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DOI: https://doi.org/10.3399/BJGPO.2025.0239

To access the most recent version of this article, please click the DOI URL in the line above.

Received 30 October 2025

Accepted 11 November 2025

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Running Head (max 50 characters): Redefining recurrent UTI and reinfection risk

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Abstract

Background

There is limited evidence to support the current standard recurrent urinary tract infection (rUTI) definition of ≥2 UTIs within 6 months or ≥3 within 12 months. Information about reinfection risk after meeting criteria for rUTI may aid decisions on the value of prophylactic approaches.

Aim

To estimate the risk of subsequent UTI associated with different rUTI definitions.

Design and Setting

Electronic health record study using Infections in Oxfordshire Research Database (IORD, 2008-2019) and the Clinical Practice Research Datalink (CPRD, 2009-2019).

Method

We identified community-acquired UTIs, separated by 28 days, in non-pregnant women aged 16+ years. We created candidate rUTI definitions varying the time window from 3-9 months, and the number of UTIs required to meet the definition from 2-3 episodes. For each definition, we calculated Kaplan-Meier risk estimates of subsequent UTIs within 6 and 12 months after meeting rUTI criteria.

Results

Of eligible women with at least one UTI, 18% (15,617/84,809) in IORD and 20% (334,487/1,703,088) in CPRD experienced ≥1 rUTI (current definition). The risk of at least two subsequent UTIs within 12 months after meeting the current rUTI definition rose from 17% (IORD) and 16% (CPRD) to 33% (IORD) and 32% (CPRD) under a rUTI definition of ≥3 UTIs within 6 months. Risk of subsequent UTI also increased with age.

Conclusion

Risk estimates of subsequent UTIs after a rUTI vary according to the definition of rUTI adopted. Estimates provided here could support shared decision making around UTI prophylaxis and stratification of populations included in future rUTI research.

Keywords (up to 6 MESH headings): Urinary Tract Infections; Reinfection; Primary Health Care

How this fits in

- Recurrent UTI (rUTI) occurs frequently among women who experience UTI.
- Current guidelines define rUTI as ≥2 UTIs within 6 months or ≥3 within 12 months, but there is no evidence underpinning this definition, and no contemporaneous estimates of how the risk of a new UTI varies over time from an index infection.
- Using two different datasets, we demonstrate that the risk of a subsequent UTI was higher in women who had more UTIs in the preceding months and in older women, enabling more personalised assessment of rUTI risk.
- Clinicians could use this to inform patient-focused, shared decision-making around starting prophylaxis and other preventative measures.

Introduction

Urinary tract infection (UTI) is the most common bacterial infection managed in primary care.(1) Most infections occur in women, with an incidence rate four times greater than men, (2) and there were >400 million cases globally in 2019.(3) Recurrent urinary tract infections (rUTI) are also common(4) and are associated with increased morbidity, sexual dysfunction, and negative physical and emotional impacts.(5, 6) UTI carries increased risk of complications such as pyelonephritis and bloodstream infection.(7)

Diagnostic criteria for UTI have been extensively reviewed,(8) but criteria for rUTI are less evidence-based. European Association of Urology guidelines define rUTI as “recurrences of uncomplicated and/or complicated UTIs, with a frequency of at least three UTIs/year or two UTIs in the last six months”.(9) National Institute for Health and Care Excellence guidelines for antimicrobial prescribing for rUTI use the same definition.(10) Others have also used an equivalent composite definition(4, 11) but some use only the first or the second part.(12) No scientific justification is offered for these definitions and their clinical utility has not been assessed.

Current guidelines advise that women who have been identified as having recurrent UTI should be offered preventative management options, including long-term antibiotics, Methenamine Hippurate, or topical vaginal oestrogen.(10) There is mostly low-quality evidence on the effectiveness of these treatment options, with effectiveness varying according to the type of treatment, duration, and study population. For instance, compared to placebo, antibiotic prophylaxis for 6-12 months significantly reduced the risk of subsequent UTIs in non-pregnant women who had experienced at least one rUTI.(13) A systematic review of the use of oestrogen for subsequent UTI prevention in postmenopausal women who had experienced at least one rUTI found similar results, but these differ depending on the type and duration of oestrogen therapy.(14) In general, the currently recommended strategies are associated with side effects, and, in the case of long term antibiotics, with higher risk of antibiotic resistance.(13) Although women meeting current criteria for rUTI have been demonstrated to have increased risk of experiencing multiple subsequent infections,(15) we do not know which women are at greatest risk of subsequent, or frequent, recurrence. Greater understanding of how likely an individual woman with rUTI is to experience further UTIs could inform shared decision-making around antibiotic prophylaxis and other preventative measures.

This study aimed to explore the relationship between a range of potential diagnostic definitions of rUTI and the risk of subsequent UTI, using primary care data from two large UK cohorts. This may enable more personalised assessment of recurrence risk to inform shared decision-making about initiating prophylaxis.

Method

We performed an electronic health record study using two sources: the Infections in Oxfordshire Research Database (IORD)(16) and the Clinical Practice Research Datalink (CPRD) Aurum database.(17) As the two databases differ in geographical coverage and criteria for UTI coding, they were analysed separately. Table 1 compares the two databases and inclusion/exclusion criteria used in this study. UTI is much less common in men, is subject to different investigation and management and may be underpinned by different aetiologies. Including men in the analysis would introduce additional heterogeneity and reduce the precision of estimates. The focus of this study was therefore on rUTI in women.

Infections in Oxfordshire Research Database

IORD is a de-identified electronic database containing microbiology and urine culture results from specimens collected in primary and secondary care which were tested at the Oxford University Hospitals NHS Foundation Trust, serving a patient population of ~750,000. These results are linked to patient demographic data and clinical records.

We extracted all urine culture results from women aged 16+ years between 2008-2019. For the primary analysis, we defined UTI as positive culture of a known uropathogen (pure or predominant growth $\geq 10^4$ cfu/mL) from a sample taken in the community, or within 48 hours after hospitalisation (i.e. microbiological definition because primary care clinical codes not available). A sensitivity analysis used any culture result (positive, mixed, equivocal or negative) as indicative of possible UTI, as a request for urine culture from primary care typically indicates clinical suspicion.

We excluded urine samples taken within 28 days after hospital admission or another index urine sample (as the latter were judged likely to be related to the index infection), and samples recorded as being taken for antenatal screening.(15)

Clinical Practice Research Datalink Aurum

CPRD Aurum contains anonymised longitudinal routinely-collected electronic patient health records from UK general practices using EMIS Web general practice patient management software. It contains the coded part of records including diagnoses, laboratory results, GP observations, and demographic information. Data quality measures include the patient 'acceptable flag' (a marker that identifies invalid records).(18) The dataset was linked to Hospital Episode Statistics (HES) Admitted Patient Care data and the CPRD Pregnancy Register.

We used CPRD data from 2010-2019 and extracted an initial cohort of women aged 16+ years from English general practices who were eligible for HES linkage and had at least one record containing a medical code for UTI or suspected UTI in their current practice. From consultations with these codes (Appendix A), we defined UTI as those that additionally met at least one of the criteria shown in Table 1. We used HES-linked hospitalisation dates to distinguish likely community-acquired vs hospital-acquired infections, as also described in Table 1.

UTI episodes

In observational datasets, it is not usually possible to distinguish between instances of relapse (or 'persistence'), in which the same organism as the index infection remains detectable, and reinfection with either the same or a different species. Other studies used a two-week threshold to distinguish between these scenarios, or required a sterile culture in the interim.(19, 20) Here, we consider that infections more than 28 days apart, whether caused by the same or a different species, are likely to represent different infection episodes. A 2010 study on the duration and severity of UTI episodes found that the average duration of a UTI episode was 3.3 days.(21) While there is a small risk of misclassification, we expect the large majority of episodes separated by 28 days to correspond to different episodes. Previous work has shown that reducing this interval to 14 days has a minimal effect on the number of distinct episodes identified.(15)

Candidate new rUTI definitions

The most widely-used composite rUTI definition is 2 UTIs within 6 months or 3 within 12 months. However, as it is impossible to have 3 UTIs in twelve months without at least one pair of these falling within a 6-month window, the 12-month element is redundant for defining the onset of a period of recurrent UTI (Supplementary Figure 1). We therefore term '2 UTIs within 6 months' the 'base definition' against which to benchmark other candidate definitions.

Based on input from a panel of public contributors with rUTI, we considered candidate rUTI definitions of the form 'X episodes of UTI within Y months'. We varied the number of UTIs required to meet the definition from X=2 episodes (base definition) to either 2 or 3 episodes, and the time window from Y=6 months (base definition) to either 3, 4, 5, 6, 7, 8 or 9 months. This creates 14 possible candidate definitions. For each dataset, the number and proportion of women meeting each rUTI definition at any time during the study period were calculated.

Performance of rUTI definitions

Input from our public contributors suggested that patients at high risk of experiencing further UTIs after being classified with rUTI are those with ≥2 subsequent UTI episodes within the next 12 months. For comparison, we also estimated the risk of ≥1 and ≥3 subsequent UTIs within 6 months and within 12 months. We planned to quantify the risk of ≥4, ≥6 and ≥8 more subsequent UTIs within 6 and 12 months, but only a small proportion of individuals experienced these numbers of UTIs in our datasets.

Statistical analysis

In both datasets, an index rUTI event for each patient, under each proposed rUTI definition, was defined as the first time within the study period at which the rUTI definition was met.

Kaplan-Meier estimates (with 95% confidence intervals) were calculated for ≥1, ≥2 and ≥3 subsequent UTIs within 6 and 12 months after first meeting the rUTI criteria, under each candidate definition, censoring patients at the end of the study period.

We quantified the extent to which rUTI definitions classified the same percentage of women as the base rUTI definition, using percentage agreement measures (overall, positive and negative). Positive percentage agreement was defined as the percentage of women who were classified as having rUTI using a candidate new definition out of those classified as having rUTI by the base definition. Negative percentage agreement was the percentage of women who were classified as not having a rUTI using a candidate definition out of those classified as not having rUTI by the base definition. Overall percentage agreement was the percentage of women who were classified equally by the candidate and base definitions.

For each definition, analyses were also stratified by decades of age at the time of meeting the definition. Analysis was performed using Stata 18.0.

Results

IORD cohort

For the IORD cohort, the primary analysis included 84,809 women with one or more positive urine culture results (167,008 UTI episodes, Figure 1), of whom 15,617 (18%) met the base rUTI definition. Median (IQR) age at this time was 68 (45-80) years; and women contributed median 3.7 (1.4-6.7) years follow-up from their first rUTI to the end of the study. For the sensitivity analysis, 201,927 women had one or more urine cultures (positive or not), of whom 64,260 (32%) met the base rUTI definition, with median 5.1 (2.2-8.3) years follow-up.

CPRD cohort

In the CPRD cohort, 9,850,773 women had acceptable data and were eligible for HES linkage. Of these, 1,803,493 (18%) met the UTI criteria at least once. After applying additional exclusion criteria, 1,703,088 of these women remained (17% of the original cohort), contributing 3,451,034 UTI episodes (Figure 1). Of these women, 695,552 had at least two UTI episodes, and 334,487 of these met the base rUTI definition (20% of those with at least one UTI). The median (IQR) age at this time was 57 (36-75) years, younger than the IORD cohort (Supplementary Figure 2). Women contributed median 3.4 (1.4-6.1) years follow-up from their first rUTI to the end of the study.

Comparison of candidate rUTI definitions

Table 2 shows the effect of changing the rUTI definition on the percentage of women ever meeting the definition during the study period. For definitions requiring two subsequent UTI episodes, changing the timeframe from the base definition of 6 months to 3 months reduced the percentage of women meeting the definition by around a third in both IORD (from 18% to 12%) and CPRD (from 20% to 12%) datasets. Changing the number of required UTI episodes from two to three caused a much greater reduction in the percentage meeting the definition; for example, for 6 months, from 18% to 4% in IORD and from 20% to 4% in CPRD. Changing the definition had relatively little impact on the age distribution of women classified with rUTI (Supplementary Table 1).

Figure 2 and Supplementary Table 2 show the risk of subsequent UTIs over time, following the index rUTI. More stringent rUTI definitions (three episodes rather than two; shorter time intervals) were associated with higher probability of subsequent UTIs within the following 6 or 12 months. Under the base definition, the risk of at least two subsequent UTIs within the following 12 months was 17% (IORD) and 16% (CPRD). This rose to 33% (IORD) and 32% (CPRD) under the '3 within 6 months' definition. Changing the timeframe of the rUTI definition had a smaller impact on the estimated risk of subsequent UTI.

Under the base definition, the risk of two subsequent UTIs within the following 12 months progressively increased with age among women aged 40+ in both datasets. In IORD, the risk changed from 13% in those aged 40-49 to 21% in those aged 70-79 and 22% in those 90+; in CPRD, from 13% to 21% to 26% in the same age groups (Figure 3). This trend was similar for the different rUTI definitions, with corresponding risks being much higher under stricter rUTI definitions across all age groups (Supplementary Tables 3-4, Supplementary Figures 3-6).

Supplementary Tables 5-7 additionally compare the proposed rUTI definitions using percentage measures, and confirm that switching from a 2-episode to a 3-episode definition had a greater impact than varying the time window between UTI episodes.

Discussion

Summary

We have demonstrated that among women meeting criteria for rUTI, more previous UTIs, UTIs that occurred closer in time, and greater age all increased the risk of additional subsequent UTI episodes. Defining rUTI as three, rather than the current two, UTIs in 6 months doubled the risk of having two UTIs in the subsequent 12 months (from 16% to 32%). The risk increased still further in the oldest age groups (under the base definition, from 13% in women aged 40-49 to 21% in those aged 70-79). Our study therefore provides novel

risk information that could be used to personalise treatment decisions with patients who have experienced multiple UTIs.

Strengths and limitations

This study used two large databases, and demonstrated consistent results in terms of risk estimates between them even though their demographic profile and procedures for identifying UTI cases differed. The data predated COVID-19 and so was unaffected by abrupt changes in diagnosis and prescribing caused by the pandemic.(22)

The lack of additional available data means that we could not contextualise the findings based on the treatment that was provided to patients once the definition of rUTI was reached. We could not capture the patients' full UTI history prior to study entry, or consider adverse outcomes after rUTI that might be important to patients, such as hospitalisation. The study is also subject to usual limitations of using routinely collected data, including accuracy of coding.(23) The IORD dataset, using urine culture results alone, may over-represent women with more complex trajectories of infection and may also include some cases of asymptomatic bacteriuria. The CPRD dataset used only coded, rather than free-text, information fields, and so some UTI episodes may have been missed. Our analyses assumed that individuals remained "at-risk" throughout the study period: some may have moved away from the area, meaning that subsequent UTIs were not ascertained. This would also bias our estimates downwards, i.e. true risk would be greater.

Comparison with existing literature

The current rUTI definition, widely adopted in guidelines and research studies, is not underpinned by any epidemiological evidence. There have been no previous attempts to characterise the impact of different possible definitions of rUTI and age on the risk of subsequent UTIs. An epidemiological study using Welsh primary care electronic records found that relatively few women who met the definition for rUTI received antibiotic prophylaxis, arguing for the value of more relevant definitions based on risk of subsequent UTI.(24) The increased UTI risk with increasing age found in this study aligns with their finding that prophylactic antibiotic prescribing increased with increasing age.

Implications for research and practice

Current guidelines recommend a number of prophylaxis options, including vaginal oestrogen, Methenamine Hippurate and antibiotic prophylaxis.(10) All are associated with potential side effects or risks, with antibiotic prophylaxis in particular being associated with potential future antibiotic resistance.(25) The new information provided by this study could allow clinicians and patients to have more nuanced conversations regarding the likely benefit of prophylaxis, balancing the need to take a daily medication against the likelihood of recurrence. It could also allow clinicians to use electronic records searches to identify and approach women who may benefit most from Methenamine Hippurate, now that this is part of national guidance. For women considering prophylactic antibiotics, a different threshold for defining rUTI could be considered, to inform discussions balancing risk of subsequent UTI with treatment-related side-effects. As more evidence emerges regarding the clinical effectiveness of antibiotic and non-antibiotic options, we envisage a decision tool that could help women understand how these treatments could modify their risk of recurrence. In research, future trials of rUTI interventions could consider using inclusion criteria appropriate for the risk profile of the intervention. The extent to which different prophylaxis approaches can modify the risk of subsequent UTI for different patient groups requires future evaluation, possibly via target trial emulation.

Funding

This research was funded by a National Institute for Health and Care Research (NIHR) Advanced fellowship awarded to G.H. MVM, TRF and GH receive funding from the NIHR HealthTech Research Centre for Community Healthcare at Oxford Health NHS Foundation Trust. TRF receives funding from the NIHR Applied Research Collaboration Oxford and Thames Valley at Oxford Health NHS Foundation Trust. MS reports a grant from The Baily Thomas Charitable Fund. ASW is an NIHR Senior Investigator. ASW and NS are supported by the NIHR Health Protection Research Unit in Healthcare Associated Infections and Antimicrobial Resistance (NIHR200915), a partnership between the UK Health Security Agency (UKHSA) and the University of Oxford, the NIHR Oxford Biomedical Research Centre (BRC). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

Ethical approval

IORD has approval from the South Central Research Ethics Committee (19SC/0403) and Confidentiality Advisory Group of the Health Research Authority (HRA) (19CAG0144) for research without individual patient consent. CPRD obtains annual ethics approval from the UK HRA Research Ethics Committee and Section 251 of the NHS Act 2006 regulatory support, through the HRA Confidentiality Advisory Group (CAG). This approvals allow CPRD to collect and share anonymized patient data for research purposes without needing individual patient consent.

The study obtained ethics approval through the CPRD Research Data Governance process (Protocol Number 20_174).

Competing interests

None.

Acknowledgements

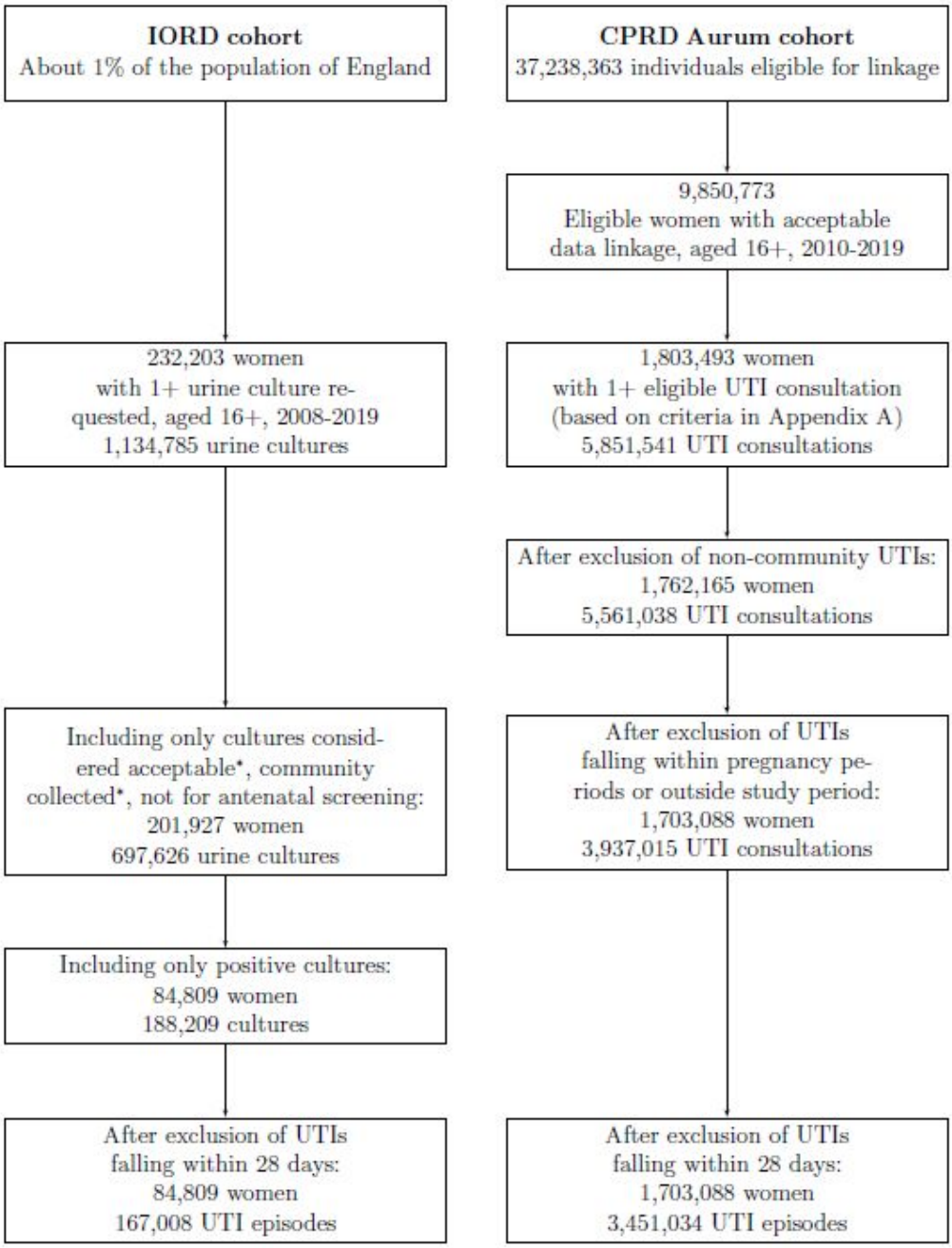
We are grateful to the five Public and Patient Involvement members, Sandra North, Val Tate, Susannah Fraser, and Feri Ghandi, for contributing to this project.

This study is based in part on data from the Clinical Practice Research Datalink obtained under licence from the UK Medicines and Healthcare products Regulatory Agency. The data is provided by patients and collected by the NHS as part of their care and support. HES Data/ONS Data copyright © (2020), re-used with the permission of The Health & Social Care Information Centre. All rights reserved.

This work uses data provided by patients and collected by the UK's National Health Service as part of their care and support. We thank all the people of Oxfordshire who contribute to the Infections in Oxfordshire Research Database.

Research Database Team: L Butcher, H Boseley, C Crichton, DW Crook, D Eyre, O Freeman, J Gearing (community), R Harrington, K Jeffery, M Landray, A Pal, TEA Peto, TP Quan, J Robinson (community), J Sellors, B Shine, AS Walker, D Waller. Patient and Public Panel: G Blower, C Mancy, P McLoughlin, B Nichols.

Figure 1: Flow chart for the IORD and CPRD cohorts



*Urine cultures requested from primary settings or within 48 hours after an inpatient admission 28+ days apart from any previous hospitalisation. Excluded: mislinked patients, patients without microbiology, catheter specimens, cultures with test results 24+ hours before collection date.

Table 1: Comparison of IORD and CPRD databases

	IORD	CPRD
Coverage	Urine samples from Oxfordshire primary and secondary care	1,491 UK general practices
Timeframe	2008-2019	2010-2019
Relevant data	Microbiology and urine culture results from specimens collected in primary and secondary care Demographic data	Diagnostic codes Prescriptions Demographic data Hospital Episode Statistics Admitted Patient Care Pregnancy Register
Eligibility	Women aged 16+ years with ≥1 urine culture result	Women aged 16+ years, with 'acceptable flag', from English practices eligible for linkage to HES with ≥1 record containing a medical code for UTI or suspected UTI
Primary UTI definition	Positive culture of a known uropathogen (pure or predominant growth ≥10^4 cfu/mL) from a sample taken in the community, or within 48 hours after inpatient hospital admission	At least one of: (i) a relevant same-day antibiotic prescription (ii) a same-day hospital admission with a UTI-relevant ICD-10 code (iii) a code indicating that a urine sample was sent for culture, and a relevant antibiotic prescription within 7 days
Exclusions	Urine samples: (i) within 48 hours after a hospital admission, if the individual had a separate hospitalisation that ended within the preceding 28 days (ii) within a hospitalisation and >48 hours after admission (iii) >48 hours after hospital admission, and after discharge from the same hospitalisation, with time between discharge and the UTI episode ≤ 28 days (iv) recorded as being taken for antenatal screening (v) within 28 days after a previous urine sample (v) not satisfying quality control checks	UTI episodes: (i) within 48 hours after a hospital admission, if the individual had a separate hospitalisation that ended within the preceding 28 days (ii) within a hospitalisation and >48 hours after admission (iii) >48 hours after hospital admission, and after discharge from the same hospitalisation, with time between discharge and the UTI episode ≤ 28 days (iv) between the estimated start and end dates of periods of pregnancy (v) within 28 days after a previous episode of UTI

Table 2: Number of women with one or more UTIs who met the rUTI definition at least once, for each rUTI definition

	Timeframe within which UTI episodes must occur to satisfy each rUTI definition						
	3 months	4 months	5 months	6 months	7 months	8 months	9 months
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
IORD positive cultures 84,809 women with one or more positive urine cultures; 167,008 UTI episodes							
2 episodes	10,457 (12)	12,722 (15)	14,322 (17)	15,617 (18)	16,718 (20)	17,579 (21)	18,352 (22)
3 episodes	592 (1)	1,657 (2)	2,658 (3)	3,491 (4)	4,251 (5)	4,899 (6)	5,445 (6)
IORD all cultures 201,927 women with one or more urine cultures with any result*; 543,011 UTI episodes							
2 episodes	45,306 (22)	53,470 (27)	59,291 (29)	64,260 (32)	68,363 (34)	71,014 (35)	73,103 (36)
3 episodes	3,209 (2)	9,112 (5)	14,295 (7)	18,692 (9)	22,341 (11)	25,035 (12)	26,984 (13)
CPRD 1,703,088 women; 3,451,034 UTI episodes							
2 episodes	207,635 (12)	262,930 (15)	302,235 (18)	334,487 (20)	361,808 (21)	385,254 (23)	405,038 (24)
3 episodes	8,513 (1)	27,596 (2)	46,653 (3)	64,648 (4)	81,033 (5)	96,204 (6)	109,645 (6)

* Urine culture positive, mixed, equivocal or negative

Figure 2: Estimated risk of at least one, two and three subsequent UTIs within 6 months (top panel) or 12 months (bottom panel) after the first time meeting a rUTI definition

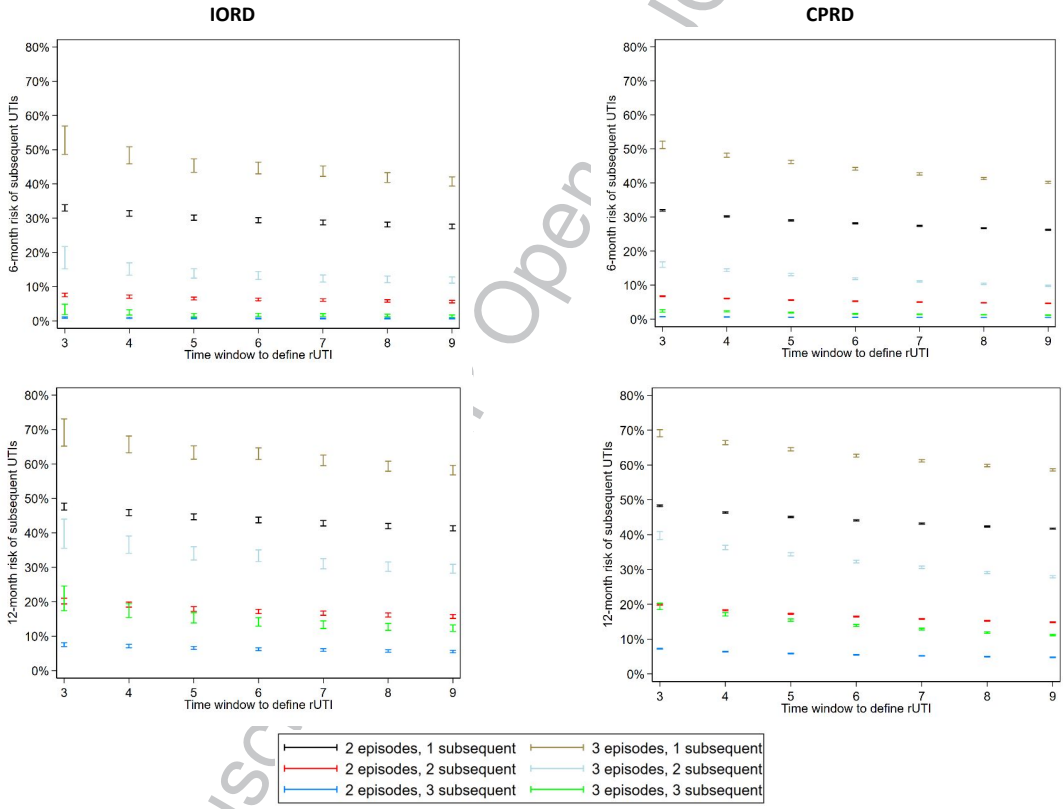
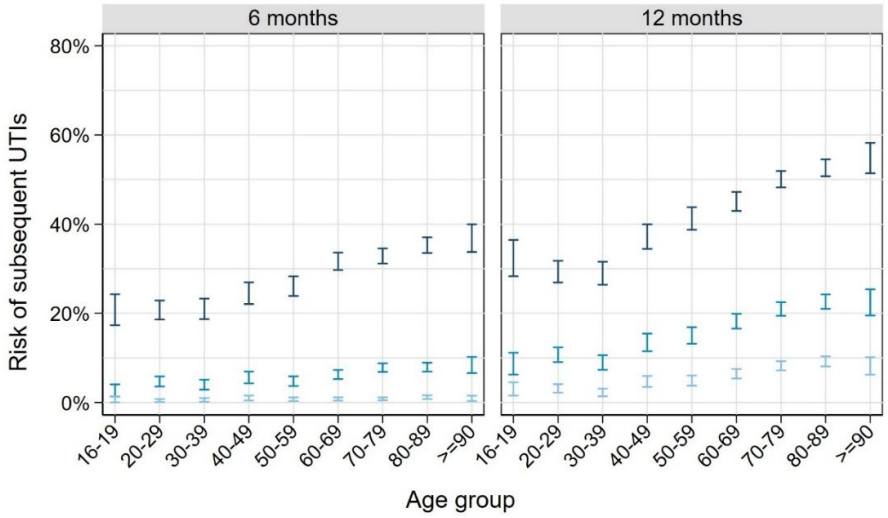
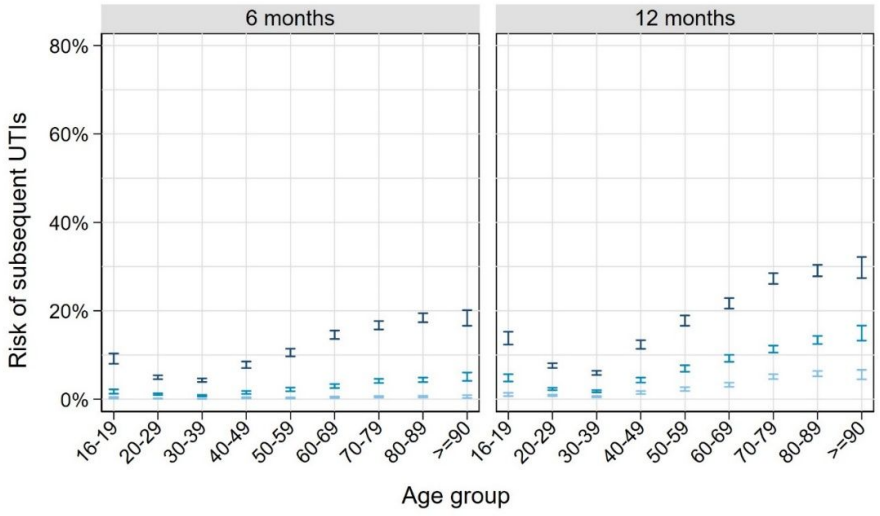


Figure 3: Risk of subsequent UTIs within 6 and 12 months after meeting the base rUTI definition, stratified by age

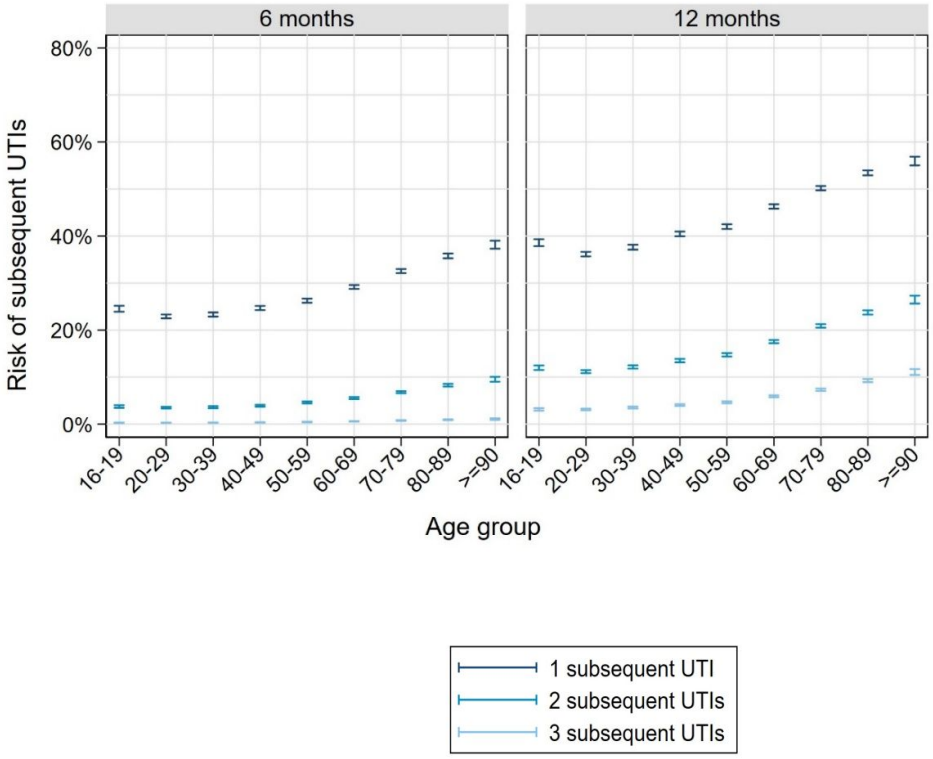
IORD Positive cultures



IORD All culture



CPRD



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