Transcript

Let's talk e-cigarettes

Podcast 35, September 2024, Professor Ben Toll, Medical University of South Carolina

@bentollphd; @muschollings; @MUSC_COM; @MedUnivSC ; @MSUCHealth

Speaker 1: Musical intro & outro
Speaker 2: Nicola Lindson, NL
Speaker 3: Jamie Hartmann-Boyce, JHB
Speaker 4: Ben Toll

Musical intro

If asking your mate down the pub about vaping is what they probably say, no one agrees if it's safer or not, so you might as well smoke anyway. Now what your mate needs is a Cochrane review. All the facts have been checked at least twice. They find there's a lot that the experts agree on might give you different advice.

Speaker 2
Hi, my name is Nicola and I'm a researcher based at the University of Oxford in the UK.

Speaker 3
And I'm Jamie and I'm a researcher based at the University of Massachusetts Amherst in the United States.

Speaker 2
We are both members of the Cochrane Tobacco Addiction Group. Welcome to this edition of let's talk e-cigarettes. This podcast is a companion to a research project being carried out at the University of Oxford, where every month we research the e-cigarrete research literature to find new studies. We then use these studies to update our Cochrane Systematic review of e-cigarettes for smoking cessation. This is called a living systematic review. In each episode, we start by going through the studies we've found that month and then go into more detail about a particular study or topic related to e-cigarettes.

Speaker 3
Welcome to the September 2024 episode of Let's Talk E Cigarettes. In this episode we are covering studies that we found in our searches in August because we took a little holiday, I hope many of you did too. As well as searches that we conducted on the 1st of September 2024, we found altogether combining results from August and September that it's been a pretty busy period. We have one new study and five new ongoing studies and I'm going to hand you over to Nicola to tell you about the first of those in a nutshell.

Speaker 2
Thanks Jamie. So, the lead author of that new included study is Mahathi Vojjala from the New York University and it was published in the journal Nicotine and Tobacco Research. It was a randomised controlled trial carried out in people with chronic illness who currently smoke. The 121 participants were randomised to e-cigarettes or

combination NRT, so that's combination like patch and gum and both were given behavioural support. The study was funded by New York University and at six month follow up 18% of the e-cigarette arm had quit smoking and 23% of the NRT arm.
Of those new ongoing studies Jamie spoke about, the first one has published a protocol in the Archives of Pharmacy Practice and is led by Doctor Madeeha Malik of Syntax Health Projects, which is a contract research organization in Pakistan. The study is a two arm RCT planning to enroll 258 participants who will be randomised to either 12 weeks of e-cigarettes or 12 weeks of NRT and in both arms, participants will receive counselling. Follow up will be over one year and smoking abstinence will be measured. This study is funded by Foundation for a Smoke Free World which has been found to have ties to the tobacco industry.
The second of the new ongoing studies, I'm going to talk about is being carried out by researchers at the University of Maryland in the US and has investigators, including Dr Bethia Kleykamp, they plan to conduct randomised controlled trial in adults over 50 years who are in treatment for opioid use disorder, who are actively trying to quit. Making participants will be randomised to receive e-cigarettes or brief advice to quit smoking, and the study plans to complete at the end of 2025 and the funding source is currently unclear based on the information that we've got.

Speaker 3
Lovely. Thanks, Nicola. So, in terms of those three other ongoing studies, the first of them we found on clinicaltrials.gov and it's entitled harm reduction for smokers with mental illness is being led by Sarah Pratt of the Dartmouth Hitchcock Medical Center. In the US, keen listeners might remember that we interviewed Dr. Pratt about her earlier work on this topic in June and 2023, so it's particularly Nice to see this come to fruition in a full trial. So, this new study is funded by the NIH. That's a randomized controlled trial in which people who smoke and live with serious mental illness are randomized to either eight week provision of android e-cigarettes only or to more intensive behavioral support for switching from smoking to vaping participants in the more intensive condition will receive a supply of e-cigarettes as well as behavioral support and coaching, which includes 7 to 10 sessions with the study coach as well as the opportunity to receive supported field trips to explore e-cigarette options based on availability, cost and preferences. The study is going to follow up participants for six months and look at a range of outcomes, including self-reported smoking behaviors. They're aiming to enroll 250 participants and to complete the study by 2028.
The next new ongoing study was also recently registered in clinicaltrials.gov and is called adaptive use of nicotine substitution to maintain. Smoking reduction / abstinence and nicotine responders. It's being led by the Rose Research Center in the US, which has been linked to the tobacco industry. The funding for the study isn't immediately clear, but the study aims to determine whether people who smoke who initially respond to nicotine products, including nicotine replacement therapy, nicotine e-cigarettes or nicotine pouches, can be successfully maintained on these other nicotine products for six months and whether this can lead to reductions in smoking. They're aiming to recruit 150 participants and complete the study at the end of next year. The way this study works, a little bit unusual, so at study start everyone will be able to choose from those nicotine products on offer. At two weeks, if people haven't managed to reduce their smoking, they're going to leave the study and then the

remaining participants will be randomized to 12 or 24 weeks of continued use of their chosen nicotine products.
Finally, Schiek 2024 is a published study protocol entitled ‘Combining app-based behavioral therapy with electronic cigarettes for smoking cessation’. This is a mixed method single arm pilot trial in which 70 adults who smoke will receive access to an app and a pod-based e-cigarette for at least three months. The e-cigarette is going to be linked with the app via Bluetooth, which allows researchers and users to track use patterns. Again, a range of outcomes will be collected, including cigarette abstinence at six months. That's being led by researchers at the Witten/Herdecke University in Germany and is being funded by the manufacturer of that program being tested in the trial. And so that program includes the electronic cigarette the pods for that electronic cigarette and the smoking cessation app.
So now we're going to change tack a little bit for this month's deep dive. So as some of you might know, Nicola and I and our colleagues have been working on a new Cochrane review of interventions to help people quit vaping. This is currently going through various editorial processes. We hope to be able to tell you more about it soon. Like our living systematic review of e-cigarettes for smoking cessation this is also funded by Cancer Research UK and we hope that it will be living as well because we know this is a super active area of research. So, what we wanted to do for this month was talk to someone about what we know so far when it comes to research on interventions for quitting vaping. And we're lucky enough this month to be joined by Ben Toll, a professor at the College of Medicine at the Medical University of South Carolina and also the current president of the Society for Research on Nicotine and Tobacco. So, can you start by telling us a bit about yourself and what got you into tobacco research?

Speaker 4
Sure. I am a clinical psychologist by training, but in Graduate School I decided that I wanted to work in health psychology. I was enamored with hospitals and hospital based care, and so I did some practica in hospitals. At the University of Miami and I really loved it. And then I transitioned. So I got my PhD in clinical psych and then I transitioned in my last year of my PhD. I went to the Yale School of Medicine and the Yale Cancer Center, where I worked for a year. And then I stayed there for two years. Worked a post-doctoral fellowship at the Yale School of Medicine and the VA in Connecticut, so I'll I'll back up a tiny bit.

Speaker 3
Mm-hmm.

Speaker 4
In grad school I worked with the Sobell’s who created the timeline follow back, which we all still use to this day or some version of the time I follow back.

Speaker 2
Obscure science term definition. The timeline follow back method was originally developed as a way to gather people's own reports of their previous alcohol drinking behaviour using a calendar format.

Speaker 4
And they did alcohol research. But at the time I met them, they were interested in starting some tobacco research and they said then the IRB here is going to be so much harder to do an alcohol study so why don't you do tobacco? And I was like. OK, I'll do it. So I did my first study on thought suppression, which was an interesting area that I wound up not pursuing. You know, like many areas in science where you're excited about one thing and then it leads to a second thing and you forget about that.

Speaker 3
Ohh yeah,

Speaker 4
I started in tobacco and then interestingly, I transitioned to the Yale School of Medicine to work with Stephanie O'Malley and Peter Salovey. Stephanie also, like me, did a lot of of alcohol research and then transitioned to doing a very large amount of tobacco work and I at some point I had an R1.

Speaker 2
An R1 is a research project grant awarded by the National Institutes of Health in the USA.

Speaker 4
That was dual quitting of both drinking and smoking, but at the end of the day I find that I'm the most passionate about tobacco treatment, broadly defined, and I still care a lot about about alcohol research. I have my own personal patients that struggle with alcohol problems and smoking, of course, and vaping and zins and dipping and all the things.

Speaker 2
Zins are oral tobacco free nicotine pouches. Dipping is the use of a pinch of ground or shredded tobacco placed between the lip or gum, which is basically a form of smokeless tobacco.

Speaker 4
It's a much larger field now than when I first started, so when I started in the late 90s, all that you had was smoking. Almost nobody dipped. Obviously, there were no vapes, and now it's a much more robust field. I've been telling my colleagues it's so interesting and such an interesting field now and it's kind of re invigorated me to have this whole new group of very broad group of products to now study. It's fascinating, frankly.

Speaker 3
Yeah, yeah. And so dynamic, yes. Awesome. So, we're particularly keen to have you on the podcast to talk about your vaping cessation research, which I've seen you present at the e,-cigarette summit in the states earlier this year. So, before kind of talking us through your research, I wondered if you could tell us a little bit about what made you decide to conduct research on vaping cessation.

Speaker 4
Sure. So, I started the tobacco treatment service at the Yale School of Medicine in about 2010, I directed that service for about 5 years. I transitioned to the Medical University of South Carolina in March of 2015, and I've run that service for many years now, and it's a large tobacco treatment program. We treat thousands of tobacco users in the state of South Carolina and what I found in the past few years is that we have many, many patients that come seeking services to quit vaping and they don't know what to do. They're very pained that they cannot quit on their own. I've had patients that tell me it's harder to quit vaping than quit smoking and there's no evidence base. So as a scientist and a practitioner, I feel it's very important for our field to create an evidence base. So, I've been a part of what we call clinical practice guidelines for smoking and I'm currently co-chairing one and what we really need is an evidence base to create a clinical practice guideline for quitting vaping.

Speaker 3
Absolutely. So, giving us kind of like a bird's eye view, can you talk us through the research you've conducted on vaping cessation so far, it's kind of headline findings, if anything surprised you?

Speaker 4
Sure. So, I would say that at this stage of my career, I have led some of these things, but really I am enthusiastic and excited about leading our younger scientists and helping them to forge these empirical studies. I'm passionate about our next generation. So, I'll start by saying one of my mentees, Amanda Palmer, has led a few of these pilots and I'll say it's fascinating. So, I predict that things are going to go in one way and they go in a different way.

Speaker3
Oh.

Speaker 4
So, in Amanda's first pilot where she was treating both dual users and mono users, interestingly, with a standard dose of patch plus lozenge, interestingly, a decent number quit that were mono vapors, but in that first pilot none of the dual users quit, which I found to be shocking. Like I was shocked that none of the dual users quit with a fairly high dose of NRT. So that led Amanda to apply for a small pilot from our Cancer Center. It was sponsored by the ACS in the States and she is now winding up. So, she has I think one or two patients left on a pilot of 45 subjects comparing a standard dose of dual NRT to two augmented doses. So. A 21 milligram patch plus a 14 milligram patch plus up to 30 up to 30 lozenges and then a 21 milligram patch plus a 21 milligram patch. So, a total of 42 milligrams plus up to 40 lozenges. We haven't assessed the data rigorously yet, although it does appear that you need at least two patches to have a robust treatment signal. We have I think it's one or two left to accrue, but I feel pretty strongly that at least look, it's 2 small pilots that that show these data. So, we need large studies, but I feel pretty strongly that the people that they, especially the dual users, so both e-cig and combusted cig. They need a high dose of nicotine. They ingest very high dose.

Speaker 3
Yeah.

Speaker 4
And we need to give them, you know, very high doses and in fact, it makes me think of my earlier treatment days for cigarette smoking in which we found and you never thought of it this way. But in fact, the people with the highest quit rates for the initial studies that tested patch plus, lozenge had lower dependence, which, if you think it through at first you're like, no, it's for high dependence if you think it through, though, it makes sense that if you have low dependence and get a lot of nicotine, it's probably easier to quit. So it's fascinating. So that was our first few studies with Dr Palmer. And then I was talking with my good friend and colleague Dr Fucito at Yale, who I've worked with for at this point, I'm hard. It's hard to count, but I think it's 15 years. It's a long time.

Speaker 3
Amazing.

Speaker 4
And we were saying so we both have done many studies with varenicline, which used to be the branded drug called Chantix or Champix, it's no longer branded so, so it's a generic. And we said that we really need to do a study of this for quitting vaping because we're confident that it's going to work.

Speaker 3
Absolutely. Yeah.

Speaker 4
And those findings were really interesting too. So, we did a small pilot of 20 subjects per site. So, 20 Yale and 20 USC and what we found was interestingly so there's a treatment effect that's very clear. So this was a small pilot with a small budget and so we instead of doing this standard 12 weeks we did 8 weeks and a one month follow up.

Speaker 3
OK.

Speaker 4
And what we found was a 15% difference that favoured the treatment group at the eight week point, then that went down to about a 10% difference at the one month follow up. So, there's a clear treatment effect, but there's a few things that are interesting. First, I'll tell you that the safety profile appears great.

Speaker 3
Wonderful.

Speaker 4

So same issues with for those who've worked with this drug. It causes GI problems, it causes sleep issues. There's some things that it causes, and we found those. But I will say that the interesting thing for me, at least, were a) the quit rate in the control group was very high. It was 30%, which is a very high rate. It's it's. It is remarkable, like I've been doing treatment studies for smoking for years and years. The control groups almost never 30. Yeah, I mean, I did one with my colleague Dr Bernstein, who was at Yale, is now at Dartmouth. We had a study where the quit rates were 12 and 4. So I mean, like, really?

Speaker 3
Yeah. Yeah. Ohh. Yeah. I totally believe that.

Speaker 4
So yeah, so. Yeah. So that was interesting to me. I've shown these data to many colleagues and their gut reaction, which might be right, although I don't know, their gut reaction is that this is just not a super-addicted population. It's certainly a younger population. So that's possible. The other thing that's very intriguing, is that when you collapse the groups, so including the control, those with the smoking history had a higher quit rate. So, for me, that's a fascinating finding, which we're still trying to understand why that's true. Of course, I would think that's probably true in the intervention group. It's a drug that works for smoking and vaping, but for the control group, I'm not sure why that would be true. So it's it's fascinating, frankly.

Speaker 3
Yeah. Yeah. That's really interesting. Oh, there's so much more to be explored in this space.

Speaker 4
It's exciting. Yeah, yeah.

Speaker 3
So very exciting, but also vaping research can be intense space and I wondered if you'd had any pushback on studying vaping cessation and how you might see these sorts of studies sitting along studies where instead of encouraging people to quit vaping, people who smoke are actually given e-cigarettes to help them switch and move away from smoking.

Speaker 4
So, I'm a big believer in the continuum of risk. On the one side, there's no risk that would be like probably breathing in air, there’s no risk, right. And then it if you go along from air, if you go along to vaping, there's some risk but less risk than smoking where there's a ton of risk. There's a massive amount of risk and there's a massive amount of data that shows unequivocally smoking causes multiple cancers and multiple human organs. That's there's no question. If you dial it back though to the vaping space, we know there's less harm. But they're not harmless. So, as a provider of treatment services, I tell my patients that want to vape and quit. That's okay if you wanna do that. But I will not consent or agree to you staying on this product.

Speaker 3
Hmm.

Speaker 4
A lot of my patients have tried varenicline. They've tried NRT. They've done a lot of things and they feel like this is a last step, so to speak. So, I consent to them trying it, but I tell them I really want them eventually to stop using them. And I'll tell you, Jamie, that I found that most of my patients and what we found through large national studies like PATH, is that most people that use vapes plan to quit. Yeah. So, they don't see themselves using long-term. And I feel very strongly, especially because I'm approached almost daily through our treatment service, by people that want help quitting. I feel very strongly that we should give those services. There's some people, especially online, that tell me that I'm doing a disservice by telling people to stop vaping. And I just don't agree with that notion, especially because I'm not telling people to stop vaping. They're coming to me and I'm trying to help them. So that's a that's a nuance, but it's an important nuance. So, I'm not publicly saying you must stop. I have people approaching me that want, and plan to quit, and my opinion is that we must help them. I feel passionately that we must help all of these patients. There are loads and loads that come and they want our help and we just don't have evidence. It, frankly, it breaks my heart that we don't have evidence based treatments to help them to quit.

Speaker 3
Yeah. It seems like there's a real moral imperative here to do this research, so that because if people want to quit vaping, they're going to try to quit vaping too, right? And what you see in space is even where there is evidence, but particularly in spaces where there isn't evidence is also you end up with people trying whatever thing they can come across, which might not be evidence based, might be harmful might cost a lot of money, whatever it might be, and so you really do want to have the data there to support people to make informed choices.

Speaker 4
And I'll say one more thing to the part that I do have a problem with ethically is that in all of my writings, so we had a high-profile paper like with Brian King, who is the director of our Center for Tobacco Products at the FDA and a lovely person and a very good scientist. In all of our writings, we are unequivocal that we do not want youth to start vaping. And one thing that really makes me unhappy is that there are many people online that allege it's OK, or maybe even good, for young people to use e-cigarettes. And I feel absolutely contrary to that notion. There is no question in my mind, especially as a provider of healthcare that our youth who have a developing brain up until the age of 25, they should not be vaping. It's not good for their brain. It's not good for their health. It will probably addict them their entire life. Like I just, I feel very strongly that they shouldn't be vaping. And I've seen some of these vapes are incredibly appealing to youth and that does bother me. So there's a vape now that you can play Pac-Man on.

Speaker 3
Yeah, I've seen that one wild. Yeah.

Speaker 4
Yeah. There's all, all sorts, there's all sorts of problems. They're very appealing. They have great flavors, which are sometimes they are labeled in a way that's appealing to youth, like gummy bear, like pina colada. My opinion is that because they may help adults to stop smoking, I am OK with flavors, but why can't we call it fruit instead of gummy bear? Like I I just don't think that we have to call a gummy bear that is an appealing label for children,

Speaker 3
Yeah. Or like Unicorn and vomit, for example. Yeah. Yeah, yeah.

Speaker 4
Yeah, I just, yeah, don't think that's necessary. Yeah, let's just call it fruit. Let's just call it mint. Like it's. And I mean, I I just don't want to call it candy ice cream, a flavored beverage that kind of thing.

Speaker 3
Well, I don't wanna get us off topic, but I just I'm so glad to hear you say that because. I think when we talk about flavors and e-cigarettes, which we have some other research looking at it, very rarely do people differentiate between the actual flavor and the name of the flavor and in terms of what that means in terms of appeal. And those two things can have very different effects on different populations. So happy to hear you say it.

Speaker 4
Yeah, of course.

Speaker 3
Yeah, yeah.
So last question for you, what research and I know there's a lot of it, needs to be done next in your opinion when it comes to vaping cessation, what are our kind of top research priorities in this space?

Speaker 4
Well, so I really think we need to be creating new treatments for vaping. I have a study with Dr Fucito that got a very good score from the NCI.

Speaker 2
NCI stands for the National Cancer Institute, which is a U.S. government institution.

Speaker 4
That will be a larger scale, a phase two trial of varenicline for mono vaping. We need to do a varenicline study for dual users too. That's on the horizon as a study that should be done. Dr Palmer has submitted a grant, again that's with me for an augmented dose of nicotine.

Speaker 3

Great.

Speaker 4
For dual users, I think that has to happen, but the key to the game is this. I am one person that has a few lovely colleagues who I'm very fond of who are doing, I think, good work, but we need a lot of people doing it. So, to have a truly robust clinical practice guideline you need a large evidentiary basis, I mean, I know I'm kind of preaching to the choir upon saying that.

Speaker 3
You are.

Speaker 4
We need a large basis of evidence, and right now, if you go on to clinicaltrials.gov, there are 7 studies that are true clinical trials to help people to quit vaping. That is an incredibly low number. If you look at the clinical practice guidelines for smoking cessation, it's hundreds of studies. Literally hundreds. And what we need in my opinion, is hundreds of studies to help people to help people stop vaping.

Speaker 3
Yeah, yeah, absolutely. Across different populations using different interventions. Yeah. Yeah. So we can triangulate data.

Speaker 4
Yes, exactly. That use pharmacology that use behavioral treatment that combine both that use one or the other like we need a mix a broad mix of all different types of rigorous scientific investigations to truly build that evidence base up, yeah.

Speaker 3
Yeah, awesome. Is there anything else you'd like to add today?

Speaker 4
No, that's been great. I just want to say, I'll say one thing. I love your podcast. And I was so honored that you, that you, asked me to come and I just love the work that you're doing with all of the metas that show, that really give that evidentiary basis. And I think that you're doing great work. And I'm just.

Speaker
OK. Thank you.

Speaker 4
Well, I'm I'm very honored to be here.

Speaker 3
Oh, well, right back at you, Ben, and thank you very much.

Speaker 2

It was great to hear what Ben had to say about interventions for quitting vaping Jamie, and it's was a really good interview. I think one of the things that we've appreciated when we've been doing our review of interventions for quitting vaping, is that what we might see working in people when they're trying to quit vaping may vary dependent on their smoking history. And that's obviously something that Ben has noticed as well that some things may work better in, in some populations than others, however. I think he was surprised and I was also surprised to hear that actually some of the the work they've done has shown that people have found it easier to quit if they've previously smoked, whereas we'd probably expect it to be the other way round. So it'll be interesting to see what further research says in that area and whether some approaches are better for people who have quit in the past and some approaches are better for people who have just vaped and have never smoked that will be really interesting to see. And I also really like Ben's discussion of that continuum of risk, because I think it's important to say that obviously our first review of e-cigarettes for smoking cessation has shown that e-cigarettes potentially have this really important role in helping people to quit smoking. But we do need to understand that there are people either who have never smoked or who have smoked, who still then want to go on to quit vaping. It doesn't mean that they want to vape forever, and being able to give people guidance on how to do that is also really import.

Speaker 3
Absolutely, Nicola. It's nice to see the research in this area grow. I'm kind of excited for all the things that review will find and hopefully subsequent versions of the review will find too, because we know there's so many studies underway in this space. And I think when you're working in vaping, nothing is straightforward. It's always tinged with a little bit of politics and controversy and we know that's because it's a topic that matters to so many people, but I really like the way that Ben spoke about this topic. You know, he was responding to the need of people who are coming in and talking to him. And I think we have a real duty to make sure that the best available evidence is there for people making any healthcare decisions, including those involving smoking and vaping. And that is it from us this month. Thank you so much for listening. Thank you to Ben for coming on for this interview and his busy schedule. And we very much hope to be speaking to you again in next month's episode of Let's Talk E Cigarettes.
Please subscribe on iTunes or Spotify and stay tuned for our next episode.

Musical outro
Vaping is safer than smoking may help you quit in the end. But remember to mention the findings we have can't tell us what will happen long term, even though we know vaping is safer than smoking, we may still find cause for concern, if you're thinking about switching to vaping do it. That's what the experts agree. Smoking so bad for you they all concur that vaping beats burning there's much to learn of effect long term yet to be seen.
Speaker 3
Thank you to Jonathan Livingstone-Banks for running searches to Ailsa Butler for producing this podcast and to all of you for tuning. In music is written with Jonny Berliner and I and performed by Johnny. Our living systematic review is supported by funding from Cancer Research UK. The views expressed in this podcast are those of Nicola and I and do not represent those of the funders.