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# ECHO: HCV AND INJECTION DRUG USE

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**[video transcript]**

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So I'm going to talk to you a little bit about Hepatitis C with a focus on people who inject drugs. You see here, just in terms of disclosure, I do, or have received research grants support to my institution from Gilead. In terms of topics, you know, it's a relatively quick talk that we're going to go through today, we're going to review the epidemiology of Hepatitis C among people who inject drugs, discuss the importance of treating this patient population in particular, and the available treatment regimens. And then sort of spend a few minutes summarizing some of the innovative strategies models of care. And specifically, I geared this talk a little bit more towards the New York and New York City, New York State models of both care and numbers. I think that was the audience that we're a little bit more focused on. But globally, you know, I think most or not all of you know that Hepatitis C is a big issue and people who inject drugs, if we look at this map here, where there is available data, almost all countries have seen a zero prevalence of Hepatitis C of greater than 40%. And people who inject drugs, and oftentimes that zero prevalence is greater than 60. And occasionally greater than 80%. There are about 10 million people who inject drugs, who have Hepatitis C. And that's about 67% of the total population of people who inject drugs. So about, you know, 15 million people who inject drugs, 10 million of them infected with Hepatitis C, and about 80% of new and that number is actually probably increasing but of new Hepatitis C infections result from injection drug use. Those numbers are pretty consistent with what we're seeing in New York state. So this is this the most recent New York State dashboard. And risk factors for newly acquired Hepatitis C 72% of the total reported a history of in injection drug use. And that number is even higher, when we start looking at people less than four years of age, where about 87% of people infected with Hepatitis C, have a history of injection drug use. What that's resulted in is sort of a shift in the epidemiology of Hepatitis C over the last decade or so. If you look at the the sort of table on the left, that was 2010 data, this is when Hepatitis C was really concentrated in the baby boomers This is was followed or correlated with the recommendation to screen sort of the birth cohort. Those that were you know, born in that era, where 1955 1965, and you can see it really did peak in that population, both men and women. Over the last decade, though, that graph has changed substantially. Now, this is active cases of chronic Hepatitis C. So a lot of the individuals on the left of the graph may have been treated and cured of their Hepatitis C. But we're starting to see a bimodal distribution in many geographic regions where we have sort of this increase in young people with Hepatitis C, and still a bit of a population in older individuals as they've aged from the birth cohort. Again, this is specifically New York City data that I'm showing here, but it represents or similar samples or graphs are seen sort of nationwide. And this includes New York state data. So this is the New York State case rates from 2019. Basically the highest rates we're seeing in individuals aged 25 to 34. And that was significantly higher than what was seen in the baby boomers. And one note that they made, which I won't make more than this one time is that 60% of the female cases are seen in women of childbearing age. Despite the growth of Hepatitis C and these young individuals, there is excitement in the field about eliminating Hepatitis C and specifically, I think around 2015 2016 That who set out the with the goal to eliminate Viral Hepatitis C is a major global health threat by 2030. They set some targets with

hope of diagnosing 90%, treating 80% and subsequently reducing Hepatitis C associated mortality by 65%. And the United States followed suit, first with the National Academies of Sciences, Engineering and medicine, basically adopting similar goals. And subsequently New York state, New York City, the Biden administration have all targeted 2030 for elimination. However, you know, not surprisingly, for people probably on this talk Hepatitis C elimination in the US is not feasible without engaging and treating and curing Hepatitis C and people who inject drugs. Where do we stand? Internationally, this is the estimated year at which each country is going to eliminate Hepatitis C, the countries on the top in green are those that are or were on target to eliminate Hepatitis C by 2030. And you can see some of them like Iceland have essentially eliminated Hepatitis C, we won't get into why, but it's a kind of an interesting case study. And you can see a lot of Western European countries are similarly on, on target. There's a few countries in yellow and orange, which are behind the 2030 target, but you know, some not far behind and some still on target to eventually eliminate. And it's buried at the bottom of the screen, partially because of alphabetical order is the United States, which is basically not on target to eliminate Hepatitis C by 2050. At its current rate. Why is that? You know, I think there's, there's multiple reasons that we'll get into, but, you know, this is slightly outdated, it's probably better than it used to be, but it still remains a challenge to successfully take Hepatitis C infected people who inject drugs and get them cured and take them through the care cascade. We, you know, in this graph, there's demonstration of huge drop offs just in screening, linkage to care, treatment, initiation, and then eventual cure. And really, we need to do better at engaging these population, to get them on treatment and figure out ways of doing so.

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That being said, we have the tools and I think some of the countries that I mentioned earlier that are on target to eliminate Hepatitis C have changed treatment models to address these barriers and improve that cascade. You know, I sort of break up the the main pillars of elimination into prevention, diagnostics and treatment, so we'll kind of touch on each of them briefly. But, you know, I think prevention is still a huge component of Hepatitis C elimination and prevention incorporates re infection prevention and in many individuals and it, it is really a combination of harm reduction, including needle syringe programs and opioid agonist therapy. Just kind of displaying some of the the literature I think this meta analysis done a couple of years ago sort of highlights the effectiveness of harm reduction in preventing Hepatitis C. So there was really a study looking at the effect of opioid agonist therapy or methadone or buprenorphine on the risk of Hepatitis C acquisition. And on the left, you can see that studies that incorporated methadone and buprenorphine or opioid agonist therapy showed a 50% reduction in Hepatitis C incidence. In the sub analysis of these studies, they broke it into studies that had high coverage of syringe service program, or SSP, versus those that had low coverage of syringe service program. And you can see here that those studies that incorporated or were associated with high needle syringe service access, the risk reduction was even more substantial 71% and those that have low coverage was about 24%. So unfortunately, in the United States coverages sporadic, not necessarily correlating with the use of injection drug use, or with where Hepatitis C is actually occurring. So I think this is a really interesting visual of where we stand. So each of these black triangles is where a syringe service program is located within the United States. You can see for the most part, it's a bicoastal phenomenon with some additional services sort of in the Midwest.

I think the exception is New Mexico, which has been doing an amazing job at harm reduction services. Then each red dot, a new case of Hepatitis C, and you can see that ideally, you know, these red cases would overlap with these black dots, but they're not and I think this is the challenge that the United States is facing when we start talking about elimination, we might be able to eliminate on a regional basis. But, you know, take a look at Florida and imagine trying to eliminate Hepatitis C, if harm reduction and reinfection prevention is going to be a big component with their one syringe service program at the University of Miami. Just in general, just to give you a perspective of where the United States stands in regards to other countries, I think this is an interesting sort of bubble plot. So the size of your circle is how many people who inject drugs you have within your country, the y axis is the number of needles or syringes distributed per person who injects drugs per year, obviously, going up more or higher SSP coverage. And then on the x axis is those that are on opioid agonist therapy with, you know, more people being on opioid agonist therapy being considered high coverage. So a lot of those countries that I showed on the earlier graph that are on target to eliminate Hepatitis C, Australia, Spain, France, they live in this sort of right hand upper corner of the graph. And you can see that the United States is not there. We don't do as well at needle distribution for various reasons. And we don't do as well and opioid agonist therapy. And I think we need to improve on both of those if we really are going to make a huge impact. Symbol testing a diagnosis, this is going to be a 32nd explanation. But basically, we have the tools to some extent to diagnose and rapidly Hepatitis C. However, the diagnostic companies are not interested in marketing it in the United States, so they're like Cepheid, for those that are familiar. The gene expert machine can do point of care, confirmatory testing. But it's not been marketed in the US and can really only be used for research purposes. So going back to this graph, we still rely on this laborious Hepatitis antibody screening, which can still be done rapidly using or quick fingerstick. But then, we still need to do confirmatory RNA testing. A lot of insurance companies are still requiring genotype testing, or fibrosis scoring. And we see a significant drop off in patients because of that lack of point of care testing despite its existence. But really, why elimination has been thought to be a possible is the change in treatment, where we now have oral medication with high cure rates and cure no side effects. So just walking us through the history of Hepatitis C treatment in the early 90s, when interferon therapy first sort of took root or first started being investigated, you can see the cure rates were abysmal, and they didn't get much better through the early 2000s. They improved slightly with a lot of toxicity with the early generation protease inhibitors. But really 2014 was the landmark year in terms of Hepatitis C treatment when sofosbuvir Vir was FDA approved, initially in combination with lupus vs Harvoni. And you can see some of the subsequent What are now considered direct acting antiviral agents, where a cure rates went from very low to greater than 90%. And we're talking oral medications, eight to 12 weeks of therapy, and quite simple and easy for people to take. However, there remains significant barriers. For people who inject drugs to access treatment. A lot of them are on the patient level. You know, a lot of these individuals have ongoing comorbidities, they have competing priorities related to managing them withdrawal symptoms or cravings. Oftentimes, they have unstable housing, they lack reliable transportation, and they have prior negative experiences with health care facilities and may feel on willing to go to these sites. There are additional provider level barriers. You know, I think there's a perceived lack of value in treating these individuals by some providers, whether that be because they just feel like they're going to get reinfected or some nihilistic view in that regards. There's concerns about adherence. A lot of

times these individuals might not show to an appointment or to and there are limited time and limited providers. And so it does get challenging and overcoming those barriers is important. And, you know, one of the biggest barriers remains sort of structure Well, barriers in terms of insurance access. Again, in New York State, its insurances will approve it, but they come up with new and novel ways to create barriers. You know, it used to be where we would have to do prolonged prior authorizations, a lot of the prior authorizations have gone away. Now, what insurance companies are doing is they're restricting their pharmaceuticals to preferred specialty pharmacies, many of them out of state, places like Magellan or a credo optim RX. And really, I think those this is my personal opinion, but these specialty pharmacies goal is to not prescribe the medication. And that's sort of maximizing profit in that regard. So you really have to be proactive and pushing these specialty pharmacies to actually dispense the medication. But we know when they medication does get into the hands of these individuals cure rates are similar to what's seen in the general population. This was a meta analysis published in 2018, with some of the earlier studies that looked at direct acting antivirals in people who inject drugs. And you can see cure rates were, you know, on average about 86%. And that's not significantly different from what's seen in the in the general population. One of the bigger concerns that I mentioned was reinfection, and reinfection does occur. And it was found to be about five or 6%. I not including them in this study, but that sort of rate of reinfection or five or 6% per 100 patient years, is still a very cost effective intervention. And we just need to be willing to retreat. And I think this is an interesting

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sort of modeling diagram to think about, which is, if we decide to treat 1% of people who inject drugs, we're going to have a nice low rate, or low number of reinfections. But we're never going to actually achieve elimination. The more we treat, the more reinfections We may see. But at some point, we're treating past the epidemic and can start thinking about elimination. So this is really, I think, a useful visual and we start thinking about elimination was peak at the time. In New York City, you know, there's been a lot of focus on better models of care delivery for people who inject drugs. A lot of it has been, you know, thinking about where this patient population frequency going to these sites and providing them easy access to care there. So this was a study done by Matt Akiyama, Alan Litwin, and the group up at Montefiore, basically a randomized control trial in an early direct acting antiviral agent, where people were randomized either to individual self administered Hepatitis C treatment, group treatment, meaning they would attend a weekly treatment group or directly observed therapy. The primary endpoint was actually adherence, secondary endpoint was treatment completion and SVR 12. There was a little bit better adherence in terms of who we want to talk about primary outcomes in the directly observed therapy arm. But you know, sort of what I highlighted here at the bottom is, even without investing in expensive directly observed therapy, individual treatment in these individuals. This is again through a methadone clinic, we're able to achieve cure rates greater than 90%. And that was one of the studies another study that we've been working on is actually co locating Hepatitis C services on site within a needle syringe program. So this was a randomized trial that was conducted a little bit more recently included people who had injected in the last 30 days and they were either randomized to onsite treatment, which included medical evaluation, phlebotomy service and treatment follow up at the lower Eastside Harm Reduction Center, or the control arm which was a referral to an on site within the needle exchange HCV

care coordinator that was funded through the New York City Department of Health Check Hep C program, and that navigator or care coordinator attempted to then link them to existing Hepatitis C providers in the community and get them treated that way. The primary outcome was the percentage of patients who achieved SVR 12 within 12 months and we had some secondary outcome outcomes looking at steps along the care continuum. So in terms of the full population, you can see in those that had basically colocated service for the accessible care study, we were able to cure 55 of the 83, who were randomized, and that included about 86% of those that initiated therapy. So again, curating those initiated therapies is in line with a lot of the other studies, in comparison, only, you know, 23 or so percent of those that were got went through the check Hep C program and refer to community providers were able to achieve cure. And as a result, you can see through these varying care cascades that a lot of the drop off is really just linking these people with providers. And I think that's sort of the the main take home message is, what we need to do is we need to make access to providers and getting these people on medication easier for this patient population, because again, independent of which arm you were on curates in this population are about 86%. But it's just getting them to initiate therapy that that took some some time. It shouldn't be getting easier. All right, this is current guidelines from if you go to HCV guidelines.org. These are sponsored by the A S LD and the IDSA. And there's really a movement for simplified Hepatitis C treatments. So unfortunately, in New York State, this doesn't always exist. But one of the things that this mentions is we're doing a lot of baseline laboratory tests that we don't need. And we don't need specifically a genotype because the two regimens that were being are being approved for treatment naive individuals are both pen genotypic. So, the reason insurance companies are requiring genotypes is simply a barrier. Similarly, a lot of work has been in gone into whether we actually need to do you know, involved fibrosis screening, and I think the consensus is becoming for most patients know, that a fib for which can be calculated with just age and platelet count as tn It is sufficient, assuming that that number is within a relatively normal range. So simplified treatment algorithm, treatment naive people without cirrhosis. Now there's a few exceptions, if they're pregnant, they should probably see and have additional screening and probably delayed treatment until we have better data. Those with cancer liver transplant should not go through this simplified model. But basically, baseline lab testing a CBC LFTs could get a kratom. At some point in the past, they should have had an HIV test or, you know, screening for Hepatitis B and A baseline confirmation of Hepatitis C infection. And that's it with the exception of the pregnancy tests. Oops. So, get these things, prescribe one of these medications. And unfortunately, you know, we're as much as we can sort of theorize that this is the way to go, it still remains a bit of a barrier, but I hope that we can we can get there soon. And, you know, piecing through these HCV guidelines. I think one of the take home messages for people that don't do a lot of Hepatitis C treatment is it's actually really easy no matter what algorithm you go through in terms of genotype, even if they have cirrhosis, but are not D compensated cirrhotic. The treatment recommendation is one of these two regimens. So this is basically the fancy word for Maverick. And this is Eplusa, which comes also as a certified generic version of Eplusa. And that's those are basically the two medications you need to know as a as sort of a basic provider. So, in conclusion, direct acting antiviral therapy is safe and effective and we can achieve high cure rates and people who inject drugs. We need to acknowledge and accept that Hepatitis C reinfection will occur when we treat HCV. And if we're not actually getting reinfection occasionally, we're probably not aggressive enough with the people that we're treating. I didn't get into that so much. But you know, a lot of these

people who get reinfected or have acute infection, they're the people that we want to treat, again, because they're probably the ones that are most at risk of transmitting their infection. They're the ones that are engaging in some of the highest risk behavior. And if we can just get rid of the infection, we can decrease transmission. Testing, diagnosis and specifically Linkage to Care remain significant barriers and must be addressed. And really, you know, there's not one size that fits all. I think it's really acting regionally. And thinking about micro elimination because you know, what we do here in New York might not be something that makes sense in various jurisdictions around the United States or around the state. But really, I think the goal is to figure out ways to make treatment accessible to bring treatment to where people who inject drugs feel comfortable, and where they're willing, they're going to be willing to come back to and finally, simplification of models of care will be essential. If we are truly to eliminate Hepatitis C.

[End Transcript]