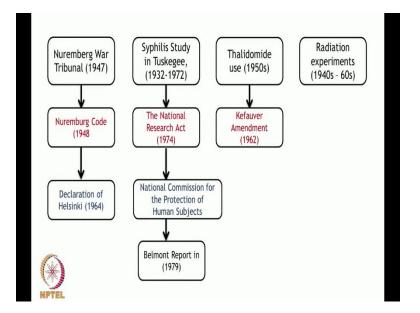
### Issues in Bioethics Dr. Sreekumar Nellickappilly Professor of Philosophy Department of Humanities and Social Sciences Indian Institute of Technology, Chennai, Tamilnadu, India

### Module No. #02 Lecture No. #10 Principle-Based Theories

Welcome back, to this course, Issues in Bioethics. This is the Unit Five of Module Two. In essence, we are going to conclude our discussions on the theoretical frameworks, which are relevant for bioethical deliberations. So, this lecture will focus on the principle based theories. We will try to understand, what these principle-based theories are. We will also briefly see, how these so-called principle-based theories have evolved historically. There is a reason behind it. So, we will see that also.

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See, this will provide you a very broad picture about the historical context, which ultimately led to the emergence of these principle-based theories. Some of these things, we have already discussed. The constitution of the Nuremberg War tribunal in 1947 and following that, they have come up with, what is known as the Nuremberg code. We have already discussed this. And also,

building upon this Nuremberg code, the declaration of Helsinki, which actually provided a broad guideline for conducting research, medical research.

Certain very important factors to be taken into account, of course reflecting certain theoretical issues. But they were not really concerned about elaborating theoretical issues. They were concerned about addressing a problem. A practical issue, which has happened, which humanity was encountering after the Second World War. So, naturally the focus was more on arriving at certain practical guidelines, which would function as regulative measures for future research, future medical research.

And then afterwards, we have also seen this Syphilis study in Tuskegee during the 1932 to 1972. Long 40 years, the study was conducted. And, this was conducted, it was an unethical study. Because, it was conducted among the blacks, without really informing them. So, it was racially motivated. It never took the consent of the participants. It never provided sufficient information to the people, who have participated in the study. So, in that way, it violated many of the norms, many human rights of the people, who have involved in it, following a huge outcry.

Because, this is the facts about the study was brought out by the media. And, there was a huge public outcry. And, following that the National research act was designed. And, the National commission for the protection of human subjects was also constituted. And, the National commission for the protection of human subjects was constituted. And they have come up with, they have submitted in 1979, what is known as the Belmont report, which became a very important event in the history of modern Bioethics. So, when we discuss the principle-based theories today, we have to keep in mind this development, this chains of development.

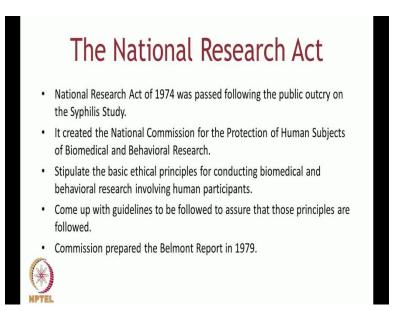
And, there are certain other issues also, certain other events, that have happened the Thalidomide use during 1950s, which is a medicine, which was given to pregnant women. And, this drug was at its experimental stage. And, the women who consumed this drug were, they have given birth to deformed babies. And such an unfortunate event, that is happened in the history of medicine. So, this has led to another very important amendment, which is known as the Kefauver amendment in 1962. And, then again, there are this radiation experiments, which was conducted in United States. For these experiments, have also violated, some of the very important human rights of the participants.

But, these study was conducted during the wartime. See, you can see that it is 1940s. And, but it went on, because it was concerned about the people, who were worked in the Manhattan Project, which made the atom bomb. So, to make the study to understand, what would be the effect of radiation, some of the federal government allowed the study to continue. But, ultimately it was proved that, the study also violated some of the human rights of the participants.

So, given this such a broad context, which demanded that, there is a need for arriving at some very strict regulations, very strict norms, ethical as well as legal to ensure that, future research will be conducted in a more ethical environment, where proper information would be given to the participants and their consent would be taken and also based on certain other very important guidelines.

So, this is ultimately led to the, as I mentioned, to the creation of the National commission for the protection of human subjects. Which have come up with their report in 1979, which is known as the Belmont report. In which, some of the principles are highlighted. It is not that case, that we never knew about this principle. Many of these principles were quite well-known. And, they were widely discussed in the philosophical traditions. See for example, the principle of autonomy. The principle of autonomy has become prominent ever since Enlightenment in Europe.

And, it has become one of the central philosophical ethical concepts. But, linking this concept with certain practical issues, which the practice of medicine was encountering. Is something which is the achievement of the Belmont report. And again, other principles like Beneficence, Non-Maleficence and Justice. These were all principles, which we already knew, we already were familiar with. But, the whole contribution is that these reports and the deliberations, which followed afterwards, linked these important concepts with practical issues in life. (Refer Slide Time: 06:32)



We will have a very brief look at the National research act. It was the National research act of 1974 was passed, following the public outcry on the Syphilis study. The National commission for the protection of human subjects of Biomedical and Behavioral Research was created. In order to stipulate the basic ethical principles for conducting biomedical and behavioral research involving human participants. And also, come up with guidelines to be followed to ensure that, those principles are followed. So, these were some of the very important concerns of the National commission for the protection of human subjects. And the commission prepared the Belmont report in 1979.

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And, it is a statement of basic ethical principles and guidelines that provide "an analytical framework to guide the resolution of the ethical problems arising from research within with human subjects". So, it was aimed at solving a practical issue, resolution of the ethical problems. It is not just discussing ethical issues. But, resolution of the problems, which actually arise out of the increasing number of experimentations, that take place in a rapidly developing world.

And, again these three discussion topics of Belmont report include boundaries between practice and research. See the practice and research, this is never a major concern earlier. Ancient medicine never bothered about to make such a distinction. Practice and research were not really distinguish from each other. One reason is that, there was no need for that and another reason is that they are so intimately interlinked. So, it was often difficult to really distinguish one from the other. But with more developments in the science of medicine, such a separation has become inevitable. Research was gradually becoming a very independent domain.

With some of the specific concerns, which are not shared by clinical practice. And of course, the domain of clinical practice was also not problem free. There was several issues, that clinical practice was also encountering. The relationship between patients and physicians, and other healthcare professionals, relatives, family members, and also hospitals and hospital administrators, it was a very complex scenario, that was evolving. So, we need to arrive at a

better, a more comprehensive framework to understand the problems, that emerges from such a scenario.

And the basic ethical principles. So, this was probably the fundamental concern to come up with some of the basic ethical principles. Because, we have already seen that the domain of ethical principles or ethical theories always a conflicting domain because there are conflicting theoretical frameworks. The same problem can be viewed and evaluated from different perspectives and we might come up with different solutions, different resolutions.

When, we are actually concerned about resolving certain issues, this would become a huge headache. So, we have to come up with another set of principles, which are on the one hand basic, at the same time would be very practical, would provide us some very practical guidelines, which we can directly or indirectly apply in our actual life context. So, this was a major concern of modern Bioethics. And, Belmont report was responding to this concern. Again, applications. I have already mentioned this

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So, now when you see this diagram, it actually gives you a whole picture of the basic ethical principles, which the Belmont report has come up with. There are three basic principles. On the one hand, you know, you have the basic ethical principles are divided into three. Respect for

persons, which is fundamentally important in the practice of medicine, particularly in today's world. Because in ancient medicine, we have seen that this is not a major concern.

Because the physicians with the good intentions, with a great spirit of social welfare and patient's welfare used to take into account, the welfare of the patients as most important concern for them. And, they almost acted as the good guardian of the patients. But this model is no more practical in today's world, in a modern world. In modern world, we have conflicting interest of the physicians and the patients and the respective personal and professional lives of people.

So, it is a very complex scenario and we need to arrive at very specific professional guidelines, professional norms, which people can follow. So, one of the fundamental features of modern life is that, people or human beings have to be treated as autonomous individuals. So, they have to be respected as persons. Which means that, they have to be treated as autonomous individuals.

This is to say that; they are the better judge, they would decide, they have the ability, they have the capacity to decide, what is good for them what is right for them. From this principle of respect for persons, we can derive the idea of informed consent process.

Which is again a very central processing todays practice of medicine. Informed consent is where you know, you are expected to or physicians and health care practitioners are expected to inform the patient. The situation, which he or she is undergoing and what would make his or her situation better. The kind of the course of treatment, which are suggested and the reason, why this was suggested and the potential benefits and harms involved in that process. So, this information needs to be given to the patient.

And, after giving this information, the patient would decide, what to do. So, it is not that the physician is deciding everything for the patient. The physician will no longer the good guardian of the patient. So, that paternalistic attitude, which we today understand as a paternalistic attitude is no longer going to function in modern societies. Even today, this happens in many societies that the physician thinks that, he or she is the better judge and he or she can take the best

decision for the patient. But this is not something, which we can accept in a rapidly changing modern situation

So, informed consent process is extremely important. And it is not only an ethical principle but also a legal requirement. And there are certain legal specifications, the governments in different countries have come up with, in order to protect the interest of the patients. Even in India, recently we have come up with certain amendments in the process.

Now it has to be recorded. It has to be audio recorded. See for example, particularly in the context of experiments, medical research. The potential harms involved in the process needs to be explained to the patient clearly and ensure that the patient has understood things properly and then take a decision.

So, initially what happens is that, you just give a piece of paper, which is actually a legal agreement between the scientist and the subject of experiment. And, the subject is expected to sign under it, which actually means, which technically means, he has understood it, read it and understood it and agree to that.

But then, whatever things have written in a very specialized language, which many patients, many participants in the research may not understand. So, that context gives rise to several concerns of exploitation. And, so the government has come up with certain very strict stipulations, that this process should be more transparent. The participant should be explained by the experimenter that the possible, the potential risk that are involved in the process.

Now, the second principle, Beneficence, which directly deals with risk and benefits. Of course, we can see that, later on another one is added along with this Non- Maleficence. Beneficence and Non- Maleficence are very closely related. Belmont report does not really distinguish them. It was distinguished by Tom Beauchamp and Childress much later.

So, here Beneficence include both Beneficence as well as Non- Maleficence, which talks about the risk-benefit analysis or assessment involved in the process. The third one is Justice. Justice is concerned with the selection of research participants taking into account various other factors. Because, Justice as a principal, talks about fairness one should adopt, when risk and benefits are distributed. Now, let us come to principle-based theories proper.

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So, this was developed by Tom Beauchamp and James Childress in their famous book, The Principles of Biomedical Ethics, which is in to its sixth or seventh edition now. More or less their own sentences, I am using here. They say that, they share with Utilitarianism and Kantian theories and emphasis on principles of obligations. So, the principles, which they are trying to derive are not really an alternative to Utilitarianism and Kantian theories.

Because, you could see that, they oppose each other. Because, they have some moral absolutes, which conflict with each other. The moral absolute in Utilitarianism is the consequences. While Kantian theories are non-consequentialism and they emphasize on duty for the sake of duty. So, because of this absolute positions, they cannot come together and find a common sharing platform.

But, the principle-based theories are trying to derive from these theoretical frameworks as well, certain insights, certain very important insights. And, they shared with these theories and

emphasis on the principles of obligation. But at the same time, Beauchamp and Childress claim that, unlike Utilitarianism and Kantian theories, they are not monistic theories.

But, they are essentially pluralistic. Because, they have two or more non-absolute principles from the general level of normative statements. So, we will see this, when we actually address the four principles, which they have put forward. We can see that, on certain occasions, these theories also or these principles also might conflict with each other. And Beauchamp and Childress have come up with certain solutions, certain suggestions, how to negotiate between such conflicting principles?

So, they say that, they rely on ordinary shared moral sense and not solely on reason or any other criterion. So, we can see that, this Enlightenment theories like Utilitarianism and Kantian theories were trying to arrive at rational theoretical frameworks. But here, there is a lot of importance is given to ordinary shared moral sense and trying to derive certain universal, they call it universal, certain universal theoretical principles, which can be applied in different context.

Because, one challenge which, we are going to face in today's world is that, we have to apply these theories in different context, different cultural context from United States to Tanzania or Uganda. So, these are the kind of cultural variations, we have to face, when doctors try to apply, when practitioners try to apply these theories in actual context. So, we have to rely on shared moral sense.

But at the same time, we have to also take into account certain universal principles that regardless of cultural and other differences will become valid, when it comes to ethical deliberations in the practice of medicine.

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# Common Morality Theory, Commonsense and Customary Moralities

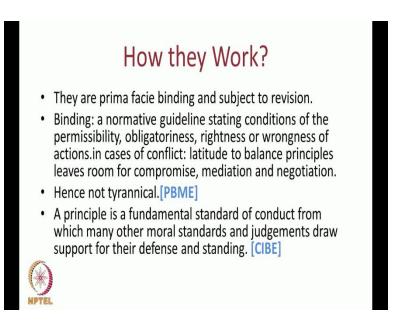
- Not synonymous.
- Not a systematization of commonsense or customary moralities.
- Common morality is a pre-theoretic moral point of view.
- Transcends the local customs and attitudes.
- Analogous to beliefs in the universality of basic human rights the principles of the common morality are universal standards.

It is a common morality theory. The common morality theory is we cannot equate it with common sense and customary moralities. The domain of common sense moralities and customary moralities excessed along with common morality theory. But, there is a fundamental difference. The fundamental difference is that, it does not promote or it does not justify all customary practices, that exist in a society.

Because, from the customary moralities might significantly different from place to place, from culture to culture. But, common morality theory is trying to arrive at, something which is common, something which will be universally present in different frameworks and different context.

So, it is not a systematization of commonsense or customary morality. And, it is a pre-theoretical moral point of view. So, this is what, they try to argue. So, it is a pre-theoretic moral point of view. And it transcends the local customs and attitudes. So, here it says that, analogous to beliefs in the universality of basic human rights, the principles of the common morality are universal standards. So, the assertion is that, they are universal standards. And now let us see, how do they work.

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Because you on the one hand, you say that they derive a lot from these theoretical frameworks. They are trying to derive from common morality, which is available. But, how do they work. They are prima facie binding and subject to revision. So, this is the interesting aspect of these theoretic, these principles. On the one hand, they are binding, they are dealing with certain common universal principles but on the other hand they are subject to revision.

So, they are binding because a normative guideline stating conditions of the permissibility, obligatoriness, rightness or wrongness of actions. In cases of conflict, latitude of balance principles leaves room for compromise, mediation and negotiation. So, they are both binding as well as subject to revision. Because, there is a lot of room for compromise for mediation and for negotiations. See, let us take an example. Killing is wrong.

We all know that, killing is wrong. And, there is an important principle called Non-Maleficence, which directly says that, no harm should be done to the patients. So, it is basically the no harm theory and under no conditions, the patient should be hopped or harm should be inflicted upon the patient. But on situations, where we allow patients to die, passive euthanasia or even active euthanasia.

If no harm principle is taken into account, then under no circumstances, we can allow euthanasia. But on certain circumstances, euthanasia becomes inevitable. And, we know that, there are certain circumstances in which, abortion becomes inevitable. So, how can you actually, how can you justify such situations? So, there need to be some sort of a revision, some sort of a negotiation between the principles.

Let us take abortion. In the case of abortion, if you respect autonomy, autonomy of the pregnant women and the women wants abortion. But, then there is always a principal called no harm and it is scientifically true that, the fetus also has life after certain stage. So, there is a conflict between the interest of the mother, the pregnant mother and the interest of fetus, which has life. So, how can you negotiate.

So, there are certain situations, where we need to have a negotiation between these principles. Because, these principles are not necessarily always subscribing to one universal theory. They are different principles, which all are important, when it comes to deliberations on ethical issues. Hence, Becuchamp and Childress claim that, they are not tyrannical. Since, they allow a lot of room for compromise and negotiation, they are not tyrannical.

And, a principal is a fundamental standard of conduct from which, many other moral standards and judgements draw support for their defense and standing. So, this is the interesting contribution, this principlist approach gives to modern bioethical theory. It is a fundamental standard of conduct from which, many other moral standards and judgements draw their support for the defense and standing.

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Now let us see, what are the principles. The first one is, as I already mentioned, this autonomy which reflects the concern for the respect for persons. The second one is Beneficence. Third one is Non-Maleficence. And, the fourth one is Justice. So, these are the four principles. The Belmont report has come up with three of them. Magnificence and Non- Maleficence were put together. But, now given the complexities of modern medical situation, Beauchamp and Childress have a specified, have made a distinction between Beneficence and Non- Maleficence probably, they would refer to the positive and negative aspects of harm and welfare.

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## Autonomy

- From the Greek words auto and nomos meaning selfgovernment indicating the political status of a city state.
- Immanuel Kant: moral freedom of the person to obey the commands of freedom independent of others.
- John Stuart Mill: freedom from coercion and the possibility of acting and deciding for oneself.
- To be autonomous: capacity to deliberate a course of action, and to put that plan into action.

when you come to autonomy, autonomy is arguably the most important principle. Beauchamp and Childress may not like this characterization. They would say that; all the four principles are at one level. They categorically deny that, their framework is giving importance to autonomy, which is to some extent correct. But, at the same time, we can also have counter arguments against their position.

Anyway, lets deal with, let us try to understand the concept of autonomy. It is derived from the Greek words auto and nomos, which meaning self-government or self-rule indicating the political status of the city states. The Greek city states, which are considered to be autonomous states, independent of each other. So, the term autonomous has a certain very important political connotation.

But, later on this term was extrapolated and got its a very important application to characterize individual human beings, how independent they are and autonomous they are. (Refer Slide Time: 25:51). When you try to understand, the conceptual history of this concept, we can see Immanuel Kant is one important philosopher, who has contributed a lot. Because, he has a concept of moral freedom of the person.

We have seen this in the previous lecture, where how Kant has considered the human being, the rational being as an autonomous individual, who is potentially independent of all other factors. Enlightenment for Kant is a freedom from all self-imposed to till ages, where one can exist independent. This human being is capable of existing independent of the commands of other people. So,the commands of freedom independent of others.

And for John Stuart Mill, another important philosopher, freedom from coercion and the possibility of acting and deciding for oneself. So, this is very important. He underlines this theory. The only thing is that; it should not harm others. That is the only reservation, he has about it. Otherwise, both Immanuel Kant and John Stuart Mill though in spite of the fact that they have subscribed to very different theoretical frameworks and philosophical outlooks.

They agree upon one important principle, the principle of freedom, the freedom of the person and the autonomy of the person. And to be autonomous in this sense is to capacity to deliberate a course of action and to put that plan into action. So, it is a very important concept, but at the same time, we can see that the demands of this concept is also very high.

For to call a human being, a person autonomous is to understand that, in that person, the ability or the capacity to deliberate upon a course of action is underlined. That rational ability should be there in an individual. Only then, we can consider that person as autonomous. But Immanuel Kant says that, every human being by nature is rational and has this ability. Only thing is that, there are several social and other factors, which might not allow us to really use this faculty, use the freedom, the autonomy.

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Now, how autonomy works in clinical and experimental contexts? See, it is very important in today's modern clinical and experimental context. No doubt.Because, the individual needs to be given the freedom to decide, what to be done on him, particularly in experimental context. When a person is voluntarily subjecting himself for an medical experiments, he or she should know every possible knowable consequences of the kind of experiment, he or she is undergoing. So, there is a moral obligation from the part of the scientist of the practitioners to tell, to inform the

patient that, these are the possible consequences, these are the things which you are going to undergo and it is going to take this many months or years or whatever. So, all possible information should be given to the patient and the patient should be allowed to take a decision.

So, giving consideration to the patient's views on treatment is very important, when it comes to clinical context. So, the doctor, the practitioner is expected to inform the patient that, this is the medical condition and these are the possible courses of treatment, he is suggesting. So, this is what the principle of informed consent refers to. Where the choices and adequate information are with the patient. The patient is voluntarily consented to undergo a certain process, medical experimentation or clinical process.

And, in that context, what is expected, what is obligatory from the part of the physician or practitioner is full disclosure of risk and benefit and to ensure that, the patient has comprehended it completely. And, no undo inducement of anything, unless it is necessary and unless it is scientifically proved, unless you are sure about it, there should not be any thought of harming the patient. And, if there is any non-factor, that is going to harm the patient, we have to be careful about it. And, also the possibility of voluntary termination. The patient can withdraw his participation, his or her participation at any time of the process.

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# Beneficence

- Was considered the most important value in medical traditions.
- Should act to benefit/welfare the patient: hence may occasionally may clash with the principle of respect for autonomy.
- Benefits need to be weighed against the risks.
- Abstain from harming and positively assist the patient by promoting his/her good.

And, when you come to the next one Beneficence, it was considered the most important value in medical traditions. We all know that, ancient medical traditions have given a lot of importance to this. And, it was underlined that, the primary concern of the physician should be the benefit, should be the welfare of the patient. And, this is not just traditional ancient consent. This is also a consent for the modern age. It should act to benefit or welfare the patient.

Hence may occasionally may clash with the principle of respect for autonomy. So, this is a situation, where a potential clash might occur between the patient autonomy, the principle of autonomy of the patient and Beneficence. Because, principle of autonomy affirms that the patient's views have to be taken into account and that should be given priority.

And Beneficence asserts that, the benefit and welfare of the patient should gain prominence. And there could be situations, where these two might clash with each other. The patient might take a wrong decision, which the physician is quite sure about. What will you do under such circumstances? Can you adopt absolute positions? In such context, we have to come up with negotiations.

The physicians have the responsibility to engage in a dialogue, a conversation with the patient and try to convince the patient about the situation. So, that we can both of them will arrive at a better picture, better view about the context and pick the right form of a decision. Yet there could be situations, where the wrong decisions will be implemented. We cannot help it.

Benefits need to be weighed against the risks. And, this is a very interesting process, at the same time extremely difficult process. Abstain from harming and positively assist the patient by promoting his or her good. (Refer Slide Time: 32:33)



We can see that, the next one is explicitly about no harming the patient. Principles like do not kill, do not cause needless pain, do not incapacitate others etc are relevant in this context. So, in one sense that, this is the other side of the principle of Beneficence, which talks about the positive consent for the welfare. Here, it is the negative implication, that do not harm the patient. (Refer Slide Time: 32:58)

# Justice Fair. Equitable and appropriate distribution of medical goods and services. To each person an equal share To each person according to individual need To each person according to individual effort To each person according to societal contribution To each person according to merit

And the last one Justice, which is fair equitable and appropriate distribution of medical goods and services to everyone. So, this is again a very important and relevant principle. Particularly it becomes more relevant in certain context, where justice, social justice does not prevail in certain context, where this becomes a more important concern.

So, there are several aspects of Justice. So, I am just going to outline that. To each person, an equal share. To each person, according to individual need. So, not mere blind equality, but also to take into account, individual need. But at the same time, you have to take into account, individual effort as well. Just because someone needs it, we do not have to give it to him or her.

That effort also needs to be taken into account. To each person, according to social contribution. That is again, another one. So, these are some of the factors, which we need to keep in mind, when we discuss fair equitable and appropriate distribution of medical goods and services.

Now, we will see the principles and their application. As we have already seen that, these principles are not hard-core theoretical frameworks. They constitute a very loose it or rather a very broad comprehensive framework, where there are different principles. Some of them might conflict with each other in specific situations, when you try to apply them into context.

So, there is a lot of room for interpretation available. And, cultural and other challenges are definitely going to be there. Because, say for instance, the principle of autonomy can be highlighted in a modern society in a modern European or democratic European society or in United States of America. Which may not be the case in countries like India or Pakistan or Bangladesh or other countries, where long-lasting traditions have their impact and influence. (Refer Slide Time: 35:04)



Another problem might arise, when there is a conflict among principles. There are certain very fundamental conflict among principles. There are no master principles available on the base of which, we can find a resolution. So, on several occasions, we might have no clue to arrive at the right resolution of the problems. So, such situations are also unavoidable in a modern context of medical practice. And then in some cultures, some principles gain prominence

As I have already mentioned, autonomy might gain prominence in certain developed modern democratic countries. But, principles like Non-Beneficence or Beneficence, Non-Maleficence, they might be more important in certain other societies. And Justice of course might find relevant in certain other social context. So, how to decide between them, is again another important task.

But in this context, we can always say that, these principles as, Becham and Childress, they are not proposing these principles as absolute theoretical frameworks. They can always, there is always a room for negotiation and compromises. And a broader approach, where we have to take into account, the culture and other factors. So, that we can promote better deliberations taking into account, different viewpoints from different stakeholders and finally arriving at more balanced and comprehensive solutions to the problems. (Refer Slide Time: 36:36)

These principles can also be taken as a good starting point, to think of norms in the complex context of todays techno-medicine. One important factor, that makes these principles relevant today is the very fact, that medicine is transforming itself into a very complex techno-scientific endeavor. So, in that context, there is an increasing need to protect the interest of individual patients.

So, though we might say that principles like autonomy may not be really relevant in certain contexts like certain Asian or African context. This is actually not correct because in such context also, we are employing this technology and science of medicine. And the possibilities of exploitation and coercion exist in such societies as well. And society everywhere is changing. No society is insulated from changes that is happening other places. Most of the societies in the world are increasingly modernizing.

Modern society is also have their own issues, their own problems, in which the individual often becomes helpless. So, there is a need for certain ethical principles to come forward and protect the individual. The individual patient in this particular context from certain other kinds of interest. Commercial interest, family interest and several other interests, that might become more and more relevant in the context of modern societies.

So, these principles in that way, can be treated as a very good starting point. Of course, we have to keep in mind that, we cannot apply this principle everywhere. A lot of negotiation is necessary, a lot of practical knowledge about the situations is necessary and sensitivity towards culture and traditions also become relevant.

From the next lecture, onwards, we will want to understand some specific issues, which are relevant in the practice of modern Bioethics in today's world. So, here we will wind up todays lecture here. And also, our deliberations on the theoretical frameworks. Thank You.