Employing a Clinical Trial Nurse Navigator to Increase Oncology Clinical Trial Awareness and Enrollment

Kerry Hepler, MSE, BSN, RN; Christine Mackay, RN, MSA, CCRP; Kirsten Erickson, MPH, PhD

Abstract
Patients who participate in clinical trials benefit from the latest advances in cancer research and closer monitoring of their disease.1 Referrals of new patients to the University of Kansas Cancer Center (KUCC) are received from numerous sources and through various media, creating challenges for identification of trial candidates. Every new patient should be informed about the possibility of participating in a clinical trial as part of their cancer treatment.2

Introduction
The goal was to streamline and track all new patient referrals and inquiries and follow these to resolution utilizing a Clinical Trial Nurse Navigator (CTNN). Specifically, the CTNN provides:
1) patients, families, and providers one point of contact for initial assessment of the appropriateness of a therapeutic treatment trial;
2) follow-up to ensure referral was assessed until resolution;
3) summaries of patient demographics to research team.

Methods and Materials
A new patient tracker (Excel spreadsheet) was developed and utilized for capturing key data points. Data is collected through:
- Coordination with KU disease-specific nurse navigators to receive records of new patients allowing CTNN to prescreen records for trial eligibility.
- If CTNN assessment determines possible patient eligibility, patient’s information is logged into tracker noting the trial(s) the patient may be eligible and forward the patient’s records to assigned study coordinators (SC) for further evaluation.
- Trial project directors work with the CTNN to ensure follow up and outcomes are Ongoing education of research personnel of the CTNN role to further increase.

New Patients Referred to KUCC
Jan-May 2015 (N=1868)

- Ineligible (N=1395)
- Detailed Screened by SC (N=473)

New Patients
Jan-May 2015 Detailed Screened by Study Coordinator (N=473)

- Detail Screened by SC-Ineligible (N=414)
- Consented (N=59)

Results
Project initiated across the clinical trial enterprise in January 2015. Data shown represent total number of new patients referred to KUCC through the CTNN.

January through May 2015: 75% new patients were ineligible for trial:
- Approximately 30% had no diagnosis of cancer at time of referral
- Approximately 30% did not have a trial available for the diagnosis
- Approximately 15% had 2nd malignancy, comorbidities, and other

Patients detailed screened that were ineligible:
- Approximately 20% Poor ECOG
- Approximately 30% Prior treatment or medications excluded
- Approximately 25% Lab values were outside sponsor criteria
- Approximately 13% Patient declined

- CTNN reports monthly to each disease specific group the numbers and types of new patients.
- Patient accrual increased 24% compared to the same timeframe from last year.
- KUCC is maintaining greater than 10% enrollment of eligible new patients each month.
- Patients that do not have a diagnosis of cancer at time of referral are followed through imaging, surgery if needed, and final pathology to identify if eligible for a trial.

Conclusions
- CTNN prioritizes prescreening of new patients, ensuring prescreen is accomplished vs. SC having many competing demands resulting in inconsistent prescreening.
- Systematic evaluation of new patient data allows for identification of appropriate trials to complete the total trial portfolio.
- Ongoing education of research personnel of the CTNN role to further increase clinical trial awareness.
- Communicating to the patient during the first office visit of possible treatment through a clinical trial may increase enrollment.
- Ongoing Assessment of reasons why patients do not enroll in trials with possible solutions:
  - Decline-Physicians discuss trial at initial appointment, clinical trial awareness material, enroll patient at community site closest to home.
  - No trial available-analyze data to procure trials to address patient demographics.
  - Criteria too restrictive/100% participation of physicians-In depth vetting of trials at each Disease Working Group.


Acknowledgments
Kerry Hepler, MSE, BSN, RN; Christine Mackay, RN, MSA, CCRP; Kirsten Erickson, MPH, PhD

A new patient tracker (Excel spreadsheet) was developed and utilized for capturing key data points. Data is collected through:
- Coordination with KU disease-specific nurse navigators to receive records of new patients allowing CTNN to prescreen records for trial eligibility.
- If CTNN assessment determines possible patient eligibility, patient’s information is logged into tracker noting the trial(s) the patient may be eligible and forward the patient’s records to assigned study coordinators (SC) for further evaluation.
- Trial project directors work with the CTNN to ensure follow up and outcomes are Ongoing education of research personnel of the CTNN role to further increase.

New Patients Referred to KUCC
Jan-May 2015 (N=1868)

- Ineligible (N=1395)
- Detailed Screened by SC (N=473)

New Patients
Jan-May 2015 Detailed Screened by Study Coordinator (N=473)

- Detail Screened by SC-Ineligible (N=414)
- Consented (N=59)

Results
Project initiated across the clinical trial enterprise in January 2015. Data shown represent total number of new patients referred to KUCC through the CTNN.

January through May 2015: 75% new patients were ineligible for trial:
- Approximately 30% had no diagnosis of cancer at time of referral
- Approximately 30% did not have a trial available for the diagnosis
- Approximately 15% had 2nd malignancy, comorbidities, and other

Patients detailed screened that were ineligible:
- Approximately 20% Poor ECOG
- Approximately 30% Prior treatment or medications excluded
- Approximately 25% Lab values were outside sponsor criteria
- Approximately 13% Patient declined

- CTNN reports monthly to each disease specific group the numbers and types of new patients.
- Patient accrual increased 24% compared to the same timeframe from last year.
- KUCC is maintaining greater than 10% enrollment of eligible new patients each month.
- Patients that do not have a diagnosis of cancer at time of referral are followed through imaging, surgery if needed, and final pathology to identify if eligible for a trial.

Conclusions
- CTNN prioritizes prescreening of new patients, ensuring prescreen is accomplished vs. SC having many competing demands resulting in inconsistent prescreening.
- Systematic evaluation of new patient data allows for identification of appropriate trials to complete the total trial portfolio.
- Ongoing education of research personnel of the CTNN role to further increase clinical trial awareness.
- Communicating to the patient during the first office visit of possible treatment through a clinical trial may increase enrollment.
- Ongoing Assessment of reasons why patients do not enroll in trials with possible solutions:
  - Decline-Physicians discuss trial at initial appointment, clinical trial awareness material, enroll patient at community site closest to home.
  - No trial available-analyze data to procure trials to address patient demographics.
  - Criteria too restrictive/100% participation of physicians-In depth vetting of trials at each Disease Working Group.


Acknowledgments
Kerry Hepler, MSE, BSN, RN; Christine Mackay, RN, MSA, CCRP; Kirsten Erickson, MPH, PhD