Promoting Patient Safety in Cancer Clinical Trials:
A Survey of Progress in Out-of-Hours Systems in the Experimental Cancer Medicine Centre (ECMC) Network

ECMC Research Nurse Network
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Background:
In 2010, the ECMC Research Nurse Network Group undertook a survey of ECMCs to gather information about the out-of-hours safety systems in place for clinical trial patients across the ECMC Network. The purpose of this survey was to:

- Identify out-of-hours patient safety systems at each Centre
- Identify common issues in safeguarding patient's safety out-of-hours
- Identify and share examples of effective and robust out-of-hours practice across the Network

The steering committee of the ECMC Research Nurse Network Group agreed that this survey should be repeated to determine how out-of-hours systems had progressed in recent years, identify new or on-going challenges, and share innovations in practice.

Methods:
The ECMC Secretariat co-ordinated the distribution of the original survey responses to appropriate contacts across the 18 Centres within the ECMC Network in March 2014. Respondents were requested to document all changes to the system that had occurred since the previous study.

Results:
Eighteen Centres[1] (100%) returned the survey between April and September 2014. 15 out of the 18 current ECMCs had also responded to the 2010 survey. New developments impacting out-of-hours patient safety systems are highlighted below.

Patient information

Wider use of patient wallet cards for study ID and out-of-hours contact details

- All Centres provide advice and written out-of-hours contact details including study-specific and/or generic materials
- Written information is supplemented with verbal information throughout the trial process

Out-of-hours support

Patients' electronic records have a research section or 'alert' notifying staff the patient is taking part in research
Wider access to clinical trial information through EDGE/internet/ shared drives, including protocols/IB/PI and study staff contacts / study decision support information
Wider awareness of trial patient triage through staff training/flow diagram at nurses' station

- It varies who centres advise patients to contact out-of-hours (see graph)
- Liaison with registrar, consultant or PI on call

Communication with research team

Acute Oncology Service (AOS) contacts the research team

- Phone/email message
- Close working relationships between teams
- Form (triage scoring sheet/proforma) shared with research team
- Recorded on electronic patient record
- Review of hospital admission list
- Not always robust as reliant on non-research staff and patients/carers to inform the research team

> "A national system whereby research patients are flagged up if attending another hospital would be ideal"

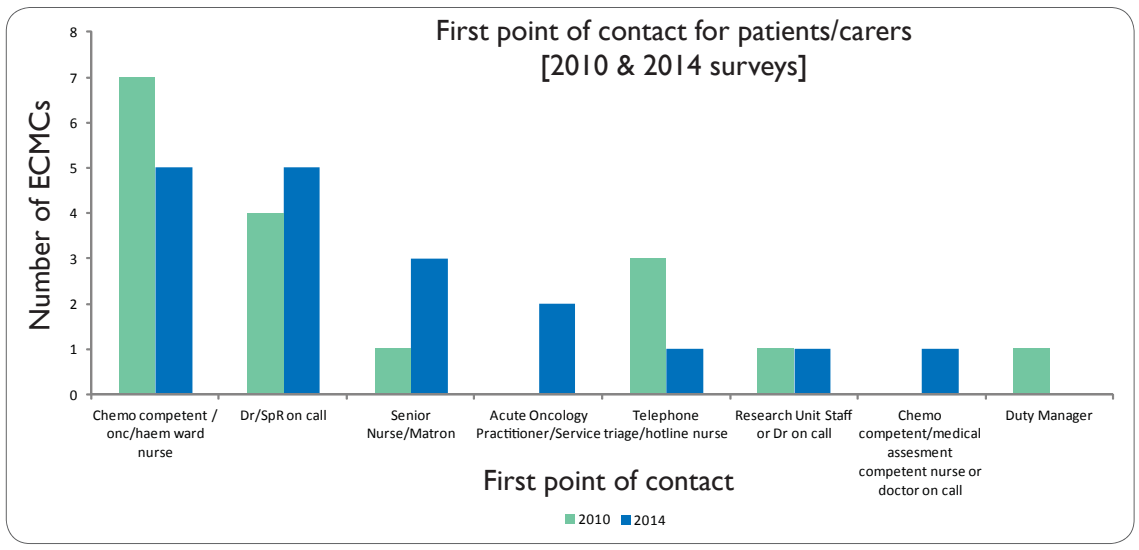
Quality issues

AOS management (or shared management) of the out-of-hours helpline and processes, at some centres

- External and internal monitoring and audit of calls and helplines
- Guidance document and policies
- Some centres didn't report anything

Barriers to best practice

- Patients not contacting the out-of-hours system or being reluctant to go to a different hospital
- Patient admission to non-treating hospital
- Patients not informing staff that they are on a trial
- Dependent on ward staff/non-research staff and ongoing training needs with staff changes



> "Hospital secure laptops for on-call medics facilitate ease of access to clinical trial protocol and associated algorithms for symptom management, if provided, speeding up the process of advice/ management prior to attending the hospital"

> "Clinical trial education sessions have become part of the mandatory and statutory training days and this change has led to an increased awareness and interest in clinical trials among non-trial staff"

Conclusions
From this survey, and comparing 2010 and 2014 responses, there is evidence that there continues to be out-of-hours patient safety systems in place throughout the network and these systems are developing to further support the needs of clinical trial patients and facilitate easier staff access to protocols and study information. Changes are actively addressing some previous challenges to best practice. A number of centres now have specific systems to oversee the whole process and various approaches are adopted to increase clinical trial and system awareness across out-of-hours staff. When a trial patient is admitted to a non-treating hospital, triage procedures and increasing availability of shared IT systems/trial information across hospitals are facilitating research communication, however, this remains the area most challenging to quality control

Implications for practice

- Since 2010 patient safety out-of-hours systems continue to develop and practice development is evident
- The role of research and clinical staff working in collaboration at each ECMC is vital, to ensure patient safety out-of-hours processes develop to meet the needs of clinical trial patients while integrating with developing hospital systems and services
- Patient/carer education remains essential, to ensure the out-of-hours systems are utilised effectively
- While Centres have unique systems, the ECMC Network provides a forum to facilitate shared learning and develop practice to address on-going challenges

For further information, please contact the ECMC Secretariat: **hannah.brown@cancer.org.uk** or 0203 469 5381.

1. Contributing ECMCs: Barts, Belfast, Birmingham, Cambridge, Cardiff, Edinburgh, Glasgow, ICR, Imperial, KCL, Leeds, Leicester, Manchester, Newcastle, Oxford, Sheffield, Southampton, UCL.

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