

CAH Enrollment Proposed Data Elements – Table A

General Considerations

- 1) Be careful about what we are asking for since most of these particular pieces of data will need to be acquired from the families and adds to the burden of the collector and family.
- 2) Who is expected to provide all this data?
- 3) We need to make sure we consider the questions and decide yea or nay based on review of the big picture and what we are really trying to ask with each question.
- 4) What is the primary goal for some of these analyses?
- 5) Do we pare down or beef up? If the intent is to only focus on CAH-related physical issues, then pare down. If the intent is broader, perhaps look at long-term intellectual outcomes (for kids with CAH), then it would be appropriate to capture very broad swathes of information on things that might affect such outcomes and confound the primary analyses (e.g. prenatal dex vs not, in context of CAH). In other words, I would err on the side of over-collection of data that might not be used, rather than missing collection of something that might be wanted later (I have seen this problem often in the studies in which I have been involved).
- 6) The balance between burden of data entry vs. value of data obtained is a critical challenge and hard to solve, but important to discuss.

Row	#	Measure	Category	Answer Type	Measure Answer or Units for Value Box	Comments	Comments	Comments
A 58	47	Was mother receiving <b>other</b> medications during pregnancy (enter 99999 if N/A or 88888 if unknown)?  [alternate wording below]  Enter any medications mother received during pregnancy.	Prenatal history	Free text  I suggest check boxes and “Other: specify”	<input type="checkbox"/> None <input type="checkbox"/> Missing/unknown <input type="checkbox"/> Anticonvulsants <input type="checkbox"/> Antidepressants <input type="checkbox"/> Antidiabetic medication <input type="checkbox"/> Antihypertensives <input type="checkbox"/> Antithyroid medication <input type="checkbox"/> Anxiolytics <input type="checkbox"/> Hormonal medications  (specify): _____ <input type="checkbox"/> Narcotics <input type="checkbox"/> Thyroid hormone <input type="checkbox"/> Other (specify): _____ [what to do about recreational drugs?]	Other than what? Do we want to know about supplements?  ?	Answer to question as stated would be yes or no or unknown. Do we need a free text to enter list of what meds?	Can/should we list some specific classes of medication that will be most common (check boxes, possibly with a free-text accompanying field for specific drug within class, if we care) and at the end an “Other: specify” field? Suggestions, see left box
A 59	48	Other <b>maternal</b> pregnancy complications and/or risk factors  [alternate wording]	Prenatal history	Check boxes	Missing/unknown data, none, <b>amniocentesis</b> , <b>chorionic villus sampling</b> , premature labor, preeclampsia, bleeding, placenta previa, placental abruption, <b>amniotic fluid infection</b> , <b>depression</b> , <b>diabetes</b> , infection, gestational diabetes, depression, hypertension,	<u>This seems random... why do we need all this info – would focus on</u>	ok	

R o w	#	Measure	Category	Answer Type	Measure Answer or Units for Value Box	Comments	Comments	Comments
		below] Pregnancy risk factors and/or complications			hypothyroidism, hyperthyroidism, virilization	<u>those relevant to CAH</u>		
A 60	4 9	<u>Was this pregnancy the result of assisted reproduction/infertility treatment?</u> Was fertility assisted in this pregnancy?  [alternate wording below] Did this pregnancy result from use of assisted reproductive technology?	Prenatal History	Check boxes	Missing/unknown data, no, ovarian hyperstimulation (e.g. clomiphene), cryopreservation of ovarian or testicular tissue, sperm donation, oocyte donation, embryo donation, clomid, in vitro fertilization, gamete intra-fallopian transfer (GIFT), zygote intra-fallopian transfer (ZIFT), intra-cytoplasmic sperm injection, sperm donation, egg donation, surrogate, pre-implantation genetic diagnosis, traditional surrogacy, gestational surrogacy.		Answer to question as stated would be yes or no or unknown.	I think this question is more logical at start of this section (before 47).
A 61	5 0	Weeks of gestation at birth (enter 88888 if unknown)	Neonatal History	decimal	Unit for value box = weeks			How many significant digits? e.g. 38.0?
A 62	5 1	Additional information about newborn period	Neonatal History	Check boxes	Missing/unknown data, none, antibiotics, breastfed, CNS bleeding, CNS infection, CNS injury, distress, hypoglycemia, hypotension, hypertension, hypoxia, meconium stain amniotic fluid, nuchal cord, sepsis, TPN, transfused	<u>This seems random... what are we going to do with this information?</u>	Add ventilator, jaundice	I would move this item after the basic birth demographics, i.e. after current #54.
A 62	5 2	Birth weight (enter 88888 if unknown)	Measurements	Decimal	Unit for value box = (kg)		Can we enter in lb oz and have automatic conversion to metric? Most parents will not report metric.	How many significant digits? e.g. 2.22?
A 63	5 3	Birth <del>length</del> height (enter 88888 if unknown)	Measurements	Decimal	Unit for value box = (cm)		Can we enter in lb oz and have automatic	How many significant digits? e.g. 54.0?

R o w	#	Measure	Category	Answer Type	Measure Answer or Units for Value Box	Comments	Comments	Comments
							conversion to metric? Most parents will not report metric.	
A 64	5 4	Birth head circumference (OFC) (enter 88888 if unknown)  Alternate wording below  Birth head circumference (HC, also known as occipitofrontal circumference, OFC) (enter 88888 if unknown)	Measurements	Decimal	Unit for value box = (cm)		Can we enter in lb oz and have automatic conversion to metric? Most parents will not report metric.	How many significant digits? e.g. 35.1?
	5 4 a	Additional information about the perinatal period.  Please check any additional events that occurred or medications received in the prenatal period	Neonatal History	Check boxes	<input type="checkbox"/> None <input type="checkbox"/> Missing/unknown <input type="checkbox"/> Fetal distress <input type="checkbox"/> Intrauterine growth retardation <input type="checkbox"/> Antibiotics <input type="checkbox"/> Corticosteroids <input type="checkbox"/> Other (specify): _____			[[I would split this into subsections for “prenatal”, “delivery” and “postnatal” for ease of analysis]]
	5 4 b	delivery			<input type="checkbox"/> None <input type="checkbox"/> Missing/unknown <input type="checkbox"/> Fetal distress <input type="checkbox"/> Hypoxia <input type="checkbox"/> Meconium staining of amniotic fluid <input type="checkbox"/> Nuchal cord			
	5 4	What about APGAR						

R o w	#	Measure	Category	Answer Type	Measure Answer or Units for Value Box	Comments	Comments	Comments
	c	score?						
	5 4 d	postnatal			<input type="checkbox"/> Antibiotics <input type="checkbox"/> Blood transfusion <input type="checkbox"/> Central nervous system bleeding <input type="checkbox"/> Central nervous system infection <input type="checkbox"/> Central nervous system injury <input type="checkbox"/> Hypertension <input type="checkbox"/> Hypoglycemia <input type="checkbox"/> Hypotension <input type="checkbox"/> Hypoxia <input type="checkbox"/> Jaundice requiring intervention <input type="checkbox"/> Parenteral nutrition <input type="checkbox"/> Seizure <input type="checkbox"/> Sepsis <input type="checkbox"/> Surgery <input type="checkbox"/> Other (specify): _____			Breastfed [this is not a complication – maybe needs a separate category]; need a neonatologist to look at this!!
A 65	5 5	State newborn screen serial number (enter 88888 if unknown)	Newborn screening	Integer		<u>This is not something we'd ever have on the clinical side</u>	ok	Do we provide precise digit number (4, 5 etc)?
	X X	Age (days) on date of newborn screen		Integer	Unit for value box = (days)	Presumably round number of days, not partial		
A 66	5 6	If newborn screened, days of age at time primary care provider or endocrine provider were notified of FIRST abnormal newborn screen for this condition (enter 88888 if unknown)	Newborn screening	Decimal Or integer?	Unit for value box = (days) Or <input type="checkbox"/> Not done <input type="checkbox"/> Missing/unknown <input type="checkbox"/> Days: __ __	<u>Same for this one</u>	ok	Presumably round number of days, not partial

R o w	#	Measure	Category	Answer Type	Measure Answer or Units for Value Box	Comments	Comments	Comments
		<p>[alternate wording below]  Age (days) at time  primary care  provider or  endocrine provider  was notified of  FIRST abnormal  newborn screen for  this condition.</p>						