CADET NEWSLETTER

ISSUE 7: December 2023 (version 1, 19 December 2023)

Newsletter

CONTENTS

1. WELCOME MESSAGE FROM THE CHIEF INVESTIGATOR

Welcome to our December Newsletter.

This newsletter will provide updates on new sites, recruitment, logs, useful guidance documents, important reminders, an insight into our social media campaigns, Christmas closure arrangements, and helpful answers to screening questions.

Thank you for your continued great work on CaDeT.

Wishing you all a very happy Christmas time.

Dr Cathy Murphy

2. WELCOMING NEW SITES TO CADET

A VERY WARM WELCOME to our new participating site **Central London. We look forward to working with you!**

We have a total of 10 sites open for recruitment.

Our next **3-weekly CADET catch-up with sites** will be held on **WEDNESDAY 3rd JANUARY @10am-11am**

3. RECRUITMENT UPDATE DECEMBER 2023

TARGET

310

ALL SITES TO CONSENT AN AVERAGE OF

1 PATIENT PER WEEK!

TOTAL CONSENTED

48

TOTAL RANDOMISED

35

AWAITING RANOMISATION

8

TARGET

EACH SITE TO CONSENT A MINIMUM OF 10 PATIENTS BETWEEN DEC 2023-12 FEB 2024

4. STUDY LOGS

A. Screening Logs

We will be requesting that you send your most updated screening logs to SCTU/ or Scottish Hub (GCU) by:

10 January 2024

B. Catheter Accountability Logs

We will also be requesting that you send your most updated accountability logs to SCTU/ or Scottish Hub (GCU) by:

10 January 2024

C. Delegation Logs

Please ensure that you keep your delegation log updated. Any changes to the Trial Research Team should be reflected on the Log. Please ensure that you send any updated logs to:

SCTU Trial Manager cadet@soton.ac.uk

Or (Scottish sites only)

GCU Trial Manager gcucadet@gcu.ac.uk

5. REMIN-DEERS OF USEFUL GUIDANCE DOCUMENTS

- ✓ PROMPT SHEET
- ✓ TENALEA USER MANUAL
- ✓ E-CONSENT GUIDANCE
- ✓ TEXT ANYWHERE MANUAL

6. RECRUITMENT

Please continue to notify SCTU/ GCU of all **completed consent visits** and let us know the date that you have booked for the patient's **Baseline Visit**!

The PROMPT sheet is a helpful guide, all the documents that we need from you during recruitment are detailed here!

OPTITIP EXPIRY DATES

Please continue to log the Optitip expiry date on the catheter accountability log.

Please notify the Trial Manager if you have Optitip at the site with an **expiry date of less than 12 months, at the time of review.** As per CaDeT protocol (v3, 27 Sep 2023), all patients randomised to the Optitip must be given 12 months' worth of catheter

7. REPORTING REQUIREMENTS FOR ADVERSE EVENTS, AND SERIOUS ADVERSE EVENTS

As per protocol (version 3, 27 Sep 2023), all related Adverse Events (AE), and Serious Adverse Events (SAE) are to be recorded on the database RAVE.

In addition to reporting on RAVE, we need you to complete an **SAE reporting form** for **related Serious Adverse Events AND unrelated Serious Adverse Events ONLY** (we don't need you to complete this form for related *Adverse Events*, **Serious ones only**….)

See the table below.

MORE IMPORTANT REMIN-DEERS

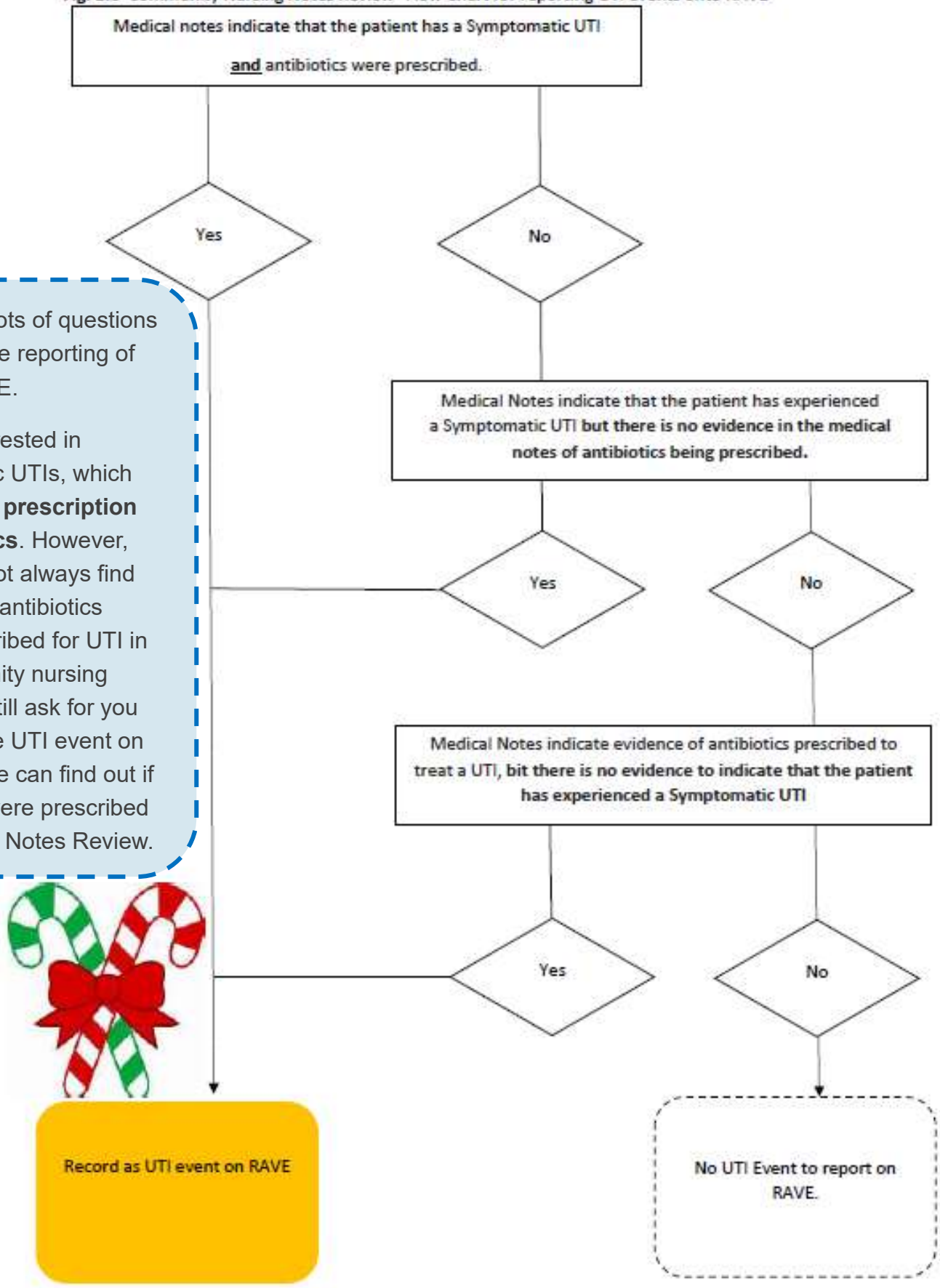
When you notify us of consented patients and their scheduled Baseline visits, please let us know if the patient is a frequent changer.

Please ensure that EVERY invited patient, who does not respond to the invite letter, is **called,** OR sent **the non-response to the invite reminder letter** within 3 weeks of posting the invite.

Please email cadet@soton.ac.uk for all Optitip order requests.

AE and SAE reporting		Record on the database?	Report to SCTU?
AE	Related to bladder/ catheter	Yes	No
	Unrelated	No	No
SAE	Related to bladder/ catheter	Yes	Yes
	Unrelated	No	Yes

Fig. 1.0 Community Nursing Notes Review- Flow Chart for reporting UTI events onto RAVE



We've had lots of questions regarding the reporting of UTI on RAVE.

We are interested in symptomatic UTIs, which **include the prescription of antibiotics**. However, you might not always find evidence of antibiotics being prescribed for UTI in the community nursing notes. We still ask for you to record the UTI event on RAVE, as we can find out if antibiotics were prescribed from the GP Notes Review.

8. CHRISTMAS CLOSURE SCTU and GCU

SCTU CHRISTMAS CLOSURE ARRANGEMENTS

Southampton Clinical Trials Unit will be closed from 5 pm, Thursday 21st December 2023 until 9 am, Tuesday 2nd January 2024

- Please continue to report SAEs by EMAIL during this period to ctu@soton.ac.uk
- For urgent clinical queries: please contact Chief Investigator Dr Cathy Murphy at c.murphy@soton.ac.uk
- For all other queries please email cadet@soton.ac.uk and they will be dealt with on our return

IF YOU HAVE ANY PATIENTS THAT ARE DUE THEIR NEXT CHANGE W/C 25TH DEC/ 1ST JAN/ 8TH JAN – PLEASE SEND THE REGISTRATION DOCUMENTS TO cadet@soton.ac.uk NO LATER THAN 2PM ON THURSDAY 21 DECEMBER SO THAT WE CAN CONDUCT THE CENTRAL MONITORING CHECKS AND ISSUE GREENLIGHT TO RANODMISE PRIO T O THE CLOSURE.

GCU CHRISTMAS CLOSURE ARRANGEMENTS

The Trial Management team at GCU will be on annual leave from the end of day Thursday 21 December 2023 until 9 am Monday 8th January 2024

- Please continue to report SAEs by EMAIL during this period to ctu@soton.ac.uk
- For urgent clinical queries: please contact Chief Investigator Dr Cathy Murphy at c.murphy@soton.ac.uk
- For all other queries please email gcucadet@gcu.ac.uk or cadet@soton.ac.uk and they will be dealt with on our return

IF YOU HAVE ANY PATIENTS THAT ARE DUE THEIR NEXT CHANGE W/C 25TH DEC/ 1ST JAN/ 8TH JAN/15TH JAN – PLEASE SEND THE REGISTRATION DOCUMENTS TO gcucadet@gcu.ac.uk NO LATER THAN 2PM ON THURSDAY 21 DECEMBER SO THAT WE CAN CONDUCT THE CENTRAL MONITORING CHECKS AND ISSUE GREENLIGHT TO RANODMISE PRIO T O THE CLOSURE.

9. SOCIAL MEDIA

- **Campaign 1**

  24 Nov 2023-27 Nov 2023

- **Campaign 2 (Targeted)**

  01 Dec 2023-04 Dec 2023

- **What have we included in the social media campaigns?**

TARGETED CAMPAIGNS INCLUDE SITE CONTACT DETAILS

VIDEO CAROUSEL

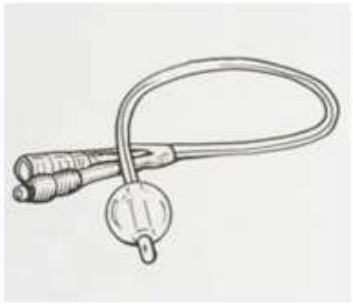
(Clips taken from cadet infographic)

STATIC IMAGE

(See page 8)

Please continue to share the **CADET INFOGRAPHIC** amongst your MDT (including community and district nursing teams).

The PIS talks about this video, and explains how the patient can learn more about the trial by visiting: www.cadettrial.com



Have you experienced catheter-associated infections in the last 12 months?

Would you like to know more about taking part in a research study?

A new catheter called Optitip has recently become available which is designed differently from the standard 'Foley' catheter which is used by most catheter users. The Optitip catheter is already used by some NHS patients, and it is used in the same way as a Foley (standard) catheter.

The CaDeT trial aims to find out whether or not the Optitip reduces:

- Infections
- Blockages
- Other catheter harms such as bladder spasms
- Offers value for money for
- the NHS.

Find out more...

Visit our website

www.cadettrial.com

Scan the QR code

UKCRC Registered Clinical Trials Units

FUNDED BY NIHR | National Institute for Health and Care Research

NHS University Hospital Southampton NHS Foundation Trust

Research Ethics number: 22/SS/0094

10. SCREENING Q&As

QUESTION	ANSWER
Can we include people with open-ended Foley catheters	*Yes, patients using any Foley catheter (open or closed and including all Folysil variants) can be included* ***and they can stay on their usual open or closed catheter (including Folysils) should they be allocated to the control group.**** **Please note that we recently have updated the decision to allow patients to stay on their usual Foley on 18 December 2023. If you have excluded patients due to them not wanting to use the standard Foley (if randomised to the Foley arm), please consider a re-approach to these patients.*
Can we include people with prophylactic antibiotics	*Yes, the use of prophylactic antibiotics would not exclude a patient.*
Can we include people with other signs/symptoms of UTI not in the definition (who have been prescribed ABx) e.g. strong smell of urine, bladder spasms, burning sensation?	*When screening for eligible participants, we're looking for people who have had a UTI in the last 12 months. This does not need to be microbiologically confirmed. Instead, patient-reported signs and symptoms can be used. This is in line with NICE guidance (Quality Standard 20 – Urinary tract infections in adults, Quality Statement 2 – Diagnosing urinary tract infections in adults with catheters). If a potential participant reports that they have had a UTI in the last 12 months (or if it is recorded in notes), this is sufficient for eligibility purposes.*
What is the definition of terminal diagnosis - timescale?	*If the individual is expected to live for 12 months or less from the time of randomisation.*
Do community nurses have to continue with bladder washouts if someone is given the Optitip? Or should they re-assess and see if they still need regular washouts? (in protocol it says to continue with previous routine, but won't this affect data if they're	*They should continue with usual care, making decisions as they normally would (e.g., continue with washouts if they are needed).*

going out to do regular washouts if they don't need to?).	
Can we include patients in hospital at home?	*Yes, as per protocol inclusion criterion 3 Community-dwelling (own home or residential care, including assisted living)*

QUESTION	**ANSWER**
How do you define unresolved urethral stricture? Is this when a catheter can't be placed easily or a special type of catheter needs to be used? I had one patient who had a stricture which seemed to be treated by having a catheter (if they removed the catheter, the stricture would return) – would they be included?	*Yes they could be included if they are anticipated to have a catheter that will be placed in the community for 12 months*
Does lifelong hormonal therapy for prostate cancer constitute ongoing interventional therapy?	*Can be included.*
Would a patient be eligible for the study, if they are taking Cranberry juice, D'mannose, or if they are on long-term antibiotics?	*Use of any of the above, would not exclude a patient, the use of prescribed concomitant medication is noted at the Baseline and follow-up.*
What happens if the catheter of a patient randomised to the Optitip catheter falls out or gets blocked and they are catheterised in A&E with the standard tipped catheter?	*As per protocol, medical records should be updated to indicate participation in the cadet trial. The patient will also have a trial card they keep with them, indicating their allocation (Foley participation Optitip). All patients should receive a box of Optitip to last them for 12 months, at randomisation, which is kept with them. In instances where the patient visits A&E the Optitip (if randomised to this) should be kept with the patient. If the Optitip is not available to use at A&E then the change back to the Foley catheter for that particular change will be picked up in follow-ups and notes review. Their next changes should be back to their allocated treatment (Optitip) unless decided otherwise by the patient or research team.*

For the purpose of this study is the catheter material of the standard Foley catheter relevant (Silicone or Latex)?	*The Optitip material is Silicone. Whilst the material type of current foley would not exclude, the patient must be aware that they have a 50:50 chance of being randomised to the Optitip, which uses the Silicone material.*

Newsletter

CaDeT

THANK YOU!

NIHR | National Institute for Health and Care Research

GCU Glasgow Caledonian University

University Hospital Southampton NHS
NHS Foundation Trust

University of BRISTOL

UNIVERSITY OF SURREY

UNIVERSITY of STIRLING

Acknowledgments to our Supporting Sites: Hertfordshire Community NHS Trust; Norfolk Community Health & Care NHS Trust; Shropshire Community Health NHS Trust; Bradford District Care; NHS Lanarkshire; NHS Fife; Hertfordshire Stevenage; Nottingham City Care; Central and North West London; Central London.

HAPPY CHRISTMAS!