For advisory meeting 1/26

The NCS cannot conduct its research without extensive collaboration and cooperation with providers in the communities in which the study operates. While this observation is especially true of the provider-based recruitment strategy, it applies to the entire study, because the study protocols require us to work with hospitals and with outpatient facilities to collect maternal and infant specimens and other kinds of data.

It must always be kept in mind that a singular distinction of the NCS from nearly all other clinical research in which practicing clinicians participate is that this study cannot choose which clinicians to work with and which not to. The commitment to a nationally representative sample means that we must follow the participant to any clinic in which she gets prenatal care and to any hospital in which she chooses to deliver. We cannot restrict our attention to facilities linked to academic centers, the locus of most clinical research; we cannot restrict our attention to volunteer physicians who have decided to devote some part of their career to research, as in, for example, the Community Clinical Oncology Program of NCI. We have to work with everyone.

This design feature means that we have no leverage at all over the practitioners who help us. Most care not a whit about publications or grant funding. What they do care about is that nothing interfere with the routines they have set up to practice medicine. Research, frankly, constitutes a nuisance and an interference in their practice. If we are to conduct this study, we need to understand that fully, and to use that knowledge to work out what will motivate practitioners to help us. If we ignore the working practitioner's perspective, and lose practitioner buy-in, we will pay the price not only in slow and inefficient enrollment, but by producing a study sample biased by the absence of participants who attend non-cooperating practices. This would totally defeat the massive efforts that have gone in to making the NCS representative of the population of the US.

In Wayne County, Michigan our 344 segment births in 2010 were delivered by more than 250 different providers, who work in at least 150 clinic settings, and who deliver in any of 26 hospitals, several of them outside of Wayne County. In the course of planning our recruitment, which begins this month, we have made contact with more than 100

provider clinics and nearly 20 hospitals. We have made provisional arrangements of one sort or another with more than 60 clinics and with 16 hospitals, accounting for some 70-80% of segment births.

Each clinic is different. We have suburban clinics serving an entirely white upper middle-class clientele, and we have inner city clinics serving only Medicaid supported minority patients. We have clinics in which the major language spoken is Arabic. Clinics vary in their daily volume of patients, in the number of segment women they serve, in the amount of space they have to accommodate research staff, in their access to the internet, in the level and training of their staff, in their dependence on physicians, nurses or other health care providers, in their experience with clinical research, and, most importantly, in their willingness to participate in the NCS.

While we find most clinics generally cooperative and interested, they all remind us that medical care comes first, and that they will have to make some sacrifice of time and risk loss of income by participating with us.

We have received only one outright clinic refusal to participate, and just one outright hospital refusal, but we also have a clinic that has not returned eight phone messages and a hospital that insists that their IRB, which meets only quarterly, must review our protocols. Perhaps we shouldn't have been surprised when the last quarterly meeting of that hospital IRB failed to assess our application for lack of a quorum. Perhaps we'll have better luck three months from now.

Against this backdrop, the Independent Study Monitoring and Oversight Committee at its December meeting said: "*The committee recommended that provider incentives not include capitation-based monetary incentives but should include a uniform menu of incentive options across all locations."*

I would like first to note, that I find the term incentive a misnomer. The practitioners we have spoken to are not seeking an incentive; they are seeking to be reimbursed fairly for the time, effort and inconvenience of accommodating our research.

The term "uniform menu" does not seem to fully recognize the extraordinary diversity of practice locations in which our study participants must be recruited. We must come up with a reimbursement policy that will help us engage all kinds of

practitioners, a policy tailored to the very different and location-specific barriers that each clinic faces in working with us.

What exactly do we ask providers to do for the NCS? Enumeration of all provider and hospital activities in the NCS, from collection of cord bloods to performing ultrasounds, is beyond the scope of this talk, so I will just focus on what we are facing immediately as we begin enrollment in the *provider-based recruitment*.

What do we ask prenatal clinics to do in this form of recruitment?

First, since only 1.3% of Wayne County women live in the selected segments, someone has to review the addresses of women in prenatal care to see if they are eligible. Some clinics wish to do address matching themselves, others allow us to match. For some clinics, we have agreed to pay one dollar to the practice for each individual they run through the address matching algorithm. Because we can exclude 2/3 of Wayne County women just by zipcode, raising our probability of a match to about 4%, it will likely cost us $25 to identify an eligible participant using this approach.

Then, HIPAA rules require us to ask the provider or staff member of the practice to communicate with the patient to permit us to contact them directly. We ask our practitioners to talk to eligible patients about our study and give out brochures, and/or author letters to patients, or call, or have staff call, potential participants in their practices. Each of these activities takes time away from providing medical care to patients. Thus far we have not finalized any overall reimbursement strategy, but we are considering, for some of our larger clinics or clinic systems, paying a negotiated percent effort of a clinic staff person who could coordinate these activities for us.

We might also reimburse clinics separately for each activity they do for us, as in the above address-matching example. Another version of the per-service option, used by the Yale NCS center in other studies, is to pay physicians a fee for each letter or form they have to deal with.

But a reasonable solution, that might work better for some clinics is indeed a single capitation-based fee to fairly and honestly cover the time and work they must undertake

with each potential subject. Thus far, we have not proposed this option in any Wayne County setting. .

The opposition to capitation-based monetary incentives has stemmed from the possibility of harm to research participants should they be steered by clinicians receiving such payments into clinical trials of potentially toxic drugs. Such harm is not conceivable in this purely observational study.

Capitation is used in other NIH initiatives, such as the Community Clinical Oncology Program, which provides a per-patient base reimbursement that has ranged from $1,500 - $2,000 to its participating groups, some of which are hospitals or universities, but some of which are private practices. In addition, CCOP uses a fee schedule, with four tiers of payment, ranging up to as much as $2,000, for extra activities undertaken by participating physicians. For example, a Tier 1 fee, which is between $100 and $200, is provided for providing names and contact information to people collecting data and/or entering this data into a database. This kind of activity seems quite similar to what I have outlined above for prenatal care providers in the provider-based recruitment effort.

The Office of the Inspector General of the U.S. Department of Health and Human Services has cautioned against payments that exceed fair market amounts for "legitimate, reasonable, and necessary services" (OIG, 2003, p. 21). This statement gives us a benchmark for estimating capitation or per-activity fees.

We studied, in the summer of 2006, 9 prenatal care clinics and 3 delivery services in Kent County, MI, a non-NCS county. We surveyed some 250 people working in those settings, from office clerks to nurses to physicians, asking them about attitudes toward the NCS protocols as we understood them at that time. Great concern was expressed about the study taking up precious time and office space and interfering with office routines. Perhaps because of this, staff generally preferred to personally undertake tasks, such as collecting specimens in the delivery room, rather than having study personnel insert themselves into the clinical setting. Reimbursements per specimen or per task were well received, and the amounts requested were very modest compared to the figures noted above for CCOP. Overall, the sense we got was that the clinical

personnel wanted to work out how best to accommodate our requests in their settings, and not have a standard solution imposed on them.

The movement of funds from NIH contracts to practitioners may raise complex issues. It has been suggested that practices who receive some forms of reimbursement may have to have all staff undergo security checks, or be certified for either human subjects research or data security skills. I can assure you that any such insistence would lead to immediate refusal by the majority of practices. Another feature of NIH contracts is that food as an incentive is, for all practical purposes, forbidden.

A key feature of working with practitioners, perhaps THE key feature, is to allow them a degree of control of the arrangements, by negotiating an individual solution to accommodate research to their own practice situation. This solution is less likely to depend on large amounts of money than it is on devising creative ways of accommodating research goals without interfering with the delivery of medical care.

Let me then finish by enunciating some principles we should follow in working with practices and hospitals.

1. Begin all interactions with practitioners by telling them that our goal is not to impose a specific solution, but to work with them to develop a way of doing research without interfering with their practice routines.
2. Assure providers that we are committed to not having the practice lose money or lose patients because of the research activities we undertake.
3. Enumerate and quantify each and every task by each and every member of the staff that is required to accommodate the research needs of the study.
4. Work out a way of equitably reimbursing the practices for their time, by using the going hourly rate for comparable services in clinical work.
5. Feel free to use appeals to generosity of community spirit and commitment to scientific discovery to motivate practitioners, **but do not make the mistake of relying on them,** or thinking they are sufficient to sustain work that will take place over several years.