should be considered as a substantial ‘red flag’, as both drugs target IL-23p19 and are used in more or less identical populations with regard to psoriasis severity, patient demographics and comorbidity profiles. While data from FAERS are based on spontaneous postmarketing reporting and lack a denominator, this is actually a further worry as it would suggest that the risk associated with risankizumab may be even greater than that which was recently suggested.[5] Since guselkumab was approved in July 2017, a total of 35 CVA cases (24 cases occurring in patients with psoriasis) were reported in patients treated with this drug.[5] Conversely, while risankizumab has been on the market only since April 2019 (for almost 2 years less than guselkumab), 176 cases of CVA (164 cases occurring in patients with psoriasis) have been reported with risankizumab.[5] Thus, even if the psoriasis market share (i.e. the denominator) of risankizumab were six times greater than guselkumab, the exposure time would still be almost 2 years shorter with risankizumab. However, any plausible biologic mechanism for an increased risk with risankizumab remains unclear. FAERS is not without its limitations and events are more likely to be reported in newly marketed products. Moreover, duplicate reporting can also occur in FAERS. Importantly, patients treated with newly available drugs, such as risankizumab, are more likely to be multifailure patients, i.e. those with long disease duration and higher disease severity.

On 19 February 2009, both the FDA and the European Medicines Agency issued statements about risk of progressive multifocal leucoencephalopathy associated with efalizumab in patients with psoriasis.[6] This was based on a very small number of events that occurred after long-term exposure and after the drug had already been approved for several years. On 8 April 2009 efalizumab was withdrawn from the market.[6] Not only did this cause concern among dermatologists, but it also highlighted the importance of postapproval studies and the need to continuously monitor the safety of a drug, not just in clinical trials, but also during the entire life cycle of that drug. While the findings in FAERS are not in themselves sufficient to provide definitive answers, the signal of a potentially serious risankizumab safety issue is important. However, because of this initial observation, future real-world studies now risk being affected by confounding by indication, as dermatologists are now going to be less likely to prescribe risankizumab in patients with a particularly high cardiovascular risk profile out of fear of inducing a CVA. Consequently, future patients treated with risankizumab are likely to be ‘healthier’, i.e. with a lower baseline risk, which may lead to an artificially low risk of CVA in future observational studies. Such channelling bias is not only inevitable, but indeed necessary. When a signal such as this appears, caution should be exercised until a clear picture emerges of whether certain patient subgroups are at increased risk. However, based on clinical trial data, IL-23 class drugs are generally considered some of the safest psoriasis therapies currently available. Therefore, while these initial data should raise a ‘red flag’ for clinicians, there is a need for prospective long-term multinational observational studies to fully understand whether there really is a safety issue. Regardless of whether such studies will confirm these initial observations, for now at least, increased awareness of a potential CVA risk with risankizumab treatment is warranted.

Alexander Egeberg[1,2] **and Jacob P. Thyssen**[1]

[1]Department of Dermatology, Copenhagen University Hospital – Bispebjerg, Copenhagen, Denmark and [2]Department of Clinical Medicine, University of Copenhagen, Copenhagen, Denmark

Correspondence: Alexander Egeberg. Email: alexander.egeberg@gmail.com

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The unbreakable journey: using photovoice to raise awareness and fight leprosy stigma in Papua, Indonesia

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Leprosy is a neglected tropical skin disease (skin-NTD) affecting the skin and peripheral nerves. Worldwide, reported new cases remain stable at around 200 000 per year.[1] Although leprosy is curable, if insufficiently managed, it can result in permanent disabilities. An estimated 3–4 million people globally live with some form of disability because of leprosy, causing discomfort, disfigurement and loss in quality of life.[1] People affected by leprosy, and their family members, are often heavily stigmatized, as myths and misconceptions surround the disease.[2] The discrimination and physical disabilities faced by people with leprosy can limit opportunities to fully participate in education, employment and society.

Indonesia has the third highest number of people with leprosy in the world. Annually, over 17 000 new cases are identified nationwide, with high endemic pockets in eastern Indonesia. In preparation of a randomized trial evaluating adjunctive metformin to mitigate leprosy reactions (MetLep, clinicaltrials.gov: NCT05243654), we conducted a community engagement project to raise public awareness, promote critical dialogue, and reach policymakers about issues and concerns related to leprosy.

We used photovoice, which is a creative, participatory visual method, developed by Wang and Burris in the 1990s, to explore community health and social issues among disadvantaged populations.[3] In photovoice, community members use photographic images that are taken and selected by themselves to capture aspects of their lives and environment, enabling them to represent and enhance their community, and giving them a voice to influence society and policymakers with the intention to provoke public debate and stimulate change.[4] Photovoice has been implemented in vulnerable and minority populations around the world to deepen understandings of community concerns and to critically reflect on public health issues,[3] for example refugees,[5] people with mental or physical disabilities[6] or those with chronic conditions, like HIV/AIDS.[7]

In January 2022, 30 persons with leprosy, their family members and healthcare workers volunteered to take pictures of their daily activities, everyday health and life conditions to document their concerns, struggles and strengths. They were guided through the process to provide narratives for the images through facilitated group discussions. Individual photographs were discussed for their meaning, contextualization and importance. Participants were encouraged to select three to five of their most compelling images to be exhibited during a photo exhibition in Jayapura, the capital of Papua province, to acknowledge World Leprosy Day (Figure 1). Over 250 people visited the exhibition, comprising community leaders, religious groups, nongovernmental organizations and local government officials. The images were compiled into a video that was broadcast at different venues throughout the city (https://www.youtube.com/watch?v=IYDTwt7vnRs). All participants provided written informed consent. Short interviews and feedback surveys were conducted among participants and visitors for evaluation.

This project generated opportunities to visualize the stigma and misunderstandings that people with leprosy face, and the social and mental burden this puts on them and those around them. Kristian, a family member, explained that his family abandoned their cousin, who was affected by leprosy. He regrets his past actions: '*If I could turn back time, I would not have let my cousin fight alone against leprosy.*' Participants reflected that they felt 'heard' after sharing their photos and stories with others. Daniel, a person with leprosy, disclosed, '*My mother pushed me to join this project and meet others who are affected by leprosy. People were interested to hear my story. It gave me confidence.*' A visitor attending the photo exhibition commented: '*Seeing the images and talking to the participants gives insight and meaning to their lives*.'

Photovoice is a powerful communication tool for health promotion and advocacy. A project among Maasai women in Tanzania to prevent and manage trachoma offers a great example of how the method helped to educate and empower the women to share their knowledge within their own communities.[8] In Nigeria and Liberia, the methodology was used to help people affected by severe stigmatizing skin diseases, including leprosy, to identify challenges and design peer-led solutions to improve community health and wellbeing (https://www.sightsavers.org/from-the-field/2021/05/living-with-skin-ntds/). To our knowledge, this is the first peer-reviewed publication on the use of photovoice in people with a skin disease.

Photovoice can empower underprivileged populations, including people with stigmatizing skin diseases, such as skin-NTDs or psoriasis, to gain a voice and address the needs of their society. It encourages participants to engage with the wider public and promote social change. Our project, set in a Papuan community, has helped to express the lived experiences and perspectives of people affected by leprosy and their household members. The project allowed them to connect with the community and local policymakers through the dissemination of their photographs and narratives demonstrating the devastating impact leprosy has on their lives. Experiences from this project are also valuable to optimize the acceptance of the MetLep Trial in the same communities.

Ragil Dien,[1] Hana Krismawati,[2] Ivon Ayomi,[2] Diana Timoria,[1] Mary Chambers,[3,4] Hardyanto Soebono[5] and Marlous L. Grijsen[1,4]

[1]Oxford University Clinical Research Unit Indonesia, Faculty of Medicine Universitas Indonesia, Jakarta, Indonesia; [2]National Institute of Health Research and Development (NIHRD), Jayapura, Papua, Indonesia; [3]Oxford University Clinical Research Unit, Ho Chi Minh City, Vietnam; [4]Centre for Tropical Medicine and Global Health, Nuffield Department of Medicine, University of Oxford, Oxford, UK and [5]Department of Dermatology and Venereology, Gadjah Mada University, Yogyakarta, Indonesia

Correspondence: Marlous Grijsen. Email: mgrijsen@oucru.org

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Figure 1 A compilation of three photographs plus captions that were presented by participants during the photo exhibition in Jayapura, Papua province, Indonesia, during World Leprosy Day 2022 [for privacy reasons, the original names of participants have been changed]. (a) Benjamin was fond of playing soccer since he was a child. He was selected to attend a football training abroad. Around the same time, he was diagnosed with leprosy. '*I was confused what to do. I decided to take care of my health and stopped playing soccer.*' (b) Maria, a healthcare worker, was afraid of leprosy. '*One day when I parked my motorbike in front of the supermarket, a security officer approached me. I saw that some of his fingers were missing and knew it was leprosy. Back home, I washed my motorbike. I was afraid of getting the disease. I know better now. Leprosy is not transmitted this way and requires close contact for a long period of time.*' (c) Johan, a person affected by leprosy: '*I was often invited to drink alcohol with my friends. In the beginning, I was able to refuse, as I was still on multi-drug therapy. But over time, I was influenced by the group and started drinking again. I lost the discipline to take my medication regularly. After some time, I motivated myself and stopped drinking to finish the treatment.*'

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