



Gout incidence and management during the COVID-19 pandemic in England, UK: a nationwide observational study using OpenSAFELY



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Summary

Lancet Rheumatol 2023; 5: e622–32
Background Gout is the most prevalent inflammatory arthritis, yet one of the worst managed. Our objective was to assess how the COVID-19 pandemic impacted incidence and quality of care for people with gout in England, UK.

Methods With the approval of National Health Service England, we did a population-level cohort study using primary care and hospital electronic health record data for 17·9 million adults registered with general practices using TPP health record software, via the OpenSAFELY platform. The study period was from March 1, 2015, to Feb 28, 2023. Individuals aged 18–110 years were defined as having incident gout if they were assigned index diagnostic codes for gout, were registered with TPP practices in England for at least 12 months before diagnosis, did not receive prescriptions for urate-lowering therapy more than 30 days before diagnosis, and had not been admitted to hospital or attended an emergency department for gout flares more than 30 days before diagnosis. Outcomes assessed were incidence and prevalence of people with recorded gout diagnoses, incidence of gout hospitalisations, initiation of urate-lowering therapy, and attainment of serum urate targets ($\leq 360 \mu\text{mol/L}$).

Findings From a reference population of 17 865 145 adults, 246 695 individuals were diagnosed with incident gout. The mean age of individuals with incident gout was 61·3 years (SD 16·2). 66 265 (26·9%) of 246 695 individuals were female, 180 430 (73·1%) were male, and 189 035 (90·9%) of 208 050 individuals with available ethnicity data were White. Incident gout diagnoses decreased by 30·9% in the year beginning March, 2020, compared with the preceding year (1·23 diagnoses vs 1·78 diagnoses per 1000 adults). Gout prevalence was 3·07% in 2015–16, and 3·21% in 2022–23. Gout hospitalisations decreased by 30·1% in the year commencing March, 2020, compared with the preceding year (9·6 admissions vs 13·7 admissions per 100 000 adults). Of 228 095 people with incident gout and available follow-up, 66 560 (29·2%) were prescribed urate-lowering therapy within 6 months. Of 65 305 individuals who initiated urate-lowering therapy with available follow-up, 16 790 (25·7%) attained a serum urate concentration of 360 $\mu\text{mol/L}$ or less within 6 months of urate-lowering therapy initiation. In interrupted time-series analyses, urate-lowering therapy prescribing improved modestly during the pandemic, compared with pre-pandemic, whereas urate target attainment was similar.

Interpretation Using gout as an exemplar disease, we showed the complexity of how health care was impacted during the COVID-19 pandemic. We observed a reduction in gout diagnoses but no effect on treatment metrics. We showed how country-wide, routinely collected data can be used to map disease epidemiology and monitor care quality.

Funding None.

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Introduction

Gout is the most prevalent inflammatory arthritis worldwide, but one of the worst managed.¹ Guidelines recommend discussing or offering preventive urate-lowering therapies (eg, allopurinol) to all individuals with gout, followed by titration of urate-lowering therapy dosing until serum urate targets are attained.^{2,3} Despite these recommendations, studies on individuals with gout from before the COVID-19 pandemic had shown persistently low uptake of urate-lowering therapy and poor attainment of urate targets.^{1,4,5}

The COVID-19 pandemic has had an enormous impact on service delivery throughout health-care systems worldwide, with abrupt changes to health-care use, redeployment of staff, and a rapid transition to virtual consultations.^{6–8} The extent to which these changes have affected care for people with long-term conditions, such as gout, is not fully understood. Data up to 2021 from the UK showed a 23% reduction in incident gout diagnoses between 2019 and 2021,⁹ and reductions in serum urate target attainment for individuals who initiated urate-lowering therapy in 2019

Published Online
 August 31, 2023
[https://doi.org/10.1016/S2665-9913\(23\)00206-0](https://doi.org/10.1016/S2665-9913(23)00206-0)

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Research in context

Evidence before this study

We did a systematic literature search to identify population-level, observational cohort studies that compared the incidence, prevalence, and management of gout before and during the COVID-19 pandemic. We searched PubMed for articles published in English from database inception to June 6, 2023, using the terms “incidence”, “prevalence”, “management”, “treatment”, “gout”, and “COVID”. We did not find any studies with data beyond 2021. A study done in the UK, with data up to 2021, reported a 23% reduction in incident gout diagnoses between 2019 and 2021; reductions in serum urate target attainment were observed for individuals initiating urate-lowering therapy in 2019 and 2020. A study in South Korea reported no significant changes in gout incidence between 2016 and 2020.

Added value of this study

We used the OpenSAFELY platform to analyse changes in gout incidence, prevalence, management, and hospitalisations between March 1, 2015, and Feb 28, 2023, among 17.9 million adults in England, UK. On a background of decreasing gout incidence and stable prevalence, we showed that newly recorded gout diagnoses decreased by 30.9% (from 1.78 diagnoses per 1000 adults before the pandemic to 1.23 diagnoses per 1000 adults in the first year of the pandemic). The incidence of gout increased in the years beginning March, 2021 (1.40 diagnoses per 1000 adults), and

March, 2022 (1.44 diagnoses per 1000 adults), but remained lower than pre-pandemic incidence. People presenting with gout during the pandemic did not have more severe disease than those presenting before the pandemic, but had proportionately fewer comorbidities. The initiation of urate-lowering therapy improved modestly for people presenting with incident gout during the pandemic, compared with those presenting before the pandemic, whereas urate target attainment was similar. However, absolute levels of urate-lowering therapy initiation and urate target attainment remained suboptimal as of February, 2023.

Implications of all the available evidence

The incidence of recorded gout diagnoses decreased markedly during the pandemic. No rebound increase in incidence has been observed as of February, 2023, which suggests that many individuals with gout are yet to be diagnosed as a result of the pandemic. For individuals who were diagnosed with gout during the pandemic, improvements in urate-lowering therapy initiation were observed compared with pre-pandemic trends. However, urate-lowering therapy initiation and urate target attainment still remain below an acceptable standard. Our study shows the potential for routinely captured health data to transform how we monitor disease epidemiology and care quality.

and 2020.¹⁰ By contrast, a study done in South Korea reported no significant changes in gout incidence between 2016 and 2020.¹¹ However, data after 2021 remain scarce.

The OpenSAFELY data analytics platform provides a unique opportunity to address questions about disease incidence, prevalence, and care delivery for chronic health conditions. Through OpenSAFELY, pseudonymised electronic health records for up to 99% of the population in England, UK, can be analysed in a highly secure environment in near real time. In a 2022 proof-of-concept study,¹² a 20% reduction in autoimmune inflammatory arthritis diagnoses was observed during the first year of the COVID-19 pandemic in England; however, for people who sought medical attention, the impact of the pandemic on the delivery of care for diagnoses such as rheumatoid arthritis was less marked than might have been expected.

Our objective was to assess how the COVID-19 pandemic has impacted the diagnostic incidence and quality of care for people with gout in England.

Methods

Study design

We did a population-level, observational, cohort study in England, using electronic health record data analysed via

the OpenSAFELY platform. We piloted our approach in OpenSAFELY-TPP, which contains data for 23 million people (approximately 40% of the population of England), including 17.9 million adults aged 18 years or older. OpenSAFELY-TPP is representative of England's population in terms of age, sex, Index of Multiple Deprivation, ethnicity, and causes of death.¹³ Primary care records managed by the general practitioner (GP) software provider, TPP, were linked to the National Health Service (NHS) Secondary Uses Service data through OpenSAFELY. The study period was from March 1, 2015, to Feb 28, 2023. Approval to undertake this study under the remit of service evaluation was obtained from King's College Hospital NHS Foundation Trust, London, UK. No further ethical approval was required as per UK Health Research Authority guidance. An information governance statement is included in the appendix (p 6).

Case definitions and outcomes

People aged 18–110 years were defined as having incident gout if they were registered with TPP practices in England for at least 12 months, and were assigned index diagnostic codes for incident gout (appendix p 5). At least 12 months of continuous registration before diagnosis was required for incident diagnoses, to ensure only index diagnoses were captured. People with incident gout

For OpenSAFELY see <https://www.opensafely.org/>

See Online for appendix

codes who had received prescriptions for urate-lowering therapy more than 30 days before their index diagnostic code were not deemed to have incident gout. People with incident gout codes who had been admitted to hospital or attended an emergency department for gout flares more than 30 days before their index diagnostic code were also not deemed to have incident gout.

Study outcomes were incidence and prevalence of people with recorded gout diagnoses, incidence of gout hospitalisations, initiation of urate-lowering therapy, and attainment of serum urate targets. The incidence of gout was defined as the number of people with index gout diagnoses within the study population during each study year (from March 1 to Feb 28). The study population was defined as people registered with TPP practices for at least 12 months at the midpoint of each study year (Sept 1), with an assumption that individuals were registered for the full study year. We calculated the point prevalence of gout by dividing the number of people with prevalent diagnostic codes for gout (appendix p 5) at a fixed timepoint, which was chosen as the midpoint of each study year (Sept 1), by the number of people registered with TPP practices at that timepoint.

Linked data on hospitalisations were available from April 1, 2016, to March 31, 2022. The incidence of gout hospitalisations was defined as the number of hospitalisations with primary admission diagnoses of gout (International Classification of Diseases 10th revision code M10) within the study population during each year (from April 1 to March 31). The study population for this outcome was defined as the number of people registered with TPP practices on Sept 1 of each study year.

With regard to initiation of urate-lowering therapy, the National Institute for Health and Care Excellence (NICE) guidelines recommend discussing the option of urate-lowering therapy with all people diagnosed with gout, followed by titration of urate-lowering therapy dosing until serum urate concentration is less than, or equal to, 360 $\mu\text{mol/L}$ ($\leq 6 \text{ mg/dL}$).³ For people with incident gout who had at least 6 months of available follow-up after diagnosis, we reported the proportion of individuals who received a prescription for urate-lowering therapy (allopurinol or febuxostat) within 6 months of diagnosis. Primary care prescriptions were captured, but prescriptions dispensed by hospital pharmacies were not. For people with incident gout who were prescribed urate-lowering therapy within 6 months of diagnosis and who had at least 6 months of available follow-up after initiating urate-lowering therapy, we reported the proportion of individuals who attained serum urate concentration of 360 $\mu\text{mol/L}$ or less within 6 months of initiating urate-lowering therapy.

Statistical analysis

Baseline sociodemographic characteristics and comorbidities were described without inferential statistics for people with incident gout and for the reference

population, which comprised all adults with and without gout aged 18–110 years registered with TPP practices in England as of March 1, 2019 (ie, the midpoint of the study). Sociodemographic characteristics, comorbidities, and surrogate markers of disease severity (serum urate concentration at diagnosis, early flare burden, and the proportion of individuals with tophaceous gout) were also described for people with incident gout during each year of the study period, to investigate changes in these characteristics before and after the onset of the pandemic. Details of comorbidity definitions and codelists are given in the appendix (p 5). Incidence and prevalence of people with recorded gout diagnoses were not standardised by age or sex because of the short study period.

Interrupted time-series analyses were done to estimate the impact of the pandemic on the proportion of people with incident gout, averaged by month, who were prescribed (1) urate-lowering therapy within 6 months of diagnosis or (2) urate-lowering therapy within 6 months of diagnosis and attained serum urate concentration of 360 $\mu\text{mol/L}$ or less within 6 months of urate-lowering therapy initiation. Trends were compared before and after the first COVID-19 lockdown in England (March, 2020) using single-group interrupted time-series analyses.¹⁴ We accounted for autocorrelation between observation periods by using Newey-West standard errors with five lags.¹⁴ Outcomes were also assessed by regions of England (nine regions according to the first level of the Nomenclature of Territorial Units for Statistics¹⁵). Because our analyses were primarily descriptive, we did not correct for multiple hypothesis testing. For statistical disclosure control, frequency counts were rounded to the nearest 5 and non-zero counts lower than 8 were redacted. We used Python (version 3.8) for data management and Stata 16 for statistical analyses.

Patient and public involvement

This analysis relies on the use of large volumes of patient data. Ensuring patient, professional, and public trust is therefore of crucial importance. Maintaining trust requires being transparent about the way OpenSAFELY works, and ensuring patient voices are represented in the design of research, analysis of the findings, and considering the implications. For transparency purposes, the OpenSAFELY public website provides a detailed description of the platform in language suitable for a lay audience; OpenSAFELY has participated in three citizens' juries exploring public trust in OpenSAFELY;¹⁶ is currently co-developing an explainer video; has expert-by-experience patient representation on the OpenSAFELY Oversight Board; has partnered with Understanding Patient Data to produce lay explainers on the importance of large datasets for research; has presented at several online public engagement events to key communities; and more. To ensure the patient voice is represented, OpenSAFELY is working closely with appropriate medical research charities.

		People with incident gout									
Reference population (n=17 865 145)		All years (n=246 695)	2015-16 (n=35 400)	2016-17 (n=34 675)	2017-18 (n=34 295)	2018-19 (n=34 415)	2019-20 (n=32 245)	2020-21 (n=22 775)	2021-22 (n=25 775)	2022-23 (n=27 140)	
		61.3 (16.2)	61.9 (16.0)	61.8 (15.9)	61.6 (16.0)	61.5 (16.1)	61.5 (16.2)	60.6 (16.3)	60.2 (16.4)	60.3 (16.4)	
Age, years	497 (18.7)	26 900 (10.9%)	3385 (9.6%)	3410 (9.8%)	3585 (10.5%)	3715 (10.8%)	3520 (10.9%)	2720 (11.9%)	3210 (12.5%)	3360 (12.4%)	
Age group											
18-39 years	6 100 895 (34.1%)	26 900 (10.9%)	3385 (9.6%)	3410 (9.8%)	3585 (10.5%)	3715 (10.8%)	3520 (10.9%)	2720 (11.9%)	3210 (12.5%)	3360 (12.4%)	
40-49 years	2 969 050 (16.6%)	34785 (14.1%)	5055 (14.3%)	4770 (13.8%)	4685 (13.7%)	4700 (13.7%)	4410 (13.7%)	3320 (14.6%)	3835 (14.9%)	4005 (14.8%)	
50-59 years	3 155 635 (17.7%)	49 090 (19.9%)	6710 (19.0%)	6765 (19.5%)	6690 (19.5%)	6825 (19.8%)	6465 (20.0%)	4710 (20.7%)	5310 (20.6%)	5625 (20.7%)	
60-69 years	2 485 900 (13.9%)	50 970 (20.7%)	7800 (22.0%)	7625 (22.0%)	7275 (21.2%)	6935 (20.2%)	6450 (20.0%)	4515 (19.8%)	5045 (19.6%)	5330 (19.6%)	
70-79 years	1 989 240 (11.1%)	50 325 (20.4%)	7375 (20.8%)	7115 (20.5%)	7195 (21.0%)	7280 (21.2%)	6695 (20.8%)	4385 (19.3%)	5030 (19.5%)	5255 (19.4%)	
≥80 years	1 164 425 (6.5%)	34 625 (14.0%)	5075 (14.3%)	4990 (14.4%)	4865 (14.2%)	4960 (14.4%)	4705 (14.6%)	3125 (13.7%)	3345 (13.0%)	3565 (13.1%)	
Sex											
Female	8 962 935 (50.2%)	66 265 (26.9%)	9665 (27.3%)	9530 (27.5%)	9290 (27.1%)	9180 (26.7%)	8750 (27.1%)	5910 (25.9%)	6820 (26.5%)	7120 (26.2%)	
Male	8 902 210 (49.8%)	180 430 (73.1%)	25 730 (72.7%)	25 145 (72.5%)	25 000 (72.9%)	25 230 (73.3%)	23 495 (72.9%)	16 860 (74.0%)	18 950 (73.5%)	20 020 (73.8%)	
Ethnicity											
White	12 704 335 (87.0%)	189 035 (90.9%)	26 970 (92.1%)	26 535 (91.6%)	26 235 (91.3%)	26 365 (91.0%)	24 810 (90.7%)	17 625 (90.8%)	19 750 (90.7%)	20 740 (90.0%)	
Asian or Asian British	1 042 195 (7.1%)	11 470 (5.5%)	1450 (4.9%)	1505 (5.2%)	1520 (5.3%)	1615 (5.6%)	1520 (5.6%)	1020 (5.3%)	1325 (6.0%)	1520 (6.5%)	
Black	349 105 (2.4%)	3455 (1.7%)	425 (1.5%)	435 (1.5%)	480 (1.7%)	455 (1.6%)	475 (1.7%)	345 (1.8%)	400 (1.8%)	440 (1.9%)	
Mixed or other	506 960 (3.5%)	4090 (2.0%)	450 (1.5%)	500 (1.7%)	510 (1.8%)	540 (1.9%)	540 (2.0%)	425 (2.2%)	530 (2.4%)	595 (2.6%)	
Missing	3 262 550	38645	6105	5700	5550	5440	4900	3355	3760	3840	
Index of multiple deprivation											
1 (most deprived)	3370 640 (19.1%)	41 135 (17.0%)	6035 (17.4%)	5725 (16.8%)	5750 (17.1%)	5705 (16.9%)	5415 (17.1%)	3785 (17.0%)	4235 (16.8%)	4485 (17.0%)	
2	3 466 375 (19.7%)	44 650 (18.5%)	6365 (18.4%)	6270 (18.4%)	6310 (18.7%)	6330 (18.7%)	5840 (18.4%)	4120 (18.5%)	4645 (18.5%)	4775 (18.1%)	
3	3 804 745 (21.6%)	53 505 (22.1%)	7560 (21.8%)	7645 (22.5%)	7315 (21.7%)	7490 (22.1%)	7125 (22.5%)	4885 (21.9%)	5550 (22.1%)	5945 (22.5%)	
4	3 610 825 (20.5%)	52 265 (21.6%)	7575 (21.8%)	7360 (21.7%)	7320 (21.7%)	7320 (21.6%)	6800 (21.5%)	4790 (21.5%)	5475 (21.8%)	5630 (21.3%)	
5 (least deprived)	3 355 730 (19.1%)	50 030 (20.7%)	7140 (20.6%)	6995 (20.6%)	6985 (20.7%)	6975 (20.6%)	6475 (20.5%)	4680 (21.0%)	5235 (20.8%)	5545 (21.0%)	
Missing	256 830	5110	725	685	610	595	590	505	635	765	
BMI											
Underweight (<18.5 kg/m ²)	321 610 (2.3%)	1195 (0.6%)	145 (0.5%)	155 (0.5%)	170 (0.6%)	165 (0.5%)	175 (0.6%)	120 (0.6%)	130 (0.6%)	140 (0.6%)	
Normal (18.5-24.9 kg/m ²)	4 895 895 (35.2%)	34 250 (15.9%)	4955 (16.0%)	4865 (16.0%)	4730 (15.8%)	4760 (15.8%)	4665 (16.5%)	3050 (15.4%)	3480 (15.6%)	3745 (16.0%)	
Overweight (25-29.9 kg/m ²)	4 817 025 (34.6%)	82 360 (38.2%)	12 260 (39.5%)	11 885 (39.0%)	11 505 (38.3%)	11 695 (38.7%)	10 645 (37.6%)	7325 (37.0%)	8385 (37.6%)	8660 (37.0%)	
Obesity class 1 (30-34.9 kg/m ²)	2 428 140 (17.4%)	59 255 (27.5%)	8530 (27.5%)	8365 (27.5%)	8325 (27.7%)	8215 (27.2%)	7735 (27.3%)	5525 (27.9%)	6070 (27.2%)	6495 (27.7%)	
Obesity class 2 (35-39.9 kg/m ²)	927 655 (6.7%)	24 345 (11.3%)	3295 (10.6%)	3340 (11.0%)	3395 (11.3%)	3420 (11.3%)	3215 (11.3%)	2355 (11.9%)	2625 (11.8%)	2695 (11.5%)	
Obesity class 3 (≥40 kg/m ²)	527 595 (3.8%)	14 120 (6.6%)	1835 (5.9%)	1850 (6.1%)	1875 (6.2%)	1965 (6.5%)	1910 (6.7%)	1395 (7.1%)	1615 (7.2%)	1685 (7.2%)	
Missing	3 947 225	31 170	4380	4220	4290	4195	3900	2995	3470	3720	
Smoking status											
Never	8 225 665 (47.9%)	95 495 (39.0%)	13 560 (38.5%)	13 520 (39.2%)	13 185 (38.7%)	13 315 (39.0%)	12 440 (38.9%)	8780 (38.9%)	9965 (39.0%)	10 735 (40.0%)	
Former	5 880 190 (34.2%)	121 020 (49.4%)	17 490 (49.7%)	17 010 (49.3%)	16 920 (49.7%)	16 975 (49.7%)	15 845 (49.5%)	11 100 (49.2%)	12 535 (49.1%)	13 150 (49.0%)	
Current	3 075 465 (17.9%)	28 285 (11.6%)	4155 (11.8%)	3955 (11.5%)	3945 (11.6%)	3875 (11.3%)	3730 (11.7%)	2660 (11.8%)	3020 (11.8%)	2945 (11.0%)	
Missing	683 825	1895	195	190	240	250	230	255	255	310	
Hypertension	3 817 990 (21.4%)	115 960 (47.0%)	17 640 (49.8%)	16 950 (48.9%)	16 460 (48.0%)	16 315 (47.4%)	15 130 (46.9%)	10 220 (44.9%)	11 360 (44.1%)	11 885 (43.8%)	

(Table continues on next page)

	Reference population (n=47 865 145)	People with incident gout									
		All years (n=246 695)	2015-16 (n=35 400)	2016-17 (n=34 675)	2017-18 (n=34 295)	2018-19 (n=34 415)	2019-20 (n=32 245)	2020-21 (n=22 775)	2021-22 (n=25 775)	2022-23 (n=27 140)	
(Continued from previous page)											
Diabetes											
No diabetes	16 153 210 (90.4%)	201 085 (81.5%)	29 615 (83.7%)	28 825 (83.1%)	28 255 (82.4%)	28 015 (81.4%)	25 860 (80.2%)	18 360 (80.6%)	20 565 (79.8%)	21 590 (79.6%)	
Diabetes with HbA _{1c} <5.8 mmol/mol (<7.5%)	1 084 050 (6.1%)	32 850 (13.3%)	3930 (11.1%)	4090 (11.8%)	4335 (12.6%)	4640 (13.5%)	4685 (14.5%)	3180 (14.0%)	3800 (14.7%)	4185 (15.4%)	
Diabetes with HbA _{1c} ≥5.8 mmol/mol (≥7.5%)	481 580 (2.7%)	10 530 (4.3%)	1525 (4.3%)	1410 (4.1%)	1405 (4.1%)	1470 (4.3%)	1440 (4.5%)	1025 (4.5%)	1115 (4.3%)	1135 (4.2%)	
Diabetes with no HbA _{1c} measure	146 305 (0.8%)	2230 (0.9%)	325 (0.9%)	345 (1.0%)	295 (0.9%)	285 (0.8%)	265 (0.8%)	205 (0.9%)	285 (1.1%)	230 (0.8%)	
Chronic cardiac disease	1 207 230 (6.8%)	49 190 (19.9%)	7300 (20.6%)	7060 (20.4%)	6850 (20.0%)	6945 (20.2%)	6530 (20.3%)	4460 (19.6%)	4970 (19.3%)	5080 (18.7%)	
Stroke	375 200 (2.1%)	11 360 (4.6%)	1690 (4.8%)	1635 (4.7%)	1575 (4.6%)	1555 (4.5%)	1600 (5.0%)	1005 (4.4%)	1120 (4.3%)	1180 (4.3%)	
Cancer	961 885 (5.4%)	22 155 (9.0%)	3035 (8.6%)	3070 (8.9%)	3085 (9.0%)	3125 (9.1%)	3005 (9.3%)	2070 (9.1%)	2320 (9.0%)	2445 (9.0%)	
Chronic respiratory disease	721 065 (4.0%)	21 255 (8.6%)	3135 (8.9%)	2940 (8.5%)	2970 (8.7%)	3055 (8.9%)	2825 (8.8%)	1975 (8.7%)	2190 (8.5%)	2170 (8.0%)	
Chronic liver disease	98 645 (0.6%)	2490 (1.0%)	325 (0.9%)	285 (0.8%)	290 (0.8%)	315 (0.9%)	350 (1.1%)	300 (1.3%)	315 (1.2%)	310 (1.1%)	
Chronic kidney disease	1 152 460 (6.5%)	59 195 (24.0%)	9140 (25.8%)	8840 (25.5%)	8375 (24.4%)	8320 (24.2%)	7600 (23.6%)	5170 (22.7%)	5700 (22.1%)	6050 (22.3%)	
Diuretic at diagnosis	1 056 465 (5.9%)	64 325 (26.1%)	10 630 (30.0%)	9855 (28.4%)	9395 (27.4%)	8935 (26.0%)	8140 (25.2%)	5365 (23.6%)	6025 (23.4%)	5970 (22.0%)	
Tophaceous gout	NA	2535 (1.0%)	340 (1.0%)	400 (1.2%)	355 (1.0%)	355 (1.0%)	305 (0.9%)	180 (0.8%)	280 (1.1%)	325 (1.2%)	
At least one additional flare within 6 months of diagnosis	NA	24 755 (10.0%)	3630 (10.3%)	3615 (10.4%)	3570 (10.4%)	3565 (10.4%)	3220 (10.0%)	2275 (10.0%)	2505 (9.7%)	..	
Serum urate at diagnosis, μmol/L	NA	466 (100)	470 (101)	468 (100)	466 (101)	462 (100)	461 (101)	467 (101)	470 (102)	463 (98)	

Data are mean (SD) or n (%). Baseline demographics and comorbidities of people with incident gout diagnoses between March 1, 2015, and Feb 28, 2023. Counts have been rounded to the nearest 5; to reduce the risk of disclosure; as such, column totals might differ from the sum of the individual variables. Data on additional gout flares were not available for the 2022-23 cohort, as insufficient follow-up time had elapsed. Serum urate concentrations are shown for patients who had concentrations of serum urate measured at baseline (157 590 [63.9%] of 246 695 individuals). NA=not applicable.

Table: Baseline demographics and comorbidities of the reference population and people with incident gout diagnoses

Role of the funding source

There was no funding source for this study.

Results

From a reference population of 17865145 adults, 246695 cases of incident gout were recorded between March 1, 2015, and Feb 28, 2023 (appendix p 2). 66265 (26.9%) of 246695 individuals with incident gout were female, 180430 (73.1%) were male, and 189035 (90.9%) of 208050 individuals with available ethnicity data were White. Compared with the reference population, people with incident gout were older (mean age 61.3 years [SD 16.2] vs 49.7 years [18.7]), were more likely to be male (180430 [73.1%] vs 8902210 [49.8%]), and had more comorbidities, including obesity (97720 [45.3%] vs 3883390 [27.9%]), hypertension (115960 [47.0%] vs 3817990 [21.4%]), diabetes (45610 [18.5%] vs 1711935 [9.6%]), chronic cardiac disease (49190 [19.9%] vs 1207230 [6.8%]), chronic kidney disease (59195 [24.0%] vs 1152460 [6.5%]), and diuretic use (64325 [26.1%] vs 1056465 [5.9%]; table). During the study period, we observed minimal differences in age or sex distribution (table). In individuals presenting with incident gout diagnoses before and after pandemic onset, age, sex, ethnicity, and sociodemographic characteristics were similar (table). Proportionately fewer individuals presenting with gout during the pandemic had comorbid hypertension, chronic kidney disease, or diuretic use compared with individuals presenting with gout before the pandemic. The proportion of individuals with tophaceous gout at diagnosis was similar before and after the onset of the pandemic, as was early flare burden. Serum urate concentrations at diagnosis were also similar in individuals presenting before and during the pandemic (table).

The incidence of newly recorded gout diagnoses decreased from 2.12 per 1000 adults in 2015–16, to 1.78 per 1000 adults in 2019–20 (figure 1; appendix p 3). A marked decrease in recorded gout diagnoses was observed in the year beginning March, 2020, compared with the year preceding the pandemic, corresponding to a 30.9% decrease in incidence (from 1.78 diagnoses to 1.23 diagnoses per 1000 adults). This decrease was driven primarily by a 39.0% decrease in recorded diagnoses between February, 2020, and April, 2020 (from 2475 monthly diagnoses to 1510 monthly diagnoses, respectively). The incidence of recorded gout diagnoses increased in the years commencing April, 2021, and March, 2022, (1.40 diagnoses and 1.44 diagnoses per 1000 adults, respectively), but remained lower than pre-pandemic incidence.

Gout prevalence remained stable during the study period, at 3.07% of adults in 2015–16, 3.25% in 2019–20, and 3.21% in 2022–23 (figure 1). Hospitalisations with primary admission diagnoses of gout increased from 12.2 per 100000 adults in 2016–17, to 13.7 per 100000 adults in 2019–20, before decreasing by 30.1% during the first year of the pandemic to 9.6 admissions per

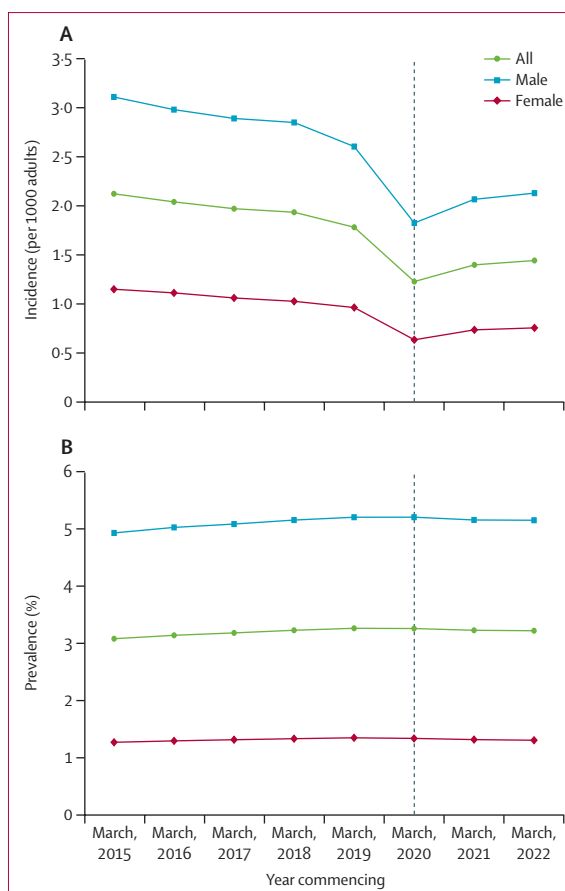


Figure 1: Incidence and prevalence of gout diagnoses recorded in primary care in England (A) Incidence. (B) Prevalence. The vertical dashed line corresponds to the onset of the first COVID-19 lockdown in England (March, 2020).

100000 adults (appendix p 4). Admissions increased in the year commencing March, 2021 (10.7 admissions per 100000 adults), but remained lower than those reported before the pandemic.

Of 246695 individuals with new gout diagnoses during the study period, 228095 (92.5%) had at least 6 months of available follow-up, 66560 (29.2%) of whom were prescribed urate-lowering therapy within 6 months of diagnosis (65680 [31.8%] of 206890 individuals within 12 months of diagnosis). In interrupted time-series analyses, modest improvements in initiation of urate-lowering therapy were observed during the study period (figure 2A). Small, statistically significant improvements in urate-lowering therapy prescribing were seen after March, 2020, compared with pre-pandemic trends: 1.19% improvement per year (95% CI 0.69–1.70) before March, 2020, and 2.96% improvement per year (1.58–4.35) after March, 2020 (difference 1.77% [0.23–3.30]; $p=0.025$). Improvements in urate-lowering therapy initiation during the pandemic were observed in most regions of England, albeit to varying degrees (figure 2B).

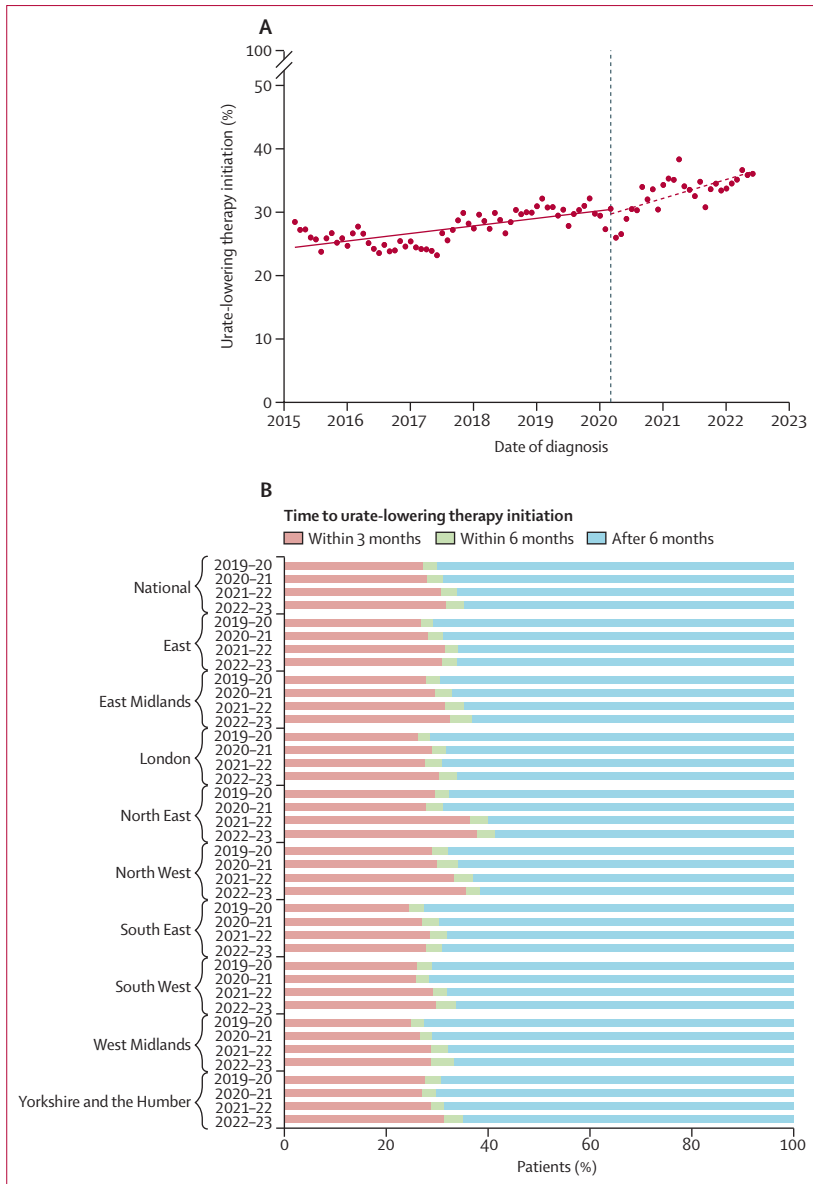


Figure 2: Individuals with incident gout who initiated urate-lowering therapy
 (A) Interrupted time series analysis showing the mean monthly proportion of individuals who initiated urate-lowering therapy within 6 months of diagnosis in England. The vertical dashed line corresponds to the onset of the first COVID-19 lockdown in England (March, 2020). (B) Proportion of individuals who were prescribed urate-lowering therapy within 3 months, 6 months, or after 6 months of diagnosis, stratified by region and by year (March, 2019–20; March, 2020–21; March, 2021–22; and March, 2022–23).

Of 66 560 individuals with incident gout who initiated urate-lowering therapy within 6 months of diagnosis, 65 305 (98.1%) had at least 6 months of available follow-up after urate-lowering therapy initiation. Of 65 305 individuals, 36 245 (55.5%) had at least one measure of serum urate concentration collected within 6 months of initiating urate-lowering therapy, and 12 990 (19.9%) had two or more measures of serum urate concentration. 16 790 (25.7%) of 65 305 individuals attained a serum urate concentration of 360 μmol/L or

less within 6 months of urate-lowering therapy initiation (18 170 [31.1%] of 58 455 individuals within 12 months of urate-lowering therapy initiation). Urate target attainment remained stable during the study period, aside from a temporary decrease in attainment for people initiating urate-lowering therapy in late 2019, and early 2020 (nadir of 18.2% in March, 2020), before returning to pre-pandemic levels by June, 2020 (figure 3). Overall, differences in urate target attainment were not significant before and after the onset of the pandemic: 0.50% improvement per year (95% CI -0.31 to 1.31) before March, 2020, and 0.75% improvement per year (-1.18 to 2.69) after March, 2020 (difference 0.25% [-2.21 to 2.71]; p=0.84). Urate target attainment varied considerably throughout England during the pandemic, with the lowest attainment seen in London (185 [16.0%] of 1155 individuals) and the highest attainment in North East England (555 [30.8%] of 1800 individuals; figure 3).

Discussion

In this study, we used the OpenSAFELY platform to show a marked reduction in recorded gout diagnoses during the COVID-19 pandemic in England. No increase in gout diagnoses above pre-pandemic levels has been observed as of 3 years after the pandemic onset, suggesting a substantial burden of undiagnosed disease. For people presenting with new gout diagnoses during the pandemic, small improvements in the initiation of urate-lowering therapy were seen compared with pre-pandemic levels, whereas serum urate target attainment was similar. Irrespective of the pandemic, urate-lowering therapy initiation and urate target attainment remain far below an acceptable standard.

This study shows the potential to transform monitoring of chronic diseases using routinely collected health data. Unlike existing national audits (eg, the National Early Inflammatory Arthritis audit in England and Wales¹⁷), the use of routinely collected health data in Trusted Research Environments obviates the need for manual data entry by clinicians, increases case ascertainment, and reduces the potential for bias.^{12,18} Trends in the incidence and prevalence of gout, and the proportion of individuals who initiated urate-lowering therapy or attained urate targets in our study were similar to the findings of studies using other data sources (eg, the Clinical Practice Research Datalink), supporting the validity of our approach.^{5,9} In contrast to these other data sources, however, analyses using OpenSAFELY can be updated in near real time and do not require any sharing of potentially identifiable patient data, minimising the risk of sensitive data disclosure.

The 39% decrease in incident gout diagnoses observed in the early months of the pandemic is similar to what has been described for autoimmune inflammatory arthritis diagnoses, such as rheumatoid arthritis.¹² This finding highlights the wide-ranging impact of the

pandemic on both primary care-led and secondary care-led rheumatological conditions, with service provision disrupted across many parts of the country due to redeployment of staff, among other factors. National data show that 10% fewer primary care appointments occurred in England between April, 2020, and April, 2021, compared with the preceding year,¹⁹ which is likely to have contributed to some but not all of the observed reduction in recorded gout diagnoses during the pandemic. Similarly, our finding of a 30% reduction in gout hospitalisations during the first year of the pandemic needs to be considered in the wider context of a 16% reduction in all-cause emergency admissions in England between April, 2020, and April, 2021, compared with the preceding year.²⁰ In addition to the marked reduction in recorded gout diagnoses observed during the pandemic, we also observed a background decrease in gout incidence during the full study period. This result supports the findings of an observational study using the Clinical Practice Research Datalink, which reported a decreasing incidence of gout that predated the COVID-19 pandemic, with a potential link to changes in alcohol intake and dietary modification over time.⁹

As was reported for autoimmune inflammatory arthritis diagnoses, the absence of a rebound increase in recorded gout diagnoses above pre-pandemic levels suggests that many people remain undiagnosed as a consequence of the pandemic.¹² It remains unclear whether people have yet to seek medical attention (eg, due to altered health-seeking behaviour) or have yet to be diagnosed due to ongoing system-wide pressures. Gout is characterised by episodic flares early in the disease course, with intercritical periods that can last several months or years. As such, individuals who did not seek medical attention for index gout flares during the pandemic might not yet have had further flares or represented to primary care; this possibility might have contributed to the absence of a rebound increase in gout diagnoses during the study period.

Our findings highlight the remarkable adaptation of the health service to the pandemic, for example in being able to deliver modest improvements in urate-lowering therapy initiation despite unprecedented pressures. This adaptation reflects what has been reported for other inflammatory arthritis diagnoses, including rheumatoid arthritis, for which the times to first rheumatology assessment and initiation of disease-modifying antirheumatic drugs were similar or improved compared with those before the pandemic.¹² The rapid transition to virtual consultations during the pandemic might have favoured conditions such as gout, for which remote titration of urate-lowering therapies is possible. Despite modest improvements, the proportion of individuals initiating urate-lowering therapy (34%) or attaining urate targets (29%) remained suboptimal at the end of the study period. Additionally, only 20% of individuals had

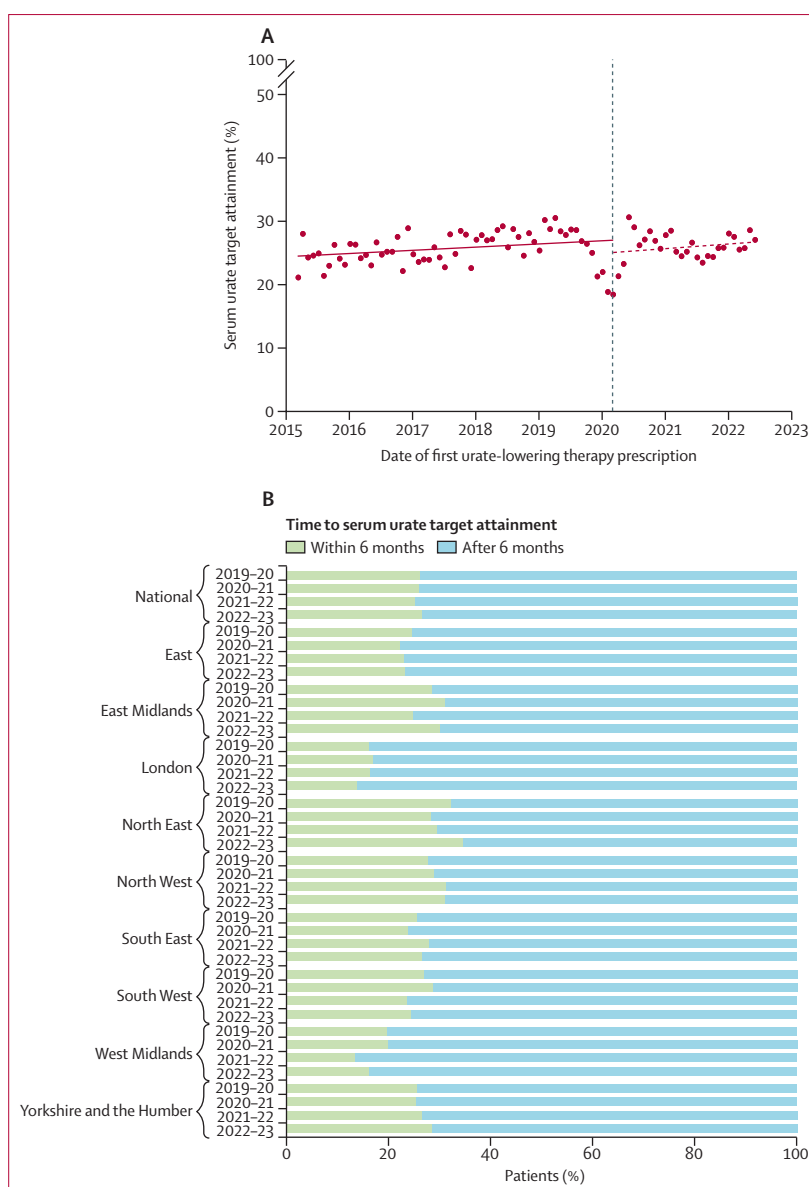


Figure 3: Individuals with incident gout who attained a serum urate concentration of 360 $\mu\text{mol/L}$ or less within 6 months of initiating urate-lowering therapy

(A) Interrupted time series analysis showing the mean monthly proportion of individuals who attained the serum urate target within 6 months of initiating urate-lowering therapy. The vertical dashed line corresponds to the onset of the first COVID-19 lockdown in England (March, 2020). (B) Proportion of individuals with incident gout who attained the serum urate target within 6 months of initiating urate-lowering therapy, stratified by region and by year (March, 2019–20; March, 2020–21; March, 2021–22; and March, 2022–23).

more than one measure of serum urate concentration collected within 6 months of initiating urate-lowering therapy. These findings indicate a pressing need for strategies to encourage uptake of treat-to-target urate-lowering therapy.

In addition to benchmarking national standards of care, our data highlight marked regional variation in gout care. Urate target attainment in some regions of England (eg, North East England) was close to double

that of other regions (eg, London). Regional disparities in care were evident before the pandemic and, in some cases, have become more pronounced since the pandemic. Further research incorporating qualitative methodology is needed to better understand the reasons behind such disparities. This improved understanding could help tailor the implementation of strategies towards addressing regional facilitators and barriers to better care, which, in turn, could be monitored over time using electronic dashboards based upon near real-time updates of these data.

In contrast to other inflammatory arthritis diagnoses, for which some markers of disease severity (eg, Disease Activity Score in 28 joints) captured by specialist clinics are not currently available for analysis in OpenSAFELY, we were able to explore differences in individuals presenting with gout during and before the pandemic. It might be hypothesised that individuals presenting during the pandemic were more likely to be those with more severe disease, particularly in the context of increased weight gain and alcohol consumption during the pandemic.^{21,22} Our findings did not support this hypothesis. The proportion of individuals who had tophaceous gout at baseline (a marker of disease severity) was similar during and before the pandemic, as was the proportion of individuals who experienced recurrent flares after diagnosis (a marker of disease burden). Serum urate concentrations at baseline were also similar. Notably, proportionately fewer individuals presenting with gout during the pandemic had comorbidities such as chronic kidney disease. This finding could represent altered health-seeking behaviour in such individuals, for example in response to government recommendations for high-risk individuals to stay at home during the pandemic.²³

Our study had limitations. Although our estimates of gout incidence and prevalence are in line with other studies using electronic health record data,^{4,9} diagnostic misclassification inherent to studies using coded health data might occur, which can lead to overestimates of incidence and prevalence. In electronic health record studies, researchers should acknowledge the challenges in determining whether observed differences in diagnostic incidence over time represent true changes in underlying disease incidence or changes in the recording of diagnoses. Although the marked decrease in gout diagnoses observed during the pandemic is likely to primarily reflect delays in presentation and the recording of diagnoses, further research is needed to establish whether long-term trends reflect true decreases in disease incidence. Because our analyses centred on gout diagnoses coded in primary care in England, they might not be representative of secondary care gout management during the pandemic or generalisable to other countries. Additionally, we could only capture primary care-issued prescriptions for urate-lowering therapies in OpenSAFELY, not secondary care-issued prescriptions;²⁴ however, as the majority of individuals with gout are

managed in primary care, the absence of secondary care prescriptions is unlikely to have meaningfully altered our findings.

When interpreting the observed changes in urate-lowering therapy prescription, changes in guideline recommendations that have occurred over time should be acknowledged, because they might have influenced prescribing behaviour. The 2017 British Society for Rheumatology gout management guidelines recommend that all individuals with gout should be offered urate-lowering therapy, including those presenting with their first flare.² The 2022 NICE gout guidelines recommend discussing the option of urate-lowering therapy with all individuals with gout, but do not specifically recommend offering urate-lowering therapy unless additional factors are present (eg, multiple flares, tophaceous gout, or chronic kidney disease).³ If the NICE criteria were applied during the full study period, then the proportion of individuals who should have been offered urate-lowering therapy and were prescribed it would have been higher. Similarly, we could not account for individuals' preference in our analyses (eg, people who were offered urate-lowering therapy by their clinician but declined to start it). Finally, we were unable to describe other important aspects of gout care in our analyses, such as patient-reported outcomes and the provision of disease education.

In conclusion, we showed that newly recorded gout diagnoses decreased by a third during the first year of the pandemic, with no rebound increase in incidence observed as of early 2023. For individuals who presented with incident gout, urate-lowering therapy initiation improved modestly during the pandemic, whereas urate target attainment was similar before and during the pandemic. Despite these findings, initiation of urate-lowering therapy and attainment of urate targets remain below an acceptable standard. This study shows the potential for routinely captured health data to revolutionise the monitoring of chronic diseases at both national and regional levels.

Contributors

MDR, BM, and JBG conceptualised the study. MDR, JM, ER, BM, AMa, AIR, SP, MAA, EA, DN, JH, KB, JML, SN, APC, and JBG developed the methodology. MDR, CDA, SN, and JBG contributed to the formal analysis. MDR and JBG developed the diagnostic codelists. JM, BM, SB, BG, CDA, GH, and AMe developed software for the OpenSAFELY platform. MDR wrote the original draft. All authors revised, reviewed, and edited the manuscript. All authors read and approved the final manuscript. MDR and JBG are the guarantors for the Article, accept full responsibility for the work and the conduct of the study, and had final responsibility for the decision to submit for publication. MDR and JM directly accessed and verified the underlying data reported in the manuscript. This study was supported by JML (Clinical Director for the National Early Inflammatory Arthritis Audit) as senior sponsor.

Declaration of interests

MDR has received honoraria from Eli Lilly, Galapagos, and Menarini; support for attending conferences from Eli Lilly, Pfizer, Janssen, and UCB; and advisory board fees from Biogen. ER has received research funding from the National Institute for Health and Care Research

(NIHR), is senior author of the 2017 British Society for Rheumatology gout guideline, and topic advisor to the 2022 National Institute for Health and Care Excellence gout guideline. BG has received research funding from the Laura and John Arnold Foundation, NIHR, NIHR School for Primary Care Research, NHS England, NIHR Oxford Biomedical Research Centre, the Mohn Westlake Foundation, NIHR Applied Research Collaboration Oxford and Thames Valley, the Wellcome Trust, the Good Thinking Foundation, Health Data Research UK, the Health Foundation, WHO, UK Research and Innovation Medical Research Council, Asthma UK, the British Lung Foundation, and the Longitudinal Health and Wellbeing strand of the National Core Studies programme; he is a Non-Executive Director at NHS Digital; he also receives personal income from speaking and writing for lay audiences on the misuse of science. AMe has received consulting fees from Induction Healthcare, and is a member of the Royal College of General Practitioners health informatics group and the NHS Digital GP Data Professional Advisory Group, which advises on access to GP Data for Pandemic Planning and Research. AMa has received speaker fees from AbbVie, Galapagos, and MEDACS, and support for attending meetings from UCB and Fresenius. AIR has received fees from Eli Lilly and UCB for attending a conference. SP reports support for attending conferences from Galapagos. EA has received funding to attend meetings from UCB. KB has received grant funding from NIHR and Versus Arthritis/Pfizer, and support to attend conferences from UCB. JML is clinical director for the National Early Inflammatory Arthritis Audit, secretary for the Federation of Joint Royal Colleges of Physicians specialist certificate exam board, and a trustee of the British Society for Rheumatology. SN has received honoraria from Janssen. APC has received grants from Bristol Myers Squibb (BMS); consulting fees from BMS, AbbVie, and GSK/Galvani; and speaker fees from BMS and AbbVie; and is on the executive committee of the European Alliance of Associations for Rheumatology research centre. JBG has received honoraria from AbbVie, BMS, Celgene, Chugai, Gilead Sciences, Janssen, Eli Lilly, Novartis, Pfizer, Roche, Sanofi, Swedish Orphan Biovitrum, and UCB. All other authors declare no competing interests.

Data sharing

All data were linked, stored, and analysed securely within the OpenSAFELY platform. Data include pseudonymised data such as coded diagnoses, medications, and physiological parameters. No free text data are included. All code for data management and analysis, as well as codelists, are shared openly for review and re-use under MIT open license (<https://github.com/opensafely/gout>). Detailed pseudonymised patient data are potentially re-identifiable and therefore not shared. Access to the underlying identifiable and potentially re-identifiable pseudonymised electronic health record data is tightly governed by various legislative and regulatory frameworks and is restricted by best practice. The data in OpenSAFELY are drawn from general practice data across England where TPP is the data processor. TPP developers initiate an automated process to create pseudonymised records in the core OpenSAFELY database, which are copies of key structured data tables in the identifiable records. These records are linked onto key external data resources that have also been pseudonymised via SHA-512 one-way hashing of NHS numbers using a shared salt. Bennett Institute for Applied Data Science developers and principal investigators hold contracts with NHS England and have access to the OpenSAFELY pseudonymised data tables as needed to develop the OpenSAFELY tools. These tools in turn enable researchers with OpenSAFELY Data Access Agreements to write and execute code for data management and data analysis without direct access to the underlying raw pseudonymised patient data, and to review the outputs of this code. All code for the full data management pipeline—from raw data to completed results for this analysis—and for the OpenSAFELY platform as a whole is available for review at <https://github.com/OpenSAFELY>.

Acknowledgments

We are grateful for the support received from the TPP Technical Operations team throughout this work, and for generous assistance from the information governance and database teams at NHS England and the NHS England Transformation Directorate. This research used data assets made available as part of the Data and Connectivity National Core Study, led by Health Data Research UK in partnership with the Office for

National Statistics and funded by UK Research and Innovation (MC_PC_20058). In addition, the OpenSAFELY platform is supported by grants from the Wellcome Trust (222097/Z/20/Z), Medical Research Council (MR/V015757/1, MC_PC-20059, and MR/W016729/1), NIHR (NIHR135559 and COV-LT2-0073), and Health Data Research UK (HDRUK2021.000 and 2021.0157). MDR is funded by an NIHR Doctoral Fellowship (NIHR300967). BG has received funding from the Peter Bennett Foundation, the Wellcome Trust, NIHR Oxford Biomedical Research Centre, NIHR Applied Research Collaboration Oxford and Thames Valley, and the Mohn Westlake Foundation; all authors employed by the Bennett Institute for Applied Data Science were supported by BG's grants on this work. BMK is employed by NHS England, working on medicines policy, and is Clinical Lead for primary care medicines data. The views expressed in this publication are those of the authors and not necessarily those of the NHS, NIHR, Public Health England, or the Department of Health and Social Care. No funding bodies had any role in study design, data collection, analysis or interpretation, manuscript writing, or in the decision to submit the article for publication.

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