Managing follow up and supporting patients coming off trial

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Managing Follow-up

Range of Methods:

• Clinic visits

• Telephone calls

• Email communication

• If survival only then GP telephone call
Managing Follow-up

Some Potential Challenges:

• Patients starting new treatments and trial follow up and treatment visits clashing.

• Patients not living local to the hospital therefore reluctant to travel for follow up visits.

• Patients ongoing disease makes it difficult to attend appointments e.g. palliative patients.

• Patients no longer being a priority for Research team if the workload means that patients in treatment take priority over patients in follow up.
Managing Follow-up

Potential Solutions and Resources e.g.

• Research nurse led follow up clinic that would include telephone calls if protocol allows, allowing for escalation to Sub I/PI if appropriate.

• Negotiating local bloods to be taken locally, sending blood cards out to GP practices.

• Negotiating with sponsor that follow up schedule follows the patient new treatment schedule to minimise visit to hospital.
Supporting patients coming off trial

Range of Context/Meaning ‘coming off trial’

• End of study visit OR unforeseen disease progression / treatment failure / toxicity OR patient preference to withdraw

• End of early phase study / last treatment option OR end of later phase study / other options still available

• Drug working but no longer supplied by sponsor

• Study delivered in research facility OR research in integrated clinical service setting

• Adults OR children setting
Supporting patients coming off trial

Some Potential Challenges:

- When to start preparation for end of study?
- Research team time available of the at this point?
- What about carers at this time?
- What early phase literature indicates:
  - Trial patients feel abandoned and want feedback at the end of study (Cox, 2000), rites of passage
    - importance of a ‘good ending’ to this stage of pathway (Wilson et al, 2007)
  - Potential role for nurse-managed intervention (de-briefing and explain further support, leaflet, follow-up phone call post exit) at the end of a study (Cox et al, 2005)
  - Need closer follow-up if hopes and expectations not met (Wootten et al, 2011)
Supporting patients coming off trial

Potential Solutions and Resources e.g.

• Individualised care and preparation / realistic expectations from the start

  e.g. linkage with CNSs etc. / palliative care

• Clear info about referral or next steps for support

• Time to mark the end / off study – acknowledgement of contribution / value

• Leaflets/thank you cards

• Sign-post - results available down the line
Supporting patients coming off trial

Resources

https://www.cancerresearchuk.org/health-professional/learning-and-support/resources/excellence-in-research-programme-for-clinical-research-nurses/working-with-patients
References

  Enhancing cancer clinical trial management: recommendations from a qualitative study of trial participants' experiences.

• Cox et al, 2005 [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2361479/](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2361479/)
  A randomised controlled trial of nurse-managed trial conclusion following early phase cancer trial participation

  Closure for patient at the end of cancer clinical trial: literature review

  A qualitative assessment of the experience of participating in a cancer-related clinical trial