



## PRND prevalence vs. impact

A number of PRNDs are more prevalent in women and girls, with both biological susceptibility and non-biological factors contributing to infection. However, 'prevalence' (proportion of people infected at a given time) alone is an insufficient indicator for understanding the gendered dimension of a disease. It is paramount to also assess and consider the 'impact', for example in terms of wider health consequences, such as availability of healthcare, stigma and discrimination, financial and social consequences. 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.

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

### ▶ APPLYING A GENDER LENS ON PRNDS NECESSITATES A FULLY-FLEDGED ANALYSIS OF THE CONDITIONS AND LIVED EXPERIENCES IN ALL DIMENSIONS

#### Examples of disease specific impact on pregnant women



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

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

Most PRNDs lack essential tools to diagnose, treat, or prevent them, and huge knowledge gaps persist on pathogens, diseases, and their impact on different sexes and genders. **A better understanding of PRNDs and new and improved vaccines, drugs, and diagnostics are needed** if we are to achieve the Sustainable Development Goals target of eliminating PRNDs by 2030.

THERE ARE A NUMBER OF 'BLIND SPOTS', 'KNOWLEDGE GAPS', AND EVEN 'KNOWLEDGE BIASES'

Although the differences in biological susceptibility, as well as the broader gender dimensions, have significant impact on health outcomes, the **differences between women and men, or people with non-binary sex-characteristics, are often not considered in medical research.** A number of 'knowledge gaps' and even 'knowledge biases' exist as a result of neglecting the gender dimension across all stages of research (from discovery, over pre-clinical, clinical, regulatory approval, to post-approval studies). For example, research studies rarely report on the sex of the cells used in-vitro, and where the sex is reported, female cells account for only 5%. Females are underrepresented in preclinical animal studies, and also clinical trials in humans tend to be skewed towards men.

Each phase of the Research and Innovation (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. Yet, **a holistic view on gender mainstreaming and gender analysis throughout the entire R&I cycle is still missing.**

# POLICY AND FUNDING RECOMMENDATIONS

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



## 1. 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 the ‘checklist tool’ 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 men and women 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. A gender lens needs to be applied to any post-approval research undertaken (such as epidemiological, modelling and pharmacoeconomic, or postmarketing surveillance studies).

## 2. Foster greater representation of women in science



Women need to be part of leadership and decision-making within research teams to facilitate the better integration of sex- and gender considerations at all levels.

## 3. Consider all people beyond the binary focus on males and females

LGBTIQ+

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.

## 4. 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.

## 5. 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 the gendered 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.

## 6. Address the lack of pregnancy safety trials and redefine concepts



Following the example of the US' Common Rule, 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 women susceptible to and becoming pregnant, 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 campaigns whenever and wherever safe and possible.

## 7. 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 increase, 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 the 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 into 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 women. Sex disaggregated cost-effectiveness analysis needs to be taken into account in the evaluation of the inclusion in national or insurance benefits lists.

## 8. Allocate (additional) dedicated funding and set new standards



The implementation of all of the above recommendations will require that funding be made available to fill knowledge, research, product, and regulatory gaps, and to increase gender capacities within responsible authorities, organisations, research teams, etc. 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, rule out 'gender blindness' of the funded research, and serve as an incentive for relevant stakeholders and organisations to make the necessary efforts. But there is also a need for additional/ dedicated funding and calls for proposals that specifically address some of the knowledge gaps, invest in further developing and implementing gender transformative approaches, and recognise women and girls, LGBTIQ+ people, transient, or minority populations as priority populations.

## Checklist tool for the application of a gender lens throughout the entire R&I cycle

