# RDS Y&H PUBLIC INVOLVEMENT FUNDS REPORT

The Impact of Depilation upon Wound Healing and Post-Surgical Complications: A Feasibility Study (The DEPILATION-Feasibility STUDY)

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# Introduction

Wound complications such as infection or dehiscence (where all or part of the wound bursts open) are the most common complication following surgery. The cost of infection alone to the NHS may be upwards of £700 million every year.

Infections are more common in areas where there are natural skin folds, such as the groin or the armpit, as they are warm and moist, and their location can make it more difficult to maintain a clean, hygienic environment both before and after an operation.

Operations may be undertaken in the groin or armpit when a patient is diagnosed as having cancer, often of the skin, breast or genital regions. To see whether the cancer may have spread via the lymph nodes, an operation may be undertaken to sample one or more of the nodes in the armpit or groin. Lymph nodes are part of the lymphatic system, which is made up of vessels (similar to blood vessels) that drain away excess fluid from the body. Large collections of these lymph nodes can be found in the armpits, groins, and the neck area. Lymph nodes are part of the immune system to fight infection, but also filter cancer cells. If a cancer has been found after sampling these nodes, an operation to remove the nodes completely may be undertaken.

An infection or other wound complication after an operation such as this may occur in up to 50% of patients. As well as causing significant problems at the time, such as repeated trips to hospital, courses of antibiotics, more time off work and the potential to make patients very unwell, infection after lymph node surgery may increase the risk of lymphoedema, or long-term swelling of the entire limb.

Strategies to reduce wound complications are in high demand, especially with the current threat of antibiotic resistance. One such strategy that our team has been working on is hair cycle modulation. Hair follicles cover the entire body, but are concentrated on the head, in the armpits and groins and on the face in men. They contain a large number of skin stem cells, that have been shown to migrate out of the hair follicle and contribute to wound healing when the surrounding skin is injured, such as when an incision is made.

Early evidence suggests that these stem cells are most active when the follicle is naturally in a growth phase. Forcing the follicle into a growth phase may maximise the effect of these stem cells on healing and contribute to a reduction in complications. Hair follicles can be forced into a growth phase by removing the strand of hair from within, by plucking or waxing.

Our team has conducted a research study in patients having skin graft surgery, where we waxed the thigh where a graft was taken from. This was tolerable to patients and shows promising results. However, we cannot be certain whether it will be effective on a larger scale and in other parts of the body, and on wounds created with a surgical blade and stitched closed at the end of the procedure. We also do not know, if it is effective, how this will compare to other strategies, such as wound dressings or negative pressure devices (dressings which apply a low level of suction to the wound). Finally, we do not know whether a study such as this would be acceptable or tolerable to patients who are in the midst of cancer diagnosis and treatments.

## Aims

The aim of this exercise, therefore, was to engage patients in focus-group discussions to explore the concepts detailed above. Specifically, we wanted to understand their experiences of post-operative wound complications, if any, and the impact this had upon them. We also wanted to gather their thoughts and opinions on whether research in general was needed in this area, and whether the research proposal outlined above would be acceptable to someone in their situation. Finally, we asked them to provide feedback on a sample plain English summary, that could be used in a future grant application.

## Methods

Suitable participants fulfilled one of the following pre-specified criteria -
A patient that has either:

(a) Had surgery to the lymph nodes and suffered a complication with their wound **or**
(b) Had surgery to the lymph nodes and has not had a complication with their wound **or**
(c) Took part in the earlier clinical study looking at waxing of skin graft donor sites

Patients undergoing surgery to the lymph nodes were identified from retrospective inpatient lists, operating theatre lists, and skin cancer MDT lists within the Plastic Surgery department in Hull University Teaching Hospitals NHS Trust. Lists were hand search covering 4-month period between mid- February 2021 and mid- June 2021, to ensure that participants' experiences were recent, and that the thoughts, feelings and ideas they expressed were contemporaneous. Eligible individuals were contacted via telephone and had supplementary material mailed through the post.

We organised two focus group sessions held in the medical school building of the University of Hull. These sessions were timed one week apart and took place in October 2021. Each session was scheduled to last a maximum of two hours, and refreshments were provided. For each session a soft topic guide was produced, but discussion was allowed to flow naturally in order to elicit as much information and opinion as possible. Each session was facilitated by the lead applicant, and recorded with the participants' permission.

## Participants

Screening identified thirteen potential participants who met either criteria (a) or (b). Unfortunately due to a change in personnel, the study team had no access to the list of participants from the previous waxing study, and so no individuals from that study could be included.
All participants were contacted by post and telephone. A number of participants were unable to attend as sessions clashed with planned treatments, such as radio- or immunotherapy – an important factor to consider in the design of future studies arising from this work.
Three participants were able to attend both sessions, and a further patient attended only the second session.
The group was made up of three males and one female. Three of the group had experienced wound infection following surgery to remove all lymph nodes in their groin, after a diagnosis of malignant melanoma. One had surgery to sample the nodes in the groin, which was uncomplicated, but did experience an infection in the site that his cancer was initially

removed from. Two of the four had experienced long-term complications following surgery (lymphoedema).

## Contributions

Across two sessions, the following topics were discussed:

- Surgical wounds following surgery to the lymph nodes in the groin or armpit
    - Problems with, not including complications, such as difficulties with cleaning and dressing of wounds, problems with mobility, etc.
    - Infection or wound complications of these wounds, treatments given, and recovery times.
- Strategies to reduce infection and complications
    - Understanding of antibiotic resistance
    - Understanding of ways to reduce infection, including wound dressings
    - The concept of hair cycle modulation in reducing wound complications
    - Whether waxing may be acceptable as an intervention for reducing wound complications

Participants gave a strong account of the impact that wound complications had had on them post-operatively. Treatments given for those complications included readmission, re-intervention and treatment with intravenous antibiotics. Those that had experienced complications described “panic”, and a feeling of “going backwards.” They stated that they sometimes had difficulty accessing care services, which caused them anxiety. Geography was significant, with those living long distances from hospital having greater difficulty.
All participants were informed of the risk of wound complications prior to undergoing surgery. They felt well informed of the risks even when looking back with the benefit of hindsight.

All participants strongly agreed that investing in, and conducting, research into preventing wound complications was needed. This was specifically in relation to surgery on the lymph nodes. All participants understood the risks posed of antibiotic overuse, and were able to give a summary of antibiotic resistance when asked. They agreed that strategies that prevent infection without using antibiotics warranted investigation.

When the concept of hair cycle modulation was explained to participants, they felt that there was “nothing to lose” given the very low cost of the intervention. All participants felt that they would tolerate hair removal in the groin in the armpit, and one participant stated that hair removal was something that they had considered before their operation specifically in order to prevent infection. All participants agreed that, had a research trial been active at the time of their operation, they would have consented to taking part. They specifically cited the low cost and low impact of the proposed intervention as being a reason to take part. The idea of delivering the intervention themselves, in their own home, was posed to the panel. Although this was a small group, all participants felt that they would be able to do so, on the proviso that they had enough information, such as a written sheet or photograph describing the area to be waxed. All participants felt that being randomly allocated to one treatment arm (as in an RCT) would not stop them taking part in a potential research study, nor would additional hospital visits that arose as a result of taking part.

At the end of the first session, participants were provided with a sample plain English summary that would potentially accompany a grant application for a feasibility randomised study. All participants provided input into this, including changes regarding wording and requiring more information in order to improve the sensibility of the document. They felt that more information regarding specifics of the study would be warranted, though this may fall outside of the intention of the document and may be more suitable for a patient information sheet in the eventual study.

Participants were asked of their views on the specifics of any future study. They were asked about the best time to be approached by research staff, given that eligible patients will all have recently been diagnosed with cancer. Patients felt that having time to consider the decision by being approached early would be beneficial. They also stated that follow up would be acceptable either in person or over the telephone if there were no concerns regarding their wounds, but that follow up in person would have to be fitted around any other appointments they might have, such as for follow-on treatments. All patients stated that since the pandemic, they have felt more digitally empowered and are more confident with video calling technology.

The insights provided by our participants have been instrumental in informing our plans for a future grant application. Firstly, our PPI group have reinforced that this is a study that is justified, addressing a problem that causes significant consequences to patients and their carers. They have also reinforced that a simple intervention, in this case hair waxing, is deliverable and acceptable to patients. In previous iterations of the study design, participants were planned to attend for a study team member to perform the waxing intervention one week before their procedure. After our sessions, we have changed this to give patients the opportunity to perform this in the comfort of their own home, with strict written instructions that would ensure consistency of the intervention. We would, however, give participants the option of having the intervention performed in hospital, if the participant did not feel confident or able to perform it. In addition to this, we have amended the time at which patients would be approached for the study. We would anticipate approaching patients with information in outpatients at the point that further surgery was decided upon, in order to give patients an adequate amount of time to make an informed decision.
Also as a result of our focus groups, we would plan to add the option to conduct follow up appointments remotely, in order to reduce the burden of visits to the patient. We recognise that post-treatment can be a busy time for patients, and that this might impact on the ability of patients to return for follow up. We also recognise that a completely remote follow up might exclude some populations, such as the elderly or those living in remote areas, and so would include the option of in person follow up for a proportion of patients in any grant applications.

## Difficulties

This PPI activity took place between waves of the COVID-19 pandemic. We elected to meet in person, as it was felt that this would lead to more organic discussion of the issues that we wished to discuss. However, it did mean that some patients, particularly those undergoing immunotherapy, were unwilling to risk meeting in public due to the risks of contracting coronavirus. It also meant that patients were asked to travel a long distance to meet, which

excluded some individuals. In future, we may look to conduct a mixture of sessions, including online and in person, to widen the availability of sessions and to obtain a variety of lived experiences.

## Future Plans

The original timeline for this research project included the preparation of a grant submission for a feasibility study in early 2022. Unfortunately, due to the ongoing pandemic, and a delay in conduct and analysis of one of the underpinning translational studies, this has been delayed. We do, however, plan to build an application in the future. For this, we plan to have at least two representatives from this PPI activity on the grant application committee. Two representatives reduces the risk of one rep feeling isolated, and reduces the burden on lay representatives to attend all meetings. Their input will be invaluable in the design of both the research plan, and in the writing of the plain English summary.

Should the team be successful in obtaining funding, these representatives will be asked to form a core patient advisory group, led by a PPI lead (a non-lay role). These roles will be fully costed and reimbursed as part of any grant application. Their roles will include document assessment and revision, dissemination of materials and results, and they will be helpful in addressing issues relating to recruitment or retention that may be encountered during the conduct of the study.

## Cost Breakdown

We conducted two sessions in person, at Hull University. We provided refreshments for both sessions. All participants were offered reimbursement for their time and travel; two participants elected not to be reimbursed.
A detailed breakdown of costs is shown below:

Travel and subsistence costs –
Claimant 1 - £43.40
Claimant 2 - £85.20

Refreshments –
Session 1 - £12.30
Session 2 – £12.30

Total Costs claimed for: £153.20