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ORIGINAL ARTICLE

Living in dressings and bandages: findings from workshops with people with Epidermolysis bullosa

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Abstract

Epidermolysis bullosa (EB) is an inherited disorder causing extensive, painful skin blistering and wounds. Currently, there is no cure and the focus of care is on the clinical management of the skin and other affected body systems, together with supportive care to individuals and families. The wound care for Epidermolysis bullosa (WEB) project is a collaboration with adults with EB, carers, clinical nurse specialists, a designer and manufacturers to develop novel products for EB wound care. This article reports the findings from workshops with adults with EB, their carers and clinical nurse specialists, together with observations of dressing changes. A cluster of significant limitations were revealed in the performance of wound care products, designed to cover a single wound, when they are used to cover extensive and whole body wounds. A working hypothesis for EB wound care was developed from the findings, together with design concepts and new products for EB wound care. In addition, a model of user engagement in medical device development and evaluation has been tested.

Introduction

This article reports the methodology and findings from a series of workshops conducted within a qualitative participatory study with a group of adults with Epidermolysis bullosa (EB). The study was initiated in the Engineering and Physical Research Council (EPSRC) funded project Multidisciplinary Assessment of Technologies for Health care. The wound care for Epidermolysis bullosa (WEB) project emerged from the findings of a previous EPSRC funded project Woundcare Research for Appropriate Products (WRAP). WRAP highlighted the difficulties faced by adults with EB, their carers and specialist nurses in the management of complex wounds.

Key Messages

- this article reports the methodology and findings from a series of workshops conducted within a qualitative participatory study with a group of adults with Epidermolysis bullosa (EB)
- when users are involved in the cycle of device development (concept, design, manufacture, testing and trials and production) this increases the likelihood of producing devices that are safe, usable, effective and appropriate to cultural contexts
- the establishment of INVOLVE (http://www.invo.org.uk) demonstrates the commitment to involving users as active participants in research, rather than subjects
- in this model, the process of device development begins with a clinically defined need and sets in action an iterative process of user engagement
- the study population comprises adults with the condition EB
- overall current products do not meet the needs of those with EB, necessitating research into products designed for their requirements
- the first phase of this engagement involved collecting and analysing data from adults with EB, their carers and specialist EB nurses through a series of workshops to define their unmet needs
- the second phase constituted a brainstorming workshop, comprising a group of experts that included designers,

material scientists, engineers and a pharmacist, along with specialist EB nurses and academic researchers

- the project progressed to the third phase: the development, finalisation and evaluation of a design concept and prototypes informed by the workshop data
- these have translated into a range of CE marked novel dressing retention garments
- at the time of writing the garments are being evaluated by a group of adults with EB in a study with the appropriate ethical and research and development permissions and approvals
- this stage of the WEB project aimed to gain insight into central aspect of living with EB, skin and wound management, and thus fell firmly within a qualitative research paradigm
- the specific questions addressed in the WEB study also relate to people with different conditions that result in extensive wounds
- the points of generalisation are that pre-sized, pre-shaped dressings do not meet the needs of individuals with extensive wounds, and that designs to wrap the body, as opposed to covering a single wound may succeed
- as to the model of user engagement, which underpins the study, the generalisations stem from the frameworks of the model, which can be applied to different clinical problems and patient groups to problem solve through medical device development and validation
- if located within an academic setting and supported with ‘start-up’ funds, the process of defining user needs and identifying design solutions can be protected from vested interests and conventions; the academic institution also owns the ensuing intellectual property
- the completion of successive successful projects has the potential to bring a revenue stream back to the institution for re-investment in this type of research, development and translation endeavour

The first aim was to identify unmet needs within the EB population in relation to wound dressings and to translate these needs into design concepts and novel products. The second was to test a knowledge transfer model, through a case study of EB wound care, which may be replicated for a range of medical device applications and user groups. A key aspect of the model is that clinical academics work with medical device users to ensure that accurate knowledge drives the creative device development process (1).

Placing the user at the centre of health care services and research is a stated commitment in UK policy (2). The establishment of INVOLVE (http://www.invo.org.uk) demonstrates the commitment to involving users as active participants in research, rather than subjects.

There is increasing recognition that health service users experiences are valid evidence that complements that of health professionals, although the true impact of involving users in research and service development is not fully understood (3).

Medical device development describes an iterative process of concept generation through to production and use of a device. A structured survey of a diverse range of literature, locating the user in medical device development and evaluation processes, highlighted a lack of user engagement in device development. The survey revealed that users were generally perceived as health care professionals using devices on behalf of patients, rather than patients themselves. It also highlighted that when users are involved in the cycle of device development (concept, design, manufacture, testing and trials and production) this increases the likelihood of producing devices that are safe, usable, effective and appropriate to cultural contexts (4).

A model of user engagement was identified in the survey, and underpins the WEB project (5). In this model, which is described in more detail later in this article, the process of device development begins with a clinically defined need and sets in action an iterative process of user engagement. This begins at the stage of concept generation with the device users and involves clinical evaluations of the devices in real life settings.

The study population

The population comprises adults with the condition EB. EB is a group of rare, inherited disorders, characterised by extreme fragility of the skin and mucous membranes The common factor for individuals with EB is skin blistering and wounds (6,7). EB is reported as occurring in approximately 1 in 17 000 live births. It is estimated that there are currently 5000 people with EB in the UK (www.debra.org.uk).

It is known that chronic dermatological conditions can have profound psychological and social effects on the individual concerned. For example, there is an increased incidence of anxiety and depression amongst individuals with psoriasis (8). Whilst individuals with EB remain positive, the nature of the condition increases the risk of psychological distress and low self esteem (9). There are significant ‘costs’ associated with having EB including the costs of purchasing skin and wound care products that are not available from health services, and not being able to pursue education and work because of hours of care, including dressing changes. EB also has a significant physical, emotional and financial impact on parents and siblings, with parents needing to take on the role of full time carers (6).

At present there is no cure for EB. Whilst it is hoped that new treatments may bring benefits in the future, current treatment revolves around supportive care to individuals and families together with clinical management of the skin and other affected body systems (6).

A priority with EB is to prevent skin breakdown, which is problematic due to the fragility of the skin. Wearing normal clothing for example can cause blistering and lead to wound formation. Difficulties are compounded by the inadequacy of current systems for managing EB wounds when they extensive. These aspects of skin and wound management are discussed in the next section.

The role of wound care products for EB

EB wounds vary in terms of cause and severity, however, there are common problems including the risk of infection, the management of exudate, malodour and prevention of further damage to delicate skin, through the use of wound care products.

The current theory underpinning wound care, and wound care products, is that of moist wound healing. It is widely accepted that a moist environment encourages epithelialisation, preventing tissue dehydration and cell death whilst allowing the interaction of cells and growth factors in the healing process (10). The wounds experienced by those with EB fall into the category of recurring and hard-to-heal wounds. These wounds can be wet, necrotic, extensive and difficult to manage within the confines of moist healing theory (11).

Modern dressings are, in the main, designed to promote the conditions required for moist wound healing and also seek to provide mechanical protection; be non-adherent; remove excess exudate; offer effective pain relief and be cost effective. However, no single product is suitable for use in all wound types and there is a lack of robust evidence as to the clinical effectiveness of products (12). This is particularly so in relation to the wounds experienced by those with EB (12).

EB wounds cover large areas of the body and extend into ‘awkward’ places, for example, the neck, groin and arm pit. Dressings come in set shapes and sizes (10 × 20 cm, 15 × 20 cm and 20 × 20 cm), therefore individuals with wounds that exceed these sizes have to resort to multiple and overlapping dressing systems. Fixation materials comprise adhesive tapes and films as well as flat and tubular bandage systems. None of these are ideal for fragile and damaged skin. EB users end up with a ’patchwork quilt’ of dressings with indifferent fixation systems, which are ineffective, uncomfortable and erode personal confidence.

Overall current products do not meet the needs of those with EB, necessitating research into products designed for their requirements. Key issues concern the pre-sized and pre-shaped convention in wound dressings. The patch-worked and layered dressings in conjunction with clothing generate heat and moisture, which further weaken the skin, aggravate itch problems, and challenge the ability to regulate body heat.

Materials and methods

A qualitative participatory research design was adopted, collaborating with the people with EB, and the people who participate closely in supporting these individuals (lay carers and professional nurse specialists). The aim was to capture their problems with current wound dressings and provide solutions to the current limitations in dressing performance for EB (13). It began in 2006 following ethical approval from King’s College London Research Ethics Committee. The project is multidisciplinary with researchers from Kings College London, specialist EB nurses working in the UK National Health Service, adults with EB and their carers, a design consultant and selected manufacturers.

As indicated above WEB is a phased research project designed to ascertain unmet needs in EB wound care, and to test a translational research model for turning clinical problems into viable commercial solutions for skin and wound care (6). The model developed from four distinct but inter-related stages for medical device development and evaluation, as described below. Stage 1 is the focus of this article (1,14).

Stage 1: A process of end-user and manufacturer engagement during the early stages of device development (14).
Stage 2: Product development from a manufacturing perspective (15).
Stage 3: Health technology assessment, adapted from the UK Medical Research Council (MRC) framework, recommended as good practice for complex clinical evaluations (16).
Stage 4: A model of economic evaluation (17).

The first phase of this engagement involved collecting and analysing data from adults with EB, their carers and specialist EB nurses through a series of workshops to define their unmet needs. This information was required to guide new product development. Workshop data were enhanced by field notes collected during observations of dressing changes, photographs of dressings being applied, and data from a questionnaire placed on the Debra UK website.

The second phase constituted a brainstorming workshop, comprising a group of experts that included designers, material scientists, engineers and a pharmacist, along with specialist EB nurses and academic researchers. The purpose of this brainstorming workshop was to begin the creative and analytic process of formulating innovative design concepts, based on the user needs expressed within the phase one workshops (18). Findings from these sessions were fed back to the user group through subsequent workshops.

The project progressed to the third phase: the development, finalisation and evaluation of a design concept and prototypes informed by the workshop data. These have translated into a range of Conformité Européene (CE) marked novel dressing retention garments.

At the time of writing the garments are being evaluated by a group of adults with EB in a study with the appropriate ethical and research and development permissions and approvals. The findings of this phase will be published elsewhere.

Study sample

A purposive sampling strategy was employed, whereby the criteria for selection is more important than the number sampled, as the characteristics of individuals are used as the basis of selection (19). The key inclusion criterion was that participants’ wounds were extensive with needs not met with conventional dressings. Carers and specialist EB nurses were included. Recruitment was predicated on informed written consent. Individuals with EB participate in a number of research studies and were somewhat sceptical of what might be achieved from further research. There were therefore challenges around keeping people motivated, and managing expectations (20). In this the support of the specialist EB nurses was vital. Their knowledge of and relationships with the end-user group allowed the research process to be managed in a sensitive and appropriate way.

Methods of data capture

Data were collected during workshops, visits to participants in their homes or in hospital to observe dressing changes, a brainstorming session with designers, materials experts and clinicians, and a questionnaire posted to the Debra UK website.

Workshops

The term ‘workshop’ was adopted purely based on the view that this term reflected the problem solving goal of the WEB project more than the term ‘focus group’. Focus groups are widely used within health services research as an effective way of gathering qualitative data (21). They are distinguished from methods such as one-to-one interviews by the explicit use of the group interaction amongst peers who share a common frame of reference (22,23).

The benefits of using focus group dynamics to collect data include the opportunity for individuals to express themselves, to interact with a group, and to develop group ownership of problems and solutions (24). For the WEB project this was particularly important given the lack of end-user representation in the UK wound dressing supply chain, revealed in Campling’s study, which included participants with EB in the study sample (25).

A total of four workshops were held at various stages of the project with numbers of participants ranging from 6 to 20. Given that people with EB are dispersed across the UK, the workshops were run to coincide with hospital EB clinics at locations in London and Birmingham. A drop-in approach was used so that participants who needed to attend an appointment left the group and re-joined at their convenience.

Data collection within the workshops

As with any method of verbal data collection, the process of data capture is critical particularly in terms of being able to identify who is speaking and using a method of data recording that does not interfere with the group dynamics (26). Audio-recording is a well accepted method of verbal data collection and was adopted in this study. The workshop facilitators made notes of who was speaking at any given time. This was important to be able to follow up questions with the individuals concerned, which also triggered visits by the researchers to observe dressing changes to witness the wound care problems they raised.

Moderation of focus groups is raised as a key issue in the literature to maximise the quality of the data generated (23,26). There were concerns that the participants might not want to talk about their personal experiences in front of other people with EB. The workshops were therefore introduced by either the lead researcher or senior EB nurse specialist, with an acknowledgement of the sensitivity of the issues that would be revealed and the need to maintain confidentiality (Box 1).

Box 1

Introduction to the workshops

Workshop Facilitator

As you will already know from the information that you have received in the post, the purpose of this workshop is to ascertain the needs and priorities of people with EB in relation to managing their wounds in order to scope future project proposals for developing innovative products. Essentially, we really want to understand any problems you are having with wound dressing. This information will be used by a design consultant to develop new ideas for wound care products. The information you give us will also be used to scope the project for further funding to develop new products. We are very much aware that some of the information offered here will be of a sensitive nature. We would like to reassure all of you that we recognise this information is given in confidence, and we hope that you will feel the same.
The workshop question is:
‘... What is the main problem about managing wounds that you have at the moment? ...”

The participants appeared to have no difficulty talking about their wound care problems, and interrogated each other freely about their experiences, which generated profound insights into their experiences as the extract in Box 2 from Workshop 1 illustrates.

Box 2

Workshop 1 extract

J: I am 25 this year, and I have never done a dressing by myself!
R: Could you?
J: I can do it, but my mum just doesn’t let me do it!...My mum has trained my little sister now to do my dressings.
T: I travel abroad, and as I say, I go on my own. That is when I find those big sheets, 50 × 20, because the way I am now, I can use just one sheet, in may be three whole areas, and then you can pull it up, just take the wrinkles out and anything else. But I just find that sticking is not ideal because I put ointment on it. You can either have it dry and it has more of a tendency to slip because it takes the stickiness away, but I don’t use my preferred choice, and I find I get more blisters by using it.
R: How long do you go away for? Do you choose hot countries, cold countries?
T: Yes. I go to America, I go to Thailand. I have been to Australia. I just find the sun and the sea, again, helps me with my condition. The salt water. It really heals. I come back looking better.... I just find the sea salt and the minerals in it – and it doesn’t sting.
R: Are you fully dressed? Are you fully covered with dressings?
T: I take as many dressings down as I can, but just so that it is not unsightly, I keep others on, and I find when I go out there, I wear three-quarter length trousers, so a lot of them can’t see them anyway, and I generally put fresh ones on for that day, so I am not polluting anything..”

These interactions revealed a number of overlapping and consistent themes, which were reinforced by the observations of wound dressing changes, and the small amount of data collected via the website questionnaire.

Observations of dressing changes

Observations of routine dressing changes and skin care revealed firsthand the problems and challenges faced by those with EB and their carers, in home and hospital settings. Photographs provided a visual image of the problems. The conversations that took place, recorded in field notes, during these visits revealed valuable insights into the struggles with conventional wound care products.

The over arching finding from these visits was the domination of dressings in the bedroom or hospital room where dressing changes took place, and the extraordinary length of time taken. One participant's bed for example was covered in the wrappings of all the dressings that had been used; dressing changes took in excess of 3 hours and were a daily event. One hospital dressing change took 7 hours. Two nurses worked from the participant's left foot, along the left side of the body and down the right side ending with the right foot. It was not possible to count the numbers of individual dressings used. At the end of the process the nurses withdrew, leaving the trolley of soiled dressings in the room, which was hot, humid and smelled. The participant looked at her feet, observed her left foot was dripping and remarked to the researcher '. . . *is that me?*. . .'. The ward team were informed and had to re-visit the dressing change.

Of particular note, which triggered a visit to observe a dressing change, was the fact that cling film was used as a wound dressing, as the field notes in Box 3 illustrate.

Box 3

Field notes from home visit: unconventional wound dressings

She has not used conventional dressings from around the age of 9 (then 22). The regime consists of a bath in the morning followed by dressing application. Her mother applies a medicated moisturiser and then places the cling film on top of this. The film is applied so that there is no break in continuity with the film. The entire body (neck to toe) is covered with inserts of gauze padding, wrapped in film to prevent any gauze sticking to the skin, placed around joints, soles of feet, buttocks, chest wall, as cushioning. A soft bandage is applied to each leg and arm, again as protection. The bandage is followed by a light elasticated bandage, applied in the centre of the upper arm/leg working upwards and then downwards. This technique stops the bandages from rolling off. On her legs ribbed stockinet 5 × 5 cm is applied and the top end taped with tape.

This mother and daughter have noted that although blisters develop, the wounds tend to heal very quickly (10 days) and antibiotics are rarely needed. She appeared to have good areas of soft and healthy skin. A major benefit of the system used related to pain. She has minimal amounts of pain compared to what is often experienced by people with EB. The wound coverings took an hour to apply and they last 24 hours.

The conclusions drawn from this visit were that finding ways of wrapping the body in breathable materials, thereby off-setting the limitation of cling wrap which is occlusive, was a potential design solution, which is currently being followed up. In addition, this was an illustration of the lengths that users go to find dressing solutions that, on balance, gave them better outcomes than conventional dressings.

Website questionnaire and responses

The following questions were posted to the Debra website:

- What dressing systems are you currently using? Please indicate the type of dressing, number used per dressing change/day/week.
- How often do you need to change dressings?
- What have you used in the past?
- What has caused you to change your dressing regime?
- What needs to be done better?

Seven responses were posted to the website, six by parents in the UK, the USA and Australia. One response was by a daughter in the USA, who said she was writing a book on EB. These data have been analysed with the workshop data.

Brainstorming workshop

Brainstorming is a process of creative thinking, in particular relating things or ideas which are not normally related, and developing creative solutions. The purpose of brainstorming is not to make decisions but to come up with as many ideas as possible that can later be analysed for suitability and potential (18). In this project, a professional workshop facilitator was engaged. The brainstorming data, comprising 63 pages of transcript material, were analysed, and resulted in the working hypothesis for EB wound care, which is the basis of new design concepts (Box 4).

Box 4

Working hypothesis

The problem with EB blistering and development of chronic wounds

- The basement membrane (BM) of the skin is the anchoring complex joining the layers (epidermis and dermis) of the skin. With EB, this structure is inherently unstable because the dermis and epidermis are not anchored to the BM as per healthy skin. In effect there is a fault line. The fault line varies according to the EB subtype.
- With minimal external force, the dermis, or epidermis, separates from the BM and a blister forms. The blister travels along the *fault line*, gaining momentum from the increasing pressure of blister fluid.
- Blister formation is a pivotal point of skin damage for patients with EB. As the blister forms, the fluid builds

and pressure within the blister is raised. This causes blister extension through the unstable EB skin.
- Current practice is to prick and slit the blisters, to drain the fluid, and retain the blister roof as the first ‘wound dressing layer’.
- The now broken skin is dressed with an oily/antibacterial cream to enhance the low adherent capacity of primary dressings, secondary dressings to take up fluid, padding to protect bony prominences and vulnerable areas, and tubular or flat bandages to secure them in place.
- Tubular bandages have to be pulled over patchworks of dressings, which roll up, fall off and are a source of repetitive irritation/frustration as well as trauma to the skin.
- The multi-layered system conserves moisture and heat.
- The skin becomes macerated, irritated and further weakened in the moist conditions.
- The warm moist environment is an ideal breeding ground for bacteria, which cause odour, increase exudates and increase the skin damage and extent of the wounds; the blister progresses to a chronic wound
- Individuals have difficulty maintaining thermoregulatory balance, EB related pruritus is aggravated.

Validity, reliability and rigour

Establishing the validity, reliability and rigour of qualitative research is a contentious issue (27). Strategies to ensure validity and reliability can be embedded within the study design, for example member checking, audit trail and interrater reliability testing of analysed data (21). Critics of this approach argue that these techniques result in a reductionist view of data and knowledge (28). Instead, emphasis is placed on the ethics of research and the role and responsibilities of the researcher to conduct meaningful and trustworthy research, and report on it (21,27,28). The responsibility for appraising the quality of research is assigned to the informed reader, with the researcher being responsible for reporting the process they followed, as opposed to an idealised version for publication (28).

Other authors challenge this approach on the grounds that judging the value of a study on completion is too late to correct problems that incur a poor rating (21). In addition, a focus on the writer of a research report and the reader diminishes the methodological value of different forms of qualitative research, and their translational aim (29).

In the WEB project, elements of both sides of the argument outlined above have been incorporated in addressing the issue of rigour. The aim was to be inclusive and non-hierarchical; the researchers would have preferred the participants to have been co-researchers, on the grounds that they are the experts in their problems, and arguably should present these themselves. At a practical level, however, someone had to take a lead with grant applications and the day to day running and governance of the project. This is particularly so given that the participants navigate, daily, an unstable long-term condition, which requires varying levels of support from lay and professional carers as well as acute care from specialist centres.

Within a researcher-led study, the priority was thereafter to create opportunities, through the methods of data capture, for the participants to define their problems with wound dressings, which first surfaced in the WRAP study and subsequently in the study by Campling (12,25). The onus was on the researchers to follow a rigorous process of data recording, analysis, interpretation and feedback to the workshop respondents to ensure that the proposed device development was consistent with their experiences of the problems. An additional aim was to avoid the potential to harm the participants through the re-presentation of their accounts, without any right of reply, prior to publication (28).

Overall, the approach taken to issues of validity, reliability and rigour comprised generating a trustworthy analysis of the problems encountered with EB wound care with a view to developing solutions. Validity and reliability therefore relate to the data analysis, where validity refers to data accuracy, and reliability to the process of analysis and member checking undertaken. Member checking with the workshop participants has been in the form of an iterative prioritisation exercise to develop solutions for EB wound care. This article has also been circulated to the workshop participants; they have contributed their vignettes and their critique. The major themes appear to be consistent across the participants’ accounts. The ultimate test of validity, however, will be the performance of the novel products that have been developed from the above data, analysis and translation.

Findings

The findings highlighted five broad areas of problems and a range of possible solutions. The problems are interrelated and include:

- Skin damage, wounds and wound-related symptoms
- Dressing failure
- Impact on daily life
- Issues related to clothing
- Issues around cost and service provision

Skin damage, wounds and wound-related symptoms

Constant blistering and wound formation were cited as an everyday part of life together with pain and discomfort. One participant objected to people with EB being referred to as ‘butterfly people’, including the butterfly logo, which has been adopted by the charitable foundation to reflect the fragility of EB skin (http://www.Debra.org). She said that the pain she experiences is akin to having razor blades against her skin.

Pain was difficult to manage and the participants voiced their reluctance to use analgesia due to side effects, for example drowsiness, that interfered with leading an active life (Box 5).

Box 5

Participant vignette

D: That pain dressing – when I feel really bad I stay in bed. It just takes the pain away. That dressing is a good idea. A couple of years ago, the nurses were putting morphine on the wound instead . . .why can't they do that, go down that route? I know you are not allowed to use it all the time, but just for an extreme case, to take the edge off the pain, so that I can walk to the toilet without crawling to the toilet instead because it is so painful.

Participants noted that the amount of exudate and associated odour and leakage meant dressings required frequent changes, which were painful and time consuming. Also evidenced in the way that pain was described was the 'pain' experienced by the carers (Box 6).

Box 6

Carer vignette

J: '. . .It is excruciating when the dressings keep coming on and off and she is in unbearable pain.'

Discomfort, as distinct from pain, was attributed to the inability of EB skin to sweat effectively. Participants were sensitive to heat and temperature alterations, including exacerbation of the itching that accompanies many skin disorders. Acute itching was also experienced under foam dressings. Scratching naturally led to further skin damage and pain.

Two inter-related aspects of wounds, infection and exudate, were highlighted. Infection was a constant risk and led to increased exudate production, which was considered a major problem leading to associated problems, for example odour, leakage and soiling.

Some participants described how substances that intuitively would cause problems in fact appear to aid wound healing. These included photography fluid, car wax and acidic secretions from gastrostomy sites, suggesting that the wound exudate is alkaline, and corrosive to the skin and that these products assist in normalising the pH of exudate (30).

Dressing failure

Participants echoed the problems highlighted earlier about the inadequacy of the design of current dressings. They described becoming adept at adapting and combining dressings to cover wounds through cutting and thinning dressings and using homemade templates. Particular ingenuity was required to fit dressings round joints, the groin and the neck. The end result was a patchwork of dressings covering areas of the body.

Linked to the above was the length of time for dressing changes, which depended on the number of wounds, their size, the number of dressings required, the positioning of the dressings, for example, around fingers, feet. Preparation and application were time consuming and changes could take anything from 30 minutes to 3–4 hours, 7 hours being the extreme. This had a significant impact on attendance at work, college or social activities. Participants also described the mind numbing boredom of repeatedly preparing for and conducting dressing changes.

Adhesion of dressings to fragile skin was highlighted. If dressings were too sticky they 'pulled' on the wound, even those designed to be low-adherent caused damage. Dressing removal was traumatic with bleeding and more skin damage. To address this problem, petroleum-based creams were used, despite the fact that these oily creams reduce the ability of the dressing to absorb exudate, and macerate the skin.

Dressings were also ineffective in controlling exudate, with the time between applying new dressings and exudate seepage being extremely short (Box 7). Participants highlighted their anxiety around exudate seepage as well as the fact that soaked dressings slipped and stuck to other parts of the body.

Box 7

Participant/Carer vignette

End-user: My mum and I usually start to do my dressings at around 7 pm after I'm back from college. I like my dressings done each day because my wounds ooze so much. I feel safer and fresher that way. It often takes up to 3 hours so we watch TV or listen to music while we're doing it. I have wounds all over but under my arms, the top of my legs and my feet cause me special problems. I can't wear high heels because of the pressure.

I use silicone mesh and silicone foam mostly and we have a fleece dressing that you get on a roll that my mum cuts this the right shapes for my wounds. For my foot she uses a template she has made. The dressings we use at the moment. . .they do quite a good job, but they do tend to buckle and move. I have bulky layers of dressings on my feet and so can only wear trainers.

A big problem is under my arms, and it is the odour that is really apparent. I should leave the silicone mesh in place to let the wound heal, but it has to come off every night because I can't stand it

The back of my leg gives me real problems if the wound is oozing a lot when I am at college. It makes the dressing drop down and then when I get up at home, it has welded itself to the inside of my jeans, so there are at the moment only a certain few pairs of trousers I can wear. Also if the wound is oozing a lot and buckles, it can stick somewhere it shouldn't. When you pull it off or you move, if you don't realise the dressing has moved the skin comes off as well.

End-users mum: I thought as she got older, things might get easier in terms of the time it takes to do dressings, but the nature of EB means that more of the skin is damaged over the years, the easier it breaks down, and the harder it is to get it to heal. It has gradually got to be a bigger and bigger deal. Of course, as she has grown, there is more and more of her to dress. But we have been using that shape for round her feet since she was a little baby.

Dressing fixation was challenging. It was impossible to fix dressings into place without assistance when wounds were in hard to reach places or when using numerous small dressings. Getting dressings to conform to body contours and body movements without pulling or bunching was also problematic. The problem is then a circular one requiring assistance for dressing changes, and also during wear-time.

Participants used a variety of products to hold the dressings in place such as bandages, tapes and elastic hosiery, although these were capable of further damaging the skin; dressings shifted, and dropped off, when clothes were necessarily removed, for example when using the toilet.

The vignette at Box 7 illustrates the above problems:

Table 1 below describes specific wound care products used by participants, and the benefits and limitations attached to them. This list is by no means exhaustive.

No product was felt by participants to really meet their needs, although some worked better than others when applied to different areas of the body. A dressing that would stay in place on a leg for example, did not stay in place, or was too bulky for dressing a foot.

Participants were very aware that using dressings and products in combination was not ideal and prevented individual products from working to their full potential, but made the 'best of a bad job'.

Impact on daily life

Participants highlighted the extent to which dressing changes eroded independence and time to achieve personal goals. A desire to grasp control could lead to individuals' managing their wounds in ways that are not optimum, harmful even. For example, one participant chose to use adhesive dressings for her buttocks on the grounds that the dressings did not slip, even though on removal the skin was removed. This sort of situation created tension with professionals and carers.

There was recognition of the negative psychological impact of the condition which included lack of confidence and self esteem which could manifest itself in a variety of ways, for example as depression, anxiety, frustration and anger (Box 8).

Box 8

Participant/Carer vignette

S: We do J's dressings most evenings. We have occasional nights off, may be a Friday night, with no Uni on Saturday. It takes about 3 hours.

Z: It takes my mum about an hour and a half, if I want to do the whole body.

R: Same with me, and having district nurses coming around, they don't understand that it takes time, and that is the word, time. Cutting them, and how to cut them for fingers – this is a stocking, anything just to save time. . .I do my hands last, because doing them with the nurses, you have cream on them, 50/50, X, Y and Z. I'm tired of it all. It gets to the point when I get my hands a bit, because I'm alone, and I have to constantly be in and out of rubber gloves, so these get wet, green line. I need proper dressings, but I can't – I just cut that, snip, snip, snip, I use some of my day to do something nice. By the time I get up, do these, it's about 4 pm, it's dark, if I want a book, I've got to quickly think of the easiest route to WH Smith, nearest the main road, so the closest one that has disabled parking. Normally I have to walk somehow, and at 5 pm they are starting to close, and 5·15, locking up, I just miss everything. . ."

A key positive impact on daily life was identified as *understanding* from a genuinely supportive team of friends, family and professionals. Indifferent carers, however, attending daily for several hours of care, induced dread, anxiety and depression in the person on the receiving end.

Issues around service provision and cost

The participants voiced their views that non-specialist health professionals [general practitioners (GPs) and community-based nurses] had limited knowledge about EB or wound care. GPs in particular were said to fail to recognise that those with EB can have intensive needs especially in relation to the type and number of dressings required.

Dressing changes could be challenging for non-specialist professionals, aggravating an already onerous situation, particularly when there was a lack of continuity of care. This lack of knowledge and insight was coupled with a failure to recognise and accept expert knowledge (Box 9).

Box 9

Participant/Carer vignette

Y: . . .when it came to going home, they gave me a shopping list to take to the pharmacy at my local hospital. . . I was at home with this new baby, she was very ill. My mum took it along, and the consultant in paediatrics was really annoyed by that and did not want to give her the prescription, and she said that 'if the doctor at the other hospital would be good enough to write to me and ask me to do it, I'll consider it'. My mum went mad and said 'we've got a sick child at home and we can't do without dressings; are you going to give them to me or not, because I'm not leaving without them, and plonked herself down on the ward'. She did eventually give a prescription to tied us over a few days.

T: I have been told my local GP practice gets an extra £2000 a year to cover my additional needs. When you think the dressings cost £10, and you have 18 on at any one time, three times a week, that £2000 soon gets blown out of the window. . . .So if I add to what I call my shopping list at the GP, they don't like adding to it, because they think I am costing them enough already. I have arguments all the time.

Difficulties in persuading GPs to prescribe some expensive types of dressing were raised, as was the burden on those with EB who worked and thus had to pay prescription charges. Obtaining adequate supplies of dressings was frustrating and time consuming. On occasion they were forced into 'making do', and to reuse dressings, increasing the risk of wound infection.

Issues relating to clothing

Above all participants wanted to wear what they regarded as normal clothes and shoes that were in keeping with their age, personality and life style. They sometimes chose fashionable

Table 1 Products used for Epidermolysis bullosa wound care

Type of dressing	Benefits	Problems
Honey dressings	• In current favour as an antimicrobial agent • Participants felt it aided healing	• Very sticky even when covered with dressing • This makes application difficult • Can sting
Silicone dressings	• Soft and adhere to dry surfaces and can theoretically be removed without trauma	• Dressings buckle, ruck and move • Some find them too sticky or not sticky enough • Can't handle exudate • Expensive and problems with supply
Foam dressings	• Encourage healing by absorbing exudate	• Cushioning effect causes overheating • In fact don't manage exudates adequately
Alginates	• Long lasting dressing that becomes a gel in the presence of exudate	• Damage to surrounding skin: further blistering • Difficult to remove • Stinging • Hardens like cement when exposed to air
Hydrocolloid	• Provide a moist environment for healing	• Harden and so difficult to remove, causing skin damage • Problematic for use on open wounds
Charcoal products	• Help control odour	• Lose effectiveness when in contact with exudate
Eclipse	• New dressing that is highly absorbent of exudates and thick	• Difficulties with conforming to body parts • Causes blistering • Sweaty
Elastic bandaging	• To hold dressings in place	• Difficult to put on over primary dressings without them moving • Hard to manage without help from a second person • Can cause further skin damage • Variable quality • Newer products tighter causing further problems for this group • It is white and so noticeable including when stained

clothes and shoes that were tight, suffering skin damage to fit in and be similar to their peers (Box 10).

Box 10
Participant vignette

M: I am a bit like H. I am not going to wear slippers all day at work, whatever, just to protect my feet. I want to be treated like any normal person – or what is normal. I want to wear proper clothes and proper shoes. So, I wear what I find adequate enough to be able to cope with it, rightly or wrongly.

The potential to develop solutions

Some of the participants were sceptical that the designer and manufacturers would come up with solutions that they would use. One mother indicated that the WEB project is for future generations, that they were set in their ways and would be unlikely to adopt anything new. Others voiced their dislike of being 'guinea pigs' (Box 11).

Box 11
Participant vignette

A: The thing is I've been let down so many times with products because all my life I have been a human guinea pig for trying this, trying that.

A further issue raised, which challenged the potential for the project to succeed, was the business case for EB dressings from a manufacturer's perspective (Box 12).

A number of solutions were, however, proposed by those with EB, carers, clinicians and researchers, and are collated in Table 2.

Two design concepts were developed with the designer from these data. The first comprises a two layer system with a primary wound contact layer and secondary dressing retention garment. The second needs to be protected until fully

Box 12

Participant vignette

T: I am arguing that from a business point of view they are there to make a profit, so if they are going to make a specific dressing that only EB people can use . . . and other people cannot use it, they are going to make a loss and they would not see that as a business game, would they?

Table 2 Potential solutions for Epidermolysis bullosa woundcare

Dressings	- Rolls of dressings that could be cut to size like material - 'wraps' for those with total body wounds - Improved odour management systems within dressings
Materials	- Breathable materials that are thin, light and absorbent - Adhesives with bonds that are easy to break - Non stick pillow cases and bedding
Clothing	- Garment system that would hold dressings in place - Easier fastenings, for example Velcro - Padding systems that offer protection to arms

developed. The retention garment was prioritised by the participants for immediate development on the grounds that the performance of patch-worked dressings would improve before a novel dressing layer to work optimally with the garment could be developed.

A two layer dressing system is not novel; the novelty lies in the detail of the designs to accommodate body shape and activities of daily living, together with EB disabilities associated with webbed fingers and loss of manual dexterity, also feeding via gastrostomy tubes. In addition, the yarn and weave of the garments have been selected to maximise independence in terms of being able to get in and out of the garments, dressing retention comfort, and moisture and heat loss. It is fully acknowledged that the garment is only part of the solution and that the dressing layer needs developing to work optimally with the retention garment. Development of the dressing layer is the focus of a separate project.

Consensus and generalisation of the workshop findings

Authors such as Sim (26) guard against using focus groups to generate consensus, however, consensus is not ruled out. Schroeder and Neil (24) advocate the use of Delphi techniques for this purpose, rather than focus group technique. The thematic analysis of the WEB data, however, enabled the process of extracting from highly personal idiographic experiences to logically comparable core propositions concerning the limitations of current approaches to EB wound care.

In terms of generalising such propositions, the literature cautions that the role of focus groups is to provide in depth insight into particular phenomena through social interactions in a particular context (22). Therefore, it may not be legitimate to generalise beyond that context. That said, as Sim (26) points out, there are different forms of generalisation, empirical and theoretical for example, with the latter viewed as a form of hypothesis generation, which remains tentative until further validation is undertaken. This position is consistent with the hypothesis generation, and prioritisation of the development of novel dressing retention garments as a first step towards improving EB wound care in this study. The novel garment proposition is currently undergoing validation. Given that the focus is on covering extensive areas of wounded skin on the body, the garment solution, if it works for EB, is potentially transferable to other patient groups with similar characteristics.

Translation of user needs into design solutions

Consistent with the model of user engagement in medical device development that underpins the WEB study, a designer and manufacturer were engaged on the project; the designer was supported by King's College London internal innovation awards. The manufacturer was selected on the basis of their flexible, computerised machinery and reputation for high quality innovative products, which were fast tracked into health services supply chains to relieve problems arising from dermatological conditions.

The development of a garment system to hold dressings in place was prioritised by the users on the grounds that immediate improvements could be made to dressing changes and the stability of dressings during wear-time. Although garments exist for retaining dressings on the body the novelty in WEB is the engagement of a fashion designer to relate techniques in clothing design and development to wound dressing design. Her knowledge of 'clothing the body' was extended to 'clothing a wounded body' as opposed to covering a single wound, which is the convention adopted currently by the wound dressing industry.

An iterative process of design, manufacture, preliminary testing with surrogates followed, culminating in a range of CE marked garments for evaluation on the grounds of clinical performance and costs. The use of surrogates, as opposed to users, to test the products was necessary because of delays in obtaining necessary ethical approvals. In addition, there were practicalities and limits to obtaining detailed and frequent feedback from people living with a long-term debilitating condition. This use of surrogates will be presented in another article.

Discussion

This stage of the WEB project aimed to gain insight into central aspect of living with EB, skin and wound management, and thus fell firmly within a qualitative research paradigm. It was concerned with collecting subjective data on the experiences of individuals with EB in relation to their wound care. A working hypothesis for EB wound care together with design concepts for new products were induced from the data in an iterative process.

As with any qualitative study there are concerns regarding the generalisability of findings. The project is dedicated to finding solutions for EB wound care. However, the specific questions addressed in the WEB study also relate to people with different conditions that result in extensive wounds. The points of generalisation are that pre-sized, pre-shaped dressings do not meet the needs of individuals with extensive wounds, and that designs to wrap the body, as opposed to covering a single wound may succeed. Such generalisation need to be tested through further applied research studies.

As to the model of user engagement, which underpins the study, the generalisations stem from the frameworks of the model, which can be applied to different clinical problems and patient groups to problem solve through medical device development and validation. If located within an academic setting and supported with 'start-up' funds, the process of defining user needs and identifying design solutions can be protected from vested interests and conventions. The academic institution also owns the ensuing intellectual property. The completion of successive successful projects has the potential to bring a revenue stream back to the institution for re-investment in this type of research, development and translation endeavour.

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