A 60 patient observational evaluation of the clinical benefits and acceptance of a silicone foam dressing for formulary inclusion within 5 NHS sites in the UK

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Introduction
Managing wound exudate, delicate tissue and preventing pain and trauma at dressing change can be challenging and confusing with the plethora of dressing materials available ranging from gauze, traditional foam, silicone backed foam, hydrofibre and superabsorbent materials. Key considerations include wound exudate type, consistency and volume, the fragility of the wound bed, tissue graft and surrounding skin to prevent additional tissue trauma. In circumstances such as post skin grafting, burn injury, where friable tissue is present or when a patient experiences severe pain during dressing change or has Chronic Regional Pain Syndrome (CRPS) a silicone backed dressing is often recommended and is widely documented within the literature as being first line product choice. The evaluations reported below are part one of the NHS Trust potential formulary inclusion evaluations to explore the clinical effectiveness and patient acceptability of a silicone foam dressing prior to undertaking a potential cost saving analysis.

Method
Five centres within England and Scotland independently agreed to evaluate an available silicone foam dressing range for potential formulary inclusion. The aim being to explore clinical effectiveness in terms of exudate handling ability, conformity, ease of application and removal, patient comfort rating and clinician acceptability ratings.

Each centre received an evaluation initiation visit consisting of product range and data capture training. Local guidelines were followed at each site for approval to conduct potential formulary listing evaluation and informed consent was obtained from each participating patient. Adverse event reporting and patient withdrawal instructions were given.

Results
A total of 60 patients were evaluated across the 5 sites, (65%) female, (42%) male (3%) gender not stated, age range 37-100 years with an average recorded age of 68 years. A variety of wound types were recruited including trauma/complicated surgical combined (72%), pressure ulcers (19%), burn/graft/donor combined (10%) and (8%) reported as other.
A total of 206 dressing changes were recorded with an average of 3.4 changes evaluated per patient.
Exudate levels recorded as (61%) Light, (30%) Moderate and (9%) Zero exudate.
Exudate management 175 responses (135) very good, (32) good, (1) average, (1) poor and (0) very poor (93%) rated in good and very good.
Conformability to the wound 197 responses (140) very good, (40) good, (7) average, (1) poor and (3) very poor (90%) rated in good and very good.
Patient comfort a total of 194 responses (160) very good, (32) good, (1) average, (1) poor and (3) very poor compared to previously experienced dressing products (93%) rated in good and very good.
Ease of use application 194 responses (156) very good, (31) good, (6) average, (6) poor and (1) very poor (81%) rated in good and very good.
Ease of use removal 183 responses (141) very good, (35) good, (7) average, (6) poor and (0) very poor (85%) rated in good and very good.
No adverse events or patient withdrawals were reported. 97% of clinicians rated product performance equal to or better than current formulary listed or previously used product and 95% stated yes that they recommended the product for future formulary listing.

Discussion/Summary
The results are positive with ease of application rated (91%) good and very good, conformity to the wound (90%) good and very good, exudate management (83%) good and very good, patient comfort (83%) good and very good and ease of removal (85%) good and very good.
Some data was not completed and are only representative of 175-197 responses in parts of the reporting of the total 206 dressing changes recorded.
A limitation to this data is that it would have further benefitted from data capture on wound bed condition, peri wound skin assessment, pain score and QoL to further validate the clinical benefits and aid the cost analysis moving forward in light that (90%) of evaluators wished to take it to next stage of formulary consideration.
The evaluation product has been retrospectively contrasted and compared to (73%) foam or silicone foam dressings and (27%) hydrofibre or superabsorbent type dressings creating some variability in expectations, results and feedback. However (97%) rated as equal to or better than previously used dressing.

Conclusion
The results of these silicone foam evaluations are favourable in terms of clinical use and effectiveness but would benefit from additional work further exploring the value of silicone in reduction of pain and trauma. Clinical cost benefit pilot analysis identified significant financial savings of 26% based on dressing unit cost and has resulted in successful formulary inclusion in all evaluators Trusts.

References
2. Drug Tariff 2020 (Prices correct from November 2020) based on T. x 10cm dressing