ABC

HD **New treatments for Hepatitis C**

WC 2,568 words

PD 5 May 2014

SN Australian Broadcasting Corporation Transcripts

SC ABCTRS

LA English

LP

Over 230,000 Australians have chronic hepatitis C infections.

Norman Swan: Hello, and welcome to the Health Report with me, Norman Swan.

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Today, does stress affect the onset or severity of breast cancer? Fascinating findings which suggest that doctors can't be quite so dismissive as in the past.

And another thing doctors used to be dismissive about: psychotherapy in psychosis. Even Freud thought it was a waste of time and he treated almost anything. Well, it turns out there is a role for talking therapies in conditions like schizophrenia.

That's all later, after what's becoming a typical good news bad news dilemma. New treatments are coming on stream for hepatitis C infection which can cure almost everyone carrying the virus. They come as pills and have few side effects, apart from their cost that is.

One of Australia's leading authorities on hep C is Professor Greg Dore who's head of the viral hepatitis research program at the University of New South Wales.

Greg Dore: Hepatitis C is a chronic viral infection that affects the liver and causes a progressive scarring process that can **lead** to cirrhosis and complications, including liver cancer.

Norman Swan: And how do you catch it?

Greg Dore: In Australia the predominant means of infection is injecting drug use, so people who share contaminated injecting equipment. On a global scale however the most common means of infection is actually contaminated injections within the healthcare setting.

Norman Swan: There used to be this cascading notion that of 100 people who got hepatitis C, so many got liver disease and so many ended up with liver failure and a liver transplant or dying. What's that story?

Greg Dore: So those that become infected, three-quarters go on to develop a chronic infection. And of those people we think about 20% to 30% will progress to cirrhosis.

Norman Swan: And is there any sexual **acquisition** of hepatitis C?

Greg Dore: Minimal. I mean, in the context of men who have sex with men, particularly HIV-infected men, there seems to be an emerging sexually transmitted epidemic. But in the heterosexual setting we very rarely see cases of sexually acquired infection.

Norman Swan: And living in the same home as somebody with hepatitis C?

Greg Dore: Almost never seen.

Norman Swan: How many Australians have chronic hepatitis C infection?

Greg Dore: Around 230,000.

Norman Swan: So it's a lot.

Greg Dore: And it's increasing in terms of the burden of disease. So a lot of people have been infected now for 20, 30 years. People who became infected through injecting drug use in the '70s, '80s and '90s, and that's producing more and more advanced liver disease.

Norman Swan: And it's almost universal on exit from Australian prisons.

Greg Dore: It is very high prevalence. So around a third of inmates would have hepatitis C, so it's a big problem in prisons across the country.

Norman Swan: So things have changed. It used to be untouchable, incurable, we only barely had a test for it.

Greg Dore: Enormously. I remember giving a presentation at a conference in the late 1990s and I said back then that no one should be treated for hepatitis C because the results were so poor and the success rate was only 5% to 10% and there were significant side-effects. But it looks like in the near future we will be curing more than 90% of people who commence therapy, if we can get access to these new regimens that have been recently developed.

Norman Swan: So what's changed?

Greg Dore: A couple of key things. Treatment has been Interferon based for the last two decades.

Norman Swan: Interferon is a drug that has some antiviral effects but also influences the immune system.

Greg Dore: Exactly, and it's given subcutaneously, so injections once a week in combination with tablets, and the main tablet being ribavirin.

Norman Swan: Which is like an antibiotic for viruses.

Greg Dore: Yes, exactly. So that sort of combination has cured around about half the people we treat. But it's had significant side effects, it’s required at least six months, often 12 months of therapy.

Norman Swan: And what's new?

Greg Dore: This amazing turnaround. We've moved from that era to an era where we look like we are going to completely remove Interferon from the treatment regimen.

Norman Swan: Because that's the cause of a lot of the side effects.

Greg Dore: Absolutely. And we will have regimens that will be all oral, will require generally only 12 weeks of therapy, will have very limited if any side-effects, and provide cure rates above 90%.

Norman Swan: And what the technology that's done that?

Greg Dore: There are classes of drugs now that directly inhibit the key enzymes that are involved in replication of the virus. Unlocking the way that the virus replicates has enabled people to develop therapies, as I said, that directly inhibit these enzymes. So combining a couple of those inhibitors together provides a very potent effect on the virus.

Norman Swan: Now, I should have a declaration of interest here; I have spoken at symposia sponsored by the drug **company** that produces the latest drug. Have you got any conflicts of interest you'd like to declare before we go on with this?

Greg Dore: I'**m** an advisor for several pharmaceutical companies that are developing different regimens.

Norman Swan: And having said that I was at a symposium sponsored by this, they're charging an outrageous price. They are charging…what is it, $100,000 for a treatment, just extraordinary sums which are hard to explain.

Greg Dore: So the first key direct acting anti-viral that I think will be part of the main treatment armoury over the next decade or so is a drug called Sofosbuvir, and it's listed…it's just been approved in the United States…listed at a price of $84,000 for a 12-week course. There is another agent, a protease inhibitor called Simeprevir, $66,000 for a 12-week course. And a lot of clinicians in the United States, now that those two drugs are approved, are in fact combining those two drugs, which is a very effective regimen, but that's $150,000 for a curative course of therapy.

Norman Swan: And of course the drug **company** will say, well, I've saved somebody from liver failure and liver cancer and saved their lives and how much do you value that, therefore it's cheap at the price. But it's a lot of money.

Greg Dore: It is a lot of money if you want to treat a lot of people.

Norman Swan: So you're saying you've got 230,000 people with chronic hep C, when do they qualify for this drug if it was approved?

Greg Dore: I think that's the key difference. To date we've only been treating 1% to 2% of that chronic infection pool per year, so only a few thousand people in Australia per year have been able to be treated, and part of the reason why the treatment numbers are so low is because of the toxicity of therapy and the difficult course of therapy. So now that we're going to transfer from that paradigm to an incredible paradigm potentially with limited side-effects, high cure rates, and therefore we expect a huge demand of those people coming forward to access that therapy. I think the government is going to be very concerned about that potential wave of the new demand and the high cost of therapy. So the next year or so in terms of evaluation of these regimens as they move through by the Pharmaceutical Benefits Advisory Committee will be obviously crucial in terms of the broad strategy.

Norman Swan: It's going to be very hard for them because it's going to be a vast amount of money in a shrinking budgetary environment. What I don't get is why don't doctors, specialists like you, rise up in arms? This is what happened at Memorial Sloan-Kettering a couple of years ago, a new cancer drug comes on, the cancer specialists there thought it was completely outrageous, the price, and hard to justify, and they just said, 'Sorry, we can't afford to buy it and we're not going to buy it.' And because they were the key opinion leaders in the United States in terms of this drug, the drug **company** immediately or relatively soon dropped their price quite dramatically. Why don't specialists get together and say to the drug **company**, 'Jack off and reduce your price, because we are not going to prescribe it. It's unfair.' You're not going to be able to afford the drugs for your HIV patients.

Greg Dore: I think it's an important point. What is happening at the moment is that there are some good partnerships across the sector between the community-based organisations, the key peak bodies in terms of clinicians, to try and come together to develop an advocacy strategy around this. We all want the best possible therapy for people affected by hepatitis C, there's no doubt about that.

I think Australia at least has a reasonable system in terms of pricing. So we won't pay those premium prices that are paid for in the United States. We always pay significantly less than that, but it still will be a sizeable amount of money. And if the bucket is not able to be enlarged in terms of the total spent on hepatitis C, we'll still be restricted in terms of the total number of people we'll be able to treat. And those restrictions will probably be based on either people with more advanced liver disease or what we call a cap on the total numbers of people who can be treated per year. So you're right in the sense that if we could help to negotiate a considerably lower price, clearly the number of people able to be treated would be expanded significantly.

Norman Swan: But it's hard to justify. I mean, I think that somebody did what the cost of, including amortising the cost of development, and it's in tens of dollars, not thousands or tens of thousands of dollars.

Greg Dore: Absolutely, there's been some really nice work recently done coming out of the UK that has stated that the production price for a 12-week course of highly curative therapy is maybe $100 to $200.

Norman Swan: They deserve to be reimbursed for their research and development.

Greg Dore: Sure, that will be the pharmaceutical industry argument, that there needs to be return on investment. It's a huge investment to bring these agents right through to licensure. But what is happening I think globally is a range of advocacy movements to try and sort out how we can improve access, and access in different settings, so access in low and middle income countries. The interesting thing about hepatitis C is that the majority of people actually live in middle income countries such as India and **China** in terms of the global burden of disease, but also access in high income countries like Australia. We have a constrained fiscal environment, as you pointed out, so we need to develop a strategy that will give us the best potential access and the best solution for people affected by hepatitis C.

Norman Swan: Of course another argument from the pharmaceutical industry I presume is, well, you know, 12 weeks and they're cured and then we don't have further use for this drug. Are there likely to be other uses of drugs such as these? Are they only active in hepatitis C or are they useful in HIV and other viral infections?

Greg Dore: They are really only active in hepatitis C in terms of their activity. I think one of the other arguments they use is that treatment for hepatitis C over the last decade or so has been expensive. So Interferon, the monitoring of that therapy, the management of the toxicity of that therapy, the length of that therapy is equal to a fairly large spend. But as I said before, the total spend has been constrained by the…

Norman Swan: Narrowness of the base.

Greg Dore: Exactly. So now in terms of a public health approach, if you really want to impact on this rising burden of advanced liver disease, we have to treat three, four, five-fold the number of people we've been treating over recent years, that's what we want to achieve at a population level. So we are only going to do that if we can get the government to increase their investment several-fold in hepatitis C or, as you say, get a much cheaper price and enable expansion in terms of the numbers that we treat.

But I think part of the solution is there in the fact that we have several companies that have what I think will be very competitive successful regimens moving through towards licensure. If it was only one or two companies it would be problematic, but if we have five or six companies that have very effective regimens, there will be competitive pricing, there will be no doubt about that.

Norman Swan: In a sense there is a big stigma around hepatitis C, that you think it's just…I shouldn't have used the word 'just'…but you think it's just people who are out on the streets mainlining heroin or cocaine or what have you, but it is much broader than that in the population.

Greg Dore: Yes, I think that's a really important point, there's enormous stigma around hepatitis C and that clearly is related to the alignment of hepatitis C with the main mode of infection being injecting drug use. But the reality of people with hepatitis C is that they are an incredibly diverse population. I see people in different clinical settings. And sure, I see people who are still injecting and have significant social and health issues related to that injecting, but I see many, many people who might have injected for a very short period of time and are what you would call…

Norman Swan: Lawyers, doctors…

Greg Dore: Exactly, like us! Very much part of…

Norman Swan: Are you about to tell me something, Professor Dore?

Greg Dore: No. Very much part of mainstream middle class Australia. And they are a very, as I said, diverse, interesting population of people, and it's a real privilege to be part of the care for those people.

Norman Swan: Greg Dore, thank you very much for joining us on the Health Report.

Greg Dore: A pleasure, Norman

Norman Swan: Professor Greg Dore who's head of the viral hepatitis research program at the Kirby Institute at the University of New South Wales.

You're listening to the Health Report here on RN with me, Norman Swan. Still to come, is breast cancer made worse or even caused by chronic stress? That's later.

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