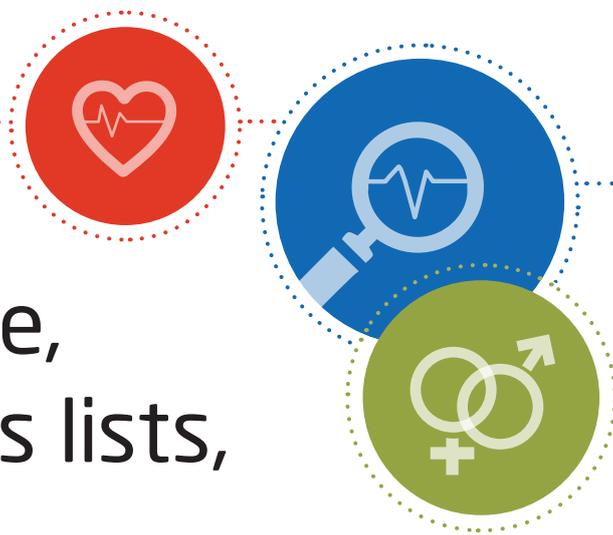


# Universal health care, essential diagnostics lists, and gender equity



Diagnostic tools are more important than ever in the effective and cost-controlled delivery of health care due to increasing health system challenges from noncommunicable and communicable diseases, ageing populations, antimicrobial resistance, and limited resources.<sup>1</sup> Emphasis on integrated approaches and primary health care is growing as health systems respond to and recover from the COVID-19 pandemic. Diagnostic tools provide critical information that help clinicians make evidence-based decisions regarding appropriate treatment and referrals across a range of health issues.

In 2018, WHO published the first Essential Diagnostics List (EDL), almost 40 years after first publishing the first WHO Essential Medicines List, publicly recognizing that diagnostics are an essential component of universal health coverage and healthier populations. The WHO EDL defines essential diagnostics as those “that satisfy the priority health care needs of the population and are selected with due regard to disease prevalence and public health relevance, evidence of efficacy and accuracy, and comparative cost-effectiveness.”<sup>2</sup>

However, the access to health services and technologies is limited by gender barriers that exist in households, communities, and health systems. If equitable access to diagnostic tools is to be achieved, a transparent and intentional effort to investigate and mitigate gender barriers to health is needed.

Gender-equitable access and delivery of diagnostics is essential to achieving Universal Health Care (UHC). It is important to incorporate an explicit review and mitigation strategy to address gender barriers to access during the development and revision of national essential diagnostic lists.



THE ACCESS AND  
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New Health Technologies for TB, Malaria and NTDs



## Diagnostics and UHC

All World Health Organization (WHO) member states signed on to the 2030 Agenda for Sustainable Development, which includes a target under the health-focused Sustainable Development Goal (SDG) 3 to provide universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all. SDG 5 also focuses on achieving gender equality, including through universal access to sexual and reproductive health and rights and use of enabling technologies.

As countries make progress toward achieving UHC, delivering gender-equitable access to diagnostic technologies is essential. Diagnostic tools and laboratory systems improve the effectiveness of health care services, reduce health system costs, and limit unnecessary drug use. However, while diagnostics influence about 70 percent of health care decisions, only 3–5 percent of health care budgets are spent on diagnostic tests.<sup>3</sup> A WHO study of ten countries found that only 2 percent of health care facilities had the eight diagnostic tests included in WHO basic service readiness index in stock for clinical care (hemoglobin test, blood glucose test, malaria test, urine dipstick for protein and sugar, HIV and syphilis tests, and pregnancy test).<sup>4</sup>

Diagnostic tools are also needed to deliver the epidemic preparedness and response systems required as part of national commitments to the International Health Regulations (2005), the importance of which is highlighted by the ongoing COVID-19 pandemic. To achieve UHC, investments in essential diagnostics by governments, private sector, and donors are needed, and these investments must support equitable access to these valuable health technologies.

## Diagnostics and gender

Gender is not determined by biological characteristics but rather by complex social systems that, alongside other factors, contribute to hard-to-reach or underserved populations.<sup>5</sup> Definitions of gender and sex are provided in Figure 1. Gender norms will impact and often limit how different populations, including the most vulnerable populations, access and benefit from diagnostic technologies.

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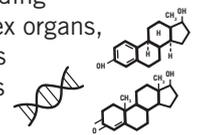
*As countries move towards universal health coverage and medicines become more available, it will be crucial to have the right diagnostic tools to ensure appropriate treatment.”*

— *Mariângela Simão,*  
*WHO Assistant Director-General*  
*for Medicines and Health Products*

**Figure 1.**  
**Definitions of Sex and Gender**

### “Sex”

Sex refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles



### “Gender”

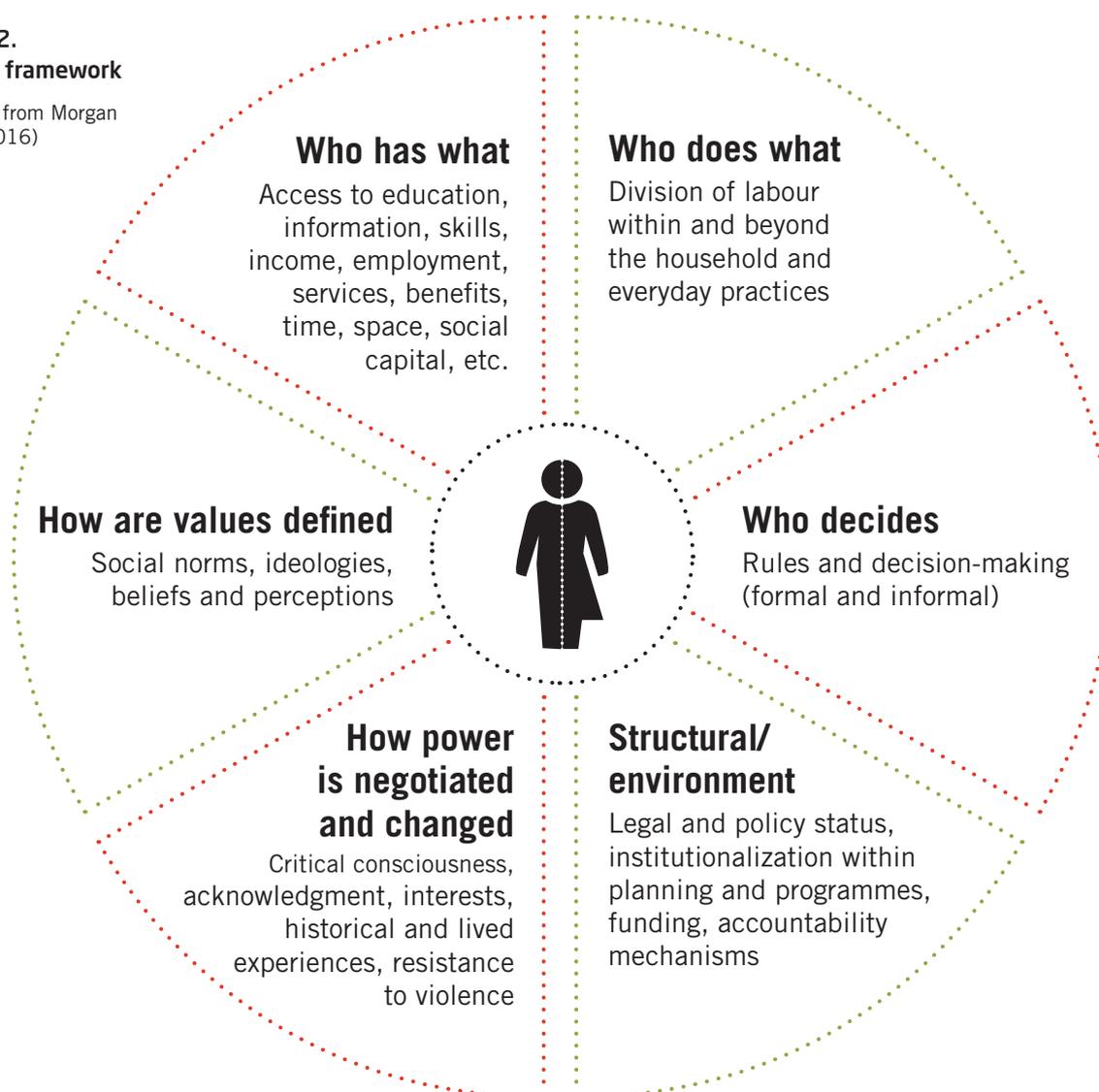
Gender refers to socially constructed and enacted roles and behaviours that occur in historical and cultural context and vary across societies and over time.



A gender framework adapted to show gender barriers to neglected tropical disease (NTD) treatment and control programs is shown in Figure 2.<sup>6</sup> This figure illustrates how division of labor, bargaining power, access to resources, and social norms, ideologies, and beliefs that result in gender barriers can affect exposure, risk of transmission, prevention, and treatment of NTD, as well as other diseases.

**Figure 2.**  
**Gender framework**

Adapted from Morgan et al. (2016)



To help inform explicit analysis on how gender impacts access to diagnostic technologies, PATH interviewed 23 internal experts in primary health care, laboratory-based testing, gender, policymaking, medical device procurement, or priority disease categories. These semi-structured qualitative interviews were conducted in mid-2020 with these experts, 8 identifying as male and 15 as female. Feedback was analyzed for key themes relating to (1) how gender impacts health care seeking, (2) how gender impacts the delivery of health care and diagnostic tests, and (3) how access to diagnostics is impacted by national policies.

Analysis identified the examples of how gender is reflected in these three themes.

## 1

### **Gender norms impact health care seeking**

- Gender norms influence care seeking through the impact on accessibility of household resources, including financial, transport, and information resources as well as decision-making authority.
- Men often believe that care seeking is a weakness, leading to delays in accessing health care and increased severity of disease at first presentation to clinicians.
- Vulnerable populations (including gender nonconforming individuals) are at increased risk of discrimination and stigma, limiting or delaying care seeking at facilities.
- Women are more often responsible for childcare, and consequently may be accessible to health care services in health facilities when taking children for Expanded Program on Immunization vaccinations.
- Occupational barriers to care seeking intersect with gender barriers, with men potentially less able to access health care during the workday or women less able to seek care due to childcare duties or lack of access to financial and transportation resources.

## 2

### **Gender norms impact health care delivery**

- Clinical guidelines and testing protocols do not fully reflect differences in disease presentations, risks, and treatments for all sex or gender identities and expressions.
- Health care providers may have stigmatizing and discriminating attitudes towards patients from vulnerable populations, often defined by gender identities or expressions.

## 3

### **Impact of national policies and systems on equitable access to diagnostic technologies**

- Integration of diagnostic tools into essential medicine and diagnostic product lists can facilitate efficient procurement and price control by the national pharmacy authority.
- Greater use of point-of-care and rapid diagnostic tests (RDTs) in the health system can support evidence-based diagnosis and treatment protocols and reduce unnecessary drug use and potential for antimicrobial resistance.
- Strong laboratory systems enable disease surveillance and rapid response systems and inform elimination programs for diseases that may have greater burdens to vulnerable populations. Recording and routine monitoring of sex-disaggregated surveillance and program data is needed to detect gender-related health inequities.

## National essential diagnostics lists and gender equity

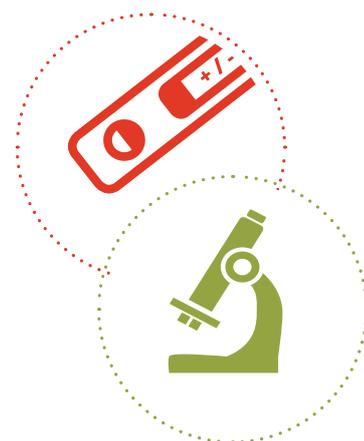
Translation of the WHO EDL into a national EDL (NEDL) is essential to achieving UCH and gender equity. NEDL will define national policies on diagnostics and laboratory systems and identify what diagnostic tools are available at each level of the health system. NEDL will help inform national health policies, including policies for UHC, procurement, supply chains, and reimbursements. These NEDL are an important opportunity to promote a national commitment to gender equity in health.

India is one of very few countries to develop a NEDL. Reflecting India's disease burdens and context, this NEDL includes 26 disease-specific tests for diagnosis of diseases like malaria, dengue, chikungunya, filariasis, scrub typhus, Japanese encephalitis, TB, HIV, and hepatitis. Prior to NEDL development, a survey of national stakeholders in 2018 identified the following NEDL target requirements:<sup>7</sup>

- NEDL must be strategic, realistic, and address the key demands of India.
- Reflect multiple levels of health care, with focus on primary health care.
- Complement national vertical health programs.
- Include logistics and infrastructure requirements.
- Identify capacities of service providers.
- Minimize movement of patients across facilities and providers.
- Prioritize innovative research in diagnostics.

Diagnostic technology recommendations included:

- Emphasize point-of-care tests for common pathogens.
- Include laboratory culture facilities for health care and antimicrobial resistance prevention.
- Bridge the gap between rapid test and central laboratory tests.
- Ensure quality of products and tests for diagnosis.
- Define in-house validation and evaluation criteria.

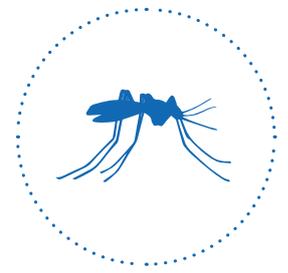


However, as seen in recent research from India, when UHC policy and programs are gender blind, they can leave many preexisting gender barriers unaddressed and accentuate others.<sup>8</sup> The complex underlying socioeconomic causes of gender inequity need to be identified and addressed by national and local governments, ideally informed by explicit gender analysis efforts.\*

Gender-related barriers to equitable access to essential diagnostic services can be illustrated in the context of malaria, tuberculosis, and neglected tropical diseases.

\* WHO TDR, the Special Programme for Research and Training in Tropical Diseases, published a toolkit for health researchers that can support national policymakers and researchers: *Incorporating Intersectional Gender Analysis Into Research on Infectious Diseases of Poverty* (2020), <https://www.who.int/tdr/publications/year/2020/tdr-intersectional-gender-toolkit/en/>.

## Malaria



Gender can affect risks of infection, access to services, prevention and control interventions, and the distribution of the burden of malaria morbidity and mortality.<sup>9</sup> Malaria infection in pregnant women is associated with high risks of both maternal and perinatal morbidity and mortality. Antenatal clinics are an essential delivery channel for preventive treatment of malaria; however, women often delay going to an antenatal clinic until the pregnancy is advanced due to a lack of money for transport.<sup>10</sup> Women's choices of antimalarial drugs during pregnancy are limited because relatively few of these drugs have proven safe and efficacious in pregnancy, due to the systematic exclusion of pregnant women from clinical trials because of risks, complexities, and cost.<sup>11</sup>

In countries targeting *Plasmodium vivax* malaria elimination, a radical cure with primaquine is required, for which an affordable point-of-use diagnostic test for glucose-6-phosphate dehydrogenase (G6PD) status is needed. The main concern limiting primaquine use for elimination efforts is the risk of acute hemolytic anemia in G6PD-deficient individuals; primaquine is also contraindicated for pregnant women. Therefore, diagnostic tests for both G6PD deficiency and pregnancy at the point of care are needed if women of child-bearing age are to have equal access to primaquine treatment.

Malaria diagnostic tests listed in the current WHO Essential Diagnostics List (EDL) include RDTs for *Plasmodium spp.* species-specific and/or pan-species antigens at the community or facility level where there is no laboratory. In laboratory settings, the semiquantitative fluorescent spot test for G6PD or G6PD activity spectrophotometric or cytochemical quantitative assay are listed. Light microscopy is recommended in both settings, with provision of quality equipment and trained technicians.

Unfortunately, gender analyses of malaria programs are few and therefore the impact of gender norms and associated gender inequities are not well recognized or addressed.<sup>12</sup> This gap in data and analysis limits investments that explicitly prioritize gender-equitable access to malaria diagnostics.

## Tuberculosis

Globally, significantly more men than women fall ill and die from tuberculosis (TB) annually; however, close to half a million women died from TB in 2018, including some 95,000 deaths among women with HIV.<sup>13</sup> While men and women face common barriers to TB care, these barriers are gender variable. Women more often experience barriers from financial and physical dependence, lower general literacy, and household stigma, while men more often face work-related financial and physical barriers and community-based stigma.

The lack of simple diagnostic tools for TB diagnosis has contributed to drug resistance, with 10 million deaths globally per year expected by 2050 if no action is taken.<sup>14</sup> Sex disaggregation of TB data is rarely available to inform programming, and epidemiological and treatment outcome data are not always available by sex and age. In 2015, a change made by WHO to the global TB reporting standards (WHO Global TB Database) required that data for indicators were disaggregated by age and sex. Country programs, implementers, donors, and WHO were requested to strengthen monitoring and evaluation of gender dimensions of TB to make key interventions gender responsive.<sup>15</sup>



TB diagnostics in the current WHO EDL include the tuberculin skin test, point-of-care nucleic acid test, and RDT for lipoarabinomannan (LAM) antigen in community or facility settings without a laboratory. In laboratory settings, the WHO EDL includes bacterial culture, including for drug sensitivity testing, nucleic acid tests (loop-mediated isothermal amplification [LAMP], line probe assay, GeneXpert inclusive), light-emitting diode fluorescence microscopy, RDTs for LAM, and the immunoassay or enzyme-linked immunospot (ELISPOT) assays. Sputum or another specimen smear microscopy is recommended for facility and laboratory settings if appropriate microscopes and trained technicians are available.

The WHO End TB Strategy recommends that health systems maximize the entry points to TB care for women and their families at all levels of the health system and that increased research is conducted to find new diagnostics, including point-of-care tests, and new drugs that consider the specific needs of women, along with increased relevant operational and social science research.

## ○ Neglected tropical diseases

Neglected tropical diseases (NTDs) are a diverse set of 20 diseases and disease groups that affect more than 1 billion people, mostly in impoverished communities, with devastating health, social, and economic consequences. Investment in new NTD diagnostics is only about 5 percent of the already modest investments made in NTD research. Often, women and girls experience a greater share of NTD burden due to their disproportionate poverty, illiteracy, lower education, and social status. Some studies suggest there is underreporting of NTDs in women in part due to the need to provide a urine or stool sample or allow intimate physical examination for diagnostic tools, which is perceived as culturally inappropriate or taboo in some settings.<sup>16</sup>



Gender factors may impact the risk of trachoma infection. One study found that female caregivers often have more frequent contact with infected children and are more likely to become infected themselves. In the case of podoconiosis, a nonfilarial elephantiasis, a study in northern Ethiopia found that women were at a greater risk of acquiring the disease due to individual, cultural, and socioeconomic barriers that influence individuals' decisions about and use of footwear.<sup>17,18</sup>

There are a very limited number of diagnostic tests listed in the WHO EDL for NTDs. An RDT for the rK39 antigen is listed for community or facility settings without laboratories for visceral leishmaniasis. For schistosomiasis and soil-transmitted helminths, the Kato-Katz stool slide examination is listed for laboratory settings. Qualitative dengue virus nucleic acid test, immunoassay, or RDT are listed for dengue immunoglobulin M or nonstructural protein 1 antigen.

“

*Addressing gender equality in health systems' design, financing, and delivery and in the health workforce, will drive the success of UHC.”*

— Alliance for Gender Equality and UHC

# Opportunities to improve gender equity

Equitable access to essential health services and technologies is limited by gender barriers that exist in households, communities, and health systems. To achieve true UHC, it will be essential that gender barriers are identified and addressed during research and development, policy-making, and health system strengthening. The following potential opportunities may help increase gender-equitable access to diagnostic technologies.

## Research and development

1. Request that clinical trials and biomedical research studies conduct gender-disaggregated analysis as part of performance, quality, and safety assessments and include pregnant women where feasible.
2. Include sex and gender in the research and product development continuum. Use appropriate specimens in the development and verification of the tests, not just the validation (clinical trials). Support independent performance evaluations of diagnostic tests on the market and make these data available.
3. Include target product profile criterion for new diagnostics to indicate the value placed on gender and other potential equity barriers factors contributing to unequal access to quality health care.
4. Prioritize development of new diagnostic technologies specifically for women in low-resource settings to address unmet needs (e.g., cervical or breast cancer diagnostics).
5. Generate new evidence on sex and gender barriers to access in development of new diagnostic tools.<sup>19</sup>
6. Identify opportunities to lower costs of diagnostics and introduce point-of-care tests to reduce direct and indirect costs (e.g., loss of income) of seeking care.

## National policies

1. Convene global and national health and equity working groups to develop an intersectoral gender analysis methodology that can integrate into NEDL development and revision processes.
2. Local governments and policymakers should incorporate gender analysis into operational research and assessment activities that can identify gender barriers to diagnostic equity and access, informing policy solutions, generating market incentives, and justifying investments.<sup>20</sup>
3. Strengthen laboratory and information systems, ensuring that sex-disaggregated data are reported and monitored.<sup>21, 22</sup>

## Diagnostic systems

1. Ensure that health information and monitoring systems support gender-segmented analysis of the clinical, surveillance, and public health metrics.
2. Provide equitable access to professional training and leadership opportunities related not only to diagnostic test implementation, but also related to diagnostic policymaking, gap analysis, resource planning, procurement, and quality assurance, at national and global levels.
3. Convene a global alliance to support diagnostic technology and system implementation at scale in low- and middle-income countries, convening donors interested in supporting UHC, global health security, solidarity, and equity, like Gavi, the Vaccine Alliance.<sup>23</sup>

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