On conflicts of interest in autism research: Interview with Kristen Bottema-Beutel and Micheal Sandbank

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Transcribed by Julie-Ann Lee

(Theme song – soft piano music)

Anne: Welcome to the Noncompliant podcast. I'm your host, Anne Borden King. Today I'm speaking with Kristen Bottema-Beutel and Micheal Sandbank.

Kristen Bottema-Beutel is an Associate Professor in the Lynch School of Education and Human Development at Boston College. Her research focuses on social and language development, and social interactive dynamics in autistic children and youth. She is interested in pairing qualitative and quantitative methods to better characterize autistic communication and sociality, and in developing community-based strategies to support meaningful engagement of autistic students. More recently, she has explored metascience topics such as research ethics and research quality in intervention research for autistic children. Dr. Bottema-Beutel is the director of the Autism Specialization at LSEHD, a program that prepares future Special Educators to support autistic students.

Micheal Sandbank is an Assistant Professor of Early Childhood Special Education at the University of Texas at Austin. She researches social communication and language interventions for young children with disabilities. Dr. Sandbank is the lead researcher on Project AIM, a scoping systematic review and meta-analysis of group design studies of interventions for young children on the autism spectrum. She was awarded the Young Investigator Award in 2021 for this work, from the International Society of Autism Research.

Doctors Bottema-Beutel and Sandbank have co-written some really ground-breaking work in the past couple of years including a research review of the research on Early Interventions for autism and some reviews specific to research on Applied Behaviour Analysis or ABA, and we're going to talk about their work today.

Welcome to the show!

Kristen: Thanks for having us!

Anne: Just to back up for listeners, I'm going to give a real basic summary. There are a number of autism therapies for younger autistic kids, sometimes used with older autistic kids and adults too. As a quick way to distinguish, I would put them into three categories: the first is **practical therapies**, so things like Occupational Therapy, Speech-Language Therapy and Life Skills; then there is **Psychotherapy,** which is obviously coming from Psychology; and the third area would be the so-called **behavioural interventions**.

When you see the word *intervention* adjacent to the word *autism*, it's often these kind of behaviourist based approaches – a school of thought influenced by B.F. Skinner and known as Applied Behaviour Analysis or ABA. The ABA approach is still popular in Canada and the U.S., not used that much in other parts of the world, and in fact often in the U.S. and Canada ABA is publicly mandated and covered by insurers where other forms of therapy are not, or are only partially covered. Here in Ontario, for example, until 2019 ABA was the *only* publicly funded form of autism therapy. So, Occupational Therapy and Psychotherapy were not covered but ABA was covered under the government's insurance.

The ABA professional association here--which hired the Pathway Group, a Bay Street lobbying firm--has argued to policymakers using the catch phrase that ABA is "the only evidence-based therapy for autism," basically trying to locate ABA as *the* standard of care for autism. But this is maybe not a sustainable argument, because America and Canada are kind of at a crossroads when it comes to the future of ABA. There's a lot of resistance to ABA, particularly from autistic people…also from psychologists, from parents sometimes and from insurers, and even states like Texas who want to assess the quality of ABA, and the quality of the research, which is what we're about to discuss.

So before we talk about conflicts of interest, Kristen, could you define what a conflict of interest is in research?

Kristen: Yes, sure. So, in intervention research, researchers hold a conflict of interest when they stand to benefit from showing a particular finding about the intervention and this is usually that the intervention is effective. Conflicts of interest can be **actual**, where there are real, material benefits from findings of intervention effectiveness or they can be **potential**. So, it can be that maybe there's no actual benefit that will happen now, but it could be something that would happen in the future. Such as when you do a research study on a device, for example. If you show it's effective, you might be able to patent the device and get profits from selling it. Or a conflict of interest can be **perceived.** There [may be] no actual conflict of interest but people might have a reasonable assumption that you hold one, even if you don't.

These conflicts of interest can include things like **financial** transactions -- that's what people usually think of when they think of conflicts of interest. But it may also be **personal relationships**, so maybe you yourself aren't going to benefit, but your spouse or someone close to you will. Or it can be **ideological commitments**, so maybe you developed an intervention and you're very tied to showing that that intervention works.

Anne: So conflicts of interest are something that it's generally expected or hoped that a researcher will disclose – that they'll put a statement on their paper saying "We as the research authors have these conflicts of interest," so that readers could be aware that there could be bias, right?

Kristen: That's exactly right. So, when researchers publish their articles in journals, most journals require their researchers disclose their conflicts of interest for example, for exactly that reason.

If a researcher has a conflict of interest, they might advertently or inadvertently do something questionable in their research practice that makes it more likely that the study will show that the intervention is effective even if it's not. So usually there's a disclosure statement right on the research paper itself that makes these kinds of conflicts clear so that appropriate scrutiny can be given to the intervention that's being studied, or can be given to the study itself.

Anne: Interesting. That leads right into what we're about to talk about next, which is your research review of 150 group design intervention studies for young autistic children where you concluded as authors that **conflicts of interest are common** in these group design intervention studies but they're **underreported** (Bottema-Beutel K. , Crowley, Sandbank, & Woynaroski, 2021). You also found other areas of potential bias as well. Micheal, what were some of your findings from this study?

Micheal: This was a large project that my lab did in collaboration with Kristen's lab as well as **Tiffany Woynaroski's** lab at Vanderbilt, and this is what we call Project AIM. We wanted to use meta-analysis as a tool to draw conclusions about the effects of early childhood interventions for supporting autistic children across a variety of developmental domains. We did this very broad search and tried to identify all the group design studies that tested an intervention against a control or comparison condition, where one group of participants in the study received an intervention and then the other group either received a different intervention or or they received "business-as-usual" supports, and then from there we categorized intervention approaches by type and the outcomes by domain. And, we actually had several categories of interventions that we were considering, maybe a little more specific than the overview of the three that you gave. But we included behavioural interventions…sort of traditional, ABA-based interventions. We also had developmental relationship based interventions, sensory-based interventions and naturalistic developmental behavioural interventions which attempt to blend both theories together.

There were several different kind of approaches that we were looking at and our goal was to look at intervention effects on different outcomes by intervention type, so that we could get a sense of overall how effective a given intervention is for supporting, you know, daily living skills, for example or some outcome like that…language development….

But there's this second issue which is quality, because very **poor quality studies are likely to overestimate the effectiveness of interventions**. So we also wanted to whittle away studies based on these key quality indicators where potential bias might emerge. One of those is **random assignment**. It's kind of a key tool that we use to ensure that there aren't other differences between the intervention and the comparison group that might explain differences

that we might see at the end of the study…between the intervention group and the comparison group.

We started to peel away studies based on whether or not the participants had been randomly assigned and we lost a lot of studies based on that. And so that really reduced our confidence in our initial estimates of how effective this intervention is.

And then we peeled away based on whether or not the studies used **masked assessors**, so are the people who are measuring the outcomes aware of whether or not the participant is receiving an intervention or not? Because even just subconsciously that can influence how they assess or measure those outcomes for those children. We also looked at whether the primary measures were caregiver reports -- so whether it was parents and teachers who were reporting on the effectiveness of the intervention, because obviously there's a potential for bias to emerge when you expect or hope for an intervention to have a sort of effect and so you rate things in that direction.

[10:03]

Micheal: And what we found is that as we continued to whittle away based on these different areas of bias or quality indicators [is] we eventually sort of ran out of studies. We **didn't have enough high quality studies that met all of these different quality indicators** that allowed us to compute or to estimate the effectiveness of these different interventions with confidence. That was a key finding that we wanted to support to the field there.

Anne: Wow! I mean, that must have been such a process and experience to go through and I'm wondering: what are some of your ideas among your team about *why* – why there was so much weakness (I guess you'd call it methodological weakness) in so many studies?

Micheal: Yeah (sighing), that's a great question. I think one shift that I observed is shifts in **funding priorities**. I do think that there has been an increase in the use of randomization and randomized control trials more recently relative to studies where participants weren't randomly assigned, but we still see a lot of these studies because major federal funders in the United States like the [National Institute of Health] are really requiring that for funding studies. Kristen might have some thoughts about why these kind of quality issues persist in our field.

Anne: Yeah, I would tag [the question] onto that too: how unique is this to your sector?

Kristen: Yeah, that's a good question. I think we have a follow up study that we just presented recently showing that these quality indicators, they're not getting better over time, so it's not just that we didn't have we didn't used to have funding to make well designed studies but now we do. It seems like it's persistent and no matter the fact that I think funding for autism has gone up slightly. We don't necessarily know, but it could be that conflicts of interest play a role.

In the Project AIM meta-analysis we found that about 70 percent of studies were authored by

researchers with conflicts of interests. And only about 6% of those conflicts of interest were fully disclosed.

Anne: Hmm.

Kristen: Failure to disclose is potentially a problem even bigger than just having the conflict of interest because that means you're not building protections into your design so that those conflicts don't bias the study. It's not necessarily a terrible thing to have a conflict of interest, but it can be. [It can] reduce confidence in researchers if they're not disclosing those COIs and then as a follow up convincing everyone "I have this COI, but it's okay – here are the protections I've built into my research design so that it's not a biased study" even with those conflicts.

We don't have definitive evidence to say that quality problems are necessarily linked to conflicts of interest, but I do think it's possible and I certainly don't think it's helping that there isn't a culture of disclosure in this field.

Anne: Right, and you'd also identified several other problems with methodology besides conflicts of interest, in terms of how it's measured.

Kristen: That's right, so it's possible that if you have conflicts of interest you're more likely to select, for example as Micheal was saying, some of the measures that were chosen by researchers to measure research outcomes couldn't be administered in a way that the rater was masked to the participants inclusion in a control or the treatment group. So, the rater- the researcher selected to measure – that could only be administered in a biased way. You might be more likely to make those design mistakes if you have a conflict of interest.

Anne: Right, absolutely. I mean it's interesting that they didn't declare them and I'm wondering, what are some reasons that someone wouldn't declare a conflict of interest?

Kristen: That's a great question. I think that it's a cultural thing. I think that because conflict of interest **disclosures are so rare**, I think there aren't good examples of conflict of interest disclosure statements and so researchers are just--at least in the autism field--just don't think this is something they have to do.

Another thing I think is **enforcement**. I have actually emailed journal editors and said this article has a conflict of interest that's not disclosed--and nothing happened. The editor didn't seem too concerned. They didn't promise to follow up. I think sometimes journal editors themselves have conflicts of interests and so there's kind of this culture that this is something that many autism intervention researchers have and no one is being held accountable for having them and not disclosing them, and so no one does it.

Anne: Right, and I think you have some data on that, right? In terms of ABA, how much of the research is being published in publications that are really kind of almost industry publications to begin with?

Kristen: Yeah, my colleague **Shannon Crowley** and I did a study that was conducted at the journal level, so it was a little bit different than the Project AIM study. We didn't just collect all the research we could find. We collected research from the ABA or Behavioural specific journals and we looked at these journals over a one-year period, and we pulled out all the articles that had to do with autism intervention, and we found 180 studies were published in these eight journals over a one-year period. And, we specifically looked for articles that were published by researchers who provided ABA intervention or provided paid consultation to ABA intervention providers, so there was some kind of **employment COI** that we were looking for, and we found that in these 180 studies more than half of the authors had this employment COI. So, that's at the author level. If you look at the study level, 84 percent of studies were authored by at least one person with a clinical or consultancy COI.

Anne: Wow.

Kristen: …but then if you look at the disclosure rates, we found that only 2% of studies stated that the author's position as an ABA clinician or consultant constituted a COI.

That was only like 3 studies out of 180, which I think is really problematic.

Another issue is that there were a high number of studies that had statements saying the authors don't have any COIs, but in fact they did. So, 4_ percent of the studies had a statement declaring no conflicts of interest but almost 90 percent of those studies had a clinical or consultancy COI, which I think that's **90 percent of statements declaring no COIs are actually untrue** and the authors have COIs that are pretty explicitly stated in journal policies as the kind of COI thathat has to be disclosed. So I think it's not just an error of omission where researchers just aren't being forthcoming. I think in some cases it's blatantly making a claim that researchers don't have a COI when in fact they do.

Anne: It sounds systematic.

Kristen: Exactly. I think that it is.

Anne: What about when people report to these publications to say "Hey, you have a COI policy but X, Y, Z paper didn't declare their COIs," what's the likelihood within those publications that they'll make a correction?

Kristen: That's a great question. I don't really know. I've only tried to do it once, and the journal editor sort of just cut up- well, the exchange was kind of the journal editor tried to make two claims, one is that "oh, is this really a COI?" Like, "are you sure that this really constitutes a conflict of interest?" Then the next claim was that "well, this is the kind of conflict of interest that *everyone* has." So, if we expected one author to disclose then everyone would have to. As if that is a bad thing.

So, I feel that conflicts of interest are so ubiquitous that it almost is like well, "we just assume everyone has that COI, we don't need to actively disclose it."

Anne: Well, it's such a marketplace. Autism services are such a marketplace to begin with…and maybe many things are, but I know the most about that. What I'm wondering is, within the broader autism research world, if there is movement to change that, to move away from these journals which are just really run by entities that have a financial stake in a certain therapy and then they are publishing articles by people who have a stake in a particular therapy and then they're being read by policymakers and other researchers and parents and a lot of dollars are being allocated based on this really problematic research. So, I'm wondering how people in the autism research world have responded to work like yours in terms of making changes?

[19:39]

Micheal: Well, you know I think I've seen a lot of evidence of positive response when Kristin initially shared her ABA researchers conflicts of interests paper as a publicly available prior to publication – a preprint, a lot of folks who were sharing it and saying "Hey, look at this" were ABA researchers, and so I took that as kind of a positive sign. But, I think what's needed really is systemic change and I think a lot of that has to happen at the journal level. But, I mean I have seen for example some ABA researchers reach out to Kristen and say "Okay, if I wrote a book on this should I declare that as a COI? What should my COI statement look like?" So, you know, I think there is progress but a lot needs to happen. That's kind of an initial signal, but systemic change is broader that that.

I don't know, Kristen, if you have any more thoughts on that…

Kristen: Yeah, I completely agree. It does seem like individual ABA researchers, among other researchers are interested in this and I do think that another reason why COIs might not really be disclosed is a **lack of training** and I include myself. I didn't learn about what conflicts of interest really were in a broad sense until I started doing this research area…So it could be a lack of training.

I think in addition to journal editors being more clear about how COIs need to be disclosed, I think that in research training programs, it needs to be part of the curriculum so that researchers understand what COIs are and know how to disclose them, and know that there will be consequences if they don't – a big one being that it just **erodes trust in research**. If you're in intervention research, you have a conflict of interest and you're not being transparent about it, it sort of undermines your efforts because the people who would ultimately be using your intervention are going to be skeptical of what you have to say if you're not being clear about what your conflicts are.

Micheal: Yeah, I would agree that. I didn't get really clear training about constituted a conflict of interest. I think I may have been able to recognize very blatant financial conflicts of interest,

but ideological conflicts of interest, whether or not I used an assessment that I had developed or if I was researching an intervention that I-myself had developed, I don't think these were treated as conflicts of interest in our doctoral programs, and so I definitely agree that training needs to be part of this.

Anne: And I'll just get back to my earlier question. Do you think that this is more prevalent in the autism sector than in other areas of research? And if so, why?

Kristen: So, I was thinking about this question. I don't think there are enough good studies to be sure. One thing to know about the two studies that our team has done on conflicts of interests is that we're looking at **undisclosed conflicts of interests**, so we're really just reporting the conflicts of interests that we were able to find. Since they're not disclosed we have to do all this kind of sleuthing to see if they exist and the number of conflicts of interest that we reported out there is probably an underestimate.

I think it's hard to figure out what the true rate of conflicts of interests are, especially if there's a culture of not disclosing them, but in reviewing the field and getting a sense of who else is doing conflict of interest research, I did find a statistic that said in the medical field the disclosure rates are about 70 percent. So, 70 percent of articles in the medical field are going to have a conflict of interest statement declaring that one exists. So, that's vastly different from the two studies that we've done where the disclosure rate were about 6 percent and 3 percent.

Anne: Mm-hmm.

Kristen: 70 percent in the medical field and, you know, 6 percent or less in the autism field.

Micheal: Yeah, I think that there's a couple of things to take from that. One that conflicts of interest are very likely. You know they're pervasive in a lot of fields, but that disclosure rates really differ.

Anne: Right. And then, what about the assessments? What about the idea of how success is measured, because that was something else that you talked about in the first paper that we spoke of – that some of the measures themselves are implicitly biased as well.

Micheal: Yeah, well, one thing we looked at in that first paper is whether the scope of change that was being measured affected the estimates of intervention effectiveness. So if I measure exactly what my intervention taught and modeled in the exact same context as it was provided, my estimate of intervention effectiveness is likely to be much higher than if I measure something that's much broader…. and often maybe much more meaningful, right? A measure of generalized development. I wouldn't call it necessarily an area of potential bias per se, but it is something that we found definitely influences our estimates of intervention effectiveness.

If we're not keeping in mind, I think the problem that happens a lot of times is when researchers and lay people look at the research, they draw conclusions that are very broad.

They might say this intervention supports development children on the autism spectrum when actually what the study showed was a given intervention might report learning a very specific skill in a very specific context. Those two things are very different. The scope of change demonstrated there is very different and we have to be very careful about attending to that rather than doing what I think a lot of folks do which is kind of this checkbox of you know, "is it an **evidence based** intervention or not an evidence based intervention". If there is any evidence that supports it improving anything, people will then call that intervention "evidence based" and I think that – we really need to say: evidence based for what? And, what's actually being shown here isn't meaningful to children's lives.

Anne: Right, and that's a much bigger question. I think that the kind of divide that I see happening in the research world is this divide between research that is assessing really quality of life, and really wanting to have a lot of subjectivity for the actually autistic *end users of the treatment*, right? And then there's the kind of older way of doing things which is give the parents a survey and have them tick off the boxes and have that the kind of standard to say whether something "worked" or not. And there's a lot of grey area with autism. How do we quantify what *working* means, who is it working for? I mean there are so many big issues in that, right?

I guess my last question to you both is: what do you see as the future of autism research? Do you see that there might be some transformations that are starting to happen?

Kristen: I think so. I don't know how slow this kind of transformation will be but I think that there are reasons to be hopeful. Like we said earlier, researchers do seem to be paying attention to this, and the exact researchers who we think should be paying attention to it. I was just looking through a study published by **Tony Charman** and his team, he's a very prominent autism researcher and his conflict of interests statement took up like half a page and this was published maybe a month ago. I haven't seen a statement like that before. I'm not saying it's definitely connected to our work, but it does seem like this issue is getting more attention. And also this issue of quality, and bias in general. I think that this topic of research quality came up a lot in our recent international autism conference, and so people are definitely talking about it. I think it will take a little while to determine if we repeated this study in a year, are we going to have a lot more high quality studies to draw from. I'm hopeful that we will. I hope that funders will be more in tune to these issues and select studies that have built in bias protections for funding versus ones that don't. Micheal, I don't know if you have any other thoughts on this?

Micheal: Yeah, I mean, I'm generally optimistic. I think that there has been a lot of, you know, positive…I think people want to do better but again, it's about a cultural change of what is our standard?...and I think we have to adjust and say it's not acceptable to have a lower standard for research and we need to do better. I'm hopeful for the Open Science movement to make it so that we're planning studies in advance and we're very transparent about that, that we're

sharing our data after studies so that we can learn even more from what happened. I think those things will be great if they can be taken up widely in our fields.

Anne: Right. I think so too and that's a huge part of it –the individual researchers getting the training and having the commitment.

But then for those who *don't* have the commitment or maybe don't get the training then there has that to be like, Kristen, what you talked about that- enforcement coming from the journals themselves. What direction do you think journals are going to go into in terms of in the field of autism, defining conflicts of interest and really demanding conflict of interest disclosures from their researchers?

Kristen: What I would like to see is maybe some more guidance from journals with examples that would help to guide authors as they submit their manuscripts to help them identify. And also some open space to declare perceived conflicts of interests that may not fit into certain boxes. So, depending on what journal I'm sending my manuscript to, sometimes the conflict of interest space where I can volunteer that information is very narrow. So, it might ask specifically about a financial conflict of interest, and perhaps I don't have a financial conflict of interest, but I have another conflict of interest or a perceived conflict of interest that I want to support and there's not a system where I can support that. So, I would like to see both of those things changing in journals.

Anne: Interesting. Is there anything that you'd like to add about the reception of your paper? I know that your paper was really, really well received and people were very interested in it. And I'm wondering where you're heading next with your work.

Micheal: Yeah.

Kristen: We have lots planned. Micheal, did you want to share some?

Micheal: Oh no, go ahead, Kristen.

Kristen: We have quite a few things planned. My colleague Shannon Crowley and I, we're doing a quality assessment of the transition age literature for autistic students. We're planning on doing an update of Project AIM. We have another- I think I mentioned already that we have another couple of studies planned, one of which where we look at quality or time that we're planning on doing.

Micheal: Yeah, we're also going to look at representation racial and ethnic representation in autism intervention studies and just generally a lot has been published actually since we did the search for this initial Project Aim study. When we update [it], which will start this fall, I think we're going to identify a lot more randomized control trials and I'm interested to see what we'll find.

Anne: Yeah, you've really inspired a lot of new research which is so amazing and I'm looking forward to and I know everyone who's listening is looking forward to seeing what you're going to be coming out with in 2021 and 2022.

Micheal: Thanks so much!

Anne: Thank you so much for being on the show. It was really interesting talking to you. Thanks!

Kristen: Thank you!

Micheal: Thanks for having us!

(Theme song: soft piano music)

Anne: I was speaking with Professor Kristen Bottema-Beutel from Boston, and Professor Micheal Sandbank speaking to us from Austin.

Thanks to everyone involved and thanks for listening.

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