

# VA Mobile Discussion Series

## GDx

**DENISE KENNEDY:** Hello everyone. Welcome and thank you for attending our VA Mobile Health Discussion Series webinar. My name is Denise Kennedy, and I'm going to run through a few brief technical reminders before we begin the discussion about GDx.

Your phone lines are muted. We will be taking questions through the chat feature, which is available to you at the right of your screen. If you experience any technical difficulties, please use the chat and someone will be in touch to offer assistance. To respect everyone's schedules, we will keep this moving.

Today we welcome Dr. Michael Icardi, National Director of VA Pathology and Laboratory Medicine Science, and Dr. Julie Lynch, Nurse Research Scientist at VA Informatics and Computing Infrastructure. Also joining us today to assist with questions is Connie Murphy, VA Program Manager.

With that, I'll turn it over to you, Dr. Lynch.

**JULIE LYNCH:** Thank you for the introduction, Denise. I will start by providing an overview of our presentation. We will first describe what the GDx mobile app is and then discuss why there is a need for this application. We will then briefly describe the role of precision medicine in the care of Veterans. Dr. Icardi will go through the functionality of the GDx App and will conclude with a description of why VA is positioned to be a leader in the delivery of precision medicine.

I want to start with a story to describe how the GDx mobile app began because I think it demonstrates the opportunity and power of VA as a national healthcare system, as well as the importance of working with good people. I joined VA as a post-doctoral fellow in VA's Health Services Research and Development Service's research center. The job of a fellow is to get research funding and publication. However, I care much more about improving clinical care. Under Dr. Icardi's direction, we started doing the work to get monthly data feeds for all the molecular tests that were sent out to contracted labs.

This initially was a totally unfunded effort. I wrote and revised a 30-page grant proposal three times; however, I failed to convince VA's Health Services Research and Development Service that what we were proposing was feasible. So, before giving up completely, I submitted a one-page online application through Connected Health. When I got an email from Lynn Blendell saying that Connected Health was interested, I was delighted that all our work would not be wasted. I remember that Dr. Icardi told me, "Julie, be like a drip of water that breaks open a canyon." Little did I know that the work was really just beginning.

The GDx App provides Veterans and VA clinicians with information including test orders, results and links to educational information about their genetic tests. We have established electronic data interfaces directly with the labs or through Cerner Reference Lab Network that will allow

labs to send genetic tests results as structured data through the mobile application environment.

Why do we need a mobile application to deliver genetic tests? Before the GDx project, results from genetic tests were being sent as faxes and scanned into the Computerized Patient Record System (CPRS) through VistA Imaging, which made it impossible to analyze whether Veterans were accessing guideline-recommended tests and what the prevalence of genetic markers was among Veterans. Lack of structured data became a problem because there were a substantial growth and use of clinical genetic tests.

The graph in the upper right-hand corner is from the National Institutes of Health (NIH) Genetic Test Registry. The red bar represents the conditions for which tests are developed and the green bar represents the number of tested genes. You can see that the number of conditions tested has doubled from 5,000 in 2014, to 10,000 in 2017. The purple bar illustrates that the growth in the number of labs does not explain the growth in tests. The blue bars in the graph next to that illustrate the number of tests. We have been lucky at VA because pathology departments are the guardians/gatekeepers to testing. There has not been the level of inappropriate testing that we've seen in other health care systems. The important thing to point out about this growth of clinical genetic testing is that it has substantially increased the complexity of care. Clinicians need decision support tools to help them guide care. Health care systems need structured data to populate those support tools.

The next slide illustrates some of the important clinical conditions where genetic testing is recommended by clinical practice guidelines. Tumor genetic testing is now standard of care for several cancers. Veterans now have access to next-generation sequencing through VA's Precision Oncology. Hereditary genetic testing is becoming important for Veterans with breast, ovarian, pancreatic and prostate cancers as BRCA mutations identify Veterans who will respond to specific FDA approved medications. Important innovations in the treatment of Hepatitis C are greatly improving health outcomes for Veterans; however, there are Veterans who do not respond to treatment. It's important to identify genetic changes in the virus that may facilitate resistance. Pharmacogenetic testing may help identify the most effective treatments for Veterans suffering from depression or post-traumatic stress disorder. As you can see, precision medicine is becoming increasingly important in the care of Veterans.

Dr. Icardi will now review the functionality of the app.

**DR. ICARDI:** The GDx App is a pretty simple. It does one thing: make the results of genetic tests available to Veterans and to their practitioners. As Julie mentioned, one of the things that is needed to support a lot of the decisions is to have data which is easily accessible and indexed for those systems to access. Additionally, if we have these specialized systems, at least the provider and the patient should also have access to that kind of data. That's what GDx does. It provides access to this database that we put together.

This happens under the mobile framework. You launch it just like you do all the other mobile apps. You need a DS Logon Level 2 (Premium) account to do so. I'm going to go first over the app for Veterans. This is the patient-facing app. This app is basic HTML, so you can access it through any sort of device that you want: your PC, tablet or phone. Most of what we're going to be showing here is going to be on one of those three.

This one that is on the screen here is the initial hamburger screen as it would appear on a cell phone, but we'll go through and I'll point to those as we go through. The menu is pretty simple. If I log in as a patient and enter "My Account," it takes me to "My Test Results." You can see the things that you have available are "My Test Results," which shows you your tests, "Educational Information" and "Secure Messaging," which is the underlying mobile environment secure messaging.

When you pull up "My Test Results," you get this no-frills display which shows you what the test name is, the date it was done and what your test result is. You can sort via any of these columns, so the patient can go in and look up any particular name or particular day that they had the test. On the side there is this button called "View Details." This is where really all the data is that talks about what happens to the test. You can go in for this test here and it will show you the name, the lab that it was done at, clinical details, Logical Observation Identifiers Names and Codes (LOINC) codes, and specimens accession and details.

On this screen, if there was a PDF report that was sent, a button will appear on the side which will say "View Report." You can click that, and it will show you the PDF that came in with the test. The other feature that it has is if there was a variant call file, or the raw data for the test, that also came in, you will have the ability to download that data as well to the device. That allows you to share that with your provider if you need to.

The reason that we do that is there are a lot of these oncology programs and Veterans are going to go out to providers who may not have access to the system or may not be our providers. Those folks still need this kind of information. What we're able to do with this is empower that Veteran to be the conduit for their own information.

If they go in and they want to check out a cancer trial and the person on the trial says, "Well, we need to have your tumor type and your genetic information," instead of having to go four or five times back to return of information, figure out where that test is, what testing lab has that data, get them to send that back by some way to the provider, they can go right away and just say, "Here, let me give it to you. Here, let me download it and I will AirDrop it to you." This gives them that option. That's really part of the power. It frees them up to go out to other places and see other types of providers, or even a VA provider who doesn't have to be signed up with Level 2 access to the mobile environment, they can get them that data.

The Veteran also has an "Educational Information" button they can get into. Right now, this points at the Veteran's Health Library and at MedlinePlus, although we are in the works to add some additional content to it and allow for ways for their providers to actually put educational

content onto this educational button for the Veteran. Then – “Secure Messaging.” This is happening under the VA Connected Health platform, so we're able to use all those other applications that are on that platform. I could go out and do Secure Messaging under that platform, this will launch it right from that site, and you can go out and use the My Health eVet link and be able to message your care team should you have any questions.

For the care teams, the logon is a little different. In this case, you can log on with your VistA credentials and your station number. What will happen if you get to “Home” and that shows you a different view? Here, you see a view it says, “Search For Patient.” This is where you can look up a particular patient. This database is available at the national level, so you can have someone who has had testing done at another site, another hospital, and if they come to see you, you can still look it up. Or, if I'm a telehealth provider I can go, and I can look up their data and have their tests appear. I can search by social security number, last name, first last names, and of course, the classic, first initial, last name and four digits of their social security number.

When you select that, it'll take you out to the test results screen. You will get a confirmation, you pull it up, and it will show the patient's date of birth, age, sex and social security number. You can look at that, confirm if that is your patient, and then select the patient and it will take you out to that test screen, which is very similar to what the patient would get. However, you have a number of other fields there. You will see the reference range field, the LOINC code field and a description which tells you what the test is in addition to the “View Details.”

“View Details” gives you a pretty similar display as to what the patient would see. This spot will also have access to any PDF or VCF files that were also sent over via buttons. For viewing, if it's a PDF, or for download if it's another type of a file. There are a couple interesting things about this that have to do with how the database is constructed. For one aspect, we are able to use our position as really an insurance carrier, although you will never hear VA referred to as an insurance company, to say, "Okay, we're going to get results on our patients, but also we can ask for all the results on all of the patients we paid for." What this means is if you have someone going after care and community, or if you have someone out at other place and actually having a non-VA provider ordering tests and billing those back to the VA, those will be in this system.

This is an example of what they've been trying to achieve with these virtual lifetime health records. The results can come flowing back in and you'll be able to see them as the provider or your patient. It will all be collected together in one place that is quite important for you if you're a telehealth practitioner. If I'm in telehealth and I'm at a distance from the patient, it can be quite challenging to get their records together or even find things. You would have to rely on the patient being able to collect everything, bring it in and somehow send it to you.

This is going to support your ability to use telehealth for genetic counseling. A provider can have national services, they can provide these services out to rural areas, but they also can get into things like in precision oncology and tumor oncology and tumor registry and with the matching of patients to study programs. If we can do that at the national level and pull that

together, and you have that data, it allows you to find the treatment plan for your patient and start all the processing to get them approved to be able to go out to what might be an outside source and receive treatment.

Due to our position and ability to streamline them together, it is allowing us to do something that can't be done in the private sector at this time. As everyone knows we have this Million Veteran Program, and they are going through their first round of papers that has come out and they're starting to find all kinds of interesting connections. Not just from an oncology standpoint but also in the pharmacogenetic environment and for diseases like heart disease and incidence of getting cancers.

This is information that is out there, and available if people can get it, that can help provide therapy. If we're going to do that, it has to be put in some sort of an easily searchable database that the provider and the patient have access to, down to their level. That's what goal of what this initial GDx is supposed to do: even in its simple form, is to get that information out of the research labs, out of the research studies and to our providers and patients so that they can have access to what is good clinical information. This can help inform their patient care and make things better.

**DENISE KENNEDY:** Excellent, thank you. I think you touched on this, but we did get an early question asking: Is pharmacogenetic testing available at VA?

**JULIE LYNCH:** That's an interesting question because pharmacogenetic testing is a very broad category. The testing that is available in VA depends on what's in the guidelines. For example, a test that's not used too frequently anymore, but was in Hepatitis C guidelines, is IL28B testing. If the pharmacogenetic test is in guidelines and the test results impact clinical care, then my research has found that pathology departments do approve that testing. There is a lot of testing that's not clinically useful, and VA has been very good about limiting Veteran access to tests that are not useful. Dr. Icardi, do you want to pick up on that?

**DR. ICARDI:** Yes. There are a couple of studies, the big one of course is the PRIME Care, which is looking at antidepressants. There is a lot of stuff that's put out there that folks will make claims that it is useful, but it hasn't necessarily been backed up very well. There's not many large-scale tests that you do right now where you can put out a panel and it will tell you what your effectiveness for every drug is. Most of the ones that are actually effective tend to be when you know there's a particular drug that you want to give.

For the most part, those are all being approved. The only time that I can think of that they end up not getting approved sometimes is when the drug is not on the formulary and they haven't necessarily arranged a way for the patient to get it. It does mean that the lab ends up having to be the gatekeeper for it. They end up having to do a lot of research and discussions with people to determine whether a test is available or not.

The standard and certainly the classical pharmacogenetic tests for the P450 system and things like that are available. When you're talking about particular cancer chemotherapeutic drugs or Hepatitis C susceptibility testing, things like that, that's available within the VA. You do run into some issues with some testing in that VA is a little bit unique in that for certain diseases, mental health is a great example of that, we have a very good system of watching and paying attention to what's going on with our Veterans. Even though you would go through what you will see in the private sector, the discussion of something like for antidepressants, it may have to go through two or three drugs to find one that's effective or that kind of thing. At VA, because of the follow-up, they're able to cycle through that fairly quickly, whereas, in the private sector, that may not occur.

What occasionally will happen with these, is you will find that because VA is doing a lot of manual work, the advantages of doing a particular testing regime may not be that demonstrable because our care is better. That's kind of born out a lot when you look at suicide rates of Veterans on antidepressants at VA versus the private sector, our numbers are a lot better. Another great example is for coumadin therapy and international normalized ratio (INR) therapy, VA rates are much better than what occurs in the private sector, but that's because we put a lot of effort into it. That does, at times, become a factor so sometimes you may have a location which will say, "We're not going to follow this regime," or there's a pharmacogenetic test people come to try to sell to you that it actually doesn't fit into the care pattern that's already been established through VA. Sometimes you will see a denial that has come from an administrative side because this new test doesn't actually fit in or demonstrate those results when compared to VA treatment protocol.

**DENISE KENNEDY:** Excellent, thank you. We got a follow-up question from this one: Are you doing pharmacogenomic testing for opioids and opioid addiction?

**DR. ICARDI:** Are we doing them for opioid and opioid addiction? I'll say we are actively trying to get someone to get us a product to offer. The answer to that is no, but we have a lot of interest in having that done. Whenever we have a talk when these pharmacogenetic companies come in and they bring us a panel, that is something that is brought up every time, "Do you have an opioid panel that is ready, or do you have one for an opioid addiction that's ready to go?" Most of them will either say no or there are a few which say, "Yes, we have those in development." That is being pursued.

**JULIE LYNCH:** I think this is a good opportunity to talk about the capacity for VA labs to do this. I know that it's part of prime that there's some discovery going on around pharmacogenetics. I think with big conditions, pharmacogenetics is germline mostly, so we will identify some of that, but can you talk about how VA labs are expanding capacity to do testing internally?

**DR. ICARDI:** It's a lot better for us if we do this testing in-house than send it out. There's a couple of reasons for that. One is that way you do get to control a panel. For an example, if we wanted an opioid panel, we would tell our lab, "Okay, you need to develop this," and they

would do it and there would be some consistency in time. That's also another problem with this whole area of molecular testing, is there are a lot of labs which appear out there, and they're only open for a couple years. Either they go bankrupt, or a lot of them are venture capitalist type set-ups and they're looking to be bought. There's a lot of movement out there, and you end up not having a consistent source for particular tests because of mergers and acquisitions and changes like that.

In doing things in-house, we're able to avoid that. It's also considerably less expensive to do it in-house. Now, we do have a number of labs across VA who have some capability to do this. We talked about GDx as the front end of this database, but on the back end, we are connecting those labs together and creating a virtual molecular referral lab, which we will be able to tap into to develop our own and to provide testing. Right now, the emphasis on that is on HCV resistance. We have two new high-throughput labs that are coming up as part of Secretary Shulkin's initiative for the laboratory of referral program in New Orleans and West Haven, which are coming up to do HPV resistance at a fraction of a cost for send out. They will be brought up on with the Paolo Alto's already existing capability. The intention is to continue to expand that and offer more of these types of molecular panels in-house, allowing us to customize for our population and our providers.

For the question about PTSD and pharmacogenomics for PTSD - this is the type of thing that they would be going out to pursue because it's unlikely if the private sector's going to come up with a test for that on their own without some kind of pushing. Whereas in the VA, in conjunction with the DoD, that's a very high interest. That will be an area of focus for pharmacogenetic tests are done in-house.

**DENISE KENNEDY:** Excellent, thank you. Just to switch gears a little bit: What are the field test and go live dates for this app?

**CONNIE MURPHY:** We're looking at a national release in spring 2018. That involves a lot of coordination and planning and rolling out.

**DENISE KENNEDY:** Is the field test happening now, or has that already happened?

**CONNIE MURPHY:** Winter. We're getting very close to starting our field test.

**DENISE KENNEDY:** Excellent. Another question: Will this app be available in the VA App Store?

**CONNIE MURPHY:** Yes, it will.

**DENISE KENNEDY:** Okay. We also have another question: Will any of the report information be available using the My HealthVet blue button report? And, will it be available via the Virtual Lifetime Electronic Record (VLER) program?

**CONNIE MURPHY:** The data is not stored in My Health<sup>e</sup>Vet, and it is not tied to My Health<sup>e</sup>Vet. You would have to access this data through the app only. Keep in mind this is the first release. These apps go through a constant iteration and updating.

**JULIE LYNCH:** Can I just comment on this, Connie? Because getting the structured data within the VA firewall, once it's there, all other apps and systems like the VLER could have access to it.

**DENISE KENNEDY:** Excellent, thank you. A final question: What type of patients will benefit the most from GDx?

**JULIE LYNCH:** All patients. Any patient for whom they think that they need a genetic test but don't until they can get education on it and for patients for whom genetic tests are ordered and who want to understand the results and share them with other providers. I would say that precision medicine, currently, is impacting about 10% of the patient population. Going forward, I think that'll expand greatly.

**DENISE KENNEDY:** Excellent. Thank you for that. It doesn't look as though there are any additional questions. I wanted to do a last call to Dr. Icardi, Dr. Lynch and Connie to see if you have any final thoughts for the group here today?

**DR. ICARDI:** My final thought is, part of the reason that we did this was because of the inability to get at data which already exists. This data is not a Blue Button. Blue Button can't access the data the way it's currently stored in VistA; it cannot access it. The same with VLER; it also could not access any of this data as it currently sits in VistA. To get this data out to patients and to providers is why we did the GDx app. By pulling this database together and then making the app able to access that database, we can give that basically right now. By right now, I mean first quarter next year or so, and get that in the hands of patients instead of waiting seven to ten years, like what has been forecast before. There are a lot of people who need this type of data that seven to ten years is probably too long for. We would like to get this out and make this available to Veterans while they can still have a chance to take advantage of it.

**JULIE LYNCH:** Yes, and I would just say that actually accessing the data already, it has, from my perspective, improved clinical care. When I started this project, it was because I was interested in seeing if Veterans with lung cancer were getting estimated glomerular filtration rate (eGFR) testing to determine a drug called Erlotinib, and at that time in 2012, there was very little testing being done. When I showed the data to national clinic leadership, they acted on it and expanded testing. We were able to see that actually when in VA, there's a much lower rate of mutation among Veterans, likely due to their smoking, but there was high utilization of the expensive drug.

I think that even though the app hasn't been released yet, the effort to pull the data into the database has already informed leadership about what the best approach is for implementing



precision medicine. I just think that what Connected Health is doing across the board is really great. It's been a great experience working with Connected Health in this area.

*DENISE KENNEDY:* Excellent. Thank you all so much. Special thanks to Dr. Icardi and Dr. Lynch and Connie for joining us today to talk us through this, and thanks everyone for joining this afternoon. You will see on your screen that there is a link to let us know how we're doing, give feedback and to tell us if there are any other topics you would like us to cover. Again, thank you all so much for joining us, and we look forward to the release of the GDx App.



**U.S. Department of Veterans Affairs**  
Veterans Health Administration  
Office of Connected Care