Assessment of the environmental impact of clinical trials

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Background

The declaration of Helsinki states "medical research should be conducted in a manner that minimises possible harm to the environment"[1]. The environmental impact of Clinical trials (CT) has been highlighted in publications which evaluated carbon emissions arising from trial coordination centres, travel and transport relating to two CT, but this study neglected the contribution of waste[2]. Collection, transport, disposal and destruction of solid waste contributes to climate change[3,4] through Greenhouse Gas (GHG) production[5] and accumulation of un-degradable materials in landfill[6]. CT result in waste via unnecessary paper use, inefficient pharmacy processes and inadequate stock management relating to sample kits containing plastic blood bottles, syringes and more. The aim of this project was to develop a tool to highlight the impact of waste in CT.

Methods

- A tool, holding 6 surveys on paper use, sample kit management and pharmacy processes was developed using the app creator Clappia© to collect data on trial management in oncology CT sites
- The surveys are scored to show whether processes are considered to have a low (L), medium (M) or high (H) environmental impact.
- The app was distributed to national Experimental Cancer Medicine Centres and international clinical trial sites via email, and a link was posted on the clinical trial pharmacist network forum.
- Results were downloaded from the app into an Excel spreadsheet for analysis

Results

- From February 2020 to July 2020 there were 38 respondents from 8 developed countries across 4 continents (figure 1).
- 32 (84%) sites host phase 1/non-randomised phase 2 (early phase) and 6 (16%) phase 2/3 trials only (late phase) (figure 2).
- Early phase CT are more likely to have a high environmental impact (10%) compared to late phase CT (0%) (figure 3). There is no significant difference in scores between early phase and late phase sites; paper (p=1), sampling kits (p=0.57), pharmacy processes (p= 0.71).

Figure 1: Number of responses from North America, Europe, Asia and Australasia

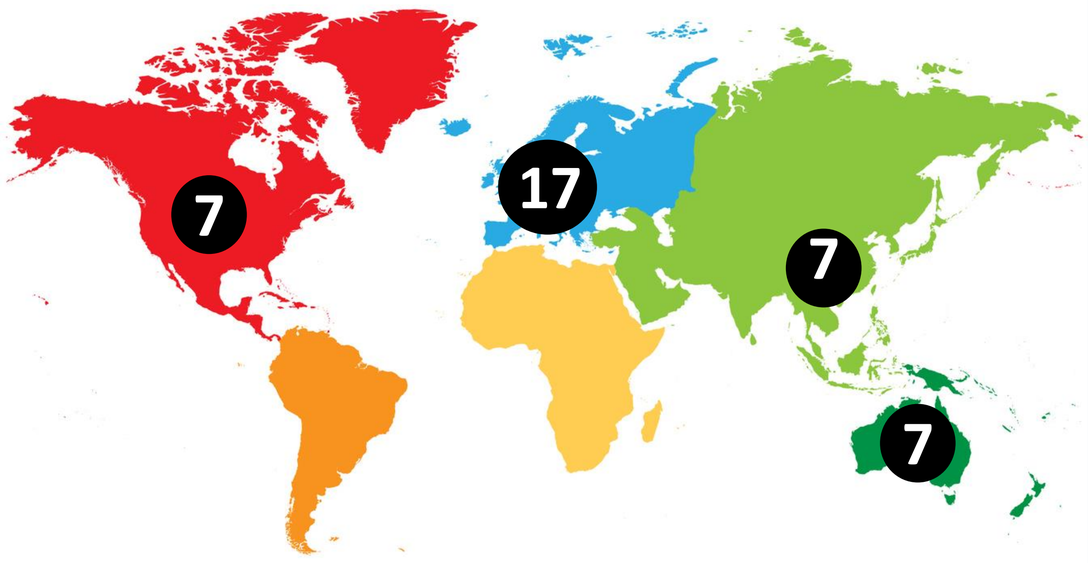


Figure 2: Phase of trials hosted by sites who completed survey

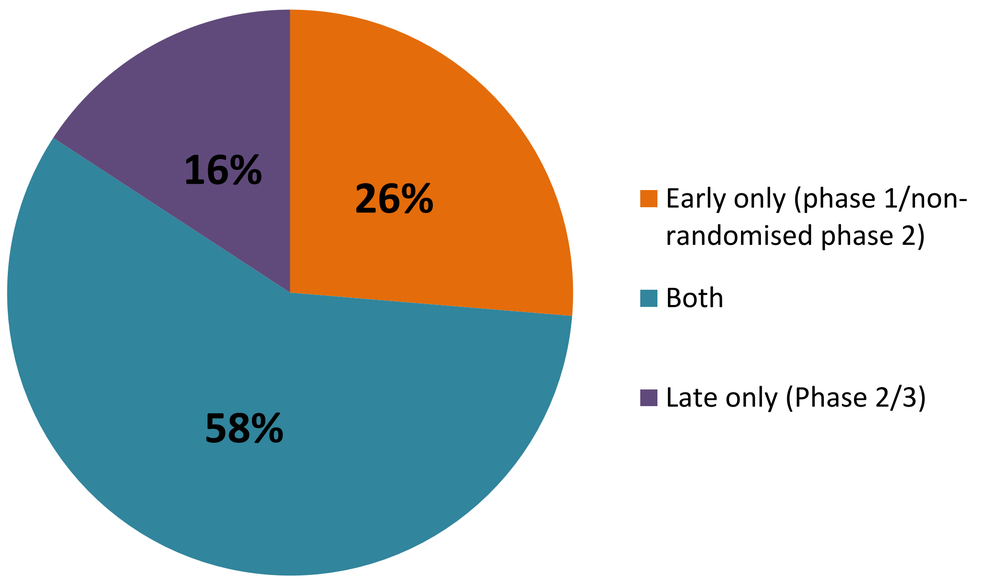
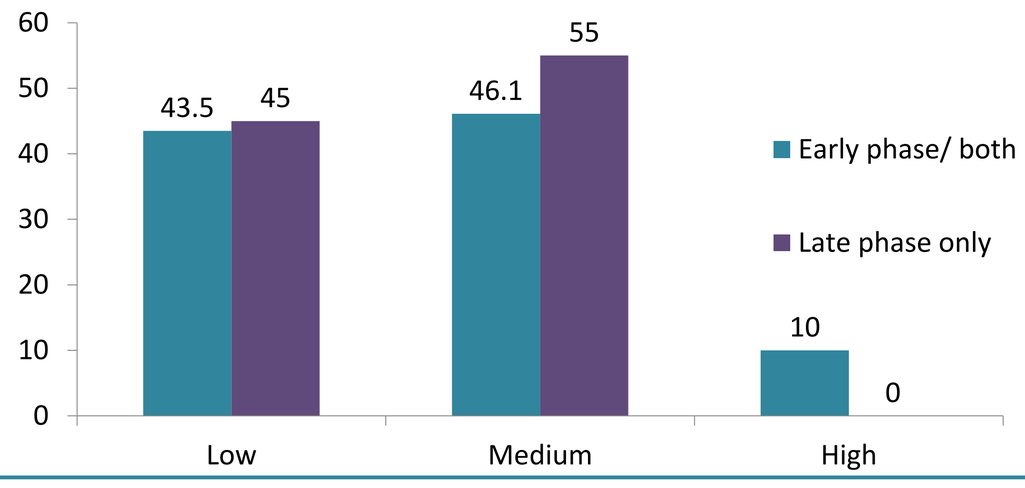
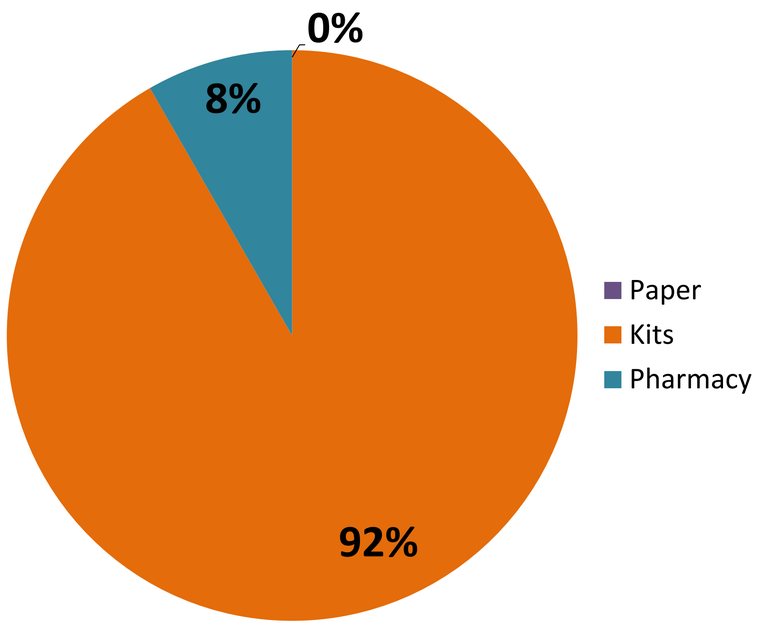


Figure 3: Percentage of sites scoring low/medium/high by site type



- Sample kit management was most likely to result in a high impact score (92%) compared to pharmacy processes (8%) and paper use (0%) (figure 4).
- Reasons for high scores include low recycling/re-use rates, provision of excess materials from CT sponsors/ clinical resource organisations and inefficient supply management processes resulting in over-ordering of stock.

Figure 4: Percentage of high scores by waste type



Conclusions

The app facilitated engagement on an important issue in global research. Early results suggest higher negative environmental impact from sites hosting early phase trials and highlight potential areas for improvement.

Data is not routinely collected on environmental impact; therefore it is difficult to make meaningful conclusions from this work. Additional research is required; further development of the tool may enable this.

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