ACLA Best Practice Recommendation for Administrative and Clinical Patient Gender used for Laboratory Testing and Reporting

American Clinical Laboratory Association

Overview

Every patient has experience with the provider's "patient demographic form"[1] which is typically completed and/or verified annually upon check in for a doctor's appointment or required for admission/registration at a care facility. Typically, these forms collect patient demographic information, such as patient name, address, contact info, date of birth, marital status, race, language, and 'sex' or 'gender', often represented as a male/female checkbox.

Since the 2004 Executive Order that prompted a national movement toward digital electronic health records, the creation of the Office of National Coordinator, the CMS Meaningful Use Electronic Health Record (EHR) Incentive Program, and most recently, the 21st Century Cures Act, the health care industry has made significant progress toward realizing the goal of 'Interoperability' as defined in 21st Century Cures Act:

> ''(10) INTEROPERABILITY.—The term 'interoperability', with respect to health information technology, means such health information technology that—
>
> > ''(A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
> >
> > ''(B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and
> >
> > ''(C) does not constitute information blocking as defined in section 3022(a).''.

Reliable patient demographic data is crucial to achieve interoperability; it is used to match patients so providers can retrieve all health care records, is used in research and data analytics to discover trends and cures, and even for administrative tasks such as clinical decision support, patient matching, trending, billing, claims, eligibility and bed assignment for inpatients.

Laboratories results are used in many medical decisions Laboratories may be located inside or adjacent to care facilities (hospitals, rehab facilities, nursing homes, doctor's offices, etc.) or established as a specimen processing center where the lab never sees the patient. The reliability of the demographic data provided to process the laboratory test is critical for a precise result. Some tests results are dependent on the patient's age, derived from the date of birth, and the patient's biological/chromosomal sex, sometimes referred to as the sex assigned at birth[2]. Additionally, results may be flagged to alert the provider based on the patient's age or biological/chromosomal gender. For example, many patients must manage their cholesterol levels with periodic laboratory testing. The reference ranges to determine if the results are acceptable differ for males vs. females.

In the evolution of the paper based "patient demographic form" to digital information in electronic health records, while the health care industry recognizes that the 'sex' reported for administrative use (billing, claims, etc.) may not be the same as the patient's clinical/biological/chromosomal gender, or

[1] A recent google search for "patient demographic form" returned over 91,300,000 results.

[2] Some states permit their residents to alter their birth certificate, therefore "sex assigned at birth" is requested.

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the patient may be in process of transforming their gender, many EHR systems still support only male, female, and unknown[3].

The Health Level Seven (HL7) standards development organization, responsible for authoring an information exchange computer language used by EHRs, recognized the need to message distinct concepts for "administrative sex" and "clinical gender" in their standards beginning in 2000.

ONC identified distinct concepts in their Interoperability Standard Advisory (ISA)[4] by defining three concepts:

- Representing Patient Sex (At Birth)
- Representing Patient Gender Identity
- Representing Patient-Identified Sexual Orientation

Many EHR systems are capturing this data as required for 2015 Edition Certification[5], but the traditional interfacing typically supports a single patient demographic data element. Therefore, they are not always messaging the relevant information to the laboratory for testing and reporting. In some cases, only the patient's provider will know the correct information to be reported to the lab.

ACLA Best Practice Recommendation

In order to provide the data needed for the laboratory to process the test, the American Clinical Laboratory Association (ACLA), a consortium of laboratories, endorses the following best practice recommendations:

- Continue to use the concepts of male, female, and unknown for administrative purposes.
- If the patient "clinical gender" does not match the "administrative sex", value the "administrative sex" as **unknown**, but additionally send a clinical observation to the laboratory using LOINC® codes from ONC's ISA:
    - LOINC® code: 76689-9 Sex assigned at birth
    - LOINC® code: 76691-5 Gender identity
- If the patient's sex/gender is unknown and no additional information is provided, the laboratory may provide reference range values for both male and female (if they differ) as non-structured data so the provider may determine which results are pertinent to their patient. This could also impact established alerting to the provider, thus impacting patient safety. Some EHR, LIS and Lab systems may have a challenge supporting results with multiple ranges.-5

[3] These are the three options used in claims processing.

[4] 2018 ISA Reference Edition: https://www.healthit.gov/isa/sites/default/files/2018%20ISA%20Reference%20Edition.pdf

[5] 2015-10-16 Department of Health and Human Services, 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Final Rule

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