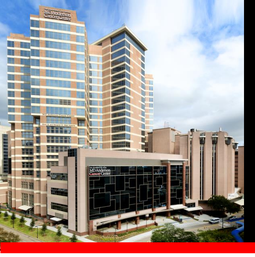

Utilization of the Standardized Assessment for Clinical Trial Enrollment (SAFE) Template to Improve Clinical Trial Screening and Enrollment

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Background and Significance

The successful enrollment of oncology patients in early phase clinical trials requires clinical and research teams to work together to identify an appropriate treatment option for the patient. The screening process is labor-intensive and requires both clinical knowledge and knowledge of study protocol requirements. Advance practice providers (APPs) are an important part of the clinical team and are heavily involved in the patient screening process. In this study, we assessed the efficacy of utilizing a novel template, known as the "Standardized Assessment for Clinical Trial Enrollment" (SAFE) template, to assist both APPs and clinical trial coordinators in screening patients for trial eligibility.

Methods

The SAFE template was utilized in six physician clinics from November 2020 to February 2021 to screen new patients and consultations for clinical trial enrollment in early phase clinical trials. The trial enrollment rate for each physician clinic from this period was compared to the trial enrollment rate from April 2020 to July 2020 when the SAFE template was not utilized. The SAFE template was completed by APPs and uploaded to MOCLIA, which is the online portal containing resources for trial enrollment, at least 24 hours before the patient's clinic visit. Study coordinators then utilized the template to screen patients. The goal of the study was to determine if completing the SAFE template improved the enrollment rate on clinical trials.

Results/Conclusion

A total of 256 new patients and consultations were screened for trial enrollment using the SAFE template. The trial enrollment rate increased in three clinics and decreased in three clinics after the implementation of the SAFE template. The average overall enrollment rate for all six clinics combined decreased (56% to 49%). For this reason, we assessed barriers to clinical trial enrollment based on documentation in the electronic health record from the clinical team. The most common barrier to enrollment was that the patient either continued standard of care (SOC) therapy or had another SOC option (35% of patients). Patients may be evaluated for trials proactively, before they have had progression of disease on current treatment. Patients would not be enrolled without evidence of progression or poor tolerance. Other major barriers included poor ECOG performance status (18%) and organ dysfunction (16%). Most trials will require ECOG PS 0-1 and require adequate renal and liver function.

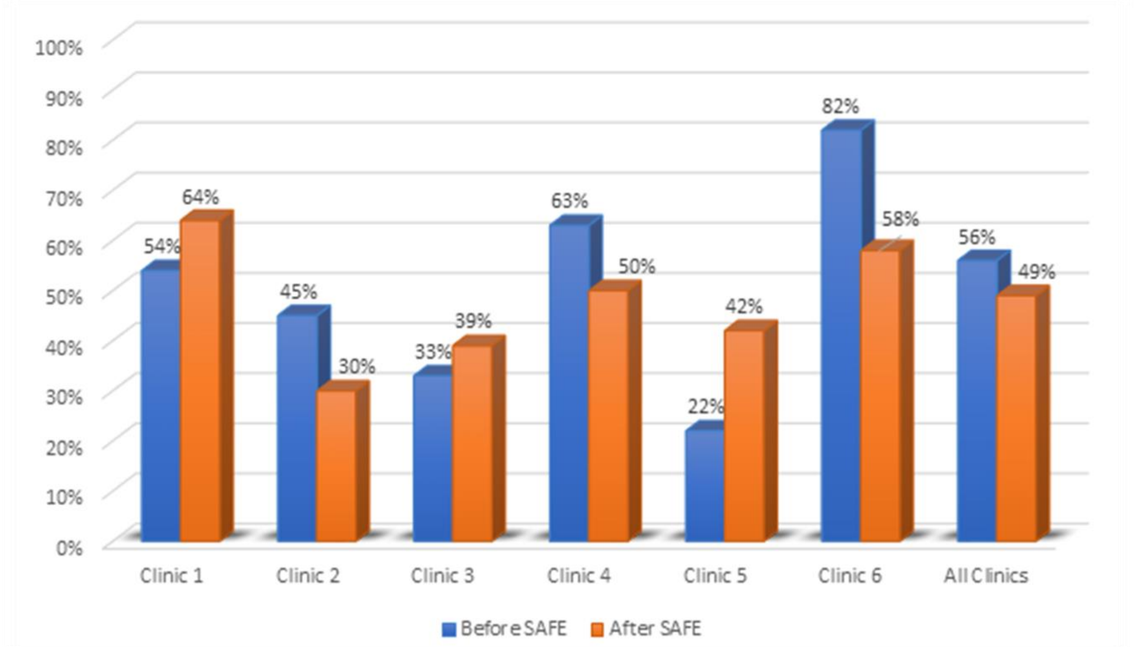

Fig. 1 Clinical Trial Enrollment Rate by Clinic Before and After SAFE Implementation

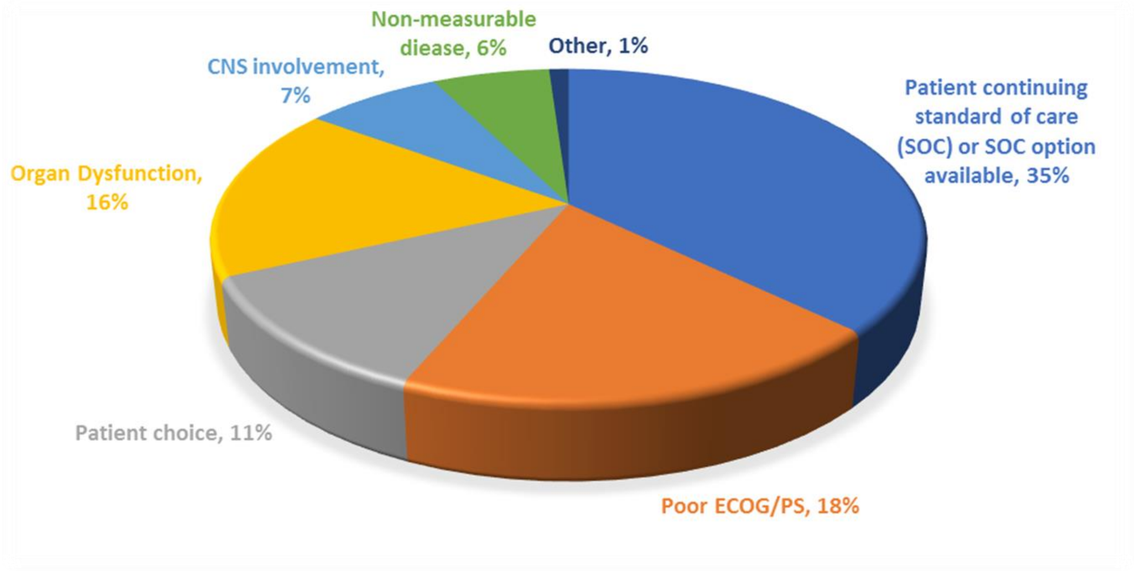

Fig. 2 Identified barriers to clinical trial enrollment

Name/MRN:	Residence:
Diagnosis/Areas of Metastatic Disease: CNS Involvement: Yes ☐ No ☐	Is disease: Yes No Measurable: ☐ ☐ Biopsy-able: ☐ ☐ Injectable: ☐ ☐
Oncologic History: Last treatment date: Prior hypersensitivity to immunotherapy: Yes ☐ No ☐	Past Medical History:
Current medications: Current steroid use: Yes ☐ No ☐	Molecular testing results:
Recent lab results:	Symptoms/ECOG:

Table 1 Sample of SAFE template

Study Limitations

The baseline data before SAFE utilization was collected shortly after the COVID-19 pandemic started, which may have impacted baseline enrollment rates. The actual utilization of the SAFE template by clinical trial coordinators for screening was not evaluated. Patients that are scheduled shortly before their appointment date or are scheduled on the actual date of the appointment limited utilization of SAFE in these situations.

Future Implications/Research

Educating referring providers, who request consultations, and nursing staff on the new patient team, who are responsible for compiling a patient summary for acceptance of new patients, regarding common barriers to clinical trial enrollment may ensure that appropriate patients for clinical trial enrollment are referred. This could increase overall enrollment rates and ensure that the screening process is more efficient. The nature of early phase clinical trials is that trial openings and slot availability change frequently. Therefore, if a patient is currently tolerating a standard of care therapy without evidence of progression, it may be prudent to defer consultation until the time of progression. Close collaboration between the referring provider and clinical trial team can also help the patient in deciding on pursing a next line standard of care therapy or pursuing a clinical trial.