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Scientific Outcome Measures

Clinical note-making and patient outcome measures using TELER

as featured in
Wounds INTERNATIONAL

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This paper describes the advances in the TELER® system of clinical note-making and patient outcome measurements, including the new digital pen and paper format. The digital pen records clinical data by reading handwriting, while Bluetooth technology transfers data from the pen as encrypted digital files and converts them to machine readable text. The text can be used to populate many computer applications. Overall these advances provide a sophisticated, yet simple tool for delivering evidence-informed wound care and patient outcomes in routine treatment and care.

INTRODUCTION

TELER is a generic system for making clinical notes and measuring patient-centred outcomes of treatment and care[1]. It can be applied to any condition or sphere of activity, clinical or non-clinical, where the outcomes of interventions need to be measured over time. The application in this paper is for clinical wound care for epidermolysis bullosa (EB).

TELER was first applied to wound care by Grocott [2-7] in a malignant wound study. The application of TELER to other patient groups was undertaken by the WRAP (Woundcare Research for Appropriate Products) collaboration, funded by the Engineering and Physical Sciences Research Council[8-12]. TELER has been subsequently incorporated into routine clinical practice by the Department of Vascular Surgery at the Bradford Teaching Hospitals NHS Foundation Trust in the UK.

The TELER System is currently being developed and validated in its new digital pen and paper (DPP) format in a collaborative study that includes patients with epidermolysis bullosa (EB), their carers and clinicians as well as researchers from King's College London and Longhand Data Ltd. The study is being funded by the Guys and St Thomas' Charitable Foundation in the UK.

The DPP technology captures and records ordinary handwriting using a digital pen, which functions and looks just like a normal pen but contains a digital camera, processor and memory. The pen transfers writing as encrypted digital files via Bluetooth. The handwriting is converted to machine-readable text, which can be used in computer applications such as databases and spreadsheets in a number of customised formats. (See Longhand Data Ltd)

THE TELER SYSTEM

The system has two main elements: clinical note-making and clinical measurement. These assess information regarding the pattern of change, or lack of, in a patient's condition. This may be coded at the individual patient level (evaluation). Patients can participate in evaluating their own outcomes, if they are able to do so. Based on measurement theory, data are recorded to measure whether patient outcomes are attributable to the care received. This involves assessing whether a pattern of outcome scores has not occurred by chance and is, therefore, attributable to the care received[8].

The clinical note-making element comprises data that are routinely collected including patient identification numbers, demographic details, clinical history, diagnostic tests, diagnoses and medical and surgical interventions, including drugs and topical dressing products.

The clinical measurement element collects observational data through the TELER Indicator, a numerically formatted ordinal scale of patient outcomes at the point of treatment and care. It records the relationship between the treatment and care given, how it was perceived by the patient and the outcomes in terms of clinically significant change. Outcome measures include patient experiences, symptom management, wound healing, palliation (when wound healing is not an achievable goal) and dressing use and performance[8].

The TELER System can discriminate between treatment effects, dressing performance failure, gaps in clinical knowledge and wound care skills, including product use[13]. It is designed to be the legal clinical record that is used at the point of care, and not as an additional data collection activity. It therefore functions as a clinical audit and governance tool, and is a mechanism for routine data capture, patient monitoring and service delivery. The system can also be used for research when incorporated into an appropriate research design, and used with ethics and research governance permissions and authorisations.

Page Points:

- Using agreed upon TELER Indicators aids patients to understand their treatment and clinicians to assess the patient's outcome
- WEB aims to develop a TELER clinical note-making system, in DPP format, specifically for the evaluation of dressings and costs of wound care for EB
- DPP pens are equipped with the technology needed to record, save and transmit handwritten evaluations
- DPP makes it easy to send TELER System data to other establishments and clinicians. It also collects data for future research

The TELER Indicator

The TELER Indicator is an ordinal measuring scale for tracking change. Six clinically significant reference points, or codes from 0 to 5, are used to determine whether outcomes have occurred by chance. If there are five successive clinically significant improvements, the probability that the outcome occurred by chance is less than 2.5%[1,4,8].

Data collection and analysis are evaluated at the individual and group level. The TELER Indicator can be used to assess whether improvements (or deteriorations) recorded by a patient or a group of patients are attributable to the care received[15].

Code 5 defines the goal of treatment and care, and is agreed upon with the patient. For example, 'No skin discolouration' [Fig 1]. When a starting code is 0 and an outcome code is 4 or 5, the latter is statistically significant, denoting 4 or 5 clinically significant improvements. When the starting code is 1 or 2 and the outcome code is 5, this denotes 4 or 3 clinically significant improvements respectively[16].

The definitions of the codes are framed in ordinary, jargon-free language that can be understood by patients, carers and a range of novice to expert clinicians. The definitions capture observable, patient-centred treatment and care objectives. These form outcomes that are clinically significant because they can be justified by appropriate theory or knowledge. Unless clinical change can be supported by clinical knowledge, the definitions of the ordinal codes will lack meaning, will not be repeatable and thereby will fail to meet fundamental requirements of a measuring scale[17].
There are three forms of TELER outcome measures:

- Function indicator
- Component indicator
- Quiz-type indicator.

Code	Definition
5	No skin discolouration
4	Skin has pale pink patches (or pale discoloured patches)
3	Skin has patchy reddening (or patchy discolouration)
2	Skin has fiery red patches (or dense discoloured patches)
1	Skin is diffuse fiery red (or diffusely discoloured)
0	Skin is diffuse fiery red and shiny (or diffusely discoloured and shiny eg in dark skin)

Figure 1 – An example of a function indicator: Skin appearance: itchy pink skin from exudate.

Function indicator

The function indicators trace change in the patient's condition, capturing improvement or deterioration in regard to the clinical goal [Fig 1].

Component indicator

Component indicators capture the individual patient experience including a number of issues in wound care. The experiences of pain, dressing change and the impact of symptoms, such as malodour, are all recorded. However, these recorded experiences do not follow a hierarchical pattern [Fig 2].

Components	Code	Definition
a. Odour evident when dressings exposed and removed at dressing changes	5	Not experiencing any components
b. Odour evident when dressings become detached inbetween dressing changes	4	Experiencing 1 component
c. Odour evident through newly changed dressings and bandages	3	Experiencing 2 components
d. I am aware that other people notice odour	2	Experiencing 3 components
e. I avoid some social situations because of odour	1	Experiencing 4 components
	0	Experiencing 5 components

Figure 2 – An example of a component Indicator: Impact of odour.

Quiz-type indicator

Quiz-type indicators decide the status of the patient based on a number of parameters, including their satisfaction with care. To date, quiz-type indicators have not been developed for wound care.

Data analysis

The data analysis is qualitative and quantitative. Qualitative analysis consists of an evaluation of the clinical note-making system. This can establish connections between diagnoses, interventions and TELER codes, and thereby develop explanations of the patient outcomes. Qualitative analysis can:

- Reveal whether clinical decisions, treatment, care delivered and wound care products meet patients' needs
- Decide whether these needs can be met at the individual and group level
- Elicit recurring patterns found throughout patients' notes[6].

Quantitative data analysis is automated and comprises the calculation of index numbers at the individual and group level. A TELER index number is the result of an aggregation of clinically significant deficits or changes recorded for a patient.

The individual level indices are as follows:

- Deficit Index: the proportion of lost function/problem, as it presents at the start of an episode of treatment and care
- Improvement Index: the proportion of the deficit recovered with treatment and care
- Maintenance Index: the proportion of clinical interventions with clinically significant deteriorations, indicating a loss of maintenance
- Effectiveness of Care Index: the proportion of clinically significant changes that were deteriorations.

The group level indices comprise:

- Health Status Index: the standardised proportion of lost function/problem
- Health Gain Index: the standardised proportion of lost function/problem recovered.

Validation of the TELER Indicators

When a measuring instrument measures what it purports to, it satisfies the laws of measurement theory[17]. A key issue for TELER Indicators is that they are not units of measurement.

The definitions of the indicator codes have to provide a valid translation medium for the attribute that is being measured; one that is observable and objective [5,8]. For example, if the aim is to measure a patient's weight, a set of measuring scales are used that translate body weight into a recognised numerical format. The scales need to be calibrated to ensure that the recording is valid, reliable and reproducible.

With regard to indicators of patient outcomes in wound care, the translating medium is observation. In the example of the Function indicator [Fig 1] itchy pink skin could be described as slight, moderate or heavy. However, these terms cannot be validated or reproduced because we cannot observe or measure what 'slight' is. The measurement of skin condition requires a translating medium, which in TELER terms consists of six observations of the condition of skin exposed to exudate, in a hierarchy of best case (code 5) to worst case (code 0) skin condition. These observations are valid, because they are based on clinical knowledge; they are reliable and repeatable when the clinicians performing the observations have been trained.

The validity of the indicators have been refined to meet the requirements of measurement theory as follows:

- Content validity is based on generating definitions for each code (0-5), that must be based on clinical knowledge as well as being able to trace clinical changes. The key issue for content validity is to avoid subjective statements. Content validity is also predicated on definitions that are acceptable and relevant to patients and clinicians in terms of tracing clinical changes in the patients' experiences over the course of treatment and care
- Construct validity is based on the definitions of the codes, which represent step-wise clinical changes in the clinically significant problems and are determined by current theory and practice in wound care, eg clinical guidelines
- Reliability is predicated on the validity and shared ownership of the language and content of the indicators, together with training in the accurate use of the system.

The WEB (Woundcare for Epidermolysis bullosa) Project

WEB is a collaborative project between King's College London, DebRA UK (the charitable foundation that supports patients and families with EB), Guy's and St Thomas' Charitable Foundation (who have funded the project), Guy's and St Thomas' Hospitals NHS Trust and Longhand Data Ltd.

The project's aim is to develop a TELER clinical note-making system, in its new DPP format, specifically for EB evaluation. Currently, this application is being used to audit the performance of dressings and costs of wound care. The data are informing new product design specifications for EB and other conditions that give rise to extensively damaged skin. The application will be used to evaluate the clinical performance and costs of the new products.

The online application of TELER is currently being piloted and will be used in a clinical audit of EB wound care. It is anticipated that these findings will be available from June 2011.

DIGITAL PEN AND PAPER

DPP technology was developed so data could be accurately recorded and transferred to a computer. This process is achieved by printing a file (using almost any office printer) that comprises both the form layout and an array of dots, each approximately 0.3mm apart. The pattern of dots varies across the page as defined by a mathematical algorithm [Fig 3]. The pens are equipped with a miniature camera and a small infra-red light (so they can work in the dark). The camera switches on when someone starts to write on the printed paper, and pen strokes are stored in the pen's memory. Files then can be uploaded from the pen via a desk cradle connected to a PC, or via Bluetooth to a mobile phone.

Since the underlying application can identify which dotted pages are associated with a particular pen-stroke file, it is possible to re-create handwriting within the computer-based digital pen platform.

At the same time as pen strokes are rendered as images, they are sent into a handwriting translation software that produces a machine readable version of the form. This allows onward transmission to hospital registries and to the TELER algorithms. A strength of this method is that the original can remain with the completing clinician and allows for copies to be electronically available for downloading and printing within minutes of the original being completed.

Using the DPP system, patients and their carers can be the data collectors. A digital paper version of the TELER form can be completed at each dressing change. The outcome codes and reports are then immediately available to managing clinicians in their offices.

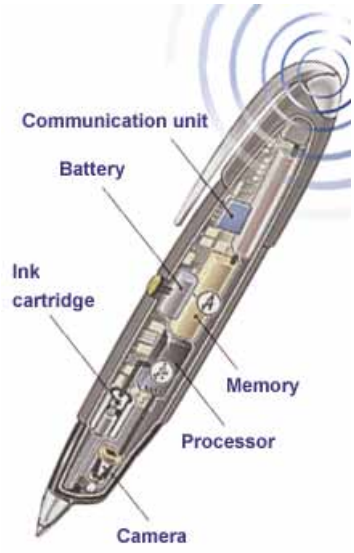

Figure 3: The mechanism of the digital pens.

CONCLUSION

To date, the TELER System has provided a robust method of routine clinical note-making and patient-outcome measurement, which can also be used as a research tool. DPP technology provides a sophisticated real-time system for data capture, analysis and archiving.

Given that the TELER system is predicated on the use of valid clinical knowledge, future applications can be developed and adopted for other wound care specialities besides EB. Evolving and disseminating these applications into the wound care community on an international level, could generate comparable data sets for information sharing, gap analysis and future evidence-informed research.

AUTHOR DETAILS

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