Medicines Development for Global Health

Gender equality, disability and social inclusion Policy

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ABBREVIATIONS & ACRONYMS

CMC Chemistry, manufacturing and controls

CDT Community-directed treatment

GEDSI Gender equality, disability, and social inclusion

HR Human resources

MDA Mass drug administration

MDGH Medicines Development for Global Health

MEL Monitoring, evaluation, and learning

NGO Non-government organisation
 NTD Neglected tropical disease
 R&D Research and development
 SOP Standard operating procedure
 WHO World Health Organization

DEFINITIONS

Access: the extent to which individuals can access opportunities to improve their health outcomes.

Agency: the capacity of individuals to take purposeful action and pursue goals towards improving their health outcomes, free from the threat of violence or retribution.

Community-directed treatment: Healthcare programs in which communities, in partnership with health professionals, can manage the prevention and treatment of selected diseases that are prevalent in their environment.

Control: the extent to which individuals can control resources or assets.

Equality: equality is achieved where opportunities and obligations to access healthcare are the same across identities i.e., these are not dependent on, nor constrained by, their gender, ability or social identity.

Equity: equity is achieved where opportunities and obligations are extended fairly across identities i.e., measures may be introduced to compensate for historical disadvantages and continued norms and expectations across identities.

GEDSI-intentional: organisation, partner or project understands the different needs and constraints of different GEDSI identities and designs projects that take them into account.

GEDSI-transformative: organisation, partner or project takes a data-driven approach to design projects that consider the different needs and constraints of different GEDSI identities and address the root causes of the inequality.

GEDSI-unintentional: organisation, partner or project does not take steps to understand the different needs and preferences of different GEDSI identities.

Intersectionality: the way in which the various aspects of one's identity overlap and interact to create complex and compounding experiences of discrimination. This includes how one person's



gender, race, ability, sexuality, age, class, or immigration status overlap to potentially drive unique inequalities in their context.

Mass drug administration: Provision of treatment for a disease to an entire population of eligible people in a geographical area, whether each individual is infected or not.

INTRODUCTION

Medicines Development for Global Health (MDGH) is an independent not-for-profit biopharmaceutical company addressing health inequity by researching, developing, and delivering new and improved medicines for neglected diseases that disproportionately affect people in low-and middle-income countries. It is a registered charity and head-quartered in Australia with wholly-owned subsidiaries in the United Kingdom and United States.

Our systems and structures aim to address disparities that exist in the world, to be an inclusive employer and improve quality of life for patients receiving our medicines regardless of their position in society, gender, disability, and country of origin.

Neglected Tropical Diseases (NTDs) affect more than 1 billion people globally. In the region where we are headquartered, NTDs affect a population of 857 million in Southeast Asia and 72 million in Western Pacific region as of 2020². These same regions see high rates of inequitable health outcomes based on gender, societal position, and ability. These diseases, such as soil-transmitted helminthiasis, leprosy type 2 reactions, scabies and lymphatic filariasis, continue to pose significant health problems.

At times, these diseases disproportionately affect some groups, including those with lower incomes, women, and persons with disabilities due to a combination of social, economic, and environmental factors that limit their ability to protect themselves from these diseases. For some NTDs, women and girls face increased exposure to disease vectors and contaminated water and food sources due to domestic chores, and lack of access to basic sanitation and hygiene facilities, which can increase their vulnerability to NTDs such as soil-transmitted helminthiasis. Conversely, the caseload for some NTDs such as visceral leishmaniasis is higher among men³. People with disabilities face additional challenges due to physical barriers, stigma, and discrimination, which can affect their ability to access healthcare services and preventative measures.

PURPOSE

A gender equality, disability, and social inclusion (GEDSI) lens is at the centre of the MDGH mission. This document aims to codify the principles and actions that MDGH lives each day. It provides a unified overview of MDGH's approach to GEDSI in how it seeks to create impact, how it partners, and how it creates a welcoming workplace.

SCOPE

The policy applies to all staff and external consultants while conducting MDGH business activities.



CONTEXT: WHY TAKING A GEDSI LENS IS CORE TO MDGH'S WORK ON NEGLECTED TROPICAL DISEASES

GEDSI and MDGH's mission

In endemic countries, NTDs are often common in rural areas, remote hard-to-reach regions, and conflict zones, thereby leaving low-income populations, already underserved by healthcare systems, vulnerable to these threats. For many NTDs, socio-economically disadvantaged groups such as women, persons with disability, and ethnic minorities have higher odds of infection.⁴

Failure to adopt an inclusive lens to programs aimed at elimination of transmission or eradication of disease can lead to higher rates of infection, perpetuate the prevalence of NTDs and delay universal healthcare access. These diseases can lead to long-term impairments and disfigurements among infected individuals but also severely limit the economic potential of those affected.

Over the past decade, public health organisations, NGOs and civil society organizations, led by World Health Organization (WHO), have launched numerous interventions to control infections, eliminate transmission, and eradicate these diseases. These programs are designed to serve marginalized and disadvantaged communities and have made significant advancements by reducing the population in need of NTD interventions by 25%. Integrating inclusivity into the design of these programs can accelerate the elimination of NTDs.

There are two mechanisms for distributing medicines and providing treatment for NTDs:

- 1. Preventive chemotherapy through mass drug administration (MDA)
- 2. Individual on-demand treatment administration

Different characteristics of each distribution method	have implications on barriers faced by socially excluded groups in accessing treatment
Patient mobilization (Active engagement with affected populations in preventive chemotherapy programs vs waiting for infected patients to seek medical help in case of on-demand treatments)	Awareness about treatmentsUptake of treatment
Program scale/coverage (Large scale programs covering affected communities at once vs focusing on individual demand over time)	Relevance of treatment for individuals
Treatment financing (Sponsored preventive chemotherapy vs a mix of subsidies and self-financing for on-demand treatment)	Uptake of treatmentContinuity of treatment

While MDA is the relevant distribution pathway for the majority of MDGH's portfolio in 2023, our policy considers barriers to both methods to ensure that the GEDSI lens applies as MDGH's portfolio develops in the future.

GEDSI and equity in addressing NTDs

Ensuring equality means providing equal opportunities and resources to all individuals, without considering the differentiated impediments faced by them. This approach could lead to differences in program outcomes, stemming from differences in starting points for individuals. Equity, on the



other hand, would mean providing special support to vulnerable and underserved groups to account for the entrenched systemic dynamics that make their starting point different from others, thus driving toward more parity in program outcomes.

GEDSI intentionality in healthcare program design and implementation can be used to achieve both equality and equity in healthcare access by solving for differentiated resource access vs. solving for disparities in health outcomes.

Understanding the differentiated barriers faced by underserved groups is critical for tailoring program design and monitoring outcomes with their unique needs in mind. Across medicine development and delivery, we consider barriers related to suitability, affordability, availability, awareness, acceptability, and accessibility (Exhibit 1).

Exhibit 1: Framework for analysing differentiated barriers

			Suitability	Does the available treatment meet target product characteristics laid out by WHO with respect to efficacy, safety, and other design considerations for different population groups?
Medicine access		Awareness	Are population groups aware about clinical trials, research studies, available treatments, and administration procedures?	
	Affordability	Does design or mode of access of the treatment impose any direct or indirect financial burden on low-income population groups?		
	Accessibility	Are patients able to reach and participate in clinical trials and available healthcare services or are they constrained?		
	Acceptability	Are patients willing to enroll in clinical studies and accept treatments or are they discouraged by personal or sociocultural barriers?		
		Availability	Is enough and adequate infrastructure, equipment, and medical personnel available for treatment?	

While not all the barriers are within our direct scope of influence, understanding the broader ecosystem is valuable for identifying best practices and designing suitable engagement strategies.

We have conducted GEDSI analyses related to gender, disability, and social inclusion (including for indigenous populations) - an overarching view of barriers these groups can face is captured in Annex 1 of this document.

PRINCIPLES

There are 6 GEDSI guiding principles that will shape MDGH's decision-making and activities:

1. We aim to create and deliver for everyone

We develop medicines that improve the quality of life for patients receiving our medicines regardless of their position in society, gender, disability, and country of origin. We will integrate a



GEDSI lens into our work to ensure we cater for those that face the greatest disparities and inequalities.

2. We include the voices of those who face inequality and marginalisation

We take a human-centric approach by integrating the expertise, perspectives, and knowledge of women, people with disabilities, and other socially excluded groups throughout our medicine delivery and development processes to ensure that their experiences shape our work.

3. We tailor our approach based on the circumstances

We design and deliver programs and medicines with a GEDSI focus that cater to the unique context we are operating in. We take into consideration the identities, incomes and barriers faced by people in the contexts we operate in and ensure that we are addressing the relevant systems and structures through our work.

4. We collaborate with mission-aligned organisations

We take a GEDSI-intentional approach to our partnerships. We are upfront and clear with partners about the centrality of GEDSI to our work, and expect a similar commitment to a GEDSI lens from our partner organisations.

5. We strive to constantly learn, adapt and course correct

We acknowledge that situations and contexts evolve. We monitor, evaluate and learn from our programs to adapt our GEDSI lens and develop the insights and experience of the overall sector in which we operate.

6. We aim to do no harm

We commit to, first, do no harm. We will not reinforce or worsen the disparities, inequalities and exclusion experienced by the marginalised groups and identities we seek to help through our medicines and programs.

OUR GEDSI APPROACH

We take an intentional GEDSI lens to ensure that we actively include underserved population groups in our research and development (R&D) program design and delivery rather than focusing on a 'do not exclude' approach.

Biological and genetic diversity among population groups (primarily on account of gender or origin) will be accounted for during the medicine development stage through inclusive studies and representative clinical trials. MDGH will tackle other differential access barriers, within its scope of influence, during medicine distribution.

We are committed to conducting thorough analyses on GEDSI issues relevant to our work for our programs. For this, we have defined program efficacy and scalability to be in our scope and we actively address these challenges at the medicine development stage through an inclusive approach to research and product development, and medicine manufacturing. Other hurdles are likely to emerge during medicine delivery, which we will approach through our collaboration with implementation partners.

We seek opportunities to be GEDSI transformative where possible, recognising this is difficult given our lower direct involvement at the household and community levels. For example, this could include identifying ways to bring communities and relevant populations along in the R&D and clinical trial process and elevate these voices so that affected groups can provide more inputs



into and ultimately have more control over how medicines are being designed for them. By gaining a better understanding of barriers to registration, supply, affordability and access at the design and development stage, we can improve the coverage of medicines for NTDs.⁵

We take steps across medicine development and access phases:

Exhibit 2: Medicine development and access value chain



Table 1: Developing medicines with a GEDSI lens

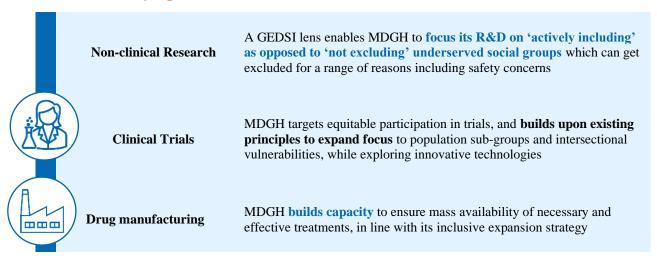


Table 2: Leveraging our partners to deliver medicines with a GEDSI lens



Monitoring, Evaluating, and Learning from our results with a GEDSI lens



We seek to integrate GEDSI across our broader monitoring, learning and evaluation (MEL) framework to track progress to ensure accountability, inform evidence-based adjustments to our approach, and drive ecosystem-wide knowledge-sharing.

Monitoring	 When possible, collect data by GEDSI population characteristics such as gender, ethnicity, socioeconomic status, etc. 	
Evaluation	 When possible: Define key performance indicators for GEDSI groups and tracking metrics with implementing partners, such as gender split of treatment group vs target population, completion rates by income level and presence of a disability, etc. Set targets for key GEDSI groups depending on context and evaluate progress on these so as to understand our GEDSI-related impact Ensure that the program is not having any unintended negative impacts (doing no harm), such as perpetuating discrimination of a GEDSI identity 	
Learning	 Use data and learnings to inform strategic decisions about the NTD treatment programs (e.g., awareness campaigns to better target groups that are being excluded, adapting roll-out to reduce physical or cost burdens for persons with disability or low incomes) Facilitate ecosystem-wide knowledge-sharing in the form of publications, guidelines, and toolkits that summarise best practices for improved access to NTD medicines globally and regionally. 	

Championing GEDSI within our organization

We integrate GEDSI considerations in our internal operations across our organisation aligned with global best practice for social inclusion policy:

- Policies: GEDSI inclusive work-life balance, provision of paid care leave, presence of a
 mechanism to report and resolve instances of misconduct (including sexual harassment),
 among others:
 - o MDGH Preventing Discrimination, Harassment, Vilification and Bullying Policy
 - o MDGH Preventing Sexual Exploitation, Abuse and Harassment Policy
 - o MDGH Complaint and Dispute Resolution Policy
 - o MDGH Hybrid and Global Work Policy

For further detail, refer to MDGH Human Resources Policy and Procedure Manual.

POLICY IMPLEMENTATION

This policy is used as a reference document in MDGH decision-making and activities. Where relevant, this document can also be used to allocate budgeting and resources depending on the activities required.



This document should be consulted and a GEDSI lens integrated (where applicable) into other MDGH documents as part of periodic or *ad hoc* reviews of other policies, Working Practices and Standard Operating Procedures (SOPs). This includes policies and SOPs relating to:

- Access to medicines
- Chemical manufacturing and controls (CMC)
- Clinical trials
- Monitoring, evaluation, and learning

RESPONSIBILITIES

The Leadership Team is responsible for providing leadership on GEDSI and are ultimately responsible for providing direction to the company on GEDSI.

All staff and external consultants are responsible for ensuring the implementation of this policy.

DOCUMENT HISTORY

Version number	Effective date	Reason for amendment	Summary of change
1	19April 2023	n/a	n/a



ANNEX 1: GEDSI analysis of the barriers to participation in medicine development and access to medicines

Gender

An individual's ability to access healthcare depends on numerous social identifiers, including gender. Women, men, and transgender/non-binary individuals face differentiated barriers to accessing NTD medicines based on their social circumstances. Gendered inequalities exist in NTD medicines due to biological differences and the impact of traditional gender roles, which can reduce efficacy and curtail access to facilities. Understanding these barriers is crucial to ensure that NTD medicines reach those who are vulnerable.

Gender intentionality in healthcare programs can solve for differentiated resource access and lack of control and agency, thereby ensuring gender equal and equitable health outcomes.

Table 1: Key barriers to consider from a gender perspective regarding MDGH's work across medicine development and delivery

Legend: Development barrier Access barrier Development & access barrier

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Suitability	 Some groups are underrepresented in research and clinical trials Limited exploration of differences in illness progression, biological outcomes, and response to medicines based on gender in research may hamper the ability to provide suitable solutions and medicines^{4,7} Women may be excluded from clinical research due to greater likelihood of adverse reactions and the need to create age-related population subgroups due to biological differences between pre- and post-menopausal women⁸ Pregnant and breastfeeding women are ineligible for some NTD medicines and clinical research due to lack of approval/ administration protocols for treatments due to potential fertility or maternal-fetal consequences and/or insufficient safety evidence^{9,10,11e}.
Awareness	 Women often have less access to available information about trials and new treatment options Women comprise 63% of Southeast Asia's illiterate population, which can reduce their ability to consume health information^{12,13} Male control over media in households can limit the ability of women to engage with information about clinical trials and treatment procedures¹³
Accessibility	 Social constraints and resource unavailability can make medicines inaccessible Limited decision-making power and agency of women can make it difficult for them to access medicines/attend clinical trials and MDAs/get treated with or without the presence of a male family member^{14,15} Lack of transport facilities can impose mobility constraints on women in traveling to remote clinical trial and administration sites¹⁵ Many women may face time restrictions in attending clinical trials and accessing treatments for NTDs (& attending MDAs), as they have caretaking responsibilities and household chore burden¹⁵ Transgender individuals are often subject to discrimination, mistreatment from providers, and procedural hurdles (e.g., showing identification proof) while accessing healthcare¹⁶



	Due to the potential benefits or outcomes of clinical trials being less clear than treatment, accessibility barriers may be even harder to overcome in the case of clinical trials
Acceptability	 Women's willingness to participate in trials can be influenced by social norms Women are more likely to let their partners, family, and social norms affect their decision to participate in clinical research.¹⁷ Social factors can also constrain groups from participating in treatments Taboos and stigma around reproductive health can discourage women, and transgender and non-binary individuals from seeking treatment for NTDs affecting reproductive health¹⁰
Availability	 Healthcare facilities often do not meet the specific needs of women Lack of female health workers can lead to hesitation in seeking care from workers of the opposite gender¹⁸ Lack of on-site childcare facilities can push to women delay or miss out on trials and treatment^{6,19}

Disability

Legend:

Development barrier

In 2023, over 15% of the global population had a disability, and 80% of persons with disabilities lived in low- and middle-income countries (LMICs). 20,21

Persons with disability suffer from long-term physical or cognitive impairments, and therefore face unique challenges to accessing healthcare. Sometimes, even when healthcare facilities are available, these cannot be used with ease. NTDs themselves can lead to impairments, making it vital to understand the unique needs of persons with disabilities, to administer adequate, convenient, and effective treatments.

Table 3: Key barriers to consider from a disability perspective regarding MDGH's work across medicine development and delivery

Access barrier

Suitability	 Treatments may not be tailored to persons with disability Lack of data on treatment efficacy and disease progression for persons with disability can make it difficult to tailor treatments to their needs¹⁸ NTD treatments often do not place enough focus on curing, eliminating, or reducing the severity of life-long impairments caused by NTDs.²²
Awareness	Lack of awareness campaigns in disability-friendly communication formats may result in information not reaching patients with disability or limit their understanding of available clinical trials and healthcare services ^{23,24}
Affordability	Persons with disability face weaker employment outcomes, which could hamper their ability to afford NTD treatment if not subsidized and/or travel to the site where treatment is offered 18 Current drug formulations and manufacturing processes have not sufficiently reduced prices to ensure affordability
Accessibility	Physical and social barriers can make treatment and participation less accessible • Persons with disability may face challenges in traveling to and reaching remote sites for clinical trials and treatment administration ²¹

Development & access barrier



	 Discrimination, negative attitudes, and lack of respect from healthcare providers and staff can deter persons with disability from seeking care and participating in health-related programs ^{21,25}
Availability	 Health services and infrastructure often do not cater to persons with disability In many regions, the health infrastructure is may not be disability-friendly and can lack basic facilities for persons with disability (e.g., assistance devices, ramps, disability-friendly communication formats, etc.) Lack of training to staff and healthcare providers to accommodate specific needs (e.g., communication mode mismatch, care for physical impairments, etc.) of persons with disability can sometimes lead to inadequate treatment and exclusion¹⁸

Social categories (based on race, ethnicity, origin)

Development barrier

Societies across the world categorise themselves into groups, based on distinct features such as race, ethnicity, caste, etc. An individual's access to basic services such as healthcare can often be affected by these social identifiers. Across the world, some social groups are more vulnerable to NTDs and other ailments but have limited access to medicines. At the same time, ethnic minorities are underrepresented in biomedical research and clinical trials for a range of reasons captured below, affecting efficacy and safety of developed medicines for use among these population groups, and ultimately influencing willingness and ability to participate in research and treatment.²⁶

In Australia, First Nations Peoples – the indigenous communities of this land – are one such social group. Recognizing that there is significant diversity even across First Nations Peoples, the barriers referenced below refer to indigenous populations more broadly. Individual MDGH programs would entail understanding the experiences of the specific groups affected.

Table 4: Key barriers to consider from an **indigeneity** perspective regarding MDGH's work across medicine development and delivery

Access barrier

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Suitability	Medication trial data may not be applicable to clinical care for indigenous groups due to inadequate representation in research and clinical trials. This is because social, cultural, and economic characteristics can lead to differences in disease susceptibility and manifestations, and treatment response even if ethnicity, and geographic ancestry do not define distinct genetic or biological groups. ^{27,28}
Awareness	Lack of tailored communication directed to indigenous communities can lead to unawareness about clinical trials, treatment availability and procedures. Mobilization campaigns can sometimes exclude ethnic groups due to linguistic barriers ^{29,30}
Affordability	Out-of-pocket treatment costs can be high for these groups due to less adequate public health systems in marginalized and remote areas and the increased reliance on private or far-off facilities ³¹ Present medicine formulation, administration methods, and production scale are not sufficiently bringing down prices to address affordability concerns of marginalized communities
Accessibility	Unavailability/high costs of transportation and accommodation facilities to travel to distant health facilities/ MDA programs/clinical studies can prove to be a deterrent for ethnic minorities/ populations residing in remote areas ²⁸

Legend:

Development & access barrier



Acceptability	Indigenous communities may be less trusting of some modern medicines and studies • In many cases, indigenous communities have lower trust in the system due to historical reasons, which can deter individuals from participating in clinical trials and seeking care ^{28,32} In some instances, indigenous groups may prefer traditional medicines and it could be useful to integrate traditional practices with biomedical science ³³
Availability	 Health services are often further away and thus less readily available Indigenous communities are more likely to reside in remote areas, where treatment administration/healthcare systems are often less adequately resourced due to lower healthcare funding Communication and language barriers between health workers and indigenous/ethnic groups can lead to improper delivery of products and services²⁸

In addition to First Nations People, other groups that inform special considerations for MDGH's work include:

Low-income groups:

There is scope to improve the cost effectiveness of available medicine formulations and current production processes to address affordability concerns in resource-poor regions.

Individuals can face indirect costs for long-term clinical studies and medicines in the form of lost wages for the days of treatment administration and transport costs to clinical or treatment sites. For diseases requiring an on-demand distribution approach, direct costs of medicine can be high depending on the level of government or other subsidization available. Low-income groups are disproportionately affected by these costs as they make up a larger percentage of their weekly budgets.

Other than medical access, an individual's economic status also influences their nutritional status, and access to resources for a healthy living, and thus affects trial eligibility and medicine efficacy. Limited resources also pose restrictions on their participation in clinical studies.³⁴

Refugees and internally displaced populations:

There is a high prevalence of NTDs among individuals that have been displaced due to conflicts, wars, and violence. At the same time, these individuals lack access to medical support as displaced populations are frequently excluded from clinical research and integrated NTD control programs due to constant movement or host countries prioritizing local populations.³⁵ Having been subject to social unrest or conflicts, displaced populations may sometimes lack trust in the community, which can make acceptance and success of clinical studies and treatment interventions that involve potential restrictions on personal liberty more challenging (i.e., active detection and isolation of cases and contact tracing). The lack of clinical trial data for these populations can further diminish suitability of medicines for NTDs. Further, these groups live in resource-scarce situations, making on-demand treatment difficult due to financial constraints.³⁶

Migrants:

Sometimes, international migration leads to adverse socio-economic consequences. Migrant workers are likely to face higher barriers to accessing healthcare programs and schemes in many regions due to documentation requirements and exclusionary local healthcare policies. Local



programs often fail to address the specific needs and vulnerabilities of migrants and their families.³⁷

Migrants tend to have low participation in clinical trials due to lower understanding of health systems and linguistic barriers, which can reduce the ability of available treatments to address their unique needs³⁸

Itinerant workers or those working at the border regions between countries or provinces may face other barriers to accessing healthcare programs.

Children:

There is a substantial gap between the burden of disease for NTDs in children and research devoted to this population. Children are often not eligible for clinical trials for NTDS, and most medications lack adequate paediatric prescription information.³⁹ This pushes children out of the ambit of medical care. Out-of-school children (due to financial constraints, disability or caregiving to an affected adult member of their household) can miss out on MDA's conducted in schools.⁴⁰

Finally, applying an intersectional approach is important to demonstrate how the multifaceted interaction among gender, disability, ethnicity, and other social identifiers impacts the ability of an individual to access healthcare services. For instance, females with a disability are often less likely to receive critical health services. ⁴¹ As reported by a 2010 study, in LMICs, only 21% of women with a disability received a mammogram compared to 32% of women without a disability. ⁴² Approaching these determinants (or identities) as singular entities that have a linear relationship to an individual's health betrays their lived experiences and sets the precedent for many of the factors determining their health outcomes and help-seeking behaviour to be missed out.

One could list many more potential social groups with differentiated needs, but the relevant set for which to design will depend on the target location for each program. The broad principles of social inclusion described in this policy can and should be applied in any case. All MDGH work in this area will begin with the identification of groups that may be especially excluded in the context of the program being designed.

Individuals may get pushed out of healthcare program coverage due to exclusion from economy, social services, and the society itself. By conducting desk research, supplemented with community consultations, we will determine which groups are likely to be underserved by the program in question.

We identify potentially excluded groups by reviewing access to health metrics where available. In the absence of these, we look at proxies such as socio-economic status and relative disease burden and supplement this with community consultation. We err on the side of being broad with this initial assessment as our GEDSI strategies aim to solve barriers across multiple groups.



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