# CAP Author Chat - Disruptive Technologies in Clinical Medicine

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**Lisa Tomcko:**

Welcome to the latest edition of the College of American Pathologist's CAPcast. I'm Lisa Tomcko, Content Specialist with the CAP. In the practice of clinical medicine and clinical pathology, novel technologies often disrupt existing paradigms in diagnostic medicine to improve patient care through more timely and accurate lab results. These disruptive technologies often don't have a precedent for best application or support in evidence-based literature. Even so, they share similar characteristics according to Dr. Frederick Kiechle. Dr. Kiechle is joining me today to discuss his new book, Disruptive Technologies in Clinical Medicine, which cover some of these technologies and their impact in practice. Dr. Kiechle, would you like to introduce yourself?

**Dr. Frederick Kiechle:**

Certainly. Thank you very much. I have an MD and a PhD in biochemistry obtained over seven years. Then I went from there to a residency and anatomic path and clinical path at William Beaumont Hospital in Royal Oak, Michigan, where I decided the better part of that would be to focus my attention on clinical path because I was red green colorblind and I was having a terrible time interpreting the stains and driving my mentors nuts. I continued to move on in that direction and have focused my life really in clinical pathology as a career.

From there, I went to a fellowship in clinical chemistry at Wash U, and that was followed by going to work at University of Pennsylvania, which two of those years was spent as an assistant professor and a co-director of the clinical lab. So I became involved in administration and politics and in the administrative leadership fairly early in the game in my career. I moved from University of Pennsylvania back to Beaumont where I stayed for 24 years as the Chairman of the Department of Clinical Path. And from there I moved to Florida where I currently live and work with a private practice group, Pathology Consultants of Broward County from Broward for about 15 years until I retired. I currently am the Clinical Medical Officer of Boca Biolistics, a reference lab in Pompano Beach, Florida. So that pretty much is the thumbnail version of me.

**Lisa Tomcko:**

Well, thanks so much for being here today to share your rich experience with us. Let's get into the questions. This book really seems like a set of personal insights gained over the course of your career. So what made you decide to pursue this topic now?

**Dr. Frederick Kiechle:**

The stimulation for writing the book was to kind of look back over that career of clinical pathology leadership and ask the question, what were some of the factors that really created a new direction, changed the workflow, made a major impact on the way your laboratory, my laboratory and other laboratories had to modify their activities in order to accommodate a new either disruptive technology or well disruptive technologies? Either the technical kind or non-technical kind. I make a distinction there, and the book itself covers three event-driven disruptive technologies and these are event-driven. As you'll see, infectious diseases, personal behavior and cultural norms, which refer to [inaudible], which refers to the reference range issues that represents for the laboratorians. I like to separate those event driven, infectious disease driven, so on and so forth from what I call 12 technical disruptive technologies, which are reviewed in the book.

The book is somewhat of a survey. It's not meant to be an overall encyclopedia of any of these topics, and they cover biosensors for physiological monitoring and biochemical sensors, smartphones, MALDI-TOF MS, microbiome, phlebotomy practices, point of care testing, microfluidics, the backbone of current development of technologies in the small size, molecular diagnostics, including ontology single molecule sequencing, isothermal amplification, CRISPR retrons, and also pharmacogenomics. Also a little bit of information about organoids, organ-on-a-chip, and finally, artificial intelligence, which was written before chatbots.

**Lisa Tomcko:**

It sounds like a lot is being covered and perhaps some important distinctions in there as to what qualifies as disruptive technologies.

**Dr. Frederick Kiechle:**

That is correct. I tried to separate the two kinds of concepts because both of them had a big impact on the way I handled business and directed the laboratory. My view of being a lab director and has always been thinking about what we're doing today, but rather also focusing on what I'm going to be doing five years from now. So attempting to gather information about some of these cutting edge, not quite ready for primetime technologies that look like they're on the verge of being successful. There's a little bit of gambling involved there. Often you'll get a great idea of what it's like just by talking to vendors and their theories of the direction they're going to go in and talking to other pathology leaders and asking the question, what did they really need?

**Lisa Tomcko:**

Definitely keeping that finger on the pulse.

**Dr. Frederick Kiechle:**

Yep. And also remain vigilant, of course.

**Lisa Tomcko:**

What benefits of experience are you sharing with readers of this new book?

**Dr. Frederick Kiechle:**

Most of the chapters written have relationships to and discussions of my experience in these areas. Probably the deepest experiences are in point of care testing, which I implemented very early in its inception, molecular diagnostics. We had one of the first molecular diagnostics laboratories at William Beaumont Hospital, and we started one of the first Molecular Diagnostics Symposium at William Beaumont Hospital. In Florida, we introduced MALDI-TOF, which of course identified mass spec, which helps identify an organism after you've cultured it without having to go through all the various biochemical steps that are required in order to identify an organism. You put it on the MALDI-TOF, you get an answer in about a minute and a half. That is truly, if you want to look for a great example, an example of a disruptive technology that rearranged all the workflow we did in the microbiology lab and the way the workstations were defined and designed.

Much of the book is drawn from my personal experiences and from what I found out in the literature about other people's experiences. There's a discussion about the effect of Ebola, for example, which is an event driven problem. My lab never had to get ready for Ebola, but we certainly were watching very closely as a couple labs in the United States were trying to gear up for the potential of an Ebola infection. So that kind of gives you a sense of my hope of what's in the book.

**Lisa Tomcko:**

Really sounds like a lot of great firsthand experience being shared.

**Dr. Frederick Kiechle:**

I try to focus on topics that I had personal experience with which I thought had a major impact on the way I did business.

**Lisa Tomcko:**

What are your predictions for future areas where pathology will meet disruptive technologies?

**Dr. Frederick Kiechle:**

That's such a fascinating question. Microfluidics, as I said, is the driver I think behind some of our future technologies. You use less reagents. It's very inexpensive. The problem with the commercialization of this particular process of miniaturization is the cost of being able to build a reproducible device on a mass scale. That's what often slows down the development of some of these things that you'll read about in the book. They sound fabulous and you wonder, why aren't they on the market? Why can't I buy this? It sounds so fabulous. It would help my patients and me so much. But all of a sudden, you realize there's six or seven steps you have to go through in order to get something from just a design concept that works well with one or two devices to a commercialized piece of merchandise that you can have Salesforce go out and sell across the counter.

Really focusing on the way we do testing, I think you're going to find biosensors will be available for many of the analytes. You can actually measure many chemistry and non chemistry analytes using skin that is just touch biosensors. They don't actually need to permeate the skin and draw interstitial fluid, which is done a lot, especially for glucose these days. I really think that the touch kind of approach is going to... Like your iPhone watch, for example, you can look down and find out what your pulse rate is. You should be able to get a device that sits on your skin and tells you what your complete metabolic panel results are just by pushing a button. So that's what I see in the future. Again, I can't tell you when. It's difficult to predict these things since I have no crystal ball, but I would say that that's the direction things are going in.

**Lisa Tomcko:**

It's a lot of exciting stuff and I hope that some of these potential technologies become more available.

**Dr. Frederick Kiechle:**

It is inevitable. And there are a lot of startup companies obviously that I'm familiar with through Boca Biolistics, and they have two histories. One, they start off with a bang and then collapse, a lack of funding and lack of successful results, or they start off with a bang and continue to grow because whatever their concept was actually works. So you can go in either direction.

A great example of a disruptive technology that was a total failure, if you want to think about that kind of approach, Theranos was a concept that was devised by a leader who had a large ego and actually no talents for leadership whatsoever. The company developed a device for measuring small quantities of serum called the Edison. The Edison device actually never really worked very well, and most of the testing done by Theranos was done in a larger room where they had devices that were available commercially from many other places, and eventually the two major players in that particular organization are now in jail. So it was fraught with wire fraud and abuse of the talents of the people that were there misrepresenting their product.

**Lisa Tomcko:**

I was definitely thinking of Theranos when you were talking about the biosensor technology in companies. It sounds a little bit similar maybe with the blood draw, but yeah, I hope other companies on the market are a little more successful and upstanding.

**Dr. Frederick Kiechle:**

Yeah. Well, I think the phlebotomy process itself is going to be simplified by developing devices that don't have to permeate the skin too. One thing to think about is sweat chloride, for example, which we collect in babies who are thought to have perhaps cystic fibrosis, but that collection system involves a osmotic collecting device. You heat up the skin, it sweats, and it pulls the sweat right out of the skin and into the device, and then you measure the sweat chloride. That kind of approach could be used for a number of other analytes, which would not require sticking a needle in your finger or in the vein.

**Lisa Tomcko:**

Oh wow. That's fascinating. I'm learning so much. Any parting thoughts you'd like to share?

**Dr. Frederick Kiechle:**

I think these topics will be, to anybody that reads it, some extremely familiar and yawn inducing and some will be ones that the reader perhaps has limited knowledge about and this book will help stimulate an interest in learning more about it. It's certainly not going to give you all the answers, but it certainly will also arouse your curiosity about some of these things, especially processes and technology that are likely to change our major direction in laboratory design and job assignments and workflow and so forth. Again, as a leader, I think it's really important to remain vigilant at all times. Have a habit of keeping your eye on what's going on. Continuous information is coming at you all the time from various technology landscapes, and your job is to try to sort through the ones that look interesting but aren't going to be useful for your particular application. And then grabbing hold of those that look like they have a future and giving them a chance.

**Lisa Tomcko:**

Definitely sounds like there's going to be a lot of thought provoking material in the book, hopefully for a lot of people.

**Dr. Frederick Kiechle:**

I certainly hope so.

**Lisa Tomcko:**

Well, thank you so much, Dr. Kiechle, for sharing some great insights into this exciting and continuing phenomenon in medicine. And congratulations again on the publication of your book. For all those listening, Disruptive Technologies in Clinical Medicine is out now and available for purchase on the CAP's e-store. The link is in the episode description. We encourage you to check it out, and of course, stay tuned for future episodes of CAPcasts. For more information about the CAP, visit CAP.org.