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PMC PERSONALIZED MEDICINE COALITION

Diaceutics Clinical Practice Gaps: Webinar Series

Understanding the challenges the precision medicine industry faces in ensuring every patient receives the right therapy for them, a NSCLC case study

Q&A

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Question 1

How reflective of real life is this study?

Susanne: This is a fairly reflective study of real-life scenarios. With any data set there are caveats, as no data set is perfect and as we were looking at this as a patient cohort and we were not looking at an individual patient journey. There could be patients that for some reason took a different direction, and there can be patients that opted out of getting tested or biopsied. This can be the case in patients who are too sick for treatment. So, there are always some caveats to consider here, but I think a lot of effort went in to deciding the right data approach. A lot of discussions mentioned in the steering group were making sure the findings were reflective and that we were considering all angles. I think we see evidence around that tells us that this is reflective. Some of what we've seen in the data is happening in other areas. I saw new data a week ago from Europe showing that 4 out of 5 eligible breast cancer patients are not informed of genomic testing options and stats like that are not uncommon and combining that with what we hear when we talk with patients or a representative of patient organizations, we hear a similar story. So, yes, I feel this study is representative.

Question 2

Have you any perspective on key shifts in this since 2019? Do you think the situation has improved or got worse? Any thought on how current the perspective we're sharing today is?

Susanne: I believe the perspective of the study is still current today despite the data being collected in 2019. There have been no major events that would have impacted the research over the last two years. Due to the Coronavirus, we would be picking up from where we left off before the pandemic.

Daryl: We are hoping to do this analysis downstream to show movement in these numbers after we have been able to get involved and make an impact. But I do think that the idea is that these numbers will improve, that personalized medicine will be implemented more successfully as we go forward. Certainly now, we can inform strategies to make that happen. But just the education and awareness component alone should have an impact to improve the situation. Have we seen a major improvement yet? As Susanne mentioned, through the COVID pandemic, it is unlikely. But we have the opportunity here to do more. The other thing to point out is that this is non-small cell lung cancer, and I think this data would be reflective of all precision oncology. With non-small cell lung cancer, you have a recognized precision oncology pathway that has been implemented tremendously, meaning the situation in other cancer types is probably worse. So, we need to work with this data to make sure we are getting all biomarker testing driven oncology care delivered appropriately. And I do believe that things are improving and will continue to improve.

Peter: If we go back to what we all saw as the poster child of precision medicine, which was the launch of Herceptin and HER2. I think the observation around these precision medicines around 20 years ago was that we were starting to see evidence of these types of diagnostic gaps. I think what the study does is crystalize a lot of other people's work, including insights and analysis that have been done in multiple diseases and brings it back and puts more of a roadmap onto what is happening in these diseases. I think it is reflective of real life as it is not single analysis, it is multiple analyses that have been done over the years.

Question 3

What impact could this have on the advancement of precision medicine and how do you think it will dictate clinical practice?

Daryl: The key thing is that we have a recognition of the value of the precision oncology approach now we have been able to demonstrate the need to address its clinical delivery. What the Personalized Medicine Coalition does is bring the personalized medicine community together, and that's what we need to do now. We need to activate that community and we can use this study to advise strategic development where we will engage the relevant community partners to address these gaps. This is at every step of the clinical pathway, from the collection of biospecimens all the way to treatment decision. What we need to do is to bring those groups together now and develop key strategies, that are vetted, that will improve the deliveries and policies around precision oncology. We've already begun, with Diaceutics as our partner, we are now developing these strategies and talking about what we need to do.

Question 4

Has the information presented here today been presented to payers, insurance companies, etc. to help expand coverage for additional testing that had not been previously covered by payers? How do you see the information presented here today influencing payers?

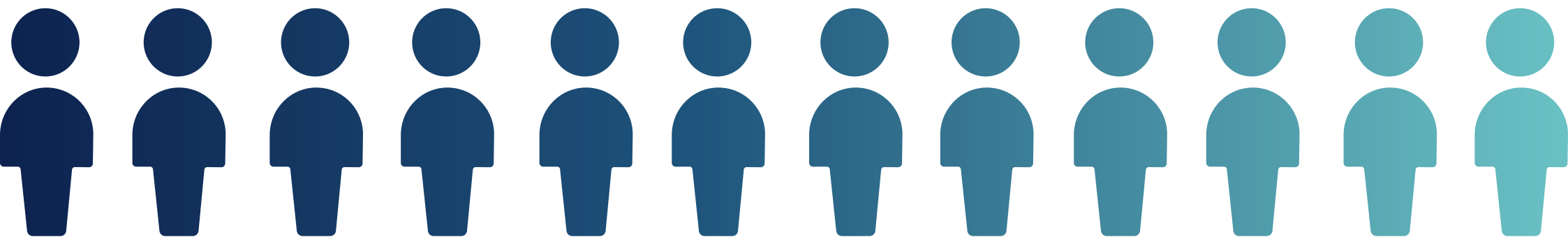
Daryl: The key thing is improving the awareness and education, especially to the providers and payers, so that we can encourage value driven policies and incentivise utilization appropriately so that there is better access to care. We are regularly in conversation with the payer community, but unfortunately it is a challenging conversation to have. The payer needs to consider the population level of the care that is administered, while we are taking a very personalized and individualized approach to looking at it. The argument I feel this paper clearly makes is that individualized care brings population level improvements to the health system and to outcomes at a population level. We need to make that point to payers and we will continue to do it, but it makes a lot more of an impact when we use real-world, practice-based data within the study. We have to make the case that payers need to make sure not to be a barrier, and to not be an added challenge to the implementation of this. We need to make sure that the value proposition can be met if we implement this appropriately and provide access to everyone. So, that is currently where we are, and we are hoping that conversation will continue.

Question 5

Susanne, could you discuss the lab community. What role do you think the labs have to play here and what do we need to do to help them?

Susanne: That's a really important aspect of this, because I do think that this paper will be that call to action, that is generates the spotlight to labs and gives the data that we needed to really understand where the challenges lie and where we need to put our focus. From a lab perspective, we do see, collectively, the bigger challenges lie with the testing aspects, such as requesting the right test, receiving the right quality, and then to a lesser degree, reporting. The labs are the centre of this, and they have had a minor role where they haven't had the focus compared to the therapy. The main focus has been on the therapy and the outcome for the patient. But really understanding that early part of the patient journey, and bringing the lab into focus there, is extremely important. It has been interesting when I have been presenting this data and discussing it with pharmaceutical companies in particular, they have said that this is providing them with the evidence they needed to have a discussion internally on what they need to do to put more focus on this and increase investment into enabling the labs to have the right focus on the testing area. We have a tendency to assume if testing rates are right, and we focus on the larger labs, we are covered. But unfortunately that is not happening. Many tests will be carried out in a community setting, and if we are not addressing these labs as well, so many patients will be lost. We need to bring labs more into the centre of the discussion and help them have more power in these discussions.

Peter: So step 1 here in our journey is to create awareness, both at a payer level, a pharma level, a lab level of what is happening here because the clinical care and duty of care that resides with all of those groups, will start to take effect here. But it starts with getting people the information they need to make a change. So what impact can we have here? I believe starting with awareness will show that we can make improvements overtime.



Question 6

If you could tackle one gap, which one would you tackle first?

Daryl: I'll make the argument that we should focus on the early the ones upstream that the clinical practice gaps around biospecimen collection, test performance and clinical decision support, because I think there's already some progress being made in these areas, but also my sense is that addressing the overall picture will be a linear progression where if we can handle the upstream problems and really address them and have good strategies to overcome some of those gaps, the downstream problems will be easier to figure out. But what I think we can and what we are addressing really first is the development of clinical pathways for sample collection, optimized and standardized laboratory processes, and there are efforts under way to do just this and some of them are more advanced than others. And then finally the optimized and updated regularly updated integrated clinical decision support including common data sets for the electronic health record. If we can handle these problems to allow for better clinical decision support for more standardized biospecimen collection and test. That test development and test performance, I think we'll go a long way.

Susanne: It's also important to focus on the hurdles around the testing and ensuring that patients are getting the opportunity to have the right test, to know their genomic alterations that eventually will lead to them getting the right treatment that can add months and years to their life. And I do appreciate that within getting the right testing, there is an underlying number of gaps or potential challenges which will be handled there. You talked about the funding, which is a big part of it. There is availability to having the right instruments and test available in a lab. It holds a lot of underlying challenges, but the focus should be on enabling the lab and making sure that at least the patient and the physician will know what is driving the disease and how to determine the best treatment option for them.

Question 7

Having delivered the practice gaps study, what do you think would be the number one takeaway for pharma?

Susanne: Having had the opportunity to talk about the data and present the data at several meetings and having had discussions with several stakeholders including pharma it does come across consistently from all conversations that that last gap, surrounding treatment decision has been a real surprise and an eye opened for everyone we've spoken to. Even if the testing is done correctly and everything else is correct, the right treatment for the patient might still not be chosen. As I mentioned before, some of the reactions I've had is that you know this is important evidence and the study is needed to have discussions internally at pharma companies on why this is relevant and why there is a role to play in applying this and supporting across the patient journey ensuring the patient has the opportunity to receive the drug. I haven't had any concrete suggestions back on how to actually do this. I think it's more been a realization that this is needed. I often hear back in discussions with pharma when we talk about testing and why testing needs to be a priority that an argument may come across that pharma are not the diagnostic company the diagnostic company needs to fix this gap. This study has probably provided some of the evidence to say, well, we're not asking pharma to be a diagnostic company, but there is an interest in supporting our some of those earlier steps to get to the end goal.

Daryl: I think that the number one take away for Pharma goes back to a regular statement that the Personalized Medicine Coalition's President Edward Abraham's regularly says and that's, 'Just because you've built it does not mean that they necessarily will come'. The adage is if you build it, they will come. But in this case, building a better treatment pathway for oncology patients that improves outcomes, provide safer and effective treatments, and potentially lowers downstream cost, shows the pharma industry might have thought if we build this, this will become health care. But we're seeing that as important as building it is developing the policies and practices to deliver this new treatment in this new paradigm, appropriately. If we talk about the evolution of healthcare, which the entire pharmaceutical industry has invested in now from a 1 size fits all, paradigm 2, the targeted value-based care that precision medicine brings. It's worthy. It's necessary and the investment is needed to make sure that the policies and practices keep up with the great science that the pharmaceutical industry is putting forward.

Question 8

Did this project look at different barriers at different stages of NSCLC? For example, prior to first line treatment or second line treatment and how relevant is this to those lines of treatment?

Susanne: As mentioned earlier, the kind of the population within non-small cell lung cancer that we looked at was the newly diagnosed advanced non-small cell lung cancer patient and we looked at that that cohort as a group and not individually. So these were untreated because they had just presented so in that sense, not relevant to talk about if they had progressed from further than first line. One of the reasons with the steering group was again to really make sure that we interrogate how we designed the data set up, how we make sure that it was as relevant as possible and as representative as possible.

Daryl: We made the conscious decision early on to reflect the clinical guidelines around advanced cancer patients, because that was identified as being the most relevant. If we could make the case that even in clinical guidelines, the standard of care is not being implemented appropriately then upstream, non-advanced cancer types, that's probably even less so. I'll also point out that if you are employing a precision oncology pathway prior to advanced cancer in early stages of non-small cell lung cancer, you're probably thinking of precision oncology as the way to move forward and you're not thinking about a non-precision oncology approach. So that's why we focused it on the advanced cancer patients.

Question 9

I think that level of complexity will increase and in fact it was one of the questions is this not going to get more confusing as additional tests and therapies emerge?

Susanne: I think it will. I addressed it earlier is that when we talked about has there been progress since 2019, I think there's been a lot of progress, but then also adding complexity.

Daryl: One thing that's clear from this is that the value proposition that a precision oncology approach can bring is not being met because of these clinical practice gaps. And payers are now aware of that and that and to recognize that value to realize that full value we need to address these gaps.

Question 10

What is the role of liquid biopsy and how does this help? Is it helping universally?

Daryl: Yes, it does help universally and there are challenges to collecting liquid biopsy samples as well. And then all those post collection challenges are probably applicable to a liquid biopsy specimen as well. Importantly, this data from 2019 showed that about 8% of the advanced cancer patients' biopsies were liquid biopsy. I think that that's probably already changed significantly, and I think it will continue to change moving forward. So, this will become more and more relevant to the liquid biopsy component and the liquid biopsy approach as well, especially as more patients are in situations where a tissue collections situation might not be applicable and there be more of a necessity to do liquid biopsy.

Susanne: We know the tissue is a challenge and it's becoming a challenge to diagnose patients in a sufficient manner so liquid biopsy is certainly going, in my opinion, having a much more profound role moving forward. I think the development we see in technologies at the moment will play a greater role. So the combination of new progress and technology and how we combine that is going to be something that we need to factor in. But that's also going to add to the complexity. But adding more options to getting the result that will enable treatment is going to improve the situation.

Peter: I think over the past 20 years and that I have been observing the diagnostic space, there's always this hope that a new technology will come along and sweep everyone off our feet and we'll solve the issue. And I think I'm more realistic way to probably think of that is every new technology puts its arm around a different problem or it puts its arm around a different patient group. And they certainly play a role, but they increase that level of complexity and one of the things that I know we talk a lot about it in Diaceutics is the frequency which diagnostic guidelines are updated or rather the lack of frequency of those diagnostic guidelines. So the pace of technology arriving into the space is not matched by our speed of response and labs feel this all the time because they're being exposed and asked to do things that are not necessarily in in the guidelines.

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