



The National Children's Study

全米子供調査

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Converging Concerns

収束する懸念



- Children are especially vulnerable to environmental exposures (e.g. lead, alcohol)

子供達は環境曝露に対して特に脆弱である(鉛、アルコールなど)

- Current known exposures of concern abound (pesticides, phthalates, violence)

現在懸念されている曝露対象物は数多い(殺虫剤、フタレート類、暴力など)

- Many high burden conditions with suspected environmental causes (e.g. birth defects, learning disabilities, autism)

環境原因が疑われる高負荷な状況が多い(先天性異常、学習障害、自閉症など)

- Existing research is limited in size and scope

既存研究は規模・範囲共に限られている

- Life-course (longitudinal) design needed to correctly link with multiple exposures and multiple outcomes

複数の曝露と成果を正しく連携するには生涯(縦方向)研究設計が必要



Directives that Created the National Children's Study 全米子供調査の発足に繋がった指令



■ The Children's Health Act of 2000

2000年の小児保健法

- ...authorize NICHD to conduct a national longitudinal study of environmental influences on children's health and development.

NICHDに小児保健と発達に関する環境影響を研究する縦方向の国家的調査を実施する許可を与えた。

- ...from birth to adulthood

出生児から成人まで

- investigate mechanisms of developmental disorders and environmental factors...that influence health and developmental processes...

発達障害のメカニズムと健康と発達過程に影響する環境要素の調査



Study Concepts

研究理念



- Hypothesis driven
仮説に基づく
- Exposure begins with pregnancy
曝露は妊娠期間から始まる
- Has power to study high priority conditions (n~100,000)
高優先度の状態を研究する力を有する(n=~100,000)
- Gene environment interaction
遺伝子環境相互作用
- Consortium of Federal Agencies
連邦政府機関の共同機関
- Public-private partnerships
官民連携
- National resource for future studies
将来の研究のための国家資源



Planning Process: NCS

立案過程:NCS



- Interagency Coordinating Committee: NICHD, NIEHS, CDC, EPA
諸機関間協調委員会:NICHD、NIEHS、CDC、EPA
- Federally Chartered Advisory Committee*
連邦設立の諮問委員会*
- Expert Working Groups
専門家作業部会
 - Hypotheses
 - Measures/methods
- Workshops*
ワークショップ*
- Literature reviews/white papers*
文献調査・白書*
- Pilot Studies*
予備的研究*
- Program Office Staff
計画事務スタッフ
- Study investigators (CC and Study Centers)
・研究調査員(CCおよび研究センター)
 - **Findings on website: nationalchildrensstudy.gov**
 - ***ウェブサイトの結果を公表**



Planning Process: NCS

立案過程:NCS



■ Stake Holders in Children's Health

小児保健の利害関係者

- Pediatricians 小児科医
- Environmental Health Professionals: Epidemiologists
環境保健専門家:疫学者
- Sociologists 社会学者
- Psychologists 心理学者
- Economists 経済学者
- Ethicists 倫理学者
- Advocacy Groups 権利擁護団体



Examples of Hypotheses Defining Questions

疑問を定義する仮説の例



- What are the health and developmental effects of persistent low level chemical exposures?

持続性低濃度化学物質曝露の健康および発達への影響とは？

- How is asthma incidence and severity influenced by the interaction of early life infection and air quality?

早期の感染や空気品質は喘息発病率と重篤度にどのような影響を及ぼすか？

- How does high level exposure to media content in early childhood affect development and behavior in children?

小児期早期のメディア情報への高い曝露により子供達の発育および行動はどのように影響されるか？

- Do pre-and post-natal exposures to endocrine-active environmental agents alter age at onset, duration, and completion of puberty?

内分泌系活性環境作用物への出生前および出生後曝露により春機発動期の開始年齢、継続期間および終了年齢に影響するかどうか？



Priority Health Outcomes/Exposures

健康への影響と曝露の優先事項



Priority Exposures	Examples
Physical Environment	Housing quality, neighborhood
Chemical Exposures	Pesticides, phthalates, heavy metals
Biologic Environment	Infectious agents, endotoxins, diet
Genetics	Interaction between genes and environment
Psychosocial milieu	Family structure, socio-economic status, parenting style, social networks, exposure to media and violence



Priority Health Outcomes	Examples
Pregnancy Outcomes	Preterm, Birth defects
Neurodevelopment & Behavior	Autism, learning disabilities, schizophrenia, conduct and behavior problems
Injury	Head trauma, Injuries requiring hospitalizations
Asthma	Asthma incidence and exacerbation
Obesity & Physical Development	Obesity, diabetes, altered puberty



Sampling and Center Strategies

サンプル採取とセンター戦略



■ National probability sample important

国家確度サンプルが重要

- Exposure-outcome relationship representative of the U.S. population

米国人口の曝露と影響の関連性についての代表値

- Important exposures with varied and unknown distributions are not missed

様々な分布不明の曝露の重要性も見逃さない

- Clustered for community attributes & logistics

地域特性や物流によりグループ化

■ Centers of Excellence important

卓越した研究拠点の重要性

- Broad scientific input

広範囲に渡る科学的情報

- Measures require center based expertise and facilities

センターを基盤とする専門知識および技術を必要とする手段



Sampling and Center Strategies

サンプル採取とセンター戦略



■ Probability sample by Centers

各センターによる確度サンプル

■ Unique combination

独自の組み合わせ

■ Requires flexibility and adaptation of center to the scientific design

各センターによる柔軟性と研究設計への適用が必要

■ Requires support and guidance by coordinating center

調整センターによる支援・指導が必要



Sites vs. Centers

拠点対センター



- Sites—geographic locations (counties) from which participants will be recruited
拠点—参加者を募る地理的位置(国)
 - Selected by stratified probability sample of primary sampling units
初期サンプリンググループの層化確度サンプルにより選択
 - 105 sites
105拠点
- Centers—entities or institutions that will carry out study at the sites
センター—各拠点において研究を実施する主体または機関
 - Selected by a competitive process
競争的過程により選択
 - Each will cover more than one site
各センターが1以上の拠点を担当
 - 30-50 centers
30～50センター



National Children's Study Locations

全美子供調査拠点



Map Legend

- ◆ 2008 Locations
- ★ 2007 Locations
- Vanguard Locations
- ⊙ 2009-2010 Locations

National Children's Study Sample

全米子供調査サンプル



All Births
in the Nation

~ 4 million
births in 3,141
counties

Sample of Study
Locations

105 Locations

Sample of Study
Segments

Selection of
neighborhoods

Sample of Study
Households

All or a sample of
households within
neighborhoods

Sample of Study
Women

All eligible women in
the household



Who will be enrolled?

登録対象者は？



- Household recruitment

家庭単位での募集

- Women who are in the first trimester of pregnancy
- Women who are planning a pregnancy
- Women of child bearing age who are not planning pregnancy but could become pregnant during the enrollment period

- Supplemental recruitment

補助的募集

- Prenatal care providers
- Community based recruitment of eligible women



Visit Schedule: Core Protocol

来訪スケジュール：中核プロトコル



Preconception (high probability) - one face to face visit, phone follow-up
受胎前(高確度)ー直接面談訪問

1st Trimester	3 years
2nd Trimester	5 years
3rd Trimester	8 years
Delivery Visit	12 years
6 months	16 years
12 months	20 years

 Clinical Setting

 Home



Sample Collected

採集サンプル



- DNA
- Environmental samples: air, water, dust from home, school
環境試料: 大気、水、ハウスダスト(家庭・学校)
- Biomarkers: blood, breast milk, hair, tissue, etc.
バイオマーカー: 血液、母乳、毛髪、組織など
- Interview and history
面談および経歴
- Cognitive measures
認知手段
- Serology and medical data
血清検査および診療データ
- Housing and living characteristics
住宅および居住特性
- Family and social experiences
家族および社会的経験
- Neighborhood, community, and school characteristics
近所、地域および学校の特徴



1st trimester visit

(T1) 妊娠第一期での来訪(T1)



- Interview

面談

- Environmental sample collection and observation

環境試料採取および観察

- Physical examination

健康診断

- Biospecimen collection

生体試料採取

- Ultrasound – gestational age dating

超音波検査－妊娠週齡決定



1st trimester visit Interview

妊娠第一期での面談



- Computer Assisted Personal Interview
コンピューター支援型個人面談
- Audio-Computer Assisted Self Interview
音声・コンピューター支援自己面談
- Self-Administered Questionnaires
自己記入アンケート



T1 Interview Topics

T1面談の題目



- Demographics
人口統計
- Current pregnancy Hx
現妊娠Hx
- Reproductive Hx
生殖Hx
- Medical conditions
健康状態
- Health behaviors
健康に関する行動
- Healthcare provider visits
医療介護提供機関
- Medicines/supplements
薬剤・栄養補助
- Housing characteristics
住居特徴
- Pesticides, product use
殺虫剤・製品使用
- Occupation, hobbies
職種、趣味
- Depression, stress
鬱、ストレス
- Social support
社会的支援
- Diet
食習慣
- Time and activity
時間と活動



Environmental Samples – Air 環境試料－大気



- Badges - aldehydes and ketones
バッジーアルデヒド類およびケトン類
- Pump - particulate matter
ポンプー粒子状物質



Environmental Samples – Water

環境試料－水



- Community supply – community samples

地域供給－地域水試料

- Well water – VOCs, nit

井戸水－VOC、硝酸塩



T1 Physical Examination

T1健康診断



- Anthropometrics

人体計測

- Weight

体重

- Height

身長

- Skin folds

皮膚のひだ



- Blood pressure

血圧



T1 Biospecimens



T1生体試料

- Blood 血液
- Urine 尿
- Hair 毛髪
- Vaginal swabs 膣スワブ
- Saliva 唾液

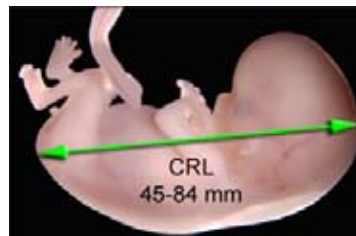


T1 Ultrasound

T1超音波検査



- For gestational age and dating
妊娠週齢および日付決定目的
- Can use clinically obtained scan
臨床スキンの利用も可能
- Otherwise will offer NCS-sponsored scan
他の場合はNCS支援のスキンを提供



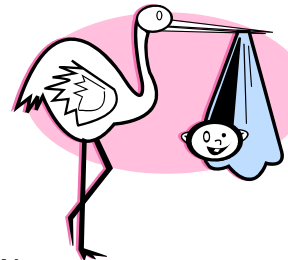
Birth visit - #1: Delivery

出生時訪問－No.1: 出産



- Focus on delivery
出産への焦点

- Biospecimens



生体試料

- Maternal blood – coordinate with clinical draw

母体血液－臨床での採血と調整

- Placenta, cord, cord blood

胎盤、臍帯、臍帯血



Other data collected

他の収集データ



- Individual level 個人レベル
 - Mail in questionnaires and samples
アンケート・試料郵送
 - Example: Breast milk at 3 months
例: 3ヶ月時の母乳
 - Diary during pregnancy
 - Observational data (e.g. HOME)
- Settings outside of the home 家庭外の状況
 - Daycare (probably on a subsample due to costs)
 - School (specifics not yet developed)
- Community samples 地域試料
 - Water
 - Air monitoring
 - Possibly food



NCS: a Platform for Adjunct Studies

NCS: 補助的研究のための基盤



- Involve a portion of the sample using some NCS infrastructure and data to address additional or in-depth question
追加的およびより掘り下げた疑問に対応するためNCS基盤とデータを使用した試料の一部を利用
- Examples 例
 - Genomic analysis for targeted gene-environment interactions
 - Functional neuro-imaging of exposed subgroup for mechanism of effect on child development
- Funding: R-01 or other grant, Public-private partnerships (foundation, industry, other), NCS
財源: R-01または他の助成金、官民連携(財団、産業その他)、NCS
- Process for review and approvals established at NCS Program Office
NCS計画事務所により評価・承認過程を作成



Use and access to data

データの利用とアクセスについて



- Planned analyses of core hypotheses by community of NCS investigators

NCS調査員によって中核仮説に関して計画された分析

- Public use data sets for respective phases of the Study level of confidentiality as soon as possible

研究の機密保持レベルの各段階を速やかに公的使用データ群に設定

- Totally anonymous limited data set with open access
 - De-identified with requirements for access
 - Restricted to use in specific location with safeguards
- For Federal programs and missions

連邦による計画および使命について使用



Status: National Children's Study 2001-2007

現況: 全米子供調査2001年～2007年



- 2001-2006: thorough planning over 6 years with input by ~3,000 scientists and other professionals

2001年～2006年: 3,000人以上の科学者および専門家による情報に基づいた6年以上に渡る徹底的な計画

- 2005: established 7 initial (Vanguard) Centers and Coordinating Center

2005年: 7カ所の初期(先駆け)センターと調整センターを設定

- 2007: first targeted federal funding for NCS

2007年: NCSへの連邦による資金調達に照準

- Establish 22 more Centers serving 30 more locations (Wave 1)
- Staff, equip and supply Vanguard Centers for enrollment
- Build the information management system



Status: NCS 2008+

現況: 2008年以降のNCS



- 2008:
 - Prepare for pilot at Vanguard Study Centers
 - Establish laboratories and specimen repository
 - Establish 35 additional Locations (Wave 2) and 12 new Study Centers
- 2009
 - Begin recruitment of pilot cohort at Vanguard Sites
 - Award NCS specimen Repository
 - Establish the last 17 locations (Wave 3)*
- 2016 Full data set for outcomes of pregnancy

* Pending funding



Funding the National Children's Study 全米子供調査の資金調達



- Total 27 year
estimated cost: \$3.2
billion for core study

27年間の合計概算コスト：
中核研究で32億ドル



Promise of the Future

将来への有望性



The National Children's Study
will form the basis of child
health guidance, interventions
and policy for generations to
come.

全米子供調査では将来世代のための小児保健指導、
調整および方針の基礎を築いていく。



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National Children's Study

全米子供調査

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