FAIR in Medicine Model Legislation

Electronic Health Records Safety

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Purpose: Legislation is needed to require electronic health record (EHR) software to indicate and clearly display a patient's biological sex at birth (as distinct from the gender, sexuality or other presentation with which they identify) within all the electronic health records (EHR). It is imperative to maintain safety for all patients to utilize clear, unambiguous language regarding biological sex. The purpose is to maintain clarity to avoid errors, not to exclude additional charting when needed to accommodate intersex and transgender individuals.

Problem: There is no longer a standard way to indicate a patient's biological sex in the EHR. Some U.S. health care systems allow transgender identifying patients to register as the gender they identify with instead of as their biological sex at birth resulting in a potential chain of errors throughout medical documentation, including the EHR (Electronic Health Record) software systems. Other systems entirely omit the terms "biological sex" opting instead for templates utilizing gender terminology such as "cis", "sex assigned at birth", "gender identity", and "legal sex" that may be unclear and confusing to diverse users, particularly health care staff, across the country.This lack of clarity may negatively affect clinical care and increase the risk of morbidity and mortality due to medical errors for all patients, including transgender patients.

Solution: Create model legislation to require healthcare systems to 1) record a patient's biological sex at birth alongside their transgender status in the medical record 2) document biological sex clearly for the general user for purposes of upholding medical safety, and 3) prevent unilaterally conflating biological sex (chromosomal) with gender, gender identity or other terminology currently being interchangeably used.

Background: Medical errors are a leading cause of preventable patient harms.[1] Although the exact number is unknown, some 98,000 deaths annually have been attributed to preventable medical errors.[2] In 2000, the Institute of Medicine published a landmark study highlighting the problem of medical errors, their root causes, and potential solutions. Furthermore, the United States government has committed to reducing medical errors through research and education. As part of this 2009 the HITECH ACT mandated healthcare entities to convert to electronic health record systems with the promise of efficiency, cost savings, and improved patient care. The majority of U.S. medical centers now use EHRs, provided by the privately held EPIC

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[1] https://www.ncbi.nlm.nih.gov/books/NBK430763/
[2] https://pubmed.ncbi.nlm.nih.gov/25077248/

Systems and Cisco's Cerner[3]. However, as more health systems adopt EHR's, new concerns have come to the fore, such as physician burnout from irrelevant data entry tasks, problems with the inaccuracies in data integration, and distracting alerts.[4]

In 2011, the government began Meaningful Use, a program of incentives (and later penalties for failure to adopt) intended to promote the use of EHRs..[5] In 2013, WPATH published recommendations for EHR reform to reflect gender identity in place of biological sex.[6] In 2015[7], the Department of Health and Human Services (HHS) mandated data fields for sexual orientation and gender identity.[8] The debate around the difference between sex and gender identity brings a new safety issue to healthcare because the definition of biological sex and gender expression are being conflated. For example, health care systems and EHR software companies like EPIC have been tasked with implementing EHR documentation regulations. In practice this means the adoption of elaborate and ever expanding descriptions of sex and gender in accordance with policy preferences.[9] Confusing templates with unclear or inconsistent terminology, are an expression of more profound sex and gender related problems plaguing health care systems. The definition of sex itself is ultimately imprecise. Is "Legal Sex" the same as biological sex? What if a trans-identified person has changed their legal sex on documents to be incongruent with their biological sex? Does "Legal Sex" trump "Gender Identity" when a patient is in the process of transitioning but hasn't legally changed their sex? How are clinicians to know when to perform pregnancy tests and or when to issue health maintenance reminders like mammograms or PSA (prostate Specific Antigen) test? Missed ruptured ectopic pregnancies is the leading cause of first trimester maternal death and identifying an ectopic is a core competency of Emergency Medicine physicians.[10] The definition of biological sex is tied to internal algorithms linked to sex specific orders. What are the implications for the system as a whole? Must all men be asked if they have a uterus? All women offered a prostate exam? If the internal algorithm is consistent with biological sex, then why would it not be reflected clearly on the user interface? It is unclear, and dovetailing with the

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https://www.beckershospitalreview.com/ehrs/epic-vs-cerner-ehr-market-share.html#:~:text=Despite%20this%2C%20Oracle%20Cerner%20comes,of%20hospital%20beds%20in%202022.

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https://www.statnews.com/2020/03/27/government-rules-led-electronic-health-records-astray-its-time-to-reimagine-them/

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https://www.ama-assn.org/practice-management/medicare-medicaid/meaningful-use-electronic-health-record-ehr-incentive

6 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3721165/

7 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6590954/

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https://www.researchgate.net/publication/352562431_Implementation_of_Gender_Identity_and_Assigned_Sex_at_Birth_Data_Collection_in_Electronic_Health_Records_Where_Are_We_Now/download and https://www.researchgate.net/figure/Epic-Demographic-Sexual-Orientation-SO-and-Gender-Identity-GI-SmartForm-C-2021-Epic_fig1_352562431

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https://lgbtqprimarycare.com/chapter-9/section-3-documenting-sexual-orientation-and-gender-identity-information/

10 https://coreem.net/core/ectopic-pregnancy/

technical support is time consuming and unrealistic during patient care. Errors can be propagated unknowingly.

One reason this area of healthcare has become politicized is due to our current regulatory infrastructure. The debate has been framed by some policy makers and activists as a civil right under the 14th Amendment and The Civil Rights Act Title VII. HHS is applying pressure to heath systems but moving to expand the definition of protected classes for the purpose of discrimination initially with the Affordable Care Act (ACA) section 1557 adding civil rights language into healthcare regulations in 2016 including gender identity as a protected class[11]. This triggered successful legal challenges by religious organizations to block gender identity as a protected class.[12] However, the current administration has renewed efforts to define gender identity as a protected class with another regulatory proposal in 2022 underway[13]. While this change is still under review, healthcare systems and affiliates are overly cautious about any opening to lead to an accusation of discrimination.

How does this classification change manifest in practice? Before health systems and EHR systems like EPIC expanded options to describe biological sex, a trans-identifying patient would be registered as their biological sex while alternatives to their name or gender identification were indicated in a common "note" space as well as verbally. For example, John Smith registers in the ER for evaluation of abdominal pain. During registration he states he is transgender and goes by Jane Smith. In the user interface, his record says "John Smith, Male, identifies as a female and goes by Jane". With the sophistication of EHRs, many presentations are possible, like Jane Smith, biologic male. There is no evidence that this practice led to patient errors.

But the new push to allow biological sex to be incorrectly documented has led to serious patient safety events. NEJM case report (2019)[14] details a story of harm done to a trans-identifying patient because of classification confusion. A pregnant female presenting as a man had a delay in care and misdiagnosis of a miscarriage and preeclampsia, a life-threatening condition. It is unknown how many other stories like this exist. Also, the aggressive response by some institutions, like Harvard, to characterize those who dissent from this political orthodoxy as bigots and intolerant subject to public shaming and possible job loss, causes a chilling work environment that may cause a health care worker to self censor a potential safety concern for fear of being demonized.[15]

Additionally, these EHR forms may come under legal scrutiny as compelled speech given the Supreme Court case 303 Creative et al vs Elenis et al[16] decided on June 30th, 2023. Because a clinician is required to use a given EHR as part of their employment, they are also being

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https://www.federalregister.gov/documents/2022/08/04/2022-16217/nondiscrimination-in-health-programs-and-activities#p-83

[12] https://ecf.ca8.uscourts.gov/opndir/22/12/211890P.pdf

[13] https://www.regulations.gov/docket/HHS-OS-2022-0012/unified-agenda

[14] https://www.nejm.org/doi/full/10.1056/NEJMp1811491

[15] ▶ Patient, Family, Visitor, and Research Participant Code of Conduct | Mass General Brigham

[16] https://www.supremecourt.gov/opinions/22pdf/21-476_c185.pdf

compelled to navigate the confusing maze of sex and gender definitions and possibly preferred pronouns. This may now be considered compelled speech, violating the First Amendment, and possibly violating Civil Rights Title VII for discriminating against a clinician's religious liberties and their right of conscience. Furthermore, the case GROFF *v*. DᴇJOY, POSTMASTER GENERAL [17] affirms a worker's right to religious accommodations that are not overly burdensome to the employer. A health system can ensure that the term "Biological Sex" is in every form and is the only field connected to the clinician facing and inner workings of the algorithms.

Preventing confusion and anticipating errors are critical safety actions incumbent on all health care clinicians, systems, and EHR software companies.

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Examples from EPIC

EPIC Template (from the web). There is no field for "Biological Sex":

Screenshot from an anonymous physician's EPIC interface with patient identifiers removed. There is no field for "biological sex":

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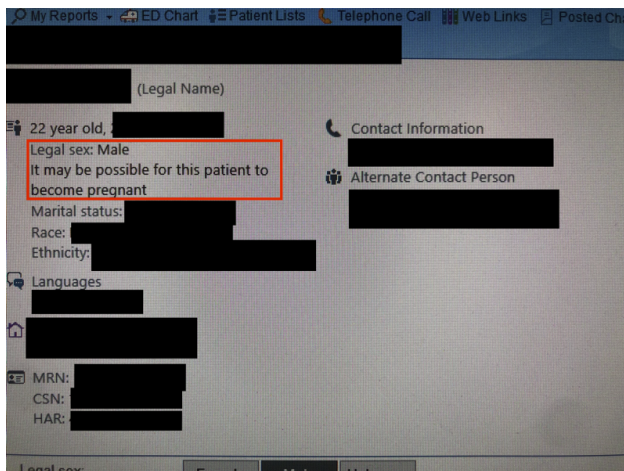[17] https://www.supremecourt.gov/opinions/22pdf/22-174_k536.pdf
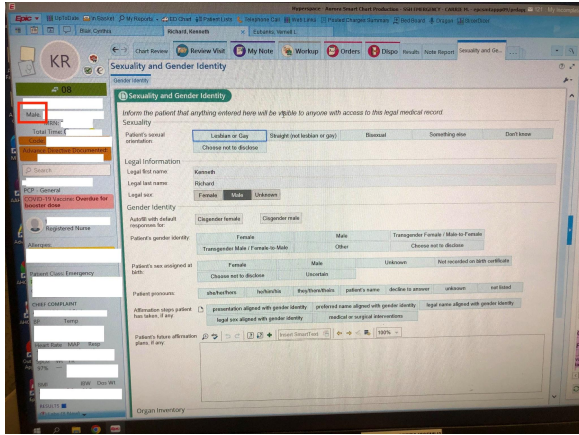
Example of confusing terminology on a patient's chart leading to errors:

1) Icon next to sex indicating additional information
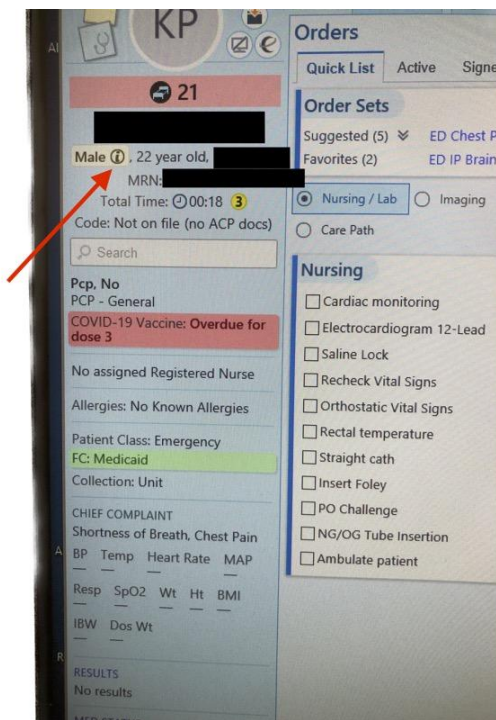
2) Additional information reveals the patient has the "Legal Sex: Male" but "it may be possible for the patient to become pregnant" indicating the patient is a biologic female.

3) A pregnancy test is ordered as part of the evaluation of the patient's chief complaint. A warning box appears "this test should only be ordered on female patients", indicating to the user the computer algorithm interprets this patient as a male and a test is being ordered in error.

4)
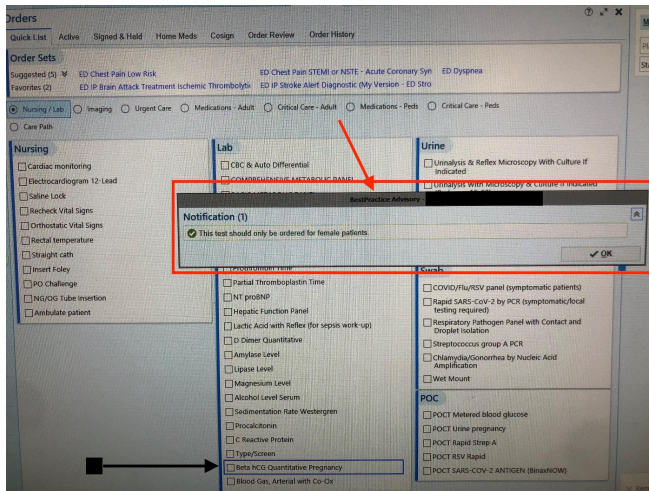
5) During patient history, the physician discovers that the patient is not transgender, and this confusing classification is an error. A pregnancy test was erroneously ordered. The conversation with the patient also gives a perception that the hospital record system is unsafe. What other errors might there be?

FAIR in Medicine's Model legislation for Medical Records, Biological Sex Requirement[18]:

Subd. 1. The sex recorded on a person's electronic health record shall be the person's biological sex at birth, either male or female.

Subd. 2. Nothing in subd. 1 shall be construed to prevent an electronic health record from also listing a person's gender identity or transgender status, provided that the person's biological sex at birth is clearly recorded on the electronic health record.

Subd. 3. The sex recorded on electronic health records shall not be changed except in the case of a scrivener's error or in the case of a person born with external biological sex characteristics that were indeterminably ambiguous at the time of birth.

Definitions:

"Sex" means a person's immutable biological sex, either male or female, at birth.

"Female" means a member of the human species who, under normal development, has XX chromosomes and produces or would produce relatively large, relatively immobile gametes, or eggs, during her life cycles and has a reproductive and endocrine system oriented around the production of those gametes. An individual who would otherwise fall within this definition, but for a biological or genetic condition, is female.

"Male" means a member of the human species who, under normal development, has XY chromosomes and produces or would produce small, mobile gametes, or sperm, during his life cycle and has a reproductive and endocrine system oriented around the production of those gametes. An individual who would fall within this definition, but for a biological or genetic condition, is male.

"Electronic health record" means an electronic record of health-related information on an individual that includes patient demographic and clinical health information and has the capacity to:

    (1) provide clinical decision support;

    (2) support provider order entry;

    (3) capture and query information relevant to health care quality; and

    (4) exchange electronic health information with, and integrate such information from, other sources.

Note: Definition of Electronic Health Record should be incorporated from the definition that already exists within that state.

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[18] Written by Dan Cragg, Esq