**Pregnancy Status Class**

Comment on the class: ACOG supports the comment already made supporting HL7s CCDA “Pregnancy Status” as it is comprehensive in this area and would better support both clinical research and public health use cases.

<https://www.hl7.org/implement/standards/product_brief.cfm?product_id=494>

**Items:**

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| 1. **Pregnancy Status**
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| **Requirement Level** | Must Have |
| **Value set** | Yes, No, Unknown, currently pregnant or confirmed pregnant, not currently pregnant or pregnancy refuted, recently pregnant, possibly pregnant. |
| **Comments** | * Values have unnecessary overlap. Clinically the importance is around confirmation of pregnancy. ACOG recommends five values in this value set:
* Yes, confirmed pregnant;
* No, confirmed not pregnant;
* Unknown, possibly pregnant;
* Recently pregnant within the last 12 months

ACOG recommends that “recently pregnant” be defined as within the last 12 months to capture pregnancy related complications. Importantly, pregnancy-related deaths may occur well beyond the early postpartum period, Per the [CDC:](https://www.cdc.gov/reproductivehealth/maternal-mortality/pregnancy-mortality-surveillance-system.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Freproductivehealth%2Fmaternalinfanthealth%2Fpregnancy-mortality-surveillance-system.htm#how)  “A pregnancy-related death is defined as the death of a woman while pregnant or within 1 year of the end of a pregnancy –regardless of the outcome, duration or site of the pregnancy–from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.”* ACOG supports a new data class called “Pregnancy Episode” of which pregnancy status would be a data element. Pregnancy Episode would have data elements that include a start and end date, pregnancy status, postpartum period, and a lactation period if relevant. End date of pregnancy would be defined both by an actual known date and be defined by a calculation off EDD such that the Pregnancy Episode would automatically close at a specified period of time post the EDD.
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| **Use Case** | The Use Case for Pregnancy Episode is to ensure that a status of pregnancy is accurate and not reflective of a pregnancy that took place in the past. It is also important to ensure that multiple pregnancies within a given time period are accurately reflected. This is important for clinical care as well as for both research and public health use cases. |
| **ACOG Related Materials** | [CO736 | Optimizing Postpartum Care (05/2018)](https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/05/optimizing-postpartum-care) |
| **Requirement Level** | Nice to Have |
| **Value set** | Patient reported, pregnancy test, urine-based pregnancy test, serum-based pregnancy test, ultrasound, clinical impression, history of hysterectomy other. |
| **Comments** | ACOG questions the need for these ‘nice to have’ values under pregnancy status as they are duplicative of values that exist elsewhere. Pregnancy tests and ultrasound are already covered in the Laboratory and Procedures Class and thus do not have a need to be restated here. History of hysterectomy more appropriately belongs with a designation of medically unable to conceive. Patient reported is a general health concern. Clinical impression is covered by yes, confirmed pregnant.  |

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| 1. **Date Pregnancy Status**
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| **Requirement Level** | Must Have |
| **Value Set** | Date |
| *No ACOG comments.* |

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| 1. **Estimated Delivery Date (EDD)**
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| **Requirement Level** | Must Have if pregnant, preferred |
| **Value Set** | Date  |
| **Comments** | * The correct clinical terminology is Estimated Due Date, not Estimated Delivery Date
* EDD and GA are calculations of one another and thus appropriately belong together as in that if you have one, you have the other. As such they need to be treated the same by USCDI in terms of “must have”/”nice to have”, the difference being that they have two different value sets. EDD is a “Must Have” as an alternative to GA; GA is a “Must Have” as an alternative to EDD.
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| **ACOG Related Materials****(ReVITALize)** | [Obstetrics Data Definitions](https://www.acog.org/en/Practice%20Management/Health%20IT%20and%20Clinical%20Informatics/reVITALize%20Obstetrics%20Data%20Definitions): Estimated Due Date (EDD): The best EDD is determined by last menstrual period if confirmed by early ultrasound or no ultrasound performed, early ultrasound if no known last menstrual period or the ultrasound is not consistent with last menstrual period, or known date of fertilization (e.g., assisted reproductive technology). |

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| 1. **EDD Determination Method**
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| **Requirement Level** | Nice to have if EDD used |
| **Value Set** | LMP, ultrasound first trimester, ultrasound second trimester, ultrasound third trimester, ultrasound, Ovulation date, Embryo transfer, Other. |
| **Comments** | * The determination method is a “Must Have” for both EDD and GA. The method reflects on the accuracy of the resulting date and is critical information to capture. Being able to assess the reliability of the EDD/GA directly impacts clinical management of a pregnant individual; being unable to assess reliability represents a patient safety issue for both the mother and fetus.

Value set comments: * ACOG recommends the following value set for EDD determination method:
	+ LMP
	+ Earliest ultrasound date and gestation age in weeks/days
	+ First trimester ultrasound
	+ Second trimester ultrasound
	+ Third trimester ultrasound
	+ Ultrasound, unknown trimester
	+ Ovulation date
	+ Embryo transfer date
	+ Intrauterine insemination date
	+ Other
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| **ACOG Related Materials** | * ACOG Committee Opinion #700 Methods for Estimating the Due Date (05/2017)
* ACOG Committee Opinion #688 Management of Sub-optimally Dated Pregnancies (03/2017)
* ACOG Committee Opinion #671 Perinatal Risks Associated with Assisted Reproductive Technology (09/2016)
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| 1. **Gestational Age**
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| **Requirement Level** | Must Have if Pregnant alternative to EDD |
| **Value Set** | Number with units = weeks or days |
| **Comments** | Should be weeks AND days, not weeks OR days |
| **ACOG Related Materials****(ReVITALize)** | [Obstetrics Data Definitions](https://www.acog.org/en/Practice%20Management/Health%20IT%20and%20Clinical%20Informatics/reVITALize%20Obstetrics%20Data%20Definitions): Gestational age (written with both weeks and days; e.g., 39 weeks and 0 days) is calculated using the best obstetrical EDD based on the following formula: gestational age = (280 - (EDD - Reference Date))/ 7   |

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| 1. **Date Gestational Age Determined**
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| **Requirement Level** | Must have if GA is used |
| **Value Set** | Date |
| *No ACOG comments.* |

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| 1. **Gestational Age Determination Method**
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| **Requirement Level** | Must have if GA is used |
| **Value Set** | Ultrasound, EDD, ovulation date, OTHERS? |
| **Comments** | Dates should be supplied with the determination method as done with EDD determination method. The same value set may be used as EDD determination method: Embryo transfer, Ovulation date, ultrasound, ultrasound third trimester, ultrasound second trimester, ultrasound first trimester, LMP, Other, with the same comment above with dates added (embryo transfer date, ultrasound dates). Intrauterine Insemination needs to be added to the value set.  |

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| 1. **Pregnancy Outcome**
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| **Requirement Level** | Nice to have if postpartum status is yes |
| **Value Set** | Molar pregnancy, elective termination, spontaneous termination <20 weeks gestation, still birth, ectopic/tubal, live birth, unknown, other, not a live birth |
| **Comments** | * This should be a “Must Have” as pregnancy outcome impacts care both in the short term and management of future pregnancies
* ACOG proposes the current proposed value set be replaced with: Live birth, Gestational Trophoblastic Disease, elective termination, early pregnancy loss (<13 weeks), early second trimester loss[[1]](#footnote-1) (loss <20 weeks), stillbirth/fetal death (20 weeks or greater), ectopic/tubal, term birth, preterm birth, unknown, other. Justification:
	+ Molar pregnancy should be replaced with Gestational Trophoblastic Disease as the more correct clinical terminology.
	+ “Not a live birth” should be removed as other values cover this value.
	+ In the first trimester, the terms miscarriage, spontaneous abortion, and early pregnancy loss are used interchangeably; ACOG prefers the term ‘early pregnancy loss’ to reflect these events, and recommends it be added to the value set. “Spontaneous termination < 20 weeks gestation” should be removed.
	+ Fetal death is widely used and thus ACOG recommends that the value be stillbirth/fetal death to reflect this.
	+ The value set should add premature delivery and term birth as both are important to clinical care, research and public health use cases.
* The Pregnancy Outcome must have the outcome date associated with it as metadata. A stand-alone Outcome Date risks not associating the correct pregnancy episode with that outcome. As such they must be linked together.
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| **ACOG Related Materials** | * ACOG Practice Bulletin #200 | Early Pregnancy Loss (08/2018): *Early pregnancy loss* is defined as a nonviable, intrauterine pregnancy with either an empty gestational sac or a gestational sac containing an embryo or fetus without fetal heart activity within the first 12 6/7 weeks of gestation.
* ACOG Obstetric Care Consensus #10 | Management of Stillbirth (03/2020): The U.S. National Center for Health Statistics defines *fetal death* as the delivery of a fetus showing no signs of life as indicated by the absence of breathing, heartbeats, pulsation of the umbilical cord, or definite movements of voluntary muscles. There is not complete uniformity among states with regard to birth weight and gestational age criteria for reporting fetal deaths. However, the suggested requirement is to report fetal deaths at 20 weeks or greater of gestation (if the gestational age is known), or a weight greater than or equal to 350 grams if the gestational age is not known. The cutoff of 350 grams is the 50th percentile for weight at 20 weeks of gestation. To promote the comparability of national data by year and state, U.S. vital statistics data are collected for fetal deaths with a stated or presumed period of gestation of 20 weeks or more. Terminations of pregnancy for life-limiting fetal anomalies and inductions of labor for previable premature rupture of membranes are specifically excluded from the stillbirth statistics and are classified as terminations of pregnancy
* ACOG Practice Bulletin #143 | Medical Management of First-Trimester Abortion (03/2014)
* ReVITALize: [Gynecology Data Definitions](https://www.acog.org/en/Practice%20Management/Health%20IT%20and%20Clinical%20Informatics/reVITALize%20Gynecology%20Data%20Definitions)
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| 1. **Pregnancy Outcome Date**
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| **Requirement Level** | Must have if postpartum status is yes |
| **Value Set** | Date |
| **Comments** | * The Pregnancy Outcome Date must have the Pregnancy Outcome linked to it. A standalone Outcome Date risks not associating the correct pregnancy episode with that outcome. As such they must be linked together.
* Pregnancy Outcome Date must also include the level of certainty in the date {certain, estimated, unknown} as some outcomes, particularly with ectopic and early pregnancy loss, may not have a known outcome date.
* The requirement level is a “Must Have” when there is *any* “Pregnancy Outcome”, not just postpartum status of yes. Not all pregnancies result in a postpartum state, such as an ectopic pregnancy.
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| 1. **Any pregnancy outcome within the last 42 days?**
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| **Requirement Level** | Must have if not pregnant |
| **Value Set** | Yes, no, unknown |
| **Comments** | * ACOG proposes that the data element of “Any pregnancy outcome within the last 42 days?” be replaced with the data element of “Not Pregnant”, with an expanded value set . The data element of “Any pregnancy outcome within the last 42 days?” is covered by data element number 8: “Pregnancy Outcome”. What is missing from the Pregnancy Status Class is a specific data element of “Not Pregnant”
* Value set for “Not Pregnant”: LMP, method of contraception, pregnancy intention, pregnancy prevention intention-reported, medically unable to conceive {hysterectomy, inability to conceive with current partner, bilateral oophorectomy, bilateral salpingectomy, genetically unable to conceive, menopause}.
* ACOG recommends the Pregnancy Intention value set include the values specified by LOINC 86645-9: Yes, I want to become pregnant; I'm OK either way; No, I don't want to become pregnant; Unsure
* ACOG recommends the Pregnancy Prevention Intention -Reported value set include the values specified by LOINC 91144-6: I am already doing something to prevent pregnancy; I want to start preventing pregnancy; I don't want to prevent pregnancy; I am unsure whether I want to prevent pregnancy; I prefer not to answer; This question does not apply to me.
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| **Use Case** | Support of clinical decision support (CDS) for medication prescribing; necessary data elements to support research which may require confirmation of protection against pregnancy. |
| **LOINC Details** | Pregnancy prevention intention – Reported has existing LOINC codes. LOINC Term Description: A patient’s current intentions to prevent pregnancy. This includes a male patient’s intentions to prevent pregnancy with a female partner. This term was created for, but not limited in use to, the Office of Population Affair’s (OPA’s) clinical performance measures for contraceptive provision endorsed by the National Quality Forum (NQF). <https://loinc.org/91144-6/>Pregnancy Intention is a component of the LOINC Pregnancy and Contraception Panel 86642-6 (FPAR) Family Planning Annual Report. LOINC Term Description: A patient's intention or desire in the next year to either become pregnant or prevent a future pregnancy. This includes male patients seeking pregnancy with a female partner. Pregnancy intention may be used to help improve preconception health screenings and decisions, such as determining an appropriate contraceptive method, taking folic acid, or avoiding toxic exposures such as alcohol, tobacco and certain medications. This term was based on, but is not limited in use to, Power to Decide's One Key Question®, used by the Office of Population Affair's (OPA's) Family Planning Annual Report (FPAR). <https://loinc.org/86645-9/> |

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| 1. **LMP (Last Menstrual Period)**
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| **Requirement Level** | Nice to have alternate to EDD/GA not dependent on pregnant |
| **Value Set** | Date |
| **Comments** | * Last menstrual period (LMP) should be a “Must Have” and not a “Nice to Have” as a data element. LMP remains important in determining EDD/GA along with the first accurate ultrasound or both.
* Value set, in addition to date, should include certain, estimated, unknown, N/A. N/A should have the ability to include the reason for no menses {pre-menarcheal, hormonal suppression, breastfeeding, hysterectomy, endometrial ablation}.
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| **ACOG Related Materials** | * ReVITALize: [Obstetrics Data Definitions](https://www.acog.org/en/Practice%20Management/Health%20IT%20and%20Clinical%20Informatics/reVITALize%20Obstetrics%20Data%20Definitions): Estimated Due Date (EDD): The best EDD is determined by last menstrual period if confirmed by early ultrasound or no ultrasound performed, early ultrasound if no known last menstrual period or the ultrasound is not consistent with last menstrual period, or known date of fertilization (e.g., assisted reproductive technology).
* ACOG Committee Opinion #700 Methods for Estimating the Due Date (05/2017)
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| 1. **Multiplicity of birth/pregnancy**
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| **Requirement Level** | Nice to have |
| **Value Set** | Numeric |
| **Comments** | * Multiplicity of birth/pregnancy should be a “Must Have” and not a “Nice to Have” data element. Twins and higher order pregnancies have an increase in fetal morbidity and mortality, primarily due to prematurity. Because of the increase in adverse outcomes with non-singleton pregnancies, it is important to capture this data for both clinical research and public health use cases.
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| **ACOG Related Materials** | * Practice Bulletin #169 Multifetal Gestations: Twin, Triplet, and Higher-Order Multifetal Pregnancies (10/2016)
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1. The term ‘early’ second trimester loss is being used to reflect the time period of 13 weeks to 19 6/7 weeks during the second trimester. Prior to 13 weeks ‘early loss’ should be used and after 20 weeks ‘stillbirth/fetal death’ applies. [↑](#footnote-ref-1)