported only in aggregate. Informed consent is required to report any individual's data. Reporting of risk from epidemiological research may constitute an ethical dilemma because the general public may misunderstand the technical terminology used and adopt the wrong disease prevention behavior. Most such misunderstandings occur when risk is reported by the mass media.

Ethics of disease screening

A major ethical consideration before the start of any disease-screening program is to make sure that the benefits of the program far outweigh its side effects. To avoid exposing participants to unnecessary risks, the efficacy of the screening procedure must have been demonstrated by a proper trial. Informed consent must be obtained from participants, who must have full disclosure of the screening procedures to be used and their side effects, if any. Confidentiality must be maintained for all personal and other information collected during the screening. Additional ethical issues relate to the accuracy of the test. A false positive screening test will subject the participant to unnecessary risks of the confirmatory procedures. A false negative test will give the patient a sense of safety, and may lead them to ignore early symptoms of the disease. Whether screening should be undertaken for diseases that are untreatable also poses an ethical question because the patient has to live with the anxiety of a diagnosis for which medical science has no cure.

Ethics of contagious disease control

In an epidemic, the civil rights of citizens are restricted in the public interest. The following coercive measures are taken without seeking informed consent: quarantine, compulsory treatment, and compulsory immunization. When a communicable disease is diagnosed, the usual medical confidentiality is broken. Contact tracing and notification of authorities involve breaches of confidentiality that are justifiable in the public interest.

Smoking and drug addiction control

Addiction to nicotine, alcohol, and psychoactive drugs is a major social problem that underlies crime and family breakdown, and highlights the issue of personal autonomy versus public interest. It is therefore in the public interest that the autonomy and other civil rights of citizens be restricted. The sale of these drugs is restricted or criminalized. Smoking is restricted in public places to avoid exposing others to the risk of passive smoking. Drug addicts must be distinguished from the criminals who sell the drugs; the former are offered treatment and rehabilitation while the latter are punished by the law. A debated ethical issue with no easy resolution is whether diseases due to addiction to alcohol and drugs should be treated at public expense. Some people ask whether healthy members of society who live responsible lifestyles should subsidize via tax the health care of those who live risky lifestyles, and develop diseases such as lung cancer from smoking or cirrhosis from heavy drinking.

Ethical issues in vaccination

Vaccination, especially of young children, helps create herd immunity that will prevent spread of endemic and epidemic communicable diseases. Unless a sizeable number of children are vaccinated, the whole population is exposed to the risk of disease transmission. It is therefore compulsory, in Saudi Arabia, that all children get scheduled immunizations at the right times. However, this violates the autonomous rights of children and their parents, and is justifiable only on the basis of public interest. Parents who object to immunization of their children reason that the side effects and complications of immunization far outweigh the benefits because childhood communicable diseases have become rare, especially in developed countries or urban areas of developing countries. In this way, they put their personal interests before those of the community.

Ethical issues in disasters

In a man-made or natural disaster situation, decisions have to be made about treatment priorities. The process of triage is very difficult because many are in need, and the resources available cannot be stretched to help everybody. Generally, priority is given to the weakest members of society: children with

their mothers, and the elderly. The assumption here is that the more able-bodied can find help by themselves; however, this assumption is rarely true. Another approach used is to give priority to the more seriously injured because of their higher risk of mortality. The opposite approach is also used when priority is given to those less seriously injured, who are likely to survive their injuries. All these decisions become more difficult to make when we have to consider the short-term against the long-term effects of a disaster. Should interventions aim at relieving immediate suffering, or should they focus on the long-term implications? Some effective interventions may have to be restricted out of respect for local culture and customs.

13.6 RULINGS AND FATWAS ON THE TOPIC

It is always important to present a summary of the Islamic approach to ethical issues. A full chapter will be devoted solely to the Islamic approach to ethical analysis, so all you need is to give a summary from Fatwas that you are aware of.

This section will be done after the research assistant compiles the Fatwas

13.7 HOW TO IMPROVE YOUR PRACTICE

Whether in the hospital or the community, a medical practitioner must be aware of the ethical issues discussed above, and should have practical alternatives to apply when a disaster strikes.

13.8 CASE DISCUSSION

Case 1: The body-mind duality

Scenario: A patient presented to the clinic with vague abdominal complaints and worries about cancer. Physical examination and investigations revealed no pathology. The doctor was angry with the patient for wasting clinic time when he was in good health. As the patient was leaving, he told the doctor that his uncle had died the week before of stomach cancer. The doctor did not respond.

Hint: The doctor was wrong to ignore the patient's feelings, worries, and anxieties, which can occur in the absence of physical disease, and need to be addressed.

Case 2: Disease versus illness

Scenario: A young man who was sent for a pre-employment examination filled out a health questionnaire and mentioned no health problems at all. Physical examination revealed a severely dislocated shoulder and an unhealed acromial fracture. When asked about them, he admitted that they caused him

pain from time to time but that he was patient, and did not worry too much about these problems.

Hint: This case illustrates the difference between disease (a physical pathological anomaly) and illness (a subjective feeling). A person may feel ill but have no physical disorder, just as a person with a physical disorder may not complain of any illness.

Case 3: Mental basis of disease

Scenario: A teenager was forcibly brought by her father to the clinic for severe anorexia. She was agitated and refused to talk to the doctor. She later opened up to the social worker, revealing that she was distressed and had lost her appetite because of multiple conflicts in the family between her parents and among her three sisters.

Hint: This case illustrates how mental factors can lead to physical disease, and underlies the importance of a holistic outlook on health.

Case 4: Mental and social basis of physical disease

Scenario: A suburban community of wealthy businessmen with good housing, health care, and educational and recreational facilities had the highest rates of suicide and illicit drug use in the whole district. A survey by the health department revealed no other health problems, but confirmed suicidal tendencies and illicit drug use.

Hint: This case illustrates that social factors can damage good health.

Case 5: Preventive versus curative medicine

Scenario: A heated argument in the city council occurred between the Public Health Officer, who wanted to get funding for a community heart disease education program that would cost SR 50,000 a year, and members of the council, who wanted to allocate a higher budget to set up a coronary care unit costing SR 5 million. Eventually, the decision was made to set up the coronary care unit because of the votes of a majority of council members who were elderly, some of who had heart disease.

Hint: This case illustrates the dilemma of choosing between prevention and cure when allocating health resources. It also demonstrates that curative medicine usually wins out because of the preferences of powerful members of society.

Case 6: Health promotion

Scenario: A large number of citizens who wanted to undertake physical exercise by walking and cycling convinced the city to allocate a large budget for construction of paths for cyclists and walkers. Some citizens were not happy with the huge budget allocation, saying that the benefit was not clear.

Hint: This case illustrates the usual skepticism of the public concerning health promotion programs because their positive outcomes are not immediate and are not easily quantifiable.

Case 7: Controversy about childhood immunization

Scenario: In a wealthy neighborhood of the city, professionals (including doctors) refused to take their children for measles vaccination, arguing that the side effects of the vaccine—though low overall—were much higher than the risk of measles, which had not been diagnosed in their community for the past 10 years. They also argued that their children went to neighborhood schools, and did not mix with children from areas where measles was endemic.

Hint: This case illustrates the unethical attitude of putting personal interests before public interests. If everybody thinks only of his own interests, the whole community will suffer. In this case, the result may be a significant reduction of herd immunity eventually leading to epidemic spread of the infection.

Case 8: Autonomy versus benefit

Scenario: Noticing a 3-fold increase in diagnosis of late stage colon cancer that was fatal within a year, the city council passed a resolution requiring all men and women above 40 to undergo colonoscopic screening once every 5 years, with the warning that those who refused screening would not be treated for free if they got cancer.

Hint: This case illustrates the frustration of public health officials, who cannot implement effective evidence-based preventive measures because of refusal by the population. Coercion is not ethical in this case.

Case 9: Benefits of early disease screening versus suffering from false negative results

Scenario: The city council introduced universal compulsory Pap smear screening for all women aged 20 and above. During the year, a false positive rate of 20% was found (i.e., women who were positive on Pap smear but negative on confirmatory biopsy). The mass media led a campaign to stop the screening program because cervical biopsy was found to be associated with many other problems.

Hint: False negative findings are inevitable, but must be minimized. Too many false negative findings outweigh the benefits of screening and will eventually discourage participation by the public. False negative findings can be minimized by reviewing the performance characteristics of the test and the procedures followed.

Case 10: Public versus individual interests and autonomy

Scenario: The Ministry of Health ordered mass vaccination in a new flu virus epidemic that had just spread from a neighboring country. Citizens objected to vaccination without their consent.

Hint: Public interest takes precedence over private interest, and will override individual autonomy. In this case, compulsory vaccination is justified if there is strong scientific evidence for its effectiveness.

Case 11: Disclosure to protect others versus patients' right to privacy and confidentiality

Scenario: A doctor examining a citizen returning from overseas found him positive for HIV. The doctor immediately looked up the man's home phone number in the telephone directory and informed the wife to take measures to avoid infection. The wife went to court and filed for divorce.

Hint: The doctor had a duty to protect the wife and the family and this duty involves breach of confidentiality. The doctor's mistake was the method used, which ended up causing an unnecessary divorce. He was supposed to notify authorities with experience in contact tracing for infectious disease so that they could handle the matter professionally.

Case 12: Public interest versus individual autonomy

Scenario: A university research center developed a vaccine that, if given to teenagers, would prevent addiction to cigarettes by generating antibodies that would prevent the nicotine from crossing the blood-brain barrier. Realizing the potential benefit, the Ministry of Health passed a law making vaccination compulsory for all boys, but not for girls.

Hint: Although vaccination benefits the public by stopping addiction, it violates individual autonomy, especially of those who would not be exposed to drugs. The antibodies constitute a permanent change in the body that could have other, as yet unknown, effects.

Case 13: Prioritization of services in an emergency: Vulnerability versus social utility

Scenario: A poisonous gas escaped from a factory in the city and only limited amounts of antidote were available. The city council held a meeting to decide priority targets for the antidote. The decision was taken to give the available doses only to emergency health workers.

Hint: This case illustrates a common dilemma with no easy solution: do we give priority to the weakest and most vulnerable members of society (children, pregnant women, and the elderly) or those who are needed to work in an emergency (health care workers, security, etc.). The emotional reaction would favor vulnerability, whereas the rational reaction would favor utility.

Case 14: Payment for unhealthy disease-causing lifestyles

Scenario: The government introduced free universal health insurance for all citizens. Anti-smoking advocates objected to coverage of smoking-related diseases, saying that the smokers should pay for their health care since they deliberately exposed themselves to a risky lifestyle.

Hint: The principle of punishing victims of disease for their “sins” is not ethically tenable because of its selective application to smokers and not to other categories: e.g., over-eating, lack of exercise, poor oral hygiene, etc. The ethical approach would be for the insurance scheme to give incentives to those who quit smoking by reducing their premiums.

13.9 CONCLUSION AND SUMMARY

Ethical issues are as many and varied in public health as they are in clinical medicine. These issues have to be taken seriously because they affect the general public, not just individual patients.

1. The concept of good health is holistic, covering physical, family, community, and public health. It is a positive state of well-being, not just the absence of disease.
2. Disease prevention takes precedence over disease treatment.
3. In public health interventions, benefits must outweigh side effects.
4. Public interest takes precedence over individual interest.

13.10 REFERENCES AND SUGGESTED READINGS

Theories of ethics for public health

1. Lee LM. Public health ethics theory: review and path to convergence. *J Law Med Ethics* 2012;40(1):85-98.
2. Petrini C. Theoretical models and operational frameworks in public health ethics. *Int J Environ Res Public Health*. 2010 Jan;7(1):189-202.

Concepts of holistic health

1. Arandjelovic M. A need for holistic approach to the occupational health developing (in Serbia). *Int J Occup Med Environ Health*. 2011;24(3):229-40

Public versus private interest

1. Shickle D. The ethics of public health practice: balancing private and public interest within tobacco policy. *Br Med Bull* 2009;91:7-22.

Disease prevention versus disease treatment

1. Pinier M, Fuhrmann G, Verdu EF, Leroux JC. Prevention measures and exploratory pharmacological treatments of celiac disease. *Am J Gastroenterol* 2010;105(12):2551-61.

Concepts of equality and equity in health care

1. Odeyemi IA, Nixon J. Assessing equity in health care through the national health insurance schemes of Nigeria and Ghana: a review-based comparative analysis. *Int J Equity Health* 2013;12:9.

Priority setting in health resource allocation

1. Maluka SO. Strengthening fairness, transparency and accountability in health care priority setting at district level in Tanzania. *Glob Health Action* 2011;4.

Epidemiological research

1. Chin LJ, Rifai-Bashjawish H, Kleinert K, Saltman A, Leu CS, Klitzman R. HIV/AIDS research conducted in the developing world and sponsored by the developed world: reporting of research ethics committee review in two countries. *J Empir Res Hum Res Ethics* 2011;6(3):83-91.

Disease screening

1. Delatycki MB. The ethics of screening for disease. *Pathology* 2012;44(2):63-8.

Contagious disease control

1. Cheyette CM. Communitarianism and the ethics of communicable disease: some preliminary thoughts. *J Law Med Ethics* 2011;39(4):678-89.

Smoking and drug addiction control

1. Pentz RD, Berg CJ. Smoking and ethics: what are the duties of oncologists? *Oncologist* 2010;15(9):987-93.
2. Shaw D, McCluskey K, Linden W, Goodall C. Reducing the harmful effects of alcohol misuse: the ethics of sobriety testing in criminal justice. *J Med Ethics* 2012;38(11):669-71.

Vaccination

1. van Delden JJ, Ashcroft R, Dawson A, Marckmann G, Upshur R, Verweij MF. The ethics of mandatory vaccination against influenza for health care workers. *Vaccine* 2008;26(44):5562-6.

Disasters

1. Holt GR. Making difficult ethical decisions in patient care during natural disasters and other mass casualty events. *Otolaryngol Head Neck Surg* 2008;139(2):181-186.

MODULE 14 - ETHICS OF EMERGENCY MEDICINE

*Abdulaziz Fahad Al Kaabba, MBBS, JMHPE,
MHS_c, DCH, ABFM*

14.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will know:

1. What is the basis of emergency ethics
2. How often ethical issues happen in the Emergency Department
3. What are the ethical issues in the Emergency Department
4. How ethical dilemmas should be disclosed and solved in the Emergency Department
5. What are the important ethical issues related to emergencies

14.2 INTRODUCTION

Hospital Emergency Departments (ED), unlike other units, may not have private and semiprivate rooms to help protect privacy and confidentiality. EDs usually have treatment bays, most of which are separated only by curtains, and patients are placed close to one another for long periods of time. Several studies have reported frequent infringements of privacy and confidentiality in hospital. In the ED, lack of privacy and confidentiality make communication difficult between patients and health care providers, especially when they discuss sensitive medical conditions and important treatment options. It may result in health care providers making misdiagnoses or medical errors, and patients receiving ineffective treatments. All these issues may erode the patient's trust and make it difficult to build a good doctor-patient relationship.

Ethics is the study of the fundamental principles that define values and determine moral duties and obligations. The concept of "right and wrong" in medicine is not only a legal issue, but also one of social custom.

In studying ethical and professional issues, caring for patients in the ED presents several unique challenges. The nature of our environment forces us to become masters at gaining trust, building therapeutic alliances with strangers, and helping guide patients to make difficult decisions rapidly. Emergency physicians have a unique opportunity to model their behaviors to exemplify the moral duties of the medical profession.

During a disaster, clinicians will ask themselves, "How will I resolve the issues facing me now?" as they struggle with the desperate demands of their patients and the obligations of their profession (American Medical Association, 2004). In these settings, the needs of the individual patient will often be in conflict with the needs of the community, and ethical conflicts will emerge in all phases of the disaster response. Advanced disaster training and emergency medical preparation must include planning and preparedness for sound ethical decision making in a time of crisis.

National and international health care organizations have outlined recommendations for emergency disaster plans. These plans often include mitigation. Preparedness, response, and recovery phases all mandate frequent drills by responders. An effective response should be rapidly put together, and integrated between communities, law enforcement, public health officials, and health care facilities.

14.3 WHY IS ETHICS IMPORTANT FOR EMERGENCY MEDICINE?

The study of ethical practices in emergency medicine is important as it relates to ethical principles, as well as affecting patients and Emergency Department staff. Treatment decisions are not based solely on medical information, and a truly "right" answer does not exist in every clinical situation. There are many reasons why ethical issues in emergency situations are different compared to other clinical situations. The place, and the timing, of consultation is often very different in emergency situations, and may not allow for many routine issues, such as privacy, documentation, confidentiality, and the relationship between the doctor and his patient.

Development of ethical and professional behaviors requires an understanding of basic ethical principles. Culture and religion also play an important role in ethics, especially in emergency cases. As clinical experience is gained, skills gradually develop and the practitioner incorporates new experiences into the framework of decision making. Beauchamp and Childress proposed a standard approach to medical ethics that includes the following four principles: beneficence, non-maleficence, respect of autonomy, and justice. Together with patient privacy and confidentiality, these principles help to guide our discussions and actions when making decisions with patients regarding their care, especially in emergency cases.

14.4 ETHICAL AND LEGAL ISSUES

1. During the management of patients in the Emergency Department, occasionally we break routine norms during an examination of our patients (male doctors may examine female patients).
2. Patient privacy and confidentiality may also have to be disregarded. In life-threatening cases, we can expose patients to a more or less public physical examination and also ask questions of a confidential nature.
3. In extreme cases, consent must be assumed without permission either from the patient (for example in coma) or a close relative.
4. Respect for autonomy and decision-making capacity are abilities that help in the understanding of the nature and consequences of medical care; this information is the basis by which decisions are made and communicated. In addition to a patient's decision-making capacity, the

patient must be free from coercion or outside influence. He or she should possess a set of values and goals necessary for evaluating the different options and be able to make decisions accordingly.

5. Beneficence is the concept of acting in the best interest of the patient or "doing good."
6. Non-maleficence dictates that we "do no harm."
7. Justice is an important ethical principle, and should prescribe actions that are fair to those involved. We have a duty to treat all fairly, distributing the risks and benefits equally. Patients in similar situations should be offered similar care unless extenuating circumstances are involved, such as for emergency cases.

14.5 ISLAMIC VIEWS ON THIS TOPIC

The Islamic Code emphasizes that the health care provider should provide first aid and emergency care to his/her patients as fast and as professionally as he/she can. The aim of to benefit the patient, and avoiding harming them, within the following guidelines:

1. The health care provider should reach the patient as fast as possible.
2. The health care provider should introduce himself and his job to the patient if the patient is conscious; if he/she is not conscious, the health care provider should start doing his job immediately.
3. The health care provider should respect his/her patient, work to benefit him/her, asking for permission, if applicable, following the Islamic guidance in terms of body exposure.
4. In life-saving conditions, the health care provider can apply life-saving interventions without the prior permission of the patient or a proxy, if gaining permission before treating would be more likely to jeopardize the patient's life.
5. The health care provider should do his/her best to relieve the patient's pain using all available means, and to support and reassure the patient's family.
6. In case of mass casualties, priority should be given to those in the most dire conditions, though the practitioner should work on being fair to his/her patients. They should not prioritize one patient over another based on the patient's social or financial rank, or the providers' feelings towards them.
7. Doctors should accelerate the admission of the patients who need the most care, so they are not left for a long time in the Emergency Department.
8. The health care provider should comply with the international guidelines and standards in the care of emergency situations.

14.6 WHY EMERGENCY CASES ARE DIFFERENT

Emergency cases are different compared to routine clinical cases. These points of difference are as follows:

1. There are many reasons why ethics in emergency situations are different from other clinical situations. The place of treatment is different and usually has not been prepared to accommodate routine requirements (privacy, confidentiality of patients' medical records, relationship between physician and patient.)
2. The time in an emergency situation is short and hurried. Therefore, emergency staff must apply ethical principles in simpler ways to meet the demands of emergency situations.
3. In emergencies, medical cases need special approaches to deal with history taking, physical examination, and also informed consent and other ethical issues.
4. Emergency staff training on ethical dilemmas is different than training of other medical staff training; this will affect patients' treatment in emergency situations.

14.7 CASE (ETHICAL SCENARIOS)

Case scenario 1

A 30-year-old female comes to the Emergency Department at midnight with a history of severe right lower abdominal pain for three days with vomiting and low-grade fever. She asks to be seen by a female physician in the ED where there are no females available; the patient shouts that she should only be examined by a female physician. How do we deal with this?

Case scenario 2

Three men were in a recent road traffic accident and were brought into the triage area of the Emergency Department, with no privacy cloths. Two of them were stable with minor injuries and bruises, the third one was in a bad situation (A 25-year-old man with difficulty in breathing, severe bleeding, and low blood pressure). When the men were brought to the ED, it was crowded with other patients and there were no beds available. How would you handle this situation?

14.8 THE ETHICAL ISSUES RELATED TO EMERGENCY: HOW TO IMPROVE YOUR PRACTICE

Professionalism

The emergency staff should practice professionalism in emergency areas. Physicians, nurses, and technicians should be professional when dealing with and managing all patients, starting with patient registration, reassurance of patients, and good handling of cases. The emergency staff should look smart,

dress well, and have a good attitude. They should also wear lab coats and gloves, if needed, during patient examination. The ED staff should not discuss care issues with family members unless the patient agrees to it. Patients should be aware of and respect the duties of the emergency staff.

Emergency staff relations with patients

Emergency physicians and nurses should respect patients' rights during the triage, administration, and management processes. They should display good attitudes to the patients. The patients should also understand the duties of the emergency staff, and treat them respectfully. The health care team is responsible for accommodating informed patient desires and, ideally, ensuring a mutually respectful encounter. Emergency physicians must realize that negative judgment and condemnation serve no goal; rather, they sever any respectful, trusting relationship. Medicine is not a transaction; it is a relationship.

Privacy of the patients

This is one of the most important ethical issues in emergency situations. We should respect the privacy of the patients and the separation of males from females during examinations. The emergency staff should ask for permission if they want to physically examine the patient, and should explain to the patient that the emergency area is different from other areas of the hospital. Sometimes, there may be no female staff available and a patient could be examined either by a male or female physician, according to the situation at hand. All of this should be taken into consideration, and the privacy of the patients should not be jeopardized.

Triage in ER cases

Triaging emergency patients should be carried out ethically according to the severity and emergency of the case, and regardless of nationality, race, gender, or position. The more severe the case, the more priority should be given to it. During the triage, we should also respect the patient's privacy, anxiety, and demands. We should explain to them with full respect about these triage and administrative processes.

Confidentiality of information and files

Because of the way the emergency area is set up, it is easy for the patient's confidentiality to be broken. Therefore, emergency staff should be aware of this, and be mindful of all aspects of patients' confidentiality (refer to Module 8) on papers, files, and during discussions with other staff.

Emergency staff should perceive the importance of confidentiality in every situation, and must consult patients first if their information needs to be

released to relatives. For example, if the patient has a communicable disease or has psychiatric problems, one must inform the patient about his/her case and explain to him/her in a proper scientific way.

Honesty

Being honest and respectful with colleagues, as well as patients, is paramount, but reminders are still needed. In an effort to protect one's ego or advance personal interests, honesty is still sometimes threatened. It is necessary to always be fully and openly honest, even if negative consequences are possible. Admitting, "Sorry, I did not complete that yet, but I will do it immediately," then following through, is the way to build trust and respect.

Truth telling

At the core of any successful doctor-patient interaction is trust. Integrity and honesty are necessary to achieve the trust of our patients. Without full honesty, the trust that is needed for a therapeutic relationship is unobtainable. Patients do not expect perfection in their care providers, but do need to know that their physician is reliable and trustworthy. Patients may overtly express a lack of trust in medical students. The student who reminds the patient that he or she is there as an addition to the care team, ideally as a patient advocate and aid, can quickly gain trust and acceptance. During more risky interventions, such as invasive procedures, the trainee must balance eagerness to perform skills with safety and proper supervision.

Equal resource distribution

The higher authorities and hospital heads should ensure the emergency areas are well-equipped and well-organized with all the machines and equipment needed. Equal resource distribution of equipment and good bed management between all emergency areas is an important issue in emergency management. These provisions should not only be for tertiary hospitals, but also for small hospitals in the country as well.

How to break bad news

Emergency staff should be trained and aware of how to deal with patients and emergency cases during the management cycle. They should know how to deal with breaking bad news to patients. They should respect the patient's situation and gradually and honestly inform the patient about his/her situation in a professional scientific manner.

Examinations of opposite gender (male to female patient or female to male patient)

The emergency department (ED) is unlike any other departments or units, as most of the emergency areas have semiprivate rooms to help protect the

privacy, confidentiality, and other ethical rights of the patient. During patient examination, emergency staff should explain to patients that they will be managed according to the situation at hand, and if there is no female staff available to examine female patients then patients should accept, and agree to, that condition. It should be noted that in Islam, and in other religions, it is acceptable that in emergencies females or males can treat either gender.

14.9 CASE DISCUSSION

Case 1

This is a real emergency case with ethical issues:

A. This is severe abdominal pain with vomiting so it's a real emergency case and needs urgent emergency intervention.

B. There are two ethical emergency issues, which are as follows:

1. She needs to be examined by female staff but there is no female staff,
2. She shouts and doesn't respect the emergency staff.

C. The emergency staff should explain to the patient with respect that her case is a real emergency, which it is midnight, and there is no female staff available. Therefore, she needs to be examined by an experienced physician for her sake, since it is an emergency. The other issue is that the ED staff should explain to her and her relative that the Islamic religion accepts that males can examine females in an emergency situation. The ED staff should also respect the patient when she shouts because she is in pain and is anxious. The ED staff should tell her that if her condition becomes stable, she could go to another hospital where she might be able to be treated by female staff.

Case 2

A. This case represents a real emergency scenario. The ED was crowded, there were no beds available, and there was no privacy for the men.

B. There are some ethical issues, which are as follows:

1. Bed availability for emergency cases
2. Priority of triaging the case
3. Privacy of these patients

C. The emergency physician in charge and his staff should quickly deal with this situation in a professional way, using the following steps:

1. The emergency staff should quickly triage the patients with full privacy. They should also reassure them about their situations and their privacies.

2. The third case should be treated very quickly and admitted with full care. The ED staff should also rearrange the bed resources in the Emergency Department.
3. The ED should contain a special reserved bed, which is kept vacant for serious emergency cases.

14.10 CONCLUSION AND SUMMARY

The Emergency Department is different from other hospital divisions in that it does not contain private rooms; rather, it may comprise semiprivate rooms that help protect patients' privacy, confidentiality, and other ethical rights.

Emergency physicians constantly encounter ethical decisions and face ethical dilemmas during their practice, and therefore should respect the Islamic culture. Our responsibility is to recognize these dilemmas and act appropriately according to the needs of emergency cases. In order to do this, it is essential to consider these ethical problems prior to encountering them, and learn how to deal with them as the culture sometimes necessitates. Otherwise, frustration and bewilderment will arise and will complicate an already difficult situation, to the detriment of our patients. Ethical knowledge better equips emergency physicians to make the best possible decision in difficult circumstances. Ultimately, understanding these issues, being familiar with societal/professional norms, and applying these principles to the ethical dilemmas in our practice will benefit our patients.

Although often overshadowed by the urgency to acquire and use medical knowledge, ethics and professionalism play essential roles in our professional lives. Difficult situations arise each day; some of the hardest decisions are ethical dilemmas. It is essential to gain insights to legal and ethical principles, understanding them deeply rather than superficially. Aristotle noted that ethics is a rough and tumble business, which cannot be understood just by thought and reflection, but requires action, decisions, and implementation in the real world. Nowhere is this truer than in the Emergency Department, where goals, values, decisions, and urgency of time can collide. We must train our residents and medical students to deal with these emergency ethical dilemmas.

14.11 REFERENCES AND SUGGESTED READINGS

1. AAMC professionalism task force, 1998. Accessed at www.aamc.org, November 2006.
 2. Adams J, Schmidt T, Sanders A, Larkin GL, Knopp R. Professionalism in emergency medicine. Acad Emerg Med 1998;5:1193-9.
 3. American Medical Association. Core Disaster Life Support, Provider Manual, version 2.0. Chicago IL: American Medical Association 2004
-

4. American Public Health Association. Guiding Principles for a Public Health Response to Terrorism. Washington, DC: American Public Health Association 2002
[\(http://www.apha.org/united/phresponseterrorism.htm\)](http://www.apha.org/united/phresponseterrorism.htm); Accessed 8 September 2006.
5. Applebaum P, Grisso T. Assessing patients' capacities to consent to treatment. *N Engl J Med* 1988;319:1635-1638.
6. Beauchamp T, Childress J. *Principles of biomedical ethics*, 5th ed. Oxford: Oxford University Press 2001.
7. Beauchamp T, Childress J. *Principles of Biomedical Ethics*, 5th ed. New York: Oxford University Press 2001.
8. Emergency Medicine. Professionalism in emergency medicine. *Acad Emerg Med* 1998;5:1193-1199.
9. Gruber MA, Pierre J, Charlton M. Patient opinions and attitudes toward medical student procedures in the emergency department. *Acad Emerg Med* 2003;10:1329-1333.
10. Knopp R. The challenges of teaching professionalism [comment]. *Ann Emerg Med* 2006;48:538-539.
11. SAEM Task Force on Physician-Patient Communication. Physician-patient communication in the emergency department, part 2: Communication strategies for specific situations. *Acad Emerg Med* 1996;3:1146-53.
12. Thomas HA, Beeson MS, Binder LS, et al. The 2005 model for the clinical practice of emergency medicine: the 2007 update. *Acad Emerg Med* 2008;15:776-9.
13. Williams CT, Fost N. Ethical considerations surrounding first time procedures: a study and analysis of patient attitudes toward spinal taps by students. *Kennedy Inst Ethics J* 1992;2:217-231.

MODULE 15 - HOW TO RESOLVE ETHICAL ISSUES IN CLINICAL PRACTICE

Ghaiath MA Hussein, MBBS, MHSc (Bioethics)
&

Omar Hasan Kasule Sr. MBChB (MUK),
MPH (Harvard), DrPH (Harvard)

15.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. Identify different approaches to identify, analyze, and resolve ethical issues encountered in clinical practice
2. Be familiar with the Islamic principle-based approach to medically relevant Fatwas
3. Utilize at least one of the approaches to identify, analyze, and present an approach to the ethical issues encountered during clinical practice

15.2 CASE (ETHICAL SCENARIO)

Batoul is a 36-year-old Saudi lady. She is the mother of two children aged 8 and 10, and is now pregnant in her 15th week of gestation with a normal and viable fetus. Two weeks ago, a huge ovarian mass (19 × 12 cm) was discovered, and was found to be a cystoadenocarcinoma with features of metastasis.

Since the patient is a candidate for chemotherapy, the oncology board of the hospital recommended the termination of pregnancy. Three consultants, including her following obstetrician and an oncologist, approved this recommendation. However, the patient did not accept that the pregnancy would have to be terminated. Accordingly, the husband was approached; he approved and signed the consent on her behalf.

Batoul felt terribly upset about what had happened, and refused to start the chemotherapy. The case was submitted to the ethics committee of the hospital.

15.3 INTRODUCTION

Bioethics is the art of defining, analyzing, and resolving ethical issues encountered during health care practice. There are two major components to this process. First, bioethics presents the different ethical theories, principles, and values according to which (health-related) acts are considered ethically justifiable. Secondly, it presents practical guidance for practitioners and policy makers through a set of tools and frameworks that help them reach an ethically justifiable decision.

The aims of this module are to present examples of how bioethics helps clinicians to approach the ethical issues they face in their practice. We need tools for ethical analysis to ensure that we do not miss any information or any possible factor that could affect the decisions we take. It is important to emphasize that this module does not endorse any of these tools/frameworks as the tools to resolve the ethical issues. These frameworks were developed

by ethicists and clinicians to help in analyzing ethical matters in a systematic way, in the hope that they can help to achieve ethically defendable decisions.

Who and what affects ethical decision making?

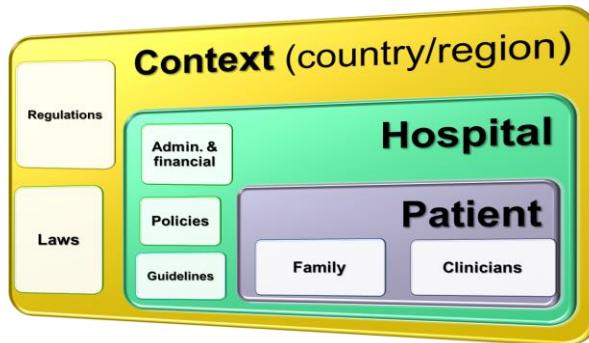


Figure 15.1 Factors affecting ethical decision making

The Clinical Ethics Committees (CECs)

The roles of the CECs are summarized in figure 15.2. These are committees formed of clinical and non-clinical personnel to discuss ethical issues that staff faces during their practice. These issues may relate to their interaction and inter-team disagreements or, more often, disagreements between the team and the patient and/or his/her family.

It is important to note that CECs have different authorities and affiliations in different settings. Sometimes they decide on what to do on behalf of the hospital. However, this is not their usual role. Usually, the main role of these committees is to facilitate communication between the team and the patient's family, to reach a common understanding. In other instances, they provide recommendations rather than decisions. In any case, they refer to particular policies or guidelines to justify their recommendation.



Figure 15.2 Steps in ethical decision making

The four boxes(quadrants) model

This is an ethical analysis tool. It mainly aims at providing the necessary information about a case in order to decide on the ethical issues being discussed.

<p>Medical Indications:</p> <p>Consider each medical condition and its proposed treatment. Ask the following questions:</p> <ul style="list-style-type: none"> • Does it fulfill any of the goals of medicine? • With what likelihood? • If not, is the proposed treatment futile? 	<p>Patient Preferences:</p> <p>Address the following:</p> <ul style="list-style-type: none"> • What does the patient want? • Does the patient have the capacity to decide? If not, who will decide for the patient? • Do the patient's wishes reflect a process that is informed? Understood? Voluntary?
<p>Quality of Life:</p> <p>Patient's quality of life in the patient's terms.</p> <ul style="list-style-type: none"> • What is the patient's subjective acceptance of likely quality of life? • What are the views of the care providers about the quality of life? • Is quality of life "less than minimal"? 	<p>Contextual Features:</p> <p>Social, legal, economic, and institutional circumstances in the case that can influence the decision,</p> <ul style="list-style-type: none"> • be influenced by the decision; e.g., inability to pay for treatment, inadequate social support.

It is crucial to utilize this tool to differentiate between facts and values (personal judgments). Sometimes we mix both, thus we cannot decide fairly. For example, read the following two sentences in which a physician explains the clinical state of his patient to the CEC to decide on an ethical issue related to one of his patients:

"This patient is an old patient. He is over 70. He has a terrible hepatomegaly. He has got a very nasty hepatocarcinoma. I think giving him a liver transplant is a mere waste of resources."

"This is a 73-year-old patient, with an enlarged liver of 12 cm below the right costal margin, which is tender on examination. He thought he could be considered a candidate for liver transplant."

The first statement uses subjective descriptions, probably based on the physician's perception of the case, like "old patient," "nasty," and "mere waste." The second is more objective, and would be more helpful in assessing the medical condition of the patient.

The CLEO approach

CLEO stands for Clinical, Legal, Ethical, and Organizational features of the case being discussed. The main feature of each is summarized in this matrix.

Clinical Diagnoses: Irreversible? Progressive? Permanent? Prognoses: Disabling? Terminal? Clinicians' level of certainty?	Legal Legally required process for treatment decision making when a patient lacks capacity to do so Family involvement: Who to involve? When and how are substitute treatment decisions to be made?
Ethical The patient's will, desires, perception of life, relationship with their family? What cultural or religious beliefs are involved? Family's stand: Why? To show their fidelity to the patient and/or deal with their individual and collective sadness/shock/grief? No longer sure what is really going on or who to trust	Organizational Any institutional pressures to avoid having a bed blocked by someone whose recovery will be long and slow, or the benefits seemingly small? Any other health care facilities better able to provide palliative/rehabilitative care for longer periods of time? Any different views as to diagnosis, prognosis, next steps among the team or other physicians?

A principle-based framework/Process for ethical decision making

The following principle-based framework/process for ethical decision making is grounded in the Mission, Vision, and Values of the institution.

Steps for resolving ethical dilemmas:

1. **Identify the problem:** Name the problem clearly. Where is the conflict?
2. **Acknowledge feelings:** What are the "gut" reactions? Biases? Loyalties?
3. **Gather the facts:**
 - a. What are the ethically relevant facts?
 - b. Whose account of the facts counts?
 - c. Have all the relevant perspectives been obtained?
 - d. **What do the institution's policies or guidelines say?**
 - e. **What does the relevant law say?** (Legal information is not the same as legal advice, which is the application of law to an individual's specific circumstances. We recommend that if you want professional legal advice, you consult a lawyer in a subject area that is appropriate to your particular situation).

✓ Facts in biomedical ethics issues include:

• Diagnosis/Prognosis	• Quality of Life
• Patient /SDM Wishes	• Contextual Features - e.g., religion, culture, psycho-social issues, relationships

✓ **Facts in business/organizational ethics issues include:**

• Governance	• Partnerships	• Allocation/Rationing of Scarce Resources
• Conscientious Objection	• Employer/Employee Relationships	• Conflict of Interest
• Alternative Sources of Revenue	• Abuse of Care Providers	• Whistle-blowing

4. **Consider alternatives:** What are the alternative courses of action? What are the likely consequences?
 5. **Examine values:** What are the preferences of the person receiving care? Are other values relevant? Which of these values conflict?
 6. **Evaluate alternatives:** Identify appropriate decision makers. Rank all relevant values i.e., values of the institution: human dignity, compassion, pride of achievement, community of service, and social responsibility. These values are derived from and relate to values set out in the CHAC Health Ethics Guide: i.e., the dignity of every human being and the interconnectedness of every human being. They also provide the basis for the ethical values of autonomy, beneficence/non-maleficence, and justice.
Justify ranking by appealing to principles as set out in the SCHS Ethics Guide. Some examples of these principles are as follows:
 - **principle of totality** (a holistic perspective of the human person and/or the institution),
 - **principle of double effect** (cannot intentionally desire to cause harm in order to do good),
 - **principle that the benefits must be equal to, or greater than, the burden/harm, principle of legitimate cooperation** (cannot intentionally cooperate with immoral acts),
 - **principle of subsidiarity**, (decisions should be taken as close to the grass roots as possible),
 - **principle of informed choice, principle of confidentiality.**
 - Evaluate the consequences in terms of principles. What alternatives are excluded?
 7. **Articulate the decision:** Which alternative best reflects the ranking of values? Which alternative best balances more of the values? Have any other alternatives come to light?
 8. **Implement the plan:** How should the decision be communicated? Who needs to know it? How best to document the process? Who needs to act?
 9. **Concluding review:** What are the feelings of those involved?
-

A structured approach to case consultation

1. What are the relevant clinical and other facts (e.g., family dynamics, GP support availability)?
2. What would constitute an appropriate decision-making process?
 - Who is to be held responsible?
 - When does the decision have to be made?
 - Who should be involved?
 - What are the procedural rules e.g., confidentiality?
3. List the available options.
4. What are the morally significant features of each option? For example:
 - What does the patient want to happen?
 - Is the patient competent?
 - If the patient is not competent, what is in his or her "best interests"?
 - What are the foreseeable consequences of each option?
5. What does the law/guidance say about each of these options?
6. For each realistic option, identify the moral arguments in favor and against.
7. Choose an option based on your judgment of the relative merits of these arguments using the following tools:
 - Are there any key terms the meaning of which need to be agreed, e.g., "best interest," "person"?
 - Are the arguments valid?
 - Consider the foreseeable consequences (local and more broad)
 - Do the options "respect persons"?
 - What would be the implications of this decision applied as a general rule?
 - How does this case compare with other cases?
8. Identify the strongest counter-argument to the option you have chosen.
9. Can you rebut this argument? What are your reasons?
10. Make a decision.
11. Review this decision in the light of what actually happens, and learn from it.

15.4 AN ISLAMIC PRINCIPLE-BASED APPROACH

Summary of Islamic Analysis



Figure 15.3 Summary of a Fiqh-based Islamic approach to ethical analysis. Reproduced with permission from a lecture by Professor Omar Hasan Kasule Sr. for 4th Year Medical Students Faculty of Medicine King Fahad Medical City Riyadh on March 12th 2012

Stages of rational systematic problem solving¹

1. Analysis of the environment
2. Recognition of the problem
3. Identification of the problem
4. Determination of the ownership of the problem
5. Definition of the problem
6. Classification of the problem
7. Prioritizing the problem
8. Collection of information
9. Making assumptions and forecasts
10. Generating decision alternatives
11. Apply laws, Fatwa and principles
12. Selection of the best alternative
13. Analysis of the impact of the chosen alternative
14. Implementation, control of the implementation
15. Evaluation of the results.

Authoritative sources

At the national/international levels

- The Mufti of the Kingdom of Saudi Arabia (مفتي المملكة)
- The Grand Ulama Authority (هيئة كبار العلماء)

¹ Reproduced with permission from Prof. Omar H. Kasule, Sr. Read the full article on this link: <http://omarkasule.tripod.com/id220.html>

- The Fiqh Academy of the Organization of the Islamic Cooperation (الاكاديمية الفقهية لمنظمة التعاون الإسلامي)
- The Fiqh Academy of the World Muslim League (الاكاديمية الفقهية لرابطة العالم الإسلامي)

Local level

- Ethics Committee in the Hospital
- Local Scholar

Existing laws and regulations

- Code of Medical Ethics by the Saudi Commission for Health Specialties
- Health Professions Practice Regulations by the Saudi Commission for Health Specialties

مقاصد الشريعة - Solutions using the goals of Sharia (Maqasid Al-Sharia)

Most of the ethical/Fiqhi issues related to clinical care result from the recent advancements in health care; for example, assisted reproduction, organ donation, etc. This explains why it is difficult to find clear, straightforward scripts (nass) in the Quran or Sunnah about these issues. This does not imply that these texts have shortcomings, as they were not intended to be medical books. However, they are extremely useful in informing us about the methodologies that were used by the Fiqhi scholars in reaching their judgments, mainly through the process of Ijtihad, which we clarified earlier.

The following sections describe the basis on which the scholarly judgments and opinions (Fatwas) were developed.

Protection of faith (diin)

Protection of diin essentially involves ibadat, in the broad sense that every human endeavor is a form of ibadat. Thus, medical treatment makes a direct contribution to ibadat by protecting and promoting good health, so that the worshipper will have the energy to undertake all the responsibilities of ibadat. The principal forms of physical worship of 4 of the 5 pillars of Islam are prayer (*salat*), fasting (*siyaam*), (*Zakaat*)¹, and pilgrimage (*hajj*). A sick or weak body cannot perform any of them properly. Balanced mental health is necessary for

¹ Zakat literally means "to be clear, to grow, to increase." Usually, it refers to the payment made annually (at the rate of 2.5% each lunar year) under Islamic law on certain kinds of property and used for charitable and religious purposes, one of the Five Pillars of Islam (Oxford Dictionary, 2014; Hidayah Foundation, 2014).

understanding aqidat (عقيدة) and avoiding false ideas that violate aqidat. Thus, medical treatment of mental disorders contributes to ibadat.

Protection of life, hifdh al nafs (حفظ النفس)

The primary purpose of medicine is to fulfill the second purpose of the Sharia, the preservation of life, hifdh al nafs. Medicine cannot prevent or postpone death, since such matters are in the hands of Allah alone. However, it tries to maintain as high a quality of life as possible until the appointed time of death arrives. Medicine contributes to the preservation and continuation of life by making sure that the nutritional functions are well-maintained. Medical knowledge is used in the prevention of disease that impairs human health. Disease treatment and rehabilitation lead to better quality health.

Protection of progeny, hifdh al nasi (حفظ النسل)

Medicine contributes to the fulfillment of this function by making sure that children are cared for well, so that they grow into healthy adults who can bear children. Treatment of infertility ensures successful childbearing. Care for pregnant women, perinatal medicine, and pediatric medicine all ensure that children are born and grow healthy. Intra-partum care, and infant and childcare ensure the survival of healthy children.

Protection of the mind, hifdh al 'aql (حفظ العقل)

Medical treatment plays a very important role in the protection of the mind. Treatment of physical illnesses removes stress that can affect mental state. Treatment of neuroses and psychoses restores intellectual and emotional functions. Medical treatment of alcohol and drug abuse prevents deterioration of the intellect.

Protection of wealth, hifdh al mal (حفظ المال)

The wealth of any community depends on the productive activities of its healthy citizens. Medicine contributes to wealth generation by prevention of disease, promotion of health, and treatment of diseases and their consequences. Communities with generally poor health are less productive than healthy vibrant communities. In cases of terminal illness, the principles of protection of life and protection of wealth may conflict. Care for the terminally ill consumes a lot of resources that could be used to treat other persons with treatable conditions. Questions related to whether the effort to protect life is worth the cost, and the issue of opportunity cost and equitable resource distribution, arise in these cases.

Solutions from principles of the law, Qawaaid Al Fiqh (قواعد الفقه)

The principle of intention

The principle of intention comprises several sub-principles. The sub-principle that "Each action is judged by the intention behind it" calls upon the physician

to consult his inner conscience and make sure that his actions, seen or not seen, are based on good intentions. The sub-principle "What matters is the intention and not the letter of the law" rejects the wrong use of data to justify wrong or immoral actions. The sub-principle that "Means are judged with the same criteria as the intentions" implies that no useful medical purpose can be achieved by using immoral methods.

The principle of certainty, qaidat al yaqeen (فَاعِدَةُ الْيَقِين)

Medical diagnosis cannot reach the legal standard of yaqeen. Treatment decisions are best made on a balance of probabilities. Each diagnosis is treated as a working diagnosis that is changed and refined as new information emerges. This provides for stability and a situation of quasi-certainty, without which practical procedures will be made reluctantly and inefficiently. Existing assertions should continue in force until there is compelling evidence to change them. Established medical procedures and protocols are treated as customs or precedents. What has been accepted as customary for a long time is not considered harmful unless there is evidence to the contrary. All medical procedures are considered permissible unless there is evidence to prove their prohibition. Exceptions to this rule are conditions related to the sexual and reproductive functions. All matters related to the sexual function are presumed forbidden unless there is evidence to prove permissibility.

The principle of injury, qaidat al dharar (فَاعِدَةُ الضرر)

Medical intervention is justified on the basic principle that injury, if it occurs, should be relieved. An injury should not be relieved by a medical procedure that leads to an injury of the same magnitude as a side effect. In a situation in which the proposed medical intervention has side effects, we follow the principle that prevention of a harm has priority over pursuit of a benefit of equal worth. If the benefit has far more importance and worth than the prevention of harm, then the pursuit of the benefit has priority. Physicians are sometimes confronted with medical interventions that are double-edged: they have both prohibited and permitted effects. The guidance of the Law is that the prohibited has priority of recognition over the permitted if the two occur together and a choice has to be made. If confronted with two medical situations, both of which are harmful, and there is no way to choose among them, the lesser harm is committed. A lesser harm is committed in order to prevent a bigger harm. In the same way, medical interventions in the public interest have priority over consideration of individual interest. The individual may have to sustain harm in order to protect public interest. In the course of combating communicable diseases, the state cannot infringe the rights of the public unless there is a public benefit to be achieved. In many situations, the line between benefit and injury is so fine that salat al istikharat (صلوة الاستخاراة) is needed to reach a solution, since no empirical methods can be used.

فَعْدَةٌ // المُشَاقَّةُ (Principle of hardship, qaidat al mashaqqat)

Medical interventions that would otherwise be prohibited actions are permitted under the principle of hardship if they are necessary. Necessity legalizes the prohibited. In a medical setting, a hardship is defined as any condition that will seriously impair physical and mental health if not relieved promptly. Hardship mitigates easing of the Sharia rules and obligations. Committing the otherwise prohibited action should not extend beyond the limits needed to preserve the Purpose of the Law that is the basis of the legalization. However, necessity does not permanently abrogate the patient's rights, which must be restored or recompensed in due course; necessity only legalizes temporary violation of rights. The temporary legalization of prohibited medical action ends with the termination of the necessity that justified it in the first place. This can be stated alternately: If the obstacle ends, enforcement of the prohibited resumes. It is illegal to get out of a difficulty by delegating to someone else to undertake a harmful act.

فَعْدَةٌ // الْعُرْفُ (The principle of custom or precedent, qaidat al urf)

The standard of medical care is defined by custom. The basic principle is that custom or precedent has legal force. What is considered customary is what is uniform, widespread, predominant, and common. The customary must also be an older, rather than a recent phenomenon, to allow the chance for a medical consensus to be formed.

15.5 WHY IS UTILIZING ETHICAL FRAMEWORKS IMPORTANT TO YOUR PRACTICE

Ethical frameworks do almost exactly the same work that the clinical guidelines and algorithms do. They help the ethicists the same way the clinical guidelines help clinicians, which is by framing a logical flow through a number of questions to derive a set of facts, which are measured against a set of values and principles, with the aim of arriving at an ethically defendable decision or recommendation.

Without frameworks and tools for analysis, ethics would seem to be a field of endless arguments, which are based on mere personal perceptions, and which ignore the facts.

15.6 ETHICAL, LEGAL, AND POLICY IMPLICATIONS

Ethically, health care providers, as individuals and institutions (i.e., hospitals) are obliged to provide the best care to their beneficiaries, mainly patients. This is to fulfill their respect to their patients' autonomy by keeping them informed, as well as giving them the chance to know how decisions are made and to contest them, if they find them unfair.

From a legal perspective, Islamic laws should guide clinicians' practices and the overall policies of hospitals. These tools and approaches help clinicians, patients, and hospitals in clarifying who has which right, in order that these rights are respected. Though many of the decisions taken by clinicians and hospitals are usually guided by clinical evidence, there are many instances where this evidence is not clear, not relevant, or not sufficient. This is where the role of the Legal-Fiqhi-Medical Committees, which are under the MOH, become important. These are constituted from judges (to represent the judiciary/Fiqhi aspects) and doctors of different specialties, who represent the medical side. Together they use these approaches (and perhaps others as well) to reach their decisions. It is important to note that some decisions may have major implications for the clinicians involved, like payment of fines, revoking professional registration, or even spending time in jail.

The policy implications of utilizing these frameworks arise from the ethical and legal commitments of health care facilities to provide the best service to their beneficiaries; not only from a technical perspective, but also to meet ethical and professional standards. These approaches provide guidance to hospitals on how to develop guidelines and policies that can help practitioners in approaching, analyzing, and deciding on the ethical issues they encounter.

15.7 HOW DO YOU USE ETHICAL ANALYSIS TOOLS AND FRAMEWORKS IN YOUR PRACTICE

Though it is usually the job of the ethics committees in your institution to go through this process, it is important that clinicians and practitioners understand how ethical issues are resolved, for two main reasons. First, there may not be an ethics committee in your hospital to which you can refer. The ethics committees in many hospitals are just starting, and some were formed only for the purpose of being accredited. In some hospitals, ethical issues are discussed by different departments; for example, the patient's affairs, patient's relations, quality assurance, and medical errors committees. Second, because of the overall shortage in staff with professional training and degrees in bioethics, there is the possibility that you become an ethics committee member by virtue of your clinical practice. You would then need to know how ethics committees function, in order to have a better input in the committees on which you sit.

These tools and frameworks are usable in many ways in your practice, and not necessarily only at the ethics committee level.

15.8 CASE DISCUSSION

There could be different approaches to this case, but we will only present the Islamic approach to ethical analysis. This is just an example, and different scholars may come up with different conclusions. You can compare the other models to see if you come up with the conclusions produced by the Islamic approach.

What are the goals of Sharia involved?

Goal	Application to the case
Preserving Religion	<ul style="list-style-type: none"> If this lady receives the chemotherapy, she would be more physically fit to practice her religious requirements. The patient may consider remaining without treatment in order to seek more rewards on her patience (endurance). Some scholars consider that seeking medical help is not always a must.
Preserving Soul/Life	<ul style="list-style-type: none"> Abortion will terminate the baby's life (depending on the reference of ensoulment - نفخ الروح). However, the reverse view is that the mother's soul and body may be seriously damaged, if not totally lost, if the termination does not take place.
Preserving Mind	<ul style="list-style-type: none"> Receiving chemotherapy may prevent the cancer from metastasis to the brain. Abortion against her may cause her depression and further psychological complications.
Preserving Progeny/Lineage	<ul style="list-style-type: none"> Abortion would stop this goal temporarily. She may be able to have further children.
Preserving Money	<ul style="list-style-type: none"> The costs of keeping her in the hospital for two conditions (pregnancy and cancer) are higher than if she was treated only for cancer. Not receiving the chemotherapy is only cheaper in the short-term, as the complications of the condition after delivery will be much more expensive.
Sub-conclusion	<ul style="list-style-type: none"> At the level of Sharia goals, termination of pregnancy seems favorable, if her consent is given voluntarily.

1. Principle of intention: Deeds are judged by intentions	
<ul style="list-style-type: none"> Sub-principle: Means are morally judged as the ends 	<ul style="list-style-type: none"> Medically-induced abortion for a genuine medical need/cause is justifiable, given that the primary intention is not killing a soul. Though the ultimate goal of abortion is legal, it should not be obtained through an illegal means, i.e., taken against her will.
Sub-conclusion: Unless voluntary consent is given, the procedure should not be carried out.	

2. The principle of certainty (Yaqeen)	
Sub-principle	Application to the case
• Certainty is not removed by doubt	The certainty that the mother will be seriously affected, or dead, versus the certainty about the loss of the fetus' life, if ensoulment took place. There is also the issue of certainty of the effectiveness of chemotherapy.
• What is proved by evidence is valid - until denied by contrary evidence	The available scientific evidence implies that there is high potential to harm the fetus if s/he is exposed to the chemotherapy, or to harm the mother, if she does not receive it. This will remain the case, until contradictory evidence appears to say, for example, that the fetus's development will not be affected by the chemotherapy.
• The rule in deeds is permission unless stated otherwise	Seeking cure from cancer is permissible, but abortion is not, unless there are genuine excuses (refer to the module on Reproductive Health).
• The rule in violating the 5 goals is restriction/prohibition	In net balance, it could be argued that in the mother's case, abortion serves more Sharia goals than it breaches.
Sub-conclusion: The treating team needs to provide more valid probabilities for both options (i.e., leave her untreated until delivery, or terminating at this phase).	

3. The principle of Injury/Harm (Dharar): Injury should be relieved	
• Harm is relieved as much as possible	Termination of pregnancy at this stage helps in relieving harm caused by disease.
• An individual should not harm others or be harmed by others	The harm here needs to be measured against her psychological, not just her bodily, needs.
• Among evils, the lesser harm is committed	Termination of pregnancy (if she accepts this) seems to be of lesser harm.
• Prevention of harm has priority over pursuit of a benefit of equal worth	Protecting fetuses and women is prior to seeking treatments.
• Harm is never the rule/norm	We shouldn't leave the sick people sick.
Sub-conclusion: The harm of termination is more justifiable (tolerated) than the harm of leaving the mother untreated.	

4. The principle of Hardship (Mashaqqat): Difficulty calls forth ease	
• Necessity legalizes the prohibited	These two sub-principles apply to the option of saving the patient's life by terminating the fetus's potential for life. No more aggressive interventions should be carried out unless necessary for her treatment.
• Necessities are judged by magnitude	
• Necessities do not overcome others' rights	Women should give consent to any operation on their organs or tissues.

Sub-conclusion: The malignancy she has is a hardship that would permit the termination of pregnancy, assuming that the necessary conditions-including her acceptance-are fulfilled.

5. The principle of Custom (Urf)	
• Customs are recognized	Customs in medical care are clinical guidelines. In this case, they are suggestive of termination.
• Only the known customs, not the rare ones, are recognized	SOPs, GCP, and other evidence-based resources are the only recognized references.
• Judgments can be changed by circumstances	Permissibility of acts related to termination may vary according to the development in practices. In other words, we cannot generalize and assume that termination is necessary in all such similar cases, as there may be future developments in the field.

From the above analysis, which may seem complicated, we arrive at the conclusion that terminating the pregnancy at this gestational age is permissible. The patient's refusal is most probably due to the way in which the decision was taken, rather than the decision itself. Sometimes doctors lack the necessary communication skills to convey treatment choices to their patients. Since the patient is competent to take the decision, bypassing her to seek her husband's approval is ethically and professionally unacceptable. Moreover, it may be legally troublesome. The husband may have other reasons to terminate this pregnancy other than seeking his wife's cure. Thus, we need to be careful, patient (endurance), and seek proper help if we feel we are failing to communicate with the patient.

15.9 CONCLUSION AND SUMMARY

This module focused on the modalities of ethical analysis using tools and frameworks developed by practitioners and ethicists to ensure, as far as possible, that they have the facts needed to give a recommendation or take a decision.

These tools and frameworks are meant to be comprehensive, easy to use, and flexible in order to be used in different settings by different professionals. However, they do not usually lead to the same conclusions. As we have explained, other factors are usually considered, including policies, local customs, and the country's laws.

1. Decisions about ethical issues are not as subjective as they might seem.
 2. There are tools and frameworks that have been developed to help ethics committees analyze ethical cases in order to reach the fairest decision.
 3. The use of these different tools is not meant to generate a set of similar conclusions.
 4. There are other factors (social, professional, and legal) that also play a role in the ethical decision-making process.
-

15.10 REFERENCES AND SUGGESTED READINGS

1. A case-based approach to ethical decision-making, Adapted from Jonsen, Albert, Siegler, Mark and Winslade, William. Clinical Ethics, 7th edition. McGraw-Hill, 2010. URL: <http://depts.washington.edu/bioethx/tools/4boxes.html>
2. La Puma, John and Schiedermayer, David. "Ethics Consultation: Skills, Roles and Training." *Annals of Internal Medicine* 114.2 (1991): 155-60.
3. La Puma, John, Schiedermayer, David and Marshall, Mary Faith. "Ethics Consultation: a Practical Guide." Springer, (1994). V 163-69.
4. Singer, Peter A., Pellegrino, Edmund D. and Siegler, Mark. "Clinical ethics revisited." *BMC Medical Ethics* 2.1 (2001): 1.
5. Sokol, D. K. "The "four quadrants" approach to clinical ethics case analysis; an application and review." *Journal of Medical Ethics* 34.7 (2008): 513-16.
6. Weijer, Charles. "The ethical analysis of risk." *The Journal of Law, Medicine & Ethics* 28.4 (2000): 344-61.

MODULE 16 - ETHICAL ISSUES IN REPRODUCTIVE HEALTH

*Omar Hasan Kasule Sr. MBChB (MUK),
MPH (Harvard), DrPH (Harvard)*

16.1 OBJECTIVES OF THE MODULE

By the end of this module, the resident will be able to:

1. List the ethico-legal issues involved in assisted reproduction
2. Explain the ethico-legal issues of various methods of contraception
3. List the potential ethical issues in human reproductive cloning
4. Explain the ethico-legal issues in pregnancy termination
5. Describe and explain the ethico-legal issues in gender selection
6. Evaluate the ethico-legal issues in gender change/gender correction operations (gender reassignment surgery)
7. Describe the ethical issues in menopausal fertility and hormonal replacement
8. Describe the issues of onco-fertility

16.2 CASE (ETHICAL SCENARIOS)

Case scenario 1

An infertile couple was in the midst of an IVF procedure when the husband died soon after his semen was frozen. The wife wanted to obtain the semen and have a baby by a surrogate mother. A former wife also wanted the semen because she had a girl with leukemia who needed a compatible bone marrow donor, preferably a sister.

Case scenario 2

A recently married woman continued taking oral contraceptives prescribed for menstrual irregularities. Her husband wanted his wife to discontinue her contraception because he wanted to start a family immediately, but the wife refused.

Case scenario 3

A 14-year-old girl was admitted to the hospital for an abortion. She was two months pregnant from what she claimed was rape. The family was distraught and wanted the doctors to carry out the abortion immediately. The physicians were reluctant because there was no medical reason for the abortion.

Case scenario 4

A couple that had eight girls in successive pregnancies desperately wished for a boy. They decided to try IVF with selection of male gametes. The obstetricians refused because there was no medical indication, since the couple had no problem in conceiving.

Case scenario 5

A child whose external appearance was female, and who had been brought up as a girl, was taken to the hospital at 14 years of age because of delayed

menstruation. The internal gonads and chromosomal patterns were male. The parents wanted a gender reassignment operation to conform to the genetic profile. The child refused to change from her familiar female identity.

Case scenario 6

A middle-aged woman without any medical condition asked her physician for hormonal treatment to appear younger. The physician refused because he judged the risk of cardiovascular and cancer complications to be greater than the benefits.

Case scenario 7

A 14-year-old girl with cancer requiring chemotherapy was advised to have her ova removed and put in cold storage for the duration of the treatment. Her parents refused the procedure because they did not believe in IVF, and because the girl was not yet married.

16.3 INTRODUCTION OF BASIC CONCEPTS

Infertility

Infertility is the inability to reproduce naturally, and is a problem that concerns both males and females. The causes may be with the male, the female, or both. Infertility is defined as failure of conception in a healthy couple with regular sexual intercourse over a specific period, usually of one year. Like any human disease, it is a problem that requires a diagnosis and treatment because of the associated psychological stress.

Assisted reproduction

This is the use of medical or surgical management to enable fertilization and conception to take place. It may take the form of introducing the male sperm into the female reproductive tract, resulting in fertilization in the fallopian tubes (in vivo insemination). It may also involve fertilizing the female ovum with male sperms outside the body, and introducing the resulting gamete to grow in the uterine cavity (in vitro fertilization, IVF).

Contraception

The use of medical or surgical procedures to prevent pregnancy in a couple that have regular sexual intercourse. Contraception methods are available for males and females.

Reproductive cloning

This is a controversial technology that attempts to reproduce a human by implanting a nucleus in a denucleated ovum. The resulting human has the genetic characteristics of the donor of the nucleus. Cloning technology can

also be used to produce organs and tissues that are used to replace damaged organs and tissues.

Abortion or pregnancy termination

This is a medical or surgical procedure to cause termination of a pregnancy before the fetus is viable to continue living. Some forms of abortion are legal and others are not, depending on the jurisdiction.

Gender selection

An antenatal procedure to select a fetus with the desired gender.

Gender change

This involves both medical and surgical management to resolve problems of indeterminate gender. Some of these procedures are also used to change the gender of transsexuals or those with a psychological problem of gender identity.

Menopause

This is the time near the end of the woman's fertile life, when menstruation stops due to hormonal changes. This period is characterized by several medical problems caused by hormonal imbalances.

16.4 WHY IS KNOWING ABOUT THE ETHICAL ISSUES IN ASSISTED REPRODUCTION IMPORTANT?

Reproduction is a deeply felt human instinct regarding the survival of the human race and individual immortality achieved through the offspring. It also has strongly associated religious and cultural values. These values give rise to ethical issues when they conflict with personal choices or certain measures dictated by medical necessity.

16.5 ETHICAL, LEGAL, AND POLICY ISSUES

Assisted reproduction

In vivo insemination is ethically acceptable if it is done by consent of both husband and wife and the sperm is inserted into a legally married wife.

In vitro fertilization requires consent by a husband and wife who are legally married at the time of the fertilization. Sperm and ovum donation are not allowed because of violation of the principle of preserving lineage, *hifdh al-nasab* (حفظ النسب). Sperm banks are not allowed because this would mix up the lineage.

Couples in whom assisted reproduction fails have several alternatives to fulfill

the natural desire for parenthood, such as foster care of orphaned children. If all these alternatives fail, they can fall back on prayer and acts of devotion.

Assisted reproduction is associated with several ethico-legal issues that have been discussed by lawyers. It is not allowed to use sperm or ova from a dead spouse because that would lead to an out-of-wedlock birth. The marital relationship is terminated at the death of either spouse. In a similar way, preserved ova or sperm cannot be used after dissolution of the marriage by divorce. Illegal procedures involving ova or sperm donation or sale, as well as surrogate motherhood, may result in paternity disputes. Usually, paternity or maternity disputes are decided on the basis of genetics.

Excess embryos from IVF procedures have human life and cannot be destroyed. They also cannot be stored forever because of the costs involved. Legal experts have permitted their use in scientific research if it can be proven to lead to better medical care.

Gender selection can be made so that only embryos of the desired gender are implanted. However, legal experts have frowned on this procedure because it involves destruction of the life of the ova that are not used. Genetic analysis to select only embryos that are free from disease also raises an ethical issue, since this also leads to destruction of the life of diseased embryos.

One of the undesirable consequences of IVF is multiple pregnancy, sometimes with three or more fetuses that will not be viable because of very premature delivery. Use of the procedure of selective fetal reduction raises an ethical issue because it involves literally killing some embryos so that the remainder may survive.

There are other procedures that are forbidden because they violate human dignity, such as developing embryos for purposes other than use in assisted reproduction; for example, mixing gametes of different couples to confuse biological parentage, commercial trading in ova, sperms, and gametes, and use of gametes from cadavers.

Contraception

The desire to reproduce is a basic human instinct prevented by contraception. Marriage and reproduction are obligatory, *wajib* (واجب), to ensure continuation of the community. Contraception as a compulsory community policy is not permitted. Contraception is *mubaah* (مباح) or *mustahabb* (مستحب) for an individual couple who have the choice to reproduce or not.

According to the Prophet, contraception by coitus interruptus is permissible. Decisions on contraception must be based by mutual consent between the

husband and wife. If the life and health of the wife will be endangered by pregnancy, the husband's consent to contraception is not required.

The choice of the method of contraception must be based on the *Sharia* (شريعة). Irreversible sterilization is generally forbidden, but there is no consensus among legal experts on sterilization.

The permissible reversible methods for males are the condom, coitus saxonius (consisting of squeezing the urethra at the base of the penis immediately prior to ejaculation), coitus reservatus (deliberate delaying or avoidance of orgasm during intercourse), and coitus interruptus (sexual intercourse deliberately interrupted by withdrawal of the penis from the vagina prior to ejaculation).

Permissible reversible methods for females are either mechanical (the diaphragm, the cervical cap, or the vaginal sponge) or chemical/hormonal (spermicides and oral contraceptive pills). Some forms of IUD are not permitted because they cause early abortion. The safest and perhaps the least effective is the rhythm method.

Availability of safe and easily obtainable contraception removes the fear of pregnancy and encourages sexual promiscuity and temporary sexual unions devoid of childbearing responsibilities. The physician must exercise due judgment before prescribing contraceptives to make sure that there are no immoral consequences.

Widespread use of contraception in the community has other undesirable consequences. Population imbalances by age and by gender may result. Widespread acceptance of contraception is a slippery slope that may make it easier for the community to accept genocide due to decreased respect for human life.

Human reproductive cloning

Reproductive cloning has been achieved in animals but has not been attempted in humans. It is a form of asexual reproduction without natural conception by a man and a woman. The Islamic tradition discourages legal speculation on matters that have not yet occurred. We therefore cannot engage in detailed hypothetical discussion of reproductive cloning until it occurs and we see its implications in practice. These may include loss of human dignity, violation of the identity of the lineage, and criminal misuse of the technology.

Legal experts have permitted tissue and organ cloning because of the benefits of transplantation to treat some diseases. Care must be taken to monitor side effects, such as the development of new diseases as a side effect of cloning.

Abortion

Induction of medical or surgical pregnancy termination can be carried out for medical or social reasons. Medical reasons for pregnancy termination usually relate to a grave risk to the mother's life and health if the pregnancy continues. Social reasons are usually associated with "unwanted pregnancy." "Unwanted pregnancy" is associated with general social determinants (hedonistic lifestyles, sexual transgression, addiction to drugs, fear of poverty, and low female status) and specific antecedent causes (sexual crimes, egoistic greed, maternal/fetal disease, and gender discrimination).

Termination because of medical reasons has few associated ethical issues. In cases of serious maternal disease, abortion is the lesser of two evils because one life is lost instead of two. Termination because of social reasons creates several ethical dilemmas, since it is destruction of life without a compelling necessity, *dharurat* (ضرورات). Legal experts differ in their interpretation of *dharurat*; while some allow termination for congenital anomalies and pregnancy from rape, others consider all termination as prohibited.

Legal experts also disagree about when termination is allowed for social reasons. Some consider fertilization as the start of life, which makes any termination unlawful. Others consider ensoulment¹ *nafakh al ruh* (نفخ الروح), at gestation age 120 days as the start of life, and are more liberal in permitting termination before 120 days.

Some legal experts prohibit termination for social reasons on the basis that it will encourage immorality in society by removing the fear of unwanted childbirth among those engaging in illegal sexual intercourse.

Whether legal or illegal, in all forms of abortion the aborted fetus must be treated with respect. It must be washed, shrouded, and buried properly.

The law prescribes severe punitive measures for causing abortion of a fetus. *Diya* (ديمة) is paid if the fetus comes out with signs of life and dies thereafter. *Ghurrat* (الغررة), which is less than *diya*, is paid if the fetus comes out dead.

¹ Ensoulment is a religious concept referring to the moment at which a human being gains a soul

The physician or any other accessory to abortion is guilty of the offense of causing abortion even if either or both parents consented to the procedure.

Gender selection

The desire to have children of a particular gender is a very human one. Some parents attempt to influence the gender of their baby, but some of the methods used give rise to ethical problems. Natural methods with no ethical implications are generally not effective and include selecting days of copulation before and after ovulation, and changing upper vaginal chemistry artificially.

There is no consensus on use of artificial methods, which include separation of male sperms by centrifuging and in vitro insemination, gender pre-selection and implanting only zygotes of the desired gender with in vitro fertilization, or gender change by genetic engineering, exposure of fetuses to specific hormones to produce the desired phenotype, and gender reassignment operations.

Gender correction/change operations

To make a person more male, or more female, changes can be made to their external appearance using surgery and hormones. These may constitute gender correction procedures or gender change procedures.

Gender correction procedures are allowed for those with an indeterminate gender, for example when someone has both male and female anatomical and physiological characteristics. The decision to make the person male or female is based on the underlying genotype or the predominant gender, which is assessed anatomically, functionally, or as a result of socialization. Some procedures may be carried out for the sole purpose of correcting anatomical anomalies to enable copulation and reproduction.

Gender change procedures carried out on persons with normal anatomical features, but who psychologically desire to be the opposite gender are generally frowned upon by legal experts. Victims of such gender identity conflict should be counseled to accept their anatomical gender.

Menopause

Women coming to the end of their reproductive life experience many health problems because of hormonal changes and imbalances. Hormonal replacement therapy (HRT) can help many of the problems of menopause, but it poses a risk of breast and other types of cancer. The ethical dilemma is how to balance the benefits of HRT with its risks. In the final analysis, the decision

is made on a case-by-case basis. Following the decision to use HRT, close monitoring is ethically required for early signs and symptoms of cancer.

Onco-fertility

Cancer treatment by radiotherapy and chemotherapy may adversely affect reproductive function. It is therefore recommended that ova and semen be withdrawn and stored in cold storage before treatment. They can be retrieved after treatment and used in IVF procedures to ensure childbearing for cancer victims.

16.6 CASE DISCUSSION

Case 1

An infertile couple was in the midst of an IVF procedure when the husband died soon after his semen was frozen. The wife wanted to obtain the semen and have a baby by a surrogate mother. A former wife also wanted the semen because she had a girl with leukemia who needed a compatible bone marrow donor, preferably a sister.

Hint: paternity outside wedlock is not permitted.

Case 2

A recently married woman continued taking oral contraceptives prescribed for menstrual irregularities. Her husband wanted his wife to discontinue her contraception because he wanted to start a family immediately, but the wife refused.

Hint: mutual consent required for contraception.

Case 3

A 14-year-old girl was admitted to hospital for an abortion. She was two months pregnant from what she claimed was rape. The family was distraught and wanted the doctors to carry out the abortion immediately. The physicians were reluctant because there was no medical reason.

Hint: preservation of life takes precedence over other considerations.

Case 4

A couple that had eight girls in successive pregnancies desperately wished for a boy. They decided to try IVF with selection of male gametes. The obstetricians refused because there was no medical indication, since the couple had no problem in conceiving.

Hint: compare risk of IVF versus benefit of desired gender.

Case 5

A child whose external appearance was female and who had been brought up as a girl was taken to hospital at 14 years of age because of delayed

menstruation. The internal gonads and chromosomal patterns were male. The parents wanted a gender change operation to conform to the genetic profile. The child refused to change from her familiar female identity.

Hint: right of autonomy and choice for a competent minor.

Case 6

A middle-aged woman without any medical condition asked her physician for hormonal treatment to appear younger. The physician refused because he judged the risk of cardiovascular and cancer complications to outweigh the benefits.

Hint: consider risk versus benefit.

Case 7

A 14-year-old girl with cancer requiring chemotherapy was advised to have her ova removed and put in cold storage for the duration of the treatment. Her parents refused the procedure because they did not believe in IVF, and she was not yet married.

Hint: consider risk versus benefit.

16.7 REFERENCES AND SUGGESTED READINGS

Assisted reproduction

1. Chatzinkolaou N. The ethics of assisted reproduction. J Reprod Immunol 2010;85(1):3-8.
2. Klein JU, Sauer MV. Ethics in egg donation: past, present, and future. Semin Reprod Med 2010;28(4):322-8.
3. Lockwood GM. Social egg freezing: the prospect of reproductive 'immortality' or a dangerous delusion? Reprod Biomed Online 2011;23(3):334-40.
4. Nakhuda GS. Posthumous assisted reproduction. Semin Reprod Med 2010;28(4):329-35
5. Scientific Advisory Committee of the Royal College of Obstetricians and Gynaecologists. Multiple pregnancy following assisted reproduction. Hum Fertil (Camb) 2011;14(1):3-7.
6. Whittaker A. Cross-border assisted reproduction care in Asia: implications for access, equity and regulations. Reprod Health Matters. 2011;19(37):107-16.

Contraception

1. Böttcher B, Radenbach K, Wildt L, Hinney B. Hormonal contraception and depression: a survey of the present state of knowledge. Arch Gynecol Obstet 2012;286(1):231-6.
 2. Gordon CM, Pitts SA. Approach to the adolescent requesting contraception. J Clin Endocrinol Metab 2012;97(1):9-15.
-

3. Gourdy P. Diabetes and oral contraception. Best Pract Res Clin Endocrinol Metab 2013;27(1):67-76.
4. Guillemette T, Yount SM. Contraception and antiepileptic drugs. J Midwifery Womens Health 2012;57(3):290-5.
5. Lalitkumar PG, Berger C, Gemzell-Danielsson K. Emergency contraception. Best Pract Res Clin Endocrinol Metab 2013;27(1):91-101.
6. Lalude OO. Risk of cardiovascular events with hormonal contraception: insights from the Danish cohort study. Curr Cardiol Rep 2013;15(7):374.
7. Plantz D, Lantos JD. Conscience, clinical ethics, and emergency contraception. Adolesc Med State Art Rev 2011;22(2):175-82, vii.
8. Shah MB, Hoffstetter S. Contraception and sexuality. Minerva Ginecol 2010;62(4):331-47.
9. Tolaymat LL, Kaunitz AM. Use of hormonal contraception in adolescents: skeletal health issues. Curr Opin Obstet Gynecol 2009;21(5):396-401.
10. Ziglar S, Hunter TS. The effect of hormonal oral contraception on acquisition of peak bone mineral density of adolescents and young women. J Pharm Pract 2012;25(3):331-40.

Reproductive cloning

1. Havstad JC. Human reproductive cloning: a conflict of liberties. Bioethics 2010;24(2):71-7.
2. Sparrow R. Therapeutic cloning and reproductive liberty. J Med Philos. 2009;34(2):102-18.

Abortion

1. Charles VE, Polis CB, Sridhara SK, Blum RW. Abortion and long-term mental health outcomes: a systematic review of the evidence. Contraception 2008;78(6):436-50.
 2. Davis AR, Beasley AD. Abortion in adolescents: epidemiology, confidentiality and methods. Curr Opin Obstet Gynecol 2009;21(5):390-5.
 3. Kirkman M, Rowe H, Hardiman A, Mallett S, Rosenthal D. Reasons women give for abortion: a review of the literature. Arch Womens Ment Health 2009;12(6):365-78.
 4. Mavroforou A, Koumantakis E, Michalodimitrakis E. Do men have rights in abortion? The Greek view. Med Law 2010;29(1):77-85.
 5. Nie JB. Non-medical sex-selective abortion in China: ethical and public policy issues in the context of 40 million missing females. Br Med Bull 2011;98:7-20.
-

6. Stotland NL. Induced abortion and adolescent mental health. *Curr Opin Obstet Gynecol* 2011;23(5):340-3.

Gender selection

1. Kalfoglou AL, Kammersell M, Philpott S, Dahl E. Ethical arguments for and against sperm sorting for non-medical sex selection: a review. *Reprod Biomed Online* 2013;26(3):231-9.
2. Leung JL, Pang SM. Ethical analysis of non-medical fetal ultrasound. *Nurs Ethics* 2009;16(5):637-46.
3. Macklin R. The ethics of sex selection and family balancing. *Semin Reprod Med* 2010;28(4):315-21.
4. Nie JB. Non-medical sex-selective abortion in China: ethical and public policy issues in the context of 40 million missing females. *Br Med Bull* 2011;98:7-20.
5. Strange H. Non-medical sex selection: ethical issues. *Br Med Bull*. 2010;94:7-20. Cesagen (ESRC centre for economic and social aspects of genomics).

Gender change

1. Sandberg DE, Gardner M, Cohen-Kettenis PT. Psychological aspects of the treatment of patients with disorders of sex development. *Semin Reprod Med* 2012;30(5):443-52.
2. Selvaggi G, Bellringer J. Gender reassignment surgery: an overview. *Nat Rev Urol* 2011;8(5):274-82.
3. Sohn M, Bosinski HA. Gender identity disorders: diagnostic and surgical aspects. *J Sex Med* 2007;4(5):1193-207; Quiz 1208.
4. Sutcliffe PA, Dixon S, Akehurst RL, Wilkinson A, Shippam A, White S, Richards R, Caddy CM. Evaluation of surgical procedures for sex reassignment: a systematic review. *J Plast Reconstr Aesthet Surg* 2009;62(3):294-306; Discussion 306-8.

Menopause

1. Lobo RA. The risk of stroke in postmenopausal women receiving hormonal therapy. *Climacteric* 2009;12 Suppl 1:81-5.
2. Narod SA. Hormone replacement therapy and the risk of breast cancer. *Nat Rev Clin Oncol* 2011;8(11):669-76.
3. Pitkin J. Cultural issues and the menopause. *Menopause Int* 2010;16(4):156-61.
4. Stevenson JC. A woman's journey through the reproductive, transitional and postmenopausal periods of life: impact on cardiovascular and musculo-skeletal risk and the role of estrogen replacement. *Maturitas* 2011;70(2):197-205.

5. Yang XP, Reckelhoff JF. Estrogen, hormonal replacement therapy and cardiovascular disease. *Curr Opin Nephrol Hypertens* 2011;20(2):133-8.

Onco-fertility

1. Schwarz EB, Hess R, Trussell J. Contraception for cancer survivors. *J Gen Intern Med* 2009;24 Suppl 2:S401-6.
2. Sönmez M, Oktay K. Assisted reproduction and fertility preservation techniques in cancer patients. *Curr Opin Endocrinol Diabetes Obes* 2008;15(6):514-22.

MODULE 17 - ORGAN TRANSPLANT AND DONATION

*Abdulaziz Fahad Al Kaabba, MBBS, JMHPE,
MHS_c, DCH, ABFM*

17.1 OBJECTIVES OF THE MODULE

At the end of this module the resident should know the:

1. Significance of organ transplantation and the Islamic perspective on this issue.
2. Definition of organ transplantation and why it is important.
3. Ethical issues related to global organ transplantation.
4. Existing guidelines, possible practical solutions, and conclusions of organ transplantation and organ trafficking.

17.2 INTRODUCTION

In the modern world, there have been many medical developments to improve the quality of life. One of the most significant improvements in health care has been the advent of organ transplantation. Organ transplantation is both a life-extending and a life-saving medical procedure in which a whole or partial organ (or cells in cell therapy) from a deceased or living person is transplanted into another individual, replacing the recipient's non-functioning organ with the donor's functioning organ or tissue (e.g., cornea).

Organ transplants have resulted in a significant reduction in mortality of patient populations in need of new functional organs. Hundreds of thousands of patients have benefited from this technology over the last four decades. Organs are harvested by two means: One is to obtain organs from brain-dead or human cadavers. The others are harvested from a living donor, who may or may not be related to the recipient. The majority of cadaveric organs are obtained by previous consent from the donor or the family. In most living donor organ transplants, the organ is donated voluntarily. Since the 1980s, advances in the science of organ transplantation have significantly broadened the range of transplantable organs and improved transplant outcomes. Transplant centers in different parts of the world successfully transplant kidneys, liver, lungs, hearts, pancreas, and intestinal organs, and the procedure is considered the preferred treatment for several indications. Since the first kidney transplant in 1954, the increasing success of, and innovations in, transplants have created a demand for organs that greatly exceeds the supply in most countries.

A major development is the procurement of organs from family members, and most recently from friends and even strangers (Matas et al., 2000; Gohh et al., 2001; Hilhorst et al., 2005). We are also witnessing desperate patients soliciting organs on the Internet (Wright & Campbell, 2006), the compensation of living donors for related expenses, or even the bestowing of financial rewards for donation (Larijani et al., 2004), and the experimental use of organs from animals (i.e., xenotransplantation; Daar & Chapman, 2004).

These recent trends are at the forefront of current ethical debate on transplantation, and they are gaining varying levels of acceptance in different countries by both the public and the transplant community. The sale of organs is another highly complex subject that has received much attention (Radcliffe-Richards et al., 1998; Phadke & Anandh, 2002; Taylor, 2002; Daar, 2003, 2004a).

Often, organs are obtained from people who are willing to sell their organs for financial compensation. Furthermore, due to the ever-increasing demand for new organs, and the finite supply, a lucrative black market of organ trafficking has been established.

The United Nations Trafficking Protocol states:

"Organ trafficking occurs where a third party recruits, transports, transfers, harbours or receives a person, using threats (or use) of force, coercion, abduction, fraud, deception, or abuse of authority or a position of vulnerability for the purpose of removing that person's organ(s). Where children are concerned, the removal of an organ(s) facilitated by a third party constitutes trafficking with or without considerations of deception or coercion. Third parties may include brokers or others such as medical professionals or laboratories acting as brokers."

(UN Trafficking Protocol)

The Islamic guidelines and Islamic law have described certain rules and regulations, which allow organ transplantation to be performed. The conditions that permit organ transplantation include (1) the recipient of the organ will definitely be helped, (2) the donor is not harmed, and (3) the donation of the organ is done voluntarily without any financial compensation (Shaheen et al., 2001). In accordance with these mandates, organ donation in return for money or any other form of compensation is strongly condemned in Islam, as it does not abide by the third rule mentioned above. Many international laws and rules have views similar to Islamic law and regulations. Organ donation in Saudi Arabia has been on the rise, as awareness of this global phenomenon, which allows people to save lives, has increased. The achievements of the organ transplantation program in Saudi Arabia during the year 2011, as well as increasing numbers of end-stage organ failure, have also boosted people's interest. During 2011, the organ failure census in Saudi Arabia showed more than 12,500 patients on kidney dialysis in 178 hospitals, and about 22.3% patients on the active waiting list, with another 20% under evaluation for inclusion. At the end of 2011, a total of 8,820 possible deceased cases were reported to the Saudi Centre for Organ Transplantation, of which 710 were reported from 97 intensive care units around the Kingdom. In the

last five years, an average of 615 cases per year were seen in the Kingdom. This will help balance out the demand and supply of organs for many patients on the active waiting list. Renal transplantation has its own special value in Saudi Arabia. Shaheen has noted that "inside the Kingdom by the end of 2011, renal transplantation has been performed with a total of 4830 living donors and 2349 cadaveric organs" (Shaheen, 2012). This shows the medical advancement of kidney transplantation in Saudi Arabia.

17.3 WHY IS ORGAN TRANSPLANTATION IMPORTANT?

This topic is very important because of the ethical and policy issues. It is also important because the black market in organ trafficking has been growing exponentially within the Middle East, as shown by a survey carried out on the specialty of organ transplantation within twenty-one countries of the region (Shaheen et al., 2001). More importantly, many of these countries do not administer fair and just policies in organ distribution, but rely heavily on third parties to gather organs.

Ethics

Organ transplantation presents several ethical challenges, including issues related to the determination of death, organ procurement, and organ allocation (Veatch, 2004). One of the questions debated is whether, after death, an individual's organs are a societal resource to be automatically recovered, or an individual's personal property, requiring his or her approval for organ recovery (Truog, 2005). The practice of obtaining consent for donation raises, for some people, ethical concerns about presuming another's wishes if the subject of donation had not been discussed with the deceased while he or she was alive (Veatch, 2004). The scarcity of organs for transplantation necessitates the establishment of criteria on which to base allocation decisions, particularly for organs from deceased donors. The distribution formula commonly used draws mainly on two general ethical principles: utility and justice. Utility is calculated according to medical benefit and justice is assessed on the equity of distribution, requiring (on some accounts) that the sickest or worst off be given some priority, to ensure that all are afforded an equal chance to be healthy (Veatch, 2000).

Many countries have enacted legislation against commerce in organs. Partly as a result of these legal prohibitions, the phenomenon of transplant tourism has emerged (Daar, 2004a). In India, for example, the sale of organs is illegal, but the legislation established to prevent it has proven ineffective (Daar, 2004a; Young, 2005). The laws in most countries require donor consent to posthumous organ donation.

Unlike payment for organs, the compensation for expenses incurred by

donation is considered completely justified. Other ethical issues include the consent form and its applications in this area; in addition, *commercial transplantation* is another important ethical issue.

Policy

Government agencies, transplant regulatory bodies, and health care institutions recommend and set policies that, in addition to legislation, guide transplant practice with respect to definitions of death, allocation decisions, and organ procurement. Despite the widely adopted legal definition of brain death, individual hospitals have varying practices used by physicians to certify death. It would be advisable to have uniformity on this issue (Powner et al., 2004).

Organs from the deceased are commonly allocated according to policies established by regional, national, or international transplant organizations. In Canada, the Trillium Gift of Life Network and the British Columbia Transplant Society are among the largest regional organizations handling the collaborative development and implementation of policies governing organ distribution. Policy management is undertaken in the USA by a national organization, the United Network for Organ Sharing, and in several European countries by an international organization, the Eurotransplant International Foundation. Generally, these transplant organizations use computer programs to allocate organs to recipients on a waiting list; recipients' registration on the list is based on acceptable criteria such as organ compatibility, medical need, wait time and geographical distance between the organ and the recipients (British Columbia Transplant Society, Eurotransplant International Foundation, Trillium Gift of Life Network, and the United Network for Organ Sharing).

Policies on living donation at most transplant centers support donations from relatives. Donations from friends and altruistic strangers are increasingly being accepted. Although policies allow donors to direct their organ to a known recipient, transplant centers that permit donations from altruistic strangers, in which the recipient is unknown, are reluctant to allow such donors to direct organs to a recipient of a specific social group (Matas et al., 2000). Instead, the recipient is selected according to the same waiting list criteria as for deceased donor organs (Hilhorst et al., 2005).

The well-established position of transplantation societies against commerce in organs has not been effective in stopping the paid growth of such transplants around the world. Individual countries need to study alternative, locally relevant, and ethical models to increase the number of transplants, protect and respect donors, and reduce the likelihood of rampant, unregulated commerce in organs.

The Kingdom of Saudi Arabia has an active deceased transplant program under the supervision of the Saudi Centre for Organ Transplantation. The Saudi Centre for Organ Transplantation is an organization in the field of medical and social care. Its main goal is organ transplantation that follows the ethical and religious rulings that are salient in this region. Their mission is to alleviate suffering and improve patients' life expectancy "by providing variable organs to all end-stage organ failure patients whether from deceased or living donors." (Source: scot.org.sa).

A number of countries in the Middle East have become the main hub of supply and demand of global organ trade and trafficking activities. One such case is Turkey, which has become a very important transplant host for North American and Israeli patient populations. They usually receive organs from Moldova, especially kidneys. On the other hand, the Southeast Asian subcontinent, the Middle East, and the Far East Asian countries have relied heavily on donors originally from Pakistan, India, and Indonesia (Shaheen et al., 2001).

"Shaheen's study on issues of renal transplantation in Middle Eastern countries identified eleven prominent problems. Some of these include considering a commercial living donor as an "easy way out" of the scarcity problem (2622) and that, like elsewhere where this trade exists, some physicians encourage commercial transplantation and thus profit financially while debates on solutions continue. These authors also report that very few countries in the Middle East have centers to coordinate non-living organ donation and that there is an absence of planned organ procurement in transplant centers. Shaheen et al. further indicates that a lack of effective health insurance and a minorities' lack of trust in the health system-due to inaccessibility of the health system and lack of social justice for many minorities-is another prominent issue related to transplants in the Middle East. Similarities in some of the featured problems of transplants exist amidst diverse policies among Islamic countries. Differences include the permissibility to procure from the non-living in countries such as Saudi Arabia and Qatar versus a complete reliance upon living donors in countries such as Egypt, Pakistan, and Syria, and the absence of transplant procedures entirely in countries as resourcefully diverse as the United Arab Emirates and Yemen." (Budiani & Shibly, 2008)

Another aspect of organ trafficking is transplant tourism, which can be defined as follows:

"Transplant tourism is an international phenomenon in which organ seekers, usually from wealthier nations, travel to developing countries where they receive organ transplants. Trips abroad are typically arranged by a third party,

often a health care provider working in the destination country (...)." (UNA-GB, 2009)

How should we approach organ transplantation in practice

In a situation in which a person's death is expected but has not yet occurred, practice guidelines for cadaveric organs urge that declarations of death or the decision to withdraw life support be made by a physician who is not a member of the transplant team, and before approaching the family about donation. Usually, the family is given information about the option to donate, if known, and is asked to give consent to such donation. These tasks are often handled by regional organ procurement agencies, which, upon being notified of a potential donor by the transplant center, find a suitable recipient and coordinate the recovery and transportation of organs (United Network for Organ Sharing).

Consensus statements and recommended ethical practice guidelines on living donation identify several practical elements as essential to ensuring the well-being of living donors. With respect to informed consent, a donor must be fully and accurately informed about, and demonstrate an understanding of, the risks and benefits of donation as it affects themselves and the recipient (Abecassis et al., 2000; Ethics Committee of the Transplantation Society, 2004; Wright et al., 2004; Zink, 2005), as well as the different surgical options available, during which the donor has an opportunity to reconsider his or her decision. The transplant center must ensure that the donor's decision to donate is voluntary and is not unduly influenced by material gain, coercion, or other factors that may reduce individual autonomy. It is recommended that, if possible, the donor and the recipient be assigned separate care teams or advocates to protect their individual interests (Abecassis et al., 2000; Ethics Committee of the Transplantation Society, 2004; Wright et al., 2004), as well as to enhance confidentiality and avoid conflicts of interest.

Assessments of medical suitability will depend on which organ is being donated, and will be carried out by the transplant team physicians. The donor's psychosocial suitability must be evaluated to rule out psychological risk factors such as a severe mental disorder. It is also advisable to evaluate other factors, such as economic constraints or domestic issues. These evaluations help to determine whether the donor is mentally competent to give informed consent, and if his or her decision is voluntary (Abecassis et al., 2000; Wright et al., 2004).

Altruistic stranger donation should follow the same guidelines as those established for donations from relatives, with an emphasis on the psychosocial assessment. In addition, the relationship between the donor and recipient,

whether strangers or familial, should not affect the degree of acceptable risk to the donor (Abecassis et al., 2000).

17.4 CASES (ETHICAL SCENARIOS)

Scenario 1

A 53-year-old single mother offers to donate a kidney to a work colleague whom she knows distantly. Although the recovery time needed away from work after donation will strain her modest income, the woman tells the transplant team that she understands this and is willing to go ahead. She explains that her motivation to donate is purely to help another human being.

Scenario 2

A 50-year-old man involved in a serious road traffic accident has suffered severe injuries and has been placed on life support while investigations are completed. The results indicate he will not survive. His relatives are not present at the hospital. The junior physician treating the patient considers withdrawing supportive treatment. He wonders whether the patient would be a candidate for a cadaveric heart donation after cardiac death is pronounced.

The first case - It would be useful to have transplant unit policies on living donations from non-relatives, especially as they are becoming increasingly common. In the first case, the transplant units must balance the need to explore ulterior motives, such as covert payments, with the need to respond to a genuinely altruistically motivated donor. A psychosocial evaluation, preferably by an independent expert in living organ donation, is usually administered, but it is difficult to establish ulterior motives. In addition, transplant units cannot control the exchange of material rewards or other events that may transpire after a transplant is completed. These are also matters of concern in donations by relatives.

The transplant center should have planned ahead to ensure that the donor had sufficient support, including legitimate financial support, during her recovery from the operation. The recipient was a distant work colleague, which made this, in the absence of any coercion, a truly altruistic donation. The donor was fully informed about, and understood, the risks and benefits of her donation, and the donation process. The transplant team concluded that the woman was a willing, informed, altruistically motivated individual, wishing to donate for rational reasons that were important to her, and she was, therefore, a suitable donor.

The second case - If there is consensus that a cadaveric transplantation should be undertaken in the second case described, it should be done

exclusively at institutions with clearly established protocols. The Maastricht classification divides the five donation types into uncontrolled and controlled groups, depending on whether cardiac death was anticipated (Ridley et al., 2005). Several decisions must be made under emergency conditions when a patient is brought in either dead, according to cardiopulmonary criteria (uncontrolled), or is in extremis with no hope for survival (controlled). In the controlled group (as with this patient), if the patient's relatives are not present, should preparation for organ retrieval proceed while they are sought? This usually takes the form of cooling the organs and may involve administering drugs to protect the organs, neither of which will benefit the injured and dying patient. If the relatives cannot be contacted, should organ retrieval proceed? These pressing issues are currently being explored with much interest at many centers.

Assuming the relatives are present, there are minor differences in the consent procedures used currently in standard practice, in which the potential donor is pronounced dead according to neurological criteria (i.e., brain death). In fact, deceased organ transplantation originally started with donation after cardiac death, not by applying brain death criteria, which entered transplant practice later. Brain death criteria continue, in some places, to be controversial.

If the heart is still beating, another question arises, based on the tension between a desire to confirm death absolutely and the desire to obtain organs that have not been damaged by ischemia: Following withdrawal of life support, how long should the surgeon wait after the heart has stopped before removing the organs (Daar, 2004b)? In this case, the relatives were found quickly and they consented first to withdrawal of life support and later to donation only of the kidneys. The physicians proceeded to cool the kidneys via an abdominal catheter but chose not to administer any drugs to help preserve them. The patient was taken to the operating theatre, life support was withdrawn (Maastricht type 3), and the surgeon waited a full ten minutes before removing the kidneys, which were offered to two recipients with their full knowledge that the kidneys came from a non-heart-beating donor. One kidney functioned straight away, while the other had mild ischemic damage, but began functioning well three days later. Both recipients are alive with functioning kidneys four years later.

17.5 CONSEQUENCES OF SELLING ORGANS

In a majority of cases, poor people who are willing to sell their organs are not aware of the numerous risks associated with organ transplants. One of the most common is post-operative infection and the need for ongoing and expensive treatment that they cannot afford. More importantly, they may not

have proper medical follow ups, which in turn, makes them more vulnerable to further sickness and, in some cases, death. In addition, due to the surgery, their daily life activity becomes limited; hence, they are unable to continue working in jobs that require physical activity over a period of time. As a result, employment opportunities become scarce.

In a study conducted in Pakistan, 93% of organ donors indicated that financial benefits were the main motive for the donation. However, 85% of them were unable to fulfill their objectives with the financial compensation (Robinson, 2008). Finally, yet importantly, there is no one to look after the rights of these organ sellers, who are very likely to have their rights violated, be mistreated, mislead, cheated, and forced to sell their organ against their will.

17.6 ISLAMIC DECLARATIONS AND OTHER BIOETHICAL GUIDELINES

Due to the rapid development of a market for organs, Islamic scholars of the Board of the Islamic Fiqh Council (a part of the Muslim World League) issued a *qarar* (resolution) on death and transplants at the Third International Conference of Islamic Jurists meeting in Amman, Jordan in 1986.¹ This resolution declared the following:

"A person (is) considered legally dead, and all the Sharia's [Islamic law] principles can be applied, when one of the following signs is established:

1. *Complete stoppage of the heart and breathing, and the doctors decide that it is irreversible.*
2. *Complete stoppage of all vital functions of the brain, the doctors decide that it is irreversible, and the brain has started to degenerate..."* (Daar, 2004).

These guidelines have secured a way of allowing donation from brain-stem death and cadaveric heart donors, and various consent requirements have been established across the Muslim world. More importantly, Islamic scholars have agreed that donation is permitted based on the conditions that:

1. It will definitely help the recipient.
2. It does not cause harm to the donor.
3. The donor donates the organ or tissue voluntarily and without financial incentive or compensation.

¹ The Islamic Fiqh Council was established in 1977 as an independent organization formed by renowned Muslim Scholars worldwide. Their objective is to respond to new challenges that Muslims confront by concluding resolutions based on Islamic laws and Fiqh and their sources, the *Quran* and the *Sunnah*.

The Unified Arab Draft Law on Human Organ Transplants states that "*Specialist physicians may perform surgical operations to transplant organs from a living or dead person to another person for the purpose of maintaining life, according to the conditions and procedures laid down in this law*" (Daar 1991, 2005). This law was established at the Twelfth Session of the Council of Arab Ministers of Health, meeting in Khartoum in March of 1987. At the same meeting, the sale or purchase of organs, and remuneration for organ donation was prohibited, and no specialist was allowed to perform a transplant operation if he had the knowledge that the organs had been acquired by such means.

Following these initial declarations, many other *fatawa* and statements have been issued against compensated organ donation, from sources such as the Islamic Charter of Medical Ethics (a document issued to the World Health Organization) and regional societies such as the Islamic Medical Association of North America (IMANA). There have also been book length statements, such as that from Kuala Lumpur (Ebrahim, 1998), as well as a statement from a *fatawa* issued by Al-Azhar University's Dar AlIftah.

Although these *fatawa* and regional draft laws have their own distinct points, they all express a common condemnation of paid donation reflected in other international declarations, including the WHO's Guiding Principles (2004), the World Medical Association's (WMA) Statement on Live Organ Trade (1985), the Resolution on Physicians' Conduct Concerning Human Organ Transplantation (1994), and the long-standing statement of the International Transplantation Society. Therefore, there is a strong agreement among Islamic and other biomedical statements with regards to the exploitation of individuals for organ donation through financial incentives.

Although the aforementioned declarations express a shared intolerance of the exploitation of the poor as a source for organs via financial gain, they have thus far not addressed this from the perspective of the goals of Islamic laws, developed by Al-Shatibi and others (*Maqasid Al-Sharia*). The *Maqasid Al-Sharia* requires universal social justice and respect of human rights; i.e., it makes sure that all the different groups of society are treated equally when prioritizing donation and transplantation. In other words, it is necessary to ensure that the practice is not exploitative, and that certain groups (e.g., people of higher class) do not benefit more than other groups (e.g., lower class; Dar Al Fikr, 2001). Strikingly enough, Islamic and other bioethical organizations lack the establishment of specific guidelines that assure just transplantation procedures. Incorporating the ideas from *Maqasid Al-Sharia*, along with other bioethical statements, could help to address the problems of exploitation and privilege in organ transplantation.

17.7 CONCLUSION AND SUMMARY

In conclusion, the real picture of organ transplantation trafficking and its effects on the Middle East and the Muslim World is a complex one, and three main aspects were discussed in this module. First, we shone some light on the modes of organ transplantation in the Middle East and other predominantly Muslim countries. Second, we discussed the Islamic guidelines and rules applicable to different aspects of organ trafficking and transplantation. Finally, we established certain practical solutions, which go hand in hand with the various Islamic regulations, and the different stakeholders of the organ trafficking business.

The literature has enlightened us on the complex concepts and contradictions involved in this developing area of medicine. The Islamic and other bioethical bodies have issued guidelines on transplantation and compensated organ donation. More importantly, Islamic scholars have agreed that donation is permitted based on the conditions that:

1. It will clearly help the recipient.
2. It does not cause harm to the donor.
3. The donor donates the organ or tissue voluntarily and without financial incentive or compensation.

In the near future, the dynamics of the organ market will become more aggressive and innovative, which will, in turn, result in a lot of suffering and inequality in this sector. We must use all the resources that are available to ensure that we have a framework for more just and acceptable transplantation regulations, which benefit the whole of society.

17.8 REFERENCES AND SUGGESTED READINGS

1. Abecassis M, Adams M, Adams P, et al. for the Live Organ Donor Consensus Group. Consensus statement on the live organ donor. *JAMA* 2000;284(22):2919-26.
2. Abouna GM. Negative impact of trading in human organs on the development of transplantation in the Middle East. *Transplant Proc* 1993;25(3):2310-3.
3. Bassoul J. Egypt's illegal organs trade thrives on poverty. *Mail Guardian* 2006. <http://mg.co.za/article/2006-04-04-egypts-illegal-organ-trade-thrives-on-poverty>
4. Budiani D, Shibly O. Islam, Organ Transplants, and Organs Trafficking In the Muslim World: Paving a Path for Solutions. In: Muslim Medical Ethics: From Theory to Practice. Brockopp JE, Eich T (eds). Columbia, South Carolina: University of South Carolina Press 2008, pp138-150.

- (Available from:
http://www.cofs.org/Publications/Budiani_and_Shibley.doc)
- 5. Canadian Public Health Association (2001). Animal-to-Human Transplantation: Should Canada Proceed? Public Consultation on Xenotransplantation.
(<http://www.cpha.ca/en/programs/xeno/background-summary.aspx#h1>).
 - 6. Daar AS. Money and organ procurement: Narratives from the real world. In: Ethical, Legal and Social Issues in Organ Transplantation. Gutmann T, Daar AS, Sells RA, Land W (eds). Lengerich: Pabst Science 2004, pp.298-317.
 - 7. Daar AS. Non-heart-beating donation: ten evidence-based ethical recommendations. *Transplant Proc* 2004;36(7):1885-7.
 - 8. Daar AS. Organ donation - World experience; the Middle East. *Transplant Proc* 1991;23(5):2505-2507.
 - 9. Daar AS. South Mediterranean, Middle East, and subcontinent organ transplant activity. *Transplant Proc* 2001;33(1-2):1993-1994.
 - 10. Dar Al Fikr JA. Toward Activating The Role Of Maqasid Alshariah. Damascus, 2004.
 - 11. Ebrahim AF. Organ transplantation: Contemporary Sunni Muslim legal and ethical perspectives. *Bioethics* 1995;9:291-302.
 - 12. Johnson C: Council Of Europe; United Nations: Organ Trafficking Treaty Proposed. Library of Congress
http://www.loc.gov/lawweb/servlet/lloc_news?disp3_l205401623_text.
 - 13. Robinson S. India's Black Market Organ Scandal. *TIME* February 1, 2008. (Available from:
<http://content.time.com/time/world/article/0,8599,1709006,00.html>)
 - 14. Shaheen F. Organ Transplantation in Saudi Arabia. QScience Proceedings 2012
 - 15. Shaheen FAM, Souqiyeh MZ, Ramprasad K, Attar MS. "Current Issues and Problems of Transplantation in the Middle East: The Arabian Gulf." *Transplantation Proceedings* 33(2001):2621-2622.
 - 16. Shahine G. "When Does The Soul Depart?" *Al-Ahram Weekly Online* 1999;<http://weekly.ahram.org.eg/1999/420/Fe2.Htm>
 - 17. Shehab S. "Between Life and Death." *Al-Ahram Weekly* 2001;528.
 - 18. United Nations Association of Greater Boston (UNA-GB) (2009). Human Organ Trafficking. Retrieved 6th of April, 2013, from [http://Rmunatunagb.Wikispaces.Com/File/View/HOT+Topic+Guide\[1\].Pdf](http://Rmunatunagb.Wikispaces.Com/File/View/HOT+Topic+Guide[1].Pdf).
-

INDEX

A

abortion, xiv, xv, 13, 15, 16, 17, 20, 21, 28, 197, 198, 203, 205, 207, 208, 210, 212, 213
advance directive, vii, viii, ix, 59, 75, 77, 81, 82, 83, 84, 85, 101, 102, 106, 108, 111, 112, 115
adverse event, 72, 134, 136, 137
analgesic, 105, 132, 139
assisted reproduction, xiv, xv, 192, 203, 204, 205, 206, 211, 214
autonomy, vii, xi, xii, 15, 20, 33, 35, 45, 52, 58, 68, 69, 70, 73, 75, 77, 78, 79, 81, 83, 84, 85, 107, 108, 135, 147, 158, 159, 161, 162, 164, 167, 168, 174, 189, 195, 211, 222
autopsy, ix, 101, 104, 110, 116, 117

B

Belmont Report, 134, 149
beneficence, 15, 20, 47, 69, 126, 142, 147, 149, 150, 174, 175, 189
Bioethics, 1, v, xvii, 1, 6, 7, 8, 9, 11, 13, 15, 19, 25, 43, 62, 63, 72, 87, 116, 137, 142, 144, 145, 183, 185, 196, 212, 228
brain death, 104, 108, 109, 116, 220, 224
brain stem death, viii, ix, 102, 104, 106, 108, 112
breach, 92, 94, 96, 97, 98, 164, 168, 198
breaking bad news, vi, 39, 43, 45, 48, 51, 52, 178

C

clinical death, 104, 106
clinical research, x, xi, 59, 131, 136, 140, 141, 142, 143, 144
cloning, xiv, xv, 203, 204, 207, 208, 212
communication skills, xvii, 29, 39, 48, 54, 199
confidentiality, viii, x, xi, xii, xiii, 35, 37, 38, 58, 59, 62, 69, 87, 89, 90, 91, 92, 93, 94, 96, 98, 131, 135, 136, 138, 139, 142, 159, 161, 163, 164, 168, 173, 174, 176, 177, 179, 180, 189, 190, 212, 222
conflict of interest, ix, x, xi, 119, 121, 124, 127, 131, 137, 138, 141, 144, 189
conscientious objection, 21, 189
consent, vii, viii, x, xi, 15, 53, 58, 59, 60, 61, 69, 73, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 92, 97, 106, 112, 116, 131, 134, 135, 137, 139, 141, 142, 158, 163, 168, 174, 181, 185, 197, 198, 205, 206, 210, 217, 219, 220, 222, 224, 225
Consequentialism, 14, 148

D

deceased donor, 219, 220
Deontology, 14, 148
Dilemmas, 188
disability, ix, 17, 59, 91, 105, 113, 148
disclosure, xi, xii, 46, 58, 59, 62, 69, 70, 71, 72, 76, 78, 80, 83, 84, 91, 113, 135, 137, 138, 139, 141, 144, 159, 163, 168

INDEX

discrimination, 33, 78, 82, 106, 208

DNR, viii, ix, 17, 101, 102, 103, 108, 109, 111, 115

Do Not Resuscitate, ix, 17, 101, 102, 103, 106, 109, 111, 115

E

endemic, 158, 163, 164, 167

end-of-life, viii, 48, 99, 104, 114, 116, 150

epidemiological research, xii, 157, 163, 170

ethical dilemmas, 173, 176, 180, 208

ethical principle, 13, 45, 52, 53, 147, 152, 174, 175, 176, 180, 219

ethics committee, xiii, 8, 53, 142, 143, 144, 151, 152, 170, 185, 186, 196, 199

euthanasia, viii, ix, 101, 102, 103, 109, 110, 111, 115, 116

F

Fatwas, vi, viii, ix, xi, xii, 3, 4, 8, 16, 22, 37, 38, 60, 69, 94, 98, 125, 142, 151, 165, 185, 192

Fiqh, v, xiv, 3, 4, 5, 18, 19, 22, 23, 60, 95, 196, 225

H

haram, 16, 125, 126, 161

Helsinki declarations, 132, 138, 140, 141

HIV, 142, 143, 153, 159, 168, 170

I

Ijtihad, xvi, 7, 16, 22, 192

informed consent, vii, 35, 45, 46, 53, 58, 59, 60, 61, 62, 67, 75, 76, 79, 80, 81, 83, 84, 85, 110, 131, 132, 134, 135, 136, 138, 139, 140, 141, 142, 162, 163, 164, 176, 222

Islamic, 3, 4, 7, 11, 13, 15, 16, 17, 19, 20, 21, 37, 41, 46, 51, 59, 60, 69, 110, 125, 126, 151, 160, 165, 175, 179, 180, 185, 191, 192, 197, 217, 218, 221, 225, 226, 227

K

Kasule, 1, ii, 16, 23, 62, 73, 99, 129, 155, 183, 191, 201

L

legal death, 106

living donor, 217, 219, 221, 222

M

malpractice, vi, vii, 65, 67, 69, 72, 79, 80

Maqasid Al-Sharia, xiv, 17, 23, 192, 226, 228

medical errors, 51, 59, 65, 67, 68, 69, 70, 72, 94, 173, 196

medical ethics, ii, v, 1, 23, 41, 62, 63, 72, 126, 174, 192, 200, 226, 227

medical futility, ix, 101, 105, 106, 108, 113, 114

mental illness, 50, 82, 115

meta-ethics, 7

INDEX

N

Normative ethics, 7
Nuremberg declaration, 134

quality of life, 106, 113, 148, 187, 188, 193, 217

Quran, xvi, 4, 7, 16, 19, 22, 94, 96, 160, 192, 225

O

organ market, 227
organ transplantation, xv, 116, 217, 218, 219, 221, 222, 224, 226, 227, 228

refusal of treatment, 58, 61, 62, 83, 84, 85

research ethics, v, x, 3, 7, 131, 134, 138, 142, 143, 144, 170
research protocol, x, xi, 131, 135, 137, 143

P

patients' rights, vi, 55, 57, 58, 59, 61, 62, 68, 71, 177
PEHR, ii, v, xvii, 3, 4, 5
pregnancy, xiv, 3, 8, 51, 57, 185, 197, 198, 199, 203, 204, 205, 206, 207, 208, 211
pregnant woman, 3, 28, 51, 89, 168, 193
Principle, 18, 19, 148, 150, 188, 193, 195, 197
Principlism, 15, 148
privacy, viii, x, xi, xii, xiii, 34, 37, 40, 58, 59, 62, 87, 89, 90, 91, 93, 94, 96, 98, 131, 136, 142, 159, 168, 173, 174, 176, 177, 179, 180
professionalism, ii, xiii, xvi, xvii, 3, 5, 9, 13, 19, 39, 176, 180, 181
public health, xii, 7, 14, 92, 97, 147, 157, 160, 161, 162, 167, 169, 174
Public health ethics, v, xii, 7, 161, 169

sale of organs, 109, 218, 219
Saudi research regulations, x,

131, 137, 143
Sharia, xiv, 17, 22, 23, 46, 84, 103, 108, 110, 112, 124, 151, 192, 193, 195, 197, 198, 207, 225

substitute decision maker, vii, viii, 50, 51, 52, 54, 60, 75, 76, 79, 81, 84, 85, 92, 97, 107

Sunnah, xvi, 4, 7, 16, 22, 96, 192, 225

T

terminal care, 101, 104, 112, 113
terminal illness, 48, 101, 103, 108, 109, 110, 113, 193
triage, xiii, 164, 176, 177, 179
truth telling, vi, xiii, 43, 45, 51, 52, 69, 178

Q

quadrants, 200

INDEX

U

UN Trafficking Protocol, 218
unconscious, 75, 76, 77, 79, 83,
 84, 97, 102, 111
Utilitarianism, 14

V

vaccination, xii, xiii, 97, 157, 158,
 159, 164, 167, 168, 170



The Saudi Commission for Health Specialties
Department of Medical Education & Postgraduate Studies

© 2015 by the Saudi Commission for Health Specialties
ISBN: 978-603-90608-2-6