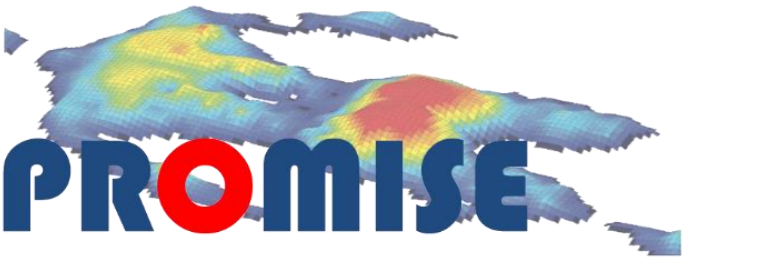
Cedar

Healthcare Technology Research Centre



Pressure Reduction through COntinuous Monitoring In the Community SEtting

Final evaluation report

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Executive Summary

The aim of the PROMISE quality improvement project was to determine if continuous pressure monitoring (CPM) in patients' homes can inform effective management for the prevention and treatment of pressure ulcers. PROMISE is a scaling up project, funded by the Health Foundation Scaling Up programme, and introducing CPM to four new sites. CPM has previously been introduced by the tissue viability team in Cornwall, where it has become a successful part of normal service provision. The key components can be summarised as:

- Pressure mapping equipment and training
- Mapping over an extended time period
- Sharing information from mapping with patients and carers
- Holistic approach to find an appropriate solution
- Ability to provide required equipment

The evaluation took a pragmatic mixed methods approach looking at the impact of PROMISE on both patients and staff, how readily it was adopted by the sites, and the adaptations that were needed. Information was taken from clinical data forms, patient questionnaires, patient interviews, staff interviews and staff surveys. In addition group activities were used to develop logic models and map relationships with equipment suppliers.

Key findings

PROMISE has had a clear impact on the staff that deliver it. They reported changes in their approach to patient centred treatment and concordance, and a journey of learning and personal development. There is strong evidence that in addition to this personal learning, a multidisciplinary approach has been fostered, which supports bringing additional knowledge to problem solving for patients.

Multidisciplinary working and access to a range of appropriate pressure relieving equipment and expertise is critical to PROMISE, and development of this is integral to the way PROMISE works, and facilitated by PROMISE. This requires time to develop and is still an ongoing process at PROMISE sites.

Implementation of PROMISE requires organisational support, and time for the learning and development process. This is partly to learn the technology, but largely to widen knowledge and develop relationships and working arrangements with other teams.

For some patients PROMISE has been very successful, enabling wound healing and a return to their normal activity. For other patients successful outcomes have not been achieved in the duration of PROMISE. Patients' situations and health are complex and heterogeneous, and so are the changes in their outcomes. Barriers to implementation and successful outcomes were investigated during the project.

The majority of patients have found the pressure monitoring process problem free and most reported the monitor display to be interesting.

All the tissue viability teams have plans in place to continue using continuous pressure mapping as part of their normal work. The district nursing team have valued the additional information from pressure mapping, but would find it difficult to fit into the time requirements and expertise levels of their team.

PROMISE has potential to result in a much wider improvement than anticipated, but for most organisations this will also require considerable commitment to change and the resource to allow this to happen.

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Glossary

AHSN	Academic Health Science Network
BMI	Body Mass Index
CCG	Clinical Commissioning Group
CIC	Community Interest Company
COVID19	Coronavirus disease 19
CPM	Continuous Interface Pressure Monitoring
CQC	Care Quality Commission
DCF	Data Collection Form
DN	District nurse
EPUAP	European Pressure Ulcer Advisory Panel
EQ-5D-5L	EuroQol 5D-5L: A standardised instrument for use as a measure of health outcome
GP	General Practitioner
GDG	Guidance Development Group
HCP	Health Care Professional
IEAG	Implementation and Evaluation Advisory Group
IQR	Interquartile range
IT	Information Technology
MDT	Multidisciplinary Team
MRC	Medical Research Council
MUST	Malnutrition Universal Screening Tool
NICE	National Institute for Health and Care Excellence
NoMAD	Normalization Process Theory Instrument
NPUAP	National Pressure Ulcer Advisory Panel
OT	Occupational Therapist
PDSA	Plan-Do-Study-Act
PU	Pressure ulcer
PUQOL	Pressure Ulcer Quality of Life
QI	Quality improvement
R	Programming language used for statistical analysis
STATA	Statistical software package used for analysis
TVN	Tissue viability nurse
EPUAP	European Pressure Ulcer Advisory Panel
UHB	University Local Health Board

Evaluation terminology

Term	Definition
Evaluation framework	An evaluation framework is a tool used to organise and link evaluation questions, outcomes or outputs, indicators, data sources, and data collection methods.
Formative assessment	Formative evaluation is ongoing. It looks at the improvement project as it evolves and suggests ways in which it can be improved.
Logic model	A logic model is a graphic which represents the theory of how an intervention produces its outcomes.
Mixed methods	An approach whereby researchers/evaluators collect and analyse both quantitative and qualitative data within the same study. **Quantitative approaches:** collection of numerical data through statistics, structured interviews, questionnaires or surveys. **Qualitative approaches:** Recording people's experiences through the use of structured, semi-structured or unstructured interviews or focus groups, observation and document analysis.
Pragmatic	Pragmatic studies are designed to evaluate the effectiveness of interventions in real-life routine practice conditions. The pragmatic approach to science involves using the method which appears best suited to the research problem.
Process evaluation	Aims to understand the internal operation of the improvement work and can include both summative and formative elements.
Quality improvement	The use of methods and tools to continuously improve quality of care and outcomes for patients.
Summative assessment	Summative evaluation gathers data to make a judgement about the success of the improvement project; it is often done at the end.
Systems approach	Recognition that an intervention takes place within a wider system that will impact on the implementation process and outcomes.
Theory of change	A description of the mechanisms that are thought to connect an intervention with its outcomes, taking context and assumptions into account. This can be developed at the beginning of a piece of work (to help with planning), or to describe an existing piece of work (to evaluate it). It is beneficial to involve a variety of stakeholders when you develop a theory of change.

1 Clinical context

1.1.1 Pressure ulcers

Pressure ulcers (PUs, also known as pressure sores or bedsores) are injuries to the skin and underlying tissue, primarily caused by prolonged pressure on the skin. They can happen to anyone, but usually affect people confined to bed or who sit in a chair or wheelchair for long periods of time (NHS Choices 2020). They are categorised into 4 levels, from grade 1 (nonblancheable redness of intact skin) to grade 4 (extensive destruction or damage to muscle, bone or supporting structures with or without full thickness skin loss). Pressure ulcers have a significant and detrimental impact on people's lives, emotionally, mentally, physically and socially (Spilsbury et al. 2007). Although anyone may develop a pressure ulcer, there is a higher risk to people who are seriously ill, have a neurological condition, or impaired mobility, nutrition or posture (NICE CG179 2014).

1.1.2 Pressure ulcers in the community

The challenges faced by patients, carers and nurses in the community are different and complex. Patients may have a wide variety of co-morbidities, they may be very independent or be reliant on paid carers or unpaid family members. Research has mostly focused on PUs in hospital settings with substantially less concerning primary and community care settings (NICE CG179 2014).

1.1.3 Pressure ulcer prevention

Regularly changing position can help reduce the risk of PUs and relieve the pressure on ulcers that have already developed. People in a hospital or care home are given a risk assessment, have their skin monitored, and preventative measures used, such as regular repositioning. Patients at risk of developing a PU may be given specialised PU prevention equipment such as cushions or mattresses. Patients report that they find pressure relieving equipment 'uncomfortable', 'too hot', and 'noisy' (Gorecki et al 2012).

People living in their own homes will have their own furniture, which may be unsuitable for pressure ulcer prevention. However, in many cases they may be reluctant to change furniture for a more medicalised solution. There may not be the infra-structure or ability to assist patients with frequent re-positioning. In addition, healthcare staff, in particular specialist tissue viability nurses, have only a limited amount of contact with patients, and it is difficult to gain insight into what happens between visits.

The importance of the complex relationship between staff, patients, and all other elements of the healthcare system in managing pressure ulcers is highlighted by McGraw et al. (2018) describing nurses' perceptions of the causes of community-acquired pressure ulcers, and Lavallee et al. (2018) consider the barriers and facilitators to pressure ulcer prevention in nursing homes.

1.1.4 Patient adherence to pressure ulcer prevention strategies

In a recently published literature review Ledger et al (2020) identified 12 papers that considered patient adherence, concordance or compliance together with patient experiences and view. They found that there were 3 key themes that affect adherence to pressure ulcer prevention strategies: individual or daily lifestyle considerations; patient involvement in decisions; and pain or discomfort.

2 PROMISE

2.1 What is the PROMISE project?

PROMISE (Pressure reduction through continuous pressure monitoring in the community) is a scaling up project, funded for 36 months by the Health Foundation. It has taken a successful pressure ulcer intervention and delivered it at scale to 4 additional sites. PROMISE is being implemented as a quality improvement (QI) project.

2.1.1 Aims and objectives of PROMISE project

The aim of the PROMISE project is to determine if CPM in patients' homes can inform effective management of the prevention and treatment of pressure ulcers, especially in those who are labelled as non-concordant or have a deteriorating pressure ulcer. PROMISE aims to promote patient choice through knowledge and information sharing with patients and carers.

The objectives of the PROMISE project are described in the box below.

Project objectives

- To implement CPM across multiple community clinical sites
- To create a supportive network for sharing learning during the implementation of the technology
- Evaluate the clinical impact of the CPM intervention on patients, carers and health professionals
- Identify differences in the translation of the CPM intervention across the adopter sites
- Evaluate the economic and societal impact of the CPM technology.

2.2 Preceding Health Foundation Innovation for Improvement project

The use of continuous pressure monitoring by tissue viability teams has already been introduced in Cornwall, and evaluated in a previous project, funded by the Health Foundation Innovation for Improvement programme, with 44 patients from February to December 2016. The study found that following the intervention patients were willing to change the equipment that they use, and that tissue viability nurses had an increased understanding of why advice was not being followed. (Aylward-Wotton 2016). As a result of this study, CPM has been adopted into routine practice in Cornwall by the tissue viability team. No other published evidence has been identified showing the impact of CPM in community

care.

> I think for patients that have got non-healing pressure ulcers and we have put what we think is the most appropriate equipment in, it would be good for us to understand what type of equipment would be better for them, and that is what the pressure map would do [S9]

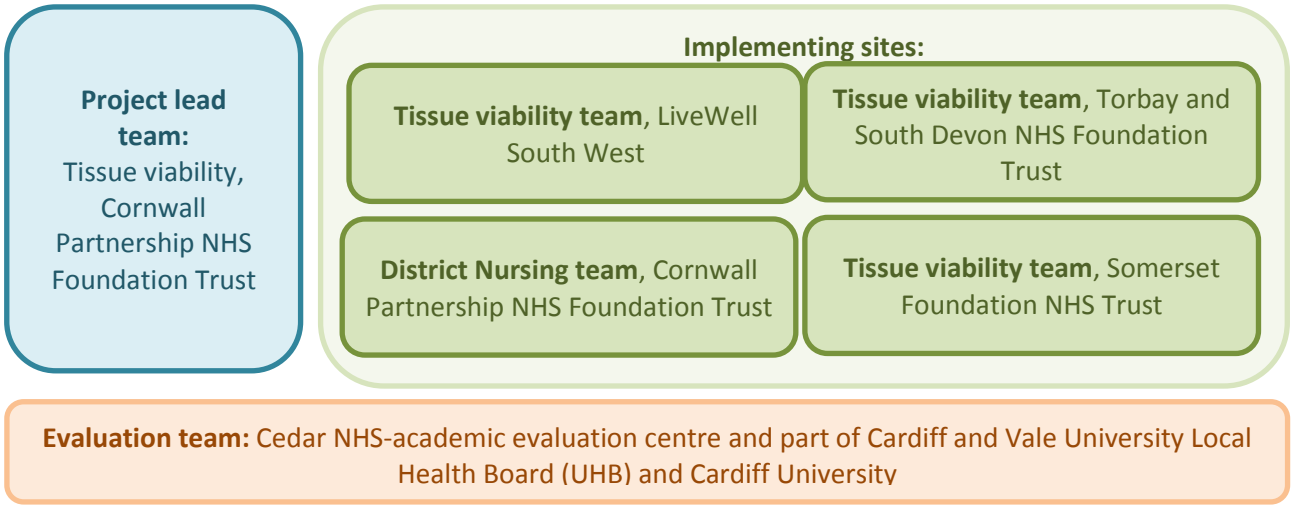
> It's the long term patients who have chronic, category 4 pressure damage who will benefit from the project. I think they feel that everybody has given up on healing / improving the issues [S5]

Quotations from implementing teams prior to starting recruitment

2.3 The project team

2.3.1 Implementation team

PROMISE is led by Cornwall Partnership NHS Foundation Trust, with 4 sites participating from 3 other health care providers (LiveWell SouthWest, Torbay and South Devon NHS Foundation Trust and Somerset Foundation NHS Trust).



2.3.2 Evaluation team

Cedar, an NHS-academic evaluation centre (Cardiff and Vale University Local Health Board (UHB) and Cardiff University) provided independent evaluation.

2.4 Pressure mapping for pressure ulcer prevention

2.4.1 What is pressure mapping?

Pressure mapping systems determine the actual pressure between a body surface and the bed the patient is lying on, or the wheelchair they are sitting in, or between the patient's foot and the floor. A mat is placed between the patient and a surface such as a mattress or chair; the mat has an array of in-built sensors which measure the level of pressure at the interface and convey the information to a computer. A colour coded image of the pressure distribution is displayed on a computer screen, with different colours showing different levels of pressure (Figure 1).

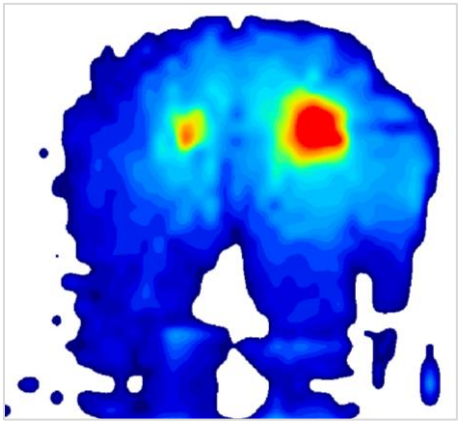


Figure 1 Pressure map output, for seat, with red showing higher pressures, and blue showing lower pressures (image provided by PROMISE project team,

2.4.2 Why use pressure mapping?

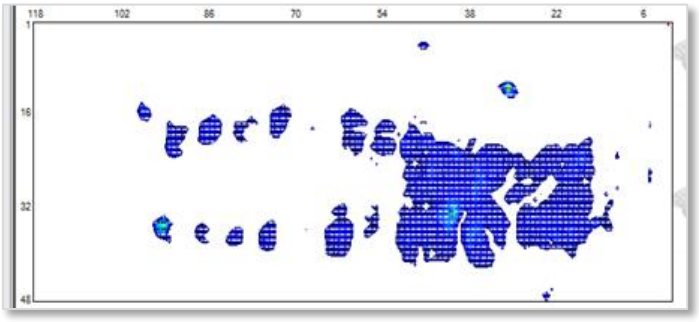
By observing the coloured distribution map on the screen and noting high areas of pressure, a trained care provider can make changes to the patient's seat or bed surface or the patient's position to reduce the risk of the patient developing a pressure ulcer (Hanson et al. 2009).

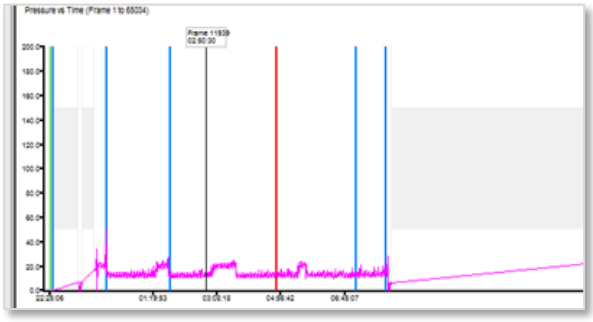
Interface pressure mapping has been in use for many years, typically in specialist clinics e.g. a seating clinic for patients with spinal cord injuries. It is used in wheelchair modifications and assessment, as well as for patient education. There is some evidence that pressure mapping can improve clinical decision making (Crawford 2005).

The normal mode of use is to map for a maximum of 20 minutes, giving a snapshot of pressure distribution in a certain sitting or lying position. This single snapshot is often performed in a clinic or wheelchair assessment centre, rather than the patients' home. This may not reflect a patients' normal sitting positions over a period of time, or show their normal activities. In addition it does not take into account the different surfaces used for support within the home.

2.4.3 Continuous pressure mapping

Continuous pressure monitoring (CPM) is when the pressure mat is left in place for longer periods of time. In this case it is likely that patients become accustomed to its presence, and their posture and movement becomes more normal. Therefore it gives a more accurate picture of the pressure profile over prolonged periods (Figure 2). This has obvious benefits over the typical short 10-20 minute mapping session. In addition, it gives health care professionals more insight into what issues may be causing





pressure damage over a normal day for that person. Advice and equipment can then be tailored to find a solution appropriate to that particular patient.

Figure 2 Pressure monitor output for bed map, showing pressure distribution over the mattress by colour contours, and changes in pressures over time [images by XSensor, provided by project team]

CPM is used in PROMISE to allow greater insight into patient use of equipment and helps health care professionals, patients and carers to balance their needs for pressure ulcer care and daily living, and inform the provision of appropriate and effective equipment.

There is little existing evidence for the use of CPM to give feedback to patients. A review of the use of assistive technology for self-managed pressure-ulcer prevention in patients with spinal cord injury (Tung et al. 2015) included 5 studies that used interface pressure mapping to give feedback to users. The feedback was audio or tactile, rather than visual, and was intended to remind users to adjust their position. The devices were intended for long term use, as a permanent reminder system, rather than an educational tool. Three of the studies found an improvement in pressure relieving behaviours following the intervention.

There is evidence of CPM being used in a hospital setting, where monitoring is in place for the duration of the patient stay and used to indicate the need for turning or to identify issues in real time (Walia 2016, Behrendt 2014, Siddiqui 2013, Gunningberg 2017). The setting for most patients is in intensive care units and staff are expected to use the monitor to optimise patient positioning and turning. Berendt et al (2014) and Siddiqui et al (2013) both report a significant reduction in the occurrence of pressure ulcers in the group using CPM. Gunningberg et al. (2017) reported a randomised controlled trial, which found no significant difference in occurrence or prevalence of PU between CPM and standard care.

There is evidence showing that specialist intervention with the time and tools to provide an individualised care plan can improve outcomes. We explored this in a previous project in collaboration with Cedar and NHS providers in South West England, including Cornwall. The specialised pressure ulcer services provided in Salisbury, Swansea and Oxford combine rehabilitation engineering and tissue viability experience to improve outcomes (Dale, 2014).

International guidelines (NPUAP/EPUAP/PPPIA 2019) recommend the use of pressure mapping as part of an individualised assessment to selecting seating for patients with spinal cord injuries, and in recommending daily routines for these patients.

2.5 The PROMISE Intervention

The CPM aspect of the intervention has been described using the TIDier checklist (Hoffmann 2014) for reference. The wider scope of the PROMISE intervention is described in the theory of change diagram

Key intervention components

- **Pressure mapping** equipment and training
- Mapping over **extended time** period
- **Sharing information** from mapping with patients and carers
- **Holistic** approach to finding an appropriate solution
- Extended **follow-up** to monitor progress
- Processes to provide **required equipment**

(Figure 3), and in the logic model table in Appendix A.

Adherence to the intervention, and changes over time to the intervention are reported in the results and discussion sections.

2.5.1 CPM Equipment

The Foresite PT Monitor was used for mapping beds (6000 sensors) and the Foresite SS Monitor for mapping seats and cushions (1296 sensors). Data analysis used the Foresite SS software. The systems incorporate a high resolution of pressure sensors to map the distribution of pressure between the individual and their support surface.

2.5.2 Use of CPM in patients' homes

A tissue viability nurse (TVN) or district nurse (DN) took the CPM equipment out to patients' homes. It was set up on their seat and /or bed and left with patients (subject to a risk assessment) for between 24 – 72 hours. The map was then collected, the nurse analysed the data and returned to the patient's home to discuss the findings. This may result in a change in the advice given to patients and carers, or a change in the pressure redistribution equipment recommended for the patient. Following a change in equipment patients was re-mapped using the new equipment to assess its suitability. Nurses then followed up the patients' progress either by visits or review of notes from routine visits by other staff until the patient was healed, or seen to have the best care solution that was possible for them.

2.5.3 Staff training

Nurses delivering the pressure mapping needed training and practice in order to be able to safely place maps securely on beds and seats, ensuring the data is correctly recorded. Some training was also needed to re-pack the pressure maps in a way that does not damage them. Additional training was needed for the nurses who analysed the data (this may not always be the same people). An initial training session in both skills was followed up by a reference guide and a mentored first use of the pressure map. Subsequent advice and additional visits were available to staff.

During this study, training on placing and repacking the map was via a demonstration, practice sessions and a laminated quick reference guide. Training for analysing the data was by presentations and practice

sessions. Those that attended the training session in both skills were further supported by a reference guide and a mentored first use of the pressure map. Subsequently advice and additional visits were available to staff. In addition peer-support was put in place using a WhatsApp group and monthly phone calls or meetings for all participating sites. Ad hoc advice from the project lead was also available via email and phone. Project meetings were held every two months, as a study day, these included peer support and learning time for site representatives.

2.5.4 Adaptations

The intervention was adapted from patient to patient depending on the complexity of patient needs and the local organisational restrictions or requirements. Variations include the number of repeat pressure mapping visits, the equipment choices tried and the extent of joint visits (where visits are with a health care professional from another discipline). Variations between sites included the experience of the person delivering the intervention, the methods of protecting time and of sharing the intervention within the team.

2.5.5 Additional resources to support CPM

In addition to the pressure monitors and associated software, sites required IT input to install the software onto appropriate PCs and to enable storage of the large amounts of data. Additional equipment purchased for the project included portable hard drives, bags storing the pressure monitor display when used on wheelchairs and stands for safely displaying the monitor in patients' homes. Resources developed during the project included a detailed quality manual with information on the key tasks, videos available on YouTube and quick reference cards for inclusion in the monitor bag. Development of these resources is part of an ongoing process led by feedback from the participating sites. All documentation was issued to sites at the start of the project, updated as changes developed and was accessible via the project team.

2.6 PROMISE Theory of change

The PROMISE theory of change (Figure 3) was developed together with the project team and implementation sites. It describes the essential elements of PROMISE and the theory of how they work together to achieve the desired outcomes.

An additional logic model including more detail, in a table format, is included in Appendix A, and is designed to sit alongside the theory of change diagram.

The logic model was developed iteratively in collaboration with the project team and health care professionals from all the included sites. Feedback on the model led to the development of a theory of change diagram to sit alongside it. The theory of change has shaped the focus of the evaluation, and helped the team understand the complex components of the intervention. It has also provided a context to understand some of the barriers and facilitators that have been experienced by the implementation teams.

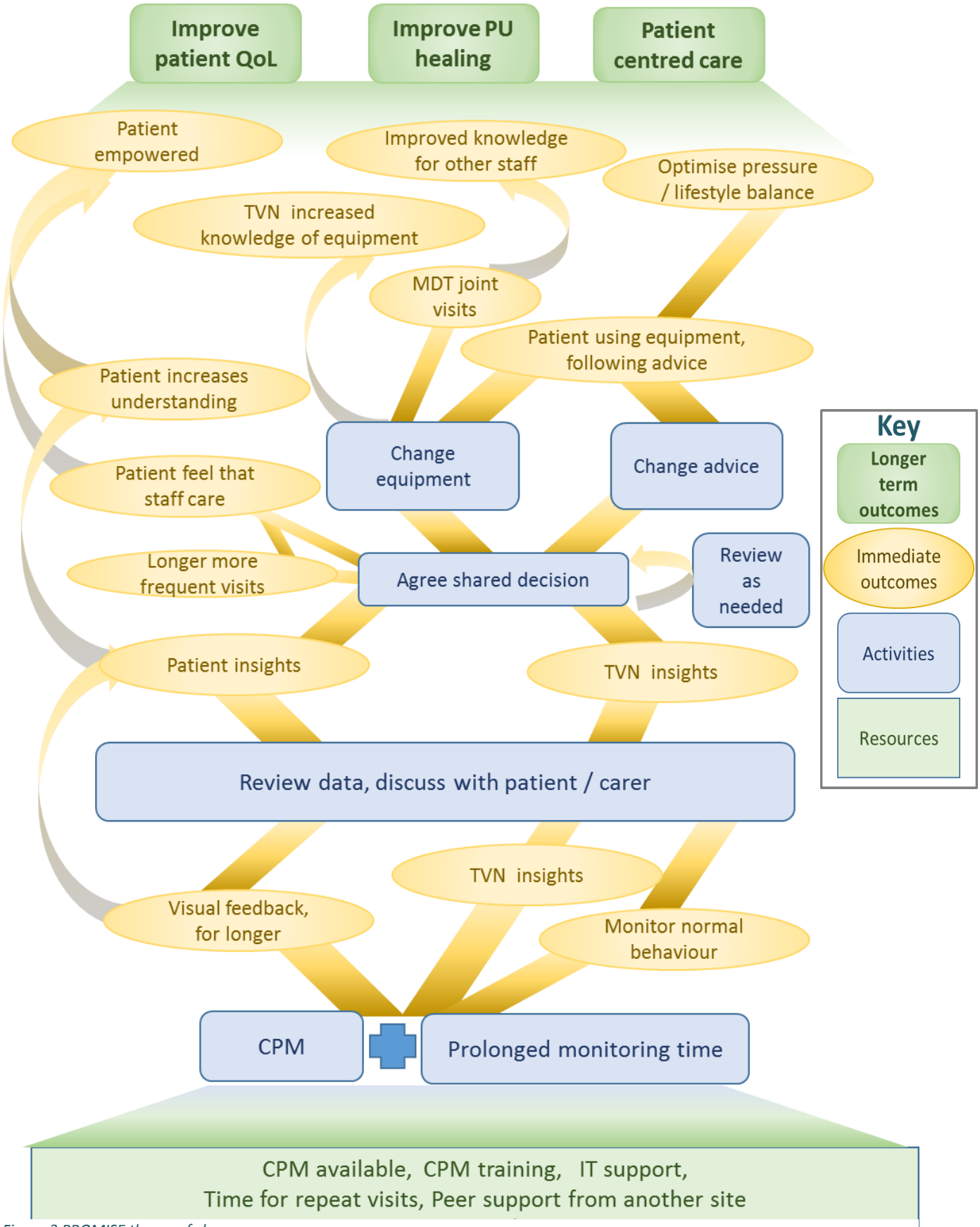


Figure 3 PROMISE theory of change

2.7 Evaluating PROMISE

This final evaluation report describes the progress made during the first 2 ½ years of the project. The implementation team are extending their work with two of the sites until December 2020 at which point they will produce an additional implementation report and a health economic report.

2.7.1 What is evaluation?

Evaluation is the systematic assessment of the implementation and impact of a project, programme or initiative. It is an essential part of quality improvement because it tells us not only whether an intervention worked, but also why and how (Health Foundation 2015). Evaluation is different from pure scientific research by its practical nature. Evaluation is intended to be of use to those needing information in order to decide action, therefore it also involves judging value plus an element of comparison (NHS Institute for Innovation and Improvement 2005).

We are following a systems approach to the evaluation, including process evaluation as a crucial part of understanding what the key elements of the intervention are and how they were implemented in different settings. The latest guidance from the Medical Research Council (MRC) states the value of including both process evaluation to understand how context influences outcomes as well as an economic evaluation to aid decision makers in future spread (Craig et al. 2019).

The scaling up process inevitably involves adaptation of the innovation to overcome local barriers and best meet the needs of local systems and populations. Successful local projects do not always achieve widespread uptake even with these adaptations (Greenhalgh et al 2019). Evaluation can capture some of these processes and help to identify the key components and mechanisms that allow the innovation to work in new environments.

2.7.2 Evaluation aims and objectives

To evaluate the implementation of PROMISE across four sites, looking at the impact on patient centred care, adaptations that were made to the intervention, and barriers and facilitators.

The evaluation objectives stated in the original protocol are highlighted below, and have largely remained appropriate. The revised project objectives explicitly include the impact on carers and health care professionals, and this is incorporated into the evaluation in the form of questionnaires and interviews.

The evaluation questions are described in the box below.

Primary evaluation questions

- Has PROMISE **improved patient-centered care** for pressure management at each adopter site, including patient education and staff understanding of patient needs?
- How have **different sites adapted PROMISE**, and has this changed the way that it works?
- What are the **barriers and facilitators** encountered by the adopter sites, and what resources would help future implementation of PROMISE?
- **Has PROMISE become embedded** into normal practice at each adopter site?

In addition secondary evaluation activities were:

- Provide formative information to sites to enable them to adapt and improve their implementation of PROMISE during the study
- Identify any usability issues encountered with the pressure monitoring technology
- Monitor changes in wound size over time
- Describe the resource implications of introducing continuous pressure monitoring in the community

3 Evaluation methods

The evaluation was a pragmatic mixed-methods approach, including process evaluation, which ran alongside the intervention as it was introduced for a two year period. Regular reporting (formative evaluation) was used to guide the implementation, using monthly data extracts, and presentations to project meetings and to the project team. Key evaluation terminology is explained in a glossary at the start of the report.

3.1 Protocol

An extract from the evaluation protocol that was set out at the start of recruitment (November 2018) is included in Appendix J. The evaluation includes qualitative and quantitative elements for both patients and staff, and was designed to evolve and adapt as increased understanding emerged from the implementation process.

3.2 Study approvals

This project was set up as a quality improvement study and therefore research ethics approval was not required. Each adopter site gave agreement to participate in the project and signed a Memorandum of Understanding with Cornwall Partnership NHS Foundation Trust as the Project Lead organisation for the Health Foundation. The Memoranda confirmed participation and set out the terms for project participation. Permissions were also requested and obtained from adopter sites for continued participation in the project when an extension was granted by the Health Foundation for the project to continue until the end of December 2020. Formal consent was obtained from all patients who took part in the project.

3.3 Data collection

3.3.1 Sampling

The initial aim was to recruit 160 patients, 40 from each site, based on the number that was seen by the tissue viability team in Cornwall, over a 2 year period. Patient selection criteria were: aged 18 and over; at high risk of PU development, recurring pressure ulcers, deteriorating pressure ulcers, or reluctant, unable or refusing to use pressure relieving equipment; being treated in the community. As a real world quality improvement study, patients were selected based on clinical judgement of the participating teams, as in normal practice. All patients provided informed consent, or this was provided by a consultee. Clinical data were collected on all participants and questionnaires were offered to all participants.

Patient interviews were based on purposive sampling, with a minimum of 12 patients, ideally continuing to interview until saturation of data was achieved. Patients were interviewed from all participating sites. Recruitment for interviews was monitored to ensure inclusion of patients who had not completed questionnaires, patients who were non-concordant, younger patients, patients who were largely self-caring as well as patients dependant on carers. We also included feedback from relatives who care for patients. Characteristics of the patients interviewed are presented in the results section.

3.3.2 Overview of data collection methods for each evaluation question

The key data collection methods are summarised in the box below.

Key data collection methods planned

- **Clinical data** for each patient, at each PROMISE visit, collected by nurses
- **Service measures**, collected weekly by treating teams and entered into run charts to allow teams to monitor basic measures directly
- **Patient and carer questionnaires** for each patient, self-completed at baseline and after a solution has been identified and implemented (equipment and / or advice), returned directly to Cedar.
- **Patients, carer and staff interviews** conducted by Cedar over the course of the project.
- **Discussions and short questionnaires to staff** tailored to reflect emerging issues in the project, and utilizing existing meetings.

A summary of how data were collected to address each of the evaluation questions is presented in Table 1.

Table 1: Data collected to address PROMISE evaluation questions (evaluation framework)

Evaluation question	What is being measured?	What data is being collected?	When is the data being collected?
Evaluation question 1A. Has PROMISE improved patient-centred care for pressure management at each adopter site ***(patient perspective)***	• Achieve goals • Change in patient quality of life • Satisfaction with service • Adherence to therapy • Interest/reaction to CPM • Reported concordance	• Before and after, using baseline questionnaires • Patient recollection during interview • Staff reporting of patient education and change in attitude • Data collection form (DCF) reporting of patient aims and concordance	• Questionnaires at baseline and 4 weeks after form D (start of healing) • Interviews of selected patients, each interviewed once, interviews in March 2019, Sept 2019 and March 2020. • DCF at start and end of treatment
Evaluation question 1B. Has PROMISE improved patient-centred care for pressure management at each adopter site ***(staff perspective)***	• Relationship with patient • Knowledge of CPM • Knowledge of equipment (mattress/cushions) • Joint visits	• Pulsecheck surveys • Staff interviews • Evaluator reflections on meetings and informal discussions	• Surveys monthly • Interviews over project duration with patients and relatives.
Evaluation question 2. How have different sites adapted PROMISE, and has this changed the way that it works?	• Process measures (how often visiting, length of visits, duration of mapping, time to find solution, time for equipment to deliver) • Staff reflections • Discussions in IEAG etc.	• Data collection forms • Support needed for implementation • Staff interviews • Evaluator reflections on meetings and informal discussions	• At each visit for DCF • Time by project lead, throughout project • Interviews over project duration with different members of team
Evaluation question 3. What are the barriers and facilitators encountered by the adopter sites, and what resources would help future implementation of PROMISE?	• Process measures (how often visiting, length of visits, duration of mapping, time to find solution, time for equipment to deliver) • Staff reflections • Whatsapp surveys • Discussions in IEAG etc. • Equipment suppliers and HCP teams	• Staff interviews • DCF • Evaluator reflections on meetings and informal discussions • Equipment / HCP survey • Information from project team work	• DCF at each visit • Equipment survey • Interviews by evaluation team throughout project • Project team implementation work
Evaluation question 4. **H**as PROMISE become embedded into normal practice at each adopter site?	• How routine has it become? • Has it spread to others in team? • Are sustainability plans developed?	• Normalization process theory questionnaire (NoMAD) • Pulsecheck surveys • Staff interviews • Evaluator reflections on meetings and informal discussions	• NoMAD at start and end project • Surveys monthly • Interviews over project duration – approx. 4 per site

The following provides a description of how data were used to answer the main evaluation question.

To identify if PROMISE can improve patient centred care for pressure management at each site, including patient education and staff understanding of patient needs

- **Patient questionnaires** were designed to help the evaluation team understand the ability and willingness of patients to use the equipment provided and follow advice given. They also explore if patients feel included in decisions about their care and fully informed (patient experience).
- **Quality of life questionnaires** captured the impact that any change in care had on patients and carers quality of life, and included measures specific to pressure ulcers. This can potentially capture not only changes due to wound improvement, but also changes to daily life that have been enabled by improved advice or equipment despite the pressure ulcer not having healed.
- **Patient interviews** covered similar topics, but with richer information and the possibility of highlighting any unintended consequences, either positive or negative.
- **Staff discussions and interviews** allowed the evaluation team to capture changes in staff attitudes, knowledge and experiences towards patient centred care, and any increased knowledge of how other services such as occupational therapy or wheelchair services contribute to this.
- **Clinical data** informed the evaluation team of changes in the reported use of equipment, adherence to advice, changes to the wound size, or the point of wound healing. For all patients we have baseline measures and can therefore see any before and after change for individual patients. Where patients have had wounds for several years, there is a possibility to show a clear improvement of the service for that patient.

3.3.3 Patient and Carer questionnaires

The patient and carer questionnaires consisted of 4 items:

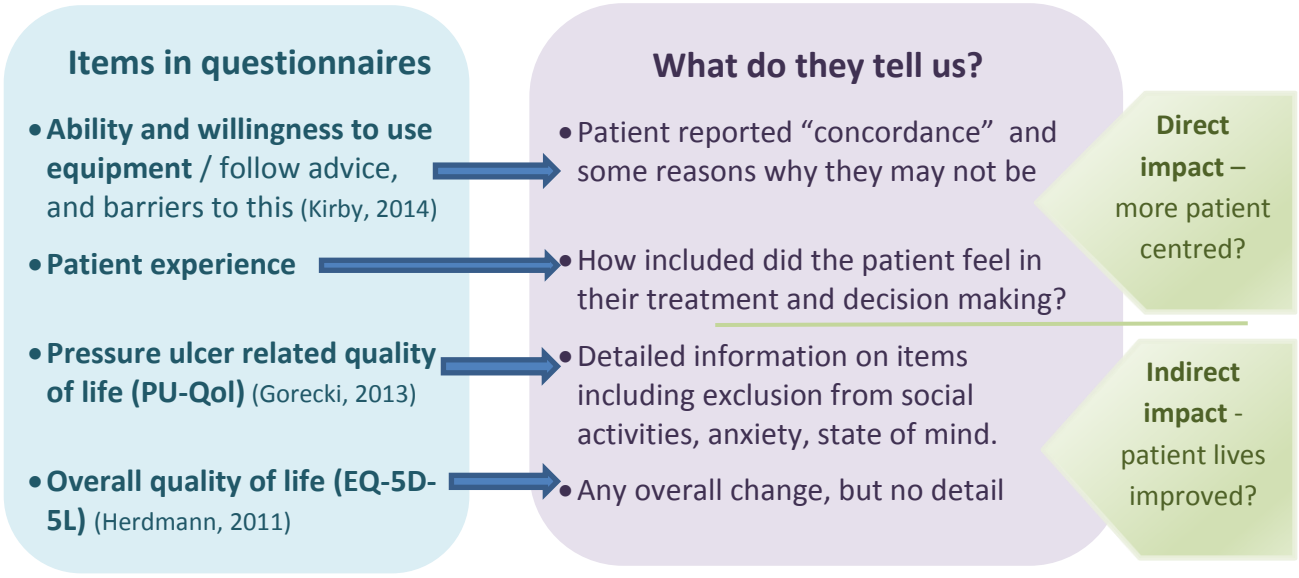


Figure 4 Items and rationale for the questionnaires that were completed by patients and relatives

Questionnaires were originally delivered at baseline, and week 4 and 16 after the first pressure mapping. Due to the time required to implement appropriate solutions for patients, the week 4 questionnaires were removed, and the final questionnaires were moved to a time-point based on the patient's progress (4 weeks after the first follow-up visit).

Implementation teams offered the first questionnaire directly to patients, unless they felt it was inappropriate (for example lack of capacity), or the patient declined them. Reminders and subsequent questionnaires were posted directly to respondents by Cedar. All questionnaires were returned by pre-paid envelope. Options to complete the questionnaire online or by telephone were also offered.

If a relative or unpaid carer was present they were offered a questionnaire. Questionnaires given to relatives contained consent forms, and follow-ups were only sent to relatives who had returned written consent. Questionnaires for relatives contained the first two items only from Figure 4.

3.3.4 Interviews with patients

Semi-structured qualitative interviews took place throughout the duration of the project to include the experience of patients and relatives. After the first round of interviews, patients were approached who had started the follow-up phase of PROMISE (form D) or later, whenever possible. This was limited by the number of patients who had opted to consent to interview, patient availability and the time for progression through PROMISE.

3.3.5 Interviews with staff

Semi-structured qualitative interviews were conducted with implementation site team members at different levels of seniority and involvement throughout the duration of the project.

3.3.6 "Pulse-check" surveys

Short survey questions were sent out to staff at implementation sites by email and WhatsApp on a regular basis (approximately monthly) and used to gather snapshots of information. These normally contained 1 or 2 multiple choice questions, and the results were fed back directly to staff the following month. Topics were chosen by both evaluators and the project team. The topics included staff confidence in using pressure mapping, sustainability, project resources and changes in clinical practice. The pulse check surveys were primarily used for formative information to guide both the project and evaluation teams, and as a triangulation element for results from other sources.

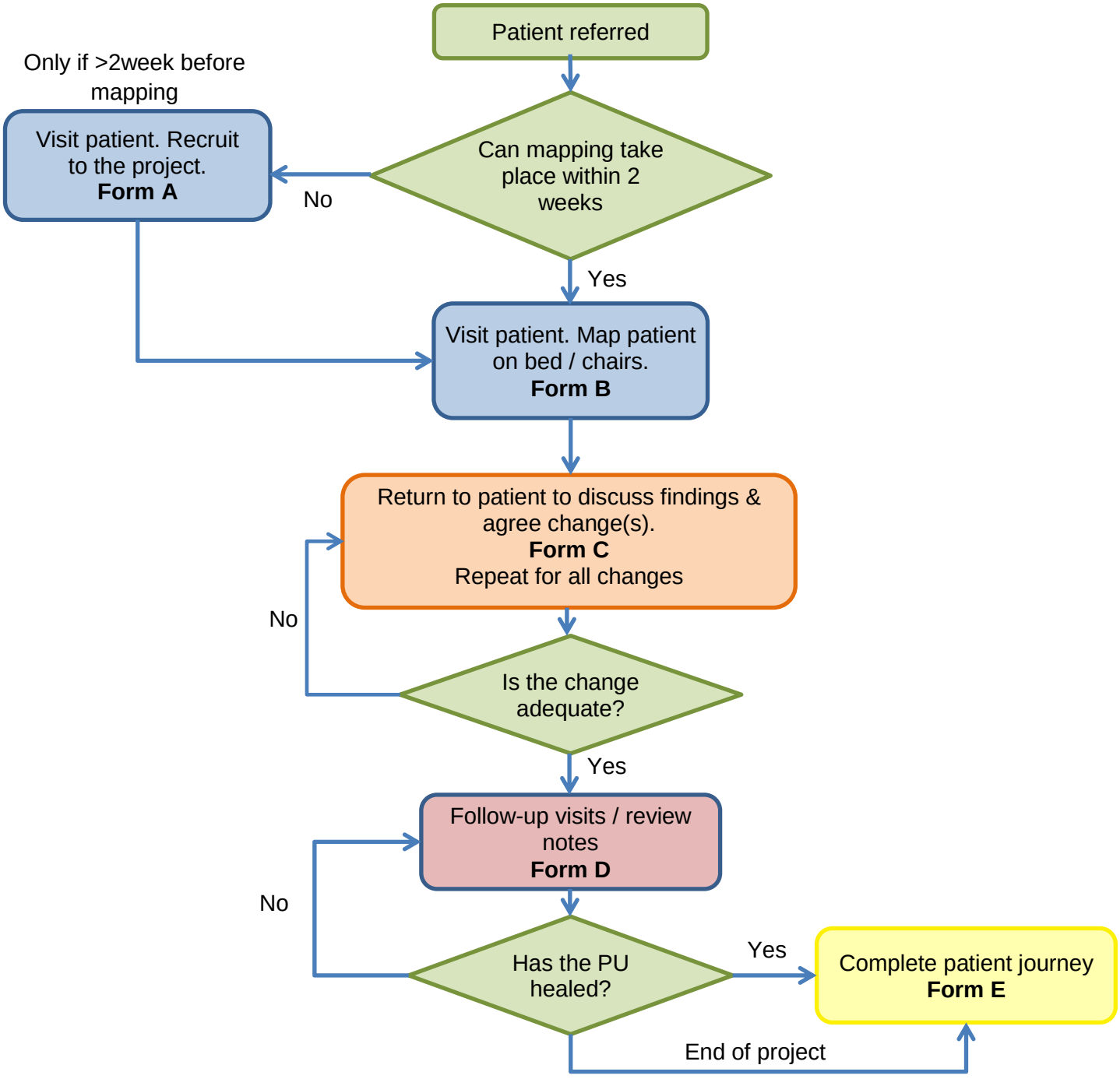
3.3.7 Data collection forms

Data collection forms (DCF) were based on the previous CPM project in Cornwall. They were completed either on paper or an excel spreadsheet and sent by secure email to Cedar. The type of form used (table 2) varied according to the patient's progress through PROMISE as illustrated in *Figure 5*, and this has been used as a surrogate outcome for some analysis and reporting.

Table 2 Data collection forms used during PROMISE

Form	Description of rationale for data and time point
A	Demographic and pressure ulcer data prior to mapping, if >2 week wait
B	Investigative pressure mapping visit
C	Changes in advice or equipment, including pressure mapping
D	Follow up once solutions are agreed and in place. Maybe a visit, phone call or review of notes
E	End of active involvement in PROMISE (pressure ulcer healed, withdrawn, deceased)
F	Final end of study data collection, for any patient.

Figure 5 Study flow chart and data collection forms (produced by project team as part of the PROMISE manual)



3.4 Changes and current methods

As a quality improvement project there was continuous evolution of both the implementation and evaluation methods.

Key project changes

- **Change from research to QI** – this was a very positive change allowing efforts to be focused more productively, and led to increased flexibility.
- **One site withdrew from project** – as research nurse was key player.
- **An additional site joined the project**
- **Recruitment delayed from May 2018 to November 2018** – changes in methodology, key staff and equipment procurement.
- **Implementation at sites** – took more time than anticipated to resolve patient needs.
- **One site paused activity** – to allow recruitment of additional staff.
- **Support to staff evolved** – development of training resources and peer support meetings.
- **New implementation process** – key stakeholder involvement from start, process mapping and barrier identification.

The implementation process at individual adopter sites took longer than originally anticipated. All adopter sites had issues with establishing IT setups and required time and practice to familiarise with the new equipment and analysis of the data. In addition PROMISE resulted in nurses increasing their involvement in identifying suitable equipment and following-up patients. This was a significant change for the adopter sites. These issues, together with staff shortages led to the temporary cessation of recruitment at Site 3. In sites 1 & 2, recruitment continued, but it became apparent that the time required to identify and implement solutions meant that increasing numbers of patients were remaining in the PROMISE process. This was felt to be putting unrealistic pressure on staff and that trying to meet study recruitment figures would not reflect the reality of how PROMISE might be implemented in the future. In addition there was a risk that this expectation could jeopardise patient care if unchanged. Due to these factors the approach was adapted to allow sites to recruit at their own pace, concentrating on finding solutions for the already identified patients.

> …normally they would have been dealt with by the neuro physio guys, and spinal guys, the community nurses……so we wouldn't have had much so involvement. [S6]

> ..I don't think we realised quite how time consuming it was, not just the actual physical mapping and doing all that, it's everything that comes along with it and everything it brings up that we're struggling with.. [S13]

The PROMISE theory of change identified that introducing CPM leads to nurses increasing their knowledge of appropriate equipment for pressure relief, and contributes to successful outcomes of CPM. This knowledge is accumulated as experience increases in trialling equipment and, alongside improved joint working with other health care professionals, pressure monitoring and consultation with patients. Although we had identified this mechanism, we had not anticipated the time required for this to happen. Staff experience with obtaining pressure redistribution equipment has been varied, with some pieces of equipment easier to obtain that others. It has become apparent that the relationship between nurses in PROMISE, equipment prescribers and equipment providers is a key contextual component for success. Following these observations, the evaluation was amended to allow flexible timing and capture information about equipment availability.

3.4.1 Data analysis

3.4.1.1 Qualitative data

All interviews were transcribed verbatim, and checked for accuracy by the evaluation lead, followed by coding using Nvivo12. Analysis of the interviews used the logic model developed jointly by the evaluation and implementation teams as a framework, while allowing additional themes or sub-themes to emerge from the data. Interviews were reviewed by at least 2 members of the evaluation team, and the findings compared and discussed. The project team also carried out staff and patient interviews, for different patients, and looking at slightly different themes. These interviews by the project team will be reported in the implementation report in December 2020, but emerging findings have been discussed and compared with the evaluation team. This has allowed reflection on the viewpoints of 2 different interviewers as well as a 3rd reviewer. The interview findings were also triangulated with comments from qualitative information included in patient and staff surveys as well as data collection forms.

All qualitative information from free text sections of data forms and surveys were also included in the analysis, as well as evaluation team notes from project meetings.

3.4.1.2 Quantitative data

There are numerous sources of quantitative data including staff and patient surveys, data collection forms, information on project team resources and routine data from the Site 1. All data collection forms were entered into a Microsoft Access (2013) database. Analysis of all data was completed using either R 3.6.1 (R Core Team 2019) or STATA MP15 (Version 15, StataCorp, College Station, Texas) with the exception of some of the very simple data analysis such as project team time spent, or short surveys which was completed in Microsoft Excel (2013). The majority of the analysis consists of descriptive statistics, however Kaplan-Meier survival curves have been used for time to event analysis to include data for patients who have not yet reached the specified end point. Analysis is per patient, per wound or per visit, as reported in the results section.

4 Results

In this section the results are presented for each individual area of data collection. This is then followed by a discussion section which draws together results from different measures to address each of the evaluation questions. The results are presented as follows:

- Implementation site characteristics
- Patient recruitment and baseline demographics
- Patient reported experience of mapping
- Patient and staff interviews
- Staff questionnaires
- Wound healing measures
- Pressure redistribution equipment measures
- Reported concordance
- Process measures
- Administrative data for previous care

The results are summarised, with additional detail, tables and graphs available in the appendices. These are then drawn together in the discussion section to address the evaluation questions.

4.1 Implementation sites: context and variation

An ecological model (Figure 6) was developed by Cedar together with the project team and participants from the first three adopter sites. This shows the layers of people and organisations that influence the experience of a patient with a pressure ulcer, in the community. The involvement of other teams, particularly for obtaining suitable equipment is very important in implementing PROMISE. The diagram is also a reminder of the number of different health care professionals that may be interacting with the patient.

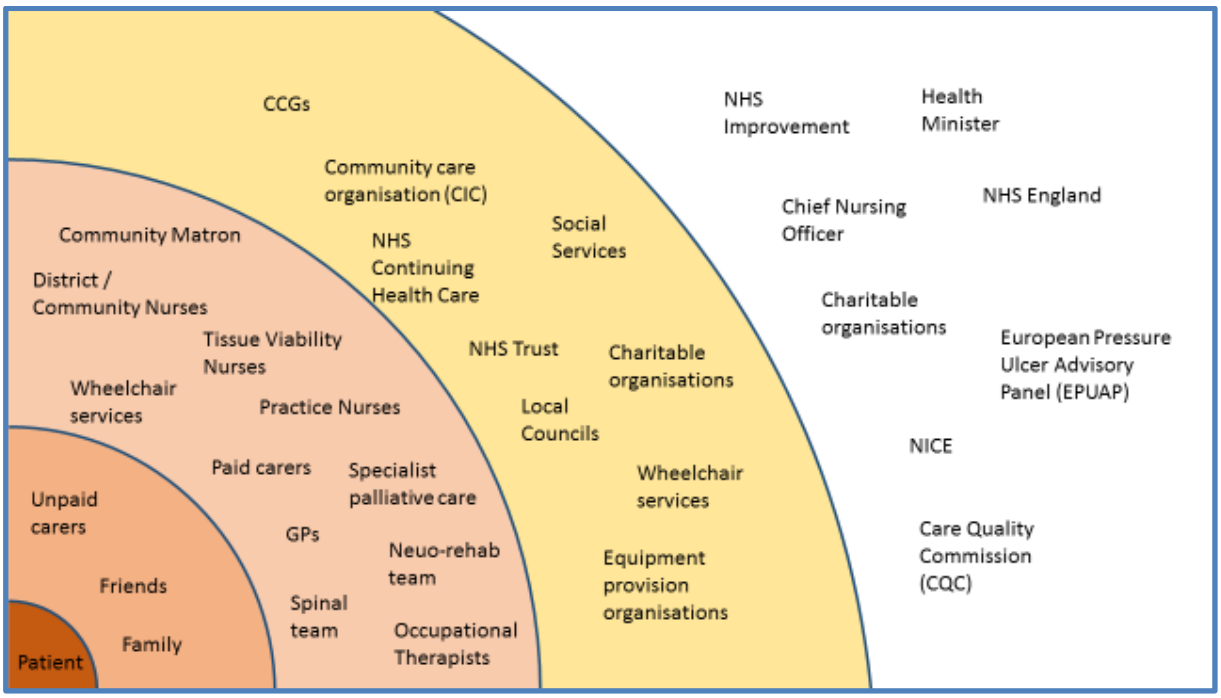


Figure 6 Ecological model showing people and organisations that influence the experience of a patient with a pressure ulcer, in the community

4.1.1 Tissue viability led sites

Three sites are run by tissue viability teams, covering relatively large geographic areas. The patients with pressure ulcers that are referred to them are likely to have grade 3 or 4 pressure ulcers, or additional clinical concerns around their care. Most patients do not continue to receive regular contact with the tissue viability teams once advice or treatment is given, however a minority may be seen every few weeks. The proportion who receive routine visits varies between sites.

Two of the TVN teams deal with community patients only, and will visit the majority of their patients face-to face at least once. One TV team see both community and acute patients, and the need to see acute patients urgently can cause difficulties in scheduling work and protecting time. The majority of their patients are electronic referrals that are dealt with by email and phone, however more severe cases (i.e. many PROMISE patients), have face to face visits.

4.1.2 District nurse led site

One site is led by a district nursing team, which leads to intrinsic differences in patient population, normal work patterns and skill sets. This team cover a much smaller area (around 15 mile radius), but is a larger team, maintaining a case load of around 1000 patients, many of whom will be seen several times a week. Patients are more likely to have grade 1 or 2 pressure ulcers, or have intact skin but high risk, or a history of recurrences.

4.1.3 Staff delivering PROMISE

All sites received staff funding equivalent to a band 6 nurse for 15 hours a week. It was open to sites to use this to recruit or redeploy staff as preferred. Three sites received this from the start of recruitment in November 2018, the fourth site also received staff funding from the start of their involvement in the project, which was in May 2019. Two sites used staff already in their team to deliver PROMISE, one site employed a new team member, and one site combined both strategies over the duration of PROMISE.

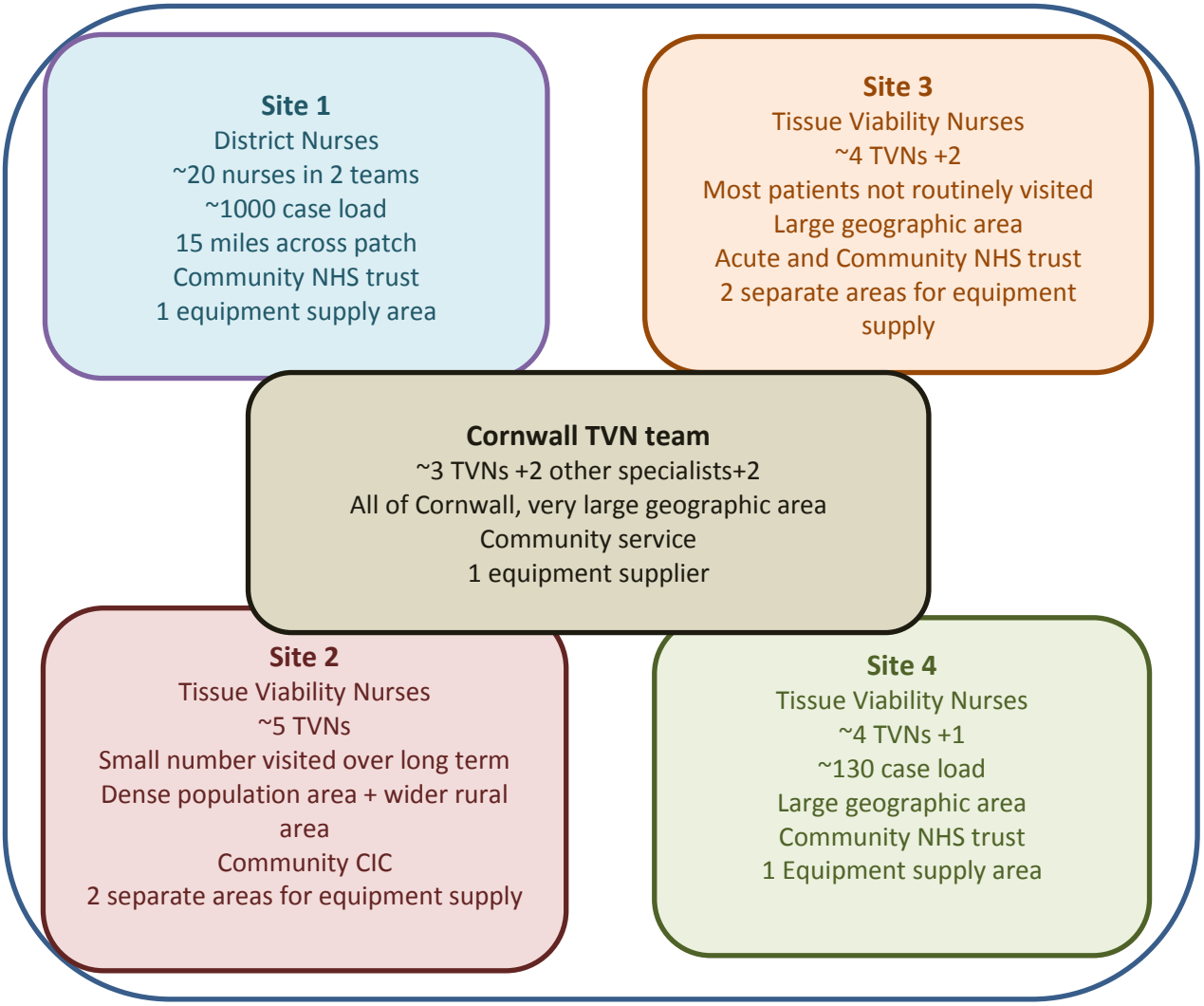


Figure 7 Summary of the 4 adopter sites, with the project lead site where PROMISE was originally implemented

4.1.4 Mapping equipment

Mapping equipment and accessories were purchased using project funds for Sites 1, 2 and 3. Site 4 purchased their own equipment in May 2019, resulting in their use of a newer model with Bluetooth capacity.

4.1.5 Pressure redistribution equipment availability

For all sites district nurses were the main route for some equipment supply, with community occupational therapists (OTs) and wheelchair services being the route for other equipment. At the start of PROMISE staff across all sites may have noted the need for different equipment, or that there were problems with seating or mattresses. They would have then either have ordered a different item from a limited range or referred the patient to a more specialist colleague.

During the project, staff delivering PROMISE became much more involved in equipment choices and follow up of equipment, increasing contact with OTs, equipment suppliers and wheelchair services. They were also more likely to look for alternative types of equipment, utilising loans from manufacturers.

4.2 Patient recruitment, and baseline demographics

During an 18 month period, from November 2017 to April 2020, 82 patients consented to take part in the PROMISE project, and 77 patients underwent CPM. Patients were recruited throughout the duration of the project, and had different lengths of exposure to the intervention.

Baseline characteristics of patients who consented to take part in the project, and who were mapped are included in Table 3. The full version of the table and the baseline characteristics, broken down by site are included in Appendix D. The number of responses (non-missing data points) is given as n for each variable, but percentages are calculated from the total population of 77 patients. For moisture and co-morbidities, patients may be in more than one group.

Table 3 Demographics for all mapped patients

	Responses (n)	
Age (Years) Mean ± SD	*77*	69.48 (15.34)
Frailty (Median (IQR))	*55*	6 (6,7)
MUST (Median (IQR))	*53*	0 (0,0)
BMI category		
Underweight		14 (18%)
Normal		30 (39%)
Overweight		28 (36%)
Not answered		5 (6%)
Moisture		
Urinary		25 (32%)
Faecal		25(32%)
Other		13 (17%)
None		24 (31%)
Not answered		9 (12%)
Wheelchair user n (%)	*67*	43 (56%)
Sleep upright n (%)	*76*	14 (18%)
Asymmetry n (%)	*63*	18 (23%)
Patient following advice n (%)	*76*	61 (79%)

	Responses (n)	
Female n (%)	*77*	37 (48%)
Own home n (%)	*77*	68 (88%)
Sensation		
Full		33(43%)
Limited		31 (40%)
None		12 (16%)
Not answered		1 (1%)
Co-morbidities		
None		10 (13%)
Stroke		12 (16%)
Cardiac failure		13 (17%)
Lung Cancer		2 (3%)
Spinal Injury		24 (31%)
MND / MS		11 (14%)
Dementia		5 (6%)
Diabetes		21 (27%)
Parkinson's		3 (4%)
PVD		11 (14%)
Renal		10 (13%)
Co-morbidities per patient Median (IQR)		1 (1,2)

Abbreviations: BMI Body Mass Index; IQR Interquartile range; MND Motor Neurone Disease; MS Multiple Sclerosis; MUST Malnutrition Universal Screening Tool ; PVD peripheral vascular disease

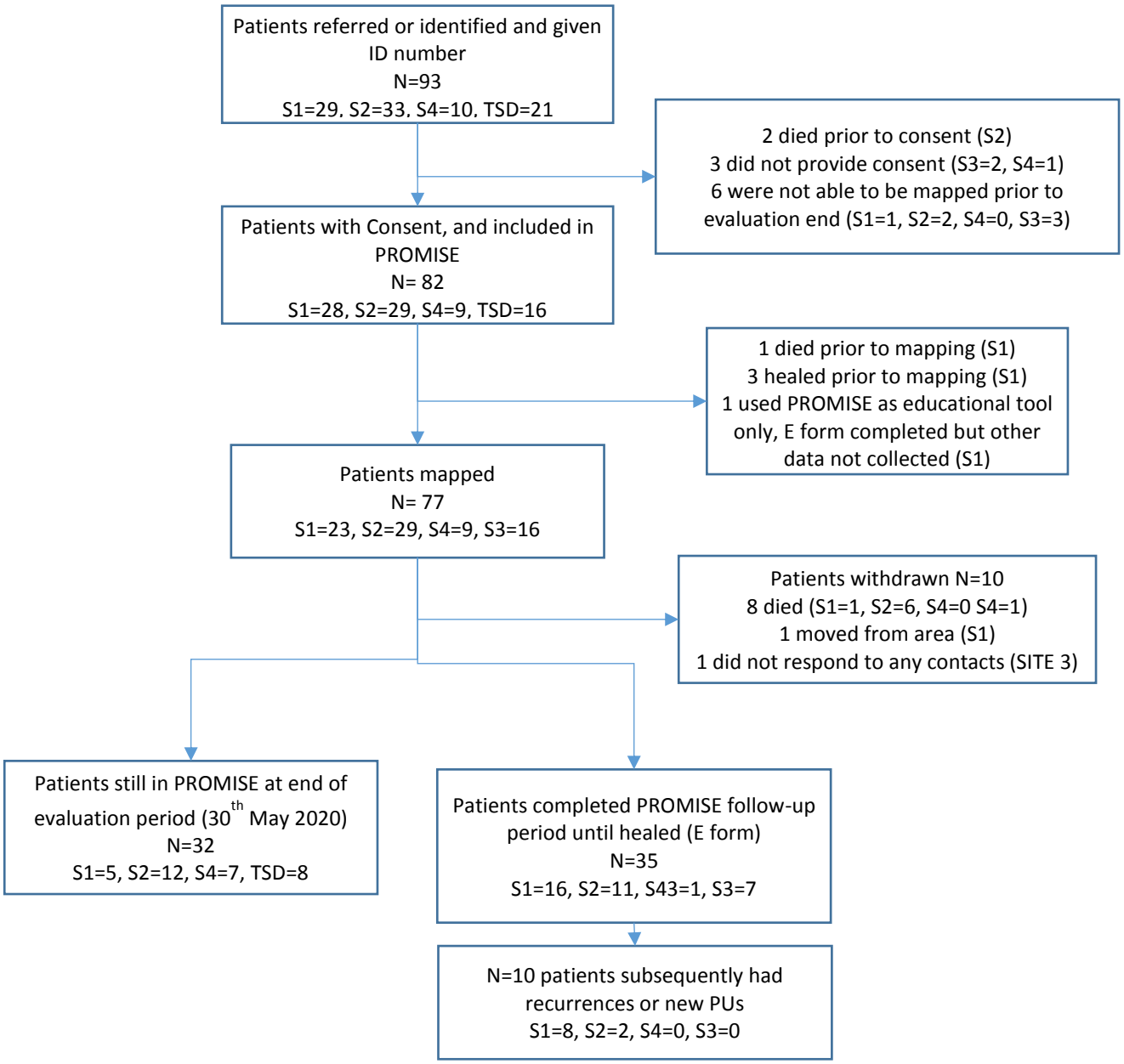


Figure 8 Study flow chart showing patients included in PROMISE project

4.3 Patient, relatives and health care professionals experience of CPM process

Equipment questionnaires were completed after the initial mapping by patients, relatives, or health care professionals, with Cedar receiving 60 responses, shown in Figure 9. From these, 82% (n=49) found the pressure map and monitor helpful, and 80% (n=48), reported that the pressure map was comfortable to use (agree and strongly agree responses). Small numbers of respondents reported issues with the equipment: 18% (n=11) found the monitor too bright; 7% (n=4) found that the cables got in the way and 10% (n=6) found it became too hot.

Of the 60 respondents, 42% (n=25) reported using the monitor to see when to change their position on the bed or chair, and 38% (n=23) used the monitor to choose the best position (agree and strongly agree responses).

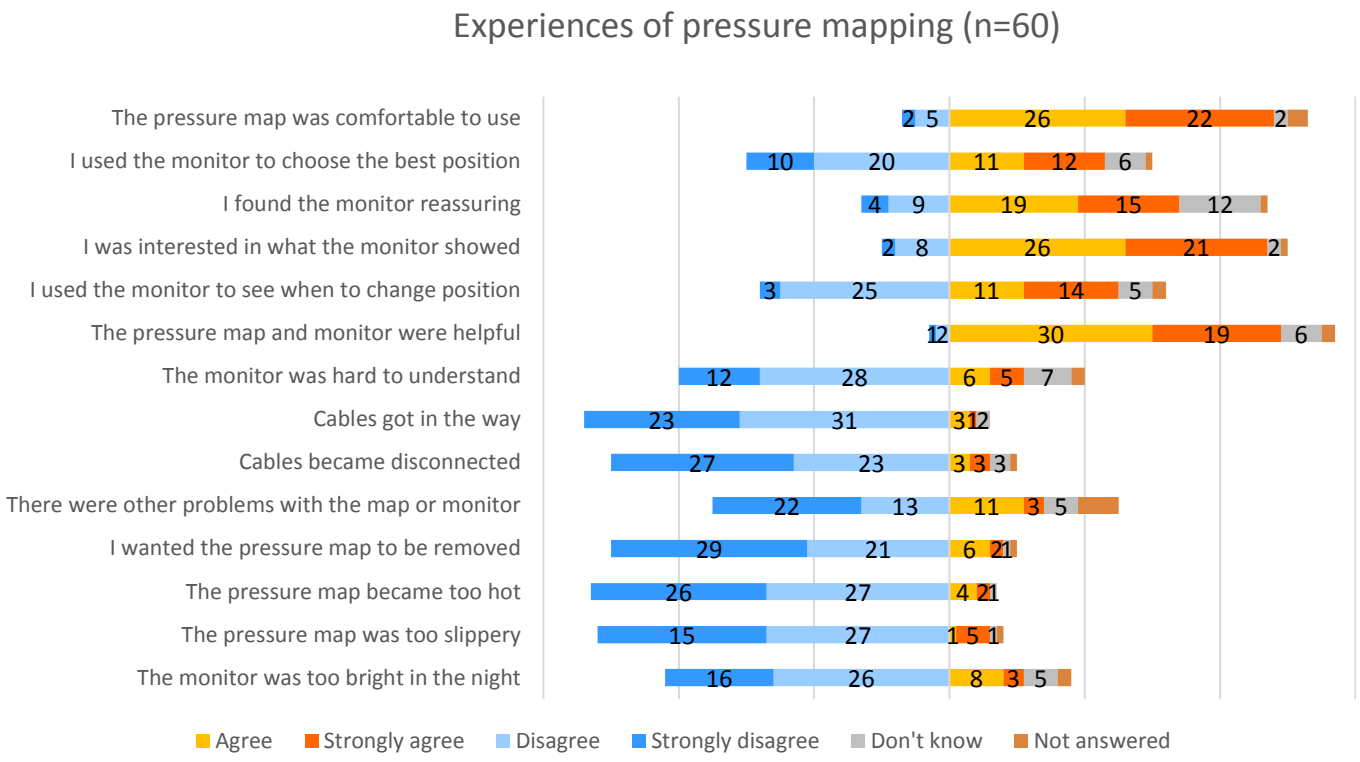


Figure 9 Patient, relative and health care professionals' experiences of pressure mapping

4.4 Patient experience and quality of life questionnaires

For the patient experience and quality of life questionnaires, at Week 0 there were 55 responses from 38 of the 77 patients participating and 17 relatives or carers. 15 of the responses from relatives or carers were related to care of patients who had also completed a questionnaire.

At follow-up there were 16 responses from 14 patients and 2 relatives or carers. Both the responses from relatives or carers were related to patients who had also completed a questionnaire.

There were 14 matched pairs of responses where both week 0 and follow-up were completed, from 12 patients, and 2 from relatives or carers. Both of the responses from relatives or carers were for patients who had also completed a questionnaire.

An additional quality of life questionnaire, containing only the EQ-5D-5L instrument, was circulated at the end of the project, and received 19 responses.

4.4.1 Reported barriers to adherence

The *Problematic experiences of therapy* (PETS) questionnaire could be completed by both carers and patients. Analysis follows the method described by Kirby et al. (2014) which takes all those who stated "strongly disagree" as having no barriers, and all other responses as having a barrier. From all 55 responses, at week 0, 55% (n= 30) stated that they had no problems carrying out treatment / advice due to symptoms, 56% (n=31) stated that they had no problems due to uncertainty or doubt about the treatment or advice, and 62% (n=34) stated they had experienced no practical problems. The full results are shown in the Appendix F.

Matching responses for Week 0 and follow-up gave 15 pairs, however 4 were blank and were excluded from the comparison. In each sub-domain between 2 to 4 respondents reported an improvement, and between 7 to 9 reported no change. No more than 1 respondent reported an increase in any of the barriers.

4.4.2 Patient and relative experience of care

At both time points, between 78% and 88% of respondents felt that they were listened to, received assistance, understood the care, had information explained and were as involved as they wanted to be. When all respondents from week 0 and follow-up are included in the analysis there appears to be some improvement in experience of care, with no patients reporting "never" or "sometimes" in any domain. However for when pairs are matched for both Week 0 and follow up, there are similar numbers where reported experience of care improved or deteriorated, and the majority were unchanged. Caution is needed as the numbers of matched responses is very small, and the baseline score is high, meaning that it would be hard to detect an improvement in experience.

Patients and relatives were also asked to score their experience of care from 0 to 10, with 10 being excellent. The median score of 9 (IQR 8,10) was unchanged between Week 0 and follow-up. Additional information and graphs are found in Appendix F.

4.4.2.1 Patient experience of pressure ulcer related quality of life

This quality of life questionnaire was distributed to patients only, although relatives and carers were able to assist in completion, or if necessary complete it on behalf of the patient. It contains 11 domains, each with a normalised score where 0 is "no bother" for all items in the domain, and 100 is "a lot of bother" for all items in the domain. Appendix F gives further detail on the methodology, included items and additional results.

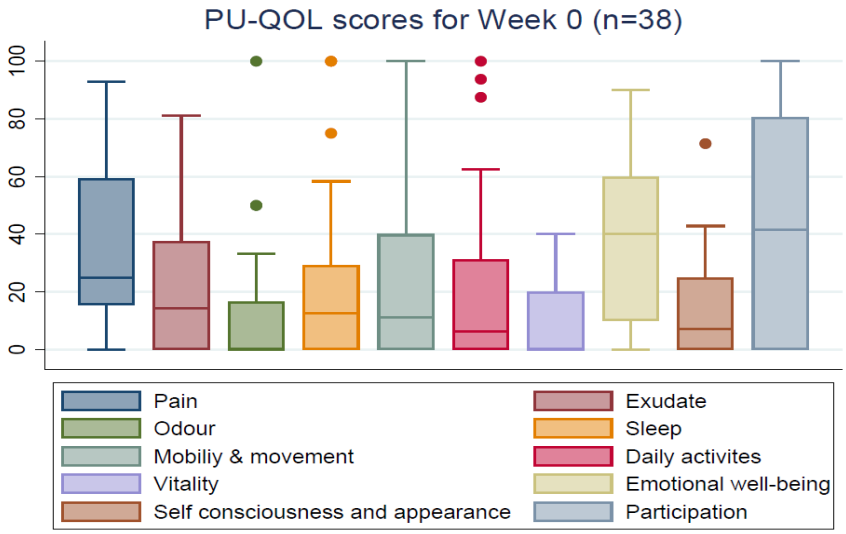


Figure 10 Pressure Ulcer related quality of life domains (baseline measure, n=38), where a score of 0 = "no bother" and a score of 100 = "lots of bother" for all items in that domain

The Week 0 results (Figure 10) reflect the wide ranging experiences and situations for patients included in PROMISE, with very wide interquartile ranges, and outlying data. The two domains with the highest median score (causing the most bother) are emotional well-being and participation. For most patients, odour and vitality were relatively unproblematic.

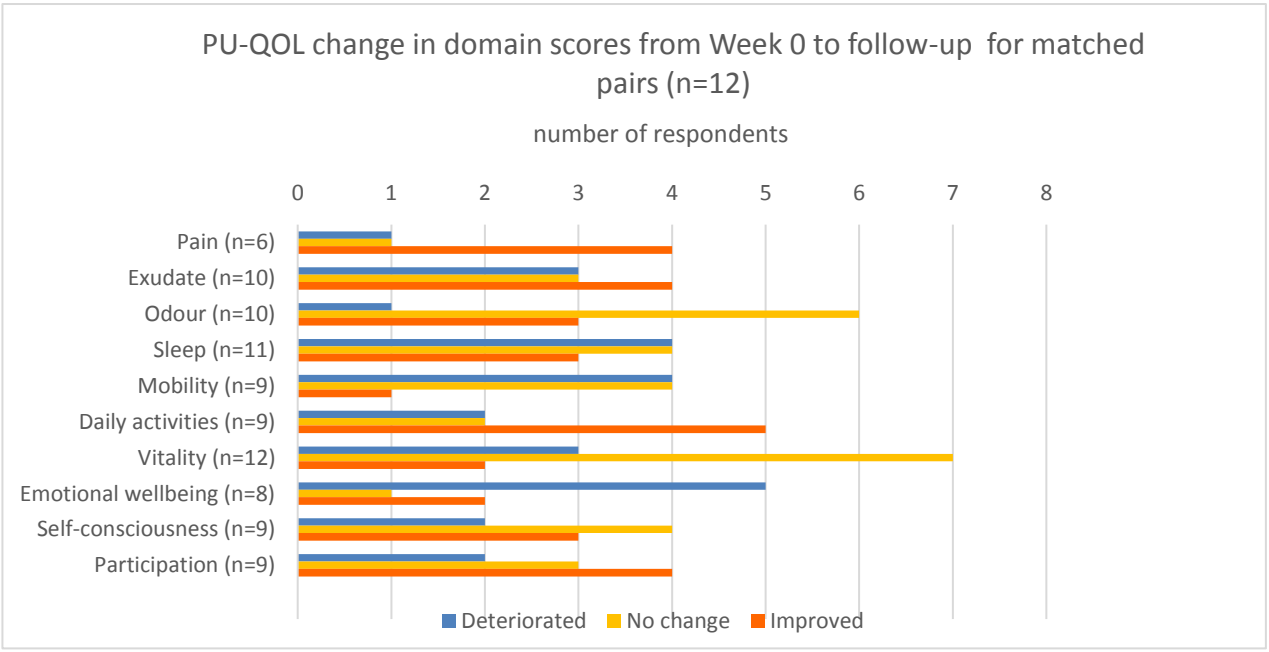


Figure 11 PU-QOL change from Week 0 to follow-up (n=12), with number of non-missing responses for each domain.

For the 12 matched pairs of patient responses, a comparison was made for each domain to show if there had been a deterioration or improvement (Figure 11). Numbers of non-missing paired responses are given for each domain. There appears to be an improvement in participation scores, daily activities and pain, and a deterioration in emotional well-being, however numbers included are very low and likely to include non-response bias.

4.4.2.2 Patient reported overall quality of life (EQ-5D-5L)

In addition to the week 0 and follow-up questionnaires responses, 19 additional EQ-5D-5L forms were returned at the end of the project. The results are presented in Appendix F, but show some increases and some decreases in quality of life, which is hard to interpret given that a number of patients will have co-morbidities that may have deteriorated, and the previously discussed issues of low numbers.

4.5 Patient and Staff Interviews

Patient interviews: 14 patients were interviewed, across the four sites. In 8 of the interviews relatives or carers were present who also joined the discussion. In addition to results reported here, comments were used to inform other areas of the reporting, for instance on the mapping process and barriers to obtaining equipment.

The mean time from baseline for interviewees was 200 days, or 6.6 months (minimum 45 days, maximum 315 days). Across all the interviews, 7 patients had reached form C (change of treatment), 5 patients had reached form D (start of the follow-up phase) and 2 had reached form E (end of PROMISE involvement). Of the patients interviewed, 4 were under 65 years old, 4 had not submitted any questionnaires, 7 only completed 1 questionnaire, and 3 were recorded by staff as not following advice at the start of PROMISE.

The first ten interviews took place in person at the patients residence, and subsequently a further 4 interviews by telephone due to COVID-19 restrictions. In June 2020, attempts were made to contact interviewees from 2019 to follow-up progress, with 5 additional interviews completed by telephone, plus one interview that had been completed by the project team more recently, as shown in table 4.

Staff interviews: 14 staff were interviewed, across all 4 sites, plus 2 staff from the project team, or site where PROMISE had already been implemented. Two interviews at Site 3 were with a group of TVNs, the remainder were one-to-one. There was a total of 23 interviews, 10 by telephone and 13 in person. **Error! Reference source not found.** Table 4 illustrates the timing and types of interview at each participating site.

Table 4 Patient and PROMISE staff interviews completed during the PROMISE project

		SITE 1	SITE 2	SITE 3	SITE 4
Patient interviews					
Face to face interviews	March 2019	✓✓	✓✓		
Face to face interviews	Sept 2019	✓✓	✓✓	✓✓	
Telephone interviews	May 2020	✓		✓	✓✓
Telephone follow-up interviews	May 2020	✓✓	✓✓	✓	n/a
Staff interviews					
Telephone interview with site lead (notes only)	Dec 2017 – March 2018	✓	✓	✓	
Interview with site lead	August 2018	✓	✓	✓	
Interview with PROMISE main implementer	January 2019	✓	✓	✓ (group)	
Interview with site lead	March 2019				✓
Short telephone update (notes only)	June 2019			✓	✓
Interview other team member	Sept-Oct 2019	✓✓	✓	✓	

Project end interview	March 2020	✓	✓	✓ (group)	✓✓

In addition information was obtained from equipment providers and other health care professionals working with PROMISE patients. Opinions were sought during informal discussions at the PROMISE conference in September 2019, followed by circulation of structured forms to equipment providers, district nurses and occupational therapists in January and February 2020. The low response was to have been followed up by phone calls, however due to COVID-19 this had to be curtailed. The evaluation includes information from four short forms, and three interviews (one by Cedar and two from the project team).

Information from staff interviews addressing patient experience and changes are reported in this section considering the impact of pressure ulcers, experience of mapping and any changes experienced by patients and carers during PROMISE. Information from staff interviews about implementation of PROMISE directly addresses aspects of the evaluation questions, and is reported in relevant sections of the discussion.

Patient quotations are identified by the prefix P; Carer or relative quotation are identified by R and staff interviews are identified using the prefix S for the PROMISE teams and OS for all other staff. Comments taken from the data collection forms are labelled DCF.

4.5.1 Quality of life

PROMISE aims to provide patient centred care, considering the overall quality of life as well as wound healing. Both patients and relatives told us how having pressure ulcers has impacted on them across many aspects of their lives.

The most common theme that occurred was around activities, with ten patients explaining how having pressure ulcers had limited their activities. In addition to needing to spend time in bed, other reasons why activities were curtailed included the limited length of time available to sit out, needing to stay in for district nurse visits, spending time caring for the pressure ulcer, being uncomfortable or in pain, feeling mentally unable to cope with going out and needing level access to get wheelchairs in and out of adapted cars. Although the activities missed varied from playing computer games; preparing lunch; cycling across moors or going on holiday, the importance of the activity to the people interviewed was significant.

"normally I'm very, very active and um I'm normally, well, I'm out every day…… this has had a huge impact on my life….. I'm very, very keen to get out of bed" P7

"so my only enjoyment is playing a football game on the computer……but to do that I'm sitting in my wheelchair. You know, but I've got to have something out of life….." P3

"I don't go out for pleasure, cos I don't get any pleasure…..[asked: so what's stops you from going out from home]…….pain – when I got the pain I get stressed out, which causes anxiety" P3

In addition, patients and carers highlighted that some of the activities that are prevented by having a pressure ulcer may be physically or mentally therapeutic, for example exercise or physiotherapy. Their limitation may have an impact on overall health and wellbeing in addition to the pressure ulcer itself.

Pain was an issue for some patients, both from the pressure ulcer and from other issues exacerbated by lying in a position to alleviate pressure.

"well he's very unhappy because he's in pain a lot of the time it's like a stinging pain, very nasty."R5

"as I'm lying on my right side here…my right leg will spasm and that's obviously uncomfortable, always causing pain"P7

Patients and relatives reported that having a pressure ulcer can completely dominate their lives, even if they have other major issues with their health.

"*it's not so bad when you haven't got a pressure sore, but when you've got a pressure sore it's diabolical." P10*

In some instances the pressure ulcer was reported as being more problematic than the health issue that actually led to it

"but seriously hand on heart and the stress that I've been under, caring for [my husband], and [my husband] himself, his bottom has caused more problems than his [primary condition]…….. his speech – his lack of speech we're dealing with that as best we can. Um, his mobility..again we're dealing with that as best we can. But his bottom, and as my son said, "mum I can't believe" – my son said "mum, they sent men to the moon 50 years ago and they can't sort [my husband]'s bum out"…"

"I think it's quite annoying how just that one mistake …… has caused such a big issue…… actually this is more umm affecting our lives more than [the primary condition]…… in a way…. it's all about the pressure sore at the moment……its controlling our lives" P11

Staff, in both interviews and data collection forms have also reported the importance of normal activities to patients. Examples of outcomes important to patients were:

"This patient wants to be able to go out in his wheelchair with friends to socialise" DCF

"….currently having bed rest and only getting up for meals. Patient has learning disability and clearly dislikes spending time on his bed, he thrives when he is in his wheelchair socialising with others ….." DCF

Staff recounted that patients may make decisions to prioritise these activities, even where it may compromise wound healing. Examples given included longer periods seated that would be recommended in order to go to work, go on holiday or to travel for long journeys.

The comments from staff, and from patients that have chronic or recurring pressure ulcers, demonstrate the need for an intervention such as PROMISE that takes a holistic approach to pressure ulcer treatment.

4.5.2 The iterative nature of interventions

Many of the patients involved in the PROMISE project have had longstanding pressure ulcers, or recurrent pressure ulcers and so have experienced pressure ulcer care over a number of months or years prior to PROMISE. An emergent theme that the majority of the patients alluded to was the iterative nature of attempting to heal pressure ulcers, the numerous solutions that might be attempted, and the time that it takes both to implement these and to see if they work. This demonstrates the magnitude of

the challenges faced by PROMISE teams, and also the patients. Also reflected in the comments is the expectation that health professionals and medical equipment need to resolve the pressure ulcer issues.

"and I think it's because you have so many dressings, so many variations, everything seems to take so long because it's a bit of, like – what we're getting now, umm, we have to wait up to a month to find out if it's gonna work or not, so that's another month gone by……" P11

"no, they just keep putting different pads on…I've had so many different ones. Some of them were not too bad others made me really painful and sore and…….. the ones I got on now are lovely……. it's trial and error isn't it?" P9

"at the moment we're all scratching our heads wondering what the best thing to do is…… really, I mean I think they're trying everything they can, to sort it out." P6

This feeling was also echoed by staff interviewed before implementation of PROMISE started, and one of the equipment providers also noted that patients may need to return to them on multiple occasions and that CPM can help to discuss this.

"really useful for clients who are referred back to you often and those who have already been given the best cushion/equipment/features to help with pressure relief but still continue to have this issue and you're at a bit of a loss and this can help you have a conversation around that." OS4

4.5.3 Cascading issues

When discussing how they came to be in the PROMISE project, several patients recounted how a single event (or a series of events that had built up very quickly) could lead to a pressure ulcer that then took many months to heal, or is still not healing. These events include injury that limits position changes or movement, general illness, problems with transfers, or the use of inappropriate equipment. Where this had occurred, patients were very aware of the impact that an apparently small event or injury could have, and this could lead to frustration if they had to wait for an appointment or equipment.

"and I was on that mattress without the Repose wasn't I….. and then BANG……" P11

"once you got them…. they get so big so quickly and they do not heal quickly and it's just …..a misery isn't it?" P10

"Unfortunately …… my wound got infected twice and then that was just a huge set back and got worse um….. because of that, that's when I just feel utter despair at times, really it just feels never ending……." P7

4.5.4 Mapping process

Most patients reported that there were no problems with the mapping process, although a very small number found the map slippery, or found the process tiring. Overall the process appears to be acceptable to both staff and the majority of patients.

"sitting on them, it's no problem at all, you hardly know they're there". P6

However two patients did report the map as being slippery, in relation to sitting in a chair

"I was in the process of sliding forward all day so I had to keep pushing myself back" P10

and for sitting in bed *"and sitting like this I would just constantly keep sliding down and I'd have to pull myself up again" P7*

Two patients found that the process of trying several cushions was very tiring, *"I was up and down like a yo-yo on that day and by the time they left I was shattered" P9*

but on each occasion they also reported staff doing all they could to make this easier.

"they have been very, very good in saying "are you getting tired?", and "do you want to stop?" P3

"they were here for more than two hours….. but they were brilliant….and every now and again –"right, we'll make a cup of tea"…."right, you sit and drink that"……I mean normally they're so busy" P9

4.5.5 Viewing the visual display during mapping

Part of the mechanism of PROMISE is that patients get visual feedback during the mapping process, and that this helps them to understand the importance of pressure redistribution and the advice that they are getting.

The CPM equipment displays the live contour map on a tablet like console attached to the map with wires (for three of the sites). During the mapping most patients were able to see the screen, although two patients found that this was limited for the mattress mapping by space or an appropriate location to place the display where they could see it.

"while I'm lying in bed I look at the screen and see what's happening", P9

"*I didn't look at it when I was on it, umm, when it was running……the only place they could put the monitor was around behind the bed" P13*

and one patient mentioned turning the display around to minimise the light

"the only problem I did have, was that when I woke up, I thought it was daylight because of all this light around the room" P12

4.5.6 Impact of the visual display

Patients found the visual display easy to understand, and recounted seeing the red and blue images, and relating red to areas of high pressure. For some patients this had a visual impact, and helped them to engage and understand the pressure monitoring process.

"The impact, the visual impact, is really….immediate" P4

Some comments indicated that the patient had had a full discussion with the PROMISE team, reviewing the data collected, and understanding the implications

"it was it was showing the differences, in the bed especially, but um …when they raise [the] back of the bed, then the pressure point was really massive wasn't it ……. I mean, when she sort of looked at it she said "that's about 9 o'clock". I said, "that's when he sits up to have his breakfast……" P12

Three patients reported using the visual feedback directly to adjust their posture while viewing the display

"you know my normal position… might be okay….and of course I can see then, other positions were not so good. From that point of view yeah very useful….." P7 and *"I found it extremely interesting to see where the pressure points were, when you sat in a chair and moved, and when you laid in the bed moved. I found it quite interesting watching the screen." P6*

Some patients although they had understood the visual display, either did not find it interesting, or had expected some more immediate changes or impact from the pressure mapping itself

"*they just showed me why it was coming up red – why it was going down blue and all the rest of it but that's about it, not……. I did have it overnight one time but it didn't make any difference.." P9*

Staff also reported that in some cases carers and relatives were more interested in the pressure mapping, and able to use the information to help the patient.

"Daughter also viewed the pressure mapping and found it valuable and helpful to see where the pressure needed reducing to help with healing of her mums pressure damage" DCF

4.5.7 Technical problems during mapping

Three patients reported technical problems with the equipment, two of these were based in Site 4, where there have been known problems over several months, and involved losing connection "*..mapping process was good, but there were times when it was temperamental. Like the machine would, like, lose connection and switch off and stop recording - that sort of thing. It is obviously good on the whole but had some niggles with it……" P8*

One may have been an issue with clarifying instructions to the patient relatives

"then we get him down and it wouldn't work. And I phoned them and they came out straight away. That's the only problem we've had to be fair. And then the next day when we came down, sure enough, I understood what they told me to do and it worked and we were able to monitor it"R13

Any equipment issues noted by staff were also mainly at Site 4.

A few patients commented on the effort taken to pack the mapping equipment away. For the first few visits staff reported that there was a learning curve to pack the mapping equipment, but that this soon became easier, unless there was very limited space.

"[Project lead] sent us out a guide that I've actually had laminated, that are actually in the bag now and so it's got a visual description how to fold it up, and everybody within our team knows that"S8

"Had to repack mattress in case on return to office due to very limited space at property" DCF

4.5.8 Changes in behaviour, improved knowledge, working together with staff

The PROMISE theory of change suggests that the CPM feedback and discussions with the PROMISE teams can lead to changes in patient understanding and behaviour, and that this additional learning and increased collaboration with staff can also empower patients.

In addition to adjusting postures during the mapping some patients did report that they have also modified their behaviour after mapping. One commented

"yeah, so it's good…..it has sort of made you think in your head - "can't do that" [relating to certain postures], which has been brilliant…" , *P11*

while another patient said

"the only difference I make is, when I'm in the chair, I can lift up on the side a little bit and it eases um the red areas." P6

There is some evidence in the feedback below of patients learning more about their care, become more expert and feeling more empowered. Two patients or relatives reported using the monitoring to back up their opinions or concerns about equipment

"….because I had a new chair fitted…[….]……and she went "yes this is really comfortable" and luckily enough [TVN] had turned up with the map and I sat on it before it was even mapped and I went "it's hard". She went "oh it's only because you're used to the [----] cushion". So of course - took me off it, put the [other cushion] on, put the map on and sat on it and it was perfect colour. Put the other one back, sat on it with the map, RED! And I thought, I told you.." P11

Some patients and relatives have a lot of visits from district nurses and professional carers, however many are very independent and largely manage their own care. One person explained how they had learnt more about their cushion and how it is adjusted

"as I said she explains everything to us and it's the same with that now - she showed me how to put my hand underneath. Because it is starting to feel a bit – you should only have an inch or something between the ROHO things,…. and how to pump it up, and….. it's been really useful hasn't it, to know these bits and pieces……". P12

Another patient felt that involvement in PROMISE had made them able to query the way care was being carried out in other aspects of their healthcare

"… the dressing wasn't put on the way [TVN] had done it and of course it had undone. So it was a bit like "you need to put it on this way" – you don't want to tell them how to do it… but I actually mentioned to [TVN] didn't I ……and so yeah, it's good in that way, we wouldn't have said anything before…" P11

4.5.9 Barriers to improved quality of life / healing

There are complex issues or health conditions that exist in many patients' lives and present additional hurdles to overcome when trying to heal pressure ulcers. PROMISE may help to identify these barriers and open conversations about them. Not all barriers will be removable, and these may limit the extent of the improvement that is possible.

Sleeping position: Patients may not be able to relieve pressure in the way that would otherwise be optimum. Three patients interviewed reported being uncomfortable or unable to lie in a bed due to arthritis, or other issues, meaning that they were sleeping in a chair overnight.

"*I can't turn in the bed because of my arthritis. I would be in agony the next day if I couldn't turn…"* P2

Patients (or their relatives) also reported having to sleep in a particular position, meaning that they were limited in their options for relieving pressure:

"He wouldn't have his problems, if he didn't lie on his back. If we could have got him to lie on his side that would have taken pressure off his bottom and it would be sorted." R13

A number of patients sleep in recliner chairs, or in a semi-upright position in bed, which again can limit options for pressure redistribution.

"Sleeps in own rise and recline armchair as able to get self in/out of chair herself. Unable to get self out of bed" DCF

Seated posture: Posture was also reported as an issue when seated in a chair, causing areas of high pressure, for some patients.

Co-morbidities: Existing health issues may limit the precautions that patients can take in preventing or treating pressure ulcers. In other cases an infection to the wound, another infection or injury may have caused additional complications to the patient's health or quality of life. They may also limit the possibilities of wound healing.

"he had to have a small operation to put a catheter in, that was in for probably for 6 weeks and that meant, in that time, he couldn't get off of his bottom, because he had the catheter in and he couldn't lie back on his tummy again." R7

"[Patient] wanted to be able to live independently …… This has been achieved, however patient has had 2 strokes since we achieved this causing a length of time in hospital and nursing home" DCF

Access to strategies to improve health / conflicting health and social priorities: Barriers to improving health might include balancing several different issues. One example given was wanting to go to the gym to help reduce weight, which might help with pressure ulcers, but not wanting to go while still being treated for the pressure ulcer. Other patients were unable to do normal exercise, or physiotherapy treatment due to their pressure ulcers.

"I had a regime of a physio coming in to sort of build me up a bit strengthwise. And since this has been so painful I've been sort of missing out on that……."P14

Equipment: Some patients and staff reported barriers to getting the equipment they were recommended, or that they wanted. These included a lack of funding availability, not being able to use wheelchair vouchers on the chair of their choice, having to travel to a mobility centre for assessment, or requests for equipment needing to be resubmitted if there were changes.

Options may also be restricted where patients have limited space in their rooms for larger chairs or beds, want to remain in a bed or room with their partner, or to retain their own furniture.

Waiting for visits or equipment: Several patients commented on the time it took, both to be seen by health professionals and to obtain equipment. The comments below are all from patients who have already been seen by PROMISE teams, although much of the timing is out of their control. It was also evident that patients were very aware that issues could escalate quickly and there was anxiety around this.

Also patients may cancel appointments due to ill health or anxiety, carers/patients having to wait around for appointments.

"*and I don't know how long it's going to be [for the chair]. They said about 6 weeks or so, but I don't know." P9*

"She said she'd get to me sometime this week to pressure map and perhaps alter the mattress, as I said…but I know, and everyone else knows, how quickly pressure problems can deteriorate and I'm left like a whole week waiting, and I fully understand that people are very busy, but I'm left you know, worrying that that particular area is just going to get worse and worse during that entire period." P7

"you wait such a long time between appointments, and sometimes I don't feel that great, you know - and I've had to cancel appointments before now - but um they came on Tuesday, and it's going to be another month before they come back with the updated cushion one they're going to try and manufacture. You know, it takes time don't it, you know, they've got other people to sort out, you know, so that's the only thing I can criticize - how long the time takes, you know." P3

Accessing specialised care: One relative reported that it was difficult getting their issue escalated by district nurses (and into the PROMISE project)

" I said "I've had enough"…..I got really angry and I was in tears ……I said "you refer him to tissue viability or else" ". R13

Another noted the change in levels of available support as patients moved from child to adult services.

COVID-19: For some patients, the arrival of COVID-19 (up to evaluation end, May 2020) meant that improvements in their quality of life due to PROMISE have been curtailed due to the need to shield, or changes in care provision. This was reported by both patients and staff during the first wave.

"he had been at home for about 1 month going out and socialising with friends prior to COVID 19, his care package has since stopped due to pandemic and patient is currently in a nursing home" DCF

4.5.10 Changes following PROMISE intervention

Equipment changes: All 14 patients interviewed mentioned changes in equipment following the mapping, 3 of the patients were still waiting for the new equipment, and 1 patient had been told that they did not need to change their mattress. For some of the patients the change in equipment had been quite recent, and so they were still unsure of the future impact. For others the equipment change had already been very important:

Recalling an earlier mattress, the impact was described as *"we're quite annoyed because we were on different levels and this thing kept on having to inflate it and it was crunching and keeping me awake…… it was like lying on a packet of crisps it was"* compared to the current mattress, provided after pressure mapping *"…the mattress umm……. it's helped us a lot……yeah -you literally don't hear anything" P11*

Quality of life: As the project was still ongoing, for most of the patients interviewed, the pressure ulcer was still having a significant impact on their quality of life, although for some this had changed as the wound had started healing:

"I am able to do more now because I'm… it is just a dressing they're putting on……. so I'm more mobile and able to more than I did with the pump on, but obviously, I'm still being sensible about it." P8

"Well, I mean, you've got to spend most of your time in bed haven't you, and every day they come ……..at least now they only come 3 times a week…… instead of 7 days a week being poked and prodded and all the rest of it, its' only 3 days a week now, which is a huge improvement."P10

During follow-up interviews, it was evident that for several patients PROMISE had contributed to a long standing pressure ulcer healing, or to being free from pressure ulcers that had been constantly re-occurring for years. Returning to normal activities had unfortunately been limited by COVID-19 for some of the interviewees.

"It's all been cleared and I've been cleared of the district nurses for that now, there's no wound as such, pumps gone back, everything" P13

"I thought they were really good. I felt safer knowing they were involved. I'd have been worried sick if they hadn't been included. Because it made us quite aware of a lot of things and I've got total faith in the cushions and the mattress topper that we've got now…….Without the pressure mapping it would've been a much longer drawn out affair than what it was. "P11

Staff also told us about patients who had been able to return to their normal activities, after involvement in PROMISE.

"He's got new equipment, he's much more – he feels more supported on that equipment and he's now able to go back to his job, which he only does 4 hours on a Wednesday, but he's been able to get out and about more. " S1

"Yes pressure ulcer has now heeled and remained intact, the patient new goes to bed at night this had not been achieved for around 30 years prior to PROMISE" DCF

Unfortunately not all patients had reached such successful outcomes

"we're doing absolutely everything in our power, I just thought, it's still an ongoing issue 18 months after it broke" R13

Hope and reassurance: For the earlier interviews where less time had passed since the start of mapping, a theme that emerged from the analysis was the hope and reassurance that PROMISE had given to a number of patients. For some pressure ulcers were something they had coped with for many years, and PROMISE represented the possibility of a solution. Other patients and carers might be trying to manage a new situation, finding it difficult to cope with different advice and needing reassurance

"Cos you know, sometimes I get frustrated, because I can't do anything……I've done everything I can do, but he's still breaking out and you're thinking "what am I doing wrong?" and I wasn't doing anything wrong…" R12

"this PROMISE thing has probably been the only bloody good thing about it ain't it. That it's been there to– we know, it's there to help us…" R11

"so at the moment, everything -umm, touch wood - if it keeps going the way we're going hopefully [pressure ulcer] may be a thing of past, please god ……..so it's wonderful that you guys have got involved, it's given us some hope really." R13

"it's been an amazing project – I just hope that in the end it does all work for us" P11

4.6 Staff questionnaire: attitudes to PROMISE, normalisation process theory

The NoMAD questionnaire builds on normalisation process theory (NPT) to understand participants' experiences implementing change over time and across settings (Rapley et al. 2018). These actions lead to the intervention becoming embedded, or normalised, and a part of normal activity. Appendix G discusses the four core constructs of NPT and gives more detailed results from the NoMAD questionnaire.

The NoMAD questionnaire was administered at 3 time points (table 5). The two dates in 2019 are grouped together for analysis, since at both time points the respondents had only recently started delivering PROMISE. The final questionnaire was during the initial period of COVID-19 re-organisation, when there were disrupted work patterns and high levels of work. This probably affected both the response rate and who was able to reply. In 2019, out of 16 responses from implementation sites, 8 respondents carried out CPM and analysis, and 4 were team leaders or managers. In 2020, there were 7 responses, 3 of which were from team leaders or managers, 3 carried out CPM, but only 1 of those did the analysis.

Table 5 Completion of NoMAD questionnaire by staff at different time points

	Cornwall TVNs	SITE 1	SITE 2	SITE 3	SITE 4
January 2019	3	3	4	3	0
August 2019	1	1	0	1	4
March 2020	0	0	4	1	2

Analysis of the NoMAD constructs for the first period, 2019 (Appendix G, Figure 39) highlight that there is a very strong positive agreement across 3 of the domains, with few disagreements, indicating that staff see the value of PROMISE, feel it is a legitimate part of their role, and can adapt and evaluate it. The area that stands out as being more problematic (although still largely positive (44% - 81% across 7 items) is "collective action", which asks about integrating PROMISE into existing work, resources and training. The responses here may reflect the issues around time and staffing levels that have been noted throughout the project and particularly during early implementation. These initial responses are also likely to reflect the learning curve for using the pressure mapping system. The project team have developed, and continue to develop, resources to help with implementation and learning, and this construct scores more positively in 2020 (Figure 40, Appendix G)

NoMAD also asks the questions shown in table 6, and there is a slight increase in score over time. When all sites combined, we can see that there is a slight increase in mean score over time. One site had 4 responses in both Jan 2019 and Jan 2020, and when this is taken on its own then a rise in can be seen, and final results are more similar to the TVN team who routinely use CPM as part of normal practice in Cornwall (Appendix G). This should be considered with great caution, and in combination with other results, as the numbers are very small.

Table 6 Responses to NoMAD questions across all implementation sites

Mean score from a scale of 0-10, across all implementation sites	2019 (n=16)	2020 (n=7)
When you work with PROMISE how familiar does it feel?	5.4	6.3
Do you feel PROMISE is currently a normal part of your work	5.3	5.7
Do you feel PROMISE will become a normal part of your work	7.9	8.6

4.7 Wound healing

Unless stated otherwise, all analysis on wound healing was on a per wound basis, and using the pressure ulcers present at baseline only. Wounds deemed to be non-pressure ulcers, or wounds that started after baseline were not included. All data from the data forms were collated into a wound table. Each wound was given an identifier for analysis, as some patients had several wounds over the period of the project.

A total of 128 pressure ulcers were identified during the project, 86 of them were present at the first patient contact. Of these 86 baseline pressure ulcers, 7 had healed prior to CPM, and an additional 49 had healed by the end of the project. Of the 42 additional pressure ulcers (new or recurrences), 33 had healed by the end of the project.

At the end of the evaluation data collection, 35 patients had healed, with 10 experiencing recurrences during the project. 32 patients had not healed at the end of the evaluation. Of these, 2 had wounds described as static, 4 had wounds described as deteriorating and 16 had wounds described as healing (the remainder had not been recorded in these categories).

As a quality improvement project, with wound dimensions as a secondary outcome, wound healing was defined by the nurses' clinical judgement. Any recurrences were notified to the implementation sites and noted on data collection forms.

Study diagram for wounds, **for patients that were pressure mapped only**.
In addition, 2 died before mapping, 2 healed before mapping and were not mapped, and 1 patient was mapped briefly as an educational tool, but not included further.

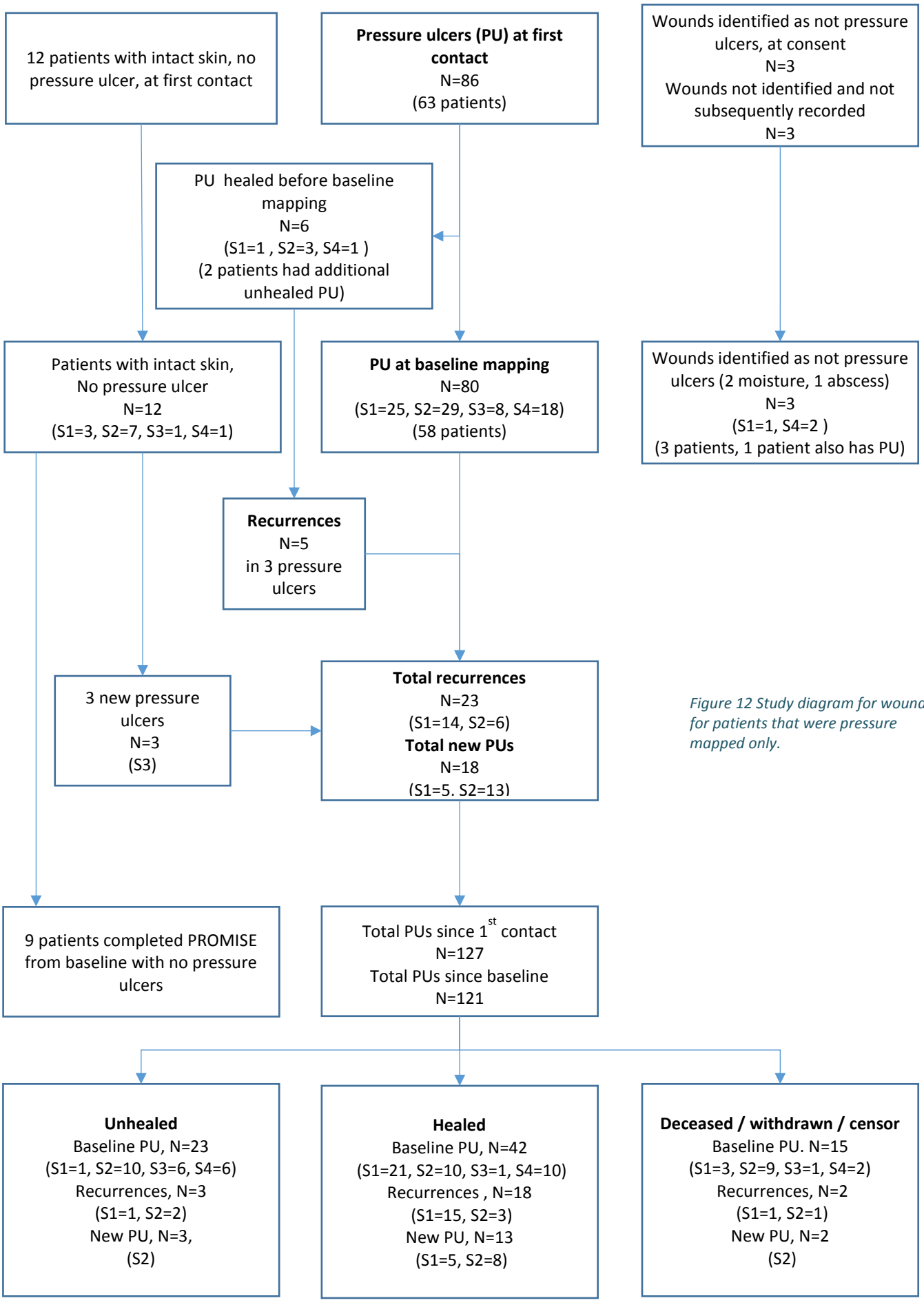


Figure 12 Study diagram for wounds, for patients that were pressure mapped only.

4.7.1.1 Time to 50% wound reduction, by area and to wound healing, from baseline.

As patients all had different start dates and durations the study, Kaplan Meier analysis was used. At day "zero" (the first mapping date) all wounds will be unhealed, and the y axis, the proportion, will be 1.0. If at 10 days there is no more information on that patient, then that data is termed "censored", and it only contributes for that initial portion of time. The proportion of wounds unhealed remains unchanged, but there are fewer wounds in the calculation and uncertainty will increase. For this reason the "number at risk" table is included in the graphs, allowing the reader to understand the strength of the evidence. This is particularly important when splitting data into sub-groups.

4.7.1.2 Time (months) to 50% wound reduction, by area

Of the 86 wounds identified, 9 had an initial area of 0cm^2, as the pressure ulcer had reduced between referral and baseline. These were not included in the analysis, leaving 77 wounds in the calculation. The median time to a 50% reduction in area from baseline was 6.5 months, with a 95% confidence interval of 4.6 months, to an undefined upper limit

Although graphs are presented by pressure ulcer grade below, and by site in Appendix H, for each of the time to event analysis, the numbers for all sites are small after the initial 5 months, meaning that there is little certainty attached to the analysis after this point.

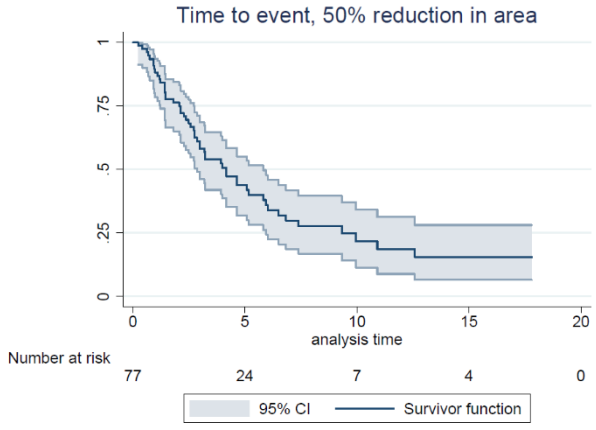


Figure 14 Time to even, reduction in area

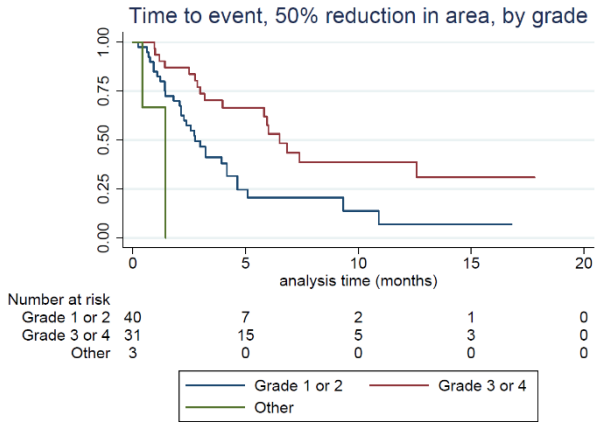


Figure 13 Time to event, 50% reduction in area, by grade

4.7.1.3 Time to wound healing

86 wounds were identified, 7 had "healed" dates that were on or before baseline, and were excluded from the analysis, leaving 79 wounds in the calculation. The median time to healing was 10.9 months, with a 95% confidence interval of 4.6 to 13.3 months.

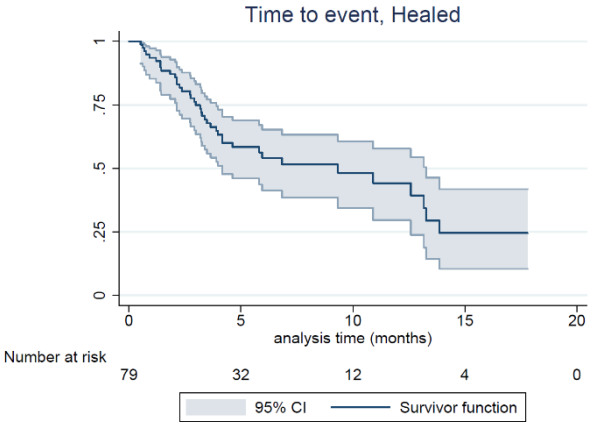


Figure 15 Time to event, healed

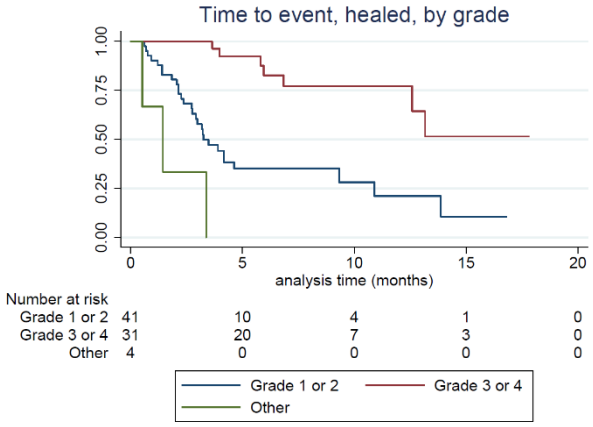


Figure 16 Time to event, healed, by grade

4.7.2 Duration of pressure ulcers prior to PROMISE baseline, and time to healing, or to end of project.

For each baseline pressure ulcer, the time is presented (in days) from the start date noted by the clinical teams to the baseline intervention and then to the date the pressure ulcer was identified as being healed. For a small number of pressure ulcers there was information until a certain date, and then the pressure ulcer was not mentioned in subsequent forms. If the next form was close in date and there was any mention of intact skin or healed ulcers then the date of that form was used as the date of healing. For some patients, the next form was over a month later and gave no additional information, however at the end of the project the patient was declared as having no pressure ulcers. In this case we know that the ulcer was healed but cannot infer when. These wounds are marked as "censored" meaning that for time to event analysis we use the information that they were present for the duration recorded, but then remove them from analysis. In the graph below these are marked in dark green as censored.

This graph shows one aspect of variation between patients in PROMISE, with the earliest start date prior to PROMISE being recorded as 2011. For some patients, the current pressure ulcer may be relatively recent (months rather than years), but they have a history of recurrent pressure ulcers over many years. This is not fully captured in this graph.

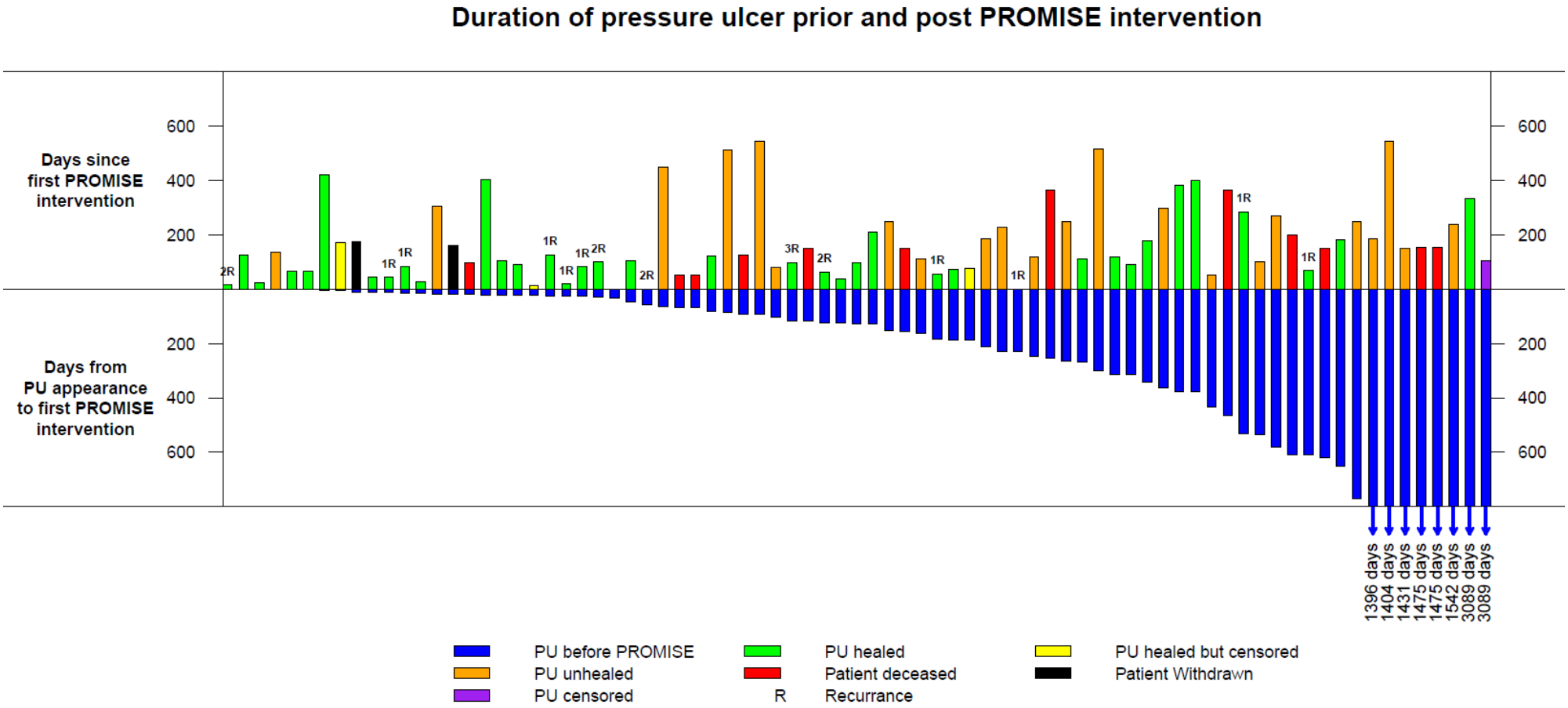


Figure 17 Pressure ulcer duration pre and post PROMISE, with outcomes, sorted by duration prior to PROMISE

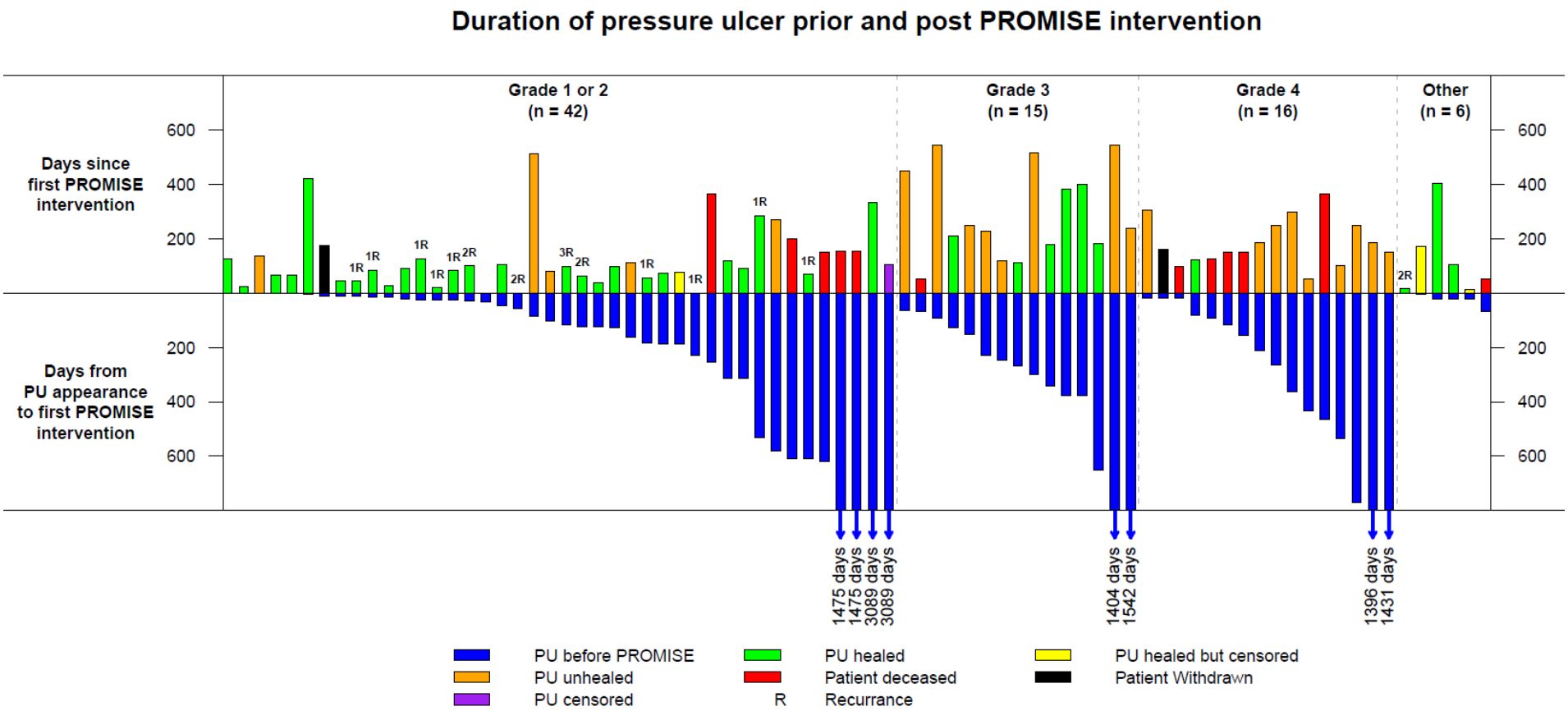


Figure 18 Pressure ulcer duration pre and post PROMISE, with outcomes, grouped by grade

4.7.3 Change in pressure ulcer area at 16 weeks after baseline

This is included in the protocol, however the approach to data collection changed to be more flexible during the course of the project, meaning that only a limited number of patients had wound measurements available at 16 weeks. Where there was data within 2 weeks on either side of the 16 week date, this was included. If that was not available, it was classed as missing data. This resulted in only 13 out of 86 pressure ulcers having data available for both baseline and a date between 14-18 weeks later. From these 4 were healed, 1 was unchanged, 3 had reduced in area and 5 had increased in area.

4.7.4 Number of recurrences and new pressure ulcers.

During the course of the project, there were 24 recurrences of pressure ulcers in 15 patients, and 19 new pressure ulcers recorded in another 15 patients. All new and recurring pressure ulcers were in patients from Site1 and 2, which is likely to be at least partly due to the increased length of time that these sites were in the project, and the larger number of patients recruited from these sites.

4.7.5 Changes between initial contact and pressure mapping

We have only very limited data to tell us what would have happened to these patients if PROMISE had not been introduced, however we have information for 41 patients who had initial data collection and were then placed on a waiting list for PROMISE. For these patients on the waiting list, over a median time of 27 days (3.6 weeks), 10 had a reduction in wound size, 4 healed, and 12 were static or wound size increased. In addition 4 had no initial PU and 11 are unclear. The mean wait was 48 days (6.9 weeks) with an outlying data point where one patient had a preventative mapping visit 370 days after the initial contact. Consent and initial data collection was collected for an additional 5 patients who were not mapped. Of these, 1 died prior to mapping, 3 healed prior to mapping and for 1 PROMISE was used as an education tool only.

A flaw with this measure is that those patients who experiencing rapid deterioration are likely to have been seen by the PROMISE team more quickly than those whose wounds are healing.

4.8 Pressure redistribution equipment

4.8.1 Mattress changes between baseline and end of project

At the end of the project, 68% (n=52) of patients had the same classification type of mattress as they had at the first mapping investigation. This includes patients that have had equipment changed for a different mattress that comes within the same classification group, or if alternative mattresses have been tried, but not continued. Figure 19 shows the types of mattresses in use.

After consultation, the project lead was able to assign a subjective ranking and approximate cost to the mattress categories. There will be a full economic report in December 2020 that will assign more accurate costs to the equipment, but this gives us a first indication. Of the 77 patients, 17% (n=13) received a higher specification mattress, 10% (n=8) received a lower specification and 73% (n=56) had either the

same classification type of mattress, or a change to one of similar specification. The change in mattress is approximately cost neutral using the estimated costs.

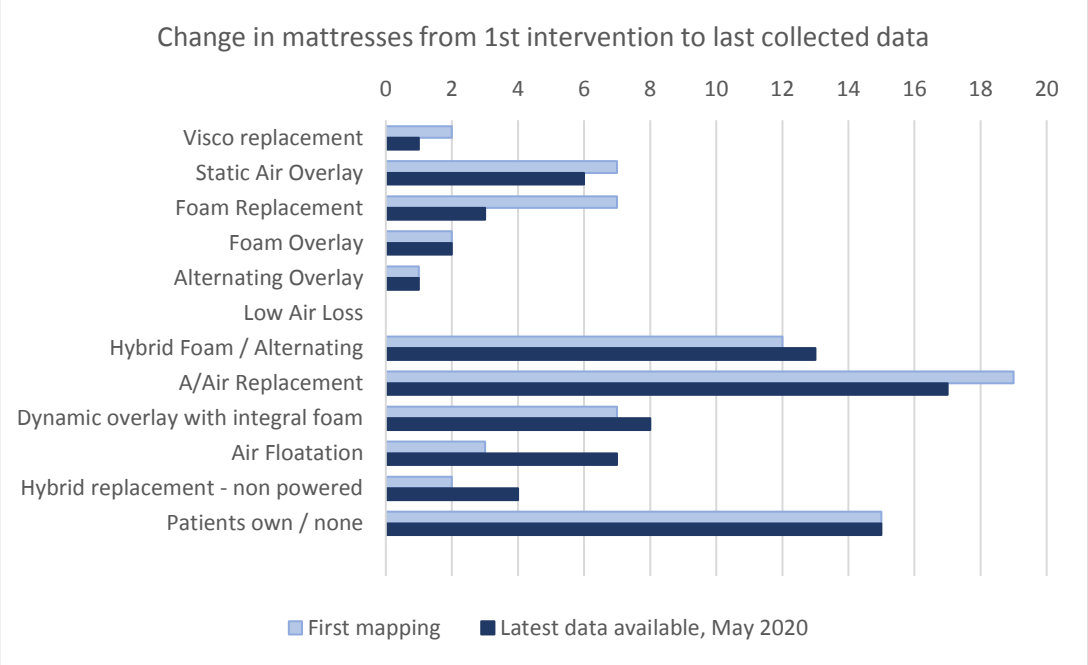


Figure 19 Change in mattresses from first intervention to last collected data

4.8.2 Cushion changes between baseline and end of project

At the end of the project, 47% (n=36) of patients had the same types of cushion as they had at the first mapping investigation. This may include patients that have had equipment changed for a similar mattress, or if alternative mattresses have been tried, but not continued. Figure 20 shows the types of cushions in use.

After consultation, the project lead was able to assign a subjective ranking and approximate cost to the mattress categories. There will be a full economic report in December 2020 that will assign more accurate costs to the equipment, but this gives us a first indication. There is a very slight decrease in cushion cost (-£15), however this is based on estimated costs and may differ from the subsequent health economic report.

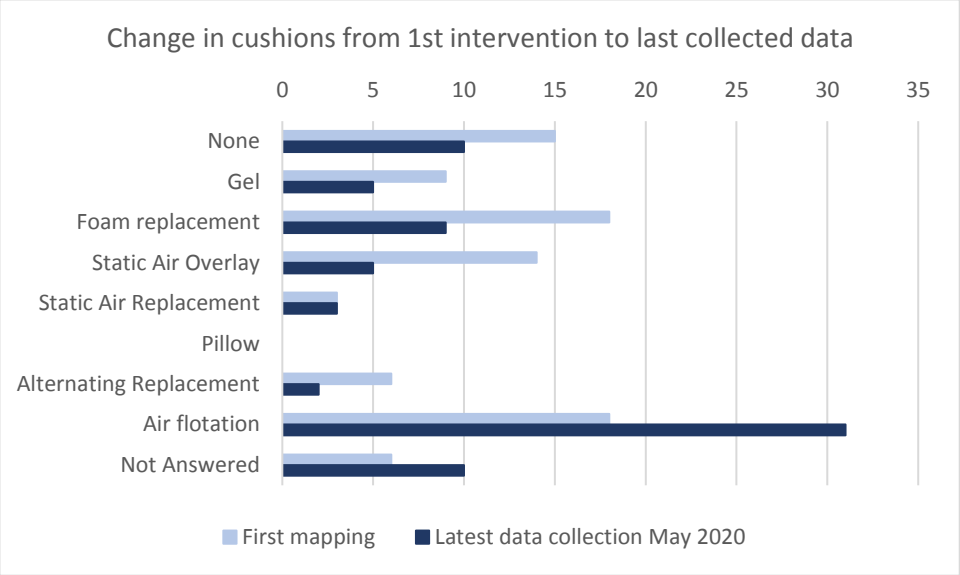


Figure 20 Change in cushions from first intervention to last collected data

4.8.3 Total number of cushions, mattresses and mappings

At the end of a patient's journey through PROMISE, data is collected on how many mappings were carried out, and the number of mattresses and cushions trialled. This was added into later data forms, as it was realised that the existing forms may not capture every mapping and equipment trial as it happened, particularly where several cushions were tested during one visit.

Table 7 Total number of cushions and mattresses trialled, and mappings

	Cushions	Mappings	Mattresses
Patients (n)	38	39	39
Occurrences (n)	76	149	60
Occurrences per patient:			
Median	2	3	1
IQR	(0.25,3)	(1,4.5)	(1,2)

Although the median is 1 mattress and 2 cushions trialled per patient, the data is skewed with some patients requiring many more trials. Histograms showing this data, split by Site are included in Appendix I.

4.8.4 Time to equipment delivery

When implementing changes of equipment or advice, in the second half of the project there was an option of completing the date of an equipment request, and when that equipment became available. Although only a small proportion of the records have recorded this information, where it is available it demonstrates the duration and variation in delay.

Table 8 Time from equipment request to delivery, by site

Any equipment	S1	S2	S3	S4
Records (n)	*23*	*15*	*4*	*3*
Average (mean), days	13.1	39.4	24	65.7
Median, days	7	26	26	49
Records (n)	23	15	4	3
IQR	4, 13	8, 36	8, 40	0, 148

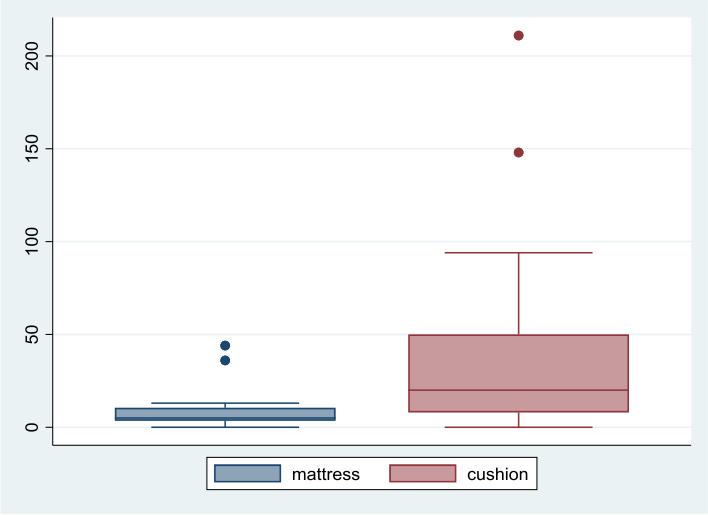


Figure 21 Time from request to delivery for mattress and cushion (days)

Although the type of equipment is not specified on the form, we have assumed that any patients only mapped in that visit for a cushion had been waiting for that cushion. We also assumed that those only mapped with a mattress have been waiting for a mattress. Using this information we can look at subgroups of waiting times for mattress and cushion suppliers, Figure 21. This demonstrates the higher median wait for cushions (20 days, IQR 8,50 days) compared to mattresses (5 days, IQR 3.5,10.5 days), but also the extreme variation that was present in the outlying data for cushions. For both cushions and mattresses some patients received their equipment on the same day that it was requested.

4.9 Reported concordance and adherence to guidelines

The numbers of patients who are using equipment and following advice, as reported by the nurse is high (80%) at baseline from the data form entry, and 82% of patients did not change. Percentages are calculated from non-missing data, and the total non-missing stated for each response category. The category "Following guidelines" was added into the data collection forms in August 2019, meaning a number of baseline responses were not collected.

Table 9 Patients following advice and guidelines at start and end of PROMISE project

	Baseline	Last form recorded	Matched responses		
			Yes - No	No change	No-Yes
	n=76	n=77		n=76	
Following advice and using equipment	61 (80%)	61 (79%)	7	63	6
	n=34	n=66		n=34	
Following guidelines	26 (76%)	51 77%)	2	30	2

4.10 Process measures

Both of the following time to event measures are for the time to the first occurrence of the event only. In some cases patients reached a follow-up phase (form D) or completion (form E), but then required re-intervention. This is not captured in the results in 4.10.1 or 4.10.2.

4.10.1 Time to event for patients to reach follow up phase

The time for patients to reach the follow-up phase of the project is indicated by the first form D completed. This is used when nurses feel they have reached an optimum solution for a patient, and they now only require follow-up either by visits or through notes, to ensure progress is continuing. The median time to reach follow-up phase is 3.91 months (Figure 22).

4.10.2 Time to event for patients to complete PROMISE

For each patient, PROMISE is completed either when they have healed, or no longer require active involvement from PROMISE teams; if they have withdrawn from the project; or when patients have died. In each case this is indicated by the site teams completing an E form, and if there are any recurrences patients are re-referred back into PROMISE. For this analysis, the patients who had died or withdrawn on the date of the E form, were counted as censored. The E form is used as an indicator of time to patient healing (as opposed to individual wound healing reported previously). The median time to patient healing (as indicated by an E form) is 8.8 months (Figure 23).

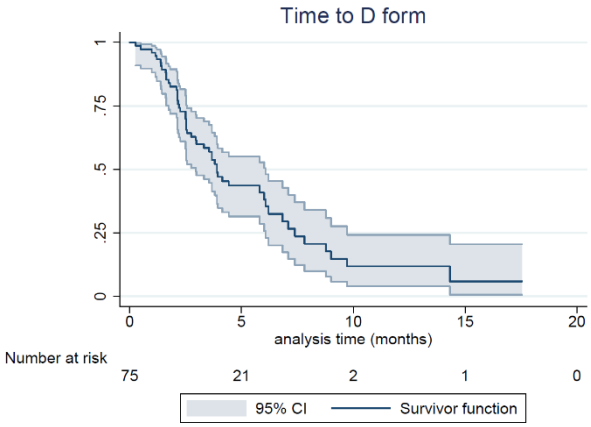


Figure 22 Time to event for patients to reach follow-up.

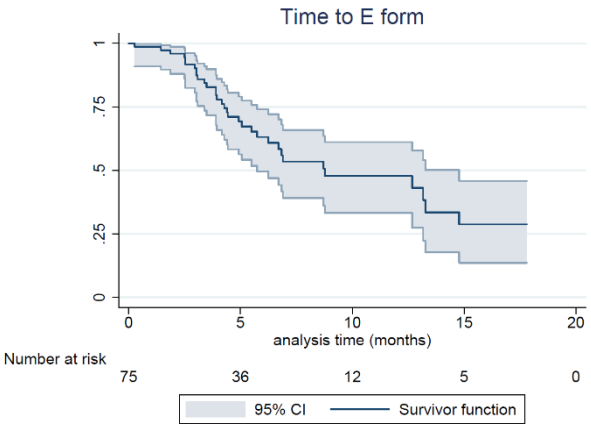


Figure 23 Time to event for patients to complete PROMISE

4.10.3 Duration of pressure monitoring

PROMISE is based on using extended pressure monitoring (CPM) as part of the initial investigation (Form B), it may also be used to investigate changes in equipment or advice (Form C).

Table 10 Median duration of pressure mapping across all sites for forms B and C

	Bed mapping		Seat mapping	
	Form B	Form C	Form B	Form C
Number of visits	62	39	62	71
Median	42 hours 13 min	24 hours	1 hour 30 min	45 min
(IQR)	(22h, 48h)	(22h, 48h)	(1h, 21h)	(25min, 1h 38min)

The data is also presented in Appendix I by site, both as a table and histogram, it is also discussed further in section 4.13.

4.10.4 Time spent per visit and total time

The visits with patients could be quite lengthy, particularly for initial mapping visits (median 93 min, IQR 66,132 min) and changes of equipment (median 75 min, IQR 54,100 min). The actual time required may be a lot longer than that recorded, if, as often happened, there is a one hour journey, or more, in each direction. Resource use will also increase if two staff are required, either for patient positioning, learning or multidisciplinary working.

Table 11 Staff time spent on patient visits

	Total visits (n)	Median (minutes / visit)	IQR
A baseline	37	45	(30,60)
B1 Mapping	86	93	(66, 132)
B2 Map collection	18	43	(30,59)
C1 Change/mapping	112	75	(54,100)
C2 Map collection	12	35	(30,60)
D Follow-up	96	23	(14,41)
E Final	51	20	(10,30)

This data does not capture the time spent, downloading and analysing the data, contacting or referring to other health care professionals, following up referrals and equipment, or any additional visits that may not have been captured by the forms. It also does not capture travel time or visits with more than one staff member. The median total time recorded in visits per patient (for all patients in PROMISE) was 255 minutes (3 hours 45 minutes) per patient. However this total includes patients who have only recently entered the PROMISE project, including only patients who have healed gives a total median time of 280 minutes (4 hours, 40 minutes). Some patients have required considerably more input, with the longest being over 22 hours of visit time.

The total time recorded for all visits in PROMISE was 25,662 minutes, or 57 days (based on 7.5 hour shift).

4.11 Project support time

A total of 132 hours of support was recorded from the project lead across all 4 sites in terms of individual site visits and remote support. This varied between sites from 14 to 55 hours, which was at least partly a reflection of duration of involvement in the project. The first sites to implement PROMISE had some support continued throughout the 18 months, whereas, the latest site to join was able to benefit from experiences of previous sites. Changes in staff at one site meant a need for some additional support.

Distances between sites meant that a substantial amount of time was required for visits, and initially face-to face support was particularly valuable as it allowed a review of data. During the course of the project, and particularly with the impact of COVID-19, the project lead and sites have started reviewing CPM data remotely. This removes significant travel time, although sites also valued the face-to –face contact.

In addition to the time captured for site specific support, the project lead team have provided support to sites in the form of regular networking or study days, combining a project meeting with more informal opportunities to discuss issues or improvements and compare experiences. They have also developed project resources such as instruction manuals, these have been created and improved throughout the project for sites to use

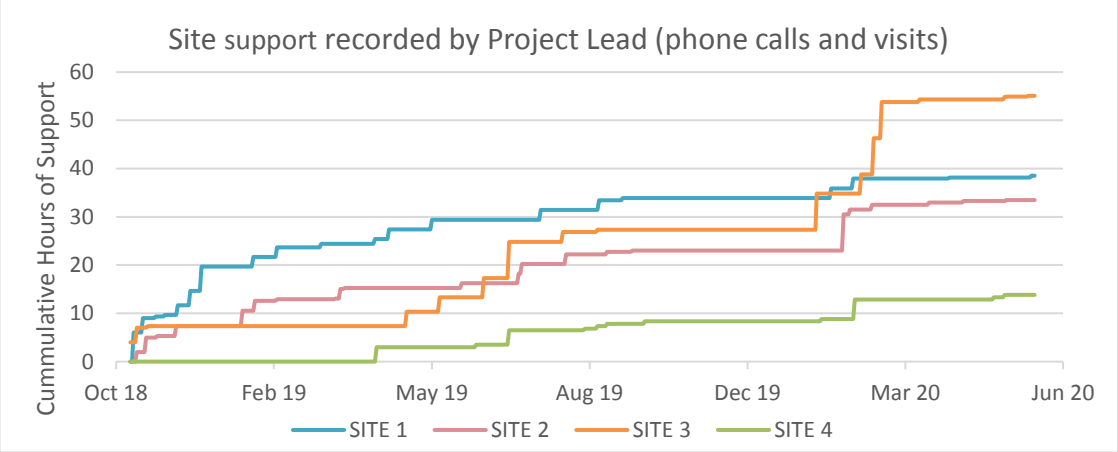


Figure 24 Support to sites by Project lead (hours)

4.12 Administrative data

For the Site 1 district nursing team, retrospective administrative data was made available for all patients in the project. The data was extracted for 2 years, from the 1st April 2018 to the 30th March 2020. This included all community visits to patients, and the time recorded per visit. Types of visits included community nursing, tissue viability teams, podiatry, rehabilitation therapy etc. The evaluation team have briefly compared visits before and after the PROMISE baseline visits for each patient. It is expected that there will be further analysis of this data, including additional sites, in subsequent reporting and economic considerations.

As start dates for patients varied, there is different lengths of data collection pre and post PROMISE for each patient. For the 23 patients mapped, there was an average of 13.4 months data prior to the first pressure mapping visit (min 7.2, max 17.4) and an average of 9.6 months of data after the first pressure mapping visit (min 1.7, max 16.7).

Comparing the mean number of visits per month before and after PROMISE, 11 patients had no change, or fewer visits per month in the period after the first PROMISE session, 12 had more visits. There was a mean change of 2.9 additional visits per month following the first mapping visit, with a median change of 0 visits per month.

Considering the total time per month in visits, 12 patients had no change or less time per month following PROMISE initial visit. There was a mean decrease of 8.8 minutes per month in visit time, with a median decrease of 1.5 minutes per month.

As with all discussions for PROMISE, there was a lot of variation between individual patients, with the largest reduction in visits being 13.8 visits per month and the largest increase being 38.9 visits per month. A more detailed analysis could consider the change in visit intensity over time, the duration of involvement in PROMISE and the impact of patient co-morbidities.

4.13 Were the elements of PROMISE delivered as expected?

The key initial components of PROMISE from the logic model are:

- CPM over an extended period of time, resulting in:
  - Visual feedback to patients
  - TNV or DN insights into patient's normal activity and posture

4.13.1 CPM over an extended period of time

CPM has consistently been used for extended monitoring periods for both cushions and mattresses across all sites, with the bed monitoring time greater than 24 hours in 51% of patients at initial pressure mapping investigations (as recorded on the B form), and a median duration of 42 hours (form B). Seat monitoring times were shorter, however 90% of patients were monitored for greater than 20 minutes and 31% for greater than 12 hours at initial investigations. The median duration of seat monitoring was 1 hour and 30 minutes. Reasons given for reduced durations (less than 24 hours) included practitioner choice (n= 24), patient choice (n= 5), concerns about falls (n= 5) and requiring the map elsewhere (n= 2). Other reasons given included patients not sitting out for long periods, staff availability to collect map, and faults recording over prolonged time (one site only).

Mapping times for later investigations and equipment changes (recorded on the C form) were shorter for both bed and seat monitoring. Staff explained, during project meetings, that they might have already identified an issue and discussed with patients, and then at this point they would be trying several different sorts of cushions, to look at the impact they had. They felt that this could often be seen in a much shorter duration of time, and in some cases an unsuitable cushion could be ruled out very rapidly.

4.13.2 Patient insights into behaviour & use of visual feedback

Patients found the visual feedback easy to understand, and some patients or relatives and carers were very engaged with the process, reporting changes in understanding and behaviour.

The visual image that goes with the map seems to be readily understood by patients that have viewed it, with the colour scheme being very intuitive and red clearly associated with there being a problem. In interviews, some patients described in detail the findings of the mapping and related this to their behaviour, the equipment they were using, or using the information to change posture. For other patients, it was not seen as very interesting, or largely as a tool for the nurses. Some patients found that the visual feedback was very powerful, and there were obvious comments relating to them taking that information on board and using it, while some described using the information to change posture. Where patients had cognitive difficulties feedback to patients may be harder, however relatives or carers were reported as finding it interesting.

From the equipment questionnaire, the majority of patients (72%), relatives and health care workers (88%) agreed that the pressure map and monitor were helpful and interesting. Around half of relatives and health care workers who responded reported using the monitor to choose the best position (48%),

and to see when to change position (56%). For patients this was slightly lower at 25% for both questions, which may reflect the reported staff experiences of engaging relatives and carers as well as patients.

The longer term impacts of this feedback are harder to identify. Interviews were carried out throughout the project, in order to gain early stage insights however it was possibly too early to find evidence of long term impact. The project team have interviewed patients at a later time point and will also be reporting on this in the final implementation report. Some staff have described the mapping as a turning point in a patient modifying behaviour to reduce the amount of time they needed to be seated.

4.13.3 TVN insights into patient lifestyle and behaviour

Staff uniformly report that involvement in the PROMISE project has had an impact in how they think about patients, their behaviour and their quality of life. This change started before patients were even recruited, with the implementation sites being very committed to, and enthusiastic about the principles underlying PROMISE. The reported attitude encountered in healthcare outside of PROMISE was *"Once you've labelled someone non-concordant, interest wanes on the health side and you go in expecting a battle" [talking about general healthcare, prior to PROMISE] S6*

The experience of using PROMISE in practice has reinforced that change in thinking

"sort of having time to engage with patients and um seeing their reaction to the equipment and again having that bio feedback from them and having the time to find out the bigger picture about what might be happening, rather than just changing the equipment to the next – you know, finding out, being more investigative really." S10

We can conclude that, although there is variation in experience for sites and individual patients, the key building blocks of PROMISE were put into place. In the following discussion section, we look at the later stages of the logic model and the resulting changes for patients and staff, using the framework of the evaluation questions.

5 Discussion: Primary evaluation questions

This discussion section brings together the reported results to address each of the evaluation questions, building in reflections on how the steps in the logic model were addressed. The component evaluation questions are then drawn further together in the final conclusions, and recommendations for future implementation.

5.1 Evaluation Q1: Patient centred care

Has PROMISE improved patient centred care for pressure management at each adopter site, including patient education and staff understanding of patient needs?

PROMISE builds on the expectation that increased patient education and empowerment, together with improved staff insight into patient lifestyle will allow more shared decision making about treatment. This includes involvement of patients in the decision, and tailoring advice and equipment to accommodate patient needs and preferences. This is shown in the theory of change, and as a very simplified version in Figure 25.

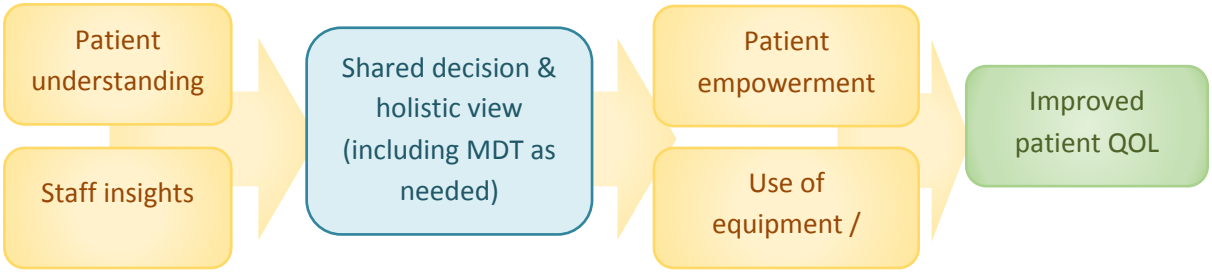


Figure 25 Simplification of selected elements taken from Theory of Change

5.1.1 Changes in patient understanding, empowerment and behaviour

The patient interview results describe instances where patients and carers had increased their understanding of how to use equipment, or what positioning is most beneficial. There are also instances where they feel empowered to query care outside of PROMISE, but attribute that confidence to the PROMISE intervention, or they have used PROMISE mapping to back up their opinions about a piece of equipment. This was discussed with the project team at the start of the project as one of the expected mechanisms.

Staff also discussed reflections from a relative that although the patient could not communicate verbally, the CPM gave a way to understand if they might be uncomfortable, and where any discomfort might originate.

However, patients may feel frustrated when they have to wait for referrals, additional appointments, or equipment. This process is very much out of their control and patients may feel worried about pressure damage occurring during the wait and that they have little control over this part of the process. The referral times are part of the existing system mechanism prior to PROMISE, and while PROMISE has started to address these issues in improving joint working, it still remains an issue raised by patients, relative and carers. When this has been mentioned, it has usually been couched in terms of "they are doing their best", and that individual staff members are doing their best, but never the less delays can cause anxiety and frustration.

During interviews and in questionnaire feedback patients are very positive about the PROMISE staff, with numerous examples such as

"the TV nurses have been absolutely fantastic, absolutely fantastic" P5

And many of the patients have felt very supported by the PROMISE teams

"Continually thinking of what she could do to help……..and that's what I love about her." P12

Where patients interviewed had not previously been seen by the PROMISE team, or tissue viability teams, they noted a large change in the quality of advice, and the level of input or expertise. This was associated with a first contact with tissue viability services, meaning that it is hard to know the extent to which it was related to PROMISE.

5.1.2 Balancing lifestyle requirements with tissue viability requirements

Patients and staff mentioned the change to encouraging sitting out more, rather than long periods with only bed rest.

"He's got new equipment, he's much more – he feels more supported on that equipment and he's now able to go back to his job, which he only does 4 hours on a Wednesday, but he's been able to get out and about more. " S1

Issues such as the importance of sleeping in the same room with a partner, or sharing a bed were mentioned as reasons for equipment choices. Practical issues such as space were also a factor.

"Has tried [mattress]but husband unable to tolerate…..[objective] is to remain in double bed with husband." DCF

"Patient is aware that the new wheelchair is too small for her but unable to have a larger chair as doorway in the home cannot be adjusted." DCF

5.1.3 Changes in patients using equipment or following advice

The patient reported quantitative data does not clearly reflect an increase in patients following advice. This is discussed with the results earlier, together with reasons why changes in staff beliefs (not wanting to label patients as non-concordant) as well as the format of the data collection form may have affected this. Staff report that their advice has adapted, together with their thinking, to consider a patient centred strategy; particularly around sitting out of bed more. This has also been mentioned by patients in interviews.

5.1.4 Increased joint working to give more holistic approach for patients

Multi-disciplinary working, combined with access to suitable equipment has been identified by all PROMISE teams as a key factor to success. This is an illustration of where PROMISE has facilitated a change in working practices, that has taken time to implement, but has grown throughout the project, and continues to grow. Therapists with skill sets that are complementary to the PROMISE staff can add additional understanding of the impact of positioning, transfers and other equipment, as well as seating and mattresses.

5.1.5 Resultant outcomes for patient quality of life

There are without doubt some patients that have experienced dramatic improvements in their quality of life, and have had healed pressure ulcers for several months. These patients have been able to return to their normal activities.

"We were able to get one patient to use her chair more and her pressure ulcer healed. That was what she wanted to do, go to Costa Coffee, and now she can. If we hadn't used the pressure maps we would have been advising to her to stay in bed." S5

However, qualitative data is mixed, even with follow up interviews. There are patients where PROMISE has not resulted in wound healing after extended period of time, and they can feel rather let down.

"well it's still going and we're still finding different cushions and seating and at the moment things have got worse."P3

Where PROMISE has not helped patients achieve their objectives, this may be because there are additional barriers to healing that PROMISE may help to identify, but remain difficult to resolve. This is discussed more in section 5.4 on barriers and facilitators.

The ultimate objective is not always to heal wounds, sometimes improving quality of life is more important to patients. The highest median score for PU-QOL measures at baseline was for social activities, and the importance of this was also clear in patient interviews.

For patients who are very frail or very unwell, wound healing may not be expected, and the main objective may be to allow the patient to be more comfortable, and avoid unnecessary interventions.

5.2 Evaluation Q2: Adaptations to PROMISE

How have different sites adapted PROMISE, and has this changed the way that it works?

Across all sites there was an adaptation from the original expectation that for most patients there would be initial pressure mapping, a change of equipment or advice, with possible additional mapping and further change. This was to be followed by reviews every four weeks, with data collection via patient notes. In reality most patients have had multiple pressure mappings and equipment trials, meaning that the expected follow-up reviews are not happening until the patient has been part of PROMISE for some weeks. A more detailed site description is found in Appendix B, with additional information on some changes specific to that site.

5.2.1 Team structure

At the start of their implementation process three of the four sites had a team lead who was active in attending meetings and contributing to the development of the project. As recruitment started, the responsibility for PROMISE started to pass to a single clinical person who would do the setting up the CPM. In one site the PROMISE work has largely rested with one person throughout the project, and in this case knowledge has not spread through the team.

Sites 1 and 2 both used existing staff to deliver PROMISE (with their time backfilled for normal clinical work). At these sites the staff were responsible for putting the map in and out, analysing the data, discussing the results with the patient and formulating a strategy. As the project progressed there was sometimes an additional person available to set up or collect the map, or follow up patients up. Site 4 recruited two new staff to share the PROMISE work, as well as other tasks, however for most of the evaluation period only one staff member was available.

5.2.2 Protected time, and set or flexible days

All teams have had strategies for protecting time to work on PROMISE. For most this has meant keeping certain days reserved for PROMISE. One site, which paused and re-started PROMISE, looked at their team structure and formalised the arrangement of a strategic lead and a clinical person. They paired this with protected time as in the example below:

"The Team have protected time on Monday and Wednesday afternoon for PROMISE. They book patients in on Monday and take the map out on Wednesday (if this is long enough). They then sit down and discuss patients and go through the folders with the whole team." S5

The use of additional staff for setting up and collecting maps or similar work can help allow sufficient resource for PROMISE.

Pressures on time were particularly severe for Site 3, as they also work in the acute setting, and could be called urgently to work in that area:

"the acute side pulls us away urgently, and then you can't plan or schedule work."S5

5.2.3 CPM durations

When the CPM duration is grouped by site, as shown in Figure 44 and Figure 45, Appendix I, together with information from interviews and meetings, it can be seen that :

SITE 1 have shorter seat mapping times, which may be due to a higher proportion of elderly patients and frail patients. Reduced CPM duration may be due to staff concerns about falls or about mental capacity.

SITE 2 have a range of shorter cushion times and also longer times of around 20-40 hours. They have a relatively high proportion of wheelchair users compared to SITE 1, and this population may spend more time seated than many other patients.

SITE 3 bed and seat CPM duration are quite strongly driven by the protected days, where patients will tend to have been seen on particular "PROMISE days" implemented at some stages.

SITE 4 CPD times are masked by attempts to overcome unreliable mapping equipment. This has now largely been overcome, and may have become clearer by the time of the implementation report in December 2020

5.2.4 Uses of CPM

Sites have reported a variety of adaptations and additional uses of CPM. This has included uses specific to single patients, such as adjustment of cushions, or reminders of positioning.

"….discussion with Tissue Viability to reduce prelude cushion lower than manufactures recommended setting for patients weight, so seat map used briefly in order to identify best setting ROHO delivery" DCF

"Advice given to nursing home with copies of the pressure mapping snapshots around positioning in bed to reduce pressure and prevent further pressure ulceration" DCF.

CPM has also been used to inform equipment purchasing decisions. Staff reported that they are now more likely to get involved in equipment purchasing decisions, that they have used CPM to test different pieces of equipment, and that this has acted as powerful evidence. They felt that involvement in PROMISE and the use of CPM gave their input more weight in the decision making process.

5.3 Evaluation Q3: Barriers and facilitators, Implementation

What are the barriers and facilitators encountered by the adopter sites, and what resources would help future implementation of PROMISE?

The PROMISE logic model recognises that PROMISE is more than the introduction of continuous pressure mapping. It also facilitates a move towards patient centred care, increased joint working and changes in equipment supply for pressure redistribution surfaces. These changes take time to come about, and this should be recognised as an integral part of PROMISE, meaning that the achieving results is a gradual process, but one that may have a broader impact beyond the patients directly involved in PROMISE.

Table 12 Barriers, areas that develop over time during implementation, as part of PROMISE, and facilitating factors in PROMISE

Area of development, or barrier	Facilitator
Time available within team, including external pressures	• Protected time planned into implementation
Developing experience in mapping	• Practice prior to visits, project manual • Support from existing implementation site
Developing or including experience in rehabilitation engineering / occupational therapy / physiotherapy skills	• Build up relationships with colleagues, increase joint visits. • Understanding that this learning is part of the implementation process • Include in stakeholder meetings and project communications
Support required from other areas: Managers, Information governance, IT	• Stakeholder meetings • Clear statement in project manual of what equipment and processes

Steep learning curve, requiring support from a HCP with experience	• Provided by project lead for PROMISE
	• Project manual has been developed and improved
	• Possible for future:
	  ○ web pages, online chat
	  ○ short placement with existing team
	  ○ support from an existing team
	  ○ support from manufacturers

Mapping equipment faults – issue for 1 site only, hopefully resolved.	• Good dialogue with manufacturers to explain how PROMISE is working and the support required
Discouragement in early phases	• Set up expectation of taking time to be in a routine – only a few months to learn pressure mapping, but may be over a year to build up experience of solutions and start spreading out to the rest of the team • Start with less chronic / less complex patients and then progress to longstanding ones
Limited range of pressure relief equipment readily available	• Understanding the range available locally, and the impact this may have on implementing PROMISE prior to start • Including key groups in early stakeholder meetings • Use PROMISE to demonstrate reasoning • Develop relationships with manufacturers to enable loan of equipment
Delays in additional visits, referrals or equipment supply	• Process mapping, or similar, to understand current service • Stakeholder meetings to involve all parties • Identify delays and work with other services to address them at an organisational level – this will take time

5.3.1 Developing experience in CPM

At the start of the project sites were nervous about the technical aspects of the equipment, the value and maintenance of the mapping equipment, and how to do the data analysis. In practice, the first few visits may have required practice to get out and pack away the equipment, but after that it is was largely problem free.

The data analysis took a little longer to get used to, but was not a long term issue. There is a learning curve, and sites found it invaluable to have support during this process (Figure 24). The project lead was very supportive and able to do in person visits to assist with the analysis in the initial stages, and also in expertise with the next steps after analysis.

"[project lead] taught me so much, the first week or so when she came down"S8

"I've gained so much more knowledge, just after speaking to [Project Lead] about um….the way the patients sit, or how long they're sitting or how they're sleeping, you know, the type of equipment they're on - you may not need to make a change, or you might need to make a change -,so just having that information seemed really invaluable" S10

During a project meeting eight months after the start of patient recruitment, the two established sites were able to demonstrate and assist the newer sites in looking at their data. In interviews some staff felt that they would be confident enough to take a supportive role with new adopters (this was specifically asked in terms of confidence rather than having time available). This support was seen as critical and several suggestions were made as to how to replace the role that the project lead had taken. These included previous adopters supporting new adopters, new adopters going out to work-shadow existing sites, support from manufacturers with clinical advisors with relevant experience, online e-learning.

The project team developed resources to help with this learning phase, and have continued improving these throughout the course of the project. A manual describing use of equipment and settings specific to PROMISE was developed and has since been improved further, following staff feedback. Laminated quick reference cards were also used as reminders for setting up and packing away equipment.

"but now we've got the paperwork changed, we've got that booklet that's been updated…. - it's a lot easier to follow now, than what it was initially" S8

Thinking about future implementation, there have been discussions about online learning or forums for exchanging knowledge, but the manual has been very useful.

"if there was an online tool to learning, like an E learning programme, to learn how to use the software. Because even now… I mean, I'm more confident ….but every day I'm ….when I'm analysing data I'm having to, look at the help manual and look back at my PROMISE bible and make sure I'm doing it right" S1

Staff felt that having someone to guide them through the initial processes was invaluable, and this relates not just to the technical side of mapping, but also to how it is best discussed with patients.

"I'd say anyone being employed into it needs to go and spend time with a team who have already done it before" S1

"I think potentially going out with someone who has done it before and actually physically seeing what goes on and what you need to do …..or being in the classroom….and actually going through …what actually happens" S8

5.3.2 Developing experience in pressure redistribution and equipment

Although this took longer, it is an integral part of the PROMISE process, rather than a barrier to success. This involved developing knowledge and understanding of posture, positioning and pressure relieving equipment. In addition, developing a closer working relationship with other health care professionals, both within the NHS and external equipment suppliers, provided an extra level of expertise and experience to work with.

"We have no relationship with these people, [mobility centre]……you're coming back from this visit and you're then having to contact various people, they're then calling you back and it sound silly, but time builds up….."S6

This has developed throughout the project across all sites, and staff using CPM all report an increase in their knowledge, and improvement in their relationships with OTs and wheelchair services. Interviews with these groups confirm that they have also seen this change as a positive move, and welcome the joint approach.

"[thinking about the future] it wouldn't take long to pressure map them….. I envisage you could work that within the week, and it wouldn't take up too much time. I guess it's having the time to look at the data and act on the data, within normal community nursing role." S10

Although the move to joint working is seen as very positive, there were many reports of delays in waiting for visits, particularly for equipment assessments, but also for tissue viability. There is no indication that this has increased during PROMISE, but may be more apparent to staff due to the more active follow-up of equipment requests, and more scrutiny of results. One site also mentioned delays for non-mobile patients being weighed as an issue, causing delays in setting the correct mattress pressures.

During the process mapping work with sites and from the implementation team reflections, it was identified that delays for seating assessment could be particularly long, and the process more complex than for mattresses. There was also often a need for several cushions to be tried, and possibly several cushions for several different chairs.

5.3.3 Availability of pressure redistribution equipment

There may be long waiting times to get some types of equipment, particularly if specialist visits are also required. Each site had certain types of equipment that are readily available, and there can be a time factor in obtaining anything that is outside of the normal provision. In addition, there are funding barriers where patients or residential homes may need to provide the funding.

"This patient is in a residential home that will not provide patient seated pressure relief therefore patient needs to self fund." DCF

5.3.4 Protecting time within the team, and external pressures on that time

All teams experienced times when they were short staffed due to staff absences, changes in staffing or changes in other areas of workload, and this is likely to be the case for any other team that takes on implementation. This has often been a barrier to spreading within the team, as that involves a second person coming on visits, and spending time to learn.

"So where we are at as a team, we're really quite stretched, and having to cover this [another service] - it makes it quite difficult for me to have a lot of double visits, where there is two of us going out…"S8

Teams need to understand to what extent the PROMISE structure is different to their existing model of care, and how they will support this. They also need to understand how doing more in-person visits will impact on a team that does not normally do them, and the time they may spend in following up changes in equipment.

Sites used different team structures, but most have combined a senior person to take a lead role initially, particularly in the organisational aspects, and a more operational person with primary responsibility for delivering CPM, analysis and changes in care.

"On reflection you need an allocated person to take the lead and be in control. It needs some dedicated time. You just can't just add it to the daily workload."S5

Although some sites attempted to spread this more widely initially, in practice there was a single person in each site who established PROMISE to some extent operationally before it spread to a wider level. The process of spreading to the rest of the team has been slow, with time pressures being the main barrier stated. At the point of this report, the tissue viability teams are all moving towards additional members of staff being comfortable with the CPM process. For the DN team, it remains mainly with one individual.

5.3.5 Support

Support from the project lead has been a huge facilitator, which all sites welcomed and appreciated. This has included technical support on pressure monitoring and analysis, support in identifying solutions for patients as well as regular injections of enthusiasm and drive.

Methods of continuing supporting a different form that would allow a wider spread, have been discussed by the project team and implementation sites. These include:

- PROMISE manuals and quick guides – these are already developed and in use
- Online support network groups for sites using PROMISE
- Work shadowing at a site that has previously implemented PROMISE
- Virtual support from a mentor who has previously implemented PROMISE
- Staff have also commented that support from the company by staff with clinical and technical experience would be a very useful resource in future spreading of PROMISE

Support from site leads, and at an organisation level is also important, in allowing PROMISE time to develop, and protecting time for implementation.

"I've made sure that TVN delegated to the project has protected time to dedicate to the project and I feel that she's worked extremely hard and has an in-depth understanding of the documentation and the map and how to use it." S9

5.3.6 Mapping equipment – initial installation and additional issues

It is recognised that when introducing a new healthcare technology there are likely to be barriers around to healthcare. In the initial stages of introduction, time had to be spent on issues such as installation of the correct software on the most appropriate devices and purchasing and connecting appropriate external hard drives. The project team are working to produce a specification of equipment required to assist this, however a certain level of IT support should be included in planning any new implementation.

In addition, the last site to come into the project, purchased a newer model of pressure map which included a Bluetooth connection between the screen and map. They experienced problems with the newer model, where the map was not staying on and did not continue to record when left over time. In some cases where patients are a 1-2 hour drive from the team base, this caused a lot of frustration to staff. Early delays were not related to the mapping equipment, but once these were resolved the site were still unable to fully implement PROMISE for several months.

"then when we finally got the hard drive sorted out, it was the continuous errors we've had on our - our equipment."

The equipment has now been repaired, and loan equipment was provided for use during this period, however it has taken several attempts for them to have reliable mapping equipment available. This has limited implementation of PROMISE as intended, with only 9 patients included at the end of the evaluation phase.

"it still doesn't work for long periods of time, so trying to get pressure over time has been a struggle,"

The Project lead has worked with the manufacturers to resolve this, and make improvements to the system based on these experiences. This included a visit to their offices in Canada to explain how the mapping system was being used in the community, and discuss improvements to support this use.

The site are now able to use the cushion map, and have started mapping for extended periods of time. They are continuing to collect data as part of the extended PROMISE project for a further 6 months, and mapping equipment improvements can be reported in the implementation report at the end of this period.

The other three sites experienced very few technical issues with the mapping equipment once the initial setting up process was completed.

5.3.7 Involving other people

Following the start of implementation in November 2018, it was soon realised that involvement from other stakeholders was going to be critical in establishing joint working practices and finding the best patient centred approaches. For the sites starting, or re-staring in spring 2019, stakeholder meetings were held during the start-up process. These involved senior managers to support the project, equipment suppliers, community OT and physio staff, community nurses and IT support.

"*I would review the way I set up the project: now I would do differently – the stakeholder group needed to be established before the launch. S5*

"The project needs to be shared in wider, multidisciplinary, team. As an example you need wound assessment, nursing, and OT skills, they're the ones in the area that did it before" S5

Two of the sites carried out process mapping with their local QI teams to look at who was involved in equipment supply process, and the evaluation team also mapped routes to equipment supply with each site. These processes informed discussions about where delays may occur, who should be involved in the project, and the level of complexity for supplying some types of equipment.

"the process mapping was really helpful to understand, who would be involved, what the processes were"S3

Both staff and patients experienced concerns and frustration about the waiting times experiences when arranging joint visits, assessments and requesting equipment. This is likely not to be something that is due to PROMISE, as referrals for assessment and equipment may have been made previously, but has been highlighted by the PROMISE project.

5.3.8 Starting gradually and setting expectations

All sites found that they wanted to start with those patients who had the greatest need, were more complex, and had long standing pressure ulcers, but this led to frustration for staff and patients at times. Pressure to find a solution, and the multiple complexities for these patients made the learning experience harder. Staff agreed that it would be better to start learning with patients that have less complex issues. They can then build up their experience and improve MDT relationships gradually, while providing a good experience for patients, and also building confidence through successes. This expertise can then be used more for the benefit of the patients who have more complex requirements, where identification of high pressure areas is only one part of the picture.

"And just do it slowly I think is the other thing, do a bit at a time and build it up…….Actually most of those people who have got those really complicated problems - pressure relief probably wasn't, wasn't the biggest part of their issue." S3

Everyone involved, including patients and staff in other areas, need to allow time for staff to learn and MDTs to become established.

"Um I think just making sure that they have really good time to learn how to - and understand how the technology works. "S3

"They need to give themselves time, in the first place… to begin with it is going to take longer…… particularly while you're getting used to the equipment and what you're looking at when downloading the information and things like that."S8

5.4 Evaluation Q3b: Barriers to healing

It is important to realise that although pressure mapping offers a unique insight into patient behaviour and pressure distributions, and facilitates improved joint working, understanding and shared decisions making, it is an investigative tool. It enables health care professionals to identify the location and possibly

the cause of problems, it opens up conversations, improves both patient and carer understanding, but may not actually provide the solution – this still has to be identified and agreed. For some patients this may be very challenging. There can be numerous barriers to healing, some of which were identified in staff and patient interviews (section 4.5.9) and in existing literature. In some cases the additional information and expertise from PROMISE may facilitate a solution. However there will be cases where PROMISE may help identify and understand the barriers but may not always be able to resolve them.

5.5 Evaluation Q4: Embedding into normal practice

Has PROMISE become embedded into normal practice at each adopter site?

There is consistent information from interviews, meetings and staff survey results that all three TVN sites plan to continue using continuous pressure monitoring. Two of these sites are part of the extension of the PROMISE project, due to delayed start of recruitment. The district nursing site is unlikely to continue PROMISE in the current form, although they do plan to use the monitoring equipment on a limited number of patients and to work further with OTs to ensure patients benefit from it.

The concepts behind PROMISE have been adopted by the staff using mapping, and they regularly and consistently report that there has been a change in how they think about patients.

"It's been a sea change in the team, how we view people and their non-concordance" S6

Joint MDT visits are implemented and welcomed by both PROMISE teams and the other disciplines, and these relationships will hopefully continue into the future. PROMISE teams have become more involved in evaluating pressure redistribution equipment, including using the monitoring equipment as part of the evaluation. This has enabled them to contribute with more authority to purchasing decisions. This is one example of PROMISE becoming more integrated into the main organisation, and additional value being found from both the equipment and expertise that have been acquired. An improved selection of equipment has potential to benefit patients from a much wider group than those directly treated during the PROMISE project.

Some plans have been hindered or delayed where equipment was not yet fully reliable, which has been frustrating for staff. However these delays have now been overcome and additional staff put in place to ensure continuation of PROMISE into the future.

"I just felt like, if we've haven't got the kit working in the way – even anyway near - the way we need it to, it just feels (pause) like it's not good use of everybody's time." [talking about meeting to plan for the future] S3

Spread to wider teams, in particular the district nursing team, was limited mainly by staff time, together with the logistics of scheduling the joint visits needed for learning. Although this was a delay to spread within the teams, it is gradually developing in the TVN teams.

"I think as far as the impact on the team it hasn't had as much of an impact as we'd expected it to do because we've had to reign it right in because we can't free up staff to learn…..and that's ultimately the issue there. " S7

And for some, the underlying message of PROMISE has spread throughout the team

"The whole team has taken that away from the project – stop nursing at people and start nursing with people" S6

The implementation report in December 2020 will update on the continued use of PROMISE and further sustainability plans for all four sites.

6 Discussion: Secondary evaluation questions

6.1 Evaluation Q5: Formative information

Provide formative information to sites to enable them to adapt and improve their implementation of PROMISE during the study

The formative elements to the PROMISE evaluation, with their contribution are summarised in Table 13

Table 13: Formative elements of PROMISE evaluation

Formative element	Contribution to project
Facilitation of logic model / theory of change development	Development of shared understanding and the broader mechanisms contributing to PROMISE
Evaluability assessment, and updates	Sharing analysis of strengths and weaknesses to improve planning of evaluation
Relationship mapping process	Contribution to understanding relationships between PROMISE teams and other health care professionals and equipment suppliers
Monthly feedback on data collection forms	Able to review data collected to date, patient progression and time in PROMISE
Graphics of patient journey	During initial implementation highlighted the differences between sites and the repeat visits required
Graphs of patients mapped and in active phase of PROMISE	Monitor progress in recruitment, allow understanding of workload encountered
Staff surveys	Rapid reviews of changes in knowledge or importance of issues – questions posed by evaluation team or project team
Presentations at team meetings	Short presentations to project team and sites to update on areas of the evaluation

The formative element of evaluation has evolved throughout the project. A formative feedback template was adopted to facilitate a monthly discussion between evaluation and project lead teams. This has been useful in some months, but has been difficult to maintain meaningfully throughout the course of the project.

The evaluation team produced an evaluability assessment report (and update) after 6 months, and an Interim report, 18 months into the project. Reports have also been made to project meetings and support given to develop logic models and mapping routes to equipment supply

6.2 Evaluation Q6: CPM usability

Identify any usability issues encountered with the pressure monitoring technology

Generally CPM is well accepted by the majority of patients. A minority may experience some issues with slipperiness, the monitor being bright, or not being able to see the display (although stands etc. have been introduced by the project team to improve this).

Staff found that they need to practice unpacking and repacking the map and equipment so that they are familiar with it, before they need to do this at the patient's house. This is not a problem, but more a suggestion for future implementation sites, so that staff feel confident.

There is a need to liaise with both IT and information governance locally to ensure that local systems are compatible with the requirements.

Issues with the Bluetooth model have been reported earlier in the report, and although they caused implementation delays in this project, they have hopefully been resolved for any future implementation.

Apart from this there were few issues reported with the monitoring equipment. One noted was that the USB connection should be left attached to the mat to avoid it becoming damaged.

Additional resources were created by the project team to improve ease of use e.g. quick guide cards, stands for monitor, cases etc. Other additional resources were purchased such as external hard drives and stands for the monitor.

6.3 Evaluation Q7: Monitor wound size

Monitor changes in wound size over time

The analysis of wound healing is presented fully in the results section, and wound sizes were used in formative reporting to project team and sites. Although there is a large amount of rich data which can be analysed, there are limitations to additional analysis.

There is no comparative group for this data, which limits the conclusions that can be drawn about the effect of PROMISE. In addition, patients included in PROMISE have complex issues, and therefore quantitative analysis does not show the whole picture. If results are split further into smaller sub groups, the numbers of patients become very small, and still retain considerable heterogeneity. For this reason any sub group analysis should be treated with great caution.

There is a difference in apparent when looking at time to healing, grouped by pressure ulcer grades. As would be expected from existing knowledge of pressure ulcers, the higher grades (3 and 4) take longer to heal than grade 1 and 2.

Future work could look at the comparison between wound healing in this project and the previous project.

6.4 Evaluation Q8: Resource implications

What are the resource implications of introducing continuous pressure monitoring in the community?

Sites had 15 hours per week of a band 6 post funded, and used that in different ways. For sites where they used this resource for one person, the project easily took up that time. It became apparent that although the recorded visit times can be over an hour in length, and repeated on several occasions, this was not the only additional time required. Travel time to patients' homes is an important consideration in geographically widespread implementation sites. Learning time is important for the CPM process and analysis, but this becomes easier over the first few months of implementation. Time to seek solutions, both individually and by working with other health care professionals was reported as very time consuming. Over time this may become easier, as staff already report improvements in their knowledge and MDT relationships. As they build experience it may become easier to identify appropriate strategies, however this will take time, and each patient has a complex and unique set of challenges that have led to their inclusion in PROMISE.

Although equipment has been changed during PROMISE to a wider selection of devices and more tailored to the patient's requirements, there is no evidence that points towards an increased cost of equipment provision. Initial analysis indicates that there is not likely to be any overall change in cost of equipment provision, although improvements in procurement processes (utilising PROMISE) may have a longer term positive impact. The economic report in December 2020 will report on this in more detail.

7 Discussion: Additional findings

7.1 Learning and personal development.

This has been very important for staff in all areas of the project, and has provided opportunities to develop beyond their previous roles. There have been many comments reflecting that participation in the PROMISE project has been challenging at times, but has resulted in a huge increase in knowledge and experience.

"Ok, well huge learning curve, so really enjoyed learning about pressure mapping and ….that has allowed more time to spend with the patient…. It's hard to gauge whether, because I was spending time pressure mapping, that I sort of identified other areas or care that need…..or whether I would have done that anyway without the mapping …."S10

7.2 Lessons for future scaling up projects

The project has been a learning experience for all involved, both challenging and rewarding. The learning event days organised by The Health Foundation enabled implementers to share experiences and encouragement, finding out that we were not alone in encountering (and overcoming) obstacles. The initial learning event was particularly mentioned as important in visualising the future of the project

"I found the work undertaken by the Health Foundation very interesting and broadened my knowledge outside of tissue viability. It gave me a vision of how this was going to look when it's complete" S9

For the evaluation team, the development of a dedicated evaluation support role and an evaluation handbook have been invaluable. This will hopefully make the initial phases of future projects a little clearer. The handbook is useful not only to evaluation teams but also to share with project teams as an aid to setting roles, responsibilities and expectations.

The process of understanding roles and responsibilities between the project and evaluation team was not easy, and consumed both time and energy throughout a substantial part of the project. This was eased during the periods when a project manager was in place.

The project manager is a critical role to have in place all the way through the project, but particularly in the initial stages, where the ground work is set for the next 3 years. In addition, it can be a slow and difficult process to release project leads from their normal clinical responsibilities, or to recruit any new staff. A project manager can smooth this process by handling some of the day to day responsibility.

Although the support and coaching received by both project and evaluation teams helped us to develop and learn, there may have been times when earlier intervention or more prescriptive guidance would have improved the project (for example approaches to ethical approval).

Evaluation of complex implementation projects is very time consuming, and the funding of an independent evaluation team protects some time to focus on this aspect alongside the project teams focus on implementation issues.

8 Key messages for future implementation

8.1 Prior to implementation

PROMISE is likely to be used for small numbers patients with more complex needs, who may already have received additional visits and follow-up. It is likely to work best when there is good multi-disciplinary working and a shared vision of patient centred care in place in the community. PROMISE proved to be a catalyst in improving these elements throughout this project.

8.1.1 Understanding current context of the team

Some community health structures will lend themselves more readily to the implementation of PROMISE. Where patients with complex needs are already visited face-to face, on a regular basis, or where there are good working relationships with equipment providers and other health care professionals, it is likely to be easier to implement.

The current pressures in the team should be understood, for instance a team covering acute areas found it much harder to plan PROMISE work, due to conflicting urgent demands on their time. Sites that do a large proportion of their advice via phone and email may experience a greater change in time demands. However. A large geographical area, can also present a challenge, meaning that additional time and organisation is required. Teams need to have sufficient drive and enthusiasm to implement what can be quite a disruptive change. Although sites displayed considerable determination and commitment to delivering PROMISE, the leadership from the project team was key to keeping the momentum going.

8.1.2 Obtain organisational support

There is a financial investment required for the equipment, and also for staff time during the implementation and learning phase. PROMISE may highlight areas where improvements could be made, including in areas outside the implementation team, and this can be seen as an opportunity to improve patient experience and multidisciplinary working. Input will also be needed from Information Technology colleagues, and possibly from information governance to set up the hardware and software required.

8.1.3 Establishing collaboration and interest from peers in other disciplines

All implementation sites found that they increased the amount of joint visits and built on their relationship with equipment providers and prescribers and other health care professionals. The ecological model (Figure 6) demonstrates the range of people involved in providing patient care and services in the community. Although it is not realistic for everyone to be included, a holistic approach will require expertise from a range of disciplines.

The lack of this relationship was rapidly established as a barrier and start-up meetings were held with colleagues for the second wave of implementation.

The PROMISE project team have created resources and posters to explain and publicise PROMISE.

8.1.4 Set expectations

Sites reported that it took a few visits or practices to become familiar with the equipment and several months to become confident with data analysis. It took much longer to accumulate experience of identifying solutions, and build up relationships with other health care professionals who could contribute expertise. This process of improvement of services and individual learning is a key part of the PROMISE theory of change, an opportunity for staff to develop, and should be embraced as part of planning a new implementation.

Sites all recommended that any new implementation should start with simple cases, and build up to more complex patients as they grew in confidence. This expectation should be shared with other who may refer into PROMISE. One site became overwhelmed by demand for CPM before they had been able to build up capacity.

8.2 During implementation

8.2.1 Build in peer support or networking opportunities

PROMISE was largely implemented by a single member of the team initially, with the support of the team lead. Staff benefited from having study days where they could exchange ideas and form a wider support network for each other. Sites also had both motivational and technical support from the PROMISE project lead.

The PROMISE team have developed resources such as a visual guides to packing up the map and user friendly guides for data analysis that are adapted for PROMISE. These resources provide some of the support that sites needed during initial implementation

8.2.2 Allow learning time

Staff all valued having protected time to develop skills with both CPM and identifying solutions. For the PROMISE project, this was 2 days per week, but included project specific tasks such as completing data forms and familiarising with project procedures.

8.2.3 Manage expectations

Implementation sites found the initial months difficult as they had started with patients who had very complex needs. Where sites were able to start with simpler cases they could build their confidence initially.

8.3 Normalisation and spread

8.3.1 Additional uses for CPM

As CPM becomes more established, staff have found additional applications such as training or evaluating pressure redistribution equipment. These may also contribute to the overall aims of PROMISE by increasing knowledge and availability of the most appropriate equipment.

8.3.2 Spread within the team

Once at least one member of the team was familiar with CPM and had built up processes for identifying and obtaining equipment or other support, they were able to start spreading the knowledge to other members of the team. This is likely to require staff visiting patients together and so will, again, require additional time to be allowed for this.

9 Conclusions

The evaluation has produced strong evidence that:

- Staff are very committed to making PROMISE work and continuing its use
- Mapping was acceptable to patients and staff can implement it
- Staff report a change in their thinking towards patient centred care and concordance
- The project led to development and learning for PROMISE teams
- More joint working resulted among staff and agencies involved in caring for patients with PUs
- Plans for sustainability are being put into place
- Pressure mapping is one element within a complex system

In addition the evaluation has found that:

- Some patients with chronic wounds or frequent recurrences over time have healed and remained healed. Staff and patients attribute this to PROMISE. It is not a universal experience, but many patients had stubborn, non-healing pressure ulcers that have healed.
- Success requires considerable drive, not just to implement PROMISE but to reorganise equipment supply and develop joint working.
- It takes time to implement and requires wider change than anticipated
- Protected time and mentoring are important

Involvement in PROMISE has had a positive impact on the staff involved and the service that they deliver. Staff report a change in the way they think about treating patients with pressure ulcers, and have increased their experience in pressure redistribution strategies. They are very positive about PROMISE, and the project team have worked very hard with adopter sites to overcome the challenges encountered and provide the best possible care for patients with complex needs.

PROMISE has facilitated the establishment of multidisciplinary working with equipment suppliers, and is starting to influence the types of equipment that are available.

Some patients report that PROMISE has been a key factor in healing chronic pressure ulcers, or preventing frequent recurrences.

Potentially the full implementation of PROMISE could mean streamlining equipment supply, re-evaluating the equipment choices available, and increased joint working between teams. In addition to increasing the knowledge of pressure relief approaches for patients and adopter teams, it has an educational role for other staff e.g. community nursing or care staff.

To conclude, PROMISE has potential to be embraced as a starting point to improve how services can work together to improve pressure ulcer prevention for patients with complex needs in the community. It encourages staff to look beyond the traditional boundaries of their specialist area, and see the bigger picture for both holistic patient centred care, and holistic service provision.

References

Aylward-Wotton (2016) Improving pressure damage detection in the community using continuous pressure monitoring of patients. The Health Foundation Innovating for improvement, final report.

Behrendt, R., Ghaznavi, A. M., Mahan, M., Craft, S., & Siddiqui, A. (2014). Continuous bedside pressure mapping and rates of hospital-associated pressure ulcers in a medical intensive care unit. American Journal of Critical Care, 23(2), 127-133.

Craig P., Dieppe P., Macintyre S., Michie S., Nazareth I., Pettigrew M. (2019) Developing and evaluating complex interventions: Following considerable development in the field since 2006, MRC and NIHR have jointly commissioned an update of this guidance to be published in 2019. Available from: https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/ Last accessed: 08 Aug 2020

Crawford, S. A., Strain, B., Gregg, B., Walsh, D. M., & Porter-Armstrong, A. P. (2005). An investigation of the impact of the Force Sensing Array pressure mapping system on the clinical judgement of occupational therapists. Clinical rehabilitation, 19(2), 224-231.

Dale, M., Cox-Martin, B., Shaw, P., & Carolan-Rees, G. (2014). Cost-effective non-surgical treatment of chronic pressure ulcers in the community. British journal of community nursing, 19(Sup3), S6-S12.

Dale M., Poole RL., Aylward-Wotton N. (2018) PROMISE: Pressure reduction through continuous monitoring in the community setting. All-Wales Medical Physics and Clinical Engineering Summer Meeting, Cardiff, UK, June 2018.

Gorecki, C., Brown, J. M., Cano, S., Lamping, D. L., Briggs, M., Coleman, S., Wilson, L. (2013). Development and validation of a new patient-reported outcome measure for patients with pressure ulcers: the PU-QOL instrument. Health and quality of life outcomes, 11(1), 95.

Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., Hinder, S., Shaw, S. (2017). Beyond adoption: a new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. Journal of medical Internet research, 19(11), e367.

Greenhalgh, T., Papoutsi, C. (2019). Spreading and scaling up innovation and improvement. BMJ, 365 :l2068

Gunningberg, L., & Carli, C. (2016). Reduced pressure for fewer pressure ulcers: can real-time feedback of interface pressure optimise repositioning in bed? International Wound Journal, 13(5), 774-779.

Hanson, D. S., Langemo, D., Anderson, J., Thompson, P., & Hunter, S. (2009). Can pressure mapping prevent ulcers. Nursing, 39(6), 50-51.

Herdman, M., Gudex, C., Lloyd, A., Janssen, M. F., Kind, P., Parkin, D. & Badia, X. (2011). Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of life research, 20(10), 1727-1736.

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., Lamb, S. E. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ, 348.

Kirby, S., Donovan-Hall, M., & Yardley, L. (2014). Measuring barriers to adherence: validation of the problematic experiences of therapy scale. Disability and rehabilitation, 36(22), 1924-1929.

National Pressure Ulcer Advisory Panel (2014), European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance, Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Emily Haesler(Ed). Cambridge Media, Osborne Park, Western Australia

NHS Choices (2020) Pressure ulcers (pressure sores). Available at: https://www.nhs.uk/conditions/pressure-sores/ Last accessed: 11 Aug 2020

NHS Institute for Innovation and Improvement (2005) Evaluating Improvement.NHS England. Available at: https://www.england.nhs.uk/improvement-hub/wp-content/uploads/sites/44/2017/11/ILG-1.5-Evaluating-Improvement.pdf Last accessed: 11 Aug 2020

Rapley, T., Girling, M., Mair, F. S., Murray, E., Treweek, S., McColl, E.,Finch, T. L. (2018). Improving the normalization of complex interventions: part 1-development of the NoMAD instrument for assessing implementation work based on normalization process theory (NPT). BMC medical research methodology, 18(1), 133.

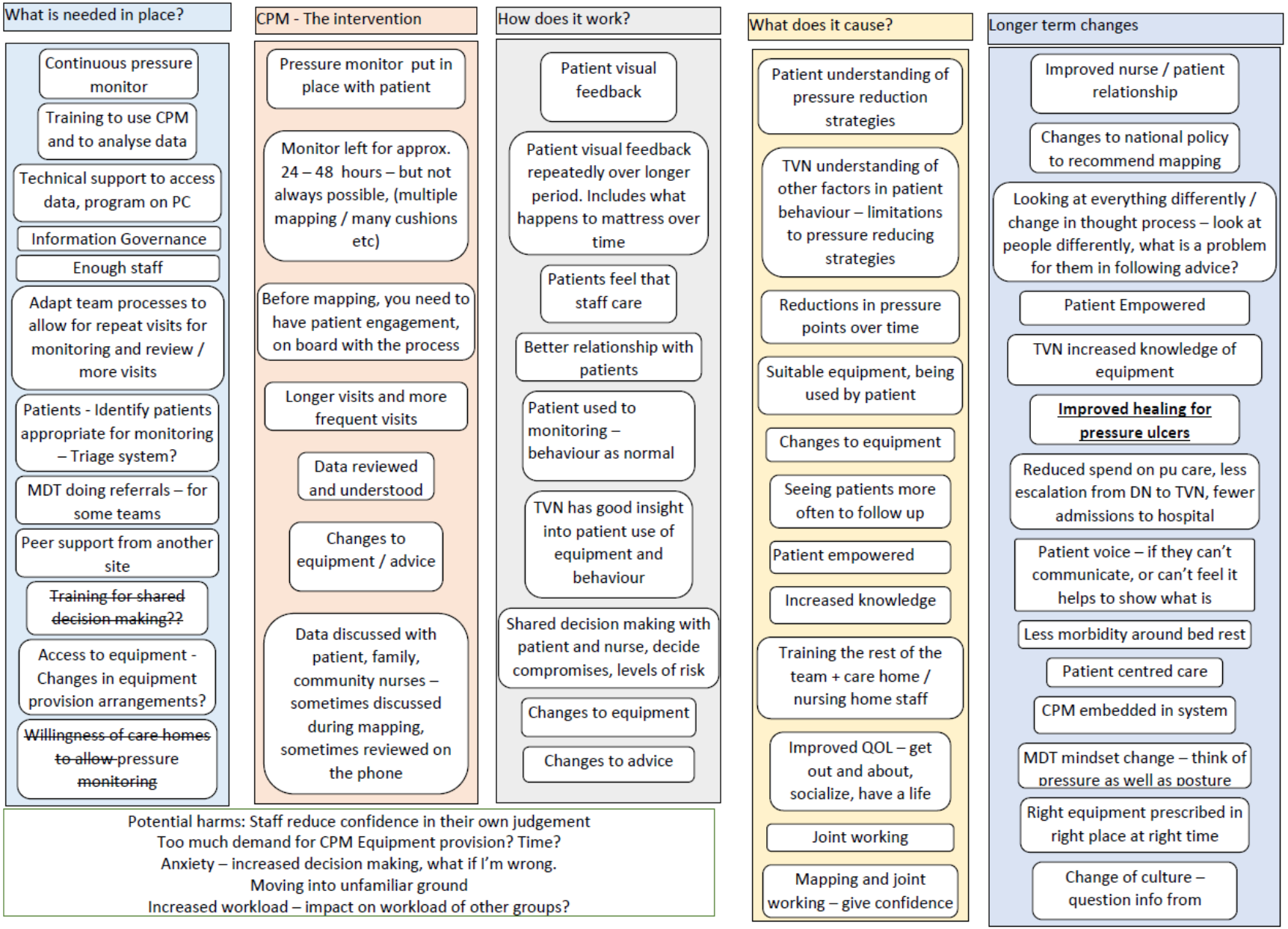
Siddiqui, A., Behrendt, R., Lafluer, M., Craft, S. (2013). A Continuous Bedside Pressure Mapping System for Prevention of Pressure Ulcer Development in the Medical ICU: A Retrospective Analysis. Wounds: a compendium of clinical research and practice, 25(12), 333.

The Health Foundation. (2015) Evaluation: What to consider. Available at: https://www.health.org.uk/publications/evaluation-what-to-consider Last accessed: 11 Aug 2020

Tung, J. Y., Stead, B., Mann, W., Pham, B., & Popovic, M. R. (2015). Assistive technologies for self-managed pressure ulcer prevention in spinal cord injury: a scoping review. *J Rehabil Res Dev*, *52*(2), 131-46.

Walia, G. S., Wong, A. L., Lo, A. Y., Mackert, G. A., Carl, H. M., Pedreira, R. A., Sacks, J. M. (2016). Efficacy of monitoring devices in support of prevention of pressure injuries: systematic review and meta-analysis. Advances in skin & wound care, 29(12), 567-574.

Appendix A PROMISE Logic model



Appendix B Context of individual sites and changes during PROMISE

Site 1 district nurse team

Setting and population

Although the large geographic spread was an issue for the TVN team who developed PROMISE, this area is split between several DN teams, with the Site 1 team covering an area approximately 15 miles across.

Normal service prior to PROMISE

In Site 1, the district nurses (DNs) are more likely to see patients who do not have pressure damage, but have a high level of risk, or who develop grade 1 or 2 pressure damage. Patients with more severe pressure ulcers would normally be referred to the TV team, although as part of PROMISE they may now initially be seen by the DN. As a DN team they have a large case load of patients (approximately 1000) that they see regularly, in some cases several times a week.

Team structure during PROMISE

In Site 1, there is one nurse who is predominantly responsible for PROMISE work, and who has protected time for this purpose. She is supported by a Health care assistant, who helps set up the map, may remove maps and arranges for weighing to adjust mattress settings. It has proved very difficult to spread PROMISE work further into the team, mainly due to staff capacity and also the additional expertise that has been required to focus more exclusively on tissue viability.

Pressure redistributing equipment

District nurses would normally request equipment for patients who need a change of mattress or cushion, or would refer to the community rehabilitation team, OTs, or wheelchair services. Since PROMISE, the DN has been more involved in trying to find the right solution and chasing up appointments and equipment than would have been the case previously.

Site 2

Setting and population

Site 2 is part of a community interest company (CIC), and the tissue viability team deal entirely with community patients, including those in residential and nursing homes. Patients are spread over a wide area making travel times a significant factor.

Normal service prior to PROMISE

All patients with a grade 3 or 4 pressure ulcer, or that are causing concern, are referred to the tissue viability nurses (TVNs). They will make an appointment and visit the patient, give advice, and then will normally not follow-up further unless there is a particular worry, or the patient is re-referred. Some patients are actively monitored, typically only 8-10 patients at any one time.

Team structure during PROMISE

The Site 2 team used the staff funding to utilise an existing member of the team to work on PROMISE for 15 hours a week, and employed (or increased hours) additional staff to cover her normal work. The clinical lead for the team ensured that the TVN had protected time to work on PROMISE, this was on a flexible basis rather than fixed days, initially, with a change to fixed days

during the project. During the course of PROMISE other staff have helped put maps in and out, attended meetings and carried out joint visits. For most of the project the PROMISE work has primarily been the responsibility of one TVN, however another nurse is increasingly being involved including downloading data and starting to learn analysis.

Pressure redistributing equipment

Mattresses: If mattresses are needed, the TVN team can access these through the district nurses. The area for Site 2 covers two separate funding bodies for mattresses, meaning that the available equipment is different depending on the patient's location

Wheelchairs & cushions: For wheelchairs, prior to PROMISE these would also be arranged through district nurses. Since PROMISE the TVNs may contact the wheelchair provider and company reps for loans of equipment, without going through DNs.

Seating: For static seating, the community OTs need to visit patients and then refer to an independent seating advisor.

Site 3

Setting and population

Site 3 are a TVN team that covers a wide area with a mix of urban and rural populations, and is unique in the implementation sites in that they run both a community and acute service. This leads to time pressures for acute work that, alongside staff shortages, have made it difficult to allocate adequate time to PROMISE on occasions.

Normal service prior to PROMISE

The team do not normally keep any patients as a case load to be routinely followed up over a length of time. If needed, patients would be re-referred back to them. The majority of referrals will be electronic, by photo and require advice without a visit, although more complex patients, as included in PROMISE would be seen in person.

Team structure during PROMISE

Site 3 have encountered some issues with implementing PROMISE, but have used this as an opportunity to reflect on their experiences and improve implementation. Initially the team were implementing PROMISE from within their existing team members, however the time required for implementation combined with staff sickness and other pressures on the team meant that this became difficult to continue. The team paused implementation, recruited an additional member of staff (an assistant practitioner), with project funding, to help with PROMISE and restarted in May 2019. The new staff member carried out initial joint visits with the TVNs, and they dealt primarily with the mapping, downloading and reviewing the data, discussing the data for advice from TVNs and requesting equipment. At this point the PROMISE work was primarily carried out by one member of staff, but with responsibility and input for wound assessment and advice spread amongst the team. Following a change of staff, the PROMISE work is now split equally between team members, each having their own patients and responsibility for the PROMISE and wider tissue viability aspects. The extended follow-up by the project team will be a chance to report on the success of this approach in sharing PROMISE across the team.

Pressure redistributing equipment

The TVNs can request mattresses with the DNs, and they have two separate suppliers for cushion and seating, depending on the geographical location of their patient, with a third supplier for wheelchairs.

Site 3

Setting and population

Site 3 have recently moved from being part of a community and mental health NHS Foundation Trust, to a merger with an acute NHS trust, however the tissue viability teams have remained separate. The team have only recently (January 2019) taken on responsibility for patients in nursing homes

Normal service prior to PROMISE

At the start of the project approximately two thirds of patients would receive a face to face visit, with some just requiring advice to the health care professional. The more complex patients will receive regular visits, depending on the clinical need. The TV team have approximately 158 patients at any one time who are being actively followed-up.

Team structure during PROMISE

Two members of staff (band 5) were initially recruited to share PROMISE work, along with other duties, however due to staff changes it has been predominantly one member of staff who has taken on PROMISE until recently. This has been coupled with some delays and equipment issues that have been unique to this site, and is discussed elsewhere in the report (Section 5.3.6). However there has been very active planning for PROMISE to be sustainable in the future and an additional member of staff is now taking on PROMISE activities, with related substantive posts having been created.

The team persisted with implementation throughout numerous delays, however for approximately 6 months of involvement in PROMISE they were unable to implement their plans fully and it has taken considerable determination to get through to a point where they are now using mapping more regularly.

Pressure redistributing equipment

Standard mattresses and cushions for low risk patients can be collected from store rooms at community hospitals, these may also be used as a temporary measure for higher risk patients.

Other equipment from the equipment store is ordered through district nurses, who also order more additional equipment as a special order.

Wheelchair assessments are by referral through the TV team or the OTS, and may be at home or in clinic.

Appendix C MDT relationship and equipment supply diagrams

The arrangements are different for each site, but we have sought to generalise in these diagrams, to understand to process and aid future implementation. Therefore it will not be wholly accurate for any one location.

Patients in PROMISE are likely to be seen by the district or community nurses. The nurses may request changes in mattress types if required, or refer to therapists or wheelchair services if they feel that the patient's seating needs improvement or adjustment. They will also liaise with GPs, care agencies, and other health care professionals. In some areas DNs will request equipment directly, in others it may need to be authorised by TVNs. DNs will also refer to TVNs if the pressure ulcer is not healing, or they need additional input.

Generally mattresses and some cushions could be ordered directly by district nurses with relative ease if they were within the normal range provided.

Static seating (such as riser-recliners) would require a referral to community OTs for assessment, and possibly a further assessment prior to final supply. There were delays in the system both for assessment and for custom manufacture of seating.

Wheelchairs and wheelchair cushions normally required a visit to the wheelchair clinic, for assessment, although this could be carried out in the patient's home if necessary. Visits to the wheelchair clinics meant that a wider range of equipment was available for trial, and that a greater number of patients could be seen in a day. However it meant that patients had to travel, and that the assessor does not see the patient in their home environment.

In all cases, equipment outside of the normal range, or above a certain price bracket may require an additional authorisation process.

In all of the new TVN sites, the TVNs had not previously been involved in the details of selecting, ordering and following-up individual items of pressure relieving equipment.

Following the introduction of PROMISE, all sites (DN and TVN) found that they were more extensively involved in working with therapists and equipment suppliers. Where previously they may have recommended that a change in seating or mattress be made, they are now more involved in identifying the solution, pursuing its implementation and following up the success. The red lines in Figure 26 indicate new relationships that have been formed. In addition to forming new relationships with local equipment suppliers they also contacted company reps to loan equipment on trial prior to purchase.

These new relationships also came with increased numbers of joint visits, although arranging these, or timing visits for equipment delivery, could be difficult on occasions.

Figure 27 shows relationships at the DN implementation site, where it should be emphasised that although there are not new lines, the type of relationship, level of joint working and the amount of time spend investigating and following up equipment requests changed in the same way that was experienced for TVN teams.

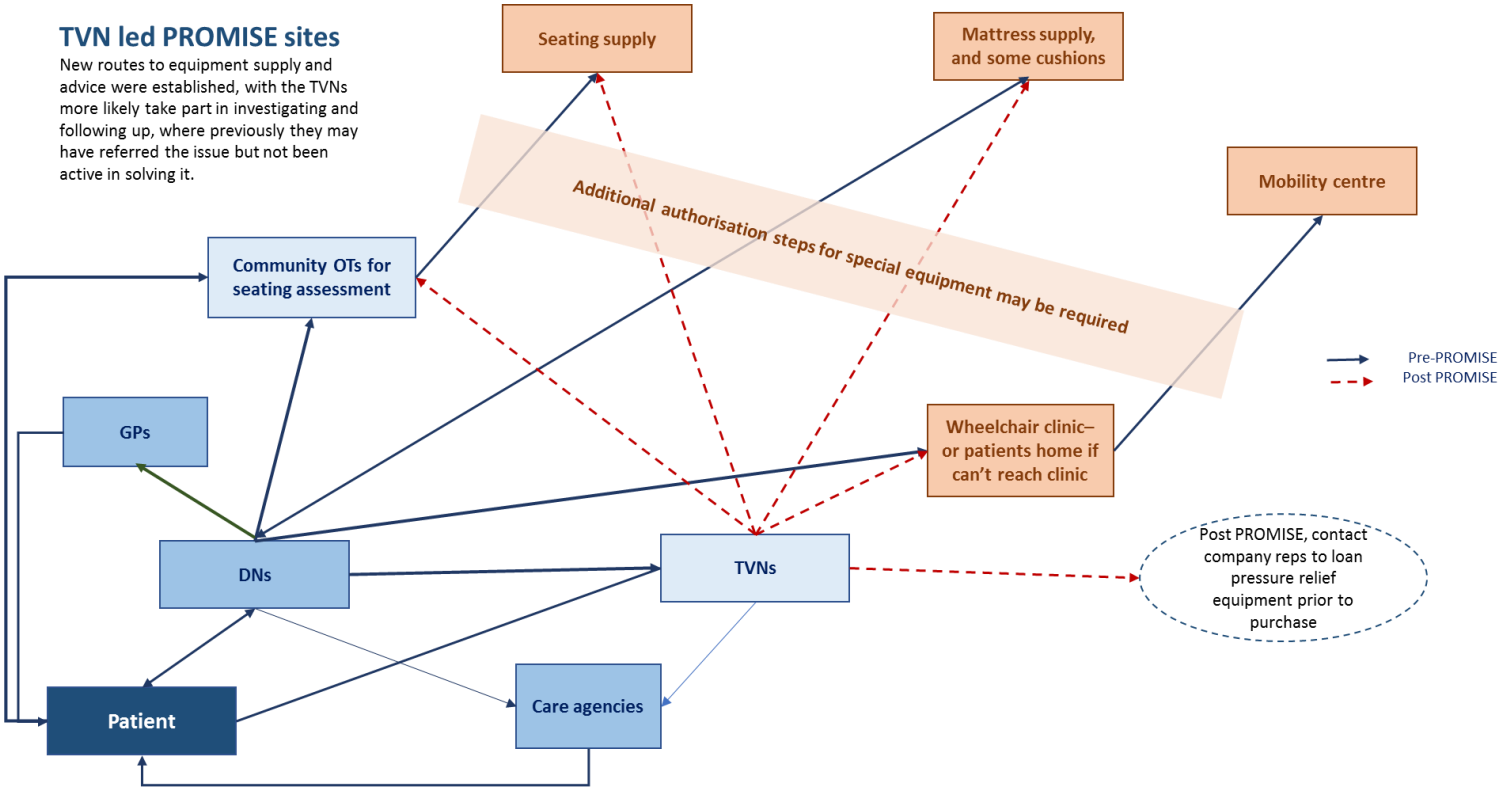


Figure 26 MDT relationships and equipment supply for TV teams

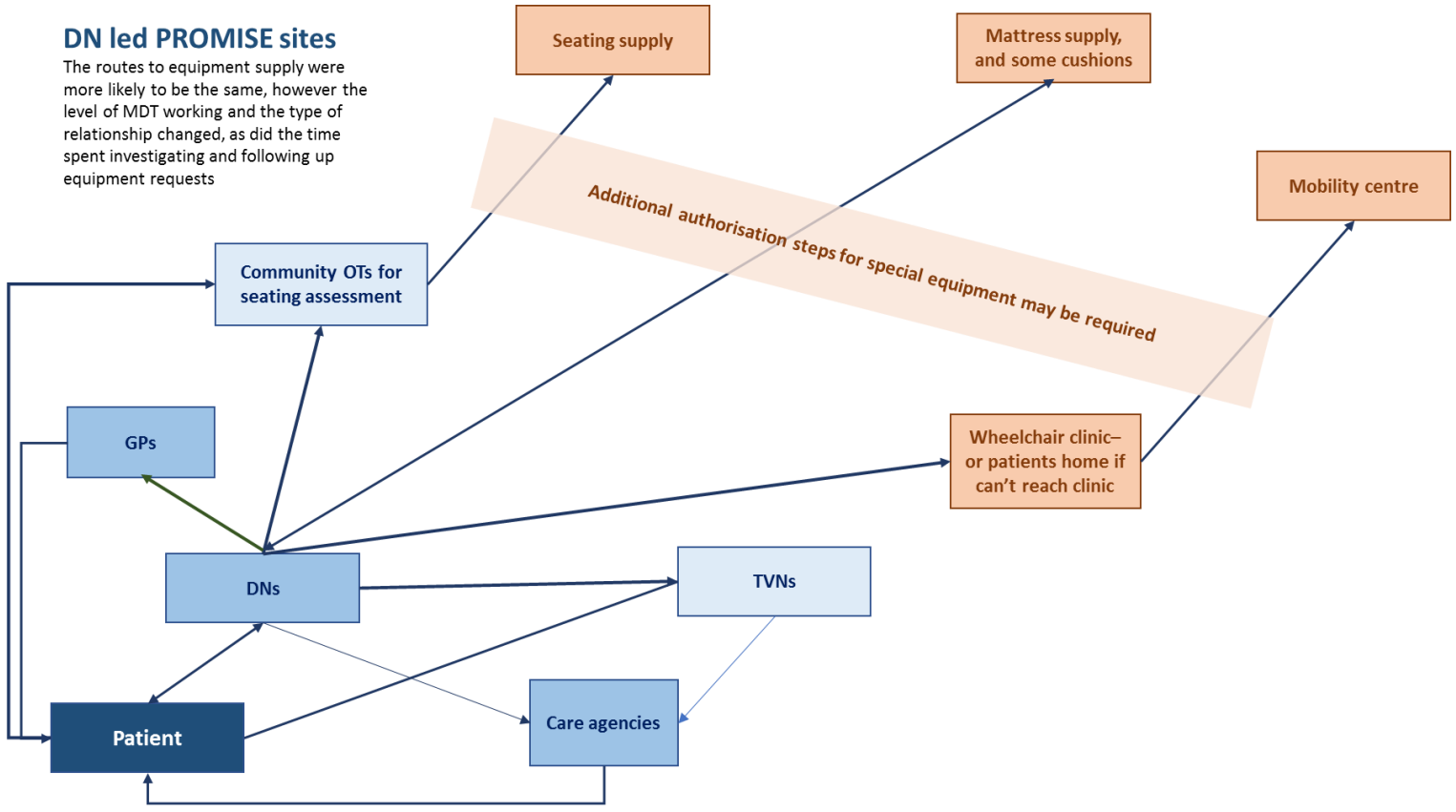


Figure 27MDT relationships and equipment supply for DN teams

Appendix D Baseline demographics, separated by site

All patients who consented and were mapped are included. Information is taken from the initial mapping visit (1st form B), or if not available from any pre-mapping visit (form A)

Table 14 Baseline demographic table, separated by site

	SITE 1		SITE 2		SITE 4		SITE 4		Total	
Participants, n	23		29		16		9		77	
Age Mean(SD)	76.2	(11.0)	69.7	(17.6)	63.6	(11.4)		(17.7)	69.5	(15.34)
Female, n (%)	12	(52%)	15	(48%)	5	(31%)		(68%)	37	(48%)
Frailty, median (IQR)	6	(6.00, 6.75)	7	(5.25, 7.00)	4	(3.50, 5.50)		(7.00, 7.00)	6	(6.00, 7.00)
Missing (frailty), n (%)	*0*		*7*		*13*				*20*	
BMI	n	%	n	%	n	%	n	%	n	%
normal	6	26%	11	38%	9	56%	4	44%	30	39%
overweight	14	61%	7	24%	3	19%	4	44%	28	36%
underweight	2	9 %	9	31%	2	13%	1	11%	14	18%
missing	*1*	*4%*	*2*	*7%*	*2*	*13%*	*0*	*0%*	*5*	*6%*
Moisture										
urinary	11	48%	8	28%	3	19%	3	33%	25	32%
faecal	7	30%	14	48%	2	13%	2	22%	25	32%
other	4	17%	6	21%	3	19%	0	0%	13	17%
none	4	17%	9	31%	5	31%	6	67%	24	31%
missing	*4*	*17%*	*1*	*3%*	*4*	*25%*	*0*	*0%*	*9*	*12%*
Medication										
analgesia	10	43%	20	69%	7	44%	8	89%	45	58%
antibiotics	3	13%	3	10%	4	25%	1	11%	11	14%
sedatives	1	4%	4	14%	2	13%	1	11%	8	10%
steroids	0	0%	3	10%	0	0%	0	0%	3	4%
meds none	6	26%	8	28%	6	38%	0	0%	20	26%
Meds stroke	3	13%	5	17%	3	19%	1	11%	12	16%
missing	*6*	*26%*	*1*	*3%*	*0*	*0%*	*1*	*11 %*	*8*	*10%*
Co-morbidities										
stroke	3	13%	5	17%	3	19%	1	11%	12	16%
cardiac failure	3	13%	7	24%	2	13%	1	11%	13	17%
lung cancer	1	4%	0	0%	0	0%	1	11%	2	3%
spinal injury	5	22%	8	28%	7	44%	4	44%	24	31%
MND / MS	2	9%	2	7%	4	25%	3	33%	11	14%
dementia	4	17%	1	3%	0	0%	0	0%	5	6%
diabetes	7	30%	6	21%	4	25%	4	44%	21	27%

Parkinson's	1	4%	2	7%	0	0%	0	0%	3	4%
pvd	0	0%	8	28%	1	6%	2	22%	11	14%
renal	1	4%	3	10%	4	25%	2	22%	10	13%
none	1	4%	7	24%	1	6%	1	11%	10	13%
missing	*2*	*9%*	*0*	*0%*	*0*	*0%*	*1*	*11%*	*3*	*4%*
Sensation										
full	17	74%	9	31%	4	25%	3	33%	33	43%
limited	6	26%	12	41%	8	50%	5	56%	31	40%
none	0	0%	8	28%	3	19%	1	11%	12	16 %
missing	*0*	*0%*	*0*	*0%*	*1*	*6%*	*0*	*0%*	*1*	*1%*
Sleeps upright	8	35%	4	14%	2	13%	0	0%	14	18%
missing	*0*	*0%*	*0*	*0%*	*1*	*6%*	*0*	*0%*	*1*	*1%*
Wheelchair user	6	26%	17	59%	13	81%	7	78%	43	56%
missing	*5*	*22%*	*3*	*10%*	*1*	*6%*	*1*	*11%*	*10*	*13%*
Asymmetry	2	9%	9	31%	6	38%	1	11%	18	23%
missing	*5*	*21.7%*	*5*	*17.2%*	*3*	*18.8%*	*1*	*11.1%*	*14*	*18.2%*
Following advice	15	65%	26	90%	14	88%	6	67%	61	79%
missing	1	4%	0	0%	0	0%	0	0%	1	1%

Appendix E Additional results: Patient Equipment questionnaire

While the results for all respondents are presented in the main report, the graphs below show the responses when they are separated out into only patients, or only health care workers and relatives. There were also 8 that were not identified as either, and these are excluded in this analysis (but are included in the main table in the report). The majority of patients, relatives and health care workers agreed that the pressure map and monitor were helpful and interesting. Around half of relatives and health care workers who responded reported using the monitor to choose the best position (49%), and to see when to change position (54%). For patients this was slightly lower at 25% for both questions.

Table 15 Experience of pressure mapping, for patients and non-patients

	The pressure map was comfortable to use	I wanted the pressure map to be removed	The pressure map became too hot	The pressure map was too slippery	I used the monitor to choose the best position	The monitor was too bright in the night	I found the monitor reassuring	I was interested in what the monitor showed	The monitor was hard to understand	I used the monitor to see when to change position	Cables got in the way	Cables became disconnected	There were other problems with the map or monitor	The pressure map and monitor were helpful
Patients (n=28)														
Strongly agree	43%	7%	4%	11%	18%	11%	18%	36%	7%	18%	4%	7%	4%	29%
Agree	36%	14%	7%	4%	7%	18%	29%	36%	7%	7%	4%	4%	7%	50%
Disagree	7%	21%	36%	36%	50%	32%	18%	18%	43%	50%	46%	32%	25%	7%
Strongly disagree	7%	57%	54%	46%	14%	29%	4%	0%	25%	4%	46%	54%	39%	0%
Don't know	0%	0%	0%	4%	7%	7%	29%	7%	14%	14%	0%	4%	11%	11%
Not answered	7%	0%	0%	0%	4%	4%	4%	4%	4%	7%	0%	0%	14%	4%
Not patients (n=24)														
Strongly agree	29%	0%	4%	8%	17%	0%	38%	33%	13%	25%	0%	0%	0%	38%
Agree	50%	4%	4%	0%	33%	13%	33%	54%	13%	29%	8%	8%	33%	46%
Disagree	8%	58%	54%	50%	21%	58%	13%	8%	54%	38%	58%	50%	17%	0%
Strongly disagree	0%	33%	38%	38%	21%	21%	13%	4%	8%	8%	25%	33%	33%	4%
Don't know	8%	4%	0%	0%	8%	8%	4%	0%	13%	0%	8%	8%	8%	8%
Not answered	4%	0%	0%	4%	0%	0%	0%	0%	0%	0%	0%	0%	8%	4%

Appendix F Additional results: Patient experience and quality of life questionnaires

Patient completed questionnaires had a reasonable response rate at baseline, but this reduced dramatically at follow-up. There is a balance between sufficiently sensitive to detect change and sufficiently simple to aid completion. The use of the simple EQ-5D-5L form at the end of the project only improved responses slightly, and is not very sensitive to change. Reasons for non-completion raised by patients included the length, being unsure what response to give, and repetition. It was not clear to patients why they were being asked the same questions on more than one occasion, and therefore they did not always complete the second one. This was compounded by the flexible timing approach, which although essential given the variations between patients, made it logistically harder to ensure questionnaires were delivered at the most appropriate time, particularly if there was any delay in receiving data collection forms.

Patients were offered internet or telephone completion but these were generally not taken up. One difference between the two questionnaires was that the first was given out by the nurse, and the second sent directly by post. It may have helped to ask staff to hand out the second questionnaire in person, but the timing was during the follow-up stage when they would not always routinely be seeing patients in person.

Reported barriers to adherence

This was asked of both patients and relatives / carers who completed questionnaires. There were 55 responses to the Week 0 Problematic experiences of therapy questionnaire, 6 of which were completely blank for the PETS section. There were 17 responses for the follow-up questionnaire, 3 of which were completely blank for the PETS section. Matching responses for Week 0 and follow-up gave 15 pairs, however 4 had missing data which was excluded from the comparison.

Table 16 Reported barriers to adherence using PETS questionnaire

	Week 0 (n=55)	Follow-up (n=17)	Matched responses (n=15, 4 blank)		
			Improved (n)	No change (n)	Worse (n)
Problems due to symptoms	**25 (45%)**	**6 (35%)**			
I had to skip the treatment/advice because it made my symptoms worse	23 (42%)	6 (35%)	3	7	1
I was prevented from carrying out the treatment/advice by severe symptoms	22(40%)	4 (24%)	3	8	0
I could not carry out the treatment/advice because it caused more symptoms	22 (40%)	5 (29%)	3	7	1
Problems due to uncertainty or doubts about the treatment/advice	**24 (44%)**	**7 (41%)**			
I could not carry out the treatment/advice because I was unsure how to do it properly	20 (36%)	3 (18%)	3	8	0
I was unable to carry out the treatment/advice because it was difficult to know what to do	20 (36%)	4 (24%)	3	7	1
I skipped the treatment/advice because I was not sure if it was helping	23 (42%)	6 (35%)	3	7	1
I skipped the treatment/advice because it did not seem relevant to my symptoms and problems	21 (38%)	4 (24%)	3	8	0
I did not carry out the treatment/advice because I was not convinced it was right for me	24 (44%)	4 (24%)	4	7	0
Practical problems	**21 (38%)**	**4 (24%)**			
Lack of time prevented me from carrying out the treatment/advice	19 (35%)	4 (24%)	2	8	1
It was not possible to find suitable opportunities to carry out the treatment/advice	19 (35%)	4 (24%)	2	8	1
I was too busy or tired to carry out the treatment/advice	21 (38%)	3 (18%)	2	9	0
I found it difficult to remember to carry out the treatment/advice	20 (36%)	3 (18%)	2	9	0

Patient and relative experience of care.

Patients and relatives or carers were both asked:

- Do you feel you are listened to?
- If you need assistance in caring for your pressure ulcer do you get it?
- Do you understand what is happening in the care for your pressure ulcer?
- Were things explained to you in a way that you can understand?
- Were you involved as much as you wanted to be in decisions about your pressure ulcer care?

Again, results are reported for all Week 0 responses, all follow-up responses, and the change for matched pairs of responses. In all cases, the majority of people replied “usually”, or “always” to the questions. When all responses are compared for week 0 and follow-up, there appears to be an improvement in the percentage of people choosing “Always” (Figure 28). When the matched pairs are considered, there is no overall improvement for these 15 respondents (Figure 29).

Where numbers are very small, all results should be treated with extreme caution. We cannot tell if those that returned pre and post questionnaires were a representative sample of all patients, or if there is a non-response bias.

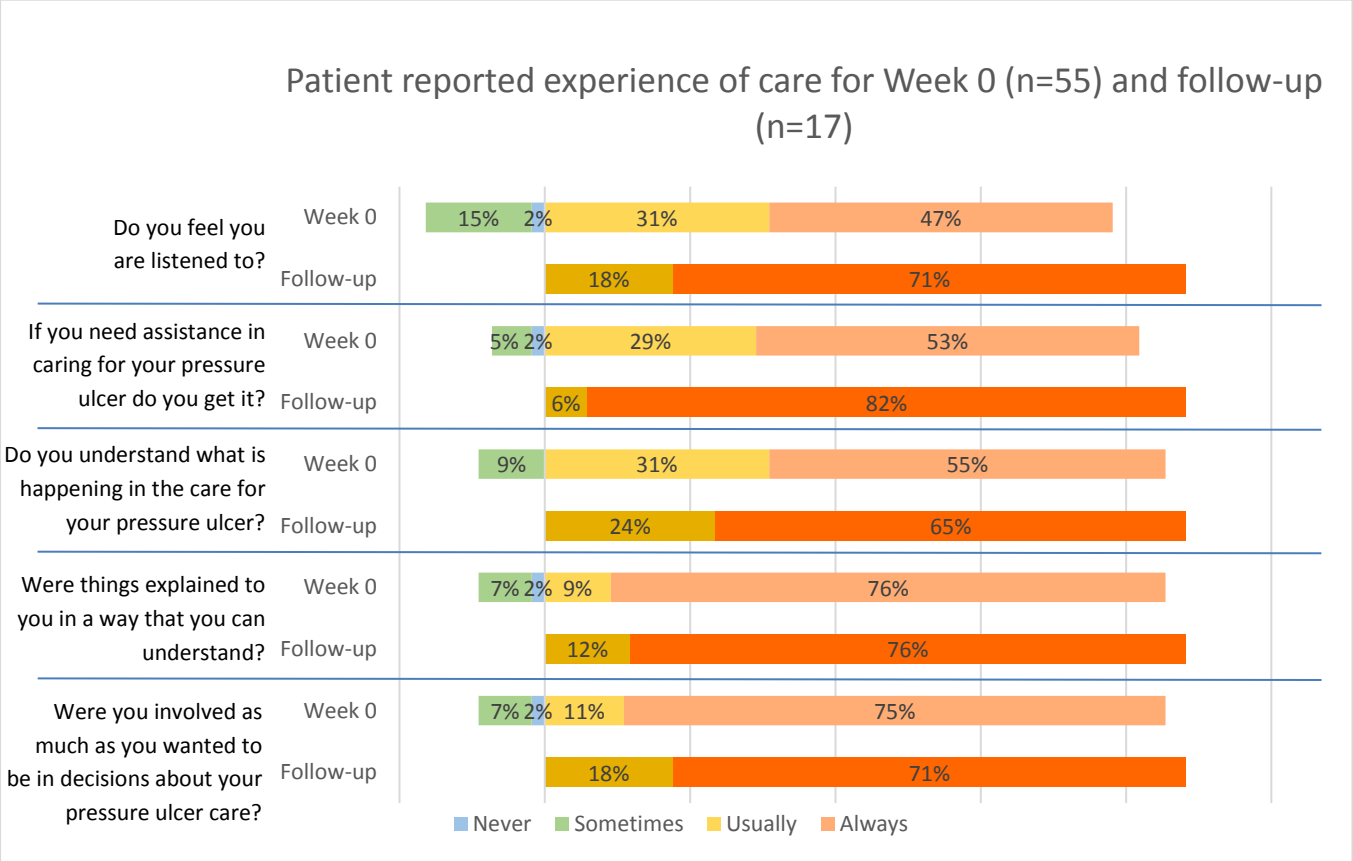


Figure 28 Experience of care as reported by patients, relatives and carers. Percentages are calculated from total number of respondents, however "not answered" are not displayed in the bar chart.

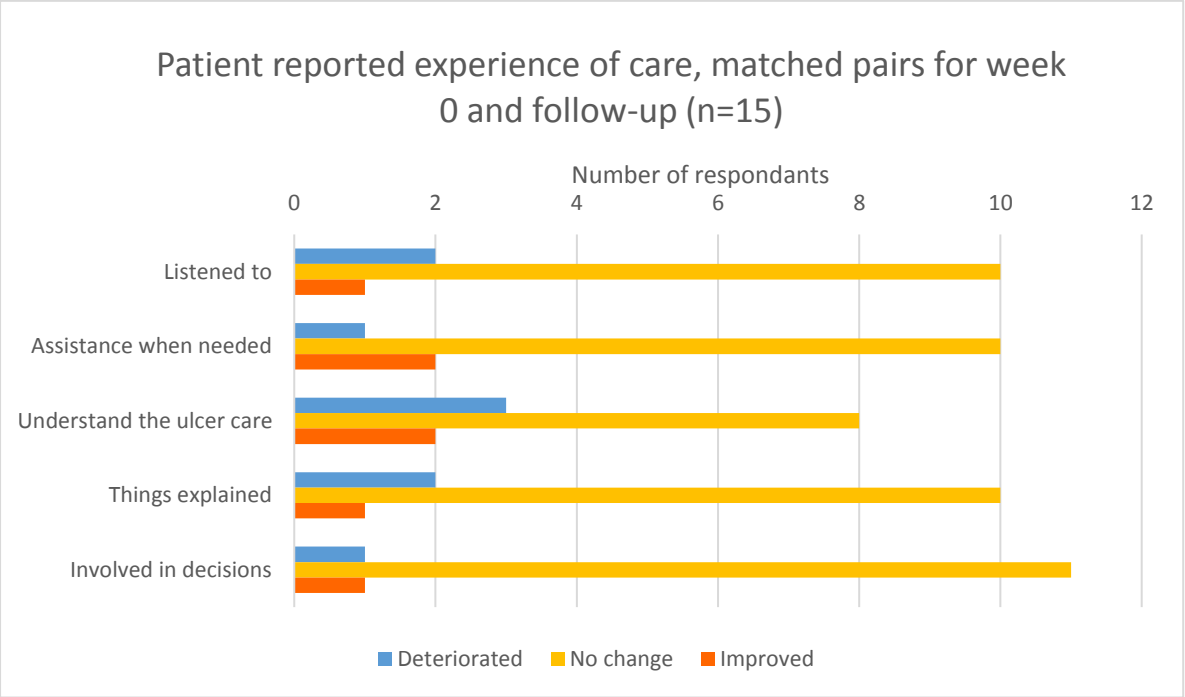


Figure 29 Change in experience of care for those respondents who competed both Week 0 and Follow-up questionnaires. Matched pairs of responses = 15, but data missing from 2 respondents

The final section of the patient reported experience of care is a rating from 0-10, where 0 is very bad and 10 is excellent. For the majority of patients and carers, at both time points, the overall rating is high, with a median of 9 (IQR 8,10).

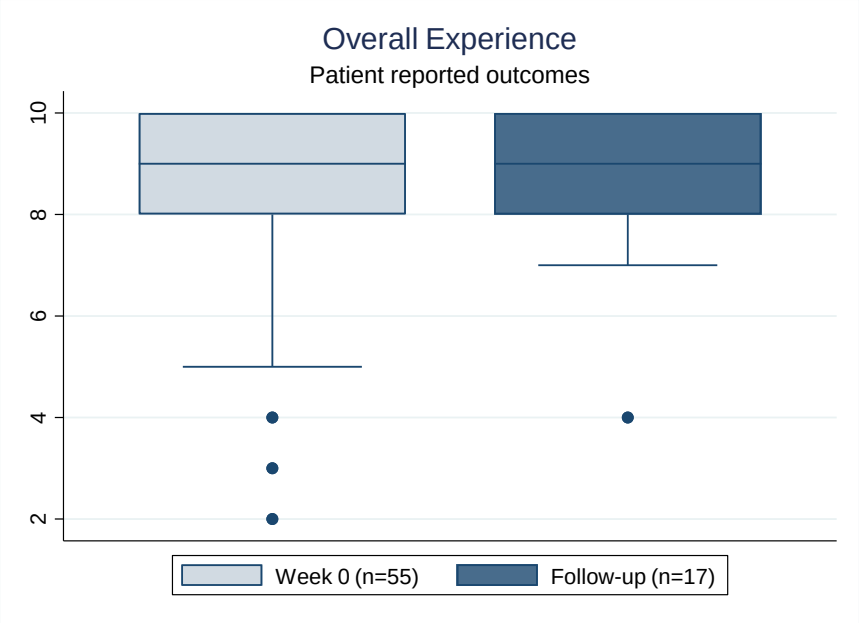


Figure 30 Overall experience of care (0= very bad, 10 = excellent). Week 0, n=55, Follow=up, n=17

With the matched pairs, it can be seen that there is no overall trend to increase or decrease the overall experience of care, but again the numbers of responses are very low. The graph shows the change per respondent from the first questionnaire at week 0, to the follow-up questionnaire.

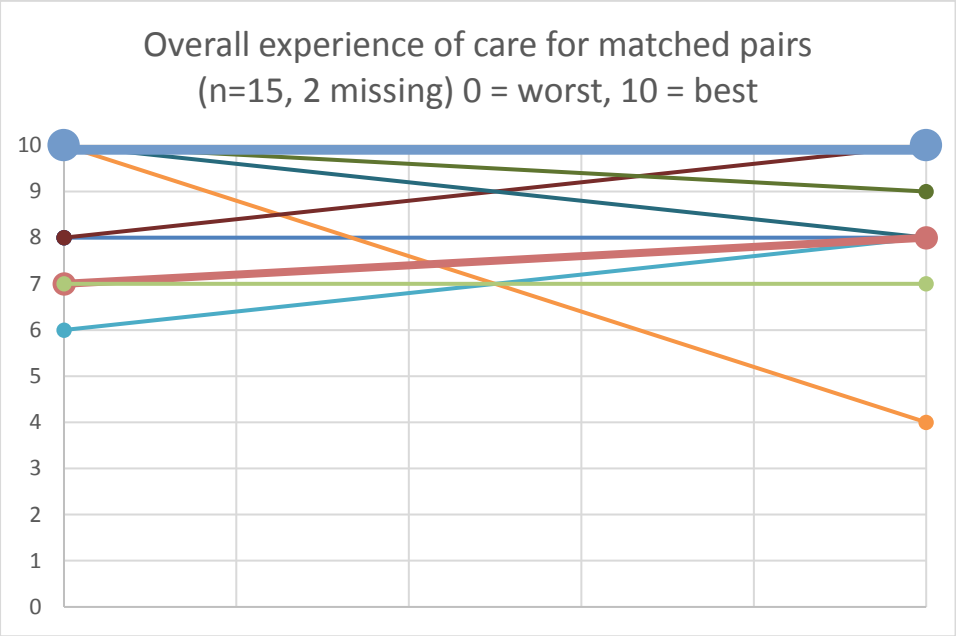


Figure 31 Patient and relative experience of care at Week 0 and follow-up. Note that there are 3 respondents that form the line from 10 - 10, and 2 which form the line between points 7 - 8

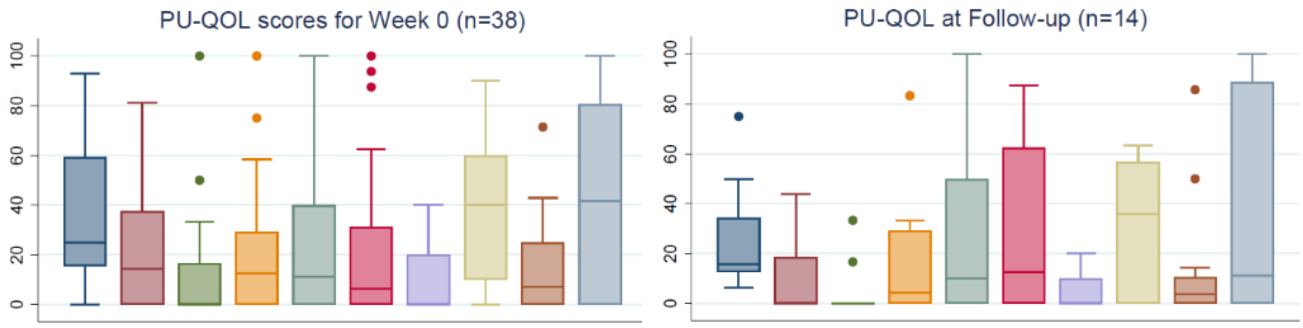
Patient experience of pressure ulcer related quality of life.

This quality of life questionnaire was distributed to patients only, although relatives and carers were able to assist in completion, or if necessary complete it on behalf of the patient.

It contains 11 sets of questions, organised into domains, containing between 5 and 15 items. Each item is scored separately, from 0 = "no bother" to 3 = "a lot of bother", the total scores are added for that domain and normalised to give a score where 0 is "no bother" across all items, and 100 is "a lot of bother" for all items. Examples of topics contained within domains are:

Daily activities:	contains items such as volunteering, shopping, daily living tasks
Participation:	includes being unable to do trips away, or stay out for lengths of time, difficulties meeting family and giving up hobbies
Vitality:	Includes feeling tired or reduced energy levels
Emotional wellbeing:	includes feeling fed up, frustrated, annoyed or miserable
Self-consciousness:	includes helplessness, lacking in confidence or embarrassment

Where less than half of the data for any one domain is missing for a patient, it was imputed using the mean, as described in the PU-QOL handbook.



Valid responses for each domain	Week 0 (n=38)	Follow-up (n=14)
Pain	*28*	*8*
Exudate	*31*	*11*
Odour	*30*	*12*
Sleep	*32*	*12*
Mobility	*31*	*10*
Daily activities	*31*	*11*
Vitality	*38*	*14*
Emotional well-being	*31*	*11*
Self-Consciousness	*32*	*12*
Participation	*33*	*11*

Figure 32 Patient reported, pressure ulcer related, quality of life scores for week 0 and follow-up

Additional graphs for this measure are included in the main body of the report

Patient reported overall quality of life (EQ-5D-5L)

EQ-5D-5L asks about overall health today, and consists of 5 multiple choice questions and a visual analogue scale. The responses for the 5 domains are reported in Figure 33 for each time point in the study. The most obvious finding is that Mobility is extremely limited for most respondents

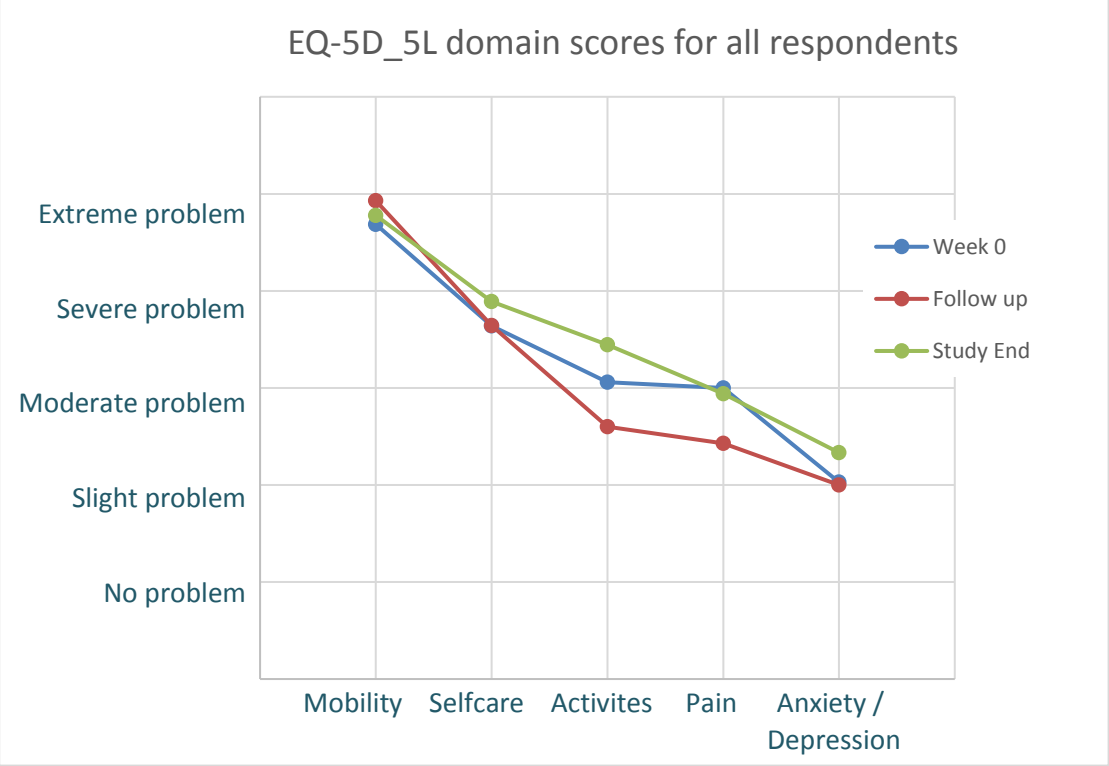


Figure 33 EQ-5D-5L domains for all respondents at each time point

The EQ-5D-5L visual analogue score, is a line where respondents mark a point from 0 to 100, where 0 is the worst imaginable and 100 is the best health imaginable. This was asked at 3 time points, at the initial mapping, at the follow-up questionnaire, and at the end of the study. The time between all points will not be the same form each patient.

	Week 0	Follow-up	End of study
Valid responses (n)	*36*	*13*	*19*
Median	50	70	50
IQR	42.5, 67.5	55, 80	30, 70

Figure 34 Median VAS score for Patient Quality of Life at Week0, follow-up and end of study

Each dot represents an individual response, where the responses are linked, there are lines drawn between the time points. The dotted lines are used where there is a gap between two data points. There is a very mixed response, which is not surprising given the patient co-morbidities and the possible changes in health irrespective of the pressure ulcer. An insight into this is from two comments received with the final EQ-5D-5L, both patients gave very low scores, however one wished to explain that they felt PROMISE was "*Sorting out my pressure sore with mapping and a different chair has healed it at last! (12 months of district nurse visits prior to this.) It healed within a few weeks. Many* thanks". The other patient expressed the view that PROMISE had not been beneficial to them at all. Although most patients were positive about PROMISE, this example

highlights the difficulty of interpreting overall health scores in such a heterogeneous population, many of whom may be expected to have changes in their overall health over time. This is exacerbated by low return rates, and the likely non-responder bias.

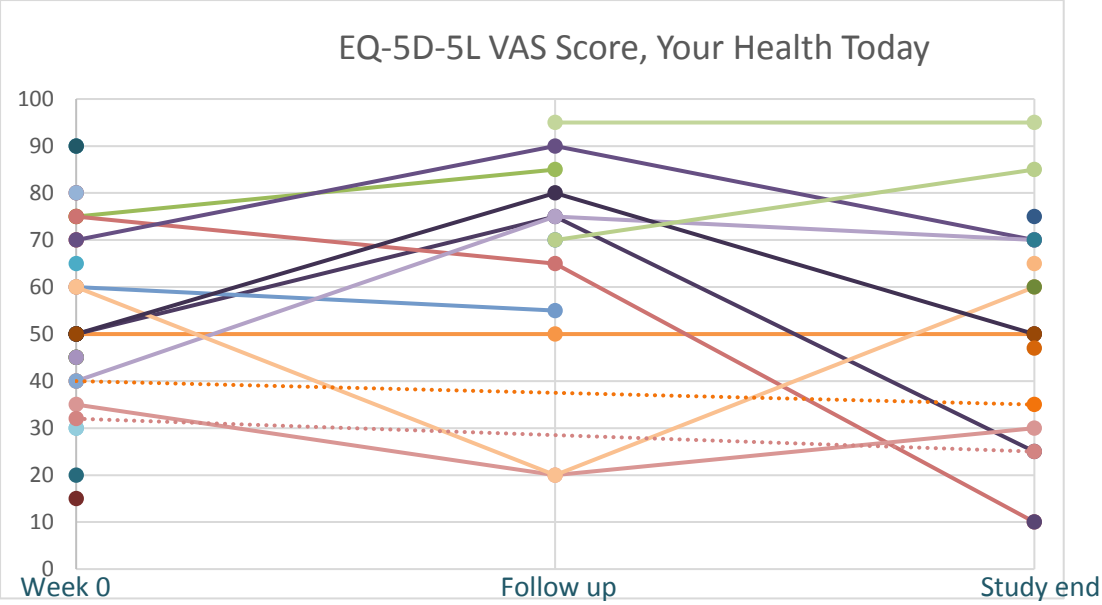


Figure 35 Changes in quality of life (overall health) from Week 0 to follow-up and study end.

Appendix G Additional Results: Staff attitudes to PROMISE, normalisation process theory

The NoMAD questionnaire builds on normalisation process theory to understand participants' experiences of working collaboratively to implement change over time and across settings (Rapley 2018). It is based on the theory that the actions of the implementers in continuously investing time in the four core areas of NPT will lead to it becoming embedded, or normalised. It then is no longer a complex intervention, but a part of normal activity. There are four core constructs, table 13 attempts to summarise these very briefly however the NPT website gives a full description.

Table 17 Core NPT constructs for NoMAD

Core NPT construct	Simplification of construct title and concept	
Coherence	Making sense of the intervention	Shared understanding of what it is, what hoping to achieve and the value of the intervention
Cognitive participation	Engaging with it	Having people to drive it forward, rethinking relationships,
Collective action	Doing it	Building a set of practices and allocation of work
Reflexive Monitoring	Appraising it	Appraise impact on team and self and change if needed

The NoMAD questionnaire was administered at 3 time points, the first was in January 2019, nearly three months after the first three sites had started implementing PROMISE. This was also circulated to the TVN team in Cornwall who had previously implemented CPM. The second was in August 2019 after Site 3 had joined the project, and it was extended to any new member of staff at the other sites who had not previously completed the survey. Finally the questionnaire was repeated in March at the end of the evaluation site. This final questionnaire had a very low response rate, which is not unexpected due to the disrupted work patterns and high level of work caused by COVID-19 in that period. The two dates in 2019 are grouped together for analysis, since at both time points the respondents had only recently started delivering PROMISE. In 2019, out of 16 responses from implementation sites, 8 respondents carried out CPM and analysis, and 4 were team leaders or managers. In 2020, there were 7 responses, 3 of which were from team leaders or managers, 3 carried out CPM, but only 1 of those did the analysis. The second questionnaire was during the initial period of COVID-19 re-organisation, and this probably affected both the response rate and who was able to reply.

Figure 28 shows the roles within PROMISE that respondents took in the two questionnaire years.

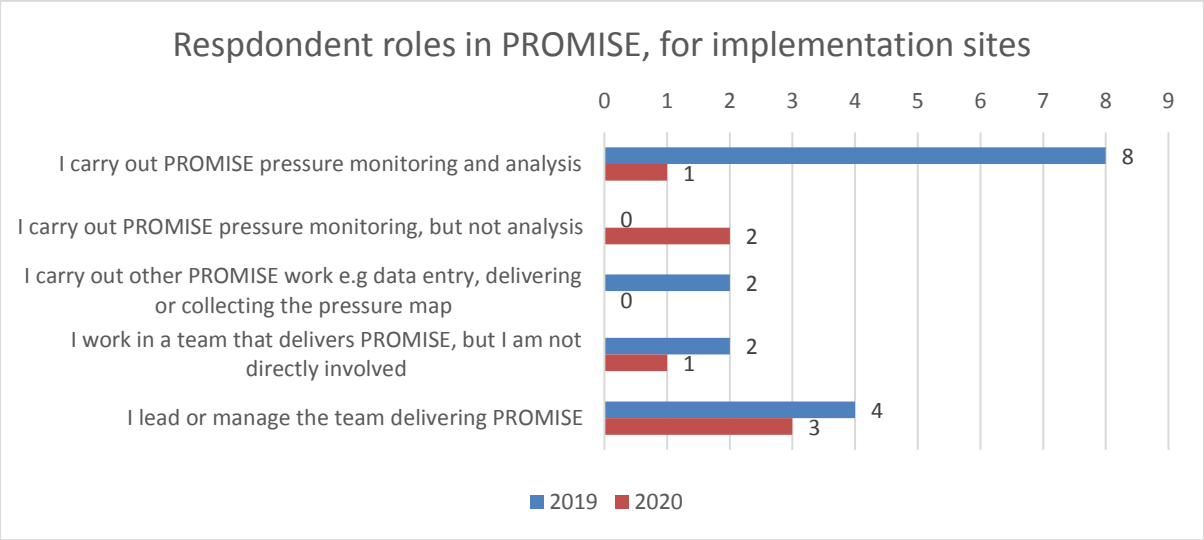


Figure 36 NoMAD respondents roles within PROMISE during the two years of project

Graphs of all responses during the initial two surveys (at the start of implementation, Figure 39) and the final survey (Figure 40) show that staff are very positive about 3 of the core constructs, however for Cognitive participation, there were some concerns. Staff saw the value of PROMISE, but had some concerns about time and resource for the project. This was also reflected in discussions, interviews and "pulsecheck" surveys. Looking at the most recent set of responses (n=7) fewer areas of concern, however staff have some concerns about having sufficient resource, management support and a person who can drive PROMISE forward.

Graphical results for the familiarity and normality of PROMISE for all implementation sitea are shown in Figure 37, together with the results for the same question asked of the TVN team in Cornwall who are using CPM as part of normal practice. Figure 38 shows the results for the one site that had similar numbers of respondents at both time periods.While the results in look promising, and fit with information from staff interviews and "pulse check" surveys, they are only for 4 respondents.

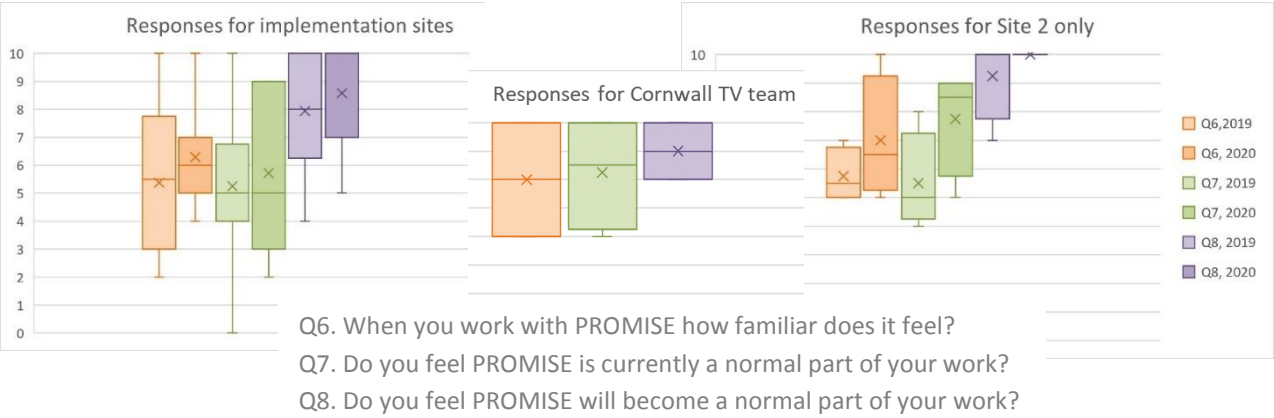


Figure 38 NoMAD responses to questions 6-8, all implementation sites, and for Cornwall TVN team

Figure 37 NoMAD responses to questions 6-8, single site only (2019 n=4, 2020 n=4)

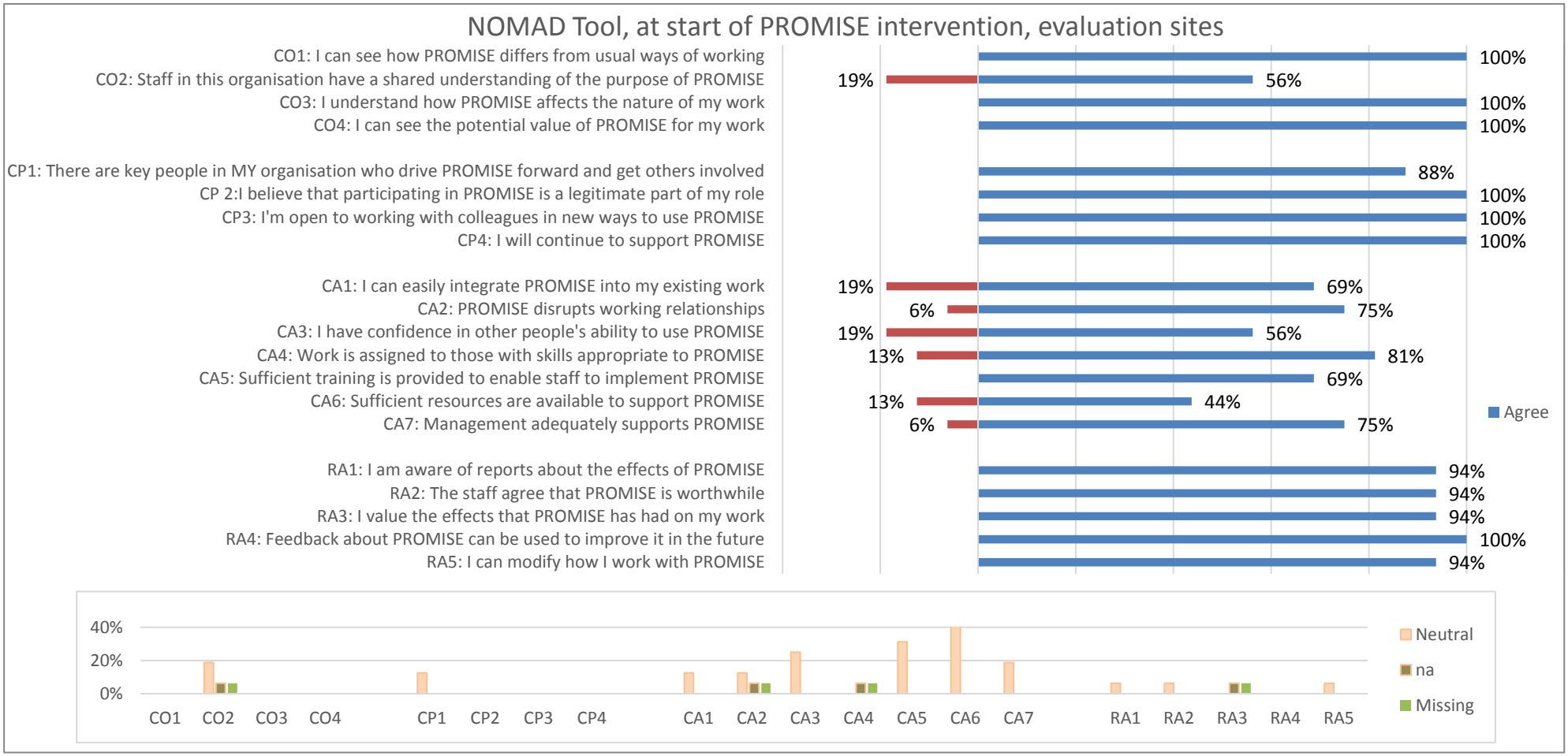


Figure 39 Staff responses to NoMAD at start of PROMISE

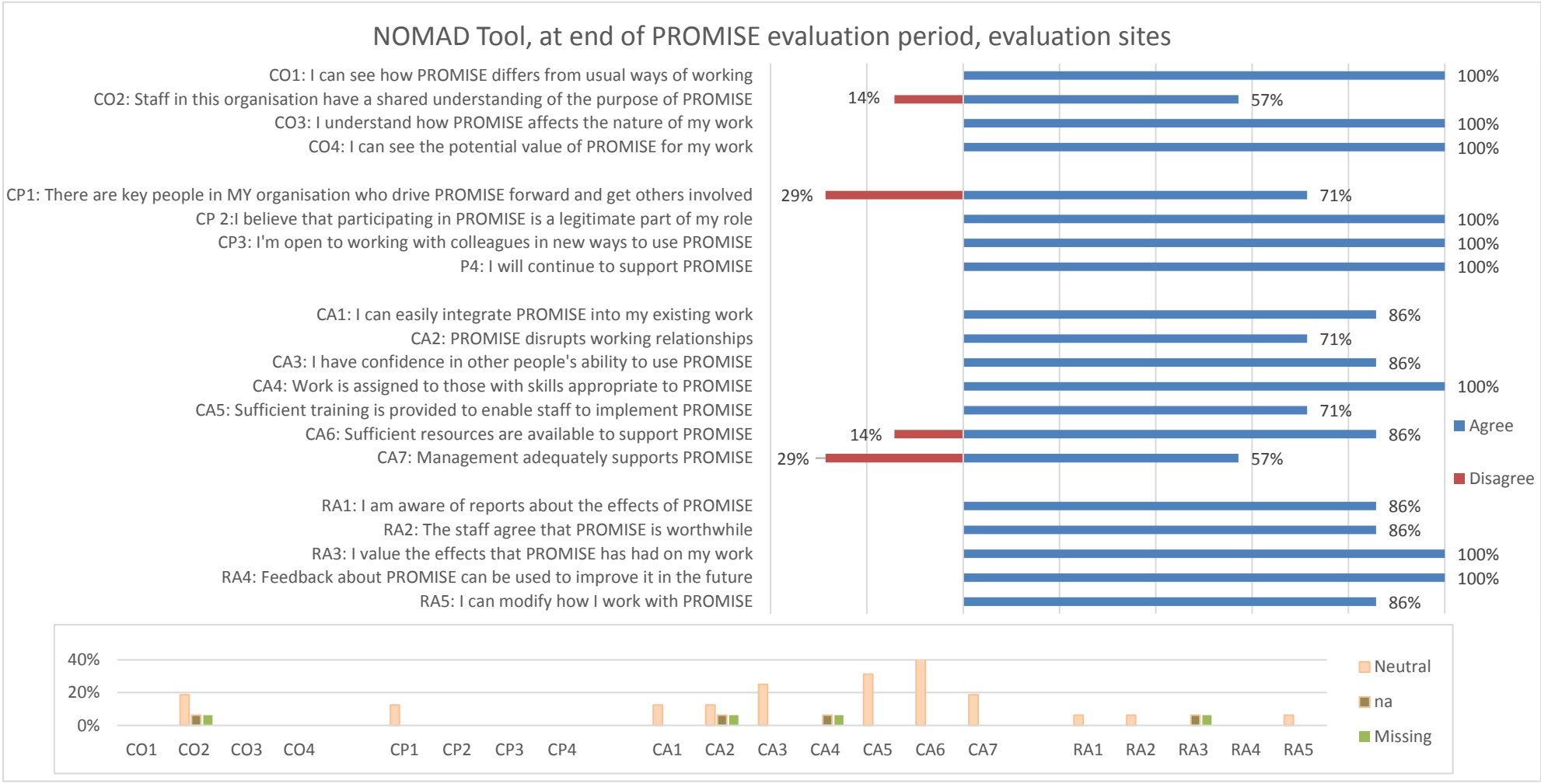


Figure 40 Staff responses to NoMAD at end of PROMISE

Appendix H Additional Results: Wound healing

Time to event for wound healing and D & E forms

The time to event data has been analysed by different subgroups, however this should be considered as hypothesis generating, rather than drawing any strong conclusions, due to the small numbers in sub groups and post-hoc approach. In addition to grouping by site, the first 8 months and last 8 months have been split into two time periods to investigate any improvements in time to healing as PROMISE became more established. There is some difference in the median time for 50% wound reduction, but it is unclear if it would still be apparent over a longer time period. Any further analysis would also have to consider the patient characteristics of each group in these time periods, as sites tended to treat the longstanding, hard to heal patients first.

Differences that are seen between sites are likely to be driven by patient characteristic, with Site 1 having a higher proportion of patients with grade 1 and 2 pressure ulcers.

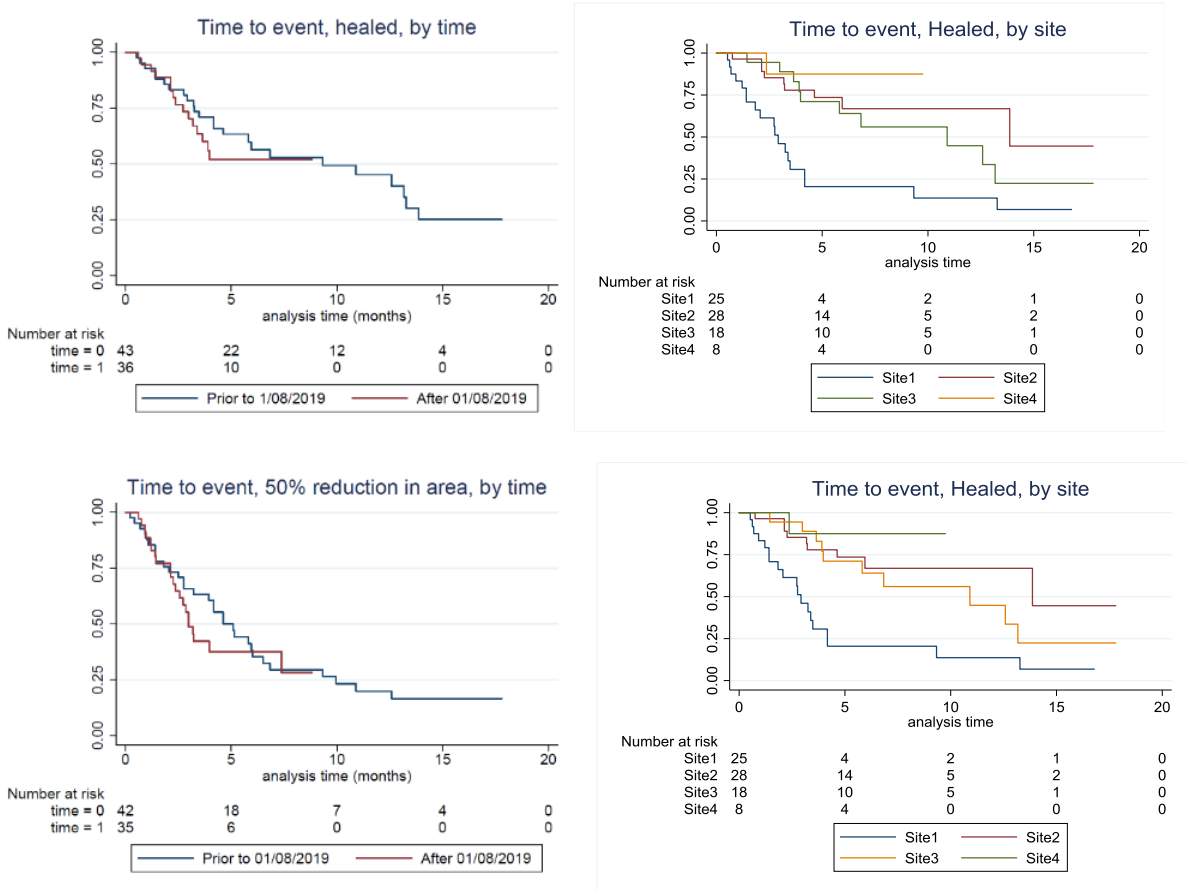
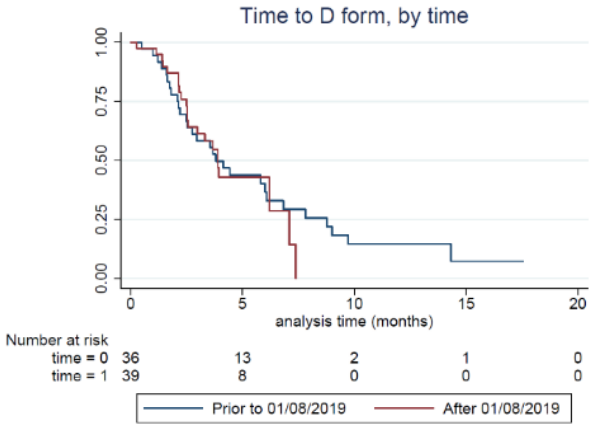
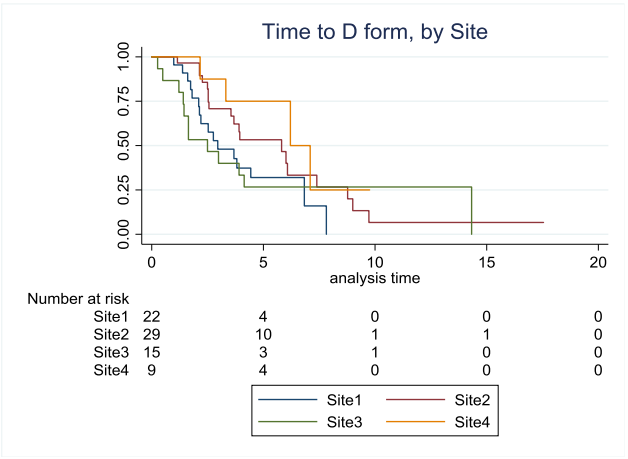
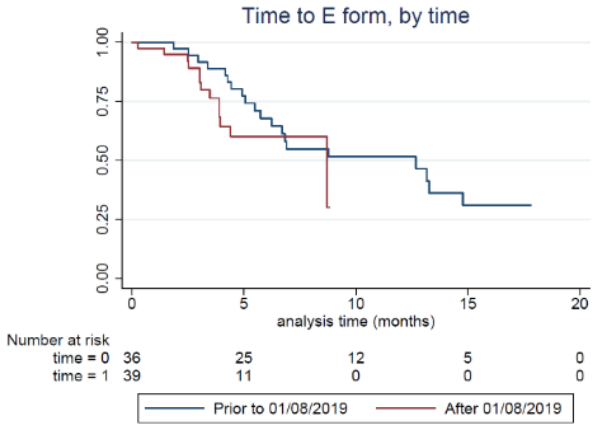


Figure 41 Additional time to event graphs for wound healing, grouped by time period and site







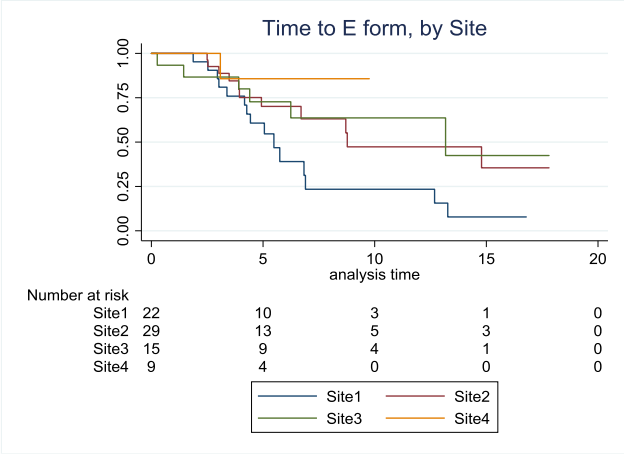


Figure 42 Additional time to event graphs for process measures, grouped by time period and site

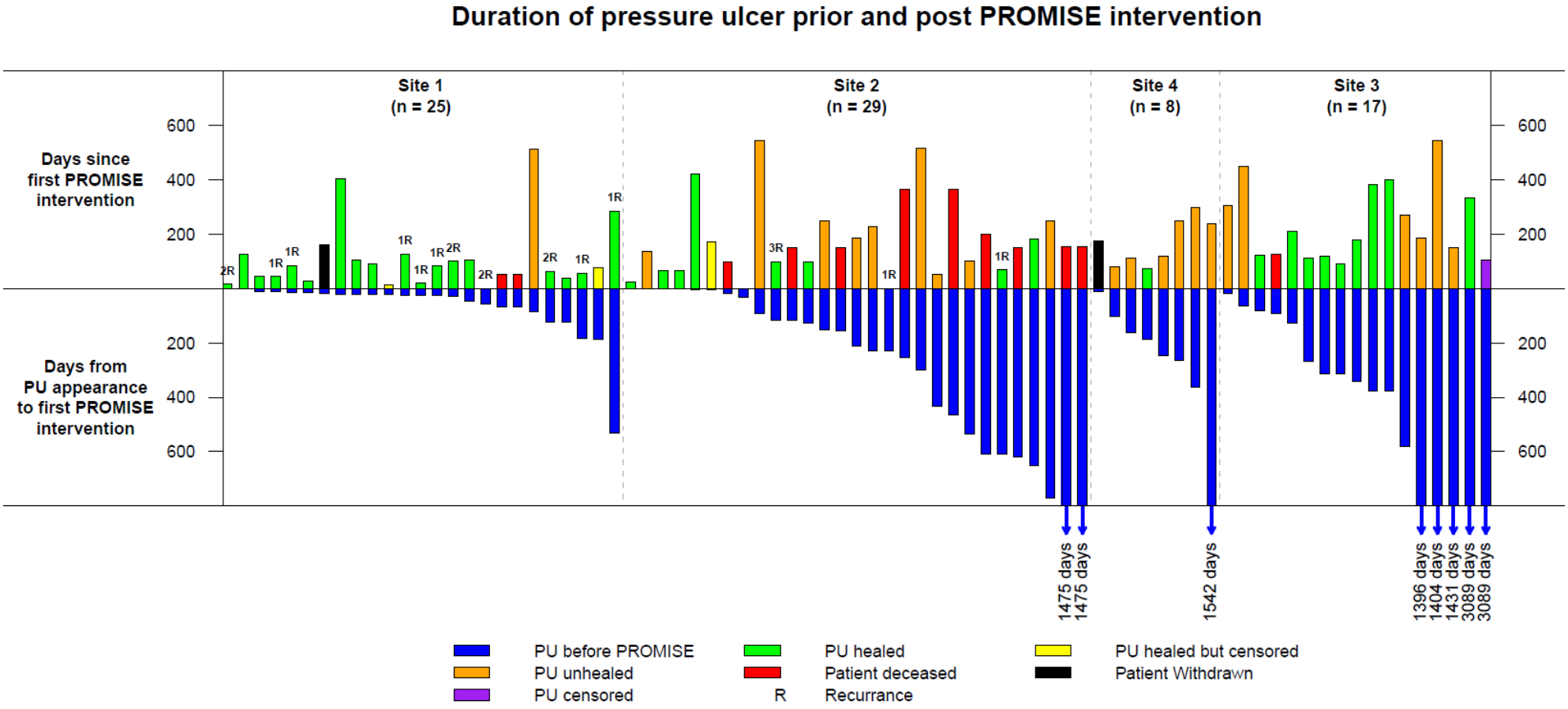


Figure 43 Duration of pressure ulcer prior and post PROMISE intervention

Appendix I Additional Results: Process Measures

Mapping times

The variation in mapping times is shown in Figure 44 and Figure 45. In each graph the red line indicates the median value. It is notable that SITE 3 have the majority of bed mappings, and half the initial cushion mappings at around 48 hours length. For some of the project duration, this site organised the monitoring process around fixed "PROMISE days", meaning mapping equipment was normally taken to patients homes on the same day each week, and then picked up 2 days later.

For all sites, the cushion monitoring times are shorter than the mattress monitoring times. Also, for all sites the cushion monitoring times for the initial investigation (form B) are longer than those for subsequent monitoring (form C).

Figure 44 Bed mapping duration, by site, forms B and C

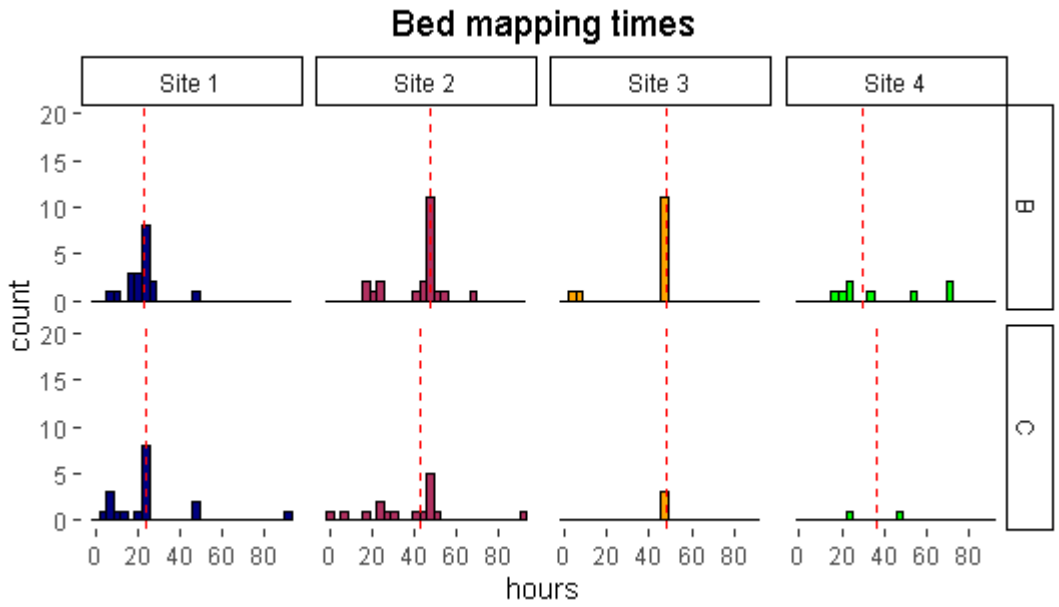


Table 18 Bed mapping duration, by site, forms B and C

	SITE 1	SITE 2	SITE 3	SITE 4	
N visits	19	22	13	8	B
Median (IQR)	23hh) (19hh, 24hh)	47hh 28min (41hh 39min, 48hh)	48hh (48hh, 48hh)	29hh 30min (21h 15min, 58hh 30min)	B
N visits	18	16	3	2	C
Median (IQR)	23hh 55min (12hh, 24hh)	42hh 55min (23hh, 48hh)	48hh (47hh 30min, 48hh)	36hh 30min (30hh 15min, 42hh 45min)	C

Figure 45 Seat mapping duration, by site, forms B and C

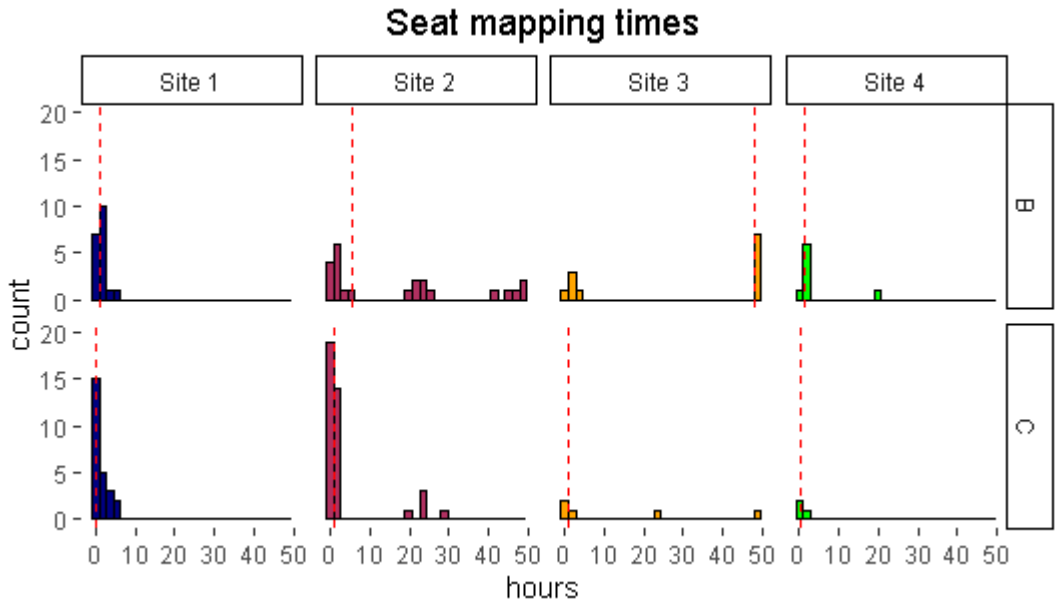


Table 19 Seat mapping duration, by site, forms B and C

	SITE 1	SITE 2	SITE 3	SITE 4	
N visits	19	23	12	8	B
Median	1h 5min	5hh 45min	48hh	1h 4min	
(IQR)	(13min, 1h 55min)	(58min, 25hh)	(1h 24min, 48hh)	(1h, 1h 38min)	
N visits	25	38	5	3	C
Median	20 min	52min	1h	30 min	
(IQR)	(15min, 1h 55min)	(30min, 1h 14min)	(30min, 24hh)	(20min, 1h 15min)	

Total number of cushions, mattresses and mappings

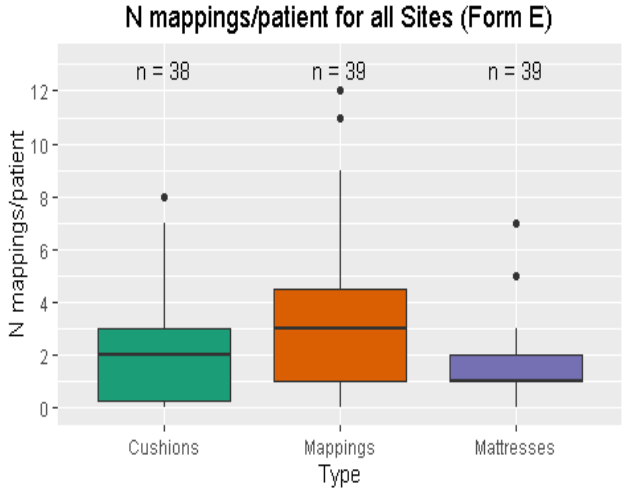


Figure 46 shows the variation, and high value outliers that have occurred during the project, with maximum numbers of 8 cushions, 7 mattresses and 12 mappings per patient.

Figure 46 Variation in the number of cushions and mattresses trialled and mappings completed

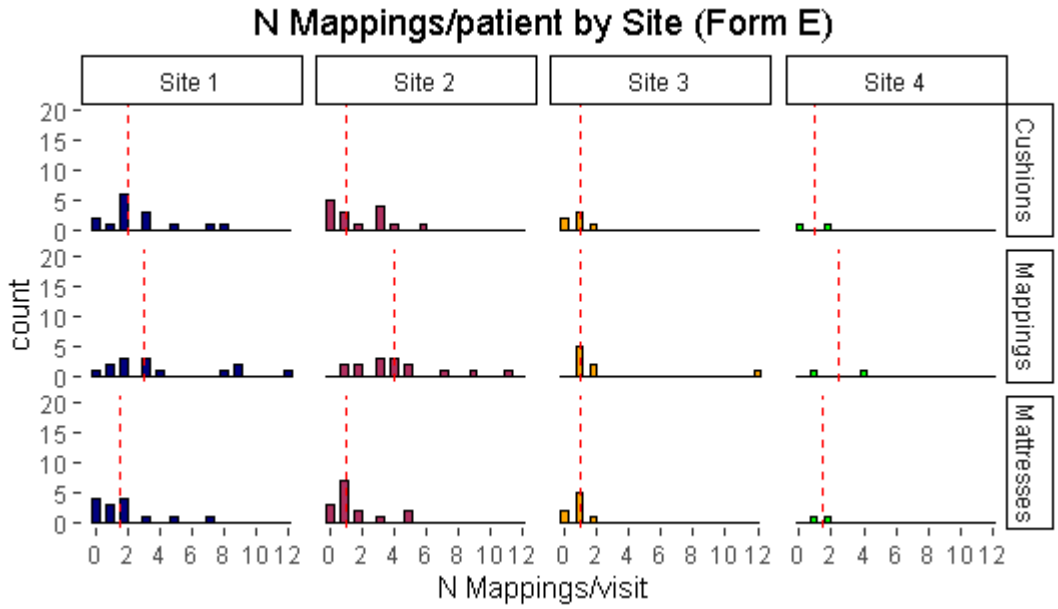


Figure 47 Mappings completed per patient per site

There are differences apparent between the sites, it can be seen that Sites 1 and 2 have had a number of patients where multiple attempts to find solutions have been required. By contrast Site 3 have a median of 1 mattress, cushion and mapping per patient, with one exception, an outlier of 12 mapping visits.

Staff time for PROMISE visits

The type of visit recorded in each form is described earlier in Table 2, but it can be seen that there are a wide range of possible visit times. Forms A (baseline prior to mapping), D (follow-up), and E (final information) all have lower values of 0 minutes as they can be completed in some cases without a visit. For some sites such as Site 3, referrals may come from the district nurses directly as a completed A form. Other sites may be more likely to go out to see the patients at this point.

For the follow-up forms, all sites may get this information from patient notes. Some staff will complete this as for example, 10 minutes to find data and complete form; other staff will complete the form as 0 minutes because no visit was involved. Travel time may also be included in the time, and there are cases noted in forms where the travel time significantly exceeds the length of the visit.

Unsurprisingly the visits where mapping takes place (forms B and C) have the highest median time per visit at 93 and 75 minutes. Shorter times for B2 and C2 reflect visits to collect the map at the end of the mapping process (however due to changes in the forms these may not be consistently grouped together).

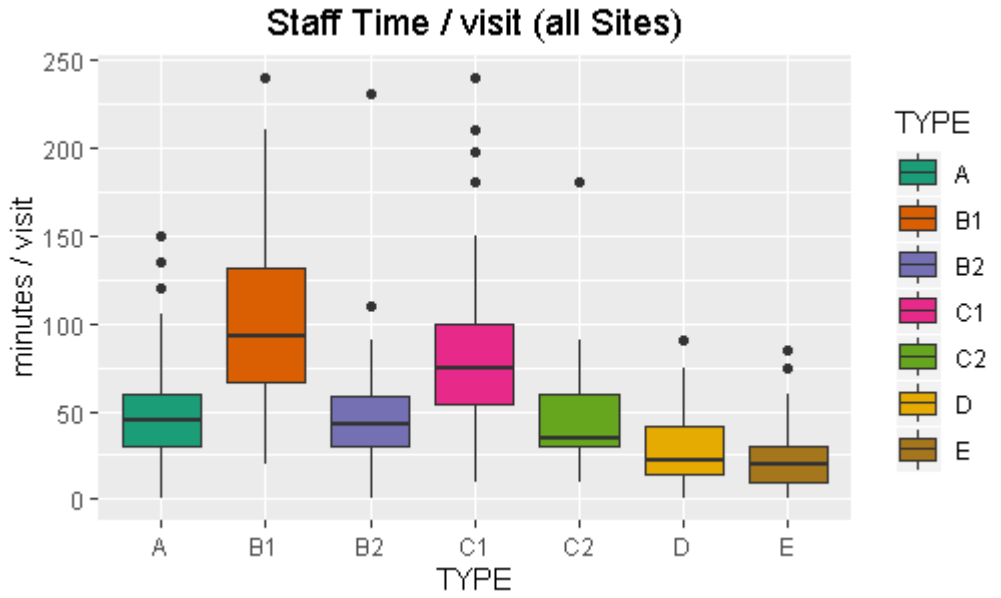


Figure 48 Staff time per visit, by type of form completed

Table 20 Time for visits, by site

		SITE 1	SITE 2	SITE 3	SITE 4	TOTAL
total number of visits	A baseline	16	13	6	2	**37**
	B1 Mapping	31	29	15	11	**86**
	B2 Map collection	10	7	0	1	**18**
	C1 Change/mapping	46	52	10	4	**112**
	C2 Map collection	5	7	0	0	**12**
	D Follow-up	33	44	16	3	**96**
	E Final	23	17	9	2	**51**
		SITE 1	**SITE 2**	**SITE 3**	**SITE 4**	**TOTAL**
Median (IQR) Staff Time[min] /visit	A baseline	60 (44,65)	30 (15,45)	15 (0,52.5)	135 (128,142)	**45 (30,60)**
	B1 Mapping	80 (58,98)	120 (75,135)	90 (84,120)	150 (120,168)	**93 (66, 132)**
	B2 Map collection	38 (31,45)	45 (30,66.5)	NA	230 (230,230)	**43 (30,59)**
	C1 Change/mapping	70 (45,94)	80 (70,105)	47.5 (22.5,85)	150 (135,158)	**75 (54,100)**
	C2 Map collection	30 (25,30)	45 (35,75)	NA	NA	**35 (30,60)**
	D Follow-up	30 (30,45)	10 (10,15)	30 (15,45)	60 (30,67.5)	**23 (14,41)**
	E Final	30 (20,32.5)	10 (10,10)	30 (15,30)	30 (15,45)	**20 (10,30)**

The total visit time recorded per patient was also considered, again by site for all patients in PROMISE, with an overall median of 255 minutes, or 4.25 hours (per patient). This does not include non-patient facing time that was spend doing paperwork, identifying and requesting equipment or following up visits with other health care professionals. It also does not include all travel time.

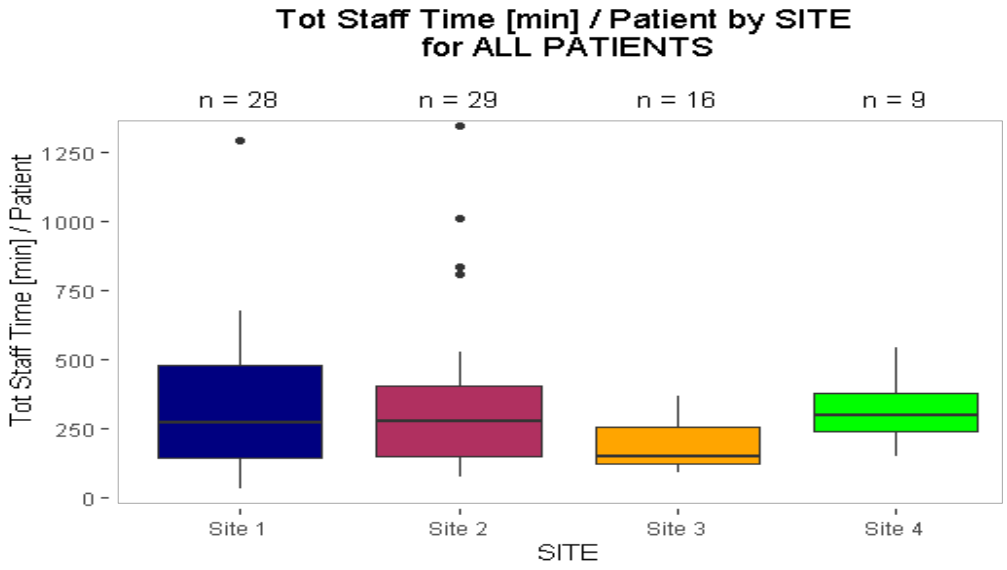


Figure 49 Total staff time spent per patient, by site

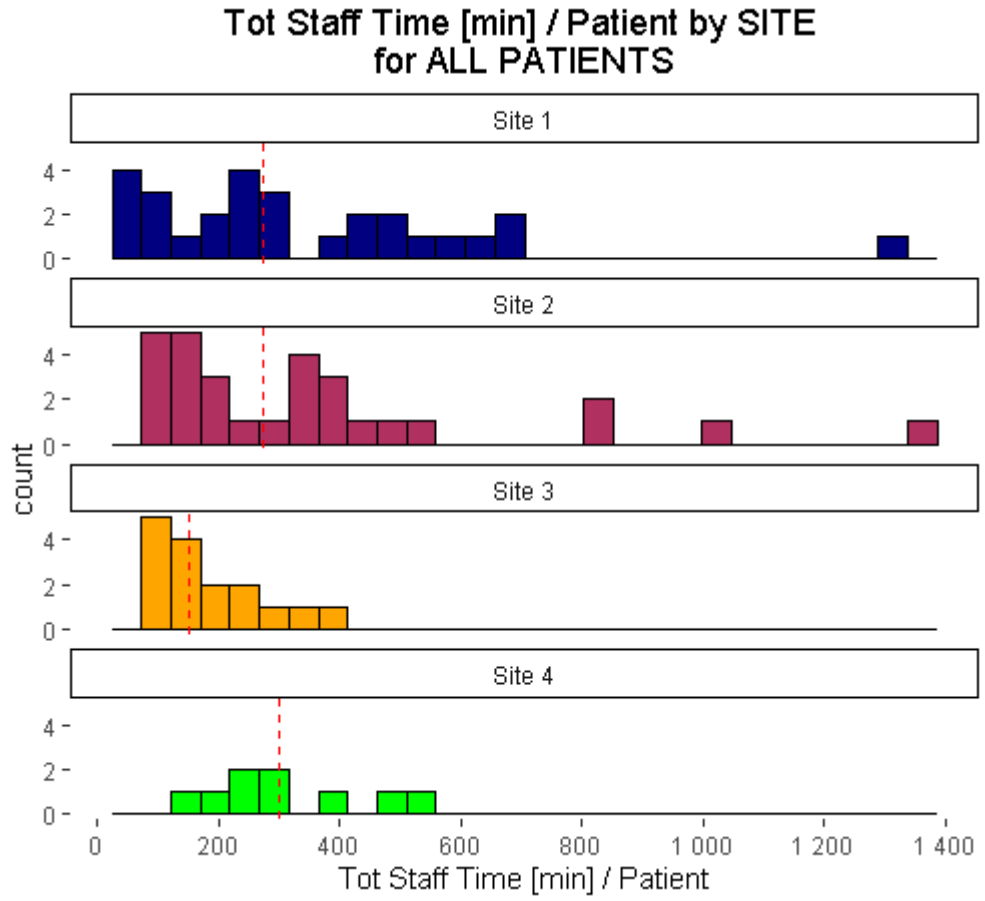


Figure 50 Total time spent per patient, by site

If only those patients who reached an E form due to healing were included this would change to 280 minutes, as patients who have only been recently recruited are excluded. However there are also a number of patients who have been participating in PROMISE for over a year and not reached an E form and these are also excluded from that analysis.

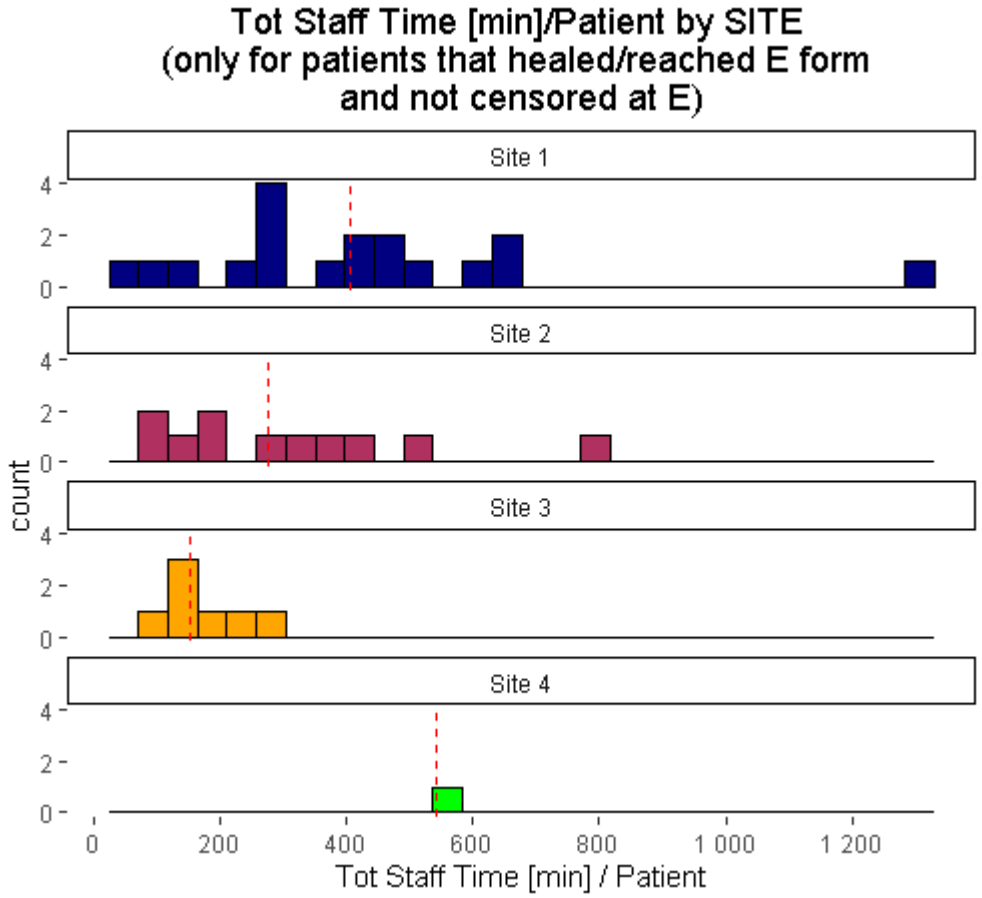


Figure 51 Total staff time per patient by site, for patients that completed PROMISE

Appendix J Extract from PROMISE Evaluation protocol (at start of recruitment)

1 Evaluation plan

1.1 Evaluation objectives

The aim of the evaluation is to explore the processes involved in introducing and delivering the intervention across a variety of sites. This is in order to understand the factors that may impact on the success or otherwise of the intervention in different contexts.

The evaluation questions are:

- Has PROMISE improved patient centred care for pressure management at each site, including patient education and staff understanding of patient needs?
- What are the cost implications of introducing continuous pressure monitoring in the community?
- How have different sites adapted PROMISE, and has this changed the way that it works?
- What are the barriers and facilitators encountered by the sites, and what resources would help future implementation of PROMISE?
- Has PROMISE become embedded into normal practice at each site

In addition the evaluation will:

- Provide formative information to sites to enable them to adapt and improve their implementation of PROMISE during the study
- Identify any usability issues encountered with the pressure monitoring technology
- Monitor changes in wound size over time

The evaluation is a pragmatic mixed-methods approach, including process evaluation, which will run alongside the intervention as it is introduced for a two year period, as shown by figure 1. Formative evaluation will be used to feedback information to the sites every 3 months. This will enable them to learn what adaptations and strategies are working well, and this can be adopted by other sites.

The key data collection routes will be:

- **Clinical data** for each patient collected by treating teams, via a project specific form, and returned to Cedar for entry on a database.
- **Service measures,** collected weekly by treating teams and entered into run charts to allow teams to monitor basic measures directly – if this is feasible within time pressures on clinical teams.
- **Patient questionnaires**, either online or on paper, posted to patients by Cedar, or returned by patients or carers in pre-paid envelopes. Each patient will receive these on three occasions.
- **Individual interviews** with patients, carers and staff conducted by Cedar in a semi-structured format. These will be limited to single interviews for a small number from each group over the course of the project.
- **Discussions and short questionnaires to staff** tailored to reflect emerging issues in the project, and to compliment other activities e.g. training events in order to minimise any impact on staff time.

Data collected will be to inform the following groups of measures:

- **Outcome measures:** the impact on the patient and the end result of the improvement work
- **Process measures:** how the system works to deliver the outcome
- **Structure measures:** describing the service or provider
- **Balancing measures:** unintended or wider consequence of the change (positive or negative)

Table 1 shows the measures that will be collected, who will be responsible for data collection, and which group of measures they belong in.

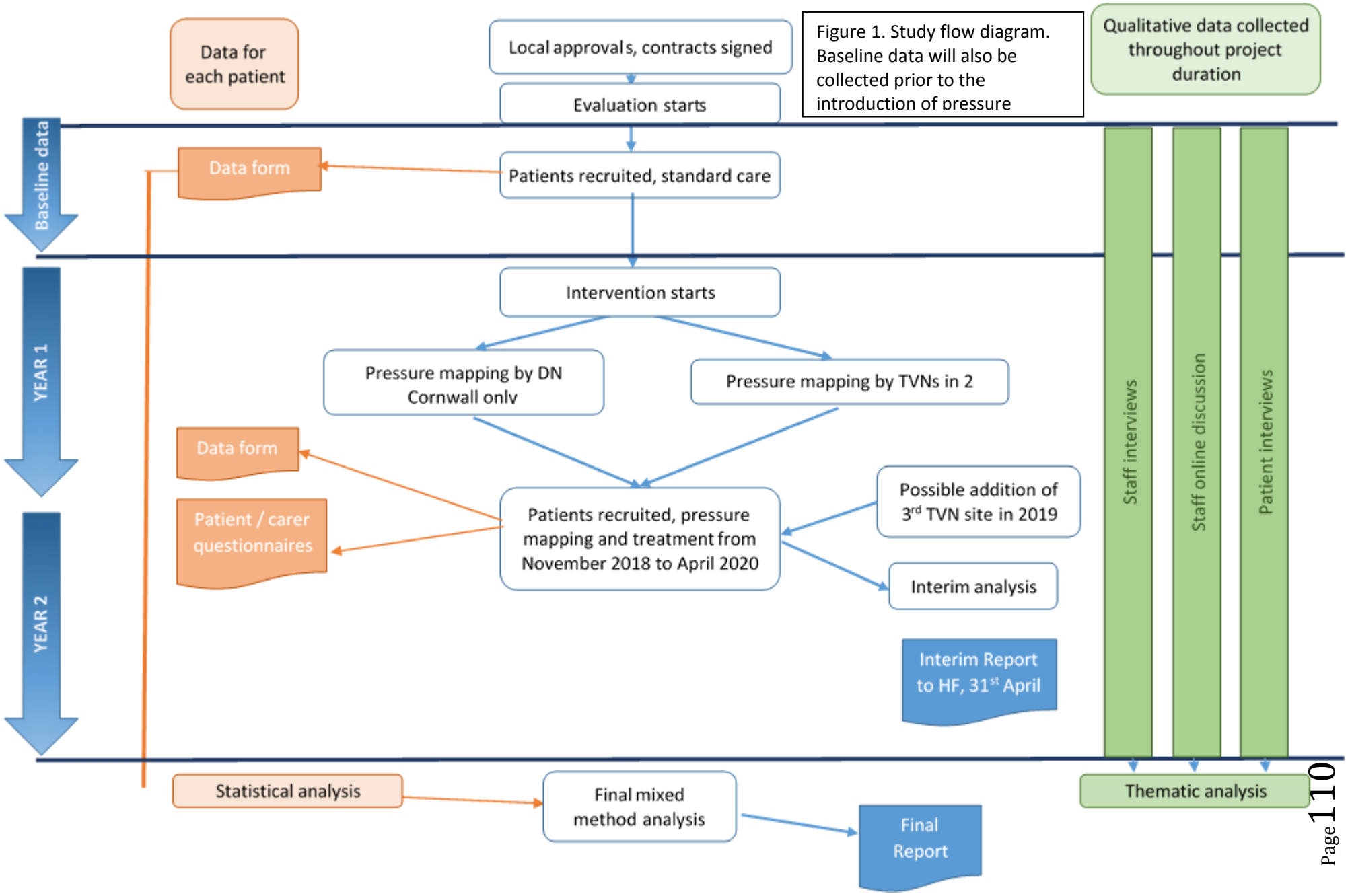


Figure 1. Study flow diagram. Baseline data will also be collected prior to the introduction of pressure

Table 1 Data Collection method	Type of data collected			
	Outcome –	**Process**	**Structure**	**Balancing**
Data collection form completed by TVNs / DN	Number of TVN patients classed as non-concordant pre and post continuous pressure monitoring	Number of visits and time spent by TVNs and DN	Basic patient demographics, including detailed Braden score	
	Change in wound size over time	Change in equipment prescribed	Reason for referral	
		Staff grades		
		Time pressure monitoring in place		Change in wound size over time
Questionnaire completed directly by patients / and /or carers. Posted by Cedar	Patient experiences via PREM Patient quality of life, related to PU			
Patient interviews, by Cedar	Patient experiences via interviews			May be identified in interviews
Patient focus groups / online, by Cedar	Group views of carer or patient experience –may not be feasible			
Staff questionnaires / online discussion groups/ focus groups/ interviews, organized by Cedar **Completed by TVN and DN staff**		Attitudes to intervention Barriers encountered How intervention delivered How intervention adapted Number of referrals	Attitudes to intervention Team structure Organisational support Equipment supply process	Will be a subject for questions and asked in staff interviews
Evaluator visits – Cedar in collaboration with sites		Qualitative insights into delivery of intervention		
Telephone interview with other staff e.g. physio., Cedar			Organisational support	Impact on other services
Routine data, Cedar			Demographics of region – deprivation, urban/rural, age etc.	
Information on project implementation and training, Cedar		Information flow Resources available to sites		

2 Baseline data collection

The evaluation process will, wherever possible, start at least 1 month prior to the introduction of the pressure monitoring intervention, to enable baseline data to be collected. Clinical data and patient questionnaires will be used to collect data as described below. Some of the patients may then go on to receive continuous pressure monitoring. In this case data will continue to be collected, but questionnaire timing may be adjusted for each patient to avoid very close timings of successive questionnaires.

In addition, sites will be asked to review five sets of patient notes to create a set of patient stories illustrating the current care pathway for individual patients. The information sent to Cedar would not contain any identifiable patient information, and would not be reported at a patient level.

3 Clinical data

The data collection forms will be posted monthly by Special Delivery to Cedar, or emailed using secure email, for entry into a database (Microsoft Access). The paper forms will be held securely at Cedar in locked storage until the end of the study at which point they will be securely archived. The data collection forms will be sent in a pseudonymised form using a trial number. No personal identifiable data will be posted or emailed to the evaluation partner using these forms.

The timing of data collection is shown in figure 2.

Data will also be used to allow each site to have a dashboard to track their progress, using one or two simple indicators, based around wound healing and non-concordance. Sites will be asked to track referrals of patients back to the PROMISE clinical team for non-concordance, and the number of PROMISE patients whose wounds are not healing each week.

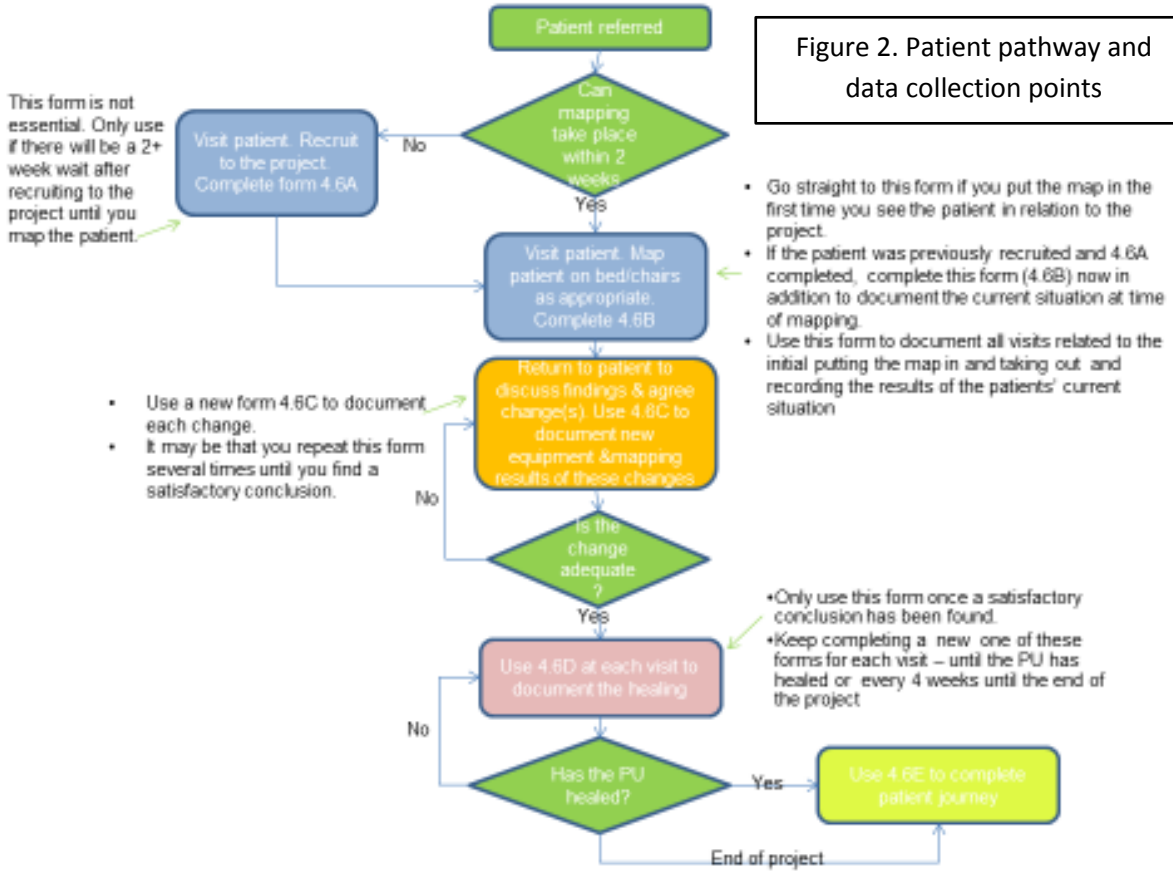


Figure 2. Patient pathway and data collection points

Table 2 Data collection measures	Intervention Phase		Follow up	
Clinical Measures	**T1-Day 0**	**T2-Day 1/2**	**T3-Week 4**	**FU**
TVN Visit duration (for all visits)	✓	✓	✓	✓
DN Visit duration (for all visits)	✓	✓	✓	✓
Braden scores for co-morbidity, Continence, mobility, posture, sensory impairment, level of consciousness, nutrition	✓			
Level of care available	✓	✓	✓	✓
Pressure ulcer grade	✓		✓	✓
Wound size	✓	✓	✓	✓
Wound photography	✓	✓	✓	✓
Equipment provision (categorises)	✓	✓	✓	✓
Reported use of mattress/cushion/foot protector	✓		✓	✓
Reported adherence to advice given (other than use of equipment)	✓		✓	✓
Patient reported measures				
Experience of pressure monitoring equipment		✓		
Patient and carer experience	✓		✓	✓ (16 week only)

4 Patient and carer questionnaires

Questionnaires will explore patients' experience of the intervention. They will capture the impact of the pressure ulcer on their quality of life, their views about changes that had been made to their treatment and the pressure relieving equipment provided to them. The first questionnaire to collect baseline data will be given to patients prior to the CPM intervention, after consent is taken. The patient can either complete the questionnaire online, or to post the completed paper form to Cedar using a pre-paid envelope. There may also be help available from volunteers if patients are unable to complete the questionnaires themselves. Subsequent reminders and questionnaires will be sent by post from Cedar.

Questionnaires will be administered at the following approximate time points:

- First visit, before pressure monitoring
- 4 weeks after first pressure monitoring
- 16 weeks after first pressure monitoring

The questionnaires for patients consist of:

- **PU-QOL** (Gorecki 2012), a pressure ulcer specific the impact that a pressure ulcer has on patient quality of life
- **Problematic Experiences of Therapy** (PET) (Kirby 2014), giving information on problems that patients may experience in carrying out the pressure reduction advice they have been given.
- **Patient reported experience measure**, unvalidated
- **EQ-5D5L,** a generic tool to enable quality of life data to be collected for health economic evaluation.

In some cases, where patients do not have capacity to consent, and do not have capacity to complete a questionnaire, a family member or friend may be asked to complete a questionnaire on behalf of the patient. Safeguards for continuing data collection where patients do not have capacity to consent are described in a later section.

Family and friend carers will be asked additional questions:

- **Problematic Experiences of Therapy** (PET) (Kirby 2014), giving information on problems that patients may experience in carrying out the pressure reduction advice they have been given.
- **Patient reported experience measure**, unvalidated

Although all the tools have been validated, except the PREM, they have not been used in combination, or in this setting. Therefore six months after the start of recruitment, the design of the questionnaire will be reviewed, informed by feedback from study PPI, as well as qualitative patient interviews. Any changes that are required to the questionnaire will be made at this point and the modified tool introduced across all the sites following agreement by the EAG and COG. Ability to change will be limited by permitted conditions of use for the tools, and the existing validation.

A short questionnaire to capture any problems encountered with the equipment will be administered by the clinical team after the first continuous pressure monitoring session.

5 Patient interviews

The aim of the interviews is to explore patients' experiences of the new intervention and to generate recommendations for further implementation. A purposive sample will be identified to ensure a suitable sample of the project (Creswell, 2013).Individual semi-structured interviews will be conducted with a minimum of 12 patients ideally until saturation of data is achieved. Saturation of data is defined as the number of interviews collected, transcribed and that during the ongoing analysis no new categories, subthemes or themes appear with the aim of exploring the experiences of the participating patients and carers (Creswell, 2003). The interviews will be conducted in the patient's home or any place of their preference and will be audio-recorded and transcribed ad verbatim by NHS staff in Cedar. During the consent process, patients will be asked if they also consent (as an additional option) to be contacted for interview by Cedar. Participants will be informed about the qualitative interviews within the Patient information leaflet. The interviews will take place over the duration of the study, and will not be at a fixed time after the initial intervention in order to access the full range of patient experiences.

6 Staff discussion and questionnaires

An online discussion will be used with staff involved in the implementation to share progress and discuss any issues that arise, occasionally prompted by focused questions from the evaluation team. All staff will be invited by email to contribute to the online discussion. Staff will be invited with an information sheet and consent will

be considered by writing their experiences on the online discussion. The discussion may take place on a private PROMISE Facebook group, WhatsApp group or group discussions on Life QI

As issues arise during the project and in response to the online discussion, Cedar will post questions to the discussion site. Cedar will also occasionally email each site team with additional questions where this format is more suitable. The format, timing and exact questions will be responsive to the discussion and site preferences. The types of questions Cedar will ask are likely to be around how staff feel implementation is progressing, availability of training, need for additional support, barriers to implementation, local adaptations that have been successful, and any unintended consequences (positive or negative).

Staff feedback is that a mix of online discussion and individual questionnaires is likely to give the most people an opportunity to contribute in a way that is conformable and convenient to them. Participation in either discussions or questionnaires is optional and consent will be implied by their contribution.

Group discussions, or contributions to physical flip charts will be scheduled to fit around any training events carried out by the implementation team. Close consultation will ensure that these do not impose an additional burden on clinical teams.

Information from the discussion and questionnaires will be used to feed back to all the sites and to improve the implementation strategies, including options for tailoring the approach according to local needs.

7 Staff Interviews

Semi-structured individual interviews with staff will be conducted with the aim of exploring the experiences of the implementing the new device (topic guide). A purposive sample will be identified to ensure a sample of the project (Creswell, 2013). This will represent a minimum of 2 staff members of each of the 4 participating sites. The interviews will be conducted at their place of work, or another site of their choice. Interviews will be audio-recorded and transcribed verbatim. The written informed consent process for the interview will be completed at the time of the interview itself. Where direct quotes are used in reporting, agreement will be sought from the interviewee.

8 Reporting from project lead / project manager

The project lead will be responsible for ensuring that that the evaluation team receive regular updates on training activities, site visits or other implementation work (although this task is likely to be delegated to the project manager). This will enable the impact of these activities to be considered in the evaluation work, and any differences in support required by the sites to be understood.

9 Evaluator visits

A member of the Cedar evaluation team will visit the participating sites to meet the team delivering the intervention at least once during the study and to conduct the interviews.

10 Interviews with other staff

The intervention may have effects on other areas of healthcare provision, such as community carers, district nurses, and rehabilitation engineering and physiotherapy teams who provide equipment. A limited number of semi-structured interviews will be completed to investigate any unanticipated effects of the intervention, either positive or negative. These interviews will be conducted either by telephone or in person depending on the availability and preferences of the staff being interviewed. The information from these interviews may also add to the understanding of possible barriers, or enabling factors, encountered by implementation sites. The

staff will be identified following discussions with the sites and are expected to vary between sites. The questions will be developed from the information gathered from the clinical sites during the trial.

11 Data storage and analysis

11.1 Clinical data

Routine clinical data will also be recorded on the data collection form, as shown in table 2. The consent form with the patient study number and contact details will be detached and posted to Cedar on recruitment. Cedar will use this information only for purposes of posting questionnaires and reminders. The PID will not be linked to collected data.

The data collection forms will be posted monthly to Cedar for entry into an electronic database held on a secure NHS server. The paper forms will be held securely at Cedar in locked storage until the end of the study at which point they will be archived. On these data collection forms, the patient will only be identified using a pseudonymised study identifier.

Data analysis will by using SPSS statistics software. Descriptive statistics will be used to present patient baseline information across site. The changes between the patient baseline measure (at first visit) and the subsequent post-mapping measures will be reported for the study as a whole, and comparing between sites using the baseline wound size as a co-variant. Change in wound size over time from day 0 to the end of treatment will be considered using repeated measures analysis.

Where retrospective data (for patients treated before the introduction of CPM) is available either from an audit of patient notes or service evaluation, then a comparison can be made between the outcomes before and after the introduction of CPM. There is no available publication on which to base a sample size calculation, and the availability and completeness of retrospective data will vary between sites.

11.2 Questionnaires

Responses recorded on hard copies of patient and staff questionnaires will be transcribed to an electronic database held on a secure NHS server by Cedar. Data transcription to the database will be checked using risk proportionate monitoring by a second Cedar researcher. Questionnaire data will be only identified on the form or database using a pseudonymised identifier. The paper copies will be held securely at Cedar in locked storage until the end of the study at which point they will be archived.

Bristol Online Surveys software will be used to collect questionnaire data electronically, depending on the preference of the respondents. Cedar researchers will securely access and download the responses to an NHS server. Again, a pseudonymised identifier will be used so that no personal identifiable data need be collected on the survey forms or database. Storage of the data will confirm to GDPR requirements.

11.3 Qualitative data

All interviews with patients and staff will be recorded using a password-protected device, with their permission Audio recordings of each interview will be saved to a secure NHS server at Cardiff & Vale University Health Board, and then deleted from the voice recorder device. Audio recordings will be transcribed verbatim by researchers at Cedar into a standard word processing document.

Where potentially patient identifiable data (PID) is present (e.g. names of relatives, home town, name of treating clinician, date of birth etc.), this will be de-identified in the transcript. Recordings and transcripts will be identified only by a study identifier. Audio files and transcripts will be archived one year following the end of the study.

Thematic analysis will be used. This method includes a strategy for identifying themes and subthemes (Braun & Clarke, 2006). The transcripts of the interviews will be uploaded to the qualitative analysis program NVivo. The first analysis step will involve familiarization of the narratives allocating the text fragments to initial codes. Meaningful text fragments will be determined, as will codes (sub-themes) and themes related to the objectives of the project. Data extracts will be accompanied by narrative to elaborate why the extract is analytically interesting. The codes will be formulated from the text fragments and will possibly be revised during the process of reading the transcripts. After this, the codes will be reviewed, and themes will be formulated. All participants will be anonymised, and pseudonyms used to demonstrate different participants' experiences. If any information is disclosed during the project that could pose a risk of harm to the participant or others, the CI where appropriate, will report and act accordingly.

12 Health Economic analysis

A health economic model will be created in Microsoft Excel comparing the costs of the patient pathway prior to the intervention, and the costs of the patient pathway after the intervention was introduced. The model will be from an NHS and personal social services perspective and based on the NICE reference case and include sensitivity analysis. Scenarios will be explored to look at the differences in cost at each site.

Costs will be calculated using tissue viability and community nurse time, changes of equipment and the cost of pressure monitoring equipment. Costs for dressings and treatments will be allocated a cost per visit based on expert opinion and published data, as the burden of collecting this data is very high and unlikely to be sufficiently rigorous for a full bottom up costing approach.

13 Dissemination

The data are owned by the Lead Organisation, with participating sites owning their own data. On completion of the trial, the data will be analysed and tabulated and a Final Study Report for the Health Foundation prepared by the Evaluation Partner. The full study report will be able to be accessed on the study web-site page. The participating investigators will have rights to publish the trial data; this will be undertaken only after discussion and in collaboration with the CI and after publication of the trial's main paper.

There are no time limits or review requirements on the publications. The Health Foundation (the funding body) will be acknowledged within the publications. They do not have review and publication rights of the data from the trial. Results will be presented at national and international conferences and published in Open Access Journals.

Participants of the study will be notified of the outcome of the study via a newsletter following the completion of the study. The final report will be available on request. The study protocol, full study report, anonymised participant level dataset and the methods used for generating the results will be made publicly available within a year of completion of the study ending.

14 Ethical considerations

14.1 Consent

A patient information sheet and a consent form will be given to all patients included in the evaluation. The information will be given by their clinical team and patients will have the opportunity to read the information and ask questions. Patients who do not want to participate in the evaluation will still be able to continue with pressure monitoring. Patients will have the opportunity to withdraw consent at any time, without it influencing their normal care. The contact details of the evaluation team will be provided and patients may either contact the team directly, or request to be withdrawn from the evaluation via the clinical team.

If the participant is unable to read the consent form a witness should be present during the entire informed consent discussion. After the informed consent form is read to the participant and signed by the participant the witness should also sign the consent form attesting that informed consent was freely given by the participant. The participant must receive a copy of the signed and dated informed consent form.

A large proportion of patients suffering from PUs or at risk of PUs have receptive or comprehension or language difficulties. They may also have general cognitive impairment affecting their understanding and/or dementia. Cognition impacts upon compliance with repositioning and self-care. To ensure that the evaluation captures the impact on this population as well as possible, these patients will be included subject to advice from family or carer. Where the patient is thought not to have capacity to consent, a relative, carer or friend who is interested in the patient's welfare will advise us. These patients would not participate in the patient questionnaires or interviews unless capacity was regained, and consent obtained. Carers could still participate in the carers' questionnaire or in interviews. Patients who regained capacity to consent would be asked to consent if they wished to participate further in in the evaluation.

If during an interview, patients request information about their clinical care, the interviewer will direct them to their care team, and will have appropriate contact details available. It is possible that, during interviews, patients, carers or staff may disclose information to the interviewer that needs to be escalated to other bodies. Prior to the start of interviews, a guide on who to escalate issues to for each site will be available. For example if there were concerns that the patient is experiencing , or at risk of, abuse the interviewer will follow relevant the Safeguarding Adults policies appropriate to the different sites which may involve Safeguarding Adults Team, Ward Manager, Department of Adult Social Care, GP or community care team.

Appendix K Evaluability assessment

PROMISE

Evaluability Assessment

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Date: 26th April 2018

Version: v1.0

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
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CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD

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10 Evaluability Assessment summary, challenges to overcome, and reflections on work so far

We have used the initial section to give a semi-structured summary of the main challenges to both the evaluation and the project as a whole and reflections on the process to date. We have used the suggested checklist from (Davies, 2013) at the end of the report.

This assessment has aimed to give information that will be useful to the project and evaluation teams in progressing with the project. Additional information can be added if required following feedback from the Health Foundation.

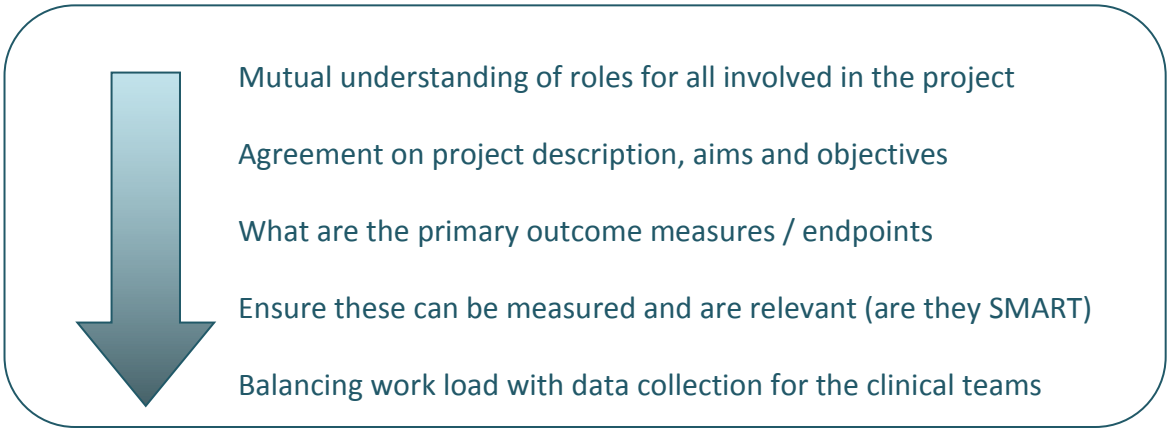
10.1 Suitability of PROMISE for evaluation (based on Davies, 2013)

PROMISE is based on an intervention that is clearly designed to benefit patients, and that has evidence to support the scaling up process. The clinical sites are interested and involved, although they can be anxious about the work load and challenges. There is a shared understanding of the key elements of the clinical intervention, and the intended outcomes for patients and staff.

There is currently a lack of clarity and consistency about the overall project objectives and the data that needs to be collected and evaluation. This needs to be resolved for a successful evaluation that meets the needs of all involved.

10.2 Greatest challenges for the evaluation

The greatest challenges, as perceived by us (Cedar Evaluation team), following use of the evaluation checklist, are listed below. My perception is that each of these follows on from the other. When we try to resolve details of an item lower in the list we find it difficult because we need to first agree on the earlier stages. This is something that requires input from both the evaluation and project teams.



SMART: Specific, Measurable, Achievable, Realistic, Time-bound

10.3 Overcoming these challenges

The Clinical Oversight Group (April 2018) was valuable, particularly with external views of the protocol that highlighted the work still to be done. This will be followed up with a meeting on 3rd May 2018 with Rubis QI to discuss roles and project objectives.

10.4 Evaluability areas that require more input from Cedar:

Consulting a wider group of stakeholders, particularly those who would be key to wider scaling up in the future. This is to make sure the evaluation covers what is important in future scaling up decisions.

Improving communications with sites to reflect their preferences. Feedback included giving clinical sites sufficient information, but in discrete organised packages such as a monthly update. This applies to communication strategies across the whole project.

Gathering more information from sites about the patients they expect to see, and problems they might encounter in the evaluation (for example ability to complete a questionnaire).

10.5 Reflections on the set up phase / evaluability assessment

The time lines and needs of the project team and the evaluation team are quite different during the set-up phase. One of the barriers that we have encountered is that we felt unable to fully engage with stakeholders in the way that we had initially envisaged. The project was in quite an early stage of development, and clinical sites had not got a clear idea of what would be happening in the project. This was compounded with uncertainties of roles and objectives within the project and evaluation team, and the delays in recruiting a project manager and administrator. We felt that it was important for the primary source of project information to be the project lead, and that communications from the project lead should take priority. Sites were receiving a lot of project related emails and by engaging with a range of stakeholders at the sites at this point in the project there was a risk that the evaluability assessment could endanger the viability of the main project. Early discussions with the Health Foundation established that it was important to have a central information point online as well. The establishment of this is not a priority for the project team at the same point of time as it would be required for the evaluability assessment, due to their different goals during the set-up phase.

The different priorities and time lines were identified in the Cedar risk register at an early stage, however they still had an impact on our activity. This may be something that can be used as a learning point for future projects.

For many reasons the evaluability assessment has had to take second place to the requirements of the whole project. By maintaining a flexible approach to some aspects of the evaluation we hope that we can continue to gather information from stakeholders on their requirements, and adapt the evaluation to meet this.

11 Evaluability checklist (Davies, 2013)

11.1 Project Design

11.1.1 Clarity

Are the long-term impact and outcomes clearly identified and are the proposed steps towards achieving these clearly defined?

We have created a logic model that clearly identifies the outputs and outcomes. Although we developed a logic model in the early stages of the project proposal, the current version has been developed following feedback from project teams and we will develop it further during the project. Long-term impacts were not identified during this process. The logic model is included with the set-up phase report to the Health Foundation.

11.1.2 Relevant?

Is the project objective clearly relevant to the needs of the target group, as identified by any form of situation analysis, baseline study, or other evidence and argument? Is the intended beneficiary group clearly identified?

The clinical objective of improving healing is clearly of benefit to the target group of patients with hard to heal pressure ulcers.

The intended beneficiary patient group has been clearly defined during recent work on the protocol as patients who meet all the following criteria, plus criteria of consent:

- The patient must be a high risk of developing a pressure ulcer identified using the Frailty Score *(Rockwood et al., 2005)* of 6 and above and recognised pressure ulcer risk assessment tool.
- At least one pressure ulcer that has been present for greater than 2 months AND
- Patient has refused equipment or has stated that they will not/have not followed advice given by the care team.

Although some concerns were raised from sites that felt they did not have sufficient numbers of patients in these categories, after discussion they felt that they could identify sufficient patients and knew who would be included.

Clinical staff and the wider NHS organisations could also be a beneficiary group if the scaling up process proves to be successful and PROMISE can be adopted more widely. Staff in the previous i4i project reported that it resulted in improvements to their practice and a preliminary economic evaluation showed it to be cost saving.

11.1.3 Plausible?

Is there a continuous causal chain, connecting the intervening agency with the final impact of concern? Is it likely that the project objective could be achieved, given the planned interventions, within the project lifespan? Is there evidence from elsewhere that it could be achieved?

There is a plausible causal chain with evidence from the NIHR i4i project completed by Cornwall Partnership Foundation NHS Trust. No other published evidence has been identified showing the impact of continuous pressure monitoring for 24 hours influencing subsequent treatment in community care.

Pressure mapping has been in accepted, if not very wide-spread, use for many years. It is used in wheelchair modifications and assessment and for patient education. Some tissue viability teams already use it, including the team in Portsmouth. There is some evidence that pressure mapping can improve clinical decision making (Crawford 2005).

There is evidence of continuous pressure monitoring in use in a hospital setting, where monitoring is constantly in place and used to indicate the need for turning or identify issues in real time (Walia 2016, Behrendt 2014, Gunningberg 2016). Both the setting and intervention are very different from PROMISE. The setting for most patients is in intensive care units and staff are expected to use the monitor information to optimise patient positioning and turning. The monitoring is in place for the duration of the patient stay.

There is also evidence showing that specialist intervention with the time and tools to provide an individualised care plan can improve outcomes. We explored this previous project in collaboration with Cedar and NHS providers in South West England, including Cornwall. The specialised service provided in Salisbury is combined rehabilitation engineering and tissue viability experience to improve outcomes (Dale, 2014). Although PROMISE does not explicitly include rehabilitation engineering experience, the pressure monitoring information may help tissue viability nurses to improve their advice in a similar way.

11.1.4 Validity and reliability?

Are there valid indicators for each expected event (output, outcome and impact levels)? i.e. will they capture what is expected to happen? Are they reliable indicators? i.e. will observations by different observers find the same thing?

This is an area that has been causing a lot of debate although agreement can be achieved during the logic model discussions about what clinical outcomes are expected. During discussions about data collection and measurement there are very different views on what is expected, what is relevant and the robustness of the measure to be used. We hope that the meeting in May 2018 will help to resolve these issues and allow the project to move forward.

11.1.5 Testable?

Is it possible to identify which linkages in the causal chain will be most critical to the success of the project, and thus should be the focus of evaluation questions?

It will be very difficult to know which part of the causal chain is most important to the success of the project. Our understanding of the causal chain is that any of the following could be critical:

- the information given by the mapping to the patient during the 24 hour period,
- the information derived by the clinician from mapping,
- the extended consultation time with an experienced specialist in tissue viability,
- an improved patient-clinician relationship due to the mapping/ consultation process.

There may be other factors not yet identified. The evaluation will be able to explore what it is in the process that both patients and staff feel are important. Differences in how the sites implement the pressure monitoring may also help us to understand the most critical parts of the chain.

In summary, we do not know in advance the most critical part to evaluate, and will be evaluating the intervention as a whole. We may be able to answer the question better at the end of the evaluation, however it is not one of the evaluation aims.

11.1.6 Contextualised?

Have assumptions about the roles of other actors outside the project been made explicit (both enablers and constrainers)? Are there plausible plans to monitor these in any practicable way?

There will be an impact on carers. This is explicit in the logic model and protocol and they will be included in questionnaires.

There may be impacts on people linked to equipment provisions (wheelchair services, physiotherapists or OTs), community nurses and also care homes. These will not be routinely monitored on a regular basis, but we will approach staff from these groups for short interviews to investigate unintended consequences, or impacts on the project success.

11.1.7 Consistent?

Is there consistency in the way the Theory of Change is described across various project multiple documents (Design, M&E plans, workplans, progress reports, etc.)?

There have been ongoing inconsistencies in describing the project aims and objectives. We are gradually resolving these, however it has been a time consuming and confusing process. The nature of the project, involving a clinical intervention, the process of scaling the intervention up to additional sites, and the evaluation of this process means that the project can be described very differently from alternative viewpoints. The evaluation and project lead teams are working at overcoming these different perspectives, however it has been a significant learning curve for all.

11.1.8 Complexity?

Are there expected to be multiple interactions between different project components [complicating attribution of causes and identification of effects]? How clearly defined are the expected interactions?

The evaluation will treat the intervention (pressure monitoring followed by extended consultation with tissue viability or district nurse team) as a single item.

In terms of scaling up, there will be multiple interactions between project components such as supply of pressure relieving equipment, relationship with care home teams, support from senior management, level of training and experience within the team. These will be different at each site, and the evaluation will aim to describe these differences.

11.1.9 Agreement?

To what extent are different stakeholders holding different views about the project objectives and how they will be achieved? How visible are the views of stakeholders who might be expected to have different views?

All teams are agreed on clinical objectives of reducing healing times and improving patient –clinician concordance on pressure reduction strategies. There are significant differences from the clinical and evaluation teams in their views of project objectives and how they will be achieved. The teams are aware of this and we are taking steps to resolve it. Hopefully a meeting on 3rd May 2018 with Rubis QI will result in greater agreement.

Objectives of the clinical sites were explored during the logic model development and are in line with the core clinical objectives.

Cedar should explore additional stakeholder views, particularly from managerial and commissioning levels. This will ensure that the evaluation meets their requirements if considering further scaling up.

11.2 Information availability

11.2.1 Is a complete set of documents available?

…relative to what could have been expected? E.g. Project proposal, Progress Reports, Evaluations / impact assessments, Commissioned studies

The project funding application is available and has been shared with all the sites, as is the final report for the i4i project. No detailed study report or data has been seen for the i4i project. The data collection tools, consent forms and patient information have been available from i4i since the start of the project and during the set-up phase these have been adapted for use in PROMISE. These were discussed at the clinical oversight group and require further development, and feedback from all parties.

11.2.2 Do baseline measures exist?

If baseline data is not yet available, are there specific plans for when baseline data would be collected and how feasible are these? If baseline data exists in the form of survey data, is the raw data available, or just selected currently relevant items? Is the sampling process clear? Are the survey instruments available? If baseline data is in the form of national or subnational statistics, how disaggregated is the data? Are time series data available, for pre-project years?

No baseline data is currently available. Cedar originally hoped to carry out a small service evaluation at each site to collect data using current pathways, using the same data collection tools that would be used during PROMISE. This will not be appropriate due to:

- time needed to create the protocol and agree what will need to be measured, and defined the patients who will be included
- lack of resources for the participating sites to take on additional work.

Sites will collect baseline data retrospectively for patients treated before PROMISE. This will give information on duration of wound healing and some limited information on the staff perspective of concordance.

There are regional and national measures of pressure ulcer numbers (eg safety thermometer), but these are unlikely to be reliable in community settings and will not identify the particular patient cohort that we are interested in.

11.2.3 Is there data on a control group?

Is it clear how the control group compares to the intervention group? Is the raw data available or just summary statistics? Are the members of the control group identifiable and potentially contactable? How frequently has data been collected on the status of the control group?

There will not be a control group running in parallel, the only comparator will be patients treated in the period before the project and full data will not be available for them.

11.2.4 Is data being collected for all the indicators?

Is it with sufficient frequency? Is there significant missing data? Are the measures being used reliable i.e. Is measurement error likely to be a problem?

This largely relates to issues that we have identified in 2.1.4 and 2.1.9

There is likely to be some missing data as it will be collected by busy clinical teams with conflicting demands on their time. We will try to minimise this by only collecting the essential data and consulting with sites on the design of the data collection tool to make it easier.

Feedback from the sites has indicated that patient self completion of the questionnaires will be difficult for some patients. We are very keen to patients to complete the information either on their own or with assistance from carers as far as possible, to remove bias that would occur if the patient were interviewed by the clinical teams. Feedback on the questionnaires will be sought from patients who participated in the previous project

11.2.5 Is critical data available?

Are the intended and actual beneficiaries identifiable? Is there a record of who was involved in what project activities and when?

The evaluation and project lead teams will be able to see a record of the number of patients recruited by each site.

11.2.6 Is gender disaggregated data available?

In the baseline? For each of the indicators during project intervention? In the control group? In any mid-term or process review?

All data collected from patients will be gender disaggregated, both prior and post intervention.

11.2.7 If reviews or evaluations have been carried out…

Are the reports available? Are the authors contactable? Is the raw data available? Is the sampling process clear? Are the survey instruments available?

Survey instruments and the final report from the i4i project have been shared across the project team. Cedar may benefit from any more detailed information about methods, successes and problems from the i4i project.

11.2.8 Do existing M&E (monitoring and evaluation) systems have the capacity to deliver?

Where data is not yet available, do existing staff and systems have the capacity to do so in the future? Are responsibilities, sources and periodicities defined and appropriate? Is the budget adequate?

There have been anxieties expressed by clinical sites about the amount of time that the data collection element of the evaluation will take. The data to be collected needs to be only that needed to achieve the project objectives.

11.3 Institutional context, Practicalities

11.3.1 Accessibility to and availability of stakeholders?

Are there physical security risks? Will weather be a constraint? Are staff and key stakeholders likely to be present, or absent on leave or secondment? Can reported availability be relied upon?

The main limitations are expected to be:

- time pressures on clinical staff
- poor health of patients limiting ability to complete questionnaires or take part in interviews
- geographical distances limiting the number of patients that clinical staff can visit, evaluation visits to patients and staff and face-to-face meetings to facilitate project implementation

11.3.2 Resources available to do the evaluation?

Time available in total and in country? Timing within the schedule of all other activities? Funding available for the relevant team and duration? People with the necessary skills available at this point?

Evaluation and clinical teams are funded by the Health foundation Scaling Up programme, which can also provide support in training and advice. Distance of evaluators from the clinical team is not ideal due to travel time for interviews and meetings, however we are working to improve communications with the project teams and sites. As we find out how people prefer to communicate we can adapt to suit this.

The Cedar team have skills in improvement science and health economics as well as facilitating research trials and working with wound healing projects. Due to changes in jobs there is less time available from Ruth Poole who has experience in improvement science, however she is still providing support and guidance for this aspect of the project. Megan Dale has also completed training in process evaluation and will be continuing with additional training.

The evaluation team role within this project is different to our normal role in research projects, and understanding our role, for both us and the project team, can be challenging.

11.3.3 Is the timing right?

Is there an opportunity for an evaluation to have an influence? Has the project accumulated enough implementation experience to enable useful lessons to be extracted? If the evaluation was planned in advance, is the evaluation still relevant?

Yes, the evaluation is being planned alongside the implementation. Formative assessment will be used to influence the implementation process.

11.3.4 Coordination requirements?

How many other donors, government departments, or NGOs need to be or want to be involved? What forms of coordination are possible and/or required?

There is only one main funding body, however there may be additional funding for extra pressure monitoring devices. There are other bodies who are supporting the project, as described in the logic model.

11.4 Institutional context, Demands

11.4.1 Who wants an evaluation?

Have the primary users been clearly identified? Can they be involved in defining the evaluation? Will they participate in an evaluation process?

The driving force for the project, together with the evaluation, comes from tissue viability teams, in particular the project lead. Tissue viability teams will be able to use evaluation outputs to make evidence based changes in practice, and justify any changes with the economic information from the evaluation.

11.4.2 What do stakeholders want to know?

What evaluation questions are of interest to whom? Are these realistic, given the project design and likely data availability? Can they be prioritised? How do people want to see the results used? Is this realistic?

This is an important question, and an important area of inconsistency between project team and evaluation team members. The meeting with Rubis QI on 3rd May 2018 should assist in answering this question.

11.4.3 What sort of evaluation process do stakeholders want?

What designs do stakeholders express interest in? Could these work given the questions of interest and likely information availability, and resources available?

The overall design of the evaluation process has not been discussed with all the stakeholders, however elements are being adapted following feedback from sites. Feedback has included the ability of patients to self-complete questionnaires, and the preferred communication methods between evaluators and clinical staff.

11.4.4 What ethical issues exist?

Are they known or knowable? Are they likely to be manageable? What constraints will they impose?

Any health care research project involving patients will have to undergo ethical scrutiny. There are particular risks to this project because the population being treated will include frail and vulnerable adults, including those lacking capacity to consent. There have been discussions around the use of consultees and different methods of recording consent (eg verbal consent with a witness).

11.4.5 What are the risks?

Will stakeholders be able to manage negative findings? Have previous evaluation experiences prejudiced stakeholder's likely participation?

We are not aware of any of the stakeholders having previous experience of similar evaluations. We hope to build up a good working relationship where we can report both positive and negative findings, and use these during the project to improve the implementation process.

12 References

Behrendt R, et al. Continuous Bedside Pressure Mapping and Rates of Hospital-Associated Pressure Ulcers in a Medical Intensive Care Unit. Am J Critical Care. 2014; 23(2): 127-133.

Dale M., Cox-Martin B., Shaw P., Carolan-Rees G. (2014) Cost-effective non-surgical treatment of chronic pressure ulcers in the community. British Journal of Community Nursing, Vol. 19, Iss. Sup1, 07, pp S6 - S12

Davies R. *Planning evaluability assessments: A synthesis of the literature with recommendations*. 2013: pp. 19–23. Available at www.gov.uk/dfid-research-outputs/planning-evaluability-assessments-a-synthesis-of-the-literature-with-recommendations-dfid-working-paper-40

Gunningberg L, Carli C. Reduced Pressure for Fewer Pressure Ulcers: Can Real-Time Feedback of Interface Pressure Optimise Repositioning in Bed? Int Wound Journal. 2014; doi: 10.1111/iwj.12374

Walia G et al. Efficacy of Monitoring Devices in Support of Prevention of Pressure Injuries: Systematic Review and Meta-analysis. Adv in Skin & Wound Care. 2016; 29(12): 567-574.