Application No: 2297/MODREC/24

Ministry of Defence

Ministry of Defence Research Ethics Committee (MODREC)

MODREC Application Form

Sixth Issue - V3.0

Application No: 2297/MODREC/24

Ministry of Defence

MODREC Application Form

Sixth Issue – V4.0

Follow the guidance in the grey box below on how to complete and submit the application form:

APPLICATION COMPLETION:

1. Populate **ALL** sections (unless you are certain it is not relevant), in which case state why.
2. Delete all blue guidance text.
3. Complete the Research Sponsors checklist at Appendix 1.
4. Append **ALL** supporting documentation **within** the application (see Section 23).
5. Create a **separate document** that contains the CVs (ideally 2-page short-form) of all investigators listed in Section 4. Include the Independent Medical Officer's CV (if relevant), and ideally the CV of the Volunteer Advocate (if relevant).
6. Guidance for researchers can be found within JSP 536, Part 2, here Defence research involving human participants (JSP 536) - GOV.UK (www.gov.uk)

APPLICATION SUBMISSION:

1. Once the application is completed in full, email this along with the CVs to the relevant Scientific Assessment Committee (SAC), for scientific review. SAC contact details can be found here - Ministry of Defence Research Ethics Committee - GOV.UK (www.gov.uk)
2. Once approved, the SAC will forward the application to the MODREC Secretariat (DST-MODRECTeam@mod.gov.uk), to undergo an ethics review.

1. Study Title (including any abbreviated titles)

A feasibility study to assess the acceptability of DECOLONISATION of *Staphylococcus aureus* to PREVENT skin and soft tissue infections

2. Version History

Version	Number	Date
MODREC Unfavourable Opinion (due to being a CTIMP and needing MHRA approval via IRAS)	2144/MODREC/22	16 Jun 2022
SAC Approved	456	26 Mar 2024
MODREC Review	1.0 1.1 1.2	27 Mar 2024 19 Apr 2024 28 Jun 2024
MODREC Favourable Opinion	1.3	22 Jul 2024
Non-Substantial Amendment 1	1.4	23 Aug 2024
Amendment 1	1.5	18 Dec 2024
Amendment 2	1.6	03 Feb 2025
Amendment 3	1.7 1.8	10 Mar 2025 21 Mar 2025
Amendment 4	1.9	23 Jun 2025
Non-Substantial Amendment 5	2.0	07 Oct 2025

3. Summary of Project

3.1 In the UK, up to 46% of *Staphylococcus aureus* (*S.aureus)* isolates from skin or soft tissue infections (SSTIs) are PVL (Panton Valentine Leukocidin)-positive [1, 2]. PVL associated SSTIs occur in 4% of recruits at Catterick and SSTIs occur in over 30% of recruits at Lympstone Commando, although the majority in this cohort are not due to PVL-Methicillin Sensitive *Staphylococcus aureus* (PVL-MSSA) [3-5]. Most of the *S. aureus* strains are methicillin-sensitive, although in certain groups MRSA isolates have been reported [6-9]. Currently, it is not clear what is the impact is of decolonisation in the UK on the acquisition of SSTIs in high-risk groups, although it is thought that it may prevent infections and limit person-to-person transmission [10]. It is known that in certain high-risk populations, nasal carriage of *S.aureus* predisposes to an increase the risk of infection [11] and subsequently decolonisation has been shown to reduce this risk [12]. This has led to patient population groups being decolonised prior to certain procedures: dialysis, cardiothoracic and orthopaedic surgery [12-14].

3.2 **The main aim of the feasibility project will be to assess the acceptability of individuals to weekly decolonisation of *S. aureus* on the prevention of SSTIs in high-risk personnel (recruits) at Catterick Infantry Training Centre (ITC).** The study will prepare the ground for a larger, definitive piece of research to assessing the impact of decolonisation on the prevention of SSTIs.

3.3 In order to meet the main aim described above, the feasibility study will assess:
1. The impact of decolonisation on the user (participants and healthcare workers) using online feedback questionnaires.
2. The willingness of individuals to adhere to decolonisation and sample collection.

4. Investigators

4**a. Chief Investigator**

Name and Title: Lucy Lamb Dr

Grade/Rank: Lt Col

Post Title: Consultant Infectious Diseases and General Medicine and Senior Lecturer Imperial College/UCL/ADMM. Lt Col Lucy Lamb will be the main Principal Investigator for this feasibility study.

Department: **Academic Department of Military Medicine (ADMM)**

Establishment: **Imperial College/ Royal Free/ ADMM**

Address: Hammersmith Hospital, Du Cane Road London W12 0NN

Telephone: 07769712402

Email: lucylamb@nhs.net

4**b. Does this project contribute towards a qualification?** No

Type of qualification: No

4c. Other Investigators/Collaborators/External Consultants

Name and Title: Shiranee Sriskandan

Grade/Rank: Professor

Post Title: Consultant in Infectious Diseases and will be a Co-Principal Investigator on the project. Her group is part of the NIHR Health Protection Research Unit in Healthcare Associated Infection and Antimicrobial Resistance.

Department: Imperial College Faculty of Medicine

Establishment: Hammersmith Hospital

Address: Du Cane Road, London W12 0NN.

Telephone: 02083833135

E-mail: s.sriskandan@imperial.ac.uk

Name and Title: David Ross

Grade/Rank: Colonel

Post Title: Parkes Professor of Preventive Medicine and will be a co-applicant on the project specifically involved with the public health implementation.

Department: Academic Department of Military Medicine, Royal Centre of Defence Medicine, Birmingham.

Establishment: Strategic Command

Address: Room 12, Robertson House, Slim Road, Camberley, GU15 4NA

Telephone: +44 (0)7962 175972

E-mail: david.ross923@mod.gov.uk
ParkesProf@btinternet.com

Name and Title: Jason Biswas

Grade/Rank: Lieutenant Colonel

Post Title: Consultant in Medical Microbiology and Infectious Diseases and will be a collaborator on the project specifically involved in the microbiological techniques and processes.

Department: Infection Sciences, Severn Pathology

Establishment: North Bristol NHS Trust

Address: Southmead Hospital, Bristol BS10 5NB

Telephone: +44 117 4146233

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Name and Title: Hannah Taylor

Grade/Rank: Lieutenant Colonel

Post Title: Consultant in Public Health and Field Epidemiology

Department: Public Health

Establishment: Army Headquarters

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Telephone:0300 167 6989

E-mail: Hannah.taylor329@mod.gov.uk

Name and Title: Dr Oliver Quantick

Grade/Rank: Lieutenant Colonel

Post Title: Force health protection
.
Department: Public Health

Establishment: NATO

Address: Force Health Protection Branch, NATO Centre of Excellence for Military Medicine, Munich, Germany.

Telephone: +44 117 4146233

E-mail: oliver.quantick180@mod.gov.uk

Name and Title: James Dunbar

Grade/Rank: Lieutenant Colonel

Post Title: Consultant Infectious Diseases and Clinical Director for acute Medicine on the Friarage site. Secondary care Physician and collaborator support for the project.

Department: Infectious Diseases and General Medicine

Establishment: Friarage Hospital

Address: Northallerton

Telephone:

E-mail: james.dunbar@stees.nhs.uk

Name and Title: Kate Wilkinson

Grade/Rank: Lieutenant Colonel

Post Title: Senior Medical Officer

Department: Medical Centre

Establishment: Infantry Training Centre (ITC)

Address: Vimy Lines, Catterick Garrison, North Yorkshire DL9 3PS.

Telephone: 01748 872685

E-mail: kate.wilkinson471@mod.gov.uk

Name and Title: Aaron Mason

Grade/Rank: Major

Post Title: Military GP trainee and will provide logistical and planning support as a collaborator.

Department: General Practice

E-mail: aaron.mason1@nhs.net

Name and Title: Will Nevin

Grade/Rank: Squadron Leader and will provide logistical and planning support as a collaborator.

Post Title: Military Infection Trainee (OOPR – PhD)

Department: Academic Department of Military Medicine

Establishment: University of Liverpool (PhD student), Imperial College London (Clinical Fellow)

E-mail: williamnevin@nhs.net

Name and Title: Kristen Morris

Grade/Rank: Major

Post Title: Military Public Health trainee and will provide public health support during the project design (particularly the online questionnaires and public engagement). She will be involved with project implementation and support the project management.

Department: Public Health

E-mail: Kristen.Morris1@student.lshtm.ac.uk

Name and Title: Colin Brown

Grade/Rank: Dr

Post Title: Director (Interim): Clinical and Emerging Infections and Deputy Director (Interim) HCAI, Fungal, AMR, AMU and Sepsis Division Clinical and Public Health Group, UK Health Security Agency. Dr Brown is a UK HSA collaborator for the project and will be involved in ensuring that the project will be applicable to the NHS as well as the military to ensure maximal project benefit.

Department: See above

Establishment: See above

Telephone: 079170723322

E-mail: colin.brown@phe.gov.uk and colinbrown1@nhs.net

Name and Title: Dr Bruno Pichon

Grade/Rank: N/A

Post Title: Lead Scientist Staphylococcus and Streptococcus Section HCAI, Fungal, AMR, AMU and Sepsis Division UK Health Security Agency. Bruno will provide expertise as the Lead Scientist of the reference unit particularly at the characterisation stage. He will focus on antimicrobial resistance and markers of chlorhexidine resistance.

Department: see above

Establishment: see above

Telephone: N/A

E-mail: Bruno.pichon@phe.gov.uk

Name and Title: Dr Elita Jaunekaite

Post Title: Advanced Research Fellow in Bacterial Genomics and Epidemiology for vaccine preventable and healthcare associated infections, Imperial College London. Dr Jaunekaite will be a co-applicant on the project, providing the vital molecular expertise to ensure the appropriate sample processing through Imperial College.

Establishment: Imperial College London

E-mail: e.jaunekaite@imperial.ac.uk

Name and Title: Ms Donna Tupper

Post Title: Nurse practitioner/Team Manager and collaborator. Donna will be part of the Clinical team for PREVENT and site collaborator.

Department: Medical Centre ITC

Establishment: Infantry training centre

Address: Vimy Barracks, Catterick, North Yorkshire, DL93PS

E-mail: donna.tupper257@mod.gov.uk

Name and Title: Mr Gary Holden

Post Title: SO2 Health Protection and collaborator for both parts particularly REDUCE. Gary Holden provides the vital link between public health and clinical teams (microbiology and infectious diseases).

Department: Defence Public Health Unit

Establishment: Joint Medical Group

Address: DMS Whittington, Lichfield, Staffs WS14 9PY

E-mail: gary.holden102@mod.gov.uk

Name and Title: Major SJC Pallett RAMC

Grade/Rank: Major

Post Title: ST6 Microbiology and Infectious diseases and PhD St Georges

Department: Department of Microbiology

Establishment: St George's hospital

E-mail : t scott.pallett@nhs.net

Name and Title: Ms Fran Husson

Grade/Rank: Lay representative (Imperial College HCAI group Health Protection Research Unit, HPRU group)

Post Title: Lay representative (Imperial College HPRU group). Fran Husson has supported the project proposal development particularly from the public and patient involvement perspective. Volunteer advocate.

Department: N/A

Establishment: N/A

E-mail: franhusson@btinternet.com

Name and Title: Jon Bishop

Grade/Rank: Dr

Post Title: Medical Statistician – Birmingham Clinical Trials Unit (BCTU)

Department: BCTU in Public Health – University of Birmingham

Establishment: University of Birmingham

E-mail: J.Bishop.1@bham.ac.uk

Name and Title: Leanna Hagyard

Grade/Rank: Ms

Post Title: Practice Nurse

Department: ITC Catterick Medical Centre

Establishment: Catterick Garrison

E-mail: leanna.hagyard100@mod.gov.uk

Name and Title: Matt Routledge

Grade/Rank: Major/Dr

Post Title: ID Registrar

Department: MRC, Cambridge

Establishment: Cambridge University

E-mail: matthew.routledge@nhs.net

Name and Title: Laura Maynard-Smith

Grade/Rank: Dr

Post Title: ID/Micro Registrar

Department: Infectious Diseases and HIV

Establishment: Royal Free London

E-mail: lauramaynardsmith@gmail.com

Name and Title: Dr Kartyk Moganeradj

Grade/Rank: N/A

Post Title: Lead Scientist Staphylococcus and Streptococcus Section HCAI, Fungal, AMR, AMU and Sepsis Division UK Health Security Agency. Kartyk will provide expertise as the Lead Scientist of the reference unit particularly at the characterisation stage.

Department: see above

Establishment: see above

Telephone: N/A

E-mail: kartyk.moganeradj@ukhsa.gov.uk

Name and Title: Dr Stephanie d'Arc

Grade/Rank: N/A

Post Title: Laboratory Manager, Leonard and Dora Colebrook Laboratory, Lab Block room 5L09, Charing Cross Hospital.

E-mail: s.darc@imperial.ac.uk

4d. Name of the Volunteer Advocate or Independent Medical Officer

Dr Mark Riley, Public Health Registrar, HQ Army Medical Services Support Unit, Robertson House, Slim Road, Camberley GU15.

Telephone: 07969998988

Email : mark.riley241@mod.gov.uk

5. Research Sponsor

Research Sponsor Contact/Authoriser: Dr Keith Boland Clinical Trials Manager Imperial College London.

Organisations: Imperial College, Research Governance and Integrity team.

Title: Dr

Position: Clinical Trials Manager (Keith Boland).

Role: Clinical Trials Manager

Address: Research Governance and Integrity, Imperial College London, Room 221, Medical School Building, St Marys Campus, Norfolk Place, London W2 1PG.

Phone Number: 020 7594 9480

Email : k.boland@imperial.ac.uk

6. Preferred Timetable

6a. Preferred Start Date: Feb 25.

6b. Expected Date of Completion: Dec 26

7. Other Organisation(s) Involved and Funding

7a. Department / Organisation Requesting the Research (if applicable):
Defence Medical Services Research Strategy Group

7b. Department / Organisation Undertaking the Research:
Imperial College London is the sponsor

7c. If you are receiving funding, please provide details here:

Funding will be allocated from £149, 895.62 secured from the DMS Research Steering Group for this and another thematically linked project (REDUCE service evaluation). This funding will be delivered and held by Imperial College London (via the Research Governance and Integrity team) and a contract is in place.

7d. Please declare any potential conflicts of interests:
No conflicts of interest

7e. Type of research: Physiological/medical/clinical

8. Scientific Assessment Committee (SAC) Approval

8a. Name of SAC that has reviewed / approved this application:
Army

8b. Date of SAC approval: 26 Mar 2024

8c. SAC reference number: ASAC456

9. Purpose of the Study and Defence Benefit

9.1 **Purpose of the Study**

9.1.1 This feasibility study aims to assess the acceptability of *S.aureus* decolonisation on individuals and healthcare staff to prevent skin and soft tissue infections (SSTIs).

9.2 **Introduction**

9.2.1 SSTIs are common, particularly in military cohorts and one of the most common military statutory diseases (FMed85) notifications [3, 6, 15]. One concern is the rise in carriage of Panton-Valentine Leukocidin-*Staphylococcus aureus* (PVL-SA) and Methicillin resistant *Staphylococcus aureus* (MRSA), which are associated with outbreaks and recurrent SSTIs [16]. Recently, this has been noticeable within training establishments like the Infantry Training Centre (ITC) Catterick, leading to hospital admissions locally within the NHS, isolation of recruits and ultimately an impact on training and civilian households.

9.2.2 In 2008, the Department of Health commissioned the Health Protection Agency to produce guidance on diagnosis and management of PVL associated infections[17]. The guidance was a pragmatic approach to managing a patient with a PVL infection; in cases of SSTI, advice was to focus on appropriate antibiotics, drainage and decolonisation following the healing of lesions. It was clear within the guidance, that further research was required on how to manage patients focussing on the effectiveness of decolonisation therapy to eradicate and prevent subsequent infections [18]. Despite the emergence of UK MRSA guidance recently there is still no further advice on how to manage PVL associated infections within the UK or the role for decolonisation therapy following infection [19]. Although recently (Sep 23) a new working group has been established led by UK HSA with National experts to review and update the 2008 PVL National Guidance.

9.3 PREVENT

9.3.3 Within the US, studies of SSTI prevention using decolonisation in the military have produced mixed results, with some prospective controlled trials demonstrating an impact on Methicillin-resistant *Staphylococcus aureus* (MRSA) colonization but no effect on SSTI rates [20-22]. However, one study showed a significant reduction in rates of overall and MRSA associated SSTI following the implementation of a multicomponent hygiene-based program[23]. In the UK and Europe, the majority of SSTIs are due to methicillin-sensitive *S.aureus* (MSSA)[17], with high rates reported in military cohorts in the UK [3, 6, 15] and there are limited studies assessing the impact of regular decolonization on SSTI rates [3, 6, 15, 24].

9.3.4 More recently the UK military have seen a rise in MRSA and PVL (Panton-Valentine Leukocidin) associated SSTIs leading to outbreaks, hospital admissions and reduction in training [4, 5]. Understanding the role of decolonisation in a high risk group like the military will refine National and military guidance [17, 18], prevent against further infections and may be used for other high risk groups which include prison populations and sport groups [25, 26]. It is known that in certain high-risk populations, nasal carriage of *S.aureus* predisposes to an increase the risk of infection [11] and subsequently decolonisation has been shown to reduce this risk [12]. This has led to patient population groups being decolonised prior to certain procedures: dialysis, cardiothoracic and orthopaedic surgery [12-14]. Furthermore, decolonisation of *S.aureus* carriers in high-risk transmission settings, such as the military, may prevent infections and limit person-to-person transmission [10]. **The PREVENT feasibility project will assess the acceptability of weekly decolonisation to prevent SSTIs in high-risk individuals using a military cohort.**

9.4 Antimicrobial resistance

9.4.1 A few studies have assessed the implications of long-term decolonisation, looking at antimicrobial resistance rates, adverse effects and patient compliance [18, 30]. There is a concern that the agents like octenisan, chlorhexidine and mupirocin used for decolonization, will promote growing resistance and reduced efficacy [31]. Antibiotic resistance to agents used for *S.aureus* decolonisation will be measured to ensure that we are not contributing to antimicrobial resistance [32, 33].

9.6 Aims

The feasibility study will assess the acceptability of *S. aureus* decolonisation therapy to prevent skin and soft tissue infections in high-risk individuals like military recruits.

9.7 Objectives

9.7.1 **To assess the acceptability** of decolonisation on the participant and healthcare staff. Participants and healthcare workers will be questioned using OpenClinica, a good clinical practice (GCP) compliant electronic database.

9.7.2 **To assess the willingness of individuals** to adhere to weekly decolonisation and sample collection. The survey used in 9.7.1 will include specific questions to specifically ask about adherence to the decolonisation. The healthcare staff involved will be able to provide feedback on the acceptability of the participant to the intervention alongside any issues with sample collection. Samples will be collected from the nose, throat, axilla, perineum and stool to assess carriage of *S. aureus* and the levels of antimicrobial resistance.

9.7.3 **To assess the study** protocol and collect the following data: adverse events, SSTI rates, admission rates to the medical centre and/or hospital, data collection processes, recruitment and retention rates.

9.8 **Defence and proposed benefits of the project.**

9.8.1 The impact of decolonisation on SSTI acquisition has been assessed by military organisations outside the UK. The United States (US) Infectious Disease Clinical Research Program (IDCRP) conducted clinical research protocols, including strategies like decolonisation and vaccination, to see the effect on SSTI epidemiology and prevention within the US military. Their work focussed on MRSA associated infections and reported that routine decolonisation had mixed results on SSTI acquisition and *S. aureus* colonisation. In comparison, the majority of skin infections seen in the UK and other European military cohorts are due to Methicillin Sensitive *S. aureus* (MSSA) although there are more recent reports of MRSA and/or PVL associated infections leading to outbreaks [6, 24]. **The feasibility work in PREVENT will be the first UK study to assess the acceptability of decolonisation.**

9.8.2 Skin infections occur within the UK and on operations and are listed as one of the top four disease & non-battle injury presentations seen at Role 1-4 [6, 15]. The Strategic Delivery Plan for DMS Research 2021-26, “Avoiding the Walker Dip” highlights the importance of the understanding the diagnosis and treatment of infectious disease. The prevention of infectious disease outbreaks is vitally important and is central to Defence healthcare engagement activities. This project is a collaboration involving the Defence Medical Services (Primary and Secondary Care, Public Health and Infectious Diseases), UK Health Security Agency and Imperial College London seeking to improve and refine guidance both within UK Armed

Forces and Nationally. It is anticipated that the feasibility work will provide vital information to refine a subsequent MODREC application to assess the impact of weekly decolonisation of *S.aureus* on the prevention of SSTIs in high-risk personnel (recruits) at Catterick.

10. Study Design, Method and Data Analysis

10.1 PREVENT

10.1.1 Overview. A feasibility study to assess the acceptability of *S. aureus* decolonisation to prevent skin and soft tissue infections. Service personnel routinely attend medical centres during the start of training and during this period study participants (SP) will be recruited, consented and screened for *S. aureus* colonisation at 4 body sites (nose, throat, axilla and perineum) and intestinal colonisation with a stool sample.

Individuals will then be randomised to receive decolonisation therapy weekly Chlorhexidine 4% bodywash and shampoo with Mupirocin 2% nasal ointment or octenisan bodywash and shampoo with Mupirocin 2% nasal ointment. Prior to decolonisation, recruits will be screened again for *S.aureus* colonisation as previously described (4 body sites and a stool sample).

10.1.2 Sample size. 50 SP will be recruited into the feasibility study **PREVENT** [35, 36]. Participants will be randomised in a 1:1 ratio, at the level of the individual, to receive either decolonisation therapy.

10.1.3 Methodology. This feasibility study will assess user acceptability of *S. aureus* decolonisation, the willingness of individuals to adhere to decolonisation and sample collection and the assessment of recruitment and retention rates, data collection and completeness.

Initially, an oral briefing will be given in civilian clothing detailing the **PREVENT** feasibility study and an information leaflet will be given to participants (**Annex A).** Once written informed consent is obtained (**Annex B**), each study participant will be enrolled into the study. Routine multi-site samples will be taken by swabbing the nose, throat, axilla and perineum and obtaining a stool sample. This part of the study will take place at the Infantry training centre Catterick or in Nepal (Gurkhas).

Recruits will be randomised to receive either type of decolonisation therapy, the data will be entered on the OpenClinica database coordinated by Imperial College. Routine multi-site samples will be taken by swabbing the nose, throat, axilla, perineum and obtaining a stool sample before initial decolonisation (intervention) around week 1-2 of training, with further samples at week 4-5 and 11- 12 post decolonisation. Weekly decolonisation will stop at week 12. Further characterisation of the samples obtained will be performed using routine bacteriological and molecular techniques. This part of the study will take place at the Infantry training centre, Catterick or Bovington.

Participants will be asked to complete a health questionnaire on enrolment (**Annex C**) and an electronic or paper-based user acceptability questionnaire (**Annex D)** when they collect their weekly decolonisation pack this will be performed electronically using OpenClinica. A further questionnaire will be given to healthcare staff at the same time point **(Annex E).** Further information that occurs as part of the routine initial medical assessment includes a full medical history and clinical examination. Skin and soft tissue infection acquisition rates will be obtained 12 weeks after the start of the decolonisation therapy through a retrospective review of case notes on the Defence Medical Information

Capability Programme (DMICP). Information acquired at the initial medical assessment will also be reviewed on DMICP. Any individual found to have an infection during the study will be assessed clinically by their primary care team and treated. Major Mark Riley will be the Independent Medical Officer and Caldicott Guardian for this feasibility study.

10.2 *S. aureus* decolonisation (suppression) therapy

10.2.1 *S.aureus* decolonisation (suppression) therapy consists of chlorhexidine 4% or octenisan bodywash for applied to wet skin directly, chlorhexidine 4% shampoo and mupirocin 2% nasal ointment administered to the inner surface of each nostril [17]. Decolonisation therapy will be administered weekly to each consented participants and continued for a total of 12 weeks. All agents have been licenced for the nasal eradication of *S.aureus* by the Medicines Health Regulatory Authorities except for Octenisan which is not a medicinal product. Subjects will be excluded from the study if they are unable to use chlorhexidine or octenisan.

10.3 Sample Analysis

10.3.1 A pre-moistened swab would be taken from the nose, throat, axilla and perineum and a stool sample obtained from the patient. The swabbing procedure is tolerated and routine practice for screening in the NHS but occasionally the participant may feel a little discomfort. A stool sample will be given by the patient to look for intestinal colonisation of S. aureus. Routine microbiological techniques and the Matrix-assisted laser desorption ionization-time of flight mass spectrometry (MALDI-TOF) will be used to identify *S. aureus*. Further antimicrobial susceptibility work will be performed focusing on resistance to decolonising agents. Further molecular work including whole genome sequencing of the samples will be performed at Imperial College London in collaboration with the UK Health Security Agency. All samples obtained from recruits will be anonymised to allow the appropriate protection for the participants.

10.4 Assessment of SSTI acquisition.

10.4.1 The incidence of SSTI will be monitored during **PREVENT.** Consent to access this information will be obtained from study participants at the start of training. Their consent will be re-confirmed at the end of training if circumstances may have changed. Service personnel who report to the Medical Centre will have the details of their skin infection complaint coded on the DMICP system according to standard procedures. The DMICP system will be searched for recruits participating in the study who have attended medical appointments; the categorisation of their presenting complaint will be identified, and the outcome of the consultation recorded with reference to their training experience. SSTIs will be recorded as PVL-associated, MRSA-associated or other. Participants will be identified through their service numbers.

10.6 Withdrawal procedures

10.6.1 Participants will have the right to refuse to participate in the study with no need to provide a reason. Furthermore, they will have the right to withdraw from the study at any time again without providing a reason for their withdrawal. SP can contact the study team and will be provided a point of contact on consent into the feasibility study. The data from the withdrawing SP will be archived.

10.7 Data Analysis

10.7.1 The primary comparison groups for **PREVENT** will be composed of two types of decolonisation therapy (chlorhexidine and mupirocin vs octenisan and mupirocin). In the first instance, all analyses will be based on the intention to treat principle, i.e. all

participants will be analysed in the treatment group to which they were randomised irrespective of compliance with the allocated treatment or other protocol deviation. The data analysis for this feasibility trial will be descriptive and mainly focus on confidence interval estimation, with no hypothesis testing performed.

10.7.2 Data will be explored to assess:

- willingness of service personnel to be randomised.
- number of participants acquiring an SSTI (PVL-associated, MRSA-associated or other) within 12 weeks following the start of decolonisation.
- adherence via user tolerability of sampling**,** acceptability of the individual participant/healthcare worker assessed using an online survey at the start of training, before decolonisation, 4-5 and 11-12 weeks following the intervention.
- antimicrobial resistance in colonising *S. aureus* carriage at 4 body sites (nose, throat, axilla and perineum) and in the stool will be assessed at the start of training, before the intervention and 4-5 and 11-12 weeks following the intervention.
- the number of individuals requiring secondary care admission
- adverse events in the individual participant
- user acceptability of the point of care testing.
- recruitment and retention rates
- data completeness.

10.10.3 Dichotomous feasibility measures, such as the recruitment and retention rates, as well as data completeness will be reported as numbers and percentages. Where appropriate, these values will be summarised across treatment groups.

10.10.4 Continuous endpoints (e.g. antimicrobial resistance): normality checks (skewness and kurtosis) of data will be undertaken and, if appropriate, data will be summarised using means and standard deviations, with differences in means with 95% confidence intervals reported.

10.10.5 Categorical (dichotomous) endpoints (e.g. rates of SPs acquiring SSTIs): The number of participants and percentages experiencing the event will be summarised between groups.

10.11 Further Information

PREVENT will be registered with ISRCTCN (https://www.isrctn.com/).

11. Safety

11a. How will the safety of the research be managed?

The Chief Investigator of the study, Dr Lucy Lamb, will have ultimate responsibility for the safety of the research that is proposed. This responsibility will be devolved to appropriate professionally regulated and briefed individuals as required to carry out initial approach, recruitment of volunteers and study investigations. To that end, a delegation log, detailing all staff that have been briefed will be kept and signed. Dr Lucy Lamb will oversee this component of the study in collaboration with the study teams at the various Defence Primary Health Care (DPHC) sites including ITC Catterick and Bovington.

11b. Who is the named person taking responsibility for the overall safety of the research? In addition, who is the named person that will be responsible for day-to-day safety of the research?

Dr Lucy Lamb will take responsibility for the overall safety of the project and Donna Tupper will be the named person for the day-to-day safety of the research.

11c. How will the researchers conducting this study be made aware of:

i. **Their responsibilities for reporting any new safety issues which arise after the start of the project, and**

ii. **Their responsibilities for reporting adverse events in the conduct of the project?**

All researchers will be briefed on their responsibilities for reporting any safety issues and adverse events at the start of the project and provided with details of where to log these events. All safety issues and adverse events will be reported to the Chief Investigator. All investigators will undertake NIHR Good Clinical Practice (GCP) training prior to being involved with the study. All investigators will also be issued with a copy of the MODREC protocol for the study.

Any new safety issues arising during the operation of this protocol will be reported as soon as practicably possible to the CI. The CI will risk assess any emerging issue and determine whether the research is safe to continue, and whether any increased mitigation is required. If the safety issue cannot be mitigated sufficiently then the SAC and MODREC committees will be informed, and the research will be suspended until both committees are content.

12. Ethical Considerations and Research Integrity

12a. Ethical Considerations:

Service Personnel including recruits undertake physically demanding military training. It is vital that the procedures and measures applied do not excessively burden the training programme. The investigations planned will require minimal additional time and are achievable within the routine medical visits or as part of a decolonisation programme following a skin infection in an index case. The **feasibility study** will assess some of the ethical issues including the requirement for consent and the implications of the study on the individual as well as the healthcare team and chain of command.

It is appreciated by the study team that the project will involve individuals from many cultures and backgrounds. All consent materials will be made available in a participant's requested language, and where required a translator will be used. Members of the investigatory team have experience in recruiting participants from outside the UK.

Swabs are taken for *S. aureus* carriage at 4 body sites of the consented individual participant under the direction of the study team and a stool sample will be given by the patient.

All recruits who consent to participate in the study will be eligible for the benefits provided by the extant no-fault compensation scheme. Recruits will be fully informed of the scheme and provided with written details during the study brief.

12b. Confirm that you have read the MOD the policy on Research Integrity (JSP 732 – see here, Research integrity (JSP 732) - GOV.UK (www.gov.uk)**), and you agree to abide by this directive.** Yes.

13. Participants

13a. Number of Participants:

50 participants

13b. Lower Age Limit:
16 years
13c. Upper Age Limit:
35 and 6 months
13d. Sex *or* Gender ratio (please state which):
Male or female (ratio not defined but will be recruits)
13e. Please provide a brief justification for the choice of sample
This is a feasibility study, so no formal sample size calculation has been performed. Following recommendations, 25-30 patients or more are typically required to obtain estimates of the parameters needed for sample size estimation [36] .

14. Selection Criteria

14a. List your participant inclusion criteria:
Research participants for the study will be recruited from recruits from the Infantry Training Centre Catterick or from Nepal. All potential research participants will be over the age of 16 and deemed fit to attend phase 1 training.

14b. List your participant exclusion criteria:
A participant will be excluded from the study if deemed inappropriate by the IMO or ITC Medical Staff.

15. Recruitment

15a. Describe how potential participants will be identified:
Potential participants will be identified at medical screening at the beginning of recruit training with the support of front-line commands to ensure the feasibility work does not impact on the training.

15b. Describe how potential participants will be approached:
Participants will be approached during an initial oral briefing, to be scheduled at the time of the initial medical screening/medical review. As detailed previously, we acknowledge that our participant populations are unique due to potential cultural differences. It will be made clear that there are no negative consequences to declining participation in the study and materials can be provided in an alternative language to English if requested. Participants will be given a full description of the study, the measures to be taken, and any possible risks and discomforts associated with participation. Potential participants will be provided with a Participant Information Sheet **(Annex A)**. There will also be opportunity for recruits to ask questions.

15c. Describe how potential participants will be recruited:
All potential study participants will be recruited during a follow-up consultation which will be done during a routine review at the medical centre by the study team during the initial week of training. A further opportunity will then be provided for recruits to ask questions. Volunteer recruits will be invited to sign a Subject Consent Form (**Annex B**). OpenClinica V4.0 is a GCP complaint database that will be used during the study and the consent form will be based electronically on this platform. The support to the OpenClinica database will be performed by an Imperial College team. The study team will have access to OpenClinica on ipads. The ipads will then be used by consented participants during the 12-week decolonisation period at week 1-2, 4-5 and 11-12. The ipads will be secured in a locked facility within the medical centre when they are not in use. Participants will have the right to refuse to participate in the study with no need to provide a reason. Furthermore, they will have the right to withdraw from the study at any time again without providing a reason for their withdrawal.

16. Consent

16a. Describe the process you will use when seeking and obtaining consent:

Written informed consent will be sought from each volunteer during the follow-up consultation and stored electronically on the Openclinica V4.0 as an econsent. The follow up consultation will take place at least 24 hours after an initial briefing. This consultation will take place during a routine medical review that at an appropriate time for the study participant and healthcare team. The Participant Information Sheet and the Participant Consent Forms for the study are presented in Annexes A and B. All potential research participants will have been deemed medically fit, healthy and competent to undertake phase 1 training and to consent to participate in this study by the SMO at ITC.

16b. Do you plan to include participants who are children (under 16 yrs)? No

16c. Do you plan to include participants who lack capacity to consent? No.

16d. Do you plan to include any prisoners? No.

16e. Are there special pressures that might make it difficult for people to refuse to take part in the study (e.g. subordinates)?

As previously alluded to, these populations may be subject to a variety of special pressures that may arise due to differences in cultural factors. However, as described above, the study team intend to address these issues robustly and pragmatically to ensure a legitimate and non-coercive invitation to participate in the study. It will be made clear on recruitment that there are no negative consequences of declining to participate.

17. Participant Involvement: Risks, Requirements and Benefits

17a. Describe potential hazards, risks or adverse effects that may be associated with the study?

Adverse Effects: There are potential minor adverse effects associated with certain elements of this study, such as discomfort from having a swab. There is also the possibility of intolerance or reactions to decolonisation regimens. The feasibility studies will enable some of the potential adverse effects or intolerances to be identified prior to the main study.

Risk Assessment: Assessment of the risks for this protocol show they are minimal given the medical monitoring and safety precautions in place and compatibility of the study demands to the physical demands experienced during training. If this assessment of risks changes during the study, the SAC and MODREC and those participating in the study will be informed fully without delay. Similarly, the SAC and MODREC will be informed without delay if unforeseen adverse events arise during this research. The latter report will contain an evaluation of the cause and severity of the adverse event.

17b. Will pregnant or nursing mothers be included? No

17c. Does your study involve invasive procedures such as blood taking, muscle biopsy or the administration of a medicinal product?

Yes, administration of a product– *S. aureus* decolonisation therapy.

Decolonisation suppression therapy consists of chlorhexidine 4% or octenisan bodywash applied to wet skin directly, chlorhexidine 4% or octenisan shampoo administered and mupirocin 2% nasal ointment administered to the inner surface of each nostril [17]. All agents have been licenced for the nasal eradication of *S. aureus* by the Medicines Health Regulatory Authorities. In all studies suppression

therapy should be administered once a skin infection has healed. For those participants who may get a skin infection through the study then their routine decolonisation should be delayed if considered to impact on the healing of an infection.

17d. If medical devices are to be used on any participant, do they comply with the requirements of the Medical Devices Directives? Not required

17e. Does your study involve the exposure of participants to ionising radiation (e.g. Dual-Energy X-ray Absorptiometry measurements (DEXA), Peripheral Quantitative Computed Tomography scans (pQCT), administration of radiopharmaceuticals etc.)? No.

i. If yes, please add details below, and provide confirmation that a review has been undertaken and approved from a Medical Physics Expert (MPE) and Clinical Radiation Expert (CRE). Note, that the Defence Consultant Advisor in Radiology may provide a CRE review. It is recommended that the MPE and CRE are involved at the earliest stages to ensure any exposures are Justified.

17f. List the locations or sites where the work will be undertaken: Catterick, Nepal and Bovington for participant consent, recruitment and acquisition of skin and soft tissue infection data. Imperial College University and Health Security Agency for *S. aureus* characterisation.

17g. Are there any other research studies being performed at the locations / sites listed at para. 17f at the same time as this study? No

i. If yes (to the above), is the Unit Chain of Command aware of and approved these potentially concurrent research activities? Yes

ii. If yes (to the above (17g / 17g.i)), what mitigations have been put in place to ensure research participants are not overburdened, and that the studies do not interfere with each other?

Questionnaires administered will be designed to capture data on previous SSTI acquisition and antibiotic use including country of origin and any relevant exposure history. The questionnaires will be explained in full to the participant, including using an interpreter, if necessary, it will be made clear that the participant may decline to answer any questions they wish. They will be administered and delivered electronically during routine medical appointments to avoid additional burden to the recruits as previously described using ipads.

17h. Will group or individual interviews / questionnaires discuss any topics or issues that might be sensitive, embarrassing or upsetting? No.

17i. Is it possible that criminal or other disclosures requiring action (e.g. evidence of professional misconduct), could be made during the study? No.

17j. Describe any expected benefits to the research participant:

Reduction in acquisition or recurrence of skin infection through decolonisation. Within the UK Military PVL associated infections have had morbidity and in rare occasions mortality implications, alongside the detrimental effect on training.

17k. Under what circumstances might a participant not continue with the study, or the study be terminated in part or as a whole?

Study participants will be withdrawn from the study on attaining any of the following:

- On the request of the study participant
- On the instruction of the unit Medical Officer
- On the decision of the Chief investigator or nominated deputy

There will be no punishment or negative consequences of withdrawing.

18. Financial Incentives, Expenses and Compensation

18a. Will travel expenses be given? Not required.

18b. Is any financial payment or other reward, apart from travel expenses, being offered to participants? Experimental test allowance £3.35 per test in JSP 752 (April 2023).

18c. Has payment of the Experimental Test Allowance (ETA) been considered for UK Service Personnel (see - JSP 752, chap 10 section 3, here JSP 752 -Tri-Service regulations for expenses and allowances - GOV.UK (www.gov.uk)**) ?** Yes, ETA will be granted for eligible participants. The aim of this allowance is to provide a small compensatory payment in recognition of the effort involved by those participating. For the purposes of this study, ETA would include the provision of samples and electronic questionnaires at each time point (weeks 1, 4 and 12). So, in total 6 tests are performed at each time point, £20.10 and in total £63.65 could be claimed.

18d. Is this a study in collaboration with a commercial organisation? No

.

19. Confidentiality, Anonymity and Data Storage

19a. What steps will be taken to ensure participant confidentiality?

Service numbers will be used during the study to identify individual participant data. Only members of the Study Team will have access to raw data linked to the recruits' names. This information will not be available, or made available, to the ITC Catterick. Any paper records will be held within a locked cabinet in the Medical Centre at ITC Catterick. Data stored electronically will be securely held on encrypted computer systems either within MOD or Imperial. The main PID file will be separate from the study data. Compliance with the Data Protection Act 1998 will be ensured.

19b. Give details of any anonymisation procedures (if applicable)

Service numbers will be used during the study to identify individual participant data. Recruit names or Service numbers will not be used or be identifiable at any stage of the write up or future presentation of this study. Only members of the Study Team will have access to raw data linked to the recruits' names.

19c. Who will have access to the records and resulting data?

Access to individual data will be restricted to members of the Study Team and to the individual (however, a study participant will not have access to the data of other research participants). The collated data (with names, military numbers and research participant numbers removed) will be analysed by the Principal Investigators. This derived data, once anonymised, will also be considered for publication as a scientific paper with prior agreement of the Crown.

19d. Where, and for how long, do you intend to store the Consent Forms and other records?

Consent forms and other paper records will be stored by the Academic Department of Military Medicine at an approved MOD or Imperial storage facility in accordance with standard operating procedures, and then destroyed. It is anticipated this will be for the study duration and most of the data will be held electronically.

19e: Have the Participant Information Sheet(s) and Consent Form(s) been reviewed and confirmed to be Data Protection Act 2018/UK GDPR compliant in accordance with your organisational arrangements? Yes

20. Participant Information Sheet

Study title: A feasibility study to assess the acceptability of DECOLONISATION of *Staphylococcus aureus* to PREVENT skin and soft tissue infections

MODREC Application No: 2297/MODREC/24

Invitation to take part:

We would like to invite you to participate in this study being undertaken by the Ministry of Defence (MOD). Before you decide whether you want to take part, it is important for you to understand why the research is being undertaken and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask the Study Team if there is anything that is not clear or if you would like more information. Thank you for reading this.

What is the purpose of the research?

The research will assess the acceptability of using decolonisation therapy consisting of a body, hair wash and nose cream to reduce the presence of a bacteria called *Staphylococcus aureus* which can cause skin and soft tissue infections.

Who is doing this research?

The study is being done by MOD personnel in the Academic Department of Military Medicine, Centre for Defence Pathology, Military Public Health, Imperial College London and UK Health and Security Agency.

Why have I been invited to take part?

As a recruit you are eligible to take part. We would like to assess how acceptable it is to you to be given decolonisation therapy (consisting of hair and body wash and nose cream) weekly over 12 weeks with the aim to prevent against skin and soft tissue infections.

Do I have to take part?

No, participation is entirely voluntary.

What will I be asked to do?

You will be asked to swab your nose, throat, armpit, and groin and provide a stool sample for the bacteria *Staphylococcus aureus.* Samples for the bacteria will be taken at the start of training and before decolonisation, during decolonisation and at the end of the decolonisation. Also, you will be asked to complete a feedback questionnaire at week 1-2, 4-5 and 11-12 following the introduction of decolonisation therapy, this should take no more than 5 to 10 minutes and will be done on paper or an iPad provided to you during a

visit to the medical centre. Additionally at week 1-2 you will be asked to complete a health questionnaire (less than 5 minutes). You will be randomised to receive one type of decolonisation therapy which you will be given weekly by the medical centre. Decolonisation therapy can be used in the shower to wash your body and hair and additionally a cream will be given to apply to the front part of your nose. Separately, your medical records will be reviewed to see whether you had a skin and soft tissue infection during the study.

What is the procedure that is being tested?

We are trying to establish the acceptability to you of using weekly decolonisation therapy and your willingness to provide samples.

Are there any direct benefits to me of taking part?

The feasibility study will provide information on which decolonisation therapy is more acceptable to you. Further information gained from the study will help the MOD refine and adjust their policies on how to manage and prevent skin and soft tissue infections.

What are the possible disadvantages (or risks) of taking part?

The specific risks associated with the measurements undertaken in this study will not add to the demands and risks of your training role. The online electronic form has been designed to minimise the disruption to those taking part and will be done at a time when you are in the medical centre. There may be a little discomfort in the nose and throat when taking the swab, this is a similar process to taking a COVID test.

Can I withdraw from the research and what will happen if I withdraw?

You may withdraw from the study at any time without giving a reason and without compromising current and future medical care.

Will I receive any expenses or payments?

The organiser will pay a MOD experimental test allowance of £3.35 per test. We estimate there are 6 tests at each time point (5 samples and 1 questionnaire) and an additional electronic health questionnaire at week 1-2. The maximum that could be paid would be £63.65.

Will my taking part or not taking part affect my career?

You should only participate if you want to; choosing not to take part will not disadvantage you in any way with regards to your Service career.

Who do I contact if I have any questions?

Name: Dr Lucy Lamb

Address: Imperial College London, Academic Department of Military Medicine

Tel No: 07769712402

E-mail: lucylamb@nhs.net

Who do I contact if I have a complaint?

If you wish to raise a complaint about how we have handled your personal data, please contact the Independent Medical Officer.

Name: Dr Mark Riley (Independent Medical Officer)

Address: HQ Army Medical Services Support Unit, Robertson House, Slim Road, Camberley GU15.

Tel No: 07969998988

Email: mark.riley241@mod.gov.uk

What happens if I suffer harm?

If you suffer any harm as a direct result of taking part in this study, you can apply for compensation under the MOD's No-Fault Compensation Scheme.

What will happen to any samples I give?

Samples will not be identifiable as yours and will be sent for processing in Imperial College and UK HSA to look for the bacteria *Staphylococcus aureus*

Will my records be kept confidential?

Records will be kept confidential and stored only within the period of the study (less than 24 months). You have the right of access to your records at any time, and to ask for them to be destroyed. All data will be handled in accordance with UK GDPR and the Data Protection Act 2018.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Ministry of Defence Research Ethics Committee (MODREC).

Further Information and Contact Details

Name: Dr Lucy Lamb

Address: Academic Department of Military Medicine and Imperial College London

Tel No : 07769712402

E-mail : lucylamb@nhs.net

Compliance with the Declaration of Helsinki

This study will be conducted in accordance with the principles defined in the Declaration of Helsinki [1] as adopted at the 64th WMA General Assembly at Fortaleza, Brazil in October 2013.

21. Consent Form for Participants in Research Studies

Title of Study: A feasibility study to assess the acceptability of DECOLONISATION of *Staphylococcus aureus* to PREVENT skin and soft tissue infections

MODREC Reference: 2297/MODREC/24

	Please Initial or Tick Boxes
1. The nature aims and risks of the research have been explained to me. I have read and understood the Participant Information Sheet and understand what is expected of me. All my questions have been answered fully to my satisfaction.	☐
2. I understand that if I decide at any time during the research that I no longer wish to participate in this project, I can notify the researchers involved and be withdrawn from it immediately without having to give a reason. I also understand that I may be withdrawn from the study at any time by the research team. In neither case will this be held against me in subsequent dealings with the Ministry of Defence.	☐
3. I understand that the screening process to decide if I am suitable to be selected as a participant may include completing a medical screening questionnaire and/or a physical examination by a Medical Officer and I consent to this.	☐
4. I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated as confidential and handled in accordance with the provisions of the Data Protection Act 2018 and UK GDPR.	☐
5. This consent is specific to the study described in the Participant Information Sheet and shall not be taken to imply my consent to participate in any subsequent or future study / data analysis or deviation from that detailed here.	☐
6. I understand that in the event of my sustaining injury, illness or death as a direct result of participating as a volunteer in this research, I or my dependants may enter a claim with the Ministry of Defence for compensation under the provisions of the No-Fault Compensation Scheme, details of which are attached.	☐

[1] World Medical Association Declaration of Helsinki [revised October 2013]. Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects. 64th WMA General Assembly, Fortaleza (Brazil).

7. I agree to participate in this study. ☐

Participant's Statement:

I …**……**

agree that the research project named above has been explained to me to my satisfaction, and I agree to take part in the study.

Signed: **Date:**

Investigator's Statement:

I …**……**

confirm that I have carefully explained the nature, demands and any foreseeable risks of the proposed research to the Participant.

Signed: **Date:**

Contact Details of Chief Investigator:

Name: Dr Lucy Lamb

Address: Academic Department of Military Medicine and Imperial College London

Tel No: 07769712402

E-mail: lucylamb@nhs.net

Contact Details of Independent Medical Officer or Volunteer Advocate:

Name: Dr Mark Riley

Address: Army Headquarters

Tel No: 07969 998988

E-mail: mark.riley241@mod.gov.uk

22. Arrangements for the Payment of No-Fault Compensation to Participants in Studies That Received a MODREC Favourable Opinion[2]

1. The MoD maintains the 'No Fault Compensation Scheme' specifically for the payment of no-fault compensation to, or in respect of, a volunteer who suffers illness and/or personal injury as a direct result of participating in research conducted on behalf of the MoD. The no-fault compensation arrangements apply to research participants (Military, Civilian, or non-MoD) who take part in a trial that has been approved by the MoD Research Ethics Committee.

2. A research participant wishing to seek no-fault compensation under these arrangements should contact the Directorate of Judicial Engagement Policy, Common Law Claims and Policy (DJEP-CLCP), Ministry of Defence, Level 1, Spine 3, Zone J, Whitehall, London, SW1A 2HB who may need to ask the Claimant to be seen by a MoD medical adviser.

3. CLCP will consider reasonable requests for reimbursement of legal or other expenses incurred by research participants in relation to pursuing their claim (eg. private medical advice, clinical tests, legal advice on the level of compensation offered) if they have been notified of the Claimant's intention to make such a claim.

4. If an injury is sufficiently serious to warrant an internal MoD inquiry, any settlement may be delayed at the request of the research participant until the outcome is known and made available to the participant in order to inform his or her decision about whether to accept no-fault compensation or proceed with a common law claim. An interim payment pending any inquiry outcome may be made in cases of special need. It is the Claimant's responsibility to do all that they reasonably can to mitigate their loss.

5. In order to claim compensation under these no-fault arrangements, a research participant must have sustained an illness and/or personal injury as a direct result of participation in a trial/study approved by MoDREC. A claim must be submitted within 3 years of when the incident giving rise to the claim occurred, or, if symptoms develop at a later stage, within 3 years of such symptoms being medically documented.

6. The fact that a research participant has been formally warned of possible injurious effects of the trial upon which a claim is subsequently based does not remove MoD's responsibility for payment of no-fault compensation. The level of compensation offered shall be determined by taking account of the level of compensation that a court would have awarded for the same injury, illness or death had it resulted from the Department's negligence.

7. In assessing the level of compensation, CLCP, in line with common law principles, will take into account the degree to which the Claimant may have been responsible for his or her injury or illness and a deduction may be made for contributory negligence accordingly.

8. In the event of CLCP and the injured party being unable to reach a mutually acceptable decision about compensation, the claim will be presented for arbitration to a nominated King's Counsel. CLCP will undertake to accept the outcome of any such arbitration. This does not affect in any way the rights of the injured party to withdraw from the negotiation and pursue his or her case as a common law claim through the Courts.

[2] Section agreed with DJEP-CLCP Dep Hd 28/10/13.

Additional/Alternative Compensation Arrangements

9. **Compensation for Service Personnel.** Service personnel who took part in studies before 06 April 2005 and who consider that they may have suffered later harm or disability due to that study should contact MoD Defence Business Services-Veterans (DBS-Vets), Service Personnel and Veterans Agency (SPVA) for consideration of a war disablement pension. The personnel who are entitled to make claims under the war disablement pension scheme are laid out on the SPVA website,[3] as are details of the claim's process.

10. In the event of service personnel suffering injury or disability as a result of their participation in MoDREC approved MoD research on or after 06 April 2005 then they may be entitled to compensation under the Armed Forces Compensations Scheme (AFCS). The details of the AFCS are promulgated on the MoD Intranet,[4,5] and are also available on the DBS-Vets website.[6] Claims should be made to DBS-Vets following the instructions available on the MoD Intranet and DBS-Vets website.

11. In the event of service personnel suffering injury or disability as a result of their participation in MoDREC approved MoD research which is sufficiently serious for subsequent medical discharge from the services, their medical records will automatically be forwarded to DBS-Vets for consideration of compensation and pension enhancements [7] in addition to whatever MoD pension/gratuity they are already entitled to by virtue of their service. Similarly, in the event of death as a result of their participation in MoDREC endorsed MoD research, their dependants may be entitled to receive a supplemented pension.

12. However, if either a Service person or their dependants receive payment under the MoD 'no fault compensation' arrangements (or as the result of a common law compensation claim) for the same condition as that for which a pension is received, any pension entitlement may be reduced since compensation should not be paid twice for the same injury, disability or death.

13. **Civilian Pensions.** In the event of a civilian research participant suffering injury or disability as a result of their participation in MoDREC endorsed MoD research sufficiently serious for them to subsequently suffer a loss in earnings capacity; they may be eligible for benefits under Section 11 of the Principal Civil Service Pension Scheme (PCSPS). Further details are available in the PCSPS booklet Injury at Work. Similarly, in the event of death as a result of participation in MoDREC approved MoD research, their dependants may be entitled to receive benefits.

14. **Common Law Compensation.** If a research participant or their representative believes that injury, disability or death was caused by the negligence of the MoD or its staff, and do not wish to pursue the possibility of a 'no-fault' compensation payment, a common law claim for compensation should be submitted to Directorate of Judicial Engagement Policy, Common Law Claims & Policy (DJEP-CLCP) (at the address in Para 2 above) detailing the full facts of the claim and stating that common law compensation is being sought.

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[3] http://www.veterans-uk.info/pensions/wdp_new_index.html

[4] DIN http://defenceintranet.diif.r.mil.uk/libraries/corporate/DINS%20Archive/2008/01102RestrictDINs.pdf

[5] Armed Forces Compensation Scheme - Statement of Policy. http://defenceintranet.diif.r.mil.uk/libraries/library1/DINSJSPS/20110714.1/974_AFCS_Statement%20of%20policy4.pdf

[6] http://www.veterans-uk.info/pensions/afcs_new.html

[7] http://www.veterans-uk.info/pensions/med_discharge.html

Multinational/Multicentre Research and Research Involving Other Government Departments

15. When MoDREC is involved in studies which involve Departments other than the MoD there may be a requirement for specific Compensation Arrangements on a study-by-study basis.

23. Supporting Documentation

List and provide the titles of all appendices:

- Appendix 1 – Research Sponsors checklist.
- Appendix 2 – List of acronyms.
- Appendix 3 – List of references.
- Appendix 4: Explicit, written approval from an individual within MOD at a minimum of OF5 / B2 level. Letter from DMS RSG with financial approval
- Appendix 5 - Letter to general practitioner.
- Appendix 6 to 8 Inclusion of questionnaires / topic guides / interview questions / subjective rating scales.
- Appendix 9: Information Governance
- Appendix 10 - Evidence of permission from organisation where research is to be conducted (DMS RSG attached).

Please list any separate documents that you are submitting to support this application:

- CVs of named investigators.
- CV of Volunteer Advocate and Independent Medical Officer.

Appendix 1. Research Sponsors Checklist

Additional Guidance for Research Sponsors[8]

Definition:

The "Research Sponsor" is a distinct role from the "Research Funder" even if in many cases the two may be the same organisation. The Research Sponsor's role is to take legal responsibility for the conduct of the research and acts as an additional point of contact should any concerns be raised by regulators, professional bodies or members of the public

1. MOD expects that an organisation that agrees to sponsor research (i.e. acts as Research Sponsor) at any level is confident in its ability to meet the responsibilities as laid down in JSP 536 (which is harmonised with the UK Policy Framework for Health and Social Care Research[9]). Research Sponsors who are not confident in all aspects of the role may use a contract research organisation (CRO) to perform one or more of the Research Sponsor's activities in order to achieve the requirement. Along with providing assurances as to the quality and feasibility of the research, meeting these standards will also ensure that any research falling under statutory regulations (e.g. Clinical Trial Regulations, Mental Capacity Act, Human Tissue Act etc.) comply with the relevant legislation.

2. Authority to represent the Research Sponsor is normally delegated to University or NHS Research and Development offices, or within the MOD, to administrative units overseen at the minimum of OF5 / B2 level. The individual representing the Research Sponsor and the Chief Investigator cannot be the same person. The following checklist may be helpful to individuals asked to sign-off on behalf of the Research Sponsor for a piece of research.

3. Single Services, MOD Organisations and TLBs have Scientific Assessment Committees (SACs) that support the Research Sponsor in ensuring the appropriateness and scientific quality of the research. Where an organisation does not have a SAC, they are required to have arrangements in place with an established SAC to ensure scientific review.

4. The Research Sponsor is also responsible for ensuring that appropriate consideration has been given to issues such as the security classification of the research work, liaising with MOD security personnel as required. There must also be data handling procedures in place that comply with current UK legislation and guidance from the Information Commissioner's Office. Advice can be sought from organisations data protection officers to ensure compliance.

[8] Adapted from "HRA Expectations of Sponsors" https://www.hra.nhs.uk/documents/794/sponsors-expectations.docx (accessed 5 Dec 19).

[9] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/ (Accessed Nov 2019).

Title of Research:	A feasibility study to assess the acceptability of DECOLONISATION of *Staphylococcus aureus* to PREVENT skin and soft tissue infections
Name of Chief Investigator:	Dr Lucy Lamb
Research Sponsor (organisation):	Imperial College London
Name and position of Research Sponsor's representative:	Dr Keith Boland, Clinical Trials Imperial College.

Responsibility		**Achieved? (Y/N)**
a. The research has been assessed by a SAC and is suitably designed, and the protocol/ethics application is of a suitable standard (as outlined in JSP536, Part 2, Chapter 2). This includes:		Yes
	1. The research considers the literature including systematic reviews of relevant existing research evidence and other relevant research in progress.	Yes
	2. Where appropriate, makes use of patient and public involvement.	Yes
	3. The methods are scientifically sound (e.g. demonstrated through independent expert review), safe, legal and feasible, and remain so for the duration of the research, taking account of developments while the research is ongoing.	Yes
	4. The research output is relevant to MOD, its partners or Other Government Departments.	Yes
b. The investigators, research team and research sites are suitable and appropriate contracts are in place for the duration of the research project.		Yes
c. The roles and responsibilities of the parties involved in the research and any delegation by the Research Sponsor of its tasks are agreed and documented.		Yes
d. Adequate provision has been made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.		Yes
e. Appropriate arrangements for making data and tissue accessible (with adequate consent and privacy safeguards) are in place after the research has finished.		Yes
f. Arrangements are in place for review by MODREC (if required) and any other relevant approval bodies before the research begins.		Yes

g. Where the Research Sponsor is not the MOD, the research has explicit written approval from an individual within MOD at the minimum of OF5 / B2 level.	Yes DMS RSG
h. Regulatory and practical arrangements (such as risk assessments, security assessment and data protection arrangements) will be in place before the research to begins.	Yes
i. Adequate finance and management arrangements for the research are in place including competent risk and data management.	Yes
j. Effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.	Yes
k. Projects are registered, disseminated and reported appropriately.	Yes
In addition to the above, Research Sponsors of clinical trials of investigational medicinal products have particular legal duties – see https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/. It is recommended that any research falling under the Clinical Trials Regulations are conducted in collaboration with an established Clinical Trials Research Unit.	

Note: regarding student research.
Universities and colleges normally accept the role of Research Sponsor for educational research conducted by their own students, unless the student is employed by a health or social care provider, or has a Military based Research Sponsor, that prefers to take on this role. Research Sponsors of educational research must ensure that supervisors can and do carry out the activities involved in fulfilling this role. Where the academic supervisor cannot adequately satisfy the Research Sponsor's oversight responsibilities due to location or expertise, the Research Sponsor must agree co-supervision arrangements with a local care practitioner, a Military co-supervisor, or other suitably qualified individual.
(JSP 536 Part 1 Chapter 3 paragraph 13)

Appendix 2: List of Acronyms.

DMICP	Defence Medical Information Capability Programme
DPHU	Defence Primary Healthcare Unit
HCW	Healthcare worker/staff
ITC	Infantry Training Centre
LFIA	Lateral flow immunoassay
MALDI-TOF	Matrix-assisted laser desorption/ionization
MSSA	Methicillin-sensitive *Staphylococcus aureus*
MRSA	Methicillin-resistant *Staphylococcus aureus*
PVL	Panton Valentine Leukocidin
SP	Service Personnel
SSTI(s)	Skin and soft tissue infection(s)
UK HSA	United Kingdom Health Security Agency

Appendix 3: List of References.

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Appendix 4: Explicit, written approval from an individual within MOD at a minimum of OF5 / B2 level. Letter from DMS RSG with financial approval.

Strategic Command
Headquarters Defence Medical Services Group

Dr Philip Woodgate
PhD MRes BSc (Hons)
Director of Research
HQ Defence Medical Services
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B15 2SQ
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E-mail: Philip.Woodgate100@mod.gov.uk

12 SEP 2022

Dear Lt Col Lucy Lamb

RE: 21/22.032 Does Staphylococcus aureus decolonisation PREVENT and/or REDUCE skin and soft tissue infections using a military cohort

I am pleased to advise that the project referenced above has been endorsed by the DMS Research Steering Group on 8 Sep 2022. Funding was also agreed up to a maximum of **£149,895.62**.

Whilst this project has been endorsed funding cannot be released until a contract has been agreed and placed between the MOD and the University. This may require DMS Commercial to issue a Request for Information (RFI) and Voluntary Transparency Notice (VTN) to assess the market. Your assistance in drafting these notices would be appreciated and RCI Research Business Manager, Sam Brown (Samantha.brown275@mod.gov.uk) will be in touch in due course for this purpose.

You may pursue other ethical and regulatory approvals whilst awaiting the placement of the contract.

Please advise Sam of the project start date when known. As a condition of endorsement, you are required to complete the DMS RCI Project Completion form, attached as a separate document, within three months of project end.

Yours sincerely,

Dr Philip Woodgate

Director of Research
Defence Medical Services, MoD

Copy

Brig Duncan Wilson, Medical Director

Appendix 5: Letter to general practitioners.

Department of Infection
Imperial College London
Tel: +44 7769712402

lucylamb@nhs.net
www.imperial.ac.uk

Jan 24

Dr Lucy Lamb
Consultant Infectious Diseases

Lt Col Kate Wilkinson and colleagues
Senior Medical Officer
Infantry Training Centre
Catterick Medical Centre
Vimy Lines
Catterick Garrison
North Yorkshire
DL9 3PS

Dear GP,

PREVENT - A feasibility study to assess the acceptability of DECOLONISATION of *Staphylococcus aureus* to PREVENT skin and soft tissue infections

Thank you for your support with PREVENT. As you are aware, this is a feasibility study to assess the acceptability of decolonisation using Octenisan and mupirocin or Hibiscrub and mupirocin to prevent against skin and soft tissue infections. The study will randomise 50 recruits to either decolonisation arm and each recruit will undergo decolonisation weekly for 12 weeks.

During this period, bacterial swabs from four body sites will be collected at week 1-2, 4-5 and 11-12, electronic questionnaires on acceptability at the same time points and then a retrospective review of the disease data will be assessed at the end of the study period. Most importantly we intend to minimise the affect the study will have on recruits but provide important information on whether a future appropriately powered study might be possible. Attached with this cover letter is the participant information sheet and contact details have been provided if you need further information.

Kind regards

Lucy Lamb

Dr L Lamb, Study Principal Investigator.

Appendix 6: Participant Initial Health Questionnaire
Participant ID Number:

Please only answer questions which you would like to. Answers will remain anonymous and not be shared with anyone outside of the study. Not answering a question will not have any impact on your training or involvement in the study. Please ask an investigator if you need help with a question.

Date of arrival in the UK if not born in the UK: ___ /___/_____

Country of birth: _____ Town of birth: _____

Apart from the UK or your country of birth, have you lived in any other countries?	Yes/No Country:	Date:
If yes, please list these with dates: (More paper can be provided if needed)	_____	_____
	_____	_____
	_____	_____
	_____	_____

Please list any jobs/work prior to joining the Army? (Write none if the Army is your first job)	Job:	Date:
	_____	_____
	_____	_____
	_____	_____
	_____	_____

As far as you know, have you ever been treated for a skin infection?

		Date/age (approximately):
Skin infections/boils	Yes/ No/ Don't Know	_____

Treatment (antibiotic/suppression therapy (a treatment applied to the skin hair and nose))

_____

Any other information (do you have any pets or children?

_____

Thank you for agreeing to take part in the study. If you have any questions, please contact:

Dr Lucy Lamb

lucylamb@nhs.net

Appendix 7: Participant user acceptability questionnaire (electronic to go onto OpenClinica)
Participant ID Number:

Please only answer the questions you would like to. Answers will remain anonymous and not be shared with anyone outside of the study. Not answering a question will not have any impact on your training or involvement in the study. Please ask an investigator if you need help with a question.

1. Did using the topical suppression therapy impact on your training?

   Yes/No

If yes, how? _____

2. Did you find administering the topical suppression therapy difficult to use?

   Yes/No

If yes, how? _____

3. Did you have any side effects from the topical suppression therapy?

   Yes/No

If yes, what? _____

4. Do you have any further comments?

_____

Appendix 8: Healthcare worker user acceptability questionnaire (electronic to go onto OpenClinica)

1. Are the criteria for suspecting PVL or MRSA infection recorded in the notes?

2. Was an appropriate sample taken and sent for laboratory culture?

3. Is laboratory confirmation of PVL or MRSA recorded in the electronic medical record?

4. Was general infection prevention information given to the patient?

5. Is the choice and rationale of antibiotic recorded in the electronic medical record (appropriate empirical antibiotic choice, or choice guided by culture results)?

6. Was topical suppression therapy prescribed for the patient?

7. Has contact tracing been recorded in the electronic medical record?

Please only answer the questions you would like to. Answers will remain anonymous and not be shared with anyone outside of the study. Not answering a question will not have any impact on your training or involvement in the study. Please ask an investigator if you need help with a question.

1. Is the study impacting your job? Yes/No

If yes, how? _____

2. Have you noticed any side effects from the decolonisation regimen? Yes/No

If yes, what? _____

3. Do you have any further comments? _____

Appendix 9: Information Governance

What are your choices about how your information is being used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.

Imperial College London is the sponsor for this study and will act as the sole Data-Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London and MOD will keep your personal data for the minimum required time after the study has completed in relation to primary research data. The study is expected to finish in April 2025 with analysis completed by end of 2025.
We will need to use information from your medical records for this research project.
This information will include your initials, military service number and name.

People within the College and study team will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact) details is accurate. People who do not need to know who you are will not be able to see your name. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

As a university we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

Imperial College London - "performance of a task carried out in the public interest"); Health and care research should serve the public interest, which means that we must demonstrate

that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research. **Defence Medical Services Research Strategy Group, Ministry of Defence** legitimate interests held by the data controller or a third party.

Where special category personal information is involved both organisations rely on “scientific or historical research purposes or statistical purposes

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third-party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies. Defence Medical. Services Research Strategy Group is a third-Party Government department involved as the data will be collected from a military site on military patients and ultimately has relevance to the military.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

Samples and data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample / data analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information by asking one of the research team, sending an email to lucylamb@nhs.net.

Appendix 10 - Evidence of permission from organisation where research is to be conducted (ARITC).

Email approval from Col Anne Fieldhouse ARTIC Med AH

Andy

An interesting study which I am happy to support. Please keep me updated.

Kind regards

Anne

Sent from Outlook for iOS

From: Roberts, Andrew Dr (ARITC-HlthPerf-Research-SnrSO) <Andrew.Roberts809@mod.gov.uk>
Sent: Friday, March 15, 2024 5:00:27 PM
To: Fieldhouse, Anne Col (ARITC-MED-AH) <Anne.Fieldhouse373@mod.gov.uk>
Subject: Study review
When: 21 March 2024 09:30-09:55.
Where:

Blocking time out in the diary for you to review. Attached are the full protocol and emails of support from ITC.

Text from my original email below:

> As discussed on Friday, attached is Lucy Lamb's planned protocol involving **50 ITC recruits**. It was originally approved by ASAC in Apr 2022, but following MODREC review it was then split into two parts, with the first part undertaken as a service evaluation and a plan to resubmit for the second part. The protocol has now been revised to just include the second part (a **feasibility study of decolonisation**involving a CTIMP (mupirocin is classed as an IMP as it is not being used post-surgery)).
>
> > **Overview.** A feasibility study to assess the acceptability of *S.aureus* decolonisation to prevent skin and soft tissue infections. Service personnel routinely attend medical centres during week 1 of training and during this period study participants (SP) will be recruited and consented. Prior to randomisation individuals will be screened for *S.aureus* colonisation at 4 body sites (nose, throat, axilla and perineum). Individuals will then be randomised to receive decolonisation therapy weeklyChlorhexidine 4% bodywash and shampoo with Mupirocin 2% nasal ointment or octenisan bodywash and shampoo with Mupirocin 2% nasal ointment.
> >
> > **What will I be asked to do?**
> > You will be asked to provide swabs of the nose, throat, armpit, and groin and complete an online feedback questionnaire at week 1, 4 and 12 of training, this should take no more than 5 to 10 minutes. At week 1 you will be asked to complete a health questionnaire (less than 5 minutes). You will be randomised to receive one type of decolonisation therapy which you will be given weekly by the medical centre. Separately your medical records will be reviewed to see whether or not you had a skin and soft tissue infection during the study
>
> As the protocol has not changed significantly for this arm, I have no major scientific concerns, so plan to approve from an ASAC perspective but, given the time since the original submission, thought you should have an opportunity to take a look at it from an organisational perspective.

Thanks

Andy