The Christie Patient pathway to Oncology Early Phase Clinical Trials. The role of the Advanced Nurse Practitioner.

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Introduction

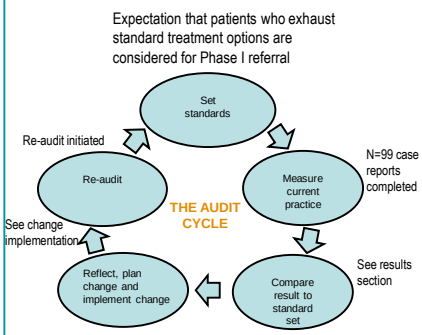
PHASE 1 TRIALS

- Phase I clinical trials of novel anti-cancer drugs provide a potential treatment option for patients with advanced cancers.
- Due to the complexities of Phase I trials in oncology they are predominantly undertaken in major cancer centres with appropriate facilities, such as The Christie NIHR CRF.
- The Experimental Cancer Medicine Team (ECMT) is dedicated to all aspects of Phase I clinical research.

Staff within The Christie NIHR Clinical Research Facility (CRF)

- The Christie NIHR CRF & ECMT has a committed team of Clinicians, research nurses, palliative care specialist, and administrative staff. In 2012 the first advanced nurse practitioner (ANP) in the UK specialising in Early phase research was appointed.
- Advanced practice in oncology is well evaluated at The Christie. The ANP role includes clinical responsibilities similar to SpR, education, leadership and nurse led research/audit.
- Despite the Christie being the largest cancer centre in Europe, patient referrals to Phase I were limited from various teams internally and geographically. Hence an audit was undertaken to look at patient referrals to the Phase I team.

Aims



- Identify the origin of patient referrals to Phase 1 trials at The Christie, and identify any potential referral gaps.
- Identify the suitability of patients referred and define the referral timelines.
- Identify changes in practice related to this audit.

Methods

- A retrospective audit was conducted to collect data from patients referred to the Phase I team between January and December 2012.
- Patients who were recorded on a list of Phase I new patient referrals was included in the Audit.
- Data was collected in five domains; patient demographics, location of referrals, distance travelled, referral timelines and patient outcomes.

Results

PATIENT DEMOGRAPHICS

- 99 patients were referred during this period, of which 91% were white British (6% ethnicity unknown). Median age was 60 years (range, 18-79), 52% were male.
- 56% of patients had received >3 chemotherapy regimens.

REFERRAL PATHWAY

- 64% of patient referrals were from treatment groups within The Christie; 70% of the Christie referrals were from medical oncologists (figure 1).

Referrals from within The Christie

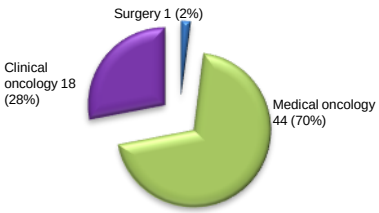


Figure 1. 64% of referrals were from within The Christie.

- Of the external referrals, 13% were from oncologists within the Greater Manchester & Cheshire Cancer Network, 23% were from external sources (figure 2).

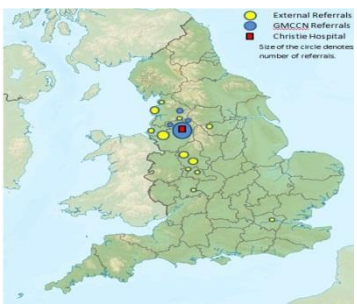


Figure 2. Referrals from the Greater Manchester & Cheshire Cancer Network and also from external Trusts.

Distance travelled by referred patients

- 24% of patients travelled more than 50 miles to attend new patient clinic.

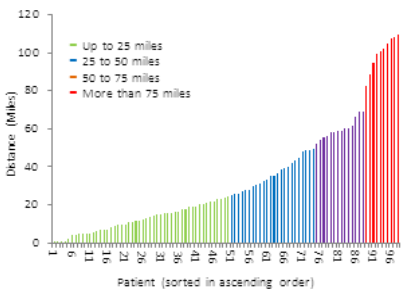


Figure 3. All patients (range 0.5 - 109.5), Christie patients (0.5 to 109.5), GMCCN patients (3.8 - 49.3), External patients (21.7 - 104.5).

Referral timelines

- The mean time from referral to first consultation was 22 days (Range 0 to 69).
- The mean number of days from patient's last treatment to referral was 66 days (Range 0 to 518).

Results - continued

PATIENT OUTCOMES

- At initial clinic consultation, 35% of patients were ineligible to participate due to poor performance status or medical history (ECOG performance status was not documented on 47% of referrals).
- 4% of patients chose best supportive care and 10% of patients withdrew interest at first consultation.
- In total 31% of patients were recruited to a Phase 1 trial (3 % of patients were screen failures, no outcome data for 6 patients).
- The mean time spent on a Phase 1 trial was 56 days (range 0–153) (figure 4).

Duration on Phase I trial

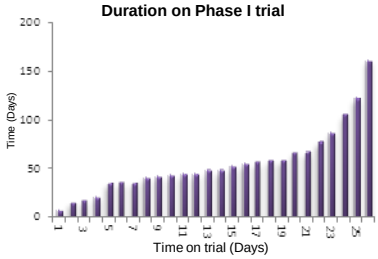


Figure 4. Mean time spent on a Phase 1 Trial.

- 11% of patients discontinued a Phase I trial due to adverse events (figure 5).

Discontinuation of a Phase 1 trial

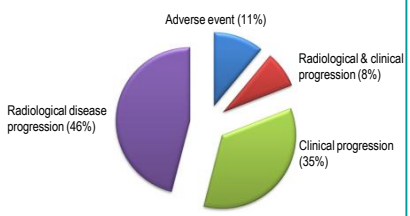


Figure 5. Reasons for discontinuing of a Phase 1 trial.

Following discontinuation of a Phase I trial

- 42% of patients who discontinued treatment went on to receive other therapy including chemotherapy, radiotherapy and a further Phase 1 trial.
- The mean length of time from trial discontinuation to death was 177 days, approximately 6 months (range 14 to 664).

Change Implementation

- The audit has led to new initiatives including a quick and easy referral proforma reducing the length of referral time and the number of inappropriate referrals.
- Potential Phase I patients are identified early in their disease trajectory via a nurse led Clinical oncology metastatic Breast MDT; attended by oncologists, research nurses, clinical nurse specialists, palliative care specialist nurse and ANP.
- An ANP works collaboratively between the ECMT, Breast research team and Breast oncology teams to help identify and match eligible patients to the most suitable trial and coordinate a seamless referral process.
- Within a 6 month period 24 patients' were identified by the ANP as eligible for Phase I trials from three clinical oncology clinics, compared to no referrals in 2012.
- Further work is ongoing to raise the awareness of Phase I trials regionally and nationally.

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