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International Journal of Nursing Studies 41 (2004) 559–571
INTERNATIONAL JOURNAL OF NURSING STUDIES
www.elsevier.com/locate/ijnurstu

Woundcare Research for Appropriate Products (WRAP): validation of the TELER method involving users

Natasha Browne[a,*], Patricia Grocott[a], Sarah Cowley[a], Janice Cameron[b], Carol Dealey[c], Anne Keogh[c], Ann Lovatt[d], Kathryn Vowden[d], Peter Vowden[d]

[a] *Florence Nightingale School of Nursing and Midwifery, King's College London, Franklin-Wilkins Building, Room 5l7, Waterloo Bridge Wing, 150 Stamford Street, London SE1 8WA, UK*
[b] *Department of Dermatology, Oxford Radcliffe Hospitals, The Churchill, Old Road, Headington, Oxford OX3 7LJ, UK*
[c] *R&D Directorate, 4th Floor, Nuffield House, The Queen Elizabeth Hospital, Edgbaston, Birmingham B15 2TH, UK*
[d] *Department of Vascular Surgery, Bradford Hospital NHS Trust, Duckworth Lane, Bradford BD9 6RY, UK*

Received 3 July 2003; received in revised form 16 December 2003; accepted 18 December 2003

Abstract

Woundcare Research for Appropriate Products (WRAP) is a novel collaboration WRAP between industry and clinicians, funded by the Engineering and Physical Research Sciences Council. WRAP objectives included the development and testing of methodologies to identify patients' and clinicians' needs with respect to wound dressings for exudate management. The management of exudate was the focus because it was demonstrated to be the pivotal problem for patients and clinicians in a study of malignant wounds, and is a recurring problem in other wound types. A clinical note-making system (Treatment Evaluation by Le Roux's method—TELER®) was validated as a method of collecting observational data of dressing performance in the context of total patient care, thereby involving the users of dressing products. The validation process was a form of consensus where multiple sources of data were used to define patient problems, within the TELER indicators, to measure a change or lack of change in the problems during a period of treatment and care and to draw conclusions about dressing performance and patient experiences.

Keywords: Chronic wounds; Dressing performance; Validation; Clinical note-making system; User involvement; Outcome measurement

1. Introduction

The study from which this paper is drawn is a novel collaboration WRAP between industry and clinicians. WRAP objectives included the development and testing of methodologies to identify patients' and clinicians' needs with respect to wound dressings for exudate management, thus providing a mechanism for developing and defining common goals within user partnerships. The management of exudate was the focus because it was demonstrated to be the pivotal problem for patients and clinicians in a study of malignant wounds (Grocott, 2000a) and is a recurring problem in other wound types.

Interest in user involvement and evaluation within healthcare is not new; it was stimulated by the development of the beginnings of consumerism in the 1960s (Edwards and Staniszewska, 2000). The rhetoric of user involvement has featured heavily in NHS policy documents for over 10 years (Harrison et al., 2002; Poulton, 1999). Most recently user involvement has been elaborated in *Strengthening Accountability: Involving Patients and the Public* (Department of Health, 2003). This drive can be seen to reflect a changing politico-cultural climate in the wider world of corporate

*Corresponding author. Tel.: +44-20-7848-3324; fax: +44-20-7848-3741.
E-mail address: natasha.browne@kcl.ac.uk (N. Browne).

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doi:10.1016/j.ijnurstu.2003.12.009

organisations and the activities of a national user movement (Harrison and Mort, 1998).

The current user involvement focus concurs with an increasingly stated recognition that individuals, particularly those with chronic diseases, are experts in their illnesses and can contribute their insights into the development of services and products. In *The Expert Patient: A New Approach to Chronic Disease Management for the Twenty-First Century* user-led self-management of chronic disease is valued and promoted:

> "…knowledge and experience held by the patient has for too long been an untapped resource. It is something that could greatly benefit the quality of patients' care and ultimately their quality of life, but which has been largely ignored in the past…they can become key decision makers in the treatment process…" (Department of Health, 2001, p. 5)

2. Definitions

User involvement has been widely researched and debated in the context of healthcare policy in the UK. However, there are a plethora of definitions as well as variation in research findings (Roberts, 2002).

The term "user involvement" encompasses a broad range of relationships between those who provide healthcare services and those who receive them (Poulton, 1999). Barnes and Wistow (1992) suggest that such involvement falls into one of two categories:

1. A desire to improve the quality of health services to make them more sensitive to the needs and preferences of the individuals who use them.
2. A strategy to extend the capacity of users to participate in the decisions about the design, management and review of health services.

In contrast, Hickey and Kipping (1998) place user involvement on a continuum rather than in two categories. The continuum ranges from a consumerist approach at one end to a democratisation approach at the other. The consumerist approach is concerned predominantly with increasing the amount of choice users have, through relaying information and providing explanations to facilitate consultation. The democratisation approach actually involves users in decision-making processes with healthcare professionals. This approach functions on the ideals of partnership and user control. Therefore, it reflects a power shift from the healthcare professional to the user, so that in terms of wound dressing design, for example, the role of the user is no longer merely evaluating the design output but actually deciding the components and design of the product.

Partnerships can be defined between the nurse and patient where the focus is placed upon enabling the user to become involved in their care. Here though both the nurse and patient must be seen as respected autonomous individuals working towards agreed and common goals (McQueen, 2000). These partnerships hinge fundamentally on effective communication and interpersonal skills (Roberts, 2002).

Within WRAP the term "user" was taken to represent both the patient and the clinician. This reflects the status of the clinician who in industry's eyes is a key user of wound care products and the patient as the end-user. The interpretation also encompassed working towards participatory relationships between the patient and clinician where the unique knowledge held by both partners is respected and used in an equitable distribution of power within the care relationship. It also took account of the context of chronic wound care particularly in primary care settings, within the patients' homes, where the majority of wound dressings are used. It is proposed here that the clinical note-making system is an effective vehicle through which users' needs in relation to dressing products, both patients and clinicians, can be represented to industry and other stakeholders in the provision of wound dressings.

3. Purpose and background

This paper outlines the validation of a clinical note-making and measurement system (the TELER® method) as a means of facilitating user involvement in chronic wound care. TELER is the acronym for Treatment Evaluation by A Le Roux's method (Le Roux, 1993). It is a system for making and presenting clinical notes for an individual receiving treatment or care. The content of the notes can be used to establish the effectiveness of the treatment or care received.

In this study the goals of an earlier malignant wound study, were expanded to ascertain whether the TELER method is applicable to chronic wound care as a whole and could be validated (Grocott, 1995, 1997, 2000a, b, 2001; Grocott and Cowley, 2001). The method was used to provide patient-focused data on user needs for wound dressings, specifically in terms of exudate management. Through this national study (involving four clinical sites) a sample of up to 100 patients with chronic wounds was accrued to validate the method. The data were analysed to provide explanations of how the method discriminated between medical treatment outcomes, shortfalls in clinical knowledge and skills and dressing performance. In addition, dressing performance outcomes were explored to begin the process of providing the industrial partners with data to drive future product design for individuals with chronically exuding wounds.

The TELER system has been previously used in a number of settings from evaluating stroke rehabilitation outcomes (Mawson, 1993, 1997), to aiding clinical audit (Mawson and McCreadie, 1993; Grocott et al., 2001a, b), outcome measurement in severe and complex brain injury rehabilitation (Bentley, 2001) and behavioural outcome measurement within a specialised service for people with acquired neurological damage and challenging behaviour problems (Alderman et al., 1999).

4. The TELER system in wound care research

TELER was used as the clinical data capture tool in WRAP as a pragmatic approach to generating evidence of interventions in chronic wound management. It was validated recruiting individuals with chronic exuding wounds of any aetiology (see sampling strategy for the inclusion criteria) in the clinical sites: London, Oxford, Birmingham and Bradford. The focus was on development and validation of a tool that could work within specific research designs and could be implemented in clinical settings for long-term surveillance of dressing performance in uncontrolled clinical settings (MRC, 2000). The validation therefore extended to evolving a system that is flexible and acceptable to practicing nurses, and can be used in electronic formats.

5. WRAP aims and objectives

The aims and objectives of WRAP comprised the development and testing of methodologies to identify and evaluate user needs with respect to wound dressings for exudate management. The deliverables, focused on communicating needs for wound care products between users and industry, included:

- validation of the TELER system applied to the evaluation of dressing performance with a sample of up to 100 individuals with chronic exuding wounds of any aetiology,
- wound and exudate characterisation, using the sample, to start the process of describing the "real life" population of patients with chronic wounds,
- explanations of dressing performance with respect to exudate from the above sample,
- standardisation of in vitro test methods taking account of patients' needs,
- development of 3D technology to explain fit and fixation parameters to guide the design of dressings that accommodate body shape and typical movements.

6. Sampling strategy

A qualitative consensus approach to validation was adopted, where consensus means reaching informed and reasoned explanations of outcomes (see the consensus approach to validation, Section 8). A compatible qualitative approach to sampling was therefore used. The sampling strategy was purposeful and strategic focusing on patients who required dressing products to manage exudate. Two sets of recruitment criteria were adopted, recruiting individuals, with chronic wet wounds. Participants were recruited using Criteria 1 or 2 to avoid sampling bias towards either the least or most complicated cases. In addition to informed consent, the key criterion for recruitment was that the wound was wet and the dressing protocol reflected that dressings recommended for use with exuding wounds were being used:

Criteria 1
1.1. Exudate is a key management problem for the clinicians
1.2. Dressings are being applied for the management of exudate
1.3. Exudate leakage is a problem identified by the patient
1.4. Dressing fit is an associated problem
1.5. Maintaining the integrity of the dressing system between planned dressing changes is an associated problem

Criteria 2
2.1. Exudate is not a key management problem for the clinicians
2.2. Dressings are being applied for the management of exudate
2.3. Exudate leakage is not a problem identified by the patient
2.4. Dressing fit is not an associated problem
2.5. Maintaining the integrity of the dressing system between planned dressing changes is not an associated problem

This sampling frame, in combination with a clinical note-making system that uses patient-derived goals, was designed to overcome the consequences of sampling using the conventional end-point, time to healing, to evaluate dressing performance. The systematic reviews of clinical trials of dressing products for chronic wound management, for example, reveal significant bias towards the least complicated wounds that may be predicted to heal within the trial period. This ignores those patients with chronic conditions for whom one of the mainstays of care is wound products. In addition, it provides limited information about aspects of wound dressing use that may be of special interest to the users,

for example, comfort, fit, stability and confidence that no soiling will occur (Bradley et al., 1999; Alvarez et al., 2000; Dziewulski et al., 2003).

7. The TELER system

TELER has two main elements: a method of clinical note making and a statistical method of measurement (Le Roux, 1993). The note-making system provides a means of recording the relationship between the care provided and outcomes in terms of clinically significant change, and meets the requirements of established measurement theory (Mawson, 1997). The method of measurement requires the use of clinical knowledge to support the definition of clinically significant change recorded on a unique ordinal measurement scale, the TELER indicator.

The system provides information regarding the pattern of change or lack of, coded for or by an individual (evaluation). Based on measurement theory, data are recorded to measure whether a pattern is unlikely to have occurred by chance and is therefore attributable to the care received (attribution).

The system encompasses a series of "givens" or assumptions on which it is based:

- effective treatment is patient centered,
- effective treatment is grounded in theory,
- the essential purpose of treatment is to induce or prevent change,
- change (or lack of change) occurs in clinically significant steps over clinically significant periods of time,
- change (or lack of change) which is unlikely to have occurred by chance was induced,
- the effects of clinically significant change are not necessarily measurable on an interval or ratio scale but they are observable.

The TELER indicator is an ordinal measuring scale for tracing change. It has six reference points labelled from 0 to 5. Six clinically significant reference points are used to determine whether outcomes could or could not have occurred by chance. If there are five successive clinically significant improvements, and clinical significance is crucial to the validity and utility of the measures, the probability that this could have occurred by chance is less than 2.5% (Le Roux, 1998).

The code of 5 denotes the goal to be achieved and is negotiated with the patient. The definitions of the codes are framed in ordinary language that is accessible to patients. They define observable, patient centred treatment objectives in the form of outcomes that are clinically significant because they can be justified by appropriate theory or knowledge. The concept that clinical change is only significant if it can be supported by clinical knowledge ensures that the definitions of the codes on the ordinal scale fulfil the theoretical requirements of measuring scales (Mawson, 1997).

The indicators within the study were defined using existing literature bases, such as the staging for pressure ulcer development and clinical knowledge. Core chronic wound indicators such as surrounding skin condition were refined with use: disease-specific indicators were developed, for example, indicators specific to vascular disease of the lower leg. There are three forms of patient-based outcome measures: hierarchical (function indicator), component (component indicator) and profile (quiz-type indicator). The function and component indicators trace change in functional and physical deficits, specifically linked to clinical interventions. The component indicators also trace change in the patient experience. The quiz-type indicator profiles status of the patient on a number of parameters, for example, satisfaction with care. The focus of the study was to trace change in function and physical deficits linked to outcomes of interventions for chronic wound management. The quiz-type indicator was considered too abstract to this focus and the function and component indicators were utilised.

The function indicators trace a hierarchical change in the patient's condition. It is necessary to define a desired goal at 5 followed by steps that reflect either deterioration away from that goal or movement towards achievement of the goal, with 0 reflecting the deficit to be avoided. The following is an example of a function indicator (Table 1).

Component indicators were used to capture the patients' experiences of a number of parameters of wound management, for example, dressing fit, discomfort from dressings and bandages, the experience of the dressing change, the impact of symptoms such as condition-related irritation and soreness and maintaining dressing supplies. Patients' experiences for these parameters did not follow a hierarchical pattern rendering function indicators inappropriate. In addition experiences between patients varied. A "one size fits all

Table 1
Exudate leakage

Code 5	Dressing marked (no strike through)
Code 4	Dressing wet, clothes unmarked (no strike through)
Code 3	Dressing sodden[a], clothes slightly marked
Code 2	Dressing and clothes sodden
Code 1	Dressing, clothes/nightclothes sodden and bedclothes marked
Code 0	Dressing, clothes/nightclothes and bedclothes sodden

[a] Sodden = dripping wet.

Table 2
Dressing change-related pain or discomfort

Components	
a.	Dressings removal made patient wince
b.	Exposure of the wound to the air caused pain/discomfort
c.	Cleaning was painful/uncomfortable, e.g., swabbing, temperature of cleaning solution, removal of dried exudate/adhesive residues
d.	The experience of having the dressing changed was unpleasant, e.g., use of probing, close proximity of another person
e.	The position for the dressing change was uncomfortable
Code 5	Not experiencing any components
Code 4	Experiencing 1 component
Code 3	Experiencing 2 components
Code 2	Experiencing 3 components
Code 1	Experiencing 4 components
Code 0	Experiencing 5 components

approach'' was not always valid. Therefore, the component indicators were principally developed on an individual basis. The following is an example of a component indicator that fitted a number of patients' experiences (Table 2).

The collection of data at the individual level does not preclude the analysis of group data. The structure of the TELER indicator was described above and the probability that a sequence of clinically significant improvements could have occurred by chance was stated to be less than 2.5%, which means that the outcome is statistically significant. Statistical significance can therefore be used to assess whether improvements (or deteriorations) recorded by a patient or group of patients whilst receiving care are attributable to the care received (Le Roux, 2002a). Table 3 reflects improvements and shows that where a starting code is 0 and an outcome code 4 or 5 the latter is statistically significant, denoting four or five clinically significant improvements respectively. Where the starting code is 1 or 2 and the outcome code 5 this is also statistically significant, denoting four or three clinically significant improvements, respectively (Le Roux, 2002b).

Thus, patterns or changes in coding for a single indicator or group of indicators, for a single patient or group of patients can be classified into 5 categories:

- strong evidence of effect (statistical significance),
- moderate evidence of effect (clinical significance),
- no evidence of effect (codes remain static),
- moderate evidence of no effect (clinical significance),
- strong evidence of no effect (statistical significance) (Le Roux, 1993).

Table 3
Indicator outcome codes that are significant at the 2.5% level of statistical significance

Code before (e.g., start of study)	Code after (e.g., end of study)
0	4, 5
1	5
2	5

The occurrence of ''no evidence of effect'' and ''moderate evidence'' outcomes occurring can be minimised by the use of more than one indicator (Le Roux, 2002b).

The indicators were validated, using the same consensus process adopted by Grocott (2000a) over an 18-month period on the clinical sites.

8. The consensus approach to validation

Chronic wound care has a reputation for being driven by subjective preferences as opposed to evidence-based standards (Ivetic, 1991). In addition, chronic wound care is complex. At any given time more than one symptom can present indicating more than one problem, for example, infection within a venous leg ulcer. The involvement of users, the challenges to establishing a formal knowledge base and the complexity of these wounds required reasoned explanations from multiple sources of potentially conflicting data, as opposed to polarised arguments leading to single cause and effect outcomes (Rickman, 1976; Toulmin et al., 1984). The consensus approach adopted was one of reaching *understanding* and refers to the process described by Rickman (1967) of collecting, classifying and comparing evidence to draw conclusions and check their truth (Rickman, 1967). The study participants, in this instance the clinicians, patients and researchers, engaged in dialogue regarding the facts that presented and finalised this dialogue process to reach agreement on the best possible explanation of a particular outcome.

The process of reaching consensus for the indicators adopted in this study involved the collection of the following data:

- factual information concerning diagnosis and treatment,
- dressing usage,
- digital images of wounds,
- participant observation.

The researchers took the lead in collecting the factual information and observed dressing changes. An aide

memoir (Appendix A) was developed to structure these observations and to examine the reliability and validity issues relative to the TELER system. The researchers addressed issues pertinent to reliability and validity with the users (patients and nurses), and recorded an agreed view within field notes to ensure that a robust system was being developed.

The process of gaining consensus resulted in the need for modifications to the definitions of the indicator codes to meet all three criteria of validity: content, concurrent and construct (Grocott, 2001). Examples of the modifications are given below.

9. Validation of the TELER indicators

A measuring instrument is valid when it measures what it purports to measure, thus satisfying the laws of measurement theory. A key issue for the TELER system is that the indicator is not a unit of measure, as is a calibrated thermometer, for example. Therefore, the definitions of the indicator codes have to provide a valid translation medium, one that is observable and objective. The content, concurrent and construct validity of the indicators were refined to meet the requirements of measurement theory as follows:

9.1. Content validity

The indicators have content validity when the definitions of the codes are based upon clinical knowledge and trace the clinical changes viewed in the presentation of the problem.

The key issue for content validity was to avoid subjectivity. The method adopted was to define the outcomes in terms of observable interventions. For example, an early format for pain-related indicators expressed a hierarchy of mild, moderate, severe and excruciating pain, which is not valid as it is not repeatable by a second observer. Instead, established theory, for example the World Health Organisation theory of pain management, was drawn on to develop the following indicator (Table 4) focusing on observable interventions, medications, which are formally documented in patient records (World Health Organisation, 1996).

Table 4
Palliation of wound pain due to underlying disease—effectiveness of interventions

Code 5	Non-opioid[a] + adjuvant[b] + opioid 2[c] pain controlled
Code 4	Non-opioid + adjuvant, opioid 2 commenced, pain persisting, doses increased
Code 3	Non-opioid + adjuvant, opioid 1[d] added, pain persisting or increasing
Code 2	Non-opioid + adjuvant, pain persisting or increasing
Code 1	Non-opioid, pain persisting or increasing
Code 0	Pain not controlled

[a] Non-opioid = non-steroidal anti-inflammatory drugs, e.g., aspirin/ibuprofen or paracetamol.
[b] Adjuvant = a drug that has a primary indication other than pain but can relieve some painful conditions, e.g., antidepressants, anticonvulsants, muscle relaxants, local anaesthetics.
[c] Opioid 2 = for moderate to severe pain, e.g., morphine/diamorphine, systemically or topically.
[d] Opioid 1 = for mild to moderate pain, e.g., codeine.

Table 5
Odour

Code 5	No odour
Code 4	Odour is detected on removal of the dressing
Code 3	Odour evident on exposure of dressing
Code 2	Odour evident at arms length from patient
Code 1	Odour evident on entering room
Code 0	Odour evident on entering house/ward/clinic

9.2. Concurrent validity

The indicators have concurrent validity when the definitions of the codes are defined acceptably to both patients and clinicians, and when the definitions are useful in tracing the clinical changes that occur.

Content and concurrent validity were issues in the measurement of odour. Validity and reliability are inherent problems in measuring odour because of subjectivity in relation to the sense of smell and therefore inherent variations between observers. In addition, odour is a sensitive issue and not all patients wish to discuss it (Grocott, 2001). However, the following indicator was validated on the basis that the definitions matched the patterns of the problems observed by the patients, nurses and researchers, in tracing the clinically significant changes between uncontrolled and controlled odour (Table 5).

In terms of construct validity, a number of patients pointed out that the above indicator did not acknowledge their anxiety that odour would be detected by others even though their codes were consistently 4 or 5. In recognition of this aspect of the patients' experiences, the following component indicator was developed by the researchers: it represents the worst-case scenario witnessed for the impact of odour (Table 6).

Participants 303 and 305 used the indicator. Pt 303 coded 1 consistently indicating he was experiencing four of the components (a, b, d, and e) and Pt 305 coded 3, indicating he was experiencing two of the components (a and b).

Table 6
Impact of odour

Components	
a.	Aware of the odour
b.	Concerned that other people will notice it
c.	Reluctance to socialise
d.	Affects appetite
e.	Nauseated by odour
Code 5	Not experiencing any components
Code 4	Experiencing 1 component
Code 3	Experiencing 2 components
Code 2	Experiencing 3 components
Code 1	Experiencing 4 components
Code 0	Experiencing 5 components

Table 7
Impact of odour

Components	
a.	
b.	
c.	
d.	
e.	
Code 5	Not experiencing any components
Code 4	Experiencing 1 component
Code 3	Experiencing 2 components
Code 2	Experiencing 3 components
Code 1	Experiencing 4 components
Code 0	Experiencing 5 components

In a further refinement, the following free-format was introduced so that five components of an individual patient's experience can be identified, to make the system truly representative of individual user concerns (Table 7).

The following is an example of an individually constructed component indicator for Pt 308.

Components:

(a) aware of the odour,
(b) concerned that others notice it,
(c) upset by the reactions of others,
(d) I get embarrassed,
(e) affects work environment.

9.3. Construct validity

The indicators have construct validity when the steps between the code definitions describe clinical changes in the problems that are both real and clinically significant (Le Roux, 1998).

Construct validity was an issue in terms of accurately incorporating current theory and practice into the definitions of the codes. For example, nationally accepted clinical guidelines for venous leg ulcer management state the following:

> "…Graduated multi-layer high compression systems (including short stretch regimens) with adequate padding capable of sustaining pressure for at least a week* should be the first line of treatment for uncomplicated venous leg ulcers (ABPI must be $\geqslant 0.8$).
>
> *If wound large and heavily exuding, more frequent dressing changes will be required…" (Royal College of Nursing, 1998, p. 13)

The vascular experts on the research team considered that the criterion for increasing the frequency of dressing changes was strike through of exudate to the compression layer: soiling of the underlying padding that did not reach the outer layer was acceptable. The following indicator was therefore constructed (Table 8).

9.4. Reliability

The indicators are reliable by the extent to which they are coded at the same point by patient, nurse and researcher.

The following parameters of reliability were addressed: a lack of consensus, random errors from the paperwork and training deficits.

9.4.1. Lack of consensus

Disagreements between the nurse, patient and researcher were usually related to complex assessment issues, such as potentially coexisting causes of peri-wound erythema. Where there was disagreement, the reasons for coding were discussed and a mutual decision sought. However, on the occasions when consensus was not achieved the underlying cause of the difference was

Table 8
Exudate leakage (compression bandaging)

Code 5	Dressing marked, compression layer unmarked
Code 4	Dressing wet, padding and compression layers unmarked
Code 3	Dressing sodden[a], padding layer soiled in patches, compression layer unmarked
Code 2	Dressing sodden, padding layer soiled, compression layer marked in patches
Code 1	Dressing sodden, padding layer wet, compression layer soiled
Code 0	Dressing sodden, padding and compression layers wet, shoes soiled

[a] Sodden = dripping wet.

identified and recorded in the researcher's field notes. Differences primarily fell into one of the following two categories:

- Deficit in clinical knowledge (a reliability issue). If the reason was a deficit in clinical knowledge experts in the area were asked to provide further information where possible.
- For many reasons (coping strategies, denial, etc.) patients did not always want to confront the problem and would give, for example a higher code than the clinician and researcher (a reliability issue).

Strategies to accommodate sensitive issues concerning patients' coding and willingness to revisit their own problems on a repeat measures basis were built into the calculation of indices of effectiveness in the data analysis (see TELER data analysis).

9.4.2. Random error: paperwork development of the TELER form

Over the course of the study the layout of the TELER form, on which the indicator codes are recorded, and the indicator sheets evolved in order to reduce the potential for random error and bias. The emphasis was on the development of a layout that was as concise and as easy to use by practicing nurses as possible, creating an effective note-making tool. The final version of the form was a single A3 sheet that enabled the dressing systems and indicators with the recorded codes to be written on one side of the page with the reverse being free form for any necessary further comments. The form allowed space for 14 data entry points to be recorded. There was agreement between the researchers, clinicians and some patients that the A3 layout was extremely useful in providing data over a relatively long period (e.g., if dressings were being changed on a twice weekly basis). On a single sheet it was possible to see exactly what care was being provided in terms of dressing usage linked to outcomes, i.e., the TELER codes.

The indicator sheets evolved to a much greater extent during the study, as some of the indicators were continuously developed to meet the validity and reliability requirements of data capture for individual patients. They evolved through a series of 20 versions with the indicators divided into five groups for ease of use: surrounding skin, wound management/dressing performance, patient experience, symptom control and evaluation of patient outcomes.

A computer software package is currently being written for the documentation and the automated quantitative data analysis.

9.4.3. TELER training

To train practicing clinical nurses to use the system, a series of workshops and training sessions were undertaken at the clinical sites. The training sessions involved discussion regarding the study and the data collection method. A number of these sessions were undertaken with the help of trainers from TELER Limited, including specialist nurses who use the method in their own practice. These sessions, which were predominantly confined to small groups, were supported by one to one training once the system was in use. The verbal teaching was reinforced by written teaching aids such as a step-by-step guide to using the system and further information about the underpinning method of measurement. Additionally, the nurses were provided with the researchers' contact numbers in order to ask queries when they arose. With the same levels of training in use of the system, it was found that nurses with all levels of experience could successfully utilise the system.

10. TELER data analysis

The data were analysed using a dual approach. They were initially read narratively. This narrative interrogation of the data elicits whether the choice of interventions and dressings were appropriate for the aetiology and local condition of the wound. The data were then analysed using a quantitative approach to calculate the following five indices of effectiveness:

- Deficit Index—shows the effect of the problems as they present,
- Improvement Index—shows the scale of improvement relative to the deficit,
- Maintenance Index—shows the patient's condition relative to the potential for deterioration,
- Effectiveness of care Index—shows the extent to which treatment and care are managed in a therapeutic process,
- Health Gain Index—standardised Index.

The indices are calculated by accounting for clinically significant changes as well as missing codes. Unexplained missing codes are interpreted as care not given and significantly affect the index of effectiveness to account for the fact that the clinicians have lost control of the patient's care. The first four indices evaluate outcomes at the individual level, the fifth is a health gain index evaluating outcomes at the group level. A forthcoming paper from the WRAP collaboration will address the indices in greater depth and the formulae for the index calculations are available from TELER Limited; http://www.teler.co.uk.

This dual approach enables clear distinctions to be made between the contributions of clinical practice and wound dressing performance. This is achieved by recording treatment variables and the episodes of care given. Thus a poor index of effectiveness cannot be inappropriately attributed to a dressing product if the

Table 9
Evaluation of patient outcomes

Components	
a.	Inappropriate choice/use of product, e.g., multiple products, antiseptics that cause stinging
b.	Lack of appropriate treatment, e.g., absence of compression/referral/diagnostic tests/access to clinicians for dressing changes
c.	Lack of appropriate goal setting, e.g., frequency of dressing changes, treatment goals
d.	Patient care needs not met (codes of three or below on the indicators)
e.	Dressing(s) did not meet needs (codes of three or below on the indicators)
Code 5	Not experiencing any components
Code 4	Experiencing 1 component
Code 3	Experiencing 2 components
Code 2	Experiencing 3 components
Code 1	Experiencing 4 components
Code 0	Experiencing 5 components

"failures" lie with clinical care/decision making. A component indicator (Table 9) was developed so that the assessors could evaluate patient outcomes on a continuous basis. For example, a patient might enter treatment with medical problems out of control and the performance of wound dressings uncertain (components b, c and d equals code 2). Once the medical problems have been brought under control anomalies of dressing performance may become clearer (component e equals code 4). Additionally, the potential for subjectivity in the process of analysis was further limited through utilisation of a system of reasoning to develop generalisable explanations of dressing performance (Grocott and Cowley, 2001).

Validation of the clinical note-making system demonstrated its utility as a method of collecting observational data of dressing performance involving the users. However, it also raised a number of sensitive and challenging issues regarding user involvement which are discussed below.

11. Participant exemplars

Earlier in this paper, definitions on user involvement were drawn from the literature and included: a desire to make services sensitive to needs and preferences, a strategy to extend user participation in the design of health services, and a user involvement continuum from consumerist approaches to democratisation and partnerships in care. Five exemplars have been selected to explore the ways in which the note-making system was embraced by the study participants in evaluating their own outcomes of care drawn from the WRAP data: the TELER forms, the contextual information sheets and the in-depth field notes written by the researchers following patient visits. The data reveal a number of facets of user involvement, which are viewed in relation to the above definitions. For example, Participant 303 substantially collected his own data (proactive involvement), Participant 305 used the data to influence care decisions (engaged involvement), Participant 120 articulated his problems and concerns to the researcher who captured these in the indicators (collaborative involvement), Participant 307 for whom involvement was a constant challenge (contradictory involvement) and Participant 308 who through negotiation defined data collection boundaries in terms of repeat measures on sensitive and apparently intractable issues (sensitivity to user experience).

Exemplar 1: proactive involvement

Participant 303 was born with epidermolysis bullosa (non-lethal junctional) and reached his 21st birthday during the data collection period. He had circumferential wounds covering his lower legs from below knee to ankle. He had experienced a number of different dressing regimes during his lifetime and was using a silicone non-adherent layer (four dressings 20×30 cm on each leg) and absorbent dressings (12 dressings size 10×20 cm on each leg) held in place by tape and tubular bandage. His district nurses visited twice during the week to assist with bathing his legs and replacing the silicone dressings. He and his mother changed the dressings between the nurses' visits and he was selective as to which of the nurses he allowed to participate in the dressing change. He preferred to do his own dressings even when the district nurses were there, cutting the dressings into shapes that he felt were most appropriate and then applied them. The absorbent dressings were changed daily according to strike through and the silicone dressings twice a week. During the data collection period, his goal was to change the secondary absorbent dressing layer on alternate days; however, exudate leakage persistently occurred within 2 hours of the dressing change (measured by the indicator for exudate leakage). He said he always wore dark clothing to try and disguise the soiling of his socks and trousers.

The researchers taught him how to complete the TELER form, which he did on a daily basis. During the research period, he remained committed to collecting the data in order to inform dressing manufacturers because he said he wanted the industry to understand how the dressings performed for him. On a number of occasions he stated that the indicators captured what was happening, demonstrating fluctuations in his problems and consequent code patterns.

Exemplar 2: engaged involvement

Pt 305 had squamous cell carcinoma of the right tonsil and base of tongue and underwent surgery in the form of a neck dissection after pre-operative chemotherapy and radiotherapy. Following this surgery he developed a cavity wound at the location of an old drain site and dehiscence of a suture line along his neck. His medical team insisted that his wound dressings were changed in the hospital, which meant three hourly round trips 2 or 3 times a week. A thin hydrocolloid was applied to the area of dehiscence; the cavity was packed with a fibrous ribbon covered with a dry gauze dressing. He stated that he was keen to join the study in order to have some other eyes on his wounds to see if things could be improved.

An indicator for erythematous maceration was used for this participant, which was initially coded at 0, with engorged, spongy (waterlogged) skin that was losing colour. He took the TELER form to the nurse who had done the dressing and asked her what she was going to do about the problem. The nurse applied a barrier film and the codes subsequently improved. The form made explicit the problem at 0, the patient and nurse took action by repeated use of a barrier product and the indicator codes subsequently recorded resolution of the problem.

Exemplar 3: collaborative involvement

Participant 120 sustained a fractured tibia and fibula in a football match. Following surgery he developed compartment syndrome. Once the wound was stabilised, topical negative pressure (TNP) was applied. In addition to being worried that surgeons would suggest a free flap to reconstruct the area, he articulated his wound care experiences. These included the length of time taken to complete the dressing change, unpleasant removal, i.e., too quick or too slow both of which could result in pain, and further pain caused by touch and cleaning. He had a number of anxieties which surfaced for about an hour prior to and during the dressing change, e.g., nurses' discussions about the progress of the wound. He was worried that the sight of the TNP system (the black sponge, the tubing and the pump) upset his children. The researcher captured these concerns in component indicators and tracked the resolution of these anxieties and experiences, which corresponded with improvements in the wound and his increasing confidence in his progress.

Exemplar 4: contradictory involvement

Pt 307 was born with dystrophic epidermolysis bullosa. She was in her thirties with wounds that covered the majority of her body surface area. The wounds on her feet were infected with methycillin resistant staphyloccocus aureus. She lived alone supported by a care package with carers, district nurses and healthcare assistants who visited up to four times per day. The main dressing system that was used during the data collection was a water-based gel dressing with diamorphine to each foot, 50/50 (liquid paraffin and soft white paraffin) coated silicone non-adherent dressings, absorbent layer, adhesive tape, flat and tubular bandages. It was difficult to count the number of dressings being used. An assortment of sizes were applied from 20×30 cm to 10×20 cm, approximately 40 dressings were applied to her legs. Whilst at home the dressings were changed on a twice-weekly basis, which was the limit to the frequency she felt she could tolerate. The indicators and the participant observations recorded that exudate leaked as soon as the dressings had been applied.

Consistent with dystrophic epidermolysis bullosa she had extensive areas of broken, weeping, bleeding and necrotic tissue interspersed with patches of exceptionally fragile skin with blisters. She also suffered from allodynia (severe hypersensitivity) when her feet wounds were exposed to the air. On one occasion whilst in hospital, for a repeat oesophageal dilatation, the changing of all her dressings took just under 7 hours causing visible distress to the participant and the nurses. She said that the experience of the dressing changes caused her to feel that she lacked control over her life. She made comments such as "I'm just my skin" and on the dressing change days she said that she wakes with the heavy feeling of "got to do it all again". She stated that she was reduced to a set of tasks. The researchers observed that she tried to take control of the dressing change situation but that her instructions in effect caused her harm, e.g., insisting on the use of an adhesive tape. The nurses, including specialist epidermolysis bullosa nurses, offered her alternative non-adhesive products. She maintained that the adhesive tape was the only product that did not slip.

The researchers concluded that they were observing overwhelming unmet needs, both patient and nurses', recorded in the TELER codes and field notes. The patient experience indicators showed an improvement in her experiences because she affected a reduction in the frequency of dressing changes and thereby episodes of allodynia when her feet were exposed to the air. Measuring her experiences meant that her outcomes apparently improved marginally,

whereas from the researchers' and nurses' observations there was no improvement: reducing the frequency of the dressing changes increased and prolonged the soiling from the exudate leakage, the infection and the odour.

Exemplar 5: sensitivity to user experience: repeat measures

Pt 308 illustrates issues relative to repeat measures (indicator coding).
This participant had lived with dystrophic epidermolysis bullosa for over 30 years. His three times a week visits to his practice nurse after work for dressing changes (the application of eight 20×15 cm foam dressings to his back secured by a tubular bandage) were a way of life. Outside of these visits he managed the wounds around his pelvic region, legs and feet. With regard to the dressing change experience his words were: it "does my head in". However, in his eyes it had been an issue for 36 years "and will be for the next 36 years". The researchers and the participant negotiated not to repeat questions on his dressing change experience, a static and distressing problem, unless there were better options regarding the dressings.
With regard to condition-related pain and irritation, these symptoms were "permanent" for this participant. He eschewed analgesics as his experience was that the pain was continual, life-long and did not go away with medications. His goal was to accept the pain as part of his life and switch off from it. He felt that it would have been "a waste of time" to repeatedly code for these symptoms, as they remained constant and he was receiving no interventions for them, thus there was nothing to evaluate in terms of the effectiveness of interventions.
For this participant the main issue, which he termed "the real problem", was that of odour. At the start of the study he said he valued the opportunity to speak about the effect on his life. He stated that he was constantly aware of the odour and unable to do anything about it, other than change the dressings more frequently which would have required daily visits to the practice. He was concerned that others noticed it; he was "embarrassed" and sensitive to reactions from colleagues in his work environment. He thought charcoal dressings had been useful but said they were currently ineffective because they could not be fitted to seal his back and prevent odour from escaping. He wanted a waistcoat he could fit himself with integral dressings incorporating a primary silicone non-adherent layer and an odour control system. Consequently, for the indicators relative to the odour issue it was agreed that because this issue was so important to him, and to the future design of dressings, coding at every dressing change for a general odour indicator would be performed. The symptom and dressing change experience indicators were only coded at the beginning and end of the 8-week period because those experiences remained constant and painful.

The exemplars of user involvement drawn on in this paper were from participants in a research study; however, the method adopted to involve the users is designed for clinical practice. On this basis, the facets of user involvement identified in the exemplars may also inform user involvement in clinical care more generally.

The exemplars appear to challenge the notion of a continuum of user involvement underpinned by the ideals of partnership and user control articulated by Hickey and Kipping (1998). Instead, they depict often complex relationships, differing levels of involvement and user control. If, as Barnes and Wistow (1992) suggest, user involvement is underpinned by a desire to make health services sensitive to user needs and to extend users' participation in the services, there need to be formal mechanisms for capturing user needs, such as the TELER method, and this information needs to be acted on in service and individual care planning, and delivery.

In addition, user involvement as illustrated in the above exemplars emphasises the skill and commitment required to maintain therapeutic relationships. In this respect user involvement in chronic wound care raises sensitive issues, which may be applicable to many other areas of care. Interpersonal skills and negotiation are crucial for both sides of the relationship: patient and professional.

12. Conclusion

This paper has described the validation of a clinical note-making system, which was used as the data capture tool in the WRAP study, concerned with developing appropriate products for exuding chronic wounds. The method was adopted to provide patient-focused data on user needs for wound dressings, specifically in terms of exudate management. The involvement of users raised a number of issues regarding the degree to which participants in the study entered into, what amounts to, a partnership. In addition, there were limits to the measurement of problems for which there was no obvious solution. Repeated measurement of such problems was not acceptable; therefore, the researchers negotiated to code the problem at the beginning and end

of the data collection period, and in the event of influential treatment change. Data were analysed to provide explanations of how the method discriminated between medical treatment outcomes, shortfalls in clinical knowledge and skills and dressing performance. Patient outcomes were explored to begin the process of providing the industrial partners with data to drive future product design for individuals with chronically exuding wounds.

Future developments of WRAP include implementation of the TELER system in practice. It has already been adopted by the vascular services at one of the clinical sites. The aim is for wider dissemination of the tool for research, clinical surveillance and data accrual for the population of individuals with chronic wounds, including product evaluation. In addition, further developmental modelling is required, both in-vitro modelling of wound dressings for greater clinical comparability and the 3D applications for improving the design of dressings to accommodate body contours, skin and body movements.

Acknowledgements

The funders: the Engineering and Physical Sciences Research Council (GR/R3902301) in conjunction with the in-kind contributions from the industrial partners, the Surgical Materials Testing Laboratory and the Surgical Dressings Manufacturers Association (see http://www/kcl.ac.uk/wrap). TELER Limited: AA Le Roux and Sue Barnston; all the users (patients and nurses).

Appendix A. Participant observation aide memoir

A.1. Reliability

Explicit instructions—are the instructions for carrying out the assessment process, use of the TELER indicators and the data recording sheets sufficiently explicit to minimise random error and bias?

Reliability of coding—do the definitions of the TELER indicators maximise the possibility that knowledgeable observers, who have received the same training, will identify the same point on the ordinal scale to describe the attribute they are observing?

Nurses' experience—is there a level of expertise necessary to use the TELER system?

A.2. Validity

Explicit, clear definitions—are the definitions of the TELER indicators sufficiently explicit not to require interpretation, as well as being clear and free of jargon?

Sensitive and objective definitions—are the definitions of the TELER indicators sufficiently broad to accommodate small variations in the presentation of a problem, but not so broad that the indicator loses its sensitivity and objectivity? The key issue here is that the definitions relate to an actual change in the attribute being measured and are hierarchical and clinically relevant.

Relevance—do the indicators capture the reality of the clinical problem?

Reflect real changes—are the definitions of the TELER indicators practical and relevant? Do the recorded changes in an attribute reflect real changes, rather than changes in an observer's expectations?

Missing indicators—are there missing indicators relevant to the specific clinical problem?

Acceptability—are the indicators acceptable to study participants and cause no distress?

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