Study Title: Health System Integration of Tools to Improve Primary Care for Autistic Adults

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Health System Integration of Tools to Improve Primary Care for Autistic Adults

Abstract:

The health system is ill-equipped to meet the needs of autistic adults. Our prior work has identified significant healthcare disparities experienced by autistic adults, including greater unmet healthcare needs, lower use of preventive services, and greater use of the Emergency Department (ED). A majority of primary care providers (PCPs) lack the skills needed to care for autistic adults, yet competing priorities make it unlikely they will attend trainings on autism. The heterogeneity of the autism spectrum may also make it challenging for PCPs to understand specific patients' needs. The Academic Autism Spectrum Partnership in Research and Education (AASPIRE), an academic-community partnership comprised of academics, autistic adults, healthcare providers, and supporters, has used a community based participatory research (CBPR) approach to develop and test an online healthcare toolkit aimed at improving primary care services for autistic adults. It was specifically designed as a low-intensity, sustainable intervention that can realistically be used in busy primary care practices that do not have a special focus on autism or other developmental disabilities. The toolkit includes the Autism Healthcare Accommodations Tool (AHAT)--an automated tool which allows patients and/or their supporters to create a personalized accommodations report for their PCP--and other targeted resources, worksheets, checklists, and information. Our pilot work has demonstrated that the AHAT has strong construct validity and test-retest stability, the toolkit is highly acceptable and accessible, and it has the potential to decrease barriers to care and increase patient-provider communication. Our long-term plan is to conduct a hybrid effectiveness-implementation trial, using a cluster randomized trial design, both to test the effectiveness of the AASPIRE Healthcare Toolkit in improving healthcare quality and utilization and to assess the utility of implementation strategies in diverse healthcare systems. The objective of this proposal is to use a CBPR approach to understand how to integrate the toolkit into these health systems, collect more robust efficacy data, and explore potential mechanisms of action. We will do so by conducting a 6-month pilot study with patients assigned to intervention and control clinics in three diverse health systems. We will meet our objectives by achieving the following specific aims: 1) *to determine how to integrate use of the toolkit within diverse health systems*; 2) t*o test the effect of the toolkit on short-term healthcare outcomes*; 3) t*o use a mixed-methods approach to further explore the toolkit's mechanisms of action*; and 4) t*o refine our recruitment, retention, data collection, and system integration strategies in preparation for the larger cluster-randomized trial*. Successful integration of this easily scalable and sustainable low-intensity intervention into primary care practices within diverse health systems will empower patients and providers to work together to improve health outcomes for a large, underserved, and understudied population with great barriers to care.

Specific Aims

Despite growing attention to the needs of autistic children, the health system is ill equipped to meet the needs of autistic adults. Our prior work has identified significant healthcare disparities experienced by autistic adults, including greater unmet healthcare needs, lower use of preventive services, and greater use of the Emergency Department (ED). These disparities likely stem from a complex interaction between patient-, provider-, and system-level factors. Autism entails atypical communication and interpersonal relationships, and challenges with executive function – factors that are critically important for effective healthcare interactions and health system navigation. Moreover, a majority of primary care providers (PCPs) lack the skills needed to care for autistic adults, yet competing priorities make it unlikely they will attend trainings on autism. The heterogeneity of the autism spectrum may also make it challenging to understand a specific patient's needs. Finally, autistic patients may be disproportionally affected by the complexity of the health system, low socio-economic status, and societal biases, yet few systems can afford autism-specific care coordination programs for adults.

The Academic Autism Spectrum Partnership in Research and Education (AASPIRE), an academic-community partnership comprised of academics, autistic adults, healthcare providers, and supporters, has used a community based participatory research (CBPR) approach to develop and test an online healthcare toolkit aimed at improving primary care services for autistic adults. It was specifically designed as a low-intensity, sustainable intervention that can realistically be used in busy primary care practices that do not have a special focus on autism or other developmental disabilities. The toolkit includes the Autism Healthcare Accommodations Tool (AHAT)--an automated tool which allows patients and/or their supporters to create a personalized accommodations report for their PCP--and other targeted resources, worksheets, checklists, and information. A series of NIMH-funded studies demonstrated that the AHAT has strong construct validity and test-retest stability, and that the toolkit is highly acceptable and accessible. In a 1-month pre-post intervention comparison, we found a decrease in barriers to care and increases in patient-provider communication and confidence in healthcare. Despite these promising preliminary results, more data is needed to test its effectiveness and understand how to best integrate it into diverse primary care practices and health systems.

Our long-term plan is to conduct a hybrid effectiveness-implementation trial, using a cluster randomized trial design, both to test the effectiveness of the AASPIRE Healthcare Toolkit in improving healthcare quality and utilization and to determine the potential utility of implementation strategies in diverse healthcare systems. The objective of this proposal is to use a CBPR approach to understand how to best integrate the toolkit into these health systems, collect more robust efficacy data, and explore potential mechanisms of action. We will do so by conducting a **6-month pilot study** with patients assigned to intervention and control clinics in three diverse health systems. We will meet our objectives by achieving the following specific aims:

1. *To determine how to integrate use of the toolkit within diverse health systems*. Our existing CBPR partnership will expand to include local patients, providers, staff, and administrators from each system. Together, we will decide how to make patients and providers aware of the toolkit, integrate the AHAT into the electronic medical record, and respond to recommendations. We will collaboratively develop implementation protocols and determine how to track them. We will then conduct a mixed-methods, formative process evaluation to optimize the likelihood of success of future implementation efforts.
2. *To test the effect of the toolkit on short-term healthcare outcomes*. We hypothesize that, over 6 months, the toolkit will increase satisfaction with patient-provider communication and decrease barriers to healthcare in patients from intervention clinics as compared to patients from control clinics.
3. *To use a mixed-methods approach to further explore the toolkit's mechanisms of action.* Quantitative data will help us refine and psychometrically test our measures of patient self-advocacy and visit preparedness; provider/staff use of desired accommodations and strategies; and patient and provider self-efficacy. Qualitative data will allow us to obtain a richer understanding of how the toolkit is affecting care and potentially suggest additional mechanisms of action.
4. *To refine our recruitment, retention, data collection, and system integration strategies in preparation for the larger cluster-randomized trial*. We will use this study to confirm or modify our change model, choose long-term health utilization outcomes to be further studied in the R01, finalize study protocols and data collection instruments, and develop a flexible implementation strategy that can be feasibly applied to diverse primary care clinics.

Successful integration of this scalable and sustainable low-intensity intervention into primary care practices within diverse health systems will empower patients and providers to work together to improve health outcomes for a large, underserved and understudied population with great barriers to care.

Significance

This project will result in the preliminary data necessary to inform a large hybrid effectiveness/implementation trial of a practical, easily scalable, and sustainable intervention to improve the healthcare of autistic[a] adults.

Autism is increasingly being recognized in the adult population. The Center for Disease Control and Prevention estimates that 1 in 68 children are identified as having an autism spectrum disorder (ASD).[1] Though the prevalence of autism has appeared to rise dramatically in the last two decades, much of that rise is likely due to changes in how diagnostic criteria are being applied.[2] A large study found a 1% prevalence of ASD, with no change in autism prevalence based on age.[3-5] Even if fewer adults currently recognize they are on the autism spectrum due to missed diagnoses during childhood, the large cohort of adolescents with known ASD are rapidly approaching adulthood and will need to receive healthcare from PCPs who care for adults.

Autistic adults face significant healthcare disparities. Our prior survey found that autistic adults had a greater number of unmet health needs, lower use of preventive services, higher use of the emergency department (ED), and lower ratings of patient-provider communication and healthcare self-efficacy than non-autistic adults.[6] Autistic adults also reported a greater overall number of barriers to healthcare and numerous autism-specific barriers to care.[7] Others have found that total mean ED charges were 2.3 times higher for autistic adults than non-autistic adults.[8] In our qualitative study, autistic patients and their supporters described many problematic healthcare interactions, illuminating a complex interplay between an individual's autistic characteristics, the healthcare provider's knowledge and attitudes about autism, and the healthcare system.[9]

Primary care providers lack the knowledge and skills necessary to care for autistic adults. PCPs' lack of sufficient knowledge on how to care for adults with developmental disabilities has been identified as a major problem.[10,11] For example, despite increased attention to developmental disabilities in pediatric residency programs,[12] there are no training requirements for the care of adults with developmental disabilities for residents in internal medicine[13] or family medicine.[14] In our co-investigator's study of 922 adult healthcare providers, 77% rated their knowledge and skills in providing care to autistic patients as poor or fair.[15] The problem is compounded by the very nature of the autism spectrum, which includes a great amount of heterogeneity. Knowledge related to taking care of one autistic patient may or may not be helpful in the care of other autistic patients with different autistic characteristics, strengths, and needs.

Autism in adults is still a low incidence condition for most PCPs, few of whom are likely to take part in time-consuming training efforts. As the cohort of autistic children diagnosed in the last two decades has started to age, there has been a growing interest in "transition" to adulthood, with many calls for increased training efforts for PCPs who care for adults.[16,17] However, autism has not yet risen to an area of concern for adult PCPs, a majority of whom have many competing priorities and only a few autistic patients in their panels. For example, even though 73% of PCPs in our survey felt uncomfortable in their ability to provide quality care for autistic adults, 84% stated that they were unlikely to seek additional training on ASD (see preliminary results). Our co-investigators found that a majority of PCPs were not even aware they had adult patients with ASD.[15] As PCPs ourselves, and as educators of PCPs, we are critically aware of the crowded curriculum in residency and continuing education programs and appreciate the need for other types of solutions.

Health systems face significant challenges to providing quality care to autistic adults. Optimally, health systems will develop local care coordination and medical home models, as well as regional consultation services with specific expertise in autism.[18] Specialized referral sources for autistic adults, however, remain scarce.[15] Moreover, coordinated care approaches in the adult health care system typically focus on common adult conditions such as depression or diabetes that drive adult healthcare costs[19] and may not automatically meet the needs of autistic adults. Interventions are needed to complement and support primary care transformation efforts. In order to ensure maximum scalability and impact, such interventions need to be implemented with a relatively low investment from health care systems.

The AASPIRE Healthcare Toolkit was created, using a CBPR approach, to be an easily scalable, low-intensity intervention that meets the needs of both patients and PCPs. Our team of autistic adults, family members, and PCPs developed this toolkit with the above challenges in mind. The toolkit allows PCPs to access information on a "need to know" basis, focusing only on the most important, personalized, and succinct

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[a] We appreciate the perspectives of people on both sides of the debate regarding the use of person-first vs. identity-first language in autism. We use identity-first language in this proposal to respect the wishes of our autistic partners. All our participant materials use the more neutral term "on the autism spectrum".

data needed to care for a particular patient. Additional information is available online for providers who desire more extensive resources. Patient resources are tailored to autistic patients, who generally prefer very detailed information in accessible language, along with practical worksheets and checklists. The toolkit is free to use and does not require specialized trainings, costly implementation strategies, or additional personnel.

Preliminary studies suggest the toolkit is highly acceptable and has the potential to improve the care of autistic adults. We evaluated the toolkit with a national convenience sample of 170 autistic adults with diverse disability-related characteristics.[20] Almost all (>94%) felt that the AHAT and the toolkit were easy to use, important, and useful. In a single arm, 1 month, pre-post intervention comparison, we found significant decreases in patient-reported barriers to healthcare and increases in satisfaction with patient-provider communication. (See preliminary results). However, our study was not designed to promote or assess integration of the toolkit into specific primary care practices, nor did it assess provider impressions in-depth.

A large, multi-site, hybrid effectiveness/implementation trial will have the greatest possible impact on improving the way healthcare is delivered to autistic adults. We had initially anticipated following our pilot work with a traditional, large effectiveness trial, which could later be followed by implementation and dissemination efforts. However, we have come to realize that that may not be an optimal strategy in this situation. Though we were pleased with our pilot results, we were concerned that the toolkit's potential utility was lessened by its lack of integration into the work-flow of primary care practices. In order to integrate the toolkit into clinical care, one would have to conduct the effectiveness trial within specific practices. Between the low number of autistic adult patients per site and the threat of contamination if the unit of randomization is the patient or the provider, such a study would need to include a large number of practices. It would be conceivable to conduct such a trial in a very large, integrated system such as Kaiser Permanente, but generalizing that experience to other primary care practices may then be challenging. Integration of the toolkit into the clinic operations of different sites requires attention to implementation issues from the outset. As such, our long-term goal is to conduct a large, cluster-randomized controlled trial using a hybrid effectiveness/ implementation approach, as outlined by Curran et al.[21] To prepare for such a trial, more data is needed on ways to integrate the healthcare toolkit and the research study into varied health systems. This project will allow us to obtain the data necessary to successfully prepare for the larger effectiveness/implementation trial.

Innovation

Little is known about how to improve healthcare services for autistic adults. Improving access to quality healthcare is a high priority for the Interagency Autism Coordinating Committee[22], the community of autistic adults,[23,24] and people who support autistic adults,[24,25] but rarely have research studies focused on this important issue. To our knowledge, our AASPIRE work[6,7,9,20,26] and that of our co-investigators at Kaiser[15,27] constitute a majority of literature on the primary care services of autistic adults. This study will provide critical information that can further our understanding of how to improve healthcare services for autistic adults.

Autism research rarely includes autistic adults in the research process in an authentic and meaningful way. Our project greatly benefits from the strengths, insights, and experiences of autistic adults and their supporters, both as research participants and collaborators. CBPR and other participatory approaches may strengthen scientific and ethical practices to improve the quality of the science.[28-33] Our group has been working together for almost a decade, during which time we have developed a strong infrastructure and processes to enable true participation in the research process by members of the autistic self-advocacy community, as well as by other stakeholders, including family members, healthcare providers, and disability professionals.[34] Despite a large increase in the use of CBPR in health services research, its use with autistic adults remains uncommon. Several reviews by authors unaffiliated with our team have pointed to AASPIRE as the only participatory research group in the published literature authentically including autistic individuals throughout the research process.[35-37] We do see gradual but steady uptake in participatory approaches in the autism field and have offered a number of consultations in recent years to autism researchers wishing to incorporate input from autistic individuals. Lessons from this project may encourage other autism researchers to authentically include autistic individuals on their team.

Few health services instruments have been adapted or tested for use with autistic adults. A common limitation in studies using autistic participants is the use of standardized instruments developed in general populations, without attention to language pragmatics issues or other challenges experienced by autistic individuals. Our experience with autistic participants and community partners, including those with high educational attainment, is that trying to answer surveys using un-adapted instruments often causes confusion, frustration, and anxiety, and may lead to incomplete or inaccurate data. We have used our CBPR approach to

adapt numerous health and health services instruments to be accessible to autistic individuals.[6,34,38] We have done so by rewording confusing items, adding hotlinks to define difficult or vague terms or offer examples, including graphics for response options using Likert scales, changing prefaces to make instructions more clear, and/or adding autism-specific items, each time reassessing psychometric properties. We also have begun to create and validate a number of new instruments to specifically address autism-specific services issues.[7,20] This project will allow us to further refine and validate these instruments. Our instruments can advance the field by helping others more accurately study autism services. Moreover, our processes can serve as an example for those wishing to adapt other surveys.

Our project may provide insight into the types of interventions and implementation strategies that can address important but uncommon conditions or topics not yet considered high priority areas by primary care providers. Our intervention approach, which provides patient-specific information on a need-to-know basis to busy PCPs, may be useful in other complex, low-incidence conditions.

Approach

Preliminary Studies

The Academic Autistic Spectrum Partnership in Research and Education (AASPIRE): AASPIRE is an academic-community partnership comprised of autistic adults, academic researchers, healthcare providers, and family members. Community partners serve as equal partners in every stage of each project, ensuring that research questions are relevant to the community, that methods and instruments are accessible, and that findings result in social change. We have created a strong infrastructure for equal and effective partnership and to develop communication and work strategies that capitalize on members' strengths and accommodate their needs.[34] One of AASPIRE's main areas of interest has been the healthcare of autistic adults. We have collaboratively conducted a series of studies (funded via a CTSA pilot grant and an NIMH R34) to inform, develop, and test the AASPIRE Healthcare Toolkit, as shown in **Figure 1**. These studies directly lead to the current proposed project, which will in turn result in the necessary data for the future R01.

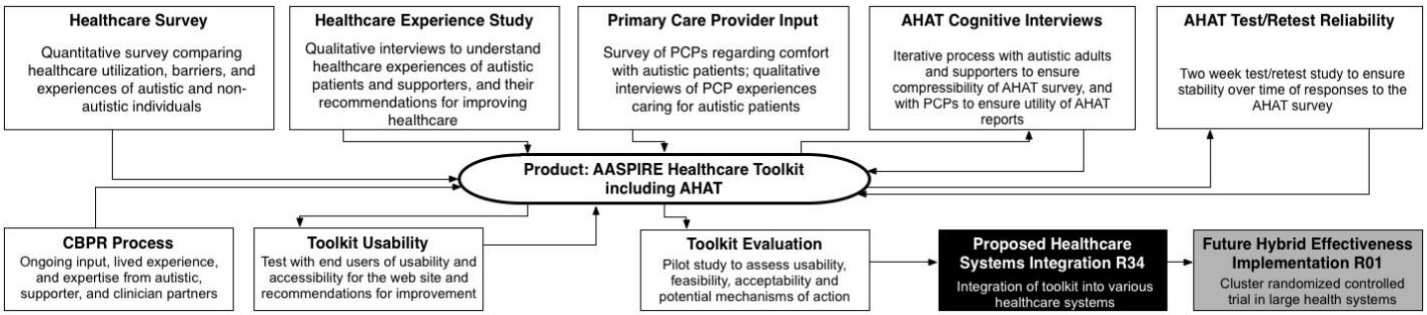


Figure 1: AASPIRE Healthcare Studies

Healthcare Disparities Survey

We conducted an online survey to compare the healthcare experiences of autistic and non-autistic adults[6]. We adapted commonly used survey instruments to be accessible to autistic adults and assessed preliminary psychometric data on the adapted scales. 437 participants completed the survey (209 autistic, 228 non-autistic, with or without other disabilities). All adapted scales had good to excellent internal consistency reliability (alpha 0.82–0.92) and strong construct validity. In multivariate analyses, after adjustment for demographic characteristics, health insurance, and overall health status, autistic adults reported lower satisfaction with patient-provider communication (beta coefficient −1.9, CI −2.9 to −0.9), general healthcare self-efficacy (beta coefficient −11.9, CI −14.0 to −8.6), and chronic condition self-efficacy (beta coefficient −4.5, CI −7.5 to −1.6); higher odds of unmet healthcare needs related to physical health (OR 1.9 CI 1.1–3.4), mental health (OR 2.2, CI 1.3–3.7), and prescription medications (OR 2.8, CI 2.2–7.5); lower self-reported rates of tetanus vaccination (OR 0.5, CI 0.3–0.9) and Papanicolaou smears (OR 0.5, CI 0.2–0.9); and greater odds of using the ED (OR 2.1, CI 1.8–3.8). These findings informed our choices regarding which healthcare outcomes to study as well as our hypotheses about which mechanisms of action to target with the toolkit.

Barriers to Healthcare Study

We also used our online survey to better understand barriers to healthcare for autistic adults. As no instrument existed to measure autism-specific barriers to care, we adapted the "Access Barriers Checklist" instrument,

created by our colleagues from a literature review.[39] To make it more accessible to autistic participants, we clarified language and sentence structure, added pop-up definitions for difficult words, and removed redundant items. We added autism-related items such as sensory discomforts, difficulty identifying symptoms, and concerns about meltdowns. We also replaced the single item on communication with a section of communication-related barriers. The final survey included an item pool of 60 barriers. We reduced the instrument to the 41 items endorsed by 10% or more of participants and sorted them into semantically related categories to create the "Barriers to Healthcare Checklist: Long Form." We created a shorter version that would be more practical in clinical or research settings by combining functionally redundant items, collapsing lower-granularity items into single higher-granularity items, and verifying that pair-wise correlations were high between combined items. We used this 16-item "Barriers to Healthcare Checklist: Short Form" instrument in our Toolkit Evaluation Study, and will use it in this proposed project.

We compared responses to the Barriers to Healthcare Checklist: Long Form between 1) autistic participants and participants without disabilities, and 2) autistic participants and participants who had other disabilities. A significantly higher proportion of autistic than non-disabled participants endorsed all barriers except lack of insurance. Autistic participants were significantly more likely than those with other disabilities to endorse items related to emotional stress, trouble following medical instructions, difficulty understanding the healthcare system or seeking care or follow-up, having behavior misinterpreted, communication, sensory barriers, and handling the waiting room. As expected, items about patient-provider communication and sensory processing were among those most selected by the autistic participants; for example, difficulty processing information fast enough to participate in real-time healthcare discussions (32%), sensory distress caused by facilities (30%), and capacity to tolerate exams and tests (24%). We built many aspects of the toolkit to target these barriers.

Qualitative study of healthcare experiences of autistic adults

We conducted a qualitative study to obtain a rich understanding of autistic adults' experiences with healthcare and their ideas for improving their care.[9] We completed semi-structured, open-ended interviews with 39 autistic adults, and 16 family members and disability services professionals who have supported autistic adults in healthcare settings. Autistic participants had a wide range of disability-related characteristics (e.g., 13% primarily communicated by methods other than speech, and over half lived in group homes or with family.) Participants expressed a range of satisfaction with healthcare, but what differentiated positive and negative experiences almost always related to the interplay among patient-, provider-, and system-level factors.

Participants identified numerous patient-level, autism-related factors that impact healthcare interactions, including verbal communication skills, atypical non-verbal communication, sensory sensitivities, challenges with body awareness (e.g., differentiating pain or other sensations), slow processing speed, and challenges with organization. These patient-level factors interacted with provider-level factors such as providers' knowledge about autism in adults, incorrect assumptions about individual patients, willingness to allow written communication, use of accessible language, openness to providing other accommodations (e.g., turning off fluorescent lights), and skill in appropriately incorporating supporters. Finally, participants' healthcare experiences could not be separated from the larger context in which they lived and received care. System-level factors included the availability of supporters, complexity of the healthcare system, accessibility of healthcare facilities, and stigma about autism. We used these findings to build a conceptual model that has guided the rest of our work **(Figure 2),** to identify potential leverage points that could be targeted with our intervention, and to inform the types of tools and resources to include in the toolkit.

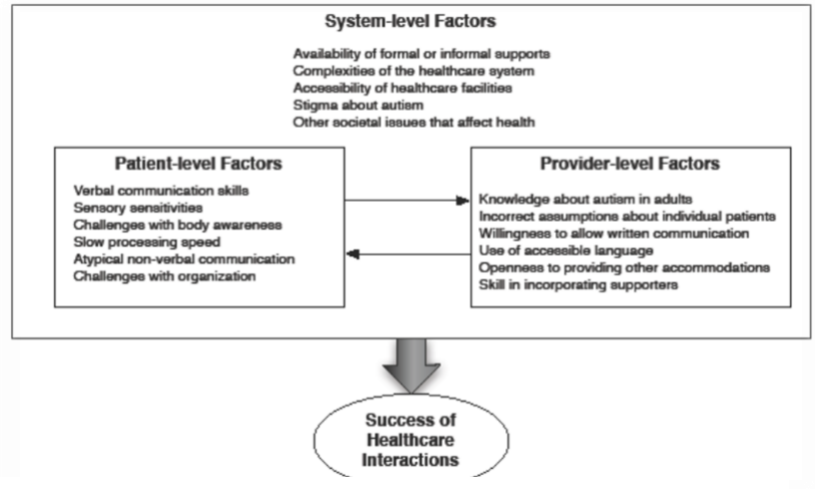


Figure 2: Conceptual Model

PCP Needs Assessment: We conducted a needs assessment survey with 129 PCPs who regularly care for adult patients. The majority, 88%, of the providers had cared for 3 or fewer autistic adults in the past year.

Even though 73% stated they felt uncomfortable in their ability to provide quality care for autistic adults, 84% stated that they were unlikely to seek additional training on ASD within the next year. Nonetheless, 88% stated they would accept an autistic patient into their practice if they presented for care. Even under those circumstances, less than half stated that they were likely to attend a CME event on ASD, but 82% stated that they were likely to search the Internet for information on ASD. We then asked respondents to imagine that an autistic patient brought them a brief customized report (like the AHAT) from a reputable source, and explained what would be included in such a report. Virtually all of the providers, 98-99%, stated they would read such a report, consider following its recommendations, and appreciate the patient's effort. Finally, we conducted in-depth interviews with 10 PCPs to better understand their experiences and recommendations.

Development and psychometric testing of the AHAT

Recognizing the substantial heterogeneity of autistic individuals, our research participants and team members felt that communicating *personalized* information about individual patients was essential.[9] The toolkit's centerpiece is thus the Autism Healthcare Accommodations Tool (AHAT), which allows patients to create a personalized accommodations report for their healthcare provider. A patient or his/her supporter completes the AHAT survey to automatically generate a customized cover letter and AHAT report for the provider.

We used the recommendations elicited in our qualitative studies, and the lived and professional experience of the community and academic partners on our team, to create the AHAT survey items. There are two versions, one for autistic adults and one for supporters. The AHAT survey includes 5 multiple-choice items about the patient's spoken and written communication abilities and use of alternatives to speech, and 12 items about areas where autistic adults may need strategies and accommodations to facilitate care, or where providers may need to be aware of autism-related characteristics. Each of these items uses a check-all response format and lists five to fourteen potential accommodations, strategies, or characteristics, an option indicating that no accommodations are needed, and one indicating that accommodations are needed, but not listed. There are also open-ended items related to patients' strengths, special interests, and strategies to recognize and address anxiety in healthcare settings, and a section eliciting information about supporters. AHAT reports translate this information into a clinically useful format, with separate sections for providers, front office and back office staff. The AHAT survey and samples of AHAT reports are provided in **Appendix A.**

We assessed content validity of the AHAT survey and reports by conducting cognitive interviews with autistic adults, supporters, and PCPs and reviewed the AHAT with local groups of PCPs and autism experts. Autistic participants consistently indicated that the AHAT was important and easy to understand. Most felt that all their necessary accommodations were included in the options. All PCPs indicated the content of the report was very helpful, but some PCPs looking at earlier versions felt it would be difficult to access the information. We altered the AHAT report format multiple times until we found one that maximized ease of use for PCPs.

We then conducted a two-week test-retest reliability study with autistic participants and supporters to test the stability of the tool over time. Taking each response option for the check-all items as a separate dichotomous variable, the original AHAT included 132 variables. We calculated the percent of the time participants gave the same response on the two versions of the survey, as well as a kappa and a phi statistic for each variable. In test-retest comparisons, participants answered AHAT items similarly 80% of the time (mean .803, std 0.08).

Evaluation of the Healthcare Toolkit

We housed the AHAT within an online Toolkit now available at www.autismandhealth.org. Our team of academic and community partners jointly created and edited materials to ensure their relevance, utility, and accessibility. In general, we found that our autistic participants and team members desired a high degree of detail and examples, especially on topics related to navigating the healthcare system. The resulting AASPIRE Healthcare Toolkit has a section for patients and supporters and another for healthcare providers. It includes general healthcare and autism-related information, checklists, worksheets, and other resources. See **Appendix B** for sample screenshots of the toolkit and a print-out of the patient and provider resources.

We evaluated the full toolkit using a mixed-methods, single arm, pre-post intervention study design. We used a convenience sample of autistic adults recruited nationally and locally via disability-oriented organizations and forums. After completing a baseline survey, autistic participants (or their supporters) used the AHAT tool to create a personalized report and decided whether to have it sent to their PCP. They then gained access to the remainder of the online toolkit. One month after using the toolkit, participants completed a post-intervention survey. In cases where participants asked us to send the AHAT report to their provider, we surveyed PCPs approximately one month after the intervention to assess whether they found the report useful.

170 autistic adults participated in the study, either independently or with support. Participants had a wide range of disability-related characteristics (e.g. approximately 1/3 required assistance to receive healthcare always or often, 1/3 required it sometimes, and 1/3 rarely or never; approximately half lived in their own place and half with family or in a group home). Almost all patient participants (>94%) felt that the AHAT and the toolkit were easy to use, important, and useful. A majority (65%) of participants gave permission for us to mail their AHAT report to their PCP. Of the thirty-five participants who answered an open-ended item about why they chose not to have their report sent, a majority indicating that they planned on bringing the report to the PCP themselves (N=8), were in the process of changing or did not have PCP (N=8), or did not need it (N=6). A small number did not wish to disclose their ASD to their PCP (N=4), had privacy concerns (N=2), didn't like the report (N=1) or worried that their PCP would not react well to it (N=2). We were able to send AHAT reports to 88 PCPs, 41 (47%) of whom completed the survey. Most of the PCPs surveyed read the AHAT (97%), rated it as moderately or very useful (82%), and would recommend it to other patients (87%).

In pre-post intervention comparisons, the mean number of barriers decreased significantly (4.07 to 2.82, $p<0.0001$, effect size -0.55). For the 43 participants who saw their PCP during the one month follow-up period, satisfaction with PCP communication improved significantly (mean 30.9 to 32.6, $p=0.03$, effect size 0.26). Of note, we also found small but significant increases (mean 37.9 to 39.4, $p=0.02$, effect size 0.12) in a 21-item scale that we created de novo to capture potential toolkit-specific changes in patients' confidence in healthcare. While the scale had demonstrated strong internal consistency (alpha 0.92), additional work is needed to refine this scale and better target it to the toolkit's potential mechanisms of action.

Responses to open-ended survey questions have started to help us understand how the toolkit may be affecting change. Patients stated the toolkit helped clarify their needs, enabled them to self-advocate and prepare for visits more effectively, and positively influenced provider's willingness to offer accommodations. For example, one participant wrote "It takes away a lot of my uncertainty about the appointments. Whether I'll bring up everything I want to bring up, whether I asked the right questions about follow up care, and being prepared for talking to new doctors. It's a game changer for me." Another wrote "<My provider> went over it with me and did what had been recommended….I felt like some of the difficulties I experience were addressed and that they wouldn't have been had I not made use of the Healthcare Toolkit." Most answers from PCPs to open-ended questions were positive and provided examples of the tool's utility (e.g. "Extremely helpful. What I needed were specific, but concise suggestions regarding how to make my patient more comfortable. The report will be in her chart and I will use it at each visit.")

Research Design and Methods

Community Academic Partnership

The Co-Directors of AASPIRE, Drs. Nicolaidis and Raymaker, will serve as PI and Co-I, respectively. Both bring dual perspectives as academic researchers and members of the larger autism community. Dr. Nicolaidis is a health services researcher, PCP, and parent of an autistic teenager. Dr. Raymaker is an autistic individual who co-founded AASPIRE as the Community PI, but who has since earned her PhD in systems science, in part thanks to AASPIRE's strong emphasis on community capacitation.[40] Our full team of academic and community partners (including additional autistic adults, family members, and PCPs) works closely together to guide all aspects of the project. A Steering Committee with representatives from each community helps resolve conflicts, as needed. Team members communicate on a very active list-serve. Meetings occur in a variety of ways (e.g., in-person, text-based chat, video-conferencing, telephone) to accommodate the social and communication needs of autistic partners as well as the geographic dispersion of our team. We break up into smaller workgroups, as needed, to accomplish specific tasks, but always make sure to have adequate representation from community partners and buy-in from the full team. Careful attention is given to making feasible accommodations to support active participation by all members. We have written memoranda of understanding guiding our collaboration, including a formal consensus-building process, and authorship and presentation guidelines. One of the main principles of CPPR is that projects should have a transparent and iterative process for evaluating progress and impact.[41] AASPIRE uses double-loop learning[42] in its standard operating procedures by doing regular "CBPR check-ins" to critically examine both our processes and our underlying understanding of who we are and what we are doing and then adjusting our processes and/or our underlying assumptions about our goals, values, or mental models to improve our operations. Additional information about our collaboration processes is described in our CBPR-focused publications.[34,43,44] In this project, our team will expand to include a new academic partner (Dr. Lisa Coen of Kaiser Permanente) and several new community partners from our partnering health care systems. These new team members will

represent local PCPs, primary care office staff, administrators, patients, and supporters. As we have done in the past, we will have meetings specifically focused on welcoming new members to the team and integrating them into the CBPR process. These new members will be critical to helping us ensure the most feasible and effective strategies for integrating the AASPIRE Healthcare Toolkit into their local health systems.

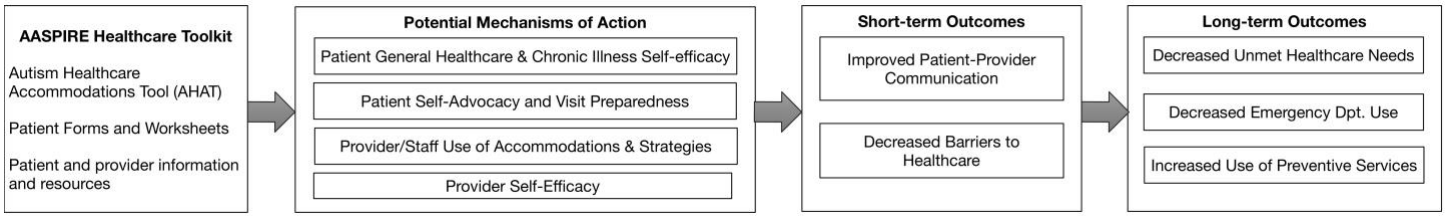
Setting:

We will conduct the study within clinics from three diverse systems. A majority of participants will be recruited from Kaiser Permanente Northern California (KPNC), an integrated healthcare delivery system with more than 3.5 million members, 20 hospitals, and over 50 outpatient clinics. KPNC has over 6600 adult members with diagnoses of Autism Spectrum Disorder (ASD). The KPNC team will select 4 intervention clinics and 4 matched control clinics to participate in the study and can select additional clinics if we do not meet anticipated recruitment goals. Seventeen KPNC clinics each have >100 adult patients with diagnosed ASD. Kaiser's great resources and commitment make it an optimal site both for this pilot study and for a future large RCT. However, we recognize that Kaiser's strengths as an integrated health system can limit generalizability. As such, we will also study a variety of additional clinics in Oregon to proactively develop an implementation plan that can be effective in diverse practices. We will work with two clinics from Legacy Health System, a private, non-profit hospital system with 6 hospitals and 26 primary care clinics. Though each of the Legacy primary care clinics has only about two-dozen adult patients with diagnosed ASD, we feel it's important to study the implementation of the toolkit in a private health system with low prevalence of diagnosed ASD, as that may be more typical. Finally we will use two of the four primary care clinics run by the Oregon Health and Science University (OHSU) Department of Family Medicine. We chose these two clinics because they represent diverse practices – the Gabriel Park Clinic is in an urban area and the Scappoose Clinic is a rural health center in a town of under 7000 people. The two clinics have a total of approximately 200 adult autistic patients. Though the two sites are so different that they cannot serve as controls for one another, they each consist of 4 "pods" that function independently, with their own group of providers, front and back office staff, and patient panels. As such, we will use two pods as the intervention site and two pods as the control site for each of the OHSU clinics. All three participating health systems use Epic as their electronic medical record (EMR).

Overview, Study Design and Change Model:

We will conduct a mixed-methods study (concurrent QUANT-qual), using a CBPR approach, in preparation for a future cluster randomized hybrid effectiveness/implementation trial. Qualitative data will supplement quantitative data to obtain a deeper understanding of implementation issues and patient and provider experiences, to further explore potential mechanisms of action, and to help interpret quantitative findings. We will start by working with representatives from each intervention site to determine how to integrate the toolkit into their practices and track implementation efforts. We will pay attention to what might be done similarly across systems and what has to differ to accommodate practice needs. We will then conduct a 6-month, non-randomized, controlled, pilot study in 5 intervention sites and 5 control sites. Though control sites are sometimes considered an unnecessary use of resources in pilot-studies, in this case, it is important to collect data from control sites to 1) ensure that we can obtain adequate recruitment and retention rates, even without offering an intervention, 2) to assess for potential contamination being that patients and providers are free to use the publicly available toolkit, and 3) to obtain more robust efficacy data on the toolkit's short-term outcomes and potential mechanisms of action than we could in our prior 1-month, single-arm trial.

Figure 2: Change Model



Our study is based on the conceptual model we developed from our qualitative work (see Preliminary Results). This model views successful healthcare outcomes as being dependent on the interaction between patient- and provider-level factors within a larger context of system-level factors. We developed the toolkit to target potential leverage points within this model. Specifically, it is meant to give patients and providers the tools they need to improve their self-efficacy while encouraging providers and staff to use desired, patient-specific accommodations and recommended strategies. We hypothesize that doing so will improve patient-provider

communication and decrease barriers to healthcare, with possible long-term impacts on unmet healthcare needs and healthcare utilization. **Figure 2** shows our proposed change model.

Our study will use multiple data sources: 1) process information from research records, EMR, and clinic protocols, 2) baseline and follow-up surveys of autistic participants in intervention and control clinics, 3) brief baseline and follow-up surveys of providers in intervention and control clinics, 4) qualitative interviews with a subset of patients, providers, staff, and administrators from intervention clinics, and 5) administrative data on healthcare utilization. **Table 1** depicts how constructs from each data source will be used to meet our aims. We intend to survey all autistic adults in the 10 participating sites, along with their PCPs, with the goal of including a minimum of 250 autistic adults. We will also obtain in-depth, qualitative data from 30 autistic adults, 15 PCPs, and 15 support staff/administrators from the five intervention sites.

Table 1: Data Sources, Constructs, Measures, and Aims

Data Source	Construct(s)	Measure(s)	Function(s)	Aims
Process data	Recruitment, retention, toolkit utilization, protocol adherence	Process information from research records, EMR, clinic protocols, other process / implementation checklists	Feasibility, fidelity, implementation strategy refinement	1,4
Patient surveys	Patient-provider communication	Adapted for ASD from 2007 Health Information National Trends Survey	Short-term outcome	2
	Barriers to healthcare	Barriers to Healthcare Checklist: Short (developed for ASD)	Short-term outcome	2
	Unmet healthcare needs and healthcare utilization	Adapted for ASD from 2002/2003 Joint US Canada Survey and 2007 National Health Interview Survey Questionnaire - Adult Access to Health Care & Utilization	Long-term outcome	4
	Chronic illness self-efficacy	Adapted for ASD from Self-Efficacy for Managing Chronic Disease Scale	Mechanism of action	3
	General healthcare self-efficacy	Adapted for ASD from Chronic Disease Self-Management (long version)	Mechanism of action	3
	Patient self-advocacy and visit preparedness	Confidence in Healthcare Scale (developed for ASD; to be further modified in proposed study)	Mechanism of action	3
	Provider/staff use of accommodations	To be developed de novo for this study	Mechanism of action	3
	Toolkit acceptability	Healthcare Toolkit evaluation items	Evaluation / fidelity	1, 4
Provider surveys	Provider self-efficacy	Items on self-efficacy, attitudes, and satisfaction with the toolkit	Mechanism of action	3
Qualitative interviews with patients, providers, and staff	Better understanding of toolkit impact	Semi-structured questions reflecting on experience with toolkit	Mechanisms of action	3
	Better understanding of implementation process	Semi-structured questions around the implementation	Implementation strategy refinement	1, 4
Administrative data	Healthcare utilization	Primary care, ED, and preventive care	Long-term outcome	4

Toolkit integration and process evaluation:

During the start-up phase, we will meet with providers, administrators, and staff from each intervention clinic to create a plan for how best to integrate the toolkit into clinical practice. For example, the clinic may choose to set up a protocol for scanning AHAT reports into the EMR, flagging patient charts to alert providers to the existence of the AHAT, communicating relevant recommendations to front office and back office staff, setting up follow-up appointments, if needed, creating EMR templates to help providers document discussions or changes, and responding to challenges implementing requested accommodations.

We will then conduct a process evaluation spanning the duration of the project. Using Stetler's classification system,[45] this assessment would be considered a formative implementation-focused evaluation. The purpose is to resolve actionable barriers, enhance identified levers of change, and refine future implementation efforts by analyzing discrepancies between the implementation plan and its operationalization. As part of this evaluation, we will measure a variety of quantitative process measures including: 1) recruitment and retention rates; 2) completion of AHAT reports; 3) use of other portions of the toolkit site; and 4) proportion of AHAT reports scanned into the EMR. We will collaboratively determine how to feasibly collect additional process information to track fidelity with the implementation protocols the clinics developed. We will use qualitative data to more fully understand the implementation experience (see below). Such data will focus on patient, provider, staff, and administrator perceptions of the Toolkit's utility, how the toolkit was used, barriers and facilitators to successful uptake and integration, and recommendations for change to the implementation plan.

Survey and Administrative Data Collection:

Participants, recruitment, and screening: Participants will be adults (age 18 and up) who have ever had ICD-9 or ICD-10 codes consistent with autism spectrum disorder (including autistic disorder, Asperger's disorder, and Pervasive Developmental Disorder Not Otherwise Specified) and who obtain primary care from the participating clinics. Of note, we will not be confirming autism spectrum diagnoses. Given the significant challenges with autism diagnoses in adults and the wide variation in care, we expect that a proportion of these ICD codes were entered into the record in error or may have changed upon further testing. However, we feel that in a real-world setting, it would be unfeasible for PCPs to confirm ASD diagnoses prior to using tools to facilitate care. Moreover, it is likely that the tools may be of benefit to other people with communication disorders. Finally, we do not want participation in the study to denote that a patient has a particular medical diagnosis. As such, on all publicly facing materials, we will be describing the tools and the study as relating "autism and other communication disabilities." (Note, the protocol continues to refer to "autistic participants" in multiple areas for the sake of conciseness.)

In cases where patients cannot participate directly, even with appropriate accommodations and supports, we will ask a supporter to participate as a proxy with as much input as possible from the autistic patient. Supporters must also be age 18 or older, must speak (or read) English, and must have experience supporting the autistic patient in healthcare settings. Participants also include primary care providers, staff, and administrators who work in the participating sites.

Each health system will identify all adult patients assigned to the participating practices who have had an ICD-9 or 10 code consistent with ASD (299.00, 299.8, and 299.9 or F84.0, F84.5, and F84.9). Staff from the partnering health systems will send a letter (via mail or Epic MyChart message) to all potential participants explaining the study. The letter will include information on how to participate and information for how to opt out of future calls. Staff will then make recruitment telephone calls to patients who did not reply to the letter. Clinic personnel can also inform patients about the study when patients come into the clinic for an appointment. Personnel will give patients a recruitment flyer and direct them to contact the study website or contact the Program Manager to learn more about the study. They will also ask participants if they would rather clinic personnel pass along their contact information to the Program Manager so that she can contact them directly. Potentially interested participants will take a screening questionnaire to assess eligibility. As in our prior studies, the screening questionnaire can be done via telephone or Internet, independently or via a supporter.

Eligible participants will be asked for informed consent. In cases where a participant cannot offer informed consent, we will ask for consent from a legally authorized representative.

Recruitment materials will include information for how participants can participate online (a URL just for this study). When participants take the online screener, the program will automatically direct them to the correct consent form (based on whether it is the patient, supporter, or an LAR, if they are in an intervention or control clinic, and so forth). At the end of the consent form, if the person has checked yes (and we have the correct supporter/LAR combination for those who need a supporter or LAR), the computer will assign them a study number and pass that number along to the registration system. They will then be asked to create a login and password. After they have set up their login/password, they will get directed into the survey using a specialized link based on the participant ID. (Our database stores the participant ID in 3 places: the screening/consent database, the registration system, and the survey database). The participant will then take the survey, and after they are done, they will be directed to the AHAT / toolkit. Six months later, we will send them a reminder (with the login name, but not the password), so they can continue to the 6-month follow-up survey. The registration system we use offers a reset for their password if they have forgotten it (as long as they still have

access to their email address. We can change the email address manually if need be.) For those people who choose to go directly online, there is no need to interact with a RA.

For those people who choose to go directly online, there is no need to interact with a RA. Those who prefer to contact us by phone or email will be given a link to a special starter page (based on which survey version they need) where they enter the patient name. The program will generate the ID number and they will then proceed like anyone who did the consent online.

Providers and staff from the intervention and control clinics will also be included as participants.

Patient Survey: All patient participants will be asked to take surveys at baseline and at six months. After logging into their secure account, participants complete surveys online (independently or with help from a supporter) using our Audio Computer Assisted Survey Instrument (ACASI), a highly accessible system with a read-aloud option and other features designed to meet the needs of people with disabilities.[46] Participants without Internet access can take the survey at their primary care clinic or the PSU or Kaiser research offices.

After completing the baseline survey, participants from intervention sites will be automatically directed to use the AHAT to create a personalized report. After reviewing the report, they will be asked permission to have the report sent directly to their PCP. Participants will then be directed to the remainder of the toolkit (on a password-protected research site), where they can read information about health and healthcare and download worksheets and checklists. The research version of the toolkit will be accessible through participants' personal accounts to better track participants' use of components of the toolkit. Clinics will be expected to use the implementation protocol they developed to ensure the AHAT report reaches appropriate staff and that recommended strategies and accommodations are incorporated into the patient's care. Six months later, all participants will be re-contacted and asked to participate in the follow-up assessment. To increase retention, we will collect various types of contact information and will request permission to use updated information from clinical records, if needed. Participants will receive $30 for completing both surveys.

We will collect data on patient provider communication using items we previously adapted[6] from 2007 Health Information National Trends Survey (HINTS).[47-50] We clarified wording and added two new items on expressive and receptive comprehension as community partners felt this was not adequately addressed in the initial scale. The scale asks patients about their last visit with their PCP. Responses use a 4-point Likert scale with anchors of "Never" to "Always". The scale is scored by summing the responses. In the post-test, participants will only be asked this scale if they have seen their PCP during the 6-month study. The original HINTS patient-provider communication scale and our adapted version both had a Cronbach's alpha of >=0.9.[6,51]

We will assess barriers to healthcare using our Barriers to Healthcare: Short scale[7]. The scale includes 16 barriers commonly experienced by autistic patients. It was found to be responsive to change in our prior Toolkit evaluation. Items can either be analyzed separately or as a count of the total number of barriers endorsed.

We will assess healthcare self-efficacy using a measure we previously adapted for use with autistic adults[6] from the Chronic Disease Self-Management Studies by Lorig et al.[52,53] Participants with at least one chronic medical condition complete the Self-Efficacy for Managing Chronic Disease 6-Item Scale.[52] All participants are also asked to complete 9 additional items about healthcare self-efficacy, selected from Lorig's original longer instrument,[53] but adapted to be applicable to individuals whether or not they have any chronic illnesses. All items are rated on a scale of 1-10 with anchors of "not at all confident" and "totally confident" and summed into a composite score (range 9-90 for general healthcare self-efficacy, 6-60 for chronic condition self-efficacy; higher values indicate greater self-efficacy). Both subscales had good internal consistency reliability (alpha 0.82 and 0.88) and strong convergent validity, with a strong correlation between general healthcare and chronic condition self-efficacy, and between both measures of self-efficacy and unmet healthcare needs.

We will explore other potential mechanisms of action by modifying a 21-item Confidence in Healthcare Scale we previously developed to capture potential toolkit-specific changes in patients' confidence in their ability to navigate the healthcare system and the systems' responsiveness to their needs. Response options use a 4-point Likert scale with anchors of "0 - Not at all confident" to "3 - Totally confident". The scale was originally scored by summing responses from the 21 items, resulting in a possible range of 0 to 63, with higher scores corresponding to higher self-efficacy. In our Toolkit Evaluation study, the scale had a Cronbach's alpha of 0.92 and was responsive to change. However, we feel that it would be useful to further develop this measure to more clearly target our proposed mechanisms of action, including self-advocacy and visit preparedness. We will use our prior data and our community partners' insights to modify this scale. We will then use our new data

to do a confirmatory factor analysis and re-test its psychometric properties in preparation for the larger RCT. We will also create and test a new measure on satisfaction with provider/staff use of desired accommodations.

We will assess unmet healthcare needs and healthcare utilization, using items we previously adapted[6] from the 2002/2003 Joint US Canada Survey[54,55] and the 2007 National Health Interview Survey (NHIS) Questionnaire - Adult Access to Health Care & Utilization.[56,57] We will measure unmet healthcare needs using the item "During the past 6 months**,** there was a time when I felt that I needed the following type of healthcare, but did not receive it. (Check all that apply)." Response options include six types of healthcare (e.g., "medical care for a physical health problem," "mental healthcare or counseling"). As in the past, we will ask a variety of questions about outpatient, ED, and hospital visits and use of preventive services, however we will also obtain EMR and claims data from each health system about participant use of these services and compare results.

In the baseline survey, we will collect data on demographic and disability-related characteristics. In the 6-month follow-up participants in the intervention arm will answer a set of close- and open-ended evaluation questions about their satisfaction with the toolkit, which parts they found most useful, why they did not give permission to share their AHAT report, whether they discussed the report with the PCP, and what changes, if any, they felt occurred in response to the toolkit. To assess for contamination, the 6-month follow-up survey will include an item asking participants if they have used the public version of the toolkit. Patients in the control clinics will be given a link to the public site at the end of the study.

Provider Surveys: We are acutely aware of the importance of minimizing the burden of this study on PCPs, both in the current study and in the future R01. As such, we will use patient surveys and administrative data to answer most of our research questions, and will only conduct in-depth interviews with 3 providers from each intervention site (N=15). However, we believe that provider self-efficacy may be an important mechanism of action that needs to be assessed directly from all providers. We will conduct an extremely brief survey (<5 minutes) at baseline and at the end of the study with all providers who have autistic patients in their panels (N 50-80). Providers may participate via email, fax, telephone, or online. The survey will include items on self-efficacy and attitudes toward autistic adults. Follow-up surveys will also include an item about whether they are aware of the AASPIRE Healthcare Toolkit and, if so, a few items about their satisfaction with the toolkit.

Administrative Data: We will use administrative data from each health system to assess healthcare utilization. Obtaining such information is relatively straightforward for a closed healthcare system such as Kaiser. However, it is more complex in non-integrated systems. We will explore how well we can capture data from the OHSU and Legacy Systems using EMR data, including Care Everywhere (an Epic System that links EMR visits from most local health systems) and claims data from Health Share (the Medicaid managed care coordinated care plan for our county). Though this study will not be powered to show a difference in unmet needs or healthcare utilization, these data can help inform the future R01. It will also give us experience working with this type of administrative data from each health system.

Quantitative Data Analysis

Our quantitative analysis plan includes descriptive and psychometric analyses, assessment of missing data and attrition, and a mixed effects regression analysis to compare results from intervention and control sites while adjusting for demographic and disability-related characteristics. We will conduct analyses using STATA 14 (Statacorp, College Station, Texas). We will use an intention-to-treat approach for all analyses.

Preliminary analyses will include careful examination of descriptive statistics and distribution for each of the study variables at baseline and the 6-month follow-up. This will include stratified analyses within the intervention and control groups. For variables measured with multiple items, psychometric analyses (Cronbach's alpha, confirmatory factor analysis) will be conducted to instigate internal reliability, and, when necessary, measurement modifications will be made to improve reliability.

We will use two independent sample T-tests to test bivariate differences between the main independent variable (intervention vs control clinic) and baseline continuous variable subject characteristics and Chi-square/Fisher-Exact test to assess differences between the main independent variable and categorical variables. We will apply similar tests to primary outcomes and secondary outcomes at each time point.

We will test Aim 2 hypotheses using multivariate regression models. The dependent variable in each of our primary analyses will be the 6-month change in short-term outcomes (patient-provider communication score and number of barriers). We will calculate change by subtracting the baseline score from the score at 6 months. We will also conduct exploratory analyses using the 6-month change in scores for the potential

mechanisms of action (e.g., self-efficacy, use of accommodations) and long-term outcomes (e.g., unmet needs, emergency department use) as the dependent variable. Analyses will use linear vs logistic models depending on whether the outcome is continuous (e.g., patient-provider communication score) or binary (e.g., ED use, unmet needs). The predictor will be study arm (intervention vs control). We will adjust for potential confounders including data source (direct report vs proxy), age, gender, race/ethnicity, residence (own home vs with family of origin); need for support to communicate with providers; health status, and unmet needs at baseline.

Power Considerations: We plan to enroll 250 participants to have complete follow-up data on at least 200 (100 intervention;100 control), which will allow us to detect an effect size of 0.4 with a power of 80% using an independent sample t-test test with a two-tailed hypothesis and an alpha of 0.05. It would provide 97% power to detect an effect size of 0.5. Though one must use caution in deriving effect sizes from small pilots, based on our preliminary results, we feel it is reasonable to expect this level of change in our short-term outcomes. For example, we noted a 0.55 effect size in the number of barriers to healthcare. We are using a conservative estimation to compensate for the complex multivariate analyses proposed in Aims 2 and 3.

Qualitative Interviews with Patients, Providers, Staff, and Administrators

Participants and Sampling: We will collect qualitative data from 30 patients, 15 providers, and 15 administrators/staff selected from the 5 intervention sites to better understand the implementation process and the tool's potential impact. We will use maximum variation sampling,[58] a purposive sampling strategy which increases depth of understanding by selecting a diverse group of individuals who are expected to have different perspectives. We will use data from our quantitative surveys to identify which patient and supporter participants to invite to the qualitative study. The goal will be to create a patient sample that has wide distribution of the following characteristics: 1) gender; 2) age, 3) race/ethnicity, 4) living situation, 5) need for assistance to receive healthcare, 6) use of alternative and augmentative communication (AAC), 7) permission (yes/no) to share AHAT report with provider, and 8) clinic site. We will primarily recruit participants who have seen their PCP after using the Toolkit, as they are the ones most likely to provide rich, interesting information. However, we will intentionally sample 5 participants who did not see their PCP to try to understand potential barriers to care that were not addressed by the toolkit. We will recruit patient participants for an interview between 4-8 months after they complete the baseline survey. We will use a similar strategy to obtain a varied sample of providers and administrators/staff from each of the clinics, purposely sampling people who serve in a variety of roles in each clinic. Participants will receive an additional $50 stipend for participating in an interview.

Data Collection: We have found that offering a choice of participation modes is key to being able to collect rich data from autistic participants, many of whom prefer written or asynchronous communication. As in our prior work, a research assistant, under the supervision of Dr. Nicolaidis, will conduct interviews in person or via telephone, email, or instant messenger, and will individually work with participants to offer accommodations. We will work with our community partners to create an interview guide with clear, concrete, specific, and easy-to-understand questions and enough framing to facilitate rich responses. Interview topics for autistic adults and supporters include impressions of the toolkit, experience using it, impressions of how it affected their healthcare interactions, and recommendations for addressing barriers to use. Interviews with providers, staff, and administrators will focus on their experience using the toolkit with patients, changes that they may have made due to AHAT reports, how the tools were (or were not) integrated into the clinic's practices, and recommendations for changes to the implementation strategy.

Qualitative Data Analysis: We will analyze data using thematic analysis[59] with an inductive approach (as is used with Grounded Theory), at a semantic level, using a constructionist paradigm. Drs. Nicolaidis and Raymaker and a research assistant will read each of the transcripts in their entirety, discuss general impressions and insights, and develop a set of preliminary codes. Dr. Raymaker and the research assistant will apply the codes to the transcripts. The three investigators will use an iterative process, meeting regularly to review the coding and generate preliminary themes and sub-themes. Disagreements will be resolved by re-reading the original transcripts until the investigators agree. Preliminary results will be discussed with the community partners, who will offer feedback on the interpretation of data. The three investigators will then meet to review and refine the final themes. We will use Atlas-TI for qualitative data management.

Anticipated Difficulties and Next Steps

We expect that we will meet recruitment targets with the initial set of clinics, but can add additional sites from each of the three health systems if needed. We also expect an adequate response rate from PCPs, but we will

work with clinic leadership, as needed, to reduce barriers and increase incentives to participation. We will use our findings to create a flexible implementation strategy that can be used by diverse practices to incorporate the toolkit into clinical care. We will also use findings to refine our change model, outcome measures, study protocols, data collection strategies, and power estimations in preparation for the R01.

Timeline

Activity	***Year 1***				***Year 2***			
Ongoing use, assessment, and refinement of CBPR collaboration processes	***x***	***x***	***x***	***x***	***x***	***x***	***x***	***x***
Project start-up; decisions re clinic integration protocols; finalization of instruments	***x***	***x***						
Participant recruitment and baseline data collection			***x***					
6 month follow-up surveys and qualitative data collection					***x***	***x***		
Process evaluation / refinement of implementation strategies for future trial		***x***	***x***	***x***	***x***	***x***	***x***	
Data analysis, writing of manuscripts, preparation for R01 proposal					***x***	***x***	***x***	***x***

Protection of Human Participants

The study will be carried out in primary care practices from the KPNC, OHSU, and Legacy Health Systems. We will start recruiting participants from 8 KPNC clinics, 2 OHSU clinics, and 2 Legacy clinics. If we have difficulty meeting recruitment goals, we may add additional practices as needed. Half the clinics from KPNC and Legacy will be designated as intervention sites and half will be designated as control sites. The two OHSU clinics do not serve comparable populations, but they each consist of 4 separate pods with distinct providers, patients, and staff. As such, two pods from each OHSU clinic will serve as an intervention site and two pods from each clinic will serve as a control site. There will thus be a total of 7 intervention sites and 7 control sites.

1. Risks to the Participants

1a. Human Participant Involvement and Characteristics

The goal of this proposal is to use a CBPR approach to understand how to best integrate the toolkit into diverse health systems as we prepare for a larger effectiveness-implementation trial. To achieve this goal, we will conduct a series of studies with autistic adults (who participate either independently or with the help of a supporter), primary care providers, and other primary care office staff. Studies include a combination of qualitative interviews and surveys. We will also access existing data from patients' electronic medical records to assess healthcare utilization (e.g. use of the emergency department, receipt of preventive care services).

Human Participant Involvement

Participants will be in the study a total of 6 months. Potentially eligible autistic participants will take a short screening survey to assess eligibility. Autistic participants will complete two online surveys, one at baseline and another at 6 month. Participants from intervention clinics will also complete an Autism Healthcare Accommodation Tool (AHAT) survey and be directed to use the online tools and resources available in the AASPIRE Healthcare Toolkit. Each baseline and follow-up survey should take approximately 30 minutes. The AHAT survey will take approximately 20 minutes. Participants can spend as much time as they wish using the resources on the online toolkit.

Primary care providers will complete a very brief survey either online, or via fax, telephone or in-person, at baseline and at the end of the study. Surveys should take less than 5 minutes to complete.

A subset of autistic participants, PCPs, and office staff who work in the intervention clinics will take part in semi-structured, open-ended interviews. Interviews will last 30-90 minutes.

Participant Characteristics / Inclusion Criteria

1) Patients: Participants will be adults (age 18 and up) who have ever had ICD-9 or ICD-10 codes consistent with autism spectrum disorder (including autistic disorder, Asperger's disorder, and Pervasive Developmental Disorder Not Otherwise Specified) and who obtain primary care from the participating clinics. Of note, we will not be confirming autism spectrum diagnoses. Given the significant challenges with autism diagnoses in adults and the wide variation in care, we expect that a proportion of these ICD codes were entered into the record in error or may have changed upon further testing. However, we feel that in a real-world setting, it would be unfeasible for PCPs to confirm ASD diagnoses prior to using tools to facilitate care. Moreover, it is likely that the tools may be of benefit to other people with communication disorders. Finally, we do not want participation in the study to denote that a patient has a particular medical diagnosis. As such, on all publicly facing materials, we will be describing the tools and the study as relating "autism and other communication disabilities." (Note, the protocol continues to refer to "autistic participants" in multiple areas for the sake of conciseness.)

In cases where patients cannot participate directly, even with appropriate accommodations and supports, we will ask a supporter to participate as a proxy with as much input as possible from the patient. Supporters must also be age 18 and older, must speak (or read) English, and must have experience supporting the patient in healthcare settings. We expect to screen up to 500 participants to obtain an initial sample of 250 participants, with complete 6-month data for 200 participants. We will purposely sample 30 of these participants to take part in the qualitative interviews.

2) Primary Care Providers: We will include all primary care providers who practice in the intervention clinics. PCPs, by definition, are over 18 and speak English. They typically have MD, DO, NP, or PA degrees and practice primary care. We expect approximately 75 PCPs to take part in the survey. We will purposefully sample 15 of these PCPs to take part in the qualitative interviews.

3) Support staff: We will include an additional 15 clinic employees in the qualitative interviews. Employees will include front office staff (e.g. receptionists), back office staff such as medical assistants or nurses, and administrators (e.g. clinic managers). Again, by definition, they will be over age 18 and speak English.

Sampling plan

We will attempt to enroll all patients, age 18 or over, who have medical diagnoses of autism spectrum disorder, and are receiving primary care in the participating sites. We also will attempt to survey all primary care providers who have autistic adults on their panels in each clinic. We will work with clinic champions from each clinic to purposefully select which additional employees to invite to the qualitative study.

1b. Sources of Materials

Data will come from surveys, semi-structured open-ended interviews, and review of exiting data available in the patients' electronic medical records (EMR).

Survey data will be collected from patient participants or supporters via an Audio-Computer Assisted Self-Interview (ACASI). A-CASI is a secure, web-based, and highly accessible tool that offers participants additional privacy by allowing them to enter data themselves. The ACASI electronic database is stored behind the PSU firewall. It will be password-protected and only the PI and specific PI-designees will have access to participant information.

The AHAT report, which serves to communicate personalized data about a specific patient to his or her PCP and other primary care clinic staff, needs to include the patient's name and date of birth in order to serve its clinical function. As such, the initial AHAT database on the ACASI system and stored copies of the AHAT reports will remain identified. We will regularly transfer data from the ACASI database into a master database for data analysis purposes. This database will be stripped of identifying information and coded with the unique participant IDs. Of note, while the surveys collected via the ACASI system include identified information, they do not include health information.

Participants will have a choice of a variety of modes in which to participate in the qualitative interviews and the PCP survey. Options include email, telephone, instant messenger, and in-person. Initial email messages and chat logs will be, by definition, identified and identifiers cannot be reliably erased from all records. Participants will be alerted to that fact in the consent materials. We will copy data from such sources into word processing files and strip them of identifying data prior to conducting any analyses, again coding them with the unique participant ID. Similarly, recordings of interviews conducted over the telephone or in-person may be recognizable, but transcripts will be stripped of identifying data and coded with a unique identifier.

Paper records will be kept in a locked cabinet in the PSU or KPNC research offices. Electronic files (including databases, transcripts of interviews, and audio-recordings of interviews will be kept on a secure, password protected computer account. Only study personnel will have access to the data. All reports will describe results in aggregate form. Data will be destroyed at the end of the study.

All three systems will share EMR data from consented participants. Data from the 3 health systems will include PHI. We will send survey data collected at PSU on patients from the OHSU and Legacy Health Systems to OHSU. We will send survey data collected at PSU on patients from the Kaiser Health System to Kaiser. OHSU and Kaiser study personnel will link the survey data to data from the EMR. They will then deidentify data and send a deidentified version of the full database to OHSU and PSU. The coded database, which does not include PHI, will be shared back to PSU to be further analyzed by PSU investigators.

All data with PHI will be stored on OHSU or Kaiser computers or on Box, a fully HIPPA compliant cloud storage and communication system with added protections in place for confidential and restricted data or protected health information. OHSU and Box have entered into a Business Associate Agreement that meets all policy compliance requirements. Dr. Nicolaidis can grant access to specific files to collaborators at other institutions. She will create one folder for each institution. OHSU and Legacy collaborators can then safely and securely place files in these folders on Box. For Kaiser, all data with PHI will be stored on Accellion Solution, a secure web user interface that has protections in place for confidential data.

KPNC staff will also conduct some of the qualitative interviews of KPNC patients and employees. They will de-identify transcripts and share with PSU investigators.

1c. Potential Risks

We believe that each of the three studies poses minimal harm to participants. Potential risks include: (1) possible discomfort due to recollecting memories related to negative experiences with healthcare, (2) possible violation of confidentiality if someone were to intercept, see or overhear participant's answers or the data are accessed by someone outside of the research team, (3) possible frustration if the participant experiences hardware or internet problems during participation, (4) possible frustration or fatigue if participant has a difficult time understanding specific questions or gets tired, (5) concern among professionals that their responses are wrong, and (6) the possibility that interview participants report abuse that is mandated as reportable under Oregon law. We will emphasize to participants that data transmitted over email or instant messenger chat is not secure and carries a greater risk of loss of confidentiality than other modalities. Participants may choose not to participate in the study.

2. Adequacy of Protection against Risks

2a. Recruitment and Informed Consent

1) Patients

Each health system will identify all adult patients assigned to the participating practices who have had an ICD-9 or 10 code consistent with ASD (299.00, 299.8, and 299.9 or F84.0, F84.5, and F84.9). Staff from the partnering health systems will send a letter (via mail or Epic MyChart) to potentially eligible patients explaining the study. The letter will include information for how to participate, as well as a post-card to indicate that a patient is not interested. Staff will then make recruitment telephone calls to patients who did not reply to the letter. Potentially interested participants will take a screening questionnaire to assess eligibility. As in our prior studies, the screening questionnaire can be done in person, over the telephone, or via the Internet, independently or via a supporter. We will confirm with the participant that the patient continues to receive primary care in the study clinic.

Optimally, we would be able to assess the autistic adult's decisional impairment and determine his or her ability to consent/assent. However, doing so is not feasible in an online survey where we will have no contact with the autistic adult that the supporter is supporting. We will first ask if a patient is participating themselves (Patient Participant), if a supporter is helping a patient participate themselves (Supported Patient Participant), or if a supporter is participating on behalf of a patient who cannot participate by themselves, even with help from a supporter (Proxy Participant).

1a. Patients who participate directly in the surveys (Patient Participants)

Due to the low risk nature of the study and the constraints of Internet data collection, we will use a modified informed consent process. Similarly, since the level of risk and participation in our study is no greater than what an autistic adult would normally do if he or she is using the Internet independently, we feel that participants who are accessing the study independently would not be considered to have a decisional impairment for the level of risk involved in this study. Participants who are consenting online will be shown an on-line Information Sheet, which they can print out if desired. As we have done in prior studies we will work with community partners to create an Information Sheet that they feel is easy to comprehend. After reading the Information Sheet, they will be asked to check a box if they agree to proceed. Because collecting signatures is not feasible in our online studies, will ask for a waiver for HIPPAA authorizations. Participants will also be given the opportunity to contact the researchers to ask any questions they may have.

During all interactions with participants, we will emphasize that no one will be upset if they decide not to participate and that they should speak to anyone in their network that they would like to as they make a decision. Consented participants will receive a unique login and password to participate in the remainder of the study.

1b. Patient who is participating with help from a supporter (Supported Patient Participant).

We will describe what is needed for a participant to take part in the study and will ask the supporter if they feel they can provide enough support for a patient to make this type of decision and answer these types of questions. If they feel that they can, then we will use the patient version of the information sheet and the patient version of the surveys. We will instruct the support to relay the information to the patient and enter the patient's answers into the online system. In this case, only the patient is a participant. If the supporter does not

feel they can provide adequate support for the patient to participate themselves, then they will be treated as a proxy participant (as below.)

1c. Supporter who is participating on behalf of a patient who cannot participate themselves (Proxy Participant).

If a patient cannot participate themselves, even with help from a supporter, then we will assume that the patient has a decisional impairment. In this case, we will need to obtain study data from a supporter who has experience supporting the patient in healthcare settings. This person may or may not be the patient's legally authorized representative (LAR). In cases where it is not the same person, then we will obtain consent both from the LAR (e.g. to allow us to use data from the patient's medical record) and from the Supporter (since they will be taking part in the study themselves).

2. PCPs and office staff

Health systems will provide a list of primary care providers who work in each clinic, including contact information to be used to invite them to the survey. We will attempt to contact PCPs via email, telephone, fax, or in-person to complete the survey. The survey will begin with a brief statement explaining the study and stating that the research in voluntary.

3. Qualitative interviews.

We will purposefully sample patients and PCPs to invite to the interview study based on their survey data. Clinic champions from each clinic will help purposefully select which other employees to invite to the qualitative study. For those participating over the telephone, we will use a modified consent process, which involves the interviewer reading a script and answering any questions and the participant voicing his or her consent. For those participating in an interview over email or IM, we will show participants an Information sheet and ask them to indicate their consent online. Those participating in person will sign written informed consent.

2b. Protection against risk

We will proactively take several steps to prevent risks and/or minimize the consequences of the risks identified above.

First, although participants may be asked questions that remind them of negative experiences accessing healthcare, our experience is that participants actually derive benefit from sharing negative experiences through being able to relate their perspective and perhaps make sense out of the experience in a novel way. Moreover, participants may receive comfort that their negative experiences are being used to inform empirical-based practices to improve healthcare for autistic adults. All researchers will also be trained in providing emotional comfort to participants who become upset during qualitative interviews.

Second, though we cannot eliminate the risk of violations of confidentiality, we are taking a variety of steps as is appropriate for the nature of participation in each study.

For individuals participating remotely via Internet survey, text-based chat, email, or telephone, we will encourage participants to engage in the research from a location where they feel adequately protected from invasions of privacy. For those participants who participate in person, we will identify places in our offices where they can complete the research measures in private. For individuals who participate via telephone, we will ask participants whether they are in a place where they feel comfortable responding to our questions.

We will also take steps to handle the data in ways that will minimize breaches of confidentiality. Participants will take baseline, AHAT, and 6-month follow-up surveys online via our ACASI system. Confidentiality will be maintained using the following safeguards: 1) All data provided will be stored on a password protected computer and only the investigators and other key personnel will have access to the data; 2) Data collected via ACASI is collected and stored behind a firewall. Research personnel need a password to access that site. 3) Project staff will directly download information from the ACASI site to a password protected account. 4) Copies of AHAT reports will need to remain identified. However, databases used for analysis purposes will be stripped of identifying information and coded with a unique identifier. 5) Contact information will be stored separately from survey data. 6) PHI will only be stored on OHSU or Kaiser computers. 7) No identifying information will be used in publications or other reports.

For those individuals participating in interviews via email, text-based chat, or telephone, we will clearly state in the informed consent materials that email, text-based chat, and telephone communications are not secure. That is, we cannot guarantee that participants' responses will not be intercepted, overheard or accessed

without participants' permission. We will encourage participants to consider other options for participation or to not participate at all if they do not feel comfortable with the level of risk inherent in using these media. Project staff will promptly compile these communications, strip all email and text-based chat data of identifying information and not make these data available to other members of the team until we have done so. We will strip identifying information from transcripts of telephone or in-person interviews.

Third, we will prepare individuals for the possibility that they may experience hardware or internet problems as they participate in the research and encourage them to participate in the study where they have a reliable computer and Internet connection.

Fourth, we will work intensively with members of our research team, including the community partners, to create questions that are understood. We will inform participants during consent procedures that they may take breaks as needed.

Fifth, to avoid coercion, we will emphasize participants' rights as a research participant, including their right to decline to participate. All of our research materials and interactions with participants will include important information about the study and their rights. We will not inform employers, supervisors, or others whether an individual participated.

Sixth, questions ask participants about their beliefs and experiences - questions to which there are no right or wrong answers. We emphasize to all participants that we are interested in hearing their opinions and experiences.

Lastly, although participants will not be directly asked questions that might lead them to report abuse, there is a small chance that participants may disclose information about abuse during qualitative interviews. Oregon law requires that researchers report abuse of children, elders, and individuals with developmental disabilities. We will clearly state in all consent materials that the researchers must report such instances of abuse. We will describe to participants the type of information that would lead to a mandatory report and describe to them what would happen when we were required to do that.

3. Potential Benefits of the Proposed Research to Participants and Others

We do not anticipate any guaranteed direct benefit to participants. However, we do believe that participants may derive substantial benefit from the research by having the opportunity to share their experience and opinion. Some participant groups included herein have few opportunities to make such a contribution and have research be inclusive of their perspectives. We believe that providing the opportunity to contribute valuable information to science will be positively experienced by participants. There is the possibility that participants may gain important insights and knowledge as part of their participation. It is also possible that participants in the intervention clinics may benefit from using the tools with their primary care providers or patients.

We do anticipate several indirect benefits. We believe the instruments and tools developed herein and the findings will provide empirically-based mechanisms that may improve autistic adults' healthcare.

4. Importance of the Knowledge Gained

The AASPIRE Healthcare Toolkit is a scalable, sustainable, low-intensity intervention that has the potential to greatly improve healthcare services for autistic adults. This project will provide critically important data to inform a larger hybrid effectiveness/implementation trial testing the AASPIRE Healthcare Toolkit in diverse health systems. Ultimately, the project can impact how care is given to this growing population that experiences significant healthcare disparities and has large unmet healthcare needs.

5. Data Safety and Monitoring Plan

Data and Safety Monitoring Plan

This non-randomized, controlled pilot intervention assesses the potential effectiveness of an online toolkit and its integration into primary care practices. It does not involve pharmaceuticals or medical devices. Data collection relies on administrative data, self-report data, and interview-based data; no invasive testing or procedures are involved. The risks related to participation are likely much lower than those of a trial involving

pharmaceuticals, medical devices, or somatic interventions or procedures. Nonetheless, we will very carefully monitor the progress of the study and any potential risks or adverse events.

Our data and safety monitoring plan includes real-time adverse event (AE) monitoring by Dr. Nicolaidis as well as AE monitoring by all staff working on the project. AEs will be identified by spontaneous reports to any study staff member, and all staff will be trained to be receptive to subject complaints and concerns about the study. Any complaints about the research process will be considered AEs. Further, any breach of confidentiality will be considered an AE.

We will classify an AE as:

0 - No AE
1 - Mild - no treatment needed
2 - Moderate - resolved with treatment
3 - Severe - inability to carry on normal activities, required professional medical attention
4 - Life-threatening or disabling
5 - Fatal

The PI will review all adverse events in real-time to determine if they meet the definition of an Unanticipated Problem (UP). The PSU IRB defines UPs as events that are not expected given the nature of the research procedures and the subject population being studied and suggest that the research places subjects or others at a greater harm or discomfort related to the research than was previously known or recognized. All Unanticipated Problems, including AEs that meet the definition of a UP as determined by Dr. Nicolaidis, including breaches of confidentiality and subject complaints, will be reported to the IRB as soon as possible and within the following time frames:

- Deaths and potentially life-threatening events within 7 days of the PI learning of the event days.
- All other unanticipated problems will be reported within 15 days of the PI learning of the event.

If any AEs or UPs requires a change to the protocol or consent form (as determined by the PI or IRB) the PI will submit the revised protocol for review and approval by the PSU IRB promptly. A brief summary of UPs and all adverse events will be submitted to the IRB at the time of annual continuing review. Adverse events, enrollment, and data collection problems will be reviewed every 3 months by the PI. In addition, dropouts and AEs will be reviewed for patterns indicating problems with the study procedures. Any protocol deviation identified during the quarterly reviews will be reported per PSU IRB policy.

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