Why do we need PRO EDI?

Systematic reviews shape healthcare guidance, research priorities, and policy decisions by bringing together findings from multiple clinical trials. Because these reviews underpin how evidence is interpreted and applied, it is vital that they consider equity, diversity, and inclusion (EDI) explicitly. Without this, reviews may overlook which populations the evidence truly represents, leading to conclusions that are less relevant for certain groups.

PRO EDI (https://www.trialforge.org/trial-diversity/pro-edi/) is an initiative led by Trial Forge (https://www.trialforge.org), Evidence Synthesis Ireland (https://evidencesynthesisireland.ie), and the Campbell Collaboration (https://www.campbellcollaboration.org). Its goal is to make EDI an explicit part of evidence synthesis by providing a standardised participant characteristics table plus guidance that help reviewers to record, summarise, and interpret participant characteristics, particularly sex, age, ethnicity, socioeconomic status, and location, so that users of systematic reviews can see who is represented in the evidence and where important gaps remain. PRO EDI emphasises not just collecting participant characteristics but also performing subgroup analyses when sufficient data exists. This analytical approach transforms data into insights that will improve reviews and the guideline recommendations that come from them, ensuring treatments are safe and effective across diverse populations.

Collecting participant characteristics is essential because treatment outcomes can vary significantly across groups. For example, females experience roughly twice as many adverse drug reactions as males due to differences in metabolic enzyme activity and hormone-mediated drug clearance. The sleep medicine zolpidem (Ambien) caused cognitive impairment in women at standard doses but not in men, leading to sex-specific dosing guidelines[1,2]. This highlights the importance of sex-stratified analyses to uncover safety and efficacy differences that pooled results might mask. Ethnicity is another example of a characteristic which impacts drug metabolism. Genetic variations in enzymes lead to wide differences in how opioids are metabolised, with poor metaboliser frequencies ranging from about 1% in Asian populations to over 30% in some African groups[3]. Analyses that include ethnicity can help identify differential treatment responses, informing tailored prescribing and monitoring. A table with more examples of how treatment or baseline disease risk can vary according to participant characteristics is provided below.

Although PRO EDI was designed for systematic reviews of randomised controlled trials, its principles apply equally to trial design. Integrating the framework early in the research process ensures that diversity is captured from recruitment through to analysis. This enriches trials, future evidence syntheses and increases confidence that healthcare decisions benefit all people, not just some.

PRO EDI Characteristic	Example of difference in treatment or baseline risk of disease or outcome
Age	Older adults often require lower starting doses for medications due to decreased renal clearance, reduced liver metabolism, and increased drug sensitivity. For example, digoxin dosing is reduced in elderly patients to avoid toxicity due to decreased renal clearance with age. Changes in how the body handles drugs affect many medications. This makes standard adult doses unsafe without adjustment, independent of body weight[4,5].
	Chronic kidney disease prevalence increases significantly with age. In England, about 2% of those aged 64 and under have chronic kidney disease. This number increases to 14% for people aged 65 to 74 and reaches around 33% for those aged 75 and older. Age also affects the risk factors and outcomes related to chronic kidney disease. Younger patients tend to progress to kidney failure more often, while older patients have a higher chance of dying from other causes before reaching kidney failure. Therefore, doctors are increasingly adjusting prognosis and treatment plans based on a patient's age [6,7].
	Older age is related to patients' response and uptake of cancer treatments. Older adults (those aged over 65) tend to have higher number of new cancer diagnosis.[8,9] However, older adults looked to have differences in their immune systems responses for Immune Checkpoint Inhibitor (ICI) treatments compared to younger patients, yet they are underrepresented in clinical trials.[9] Additionally, those aged over 80 years may be less likely to receive cancer treatment or palliative hospital care then younger patients (aged under 60).[10]
Sex	Females have a four times higher risk of developing autoimmune diseases like rheumatoid arthritis, multiple sclerosis, and systemic lupus erythematosus. This difference may come from how immune system regulation varies by sex, including the influence of X-linked genes and sex hormones such as estrogen, which can improve certain immune responses and increase susceptibility to autoimmune disease[11].
	Females consistently experience about twice as many negative drug reactions as males across various drug classes. For instance, the standard dose of zolpidem (Ambien) caused cognitive impairment in women, which led to the development of dosing guidelines based on sex. These differences can't be fully explained by body weight or size. Instead, they often come from variations in metabolic enzymes and hormone-driven differences in how drugs are absorbed and cleared. As a result, female patients might face side effects or toxicity even when doses are adjusted for body weight[1,2].
	Male breast cancer is rare, and most clinical trials focus on breast cancer in women. Male breast cancer represents roughly 1% of all breast cancers in the world.[12] Research has demonstrated there may be different genetic variation between males and females.[12,13] Male breast cancer is often diagnosed at a later stage compared to females.[12] Treatment

	options for Male Breast Cancer has mainly been focussed on adapting female-tested treatments and approaches for this group.[12,13]
Gender	Women with cardiovascular disease symptoms are much more likely than men to be misdiagnosed with anxiety or panic disorders. This often leads to delays in getting referred to cardiology and receiving treatment. For instance, in the UK, women have a 50% chance of being misdiagnosed when experiencing a heart attack, compared to men. Such delays heighten the risk of lasting heart muscle damage and death. In addition to differences in how symptoms appear, women are often more likely to have their symptoms dismissed or attributed to anxiety or other non-cardiac causes[14].
	Transgender and non-binary individuals have a much higher risk of mental health issues, including depression, anxiety, and suicide. About 30% of transgender people have attempted suicide at least once in their lifetime. This figure is significantly higher than the lifetime suicide attempt rate of under 10% found in the general population. These disparities are largely driven by social risk factors such as stigma, rejection, and discrimination linked to gender identity[15].
	Medication dosing is a consideration for ensuring that transgender patients receive safe and effective care. For those taking gender-affirming hormonal therapy, this could be impactful for assessing the appropriate dosage of other medications due to the potential physiological changes.[16] Yet, transgender patients are under-represented in clinical trials, with a lack of dosing guidance as a barrier, which presents further issues around identifying safe dosage guidelines.[17]
Sexual identity	Sexual identity can impact health outcomes after cancer treatment. Men who have sex with men report worse mental health, more relationship issues, and greater genitourinary problems after prostate cancer compared to heterosexual men. After breast cancer, women who have sex with women tend to show more resilience and lower fear of recurrence, but they face more complications from mastectomy and radiation than heterosexual women. Adolescent and young adult survivors from sexual minority groups are nearly twice as likely to experience anxiety compared to their heterosexual peers, though they are less worried about infertility and more receptive to non-biological parenting[18].
	Lesbian, gay, and bisexual people face notable health inequalities due to heteronormativity and minority stress. Sexual minority individuals often report worse health outcomes, including higher rates of long-term conditions like musculoskeletal issues and specific cancers. Mental health disparities are also significant, with rates of psychological distress, suicide attempts, and substance dependence two to three times higher, especially among bisexual individuals[19].
	Sexual identity can impact end-of-life care. Systemic barriers are present through heteronormative culture, such as organisational policies (e.g. policies around decision makers and non-traditional families).[20] People of the LGBTQ+ community have fears around end-of-life care, such as the risk of discrimination and an "undignified death".[21] Yet, there is

	a lack of research on the experiences of the LGBTQ+ community on end-of-life care, and the literature which does exist demonstrates a distrust in the services available.[20]
Race, ethnicity and ancestry	Opioid metabolism differs by ethnicity because of genetic differences that affect the enzymes responsible for processing drugs. For instance, Chinese patients tend to clear morphine more quickly, leading to lower morphine levels in their bodies. The rate of poor metabolisers (people whose genetic variants lessen opioid effectiveness or increase toxicity) is about 1% in Asian populations, compared to 5% to 10% in Caucasians, and varies widely among African populations, from 0% to 34%[22].
	Black women in the UK face about three times the risk of maternal mortality compared to White women, even when considering socioeconomic factors, health conditions, and lifestyle differences. The highest risk occurs among women of Caribbean ethnic origin. This increased risk results from a mix of systemic healthcare biases, delays in care, and a higher rate of pregnancy-related complications like hypertension and pre-eclampsia among Black women[23].
	The Covid-19 pandemic disproportionately impacted ethnic minority groups in the UK. Death rates were higher amongst black and Asian patients – with research showing that hospital deaths (compared to white British patients) were two times higher for Bangladeshi patients, 2.9 times higher for Pakistani patients and 3.7 times higher for black African patients.[24] In addition, the mental health impacts of lockdown were seen to be higher in ethnic minority groups, and these groups were found to be less likely to access structured mental health support.[25]
Socio-economic status (SES)	Patients in low socioeconomic status (SES) neighbourhoods begin cancer treatment later and receive poorer care than those in higher SES areas. For instance, lower SES is linked to delays in starting treatment and a 20% lower chance of receiving immunotherapy. This gap leads to worse survival rates for different cancers, including advanced endometrial, gastric, and ovarian cancers. Income-based differences also impact treatment adherence and discontinuation, especially in rural or underserved areas where financial barriers limit access to care[26.]
	People with lower socioeconomic status (SES) have a much higher risk of type 2 diabetes. In the UK, the rate is estimated to be over twice as high for women and about 1.5 times higher for men in the poorest group compared to the wealthiest. Contributing factors include chronic stress, financial strain, food insecurity, limited access to healthcare, and poor living conditions. These issues lead to inflammation, insulin resistance, and metabolic problems throughout life[27,28].
	Those with lower socioeconomic status are more likely to have poor oral health. Previous research has found that children with lower SES may be more likely to have dental decay – reaching up to 85% prevalence in some groups at early childhood (aged 0-5 years).[29] Children and young people with lower SES are also less likely to use dental services.[30] However, dental caries is more commonly seen in children and adults with lower SES, even where they can access dental

	services without cost.[31] In addition, the cost-of-living crisis within the UK has been suggested to have an impact oral health due to some being unable to afford dental hygiene or treatments. This may also result in some increasing their reliance on energy-dense foods which may be high in sugar.[32] This could further push divisions along socioeconomic status and oral health.
Level of education	Higher education is closely associated with better medication adherence and use of preventive services. This is mainly because people with more education often have higher health literacy and better skills to navigate healthcare systems. For instance, patients with higher health literacy are almost twice as likely to stick to their medication compared to those with lower health literacy. This effect is especially significant for medication regimes related to cardiovascular diseases[33].
	Level of education is linked to all-cause mortality in patients with atrial fibrillation, regardless of other health conditions. Compared to people with only primary education, those with secondary education faced a 12% lower risk of death. Those with academic education had a 30% lower risk. This connection likely comes from factors like lower health literacy, limited awareness of diseases, lower quality of life, and poorer access to or adherence to better treatments[34.]
Disability	People with intellectual disability are more likely to experience drug-related side effects. Many have existing brain issues that can worsen neuropsychiatric side effects, especially when taking psychotropic medicines, which often produce unpredictable responses. In adults with intellectual disability, there is a wide range of physical size and bodily function compared to the general population. These differences influence how drugs are distributed in the body and may change how the liver and kidneys process medicines, resulting in shifts in both drug levels and effects[35].
	People with spinal cord injury have about a 1.5 times greater overall risk of developing cardiovascular disease than the general population. They also face higher risks of serious complications, such as heart failure and heart attacks. This increased risk comes from factors like problems with the autonomic nervous system, significantly reduced physical activity, and different anatomical, metabolic, and physiological changes. Moreover, sensory and autonomic issues in spinal cord injury can hide severe cardiovascular events, which often leads to these conditions going unnoticed or being diagnosed late[36].
	People with intellectual disabilities are more likely to have adverse outcomes and poorer experiences in pregnancy and giving birth. This group are more likely to experience issues such as gestational hypertension and urinary tract infections during their pregnancy.[37] There are also issues around giving birth, such as a lack of accessible communication, and healthcare professionals feel they did not receive appropriate training in providing support for those with intellectual disabilities.[38] Even after birth, there is a higher risk of issues such as postpartum haemorrhage and longer hospital stays for their baby.[37]

Location (country/countries of data collection and site coordination)	Differences in self-management after primary cancer treatment exist between rural and urban patients in the UK. Rural patients feel more confident in managing their recovery. They report being better at handling medical treatments at home, understanding available treatments, maintaining lifestyle changes, and preventing future health issues. However, rural areas lack specialised support designed for people living with cancer. This indicates that, even with challenges during active treatment, living in a rural setting may promote better engagement with self-management as patients move into survivorship[39].
	Infectious disease risks differ significantly by region. For example, tuberculosis cases reach about 240 per 100,000 people in South Asia, while Europe has only around 25 per 100,000. Key risk factors contributing to regional differences include diabetes (which triples tuberculosis risk), undernourishment, air pollution exposure, low socioeconomic status, and limited literacy. The variation also reflects differences in healthcare infrastructure, diagnostic capacity, and delays in treatment that allow transmission to continue.[40,41]
	There are considerable differences in healthcare systems across the world and knowing the location can help when developing policies. Health systems are unique to each country and the social and economic context held within them, as well as being shaped by their demographics.[42] However, international comparisons can be useful for health systems improvement, but there can be variability between countries on aspects such as disease classifications.[43] Therefore, knowing which country or countries have been involved in the research may be vital for those making policies to consider such contexts in relation to their own healthcare system.

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