POVERTY-RELATED AND NEGLECTED DISEASES THROUGH A GENDER LENS

DSW
Deutsche Stiftung Weltbevölkerung

youth car

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ABOUT DSW

DSW is a global development organisation that addresses the challenges faced by youth to exercise their sexual and reproductive health and rights (SRHR) and to meet their need for health services. We work with young people to raise awareness on SRHR, gender equality, and improving access to modern contraceptives, and with partners to address SRHR challenges through multisectoral approaches. We advocate towards policy-makers to ensure political and financial support for SRHR and youth-friendly services, and for critical investments into global health and research & innovation for poverty-related and neglected diseases (PRNDs). We work in close collaboration with research-based organisations, academia, and product development partnerships on PRND advocacy.

With headquarters in Hannover, Germany, two liaison offices in Berlin and Brussels, as well as country offices in east Africa (Ethiopia, Kenya, Tanzania, and the partner organisation Action 4 Health Uganda, we combine advocacy expertise in different geographies, youth-oriented programmes in east Africa, and research activities generating unique insights about effectively advancing the SRHR agenda. Our vision: a world where all youth - especially girls and young women - live free from disease and make independent and informed choices about their lives with full access to sexuality education, health services, and modern contraceptives.

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DISCLAIMER

ACRONYMS

CDD	Community Drug Distributor
DALY	Disability-Adjusted Life Year
DSW	Deutsche Stiftung Weltbevölkerung
EMA	European Medicines Agency
EC	European Commission
EU	European Union
FDA	US Food and Drug Administration
FGS	Female Genital Schistosomiasis
GBD	Global Burden of Disease
GDP	Gross Domestic Product
HIV	Human Immunodeficiency Virus
HPV	Human Papillomavirus
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
IHME	Institute of Health Metrics and Evaluation
IDM	Innovative and Intensified Disease Management
LGBTIQ+	Lesbian, Gay, Bisexual, Transgender, Intersex or Questioning
LF	Lymphatic filariasis
LMIC	Low- and Middle-Income Country
MDA	Mass Drug Administration
MDR	Multidrug Resistance
MSM	Men who have Sex with Men
NIH	National Institute of Health
NTDs	Neglected Tropical Diseases
OV	Onchocerciasis
PC	Preventive Chemotherapy
PrEP	Pre-Exposure Prophylaxis
PRNDs	Poverty-Related and Neglected Diseases
R&I	Research & Innovation
SCH	Schistosomiasis
SDGs	Sustainable Development Goals
STDs	Sexually Transmitted Diseases
STH	Soil-Transmitted Helminths
TB	Tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
UNAIDS	Joint United Nations Programme on HIV/AIDS
UHC	Universal Health Coverage
UNDP	United Nations Development Programme
US	United States of America
WHO	World Health Organization
WoSuP	Women Susceptible to and becoming Pregnant

Photo: Jonathan Torgovnik/Getty Images/Images of Empowerment

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DEEP DIVES

CASE STUDIES

GRAPHS

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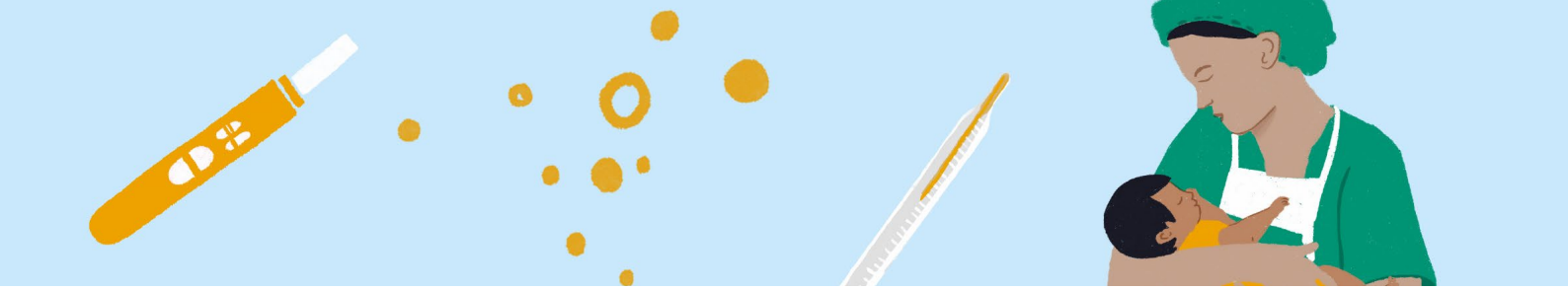
FIGURES



1 INTRODUCTION

Worldwide, 2.8 billion people are affected by poverty-related and neglected diseases (PRNDs), including the three major diseases of Human Immunodeficiency Virus and Acquired immunodeficiency syndrome (HIV & AIDS), tuberculosis (TB), malaria and neglected tropical diseases (NTDs)[1]. PRNDs are both a cause and a consequence of poverty, hampering human and economic development.

WORLDWIDE, **2.8 BILLION** PEOPLE ARE AFFECTED BY PRNDS

Over the past 25 years, extreme poverty has been in continuous decline, but according to the World Bank the COVID-19 pandemic pushed around 70 million people into extreme poverty in 2020. Global development is in danger of being reversed, with a swift recovery threatened by overlapping events, including the Russian invasion of Ukraine, other conflicts, climate change and global inflation[2]. COVID-19 has also caused devastating setbacks in global health gains, with the Joint United Nations Programme on HIV/AIDS (UNAIDS) sharing that faltering progress resulted in approximately 1.5 million new HIV infections in 2021 - an excess of 1 million to global targets[3]. Approximately 47,000 of the 69,000 additional deaths caused by malaria in 2020 were linked to disruptions in the provision of malaria prevention, diagnosis and treatment during the pandemic[4]. The World Health Organization (WHO) also estimated an increase of 4.5% in the number of people who fell ill with TB between 2020 and 2021[5]; while services for NTDs were the second most frequently disrupted by the pandemic[6]. Overall, no matter which disease we speak of, the economic downturn due to COVID-19 has meant that funding and implementation efforts to tackle these diseases are stalling. Progress made over recent decades on eliminating PRNDs is thus at major risk of being reversed.

A STRONG GENDER LENS IS CRUCIAL TO ACHIEVING POSITIVE HEALTH IMPACTS

Women and girls have been particularly affected by the COVID-19 pandemic and the resulting economic downturn as they generally earn less, have less job security, are major caregivers, including caring for the elderly, and are adversely impacted by a lack of access to healthcare[7]. The latter includes exacerbated obstacles to accessing sexual and reproductive health services, and all of this is compounded by dramatic increases in domestic violence[8]. Similarly, people who face discrimination, stigmatisation, intolerance, or violence because of their actual or perceived sexual orientation, gender identity and expression, or sex characteristics are particularly at risk[9].

Therefore, **keeping a strong gender focus is key to staving off what is for now an almost silent but imminent and multifactorial global health crisis.** A strong gender lens on PRNDs in this context is all the more crucial to achieving positive health impacts. This study highlights a number of gender-related aspects of PRNDs, analysing the implications on research and innovation (R&I) needs and the role of gender-sensitive and gender-responsive approaches in fighting PRNDs.

What are PRNDs? What is gender?

It is through the lens of the exacerbated economically and socially vulnerable situations for women and girls, people who identify as Lesbian, Gay, Bisexual, Transgender, Intersex or Questioning (LGBTIQ+) and for all people suffering from PRNDs that we read the following definition of **'infectious diseases of poverty'** from the WHO Global Report for Research on Neglected Diseases[10]

> *"an umbrella term used to describe a number of diseases which are known to be more prevalent among poorer populations, rather than a definitive group of diseases. It is an overarching concept, recognising the need to focus on the poor and vulnerable, who have less power to intervene. […| Infectious diseases of poverty are not restricted to low and middle-income countries, but manifest in poor populations globally"*[10:13].

POVERTY IS ABOUT ECONOMIC STATUS BUT ALSO ABOUT **POWER**

This definition is of particular relevance because it **relates the term 'poverty' not only to income and economic status but also to a concept of power**, and thus, also to a deprivation of capability[11]. This leads to a vicious cycle in which these diseases increase poverty but poverty in itself also increases the chances of developing these diseases[12]. Such a conceptualisation moves the attention **away from the notion of 'neglected diseases' to a notion of 'neglected populations'**, creating space for a more differentiated analysis. Diseases of poverty are, however, also 'neglected' in the sense that there is a lack of private sector interest in investing into R&I for new or improved health tools and technologies. This is the case despite the immense disease burden and the persisting and consequential research and product development gaps. Due in part to the limited market incentive for innovations targeting 'neglected populations', as well as weak policy frameworks[15].

SEX REFERS TO BIOLOGICAL ATTRIBUTES, **GENDER IS A SOCIAL CONSTRUCT**

For the purpose of this report, **23 'diseases of poverty' will be considered** *(see Annex 1)*, including NTDs prevailing mainly in 149 low- and middle-income countries (LMICs)[13], as well as HIV & AIDS, malaria, and TB[12]. The focus however will be on the differential impact these diseases may have on neglected populations, among them in particular women and girls. 'Sex' refers to the biologically designated attributions at birth as male, female, or intersex person and may differ from one's gender identity and expression. Even though often related, they are distinct concepts. WHO defines 'gender' as a social construct that

> *"includes norms, behaviors, and roles associated with being a woman, man, girl or boy, as well as relationships with each other. …[It] varies from society to society and can change over time"*[14].

Political, social, historical, cultural, and economic realities shape gender norms, roles, and identities. Prescribed roles, behaviours and attitudes can be the "cause, consequence and mechanism of power relations"[15]. Therefore, gender is "hierarchical and produces inequalities that intersect with other social and economic inequalities"[14]. The inequalities and discrimination that women and girls, intersex people or people with non-binary gender identity or expression, or of non-heterosexual sexual orientations may face can put their health and well-being at risk and thus, make them more vulnerable, for example to the impact of PRNDs. Pregnant women and children are often more exposed to diseases, including unique complications, for example, placental malaria, as well as increased severity of disease. Congenital transmission can result in mental and physical health complications, and can have a lifelong impact.

What are the methods of data collection used?

The methods used to gather information are based on secondary and primary data collection. Firstly, an extensive literature search was conducted (see *Annex 2* for the search terms) with an attempt to filter relevant literature from a gender perspective. Secondly, quantitative data was extracted from the Global Burden of Disease (GBD) / Institute for Health Metrics and Evaluation (IHME) database[16] on the 23 diseases and further data extracted from the WHO[13] and G-Finder[17] websites. Relevant information from this data collection process was thereafter consolidated and integrated into the report as appropriate. Regional data has been classified according to the WHO regions and diseases with a variation between females and males of more than 20 percentage points highlighted in the text. Thirdly, semi-structured in-depth interviews were carried out with key stakeholders. In total, 18 interviews were conducted with representatives of ten organisations (see a list of interviewed organisations in alphabetical order in Annex 3), and with leading experts. A qualitative analysis of the interviews was carried out with the help of code-and-retrieve software and has been used to substantiate the specific literature. Key stakeholders were identified through a snowball technique. Both literature review and interviews contributed to identifying case studies. All interviews were carried out remotely via different video platforms. This study includes the same data-set as the original study published in 2021.

What are the limitations of this study?

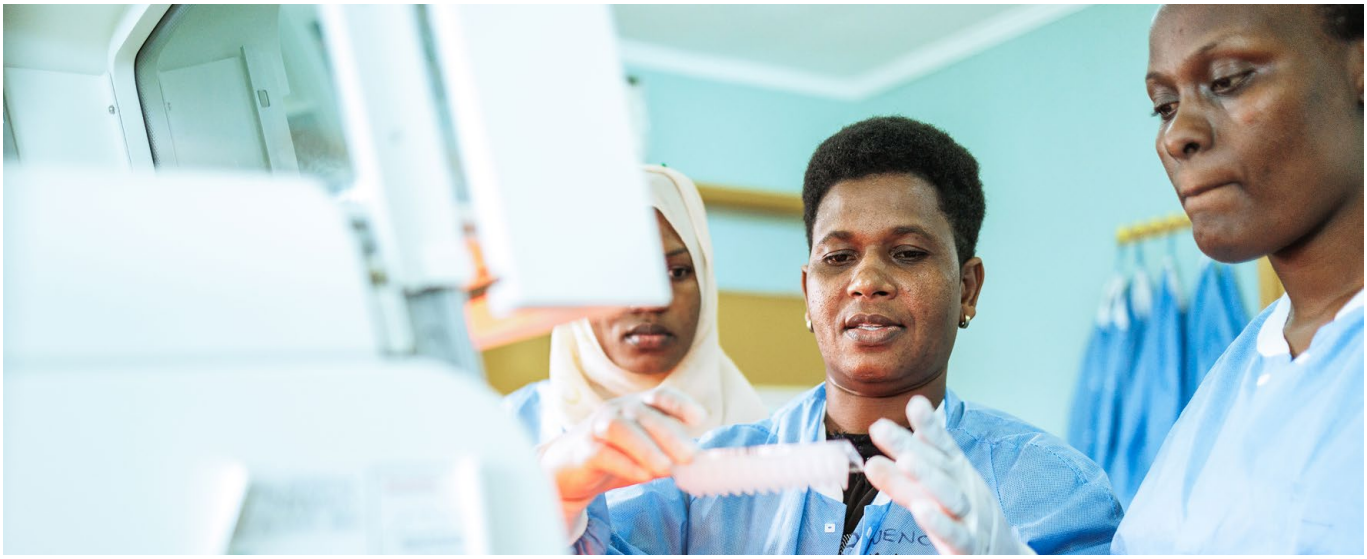
This study has attempted to consolidate and create a knowledge base on existing literature in regard to PRNDs, gender, and R&I needs. Even though a comprehensive literature search was conducted, restrictions had to be introduced for the search terms. In addition, diseases are not covered on an equal footing, partly because gender-specific literature was not available or not accessible for all diseases. Data on yaws and mycetoma were not available in the GBD Database for the year 2017; thus, reference is made only through the available literature. Despite these limitations, an attempt was undertaken to triangulate the information through the different interviews and the existing literature[18].

The GBD database has been criticised for various reasons, one of them being that the source data and modelling assumptions may not provide sufficient comparability[19] but also that data disaggregation is limited to the binary divide between males and females, or that source data excludes women as their disease may not be registered. The limited data and literature available on PRNDs and intersex people, or people with non-binary gender identity or expression, or of non-heterosexual sexual orientations have made it in many areas impossible to extend the analysis beyond differentiation of males and females. Much of this study therefore focuses more specifically on women and girls instead of applying a broader gender lens.

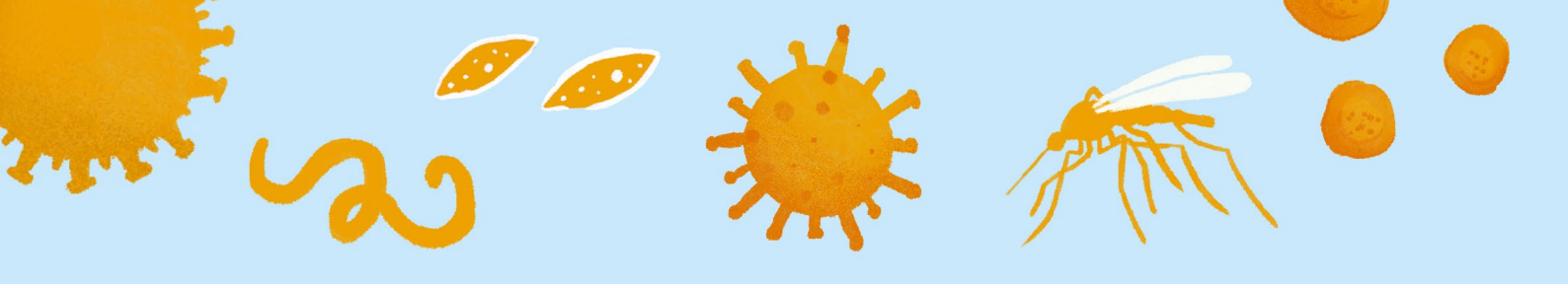
IN PRACTICE

Consider all people beyond the binary focus on males and females

Further research is needed to understand – within the often restrictive political and legal environments – the impact of PRNDs on the entire gender identity spectrum, particularly the needs of the LGBTIQ+ population, and the resulting implications for the R&I process.



Scientists at the Joint Clinical Research Centre, in Kampala, Uganda © DSW/ JCRC



2 GLOBAL BURDEN OF PRNDS BASED ON GENDER AND SEX-BASED DIFFERENCES

PRNDs impact in particular discriminated groups who more easily find themselves in vulnerable situations, such as women and girls, LGBTIQ+, transient or minority populations, due to their different social, cultural, and economic realities, such as lack of access to education, land ownership, and political power[20]. However, biological (sex-related) susceptibility is also an important influencing factor when measuring disease prevalence and impact[22]. Out of these groups, this chapter hereafter mainly focuses on women and girls due to the aforementioned limitations in data and literature availability.

Different factors together exacerbate gender inequalities that limit women and girls' lives, opportunities, and development[21]. **The effects of PRNDs are felt by all affected individuals on multiple levels, but studies suggest that women are particularly affected** not only on physical, reproductive, sexual, and economic levels, but also on social and emotional levels[22, 23]. For example, exclusion and social stigma are particularly associated with some of the diseases, such as Buruli ulcer, (cutaneous) leishmaniasis, lymphatic filariasis (LF), onchocerciasis (OV), and trachoma and bear a much higher toll on **females than males**[24]. The differential impact of PRNDs is felt at the household level as women and girls may not be able to fulfil prescribed caretaking roles and men may be less able to fulfil prescribed income-earning roles[25]. These dynamics, existing gender norms, and power relations consequently impact on the health-seeking behaviour of women and men[26,27].

THERE IS AN IMPORTANT DIFFERENCE BETWEEN PRND **'PREVALENCE' AND 'IMPACT'**

The global burden of PRNDs on women and girls has to be considered against this background, bearing in mind the potential limitation of the GBD Database in regard to source data and implications for women and girls for prevention, treatment, and post-treatment. Considering these different factors, **it is pertinent to distinguish between PRND 'prevalence' and 'impact' and consider both when assessing PRNDs through a gender lens.** Looking at prevalence (proportion of people infected at a given time) alone would fail to paint a full picture of the burden of PRNDs on women and girls. This is an important first finding which is taken into account in the following chapters, which also consider 'impact' (e.g., in terms of direct affect on men and women in regard to wider health consequences, availability of healthcare, stigma and discrimination, financial and social consequences) and in the development of recommendations in this study. Faramand et al. (2019) have conducted an extensive desk review on gender issues and NTDs and *Table 1* highlights some of their findings in regard to risk of infection and impact of diseases on women concerning lymphatic filariasis, trachoma, onchocerciasis, soil-transmitted helminths (STH), and schistosomiasis (SCH).

"These diseases really affect us even when you look at the domestic [sexual] relations it is really affected because it slows down and this interferes with the marriage, and the man will leave you"[28].

Grace, female, 24 years, Kenya

"I can say there is stigma and discrimination because when I say I am unwell as a woman; people do not take me seriously. When I say I need money to go to the hospital, they take it lightly. I cannot work, and this forces me to stay home even for a whole month, so I see a lot of discrimination"[28].

Aisha, female, 37 years, Kenya

IN PRACTICE

Move beyond the biomedical focus and introduce a holistic approach

Going beyond the traditional biomedical model that relies primarily on quantitative, medical data will require research to systematically integrate a gender perspective, rooted in a contextual (local) analysis based on sociology, political sciences, and anthropology. This calls for studies contributing to understanding the gender-specific impact (and not only prevalence) of diseases and conditions, and more socio-behavioural and implementation research. Gender mainstreaming and intersectional gender analysis can be useful tools that need to be solidified and mandatory in the R&I process beyond the generic requirements of 'ticking the gender box' in project proposals. It implies, for example, establishing impact indicators specifically on gender.

TABLE 1

Overview of selected NTDs, their cause, symptoms and intersection with gender and sex

			NTD intersection with gender and sex	
Disease	Cause	Symptoms	With risk infection	With impact of disease
LF	Parasitic worms transmitted by mosquitos	Damage to the lymphatic system, resulting in swelling of arms, legs, or genitals	Preventive treatments are not safe for pregnant women. Men and boys are at greater risk in many countries.	Disfigurement and disability can impact employability and marriageability of men and women differently. Hydrocele in males. Men may not seek treatment due to perception of masculinity.
Trachoma	Bacteria spread by people and houseflies; exacerbated by poor hygiene	Eyelid turns inward; can lead to visual impairment or irreversible blindness	Child-care and caregiving increase women's risk. Preventive treatment safe for pregnant women, but often not offered.	Women are four times as likely to need eye surgery. Women account for 86% of trichiasis cases.
OV	Filarial worm, transmitted by black fly bites	Visual impairment, i.e. permanent blindness; intense itching and skin disfigurement	2/3 of water-based domestic activities are completed by women, increasing risk. Preventive treatments not safe for pregnant women.	Disfigurement and disability can impact employability and marriageability of both men and women in different ways.
STH	Egg ingestion from contaminated soil, poor hygiene, or skin penetration by lavrae in soil	Aggravate malnutrition, amplify rates of anemia, and lead to cognitive impairment	Men or women working in agriculture. Gendered cultural norms, such as open defecation. Out of school children may not access deworming campaings.	Severe hookworm-related anemia in pregnant women. Low birth weight babies and/or premature birth. Infertility (caused by hookworm) for females.
SCH	Parasitic larvae in water	Leads to chronic ill health (e.g. damage of the bladder and urinary tract)	2/3 of water-based domestic activities are completed by women. Disease is exacerbated during pregnancy. Men and boy's work can increase risk.	Female Genital SCH causes reproductive organ damage, infertility, and increased risk of HIV. Can increase females' risk of anemia.

Source: Faramand T.H, Dale K. et al. (2019)[27:11], design adapted for this report

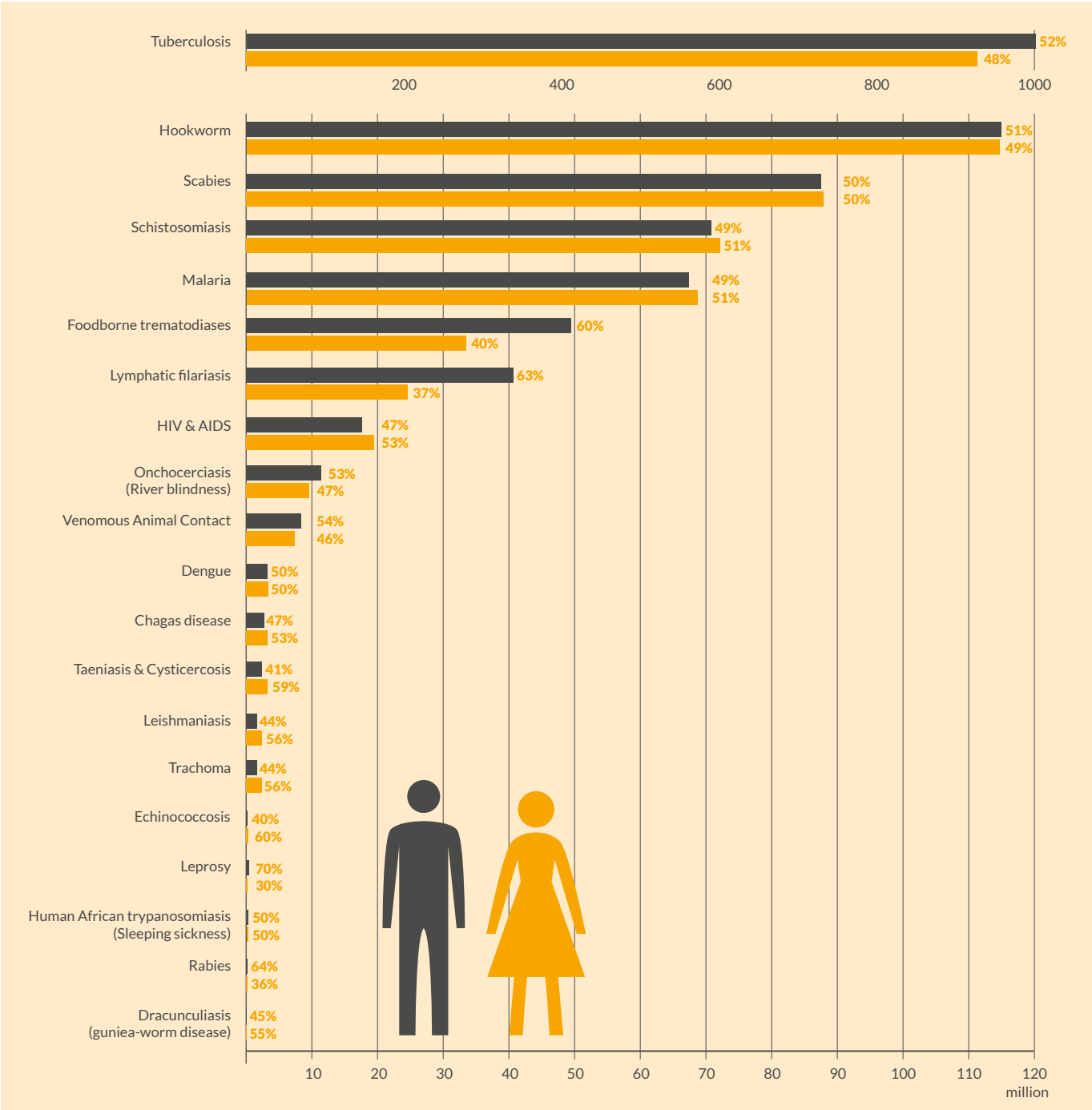
Global and regional PRND prevalence

When considering global prevalence rates, and without taking into consideration missing data, the disease with the highest prevalence by far is TB, with males more affected than females. Hookworm, scabies, SCH, and malaria follow, with up to two percentage points difference in the global prevalence rates between females and males for all four diseases (see *Graph 1*). In the context of TB, the health-seeking behaviour of women has been studied in different contexts [29-32]. Even if in theory women can often access health care in the same way as men, in practice the availability of healthcare facilities, knowledge and awareness of the disease, socio-economic and cultural factors [34], and stigma associated with the disease [34] influence health-seeking behaviour and can therefore negatively impact detection and notification of TB in women [35].

TB IS THE MOST PREVALENT PRND GLOBALLY, MALES ARE MORE AFFECTED THAN FEMALES

GRAPH 1 Global prevalence of PRNDs

Source of data: Global Health Data Exchange (GHDx) 2017

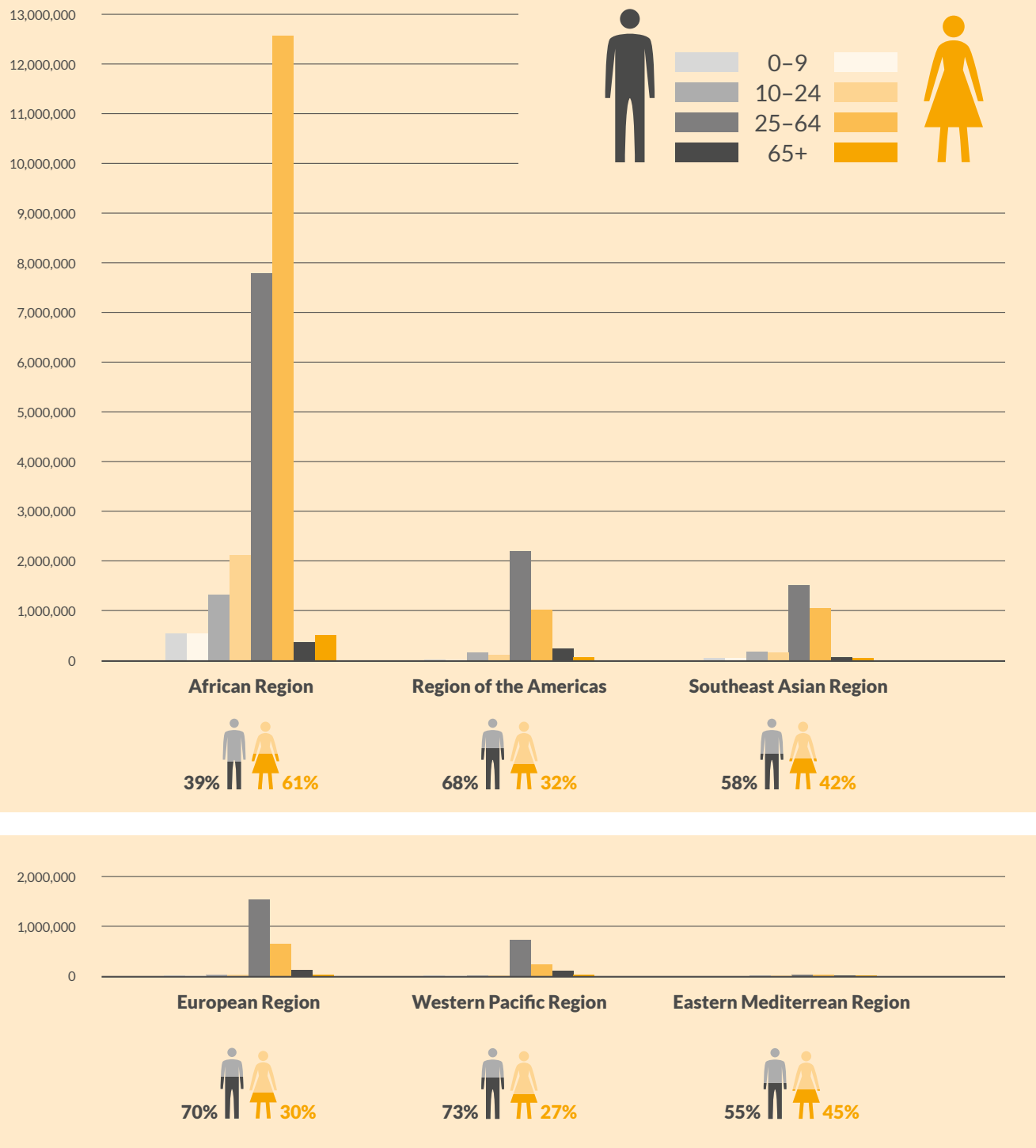


The overall **global prevalence of PRNDs may not always correspond to the regional prevalence** rates as evident in the example of HIV. The global prevalence of HIV shows rates of 53% among females vs. 47% among males. If data is disaggregated regionally, the prevalence rates paint a significantly different picture *(see Graph 2)*. Prevalence generally is highest in Africa, but also the prevalence of HIV in females (61%) is much higher than in males. All other regions not only have lower prevalence in general but also the prevalence in males is higher than in females, with the Americas, Europe, and the western Pacific regions having a difference of 36 – 46 percentage points.

HIV PREVALENCE IS HIGHEST IN AFRICA, WITH A **HIGHER PREVALENCE IN FEMALES**

GRAPH 2 Regional prevalence of HIV

Source of data: Global Health Data Exchange (GHDx) 2017



"Gender inequality is a threat to everyone. We cannot uphold patriarchy and defeat AIDS."

Winnie Byanyima,
Executive Director of UNAIDS

Photo: Participants of the CHEDRA Adolescent Girls and Young Women Ring Program, Masaka, Uganda. © DSW/ CHEDRA

DEEP DIVE 1
HIV IN SUB-SAHARAN AFRICA

Sub-Saharan Africa remains the region most affected by HIV, with **women disproportionately infected compared to their male counterparts**. In the region, girls and young women account for six in seven new HIV infections among adolescents aged 15–19 years[36]. Writing in 2013, Ramjee and Daniels[37] detailed that a combination of **biological, social, behavioural, cultural, economic and structural factors** have led to disparate infection rates.

Females are at a greater physiological risk of contracting HIV than males because of a number of contributing biological risk factors. Females have a greater mucosal surface area exposed to pathogens and infectious fluid for longer periods during sexual intercourse. Changes in hormones such as progesterone and oestrogen, including during the menstrual cycle, and brought about by contraception use or pregnancy, influence both the structure of the genital mucosa and the immune response.

Contextual risk factors play out at both an individual level - for example, the infectiousness of a sexual partner - and at a societal level. At the latter level, risk factors are often out of the control of the individual and include sexual practices, the prevalence of sexually transmitted infections (STIs), and cultural norms. **Women's differing health status is exacerbated by the dominant patriarchal culture and society** present in many African countries: in certain cultures, men are seen as the heads of the family, while women are expected to respect their husbands; women playing a part in sexual decision-making may lead to violent consequences; women are expected to accept polygamous relationships; rituals such as 'dry sex'; practices including early marriage lead to increased risk of HIV infection. UNAIDS reports that in areas of high HIV burden, **women subjected to intimate partner violence face up to a 50% higher chance of acquiring HIV**[38].

Poverty remains a driving force of HIV transmission in women. Lower use of condoms, higher probability of having had transactional sex or being physically forced to have sex, and having multiple sexual partners have all been associated with lower economic status. In the majority of high-inequality countries, sex-related inequality **in HIV incidence and AIDS-related mortality is unchanged or has worsened** since 2010[39].

Relative HIV acquisition risk is evidently even higher in different key populations. The risk of acquiring HIV is 30 times higher for female sex workers than adult women, 28 times higher among gay men and other men who have sex with men than adult men and 14 times higher for transgender women than adult women[36]. UNAIDS highlights that the gaps in HIV responses and resulting HIV infections and AIDS-related deaths lie upon fault lines of inequality, pinpointing the failure to address the **societal and structural factors that increase HIV vulnerability** and diminish people's abilities to access and effectively benefit from HIV services as a central reason for such stark and persistent disparities in the HIV response.

CASE STUDY 1 EXPANDING WOMEN'S ACCESS TO HIV TOOLS

Microbicides are topical Pre-exposure Prophylaxis (PrEP) products configured to protect individuals from the transmission of HIV during intercourse by inhibiting the early stages of the infection process at the vaginal or rectal mucosa. Microbicides have been considered a **technology that could expand women's HIV prevention options**. One such product is the monthly dapivirine ring[40], originally developed by the International Partnership for Microbicides (IPM), now included within the Population Council's portfolio of products.

Made of flexible silicone, the monthly dapivirine ring releases an antiretroviral drug called dapivirine over the course of one month. The ring can be inserted and replaced by the user and was designed to offer women **a discreet and long-acting HIV prevention choice that they can control**. IPM's approach to product development was centred on the needs and expectations of women. Product acceptability studies were undertaken to gather the preferences of women and their partners, including assessing different product forms[41]. Studies were also undertaken to understand how the dapivirine ring could meet the needs of women throughout their lives, including among adolescent girls and young women[42, 43] as well as pregnant and breastfeeding women[44].

Throughout the R&I cycle, from the preclinical stage via pharmacokinetic investigations, toxicology, virology and other studies, to clinical trials and the post-approval stage, the **biological dimension of HIV, as well as its gendered impact were considered**. A 2021 study by Doggett et al. underlines that the 'gender-related norms and inequalities that place women and girls at risk of acquiring HIV are also likely to affect their ability to use microbicides', identifying norms related to women and men's sexuality, and power dynamics with intimate relationships as the two broad categories of gender norms, roles and relations that will likely affect women's ability to access and use microbicides[45].

The study concludes that microbicides will only deliver their potential if gender norms are considered when trialling and implementing new technologies. Furthermore, integrating strategies into introductory programmes to overcome such gender-based obstacles has the potential to break them down. Examples of such include increasing couples' communication, giving women increased knowledge about sexuality and enhancing women's power to prevent HIV; underlining that the holistic application of a gender lens throughout the R&I cycle holds promise in both tackling and dismantling gender inequality.

Protecting women with women-centered tools

"We didn't get any issue from the ring, and we didn't experience any issue with it. It is not inconvenient to insert or remove. It had no issues. I support it because a woman will also have gotten some protection, because we as women didn't have anything to protect us. As an individual, the woman also now has some protection. That ring, the women who weren't involved in the study, we told some about it. They also yearn to have it because she can tell you that her husband is in a relationship with a widow. When she tells him to test for HIV, he doesn't want to. They had brought the female condoms, but they are not available anymore and he resorts to beating her, claiming she has learnt all that from sleeping around. That becomes a new source of contention because he cannot accept - they don't care. But, with the ring, everyone is asking - when is it available, where can we get it from?"

© DSW/ MRC/ UVRI and LSHTM Uganda Research Unit

Testimony shared by Ritah, Joyce and Josephine; participants of a clinical trial conducted on the Dapivirine Vaginal Ring at the MRC/UVRI and LSHTM Masaka Site, Uganda.

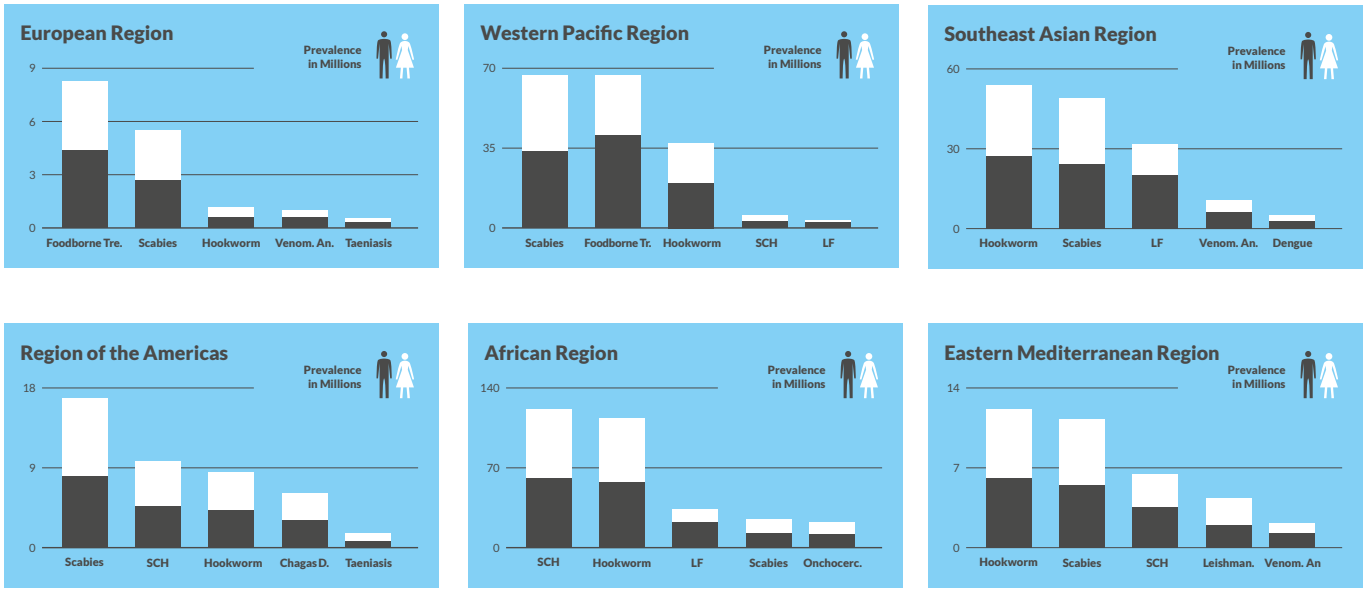
Pictured above at the site.

Regional prevalence of NTDs

A comparison of the regional prevalence rates of NTDs show that in five regions of the world (all except Europe) hookworm, scabies, and schistosomiasis are among the five most prevalent NTDs *(see Graph 3)*. In Europe and the western Pacific, both foodborne trematodiases and scabies are the two most prevalent diseases, whereas in southeast Asia and the eastern Mediterranean, hookworm and scabies are most prevalent. In the African region, schistosomiasis is ranked first followed by hookworm disease and in the Americas, scabies has the highest prevalence followed by schistosomiasis.

Graph 3 illustrates the prevalence rates among males and females across regions with little striking difference among the top five NTDs per region. It is thus of greater importance to consider the gendered impact of these diseases.

GRAPH 3 Five most prevalent NTDs by region



Source of data: Global Health Data Exchange (GHDx) 2017

CHAGAS DISEASE
GUINEA-WORM DISEASE
ECHINOCOCCOSIS
LEISHMANIASIS
RIVER BLINDNESS
SCHISTOSOMIASIS
TAENIASIS & CYSTICERCOSIS
TRACHOMA
HIV & AIDS

disproportionately affect women and girls

Diseases that disproportionately affect women and girls

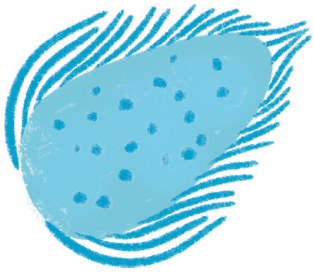
Chagas disease, dracunculiasis (Guinea-worm disease), echinococcosis, leishmaniasis, onchocerciasis (river blindness), schistosomiasis, taeniasis & cysticercosis, trachoma, and HIV & AIDS are the nine diseases with a higher global prevalence among females than males.

Schistosomiasis takes a heavy toll on females as it promotes horizontal transmission of HIV & AIDS[46] and is also interlinked with cervical cancer[47]. In addition, 40 million women of childbearing age suffer from female genital schistosomiasis and having the disease during pregnancy is yet another concern, especially in regard to anaemia, miscarriage, preterm labour, and in regards to the ability to become pregnant. Accurate numbers of pregnant and breastfeeding women affected by schistosomiasis, however, are missing[22].

Similar to schistosomiasis, **echinococcosis is a zoonotic disease (tapeworm infection) that has a disproportionately high prevalence rate among females**, globally and in most regions of the world (except the Americas and western Pacific). The highest prevalence is in the European region followed by the eastern Mediterranean region, in both cases with a prevalence rate that is 20 percentage points higher among females than males *(see Graph 4)*.

"Female Genital Schistosomiasis exemplifies the experiences of marginalised women and girls, who face multiple and intersecting health, sociocultural, environmental, and economic challenges."

UNAIDS



DEEP DIVE 2 FEMALE GENITAL SCHISTOSOMIASIS

Female Genital Schistosomiasis (FGS) is a manifestation of schistosomiasis caused by *Schistosoma haematobium*, a waterborne parasite. FGS develops when parasite eggs damage the urinary tract and reproductive organs of women and girls, causing gynaecological symptoms.

An estimated **56 million young and adult women in sub-Saharan Africa suffer from FGS** [48,49] with the burden of disease highest among young women between 18 and 29 years old. The risk of infection is heightened by activities that require people to spend considerable amounts of time in contaminated water, for example for livelihood activities and domestic chores, such as washing clothes or dishes and collecting water - activities that are most often undertaken by women and girls.

FGS triples the risk of women and girls contracting HIV, and is also interlinked with cervical cancer [50]. When seeking healthcare, women with FGS often complain of infertility or symptoms of sexually transmitted infections (STIs). As a result, and due to the low awareness among clinicians of FGS, patients are often misdiagnosed. This can lead to women being wrongly accused of sexual promiscuity, which in some communities can have serious ramifications, including gender-based violence and social exclusion.

Furthermore, when patients are misdiagnosed and do not receive the appropriate treatment, established FGS can result in genital ulcers, infertility, miscarriage, ectopic pregnancy, disorders of menstruation and maternal death. These complications **can lead to social isolation and stigma**, further exacerbated by the low awareness of the disease within communities and health systems, with women and adolescent girls with FGS at an increased risk of mental ill-health, including depression [51].

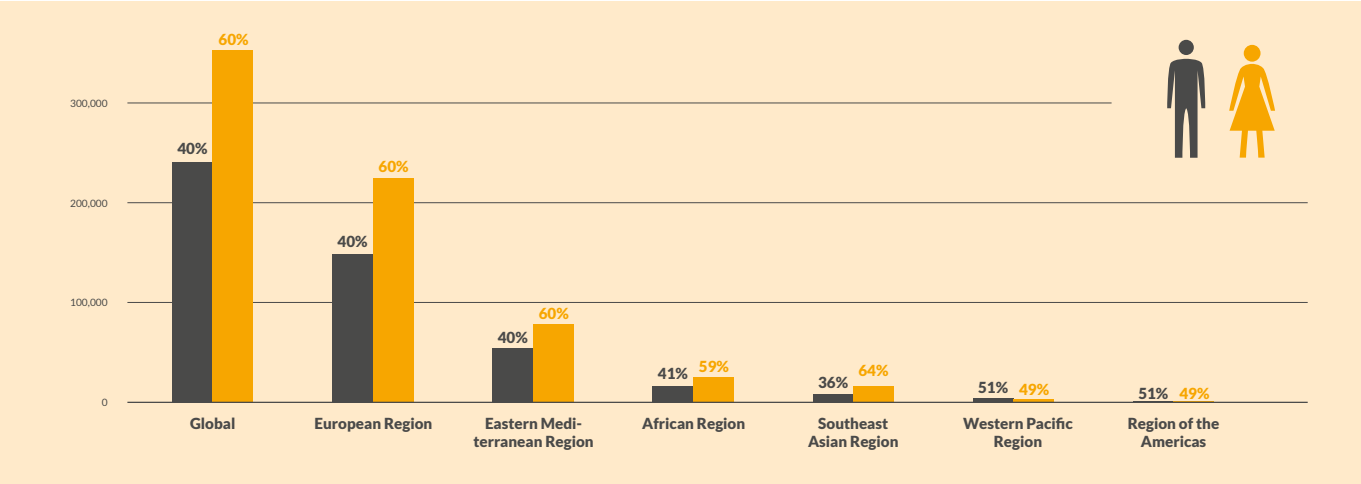
While diagnosing infection with Schistosoma can be done with a fairly simple test, diagnosing FGS is much more difficult. The current approach to effectively diagnosing FGS requires a visual examination of the cervix and the vaginal wall. This procedure is far from ideal, with efforts to diagnose constrained in low resource settings. Ethical and cultural considerations can create barriers to invasive diagnostic procedures and taking a biopsy can leave a patient at increased risk of HIV infection or transmission.

The main pillar of schistosomiasis control is the mass administration of Praziquantel, usually for school-aged children [52]. Significant **gender disparities in access to education cause inequalities in treatment**. Across sub-Saharan Africa, 9 million girls will never attend school compared to 6 million boys, and in order to reduce the gender disparities, platforms for FGS prevention and control must strive to reach girls that are not in school, as well as those who are [53]. While Praziquantel is effective in preventing schistosomiasis, it cannot reverse morbidities caused by chronic infection, such as genital lesions once they have formed. There are currently no validated therapeutic options for FGS.

Echinococcosis

Studies on echinococcosis are few, and if available mostly focus on countries in the Middle East[54–56] and a few in Europe[57]. Sex-disaggregated data is generally very limited. The **higher prevalence rates in females are – if mentioned – directly related to gender roles in the household** in predominantly rural settings. Women and girls more often take care of the dogs or other animals (whose faeces can be contaminated with tapeworm eggs), undertake the gardening, and prepare the food, all of which enhance the likelihood of transmission of this zoonotic tapeworm[55, 56, 58]. As symptoms are developed on average over a period of ten years, medical care rates are usually much lower, also influenced by the availability, or lack of financial resources to pay for the treatment[58].

GRAPH 4 Global and regional prevalence of Echinococcosis

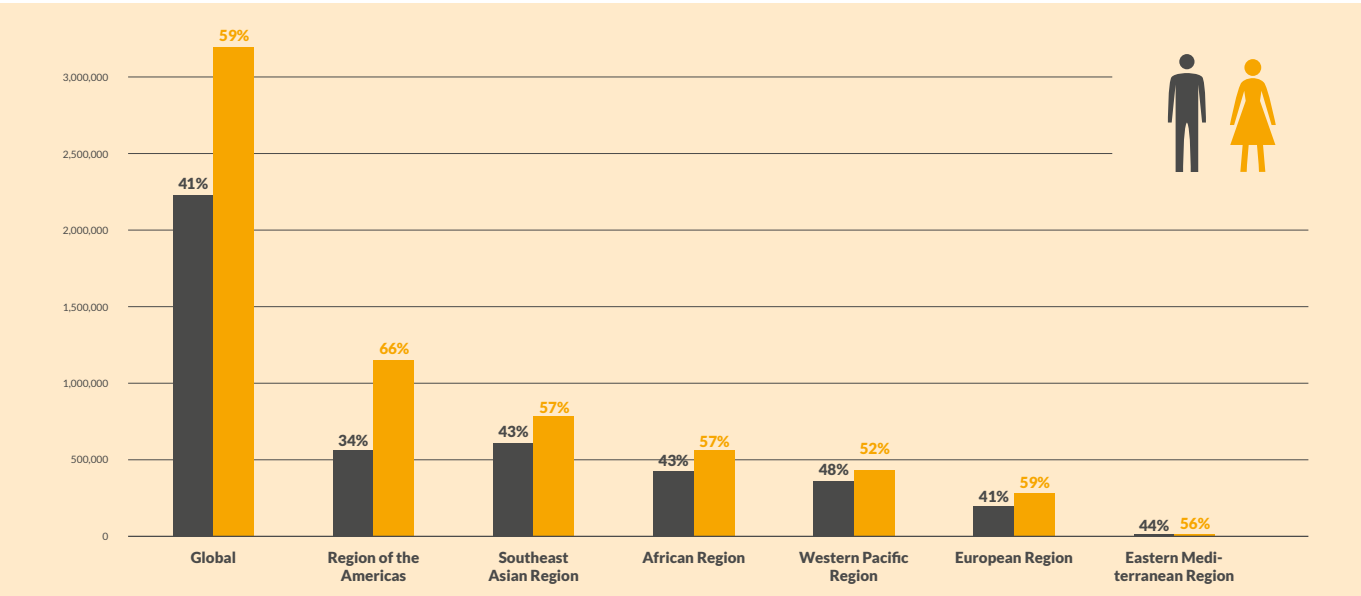


Source of data: Global Health Data Exchange (GHDx) 2017

Taeniasis

The prevalence rate of taeniasis (another tapeworm infection) is similar to echinococcosis, thus higher among females than males around the globe. In the Americas, the most endemic region, **the burden of taeniasis in females is 32 percentage points higher than in males.** Southeast Asia and Africa also remain considerably affected regions *(see Graph 5)*. Transmission takes place through the tapeworm eggs, linked to rearing livestock, especially pigs, and is exacerbated by a lack of hygiene and sanitary measures[59, 60]. The reviewed literature[60–62] does not provide information on the gender-related impact of the disease but similarities to echinococcosis exist in as far as gender roles in the household are likely to play a crucial role and may provide some explanation for the higher burden of the disease on females.

GRAPH 5 Global and regional prevalence of taeniasis & cysticercosis



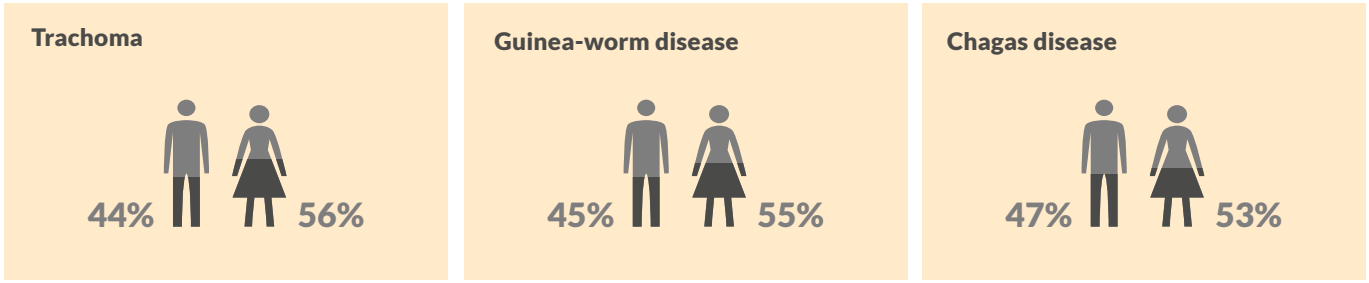
Source of data: Global Health Data Exchange (GHDx) 2017

Leishmaniasis

(Cutaneous) Leishmaniasis is one of the five NTDs with the highest prevalence rate in the eastern Mediterranean region, which is also reflected in the available literature (e.g. Yemen [63], Tunisia [64], Iraq [65]). Common to the different studies across regions – independent of the prevalence rates – is the higher disease burden in women due to reduced health care access [66] and the socio-aesthetic impact of the cutaneous form of the disease, resulting in **increased professional exclusion and social isolation**, even within the family [63, 67].

Trachoma, Guinea-worm, and Chagas disease all have a global prevalence rate between 6 and 12 percentage points higher among females than males *(see Graph 6)*, yet, the consequences of these diseases may go beyond what figures portray.

GRAPH 6 Global prevalence of trachoma, Guinea-worm, and Chagas disease



Source of data: Global Health Data Exchange (GHDx) 2017

Chagas disease

Even though **Chagas disease** has a higher overall global prevalence in females, the picture is more differentiated across age groups. Young males and females have an equal prevalence rate but the prevalence rate in females between 40 – 60 years of age is higher. **Men suffer from higher morbidity from Chagas disease**, reflected in a more frequent evolution of a chronic form, resulting in higher mortality. Even though the chronic form of the disease is much milder in women, the higher morbidity and mortality rates in men place women under physical, psychological, and financial stress [68].

Guinea-worm disease

Guinea-worm disease has a prevalence rate of 55% in females compared to 45% in males. Beyond the differing prevalence, **one of the gendered consequences of the diseases is women's reduced ability to look after their children** as a result of reduced mobility caused by the disease [69]. This goes beyond household level, with mothers relying on support from their wider community, with potential knock on effects on wellbeing and productivity. The disease also impacts negatively on married life and the ability to work in agriculture or generate an income [70, 71].

Trachoma

The **risk factors for developing trachoma are embedded in women and girls' ascribed household-related gender roles**, such as the responsibility for water collection and household sanitation [72], as well as for childcare [73-77]. In endemic countries, trichiasis may be prevalent in girls between one to nine years already [75, 77] and may then lead to higher prevalence rates of trachoma at an adult age [64].

> *"I can't differentiate between people, I can't cut my nails or really take care of myself, I have terrible pain and I can't clean or do anything useful. It was two years ago that I started feeling the pain in my eyes and head, and now I have to sleep through half of the day because of the severe headaches. The light hurts my eyes. It is an awful feeling"* [81].
>
> Haimamote, female, Mekelle, Ethiopia

"Millions of women endure trachoma because, according to the evidence, their gender-determined roles in their families and their communities expose them to increased risk."

Sightsavers [82]

DEEP DIVE 3 TRACHOMA

Trachoma is an eye disease caused by the bacterial infection *chlamydia trachomatis*. Left untreated, and over time, scarring to the eyelid causes the eyelashes to pull inward, causing the eyelashes to rub against the eyeball in an advanced form of the disease called *trachomatous trichiasis*. This can result in chronic pain and light intolerance and can lead to scarring of the cornea. Again, if left untreated, **trichiasis can lead to irreversible opacities, resulting in visual impairment or blindness**.

The infection spreads through contact via hands, clothes or bedding that has been in contact with an infected person, or through flies that have been in contact with discharge from the eyes or nose of an infected person. **The disease thrives where there are infestations of flies, water shortages and poor sanitation** [79]. These risk factors for developing trachoma are embedded in women and girls' ascribed household-related gender roles, such as the responsibility for water collection and household sanitation and childcare [21,22,23,24].

Trachoma's global prevalence rate is **12 percentage points higher in women than in men** [30]. In Ethiopia, the prevalence of Trachoma in women is at 67%, compared to 33% in men. Women's greater exposure and limited access to treatment and care result in them being two to three times more likely to become permanently blinded by the disease than men [74,22]. Blindness as an effect of trachoma, however, means more than just not being able to see, it also affects women's ability to care for children, earn an income, and get, or stay married [22], and can lead to a cycle of poverty and exclusion. Across the board, **from the health to social and economic impacts of blindness as a result of trachoma, it is felt more strongly by women**.

HOOKWORM
DENGUE
MALARIA
SCABIES
SLEEPING SICKNESS

have similar prevalence in females and males

Diseases with similar prevalence rates in females and males

Some diseases, namely hookworm, dengue, malaria, scabies, and sleeping sickness have an equal global prevalence rate and do not show significant variations between females and males. Nevertheless, some of them do have considerably different physiological impacts between sexes impacts: hookworm morbidity is higher among females as they need more iron than males and thus are predisposed to iron deficiency anaemia caused by hookworm. For females of reproductive age, especially pregnant and breastfeeding women, this can be aggravated and cause stillbirth, miscarriage, or infertility [23, 71].

Globally, the prevalence rate of malaria is balanced between females and males, sometimes with a slightly higher prevalence among males due to their increased exposure to the transmitting mosquitoes. However, morbidity between sexes differs, with females at greater risk of malaria, when the immune reaction can weaken, and the added complication of placental malaria [68]. Furthermore, malaria can pose a gendered burden on women, who often take up care giving activities of other family members who may become infected. Women also commonly postpone their own treatment in order to give priority to other sick family members or to care for them despite sickness.

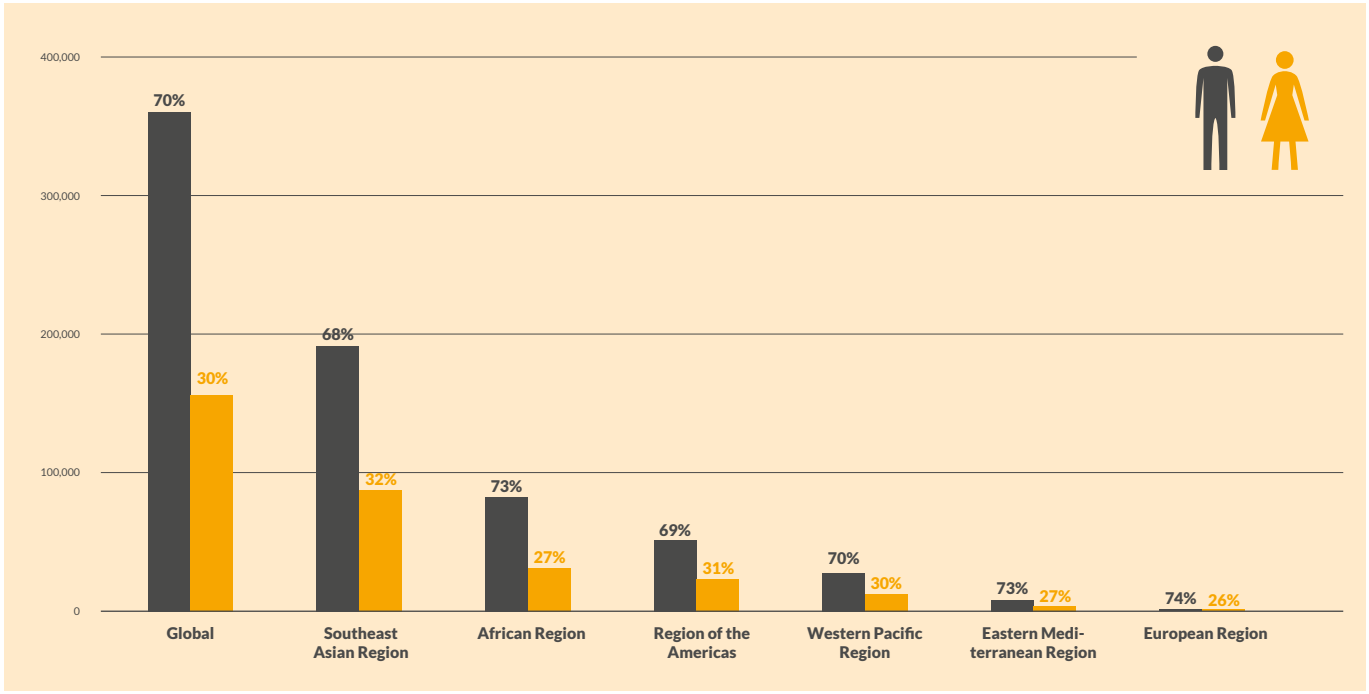
LEPROSY
LYMPHATIC FILARIASIS
RABIES

show higher prevalence in males

Diseases that disproportionately affect men

Traditional male occupational roles, for example in agriculture or in fishing, expose them to a higher risk of contracting some diseases [25]. Among the 23 diseases, there are three which show a much higher prevalence among males than females, namely leprosy, lymphatic filariasis, and rabies. Even though males have higher prevalence rates for these diseases [83], the gendered impact on women can be quite significant. The global prevalence rate of leprosy is for males 40 percentage points higher than for females and these higher rates are seen across all regions of the world *(see Graph 7)*.

GRAPH 7 Global and regional prevalence of leprosy



Source of data *(Graphs 7,8,9)*: Global Health Data Exchange (GHDx) 2017

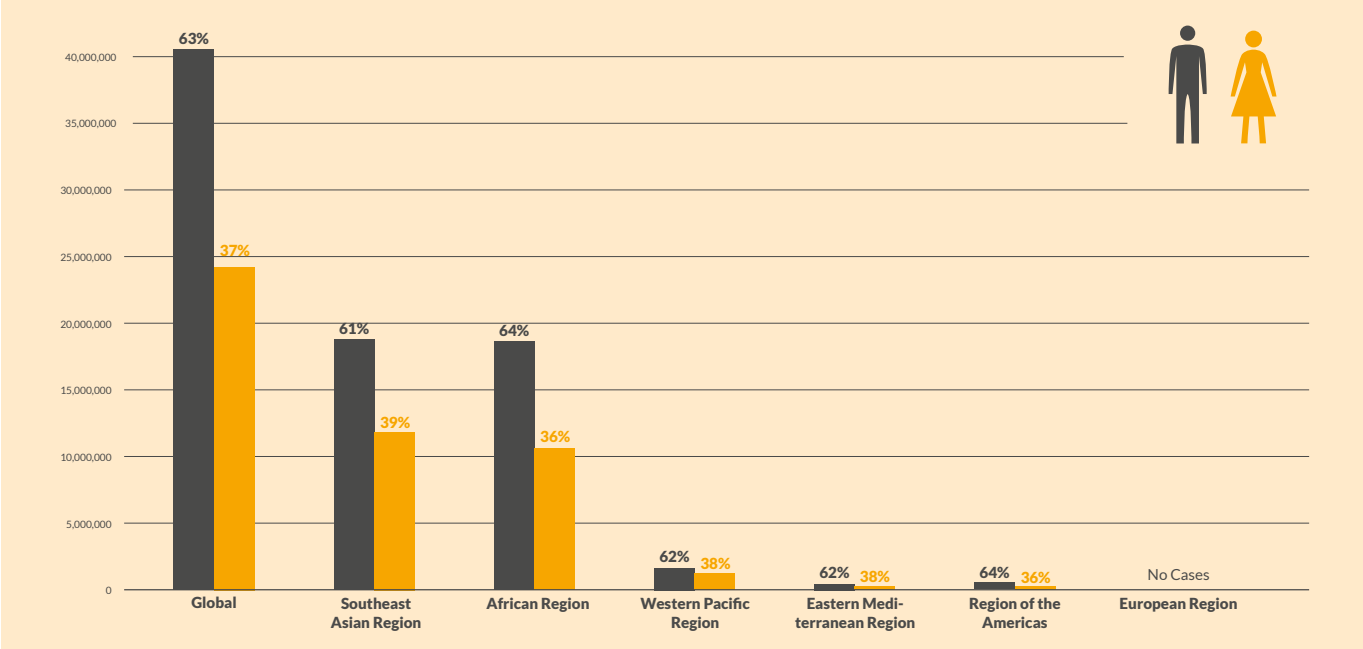
Leprosy

Southeast Asia has the highest regional prevalence of leprosy with males accounting for 68% of the disease burden, and females for 32%. Africa follows, with a disease prevalence of 73% in males, and 27% in females. Stigma and isolation associated with leprosy are felt both by males and females, but a number of studies and systematic reviews have highlighted the more severe impact on women[84]. In addition, Varkevisser et al. in case studies from Nepal, Indonesia, Brazil, and Nigeria pointed out that women with the disease are underreported because of their low status, limited mobility, and poor educational levels[85].

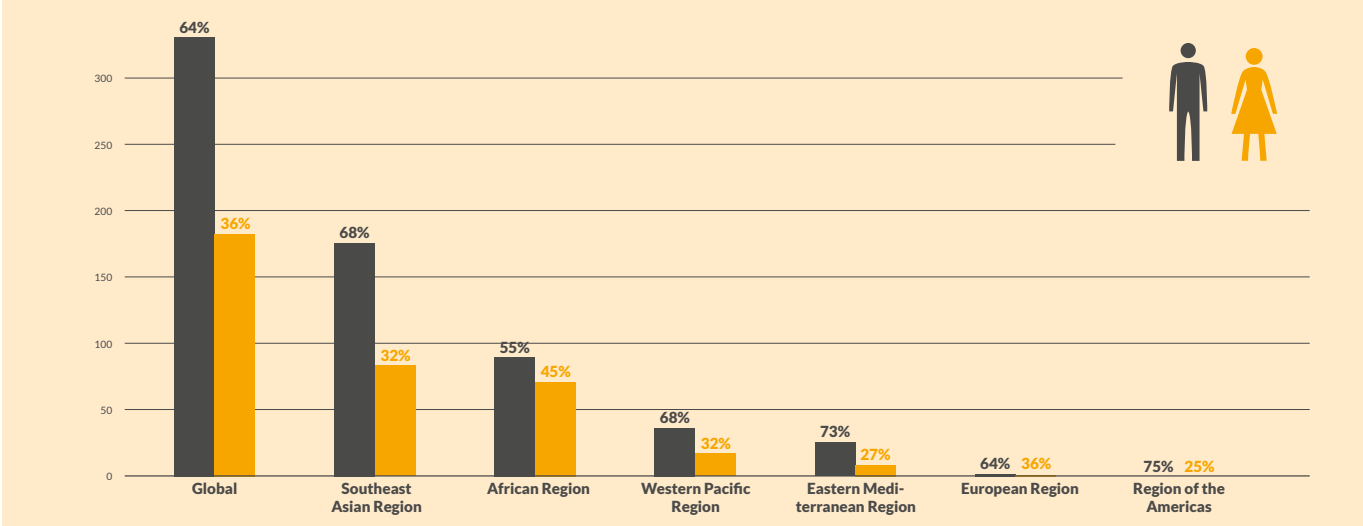
Lymphatic filariasis

Lymphatic filariasis is among the top five ranked NTDs in the western Pacific, in Southeast Asia, and the African region and results in social stigma and isolation that can go as far as losing jobs and wages, or being abandoned by family[86]. Lymphatic filariasis has a higher prevalence rate among males *(see Graph 8)* but the social impact is felt by both men and women. **Men may experience the disease as a 'silent burden'[87], whereas women may face a double burden** as their role and identity in society can depend upon marriageability and the ability to bear children[88]. If unmarried young women develop the disease, they may not be able to continue any education and are unable to marry and with this, enter into a spiral of distress, anxiety, shame, and exclusion[89].

GRAPH 8 Global and regional prevalence of lymphatic filariasis



GRAPH 9 Global and regional prevalence of rabies



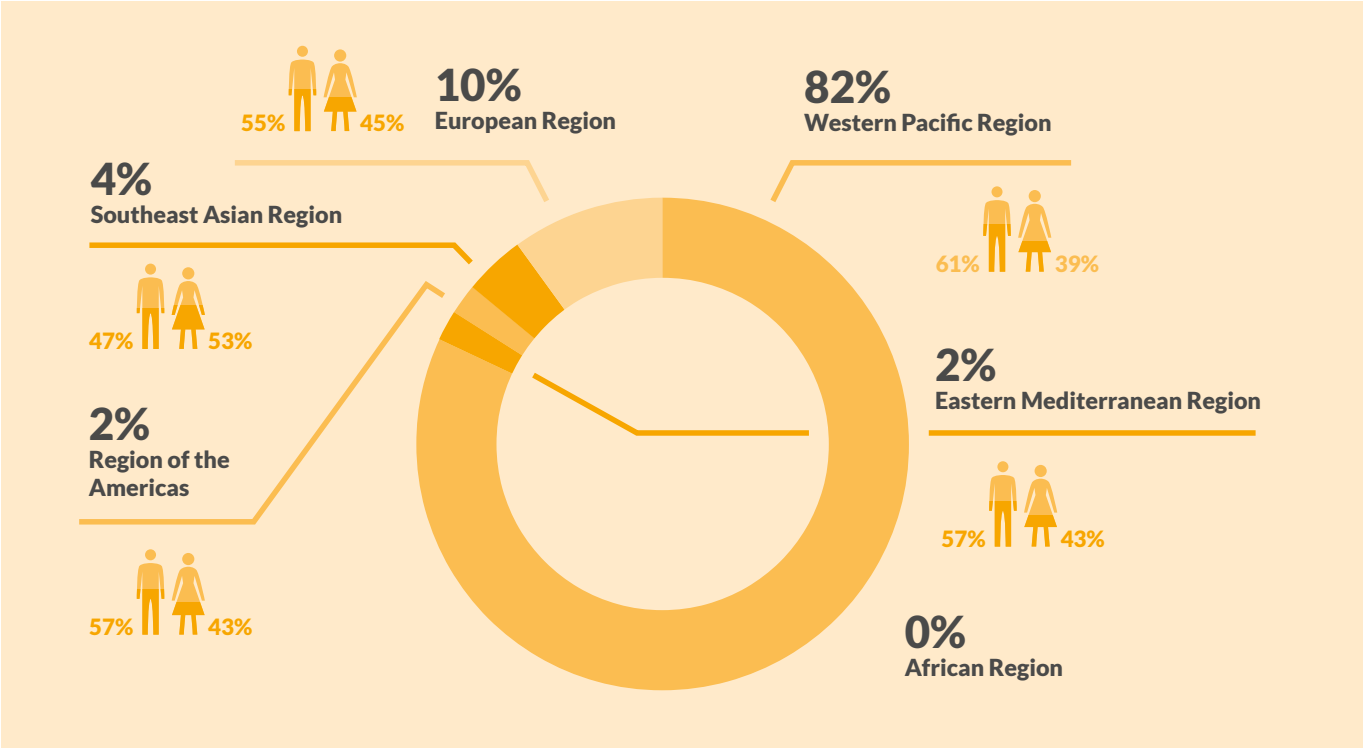
Rabies

Rabies is a zoonotic disease that disproportionately affects males with a global prevalence rate of 64% in males vs. 36% in females. Southeast Asia has the highest burden followed by the African region. All regions except Africa have a 27 to 50 percentage point difference in the prevalence between males and females. Africa has the lowest male – female gap with only ten percentage points difference *(see Graph 9)*. A number of Knowledge, Attitude and Practices (KAP) surveys exist, which do not have an explicit gender focus but mention the differences between males and females with males usually having more awareness about the disease than females [90-93].

Foodborne trematodiases

A number of other diseases do not have variations beyond 20 percentage points and thus are not specifically investigated, even if **stark regional differences exist, such as in the case of foodborne trematodiases** *(see Graph 10)*. The African region has no recorded cases, whereas the western Pacific Region has a prevalence rate of 82% , with males accounting for 61% of the total prevalence, and females for 39%.

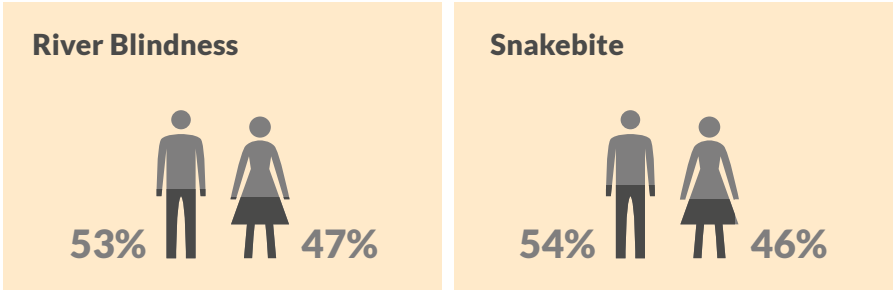
GRAPH 10 Regional prevalence of foodborne trematodiases



Source of data: Global Health Data Exchange (GHDx) 2017

Onchocerciasis (River Blindness) and snakebite both have a slightly higher global prevalence rate in males *(see Graph 11)*. The GBD database does not provide any data on Buruli ulcer, a skin infection which places a social and economic burden on the affected person and the family as a whole [94].

GRAPH 11 Global prevalence of river blindness and snakebite



Source of data: Global Health Data Exchange (GHDx) 2017

How do (certain) PRNDs affect LGBTIQ + individuals?

Research into PRNDs and sex and/ or gender is limited and - if conducted and depending on the disease – very often focuses on the consequences of a disease on women. **Where data is disaggregated, it mostly distinguishes between males and females without taking into account intersex people or people with non-binary gender identity or expression, or of non-heterosexual sexual orientations. The wider gender impact of PRNDs is therefore much less examined**[27]. In the literature search conducted for this study, studies concerned mainly HIV & AIDS and the north American context (with few exceptions, e.g. Fearon[95], Silva-Santisteban[96], Pal[97]). The thematic focus across all of these studies, however, varies.

Among others, existing studies investigate:

- the HIV and STIs risk among LGBTIQ+ individuals in abusive relationships[98], as well as among male-to-female transgender individuals[99];
- testing and care behavior, for example of HIV-negative men who have sex with men (MSM) and transgender individuals in South Africa[100] or of MSM, transgender women and female entertainment workers in Cambodia[97];
- the epidemiology of HIV and TB (among others) of transgender individuals in prisons[100];
- the access/ barriers to care for transgender and gender non-conforming adults[101], as well as access to treatment for MSM[102];
- the project funded by the National Institute of Health (NIH) to address the needs of LGBTIQ+ populations[103];
- the Sexual Orientation and Gender Identities Strategy of the Global Fund to Fight AIDS, Tuberculosis and Malaria to meet the needs of the LGBTIQ+ community[104];
- the prevention of HIV among transgender women in Latin America[96].

One study addressed knowledge, attitudes, and practices among transgender people in Sao Paolo in Brazil and concludes that health educational activities insufficiently reach the transgender population[105]. The conclusions of the research studies in HIV and LGBTIQ+ individuals are similarly grim, in so far as **LGBTIQ+ individuals face either disadvantaged access, lack knowledge, or face more stigma, discrimination, and violence**, and most of them call for more research, collaboration or better programming to address their needs. This is also coherent with the United Nations Development Programme (UNDP) Discussion Paper that states that "[h]ealth outcomes for transgender people are generally poorer than for cisgender (i.e. not transgender) men and women'[27:3] and further notes that 'sex- and gender-disaggregated data are often collected for binary, mutually-exclusive categories only, leaving out important insights about the health of transgender and intersex people"[27:16]. The present study and literature confirm this observation. In addition, the GBD database does not provide data along those lines. The collection of valid, reliable, and accurate data on different gender identities and sexual orientations may not only be very difficult but also dangerous in some contexts.

How do certain PRNDs affect pregnant women?

As highlighted throughout the text, some PRNDs have specific implications for pregnant women, from the risk of vertical transmission, to more severe or even unique manifestations of diseases. *Table 2* provides a brief summary.

TABLE 2 Examples of disease-specific impacts on pregnant women

Malaria	has a high prevalence among pregnant women and can pose a risk for both mother and foetus because the immune reaction in females can weaken during pregnancy, increasing the risk of contracting malaria[106]. In addition, malaria may cause anaemia in pregnant women[107].
Chagas disease	bears the risk of vertical transmission of the disease to the foetus[106], and certain drugs are contraindicated in at least the first trimester of pregnancy[130].
Hookworm	may cause anaemia in pregnant women[107].
Leishmaniasis	decreases the fertility rates of women and impacts the perception of women in society.
Lymphatic filariasis	may increase susceptibility in infants and children to the infection, despite treatment of the mother[108].
Sleeping sickness	bears the risk of vertical transmission of the disease to the foetus[106], and decreases the fertility rates of women, impacting the perception of women in society.

DEEP DIVE 4 BURDEN OF DISEASE IN ETHIOPIA

Ethiopia is a landlocked country in east Africa, positioned in the Horn of Africa with more than 110 million inhabitants and a gross domestic product (GDP) of 96 billion USD[109]. The country is regularly hit by crises, such as droughts, epidemics, displacements, and armed conflict[110]. It is one of the poorest countries in Africa with 8% of its population living in multidimensional poverty[111]. The health expenditure per capita is at 3.5% of the GDP and the general government health expenditure per capita amounts to 0.87% of the GDP. 34% of the health expenditure is paid out-of-pocket and 53% of the current health expenditure concerns domestic private health expenditure[109]. The access to health services is hampered by a limited number of health institutions, inefficient distribution of medical supplies, disparities between urban and rural areas and poor transportation infrastructure with more than half of the population living more than ten kilometers away from the nearest health facility, as well as by general underfunding of the health sector[110].

The 'big three'

Malaria, TB and HIV & AIDS, together with maternal mortality, acute malnutrition, and lack of access to clean water and sanitation are the main health concerns. Even though Ethiopia is considered a low-to-moderate transmission intensity country for malaria, climate change impacts on the transmission cycle of vector-borne infectious diseases[112]. According to the GBD database, **malaria is almost equally common in males (51% prevalence) and in females (49% prevalence)**, nevertheless, it is particularly serious for pregnant women and can lead to death.

In regard to TB, Ethiopia is one of the 22 high burden countries[112, 113] and has similar prevalence rates among males (51%) and females (49%). The disease remains one of the leading causes of mortality with a rate of 64% in males and 36% for females[1]. **TB detection rates among males are higher than in females**[112], which suggests that decentralised diagnostic and treatment services need to be enhanced in order for women to access these services[114]. In addition, 13% of all new TB cases are HIV co-infected[112], bringing along stigma and mental health problems for both women and men[114]. In addition, the country has a high level of multidrug resistant (MDR) TB. According to a national TB-resistance surveillance report, 2.3% of new TB cases and 17.8% of previously treated TB cases were estimated to have MDR-TB[112], requiring expensive and more toxic drugs[115].

As in many African countries, **the prevalence of HIV & AIDS in Ethiopia is 60% in females and 40% in males.** Despite increasing awareness about the disease within the country, married women especially remain proportionately susceptible to HIV infection. Even though marriage was believed to be a protective factor against HIV, this does not seem to be the reality[116]. HIV & AIDS awareness and the ability to negotiate safer sex is associated with higher education and higher socioeconomic status[116]. Co-infection with TB is more likely to occur among **the poor, with less or no access to education**, suggesting that further efforts are needed to reach out to this strata of society, and in particular to women and girls[117].

NTDs in Ethiopia

Ethiopia bears a significant burden of NTDs in Africa[112]. Hookworm, schistosomiasis, scabies, river blindness, snakebite, and trachoma are the top six NTDs prevalent in the country. Of these six diseases, all have a prevalence rate difference of less than two percentage points between males and females, except for river blindness, where the percentage point difference is ten, and trachoma, where the prevalence in females is 67% compared to 33% in males.

This disproportionally **high prevalence of trachoma in females can be explained through their roles in caring for infected children** through whom they themselves get infected. The high prevalence among children between age 1 and 9 is often associated with risk factors including access to water and latrine facilities[77]. Women have greater exposure and less access to treatment and care, which results in them being **two to three times more likely to become permanently blinded by trachoma than men**[74]. Similarly to what was outlined earlier, the impact of blindness on social, economic, and family life is often felt more strongly by women.

In addition, a recent qualitative study on the gender-related factors affecting health-seeking behavior for NTDs[118] highlights that **women may delay care seeking or may not seek care at all because of reservations about disclosing diseases affecting 'hidden' ('private') body parts** as in the case of schistosomiasis. Men may also delay seeking care if they are affected by hydrocele, scrotal swelling as in the case of lymphatic filariasis. This confirms the complex and multi-layered impact of NTDs and the need to adopt a differentiated gendered approach to NTDs.

3 PRND RESEARCH AND INNOVATION NEEDS TO ENSURE GENDER EQUITY IN HEALTH

Following COVID-19, R&I needs for diagnostics, treatments, and vaccines received unprecedented global attention, as did the consequence of failing to include diverse populations in the development of new tools. For PRNDs, where there is a high prevalence in females, the gender dimensions in R&I and their significant impacts on health outcomes are often overlooked.[21]. The biological differences between females, males, and intersex people are simply not considered in clinical research, and **a number of 'blind spots', 'knowledge gaps'**[119] **and even 'knowledge biases' exist**. Nevertheless, diseases may have a differential impact on different genders, and treatment efficacy, for example, could benefit from capturing differences at both biological and social levels. The lack of gender and sex specificity begins at the earliest research stages and sometimes persists throughout the entire R&I process[120]. This chapter provides an overview of the ongoing debates on sex and gender aspects within the R&I process and identifies the resulting PRND R&I needs that ought to be tackled to contribute to greater gender equity in health. Even though diagnostics, drugs, and vaccines require distinct R&I processes, for the purpose of this study a generalised view will be provided, and illustrative examples will highlight the gendered dimensions of the R&I process.

THERE ARE A NUMBER OF 'BLIND SPOTS', 'KNOWLEDGE GAPS', AND EVEN **'KNOWLEDGE BIASES' IN CLINICAL RESEARCH**

Figure 1 illustrates in generic terms the R&I pipeline. This illustration differs from other commonly used pipeline representations as it integrates the crosscutting and integral activities of research design and publication, carried out throughout the R&I process. It also recognises that research teams, health workers, and implementers collaborate throughout the process.

FIGURE 1 Research & innovation process

Source: Adapted from TDR (2016)[121] by Told & Landry Chappuis, HumanImpact5 HI5.

While knowledge of gender specific R&I needs and gaps exists in different institutions and organisations working in this field, **a holistic view on gender mainstreaming and gender analysis throughout the entire R&I cycle is still missing.** Research and publications addressing sex and/ or gender in an integrated continuum across the R&I cycle are scant. The existing literature focuses mainly on the following distinct areas: data disaggregation, pregnant and breastfeeding women, diagnostics and screening, clinical trials in humans, regulatory approval processes, and access and delivery. The vast majority of publications specifically address the challenges in conducting clinical trials in pregnant and breastfeeding women, and the issues of access and delivery.

Design and publication

Health research attempts to address a wide range of factors that affect population health and clinical and biomedical research evaluates the safety and efficacy of medications (including drugs and vaccines), medical devices, diagnostic procedures, and treatment regimens for preventing, treating, diagnosing, monitoring, or alleviating symptoms of a disease[122]. Both sex and gender considerations are increasingly recognised as important factors influencing health inequities and related health outcomes. Conceptual clarity on the construction of sex and gender, as well as its multifaceted intersections are important prerequisites for both the design and reporting of health research studies [123]. Growing literature and specific training modules for health researchers provide clarity and guidance as how to increase and improve sex and gender considerations in research[124]. **An understanding of the disease or condition, its gender-specific prevalence, and its sex-specific impact is needed at an early stage** in order to meaningfully design and engage in research that incorporates sex and gender dimensions and hence has the potential to develop knowledge and tools that work better for everyone.

UNDERSTANDING OF SEX-SPECIFIC PREVALENCE AND GENDER-SPECIFIC IMPACT IS NEEDED AT AN EARLY STAGE

Research study design and knowledge translation activities carried out along the R&I continuum are inextricably linked. The sharing of research results through a sex and gender lens is only possible if sex and gender considerations are integrated into research projects from the very beginning in order to produce more accurate, rigorous, and valid results[125]. **The consistent uptake of sex and gender aspects across health research publications is, however, generally missing.**

IN PRACTICE

Disaggregate data by sex and gender at each step and at each level

The call for disaggregating data by sex and gender has been made many times, and yet, it needs to be reiterated once again because it is – together with a more holistic approach – an important prerequisite to be able to consider sex and gender dimensions in the R&I process. This disaggregation needs to start at the very beginning of the chain and information collected at every phase has to be captured, reported, analysed, and delivered to the appropriate entities in order to fully take the information into account in the decision-making processes at different phases of R&I. The data disaggregation chain has to be ensured horizontally and vertically. Health research journals should incentivise the production and dissemination of sex-disaggregated health research evidence, for example through editorial policies that enforce disaggregated outcome reporting [114, 117].

Research teams, health care workers and implementers

Studies [126, 127] show that **women are underrepresented in positions of power, are less likely to lead a research team or be the head of a laboratory**, which then means that they are also less likely to appear as the first author in high impact journals. The greater representation of women in leadership and decision-making within research teams is particularly important because they are more likely to consider and report sex-differentiated outcomes[126]. Key decisions made by the research teams but also implementers in the process are crucial – or detrimental - to sex- and gender-sensitive research[128]. Science that works for women, thus also means science by (i.e. that is developed and led by) women.

Scientists at the Joint Clinical Research Centre, in Kampala, Uganda, © DSW/ JCRC

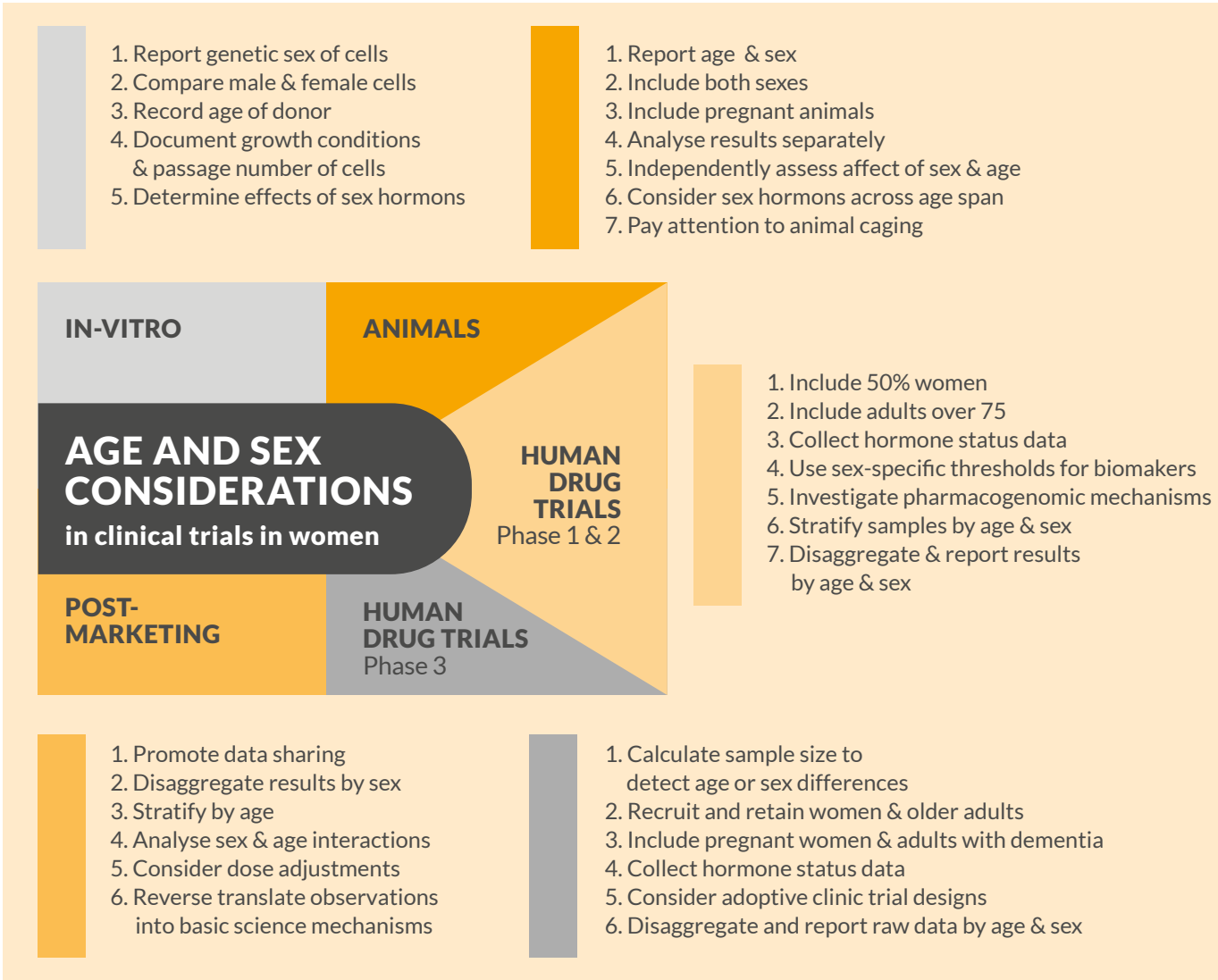
IN PRACTICE

Foster greater representation of women in science

Women need to be part of leadership and decision-making within research teams to facilitate better integration of sex- and gender considerations at all levels. Equal pay should be guaranteed, and greater support made available for women and minority researchers, including the provision of parental leave or child-care support. Novel mechanisms such as a roving-researcher programme should be explored and strengthened to ensure the career continuation of researchers that take lengthy breaks, such as for parental leave or caretaker responsibilities. Institutions should have clear guidelines and structures in place to address sexual and gender harassment and other forms of Gender-Based Violence (GBV) to foster a non-discriminatory workplace.

Furthermore, publications that integrate recommendations for intersectional issues such as age and sex considerations along the full R&I process *(see Figure 2 from Tannenbaum and Day*[129]*)* are far too rare. **Literature otherwise mainly focuses on a specific research phase or specific aspects within a research phase, thus lacking intersectional approaches.**

FIGURE 2 Sex and age considerations in drug clinical trials



Source: Tannenbaum and Day (2017)[129], design adapted for this study

Discovery

This phase of the process includes, for example for drug development, the target identification and screening of molecules to find one or more lead compounds that show activity against the pathogen, eliciting the intended biochemical or physiological changes for which the research is conducted. This phase should include experiments on both genetically male and female cells in order to be able to identify sex differences early [126, 129, 130]. Differences at the cellular level can lead to differences on how PRNDs and treatments affect women and men [120]. However, **up to 75% of research articles do not report on the sex of the cells used. Where cell sex is specified, studies show that female cells account for only 5% of cells used** [131]. Inclusion of male and female cells to identify the sex differences at this early stage of research is needed, as is comparing, analysing and reporting data by sex for, and in subsequent research stages [120, 139].

UP TO 75% OF RESEARCH ARTICLES **DO NOT REPORT ON THE SEX OF CELLS** USED IN STUDIES

Pre-clinical stage

FEMALES ARE UNDER-REPRESENTED IN ANIMAL STUDIES

The pre-clinical stage involves laboratory and animal studies to evaluate efficacy and potential risks involved in the usage of the identified compounds: plans for clinical trials are also developed and applications to the regulatory authorities are prepared in this phase [126]. Sex and even gender play a role in animal research, and sex-gender interaction is significant in the specific context of this phase of research. For example, through the caging conditions and dynamics of male and female animals, or through the way the sex of research personnel interacts with hormonal, genetic, reproductive, and stress factors of the animals. Animal studies should include male and female study animals. However, **females are generally underrepresented, and a major gap exists in the reporting of the sex of the animals** [126, 132–134]. A survey conducted in 2000 found that 80% of animal studies had a male bias [135] and in 2016, 70% of the biomedical research did not report sex; among those studies reporting sex, less than half have included both sexes in the study sample [122]. This can result in gaps to examine the safety and efficacy of the therapeutic agents for females, ultimately leading to, for example, **unsafe dosage recommendations and adverse drug reactions in females** that originate from the insufficient attention given to the sex-specific pharmacokinetic variations during this phase [136].

Clinical trials (phases I – III)

The different phases of this research stage concern trials on humans to identify the suitable dosage ranges, product efficacy, and side effects. Phase I usually concerns testing of the molecules in a small group of people, usually healthy human volunteers, in order to test the safety of a drug, for example, and to establish a maximum tolerated dose of a drug. **Studies at this stage are generally skewed towards men (approx. 67%)** [131]. Phase II entails trials with a patient pool of about 100 or more persons who carry the disease. It is focused on the safety and short-time side effects of the developed drug and on finding the optimal dosage [137]. The design of phase I and II trials is based on the evidence received from the pre-clinical stage. The data required before initiation of the trials and the inclusion of women are defined in the Guidelines of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) [138, 139]. This data concerns, for example, the reproductive toxicity and carcinogenicity but also safety considerations, yet are entirely dependent upon existing knowledge of the product, type, and indication [139]. The more robust the sex- and gender-differentiated knowledge database, both from pre-clinical data but also epidemiological data (e.g. disease prevalence in different sexes) and disease or condition impact data on different genders, the more reliable the clinical research will be. Phase III aims to confirm on a large-scale the efficacy and the safety of the drug and if successful, preparations are made for the approval of the drug with the regulatory authorities.

While women are more likely to be included in phase III studies, they are still generally underrepresented in all the phases of clinical trials, despite recommendations, and in some cases regulations, to include sex and gender considerations in study design to ensure better outcomes, even at the early clinical study phases [140]. Meaningful inclusion of women, and the full analysis and reporting of outcomes by sex is yet to be fully achieved [126, 141]. More recent guidelines suggest that women should be represented in trials in proportion to the prevalence rate of the disease [142]. As outlined in the previous chapter, however, prevalence rates do not sufficiently capture the gendered impact of a disease, and thus its impact on women and girls.

IN PRACTICE

Integrate both female and male sex in all phases of research and product development

From discovery to post-approval studies on PRNDs, all relevant elements depicted in *Figure 2* need to be considered, for example by including male and female cells in in-vitro studies, males and females in animal studies, taking into account the sex and gender of research and laboratory team members, and including representative numbers of men, women and non-binary people in clinical trials. Misleading or erroneous conclusions in regards to sex and gender differences of pharmaceutical and non-pharmaceutical interventions need to be avoided and differences at biological and social levels need to be captured to improve treatment efficacy, efficiency, and safety.

Regulatory authorities have an essential role to play in increasing the inclusion of women, and intersex people in clinical trials. For example, the NIH Revitalization Act recognises that women's exclusion from clinical trials has led to deficits in the understanding of women's health and sex-based differences[143]. The challenge remains that if no distinct, sex-disaggregated analysis is carried out, study conclusions could be either misleading or erroneous in regards to detecting sex and gender differences of pharmaceutical and non-pharmaceutical interventions[144]. Consequently, **women's health care can be compromised due to lack of sex-specific** information about drug dosage and unique use of drugs[145]. Adaptive design can be a useful tool to allow for making planned changes in the course of an ongoing trial on the basis of accumulated data from the trial itself. This could then lead to the adaptation or discontinuation of a drug dosage, for example[140]. Furthermore, the current bias in research can be addressed not only by reporting the sex of the animals, cells, or cell culture models used[144] in early research phases, but also by including women in all phases and by regular monitoring of the studies[145].

A recent publication by Couderc-Pétry et al. (2020) proposes to **include women susceptible to and becoming pregnant (WoSuP) in NTD clinical trials** from an ethical and regulatory standpoint. The authors outline the following conditions so that such clinical trials can happen [139]:

- women receive "prior and complete information on potential risks and benefits of treatment for themselves, their unexpected but potential pregnancy, and resultant offspring and their fertility;
- research is relevant to the healthcare needs of WoSuP; and
- pre-clinical trials in animals have provided sufficient reliable results in regard to 'risks for reproductive toxicity and genotoxicity" [139:5].

WOMEN SUSCEPTIBLE TO AND BECOMING PREGNANT **NEED TO BE INCLUDED IN CLINICAL TRIALS**

RESEARCH INTERESTS OF PREGNANT WOMEN REQUIRE MORE ATTENTION

Finally, **ethical considerations are an important component within the clinical trial stage**[146]. Ample literature exists on clinical trials, ethics, and pregnant women *(see Deep Dive 2)* and less but still some on breastfeeding women. Excluding pregnant, breastfeeding, and menopausal women from trials may also slow down the recruitment rate and delay the availability of a helpful drug, for example, for these population groups[139]. Fair inclusion of pregnant women in clinical trials requires, on the one hand, that eligible pregnant women are not excluded from the trials only due to their pregnancy and, on the other hand, that research interests of pregnant women receive more attention. Depending on the research, this **could also necessitate oversampling WoSuP, or promoting separate trials in pregnant women**[147]. This implies that there is an ethical aspect to including WoSuP and that they should be able to make informed decisions about participation in trials, aware of the potential risks. They should also have the liberty of withdrawing voluntarily from the trial at any time or to terminate their pregnancy if legally allowed and wished so by the woman herself. This would nonetheless require a guaranteed medical follow up and the availability of contraceptives[139]. Contraceptives may not always be widely available, socially or culturally accepted, or even effective in preventing pregnancy, calling yet again for a differentiated understanding of the social, cultural, religious, and legal conditions.

While much of what is outlined above applies to any disease or condition, some specific PRND considerations are noteworthy. As outlined earlier in the study, some PRNDs have often exacerbated, or different impacts on pregnant women and require specific attention in the R&I process, (as detailed in *Deep Dive* 2).

In addition, studies conducted in LMIC settings may need to give specific attention to the capacity for clinical data management and building of capacities at the local research sites[148].

"...pregnant women should not be protected from research but through research."

Kristen Sullivan, Research Scientist, Center for Bioethics, Social Medicine, UNC-Chapel Hill, PHASES Project Director

DEEP DIVE 5 CLINICAL TRIALS AND PREGNANT WOMEN

The development of safe and effective diagnostic tools or treatment requires prior knowledge as to whether NTDs affect women with the potential to fall pregnant in the same way as other adult populations[139]. Despite existing guidelines, particularly the ICH guidelines[149], pregnant women, breastfeeding women or women who potentially can become **pregnant are frequently excluded from clinical trials[138] due to ethical and safety considerations**. This may then lead to no treatment or treatment with medication for which little data on efficacious dosing during pregnancy or safety and effectiveness is available[150]. Some PRNDs could be treated in pregnancy, such as soil-transmitted helminths or schistosomiasis, but pregnant women do not receive treatment, - in part, due to lack of pregnancy safety trials[21]. Other PRNDs cannot be treated at all in pregnant women, such as lymphatic filariasis, or treatment is contraindicated, such as in onchocerciasis[71].

Interviewees suggest that the exclusion of pregnant or breastfeeding women from clinical trials needs to be addressed, as testing a drug in a (healthy, non-pregnant, potentially mainly male) sample of volunteers is not representative of the average health and risk profile of the entire population, and does not assess safety for pregnant women. It may also mean that drugs are developed for men only, leaving out a large percentage of the population from accessing to treatment, protecting the fetus but nevertheless having major implications for women's health. A critical balance needs to be found here. The US Food and Drug Administration (FDA) refers to this in explaining the purpose of the 2018 draft Guidance Note on 'Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials' in the following way:

"to support an informed and balanced approach to gathering data on the use of drugs and biological products during pregnancy through judicious inclusion of pregnant women in clinical trials and careful attention to potential fetal risk"[151].

A milestone was reached when the 'Common Rule', the US federal regulations governing research in humans was revised to remove the category of "pregnant women" as a "vulnerable population" of research participants. This revision came into effect on 1 January 2019 and now allows, under certain conditions, pregnant women to participate in clinical research[150]. However, the draft European Medicines Agency (EMA) guideline on good pharmacovigilance practices on product- and population-specific consideration details, "pregnant and breastfeeding women are considered vulnerable, or special populations"[152], highlighting the discrepancies that exist in the regulatory framework, and the need for alignment.

Most progress in including women with the potential to fall pregnant in clinical trialswas made in the development of tools against malaria. On the one hand, vaccines are being developed that can serve as a preventive measure before pregnancy and clinical trials have shown positive results, even though they did not include pregnant women as volunteers in the clinical trials[153, 154]. On the other hand, **a number of initiatives are ongoing that actively recruit pregnant women into the clinical trials** in order to develop new drugs that can be effective and safe during pregnancy itself. Alongside these efforts, networks are established to include pregnant women in clinical trials[155]. **In addition, data is collected among pregnant women on existing drugs, and pregnancy registries are established that can inform their use during pregnancy** (see *Case Study 2*) [155].

These activities, however, require an active involvement of ethical review committees and regulatory authorities, such as the FDA, the EMA or national pharmacovigilance centres[147]. Regulatory authorities' participation and ownership in the research needs to be established early on in the R&I cycle in order for them to support the clinical trial phase. An extra layer of complexity is added here through the heterogeneity of country regulations and the need to receive national approval in each country **suggesting the need for including gender considerations in regulatory harmonisation efforts** between countries and regions.

"PREGART is a clinical trial that involves pregnant mothers who are HIV-infected, and it specifically assesses the safety and efficacy of the Dolutegravir-based regimen - a newly introduced drug, especially in resource limited settings. We want to look at how safe it is, but also how efficacious it is in this population of pregnant mothers, as pregnant mothers are generally excluded from the main clinical trials. We know that pregnant women are generally looked at as a vulnerable population because it involves quite a number of people. It involves, first of all, the woman, the husband and the baby to be born. And so really a lot of care needs to be taken. But also the circumstances where doing a study among this specific population is actually good for the population and cannot be done elsewhere. So there are definitely challenges and there are implications for leaving them out. For instance, in this particular trial that we are doing, Dolutegravir-based ART, it has been proven to be efficacious in HIV populations, but we know that transmission from mothers to newborn babies is just unique to the pregnant population. You cannot determine that in any other population, so it has to be pregnant mothers for us to have facts that we are sure about in that respect. So I think the inclusion is beneficial, but definitely with care, considering the baby and several other parties and generally the vulnerability of the pregnant mother."

Jackson Mukonzo, Associate Professor in the Department of Pharmacology and Therapeutics, Makerere University, Uganda and Country Principal Investigator for the PREGART clinical trial. Photo: © DSW/ Makerere University

CASE STUDY 2 MALARIA IN MOTHERS AND BABIES (MIMBA)

Around the world, approximately **125 million pregnancies per year are at risk of malaria**. Malaria is potentially life-threatening for both mother and child. **11% of newborn deaths and 20% of stillbirths in sub-Saharan Africa** are caused by malaria in pregnancy. Pregnancy reduces immunity to malaria, making women who are pregnant more susceptible to malaria infection and increasing the risk of illness, severe anaemia and death. While pregnant and lactating women are disproportionately affected by malaria, there are fewer therapeutic options available to them compared to the general population.

Pregnant and lactating women are actively excluded from the clinical development of most new antimalarials. Data to support the use of medicines during pregnancy is typically only collected once the product is marketed. This results in a delay in access to medicines for this population - as compared to the non-pregnant adult population - which can lead to uninformed decision-making, leaving mothers and **babies** at risk, as well as driving hesitancy and mistrust. In a bid to overcome these challenges, the Medicines for Malaria Venture (MMV), a product development partnership committed to providing informed therapeutic choices for malaria treatment and protection across all populations, including pregnant and lactating women, implemented the MiMBa strategy.

Key elements of the new strategy include expanding access to current antimalarials by collecting data on the safety and efficacy of existing compounds used during pregnancy and lactaction and ensuring the supply of quality-assured medicines; developing new antimalarial medicines to address the needs of pregnant women and neonates; and advocating for the greater inclusion of pregnant women in clinical studies.

Across MMV-supported phase III & IV studies, female representation averages at 51%. MMV's drug discovery strategy includes an early focus on admitting drug candidates to the development portfolio that might have an acceptable safety profile in pregnancy. This includes conducting reproductive toxicology studies in animal species in parallel with phase I human studies. MMV is also investigating how it could safely conduct pharmacokinetic/ pharmacodynamic studies in pregnant women, in parallel to phase III development, when the candidate drug profile is appropriate. MMV has also initiated a programme leveraging cutting-edge modelling and simulation platforms to predict the concentrations of drugs in breast milk to inform the use of medicines in lactating women.

IN PRACTICE

Address the lack of pregnancy safety trials and redefine existing concepts

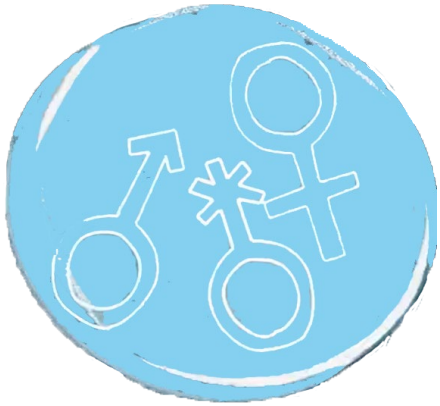
Following the example of the US Common Rule, pregnat women should no longer be defined as a 'vulnerable population'. Pregnant women or breastfeeding women need to be included in the research process, for example, in clinical trials - in a safe and ethically sound way. It might be necessary to oversample pregnant women or WoSuP, or to conduct specific separate trials. The reconceptualisation of women as equal participants who face conditions that can render them more vulnerable is crucial for more gender-sensitive research. It also implies that priorities have to be newly set, not only focusing on women as part of a process but also as separate research subjects. Moreover, as women often face serial pregnancies in some low-income settings, new strategies need to be devised to consistently and safely include them in Mass Drug Administration (MDA) campaigns whenever and wherever it is safe and possible.

Regulatory approval and reimbursement

THE **REGULATORY APPROACH** TO SEX AND GENDER REMAINS **FRAGMENTED AND UNENFORCED**

During phase III clinical trials, the application for regulatory approval is usually already prepared. In this approval stage, trial data is submitted to the regulatory authorities for approval for the specific use of the drug, vaccine, or diagnostic[126]. While progress has been made to include women in clinical study phases, **the regulatory approach to sex and gender remains fragmented and unenforced**, with the US and Canada being the most stringent in this respect. Few regulatory agencies have requirements around the provision of sex- and gender- related information[156]. Where guidelines do exist, entities engaged in R&I often insufficiently adapt their models to account for sex- and gender-related differences[126].

Reimbursement policies and drug or diagnostic formularies are other aspects in this phase but often lack sex and gender data, although sex-disaggregated cost-effectiveness analysis could prove critical to evaluate the usefulness of including the product in national or insurance benefits lists. This lack of data may lead to interventions that could be highly impactful and cost-reducing for health systems to not to be included, or to interventions being included that might not be impactful or cost-effective for parts of the population. **Therefore, there is a clear need to use regulatory enforcement, penalties, and incentives to foster the inclusion of sex and gender data in drug evaluation**. It would be useful to set up sex- and gender-disaggregated global performance indicators, for example through WHO's global benchmarking tool for the evaluation mechanisms of national regulatory systems. This could be an important area for collaboration and harmonisation efforts among regulatory agencies between different countries and regions. Other international strategies to foster the application of a gender lens can concern the research design support, fee waivers, expedited reviews and regulatory penalties for insufficient sex- and gender data disaggregation[126].



CASE STUDY 3 WHITE BOOK OF RECOMMENDATIONS FOR GENDER MAINSTREAMING IN NATIONAL RESEARCH ETHICS COMMITTEES IN WEST AFRICA

The BCA-WA-ETHICS-II [157] project, and its predecessor BCA-WA-ETHICS-I is a **European & Developing Countries Clinical Trials Partnership (EDCTP)** funded project focused on building the capacities of West African National Research Ethics Committees (NREC)-affiliated ethicists and scientists in gender mainstreaming in health research ethics. The project included a range of training, networking, and regulatory support activities with the aim of strengthening and harmonising the ethical research review process in West Africa.

The **White Book of Recommendations for Gender Mainstreaming in National Research Ethics Committees** in West Africa is one of the project's outputs that contains hands-on guidelines for gender equality planning and sex- and gender appraisal in research protocols. Developed together with the Benin NREC, the White Book puts forward a number of recommendations on how to integrate gender mainstreaming into ethical review processes [158].

Recommendations include organising **annual internal and external gender audits; developing a gender equality plan** in line with the recommendations of the gender audit and revising it annually; revising the regulatory texts; statutes and internal regulations, codes of health research ethics that are used by NRECs from a sex and gender perspective and propose adaptations if necessary to fill the sex and gender gaps; carry out a **gender budgeting exercise** for the NREC by integrating aspects related to funds allocated to gender equality training, field visits to monitor sex- and gender-sensitive research, and other activities related to gender equality; develop a 'researcher's guide' with detailed explanations on how to take sex and gender into account in the design of research protocols.

*"Gender mainstreaming in health research goes beyond the systematic inclusion of women in clinical trials. It also means **taking into account how existing gender inequalities affect women's access** to and uptake of health care interventions. We call on all ethics committees to include gender mainstreaming as a standard consideration in their reviews and procedures. Ethics committees are in a position to end the conduct of sex- and gender-blind research. The White Book can assist ethics committees in this process. It takes a lot of time, effort and capacity building to achieve gender equity, but in the end, it will lead us towards sustainable development of West African populations and health for all."*
Farah Nabil, Project Manager of the BCA-WA-ETHICS II Project [159]

IN PRACTICE

Adopt a gender-sensitive approach in medical regulation and international regulatory harmonisation efforts

There is a clear need to use regulatory enforcement, penalties, incentives, and other tools (such as research design support, fee waivers, expedited reviews, etc.) to foster the inclusion of sex and gender data in drug evaluation. National ethics committees and regulatory authorities understanding of integrating a gender perspective needs to improve, allowing for the necessary guidelines, regulations, and directives to be set. International regulatory collaboration and harmonisation efforts should include this field of work. **It would be useful to set up sex- and gender-disaggregated global performance indicators, for example through WHO's global benchmarking tool for the evaluation mechanisms of national regulatory systems.** It is important to build on existing regulations and committees and inject new parameters on gender in their work. Existing governance structures can be expanded, for example, through the establishment of pregnancy committees and pregnancy investigation plans if the diagnostic tool, drug, or vaccine is to be used by pregnant people. Sex-disaggregated cost-effectiveness analysis needs to be taken into account in the evaluation of product inclusion in national or insurance benefits lists.

THE IMPACT OF DISEASES ON DIFFERENT SEXES AND GENDERS NEEDS TO BE CONSIDERED IN ANY POST-APPROVAL RESEARCH

Interventions that work in small-scale pilot studies too often fail when rolled out in larger scale or national strategies. Once health tools are approved and used in real-life settings, sex and gender are (next to other factors) crucial to understanding the gendered impact of health interventions[160]. A differentiated understanding of prevalence rates and of the (physical and mental health, social, economic, etc.) impact of diseases on different sexes and genders as outlined in *Chapter 2* thus needs to be applied to any post-approval research undertaken (such as epidemiological, modelling and pharmacoeconomic, or post-marketing surveillance studies). These aspects will be relevant regarding access and delivery of the diagnostic, drug, or vaccine to the population, in particular to women and girls. Knowledge gained in the phase of implementation research can then also feedback into the earlier phases of the R&I process.

TABLE 3 Sex and gender considerations in the different stages of R&I

Design and publication	An understanding of the disease or condition, its gender-specific prevalence, and its gender-specific impact is needed at an early stage in order to meaningfully design and engage in research that incorporates sex and gender dimensions and hence has the potential to develop knowledge and tools that work – better - for everyone.
Discovery	Equal inclusion of male and female cells to identify the sex differences at this early stage of research is needed to compare, analyse and report data by sex for subsequent research stages.
Pre-clinical stage	Sex and even gender play a role in animal research, and sex-gender interaction is significant in the specific context of this phase of research. Animal studies should include male and female study animals. The sex of researchers should be recorded, and affects thereof taken into account. Failing to allocate sufficient attention to sex-specific pharmacokinetic variations during this phase risks the safety and efficacy of the end-product for different sexes.
Clinical trials (phases I – III)	Women should be proportionately represented in all phases of clinical trials, and sex-disaggregated reporting made available. WoSuP, pregnant, and lactating people should be included in clinical trials, with all due ethical and safety considerations taken into account.
Regulatory approval and reimbursement	Sex and gender data must be included in drug evaluation. Ethics committees and regulatory authorities should better their understanding and requirements of integrating a gender perspective into medical regulation. Sex-disaggregated cost-effectiveness analysis needs to be taken into account in the evaluation of product inclusion in national or insurance benefits lists.
Post-approval studies and access	A differentiated understanding of prevalence rates and the impact of diseases on different sexes and genders needs to be applied to post-approval research. In every phase of the R&I cycle – from design to post-approval studies - scientists and researchers have to keep in mind the gendered impact of access and delivery modes.
Research team, healthcare workers and implementers	Greater representation of women in leadership and decision-making within research teams is particularly important because they are more likely to consider and report sex-differentiated outcomes and gender dimensions.

Sex and gender considerations in NTD intervention strategies

WHO defines five main intervention strategies to access populations affected by NTDs and deliver treatment, namely preventive chemotherapy (PC), innovative and intensified disease management (IDM), vector ecology and management; veterinary public health services, and the provision of safe water, sanitation and hygiene (WASH)[161]. PC and IDM are further elaborated and analysed in the context of this study, even if the other intervention areas would also merit an analysis through a gender lens.

MANY **PRNDS REQUIRE** INNOVATIVE AND **INTENSIFIED DISEASE MANAGEMENT** (IDM)

Many PRNDs, such as Buruli ulcer, Chagas disease, leishmaniasis, sleeping sickness, and yaws, require the use of IDM because cost-effective control tools either do not exist or their large-scale use is limited. IDM uses different interventions, from medicine to surgery, to relieve symptoms and to treat patients[161]. Diseases to which IDM is applied share several common characteristics that influence access and delivery, such as costly management concerning diagnosis, treatment, and follow-up, difficult access to the affected population, and a lack of understanding of the burden of disease and its social consequences[162]. All of these aspects are likely to negatively impact women and girls, intersex people, individuals who face discrimination because of their **gender identity, and expression, or sexual orientation**. Availability of treatment, its pricing, and protocols further influence access. Many other factors determine the access of medical tools for women and girls, such as cultural norms and practices, economic and social status, power relations and decision-making structures within the household, but also the educational level of health care personnel, the availability of infrastructure and health care facilities. IDM requires not only an intersectional gender analysis that considers all these factors and their influence upon each other but also draws conclusions for the R&I cycle.

IN EVERY PHASE OF THE R&I CYCLE THE **GENDERED IMPACTS OF ACCESS AND DELIVERY NEED TO BE CONSIDERED**

Indeed, **in every phase of the R&I cycle – from design to post-approval studies - scientists and researchers have to keep in mind the gendered impact of access and delivery modes.** Even if drugs that are safe and effective for women and children are developed, these efforts only bear fruit if, for example, women and girls can travel the distance to distribution points, receive the permission to get treatment from their partner and receive the drug prescribed by the health workers.

An effective intervention for PRNDs is PC or MDA[161]. However, it can only be used for some PRNDs against which the relevant tools exist, such as lymphatic filariasis, schistosomiasis, trachoma, and a group of soil-transmitted helminths[163], and is usually implemented in endemic areas to prevent and alleviate symptoms and morbidity[164]. MDA is …

> *"a means of delivering safe and inexpensive essential medicines based on the principles of preventive chemotherapy, where populations or sub-populations are offered treatment without individual diagnosis"*[164:1].

MDA will therefore be distributed to every person or a defined population – unless contraindicated – in a specific geographical area. Where vaccines exist and can be applied, mass vaccine programmes may be carried out to reach a wide coverage, such as in school-based campaigns[165]. However, MDA can also be contested because of its compulsory nature, the potential development of drug resistance, and the missing follow-up with patients.

MDA REQUIRES **80% COVERAGE TO BE EFFECTIVE**

The success of MDA, usually carried out by ministries of health, depends on the reach of the targeted population. Depending on the intensity of transmission and the objective of the outreach campaign, usually more than 80% coverage is needed for it to be effective. This requires a high level of community engagement, correct and full completion of the treatment, high acceptance of the intervention in the population, willingness to participate by the individual[166], and hence presupposes equal inclusion of women and girls.

WOMEN ARE REGULARLY EXCLUDED FROM MDA CAMPAIGNS

However, **MDA programmes, including vaccination programmes, entail several specific challenges for women and girls, particularly pregnant and breastfeeding women.** As a result of the exclusion of women in the clinical trial phase and the unknown safety profile for some medication during pregnancy, pregnant and breastfeeding women are regularly excluded from treatment. It also occurs that community drug distributors (CDDs) withhold the drug from pregnant and breastfeeding women due to erroneous safety concerns[167]. As women often face serial pregnancies in some low-income settings, new strategies need to be devised to consistently and safely include them in MDA campaigns whenever and wherever safe and possible[22].

COMMUNITY DRUG DISTRIBUTORS' COMPETENCES NEED TO **INCLUDE GENDER-SENSITIVE APPROACHES**

Oral drugs and rapid tests that can be delivered at primary health care (PHC) clinics are critical for ensuring women's equal access. If there is a delivery at home, men might miss out on the treatment as they are away from home due to their occupational role. Another gendered challenge concerning MDA programmes is that in some cultural contexts, older men refuse to take the medicines offered by younger women as CDDs, or in other contexts, women living alone can only receive the medicines from female CDDs[168]. **The confidence in and competence of the CDDs thus play a crucial role** here[169], and competencies need to include gender-sensitive approaches, considering the cultural, social or other barriers women and girls might be facing in participating in MDA campaigns.

A study examining gender equity of MDA for NTDs across 16 countries (2019)[163] highlighted the importance of sex- and gender-disaggregated data. Even though the coverage of MDA programmes is **gender-equal at the national level, differences exist at the sub-national level** where sex-, gender- and age-disaggregated data are often missing or (if collected) are not communicated upstream[170]. The study[163] pointed out that while females, in general, have not necessarily lower coverage rates, the gendered barriers to coverage need to be investigated with location-specific knowledge in order to understand the differences among males and females. *Table 4* by Theobald et al. (2017)[168] gives an overview of different elements of and approaches to MDA, the extent to which data is disaggregated, and poses questions concerning gender.

Youth and health workers at the dispensary of the Katoogo Health Centre III, Nama sub-County, Mukono District, Uganda.
© DSW/ A4Health Uganda

TABLE 4 Approaches to MDA and why gender matters

Approach to MDA	Data sex-disaggregated	Questions for programme managers to consider from a gender perspective
House to house CDDs visit households to register the household members and distribute drugs	Routinely reported data may be sex-disaggregated at community level but frequently not cascaded to national level	• Who is chosen to distribute the drugs and why? • How are they chosen and who is involved? • Are they remunerated? • Does this influence who is involved? • At what time are drugs distributed? • If it is in the evenings is it acceptable/ does it prompt security concerns? • If daytime, does this affect the involvement of those who have activities outside the home? • Does this access influence individual, household and community adherence? • Who has the power to decide whether the medicines are taken or not? • Who has the power to provide consent for household members under the age of 18? • Do power relations at the community level also shape this?
Fixed point approaches: health post clinic/ distribution point Drugs are distributed by CDD or health workers at a fixed point	Routinely reported data may be sex-disaggregated at facility level but frequently not cascaded to national level	• How and to whom is information communicated about the distribution – how does this affect the needs of migrants, inhabitants of informal settlements, women, men, people of other genders? • How does it reflect the literacy levels? • Who is able to attend the distribution? How do livelihoods, gender, power and autonomy affect this? • Does the location of distribution points influence distribution of medicines? • What is the impact on community coverage or the coverage of any specific group within the community?
Child (under 5) health/ special events Particularly common in the African context, drugs are provided at these gatherings	Routinely reported data may not be sex-disaggregated at national level with the possible exception of nutrition	• How and to whom is information communicated about the distribution – to what extent does this reflect the needs of women, men, people of other genders, migrants, inhabitants of informal settlements? • Who is able to attend the distribution? How do livelihoods, gender, power and autonomy affect this? • Who has the power to provide consent for the treatment of those under 18 years of age?
School-based programme Teachers and/ or others distribute drugs in schools	Routinely reported data may be sex-disaggregated at school level but frequently not cascaded to national level	• Who attends school? • How is this linked to gender and poverty? • How is informed consent negotiated? • What happens to those who do not attend school on a regular basis? • What happens to those who drop out of school/ do not complete primary education?
Coverage improvement activities, for example mop-up. Additional 'pro-equity' activities undertaken to try to ensure everyone is covered	No sex-disaggregated information and limited documentation on types of approaches	• What are the 'coverage improvements' strategies? • Who decided on them? • What baseline/ census material do they relate to and who might be potentially excluded from these? • Where appropriate how can we ensure women who are pregnant (and unable to take certain drugs) do access them at a later more appropriate date?

Source: Theobald S., MacPherson E.E. (2017)[168:3], design adapted for this study

Even though the above *Table 4* may neither be exhaustive nor applicable to all settings, it can be an useful entry point to develop a deeper understanding of gender issues in MDA. Such gender frameworks create awareness and better understanding. They are useful tools to trigger action on the gendered dimensions of PRNDs. The following chapter provides an overview of such frameworks that either have been specifically developed for PRNDs or may be usefully applied to PRNDs.

GENDER FRAMEWORKS ARE USEFOOL TOOLS TO TRIGGER ACTION

Mainstreaming sex and gender considerations with new standards and funding requirements

Standards and requirements for project funding proposals need to be re-defined, including through setting relevant indicators that can support the mainstreaming of sex-, and gender considerations in PRND R&I. This will serve to rule out the 'gender blindness' of funded research and serve as an incentive for relevant stakeholders and organisations to make the necessary efforts. Furthermore, conducting unconscious bias training with evaluators, and ensuring gender balance in evaluation panels, and recording the gender of the chairs of such panels are important steps that contribute to mainstreaming sex and gender considerations in funding decisions.

EFFORTS TO **AVOID GENDER BLINDNESS** NEED TO BE INCENTIVISED

A number of research funding organsiations have introduced such measures. In 2008, the Swedish Research Council introduced gender equality observations in evaluation panels. The Canadian Institutes of Health Research introduced in 2006 a **mandatory requirement for applicants to explain the integration of sex/ gender analysis** into research in the content of submitted proposals. Among other actions, as of 2019, the Irish Research Council requires higher education institutions to have secured the minimum Athena SWAN gender equality accreditation in order to be eligible to compete for research funding, with institutions required to hold the intermediate (silver) level accreditation by 2023 in order to be eligible.

CASE STUDY 4
GENDER EQUALITY PLANS:
A NEW ELIGIBILITY REQUIREMENT FOR EU RESEARCH FUNDING

As of 2022, all organisations (with some exceptions) applying for Horizon Europe funding are required to have a Gender Equality Plan (GEP) or equivalent document in place in order to be eligible for funding. A GEP must meet four mandatory process-related requirements; (1) the GEP must **be a public document**, accessible on the organisation's website; (2) the GEP must have **dedicated resources** and the organisation should **evidence adequate expertise** in gender equality to implement it; (3) the GEP should be **informed and its implementation monitored using sex/ gender-disaggregated data on personnel, with annual reporting based on indicators**; and (4) the GEP must also include **awareness-raising and training actions on gender equality, such as unconscious bias training**, and should involve all members of staff on all levels. Additionally, it is recommended that a GEP address five recommended areas, namely: **work-life balance and organisational culture** (e.g. parental leave policies, flexible working time arrangements); **gender balance in leadership and decision-making** (e.g. ensuring gender balance through gender quotas); **gender equality in recruitment and career progression** (e.g. proactively identifying women in underrepresented fields); **integration of the gender dimension into research and teaching content** (e.g. incorporating sex and gender in an organisation's research priorities); and enshrining **measures against gender-based violence, including sexual harassment**, in clear policies [171].

IN PRACTICE

Allocate (additional) dedicated funding and set new standards

The implementation of all of the recommendations made throughout this study, including setting new standards and requirements for research funding will require that additional funding is made available to fill knowledge, research, product, and regulatory gaps, and to increase gender capacities within responsible authorities, organisations, research teams, etc. There is also a need for additional/ dedicated funding and calls for proposals that specifically address some of the knowledge gaps that persist, and invest in further developing and implementing gender transformative approaches, and recognise women and girls, LGBTIQ+ people, and transient, or minority populations as priority populations.

4 GENDERED APPROACHES TO ADDRESSING PRNDS

GENDER MAINSTREAMING REMAINS A VALID TOOL TO ADDRESS WOMEN'S SPECIFIC HEALTH NEEDS

Many different approaches towards women and girls in vulnerable or disadvantaged situations exist and this chapter will focus on highlighting some of the most relevant existing frameworks.

Rights-based approaches[25] **and other integrated 'pro-poor' approaches** [172] **as very generic approaches**, addressing the vulnerable situation in which women and girls live, can be applied to PRNDs, even if such approaches often lack the gender specificity needed.

In a publication from 2002, the WHO examined seventeen existing tools and their usefulness for gender analysis in health[173]. The publication describes the approach taken by different donors and focuses on gender mainstreaming in health, which was the predominant approach at the time. **Gender mainstreaming is still today a valid tool** to address women's specific health needs through the identification of the differences and disparities between men and women. It also allows integrating a gender perspective within an organisation and/ or within an ongoing process, for example, as outlined earlier in the R&I process. Gender mainstreaming includes decision-making processes, and aims to catalyse change and ultimately achieve gender equality.

ADDRESSING THE ROOT CAUSES OF INEQUITIES AND POWER RELATIONS ARE IN FOCUS WITHIN GENDER TRANSFORMATIVE APPROACHES

Around a decade later, WHO published a facilitator's guide on 'Gender mainstreaming for health managers: a practical approach' (2011)[174]. This publication not only addresses gender mainstreaming but specifically addresses the processes involved in its implementation. It focuses on creating awareness, conducting (gender) analysis, and finally acting in a gender-responsive way. It introduces a **gender assessment scale, allowing projects or research to be classified from gender-unequal, gender-blind to gender-sensitive, and gender-specific to gender-transformative.** Even though the publication does not specifically focus on PRNDs, it remains a useful resource. The network on Research in Gender and Ethics (RinGs) describes ten gender analysis tools (2015), their key dimensions and intended audience[175]. This document highlights among others the 'UNAIDS Gender Assessment Tool: Towards a Gender-Transformative HIV Response' [176]. Research in this area on PRNDs is limited but in recent years, some specific studies and reports have been published referring specifically to women and gender, often offering an analytical framework but hardly ever considering the specificities for the R&I cycle [15,21,23,26,177,33,178,168,179,180].

The field has developed since then, and **addressing the root causes of gender inequities and power relations are now much more in focus** within gender transformative approaches. *Figure 3* reproduces the adapted gender framework by Morgan et al. (2016) and is geared towards addressing gender power relations. It is a tool that allows addressing the gendered dimensions of PRNDs in a holistic, systematic way and is applicable to all settings.

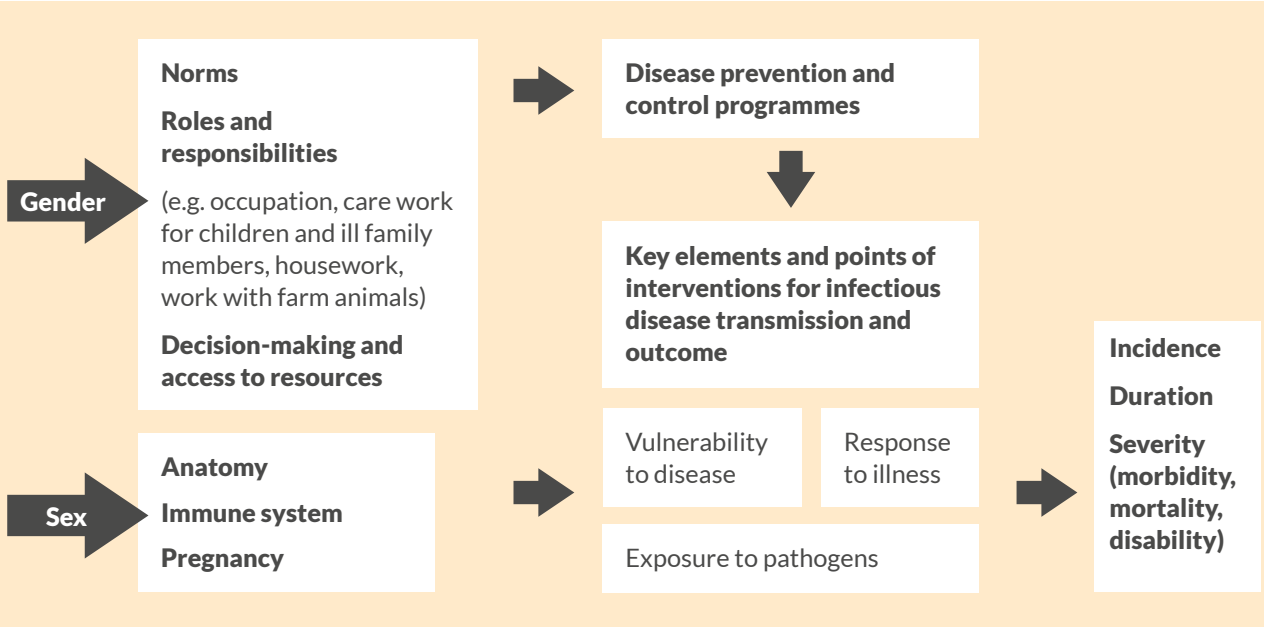
FIGURE 3 Addressing gender power relations

Who has what? Access to education, information, skills, income, employment, services, benefits, time, space, social capital, etc.	**Who does what?** Division of labour within and beyond the household and everyday practices
How are values defined? Social norms, ideologies, beliefs and perceptions	**Who decides?** Rules and decision-making (formal and informal)
How is power negotiated and changed? Critical consciousness, acknowledgement, agency/ apathy, interests, historical and lived experiences, resistance or violence	**Structural/ environmental conditions?** Legal and policy status, institutionalization within planning and programmes, funding, accountability mechanisms

Source: Adapted from Morgan et al. (2016) in UNDP (2019) [27:20]

The WHO Regional Office for the Western Pacific (2011) has created a useful tool that helps to analyse the influence of sex and gender differences on emerging infectious disease prevention and control programs. In doing so, the proposed analytical framework describes differential sex and gender effects on vulnerability, exposure, response to the infection, and public health interventions. *Figure 4* illustrates how this relationship can be transformed into a gender analysis matrix in which each row corresponds to one of the elements of the framework. The overall framework applies to several disease groups and social and geographical environments. [181]

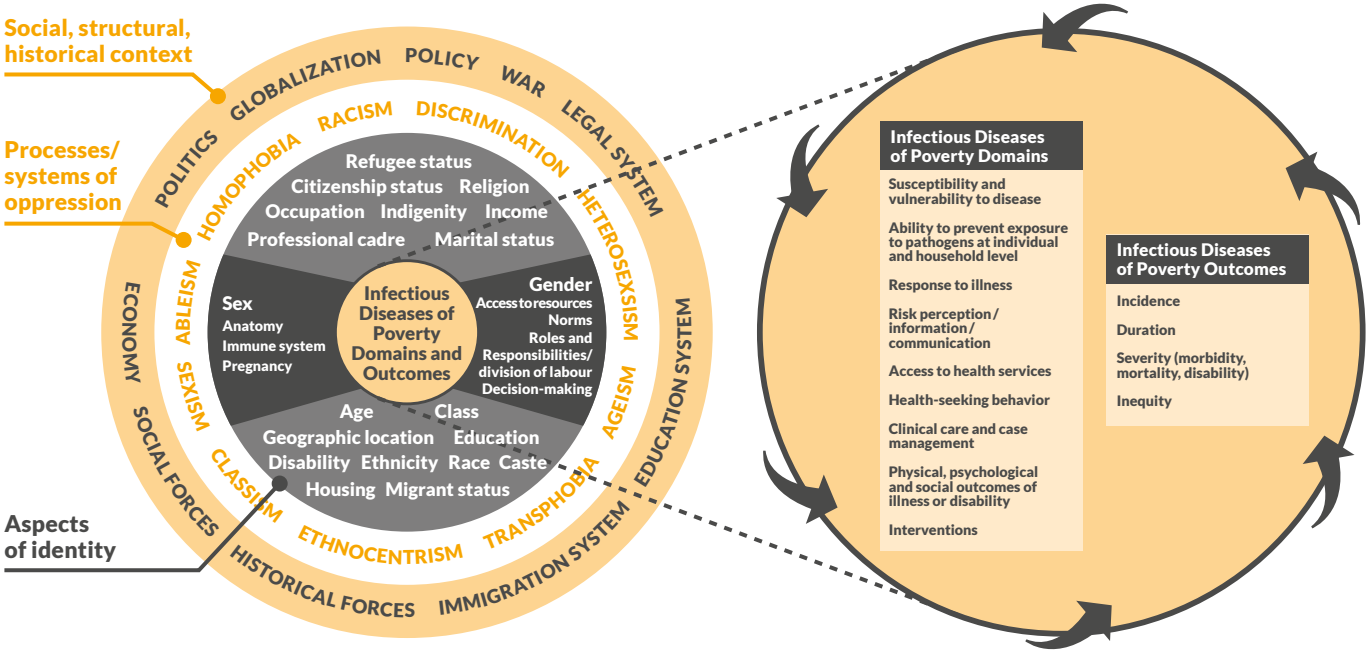
FIGURE 4 Framework for sex and gender and emerging infectious diseases



Source: WHO Western Pacific Region (2011) [181:8], design adapted for this study

Expanding on the gender dimensions of power relations and specifically applying it to health research, TDR (2020) has published an interactive toolkit entitled "Incorporating Intersectional Gender Analysis into Research on Infectious Diseases of Poverty"[15]. The interface of gender power relations with other stratifiers, such as age, class, gender, sex, ability, disability, ethnicity, sexuality, etc., are at the core of intersectional gender analysis. *Figure 5* illustrates the many factors that influence infectious disease impact and that need to be considered, further combining it with the framework presented in *Figure 4*.

FIGURE 5 Intersectional gender analysis framework for research on infectious diseases of poverty



Source: TDR (2020)[16:37], design adapted for this study

The TDR publication not only focuses on an intersectional gender analysis but also specifically targets researchers of infectious diseases of poverty. Hence, it provides detailed advice on how to conduct an intersectional gender analysis within the four stages of the research process, namely:

1. **design and development of research, including the development of research protocol,**
2. **data collection,**
3. **data analysis, and**
4. **dissemination and reporting**[15]**.**

These specific gender frameworks are just some of the tools that can be applied to analysing the gendered dimensions of the R&I cycle. More generic approaches used for PRNDs, such as multisectoral or integrated approaches[47], can enhance these specific gender frameworks and can be considered complementary.

As mentioned throughout the study, **a major prerequisite for the systematic integration of gender dimensions in medical research and thus for all the approaches outlined above is the continuous disaggregation of data by sex and gender.** This not only refers to greater equality of male and female research subjects but also to the use of methodological tools that do not show any gender bias. For example, the use of the disability-adjusted life year (DALY), even though disaggregated in the database has been criticised to underrepresent the burden of disease on women. This highlights a broader failure to capture the interconnected nature of the myriad health issues faced by women; the cumulative complexity of which is often not sufficiently represented via currently available measuring tools [182].

DISAGGREGATION OF DATA IS A CRUCIAL PREREQUISITE FOR ANY GENDERED APPROACHES TO ADDRESSING PRNDS

Data is mostly collected based on sex only; broader gender aspects are not yet part of a standardised data collection process, even if awareness around this is increasing. In addition, data on some PRNDs are totally missing, for example, neither DALY nor prevalence rates are available for Buruli ulcer and yaws in the GBD, or specific aspects are missing, with, for example, data on schistosomiasis in pregnant women unavailable [22]. Even if sex- and gender-disaggregated data is collected at the local level, this data has to be reflected in the available reporting systems and information flow needs to be ensured, for example to the regional or national level, for data to be captured in national databases and reports. Failing to do this can result in a distorted picture of the reality and neither interventions nor research priorities will be able to adequately address the needs of women and girls.

As an example, the over-reliability on 'evidence' and hard data as a basis of intervention, and **overlooking the social, cultural, and psychological factors that influence the impact of an intervention can cause major diagnostic delays** [31].

OVERLOOKING THE SOCIAL, CULTURAL, AND PSYCHOLOGICAL FACTORS THAT INFLUENCE THE IMPACT OF AN INTERVENTION **CAN HAVE SERIOUS NEGATIVE EFFECTS**

DEEP DIVE 6
DIFFERENT AND INTERACTING GENDER BARRIERS TO DIAGNOSIS

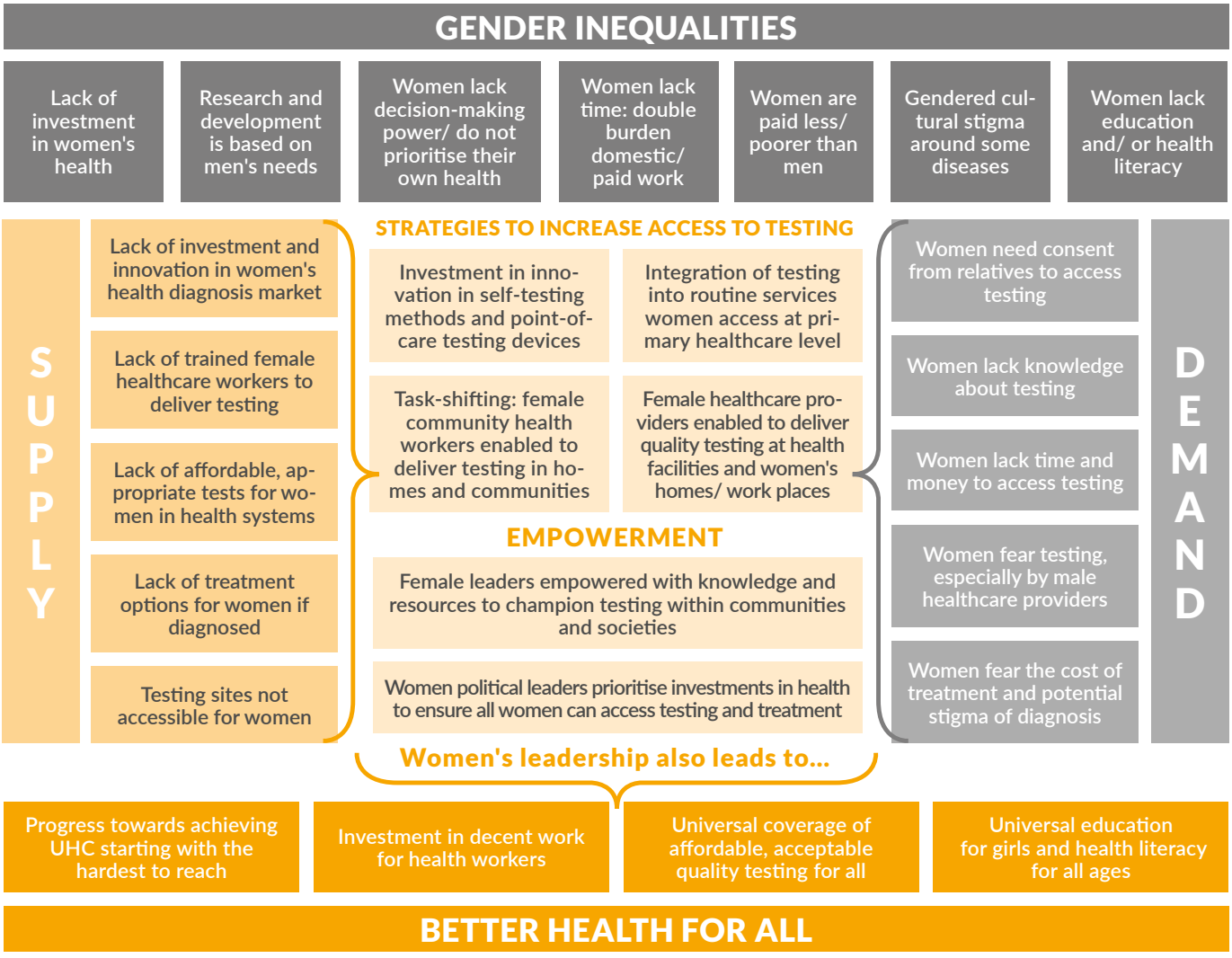
Testing for all is crucial because it enables the detection, diagnosis and monitoring of diseases. Despite this, **women face many barriers in accessing testing**, from cultural barriers to inadequate testing infrastructure and hurdles in accessing accurate information. These challenges were presented in a 2020 report, Health In Their Hands [183], authored by the Foundation for Innovative Diagnostics (FIND) and Women in Global Health.

Many of the barriers that women face in accessing testing are rooted in socio-cultural issues, with gender inequality undermining testing and women's health. At a household level, **relationship dynamics where women lack decision-making power can be a major barrier to accessing testing**. Time constraints can also be a barrier for women who are juggling a heavy workload, as well as gendered financial barriers, with tests oftentimes unaffordable, transport, both in terms of income foregone and its cost makes testing less accessible for women. Additionally, the location, timing of appointments, and the means of transport can be added obstacles because of safety concerns.

Fear and stigma as a result of information gaps caused by gender inequalities can prevent women from seeking testing services. Poor literacy, including health literacy, the digital divide, mixed messages from health providers, negative experiences, myths and misconceptions, oftentimes spread through social networks all compound practical barriers to testing. Gendered biassed perceptions matter too. Every year, more women die from TB than all causes of maternal mortality combined, yet TB continues to be considered a 'male disease'. This often results in women not being targeted for screening in the same way, with a FIND study undertaken in Swaziland unveiling that a screening tool was found to miss 85% of active TB cases in women.

Demonstration of the rapid oral HIV test kit in Mukono district, Uganda, © DSW/ A4Health Uganda

FIGURE 6 Gender inequalities in testing and remedial strategies



Source: FIND & Women in Global Health (2020)[184:11], design adapted for this study

Health worker talks to youth about modern contraceptives at Katoogo Health Centre III in Mukono District, Uganda. @ DSW/ Action4HealthUganda

5 CONCLUSIONS

This study highlights several gender-related aspects of PRNDs, in particular, the global prevalence of PRNDs in relation to their impact. It draws conclusions regarding the considerations, and changes needed in R&I to better address PRNDs in women and girls. It also provides some insights from existing gender frameworks and their usefulness and briefly outlines challenges for pregnant women and selected knowledge gaps. The study does not deliver a comprehensive analysis but provides evidence on key messages from the scoped literature. **A more detailed analysis of age groups and geographical distribution would be necessary to get more differentiated insights on the issues outlined**.

Key findings

The analysis has identified a number of diseases that have significantly higher prevalence rates in females than in males and has shown that when looking at prevalence, both biological susceptibility and non-biological factors that contribute to infection need to be taken into account. More importantly, however, the study found that applying a gender lens to PRNDs necessitates a full-fledged analysis of the conditions and lived experiences of different genders to consider the determinants of health in all dimensions. The first key finding is that **it is crucial to distinguish between PRND 'prevalence' and 'impact' and consider both when assessing PRNDs through a gender lens.** Prevalence rates alone are an insufficient indicator for understanding the gendered dimension of a disease, for example in terms of wider health consequences, availability of healthcare, stigma, and discrimination, financial and social consequences. Decision-making on R&I or programmes addressing PRNDs cannot and should not rely on such figures alone.

A differentiated understanding of the gendered realities inherent in PRNDs is thus a prerequisite to further delve into the R&I needs of women and girls. The existing literature points to a number of knowledge gaps and blind spots when it comes to considering biological and non-biological differences between different sexes and gender. Each phase of the R&I process involves certain challenges and considerations that specifically concern women and girls. Research (re-)design and publication and all the stakeholders involved in the process influence each phase. Therefore, **the second key finding is the need for the consistent application of a gender lens throughout the entire R&I cycle. Integrating a gender perspective in R&I needs to happen with due respect to all ethical considerations, and needs to be incentivised or mandatory, despite potential resource implications**. *Figure 7* translates some of the key findings of each phase into a checklist tool applicable to the entire R&I cycle for health. Some modifications may be worth considering for the distinct diagnostic, drug, and vaccine development processes. This suggested checklist is not an endpoint but a means to trigger and inspire further holistic thinking on the gendered nature of the R&I process and thus should be considered as a dynamic and evolving tool.

As highlighted throughout the study, the lack of data makes it difficult to conclude on the impact of PRNDs on intersex people or individuals with non-binary gender identity or expression, or of non-heterosexual sexual orientations. The needs of the LGBTIQ+ population are only selectively mentioned throughout the literature, with the HIV & AIDS community being the most vocal to consider their needs specifically. Some agencies and organisations have, however, undertaken steps to more coherently integrate a broader gender perspective in their medical research.

Policy and funding recommendations

This study aims to provide a more holistic and gendered understanding of PRNDs and the R&I process around PRNDs. The study identified several recommendations which can be summarised in the below eight key points aiming to contribute to and strengthen the implementation of a gendered approach in R&I for PRNDs.

Legislators when setting the relevant rules, governments (more specifically, R&I and PRND programmes agencies in their funding requirements and funding allocation priorities), regulators, and research teams should, in collaboration…

IN PRACTICE

Consider all people beyond the binary focus on males and females

Further research is needed to understand – within the often restrictive political and legal environments – the impact of PRNDs on the entire gender identity spectrum, particularly the needs of the LGBTIQ+ population, and the resulting implications for the R&I process.

IN PRACTICE

Move beyond the biomedical focus and introduce a holistic approach

Going beyond the traditional biomedical model that relies primarily on quantitative, medical data will require research to systematically integrate a gender perspective, rooted in a contextual (local) analysis based on sociology, political sciences, and anthropology. This calls for studies contributing to understanding the gender-specific impact (and not only prevalence) of diseases and conditions, and more socio-behavioural and implementation research. Gender mainstreaming and intersectional gender analysis can be useful tools that need to be solidified and mandatory in the R&I process beyond the generic requirements of 'ticking the gender box' in project proposals. It implies, for example, establishing impact indicators specifically on gender.

IN PRACTICE

Disaggregate data by sex and gender at each step and at each level

The call for disaggregating data by sex and gender has been made many times, and yet, it needs to be reiterated once again because it is – together with a more holistic approach – an important prerequisite to be able to consider sex and gender dimensions in the R&I process. This disaggregation needs to start at the very beginning of the chain and information collected at every phase has to be captured, reported, analysed, and delivered to the appropriate entities in order to fully take the information into account in the decision-making processes at different phases of R&I. The data disaggregation chain has to be ensured horizontally and vertically. Health research journals should incentivise the production and dissemination of sex-disaggregated health research evidence, for example through editorial policies that enforce disaggregated outcome reporting [114, 117].

IN PRACTICE

Foster greater representation of women in science

Women need to be part of leadership and decision-making within research teams to facilitate better integration of sex- and gender considerations at all levels. Equal pay should be guaranteed, and greater support made available for women and minority researchers, including the provision of parental leave or child-care support. Novel mechanisms such as a roving-researcher programme should be explored and strengthened to ensure the career continuation of researchers that take lengthy breaks, such as for parental leave or caretaker responsibilities. Institutions should have clear guidelines and structures in place to address sexual and gender harassment and other forms of Gender-Based Violence (GBV) to foster a nondiscriminatory workplace.

IN PRACTICE

Integrate both female and male sex in all phases of research and development

From discovery to post-approval studies on PRNDs all relevant elements depicted in *Figure 2* need to be considered, for example by including male and female cells in in-vitro studies, males and females in animal studies, taking into account the sex and gender of research and laboratory team members, and including representative numbers of men, women and non-binary people in clinical trials. Misleading or erroneous conclusions in regards to sex and gender differences of pharmaceutical and non-pharmaceutical interventions need to be avoided and differences at biological and social levels need to be captured to improve treatment efficacy, efficiency, and safety.

IN PRACTICE

Address the lack of pregnancy safety trials and redefine existing concepts

Pregnat women should no longer be defined as a 'vulnerable population'. Pregnant women or breastfeeding women need to be included in the research process, for example, in clinical trials - in a safe and ethically sound way. It might be necessary to oversample pregnant women or WoSuP, or to conduct specific separate trials. Priorities have to be newly set, not only focusing on women as part of a process but also as separate research subjects. Moreover, as women often face serial pregnancies in some low-income settings, new strategies need to be devised to consistently and safely include them in Mass Drug Administration (MDA) campaigns whenever and wherever it is safe and possible.

IN PRACTICE

Adopt a gender-sensitive approach in medical regulation and international regulatory harmonisation efforts

There is a clear need to use regulatory enforcement, penalties, incentives, and other tools (such as research design support, fee waivers, expedited reviews, etc.) to foster the inclusion of sex and gender data in drug evaluation. National ethics committees and regulatory authorities' understanding of integrating a gender perspective needs to improve, allowing for the necessary guidelines, regulations, and directives to be set. International regulatory collaboration and harmonisation efforts should include this field of work. It would be useful to set up sex- and gender-disaggregated global performance indicators, for example through WHO's global benchmarking tool for the evaluation mechanisms of national regulatory systems. It is important to build on existing regulations and committees and inject new parameters on gender in their work. Existing governance structures can be expanded, for example, through the establishment of pregnancy committees and pregnancy investigation plans. Sex-disaggregated cost-effectiveness analysis needs to be taken into account in the evaluation of product inclusion in national or insurance benefits lists.

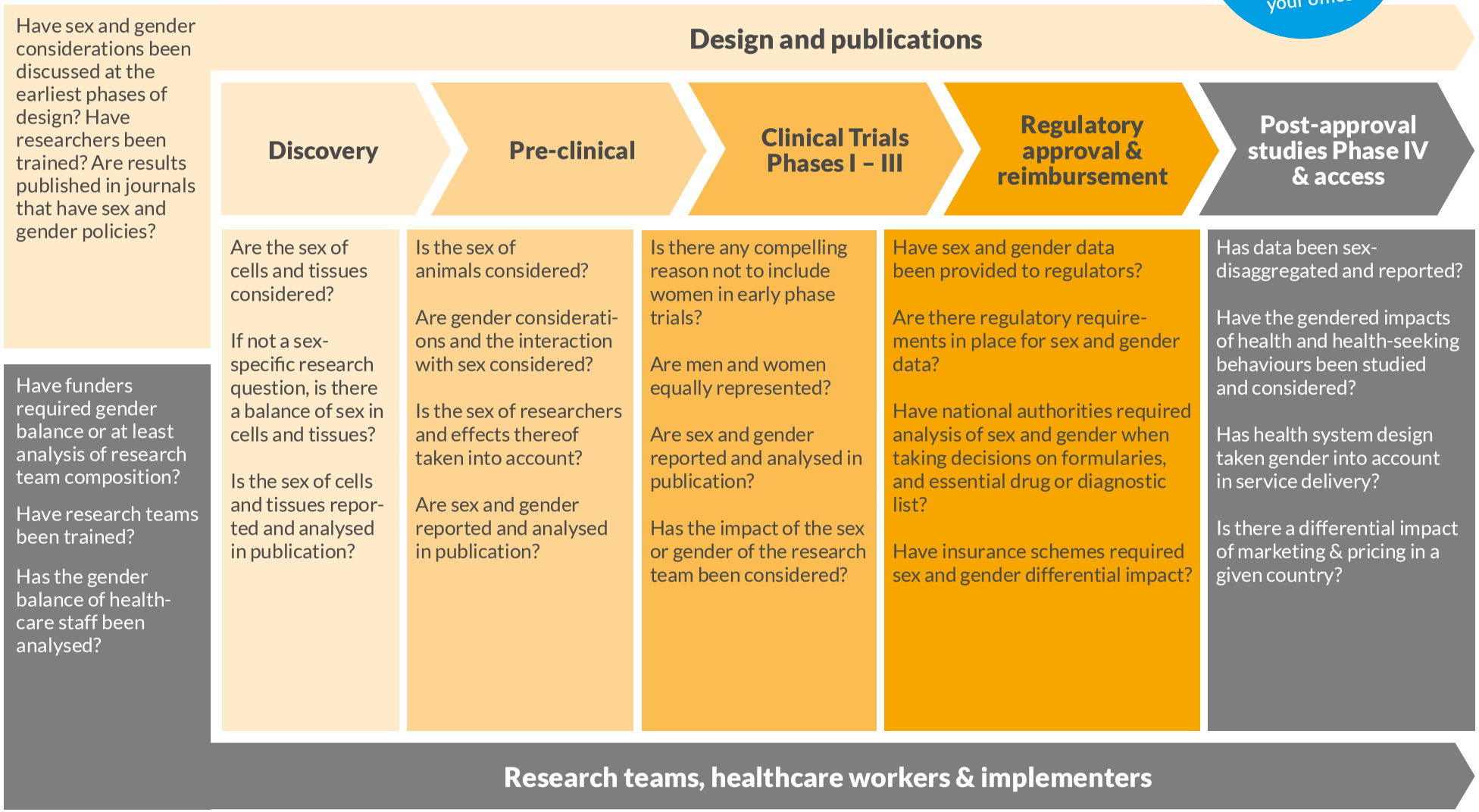
IN PRACTICE

Allocate (additional) dedicated funding and set new standards

The implementation of all of the recommendations made throughout this study, including setting new standards and requirements for research funding will require that additional funding is made available to fill knowledge, research, product, and regulatory gaps, and to increase gender capacities within responsible authorities, organisations, research teams, etc. There is also a need for additional/ dedicated funding and calls for proposals that specifically address some of the knowledge gaps that persist, and invest in further developing and implementing gender transformative approaches, and recognise women and girls, LGBTIQ+ people, and transient, or minority populations as priority populations.

FIGURE Research & Innovation needs through a gender lens

PRINT ME! and hang me in your office



Source: Told & Landry Chappuis, HumanImpact5 HI5 (2020)

6. ANNEXES

Annex 1: Overview of Poverty-Related and Neglected Diseases

The below list of diseases defines the scope of this study. WHO definitions are used [20].

- **Buruli ulcer:** A debilitating mycobacterial skin infection causing severe destruction of the skin, bone and soft tissue.
- **Chagas disease:** A life-threatening illness transmitted to humans through contact with vector insects (triatomine bugs), ingestion of contaminated food, infected blood transfusions, congenital transmission, organ transplantation or laboratory accidents.
- **Dengue**: A mosquito-borne infection causing flu-like illness that may develop into severe dengue and cause lethal complications.
- **Dracunculiasis (Guinea-worm disease):** A nematode infection transmitted exclusively by drinking-water contaminated with parasite-infected water fleas.
- **Echinococcosis:** Infection caused by the larval stages of tapeworms forming pathogenic cysts in humans and transmitted when ingesting eggs most commonly shed in faeces of dogs and wild animals.
- **Foodborne trematodiases**: Infection acquired by consuming fish, vegetables and crustaceans contaminated with larval parasites; clonorchiasis, opisthorchiasis and fascioliasis are the main diseases.
- **Human African trypanosomiasis (sleeping sickness):** A parasitic infection spread by the bites of tsetse flies that is almost 100% fatal without prompt diagnosis and treatment to prevent the parasites invading the central nervous system.
- **Human Immunodeficiency Virus (HIV) & Acquired Immunodeficiency Syndrome (AIDS):** An infection that attacks the body's immune system, specifically the white blood cells called CD4 cells. HIV destroys these CD4 cells, weakening a person's immunity against infections such as TB and some cancers. If the person's CD4 cell count falls below 200, their immunity is severely compromised. Someone with a CD4 count below 200 is described as having AIDS.
- **Malaria:** A disease caused by parasites that are transmitted to people through the bites of infected female Anopheles mosquitoes. There are five parasite species that cause malaria in humans, and two of these species – Plasmodium falciparum and Plasmodium vivax – pose the greatest threat.
- **Leishmaniases:** Disease transmitted through the bites of infected female sandflies that in its most severe (visceral) form attacks the internal organs and in its most prevalent (cutaneous) form causes face ulcers, disfiguring scars and disability.
- **Leprosy:** A complex disease caused by infection mainly of the skin, peripheral nerves, mucosa of the upper respiratory tract and eyes.
- **Lymphatic filariasis:** Infection transmitted by mosquitoes causing abnormal enlargement of limbs and genitals from adult worms inhabiting and reproducing in the lymphatic system.
- **(Mycobacterium) Tuberculosis:** A bacterial infection most often affecting the lungs and spread through the air when people with lung TB cough, sneeze or spit. A person needs to inhale only a few germs to become infected.
- **Mycetoma** is a chronic, progressively destructive inflammatory skin disease which usually affects the lower limbs. Infection is thought to be caused by the inoculation, through a thorn prick or skin damage, of fungi or bacteria into the subcutaneous tissue.
- **Onchocerciasis (river blindness):** Infection transmitted by the bite of infected blackflies causing severe itching and eye lesions as the adult worm produces larvae and leading to visual impairment and permanent blindness.
- **Rabies:** A preventable viral disease transmitted to humans through the bites of infected dogs that is invariably fatal once symptoms develop.
- **Schistosomiasis:** Trematode infections transmitted when larval forms released by freshwater snails penetrate human skin during contact with infested water.
- **Soil-transmitted helminthiases:** Nematode infections transmitted through soil contaminated by human faeces causing anaemia, vitamin A deficiency, stunted growth, malnutrition, intestinal obstruction and impaired development.
- **Taeniasis & cysticercosis:** An infection caused by adult tapeworms in human intestines; cysticercosis results when humans ingest tapeworm eggs that develop as larvae in tissues.
- **Trachoma:** A chlamydial infection transmitted through direct contact with infectious eye or nasal discharge, or through indirect contact with unsafe living conditions and hygiene practices, which left untreated causes irreversible corneal opacities and blindness.
- **Yaws:** A chronic bacterial infection affecting mainly the skin and bone.

Annex 2: Search Terms

Neglected Tropical Diseases / NTDs

… and gender
… among females
… among women
Impact of …. on women / girls
Sex differentials of ….
… among LGBT communities / transgender people
Gender-sensitive approaches to …
… and gender and innovation
… and gender and funding
Clinical trials on …
Financing / Funding / Health Systems / SDGs / UHC & …
Gender sensitive clinical trials on …
Gender related findings from clinical trials on …
Financing / Funding / Health Systems / SDGs / UHC, and
… and gender
… and access to medicines
… and women's /girls' access to medicines
… and access to medicines of transgender communities / of LGBT communities
UHC for women / transgender people / LGBT communities and …
Gender and diagnostics of …
Diagnostics of … in women / girls
Diagnostics of … among transgender people / LGBT communities
Case studies on …

Buruli ulcer
Chagas disease
Dengue
Chikungunya
Dracunculiasis
Guinea worm disease
Echinococcosis
Foodborne trematodiases
Foodborne trematodiases
Human African trypanosomiasis
Leprosy
Leishmaniasis
Lymphatic filariasis
Mycetoma, chromoblastomycosis and other deep mycoses
Onchocerciasis
River blindness
Rabies
Scabies and other ectoparasites
Schistosomiasis
Soil-transmitted helminthiases
Snakebite envenoming
Taeniasis/Cysticercosis
Trachoma
Yaws

… and gender
… among females / women
Impact of …. on women / girls
…among LGBT communities / transgender people
Sex differentials of ….
Gender-sensitive approaches to …
…and gender and poverty and funding
…and gender and poverty and innovation
Case studies on ...

Annex 2: Search Terms

HIV

… and gender
… among females
… among women
Impact of …. on women
Impact of …. on girls
Sex differentials of ….
… among LGBT communities
… among transgender people
Gender-sensitive approaches to …
… and gender and innovation
… and gender and funding
… and gender and poverty and funding
… and gender and poverty and funding and Kenya /Uganda / Tanzania / Ethiopia
… and gender and funding and Kenya / Ethiopia
… and gender and Tanzania / Ethiopia
Case studies on …
Clinical trial/ Financing/ research and innovation/ access to medicines / SDGs / UHC / Health systems /diagnostics /case studies and gender and …
Case studies on ...

Malaria
Tuberculosis

… and gender
… among females / women
… among LGBT communities / transgender people
Impact of … on women/ girls
Sex differentials of …
Gender-sensitive approaches of …
… and gender and poverty and innovation
… and gender and poverty and funding
… and gender and poverty and funding and Kenya / Uganda
… and gender and funding and Uganda
… and gender and Uganda / Tanzania /Ethiopia / Kenya
Case studies on …
Clinical trials / Financing / R&D / research and innovation / access to medicines / SDGs / UHC / Health systems / diagnostics / case studies and gender and …

Clinical trials
Diagnostics

Gender and …
Gender sersitive … on NTDs
Gender bias in …

DATA BASE USED

1. Global Health Data Exchange (GHDx) – Global Burden of Disease Results Tool
http://ghdx.healthdata.org/gbd-results-tool

2. WHO website and sources
https://www.who.int/ or https://apps.who.int/

3. G-Finder – Policy Cures Research Database
https://gfinderdata.policycuresresearch.org/pages/data-visualisations

Annex 3: List of Interviewed Organisations

1. **Drugs for Neglected Disease initiative (DNDi)**
2. **European & Developing Countries Clinical Trials Partnership (EDCTP)**
3. **Foundation for Innovative New Diagnostics (FIND)**
4. **Medicines for Malaria Venture (MMV)**
5. **PATH**
6. **TB Alliance**
7. **The Global Fund to fight AIDS, Tuberculosis and Malaria**
8. **Tuberculosis Vaccine Initiative (TBVI)**
9. **University College, London**
10. **WHO**

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