Summary of EDF Workshop, "Understanding Chemical Exposure, Accelerating the Market for Wearable Monitors"

Prepared by Research Into Action

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Executive Summary

Chemicals are used to make 96% of products in the United States, from couches and carpets to the clothes we wear. While chemicals are a critical part of our economy, they are also released into our environment—and end up in our food, water and air—which can result in harmful exposures. Although some promising tools exist to measure individuals' chemical exposures, technological limitations and expense have limited widespread adoption.

On October 26th and 27th 2017, Environmental Defense Fund (EDF) convened a workshop of public health, engineering, entrepreneur, and policy experts to explore opportunities to enable the development and use of lower-cost, portable or wearable personal chemical exposure monitors (PCEMs). The motivation behind this workshop was to accelerate the development of technologies that can ultimately generate increasing amounts of individual exposure information across large segments of the population over time. This data can subsequently inform scientists, occupational health professionals, and the public about chemical exposure and, if needed, help people take corrective actions.

The objectives of this workshop were as follows.

1. Identify key challenges and opportunities in developing and scaling (PCEMs);
2. Identify lessons that can be applied from VOC monitors to the broader PCEM market;
3. Develop a shared understanding of strategies to drive development and adoption of PCEM technologies; and
4. Activate a diverse network of players to jointly identify priority areas for action.

The topical scope of the workshop emerged largely out of insights from the research reported in the PCEM analysis brief. The workshops covered seven key topics:

1. Assessing what users want from new technologies?
2. Current and upcoming technologies.
3. Recent developments and opportunities for improving VOC monitoring devices
4. Lessons from different fields that can be applied to PCEM development
5. Acquiring funding for PCEMs

6. Validating and ensuring quality of devices.
7. Ideas for short, medium, and long-term strategies to drive PCEM development.

Certain themes emerged over the two days of the workshop. They are:

- Participants fell into four groups sometimes falling into more than one group. Participants expressed interest in 1) Technical RD&D advancements, 2) Identifying funding strategies to drive PCEM development, 3) Identifying and initiating health research in the near term using PCEMs, and 4) Developing community collaboration and engagement strategies to share PCEM developments.
- There are many potential sources of demand for PCEMs from researchers and professionals to the public.
- PCEMs straddle the environmental technology field and the public health fields. Depending on which field they become aligned with may affect how they are perceived and how long they will take to develop.
- PCEM specifications need to be made available so users with different needs can judge for themselves the appropriate use of the device and be able to compare device results with other technologies.
- It will be important to be creative when seeking funding for PCEM development. Developers will need to leverage all funding sources and do things like use crowdfunding to demonstrate market interest in PCEMs.
- Communicating the results from a PCEM will require care and consideration. Communicating the results of PCEMS and the risks associated with exposure to detected chemicals will require careful attention by those developing PCEMs and those first groups of users so as not to cause unwarranted panic or concern.
- Developing a single device usable by many types of people will take a series of incremental steps starting with devices that detect small numbers of chemicals for specific purposes.

Across all topic areas, the workshop led to two key overarching considerations regarding the development of PCEMs.

1. The development of a PCEM that is inexpensive, wearable, applicable to many user-types, and provides actionable data is likely many years away. However, there are incremental steps that can be taken in the near-term that can serve some specific audiences that will in-turn help to accelerate the development of these devices.
2. Identifying some key audiences and supporting the development of devices serving those key groups will likely lead to improvements in instrumentation and data analysis. Establishing consortia of stakeholders to develop instrument validation, share ideas across the PCEM space, and identify potential user groups of PCEMs are one key way to accelerate the development of PCEMs.

A review of the results of this workshop and the PCEM analysis brief prepared in the summer of 2017 will contribute to a program design memo in December 2017 providing direction to EDF with a few key ways they can facilitate PCEM development.

Cross-Cutting Themes

Across all parts of the workshop, there were certain topics and themes that appeared particularly relevant to participants. The research brief covered some of these topics and themes and some topics and themes emerged or were further emphasized during the workshop discussions. The list below covers the themes and topics that appeared particularly salient to participants.

- **Participant Interests:** Workshop participants' interest in PCEMs could be categorized into four areas, acknowledging that participants can be interested in one or more of these areas. Specifically, there was interest in 1) Technical RD&D advancements, 2) Identifying funding strategies to drive PCEM development, 3) Identifying and initiating health research in the near term using PCEMs, and 4) Developing community collaboration and engagement strategies to share PCEM developments.
- **Sources of Demand:** There was extensive discussion about who are potential sources of demand for PCEMs. For example, occupational health experts are interested in PCEMs for monitoring the health of workers in environments from offices, to clean rooms, to warehouses, and industrial facilities. Safety and security experts are interested in PCEMs for immediate dangers like detecting explosives and providing firefighters with information about when they are being exposed to something when fighting fires. Public health researchers are interested in understanding children's exposure to flame retardants, and biker's exposure to diesel particulate. Citizen scientists and the public may be interested to know about their exposure to specific hazards, for example, particulates in the air due to wildfires.
- **Funding and Development Pathways:** There is an unresolved tension between whether chemical monitoring is an environmental technology appropriate for clean tech or energy commercialization pathways, which usually require a 6-24 month payback, or a health/medical device technology, which typically involves a longer time-period for product development, with valuation at exit that assumes market advantages conferred by FDA approval.
- **User Needs:** Different users will have different needs and different standards for PCEMs based on their intended application. Therefore, a universal standard for PCEMs is unrealistic and unnecessary. However, PCEM specifications need to be made available so users can judge for themselves the appropriate use of the device and be able to compare device results with other technologies.
- **Funding Opportunities:** Participants generated a list of many different funding sources. These included crowd-funding, pre-buying agreements, lending libraries, challenge programs, prizes, traditional grant awards from government, and venture capital. Furthermore, participants spoke about the need to leverage funding methods into additional funds. For example, crowdfunding can demonstrate interest in demand for a product which in turn can be used to access funds from a venture capital firm.

- **Risk Communication:** Communicating the results of PCEMS and the risks associated with exposure to detected chemicals will require careful attention by those developing PCEMs and those first groups of users. This is particularly important when there is no existing evidence-based recommendation to reduce personal exposure to the identified chemical(s).

- **Near Term Goals:** Incremental and evolutionary development of PCEMs can and should happen before the development of a single device that satisfies multiple stakeholders. It will be important to have "early wins" where, for example, a device is used to meet an immediate need and to drive interest in further development. The group emphasized the need to not let the perfect be the enemy of the good.

Meeting Summary by Session Topic

S1. What do users want from new technologies?

Different users may require different functionality from personal chemical exposure monitors (PCEM). This session addressed two questions: What key functions do users need? Where is there broad overlap between functions needed by various users? A summary of responses to these questions are provided here.

What key functions do users need?

Users noted several functions they will need from PCEMs including the ability to have data about individuals' exposure and the ability to aggregate data to the population. A key function of PCEMs noted by multiple participants will be ensuring that the context in which a PCEM is being used is attached to the chemical sensing capabilities of the device. Logging characteristics like temperature and humidity will be critical to validation of the device and location will be critical to understanding possible sources of exposure.

One strategy for understanding the context in which PCEMs are used would be to integrate the devices into other products. For example, a sensor in a grocery cart could measure exposure to specific chemicals for employees and customers. In this case, the location would be understood by the application of the sensor, a grocery store. Similarly, a sensor in a car seat may help parents understand their child's exposure and the context of the device use is immediately understood.

Where is there broad overlap between functions needed by various users?

Understanding the context in which a device is used applies to all potential users of a PCEMs. Public health researchers, occupational safety professionals, and consumers will all need to know the context in which a device is used in order to accurately analyze the data and take action based on the results.

S2. Exploring the horizon: Current and upcoming technologies.

This exercise was designed to address the following questions: What specific new devices are on the horizon? What are their cost drivers? As noted in Appendix 1, this session did not directly address the cost drivers question but did result in three examples of devices that could be developed in the relatively near term using.

The session moderator divided the participants into three groups and asked each group to develop a pitch to a venture capital group promoting a PCEM approach. Each group had to identify a specific problem a PCEM could address in the near term and demonstrate how their device could address the problem.

What specific new devices are on the horizon?

The three groups of participants each identified one product that appeared to be developable in the near term. The items were: a formaldehyde sensor for indoor use, a filter and sensor system to detect lead in drinking water, and a particulate matter (PM2.5) sensor for outdoor use. A brief description of each device and possible uses is described in the named sections below.

This exercise ultimately led to a discussion about the importance of identifying a specific market for a device. Each participant group chose to develop a device that measured things people are largely already aware of as harmful. Detecting particulate matter from wildfires, formaldehyde in consumer products, and lead in water are all topics covered widely in the popular media. Each group appeared to use that general knowledge of harm to generate interest in a device.

Additionally, there were specific groups within the public that may have interest in the devices discussed. Recreational runners and athletes may have a specific interest in particulate matter in the air, pregnant mothers may be particularly concerned about their exposure to formaldehyde, and private well owners may have an interest to know if there is lead in their water.

Formaldehyde sensor

This group presented the need to develop a sensor to monitor exposure to formaldehyde in consumer goods such as furniture and carpeting. Formaldehyde is a major issue and it is something many people have heard of is a problem. For example, the trailers used to house people after Hurricane Katrina had high levels of formaldehyde which resulted in health consequences for those people.[1] These sensors could be placed in offices, homes, and other occupied spaces to detect formaldehyde over time and help people limit their exposure to this carcinogen. Property managers and households with concerns about exposure (e.g. – pregnant mothers, people with other health conditions) may have interest in such a sensor.

[1] Katrina, Rita Victims get $42.6M in toxic FEMA Trailer Suit. https://www.cbsnews.com/news/katrina-rita-victims-get-426m-in-toxic-fema-trailer-suit/ , September 28, 2012 (Accessed on 11/28/17).

Water filter and sensor

This group suggested partnering with a filter manufacturer such as Brita to offer a service where people could have their water tested by sending filters to a lab for analysis. The market for this would be households using wells, where drinking water regulations do not apply like they do for public water systems, and people concerned about their water quality.

Particulate Matter (PM2.5) sensor

The group presented the need for a device that will inform the public, specifically runners, walkers, and those that spend time outside, about localized air quality information. This device would attach to a smartphone and detect harmful levels of PM2.5 and communicate that to the user through an app. This data would be aggregated with those of other users and displayed on a website to show PM2.5 levels across a region. Public health professionals could use this data to inform the broader public about air quality concerns across a region.

Lunch Discussion on Market Demand

This session brought together panelists with experience in either developing or utilizing emerging technologies in personal chemical exposure monitoring and the broader monitored-self space in a discussion about catalyzing a new market.

Participants mentioned many possible customers and users of PCEMs based on their experience as researchers, occupational health advocates, and developers. The list of users included the following and are in no particular order

- Property managers, housing authorities, and aid agencies such interested in knowing their tenant’s exposure
- Military personnel interested in keeping soldiers away from acute dangers like explosives.
- Security personnel interested in finding things like ingredients used to make explosives.
- Industrial hygienists interested in protecting products from exposure to certain particulates.
- Consumers interested in knowing their exposure to chemicals in their home.
- Companies interested in monetizing the data that can be gleaned from broad PCEM use.
- Patients of diseases interested in understanding if their disease was a result of exposure.
- Vulnerable populations that may have a particular risk associated with exposure (E.g. pregnant women)

Ideally, a device or devices would serve all these users because as one participant noted, the goal is not to create a device for one company that can afford a device, but to create a broad market for devices and to use that data to make better decisions about individuals exposure to potential harm. To achieve that end, incremental advancements will be necessary.

S3. VOC Monitors: Recent development and opportunities for improvements

There are several distinct categories of VOC monitors, broadly including samplers and sensors. This session discussed the existing value chain for VOC monitors and discussed ways of communicating the value of devices? The question "Are there key 'value-chain' lessons learned that could be applied to advance other personal chemical exposure monitors?" was not directly addressed and this unanswered question is listed in Appendix 1.

What specific aspects of the value chain present the lowest hanging opportunities for VOC monitors?

There are opportunities and interest in using lower cost and less accurate VOC monitors as a first step in understanding exposure. This interest is particularly prevalent among public health researchers and occupational health professionals. Lower cost and less accurate monitors could be deployed, and thresholds developed to trigger more detailed, sophisticated, and costly VOC monitor deployment to investigate specific areas. Taking this approach could lead to new uses of VOC monitors which in turn could lead to new markets.

The workshop also discussed describing the value of more sophisticated monitors in new ways that motivated interest and action. For example, rather than emphasizing the purchase price, a proponent of VOC monitoring at a school could describe the value as protecting the health of the students for under $5 a year.

S4. PCEMS: Lessons from different fields

Within research disciplines but outside of the public health system, essential know-how and resources for developing PCEMs exist. This session explored ways in which technological and process innovations within other disciplines can support PCEM development. Participants addressed the following questions: What were the successes and challenges from the advent of other monitored-self technologies? What key lessons learn can be applied to the PCEM space?

This session focused on how the intelligence community, specifically IARPA (the Intelligence Advanced Research Projects Activity) worked to develop PCEMs and related technologies and what lessons can be learned from their experience developing difficult to develop instrumentation. As a result of the discussion, participants shared their knowledge of developing instrumentation and methods from other fields.

What were the successes and challenges from the advent of the environmental monitoring and monitored-self technologies?

Intelligence agencies have traditionally been interested in developing devices with specific end-uses in mind. These successes can sometimes lead to an expansion of end uses. For example, the development of facial recognition software, which was developed for the intelligence community, now resides in the latest generation of consumer electronics. Similarly, the 23 and Me products started as a tool for researchers that emerged into a consumer-based product that now feeds back to researchers in the form of a massive dataset about the human genome. Broader interests in PCEMs may evolve from more narrow and specific applications.

One challenge faced in developing new devices is getting the intended audience to use the device because of practical considerations. For example, adding two pounds to a soldier's heavy backpack may be met with resistance by those soldiers, particularly if the device is ancillary to their core mission and the device is unproven in the field.

What key lessons learned can be applied to PCEM space?

Taking risk in developing technologies is a key to success. IARPA exists to take risks and develop technologies other intelligence agencies failed to create. IAPRA is "graded" not on how often they succeed, but on how often they fail. If more than 20% of ideas that come to IARPA result in successful projects, they are not taking enough risk to fulfill their mission. While the intelligence community has significant budgets to develop tools – something that public health and environmental researchers often do not have –the key lesson to take from IARPA is the importance of taking risks in technology development. It is those risks and trying multiple ways to achieve a goal that eventually lead to successful technologies. Developing a civilian version of the IARPA effort, something akin the ARPA-E efforts, could be the foundation of an effort to enhance the capability of those in this space to take risks.

One way to diffuse the risk away from any one organization, a problem IARPA does not have, is to issue challenges to labs, universities, and others asking for their ideas about how to develop devices. With a challenge, you may unearth new ideas or creative methods to solve a problem and an organization can do this with limited risk to their budgets or reputation.

S5. Funding: Thinking creatively about funding strategies

The funding to develop PCEMs is often part of larger, purpose-specific funding. This can lead to inadequate funding for development, testing, and validation. This session addressed two questions: Which aspects of the PCEM critical technology path are most likely to need funding support outside the current system? What opportunities exist to make underfunded development activities more appealing to the PCEM funders? A summary of responses to these questions are provided here.

Which aspects of the PCEM critical technology path are most likely to need funding support outside the current system?

Workshop participants noted several aspects of developing PCEMs that will require specific support from those trying to accelerate the development of these devices. They are as follows.

- Organize demand side of PCEMs by assisting developers of specific chemical sensors, not just those developing multi-chemical-sensitive devices. The development of multiplex PCEMs will likely be evolutionary starting with a few key chemicals and grow from there. Assist those developing specific chemical sensors identify end-user markets. For example, parents undergoing in-vitro fertilization (IVF) treatments may want to take every precaution possible to ensure a successful pregnancy and would be willing to pay for monitoring devices.

- Develop consortiums of those interested in developing PCEMs to share technological ideas and paths to market devices. Create infrastructure and networks among developers, researchers, and technicians interested in developing devices by doing things like sponsoring conferences and workshops that bring together various stakeholders.
- Help researchers and developers interested in using large federal grants to fund development activities "decode solicitations" to improve chances of being funded. Some federal solicitations require skilled and experienced grant writers to be successful in obtaining funds and those writers need to know the language and "code" the federal funders often use.
- Pitch any federal grants for PCEM development as a tool for monitoring health or improving the safety of people like first responders. Devices used for environmental science applications are less likely to be funded in the current political and social environment.

What opportunities exist to make underfunded development activities more appealing to the PCEM funders?

Participants identified several opportunities to make PCEM development attractive to funders and investors. These ideas coalesced around defining a market for devices and limiting their risk.

- Define key markets in the near term.
    - Two groups identified as possible markets were firefighters and pregnant women. Firefighters may be interested in their exposure to specific chemicals at different stages of fighting a fire, which could inform what protective equipment to wear and when they should wear it. Pregnant women may be particularly concerned about their exposure to specific known chemicals that could affect the development of their child.
    - To overcome the high cost of PCEM devices which could limit the market size for a device, consider developing device sharing platforms. For example, researchers could borrow expensive devices instead of purchasing the device. Sharing the device results in a lower cost per transaction making the device more affordable for the user but still supporting the high cost of the device.
    - Targeting specific chemical sensor development in the near term could lead to the development of broader chemical sensor technologies that would appeal to a wider audience.
- Limit the risk associated with funding PCEMs sensors.
    - Diffuse risk of supporting PCEM development by using multiple funders so that one funder is not disproportionally risking their investment. Strategies to do this include using a sponsor such as EDF to support crowdfunding, which in turn can demonstrate broad interest in device development to additional funders.
    - Make the intellectual property rights clear to investors and provide investors some stake in the intellectual property rights to generate interest. Some universities require they keep all intellectual property while others share intellectual property. Investors will likely want a stake in the intellectual property of the device.

S6. Validation: Ensuring quality in the promise of new technologies

The pace of studies to validate PCEM integrity, processes, and data is very slow, due to lack of funding, and impedes development and updates of promising new technologies. This session explored the opportunity to programmatically call for and fund validation studies in coordination with researchers and key organizations in the PCEM ecosystem.

What approaches to validation are most convincing?

Validation requires multiple studies, and ideally involves stakeholders in the validation study design. It is important that stakeholders such as public researchers understand the strengths and weaknesses of the device and understand how the device was validated. This can help inform users about the appropriate applications of the device.

To adequately test and ensure effectiveness, validation must include a series of studies testing a device for different thresholds. Devices will have different applications and different applications will have different tolerances for error and accuracy. Therefore, it is important to develop specifications for the different applications and understand the performance characteristics. Validation should start with lab testing, but also include field tests, keeping the various stakeholders abreast of the results of the validation efforts throughout the process.

What opportunities exist to systematically call for and fund validation studies in coordination with researchers and key organizations in the PCEM ecosystem? What is the role of standards here?

EDF or other organizations could issue challenges to researchers in academia and industry to develop validation studies for PCEM devices. An organization such as NIST could assist with reviewing the validation systems and help develop a standard that all instruments must meet. Developing a common language for sensors to share data across platforms could be one best practice to use during development. One recent example of how this was done was the NFL and Under Armour's work with NIST on the development of a new football helmet designed to limit concussions. NIST created a test bed for the NFL and Under Armour's challenge to developers to create a helmet that could mitigate concussions. NIST became the independent third party that tested the products and prepared the standardized result.

S7. Short, medium, and long-term strategies and programmatic ideas: Overview, discussion, and prioritization

Historically, in a few cases, agencies have organized programs that create and sustain linkages between various public health researchers, technology developers, and end users. This session sought to explore strategies and programmatic ideas where EDF and other stakeholders could make a contribution to the advancement of PCEMs

Workshop participants identified eleven strategies throughout the workshop and in this session narrowed the list of strategies down to two key strategies EDF could pursue. They are:

1. **Organize demand for PCEMs.** Target possible user groups for devices to show how these devices can serve their interests. Two examples of end-users noted by participants were pregnant mothers and first responders.
2. **Establish test methods that will serve the demand being targeted.** Work with researchers, end-users, and agencies to develop methods to validate devices for the specific group being targeted. This could include bringing together stakeholders, both researchers and technicians, at conferences to determine the appropriate test methods.

Conclusion

As noted in the beginning of this memo, prior to the workshop, the EDF and Research Into Action teams identified eight key questions they wanted answered by the workshop. Table 1 provides a brief summary of how each of those questions were addressed by workshop attendees.

Table 1: Eight Key Questions and How Workshop Addressed Summary

EIGHT KEY QUESTIONS	Summary of How They were Addressed
1. What is the existing landscape/ are most promising technologies?	• Develop sensors that detect limited number of chemicals and expand from the development of those devices into multiplex devices
2. What are the technical capabilities and constraints of tools, inclusive of both the wearable monitors as well as analytical instruments, for non-targeted analysis of individual chemical exposures? What are near term opportunities for improvement?	• Tools exist to detect small numbers of chemicals. Developing methods to make these devices wearable.
3. What are the current, most pressing barriers and challenges to achieving the vision? How can they be overcome?	• Acquiring funds is a key and persistent barrier. Creatively supporting funding efforts through efforts like crowdfunding and building credibility around research through sponsorship of promising technologies are two ways to achieve the vision.
4. What would it take for researchers to utilize a given chemical exposure monitoring tool in their research? (e.g., cost considerations, functionality)	• Ability to compare results to existing already proven technologies. • Low cost per unit of measurement. • A device that includes the context in which it is operating so characteristics like location, temperature, and humidity are understood in addition to exposure to chemicals.
5. For any chemical monitoring technology, what are the major cost drivers at each step along the supply chain (e.g., manufacture, analysis, distribution), and how might EDF engage to reduce costs?	• This question was not addressed.

6. What are promising opportunities for technological innovation and/or process improvement that would 1) improve the quality/capability of chemical exposure monitors, and/or 2) increase uptake and commercial distribution of technologies?	• Continuing to bring stakeholders from various disciplines together to share ideas and innovations will be critical. • Supporting the validation of instrumentation will be critical to getting a broad spectrum of users to value and use devices.
7. What is the role of an organization like EDF in this space?	• EDF can facilitate the development of consortiums of technical and financial stakeholders in the PCEM space. • EDF can issues challenges to developers and researchers to design instrumentation and methods.
8. What is the role of workshop participants – from public health researchers to technology innovators – to advancing the field of wearable chemical exposure monitors?	• Continue to participate in consortium efforts to push for the development of devices, the validation of devices, and the funding of devices. • Continue to share their expertise in the development of these devices with their colleagues and look for ways to use devices in existing research.

Distilling these eight questions into information that EDF can act upon leads us to the following understanding of where EDF is in terms of supporting PCEM development.

How close is EDF to our vision?

The development of a PCEM that is inexpensive, wearable, applicable to many user-types, and provides actionable data is likely many years away. However, there are incremental steps that can be taken in the near-term that can serve some specific audiences that will in-turn help to accelerate the development of these devices.

What can EDF do in the near-term to get us closer to the vision?

Identifying some key audiences and supporting the development of devices serving those key groups will likely lead to improvements in instrumentation and data analysis. Establishing consortia of stakeholders to develop instrument validation, share ideas across the PCEM space, and identify potential user groups of PCEMs are one key way to accelerate the development of PCEMs. Furthermore, the program design memo being prepared in late 2017 will provide additional suggestions for ways EDF can accelerate the development of PCEMs.

Appendix 1: Discussion questions not addressed during sessions

Session	Discussion question
S2. Emerging Technologies: How to understand new technologies?	What are their cost drivers?
S3. VOC Monitors: Recent development and opportunities for improvements	Are there key "value-chain" lessons learned that could be applied to advance other personal chemical exposure monitors?