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PRESCRIPTION

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EXPLORING THE CULTURE OF EXCELLENCE IN A CLINICAL TRIAL UNIT: AN ETHNOGRAPHIC REFLECTION

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Ethnography is a powerful yet underutilized research methodology that involves immersive, long-term observation to understand cultural and organisational dynamics. During my year-long fellowship at the Oxford Centre for Clinical Magnetic Resonance Research, Radcliffe Department of Medicine, University of Oxford, I had the privilege of experiencing this firsthand. This opportunity honed my skills as a researcher, challenged my comfort zone, and fostered resilience.

Throughout the fellowship, I observed the culture within a high-performing clinical trial unit conducting multiple studies. My focus was on understanding the teamwork dynamics and identifying the factors contributing to their success.

IN THIS ISSUE

Simultaneously, I delved into the study of aficamten, a novel therapy for hypertrophic cardiomyopathy (HCM). This required revisiting the disease's pathophysiology and exploring the pharmacology of this innovative treatment.

HCM is a genetic heart condition marked by abnormal thickening of the left ventricular wall, impairing its ability to pump blood efficiently and often leading to heart failure. Traditional treatments, such as beta-blockers, calcium channel blockers, and disopyramide, focus on symptom management without addressing the disease's root cause. Aficamten, a second-in-class cardiac myosin inhibitor, offers a breakthrough by targeting hypercontractility and improving diastolic function (Hartman et al., 2024). Clinical trials have demonstrated sustained reductions in left ventricular outflow tract (LVOT) gradients and significant improvement in heart failure symptoms. Compared to its predecessor mavacamten, aficamten's shorter half-life and reduced drug-drug interactions provide a notable safety advantage.

As part of this open label trial team, I collaborated with cardiologists, echocardiographers, pharmacists, research practitioners, and nurses. The team's meticulous approach was evident in their adherence to detailed protocols and efforts to simplify complex processes into actionable, single-page workflow instructions. Inspired by this, I created an echo-based dosage titration guide for aficamten to assist physicians in decision-making, enhancing trial efficiency and safety.

One of the most inspiring aspects of the experience was witnessing the reversibility of participants' New York Heart Association (NYHA) functional class. Patients previously classified as Class III or II improved to Class II or I, regaining the ability to perform daily activities like walking and climbing stairs. This transformation, supported by clinical data showing reduced LVOT gradients and enhanced diastolic function, was both humbling and uplifting. Participants' enthusiasm and gratitude for their improved quality of life were deeply moving.

While the reliance on frequent echocardiograms for dosage adjustment posed challenges, it also highlighted aficamten's superior pharmacokinetics, which offer enhanced safety and adaptability compared to mavacamten. The success of the clinical trial was further supported by meticulous planning and coordination. Patient schedules were carefully organised to ensure efficient, patient-friendly visits, and laboratory procedures—from blood collection to storage—were executed with precision.

I was particularly struck by the professionalism of the physicians, who skilfully addressed participants' concerns and balanced the risks and benefits of investigational medications. My role extended to providing pharmaceutical care, conducting medication history taking, identifying potential drug interactions, and ensuring compliance with study protocols. Despite occasional adverse events, the overall improvements in patient conditions underscored the transformative value of clinical research.

This experience also highlighted the critical importance of dedicated research roles, such as research pharmacist, research nurses and practitioners, in maintaining high standards in clinical trials. These resources are essential for the effective conduct of trials.

In conclusion, my fellowship highlighted the indispensable role of clinical research in improving health outcomes. It also emphasised the need for well-trained personnel to sustain high-quality trials. This journey of discovery and collaboration deepened my appreciation for the transformative power of research in advancing medical science and shaping patient care.

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Questions

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About the Main Author

Assoc. Prof. Dr. Shubashini Gnanasan obtained her PhD from Universiti of Nottingham (UK) in 2012. She is a passionate researcher of qualitative study and had published various studies incorporating this method to explore the unique perception of the participants in particular issues.