SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

PATIENT ENGAGEMENT ADVISORY COMMITTEE

October 22, 2020

Via Video Conference

Attendees:

Chairperson

Paul T. Conway
Chair, Policy and Global Affairs
American Association of Kidney Patients

Committee Members

Cynthia L. Chauhan, M.S.W.
Patient Advocacy

Bennet R. Dunlap, M.S.
Health Communication Consultant
Diabetes Patient Advocacy

Amye L. Leong, M.B.A.
Healthy Motivation
Patient Engagement in Care & Translational Research

Monica Parker, M.D.
Emory Alzheimer's Disease Research Center
Emory University

Rita Roy, M.D.
Partner, HealthComm Associates

Mary (Suzanne) Schrandt, J.D.
Founder, CEO & Chief Patient Advocate, ExPPect
Senior Patient Engagement Advisor, Society to Improve Diagnosis in Medicine

Temporary Non-Voting Member

Stephen B. Wilcox, Ph.D., FIDSA
Principal and Founder, Design Science

Industry Representative

Diane M. Johnson
North American Regulatory Affairs, Policy, Medical Devices, Digital Health Policy Lead
Johnson & Johnson

Consumer Representative

Katherine D. Seelman, Ph.D., Professor Emerita (Retired)
School of Health & Rehabilitation Sciences
University of Pittsburgh

Consultant

Philip Rutherford, Director of Operation
Faces & Voices Recovery

Food and Drug Administration

Michelle Tarver, M.D., Ph.D., Director
Patient Science and Engagement Program

Bakul Patel, M.S.E.E., M.B.A., Director
Digital Health Center of Excellence

Letise Williams, Designated Federal Official

CALL TO ORDER

Panel Chairperson Paul T. Conway called the meeting to order at 10:00 a.m. He noted the presence of a quorum and affirmed that the Committee members had received training in FDA device law and regulations. He gave a brief overview of the Committee's history and highlighted outcomes of its recommendations to date. He announced that the Committee would be discussing and making recommendations on artificial intelligence and machine learning in medical devices.

He then asked the Committee members and the FDA staff to introduce themselves.

CONFLICT OF INTEREST STATEMENT

Letise Williams, Designated Federal Officer, read the Conflict of Interest statement and reported that no conflict of interest waivers had been issued.

She introduced Diane Johnson as the Industry Representative.

GENERAL ANNOUNCEMENTS

Ms. Williams then made general announcements to the public regarding speaker identification, transcripts, and breakout session procedures.

She introduced Nicole Mueller as the FDA press contact.

WELCOME AND OPENING REMARKS

Jeffrey Shuren, M.D., J.D., provided updates on work that is being done at CDRH with respect to patient science and engagement, COVID-19 efforts, and outcomes from previous panel meetings. He apprised the Committee of recent endeavors in the area of digital health technology and artificial intelligence, including a boot camp for small businesses and digital health companies, and collaborative efforts involving patients. He also announced the initiation of the Digital Health Center of Excellence and provided information about upcoming meetings focusing on the safety of medical devices and patient engagement.

PRESENTATIONS

Artificial Intelligence - Machine Learning Validation

Bakul Patel, M.S.E.E., M.B.A., highlighted the possibilities and opportunities of AI/ML. He noted that artificial intelligence can address unmet clinical demand, provide easier access to information, and transform the delivery of healthcare. He related that AI/ML-based medical devices provide earlier disease detection, produce more accurate diagnoses, and generate fresh insights into human physiology. He then presented a proposed total product lifecycle approach that is expected to leverage transparency and provide a level of trust to users, and goals for a regulatory framework that is anticipated to provide enhanced access to high quality digital medical devices and facilitate rapid improvement of software

products.

Artificial Intelligence - Machine Learning Communication

Pat Baird, Head of Global Software Standards at Philips, discussed the potential impact and challenges of AI in healthcare. He highlighted the need to become more familiar with patients in order to help support them and to better understand potentially confounding factors that drive some of the trends in collected data. He then discussed the topics of bias and trustworthiness. He suggested that classification of bias types will help in the identification of potential distortions during product development. He noted that AI has the ability to improve healthcare in many ways, that one of the challenges will be turning data into knowledge, and that all stakeholders need to be engaged.

Representation of Diverse Groups in Test Sets

Captain Terri Cornelison, M.D., Ph.D., FACOG, discussed the importance of diverse representation in test sets. She stated that AI/ML devices may be learning a narrow perspective if training compilations do not represent a diverse set of patients. She informed the Committee that most algorithm designs ignore sex, gender, age, race, and ethnicity dimensions and their contributions to health and disease differences. She noted that these attributes affect behavior and perception, as well as health, and create significant sources of variation in a number of clinical conditions. She then discussed global patterns of gene expression and the impact of experimental design, emphasizing the importance of including all populations in clinical trials and datasets. She concluded that AI/ML statistical methods provide exceptional opportunities for improving the efficiency and efficacy of health care delivery, and underscored the significance of ensuring that diverse patient demographics are adequately represented in AI algorithms.

Cognitive Human Factors

Kimberly Kontson, Ph.D., discussed the advantages of incorporating human factors principles into medical device design and development. She explained how the perception/cognition/action model is utilized in helping to understand user interactions with devices. She emphasized that the scientific discipline of human factors is important for identifying use-related risks associated with AI/ML devices, for reducing the likelihood of errors in use, and for having a clear understanding of how users perceive, comprehend, and use AI/ML devices.

Q&A

Mary (Suzanne) Schrandt, J.D., asked for current examples of patient involvement in the development of algorithms, particularly with respect to the consolidation of patient language and clinical terminology. **Mr. Baird** replied that there is much variation depending on what the product is and who is involved. He specified that no work is currently being done on the development of guidelines or standards, and asked for feedback on what the focal point should be.

Cynthia L. Chauhan, M.S.W., asked what is being done to include patients in the development of these ideas. **Mr. Baird** explained that input is obtained from targeted users and focus groups during initial research with intermittent follow up. Ms. Chauhan recommended early inclusion of patients as collaborative team members with special and distinct expertise.

Monica Parker, M.D., commented that she was confused by the statement that most algorithm designs ignore the attributes of sex, gender, age, race, and ethnicity. She speculated as to how this could be made equitable and work for everybody. **Dr. Cornelison** specified that demographic identifiers are clinically relevant variables and not just categorical information. She emphasized that their removal could lead to suboptimal results and mistakes, and that their inclusion can eventually aid in nonbiased application across broader populations.

BREAKOUT SESSION

A virtual breakout session for discussion of scenario questions was held from 12:00 to 12:40 p.m.

BREAKOUT SESSION SUMMATIONS

Breakout Room Number 1:

Tracy Gray, M.B.A., M.S, reported that her group discussed the following issues:

- Application performance:
  - How does it relate to the standard of care?
  - How does it fit into the practice of medicine?
  - What is its relevance to the output of medical care?
- As a result of an application's output, is it FDA approved?
- Is it safe, effective, and secure?
- Are demographics validated during performance testing?
- Who develops the applications and is there a potential for conflict of interest?

Breakout Room Number 2:

Anindita Saha, B.S., reported that her group discussed the following issues:

- privacy concerns regarding data use and storage
- whether patient data could potentially be used for future training datasets and how that would affect informed consent and privacy considerations
- understanding the race and ethnicity of datasets and how it affects patients
- next steps regarding results, what it means, and what should be done with the information

Breakout Room Number 3:

Heike Sichtig, Ph.D., M.S., reported that her group discussed the following issues:

- the need for more data on demographics
- clarity regarding what other information is computed into learning algorithms such as age, sex, and other nationalities, and availability of that information

Breakout Room Number 4:

Irada Isayeva, Ph.D., M.S., reported that her group discussed the following issues:

- availability of supplemental information with contextual links that are relevant and targeted to results
- having a streamlined real-time way to follow up with clinicians
- information regarding variables used in training and validation of devices
- the importance of having information on overall demographics

Breakout Room Number 5:

Ian Marcus, M.S., reported that his group had similar conversations in addition to discussing the following two issues:

- materials that will help patients understand how training and validation data relate to their demographic information
- concerns about the accuracy of applications with regard to temporal considerations and disease progression over time

Breakout Room Number 6:

Fraser Bocell, M.Ed., Ph.D., reported that his group discussed the following issues:

- Would an app be trusted if the results are not what was expected?
- Positive bias consideration: People are more inclined to believe something if it matches their expectations.
- What action should be taken as a result of low or high risk assessment?
- Do similar patients get similar results?
- How do their results compare to other people in real-world data?

Breakout Room Number 7:

Jessica Weinberg, MPP, reported that her group discussed the following issues:

- Which diseases has the device been tested for?

- Does photo quality make a difference?
- Is it possible to input other types of information?

Breakout Room Number 8:

Allen Chen, Ph.D., reported that his group discussed the following issues:

- Additional information when receiving test results:
  - types of approaches used to ensure inclusive patient population in the development of the app
  - the expected population
  - false positives/false negatives
  - any evidence of the pathology
  - various factors such as age and sex
  - postmarket performance
  - FDA approval
- Additional features to assuage concerns and direct patients to next steps:
  - having a person to interact with for guidance
  - having a direct connection for setting up doctor's appointments or contacting other experts
  - use of terminology that will not create bias or panic
  - apps should specify that they are not diagnostic and should suggest next steps
  - additional patient demographic performance information should be provided

Breakout Room Number 9:

Tosia Hazlett, MSN, RN, reported that her group discussed the following issues:

- having directions of where to proceed
- links to other sources to verify the information
- importance of understanding the risks
- information on where to go for referrals
- the need for having a professional involved
- specifics of performance characteristics
- definitive measures on how people interpret the metrics, especially for low-prevalence events

Breakout Room Number 10:

Susan Chittooran, MSW, reported that her group discussed the following issues:

- What should the next steps be?
- Is there a way to do a follow-up appointment?

- Can a virtual appointment be scheduled?
- Can someone with a high risk determination get an appointment sooner rather than later?
- Resources should be vetted and reputable.
- In what ways could information from the app be used to collaborate with other physicians as part of the standard of care?

OPEN PUBLIC HEARING

Zack Hornberger spoke on behalf of the Medical Imaging and Technology Alliance. He acknowledged that FDA remains the most significant source of trust in the healthcare sector and urged the Agency to maintain its role as protector of public health through engagement with industry. He noted that training datasets are often the most important part of a machine-learning algorithm, that the inclusion or omission of data has a direct impact on outcomes, and that the intended use of a device drives what is and is not an appropriate dataset. He stated that doctors and patients should be made aware of the capabilities, appropriate usage, and potential limitations of algorithms relevant to the chosen care path and intended use of a device. He further stated that the potential benefits of machine learning for medical imaging are enormous and promises to help individual patients through improved access to care.

Erika Hanson Brown, CEO and founder of the PALTOWN Development Foundation, related that she is a survivor of late stage colorectal cancer. She told the Committee that the stigmatism of the disease and the loneliness that she felt drove her to create COLONTOWN, an online community for colorectal patients, survivors, and care partners. She stated that artificial intelligence, if done correctly, can help diagnose diseases that would otherwise not be caught, reduce unnecessary scans, and do much to eliminate health disparities. She encouraged FDA to continue focusing on ways that AI can be used to identify diseases that could be missed, to stimulate better use of imaging, and to eliminate care gaps based on gender, race, and/or socioeconomic status.

Cecil Motley, M.D., Ph.D., BSSE, MSSE, CEO of Cardiometric Medical Systems, addressed the questions of how FDA should validate the safety and efficacy of AI software codes in medical devices, and why it should get involved. He provided a general description of what medical artificial intelligence is, discussed system architecture and implementation configurations, and walked the Committee through an AI-based medical treatment example. He encouraged FDA to adopt similar procedures to those used by the Department of Defense to validate life-critical software.

Keith J. Dreyer, D.O., Ph.D., FACR, FSIIM, Chief Science Officer of the American College of Radiology's Data Science Institute, addressed the topic of ensuring the trustworthiness of diagnostic imaging AI. He discussed ACR's background, challenges in approving artificial intelligence, and the future of AI in healthcare. He noted that FDA-cleared algorithms appear to be inconsistent across patients and institutions, that patients have no way of knowing which algorithms are used in their diagnoses, and that without continuous monitoring, algorithm performance is unknown. He encouraged FDA to ensure

generalizability and enforce continuous AI monitoring. He also cautioned that it is too soon for FDA to consider clearance of algorithms designed to provide autonomous image interpretation.

Noah Zimmerman, Ph.D., offered perspectives on the use of AI in medical devices. He addressed the issue of demographic representation, noting that although FDA has been leading the effort to improve diversity of clinical trials, many challenges remain. He pointed out that the nature of AI device development creates an unprecedented opportunity to incorporate diversity and representation in the evaluation of medical devices through the use of real-world data. He noted that real-world data is efficient to collect and as a result, development and validation of AI-based medical devices can occur quickly. He encouraged patient communities, patient advocates, regulators, and AI developers to work together to establish best practices for defining validation sets for medical devices.

Amit Kaushal, M.D., Ph.D., discussed the results of a recently-published study investigating data used in medical applications of AI. He informed the Committee that this research supports the existence of data deserts in biomedical AI in the United States. He noted that artificial intelligence algorithms don't often work as well for underrepresented populations in training data, that biased training datasets can lead to biased algorithms, and that researchers might not be able to study problems relevant to certain subgroups due to lack of data.

OPEN COMMITTEE DISCUSSION

Ms. Saha and **Ms. Gray** addressed a question posed by **Amye L. Leong, M.B.A.,** regarding metrics or guidelines for determining the greatest amount of diversity for appropriate representation of the U.S. population.

Rita Roy, M.D., commented on the issue of health literacy and its impact on data collection outcomes. **Ms. Hazlett** noted that her group discussed concerns surrounding public understanding of risks, pros and cons, and where to go for referrals. **Dr. Chen** noted that his group discussed the meaning of high risk and the use of layperson terms that are more easily understandable.

Ms. Chittooran addressed a question posed by **Dr. Parker** regarding accountability and where data is being generated from. She noted that her group discussed the need for having more information about the developers of applications, how the data is being used, how companies are profiting from it, and what happens to it when devices are acquired by other companies.

Katherine D. Seelman, Ph.D., Consumer Representative, remarked that it would be useful to have more knowledge about data collection models and procedures. **Ms. Saha** indicated that her group discussed and expressed interest in understanding what the data is, what it means, and where it comes from so that patients can have better confidence in the results that come from their apps.

FDA QUESTIONS

Commander Chinyelum Olele read Question 1: Artificial Intelligence (AI) and

Machine Learning (ML) medical devices are often developed using training and validation datasets that represent or capture patient outcomes. If the data used to train these devices are not representative across various demographic subgroups or across the disease spectrum (for a specific intended use), it would be unclear how well the devices will perform across the entire population of patients living with the condition. Research shows that multiple medical conditions show differences in outcomes by sex, gender, age, race, and ethnicity. In addition to demographic factors, there are multiple aspects of the dataset (e.g., types of diseases, severity of disease, comorbidities, duration of disease) that may impact the accuracy and applicability of the AI/ML device. Please address the following questions:

a. What do you believe is the best approach for a developer to clearly convey the demographic composition of the training and validation datasets?
b. What approaches do you think the FDA and industry should consider to help assure diverse groups of patients are reflected in training and validation datasets for the proposed intended use?
c. Should the description of the data used to inform the algorithms be made publicly available or made available only to the users?
d. What assurances do you think the FDA and industry could provide that would encourage patients to share their data to be used in these algorithms? In datasets that could be used for any algorithms?

Stephen B. Wilcox, Ph.D., FIDSA, stated that it is necessary for manufacturers to use different patient groups in the development of AI devices and that the main focus should be on diversification of validation.

Dr. Parker recommended that verification be done in clinical sites external to academic training centers to achieve a broader range of diversity.

Ms. Chauhan remarked that obtaining an aggregation of patients would be best assured if it is required by FDA.

Ms. Leong agreed. She suggested a partnership between FDA and patient support groups for the purpose of educating patients about the value and usefulness of data.

Ms. Schrandt suggested legitimate standardization of patient advisors that would include patient committees, councils, and advisory groups as part of the process.

Bennet R. Dunlap, M.S., remarked that consent to treatment is crucial, that data should not be used without patient approval, and that medical devices developed without patient participation should not be accepted.

Dr. Parker insisted that providers who use the devices should be knowledgeable about them and that they should be involved in the selection of patient advisory boards.

Philip Rutherford, Committee Consultant, underscored the importance of ensuring diversification in data collection and software development.

Ms. Chauhan commented that intentionality and unconscious bias have a definite effect on the development and use of devices.

Dr. Roy suggested a partnership between FDA and industry for the purpose of educating patients about what is being asked of them and why.

Chairperson Conway concluded that patients frequently share their information when they have a clear understanding of what it might be used for. He underscored the

necessity of informing the public about the ways that data is utilized.

He then summarized the Committee's response:

- Increased diversity in datasets can be more readily obtained by going out into the communities of practitioners who are closest to the target populations.
- Providers and other professionals who actually work with these groups should be included on advisory boards, and there is strong consensus that this will require the involvement of FDA.
- The concept of having fully representative developers should be considered.
- Ways of encouraging participation should also be considered.
- Transparency is essential throughout the entire process.
- The collaboration of FDA with industry, patient organizations, and practitioners is crucial in ensuring that this process is not confined to academic institutions or research centers.

Michelle Tarver, M.D., Ph.D., requested clarification on what the Committee feels that FDA should do about the informed consent process.

Mr. Dunlap replied that patients need to know what their data is going to be used for, that data should be collected by third parties, and that patients should be informed as to whether or not they will be included in a database before giving consent.

Ms. Chauhan insisted that patients be thoroughly informed as to how they are being protected so they can know what the risks are.

Dr. Roy recommended understandable informed consent language that is evaluated by patient groups.

Mr. Dunlap asserted that companies should be not allowed to obtain or use patient data as a condition of treatment.

Dr. Parker suggested that informed consent documents be explicit, clear, and written at an eighth-grade level.

Ms. Schrandt endorsed integrated partnership of all stakeholders in every aspect of development.

Commander Olele read Question 2: AI/ML device manufacturers update their programming for a variety of reasons. Some of these changes are submitted to FDA prior to implementation for marketing authorization while other updates can be implemented and documented for later review by the FDA. The different types of modifications include:

- Modifications related to device performance, with no change to the intended use or type of input signals. This type of modification includes re-training with new data sets of the same input signals and a change in the AI/ML architecture.
- Modifications related to inputs, with no change to the intended use. This type of modification includes changes to the algorithm for use with new types of input signals but does not change the intended use of the device.
- Modifications related to the device's intended use. These types of modifications include those that change how the device is used. For example, a device that was previously used to aid in the diagnosis of a condition would instead provide a

diagnosis to the patient.

The determination of what information should be submitted and when that information is submitted to FDA is based on risk. Risk is defined as a combination of the probability of harm occurring and the severity of that harm. As such, every medical device including AI/ML devices has some associated risks that are considered by the FDA.

a. What types of software modifications to AI/ML medical devices would be more concerning to you that warrant notifying FDA prior to implementation? Which types of modifications do you believe should trigger a communication update to the patients and the public?
b. Would your decision on communicating about modifications be different based on where the device is used (e.g., in the home, in the clinic) or by who is using it (e.g., doctor, patient)?
c. What approaches should FDA and industry use to share with the patients any added benefits (such as improvement in accuracy), changes in performance (such as decreased performance) or risks (such as limited applicability in certain populations) associated with using the AI/ML medical devices?
d. For some devices, at the time of the marketing authorization, there are periodic planned modifications (types of anticipated modifications and method to implement the modifications) to the AI/ML device. What information including level of detail about the planned changes do you believe should be made available to patients to increase their trust in the device?

Dr. Parker expressed concern about modifications that make devices more independent of providers and alterations that change the intended use.

Dr. Wilcox surmised that 510(k)s would still be needed for each type of modification and that longer timelines for approval may be necessary.

Ms. Schrandt stated that over-disclosure and over-communication would be preferable at first to allow for ample analysis of what the changes may look like.

Diane M. Johnson, Industry Representative, asked for opinions on patient-facing apps and how they're regulated as opposed to physician-facing apps.

Mr. Dunlap remarked that physicians getting information that patients don't is highly problematic.

Ms. Leong stated that patients have a right to know why modifications are made to devices.

Dr. Roy insisted that information regarding device modifications should be made available to patients.

Chairperson Conway summarized the Committee's response:

- Transparency is a good thing on all fronts in regard to updates.
- The process of updating can provide the potential for continued patient/physician conversations on a variety of issues.
- There are differing viewpoints regarding information that is held by doctors and companies, one being that it is unclear to patients what companies are going to do

with their own personal data.

- It is also troubling that healthcare providers are getting information that patients don't have access to.
- There is concern about updates being done in order to meet the promise of what the technology was originally intended to do.
- There is also concern about the possibility of devices being used in ways other than their original purpose and what they were authorized for.
- Because AI devices evolve over time, they may need longer approval periods.

Mr. Patel asked the Committee for further discussion on modifications with regard to interoperability and safety. He also asked how risks and benefits should be communicated.

Ms. Chauhan stated that patients should be made aware of what external devices such as MRIs are being used for and that informed consent should be required for updates to devices that are placed in or on the body

Ms. Leong agreed. She encouraged the formation of a global framework for developers and patient advocates.

Mr. Patel asked for examples of things that could change after initial market authorization resulting in planned modification. He also asked what information should be transparent while the device is still within the bounds of what it was authorized for.

Dr. Wilcox stated that there should be transparency with respect to a system's operating principle or meta-algorithm as opposed to the input/output relationship.

Dr. Tarver asked for further discussion about approaches that FDA and industry should use to communicate benefits to patients.

Dr. Parker suggested general announcements, the healthcare community, and patient advocacy groups as sources for conveying information with broader discussions for the general public, and more precise dialog between healthcare entities and specific patient populations.

Ms. Chauhan stated that companies should be responsible for contacting individuals and suggested that FDA monitor whether they are meeting that responsibility.

Mr. Dunlap suggested that FDA engage with the patient community in the same way that it did when automated insulin delivery was first introduced.

Dr. Roy commented that it is important for industry to partner with patient support groups. She suggested that the best way to get information out is by utilizing electronic media.

Commander Olele read Question 3: With all AI/ML including those that are continuously learning, there is the potential for the performance of the software algorithm to exceed the original reference gold standard (such as the current standard of care). This increased performance may raise the bar for other devices that may be seeking entry into the market. How do you weigh the benefits of infusing this improved performance standard (i.e., "better than standard of care" bar) for subsequent devices with the potential risk of inhibiting innovative technologies from having a chance to enter the marketplace?

Mr. Dunlap stated that enforcing a high standard will promote, and not stifle,

innovation.

Mr. Rutherford agreed. He observed that the development of new technology can be very beneficial as long as it is properly validated.

Dr. Wilcox remarked that this is no different than what has already been happening. He advised that it may be necessary to rethink the way that postmarket analysis is currently being done.

Dr. Seelman pointed out that compatibility and interoperability are important considerations since this is a software situation.

Chairperson Conway summarized the Committee's response:

- There is a strong feeling that elevation of the standard may be beneficial.
- Some concern was expressed that innovation could choke out technologies that are currently working at an acceptable level and be detrimental to existing care options.
- The software will probably evolve faster than the hardware.
- There is concern about postmarket surveillance and what the impact might be.

Dr. Tarver asked Dr. Wilcox to expound on what the postmarket consideration would be. **Dr. Wilcox** clarified that there may be some unintended circumstances that would have to be guarded against given that these are not static devices.

Commander Olele read Question 4: Some AI/ML algorithms are shifting decision making from the current settings of a specialist to that of generalist or to the patient at their home. In addition, AI/ML devices are becoming capable of taking autonomous actions such as to call 911 or alerts their health care provider.

a. What mitigations do you believe should be put in place to protect patients (e.g., informed consent, qualifying language in the diagnosis provided, warning/caution statements) if the decision making setting is shifted as described above?
b. What are some approaches you believe will help patients understand the probability of the harm and the severity of that harm (i.e., risk) associated with devices that take autonomous actions.

Ms. Schrandt opined that there would be less need for mitigation if patient/clinician interaction, data management, and validation testing are done properly. She expressed concern about autonomous actions for specific conditions in patients who have multiple diseases and what the effects might be.

Dr. Seelman remarked that the issues of accountability and liability in this area seem vague.

Dr. Roy expressed concern about the possibility of it not working or what would happen if a device is assumed to be functioning and isn't.

Dr. Wilcox remarked that there does not seem to be anything unique about AI systems, that the same questions could be asked about an implanted defibrillator.

Ms. Leong insisted that patients should have the right to choose what level of information they want at any given time. She also stressed the importance of informed

consent.

Mr. Rutherford brought up the possibility of risk standardization. He surmised that there probably isn't a big difference in the risk that these devices present as opposed to what is currently happening, and that they should be managed with proper education and review.

Chairperson Conway summarized the Committee's response:

- If collaboration and patient engagement are being done correctly, the issue of mitigation will become less of a concern.
- There is a question as to how these devices will work for patients who have multiple diseases.
- With respect to the possibility of failure and breakage, these devices are probably not all that different from any other medical device.
- There is a question as to whether or not patient preference could be involved in the development of thresholds for alerts and notifications.
- The issue of accountability and liability should be considered.

Dr. Tarver asked what mitigations should be considered for diagnostic devices that are used by patients at home.

Dr. Parker replied that there needs to be accountability, specific instructions about how results should be managed and by whom, and steps for patients to take when they have results that they're not familiar with.

Chairperson Conway pointed out that some diagnoses can cause a lot of emotional stress on patients who do not have context or immediate access to a medical professional, and the impact that this could have should be taken into account.

Commander Olele read Question 5: For AI/ML devices intended to be used by patients, the "information" that patients may see includes GUI (Graphical User Interface), menus, dialog boxes, and error and status messages. In addition, there may be information associated with the device placed directly on the device, on the company's website, and in tutorials informing how to use the device. These communication materials often include the software version number, the instructions for use, the user's guide, the "About" menu button and other information typically found in the software's splash-screen. In contrast, other devices may be intuitive to use, where patients do not need an instruction manual or how-to guide to begin using them. Some devices may have functions that are locked to patients and only visible/available to their providers, while others may display readings to the patients to share with their healthcare provider.

a. As you think of devices that you intuitively use, what features do you consider to be intuitive? What do you believe manufacturers of AI/ML medical devices should consider to integrate intuitive features in their devices?
b. For understanding the effectiveness of mitigations such as warnings/caution statements and information for use, do you consider human factors/usability testing to be an important step? Please explain your response.
c. What information do you think should be included in the communication materials

made available to patients using AI/ML medical devices?

d. Do you believe patients should have the ability to see functions or data that may only be visible to their healthcare provider? Please explain your response. If yes, what mitigations should be put in place to ensure patients understand and appropriately respond to the information presented?

Dr. Wilcox noted that these are all empirical questions. He pointed out that what seems to be intuitive to some people can be incomprehensible to others and that everything has to be tested.

Dr. Parker recommended that patients who get newer devices should have access to technological assistance. She also affirmed that no information should be made available to physicians that is not available to patients.

Ms. Schrandt emphasized that human factors have to be specific and not based on the average person. She agreed that information that is available to doctors should also be available to patients.

Mr. Dunlap stated that user factors may need to be adjustable.

Dr. Wilcox remarked that it cannot even be assumed that people know how to turn devices on and off.

Dr. Roy suggested finding ways for patients to connect with each other for support and to share experiences.

Dr. Parker pointed out that many rural areas do not have proper internet capability, which places limitations on the usability of these devices.

Mr. Rutherford asserted that healthcare data needs to be protected. He opined that it seems like a relearning is needed, especially for these types of products.

Ms. Chauhan commented that patients aren't always aware that their data is being given away.

Chairperson Conway summarized the Committee's response:

- There is strong consensus that patients should have the same amount of information as doctors and it should be presented in a way that is easily understandable.
- There is strong consensus regarding human factors, usability, and connectivity.
- The ability to connect devices and the capacity for communication between similar devices and patients with comparable issues should be considered.
- There is a question as to how knowledgeable patients are about the amount of information that they provide.
- Patients should know what their data is being used for and how much they are giving up.
- There is a question as to whether patients are being informed of all of the implications of saying yes.
- It should never be assumed that people do or do not know how to do certain things.
- Patients should be involved in the process from the start and they should determine what human factors need to be included.

ADJOURNMENT

Chairperson Conway gave final remarks and thanked everyone who participated in the meeting. He then adjourned the meeting at 4:37 p.m.

I certify that I attended this meeting on October 22, 2020 and that these minutes accurately reflect what transpired.

_____/S/_____
Letise Williams
Designated Federal Officer

I approve the minutes of this meeting as recorded in this summary.

_____/S/_____
Paul T. Conway
Chairperson

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