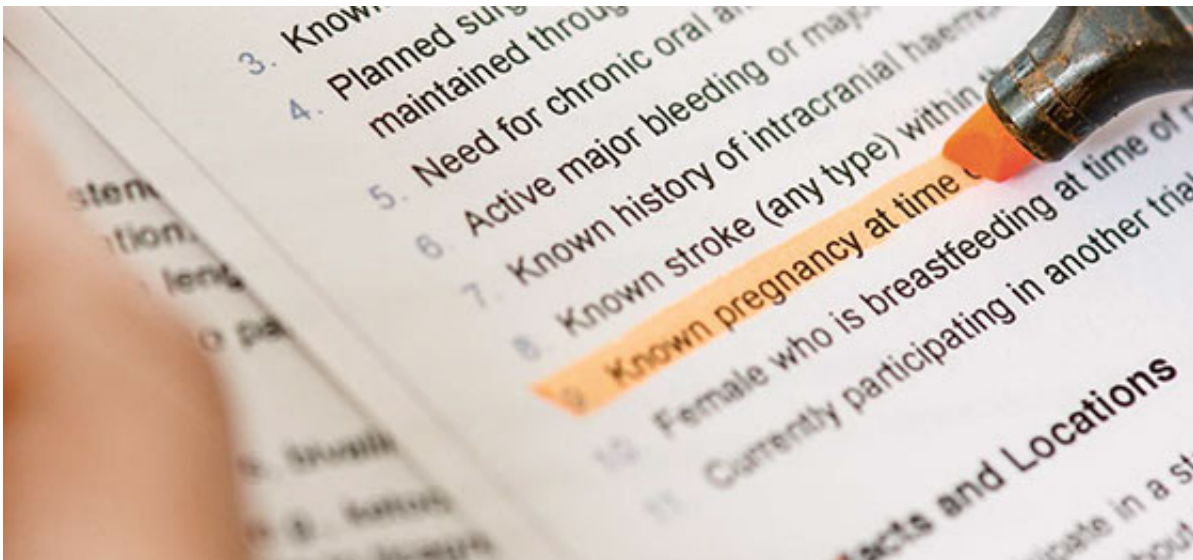


Dangerous generalisations in medical research

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Credit: Swiss National Science Foundation

Drugs are taboo during pregnancy. That's the guiding principle. But the reality is different. According to an international study that was published in 2014 in the *British Medical Journal*, 80 percent of all women take drugs during pregnancy. So it's all the more important for medical personnel to know which substances could be dangerous to the unborn child, and which are safe. But pregnant women are often excluded from medical studies because no one is prepared to take a deliberate risk with the health of the foetus.

Although no one denies the fact that women and men are fundamentally different, medical researchers still generally test their new drugs and therapies on men. It's simply assumed that they will have the same impact on women. But that's by no means always the case.

The metabolisms of men and women sometimes process drugs differently. The female liver contains certain other enzymes that can ensure that drugs work (or not). Furthermore, drugs are distributed differently in a woman's body. Women are mostly smaller than men, and have a higher proportion of fatty tissue. Certain drugs collect there, which again has an impact on their effectiveness. Then there's the female kidney, which only performs to 80 percent of the capacity of the male kidney. This fact naturally has an impact on how metabolites are excreted from the body. And this is all without taking women's menstrual cycle into consideration.

Reactions to the Thalidomide scandal

The situation with children is at least as difficult. Like women, they are barely taken into account in medical research. Researchers only develop very few drugs specifically for them. But when it comes to drugs and therapies, children are not merely small adults for whom one can simply reduce the dose according to their weight. And paediatric medicine covers a vast range of ages: you can't compare new-born babies with school-age children, any more than you can compare young people in puberty with toddlers.

Various initiatives have been set up in Switzerland that hope to change this untenable state of affairs. Alice Panchaud is a pharmacologist at the University Hospital in Lausanne (CHUV) and is investigating methods to help find non-hazardous drugs for [pregnant women](#). There was little awareness of this topic until the 1960s, when the Thalidomide scandal happened. Children were born with deformed arms and legs after their

mothers took the sedative Thalidomide to help mitigate morning sickness during pregnancy. Since that scandal, everything has been done to try and keep pregnant women from taking any drugs at all.

"Regrettably, that isn't realistic", says Panchaud, who is currently on a two-year research visit to the Harvard School of Public Health. There are diseases that you simply have to treat during pregnancy because they would be more dangerous for the [unborn child](#) than any drugs used to treat them.

Collecting data on individual cases

Even if pregnant women don't take part in clinical trials, there are still two ways of getting usable data about them. Time and again there are cases of women taking drugs without being aware that they are pregnant. Then there are women who for medical reasons are compelled to take certain substances. "We urgently have to collect and analyse the data of these two groups", says Panchaud. In this manner, a database could be constructed, listing drugs that are harmless to pregnant women. The rule of thumb is: wherever possible, no new drugs should be given to a pregnant woman, because we just don't know enough about them.

In the USA and northern Europe, good progress is being made on just such databases. In Switzerland, however, too little effort is being invested, and the situation is made more difficult by the far more modest amounts of data available. It's not just about determining whether a [drug](#) is harmless to pregnant women. The permissible dose can also often vary during pregnancy. Women gain weight and retain more water in their bodies, which mostly means that doctors have to increase their dosage. And for this, too, doctors ought to have the relevant data to help them make the right decision in individual cases. So at the CHUV in Lausanne, the relevant authorities are now setting up a biobank with blood samples of pregnant women who are being given drugs.

Children have different cancers

Efforts are also being made to improve the situation with children. The research network Swiss Pednet, which links the Swiss children's hospitals, is campaigning for the development of more drugs and therapies specifically for children. The dilemma is similar to that with pregnant women. No one wants to test drugs on healthy children, but at the same time there are many situations in which children need drugs. "We don't want to subject sick children to experiments", says David Nadal, Head of the Division of Infectious Diseases at the Zurich Children's Hospital and co-founder of Swiss Pednet. That is why a professional research structure is needed in paediatrics, along with the corresponding finances to enable researchers to collect and analyse data. "Society has to increase its awareness of just how important [medical studies](#) are in general, and especially for children", says Nadal. Today, already more than 80 percent of children hospitalised with cancer are being treated within the framework of such studies. Especially in the case of cancer, there is a great need for [new drugs](#) that can specifically help children, because they usually fall sick from cancers that are different from those that affect adults.

Thanks to the initiative of various researchers, it has been proven in recent years that there is a clear gender difference in cases of heart disease. "Women die of heart attacks twice as often as men", says Catherine Gebhard, a cardiologist at the Zurich University Hospital. And if they withstand an actual heart attack, they also have less chances of surviving afterwards. Nevertheless, only 24 percent of the test subjects in heart studies are female, and older women are barely represented at all, even though it has meanwhile become clear that male and female hearts develop differently in old age.

"We still know far too little about why women die more often than men after a heart attack", says Gebhard. The problems begin already at the

lowest level. Tests on lab animals are carried out in advance of clinical studies on humans, but almost all the lab animals used are male. The assumption is that the results will also be valid for female animals. Gebhard is now running a research project in which she hopes to find out why women's hearts age differently. In the near future, women with heart disease should be able to get targeted medical help just the same as pregnant women and [children](#).

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