



**Article:**

Ping Wang and Larry J. Kricka.

*Current and Emerging Trends in Point-of-Care Technology and Strategies for Clinical Validation and Implementation.*

Clin Chem 2018;64:1439-52.

<http://clinchem.aaccjnls.org/content/64/10/1439>

**Guest:** Dr. Ping Wang is Associate Professor of Pathology and Laboratory Medicine at the University of Pennsylvania, and Director of Clinical Chemistry and Core Laboratory at the Hospital of the University of Pennsylvania.

Bob Barrett:

This is a podcast from *Clinical Chemistry*, sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I am Bob Barrett.

Point-of-care technologies provides clinicians access to rapid and actionable diagnostic results. Changing reimbursement and regulatory requirements are focused on shifting healthcare from being reactive, episodic, and volume-based to being preventive, coordinated, and value-based. Patients' desire to engage in their healthcare decisions and interest in healthcare consumerism and wearable smart devices is growing. These trends have increased the relevance of diagnosing or monitoring diseases in a patient-centered way at the point-of-care, with applications in population health and chronic disease management, and in prevention of acute admissions and unnecessary readmissions. In addition to these drivers for demand, a number of scientific advances are enabling user-friendly, analytically and clinically valid point-of-care technologies that have either entered the clinical marketplace or demonstrating potential to do so in the near future.

A Review appearing in the October 2018 issue of *Clinical Chemistry* describes the trends and the technologies that have emerged in the past decade and are shaping contemporary point-of-care testing. We are joined by the Review's first author, Dr. Ping Wang. She is Associate Professor of Pathology and Laboratory Medicine at the University of Pennsylvania, and Director of Clinical Chemistry and Core Laboratory at the Hospital of the University of Pennsylvania. Dr. Wang also directs the George Woodward Post-Doctoral Program in Physiological Chemistry. So Dr. Wang, first of all, why did you write this Review?

Dr. Ping Wang:

Well, we put together the review mostly because of two main reasons. First, as clinical laboratorians, we know the healthcare landscape is changing, and we're going towards a lot more emphasis on population health, precision medicine, disease prevention, and chronic disease management. And

we know that point-of-care technologies have a lot of value to offer in these spaces. And this is also demonstrated by the strong growth in research in many point-of-care technologies, with lots of academic labs and startup companies developing exciting devices or tests. And the second reason is because we have seen strong growth and uptake in consumer-based point-of-care technologies. For example, wearables. We talk a lot about Fitbit, we use it to monitor vital signs and we use it to monitor physical activities, the number of steps and sleep activity and the quality of sleep, for example. On the other hand, the implementation and uptake in the laboratory diagnostic sector has been relatively slow.

So, putting these two facts together, we think it'll be timely to look at what has been developed in the past ten years in terms of technologies, what has been implemented clinically, and what other strategies were key to successfully translate technologies from bench to bedside in order to achieve clinical impact. So again, to come back to the original question, we hope the Review would be useful for academic industry technology developers who want their technologies to have eventual clinical impact, and also be useful for clinical laboratorians or clinicians who may want to know the emerging technologies they may be able to use in the near future.

Bob Barrett: What are the major growth points and emerging trends in the point-of-care technology field?

Dr. Ping Wang: So we have seen many major growth points in different aspects in the field. So, this includes specimen types, testing mode materials, and analyzers themselves. Generally speaking, there is a trend going towards less invasive, more continuous testing, and there is also a trend to integrate testing with artificial intelligence with data processing, and with tele-medicine for remote monitoring. When it comes to analyzers, we are seeing a lot more technologies being miniaturized, at least in the research laboratory settings. So, this includes not only in the usual sets of tests which we used to see a lot in miniaturization, including spectral for the metric assays, immunoassays, but there are also devices such as mass spectrometry and NMR which in the past, typically they are very large central lab instruments occupying lots of spaces.

So we're seeing these devices being miniaturized as well. And the testing manual is being expanded to include more analytes than the usual. And most importantly, nanotechnologies and microphonics have enabled more sensitive detection and quantification as well. So, summarizing these growth points and trends, we have put together a Table 1 in the Review to get everything together.

Bob Barrett: So, which point-of-care technologies have been adopted quickly in recent years?

Dr. Ping Wang: We mentioned this a little bit in our previous question discussions. Particularly, two technologies in the consumer market, including wearables, we talked about Fitbit, and some other smartphone plug-in devices and apps have developed very rapidly and have been adopted quickly in recent years.

So, these started with vital sign monitoring, as we discussed before, heart rate, breath, and then temperature, et cetera, but are now expanding into the diagnostics and imaging areas. For example, we're seeing a lot more biomarker monitoring, and we are seeing ultrasound by bedside and many, many other applications. So the technologies are summarized in Tables 2 and 3 in the Review.

These technologies, when they are combined with artificial intelligence pattern recognition, they have the potential to truly put diagnostics in the hands of patients or primary care providers. The rapid adoption reflects the needs of the population to gain insights into what we call quantified self, which is reflected by the patient's will to know more about their health status and gain more control over their own health care as well.

Bob Barrett: Doctor, what can we learn from the success of these technologies and what are the keys to achieve clinical translation?

Dr. Ping Wang: Well, that's a very good question. I think to follow up with the previous question, one key lesson to take away from the success of these technologies and from the rapid adoption of these technologies is that they truly fit a clinical need or marketing need, which is to gain actionable diagnostic information very quickly and very conveniently. And this is something I think all of the point-of-care technology developers should keep in mind and it's also something we focused a lot on in the latter half of the Review.

So, we talked about gaining actionable diagnostic information more quickly and more conveniently. People tend to think a lot more about the quickly and conveniently aspects, but less about the actionable aspect. So, actionable means the testing results need to provide meaningful information to the patients or providers in the context of the care pathway and help them decide the next step of action. And technology development should always start with clinical needs assessment and the solution used to fill an unmet need will bridge a gap.

So, as technology development progresses, the question of clinical needs should be revisited often as well and be used as a guidance throughout the whole process. So one key here is to understand the current clinical care pathway very, very well, where the gaps are and how to position your technology within that pathway in order to form a new care pathway. How will this impact clinical and economic outcomes as a result of the new care pathway as well as patient satisfaction, how would the patient's satisfaction be affected as well, because now you have a new care pathway. So, the answer to these questions will eventually determine the success of the clinical translation of new technology. And this is why the technology developers should have clinical laboratorians and clinicians on their teams as early as possible when they start a journey of point-of-care technology development.

Bob Barrett: Well finally, Doctor, what tools can you provide to technology developers or users when developing or evaluating a novel technology?

Dr. Ping Wang: So, there is a saying, "The devil is in the details." So, we talked about the big picture question of the clinical needs in the previous question. And besides that big picture question, the needs and the care pathway, I think a lot more attention should also be paid to details, such as target population. So, which is the patient population you are trying to target? Is it the specific disease group or is a specific population in the hospital or in the clinics?

The analytical performance of your technology, this includes sensitivity, specificity, and testing matrix selection. Is it plasma, is it whole blood, is it urine, is it saliva? So, the different matrix selection will also impact your analytical performance as well as the convenience of testing as well. And IT connectivity, how are you going to transmit results of your device to the final reporting format? How do you get the results to the physicians or the patients who need the results? The user interface, is it conveniently formulated so that it is user friendly?

The implementation infrastructure, the reimbursement strategy, user engagement, and the training and the support as well, and finally the workflow logistics; these are all important aspects, and they're summarized in Figure 1 and Table 4 in the Review. So a good technology, when it's coupled with a strong validation and implementation strategy, can achieve maximum clinical impact.

There may be many, many hurdles along the way as well, which we also addressed in the Review, in the latter half of the Review. So, with these tools, we hope to bridge the sometimes idealistic research world with the practical day-

to-day operational world of clinical practice. We also hope that these tools are useful for researchers, for clinicians, and other stakeholders interested in the point-of-care technology field.

Bob Barrett:

Dr. Ping Wang is Associate Professor of Pathology and Laboratory Medicine at the University of Pennsylvania, and Director of Clinical Chemistry and Core Laboratory at the Hospital of the University of Pennsylvania. She's been our guest in this podcast from *Clinical Chemistry*. I'm Bob Barrett. Thanks for listening.