

# Confidentiality, Telling the truth and Withholding Information



Medical Ethics

Dr. Reema Karasneh

# Confidentiality



## Confidentiality

- Confidentiality is one of the core duties of medical practice.
- It requires health care providers to keep a patient's personal health information private unless consent to release the information is provided by the patient.

## The limits of confidentiality

- The rule of confidentiality is that all health care workers (physicians) are **ethically obliged** not to release to a third party any information about patient that was obtained during the course of treatment

# Principles of confidentiality

- **If you were asked to provide information about patients you should:**
  1. Seek the patient's consent to disclosure of information wherever possible, whether or not you judge that the patient can be identified from the disclosure
  2. Anonymize data, where unidentifiable data will serve the purpose
  3. Keep disclosures to the minimum necessary
- **Note:** Information about patients is requested for a wide variety of purposes, including education, research, monitoring and epidemiology, public health surveillance, clinical audit, administration and planning
- **No breach of confidentiality has occurred if:**
  - A patient gives consent, or
  - The patient cannot be identified

# Four grounds for the importance of confidentiality

1. **Respect for patient autonomy**
  - Patients' rights to control personal information and protects privacy
2. **Implied promise**
  - Depends on a concept of the doctor-patient relationship (the moral relationship in medicine) : patient required to reveal intimate information and physicians required to keep them
3. **Virtue ethics**
  - Focuses on the position of the doctor
4. **Consequentialism**
  - The consequences of the breach of confidentiality that determine the seriousness of the breach

# Types of consequences

## Effect on patients (if discover the breach in confidentiality)

- Discrimination against them
- Deprives them from social rights
- Bring physical or emotional harm to them
- Loses **trust** in that particular doctor or in doctors in general
- Receiving poorer health care

## Effect on others

- Patients make a complaint leading to other people losing **trust** in that specific doctor or in doctors generally
- Lead to poorer health care for a larger number of people
- Lead to consequences of untreated illness
- E.g. Epilepsy and driving, STDs patients

## It is in the **public interest** for people to **trust** their doctors so that they receive treatment for disease, because:

- It is a general public interest for people to receive good health care
- Consequences of illness on others

# The Child and Incompetent Patient

- The child and incompetent patient cannot give consent for information to be passed on to someone else
- They may be harmed by confidentiality
- Doctors act in the patient's best interests
- Sharing information (diagnosis, treatment, prognosis) with close relatives or key carers would normally be seen as in a patient's best interests
- An incompetent patient has the same legal protection from:
  - Casual breaches of confidentiality
  - Being harmed through a breach of confidentiality

## Key legal aspects of confidentiality

- There is a general legal obligation for doctors to keep confidential what patients tell them. This obligation is not absolute:
  - There are situations when the law obliges doctors to breach confidentiality.
  - There are situations when the law allows doctors to breach confidentiality.
- In both of these situations it is important that the doctor breaches confidentiality only to the relevant person(s) or authority(ies).
- Therefore, the issue of when it is lawful, and when not lawful, for a doctor to breach confidentiality is often a question of **balancing public interests**

## When doctors should not breach confidentiality (unless with consent of patient)

- 'Casual breaches', e.g. for amusement, or carelessly
- Simply to satisfy another person's curiosity
- To prevent minor crime, or to help conviction in the case of minor crime (e.g. crime against property)
- To prevent minor harm to someone else
- In the case of doctors working in a genitourinary clinic, no information that might identify a patient examined or treated for any sexually transmitted disease should be provided to a third party, except in a few specific situations
- A doctor should not write a report, or fill in a form, disclosing confidential information without the patient's consent (preferably written)

## When doctors must breach confidentiality (to specific authorities only)

- Reportable diseases
  - Communicable/infectious
  - measles, rabies, anthrax, botulism, STDs, and TB
- Termination of pregnancy
- Suspected cases of child or elder abuse
- Gunshot wounds
- Births/ Deaths
- To police, on request/ Under court orders

## When doctors have discretion (Based on public interest)

- Sharing information with other members of the healthcare team in the interests of the patient
- Cases involve threat of violence against identifiable third parties
  - Patient continuing to drive who is not medically fit to do so
  - Homicidal ideation, when the patient shares a specific plan with a physician or psychotherapist to harm a particular individual
- When a third party is at significant risk of harm
  - e.g. spouse of HIV-positive person
- The detection or prevention of serious crime

## Types of errors

There are two types of errors physicians may make:

Disclose information for those who have no right for it, or

Fail to disclose information for those who have the right to know it

## Electronic Medical Records

- Electronic medical records can pose challenges to confidentiality
- Institutions are required to have policies to protect the privacy of patients' electronic information, including procedures for computer access and security

*What if a family member asks how the patient is doing?*

- If there is not **explicit** (or **implied** as with children) permission from the patient to share information with family member, it is generally not ethically justifiable to do so
- Except in cases where the spouse is at specific risk of harm directly related to the diagnosis

## Case study

Your 36-year-old patient has just tested positive for HIV. He asks that you not inform his wife of the results and claims he is not ready to tell her yet.

***What is your role legally? What would you say to your patient?***

## Case Discussion

Because the patient's wife is at serious risk for being infected with HIV, you have a duty to ensure that she knows of the risk

It is generally advisable to encourage the patient to share this information with his wife on his own, giving him a bit more time if necessary

## Truth-telling and Withholding Information



### Do patients want to know the truth about their condition?

- When physicians communicate with patients, **being honest** is an important way to foster trust and show respect for the patient
- A number of studies have demonstrated that patients do want their physicians to tell them the truth about diagnosis, prognosis, and therapy.
  - 90% of patients surveyed said they would want to be told of a diagnosis of cancer or Alzheimer's disease
- A number of studies of physician attitudes reveal support for truthful disclosure
  - In 1961 only 10% of physicians surveyed believed it was correct to tell a patient of a fatal cancer diagnosis, by 1979 97% felt that such disclosure was correct

### Why it is important to tell the truth?

From an ethical perspective, truthful information is important for several reasons:

#### For reasons of autonomy

- Truthful information helps patients to decide how to proceed with treatment
- Patient may still wish to know information about their health, because their health is intricately linked with their sense of self

#### For reasons of trust

- It is generally accepted that truth-telling promotes a sense of trust between both the doctor and their patient, and in general between doctors and the public at large

## What if the truth could be harmful?

- There is still uncertainty among health care workers (physicians) on how to communicate bad news to patients (e.g. Incurable cancer, Pregnant with handicapped fetus)
- It all depends on how you tell the truth.
  - Physicians should discuss the information in a gentle manner (sensitivity, caring, provide full support and not abandon their patients)

## When is it justified for me to withhold the truth from a patient?

There are two main situations in which it is justified to withhold the truth from a patient:

If the physician has compelling evidence that disclosure will cause real and predictable harm, truthful disclosure may be withheld

if the patient him- or herself states an informed preference not to be told the truth

## Withholding the truth includes:

- Outright lies
- Temporary deception
- Not answering direct questions
- Giving false hope
  
- The long-term effect of lying is severe to patient, family and society

### Physicians' Knowledge, Perceptions, and Attitudes Related to Patient Confidentiality and Data Sharing

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Reema Karasneh<sup>1</sup>  
Abdel-Hameed Al-Mistarehi<sup>2</sup>  
Sayer Al-Azzani<sup>3</sup>  
Sawsan Abuhammad<sup>4</sup>  
Suhail M Muflih<sup>5</sup>  
Sahar Hawamdeh<sup>6</sup>

Karem H Alzabadi<sup>1,3,5</sup>

<sup>1</sup>Department of Basic Medical Sciences, Faculty of Medicine, Yarmouk University, Irbid, Jordan; <sup>2</sup>Department of Public Health and Family Medicine, Faculty of Medicine, Jordan University of Science and Technology, Irbid, Jordan; <sup>3</sup>Department of Clinical Pharmacy, Jordan University of Science and Technology, Irbid, Jordan; <sup>4</sup>Department of Hospital and Child Health, Jordan University of Science and Technology, Irbid, 22110, Jordan; <sup>5</sup>Department of Pharmacy Practice and Pharmacotherapeutics, College of Pharmacy, University of Sharjah, Sharjah, United Arab Emirates

**Background:** The protection of patient confidentiality is an essential practice for the successful provision of healthcare. This study examines physicians' knowledge and attitudes related to data sharing and patient confidentiality.

**Methods:** This is a descriptive, questionnaire-based study. Physicians were invited via e-mail to complete the study survey. The survey comprised three sections related to knowledge, attitudes, and demographic characteristics.

**Results:** A total of 221 physicians, with varying levels of experience and from a range of specialty areas, completed the study survey. Ethical dilemmas were encountered annually by physicians specialized in family medicine and daily by physicians in internal medicine wards more often than those in other departments. The mean score for knowledge was 7.34 (out of 14; SD=2.92) and had a positive correlation with attitudes towards the protection of data confidentiality ( $r^2=0.282$ ,  $p<0.001$ ). Undergraduate courses were the main source of knowledge related to ethical issues (167; 74.9%). Sex ( $B=1.47$ ,  $p=0.001$ ), marriage ( $B=-1.58$ ,  $p=0.021$ ), and source of consultation ( $B=-2.48$ ,  $p=0.02$ ) were all found to predict knowledge scores. Likewise, attitudes were predicted by experience ( $B=0.279$ ,  $p<0.001$ ), sex ( $B=-2.797$ ,  $p=0.002$ ), marriage ( $B=1.91$ ,  $p=0.02$ ), and number of ethical dilemmas faced ( $B=1.695$ ,  $p<0.001$ ).

**Conclusion:** Physicians from different departments were found to lack sufficient knowledge about many aspects of patient confidentiality. While some of the physicians' practices complied with the law, other practices were identified as patient confidentiality breaches.

**Keywords:** confidentiality, physician, knowledge, attitudes, data sharing, ethical dilemma

#### Introduction

Dedicated in the infamous Hippocratic Oath, preserving patient confidentiality is one of the oldest cornerstones of healthcare practice.<sup>1,2</sup> Therefore, physicians are ethically and legally obliged to maintain their patients' data privacy and protect their autonomy.<sup>3-6</sup> However, sharing patients data with unauthorized people still frequently occur in different clinical settings and departments and, unfortunately, involve most healthcare personnel.<sup>5,6</sup> These breaches include disclosing patient data to third parties, discussing patient information in public areas, incorrectly disposing of patient records, leaving electronic or paper health records unattended, and providing care with open doors.<sup>5-8</sup>

Concerns about sharing patients data with unauthorized people by physicians may have undesirable effects on patients' health. Breaches of confidentiality may lead to forgone healthcare, making healthcare seekers more likely to engage in dangerous behaviors or report psychological problems.<sup>9</sup> Likewise, as these concerns may diminish

Correspondence: Reema Karasneh, Department of Basic Medical Sciences, Faculty of Medicine, Yarmouk University, P.O. Box 566, Irbid, 21161, Jordan. Tel: +962 2 7211111, Fax: 7211162. Email: reema.karasneh@yu.edu.jo

patient's trust in their physicians, patients may hesitate to seek help, attend follow-up appointments, or even decline essential information for the establishment of an efficient healthcare plan.<sup>10,11</sup>

These confidentiality concerns have been acknowledged as being global concerns. Therefore, various internationally agreed recommendations and guidelines that apply to protecting the sanctity of patients' private lives during treatment had been developed that used in some countries such as United Kingdom. These regulations called Data Protection Act and it was implemented in 1998 and updated on 2018.<sup>12-14</sup> The Data Protection Act was developed to give protection and lay down rules about how data about people can be used.<sup>15</sup> Knowledge of these codes of ethics and laws is essential for physicians to maintain ethical practices. Few studies have investigated physicians' levels of knowledge related to ethical codes<sup>16,17</sup> and laws of data security and sharing.<sup>18,19</sup> All professionals in healthcare, especially physicians, should be informed, aware of patients' rights. For an integrated approach to be realized in the health sector, it is obligatory that physicians persistently include the rights of patients in their actions. The most important aspect of this study is that addresses the widely emerging trend of patient data sharing information and confidentiality among physicians in developing countries taking Jordan as an example. As a result, the authors in the study aim to examine practicing physicians' knowledge, perceptions, and attitudes related to different aspects of patient confidentiality and data sharing. Therefore, they aimed to identify the frequency of ethical dilemmas that faced in different medical departments.

## Methods

### Study Design

A cross-sectional survey was used to recruit responses from physicians who were employed either full-time or part-time in private or public healthcare institutions in Jordan. Physicians from all specialty areas, departments, and levels of experience were eligible to participate. This study's data were collected from May 15 to July 18, 2020 using web-based survey software (Google Forms). The validation options "Required" and "Limit to one response" were applied to minimize any cases of missing data and prevent the duplication of responses.

Physicians were recruited through e-mail and social media platforms. All participants were provided with a brief description of the study and made aware that all responses would be anonymized and treated as confidential. The participants were also informed that their

participation was voluntary and that they had the right to withdraw from the study at any point.

### Instrument

The survey used in the current study was developed based on an extensive review of similar literature.<sup>12-17</sup> The following sections were included in the survey: a) sociodemographic characteristics, b) knowledge of ethical conduct, c) degree of perceived confidentiality in different clinical situations, and d) attitudes towards data sharing. The knowledge section included seven questions with the response options of "yes", "no", and "I don't know". Each correct answer was equal to two points, while each incorrect answer was equal to one point, with a maximum possible score of 14 for the knowledge section. This section was scored from 14 to 28, as the score increase means more knowledge regarding confidentiality for patient data. The second section included seven areas about patients' data and opinions of the physician regarding the importance of keeping confidential. These situations are psychiatric diseases, chronic diseases, acute diseases, illegal drugs, food habits, sexual diseases, and therapeutic plan which the participants could respond with 'not important' or 'important'.<sup>7</sup> The score was ranged from 7 to 14, greater score means more importance for keeping confidentiality toward these areas. Meanwhile, the attitudes section consisted of 14 questions scored on a 4-point Likert scale ranging from "never" to "always". This section was scored accordingly from "never" to "always". The score in this section ranges from 14 to 56. As the score was increased, this means more confidentiality toward patient data sharing. The survey items were reviewed by five experts in the field to identify any necessary changes and establish both face and content validity. This was followed by pilot testing the survey on 7 participants who were not included in the study sample. Cronbach's alpha values of 0.83 and 0.78 were calculated for the physicians' knowledge and attitudes, respectively, which indicated acceptable internal consistency and reliability.

### Ethical Considerations

The study was conducted in compliance with the Helsinki Declaration. Ethical approval was obtained from the Institutional Review Board (IRB) at the authors' institution (IRB, Reference# 16/121/2019). No names, addresses, or other identifying personal details were collected from the participants.

**Table 1** Demographic and Work Characteristics of the Study Participants

Variable	Category	N (%)
<b>Age</b>		
	18-33 (SD=10.3)	
	34-49 (SD=9.9)	
<b>Years of experience</b>		
	1-10 (SD=9.9)	
	11-20 (SD=9.9)	
<b>Sex</b>		
	Male	150 (67.9)
	Female	71 (32.1)
<b>Marital status</b>		
	Single	108 (48.9)
	Married	112 (50.7)
	Divorced	6 (0.5)
<b>Specialty area</b>		
	General Surgery	14 (7.3)
	Special surgery	5 (2.3)
	Family Medicine	74 (33.5)
	Internal Medicine	37 (16.7)
	Obstetrics and gynecology	5 (2.3)
	Pediatrics	12 (5.6)
	Emergency Medicine	27 (12.2)
	Neurology	41 (19.3)
<b>Working setting</b>		
	Health center	31 (14.0)
	Public hospital	44 (19.9)
	Private hospital	35 (15.8)
	Private clinic	7 (4.1)
	Military medical services	28 (12.8)
	University hospital	66 (29.9)
<b>Number of patients treated/day</b>		
	Less Than 30	75 (33.9)
	31-40	77 (34.8)
	40 To 49	24 (10.9)
	More Than 60	45 (20.4)
<b>Frequency of ethical dilemmas faced by physicians</b>		
	Never	22 (10.0)
	Rarely	62 (27.1)
	Monthly	44 (19.9)
	Weekly	52 (24.0)
	Daily	28 (12.6)
<b>Preference in consulting an ethical dilemmas</b>		
	Colleagues	145 (65.6)
	Head of Department	2 (0.9)
	Head of Medical Team	20 (9.0)
	Head of Hospital	2 (0.9)
	Ethics	17 (7.7)
	Religious Scholar	14 (7.2)
	Friend	19 (8.6)
<b>Further training on medical ethics is required</b>		
	Yes	197 (89.1)
	No	24 (10.9)

confidentiality among the participating physicians ( $r^2=0.282$ ,  $p<0.001$ ). This correlation was positive, indicating that an increase in knowledge about data sharing and confidentiality is associated with better patient privacy protection by physicians.

**Predictors of Physicians' Knowledge About Patient Confidentiality and Data Sharing**  
A multiple regression test was conducted to identify the demographic variables (ie, age, sex, educational level, work experience, and job role), which predicted

## Statistical Analysis

Data collected on Google Forms were exported to a Microsoft Excel file directly imported into IBM SPSS<sup>®</sup> version 24.0 for statistical analysis. Descriptive analysis was used to describe the sociodemographic characteristics of the participants. Pearson's correlation was conducted to determine the correlation between specialty area and frequency of ethical dilemmas and the correlation between knowledge and attitudes related to data sharing and confidentiality among the physicians. Multiple regression tests were conducted to determine the predictors of knowledge and attitudes among the physicians while controlling for demographic variables (ie, age, sex, educational level, work experience, and area of specialty).

## Results

### Demographic Characteristics

The results showed that the participants' average age was 33.0 (SD=10.3) years and 67.9% (n=150) were men. Half of the participants were married (50.7%). Detailed demographic and work characteristics of the study participants are summarized in Table 1. Ethical dilemmas were encountered weekly by 24% of the physicians, with the "colleague" was the main source for consultations in such situations. Finally, the majority of the physicians (89.1%) showed an interest in taking a course in medical ethics.

### Description of Ethical Dilemmas Among Different Medical Specialties

The results showed that physicians working in specific specialty areas faced ethical dilemmas more frequently than physicians in other areas. For example, physicians in internal medicine wards reported facing ethical dilemmas on a daily basis more often than did physicians in other departments, including surgery, family medicine, and special surgery. In comparison, physicians in family health wards reported facing ethical dilemmas on an annual basis more often than those in other areas (Figure 1).

### Knowledge About Patient Confidentiality and Data Sharing Among the Physicians

Table 2 illustrates the participating physicians' responses to the knowledge about data sharing and confidentiality section. The average score for knowledge about data security among the physicians was 7.34 (SD=2.92) (out of a maximum of 14 points). The questions which were most frequently answered correctly were: "Can patients' confidentiality be breached if the disease is not contagious?" (69.7%, n=154) and "Is

confidentiality and access to medical records governed by law (or special recommendations and instructions)" (71.9%, n=159). Meanwhile, most of the respondents did not know the answer to the question: "Are the police allowed to access medical records freely?" (42.1%, n=93).

Among the participants, the primary sources of medical ethics information were residency programs (58.3%, n=130), undergraduate study (74.9%, n=167), and work experience (60.5%, n=134) (Figure 2). Other sources included lectures and seminars, personal reading, and the United States Medical Licensing Examination (USMLE).

### Degree of Perceived Importance of Patient Confidentiality in Different Clinical Situations

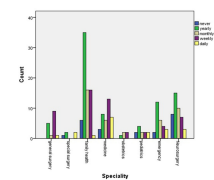
The vast majority of the participating physicians agreed that it is "important" to maintain confidentiality when dealing with patients with psychiatric diseases (97.3%, n=215), sexual diseases (94.1%, n=208), or addiction to illegal drugs (95.9%, n=212). However, maintaining confidentiality when dealing with patients with chronic diseases or when handling data related to patients' food habits was agreed to be "not important" by almost half of the participating physicians (46.6% and 47.5%, respectively) (Table 3).

### Attitudes Towards Patient Confidentiality and Data Sharing Among the Physicians

The mean score for attitudes towards data protection among the physicians was 29.3 (out of a maximum of 56 points). The majority of the physicians agreed that they collected information from patients and documented it in an entirely confidential manner (98.2%, n=217). They also agreed that they made sure to deal with sensitive information (eg, mental illnesses, sexual diseases) with extra caution (84.1%, n=186). Few physicians reported that they always or sometimes discussed their patients' conditions with colleagues in open spaces, such as reception areas and corridors (18.5%, n=41). Finally, only 17.2% of the participating physicians reported storing patient information on a personal computer (Table 4).

### Correlation Between Physicians' Knowledge and Attitudes Related to Data Sharing and Patient Confidentiality

A significant correlation was identified between knowledge and attitudes related to data sharing and patient



**Figure 1** The distribution of ethical dilemmas per physician specialty area.

knowledge about data sharing and confidentiality among the participating physicians. The variables were found to be fit within the model ( $F=7.76$ ,  $p<0.01$ ). Table 5 summarizes the results of the multiple regression test. All of the listed factors, except for sex ( $B=-1.47$ ,  $p=0.001$ ), marriage ( $B=-1.98$ ,  $p<0.02$ ), and source of consultation ( $B=-248$ ,  $p=0.02$ ). This means higher knowledge regarding confidentiality among men compared to women. Also, the single marital status showed greater knowledge about confidentiality toward patients' data. The source of consultation was considered as a predictor which means that

physicians had higher knowledge, if took the consultation from colleagues or head of departments. Other factors were found to be unassociated with knowledge about data sharing and confidentiality among the physicians ( $p>0.05$ ).

### Predictors of Physicians' Attitudes Towards Patients Confidentiality and Data Sharing

A multiple regression test was conducted to identify the demographic variables (ie, age, sex, educational level, work experience, and job role), which predicted attitudes towards data sharing and confidentiality among the participating physicians. The variables were found to be fit within the model ( $F=3.24$ ,  $p<0.001$ ). Table 6 summarizes the results of the multiple regression test. Experience ( $B=0.279$ ,  $p<0.001$ ), sex ( $B=-2.797$ ,  $p<0.002$ ), marriage ( $B=1.91$ ,  $p=0.02$ ) and the number of ethical dilemmas faced/day ( $B=1.695$ ,  $p<0.001$ ) were all found to correlate with attitudes towards data sharing and confidentiality among the participating physicians. This means more positive attitudes regarding confidentiality among men compared to women. Also, the single marital status showed more positive attitude about confidentiality toward patients' data. The number of ethical dilemmas faced. As the number of dilemmas were increased more positive attitude were shown toward confidentiality. Moreover, as the physician's year of

**Table 2** Physicians' Response Related to Knowledge About Data Sharing and Confidentiality

	No		Yes		I Do Not Know	
	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
1. Is confidentiality and access to medical records governed by law (or unique recommendations and instructions)	23 (16.4)	159 (71.9)	39 (17.6)			
2. Is the non-medical information in the medical record confidential	40 (18.1)	136 (61.5)	45 (20.4)			
3. Are the police allowed to access medical records freely?	111 (50.2)	17 (7.7)	93 (42.1)			
4. Can third parties (such as insurance companies) access examination results without patients consent?	124 (56.1)	23 (10.6)	74 (33.5)			
5. Can patients' confidentiality be breached if he/she dies?	154 (67.1)	28 (12.7)	89 (40.3)			
6. Can patients' confidentiality be breached if the disease is contagious?	53 (24.0)	126 (57.0)	42 (19.0)			
7. Can patients' confidentiality be breached if the disease is not contagious?	154 (67.3)	18 (8.1)	49 (22.3)			

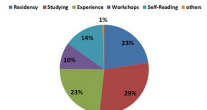


Figure 3 Sources of ethics knowledge among the physicians.

experience were increased, they showed more positive attitude toward confidentiality toward patient's data.

### Discussion

Patient confidentiality and data sharing practices are guided by ethical and legal principles,<sup>10</sup> and having sufficient knowledge of these principles would help physicians resolve many of the ethical dilemmas they encounter during their clinical practice. Around two-thirds of the participants in our study reported that they were at least aware of the existence of basic governing rules related to data access and patient confidentiality. However, the participating physicians were found to have suboptimal levels of knowledge about patient confidentiality and data sharing. This suboptimal knowledge was also found to impact the physicians' attitudes and practices related to patient confidentiality and data sharing in different clinical settings. This is particularly important given the fact that many ethical dilemmas were reported to be encountered on

a weekly basis by around a quarter of the participating physicians. Further, physicians in internal medicine wards reported facing ethical dilemmas on a daily basis more often than did physicians in other departments.

Our study's physicians achieved an average score of approximately 7 out of 14 on the knowledge scale, which is considered low compared to scores reported in other studies. For example, in a recent study by Beltran et al, respondents achieved an average score of 8 out of 10 for knowledge.<sup>11</sup> Insufficient knowledge of medical ethics regulations was also reported in a sample of 159 healthcare practitioners in a tertiary care teaching hospital.<sup>12</sup> Our findings also indicated that half of the participating physicians did not know if confidentiality should be protected after the patient's death. Meanwhile, in the study of Beltran et al, almost all of the participants answered that death does not override the physician's ethical obligation to protect the patient's confidentiality.<sup>12</sup> Furthermore, in a study conducted in the Family Medicine Teaching Units (FMTUs) at McGill University, staff members, including physicians, were asked if the police or third parties had the right to access medical files freely. Among the participating staff members, 72% correctly answered that police have restricted access, and 93% correctly answered that without patient consent, non-healthcare personnel are denied access to medical files.<sup>16</sup> Meanwhile, in our study, only 50.2% of the participants answered correctly with regards to police access and 56.1% with regards to the right of third parties to access patients' medical files. Similar to the physicians in our study, the physicians in the study of Beltran et al in Spain correctly agreed that patient confidentiality could be breached in cases of contagious diseases.<sup>11</sup>

Essential knowledge for identifying ethical problems in different patient care settings is based on ethics education,<sup>19</sup> therefore, advances in modern medicine included introducing medical ethics education in medical school curricula.<sup>19</sup> In our study, most physicians reported having acquired their knowledge about data sharing during undergraduate study, and a similar percentage of the participants (23%) reported having acquired their knowledge from experience and residency programs, suggesting better undergraduate ethics education for physicians. However, in the study of Harbarth et al, more than 70% of the participants reported having gained their knowledge about data sharing from their work experience.<sup>13</sup> Despite this, and in congruence with our findings, most of the physicians in the study of Harbarth et al agreed that

Table 3 Perceived Importance of Maintaining Confidentiality in Different Clinical Settings

	Not Important	Important
	N (%)	N (%)
1. Psychiatric diseases	4 (27)	11 (97.3)
2. Chronic diseases	103 (46.6)	118 (53.4)
3. Acute diseases	75 (33.9)	146 (66.1)
4. Illegal drugs	9 (4.1)	212 (95.9)
5. Food habits	105 (47.5)	114 (52.5)
6. Sexual diseases	13 (5.9)	208 (94.1)
7. Therapeutic plan	89 (40.3)	132 (59.7)

Table 4 Predictors of Physicians' Attitudes Toward Patient Confidentiality and Data Sharing

Model	Unstandardized Coefficients	Standardized Coefficients	t	Sig.
	B	Beta		
(Constant)	28.059	4.027	7.203	0.000
Specialty	-0.083	0.183	-0.454	0.650
Sex	-2.797	0.911	-3.070	0.002
Years of experience	0.279	0.077	3.634	0.000
Age	-0.087	0.074	-1.166	0.246
Marriage	-1.633	0.938	-1.741	0.083
Number of treated patients/day	0.277	0.269	1.028	0.306
Working setting	0.127	0.230	0.551	0.583
Frequency of ethical dilemmas faced	1.495	0.382	3.918	0.000
Preference in consulting on ethical dilemmas	0.957	0.191	5.019	0.000
Knowledge	0.894	1.135	0.782	0.434

further training on confidentiality laws is required.<sup>14</sup> These raises concerns regarding whether physicians are provided with adequate ethics education after they graduate and engage in clinical practice.

In the present study, the factors that were found to predict knowledge scores were sex ( $P=0.004$ ), marriage ( $P=0.021$ ), and the preference in consulting on the ethical dilemmas ( $P=0.020$ ). Similarly, sex was found to predict knowledge in a study conducted in the United States (US) ( $P=0.01$ ).<sup>17</sup> Furthermore, Beltran-Aroca et al reported that men outperformed women in knowledge about confidentiality.<sup>11</sup> This difference between sexes may be related to the sharing information between men and ease of reaching access of information and advance of technology.<sup>17</sup> Noticeably, age, experience, and specialty were not associated with knowledge among our sample. This is consistent with the findings of the aforementioned US study, whereby the number of years of experience, specialty, and level of training were not found to correlate with knowledge.<sup>17</sup> Similarly, the multiple regression analysis that conducted by Abuhammad et al<sup>21</sup> to comprehend the effect of the demographic attributes of nurses on data sharing and confidentiality of their patients, indicated that there was some connection between these attributes and the nurses on data sharing and confidentiality of their patients. These factors include age, gender, marriage status, and attending a security course before practice. Young age, female, not attending a data sharing course, and single

nurses are less engaging with data sharing and confidentiality of the patients for unauthorized people.

Our study's physicians believed patient confidentiality to be particularly essential when dealing with patients with psychiatric or sexual diseases or patients taking illegal drugs. However, lack of sufficient knowledge may impact physicians' attitudes towards implementing patient confidentiality practices in different clinical settings.<sup>22</sup> The mean score for attitudes towards confidentiality and data protection among the physicians in our study is similar to the low scores reported in Beltran et al study.<sup>11</sup> Several studies have reported ethical misconduct among residents in different clinical settings.<sup>6,20,21</sup> Mineek et al, for instance, observed and recorded 26 sharing patients data with unauthorized people out of the 32 patients who existed in an emergency department (ED) waiting area at a university hospital in about 6 hours of observation.<sup>6</sup> Moreover, 3–24 breaches per hour were recorded in the patient care area.<sup>2</sup> Another study recorded breaches in 16 hospital departments for over more than 700 days, with around one breach occurring every 62.5 hours and 46.7% of the breaches being severe and 9.5% being repeated.<sup>8</sup> Furthermore, similar to our findings, two previous studies reported that physicians primarily consult their colleagues when faced with an ethical dilemma.<sup>11,14</sup> This suggests that patient privacy may be compromised by physicians consulting other physicians who are not involved in the patient's care.<sup>14</sup> Interestingly, less than 10% of the

Table 4 Physician's Response Related to Attitudes Towards Patient Confidentiality and Data Sharing

	Never	Rarely	Sometimes	Always
	N (%)	N (%)	N (%)	N (%)
1. I make sure to take the information from the patient and document it completely confidentially	2 (0.0)	4 (1.8)	46 (21.7)	149 (78.5)
2. I discuss a patient's conditions with them in front of other patients to save time and place	87 (39.4)	71 (33.0)	45 (26.6)	16 (7.2)
3. I allow non-medical personnel (eg, cleaning staff) to enter the examination room while I am providing care to patients	151 (68.3)	31 (14.0)	32 (14.5)	7 (3.2)
4. I use a universal serial bus (USB) to store patient information	153 (69.2)	30 (13.6)	25 (11.3)	13 (6.9)
5. I use a personal computer to store patient information	148 (67.6)	35 (15.8)	22 (10.6)	16 (7.2)
6. I send patient information online	142 (64.3)	42 (19.0)	27 (12.2)	10 (4.5)
7. I send information by phone	96 (43.4)	58 (26.2)	40 (27.1)	7 (3.2)
8. I deal with the information of patients with sensitive diseases (mental diseases, sexual diseases, etc) with more caution	19 (8.6)	16 (7.2)	37 (16.7)	149 (67.4)
9. I use virus protection and encryption software on the devices on which I store patient information	84 (38.0)	35 (15.8)	37 (16.7)	45 (29.4)
10. I discuss my patients' conditions with my colleagues during work breaks	15 (6.8)	50 (22.6)	124 (56.1)	32 (14.5)
11. I discuss my patients' conditions with my colleagues in open spaces, such as reception areas and corridors	111 (60.2)	49 (21.2)	29 (13.1)	12 (5.4)
12. I discuss my patients' conditions with my friends outside the workplace	90 (46.7)	42 (28.1)	58 (26.2)	11 (5.0)
13. I leave notes about my patients' conditions on my desk	133 (60.2)	53 (24.0)	29 (13.1)	4 (2.7)
14. I make and receive phone calls about patients' conditions when I am near other patients	124 (56.1)	55 (24.9)	36 (16.3)	4 (2.7)

Table 5 Predictors of Physicians' Knowledge About Patient Confidentiality and Data Sharing

Model	Unstandardized Coefficients	Standardized Coefficients	t	Sig.
	B	Beta		
(Constant)	12.691	2.216	5.727	0.000
Specialty	0.168	0.100	0.111	1.675
Sex	1.471	0.501	0.200	2.933
Years of experience	-0.028	0.042	-0.077	-0.660
Age	0.000	0.041	-0.001	-0.007
Marriage	-1.198	0.616	-1.777	-1.322
Number of treated patients/day	-0.058	0.148	-0.026	-0.293
Working setting	0.010	0.127	0.006	0.980
Number of ethical dilemmas faced	0.105	0.199	0.035	0.526
Preference in consulting on ethical dilemmas	0.240	0.105	0.155	1.251
Interest in taking medical ethics course	0.103	0.235	0.059	0.141

participants in our study reported that they consulted their department's head or ethical committee when faced with ethical problems. Harbarth et al suggested that this may explain why junior practitioners face more problems than their consultant counterparts, as juniors may not report such problems to their seniors in the first place.<sup>13</sup> This form of violation, which includes revealing patients' personal and medical data to third parties, was the most commonly reported form in Beltran et al study.<sup>11</sup> Moreover, an observational study noted that 37.9% of sharing patients data with unauthorized people occurred in public areas, with over half of the observed incidents being related to consultations with uninvolved personnel.<sup>13</sup> Likewise, discussing patient information outside the work place is considered a confidentiality breach in communal areas.<sup>13</sup> This includes patients in rooms closer to the nursing or physicians' station, waiting areas in emergency departments, and/or elevators.<sup>13</sup> Remarkably, around two-thirds of the physicians in our study reported that they would never or rarely conduct such practice. Also, only 7% of the participating physicians reported that they would discuss patient information in front of other patients to save time. These practices, however, may be simply habitual rather than intentional, as suggested in several studies.<sup>20,22</sup> However, our results indicated no correlation between the number of patients seen per day and physicians' attitudes towards data sharing and patient confidentiality. One previous study also attributed discussing patients data with unauthorized people to building design and floor planning.<sup>2</sup> As expected, our results indicated that physicians with more years of experience and those who encountered more ethical dilemmas were more likely to adhere to practices that protected their patients' confidentiality.

The protection of patient confidentiality in daily medical practice includes the handling, communication, and management of a large amount of identifiable medical data.<sup>11</sup> Only 17% of the physicians in our study reported that they stored patient data on their private computers, and more than 40% reported using virus protection and encryption software on the devices they used to store patient information. Other studies have suggested other practices that may lead to confidential data being leaked, including the failure to anonymize patient data and data storage on unprotected spaces, such as personal e-mails, personal laptops, and USB flash drives.<sup>23</sup> A recent study reported the use of USB flash drives by 274 nurses (14.3%) and e-mail by 127 nurses (21%) for the storage of patient data.<sup>24</sup> Meanwhile, only 17% of the physicians

in our study reported that they always or sometimes used a USB flash drive or online spaces to store patient data.

### Implication of the Study

The study findings showed that it may be important when amending regulations and guidelines imposed by Jordanian health authorities and other countries experiencing the same situation of confidentiality. Furthermore, it is also important to consider and develop a concise strategy to ensure the confidentiality, safety, and security of patient information while planning for the development and implementation of computerized systems and case management processes. Training is essential for all the physicians and health care providers who is working with patients since it will have a beneficial relationship with knowledge, opinions, views, and actions. Thus, planning continuous training on policies and regulations about data safety and privacy may assist in improving healthcare settings' practices.

### Limitation

This study is a cross-sectional study that provides no evidence regarding the causes of our sample's observed knowledge and attitudes' levels. Furthermore, two-thirds of the participants were men (67.5%). However, this is considered to be representative of the sex ratio in the healthcare sector in Jordan.<sup>25</sup> Besides, the participants' reporting of how frequently they faced ethical dilemmas may have been impacted by their limited awareness of what constitutes an ethical dilemma. Another limitation is response bias, which does not reflect the actual knowledge and attitude in the clinical area.

### Conclusion

This study provides insight into physicians' knowledge and practices related to confidentiality. Despite being well aware of the importance of protecting patient confidentiality, the participating physicians were found to commit frequent sharing patients data with unauthorized people in their medical practice. Moreover, the participants were found to have inadequate levels of knowledge about correct data sharing practices, suggesting that they did not fully understand their obligations towards patient confidentiality. Future studies that investigate the factors that contribute to ethical misconduct and the impact of continued ethics education on physicians' knowledge and practices are recommended.

### Data Sharing Statement

The datasets generated and analyzed during the current study are available with the corresponding author.



# Reproductive medicine

## Medical Ethics

Dr. Reema Karasneh

# Introduction

- Medical technology can increase reproductive choice for three main reasons:
  1. It provides the possibility of **terminating the pregnancy** (abortion), and this is carried out most safely in a clinical setting
  2. It provides the means of **assisting conception**, using an increasing array of techniques
  3. It makes available a range of investigations that help **predict the likely health status**, and much more, of the fetus or potential child.
- To what extent should health professionals control reproductive choice?

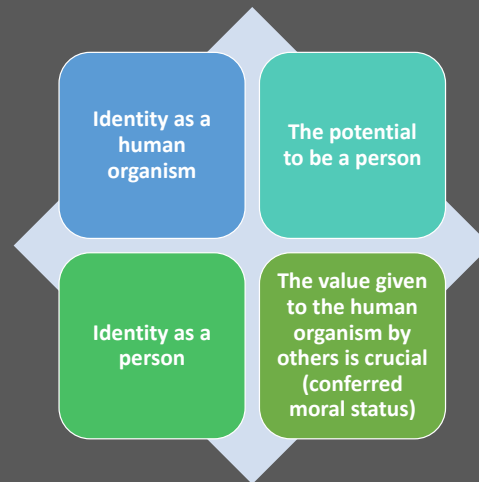
## FOUR APPROACHES TO THE ISSUE OF REPRODUCTIVE CHOICE

- 1. Procreative autonomy - the interests of parents**
  - Emphasizes the value or the right of adults to make their own reproductive choices
  - Professional interference should be kept to a minimum
- 2. The interests of the future child**
  - It is particularly relevant to assisted reproduction
  - Health professionals can prevent access to assisted reproduction if they believe that it is in the interests of the potential or future child
- 3. The interests of the public**
  - Reproductive choices affect the composition of the future population
    - for example to select the sex of their children
- 4. Preserving life**
  - Central to the issue of abortion is the morality of killing a fetus

## ABORTION

- The intentional termination of pregnancy with the resulting death of the embryo or fetus
- Abortion continues to raise a number of ethical issues related to the rights of the women versus the rights of the fetus
- At what stage in the development of the human organism from egg to child does it become a significant wrong to kill the organism?

## Four views on what is important in determining the moral status of the embryo



## Identity as a human organism

- The view that the moral status of an embryo depends on its identity (what they are)
- An embryo, from the point of conception, has the same moral status (same identity) as a child into which it develops.
  - Some starts from 14 days after conception, after the "pre-embryo" period (until the potential for twinning is lost)
- Problems:**
  - Give too much moral protection to very early embryos
  - Faces particular difficulties when the reasons a woman has for wanting an abortion are very powerful
  - It implies that killing that cell (or that early embryo) is, from a moral point of view, the same as killing a 10-year-old child
    - Intrauterine contraceptive device????
    - Morning after pill???

## The potential to be a person

- The view that the moral status of an embryo depends on its potential
- You are in effect killing a potential child.
  - It is wrong to kill a child; if you kill an embryo or fetus, at any stage, you are carrying out an act that will have the effect that the potential future child will not exist
- **Problem:**
  - Give too much moral protection to very early embryos
    - A single sperm about to be injected into an egg constitutes a potential person!!!

## Identity as a person

- The view that the moral status of an embryo depends on its properties
- An embryo or fetus is a moral entity at the point when it becomes a person
- What determines the stage during development when a human organism becomes a person?
  - **Degree of consciousness in the sense of feeling pain**
    - Starts at about 24weeks' gestation
    - Animals feel pain!!!
  - **Self-consciousness** (has future-directed plans and goals), **rationality** (the ability to reason) and **the ability to form relationships**
    - Infants, and incompetent patients!!!!
  - **Ensolement** (the point when the soul enters the body)
    - Various times, from conception to birth, have been proposed as the moment of ensoulment (No objective criteria for identifying that moment)
- **Problems:**
  - Give too little protection to infants and incompetent people
  - Has problems in justifying features that is taken to characterize a person

## The value given to the human organism by others is crucial

- Moral status can be conferred by others
- Conferring moral status at birth can be justified in terms of the consequences for others and in terms of fostering concern, warmth and sympathy for others.
- **Problem:**
  - Justify intuitions about the moral importance of infants for wrong reasons.
    - It seems to suggest that we should not kill an infant on grounds such as that the infant's parents (and a few others) would be terribly upset.

## So...When is it wrong to kill a fetus?

- One view that is intuitively attractive to many people is that the moral status of the fetus develops as the fetus itself develops.
  - It may be wrong to kill even an early fetus, but the degree of wrong would be very much less than killing a late fetus.
- The grounds that would justify killing a fetus need to become stronger and stronger as the fetus develops.
- Parental convenience may be sufficient to justify the abortion of an early fetus, but it would need something much more significant to justify the of an older fetus

# Maternal-Fetal Conflict

- **Mother's self determination and autonomy**

- A woman should be allowed to determine her own actions without external forces influencing her
  - (e.g. refuse treatment of any kind for herself and for her fetus, even when that treatment is in both of their best interests)
- Pregnancy affects a woman's health and life; if she makes a choice then she has the right to do so without intervention

- **The concept of personhood**

## Arguments against constraining a pregnant woman's behaviour for the sake of the fetus (or future child)

1. **Autonomy**- such constraints infringe the woman's autonomy.
2. **Privacy** - the woman has a right not to have her body invaded or even touched without consent. Many constraints on her behaviour would involve such battery.
3. **Fetal status** - in English law the fetus has no status as a person until birth. The rights of a person (the woman) should not be subjugated to the rights, if any, of an entity that is not a person.
4. **Public policy** - the likely consequences of allowing fetal interests to affect the legal provisions for restraining people's behaviour are undesirable.
5. Even if there are good arguments that it is morally wrong for a pregnant woman to behave in ways that might harm the fetus or future child, it does not follow that such behaviour should be the subject of legal restraint.

## An argument in favour of constraining a pregnant woman's behaviour for the sake of the fetus (or future child)

- **Example:**

- The banning of the sedative Thalidomide.
  - No significant adverse effects on mothers but interfere with limb development of fetus.
  - Rather than informing women of these possible effects and allowing them to choose whether to take this sedative, it was banned in the interests of future people.

- Such constraint would be on the basis of the principle of preventing harm to others.

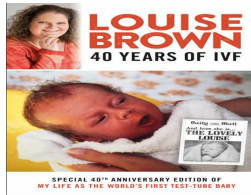
# ASSISTED REPRODUCTION

Understanding acceptable versus unacceptable harm

- **In Vitro Fertilization**
- **Pre-implantation genetic diagnosis:** Choosing which embryos to implant
  - Discrimination, "Designer" babies, Sex selection, Destruction of unwanted embryos
- **Surrogacy:** Carrying Someone Else's Child
  - the right of autonomy and privacy of the parents; the right of privacy of the donor; the right of the child to know his/her origins.
- **Sterilization:** Preventing Reproduction

## In Vitro Fertilization

- Louise Brown's conception (1978), was made possible through in-vitro fertilization (IVF)
- Several more sophisticated techniques have been developed
- Some believe that IVF and related techniques are always wrong.



Reasons for considering IVF, and some other types of fertility treatment, as ethically wrong

Killing embryos is wrong

IVF is unnatural

IVF is harmful to marriage

IVF harms women

## Killing embryos is wrong

- Some types of fertility treatment involve the production of embryos that are subsequently not used in treatment and are destroyed.
- The force of this argument depends on the moral status accorded to embryos

## IVF is unnatural

- The argument about unnaturalness is used in many situations involving modern technology
- There are three major problems with the argument in general
  1. To determine what is natural and what unnatural
  2. That so much of medicine (and indeed so much of modern life) is unnatural
    - Few would argue that intravenous antibiotics should not be given to someone with septicaemia
  3. The third is to provide reasons why something that is unnatural is therefore morally wrong

## IVF is harmful to marriage

- Reproductive technologies separate the procreative aspects of marriage from the conjugal aspects.
- Some argue that this is harmful to the institution of marriage
- The problem with this is to clarify in what way this is harmful to the marriage

## IVF harms women

- **Centre on claims that:**
  - Men control these technologies and hence control female reproduction
  - Such technologies help to perpetuate a view that women cannot be completely fulfilled unless they have children
- Many women take the opposite view and see the reproductive technologies as enhancing their freedom and choice by enabling them to have children if they so wish

## End of life issues



### Medical Ethics

Dr. Reema Karasneh

## Good Death!!! A medical perspective

- Over the past 100 years, there has been an epidemiologic shift in the reasons people die.
  - In the pre-antibiotic era
    - people most often died young, of infectious diseases
  - Now
    - Because of medical technology people live much longer, to die of degenerative, neoplastic, and man-made diseases.

## Medical care in in-hospital death Intensive Care Unit (ICU)

- **Bad death**
  - Severe pain (common)
  - Decisions to withhold invasive treatments were made at the last minute
  - Physicians often had no knowledge of patient preferences not to have Cardiopulmonary Resuscitation (CPR)

## What would make the experience of dying "good" (Good death)

- It is an important goal for physicians and other members of the care team
- Physician should help person to get ready-and contribute to a death that is decent.
  - To be sincere and patient and interested
  - Listen more and talk less
  - Try asking something like
    - “Knowing that all of us have to think about dying at some point”
    - “What would be a good death for you?”
- What people choose when they think about a good death for themselves is often beyond what medicine can
  - A completion of important work
  - A last visit with an important person

## Clinical goals when caring for someone near the end of life

1. **Control of pain and other physical symptoms.**
  - The physical aspects of care are a prerequisite for everything that follows.
2. **Involvement of people important to the patient.**
  - Death is not usually an individual experience; it occurs within a social context of family, significant others, friends, and caregivers.
3. **A degree of acceptance by the patient.**
  - Acceptance doesn't mean that the patient likes what is going on, and it doesn't mean that a patient has no hopes—it just means that he can be realistic about the situation.
4. **A medical understanding of the patient's disease.**
  - Most patients, families, and caregivers come to physicians in order to learn something about what is happening medically, and it is important to recognize their need for information.
5. **A process of care that guides patient understanding and decision making.**
  - One great physician does not equal great care—it takes a coordinated system of providers.

## How do you know when someone is dying?

- This question is not as simple as it might sound.
- Even for patients with a high probability of dying, it is still difficult for a clinician to predict that a particular patient is about to die.
- Clinicians should
  - Give up relying on their predictive skills
  - Look at the common clinical paths (or trajectories) taken by dying patients
  - Design medical care that includes "contingency plans" for clinical problems
    - Advance directives
    - Do Not Attempt Resuscitation (DNAR ) orders

## Medical Practices in end of life issues

- **Withholding/withdrawing life-sustaining treatments**
- **Pain medication that may hasten death**
- **Palliative sedation**

## Withholding / withdrawing life-sustaining treatments

- When a competent adult patient makes an informed decision to refuse life-sustaining treatment, their wishes are generally respected.
- The right of a competent adult patient to refuse life-sustaining treatments is supported by law.

## Pain medication that may hasten death

- Often a terminally ill, suffering patient may require dosages of pain medication that have side effects that may hasten death, such as impairing respiration.
- Using the ethical principle of **double effect** as the foundational argument, it is generally held by most professional societies, and supported in court decisions, that this action is justifiable.
- Since the primary goal and intention of administering these medications is to relieve suffering, the secondary outcome of potentially hastening death is recognized as an expected and acceptable side-effect in a terminally ill patient.

## Palliative sedation

- This term refers to the practice of sedating a terminally ill patient to the point of unconsciousness, due to intractable pain and suffering that has been refractory to traditional medical management.
- Such patients are imminently dying, usually hours or days from death.
- Often other life-sustaining interventions continue to be withheld (CPR, respirator, antibiotics, artificial nutrition and hydration, etc.) while the patient is sedated.
- Palliative sedation may occur for a short period, or the patient may be sedated until s/he dies.



## Persistent states of unconsciousness

- Persistent/permanent vegetative state (PVS):
  - Following devastating brain injury patients may be unconscious with no prospect of regaining consciousness - patients in such a state require assistance in order to remain alive (artificial nutrition, hydration, mechanical ventilation, ..., etc.)
- The question arises as to whether it is lawful to withdraw the life support measures, allowing the patient to die.
- The principle on which the judgment is based is called the principle of '**not against the best interests**'.

## When is it justifiable to discontinue life-sustaining treatments?

- If the patient has the ability to make decisions, fully understands the consequences of their decision, and states they no longer want a treatment, it is justifiable to withdraw the treatment.
- Treatment withdrawal is also justifiable if the treatment no longer offers benefit to the patient.

## Medical futility

- The term medical futility applies when a treating health care provider determines that an intervention is no longer beneficial (based on medical data and professional experience)
- Two kinds of medical futility are often distinguished:
  - **Quantitative futility**
    - The likelihood that an intervention will benefit the patient is exceedingly poor
  - **Qualitative futility**
    - The quality of benefit an intervention will produce is exceedingly poor
- Both quantitative and qualitative futility refer to the prospect that a specific treatment will **benefit** (not simply have a physiological effect) on the patient.
- The concept of 'futility' combines
  - **Probability** of a successful outcome
  - **Evaluation** of what counts as a successful outcome
    - Length of life
    - Quality of life

## Medical futility

- Futility refers to a particular intervention at a particular time, for a specific patient.
  - Example:
    - "It is futile to continue to treat this patient," No
    - "CPR would be medically futile for this patient." Yes
- CPR has been shown to have less than 1% probability of success in the following clinical circumstances:
  - Septic shock
  - Acute stroke
  - Metastatic cancer
  - Severe pneumonia
- In other clinical situations, survival from CPR is extremely limited:
  - Hypotension (2% survival)
  - Renal failure (3%)
  - AIDS (2%)
  - Age greater than 70 (4% survival to discharge from hospital)

## Ethical obligations of physicians when a health care provider judges an intervention is futile

- Physicians have no obligation to offer treatments that do not benefit patients.
- Determining which interventions are beneficial to a patient can be difficult, since the patient or surrogate might see an intervention as beneficial while the physician does not.
- Ethical obligations of physicians include:
  - Following professional standards of care in offering treatments that confer benefit to the patient
  - Considering empirical studies and their own clinical experience when making futility judgments
  - Showing sensitivity to patients and families in carrying out decisions to withhold or withdraw futile interventions.
- Although the ethical requirement to respect patient autonomy entitles a patient to choose from among medically acceptable treatment options (or to reject all options), it does not entitle patients to receive whatever treatments they ask for.

## The Decision of Futile Treatment

- Physicians have the ethical authority to withhold or withdraw medically futile interventions
- To improve the experience and outcome for all:
  - All members of the health care team would ideally reach consensus
  - Communicating with professional colleagues involved in a patient's care
  - Communicating with patients and family
- Effects of futile interventions
  - Increase a patient's pain and discomfort in the final days and weeks of life
  - Give patients and family false hope
  - Delay palliative and comfort care
  - Expend finite medical resources

## Medical futility and elderly patients

- Futility has no necessary correlation with a patient's age.
- What determines whether a treatment is futile is whether or not the treatment benefits the patient.
- In cases where evidence clearly shows that older patients have poorer outcomes than younger patients, age may be a reliable indicator of patient benefit
- For patients of all ages, health care professionals should advocate for medically beneficial care, and refrain from treatments that do not help the patient.

## Do Not Attempt Resuscitation (DNAR) Orders

- A Do Not Attempt Resuscitation (DNAR) Order, also known as a do not resuscitate (DNR) order
  - Written by a licensed physician in consultation with a patient or surrogate decision maker that indicates whether or not the patient will receive cardiopulmonary resuscitation (CPR) in the setting of cardiac and/or respiratory arrest.
- CPR is a series of specific medical procedures that attempt to maintain perfusion to vital organs while efforts are made to reverse the underlying cause for the cardiopulmonary arrest.
- Although a DNAR order may be a component of an advance directive or indicated through advance care planning, it is valid without an advance directive.

## History of CPR and DNAR Orders

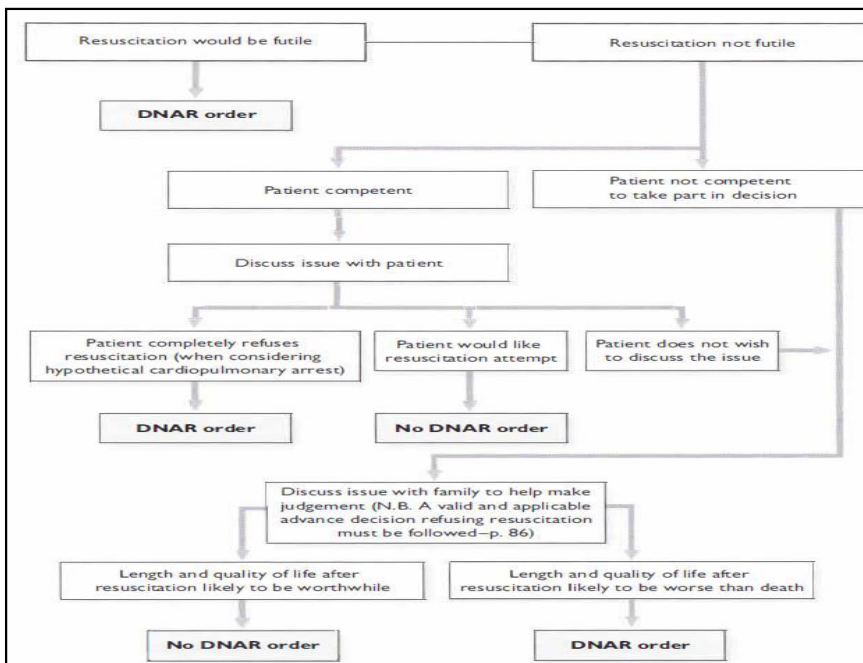
- **In the 1960s**
  - CPR was initially performed by anesthesiologists on adults and children who suffered from *witnessed cardiac arrest following reversible* illnesses and injuries.
  - Based on the success of this intervention, CPR became the standard of care for all etiologies of cardiopulmonary arrest and the universal presumptive consent to resuscitation evolved
- **In 1974**
  - the American Heart Association (AHA) recognized that many patients who received CPR survived with significant morbidities and recommended that physicians document in the chart when CPR is not indicated after obtaining patient or surrogate consent
  - This documentation formally became known as the DNR order.
- Recent medical literature encourages reference to this documentation as do-not-attempt-resuscitation (DNAR) and allow a natural death (AND) based on the practical reality that performing CPR is an attempt to save life rather than a guarantee

## The Role of Patient Autonomy: DNR orders in terminally ill competent patient

- **These should be considered:**
  - **The possible outcomes following CPR**
    1. Immediate death
    2. Some prolongation of life in a state similar to that prior to the cardiac arrest
    3. Some prolongation of life in a state that is worse than that prior to the cardiac arrest (may be worse than death)
  - **The cost-effectiveness of CPR should be considered**
- The patient is to decide on his/her resuscitation status, He/she would need to know all these information and probabilities

## Withholding CPR

- Virtually all hospitals have policies which describe circumstances under which CPR can be withheld.
- Generally, It is appropriate to consider a DNR decision in the following circumstances:
  1. CPR is unlikely to be successful (**medical futility**).
  2. CPR is not in accord with the recorded, sustained wishes of the patient who is mentally **competent**.
  3. Where CPR is not in accord with a valid **advance directive** (living will).
  4. Resuscitation is likely to be followed by a **length and quality of life** that would not be in the best interests of the patient to sustain.



# Resource Allocation



## Medical Ethics

Dr. Reema Karasneh

# Introduction

- Healthcare systems throughout the world face the problem of how the resources available should best be allocated
- No system has sufficient funds to provide the best possible treatment for all patients in all situations

# Resources

- Resources include:
  - Equipment
  - Beds
  - Drugs
  - Time
  - Excessive numbers of persons in need
- Often scarcity of resources make it difficult, if not impossible, to provide “the full measure of service and devotion”
- Examples of reasons for shortage may include:
  - there are many more patients with end stage cardiac disease or liver disease than there are organs available
  - expensive equipment may be lacking in a particular region
  - tertiary care hospital beds may be limited
  - a particular medication may be extremely costly
  - few personnel might be trained for a certain technical procedure
  - insurance coverage is unavailable or of prohibitive cost

# What limits resources...?

- **Financial Constraints**
  - No money to spend
  - Unfair distribution
- **Increased supply and demand**
  - Improved treatments and technology allows medicine to treat more disease.
  - Innovations are frequently brought ‘to the market’ by biotechnology/ pharmaceutical companies who need to generate profit from their investment
- People live longer and expect to live longer
- With longer lives the nature of the treatment to be delivered changes over time.

## Types of distribution problems

- **Macro-allocation**
  - Global
    - Clear problems in terms of equity
      - e.g. insufficient resources for essential medicines, trained doctors, ..., etc.
  - National
    - Department of Health, hospitals
- **Micro-allocation**
  - Deciding between patients

## Theories of Resource Allocation

- The purpose of health care in general is to increase both the quantity and the quality of life
  - We need to trade these two factors against each other
  - The combination of quantity and quality is called the overall *welfare* for a patient
- Allocating resources within health care should maximize the amount of welfare
- There are a number of theories that address the question of how to distribute health resources fairly:
  - **QALY theory** (utilitarianism), the most thoroughly worked approach cost-effectiveness analysis
  - **Needs based theory**
  - **Responsibility for bringing condition on oneself**

## What is QALY?

- The acronym QALY stands for quality-adjusted life year
- Used as a concept of resource allocation
- Is a measure of a value of **health outcomes**
  - A year of life in perfect health is given value of 1
  - Year of unhealthy life is given value <1 (e.g. 0.5)
- A health care system which maximises QALY is one which provides the most benefit

## Cost effectiveness of QALY

- Utilitarian stance of maximising healthcare with available resources (a calculus of happiness)
- The most efficient healthcare system is one where cost per QALY is low
  - Maximum QALY per Pound/Dollar

## Why should we use QALYs? Arguments for QALY

- Provides maximum benefit for public with available finances
  - Therefore it maximises healthcare budget
- Not only promotes health but the quality and quantity of patients lives

## Arguments against QALY

### 1. Discriminates against those with expensive healthcare problems

- A 60 year old burn patient may require prolonged stay on intensive care, repeated surgery
  - Total cost of care can enter hundreds of thousands
  - Patient may only live another 10 years
  - Cost to QALY is High
  - Little benefit to society
  - **Maximum** benefit for **individual** in need
- For the same amount of financial resources we can provide smoking cessation advice to tens of thousands
  - Cost of QALY is low
  - **Maximum** benefit for **society**

## Arguments against QALY

### 2. Unjust method of service allocation

- Two patients both requiring treatment for community acquired pneumonia
  - Patient A is fit and well
  - Patient B has chronic obstructive pulmonary disease (COPD), congestive cardiac failure (CCF), ischemic heart disease (IHD)
    - QALY would favour the treatment of patient A
- Under bioethical **principle of justice** both patients should have equal access to treatment
- Is it fair for the patient who's got all the medical conditions to not receive the appropriate treatment just because the other person will have a higher value of healthy years gained?

## Are QALYs Ageist?

- Older patients have increasing likelihood of co-morbidities
  - Thus limiting Quality of Life Years gained
- Therefore, treatment would generally favour treatment of younger healthier patients
- Do not specifically discriminate based upon age
  - 10 year old with condition resulting short life expectancy
    - Treatment provides less QALY gain
  - 70 year old, marathon runner, with no medical concerns. May go on to live another 10-20 years
    - Greater potential for QALY gain
- Should preference be given to young as elderly have already lived their life?

## Needs Based Model

- Based upon the concept that resources should be allocated to those with most need
  - Priorities the most risk
    - A 60 year old burn patient would justify having the treatment
    - 10 year old with condition resulting short life expectancy Should be treated
- Rational citizens would wish for those whom are worst off in society to have maximal wellbeing

## Arguments against Needs Model

- Doesn't provide for a society as a whole
  - i.e. spending all money on one burn patients as opposed to 1,000 excision of premalignant skin lesions
- Less efficient allocation of resources
  - Increased costs to provide healthcare
- Patients may only have access to healthcare when life threatening illness occurs
  - Neglect of chronic disease (Angina)
  - Only treated when acute problem arises (Myocardial Infarction)

## Summary

### QALYs

- Method for maximising efficiency of resource allocation
  - Utilitarian
- Provides resource allocation which is best for society and not individual
- May discriminate against:
  - Elderly patients
  - Those requiring the most help

### Needs Model

- Provided to patient most in need of treatment
- Less efficient method for resource allocation
- Reduced resource allocation for those with chronic disease

## RESPONSIBILITY FOR BRINGING CONDITION ON ONESELF

- Most patients have contributed to some extent to their health problems:
- Examples
  - Lung disease or heart disease in someone who smokes
  - Liver failure in someone who drinks large amounts of alcohol
  - Tattoo that the patient now wants removed
  - Reversal of sterilization
  - Soft tissue injury from sport
  - Accident in someone engaging in risky behaviour, for example hang-gliding or cycling along a busy road
  - Accident due to person's own careless driving
  - Heart disease in obese person
  - Respiratory infection in someone who travelled in a crowded train
  - Renal disease in someone with diabetes who has not controlled their diabetes carefully

### Arguments in favour of responsibility affecting priority

- An argument in favour of responsibility affecting healthcare priority can be made in two stages:
  1. That the person is responsible, at least to some extent, for bringing the problem on himself/herself
  2. That such responsibility is a reason for reducing priority for health care

### Arguments against responsibility affecting priority

- Attributing responsibility is too imprecise
  - people have little effective choice over most of the factors that affect health
    - E.g Smoking can be attributed to peer group pressure, perhaps genetic factors, or may have become addicted to smoking when a teenager.
- Access to health care, and priority, should depend on factors such as clinical need, not responsibility

### FAIR PROCEDURE FOR MAKING ALLOCATION DECISIONS

Each theory of resource allocation highlights some relevant values, and each has some strengths and some weaknesses.

There seems to be no one theory that should determine the use of resources.

Recent work has focused not on the theories but on the process by which decisions should be made.

### Conditions to implement 'accountability for reasonableness' in allocation decisions

**(Publicity)** Decisions regarding coverage for new technologies (and other limit-setting decisions) and their rationales must be publicly accessible.

**(Reasonableness)** The rationales for coverage decisions should aim to provide a reasonable construal of how the organisation should provide "value for money" in meeting the varied health needs of a defined population under reasonable resource constraints.

**(Appeals)** There is a mechanism for challenge and dispute resolution regarding limit-setting decisions, including the opportunity for revising decisions in light of further evidence or arguments

**(Enforcement)** There is either voluntary or public regulation of the process to ensure that conditions 1-3 are met.



# Research Ethics



## Medical ethics

Dr. Reema Karasneh

## Historical events that have influenced human research



- First Documented Human Subject Research (1700's)
- The Era of Modern Science (1900's)
- Nuremberg Code (December 9, 1946 World war II)
- Thalidomide (In the late 1950s)
- Tuskegee Syphilis Study (1932-1972)
- Declaration of Helsinki (1964)
- Beecher Article (1966)

## First Documented Human Subject Research (1700's)

- Among the first human subject research experiments to be documented were vaccination trials
- In these early trials physicians used themselves or their family members as test subjects. For example:
  - **Edward Jenner (1749-1823)** first tested smallpox vaccines on his son and on neighbourhood children.
  - **Johann Jorg (1779-1856)** swallowed 17 drugs in various doses to record their properties.
  - **Louis Pasteur (1822-1895)** "agonized over treating humans," even though he was confident of the results obtained through animal trials. He finally did so only when he was convinced the death of the child, the first test subject (Joseph Meister), "appeared inevitable." was the first person to be inoculated against rabies by Louis Pasteur, and the first person to be successfully treated for the infection.

## The Era of Modern Science (1900's)

- Walter Reed's well-known experiments to develop an inoculation for yellow fever were at the forefront of these advances.
- These experiments, however, unlike earlier experiments with vaccinations, were carefully examined.

## Nuremberg Code

December 9, 1946  
World war II

- American military court opened criminal proceedings against 23 leading German physicians and administrators for their participation in war crimes and crimes against humanity.
- German physicians conducted medical experiments on thousands of camp prisoners without their consent. Most of the subjects of these experiments died or were permanently disabled as a result.
- As a direct result of the trial, the Nuremberg Code was established in 1948, stating that:
  - Informed consent is essential.
  - Research should be based on prior animal work.
  - The risks should be justified by the anticipated benefits.
  - Only qualified scientists must conduct research.
  - Physical and mental suffering must be avoided.
  - Research in which death or disabling injury is expected should not be conducted
- Although it did not carry the force of law, the Nuremberg Code was the first international document which advocated voluntary participation and informed consent

## Thalidomide

In the late 1950s



- Thalidomide was approved as a sedative in Europe; it was not approved in the United States by the FDA.
- The drug was prescribed to control sleep and nausea throughout pregnancy, but it was soon found that taking this drug during pregnancy caused severe deformities in the fetus.
- Many patients did not know they were taking a drug that was not approved for use by the FDA, nor did they give informed consent. 12,000 babies were born with severe deformities due to thalidomide.
- For the first time, drug manufacturers were required to prove to FDA the effectiveness of their products before marketing them.

## Tuskegee Syphilis Study 1932-1972



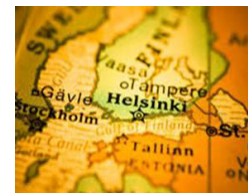
### The New York Times

Syphilis Victims in U.S. Study  
Went Untreated for 40 Years

WASHINGTON, July 28—For 40 years the United States went to lengths to keep the secret of a study in which doctors had given the disease to poor Negro men in a rural area of Alabama. The study was conducted by the U.S. Public Health Service. The study was conducted in Tuskegee, Ala., and the subjects were poor Negro men who had been infected with the disease. The study was conducted in 1932 and continued until 1972. The study was conducted in Tuskegee, Ala., and the subjects were poor Negro men who had been infected with the disease. The study was conducted in 1932 and continued until 1972.

- A research project conducted by the U.S. Public Health Service.
- Six hundred low-income African-American males, 400 of whom were infected with syphilis, were monitored for 40 years. Free medical examinations were given; however, subjects were not told about their disease.
- Even though a proven cure (penicillin) became available in the 1950s, the study continued until 1972 with participants being denied treatment. In some cases, when subjects were diagnosed as having syphilis by other physicians, researchers intervened to prevent treatment.
- Many subjects died of syphilis during the study.
- The study was stopped in 1973 by the U.S. Department of Health, Education, and Welfare only after its existence was publicized and it became a political embarrassment.

## Declaration of Helsinki 1964

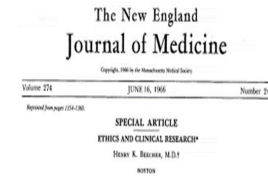


- In 1964 the World Medical Association (WMA) developed a code of research ethics that came to be known as the **Declaration of Helsinki**.
- It is a reinterpretation of the Nuremberg Code
- It is a set of ethical principles and recommendations guiding medical doctors in biomedical research involving human participants.
- Journal editors required that research be performed in accordance with the Declaration.
- This document set the stage for the implementation of the **Institutional Review Board (IRB)** process.
- Revised and amended in 1975, 1983, 1989, 1996, 2000, 2002, 2004, and 2008
- Is the basis for **Good Clinical Practices** used today



- **Issues addressed in the Declaration of Helsinki include:**
  - Research with humans should be based on the results from laboratory and animal experimentation
  - Research protocols should be reviewed by an independent committee prior to initiation
  - Informed consent from research participants is necessary
  - Research should be conducted by medically/scientifically qualified individuals
  - Risks should not exceed benefits

## Beecher Article (1966)



- In 1966 Dr. Henry K. Beecher, an anesthesiologist, wrote an article describing 22 examples of research studies with controversial ethics that had been conducted by reputable researchers and published in major journals
- (Beecher HK. "Ethics and Clinical Research" NEJM June 16, 1966) (<http://www.dartmouth.edu/~cphs/docs/beecher-article.pdf%20>).
- Beecher's article played an important role in heightening the awareness of researchers, the public, and the press to the problem of unethical human subjects research.

## Ethical Problems with Past Studies

Lack of informed consent

Coercion or undue pressure on volunteers (or on a parent to volunteer their child)

Use or exploitation of a vulnerable populations (children, prisoners, and pregnant women)

Withholding information (e.g. risk) or available treatment

Risks to subjects outweigh benefits

Deception

Violation of rights

## Research ethics



- **'Research ethics'** refers to the moral principles guiding research, from its inception through to its completion and publication of results and beyond

## Why Are Ethics Necessary

- There are many advantages to understanding research ethics. Concepts of research ethics:
  - Provide us with a structure for analysis and decision-making.
  - Support and remind researchers to protect human subjects.
  - Provide workable definitions of benefits and risks, along with guidelines for evaluating and balancing the benefits and risks of research studies

## ETHICAL PRINCIPLES RELEVANT TO MEDICAL RESEARCH

- **The autonomy of the research participant**
- **The risk of harm to the research participant**
- **The consequences of the research**

## The autonomy of the research participant

- To give almost exclusive weight to respecting participant autonomy (**the 'libertarian position'**).
- If a potential research participant is fully informed, competent and not coerced, then that person has a perfect right to take part in even very dangerous research.

## The risk of harm to the research participant

- The duty of the researcher to ensure that the potential participant is not put at risk of harm through taking part in the research.
- Almost exclusive concern for such risk gives rise to what might be called **the paternalistic position**
- Would consider research that involves more than minimal harm unethical, even if the potential participant gives fully informed consent
- Would be little concerned with research that involved no risk of harm but did take place without the consent of the participants
  - E.g. Research that involved collecting information from patients' medical notes without consent

## The consequences of the research

- **Consequentialist** approaches to ethics
  - It sees the consequences of our choices as being of crucial importance
  - Benefits and harms both to participants and to those in the future are to be considered.
  - The risk of harm to research participants may be justified by the good to people in the future who will benefit from the research.
- The Declaration of Helsinki rejects this position

**Box 14.2** A comparison of three different ethical approaches to research

	<b>Research where participants knowingly expose themselves to high risk</b>	<b>Low-risk research where participants do not know they are taking risks</b>	<b>Low-risk research where participants are fully informed</b>	<b>Poor-quality research that is of little value but where participants are fully informed</b>
Libertarian (rights based)	Yes	No	Yes	Yes
Paternalistic (duty based)	No	Yes	Yes	No
Utilitarian (consequentialist)	Yes	Yes	Yes	No

## CONTRASTING THESE ETHICAL APPROACHES

- These different approaches are contrasted
- Each approach highlights different values, and the international guidelines on research ethics make use of all three approaches
  - The importance of consent and confidentiality reflect respect for the autonomy of the participant
  - The general prohibition on putting the participant at more than minimal risk, reflecting the duty not to harm
  - The consequentialist approach informs the view that the potential for the research to benefit people in the future is a necessary condition for the research to be undertaken

## Summary of international guidelines on research ethics

1. Research participants should not be put at more than minimal risk of harm as a result of taking part in research
2. Potential research participants should be fully informed about both the purpose of the study and what will be involved in taking part, including an honest account of risks and benefits
3. It is difficult or even impossible to carry out some research with individual consent from participants (research using data from case notes or clinical databases). Ethics committees need to be satisfied that such research is of sufficient value to justify the breach of autonomy (confidentiality) and that the research cannot be carried out satisfactorily in any other way.

4. No coercion must be brought to bear on people to take part in research.
5. Participant should not feel an obligation to take part
6. Patients clinical care (outside the research study) should not be affected by their refusal to take part in research.
7. Payments may be made to patients only to offset reasonable costs, and must not be such as to act as inducement for the person to take part in the research.
8. Patients who are not competent to give consent for research may still be eligible to take part in research. Ethics committees will need to be satisfied that:
  - the risk of harm is very low, probably lower than the risk that is acceptable in the case of competent participants
  - the research aims cannot be achieved by other means
  - the research is of considerable value
  - a relevant person (usually a close relative) gives valid consent.

## MONITORING ETHICS IN RESEARCH: Institutional Review Boards

- Each institution or agency is required to establish a committee called an **Institutional Review Board (IRB)**
- IRBs are composed of five or more members who are representatives of the institution as well as laypeople who have no association with the institution (scientists and non-scientists e.g., faculty members or administrators)
- **IRB criteria for reviewing and approving research:**
  - Risks to subjects minimised
  - Risks reasonable in relation to anticipated benefits
  - Selection of subjects equitable
  - Data monitored for subjects' safety
  - Subjects' privacy protected and confidentiality of data maintained
- You must not begin any data collection involving human beings or animals until you have received ethical approval for your research

## Research proposals

- **Aims of the research**
- **Scientific background of the research**
- **Study design**
- **Participants**
  - who (inclusion and exclusion criteria), how many, how potential participants are identified and recruited, vulnerable groups
- **Methods of data collection**
  - Procedures for informed consent
  - Measures taken to ensure confidentiality, privacy and data protection
- **Methods of data analyses**
- **Expected outcomes, impacts and benefits of research**

## Human participants' (or subjects)

- Living human beings
- Human beings who have recently died
- Embryos and foetuses
- Human tissue and bodily fluids
- Human data and records
  - Medical, genetic, financial, personnel, criminal and administrative records, test results, ..., etc.

## 'Risk' to participants in research

- The potential physical or psychological harm, discomfort or stress to human participants that a research project might generate
- Ethical issues related to risks participants can arise at any stage of a research project
  - The nature of the project itself
  - The context of the research
  - Procedures adopted
  - Methods of data collection
  - Nature of the participants
  - The type of data collected
  - What is done with the data and how it is disseminated

## Potential benefits

- Basic knowledge
- Improvement of research or assessment techniques
- Practical outcomes
- Benefits for researchers
- Benefits for research participants

## KEY ETHICAL CONSIDERATIONS IN CARRYING OUT RESEARCH

- **Scientific validity**
- **Safety**
- **Consent procedure**
- **Competency/ Vulnerable groups**
- **Confidentiality**
- **In conducting quantitative and qualitative research**
- **In writing up the research/ Publication**

## Scientific validity

- ***Are the aims worthwhile?***
- ***Is the method appropriate to the aims?***
- Research that is scientifically poor may be considered unethical for two reasons:
  1. It will not benefit people in the future and so any risk of harm to participants cannot be justified
  2. It may harm people in the future because the results are misleading
- Sample size
  - If the sample size is not large enough to ensure adequate power then the research participants have been put at risk for no scientific gain
  - A sample size that is too large then more people will have been exposed to risk needlessly

## Safety

- ***Are the procedures safe, and are all reasonable precautions being taken?***
- ***Is the degree of risk for participants acceptable?***
- Research participants must be protected from being at much risk of harm, even if the benefit of the research to people in the future is considerable
- The term '**minimal risk**' is often used to describe an acceptable level of risk
  - **A small chance of a reaction which itself is trivial**
    - e.g. A mild headache or feeling of lethargy
  - **A very remote chance of serious injury or death'**

## Consent procedure

- **Informed**
  - Information must be clearly written, honest, sufficient, and balanced
- **Voluntary (absence of coercion)**
  - Participant must be aware that refusal to take part will not affect clinical care
  - The relationship between researcher and participant should be free from potential coercion
    - e.g. Clinician tries to recruit their own patients for research
  - Payments to encourage participation are coercion and only fair remuneration for expenses should be offered; otherwise people may be encouraged to take risks they ordinarily wouldn't in return for financial reward
  - Participants must be made aware that they have the right to withdraw their consent at any stage of the study.

### A. If the research involves the testing of medicines on human participants:

- A consent must be obtained
- The consent should be given freely after that person is informed of the nature, significance, implications and risks of the trial.
  - Failure to provide sufficient information may give rise to criminal liability
- The participant must have an interview with the researcher during which he must have been given the opportunity to understand the:
  - Objectives
  - Risks and inconveniences of the trial
  - The conditions under which the trial to be conducted
- Consent must be formally recorded on a signed, written consent form
- Consent once given can be withdrawn at any time

### B. If the research does not involve medicines:

- **If the research does not involve medicines:**
  - The relevant '**key information**' would include:
    - The purpose of the research
    - What is involved in taking part
    - The risks and benefits
    - General methodology



## Vulnerable groups

- ***Are the potential participants competent to decide whether or not to take part?***
- ***Is such competence being assessed, when relevant?***
- Vulnerable group may encompass a multitude of populations:
  - Children
  - People with mental illness, learning difficulties, communication difficulties
  - Prisoners
  - The disabled
  - Those who do not readily understand the spoken language
  - Asylum seekers
  - Travellers
  - House-bound people
  - The homeless

## Vulnerable groups

- **In research terms**
  - This may equate to the individual not being able to understand what their participation in a study will involve
  - They may find it difficult to make their wishes and preferences understood
  - This could result in them being less able to make an informed or reasoned decision about their participation
  - This in turn leads to the potential for the individual to be either manipulated or misled, or to make a decision they later regret
  - Every effort must be made to secure informed consent from participants (or proxies)

## Vulnerable groups

- In the case of research and children, parents alone can give consent but every effort must be made to involve the child in the discussions and obtain their approval to be included in the research
- Involving vulnerable populations in research is often
  - Complex
  - Time-consuming
  - ethically challenging process
- Involving vulnerable populations in research remains an absolute necessity:
  - They account for a substantial proportion of the population and need to be considered in all aspects of healthcare and medical research
  - If vulnerable groups remain 'invisible' in research then they will only become further disadvantaged
    - Their views, experiences, and needs will not be represented within the evidence base

## Confidentiality

- ***Have participants given consent for confidential data to be accessed in the research?***
- ***Are the safeguards to prevent those not involved in the research from having access to confidential data adequate?***
- Most medical research involves collecting information concerning individuals that should be kept confidential
- A researcher could be found negligent if
  - Reasonable precautions were not taken to ensure that information gained was stored in a secure manner
  - Information were passed to another person without explicit consent of the research participant

## Protecting Privacy and Confidentiality in Research

- The ethical principle of autonomy argues strongly for a meaningful informed consent in many areas related to research, including privacy and confidentiality.
- Therefore, concerns about protection of confidentiality in the research arena are valid.
- Over the years, these concerns have led to two major legislative. The two proposals are as follows:
  1. Patient consent should be required before investigators are allowed access to medical records.
  2. Data from medical records should be made available to investigators without any information that would identify an individual.
- Both proposals are consistent with the ethical principle of nonmaleficence—doing no harm—to the subjects participating in a research study.

## Problem in Protecting Privacy and Confidentiality in Research

- **Clinical research that requires access to patient details for recruitment purposes**
  - Researchers may wish to contact all patients who were admitted to hospital with a particular disease
  - If the hospital gives the contact details of such patients to the researchers, then patients confidentiality will have been breached
  - This problem can usually be avoided by the hospital or relevant clinician contacting the patient directly to seek consent for contact details to be passed on to the researchers

## Problem in Protecting Privacy and Confidentiality in Research

- **Research that is based on the collection and analysis of existing information in medical records**
  - Seeking individual consent from each patient for access to health records may not be possible in the case of large studies or studies involving records from a long time ago
  - Information from medical records that identifies individuals is essential for most epidemiologic studies
    - Review of medical records is often the first step in identifying a group of persons with a disease who will receive subsequent follow-up
    - Identifying information is essential for linking the records of specific individuals from different sources
      - (such as hospital records, physicians' records, employment records, and death certificates in studies of occupational cancer)
- If society has a vested interest in the findings from epidemiologic and other biomedical studies, it is necessary to strike a balance between the interests of the individual and those of the community

## Procedures designed to protect the confidentiality of subjects in epidemiologic studies

- Informed consent is required from study participants for all phases of research, except review of medical records
- All data obtained are stored under lock and key
- Only study numbers are used on data forms. The key for linking these numbers to individual names is kept separately under lock and key
- Individual identifying information is destroyed at the end of the study unless there is a specific justification for retaining this information. Such retention must be approved by the institutional review board (IRB) or committee on human research

## Procedures designed to protect the confidentiality of subjects in epidemiologic studies- Cont'd

- All results are published only in aggregate or group form so that individuals are never identified
- Unless it is essential for the study, individual identifying information is not entered in computer files, and individual identifiers are not included in routine tabulations generated from computerized data
- The importance of maintaining privacy and confidentiality is regularly emphasized to the research staff

## Quantitative Research

- Quantitative research involves studies in which the data that are analyzed are in the form of numbers
  - Behaviours
  - Correct answers or errors
  - Measures are recorded in terms of quantity
- Quantitative research involves both experimental and nonexperimental research

## Ethical issues in experimental research

- Focus on protecting:
  - Individuals that receive an intervention
  - Those who are in a “placebo” or control group
    - e.g., newly developed science program

## Ethical issues in nonexperimental research

- Nonexperimental research such as survey research focus on:
  - **Protecting the participants**
    - Should be fully informed as to the purpose of the study
    - Participant demographics
      - e.g., teachers, college students, the general public
    - Confidentiality of responses
    - How the results are intended to be used
    - Who will have access to the data
  - **Responsibility of “not wasting” a respondent’s time**
  - **Only collecting data that has utility (real use)**

## Qualitative Research

- Qualitative research involves data that are recorded in narrative descriptions, not numbers
- Researchers use qualitative methods to observe and describe conditions

## Ethics and Qualitative Research

- **Informed consent**
  - **Necessary but can be problematic when there is a substantial threat to privacy**
    - A revelation of observed conversations and behaviours could cause harm to participants in their families, communities, or place of employment
    - The actual research participants, who have given consent, may not be the only people observed.
      - e.g. a student in a school???
  - **consent is not necessary when**
    - Access to the setting is approved by the agency or institution
    - Participants who are actively involved have given informed consent
    - Other observed behaviour is considered public and observable by anyone present in the setting

## Publication

- Once your data collection is complete, analysed, and the final report formulated the next stage is publication of your findings
- As a researcher it is beholden upon you to publish your study, even if your findings are unexpected or unwanted
- Many journals expect to see evidence of your ethical review process before they will publish your work
- It may also be expected of you to sign a declaration stating your honesty and ethical approach to your research

## Core principles that must be adhered to in publication



Authority



Duplicate publication



Research misconduct (falsification, fabrication and plagiarism)



Conflict of interest



Accurate reporting

## Authority

- Only those who have made a significant contribution should be credited as authors
- Significant contributions include
  - Design of the research
  - Designing and conducting major analysis
  - Interpreting findings
  - Writing a major section of the publication
- If someone has made a more minor contribution then they should be acknowledged in a note
- The order in which the authors' names appear should be in relation to their contribution to the work
  - i.e. whoever did the greatest part comes first and so on
- The status of an individual has no role in determining where, or if, their name appears on the publication

## Duplicate publication

- This is where research is presented as original material but has in fact been published, either in part or entirety, elsewhere
  - This would deceive the scientific community
- Work must not, therefore, be submitted if it has been published in another outlet
  - e.g. submitted for publication in a journal when it has already been published as a book chapter
- Work should only be submitted to one publisher at a time for consideration of publication. Only if it is rejected should it then be offered to another publisher. This increases the length of time it takes to go from writing to publication but will help prevent copyright infringements and duplicate publication
- Duplicate publication does not include:
  - Previous publication as a conference abstract (have a limited audience)
  - Publication in another language (as long as it is made clear that it is a translation)

## Research misconduct

- 1. Fabrication**  
Making up data or results and recording or reporting them
  - 2. Falsification**  
Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record
  - 3. Plagiarism**  
The appropriation of another person's ideas, processes, results or words without giving appropriate credit (quotations and referencing)
- Research misconduct does not include honest error or differences of opinion

## Conflict of interest

- A situation in which one experiences conflicting pulls from one's personal interests and from one's professional obligations
- **Direct:**
  - Being paid to say something untrue
- **Indirect:**
  - Knowing that if you say something positive about a company that gave you a grant, you may be more likely to get a grant from them again in the future
  - A funding agency may stipulate that they have a right to decide whether you can publish your findings or may delay publication

## Accurate reporting

- A **true and accurate account** of your work must be presented.
- A **full explanation** of your study is required including data collection tools, plus methods and analysis.
- An **objective discussion with conclusion** should be provided
- **Editors** are fully entitled to question you about your work and have the right to review your data.
- **All findings should be reported**, even if they don't fit neatly with your study.
- It is imperative that all sources of **funding and conflicts of interest** are disclosed.
- Journal editors have the final responsibility for ensuring that the publications in their journals consist of ethical research practices and report writing

## HISTORIC CASE STUDIES

### Willowbrook Hepatitis Study (1956)



- At an institution for mentally retarded children in Staten Island, New York, a study was initiated to determine the natural history of viral hepatitis and to test the effectiveness of gamma globulin as an agent for inoculating against hepatitis.
- Children were deliberately (on purpose) infected with a mild form of hepatitis.
- Although permission was obtained from parents, the parents were not fully informed of the possible hazards involved in the study.
- There is evidence that the parents were led to believe that the child would not be enrolled at the school unless the parents signed the consent form.
- **Ethical problems:** exploitation of a vulnerable group of subjects, withholding information about risks, coercion or undue pressure on parents to volunteer their children.

### Jewish Chronic Disease Study (1963)



- Live cancer cells were injected into senile patients (or patients who were hospitalised with various chronic debilitating diseases) without their knowledge as part of a study of immunity to cancer.
- Since the investigators believed that the cells would be rejected, the researchers did not inform the patients or seek consent because they did not want to frighten them.
- **Ethical problems:** lack of informed consent, use of a vulnerable group of subjects.

## San Antonio Contraceptive Study (1971)



- In San Antonio, Texas, a number of Mexican-American women participated in a study to determine side effects of an oral contraceptive.
- The women came to a clinic seeking contraceptives.
- Unbeknownst to them, the study was designed so that half the women would receive oral contraceptives for the first half of the study, then switched to placebo. The women initially receiving placebo were placed on the oral contraceptive for the second half of the study.
- 10 of the 76 subjects became pregnant while using placebo.
- **Ethical problems:** lack of informed consent, use of a vulnerable group of subjects, risks to subjects outweighed benefits.



The End

🌸 Adrenaline2015/mid 🌸

1. Nuremberg code is:

The first international document which advocated voluntary participation and informed consent and declaration of Helsinki is a reinterpretation of it.

2. Application of respect of persons is:

Informed consent.

3. The four principles of bioethics are:

Autonomy, Beneficence, Non maleficence (to do no harm), Justice.

4. Differences between normative and non-normative:

All of listed

5. Definition of ethical theories:

6. About consequences and Utilitarianism:

A-Consequences is part of Utilitarianism.

B-Utilitarianism is part of Consequence.

C-They are the same.

D-They are completely opposite theories.

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A-The desire for alcohol is a second-order' desire.

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C-Autonomy implies respecting The desire not to desire alcohol.

15. In what case can the patient sue the doctor on battery:

Touching him without his consent.

16. The ability to give or withhold consent is:

A

Competence.

17. About withdrawal of the consent by the patient:

A-He can't withdraw it.

B-he can withdraw it any time without giving a reason.

C-He can withdraw it only if he gives a logical reason.

18. A patient's decision-making capacity is variable as their medications or underlying disease processes ebb and flow. You should do what you can to catch a patient in a lucid state even lightening up on the medications if necessary and safe:

True.

19. What's wrong about confidentiality:

Its absolute

20. Definition of confidentiality:

21. Why is it important to tell truth:

For reasons of autonomy and trust.

22. When is it justified to hold the truth?

If the patient him- or herself states an informed preference not to be told the truth.

🍁 Hope2016/mid 🍁

23. Nuremberg Code:

A- Was the First Documented Human Subject Research.

B- It is a reinterpretation of Declaration of Helsinki.

C- Was the first international document which advocated voluntary participation and informed consent.

24. Not true about medical ethics:

They are static.

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A- Lack of informed consent.

B- Use of a vulnerable populations.

C- Withholding information or available treatment.

D- Risks to subjects outweigh benefits.

E- All of above.

26. The Four Principles of Biomedical Ethics:

Autonomy, Beneficence, Nonmaleficence, Justice.

27. One of the major challenges to health professionals is giving patients bad news about their prognosis:

True.

28. Which of the following is NOT an ethical theory:

A- Utilitarianism.

B- Obligation-Based.

C- Virtue-Based.

D- Confidentiality.

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Utilitarianism.

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False.

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True.

35.The success of frequent or regular meetings between doctor and patient depends on only the doctors' clinical knowledge and technical skills:

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36.Which of the following is NOT part of the social system:

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C-Determine the diagnosis and prognosis.

39.Paternalism conflicts with:

A-Patient's duty.

B-Physician duty.

C-Physician's autonomy.

D-Patient's autonomy.

40.Low physician and patient control:

Default.

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Are two polars.

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D-Less time identify psychological problems.

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**False.**

45 Principle criteria for valid consent include all of the following EXCEPT:

A-Informed patient.

B-Competent.

C-Voluntary choice.

**D-Coerced choice.**

46. The ability to give or withhold consent: **Competence**

47. A battery occurs:

A-When they physical contact with patient is harmful.

**B-Any contact without patient consent.**

48. A competent patient with end stage renal failure who refuses any kind of treatment. You decided to put the patient in renal dialysis:

A-Patient's consent is necessary, otherwise a negligence.

**B-Patient's consent is necessary, otherwise a battery.**

49. The consent must be written:

**False.**

50. A patient wants to withdraw his consent:

A-A patient may withdraw consent at any time without giving a reason.

B-A patient may withdraw consent if he gives reasonable causes.

C-You do the first consent ignoring the withdrawal.

51. If a patient is incompetent:

A-You start the procedures without taking his decision.

B-You try to enable the patient to have the competence to make decisions.

52. All of the following are ways to enhance capacity EXCEPT:

A-Lightening up on the medications if they affect capacity and if necessary and safe.

B-By allowing the person time to take in and process information.

C-If there is a need to assess capacity for different tasks or decisions, assess these at once.

53. .... requires health care providers to keep a patient's personal health information:

Confidentiality.

54. No breach of confidentiality has occurred if:

A-A patient consent is obtained.

B-Telling His/Her friend.

55. Wrong statement regarding Confidentiality:

Obligation is absolute.

56. Truthful information is important for reasons of autonomy and trust:

True.

57. When is it justified to withhold the truth from a patient?

A-When this makes the patient happier.

B-If the patient himself states an informed preference not to be told the truth.

58. Withholding the truth includes all of the following EXCEPT:

A-Outright lies.

B-Temporary deception.

C-Answering direct questions.

D-Giving false hope.

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59. All of the following are associated to the principle of non-maleficence EXCEPT:

A-End of life decisions.

B-Treatment decisions.

C-Defending others rights.

D-Negligence.

60. Autonomous evaluation:

A-Should be reasonable.

B-Is based on person's best understanding of facts.

C-Has nothing to do with the capacity to consent.

D-All of the above.

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B-Equity.

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B-Implies that person's decision should be honest.

C-Implies respecting first order desire.

D-Implies that a person has the ability to act on desires for his life plan.

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C-An optional requirement for good clinical practice.

D-All of the above.

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A-Costs.

B-Battery.

C-Battery and negligence.

D-Negligence.

E-All of the above.

70. Healthcare systems throughout the world has sufficient funds to provide the best possible treatment for all patients in all s

False.

71. Quantitative futility is when the quality of benefit an intervention will produce is exceedingly poor.

False.

72. There is no difference in the way the law deals with competent and incompetent patients.

False.

73. The paternalistic position would be very concerned with research that take place without the True or False??

74. As a direct result of the trial of German physicians who conducted medical experiments on thousands of permanently disabled as a result, the Nuremberg Code was established in 1948.

False.

75. Medical technology can increase reproductive choice by:

A-Providing the means of assisting conception.

B-Making available range of investigations that help predict the likely health status of

C-Providing the possibility of abortion.

D-All of the above.

76. All the following were stated in Nuremberg Code, EXCEPT:

A-An institutional review board should be implemented.

B-The risks should be justified by the anticipated benefits.

C-Only qualified scientists must conduct research.

D-Research should be based on prior animal work.

E-Informed consent is essential.

77. Medicine was established in response to social needs to:

A-Protect the social system from being misused by individual members.

B-Take care of the sick.

C-A+B.

D-None of the above.

78. Approaches to the issue of reproductive choice include all the following EXCEPT:

A-The interests of the public.

B-The interests of the physicians.

C-The interests of parents.

D-The interest of future child.

79. Children and incompetent patients may be harmed by confidentiality.

True.

80. All the following are resources of healthcare systems EXCEPT:

A-Insurance.

B-Time.

C-Beds.

D-Drugs.

E-Equipment.

81. Success of frequent or regular meetings between doctor and patient depends on:

A-The nature of the social relationship.

B-The doctor's technical skills.

C-The doctor's clinical knowledge.

D-All of the above.

82. The risk of the harm to the research participant gives rise to the paternalistic position.

True.

83. Abortion continues to raise several ethical issues related to the rights of the women versus the rights of the fetus.

True.

82. The philosophical basis of informed consent rests on the principle of patient:

A-Justice.

B-Non-maleficence.

C-Beneficence.

D-Autonomy.

83. The principle in which the judgment is based on persistent states of un

A-Public best interests.

B-Not against the best interests of the patient.

C-Patients best interests.

D-Against best interests of the patient.

84. When consent form was not obtained from patients then proving suffering from harm is required to successfully

False.



85. The consequences of the breach of confidentiality that may have effects on patients include all the following EXCEPT:

A-Brings physical or emotional harm to them

B-Deprives patients from their social rights.

C-Discrimination against patients.

86. Competency includes all the following EXCEPT:

A-Capacity.

B-Coercion.

C-Understanding.

D-Deciding.

87. The purpose of health care in general is to increase both the quantity and the quality of life.

True.

88. Bad death may include all the following EXCEPT:

A-Having no knowledge of patient preferences of having CPR.

B-Any intervention designed to provide physicians with better prognostic information had no effect on medical decision making prior to death.

C-Severe pain.

D-Decisions to withhold invasive treatments were made on line.

89. All the following are uses of patients' information, EXCEPT:

A-Research.

B-Education.

C-Social media.

D-Administration and planning.

90. Walter Reed's well known experiments to develop an inoculation for yellow fever were carefully examined.

True.

91. All the following are ethical problems with past studies, EXCEPT:

A-Risks to subjects outweigh the benefits.

? B-Voluntary participation.

? C-Lack of informed consent.

D-withholding information.

E-Use or exploitation of a vulnerable population.

92. Allocating resources within health care should minimize the amount of welfare.

False.

93. The patient-physician relationship is fundamental for all the following EXCEPT:

A-Promoting healing process.

B-Decreasing survival.

C-Providing excellent care.

D-Improving outcomes.

94. In Parsons' model of the patient physician relationship:

A-Patients should counteract the doctor.

**B-Patients should be regarded as needing care.**

C-Patients must get well by their own.

D-Patients must complete their normal activities.

95. "Research ethics" refers to the moral principle guiding research, from its inception through to its completion and publication of results and beyond.

**True.**

96. All the following pertaining Dr. Henry K. Beecher's article are correct EXCEPT:

A-It played an important role in heightening the awareness of researchers, the public and the pre research.

B-It was published in the New England Journal of Medicine. (NEJM).

C-Its title is "Ethics and Clinical Research".

**D-It described 20 examples of research studies with controversial ethics.**

97. Breach of confidentiality may occur etc etc etc

A-Data were anonymized.

B-The patient gives consent to dis----

**C-The patient can be identified.**

**D-All of the above.**

98. Reasons of dying in the present time comp---

A-Man made diseases.

B-Medical advancement.

C-Neoplastic diseases.

D-Degenerative diseases.

E-All of the above.

**99. An application of autonomy :**

**informed consent**

Medicine – Yarmouk University  
**Elixir Batch**  
**Medical Ethics - Final Exam**  
(20 Questions out of 20)

**1. Not of Requirements of Research Ethics:**

- Community Partnership
- Social value
- Scientific validity
- Fair subject selection
- + Any risk-benefit ratio

**2. Unethical Research uses are all of the following except:**

- Samples
- Questions
- Statistical methods
- Sample size
- + Conducted in accurate manner

**3. all are true regarding Favorable Risk-Benefit Ratio, except:**

- Proper design
- Withdrawal criteria
- + include high risk subjects

**4. Regarding Independent Review - Investigators have interests in all of the following except:**

- To conduct high quality research
- To complete research expeditiously
- To protect research subjects
- To obtain funding
- To advance their career
- ++++ الإجابة غير النقاط المذكورة

**5. Independent Review protects all of the following except:**

- the research subjects
- the researchers
- the institutes
- the community
- ++++ الإجابة غير النقاط المذكورة

**6. Quality of the Informed consent. All are true except:**

- understandability
- documentation
- purpose of the research
- +safety monitoring

**7. All are contents of informed consent, except :**

- Procedures
- Risks
- Withdrawal
- Compensation
- + inconfidentiality

**8. Regarding Respect for Enrolled Subjects, all are true except:**

- Permitting withdrawal
- Protecting confidentiality
- Informing of new risks & benefits
- Maintaining welfare of subjects
- +Ignore results of clinical research

**9. Not of the Legal rules that should be followed before Blood transfusion:**

- The need for blood transfusions
- No alternative method of treatment
- No harm or damage to the donor
- Consent of the donor
- Donor should be clinically free from transmissible disease
- + Not Under medical supervision

**10. The major clinical problems regarding organ transplantation Include all of the following except:**

- Tissue rejection
- Organ preservation
- Insufficient facilities and manpower
- The high cost of each operation
- +The law has no additional restriction

**11. Not of the Reasons why people sue their doctors:**

- Advised to sue by another person
- Need money
- Believed there was a cover-up
- Child would have no future
- Revenge
- +extensive information

**12. Medical errors are NOT associated with:**

- Inexperienced clinicians
- Extremes of age
- Complex and urgent care
- Poor communication
- +Old procedures

**13. All of the following are Elements of The Bolam Test, except:**

- The ordinary skills of an ordinary competent doctor
- Not highest expert skill
- In accordance with responsible body of medical opinion
- +It means that a Court is bound to accept expert medical evidence.

**14. Regarding Malpractice in diagnosis, all of the following are true except:**

- the physician should take a careful history, examine his patient thoroughly
- the physician expected by the law to use the same degree of care in making a diagnosis that is required from him in all his dealing with his patients
- one of the problems in determining whether there has been a mistake in diagnosis lies in the deciding what investigative techniques need to be used in a particular case
- ++Ordinary laboratory tests must not be used if symptoms suggest their use but elaborate and expensive investigative procedures would not be expected other than in complicated cases/

**15. Types of Medication Error**

- Wrong drug.
- Wrong dose.
- Wrong route of administration.
- Wrong time of administration.
- ++++ الإجابة غير النقاط المذكورة

**16. The responsible for the error may be one of the following except:**

- Prescribers (doctors)
- Dispensers (pharmacists)
- Nursing staff
- Patient himself
- ++++ الإجابة غير النقاط المذكورة

**17. Which patient is NOT at risk?**

- undergoing cardiothoracic surgery, vascular surgery, or neurosurgery
- with complex conditions
- in the emergency room
- looked after by inexperienced doctors
- Older patients
- ++++ الإجابة غير النقاط المذكورة

**18. NOT of the Most Frequent Cases of Malpractice in Emergency Room:**

- Failure to diagnose a fracture or dislocation
- Failure to diagnose a Foreign body in a wound
- Failure to diagnose complications of lacerations, tendon or nerve damage
- Failure to diagnose and treat myocardial infarction
- +Failure to diagnose osteoarthritis

**19. All of the following are High-Risk situations and scenarios in Emergency Room, except:**

- Temporal Factors: Between 6 pm and 1 am on weekend and holidays
- Physical Shift Change
- Physician Orders By Telephone
- Unaccompanied Unconscious patients
- ++++ الإجابة غير النقاط المذكورة

**20. Not true about Legal advice:**

- Get the patient's informed consent for all procedures at least for all surgical procedures
- When in doubt ask for consultation. No one knows it all.
- Do not criticize another practitioner
- Do not fail to provide maximum care in the selection of assistants
- +Base an important diagnosis on a clinical, impression alone if reliable laboratory diagnostic aids are available.

# GOOD LUCK

Collected by Ameera Mazen Mousa/Elixir Batch

دعواتكم

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**A-You start the procedures without taking his decision.**

**B-You try to enable the patient to have the competence to make decisions.**

**18.A patient's decision-making capacity is variable as their medications or underlying disease processes ebb and flow. You should do what you can to catch a patient in a lucid state even lightening up on the medications if necessary and safe:**

**True.**

**52.All of the following are ways to enhance capacity EXCEPT:**

**A-Lightening up on the medications if they affect capacity and if necessary and safe.**

**B-By allowing the person time to take in and process information.**

**C-If there is a need to assess capacity for different tasks or decisions, assess these at once.**

**Respecting a person's autonomy is always the same as respecting their choice:**

**true**