Inclusive innovation
A MEDTECH HANDBOOK
Welcome!

This guide has the potential to take you on a mental journey. It contains examples and references that can trigger an entire world of new thoughts. It also has the potential to contribute to more precise, relevant, and powerful medical device innovation. It will hopefully lead you to new target groups, to more attractive work environments and ultimately to more efficient and equal healthcare. In other words, this guide may lead you to more inclusive innovation.
What is inclusive innovation?

By inclusive innovation we mean the ability to challenge and reshape norms to better develop existing - or to design new - medical device products and services.

This guide is primarily for you working within research, development, innovation in the Life Sciences in general, and within the medical device sector specifically. Anyone is of course more than welcome to the material, whether you’re a patient, a healthcare professional, or simply curious.

The medical device sector has great potential to deliver solutions that can help us meet several of our major future societal challenges. Research shows, however, that the ability to innovate is hampered by prejudice and traditional, preconceived notions. This may be due to failure to truly understand the real needs of the user. To improve this understanding, we need to have sufficient knowledge about the potential target group or and to become more knowledgeable about gender equality and diversity.

Moreover, medical device companies can benefit by having an organization that reflects society. Inclusion and gender equality not only improve the potential to identify new target groups for an innovative diagnostic, treatment or monitoring device or service, but also lead to more optimal and precise solutions, as well as to increased competitive advantages.

To achieve all this, we first need to understand what is meant by inclusion and gender equality. Which are the prevailing norms in our sector, and which tools and strategies are necessary to understand, challenge and reshape these norms? In this way, we can create medical device innovations that include more people [1].

A first step is to understand how norm criticism can help us to identify and minimize the risk of excluding groups or individuals. When we understand and acknowledge how we create and re-create norms, we can use this as a tool to work in new ways and achieve new results. It can however be hard to question things that we take for granted. Perhaps especially in healthcare development where it can feel like risking patient safety to test novel, potentially better, approaches and to question routines. Despite efforts to reduce it there are numerous health disparities today between different socioeconomic groups and gender health disparities in Swedish healthcare. Thus, everything we can do to highlight and remove inequalities will take us towards a more equal, fair and above all safer healthcare for more people.
Key concepts and definitions

What is equality?
Equality means that all people have equal rights, value and opportunities.

What is gender equality?
Gender equality refers to equal rights, value and opportunities regardless of gender.

What are norms?
A norm is an unwritten rule that reflects the “normal”, considered to be the more common, or accepted behavior of a social group. It is something we learn as part of our upbringing and influences the way we use language, the way we live and the way we work. Norms form the bases of how we view the world around us. They can be classified as legal, economic, moral, aesthetic, technical and they can also appear different depending on whether we are in the workplace or with family and friends. They can be hidden - based on unspoken premises and expressed as stereotypical assertions about, for example, ethnicities, femininity, and masculinity. If a norm becomes part of one’s own morality, we can say that the norm has been internalized. Norms may facilitate interaction between people but can also be limiting and act excluding. The norms that exist in society in general spill over into healthcare and influence interactions and expectations between patient and caregiver. These norms are the ones we want to identify and broaden so that more people can feel included.

What is gender?
Gender is a social construction largely based on the social and cultural attributes of the sexes; what is understood as feminine or masculine. Taking a gender perspective on medical device innovation means looking at why there are gender differences in healthcare. What norms and choices come into play? How can we change the conditions to create more inclusive and equal health and social care?

What is discrimination?
Discrimination, i.e., the unjust or prejudicial treatment of different categories of people, is illegal in healthcare, which means that hospitals and health centers should not discriminate against their patients. For unfair treatment to constitute discrimination under the Discrimination Act, it must be linked to one of the seven forms of discrimination: sex, transgender identity or expression, ethnicity, religion or belief, disability, sexual orientation, or age.
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In search of the unwritten rules in healthcare

Improved medical devices such as diagnostics, treatment methods and assistive devices have enabled more patients to be treated, cured and live better and more independent lives.

At the same time, society does not have infinite resources, as there is not enough money for all the care that could be possible. Therefore, we must choose how healthcare resources are best used by prioritizing. Seriously - and acutely - ill patients, for example, must be treated prior to the less ill patients. Prioritization must be based on the Health and Medical Care Act, (Hälso- och sjukvårdslagen) which states that healthcare should be provided on equal terms and that those most in need of care should receive it first*.

However, patients are not treated equally in today’s healthcare. Inequalities are seen for people who are economically vulnerable, for people who are violating prevailing norms, such as transgender people, homosexuals or for people who do not know the Swedish language. It is even possible to detect differences in healthcare provision depending on the level of education and age.

For example, women with a lower level of education are less likely to survive breast cancer than women with a higher-level education [2]. Elderly with lower levels of education have higher risk to be treated with older medicines or unsafe drug combinations than elderly with higher levels of education. The National Board of Health and Welfare (Socialstyrelsen) has seen trends indicating that people with low education as well as unemployed people experience poorer treatment in care [3]. Among other things, healthcare providers address lifestyle habits more with these patients, which may be based on cognitive biases (unconscious preconceptions) and prejudices.

To ensure equality in today’s health and social care, we must constantly challenge prevailing norms and our own preconceptions. It may feel risky to challenge norms in an area where patient safety is always a priority, where the primary goal is to contribute to a patient’s health and, where possible, to cure, often to relieve and always to comfort. But if we do not challenge norms, we risk missing the individuals or groups who are excluded when they do not meet our expectations. And this exclusion is in itself also unsafe.
Gender norms and gender inequalities in care

One way to approach a norm critical method of innovation is to start from the seven forms of discrimination. All seven will be introduced, but one of them, which will be addressed here, is sex. Women and men are both the same and different. Often, a certain treatment may have the same result for women as for men, but in some respects the outcomes may differ.

For example, unequal care can occur when women are treated according to guidelines based on research carried out only on men. Or when medical doctors prescribe anti-depressants more often to women than to men [4]. Inequalities in care is detected by analyzing the care itself. Also, patients’ experiences and outcomes of care based on sex and our notions of sex (gender) are important indicators. Together, the experiences, outcomes and notions form a gender equality perspective on health and social care, which means that women and men at a group level should have the same rights, be assessed on an equal basis, and have the same power to influence their care.

From a gender perspective, the “macho” norm may be interesting to mention. Men as a group more often die of diseases because they wait too long before first seeking healthcare. This is related to the social expectation on men to not complain or ask for help – to “take it like a man”. In contrast, women have been known to receive worse treatment following heart attacks than men, which might also be multifactorial, including for expressing their complaints in any manners, “diffusely, complaining on many things” [5].
Examples of gender inequalities in Swedish healthcare [6]

- Research shows that women are twice as likely as men to claim to have been violated in a care setting.
- Women suffer to a greater extent by healthcare associated injuries.
- According to the national general vaccination program for children, HPV vaccine should be given to girls, even though it is now known that HPV infections can be linked to several cancers that affect both women and men.
- When diagnosing asthma and chronic obstructive lung disease, women are to lesser extent than men diagnosed using methods recommended in the national guidelines.
- Women with Alzheimer’s disease receive three hours less home care per week than men in the same situation.
- In the treatment of kidney failure, men more often have access to newer dialysis technology than women.
- Women, people born outside the Nordic countries, people with lower incomes and people without university level education have longer waiting times than others for cataract surgery.
- Women with knee osteoarthritis, hip osteoarthritis and spinal stenosis have more symptoms and greater functional impairment than men at the time of surgery.
Norms to be aware of

The HETEROSEXUAL NORM assumes that everyone is heterosexual, and that heterosexuality is the natural way to be. The norm can be summed up simply as men being expected to desire and form romantic and sexual relationships with women, and vice versa. Often this is not a problem, but for those who do not lead a heterosexual life it can mean poorer treatment and care [7, 8, 9].

The CIS NORM assumes that everyone has a defined gender that they are born with, are comfortable with and do not want to change. Medically, it may mean that we are unprepared for people who have a biological body (sex hormones, chromosomes, genitalia) that may fall outside or between the categories of male and female, or who challenge our expectations through their choice of preferred names or gender expression. For example, the preconceptions of health care providers may influence the questions asked to patients and the way in which their complaints are assessed [7, 8].

FUNCTIONAL NORMS are norms that speak specifically to which functional variation(s) are normative in society. In medical terms, this may mean that everyone is expected to be neurotypical and we are unprepared for different reactions or behavior [8].

The MALE NORM means that the male is seen as the neutral, the starting point, the norm that others must conform to. Medically, it may mean that we miss symptoms of heart attack in women or autism in girls because the research that sets the norm for how symptoms of these illnesses are described has been carried out on men and boys [8].

The WHITE NORM is a global phenomenon that assumes people are normally white or have light skin. Medically, it may mean that people with dark skin are misdiagnosed because medical doctors have not been taught to assess dark skin, or that technological innovations being developed are only reliable on lighter skin [10].

For example, on 1177 (the Swedish national service providing healthcare by phone and online) there is a growing awareness of the white norm, and more examples and pictures now address how, for example, skin rashes manifest themselves on different colors of skin.
Examples of the consequences of norms

Regularly being treated ill might lead to an expectation of poor-treatment, with chronic stress and poor health as a result. This is called minority stress and happens when people who deviate from the norm are constantly confronted with prejudice and negative expectations. Psychologist Hanna Wallensteen describes minority stress as an experience of not being seen as equal. Being exposed to prolonged negative stress increases the risk for several diseases. It is a drain on health, both physically and psychologically, to constantly be prepared to meet prejudice [11].

In the thesis “Alla utgick från att man var hetero” (“Everyone assumed you were straight”), gay women are interviewed about being treated in healthcare and how the heteronormative assumptions of the healthcare staff affected them. The informants talked about how they were constantly questioning whether they should “come out”, calculating whether they could cope, as well as assessing the risk of receiving a negative reaction [9].

Ethical principles

There are ethical principles in Swedish healthcare management. These are priorities in the healthcare sector based on a set of values adopted by the Swedish Riksdag (Parliament) [12]. The core values include three principles:

✚ The Principle of Human Dignity recognizes that all people are of equal worth and have the same right to receive care, regardless of age, gender, education, social or economic status.

✚ The Principle of Need and Solidarity prescribes those resources should be awarded to the patient most in need of them, but also that health care providers should pay special attention to individuals from vulnerable groups, such as those who cannot speak for themselves and who do not know their rights.

✚ The Principle of Cost-Effectiveness entails a reasonable relationship between the cost and the effectiveness of treatment. For example, if two different treatments have the same effect, the one that costs less should be chosen.

In accordance with the Swedish Government’s resolution, the three principles are ranked so that the Principle of Human Dignity takes precedence over the Principle of Need and Solidarity, which in turn takes precedence over the Principle of Cost-Effectiveness.

The Swedish Medical Association has also adopted a code of ethics consisting of nineteen points dealing with fundamental values in medical ethics. These principles are intended to guide these professionals and to promote a good patient-doctor relationship [13].
Social norms in medical device innovation

In the field of biomedical engineering and in the development of medical devices, norms may relate to health care professions, care processes, methods, target and focus groups, patient populations, research hierarchies, etc.

These norms can affect the recruiting process in medical device companies and which profiles they seek, how the innovation ecosystems enable or restrict the development of certain types of innovations and companies, how symptoms sometimes emanate from a male perspective, or how innovation models support certain types of innovations and innovators. But it also concerns the way people are regarded and treated, be it within a developing team, a team of care professionals or as a patient.

When we fail to include more perspectives than the norms generally “allow”, we risk preserving imbalances in power between different groups. The products and services we develop, or implement can be directly or indirectly discriminatory and can ultimately lead to malpractice or people falling ill.

The sooner in a development or implementation process we think critically about norms, the quicker we turn away from ideas and approaches that do not benefit the many, or that risk leading to exclusion, albeit unintentional. For instance, we can avoid outcomes such as a voice service that can’t decipher women’s voices or certain dialects, or a sensor in a soap pump that can only detect light skin.

Regardless of how diverse a team is, or how important gender equality and other inclusive perspectives are in the development or implementation process of a product or service, there are great benefits to working more inclusively and we will highlight some of them here.
Economic aspect

There is, of course, an economic aspect to increased inclusion, diversity, and equality. Companies that are gender equal have been shown to be more profitable in many studies conducted on tens of thousands of companies around the world [14, 15, 16]. At the same time, a survey by Informa Connect Life Sciences [17] of employees in the life sciences sector shows that:

- 34% see the lack of minorities in leadership positions as the biggest problem in diversity and inclusion.
- 63% feel that women are underrepresented in most senior roles in their own organization.
- 41% say they have experienced prejudice or exclusion based on gender, sexual orientation, ethnicity, or other factors.
How to achieve norm creativity and inclusion

Norms are the invisible rules that we all follow without perhaps thinking about it.

Norms are essential for us to feel safe in our interactions with others because they give us a preliminary understanding of what is expected in different situations. But it is also because of norms that some people are at risk of being excluded in society and in healthcare.

What is norm criticism?

Norm criticism means becoming aware of how norms work and when someone is at risk of exclusion because of rooted norms. Thinking critically about norms is not about identifying those who deviate or challenge the norm, but about looking at the norm itself and how it works. By exploring norms and trying to reverse concepts, we can gain insights and broaden our horizons, finding even better solutions.

What is norm critical innovation?

Norm criticism can also help us to identify norms in our innovation process and increase our innovation capacity. Working in a norm critical way in an innovation process is about reversing and widening perspectives, approaching issues differently to identify and develop smarter solutions. The way we view customers or target groups, who we involve in the innovation process, whose voices are heard in meetings, and whose ideas are considered worth taking forward, are all actions that may include or exclude groups and ideas.

What is norm creative innovation?

But we need to move on from analysis to action in order to become norm-creative. If norm-critical processes are about making norms visible and analysing them, norm-creativity is about actively breaking those norms – doing things in a more inclusive way based on what we have learned from norm-critical analysis. If we look at the bigger picture, when we have a more comprehensive basis for decision-making based on greater understanding of norms and differences, we can adapt, challenge and broaden the norm so that our innovation suits more people. When we succeed, we create better, more innovative and more inclusive solutions, products and services. [15]
Tools for inclusive medical device innovation

The medical device and healthcare sectors are innovative and growing, but there are certain factors complicating our path to successful development and implementation.

The closer a developed medical device or service is the commercialization phase, the harder it may be to include the patient perspective. In the worst case, we might end up with a product that is of use to everyone except the patient. Sometimes we don’t even reach the patient, as some patients are completely missing in reference groups for innovations. Patients are also rarely represented at trade fairs and the like, so we need to actively seek out our target groups to get the relevant people involved through the entire innovation process.

We will now review different tools to enable a more inclusive medical device product, service or innovation process:

✚ Norm creativity in the form of micro actions
✚ Bring more perspectives into your innovation process
✚ Ensure inclusive conversations
✚ Roundtable discussions

✚ Norm creativity in the form of micro-actions

When you start your norm-creativity work, the possibilities can sometimes seem overwhelming. As you begin to identify your blind spots, you may feel that you are challenging too many truths and breaking the norms may seem insurmountable. It can be comforting then to remember that there is a learning curve and that you at least have started a process of inclusion. Much can be done, but it all starts with a first step: insight.

Do not underestimate the small decisions, the so-called micro-actions. They can make a big difference. As an example: The heterosexual norm is strong - a micro-action in healthcare or with people in focus groups can be to use the preferred pronoun and the same terms that an individual uses for his or her life partner, such as cohabitant, partner, or spouse. Otherwise, if you assume that the person has a certain sexual orientation, you may put them in a situation where they must choose to conform, come out, or where they feel excluded. Start by trying to not assume that a person you meet is married, heterosexual and living in accordance with their assigned gender.

And remember: if you make mistakes, you will learn a lot; daring to try is always better than hesitating!
Bring more perspectives into your innovation process

In the innovation process, relevant feedback on a proposed solution can be crucial. We can assure this by for instance including participants with varying levels of expertise to help us break established patterns, to prompt more and different questions, and to challenge norms about how patients are cared for. We can for example invite people from other sectors, perhaps even those who have never worked in healthcare. We can ask people who are not using the product or service in question. Why don’t they use the product? What would it take for them to consider using it? Learning about attitudes towards a product or service can influence your development process. Be curious and not too quick to judge others’ views as irrelevant. Try testing the product on the user at an early stage of development. There are several stakeholder groups to learn and collect information from, but also different ways to bring in different perspectives.

Healthcare professions are key when it comes to identifying and testing medical device innovations. They often identify problems or needs in their work and may even have ideas for solutions themselves. It is important to have processes in place to allow them to reflect on their problems and needs, processes to capture these needs and ideas, and processes that allow healthcare personnel to be involved in developing and testing their and other’s ideas.

An important stakeholder group is, of course, the patients. By listening to patients’ stories, we can identify needs that can form the basis for new solutions. A patient’s experience is not limited to a healthcare visit, but rather starts long before the visit and continues afterwards. Thus, we can uncover needs not visible within the healthcare system. If we look at the whole experience “before-during-after” from the perspective of norms, we can discover needs to build solutions upon.

Patient associations and interest groups often provide valuable information. How can they become more involved? Can you work with patient representatives in reference and focus groups, steering committees, or boards? Remember to appreciate their contribution, such as time spent consulting, and find a way of working that adds value for the representative as well.
If an innovation is to successfully include the target groups, then by necessity the processes leading up to the final product or service must be inclusive. If you have endeavored to create a diverse and norm-breaking working group, development group or team, i.e., participants have been actively selected because they challenge norms in healthcare or in target groups, then it is also important to ensure an inclusive dialogue. Language, terminology, and culture will differ between participants – as it differs between professions and disciplines, patient groups and other stakeholders.

In the work of the Inclusive Innovation project, we thus chose to develop four principles for inclusive conversations:

✚ We enter the conversation with an open mind, a willingness to learn and an expectation of breaking ingrained thought patterns.

✚ We reflect on our own position in the group and recognize that everyone’s voice is equally important in a discussion; we all help to put a stop to disrespectful discussions.

✚ Our goal is to include all representatives from all target groups, providing them with an opportunity to express themselves and contribute to the innovation process. Therefore, we encourage differences in opinions, we speak plainly and explain relevant concepts so that everyone understands.

✚ By following certain formalities, such as waiting for you turn to speak, allowing everyone a chance to speak and keeping the discussion factual. Together we create an innovative and relaxed environment that fosters an inclusive conversation.

Some people may find it obvious and unnecessary to agree on common principles of conversation before a meeting, while others find it easier to agree in writing on how conversations should be conducted. This is perhaps especially important for teams with participants of different backgrounds, assignments, and motives. During the project, we found that the principles of inclusive conversations have been a success factor, which is why we share them here.

The most important thing is not to let hierarchies and status affect and hinder the purpose: to bring forth more and wider perspectives for improved innovation.
**Roundtable discussions**

A roundtable discussion is a method where all participants are given the same status and where everyone’s voice is equally important. The method can be used in various settings to resolve dilemmas and have constructive discussions. As an example, the material for this guide was collected at several roundtable discussions and is thus a fusion of several voices, opinions, experiences, and backgrounds. In other words, a roundtable is a way of ensuring an open climate in which all participants are given equal time to express their thoughts and opinions and share their experiences and knowledge.

This format is meant to open for a conversation in which participants in a supportive and open atmosphere are permitted to ask questions and learn from others; an appointed chairperson welcomes participants and explains the rules of the conversation, moderators participate in smaller group conversations to take notes if necessary and allocate speaking time, allowing participants to fully focus on the actual conversation.

In addition to the conversation principles outlined earlier, i.e., the rules of the conversation to ensure that all participants can participate on equal terms, it is also important to establish the following, prior to the roundtable:

- What will the participants discuss during the roundtable?
- How can participants ask questions? Should they raise their hands or speak freely?
- What is the goal of the discussion?
- Should the discussion be summarized and if so, how?

Additionally, think about the timing and format of the roundtable when planning. Do you need to provide visual and auditory interpretation, check accessibility, etc.? Remind participants that everyone has a shared responsibility to make sure that the conversation is conducted in a respectful manner. All participants should have the opportunity to express themselves and contribute to the outcome. In case of misunderstandings, consider that instead of saying, for example, “You’re wrong!” you can ask “What do you mean?” or “Could you elaborate on that?”.

This kind of conversation is important for identifying and breaking down existing norms about who can speak and when. By keeping a formalized format and, to some extent, a controlled conversation, where the conditions are known beforehand, everyone can have their say, which in turn will lead to constructive and innovative solutions.
Success stories and further reading

Unless otherwise stated, the following material is in Swedish.

Socialstyrelsen (Swedish National Board of Health and Welfare)

The National Board of Health and Welfare’s website provides information on national guidelines in English. However, if you can read Swedish or are prepared to make use of on-line translation software, the site also offers educational materials, reports, and open comparisons. For example, “Samlat stöd för patientsäkerhet” ("The Patient Safety Toolkit") contains information on patient safety and links to manuals, action plans, reports, statistics, training and podcasts, among other things. The website also contains an online training course aimed at increasing LGBTQ people’s confidence in social services, and a glossary of LGBTQ concepts.

www.socialstyrelsen.se

Sveriges Kommuner och Regioner (SKR) (Swedish Association of Local Authorities and Regions)

SKR’s website has several case studies, films, checklists, and other tools for gender equality work in municipalities and regions. Together with its members, SKR develops methods and tools for integrating gender equality into governance, management, and monitoring. Through publications, films, fact sheets and case studies, SKR contributes to increased awareness and knowledge of gender equality challenges and strategies for change. For example, see their checklist for gender sensitive decision making, or learn about the challenges and success factors of local and regional Agenda 2030 work.

www.skr.se

Kunskapscentrum för jämlvik vård (KVJ) (Centre of Knowledge for Equal Care)

KVJ was established in the Västra Götaland Region to ensure that healthcare is provided on equal terms, because people’s needs, and experiences are different, and care is meant to vary to accommodate them. Through research, education, and operational development, KVJ is shaping the conditions for levelling out unwarranted differences. KVJ identifies problems and contributes to solutions by supporting the health sector with tools and training that contribute to working towards equality. They offer tools for equal parenting, reflection tools on gender perspectives, methods for discussions on norms, and methods that contribute to good communication between patients and health professionals.

www.vgregion.se/halsa-och-vard/vardgivarwebben/ammenomraden/jamlik-vard/
Success stories and further reading

Unless otherwise stated, the following material is in Swedish.

Region Stockholm

On the site Janusinfo, Region Stockholm provides a text on gender medicine in which the authors describe the importance of understanding that diseases can be expressed and present differently in women and men. They describe how the analysis of disease and health is very important from a gender perspective to optimize healthcare for both women and men. The authors go on to explain that women are more prone to certain diseases such as MS (multiple sclerosis), depression, migraines, eating disorders and more. Men, on the other hand, are more prone to other diseases such as, for instance, heart attacks, diabetes mellitus, schizophrenia, ADHD, alcoholism and more.

Social and normative factors therefore become very important in understanding why women and men are more likely to develop certain diseases. Behind women’s propensity for eating disorders are society’s fluctuating ideals of beauty that women are expected to live up to. Beauty ideals lead to body dysmorphia which ultimately leads to eating disorders. Underlying a greater propensity for alcoholism may be the existence of masculinity norms in men with certain assumptions about how a man is supposed to live and behave.

https://www.janusinfo.se/beslutsstod/janusmedkonochgenus/janusmedsex-­andgender/inenglish/aboutgendermedicine.5.728c0e316219da8135e7363.html

“Medtronic Is an Example of Why Diversity Matters”

An article (in English) on why diversity is important in medicine. The article describes the motivation of some companies to do more in their work to achieve diversity than just “count heads”. A quote in the article from Sophia Khan explains that broader diversity leads to better decisions as different perspectives highlight different challenges and possible solutions. Looking at different people’s perspectives can ultimately contribute to better solutions, both for patients and for public welfare. [19]

www.mddionline.com/business/medtronic-example-­why-­diversity-­matters
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