Title

The Default Body: How Clinical Trial Exclusions and Medical Device Design Encode Systemic Inequality

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Abstract: Medicine treats the white male body as the norm, harming women and darker-skinned patients. Using Standpoint Theory and Theory of Change, I analyze Ambien dosing, pacemaker complications, pulse oximeter bias, and surgical ergonomics.

INTRODUCTION

Many medical technologies were designed for a specific patient: a young, healthy white man. Over time, that body became the "default." So, when a doctor gives a standard drug dose or trusts a device reading, they may be working with tools built for that one type of body — which fit everyone else a little worse. A clear example is "Reference Man," a model used in radiation protection. ICRP Publication 23 described him as a 20-30-year-old, 70 kg, white man from Western Europe or North America (International Commission on Radiological Protection [ICRP], 1975). Every standard must start with somebody, but that choice ended up shaping what counted as "normal" across all of medicine. This same kind of thinking shaped how drugs and devices were developed. For a long time, women were left out of clinical trials, and policies changed slowly (Institute of Medicine, 2010). That means women and other excluded groups often show up as side categories in research, instead of being part of how "standard" doses and devices were designed in the first place. The harms are not random - they follow a pattern. Heart disease standards can miss women's symptoms (Healy, 1991), and women also face higher pacemaker complication rates (Moore et al., 2019). Pulse oximeters can misread oxygen levels in darker-skinned patients (Sjoding et al., 2020). Some surgical tools are sized for larger hands, which can hurt smaller-handed surgeons (Sutton et al., 2014; Tsumanuma et al., 2024). Using Standpoint Theory, the heteropatriarchal triad, and Theory of Change, this paper asks: whose body became the standard, who gets hurt by that choice, and what would it take to fix it. This work is in partial fulfillment of the ENGR184 course using the blueprint curriculum in Ref [1,2] and captured in a collection [3].

METHODS

In this paper, I treat medical "standards" as design choices made by people and institutions. Instead of assuming bias is accidental, I point to specific research, design, and regulatory choices that lead to specific harms.

First, I use Standpoint Theory. Sandra Harding (1991) argues for "strong objectivity," which means science can become more accurate when it includes the perspectives of people who were left out. Their experiences can reveal assumptions and blind spots that the dominant group might not notice.

Second, I use the heteropatriarchal triad — a framework from class — which focuses on sovereign authority, property, and personhood. I use it to track who makes the rules (regulators), who profits (companies and patents), and whose body gets treated as the "normal patient." When all three point in the same direction, the system keeps treating some bodies as the standard and everyone else as a special case.

Finally, I use Theory of Change to think about solutions at different levels: small fixes, bigger rule changes, and changes that go beyond the current system. I apply this to four cases: Ambien dosing (U.S. Food and Drug Administration [FDA], 2013), cardiovascular care and pacemaker complications (Healy, 1991; Moore et al., 2019), pulse oximeter racial bias (Sjoding et al., 2020), and surgical tool ergonomics (Sutton et al., 2014; Tsumanuma et al., 2024).

RESULTS AND INTERPRETATION

All four cases come back to the same question: whose body was treated as "normal," and what happens when that gets mistaken for everyone?

Case 1: Drug dosing - from Reference Man to Ambien. Drug labels often assume adults process medication in the same way. But metabolism can vary by sex, age, and body size. Because many drugs were tested mostly on men, the "standard dose" tends to work better for men than for everyone else (Institute of Medicine, 2010). Zolpidem (Ambien) shows this clearly. The FDA did not recommend lower doses for women until 2013, after evidence showed women were more likely to be impaired the next morning at the usual dose (FDA, 2013). The FDA required lower recommended doses for women (for example, lowering some immediate-release products from 10 mg to 5 mg) (FDA, 2013). Sex differences were treated like a secondary detail to figure out later, rather than something to build around from the beginning (Institute of Medicine, 2010). It is also worth noting that the harm from Ambien was not discovered through proactive research. It came to light because enough women reported impairment after a full night's sleep that the pattern could no longer be ignored. That is a recurring problem across medicine: harm must accumulate and become visible before anyone asks whether the original design was right.

Case 2: Heart disease and pacemakers - Yentl Syndrome. Cardiologist Bernadine Healy (1991) used "Yentl Syndrome" to describe how women with heart disease are often taken seriously only when they show the same symptoms as men. The issue is that "classic" heart attack symptoms were mostly defined using men in the first place. One reason is that women were underrepresented in the studies that shaped diagnosis and treatment. When the study population does not match who actually gets the treatment, patients end up being tested on without consenting to it (Institute of Medicine, 2010). This shows up in pacemakers too. In a study of more than 81,000 implants, women had higher complication rates within 90 days (8.5% compared to 8.0% in men) and were significantly more likely to need drainage procedures (Moore et al., 2019). These numbers could be written off as "just anatomy," but the pattern also raises a structural question: are devices, tools, and implant techniques optimized around larger bodies and then treated as neutral? Even small percentage differences matter when millions of people rely on these devices.

Case 3: Pulse oximeters and racial bias. Pulse oximeters estimate oxygen levels by shining light through the skin. Accuracy depends on calibration, and many devices were calibrated mostly using light-skinned people. Sjoding et al. (2020) found that when pulse oximetry read 92–96%, occult hypoxemia (arterial oxygen saturation <88%) happened about three times as often in Black patients as in White patients (11.7% vs 3.6% in one hospital cohort). This matters because pulse oximeters are used to decide when to

give treatment, when to escalate care, and who qualifies for certain therapies. If the device says someone is fine when they are not, care can be delayed - which is especially risky in busy ERs or during something like the COVID-19 pandemic. The heteropatriarchal triad helps explain why this problem lasted. Regulators did not require strong performance across skin tones, companies had little incentive to redesign or re-test, and the result is a device that works better for some bodies than others. In practice, darker-skinned patients can become invisible in the data — and invisible to the care they need. The COVID-19 pandemic made this especially visible. As hospitals scrambled to manage surging patient loads, pulse oximeters were used to triage who needed immediate attention and who could wait. The racial bias in those readings was not a coincidence or a minor technical flaw — it was a design choice baked in decades earlier that quietly redistributed risk onto Black patients at exactly the worst moment.

Case 4: Surgical tools. Many operating rooms and instruments were designed around taller surgeons with larger hands. Sutton et al. (2014) found that women surgeons reported high rates of discomfort during laparoscopic operating and were more likely to need treatment for hand problems (wrist, thumb, fingers), which the authors connected to instrument and table design. Other studies show tool design can affect performance, not just comfort. In a randomized crossover trial using a simulator, handle size changed how quickly and accurately participants completed laparoscopic-style tasks (Tsumanuma et al., 2024). A tool that does not fit the person using it can affect both the surgeon's wellbeing and the quality of care the patient receives.

DISCUSSION AND THEORY OF CHANGE

Across all four cases, the pattern is similar: a narrow group was treated as "normal," and everyone else must deal with the mismatch. Women, Black patients, disabled people, and others end up facing higher risk — not because their bodies are inherently more complicated, but because they were not included when the standards were set. Over time, this can also erode trust in healthcare. There are economic and cultural consequences too. Complications and delayed care cost more for patients and hospitals. At the same time, companies can save money by running cheaper, less diverse trials. And when these gaps get framed as neutral science, the burden falls on patients to prove a tool failed them, rather than on institutions to prove it works for everyone. Theory of Change helps me sort possible solutions into levels. Soft reforms are small fixes inside the current system, like updating drug labels after problems are found—for example, the FDA's dose change for Ambien (FDA, 2013)—improving demographic reporting, and training clinicians to watch for known gaps in care (Moore et al., 2019). Radical reforms would change the rules—for example, requiring devices to be tested across skin tones before approval, and making sex- and race-disaggregated data mandatory from the start, not just added after harm is already reported. Beyond those reforms, communities can push back more directly through patient-led research, public registries that track device performance by demographic group, and clear "bias labels" for tools that have not been validated across different populations. For a community engagement project, I would partner with a local clinic or teaching hospital to run a "Device Bias and Dosing Equity Audit." This could produce three outputs: (a) a plain-language handout for patients about pulse oximeter limits and when to ask follow-up questions, (b) a checklist for clinicians doing pacemaker implants in smaller-bodied patients, and (c) a short annual report on known performance gaps in

commonly used devices. Open questions remain: Who gets to say a standard is no longer acceptable? What should the FDA require before approving a device as "universal"? And how can the communities most affected by these gaps have real input in research priorities and procurement decisions?

It is also important to name what these gaps cost culturally. When a patient's pain is underestimated, when their oxygen level is misread, or when their complication is attributed to their anatomy instead of a flawed tool, it sends a message: your body is the problem, not the system. Over time, that message shapes whether people seek care at all. Repeated experiences of being dismissed or mismeasured can build mistrust, especially for communities that have been excluded from research or harmed by the medical system.

This is where Standpoint Theory becomes practically important, not just theoretically interesting. Harding's argument is that knowledge produced without including marginalized standpoints is not neutral — it is incomplete. A pulse oximeter that only works well on light skin is not a "universal device with limitations"; it is a device built for some people and exported to everyone. Naming that difference clearly is the first step toward demanding something better.

CONCLUSIONS

The "default body" in medicine is not just a scientific shortcut — it is the result of choices made by institutions that had the power to include some people and leave others out. From Reference Man to Ambien dosing, from pulse oximeters to pacemakers to surgical tools, the pattern is the same: one type of body got treated as universal, and everyone else ended up with more risk and worse outcomes. Standpoint Theory helps explain why this happens: when your data mostly comes from one group, your "standard" is just that group's experience dressed up as a universal truth. The heteropatriarchal triad helps explain why change is slow: the institutions that set the rules and benefit from them are not the first ones harmed by the gaps.

Fixing this is not only about adding "diversity" later or writing warnings. It means redesigning how standards are built, starting with the bodies most at risk instead of bolting them on after the fact. Harding's idea of strong objectivity actually suggests that medicine designed this way would be more accurate, not less — because it would finally be accountable to the full range of patients it claims to serve.

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