PART 1 | IMAGING IN CLINICAL PRACTICE

Atheer Emad Abas
Department of Radiology, Medical College, Baghdad, University.

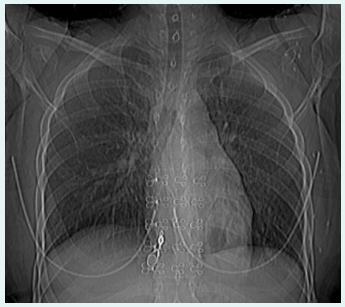
A 22 year-old female presented with 2 months history of haemoptysis with intermittent attacks of drenching night sweat and rigor. A year before presentation, she underwent sleeve gastrectomy complicated by leakage of gastric secretions for which she had admitted multiple times to the hospital. At time of presentation and on clinical examination , she looks well , breathing comfortably ,vitally stable , afebrile, no digital clubbing and chest auscultation was unremarkable. Initial laboratory investigations showed WBC count of 16000 cell/mm^3 and high ESR 80 mm/hour.

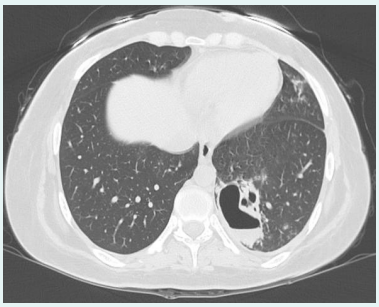
Q1: What is the radiological finding seen in CT scan?

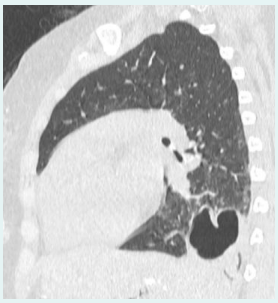
Q2: What is the definition of cavity?

Q3: What are the differential diagnoses of these findings?

Q4: How could radiologic characteristics of the lesion help you reach a definitive diagnosis?


A: Chest X Ray


B: CT chest, Cross section


C: CT chest sagittal Section

ANSWER OF Q1:

A: Chest X Ray shows cavitory lesion seen through the cardiac shadow above the medial part of the left diaphram. **B:** Cross section of the CT chest shows a cavitary lung lesion with thick irregular wall seen in the posterior segment of left lower lobe with evidence of air-fluid level and wall enhancement with IV contrast, so an initial diagnosis of "cavitating solitary pulmonary opacity" was made based on these findings. **C:** the sagittal section of the CT scan shows the same lesion at the posterior segment of the left lower lobe.

ANSWER OF Q2:

A cavity is a gas-filled space, shown as a lucency or low attenuation area, with identifiable wall (usually >4 mm in thickness) .It can be seen within pulmonary consolidation, a mass, or a nodule. A cavity is usually produced by the expulsion or drainage of a necrotic portion of the lesion via the airways. It may contain air fluid level and it usually indicate the presence of serious underlying disease.

ANSWER OF Q3:

Pulmonary cavity could be seen in a wide variety of causes including:

1. Infections:

Bacterial infection especially *Staphylococcus aureus* and *klebsiella pneumoniae* and *Pseudomonas aeruginosa*.

Mycobacterial infection especially *mycobacterium tuberculosis*.

Fungal infection *aspergillosis*, *coccidiomycosis*.

2. Pulmonary malignancies:

Primary lung tumours especially squamous cell carcinoma and primary lymphoma

Metastatic tumours (squamous or adenocarcinoma)

3. Other less common causes:

Rheumatoid nodule
Wegners granulomatosis
Pulmonary embolism with infarction and necrosis

ANSWER OF Q4:

1. Site of the cavity within the lung

Pyogenic bacterial infection (lung abscess) tend to affect any segment or lobe within the lung.

Aspiration pneumonia in patients at risk tend to affect the posterior segments of the upper lobe or upper segment of the lower lobe especially of the right lung.

Post primary TB infection tend to occur in the upper lobes in one or both lungs.

Fungal infection has no particular predilection site within the lung field.

Cavitating primary squamous cell carcinoma of the lung tend to be central near the hilum.

Metastatic tumours tend to occur in the lower zones of the lung due to greater blood flow.

Lung infarction with necrosis usually occur after pulmonary embolism and it is seen in the subpleural peripheral lung.

2. Cavity wall thickness

In ***lung abscess*** the wall is usually of intermediate thickness. ***TB infection*** the cavity wall is usually thin but it could be thick, in cavitary ***primary and metastatic lung tumors*** the cavity wall is thick .

REFERENCES

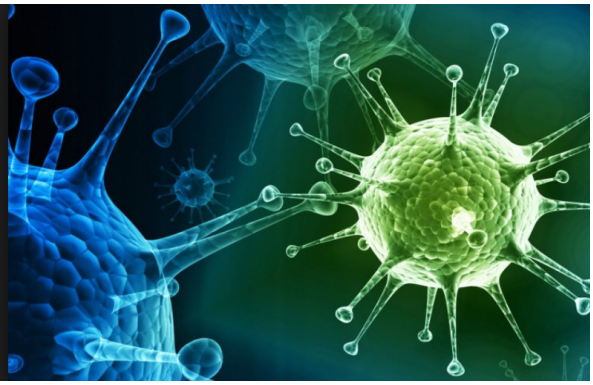
1. Lee KS. decreased opacity with cystic air space. In: Radiology illustrated: chest radiology. New York: Springer; 2013. p. 95–116.
2. Parkar AP and Kandiah P. Differential Diagnosis of Cavitary Lung Lesions. *Journal of the Belgian Society of Radiology*, 2016;100(1):100,1–8, *DOI: http://dx.doi.org/10.5334/jbr-btr.1202*

PART 2 | WHAT DO YOU KNOW ABOUT?

Influenza and It's vaccine

Ala Sh. Ali*

Influenza is the commonest upper respiratory tract infection. It carries a high morbidity and mortality rate, in addition to high direct and indirect economic burden on health budgets all over the world. In the absence of effective drug therapy, preventive strategies are the most effective way of overcoming this disease.



By the end of 2018, a century has passed since the first influenza pandemic that killed more than 20 million people world-wide, many of whom were young adults. Three more influenza pandemics have occurred since that time, the last one was influenza A (H1N1) in 2009.[1]

In 1933, the first influenza virus has been isolated. Influenza viruses are orthomyxoviruses of 3 antigenic subtypes (A, B, and C). Epidemics are caused by influenza virus types A and B. Influenza A viruses are sub-classified by two surface antigens, haemagglutinin (HA) and neuraminidase (NA). Hence the nomenclature of each pandemic according to the subtypes of these antigens, like (H1N1) and etc.[2]

Major changes leading to the emergence of new haemagglutinin such as H1 to H2 or the emergence of new haemagglutinin or new neuraminidase called antigenic shifts. Minor antigenic variations within the same subtypes are called antigenic drifts. Antigenic shifts has occurred only with influenza A, usually at irregular intervals of 10 or more years. Antigenic drift occurs continuously and results in variant influenza A and B viruses. Influenza B viruses change more slowly and are not divided into subtypes.[2]

Surveillance data from May 2013 through December 2016 showed that influenza C accounts for 0.5% of influenza-related outpatient visits and hospitalizations in the US, particularly affecting children ages 6 to 24 months. Diagnostic tests for influenza C are not widely available.[3]

Until very recently the neuraminidase inhibitors were the only available antiviral agents for treatment of influenza like oseltamivir which is an oral drug used for both influenza A and B and it can be used for prophylaxis.[4]

Baloxavir marboxil is a new anti-influenza medication approved in Japan in February 2018 and anticipated to be available in the United States sometime in 2019. This prodrug is hydrolysed in vivo to the active metabolite, which selectively inhibits cap-dependent endonuclease enzyme, a key enzyme in initiation of messenger ribonucleic acid synthesis required for influenza viral replication.[5]

The best way to control influenza and probably to prevent pandemics or at least to have less serious outbreaks is vaccination. With the isolation of the virus, the first vaccine had developed. The inactivated vaccines are egg-based and associated with minimal adverse effects.

*Associate editor, Consultant Nephrologist and Transplant Physician, Nephrology and Renal Transplantation Centre, Medical City, Baghdad, Iraq. E mail: ala.ali@iraqinmj.com@yahoo.com

These multivalent vaccines contain three virus strains (usually 2 type A and 1 Type B). Typically, 1 or 2/ strains are changed each year in anticipation over the predominant influenza strains expected to circulate.[2]

A 2018 Cochrane review concluded that vaccination reduced the incidence of influenza by about half, with 2.3% of the population contracting the flu without vaccination compared with 0.9% with vaccination (risk ratio 0.41, 95% confidence interval 0.36–0.47). The same review found that 71 healthy adults need to be vaccinated to prevent 1 from experiencing influenza, and 29 to prevent 1 influenza-like illness.[6]

The first non-egg based vaccine produced in 2013. The cell-based baculovirus influenza vaccine grown in dog kidney cells has higher antigenic content and is not subject to the limitations of egg-based vaccine, although it still requires annual updates. A recombinant influenza vaccine reduces the probability of influenza-like illness by 30% compared with the egg-based influenza vaccine, but also still requires annual updates.[1,7]

An ideal universal vaccine would be suitable for all age groups, at least 75% effective against symptomatic influenza virus infection, protective against all influenza A viruses (influenza A, not B, causes pandemics and seasonal epidemics), and durable through multiple influenza seasons.[8]

Research and production of such a vaccine are expected to require funding of about $1 billion over the next 5 years in the United States.[1]

In this issue we will try to review some facts and evidences about influenza virus and its vaccine.

Choose the best appropriate answer for each statement:

1. Influenza Transmission:

(a) Humidity destabilizes the virus in aerosols.

(b) One sick passenger on airplane flight should raise a red flag for infecting all passengers.

(c) Home pets may be a possible source of major threats.

(d) Pigs and birds are the major reservoirs of influenza.

2. Influenza and cardiovascular health:

(a) Obesity is a major risk factor for severe influenza.

(b) Obesity increases the duration of virus shedding.

(c) Influenza increases the risk of myocardial infarction.

(d) The risk of stroke would be increased up to 4 weeks after infection.

3. Vaccine effectiveness:

(a) It would be higher in people aged > 65 years.

(b) *The number needed to vaccinate to prevent one case of influenza like illness in adults is 29.*

(c) *For some strains, annual vaccination may blunt its effectiveness.*

(d) *Statins are associated with better effectiveness of the vaccine.*

4. Vaccination in special populations:

(a) High-dose influenza vaccine is licensed for people less than 13 years of age.

(b) Prenatal and postpartum maternal influenza vaccine decrease the odds of influenza by about 60%.

(c) The high-dose influenza vaccine is more immunogenic than the standard-dose vaccine in solid organ transplant recipients.

(d) Persons with a history of egg allergy who have experienced urticaria after exposure to egg should not receive influenza vaccine.

5. Anti influenza medications:

(a) They are still under used.

(b) Should be used within 48 hours of the onset of the symptoms.

(c) Still the benefit of neuraminidase inhibitors in hospitalized patients is less well established.

(d) Baloxavir marboxil showed no emergence of resistance.

6. Contraindications and precautions to the use of Live Attenuated Influenza Vaccine:

(a) Receipt of influenza antiviral medication within the previous 48 hours.

(b) Immune competent people.

(c) Concomitant aspirin- or salicylate-containing therapy in children and adolescents .

(d) *Asthma or recurrent wheezing episodes in the last 12 months.*

7. Vaccination for travellers:

(a) It is preferable to be used at least 2 weeks before travel.

(b) Influenza vaccine formulated for the Southern Hemisphere has the same viral composition from the Northern Hemisphere vaccine and can be used the same way for travel purposes.

(c) Traveller to temperate climates should expect influenza all the year time.

(d) Vaccination is mandatory for summer travel even you had a vaccine in the previous fall.

8. Vaccine administration:

(a) Inactivated or recombinant influenza vaccines can't be given concomitantly with other vaccines.

(b) Four weeks should pass before administration of other live vaccine if live attenuated influenza vaccine already given.

(c) Inactivated influenza vaccine should be administered intranasally.

(d) Intranasal administration of vaccine should be deferred after complete resolution of nasal congestion.

9. Neurological complications post vaccination:

(a) Guillain-Barré Syndrome (GBS) can occur within 6 weeks post vaccination.

(b) Those with high risk can't be vaccinated.

(c) Intranasal vaccine is a good substitute for vaccination for patients with high risk for neurological complications.

(d) Antiviral chemoprophylaxis for persons who can not being vaccinated due to high risk.

10. Promoting vaccination:

(a) Vaccination rates remain low.

(b) A national goal is to immunize 80% of the targeted population.

(c) Antivaxxers attitude (those refuse having vaccines) is rising in spite of all evidences of benefit and cost effectiveness.

(d) At least 50% of a community needs to be vaccinated to prevent community outbreaks.

11. Timing of influenza vaccination:

(a) Eligible persons should be vaccinated every other year.

(b) The best time for vaccination is September and early November .

(c) The influenza vaccine protection lasts for one season.

(d) Persons should not be vaccinated during winter.

12. The followings should receive influenza vaccine:

(a) Pregnant women.

(b) Patient with Asthma.

(c) Any person aged over 45 years.

(d) Patients receiving glucocorticoid therapy.

Answers are on the next page

Influenza and It's vaccine

Answers of the Questions

1. ***Answer is F, F, T, T*** : A recent study used humidity-controlled chambers to investigate the stability of the 2009 influenza A(H1N1) virus in suspended aerosols and stationary droplets, the virus remained infectious in aerosols across a wide range of relative humidities. There is a low probability of direct transmission on the airplane, except for passengers seated in close proximity to an infectious passenger.[9,10]

Message: (**Pets, pigs and birds are the major source of influenza, infectivity need close contact**)

2. ***Answer is T, T, T, T***: Obesity increases the duration of influenza A virus shedding, thus increasing duration of contagiousness. Two recent epidemiologic studies from the United Kingdom showed that influenza is associated with higher rates of myocardial infarction and stroke for up to 4 weeks.[11,12]

Message: (**Obesity increases the duration of contagiousness, influenza associated with higher rate of myocardial infarction and stroke.**)

3. ***Answer is F, T, T, F***: Age and frailty reduce vaccine effectiveness. Effectiveness may be influenced by more than 1 previous season, particularly for influenza A (H3N2), in which repeated vaccination can blunt the haemagglutinin antibody response. Statins are associated with reduced influenza vaccine effectiveness against medically attended acute respiratory illness, but their benefits in preventing cardiovascular events outweigh this risk.[13,14]

Message: (**Age and immune compromise state reduce effectiveness of the vaccine. Although statins reduce vaccine effectiveness, it should not being stopped during vaccination**)

4. ***Answer is F, T, T, F***: The high-dose influenza vaccine has been licensed since 2009 for use in the United States for people ages 65 and older. Persons with a history of egg allergy who have experienced only urticaria (hives) after exposure to egg should receive any licensed, recommended, and age-appropriate influenza vaccine that is otherwise appropriate for the recipient's health status may be used.[13,15]

Message: (**Urticaria to eggs is not a contraindication for influenza vaccine**)

5. ***Answer is T, T, T, F***: Numerous studies have found anti-influenza medications to be effective. Nevertheless, in an analysis of the 2011–2016 influenza seasons, only 15% of high-risk patients were prescribed anti-influenza medications. Treatment with a neuraminidase inhibitor within 2 days of illness has recently been shown to improve survival and shorten duration of viral shedding in patients with avian influenza A(H7N9) infection. Of concern is the emergence of nucleic acid substitutions conferring resistance to baloxavir; this occurred in 2.2% and 9.7% of baloxavir recipients in the phase 2 and 3 trials, respectively. [1,16,17]

Message: (**Drugs for influenza are underused, they should be used within first 2 days to reduce duration of symptoms**)

6. ***Answer is T, F, T, T***: Children and adults who are immunocompromised due to any cause (including immunosuppression caused by medications or by HIV infection) should not receive live attenuated vaccine. [15]

Message: (**life attenuated vaccine can be given to immune competent person but not immune compromise one**)

7. ***Answer is T, F, T, F***: People should get vaccinated at least 2 weeks before travel because it takes 2 weeks for vaccine immunity to develop after vaccination. No information is available about the benefits of getting revaccinated before summer travel for those peo-

ple who already were vaccinated during the preceding fall, so revaccination is not recommended. Vaccine formulations for northern hemisphere are different from those for the southern hemisphere because of the different strains that circulate in each one.[15]

Message: (**travellers should be vaccinated 2 weeks before travel**)

8. Answer is F, T, F, T: Inactivated or recombinant vaccine may be administered concomitantly or sequentially with other inactivated vaccines or with live vaccines. Following administration of a live vaccine, at least 4 weeks should pass before another live vaccine is administered. Life attenuated vaccine is administered intranasally using the supplied prefilled, single-use sprayer containing 0.2 mL of vaccine.[15]

Message: (**Influenza vaccine can be given with the inactivated or life attenuated vaccines of other diseases**)

9. Answer is T, T, F, T: A history of Guillain-Barré Syndrome (GBS) within 6 weeks following a previous dose of any type of influenza vaccine is considered a precaution to vaccination. Generally, those should not be vaccinated. As an alternative to vaccination, physicians might consider using influenza antiviral chemoprophylaxis for these persons.[15]

Message: (**Persons with high risk for complications should not receive any type of influenza vaccine, instead antiviral chemoprophylaxis can be used**)

10. Answer is T, T, T, F: Despite hundreds of studies demonstrating the efficacy, safety, and cost savings of influenza vaccination, the antivaccine movement has been growing in the United States and worldwide. A key educational point is that at least 70% of a community needs to be vaccinated to prevent community outbreaks.[1,18]

Message: (**rate of vaccination is still low, at least 70 % of the community should be vaccinated to prevent community outbreaks**)

11. Answer is F, T, T, T: The influenza vaccine protection lasts for one season and any eligible person should be advised for having the vaccine yearly. The vaccine should be given during September and early November every year. If the person forget to have the dose in Autumn he/she can take it during winter but it should be kept in mind that the antibody response develops after 2 weeks.[19]

Message: (**Eligible person should be vaccinated every year in September to early November**)

12.Answer is T, T, F, T: Any person over the age of 65 years should be vaccinated regardless of his health status. Pregnant women, patient with asthma, or using drugs that affect immune system like glucocorticosteroids should be vaccinated.[20] **Table 1 and 2**

Message: (**indications and contraindication for influenza vaccine**)

Table 1: the indications for influenza vaccination[20]

People aged from six months to less than 65 years with:

- **Chronic respiratory disease. This includes people with asthma who need repeated use of inhaled or systemic steroids, or with previous exacerbations that resulted in hospital admission. It also includes children who have been admitted to hospital for lower respiratory tract disease**
- **Chronic heart disease, including congenital heart disease**
- **Chronic renal failure, including chronic kidney failure and kidney transplantation**
- **Chronic liver disease**
- **Chronic neurological disease**
- **Diabetes mellitus (people requiring insulin or oral hypoglycaemic drugs as well as diet controlled diabetes)**
- **Immunosuppression due to disease or treatment**
- **Asplenia or splenic dysfunction**
- **Morbid obesity**

Everyone older than 65
People who live in care homes
Pregnant women
Staff who work in health and social care
Carers
Children aged 2 to 9 years old on 31 August 2018.

Table 2: The contra-indications for influenza vaccination[20]

- **A confirmed anaphylactic reaction to a previous dose of the vaccine.**
- **A confirmed anaphylactic reaction to any component of the vaccine.**

REFERENCES

1. Mossad SB. Influenza update 2018-2019: 100 years after the great pandemic. *Cleve Clin J Med*. 2018;85(11):861-9.
2. Wright PF and Webster RG (2001) Orthomyxoviruses. In: Fields BN and Knipe DM Eds., Fields Virology, 4th Edition, Lippincott Williams & Wilkins, Philadelphia, 1533-1579.
3. Thielen BK, Friedlander H, Bistodeau S, Shu B, Lynch B, Martin K, et al. Detection of Influenza C Viruses Among Outpatients and Patients Hospitalized for Severe Acute Respiratory Infection, Minnesota, 2013-2016. *Clin Infect Dis*. 2018;66(7):1092-8.
4. Hayden FG, Atmar RL, Schilling M, Johnson C, Poretz D, Paar D, et al. Use of the selective oral neuraminidase inhibitor oseltamivir to prevent influenza. *N Engl J Med*. 1999;341(18):1336-43.
5. Portsmouth S, Kawaguchi K, Arai M, Tsuchiya K, Uehara T. Cap-dependent Endonuclease Inhibitor S-033188 for the Treatment of Influenza: Results from a Phase 3, Randomized, Double-Blind, Placebo- and Active-Controlled Study in Otherwise Healthy Adolescents and Adults with Seasonal Influenza. *Open Forum Infectious Diseases*. 2017;4(Suppl 1):S734-S.
6. Demicheli V, Jefferson T, Di Pietrantonj C, Ferroni E, Thorning S, Thomas RE, et al. Vaccines for preventing influenza in the elderly. *Cochrane Database Syst Rev*. 2018;2:CD004876.
7. Dunkle LM, Izikson R, Patriarca P, Goldenthal KL, Muse D, Callahan J, et al. Efficacy of Recombinant Influenza Vaccine in Adults 50 Years of Age or Older. *N Engl J Med*. 2017;376(25):2427-36.
8. Erbelding EJ, Post DJ, Stemmy EJ, Roberts PC, Augustine AD, Ferguson S, et al. A Universal Influenza Vaccine: The Strategic Plan for the National Institute of Allergy and Infectious Diseases. *J Infect Dis*. 2018;218(3):347-54.
9. Kormuth KA, Lin K, Prussin AJ, 2nd, Vejerano EP, Tiwari AJ, Cox SS, et al. Influenza Virus Infectivity Is Retained in Aerosols and Droplets Independent of Relative Humidity. *J Infect Dis*. 2018;218(5):739-47.
10. Hertzberg VS, Weiss H, Elon L, Si W, Norris SL, FlyHealthy Research T. Behaviors, movements, and transmission of droplet-mediated respiratory diseases during transcontinental airline flights. *Proc Natl Acad Sci USA*. 2018;115(14):3623-7
11. Maier HE, Lopez R, Sanchez N, Ng S, Gresh L, Ojeda S, et al. Obesity Increases the Duration of Influenza A Virus Shedding in Adults. *J Infect Dis*. 2018;218(9):1378-82.
12. Blackburn R, Zhao H, Pebody R, Hayward A, Warren-Gash C. Laboratory-Confirmed Respiratory Infections as Predictors of Hospital Admission for Myocardial Infarction and Stroke: Time-Series Analysis of English Data for 2004-2015. *Clin Infect Dis*. 2018;67(1):8-17.
13. Young-Xu Y, Van Aalst R, Mahmud SM, Rothman KJ, Snider JT, Westreich D, et al. Relative Vaccine Effectiveness of High-Dose Versus Standard-Dose Influenza Vaccines Among Veterans Health Administration Patients. *J Infect Dis*. 2018;217(11):1718-27.
14. Omer SB, Phadke VK, Bednarczyk RA, Chamberlain AT, Brosseau JL, Orenstein WA. Impact of Statins on Influenza Vaccine Effectiveness Against Medically Attended Acute Respiratory Illness. *J Infect Dis*. 2016;213(8):1216-23.
15. Grohskopf LA, Sokolow LZ, Broder KR, Walter EB, Fry AM, Jernigan DB. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices-United States, 2018-19 Influenza Season. *MMWR Recomm Rep*. 2018;67(3):1-20.
16. Zheng S, Tang L, Gao H, Wang Y, Yu F, Cui D, et al. Benefit of Early Initiation of Neuraminidase Inhibitor Treatment to Hospitalized Patients with Avian Influenza A(H7N9) Virus. *Clin Infect Dis*. 2018;66(7):1054-60.
17. Hayden FG, Sugaya N, Hirotsu N, Lee N, de Jong MD, Hurt AC, et al. Baloxavir Marboxil for Uncomplicated Influenza in Adults and Adolescents. *New England Journal of Medicine*. 2018;379(10):913-23.
18. Olive JK, Hotez PJ, Damania A, Nolan MS. The state of the anti-vaccine movement in the United States: A focused examination of nonmedical exemptions in states and counties. *PLoS Med*. 2018;15(6):e1002578.
19. Public Health England. Influenza: the green book, chapter 19. 2018.
20. Public Health England. National flu immunisation programme 2018-2019 letter. 2018.

PART 3 | Medical Ethics in Clinical Practice

Clinical research and medical ethics

Huda Adnan Habib

MBChB, FICMS FM, Consultant Family Physician, Professor, Department of Family and Community Medicine / Al-Kindy College of Medicine / University of Baghdad. Iraq. E mail: huda_adnan70@yahoo.com

Clinical research is a branch of healthcare science that determines the safety and effectiveness (efficacy) of medications, devices, diagnostic products and treatment regimens intended for human use.[1] Clinical research is medical research which study of health and illness in people.[2]

There are two types, clinical studies and clinical trials. ***Clinical studies*** (sometimes called observational studies) observe people in normal settings. These studies may help identify new possibilities for clinical trials. ***Clinical trials*** are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioural intervention.[3]

Ethics, an essential dimension of human research, is considered both as discipline and practice. For clinical research, ethically justified criteria for the design, conduct, and review of clinical investigation can be identified by obligations to both the researcher and human subject. Informed consent, confidentiality, privacy, privileged communication, and respect and responsibility are key elements of ethics in research.[4]

It is important to adhere to ethical principles in order to protect the dignity, rights and welfare of research participants. As such, all research involving human beings should be reviewed by an ethics committee to ensure that the appropriate ethical standards are being upheld.[5]

According to The Code of Medical Ethics: Research & innovation in May 06, 2018; Physicians performing clinical research have responsibilities to their patients. Find out how to protect the rights and safety of research participants that include matters of study design, informed consent and selection of participants.[6]

There are several ethical principles that should be considered when performing a clinical research.[7]

- Principle one: Minimizing the risk of harm.
- Principle two: Obtaining informed consent.
- Principle three: Protecting privacy and confidentiality.
- Principle four: Avoiding deceptive practices.
- Principle five: Providing the right to withdraw

There are a number of types of harm that participants can be subjected to. These include: physical, psychological distress, invasion of privacy and confidentiality social disadvantage and financial harm.[7,8]

One of the foundations of research ethics is the idea of informed consent. Simply put, informed consent means that participants should understand that (**a**) they are taking part in research and (**b**) what the research requires of them. Such information may include the purpose of the research, the methods being used, the possible outcomes of the research, as well as associated demands, discomforts, inconveniences and risks that the participants may face.[7,9] Participants will typically only be willing to volunteer information, especially information of a private or sensitive nature, if the researcher agrees to hold such information in confidence.[7,10] Deceptive practices fly in the face of informed consent. After all, how can participants know (**a**) that

they are taking part in research and (**b**) what the research requires of them if they are being deceived? This is part of what makes the use of deceptive practices controversial.[7,11]

Research participants should always have the right to withdraw from the research process. Furthermore, participants should have the right to withdraw at any stage in the research process. When a participant chooses to withdraw from the research process, they should not be pressured or coerced in any way to try and stop them from withdrawing.[7,12]

There are several reasons why it is important to adhere to ethical norms in research. ***First***, norms promote the aims of research, such as knowledge, truth, and avoidance of error. ***Second***, ethical standards promote the values that are essential to collaborative work, such as trust, accountability, mutual respect, and fairness. ***Third***, many of the ethical norms help to ensure that researchers can be held accountable to the public. ***Fourth***, ethical norms in research also help to build public support for research. ***Finally***, many of the norms of research promote a variety of other important moral and social values, such as social responsibility and human rights.[13]

CHOOSE THE MOST APPROPRIATE ANSWER:

Q 1: Why is it important that personal data about research participants are kept within secure, confidential records?

a) So that the participants cannot find out what has been written about them.

b) In case individuals, places, or organizations can be harmed through identification or disclosure of personal information.

c) So that government officials, teachers, and other people in authority can have easy access to the data.

d) To enable the researcher to track down individuals and find out more about their lives.

Q 2: Apart from the fact that it is "not a nice thing to do", what is an important ethical disadvantage of deceiving participants?

a) It can damage the professional reputation of the researcher and their discipline.

b) It makes it more difficult to gain access to deviant or hidden populations.

c) It means that records of personal data about the participants cannot be made anonymous.

d) None of the above.

Q 3: Which of the following is a form of harm that might be suffered by research participants?

a) Physical injury.

b) Stress and anxiety.

c) Impaired development.

d) All of the above.

ANSWERS

Correct answer for Q 1 is "b":

Feedback: When maintaining records of personal information about your participants, it is important that these data are kept in a safe, secure place to which no one but you has access (unless the participants have consented to other arrangements). Participants have the right to see what has been written about them, or which is stored on computer files about them. Much quantitative data can be made anonymous (privacy) quite easily (and in any event, the identity of the respondent is not a focus of study), but in qualitative research, this is not as easily done. Great care must be taken with the handling of this data, particularly in the final published reports, so that individuals cannot be identified from their comments or any details about their backgrounds.

Correct answer for Q 2 is "a":

Feedback: It is widely regarded as unacceptable to deceive participants about the nature of the research and their involvement in it. This is mainly because it is unfair and unkind to force people to participate in a project without their being aware that they are being studied and giving informed consent. However, it can also be very damaging for the researcher's professional reputation if they are known to have indulged in such unethical practices, and this in turn can reflect negatively upon their discipline as a whole. It is therefore each researcher's responsibility to ensure that their research is as ethically sound as possible and to "leave the field clean" for future researchers.

Correct answer for Q 3 is "d":

Feedback: One of the most commonly cited ethical principles is that we should not cause harm to our research participants. This can take many forms, including physical injury, psychological distress or emotional harm, loss of self-esteem, being persuaded to conduct morally reprehensible acts, and having one's physical, intellectual or emotional development hindered. We must also be careful about security of our research records, so that respondents may not be identified or otherwise harmed through loss of confidentiality.

REFERENCES

1. WHO. Global health ethics: Guidelines on submitting research proposals for ethics review. Available from: *https://www.who.int/ethics/review-committee/guidelines/en/*. Access date in December 2018.
2. University of Virginia School of Medicine: Participate in a Trial : What is Clinical Research? Available from: *https://research.med.virginia.edu/clinicalresearch/participate-in-a-trial/what-is-medical-research/*. Access date in December 2018.
3. U.S. Food and Drug Administration. What Are Clinical Trials and Studies? Available from: *https://www.nia.nih.gov/health/what-are-clinical-trials-and- studies*. Access date in December 2018.
4. Guraya SY, Guraya SS. Ethics in Medical Research. *Journal of Microscopy and Ultrastructure*, 2014;2(3):121-126.
5. WHO. Ethics and health: Ethical standards and procedures for research with human beings. Available from: *https://www.who.int/ethics/research/en/*. Access date in December 2018.
6. American Medical Association. Code of Medical Ethics: Research & innovation. Available from: *https://www.ama-assn.org/delivering-care/ethics/code-medical-ethics-research-innovation*. Access date in December 2018.
7. CIOMS & WHO. International Ethical Guidelines for Health-related Research Involving Humans. Available from: *https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf*. Access date in December 2018.
8. The University of Leicester. Ethics / Guidance on research ethics/ Planning your research / Assessing and minimising risk. Available from: *https://www2.le.ac.uk/institution/ethics/guidance/planning/minimising-risk*. Access date in December 2018.
9. Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, et al. Ethical and scientific implications of the globalization of clinical research. *N Engl J Med*, 2009;360 (8):816-823.
10. University of California. Privacy and Confidentiality. Available from: *https://www.research.uci.edu/compliance/human-research-protections/researchers/privacy-and-confidentiality.html*. Access date in December 2018.
11. Smith D. Five principles for research ethics: Cover your bases with these ethical strategies. American Psychological Association, 2018. Available from: *https://www.apa.org/monitor/jan03/principles.aspx*. Access date in December 2018.
12. Schaefer GO, Wertheimer A. The Right to Withdraw from Research. *Kennedy Institute of Ethics Journal*, 2010;20(4): 329–352.
13. Resnik DB. What is Ethics in Research & Why is it Important? National Institute of Environmental Health Sciences,2015. Available from: *https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm*. Access date in December 2018.
14. Oxford University Press. MULTIPLE CHOICE QUESTION, 2016. Available from: *https://global.oup.com/uk/orc/busecon/business/brymanbrm4e/student/mcqs/cho6/*. Access date in December 2018.