Category: Trial Recruitment & Community Outreach and Engagement – Work in Progress

Prescreening GI Cancer Clinic Schedules for Clinical Trial Recruitment – Plan to Make a Difference in Study Accruals

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1. Background

Inability to reach site-specific target recruitment goals for clinical trials is a challenge faced by most clinical research institutions. There are various ways to identify potential patients for clinical trial participation: physician's screening while seeing patients; referrals from outside physicians; attending tumor board; and advertising through electronic applications/emails.

At University of Cincinnati Cancer Center (UCCC), our gastrointestinal (GI) clinical research group recently started prescreening physician schedules for potentially eligible patients for available GI cancer trials in attempt to increase accrual.

Prescreening started in September of 2021 with research staff identifying all new patients coming to UCCC with the diagnosis of any GI cancer and looking at eligibility criteria for open clinical trials, so physicians and researchers don't miss any patient due to unforeseeable reasons like a physician's busy clinic.

2. Goals

The goal of this work is to increase patient accrual to open GI cancer trials at UCCC, particularly to trials which have not yet achieved target goal

3. Solutions and Methods

Prescreening activity which included going through each new patient identified on the physician schedules started in September 2021. The UCCC GI research coordinators screen the GI medical and radiology oncology physician schedules for the upcoming week for new patient visits. A list of all potentially eligible patients, and the trial(s) for which they may be a good match, is emailed to the clinical team. Research coordinators prepare to consult/consent the potential patients, should the physician deem the matched clinical trial an appropriate option for the patient. If the eligibility is unclear and the study cannot be immediately offered, the patient is followed via electronic medical record (EMR) review. The rationale behind this method is to offer clinical trials to as many eligible patients as possible before standard of care treatment has begun and, in turn, increase clinical trial accrual.

We are maintaining a database to log our prescreening efforts with patient details including:

1) Which clinical trial(s) patient might fit in
2) After new patient visit, if patient is considered eligible
3) Whether the patient was consulted/consented/ enrolled
4) Reasons for being ineligible for clinical trial(s)

4. Outcomes

Prescreening data has been collected from September 2021 through February 2022. There was a total of 62 patients identified from the physician schedules during this period who might fit in one of the open trials, out of 165 new patient charts reviewed.

Eligible patients

Total consented subjects for all open trials between September 2021 and February 2022 (5 months) is 15. Total enrolled patients for all open trials from September 2021-February 2022 (5 months) is 10. We compared it to the previous 5 months (April-August 2021); during that time, total consented were 15 and enrolled were 9. We did notice that for some of the active trials where there was no enrollment since 2020, we have consented at least 1 or more patients during this period.

Ineligible patients

The following are the reasons for ineligibility out of the ones identified on prescreening:

- Incorrect cancer staging in the chart
- Patient plan to pursue care somewhere else
- Started on standard of care treatment
- Poor performance score
- Insurance and transport issues
- Slot unavailable for the study
- Declined participation
- Widespread disease on imaging
- CA-19-9 too low on recent results
- Deranged liver function on recent labs

5. Lessons Learned and Future Directions

On this preliminary data review, we did not find any difference in accrual rates by adding this extra effort of prescreening.

It is too early to say if it has an impact on our overall accrual as we started in September 2021, but it has certainly helped in identifying patients for low accruing trials. This has also definitely increased the engagement between research staff and clinical teams and has increased awareness about the clinical trials available due to communication on a weekly basis.

In the future it will be effective in identifying the causes or some consistent reasoning for ineligibility and will lead to further discussion.

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