Nursing Practice
Discussion
Clinical research

Changes in the way clinical research is embedded in healthcare mean every nurse can engage with it, so it is vital that all nurses understand the implications on their practice

The nurse's changing role in clinical research

In this article...
› Changes to the clinical research environment in the last 10 years
› The link between research and practice
› Guidance on the handling of patient data

5 key points

1 Every nurse can now be actively involved in clinical research

2 Clinical research is now carried out as part of NHS core services

3 Frontline routine data is an important resource for clinical research and needs to be collected to the highest standard

4 The Nursing and Midwifery Council's code identifies key skills closely associated with supporting high standards of clinical research practice

5 Patients are increasingly creating and sharing their own data, and need to be empowered to do this safely and effectively

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Abstract Hamer S (2015) The nurse's changing role in clinical research. *Nursing Times*; 111: 39, 12-14.
The possibility of systematically sharing clinical data more quickly and effectively has increased its potential to be used in research and, as a result of changes in policy over the last decade, all nurses can now be involved in clinical research. To do this, they must think actively about the quality of data they gather, as it becomes increasingly visible to more users and can be used many times for multiple purposes. This article outlines how the research environment has changed and the implications for clinical practice.

It is sometimes easy to underestimate the significance of policy amendments on contemporary clinical practice, but the last 10 years have seen major changes to the clinical research environment. These changes have made it possible for every nurse to be actively involved in clinical research.

Growth of clinical research
There has been a significant growth in clinical research in the last 10 years. Initially this was driven by the establishment of the National Institute for Health Research but, more recently, it is a result of the government's commitment to increase the role of life sciences and innovation in health.

The NIHR was created in April 2006. Funded by the Department of Health, its focus is to improve the health and wealth of the nation through research. It is a large, multi-faceted, and nationally distributed organisation, and one of the most integrated clinical research systems in the world. It has increased the volume of applied health research being carried out in the NHS for the benefit of patients and the general public. In 2014, more than 630,000 people participated in studies hosted by the NIHR Clinical Research Network, and nearly all NHS trusts are now involved in research and deliver studies across a wide range of care settings.

More recently a change in policy introduced by the Health and Social Care Act (2012) placed a statutory duty to promote research, and powers to support it, on the health secretary and all levels of the NHS, including NHS England and clinical commissioning groups. Research is now a mainstream activity of nearly all NHS-funded organisations and is an expectation of standard care delivery, actively supported by *The NHS Constitution* (Department of Health, 2015), which includes:
» A commitment to promote, conduct and use research to improve the current and future health and care of the population, as enshrined in NHS England's seven key principles;
» A pledge to use anonymised information to support research and improve care for others;
» A commitment to inform patients of research studies in which they may be eligible to participate.

Why research is important
Increasing clinical research activity is about generating evidence for future practice; as nursing is an evidence-based profession, nurses have a commitment to do

All nurses can be involved in research

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this. However, there is increasing evidence that research also benefits clinical outcomes: healthcare organisations that are research active are more likely to show better performance (Ozdemir et al, 2015).

The rapid expansion in both the type and volume of clinical research – which will be a feature of an increasing number of practice environments – presents a development opportunity, as all nurses need to think more actively about their individual professional role as it relates to clinical research.

Questions outlined in Box 1 are typical of those nurses may encounter in day-to-day practice, and illustrate just how much more frequently research is becoming part of routine care. On the surface, these questions are straightforward but underlying each one is a need to understand a world where the nature of research, data and information sharing is rapidly changing, and where some of the decisions are now much more complex. The increasing role the public, patients and carers will share in this world is an important opportunity and practice challenge. Having confident answers to the questions posed requires practitioners to be clear about the relationship between, data, information, knowledge and practice.
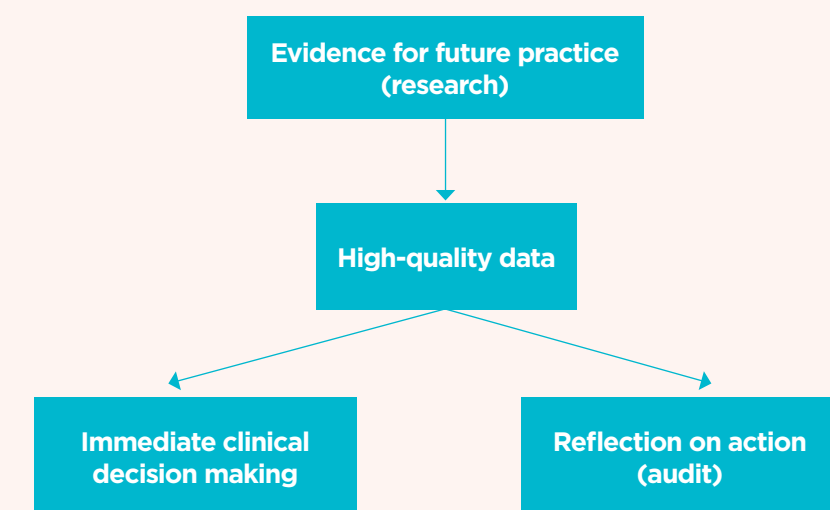
Data, information and knowledge

It is easy to underestimate the value of day-to-day clinical practice and its associated data. Each aspect of care and its documentation – whether by a health professional or a patient – provides valuable data that can be used for multiple activities (Fig 1). Day-to-day data is still predominantly used to inform a clinical decision happening at that point in time; the paper notes are then filed and rarely seen again – the data within is considered by many staff as having little, if any, ongoing value.

Now, however, the same data is increasingly used to reflect on aspects of care and audit our activities to learn as part of our review processes. The increased use of electronic systems certainly helps in this respect but the time lag to feeding the data back to inform clinicians can lead to a lack of commitment to data quality and a view that the data is for management purposes, not to support clinical decision making. It is far less common for this routine clinical data to be used to contribute to building the evidence base for practice or for research.

In the past, research was viewed as a separate activity with its own systems and processes – this is no longer the case. Research (and its associated data

FIG 1. USES OF EVERYDAY DATA

collection) is now commonly embedded in a care pathway, which, in turn, brings much closer the reality of every nurse contributing to research in real time. The increasing role of patients in this process is also evident.

The question about who is using the information collected in daily practice, then, has a different answer – yes, it could be researchers, but it could also be the nurse, the patient, managers, regulators or auditors. Nurses therefore need to be able to detail these potential uses and users, and understand the practice implications.

Sharing data and information

Nurses commonly share data and information; the Nursing and Midwifery Council's Code (NMC, 2015) is clear about the accountability associated with this (Box 2). Health and care records, together with the data they contain, are now visible to an increasing number of people and must therefore be secure to protect patient confidentiality.

BOX 1. QUESTIONS PATIENTS MIGHT ASK

● I saw a sign in the outpatients saying that this organisation takes part in clinical research studies. I would like to be involved in this. What would it mean for me?
● I read about a trial of this new treatment on the internet and would like to be part of that trial. How would I go about it?
● You are collecting a lot of information about me. Who will it be shared with?

Impact on patients

As we increase the frequency with which this same data is used for clinical research, the implications for patients and carers, and the role of the practitioner in supporting them, similarly increases. In particular, we need to consider the changing nature of how patients and the public are engaged and involved in research.

Patients involved in research can benefit in a number of ways and it can also improve their experience of care by more actively involving them in the outcomes of their care (Foot et al, 2014; Coulter, 2011). As patients' expectations change and they become more active throughout the research pathway, so too must nurses' professional response change.

A good example that indicates the scale and ambition of patient-led communities is PatientsLikeMe (www.patientslikeme.com), an online network of around 250,000 people with long-term conditions who share information about symptoms, treatments and coping mechanisms. The largest communities within the network are built around fibromyalgia, multiple sclerosis and amyotrophic lateral sclerosis, but as many as 2,000 conditions are represented. The goal of these communities is that the information shared by people with long-term conditions will help the life sciences industry to identify unmet needs in patients and generate an evidence base that will be used to influence future treatments.

There are also examples of current trials in which data from day-to-day clinical practice are being used in real time. For example, the purpose of the Salford Lung Study (www.salfordlungstudy.co.uk) is to

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test the safety and effectiveness of a new treatment for chronic obstructive pulmonary disorder compared with the standard medications currently used to treat it. The new treatment, an inhalation powder, is investigational and so is, as yet, unlicensed to be prescribed.

There are also many examples of websites directly providing information on trials. These include one run by the NIHR, the UK Clinical Trials Gateway (www.ukctg.nihr.ac.uk). This provides easy-to-understand information about ongoing clinical research trials running in the UK, and gives access to a wide range of information about them. It is designed to enable patients and clinicians to locate and contact trials of interest.

Impact on health professionals

Supporting the public, patients and carers to consider taking part in clinical trials is now a much more complicated landscape and may happen in any part of the health system. It is important to be positive and clear about how to signpost patients to high-quality information that supports their decision making, but it might be equally important that nurses are supported to look again at their role in respect of this competence.

If you are becoming more active in relation to clinical research you may want to consider undertaking an Introduction to Good Clinical Practice course. The key aim of this online course is to help participants understand how to use excellent clinical practice when they return to their workplace to ensure the rights, safety and wellbeing of patients as well as the quality of the research data (Bit.ly/NIHRClinical Practice).

Valuing our data

A final area to think about when considering developments in clinical research nursing is the professional value we place on the data we collect. The economic value of health and care data is clearly a topical issue and ensuring patients' health data is used appropriately is important if we are to maintain public confidence and trust. The Health and Social Care Information Centre was set up in 2013 to do this task; its responsibilities are outlined in Box 3.

The need for sharable, comparable information in healthcare is evident, not just in the UK but globally. The ability to store, aggregate and combine this data to perform analyses has become ever more important. This trend to share and compare large data sets is known as "big data" and nursing cannot be left behind. Anne Cooper, a nurse who also has a long-term condition, has written about the importance of big data (Bit.ly/ACBigData).

Unfortunately, nursing care data and frontline clinical research data collected by nurses – beyond that on basic compliance – is seldom stored electronically. This is despite the fact that research has demonstrated that including nursing problems improves the accuracy of costing healthcare and predicting outcomes (Welton et al, 2006).

If electronic healthcare documentation contains little data about the decisions nurses make, nursing data will not be used in healthcare research and planning (Healthcare Information and Management Systems Society, 2015; Royal College of Nursing, 2010). If this is the case, the crucial role of nursing in healthcare will remain invisible, and the profession's contribution to clinical research will not be considered in healthcare policy.

Conclusion

This article has provided examples of how changes in the clinical research environment are affecting current practice, and seeks to encourage nurses to use some practice reflection time to assess their role and competence in supporting this rapidly expanding field of practice. The overall aim is for all practitioners to understand the valuable contribution they have to make on a daily basis in generating the evidence for future clinical practice and supporting patient decision making. **NT**

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