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## Clinical science

# Development and testing of a bespoke cultural intervention to support healthcare professionals with patients from a diverse background

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## Abstract

**Objective:** Development and test of a culturally sensitive intervention for rheumatology healthcare professionals (HCPs).

**Methods:** Using a before and after study design, 15 HCPs were recruited to undertake the bespoke intervention from four National Health Service sites across England, in areas serving a diverse population. The intervention was evaluated using two validated outcomes: (i) Patient Reported Physician Cultural Competency (PRPCC); and (ii) Patient Enablement Instrument (PEI), measuring patients' perceptions of their overall healthcare delivery. Additionally, HCPs completed the COM-B questionnaire for capability (C), opportunity (O) and motivation (M) to perform behaviour (B), measuring behaviour change.

**Results:** Two hundred patients were recruited before HCPs undertook the intervention (cohort 1), and 200 were recruited after (cohort 2) from 15 HCPs; after exclusions 178 patients remained in cohort 1 and 186 in cohort 2. Sixty percent of patients identified as white in both recruited cohorts, compared with 29% and 33% of patients (cohorts 1 and 2, respectively) who identified as being of South Asian origin. After the intervention, the COM-B scores indicated that HCPs felt more skilled and equipped for consultations. No significant differences were noted in the average overall cultural competency score between the two cohorts in white patients (57.3 vs 56.8,  $P=0.8$ ), however in the South Asian cohort there was a statistically significant improvement in mean scores (64.1 vs 56.7,  $P=0.014$ ). Overall, the enablement score also showed a statistically significant improvement following intervention (7.3 vs 4.3,  $P<0.001$ ) in the white patients and in the South Asian patients (8.0 vs 2.2,  $P<0.001$ ).

**Conclusion:** This novel study provides evidence for improving cultural competency and patient enablement in rheumatology settings.

**Keywords:** ethnicity, education, cultural competency, clinical outcomes

### Rheumatology key messages

- Meaningful patient–healthcare professional (HCP) communication reduces health disparities, improving clinical outcomes and addressing inequalities.
- A tailored online intervention programme enhances cultural competency and patient enablement among rheumatology HCPs.
- Cultural competency interventions improve patient experience in rheumatology clinics, especially for South Asian individuals.

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## Introduction

Cultural competence in healthcare is primarily exemplified by the behaviours exhibited by healthcare professionals (HCPs) in addressing the needs of individuals from diverse cultural and ethnic backgrounds [1]. It is an expectation of people to anticipate that their HCPs will demonstrate cultural competence by engaging in communication and interactions that manifest an understanding of customs, languages, beliefs and values [2]. HCPs can take the initial steps towards developing cultural sensitivity by acknowledging the multiplicity of cultures and worldviews that exist within a remarkably diverse nation [2]. Furthermore, HCPs should acknowledge that one's perception of the world is profoundly influenced by their personal background and experiences [3]. Recognizing that, like others, they too may hold biases and preconceptions is crucial for HCPs [3]. Sustaining a heightened level of self-awareness serves as a constant reminder to HCPs regarding how their worldview influences their healthcare practices. In numerous Western nations, including the UK, considerable health disparities stem from the absence of adequately tailored models of care that incorporate cultural sensitivity [4]. As minority populations continue to grow within Western nations, the imperative to train HCPs in delivering culturally sensitive care has been emphasized for at least the past two decades [1].

Numerous specialties have independently devised cultural competence interventions within their respective practices [1, 3, 4], albeit often lacking in freely accessible resources. Notably, disciplines such as general medicine, mental health, diabetes and cardiovascular specialties have been at the forefront of pioneering efforts in developing cultural competency interventions [1, 3, 4]. Studies focusing on diabetes care for patients of African American, Asian/Pacific Islander and Latino backgrounds have provided evidence demonstrating that cultural competence interventions enhance HCPs' knowledge regarding cultural aspects [5]. Furthermore, these interventions have been shown to significantly enhance patient satisfaction and overall experience [5]. A comprehensive review of studies [6] indicated that cultural competency programmes effectively augment practitioners' knowledge, awareness and cultural sensitivity [6]. Additionally, a study conducted in the UK revealed tangible improvements in the skills and confidence of HCPs when providing support to individuals of South Asian origin with type 1 diabetes [4].

Within the realm of rheumatology practice, our research has also documented poor disease outcomes in patients of South Asian origin [7]. Our extensive mixed methods investigations have yielded valuable insights into the multifaceted factors contributing to these suboptimal disease outcomes [7–9]. Given the intricate and multi-level nature of disparities in rheumatology, it is imperative that strategies aimed at addressing these disparities adopt a comprehensive approach, targeting various facets of rheumatology care. It is unrealistic to rely solely on patient-centred interventions within the healthcare sector to substantially narrow this disparity gap [7]. HCPs in rheumatology have expressed a deficiency in skills required to effectively engage with patients of South Asian origin [10]. Our preliminary studies have revealed a lack of confidence among rheumatology HCPs in providing support to patients from South Asian backgrounds, resulting in perceived deficiencies in their ability to engage with this patient population, ultimately impacting patients' satisfaction

with clinical services [8, 10]. HCPs have identified a crucial need for interventions that address both consultation skills and the establishment of culturally sensitive services to address these challenges.

This project involved a comprehensive examination of the existing body of evidence [1–3, 5], incorporating insights derived from studies on culturally sensitive communication interventions. Additionally, we undertook the novel task of developing and evaluating a customized intervention programme specific to rheumatology. Given the unique manifestations of rheumatological conditions compared with other chronic ailments, healthcare HCPs must possess specialized skills to effectively engage with patients in this context. The intervention programme developed as part of this project encompassed patient role plays that focused on disease-specific concepts, enabling HCPs to reflect upon and navigate challenging scenarios.

## Methods

We report data aligned with the SQUIRE (Standard for Quality Improvement Reporting Excellence) guidelines version 2. (<https://www.equator-network.org/reporting-guidelines/squire/>).

### Study design

Before and after study design to assess the effect of the culturally sensitive intervention.

### Content development of the culturally sensitive intervention programme

The culturally sensitive communication intervention aimed to support rheumatology HCPs to further develop their communication skills, specifically around cultural sensitivity, shared decision-making and attention to health literacy. Developmental was in three parts: stage 1, lessons from the current data; stage 2, content planning with the independent group; and stage 3, recording and creating the intervention.

### Lessons from the literature

Before developing the content for the intervention, we reflected on the current studies [1–3, 5]. We used a stepwise methodology to identify the highest quality evidence hierarchically and systematically. Using an iterative team approach as outlined by Arksey and O'Malley [11], we focused on reaching consensus, clarity of purpose, and balance between breadth and comprehensiveness of the review in addressing cultural competency intervention. This process involved input from a team outlined below.

### Public patient involvement and engagement

We employed the WHO 2009 definition for a taxonomy [12]: 'a system for organizing information or naming and organizing items into groups that share similar characteristics', in this case, information around cultural competency and clinical variables being impacted in the review. We took the compiled list from the literature review [1–3, 5] and assembled an independent group including three clinicians, and three patient partners to explore the complexity and challenges in engaging with the diverse population to capture the full range of contributory factors across the care pathway. A list was compiled detailing: where the communication problem occurs, the stage

of healthcare delivery that the problem relates to (for example we explored the diagnosis, medication adherence and promoting self-management) and the prevalence of the problem (for example we explored whether certain types of culturally related communication failings had worse patient outcomes).

### Developing the intervention

The research team with expertise in behavioural science, clinical, communication and ethnicity together with the independent group identified areas in the consultation where skills could be used to tailor the interaction and enhance patient-centredness. The independent group suggested online delivery of the intervention, as it would be more flexible and practical, saving clinicians' time and minimizing the costs of delivery. This method of delivery was favoured particularly due to the post-pandemic era, importantly an online delivery would increase the useability and allow broader implementation. Key findings from the independent group and evidence base were synthesized and themes were identified from the cultural factors, relevant to the UK context. This was used to drive the content of the rheumatology-focused intervention programme (disease-specific related content, attitude of HCPs to cultural skills, collaboration and teamwork, effective communication skills, knowledge, skills and performance, society and culture) to the online intervention programme was developed using rheumatology clinical scenarios.

The programme comprised the following topics, with a total duration of around 90 min: brief presentations, reflections, shared experiences by patient representatives and role plays working with a patient partner to demonstrate the challenges of communicating diagnosis or treatment with a patient from a minority ethnic background. The content specifically addressed how HCPs can manage culturally related expectations, attitudes and illness beliefs, using scenarios and videos of patients, enabling HCPs to address complex issues via case studies. Learners were then given some ideas of how to address these challenges and optimize a person-centred approach: (i) identify working definitions of 'culture' and 'cultural diversity'; (ii) support HCPs to reflect on their own attitudes and perceptions (including personal bias) and practices of working with different groups within society; (iii) identify how practitioner culture may influence clinical practice; (iv) reflect on behavioural models and their use of the clinical practice; (v) compare and contrast the clinical scenarios, observing effective interventions to create culturally appropriate services; (vi) reflect on communication strategies including motivational interviewing; (vii) reflect on chronic disease models and integration of those in the ethnic population; and (viii) apply this knowledge and these attitudes to their clinical practice via a series of exercises, noting issues arising from cultural diversity.

### Delivery

Once the content was fully developed, a media specialist assisted with the recording, editing and creation of an online link for the culturally sensitive intervention programme.

Ethical approval was granted by the East of England Cambridge South Research Ethics Committee (300582). HCPs and patients gave written consent before participating in the study once they had the opportunity to ask questions.

### Recruitment

Clinicians' inclusion criteria were: HCP running rheumatology clinics. HCPs were recruited from four National Health Service (NHS) sites in England serving a diverse population. Following the initial e-mail contact to the department offering uptake of the intervention, HCPs who expressed an interest were asked to contact the research team. Consent was obtained before commencing the study.

Patients' inclusion criteria were: patients attending the HCP clinics who agreed to take part in the study. Letters to patients were sent before the hospital visit alerting them of their HCPs undertaking an intervention programme to enhance communication during the consultation. Patients were given contact details for the research team. Those who expressed an interest were approached at the clinic appointment and written consent was obtained once they had the opportunity to ask questions. Some patients had telephone consultation appointments, therefore the consent was sent via the post and questionnaires were read to patients over the telephone. In terms of patient recruitment, patients from 'all' ethnic backgrounds were in a convenience sample to determine whether HCPs' interaction varied between groups. Patients self-reported their ethnicity.

### Data collection from HCPs

HCPs who showed an interest in each centre were enrolled on the study. Before receiving the link to the intervention, all patients were invited to join the study and were allowed a week to think about taking part. Data from a convenience sample of 200 patients were required before the HCPs undertook the intervention, as a baseline. The HCPs were then offered the intervention programme through an online link and were given 1 week to complete the online intervention, which took around 90 min to complete. Each HCP confirmed once training had been completed by sending an e-mail to the Research Associate. Due to clinic appointments and the length of follow-up, we were not able to recruit the same patients to complete the questionnaires (before and after).

Patients were given two questionnaires to rate the interaction: (i) the Patient-Reported Physician Cultural Competency (PRPCC) [13]; and (ii) the Patient Enablement Instrument (PEI) [14]. In total, 200 patients were recruited before the HCPs undertook the intervention and a further 200 (different) patients completed the questions after the HCPs' intervention was complete.

### Sample size

Since there are no culturally sensitive interventional studies in rheumatology, the sample size in this project was derived with two aims in mind, assuming 30% of the patient population to be South Asian: to generate a standard deviation in the South Asian patients, and to be able to perform a multiple linear regression adjusting for four factors.

### Questionnaires

The HCPs completed the validated COM-B questionnaire for capability (C), opportunity (O) and motivation (M) to perform a behaviour (B) before and after intervention [15]. The use of the COM-B questionnaire enabled us to evaluate the success of the intervention.

Our literature review reflection identified the most used valid questionnaires used when testing a culturally tailored

programme to be the PRPCC [13]. This tool, also favoured by our patient steering group, was initially developed for diabetes and has been shown to be valid, reliable and responsive [5]. The tool asks patients to report on the frequency of 13 HCP behaviours previously identified as being important for cultural competency. All responses were scored on a Likert scale [1 = never to 5 = always]. An overall mean score (ranging from 1 = answered 'never' to all questions to 100 = answered 'always' to all questions) can then be generated using the following formula:  $\left(\frac{\text{Overall score}}{13} - 1\right) \times 25$ . In addition to the overall score, there are two subscales within the PRPCC. History-taking questions (1–5) and explaining (6–13). These subscales can also be transformed to give a mean score (ranging from 1 to 100).

The second questionnaire, the 6-item PEI [14], measured 'enablement', a construct that is related to patient experience and satisfaction since it measures whether there has been any achievement of specific health gain, rather than focusing on the extent to which expectations relating to the process of care delivery have been met. Our patient steering group preferred this, as it captured patients' level of motivation to live with a long-term condition and the encouragement they feel has been provided by the HCPs. Patients found the questionnaire user-friendly as such it was a short tool to complete. The questions have five response categories 'much more/better' (score = 2), 'more/better' (score = 1), and 'same', 'less' or 'not applicable' (all score = 0). Therefore, the mean PEI score ranges from 0 to 12 points, with a score of 6 or more being considered 'good'.

### Statistical analysis

The primary measures were PRPCC and PEI [13, 14]. Data are described as counts and percentages (categorical variables) and medians with interquartile ranges or means and s.d. (continuous variables). Comparisons between cohorts were performed using Kruskal–Wallis test or unpaired *t*-tests for continuous variables and  $\chi^2$  test for categorical or Fisher's exact test in the case of small numbers. Tests used are referenced in each table legend. For the COM-B analysis, a paired *t*-test was used. A multivariable linear regression was generated for with the overall scores for the PRPCC and PEI as the dependent variable and all demographic variables and cohort as

explanatory variables. All analyses were performed in Stata SE 15.1. (<https://www.stata.com/stata15/>).

## Results

### Patient characteristics

The HCPs were a mixture of rheumatology consultants (four), trainee doctors (four), nurses (four) and allied health professionals such as physiotherapists (three). In total, 15 HCPs and 400 patients were recruited for this study (Table 1). The HCPs were from a range of different backgrounds, such as white, Chinese and South Asian. COM-B scores indicated HCPs felt more capable, motivated and perceived greater social opportunities to deliver culturally sensitive care after intervention (Table 2). Two hundred patients were recruited before the HCPs undertook the intervention (cohort 1), and 200 were recruited after (cohort 2), from 15 clinics. Data were collected from patients presenting from all ethnic backgrounds. However, there were very few patients from Black and European backgrounds (before = 22) and (after = 14), and since we could not draw any meaningful results from these small numbers, they were excluded from the analysis. Thus, results are described for total of 178 (cohort 1) and 186 (cohort 2) patients.

Patients in the two cohorts were reasonably well matched in terms of gender ( $P = 0.6$ ), employment status ( $P = 0.1$ ), country of birth ( $P = 0.7$ ) and language spoken ( $P = 0.8$ ). No

**Table 2.** Results from the COM-B questionnaire given to healthcare professional prior to and after they received the intervention

	Pre	Post	P-value
Physical opportunity	10.3 (9.9)	10.6 (10.2)	$P = 0.265$
Social opportunity	26.4 (11.0)	64.9 (9.4)	$P < 0.001$
Motivation	55.9 (11.8)	77.1 (10.8)	$P < 0.001$
Automatic motivation	61.5 (14.7)	81.9 (9.9)	$P < 0.001$
Physical capability	54.6 (7.2)	87.0 (6.2)	$P < 0.001$
Psychological capability	55.1 (5.6)	91.9 (5.9)	$P < 0.001$

On average healthcare professionals indicated they served between 40% and 65% of patients from a diverse background in their clinics. Mean (s.d.) for each question is given, along with results of a paired *t*-test. COM-B: capability (C), opportunity (O) and motivation (M) to perform behaviour (B).

**Table 1.** Patient demographics comparing the two cohorts in patients who identify as either white or South Asian

	<i>n</i>	White patients			South Asian patients		
		Cohort 1 120	Cohort 2 120	P-value	Cohort 1 58	Cohort 2 66	P-value
Age	Median (IQR)	58.5 (45–68.5)	57 (47–62)	$P = 0.316^a$	57.5 (50–61)	49 (38–59)	$P = 0.005^a$
Gender	Female, <i>n</i> (%)	83 (69.2)	78 (65.0)	$P = 0.492$	53 (80.3)	45 (77.6)	$P = 0.711$
	Male, <i>n</i> (%)	37 (30.8)	42 (35.0)		13 (19.7)	13 (22.4)	
Employment	In some form of employment, <i>n</i> (%)	71 (59.2)	78 (65.6)	$P = 0.309$	46 (69.7)	43 (74.1)	$P = 0.584$
	Not in employment, <i>n</i> (%)	49 (40.8)	41 (34.5)		20 (30.3)	15 (25.9)	
Country of birth	UK, <i>n</i> (%)	116 (96.7)	112 (93.3)	$P = 0.102^b$	35 (53.0)	34 (58.6)	$P = 0.966^b$
	India, <i>n</i> (%)	1 (0.8)	0		16 (24.2)	14 (24.1)	
	Pakistan, <i>n</i> (%)	0	0		9 (13.6)	6 (10.3)	
	Europe, <i>n</i> (%)	2 (1.7)	8 (6.7)		1 (1.5)	0	
	Other, <i>n</i> (%)	1 (0.8)	0		5 (7.6)	4 (6.9)	
Language Spoken	English, <i>n</i> (%)	119 (99.2)	120 (100)	$P = 0.316^b$	51 (77.3)	42 (72.4)	$P = 0.533$
	Not English, <i>n</i> (%)	1 (0.8)	0		15 (22.7)	16 (27.6)	

<sup>a</sup> Kruskal–Wallis test used to determine *P*-value.

<sup>b</sup> Fisher's exact test used to calculate *P*-value, otherwise a Chi-squared test is used.

significant differences were noted in the average overall PRPCC score between the two cohorts in white patients (57.3 vs 56.8,  $P=0.8$ ). However, in the South Asian patients, average PRPCC scores were higher in cohort 2 compared with cohort 1 (64.1 vs 56.7,  $P=0.014$ ). PEI scores also improved significantly in cohort 2 compared with cohort 1 (7.3 vs 4.3,  $P<0.001$ ) in the white patients, and the percentage of the white increased from 27.5% to 65.0%. Similarly, there was a significant increase in the average PEI score in cohort 2 compared with cohort 1 (8.0 vs 2.2,  $P<0.001$ ) in the South Asian patients (Table 1). For the 33 patients who were not able to complete the questionnaires in English, both the PRPCC and PEI were audio-recorded verbatim on a Dictaphone in Hindi (commonly understood by many South Asian people) by the research team using established guidelines. The audio recording was then played to our patient partners for verification and clarity. They tested the questionnaires using the audio recording and did not encounter any issues. Using Cronbach's alpha, the responses made by those who read the questionnaires in English and those who listened to the audio recording were compared and were not statistically different. Patient demographics such as age, gender, ethnicity, employment, country of birth and language spoken were collected. Two patients only completed the first five questions of the PRPCC and were excluded from the PRPCC analysis. Other missing responses were scored as 0.

### COM-B questionnaire

Before and after intervention, the COM-B scoring did not change for the opportunity for engaging South Asian patients, indicating limited information and resources. However, a difference in HCPs' scoring for the remaining questions was noted after intervention, indicating that HCPs felt more skilled and equipped for consultations. On average HCPs indicated they served between 40% and 65% of patients from a diverse background in their clinics (Table 2).

### PRPCC univariable and regression model

There was no statistically significant difference in the average overall PRPCC score between the two cohorts in white

patients (57.3 vs 56.8,  $P=0.8$ ), or in the sub-domains score (Tables 3 and 4). There was however, a statistically significant improvement in mean PRPCC score in cohort 2 compared with cohort 1 (64.1 vs 56.7,  $P=0.014$ ) in the South Asian patients, suggesting the intervention had made a significant difference to the HCPs skills, when rated by their patients. When examining the mean scores in the sub-domains, there was no significant difference in history-taking (45.3 vs 40.2,  $P=0.2$ ); however, there was a significant difference noted in the explaining sub-domain (75.9 vs 67.1,  $P=0.005$ ), which involved communicating and ensuring that the patients understood what the HCP was saying. A high proportion of both white and South Asian patients reported that the HCPs never informed them about available help in the community and patient support groups. The significant difference between the cohorts remained after adjusting for age, sex and employment status in South Asian patients. Although the intervention made a difference to all patients, South Asian patients noted a beneficial impact to consultation after the HCPs had undertaken the intervention (Tables 3 and 4).

### PEI univariable and regression model

Significant increases were noted in the average overall PEI scores in cohort 2 compared with cohort 1 (7.3 vs 4.3,  $P<0.001$ ), in the white patients, and the percentage of white respondents who scored at least 6 (deemed 'good') increased from 27.5% to 65.0% (Tables 3 and 4).

Similarly, there was a significant increase noted in the average overall PEI score in cohort 2 compared with cohort 1 (8.0 vs 2.2,  $P<0.001$ ) in the South Asian patients, and the percentage of white respondents who scored at least 6 ('good') increased from 12.1% to 71.2%, indicating that the patients reported being more capable of understanding and coping with their health issues in cohort 2 than in cohort 1. In cohort 1, 20–30% of South Asian patients stated that they felt better or much better as a result of their visit to the doctor, whereas in cohort 2, this increased to 70–90%. These differences remained statistically significant even after adjusting for age, gender and employment status.

## Discussion

The culturally sensitive communication intervention in this study exhibited statistically significant enhancements in the cultural competence of HCPs. Notably, this is the first study to develop and assess a culturally sensitive intervention programme specifically tailored for rheumatology practice, leading to notable improvements in the PRPCC and PEI, as reported by patients of South Asian origin. These findings offer a promising avenue for potential improvements in medication adherence and the facilitation of shared decision-making in patient care.

HCPs displayed a commendable willingness to motivate individuals from minority ethnic backgrounds, but they also reported facing resource constraints within their respective departments. The innovative nature of our intervention highlights the value of incorporating psychological and behavioural change strategies, enabling HCPs to effectively understand and address the unique needs of patients from diverse cultural backgrounds.

Our project builds on existing work [1–3, 5] on better understanding cultural dynamics in consultations. Like other specialities, rheumatology HCPs should also have access to

**Table 3.** Results from both sets of questionnaires by ethnicity, the cohort mean score (s.d.) given unless otherwise specified

	Cohort 1	Cohort 2	P-value
White			
PRPCC overall score	56.8 (14.7)	57.3 (21.9)	$P=0.849$
History-taking sub-domain	31.5 (18.2)	36.6 (22.5)	$P=0.056$
Explaining sub-domain	72.5 (15.9)	70.2 (24.9)	$P=0.407$
PEI overall score	4.3 (3.4)	7.3 (3.9)	$P<0.001$
PEI score $\geq 6^a$	33 (27.5%)	78 (65.0%)	$P<0.001$
South Asian			
PRPCC overall score	56.7 (16.0)	64.1 (16.6)	$P=0.014$
History-taking sub-domain	40.2 (19.1)	45.3 (24.1)	$P=0.196$
Explaining sub-domain	67.1 (16.0)	75.9 (17.6)	$P=0.005$
PEI overall score	2.2 (3.3)	8.0 (3.4)	$P<0.001$
PEI score $\geq 6^a$	7 (12.1%)	47 (71.2%)	$P<0.001$

Two patients were excluded from the PRPCC analysis as they only completed five questions.

<sup>a</sup> This is a count and percentage, P-values have been calculated using Chi-squared test. P-values otherwise are calculated using unpaired *t*-tests. The PRPCC overall score, history-taking and explaining sub-domains ranges from 0 to 100, the PEI overall score ranges from 0 to 12. PRPCC: Patient Reported Physician Cultural Competency; PEI: Patient Enablement Instrument.

**Table 4.** Results from multivariable analysis, looking at the overall score of each of the questionnaires

	PRPCC score				PEI score			
	White		Asian		White		Asian	
	$\beta$ (95% CI)	<i>P</i> -value	$\beta$ (95% CI)	<i>P</i> -value	$\beta$ (95% CI)	<i>P</i> -value	$\beta$ (95% CI)	<i>P</i> -value
Age	-0.10 (-0.27, 0.07)	<i>P</i> = 0.233	0.01 (-0.02, 0.05)	<i>P</i> = 0.468	0.01 (-0.02, 0.05)	<i>P</i> = 0.468	0.08 (0.03, 0.13)	<i>P</i> = 0.004
Male gender	4.64 (-0.45, 9.74)	<i>P</i> = 0.074	-0.68 (-1.68, 0.32)	<i>P</i> = 0.183	-0.68 (-1.68, 0.32)	<i>P</i> = 0.183	3.26 (1.89, 4.63)	<i>P</i> < 0.001
Not in employment	5.89 (0.46, 11.31)	<i>P</i> = 0.034	0.04 (-1.03, 1.11)	<i>P</i> = 0.942	0.04 (-1.03, 1.11)	<i>P</i> = 0.942	-1.16 (-2.52, 0.19)	<i>P</i> = 0.091
Cohort 2	0.28 (-4.48, 5.05)	<i>P</i> = 0.907	3.02 (2.08, 3.96)	<i>P</i> < 0.001	3.02 (2.08, 3.96)	<i>P</i> < 0.001	6.54 (5.38, 7.70)	<i>P</i> < 0.001
R <sup>2</sup>	0.0299		0.1815		0.1544		0.5405	
Adjusted R <sup>2</sup>	0.0132		0.154		0.141		0.525	

PRPCC: Patient Reported Physician Cultural Competency; PEI: Patient Enablement Instrument.

cultural intervention if we are to bridge health inequalities and improve patient outcomes. Despite NHS services offering short courses on cultural intervention to HCPs upon joining posts, HCPs report remaining inadequately trained. This suggests a need to evaluate and review the content and measure the impact this has on HCPs' skills and patient outcomes. It also adds to existing calls for all undergraduate health degrees to ensure adequate culturally sensitive intervention for better preparedness to work with diverse populations in future practice [16]. In our previous study, rheumatology HCPs reported that undergraduate education only scratched the surface of cultural sensitivity interventions and did not adequately prepare medical students for future practice [10]. In that study, rheumatology HCPs also reported junior doctors' intervention lacked such content and were at risk of contributing towards widening health inequalities, due to their sub-optimal consultation skills. Moreover, improving HCPs' education through targeted cultural skill-building is crucial as people from minority ethnic backgrounds receive inequitable care in early inflammatory arthritis clinics [7] and have been noted to display different patterns of engagement at the start of the disease journey [7]. Consequently, such intervention could lead to direct translational implications in reducing disparities among diverse rheumatology patient groups. To ensure this agenda reaches educational commissioners, the next steps would be to test the long-term impact and cost-effectiveness of this intervention, however this would take time and the results show that with a brief (90-min) intervention package, clinicians can improve their clinical competency and crucially, their patients' experiences.

### Limitations

We acknowledge the potential limitations of this study. It is plausible that the HCPs who participated in the study were those driven by a motivation to address health inequalities, while certain HCPs might have lacked the confidence to partake in the study. Moreover, the demanding nature of clinical workloads could have posed obstacles for some individuals to engage in the study. Furthermore, the recruitment of patients failed to adequately represent other ethnic groups, including African-Caribbean, Somali and Chinese populations. The duration of the intervention was insufficient to assess the longitudinal impact on the HCPs' enduring skills or measure outcomes such as enhanced medication adherence. Consequently, a subsequent longitudinal investigation is imperative in the future.

### Conclusion

Our findings make a noteworthy contribution to the advancement of cultural competency interventions centred around behavioural change. Importantly, we have made the intervention programme freely accessible for implementation within the broader realms of the British Society for Rheumatology, EULAR and the ACR registrations, thereby fostering wider dissemination and utilization of this valuable resource.

### Data availability

Data will be provided by the corresponding author on reasonable request.

### Funding

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# Consistent safety profile with over 8 years of real-world evidence, across licensed indications<sup>1-3</sup>



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**100+** clinical trials\*<sup>5</sup>



**8+** years of real-world evidence<sup>1-3</sup>



**8** indications<sup>1-3</sup>



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## Real-world evidence shows a consistent safety profile over 6 years<sup>6,7</sup>

No trend toward increased AE rates over time (pooled PsA, AS, PsO):<sup>16</sup>

AEs of select interest (EAIR per 100 PY)	1 year	2 years	3 years	4 years	5 years	6 years	Cumulative rate
Serious infections Cases	2.0 n=149	1.7 n=475	0.7 n=649	1.3 n=1,841	1.3 n=2,285	1.1 n=2,226	1.3 n=8,719
Malignant or unspecified tumours Cases	0.2 n=15	0.2 n=50	0.2 n=225	0.3 n=422	0.3 n=520	0.3 n=573	0.3 n=1,896
MACE Cases	0.2 n=15	0.1 n=39	0.2 n=151	0.2 n=238	0.2 n=264	0.1 n=287	0.2 n=1,031
Total IBD Cases	0.2 n=12	0.2 n=46	0.2 n=185	0.3 n=340	0.2 n=312	0.1 n=261	0.2 n=1,291
Exposure (PY)	7450	28,549	93,744	137,325	182,024	212,636	680,470

**No trend towards increased rates of malignancy, MACE or IBD over time<sup>6</sup>**

**The most frequently reported adverse reactions are upper respiratory tract infections (17.1%) (most frequently nasopharyngitis, rhinitis).<sup>1,2</sup> Refer to the prescribing information for a summary of adverse events.**

Adapted from Novartis Data on File. 2021.<sup>6</sup>

**Refer to the Cosentyx Summary of Product Characteristics for full details, dosing and administration, including special populations.**

**Cosentyx® (secukinumab) licensed indications in rheumatology:** Cosentyx, alone or in combination with methotrexate, is indicated for the treatment of active **psoriatic arthritis** in adult patients when the response to previous disease-modifying anti-rheumatic drug therapy has been inadequate; active **ankylosing spondylitis** in adults who have responded inadequately to conventional therapy; active **non-radiographic axial spondyloarthritis** with objective signs of inflammation as indicated by elevated C-reactive protein and/or magnetic resonance imaging evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active **enthesitis-related arthritis** in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate conventional therapy; active **juvenile psoriatic arthritis** in patients 6 years or older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy.<sup>1,2</sup>

**Prescribing information, adverse event reporting and full indication can be found on the next page.**

\*Patients prescribed Cosentyx for any indication since launch.

<sup>1</sup>Successive time periods of PSUR shown with cumulative rate: 26 Dec 2014 to 25 Dec 2015; 26 Dec 2015 to 25 Dec 2016; 26 Dec 2016 to 25 Dec 2017; 26 Dec 2017 to 25 Dec 2018; 26 Dec 2018 to 25 Dec 2019; 26 Dec 2019 to 25 Dec 2020.<sup>6</sup>

**Abbreviations:** AE, adverse event; AS, ankylosing spondylitis; EAIR, exposure-adjusted incidence rate; HCP, healthcare professional; IBD, inflammatory bowel disease; MACE, major adverse cardiac event; PsA, psoriatic arthritis; PsO, plaque psoriasis; PY, patient year.

**References:** **1.** Cosentyx® (secukinumab) GB Summary of Product Characteristics; **2.** Cosentyx® (secukinumab) NI Summary of Product Characteristics; **3.** European Medicines Agency. European public assessment report. Available at: [https://www.ema.europa.eu/en/documents/overview/cosentyx-epar-medicine-overview\\_en.pdf](https://www.ema.europa.eu/en/documents/overview/cosentyx-epar-medicine-overview_en.pdf) [Accessed February 2024]; **4.** Novartis Data on File. Secukinumab – Sec008. 2023; **5.** Novartis. Novartis Cosentyx® positive 16-week PREVENT results advance potential new indication for patients with axial spondyloarthritis. Available at: <https://www.novartis.com/news/media-releases/novartis-cosentyx-positive-16-week-prevent-results-advance-potential-new-indication-patients-axial-spondyloarthritis> [Accessed February 2024]; **6.** Novartis data on file. Cosentyx Periodic Safety Update Report (PSUR); 26 December 2019 – 25 December 2020. 22 February 2021; **7.** Deodhar A, et al. Arthritis Res Ther 2019;21(1):111.



## **Cosentyx® (secukinumab) Northern Ireland Prescribing Information.**

### **Please refer to the Summary of Product Characteristics (SmPC) before prescribing.**

**Indications:** Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active enthesitis-related arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Presentations:** Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. **Plaque Psoriasis:** Adult recommended dose is 300 mg monthly. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight  $\geq 50$  kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight  $< 50$  kg, recommended dose is 75 mg. However, 150mg solution for injection in pre-filled pen is not indicated for administration of this dose and no suitable alternative formulation is available. **Psoriatic Arthritis:** For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNF $\alpha$  inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. **Ankylosing Spondylitis:** Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. **nr-axSpA:** Recommended dose 150 mg. **Enthesitis-related arthritis and juvenile psoriatic arthritis:** From the age of 6 years, if weight  $\geq 50$  kg, recommended dose is 150 mg. If weight  $< 50$  kg, recommended dose is 75 mg.

## **Cosentyx® (secukinumab) Great Britain Prescribing Information.**

### **Please refer to the Summary of Product Characteristics (SmPC) before prescribing.**

**Indications:** Treatment of: moderate to severe plaque psoriasis in adults, children and adolescents from the age of 6 years who are candidates for systemic therapy; active psoriatic arthritis in adults (alone or in combination with methotrexate) who have responded inadequately to disease-modifying anti-rheumatic drug therapy; active ankylosing spondylitis in adults who have responded inadequately to conventional therapy; active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs; active enthesitis-related arthritis and juvenile psoriatic arthritis in patients 6 years and older (alone or in combination with methotrexate) whose disease has responded inadequately to, or who cannot tolerate, conventional therapy; active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Presentations:** Cosentyx 75 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled syringe; Cosentyx 150 mg solution for injection in pre-filled pen; Cosentyx 300 mg solution for injection in pre-filled pen. **Dosage & Administration:** Administered by subcutaneous injection at weeks 0, 1, 2, 3 and 4, followed by monthly maintenance dosing. Consider discontinuation if no response after 16 weeks of treatment. Each 75 mg dose is given as one injection of 75 mg. Each 150 mg dose is given as one injection of 150 mg. Each 300 mg dose is given as two injections of 150 mg or one injection of 300 mg. If possible avoid areas of the skin showing psoriasis. **Plaque Psoriasis:** Adult recommended dose is 300 mg. Based on clinical response, a maintenance dose of 300 mg every 2 weeks may provide additional benefit for patients with a body weight of 90 kg or higher. Adolescents and children from the age of 6 years: if weight  $\geq 50$  kg, recommended dose is 150 mg (may be increased to 300 mg as some patients may derive additional benefit from the higher dose). If weight  $< 50$  kg, recommended dose is 75 mg. **Psoriatic Arthritis:** For patients with concomitant moderate to severe plaque psoriasis see adult plaque psoriasis recommendation. For patients who are anti-TNF $\alpha$  inadequate responders, the recommended dose is 300 mg, 150 mg in other patients. Can be increased to 300 mg based on clinical response. **Ankylosing Spondylitis:** Recommended dose 150 mg. Can be increased to 300 mg based on clinical response. **nr-axSpA:** Recommended dose 150 mg. **Enthesitis-related arthritis and juvenile psoriatic arthritis:** From the age of 6 years, if weight  $\geq 50$  kg, recommended dose is 150 mg. If

weight  $< 50$  kg, recommended dose is 75 mg. **Hidradenitis suppurativa:** Recommended dose is 300 mg monthly. Based on clinical response, the maintenance dose can be increased to 300 mg every 2 weeks. **Contraindications:** Hypersensitivity to the active substance or excipients. Clinically important, active infection. **Warnings & Precautions:** Infections: Potential to increase risk of infections; serious infections have been observed. Caution in patients with chronic infection or history of recurrent infection. Advise patients to seek medical advice if signs/symptoms of infection occur. Monitor patients with serious infection closely and do not administer Cosentyx until the infection resolves. Non-serious mucocutaneous candida infections were more frequently reported for secukinumab than placebo in the psoriasis clinical studies. Should not be given to patients with active tuberculosis (TB). Consider anti-tuberculosis therapy before starting Cosentyx in patients with latent TB. **Inflammatory bowel disease (including Crohn's disease and ulcerative colitis):** New cases or exacerbations of inflammatory bowel disease have been reported with secukinumab. Secukinumab, is not recommended in patients with inflammatory bowel disease. If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, secukinumab should be discontinued and appropriate medical management should be initiated. **Hypersensitivity reactions:** Rare cases of anaphylactic reactions have been observed. If an anaphylactic or serious allergic reactions occur, discontinue immediately and initiate appropriate therapy. **Vaccinations:** Do not give live vaccines concurrently with Cosentyx; inactivated or non-live vaccinations may be given. Paediatric patients should receive all age appropriate immunisations before treatment with Cosentyx. **Latex-Sensitive Individuals:** The removable needle cap of the 150mg pre-filled pen contains a derivative of natural rubber latex. **Concomitant immunosuppressive therapy:** Combination with immunosuppressants, including biologics, or phototherapy has not been evaluated in psoriasis studies. Cosentyx was given concomitantly with methotrexate, sulfasalazine and/or corticosteroids in arthritis studies. Caution when considering concomitant use of other immunosuppressants. **Interactions:** Live vaccines should not be given concurrently with secukinumab. No interaction between Cosentyx and midazolam (CYP3A4 substrate) seen in adult psoriasis study. No interaction between Cosentyx and methotrexate and/or corticosteroids seen in arthritis studies. **Fertility, pregnancy and lactation:** **Women of childbearing potential:** Use an effective method of contraception during and for at least 20 weeks after treatment. **Pregnancy:** Preferably avoid use of Cosentyx in pregnancy. **Breast feeding:** It is not known if secukinumab is excreted in human breast milk. A clinical decision should be made on continuation of breast feeding during Cosentyx treatment (and up to 20 weeks after

discontinuation) based on benefit of breast feeding to the child and benefit of Cosentyx therapy to the woman. **Fertility:** Effect on human fertility not evaluated. **Adverse Reactions:** *Very Common* ( $\geq 1/10$ ): Upper respiratory tract infection. *Common* ( $\geq 1/100$  to  $< 1/10$ ): Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon* ( $\geq 1/1,000$  to  $< 1/100$ ): Oral candidiasis, lower respiratory tract infections, neutropenia, inflammatory bowel disease. *Rare* ( $\geq 1/10,000$  to  $< 1/1,000$ ): anaphylactic reactions, exfoliative dermatitis (psoriasis patients), hypersensitivity vasculitis. *Not known:* Mucosal and cutaneous candidiasis (including oesophageal candidiasis). **Infections:** Most infections were non-serious and mild to moderate upper respiratory tract infections, e.g. nasopharyngitis, and did not necessitate treatment discontinuation. There was an increase in mucosal and cutaneous (including oesophageal) candidiasis, but cases were mild or moderate in severity, non-serious, responsive to standard treatment and did not necessitate treatment discontinuation. Serious infections occurred in a small proportion of patients (0.015 serious infections reported per patient year of follow up). **Neutropenia:** Neutropenia was more frequent with secukinumab than placebo, but most cases were mild, transient and reversible. Rare cases of neutropenia CTCAE Grade 4 were reported. **Hypersensitivity reactions:** Urticaria and rare cases of anaphylactic reactions were seen. **Immunogenicity:** Less than 1% of patients treated with Cosentyx developed antibodies to secukinumab up to 52 weeks of treatment. **Other Adverse Effects:** The list of adverse events is not exhaustive, please consult the SmPC for a detailed listing of all adverse events before prescribing. **Legal Category:** POM. **MA Number & List Price:** PLGB 00101/1205 – 75 mg pre-filled syringe x 1 - £304.70; PLGB 00101/1029 – 150 mg pre-filled pen x2 £1,218.78; PLGB 00101/1030 – 150 mg pre-filled syringe x2 £1,218.78; PLGB 00101/1198 – 300 mg pre-filled pen x 1 £1218.78. **PI Last Revised:** June 2023. Full prescribing information, (SmPC) is available from: Novartis Pharmaceuticals UK Limited, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Telephone: (01276) 692255.

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