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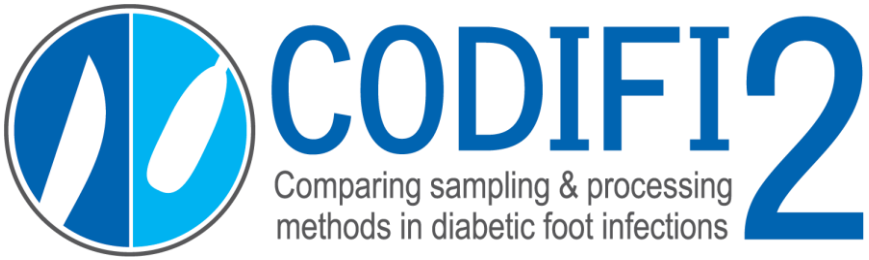


CODIFI2 Comparing Sampling and Processing Methods in Diabetic Foot Ulcers

Dr Angela Oates

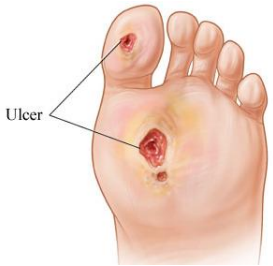
- Patient & Microbiology Sampling Pathways

Clinic Appointment

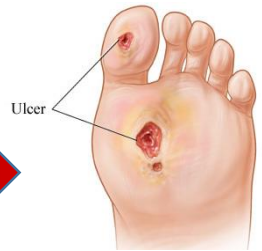
Next clinic appointment

Clinician suspect infection

Prescribe empiric antibiotics



Samples taken for microbiology



Antibiotics reviewed

24-48hrs

Microbiology Laboratory

Result released

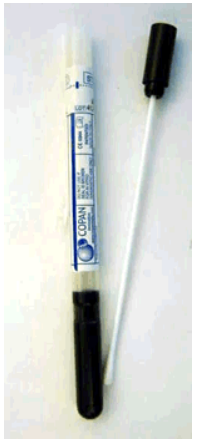
- **Standard care pathways -** no guidance for use of swab or tissue sampling

- **Clinical practice guidelines -** recommend tissue sampling and yet swab sampling is very common.

- There is variation in current practice at each clinic, as to which sample is taken for microbiology investigations for individual patients.

Sampling Methods- Swab & Tissue sampling

CODIFI
Comparing sampling methods in diabetic foot infections



1. When comparing the results from paired swab and tissues samples

   - Cultures of tissue samples identified bacteria from DFUs more often than swabs and found more isolates per sample.

2. When a clinical panel (blinded to sample type: tissue or swab) were provided with microbiology results in a virtual clinic

   - Tissue sample results led to intention to change antibiotic treatment more often (44%) than the corresponding swab result (36%)

Tissue Sampling – Potential Benefit

➢If it represents a higher yield of infecting pathogens…

- If finding more pathogens leads to better tailoring of antibiotic therapy….tissue sampling could lead to
  - Improved prescribing
  - Quicker and more likely resolution of infection-which should lead to quicker healing
  - Reduce overuse of broad-spectrum antibiotics
  - Minimise risk antibiotic resistance

Tissue Sampling – Potential Harm

- This greater sensitivity may detect more clinically non-pathogenic (colonising) bacteria or non-infectious bacteria.

- If tissue sampling detects more colonising organisms/non-infecting pathogens
  - Increase inappropriate prescribing (especially of overly broad-spectrum antibiotics) of drug regimens
  - Increased costs
  - Delayed healing/infection resolution
  - Increase risk antibiotic resistance.

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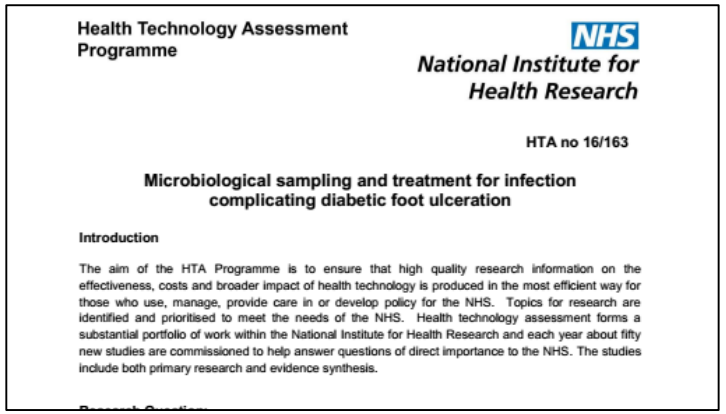
CODIFI2

Comparing sampling & processing methods in diabetic foot infections

Randomised controlled trial comparing two wound sample collection techniques (swab and tissue sampling) in clinically infected diabetic foot ulcer (DFU) patients, with blinded outcome assessment.



Health Technology Assessment Programme

NHS National Institute for Health Research

HTA no 16/163

Microbiological sampling and treatment for infection complicating diabetic foot ulceration

Introduction

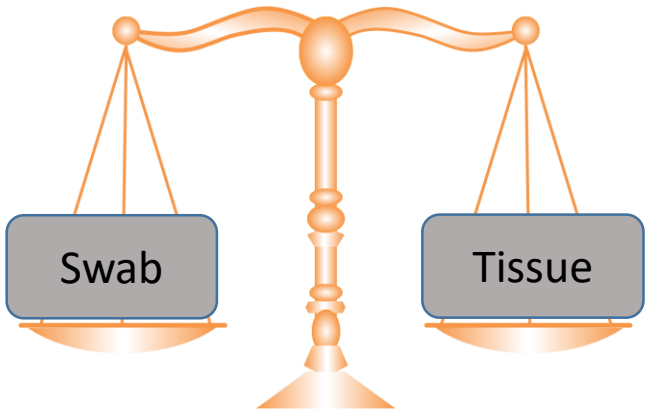
The aim of the HTA Programme is to ensure that high quality research information on the effectiveness, costs and broader impact of health technology is produced in the most efficient way for those who use, manage, provide care in or develop policy for the NHS. Topics for research are identified and prioritised to meet the needs of the NHS. Health technology assessment forms a substantial portfolio of work within the National Institute for Health Research and each year about fifty new studies are commissioned to help answer questions of direct importance to the NHS. The studies include both primary research and evidence synthesis.

- **Population:** patient with DFU with suspected infection
- **Intervention:** tissue sample
- **Comparator:** swab
- **Outcome:** time to healing of index ulcer
- **Design:** diagnostic effectiveness
- **Sample size:** 730
- **Randomisation:** 1:1 allocation to either swab or tissue sampling
- **Intervention Period:** 52 weeks
- **Follow-up:** 52-104 weeks

Challenges:

- Equipoise
  - "Clinical equipoise exists when the overall benefit or harm offered by the treatment is uncertain"
    - Avoid preferential treatment of one intervention against another

➢ Active engagement with sites
➢ Understand their procedures



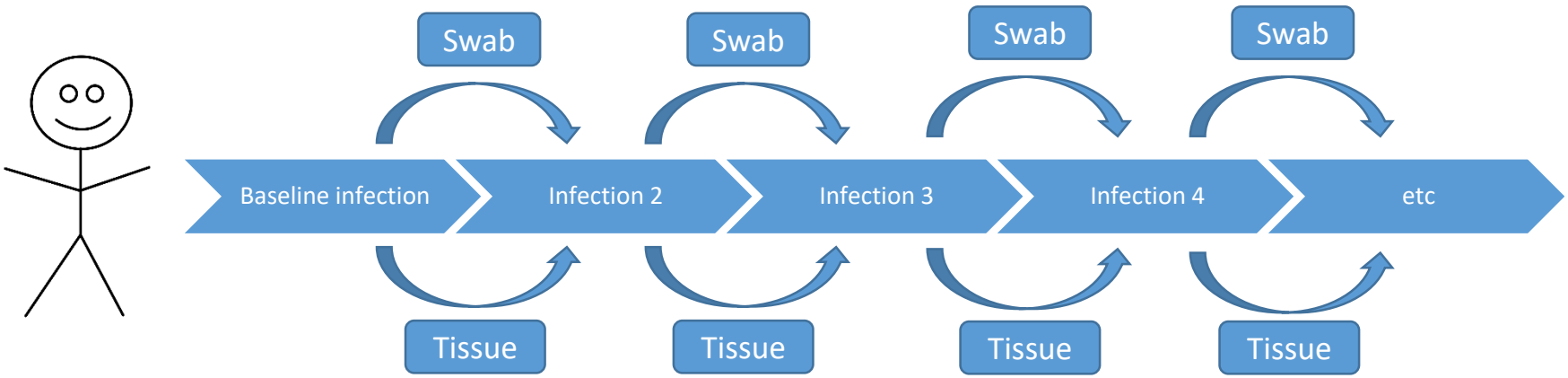
Challenges:

Follow-up-compliance/contamination

- Randomised sampling strategy is maintained throughout the study
  - Any incidence of infection where a sample for microbiology would be taken-need to be by the randomised sampling method.
  - Risk samples may be taken outside the clinic in the community
  - Risk sampling strategy not maintained throughout the study

➢ Patients to be given information cards to give to clinicians in the community

➢ Exploring printed/branded dressing tape –act as a reminder/notification



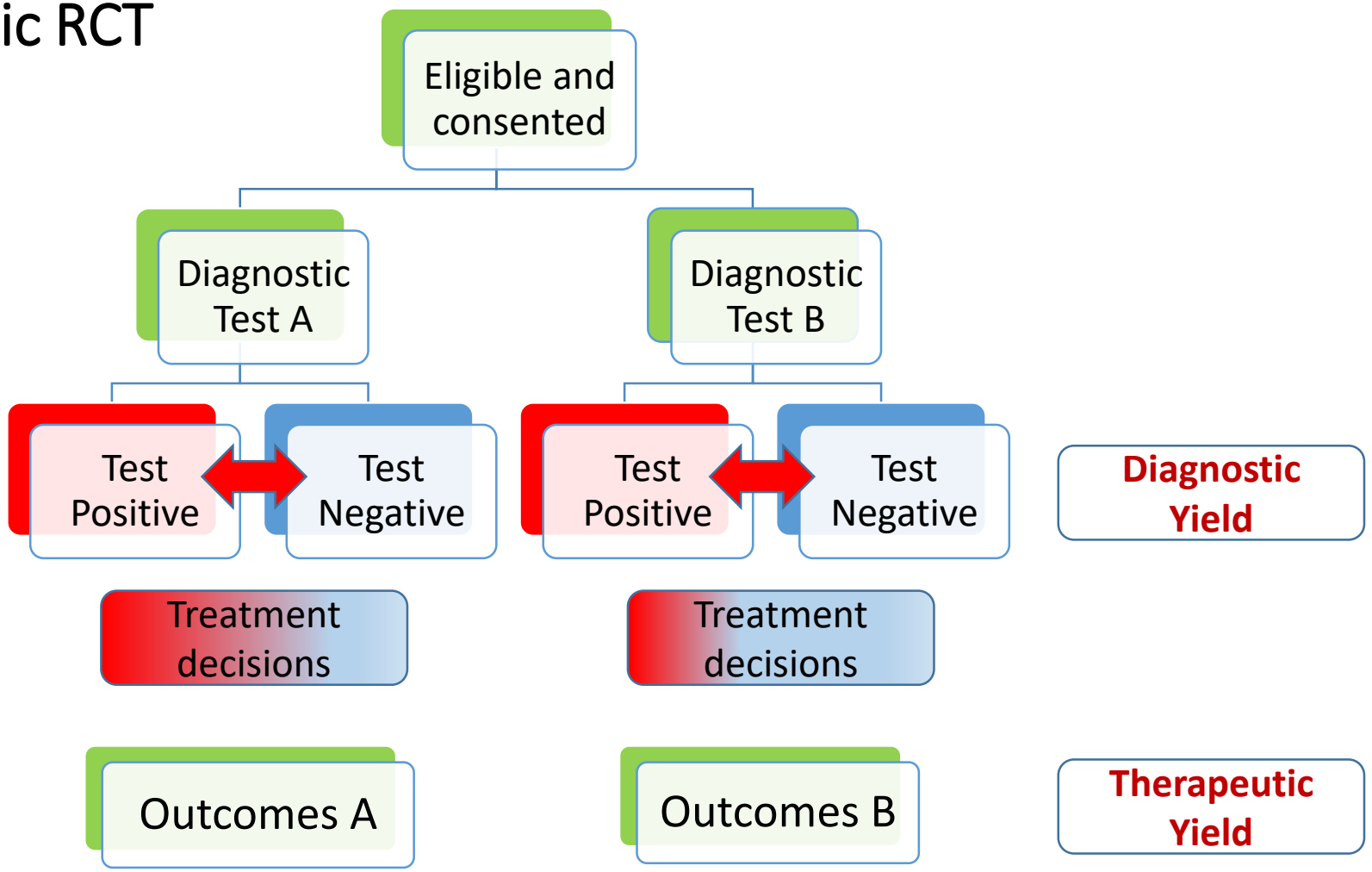
Challenges:

- Randomisation same day
  - Upon clinical suspicion of infection samples will be taken for microbiology
  - Therefore need to consent and randomise and on the day
  - Clinical appointment time is limited

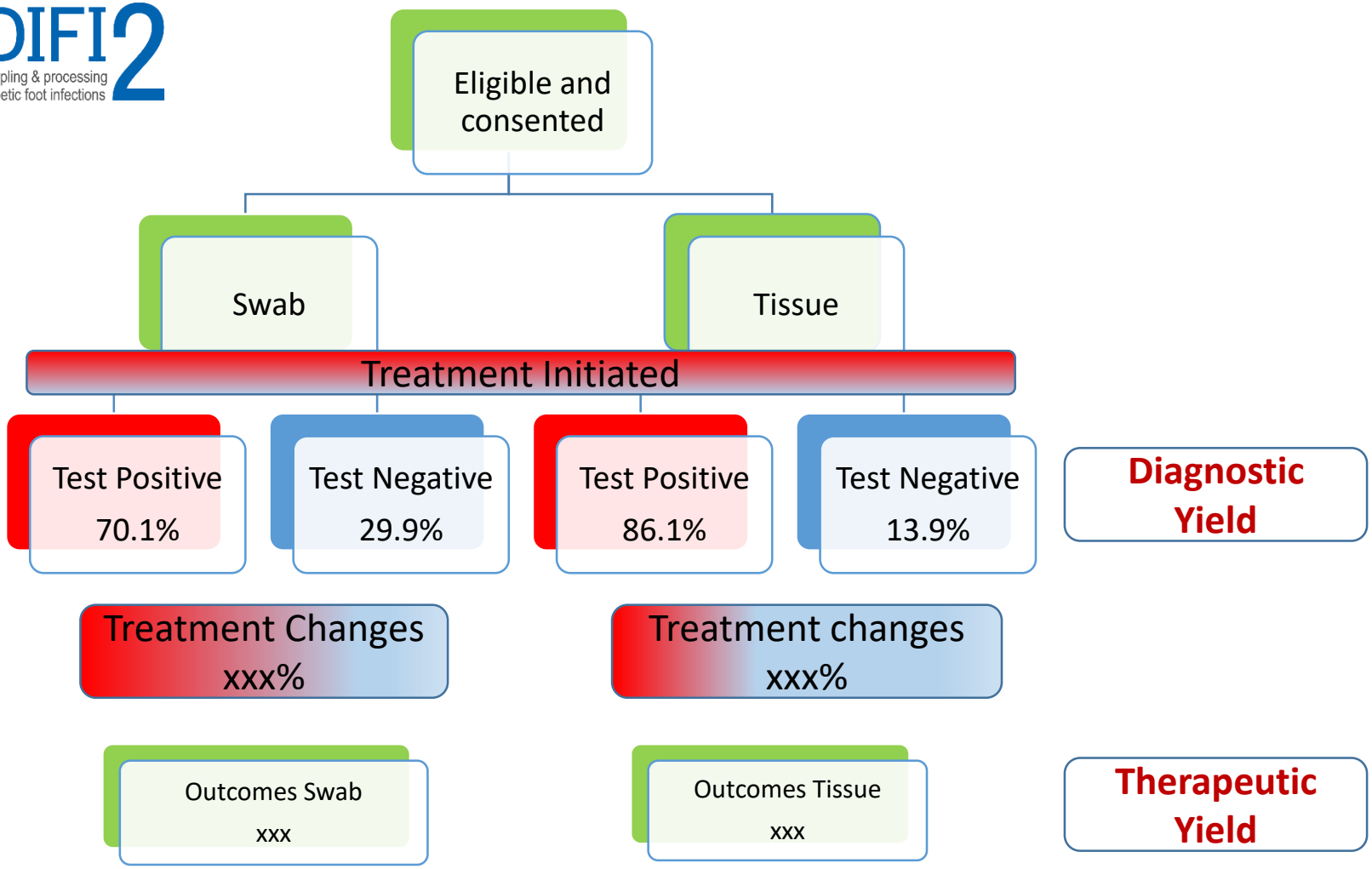
➢ Increase awareness of the study within clinics –posters, leaflets within appointment letters etc

- Therapy commenced prior to test result

Diagnostic RCT



CODIFI2
Comparing sampling & processing methods in diabetic foot infections



Thank you

For more details or to Express Interest please contact Study Manager, Claire Davies

- **C.L.Davies@leeds.ac.uk**