Hi, welcome come back to the course, Issues in Bioethics. This is the Unit one of Module Three. Bioethics in one sense, particularly the Modern Bioethics is concerned about the individual. We have already seen this. How individual has become so important, so central in Modern Bioethics. So, we have seen that historically this has become so important with the emergence of Individualism during Enlightenment. And, afterwards individual has been very important. Individual has been at the center. In the last lecture, we have examined the principles of Bioethics. The four principles among which, the first one deals with autonomy.

And, while discussing that, I have mentioned that, this is one of the very important concepts of Modern Bioethics, the autonomy recognizing the autonomy of the individual patient which means that, one has to respect, the person of the individual, the person of the patient or respect for the person of the individual and also dignity of man. All these concepts become relevant in this context.

So, from here after, from this module is primarily concerned with the individual. The individual as it appears in various context in Modern Bioethics. And, also the kind of challenges which the individual faces. And, how Modern Bioethics is trying to counter these challenges and tackle them. So, these are some of the major issues, which we are going to discuss in this module, challenges to the person of the individual. And, we will be taking some important concepts.

So, what I am planning to do is, I will basically address the problem from the perspective of four important challenges. Of course, that does not mean that, there are no other important issues. There are many. But I am just trying to cover only four of them, which I consider are very
important. The first one is, I will try to see the individual in the context of clinical research, which we have already seen. Considerable discussions, we already had on this topic, when we discussed the emergence of Bioethics. But I thought in this context, it is not only relevant, but also important to raise this issue once again.

The second one is the context of the Patient-Physician relationship, which is a very crucial domain. Because on many occasions, all of us are interacting with physicians, when we go to hospitals, when we have a particular illness. We have to deal with them. We go to the hospital and sit with them and discuss with them and this is a very intimate process, that used to happen in those days, early days.

But nowadays, because everyone is busy because medicine itself has become the domain of professional experts. The kind of relationship between Patient and Physician has also undergone dramatic changes. So, naturally be it, the situation today calls for a different kind of relationship. So, the context of Physician-Patient relationship has to be taken into account specifically.

Then, there are certain exploitation issues, which we are all familiar with. Then finally, we will also deal with a specific problem, which has got several dimensions, which is the problems
facing vulnerable groups. What I mean by vulnerable groups are old people for example, because the kind of status, they have in the society, the inabilities they have, all these make them a little special in the society. And, another interesting thing is that, it is the old people, who might need the medical attention more than anyone else. But, how does the medical world respond to this such demands and requirements. And, then, what are the ethical issues involved in such contexts.

So, these are some of the issues, which we will be interested in this context. Then again, there are certain other groups like mentally challenged people, people with other disabilities, children, then in certain situations, particularly in countries like India, women. They also belong to the vulnerable groups, where there is a possibility of exploitation. Particularly, when medicine is redefining itself as an industry. As an industry, where profit concern is a major aspect. So, naturally these issues, the possibility of exploitation, one must be very careful about. So, all these issues, we will try to cover in this lecture.

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When we try to address the first one, the context of clinical research, this is one of the initial concerns of Modern Bioethics. We have already examined this and discussed this in detail. Like, we could see that, it is, it appears even the protection of the individual from unethical treatment by researchers. And, this is one of the major concerns, which the Nuremberg codes have reflected,
because there was a historical context in which, Nuremberg codes have evolved.

And, the previous lecture, we have seen there are certain another historical reason, why the ethical concerns related to medical research have become very important for Modern Bioethics. You know all, these developments have happened in 20\textsuperscript{th} century, which also indicates that, they have happened, they have become more relevant in the context of the developments, that are happening in the world of medicine.

Medicine is becoming increasingly a technologized activity. It has become a highly sophisticated science. So, in this context, this becomes very relevant. And, on the other hand, we all know that medical research is an inevitable part of modern medicine. Without research, nothing new is going to happen in medicine. Lot of developments, we could achieve in the world of medicine. Thanks to the kind of research and researchers, who have spent a lot of time and money and for various other efforts, for rooting out important diseases from this world.

Domain of research is an extremely important domain. And pharmaceutical firms, which sponsor this research is concerned about this. Because all of us know that, it takes years for pharmaceutical firms to develop a drug. And, sometimes in between, they will have to discontinue the process because someone else would have already developed it or they might find that, this is not going to be fruitful.

So, there are various reasons, various threats, various challenges, pharmaceutical firms nowadays face. And, the entire process of medical experimentation is highly expensive. So, a lot of money is involved in this process. Pharmaceutical firms are looking for places and the ways to conduct research in a cost-effective manner. So, there are certain places, where they can do that in a better way, in a more cost-effective way.

So, the new dimensions were added later. The Nuremberg codes have come up with certain stipulations, certain guidelines. But later on, more important codes were developed on the basis of this initial codes. And, we had also seen the development of International Code of Medical Ethics in 1949 by the Third General Assembly of the World Medical Association at London in
October 1949. Again, the new directions in clinical medicines, these developments have also taken place during this time mostly after 1950’s

there are a lot of developments, that the world has already witnessed. The development of many new institutions and hospitals, which have necessitated certain very strong regulations in the direction of protecting the individuals. More and more democratization, that is happening in our societies. Our societies have increasingly becoming more and more sensitive towards a specific issue of people, like I mentioned older women, children, mentally ill and, many others. (Refer Slide Time: 08:22)

Now, when you specifically try to understand, the context of clinical research, one would wonder whether something called an ethical research is possible at all. Because, it is no doubt globally a highly regulated domain. There are very strict stipulations and rules, that govern, that regulate medical research all over the world.

Nowadays with globalization, it is many multinational firms have their experiments happening in different parts of the world. But in almost all these places, this medical research is a highly regulated endeavour, no doubt about it. And, there is a lot of emphasis on consent, disclosure and transparency. Because, when you consider the individual, who have come forward to be the
subjects of these medical research, it is very important that, there is informed consent. So, the term informed consent has now become one of the central pillars of modern medical ethics.

People should know, what is happening to them and what is going around because they are involved in a very important process, a highly risky process and they should know the risk and also the benefits. This has made the concept of inform content, centrally important in the whole process. And, then of course disclosure, that is another very important concept.

Because, physicians or the people, who conduct the experiment have their primary responsibility to reveal, to disclose to their participants, the kind of risk that are involved in the process. All foreseeable risk had to be revealed to the participants. So, that the participants can take an informed decision after evaluating the risk and the benefit. Again, the whole process needs to be transparent.

The participants have the right to withdraw from the experiment at any time. And, all kinds of other norms, which are stipulated in this context stresses the principle of Non-Maleficence. No doubt about it. No harm to the patient is a central theme in this context. But, what is the reality.

These are the ideals. These are, what are stipulated globally. And, medical research, wherever it happens in the world have to be highly regulated. No doubt in that. And, pharmaceutical firms are expected to conduct the research following all norms, ethical as well as legal norms and follow them very strictly. But, what is happening actually in this world, that is a question. So, the reality is that, many people complaint that the subjects are often exploited by the pharmaceutical firms.

And, now with globalization after 95 till 1995, most of the medical research were happening in developed countries like the European countries and North America and also in Japan. But, after 95 with globalization, the possibility was opened to conduct this research, anywhere in the world. Rather the pharmaceutical firms in North America can outsource subjects and researchers from other countries, which would drastically bring down the cost of research, which is actually
going to help the pharmaceutical industry all over the world. And, also proceed with the ideas of developing new drugs, which would definitely help humanity in a long run. (Refer Slide Time: 11:54)

When we try to understand, the ethics of clinical trials, it is not a very simple issue. We need to have an understanding about the broad background. There are several factors, that are involved in. It is not just a pharmaceutical company appointing certain researchers and they are conducting certain experiments. Certain experiments are conducted in certain social context. Social context is extremely relevant often. So, in that way, we have to understand the whole context before we really start evaluating the ethics of clinical trials.

And, we, I have already mentioned, globalization enabled drug companies to outsource their research out outside these developed countries. And, also it has made research quicker and cheaper. Patient diversity in countries like India was a great help for coming up with new ideas and new medicines. Like a social cultural context in India provided these companies, a wonderful diversity with economic diversity and ethnic diversity all kinds of diseases, we find here.

So, this possibility has enabled medical firms or pharmaceutical firms to think about new medicines, development of new medicines. This is another positive aspect of it because, when
pharmaceutical firms come to a developing country. When they are planning to conduct a research in a developing country, they are also bringing in a lot of resources to that country.

And, definitely the medical infrastructure in that particular country is going to definitely improve. So, all these factors would definitely add to the positive aspects of medical research. But at the same time, there is a concern for exploitation, deception, coercion and betrayal. This also needs to be kept in mind.

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So, let us see some of the newspaper articles, which have appeared in the last few years. This is appeared in business standard, where it says that, clinical trial gone haywire. So, here the particular focus is on the tarnished Indian advantage. Because, we have been talking about the Indian advantage, because of the cheaper cost, that is involved in conducting research

and, also the kind of ethnic and other forms of economic diversity, that we have in this country. India has become a preferred destination for global pharmaceutical firms. What is happening now? There are reports that, there is a sharp rise in the number of deaths among subjects participating in clinical trials, revealed by the government in Parliament. So, this is a shocking revelation.
Why is it happening in a country like India? Because of various factors like poverty and other social factors, that exist in the country. Today the chances of exploitation is relatively high compared to the developing countries. And, again many NGO’s have move to the courts on matter through public interest litigation. So, there was a pressure on the judiciary and the government to control certain activities, that are happening in this domain.

So, the supreme court judges issued a Obiter Dicta, reflective of the public mood built up ahead of the announcement of actual judicial verdict. So, this was a kind of an importance, this issue had, this problem had acquired in our society.

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And again, there is another newspaper report, which has appeared in the Independent, in November 14th, 2011, which says that, without consent, how drug companies exploit India, Indian guinea pigs. So, how Indians are being treated like animals, when it comes to medical research. It says that, over the past five years, western pharmaceutical companies made India as a testing ground for drugs. So, this is what, this report says. And, again making the most of a huge population, that exist in India.

The loose regulations in the country helped these pharmaceutical companies to dramatically cut research cost for the lucrative products to be sold in the west. These medicines may not have any
users in this country, where it is developed. But, it they sell, they are sold in the west. The kind of relationship that exist is highly exploitative. And, the author of this article says that, it represents a new form of colonialism. Outsourcing certain things from this country, using the resources and exploiting the people.

(Refer Slide Time: 16:30)

And, the response from Stephen Whitehead, the ABPI chief executive to this criticism is also very interesting. The most of the pharmaceutical firms according to him, do not have double standards or different standards in different cultural or social context. The standards are global and they follow it. That is what, he says.

The accusations that, this is the new colonialism is completely unfounded according to him. And no matter, where their trials are take place, whether in India or China in east or in the US and Europe in the west, the standards are same according to him. Again, the article suggest that, in India, doctors and members of government are not adhering to the regulations. This actually, Whitehead considers is a major ethical concern and should be investigated.

So, it is not that, Whitehead is blatantly denying these acquisitions. But he says that, there might be certain concerns. Because, the article suggests that, Indian doctors and members of government are not adhering to the regulations. So, he is in a sense saying that, the multinational
pharmaceutical firms, which are originally conducting these studies are not directly responsible for these exploitative practices, may be the doctors in India and, the government, the Indian government is responsible for that.

And, that has to be investigated according to him. So, in a sense he says that, these companies are not responsible. Which is a very serious issue. Whether you can really run away from such responsibilities is a matter of concern. I am not getting into that debate here. (Refer Slide Time: 18:12)

But rather, I will try to clarify certain theoretical points in this context. We will now straight away come to the context of Patient-Physician relationship. Because, this lecture is trying to introduce some of the concepts. So, I will now go to the other domain, where the relationship, where the person of the individual patient becomes relevant.

And, threat to this person also becomes relevant. So, that happens in the Patient-Physician relationship. What is to be taken in to account here is, the concepts of autonomy and respects for person are fundamental in this context. As far as the individual patient is concerned, whether it is the context of clinical research or context of Patient-Physician relationship in a typical clinical context in hospitals,
wherever it happens, what is more important is to recognize and respect the autonomy and the person of the individual patient. So, this is extremely important. And, only then, you know, you can talk about concepts like consent or confidentiality and all other things, which follow from there. So, we have to deal with certain concepts in this context. And, we have to understand, the significance of this context.

What do you mean by consent? What do you mean by confidentiality? Why these principles? Why these notions are important in this context. We have already seen, what autonomy is? (Refer Slide Time: 19:40)

Before, we get into these issues, let us have some clarity about, the philosophy behind very idea of confidentiality and consent. Because, we are primarily going to address these issues. Inform consent is a central notion. I have already mentioned this. So, what do you mean by autonomy, which we have already discussed. And, the importance of patient autonomy has to be underlined.

Any physician-patient relationship, that happens in a clinical context and it should be based on the respect for autonomy and persons.

So, it demands that, or it says that, physicians have an obligation to respect the person of the individual and also the autonomy of the individual. What does it mean is that, you have to recognize the patient as an individual, who has the ability to take the right kind of decisions about his life? Because, ultimately, he has come to you. He has come to the physician with a
certain problem and the physician's responsibility is to help them out to come out of this problem.

So, in that process, they come into a certain kind of relationship. But then, that does not mean that, the patient has surrendered all this autonomy and all his authority to the physician. The patient even under such circumstances ideally has to retain the authority of decision making with him, the autonomy with him.

And, it is with the help of the physician, the idea of relationship should be like this. With the help of the physician, the patient would be trying to solve his problem. He would be making the right choices, the kind of informed choices, which of course he would not be able to make without the help of the physician. So, these two are extremely important. No doubt. And, they have specific roles. But as far as the person of the individual patient is concerned, that has to be respected.

It is a kind of professional help, that you expect the physician to deliver. Not a kind of personal help in modern context. The necessity of valid consent based on capacity, disclosure and voluntariness. All these concepts are extremely important, which I will discuss slightly later. And, physicians are obliged to seek highest degree of patient consent. (Refer Slide Time: 22:04)
So, these concepts are central in this context. Consent is an autonomous authorization of a medical intervention by individual patient. So, the patient authorize the physician to do certain things to examine and also to come up with certain suggestions, to come up with certain diagnosis as well as treatment method, which might include prescription of drugs, right from prescription of drugs to surgical interventions. For all this, the patient has to authorize the physician. Only then, the physician can proceed. So, that is the understanding.

And, consent also involves a choice among alternative treatments and refusal to treatment. Consent does not mean that, whatever the physician says. It is not a black and white thing, that the physician tells the patient, that you have to do this, either he has to decide yes or no. No, that is not the typical context of medical informed consent. In a typical context, what happens is that, the patient has been given alternatives, choices and he can choose among alternatives. And, also he has a right to refuse treatment.

This can be made explicit or implied. Because in certain circumstances, you cannot, you are not expecting the patient to give an very explicit written form of consent with his signature. See for example, when you go to the hospital, I am going to give an injection and he takes a syringe and in the such context, you cannot expect the patient to give it in writing that, the physician has the authority to do that or rather he might, just raises hand, like this, ok you can take the injection here. That whole action involves the process of consent. That is implicating that, he has consented to the process or he is just accepting that and sitting silently, that implicates the consent of the physician. Again, this outlook should guide all Patient-Physician relationship. It is not that only on certain occasions, this become relevant. In all relevant physician-patient relationship, the idea of consent is a universal process. (Refer Slide Time: 24:21)
So, let us try to understand, consent by placing it in a broader context. So, as I mentioned, the whole notion of consent involves three things. Disclosure, Capacity and Voluntariness. So, when I say disclosure, disclosure again has two branches. The patient has to disclose certain things to the physician, that is also disclosure. The patient goes to the physician and tells him that he or she has certain problems. And, the physician in turn has to keep it highly confidential. He is not expected to reveal this information to a third party, anyone else without the consent of the patient.

So, when the patient reveals the physician or discloses to the physician about his illness, about his physical or mental condition, there is a primary responsibility from the part of the physician, to keep it as confidential. Then, when it comes to physician to patient, the physician is expected to tell the patient as much as possible information about the disease. So, this is what is meant by disclosure and truth telling in that context. The physician is not expected to hide certain important information about the patient, which he knows. And, in this process, communication of relevant information by physicians and patient’s comprehension of this information are equally important.

It is in this context, we are going to talk about the second one, something called capacity, the capacity of the patient. The patient should have the capacity or competence to understand the medical problem, which he is undergoing. Does not mean that, he has to know all the complicated scientific terminologies. It is not to understand his disease in pure scientific terms.
But in a reasonable way, the ability to understand, the situation should be there with the patient. And, this is the ability of the patient to understand. And, also appreciate the foreseeable consequences of his or her decision. Only then a consent would become relevant. Otherwise, it is not a true consent. Then, there is voluntariness. Patient’s rights to take independent decision and freedom from coercion and manipulation.

So, all these things are part of the consent process. So, consent though it appears to be a very simple term, it involves all these things. That, there should be disclosure capacity and voluntariness, confidentiality, truth telling, ability to understand, ability to explain things. physician needs to explain the patient. He should have the patience to explain the patient, his situation in a language, which the patient might understand, not in a highly complex scientific language. So, communication is very important. It is his responsibility to get the consent from the patient in the more fruitful manner.

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And, in this context, we can talk about decision making. Because, only then, the process of decision-making would become relevant and fruitful. It begins with diagnosis and decision making. These two are, the two important pillars of physician-patient relationship. So, diagnosis is made by the physician, on the basis of certain inputs, information given by the patient to the
physician. And, decision is again made by the patient, based on the advice and on the discussion, he or she had, with the physician. So, the process of decision-making is respect for autonomy and patients come into picture.

So here, this fact has to be reiterated, because, this is something, which is very important in Modern Bioethics. In an ideal decision-making process, the patient makes the ultimate call. He takes the decision and the physician’s role is only to assist him, to take, to arrive at the right form of a decision. Right of the patient to decide, what is good for him or her, it is not that, the physician would decide, what is good and what is right for the patient. The patient has the right to do that. (Refer Slide Time: 28:52)

But, there are certain exceptions to this process. Because, it is not that, it is not possible in all context. The decision-making is purely done by the patient. So, there are certain exceptions like the voluntary waiver of the authority. On certain occasions, where the patient might think that, the physician or another person, a third party is a better decision-making authority than him. So, he might tell the physician that, doctor you decide, you know better than me. So, you please decide. I trust you. Again on certain situations, which are highly complex, which are very common in clinical process.
So, there also, you know patients might waive the authority to take decision and request the doctor to take the right kind of decision for them. And, there are certain other interesting occasions, where which is called as therapeutic privilege which was very common among traditional medicine, where the physicians do not disclose information, as they might harm the patient.

Physician convincingly knows that, if he reveals, if he discloses the medical condition to the patient, that is going to ultimately harm the patient. So, psychologically harm the patient, which might ultimately not good for patient welfare. So, he withholds the information and does not reveal it to the patient. So, even in modern medicine, this is allowed to some extent.

But, then the problem is that, it is a very highly complex situation. Because, on what occasions, physicians come to the conclusion that, this information might ultimately harm the patient. On what occasions, they can assert their therapeutic privilege, is a highly challenging issue in today’s Modern Bioethics. And occasionally, what happens is that, physicians have the option to discuss matters with the patient's relatives.

Even doing that is also not strictly good, because that might involve breaking of confidentiality on certain occasions of course. But in a typical Indian context, this may not happen. Often patients go to the physicians along with the relatives and information is shared in the presence of the relatives, close relative or husband or wife, whoever it is. So, there is a possibility that, physicians can interact with the relatives and understand the situation in a better way.

And, it ought to be used on a limited occasion. So, Modern Bioethics wants that therapeutic privilege can lead to certain kind of exploitation. So, it might not be used in all occasions. You should use only in extreme situations. And, then I have already mentioned the importance of capacity or competence. It is the ability to understand, the situation with the help of relevant information and in the light of foreseeable consequences.

So, this is what you normally expect from a patient. A physician expects this and in the absence of this, the physician has strong reasons to feel that, the patient has no capacity to understand the
situation. Then the things are different. Then probably, we may have to take another decision. See for instance, when a woman refuses for abortion. While the physicians know that, if she does not go for abortion, that would be dangerous for both the kid as well as for the mother.

There could be situations of conflicts like patient’s membership in a particular diagnostic group or situations, where patient refuses treatment. (Refer Slide Time: 32:36)

Now, when we go to the third one, the exploitation issues, which is very common, where physicians prescribing unnecessary drugs, non-essential diagnostic examinations, this and exorbitant consultation fees, these are quite common in today’s world. In certain context, we will find that, there is a kind of unholy relationship between pharmaceutical firms and physicians. So, that the pharmaceutical firms try to push their drugs, to the patients through the physicians. And, physicians function as a facilitator, to this business interest of the pharmaceutical firms. And, in return, gain certain benefits out of it

So, these are highly unethical practices. But unfortunately, which is quite rampant in our culture. And, there is this, non-essential diagnostic examinations. Because, those who have gone to diagnostic centres might know that in most places, there are no standard charges for diagnostic test. It depends on people, who go there, which doctor sends you, from which hospital you go.
So, all these things make the entire process highly doubtful, highly arbitrary and doubtful. The possibility for exploitation, patient exploitation is quite high in today’s world of medical practice. Then unnecessary hospitalization is another very important concern. (Refer Slide Time: 34:04)

Now, when you go to the problems of vulnerable groups. I will be discussing, some of these issues, later as well. Here, as I already mentioned, people who are unable to protect their own interest, due to physical, psychological, social and cultural problems. So, there are physical as well as social issues involved in this context. Vulnerability is not just a physical condition always. It can happen due to social situations as well. But, in India for example, certain groups of people are more vulnerable.

Certain weaker sections of the society are more vulnerable than others. Women for example, in India and many other countries are more vulnerable. So, they are not able to adequately perform or obtain services necessary to meet their essential human needs. And, senior people, this people with disability, I have already discussed this. And in India caste dimension is also important.

So, in such context, what happens is that, violation of rights like the denial and refusal of treatment. They are quite rampant. Unfortunately, this happens even today, almost every day, we
find news in newspapers and channels about people were denied treatment. And, what is happening to the weaker sections, particularly the Adivasis and all that.

They do not enjoy the kind of facilities, people in the cities enjoy. And, neglect and carelessness are also quite rampant in this domain. Certain people have certain special needs and the entire medical fraternity becoming insensitive to such needs is also a common phenomenon. So, all these issues make the problems of vulnerable groups very important in the context of Biomedical Ethics in today’s world.

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So, we will now wind up this lecture. We will continue with topics, where we are going to discuss, where individuals are involved as individual human beings, as well as groups. In this module is meant for discussing certain issues, where individuals are directly as well as indirectly involved. So, will right now wind up this lecture here. Thank You.