The eXtraordinarY Babies Study:
Health and Neurodevelopment in Infants with Prenatal Diagnoses of Sex Chromosome Trisomy

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School of Medicine
UNIVERSITY OF COLORADO
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NEMOURS
CHILDREN'S HEALTH

Children's Hospital Colorado Team

Nemours Children's Hospital Team

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Coordinator: Madeline Austria MS, BS

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ACKNOWLEDGEMENTS

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Research Participants, Families and Students!

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NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

eXtraordinarY Kids

University of Colorado Anschutz Medical Campus

Colorado Clinical and Translational Sciences Institute (CCTSI)
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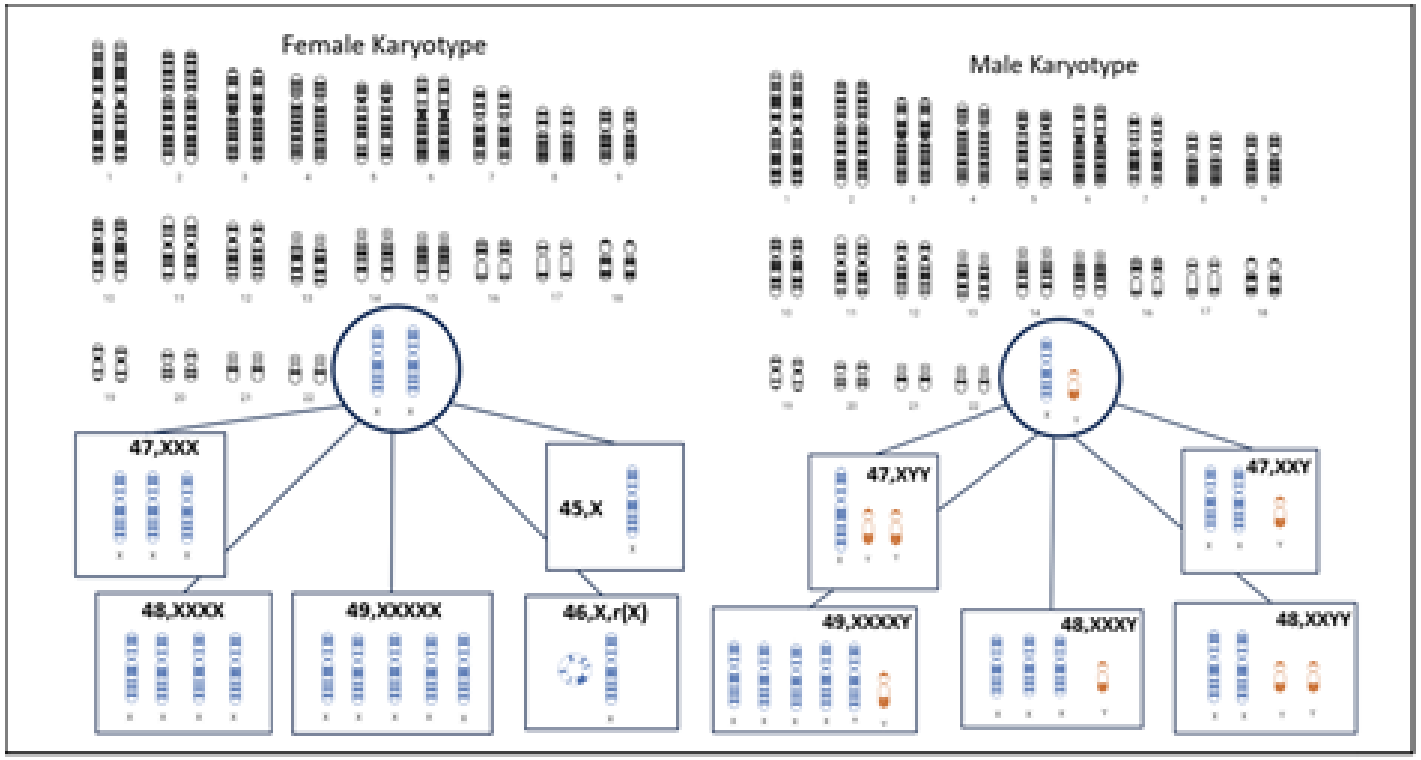
Outline

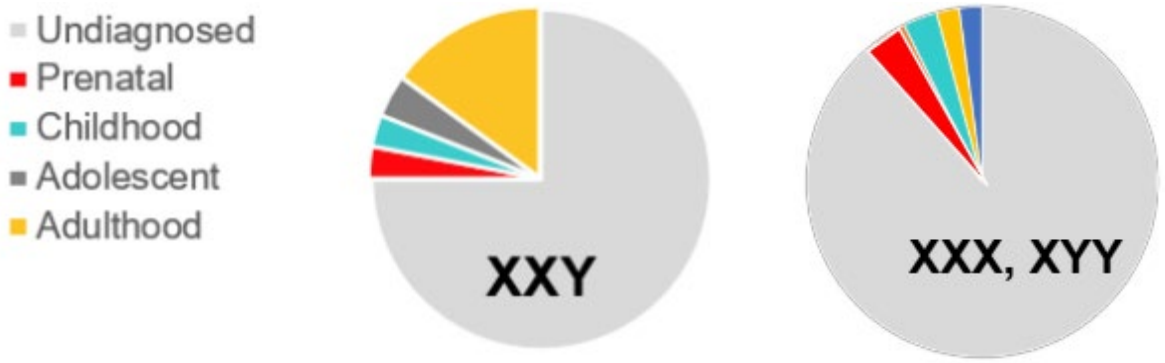
- eXtraordinarY Babies Study
  - Background & Study Aims
  - Protocol
  - Study participants
- Progress Report:
  - Medical Features in Year 1 of life
  - Developmental Milestones
  - Predictors of Outcomes at 3 years of age
  - Role of Infant Testosterone Treatment in Developmental Outcomes
  - XXYY syndrome results



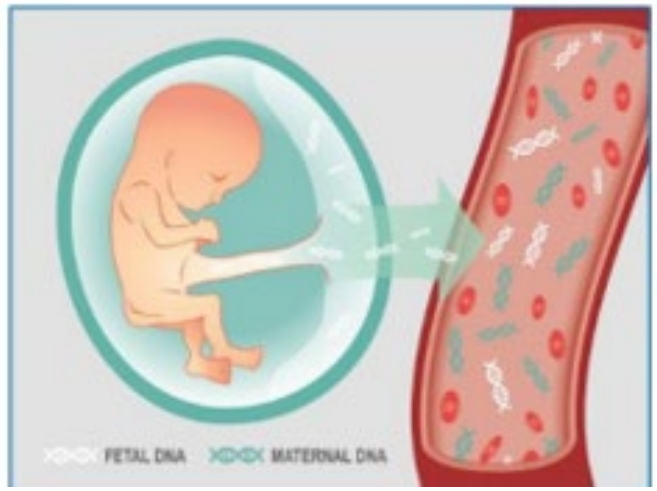
BACKGROUND

Historically, X&Y Chromosome Variations have been underdiagnosed by medical professionals

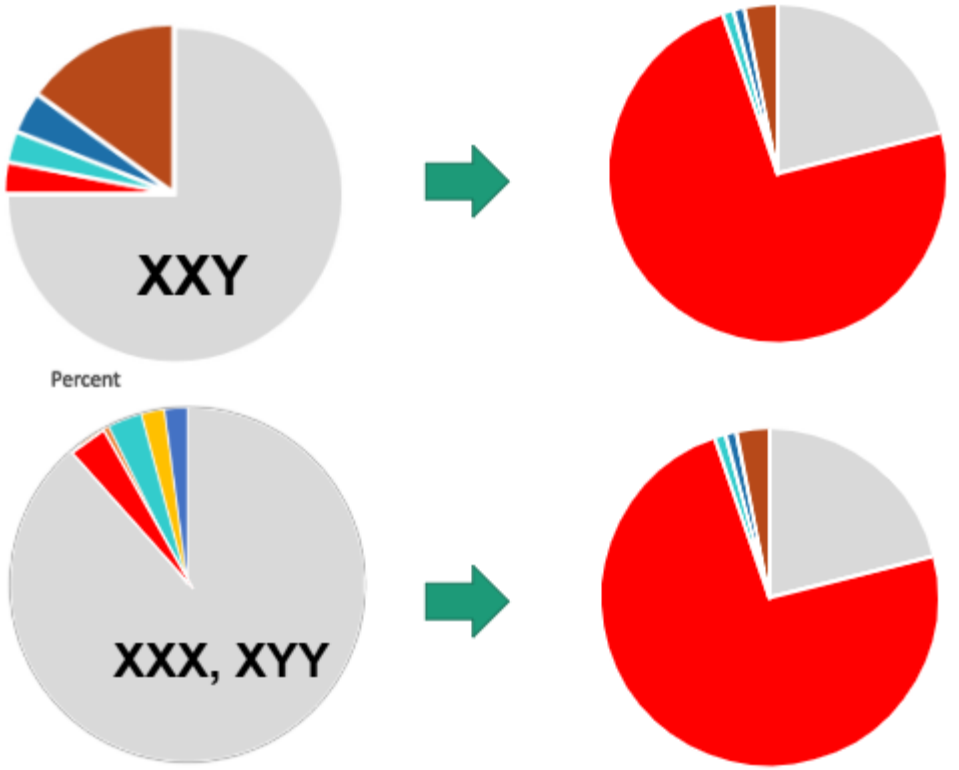
Individuals diagnosed with X&Y variations were just a fraction of those who actually have the condition



- Since 2011 in US….



Noninvasive Prenatal Screening



IMPACTS OF INCREASED DIAGNOSES:

Increased need for genetic counseling for X&Y variations

Many more babies presenting to pediatric offices as newborns for medical care

Many more babies presenting for developmental care / therapies

OPPORTUNITY:

Large cohort of babies to follow prospectively from birth

Less bias than previous research and clinical samples

Opportunity to understand family experience

Opportunity to improve genetic counseling

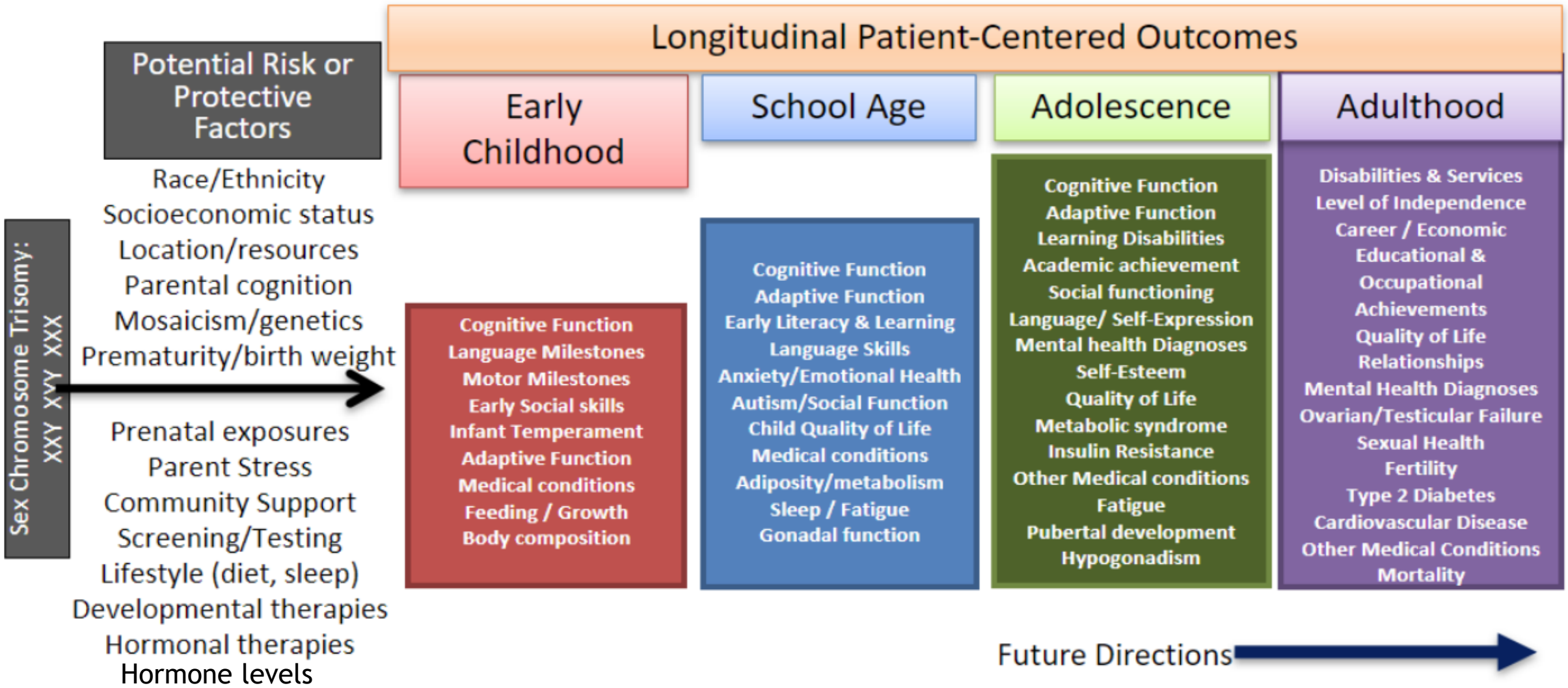
Opportunity to improve medical care and developmental care

Natural History of Health and Neurodevelopment Infants with a Prenatal Diagnosis of Sex Chromosome Trisomy

The eXtraordinarY Babies Study:

Natural History of Health and Neurodevelopment in Infants with Prenatal Diagnoses of Sex Chromosome Trisomy

eXtraordinarY Babies Study



Inclusion Criteria:

- Prenatal identification of sex chromosome variation
- Diagnostic confirmatory testing
- English or Spanish speaking
- Child age 6 weeks to 12 months on enrollment

Exclusion Criteria:

- Previous diagnosis of a different genetic or metabolic disorder with neurodevelopmental or endocrine involvement
- Prematurity less than 34 weeks gestational age
- Complex congenital malformation not previously associated with X&Y variations
- History of significant neonatal complications
- Known brain malformation identified by neuroimaging

Study Protocol

Family participation:

- Complete 13 study visits
  - 5 in-person visits
  - 8 telehealth

Data Collected:

- Demographics
- Prenatal/birth history
- Health history
- Developmental skills
- Interventions/education
- Family history

Direct assessments (in-person visits):

- Cognitive, academic, executive functioning, language, social and motor assessments
- Physical examination
- Sample collection (blood/urine/stool)
  - Biobanking
- Body composition (pea pod/bod pod)
- Parent cognitive testing

Study Participants

- Enrollment closed!
  - Original goal: 200
- Current Youngest: 5m old
- Oldest: 9y old
- 114 participate at Nemours Children's Hospital
- 258 participate at Children's Hospital Colorado
- Funding until March 2028

Total Study Enrollment	
XXY	201
XYY	35
XXX	87
XXYY	15
XXXY	3
XXXX	1
Total	**372**

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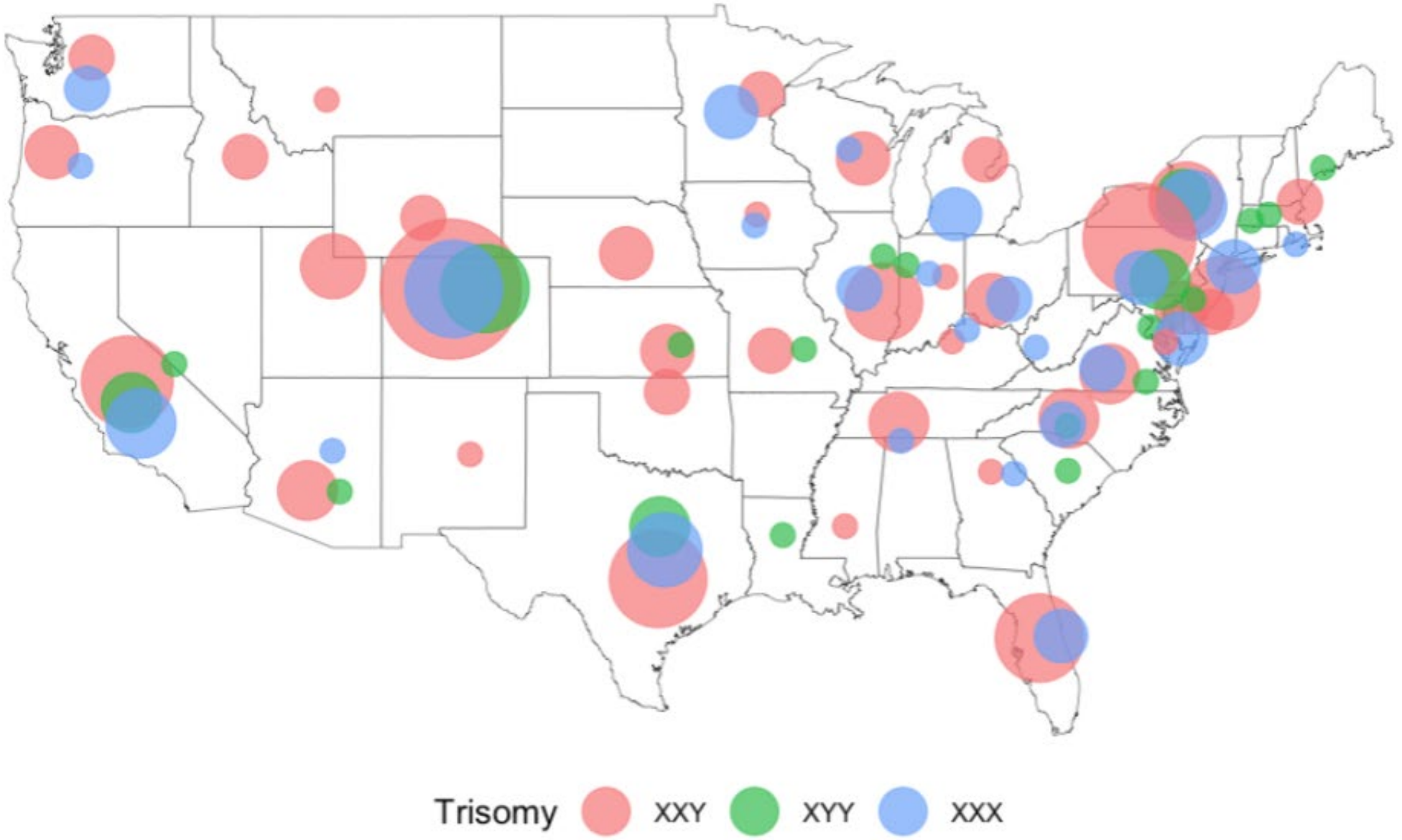
FIGURE 2: Participant US Regional Representation



Point Sizes range from N = 1 to N = 38. Hawaii and Alaska are both represented with N = 1. N = 9 patients are international.

Demographics

	All (%)	XXX	XXY	XYY	p-value
Race(%)					
Asian	3.1	5.1	3.1	0	0.364
Black	2.8	1.3	2.6	5.7	
>1 race	11.6	7.6	12.8	2.6	
White	82.6	86.1	81.5	81.1	
Ethnicity (%)					
Hispanic	15.3	13.9	15.9	15.1	0.969
Non-Hispanic	84.7	86.1	84.1	84.9	
Annual Household Income (%)					
<$75K	13.1	10.1	12.8	18.9	0.604
$75-150K	33.3	32.9	33.3	34.0	
$150-250K	26.0	32.9	24.6	20.8	
>$250K	26.9	22.8	28.7	26.4	

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2024 & 2025 updates

eXtraordinarY Babies Study Visits: 390 (2024), ~150 (2025)

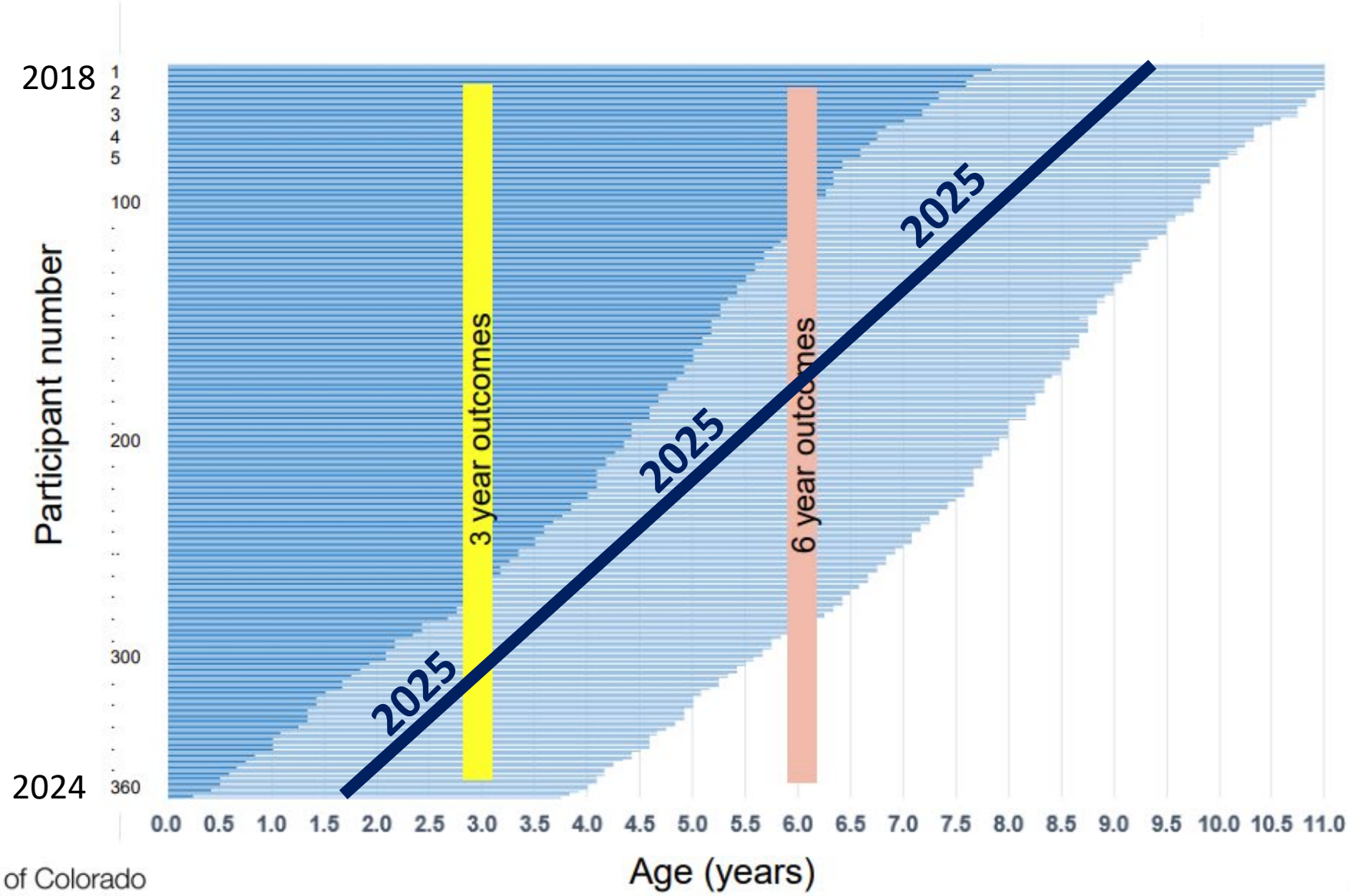
Publications: 12 (published), 2 (in press), 6 (in preparation)

Students & Trainees: 20 (2024), 11 (2025)

Professional Presentations: 25 (2024), 13 (2025)

STUDY RESULTS

Ages of Study Participants



Medical Care for SCT in the 1st Year of Life: Results from *eXtraordinarY Babies Study*

TABLE 5: Medical Conditions at Higher Risk in Infants with Prenatal SCT Diagnosis and Guidance for Clinical Care

Feature	General Population Prevalence[a]	SCT Prevalence[b] (95%CI)	Relative Risk[b] in SCT
Infant-related breastfeeding difficulties	19%[43]	51.1% (45.6-56.7%)	2.7 (2.1-3.4)
Failure to Thrive / Growth Faltering	10% [44]	18.4% (14.1-22.8%)	1.8 (1.4.-2.5)
Constipation (requiring intervention)	7.0% [45,46]	33.7% (28.4-38.9%)	5.1 (4.2-6.2)
Any Allergies	10.4%	24.3% (19.5-29.1%)	2.6 (2.1-3.2)
Food / Formula Allergies	8.8% [47]	19.4% (15-23.8%)	2.4 (1.9-3.1)
Eczema All SCT XXX Only XXY and XYY	13.7%[48]	 47.6% (42-53.1%) 31.6% (21.1-42%) 52.8% (46.4-59.2%)	 3.5 (3.1-3.9) 2.3 (1.7-3.2) 3.9 (3.4-4.4)

Medical Care for SCT in the 1st Year of Life: Results from *eXtraordinarY Babies Study*

TABLE 5: Medical Conditions at Higher Risk in Infants with Prenatal SCT Diagnosis and Guidance for Clinical Care

Feature	General Population Prevalence[a]	SCT Prevalence[b] (95%CI)	Relative Risk[b] in SCT	Considerations for Clinical Care
Infant-related breastfeeding difficulties	19%[43]	51.1% (45.6-56.7%)	2.7 (2.1-3.4)	Encourage prenatal breastfeeding classes if parent plans to breastfeed Proactive lactation consultation after delivery Breast pump for expressed breastmilk in case of delay with successful latch or ongoing breastfeeding challenges Targeted history in newborn nursery and first well child checks Evaluate for ankyloglossia and consider referral for further evaluation
Failure to Thrive / Growth Faltering	10% [44]	18.4% (14.1-22.8%)	1.8 (1.4.-2.5)	Early feeding / breastfeeding support as above Close follow-up for growth / weight gain in first months of life Caloric supplementation and other medical work-up as indicated Consideration of feeding therapy by feeding specialist, speech, or occupational therapy
Constipation (requiring intervention)	7.0% [45,46]	33.7% (28.4-38.9%)	5.1 (4.2-6.2)	Sorbitol-containing juices (eg, apple, prune, or pear) Lactulose, polyethylene glycol, glycerin suppositories under physician supervision; Referral to gastroenterology if needed
Any Allergies	10.4%	24.3% (19.5-29.1%)	2.6 (2.1-3.2)	Awareness of increased risk and consideration of allergic etiology for skin, sleeping, or gastrointestinal concerns
Food / Formula Allergies	8.8% [47]	19.4% (15-23.8%)	2.4 (1.9-3.1)	Parent education of milk protein and food allergy symptoms, staged introduction of new foods, indications for diphenhydramine administration, and when to seek emergent care
Eczema All SCT XXX Only XXY and XYY	13.7%[48]	47.6% (42-53.1%) 31.6% (21.1-42%) 52.8% (46.4-59.2%)	3.5 (3.1-3.9) 2.3 (1.7-3.2) 3.9 (3.4-4.4)	Awareness of increased risk, targeted physical exam, standard pediatric eczema interventions

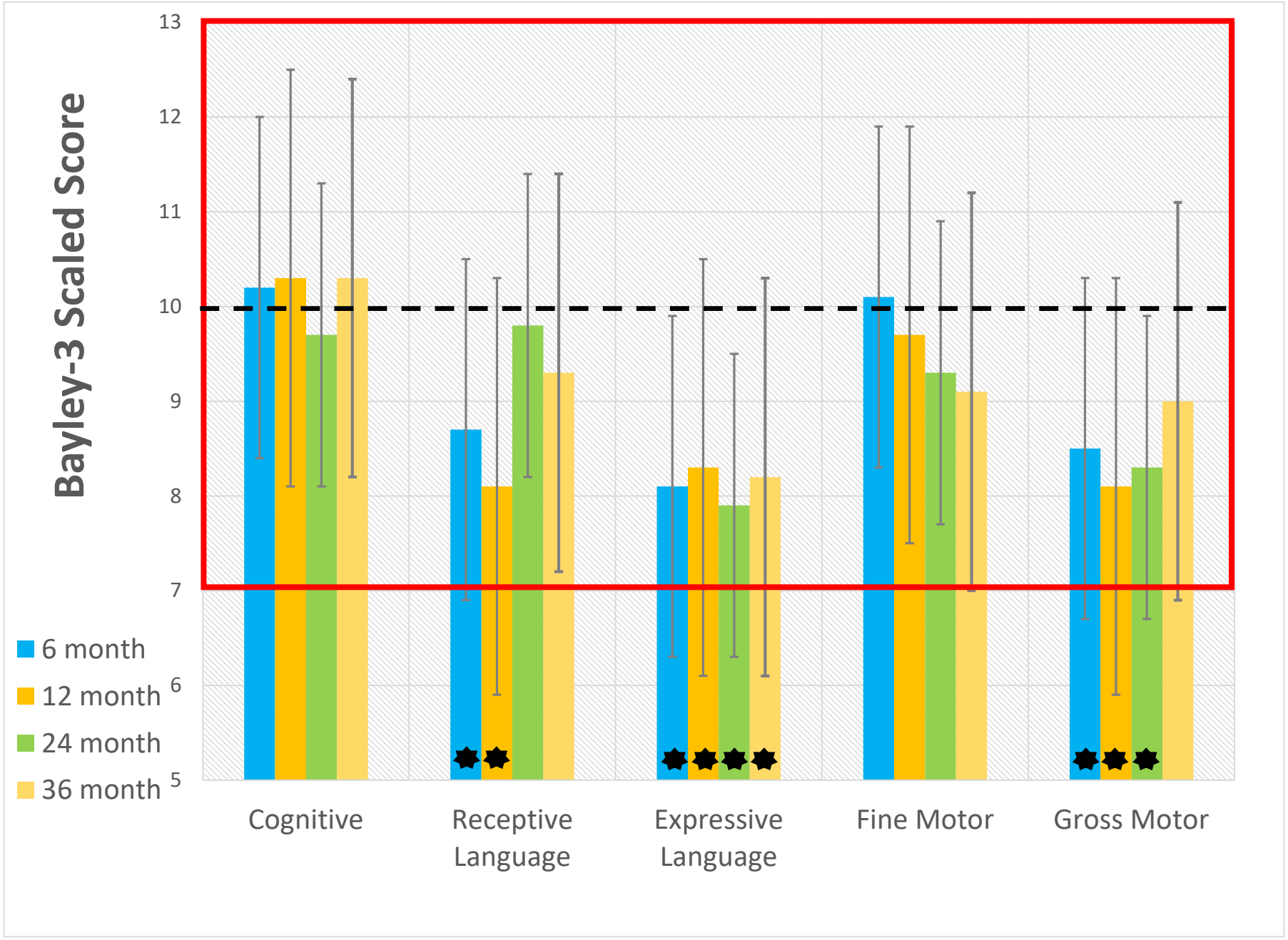
Positional Torticollis	3.9% [49,50]	29.4% (24.4-34.5%)	7.5 (5.3-10.7)
Male genitourinary abnormalities Cryptorchidism (XXY only)^ Hypospadias Chordee Penis length z-score <-2.0	 1.1% [51] 0.4% [52] 4.5% [53] 2.5%	 3.4% (1.4-5.5%) 1.3% (0-2.5%) 5.2% (2.7-7.6%) 3.4% (1.4-5.5%)	 2.2 (1.1-4.5) 3.0 (1.0-9.4) 1.3 (0.73-2.3) 1.7 (0.37, 8.0)
Strabismus	2.4% [54]	7.1% (4.3-10%)	3.3 (2.2-5.0)
Cardiac septal defects All SCT XXX Only XXY and XYY	0.45% [55]	 7.8% (4.8-10.8%) 15.8% (7.6-24%) 5.2% (2.3-8%)	 17.3 (11.8-25.3) 35 (20.9-59) 11.4 (6.6-19.9)
Renal malformations All SCT XXX Only XXY and XYY	0.46% [56]	 4.5% (2.2-6.8%) 13.2% (5.6-20.8%) 1.7% (0-3.4%)	 10.1 (6.0-16.8) 29.2 (16.4-52.1) 3.8 (1.4-10.1)
Hypotonia	8% [57]	38.5% (33.1-43.9%)	3.9 (3.0-5.1)
Other minor dysmorphologies (epicanthal folds, increased intercanthal distance, clinodactyly, ear differences)	--	--	--

[a]Estimated general pediatric population based on cited literature references; SCT = sex chromosome trisomy
[b]Reported as a single value for the pooled SCT study cohort if there were no statistically significant differences between SCT conditions. Otherwise, results reported as pooled value followed by individual percentages or RRs by SCT condition.
^XYY prevalence not different than the general population

Positional Torticollis	3.9% [49,50]	29.4% (24.4-34.5%)	7.5 (5.3-10.7)	Targeted physical examination for identification Recommend tummy time, neck stretching exercises, and positioning Consider referral to physical therapy Consider referral for molding helmet if associated with plagiocephaly
Male genitourinary abnormalities Cryptorchidism (XXY only)^ Hypospadias Chordee Penis length z-score <-2.0	 1.1% [51] 0.4% [52] 4.5% [53] 2.5%	 3.4% (1.4-5.5%) 1.3% (0-2.5%) 5.2% (2.7-7.6%) 3.4% (1.4-5.5%)	 2.2 (1.1-4.5) 3.0 (1.0-9.4) 1.3 (0.73-2.3) 1.7 (0.37, 8.0)	Targeted physical examination for cryptorchidism, hypospadias, chordee, webbing, short phallus Referral to Pediatric Urology if abnormalities identified Consider infant testosterone therapy if stretched penile length < 2cm in term infant
Strabismus	2.4% [54]	7.1% (4.3-10%)	3.3 (2.2-5.0)	Targeted physical examination with awareness of possible pseudostrabismus related to epicanthal folds Referral to ophthalmology if present after 6 months of age
Cardiac septal defects All SCT XXX Only XXY and XYY	0.45% [55]	 7.8% (4.8-10.8%) 15.8% (7.6-24%) 5.2% (2.3-8%)	 17.3 (11.8-25.3) 35 (20.9-59) 11.4 (6.6-19.9)	Targeted cardiac examination Echocardiogram and referral to cardiology if abnormal findings
Renal malformations All SCT XXX Only XXY and XYY	0.46% [56]	 4.5% (2.2-6.8%) 13.2% (5.6-20.8%) 1.7% (0-3.4%)	 10.1 (6.0-16.8) 29.2 (16.4-52.1) 3.8 (1.4-10.1)	Renal ultrasound to evaluate for structural abnormalities Referral to pediatric nephrology and/or urology if structural defects found
Hypotonia	8% [57]	38.5% (33.1-43.9%)	3.9 (3.0-5.1)	Close monitoring of motor development due to increased risk for delays Referral for physical therapy if associated with delays Further neurologic evaluation if severe or asymmetric
Other minor dysmorphologies (epicanthal folds, increased intercanthal distance, clinodactyly, ear differences)	--	--	--	No clinical implications, reassurance to family

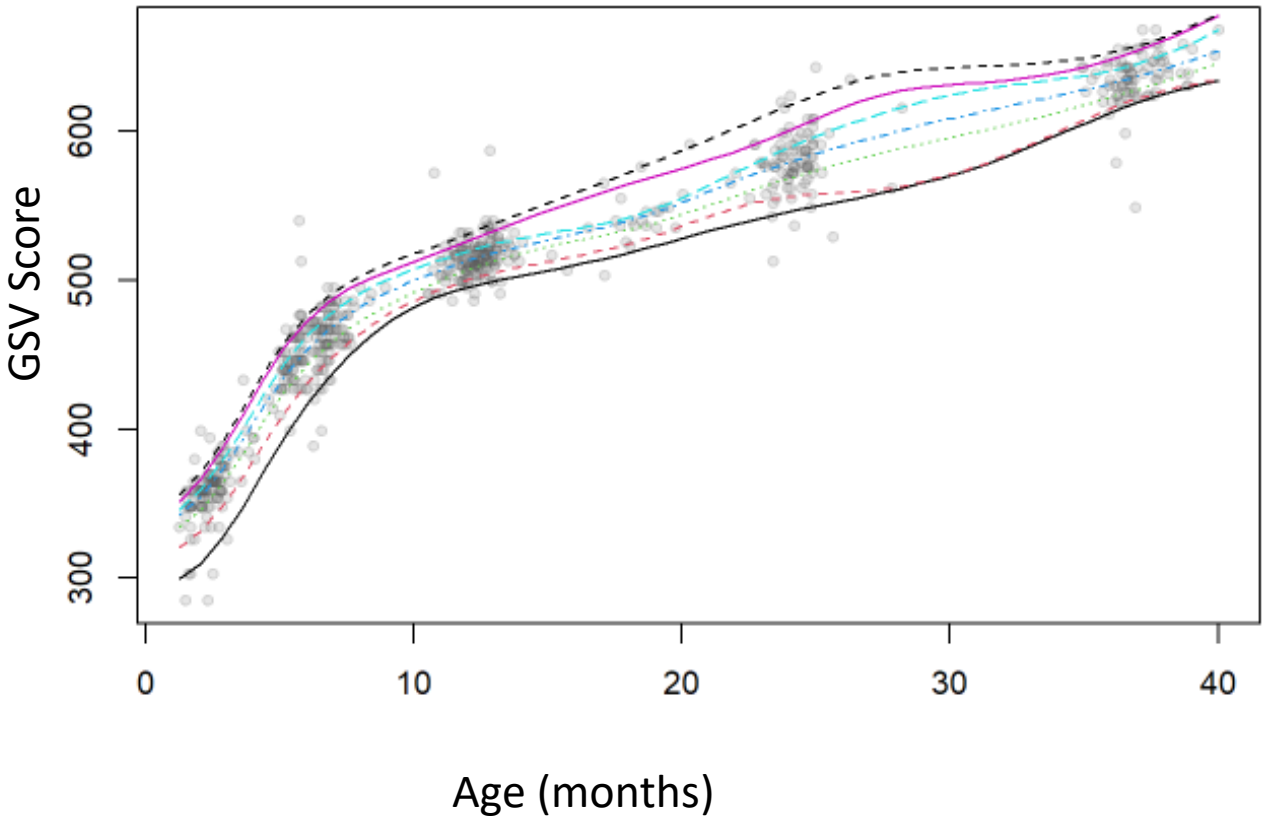
[a]Estimated general pediatric population based on cited literature references; SCT = sex chromosome trisomy
[b]Reported as a single value for the pooled SCT study cohort if there were no statistically significant differences between SCT conditions. Otherwise, results reported as pooled value followed by individual percentages or RRs by SCT condition.
^XYY prevalence not different than the general population

Developmental Testing Results

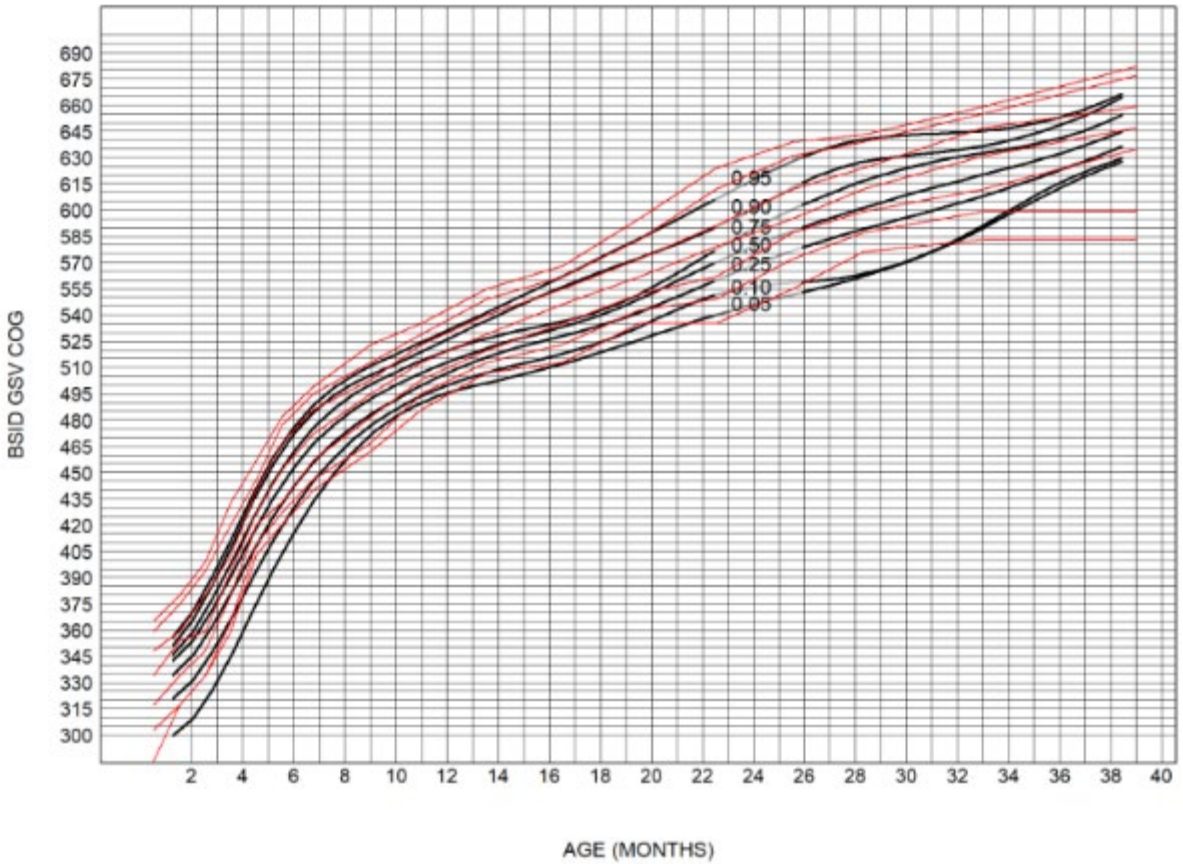


DEVELOPMENTAL GROWTH CURVES: COGNITIVE

Bayley Cognitive Subdomain
Growth Scale Value (GSV) Ability scores over time

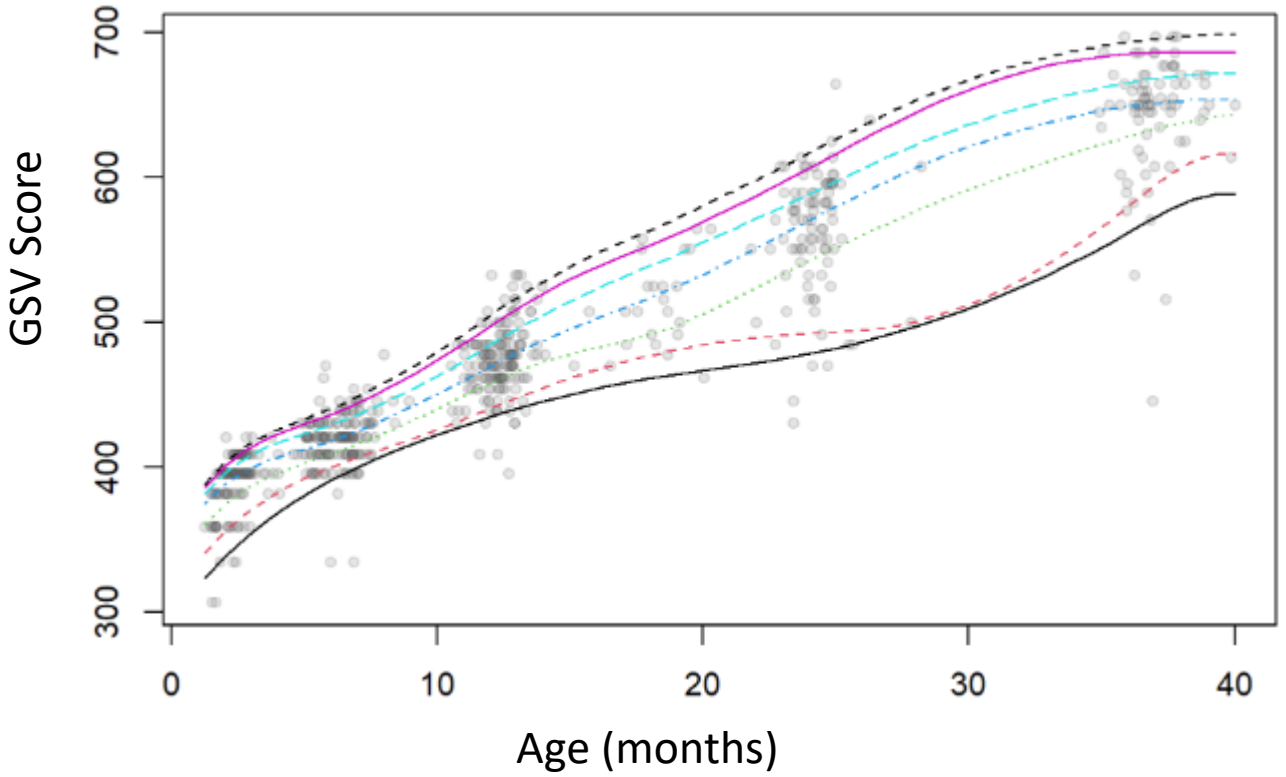


RED = General Population
BLACK = SCT



DEVELOPMENTAL GROWTH CURVES: LANGUAGE

Bayley Expressive Language Subdomain
Growth Scale Value (GSV) Ability scores over time



RED = General Population
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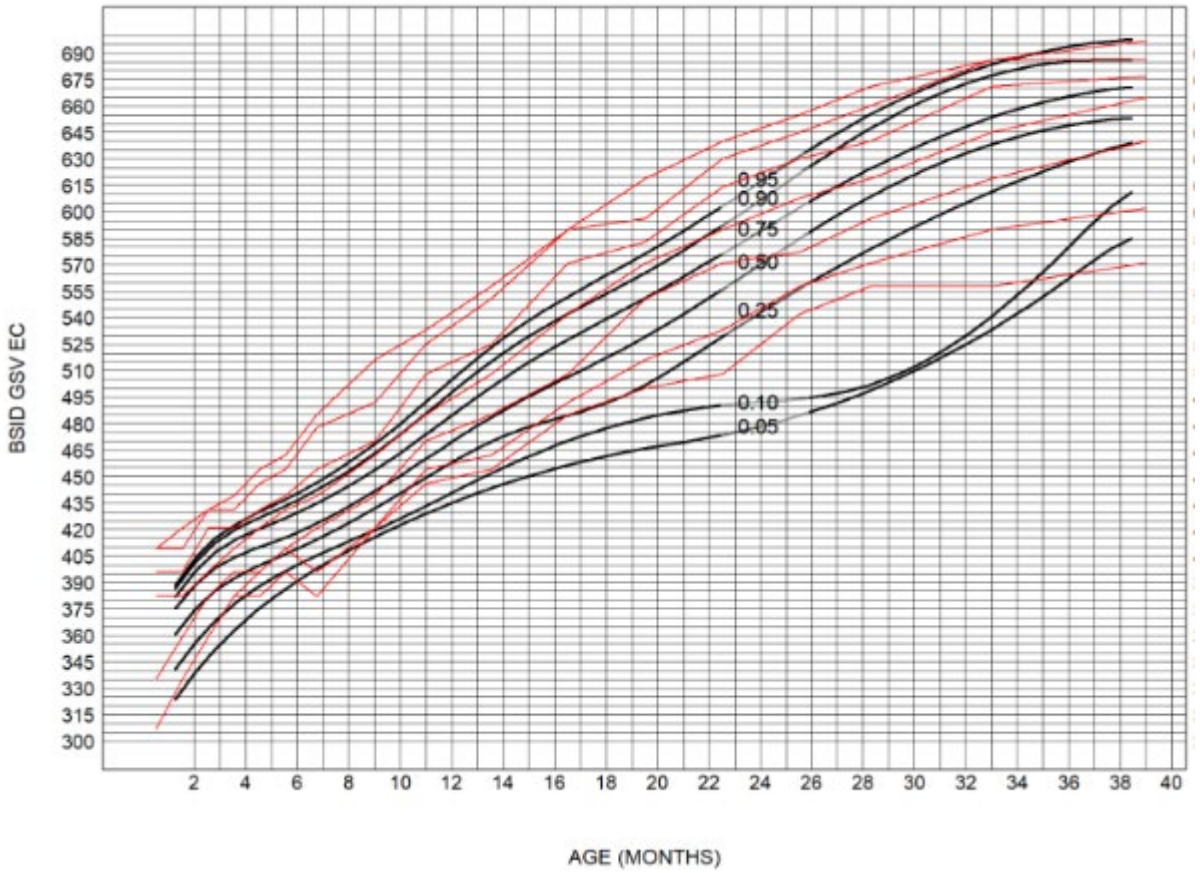
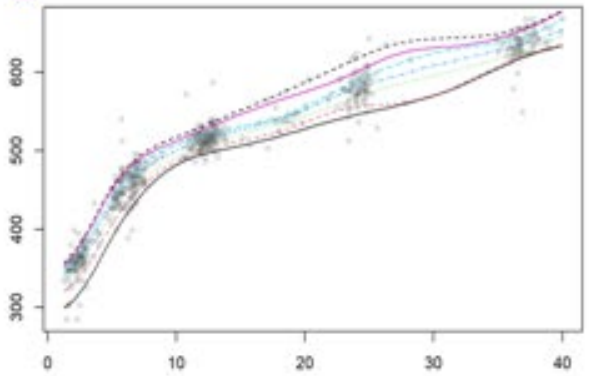
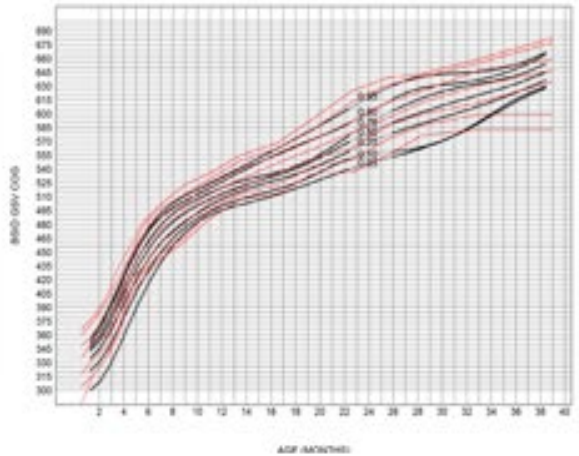


eXtraordinarY Babies SCT Developmental Growth Curves

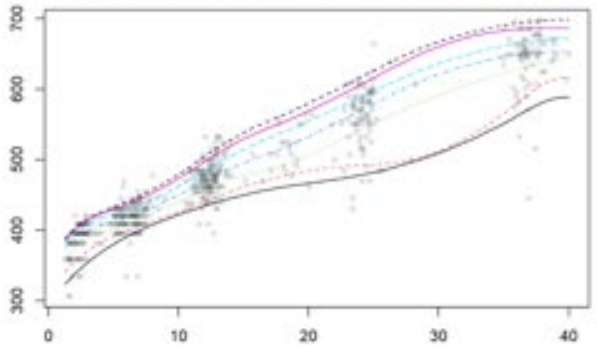
Black lines = SCT curves
Red lines = Normative sample

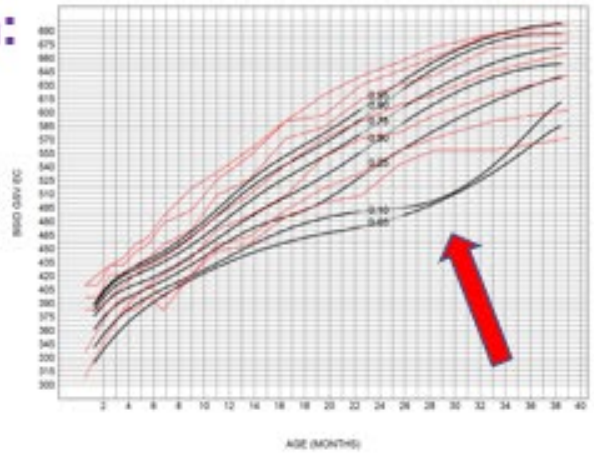
Cognitive:



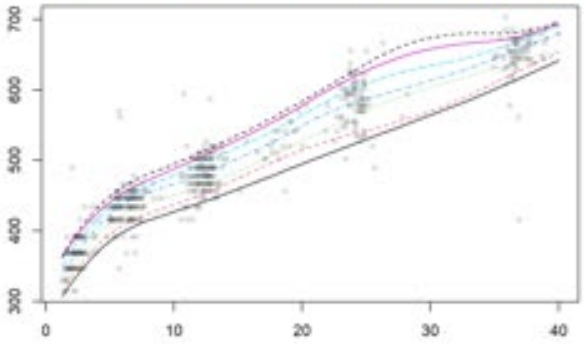


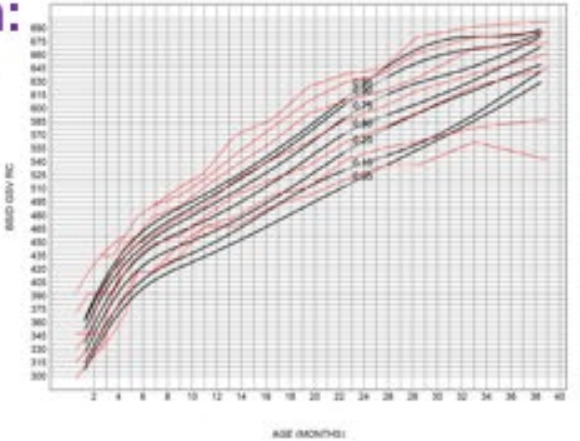
Expressive Communication:



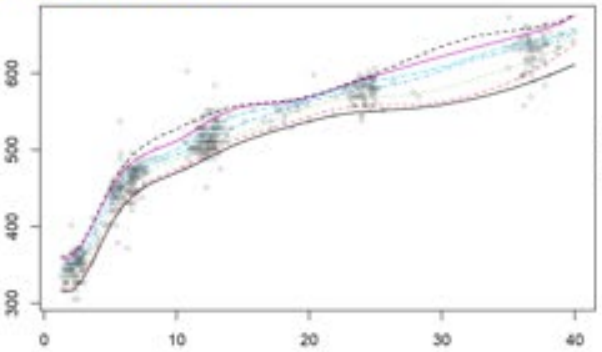


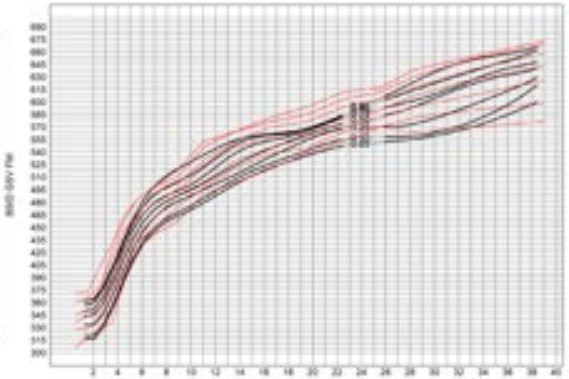
Receptive Communication:



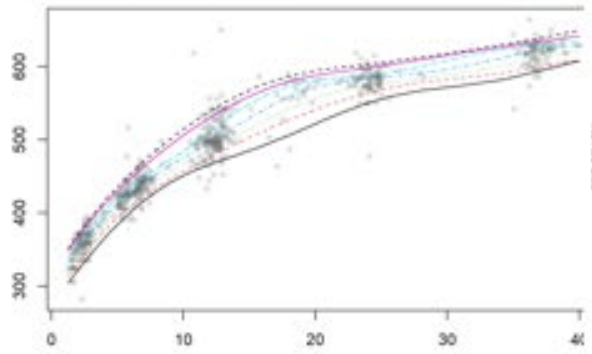


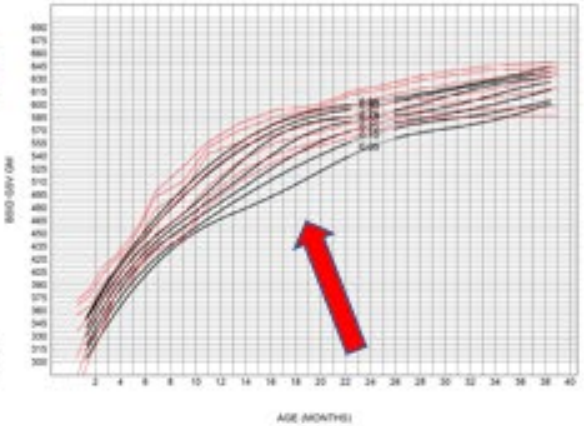
Fine Motor:





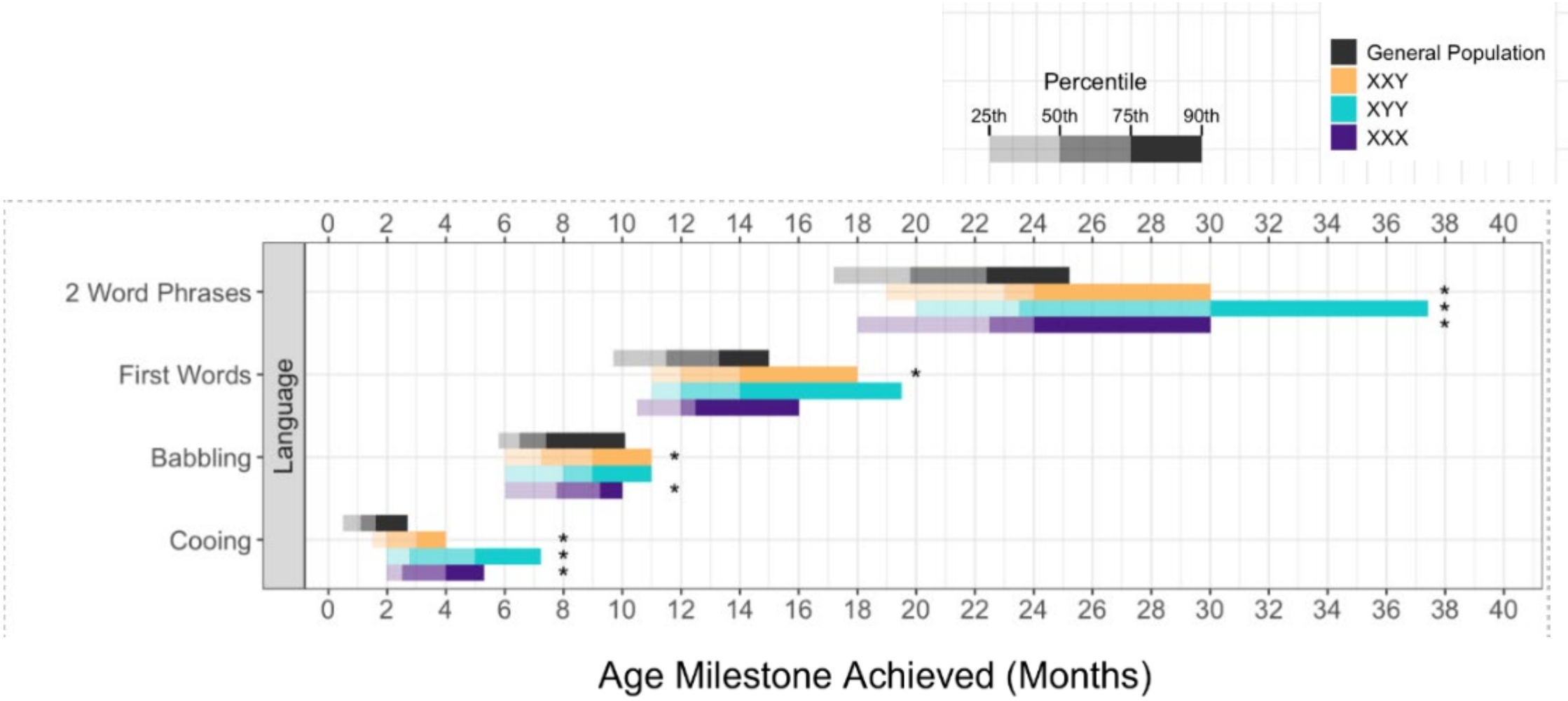
Gross Motor:



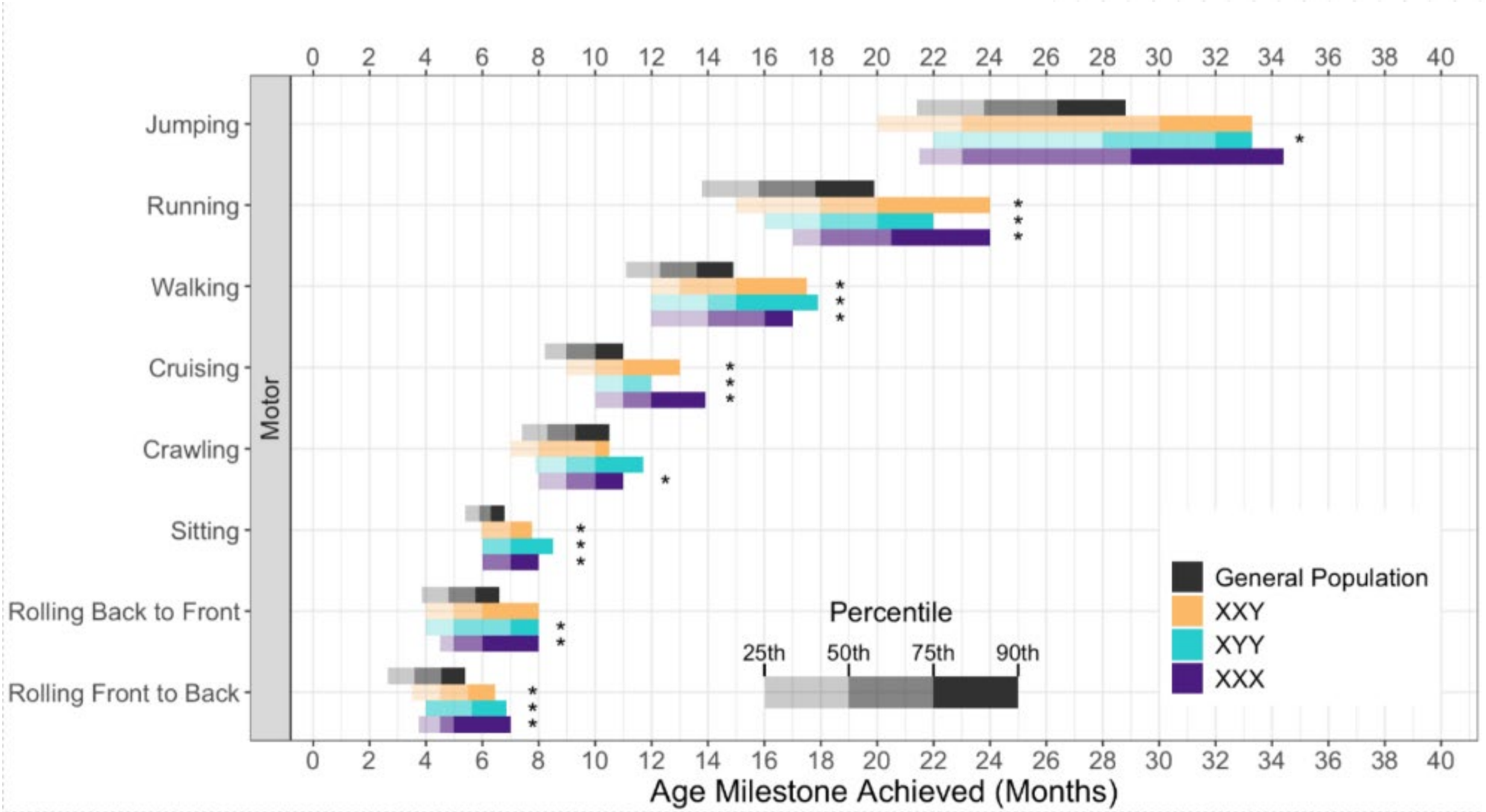


Black lines = SCT curves
Red lines = Normative sample

SCT Language Milestone Chart



SCT Motor Milestone Chart



Early Diagnosis of Developmental Delays

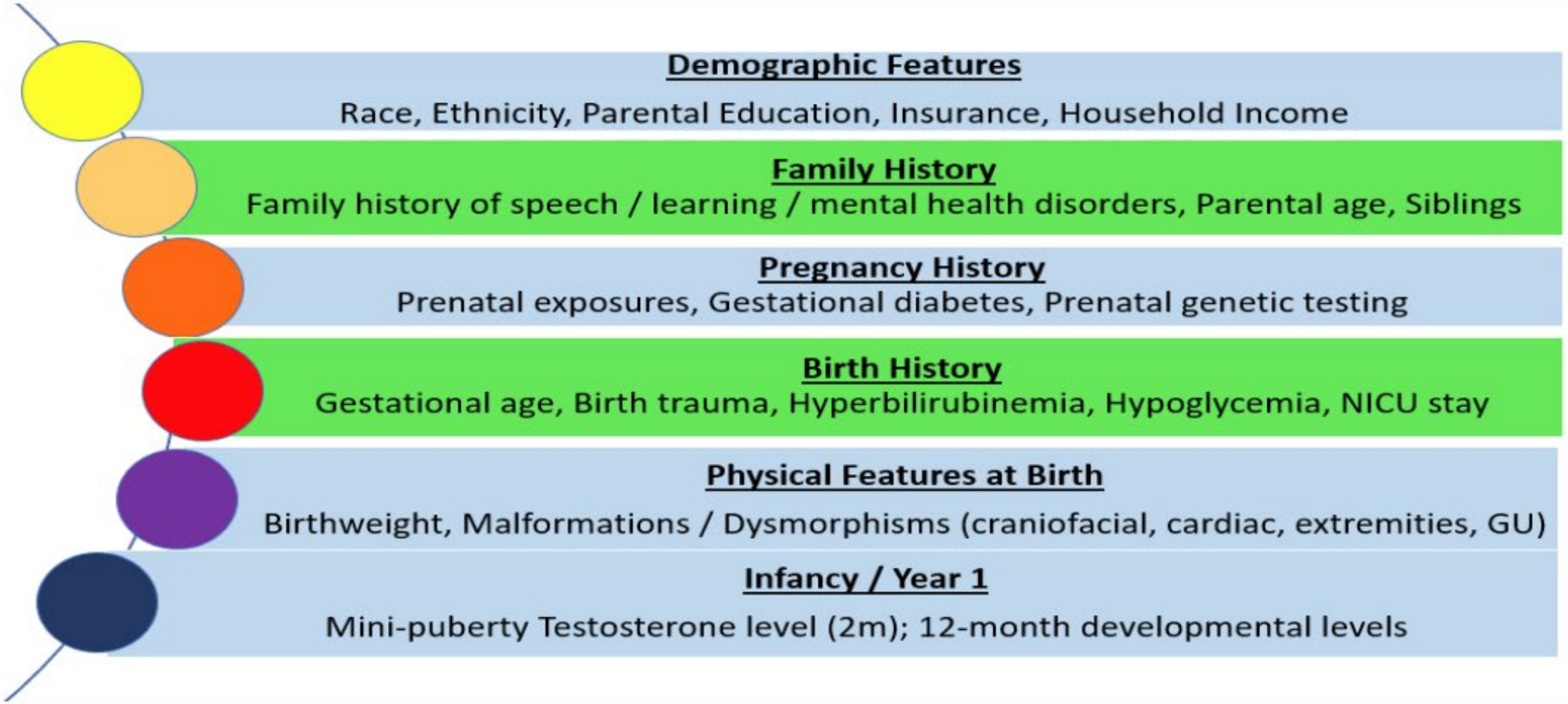
Are there predictors of which babies will have lower developmental outcomes?

- Identifying a high risk group to target with interventions / therapies

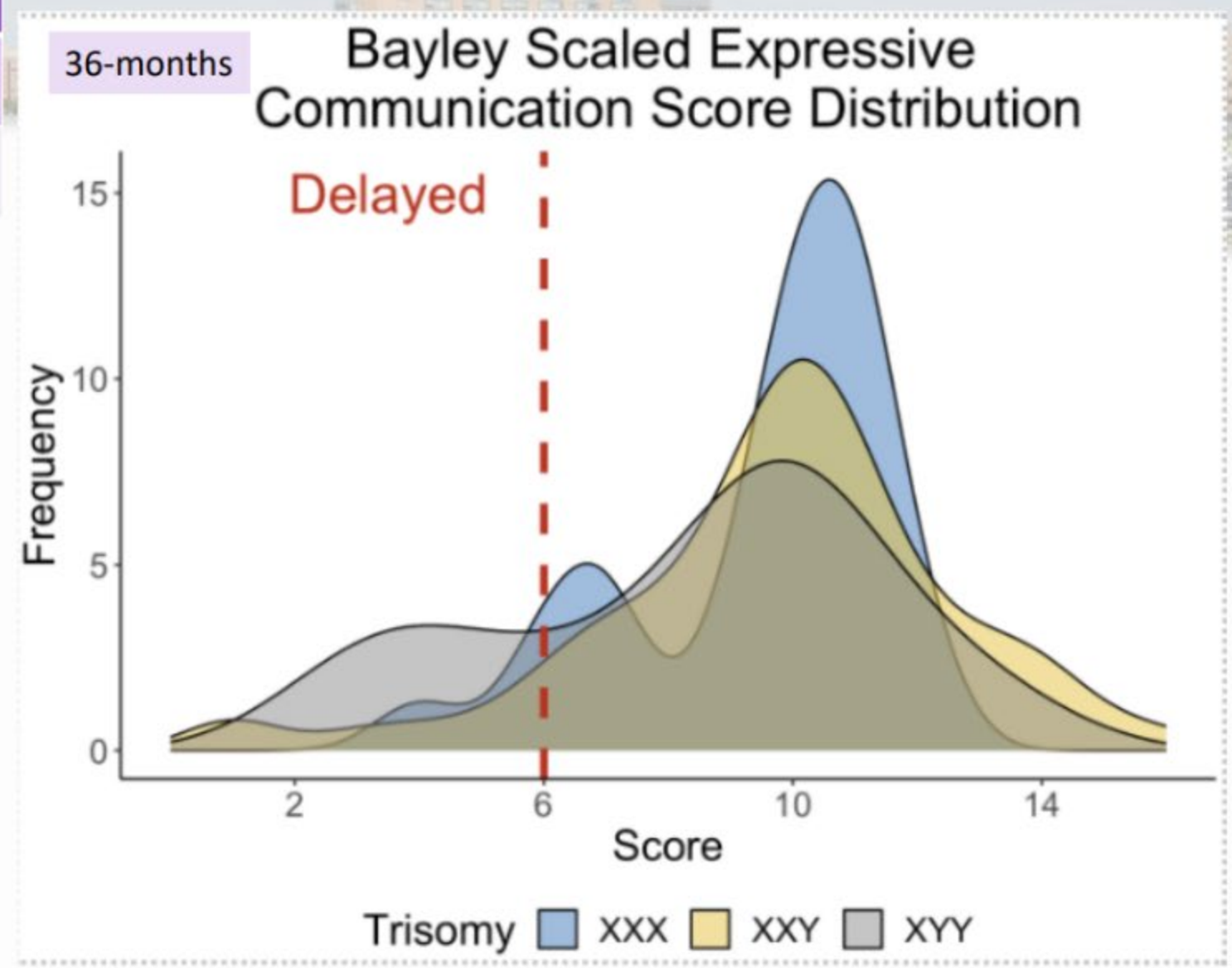
METHODS

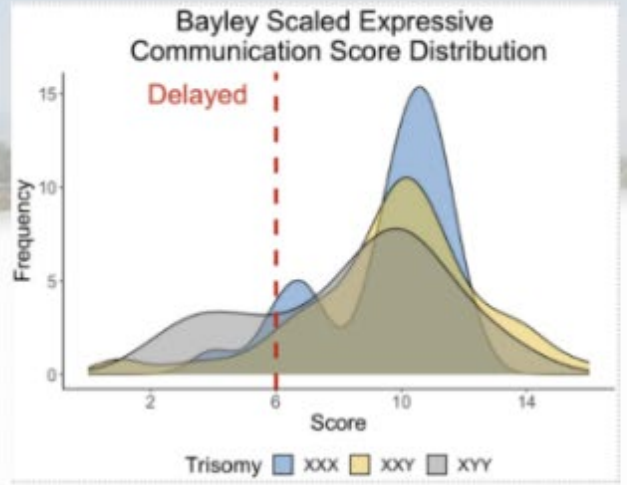
Primary Outcome: Bayley-3 Expressive Language & Gross Motor Scaled score at 36-months of age

Univariate Logistic Regression with variables:

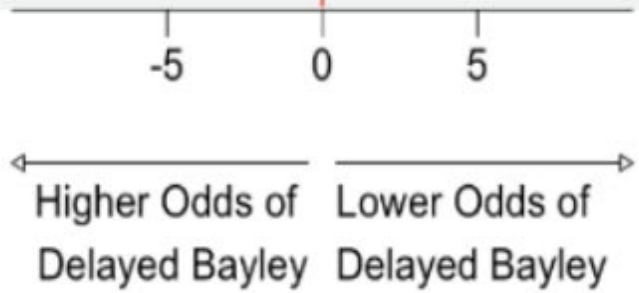


	All	XXY/KS	XXX	XYY
TOTAL ENROLLED	364	198	86	60
36-month Visit	214	143	43	21

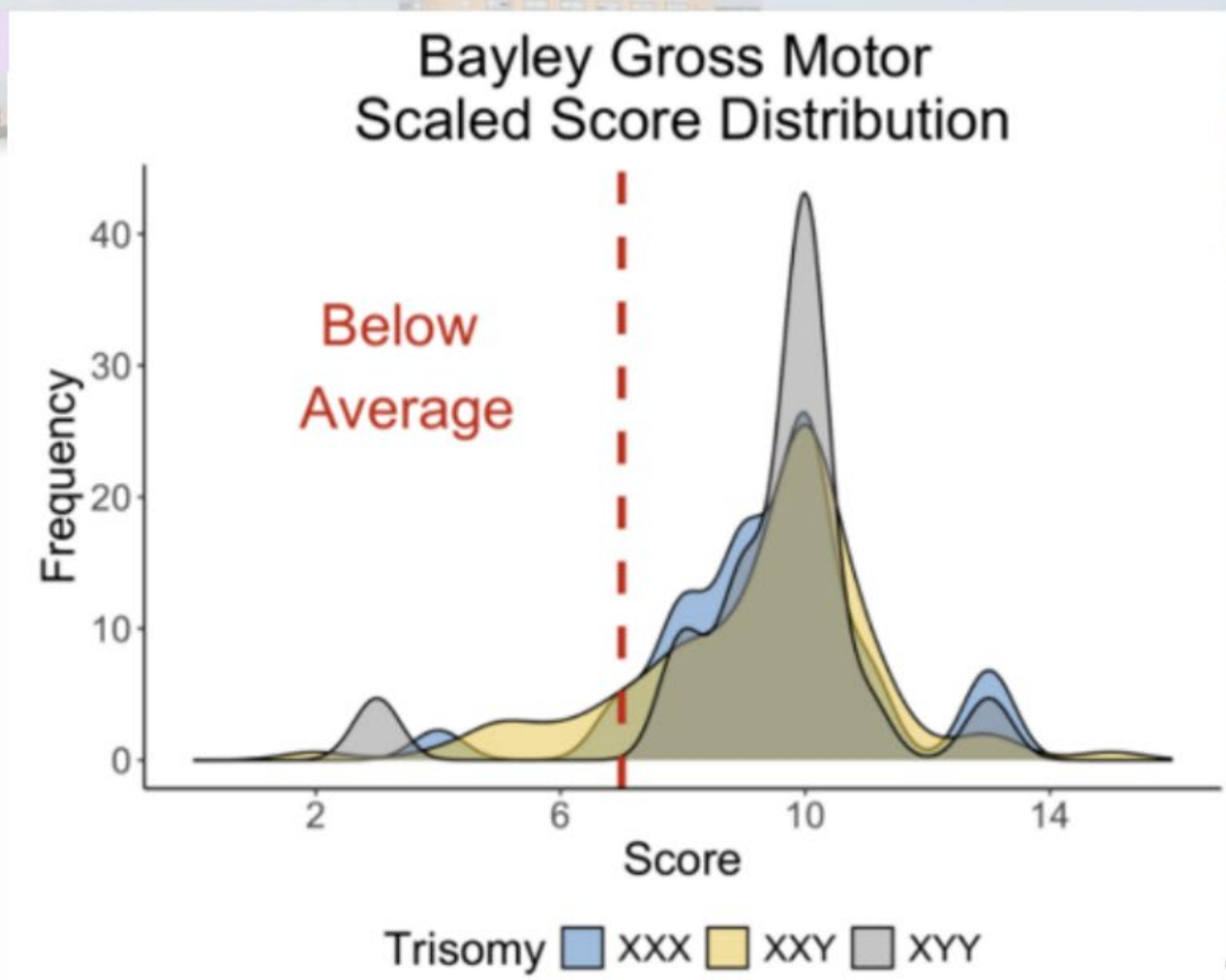


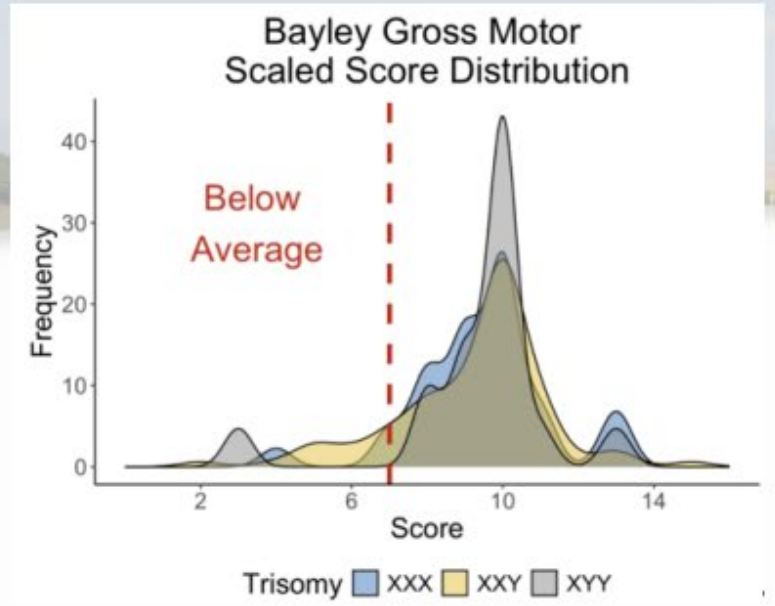


Variable	Log(Odds)	P-Value
Bayley 12 Month Expressive Communication Score		0.006
Prenatal Exposures (EtOH/tobacco/drugs/other toxins)		0.027
Special Education in a First Degree Relative		0.027
Ethnicity = Non-Hispanic or Latinx		0.025
Hollingshead Family		0.036

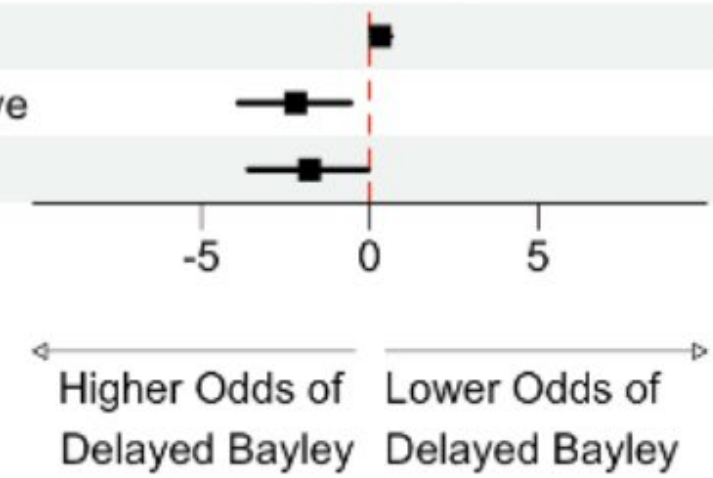


36-months

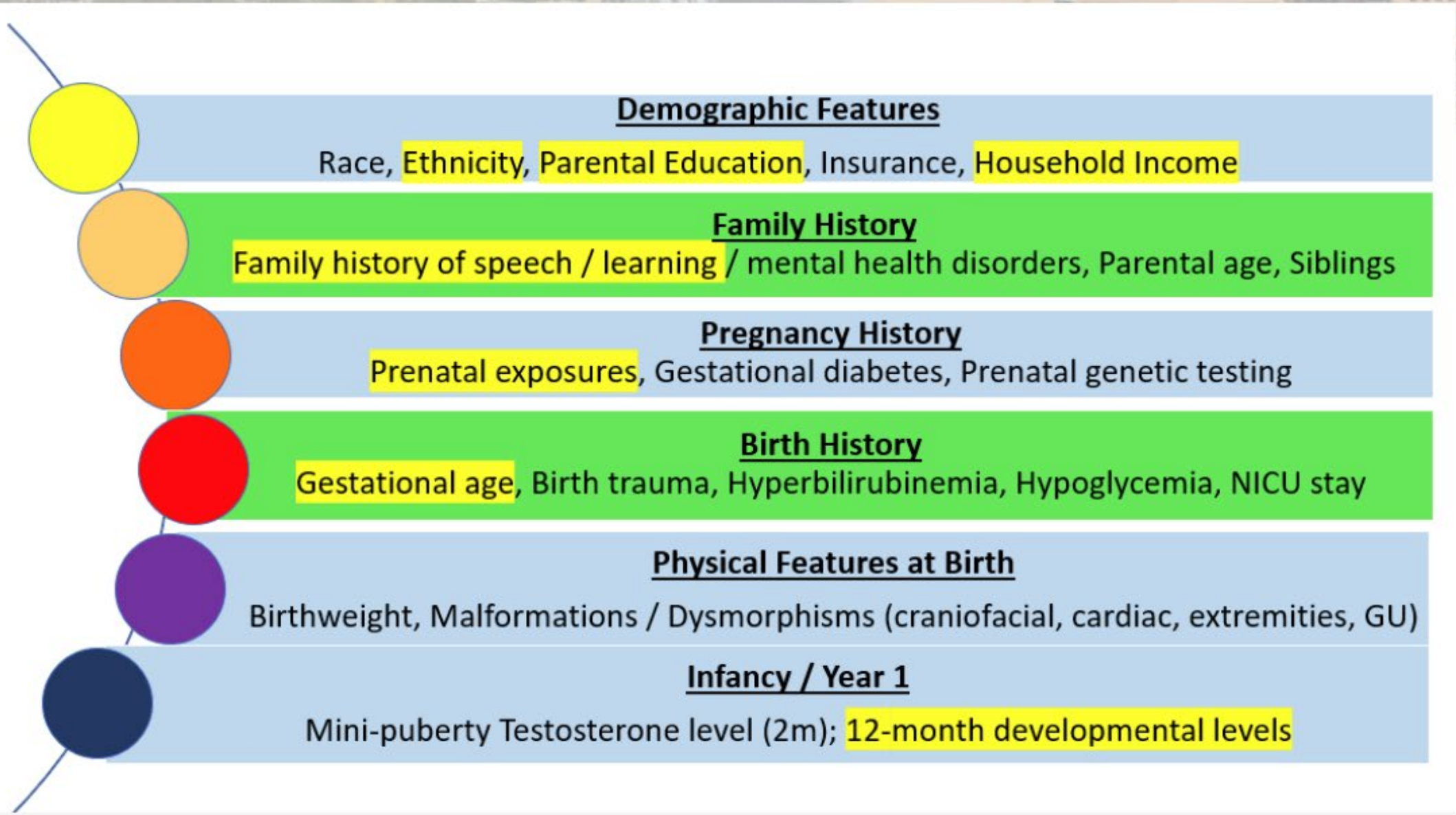

Bayley Gross Motor
Scaled Score Distribution
Below
Average
Frequency
40
30
20
10
0
2
6
10
14
Score
Trisomy
XXX
XXY
XYY



Variable	Log(Odds)	P-Value
Bayley 12 Month Gross Motor Score		0.017
Special Education in a First Degree Relative		0.007
Premature Birth		0.033



RESULTS

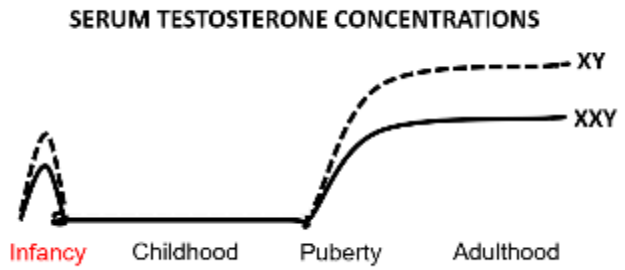

Demographic Features
Race, Ethnicity, Parental Education, Insurance, Household Income
Family History
Family history of speech / learning / mental health disorders, Parental age, Siblings
Pregnancy History
Prenatal exposures, Gestational diabetes, Prenatal genetic testing
Birth History
Gestational age, Birth trauma, Hyperbilirubinemia, Hypoglycemia, NICU stay
Physical Features at Birth
Birthweight, Malformations / Dysmorphisms (craniofacial, cardiac, extremities, GU)
Infancy / Year 1
Mini-puberty Testosterone level (2m); 12-month developmental levels

Summary:

- Developmental profiles in SCTs with prenatal identification have significant overlap with the general population
- Variables associated with delayed expressive language and gross motor skills are commonly known risk factors:
  - Background genetics, prenatal exposures, prematurity, etc.
- In XXY, early testosterone levels do not seem to be associated, but more analyses are needed
- 12-month developmental levels do predict later outcomes, suggesting targeting those with delays at 12 months as a high-risk group

WHAT ABOUT TESTOSTERONE IN INFANCY?

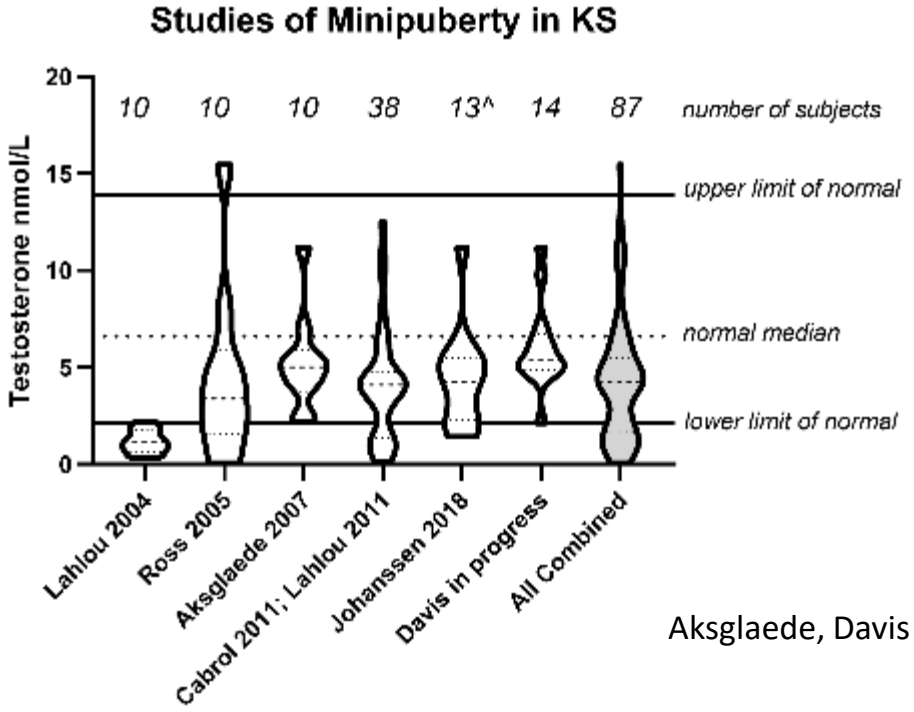
Shanlee Davis, MD, PhD



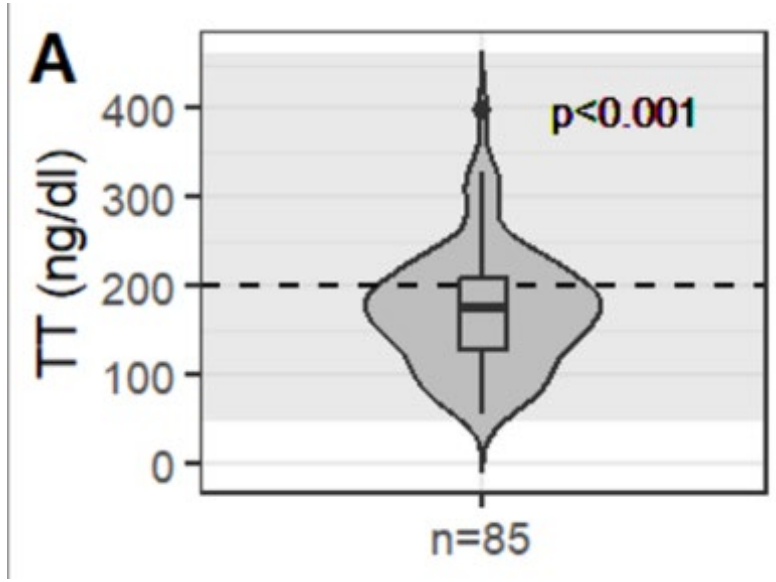
- Shorter penile length (but <5% have micropenis)
- Lack of penile growth in year 1
- Mini-puberty surge may be lower

Baby study cohort n=85

median age 2.3 months (range 1-3.6 months)



Aksglaede, Davis et al, 2020



TESTOSTERONE TREATMENT IN INFANCY?

- Retrospective study has reported boys with 47,XXY who received testosterone in infants have:
  - Higher cognitive ability
  - Higher fine motor and coordination abilities
  - Higher expressive and receptive language abilities
  - Better reading skills
  - Better social skills
  - Lower parent-reported behavior concerns
  - *Is this due to testosterone or other confounders?*

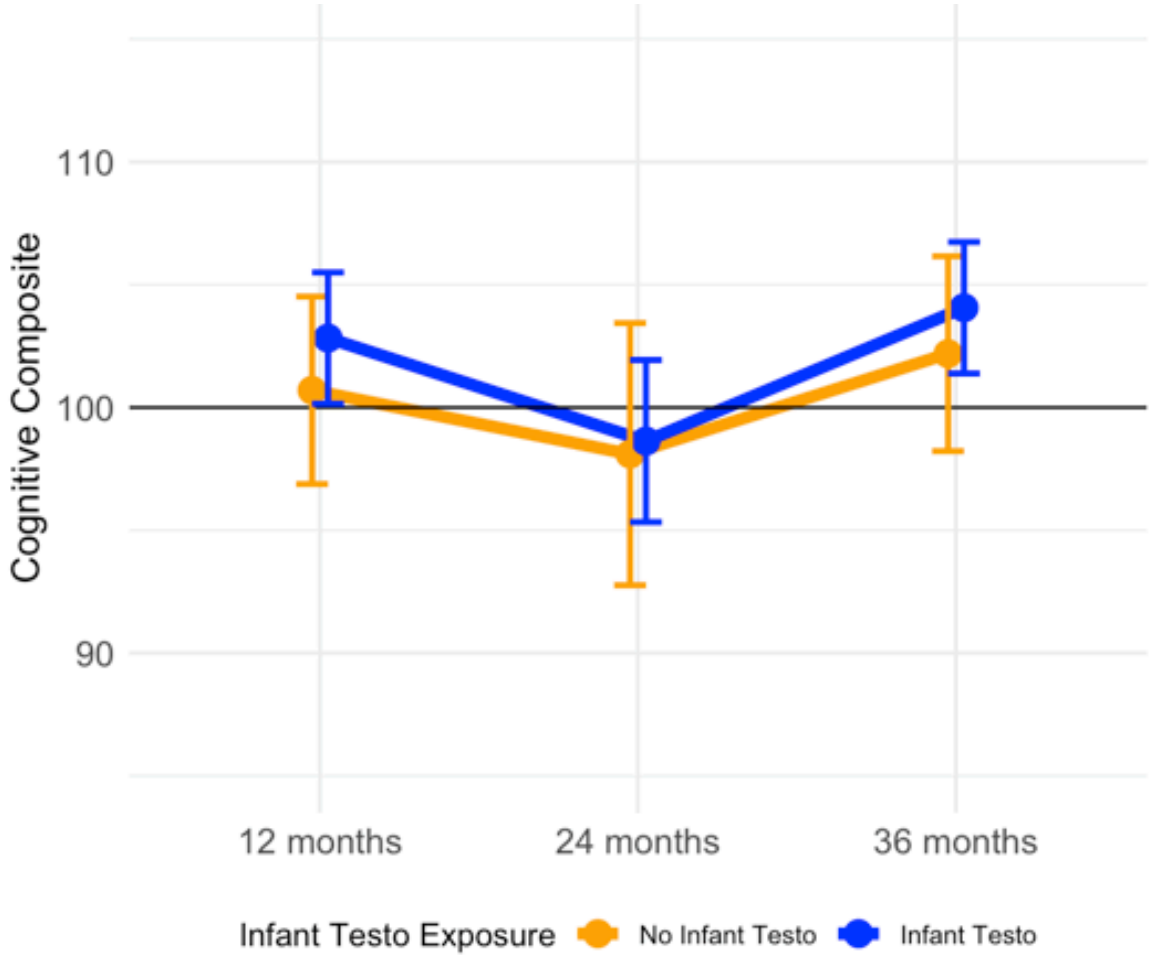
Samango-Sprouse et al, 2013, 2015, 2019, 2020, 2021, 2023

Demographic and Exposure Variables

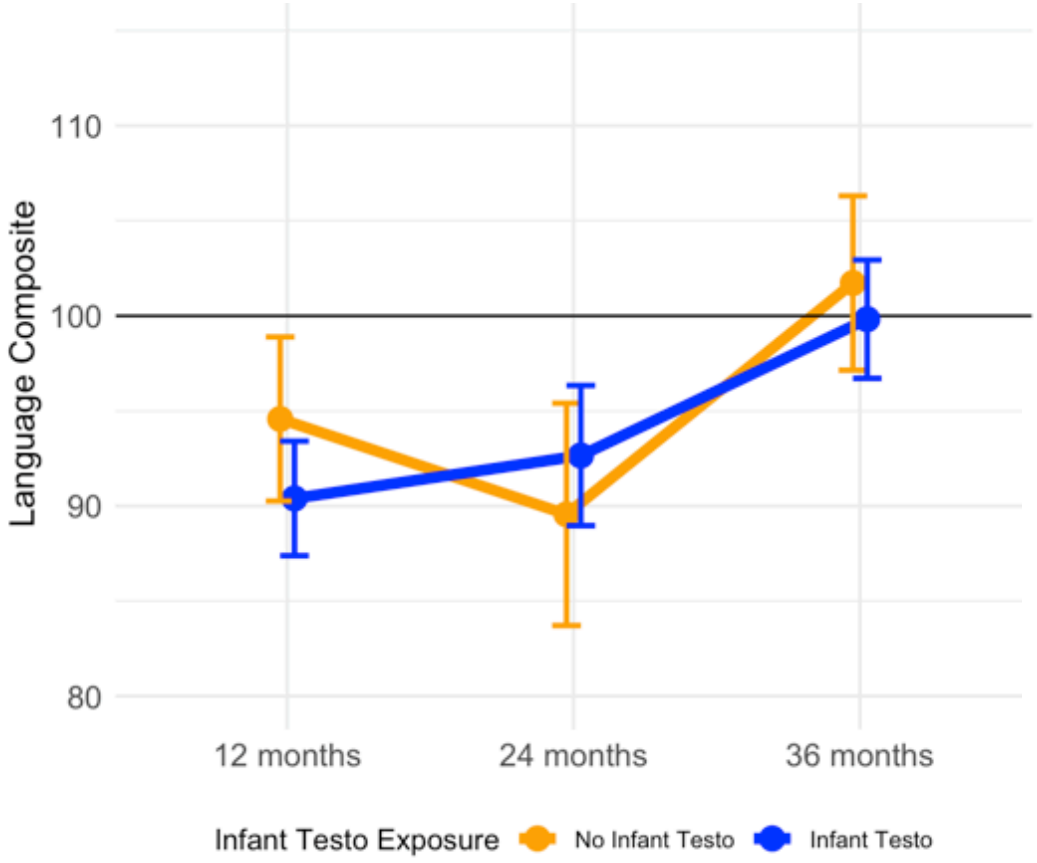
	Testo (n=105)	No Testo (n=55)	p-value
Nemours Site	23.8%	34.5%	0.208
Race: White	79%	83.6%	0.868
Ethnicity: Hispanic	16%	11%	0.505
Hollingshead Index	**53.9 (9.6)**	**49.3 (9.4)**	**0.004**
Breast milk	**75%**	**53%**	**0.007**
Physical therapy (% yes)	47%	36%	0.279
Speech therapy (% yes)	**65%**	**46%**	**0.029**
Maternal IQ	**116 (13.5)**	**110 (16.6)**	**0.073**
Paternal IQ	**119 (12.8)**	**108 (13.3)**	**0.016**

Outcome: BSID3 Cognitive Composite

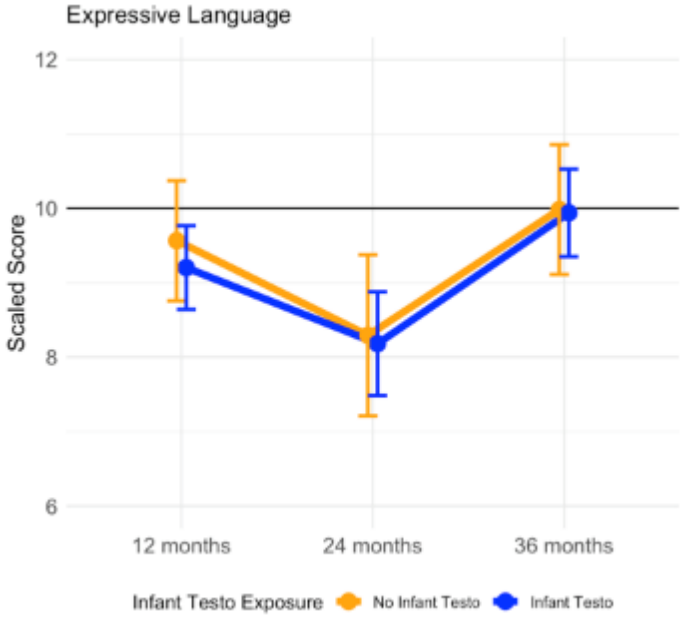
- Unadjusted at 12, 24, 36m:
  - 3 points higher at 12m (p=0.046)
  - Insignificant at 24 and 36m
- Adjusted model: p=<0.001
  - Infant T: 2.1 [-1.7, 6.1], p=0.30
  - T*time: p=0.63 and p=0.92
- *No effect of T on cog composite*
- *No effect of T on cog composite trajectory; any effect of T is not time-dependent*

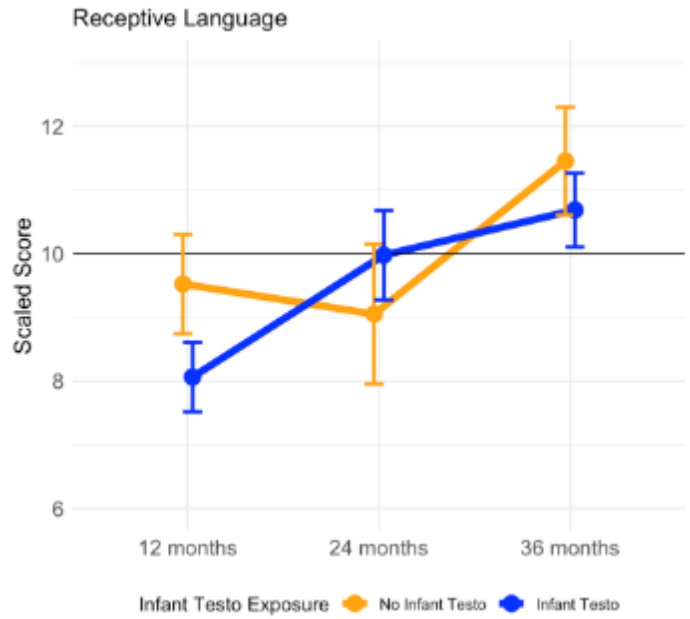


Outcome: BSID3 Language

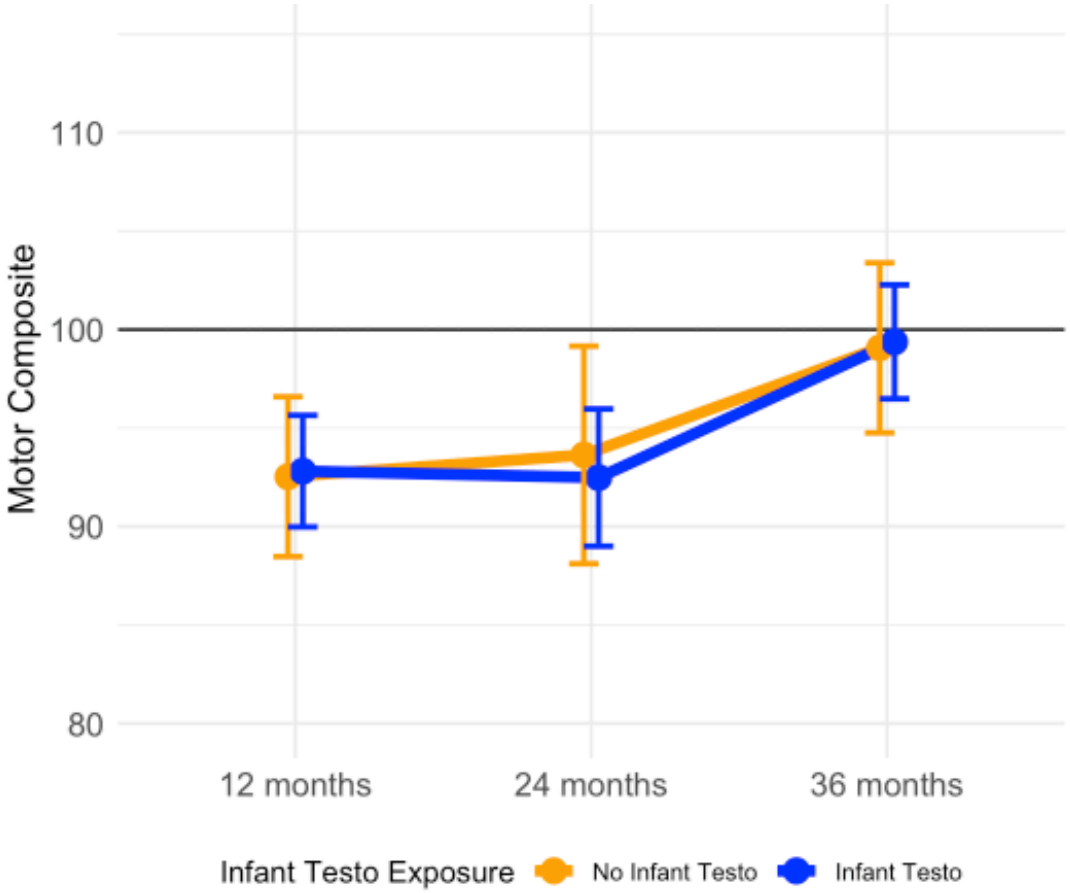


- Adjusted language model:
  - Infant T: -4.2 [-8.6, 0.21], p=0.07
  - T * time: p=0.04 and p=0.46
- *Borderline negative effect of T on language composite*
- *Potential effect of T on the trajectory?*

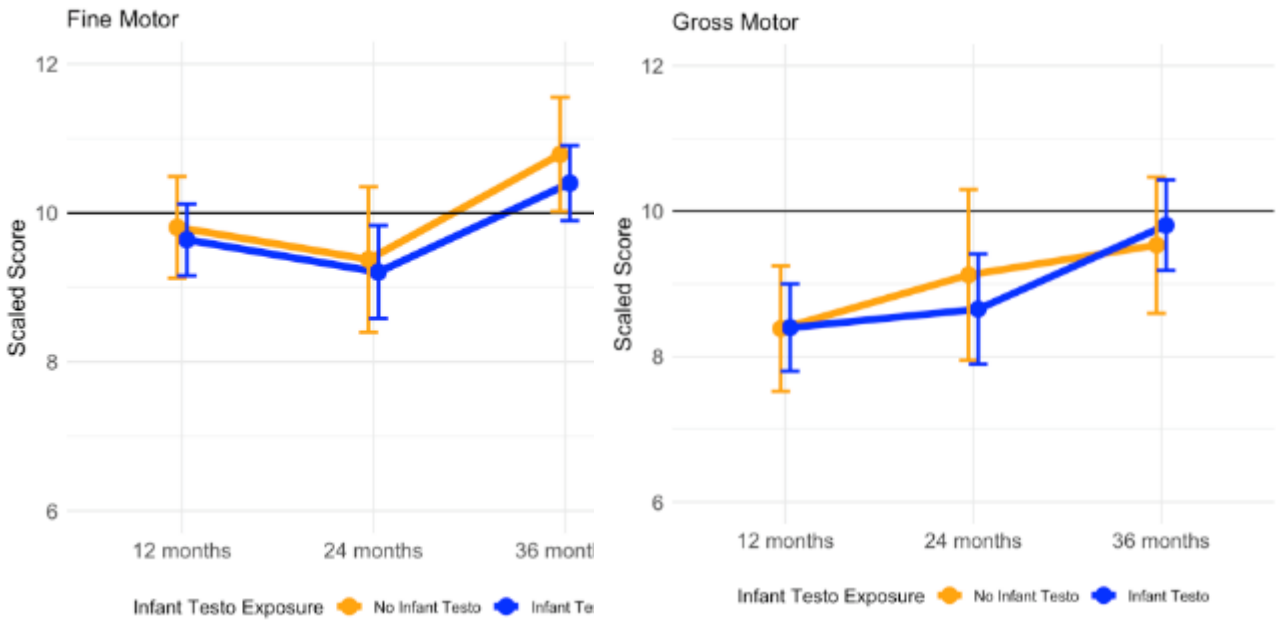




Outcome: BSID3 Motor



- Adjusted motor model:
  - Infant T: 0.28 [-3.8, 4.4], p=0.89
  - T * time: p=0.67 and p=0.99
- *No effect of T on motor composite*
- *No effect of T on the trajectory*



SUMMARY OF RESULTS

The group of infants with 47,XXY receiving testosterone have protectant features at baseline

No effect of testosterone on directly assessed (Bayley) or parent-reported (Vineland) development in the first 3 years of life

No effect of testosterone on the developmental trajectory in the first 3 years of life

The 95% CI for the maximal beneficial effect of infant testosterone on any neurodevelopmental outcome within the first 3 years of life is <5 points

What about XXYY? (n=15)

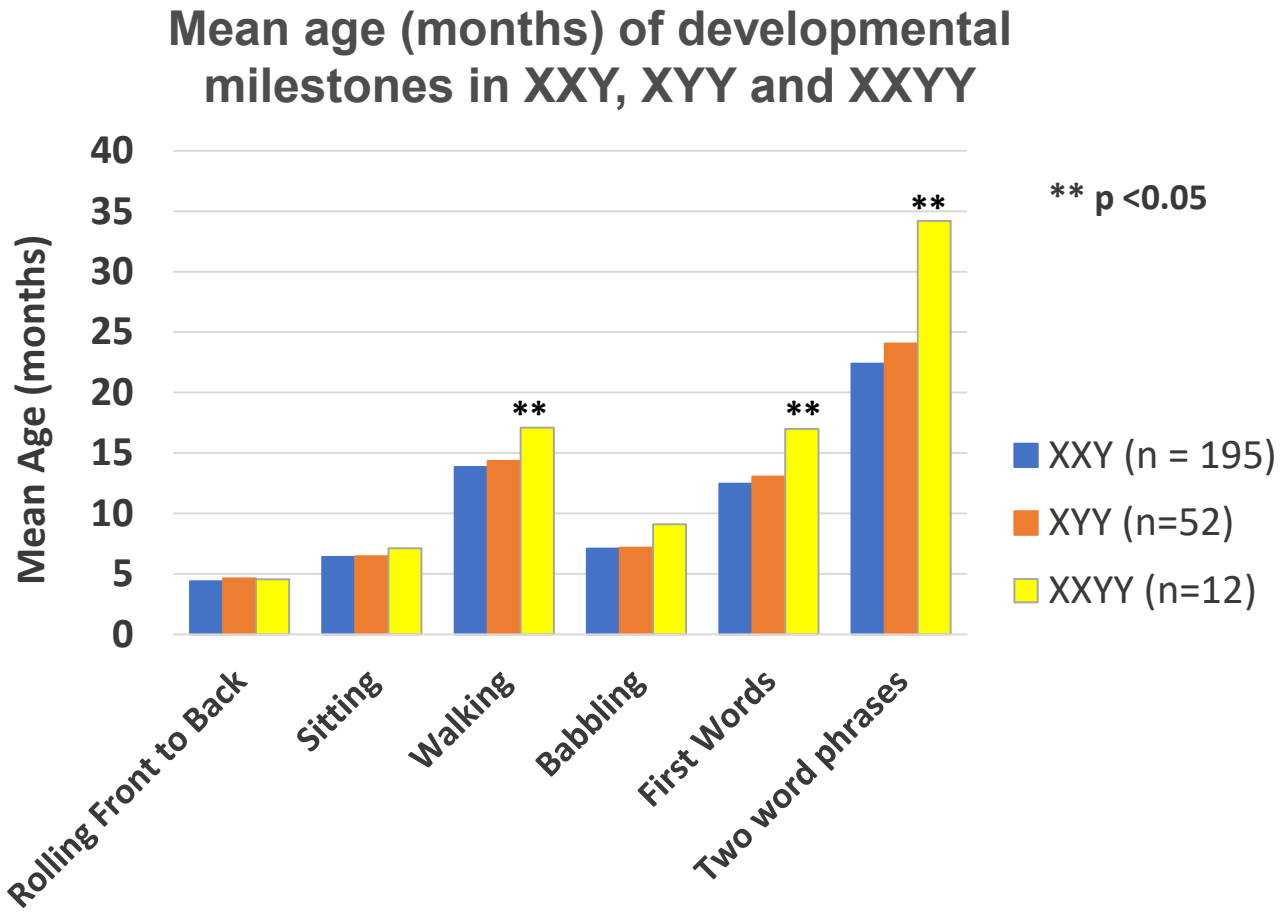
- Come to Kayla's poster!!!

Medical Problems & Physical Features from Birth to 12 months

	XXYY	XXY	XYY	p
n	12	172	25	
Breastfeeding Problems (%)	92.0	50.0	44.0	0.014*
Allergies				
Food/Formula Allergies	41.7	22.1	24.0	0.301
Environmental/Seasonal Allergies	33.3	7.0	12.0	0.008*
Eczema	33.3	52.9	40.0	0.233
Reactive Airway Disease	33.3	2.3	4.0	<0.001*
Otitis Media	50.0	26.7	32.0	0.210
Preauricular Ear Tag	16.6	5.0	0	0.006*
Bronchiolitis	50.0	15.7	12.0	0.007*
Pneumonia	8.3	3.5	0	0.644
Gastroesophageal Reflux Disease	66.6	38.4	24.0	0.043*
Constipation	25.0	32.0	40.0	0.616
Failure to Thrive (FTT)2	33.3	15.1	8.0	0.132
Strabismus	8.3	6.4	4.0	0.855
Torticollis	41.7	30.2	24.0	0.542
Plagiocephaly	16.7	22.1	12.0	0.424
Cardiac ASD or VSD3 – echo subset (n=87)	25.0	21.4	25.0	0.475
Inguinal Hernia	8.3	0.6	0	0.037*
Congenital Hip Dislocation / Dysplasia	8.3	0.6	4.3	0.047*
Cleft Lip / Palate	8.3	0.6	0	0.037*
Hypotonia	58.3	33.7	20.0	0.048*
Febrile Seizure	0	1 (0.6)	0	0.891
Epilepsy	0	0	0	NA
Cryptorchidism	8.3	63.5	4.0	0.699
Any hospitalization	33.3	12.1	28.0	0.017*

XXYY Developmental Milestones

- Early milestones of rolling and sitting are similar between groups
- Milestones of walking, first words, and 2-word phrases later in XXYY
- Most significant difference in XXYY is in acquisition of 2-word phrases (35 months)



XXYY Walking:
Mean 17.1 months (range 16-20 months)
Previous literature mean 18.0 months (range 12-33 months)

Other Projects:

- Infant Temperament (Louderman)
- Early Social Development / Autism features (Wilson)
- Executive Functioning profiles (Janusz / Jolliffe)
- Cognitive & Adaptive Trajectories (Janusz)
- Language outcome measures as predictors / screening measures (George)
- Metabolomics (Davis)
- XXYY syndrome prenatal diagnosis phenotype (Nocon)
- “Aim 3” – Genetic counseling experiences qualitative project (Howell, Molison, Thompson)

Family Resources for X&Y Variations

- New Book! “What you Need to Know When You Are Expecting or Have a New Baby with XXY” available on Amazon.com

- Trisomy X in progress
- XYY next
- Need $$

QUESTIONS?