

PROGRAM BUILDER PORTFOLIO

Nancy Hutton, MD

DRAFT - 1/19/2011

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A. LEADERSHIP PHILOSOPHY

B. PROFESSIONAL DEVELOPMENT

PDIA

CAPC

National Board of Medical Examiners (1980)

American Board of Pediatrics (1984)

American Board of Hospice and Palliative Medicine (2003)

Hospice & Palliative Medicine (American Board of Pediatrics) (2008)

C. PROGRAM DEVELOPMENT, DESIGN, INNOVATION, LEADERSHIP

1985- Director, Johns Hopkins Pediatric & Adolescent HIV/AIDS Program

Pediatric & Adolescent HIV/AIDS: “Intensive” Primary Care

I launched my career as an academic general pediatrician in 1984 with a focus on advancing the quality of care and health outcomes for children living with chronic and complex conditions through an enhanced primary care model that crossed diagnostic and subspecialty boundaries. Before the end of my first faculty year, I recognized that Baltimore’s children and families were already in the midst of the newest chronic, complex, and life-threatening condition of childhood – pediatric AIDS. I seized the opportunity and the challenge to develop a new model of primary care for children born in families living with AIDS – one that would serve our local community through excellence in clinical care while simultaneously seeking new knowledge about this little understood disease.

I encountered immediate barriers. The AIDS work being done at Johns Hopkins at this time was the groundbreaking Multicenter AIDS Cohort Study (MACS), a longitudinal observational cohort of homosexual men who visited the GCRC “Moore” clinic for periodic research visits. Nationally there were only a few case reports of children with transfusion acquired AIDS. When I observed that the injection drug epidemic in Baltimore was already spreading HIV to sexual partners and children (the index patient and family for whom I cared in our primary care “well baby” clinic), I met with resistance from leaders in adult and pediatric infectious diseases who assured me that the focus for adults was in the gay community and for children was in being prepared for public relations questions about children with transfusion disease attending schools with other children. When I invested my academic time and talents to this new disease, one of my pediatric supervisors routinely discouraged my work. The pediatric immunologists, whose experience included caring for the few children in the region with severe combined immunodeficiency, anticipated what was ahead and declined taking on this emerging problem.

I persisted. I created my own “private practice” of HIV-exposed or infected infants and children in the Harriet Lane Primary Care Clinic and applied successfully for a grant from a local foundation, the Thomas Wilson Sanitorium, to cover my effort. Shortly thereafter, a faculty member in pediatric infectious diseases received a supplement to the newly created AIDS Clinical Trials Unit (ACTU) housed within the adult infectious diseases division. He came to me seeking access to patients for research specimens and for clinical trial enrollment. In collaboration with University of Maryland pediatric immunology program, we successfully competed as a site in the newly created network, the Pediatric AIDS Clinical Trials Group (PACTG). Although the PACTG funded the research effort for investigators and research coordinators, it did not support the core clinical mission, without which there was no pool of eligible subjects for study.

My focus as an academic generalist was to create the innovative interdisciplinary Intensive Primary Care Clinic (IPC) to provide continuity of care from outpatient to inpatient to home settings. A strong collaboration with a faculty member in the School of Nursing led to R01 funding that supported an interdisciplinary care team (physician, nurse practitioner, social worker, home visiting nurse) to provide longitudinal primary care and research observation of cohorts of HIV-exposed and at-risk infants. The number of patients in the IPC Clinic increased steadily and their medical and psychosocial needs became more complex over time.

I continuously innovate, shaping the care model in response to the changing demographics and clinical needs of the HIV population of children, youth, and families. Early on, I added a nurse case manager to

coordinate patient care and a child life specialist to provide psychological preparation and coping for children, enhancing not only their experience but significantly decreasing our “no show” rate. I co-located specialty services, such as mental health care and dental services, within the primary care clinic to improve access and utilization. As children born with HIV survived into adolescence and increasing numbers of adolescents were acquiring HIV through risky behaviors, I redesigned the model and scope of the IPC Clinic to integrate with the Adolescent Medicine practice. This unique approach stands in contrast to other centers in the US that created separate pediatric and adolescent programs or that assigned HIV care to a specialty-only clinic. Now I am leading our clinical team through the development and implementation of a detailed process to transition young adult patients to adult medicine focused clinics and providers.

Since 1990, I have competed successfully for numerous peer-reviewed extramural awards funded by the federal Ryan White CARE Act and administered by the Maryland AIDS Administration and Baltimore City Health Department, continuously funding the expanding IPC Clinic over two decades. My program is evaluated rigorously through annual detailed written proposals, annual site visits, quality assurance chart audits, fiscal site visits, and client satisfaction surveys. The IPC receives excellent reviews in all areas. Total clinical program funding awards for 2009 -2010 total more than \$1,000,000 annually. In order to maintain this program, I devote substantial effort to writing nine or more grant proposals per year and preparing and submitting quarterly narrative and monthly data program reports that vary in form and format across funding streams and over time.

The IPC staff consists of a pediatrician/director, adolescent medicine specialists, pediatric and adult infectious disease specialists, two pediatric nurse practitioners, two nurse case managers, two social workers, a part-time psychiatrist, a child life specialist, a youth advocate, and an outreach worker. This team is sensitive to cultural issues with regard to age, gender, race/ethnicity, childbearing decision-making, sexual orientation, and history of substance abuse. The team is comprised of members who reflect the diversity of the clients we serve: women and men; birth parent, adoptive parent, and grandparent; gay/lesbian and straight; African American and Caucasian. The services currently provided by the IPC Clinic team are listed below:

Ambulatory Primary Medical Care Services (1985), including:

1. Infant therapies to prevent mother to child transmission of HIV (PMTCT)
2. Pediatric and adolescent HIV diagnostic counseling and testing
3. Comprehensive pediatric and adolescent HIV evaluation
4. Pediatric and adolescent HIV specific therapies (antiretroviral)
5. Pediatric and adolescent prevention therapies (opportunistic infections)
6. Periodic monitoring of disease progression and treatment outcomes (CD4, viral load, resistance testing)
7. Pediatric and adolescent health maintenance care
8. Pediatric and adolescent nutritional screening and counseling
9. Pediatric and adolescent acute illness and injury care
10. 24 hour on call for pediatric and adolescent concerns
11. Adolescent screening, diagnosis, and treatment of sexually transmitted infections
12. Adolescent family planning services
13. Adolescent screening, assessment, and referral for substance abuse treatment
14. Pediatric and adolescent screening and referral for mental health services
15. Pediatric and adolescent adherence counseling

Inpatient Care (1985) for pediatric and adolescent patients

Social Work Services (1988), including:

1. Psychosocial screening and assessment
2. Supportive counseling
3. Crisis intervention
4. Child abuse and neglect evaluation and referral
5. Caretaker support group
6. Referral of adult family members to medical care
7. Referral of adult family members for financial and housing assistance
8. Permanency planning

Case Management (1990) for those without Medical Assistance

1. Intake and assessment
2. Care plan development in collaboration with client
3. Monitoring of goals
4. Referrals to needed services

Care Coordination (1990) for those with Medical Assistance, including:

1. Referral of eligible patients to the REM Program
2. Linkage with REM case managers
3. Referrals for home care services
4. Prescription refills to assure adherence

Child Life Services (1993), including:

1. Developmentally appropriate psychological preparation and support for medical care interventions
2. Support for HIV disclosure
3. Teaching about HIV and medications
4. Peer support groups and social gatherings
5. Therapeutic camping programs

Mental Health Services (1997), including:

1. Psychiatric evaluation, diagnosis, and treatment planning
2. Psychotherapy
3. Pharmacotherapy and monitoring
4. Family therapy

Substance Abuse Assessment and Intervention Services (1997), including:

1. Assessment by interdisciplinary substance abuse team
2. Intervention by substance abuse counselor
3. Referral for inpatient treatment
4. Support groups for children and youth of substance abusing parents

Adherence Services (1999), including:

1. Adherence assessment at each visit
2. Collaborative treatment planning with client and family
3. Specific medication adherence strategies and supplies

4. Referral for intensive outpatient behavioral psychology as needed
5. Referral for intensive inpatient adherence rehabilitation as needed
6. Intensive home-based adherence support
7. Directly observed therapy

Buddy Program (2000), including:

1. One-to-one relationships between interested clients and volunteer medical students
2. Monthly group social or recreational activities
3. Individual mentoring regarding peers, school, career

Outreach Services (2001), including:

1. Community-based HIV counseling, testing, and referral
2. Clinic-based rapid HIV testing
3. Outreach for missed appointments
4. Partner notification of exposure to HIV and other sexually transmitted infections
5. Risk reduction counseling for HIV positive clients

Legal Services (2003), including:

1. Assistance with standby guardianship and health care proxy
2. Legal advocacy

Oral Health Services (2005), including:

1. Complete dental examination
2. Teeth cleaning
3. Basic restorative dental procedures

Transitions Program from Youth to Adult (2006), including:

1. Anticipatory guidance regarding future transfer of care
2. "Med-Peds" trained physicians as primary providers
3. Assist clients in identifying adult clinic
4. Practice self-efficacy skills

Research in Pediatric & Adolescent HIV/AIDS: The Role of the IPC Clinic in Advancing AIDS Clinical Trials

As Director of the IPC Clinic's comprehensive care program, I pioneered the integration of the PACTG's clinical trials research into our clinical care site, optimizing access to new investigational treatments for infants and young children while maintaining continuity of care before, during, and after a patient's participation in a clinical trial. This approach maximizes the identification, enrollment, and retention of eligible study subjects in several ways. The clinical care team is always aware of open research protocols and the eligibility and exclusion criteria. Wary parents or adolescents learn from trusted clinicians about the safeguards and ethical principles that are the foundation of any clinical research. Subjects who miss research appointments are seen when they come for clinical appointments to minimize "missing data." Whenever possible, clinical and research appointments are coordinated on the same day and in the same location. The IPC wraparound support services minimize practical barriers to participation in research so that subjects are free to make informed choices based on the merits of the research proposed.

Despite this intensive effort to make research participation accessible for patients, the inclusion and exclusion criteria of newer protocols became increasingly exclusionary for our patient population. Our response as a research site was to open as many protocols as possible in order to hit enrollment targets. This approach is remarkably labor-intensive given how few subjects could be enrolled in many of the protocols. From 1986-2006, we opened 51 protocols but were able to enroll subjects in only 42. Our site's study enrollments totaled 376 during this period (appendix). Our experience was shared by other centers, emphasizing the need for multiple centers contributing even small enrollments to answer pediatric-specific hypotheses.

In addition to my role as leader of the IPC clinical core, I served as site principal investigator for several PACTG studies, including the highest enrolling protocol at our site, PACTG 219/219C Late Outcomes Study and the second highest enrolling antiretroviral treatment study, ACTG 128, an early study that confirmed equivalent efficacy with improved safety of lower dose zidovudine (AZT) compared to standard dose in the treatment of children with mild-moderate HIV disease. I co-authored the publication from ACTG 128.

In recognition of my unique expertise as an HIV primary care pediatrician and co-investigator, the 219 protocol team chair asked me to join the national protocol team in 2000 during the expansion and revision from 219 to 219C as a hypothesis-driven longitudinal study. I participated in monthly team conference calls monitoring enrollment and data collection, reviewing new work concept sheets, and approving lay summaries for study participants. The study team published 24 publications (appendix) during my membership. I personally co-authored two of these publications in areas of particular expertise: palliative and end-of-life care and HIV diagnosis disclosure to children.

My work as a "team scientist" is acknowledged in xx PACTG/IMPAACT publications for which I served as the lead investigator at the Johns Hopkins site, enrolling and retaining subjects in study, performing study procedures, reviewing laboratory data, and overseeing research staff (see appendix). These studies span the history of HIV treatment in children from mono to dual to triple drug therapy. Our IPC clinic model provided the perfect framework for our contribution to the extraordinary results of PACTG 076 which originally proved that antiretroviral medication could prevent the transmission of HIV from mother to infant. We tested medications and vaccines to prevent opportunistic infections. Our IMPAACT team continues to focus on prevention of mother to child transmission, the testing of new antiretroviral agents in children and adolescents, and the comparison of treatment strategies for effectiveness, tolerability, and durability. We currently have 11 protocols open with 25 IPC patients enrolled as subjects in active follow-up.

In order to represent my contributions as a team scientist in my CV, I have listed publications from the PACTG trials in which our site participated and for which I was responsible for enrollment and retention of subjects. No multicenter clinical trial can be completed without the significant contributions of many individuals whose names cannot appear as authors on the resulting paper(s).

List funding summary tables below in text or as appendix?

Intensive Primary Care Clinic – Extramural Funding for Clinical Services Core		
Funding Period	Funding Source	Total Award
1990-2011	HRSA (multiple grants)	\$ 9,664,860
	State of Maryland	\$ 1,589,629
	Private Foundations	\$ 121,374
TOTAL		\$11,375,863

Pediatric & Adolescent HIV Research – Extramural Funding dependent on IPC Clinical Services Core		
Funding Period	Funding Source	Total Award
1986?-2011	NIH	\$15,701,004 +
	HRSA	Kass
	CDC	Gielen
	Private Foundations	\$ 74,929
TOTAL		