Persistent inequalities in consultation incidence and prevalence of low back pain and osteoarthritis in England between 2004-2019

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ABSTRACT

Objective

To determine whether socioeconomic inequalities in primary care consultation rates for two major, disabling musculoskeletal conditions in England narrowed or widened between 2004-2019.

Methods

We analysed data from Clinical Practice Research Datalink Aurum, a national general practice electronic health records database, linked to national deprivation ranking of each patients' registered residential postcode. For each year we estimated the age-sex standardised consultation incidence and prevalence for low back pain and osteoarthritis for the most deprived 10% of neighbourhoods through to the least deprived 10%. We then calculated the Slope Index of Inequality and Relative Index of Inequality overall, and by sex, age-group, and geographical region.

Results

Inequalities in LBP incidence and prevalence over socioeconomic status widened between 2004-2013 and stabilised between 2014-2019. Inequalities in OA incidence remained stable over socioeconomic status within study period, whereas inequalities in OA prevalence markedly widened over socioeconomic status between 2004-2019. Widest gap in LBP incidence and prevalence over socioeconomic status was observed in population resident in Northern English regions and London, and in those of working age, peaking at 45-54 years.

Conclusions

We found persistent, and generally increasing, socioeconomic inequalities in the rate of adults presenting to primary care in England with low back pain and osteoarthritis between 2004-2019.

Key words: Low back pain; osteoarthritis; incidence; prevalence; deprivation; CPRD; socioeconomic inequality; slope index of inequality; relative index of inequality

KEY MESSAGE

- Socioeconomic inequalities in consultation rates of low back pain and osteoarthritis persist and have increased in England since 2004.
- Inequalities are more common for low back pain, and are wider among women, people of working age, and in the North.

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Lay summary

What does this mean for patients?

Our study describes the extent of social inequalities in how many adults present to primary care with a painful musculoskeletal condition. We focussed on two of the most common, disabling conditions: back pain and osteoarthritis. We analysed information from primary care electronic medical records across England. People living in the most deprived ("poorest") neighbourhoods were more likely to seek the help of primary care than people of the same age and sex who lived in the least deprived ("richest") neighbourhoods. Compared to general practices serving the richest neighbourhoods, a general practice serving the poorest neighbourhoods in England could see 15-40% more patients presenting with a new episode of back pain or osteoarthritis each year. These differences in rates between rich and poor were particularly noticeable among women, among working-age adults, and in the north of England and in London. Inequalities did not appear to have reduced between 2004 and 2019. Our study did not investigate underlying causes. However, it does highlight issues around workload and resourcing of general practices and the need for earlier and sustained preventive actions focussed towards poorer communities across England.

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INTRODUCTION

The rates of many non-communicable diseases are higher among disadvantaged and marginalised people and communities [1]. Musculoskeletal disorders such as low back pain, neck pain, osteoarthritis are important and increasing causes of disability and societal costs in populations worldwide [2] and show the same pattern in which the occurrence, severity, and impact tend to be inversely related to socioeconomic position. [3]

Evidence on the extent of socioeconomic inequalities in the prevalence of musculoskeletal pain disorders comes mainly from cross-sectional population surveys and, to a lesser extent, cross-sectional analysis of single waves of longitudinal studies, including birth cohorts. Despite heterogeneous case definitions and methods, a consistent finding has emerged of higher prevalence of musculoskeletal pain, [4] low back pain, [5] hip or knee pain, [6] [7] widespread pain, [8] and chronic pain in general [9]among adults with lower individual socioeconomic position or living in more deprived neighbourhoods. Inequalities may be greater for some disorders (e.g. back pain) than others [4](e.g. self-reported and doctor-diagnosed osteoarthritis). However, a paucity of repeated survey data on musculoskeletal pain means that it is unclear whether inequalities in musculoskeletal pain, severity, and impact are widening or narrowing over time. In England, the current Public Health Outcomes Framework [10] includes one indicator on the prevalence of long-term musculoskeletal problems obtained from the national General Practice Patient Survey and available annually only from 2018. Understanding the long-term health inequalities might help the government's place-based approaches to support the most deprived areas with the poorest health to narrow the national health inequalities gap [11].

Continuous morbidity recording in primary care may offer an additional source of data to examine trends over time in the magnitude of inequalities at national and subnational levels. Using these data, investigators in other fields have reported growing inequalities by neighbourhood deprivation

in the rates of multimorbidity [12], age at first presentation of heart failure [13], and incidence of fracture [14]. To our knowledge, a similar approach has not previously been applied to studying trends over time in inequalities for the most common, disabling musculoskeletal pain conditions. The objective of our study was to determine whether the rate of adults presenting to general practice for low back pain and osteoarthritis differed by area-level deprivation and whether any such differences have widened or reduced between 2004-2019 in England.

METHODS

Data sources and study population

CPRD Aurum is a database including anonymised data from patient electronic health records in primary care on demographics, diagnoses, symptoms, prescriptions, referrals, immunizations, lifestyle factors, tests and results. Patient-level data linkage to national deprivation measures is used in this study. As of February 2021, CPRD Aurum included data on 39.7 million patients from 1489 practices, of whom 13.3 million currently contribute data (20% of the population of England) [15].

Neighbourhood deprivation

We used the English Index of Multiple Deprivation (IMD) 2015 rank as a composite measure of neighbourhood deprivation which combines 37 indicators covering seven domains of material deprivation (health deprivation and disability; barriers to housing and services; employment deprivation; income deprivation; education, skills, and training deprivation; crime; living environment deprivation) presented at the level of lower super output area (LSOA: areas with mean population size 1500, minimum 1,000) [16, 17]. Our analyses were restricted to English practices in CPRD who consented to the linkage. Individual-level IMD linkage is available for those general practices that agreed to this linkage and, where the individual themselves has not opted out, covering around 70% of CPRD participants. IMD rank was categorised by decile score where 1 = the least deprived 10% of neighbourhoods and 10 = the most deprived 10% [18].

Case definitions

Case definitions and definitions of consultation incidence (new cases presenting to general practice) and prevalence (all cases presenting to general practice, including new and ongoing cases) matched those we previously used to determine overall trends in prevalence and incidence of LBP and OA in CPRD [19]. In UK primary care, symptom and diagnosis problems were recorded using Read codes up to 2018 when SNOMED codes began to replace Read codes. High validity of diagnostic coding has been previously reported [20] [21] [22].

Cases of non-specific low back pain among those aged ≥ 15 years were defined as having ≥ 1 recorded coded event of low back pain in a calendar year. We applied a Read code list previously developed [19] to define low back pain. Cases of osteoarthritis were defined as having ≥ 1 recorded clinical event of osteoarthritis (based on Read codes starting N05 ‘Osteoarthritis and allied disorders’) among those aged ≥ 45 years in each calendar year.

Defining the at-risk population

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To estimate annual prevalence, the denominator population included all patients with a full registration history over the prior three calendar years. In the estimation of annual incidence, the denominator population was restricted to those with no recorded codes of the outcome of interest (low back pain, osteoarthritis) over the previous three years. A three-year 'look back period' has previously been shown to be optimal for common musculoskeletal disorders [23]. A period shorter than three years may increase the risk of including prevalent cases as new cases whilst a longer period may increase the risk of selection bias as patients would need to have been registered at their practice for a longer time to be included in the study. The numerator population incorporated all patients in the denominator population who fulfilled our case definitions above. [23]

Statistical analysis

The annual age-sex-standardized rates, stratified by deprivation, were estimated using the mid-2019 England population (ONS code: E92000001) as the standard with 95% confidence intervals (CI) estimated by Poisson regression for the whole English population, and the population in each English geographical region between 2004-2019. The annual age-standardised incidence and prevalence for men and women by deprivation status were also determined.

The annual incidence and prevalence population-weighted, regression-based slope index of inequality (SII) and relative index of inequality (RII) were estimated [24] [25] (**Supplemental Technical Note**). A value of zero on the SII indicates no inequality. Positive values of the SII indicate a higher concentration of LBP/OA among those in the most deprived areas and negative values indicate a higher concentration among those in the least deprived areas. RII has the value one when there is no inequality. Values of the RII larger than one indicates a higher concentration of LBP/OA in most deprived areas and values smaller than one indicate a higher concentration in the least deprived areas. SIIs and RIIs were calculated using a standard analytical tool provided by England Office for Health Improvement and Disparities. The confidence intervals for each SII and RII were estimated using bootstrapping with resampling 10,000 times. Stata MP 16.0 was used for data management and statistical analysis.

Ethical approval

The study was approved by the Independent Scientific Advisory Committee for CPRD research (protocol reference: 20_054R). No further ethical permissions were required for the analyses of these anonymized patient level data.

RESULTS

Adults living in more deprived neighbourhoods had higher age-sex standardised incidence rates for low back pain than adults living in less deprived neighbourhoods. The gap between annual incidence rates in the most and least deprived neighbourhoods widened between 2004 and 2013 as incidence rates rose among the most deprived while remaining stable among the least deprived (SII rose from 6.01 to 13.75 per 1,000 person-years, RII from 1.18 to 1.37). From 2014-2019, incidence rates fell across all groups, narrowing slightly the absolute inequality gap but not the relative index of inequality (SII in 2019 = 12.88 per 1,000 person-years; RII = 1.41: **Figure 1; Supplemental Table S1&S2, available at *Rheumatology Advances in Practice* online**). The same pattern was observed for

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the age-sex standardised prevalence of low back pain; **Supplemental Figure S1; Supplemental Table S1&S2**).

Inequalities in age-sex standardised incidence of osteoarthritis increased between 2004 and 2014 (SII rose from 2.69 to 5.14 per 1,000 person-years, RII from 1.16 to 1.29) and then decreased to 2019 (SII fell from 5.14 to 3.53 per 1,000 person-years, RII from 1,29 to 1.18) (**Figure 1; Supplemental Table S1&S2**)). A similar pattern was seen for age-sex standardised prevalence of osteoarthritis where both SII and RII increased between 2004 and 2016 before slightly decreasing to 2019; **Supplemental Figure S1; Supplemental Table S1&S2**).

In each year from 2004 to 2019 absolute and relative socioeconomic inequalities in the age-standardised incidence and prevalence of low back pain and osteoarthritis were higher among women than among men (**Figure 2-3; Supplemental Figure S2&S3; Supplemental Table S2&S3, available at *Rheumatology Advances in Practice* online**). The trends across time in absolute and relative socioeconomic inequalities for men and for women were broadly similar, following the overall trend.

In age-stratified analyses, socioeconomic inequalities for low back pain and osteoarthritis incidence and prevalence rates were greatest in adults below 65 years of age. (**Figure 4-5; Supplemental Figure S4&S5; Supplemental Table S4&S5, available at *Rheumatology Advances in Practice* online**). Consistent with the overall trend over time, relative socioeconomic inequalities in low back pain incidence increased over time within all age groups from 15 to 64 years. Among 75-84-year-olds and over-85s, a much greater increase in the incidence and prevalence of low back pain between 2004 to 2019 was seen among those living in the most deprived neighbourhoods, compared to the least deprived. For osteoarthritis, relative socioeconomic inequalities in both incidence and prevalence were associated with age group with RII across 2004-2019 consistently highest in the 45-54 years age category and lowest in adults aged 75 years and over.

Region-specific trends

Similar trend of SIIs and RIIs for age-sex-standardised incidence and prevalence by geographical region were identified with generally greater socioeconomic inequalities in the North West and North East, both for low back pain and osteoarthritis (**Figure 6, Supplemental Figure S6-S8; Supplemental Table S6&S7, available at *Rheumatology Advances in Practice* online**). Over the study period, the socioeconomic gap in incidence and prevalence widened in several regions, especially for low back pain. For example, in the North East, the estimate of SII for low back pain incidence widened from 8.48 in 2004 to 17.13 per 1,000 person-years in 2019. In London, the corresponding increases were from 4.15 to 15.03 per 1,000 person-years. By comparison, in South Central, SII increased less from 8.13 to 12.09 per 1,000 person-years. Under-representation of GP practices from the East Midlands resulted in unstable region-specific estimates for that region.

DISCUSSION

Main findings

Our descriptive study found evidence of persistent socioeconomic inequalities in the annual rate of recorded cases of low back pain and osteoarthritis presenting to primary care in England over the

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16-year period between 2004 and 2019. Consultation rates were, in general, between 15% and 55% higher among adults living in the most deprived decile of neighbourhoods compared to those living in the least deprived decile. Inequalities were generally greater for low back pain than for osteoarthritis, and were greatest among women, adults under the age of statutory retirement, and in northern regions and London. Overall, absolute and relative inequalities widened in the period between 2004 and 2013 although this pattern was not consistently observed in stratified analyses. These inequalities have not reduced since 2013.

Comparison with previous studies

Our estimates of the direction and magnitude of relative inequalities for these two common musculoskeletal conditions are broadly consistent with available national survey data from 2018-2020 on deprivation-specific prevalence of self-reported long-term back pain or joint pain and chronic pain. These sources respectively suggest a 20-30% and a 36% higher prevalence among adults living in the most deprived neighbourhoods. There are few published estimates of sex-, age- and region-specific inequalities for direct comparison. Our study found greater socioeconomic inequalities for low back pain and osteoarthritis among women than among men. Higher levels of opportunistic consultation and coding of osteoarthritis, especially among women living in more deprived settings, may contribute to this. Women have higher levels of multimorbidity [26], more contacts with primary care [27], and there may be a stronger gradient in consultation rates by deprivation among women [28]. We are unaware of previous studies finding greater, and widening, inequalities in musculoskeletal conditions among young- and middle-aged adults and this warrants further investigation. However, this pattern, and the absence or reversal of inequalities in old age, was also found for multimorbidity rates by an independent research group using the same data source [12].

Our study did not explore potential mechanisms underlying the observed inequalities but future research to further explicate how exposure to inequitable social structures and systems becomes embodied as osteoarthritis would be valuable. We hypothesise that persistent inequalities in the rate of new diagnoses of low back pain and osteoarthritis are likely to arise, in part at least, from inequalities in the distribution of one or more key proximal causal exposures, including obesity, occupational physical exposures, injury, physical inactivity, and mood. The causal action of some of these exposures begins earlier in life and may be cumulative over many years [29] [30] [31] [32], implying the need for earlier and sustained equity-focussed prevention to reduce the inequalities in osteoarthritis incidence seen in middle age.

Relying on coded diagnoses in the primary care EHR to define a case of osteoarthritis does not provide an unfiltered measure of disease incidence in the population: it also reflects the propensity to consult, access to primary care, and coding behaviours among primary healthcare professionals. Inequalities by deprivation in these factors may also contribute to observed inequalities in consultation incidence and prevalence. It is interesting that the period during which we observed the clearest widening of inequalities in LBP/OA incidence/prevalence coincided with when there appeared to have been success in achieving a more equitable supply of GP [33, 34]. This apparent paradox could reflect better access or more complete problem coding in deprived areas when there is a greater supply of GPs.

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Strengths and limitations

Our study used established code lists and a recognised area-level measure of deprivation based on patients' postcode applied to a large primary care electronic health record database representative of the English population [35]. Individual-level measures of socioeconomic position such as educational attainment, occupation, or income, are not routinely recorded or available. The result is that our analyses are based on the marker 'living in a deprived area' rather than being socioeconomically disadvantaged. Moscrop et al argue that this can result in under-estimating 'true' socioeconomic inequalities as well as obscuring the actual social determinants responsible for the observed inequalities [36]. Under-estimating inequalities might also result from analytic decisions. We modelled the slope index of inequality and relative index of inequality as a linear function hence assuming a linear relationship between indicator and population socioeconomic status. This may be suboptimal in situations where the relationship between indicator and deprivation is non-linear. Future methodological exploration of optimal models to fit for non-linear relationships are warranted. Due to restricted access to clinical records and measurements in the denominator population, confounding effects from obesity and multimorbidity on the research findings were not further explored in the current study. Future research to test the effects of these confounders are warranted. We relied on a clinician coded record of osteoarthritis rather than need for radiographic evidence. Clinical guidance suggests non-radiographic features alone are sufficient to make diagnosis for osteoarthritis [37, 38], and a previous study revealed the good specificity of general practitioner diagnosed osteoarthritis [39]. Studies based on electronic health records might be subject to misclassification that have the potential to bias results. However, in the current study, the established codes list and methods used to estimate incidence and prevalence have been validated and yielded internationally comparable estimations [23].

Conclusion

In conclusion, the current study found persistent, and in some cases, widening, inequalities by deprivation in the rates of two of the most common, disabling musculoskeletal conditions presenting to primary care in England between 2004 and 2019.

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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 are provided by patients and collected by the NHS as part of their care and support. The interpretation and conclusions contained in this study are those of the authors alone.

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Conflict of interests

Authors have declared no conflicts of interests.

Data Availability Statement

Data may be obtained from a third party and are not publicly available. The data were obtained from the Clinical Practice Research Datalink (CPRD). CPRD data governance does not allow us to distribute patient data to other parties. Researchers may apply for data access at http://www.CPRD.com/.

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Figure Legend

Figure 1. Standardised incidence of low back pain and osteoarthritis by neighbourhood deprivation

Figure 2. Slope index of inequality for sex-specific standardised incidence of low back pain and osteoarthritis between 2004-2019 in England. *SII indicates slope index of inequality; PYRS indicates person-years.*

Figure 3. Relative index of inequality for sex-specific standardised incidence of low back pain and osteoarthritis between 2004-2019 in England. *RII indicates relative index of inequality.*

Figure 4. Slope index of inequality for age-stratified standardised incidence of low back pain and osteoarthritis between 2004-2019 in England. *SII indicates slope index of inequality; PYRS indicates person-years.*

Figure 5. Relative index of inequality for age-stratified standardised incidence of low back pain and osteoarthritis between 2004-2019 in England. *RII indicates relative index of inequality.*

Figure 6. Slope index of inequality for standardised incidence of low back pain and osteoarthritis between 2004-2019 in each of 10 English regions. *SII indicates slope index of inequality; PYRS indicates person-years. Dot and diamond indicate SII for low back pain and osteoarthritis, respectively.*

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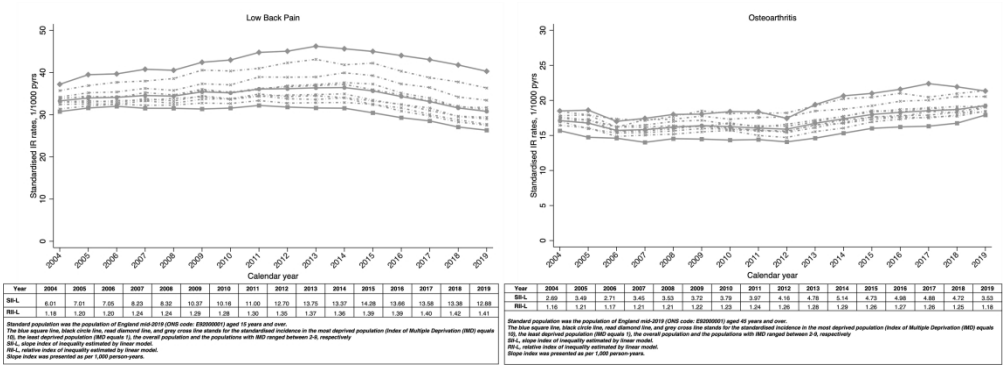

Year	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
SII-L	6.01	7.01	7.05	8.23	8.32	10.37	10.16	11.00	12.70	13.75	13.37	14.28	13.66	13.58	13.38	12.88
RII-L	1.18	1.20	1.20	1.24	1.24	1.29	1.28	1.30	1.35	1.37	1.36	1.39	1.39	1.40	1.42	1.41

Standard population was the population of England mid-2019 (ONS code: E92000001) aged 15 years and over.
The blue square line, black circle line, read diamond line, and grey cross line stands for the standardised incidence in the most deprived population (Index of Multiple Deprivation (IMD) equals 10), the least deprived population (IMD equals 1), the overall population and the populations with IMD ranged between 2-9, respectively
SII-L, slope index of inequality estimated by linear model.
RII-L, relative index of inequality estimated by linear model.
Slope index was presented as per 1,000 person-years.

Year	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
SII-L	2.69	3.49	2.71	3.45	3.53	3.72	3.79	3.97	4.16	4.78	5.14	4.73	4.98	4.88	4.72	3.53
RII-L	1.16	1.21	1.17	1.21	1.21	1.22	1.23	1.24	1.26	1.28	1.29	1.26	1.27	1.26	1.25	1.18

Standard population was the population of England mid-2019 (ONS code: E92000001) aged 40 years and over.
The blue square line, black circle line, read diamond line, and grey cross line stands for the standardised incidence in the most deprived population (Index of Multiple Deprivation (IMD) equals 10), the least deprived population (IMD equals 1), the overall population and the populations with IMD ranged between 2-9, respectively
SII-L, slope index of inequality estimated by linear model.
RII-L, relative index of inequality estimated by linear model.
Slope index was presented as per 1,000 person-years.

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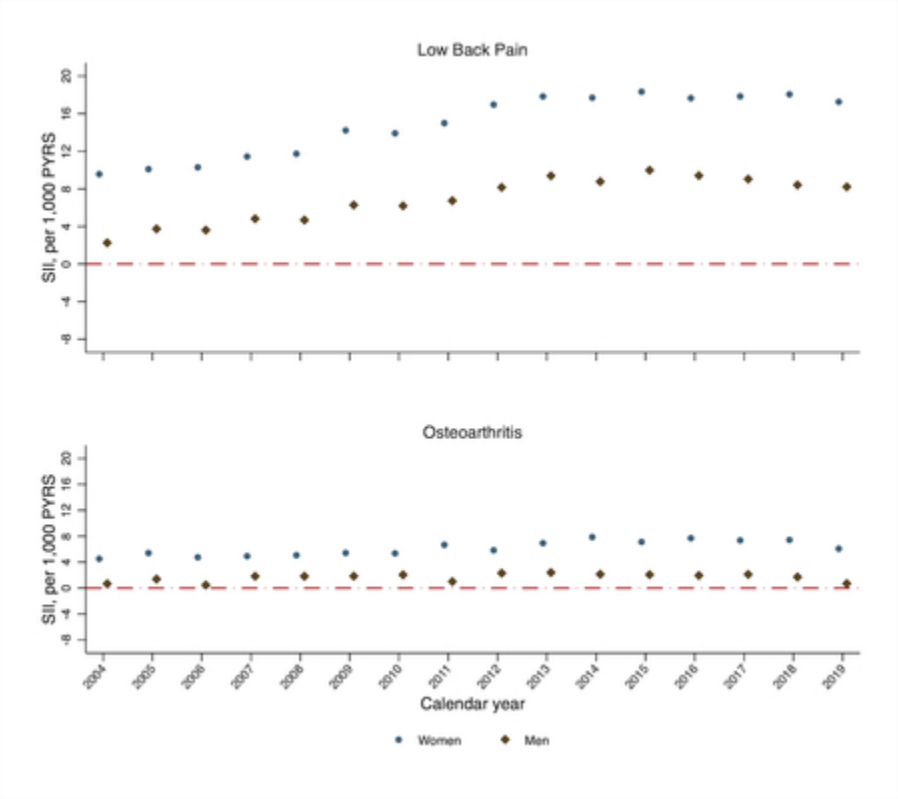

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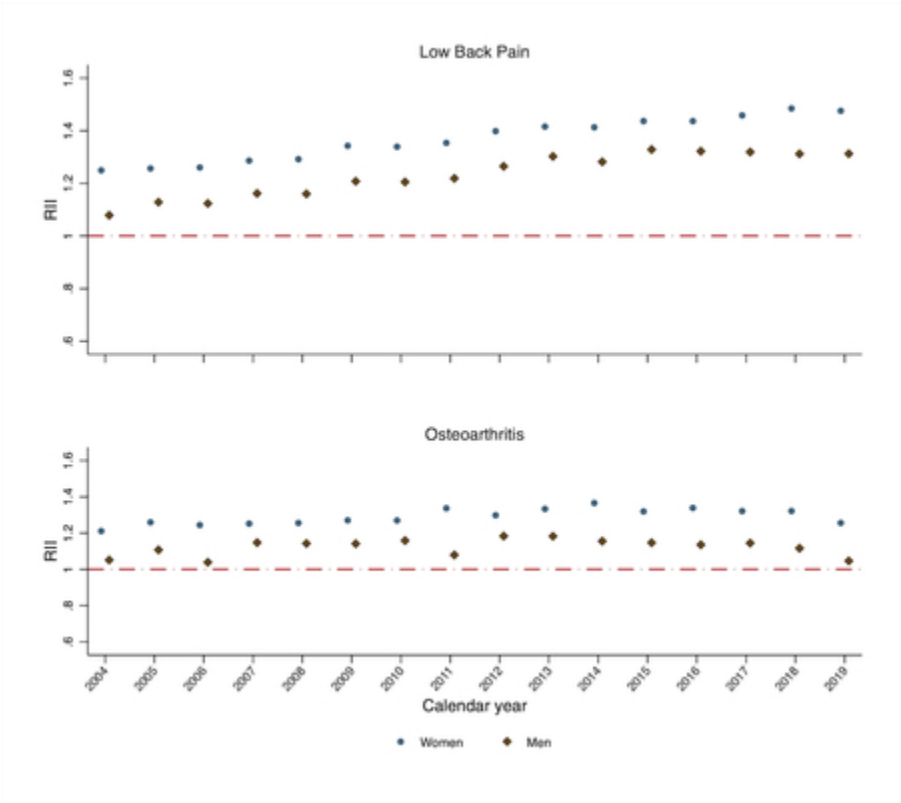

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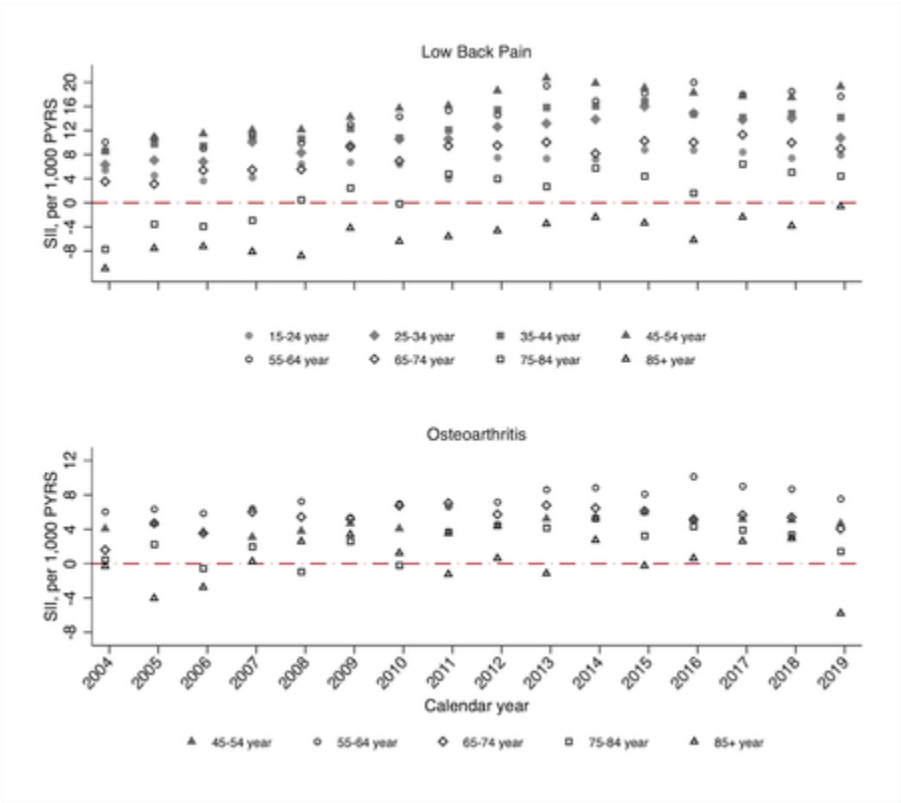

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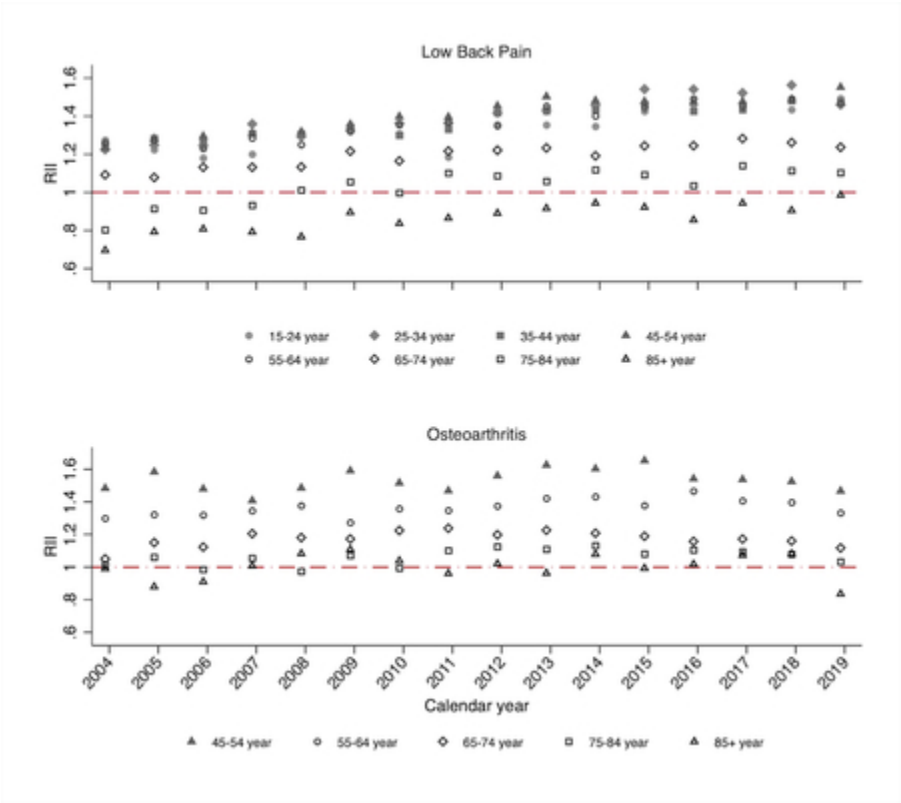

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A 2nd generation, JAK1 preferential inhibitor for moderate to severe RA[1-6]

While 1st generation JAK inhibitors are relatively non-selective,[2-6] JYSELECA has over 5x greater potency for JAK1 over JAK2/3 and TYK2[1]*

Balancing sustained efficacy[7-11] with acceptable tolerability[1,12]

Indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti-rheumatic drugs.[1] May be used as monotherapy or in combination with methotrexate.[1]

*From biochemical assays, the clinical relevance of which is uncertain.
JAK, Janus kinase; RA, rheumatoid arthritis; TYK, tyrosine kinase.

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Refer to Summary of Product Characteristics (SmPC) before prescribing, and for full prescribing information.

JYSELECA® ▽ filgotinib 100 mg or 200 mg film-coated tablets. **Indication:** Jyseleca is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti rheumatic drugs (DMARDs). Jyseleca may be used as monotherapy or in combination with methotrexate (MTX). **Dosage:** Adults: 200 mg once daily. Taken orally with/without food. It is recommended that tablets are swallowed whole. Laboratory Monitoring: Refer to the SmPC for information regarding laboratory monitoring and dose initiation or interruption. Elderly: A starting dose of 100 mg once daily is recommended for patients aged 75 years and older as clinical experience is limited. Renal impairment: No dose adjustment required in patients with estimated creatinine clearance (CrCl) ≥ 60 mL/min. A dose of 100 mg of filgotinib once daily is recommended for patients with moderate or severe renal impairment (CrCl 15 to < 60 mL/min). Not recommended in patients with CrCl < 15 mL/min. Hepatic impairment: Mild/moderate hepatic impairment: no dose adjustment required. Severe hepatic impairment: not recommended. Children (< 18years): Safety and efficacy not yet established. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Active tuberculosis (TB) or active serious infections. Pregnancy. **Warnings/Precautions:** See SmPC for full information. Immunosuppression: Combination use, with immunosuppressants e.g., ciclosporin, tacrolimus, biologics or other Janus kinase (JAK) inhibitors is not recommended as a risk of additive immunosuppression cannot be excluded. Infections: Infections, including serious infections such as pneumonia and opportunistic infections e.g. tuberculosis (TB), oesophageal candidiasis, and cryptococcosis have been reported. Risk benefit should be assessed prior to initiating in patients with risk factors for infections (see SmPC). Patients should be closely monitored for the development of signs and symptoms of infections during and after filgotinib treatment. Treatment should be interrupted if the patient is not responding to antimicrobial therapy, until infection is controlled. There is a higher incidence of serious infections in the elderly aged 75 years and older, caution should be used when treating this population. Tuberculosis: Patients should be screened for TB before initiating filgotinib, and filgotinib should not be administered to patients with active TB. Viral reactivation: Cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies (see SmPC). If a patient develops herpes zoster, filgotinib treatment should be temporarily interrupted until the episode resolves. Screening for viral hepatitis and monitoring for reactivation should be performed. Malignancy: Immunomodulatory medicinal products may increase the risk of malignancies. Malignancies were observed in clinical studies (see SmPC). Fertility: In animal studies, decreased fertility, impaired spermatogenesis, and histopathological effects on male reproductive organs were observed (see SmPC). The potential effect of filgotinib on sperm production and male fertility in humans is currently unknown. Haematological abnormalities: Do not start therapy, or temporarily stop, if Absolute Neutrophil Count (ANC) <1 × 10^9 cells/L, ALC <0.5 × 10^9 cells/L or haemoglobin <8 g/dL. Temporarily stop therapy if these values are observed during routine patient management. Vaccinations: Use of live vaccines during, or immediately prior to, filgotinib treatment is not recommended. Lipids: Treatment with filgotinib was associated with dose dependent increases in lipid parameters, including total cholesterol, and high-density lipoprotein (HDL) levels, while low density lipoprotein (LDL) levels were slightly increased (see SmPC). Cardiovascular risk: Rheumatoid arthritis patients have an increased risk for cardiovascular disorders. Patients should have risk factors (e.g., hypertension, hyperlipidaemia) managed as part of usual standard of care. Venous thromboembolism: Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving JAK inhibitors including filgotinib. Caution should be used in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery, and prolonged immobilisation. Lactose content: Contains lactose; patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take filgotinib. **Pregnancy/Lactation:** Filgotinib is contraindicated in pregnancy. Filgotinib should not be used during breast-feeding. Women of childbearing potential must use effective contraception during and for at least 1 week after cessation of treatment. **Driving/Using machinery:** No or negligible influence, however dizziness has been reported. **Side effects:** See SmPC for full information. Common (≥1/100 to <1/10): nausea, upper respiratory tract infection, urinary tract infection and dizziness. Uncommon (≥1/1000 to <1/100): herpes zoster, pneumonia, neutropenia, hypercholesterolaemia and blood creatine phosphokinase increase. Serious side effects: See SmPC for full information **Legal category:** POM **Pack:** 30 film-coated tablets/bottle **Price:** UK Basic NHS cost: £863.10 **Marketing authorisation number(s):** Great Britain Jyseleca 100mg film-coated tablets PLGB 42147/0001 Jyseleca 200mg film-coated tablets PLGB 42147/0002 Northern Ireland Jyseleca 100mg film-coated tablets EU/1/20/1480/001 EU/1/20/1480/002 Jyseleca 200mg film-coated tablets EU/1/20/1480/003 EU/1/20/1480/004 **Further information:** Galapagos UK, Belmont House, 148 Belmont Road, Uxbridge UB8 1QS, United Kingdom 00800 7878 1345 medicalinfo@glpg.com Jyseleca® is a trademark. **Date of Preparation:** January 2022 UK-RA-FIL-202201-00019

▽ Additional monitoring required

Adverse events should be reported.
For Great Britain and Northern Ireland, reporting forms and information can be found at yellowcard.mhra.gov.uk or via the Yellow Card app (download from the Apple App Store or Google Play Store).
Adverse events should also be reported to Galapagos via email to DrugSafety.UK.Ireland@glpg.com or 00800 7878 1345

References: 1. JYSELECA SPC. Available at: www.medicines.org.uk. Last accessed: June 2022. **2.** Angelini J, *et al.* Biomolecules 2020;10(7):E1002. **3.** Banerjee S, *et al.* Drugs 2017;77:521–546. **4.** O'Shea JJ, *et al.* Nat Rev Rheumatol 2013;9(3):173–182. **5.** Traves PG, *et al.* Ann Rheum Dis 2021;0:1–11. **6.** McInnes IB, *et al.* Arthr Res Ther 2019;21:183. **7.** Combe B, *et al.* Ann Rheum Dis 2021;doi:10.1136/annrheumdis-2020-219214. **8.** Genovese MC, *et al.* JAMA 2019;322 (4):315–325. **9.** Westhovens R, *et al.* Ann Rheum Dis 2021;doi:10.1136/annrheumdis-2020-219213. **10.** Combe B, *et al.* Arthritis Rheumatol 2021;73(suppl 10). https://acrabstracts.org/abstract/clinical-outcomes-up-to-week-48-of-filgotinib-treatment-in-an-ongoing-long-term-extension-trial-of-ra-patients-with-inadequate-response-to-mtx-initially-treated-with-filgotinib-or-adalimumab-during-th/. Last accessed: June 2022. **11.** Buch MH, *et al.* Arthritis Rheumatol 2021;73 (suppl 10). https://acrabstracts.org/abstract/clinical-outcomes-up-to-week-48-of-ongoing-filgotinib-ra-long-term-extension-trial-of-biologic-dmard-inadequate-responders-initially-on-filgotinib-or-placebo-in-a-phase-3-trial/. Last accessed: June 2022. **12.** Winthrop K, *et al.* Arthritis Rheumatol 2021;73(suppl 10). Available at: https://acrabstracts.org/abstract/integrated-safety-analysis-update-for-filgotinib-in-patients-with-moderately-to-severely-active-rheumatoid-arthritis-receiving-treatment-over-a-median-of-2-2-years/. Last accessed: June 2022.

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