

“A Chronic Wound Healing Information Technology System: Design, Testing, and Evaluation in Clinic”

Antonio Sánchez

School of Computing, University of Glamorgan, Wales

asanchez@glam.ac.uk

Abstract: In the UK, chronic wound healing is an area of specialist clinical medicine that operates within the framework of the National Health Service. It has been the basis for the design, testing and evaluation of a prototype system of information and communication technology (ICT), specifically adapted to the domain. Different wound healing clinics were examined using a combination of ‘hard’ and ‘soft’ methods to allow a richer perspective of the activity and gain a deeper understanding of the human activity, its relation to the working information system, the existing information technology (IT), and the potential of a comprehensive IT system to manipulate live data in clinic. Clinicians and administration staff were included in all aspects of the process to enhance the design lifecycle and the understanding of the process. An observe, report, plan and act (ORPA) cycle, based on the dictates of action research, was established to accomplish the design and testing of a system that clinicians were comfortable enough with to consider its use in clinic. Three different strategies were applied to evaluate its use in participating clinics. Cultural historical activity theory was used as the main framework to analyse the activity system, and to interpret the clinicians and the systems performance, as well as their evaluation of the experience. Activity breakdown areas are suggested and reasons for them are considered in the light of wound care workers feedback, and the researcher’s observations, notes, and analysis.

Keywords: Electronic data manipulation, clinical ICT, information technology evaluation.

1. Introduction

The introduction of information technology (IT) into clinical medicine is not a new problem (Avgerou 1995). Many specialities have been host to the development of systems of information management based on the potential for superior control of data that information and communication technology (ICT) promises. However, in spite of numerous projects that have been deemed more or less successful by the researchers carrying them out (Littlejohns 2003, Heathfield 1998), a look at clinics in the NHS today does not reveal much IT being used to manage the clinical data, which are so important to the treatment and cure of the patient. The root of this discrepancy could lie in the criteria that are used to assess and evaluate the outcome of these interventions, and the contention that evaluation in general is value bound, and hence conditioned by the views of those conducting the research and the original premises on which it is based (Stone 2001).

The potential of a functioning IT system that is specific to wound healing, a discipline of healthcare and clinical medicine, is a promising area of research and development. ICT is slowly finding its way into the clinic (Simpson 1998, Benson 2002, Benson 2002), and clinicians working in wound care have expressed an active interest in the benefits that technology can bring them and their patients. With the NHS’s second strategic plan for the introduction of information technology into healthcare in the UK currently underway

(The Department of Health 1998) and set to run from 1998-2005 the climate is right to investigate this in more detail.

This paper considers the process of developing a chronic wound healing information technology system (CWHITS) from the perspective of those actively engaged in wound care. The requirements elicitation, design and testing strategies will draw on a combination of different methods from both systems and social camps, with the main focus of evaluation being drawn from current theories and work in cultural and historical activity theory –CHAT (this will be referred to as ‘activity theory’ hereafter) (Engeström 1987). Activity theory provides a framework in which to consider the triad of wound carers, the clinical environment in which they work and the ‘instruments or tools’ that they use to treat patients.

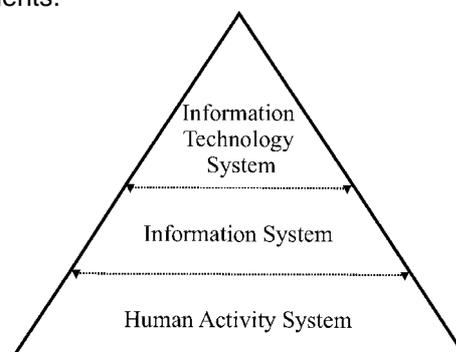


Figure 1: Layers of abstraction of the wound healing activity

In adopting the view of the wound care worker, it is hoped to bridge the gap between the

activity as perceived by the users, the information systems currently in place, and information technology that is overlaid onto that system (figure 1). Devolution of evaluation to the users, and their satisfaction that any system of data manipulation that is put in place helps both them, and their patients, are important considerations for judging any level of success (Thomas 1998). How such a system will accommodate problems, or complications that might arise at the organisational level of the NHS, is a matter that only time and continuing research can resolve.

2. Chronic wounds and consultant clinics in the NHS

Wound healing is probably one of the oldest branches of medicine. Wounds have always been present throughout mankind's existence, and unlike some other medical conditions and problems, they have always been easy to locate and easily assessed in terms of if they have healed or not. The science of wound healing has advanced, however there are still certain wounds that for reasons unknown do not heal as they should. These are termed chronic wounds (Harding 2002) and the savoir-faire to treat and heal them has become the speciality of clinicians who work in chronic wound care. In spite of scientific advances in the drugs and dressings used, as well as to the instruments available, it still remains a complex issue, to fully understand why one wound heals given a certain treatment regime for a particular patient, while another does not.

In the NHS, clinical medicine is the domain of specialist doctor's known as consultants, doctors that have acquired a certain expertise in their particular field, and are regarded as an authority in that area of specialisation. The last 10 years has seen the rise of these specialist clinics, and a shift in the power-base within hospitals and NHS trusts towards these clinics and the consultants that head them (Moss 1995). Unlike administrative healthcare systems, it is generally accepted that clinical specialities do not make full use of the potential of information technology (Benson 2002). The reasons for this are complex and to date inconclusive. This paper expands on existing theories (Huerta-Arribas 1999, Martinko 1996, Silverman 1998, Serafeimidis 2000) and provides new insight into these problems.

3. New technology in the clinic

Clinical healthcare is currently in a state of technological change (Ball 2003). It is only a

question of time before technological support tools find their way into the clinic and involve all parts of the medical and healthcare domain. New technology may make this easier, as will user training and technical skill. But to date the numerous documented cases of 'successful' incorporations of technology into healthcare, have been rather limited in scope (Mitchell 2001). What has yet to be seen is a wide scale introduction and implementation of functioning technology tailored to a specific domain in a conclusive way.

Wound healing has already begun to adapt to the incorporation of new computer-based technology. For example, the MAVIS project introduced a tool that allowed non-invasive measurement of wound area and volume using structured light (Plassmann 1998). MAVIS was a device designed specifically for use in wound healing clinics, and in some ways, can be considered as the progenitor of IT in the clinics that it was designed for, and where it was first used. In spite of its main function as a measurement tool, and its limited IT capabilities, this first contact with 'a computer', served to make clinicians, working in those clinics, directly aware of the existence and the potential of computer tools as a benefit to their work activity and their patient's health.

This paper addresses the potential of IT in wound healing, and by prototyping a system that wound care workers feel has taken their needs into consideration, one that they feel can be used in a clinic, to record, access and display, in a reliable structured manner, the different data types that they manipulate, it is hoped that feedback and evaluation will be both insightful and based on values established by those active in the field. Securing the actor's trust (clinicians and administration staff) is vital to achieving successful feedback, and by adopting a policy of inclusion throughout, reporting of the design, testing and evaluation processes, should be clearer and more transparent.

4. Research method

In the case of 'new' information technology, design has tended to centre around the development of new software based on a systems analyst's view of a particular system and user requirements. The tools used for this are based on software engineering precepts, with linear views of the design process. Designers focus on requirement elicitation, software design and testing, systems maintenance and user support. These 'hard' engineering methods lack the scope or depth

of field to include human factors, which are a prime factor in areas of medicine and healthcare.

Nevertheless, these 'hard' methods are necessary if functional software is to be engineered. The real difficulty lies in understanding the systems in place, which the software is to serve. In this work, methodologies and tools, based on understanding the social, political, and organisational aspects of changes to a work activity are used to provide greater insight into the design process. They follow a qualitative research philosophy and have a mainly interpretive view of observed phenomena.

Tools from both 'hard' and 'soft' schools of thought are combined, in the expectation that a richer perspective will give a greater understanding of the relationship between the systems involved (human, information and technology) and produce a richer data set on which to build a cohesive and functioning wound healing information technology system. It should also greatly contribute to any system being considered a viable alternative to paper assessment forms and actually being used by the clinicians.

With regards to practical design, systems thinking and social science methods are now tending to converge on a functional level of application, (McGrath 1998, 2000) but the systems model is more pragmatic and task driven, whereas social methodologies are more concerned with interaction and the process of how things are done, functioning in and as a group, as opposed to as an isolable part of a whole.

5. Strategies of inquiry and sources of data

Depending on the base philosophy they adopt, strategies can fall into two categories (Murphy 1998):

1. Systems theory and software engineering methods provide tried and tested practical tools with which to 'design' an information technology system. In this research entity relationship diagramming, data flow diagramming, and rapid application prototyping have been used.
2. Social science and qualitative research methods provide techniques for immersing the researcher in the social, political, cultural and organisational relationships of a distinct group or system of human activity. In this research ethnography,

action research, and activity theory have been applied.

Data was collected at the four participating clinics using a combination of techniques. Depending on which clinic was visited the problem was approached in a different way. The principle sources of data were: Observation: passive and active (semi-participant or involved, and non-interventionist); Interviews (formal and informal); Dedicated focus groups; Questionnaires (structured and semi-structured).

Data was collected, or recorded using a combination of both hard and softcopy tools and media:

Physical (hard)

- Pencil and paper field notes made at wound healing clinics, at focus groups and during interviews with clinicians
- A paper research diary was kept from the start of the study
- Audio tape recordings of focus group sessions and of interviews with wound carers and other personnel
- Completed questionnaires

Digital (soft):

- Data typed on a PDA (personal digital assistant), a Psion V with 8Mb or RAM and a 48Mb smart card was used to enter field notes in clinic, at focus groups, and during interviews and meetings with clinicians and administrative staff
- Recordings were made on the PDA of focus group sessions, interviews, and meetings that took place.
- Voice notes were recorded on the PDA during observation of the clinics
- An electronic diary of the work was kept on a PC and was typed up on the same day as visits to hospitals

6. Participating clinics

The practical implementation of this study took place in four NHS wound healing clinics in England and Wales. They were all led by consultants specialising in the healing of chronic wounds.

Clinic one: a large outpatient clinic based in Wales.

The clinic was managed by the clinical controller, with a PC (personal computer) and access to the hospital trust's PAS (patient admission system), used to keep track of demographic and appointment data. There

were 6 treatment rooms with a communal area where clinicians could consult patient notes, enter observations or dictate their findings to be written up by dedicated 'clinical' secretaries. It was held once a week and was attended by between 30 and 50 patients. Clinical staff consisted of up to 7 wound care nurses, 3 doctors and a consultant, if they were available. The atmosphere was hectic and clinicians had to proceed from one patient to the next without respite. The patient's notes were on a trolley, which had been brought from clinical records by the controller, and were taken in by one of the nurses prior to the patient being summoned.

Clinic two: a medium outpatient clinic based in Wales.

This clinic was also managed by a clinical controller, but with no PC access to the PAS. There were 4 treatment rooms, one being substantially larger than the others, where the clinicians based themselves, to dictate notes or consult patient notes. The clinic was held twice a week and was attended by between 20-30 patients. Clinical staff consisted of up to 6 wound care nurses, 2 doctors and sometimes a consultant. The atmosphere was also hectic, but less so than in clinic one. The patient's notes were in a plastic box with the clinical controller, and the procedure was the same as for clinic one.

Clinic three: a small outpatient clinic based in the west of England.

This clinic took place in only one treatment room; there was no controller and no PC access. Clinical staff consisted of a wound care nurse, an assistant nurse and a consultant. Patient's notes were brought in when the assistant nurse called the patient's appointment. Only one patient was seen at a time, which allowed for the clinicians to dedicate themselves entirely to the patient and their wound.

Clinic four: an inpatient clinic based in the west of England.

This clinic took place on the wards. Treatment was dispensed either at the bedside, or in a nearby treatment room, depending on each individual case and the clinician's assessment of the patient's requirements. As inpatients, sometime treatment could take place up to 3 times in 24 hours, and in each case the consultant would decide how frequently reassessment was required, normally twice a

week. Numbers were relatively low, between 7-15 patients were seen by the consultant, and while less intense than clinics one and two, time was an important factor in the clinician's day. The patient's notes were collected from clinical records by wound care nurses and stored in 'nurse's rooms' located adjacent to the wards. There were PCs in these rooms, but they were not connected to the hospital's PAS.

7. The wound healing activity: field observation and process modelling

Hospital visits to observe wound healing clinics, and meet clinicians and other NHS personnel took place over a period of 15 months. Clinics were visited regularly, sometimes up to 3 clinics a week, other times none. Focus groups and interviews were organised around staff availability. After initial visits to the clinics and attendance at wound care group meetings, questionnaires were prepared to gauge the mood, technical skills, expectations, and have a written record of suggestions from staff. The first set of questionnaires had to be completed again, individually, to correct for clinicians conferring and copying answers, or else providing a collective answer after discussion.

Semi-participant observation of the clinics was undertaken and extensive field notes were recorded, both on paper in a dedicated logbook for each clinic, and digitally recorded on the PDA. A diary was kept from the start. This had an informal structure and was written up immediately after returning from all hospital visits. Additional formal meetings and interviews were carried out with staff responsible for administrative tasks necessary for clinics to function at a hospital level. This included personnel working in clinical records departments and in IT departments. At dedicated focus groups, and after having reviewed the data collected, all clinical parties were gathered together and various strategies were discussed with them as to how to proceed. This involved them in any decisions, and it was hoped would achieve a sense of ownership and inspire use.

Based on the data collected, initial models of wound healing (process, information and data flow) were drawn up. These consisted of entity relationship diagrams and data flow diagrams. These were then shown to wound care workers and explained to them in plain English, to ascertain if they were an accurate representation of their activity. The models

were revised based on feedback from the wound carers and the processes were re-engineered (O'Leary 2000) until a consensus was reached. The models were then synthesised and a compound model for a wound healing information technology system formulated (Sánchez 2004).

The main conclusions reached at the end of this first stage were that any working system would need:

- To have an interface that clinicians were familiar with
- To be able to manage the patient data as structured on the paper wound assessment sheets
- To be able to record dictated voice notes, and ensure their transfer to clinical secretaries
- To index analogue and digital photographs taken of patients' wounds
- To have a system of backing up the data on to a PC, to secure the data, given the limitations of physical memory available on a portable device

8. Introduction of the prototype

After the social and the technical side of wound healing had been expounded and the business process was re-engineered to accommodate the balance between feasible and desirable changes, a practical implementation could be developed, tested, and user feedback and observation used to refine the system. Development of the prototype was an iterative process. It was based on the models produced, and the functional specifications or requirements, as agreed with clinicians in focus groups. This could then be refined in accordance with observations made and feedback received. This cycle of user testing, feedback and observations made, followed by changes to the prototype, adheres to the tenets of action research as prescribed by Baskerville 1998, and with the researchers involved to some extent in all parts of the clinical action, they were able to extensively observe and document the process. This 'ORPA' cycle is represented in figure 2.

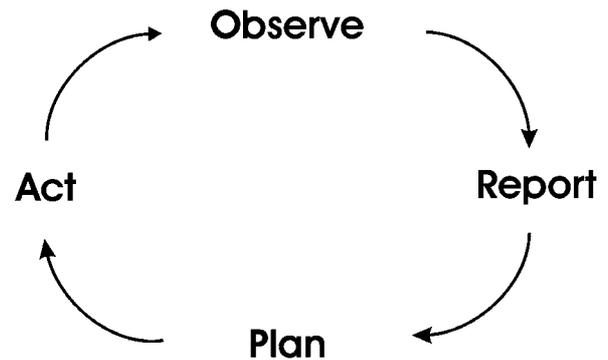


Figure 2: The ORPA cycle used to refine the system

It was agreed that a Psion V MMX with a 96Mb smartcard PDA would be used as the data collection tool. Specific software was written in OPL (organiser programming language), to the agreed specifications, this included a backing-up routine, which would allow for the data collected on the PDA to be transferred via infrared wireless link to a laptop computer, held by each clinic's consultant, and which was to act as a data repository. Ideally this should be done after each clinical session, and at least once every day that it was used.

Once complete the system was tested by the researcher, who found that it could satisfactorily perform the tasks required. User manuals and help files were prepared and the clinicians attended training sessions where they were shown how to use both the PDA and the laptop. Due to the clinicians lack of IT skills, training took longer than anticipated, but at the end they appeared confident and could carry out the tasks necessary to collect data as they did using the paper wound care assessment forms.

The next step was to test the system in live wound healing clinics. There was some concern about this process as clinicians wanted to be sure that it would not compromise the patient's treatment, or that any data be lost. Eventually it was agreed that the data would have to be entered into both the paper assessment forms, and into the PDA. Initial tests involved the researcher entering the data into the PDA, as dictated by the clinicians. The next phase of the test plan was that one clinician would enter the data directly into the PDA, while another entered the same data into the wound assessment sheets. If photos were taken this data was also included. This process was protracted, with the researcher having to answer many questions about usage of the device. The final phase of the test plan was to get the clinicians to use the PDA without any help from the researcher,

who would only be there to observe, and could not intervene. This would be the real test of if IT could be introduced into wound healing clinics in the current climate. The outcome of the experiment is discussed in subsequent sections.

9. Feedback and reporting of the process

The clinician's evaluation on the performance of the CWHITS was injected back into the prototype, which was continually refined through the testing and evaluation process as outlined in figure 3. This process was documented using the same methods as used to observe the activity. The researchers were limited to passive observation for the final tests. The same system of classification was used for the field notes, which were recorded both on the PDA and in the clinical logbooks. An electronic diary was written up for each test run, and this data was invaluable in interpreting the wound care workers actions in terms of their activity. Activity theory was used as a framework for this.

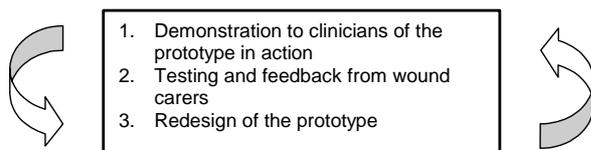


Figure 3: The action research loop

The main ideas offered by clinicians were more conceptual than practical. They were on the whole enthusiastic, but were held back by their limited experience with the technology that was used to replicate existing information systems. Some expressed an interest in attending training courses to obtain basic computer literacy, this was in the form of the ECDL (European computer driving licence). Astonishingly they would have to pay for this themselves.

10. Findings from testing the prototype in clinic

When the prototype was used by the researcher there were no problems of application, as was to be expected. The data was collected electronically on the PDA, and when compared to paper assessment forms the data were the same. When it was a clinician who used the prototype with the researcher's guidance, the data were the same, but the process took much longer, and the clinicians had some problems using the technology. The most important one was being able to see the PDA's screen enough to read it. A solution was found, but it required that the

screen be illuminated using the backlight at all times. Battery life thus became a problem, as it was reduced from approximately 18 to 20 hours to only about 2 to 3.

When the clinicians tested the prototype unassisted the result was not positive. They struggled to use the PDA and soon gave up looking for the help files when there was a patient who's wound needed to be dressed. In the end they were unable to balance the limited time that they had to do their job, the need to treat the patient, and their lack of training and IT skills, with the use of this new information system (anecdotally in an attempt to 'make it work' the batteries were removed, and in one instance even the backup battery was removed, which erased all the data stored in memory). This resulted in frustration on behalf of the clinicians and a desire to return to using the assessment forms that they all knew well.

In all three cases there was 'never enough time' to back up the PDA's data, and this resulted in the researcher having to do it independently. However, even this was not achieved without complications, as the laptop was always 'difficult to get at' and in some cases was even stored in a locked room, which nobody seemed to have the key to!. While a certain persistence ensured that it was eventually done for the first testing strategy, there seemed little point in doing it for the other two, as the researcher was only meant to help the clinicians in the second one, not perform their activity for them, and was meant to be an observer in the third.

As seen there were technical problems of not being able to use the hardware in the clinic as had been envisaged from what had occurred during testing and training. These tended to overshadow the problems of software usage. In the first case there were none, in the second the researcher had to respond to many queries, sometimes repeated, during the examination of a wound, and it was clear that the clinicians were not fully comfortable using the PDA, even when they could see the screen. In the final case, usage of the software was not an issue as, in most cases, the clinicians did not persist in their endeavour to use it, especially with the patient waiting to be attended to.

11. Analysis of the data collected and findings

Analysis of observations made and the data collected has been interpreted using activity theory as a framework, and has resulted in the diagrammatic representation seen in figure 4. This illustrates where the main breakdowns, in this case, secondary contradictions occur in the activity system. The dashed arrows represent problem areas: the relationship between the wound care workers and the data

management system, and also between the wound carers and the hierarchical organisation and infrastructure of the NHS. The relationship between the NHS and the clinical information system only has meaning if mediated by the wound carer. As the NHS tries to relate directly to the wound carer they run into problems of contextual definition, which stems from trying to impose something from the top down, instead of trying to combine a bottom up strategy with integration into higher levels of organisational change.

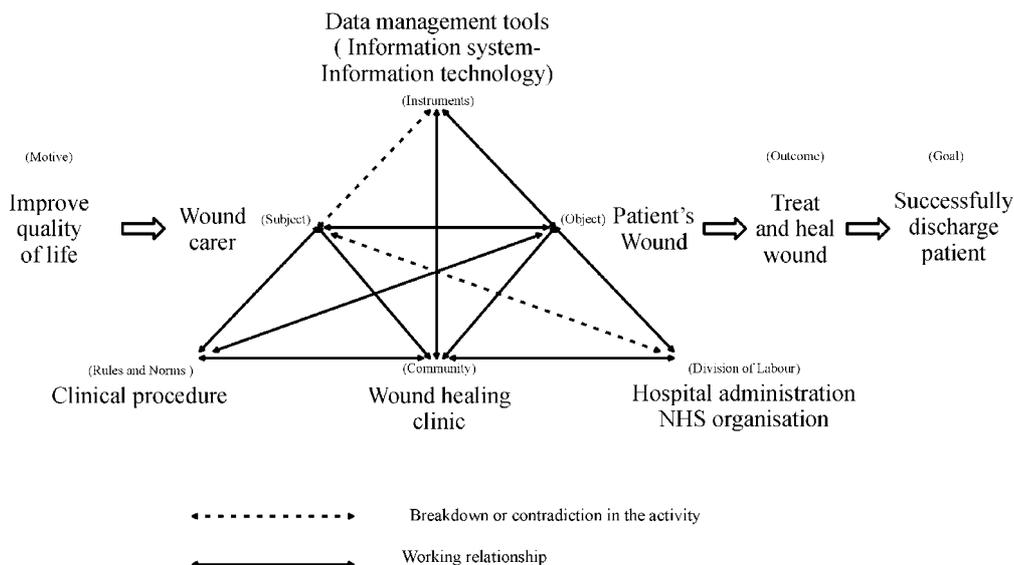


Figure 4: Activity theory model of wound healing in the NHS. (Based on Engeström 1990)

From the point of view of the wound carer, the main contradiction to achieving the object of treating and healing a wound, arises from their relationship with the new instruments, or tools introduced, (CWHITS) and the division of labour inasmuch as wound healing takes place within the structure and organisation of the NHS. The British health minister, Stephen Ladyman (BBC interview 2003), has stressed that the last word with regards to clinical decisions can only be made by the clinician, yet the strategy is already in its fifth and final year, and so far no one has asked the clinicians working in wound healing in hospitals included in this study, what they think about it.

12. Clinicians perceptions of IT in their clinic

In general clinicians seemed keen to think of an IT system as potentially beneficial to their clinical activity. Consultants and doctors were more reserved than nurses, voicing concerns over data security and patient confidentiality (Rindfleisch 1997) - indeed this last point was stressed when obtaining permission to perform this study. They were more practical in their

appreciation that there was a gap between their capabilities, existing technology and the technology available. Some believed that any system, not just the one tested was not as reliable as existing hardcopy information systems (even in those clinics where digital cameras are used, photos are printed out, a hardcopy is placed in the notes and the digital photo deleted), and were concerned that 'not having access to their data', could lead to setbacks in the treatment of patients. They failed to realise that they would still have access to the wound data, just that it would be in an electronic format.

Nurses, on the whole, were very enthusiastic about the potential of IT in the clinic, and to their credit, were not dissuaded by their inability to independently use a very simple IT system, the design of which they had participated in. On the whole clinical personal did not appear to feel overly threatened by the new technology, although in one clinic, a nurse had put in place a filing system and was 'in charge' of it, and did perceive the new IT system as a threat to the status quo.

Of the non clinical personal, the only ones who would have direct contact with a new IT system, such as the one proposed here, are the data co-ordinators or clinical controllers, in charge of managing the patient's notes and their appointments, and the clinical secretaries who type up the clinicians' Dictaphone notes. Controllers did appear to perceive the new technology as a direct threat to their jobs, even though they were not involved in the use of the prototype. Clinical secretaries seemed for the most part indifferent, given that the only change to their activity was the media on which the voice notes were recorded. This could change if voice recognition were to be incorporated into the system, and should do so as technological advances take place.

13. Conclusions

In conclusion it is felt that overarching strategies to incorporate technology into clinical medicine can lose sight of their base. By failing to realise that the only ones who can really claim to know what is going on in the clinics are the clinicians, the NHS strategic drive for incorporating IT has failed to take into account that users are the ones that need to be the principle source of consultation. Not the managers, IT designers or other specialists, who have a second hand view of any activity, and whose influence may serve to exclude those who's work it will most affect, and perhaps most important of all, those who's health it could affect.

In this paper, the importance of the conceptual nature of the feedback obtained from clinicians has been stressed. However the current IT strategy for healthcare in the NHS does not seem to include them in its grand designs and instead seems to attribute greater importance to solving managerial or organisational and technical problems related to the desired goal, rather than looking for a realistic and practical solution driven by it.

Lack of proactive IT personal that can motivate clinicians in the hospital trusts where the clinics are based could be one of the main problems in what would be a necessary 'period of transition' from paper to paperless. This accompanied by the apathy that hectic, overworked, understaffed work conditions can induce with regards to "...learning to use a new gadget, when it doesn't help treat the patient or heal the wound, and just takes up more time..." as put by one clinician, does not provide a good foundation on which to build the information strategy for the modern NHS.

14. Final remarks

When undertaking a study of this nature, the researcher felt it important to maintain a certain level of detachment and impartiality, so as to not become attached to any potential prejudices. This was felt necessary, as the researcher was also the designer of the CWHIT, and there was always the potential that their objectivity could be compromised by their desire to see the project succeed - known as 'my baby' syndrome (Littlejohns 2003). The researcher feels that the required level of objectivity was achieved, and that total participation was the only way to give the designer an emic (insiders) view of the world of chronic wound healing in the context of the NHS, and of understanding the somewhat unclear relationship between them.

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