

Individualising wound care research: The Woundcare for Epidermolysis Bullosa Project

The authors report The Woundcare for Epidermolysis Bullosa (WEB) Project, which undertook to design dressing retention garments to replace flat and tubular bandages traditionally used in wound care for EB. Participants with EB reported greater comfort, healing of persistent wounds, and enhanced self-esteem using the new garments, and an average annual saving of £10943 per patient is estimated.

Epidermolysis Bullosa (EB) is an inherited chronic and lifelong condition, affecting the skin and other organs. It is rare and affects approximately 1 in 17000 live births. It is estimated that there are currently 5000 people with EB in the UK (www.debra.org.uk). The care of people with EB is aimed at minimising the impact of the condition and delaying deterioration in their physical and psychosocial functioning.

Those with the most severe form of EB – dystrophic EB – experience extensive wounds (Dures et al, 2011). The majority of dressings currently on the market are pre-sized and shaped, and people with EB have to patchwork dressings over their wounds, holding them in place with layers of flat and tubular bandages. Dressing changes take hours, using significant quantities of products, and often require patching-up and replacement dressings. This leads to an unstable dressing system and a significant reduction in time available for other activities during the day. A need existed for a more effective and comfortable dressing retention system for people with EB.

BACKGROUND

The Woundcare for Epidermolysis Bullosa (WEB) Project is a collaboration between people with EB, carers, clinical nurse specialists, designers, and manufacturers. The aim of the project is to understand the experiences of people with EB with regard to wound care, and so to turn unmet needs into design solutions.

WEB undertook to explore wound care experiences during four audio-recorded workshops with adults with EB, carers, and clinicians. These

data were analysed thematically and a detailed report of the workshops has been published elsewhere (Grocott et al, 2013a).

Broadly, the workshops revealed that the flat and tubular bandages habitually used to hold dressings in place are time-consuming to apply and inefficient in holding multiple patchworked dressings in place. The quality of the tubular bandages was described as variable, leading to fraying and disintegration, and insufficient stretch to put over dressings without the dressings rucking up. The layers of bandages were also associated with excessive heat and moisture retention.

Feedback received at the workshops led to the development of prototype high-stretch dressing retention garments (Grocott et al, 2013b). The garments were subjected to surrogate tests and were iteratively refined with the manufacturer. Here, the authors report detailed results from the subsequent proof-of concept study for the novel garments.

Notes on study design

Given the highly individual nature of wounds and experiences of patients with wounds, research methodologies that focus on the individual – as opposed to group statistical approaches – offer a valuable addition to the portfolio for wound care research. Such methods are also consistent with the growing emphasis on individualised medicine (Cortese, 2007).

In the present study, an experience-based co-design (EBCD) approach was used. EBCD places patients and clinicians together – as partners – in a planned process of co-design to improve a technology or service (Bate and Robert,

KEY WORDS

- ▶▶ Dressing retention
- ▶▶ Epidermolysis bullosa
- ▶▶ Experience-based co-design
- ▶▶ n-of-1 research design

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Box 1. The 11 TELER indicators measured.

1. Recovery from pain induced at dressing change
2. Recovery from exhaustion induced at dressing change
3. Dressings sticking
4. Dressing trauma and bleeding
5. Your experience of exudate leaking through bandages
6. Cleaning dead tissue from the wounds
7. Condition of the skin under dressings
8. Disruption of sleep
9. Adapting dressings to make them 'EB friendly'
10. Interventions between planned dressing changes
11. Impact of odour

2006; Tsianakas et al, 2012). EBCD stresses the identification of patients' experiences and needs to aid clinicians and industry partners in the development of concepts and prototypes to improve negative experiences (Grocott et al, 2013a). EBCD was determined to be the most appropriate method for achieving the WEB Project's goal of developing improved dressing retention garments with the direct input of people with EB.

Prior to undertaking the proof-of-concept testing reported here, the garments were surrogate tested. Surrogate – rather than end-user – testing was undertaken initially due to delays in obtaining research and development permissions to test non-CE marked garments with patients; these delays posed threats to the project in terms of maintaining the momentum of product development with the designer and manufacturer. Furthermore, the level of iterative feedback required to refine early prototypes was more than could be asked of the study participants, given the challenges of living with EB. The research assistant and designer conducted the surrogate tests using a rigorous and systematic process that is reported in detail elsewhere (Grocott et al, 2013b).

AIM

At the request of people with EB, the WEB Project developed a range of novel, high-stretch, dressing retention garments designed to replace the flat and tubular bandages traditionally used to hold wound dressings in place, and so improve the wound care experience of people with EB.

Ethical and research and development approvals and permissions

Ethical approval for the study was granted by the National Research Ethics Service (11/LO/0873) and local National Health Service research governance procedures were overseen and granted (RJ111/N243).

METHODS

EBCD was used to undertake the development of the dressing retention garments. Once surrogate testing of the garments was finalised against explicit performance criteria, they were proof-of-concept tested with a sample of adults with EB in an n-of-1 non-randomised trial using TELER® indicators (<http://www.longhanddata.com>) that allowed

participants to digitally record outcomes via a hand-held device. Data were collected into the Longhand database from which indices were calculated and reports generated. Time and cost comparisons before and after the introduction of the garments were also assessed.

Data collection was at six data points for the baseline period (pre-garment) and six data points following the crossover to the novel garments. The interval between data points was determined by the frequency of dressing changes appropriate to the individual participant. Date of commencement of the garment trial depended on delivery of the garments order to the individual concerned. The data points either side of the crossover to the garments were excluded in the analysis to minimise bias.

Study sample and inclusion criteria

Participants comprised a convenience sample of adults with EB recruited from the population of 160 adults with EB registered with a UK EB specialist centre.

Inclusion criteria were based simply on informed consent from participants over 18 years old with a diagnosis of EB who experience wounds that are difficult to manage with conventional dressings.

TELER indicators

TELER indicators were developed based on feedback from the participants to measure the quality of treatment and care against predefined, achievable goals. The 11 indicators measured are listed in *Box 1*.

Each indicator is an ordinal scale of six clinical steps, or "codes". Code 5 was the treatment outcome goal, desired by the patient, and was achievable; code 0 was the problem to be avoided; codes 4, 3, 2, 1 were clinically significant steps towards or away from achieving the goal (Grocott, 2011). Thus, outcomes were defined as follows:

- ▶▶ Standard achieved: code 5.
- ▶▶ Standard nearly achieved: code 4.
- ▶▶ Standard not achieved: codes 3, 2, 1, 0.

Individual and group level responses to the introduction of the novel garments were measured against the predicted mode of action of those responses. This enabled the WEB Project team to determine who benefited and how, as well as those who did not, and why, so that shortfalls in garment performance could be rectified by the designer and manufacturer.

Cost

The number and type of dressings used in conjunction with the novel dressing retention garments, together with the time taken for each dressing change and the people involved, were recorded. Dressing costs were estimated from monthly orders for dressings. The cost of professional nurses and lay carers was calculated from current pay scales (Royal College of Nursing, 2012).

Deficit, improvement, variability, and effectiveness indices

Index numbers for deficit, improvement, variability, and effectiveness (Box 2) were calculated to give an overall picture of the scale of the wound care problem for the individual participant before and after the introduction of the garments. The indices are patient specific and do not permit valid between-patient comparisons.

Qualitative participant feedback

Visual inspection of TELER codes was conducted with interpretation of outcomes using the qualitative data. The latter were written on the TELER forms or sent by unsolicited emails from participants. This approach to data analysis was important to determine the specific problems experienced by each participant for each indicator, and whether or why not the garments were improving previous poor experiences.

RESULTS

A total of 15 adults with EB participated in the study. The sample’s demographics (diagnosis, age, gender, number of data points) are shown in Table 1. The sample was heterogeneous in terms of EB diagnoses.

The analysis focused on changes in individual TELER indicators as a result of replacing bandages with the novel garments. Data from participants WEB-01 (Table 2) and WEB-02 (Table 3) are used to demonstrate the qualitative approach to analysing the quantitative TELER data.

Participant WEB-01

Data from before the introduction of the dressing retention garments indicate that participant WEB-01 experienced variable outcomes for nine of the 11 indicators. After the introduction of the dressing retention garments, the data

indicate stable code 5s for all indicators, apart from 9 and 3. Odour was not a problem for this participant either before or after the intervention. For indicator 9, a persistent shortfall in dressing performance was found (Table 2), explained by the continued need to patchwork pre-sized and shaped dressings.

The qualitative data from participant WEB-01 support the near-optimal TELER codes achieved:

“The garments are still continuing to do [their] job and I drove in them for the first time since having them yesterday. It was brilliant not to have the restriction in my knee like I did with the bandaging, making it less painful and stiff to swap between accelerator to brake and vice versa.”

“I see what you meant by them being designed to repel heat and moisture, which it did. It made a change to enjoy this warm spell without getting too hot under [the] bandages. Normally, I hate the warm weather for obvious reasons, but now I can enjoy it.”

“[I] am continuing to see improvement in my skin due to the air being able to get through to my skin, more than [was possible with] the bandage.”

The before and after data demonstrate few differences and for indicators 1 and 2. There is some

Box 2. Definitions of the four index numbers collected for each participant.

- ▶ Deficit Index measures the loss of physiological, psychological or other clinically significant function experienced by a patient.
- ▶ Improvement Index measures the lost function recovered during treatment and care.
- ▶ Variability Index is a measure of variable outcomes and stability/instability of the TELER codes and a measure of the inhibiting effect of changes in type of treatment outcome.
- ▶ Effectiveness Index is a measure of the number of improvements and deteriorations on the TELER codes.

Table 1. Participant demographics.

Participant #	Diagnosis	Age (years)	Sex	Data points
WEB-01	Generalised dystrophic EB pruriginosa	31	F	13
WEB-02	Severe generalised recessive dystrophic EB	41	M	12
WEB-03	Severe generalised recessive dystrophic EB	28	F	12
WEB-04	Junctional EB non-Herlitz generalised	57	M	11
WEB-05	Recessive dystrophic EB inversa	28	M	11
WEB-06	Severe generalised recessive dystrophic EB	23	M	12
WEB-07	Severe generalised recessive dystrophic EB	26	F	13
WEB-08	Generalised dominant EB	30	M	9
WEB-09	Generalised dominant EB	21	F	14
WEB-10	Recessive dystrophic EB pruriginosa	31	M	12
WEB-11	Severe generalised recessive dystrophic EB	29	F	12
WEB-12	Severe generalised recessive dystrophic EB	24	F	12
WEB-13	Severe generalised recessive dystrophic EB	30	M	12
WEB-14	Severe generalised recessive dystrophic EB	18	F	12
WEB-15	Severe generalised recessive dystrophic EB	25	F	12

“[Participant WEB-01 said: ‘I see what you meant by them [the novel dressing retention garments] being designed to repel heat and moisture, which it did. It made a change to enjoy this warm spell.’”

deterioration in recovery from pain and exhaustion at dressing changes following the introduction of the garments. One explanation for this pattern is that skills and consistent application of bandages can result in stable dressings; however the garments may do this with less effort, more comfort and less costs.

Participant WEB-02

For participant WEB-02, improvements came after the data collection period had finished. He emailed the following unsolicited feedback and has continued to send positive feedback:

“Some minor improvements – sleeping better, more comfortable, etc – [but this] didn’t happen until about 4–5 days [after] the 6-day trial. These improvements then took a couple of days to be noticeable. The wounds on my shoulder only started to show an improvement when the dressing was able to be kept on for a couple of days without being disturbed. This sort of issue was very difficult to reflect in the forms as there was no immediate change in pain or appearance of any wounds on my back.”

“[The dressing retention garments are] comfortable, easy to change, and hold all ‘wound contact’ layers firmly, yet gently, in place.”

These latent effects support the need for post-trial recording of clinical outcomes, which can be easily undertaken if digital data capture systems, such as TELER, are adopted in routine clinical practice.

Participant WEB-07

Where participants did not experience improvements in performance, the garments were modified. For example, participant WEB-07 reported the following via her clinical nurse specialist:

“The (i) T-shirt is too short and rides-up and digs in around her waist. It keeps the dressing in place over her shoulders; (ii) leg and arm tubes roll up – she wondered about a larger size; (iii) gloves are too large and baggy; (iv) skull cap [is] too tight. Overall, she said there are pluses and minuses.”

The designer contacted participant WEB-07 with alternatives and a waist tube was developed to overcome the problem of the top riding-up.

Costs

Table 4 displays the cost data per participant and Table 5 the average costs per month and per annum.

The WEB Project data demonstrate potential net savings of £10943 per year per EB patient, taking into account the additional estimated cost of the garments.

Table 2. TELER indicator outcome data and indices for participant WEB-01.

Data point	BEFORE					Outcome	AFTER					Outcome
	1	2	3	4	5		2	3	4	5	6	
Date (day / months / 2011)	19/08	20/08	21/08	22/08	24/08		09/09	12/09	14/09	16/09	19/09	
TELER indicator												
1. Recovery from pain induced at dressing change	4	0	0	4	4	Not achieved	5	5	5	5	5	Achieved
2. Recovery from dressing change-induced exhaustion	3	0	0	4	4	Not achieved	5	5	5	5	5	Achieved
3. Dressings sticking	4	0	0	4	5	Not achieved	4	5	5	5	5	Achieved
4. Dressing trauma and bleeding	3	0	0	5	5	Not achieved	5	5	5	5	5	Achieved
5. Exudate leaking through bandages	5	0	0	5	5	Not achieved	5	5	5	5	5	Achieved
6. Cleaning dead tissue from the wounds	5	0	0	5	5	Not achieved	5	5	5	5	5	Achieved
7. Condition of the skin under dressings	5	0	0	5	5	Not achieved	5	5	5	5	5	Achieved
8. Disruption of sleep	5	5	0	4	1	Not achieved	5	5	5	5	5	Achieved
9. Adapting dressings to make them ‘EB friendly’	4	4	4	4	4	Nearly achieved	4	4	4	4	4	Nearly achieved
10. Interventions between planned dressing changes	5	2	2	5	5	Not achieved	5	5	5	5	5	Achieved
11. Impact of odour	5	5	5	5	5	Achieved	5	5	5	5	5	Achieved
Deficit index	13	71	75	9	13		4	2	2	2	2	
Improvement index	0	0	0	29	0		0	50	50	50	50	
Variability index	0	73	41	55	45		0	9	3	3	2	
Effectiveness index	0	0	0	50	50		0	100	100	100	100	

DISCUSSION

Based on the proof-of-concept data presented here, the dressing retention garments developed by the WEB Project were accepted onto Drug Tariff listing on 1 May 2013. The WEB Project was also awarded the 2013 Guardian Higher Education Award for Outstanding Research Impact (Tickle, 2013).

The garments appear to reduce costs by being reusable (30–40 re-use cycles when washed at 60°C). By contrast, the conventional flat and tubular bandages – although considered to be multi-use dressings – are always cut off in EB patients after a single use and disposed of due to heavy soiling from wound exudate.

It is clear from the results relating to indicator 9 that there is a persistent shortfall in dressing performance. The need to adapt and patchwork dressings to cover extensive areas of broken skin is a common feature of the wound care experience of people with EB. This problem will be difficult to resolve until a novel body wrap dressing is developed for EB. At the time of writing, a project proposal is in preparation.

Inclusivity, representation, and generalisability are challenges for all research studies, not least the WEB Project. While only a small number of people with EB participated, it is important to be

Table 3. TELER indicator outcome data and indices for participant WEB-02.

Data point	BEFORE					Outcome	AFTER					Outcome
	1	2	3	4	5		2	3	4	5	6	
Date (day / months / 2011)	27/09	28/09	29/09	30/09	01/10		05/11	06/11	07/11	08/11	09/11	
TELER indicator												
1. Recovery from pain induced at dressing change	4	4	4	4	4	Not achieved	4	3	4	4	3	Not achieved
2. Recovery from dressing change-induced exhaustion	5	4	4	3	4	Not achieved	4	4	3	3	3	Not achieved
3. Dressings sticking	4	4	4	4	4	Nearly achieved	4	4	4	4	4	Nearly achieved
4. Dressing trauma and bleeding	4	4	4	4	4	Nearly achieved	4	4	4	4	4	Nearly achieved
5. Exudate leaking through bandages	4	4	4	4	4	Nearly achieved	4	4	4	4	4	Nearly achieved
6. Cleaning dead tissue from the wounds	4	4	4	4	4	Nearly achieved	4	4	4	4	4	Nearly achieved
7. Condition of the skin under dressings	3	3	3	3	3	Nearly achieved	4	4	4	4	4	Nearly achieved
8. Disruption of sleep	4	4	4	4	4	Nearly achieved	4	4	4	4	4	Nearly achieved
9. Adapting dressings to make them 'EB friendly'	4	4	4	4	4	Nearly achieved	4	4	4	4	4	Nearly achieved
10. Interventions between planned dressing changes	4	4	4	4	4	Nearly achieved	4	4	4	4	4	Nearly achieved
11. Impact of odour	4	4	4	4	4	Nearly achieved	4	4	4	4	4	Nearly achieved
Deficit index	20	22	22	24	22		20	22	22	22	24	
Improvement index	0	0	0	0	0		0	0	0	0	0	
Variability index	0	9	5	6	7		0	9	9	9	7	
Effectiveness index	0	0	0	0	50		0	0	33	33	25	

Table 4. Direct costs of dressing products and time spent on dressing changes and patch-ups per participant.

WEB participant #	01	02	03	04	05	06	07	08	09	10	11	12	13	14	15
Data collection period (days)	20	12	23	12	15	19	12	8	12	17	16	12	12	21	21
Dressing time (h/month)															
Pre-garment	21	101	24	70	159	117	44	97	56	165	140	112	37	23	84
Post-garment	6	89	7	69	84	112	30	88	49	125	130	112	30	15	44
Total time saved	15	13	18	1	75	5	14	9	7	41	10	0	7	8	40
Value of time saved (£/month)															
<i>Healthcare assistant</i>															
Band 3 weekdays (@£9.06/h)	133	115	160	13	680	48	127	79	63	368	91	0	60	76	362
Band 3 weekends (@£12.04/h)	177	153	213	17	903	64	169	104	84	490	120	0	80	100	482
<i>District nurse</i>															
Band 7 weekdays (@£17.36/h)	255	220	307	24	1302	93	243	151	122	706	174	0	116	145	694
Cost of dressing products (£/month)															
Pre-garment	3222	11645	346	1723	1022	2443	1829	2720	775	35865	411	1694	12633	386	7,963
Post-garment	2254	10889	214	1719	721	2129	1614	2079	709	32973	362	1630	12555	293	7482
Dressing costs saved (£)	968	756	132	4	300	314	216	641	66	2892	49	64	78	93	481

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mindful that people with EB are often asked to contribute to research projects, and day-to-day living with EB is onerous. Therefore, no claims are made that the dressing retention garments meet the needs of all people with EB and extensive wounds. Further work is underway to extend the reach and impact of this research, including: (i) the development of a novel wound-contact layer to work with the garments in a two-layer system; (ii) miniaturising the garments for the children; and (iii) assessing the garments for use in the management of extensive wounds in non-EB populations.

Limitations

The authors acknowledge the following limitations of this study:

- ▶ Insufficient time was allowed for the garments to be fitted, and for patients to adapt to a new way of applying dressings and become accustomed to using the garments. While a post-trial surveillance period (six data points) to determine the sustained performance was planned, time and financial constraints precluded this. However, as shown here, the participants did spontaneously email their experiences to the clinical nurse specialists and the researchers.
- ▶ The costs of the products consumed were not based on usage as shown by stocktaking before and after the treatment period. Thus, garment usage per annum has been estimated based on the basis of use during the study period, which

may change because of the fluctuating nature of EB skin problems.

CONCLUSION

The management of a chronic, unstable condition, such as EB, calls for management to focus on the prevention of deterioration. Clinical goals need to be realistic and wanted (i.e. both clinically and personally significant) by the people affected.

The WEB Project, has achieved clinically significant improvements in terms of comfort, healing of long-standing wounds, and self esteem – as reported by patients themselves – following the introduction of novel dressing retention garments. Reductions in time spent on dressing changes and product use and costs were also found. Furthermore, the WEB Project illustrates a novel approach to wound care research and development, which is consistent with the trend towards individualised medicine. WUK

DECLARATION OF INTEREST

King’s College London has a licence and revenue share agreement with Skinwear Limited and Dermacea Limited to manufacture and market the Skinnies WEB™ garments.

Table 5. Averaged savings in products and time across the sample (n=15; data collection period, 232 dates).

	Total sample		Average/participant/year
	Monthly	Yearly	
Pre-garment dressing time (h)	1251	15012	1001
Post-garment dressing time (h)	989	11867	791
Total time saved (h)	262	3145	210
Value of time saved (£)			
Healthcare assistant (band 3 weekdays @£9.06/h)	2375	28494	1900
Healthcare assistant (band 3 weekends @£12.04/h)	3156	37867	2524
District nurse (band 7 weekdays @£17.36/h)	4550	54599	3640
Cost of dressing products (£)			
Pre-garment	84676	1016108	67741
Post-garment	77623	931476	62098
Dressing costs saved	7053	84632	5642
Gross savings (time + products in £)	11603	139231	11603
Additional cost of Skinnies™ WEB garments (£)			660
Net saving (time + products in £)			10943