Implementing Essence of Care in a clinical research facility

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Since Essence of Care was introduced there have been a number of documents published on benchmarking in clinical areas. However, there is a lack of information on implementing the benchmarks in a research setting. This article describes how the Essence of Care framework has been translated for use at the Wellcome Trust Clinical Research Facility, detailing the implementation cycle, difficulties, achievements and future plans.

Essence of Care was issued by the Department of Health in February 2001 (DH, 2001a) as part of the clinical governance agenda to support quality improvement measures set out in A First Class Service (DH, 1998). The idea is that through comparing, sharing and developing best practice by means of clinical benchmarking, the quality of fundamental aspects of care can be improved. The advantage of clinical benchmarking at a local level is that by using a bottom-up approach frontline workers can influence the quality of care delivered by ‘getting the basics right’ as outlined in The NHS Plan (DH, 2000).

The clinical research facility

In a collaborative venture with the English and Scottish Health Departments, the Wellcome Trust invested in the development of five clinical research facilities (WTCRFs) in Birmingham, Cambridge, Edinburgh, Manchester and Southampton. The objectives of the WTCRFs (the Wellcome Trust, 2004) were to:

- Offer sites in order to conduct high-quality patient-oriented research;
- Encourage collaborations between clinical and other scientists;
- Help to nurture a population of talented clinical researchers;
- Provide an environment in which other health professionals could train in research.

The specialist facilities at the Southampton WTCRF include consulting rooms, an adult ward area, a bronchoscopy suite, a sleep laboratory, a physiology laboratory, an environmental laboratory, and a children’s ward and treatment area.

The purpose of the unit is to create an environment that respects the role of research participants. The staff at the unit strive to achieve the highest standards of practice by complying with the principles set out by the International Conference on Harmonisation and Good Clinical Practice (ICH GCP) (International Conference on Harmonisation, 2002) and the Declaration of Helsinki (World Medical Association, 2000).

With the adoption of the Medicines for Human Use (Clinical Trials) Regulations (DH, 2004), it became a legal requirement to comply with the principles of ICH GCP (ICH, 2002). Furthermore, the research governance framework (DH, 2001b) includes respect for participants’ dignity, rights, safety and well-being. The Essence of Care framework addresses these fundamental aspects of care within 10 benchmarks.

Although a clinical research facility may not seem an obvious place in which to implement Essence of Care, the research staff are committed to delivering the best care possible while adhering to individual research protocols. Research participants deserve the same high standards of care as any other patients. Using the Essence of Care framework has provided a structured approach to evaluating and improving practice within the unit.

Getting started

The most difficult parts of the process were:

- Finding a starting point for the implementation of the cycle;
- Understanding the concept of Essence of Care and how it could be applied in a research setting.

The first step was to set up an Essence of Care group within the clinical research facility to implement the benchmarks. The group was made up of an education and development lead nurse, a research sister and two research nurses, all from the adult and children’s nursing teams.

Initial discussions highlighted that not all 10 benchmarks would apply to the unit. The group initially decided to concentrate on four benchmarks: communication; privacy and dignity; record-keeping; and health promotion. The food and nutrition benchmark was selected as a possible fifth area.
Communication was the first benchmark to be developed. An initial brainstorming exercise highlighted the following issues that were perceived to be important in the research setting:
- Informed consent;
- Explanation of procedures;
- Age-specific communication;
- Communication between multidisciplinary research staff.

A recent satisfaction survey delivered to research participants and the parents of children taking part in research had already addressed these particular issues. The results of the survey were mainly positive. However, one consideration raised during group discussions was whether research study information was being given at the right time for all studies thus allowing the participant to be adequately prepared for their involvement. This is particularly pertinent in research if practice is to be in accordance with ethical guidelines.

The decision was made not to re-audit communication at this stage as the satisfaction survey results had been collated so recently.

The implementation cycle

**Stage 1: agree best practice**

A participant-focused outcome for communication was developed using the recommended guidelines (Box 1, p35). This outcome reflected the high standards of communication that participants should ideally experience. This was then broken down into 12 factors, each focusing on an aspect of communication specific to the research setting. These factors represented the best practice that could be achieved. This was particularly difficult and time consuming with no equivalent examples to draw on. It was with tentative steps that the guidelines were altered to fit the needs of the research facility and the participants within it.

Each member of the team was responsible for developing three factors into scoring criteria, which had to be written in a way that was measurable. As each factor represented best practice, the current practice in the unit also needed to be identified as measures.

**Stage 2: assess the clinical area**

Once the participant-focused outcome had been broken down into specific factors, the scoring criteria for each factor was agreed. A traffic light system was adapted from a well-established clinical governance tool (Lewis et al, 2002) and used as follows:
- Green – excellent practice;
- Yellow – some room for improvement;
- Red – poor practice with areas in need of attention.

Group discussions were utilised to identify areas of good practice in the unit. These were documented as evidence, which related to each factor.

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Stage 3: identify areas of development
Using the evidence for good practice, each factor could be assigned a score of red, yellow or green. Although difficult at first, reflecting on practice became easier. By stepping back from the clinical area and looking in the group realised that they could act as the participants’ advocate by being critical of the practice in their own work setting.

Having given each factor a score, thus highlighting current practice in the unit, the group was able to identify areas of development (Table 1, p33; Table 2, p34). These were areas of practice that needed improvement or were barriers to best practice.

Stage 4: produce and implement action plan
The group used the areas of development to produce an action plan for the benchmark (Table 2). Although the action plans were quite straightforward to write, implementation was more difficult.

Table 2 gives an example of an action plan for information giving. The area of development involved a problem with one research study, which was set up in such a way that the participants were recruited while attending outpatient appointments.

This resulted in them having limited time to consider the information before signing the consent form. Research ethics dictate that adequate time and appropriate circumstances should be available to enable the participant to fully consider the implications of taking part in a study, ideally at least 24 hours (Central Office for Research Ethics Committees, 2005).

As this study had been ethically approved, it was not feasible to create an action plan around changing the study set-up. Instead the action plan concentrated on ensuring research nurses were fully aware of the ethical issues of taking informed consent. This included allowing the participant enough time to consider the information and ask questions as well as informing them of their right to withdraw their consent at any time, thus allowing them time to reflect on their decision.

The group required the cooperation of all staff in the research facility and so it was decided to disseminate the concept and the proposed plans. The group felt that all staff should be involved as this was not just a nursing concern. The in-house sessions were well attended by nursing, administrative, laboratory, housekeeping and research support staff. Fortunately the medical team was also engaged by raising Essence of Care issues at operations meetings thereby ensuring a multidisciplinary approach.

Stage 5: review the action plan
This stage is still to be fully addressed. However, the group intends to use participant feedback from satisfaction surveys, a comments book and a recent trustwide audit of privacy and dignity to review the action plans. The aim will then be to share the findings with staff from other clinical areas and clinical research facilities around the country.

Practical interventions
The following are examples of practical interventions that have been considered or applied within the research facility as a result of Essence of Care.

Privacy and dignity
An increase in research capacity – more rooms are being used for consultations and clinical examinations – has created the need for more engaged signs and blinds for doors. Funding for
these measures was approved at operations meetings. As a temporary measure, laminated ‘please do not disturb’ signs were produced and resulted in fewer interruptions. Since acquiring the extra engaged signs and blinds, a simple pre-intervention and post-intervention audit tool has demonstrated increased usage.

It was agreed that all staff needed to pay more attention to pronunciation and spelling when booking in participants for a research study in order to address their dignity needs. This also ensured that the correct hospital records were requested.

One of the telephone extensions within the research facility was linked to two handsets, which created confidentiality problems as calls were being interrupted. This issue was raised during a meeting resulting in a second telephone line being installed.

The team is considering installing a pay phone to allow participants to make private telephone calls in a mobile-free hospital. However, the cost of this may prove to be prohibitive.

The group feel that hospital gown design and size of towels for participants/patients should be reviewed but these areas will need backing at corporate level. Concerns will be put forward at the next trust Essence of Care steering group meeting.

**Communication**

A comments book was created as a result of the communication benchmark action plan. One participant commented that the magazines in the reception area had not changed in three months. An email went out that same day to all staff requesting any recent magazines, which were subsequently brought in.

**Difficulties and limitations**

As previously stated, getting started and understanding the meaning of Essence of Care were initially difficult challenges. However, both of these areas became easier with an increasing group awareness of the importance of advocacy and its subsequent impact on care.

Some staff had difficulty accepting the concept owing to a belief that the unit was already operating to a ‘gold standard’. But once the process began it soon became apparent that improvements were necessary. Moreover, some of the more experienced nurses were reluctant to embrace the idea having witnessed other government initiatives that had failed to gather momentum.

Applying the recommended guidelines to the research setting was a limiting factor that initially hindered progress. Once the decision was made to deviate from the guidelines, the group was able to make progress.

The traffic light system of scoring was easy to use, although there were still some difficulties in wording the criteria. For example, the yellow scoring criteria could not contain words such as ‘sometimes’ or ‘occasionally’ as they are not measurable terms. This led to some of the factors being scored only as red or green.

In general the ideas for improvement have been well accepted by staff although cost issues may arise for some of the implementation plans, such as installing the pay phone.

Cost has also been a barrier when expressing an interest in attending Essence of Care conferences, which would present an ideal opportunity to bring new ideas into the research facility as well as a chance to share the group’s ideas about implementation with others.

Despite these limitations the Essence of Care group has kept the momentum going by employing the following tactics:

- Keeping the team small;
- Holding monthly meetings;
- Ensuring that meetings are held within protected time;
- Giving each group member small amounts of ‘homework’ to deliver at the next meeting;
- Generating staff support through education and regular updates;
- Including Essence of Care as a standing item on the unit agenda for monthly meetings.

**BOX 1. PARTICIPANT-FOCUSED OUTCOME AND FACTORS FOR COMMUNICATION**

**Participant-focused outcome**

Participants experience effective communication that is sensitive to their individual needs, promoting an appropriate environment in which to conduct high-quality research. This applies to research conducted within the research facility and in other clinical areas supported by the research nurse outreach service.

**Communication factors**

- Opportunity for communication
- Assessment of communication needs
- Information giving
- Information sharing
- Information resources
- Information assistance
- Empowerment to perform role
- Coordination of care
- Recognising children as individuals
- Valuing the participants’ expertise and contribution
- Training needs (staff)
- Training needs (participants – study specific)

**REFERENCES**


