Reviewer's report

Title: Impact of radiographer immediate reporting of chest X-rays from general practice on the lung cancer pathway (radioX): study protocol for a randomised control trial

Version: 0 Date: 11 Sep 2017

Reviewer: P Murchie

Reviewer's report:

OVERALL

Thank you for asking me to review this manuscript protocol for consideration for publication in Trials. It describes a single-centre randomized trial of a revised reporting pathway for chest x-rays requested from general practice when lung cancer is suspected. I note the study has been funded by CRUK's EDAG programme. Generally, it is a clear and well-written protocol. I have some concerns around the primary outcome and purpose of the trial, the description of the intervention, and it's external applicability which I outline in my comments below. As a general point it seems unlikely to me that the trial will have a meaningful impact on clinical outcomes for lung cancer - I think the authors need to be much stronger in the introduction and discussion why they think it will. It would, however, seem likely to have a greater impact on patient satisfaction and I'm a little surprised that wasn't the primary outcome.

BACKGROUND

The background to the trial is reasonably well-described. However, it would be useful (line 72) to quantify the impact of time to clinical report on diagnostic delays and whether these delays are clinically meaningful?

Line 79 - the authors cite that radiographers have been trained to report CXRs. A bit more detail on how effective this has been would appear to be essential - i.e. how do they compare to radiologists?

METHODS

Line 85 - Has any feasibility testing of the intervention been attempted up to this point? Are any of the outcomes assessing feasibility for a larger UK-trial, or is this trial simply for local service improvement?
Line 94 - It's not entirely clear why a comparison is being made with Newham University hospital? What will be gained from this? What is the basis for the choice of comparator site? Why not randomize there too, presumably that could quite efficiently give a more powerful trial.

Line 100 - I'm struck that the study will not directly recruit patients. How will patient's be informed that their data is being used in a clinical trial - more details on this would be important?

Line 106 - What has been the effect of radiographer reporting at other sites? Why do the protocol authors feel this study is necessary in the light of those experiences?

Line 129/148 - The protocol seems to suggest that the new pathway will only reduce diagnostic delays by a few days - I think it would be useful for the authors to explicitly state somewhere what sort of reduction in delay they think they will achieve.

Line 150 - I would have thought patient satisfaction would have been the most appropriate primary outcome for the trial. It would be good to see a stronger justification for powering the study on what could be clinically insignificant gains in diagnostic delay.

Line 153 - do the authors envision a larger definitive trial? If so I would have thought stage at diagnosis was an important outcome to collect too?

Line 168 - considerably more detail on the methods planned to assess patient satisfaction are required.

Line 169/170 - as above a clearer explanation of the rationale for the comparison with a second site not taking part in the study, and how this data will be used, would be important.

Line 182 - I'm a little confused by the section on "Off Protocol Radiographer Reporting." This suggests that when a serious pathology is suspected during immediate radiographer report, then that patient will be subsequently excluded from analysis. But surely that can only occur in those randomized to control, and would that not then be a source of bias? Perhaps I'm misinterpreting this, but it needs to be clarified.

Line 258 - The study is powered on an eleven day reduction in diagnostic interval. Is there evidence that this is clinically meaningful?
Line 261 - the study is powered on 26 cancers in each group. It appears that the expectation of 50 lung cancer each year gives very little margin on this power calculation. That's not a problem if this is a feasibility study, but it doesn't look that way?

Line 275 - I think patient satisfaction is potentially the most important outcome from this study in my view. Much more information is required around how this will be collected. The instrument should be included as an appendix.

Line 285 - The health economic assessment is very briefly described. It is not clear to me that data will be collected on primary care costs if costs are being calculated from an NHS perspective. Have the triallists assumed the intervention will be cost neutral in primary care? It may not be.

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