**Ethics in Research: A Science Lifecycle Approach**

**Presenters:**

**Jessica Mankowski and Jaime Flamenbaum**

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Joann Starks: Good afternoon, everyone. I am Joann Starks of S-E-D-L or SEDL in Austin, Texas, and I will be moderating today’s webcast on “Ethics in Research: A Science Lifecycle Approach.” The webcast is offered through the Center on Knowledge Translation for Disability and Rehabilitation Research, or KTDRR, which is funded by the National Institute on Disability, Independent Living, and Rehabilitation Research or NIDRR in the US Department of Education.

I want to thank my colleague Ann Williams, our webinar administrator, for her logistical and technical support for today’s webcast. A reminder that we will ask you to complete a brief evaluation at the end of today’s webcast — I’ll give more instructions following the presentation. And, since the slides are small on your screen, it might be helpful to download a copy of the presentation file from the KTDRR’s website at [www.ktdrr.org](http://www.ktdrr.org/).

The Center on KTDRR is working with a number of national and international partners, and one of those is the Canadian Institutes of Health Research (CIHR). You are probably aware of the fact that CIHR, which is the Government of Canada's health research investment agency, was the first to define and embrace the term “knowledge translation” or “KT.” We are partnering with CIHR's Knowledge Translation Strategy Unit to learn about the innovative KT strategies they are continuing to develop and implement.

This webcast on Ethics is part of a series of four webcasts that also include: "KT 101: CIHR's KT Initiatives," "KT and Evidence-informed Policy Making," and "Patient Engagement in KT."

“Ethics in Research: a scientific lifecycle approach” is intended to introduce investigators to the ethical issues that might arise at each step in the research life cycle. The research life cycle is inspired by Ian Graham’s “Knowledge to Action or KTA cycle”, and depicts the process of both Knowledge Generation and Knowledge Translation, as well as the infinite and iterative feedback between these two processes. Within this framework, the junctures for ethical consideration are presented along the cycle.

By working through vignettes that deal with everyday situations in the research environment, participants are encouraged to critically examine the narratives against this KTA-Ethics framework in order to reveal some of the ethical issues and pitfalls of scientific research that might not be obvious at first glance. While ethical concerns such as protection of research subjects, consent, privacy and data stewardship are well-known to any researcher who has submitted a project to a research ethics board (known in the US as Institutional Review Board or IRB), the focus here is on the more subtle and perhaps ‘bigger picture’ concerns. Moving beyond mere compliance, investigators are encouraged to think critically about the ethical challenges and opportunities that emerge throughout the research lifecycle.

Joining us today from CIHR are Jessica Mankowski and Jaime Flamenbaum.

Jessica Mankowski is the Acting Manager of Knowledge Translation Strategy. She has enjoyed working over the past decade in the knowledge translation, capacity building and cross-sector partnership space. At CIHR, Jessica and the rest of the Knowledge Translation team work to support the integration of KT in CIHR’s activities and to build capacity in the health research community. Jessica also has an active life outside of work with a number of volunteer activities.

Our major presenter today is Dr. Jaime Flamenbaum, a bioethicist currently working as senior ethics advisor at CIHR. He is leading the ethics education project, among other activities. His areas of concentration are: ethics of disrupting technologies; ethics of trials, and methodology of health sciences. He has published on ethics of knowledge translation and the epistemology of medicine.

Jessica, are you ready to begin?

Jessica Mankowski: Yes. Thank you so much for that kind introduction, Joan n. What I’ll do first is provide a little bit of background information on the Canadian Institutes of Health Research. If you’d like to know more about CIHR, I would invite you to check out the KT 101 website or webcast which will produce more information about CIHR. CIHR was created in 2000 and is the Government of Canada’s Health Research Investment Agency. Its mission is to create new scientific knowledge and to enable its translation into improved health, more effective health services and products and a strengthened Canadian health care system. There are 13 institutes within CIHR and CIHR provides leadership and support to health researchers and trainees across Canada. CIHR uses a definition of knowledge translation that has two major parts. The first part describes knowledge translation as the dynamic and iterative process that includes synthesis, dissemination exchange and ethically sound application of knowledge, to improve the health of Canadians, provide more effective health services and products and strengthen the health care system. Today’s webcast will focus specifically on what that ethically sound application means.

 The second part of the definition describes the process that takes place within a complex system of interactions between researchers and knowledge users that may vary in intensity, complexity and level of engagement, depending on the nature of the research and the findings as well as the needs of the particular knowledge user. I will now turn it over to Jamie for the rest of the presentation.

Jaime Flamenbaum: Good day. As in the introduction, it was said that through vignettes we try to give an ethics lens to the process of knowledge creation and knowledge to action. The vignette that was chosen for today’s presentation is one that was published by the Journal of American Medical Association. I choose particularly this vignette because it echoes a lot of what we do on a daily basis. What happens was that a researcher was requested by a relative to check the prices of hip replacement that she was in need. This researcher, just as a favor to the relative, phoned a series of institutions, asking for the price and asking for the type of service that was associated with the price. The researcher concluded in his paper that the variability of prices was huge across the United States and the types of services that were associated with the value was also very big. This is, we can say, a research in health. At the same time, it’s what we do normally when we want to buy a car, a fridge or when we go to the supermarket and check for groceries. In fact, we do knowledge creation at every moment and all moments. There is absolutely no difference between the research that we have at hand that it is titled “Research” because it was published and our day-to-day lives.

We are going to take this concept, this idea, this project of checking how much a hip replacement costs in the United States and try to understand it through the “Knowledge Creation to Action Cycle” published by Dr. Graham. I want to call the attention for those that know the cycle that this is not exactly what Dr. Graham published. What he published is one single cycle that circles through knowledge creation and knowledge translation, superposing one activity on top of the other. Because of the didactic problems that we have with that, because I am going to apply an ethics lens, if I let everything in one single cycle at the end, all the labels that I am going to apply would be very confusing and so for a didactic purpose, I divided it into two cycles: knowledge creation and knowledge translation. It has to be understood that this is only one single process. If we repeat the process of buying a car, buying a house, buying groceries or checking the price of a hip replacement, every time that we have to proceed again and check a new price, and check a new process, we are repeating the whole cycle over and over again, without going into different cycles or different contexts. Let’s start putting an ethics lens on top of the knowledge creation to action cycle. The first thing that we really do is what we intend to do. What type of knowledge we intend to create, what we are going to investigate, what are our needs and what questions we are trying to answer. This is exactly what is the research agenda. On a more academic way of putting that, that’s the epistemological lens. That’s how we are going to understand what we are designing, that’s what we are going to frame whatever we are going to ask, and more importantly, that’s what we are committed to do. We have a mission. We are people on a mission that is answer a specific question. Because we have a mission, we have an ethics commitment to our mission.

When we go into the cycle of knowledge creation, the first thing that we are going to do is to establish partnerships. These partnerships are our colleagues or the spouse that is going to use the car or who is going to the supermarket to do the groceries? We are going to put the groceries, so our partners. Who is going to use the service? This is the person that we are doing the research for. In what level of equity, in what level of equality of power these individuals are participating with us? Are we dictating the norms? Are we being the boss? Are we being the only voice? Or are we taking everything that what they are saying and we are dividing with them results and responsibilities? Dividing with them or not dividing with them, we are going to formulate the question. We are going to establish what are the context, we are going to frame what is the theory that we are going to use, what is methodological issues that we are going to frame exactly at this point. Then we are going to discuss what are the resources that we need, what theory we are going to apply.

Of course, when we are talking about buying a car and checking the prices or hip replacement, checking the prices or going to the grocery store, we are using low key methods or anything. That’s very,, almost no difference at this point of framing questions, if we are talking about designing something in the realm of synthetic biology or if we are doing epigenetic research or anything like that. The frame and the ethics lens is exactly the same. What change are the methods that we are going to use. Our mindset continues there. Then of course, who is going to pay the bill? Who is going to drive us to the supermarket? Who is going to pay the phone bill? Who is going to pay for the reagents, the lab, the secretary and everything that we need in the context of doing research? There is a funding that is needed and what are our obligations to these funds? Are these funds public and we have a commitment to the public? Or are these funds private and we have a commitment to the private sector?

 So after everything is obtained in terms of obtaining funds and everything else, researchers in general, and this is not the case of the project that I am using as an example - will have if the research involves human or non-human subjects to submit the protocol to an Animal Research Board in the case of non-humans or to an institutional review board in the United States, in Canada to a Research Ethics Board. These boards are responsible for the compliance of the specific research, the research protocol, to specific guidance documents that are mandated by law. Normally the compliance is what concerned most of the researchers when we talk about the ethics because it’s the most visible part. That’s when we discuss about privacy, rights, protection of the subject, informed consent. All issues that have to be addressed because legislation so dictates. This is the most visible part of ethics and is related to compliance ethics. We are here talking about a more broad ethics that it’s related to how we behave in relation to knowledge creation.

Once researchers receive the approval, or in our case, once we have everything done in terms of collecting the data, because data can only be collected after the approval by an IRB or REB, then we are going to analyze the data that we have. In the case of the supermarket, is this the best price? In the case of hip replacement, we have to put a cost-benefit analysis. We have to see what are the services that are given in exchange for the price. Is the higher price really the best service? Is there a cost-benefit that justifies sometimes three times the difference of price? Interpretation of data, to be ethical, it has to be done in the context of who is collaborating with us. In the case of the hip replacement, the person that is going to receive the hip replacement has a voice on what is the best choice. When we are going to buy a car, is not only the best price in the car but who is going to use the car and for what. In the case of the supermarket, it’s not only the price but the freshness, the variation, all the products that we have to buy for a specific recipe that we want to do on that day. Then we are going to draw our conclusions. Based on that collaboration, based on the information that we receive from the users, we are going to check the implications to groups, individuals, populations and everybody that is involved. Note that the potential for conflict of interest is huge and when we talk about research of any case, any type, conflict of interest is always present. Remember that conflict of interest can be real but can be perceived and can be implied. In reality, it’s something that we have always to have in the back of our mind. If we are designing a research project, if we are saying what we are going to do automatically we have a conflict of interest because we have that objective in mind. We want to get there.

Then we are going to disseminate our data and publishing the data. Everybody wants to be front page of New England Journal of Medicine. When we want to publish something, we want to be read by everybody. We want to be thought about when Nobel awards are being handed out. We want to be famous, rich and happy. That’s the objective of making our knowledge, our discovery, our creation, the product of our imagination and work to be known by everybody. Not hiding anything. This is the objective of what I’m doing here. I am trying to be famous, I’m trying to be known. There is a conflict of interest. This is the choice of how I am doing addressing the issue and presenting what I am doing. This will bring us back to knowledge creation again. We have a result. We discovered the hip replacement, we discovered what is the best for our relative in the case of the publication but that’s a limited answer. If we want to go and interact again in the context of knowledge creation, we may want to see how does it compare with other countries and other services. How one service compares with the other? What is the long term results of a higher cost with a lower cost? This is not included on the first work. This is something that can appear on the next direction of the same article.

Jessica Mankowski: Jamie, I have a question for you about the Knowledge Translation Cycle. So we just looked at knowledge creation and where within that cycle do you think that researchers are most often unaware of the ethical considerations they could be including in their work?

Jaime Flamenbaum: There is one side as I said before that researchers are really, really aware and they are aware of the responsibilities that they have to the system, to the funders. They are very compliant and very cognizant and very conscious about what they have to do in the context of compliance. There is no issues related to submitting to institute review boards, no discussion about what are the documents that have to be handed to the institute review board. However, researchers in general, today they have very little understanding of the social responsibility of research. Researchers don’t think in terms that they are on a context where they serve the whole society. What they are doing is the result of the investment of society on them through donations, to building universities, to supporting hospitals and research institutes and even the commercial aspect of it, the fact that society is the client of pharmaceutical industry but at the same time they are the shareholders of the pharmaceutical industry. The social aspect, the ethical issues that are related to social responsibility of research, the researchers do not touch it on a more responsive way.

Jessica Mankowski: Thank you.

Jaime Flamenbaum: Once a new cycle is created and reiterated, we are going to abandon for a few minutes the knowledge creation side of it and we are going to talk about the knowledge translation part of it. Knowledge translation relates not only to translation to other researchers but translation to the end user. In health sciences, end user is a very problematic word. Who is the end user? The clinician? The nurse? The patient? The society? The institutions? Who is the end user? This is a very fluid kind of concept and when we talk about translating knowledge, we have to have all these focus in mind because we don’t know where the knowledge is going to be used in the end. We have to have a knowledge translator. We have someone that is going to put knowledge out there to be used and to be applied, review and select that knowledge. Selection of knowledge does not mean that we are going with a bias, say what is to be used, what is not to be used, but make a fair offering of all the knowledge that it is and comment on the knowledge the way it is.

One example of this is Cochrane reports. Cochran reports do exactly that. They review the knowledge and allow individuals that are using that knowledge to select according to some standards. This is related totally to the theory that is used. What are the biases because we are really on a world where positive results are published everywhere. Negative results are very, very hard to find. What is the access to the data, intellectual property and other issues related to that? Then we have to get the knowledge and adapt to a context. We are talking in particular about an issue of costs in hip replacement. That’s what the study was about. If we tend to expand that study and think that the same thing would apply to a coronary bypass in the same institutions, we are going to be adapting knowledge that is not there. We are going to be making relations that are not there. We have to respect the context, we have to respect the knowledge that we have.

Again, we have to talk about who is the voice, who is going to use and how this is going to be used. Access to information. This is very important when we talk about published data related to health. We know that if you don’t have a subscription to most of the journals, you are not going to have access to the most recent data. This is one of the reasons of the movement to open access. Because when we think about United States, Canada, UK, France, Germany and Sweden, Netherland, Norway - maybe I am forgetting one or another – Japan. I would guess the problem of not having access to information is very limited. Those that are professionals and need the information, they have access to it. However, other countries in the world and even countries in Europe, they do not have access to information even if the individuals are professional. If they are not directly linked to the university, they have no access to the latest published material. You know how this is important and this is one of the reasons of open access. It’s not only related to Canada and the United States, the fact that we already have enormous mechanisms to not suffer the lack of information. Access to information and knowledge translation imply resource allocation. If you know something but you don’t have the means to use it, to apply it, the knowledge has no meaning. In the context of our hip replacement, if an individual has $60,000.00 for a hip replacement and he wants to go to a $120,000.00 facility, it’s not going to happen. The resources are not there even if the service is there, is available. The problem is regarding resources.

 Then we have to monitor the knowledge use. We created the knowledge. We translated the knowledge. Is it being used and is it being used in the context and in the purpose? We have to know that and we do very little in terms of monitoring the use of the knowledge. There are not many techniques, there are not many ways of doing it and fact is, many scientists, many individuals that are related with the creation of knowledge are not really worried about monitoring how this knowledge is going to be used. Evaluating is getting the results. Once the knowledge is used, what happens? Does it really make a difference? What are the criteria that we are using to measure differences? Again, we return to the issue of conflict of interest because we created the theory, we gave an idea, we have a research agenda. We want to prove that it makes a difference. When we evaluate at the end, if we evaluate at the end, the issue of conflict of interest has to be very carefully seen.

Sustainability is a very important issue. It’s the fact that okay, we discover about hip replacement costs. Is it important to continue the research and who is going to continue the research? Where it’s going to be published. What are the other questions that we want to make about it? To do that, we have to build capacity on the questions that we are asking. We have to give a chance for people to come into these research areas and increase them. Create robustness in research is one of the main objectives of the whole theory that surrounds knowledge creation and translation. Some people may not think in that terms, but one of the concerns of ethics in research is to protect the research endeavor. Make it credible, make it transparent, make it clear so that people will believe in what science is delivering and will invest in science.

 When we talk about continuing KT, when we talk about continuing knowledge creation, we are talking about a situation where we justify science and where we make resources come into the cycle.

Jessica Mankowski: Jamie, if I can, one more question for you, in the Knowledge Translation Cycle, when you speak about in Step seven, the Ethics of Sustainability, how can researchers support the Ethics of Sustainability when they are dependent on funding from an external source?

Jaime Flamenbaum: We have to go out of what you think in terms of knowledge creation and even in terms of ethics. The fact is that researchers should – they have to – not should. They must inform policy. Researchers have to learn to talk about what they do to the real stakeholders. Those are individuals that are in position of command in institutions and governments and agencies. They have to teach science. They have to teach science in a broad way, what it means and what resources it needs, but also science in its particularities. Each and every research agenda. That’s the only way of making it more robust is making sure that policies in our countries are scientifically-based, evidence-based policy.

Jessica Mankowski: Thank you so much Jamie. Joann, over to you.

Joann Starks: I want to thank you both very much for a really interesting presentation on ethics in the research lifecycle. Jamie, you really brought that Knowledge to Action cycle alive! It’s really interesting. I also want to thank everyone for participating in today’s webcast. Let me ask if either of our presenters has any final words for the audience today?

Jessica Mankowski: Thank you for joining us and we hope to learn more about your work. You can contact Jamie. His contact information is on Slide nine.

Jaime Flamenbaum: Thank you very much and hope to hear from you.

Joann Starks: Well thank you. We hope everyone found today’s session to be informative. As a reminder, the webcast will be archived on the KTDRR’s website at [www.ktdrr.org](http://www.ktdrr.org/).

We also have a brief online evaluation form and would appreciate your input about the webcast. The link is here on the last page of the presentation file, and everyone who registered will also get an email with a link to the evaluation form.

Once again, a big thank you to our presenters, Jessica Mankowski and Jaime Flamenbaum, from the staff at the Center on KTDRR. We also appreciate the support from NIDRR to carry out the webcast and other Center activities. On this final note, I will conclude today’s webcast and invite you to participate in the others from this series.