Expanding Patient Access and Engagement

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Access to healthcare in the United States is drastically changing. The governmental response to the coronavirus greatly upended our ways of business. Rationing care damaged trust, instilled hesitancy for treatments and prevention, and functionally introduced medical deserts to poor and rural areas. The response by the practitioners was positive - empowering nurses, physician associates, and pharmacists to perform most patient-facing functions. This paper focuses on community care, primarily by nurse practitioners, where practitioners provide primary care and urgent care near or in existing pharmacies and supermarkets, building on relationships and convenience, thus maximizing patient access and mitigating risks.

Keywords: clinic, clinical contracts, community care, decentralized trials, diversity, empowerment, patient access, patient safety, risk mitigation, nurse practitioner, pharmacist, supermarkets, convenience

INTRODUCTION

According to Bradham and Fishburne (2023), Fisher-Hoch et al. (2023), and ICON (2021), clinical trials have historically done a poor job of accessing minority populations and people with stringent work schedules and perhaps even rural community dwellers in the United States. Patient treatment, post-pandemic, has followed a similar pathway. This situation disproportionately impacts underserved populations and geographies. When coupled with the fact that more than 80% of trials failing to enroll on time (Desai, 2020; Schell, 2024). Further Schell (2024) noted much of the issues with patient recruitment is probably due to "sticking with the status quo" when it comes to enrollment planning (p.1). The recent FDA guidance's on decentralization and diversity empower both the providers and the participants to

change that historical reality. Incorporating decentralized trials into the clinical trial frame has the hope of increasing the quality of care and lowering the patient burden while care centers can serve end-to-end care.

DECENTRALIZED TRIALS

Empowerment of Patients

Understanding patient preferences is paramount to successful treatment and recruitment of patients. Specific to clinical research, recruitment is a widely studied topic, with many attempts to identify methods for successful recruitment strategies. A systematic review conducted prior to the pandemic by Caldwell et al. (2010) discusses that patients were more willing to participate in a clinical study when they were well informed of why they were being asked to participate and how it may affect them and their health. A direct-to-patient model of Clinical trial research is becoming more participant-centered through the use of decentralized trials (Duff, 2022).

The aftermath of the COVID-19 global pandemic has shown patient preferences are increasingly trending toward flexibility, with the increase in work-from-home opportunities (Stella et al., 2020), or in the case of medical care, increased utilization of telehealth (Gellard et al., 2020; Harvey et al., 2024; Wosik et al., 2020). The use of social media has also changed the way individuals interact with each other. Individuals are more empowered and more informed with a whole world of information carried with them at all times, Naeem (2021) noted that before the pandemic.

Additionally, Berenbrock et al (2022) noted that over 95% of people in the United States live within a 10-mile radius of a pharmacy. This increased access to potential clinical trial sites within their communities makes sense to improve recruitment and retention. The decentralized trial model, sometimes referred to as direct-to-patient, within clinical research is an emerging method that expands the potential for patient-reported outcomes, expands fields of study, and has a positive outlook for patient enrollment, retention, and diversity of the recruited patients (Duff, 2022).

Empowerment of Practitioners

Clinical treatments and research are collaborative efforts requiring principal investigators (PIs) from a range of disciplines including doctors, nurses, and researchers. A clinical trial principal investigator (PI) involves many responsibilities outlined in the FDA's 21 CFR 312/812. This can also be found in FDA 21 CFR 11/50/54/56 and is memorialized on the FDA Form 1572 (Ceh, 2022). Responsibilities encompass activities required to protect human subjects and ensure the integrity of the collected data (FDA, 2009). Nurse practitioners (NP) are among those with a level of qualification to take on the PI role. They have training, direct patient care experience, and health data collection integrity (Grady & Edgerly, 2009). According to the American Association of Nurse Practitioners [AANP] (2024), NPs are licensed medical practitioners in the continental United States. They practice under the rules and regulations of the state in which they are licensed, while providing autonomous and collective quality healthcare in a variety of medical settings such as family, pediatric, acute and specialty care. NPs have been credited for lowering healthcare costs, and more than 1.06 billion of health care visits occur with an NP each year (AANP, 2024). Patients report a high level of satisfaction with the care they receive under an NP, according to sources including Jennings et al. (2009), Kippenbrock et al (2019).

Nurses have always been integral to the conduct of clinical research at every level, including providing care to participants, coordinating, and implementing studies, and designing and implementing programs of research as principal investigators (Bevans et al., 2011; Hastings et al., 2012).The Clinical Center Nursing Department at the National Institutes of Health (NIH) launched an initiative that defines the role of the clinical research nurse due to their prevailing and impactful presence (Freehan & Garcia-Diaz, 2020; NIH Clinical Center Department of Nursing, 2009).

Most states allow NPs to serve as PIs and co-PIs in clinical trials (Ceh, 2022). The specific requirements for serving as a PI and co-PI may vary depending on the state, institution, funding agency, and type of research being conducted. For example, the NP has full medical practice rights in 22 of the 50 states (See Ceh, 2022). However, in the event the clinical research protocol dictates a physician-level licensure

condition for some tasks, it must be followed. The NP may still engage in these cases when a licensed physician as a co- or sub-investigator to fulfill the protocol requirements (Ceh, 2022).

Like any clinician, the NP PI must be proficient in the intricate ethical, scientific, and regulatory areas of clinical research and patient treatment. When serving as a PI must identify appropriate research participants, obtain informed and voluntary consent, and minimize research risks. They must respect the requirements of ethical study review (IRB) and oversee all delegated study staff and their contributions to the research while carefully monitoring and respecting participants' rights and well-being throughout the study (FDA 2009; Grady & Edgerly, 2009).

Decentralization of Trials

Patient advocacy is an integral component of nursing regardless of the setting. Bevans et al., 2011, Feehan & Garcia-Diaz, 2020, Gerber, 2018, and Grady & Edgerly, 2009 write extensively on this advocacy. Nurses, on average, spend more time with patients compared to other healthcare professionals (Butler et al., 2018). Therefore, they have a key responsibility and opportunity to evaluate whether research participation continues to be consistent with a patient's best interests as well as preferences.

The value of remote Decentralized Clinical Trial (DCT) model from on-site visits in clinical trials, like nurses, may be underrated. The DCT model may help reduce health disparities by increasing access for underrepresented groups. DCT provides a variety of means of inclusion to an often-underserved population (International Association of Clinical Research Nurses, 2023; Van Norman, 2021). For example, The FDA directly calls for diversity in clinical trials (FDA, 2019; FDA, 2023), and DCT trials appear to be paving access to research for more vast populations than in traditional models alone (Harvey et al., 2024; Johnson & Marsh, 2023; Van Norman, 2021). As an added benefit, DCT may decrease recruitment timelines (Van Norman, 2021). When converting to DCT from on-site visit, a 13% reduction in enrollment challenges and trial delays were observed (Johnson & Marsh, 2023; Thakur & Lahiry, 2021). While decentralization of trials may be beneficial to increase diversity, increase access, and lessen travel burden of the participant, expertise of those on the DCT trial is crucial to maintain patient safety (Johnson & Marsh, 2023). It is, imperative that DCT is used in clinical research with well-trained, experienced personnel which may be an excellent fit for the NP.

Whether it's a DCT or traditional clinical trial, those who hold licensure as a NP can and should be considered in the PI role. In the case of DCT, private residence administration of an IP and close, but remote, monitoring of adverse events are important for the focus on participant safety. DCT and NP PI are well matched.

DIVERSITY IN CLINICAL TREATMENTS AND TRIALS

Relationships Where the Patients Are

Finding successful treatments for illness and disease is a long road. Bradham and Fishburne (2023) notes that "perhaps no one appreciates that more than the clinical trial participants who help discover those cures" (p.1). According to Bradham and Fishburne's estimates, the average clinical trial participant drives more than 50 miles to reach their assigned clinical trial site with rare disease, sometimes exceeding a hundred miles (Bradham and Fishburne 2023). Lam et al. (2018) reminds readers that many rural Americans find access to good hospitals and even doctors a major problem when compared to Americans in urban communities. A wave of rural hospital closures in recent years has elevated concerns about health care access (Lam et al., 2018).

Large retail chains sometimes supplement care with onsite clinics working to collaborate with the "local ecosystem" while concurringly striving to build relationships with "health systems, payers, non-profits, and other stakeholders within the communities we serve" (Alsumidaie, 2023, p1). Clinical trials rely heavily on working with the local community while incorporating diversity and representation as a major goal of their clinical trial foundation. Therefore, DCT holds significant promise in supporting these goals. In fact, in-home clinical trial participant data collection through DCT, not only holds the promise of greater diversity, but also less travel burden on the participant, reducing site visits, easing the workload of onsite staff and

monitoring teams (Clinical Leader, 2023). DCT enables more patients to be reached while maintaining high-quality of clinical trials management and oversight.

End to End Care

Landon et al (2022) explored the status of primary care coverage from a physician's standpoint. They noted several challenges beginning with scarcity, particularly post-pandemic, referencing that there are not enough doctors graduating from school to replace those who retire annually. Further they note on the bookends that the young and healthy population chooses not to go to a primary care check-up and nearly a third of the elderly do not go to their respective primary check-ups. As a result, the authors (Landon et al, 2022) mention the influx of what they call focused care providers – urgent care and clinics. The focused care offerings tend to cater to younger, rural, and underinsured individuals.

The authors note these focused care centers increasingly serve end to end care. Jain (2022) noted many practitioners work at the top of their license to achieve this reality - to paraphrase the Spiderman franchise, with great delegation comes great responsibility. Horseman et al. (2023) stress the need for human protection and equal access to treatment and in research: respect, generosity, and equity. They note that the current structure of the Food and Drug Administration and the Health and Human Services are built on this understanding and seek to assure equal access to the drugs and compounds that are under their respective purview. This framework, including review boards and ethics checks, help to govern the interactions with practitioners, patients, and overseeing agencies.

Recognizing this trend several large pharmacy chains entered the clinical trials setting as noted by McLymore (2022) and PR Newswire (2023). Each business making use of their data from their respective clinics. This data is an output from the end-to-end care reality within the clinic space. The FDA (2022) and Alsumidaie (2023) focus their attention to underserved populations in the traditional sense and Landon et al (2022) by underserved geographies. The Washington Examiner coined the term 'medical desert' to describe areas of inadequate healthcare. In these areas some patients have a half hour drive to the nearest health professional, a pharmacist, and may need to commute to another state for level one care (Chakraborty, 2022). This reality could make care in traditional settings out of reach, as Landon et al (2022) noted, and provides opportunities for the patient and provider by way of focused care services.

MAXIMIZING IMPACT MINIMIZING RISK

Patient Risk Reduction

The FDA's decentralization guidance, which was formalized into law recently, explores delegation of authority outside of the traditional office setting and explores the parallel obligations between onsite and remote studies (FDA, 2022, III-A) and recognizes the current realities related to remote visits, telehealth, and data driven monitoring. The support staff, such as technicians, may engage but do not have specific authorization or log within the respective study file or 1572 reporting (FDA, 2022, III-B & III-D).The investigator is authorized to include credentialed specialists as allowed by respective state law and is encouraged to meet with the research team by way of video as the administration considers real-time conversation online equal to that in person (FDA, 2022, III-D & III-I).The study design includes a few special modifications to assure patient safety including direct phone-lines to the investigator, facetime and inclusion during treatment and consent, specific directions for potential adverse and unexpected events, and generally access to local staffing (FDA, 2022, III-B & III-H).Further the CRF includes notation of where data was collected, which may include patient entries, - all of which is crosschecked against the same query string, and a central IRB is engaged to assure consistent study-wide application of protocol and safeguards (FDA, 2022, III-C & III-D).

As the local health institution becomes a primary, if not exclusive, touchpoint for the patients (FDA, 2022, III D) there are new areas of service, protection, and support. Alsumidaie (2023) infers this local touch allows for engagement with staff with existing relationships and trust. Traditional trials include health and safety assessments by the principal investigator, usually a medical doctor. Both FDA (2022) and Alsumidaie (2023) explicitly note that the nurse practitioners and pharmacists gain new responsibilities

under a decentralized model. The local health institution check points would include a drug utilization review and wholistic practical examination. In some areas there are also registered dietitians on staff which would also add an added later of consideration as it relates to the 'food as medicine' mindset. The authors posit the engagement of these extra services – medical doctor, nurse practitioner, physician associate, registered pharmacist and registered dietitian - with their respective reviews of patient safety often exceed even hospital setting.

The allowance for home visits if required as well as limited reporting through patient facing EDC further build on the trust. The likelihood of serious events is lessoned by these crosschecks and perhaps, with it, the unexpected events that come during real world trials. It's more likely, Khozin & Coravos (2019, p25) suggest that unexpected events turn up in by phase III and before the observational phase IV trials, caught by the respective specialties at trial phase, as the patients may act in a less structured manner than desired. Which may, in the end, be a good thing for safety. Further, Khozin & Coravos (2019, p26) mention the need for appropriateness of study type and the influx of new technologies such as wearables bring to convenience and consistency in the data.

Organization Risk Assessment

Yu et al (2016) along with Ogg (2006) both urge the importance of building quality into the study and protocol design. For Ogg (2006, Ch6), the focus is from the lens of compliance: what needs to happen, how we need to document what happened, and how we can ensure things are correct. Yu et all (2016, p771 & 781) take a more holistic approach, working to build in safety throughout the process from design to study implementation, assess continuous improvement from other studies and models, as well as ensure there is open communication amongst the groups, here the sponsor, the site, and the patient. The diversity and decentralization guidance from the FDA (2019, 2022) do the same. In order to achieve the desired outcome, many organizations urge their professional staff to work at the top of their licenses. The goal of this, according to Jain (2022, section 1), is to improve the work experience, increase the quality of care, and lower the patient share of the cost. There are significant and consistent examples of improved access particularly with vaccinations; recently COVID-19 and RSV. The introduction of additional types of professionals, potential adding medical assistants and registered pharmacy technicians to the mix, allow for specialization of care and using the right resources at the right places. Jain (2022, Section 1 & Section 3) notes that although clinical trials have extra safeguards proactive distribution of responsibilities and clearly delineated guardrails would improve the patient experience.

It is important to work from the position of 'what we should do versus what we must do' and considering respect, benefit, justice and integrity. And with it assure billing is clearly defined for standard of care versus research; all patients must be handled the same. (Horseman et al, 2023). The authors therefore frequently suggest all medicine in research is considered a study drug to avoid risk of federal penalties on alleged double dipping as well as have a known reimbursement rate. As added value this assures consistent reimbursement not subject to the patient's insurance schema. Binik-Thomas (2023, Section 1 & 2) notes that patient safety is paramount in the studies and the study site and the research body must first ensure safety without regard to payment – both for the treatment and the payment. This reality requires the parties to build in both risk (Binik-Thomas, 2023) and quality (Ogg, 2006) within the business plan and treatment plan which may come in the form of a bowtie risk assessment prior to the start of trial.

Ethical approaches to the relationship, in addition to the study, when held by all parties to improve the outcomes and reduce the risk of each party according to Binik-Thomas (2023, Section 4) and may be in a predetermined and consistent methodology such as the Four Way Test or the Virtuous Business Model. The authors posit that when all parties – signatories and participants – work in good faith the communication and data flow tend to be more honest, the outcomes more diligently reported, and the patients are more engaged as well as trusting in the healthcare experience. Decentralized services allow the patients to interact with their provider in a way that is most comfortable to them without the cost and inconvenience of travel (Bradham and Fishburne 2023 & Lam et al., 2018).

CONCLUSION

The empowerment of patient facing healthcare practitioners provides patients with the ability to engage care on their own terms, in their own geographies and make it personalized. Nurse practitioners, physician associates, and pharmacists that engage in the community setting help to remove barriers to healthcare. Together the practitioners minimize and remove healthcare deserts in the United States that resulted from the governmental response to the pandemic. Decentralized access to trials and care helps to improve trust between practitioner and patient, allows for proactive and reactive medicine, and bolsters businesses located within the area where the patient lives – limiting, if not eliminating, the need to invest in day-to-find care. The existing infrastructure of pharmacies and supermarkets, staffed with trusted members of the community, help to provide the comfort needed to improve patient safety and health. Further, the empowerment of the practitioners may help to alleviate the expected shortage of other medical-trained personnel. Further, the FDA's guidance on clinical research accessibility, diversity, and decentralization tie well into the clinical space, and the resulting research may improve future lives and health outcomes.

ACKNOWLEDGEMENTS

The authors wish to acknowledge the first collaborative research between The Kroger Co. department of Health and Wellness and Arizona State University Department of Clinical Research Management and Regulatory Science. The senior leadership recognizes that we can work together to achieve healthier outcomes for our patients and our future. The cross-functional team of authors and editors included thought leaders with earned doctorates in business, nursing, pharmacy, and psychiatry. It is with gratitude we recognize Drs. Amber Kayse, Barbara Marusiak, Kaushal Shah, Bill Shinton and Marc Watkins.

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