Recommendations for 46,XX Congenital Adrenal Hyperplasia Across Two Decades: Insights from the North American Differences of Sex Development Clinician Survey

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Short Title: N Amer DSD Clin Survey: CAH Care

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Abbreviations. CAH (congenital adrenal hyperplasia), PES (Pediatric Endocrine Society), SPU (Societies for Pediatric Urology), clinical practice guidelines (CPGs), disorders/differences of

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sex development (DSD)

Key words: Congenital adrenal hyperplasia, differences of sex development, decision-making, gender assignment, surgery, disclosure, clinical practice guidelines

DSD Clinician Survey: Survey and Participant Profile Congenital Adrenal Hyperplasia

Summary

A survey of pediatric endocrinologists and urologists on clinical management practices regarding disorders (differences) of sex development / intersex conditions was administered at three timepoints. Participants were recruited from membership rosters of two North American-based professional societies: the (Lawson-Wilkins) Pediatric Endocrine Society and the Societies for Pediatric Urology. Members were sent invitations to complete the online survey at three timepoints: three years prior to publication of the 2006 "Consensus statement on management of intersex disorders," four years following it, and four years following publication of the 2020 Consensus statement update.

Survey Development

Initial Survey Development

Provisional survey items were generated based on a literature review and focus groups conducted by conference call. Focus groups were convened to identify themes pertinent to the investigation and canvass opinion regarding optimal survey administration format. Focus group participants included 16 junior and senior members of the (Lawson-Wilkins)¹ Pediatric Endocrine Society (PES) and the Societies for Pediatric Urology (SPU) nominated for participation by colleagues who thought their opinions would be particularly informative; a geographically diverse sample was sought. Web-based administration to facilitate recruitment was the consensus of focus group participants. A preliminary survey was pilottested with a subgroup of focus group members with other members checking for comprehensiveness of content coverage and survey response options.

The final version of the Time 1 (T1) Intersex Survey was administered in 2003-2004 and comprised five sections: 1) Case Presentations, 2) Factors Affecting Life Satisfaction, 3) Surgical Informed Consent, 4) Mental Health Services and the DSD Team, and 5) Demographics.

This document provides a detailed description of the survey and participant recruitment pertaining to the 46,XX congenital adrenal hyperplasia (CAH) case presentations in 2003-2004 as well as two subsequent survey administrations in 2010-2011 and 2020.

Subsequent Survey Iterations

Items in the T1 survey were edited over time reflecting terminology changes. Use of earlier data collection and analyses guided later data collection. Limited changes were made to item presentation, wording, and order. When considering changes, goals were to limit the extent of changes made to allow for direct comparisons across time.

Revised surveys, T2 and T3, were administered in 2010-2011 and 2020, respectively.

¹ Founded in 1972, the Lawson Wilkins Pediatric Endocrine Society formally changed its name to the Pediatric Endocrine Society (PES) in 2010.

When data collection spanned >1 year, the first year in which data collection occurred is used in the label. These are hereafter referred to as the T1 2003, T2 2010, and T3 2020 surveys.

Edits to CAH and Demographic items over time:

- Terminology changed from Intersex to DSD. In 2003, intersex applied to the medical condition; it was replaced by disorders of sex development following the 2006 Consensus Statement; by 2020, use of the term intersex re-emerged, but carried a different connotation for some applying more to an identity than a medical condition, per se. Additionally, by 2020 the word disorder was viewed negatively by some who supported the term difference of sex development. Changes in wording were intended to maintain a focus on the same set of medical conditions, despite changes in vernacular used to describe these conditions.
 - o T1 2003: "Intersex" and "Intersexuality"
 - T2 2010: "Disorder of Sex Development (DSD)"
 - T3 2020: "Disorders/differences of sex development (DSD)"
- Use of earlier data collection and analyses to guide later data collection item order
 - T1 2003 began with case presentations and ended with demographics
 - o T2 2010 began with demographics
 - T3 2020 began with introduction, then demographics; the introduction included a selfadministered eligibility screen and opt-out with pre-populated reasons for opting out
 - T3 2020 included an "other" option for recommended gender of rearing (Case Presentation) and for participant gender (Demographics)

Survey Components

Table 1. CAH-focused survey components

Section	Contents: Major Components				
Introduction	Overview of survey				
	Eligibility screener – 2020 only				
Demographics	Clinical practice and demographic characteristics				
Clinical Case	Cases:				
Presentations	1. Mild/Moderate CAH				
	2. Severe CAH				
	ecisions:				
	1. Gender of rearing				
	2. Who makes the decision about genital surgery				
	3. Timing of surgery (lists case-specific procedures)				
	4. Timing of disclosing early surgical procedures to patient				
	5. Timing of disclosing discordant karyotype to patient				

Table 2. CAH-focused survey component order

Section	T1: 2003	T2: 2010	T3: 2020
1	Introduction	Introduction	Introduction
2	Clinical Case Presentations	Demographics	Demographics
3	Demographics	Clinical Case Presentations	Clinical Case Presentations

Figure 1. Branching and skip logic used in survey administration

Brief Overview of the Survey						
	—					
	Eligibility Assessed [2020 only]					
Y	es	No				
1	-					
	Enrollment Question [all years]					
		•				
Proceed to Survey	Decline Participation	End Survey				
-	-					
Survey	Characterize reason for declining					
•	-					
End Survey	End Survey					

Figure 2: Branching and skip logic used in the clinical case presentation section

Clin	nical Case Vignette	
	1	
G	ender of Rearing	
	ly for Mild/Moderate CAH]	
[all	years for Severe CAH]	
	1	
Воу	Girl	Other [2020 only]
Genital & Gonadal Sur	gery: Who Decides	
Parent	Patient	
(with help from providers)	(defer surgery, revisit in adolescence)	
 Before 6 months Before 1 year Before school entry During pre-adolescence (6-10 years) Adolescence (11 years or older) I would recommend against surgery 	ing Early Procedures to Patient	•
Genital & Gonadal Surgery: DisclosBefore school entry (5 years)	ing Early Procedures to Patient	
 During middle childhood (6-10 years) 		
 During adolescence (11-17 years) 		
During adulthood (18 years or older)		
I would recommend against disclosure		
	,	
If Karyotype is Discordant with G	Gender: Disclosing to Patient	
Before school entry (5 years)		
• During middle childhood (6-10 years)		
 During adolescence (11-17 years) 		
• During adulthood (18 years or older)		
I would recommend against disclosure		
ŇI.	ext Case Vignette	

Survey Items

Notes: This survey was administered online; branching and skip logic were employed. Instances of branching and skip logic are shown below with logic described in bracketed sections. Additional changes specific to one or more years are noted in bracketed sections. The order of items presented below reflects that used in the 2020 survey.

Introduction: Eligibility [2020 only]

You were selected to complete this survey due to membership in the [relevant society name is displayed].

Disorders/differences of sex development (DSD) are "congenital conditions in which development of chromosomal, gonadal, or anatomical sex is atypical."

We are aware that not every society member is a practicing clinician working the area of DSD. You can indicate below whether or not you provide care to these patients or if you do not want to participate in the study. By either completing the survey or declining participation, you will not receive any more follow-up reminders to participate.

[2020 only]

Eligibility to participate:

Have you been involved in the clinical management of at least one patient with DSD?

☐ Yes

□ No

- Yes [proceed to Enrollment question]
- [if selected "no"]
 - o Please complete this last question so we can describe non-participants in any publication.
 - Are you (please select all that apply):
 - In clinical practice, with a different patient population (e.g., diabetes...)
 - In research
 - In teaching
 - In admin
 - Retired
 - Other
 - Other text
 - Thank you for your time

[all years]

Enrollment question:

- ☐ Proceed to Survey
- ☐ Decline Participation
- Yes [proceed to survey]
- [2010, 2020: if selected "decline participation"]
 - o So that we can describe non-participants, are you (please select all that apply):
 - In clinical practice with DSD patients
 - In clinical practice, with a different patient population (e.g., diabetes...)
 - In research
 - In teaching
 - In admin
 - Retired
 - Other: [Write-in test response]
 - o Thank you for your time

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Please describe some characteristics of your practice. The data will be used ONLY for this research study. All responses are strictly confidential. Only averaged data from respondents will be utilized. No information from individual respondents will be provided to any person, group, or agency.

	how many children/adolescents/adults do you see annually who were born with DSD? bout how many children/adolescents/adults do you see annually who were born with intersexuality? cases per year
About I	now many individuals born with DSD have you seen over your entire career? cases over entire career
Please i	indicate the average number of hours per week that you spend in patient care hours per week
	Gyour area of specialization? Urology Endocrinology Other:
	describe the community in which your main office/practice is located. Large metropolitan: (Total city and suburban population: 1,000,000 and over) Small metropolitan: (Total city and suburban population: 50,000 - 999,999) Nonmetropolitan/Rural: (Total population: 49,999 or less)
For US	Addresses, please indicate the first digit of your office zip code.
	is your practice located? United States Canada Mexico
	Other

[Note: the following practice location data were not directly collected in 2003 and 2010, but derived from other items (zip code) + recruitment material and added to the dataset]
[2020: if practice location is United States] Where is your practice located: State or District (USA)
[2020: if practice location is Canada] Where is your practice located: Providence or Territory (Canada)
[2020: if practice location is Mexico] Where is your practice located: State (Mexico)
[2020: if practice location is Other] Where is your practice located:
Primary Practice Setting: Solo or two-physician practice Group practice HMO Medical school or hospital-based Other patient care employment: Other non-patient care employment: [2010 only]
[if (2003 or 2010) AND if practice setting – medical school or hospital] If you are medical school or hospital-based, please indicate the percentage of time devoted to the following in your medical school or hospital-based practice: % research % patient care % other ———
What is your gender? Male Female Other, specify:
In what year were you born?

CI	INI	CVI	$C\Lambda$	SF	DR	FSFN	ITA	TIO	NIC

[Note: The option for "other" gender was added in the 2020 survey; previously, there was no option to recommend gender, subsequent items were based on a presumed gender of rearing as a girl) and the remainder of cases were limited to boy vs girl]

Case #1. Newborn with ambiguous genitalia identified by newborn screen and diagnosis of 21-hydroxylase congenital adrenal hyperplasia confirmed by Day 4. The clitoris was enlarged both in length (2 cm) and diameter, and there was partial posterior labioscrotal fusion.

[Note: Two color photographs were shown side-by-side. Each showed external genitalia as described in the text. In the n

first pic	ture (left side panel), tissue surrounding the clitoris is shown retracted between a glove ing tape is present.]	
· □	In your professional judgment, which sex assignment/gender of rearing would result of life outcome ['sex assignment' does NOT necessarily imply genital surgery]? Boy Girl Other (e.g., Intersex, non-binary)	in the best long-term
0b. □	if sex assignment is Boy] Who should decide whether genital surgery (hypospadias repair) should be performed the patient should make the decision (likely during adolescence) The parents should make the decision in conjunction with the physician specialists (En Urologists)	
[2020: 0c.	if sex assignment is Boy AND if who decides is Parents] In your professional judgment, genital surgery should be performed Before 6 months Before 1 year Before school entry During pre-adolescence (Ages 6-10 years) Adolescence (11 years or older) I would recommend against surgery	

[2020: if sex assignment is Boy] 0d. Hypospadias repair is sometimes completed at an early age such that the boy will have no memory of the procedure. If surgery had been performed at such an age in the case of this particular patient, do you think that information regarding the details of the surgery or karyotype should be disclosed to the patient? If so, when? Karyotype Genital surgery Disclosure before school entry (5 years) Disclosure during middle childhood (6-10 years) Disclosure during adolescence (11-17 years) Disclosure during adulthood (18 years or older) I would recommend against disclosure [2003 & 2010: first case presentation question for all] [2020: if sex assignment is Girl] 1a. Who should decide whether genital surgery (genitoplasty/clitoroplasty, vaginoplasty) should be performed? ☐ The **patient** should make the decision (likely during adolescence) ☐ The parents should make the decision in conjunction with the physician specialists (Endocrinologists and Urologists) [2003 & 2010: if who decides is Parent] [2020: if sex assignment is Girl AND if who decides is Parent] In your professional judgment, genital surgery (genitoplasty/clitoroplasty, vaginoplasty) should be 1b. performed Genitoplasty / clitoroplasty Vaginoplasty Before 6 months Before 1 year Before school entry During pre-adolescence (Ages 6-10 years) Adolescence (11 years or older) I would recommend against surgery [2003 & 2010: all] [2020: if sex assignment is Girl] 1c. Genital surgery is sometimes completed at an early age such that the child will have no memory of the procedure. If surgery had been performed at an early age in the case of this particular child, do you think that information regarding details of the surgery should be disclosed to the patient? Disclosure before school entry (5 years) Disclosure during middle childhood (6-10 years) Disclosure during adolescence (11-17 years) Disclosure during adulthood (18 years or older) I would recommend against disclosure

Case #2. The child, announced as a boy at birth, is first referred to you at 3 weeks of age with a salt-wasting crisis. The phallic structure measured 3.5 cm with fusion of the labial-urethral folds to the distal shaft (i.e., distal hypospadias). The labio-scrotal folds were fused and "scrotalized" so that complete scrotal development was present. Workup reveals 46, XX 21-hydroxylase congenital adrenal hyperplasia.

[Note: Two color photographs were shown side-by-side. In both pictures, the genitalia are shown as described in the text. In the second (right side panel), the underside of the clitorophallus with distal hypospadias is shown with the field

	nded by sterile surgical drapes.]	manas with distal hypospadias is	Shown with the here
[Note:	"/gender of rearing" was added in the 2020 survey]		
2a. quality 	In your professional judgment, which sex assignment/ge of life outcome ['sex assignment' does NOT necessarily in Boy Girl Other (e.g., Intersex, non-binary)	<u> </u>	he best long-term
2b.	assignment is Boy] Who should decide whether genital surgery (hypospadia The patient should make the decision (likely during adoles The parents should make the decision in conjunction with Urologists)	scence)	inologists and
[if sex a	Assignment is Boy AND if who decides is Parents] In your professional judgment, genital surgery (hypospose) Before 6 months Before 1 year Before school entry During pre-adolescence (Ages 6-10 years) Adolescence (11 years or older)	adias repair, gonadectomy) sho Hypospadias repair	uld be performed Gonadectomy
[if sex 2d.	assignment is Boy] Hypospadias repair is sometimes completed at an early procedure. If surgery had been performed at such an a that information regarding the details of the surgery o when?	□ y age such that the boy will have ge in the case of this particular	□ e no memory of the patient, do you thin
	Disclosure before school entry (5 years) Disclosure during middle childhood (6-10 years) Disclosure during adolescence (11-17 years) Disclosure during adulthood (18 years or older) I would recommend against disclosure	Genital surgery	Karyotype

[if sex a	assignment is Girl]					
2e.	Who should decide whether genital surgery (genitop	lasty/clitoroplasty, vaginoplasty) sh	ould be performed?			
	The patient should make the decision (likely during adolescence)					
	The parents should make the decision in conjunction v	with the physician specialists (Endoc	rinologists and			
	Urologists)					
_	assignment is Girl AND if who decides is Parents]					
2f.	In your professional judgment, genital surgery (gen	itoplasty/clitoroplasty, vaginoplast	y) should be			
	performed	Construction / althoughout	Markardan			
		Genitoplasty / clitoroplasty	Vaginoplasty			
	Before 6 months					
	Before 1 year					
	Before school entry					
	During pre-adolescence (Ages 6-10 years)					
	Adolescence (11 years or older)					
	I would recommend against surgery					
[if sex a	assignment is Girl]					
2g.	Surgery is sometimes completed at an early age su	ch that the child will have no memo	ory of the procedure.			
_	If surgery had been performed at an early age in th	e case of this particular child, do yo	ou think that			
	information regarding details of the surgery should					
	Disclosure before school entry (5 years)					
	Disclosure during middle childhood (6-10 years)					
	Disclosure during adolescence (11-17 years)					
	Disclosure during adulthood (18 years or older)					
	I would recommend against disclosure					
	•					

Participants

Recruitment - Procedures

At each timepoint, the research team sought approval from leadership of both the (Lawson Wilkins) Pediatric Endocrine Society (PES) the Societies for Pediatric Urology (SPU) to survey their membership and to provide member rosters that include contact information. Leadership of each society approved the research provided rosters, apart from PES at T3 2020 - citing concerns about burden. As such, at T3 for PES, only those who had previously participated at T1 or T2 were invited for participation. A publicly available directory PES was reviewed to remove names of those who were no longer listed as PES members; no new members were added.

To account for slightly differing timelines for study approval by PES and SPU and to manage the number of individuals targeted for participation and anticipated follow-up reminders, survey invitations were sent in waves, rather than to all participants at once. Invitation letters that included an explanation of the study and survey login instructions were sent society members in 2003-04 (T1), 2010-11 (T2), and 2020 (T3). Participants were also offered a paper-and-pencil version upon request. To optimize recruitment, eligible respondents received up to three follow-up requests to participate. After rates of survey completion dropped to minimal levels for several weeks, final requests for participation to non-responders took the form of a phone call and/or a single-page faxed letter encouraging either participation or to otherwise provide a reason for declining to participate at T1. Through this process, it was learned non-responders were frequently either retired, not in clinical practice, were exclusively involved in research, or not providing care to patients with a DSD. At T2 and T3, final follow-ups took place via email. Additionally, a screening and opt-out survey was added to the beginning of the T3 survey to simplify and streamline efforts at identifying participant (in)eligibility and reduce burden associated with follow-ups contacts for non-responders.

EligibilityCommon across all timepoints: Current members of either PES or SPU

Table 3. Eligibility requirements unique to specific timepoint:

		T1	T2	T3
Clinical	Is currently providing care for patients with intersex/DSD conditions	Х	Х	Х
Management	lanagement Has not provided care for patients with intersex/DSD conditions, but			
	are in a position where they could, potentially, do so now or in the			
	future or otherwise influence clinical care			
	Provided care for patients with intersex/DSD conditions in past only ¹	Х	Х	Χ
Professional	Pediatric Endocrinologist, Other Endocrinologist	Х	Χ	Χ
Background	Pediatric Urologist, Other Urologist	Χ	Χ	Χ
	Other professional degree (eg, PhD)	Χ		
Practice	United States	Χ	Χ	Χ
Location	Canada	Х	Χ	Χ
	Mexico	Χ	Χ	Χ
	Other		Х	

¹ Emeriti were, initially, included in the T1 survey; a combination of difficulty reaching these potential participants due to missing or inaccurate contact information, low participation rates, and feedback from several who targeted for participation that they are retired / unable to provide valid input (in their estimation) lead to discontinuing recruitment of emeriti as the project progressed.

Participants were promised confidentially of their responses; procedures were approved by the authors' Institutional Review Boards at the University at Buffalo School of Medicine and Biomedical Sciences (T1 2003) and University of Michigan Medical School (T2 2010 and T3 2020).

Participation Rates and Demographics

Given small differences in eligibility criteria for recruitment, participation rates are calculated using the most restrictive eligibility criteria.

Table 4. Participant ascertainment, recruitment, and participation

Table 4. Farticipant ascertainment, recruitment, and participation								
	T1 2003		T2 2	1010	T3 2020			
	PES	SPU	PES	SPU	PES	SPU		
Names in Directory	764	263	868	237	494 ⁶	354		
Ineligible ¹								
Co-I, FG, or PT participant ²	14	9	12	8	10	8		
Emeriti	117							
Retired	11	5	10	6	10	21		
Deceased	2		1					
No DSD patients	34	6	29	3	15	37		
No clinical practice	16	1	16		4	3		
Practice outside N. America	1		13		8	2		
Other; >1 criteria met	53	52	10	2	13	2		
Eligible, invited, sample	516	190	777	218	434	281		
Darticipated	300	132	323	118	118	154		
Participated	(58.1%)	(69.5%)	(41.6%)	(54.1%)	(27.2%)	(54.8%)		
Logged in / consented only ³					5	10		
Declined participation⁴	48	10	27	3	5	5		
No Response	168	48	425	96	304	107		
Eligible but not invited	0	0	1	1	0	0		
No contact information	0	0	1	0	2	5		

¹ Ineligibility was determined at multiple stages. Determinations were made prior to sending survey invitations to members; for others, it occurred after invitations were sent. It is possible that some of those for whom no responses are recorded are ineligible.

² Co-investigators, focus group members, and pilot test participants involved in the design of this project.

³ At T3, several targeted participants had logged into the survey and completed portions of the screening survey or demographics, but did not provide responses to items in any other section; this was not possible in earlier years.

⁴A common reason cited for declining participation was being "too busy."

⁵ Reflects an error in recruitment

⁶ Only current members of PES who had participated in the past were included in the 2020 PES sample; this does not represent the total number of names listed in the PES directory.

Provided they maintained membership in their respective professional society over time, members had the opportunity to participate in up to three waves of the survey. The majority participated on only one occasion; however, within-subjects comparisons are made possible on a limited basis:

Table 5. Participation over time

Participation	Participants (n)							
	PES	SPU	Total (PES+SPU)					
T1 only	153	51	204					
T2 only	130	31	161					
T3 only	0	93	93					
T1 & T2	87	35	122					
T1 & T3	12	9	21					
T2 & T3	58	15	73					
T1, T2, & T3	48	38	86					

Survey Completeness

In line with research ethics, participants were free to skip over questions they did not wish to answer and discontinue participation at any time. As such, not all surveys have 100% of items answered – the use of branching and skip logic notwithstanding.

Given the order in which major sections of the survey were presented and order of items within sections (see Survey Components, above), discontinuation disproportionately affected response rates of individual items depending on the year of administration.

Table 6. Participant demographics

	T1 2003			T2 2010				T3 2020				
	PES		SPU		PES		SPU		PES		SPU	
	n	%	n	%	n	%	n	%	n	%	n	%
Sex												
Male	182	60.7	126	95.5	161	49.8	111	94.1	59	50.0	129	83.8
Female	118	39.3	6	4.5	162	50.2	7	5.9	58	49.2	25	16.2
• Other¹									1	0.8	0	0
Practice Community ²												
Large Metropolitan	173	60.7	86	71.7	203	62.8	81	68.6	81	68.6	115	74.7
Small Metropolitan	107	37.5	33	27.5	120	27.2	35	29.7	36	30.5	37	24.0
Nonmetropolitan / Rural	5	1.8	1	0.8	120	37.2	2	1.7	1	0.8	2	1.3
Practice Country												
 United States 	282	94.0	125	94.7	304	94.1	113	95.8	109	92.4	147	95.5
Canada	18	6.0	7	5.3	19	5.9	5	4.2	9	7.6	7	4.5
Practice Setting ³												
Medical School or Hospital	212	76.8	78	65.5	251	77.7	73	61.9	99	83.9	113	73.4
Solo or 2-physician Practice	22	8.0	16	13.4			45	38.1	5	4.2	7	4.5
Group Practice	33	12.0	24	20.2	72	22.3			12	10.2	31	20.1
• HMO	9	3.3	1	0.8	/2	22.3	45		1	0.8	3	1.9
Other	0	0	0	0					1	0.8	0	0
	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD	mean	SD
Year of Birth	1950.9	9.1	1951.5	8.9	1960.0	10.8	1955.7	8.1	1960.7	9.2	1965.9	9.4
Cases Seen												
In Past Year	10.1	25.4	8.3	8.6	14.7	57.3	11.0	16.2	13.8	21.7	11.1	18.0
Over Career	65.9	87.8	91.3	121.8	84.8	135.0	131.9	230.8	99.5	155.2	133.8	426.6
Hours/Week in Patient Care	28.0	15.6	52.6	15.5	28.4	15.6	50.0	15.3	26.2	12.9	46.1	13.3
Proportion of Time Spent in ⁴												
Research	25.0	23.4	11.5	11.0	27.7	27.4	10.7	9.9				
Patient Care	55.8	25.5	77.6	13.8	56.3	27.2	77.8	15.5				
Other	19.2	16.6	10.9	11.2	16.3	14.8	11.4	12.6				

Note: Not all participants answered every item; percentages are calculated based on number of valid responses to each item rather than on cohort size

1 "Other" was included as a response option at T3 only; 2 Small Metropolitan and Nonmetropolitan / Rural were collapsed for PES members at T2; 3 Practice Setting was parsed into 2 categories at T2; 4 Items was asked only of those who indicated working in a "Medical School of Hospital" Practice setting; Item was not included at T3