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The patients missing from clinical research

Clinical studies do not always accurately reflect the people who will ultimately receive new treatments. Researchers across Europe are exploring how to close the gaps and make clinical research more representative and inclusive.

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Women are more likely to die after a heart attack than men. After menopause, they face a similar or greater risk of having one than men with similar levels of coronary artery disease. Yet, despite being one of the leading causes of death among women, heart disease remains widely seen as a male problem.

"Decades of male-focused studies, combined with lower awareness of heart attack symptoms in women, have contributed to the poorer outcomes we see today," said Karen Padilla, who leads the Women & Heart Patient Network at the Global Heart Hub, the first global umbrella organisation for cardiovascular patient groups.

Clinical studies test medicines, treatments and ways of delivering care. But their findings can only tell us about the people who take part. Women have historically been underrepresented in clinical trials for several reasons: concerns about harm to unborn children often led to women of childbearing age being excluded; caring responsibilities could make participation difficult; and researchers long assumed that findings in men would apply equally to women.

The Global Heart Hub is part of an EU-wide effort to make clinical research more inclusive. The READI project is looking at the barriers that prevent some people (women, people with disabilities, ethnic minorities, rural communities and older adults) from accessing and participating in clinical research and what can be done to make it easier for them to take part and stay involved. The project is supported by the Innovative Health Initiative (IHI), a public-private partnership under the EU's Horizon Europe research programme.

The problem with the "typical patient"

While awareness of research bias started emerging in the 1990s, the issue has received growing attention in recent years. Under Horizon Europe, researchers are now expected to consider how bias may influence health outcomes and to ensure studies better reflect the populations they set out to serve.

Yet gaps remain. Women accounted for just 41% of participants in cardiovascular clinical trials between 2017 and 2023. Also, clinical trials commonly run tests on populations of people aged under 75, although many patients in real life get sick at a later life stage.

Part of the problem is that heart disease was long regarded as a predominantly male issue, partly because men tend to experience heart attacks at younger ages. That helped shape the classic symptoms taught to doctors: chest pain or pressure, sometimes spreading to the left arm or jaw, together with sweating and shortness of breath.

Women can experience these symptoms too. But they may also have nausea, unusual fatigue, dizziness or upper back pain – symptoms that can be mistaken for less serious conditions or anxiety.

"We need more women-focused research to close the knowledge gap around how heart attacks present in women," said Padilla. "The hope is that as evidence grows, healthcare professionals will better understand sex differences in cardiovascular disease and improve both the recognition of heart attacks and their treatment in emergency departments. Ultimately, that will save lives."

Beyond women's health

Women are not the only people who may be missing from clinical research. People from racial and ethnic groups historically excluded from research, those living in rural areas, older adults, people with disabilities and other underserved groups can also face barriers to taking part.

A study site may be difficult to reach. Information about a trial may be hard to understand. Appointments may be impossible to fit around work, caring responsibilities or health conditions.

"These factors can leave important gaps in our understanding of how different treatments, medicines and healthcare approaches work across diverse patient populations," said Dr Alberto Borobia, head of Clinical Pharmacology at Hospital Universitario La Paz in Madrid and coordinator of the READI project.

"As a result, some of the very people who stand to benefit most from advances in medicine are less likely to be represented in the research that underpins them."

Borobia points to a recent heart failure trial in which the average participant was 67 years old and more than 60% were male.

"In Spain, and many other European countries, the average heart failure patient is closer to 87 years old and around 55% are female," he said. "As a result, approved medicines may lack robust evidence on safety and efficacy in the patients most likely to receive them, particularly elderly people and women."

People with multiple long-term conditions can also be excluded, leaving doctors with less evidence about how a treatment works alongside other medicines.

Bringing research closer to patients

The researchers working on READI are looking across the research process, from how studies are designed and advertised to how people are supported once they have joined.

“We’re aiming for truly representative clinical research and healthcare throughout Europe, and hopefully beyond,” said Borobia. “Without fair representation in clinical research, it’s difficult to generate evidence that truly reflects patients’ needs.”

A key question is how to make research easier to access. A lack of trust in healthcare systems and simple lack of awareness that studies are looking for participants can discourage people from taking part.

Engaging communities locally is therefore important. Researchers need to understand how to improve the representativeness of participation, while patients, carers and family doctors need clear information about what taking part involves.

Family doctors can play a useful role by identifying potential participants, explaining research opportunities and directing people to study sites, Borobia explained.

The researchers are also developing tools and training, and bringing together patients, healthcare professionals, patient organisations, researchers, pharmaceutical companies, health technology assessment bodies and regulators to tackle barriers to participation.

One of the tools under development is an open, patient-centred digital platform where people can find information about clinical studies, learn about inclusive research and connect with patient communities.

Putting inclusion to the test

Now, the researchers are taking their ideas out into the real world. Working with 88 partners across 20 countries, they will test their approach in clinical studies and pilot settings to see whether these approaches can improve the representativeness of participation in clinical studies.

Dr Juliette Guillot from the pharmaceutical company Novartis and READI’s project lead said there has been a significant shift in mindset among researchers, pharmaceutical companies and regulators in recent years.

“If a drug reaches market and unexpected adverse events emerge because certain populations were under-represented in trials, no one benefits.”

Where previously certain groups, such as women, were often excluded because the perceived risk was too high, the new approach is to put appropriate safeguards in place, assess the risks properly and make inclusion the starting point of research, she explained.

Guillot, who has worked in global drug development for more than two decades, said the shift is not limited to gender. Age is also becoming a more important consideration.

“Definitions around age are changing. People are living longer and staying healthy for longer, so clinical studies must evolve to reflect the populations they are designed to serve,” she said.

For the researchers involved, progress will ultimately mean more than enrolling a wider range of people in clinical studies. It will mean generating medical evidence that better reflects the patients who may one day rely on the medicines and treatments being tested.

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More info

- READI (CORDIS)
- READI project website
- Gender equality in research and innovation
- EU support for research and innovation in women's health
- Innovative Health Initiative
- Women & Heart Patient Network