Introduction to One Health
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Lecture – 3
ABCs of Research Ethics: A Basic Introduction

Hi everyone, welcome back to yet another session in the One Health Course. Today's topic is an Introduction to the Basics of Research Ethics, with a special focus on One health Research. I am Pranab Chatterjee from the Department of International Health at the John's Hopkins Bloomberg School of Public Health. And I hope you enjoy today's session as well. So, today's topic will be a gentle introduction to the exciting and complex world of research ethics, especially One health research.

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In today's session we will cover the fundamental principles of ethics, some general ethical principles, the role of institutional review boards or institutional ethics committees. We will look at the ABC of applying the principles of ethics and we will see a few examples of how unethical research can cause long-lasting harm.

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It is my hope that after you have gone through this session, you will be able to define the fundamental ethical principles of research. You will be able to understand some general principles associated with ethical and responsible conduct of research. You will be able to describe the ethical complexities of doing One health research and you will be able to describe the harms that can be caused by conducting research in an unethical manner.

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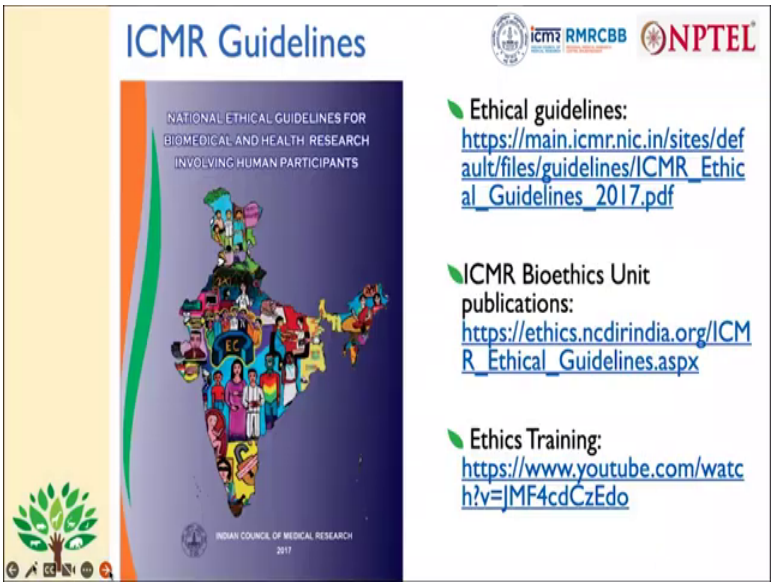

Before diving into today's session, I would like to strongly recommend that you take a deep look at the Indian Council of Medical Researchers that is ICMR's National ethical guidelines for biomedical and health research involving human participants. This is the standard by which

human subject research is conducted in India and in my opinion, it is amongst the finest most comprehensive, yet pragmatic guidelines available for health researchers globally.

I would also refer you to the ICMR bioethics unit Publications webpage which is continually updated to showcase the latest work being done in the realm of bioethics at the national and regional levels. I would strongly recommend going through the relevant documents to identify the ones which are pertinent to your work and which may guide your actions as a One health researcher.

Further, the ICMR bioethics centre organizes several ethics training programs each year. And many of them can be attended online as well. I am putting up the YouTube link for one of these programs. Please feel free to pause this video and go over to YouTube to check out this their webinar. It is a very useful session and introduces the nitty-gritty of ethical research that we will not be able to cover in today's short session here.

In today's session we will do a brief overview of the basic ethical principles and look through the core concepts associated with ethical research. The world of ethics and biomedical research is quite complex and in the case of multi-sectoral challenges addressed by One health, it may have many shades of gray as well. This session serves as a primer for peaking your interest in this matter and introducing you to the basic concepts.

And it rather than functioning as a comprehensive overview of the ethical connotations of One health research.

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So let us come to the first point: the fundamental principles of ethics. The principle of beneficence makes it the obligation of the researcher to work for the benefit of the research participants and is guided by several moral, ethical and legal requirements in order to protect research participants. To defend their rights, to remove conditions that may predispose them to harm.

To address any participants suffering from a harm or to help or assist those in a dangerous situation and to provide optimal support needed for participants with disabilities or other vulnerabilities. Please note that this concept works in a positive sense, in that, it does not only limit itself to avoiding harm but it actually asks to act in a fashion which improves the welfare of research participants or their communities.

The second principle is non-maleficence and to explain simply, it is the researcher's duty to not cause any harm to the research participants. Like the old adage goes, ‘primum non nocere’:first, do no harm. All efforts must be taken by the researcher to ensure that the potential harms to the research participants are minimized. The third principle is that of autonomy. Autonomy ensures that the research participant has the freedom to decide whether they want to participate in the research process or not.

And they do so voluntarily out of their own free will without any undue pressure, coercion or fear of retribution, to name a few. One of the ways we, as researchers can try to ensure that this happens is by providing the potential eligible research participants with the best available information about the risks or benefits of participating in the research process to the best of our ability.

The fourth and final fundamental principle is justice which is also sometimes referred to as distributive justice. This is the concept that the risks, benefits and burdens of participating in a research effort should be distributed fairly and equitably. Vulnerable groups should not be included solely because they bear the risks or burden of research, while the fruits of the findings are enjoyed by others who are better off.

The researcher must ensure that the research process itself does not contribute to any iniquities amongst the research participants. Please note that whilst explaining these principles, I often refer to research participants but that is not meant only to be limited to an individual research participant. This term may be taken to extent to the family or community, to which the participant belongs and as such should consider those stakeholders as well.

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The four basic principles that we just discussed have been expanded into twelve general principles according to the ICMR guidelines. And they are applicable for all biomedical, social

and behavioural science research involving human participants, their biological materials and data. I will try to quickly go through the definitions of these principles, as outlined in the ICMR document, in order to introduce you to these important principles.

The principle of essentiality states that human research participants should be included only after due consideration of all alternatives. And after reaching the conclusion that human participation is absolutely necessary to answer the post research questions. Voluntariness respects the right of the participants to accept or refuse, to become a participant in a research effort. And it also enshrines their right to withdraw from the research process at any time.

Non-exploitation is the principle which allows research participants to be equitably selected so that the benefits and burdens of the research processes are distributed fairly and without arbitrariness or discrimination. The social responsibility principle ensures that research is planned and conducted in a manner which avoids creation or deepening of social and historic divisions or inequities or in any way disturb existing social harmony in community relationships.

Researchers also have the beauty of ensuring that the privacy and confidentiality of the potential research participants are protected, their identity and records are kept confidential and access to all of these sensitive documents is limited to only those who are authorized. However, under certain circumstances, such as suicidal ideation, homicidal tendencies, HIV positive status, when required by court of law to name a few.

The privacy of the information can be breached in consultation with the ethics committee. Given that there are valid scientific or legal concerns as to the right to life of an individual which supersedes the right to privacy of the research participant. The principle of risk minimization is one which asks the researchers to ensure that due care is taken by all stakeholders, including researchers, ethics committee members, sponsors and regulators, at all stages of the research.

To ensure that the risks are minimized and appropriate care and compensation is provided to research participants in case any harm is encountered. Professional competence is the principle through which the research is planned, conducted, evaluated and monitored throughout the

process by persons who are competent and have the appropriate and relevant qualification experience and training.

Maximization of benefit ensures that due care is taken to design and conduct the research in such a way that directly or indirectly maximizes the benefits to the research participants or to the society as a whole. Under the principle of institutional arrangements, institutes where the research has been conducted should have policies for appropriate research governance. And should take the responsibility to facilitate research by providing required infrastructure manpower funds and training opportunities.

The principle of transparency and accountability is one through which the research plan and outcomes emanating from the research processes are brought into the public domain through registries, reports, publications, scientific monographs and other sorts of mechanisms. While safeguarding the right to privacy of the individual participants. This principle also requests. This principle also enshrines the fact that stakeholders involved in research should disclose any existing conflict of interest and manage it appropriately.

The principle of totality of responsibility is one whereby all stakeholders involved in research are responsible for their actions. The professional social and moral responsibilities compliant with ethical guidelines and related regulations are binding on all stakeholders directly or indirectly. And finally, the principle of environmental protection is one whereby researchers are accountable for ensuring protection of the environment and resources at all stages of the research. In compliance with existing guidelines and regulations.

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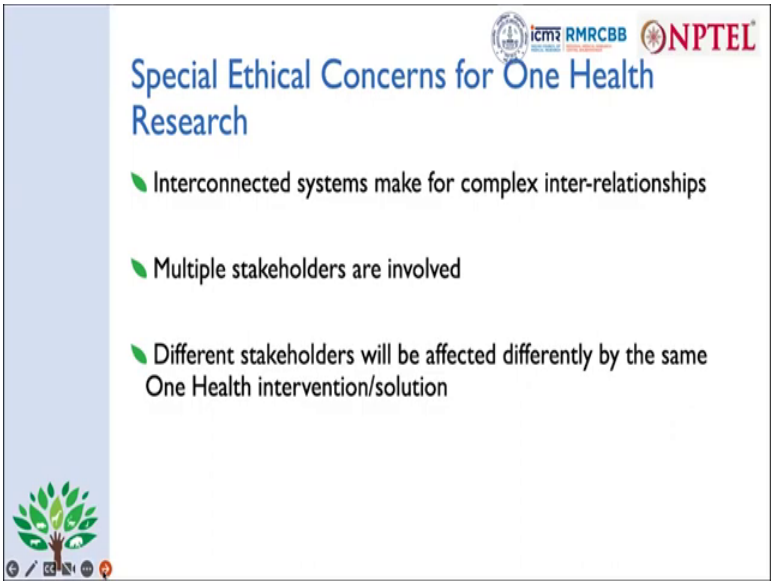

As we have discussed in prior sessions, One health works across multiple sectors involving a wide spectrum of stakeholders. Different interventions or research activities are likely to have different impacts on these stakeholders. Take for instance, the case of avian influenza or bird flu in Southeast Asia. The concerns of backyard poultry farmers who have small flocks and function on a razor thin margin of profits is quite different from those of the larger firms, often called factory farms.

Who may have a larger financial leveraging power, may be able to purchase protection through insurance and have a stronger bottom line to help them tide over such challenging times. In case a spill over happens where the viral agent spills over from birds into humans. The interests of public health functionaries in the affected area may be at odds with the interests of the shareholders in poultry food companies who may not be facing the immediate threat of the disease occurrence.

In addition, in many cases, one of the preferred solution to deal with the rapidly spreading zoonotic disease is to cull all animals. This can lead to not only immediate economic hardships for the farmers but also may lead to long-standing food insecurity in the regions depending on these food production pipelines. Moreover, in One health, research is often intertwined with practice and solutions of immediately pressing problems may emanate from findings of research studies.

Thus, the deep interconnections across sectors and approximate linkage between the research and practice of One health makes for interesting case studies and thought experiments in the realm of One health ethics. Taking the concept of the thought experiment one step further, let us widen the context and look beyond the lens of human and animal health concerns. We will quickly recognize that there are deeper and more complex issues such as environmental health and social justice which may be linked to One health efforts.

For instance, use of antibiotic containing feed in poultry which is often used to boost the health of the birds can lead to entry of antibiotics through the excretory systems of the birds and into the environment. Some studies suggest that in case of antibiotics administered to animals, 60 to 90 % of the antibiotics consumed can be excreted back into the environment. These levels may vary for different classes of antibiotics and in different species of animals.

But suffice to say, a significant proportion of antibiotics consumed by animals is excreted back into the environment. It has been seen that in addition to increasing the risk of antimicrobial resistance, these antibiotic residues can also create ecotoxicological effects. What this means is the antibiotics entering the ecosystems can have unintended and often unpredictable impact on the ecosystem as well as the organisms living in the ecosystem.

One prime example is the disruption of food chain which may lead to elimination of specific vulnerable species of animals from a particular ecosystem niche. So, as you can see, the single issue of bird flu is quite easily linked across so many ethical and moral concerns crossing social, biological, food systems, environment, conservation and health systems and other political systems and other factors as well.

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One of the major concerns around these emerging ethical dilemmas, around One health has been the challenge of whether the humanistic or human-centric principles of ethical research can be easily translated to the context of One health research as well. Traditionally, because of the colonial legacies of economic and structural violence, animals, whether domestic livestock or wildlife.

And the natural environment have been viewed as assets or resources that are exploited for the furthering of human interests. This has made some One health experts to think about the appropriateness of using the currently accepted ethical models which have been primarily put in place to protect the rights and welfare of the human participants. There are animal research ethics guidelines as well.

But they are usually in the context of using animals in controlled research environments such as laboratories or specific research contexts. One health takes the ambit of research beyond the laboratory. It encompasses a much wider world and thus makes the existing research ethics frameworks somewhat unprepared for the complex challenges emanating from these research contexts.

That then raises the uncomfortable question, do we need a different set of ethical principles for guiding One health research? Well, honestly that is a question to which I have no straightforward

answer and if we were in an in-person class, I would probably have invited you to debate on the pros and cons of looking at a different set of principles for One health research.

A small but emerging school of thought is that the ethical principles guiding One health research could be founded on the existing public health research principles. But these should be augmented with a theory of agency. This theory should posit that humans, animals and the environment are agents existing in balance with one another. And as such, the ethical principles which protect the rights and welfare of human beings should also extend to the other counterparts in the One health matrix.

This is, in principle, a nice theoretical and philosophical argument to make but in my mind, the challenge remains. Because we actually need to figure out how to frame a set of principles which are interoperable between the sectors, are comprehensive and pragmatic and implementable. Not a small challenge.

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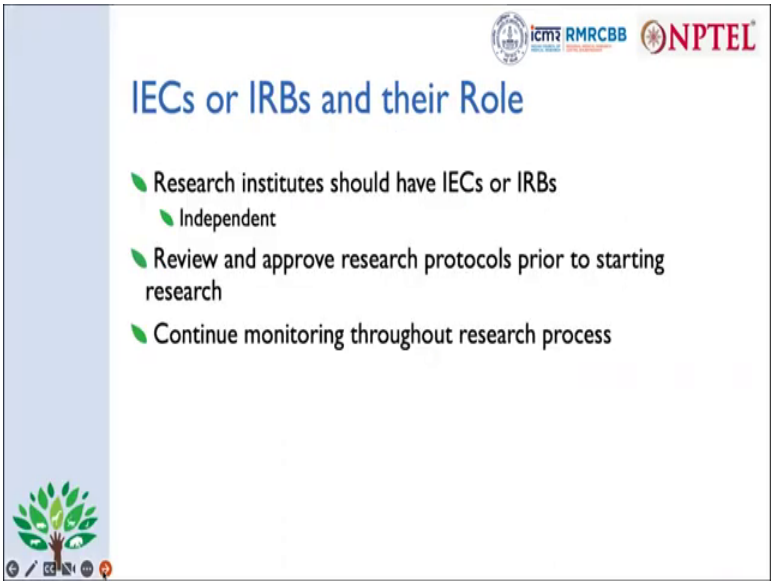

This brings us to the role of the IECS or Institutional Ethics Committees or IRBS or Institutional Review Boards. Most research institutes have one or more special board of experts that oversee the quality and ethical nature of the research being conducted at the institute. This is an independent body which is responsible for ensuring that the research process is being conducted in a manner which safeguards the safety, dignity, rights and welfare of all research participants.

Institutes which are involved in animal research also have similar boards to safeguard the welfare of animals being used to conduct research. The ICMR guidelines have detailed information on how to constitute an institutional ethics committee or how to constitute an IRB. The IEC or IRB is tasked with reviewing research proposals prior to initiation of research work and approve them if they meet the ethical guidelines.

The IEC or IRB is also tasked with following, through with the researchers once the research project has started and they should continue monitoring the research work is actually being done in the way it was envisioned within the protocol. Any changes in the protocol need to be reported back to the ethics committee immediately. In my experience, a typical ethics committee meeting will be one, where the committee will review and approve or provide comments and feedback to new research proposals.

And then in a subsequent session, review ongoing research projects to ensure that they are meeting the proposed research plan and are being carried out in an ethical manner. Ethics committees play a really vital role in ensuring that the research is conducted in an ethical and appropriate manner. It is not only unethical to bypass the ethics committee prior to conducting research. But also such actions can attract penalties.

It is also recommended that even projects which are based on secondary data analysis or public domain data should get a waiver from the IEC or IRB before starting work. I would again refer you to the ICMR guidelines which have detailed explanation on the role of the researchers and the ethics committees in ensuring that research is done in an appropriate manner.

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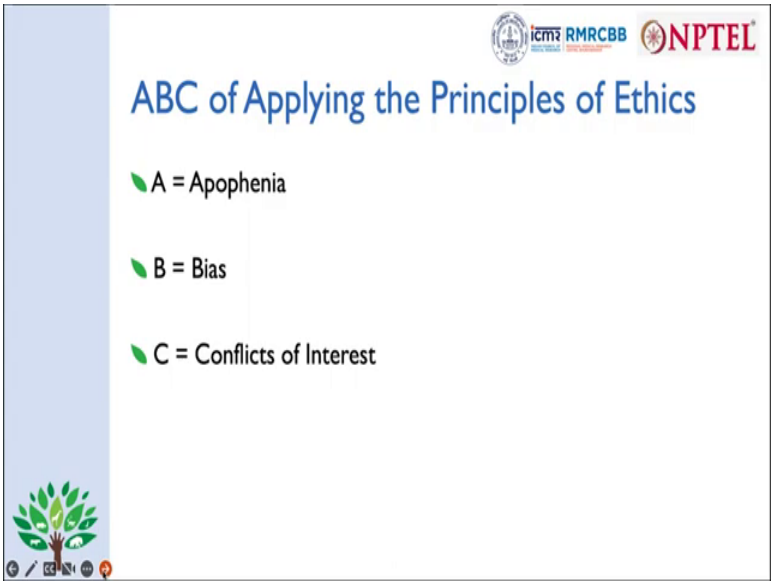

Now that we have spent quite some time talking about the theoretical underpinnings and principles of ethical research. I want to bring up the concept of the ABC of applying these principles in our work. Through these ABC factors, I want to highlight three conceptual examples which are intertwined with many ethical issues around us. A is for apophenia, which is just a nice way of saying that we have a tendency of finding patterns where there is none.

B is for bias which is a systematic error that may lead to an inaccurate estimate of the association between different factors. And C is for conflicts of interest which may refer to any set of circumstances or relationships through which the professional judgment and objectivity of a researcher may be affected. I will speak a little bit about each of these terms and highlight how they lead to ethically questionable or methodologically compromised research studies.

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So, the first one, apophenia, as I said before, apophenia, is the tendency of seeing patterns where none actually exist. One of the best examples is from all of our childhoods. I am sure we have all looked at cloud shapes and tried to imagine what animals there were hidden in the skies above us. Surely the cloud patterns were a random event and it was not intentioned to create the likeness of an animal. But we did find some animals in those clouds just for fun.

Let us see if you can spot the animals from these cloud pictures. Here's the first one. What animal do you see? Here's the second one and what you think this is. Do you see an animal here? And finally, the third one, well you cannot miss this one. This one's quite easy too. Just for the record, I see a horse, a dolphin and a rabbit, apophenia at work.

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Just before we move on and start thinking about how apophenia may contaminate research findings. Let me take a minute to talk about yet another interesting example. Do you know about this one? This image is actually a picture of a grilled cheese sandwich. Do you see anything on it? Why don't you pause the video for a minute and see if you can figure out what is going on in this piece of grilled cheese sandwich?

Hope you pause the video and had a little bit of time to think through it. Apparently, this piece of toasted grilled sandwich bread carries the likeness of the Virgin Mary. And the person who made these grilled cheese sandwich, was able to sell it for a whopping twenty eight thousand dollars again apophenia at work. I feel sad to say that I have made many sandwiches and toasts in my life but never one that could get me so rich.

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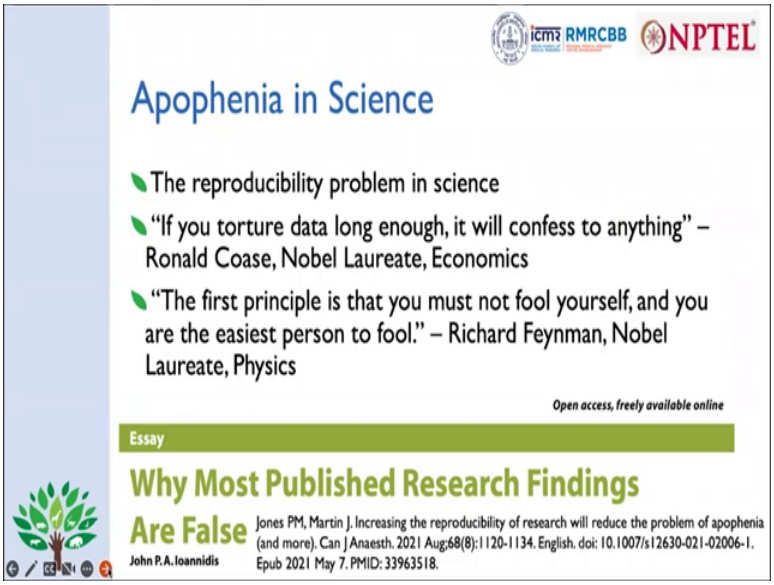

Anyways, moving on, in science, there is a possibility that if we over interpret our findings, we may end up reaching conclusions that are not warranted and that can be a dangerous thing. We may end up with results that are not supported by the data and not only will this distort the state of the evidence. But it is also likely to result in misguiding future generations of researchers and consumers of the research outputs.

This has given rise to what is now known as the reproducibility crisis in science. Put simply, reproducibility is the principle which states that if another researcher were to repeat an experiment or research study following the exact same specifications, methods and settings used by a primary researcher, then they would reach the same conclusions. Both the studies would arrive at the same findings.

And although this seems like quite an intuitive thing, despite our best efforts, we seem to have quite an inordinate amount of difficulty in reproducing research findings. In basic science, a survey of 1500 researchers showed that almost half of them were unable to reproduce their very own findings from prior research efforts. This was quite surprising. Amgen, the biotech company tried to reproduce 53 landmark studies in a pre-clinical cancer research area.

And were able to confirm only 6 of them around 10 or 11%. This problem has been seen across multiple fields and there is a very engaging but short article that you may read. If you are

intrigued by this paradox, I have kept the reference to the paper at the bottom of this slide. One of the mechanisms which underlies this problem of seeing patterns where there are not any has been described by Ronald Coase, a Nobel Laureate in the economic Sciences.

He famously stated that if you torture data long enough, it will confess to anything. So if we get too attached to our research hypotheses, we may end up distorting the data to an extent where it starts giving us findings that we want to see rather than findings that actually exist. A warning against this kind of problem has been enshrined. In the words of yet another Nobel Laureate, this time from the world of physics, Richard Feynman, who said the first principle, is that you must not fool yourself.

And you are the easiest person to fool. This is a good thing for us to remember as researcher as it reminds us to stay mindful and objective about the data being collected, analysed and interpreted by us. On a side note, I must admit, I am a great admirer of Feynman and although I did not choose to pursue a career in the physical sciences, his approach to scientific thinking, rationality and skepticism has been a driving force in my journey in science.

For all those who are interested in reading beyond the usual books, I would strongly recommend reading his masterful classics. Beginning with, surely you are joking, Mr Feynman. This is a book that I reread once every couple of years. It is a wonderful exposition of the man, his eccentricities, his brilliant mind and his unadulterated junk free approach to scientific thinking.

And finally, in the recent years there has been the rise of a new field, the so-called field of Meta science. It is the field of study which uses scientific methods to study science and how scientific truths are developed. One of the premier researchers in the meta science of health and medicine, is Dr. John Ioannidis. His essay which is quite inflammatory titled why most published research findings are false?

Is amongst the most widely read scientific peer-reviewed articles ever. It was published in floss medicine and I would strongly recommend reading this article to have a short, quick glimpse into

the problems that can be left behind. In the wake of overzealous efforts, sometimes which results in apophenia.

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B is for bias, as we mentioned before, it is a systematic error which results in an incorrect estimation. Just to give you an easy and simple sort of a silly example. Imagine you are measuring the weights of people but your weighing scale is wrong and it always gives you a measure which is higher by 2 kilograms. And if you do not know about this anomaly then the weights that you measure are all going to be systematically inaccurate.

In the epidemiological sense, biases are inevitable and we must remain vigilant to try and reduce them and minimize their effect on our research findings. That is one of our ethical imperatives. There are many different kinds of biases and they have a myriad effect on how they impact our research findings as well. A more detailed discussion on biases in epidemiologic research is out of the scope of today's discussion.

So I am leaving you with a couple of nice references for optional, additional reading about biases and a link to a quirky website. This website called yourbias.is, lists out cognitive biases, rather than simply epidemiological one's and it defines how they affect our ability to see the world and interpret the reality around us and for many of us that reality includes our very own research findings as well.

I hope you remember the twelve general ethical concepts. We spoke about a little while earlier in today's session. Several of them can be thought to be associated with efforts to reduce bias. In my opinion, professional competence, institutional arrangements and transparency and accountability are the three top factors which may be associated with efforts to reduce bias. Do you agree with me or do you think that there are other factors out of those twelve ethical concepts that may be associated with reducing biases?

You can pause the video for a minute, go back to the slide about the twelve ideas, twelve general concepts and see if there are any other that may help you to counter biases.

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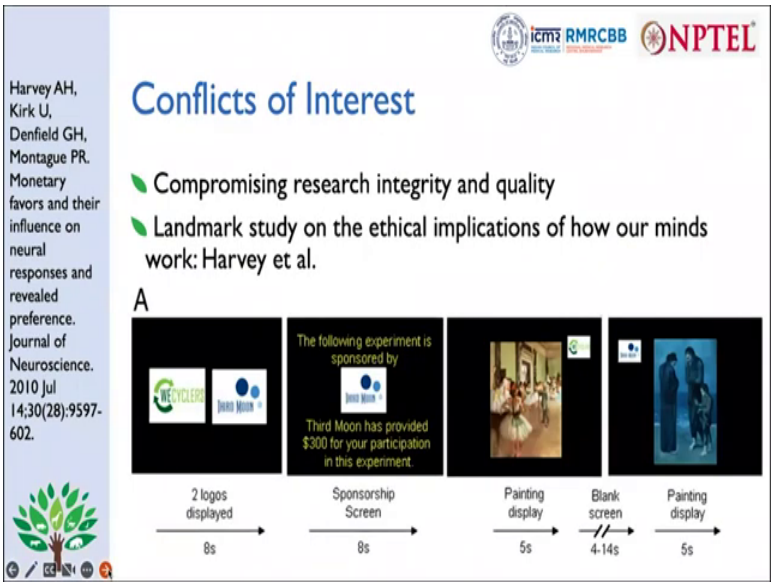

Let us move to the third instance C, C is for conflicts of interest in research. And conflicts of interest refers to situations in which financial relationships, personal considerations or other circumstances may compromise, or even just simply give the appearance of compromising a researcher's professional judgment. While they are conducting or reporting or interpreting their research work.

Now, we may think that we are honest people and are immune to these types of coercion but in a landmark study in 2010, Harvey et al., showed evidence to the contrary. In this study, the complete reference to which I have given in the left panel of this slide, 151 participants were

asked to rate sixty classic paintings. The study participants were provided 300 dollors for this simple exercise.

That is not a small amount of money, especially for given that it was quite a simple and easy task that the participants were undertaking. The study was structured in the following manner. First, the participants were shown a screen with logos of two companies for 8 seconds. The next screen showed a sponsorship statement where it was noted that one of the two companies whose logo was displayed on this screen was the sponsor providing the participant with a generous compensation of 300 dollars for participating in the study.

And then a series of pictures would come up and the participants were asked to note their preferences for the pictures simply state whether they liked it or not. Now, the twist was that these pictures were randomly tagged with the logo of one of the two companies shown in the first screen.

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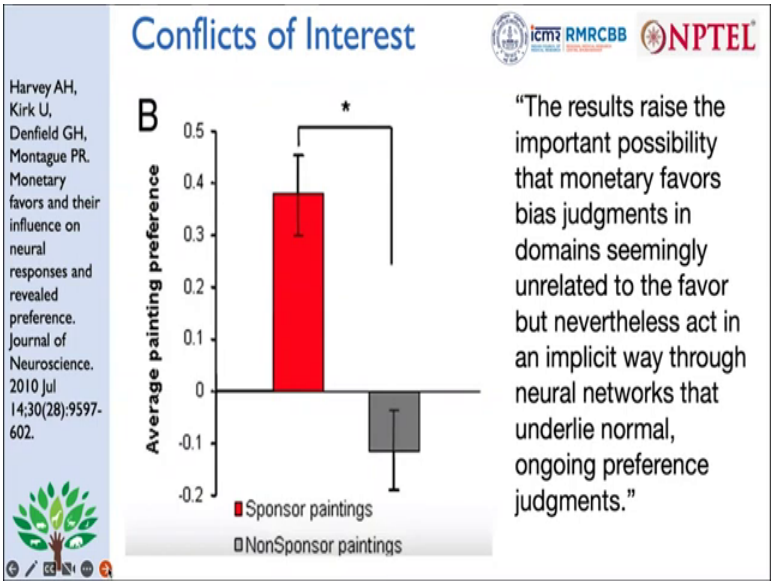

So I think by now you have guessed what is going on, if you guessed that the respondents had a preference for the paintings in which the logo of the sponsoring companies was present, then you are absolutely correct. Now, you may argue that this may not actually have been their real preference and the respondents were just trying to be polite and they were just saying this preference in order to please the sponsor.

There is another twist in the tail here. The participants were not directly asked about their preference for the pictures in the conventional sense. And instead, when these screens were being displayed, the participants were actually placed within a functional MRI machine which was scanning their brains, picking up signals and interpreting whether or not there were experiencing a greater amount of pleasure when looking at a particular image.

And it did show that when the participant was looking at images with the sponsoring company's logo tagged on it, they experienced a greater extent of pleasure. At this juncture the authors conclude and I quote; 'the results raise the important possibility that monetary favours bias judgments in domains seemingly unrelated to the favour but nevertheless act in an implicit way through neural networks that underline normal, ongoing preference judgments.'

So, despite our best intentions, our brains may be wired in a way which sets up our preferences. The best practice is to declare your conflicts of interest. Almost all reputable journals will request you to submit a declaration of conflicts before they publish your paper. At this point, I will just give you a quick rejoinder. In my opinion, there is nothing wrong in noting down all your possible conflicts and being honest about them up front.

If in any case, it comes out later on that you had a conflict of interest, financial or otherwise and you did not declare it early on. This might cause some consternation and controversy which could have been easily avoided.

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That brings us to the final section where we talk about a few case studies where unethical research has led to long-lasting harms. One of the major examples of how much harm can be caused by fraudulent research, comes from the story of Andrew Wakefield. In 1998, Wakefield published a paper in the Lancet indicating that the MMR vaccine was linked to autism. He made this claim based on only twelve cases.

However, investigations later on revealed that not only had Wakefield falsified the data in his paper but he also had major conflicts of interest. He had received money from a lawyer with the specific intent of identifying this association between the MMR vaccine and autism. This deliberate fraud attempt was identified in the aftermath of an investigation initiated by the general medical council of UK.

The paper was retracted by the Lancet and the author was discredited to the global academic community. Investigative journalist, Brian Deer, who was responsible for bringing a lot of these stories to the fore. And in addition, he wrote a series of papers in the British medical journal in which he detailed his findings. He also wrote a book; The doctor who fooled the World, which is frankly a thrilling read.

Anyway, although weak field, the scientist and author was discredited and his research findings were debunked. His small study with fraudulent data became the cornerstone of a burgeoning

anti-vaccine movement in many developed countries. This anti-vaccine movement has led to the re-emergence of vaccine preventable diseases like measles, which were virtually unknown in the developed world countries such as the US.

This has also affected the uptake of covid vaccines and boosters across several developed countries. In fact, this single piece of fraudulent research may be responsible for a lot of avoidable human misery and morbidity. And this is just one example of how unethical research can have long lasting impact.

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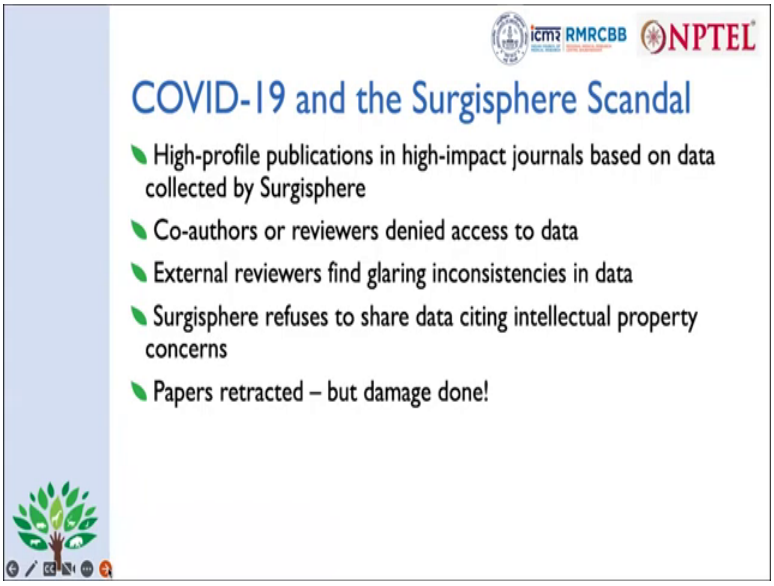

Another example comes from a more recent experience around the Surgisphere Scandal. Surgisphere, a private entity which contended that they use machine learning and artificial intelligence to provide big data analytics for empowering healthcare providers published too highly publicized articles based on registry analyses, outlining the effectiveness of various treatment strategies for Covid-19.

These papers were published in the Lancet and the New England Journal of Medicine, both very highly reputed publication avenues. After the publication of these studies, several inconsistencies in the data were noted by external reviewers and many prominent scientists came together to write a letter to the editors of the two journals asking them to take a deeper look.

Background investigation started by the newspaper Guardian, in the UK could not corroborate the participating country health authorities that Surgisphere had legitimate access to data. Soon, both Lancet and NEJM came out with expressions of concerns regarding the veracity of the data. Especially since, it emerged during this investigation that several of the authors actually did not have access to the raw data.

And had co-authored the paper on the basis of giving of having access to some analysed outputs. When further calls emerged for an audit of the data behind these papers. Surgisphere, the data holding author and authority rejected the requests on the ground of proprietary ownership. Within a couple of hours of both the papers were retracted.

It needs to be noted that health research functions on a level of trust and expectation of academic and research integrity. When these sacred principles are breached. They are not only a major problem for the involved authors but also for the wider audience. In today's hyper-connected world, important findings such as the ones that were in the surgisphere papers, rapidly spread across Twitter, WhatsApp and other social media outlets.

This initiated a rush to acquire drugs like hydroxychloroquine and chloroquine which at that point, had no proper evidence of efficacy against Covid-19. The whole issue was quite murky and it hampered not only the process of scientific progress. It also led a lot of people in the wrong direction.

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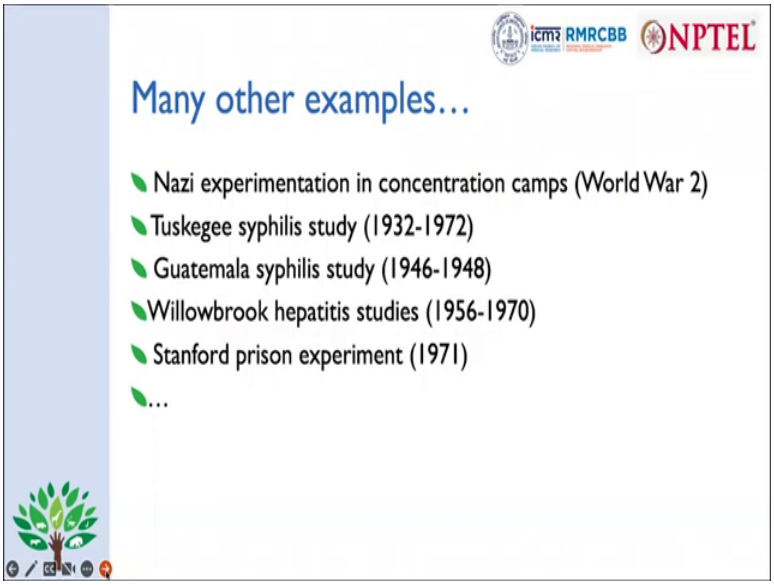

There are many, many classic examples of how unethical research studies have been conducted in the name of scientific process and has contributed to human misery and pain. The foremost example remains, of course, the experimentations by the Nazi doctors in concentration camps during the Second World War. Physicians, like Yosef Mengele, who was known as the angel of death, undertook lethal experiments on prisoners.

Prisoners held in concentration camps in the aftermath of the Second World War. These atrocities were brought to the fore during the Nuremberg trials, where the first stirrings of modern research ethics were seeded. The Tuskegee syphilis study is yet another ghastly example. This study was conducted in African-American people in Alabama in the U.S to study the natural history of syphilis.

How would the disease evolve if it was left untreated? The most painful part was that the study went on for 40 years and actually, in the later decades of the study, penicillin, an extremely effective treatment for the condition was in widespread use. Although the study participants were provided with some medical and mental health care, they were greatly deceived by the researchers.

Because they never received information about their syphilis diagnosis and instead of the effective treatment option available, they were provided disguised placebos, ineffective

interventions and other diagnostic procedures labeled as treatment for bad blood. A similar study was conducted in Guatemala by a physician who had been part of the Tuskegee studies earlier. Almost 1300 people, including people from lowering socio-economic status.

And other vulnerable groups such as sex workers, orphans inmidst of mental health, hospitals and prisoners to name a few were injected with a range of sexually transmitted infections like syphilis, gonorrhea and chancroid, without their knowledge or consent. About half of them received some form of treatment and it is estimated that around 5500 people were involved in the various stages of this research process which resulted in much pain, suffering and death during the years it was operational.

The story of Willowbrook's state school is also quite painful. Willowbrook state school was an institution in Staten Island, New York, again in the U.S which was tasked by the state to care for children with developmental and learning disorders. Over a period of 14 years, these children, who were an extremely vulnerable group, were given hepatitis to study the progression of the disease.

Rather than improving the already deployable conditions in which these vulnerable children were residing, the staff used it as an excuse to justify giving them Hepatitis stating that it was inevitable that these children would get infected sooner or later. There was a major public outrage once the details of these extremely unsettling and unethical experiments were exposed. And finally, the institution was formally shut down in 1987.

One final example is the Stanford prison experiment. The Stanford prison experiment was a psychological study where male students role played as guards or prisoners in a simulated prison environment. Within 5 days the members who had chosen to be guards had started vicious psychological abuse of the prisoners and the study was shut down on the 6th day. The study remains widely criticized as one of the most inhumane and unethical experiments in Psychology.

It is also quite an unsettling glimpse into how the human mind works. This experiment resulted in the framing of regulations to protect research participants in university led research efforts.

These are just some examples of the many many unethical historical mistakes we have made, whether through omission or through commission. As researchers and physicians and veterinarians and practitioners of public health and One health.

We should take our lessons from these historical mistakes and work to ensure that we do not perpetuate any of these unethical practices. And rather focus on the best possible way to protect the dignity, right and welfare of our research participants. Whether they are human, animal or environmental factors. After all, it is through the participation of these research participants that we are able to conduct our life's work.

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So to round it up, in summary, we have looked at the four pillars, beneficence, non-maleficence, justice and autonomy. We have then extended it to cover twelve essential concepts which are identified in the ICMR guidelines on ethical conduct of research. We have talked about the importance of informed consent in various situations and the role and importance of institutional ethics committees or institutional review boards in ensuring that research is done in an ethical manner.

We have also explored the fact that researchers should stay aware of their personal preferences and cognitive biases. And we have also looked at the fact that responsible research and moral and ethical integrity form the foundation stone of science today.

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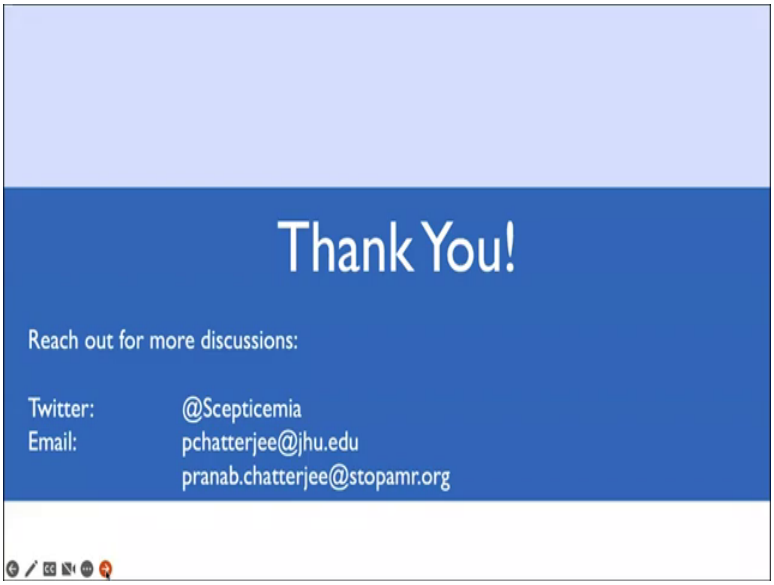

So that brings me to the end of the two sessions. I had the privilege of spending in your company. I hope you were able to enjoy these sessions and I must say I had a lot of fun, bringing them to you. As always, I am always interested in talking and discussing about One Health and related ideas. Please feel free to connect with me on Twitter. My handle is Scepticemia, it is right there on the screen.

I know it has a weird spelling, so I hope you can get it right. Alternatively, if you prefer email, you can write to me either at pchatterjee@jhu.edu, or pranab.chatterjee@stopamr.org. I am happy and look forward to chat about One Health, infectious disease AMR or any of these historical ethical questions we just dealt with. I wish you all the best as you embark on this course on one health and thank you for your patient listening.