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Editorial

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Editorial

Evidencing the clinical and economic burden of musculoskeletal disorders in Tanzania: paving the way for urgent rheumatology service development

This editorial refers to 'Musculoskeletal (MSK) disorders with arthritis screening in Tanzania: new insights into the growing clinical, economic and societal burden of non-communicable disease', by Mmbaga BT *et al.*, https://eprints.gla.ac.uk/300074/.

Since 1990, there has been a dramatic rise in non-communicable diseases (NCDs) within low- and middle-income countries (LMICs); the burden of NCDs in LMICs rose from accounting for 39% of disability-adjusted life years in 1990 to 66% in 2019 [1]. In response to this growing burden, global, regional and national health institutions have become increasingly active in orchestrating a response to NCDs. The global response to NCDs has prioritized cardiovascular disease, cancer, chronic respiratory disease and diabetes, with the World Health Organization Regional Office in Africa adding region-specific NCD burdens, such as sickle cell disease, to broaden priorities [2]. Amidst this galvanization of efforts to tackle NCDs, musculoskeletal (MSK) conditions have been relatively overlooked and neglected, resulting in an urgent need for service development to respond to MSK conditions in LMICs [1].

The low status of MSK conditions within the health landscape does not align with the burden of MSK conditions [1]. MSK conditions represented 17% of years lived with disability in 2019 globally and 'account[ed] for more than 75% of disease burden for NCDs and injuries for the poorest billion people aged 5–50 years and greater than 40 years' [1]. Furthermore, in LMICs, the prevalence of MSK conditions increased by 60% between 1990 and 2010 [3]. It is anticipated this upward trend will continue, with the future impacts of MSK disorders in LMICs set to be compounded by demographic and lifestyle changes [3]. Although regional summary health estimates can help to illustrate the broad health, economic and social impacts of MSK conditions, the lack of empirical data from LMICs might be underestimating or misrepresenting the burden [4]. Here, place-specific understanding of the impacts of MSK conditions is vital to implementation of increased and tailored resourcing to improve health workforce knowledge and training, therapy availability, treatment guidelines and appropriate, contextually informed interventions and support [1, 5].

Better place-specific understanding is crucial; although global health impacts are estimated, and biological markers of MSK are universal, MSK conditions are experienced and mediated in place and shaped by social worlds, cultural norms and the ability of health systems to treat individuals, all of which influence the understanding and impacts of MSK conditions [5, 6]. In Tanzania, the inaugural *Strategic and Action Plan for the Prevention and Control for the Prevention and Control of Non-Communicable Diseases in Tanzania* (2016–2020) laid out the need for the health service to expand its focus on communicable diseases to include NCDs; it made little mention of MSK conditions, reflective of the global policy landscape. Recent UK National Institute for Health (NIHR)-funded research, however, has shed light on the prevalence and the clinical and economic burden of MSK disorders [5, 7].

As sketched out by Kilonzo *et al.* [8], a multidisciplinary approach established critical prevalence data and economic, social and cultural impacts for those living with MSK conditions (see Fig. 1). Although retrospective analysis of hospital records reveals a huge underdiagnosis of MSK disorders within the health system [5], clinical screening of >2500 households within the Hai District of Tanzania found 1 in 17 people (5.9%) living with confirmed joint problems; 1 in 20 (5%) with degenerative 'wear and tear' arthritis, and 1 in 100 with inflammatory arthritis [5]. Those living with confirmed joint problems experienced significant economic impacts, incurring two to three times higher health-care costs than those without MSK conditions. For many with MSK disorders, this involved spending >10% of their income on health care, surpassing the World Health Organization's classification of 'catastrophic' health-care expenditure, where their ability to meet basic needs becomes compromised [5]. Economic impacts were coupled with, and compounded by, a reduced ability to work, causing stress and worry [6]. The associated pain and restriction of joint movement reduced the ability of an individual to conduct essential self-care (from going to the toilet to cleaning themselves) or partaking in social and community events; the cumulative effect was found to cause a 25% reduction in the health-related quality of life of those with MSK conditions compared with those without [5].

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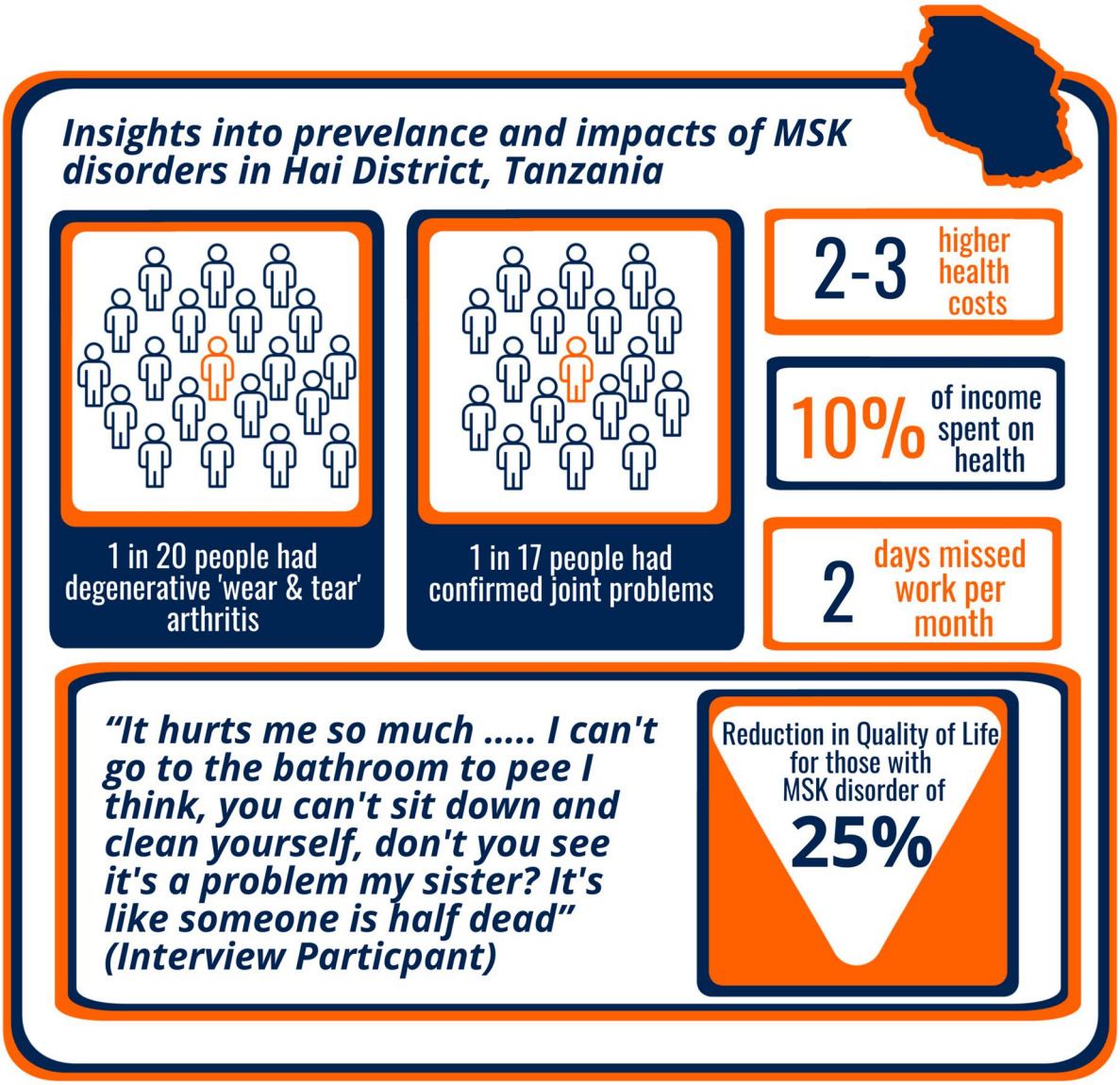

Figure 1. Insights into the prevalence and impact of musculoskeletal disorders in Hai District, Tanzania. After Mmbaga *et al.* (2023) [5]. MSK: musculoskeletal

Such insights reveal, for the first time, the full extent of the clinical and resulting economic burden of MSK disorders within parts of Tanzania, a burden only set to rise as demographic and lifestyle changes play out over the coming decades and which will, no doubt, be replicated throughout the country and region [3]. To respond to the growing burden, we call for ensuring MSK disorders are included in the suite of NCD challenges faced by LMICs to ensure that policies are devised to address the evidenced burdens. As detailed elsewhere, models of care for MSK disorders require multilevel responses [9]. Our findings in Tanzania reinforce this call; central to this, we recommend increased training for health workers at all levels to improve the diagnosis and management of MSK conditions. We suggest incorporating MSK diagnostic training within university curricula, continuous professional development programmes, and support for specialist training [3]. To do so effectively requires practical training resources appropriate for populations, including visual training aids that illustrate how MSK disorders display in diverse populations [10] and the development of clinical guidelines and treatment options suited to places and populations [3].

To do so requires recognition and prioritization of MSK disorders in NCD initiatives. For decades, with a rigid focus on infectious diseases, there existed a category dubbed 'neglected tropical diseases'; we must ensure that as the health policy agenda opens up to respond to NCDs, we do not replicate a similar class of neglected NCDs, of which MSK conditions are at risk of being the foremost.

Data availability

Summary data are available on request.

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ULTIMATE (N=166), a multicentre, randomised, double-blind, placebo-controlled, 52-week Phase III trial in patients with PsA. Patients were randomly assigned to receive either weekly subcutaneous Cosentyx (300 mg or 150 mg according to the severity of psoriasis) or placebo followed by 4-weekly dosing thereafter. The primary outcome of mean change in the ultrasound GLOESS from baseline to Week 12 was met (−9 vs −6; p=0.004).[2,3]
MATURE (N=122), a 52-week, multicentre, double-blind, randomised, placebo-controlled, Phase III trial in patients with PsO. Eligible patients were randomised to Cosentyx 300 mg or placebo. The co-primary endpoints were PASI75 and IGA mod 2011 0/1 responses at Week 12. The study met the co-primary endpoints: PASI75 and IGA mod 2011 0/1 response at Week 12 were met for Cosentyx 300 mg vs placebo (95% vs 10% and 76% vs 8% respectively, p<0.0001).[4]
MAXIMISE (N=498) a double blind, placebo-controlled, multicentre, Phase IIIb study in patients with PsA. Patients were randomised in a 1:1:1 ratio to receive Cosentyx 300 mg, 150 mg or placebo. The primary endpoint of the proportion of patients achieving and ASAS20 response with Cosentyx 300 mg at Week 12 vs placebo was met (63% vs 31% respectively, p<0.0001).[1]

ACR, American College of Rheumatology; AI, auto-injector; ASAS, Assessment of SpondyloArthritis International Society; BASDAI, Bath; ankylosing spondylitis disease activity index; EULAR, European Alliance of Associations for Rheumatology; GLOESS, Global EULAR and OMERACT synovitis score; IGA mod 2011 0/1, investigator global assessment modified 2011 0/1; OMERACT, outcome measures in rheumatology; PASI, psoriasis area and severity index; PsA, psoriatic arthritis; PsO, plaque psoriasis.

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

UK | May 2024 | 425034

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 ≥ 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-TNFα 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 ≥ 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 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 75mg and 150 mg pre-filled syringe and 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 (≥1/10):* Upper respiratory tract infection. *Common (≥1/100 to <1/10):* Oral herpes, headache, rhinorrhoea, diarrhoea, nausea, fatigue. *Uncommon (≥1/1,000 to <1/100):* Oral candidiasis, lower respiratory tract infections, neutropenia, inflammatory bowel disease. *Rare (≥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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If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com

Cosentyx® (secukinumab) Northern Ireland Prescribing Information.

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Adverse Event Reporting:

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report

If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com