NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Review Decision

Review of MTG21: The ReCell Spray‑On Skin system for treating skin loss, scarring and depigmentation after burn injury

This guidance was issued in November 2014.

At any point during the development of a review proposal or decision, NICE may decide that it is not appropriate to proceed with the review and propose to defer the review. This may happen for example where NICE has become aware of important developing evidence that is not yet available but is considered likely to have a material effect on the existing guidance recommendations.

1. Review decision

The review of this guidance is deferred until August 2019.

2. Original objective of guidance

To evaluate the case for adoption of the ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury.

3. Current guidance

The recommendations in MTG21 are:

> "1.1 The ReCell Spray‑On Skin system shows potential to improve healing in acute burns. However, there is insufficient evidence on its use in clinical practice, particularly in relation to which patients might benefit most from its use, to support the case for its routine adoption in the NHS."
>
> "1.2 Research is recommended to address uncertainties about the claimed patient and system benefits of the ReCell Spray‑On Skin system. Clinical outcomes should include time to 95% healing, length of hospital stay, cosmetic appearance of the scar and function of the burned area, compared with standard care. As relevant databases and registers are available, the research might include analysis of data generated from these. NICE will explore the development of appropriate further evidence, in collaboration with the technology sponsor and with clinical and academic partners, and will

update this guidance if and when new and substantive evidence becomes available."

4. Rationale

NICE has facilitated, through the MTEP research commissioning workstream, evidence generation on ReCell which is expected to directly address the committee's research recommendations. No other relevant evidence has been identified since the guidance was published nor has there been a change in the care pathway requiring an earlier review.

5. NICE-facilitated research

Following the publication of this guidance NICE commissioned 2 studies from the External Assessment Centres (EAC) to facilitate the research recommended in section 1 and described in more detail in section 6 of the guidance:

The committee's considerations on further research included the possibility that relevant information could be collected by working with the existing data sources such as the International Burns Injury Database. NICE therefore commissioned the Newcastle & York EAC to conduct an exploratory study into using existing data sources to provide useful information. The EAC conducted an expert elicitation study and considered the data fields collected in the International Burns Injury Database and concluded that this approach was unlikely to provide useful information for any future update.

NICE also commissioned the Cedar EAC to design and facilitate a pragmatic randomised controlled trial on people undergoing therapy with ReCell compared with those receiving standard care for healing, graft skin sparing and scar outcome. Attempts to secure competitive funding from the NIHR and other sources were unsuccessful, leading to delays to the start of this research. More recently Cedar have received agreement for unrestricted funding from the company (Avita, £0.250 M), a favourable multi-centre ethical opinion and the project has been placed on the NIHR portfolio. The study is currently recruiting and scientific manuscripts arising from this work are expected to be complete in July 2019 and will be available to NICE with anonymised patient-level detail.

6. Equality issues

The guidance and the research protocol identified that the trypsin enzyme in the ReCell kits is derived from pigs. For the study this is described in the participant and

consultee information sheets and objection to porcine-related products is an exclusion criteria for recruitment.

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