WRAP: Defining clinical needs for fluid handling devices

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Abstract

Background: Woundcare Research for Appropriate Products (WRAP) is an on-going collaboration between industry, clinicians and academics led by King's College London (KCL). The study that established the collaboration was funded for 2 years (2001–2003) by the Engineering and Physical Sciences Research Council. *Objectives:* The objectives included the development and testing of methodologies to identify patients' and clinicians' needs with respect to wound dressings for exudate management. *Results:* These comprised: a validated clinical note-making system for the purpose of collecting observational data of dressing performance in the context of total patient care; a validated industrial in vitro test method for measuring absorbent capacity; and 3-D imaging techniques which measured skin deformation and its impact upon the fixing of dressings for leg ulcers, pressure sores and post-operative wounds. *Conclusions:* Through methodological development, WRAP has responded to the paucity of objective data on user needs and product evaluation. The methodologies can be taken forward into future studies for continuing data accrual. *Declaration of interest:* None.

KEY WORDS

Collaborative research
Wound exudate
Clinical note-making
3-D imaging
In vitro test method validation

WRAP (Woundcare Research for Appropriate Products) is an ongoing collaboration between 12 industrial companies, the Surgical Materials Testing Laboratory, Southern Medical Alliance, the Surgical Dressings Manufacturing Association, and 4 clinical centres, led by King's College London (KCL). WRAP was funded for 2 years (2001–2003) by the Engineering and Physical Science Research Council (EPSRC) (GR/R39023/01), and future funding is currently being pursued for WRAP2.

The EPSRC invests in research that forms the basis for future economic development in the UK and leads to improvements in health, well-being and lifestyle. The aims of WRAP reflect the major themes of the EPSRC. They include generating methodologies to inform the development of patient-focused dressings (thereby improving the health, well-being and lifestyle of patients with chronic exuding wounds) and facilitating advances in technologies.

The objectives of WRAP included the development and testing of methodologies to identify the needs of patients and clinicians 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 it is a recurring problem in other wound types (Grocott, 1998; Cutting, 1999). The topic of exudate is complex and all-encompassing to the point where exudate management needs to be considered synonymous with the management of the wound environment. The purpose of this paper is to provide a summary of the outputs of the two-year funded period and the future aims of the collaboration.

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Purpose and background

Considerable work, both theoretical and applied, has been done by the healthcare industry, and clinical and pharmaceutical groups to produce devices to manage wound exudate. However, anomalies in device performance for chronic exuding wounds persist.

The anomalies that were the focus of this study included mismatches between the size and shape of a wound and pre-sized, pre-shaped dressings; and the sequestration of exudate under semi-occlusive dressings, which results in leakage, and often, maceration. Dressing fit is crucial. Unless the dressing fits, exudate inevitably leaks. The inherent fluid handling properties of an individual dressing may be adequate. However, in practice, woeful examples of the mismatch between products and needs can be found. For example, the overlap of between ten and fifteen 10cmx20cm dressings to cover the chest wall or a limb is impractical, inefficient, and can take hours of experimentation on the patient to achieve. The impact of this scenario on the patient is considerable, for example, the inability to meet social goals because of the embarrassment of soiled clothes (Grocott, 2000).

In addition to the focus on wound exudate, the current business and technological environment demanded renewed focus on defining appropriate standards to create competitive advantage for UK device industries, in line with EPSRC objectives. Such standardisation requires strategies for achieving agreed, generalisable solutions to problems, which include balancing diverse interests across a number of stakeholders: the users of devices, health services, company employees and share holders (NSSF, 2003).

The goal of WRAP was to develop core methodologies to inform the design and manufacture of dressings for chronic wound exudate management, including the provision of explanations of where current fluid handling dressings do not meet clinical needs. The priority was to reach a better understanding between industry and clinical partners of what is needed from medical devices with respect to their fluid handling characteristics. The onus was on the clinical partners to develop and validate methods to represent user needs to industry, and influence the development of user-focused products.

Aims and objectives

The following five aims and objectives reflect the multidisciplinary focus of WRAP and the contributions that the disciplines need to make to understand the clinical problem of wound exudate and to provide appropriate devices for its management:

1. Inter-laboratory validation of an in vitro test rig and method for evaluating absorbency
2. 3-D techniques for the investigation of skin deformation with application to wound dressing fixation
3. Validation of a clinical note-making system (treatment evaluation by LE Roux's method) to evaluate dressing performance in the context of patient care from a sample of patients with chronically exuding wounds
4. Wound and exudate characterisation
5. Explanations of dressing performance with respect to exudate, drawing on the sample of patients.

The project was positioned within the MRC framework for the design of complex evaluations focusing on the first 3 components of the framework:

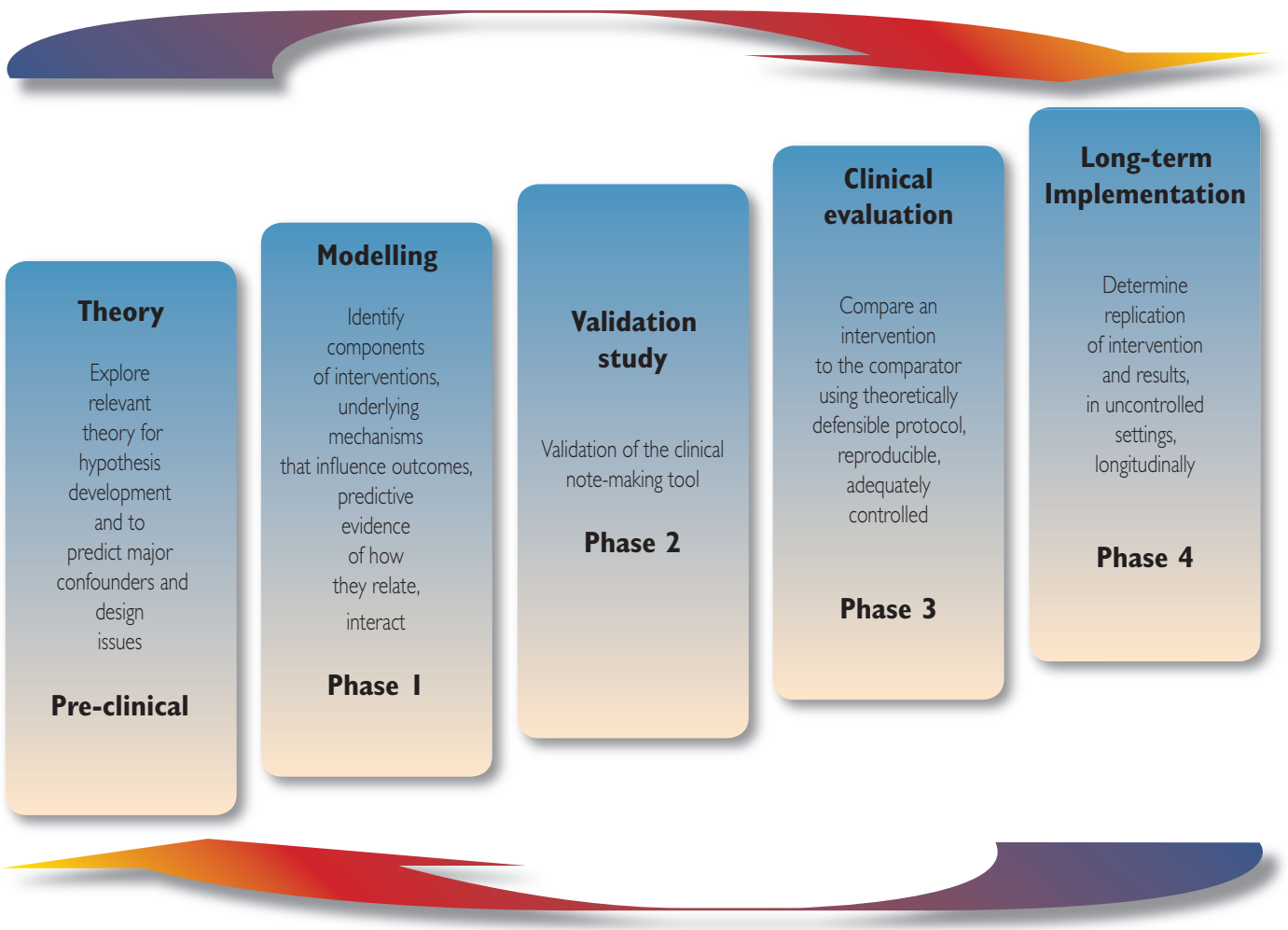

Figure 1. A framework for evaluating wound management. Iterative process of evidence generation for design and clinical validation. Adapted from MRC, Health Services and Public Health Research Board (2000; www.mrc.ac.uk).

- Pre-clinical theory development
- Metrics, methods and modelling
- Validation (MRC Health Services and Public Health Research Board, 2000)(*Figure 1*).

The phases ran concurrently during the 2-year project. The methodologies are now ready to be taken forward into further projects, including the last 2 components of the framework, namely: phase 3 clinical evaluation and phase 4 long-term implementation.

Theory: pre-clinical

Exudate management was positioned within the two prevailing theories that underpin interventions: moist wound healing theory (Winter, 1962), and wound bed preparation (Falanga, 2000). The problem of exudate management was discussed using clinical examples, characterising the causes, complications and methods of containing exudate. This theoretical work is summarised in the WRAP Position Paper (http://www.kcl.ac.uk/wrap). Though not novel, this work helped to articulate the limitations in understanding the problem of exudate management and shaped the Phase 1 methods and modelling of the MRC framework: the clinical note-making system, in vitro test methods, and 3-D imaging.

The development of the methods raised substantive issues about the role of dressings in the management of a complex phenomenon such as exudate, including what is required from a dressing and how dressing performance should be measured. It was concluded that wound dressings play an important role in assisting wound healing and containing breaches in the integrity of the skin, but they do not heal wounds in isolation from medical treatment. Where wounds are being managed palliatively, because of the limits to treatment, the mainstays of care include supportive care and symptom control, with dressings playing a major role (Dunlop, 1998; Grocott, 2000).

Assumptions regarding exudate management were critically reviewed. Pathologies that affect the presentation and management of exudate in chronic wounds, for example, venous hypertension and oedema, were identified to determine the range of medical interventions and devices that are required to manage these varying pathologies. Conditions that affect the constitution and amount of exudate generated from a wound, for example, inflammation, were explored. Distinctions were also made between the various existing approaches to exudate management, for example:

- Devices that divert extracellular fluid back into the circulation (compression therapies)
- Hydrophobic materials that oppose an osmotic gradient and the exit of exudate from the wound
- Hydrophilic absorbent dressings that draw exudate away from the wound along an osmotic gradient and contain it within the matrix of the dressing
- Hydrophilic, high moisture vapour loss systems that handle exudate by reducing volume through evaporation of water content
- A topical negative pressure device that removes exudate and drains congested peri-wound tissues.

As chronic wound exudate is known to have detrimental effects on the wound and peri-wound skin, products for protecting the skin and neutralising harmful enzymes were also acknowledged.

A number of questions were raised from this aspect of the study. These have been taken forward into a proposal for a WRAP2 study. Specifically for WRAP2, the aim is to identify exudate constituents to answer questions concerning:

- The impact of dressings on biological mediators
- The absorption profile of dressings over time
- The impact of concentrated exudate on repair, tissue viability and the palliative management of non-healing wounds.

Phase 1. Modelling: Design issues for in vitro test methods and 3-D imaging

Two core methodologies were developed to assist the process of predicting how dressings may perform in clinical practice: an in vitro test method system and a 3-D imaging system.

In vitro test method for absorbency

Led by the Surgical Materials Testing Laboratory (SMTL), reproducibility data for absorbency measurement were obtained from a novel in vitro test rig. The developed rig facilitates direct comparisons between products that are different in structure and composition and provides, perhaps for the first time, a method that may be used to predict the time for which dressings might be expected to remain effective on exuding wounds.

In a previous study, Thomas and Fram (2001) identified substantial limitations with in vitro methods for dressing specifications, i.e. that most are based upon material structure rather than performance of the products concerned.

On a number of parameters of dressing performance, for example, absorbency, the authors argued that numerous methods have been developed for measuring the absorbency of wound dressings, but many are product specific and do not permit comparisons between different dressing types. They designed a new wound model that could be used to produce clinically comparable information on the fluid handling properties of a range of wound dressings, including the following functions:

- Absorbency
- Gelling
- Moisture vapour transfer (MVTR)
- Exudate strikethrough
- Bacterial strikethrough.

For the first time, a test method had been developed capable of generating data on the fluid handling capabilities of most types of dressings.

The equipment was refined within the WRAP study and the validation work on the parameter of absorbency has been done in six separate laboratories:

- SMTL
- Acordis
- Johnson & Johnson Medical

- Mölnlycke Healthcare
- Smith & Nephew Ltd
- Medlock Medical.

The test rig and the basic absorbency test method have been well defined and the inter-laboratory testing contributed to establishing the robustness of the absorbency test method in the horizontal plane. Future plans include a detailed review of the absorbency test method, incorporating protocol development before proceeding to further validation work on optimal systems for fluid handling. This work will include the evaluation of a novel wound simulation device to model wound dressing performance, accommodating gravity effects and, thus, enhancing clinical comparability of the test rig.

3-D techniques for the investigation of skin deformation with application to wound dressing fixation

Despite extensive collective experience in nursing care, there remains uncertainty about the parameters such as dressing shape, extensibility and fixing position that affect performance. The work on imaging included:

- The creation of new procedures and software to enable skin surface movements to be detected and quantified in 3-D
- Image capture of healthy volunteers and patients
- Data analysis of the images.

The method is non-invasive, convenient, rapid and easy to employ (Gardner et al, 2004).

The studies have highlighted the complex and sometimes counter-intuitive response of skin to joint articulation. It was observed in the neck study, for example, that while skin in the central part of the neck was stretching, the skin over the adjacent shoulder compressed in a direction orthogonal (at right angles) to the direction of stretch. In the ankle study, it was observed that while skin deformed uniformly without a dressing, there was significant wrinkling of the skin with a dressing. This strand of WRAP suggests reasons why the fixation of dressings may fail in practice. Further investigation of this system is planned to demonstrate whether the counter-intuitive stretch and compression has a significant impact on dressing performance, and whether improved understanding of this skin movement can be used to improve dressing design, fixation and performance.

Phase 2. Validation study: The clinical note-making system

A clinical note-making system (TELER® — Treatment Evaluation by Le Roux's method) was validated as a method of collecting observational data of dressing performance in the context of total patient care, including patient experiences, symptom management, dressing usage, and dressing performance measured on a number of parameters to encompass the complexity of exudate management (Le Roux, 1993).

The system has two main elements: clinical note-making and clinical measurement. It records the relationship between the elements of care given and outcomes in terms of clinically significant change, and meets the requirements of established measurement theory. The measuring mechanism, the indicator, uses clinical knowledge to support the definition of clinically significant change recorded on an ordinal measurement scale (Browne et al, 2004).

To accommodate the inherent complexity of evaluating wound care outcomes, the clinical note-making method of measuring dressing performance was designed to discriminate between treatment effects and a true anomaly in dressing performance. Additionally, the method is capable of identifying important contextual variables, such as gaps in clinical knowledge and skills for chronic wound care, including product use (Grocott et al, 2005).

With ethical approval and research governance processes in place, a sample of 85 participants were recruited to validate the system on four clinical sites: London, Oxford, Birmingham and Bradford. The sampling strategy was inclusive to ensure a range of wounds of varying aetiologies, positions and sizes. This was necessary to avoid the limitations of sampling from the least complicated clinical conditions, evident in the systematic reviews of topical applications for chronic wound management, and raised as a critical flaw in the Food and Drug Administration's Guidance to industry for developing products for chronic cutaneous ulcers and burns (Bradley et al, 1999 a and b; Alvarez et al, 2000; FDA, 2000).

A consensus approach to validation was adopted, which involved reaching an understanding and refers to a process of reasoning from sources of evidence to develop explanations of outcomes (Rickman, 1967). A direct development of the note-making system from WRAP is an automated method of analysing the quantitative data: the Patient Outcome Index and the Quality of Care Index. These will be incorporated into a licensed software version of the system. The software has the option of using external reference numbers or codes to link the software to other databases. The system is designed to be the clinical record that is used at the point of care delivery, not an additional data collection activity. It,

Key Points

- WRAP is a clinical, academic and industrial collaboration for the purpose of defining clinical needs to guide dressing design.
- WRAP validated industrial and clinical methodologies to inform the development of patient-focused dressings for the management of wound exudate.
- The methodologies can now be taken forward to generate objective data of needs and to evaluate, in vitro and clinically, the fluid handling properties of current and novel dressings.

therefore, performs a function of clinical governance and is a practical mechanism for both raising standards of care, and innovation in wound care.

Phase 3. Clinical evaluation

WRAP focused on the initial 3 components of the MRC evaluation framework: development of theory, metrics and measurement. The framework assumes that the next step in a complex evaluation involves a comparison between an intervention and a comparator, using a theoretically defensible and reproducible protocol, in an adequately controlled design. This was not part of the WRAP objectives and future evaluations will require suitable research designs, including Phase 4 prospective observational surveillance studies.

Phase 4. Long-term Implementation: A pragmatic trial in uncontrolled 'real life' settings

WRAP has developed and validated a model for including users, patients and healthcare professionals, in prospective observational surveillance studies. The model integrates evidence-based knowledge, involving the users, in the clinical note-making system, which can be taken forward into other applications and projects. The measurable objectives of the model include: the explicit integration of clinical knowledge and skills into patient care and outcome measurement, appropriate evaluation methodologies to demonstrate the performance of a medical device in the context of treatment and care, and the generation of valid and robust data.

Future plans include an in-depth study of a Strategic Health Authority to determine the profile of patients with chronic wounds, including quantification of product usage and unmet needs. Data accrued via future planned use of the note-making system will additionally provide a feedback mechanism to assist this aim.

Conclusions

The outcomes from WRAP are:

- A large collaboration between industrial partners ranging from multinationals to small- to medium-sized enterprises, clinicians and academics
- Alternative validated measures of clinical dressing performance in a clinical note-making system
- Standardisation of an industrial test method and equipment for fluid handling by absorbency
- Development of 3-D applications for wound dressing design
- Wound and exudate characterisation
- Explanation of dressing performance with respect to exudate.

WRAP has drawn together the major manufacturers of wound care products, committed SMEs, clinicians, academics and clinical consultants in the wound care sector in a non-competitive scope within which industry is willing to collaborate. It has responded to the paucity of objective data on user needs and product evaluation by developing methodologies to communicate needs in a data-

driven model. The plans for WRAP2 comprise a programme of research, the express purpose of which is knowledge acquisition and transfer that can lead to novel products and their intelligent use. **WUK**

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