



Health Resources and Services Administration

OPTN Industry Day

Transcript

7/21/2023

Chat History

08:51:33 From OPTN Meeting to Captioner (Direct Message):

Hi ...thanks for assisting us today, I'm attaching the run of show for you

08:52:18 From Captioner to OPTN Meeting(Direct Message):

Thank you!

08:52:38 From Captioner to OPTN Meeting(Direct Message):

All set

08:52:48 From OPTN Meeting to Captioner (Direct Message):

Thank you

09:54:11 From ATTENDEE to OPTN Meeting(Direct Message):

How will HRSA ensure successful collaboration between UNOS and a potential new IT contractor?

How will HRSA work towards improving organ donation systems, such as UNET, to ensure they do not go down. Will there be clauses in the contract?

09:54:24 From ATTENDEE to OPTN Meeting(Direct Message):

Can you go over who reviews the proposals and the review process, and who at HRSA decides who gets awarded the different components of the contract?

10:01:19 From ATTENDEE to OPTN Meeting(Direct Message):

How will HRSA work towards improving organ donation systems, such as UNET, to ensure they do not go down. Will there be clauses in the contract?

10:01:50 From ATTENDEE to OPTN Meeting(Direct Message):

Would it be possible to touch on proposed task area 3, communications? Current ideations etc..

10:01:56 From ATTENDEE to OPTN Meeting(Direct Message):

How will HRSA work towards improving organ donation systems, such as UNET, to ensure they do not go down. Will there be clauses in the contract? [not sure I am sending this to the right channel]

10:03:05 From ATTENDEE to OPTN Meeting(Direct Message):

Have those criteria been developed yet?

10:12:05 From ATTENDEE to OPTN Meeting(Direct Message):

Has HRSA determined a ceiling value for either IDIQ discussed?

10:13:31 From ATTENDEE to OPTN Meeting(Direct Message):

What happens in the case you see a solution that could drastically improve current state? Would you still wait until spring to award?

10:13:54 From ATTENDEE to OPTN Meeting(Direct Message):

Can HRSA please clarify if there will be multiple vendors per domain, or will there be a single vendor per domain, hence forming a team of collaborative vendors working across domains on the transition contract.

10:14:19 From ATTENDEE to OPTN Meeting(Direct Message):

Contracting Question: Knowing that teams can bid for selective task areas (besides Task 5), will teams be scored more favorably if they can cover more, or all, task areas?

10:14:37 From ATTENDEE to OPTN Meeting(Direct Message):

What happens to the current Donor Match system on an after the date the UNOS contract is terminated?

10:15:00 From ATTENDEE to OPTN Meeting(Direct Message):

With regard to Domain 5 ... How will new and existing suppliers be managed under Domain 5 requirements? What are the specific processes and procedures that will be used to manage suppliers, ensure they meet required standards, and how deep into the supply chain will that management go? Will HRSA and/or a new/existing vendor be the entity responsible for monitoring, reporting, follow up, and continuous communications and collaboration with vendors? If HRSA will be the entity responsible, what specific roles and responsibilities will they have?

If a new/existing vendor will be the entity responsible, what specific roles and responsibilities will they have?

10:17:10 From ATTENDEE to OPTN Meeting(Direct Message):

Based on what has been said, it appears that each of the contractors is going to be responsible for ensuring that everyone is coordinated. If there are differences of view or lack of cooperation, who resolves the problem and how? In other words, who is charge? Where does the buck stop?

10:17:19 From ATTENDEE to OPTN Meeting(Direct Message):

are typical federal certifications required of the vendors for the IT domain? For example, 508 compliance?

10:17:38 From ATTENDEE to OPTN Meeting(Direct Message):

Will there be any OCI (conflict of interest) issues with participation on the Transition and Next Generation Contracts ?

10:18:40 From ATTENDEE to OPTN Meeting(Direct Message):

Noting FY 2024 adds funding for OPTN, how might the modernization process also address transplant center reimbursement for increasing costs (innovative technology, increased higher risk donor and recipient costs, etc.)? Is there coordination with CMS/payers regarding this modernization effort?

10:20:44 From ATTENDEE to OPTN Meeting(Direct Message):

Will there be restrictions or conflicts of interest between Transition contract holders and Next Gen, whether participating either as a prime contractor or as a subcontractor? It sounds like HRSA is looking to have separate cohorts to do different kinds of work. We would respectfully suggest there not be, so talented vendors can participate as both prime and sub, so the vendor talent pool is as broad as possible.

10:24:18 From ATTENDEE to OPTN Meeting(Direct Message):

If the current contract holder will have a role for board separation or management, what safeguards will be in place to ensure transparent oversight of the transition, and to avoid all conflicts of interest?

10:25:43 From ATTENDEE to OPTN Meeting(Direct Message):

The fundamental question is how the accountability matrix will work to ensure that the OPTN Board works together with HRSA to ensure that the contractors work together effectively to improve outcomes.

10:26:09 From ATTENDEE to OPTN Meeting(Direct Message):

To clarify, will the government be issuing one IDIQ for Transition and then another IDIQ for Next Generation

10:28:16 From ATTENDEE to OPTN Meeting(Direct Message):

How soon GOCO vs COCO model for this contract will be determined which will influence/ help contactors with right teaming and solutioning.

10:56:03 From Captioner to OPTN Meeting(Direct Message):

Good morning! In my notes it said I was assigned to Breakout room 1. There are many breakout rooms I see LOL Is there one I should join, or will you send me there?

11:23:36 From ATTENDEE to OPTN Meeting(Direct Message):

Is there a conflict to bid on both NextGen and Transition IDIQ? If a contractor bids on Transition does it preclude them from pursuing NextGen?

11:24:03 From Captioner to OPTN Meeting(Direct Message):

hello! I'm here and standing by if there are any breakout rooms that still need a captioner

11:25:31 From ATTENDEE to OPTN Meeting(Direct Message):

That gets back to the question of who is ultimately in charge of all of the contractors...

11:28:17 From ATTENDEE to OPTN Meeting(Direct Message):

It is my understanding that OPTN operations will be invested in different contractors while policymaking will be in scope the OPTN. Will the Operations contractors be directly responsible to the OPTN, or will they be responsible to HRSA? Or both? If they are directly responsible to the OPTN, how will the OPTN exercise oversight without any independent staff ?

11:28:27 From OPTN Meeting to Captioner Direct Message):

Hi ...apologies....evidently once we assigned the captioner to our main session...Zoom wouldn't allow us to assign additional captioners to the breakout rooms...it views the breakouts as extension of the main room

11:29:43 From Captioner to OPTN Meeting(Direct Message):

ah. we could provide a Streamtext link with captions to the participants in the breakout rooms instead of showing the captions in Zoom, if that would be helpful?

11:34:13 From ATTENDEE to OPTN Meeting(Direct Message):

How will the OPTN be operated beginning the day after the UNOS contract is terminated. Is HRSA building into its timeline and contracts a period for new contractor staff to be trained by current staff?

11:34:39 From ATTENDEE to OPTN Meeting(Direct Message):

Are you considering the use of artificial intelligence and machine learning for prediction, such as to predict organ availability to pre-stage for procurement?

11:37:28 From ATTENDEE to OPTN Meeting(Direct Message):

Given concern that current Board of Directors has inherent bias or conflict, how will HRSA and the contracts help ensure that the OPTN board has representation from all stakeholders and transparency/lack of bias in selection of board members - will there be requirements in the contract about board member selection and policy development to ensure that these processes are transparent, truly inclusive of all stakeholders?

11:40:58 From ATTENDEE to OPTN Meeting(Direct Message):

Are you considering data mesh and data fabric cloud architectures to enable federated data sharing at scale?

11:56:20 From ATTENDEE OPTN Meeting(Direct Message):

Just having public data/researcher accessible data on pre-waitlist period would be beneficial

**12:10:54 From ATTENDEE to OPTN Meeting(Direct Message):
Data on prewaitlist AND donor procurement**

**12:16:55 From ATTENDEE to OPTN Meeting(Direct Message):
Would HRSA share the slides and/or the transcript?**

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>> BONNIE GARCIA: Hello. Hello. If everyone can please come in. We're going to get started in a few minutes. So if you could please come in, grab a seat. And we also appreciate it if you can sit in the middle. The seats in the middle first. Yeah. Nolan?

I have one little ask. If we can take all the seats in the middle. We really appreciate it.

All right. First of all, good morning, and welcome to the Health Resources and Service Administration Organ Procurement Transplantation Day. I'm Bonnie Garcia the HRSA Head of Contracting Activity. It's a pleasure to see so many of you here. I want to thank you advance for coming to this event.

Before we get started, let's go over a few housekeeping items. Please, please, do not record this event or any other sessions. We're also asking you to please turn off your phones, so we don't have any interruptions.

For those of you who are joining us virtually, we appreciate if you can turn on your camera so we can have a more cohesive experience.

And we also ask that if you have a question during the question session to please put it in the chat or raise your hand. Those of you who are here in person, if you have a question, please raise your hand. We'll make sure that we receive your question.

The restrooms are located outside the door to the right and left. If you need to use them, feel free to stand up. The cafeteria is in front of this room. During the break if you need coffee or another snack, please feel free to go to the cafeteria. We have a little network area as well where you can join. We also have waters on both sides of the room. Please feel free to have some it's there for your convenience. Please feel free to use it.

So sorry. So what do we have in store for you today? The first thing I would like to do is go over the goals then we're going to go over the agenda. The goals of the industry the first goal for us is to provide information regarding the transition procurement and draft performance work statement that we have issued.

Our second goal is to foster collaboration and to work together so we can come up with ideas and you can help us on how to improve this procurement as we're getting ready to issue it.

We then are going to hear Dr. Suma Nair who's going to give us the vision of the OPTN organization. Then Manjot Singh is going to provide to us the OPTN current state. I will cover the overview of the procurement process. Then we'll have a panel to answer some of the questions that we have received. And then we'll have an open floor for questions and answers.

During the question and answer, please note we may not be able to answer all the questions. Please note the questions you have given us, asked us, help shape the procurement and shape that OPTN modernization vision.

We then are going to break out into what we call our Focus Conversation Sessions. All of you that come in, you have a tag with your name and a dot. The dot indicates that session that you selected during registration. The session that you were interested. And the staff will lead you to the room where we're going to have those sessions.

Then after that, we'll have the closeout, the conclusion, of the event. Please know just like we escorted you in, we have to escort you out.

So again, I thank you in advance. I hope that we have a very fruitful and productive event today. And we really are eager to hear your ideas.

And with that, I'm going to turn it over to Dr. Nair.

>> SUMA NAIR: Thank you, Bonnie. Good morning, everyone. We are incredibly excited to have you all here. Let me also extend my welcome to all of you joining us online and in person here at HRSA headquarters. 5600. We're incredibly excited about this Industry Day and the opportunity it presents to our collective effort to help modernize the national organ donation and transplantation system to better meet the needs of patients and families.

This Industry Day is a significant step toward achieving our critical milestone in our modernization initiative. The issuance of our first multi-vendor solicitation.

As we embark upon our modernization journey, we're fully aware that the profound impact it can have on the lives of countless individuals awaiting lifesaving transplant.

As you know, there are over 100,000 individuals on the transplant waiting list. And there should probably be several thousand more on that list.

Every ten minutes, another person is added to the list. And, sadly, devastatingly, on average, 17 people die a day waiting for a transplant.

The modernization initiative and the solicitation represent our unwavering commitment here at HRSA to increase access to organ transplantation so everyone who needs a transplant can get one in a timely manner and their lives are improved because of that transplant.

Through this collaborative effort, we aim to foster competition, spur innovation, and propel the field of organ transplantation forward. By leveraging a diverse array of perspectives and expertise, the OPTN will be better positioned to overcome challenges, seize opportunities, and improve the system performance. Ultimately, and most importantly, saving the lives of hundreds of thousands of individuals.

Before we dive into the details of the transition contract, and the contracting process and timelines as Bonnie mentioned, let me provide a brief background on the OPTN Modernization Initiative.

So let's start with an orientation to the OPTN or the Organ Procurement & Transplantation Network and the related organizations and stakeholders. So almost 40 years ago, the National

Organ Transplant Act established the OPTN to coordinate and operate the nation's organ procurement allocation and transplantation system. To increase access to donor organs for patients with end stage organ failure. Specifically, the statute charges the OPTN with operating a national list of individuals who need organs and a national computer system to match organs with individuals on the waiting list.

The OPTN is overseen by the HRSA. HRSA is responsible for administering a variety of health care related programs and initiatives. One of our key roles is to oversee the nation's transplant system through the Organ Procurement & Transplantation Network.

The OPTN, itself, is a network of transplant professionals, organ procurement organizations, transplant centers, patients, families, compatibility labs, and other stakeholders who work collectively to develop, implement, and monitor organ allocation policy and performance of the organ transplant system here in the United States.

While the OPTN operates under the oversight of HRSA, it relies on the expertise of members and Board of Directors to carry out its mission. The Board of Directors is comprised of 42 volunteers representing the various segments of the OPTN members, such as transplant surgeons, transplant recipients, donors' families. And they're elected by the OPTN membership.

There are 26 committees that support the Board of Directors in executing their governance role. The OPTN Board of Directors is charged with the development and implementation of policies regarding organ allocation, assisting in the nationwide distribution of organs among transplant patients by operating a 24/7 system to match potential donors. And individuals on the wait list. By actively

working to increase the supply of donated organs. Adopting and using quality standards for collecting and transporting donated organs. By providing information to health care professionals, by collecting, analyzing, and publishing data on organ donation and transplantation. And by conducting studies and demonstration projects to improve procedures for organ procurement and allocation.

HRSA also administers two contracts that support the OPTN and Board of Directors to execute their mission. That's very germane to our conversation today. The two contracts are the OPTN contract and the SRTR contract. So SRTR is the Scientific Registry of Transplant Recipients.

With our modernization initiative, our discussion today is focused on support of the OPTN contract and the support that that contract provides to the OPTN and the OPTN Board of Directors.

So with that grounding, let's take a look at our modernization initiative. So over the last several years, there's been a growing interest in the organ transplant system and the opportunities present to strengthen that system given the significant and growing need for life saving transplants. In response to our efforts to improve the system to date, robust market research, a request for information that HRSA put out last year to get information from the community and the field about what the opportunities were for improving and modernizing the system. Expert feedback. And engagement with our wonderful colleagues, the U.S. Digital Service, to help the country's leading digital experts. We've concluded that achieving our objectives for increasing access, equitable access to transplant, and having a high performing system, and our objectives for enhanced accountability,

equity, and performance, we need to modernize the system. And given the complexity and the criticality of this system, it requires an iterative and modular approach.

So this approach is increasingly used by federal agencies and commercial organizations to help modernize your programs that are anchored in legacy systems and processes. It really allows us to look at incorporating different components into the system and processes that are developed and tested and integrated in parallel with the existing system. So you don't have disruption to the existing system. And that allows us to maintain patient safety throughout the process. While we mitigate any risks associated with transforming the system. But it still creates room for transforming the system. Especially the system that provides 24/7 access to these lifesaving services.

So in March of this year, we announced our multiyear initiative to modernize the OPTN with a goal of increasing access to high quality organ donation and transplantation. It's very important to us that this initiative was designed in a way to meet the needs of patients and families. To further strengthen and provide equitable access to transplantation, improving safety and health outcomes, and truly empowering patients and providers with the data and information they need to make good decisions together. And bring some light into what many in the patient community have called a black box.

We also want to think about the needs of the organ donation, procurement, and transplantation community. So many professionals in that community have dedicated their entire lives to improving the lives of others through transplant. And So we want to honor that commitment by making sure that we support and facilitate their

delivery of high quality care, equitable care, and support a system capacity for continuous quality improvement.

We also want to advance the field. So want to consider the needs of researchers, scientists and other stakeholders by investing in innovation in the Organ Procurement & Transplantation Network.

And to the public by providing transparency and accountability.

To meet these needs, we're focused on five areas of improvement as part of our initiative. In a manner that puts patients first. That prioritizes information flow to clinicians and care teams. Promotes innovation through continuous competition. Enhances transparency and accountability.

So what are the aims of our modernization initiative? You see it here. It really aims to accelerate progress in these five areas. So this is kind of the future state that we aspire to. In the arena of technology, we want to have the OPTN IT system, the backbone for matching and really a key facilitator, right, technology is an enabler to efficiency. To be reliable, secure, patient centered, user friendly, and really reflective of modern technology practices.

We want to make sure that there's a continued focus on improving the modernized technology. The system, the functionality, the security. While protecting patient safety and accelerating innovation in line with industry leading standards.

Part and parcel of that, when you have a system, you have a lot of data that is created and it's critical to make sure that that data is accessible, user friendly, and patient oriented. Modernization allows us to make sure that we have easily accessible data, high quality

standardized data, and timely data to make sure that we have the right data and information at the point of care. So the care team, patients, families, providers, have the information they need to make the right clinical decisions. Then you also build up the capacity to learn across the entire system more quickly. So we can look at that data and learn from it. Again, rapidly increasing our opportunity to become a learning health system.

We want to make sure that we have this data that helps us not only with clinical decision making, but to measure and evaluate program and performance and inform oversight and compliance activities. And ultimately, really support advancement of scientific research.

Governance is critically important. I think we all know the people at the table making the decisions have an incredibly important role in advancing the system performance. And so the OPTN Board of Directors, we want to strengthen their capacity to use best in class practices to be a high functioning independent board that represents the diversity of the communities that the OPTN serves. And that delivers effective policy development and oversight.

And we want the operations of the OPTN to be effective and accountable. That they're able to implement organ policy, patient safety, compliance monitoring, organ transport. Better support of the OPTN members. And education of patients, families, and the public around organ donation and transplantation.

Finally, we want to strengthen the system's capacity for quality improvement and innovation. We want to make sure there's a promotion of the culture of quality improvement and innovation across the network and by leveraging timely data and performance

feedback that we improve and that we're also able to leverage collaborative learning and strategic partnerships to make a significant advancement in the field.

So those are our aspirations. The steps that we've taken to date to help us move forward in this direction include first working with industry. As I mentioned over the past year, year and a half, HRSA has been engaging with all of our stakeholders to understand what are the opportunities, what are the considerations and challenges associated with making some improvements here. So we've engaged the IT community and other industry to get a high-level overview and figure out what's possible. When you want to change from a single vendor environment and really open up and get new thinking and innovation, you have to engage with folks who have not typically been engaged in this arena. So we've been working very diligently on that effort. This, indeed, again represents that intent.

We made efforts to make data available with the data we have. We built out some dash boards. That's our first version. We look forward to continuously enhancing those dashboards and adding more data there.

Engaging stakeholders. It's very clear that our focus is on patients and families. While we have an imperative to modernize the system, we have to do it in collaboration with our stakeholders. And so we have already done a lot of engagement work. Last July, we had our consensus conference where we put a focus on patient and family voice into the metrics and data that are needed not only for the system but for them in their transplant journey. We continued those engagements. Now we're building upon that and strengthening our

own capacity by working with a vendor to go out into the community, go deep and really engage with the segments of our stakeholder population to make sure that we understand what they see as the primary opportunities and that we sequence those up and through as we work through our modernization.

We also have to build our capacity. When you think of modernizing the system, it requires modernization of each of the parts and players in the system. We're putting a mirror up to ourselves and looking at what our capacity should be to advance the aims that we've laid out there. We've been so privileged to have the ongoing opportunity and consultancy and support the U.S. Digital Service. Experts in the field of transformation and modernization and digital health. Digital technology and digital health in this context. We're very happy to be able to continue to get their support. You will see many of their team members engage with us here today.

Finally, all of these are just interesting ideas. If we don't do the work of securing the support that we need to execute on our vision. So as you may be aware, in the fiscal year '24 president's budget, there was a doubling of the resources for the organ transplantation programs and to advance our modernization effort. And the request for some key legislative proposals that are critical to advancing HRSA's ability to modernize and achieve the modernization aim.

So increasing our flexibility to go from kind of the model that we had 40 years ago, to bring us up into current times and to invite fuller engagement by a wide array of expertise. The health care system and technology and logistics and everything have dramatically shifted in

the last several decades. So really bringing in a full range of expertise to help us achieve those aims is absolutely essential.

Then the final thing that we said in March when we rolled out our initiative is our intention to solicit proposals for modernization in a way that is departure from past. We talked about two solicitations. A transition solicitation which we're going to talk about here in depth and a next gen solicitation. Both to be multi-vendor solicitations that we would put out.

Which brings us to we talked about one being in the fall and one being in the spring.

So on that note, let's take a high-level view of our contracting strategy to get us from current state to our modernized future. We'll do a deep dive into the transition contract. You'll get a lot more information there. I want to give you a lay of the land.

The support contract is up and running. Many of you have begun engagement with them. They're pressing forward in our commitment to robust stakeholder engagement and developing a comprehensive plan for a meaningful, thoughtful, deliberative process around modernization that supports all the interested members in the community. And really helps us mitigate and manage the implications of any change or transformation that will come with our modernization efforts.

So next, you see we have the transition contract. And we're going to get into that here in depth in a moment. This contract is meant to bridge between the current state and our future state. It will help us ensure continuity, as we said, patient safety is key. Continued access

to the system is absolutely essential to us. So it will help us there so donations and transplantaion continue. And, perhaps, there's some room even within to optimize. We'll be seeking to do that as well. That's an opportunity. Hopefully you all hear that. Our goal today is to highlight some opportunities for folks to engage. Even in kind of maintaining the current operations.

We also think that the entities that come in for this contract will be squarely focused not we think, we know on ensuring the system works for patients and families and the transplant community at large while we look in parallel, so this is the next contract to start our innovation and our significant improvement work. They're going to keep the system running while in parallel, we begin our next generation contract work.

So the transition contract is the one we plan to put a solicitation out for this fall. The next gen one will be one we issue a solicitation for in the spring of next year.

The next gen at a high level, again, not the focus of this. We'll be focused on transition. We're planning to host an Industry Day and conduct market research as we have for the transition contract. It will allow us to partner with the OPTN community and innovative thinkers and people with expertise to tackle some of the important opportunities to significantly improve the system. Whether that's technology innovations, innovation in organ transport, patient safety, logistics, operations. It will allow you to take an idea, work with a group of stakeholders, build out prototypes, test those on a small scale, test them on a grander scale, and then really thoughtfully think about integration to the system at large. That gets back to our

premise around patient safety and continuity being absolutely imperative. We're going to keep the system running, while in parallel, we're going to start building out the opportunities to improve this and do it in a thoughtful way.

So our charge for today. Throughout the course of this industry day, we encourage discussion, knowledge sharing and thoughtful exchanges. This is your opportunity to help HRSA shape the requirements for the new transition contract by sharing your insights and recommendations. Obviously, we're going to share our initial thinking about the work that's needed to support the OPTN. Many OPTN members are here. And engaged with us online. So we're going to get your feedback on that. We'll also share how we think about parsing out the work in the different domains. Again, that's subject to change. It's our initial thinking. And we'll talk about how the contract vehicle will work, et cetera.

We're going to be highlighting the opportunities for new partners to join us in our mission to strengthen the system. And showcase how we believe we can create space for new and innovative thinking and support in this system.

So these ideas were borne out of our team's collective expertise, but the opportunity today is for all of you to help us expand our thinking and ideas. Potentially creating a whole range of other possibilities. Strategies, approaches. To support the OPTN and the transplant system.

So be bold. Speak up. Let the organ transplantation system benefit from your expertise. And help us strengthen the final solicitation that we plan to issue this fall.

I acknowledge there's a lot of interest and there's a lot of moving pieces and variables in this space. So there's some variables connected to legislation and other things that are not definitive. They're being considered. Right? So rest assured our final solicitation will reflect the current state of legislation at play when we issue that this fall.

And if there's needed changes even after that, there's contract process to make amendments and things, too. So stay in close communications and we will do the same.

So thank you for sending in all of your questions and curiosities in advance of our session today. We'll try to address them. We've tried to address them in our presentation. Jot and Bonnie in her remarks. Then in our panel discussion. There will be a opportunity for Q&A for all of you as Bonnie mentioned. It's inevitable that you'll leave the session today. As you go about your way, you'll have additional questions. Hopefully, you'll have additional ideas and inspiration. So this is you can contact us should any of those insights and ideas hit you after you leave the building or the Zoom link today.

So we really encourage you to reach out to us through the contact form. And make sure that we have that information as we shape this work moving forward.

So as we reflect on the transformative journey that lies ahead with OPTN modernization, the real impact will be measured by the lives that we touch and the families that we support.

The Industry Day is not merely an event. It's really a testament to our commitment to modernize and improve the system. It's our

commitment to a vision for a better future. And it's our commitment, most importantly, to patients and families that we serve.

Once again, welcome everybody here and online. We eagerly await your insights, the connections, and the solutions that will emerge from our time together.

With that, I will invite Manjot up.

>> MANJOT SINGH: Good morning, everybody. My name is Manjot as it implies on the slide. I want to extend a warm welcome to each and every one of you joined us on the Industry Day. Whether you're here physically or joining us remotely, your presence and interest in this effort is immensely valued.

So picking up from where Suma left off, let me talk about how these contracts come together to facilitate and move toward a modernized OPTN.

As has been mentioned already, we have in place a program support contract. Let me instead focus on how the transition and next gen contracts complement each other.

With the transition contract and all subsequent OPTN contracts, the goal is to encourage diverse participation and innovation through multiple awards solicitations. Our first critical steps will be establishing an independent Board of Directors which will provide governance, oversight, and strategic direction.

Moving forward, we anticipate issuing multiple contract actions that will align with the areas of improvement that have been identified within the PWS that's been shared with you all. By doing this, we plan

to foster a climate of competitive innovation and continuous improvements. What's important about what the slide is depicting is an incremental ramp up of activities as you advance through our multi year plan. The intent is not to migrate to next gen. Both of these efforts would happen concurrently. Both have different purposes. They're collaboratively leading us toward the horizon which is a future state OPTN contract.

The purpose of next gen is ideation and technology transformation. It's important to note this does not necessarily negate the possibility of enhancements within the transition IDIQ, itself. In fact, it's anticipated that necessary innovation and improvement will be embedded within the transition contract to seamlessly support and drive progress toward next gen activities. This synergistic approach ensures growth, moving us close to the future state of the OPTN.

So building upon the foundational and continued support of the transition contract, next gen aims to continue incorporating multiple vendors into the contract strategy, employing a human centered design practice, to build and test modernization concepts, then initiate implementation of modern technology strategies and integrate successful innovations into the existing system. All of this is to support the future state of the OPTN that you see in the blue arrow.

So now, I will go over the really exciting part about this contract. The language. I'm sure everyone has read the 20 page document. But for the few that haven't or for the folks that need a quick reminder, let me take a moment and cover some of the highlights of the PWS.

The first task area covers a wide range of operational aspects of the OPTN, excluding only IT, data and the communication tasks. It involves not only the day to day operations but also strategic tasks like policy development, implementation, member compliance, and performance monitoring. A significant part of task area 1 is dedicated to ensuring compliance with legal and regulatory requirements and promoting transparency and accountability.

Stakeholder engagement including OPTN members, Board of Directors, policy committees and patients is a recurring theme across the several tasks within this task area.

Lastly, on task area 1, this task area underscores the importance of having robust financial management and internal control systems in place to support the OPTN.

Moving over to task area 2. Task area 2 emphasizes the vital role of maintaining a robust and secure IT system for organ matching. Ensuring efficient data management and offering technical support. Task area 2 underscores the need for a reliable 24/7 operational IT system that meets the needs of the OPTN. This system, of course, should adhere to the federal IT requirements. This system should have high system availability. Data redundancy measures. The system should be capable of running matching algorithms, handle sensitive data. Additionally, it should incorporate APIs for direct data transmission and accommodate high data volumes while safeguarding sensitive information.

This task area also necessitates the need for provisioning technical support for the OPTN members. Finally on task area 2, all data should

be collected in accordance with regulatory requirements and ensure a high standard of quality, accuracy, and transparency.

This is a lot faster than the 20 page document. Okay. So task area 3. Overall, this task area places emphasis on the key role of effective communication, transparency, and education. In the OPTN's operations. Some of the main objectives as part of task area 3 are ensuring visibility into the OPTN activities through regular updates to take holders and the general public. Maintaining and updating the OPTN website to ensure user friendly and compliant also include compliance with all the federal requirements for a government website. The website should be readily available and provide interactive experiences with the OPTN data.

Developing and disseminating educational resources is also critical as part of this task area. These are resources for patients, transplant professionals and the public. Additionally, communicating about OPTN activities via multiple channels and ensuring the OPTN products are branded correctly to avoid any conflicts of interest or confusion.

And finally, another aspect of task area 3 is preparing presentations and articles for public meetings, conferences, and publications. And contributing to the official reports such as reports to Congress.

Moving over to task area 4, research and evaluation. Task area 4 emphasizes the importance of research and evaluation and also continues improvement in maintaining and enhancing the OPTN operations and procedures. We expect to do this by conducting studies and developing demonstration products on procurement and education procedures. Carrying out current state assessments of how OPTN manages data, specifically its capture analysis, coding, and

sharing processes. This should include identifying opportunities to enhance data usability, accessibility, and security as well as integrity.

Another key aspect of finally, task area 4 focuses on evaluating OPTN operations. Programs and functions to provide some of the improvement recommendations based on the current best practices.

I'll move over to task area 5. And finally, task area 5. Here, let me focus on some of the key takeaways beyond the general contractual requirements such as records management, training and compliance with federal laws and policies. Some of highlights of this task area focus on foster effective collaboration, providing them with data and information. Furthermore, this task emphasizes facilitating smooth transitions of contract activities to new entities as applicable. Includes coordinating and sunseting of legacy OPTN components to ensure seamless user experiences, developing APIs and other interfaces for daily exchange and supporting other contracts during this transition.

And with this rough highlight of all five task areas, I hope you can have a good understanding of what is expected as part of the transition contract IDIQ.

Furthermore, I want to address the subject to change piece. As part of the feedback we receive from you today and the continued feedback we're going to receive from you in the future. I hope that we can include and foster that feedback as part of this contract and make the appropriate changes prior to the solicitation.

And with that, let me turn back over to Bonnie to talk about the procurement goals and timelines. Thank you.

>> BONNIE GARCIA: Thank you, Manjot and Suma. I'll go over the procurement goals. As you heard today, one of our goals and foremost for us is to ensure that there's no negative impact to the patient safety. We want to ensure that we protect the patient outcome.

Our second goal is to focus on the transition to a clear separation and independence of the OPTN Board of Directors. To avoid any conflicts of interest between a contractor board and OPTN board.

Lastly but not least is to encourage participation for a multi-vendor environment where we can share, learn from each other, and have transparency into the process.

How are we going to do that, right? How are we going to move? So with the support of the Administration and after nearly 40 years, we are now able to move forward and make changes to the OPTN procurement. We're moving from a standalone with a single vendor contract to an indefinite delivery indefinite quantity with multiple vendor contracts. Why, what is the difference between a single contract standalone and an IDIQ? The single standalone contract, what it does is has a fixed scope of work for a period of performance. Fixed quantities. goods and services. The resources that are needed to adapt from the changing technologies and methodologies, are limited. Or the contract is not able to keep up with the latest changes in the market and technology.

While the IDIQ is the contract vehicle that is adaptable and flexible. And what do we mean by that? It's that the IDIQ allows us to set up a framework for future task orders that we can issue as the need arises. The flexibility provided by the IDIQs also allows to embrace new

methodologies, changes in technologies and the changes in our needs as the requirements shift as industry standards change.

The IDIQ also provides the flexibility to issue cost reimbursement, time and materials and firm fixed price task orders.

Multiple IDIQs will reduce the risk of a vendor lock, will provide us the best value, best solutions, and the ability to streamline the procurement process to reduce the timeline to issue those awards.

Our plan is to set up IDIQ contracts with multiple vendors with options from where we can select from those task areas that Manjot mentioned.

I know that we gave you a performance work statement when we first issued the notice. Then we gave you another when you registered because we're changing, shifting, depending on you to help us, give us that input to ensure we have the best procurement solicitation that we can put out for bidders to bid.

How we intend to do that? We intend to issue one solicitation which will allow bids for the different task areas and domains. If you look at your PWS and look at the task areas, they're really domains. The domains that Manjot mentioned. We have five domains currently. That can change depending on the feedback that we receive from you.

Under those domains, domain 5 is the general requirement. That domain, we're requiring all bidders to submit a proposal for. Why? That domain allows for the transition in and transition out. It also has records management and security requirements. But importantly, to us, it also has performance for collaborations among the many vendors that we envision.

Again, for that domain, you need to bid. The other domains, we have the OPTN operations as domain 1. The IT systems as domain 2. Communications domain 3 and evaluation domain 4. We're relying on you to submit proposals. We understand that each of the domains may not read as they do right now because we want your input.

Also understand that all these domains need to be in compliance with applicable federal acquisitions regulations including the limitations on profits. So keep that in mind as you are thinking about bidding for these proposals.

How are we going to move this needle? Here's the phases of the procurement process. We know we have a need for an OPTN contract. We develop a plan, research, which is what we have been doing as my colleagues mentioned for the past year and now. We then are going to issue the solicitation, Request for Proposal, RFP. We're going to make the award, then performance. Contract administration, performance, accountability. That's a big one for us. As we issue these contracts, that we also monitor that performance and accountability.

So those are the phases that we have. And we are right now in market research phase. That's where we are on that plan. Developing the plan. We're asking you for your help with that. During the conversation sessions, we hope that the topics of discussion will generate ideas that will help us shape this new procurement.

I want to move to the next slide. Please keep in mind without your input and collaboration, what I really want you to take home from this day is without collaborations and transparency, we might not be successful. So we are asking for everyone's participation.

So here's the timeline that we envision. In the summer, we have the industry day, the market research, the planning. In the fall, we plan to issue hopefully the solicitation will come out. Single solicitation, allowing you to bid for the different domains. In the winter, the proposal will be due to us. We are trying to provide as much time as well. Do the evaluation, receive proposals, and negotiations we have in the spring. If we can start earlier, we can really accelerate that timeframe. This is our proposed estimated timeline. Negotiations in the spring.

And then to make the awards.

The other thing that we have thinking is we're not just going to issue the IDIQ solicitation. Along with it is going to be the task orders. Some of the task orders so we can immediately not just issue the IDQ but issue a task order to start implementation of OPTN program.

Given the complexity of the solicitation, because we really are trying to use innovative process and procedures, we will have in between the release of the solicitation probably an industry contract clinic to go over the solicitation. Because we want to make sure, one, that we get multiple vendors with capabilities and expertise to compete. But also to explain to you the thoughts, the evaluation criteria, that each of the domain will have. Specific requirements that we're going to put in them. And to make sure everyone is a level playing field.

So with that, to sum it up, our approach to this complex procurement involves collaboration, transparency, and innovative contracting methodologies that we can use. I believe that working together and you have started to work together with us and not just us working together internally, as you heard Suma, the United States Digital

Service colleagues are also joining us, as well as our IT office, the program office and contracts. We all have rallied up internally to work together toward this initiative. Also working together with industry, with the stakeholders. If we work together toward this important contract that affects all of us across the nation, we can come up with an innovative solution to move forward and modernize the OPTN, not just the systems or the program, but the procurement that we want to put out for all of you.

So with that, I'm going to turn it over to Manjot. Sorry.

>> MANJOT SINGH: Thank you very much, Bonnie. I want to thank everyone for all the questions you have submitted prior to today. We, as Suma said, we analyzed them. We built them we hoped to build some of the answers to the questions into the presentation that we just went through. We think we answered a majority of them. But for ones that were left outstanding or ones we haven't answered, our hope today is to carry on addressing them through our panel.

So let me welcome back to the stage Suma, Bonnie, and also let me introduce the HRSA CIO, Adriane Burton. So I'll pull up the questions. I think, Suma, this first one probably makes sense more for you. Some of the questions we received, the theme focused on essentially how does HRSA plan to transition the contract seamlessly? How would we ensure coordination happens effectively amongst all the contractors including the incumbent?

>> SUMA NAIR: Yeah. All right. That's a great question. Thank you. I think as we stated from the beginning, right, we're doing modernization to improve the system for patients and families. And so first and foremost, our guiding principle is to do no harm. To

ensure patient safety as we move forward. We have to take a thoughtful approach in that endeavor. A transition is critically important to that. Bonnie mentioned, that's why we have a transition contract. To support that and we have domains associated specifically to foster collaboration and coordination amongst the experts that we pull in to support the OPTN. Right? I'll also say transition and multi vendor environments are the norm across many federal procurements. I think this is an anomaly that there's only been a solo vendor for the past 40 years. Right? And so there's a large body of tools and resources and expertise associated with transitions and collaboration that we leverage. So you saw it automatically already in the design of the PWS. There's a contract to enable that in tools. We're working on our plan, how we plan to design this so we ensure coordination between all the vendors.

I mentioned that leaves space for a separate group of folks to really think about innovation, next generation, where we want to go. Those innovations that we do, we will be carefully working with the community to do our research, interview, continuous engagement to test, to pilot, to consider scale and integration with the existing systems and processes, these innovations. Right? We'll be doing it very deliberately. Thinking about the best change management practices and principles. Community adoption ability. Rate of change capacity. In doing that. Those are some of the strategies that we're deliberately putting forward to help foster seamless transition where transition is necessary to foster innovation and change. Where that is an opportunity. And to do it at a rate that supports the entire community to understand that change. And come along with it and adopt it. And continuous monitoring. We're going to assess the

impacts of those changes and taking an agile approach, change as needed.

>> Thank you. Bonnie, I think the next one is for you. How will HRSA ensure if more than one contractor is selected to carry out the functions of the OPTN that there will be close coordination and communication amongst all the contractors to ensure the entire OPTN is working in alignment?

>> BONNIE GARCIA: So ensuring, we have multiple vendors, is to ensure that we open competition. One is we need to open communication, we need to hear from you this is how we put that whole procurement together.

Important is also that you bid for task area 5, which has the transition, which has the collaboration that needs to happen. But in addition to that, Suma mentioned in one of her slides, we need to also increase and modernize. So some of the things that we're doing to make sure that there's that transition and collaboration going on among the vendors that we envision is that we appoint contracting officer representatives for the different task orders. Different with the different expertise so they collaborate. Important to us is to have a project and program manager that's going to be the lead among them. Those are contracting methods that we plan to use that is not new, but it is something that we need to apply to this contract. And also important to us today is what we hear during the session, multi vendor. We hope to obtain feedback from you on how do you envision? We don't want to be on a silo. We want to hear whether it's a positive or negative comment. We want to hear how do you also

see us, you know, coordinating the multiple vendors? We have our ideas. But we also need the information from the sessions.

>> Thank you, Bonnie. Welcome, Adriane. I think this fits more in line with what your expertise and I don't think I covered this in task area 2. So to help us understand what it might look like to do work as part of task area 2, could you provide any information about what tools and technologies are in use today?

>> ADRIANE BURTON: We use a contractor system that involves the OPTN functions right now. The system, of course, has to integrate with different applications as well as meeting security NIST 853 requirements.

>> MANJOT SINGH: Understood. Thank you. Suma, I'll go back to you. So coming from the heels of a Senate Finance Committee hearing yesterday, discussion, rather, has HRSA thought about the implications about moving to an ecosystem where for profit ventures are present?

>> SUMA NAIR: Yeah, thank you for that question. Absolutely. We're very excited about the opportunity to bring in a diversity of expertise to support the complex system that we have. There's so many activities and functional areas that go into having a high functioning organ procurement and transplantation system. I mean, just think about the technology we have in our pockets and bags today. What you have today is probably different than what you had three years ago let alone 20 or 30 years ago. The advancement of data, technology. All of that has really expanded. So we are very excited by in fact, as part of our president's budget request, is the flexibility to bring in the broadest range of expertise we can to help this life saving

system. Anywhere deserves to have the best thinkers and technology, it is people who are waiting for a life saving transplant. And to support all the dedicated clinicians and care team members who spend their entire lives toward this mission of transplant.

So we're very excited about that opportunity. And we want to be clear about our intention with the OPTN board. The first graphic that I shared, the OPTN, right, the body with its 400 plus member institutions. The 400 plus volunteers who serve directly on the board. Or through Operating Committee or the different committees of the board. They set the policy and the like. Our intention it for the contractor who supports their work. Bringing the board together.

Calling the meetings. Doing the minutes. All of that kind of management is a non profit. That expands the opportunity then for all of the other operations, logistics, IT, to bring in whoever is best seated to execute those functions. We're very excited about that. If you have a strong, independent board, then they are fully empowered to exercise their oversight with HRSA over the functions. What is necessary to accomplish the mission of the OPTN. It is the members of that community, the surgeons who are doing the work day to day. The procurement officials who are professionals who are getting the gift of life and making sure those who need it get them. Who will set the policy and implement the policy. Help make sure people are we have right expertise to implement those policies. And oversee the compliance with them. We feel confident with that independent leadership, HRSA's federal oversight, all of the far clauses and governing laws and regulations, we have all the guardrails necessary to advance competition, get best in class support for the OPTN in the system, and have the appropriate guardrails in place.

Bonnie mentioned some of the guardrails associated with contracting. So we think it will be a tremendous leap forward for supporting the system.

>> MANJOT SINGH: Thank you. Bonnie, I apologize, this is a multi part question. About three questions in one. For the transition IDIQ does HRSA attend to have multiple awardees? Will awardees need to be able to support all performance work statement task areas or could they get an award if they only supported certain performance work area tasks? There's a follow up on this as well. But I'll just ask. Can bidders indicate specific task areas or domains that they want to bid on?

>> BONNIE GARCIA: So yes. HRSA's intent, again, is to have a multiple IDIQs. We hope to hone on the different expertise that the vendors have. However, to bid under the domains, again, I want to emphasize that you need to bid for domain 5. It's required. Hopefully everyone got that message. It's really up to your capabilities and expertise which domain you will be submitting proposals. Once we issue the solicitation, you will see if you can bid when we have the final performance work statement that will describe what the work is. And then we'll have the technical criteria. You're open to bid for all the domains that we have laid out.

>> MANJOT SINGH: Okay. I guess a follow up to that is what is the eligible criteria for the organizations interested in becoming an OPTN IDIQ holder?

>> BONNIE GARCIA: So here's where right now we're having our open sessions. We are hoping to get ideas as well as recommendations. Like I said, we have our own for each of those domains. Our plan is one

solicitation to award multiple IDIQs. But each of those domains is going to have their own technical criteria, technical requirements, that you will be required to meet. So that's the plan right now. Please participate in the sessions. I keep emphasizing that. Because it's very important to get that feedback.

>> MANJOT SINGH: Thank you, Bonnie. There's another IT question. If most of the new IT development will be on the next gen contract asks, and the current solution is proprietary, what are the type of things that vendors can expect to work on under this transition contract on the IT task area?

>> ADRIANE BURTON: There's a lot that can be done for future innovations, the contract, member security and compliance, that's really big right now. Member compliance with cybersecurity. Interoperability with EHR systems. As well as API adoptions. So those are some key areas that we really need assistance with.

>> MANJOT SINGH: Thank you. Suma, I think you may have potentially answered this. Perhaps this is worded differently. How will potential legislative changes or funding limitations affect the procurement process and future contracts?

>> SUMA NAIR: It's hard to speculate, but if you're asking for my hope, I hope it will greatly advance and accelerate our aims as people laid them out in our request for some of the tools including legislative proposals to really kind of unencumber us from the 40 year old statute that didn't realize the full range of complexity that would be today 40 years later that is faced by the organ transplantation system. So I'm optimistic that those changes will really accelerate our efforts toward modernization.

As I mentioned, right, while we work through these pieces, we're getting your ideas. We have our ideas. We're exploring a whole range of different options. When we get the final time to issue the solicitation, we're going to go with what is the law at that point. And the good news is we have ways to flex and add amendments as necessary as well. We're very optimistic about those changes. And their ability to really facilitate our work toward increasing access to organ transplantation to everyone who needs it.

>> MANJOT SINGH: Thank you. So Bonnie, this is a loaded question. Will there be small and large business awards as part of this contract?

>> BONNIE GARCIA: We're encouraging all business to have the capabilities and the expertise to submit proposals for their awards. We also encourage you to maybe come up with teaming arrangements or joint ventures. You know? Because we do understand a single vendor might not have all the expertise that is necessary. We're encouraging that. We encourage small and large to network. Get together. And really take advantage of those expertise to submit proposals. So at this point, at this time, we just encourage all business of all sizes and all public and private institutions to submit proposals if they have the capabilities and expertise on these domains. You want to hear from joint ventures, teaming arrangement. Please, know, that's what we're talking about when we talk about collaboration. When we're talking about really sharing ideas of how we move this procurement forward.

So Manjot, we encourage everyone to submit proposals, to gather and submit their ideas. Please select the domain that best fits those capabilities and expertise that you have.

>> MANJOT SINGH: Thank you. Adriane, can HRSA elaborate on data standards for interoperability in this transition contract?

>> ADRIANE BURTON: We haven't exactly defined it yet. We're looking at HL7 as well as fire standards. Other programs within HRSA. We're looking for interoperability especially with the OPTN system today, in the future and going forward.

>> SUMA NAIR: I'll add on to that to bring it to layman's terms. That's absolutely right as someone who's pursued APIs in other arenas and know how critically important that is. For the care team members, we talked about patient safety. Doing no harm. How easy is it when you're typing in information for one number to get transposed. Matching organs and the criticality there. How do we take out those opportunities where there's technology that can better serve us. It reduces burden on providers and care teams. It reduces opportunities for patient safety adverse events. How we leverage the technology better and information we have to better serve to bring light to the patients and families about the transplant journey. How do we use the technology to help them have the information in a way that's accessible to support their decision making with their care team? So I think those are some of the areas that we're really interested in. In terms of the technology. Not just the technology because it's shiny and interesting for technology sake. That's interesting. But really the what it can mean to patients, families, the care teams providing the care and ultimately make it easier for us to improve and have transparency in the system.

>> BONNIE GARCIA: That will be short term solution with this transition contract and then the next gen.

>> MANJOT SINGH: Thank you, Suma. Thank you, Adriane. I think one of the outstanding questions remaining how is HRSA preventing unintended consequences to the larger community during the OPTN modernization effort or OPTN modernization initiative?

>> SUMA NAIR: Yeah, this is going to sound redundant because I keep saying it because it's front of mind for me. I was working on patient safety 15 years before I joined this program. Front of mind to me. The way we'll do it, we have multiple opportunities. Right? First and foremost, by keeping that front of mind. As we design the modernization. And as we think about how we manage the change. Second, as I said, what we're doing is not an interesting idea that the wonderful HRSA team is conceiving here in our headquarters by ourselves. It's grounded in the research that we're doing with stakeholders. This environment is so complex. And interconnected. Right? If you think of the transplant journey maps you all have seen. Maybe you've done some of your homework and you're understanding. None of those pictures really give you a full sense of the complexity of the system and the intertwined nature of all of the different parts and processes. Right?

And so we are very carefully thinking through, okay, if this is the recommendation, and that's the end, what are all the places along the way where things can go wrong? How do we correct for all of those with all the relevant stakeholders then think about that in advance before designing it. Right?

So we're going to use all of those strategies. We're going to monitor to ensure what we're putting forward really works out.

I would draw a parallel to the way the OPTN works and their policymaking. There's a great amount of data that goes into understanding an issue or opportunity. There's great deliberations in thinking about a policy and its implications. Then there's continued longitudinal evaluation of the impact of some of those. I think we would take similar tasks in our efforts around modernization. We want to improve the system but in a way that the system has the capacity to absorb and come along with. And that doesn't cause any harm. So we will make every effort to mitigate any unintended consequences.

>> MANJOT SINGH: Thank you. So it appears that we've addressed most of the questions that were posed by the industry. Thank you, all, very much. But, before you guys leave before we move on to the next session, I hope you will allow me to sort of field any questions from the folks that are here in the audience or the folks on Zoom. If any of you all have any questions you would like to ask, please raise your hand and flag one of the staff members that are equipped with the mic. For folks on the call, please submit your questions to the host via the chat. I'll start by one of the questions we already received in the chat. Which is I think, Bonnie, this would make sense for you. Can you go over who reviews the proposal in the review process? Who at HRSA gets awarded the different components of the contract?

>> BONNIE GARCIA: Okay. So what we have is a technical evaluation panel of experts. Sometimes we rely on our own experts that we have. Other times, probably in this one, we might bring experts from outside to help evaluate. It's not Suma evaluating or Bonnie or Adriane. It's experts we have that will create the different panels with the different expertise. We don't envision one panel of experts. We

envision different panel of experts evaluating the different domains because they require different expertise.

>> MANJOT SINGH: I think so. Before I start with the questions there's one more question that just came in as well from the chat. I think I can take a quick stab at it before I turn it over to you, Suma.

The question is how will HRSA work toward improving the organ donation systems to ensure that they do not go down? Will there be clauses in the contract? I think there was a follow up. So yes. In task area 2, we have defined the objective that we would institute SLAs as part of the as the task orders for an IT system. I don't know if there's anything else you want to add on maintaining on ensuring there are clauses in the contract to maintain reliability.

>> BONNIE GARCIA: Yeah, we definitely want to make sure there's some clauses in the contract that tighten up over time. Then also potentially providing some type of external monitoring to make sure it's in compliance as well.

>> SUMA NAIR: I'll carry that thread through. It's not only an issue on technology, it's all elements. Part of the modernization, our intent is to ensure this is where you all can provide feedback as well, what are the right metrics to evaluate success of any function? Let's say there's several functions essential to support the OPTN in meeting its mission or executing its mission. Consequently, how do we know that the vendors we bring are doing a good job supporting the OPTN? Obviously, we would want to build in performance metrics, service level agreements, et cetera, in the contracts. I also think we're thinking about so for members of the OPTN, how do we then get because you are the customer for those services, right, we're

presenting the contracts, obviously, on your behalf. So how do we get your feedback into in addition to HRSA's independent assessment of the contractors. How are these working out for you?

So for certain functions, right, because this is a national public resource, OPTN and the organ transplantation system, what are our opportunities to make this information publicly available? So if we have a core set of metrics on the functionality of the different vendors and their performance, do we make these publicly available? What's the data set? What's the frequency? So we can all see. We're shining a light into what's happening. Where it's not meeting the mark. We have all the, of course, contract levers to support performance improvement and hold people accountable. That kind of transparency and accountability is what we're trying to build in with a modernized system. Welcome your feedback on metrics. How to share that. Et cetera. That would go across all the lines of the support functions that we're looking for the OPTN.

>> Suma mentioned the contracts. From Adriane's group, the surveillance. The quality surveillance plans that we want to ensure that we put under each of those contracts, each of those task orders, actually. Not the parent contract, but the task orders need to be meaningful and have those metrics that we are going to be able to have the surveillance plan to ensure that they're met. Shows that you have met these metrics. Having experts to be able to measure that the metrics have been met. That's what we're thinking within the contract parameters as well. Like you said, to show proof.

>> MANJOT SINGH: Thank you. I will stop taking questions from Zoom and turn it back over to the room.

>> Hi, I'm **ATTENDEE AT ORGANIZATION** and a kidney transplant recipient.

>> MANJOT SINGH: You may have to turn up the mic. There's a button on it.

>> Closer? Okay. Yeah. Hi, I'm **ATTENDEE AT ORGANIZATION** and a kidney transplant recipient. I was going to say I appreciate you starting the conversation about patient the transplant system is not patient centric. I appreciated you talking more about accountability and transparency because we need more of that. What I was trying to track in the presentations is how are we re evaluating metrics? The metric that is patient centric is 17 people die on the wait list today. Will die on the wait list today. A transplant system metric is we're number one in the world if volume. That's not the right metric. Just because we did one more transplant this year than last year is not acceptable when 17 people are dying every day. So I think you really touched really well on how you're open to redefining and rethinking the metrics which is what my question was because I didn't see that in the presentation. I actually believe that's the key to all of this. We can have accountability and agreement consensus in transparency, what the metrics are and how we're doing. Thank you for that.

>> BONNIE GARCIA: I think it also ties to data collection. The data that we're actually collecting and generating the different reports. Are we collecting the right data? I can see that as part of the task 2 as well.

>> You can hear me, right? Good morning. **ATTENDEE AT ORGANIZATION**. So I know in the past, system ownership, data ownership, has been an issue. Adriane, I heard you say the new system will have to meet the governance standards, NIST standards

and all the others. My question is who will own the new system? Will it be the vendor? Who will own the data? The data is the key here. System ownership is in my mind secondary. Is there going to be a federal data steward or somebody who can always ensure they have access to that information?

>> ADRIANE BURTON: System ownership is still up to debate. I think that's still being evaluated. But, of course, we want to make sure whatever is decided is in the best interest of competition and flexibility.

>> SUMA NAIR: Would say we have clarity around the data. This is not the focus of today, but our next generation, we're thinking about ideating new technology, building out pieces. To the extent those are funded by the Federal Government. The code outright, that is federal property. So we would have that. Use that to build up to a new system. I think that's part of our plan. The things we support and build out to get us to a next gen future would support us with having a system that is available for regular transitions and updates and continuous modernization.

>> Thanks. It's never too early to start thinking about it.

>> SUMA NAIR: We have full access to the data now. Our intention it to continue that. I think it's in some of the it's in domain 5 around part of the as Bonnie mentioned, give you guys some comfort, folks who are new to the face, folks to transition in as well as support for transitioning out, downshifting on certain activities and ensuring that data is necessary to execute the different functions is shared seamlessly to all of those in this space.

>> BONNIE GARCIA: We started some work with data dashboards we released in March around the OPTN. Those will continue to increase over time in terms of the different types of dashboards.

>> MANJOT SINGH: Thank you. A question in the back. Right side?

>> I'm ATTENDEE. I have two questions, if you don't mind. One on the vendor performance measurement. The other on general operations and technology. From a vendor performance perspective, obviously, you already answered a little bit of that, talking about other contractual mechanisms to hold vendors accountable for operations and all of that. Have you thought through well, in my experience in contracting, they're thought through. Have you thought of audits throughout each year so that as operations are going on, continuous monitoring and evaluation can happen and to ensure patient safety? That's the first question.

I think it's a misconception for that it should only be reviewed annually. We should be doing a quarterly review of using them. Also shifting. Those should not be one standard. As the need, as requirements change, we need to change with it. That's why we're trying to do it. That's why we want the ideas. Normally, they review once a year. That's not what we want to do. As we move with procurements, the OPTN procurements are focused, we want to strengthen that and change how we use it. So it's not just a checkbox. It is as Adriane mentioned some audits. She said, hey, some of the audits that needs to be done. We want it to strengthen.

>> MANJOT SINGH: Thank you so much. The second question has to do with technology innovation and the role that policy, possibly the Board of Directors might play in that. Have you thought through

official mechanisms to ensure that as innovations happen and new technology to help get the operational side of OPTN done better, faster, more efficiently, through the policy aspects that might impact or possibly undercut that. So for example, if there's innovations or solutions tracking but let's say there's not a policy requiring tracking from the OPO standpoint, different things like that. Have you thought through matching those two things together? As there are innovations, ensuring that the board has within its purview to institute policies to make some of those innovations a requirement through the operations. Does that make sense?

>> I can talk about that from the IT perspective. We actively participate in the OPTN nook that's responsible for IT oversight. In addition, we meet on a regular basis with a current contractor. So we talked a little bit about the it's not like you're awarded contracting. You wait the entire year and wait for performance. No, we're meeting weekly at least at a minimum maybe more than that, depending on what's going on. So we have different ways to monitor and improve the system.

For instance, there was a new security policy that was just approved through the OPTN nook and the bigger board. But there was a lot of collaboration with HRSA and the current contractor as well as a nook to even push this forward. So we actually worked on that for a year to get that approved and proud was the policy that was just implemented.

>> SUMA NAIR: I'll add on, like, maybe this is my impression I took away from your question there. Maybe there's a push and pull between policy and OPTN members and the technologists and the

technology. I'll say in our work for stakeholder engagement, talking to OPTN, the OPTN members, patients and families, there's strong alignment. They're very interested in having world class technology to support their work, to make sure they have the data. Make sure they're getting the information. It's not a black box. Making sure the clinicians who are putting the information about donors and those who are looking to match that information and have the right information they need for successful transplants are asking for this. So I think that, remember, at least from my world view, technology is an enabler. It's not an end to itself. And so the policy and the oversight work of the OPTN, they are going to identify areas to strengthen the system. And that will necessitate technology to enable that. I think my observation to date, limited as it may be, there's a greater appetite and desire for a pace of change and technology to really support the OPTN in executing its mission.

>> MANJOT SINGH: Thank you. Let me go to let me yeah. A couple of questions that are coming in online. I guess, Bonnie, this may apply to you. Can HRSA provide clarity if there will be multiple vendors per domain, or a team of collaborative vendors working across all domains on this transition contract?

>> BONNIE GARCIA: Our intent is to have multiple vendors per domain. Of course, we cannot predict me coming from contracting, I can't give you a preset of numbers of the vendors. Our intent is to have multiple vendors. We have to see what's the capability and expertise that the panels are going to evaluate that will be the determination at that point. We intend to have multiple vendors under the domains for right now.

>> MANJOT SINGH: Got it. Let me take one more question from Zoom and one more question from the room. Because we are running out of time. I have a glaring clock here on the right side.

So this is question I think it's from **ATTENDEE**. What happens in case you see a solution that could drastically improve the OPTN and operations today? Would we still wait until spring to award?

>> No. I think that's why we're, right, the idea is transition. Even as within transition as Adriane laid out in the technology space, there's room to optimize the current state. We seek that opportunity. I think there's some opportunity there for sure. And then the next gen is where it's a good idea. It holds promise. Maybe it's a seedling idea. We really need to flesh it out. We need to do the due diligence and research with the community. Think about the touch points across the system. We need to implement it small scale then think about if it's something more if that ilk of an idea, it's more in the next gen space. There are a fair amount of opportunities to even optimize the current state and we really look forward to people bringing those forward and bringing your ideas and proposals forward for those kind of ideas in the transition contract.

>> MANJOT SINGH: Got it. Thank you. In the interest of time, I'll take one more question from the room. Sure.

>> Good morning, my name is **ATTENDEE**. I'm the Director of **ORGANIZATION**. I, too, am a kidney recipient like **ATTENDEE**. Together, we make a pair of kidneys.

Historically, HRSA provided oversight to a single vendor and moving toward providing oversight for multiple vendors. I'd like to ask you to

elaborate on that more. How do you plan to ensure these multiple vendors are federally compliant with the laws and regulations surrounding organ donation and transplantation to ensure that we are mitigating life threatening inefficiencies and inequities that exist now. How do we plan to provide oversight to different vendors to make sure we have a superior best in class transplant system that is, you know, patient centric?

>> SUMA NAIR: Yeah. I'll start. Then, Bonnie, I think you addressed some of this as well. We can re up some of those thoughts. So we're going to get that by design. So first, we start with holding the mirror to ourselves. What are the capacity we need here in HRSA to really as we modernize and have stronger focuses in technology and operations, all of these different areas, we're going to make sure we have the staff capacity, project managers, et cetera, to really do that. We're taking a thoughtful look into what is the right structure we need here in our team in HSB to do that.

So that's one element of design. Of the kind of oversight capacity then there's the element of in the contract, itself. I discussed the metrics and things. Accountability measures that we want. Right? And not only having those and looking at them regularly. Not once a year, quarterly, either, for some of them. Making that information transparent available. So we have partners in our effort to assures right, that we getting what we need to advance the system. So that kind of public transparency. Of course, we have the contractual arenas as well. So Bonnie, I'll turn it over to you to talk about some of that.

>> BONNIE GARCIA: Yeah, in the past, one of the shifts we have is that we normally have an integrated project team at the beginning of the procurement. Right now, we have an integrated project team. Once it's awarded, it disseminates. We're shifting to have the team not just to be with us during the solicitation but help with the Contract Oversight Administration as well. We also shift from having an entity with specific expertise to having entities that have expertise on the different domains to be able to participate and provide feedback. More than that, what Suma was saying is strengthening her staff that has that expertise to be able to provide feedback as the meeting happens.

So the other thing is we do our planning and working on having dedicated CORs. That's their job. Their job is to ensure the contractor is performing. And to flag when there are issues as well. Not just that, but work collaboratively, more of a team effort between that vendor and us. That we have collaboration. That's our intent and hopes and dreams as we move forward.

>> SUMA NAIR: Makes me think a patient centered integrated care team. That context, that really matters to patients and families. All the people who provide the care for them on the variety of different issues. Working together. Looking at the same information. And putting the patient at the center. So here, our patient is at the absolute core. One level up is how we get to the patients and supporting them through the OPTN and OPTN members. Taking that integrative holistic approach across all the domains of how we're supporting the OPTN and what changes need to be made and what information do we have collectively to do that. We're committed to

bringing the full complement of expertise necessary to support our arena and a places around OPTN.

>> My father had a kidney transplant, my cousin a heart transplant. For me, I look at the responsibility that have to make sure the vendors are able to deliver. I think by having multiple contracts, it will provide us the ability to have best in class and not just a general vendor that may be good in one area but not so good in others. When you it awarded to one, you don't have those options. This will provide us long term options.

>> MANJOT SINGH: Great. Thank you. So I will try to conclude. Thank you for engaging questions and answering all the questions. The discussions certainly don't need to end here. For any additional input or feedback that you may have, please visit the OPTN modernization web page. At the very bottom of the page, you'll find a Contact Us form. We welcome or appreciate input or feedback that you may have.

So with that, it concludes our plenary part of today's presentation. Next, we're going to try to take what I was hoping to be a 30 minute break. More like 20 minutes. So before we resume, we need a little bit of time to ensure all the rooms are set up for the continued discussions. I guess this would be a good opportunity to network.

Please feel free to grab some water, which is available on either side of the hall here. There is a marketplace in the corner. Trying to think of a better word. That you can pick up some snacks or anything else. A cafeteria, of course.

The next set of discussions will be split into three topic areas. These three topic areas were selected by you all as the top three topic areas you're most interested in having continued discussions. There's a button on the name tag that corresponds to the session that you had selected. These are the three sessions. If the session that you selected did not make the cut, please feel free to join any one of these three.

For the operations discussion, that will be held here in the pavilion. And the other two topics will be held in the conference rooms directly behind the pavilion. There will be folks here that can show you how to get there.

For the folks on Zoom, shortly, you should see a breakout icon. That should appear at the bottom menu tray. Please click on the icon and select the session that you expressed interest.

Much like the folks here in person, if you remain in the main room in Zoom, you'll be part of the operations discussion.

If you, again, if you need any help finding the appropriate session, please flag any of the HRSA staff members, myself also. Or on the Zoom call, please let the host know by chat that you need some assistance. Thank you, again. And we hope to resume shortly. Thanks.

[END PLENARY]

(Break)

>> Hello, everyone. This is a five minute warning before you're breaking to your focus groups. Please try and find your spaces.

Nobody is listening. Five minute warning, everyone, for the breakout sessions. Our focus group conversation. Thank you. Participants that in the operation group, please stay in this room. The other two groups, it's around the corner. Turn left from this conference room. Operation group, please concentrate on the right side of the room. Operation focus group, please concentrate on the right side of the room. Thank you.

[START FOCUSED CONVERSATION]

>> Hello, hello.

>> Good morning again. So we're happy to have this little kind of breakout. Rachel is going to be leading it. We want to let you know it's informal as we talk about various ideas. It will be free flowing. After, we'll be able to pass mics around if you have questions. I'll bring Rachel up who is our facilitator for this session.

>> RACHEL: That's right. Thank you, Frank. No worries. I'm getting my notes here. Before we get into discussion and hearing all your ideas, I have just some opening points to make before we get started here. My name is Rachel. I'm part of the OPTN modernization team. I'm here today with Frank Holloman. We're here to hear your suggestions on how to make it as attractive as can be.

This is a chance to let us know what's on your mind. Even if it means don't have that as a task area 1, you know, break it up in this way

instead. We're totally opening to hearing any suggestions that you have. Suggestions around how the evaluation process be the best to attract excellent people to the table and get the right folks if place to do this type of work. That's really the point of this session.

If in the context of our conversation today, any additional context is necessary, Frank is our subject matter expert on all things OPTN. He's here to provide extra color if it helps in the ideation session that we have. Let's see. Some ground rules. Please participate. There's no such thing as a dumb question or comment. We want to hear everything that you're thinking because it will help us best shape the future of this procurement. Let me see if there are any other notes that I have.

This was mentioned a couple of times. Thank you. This was mentioned a couple of times in the plenary presentation. But if you do have additional questions or comments we don't get into this in this, again, feel free to go to the modernization web page on OPTN.gov, sorry, HRSA.gov. Submit them through that form that's at the bottom of that page. We may not be able to respond to all the questions but having them in our hands will help us best shape the future of the procurement.

I think those are all my ground rules. So with that, oh, one more thing I wanted to say about my role here. I'm the moderator

>> Maybe tomorrow, maybe next week. Maybe in a month, something will fire off for you

>> RACHEL: That's another breakout room. Give it a sec.

Okay. Let's see. In my job as moderator, I'm going to keep the conversation focused really on operations domain or task area. And

the procurement, itself. So there are other venues, namely stakeholder engagement and research sessions that we're holding to be able to talk with the stakeholder community about how to improve policy. How to improve the allocation process. You know, how we improve the OPTN, itself. This conversation today is really how can we make sure the procurement gets the best folks in the room to work on the operations stuff.

So as moderator, I'm going to try to keep the discussion focused on that today. If I interrupt or interject, that's I'm just trying to do my job.

Okay. I think that's it. Let's get started. I'm going to pose a big, broad, question out to you all first to start. Which is does anyone is any recommendations, or thoughts about what you saw in the operations task area that was posted in the PWS? Ideas or recommendations about how to make that better, more clear, more attractive to bid on? Anything like that? Thanks, Jimmy.

>> Can you do me a favor and get a second one and you can handle anybody on this side? Thank you.

>> Hi, my name is **ATTENDEE**. I spent the last 16 years at universities spinning companies out. And so my question was is there an SBIR element to this? In the next gen. I didn't see that addressed. It seems to me that would be a great opportunity to encourage some of the great resources coming out of universities to get commercialized.

>> RACHEL: Is that a question about next gen or transition?

>> Next gen.

>> RACHEL: I'll note that down as a suggestion. Appreciate it.

Also for the technology staff, would it be possible to get a charger so I can take notes on my computer? Thank you.

>> My name is ATTENDEE AT ORGANIZATION here at HRSA. Leading a number of large collaboratives. One of the things that was very successful in our execution was also having an interagency agreement with other organizations. Such as CMS or ARC. Being previously also at CMS, the end stage renal disease program is a huge variable in terms of informing patients. You know, I heard you all saying keeping patients at the center of this body of work. There are some disparities where patients are not aware of the processes and working with their nephrologist. Has HRSA considered agencies within HHS as part of this transition and modernization of the OPTN network?

>> FRANK HOLLOMAN: I can take that one. Part of the information we put out is we heard from the community. We want to make that clear. We've been listening. So everyone has said you must work closely. HRSA and CMS must work very closely together. So we have already forged over the last year and a half an organ transplantation affinity group. So we have that in place. I think we'll be sending out more through a blog. Yes, you're absolutely right. We're working closely with our CMS colleagues. We also have connections with CDC, FDA. They're all part of this. Sometimes we show a slide that shows the multiple HHS agencies that are involved in some form or fashion with transplantation. We're working close we with our colleagues.

>> My follow up question, task 1.7. Thinking how you roll that out. It may be helpful to have a separation between the carrot and the stick. Between quality improvement and enforcement. When you're

working to have leaders make commitments to improve the process.

Whether it be the surgeons or the process relative to discarded organs. It's very good to be able to have and make commitments and to move on those commitments in a way that they're seeing it separate as a quality improvement activity. Versus an enforcement action as part of the overall execution of the work.

>> FRANK HOLLOWMAN: You're trying to type. We're grabbing ideas today. That's great.

>> Could I get a follow up real quick? Right back to you. Regarding the interagency agreements beyond what is happening today, did you have specific thoughts on what, how additionally you'd like to see that manifest and how it might connect with the work happening on transition? Or just a general request that we make sure it's top of mind?

>> I think it's important, there's a significant investment that's done, for example, with the network for scope of work. There's a huge opportunity to build on the data. Oftentimes, you're using claims, looking for improvement. Real time data would be more helpful. In thinking about the process of the patient moving toward ensuring the patients are working, knowledgeable about the opportunities to work with a nephrologist that would facilitate their entry into the process of transplantation. Interagency agreement

>> We can't hear you online.

>> As a part of the execution of the transforming clinical practice initiative where we reduce hospital admissions by 40% and readmissions by more than 20%. First time the 30 day readmissions

rate at CMS had ever dropped. We carried that work with a partnership for patients into the transforming clinical practice initiative. Where we were able to facilitate the support of clinicians moved from fee for service to pay for value.

Utilizing an interagency agreement, keeping the quality improvement separate from the actual enforcement, enabled us to have individuals commit in a way that had us exceed expectations and goals in both of the programs.

>> Thank you very much.

>> **ATTENDEE AT ORGANIZATION**. We do the logistics and tracking of, you know, about 40% of the organs in the country. So my focus as this whole OPTN contract came up is the importance of being able to see not just the logistical movement but more of a supply chain approach from a contract and management, transparency and coordination perspective from the OPTN's perspective. Ability to bring all these different disparate groups that are all trying to serve that mission of procurement, whether it's surgeons, pilots, everybody within a system that you have the data transparency real time, live. If something happens, the ability to reuse the organ or redo allocation on the fly. There's a lot of opportunity in looking at this as supply chain, really, not the even just logistics. But back to all the different groups. I think that digging in in that respect, a lot of what we hear about at the senate hearings and different things are often stories about logistics. Not just a match and a surgery. So being able to bring a lens of logistics and supply chain into this contract opportunity I think is important.

>> Thank you very much for that feedback. Do you feel the current operations domain allows the space for proposals like that to come through? Or would you foresee wanting it to change somehow in what is in the requirements and how we evaluate all that stuff to make space for things like that.

>> In reading everything that's happened thus far relative to OPTN modernization, not as a criticism, but I don't think there's a singular focus around supply chain and logistics. I know we're talking in this room about procurement. But this even goes back to the equity issues of the patient candidacy becoming an active potential recipient of an organ. There's a tremendous amount of breakdown in the logistics aspects of the candidacy process that we've studied. I think there's a whole host of super talented other companies. You know, supply chain oriented groups that need to be brought together into a singular platform. So that we all can coordinate more fluidly together. It's very, very difficult to create the coordination with the current system. I think OPTN and the contract would be best served to almost I'd almost say it's a whole other task order. There's a huge area of gap that's happening between the done and the recipient.

>> Great. Thank you very much for the idea. So just as a follow up to your I can tell you we have received again, we're just ideating this group. We have received kind of negative comments about using supply and demand when it comes to organs. Because it's life saving. Are you proposing we try to go back to using that language supply chain? That's because we migrated to logistics. People didn't really like it.

>> Words have meaning. I appreciate the question. I don't see it as a supply and demand as much as I see it as logistics is just the table to table focus of each little step. Supply changes, all the way back, for example, we're now starting to track the people that are doing the procurement that are responding to the donor hospital. Let the donor hospital know the person with that family is 15 minutes out. It's not a matter of a box and an organ moving. When I say supply chain, I'm really focused earlier in the process. All the way back to the actual before the person's legally a donor and they're just a referral. How can we take all these technologies that all these private companies are developing, pull them together into a meaningful way so we're not all separate platforms, if you will. And so maybe supply is not the

>> Thank you for your clarification.

>> That's the supply chain it's a bigger solution than logistics. Logistics is a lower level. I think supply chain is a broader perspective.

The candidate come back here to have a referral. How do we connect those?

>> Great. Thank you. Right here.

>> Good morning, my name is **ATTENDEE**. I have two questions. During the initial when you guys dropped the RFP, is it possible to have multiple question and answer sessions such as instead of just having one hard deadline, having multiple of that?

>> Great suggestion. Thank you. To make sure I'm capturing it. When we drop the RFP, have multiple Q&A sessions instead of are you saying, like, in person sessions to facilitate discussion or multiple rounds of accepting questions and answers?

>> Multiple rounds of accepting questions. This is going to be fluid. I think you have a hard deadline of whatever. With you guys answer the questions, there's going to be follow up questions. I think it will be important to have multiple days of being able to answer questions.

>> Great. Thank you. I think Bonnie mentioned when she was up here because we recognized that how complex this is, once we put it out, we'd have sessions to make sure anybody who's interested in bidding would have an opportunity to come to our library, have a conversation, webinar, to make sure you're understanding any questions that's in the RFP. So great, thank you. You had a sec one?

>> Some of the task orders are very, well, as detailed as you can be. Some of them are one or two I'm assuming it's going to be fleshed out more. So the follow up of that that wasn't a question. That was just an observation. That wasn't a question.

>> I can confirm for folks who are on Zoom and can't see me nodding my head, or maybe you can. I don't know where the camera is. Yes. The intent is to have the more general requirements of the task area level. Then whoever gets on the vehicle would receive task orders with a lot more detailed information. I don't know if you could see this on Manjot's slide when he was talking about the PMO transition and next gen contracts. Our intent is to issue a bunch of onboarding tasks across each task area to start. So that vendors have the opportunity new vendors to the space have the opportunity to get up to speed on things. So yes, each task order will have a lot more detailed information. That's where the SLAs for the tech stuff, et cetera, would come into play.

>> This is an actual question. I don't think I don't know if you'd be able to answer this. If you have multiple vendors, I want to say thank you for that. I think it's a good idea. If you have multiple vendors or something such as communication, if you have multiple vendors on that task order, how you going to how will we as the vendors come across with one voice is the communication is such as the messaging or the branding? If you have multiple vendors having multiple ideas, multiple voices.

>> I'll answer with a statement then a question back to you. Which is the beauty of an IDIQ is we have so much flexibility to have the task orders be whatever we want within the scope of the task area. And they can change over time. If we try something out and it's not working we can change the task orders the next time around to include different requirements in them.

So my question back to you would be in the communications space, we can entertain the communications thing for little bit even though we're in the operations session. I know there isn't one for communications. We can talk about that here. Using that as the example. So in that task area, there's a lot of different work. There's the OPTN website. There's, like, education materials, all that stuff. In your mind, would there be an appropriate way to issue different things on different task orders that would enable multiple vendors to participate, but at the same time facilitate or at the same time not contribute to a disparate experience for the end user?

>> Well, you know they can't hear online. She'll need the mic back.

>> I actually don't know. That's why I had the question. I'll just throw a number out. I don't know. Let's say you have five marketing

companies. And three of them think of one way, and two think the other. How would the five come together for the one message? I don't know. The lead company, the four under them. They just come collectively I have no idea.

>> Okay. Gotcha. I see your question. I'll just say each task order will be for different work and each task order will be a single order. Each task order as it's issued will go to one entity.

>> I have experience within Veterans Affairs. They have an contract in place in and have a vendor that sets up their broad communication plan for the organization as a whole. They do issue task orders with various areas of specialty. There might be a vendor that's responsible for the website. A vendor that's responsible for a large event management or partnerships. I think the key there is the management of the overall IDIQ and task order. So the vendor that set up that broader plan at the office level needs to engage collaboratively with the other contractors and execution. It needs to be knowing they're responsible for the overall branding, tone, themes and messages, et cetera. I think there's opportunity to engage multiple vendors as well as it's known who played point on the overall holistic strategic communications point.

>> Great. Thank you. That's why we're here. To hear different things going on in the community already. Fred?

>> I really appreciate you incorporating the communications into this discussion. And I see the detail and the effort that has been put forward relative to the website. In my experience, we had a lot of success with having both a federal website and then a public website. In that public portal, what used to be health carecommunities.org, it

facilitated peer to peer communication. Whether through organizations supporting improvement in a different way. It was a safe space where people could ask questions and get answer from across the nation. Within the hour. It was also an area where we were able to capture quality improvement data measured against the outcomes of each particular organization, and be able to benchmark at the state, national, regional, and national level. So has HRSA considered a website functionality that would facilitate some more of that peer to peer communication versus just posting information that's accessible?

>> I think it's a great suggestion for an idea of some of the type of work that could happen under that domain. Thank you. I got it down.

>> So we don't forget, are we getting any questions from people online? Please let us know. We can handle those, too.

>> Hi, **ATTENDEE** here. Two comments. And this is really a follow up to your suggestion. I strongly encourage you to think about that. Because there does have to be peer to peer. And more technical and supply chain discussions. But then also as the parent of a child who we donated organs to, you know, from a parental perspective, I don't want to hear supply chain. Right? You want to use for the public a human centered design approach to communication. We use human centered design as we're thinking about the business requirements and the IT systems. Let's apply that same thinking to communications.

And then my second question/comment is about a year ago, there was a pretty comprehensive report that came out that focused on diversity and inclusion and the underserved population. And if we think about the task orders as verticals, will there be horizontal

requirements, if you will, that address diversity and inclusion throughout all of the task orders to make sure that everyone is being served throughout the process?

>> I think that is a great topic for discussion. It certainly is HRSA's intent to center equity across all of the work that's happening in OPTN. Whether those measures are incorporated at a contract level and/or at the, like, OPTN oversight level, I think is a great discussion topic. So if we're thinking about the operations domain, does anyone have ideas or thoughts on measures for tracking equitable support of operations?

>> Yes. This is **ATTENDEE** online.

>> Great. Hi, **ATTENDEE**.

>> Oz you guys are all looking around. So this is so with 20 plus years as an operator for the OPOs, I can tell you that it's not the process of movement that is broken. It's the series of providers that are producing the movement for the OPOs and the labs and the transplant centers. That is broken. Their technology is broken. So what needs to happen is what we do, what we built, after the experience.

To your point, now, a lot needs to change. But the process that's currently happening doesn't necessarily need to change. We need to move it to a visibility platform and have visibility to everything versus just, you know, manual tracking from the various OPOs.

>> RACHEL: Thanks, **ATTENDEE**. Another thing that I can say, I think this might be more of a, like, policy measurement and process management question. But I can say that our intention HRSA's

intention is also to incorporate human centered design across the board for not board like OPTN board, but across everything. One way that we measure a commitment to equity and human centered design is tracking the composition of the folks that we talk to in the research sessions that we have. So that's, like, one example that I can throw out of like, an actual metric that we can look at that's, like, incorporated into the work that happens. So that could be something that we could talk about using as a metric in the operations domain. So for the work that's happening there, any research that's being done with the community to inform improvements in the operation space. Tracking the composition of the people who participate in the research sessions to make sure that we're really listening to all voices equitably and not simply focusing on the loudest or most powerful historically voices.

So if anyone else has other ideas for metrics, performance metrics that we could incorporate in to make sure that we are actually delivering on our commitment to equity, all ears.

>> You may consider let me first say that aims create systems and systems generate results. To have bold aims for each of the components as a body of work, kind of aligned with the procurement in how you're wanting to change the system, having that bold aim then having individuals make commitments to those aims, is a way to not only generate the improvement but see that it's actually occurring. It enables that learning system to pick up things that other systems may be doing and integrate them into the work that they're doing. Aims create systems and systems generate results.

>> Can you all hear me?

>> With respect to human centered design and the approach, I read the operations task area as being about governance, the policy development, how the governance board is informed and helps develop policy and policy implementation. A critique I would have there is just the traceability to the budget task area. It gets very technical in terms of audit and internal control. That's something that might be best served in task 5 or different a domain and live somewhere else. You'll get a very nice integrated story about governance, stakeholder engagement, engagement with the field. How those ideas inform policy.

The budget piece didn't feel like a strong fit there. That's one thought.

A broader thought

>> RACHEL: Can I go deeper on your first one so I can make sure I'm understanding? Traceability into the budget, is that a separate thing in task order 5, everything across the board that's happening with this contract, how that plays into budgetary impacts?

>> That's my view of the program. Maybe budgetary impact would be broader and not necessarily specific to policy development and governance. And there's a nice story there. Budget seems it could potentially live elsewhere.

>> RACHEL: Very interesting, thanks.

>> Would be good to see strategic planning built out more. To the comments earlier, strategic planning traces to the metrics discussion. Metrics want to align to strategic objectives and goals and plans. If that was built out more and had a performance measurement,

element, of the strategic planning section, that could be a nice put there.

Final comment, there's been a lot of dialogue today about domains. Within this domain, within this domain. The conversation sounds like there's verticals where a task order would only be within a given domain. It would be really valuable to know that a given task order could cross cut domains or require functional expertise that spans across. That's a consideration for you guys in terms of how to administer the contract. I think the needs will cross cut from operations into IT or data. I heard you mention assigning expertise per domain. I understand that's important. In execution, you might need to be a little more nimble. Just for consideration on that front.

>> RACHEL: Thank you, great point.

>> FRANK HOLLOWMAN: We'll take the call from people online.

>> The first one is in from **ATTENDEE**. She asks is there a conflict to bid on both next gen and transition IDIQ? If a contractor bids on transition, does it preclude them from pursuing next gen?

>> RACHEL: Thank you for that question. We recognize that's a top of mind question for anyone who's interested in bidding on these contracts. I don't have an answer for you yet. Just know it's something we're actively thinking about and hope to have an answer for you soon.

>> All right. The next is from **ATTENDEE**. This is more of a comment and question. He says that gets back to the question of who is ultimately in charge of all of the contractors.

>> ATTENDEE: Can I speak to that? Is that okay? Actually, I have two comments. The first one that I wanted to make goes back to the original mention of interagency collaboration. I think a lot of the feedback that's driven this discussion is about OPO performance. And a lot of the oversight of the OPO performance lives with CMS. And the OPTN tools to help OPOs get better are more limited. So anybody who's looking at the operations component of this contract is going to ask the question how am I going to be able to work effectively with CMS to get the end results we need? I would encourage us to talk about in your solicitation in the details of your performance work statement how that's going to actually happen. Because, or otherwise, a contractor will look at this and say I can't have effective oversight of the OPO because really that's CMS' job. That's comment number one.

Comment number two is at the end of the day one of the things that's going to have to happen to make all of this work effectively is somebody's going to have to be in charge across all the different domains we've been talking about. It's not clear to me from the discussion so far where that's the OPTN board, HRSA, whether that's at a matrix. How that's going to work so the priorities, community needs to have, get moved forward in a coherent and effective way.

>> RACHEL: Thank you for bringing up that point. Both points, really. I'll address the first point and the second one. The first, solicitation details of the PWS, if we can describe what oversight will be like between CMS, HRSA, et cetera. Thank you for that suggestion. I am curious, are folks still going to be, like, have enough information to want to bid for this work if that information isn't defined in the task

area level but comes through more at the task order level. Where we can try out different things. I'm curious.

>> I'll be honest with you, the OPTN has been trying to make that happen for 30 years. It's really challenging based on the way things are structured. So I would strongly encouraged to have some framework in your PWS that helps people understand how this is going to be more effective than it has been in the past.

>> RACHEL ROUECHE: Sorry. Could you say that again? Oh, sorry. In the room, we have a non mic answer.

>> No, I was just saying it's what patients want to know, too. How do you plan to do this? To ATTENDEE's point the framework, what does that look like?

>> FRANK HOLLOWMAN: I think that's what we're here for. Stuart, as you were posing that question, I was thinking through that. Whether it's HRSA, some overseeing vendor. That's what we're here for. What have you seen, what works. In this kind of context. If anybody had something they worked through A similar structure that works best, that's why we're here to engage, exchange those ideas and concepts.

>> One quick follow up. On the surface the intent is for the OPTN to be an integrated organization that operates all the different pieces. What's not clear yet is the board in charge? Is there staff that the board hires in the OPTN through the contractor, through the operations contract, whatever, that helps them execute what the final rule or note tells us what they need to do or some other organizational structure that oversees this? Otherwise, I'm concerned you going to have silos that won't work effectively together.

>> RACHEL: Yeah, that's 100% a top concern and something HRSA is actively putting a lot of work and thought into. It's not something that we have more information to share on right now because the decision making around what that's going to look like is in progress. This is specifically around the question of what will the board's responsibility and HRSA's responsibility be in oversight in this new multivendor landscape? That's the piece that I'm speaking to right now.

So where was I going with that. We don't have more information to provide on what the decision is yet. On what exactly that's going to look like. If you do have recommendations, feel free to share them. Because we're actively working on defining that right now. So we're happy to incorporate any thoughts that exist from the community.

>> Just one final follow up. In the absence of guidance, the final rule and note guide the OPTN, list of tasks and so forth. And so if you don't have a change, the OPTN is responsible for all the tasks that you're just laying out. And the board is set up to govern the OPTN. So if you intend to change that, it needs to be clear.

>> FRANK HOLLOMAN: We're certainly taking those notes. Thank you, **ATTENDEE**. I think we have one more online. A third question.

>> Yes. This is from **ATTENDEE**. She writes it's my understanding that OPTN operations will be invested in different contractors, while policymaking will be in scope. **ATTENDEE**, if you're online, if you care to articulate this because it looks like there may be You can unmute yourself if you can hear me. Okay.

>> FRANK HOLLOMAN: I'll take a stab where **ATTENDEE** was heading.

>> Let me read the second part. Will the operation contractors be directly responsible through the OPTN or responsible to HRSA or both? If they're directly responsible to the OPTN, how will the OPTN exercise oversight without any independent staff?

>> FRANK HOLLOMAN: Working backwards, the first one is what we just addressed. I think what she's driving at is, yes, the OPTN policymaking still will be done by the OPTN. The board. Sorry. The board. The process, really, they work. The committees kind of make proposals. Seeing the issues. Concerns. Come up with new policies. Propose them to the overall board. The board approves them. Public comment and all the other pieces that are there. Then the board votes to approve or not approve certain policy.

So that part will not change based on OPTN contractors and vendors. That part will still be left in the hands of the OPTN board.

>> RACHEL ROUECHE: What we currently know is in the task order is support. This task area is also for supporting that separate body and policy development. Monitoring member compliance and performance. Those are the main areas.

I think we had a couple more questions or comments in the room.

>> Yeah, I just wanted to go back to the diversity part. I would request since there's multiple vendors that you guys maybe sit aside for women owned smart business or hub zone or something. That would help with making sure there's a diverse population of vendors.

>> FRANK HOLLOMAN: Sorry. Thank you for that recommendation.

>> RACHEL ROUECHE: Thank you.

>> ATTENDEE AT ORGANIZATION. I want to make the point there was nothing in previous contracts that required the OPTN to fight against the rule to conduct the Member Professional Standards Committee in a way that has earned it bipartisan congressional investigations or to not release more data. So I just want to make the point that whatever incumbent behavior has happened doesn't mean that just because it wasn't written down that an entity had to do something or not do something doesn't mean that that's the last word on performance and patient care.

>> RACHEL ROUCHE: Thank you. That leads into the fact that we have the flexibility to have different performance measures on each task order. If anybody has recommendations on what you think some task orders should look like in this task area and how to effectively monitor performance of those, feel free to let us know. We're actively putting all that together as we approach the fall.

>> Just to I want to build on something that Jennifer was saying. I know that especially as HRSA is moving into sort of multiple contractor situation, the importance of HRSA being able to have oversight over all the contractors. There's currently as I understand in regulation, broadly speaking, that any designated secretary, HRSA included, can request a broad set of documents from any organ donation stakeholder. I don't know if this is a question or suggestion. Strengthening language in terms of what it is from contractors relevant to performance of the organ donation system that HRSA is entitled to. This is a different flavor of who owns the data in Donor Net.

A lot of the problems from our perspective historically has been respectively is the erosion of leverage at HRSA. It isn't that HRSA didn't have the best ideas of what to ask for. One example, HRSA mandated the separation of the boards in 2018. I know the current contractor opposed that, filed a GAO complaint. GAO said the complaint was not grounded. The boards were still not separated.

I'm making a point, the best laid plans, HRSA can make structures in terms of what the contractors can do. From my perspective, it's important to write and contract leverage about how HRSA can receive information. Even Senate Finance Committee had to escalate to subpoena. Right? What are the ways that HRSA can strengthen its own hand in the contract, writing whoever the contractors are, you're entitled to the information that will allow you to oversee how well the contract functions are being served.

>> RACHEL ROUECHE: Would you recommend that be incorporated into the domain or task order 5 applying to everything?

>> You guys have smart people at HRSA that are thinking about this. I don't have a particular mechanistic. From a systems dynamic perspective, from my perspective I've been a patient advocate. My father had a heart transplant. I've done a lot of advocacy for better patient outcomes. I think a lot of the frustration, when I've talked to, you know, hey, I heard this in the field, I heard this was going on. I bring it to places where I think they should theoretically have the regulatory or sort of oversight ability to do something about it. A lot of the problem has been accessing information to substantiate. That's where HRSA can best strengthen its hand. Whether it's in contracting or elsewhere. To include language that entitles it to more information

so things don't have to escalate to a Senate Finance Committee subpoena in order to get basic information about patient safety.

>> RACHEL ROUECHE: Great. Thanks very much for the comment.

>> Just as a thought while you're talking about performance, you ought to put in your solicitation a self assessment may be a good idea. Some agencies are doing. Just a thought.

>> Thank you.

>> RACHEL ROUECHE: Thank you very much.

>> I appreciate the focus on becoming more patient centric and keeping that front of mind throughout. I appreciate there's a lot of difficult problems you're trying to modernize or optimize, right? What I don't see in here as much that would be I think improve patient outcomes I should say **ATTENDEE AT ORGANIZATION**. Don't want to not tell you who I'm from. Is around the supply side. How can we really increase the number of donations and supplies into the system? Obviously, when you get to logistics, it's easier to do the matches and make the outcome better if there's more supply. I think you couldn't do more in the PWS to make that its own domain area or within operations really focusing more on the supply side.

>> FRANK HOLLOMAN: Gentleman right there. It's coming to your right.

>> **ATTENDEE AT ORGANIZATION**. Piggybacking off what he just said. A very, very important point. You know, the way you register to be a donor now, kind of being able to potentially on the supply list. Whatever you want to call it. Or you register on the website. Different

things like that. Then it stops. There are other things you can do proactively. Go to get genotyping or phenotyping out of the gate so that stuff can be on record already. You're already part way there to understand biologically from a matching capability perspective. Does that make sense?

>> RACHEL ROUECHE: That makes sense. It's relevant to get idea around how we can improve the way the OPTN works. The mechanism that we're using to try and enable some of that change is the transition contract and next gen contract. We have about ten minutes left. I want to make sure we hear ideas for how we make sure we make this contract attractive to y'all so we get multiple vendors in the space and between the future together with a group of committed folks.

>> Just a quick comment. This isn't on the procurement side. I touched on this briefly. All the work I've done with transplant centers and different spaces. I think one of the biggest equity injustices is the candidacy process. And there's a tremendous amount of fallout. I can go long winded as to what's really happening in that space. I think from a contracting perspective, if you want to really drive equity, you're going to want to study and drive contractual solution around making sure that everybody has access to becoming a recipient. There's a tremendous amount of fallout in that area. A lot is logistics. A lot is not. There's a lot of fertile ground in that space. It's not just the organ side of procurement. To me, probably the largest injustice that I've seen is on the candidacy side.

>> You're speaking to the referral evaluation end of the spectrum.

>> Getting the family to say yes to donation. I'm overhearing people on dialysis. How they're getting on lists. How they're going through a 17 step process with transplant centers and following up consistently. They can't get ride share. There's all kinds of solution plans that could be brought to actually having equity. If you actually look at the statistics, one of the largest reasons, my personal opinion, there's not a broader equal perspective of people receiving organs, is a tremendous amount of people give up or don't have a family advocate. There's a lot of work that needs to be done contractually on equity on the candidacy side. I mean, I could go really long winded. Every time I look at it and every time I get involved in logistics side with hospitals, doctors, and leaders. Got to go in that direction. From a contract perspective, if we're going to drive equity, to me, there's a lot of equity issues on the candidacy side. Candidacy meaning I'd become approved to become a recipient.

>> FRANK HOLLOWMAN: Generally, we consider that the pre wait list. Something this group thinks would benefit the system as having, as we were talking about, domain. Domain focuses just on pre wait list.

>> I think I would have a domain focused on pre wait list. The idea that when I'm going on dialysis I'm required to be put on the list. I don't have is to go to a transplant center and go through so many different tests. It's difficult for me to show up and go through that process. There's a lot of things there's a lot of fertile ground that needs to be done. And how somebody becomes on the list as opposed to being a requirement of dialysis, through CMS, or other means, much earlier in the phase. These people need to be talk about metrics and statistics and aims. If we don't capture the data points early and we're dependent on people finding the way through that

process, which they cannot, that's where the equity process and statistic problems start to show up. If we demand they're listed much earlier in the phase and have an aim to get them through the candidacy and have a statistic and benchmark we can hold to, that's how you're going to equalize the system.

>> RACHEL ROUCHE: Thank you very much. It's true that the process of getting on getting on the wait list is part of inequality in organ transplantation today. I think that's an important thing. I'm not sure it's something that can be handled necessarily in a contract level. It's probably a board policy change situation that needs to happen. But I'm taking down all the ideas that come up here. Because it doesn't hurt to have them available to talk to with those entities. Thank you.

>> I'm sorry. Go in order.

>> My name is **ATTENDEE**. I'm a recent heart transplant recipient, myself. I'm also an executive chairman. I had a question about 1.7 OPTN member compliance and performance monitoring. And trying to understand if there's an openness if it's in the interest of the system to actually create a separate task area for that. That would be able to effectively bifurcate where you have governance and management and separately an honest broker that's responsible for the compliance and monitoring to then make recommendation back to the OPTN board. And management committee.

>> RACHEL ROUCHE: The recommendation is to have a separate one for the compliance and auditing stuff. It's all in operations right now.

>> Independent third party you're saying.

>> Looking at what is currently listed as task order 1.7 which is that member compliance side of that. Trying to understand if in the interest of the OPTN board management and governance of the system if it would be beneficial to have an independent third party that's not that same vendor that is the one that's ultimately facilitating the compliance, the review and making a recommendation back to the vendor assuming that's vendor overseeing one 1.1 through 1.6 to be able to go and execute those changes accordingly based off the recommendations.

>> RACHEL ROUECHE: Thank you. Really good point. One of the maybe not even one of. Could be the top goal right now of HRSA is to establish a separate and independent board. So that there isn't a conflict of interest in that type of oversight. And I just want to make sure that I'm capturing notes correctly for your suggestion. Because support for that board is intended to happen through this task order. But the policy development, et cetera, would happen via that independent board, themselves. So with that piece of clarity, the recommendation would be to have the board support operations also happen perhaps in a separate domain from the compliance and oversight.

>> Yeah. I think the consideration would be to keep 1.1 through 1.6 then make 1.7 its own task area. And be fully independent from the vendor responsible for 1.1 through 1.6.

>> RACHEL ROUECHE: Thank you very much. Sorry I had to ask a couple follow up questions.

>> There's one in the back.

(Captioner switch)

>> I would suggest maybe adding an area in the realm of living donors and getting worked up pre transplant. Many of those I have worked with have complained about the time it takes once the living donor gets into the system to when the diagnostics can get done.

So it seems to me there is no logistics or process around that piece of how to get living donors worked up, and how to get it done quickly.

>> We have two online, and it sounds like we are winding down.

>> Great, thank you. I have two questions. Go ahead.

>> This question is from **ATTENDEE. Are you considering data mesh and data fabric Cloud architectures to enable data enabled sharing at scale? Go ahead.**

>> I was going to say, thank you for the question. A really important topic.

I would say that is under consideration more in the Next Gen realm, versus transition where we are thinking about how to optimize the current system to facilitate continuity of patient safety in a separate board.

>> All right. The next question is from **ATTENDEE. Given the concern that the current Board of Directors has inherent bias or conflict, how will HRSA and the contracts ensure the OPTN Board has representation from all stakeholders and transparency, lack of bias**

from Board Members. Will there be compliance and contract about the Board selection and policy development to ensure these processes are transparent and truly inclusive of all stakeholders?

>> I am going to turn that question into a suggestion for us, which is well, I can answer it first by saying we are actively defining what I am looking up at the cameras all here. We are actively defining what the Board separation will look like. We know the support for the separate Board will come from this contract, So thank you for hammering home on the points that there needs to be a very clear process and transparency around what the requirements are for Board Member selection, and for transparency into how policies are developed, et cetera, et cetera.

So I am taking down more notes. I don't have information I can share today on exactly what the plans are and get into practice and getting into current state to the next state of practice in a separate independent board, but thank you very much for the comments. I have them down.

>> I think we want to make it clear in the beginning there was a lot of talk about the language of separating the Boards, so HRSA is going the next step to say we are not using speculation of the Board, but establishing an independent OPTN Board, so hopefully that makes it clearer to people in the public that establishing a completely independent OPTN Board versus speculation, so hopefully that language helps add some clarity.

>> I think you are getting a number of very nice, specific comments around what you can do with governance and policy. There are ideas coming from the room that I think are starting to encourage you to

think about developing separate buckets, right? I think the level of buckets you have is appropriate for an IDIQ. You don't want to get too granular when vendors are responding at that level.

So I would advise you to take the ideas and be at the forefront of the vendors issuing bids. Often I see you have task areas come out and they are all in Data Analytics, and none in operations, right? You need the task orders to come out being truly representative of the work you are going to perform. I think the ideas you are getting today need to be at the forefront and put it out with the initial bid so the vendors understand and want to bid on that.

All too often it comes from one area and then maybe vendors don't express an interest because there is too much of a specialization in the task orders.

>> Thank you for the recommendation.

>> Thank you very much.

>> **ATTENDEE AT ORGANIZATION**. You talk about a period of transition. I know there is decision out there for vendors being able to participate in both. My encouragement would be to allow any of the companies here to do that, to participate in both. We talk about governance, policy. Some of our businesses, this will be the first time they will have some type of strong regulation that is watching them move. That is a lot of transition for an organization.

If we all want strong transplantation, we all want that. If we are going to succumb to that process of being the intermediary to make sure there is a smooth transition, I would encourage you to allow the

private businesses to participate in the competitive process for the
Next Gen.

>> Thank you for that. We are tracking all of these comments. Thank you. **ATTENDEE?**

>> Good morning, I am **ATTENDEE** and I am here from Seattle, which is my hometown. I was here yesterday in the Sentence Finance hearing. More importantly, I am a three time living transplant recipient.

Once from a living donor and twice from the other donors. While going to policymaking, and I think I understand your intent, that made my heart skip a couple of beats there because having seen the evolution of policy making actually happens as a patient, it takes too long, and so there are too many people that will die between now and the time a policy would come to life.

But I think there are ways we can solicit those donors and build that framework.

>> Thank you for that feedback. I really appreciate you being candid with me. And I apologize for that. I also appreciate I want to clarify something. I believe in the current contract, even there is there are requirements to facilitate engagement with the donor community, to facilitate that more. The way things currently stand, the way we have the final role, we have the ability to manage that from the contract.

>> To be clear, I heard that, and I thought what I pattern matched my brain to is it is eight years before something will actually happen, and we can't afford for that to take eight years.

>> I hear that. Thank you for sharing.

>> We have about two minutes left. Any other questions? Hold on one second.

>> Need a mic. Can you all hear me now?

>> Yes.

>> Thank you for letting me speak twice. This is going backwards. There was a question about the inequity and access to the transplant waiting list and what could HRSA be doing on it. I don't know if I agree in solution contracting. I have a global solution, or suggestion that I will make strongly.

My father waited five years for a heart transplant and he received one. You can look it up in the data. My aunt died. She needed a transplant and was never on the waiting list. The suggestion I am making is that HRSA can respectfully be clear and stronger in its language as it talks about the toll of the failures, because it is easier to hide the inequities if nobody if people go to the HRSA website and see that 17 people died a day. What you don't see is how many people, in that language, were chosen as a transplant recipient and ultimately died. Most were like my aunt that didn't make the waiting list. There is a lot of coded language.

I appreciate there can be contractual limitations and logistical complications to accessing the data, but HRSA, in my mind, minimizes the toll of the failures which erases a lot of the deaths from public knowledge.

If you are thinking about how you can keep checks on the behavior that is going on in the field, at least some of it, as we have seen the last three years to move this industry, has been Journalistic and

Congressional pressure. And I think HRSA can play an enabling function in telling what the story is.

I appreciate the constraints the government can have in this language, but being clear in the numbers put out makes it harder, if any contractor in good faith or bad, I think HRSA can set the picture and you are enabling then, of other actors on the outside, help keep the localized pressure of what we are hoping for as more access that is streamlined.

>> Thank you for acknowledging how difficult it is for Federal agencies to respond to written reports and articles. So thank you.

>> Yes. Thank you. Thank you for sharing that story. I think it is just grounding to remember the impact that this network that we are all working on has in the real world, so I really appreciate you sharing.

I think what you are speaking to is also like another call for data transparency with data that is actually meaningful to people. Because there is so much data out there today published in a lot of places.

I think what we have been hearing and is echoed here today, there are certain pieces of data that would be really valuable to know, to speak about more publicly and be more transparent about that are not publicized in an easily consumable way today. Thank you very much.

>> One final question and I will wrap this session up.

>> This is more of a comment **ATTENDEE. Having public researchable accessible data on pre wait list periods would be beneficial.**

>> Thank you.

>> Thank you very much. I got that down.

>> This has been an absolute pleasure to be able to pull from the minds of many of you in the community and doing work, very positive work in the community, so this is helping us. This won't be the last time we reach out to kind of extract some ideas from your brain, So thank you all for your time today. I will give it to Rachel.

>> You said it very well, Frank. Time flies. I can't believe we have already gone through that hour. Thank you So much for all the feedback you have given us today. If you are questions or points of feedback that come out later on, feel free to submit them on the OPTN Modernization website. Have a wonderful rest of the day.

If you stay here, we will wrap up, do a quick wrap up session with everybody else, and we should be out of here in 10 or 15 minutes.

Thank you.

[END FOCUSED CONVERSATION, START CLOSING REMARKS]

**>> Hi, everyone. If you can find a seat for Closing Remarks, thank you.
Find a seat for Closing Remarks. Thank you.**

All right, folks. We encourage you to have a seat and we can address some of the questions you guys had and share some of our closing thoughts and let you either continue your networking or be on your way.

Perfect. That was a small utilization of the space. (Chuckles)

Okay?

I think we will just jump in since we have folks, right? I think we did you get everyone in here? Yes? Okay. They are having good networking. I know. I have to be the bad guy to shut it down! Okay. You want to whistle, ring chimes or something? No, no? Okay! Well, that was effective!

Is that a requirement of all of the heads of contracting in a Federal agency? That is great! All right.

Good afternoon, everyone. We reached the afternoon portion. So just a couple of comments based on some questions that have come up and things that we have heard. I guess, housekeeping for the end of any Industry Day session like this. Thank you for your active engagement and participation today.

Just to let you know, the slides that we covered, the transcripts and highlights of the different breakout conversations that we had will all be made available on HRSA.gov soon, shortly, so give us a little time and you can find the information there.

Again, to memorialize our time together, for further dialogue and anyone that didn't get to join us today, then they can also benefit from the discussions and information here, again, all in our aspiration

to increase transparency and get the pool of people joining our efforts to improve the organ transplantation system.

So as we come to the conclusion of our Industry Day, it really is, you know, a sigh of relief. People showed up to our party. They look like they had fun. So that is a great relief, but also I think, a sigh of contentment and, like, gratitude for all of the engagement, the passion, and some inspiration for the road ahead, which I think will really help us through all of the bumps and difficult challenges that inevitably will be here when you try to take on a change of this magnitude.

In fact, many of you have said, this is really great. We come mend you. Truly, you will be our biggest cheerleader. I am really sure what you are undertaking here do you understand magnitude of what you want to take on? I assure you, maybe a little naively, but I feel confident, that we are. We are ready. We are up to the task. We have a shared commitment to make the system better.

One day in the not too distant future I would like to stand up here and be able to say we don't have deaths from people waiting for organ transplants.

So I want to acknowledge the interest and how do we leverage that to support the patients and families. We have strong support of this administration. They have prioritized improvement. I would say even the previous administrations have seen the importance and the opportunity here.

We have that rare moment the rainbow of strong, bi partisan the rainbow and unicorn of strong bi partisan support in Congress, trying to advance the work that we are trying to do here.

Their support, the administration's support, hearten us that we will have the resources, the legislative changes, necessary to fully lean into our Modernization aims. It is not always, you know, that you can get that, hence the rainbows and unicorns!

And, right, we are confident with all your engagement here today, that we are not going to be in this effort alone. You all have demonstrated a commitment, and so we are going to hold you all to it, and we will be in regular contact, because we want to figure out how we work together .

So first and foremost, I think today has been a great testament to the power of collaboration, innovation, and the shared commitment to really modernizing the organ transplantation here in the United States. First and foremost, I want to express my gratitude to each and every one of you who took part in our session, both those in person here, and all those who joined and really spent their time with us virtually.

Your robust participation, insightful contributions and passion, have made this Industry Day a success.

I also want to extend my special thanks to all the organizers and our amazing HRSA team who is here behind the scenes working tirelessly, weeks on end, extra overtime in the last couple of days, to ensure that they paid they had meticulous planning, paid attention to every detail to ensure that we curated this opportunity, in person and

virtually, to get all of you together, and get the best thinking and ideas.

Far more than that, that this energy transcends this time and space, and we will continue to build as we get closer and closer to our efforts and solicitation in the fall.

It was their effort that really helped us create this environment conducive to open dialogue, knowledge sharing and meaningful connection.

So throughout the day we witnessed an array of innovative ideas, diverse perspectives. I think I got to go to each of the rooms. You were up to the task of being bold in offering ideas on how to do things differently.

So we know that holds a lot of promise for the prospects and outcomes of our Modernization efforts.

Our work doesn't end here. In many ways it just starts here. So let's continue to push the boundaries of what is possible, seek out every opportunity for improvement, and champion equity and accessibility in the organ transplant system.

The success of modernized OPTN hinges not only on the strength of our ideas, but also in our collective resolve to see them through.

Thank you, and we look forward to our continued engagement with all of you, and receiving many compelling proposals, seeing lots of interesting ventures and partnerships that will really help us as we put forward our transition contract this fall, and then invite you all to

our next Industry Day at some point in the future as we get ready to talk about some of our Next Gen contracting efforts.

So thank you, again, and I look forward to our continued engagement.

(concluded session)

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HRSA

Industry Day-Breakout Room 1

Multi-Vendor

July 21, 2023

11:00 A.M. EST

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>> Will HRSA be standing up the organization or department or group that manages all these vendors? Manages the overlaps, the handoffs,

I ask that in a broader group but they didn't get to it. I'm hoping we cover that here at some point. Thank you.

>> Yeah. Do you want

>> Yeah. I'm going

>> Sorry. You know, I should eat my own dog food, I'm telling people to use the mic and I'm not myself. Sorry. Yes, so I mean I hate to give you an obvious answer, **ATTENDEE**, but thank you for that question. I appreciate it and I appreciate the perspective of sort of looking at nongovernmental entities to see where this is potentially being done right. And I'm emphasizing not federal government. It could be commercial, state or local or it could be some different sort of nonprofit or other sort of partnership.

I really appreciate everyone's thoughts, input and it does not have to be exclusive to what has worked well for the government. It's unique in its operations here within the federal government so I think any sort of perspective is certainly valued.

To answer your question about whether HRSA would stand up an organization to sort of provide this multi the coordination and the collaborative oversight of multiple vendors. I mean, the answer is yes. But we already have that. That is the health systems bureau that is being led by Dr. Suma Nair. This is the bureau that is tasked with providing oversight so it does not limit us from providing that level of oversight vendors will need as part of this multivendor landscape.

One of the slides that Suma went over the one with the red circle talked about organizational capacity building that HRSA, ourselves will be, you know, look at a mirror and we think those were the words

and reflect on what we need to be able to support this effort as we stated in the plenary session. A long way to answer yes and we are working on that.

>> I can ask a follow up question.

>> No more questions.

>> And I don't think we quite determined this we're not going to have a systems integrator in one contract and having multiples. I know a lot of people think that and also quite a few bit organizations, like that's the model. At this point, I don't think anything we say or think may change at some point based on input or situations. If that requires a system integrator, okay. We're trying to be open to ideas to innovation on how we can move this forward and sort of really have our focus on patient equity and patient outcomes.

>> Oh, yeah. So one thing I've seen in many different instances, you know, culture, I think really follows your organization, the organizational structure. And when we break into a multivendor, any kind of environment where there is silos or fragmentation, it's very easy for the organization as a whole lose sight of what the main objective is. I've seen this in many different places, when you move into that kind of environment the teams become focused on their piece of the puzzle. The best example I can give you is the healthcare.gov launch and issue there. You had there's many other examples, that's probably the best one that I could give you.

That is a situation where there's lots of different moving parts. And the objective which was build a website that people can sign up for healthcare, no one was really focused on that. And so that resulted in

you all seen the news and read the articles. It's a very easy thing to happen when you fragment. I've seen strategies for that, some have worked better than others but I think it's a real and probably I would say the most important concern to be considering when you're building out this organization. How to make it function as a single unit and stay focused on that objective.

>> I think part of required training to talk about how healthcare.gov went. You know, I think that was part of the inception, the reason for the inception of USDS was the lessons learned from history of. I think that's a valuable lesson and we hope our colleagues teach that us every day.

>> Here's a question to follow up on that. my dream as a contracting person is to have a metric that says plays well with others. Literally verbatim on a contract. What incentives are there? Different incentives. And at the end of the day everyone goes yeah, yeah, but we've got the finish line and we need to do this thing by next week, whether it's an industry day, whether that's a solicitation, whether that's a work output. How do you keep people aligned throughout that? How do you get so maybe can like, pull the red lever and say hold on, we need to do something different. I'll tell you it's also why we have task orders and not one big contract. Because we want to evolve and change and the metrics will be at the task order levels. We have to look at them again and we can't say exercise that option, and oh, we'll get to the metrics next time. Of course we'll do them in task orders. Kind of joking, it does happen. But it gives us a bit more intentionality.

>> Have you considered like a metric where you send out a survey to, you know company A, how easy is it to work with company A on the all the other companies and do the same thing and then you have an objective metric right there.

>> Okay, that's a good idea.

>> I have a

>> Yeah, I want to make sure we're getting to Zoom as well. So trying to try to go back and forth between Zoom and who is here in the room if we can. **ATTENDEE**, you're next up, if you don't mind unmuting yourself.

>> Yes, thank you. So as someone else in the room mentioned, CMS' history of and the overall federally facilitated market place I think offers lots of lessons. And you know, I think being a mission critical health system that must be no fail, looking at the SLAs they have in place with individual vendors and among the entire, you know, marketplace, which is multivendor I think can provide lots of learnings.

While I might not necessarily love cost plus award fee type contracts and that might deter certain types of competition. I will say when you're evaluated on a quarterly basis and your profit is contingent on those evaluations, it is an excellent way to influence behavior. I do think there's lots of within the HHS lessons learned there.

>> I guess here is one follow up question on that, and we'll get to you in a minute. So cost plus, in my opinion, is I would rather fire the company and move on to another company and end the profit there instead of beat them with a stick.

>> No, no

>> Sure, sorry.

>>ATTENDEE: I didn't mean to act like that, I did see a bunch of hands up. I wanted to put something out there that is I don't want to be difficult. But the way in which it's really important for some of us to hear this conversation go is a little different. There's a lot of people in this room who do not really have a lot of experience in transplantation. There are a lot of people in this country who are very, very dependent, their lives are dependent on this system.

And metrics are nice, that's great. I deal with metrics constantly. I deal with kidney metrics in Medicare and deal with all the things you ask for in the RFI. For the people in here, this conversation really needs to you need to really think about getting your hands around what you're taking on, in my opinion, because you are taking on a system that's extremely fragmented I don't mean HRSA, I mean from where the doctor sending one person to specialist, many people go to transplant centers that they don't know the barrier. For example, there's some transplant centers who will not transplant people over a certain body mass index but you don't know that.

You could be thinking you're in line for transplantation and you're not on there and then you have a whole system where the transplant facility itself is being run by the hospital. That's got a whole different set of priorities into it. None of this stuff is talking to each other half the time. And people have no real transparency about exactly when and where they are. We are so excited to see this initiative going on.

But there are a lot of people out there who are very nervous that contractors might not understand just how ready on day one they're

going to have to be. And that there is no time to let this I'm sorry,
I'm rambling on.

I got to say, I see a patient group, I see transplant families up there on the list as well. And we are just here to say, look, you know, this is if you go listen to patient groups, which I would suggest any of you do. If you're going to be in this thing you have a client that's not HRSA, it will be patients. HRSA will hear from the patient whose say we don't know. We don't know where we R. this long stuff, you can be worked up at a transplant center and still not know whether you're active on the list. You can have holds at a transplant center and you don't know the data they're looking for doesn't even allow you to get an offer, because they're not taking a certain KBI index kidney at a certain level. You know, this whole thing is making people extremely frustrated. But it is a very good system it just can be a lot better. You guys are going to be critical to that.

>> I think that's one of the concerns that HRSA has. When we started this conversation, I think you can say patient safety is our number one concern. I think you heard that throughout the whole presentations earlier today. And we're not like I think all these vendors don't want to ever come on board and drop the ball on the first day, you know.

We are thoughtfully I think these are the conversations we are having right now, is to make sure there's not such thing as dropping the ball. I think there's been a lot of market research, we've been talking to different groups. This is another avenue. I think that's the key here. Yeah.

>> I believe you, I didn't mean to suggest

>> But I'm glad you said it, too because it's our number one I can tell you every time we always think about that. It's not just like, we're going to be able to pop into one, pop out. We are thinking clearly how to approach this.

>> Great, so the next one is coming from Zoom that's going to be **ATTENDEE**. If you don't mind coming off mute.

>> Hi, everybody, can you hear me? So I was actually spoke at the organ donation summit that happened when President Obama was in office. And I stood for with a multistakeholder group that there would be equitable access to information about transplantation. And I want to say that we created a multistakeholder win there afterwards.

I want to put a couple things for the transcript. So the first part that I hear right now and where we are when we're building bridges between what's currently here and what's innovative and possible, is that we need really partnering members of the current people who are experts in each of these stakeholder groups, and for innovators and for profit people and all that. We need patients at every point of this so that you're hearing what's possible now in addition, what all of the different vendors can maybe provide.

I think there needs to be a partnership with HRSA and what I would say is a mediator leader, because everyone's coming with the their own, you know, eye to the problem. I always say it's like diamond. Everyone can see a facet to see what needs to be done. We have to spin the diamond and have it centered with the main goals. I like what somebody said. And somebody can hear neutrally, that needs to happen.

The win we found was a series of concentric circles where you had different groups that included patients at every level and families and that groups that had a lot of time and focus on certain parts were then meeting with different groups. Every nonprofit organization reviewed what we did and we ended up putting our education on the UNOS website at the end of this. I can put a link to that in the chat. But I want to say that we did that successfully and I would be happy to deep dive with anyone who is building to talk about the process of it in the transplantation space.

>> Cool, we'll take one more. I also just one of the things that I kind of play get a little excited in my last answer. You know, how does competition play with collaboration? When you do have you got multiple vendors on a contract, you need to collaborate with each other. But you also have this sense that they're going to be competing for the work you might have just done. They might be able to say they've done better. You might be competing for work they've just done or something else similar within these different domains. So how does that spirit of competition and collaboration work.

If you want to someone wants to mention something else, not according to that topic, I kind of wanted to clarify there as far as the last answer I gave.

>> Hi. I'm an end user of product, I've been in this profession for almost 40 years. I applaud everybody talking about the patient. But there's multiple steps there that are critical with healthcare providers that are not even within the transfund centers, we've got to think about the organ donor centers, donor families, living and deceased donors. If we could have fixed it we would have fixed it. We need

energy and synergy to bring together technology so we can make this work. It has to be from the beginning through the end. There's mapping process, it's out there. SRTR has demonstrated a really nice mapping process. Showing what this end to end process looks like. And there's a lot of people out there that end users want to help you all bring this together.

>> I think that what I hear from that is there's a theme of keeping the focus and the outcomes through a patient centric approach. We have another focus conversation on research and evaluation and opportunities to go do some studies to see where we can improve.

From a multivendor perspective, how does it necessarily work? What could we use as far as like driving good behavior other than just like, you know, the spectra of if we don't pull this off there might be someone else who comes behind it and does it differently, different time, you know not get that contract or the task order ordered the second time or the third time.

What other themes are in there as far as making sure that we have a collaborative outcome driven patient centric approach while having competition amongst the same people who might be in the room, also you know, yearning for a piece of that pie. Hopefully it will grow large over time, but at some point it might just finite at certain times. I'm going to throw it to **ATTENDEE** if you don't mind coming off mute.

>> I'll answer that question and the previous questions you mentioned around incentives and metrics of multivendor delivery. I want today give a few example and ideas around that, particularly around the delivery side as it relates to software development. And

so some tangible examples I've seen in the past incentivizing at the team level, not just at the contracting level. So figuring out how to use common engineering or design frameworks so teams can speed up development across vendors.

There has to be incentivized to contribute to those frameworks, incentives to keep those frameworks up to date to make their lives easier. You incentivize collaboration by incentivizing the fact that, you know, their own individual team can be improved as well.

Second from the delivery side as well, across multivendor products, we've seen example where's government has implemented things like common communities of practice. Forms for engineers and designers and researchers across vendors to collaborate. With a government stakeholder owning those meetings. I've also seen successful implementations where government product owners are integrated with contractor product owners. And so having that tight cohesion between government and contractors kind of creates the cohesion, and, thus, across multivendor. And you mention before you're not necessarily going to be implementing a system integrated task order.

But I have seen successful implementations in multivendor environments where there's an initial order for a task team to build some underlying infrastructure, develop some of the common practices, deployment standards, tools, languages, et cetera that set the groundwork for future task orders.

And so lastly, last thing I mentioned I'll mention is just around delivery frameworks. So having a common agile delivery framework built into the PWS requirements. So vendors have to have past performance and expertise around the safe framework, for instance

that is a well tried and tested framework used across multivendor environments for delivering it across different scrum teams. There's a few tangible ideas to have for the record to include in the PWS and procurement.

>> Thanks just a follow up question. I think it's a follow up question to everyone. I keep on hearing incentives but no one is telling me what incentives we're looking for. Everyone thinks about profit margins but there are other incentives than profit margins. What incentives will fuel you to be a partner in this organization, in this business if you get it? We know profit, government knows, everybody is for profit but there's more to this than just profit. What's going to fuel you? What's going to keep you engaged with this team? We need that kind of feedback.

>> I actually was the HHS entrepreneur that worked for department of transplantation to implement the package labeling system and tracking system component. I've had a chance to see 70 organ recoveries and cover ten of those to transplant. My brother was an organ donor. And so passion certainly drove me there.

Your question, your last question is, you know, how do we measure and first and foremost is saving lives. It's complicated. I will tell you what **ATTENDEE** just said, this whole system is way more complicated than anybody realizes. Way more complicated. Not only that, and the first question was, you know, what's an example of something similar. My question would be back to you and contracts and in what case have you had a contract in place for almost 40 years with the complexity of this and the lives that are potentially at risk.

So I think that needs to shake everybody to their core, this is change that needs to happen. It can make the system better. But it's eyes wide open and you've got to take a look at that. I don't think I mean, there's a lot more to learn and you guys are here learning, I think this is fantastic, fantastic what you're doing. It's going to be interesting as to when spring comes and what contracts you make available. I kind of lean towards if we think we're going to have all these contracts laid out at the same time for three or four or five or ten, I would say keep an open mind on that because we may thought be ready for that. For the sake of saving lives.

From a metrics standpoint, yes, there's going to be a vendor and task specific metrics but I think also there's going to be shared metrics that have to come into play. And it's going to be the high and most important ones that the world is concerned with. As a donor family member, when I jumped into what I was doing, my biggest fear of coming into organ donation and working in the system was am I going to like what I see? Am I going to see that and see what the OPOs I didn't know what OPO was. Am I going to look at that and run away from it and say oh, my god, it's the worst. I will tell you it's good, it's passionate people on the transplant side, on the OPO side. Everyone's trying to do their best job. There's absolute opportunity to bring in new ideas and make the system better.

I do think the direction you're going is fantastic. But, again, I think I would say, hey, you know, the people that are looking to jump into this I mean, lives are at stake. Someone could die. And our goal is to when I moved into it, it was 21 deaths per day and now it's 17. A lot has happened. Death rates impact how many people have died, how many is available. It may be direct, may not be direct. We're

talking about metrics. At the end of the day if one of us takes on one of these elements and say we're going to manage the metrics or whatever it is, and at the end of the day an OPO suffers because they can't do their job because someone up here at one of these tasks screw it up, it affects people downstream that's not measured directly. So we need to consider that.

>> I guess here's a question, are there any tools out there? I've heard value stream mapping or skilled agile framework or other things? Are there other tools out there that you see that do drive good behavior and show, you know, teams of teams working towards similar goals or even just teams even across the domains. Like are there anything you've seen that's been particularly, you know, work well with commercial, federal, et cetera that can help us get there a little bit faster?

>> Yeah, **ATTENDEE**, I see on Zoom, so if you want to come off mute.

>> Hi, everyone, good morning. I'm definitely not going to I wanted to provide my response based on the last question, but I'll try to maybe come back and contribute to the current question.

But what drives me and what I'm sure drives multiple vendors to be part of this mission is the intrinsic motivation to help. So I answer this from a lens of emergency management and business continuity. When I heard about this opportunity to be part of this mission or be a part of this meeting, I was super excited because at my tactical level I'm always thinking about the emergency preparedness and continuity of all of my healthcare organizations that are prospective clients of my organization, hospitals, urgent cares, whatever.

An example that brought me here, was I was tasked or solicited to provide emergency management continuity exercise evaluation services to an organ procurement organization. Super excited, that's what I care about. I want to make sure these organizations are ready for any interruptions. What these transplant organizations do is extremely important. I don't have to say that to this group.

Where we came to an issue was resources. I identified this is what we'll need to do, this is what I need to identify. If I need a team this is how large my team is going to be. Here is what we're going to do to build your capability to prepare for this set of emergency, this set of interruption. It went from a particular timeframe that would optimize their timeframe to a smaller timeframe. Here is what I could do and it continuously went smaller and to the point where it didn't happen. I say that because once this opportunity came from me to advocate for the importance of continuity I'm looking at the lens from the tactical organ procurement organizations, because once these changes happen, no one is going to care if a business interruption happens or an emergency weather event happened that caused some sort of disruption. Our patients need the organs to be delivered to them to save lives.

I reached out to my prospective clients and said I'm going to participate in this to advocate for them. To answer the first question, basically, what brings me here, what makes me want to be part of this is the continuous thought that keeps me up at night that says what could I have done to prepare my clients, my organ procurement centers, my hospitals for the next emergency so that's what brought me here. I'm hoping this multivendor delivery contract allows me as well as any other competition I'm not worried about that.

Anybody who is in the space of emergency management we do it because we care. If somebody is going to do it better than me, I'm going to go to somewhere else and see if I can do it better or as well.

We care about the preparedness of our organizations we serve. I wanted to share that. But that's what brings me to the table as well other professionals in my profession we care. We want to make sure we have continuous operations. That's nothing that's ever going to change. I appreciate everyone allowing me to share that, thank you very much.

>> Thanks.

>> From a HRSA perspective you have a win with what I consider a win. It's gone through changes. It went to the University of Michigan and then it went to Hennepin county and we've seen demonstration where they're able to put out product at the request of the transplant community and HRSA, you as vendors can go to a website and look up every OPO, transplant center and find statistical data that can make you make a decision. It's out there and I think we can hopefully dep straight from activities like that. You should take that success. You did a good job at that. Then we need to be able to take that other component which is the OPTN and move that forward so that we can take the technology and rebuild it to what we are in 2023.

>> Yeah. No, certainly the we are the conversation today really, you know, we're focusing on how we're trying to improve and move the needle forward for the OPTN contract itself. So that first diagram shown about the relationship between the OPTN. I'm trying to think of a good way to sort of address your comment.

We're our intent is certainly to leverage our existing contracts we have in place, whether that's the SRTR contract whether that's the program management contract that we have already in place to help us sort of build the foundational capacity to sort of tackle other emerging challenges that's part of transition and NextGen that we have sort of encountered over the last couple of I guess last couple years within the OPTN.

I don't know if there's anything else I can add?

>> I would add like it's not just those we're looking at everything. It's I know it's ambiguous because we're trying to figure out the plan to walk through this. I would leave that. It's not just SRTR, we are looking, we're talking, there is a fair amount of other areas we're looking at, too.

>> I think SRTR was the first opportunity for us to get into a multivendor construct and now we're looking at doing it, you know, at a much larger scale. You know, within IDIQs are nothing novel. So what other inputs do yeah.

>> **ATTENDEE**, go ahead.

>> Thanks, can folks hear me okay? Yes. So I wanted to respond to a couple of different points and thank you for organizing this discussion. Specifically I wanted to come back to the question of what's going to fuel us, aside from just profit.

Something that stands out to me is we worked on worked with a couple of different states during their COVID response in 2020. Where we were working on standing up IT systems to support various different programs around that COVID response. And we worked

successfully in multivendor collaboration in that setting, and what was really motivating to everyone that was on the multiple vendor teams was a sense of urgency and clarity of focus on the mission that was right in front of us. There wasn't really time to candidly think about profit. There wasn't time to think about like all of the different incentives of who is fighting for which piece of the puzzle. There was a very, very, very clear mission. And daily, like, basically S.W.A.T. team meetings of like, we need to work on getting this done.

So I think where possible, if you can have just like the ownership coming from HRSA where in every meeting you're aligning the team to say this is the mission, this is what we're executing against, this is the impact we're trying to accomplish for patients, families, clinicians supporting them across the overall program. I think that that is incredibly motivating for teams, not just like the vendor but you think about like the individual people who are staffed by each vendor. That have to get up every day and care about their work and do a really good job. And so that's something that I would really encourage, is breaking it into those smaller groups. If that makes sense.

I also want to mention a tactic that I think is useful to support that. There is a framework called the post project Kizen, which advocates for reflection on lessons learned as a team and also using like a blame free environment. So you want to avoid I don't know if anyone has seen the spiderman meme where there is a bunch of spider mans pointing fingers at each other. You want to avoid that and have the meeting structure where everyone from different vendor teams are coming together and just looking at the facts and identifying how could we as a team have improved. Yes, of course there is like the impact on vendors can get fired if they're underperforming. But I

think having the individuals on the team have a sense of let me just be honest and work together towards the mission is what can really support the multivendor collaboration. Thank you.

>> Just real fast, first of all I wanted to echo what **ATTENDEE** said. I had forgotten about it. If you really want to see something that will demonstrate what happened, do look at the first six months of COVID between you guys and I give you all you guys, CMS, CDC, because we particularly since CMS has such a big role in dialysis. We had to redo regulatory stuff overnight because basically think about it. If you're going on dialysis it didn't matter if you had COVID you had to go to the dialysis facility. They had to set up cohorts of people with COVID to be dialyzed. That's a really good example.

I would also suggest you guys brought it up, I'm sorry the gentleman down there brought it up there also. SRTR timeline of going through transplantation, and where you touch the patient is an excellent resource for anyone looking to see basically how complicated the system is and where they're going to go. If you're an IT provider you're going to be looking at things all up and down scale that you might not ever have thought about actually that you could impact, but you will be able to impact a lot.

>> Just curious question, I heard this in the main room earlier. We talked a little bit about intellectual property rights, talking about data rights, system rights and those sorts of things. I haven't heard anyone saying anything about that. Anyone thinking about it and not mentioning it, I would love to hear comments.

>> My name is **ATTENDEE** come more from a thought process of open source, are y'all open to open sourcing the software?

>> I'll definitely say this at this time this is more transition contract focus so I don't think we're looking at NextGen things. I think I'm required to say yes but that's more of us humor. I think we're looking for all the solutions out there for things. Especially as we get into modernization. That's going to be something down the line.

>> I don't have much to add from what Jason said. Hopefully not a vulnerable version of open SSL that will cause, you know, chaos in the system. Yeah, I don't think we're against the idea of using open source technology or anything like that. And the OTTN system. Yeah, I mean, I apologize, we're open to anything.

>> One of the things I'm interested in, this literally came out of the thought just crossed now. We've been thinking about a task order in this domain to this company. Would it be attractive if we had like, let's say, I don't know, three or four people from all the companies come onto that task domain working towards something similar? Is that attractive or do people want to own it? Kind of sparking that conversation, what is attractive to you in this? Knowing you might have to sit on the sidelines for six months, a year, two years before you get that task order to go and drive this further. What's attractive? What are we going to do if we build this poorly and you're going to say no thanks. What is going to make it so enthusiastic that you're willing to go invest time today for a future opportunity to contribute tomorrow.

>> This I want to give credit I think it was **ATTENDEE** who said it on the phone. Incentivizing at the team level, not necessarily across vendors to where you have teams that are built up of several vendors, I assume that's the theme of the question.

>> That's what sparked me and that's why this conversation is good.
Yes.

>> Yeah, I think that the thing we lose in federal contracting because of all the regulation and wanting to keep it fair and honest and all those kind of things what happens in the private sector you tend to work with people you trust. There's a level of trust that is really, you know, when you do business, is at the basis of, you know, how problems get solved. As far as I know the only way to build trust is to work together. And so I think, you know, when you talk about incentive and you talk about how do you build that, you know, those kinds of things, I think that a multivendor environment is helpful for understanding who are the people that we have that trust in? You know that when we work with them, we can see, hey, they executed on this, you know, small task very well. You know, now it's time for them to maybe step up to the next level and grow incrementally from there. That's a kind of thing to kind of think about in this context.

You know, not necessarily you know, the ecosystem and how we can set it up the right way to start, but how can we create an ecosystem where it facilitates us building trust with people, the ones that we build that increased trust with or get the sense of they can really come through for us, you can see what they can do. They're the ones you can rely on more and more as you face new challenges.

>> That brings me to something interesting. I would love to hear thoughts but also follow up on, you know, with some contacts. So talking about building trust. And maybe we fail at something, right? That doesn't mean that they're awful but maybe there's metrics there we can see. Do you have the routines, do you have the day to day

routines to be reflective and are you doing things that get you stronger so you can take the bigger things on later on, versus did you deliver the widget on time and I'll make fun of the government a little bit here. It's the government's fault because we didn't review the deliverable or yada whatever it was that held you up. Maybe that's an opportunity to go and see like are you reflective, are you working well with others, are you open to receptive information. Then you have the trust factor that builds it up versus, you know yeah, the metric on the deliverable that has external factors that we're going to cause you to fail anyway. Does that sound something good.

We've got about ten minutes, 12:10 is when we're going to wrap up and we're hoping to leave the room by 12:10.

>> You're up.

>> Hi, I just wanted to introduce myself, surgical director of the SRTR. In reference to who owns the data, I want to make sure we don't conflate this question as to intellectual property rights or software that's developed as a result of the contract.

In terms of data that's actually collected that's clear who owns it, it's all of us that owns it. It has to be transparent, it's mandated by government to collect it, it's mandated by the government to submit it. It's mandated by us to analyze it and disseminate it. There's no question who owns it. Everyone owns it. It's a public domain. So there should be no question as to who owns the data. The data has to be transparent, the data is submitted and given to anybody who requests it. I hope there's clarity on that subject.

That's different from developing metrics, which should be on a metric, what are the metrics of performance, what should be publicly reported. Those are very important questions. As far as transparency is concerned, we do not have good interactions between interagency right now. CMS data are not seamlessly given to HRSA or vice versa.

That is an area that needs to work right now, it has to happen immediately. The notion one agency cannot share freely with another agency is a problem that's been pointed out multiple times and needs to be fixed. Thanks for allowing me to comment.

>> Thanks for your input on that.

>> Unless there's one in the room we're going to go to William next.

>> Hi, I'll be very quick. In terms of transplant centers that are mostly associated with health centers that with required to have emergency management personnel, OPOs don't. What will keep us interested or from an emergency management business continuity perspective what will keep us interested is this capability is currently not being addressed at the OPO level. Most if not OPOs do not have a continuity of operations plan or strategy to continue operations in the event of any event of an interpretation. They have emergency preparedness plans but that doesn't address interruptions that aren't necessarily emergency. I know the gap exists and if this future procurement is going to possibly address that gap, we'll wait as long as it takes. If we have to wait our turn to be able to again, address and sustain and strengthen and make the OPO continuity more robust. That continuity planning strategy or planning document is usually not available at OPOs. We've identified gaps in my

geographical area. I'm sure that is shared in other areas as well. We'll wait as long as it take.

>> Thanks, **ATTENDEE**. Yeah, so we'll finish up with the Zoom and go back to the room and try to wrap up.

>> **ATTENDEE?**

>> Thanks so much. I've heard a lot about the patient and donor family voice today and we definitely appreciate that. I want to know how that thread will be continued through the process that is happening here. I'll give you great example of what we appreciated as a opportunity. Thank you.

>> So I'm trying to understand, make sure I grasped your question. How can the patient and families continue to be involved in this process as we move forward. So when we announced the modernization initiative back in March we put out a commitment to transparency, we've provided regular updates to our website on some of the efforts that we're undertaking as we move forward with the contract activities.

Since then, we've also published new dashboards to the HRSA data warehouse. To try to provide greater visibility into some of the work that the OPTN does. We hope to continue that trend. And try to build upon those data analytics and tool that are part of the HRSA data warehouse and what the SRTR provides. I think we're just going to keep continuing down the trend of providing transparency into this whole process as we are today. And we have been.

Yeah, I think that's about it. Do you want to add anything?

>> I would add like human centered design is the keep point of this. I think we've talked about it a little bit. That I think that's where we're going to be including the patient. We're doing constant stakeholder engagements. It's continuing going forward, so I think those are some of the other areas as we're building these requirements we will be reaching out. All the stakeholders, it's not just the patients, it's also the doctors and everyone else involved. Hospitals, OPOs as well.

>> So throughout this I had a question of how involved is HRSA going to be, and what I'm hearing is very involved. To your question around competition I was thinking you're going to need a good referee. Because that's going to happen. When it comes to engagement, I go out as a vendor and say I want to engage the community. That's great. If HRSA says they want to engage a community everybody comes to the table. The long term involvement of HRSA is going to be incredibly successful, day to day involvement. But it sounds like me it's set up for that and that's your goal as well. I want to make sure I'm hearing that clear.

>> Yeah, I think you are. And actually what I would say I know we're running desperately short on time. We're interested to understand the metrics the government can hold themselves accountable to in order to foster that environment. So level of resource, anything else, like that, that you've seen at other place that would faster success.

Yeah, I'm a firm believer that we have to come together as a partnership and we have to have a learning environment and keep the curiosity of how we can continually do better and build processes and really the culture in place to go do that.

If you get recommendations on what we need to do to make sure that we are being proper stewards so we can be the referee when things get a little bit messy and you can also call us out when we're not necessarily doing the things that we should be doing or focusing on things that we really need, we want to hear all of this. So we do have I think we'll go back to the primary session, we've got a contact form. Contact link. Please send us your stuff. We're hoping to have regular engagements in the future with companies throughout. At the same time too we have a very large amount of work. Unfortunately the federal contracting process, especially to set up a large multivendor contract is pretty onerous.

We want to get this right. And we want to learn along the way so you can see some iterations, we're going to try to get your feedback as much as possible and we're going to end up moving along and also the nice thing about the task orders is we can go and evolve over time. It's not set in stone today for another five years. With that, I think the goal is to be out of the room in like, three minutes.

>> I want to add if you guys could fill out your survey, this is the novel ideas we're doing, compared to most other industry days. We would like your feedback on this as well. I'm sure that's going to be reiterated in the main room. But we had a lot of discussions trying to set up this type of meeting. I really would love your feedback as well.

>> Yeah, I just want to add that, you know, we have two, three minutes left. I am sure there is 47, 46 people on Zoom and, you know, a room full of folks. Perhaps we do not have the opportunity to hear your voice or get an opportunity to hear your input. So I would again like to emphasize if you can the link, we'll provide that back when we

go to the pavilion. Please take the time to provide any particular input. We do take it very seriously. We're using it as we try to formulate our ideas on how we move this forward. Thank you all.

>> Thank you all and we'll be around a little bit to talk, too.

RAW FILE

HEALTH RESOURCES AND SERVICES ADMINISTRATION

INDUSTRY DAY BREAKOUT ROOM 2

Research and Evaluation

JULY 21, 2023

11:00 AM ET

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(Captioner waiting to be moved to breakout room)

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>> MODERATOR: that could be implemented in next gen? Do you see it as an on ramp? I'll take hands maybe from in the room first. Take a moment to think it through first.

>> ATTENDEE: ATTENDEE with ORGANIZATION. We support through the subcommittee. We've done work through CMS and support the current are contractor as well with technology projects.

>> MODERATOR: For a quick follow up to restate it, you're seen as a priority to do the metrics, to measure success, to prioritize goals throughout the transmission and beyond?

>> ATTENDEE: The answer is yes. To summarize, the most important is the special studies of research projects are focusing on the parts of the system where we need to desperately move the needle on to drive better access to patients.

We'll start with the big rocks and the measures of success and cascade from there to scope out the priority projects over the life of the task order.

>> ATTENDEE: Thank you so much ATTENDEE. I'll take your question.

>> ATTENDEE: Hi, my name is ATTENDEE of ORGANIZATION. I think this is going to be an incubator. At the kidney association they're talking about the hard questions that need to be answered, for example, how many kidneys, per se, are going are being disposed of instead of going to patients. Once you measure things like that, you can get an evidence based way to make changes.

>> MODERATOR: Thank you for that, ATTENDEE.

>> ATTENDEE: Good morning. With ORGANIZATION. The answer is yes. There's an implementation concern I have and something for you all to consider. So the implementation concern is in the morning plenary I heard Adrian talk a little bit about some of the IT scope which also included some discovery, some requirements gathering, some business analysis. I agree with my colleague ATTENDEE AT ORGANIZATION this needs to start with, what do we need to solve for? What is the right problem to address? I'm concerned about how you're going to coordinate some of the task orders that you might release here once you've figured out the prioritization scheme. How are you going to coordinate that with some of the other task areas that frankly need to be integrated in and communicated with and orchestrated around as you come up with the right sorts of solutions

that may end up being complemented in next gen. No answers today, but I think that's something you have to consider.

>> MODERATOR: Thank you for that. I'll go ahead and check with Jennifer and Russell if there's folks to queue up for questions over Zoom? I don't have Zoom enabling manual captions.

>> ATTENDEE: I think that has a question. He's unmuted.

>> ATTENDEE: I think you're calling my name. This is **ATTENDEE AT ORGANIZATION**. I'm a researcher. Echoing **ATTENDEE**'s comments about looking for opportunities for high impact research, I think the real focus on OP is a key area. The OPO practices how that impacts donation, procurement and ultimately outcomes for patients. A key area we think is important.

>> MODERATOR: Thank you for that input, **ATTENDEE**. Question from here?

>> ATTENDEE: Yeah, **ATTENDEE AT ORGANIZATION**. Thank you for the comment. I appreciate what **ATTENDEE** said also. I think it is a huge opportunity for innovation. I think the concern I heard in the earlier session, I could have heard it incorrectly but I think there's still an open question about who owns the data and is it the contractor or is it some other group. I think that has to get resolved as well as the ground rules for who has access to the data. To me, my opinion is that this is a national resource. It's not something that a contractor should own and that we should have a lot of ways to get access to the data through APIs but also from a governance standpoint. That needs to be resolved before we can do any of these studies that were suggested already.

>> MODERATOR: Thank you, **ATTENDEE**. Well noted.

>> MODERATOR: Yes.

>> ATTENDEE: This is **ATTENDEE** again. In order to ingrain the insights from different stakeholders into the process so that it's used widely the US cordate for interoperability and the number of kidneys being wasted, so you can track that information so it's naturally being reported.

>> MODERATOR: US core data for it's a dataset?

>> ATTENDEE: Yes, OSV.

>> MODERATOR: Thank you.

>> ATTENDEE: Chris, can you address the ownership? I was under the impression, there was a mod to the contract to say it now needs to be called OPT in data and it's 100% accessible. Can you comment on that and clarify whether that is true?

>> ATTENDEE [SME Chris]: The data are the data are we have unlimited rights to use of the data, the government does, and the government would share those data with anyone coming in for any of these research projects. Someone mentioned that but I got lost. But they are technically right now OPTN data but the Government has unlimited rights to them. And they will be provided to other contractors and there would be requirements through the past five domain that anyone involved in these contracts would work together and there would be data use agreements and so forth set up. The data would be available regardless of the technical ownership.

>> ATTENDEE: I wanted to follow up. This is **ATTENDEE AT ORGANIZATION** I want to follow up on a comment Chris made and talk about data. An important component to think about is that the data architecture to be sort of helping us with the needs in ten years. Think about it so that it's sort of perspective it will provide and feed to policy also for ten years. And also to be real data, real on top, right, and real-time, real world data on top so that that also feeds policy in real-time and have that mechanism as well. Thanks.

>> MODERATOR: Thank you for your comment, **ATTENDEE**. We'll go to the person on Zoom. This is **ATTENDEE AT ORGANIZATION**. Thank you for raising data. I think one other comment I want to make about data is provisions for access to or some sort of mechanism to get data from the OPTN membership, particularly transplant centers and OPOs and having a mechanism to collect that or video adjudicate which data can be shared. I think that would also help evaluations as well.

>> ATTENDEE: I'll follow up on that, are you asking for data that are currently not collected by the OPTN by members or are you thinking of other data that may reside within the members that are not currently collected by the OPTN?

>> ATTENDEE: I'm thinking there might be data by members whether they're OPOs or transplant centers that may be germane to OPTN processes, how organs are allocated, that sort of decision making that may impact evaluations or research to inform best practices and having some sort of willingness from the membership and constituency to share that data I think would go a long way potentially to improving the system in the long run.

>> ATTENDEE: If I can echo and expand that. **ATTENDEE AT ORGANIZATION**, one of our objectives to build out the prewait list experience. We don't understand performance at the referral, evaluation, anything prior to wait listing. All we know is how long patients have been on the wait list. When a patient is trying to decide where to get care and how to choose among transplant centers, it's helpful for them to have information about the socioeconomic status, racial and ethnic status by patients served by that center. Whether their clinical profiles are the same. I think it would help with performance improvement. We right now don't know where patients are falling through the gaps in transplants whether they're getting referred and not evaluated, what the process is and what the timeline is. We need better data collection on the prewait list experience. Again, having that reported to the patient so they can make informed decisions about where they get their care. We're firm believers that sunlight is the best disinfectant. If one center is not performing as highly as its neighbor, maybe some additional reporting of that will come through.

Then the final note I'll make about this and this is essential, living donor evaluation. Right now there's a lot of variability about how quickly transplant centers are evaluating prospective donors. There's

a lot of variation in reporting it and patients being able to make informed decisions is really essential.

>> ATTENDEE: This is **ATTENDEE** and I would wholeheartedly agree

>> MODERATOR: Go to the mic.

>> ATTENDEE: This is **ATTENDEE** I agree with what my colleague just said wholeheartedly. I would also in addition to making sure that we're putting this information about transplant center processes out and standardized in uniform fashions that are acceptable to patients and make sure it's accessible to the general nephrology team as well who want a greater role in helping their patients navigate the system and get to the goal of transplant. They can only do that if they have access to the information which is currently not possible as much as we would like.

>> MODERATOR: Thank you. Go ahead.

>> ATTENDEE: This is CTO of (?) solutions. One of the other things is also like data transparency like the schemas and the actual data is more open source and there's a common language across OPTN, OPOs, referral organizations and there's a transparency in the process itself and it's well documented across these different systems so there's an awareness of what's going on. It helps the researchers who are looking at the data to understand what's going on? What's the critical processes? What's the bottlenecks and that can help provide more transparency in this whole process is, I think, open sourcing schemas and really documenting what they are and what are they used for. And it's very transparent for the public. But also organizations that are trying to use this data for their own purposes.

>> MODERATOR: Thank you so much for your comment. So thanks, everybody, for this a couple more. Okay. Let's see. I'm going to take **ATTENDEE** from Zoom first.

>> ATTENDEE: Sure, thank you. I just wanted to say, I'm with **ORGANIZATION**. But in past lives I was with I worked on Wall Street and Silicon Valley. I think there's a lot of opportunities to leverage best practices in other areas. In some ways financial services provides

a bit of a roadmap. There is a lot of work that folks from **ORGANIZATION** and **ORGANIZATION** have mentioned around data hygiene and the work needing to be done around standardizing. Once we unlock the data to anonymize it and digitize it in a HIPAA compliant way so we can make better policy informed decisions and improved access and help for folks.

So I think the data hygiene piece is really foundational and it happens at the same time that you're thinking about next generation, because data hygiene is really about making the existing infrastructure work and pulling together what we have.

What's interesting is just by the way that the space has evolved, Silicon Valley companies spend 80% of their time and energy on data hygiene. And if you think about it in our space, it's been really a much smaller component for lots of different reasons, including the decentralized network and things like that.

But there's a real opportunity to unlock the data and to put the right agreements in place and put the right technology in place. So we get the most out of what exists today and build an infrastructure that's capable of handling much more data that conforms with AIs and APIs.

>> MODERATOR: I'll take one more question or comment. Thank you.

>> ATTENDEE: Sure. **ATTENDEE AT ORGANIZATION**. I think in terms of data somethings that hasn't been collected but would be of true value is regarding the transportation and especially as an outcome of that Senate hearing, I would like to hear something like that put into the contract regarding transparency there.

>> MODERATOR: Thank you, **ATTENDEE**. So I really appreciate how this conversation was so rich and on the topics of how this task area can generate ideas in innovation and getting into all this nuance around data transparency, accessibility, making it patient centered, standard best practices. I appreciate that so much.

I'm going to actually move us on to a slightly different topic. So the prompt would be, what factors are most important when conducting special studies? That's coming from a place, obviously there's the goals of OPTN initiative discussed at the plenary. This session we want to hear your thoughts. What factors are most important when conducting special studies?

>> ATTENDEE: It's **ORGANIZATION**. We talked about this the previous session, making sure we understand the purpose of that study. I mean it at a ground truth level. If we're going to talk about equity. I heard a colleague talk about prewait lists analysis. Okay. I get the health equity aspect of it. How am I going to get the data? Because the technical approach for that is going to be complicated. I don't mean technical as in IT technical. I'm talking about the way you're going to do this. How do we get access to that data? I think every study is going to have a very clear objective associated with it so that we don't just spin our wheels collecting information that is not germane to the particular outcome you are seeking as a result of that study. I think this is back to the right problem, right solution comment.

>> MODERATOR: Thank you. I'll go to **ATTENDEE**
>> I think once we define the big rocks we're trying to go after with these research with these special studies, I think making sure that you have a combination of deep, deep expertise, transplant is a complex business. So having thought leaders from around the community with deep, deep expertise, but also with that, it has to have diversity of thought. There's a lot of constituencies. I would encourage us to always have a patient voice in the room in each of the studies. But also an OPO and transplant coordinator, his toe lab, government, even this has become a very political issue, so even the political voice.

So making sure that diverse thoughts combined with that deep expertise but I'll make a statement and pose it as a question if Chris or anyone wants to respond to this or maybe even Suma. But I think

we have to be careful to not introduce biases. Like there are transplant centers in the room, **ATTENDEE** down there, at the end of the day there are things in the system that transplant centers want and care about, and those are important. And we need to hear those. I think having an unbiased process maybe the people running the study who don't have a stake in the game either way I think a lot of the critique of the current OPTN structure is it's largely a self regulating entity. Sometimes there's a question of how often the patient's voice is represented in the policy making. In the same spirit of policy had making, we need to make sure we're thinking in a very unbiased way and keeping the patient voice central in all decisions.

For example, offer acceptance ratio. New MPSC metric that went into effect this month. Somebody decided you have to be below 0.3 to be flagged. Is that the best interest of patients? It's not.

Deep expertise, diversity of thought, patient voice in the room, unbiased leadership running the studies.

>> MODERATOR: We'll take **ATTENDEE** and then **ATTENDEE** online.

>> ATTENDEE: In support of what you said, focusing on the lived experiences of both patients and family members because the family members are probably taking the patient to care. And every single healthcare professional involved in that process too. Maybe interviewing them until saturation. That helps you to identify the rocks and then digging into each rock to see what you can see.

>> MODERATOR: Thank you. We'll take **ATTENDEE** 's question or comment

>> Thanks, the need for independence in an evaluator is crucial to making the results of having the most impact. I think one additional way that this can be done is through a peer review process. Are there any findings from the special studies going through some sort of transparent and open peer review process where you may get perspectives from different stakeholders on the research. Additionally, I think multidisciplinary studies can be impactful so drawing in expertise from different methodologies,

whether economists, psychologists, operations researchers, pulling in that multidisciplinary expertise can make for really strong special studies that incorporate quantitative, qualitative, mixed methods approaches to strong research and evaluation.

>> MODERATOR: Thank you for that insight. I'll take **ATTENDEE** next

>> Thank you. I'm **ATTENDEE AT ORGANIZATION**. I want to echo and extend some of the comments that have been made. I truly believe in the studies that we've done with respect to these types of networks and the complexity that was mentioned and we know of in terms of this organ transplant network.

One of the things is to really set the stage for I almost call it baby steps. It's the metrics associated with these early studies. I like the comment that was made earlier today, be bold, bring innovation.

I think we've gone past the times where we're looking at small changes, modest changes. To transform this network we've got to be thinking about the bold changes and then experiment with that at a small level with well understood developed metrics.

And if we see those changes and I package those changes, the modernization experimentation, we see some evidence of success on a small scale. We then have that opportunity to then expand to larger studies. I think we've been very successful as have many of our partners in that type of methodology where you take that step wise approach to innovation through that experimentation that then translates into a future, desired end state that is really robust with respect to the data that's captured, the analytics that's performed, the patients that are supported and helped through this type of network. So thank you.

>> MODERATOR: Thank you for your comment, **ATTENDEE**. I'll shift us again. We got to speak at a high level and got a good conversation around different considerations. I would like to take us to thinking more about the specifics of what the task orders could look like. So I'll put this out there.

What should what do you think the first task order should look like within this task area. I'll also note I highly encourage if people haven't are thinking about a comment and they haven't had the chance to put in a comment, please raise your hand. Thank you. And the prompt again is what should the first task order look like?

>> ATTENDEE: This is a very difficult question obviously because everyone was looking at me for this. I was whispering to ATTENDEE. It depends on the problem you're trying to solve first. If the problem is, I need to find a mechanism to onboard a bunch of contractors that haven't really been deep in this environment because I have an objective to creating this multivendor model, then your first set of task orders necessarily have to be discovery in nature so that, depending on the different aspects of this very complex ecosystem, vendors that are successful offers on the BPA or the IDIQ have a method by which to start absorbing some of these detailed that are frankly unknown. There are things you, ATTENDEE, know it will take a lifetime for other people to figure out.

The first set of task orders have to be evenly spread out. This has been my advice through the RFI process. The biggest issue is organizational issue. I'm not talking about HRSA, but the ecosystem of partners, suppliers and this multistakeholder, how do we bring everybody up from a knowledge base to a level set so you now have some ability to leverage that ecosystem for the betterment of the system.

I'll stop there. I could keep on going. But I think you have to really think about what's going to you've got to think almost about you're building a supply chain here. You're building a supplier chain. Your biggest impediment to all the change is how do I embed knowledge of all the skeletons in the closets and all this stuff that's sitting out there that people are going to miss as part of any transformation you're going to do and then oh, my, God, in four years we're going to be talking about this again. And it's going to be a problem. I'm

passionate about this. I think you're going to have to help people get up the learning curve

>> One thing to add to that. My name is **ATTENDEE**. We're a research and development not for profit. I think the former question and the answer to the current question tie together. You could start with the focus groups that define what the studies need to be. So the multidisciplinary stakeholders that come to the table. Obviously you have an idea of what your preliminary requirements are, but there are very rigorous processes that organizations that all sit around the table representing multiple stakeholders have to level set what the requirements are. Sometimes consensus based decision making hamstrings us. I think you need it right now to feel like that ground zero, that foundational set of requirements and studies that you're deciding to do are both efficacious and efficient with your funds. So maybe the outcome of that initial task order is, here's what, pick your number, five to ten studies need to be.

>> MODERATOR: Thank you for that.

>> ATTENDEE: I was going to build off that. The first task order should be to define the task orders. But that should be a fact based approach which is what I think **ATTENDEE** was just saying. And the good news is there's a lot of transplant is one of the most researched and studied systems in our healthcare system. There's wide amounts of published research, there's bodies of work and analysis going on now.

The bottom line is there's a lot of information out there. We probably can very quickly know what the big rocks are. I think creating a value management framework on how you're going to measure the impact of different initiatives and then translating that to a research or special studies pipeline which will then convert to task orders.

>> MODERATOR: Thank you, **ATTENDEE**. I'll take **ATTENDEE** online.

>> ATTENDEE: I think once as people have discussed priorities have been assessed or measured in some way, perhaps the first task orders

are some combination of assessments and roadmaps. For example, if the priority is assessing the current data architecture and the transition and then really having many competitive proposals on what the future roadmap on what the data could look like, for example. And then also across different areas of interest as well, having a similar assessment or roadmap sort of concept.

>> MODERATOR: Great. Thank you. Any other please.

>> ATTENDEE: This is ATTENDEE. Similar thoughts, the first task order should be on the strategy for the modernization. The vision is not really clear what all you want to do. That can define the different stakeholders. I think this particular area, not necessarily next gen scope looking at your current call order, you can implement documentation that this can come.

>> MODERATOR: Thank you. ATTENDEE?

>> ATTENDEE: One piece of advice is engage with the Office of National coordinator early, because at

>> MODERATOR: Say that one more time.

>> ATTENDEE: Please engage with the Office of National coordinator early because they're doing that for digital quality and CDC for DMAC. They have lessons learned and how it can be translated into requirements.

>> MODERATOR: Thank you for that. Any other comments from online before I move us on to a new discussion prompt?

>> ATTENDEE: How about in the room? I appreciate raising hands just to make sure.

>> ATTENDEE: Just to build on that, I love the comment you made. We're also in the business of quality measure, development access and equality. What might come out of that task order too if there are quality measures that need to be developed for this specific community. Right?

>> MODERATOR: Thank you for that. I'm just making a note. Okay. Great. So I would put out there for you all to consider and discuss, do you think a study to determine how to make the OPTN

responsive to patient needs would make sense as a task order? If you could see this.

Do you think a study to determine how to make the OPTN responsive to patient needs would make sense as a task order? And if

So how might this be done? Again great. I'll take yes.

>> ATTENDEE: I was going to answer that with a yes. ATTENDEE you also mentioned yes, my name is ATTENDEE AT ORGANIZATION. I think in addition to patient needs, I think understanding that full ecosystem of people that interact with OPTN and their needs is equally as important. So in addition to patients, their care providers, care teams working with this data as well would be relevant to that special study.

>> MODERATOR: Thank you for that. Yes?

>> ATTENDEE: This is ATTENDEE AT ORGANIZATION we need to maintain that the gift of the donor is also honored. And I think like some of the conversation needs to be centered around that as well in tandem with the patient.

>> MODERATOR: Any additional thoughts, comments? Great.

>> ATTENDEE: Since no one else is talking this is ATTENDEE. We agree with the concept of a study to assess how the system can better serve patients as well as to your point expanding that to other members of the care team that would like more access to information to help those patients to navigate and understand it along the way.

>> MODERATOR: ATTENDEE?

>> ATTENDEE: I would encourage that if you're going to do that, that we should be bold in what the possible is. I think there's a controversial idea that's been out there for quite some time around exposing patients to the offers that are declined on their behalf. The stat is that you heard 17 patients die every day on the wait list. The average patient who dies has 16 offers that the are declined on their behalf that went on to be successfully transplanted in other people. So 16 chances to leave, 16 noes. That's criminal. So there's a lot of again, there's a lot of research that's been done in this space.

I go back to that independence, because some of these ideas and solutions don't always sit or resonate very well with different constituencies within the OPTN. There are very loud voices against this idea of exposing patients to the offers that were declined on their behalf. The question is what's best for the patient? What's best for the system.

>> MODERATOR: Any or questions.

>> ATTENDEE: This is **ATTENDEE AT ORGANIZATION**, this is music to my ears, the things we've said. I didn't want to go first on a question like that since we're a patient advocacy organization. The statistics that **ATTENDEE** just mentioned were spot on. And we've met a lot of resistance it talking to individual members of OPTN as well as the transplant community at large about this one area. We've also had a lot of difficulty getting some kind of consensus or any work group together outside of HRSA, outside of OPTN to talk about what are patient centered metrics? What is quality of life? What does a good outcome look like? We continue to push the rope around that, if you will.

I think it's back to things already said. We have to be really clear about what we're looking for. Absolutely, we should entertain that because it's not happening organically. After being in this job for eight years, it's not going to happen organically unless we overtly be bold, as **ATTENDEE** said and put down the requirements in what we're looking for.

>> MODERATOR: Thank you for that, **ATTENDEE**. Additional hands from online oh, agree great.

>> ATTENDEE: You had asked also how do we go about doing this and maybe the bit I would add maybe along the ideas of being bold, really involve the patients and the folks that we're looking to improve their experience around in the generative aspect of finding solutions. So have them involved in co creating the things that we're testing and trying to understand how this will help meet their needs

as opposed to just seeking through traditional research, trying to document their needs.

>> ATTENDEE: I'm sorry, one more one thing. This is ATTENDEE. We did do a study about patient preferences a couple years ago with a doctor from Columbia and demonstrated the last thing that patients care about is one year graph survivability. The last thing they think about it if at all, that's the common center metric in the transplant system right now. .

>> MODERATOR: Thanks, everybody, for your input. We have some chat in the Zoom? Okay. Thank you. So from ATTENDEE, what quality do you think is it now? Sorry. Yeah. It's hard to know how to address the comments in chat. But feel free we'll give a minute for this topic before pivoting to the next discussion prompt. ATTENDEE, hi.

>> ATTENDEE: Thanks for the opportunity. This is ATTENDEE AT ORGANIZATION the current contractor for the transplant recipients. I just want to add support to ATTENDEE 's comments, ATTENDEE 's comments, others in the room. We're highly focused right now how we can make this information best used most useful to patients in their transplant journey. We have a lot of ongoing work. ATTENDEE chairs our subcommittee and has been instrumental in helping us think about how we can effectively convey information to patients. So I would think having a task order on the OPTN side to really address how we can how this system can pivot and focus on the needs of the patients is exactly where we need to be headed.

I want to second ATTENDEE 's comment early on. There should be patients early on in every one of these discussion. We've been trying to live by that on our side as well. We look forward to this and how we can best partner with those that will be making this happen.

>> MODERATOR: Thank you for that comment. ATTENDEE. Any other comments I'm going to try to get us to cover one more discussion point. Yes, please?

>> ATTENDEE: My question since ATTENDEE just spoke up, can someone talk about the different the governance vision of the difference between task order 4 research evaluation and the SRT contract scope? Because they're in the business of evaluating as well. My personal interpretation was is that there are more quantitative and measures based and this is more qualitative and evaluation and recommendation and visioning. Can you talk about a bit about how we see the two? Is there over lap? How would they work together? I think it would be helpful for those of us in the community.

>> ATTENDEE: I can try to address that. I think the SRT contract ATTENDEE, you can challenge me if you don't agree. I don't believe it's focused on evaluating the system. It's evaluating it's looking at performance metrics of measuring kind of the way sort of certain key measures within the system. I think what we're talking about in task 4 is evaluating the way the whole process is working right now. And that's different from the evaluation as the SRT goes.

>> ATTENDEE: Yeah, I welcome the comment and certainly we want to partner with HRSA to sort out these issues. I do see that the SRTR, part of our mission, I think, is trying to answer the question, how is this system performing, both broadly and in key subcomponents. We do a lot of evaluations of OPO performance of trans pleasant performance of more global system performance through various reporting mechanisms we have as well as supporting the OPTN infrastructure in the policy work and policy simulation work or policy analysis work.

So yeah, I think that we need to work out what that balance is. I think, ATTENDEE, your comment, I think is more about the operation of the system versus what I think of as system performance metrics. We had a lot of talk just in your offices earlier this week about how we think about national system performance goals. And I think we need the community to come together around that. And we need a centralized location where we're going to monitor and track

those goals and try to address the question of how we're doing against those goals.

But, **ATTENDEE**, is your comment more so in line with the idea that you're studying the operational components of the system? I would tend to agree that perhaps that's not the wheelhouse of the SRTR. I would say that systems monitoring, systems performance is very much in the wheelhouse of what the SRTR exists to do.

But maybe I'm misunderstanding your comment, **ATTENDEE**.

>> **ATTENDEE**: That's **ATTENDEE**. Which **ATTENDEE**?

>> **ATTENDEE**: **ATTENDEE**, I'm sorry.

>> **ATTENDEE**: As this conversation, as we've covered the OPTN data collection, there's also things like policy making, compliance monitoring. There are a range of functions that the OPTN undertakes. I think task 4 was initially envisioned as a way of evaluating and assessing those activities so that we know what is being done correctly now? What is the current state and objective independent assessment of the current state. And then how do we identify what do we want in the future state as a result of that assessment.

And that is like he see I guess I see the work of the SRTR would be looking at how our, the OPTN members are operating in the current state and in the future they will be evaluating how well OPTN members are operating in that future state. So it is I see it as a different level of assessment.

>> **ATTENDEE**: I'm hearing two things in your answer. They're focused mostly on performance. This is more broad than performance. Secondly, they're measuring this is about evaluating. Their measures would feed these evaluations.

>> **ATTENDEE**: Correct.

>> **MODERATOR**: I'm glad we were able to dive deep into that. We only have a few more minutes. I'm going to be greedy and put one more prompt in there. Squeeze one more in.

What eval criteria and type of evaluation process would ensure we get the best possible vendors for these task area 4 activities? What eval criteria and type of evaluation process would ensure we get the best possible vendors? We can see if anybody says just pick me.

>> ATTENDEE: I think it goes back to my first answer around combination of deep expertise in transplant. I don't think our system can afford to have folks who have zero experience in transplant come up to speed but also fresh new thinking unbiased outside thinking and proven methods. Proven methods that result in outcomes, not just studies that sit up on the shelf and collect dust.

>> MODERATOR: Thanks, ATTENDEE. ATTENDEE.

>> ATTENDEE: Completely agree with ATTENDEE. I think I have a huge respect for the space. I'm trying to learn as quickly as possible. I think that the data issues and the technology infrastructure issues are inextricably intertwined. And so whoever you bring in for the different components of this need to still have a holistic view of the space and understanding of the role of the technology, not just be data focused. Because they're so wrapped up together.

>> MODERATOR: Thank you, ATTENDEE. Any other comments, thoughts to share from Zoom or in the room? Yes, please.

>> ATTENDEE: ATTENDEE AT ORGANIZATION. I want to make sure you're thinking about the fact that CMS does their own has their own metric system and evaluations and there's coordination that's really important between HRSA and CMS. I know there's a committee set up that I there's not a lot of I have no idea how that's operating, internal HRSA and CMS coordination team. I think making sure you have input from people really working out in the field in this space, input from them is critical. And that coordination between the two is really happening. Because people have to be able to do their day jobs and make the system work and constantly having to report on we have to really be mindful of the volume of things that we're asking

people to report and really collect data on the most important things.

And I just a plug also. We have a real problem with death certificate data. That's really an imperfect thing to include in the measure in the evaluation of entities. We just have to do a better job of figuring out how to get a better data source there just to inform all of these efforts. So thanks.

>> MODERATOR: Thank you, ATTENDEE. There's a hand. Sorry. Thank you.

>> ATTENDEE: I just wanted this is ATTENDEE again. I want to echo the point. We talked earlier, I think the gentleman to my right referenced we're really talking about a supply chain. I haven't heard anyone talk today about donor hospitals and their relationship and the interface and the API and the workflow and the visibility.

>> ATTENDEE: And payers too.

>> ATTENDEE: We have to include that.

>> ATTENDEE: I support that.

>> MODERATOR: Thank you for raising that. We are at our time to wrap up. I really want to thank everyone one of you for being a part of this conversation, this really rich dialogue. You gave us a lot of things to consider as we work on updating the transition IDIQ and planning for task orders. So thank you all. It was a pleasure to speak with all of you. Thank you for sharing your insights.

(Event concluded at 12:05 PM ET)

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