**Written evidence submitted by the British Pharmacological Society to the consultation on the government’s Women’s Health Strategy.**

**About us**

The British Pharmacological Society (BPS) is the primary UK learned society concerned with research into drugs and the way they work. The Society has around 4,000 members working in academia, industry, regulatory agencies, and the health services, and many are medically qualified. The Society covers the whole spectrum of pharmacology, including laboratory, clinical, and toxicological aspects. Pharmacology is a key knowledge and skills base for developments in the pharmaceutical and biotech industries, and is therefore fundamental to a thriving UK industry and R&D. These skills allow members of the Society to identify therapeutic areas of clinical need, develop novel treatments that target these areas and ensure these new treatments are incorporated into healthcare practice bringing benefit to patients. The Society publishes three scientific journals: the British Journal of Pharmacology, the British Journal of Clinical Pharmacology, and Pharmacology Research and Perspectives.

**Executive Summary**

We would like to highlight some cross-cutting themes and recommendations, please see the main response for our detailed comments:

**Sociocultural impact, intersectionality, and inclusivity**

* We welcome recognition of the sociocultural context of women’s health in the consultation. The final strategy should continue to be explicit about the legacy of undervaluing women, women’s health and women’s voices. The strategy should include the principle that research, healthcare and the workplace have a responsibility to adapt for women – not the other way around.
* The strategy should be intersectional and holistic, recognising that women face different barriers and have different needs that depend on their background and lived experience – for example, ethnicity, socioeconomic background, disability, sexual orientation, and gender identity. It should also recognise that the social determinants of health are multi-factorial, and that a long-term, cross-government approach will be needed to fully realise its ambitions.
* We would like to see an inclusive definition of ‘women’ in the final strategy, and a subsequent proactive review of language use to ensure inclusivity. We have considered such a definition to cover those of female sex and those who include ‘woman’ in their gender identity: trans women and femme/feminine-identifying genderqueer and non-binary people. By using an inclusive definition, the strategy would also capture everyone who menstruates or becomes pregnant - and recognise that healthcare needs may differ depending on gender identity.

**Research**

* The legacy of undervaluing women has resulted in less funding for women’s health research, and thus a data gap for women.
* Including a research pillar as part of the strategy is an opportunity for research, regulatory and clinical communities come together to ensure that research at all stages considers the impact of female sex, genetic ancestry, and the needs of women across the life course – so that medicines are developed with and for the patients who need their benefit. For example, there is currently limited advice on medicines for use in pregnancy and breastfeeding, and more studies (particularly clinical lactation studies) need to be done at the licencing stage of a new medicine.
* A research pillar should include measures to improve women’s participation in research, ensure research funding decisions actively include women’s health needs, and develop requirements for the disaggregation of data so research, development and clinical care is evidence-based. As part of this, and in collaboration with UK funders and charities, the strategy should include a roadmap for investment in women’s health research and the development of therapeutics that meet women’s health needs.
* The strategy should also recognise the importance of developing and retaining women research leaders (and those from other under-represented groups) as part of bringing a diversity of perspectives to research strategy, including funding and priority setting.

**Education**

* Women should be able to access information about their health and medication and be able to expect supportive discussions with healthcare professionals about their options.
* We would encourage a review of education at UK medical schools, at postgraduate levels and of CPD/lifelong learning, with the aim of understanding how women’s health is represented in curricula and training, and to set minimum standards through learning outcomes and capabilities in practice.

The Society would like to continue contributing to the development of the strategy and would be happy to discuss any of the points raised in our response. Please contact Dr Anna Zecharia via [anna.zecharia@bps.ac.uk](mailto:anna.zecharia@bps.ac.uk)

**Main response**

**1. Women’s voices**

* 1. As the consultation notes, there is a legacy of undervaluing women’s voices. Our response to this section focuses on some principles that could help improve this in the future.
  2. We suggest that the NIHR INCLUDE Framework[[1]](#endnote-1) for clinical research is a good model for proactively including women’s voices, and those of other under-served groups in research and healthcare decision-making. The project roadmap supports research that is inclusive by design, identifying checkpoints in the research journey for patients, public, funders, clinicians, researchers, regulators, industry, policymakers. It recognises that barriers to inclusion are context specific and intersectional, ranging from logistical issues to deeper problems with lack of trust.
  3. In 2018, the British Psychological Society published the Power Threat Meaning (PTM) Framework[[2]](#endnote-2), building on the understanding that women’s healthcare inequalities are impacted by sociocultural factors, e.g., the World Health Organisation recognises[[3]](#endnote-3) that such factors include:
* unequal power relationships between men and women;
* social norms that decrease education and paid employment opportunities;
* an exclusive focus on women’s reproductive roles; and
* potential or actual experience of physical, sexual and emotional violence.

The PTM Framework empowers women’s voices by building this recognition into its therapeutic framework. It replaces the question ‘What is wrong with you?’ with four key questions:

* ‘What has happened to you?’ (How is Power operating in your life?)
* ‘How did it affect you?’ (What kind of Threats does this pose?)
* ‘What sense did you make of it?’ (What is the Meaning of these situations and experiences to you?)
* ‘What did you have to do to survive?’ (What kinds of Threat Response are you using?)

Whilst these questions would need to be adapted in different therapeutic settings, the principle is sound: that the healthcare system has a responsibility to shift and adapt to the needs and realities of women – women should not be expected to fit into it. We welcome recognition of the sociocultural context in the consultation and would like to see the strategy continue to do so, by explicitly recognising this principle.

* 1. We would like to see an inclusive definition of ‘women’ in the final strategy. We have considered such a definition to cover those of female sex and those who include ‘woman’ in their gender identity: trans women and femme/feminine-identifying genderqueer and non-binary people. The strategy must also proactively address intersectionality and recognise that women face different barriers and have different needs that depend on their background and lived experience – for example, ethnicity, socioeconomic background, disability, language, cultural background, sexual orientation, and gender identity. An important aspect of this is a gendered experience of health inequality due to socioeconomic deprivation, as highlighted by the recent report “The Marmot Review: 10 years on”[[4]](#endnote-4). Further, poorer, migrant women suffer the worst health and there are differences in health outcomes between ethnic groups for women[[5]](#endnote-5). Encouraging a whole-person, integrated approach to care in the NHS will also recognise that experience can never be fully categorised and will ensure that the needs of the individual are considered. The strategy must also recognise men as a key stakeholder in women’s health and there must be a parallel focus on men’s education and awareness.
  2. We welcome the government’s intention to put women’s voices at the centre of their health and care. As the consultation recognises, this must be done at all levels. Working at a systems-level, building on existing frameworks and good practice, and including a focus on education, training and shared learning would be a positive step forward. The strategy should recognise that the social determinants of health are multi-factorial, and that a long-term, cross-government approach will be needed to fully realise its ambitions.

**2. Information and education on women’s health**

* 1. Women should be empowered to take ownership of their health. Historically medicines development and prescribing has been based on male norms and so information designed specifically for women (e.g. adverse drug reactions, drugs in pregnancy) needs further attention. For example, the Society attempted to confirm how many drugs are licenced for use in pregnancy and the information was not readily available. Women should be able to access information about medication to support discussions with their doctor about their options. For pregnancy and breastfeeding, a campaign [“Don’t Say Stop, Look it Up”](https://www.hifn.org/dontsaystop)[[6]](#endnote-6) seeks to raise awareness among prescribers and dispensers about the importance of getting accurate information about medication and lactation. The campaign provides core knowledge and prescribing guidance for healthcare professionals. Similarly, [LactMed](https://www.ncbi.nlm.nih.gov/books/NBK501922/)[[7]](#endnote-7), [UKDilas](https://www.sps.nhs.uk/articles/ukdilas/)[[8]](#endnote-8) and [Boobingit](https://boobingit.com/medicine-use-while-breastfeeding)[[9]](#endnote-9) provide evidence-based information to support prescribing in breastfeeding mothers. We recommend that healthcare providers (and importantly, prescribers) should be directed to these sources of information through the NHS, and that CPD is available to support lifelong education in these areas. We are not aware of comparable sites for pregnant mothers but would encourage investment in such resources and education. The Society developed and delivers the national [Prescribing Safety Assessment](https://prescribingsafetyassessment.ac.uk/)[[10]](#endnote-10) with the Medical Schools Council. This assessment seeks to ensure that all UK medical graduates have demonstrated appropriate knowledge and skills in relation to safe use of medicines before they begin their training as independent prescribers in the NHS. The assessment includes a proportion of questions that are focused on safe prescribing for women at different stages of their life, including pregnancy and breastfeeding. The Society is also developing other resources to support the education of prescribe through [BPS Assessment](https://www.bpsassessment.com/)[[11]](#endnote-11), notably including a collaboration with the MHRA’s pregnancy consortium. We would be well-placed to advise on this and would welcome the opportunity to discuss.
  2. Many areas of women’s health are hidden because they are viewed as taboo or embarrassing and have been undervalued in a patriarchal society. Encouraging a shift in cultural attitudes and open discussion by opening discussion of women’s experiences in a wider societal setting (e.g. in collaboration with the Department for Digital Culture, Media & Sport, the Arts Council and other funders – for example the BFI has diversity standards[[12]](#endnote-12) to support equality of opportunity and to increase diversity in on-screen narratives) would represent a holistic approach to women’s health and valuing women’s voices.
  3. Healthcare professionals should be supported to have conversations with women about topics that can be seen as difficult or embarrassing. For example, education and training should seek to inform healthcare professionals about women’s health across the life course and enable/normalise discussions about areas including sexual function, contraception, complications after childbirth, gender identity and menopause. This should be embedded into postgraduate training and offered as CPD. We would also encourage a review of education at UK medical schools with the aims of understanding how women’s health is represented in curricula and teaching - and setting minimum standards on coverage through learning outcomes and graduate capabilities in practice. The Society has launched an inclusive pharmacology steering group with the aim of developing resources to support inclusivity in education about medicines development and use – we would be happy to share our findings as this project progresses. Similarly, more patient-facing information that helps empower women and normalise such discussion would be welcome.

**3. Women’s health across the life course**

* 1. We welcome the decision to take a life course approach to women’s health. We also welcome the choice of language that ‘women have specific needs’, rather than use of words such as ‘different’, ‘special’, or ‘complex’ that treat women as ‘other’. As outlined in our response to question 1, this approach should prioritise areas of unmet need5,[[13]](#endnote-13),[[14]](#endnote-14) and recognise where health disparities have roots in society that need to be addressed in parallel. Women’s needs across the life course have been historically hidden and under-valued. The healthcare system must fit women, not the other way around. A key principle should be enabling people to feel comfortable and empowered in having these conversations in the first place.
  2. Certain medications have pregnancy prevention programmes (PPP, PREVENT) regimes as a condition of treatment. For example, use of sodium valproate (licensed for use in the treatment of epilepsy and bipolar disorder) in pregnancy is associated with a high risk of persistent neurodevelopmental disorders and risk of physical birth defects. The Royal College of General Practitioners and Association of British Neurologists and Royal College of Physicians have developed an extensive guidance document to inform use of valproate[[15]](#endnote-15). The guidance recognises that “prescription and use of valproate in a woman of childbearing potential without a PPP would be outside its licence”, recognising that this is contentious and offering support for decision-making - but also noting that the “right to autonomy and societal values” are beyond their scope. The MHRA have also [issued advice](https://www.gov.uk/drug-safety-update/medicines-with-teratogenic-potential-what-is-effective-contraception-and-how-often-is-pregnancy-testing-needed) on pregnancy prevention for medicines with teratogenic potential. We suggest that issues of autonomy and ethics of decision making, particularly regarding an unborn or breastfeeding child - and supporting healthcare providers and patients to engage with them, are acknowledged in the strategy. Some of these issues have been explored from the perspective of breastfeeding choice for mothers who are HIV positive[[16]](#endnote-16). Until 2017, all guidance in high income countries prohibited breastfeeding, even if a woman was virologically suppressed and aware of the potential (but very low) risk. It was grounds for social work referral and considered a ‘child protection’ issue. The shift began with European guidelines in 2017, then British and North American guidelines in 2018. It is still not recommended anywhere, but it is accepted that if a woman really understands the risks, she should be supported in her decision.
  3. NHS England has [announced](https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/update-following-recent-court-rulings-on-puberty-blockers-and-consent/) that a new independent group will review the prescription of puberty blockers (gonadotropin-releasing hormone [GnRH] antagonists that block sex hormone production and thus prevent puberty) following the 26 March 2021 High Court ruling that parents can consent to their children being prescribed puberty blockers without needing to go to court, and that puberty blockers are not a special category of treatment which has to be authorised by a court order[[17]](#endnote-17),[[18]](#endnote-18). The effects of puberty blockers are thought to be reversible and therefore give young people much needed time to explore their gender identity and choices about transition. However, we would caution that we are not aware of studies that examine their long-term impact: there are unknown potential risks of hormonal deprivation on the developing brain and body[[19]](#endnote-19). Prescribing guidance suggests short-term exposure for this reason, but we would like to see improvements in the quality of data[[20]](#endnote-20) about the long-term impact of puberty blockers to support risk-benefit decisions, but also support a pragmatic approach (given the potential strength of benefit for young people) that ensures monitoring of bone mineral density during treatment[[21]](#endnote-21). Puberty can be a difficult time for young people whose gender identity is still forming – and we also caution that not everyone has a supportive family. Puberty blockers are available through disreputable sources and there is little high-quality information to support young people who may not be able to have these discussions openly. The strategy should consider the quality of information and support for young people, particularly those at risk of isolation – for example, the NHS [will review its Gender Dysphoria Clinical Programme in 2021-22](https://www.england.nhs.uk/commissioning/spec-services/npc-crg/gender-dysphoria-clinical-programme/update-following-recent-court-rulings-on-puberty-blockers-and-consent/). Young people must be supported as they make decisions about their gender identity. Trans medicine, including but not limited to the use of puberty blockers, should be included in the strategy.
  4. A report from the BMA5 notes that “women with dementia have fewer visits to the GP, receive less health monitoring and take more potentially harmful medication than men with dementia. Furthermore, women were found to be at particular risk of staying on antipsychotic or sedative medication for longer, probably due to the lower number of appointments where their treatment can be reviewed”.
  5. Hormonal treatment, whether for contraception, management of menstrual cycles or in response to menopause, is something that many women are likely to encounter during their lifetime. There must be the time and access to unbiased information to support informed decisions about options and risk-benefit. We would also like to see a focus on improving awareness of rare side effects, as part of the wider drive to ensure that women’s voices are listened to. For example, some women experience progesterone-induced side effects with the intrauterine system (IUS), which is a contraceptive device that releases low doses of progesterone locally into the uterus. We are aware of cases where women report side effects to their doctor but are told the dose of progesterone is too small to be responsible, and their concerns are dismissed. In fact, the literature does show about 15% of women having troublesome adverse events necessitating removal[[22]](#endnote-22). In terms of treatment options for menopause, women want “unbiased, truthful and summarised information” that allows them to make holistic decisions about their own health[[23]](#endnote-23).
  6. It is important to raise awareness of the interplay between pharmacogenomics (how knowledge of genetic ancestry can inform use of medicines) and pregnancy, and the need for further investigation of this[[24]](#endnote-24). For example, a reduced dose of the antiretroviral efavirenz should be used in those with polymorphisms leading to higher concentrations and greater risk of toxicity, the presence of which was more common in people of African origin[[25]](#endnote-25). The NHS will begin implementation of pharmacogenomics this year, and the Society is partnering on a working group with the Royal College of Physicians to make recommendations about education and training needs of the workforce.
  7. Other comments regarding the life course have been covered in our response to question 5, so we also refer you to these.

**4. Women’s health in the workplace**

* 1. The early career stage is known to be a critical point for loss of women and other under-represented groups in scientific careers, and the Society is concerned that the impact of the pandemic[[26]](#endnote-26) will have a compounding detrimental effect. Investing in women research leaders, and research leaders from other under-represented groups, should be a priority – not least because improving the diversity of perspectives (including perspectives on women’s health) will ensure a wider range of voices contribute to decisions about scientific funding and priority setting.
  2. The pandemic has had an impact on family life. For some individuals, this has been a positive, they have had the opportunity to spend more time at home, and with their family – and would like to consider additional flexibility in working patterns in the future. The flip side of the coin is that for many, it is harder to get work done because they are juggling home-schooling, childcare, working and any number of other responsibilities. We are concerned that this will in turn have an impact on the careers and progression of those who have caring responsibilities, often likely to be women[[27]](#endnote-27). Therefore, this is likely to compound existing disparities[[28]](#endnote-28).
  3. It is critical that early career researchers be given additional support (in terms of funding, or post-hoc normalisation of any CV gaps) so that under-represented groups are not over-represented when it comes to negative impacts of the pandemic on scientific careers. The pandemic should cause the sector to reflect – and more importantly, act – on long-standing issues that result in precarious scientific careers. Wellcome’s ‘Reimagine Research’ Festival[[29]](#endnote-29) is a good example of raising and responding to issues within science that contribute to negative culture and have a disproportionate impact on women and other under-represented groups. This should be a priority in the new People & Culture Strategy as part of the R&D Roadmap. The Society has set out our views on this in response to the APPG on Diversity in STEM’s current inquiry on ‘Equity in STEM careers’ and has long supported team science and a systems approach to a positive research culture, most recently as part of our new vision for inclusive pharmacology[[30]](#endnote-30).
  4. The Society also supports flexibility for all employees and ways in which to better understand and support women with things such as women’s health issues e.g., menstrual symptoms, miscarriages, pregnancy, and breastfeeding, menopause symptoms. Women should be helped to work flexibly at times when they are affected whether this is by working from home, taking breaks from work when required, and through a supportive environment and facilities. Supportive measures and flexibility should be the preferred option - unless sick leave cannot be avoided.

**5. Research, evidence and data**

* 1. The Society recently published an article covering aspects of sex and gender-based inequalities in research and health[[31]](#endnote-31), which we have reproduced in part, and developed in our response to this question. The legacy of undervaluing women has led to under-funding of women’s health (for example, reproductive and gynaecological health receives 2% of UK public funding[[32]](#endnote-32), despite around a third of women experiencing severe reproductive health issues[[33]](#endnote-33)) and a data gap for women across the breadth of health research and therapeutics development. We would like to see a focus on closing the funding and data gap for women’s health in the strategy, including trans medicine.
  2. Understanding how sex differences influence physiology and the response to medicines in pre-clinical research can help ensure a smooth transition from clinical development into practice. Conversely, a bias towards studying male physiology and the male drug response may be harmful if this leads to inappropriate treatment recommendations for female bodies[[34]](#endnote-34). The US National Institutes of Health implemented a requirement for inclusion of both male and female samples in 2016. A recent retrospective analysis of impact concluded there have been notable improvements in reporting in 2019 compared with 2009[[35]](#endnote-35). The number of pharmacology articles reporting use of both sexes remained static. However, pharmacology was the only biological discipline to demonstrate a significant increase in sex-based analyses over the ten-year period: from 19% to 48%. In 2019, The British Journal of Pharmacology set expectations that sex should be considered an experimental variable in all studies submitted for publication[[36]](#endnote-36), and we hope this move will support positive trends in research practice for the discipline. The UK does not have an equivalent requirement, and this should be reviewed - although funders have begun to act (see 5.8).
  3. The representation of women in clinical research has been improving since the introduction of the 1993 National Institute of Health (NIH) Revitalization Act (amended in 2001) in the United States of America. The Act requires that researchers funded by the US NIH include women as well as men in clinical studies and analyse their results by sex or gender. As noted in 5.2, the UK does not have a similar requirement and this should be reviewed. We would support a requirement for trials conducted for regulatory approval purposes to stratify appropriately and analyse outcomes by sex. There is limited data on the impact of the US legislation (and other requirements) on representation, but a recent small study noted persistent lower representation of women in phase I studies (at 22%). Phase II/III trials were more equitable, with an average of 48% (range 25%-87%) of women included in trials across nine drugs approved by the FDA since the legislation. It is important to account for sex-specific differences when making choices about safe and effective doses so the needs of the full population are covered. Early phase clinical trials are used to establish safety parameters, and differences between the sexes can affect pharmacodynamic and pharmacokinetic factors. For example, differences in average body weight can lead to higher plasma concentrations of zolpidem, which led to the FDA making female specific dose recommendation[[37]](#endnote-37). Another concern is that a lack of safety information gathered from females can lead to higher incidence of adverse drug reactions, for example to common cardiovascular medicines. A 2016 study[[38]](#endnote-38) looked at randomised controlled trials (RCTs) published in The Lancet and the New England Journal of Medicine showed representation of women at 40%. This was an improvement on a comparable study published in 2009, which showed representation at 37%. However, the authors stress that inclusion of women was “not linked to meaningful analysis of outcomes by sex”. In some disease areas, this translates to disproportionate negative impacts on health outcomes. For example, The Lancet have recently launched[[39]](#endnote-39) a Commission on Women and Cancer to examine the intersection of social inequality, cancer risk, and outcomes, and the status of women in society. Their Commission on Women and Cardiovascular Disease[[40]](#endnote-40) aims to address known research gaps and barriers that mean women with this disease still have worse outcomes than men.
  4. Further, the thalidomide tragedy[[41]](#endnote-41) of the 1960s led to development of important regulatory processes designed to promote safety. Part of the resulting legislation was to exclude pregnant women and women of child-bearing age from clinical trials. Whilst well-intentioned, this protectionist policy has meant there are gaps in our knowledge about the effects of drugs in pregnancy, and a legacy of paternalism when it comes to women’s ability and right to make informed choices about their participation in research. There are the extremes of mandating against something or giving absolutely free choice. Ethical tensions will remain and should be discussed openly - each case may need an individualised consideration of risk benefit ratio. We recognise the need for a cautious approach, particularly regarding novel compounds where the safety profile is less well defined. However, this must be balanced by discussion about the risk from the disease itself and the individual woman’s health needs. Women’s voices must be proactively included in decision-making about research and healthcare, as outlined in our response to question 1. We would like to see a continuing shift from ‘protecting women from research’ to ‘protecting women through research’[[42]](#endnote-42).
  5. Whilst regulators such as the FDA agree that clinical lactation studies should be done around the time of drug licensing for any drug that is anticipated to be used in women of childbearing age, this is not usual practice. There is increasing recognition of the benefits and potential harms (to mother and child, both physical and psychosocial) of mandating not to breastfeed on a drug. It is not acceptable to deprive a mother-infant pair of potential benefits, and risk harms, simply because the research has not been done. The research and regulatory community must come together to ensure evidence is generated from the population in whom the drugs are likely to be used in order to inform safe, evidence-based shared clinical decision making.
  6. The UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) is exploring with other regulators how evidence on benefits and risks of medicines in pregnancy and breastfeeding can be obtained earlier in a medicine’s development[[43]](#endnote-43), and the UK has launched a new partnership to support clear and consistent evidence-based guidance on medicines for pregnant and breastfeeding women[[44]](#endnote-44). The BPS is collaborating with this Safer Medicines in Pregnancy and Breastfeeding Consortium, to produce online training resources materials in the safe prescribing of medicines in this important area. The consortium is a partnership of 16 leading organisations who are working together to improve the health information available to women thinking about becoming pregnant, who are pregnant, or who are breastfeeding.
  7. Early phase trials are used to understand the safety of a potential therapeutic, so caution in the form of pregnancy prevention is also a feature of early phase adult trials – this applies to both male and female participants of trials. The HMA (Heads of Medicines Agencies) has issued guidance on contraception and pregnancy testing in clinical trials[[45]](#endnote-45). We are aware that there have been concerns[[46]](#endnote-46) about the consistency and robustness of practice in this area, but we are not aware of studies that assess whether this guidance has had a positive impact. Such trials often require a male participant to disclose information about a partner’s pregnancy (because of concerns that a drug may be excreted in seminal fluid and thus affect a potential pregnancy) but our understanding is that processes to ensure that the female partner has consented to share this information are variable – this should be reviewed and formalised. In early phase paediatric drug trials, while there have been improvements in the paediatric aspects of protocol design over the last decade, many still apply strict contraception requirements to girls who are not physiologically or psychologically mature enough to consider intimate relationships. The form of words related to contraception in patient and parent information sheets for early phase trials is very rigid and does not provide much variance for peri-and younger post-pubertal girls. This could deter both the girls, and her parent/guardian (who would be consenting), from considering participation. This may be one reason that studies are weighted towards the male sex.
  8. Several funders of clinical trials are making headway in terms of ensuring applicants for funding consider diversity in their trial design. Wellcome, for example, expect the demographic of trial participants to represent the population needing the healthcare intervention[[47]](#endnote-47). The NIHR Include project[[48]](#endnote-48) is examining how to improve inclusion of underrepresented groups into clinical research. In the US, the FDA has specific guidance[[49]](#endnote-49) in relation to the collecting and reporting of race and ethnicity data so that it is representative of the real-world burden of disease. Further, the European Commission has recently announced that it will require grant recipients to incorporate sex and gender analyses into the design of research studies[[50]](#endnote-50). The UK needs to improve its data collection and requirements to support both analysis (for products licenced by the MHRA and representation in clinical research) and to assess/track progress towards inclusive research. There is opportunity for medicines regulators to insist on measures to close the data gap relating to drug effects in women and children, particularly for new products coming to market. For example, as part of post-marketing surveillance, regulators could require marketing authorisation holders to study uptake and outcomes among these groups. COVID-19 vaccine surveillance is an opportunity to trial this at scale. Developing UK patient registries[[51]](#endnote-51) that are linked to prescription/dispensing databases & population registries is one way to improve real world evidence through realising the power of linked data. The ultimate aim should be to shift to proactive regulatory measures, and away from the reactive regulatory responses (e.g., to valproate harms) that are too little, too late.
  9. Ultimately, people should be at the centre of health research. In striving for sex and gender equality in research, this means asking women what they want from their healthcare, understanding perceptions of research or equity of access to it – and working in partnership with women and across the research system (including increasing funding for women’s health) to fully realise the benefits of evidence-based healthcare.

**References**

1. Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project. (2020). NIHR. Available online at: <https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435> [↑](#endnote-ref-1)
2. The Power Threat Meaning Framework. (2018) The British Psychological Society. Available online at: <https://www.bps.org.uk/sites/www.bps.org.uk/files/Policy/Policy%20-%20Files/PTM%20Framework%20%28January%202018%29_0.pdf> [↑](#endnote-ref-2)
3. Women’s Health. The World Health Organisation. Available online at: <https://www.who.int/health-topics/women-s-health/> (last accessed 10 May 2021). [↑](#endnote-ref-3)
4. Health Equity in England: The Marmot Review 10 Years On. (2020). The Institute of Health Equity. Available online at: <https://www.health.org.uk/publications/reports/the-marmot-review-10-years-on> [↑](#endnote-ref-4)
5. Health inequalities and women – addressing unmet needs. (2018) BMA. Available online at: <https://www.bma.org.uk/media/2116/bma-womens-health-inequalities-report-aug-2018.pdf> [↑](#endnote-ref-5)
6. Don’t Say Stop, Look it Up. Hospital Infant Feeding Network. <https://www.hifn.org/dontsaystop> (last accessed 10 May 2021). [↑](#endnote-ref-6)
7. Drugs and Lactation Database (LactMed). <https://www.ncbi.nlm.nih.gov/books/NBK501922/> (last accessed 10 May 2021). [↑](#endnote-ref-7)
8. UK Drugs in Lactation Advisory Service (UKDILAS). <https://www.sps.nhs.uk/articles/ukdilas/> (last accessed 10 May 2021). [↑](#endnote-ref-8)
9. Boobingit. <https://boobingit.com/> (last accessed 10 May 2021). [↑](#endnote-ref-9)
10. Prescribing Safety Assessment. <https://prescribingsafetyassessment.ac.uk/> (last accessed 10 May 2021). [↑](#endnote-ref-10)
11. BPS Assessment. <https://www.bpsassessment.com/> (last accessed 10 May 2021). [↑](#endnote-ref-11)
12. Diversity Standards (2019) British Film Institute. Available online at: <https://www.bfi.org.uk/inclusion-film-industry/bfi-diversity-standards> (last accessed 24 May 2021). [↑](#endnote-ref-12)
13. Addressing unmet needs in women’s health. (2018) Cancer Research UK. Available online at: <https://www.cancerresearchuk.org/sites/default/files/womens-health-full-report-aug2018_0.pdf> [↑](#endnote-ref-13)
14. Racial disparities in women’s healthcare. (2020). The Royal College of Obstetricians & Gynaecologists. Available online at: <https://www.rcog.org.uk/globalassets/documents/news/position-statements/racial-disparities-womens-healthcare-march-2020.pdf> [↑](#endnote-ref-14)
15. Guidance Document on Valproate Use in Women and Girls of Childbearing Years, Version 2.1. (2020). Royal College of General Practitioners, Association of British Neurologists, Royal College of Physicians. Available online at: <https://www.rcgp.org.uk/-/media/Files/CIRC/Epilepsy/Guidance-on-Valproate-use---Dec-2020.ashx?la=en> [↑](#endnote-ref-15)
16. Waitt et al (2018). Lancet HIV 5(9):e531-e536. doi: 10.1016/S2352-3018(18)30098-5. Available online at: <https://pubmed.ncbi.nlm.nih.gov/29960731/> [↑](#endnote-ref-16)
17. R (on the application of) Quincy Bell and A v Tavistock and Portman NHS Trust and others [2020] EWHC 3274. (2020) Judiciary of England and Wales. Available online at: <https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Clinic-and-ors-Summary.pdf> [↑](#endnote-ref-17)
18. High Court ruling means most won’t need to go to court to access puberty blockers. (2020). Mermaids. Available online at:<https://mermaidsuk.org.uk/news/high-court-ruling-means-most-wont-need-to-go-to-court-to-access-puberty-blockers/> (last accessed 10 May 2021). [↑](#endnote-ref-18)
19. Lee et al (2020). J Endocr Soc 4(9):bvaa065. doi: 0.1210/jendso/bvaa065. Available online at: <https://pubmed.ncbi.nlm.nih.gov/32832823/> [↑](#endnote-ref-19)
20. Rew et al (2021). Child Adolesc Ment Health 26(1):3-14. doi: 10.1111/camh.12437. Available online at: <https://pubmed.ncbi.nlm.nih.gov/33320999/> [↑](#endnote-ref-20)
21. Joseph et al (2019). J Pediatr Endocrinol Metab 32(10):1077-1081. doi: 10.1515/jpem-2019-0046. Available online at: <https://pubmed.ncbi.nlm.nih.gov/31472062/> [↑](#endnote-ref-21)
22. Teunissen et al (2019). The European Journal of Contraception & Reproductive Health Care24(6):449-456. Available online at: <https://doi.org/10.1080/13625187.2019.1682134> [↑](#endnote-ref-22)
23. Walter et al (2004). Patient Educ Couns 53(2):121-8. Available online at: <https://doi.org/10.1016/j.pec.2003.11.001> [↑](#endnote-ref-23)
24. Olagunju et al (2012). Pharmacogenomics 13(13):1501-22. Available online at: [10.2217/pgs.12.138](https://doi.org/10.2217/pgs.12.138) [↑](#endnote-ref-24)
25. Lamorde et al (2018). Clin Infect Dis 67(5):785-790. Available online at: DOI: [10.1093/cid/ciy161](https://doi.org/10.1093/cid/ciy161) [↑](#endnote-ref-25)
26. Gould, J. (2020) *The career costs of COVID-19: how postdocs and PhD students are paying the price.* Nature Careers Podcast. Nature. 25.11.20. <https://www.nature.com/articles/d41586-020-03108-4>. (Accessed 19 January 2021). [↑](#endnote-ref-26)
27. Bellingan, L. (2020). Coping with COVID. The Biologist. Available online at: <https://thebiologist.rsb.org.uk/biologist-covid-19/coping-with-covid-2>. (last accessed 10 May 2021). [↑](#endnote-ref-27)
28. Godlee, F. (2020). Covid-19: Why we still need more women in academia BMJ 371:M4161. Available online at: <https://www.bmj.com/content/371/bmj.m4161> (last accessed 10 May 2021). [↑](#endnote-ref-28)
29. Reimagine Research Festival (2021) Wellcome. Available online at: <https://wellcome.org/what-we-do/our-work/research-culture/reimagine-research-culture-festival> (last accessed 10 May 2021). [↑](#endnote-ref-29)
30. Equality, Diversity and Inclusion in Pharmacology (2020). British Pharmacological Society. Available online at: <https://www.bps.ac.uk/about/our-campaigns/equality,-diversity-inclusion-in-pharmacology> (last accessed 10 May 2021). [↑](#endnote-ref-30)
31. International Women's Day: Celebration and challenge. (2021). British Pharmacological Society. Available online at: <https://www.bps.ac.uk/news-events/news/articles/2021/international-women-s-day-celebration-and-challen> (last accessed 10 May 2021). [↑](#endnote-ref-31)
32. Without Charities. (2020) AMRC. Available online at: <https://www.amrc.org.uk/without-charities> (last accessed 24 May 2021) [↑](#endnote-ref-32)
33. Reproductive health: what women say. (2018). Public Health England. Available online at: <https://www.gov.uk/government/publications/reproductive-health-what-women-say> (last accessed 24 May 2021) [↑](#endnote-ref-33)
34. Franconi F. et al (2007) Gender differences in drug response. Pharmacology Research 55 (2):81-95. Available online at: <https://doi.org/10.1016/j.phrs.2006.11.001> [↑](#endnote-ref-34)
35. Woitowich, N.C., et al (2020). A 10-year follow-up study of sex inclusion in the biological sciences. eLife 9: e56344. Available online at: [10.7554/eLife.56344](https://dx.doi.org/10.7554%2FeLife.56344) [↑](#endnote-ref-35)
36. Docherty, J.R., et al (2019), Sex: A change in our guidelines to authors to ensure that this is no longer an ignored experimental variable. Br J Pharmacol, 176: 4081-4086. Available online at: <https://doi.org/10.1111/bph.14761> [↑](#endnote-ref-36)
37. Questions and Answers: Risk of next-morning impairment after use of insomnia drugs; FDA requires lower recommended doses for certain drugs containing zolpidem (Ambien, Ambien CR, Edluar, and Zolpimist). (2018) FDA. Available online at: <https://www.fda.gov/drugs/drug-safety-and-availability/questions-and-answers-risk-next-morning-impairment-after-use-insomnia-drugs-fda-requires-lower#:~:text=in%20treating%20insomnia%3F-,A.,release%20products%20(Ambien%20CR)> (last accessed 10 May 2021). [↑](#endnote-ref-37)
38. Avery, E. & Clark, J. (2016) Sex-related reporting in randomised controlled trials in medical journals. 388(10062):2839-2840. Available online at: <https://doi.org/10.1016/S0140-6736(16)32393-5> [↑](#endnote-ref-38)
39. Ginsburg, O. & Horton, R. (2020) A *Lancet* Commission on women and cancer. 396(10243):11-13. Available online at: <https://doi.org/10.1016/S0140-6736(20)31479-3> [↑](#endnote-ref-39)
40. Mehran, R. et al (2019). *The Lancet* Commission on women and cardiovascular disease: time for a shift in women's health. 393(10175):967-968. Available online at: <https://doi.org/10.1016/S0140-6736(19)30315-0> [↑](#endnote-ref-40)
41. Kim, J.h. & Scialli, A.R. (2011). *Toxicological Sciences*. 122(1):1–6. Available online at: <https://doi.org/10.1093/toxsci/kfr088> [↑](#endnote-ref-41)
42. Weld E., Bailey, T, Waitt, C. Ethical issues in therapeutic use and research in pregnant and breastfeeding women. *Authorea.* March 25, 2021. Available online at: <https://doi.org/10.22541/au.161668217.75464337/v1> [↑](#endnote-ref-42)
43. Nooney, J. et al (2021) Assuring Access to Safe Medicines in Pregnancy and Breastfeeding. Clinical Pharmacology & Therapeutics. doi: 10.1002/cpt.2212. Available online ahead of print: <https://ascpt.onlinelibrary.wiley.com/doi/epdf/10.1002/cpt.2212> [↑](#endnote-ref-43)
44. New partnership pledges clear and consistent evidence-based guidance on medicines for pregnant and breastfeeding women. (2021) UK Government. Available online at: <https://www.gov.uk/government/news/new-partnership-pledges-clear-and-consistent-evidence-based-guidance-on-medicines-for-pregnant-and-breastfeeding-women--2> (last accessed 4 March 2021) [↑](#endnote-ref-44)
45. Recommendations related to contraception and pregnancy testing in clinical trials. (2015) HMA. Available online at: <https://www.hma.eu/fileadmin/dateien/Human_Medicines/01-About_HMA/Working_Groups/CTFG/2014_09_HMA_CTFG_Contraception.pdf?fbclid=IwAR3AY5Ha0ESDyqIBeUaYI9VTFWmx9bbt8NZ-80N-5ME6pkBb1UHvFsTwqlQ> [↑](#endnote-ref-45)
46. Stewart, J. et al (2016). [Ther Innov Regul Sci.](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4766962/) 50(2): 155–168. Available online at: [0.1177/2168479015608415](https://dx.doi.org/10.1177%2F2168479015608415) [↑](#endnote-ref-46)
47. Clinical Trials Policy. Wellcome. Available online at: <https://wellcome.org/grant-funding/guidance/clinical-trials-policy> (Last accessed 4 March 2021) [↑](#endnote-ref-47)
48. Improving inclusion of under-served groups in clinical research: Guidance from INCLUDE project. National Institute for Health Research. Available online at:

    <https://www.nihr.ac.uk/documents/improving-inclusion-of-under-served-groups-in-clinical-research-guidance-from-include-project/25435> (Last accessed 4 March 2021) [↑](#endnote-ref-48)
49. Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrolment Practices, and Trial Design Guidance for Industry. FDA-2019-D-1264. FDA. Available online at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial> (Last accessed 4 March 2021) [↑](#endnote-ref-49)
50. Editorial: Accounting for sex and gender makes for better science. (2020) Nature. Available online at: <https://www.nature.com/articles/d41586-020-03459-y> (Last accessed 4 March 2021). [↑](#endnote-ref-50)
51. Patient registries. European Medicines Agency. Available online at: <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/patient-registries> (last accessed 10 May 2021). [↑](#endnote-ref-51)