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Applying Participatory Action Research in Traumatic Brain Injury Studies to Prevent Post-traumatic Epilepsy

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Abstract

The increased focus on stakeholder engagement in determining the aims, design, conduct of research and dissemination of results is substantially changing the biomedical research paradigm. In this era of patient-centered care, incorporating participatory action research methodology into large-scale multicenter studies is essential. The adoption of community engagement facilitates meaningful contribution to the design and implementation of clinical studies. Consequently, encouraging citizen participation and involving key organizations may guide the effective development of future clinical research protocols. Here, we discuss our experience in engaging individuals, their caregivers, as well as scientific and consumer organizations in public outreach and knowledge transfer to assist in the development of effective strategies for recruitment and retention in a future post-traumatic epilepsy prevention randomized controlled trial within the National Institute of Neurologic Disorders and Stroke Center Without Walls, Epilepsy Bioinformatics Study for Antiepileptogenic Therapy (EpiBioS4Rx). The study includes a Public

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Engagement Core with a diverse consortium of stakeholder partners. Based on the Core's ongoing experience, it is recommended that multicenter studies integrate a participatory action research based approach to harness the benefits of a collective inquiry. The blueprint created by the EpiBioS4Rx Public Engagement Core is a resource that could be applied in other areas of biomedical research.

Keywords

Community Engagement; Participatory Action Research; Patient-Centered Outcomes; Patient Reported Outcomes; Clinical Trials; Traumatic Brain Injury; Epilepsy; Post-Traumatic Epilepsy

BACKGROUND

Introduction to Participatory Action Research (PAR)

The goal of this paper is to discuss our experience in engaging individuals, their caregivers, as well as scientific and consumer organizations in public outreach and knowledge transfer to assist in the development of effective strategies for recruitment and retention in a future post-traumatic epilepsy prevention randomized controlled trial. Participatory action research (PAR is a qualitative research approach that emphasizes ongoing and continuous collaboration among investigators and a community targeted for research or an intervention (Reason and Bradbury, 2008). The community members participate in all stages of the research from planning, analysis to implementation as active participants. In contrast to other projects that involve community members in some aspects, PAR is designed specifically to meet the community's needs and to empower community members throughout the research process (Attree et al., 2011).

To define the aspirations and expectations of the stakeholders in a participatory process, the International Association for Public Participation (IAP2) has developed goals and core values (Participation, 2016) to ensure the relevance of the results to the participating individuals and caregivers **(Figure 1).** Guided by the knowledge-to-action cycle (Graham et al., 2006), this interactive approach starts with existing knowledge (e.g. current literature/ qualitative interviews/ and focus groups), which is incorporated in the development of tools for consumers or other end-users, including educational tools. The barriers and facilitators are then evaluated, the tools are improved, implemented, and the outcomes subsequently appraised.

Organizations such as the Alliance for Taxpayer Access have advocated for an open access policy to all publicly-funded research data and results for citizens (Combs, 2018). In 2013, 2015 and 2017, the United States (US) legislative branch introduced into legislative debate the Fair Access to Science and Technology Research Act (FASTR, 2018). This bill aims to accelerate scientific discovery and fuel innovation by allowing free access online for anyone to read and build upon publicly funded scientific research (FASTR, 2018). Using a PAR based approach can increase the quality and relevance of clinical and translational studies (Michener et al., 2012; Wilkins et al., 2013).

The incorporation of PAR into US healthcare research is increasingly evident following recent US legislation, including the Affordable Care Act's creation of the Patient-Centered Outcomes Research Institute (PCORI) and the 21st Century Cures Act's emphasis on putting patient perspectives first (FDA, 2016). PCORI developed a patient engagement rubric (Sheridan et al., 2017) to guide grant applicants, reviewers, and awardees on patient engagement opportunities. Also, the Milken Institute's *FasterCures* action tank developed rigorous methods to integrate the individual's perspective, needs and priorities across therapy development pipelines (FasterCures, 2017). This action tank evaluated 70 collaborative initiatives and identified 40 discrete entities providing direction for integrating perspectives of individuals and community collaboration into patient-centered care and research (Anderson and McCleary, 2015; Anderson and McCleary, 2016). Among these, the Clinical Trials Transformation Initiative developed a framework that identifies points at which clinical trial sponsors and regulators can engage patients and stakeholders in research and development (PGCT, 2017). To facilitate patient engagement in research, *FasterCures* developed a toolkit to help navigate the path to patient input highlighting the above and other resources (Anderson and McCleary, 2016; FasterCures, 2017).,

Potential Barriers to PAR in Clinical Trials

There is a paucity of research regarding the value and effectiveness of different theory-informed engagement models to support actions in head equity (Davison et al., 2015; Leeuw et al., 2008). To date, clinicians and research teams design studies from their perspective of clinical equipoise between treatment arms. However, recruited individuals may have different viewpoints regarding the potential risks and benefits of treatment randomization (McGovern and McKhann, 2012). These different view points may have contributed to limited recruitment in two randomized controlled trials (RCT) regarding the surgical treatment of drug-resistant epilepsy (Barbaro et al., 2018; Engel et al., 2012). To date, community engagement has not been widely used throughout the conception and implementation of a clinical trial. A 2006 Cochrane review of methods of consumer engagement in healthcare and research found that studies examining the impact of community engagement on researcher directed design were in the mental health and pain management fields (Nilsen et al., 2006). These included interventions related to consumer involvement in policy, health care implementation and development of public materials. As clinical trials differ substantially in their study design and execution, it remains unclear what are the best methods to optimize community engagement in clinical research (Nilsen et al., 2006; Richard et al., 2017).

A number of interventions to improve RCT recruitment were evaluated in several systematic reviews (Caldwell et al., 2010; Treweek et al., 2013; Watson and Torgerson, 2006). Successful recruitment interventions include telephone reminders and financial incentives. The other successful recruitment methods in this review, open-trial designs and opt-out strategies, could present logistical and ethical concerns within a preventative treatment trial (Treweek et al., 2013). A review of five United Kingdom clinical trials across a variety of conditions (obesity, renal, mental health, falls prevention, dementia) found that in order to sustain successful recruitment of participants it is essential that all levels of the study team (e.g. site PIs, coordinators, research assistants) stay engaged in the recruitment effort

(Daykin et al., 2018). A 2013 Cochrane review of RCT retention strategies, across a spectrum of conditions, focused on the participation and return of questionnaires and biomedical test kits from individuals participating in screening, treatment, or prevention interventions. This review found significantly improved retention with the addition of monetary incentives (compared with no incentive) (Brueton et al., 2013). Similarly, other reviews of retention strategies have been limited to methods of enhancing responses to telephone, postal, and/or in-person collection methods for questionnaires and longitudinal population health research (Booker et al., 2011; Edwards et al., 2009).

Public Materials as a Tool for Public Engagement

Public education materials are necessary to address the needs of individuals and their families and help in designing PAR-based RCTs. While public materials and websites may be beneficial, they can only be advantageous if individuals can read and comprehend them. The National Center for Education Statistics 2003 assessment of average reading level among Americans found an average document literacy level of 271, with 53% of adults (≥age 16) demonstrating “intermediate” document literacy (NCES, 2003). At this level (250 to 334), adults are able to locate information in dense, complex documents and make simple inferences about the information, corresponding to a US education grade level between 7th and 9th grade (NCES, 2003). The United States Department of Health and Human Services (USDHHS) concluded that material is considered “easy to read” only if written below a 6th-grade level, 7th and 9th as “average difficulty,” and material above the 9th-grade level is regarded as “difficult”. Based on the USDHHS and recent federal guidelines on the use of plain language, public materials should be written below a 6th-grade level or when necessary at a 7th-9th grade level of reading (NIH, 2017; PLAIN, 2011).

A readability score is a calculated index that suggests a reading level or range of education needed to read and comprehend a text. One of the most common scales is the Flesch-Kincaid grade level and is bundled with word processing software such as Microsoft Word. The formula considers the average number of words per sentence as well as the average number of syllables per word (Kincaid et al., 1975). In a 2008 review of 100 consumer-oriented webpage articles from consumer organizations representing major health-related causes of death (e.g. heart disease, cancer, stroke, COPD, diabetes), the majority of the materials were written above USDHHS recommended reading levels, and 46% were above a 12th-grade level. Similar findings were reported by publications evaluating TBI and epilepsy websites (Ahmed et al., 2012; Brigo et al., 2015; Elliott et al., 2007; Elliott and Shneker, 2009).

PAR in the Traumatic Brain Injury and Epilepsy Communities

Within the TBI community, the Traumatic Brain Injury Model Systems (TBIMS) is a multicenter research project focused on assessing the delivery, demonstration, and evaluation of the ability of medical, rehabilitation and other services to meet the needs of individuals with TBI (Bushnik, 2003). The Ohio Valley Center for Brain Injury Prevention and Rehabilitation (OVC) TBIMS site pioneered PAR methods in TBI research. The OVC TBIMS has applied participatory concepts by incorporating input from an advisory panel, which included individuals living with TBI, families, and caregivers (OVC, 2017). Also at OVC, a separate PCORI-funded comparative effectiveness study of different rehabilitation

approaches incorporated aspects of a PAR approach by collaborating with three stakeholder groups: a) community advisory council (individuals living with TBI), b) research team (including consumer and clinician stakeholders), c) provider advisory group (hospital administrators and researchers) on outcomes and components of the design (Bogner, 2016; OVC, 2014). Also within the TBIMS program, the Craig Hospital site in Colorado is using a stakeholder advisory committee, qualitative interviews, online surveys, and public kits for community engagement and shared-decision making to advance patient-centered outcomes for adults living with moderate to severe TBI (CRITICAL, 2017).

Several other TBIMS centers have incorporated PAR into various pharmacologic RCTs for post-brain injury management and comparative effectiveness studies (Giacino et al., 2012; Jha et al., 2008; Morey et al., 2003). Specifically, a multicenter prospective RCT on the effectiveness of amantadine in promoting functional recovery after severe TBI required extensive stakeholder engagement due to the emotionally difficult characteristics of the study for both families and clinicians that incorporated placeboes as one of the treatment arms (Giacino et al., 2012). Through multiple stakeholder forums, they explored the circumstances they would consider for participating in a placebo-controlled trial, how long families and clinicians would be comfortable with placebo treatment if an individual did not improve, concerns with enrollment and what may allay those concerns, among other themes. To our knowledge, until now, PAR methods have not been integrated into a preventative pharmacologic interventional TBI RCT or specifically to guide efforts to prevent post-traumatic epilepsy (PTE).

Within the epilepsy community, various PAR efforts have been explored. Recent examples include the establishment of the Rare Epilepsy Network (REN) (Chopra and Isom, 2014; Gattone and Lammert, 2014). The idea of a Rare Epilepsy Network originated from a discussion at the 2013 NINDS Curing the Epilepsies meeting, forging a partnership with epilepsy advocacy and professional organizations. Attending caregivers of children with rare epilepsies discussed their difficulties in deciding to create their own database or to unite across the rare epilepsy groups. This led to the PCORI funded Patient-Powered Research Network in PCORnet (Gattone and Lammert, 2014). The REN was designed to provide patients and their families an opportunity to participate in research that will improve the lives and quality of care for people with rare epilepsies. As of April 2018, the REN has enrolled 1379 participants from the US and internationally, across approximately thirty rare epilepsy syndromes (Gattone and Lammert, 2014; REN, 2018). There has been rapid progress in functional analysis and phenotypic classification of seizure types and syndromes with an acceleration of efforts to identify the underlying molecular causes and develop strategies for drug screening and prioritizing patient-centered care (Meisler et al., 2016). The data in the REN database is being analyzed in a number of ways. It is also available for researchers upon request and is publicly available for viewing on a dashboard (REN, 2018). Currently, the REN is exploring the available tools for measuring Patient-Centered Outcomes (PCOs) across epilepsy such as quality of life (for both people with epilepsy and caregivers), seizure burden, improved cognition, sleep and behavioral issues to complement existing seizure frequency measures used in studies of rare epilepsy populations.

Consumer organizations and support groups, such as the Epilepsy Foundation, are also working to define and monitor epilepsy PCOs. Using a 2016 online community survey, the Epilepsy Foundation's Epilepsy Innovation Institute collected individual and caregiver input on aspects of epilepsy that most greatly impact their lives, the frustrations they face and hopes for advancement in epilepsy research. The majority of the 1056 respondents selected unpredictability of seizures as a top issue, regardless of seizure frequency and type (Ei^2, 2016). With this feedback, the Epilepsy Innovation Institute (Ei^2) convened a diverse group of stakeholders (patient organizations, providers, academics, professional organizations, and representatives of the pharmaceutical and device industries) in a "Seizure Gauge" workshop to assess the state of science in seizure-forecasting algorithms. This stakeholder group identified multiple non-invasive parameters to consider in addition to EEG recordings in the design of a seizure prediction device and personalized approaches to seizure forecasting (Dumanis et al., 2017).

THE EPILEPSY BIOINFORMATICS STUDY FOR ANTI EPILEPTOGENIC THERAPY (EpiBioS4Rx)

In this report, we discuss our experience in engaging individuals, their caregivers, as well as scientific and consumer organizations in public outreach and knowledge transfer toward the development of effective strategies for recruitment and retention in a future randomized controlled trial study to prevent post-traumatic epilepsy.

This is part of the Epilepsy Bioinformatics Study for Antiepileptogenic Therapy (EpiBioS4Rx) is a US based National Institute of Neurologic Disorders and Stroke Center Without Walls with international participation. EpiBioS4Rx includes a preclinical and clinical platform to identify candidate antiepileptogenic treatments for PTE (EpiBioS4Rx, 2016). Its objectives are to: 1) identify biomarkers of epileptogenesis in an animal model and in patients, 2) develop a standardized protocol for preclinical trials of potential antiepileptogenic therapies, and 3) create open shared resources for the entire epilepsy research community with a network of TBI centers capable of carrying out future clinical trials of potential antiepileptogenic therapies. The inclusion of public outreach and engagement is a key component for the planning of future RCTs of antiepileptogenic therapies (Engel, 2018).

The Public Engagement Core (PEC) of EpiBioS4Rx

The PEC consists of a consortium of TBI and epilepsy stakeholders (Table 1) committed to community outreach to address issues related to future RCT recruitment and retention. The PEC sought to involve a diverse sample of TBI and epilepsy stakeholders. This PTE PAR model integrates the EpiBioS4Rx research team's perspectives along with outside stakeholders including members representing the Veterans Affairs TBIMS study teams, TBI and epilepsy clinicians, consumer organizations and families/caregivers in the design of future clinical RCTs where the community has a vested interest to participate. The consumers and organizations that have dedicated their time and effort to the EpiBioS4Rx PEC are listed in Table 1. The PEC consortium model is based on an integrated knowledge

transfer strategy (Straus et al., 2009). This approach engages the consortium partners from study inception to dissemination.

The PEC Approach

The PEC project phases are listed below in Figure 2.

The PEC will use a mixed-methods (qualitative and quantitative) approach to examine the determinants of public engagement, the usability of the public outreach kit (print and online materials), facilitators and barriers to RCT recruitment/retention, and future clinical RCT recruitment/retention strategy. To monitor for successful engagement, a satisfaction survey will be administered to PEC members annually, guided in part by prior satisfaction surveys (Roberts et al., 2012; Sauro et al., 2012). Findings are shared with collaborators and concerns or changes addressed to optimize team satisfaction with the engagement processes. In the questionnaire, members are invited to anonymously address the following themes: inclusiveness of the processes, respectful collaboration, the value of experiential knowledge of stakeholders, shared goals of implementation (Collier, 2011; PatientsLikeMe, 2005–2018).

Phase 1A: Consortium and Working Group Outreach and Development

A round of development was achieved with a core group of stakeholder organizations already engaged in TBI and epilepsy community health education and outreach. This core stakeholder group proposed additional members to grow the consortium through peer-to-peer outreach. PEC members were asked to participate in one of two working groups: one representing the scientific and/or researcher perspective; the other representing the perspectives of individuals, caregivers and advocacy organizations (community). The scientific working group will develop an introduction to PAR webinar and incorporate the community perspective into a recruitment and retention strategy for the future RCT. The community perspective working group is defining the important issues to individuals at risk, their families, and related community-based organizations (i.e., educational needs, concerns with research participation in RCT). Together the groups are developing an EpiBioS4Rx public outreach kit.

Phase 1B: Educate Investigators and Consumers about PAR

A review of current literature identifying PAR best practices and methodology, particularly for related studies (e.g., disease prevention studies), guided the development of a PAR webinar for PEC members. The webinar is undergoing several revisions; the final version may serve as a prologue for use in future epilepsy and TBI studies that incorporate a PAR approach.

Phase 1C: Public Outreach Kit as a Tool for Education and Engagement

To develop this kit, the PEC members were asked for information about the perceived educational needs (topics). Identified educational needs included epidemiology of TBI and PTE, epilepsy comorbidities, meaningful use of biomarkers, concerns regarding participation in RCTs and experiential stories from individuals and families that have participated in prior TBI and epilepsy research.

An exploratory TBI focus group (consisting of individuals living with TBI) was run by one of the PEC member consumer organizations to determine if the suggested educational needs were adequate or if there were additional gaps. One of the gaps identified included confusion with terms related to epilepsy, PTE, biomarkers, and RCTs. Several PEC members with experience in public education materials for persons with TBI and/or epilepsy also raised concerns about the target age/grade levels for reading comprehension (readability of text). This feedback informed the development of a draft of educational materials, consisting of definitions of key terms related to TBI, epilepsy, PTE, and EpiBioS4Rx.

To develop these education materials, the Flesch-Kincaid reading ease score and grade level tests were used to assess the readability of a convenience sample of public materials on TBI, epilepsy, and PTE. A majority of the publicly available content in this convenience sample scored at a Flesch-Kincaid 12th-grade level or higher. The exceptions were the epilepsy materials from the “Living well with Epilepsy” and the Epilepsy Foundation web pages, which scored with an average of 7th and 9th-grade levels respectively (EpilepsyFoundation, 2017; LivingWellWithEpilepsy, 2017). For the Epilepsy Foundation, this represents an improvement in readability after a 2009 health literacy assessment found that only 25% of its webpage content was at or below the 9th-grade level, averaging at the 11th-grade level (Elliott and Shneker, 2009). Based on the Department of Health and Human Services recommendations and the complexity of the concepts related to TBI and PTE, it was determined that the PEC public materials should target a 9th grade English reading level. After modifying the materials, the TBI focus group reevaluated the first round of public materials, and their feedback will be incorporated into the continued development of the kit. The public materials kit will include items such as a TBI and PTE factsheet (English and Spanish), content related to RCT participation, ICU care, and secondary outcomes associated with TBI, including the association with epilepsy. Once the website and toolkit are developed, the utilization will be examined over time. The prototype public outreach kit (including the associated website), with the existing and the newly developed materials, will then undergo further usability testing to ensure the materials and website meets the needs of the intended users. Focus groups will also be run with a sample of 5–8 potential end users, representing a cross-section of experiences from people with TBI, PTE, family members, and consumer groups.

The final toolkit will be provided to members for coordinated dissemination. The partner organizations’ online portals will be monitored for which materials are disseminated (e.g. via the internet or social networks). The success of the distribution will be assessed by correlating increases in web traffic to the EpiBioS4Rx public engagement website with the distribution time points. The tracking will help identify which materials and messages are most relevant to various subpopulations (e.g., those with PTE, those at risk of PTE, civilian, military, caregivers, providers, outside investigators), and which formats are most likely to be voluntarily distributed online by organizations. Increasing the understanding of how message content, formats, the timing of public engagement (i.e., what prompts action and when) will add to the body of knowledge on PAR implementation and knowledge translation methods in both epilepsy and TBI.

Phase 2: Community Engagement and Evaluation of Tools

The second phase is focused on the development and testing of strategies for involving both consumers and consumer groups in the design of studies, the determination of usability of the developed tools, and identification of potential facilitators and barriers to future RCT recruitment and retention. Following the evaluation of each tool, a Knowledge Exchange Forum will be hosted with the stakeholders to share the findings (Holroyd-Leduc et al., 2017; Sauro et al., 2016). This will allow for meaningful feedback from stakeholders and ensure the objectives and tools developed are focused on issues that resonate with them.

In addition to focus groups, the PEC will seek input from outside investigators and larger consumer groups through the development of qualitative and quantitative, population-based, cross-sectional surveys of potential consumers. Questions for consumers (stratified by multiple variables including respondent demographics such as age, sex, race, socioeconomic status, education) will examine topics such as the right time to discuss PTE risk, right person with whom to discuss risk, factors that are mandatory knowledge for participation, aspects that would facilitate participation, previous history of any study participation and optimal methods of communication.

Using the public website as a web-based public engagement platform, PEC members, consumers, and consumer groups will be asked to participate by providing feedback to inform the design characteristics of the ‘mock’ therapeutic trial of antiepileptogenesis after TBI. Quantitative analysis will include measures on the stakeholder’s perspective of specific RCT design, intervention type, and monitoring methods characteristics as facilitators or barriers to future study recruitment and retention. These qualitative and quantitative findings will help optimize and enhance the public engagement tools and future trial design.

As needed, multiple rounds of an iterative Delphi-like approach (Bennett et al., 2015; Eubank et al., 2016; Jette et al., 2012; McMillan et al., 2016) will be used to reach consensus regarding final components of the trial design, recruitment and retention strategies. The data will be analyzed by determining the number and quality of changes proposed by the consumer/consumer groups that are successfully incorporated in the RCT design as well as the number of Delphi-like rounds required.

Phase 3: Evaluation of Findings and Trial Design

The sustained engagement of the PEC collaborators will be assessed by compiling results of the evaluation plans associated with each step of the study and metrics such as website visitation rates and satisfaction scores for produced outside materials. The final evaluative variables of the PAR approach will be determined in collaboration with the PEC and the working groups but may include indicators such as length of participation or service on working groups and number of attendees at events.

Using the outcome measures defined by the PEC and EpiBioS4Rx research team, a template recruitment/retention strategy will be developed by the PEC. This strategy, along with the findings from each of the EpiBioS4Rx projects will be incorporated into a blueprint for the future clinical RCT of TBI antiepileptogenesis design. Once the future RCT is completed;

the data will be reassessed to determine the impact of the incorporated suggestions on recruitment and retention.

DISCUSSION AND RECOMMENDATIONS:

The unique design of the EpiBioS4Rx study with multi-center collaboration of concurrent studies in basic science, clinical biomarkers, and drug screening provides the community with a unique engagement effort to benefit patients with TBI who may develop PTE. To achieve this goal, stakeholders were selected based on knowledge, clinical expertise or research area through peer-to-peer outreach. At this stage, the consortium represents a multi-level group of stakeholders that is broad and representative of the fields of TBI and epilepsy. Moving forward, representation will be expanded by recruiting other stakeholders through multiple organizations and seeking a broad range of educational levels, sex, race, ethnicity and socioeconomic status.

Using this PAR approach, EpiBioS4Rx and the PEC are innovating clinical trial development in several ways through:

1. The development of research strategy and goals with the active participation of consumer groups and researchers.
2. The inclusion of specific populations particularly those more likely to experience head trauma, such as veterans. The exploration of sex differences and the best way to engage underserved populations.
3. Early public engagement from study inception to identify best strategies for recruitment, retention and knowledge transfer for a future PTE prevention trial.
4. Participation of international organizations for greater universal applicability and incorporation of feedback from other countries that have large populations with different attitudes regarding epilepsy and TBI.

The purpose of the PEC's contribution to EpiBioS4Rx is a rigorous study with public members as active partners with a vested stake in a future RCT. The EpiBioS4Rx clinical study is recruiting individuals who have suffered a moderate or severe TBI who do not have a diagnosis of epilepsy, although deemed at risk of developing PTE.

The PEC is working to remove possible barriers through education and support. For example, the ICU setting poses unique changes in the design and implementation of an RCT. Acutely, many individuals with moderate to severe TBIs may be mechanically ventilated and/or unresponsive (e.g., comatose).

When the individual is unresponsive, there may be limited understanding and even with adequate understanding, the barrage of emotions in an ICU can make the commitment to a long-term preventative RCT seem abstract. In addition, individuals with TBI may require extended monitoring due to the biphasic nature of the acute TBI and subsequent PTE with often a prolonged interval of months to years between TBI (first phase/stimulus) and the clinical presentation of epilepsy (second phase/response). Furthermore, during the prolonged rehabilitation phase after TBI, individuals may depend substantially on their family for

decision-making and logistical and emotional support. Identifying and addressing the needs and concerns of individuals and their families early on is essential to the enrollment process, sustained participation, and implementation of the RCT.

A significant concern is that, in a prevention study such as the proposed future PTE prevention trial, the physical and psychological consequences of a seizure to individuals/caregivers are theoretical at the time of the enrollment. The PEC begun addressing this problem by creating educational materials emphasizing two specific needs of the TBI community: the importance of an appropriate reading level and the need for translated and culturally sensitive content. In particular, Spanish-language materials were identified as important given the growing United States Spanish-speaking community. Within the future RCT, this may be the largest potential “English as a second language” group. To address this need, the PEC added a Spanish language subgroup of three clinicians (representing a variety of Spanish dialects) and a Spanish-speaking veteran living with TBI. This subgroup will assist in translating the produced materials and ensuring they are culturally sensitive.

Given the growing complexities of healthcare and medical research paradigms, we recommend that investigators consider community engagement, i.e., PAR, in all stages of clinical study design. PAR is unique because it integrates theory, basic science, clinical perspectives and community input to improve clinical studies, fosters a feedback loop, and ensure relevance of research aims and outcomes to the community of interest. PAR engagement may be enhanced by social media, the development of public materials (including websites) and a strong marketing strategy. These approaches can be resource intensive; therefore, incorporating PAR in clinical research must be planned carefully. Research teams should consider budgeting for additional resources to optimize their public outreach strategy and the success of any PAR guided clinical studies. Employing PAR methodology in the planning and implementation of future clinical trials has the potential to enhance study participation, retention, implementation and ultimately outcomes for those living with neurological conditions such as epilepsy and TBI. Prospective research is needed to identify best methods and evaluate the efficacy of integrating PAR into an RCT.

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Appendix

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Abbreviations:

CWOW	Center Without Walls
EpiBioS4Rx	The Epilepsy Bioinformatics Study for Antiepileptogenic Therapy
ESC	Epilepsy Study Consortium
IRB	Institutional Review Board
NINDS	National Institute of Neurologic Disorders and Stroke
OVC	Ohio Valley Center for Brain Injury Prevention and Rehabilitation
PAR	Participatory Action Research
PCC	Project Coordinating Committee
PCORI	Patient-Centered Outcomes Research Institute
PEC	Public Engagement Core
PCOs	Patient-Centered Outcomes
PTE	Post-Traumatic Epilepsy
REN	Rare Epilepsy Network
RCT	Randomized Controlled Trial
TBI	Traumatic Brain Injury
TBIMS	Traumatic Brain Injury Model Systems
USDHHS	United States Department of Health and Human Services
VA ECoE	Veterans Affairs Epilepsy Centers of Excellence

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Figure 1:

Spectrum of public/stakeholder involvement and impact in participatory action research (PAR). Adapted version of the International association of public participation (IAP2) spectrum of public participation. Copyright permission obtained from the IAP2 (Participation, 2016).

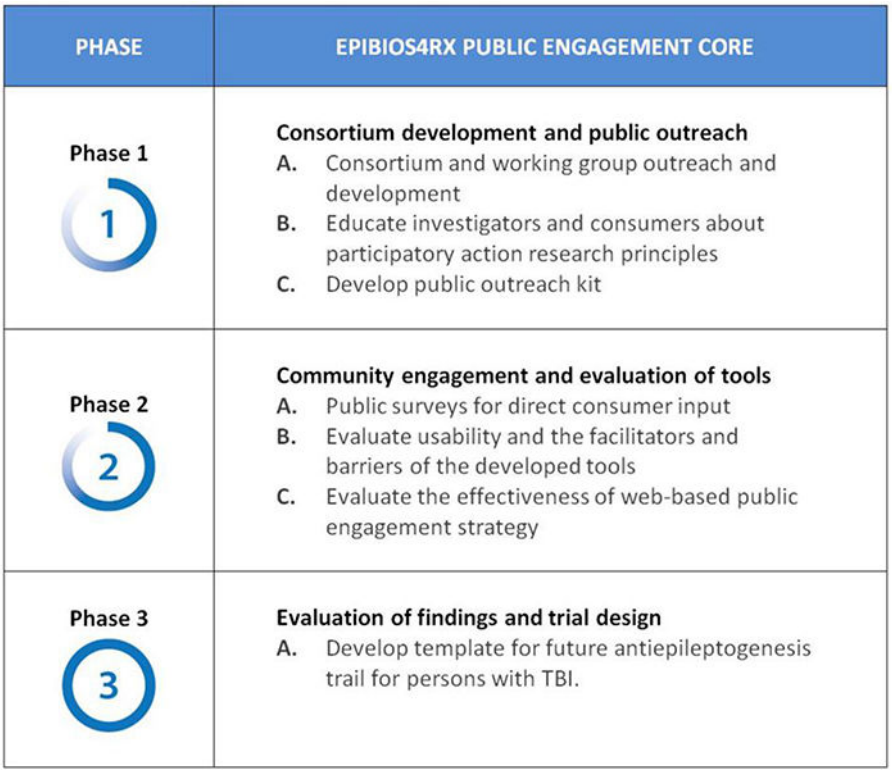

Figure 2:
Summary of the project phases and components for the EpiBioS4Rx Public Engagement Core (PEC) over a 5-year NIH grant period

Table 1:

Participating organizations within the Public Engagement Core (PEC) of the Epilepsy Bioinformatics Study for Anti-Epileptogenic Therapy (EpiBioS4Rx)

EPIBIOS4RX PUBLIC ENGAGEMENT CORE PARTNERS		
	Epilepsy	**Traumatic Brain Injury**
Service, Advocacy, Consumer, And Research Groups	Epilepsy Foundation (www.epilepsy.com)	Brain Injury Association of America (BIAA) (www.biausa.org)
	International Bureau for Epilepsy (IBE) (www.ibe.epilepsy.org)	TBI Model Systems (TBIMS) (www.tbindsc.org)
	Citizen United for Research in Epilepsy (CURE) (www.cureepilepsy.org)	
	Epilepsy Support Centre (www.epilepsysupport.ca)	
	Living Well With Epilepsy (www.livingwellwithepilepsy.com)	
	Epilepsy Awareness Organization (www.epilepsyawarenessday.org)	
	The Epilepsy Study Consortium (www.epilepsyconsortium.org)	
Veteran Organizations	Veterans Affairs (VA) Epilepsy Centers of Excellence (www.epilepsy.va.gov)	
Professional Societies	International League Against Epilepsy (ILAE) (www.ilae.org)	National Neurotrauma Society (NSS) (www.neurotrauma.org)
	American Epilepsy Society (AES) (www.aesnet.org)	International Neurotrauma Society (INS) (www.ints2014.com)
Health Organizations		World Health Organization (WHO) (www.who.int)
		Pan American Health Organization (www.paho.org)