

Prof Neena Modi - Written evidence (PRT0037)

Variation in care and health inequalities

There are numerous data from my research group and others quantifying the variation that exists in preterm birth rates, care provision, and outcomes in the UK. Variations exist by ethnicity, geography, socio-economic status, and across time. Data (unpublished) from our [National Neonatal Research Database](#) for the 10-year period, 1st Jan 2013 to 31st Dec 2022, show e.g.,

- There were 924,676 infants admitted to neonatal units in England and Wales over the 10-year period; of these, 23,829 were extremely preterm (EPT; <28 weeks gestation) and 51,140 were very preterm (VPT; 28 to <32 weeks gestation); across all years, mothers of Black ethnicity had the highest rates of EPT and VPT admissions
- Nationally, there has been no significant change in EPT and VPT admission rates in England and Wales over 10 years
- Compared to mothers of White ethnicity, stillbirth rates are around twice as high for mothers of Black ethnicity and 60% higher for Asian mothers
- There has been an increase in antenatal steroid use, birth in a hospital with a neonatal intensive care, birth by emergency Caesarean section and receipt of any own mother's milk at discharge for EPT and VPT admissions
- There have been significant decreases in invasive neonatal procedures and postnatal transfers (EPT)
- However, the proportion of EPT and VPT infants undergoing early postnatal transfer is around 20% and 10% respectively, a concern as early transfer increases the risk of severe brain injury

- There has been a significant decrease in the rate of treated retinopathy of prematurity (VPT) but significant increases in the rates of bronchopulmonary dysplasia (EPT and VPT) and late onset bloodstream infection (EPT)
- Rates of severe necrotising enterocolitis, severe brain injury, mortality, and survival to discharge without major morbidity have not altered significantly in either EPT or VPT groups over the 10-year period
- There is also marked variation in severe brain injury in relation to ethnicity, deprivation, and geography

Comment

- Our observations are consistent with clinical practice that has moved towards more frequent obstetric intervention and less invasive postnatal neonatal care; of note, though there have been several local, regional, and national quality improvement programmes over the 10-year period, these have not translated into substantial improvements in preterm birth rates or improvements in most important neonatal outcomes
- Some variation is normal and acceptable; however, some is not; careful analysis is required to distinguish the former from the latter
- It is also necessary to distinguish mere associations from true causal relationships (e.g., there is a strong *association* between ice-cream sales and good weather, but ice-cream sales do not *cause* good weather); it is dangerous to build policy on associations; an understanding of causality is required
- Research and quality improvement are different; research is about identifying what works; quality improvement is about implementing what works; unfortunately, much quality improvement is not evaluated; or evaluated in a methodologically inadequate manner (such as a before and after comparison)

- Audit and quality improvement programmes can be beneficial, but can also be costly, impose burdens on clinical teams, and benefits seen in some settings may not necessarily translate well across all locations, hence an inherent assumption of universal benefit may not be justified

Prevention and treatment

- **No medical interventions have been identified that successfully prevent preterm birth;** however, during the Covid-19 pandemic the absolute number of admissions in all preterm gestational age categories over April-June 2020 (7882) was the lowest for any April-June or December-February period over the previous 7 years (range 8505-9184); the fall in EPT and VPT admissions continued into July-September 2020. These data indicate the urgent need to identify the causal factors that led to this substantial fall as this offers huge opportunity to reduce preterm births (*Greenbury SF, Ougham K, K, Angelini ED, Battersby C, Uthaya S, Modi N Changes in neonatal admissions, care processes and outcomes in England and Wales during the COVID-19 pandemic: a whole population cohort study. BMJ Open 2021 Oct 1;11(10): e054410*).
- It should also be appreciated that a fetus may sustain serious damage through being kept in an unfavourable intrauterine environment; hence, preventing preterm birth is not necessarily the appropriate goal; the goal must be a sound basic science understanding the upstream causes that lead to a curtailed pregnancy
- There is a very sparse development pipeline for maternal and neonatal medicines, diagnostics, and devices; thus e.g., there have been only two medicines developed specifically for use in pregnancy

in the last 30 years (atosiban, a tocolytic now rarely used; and hydroxyprogesterone caproate, now withdrawn from the market). There has only ever been one medicine ever developed specifically for a neonatal condition, surfactant.

Comment

- Though preterm birth is widely perceived as a medical issue, it is possibly far more a societal or public health issue and research to reduce preterm birth should reflect this understanding.
- Strong parent-public-patient involvement and engagement in research is a UK strength
- Consideration is needed as to how to incentivise industry to address needs in this area

Data and monitoring

The UK has enormous strengths in national data; these should be protected and enhanced. For example, the UK [National Neonatal Research Database](#), developed with start-up funding from the Department of Health, followed by grants from the National Institute for Health Research and Medical Research Council, is a national data asset, used by a wide range of national and international researchers. Use of this one-stop source of quality-assured, curated data has supported policy development (e.g. the extension of parental leave for families with babies in intensive care); quality-improvement evaluations (e.g. the PRECEPT programme); service development (e.g. demonstration of increased brain injury with postnatal transfer of preterm babies); and innumerable observational and interventional research studies.

There is currently no equivalent source of quality-assured, curated, timely data relating to maternity care and services. This is urgently needed. Health Data Research UK is currently considering the development of a **Mother and Baby Data Hub** to redress this gap and bring together

multiple related datasets relevant to mothers and babies in a federated resource. This would considerably advance UK ability across the entire patient benefit pathway, from basic science investigations through clinical research to surveillance, quality improvement, and audit. Such a national resource would also establish UK leadership in mother and baby healthcare globally.

Recommendations

Research

- If unwarranted variation is to be reduced, research to understand the causes of the variation is essential, e.g., is this due to biological factors (race and genetics), cultural factors (ethnicity), socio-economic factors (poverty), availability of care (geography and NHS capability), or provision of high-quality care (skill and expertise of healthcare staff) care
- Public health research should be prioritised to identify and evaluate non-medical interventions that reduce preterm births
- The UK would benefit from establishing integrated networks of research groups addressing the problems of preterm births from pre-clinical basic science exploration of molecular and cellular mechanisms through hypothesis generating observational studies, interventional randomised trials, and implementation
- The UK would benefit from iterative, collaborative development of randomised controlled trials rather than the present system in which an investigator may spend around 9 months developing a study, another 9 months waiting for a stage one outcome, a further 4-6 months submitting a stage 2 application and hearing the outcome 6 months late. If it is turned down at stage two, almost three years will have been wasted. Far more efficient would be for iterative development between applicant and funder.

- Support the development and infrastructure required for smarter study designs such as platform trials that enable multiple interventions to be tested simultaneously and incrementally
- A working party would be beneficial to address how to promote currently limited industry interest and activity in the development of maternal and neonatal medicines, devices, and diagnostics

Practice

- It should be considered essential to publish and subject to peer review the methodological approach to evaluating the efficacy, cost-effectiveness, and safety of Quality Improvement programmes
- All Quality Improvement programmes should be rigorously evaluated before scale-up to ensure value for the public purse
- Integrate neonatal and obstetric operational delivery networks to redress the current unhelpful divide between these services
- Bringing together NHSE, devolved nations, heads of medical and nursing schools and Royal Colleges to improve the ethos of research and evaluation within the NHS and strengthen clinical academic career pathways is essential if the field is to advance
- Smarter use of national data would enable rigorous monitoring of prevalences, practice, and outcomes, and detection of outliers in timely fashion to enable investigation of causes.

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