

Testimony before the Joint Fiscal Committees on the SFY 2019-20 Executive Budget Health/Medicaid Budget Hearing February 5, 2019

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Schuyler Center would like to thank the chairs and members of the respective committees for the opportunity to submit testimony on the 2019–2020 Executive Budget. The Schuyler Center is a 146-year-old statewide, nonprofit organization dedicated to policy analysis and advocacy in support of public systems that meet the needs of disenfranchised populations and people living in poverty. We often work in areas that fall between multiple systems, including physical health and mental health; child welfare; human services; and early childhood development.

Schuyler Center is the home and part of the leadership team for Medicaid Matters New York, a coalition that advocates on behalf of Medicaid members. We also serve on the Steering Committee for Health Care for All New York, a coalition dedicated to affordable high-quality insurance for all New Yorkers. Kate Breslin, Schuyler Center President and CEO, has led several recent initiatives, including the First 1,000 Days on Medicaid Workgroup, the Value-Based Payment for Children and Adolescents Clinical Advisory Group, and the Value-Based Payment Social Determinants of Health and CBO Workgroup. For more about Schuyler Center and our work, please visit our website www.scaany.org.

Planning in an Uncertain Environment

Uncertainty remains the rule of the day. While we expect fewer proposals from Congress and the President to radically change Medicaid and health care financing, the environment, public health, and health care financing are in flux. We continue to monitor Washington, DC to anticipate where funding and policies are headed and what will be the impacts on New Yorkers. Low-income children and families and the systems that serve them are likely to be affected by last year's federal tax cuts, the immediate-past and potential future government shut-down(s), and policies and rhetoric focused on immigrants.

Ensure that All New Yorkers Have Health Insurance

One of the Schuyler Center's overarching priorities is ensuring comprehensive and strategic investment in young New Yorkers, with special attention to healthy development when their brains and bodies are most rapidly developing, with impacts that can last a lifetime. Affordable, quality health insurance coverage for adults, as well as children, is critical since insurance is the gateway to accessing the services that keep people healthy and treat diseases and conditions early.

Moreover, children's healthy development depends to a large extent on the health and well-being of their parents and caregivers. Ensuring that all parents and caregivers have coverage helps children get the care and family financial stability they need to thrive. It is important to cover <u>all</u> adults because young people will become future parents and their good health will impact the health of their children.

Last year saw the nation's first increase in the number of uninsured children in nearly a decade, and young children in New York were not immune to this troubling trend. New York was one of a handful of states that saw a statistical increase in the number of uninsured young children, from 1.9% to 2.9%. This increase is happening despite the economic recovery.

The Governor and the Legislature should find this data on erosion of children's health coverage as alarming as we do. New York has prided itself in being a leader in providing coverage to children since all children are eligible to enroll in some coverage, whether through Medicaid or Child Health Plus. A review of insurance data by the Georgetown University Center on Children and Families indicates that children living in or near poverty experienced the highest increases in uninsured rates.² The report suggests consumer worries that the national political dialogues means public coverage is at risk and the proposed "public charge" rule as possible reasons for the erosion in coverage.

There is no time to wait. New York must immediately increase funding for **outreach**, **enrollment**, **and retention** activities to find children who do not have coverage and assure families that here in New York, they can enroll their children in health insurance. New York should also continue to lead the way to expand affordable and high quality coverage to all who need it.

The Schuyler Center urges the Legislature to:

- Provide \$2 million for community-based organizations to conduct outreach and educate families in the hardest-to-reach communities. This is especially important for families in immigrant communities who fear federal threats such as the public charge rule.
- Increase navigator funding from \$30 million to \$32 million. Navigators are local, in-person assistors that help families shop for and enroll in health insurance.

In addition, to reach the balance of New York residents who still need affordable coverage, New York State should:

- Fund health coverage for adult immigrants left behind by the Affordable Care Act (ACA): \$532 million to expand the Essential Plan.
- Fund a state premium assistance program: Approximately \$250 million.
- Authorize a public option for Essential Plan for working adults up to 250% of the federal poverty level (FPL): \$132 million (premiums would be \$50 per month).
- Adopt a state individual mandate: \$271 million in revenue to help pay for above.

Maternal Health

The Executive Budget contains a number of measures and resources to improve maternal health from pregnancy through childbirth and into the postpartum period. We applied the emphasis that the Governor has placed on maternal mortality and morbidity and the underlying inequities that contribute to the worsening statistics here in New York and the rest of the US.

The Schuyler Center is partnering with the NYS Office of Mental Health, the Department of Health and other state agencies to improve the State's response to *maternal mental health*, which must play a prominent role in conversations about maternal mortality. A report on findings from nine maternal mortality review committees found that seven percent of pregnancy-related deaths were associated with underlying mental health conditions.³

The Executive Budget proposal includes expansion of community health worker programs, creation of a Maternal Morality Review Board, a data warehouse, and an expert workgroup on postpartum care, value-based payment initiatives, expanding community-based services, and promoting a diverse workforce. The Governor's State of the State briefing book articulates the importance of addressing disparities and engaging community stakeholders. The budget earmarks \$4 million for these activities.

The Schuyler Center urges the Legislature to support the maternal health provisions included in the Executive Budget and ensure that there are sufficient funds to support those initiatives without stripping resources from other essential public health priorities.

Support Behavioral Health Insurance Parity

The Executive Budget includes several positive proposals aiming to ensure people with mental health and substance use disorder (SUD) are not restricted from accessing health insurance benefits, by requiring insurers to apply the same treatment and financial rules to behavioral health services as those used for medical and surgical benefits. Costs of the proposal will predominantly be borne by health insurance companies. The Governor's estimates of budget implications are Department of Financial Services staffing costs to monitor compliance \$1.7 million, to be funded through assessments on insurance carriers, and \$1.05 million at the Department of Health, to be "absorbed within existing agency resources." The proposal also is expected to cost the New York State Health Insurance Program (NYSHIP) approximately \$500,000 per year.

The Schuyler Center urges the Legislature to support the Executive's proposal to improve access to mental health and SUD services.

Support Increased Early Intervention Funding; Expand to Other Providers

Early Intervention (EI) provides evaluation and targeted therapy and support services for young children who have developmental delays or specific health conditions, and their families. Specialists work with children to provide the services they need to catch up and increase their chances for success in school and life overall.

New York's low payment rates have driven providers out of the program, jeopardizing services for children across the state. These shortages have impacted children in urban, suburban, and rural communities. In fact, the latest data show that, in New York, *one out of every four children* did not receive their mandated Early Intervention services within the required timeframe.

The Schuyler Center is pleased that the Executive Budget proposes \$4.4 million (\$3.6 million Medicaid and \$800,000 non-Medicaid) for a five percent increase in reimbursement rates for EI services provided by three types of professionals – occupational therapists, physical therapists, and speech-language pathologists – to help address the provider shortages. We commend Governor Cuomo for recognizing the need to begin restoring reimbursement rates to help address provider shortages. While this proposal is a positive step, *all* EI providers, evaluators, and service coordinators should receive a rate increase of at least five percent, to begin to restore rates to where they need to be to ensure that children with developmental delays or disabilities get timely access to the services they urgently need. Special education teachers, psychologists, licensed behavior analysts, and teachers of the blind or deaf provide critical Early Intervention services. Failing to extend the five percent rate increase to these providers may drive them out of the field, further increasing shortages in these areas.

The Schuyler Center is a steering committee member of *Winning Beginning New York* (WBNY), which has carefully examined the EI landscape in New York and has crafted thoughtful budget proposals to strengthen EI services and reverse the shortage of providers from the program.

Both the Schuyler Center and WBNY urge the Legislature to:

- Extend the five percent increase proposed in the Executive Budget to all EI providers, evaluators, and service providers.
- Increase reimbursement from private health insurance companies by supporting a "covered lives" proposal, which would assess a fee to help cover the cost of EI services instead of asking private health insurance companies to review each claim for EI services. To ensure that private health insurance companies are paying their fair share, the State should assess at least \$45 million from these companies. The State should reinvest this funding into the EI program to pay for rate restorations and to support quality improvement efforts and recruitment and retention of high-quality professionals.
- Fund a cost study, with stakeholder input, to assess and recommend changes to the methodology used to determine payment for EI evaluations, service coordination, and service provision.

Increase Funding to Achieve the Goal of Eliminating Childhood Lead Exposure

According to the Centers for Disease Control and Prevention (CDC), childhood lead poisoning is considered the most preventable environmental disease among young children, yet approximately half a million U.S. children have blood lead levels above 5 micrograms per deciliter, the reference level at which the CDC recommends public health actions be initiated.⁴ There is no safe level of lead exposure and even at low levels lead can significantly impair learning, educational attainment, and neurodevelopment in children.

As child health advocates we strongly endorse the provisions in the Executive Budget to lower the blood lead level that constitutes an elevated lead level from ten to five micrograms per deciliter, consistent with the CDC's recommendation. We also support, in concept, the Governor's proposal to direct the Commissioner of Health to promulgate regulations to ensure residential properties are maintained in a condition to reduce exposure to lead-based hazards. This proposal needs resources.

It is critical that children live and grow in conditions that protect their health and the focus on ensuring that housing units are free from lead hazards is a vital part of the prevention equation. However, activities of surveillance, enforcement and abatement, as outlined in the budget, should be accompanied with sufficient funding for local county health departments to undertake them.

The Schuyler Center urges the Legislature to support the lead provisions of the Executive Budget but with funding that is appropriate to ensure that the activities can be successfully implemented by localities across the state.

Increase State Funding for Maternal, Infant and Early Childhood Home Visiting

Maternal, infant, and early childhood home visiting is recognized across the nation as a uniquely effective approach to family strengthening, with myriad benefits to children and families' health, well-being and economic security. Home visiting has been proven to improve

birth outcomes;⁵ increase high school graduation rates for children who received home visiting services while young;⁶ increase workforce participation and lower rates of welfare dependency;⁷ and reduce instances of child maltreatment.^{8, 9} And, home visiting has been proven a cost-effective intervention that yields tremendous savings over the lifetime of children in the form of lower health care costs and improved earnings as adults.¹⁰

Yet, New York State has for years failed to make a substantial investment in these programs. As a result, fewer than five percent of New York children ages 0 to 5 in families with income below poverty live in communities with access to home visiting. We are pleased that last year's Executive Budget supported a recommendation from the *First 1,000 Days on Medicaid* initiative focused on universal access to home visiting. That support is continued this year.

The Executive Budget proposes \$3 million in funding for the Nurse-Family Partnership program, level funding compared to the last several years. The budget also includes funding for Healthy Families New York at \$26,162,200, an increase of nearly \$3 million over last year, to address the impact of the minimum wage increase. No funding was proposed for Attachment Biobehavioral Catch-up, Parents as Teachers, Power of Two, or the Parent Child Home Program. These programs operate in New York but need state funding to expand existing services and eliminate waiting lists.

The Schuyler Center coordinates the statewide Home Visiting Workgroup, composed of child welfare, health and education advocates, and home visiting programs. This year the evidence-based home visiting models came together to develop a joint request for funding that would enable additional investments in proven home visiting programs.

Schuyler Center urges the Legislature to increase State investment in home visiting to maintain existing programs and expand services to more families. Specifically, to support home visiting programs and infrastructure, we request the following investments:

- Parent Child Home Program: Invest \$2 million to bring the program to unserved areas.
- Parents as Teachers: Invest \$3 million to reduce waiting lists and expand to unserved areas.
- Healthy Families NY: Adopt Executive's proposed \$3 million investment and add \$3 million, to serve more families annually.
- Nurse-Family Partnership: Invest \$3 million more to enable growth in underserved communities.
- Power of Two: Invest \$1.5 million to help 800 children in New York's vulnerable communities reach their full potential.
- Invest \$200,000 in the NYS Home Visiting Coordination Initiative which aims to provide cutting-edge information, build cross-program relationships, and offer additional opportunities for cross-systems operations.

Reject Reduction of Public Health Programs

The Executive Budget proposes to cut the General Public Health Works funding for New York City from 36% to 20%. The budget acknowledges that the cut would reduce spending for New York City by \$27 million this year and \$54 million when fully annualized. This represents a substantial cut in funding on top of a cut last year to public health administrative funding for New York City.

The Executive's explanation for this cut is that New York City receives other public health funding, but it seems unreasonable to expect that a reduction in state funding would be filled with federal funding that is already committed to programming.

Public health is a vital government function and addresses government's responsibility for keeping residents and communities safe and healthy. At a time when the state is recognizing the impacts of and costs associated with the social determinants of health and population health on the overall cost and quality of health care, public health programs that prevent or mitigate disease should be strengthened, not cut.

Schuyler Center urges the Legislature to reject the Executive's penny-wise, pound-foolish proposal to reduce public health spending in New York City.

Support Community Water Fluoridation Funding

The Executive Budget includes a re-appropriation of funds for communities to repair, upgrade, or purchase fluoridation equipment. This re-appropriation allocates the remainder of the \$10 million Drinking Water Fluoridation Fund (DWF).

Tooth decay is a disease and unless it is prevented, it must be treated. Numerous preventive health strategies help address tooth decay and save costs, but community water fluoridation is the most effective and offers the largest return-on-investment of any public health effort. By reducing the need for fillings and extractions, fluoridation saves money for families and taxpayers.

Tooth decay brings innumerable costs: pain, time away from school and work, and health care spending. This is why the New York State Department of Health has made the reduction of tooth decay among children a centerpiece of its 2019-2024 Prevention Agenda.¹¹

A 2010 study done by the New York State Department of Health revealed that low-income children covered by Medicaid in less fluoridated counties of New York needed 33% more fillings, root canals and tooth extractions than those in counties where optimally fluoridated water was available.¹² As a result, over the study period, the treatment costs per child covered by Medicaid were \$23.65 higher per person for those living in less fluoridated counties.¹³

As beneficial as community water fluoridation is, there are large areas of New York State that do not yet adjust fluoride to the optimal levels to prevent cavities. Outside New York City, fewer than 50% of New York residents on community water systems are receiving fluoridated water. A study modeling practices in New York to prevent oral disease found that raising the share of children outside of New York City who have access to fluoridated water from 49% to 87% has the potential to save the State Medicaid program \$27.7 million over ten years by reducing the need for fillings and other dental treatment. This strategy could save \$6.13 for every dollar spent.¹⁴

The Schuyler Center urges the Legislature to support the Executive Budget policy to improve children's oral health in a cost-effective way, by approving the re-appropriation of the Drinking Water Fluoridation Fund so communities can repair, upgrade, or purchase fluoridation equipment.

Preparation for the 2020 Census

We mention New York's preparation for the 2020 Census in our health testimony because so many services that are vital to the well-being of low-income New Yorkers are allocated from federal and state funds, depending upon census data. Also of critical importance, is that New Yorkers receive fair representation, also determined by the Decennial Census.

In 2010, New York experienced a significant undercount, particularly in some "hard to count" communities, including immigrant communities, densely populated cities, and children under age five. Due to the current climate of distrust in the country, particularly among immigrants, along with other complicating factors, there is real concern that New York could experience an even greater undercount in 2020 than it did in 2010.

Specifically, every year, more than \$53 billion in federal funds are allocated to New York and localities based on Census data either directly or through Census population estimates or surveys that in turn rely on the Decennial Census.¹⁵ This includes \$6.7 billion for programs that benefit children, such as Medicaid, the Children's Health Insurance Program (Child Health Plus), education grants, Head Start, foster care and child care assistance.¹⁶

However, for many reasons, young children in New York and nationally are historically undercounted in the Census. An undercount could lead to a significant cut in programs that New York children and families rely upon. It could also lead to a loss of representation for New Yorkers in Congress and beyond, and distorted, inaccurate data. And, the impacts of an undercount would haunt us for a decade.

Schuyler Center is part of a statewide coalition, *New York Counts* 2020, which is comprised of more than 100 racial, ethnic, labor, immigrant, religious and human services organizations, working in partnership with state and local officials, to maximize all New Yorkers' participation in the census. New York Counts 2020 has called upon the State to invest a minimum of \$40 million in this state budget to support trusted community-based organizations (CBO) in efforts to engage residents in "hard to count" communities to participate, and be counted, in the 2020 Census.

The Schuyler Center urges the Legislature to invest at least \$40 million this year to enable CBOs to engage New Yorkers across the state to ensure as full and fair a count as possible. Significant state funding is needed this year; next year will be too late to engage in the preparations necessary before the count begins.

Increase Funding for Consumer Assistance for Health Insurance

The Governor's proposed budget contains \$2.5 million for the Community Health Advocates (CHA) program. Health care and insurance are complicated. They often use terms that people are not familiar with (premiums, co-pays) and rules (out-of-network, denial of care) that seem daunting. Using a central, toll-free helpline as well as community and small-business serving agencies, the CHA program helps New Yorkers understand, use and keep their health insurance. The CHA program also helps consumers resolve problems with insurance billing regardless of the type of insurance coverage. Since 2010, CHA has saved more than \$27 million for consumers and worked on more than 300,000 cases for people who needed help getting the care they need covered or resolving billing disputes.

Helping New Yorkers understand their rights and how to use the health care delivery system will decrease reliance on emergency care services and increase use of preventive care so they can get the care they need at the right time and from the right place. To aid consumers, CHA information is currently listed on commercial "Explanation of Benefits (EOB)" notices but not Medicaid EOBs. Medicaid enrollees should receive CHA information to manage that appeal process as people in the commercial market already do. To do this, CHA's will require additional resources so that all New Yorkers, including Medicaid enrollees facing an appeals process can take advantage of this service.

Schuyler Center urges the Legislature to support the \$2.5 million appropriation in the Executive Budget and request an additional \$5.5 million to ensure that CHA's can adequately serve all New Yorkers regardless of insurance type.

Target Indigent Care Pool to the Safety-Net

The Schuyler Center is a Steering Committee Member of Health Care for All New York (HCFANY) which has been monitoring regulations around the indigent care pools and made thoughtful recommendations on a more equitable distribution of the funds. Studies done by another HCFANY member, Community Service Society, have clearly demonstrated that current law does not target funds to hospitals that provide the most financial assistance due in part to what was supposed to be a temporary "transition collar" designed to help hospitals adjust to a new funding formula. However the formula for that collar has been renewed several time so that nearly \$150 million in Indigent Care Pool funds continue to be distributed in a manner that penalizes more distressed facilities.

Both the Schuyler Center and HCFANY urge the Legislature to eliminate the "transition collar" and develop a fairer way to distribute the funds by adopting a new formula that prioritizes hospitals providing the most uncompensated care to New Yorkers.

Both the Schuyler Center and HCFANY urge the Legislature to eliminate the "transition collar" to more equitably distribute funding in the indigent care pools.

Exercise Caution with Recreational Cannabis

While the Schuyler Center has not taken a position on recreational cannabis, we do want to raise concerns related to the public health aspects of legalization. Science informs us that the adolescent brain is still developing through the early twenties and cannabis has been shown to impair cognitive function in this age group.¹⁷ Concerns have also been raised that the effects of cannabis use by pregnant women, particularly in the critical first trimester, have not been studied enough to understand the impact on the neurodevelopment of the child.¹⁸

Should the State move forward with the Governor's proposal, any move to legalize recreational cannabis must include sufficient funding for local public health departments to conduct appropriate surveillance activities to monitor health impacts on the population. There must also be funding for educational activities to inform the public of the risks involved and the laws regarding cannabis use. Particular attention should be paid to keeping adolescents from accessing the drug and informing pregnant women of risks. Lessons from tobacco control might be useful. Steps toward expansion of cannabis policies should be taken only after careful study of evidence, public health experience, and advice from other states that have legalized recreational use of this drug.

Focus on Adult Home Residents with Psychiatric Disabilities

For many years, Schuyler Center has worked with other advocates in a Coalition for Adult Home Reform, advocating for improved community and supported housing options for persons with psychiatric disabilities living in adult homes and for improved conditions in and more robust oversight of adult homes. The Executive Budget contains an additional \$10 million, for a total of \$48 million, for education, assessment, and supported housing for residents wishing to transition out of adult homes. In addition, the budget maintains \$6.5 million for quality initiatives inside adult homes, through the Enhancing the Quality of Adult Living (EQUAL) program.

The Schuyler Center urges the Legislature to ensure that New York State robustly supports and assists adult home residents with psychiatric disabilities when they choose to move to community housing. We additionally urge the Legislature to support funding to improve quality of life for residents of adult homes.

Thank you. We appreciate the opportunity to present this testimony and look forward to continuing to work with you to build a strong and healthy New York that cares for its most vulnerable residents.

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¹ Georgetown University Health Policy Institute Center on Children and Families. Nation's Progress on Children's Health Coverage Reverses Course. (2018) https://ccf.georgetown.edu/wp-content/uploads/2018/11/UninsuredKids2018_Final_asof1128743pm.pdf

²Georgetown University Health Policy Institute Center on Children and Families. Nation's Progress on Children's Health Coverage Reverses Course. (2018) https://ccf.georgetown.edu/wp-content/uploads/2018/11/UninsuredKids2018_Final_asof1128743pm.pdf

³ Building U.S. Capacity to Review and Prevent Maternal Deaths. (2018). Report from nine maternal mortality review committees. Retrieved from http://reviewtoaction.org/Report_from_Nine_MMRCs

⁴ Centers for Disease Control and Prevention Lead. https://www.cdc.gov/nceh/lead/nlppw.htm

⁵ Percentage refers to Healthy Families NY. See: Lee et al. (2009). Reducing low birth weight through home visitation: a randomized controlled trial; *American Journal of Preventive Medicine*.

⁶ Multiple programs impact child development and school readiness, see: *Home Visiting Evidence of Effectiveness: Child Development and School Readiness.* http://homvee.acf.hhs.gov/Outcome/2/Child-Development-and-School-Readiness/3/1

⁷ Refers to multiple programs. See: Administration for Children & Families. *Home Visiting Evidence of Effectiveness*. http://homvee.acf.hhs.gov/Outcome/2/Family-Economic-Self-Sufficiency/7/1

⁸ Reanalysis of Kitzman et al; *Journal of the American Medical Association*.

⁹ Dumont, et al. (2010). Final Report: A Randomized Trial of Healthy Families New York: Does Home Visiting Prevent Child Maltreatment.

¹⁰ Burwick, Andrew, Heather Zaveri, Lisa Shang, Kimberly Boller, Deborah Daro, Debra A. Strong. (2014). Costs of Early Childhood Home Visiting: An Analysis of Programs Implemented in the Supporting Evidence-Based Home Visiting to Prevent Child Maltreatment Initiative. Final Report. Mathematica Policy Research. Retrieved from: http://www.mathematica-

mpr.com/~/media/publications/PDFs/earlychildhood/EBHV_costs.pdf

¹¹ New York State Department of Health, "New York State Prevention Agenda: Promoting Healthy Women, Infants and Children Action Plan", 2013, Accessed January 29, 2014 from https://health.ny.gov/prevention/prevention_agenda/2013-

2017/docs/healthy_women_children_infants.pdf

- ¹² Kumar J.V., Adekugbe O., Melnik T.A., "Geographic Variation in Medicaid Claims for Dental Procedures in New York State: Role of Fluoridation Under Contemporary Conditions," Public Health Reports, (September-October 2010) Vol. 125, No.5, 647-54.
- ¹³ Public Health Reports (November-December 2010), Vol. 125, p. 788 (http://www.publichealthreports.org/)
- ¹⁴ Presson S, Kumar J, Williams K. Public-Private Partnership to Plan ECC Interventions. Applications of Systems Dynamic Modeling for Prevention of Early Childhood Caries in New York State. Presented at the National Oral Health conference, Fort Worth, TX 2014.
- ¹⁵ Counting for Dollars 2020 16 Large Federal Assistance Programs that Distribute Funds on Basis of Decennial Census-derived Statistics (Fiscal Year 2015) New York, George Washington University, Washington DC.
- $\underline{https://gwipp.gwu.edu/sites/g/files/zaxdzs2181/f/downloads/New\%20York\%20CFD\%2008-18-17.pdf}$
- ¹⁶ Community Leaders Can Help New York Count! New York State Council on Children and Families. https://www.ccf.ny.gov/index.php?cID=373
- ¹⁷ Morin, Afzali, Bourque, Stewart et al. A Population-Based Analysis of the Relationship Between Substance Use and Adolescent Cognitive Development. (2018). The American Journal of Psychiatry. Published Online: 3 Oct 2018https://doi.org/10.1176/appi.ajp.2018.18020202
- ¹⁸ Committee Opinion: Marijuana Use During Pregnancy and Lactation (2017) American College of Obstetricians and Gynecologists. https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation