EDF Year of Innovation

Analysis Brief

September 27, 2017



Prepared by

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Funded By:

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1. Introduction

In early 2017, Environmental Defense Fund (EDF) set out to design a process to catalyze the innovation of, investments in, and, ultimately, the use and adoption of personal chemical exposure monitors (PCEMs) that measure an individual's chemical exposure. This Year of Innovation project ("Project") seeks to: (1) identify key resources, network actors, and network strategies for a successful PCEM market acceleration program, and (2) activate network strategies and engage key actors and resources in accelerating the PCEM market.

For the initial stage of the Project, EDF and Research Into Action collaborated to design an expert elicitation study to understand the state of the art in PCEMs. Because definitions vary, we began by defining PCEMs to include chemical sensors and chemical samplers. Chemical sensors include technologies or tools that identify analytes at the point of detection by transforming chemical information into a signal; chemical samplers include technologies that collect compounds in a physical matrix over a certain time period.

We collaborated with EDF staff for several weeks to operationalize the study and identify the researchable issues that stem from three high-level research questions:

- What is known about resolving deployment bottlenecks for similar technologies?
- What are the technology capabilities and use needs of public health researchers?
- What is the technical and market potential for PCEMs to meet the needs of chemical exposure research?

This brief provides a summary of findings from expert elicitation interviews Research Into Action conducted with 20 subject matter experts (SMEs) with unique experience in cutting-edge applied public health research and PCEM technology development.[1] We supplemented these findings with insights from a systematic scan of relevant business case literature.

Section 1.1 introduces the pipeline model of innovation and discusses specific lessons learned from case studies and the experience of SMEs. Section 1.2 provides an overview of the study methodology and SME profiles. Section 2 provides in-depth discussion of the interview findings. Finally, Section 3 presents conclusions, potential implications of the findings, and areas for further exploration.

1.1. Innovation Pipeline Model

Technology innovation is a dynamic process, and PCEMs are no exception. Research Into Action's assessment of the state of the art in PCEMs examines how numerous components fall along a known spectrum of development toward commercial readiness. Before assessing the state of the art and user needs, we first introduce the generalized innovation pipeline model popularized by Branscomb and

[1] See Section 1.2 for more detail on subject composition.

Auerswald.[2] Additionally, we draw specific insights from similar technology case studies and from the professional experience of our interview subjects to better understand the current locations of PCEMs in the innovation-commercialization pipeline.

The innovation pipeline model is a simple framework that describes a generalized path to commercialization for technologies like PCEMs. The model consists of four innovation process stages that link basic research to technology development; product development and commercialization:

- **Stage 1:** The process of basic research, proof of concept, and invention leading to functional inventions and patents.
- **Stage 2:** Early-stage technology development leading to business validation.
- **Stage 3:** Product development leading to the creation of new firms or programs.
- **Stage 4:** Product manufacturing, commercialization, and marketing that leads to continued growth of new firms and programs, and, ultimately, to viable businesses.

Each stage is linked by learning and feedback processes that represent both "downstream" and "upstream" flows across the continuum from research to development to commercialization. The "overlap and redundancy" that results from the feedback flows provides peer review, verification and validation all of which increase the ability for innovations to attract funds and funders. Across the four stages, funding sources can vary, with foundational funding coming from government agencies, corporate research, and angel investors. As innovation progresses, project funding sources diversify into venture capital, equity, corporate venture funds, and commercial debt. Each stage of the innovation pipeline has a set of unique challenges that must be overcome to continue to the subsequent stages of innovation.

Early-stage innovation challenges include problems associated with knowledge creation, information sharing, lab testing, resource acquisition, team creation, and business analysis. Later stage innovation challenges include the potential continuation of early-stage challenges, in addition to obstacles related to product assemblage, as well as issues with forming a business management team, defining and maintaining the firm's values and logic, and expanding into the broader market.

The range of technologies and processes that compose PCEMs currently falls primarily along stages 1 and 2 of the innovation pipeline model. The following discussion reviews the progression of relevant technologies at each of these two stages, as published in case studies or reported by SMEs.

1.1.1. First-hand early stage experience with PCEMs from SMEs and case studies

Most PCEM research and information available in public forums describes the early stages of the innovation process. We searched several relevant journals and case study repositories for published case studies with insights related to the fundamental components of the Branscomb and Auerswald model, as well as issues related to the following:

- The impact that firm size has on the commercialization outcomes for PCEM

[2] Branscomb, L.M. and P.E. Auerswald. Between Invention and Innovation: An Analysis of Funding for Early-Stage Technology Development, 2002.

- The outcome of more disruptive technologies, especially those that feature multidisciplinary technology components
- The inclusion of firms that have experience improving their processes as the underlying science evolves
- Variation across firms that develop technologies with varying means of analysis

As we anticipated, the search returned few results that met a minimum threshold of relevance, likely due to the emerging state of PCEMs. To supplement case study insights, we reviewed the relevant experience of SMEs, which yielded additional insights to help develop an initial understanding of development pathway experienced by some PCEM developers to date. The following discussion summarizes key takeaways from the review.

Stage 1

We identified two case studies that highlighted technologies that were in the process of basic research and proof of concept. One study described a PCEM that detects toxic hydrocarbons and acids in the environment.[3] The developers followed two proof of concept validation processes to contextualize their findings on device efficacy. First, the team used an inter-lab validation approach to test device sensitivity compared against the standard bearer methodology from the National Institute for Occupational Safety and Health (NIOSH). Using this approach, they confirmed device sensitivity was on par with the NIOSH standard. Second, the team conducted field testing that demonstrated the spectrum of accurate detection as well as real-time detection. Benchmarking against the NIOSH standard was key to the teams' relatively swift proof of concept.

Another study on ambient measurements of air pollution[4] illustrated persistent challenges to chemical monitoring technology innovation. One issue identified is a lack of accessible data for calibration, validation, and testing, due to the expense and feasibility issues associated with generating personal exposure monitoring.[5] Separately, the authors found a high prevalence of measurement error, disproportionately high for some compounds, while identifying that spatial and environmental considerations appear to be the main source of device measurement error. Ultimately, the authors determine that new methods are needed to validate the outputs from the current generation of detection devices.

SMEs provided details regarding their own experience relevant to stage 1:

- **Laboratory technology development involves user experience feedback** – While developing a chemical sampler for research practitioners, a team encountered a litany of technical challenges related to user experience. With user feedback, it became necessary to address a number of issues related to environmental factors such as exposure to sunlight that become salient due to

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3 Negi, Indira, et.el., *Novel monitor paradigm for real-time exposure assessment*, 2011.

4 Study used daily measurement collected by the EPA of total mass of chemical constituents, including ion chromatography for nitrate (NO3-), sulfate (SO2−4), ammonium (NH+4), and sodium ion (Na+); thermal optical analysis for elemental carbon (EC) and organic carbon; and X-ray fluorescence for silicon (Si).

5 Bell, Michelle, Ebisu, Keita, and Peng, Roger, *Community-level spatial heterogeneity of chemical constituent levels of fine particulates and implications for epidemiological research*, 2011.

mail delivery of the devices and return of samples. In another example, a development team found that fine tuning a sensor was expensive but manageable. The more complicated challenges for the developer surfaced when trying to develop data protocols that would work well for users and lead to quality data for analysis. Lack of interoperability between analysis and data management software impeded the team's progression to viable prototypes.

- **Manufacturing practices need to be defined and product-focused during the prototype phase.** According to one SME, to ensure that a PCEM has the potential to scale, it is necessary to create a criteria checklist to help ensure that the considerations involved in developing manufacturing specification improve and don't hinder the usability of the device. The criteria may include reasonable storage and transportation requirements for end-users.

Stage 2

We identified two case studies that highlighted some challenges of moving an innovative technology into product development. In one case study, a private firm that attempted to gain regulatory approval in the U.S. for a device that treats emphysema had to abandon the project and sell its assets after the U.S. Food and Drug Administration (FDA) did not approve the device.[6] This case highlighted the challenges associated with moving an innovative medical technology from Stage 2 into Stage 3 of the innovation pipeline model.

The FDA pushed back on another firm with a warning letter, which developed an innovative technology related to personal genetic testing, due to uncertainty on how to regulate the new industry.[7] These regulatory issues eventually made it difficult for the firm to attract and maintain investors.

SMEs provided details regarding their own experience relevant to stage 2:

- **Public funding may shift focus** – Currently, a great deal of funding that supports development of PCEMs flows from federal research and development funds. A limitation for technology developers has been a lack of alignment between the requirements of funding sources, usually tailored toward specific outcomes such as treating asthma or cancer, and technology gaps the developers want to close. Usually, some sort of workaround is needed. Once new technologies are validated, private funding is more likely to flow the technologies. Private funding sources typically expect the technology to be mature and relatively close to being market-ready.
- **Product validation is a simultaneous up- and downstream challenge** – Organizing structures specific to PCEMs that could support market development, like standards and testing organizations, are lacking. This makes it difficult to convince funders that a product will align with user expectations. Looking downstream, this also poses a problem when conveying to potential users that results will be valid and accepted.

6 Denend, Lyn, et. al., *Emphasys Medical: Navigating Complex Clinical and Regulatory Challenges on the Path to Market*, 2010.

7 Siegal, Robert and Rosenthal, Sara, *23andMe*, 2017

1.2. Methodology

In-depth interviews with SMEs were the main source of data for this study. They provided valuable insights surrounding issues that address the central questions of the study. We interviewed 20 SMEs between May and July 2017 (Table 1-1). These respondents represented a variety of organizations involved in the PCEM market chain, from academia, government, and non-profit and private sectors.

To ensure that the interviews captured the full range of perspectives and adequately addressed all research objectives, we determined that the sampling frame should include input from public health practitioners with experience deploying PCEMs in an applied setting, as well as SMEs with broad experience in public health and occupational health administration. We also included SMEs with direct experience developing PCEM technologies and processes for using and validating device outputs. Table 1-1 provides a breakdown of the subject composition within each group of SMEs.

Table 1-1: Respondents by SME Group

Public Health		Technical Developers		Total Respondents
Public Health Users	Public Health or Occupational Health Experts	Developers	Process Experts	
4	5	6	5	20

Study SMEs were invited by email for 30-60 minute phone interviews. The interviews followed a semi-structured format, tailored to the SMEs' background and expertise.[8] This interview approach was appropriate as a means to address a wide range of research questions for which expertise across several distinct disciplines was necessary.

[8] Additional information about the research questions can be found in the next section, and study questionnaires can be found in Appendix A.

2. Findings

The discussion in this section highlights the main findings that address the study's three high-level research questions. Table 2-1 provides a summary of sub-questions the team developed to explore the central research questions.

Table 2-1: Research Questions and Sub Questions

Research Questions	Sub Question
What is known about resolving deployment bottlenecks for similar technologies?	What has been the role of network mobilization/engagement?
	What strategies have been used?
	Which have been most successful?
	What cost factors – such as manufacturing, data processing, and analysis – were meaningful?
What are the technology functionalities and use needs of public health researchers?	What are public health researchers' priorities for front-end* functionality?
	What are public health researchers' priorities for back-end functionality?
	How do the use needs of researchers vary?
	What is the relationship between different use needs and technical requirements of a specific technology?
	Do use needs correlate with other fields that, if addressed, would solve a need in the research field?
What is the technical and market potential for PCEMs to meet the needs of chemical exposure research?	What underlying technical components correspond with the spectrum of user needs?
	Where do potential features lie on a spectrum from most to least market ready?
	Among the user needs for which there are no market ready solutions, what type of R&D or innovation is needed?
	How have investors responded to wearable "monitored self" business concepts?

* Front-end functionality refers to what PCEMs can do, or what data they can collect. Back-end functionality refers to how the PCEMs facilitate data management

As context for the sections below, our SMEs informed us of the following ways a PCEM might be used.

- Public health researchers can use PCEMs as part of their research to assess risk factors associated with asthma, cancer, and other ailments.
- Occupational health specialists and industrial hygienists could use these devices to protect workers in hazardous environments.
- The military could use them to alert soldiers when they may be exposed to a hazardous environment

- Police and security professionals could use them to help detect explosives or narcotics at airports, train stations, and other public places.
- Space research programs and organizations such as NASA could use PCEMs as part of assessing risk for astronauts.
- Coaches and trainers could use PCEMs to improve athletic performance by minimizing exposure to chemicals that may inhibit performance.
- Like the activity trackers put on the market over the last several years, the public could use them to inform themselves about their exposure to potentially harmful chemicals, particulates, or metals.

The remaining sections go into detail about the issues around PCEMs and their use for these different groups.

2.1. What barriers exist to bringing a technology like wearables to the market and what can be done to address those barriers?

Many factors shape the arc of technology development. For technologies like PCEMs, which are largely underwritten by public research and public-private efforts, the interplay between key network actors (e.g., researchers, practitioners, public and occupational health administrators, and agencies that fund research, development and demonstration (RD&D) is as essential to success or failure as any other factor. Inadequate network composition can stymie production of social, technological, and economic value, while well-cultivated networks can play an outsized role in accelerating development and improving outcomes.

Network Signals and Structure

The experts in our study devoted a significant amount of time to the topic of network signals and structure, pointing to deficiencies and opportunities. Shared efforts, especially across disciplines, benefit immensely from clear, shared understanding of the strengths and limitations of the current generation of a technology. This shared understanding has been lacking for PCEMs.

In some cases, it has been effective to involve a heavyweight issue "champion" – one SME mentioned organizations like the Kaiser Family Foundation – to help mitigate the natural silos across the research and technology communities. Along the same lines, many SMEs across our study populations noted that lack of coordination among federal public agencies, as well as between federal and state agencies, impedes the development of effective networks. Experts cited several barriers that may result from this lack of coordination, including:

- Needlessly redundant efforts
- Competing agency goals
- Inconsistent priorities
- Higher burden around long-term funding and development strategies

Mobilization Techniques and Elimination of Bottlenecks

The mobilization technique most cited by the study experts was narrow, focused meetings or workshops with professionals with similar interests or potential use needs. These are generally led by early technology adopters or methodology pioneers, and tend to be small and loosely structured, or even ad hoc. Over time, consortia-level interaction can emerge. Currently in the PCEM space, the organizations and customs that facilitate these interactions largely have not formed.

One expert described a further possible step, which has not yet occurred in the PCEM area. Public health agencies in Europe have organized groups to routinely connect interested parties to emerging technologies to communicate their potential benefits and facilitate network coordination.

SMEs discussed several key opportunities to resolve development bottlenecks, including:

- Improving coordination across disciplines to develop a PCEM
- Improving access to funding for research and development of PCEMs
- Tolerating the long timeline needed to produce PCEMs relative to other recent technologies
- Considering all the potential pitfalls a wearable could run into by validating the technology extensively
- Overcoming skepticism toward new instruments and methods
- Accessing personnel who can develop wearables

Each of these topics is described in further detail below.

2.1.1. Collaboration and coordination across disciplines interested in the development and use of wearables is limited.

Existing PCEM research appears largely to be happening in academic settings, and the development of these devices will require academic disciplines to collaborate with groups outside of academia to develop devices. Users of data that could come from a PCEM, such as public health researchers and those responsible for occupational health in commercial and industrial settings, need to work with materials scientists and engineers to develop practical and useful devices.

SMEs provided vivid examples of the efforts they make to cultivate multidisciplinary relationships, from attending material science conferences as the only participant from the public health field, to direct outreach to instrumentation experts in other departments. When asked how they kept abreast of developments in wearable technologies, most SMEs noted they monitored public health journals and the popular press, but overall had little interaction with other disciplines, such as materials science or engineering, that may be developing useful wearable technologies.

Key take-away: Researchers and developers working with PCEMs make ad-hoc efforts to forge necessary relationships, but outcomes would improve if more formal multidisciplinary collaborations were facilitated.

2.1.2. Funding for research and development is limited.

Acquiring funds to support research related to developing a device that does not connect to a specific health problem such as cancer or asthma can be challenging. According to one respondent, "No one wants to pay for development costs of a device that does not address a specific concern." A PCEM might potentially inform what is associated with cancer, for example, but groups like the National Institutes of Health (NIH) want a device they are confident will provide this information. Funders resist investing in unproven methods, making it difficult to secure funding for PCEM development. Two respondents actively trying to validate PCEMs noted they use their own money or resources to validate so they can eventually convince funders that their wearable can be valuable to cancer, asthma, or other public health research.

Key take-away: Fostering support for PCEM research and development among health-related funding agencies, independent of outcome-oriented funding, may help developers on a number of fronts, including financing to develop practical PCEMs.

2.1.3. The timeline needed to create a practical PCEM device will take longer than the development of other recent advancements in wearables.

Funding for research and development of a novel, untested product can be difficult. Developing an entirely new product takes far longer than modifying an existing product into a wearable. For example, activity monitors such as the FitBit used existing technologies like accelerometers and GPS to create a product. There is nothing comparable to an accelerometer or GPS in the PCEM space, and developing corollaries for chemical detection will take large sums of money, resources, and time.

Key take-away: PCEMs have a longer development path because they are largely creating entirely new devices and methods, as opposed to devices like activity monitors, which were built largely on existing technologies.

2.1.4. Validating data outputs to ensure confidence among users will take time, resources, and coordination.

Validating PCEMs to ensure they work in a variety of settings, can be transported without eroding data, and compare favorably to proven methodologies will be costly and time consuming. Furthermore, it may require time to overcome the skepticism among a research community accustomed to traditional analysis methods and inspire confidence that a PCEM is "fit-for-purpose."[9]

Respondents mentioned the following study types that are being done or will need to be done to adequately validate PCEMs:

- Transportation of devices: Can a sampler be transported via mail for analysis without compromising data?

[9] "Fit for purpose" describes a product developed to satisfy specific uses for its intended user audience.

- Exposure of devices to different environments: Can a sensor or sampler be left in direct sunlight? Can a sensor or sampler be reliable when exposed to large temperature fluctuations? How does humidity affect a sensor or sampler?
- Replicability of sampler analysis: What is the protocol for analysis to ensure that different labs arrive at the same results when analyzing samplers?
- Comparison of data from a sensor or sampler to known analytical techniques: For example, how PCEMs compare to stationary air pollution monitors?

Key take-away: Supporting research aimed at validating wearable technology is key to the adoption of wearables by public health researchers.

2.1.5. Skepticism about generating reliable data from devices inhibits development of PCEMs and can limit their uptake.

According to many of our study experts, consistent data quality and demonstration of accepted results across the multiple disciplines likely to use device data is an observed or anticipated challenge. Even without observed data quality issues, the risk of inadequate quality data alone is a barrier to development, according to SMEs who observed blowback after new devices delivered data of low or inconsistent quality.

In addition to data quality, important cost drivers included end-user acceptance and access to in-demand labor. Educating potential adopters about the technology potential of an emerging PCEM is a non-obvious and acute challenge. On the one hand, the device capabilities, uses, and value-add of a device can be difficult to communicate, or differentiate. Presumably, this challenge makes adopter "acquisition" more expensive. Some middle market challenges crop up as well. For instance, device users or data users may not understand these new data sources or formats can limit opportunities for demonstration and diffusion.

Key take-away: Work to overcome skepticism of new instruments by continuing to support efforts to validate instruments, widely promote how wearables are being validated in scientific literature and conferences, and promote the best applications (e.g. occupational health, public health) for specific PCEMs.

2.1.6. The pool of staff or researchers qualified to develop PCEMs is very small.

The skillset required to develop user friendly PCEMs is unique and in demand. To illustrate how in demand the talent pool tends to be, one subject described the ideal job candidate as a software engineer with expertise in either electro chemistry or molecular biology. In the RD&D space where many of the device development teams are working, it can be challenging to secure quality staff.

Key take-away: The availability of essential personnel may impact the growth of PCEM developers.

2.2. What do public health researchers want from a wearable device?

For PCEMs to be useful to public health researchers, they should meet some of the following criteria:

- Can accurately detect multiple chemicals, be relatively inexpensive to analyze, and be deployable to large populations.
- If the device is electronic, it must have a long battery life.
- The device should have the ability to provide data in a format that can be easily compared to existing, vetted data.
- Have multiple applications, including informing public health research, occupational safety, law enforcement, and public safety.

The following discusses each of these needs in further detail.

2.2.1. Sensitivity to multiple chemicals must become reliable, inexpensive, and deployable to large populations.

We asked the SMEs to identify technical shortcomings of the current generation of PCEMs that need to be addressed for the technology to improve. The technical gaps they pointed to were largely a consequence of developing devices as part of cause-specific funding, wherein researchers develop technology with funding around the edges of purpose-specific research. As a result, technologies tend to be tailored for specific purposes and somewhat path dependent.

Respondents provided some insights into the characteristics of a PCEM they would like to see.

- **Accurate multiple chemical detection** – Scalable portable chemical detection devices that effectively distinguish between priority compounds have not emerged. Stationary devices that accurately analyze samples exist, but they are too expensive for widespread deployment, while devices at accessible price points lack accuracy, validation, and broad-spectrum capacity.
- **Cost of analysis** – Accurate and scalable tend to be competing technical gaps. Less accurate devices can produce data that is less expensive to access, while more accurate devices, especially samplers, have additional steps in the analysis process that add expense. Post-collection analysis processes, such as analytical chemistry, are difficult to effectively address, because, unlike digital-only platforms, the cost can only be reduced but not eliminated. And, according to several SMEs, the cost of post-collection analysis has not been falling.
- **Population scale PCEMs** – Deployment of population-scale data collection has lagged due to lack of certainty in data quality and in the reliability of devices. Multiple SMEs conveyed their perception that PCEMs, rightly or wrongly, are viewed not to produce sufficiently reliable data to justify long-term investment in population scale research.

Key Take-away: Because PCEM funding flows largely from purpose-specific programs, technology gaps that impact widespread usability are persistent.

2.2.2. Developing comparable data formats to existing vetted data are necessary.

We asked SMEs about the critical device components for PCEMs to meet essential user needs. They identified reference materials that allow users to compare results to data previously collected by a validated data source, as a priority component of PCEMs.

Key take-away: To build trust in the community of potential PCEM users, demonstrating how results from wearable devices compare to existing trusted sources will be necessary.

2.2.3. For electronic PCEMs, the device must have specific characteristics.

The other components that our experts tied to improved usability applied to digital platforms. A high-quality dissemitor, paired with processes to produce quantitative data, not limited to threshold levels, was a priority component of digital technology platforms. To be used in the public health space, device batteries need to be rechargeable, small, light-weight, and have a long lifespan. Battery life should aim for five to seven days per charge.

Key take-away: Electronic PCEMs must have specific characteristics, including long lasting battery life and ability to produce quantitative data easily.

2.2.4. Different users have different threshold needs related to the accuracy of wearable devices.

In general, many public health researchers were willing to sacrifice some accuracy of a wearable device for lower cost and the ability to disseminate devices widely. This differs from users interested in commercial deployment and occupational health applications, which require higher levels of accuracy. Twelve subjects discussed the need to provide different user audiences accuracy levels commensurate to their needs. For example, a less accurate, inexpensive, and easily deployable device was preferable to a highly accurate yet expensive and cumbersome device. One respondent from an academic organization provided a succinct explanation about the accuracy needs of different groups this way:

> *"In the public health arena…we want to collect data on large populations. Of course, that has particular requirements, so we need to have something that is scalable, and we may not be concerned about being accurate to a certain decimal... we are more interested in getting samplers out and averaging the error across the population… we are interested in the average to get it right, not one sampler to get it right."*

Conversely, respondents interested in occupational health and commercial applications aimed at specific audiences, such as soldiers or athletes, reported a greater interest in the accuracy of a single device. These populations require a high level of accuracy from the wearable device because the device needs to alert an individual to a risk or hazard in real time. Additionally, high accuracy devices are required for anyone using PCEMs where data may be reported to a regulatory body such as the Occupational Health and Safety Administration (OSHA).

Key take-away: Do not let imperfect device accuracy hinder development and fielding of devices. Populations such as academic health researchers that need devices to be inexpensive and distributable can tolerate slightly less accuracy than those that need devices that can alert workers or

others about a risk. Opportunities exist to develop technology variants that accomplish both on parallel paths.

2.3. What is the market potential for wearables, and what technical and cost barriers need to be addressed before being market ready?

Experts identified many potential uses for PCEMs from the very specific, occupational health and safety applications, to general consumer use similar to activity trackers. Regardless of the application, there are considerable technical barriers to overcome, including developing low-cost analytical techniques and putting detected data in context with other data, such as location and time exposure to turn the data into useful information. Furthermore, regardless of the market application, PCEMs and the information they provide must be in the low hundreds of dollars range per unit to be useful for public health researchers. Each of these topics is further described below.

2.3.1. There are several technical issues with a wearable that need resolution before they can be market ready.

There are several technical barriers that must be overcome before a market for PCEMs is realistic. We heard from experts about the following technical issues.

- **Developing a low-cost process using existing analytical methods to lower the analysis costs.** The analysis necessary to detect a broad array of chemicals cannot likely be done with one process, machine or device. For example, analyzing sampler data requires an expensive and time-consuming laboratory environment for analysis. To overcome this problem, one respondent noted that developing a "crowdsourced" and open source approach to analysis, where multiple labs analyze results from a single device and look for specific compounds, may offer a way to lower the analytical costs. Another respondent suggested a more traditional approach to lowering analytical costs: Negotiating bulk discounts with labs by guaranteeing the labs a certain number of items to analyze.
- **Overcoming the size of instrumentation to make PCEMs useful.** Equipment size is often associated with the accuracy and precision of equipment. The larger the equipment, the more precise and accurate; the smaller it is, the less precise and accurate. Current PCEMs often have limited applications because they identify a limited set of chemicals, and they only provide users an indication they may be exposed to something. These PCEMs can alert users that additional, more expensive analysis, using larger instruments and specifically trained staff to interpret, may be warranted. However, these PCEMs are not useful beyond this rudimentary level and it will be a large technical hurdle to develop a small, yet useful instrument.
- **Linking ancillary data such as exposure time and location to detected chemical data is crucial for PCEMs to be useful in public health.** Analysis of data from a PCEM includes detection of chemicals and the length of time exposed and location of exposure. Understanding what detection of a chemical means as it relates to location and duration of exposure is critical.

- **Devices must be rugged.** To be useful, PCEMs must work in a variety of environments, and survive activities like being dropped to a hard surface and exposure to direct sunlight for prolonged periods of time. While this is a technical hurdle, there is precedent to making rugged devices.

Key take-away: The number and complexity of technical challenges to developing PCEMs is extensive. Supporting research aimed at overcoming these barriers, especially development of open-source and crowd-sourced approaches to analysis, could accelerate development of PCEMs.

2.3.2. To be widely employed, PCEMs must cost in the low hundreds of dollars, particularly if they are to be used in public health research.

Before devices can be widely employed in public health research, the per-unit cost of PCEMs and analysis must be in the low hundreds of dollars. Public health researchers need a device they can provide to large populations and easily replace if lost, damaged, or stolen, without dramatically affecting project budgets. As alluded to above (section 2.2.4), one way to reduce costs for public health researchers is by sacrificing some device accuracy for a less expensive readily deployable device.

Those designing devices for specific populations, such as employees of a specific kind of manufacturing facility or soldiers potentially exposed to hazardous materials, however, might be able to spend more per unit than public health researchers because they don't need to deploy the devices to large populations. However, SMEs still noted that there is a preference for devices to cost hundreds of dollars per unit – not thousands.

Key take-away: The cost per unit of a wearable can differ based on the application but the cost has to be in the low hundreds of dollars range (or less) to be used by public health researchers.

3. Conclusions and Takeaways

Our interviews with SMEs operating at the cutting edge of WMCD research and development makes clear a few overall takeaways:

- To date, little experience exists commercializing PCEMs.
- Most development funding flow from public agencies, and includes purpose-oriented restrictions.
- The connective fibers that produce enabling environments for innovation and diffusion of emerging technologies, such as consortia, trade associations, and standards and testing organization, have yet to form and take root for PCEMs.
- Validation of the veracity of data outputs, and perceptions of data quality overall, are significant barriers to broader uptake of PCEMs, and therefore the current market potential.

Across the three central research questions that this study posed, a cross-cutting finding is that greater clarity is needed around how PCEMs will be used by practitioners across various and unrelated disciplines. To clearly align the priorities of technology development and demonstration, the diverse spectrum of use needs must be categorized, prioritized, and RD&D focus harmonized accordingly. A second cross-cutting finding, which was echoed across all four SME groups, was the extent to which purpose-specific funding negatively impacts the development of broadly applicable PCEMs.

These takeaways and findings are consistent with systemic barriers that are common for emerging technology systems. There are, however, favorable conditions that set the stage for addressing these barriers. The community of PCEM users and developers have established informal networks of working relationships and collaborations. Additionally, SMEs expressed awareness of ancillary applications for PCEMs for in fields such as defense, personal health, and sports that could help to broaden the sources of funding for technology development.

Appendix A. Interview Guides

A.1. Health Expert Interview Guide

We are conducting research on behalf of the Environmental Defense Fund, exploring the state of the art in wearable chemical monitors able to detect diverse array organic compounds, as well as strategies that have been used to help reduce cost and improve accessibility for other technologies used for public health research.

Because of your unique experience, we would like to get your perspective on a number of topics under consideration for further research.

We use the term chemical monitors to mean chemical sensors and chemical samplers. Chemical sensors are technologies (or tools) that identify analytes at the point of detection by transforming chemical information into a signal. Chemical samplers are technologies that collect compounds in a matrix over a certain period of time. Subsequent laboratory analysis is then used to identify the collected compounds.

I would like to record this interview for my note-taking purposes, the recordings will not be released outside of our study team and are for reference only. Do I have your permission? Do you have any questions before we start?

A.1.1. Subject Background

The first portion of the interview will be about your experience with the application of uptake of emerging technologies broadly.

Based on your experience, I'd like to hear how public health or research communities have mobilized to bring promising new technologies or methodologies into use. To get started, I have a few questions about your professional experience

Q1. Please provide a brief overview of your role at your current organization, and any relevant details from previous posts.

[*PROBE ABOUT*] Have you also worked in the private / public sector?

Q2. In your current or prior roles, what experience have you had validating or otherwise demonstrating emerging technologies or methodologies?

A.1.2. Identifying and Resolving Use Barriers

Sometimes new technologies or methodologies are market ready before professionals are aware of them or able to use them. I have a few questions about how you and your colleagues come to be aware of new technologies or methodologies.

Q3. How do you normally become aware of promising new technologies or methodologies?

Q4. At which point do you or your colleagues begin to make an effort to make a new technology or methodology available or accessible to other professionals?

[*PROBE ABOUT*] If not you, do other professionals play this role? If so, who?

Sometimes there are reasons that make it difficult to begin to demonstrate or use new technologies and methodologies. These we call use barriers and they can be technological, economic, professional, or regulatory, such as need for formal approval. I have a couple questions about your experience with use barriers.

Q5. Whether or not you were involved, can you recall any times that experts in your field needed to actively address barriers to using a new technology or methodology? Yes/No - Please explain.

- If yes, what factors made up the barrier(s) – financial, technological, regulatory?

Q6. How have you seen different groups of public health professionals brought together to accelerate the usability of new technologies or methodologies?

[*PROBE IF NOT ADDRESSED*] Which professionals are often early movers in taking action to resolve use barriers?

Do you recall any individuals or organizations who were especially effective at capturing the attention of colleagues?

Q7. How were other professionals identified that could improve the effectiveness of these acceleration efforts?

- How were they engaged?
- Were any consortia or outside organizations involved?

[*If YES, PROBE*]

- At what stage did they become involved?
- What was their role? Were they effective?

Q8. Apart from what you've already told me, what strategies can be effective for reducing use barriers?

Q9. Some strategies are probably more effective for some barriers than others. What strategies are most effective for addressing use barriers stemming from professional or regulatory standards?

- • What are most effective for addressing economic use barriers?
- • What are most effective for addressing technologies use barriers?

A.1.3. Wearable Chemical Monitoring Devices

I'd now like to discuss wearable chemical samplers and sensors. The Environmental Defense Fund's Year of Innovation Program is exploring opportunities to make wearable chemical monitoring devices cheaper and increase their functionality. We would like your input on a few related topics.

Q10. Sampling is important to the study of human exposure to a range of chemicals, and wearable samplers and sensors increasingly play a role in environmental health research. In your experience, what sampling capabilities are most important?

Q11. What are the common ways that wearable chemical monitors are used for assessing human chemical exposure?

[*PROBE IF NOT ADDRESSED*] How do researchers in different research areas differ in how they use wearable chemical monitors?

Q12. In your area of research, how would you use or how else might you use a wearable chemical monitor?

[*PROBE IF NOT ADDRESSED*] What capabilities would it have to have for you to begin using?

What price point or range would a device need to meet before you could begin integrating it into your work?

What type of study design would make use of a wearable chemical monitor most valuable, in a best-case scenario?

[Potential follow up: What is the minimum subject cohort size that would be necessary to make use of a wearable chemical monitor?]

Wearable samplers and sensors have been used for many years across the public health field. I'd like to hear your thoughts about the technological potential they hold.

Q13. For any wearable chemical monitor capabilities that lack broad uptake, to what extent is this a consequence of lacking technological capacity?

[*PROBE IF NOT ADDRESSED*]

- To what extent is it due to lack of demonstration or validation?
- To what extent is it due to lack of professional or regulatory approval?
- To what extent is it due to the cost of integrating a wearable chemical monitor into the study design?
- To what extent is it due to data quality issues?

Q14. I'm going to read a list of a few aspects of wearable monitors. For each aspect, please tell me if you have observed challenges to successfully using a wearable monitor: [If NEEDED: In your research, or a colleague's research.]

- Collecting samples
- Developing data from samples
- In the context of sensors, transferring data from the wearable device to a data storage host

Q15. Once samples are collected by wearable monitors, the data must be transformed into a meaningful, usable dataset. For simplicity, we term all the related capabilities as "back-end" functionality. In your experience, what back end functionalities are most important?

[*PROBE IF NOT ADDRESSED*]

- In what ways could back-end functionality be improved?
- Would tracking of time-activity-exposure improve?

Q16. I'm going to read a list of data processing aspects of back end functionality. For each aspect, please tell me if you have observed challenges to successfully using wearable monitors: [If NEEDED: In your research, or a colleague's research.]

- The mechanism for exporting data from the device into a computational format
- The quality of initial data
- The format of initial data
- The ease of identifying the data of interest
- The ease of identifying the completeness of data

Q17. Wearable chemical monitors have been used in fields other than public health. Are you aware of any non-public heath fields using wearable chemical monitors in a manner that could be repurposed for public health research? If yes, what are those fields and how are they using the monitors?

Q18. Do you know of any monitor capabilities in development for other fields that, if made operable, could also be used in the study of chemical exposure?

Q19. Do you know of anyone else we should speak with on this topic? Would you be willing to make an introduction?

EDF will be hosting a workshop in late summer or early fall to delve into these issues further. The team at EDF may reach out to you in the coming weeks with an invitation to participate.

A.2. Technology Producer Interview Guide

We are conducting research on behalf of the Environmental Defense Fund, exploring the state of the art in wearable chemical monitors able to detect diverse array organic compounds, as well as strategies that have been used to help reduce cost and improve accessibility for other technologies used for public health research.

Because of your unique experience, we would like to get your perspective on a number of topics under consideration for further research.

We use the term chemical monitors to mean chemical sensors and chemical samplers. Chemical sensors are technologies (or tools) that identify analytes at the point of detection by transforming chemical information into a signal. Chemical samplers are technologies that collect compounds in a matrix over a certain period of time. Subsequent laboratory analysis is then used to identify the collected compounds.

I would like to record this interview for my note-taking purposes, the recordings will not be released outside of our study team and are for reference only. Do I have your permission? Do you have any questions before we start?

A.2.1. Subject Background

The first portion of the interview will be about your experience with the application of uptake of emerging technologies broadly.

I'd like to hear about your experience with innovative technologies. To get started, I have a few questions about your professional experience.

Q1. Please provide a brief overview of your role at your current organization, and any relevant details from previous posts.

[*PROBE ABOUT*] Have you also worked in the private / public sector?

Q2. In your current or prior roles, what experience have you had introducing or demonstrating emerging technologies?

A.2.2. Technology Bottlenecks

Sometimes new technologies are market ready before professionals are aware of them or able to use them. I have a few questions about your experience taking to market wearable devices and other innovative technology.

Q3. Have you been involved in, or privy to, a go-to-market strategy for technologies to be used, at least in part, for public health research?

Q4. Have you been involved in, or privy to, a go-to-market strategy for wearable devices?

Q5. Please describe any barriers to customer uptake that you encountered?

Q6. Which barriers to customer uptake were most challenging to resolve? [If NEEDED: Were any challenges unresolvable?]

In the public health setting, numerous factors can affect costs and play a role in helping or hindering acceptance and use of promising new technologies. These cost factors may include regulatory hurdles, demonstration of bankability, manufacturing and tooling, cleaning data or performing analysis, or handling samples. I now have a few questions about factors that might have hindered your progress when developing a technology or getting it to market.

Q7. Considering all the barriers to customer uptake that you've encountered, what cost factors helped or hindered the go-to-market strategy?

[*PROBE ABOUT*] Was manufacturing or tooling an issue?

Q8. Did uncertainty about how accepting or trusting users would be of the product's data play a role?

Q9. Did any factors that slowed down the go-to-market strategy reduce or slow the amount of internal development capital invested in the product?

[If subject is from Tech Developer cohort, proceed to Q10; from Process Expert cohort, skip to Q23]

A.2.3. Wearable Chemical Monitoring Device User Needs

We are investigating the opportunities and barriers to advancing wearable chemical monitors for the study of human exposure to chemicals. The remainder of our conversation will focus on wearable chemical monitors, include sensing and sampling devices.

Q10. Wearable chemical monitors have been used in fields other than public health. Are you aware of any non-public heath fields using wearable chemical monitors in a manner that could be repurposed for public health research? [If YES, what are those fields and how are they using the monitors?

Q11. Do you know of any monitor capabilities in development for other fields that, if made operable, could also be used in the study of chemical exposure?

A.2.4. Wearable Chemical Monitoring Device Market and Technology Potential

Our current understanding is that wearable chemical monitoring devices are usually made up of various component technologies from separate original equipment manufacturers (OEMs), combined to provide monitoring, and in some cases data analysis and management functions. I now have a few questions about the current and potential product features of wearable chemical monitors.

Q12. What are the key components of chemical monitoring devices that monitor individual chemical exposure?

Q13. What device functions correspond to each technical component?

Q14. Based on your understanding of wearable chemical monitors, what current applied research uses are you aware of?

Q15. Based on your understanding of wearable chemical monitors, what potential applied research uses do you think are promising?

[*PROBE ABOUT*] Are the limitations for introducing potential research uses technical in nature? [IF NO] Are they professional? Regulatory? Cost? Access? Awareness of capabilities?

Q16. What technology improvements are needed to expand the available research applications of wearable chemical monitors?

[*PROBE ABOUT*] What type of development activities are needed to carry out the improvements?

Q17. Are there opportunities to broaden geospatial tracking capabilities?

Q18. Are there opportunities to broaden the ability of chemical monitors to detect multiple classes of chemicals, in a non-targeted fashion?

Q19. Where do potential features lie on a spectrum from most to least market ready?

Q20. Whether for public health research or other uses, to the best of your knowledge how have investors responded to wearable "monitored self" business concepts?

[*PROBE ABOUT*] What end users do you feel are of greatest interest to investors?

Q21. What wearable device applications have received the most investment?

Q22. Do you know of anyone else we should speak with on this topic? Would you be willing to make an introduction?

We are investigating the opportunities and barriers to advancing wearable chemical monitors for the study of human exposure to chemicals. The remainder of our conversation will focus on the cost and quality factors that affect sensing and sampling technologies, that could also apply to wearable chemical monitors.

Q23. What approaches do you use to process and analyze samples in your work?

Q24. What aspects of processing and analysis drive costs?

Q25. In your experience, what has helped you to minimize the cost of this analysis?

Q26. What do see as the tradeoffs between cost and quality of post-collection analysis?

Q27. What do you see as the barriers to further reductions in cost?

Q28. What do you see as the barriers to further improvements in quality of analysis?

Q29. Do you know of anyone else we should speak with on this topic? Would you be willing to make an introduction?

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