

## ***Airing Pain* Programme 79 – Side-effects, placebos and a brief history of nerve pain**

***Making sense of side effects, the power of placebo, and the improving treatment of neuropathic pain.***

*Tens of thousands of soldiers in the first World War survived with limb amputations but doctors and wider society were unprepared for and often unsympathetic to the long term pain they experienced. Professor Andrew Rice brings us to date with developments since then in treating pain caused by nerve damage and explains what makes neuropathic pain different from everyday pain.*

*Although the drugs used to treat neuropathic pain may have improved, side effects are still a major problem for many. Researcher Sheena Derry discusses how we can balance out the risks and benefits.*

*Understanding the harm caused by a drug can be challenging because even research study participants give sugar pills rather than real drugs may experience adverse effects. Psychologist Lena Vase explains that the latest research on the placebo effect shows that it's always worth a doctor's time to listen sympathetically to a patient.*

**Paul Evans:** This is ***Airing Pain***, the programme brought to you by Pain Concern, the UK charity providing information and support for those of us living with pain and for healthcare professionals. I'm Paul Evans and this edition is being supported by friends and supporters of Pain Concern.

Now, the eminent neuroscientist Patrick Wall was one of the founding fathers of pain research. One of his legacies was that he trained many of the leaders in pain research today – so it comes as no surprise that the annual Patrick Wall Lecture in his memory is awarded to established senior clinicians, academic experts – all pioneers who have advanced the science or art of pain medicine practice. The 2015 Patrick Wall Lecture took place at The British Pain Society's Annual Scientific Meeting in Glasgow. It was given by Andrew Rice, who is Professor of Pain Research at University College London.

**Andrew Rice:** I first entered pain research because of a particular patient. I was doing oncology as a very junior doctor and we had a patient who was dying – a young man who had a tumour invading... a lung cancer invading the nerves that go down to the arm (the brachial plexus). And there was nothing that could really touch his pain and it was a horrible way for him to die and a great lesson.

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So, I started to read about pain research and that was at the time that Patrick Wall was really in his pomp and making huge contributions. So, I had this intractable clinical problem on the one side and this hugely exciting area of basic research on the other and they just seemed to marry up to me and that has remained my stimulus ever since.

**Paul Evans:** Now, I'm not going to ask how old you are but let's say that that patient was 20 years ago.

**Rice:** [laughing] Considerably more!

**Evans:** Twenty years plus, then. Can I ask what has changed since then – how would you view that patient today?

**Rice:** Some things have changed; other things have not changed. Our understanding of neuropathic pain in particular has changed unrecognisably – we understand a huge amount about the mechanisms and the different types of diseases that can cause neuropathic pain – it is not only cancer – we can see it, for example, in diabetes or areas I work in particularly which is infection. We have more techniques to be able to treat the pain in those patients.

They are mainly drugs-based – there is very little evidence to support other techniques for relieving neuropathic pain in particular. Those drugs are certainly better than they were, some 35 years ago but they are still rather modest in their efficacy and they give people side effects so there is a long way to go.

**Evans:** Explain to me what neuropathic pain is. 'Neuro' is the nervous system...

**Rice:** Yes, so neuropathic pain is pain that is directly caused by damage to the nervous system. So that could be trauma, for example, an injury to a nerve or it can be damage to nerves caused by diabetes.

What distinguishes neuropathic pain from any other – in fact, Patrick Wall was one of the first people to point this out – is that most sorts of pain are useful to us in a perverse sort of way. If you have got an inflamed joint, the pain tells you that perhaps you shouldn't be moving that joint as much as you should. If you stick your hand on a hot coal, the pain will tell you to take your hand away.

Neuropathic pain is a disease of the pain system – something has gone wrong with pain processing. There is no painful stimulus, but people feel this spontaneous pain and often for many, many years, so it has no biological function – it is a sort of disease of the pain system

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if you like and you see it in the context of many, many different diseases. My own area of particular interest is infectious diseases.

**Evans:** So it's the brain pain signal working in overdrive, when it shouldn't be working at all?

**Rice:** Yes, exactly – but, it is not just the brain, it is also the nerves that go out to your skin, it is the whole passage of painful information from the very tips of your finger right up through the spinal cord to the brain – all aspects of that are involved.

In fact, one of the downsides of Patrick Wall's massive contribution was that he focused mainly on the spinal cord and it has taken us some 30 or 40 years to wake up to the fact that there is quite an important part of pain that sits above the spinal cord called the brain. We couldn't look at the brain 30 years ago – there were no real techniques. Now with modern brain scanning techniques – the people who do that kind of work are telling us huge amounts about the brain and pain and we know that there are profound changes in the brain in people who have had nerve injury.

**Evans;** So what's going on do you think?

**Rice:** One of the biggest questions is why not everybody with a nerve injury doesn't develop neuropathic pain. It's only about 25% of them – it's absolutely dreadful for that 25%. Why only about 20% of people with diabetes develop a painful neuropathy or nerve damage and it's trying to understand those differences – what differentiates that person from that person, why someone gets pain, is important.

What we think is going on pathologically if you like, in terms of the people who do get pain is, we think, an attempt by the nervous system to repair itself and it goes wrong and you get short circuits and things like that to put it crudely. One of great mysteries is that it doesn't seem to happen very often in children, very young children – I'm not an expert in that area – but it certainly seems to be the case – maybe their nervous system is more able to change itself correctly.

**Evans:** I'm trying to think about how that works. If I had an electrician to mend or change a light bulb and he did something very fancy that took out the whole electrics in the house, for no reason – that could be neuropathic pain?

**Rice:** Yes, in a way and the light bulb starts coming on when it shouldn't come on. I think one of the best examples of neuropathic pain that most people can understand is something we have been quite interested in this year particularly, with the anniversary of the first world war,

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is people who get pain following amputations of legs or arms – so called ‘phantom limb pain’ – that is a type of neuropathic pain – they are feeling pain in a leg which isn’t there anymore. That is quite a graphic way of describing what neuropathic pain is. Another feature of it is – some people feel pain where they are numb which is counter-intuitive – it doesn’t make any sense to some people. A lot of our patients find difficulty in finding the right words to describe their pain because it fits outside your normal experiences – but to feel pain where you are also feeling numb seems to be very odd but that is exactly what is going on.

**Evans:** A friend of mine describes it as *like putting your hand in hot water, a burning sensation that he can’t move away from.*

**Rice:** Yes, that is exactly the description that many of our patients give particularly the ones who have diabetes or nerve damage associated with HIV infection – *continuous burning sensation – never leaves them*, particularly bad at night, often.

One of the best descriptions of it came from a source that we have only recently found – someone who was way ahead of his time, a man called Weary Dunlop who was an Australian doctor and soldier and he was a prisoner of war in Malaya. Those people got neuropathic pain because their nerves were damaged by starvation, essentially. He gives a very succinct and evocative description of it which I still use in all my lectures to introduce it.

The people that had it (of course they had no shoes) they felt a continuous burning sensation that never left them and they suddenly also got attacks, lightning attacks of pain. Their feet were so sensitive they couldn’t even sleep.

One of the things that has happened over the last few years is – we have come to both in laboratory research into neuropathic pain and clinical research and clinical practice – we have come to regard neuropathic pain as a single entity whatever disease is underlying it – whether it is diabetes or an injury or a side-effect of being treated with certain drugs to treat cancer and we have tended to lump them all together and that is the way we have done the clinical trials of new treatments. That may be a huge over-simplification because most people in clinical practice and many of our patients will tell us that we know that certain drugs have an effect in some people but they seem to be ineffective in others and we can’t understand why that patient responds very well to this drug and this patient has no response at all – to exactly the same drug.

So, one of the important things in the field at the moment is to try and understand how patients with the same disease differ in the characteristics of their neuropathic pain – whether it is the

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symptoms they tell you about – some patients report this continuous burning sensation – other patients can say ‘I feel numb and I get these lightning attacks of pain that last a few seconds and then they go away and I don’t have the long term burning’. So, you can do it with symptoms perhaps or there are various measurements we can make and see how numb they are, see what they can feel. And that may enable us to predict which drugs work in some patients and which drugs won’t in others.

At the moment it is trial and error – we try that drug, if it works then we’ve got that. But usually we have got to go through two or three drugs before we find one that best suits our patient. The other problem is that although we have got a lot of new drugs and they are somewhat effective – they are only modestly effective. If I tell you that the best of the drugs we have only gives 50% of pain relief in every three or four patients treated – that is not very impressive to be honest – there is a long way to go in terms of developing new drugs. One of the ways that might do that is to target them to specific patient groups and there is emerging research to tell us that that might be important.

**Evans:** One of the issues that people with neuropathic pain face is that sometimes the treatment is worse than the disease or not worse than the condition but makes life unbearable.

**Rice:** You are absolutely right. Most of the drugs we have in our ammunition pouch if you like, have side effects – usually you get side effects at the dose that we need to treat the pain and they are not ideal.

Take a drug called amitriptyline, for example, which is commonly used for neuropathic pain – it is quite effective but most people tend to get side effects particularly the elderly and it may stop someone driving a car, for example. Now, we may have made their pain a bit better but if someone is no longer able to drive their car, that makes them much more socially isolated, so the balance may be that they would stop taking the drug because having the pain relief put them in a worse situation than not having the pain relief.

**Evans:** Professor Andrew Rice. Now I am just reading through the patient leaflet that comes in each packet of amitriptyline and the possible side effects that range from dizziness, confusion, fits, hepatitis, diarrhoea, high blood pressure, low blood pressure and on and on – enough to frighten the living daylights out of anyone who fails to read the caveat that as the leaflet says, ‘all medicines can cause side effects although not everybody gets them’.

I certainly experienced several of those side effects – a medicines review with my local pharmacist helped me identify them and put my mind to rest – but it is a bit of a conundrum

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isn't it? Too much information, which could lead the patient to forgo a highly effective and generally safe treatment or too little information that I suspect the lawyers would have something to say about. Sheena Derry is Senior Scientific Officer in the Pain Research Unit in Oxford. I met her at the 2015 British Pain Society Annual Scientific Meeting, where she was speaking about problems in identifying harm from medical interventions and how best to present information on harm to the user.

**Sheena Derry:** The dictionary definition of the verb 'to harm' is to damage or injure somebody or something. There is a clear implication of cause and effect there and in medicine it isn't always that simple. And one of the problems that we have in looking at harm with medical interventions is determining what adverse symptoms, adverse events are caused by the intervention and which are naturally occurring.

People can experience adverse symptoms even if they are not taking medication and some of those symptoms are the same as the symptoms that people experience as a result of taking medication. And one of the problems when we are trying to assess harm in medicine is trying to work out which of the events are due to the intervention and which would happen anyway. It is not always easy to do, in fact, it is usually not easy to do. There are other factors which can influence the harm that people experience.

**Evans:** In what way?

**Derry:** Well, for example, we know that participants in blinded clinical trials report adverse events even when they are taking an inert placebo. Now they have to be told about potential adverse events when they enter the trial – they receive the same information as the people who get the active treatment and there are studies that show that people [given the placebo] report – experience and report – precisely the adverse events they have been led to believe they might experience if they were taking the active treatment.

**Evans:** So at a very basic level, if I opened my packet of whatever I might be taking and looked through all the side effects that it could give me – if that was a placebo, it should have no effect on me whatsoever, I could experience the drowsiness, the whatever.

**Derry:** You could but we wouldn't necessarily know whether you would have experienced the drowsiness anyway or whether you are experiencing the drowsiness because you have seen it written down and it has been suggested to you.

**Evans:** The trick would be not to suggest it to me.

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**Derry:** It would and that is the dilemma that doctors have. There are doctors who say to me that they sometimes think, because they legally have to tell their patients about potential adverse events, they worry sometimes that they are actually causing events that the patient may otherwise not experience.

**Evans:** That actually is very pertinent because when you do read the list of possible risks of adverse events, you begin to wonder in real life – is this caused by the tablet? am I drowsy because I am tired? am I feeling nauseous because I've had some bad food or something? You could become a hypochondriac just by reading the booklet.

**Derry:** You could and there are patients who look at the list of adverse events in patient information leaflets and say 'I'd rather have the problem [laughing] and not bother with the medication and have this whole set of other things to deal with'.

They have to be listed there by law. People have to be informed. It doesn't mean that you *will* experience them, but clearly some people do if it is suggested.

There is some very interesting work going on at the moment, on how well adverse events are reported in clinical trials, which is badly, I have to say, and there are initiatives to try to improve that. Beyond that, there are attempts to, for example, start collecting core outcome data for specific therapeutic areas so that in clinical trials people are collecting the same information in the same way, so that we can then combine the trials together in a meta-analysis and get more robust answers. Because at the moment what is happening is that – a lot of the time different trials may be measuring the same thing, they are measuring a slightly different thing or they are measuring it in a slightly different way which then makes it impossible to combine it for meta-analysis or even just to compare it with another trial.

**Evans:** Somebody once told me that the perfect drug would have no side effects, would hit the spot for whatever it was taken and you wouldn't need the little slip inside that says you're going to have diarrhoea, you are going to be constipated all in the same go and this that and the other.

**Derry:** Or even that it probably won't work [laughing].

**Evans:** [laughing] Or even that it won't work, yes.

**Derry:** ...which is the likelihood, that you won't get the benefit either. It's all about putting it into perspective and there's no point in considering harm on its own unless whatever you are doing is so rare that you can just dismiss it.

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I had one slide up today where I had the risk of death from a gastro-intestinal bleed and risk of death from a heart attack that was associated with the use of an NSAID and that risk was coming in at round about the same as the risk of dying from any accident. I then put up the risk, the chance of the benefit, in this case it was 50 per cent pain relief and that was coming in very high at about 1 in 2. When you see it visually like that you might think, 'well, that seems worthwhile' but if that benefit was way down, near where those risks were – those risks take on a whole new dimension don't they? You can't consider one without the other really. There's *always* going to be a trade-off – one against the other.

I had another slide that looked at how patients do that trade off – what do they decide is an acceptable risk? So they looked at patients with osteoarthritis and they asked them what maximum risk increment would you be prepared to accept for each of a number of different adverse events in a trade-off for increased pain relief.

So they were offered an increase in pain relief for 2 out of 10 or 5 out of 10 and they were asked how much risk increment would you accept and as you would expect, they were prepared to accept a bigger risk increment for the less severe adverse events so oedema and dyspepsia were the two I had up. And they were also prepared to accept a bigger risk increment for a bigger amount of pain relief. So they were prepared to go higher for 5 out of 10 than they would for 2 out of 10.

But within those general observations, there was a huge variation between individual patients and what they felt was an acceptable risk increment. So, it is impossible to tell where any individual patient is going to balance that benefit and harm and where they decide to balance it now may change six months down the line. You know, it changes with time, it changes with circumstance so, it is a very fluid thing and it is a very individual choice as well.

**Evans:** Sheena Derry, Senior Scientific Officer in the Pain Research Unit in Oxford. She brought up the topic of the placebo effect and the psychological influence it can have on a patient's pain. Dr Lena Vase is a psychologist based in Denmark and placebo and pain is her area of expertise.

Now, I thought that a placebo used in blind clinical trials or even to placate a demanding patient by prescribing an inert medicine relied on deception – if the subject or the patient thinks it is the real thing, it may or may not have the same outcome as the genuine article.

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**Lena Vase:** It has been a common understanding that a placebo only works if patients are fooled and they don't know it is a placebo but no-one had actually tested that, up until recently. So a group led by Ted Kaptchuk, located at Harvard – they have conducted studies both within pain and antidepressive medicine where they have told patients 'what we are giving you now is a sugar pill. It is what we call a "placebo". There is no active ingredient in it but we know that if people believe that this may have an effect, they may be able to activate their own descending pain regulating system'. And then they took time to talk with the patient and ask how they felt and express empathy and it turned out that even though people knew it was a placebo, it did have a pain relieving effect.

**Evans:** That's astonishing.

**Vase:** Yeah [laughing]!

**Evans:** You're a psychologist [laughing] – what's going on?

**Vase:** It's simply that the patient's perception of the treatment does influence the pain experience to a high extent.

**Evans:** But the patient knows that there is no treatment...

**Vase:** Yeah, but still they are in a good treatment context, meeting a nice doctor, who takes time to talk about their symptoms and express empathy and tell them that this might be something that might help someone and that it might even help them.

**Evans:** The fact that a patient is speaking to a doctor, who may have a white coat or whatever, he may be in a hospital situation – the fact that he is there says something to him – I am being taken seriously.

**Vase:** Exactly, yeah. And we also have the opposite effect. Ulrika Bingel has conducted a very nice study where she gave active pain medication – remifentanil – to patients, which is known in a dozen studies to reduce pain, but she told the people that this is going to increase their pain, which was actually a lie, because the pharmacology of remifentanil works on reducing pain, but there she saw that the pain was increased.

So it simply tells us that the patient's perception of the treatment situation is also working on either reducing or enhancing the pain. What we really want is to have their own perception work along with the pain treatment we are giving and not work against it.

**Evans:** So as a psychologist, how do you do that?

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**Vase:** Well, first of all it is important to know that patient's perception of a treatment actually matters. Sometimes when you are in a hospital setting and you are very busy and you have a lot on your schedule and you only see a patient for a short period of time, then it is important to know that the patient's perception of this treatment actually also matters. So, all the basic things taking time to talk with the patient and hear how they are feeling and tell them what this treatment is going to do for them – that matters.

**Evans:** What does that mean for the health professional? How can she or he use that?

**Vase:** A lot of clinicians are really good at this and if they had good time, most of them would do it naturally. But sometimes they are under pressure and they don't have a lot of time and then we can be so focused that we think that the medicine is going to do all of the work by itself. So we just prescribe some medicine, give it to the patient and then they are out of the door.

We should try to avoid that and instead always have time to talk with the patient, hear how they are feeling, hear about their expectation and their emotions and try to optimise them in a realistic manner, so the patient's own pain regulation can work alongside the pain medication that we are prescribing.

**Evans:** So, it is a matter for the doctor to sit down, just take an interest in the patient rather than be clicking away on his computer screen and looking over this, that and the other.

**Vase:** Yeah.

**Evans:** It's common sense isn't it?

**Vase:** Yeah, absolute common sense, but now we can show it on brain imaging and all other stuff – that it actually matters.

**Evans:** That's the great thing about science, that common sense isn't believed [laughing] until you see it on a computer.

**Vase:** Yeah [laughing].

**Evans:** That was Dr Lena Vase. And I'll just remind you that whilst we at Pain Concern believe the information and opinions on *Airing Pain* are accurate and sound based on the best judgements available, you should always consult your health professional on any matter relating to your health and wellbeing. He or she is the only person who knows you and your circumstances and therefore the appropriate action to take on your behalf.

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Now, cast your mind back to the beginning of this edition of *Airing Pain* and you will remember that Professor Andrew Rice raised the topic of phantom limb pain. He is collaborating with medical historian Dr Emily Mayhew of Imperial College to see what can be learnt from the cases of British soldier amputees in the first world war.

**Rice:** After the first world war there were 41,000 surviving amputees. That's actually enough to fill Stamford Bridge, Chelsea Football's Club ground to give you some idea of the magnitude of it. These people lived – they were young men at that time, they had pretty much normal life expectancies and there was a lot of focus on artificial limb technology and that improved dramatically over the course of their rehabilitation. At the beginning of the first world war you had artificial limbs that were little more than wooden peg legs. By the end of the first world war you actually had ones with joints, they were articulated – a huge technological advance.

But their pain was largely ignored. Now, we know that a large proportion of them must have had phantom limb pain and others of them had a type of pain in the amputation stump where anything that touched a damaged nerve in the amputation stump – it would give them a lot of pain and obviously that means fitting their false leg was quite difficult. Their pain was ignored and there are two points to this which are relevant to modern day life: the first is that all the systems for assessing pensions, disability pensions... were based on what they could measure physically. So, if you had one leg missing you got less pension than if you had two legs missing. If you had an amputation above the knee, you got a higher pension than someone who had had one below the knee. So, it was an easy way of assessing the disability. They didn't assess pain at all as a disability and I think to some regard, we are often actually in that position still today, because pain is difficult to measure.

The second aspect of it is that damage to limbs and amputations and damage to nerves and things was the single most survivable injury, the biggest survivable injury of the first world war. If you were injured in the head or the chest, your chances of survival were quite poor. Most of the people who survived with injuries had damage to their legs or arms. That is exactly the same today with respect to conflict.

We see it both in victims of landmines in places like Cambodia and Sierra Leone, but we also see it in returning soldiers from Afghanistan. And what has changed through doctors in the military particularly – Dominic Aldington is one of them – they recognise pain much more

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as a disability now, than they did. So these soldiers are more likely to tell you about their pain and they are more proactive about managing it than they were 100 years ago, so we have learnt something about it then. But it is still the same injuries as it was 100 years ago – nothing has changed from that point of view.

**Evans:** That was Professor Andrew Rice – now taking up the point he was making, the next two editions of *Airing Pain* along with articles in our sister magazine *Pain Matters* will be devoted to supporting the needs of veterans injured in service. I will leave you with the words of army veteran Michael Clough whose horrific injuries following a parachute accident in Afghanistan resulted in an amputation and CRPS – that's complex regional pain syndrome.

**Michael Clough:** It's embedded into you from the day that you join the military that you are a fighting soldier. People carry on with broken bones, sprained ankles – it is just a part of the way of life that is embedded into you – that you continue to fight – that is installed into you from the day that you walk through the door at training camp. So if you turn around to a Clinician at Hedley Court and say that you have got severe pain – they know that you have got severe pain, that you are not saying you have got severe pain for the sake of it – you have actually got severe pain of some type.

**Evans:** Do you think that GPs in civilian life don't understand that?

**Clough:** Yeah, I think some of them believe that you are in the pain that you say that you are in. The pain team in the military Colonel Aldington and Sarah Lewis, the nurse – I think they will have provided the GP with enough information. The only trouble is that I think that the transfer of information is all done paperwork wise – a phone call would represent far better than paperwork being submitted via emails and things like that – because you can't tell a story via written paper – I think it is very difficult for them to explain someone's pain condition via a text format. I think it would be better for them to ring up and say 'I've got a soldier who's leaving the military now, he's got severe pain conditions – this is what he has tried – these are the paths that we have gone down with him and his pain condition is real' Ten seconds of talking there says more than 2,000 words would do on a written text page.

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## Contributors

Andrew Rice, Professor of Pain Research, University College London

Sheena Derry, Senior Scientific Officer, Pain Research Unit, University of Oxford

Leena Vase, Professor of Psychology, Aarhus University

Michael Clough, army veteran

## Contact

Pain Concern, 62-66 Newcraighall Road,  
Edinburgh, EH15 3HS

Telephone: 0131 669 5951      Email: [info@painconcern.org.uk](mailto:info@painconcern.org.uk)

[Helpline](tel:03001230789): 0300 123 0789

Open from 10am-4pm on weekdays.

Email: [help@painconcern.org.uk](mailto:help@painconcern.org.uk)

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