

Clinical Trials

Shelly Jofre Interview with Mina Dulcan

Tape No – 10

INTERVIEWER (INT) is Shelly Jofre

MD is Mina Dulcan

INT: Maybe you can just set the scene for me first. What kind of people read the journal?

MD: It's the Journal of the American Academy of Child and Adolescent Psychiatry and it is read, it's a professional Journal so it's not meant for lay people although lay people could certainly access it, particularly now that things are on the internet. It is the Journal that belongs to the American Academy of Child and Adolescent Psychiatry which is the national organisation for Child Psychiatrist so all the members get it, but then we have quite a lot of other subscribers who are adult Psychiatrists, Psychologists, Neurologists, people who treat child mental health.

INT: So basically anybody who is interested in childrens mental health would read this?

MD: We hope so.

INT: Is it quite influential?

MD: Yes, there is a measure called impact factor which I don't know if you are familiar with. It has to do with how often the average article in a journal is cited in other journals and we rank, and this is a worldwide ranking, we rank number 1 in child mental health and number 2 in paediatrics.

INT: So, it's read around the world by Doctors.

MD: Yes, very much and we have manuscripts, papers from around the world and its read around the world.

INT: Most medicines that children are given haven't actually been licenced specifically for children so does a lot of research in your journal refer to off label use?

MD: Well, yes in terms of the FDA most medicines. They are actually used in all paediatrics and not just child psychiatry, don't have indications for children or maybe for children or not for young children so to the extent that there are drug trials in the journal and of course we cover a whole lot of topics. Many of them are indications that are not yet approved.

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INT: So when something appears in a journal for an indication that hasn't been approved do you think Doctors pay quite a lot of attention to it?

MD: I think Doctors are always looking for research. The problem is we have sick children who come to us and in many instances there are no approved medications and there are no evidence based other treatments and so you have a suffering child and family and a Physician is duty bound to try to do something and so yes, to the extent that there is research people are very interested in the research.

INT: Now study 329 was the first properly controlled trial of Seroxate in adolescent depression. Do you think Doctors would have been influenced to prescribe Seroxate once they read the positive results?

MD: Actually, my sense is probably not. What you have to remember is because we had children in adolescence with depression already people were already doing something and although Fluoxatine, Prozac had data, many people would have side-effects and the older anti-depressants were also not approved and were much more dangerous so the fact is and if you look at the statistics on prescribing patterns actually people were already prescribing the medicine and my sense, although obviously I don't have direct information on this, is probably after that article if anything prescriptions went down.

INT: Why do you say that?

MD: Well, because it was an article that said, you know, not better than Placebo on some things, a little bit better than Placebo on others things, some side-effects, none that we didn't anticipate, those were all known side-effects and we all know that any medicine that's strong enough to work is strong enough to have side-effects so with Clinicians most of the time that doesn't surprise us that there would be side-effects, unless it is something unusual, you know that's quite rare and that nobody has seen before.

So it was not actually a thrillingly positive study.

INT: Well, the conclusion was that Seroxate was generally well tolerated and effective in the treatment of adolescent depression. That sounds quite positive.

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MD: Well, if you were a lay person, yes, it would, but if you are one of us reading that you don't read that sentence. You read on this measure it was better, on this measure it wasn't better, on this measure it was a little better, on this measure they looked they same, so I think the kinds of clinicians who read a scholarly journal don't just take the headline or the last sentence.

INT: Do you think Doctors always read the detail?

MD: I think Doctors read the abstracts.

INT: And the abstracts say generally well tolerated and effective.

MD: Yes, that's true, but if you look at the rest of the abstract it says on this and this measure not better than Placebo and on this measure it was so even in the abstract its more ? and in our journal we require a section called limitations because in fact many Doctors don't read every detail of the methodology or every number in a table, but we require that every paper have a section called limitations and that talks about, you know what might have been a problem with the study.

So, my sense of people who read our journal, and I can't speak for other journals, is they read the abstract and then they often go to the limitations because that helps them understand because no study is perfect. Every study has some things you would of rather done one way or rather done another way and either you couldn't afford it or it wasn't feasible or you didn't know when you started the study what you knew at the end of the study. Virtually, every study, if you knew at the beginning what you learn at the end you would have done it differently and that's just how science is.

So, I think people, I think when people read newspapers perhaps they read just one line or even really if you look at sort of the popular professional news magazines that report on whats on a journal, even those talk more specifically about things so I don't think certainly the kinds of people who read our journal are that simplistic.

INT: You don't think the actual study as it was published overstated the effectiveness and underplayed the side-effects?

MD: Well, all of that is a matter of opinion to some extent how much is over and how much is under. Certainly.

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INT: But, whats your opinion?

MD: I mean it certainly listed the side-effects.

INT: It didn't list them very clearly did it?

MD: It depends on what you mean by clearly. It was clearly enough that a Clinician who is familiar with these kind of cases and familiar with these medicines could perfectly well understand it. If you were say a General Practitioner you might not.

INT: Hang on a minute. It took the Medicines Regulator in this country about 3 years to work out exactly what was contained within the data. When they did their own line by line analysis of the data they discovered that the adolescents on Seroxate were 6 times more likely to suffer a suicide-related event than the kids on Placebo. That wasn't in the published study.

MD: That was a whole different kind of analysis. In other words a lot of that whole reanalysis was done as a result of the concerns when people looked at the study, so there was obviously enough of a signal in the study for somebody to say, gosh.

INT: Isn't that why you compare a drug to Placebo? Why weren't the authors saying at the time, gosh, there is something really odd happening to the kids who are taking Seroxate. This is a drug that is meant to prevent suicide and in fact it looks like a lot more of the kids on the drug are feeling suicidal than the kids on Placebo. Why didn't they notice that?

MD: Well, it was reported. I think what you are talking about is why didn't they make a big banner about it. It was in the study that's how people found it. It was in the report.

INT: The Regulations reanalysis found a few extra cases.

MD: Well, they looked at it in a different way, but what you have to remember is.

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INT: Well, perhaps the authors were looking at it in a far too optimistic way.

MD: Well, I suppose human beings are generally pretty optimistic. In my experience.

INT: Here is what one of your own peer reviewers said about the study?

MD: You couldn't have one of my own peer reviewers, what do you mean by that?

INT: I have got the peer reviewers comments on study 329.

MD: From the journal?

INT: It says the relatively high rate of serious adverse effects of the drug was not addressed in the discussion. Given the high Placebo response rate are these drugs an acceptable first line therapy for depressed teenagers. The results do not clearly indicate efficacy for the drug. I mean, these are pretty damning comments aren't they?

MD: First of all I don't know how you would have gotten that and second we often have several series of reviews and on virtually any paper if you read the reviews that came in on the first version they might have very little to do with the actual published version so I really can't comment on that.

INT: Don't you think they sound pretty damning?

MD: I am not going to comment on how they sound because they could easily be out of context. In other words what I am telling you is the reviews that come in on the first version of a paper, which those could have been, may have very little resemblance to what is actually said in the actual published version because there are major changes as papers go through the process. So I cant really comment on that.

INT: This whole point about the high rate of serious adverse effects I mean it is not clearly laid out in the published article what exactly happened to these kids.

MD: No one actually committed suicide. Well, in any of the studies.

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INT: Would you expect that to happen when they are getting such intensive support? We do know that lots of children have committed suicide out there in the real world shortly after taking this drug, but this is why you compare the drug with Placebo, that's science isn't it?

MD: Science isn't that simple. Of course you always want to compare with Placebo. That's the gold standard, the randomized controlled trial, but it doesn't mean that you know everything there is to know and the fact is we all know that there are children who commit suicide in hospitals so the fact that they are in the study will of course they wouldn't have done it then that's not the case, there are children who are in hospital.

INT: You don't want to believe this information, whats the point in going to all the trouble of comparing the drug to Placebo and then sort of ignoring the results?

MD: I think that I would say people are not ignoring it. I think.

INT: This study was finished in 1997. We didn't find out the problems with this drug for another 6 years and 2 years after it was published in the journal. Your journal didn't help expose what the problems with this drug were. This is a drug that children are now not allowed to take because it is so harmful.

MD: In the UK. Its not true in this country although we are not using it by and large because there are other medicines that appear to be safer. The job of a scientific journal is not to be the same a public health. In other words that's, first of all we can't do anything until it is submitted to us, so the fact that it was finished many years before is irrelevant. But, the job of a journal is to present as best as possible based on of course what the author sends you because you have no idea whats really there, the data, so then people can and to the extent that you can in an article present, you cant present every single thing. I think child Psychiatrists always worry about suicidality when treating depressed children so that's not big news.

INT: Well you say its not big news, why would you not notice a signal? If you are carrying out a study in a very controlled condition and it seems that the kids on the drug that you are looking at have 6 times, that's pretty high, 6 times more likelihood of suffering suicide related events.

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MD: Six times is a statistic.

INT: From the Medicines Regulator.

MD: Yes, I understand that, but let me give you an example which is not this example here, but you can use statistics in ways that sound better or worse. If one in 1,000 gets something and 6 times more get it that's only 5 people, that's not a huge thing. Actually, my reading of the data on the suicidality was more like twice.

INT: The Medicines Regulator said it was 6 times, in fact more than 6 times more likely that the children on Placebo to suffer the suicide related.

MD: The Regulator came after the paper and that continues to be a great deal of discussion among reasonable scientific people about the data that the Regulators presented, how they analysed the study, how they, this is again not like reading a newspaper where its all right there and you could see it. These are very complicated questions.

Even the question of how you code what was called a suicidal event, most of us were not actually. If you say event what do you think of.

INT: The same code was applied to the drug as was applied to Placebo and by whatever definition you use 6 times more kids on the drug were having problems in that respect than on Placebo now that surely should have rung alarm bells.

MD: Well, the data is there. The alarm bells are a relative question. I am no defender of either drug companies or this particular drug, but I think what you have to consider is the context. One of the thing the child Psychiatrist has known since I was in training, quite some time ago, is that when you have children who are depressed, they often don't talk very much, they don't say they are depressed if they don't talk very much. As they start to get better, however, they are getting better, whether its on their own or however it is, they often start talking and what they start talking about before they are completely better is, oh gosh, I am really depressed, I am really thinking about killing myself. Does that mean that that's a new thought or does that mean that you are just not hearing whats been going on all along? That's why I am saying that these phenomena are ones that are familiar to us.

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INT: Surely the whole point of randomised control trials is to try and work out quite clearly what the drug is doing and what the drug is not doing.

MD: That is the concept, but it's not that simple.

INT: Not trying to complicate things, but what is quite clear is that the kids on the drug were having more psychiatric side-effects than the kids who weren't taking the drug.

MD: That was reported.

INT: It wasn't clearly reported and it wasn't accurately reported and the conclusion was that this was a drug that was generally well tolerated. It looks like 10% of the children who took Seroxate self harmed; started to feel suicidal.

MD: They didn't self harm, not that many self harmed. That includes verbalising suicidal thoughts, being agitated, a lot of things that really are not directly what most people think of when they think of suicide. It was a very broad ?.

INT: The kids were suffering on sugar pills, that is the point surely that you have to keep coming back to whatever it was they were suffering the kids on Placebo weren't suffering as much.

MD: I think unless you understand the clinical condition sometimes as people are getting better they appear to be suffering more. That's how the phenomenon works.

INT: That's an argument that certainly the drug companies have put forward for a very long time.

MD: I am not making any argument for the drug company I am speaking to the clinical experience which is that often happens, that things appear to be worse before they are better. Often true if you do surgery on someone, they feel a lot worse before they feel better. It has nothing to do with the drug companies, they can say whatever they want to say.



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INT: Looking at the study that was carried out and the data that was generated. The drug really didn't do much better than Placebo.

MD: A small amount, not much.

INT: One of the things that happened was that the children were given intensive weekly therapy and support.

MD: Which is why it is not really a sugar pill, its sort of non specific treatment.

INT: Exactly, but surely then when 50% of the kids on Placebo get better too wouldn't an objective conclusion be that maybe this intensive weekly support worked for kids?

MD: Well, I think that's what everybody who understands the scientific literature would understand. When we say Placebo.

INT: That's not what the published study says.

MD: They described the support. When we say Placebo.

INT: Why did the abstract did not say instead of saying the drug was generally well tolerated and effective why did it not say the drug really wasn't very useful, but what was useful was this weekly therapy? Isn't it because it was a drug company sponsored study and nobody wanted that to be the conclusion?

MD: Well, I think what the drug company wanted is really not relevant to what anybody else thinks. The fact of the matter is human beings when they do a study get very involved with it and I have to tell you that virtually every paper that comes to me, whether it's a medicine that's sponsored by a drug company, whether it's a medicine that's sponsored by an IMH, whether it's a psychotherapy study, which I actually have a great deal more difficulty with in this way, or whether its a risk factor study.

When they first come in nearly always the authors are more convinced of whatever it is than the reviewers that I subsequently think is the case. That's just how people are when they write things whether there is a drug company involved or not. To be honest with you if I look at all the papers where I have to moderate

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conclusions it is actually much more of a problem with the psychotherapy papers that go beyond their data in terms of claiming that something is effective than I do with the drug company stuff.

INT: That's why you have peer review and that's why what your peer reviewers said was so interesting because the criticisms they made of the manuscript they read could easily be applied to the finished article because they were saying the effects were overstated and that seems to be the case from the article and that the adverse effects were underplayed. That's certainly how the Regulator sees it.

MD: Well except that the paper doesn't get published until the Reviewers are satisfied. So, they may have said that the first go round, but then the papers in our journal always go through one revision and often more. I have no way of knowing how many, remembering how many in this one, but the early reviews as I said may not be relevant to what comes out. The paper doesn't get published until the Reviewers are satisfied.

INT: It was rejected from another publication for exactly the same sort of reasons.

MD: We don't have a little chip in them to tell where they have been before.

INT: The interesting thing is that Glaxo Smith Klein actually acknowledged internally 3 years before you even published study 329 that it had failed to show that Seroxate was better than Placebo. They took a marketing decision effectively pick out the best bits of the study and see if they could get it published.

MD: That may be. That's not something that journals have any access to, that information.

INT: How do you feel about that? A very deliberate decision. They said the study hadn't shown anything useful about this drug, but we will try and repackage it.

MD: It could be true. I mean I have no way to evaluate that. It could be true.

INT: Do you have no regrets about publishing the study?

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MD: I don't have any regrets about publishing at all. It generated all sorts of useful discussion which is the purpose of a scholarly journal. The purpose of a scholarly journal is not to tell people what to do. The purpose of a scholarly journal is to put out the data. Now you could argue it should be here this way or should be that way, almost any paper you argue it should be one way or another.

INT: It was misleading and it would have had an effect on the way people prescribe. It was saying the drug was safe and effective, but in fact it wasn't true.

MD: Said well tolerated and in fact the majority of the children did tolerate it well although I am no particular advocate for this drug. Well tolerated. You have to remember that they were also talking about Imipramine and Imipramine which were the older anti-depressants, large numbers of children had to be actually taken off the medicine because of serious problems. So you have to consider.

INT: There was a whole other set of problems about how they compared it to Imipramine. I am sure. I wasn't going to go into that.

MD: You can always. Even among the investigators on a study there are also disagreements about how to present the data. Its not simple. Its not simple.

There will always be disagreements, but I think you have to remember that people were already prescribing this medicine. I don't think there is any reason to think that more people prescribed it as a result of this article. People were already prescribing it, were hoping that there would be research to support what they were doing and I haven't talked to anybody who thought, oh golly gee, this is great support for this.

INT: I can tell you that Glaxo Smith Klein though it was fantastic and their sales rep were saying you know using your journal's name and influence to then say to Doctors, here look, theres a published study, it works.

MD: Well, I think we all see salesmen of a whole variety of kinds, whether they are drug company salesmen or insurance salesmen and we certainly have no control over how they use something.

INT: But, given what you know now about this drug and what it can do to children don't you have any regrets that that published article was able to use your

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journal's good name to basically, as a cloak of respectability to say look, I have been in this journal. It must be true look at the authors.

MD: I can't control the authors. No, I don't have regrets because it presented. I mean you are settling on one sentence, but if you read even the abstract and that is part of what the letters that came in said, well what about this measure, what about that measure, we think this one was more important, we think that one is less important, that's the purpose of a scientific journal. If someone misuses our journal we really have very little control over that.

INT: In the published article I know myself it was not very clear exactly what happened to the children who we later discovered either became suicidal or self harmed. It was written up in a way that was almost deliberately confusing and certainly wasn't accurate because it didn't include the full number of children who suffered those side-effects.

MD: That was because, if you read all of this material and its not just about this paper, but the whole thing around the FDA in this country and all of these kinds of medicines there is a great deal of disagreement about how these events are solicited. Are they asked for, are they spontaneous, how do you code them? They put together after the fact a whole coding system, but that was not implemented before.

INT: Isn't it the truth that the authors really weren't looking for this. They didn't want to know about this?

MD: I can't really speak to their motivation. I know many of them. I know many of them are extremely dedicated Clinicians who are taking care of sick children and would, could you say someone might hope that a medicine could work. That's how human beings work.

INT: That's where you are meant to cut through all that and its meant to be pure science isn't it?

MD: Well, we would love to have pure science, but you know what there is no such thing it turns out. I don't know how much you follow research and a whole variety of specialties, not just child psychiatry, but you know there is a study that will show one thing and then the study the next time shows something else. Does

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that mean somebody lied, somebody made up things. Science is not that clear, its not that simple.

INT: It seems that one of the problems in this was about who actually takes full responsibility for the data at the end of the day because you had the people who were named as the authors, then you had a kind of ghost writing medical PR agency who actually was responsible for writing it up, not the person who is listed as the author.

MD: That's possible. We are not the FBI. We know what people send us. There are rules that journals have about ghost authorship and what not, but you cant go into someones study and see who is sitting at the computer. We have to base on what they tell us.

INT: Are you aware that 329 was ghost written?

MD: I have no way of knowing that. It doesn't surprise me to know it happens, but we have no way of having that information.

INT: Does it worry you, do you think it matters?

MD: Well, certainly if I were an author I would not put my name on anything that I didn't feel was accurate. I can't speak to what those authors, to the extent, how much they saw the data. Someone can write something and you may or may not agree with it. The fact that someone puts the words together may be a good thing or a bad thing depending on what the words are. I cant really speak to what was in their heads.

INT: But, ultimately the person who listed it as the principal investigator really ought to have seen all the data don't you agree?

MD: Well, again science is complicated. They certainly should have seen the data. The way science is conducted is they had seen every single rating scale, every single paper one, probably not, but they probably should have seen the data as it came out of the computer. I have no reason, I mean I have no information to know whether they did or they didn't.

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INT: What I find hard to understand is how it could take another 3 years after this study was published that the so called authors of the paper found out about the extra suicidal cases in the study that they supposedly conducted.

MD: I really cant comment on that.

INT: It suggests to me that they probably did have access to the data. It is obviously a challenge for medical.

MD: It wasn't coded that way. It wasn't coded that way until later until all of the issues arose.

INT: But suicide and SSRI's has been an issue for you know 10 years, 15 years.

MD: There have been questions raised about it, yes.

INT: It wasn't a surprise, it wasn't something that cropped up, but you should have been alert to it.

MD: But, remember most of the events that were so called events that were coded that way were not suicides. Nobody committed suicide. So you are changing the definition after the fact and wondering why somebody did see it in the first place. Now, gosh, if I talked to the authors what would they say, would they now wish, I mean who knows. You always have afterthoughts. After you do nearly anything, almost after any paper you have written if you go back 3 years later knowing what you know now you think oh I wish I had said it differently or looked for something differently because science is advancing, that's inevitable. You are always knowing more later than you knew at the time.

INT: This was a failed study. The drug company admitted in the nineties it was a failed study and it was given a cloak of respectability by actually being published in your journal. Doesn't that worry you?

MD: We, a scientific journal, takes what is sent to them and cannot investigate what the drug company thought, what they didn't send you. If you look at the history of research fraud in science there is recurrent research fraud, most of it not drug company sponsored, most of the large research frauds are actually NIH sponsored studies and there is no way that a journal can find that out because you don't have

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the original data. What happens with science is people try to replicate it, people combine it with other studies, people ask additional questions and then something more informative comes out later, that's how it works.

INT: Well, now that you know that there were more serious psychiatric effects for the children who were taking Seroxate compared to Placebo it means that the study published wasn't accurate. Have you got any plans to publish a correction or even pull it, because it's in your archives?

MD: Well, there were, no, we certainly have no plans to either pull it, you can't actually pull it. You could issue a retraction, but once it's there its always there, you cant, there is no way to pull something because its out there.

INT: But, why not issue a retraction because it's not accurate? What is reported in that study is not accurate.

MD: I think if we found something that was fraudulent, that data were invented for example, that would be something. This is a difference in interpretation and of all of the data available how it was coded.

INT: It was an attempt to try and make a drug look a) that it was more effective than it actually was and much more worryingly that it was safer than it was, but much more worryingly that it was safer than it was. There are a lot of bereaved families out there whose children killed themselves after a short time on this drug and that is what, if you look at the data, the data shows it was producing an effect on the kids.

MD: There was not a single completed suicide in any single trial. We feel terrible when there are bereaved families, but you mentioned before about anecdotes, that's about as anecdotal as can get. We had in a journal comment on someone elses motivation. We have no way of knowing someones motivation when a paper is submitted to us.

INT: But, you point out that nobody actually killed themselves thank goodness in any of these studies.

MD: Right.

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INT: Buts, its quite clear that the children on Seroxate were having suicidal thoughts, some of them were self harming, that the whole effect of the drug was quite clear from the data, they just chose not to write it up that way and that is fraudulent.

MD: It actually wasn't that clear and what you don't know, and I would have to have a great deal more data then I have, its entirely possible that someone on the way to feeling better has these episodes, but no one is saying that these were persistent or continued throughout. If you had one time.

INT: Why are you trying to put an optimistic gloss on this? The facts are and the Medicines Regulator has established that kids were 6 times more likely to have these.

MD: I am not actually interested in being either optimistic or as you actually, quite pessimistic.

INT: The results are pretty negative. That's the point isn't it and they weren't really presented in an accurate way in your journal?

MD: Well, I think there is always room for interpretation and it really feels to me as though this discussion has reached a point at which it is not going anywhere. You are really badgering me to try to get me to say something that you believe and really it is not consistent with the way a scientific journal operates.

INT: So you don't have any regrets at all?

MD: I don't, no, because it does what science does, which is it puts something out there, people ask questions, more analysis is there, the Regulators look at all the data, they open things up, that's how science works. The purpose of a scientific journal is not to tell people what to do.