Inaugural College of Obstetricians & Gynaecologists Lecture: Recent Developments in Obstetric Care and Maternal Fetal Medicine in Singapore†

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Maternal Fetal Medicine Emerged as an Obstetric Subspecialty

Has it done any good to pregnancy outcome as promised?

Pregnancy outcome is commonly represented by both maternal mortality and neonatal mortality. Maternal mortality is a rare event in Singapore. It is no longer a sensitive indicator of changes in the quality and standards of care because of the strong influence of many confounding factors and the low observed incidence. Our incidence of 12 per 100,000 deliveries is very similar to that reported in the UK.

On the other hand, neonatal mortality at a frequency of 100 times the incidence of maternal deaths is a pertinent yardstick. There is strong evidence showing a significant difference between the neonatal mortalities of the restructured hospitals in the last 10 years at any point of time.[1] In a small country with homogenous social geopolitical factors across the pregnant population, this reflects the difference in the organisational decisions of the perinatal practices in the hospitals. In KK Women's and Children's Hospital (KKH), significance is also demonstrated when neonatal mortality is benchmarked by trending over the last 10 years. Neonatal mortality showed a marked change around 1993 to 1994. In 1993, KKH made a major commitment to subspecialty development and revamped its obstetrics clinical systems and processes. The neonatal mortality of the years before 1993 differs significantly from that of the years 1994 and after.[2] This is a strong message that the change in organisational decisions made in maternal fetal medicine (MFM) from 1993 to 1994 has a powerful effect on the improvement of pregnancy outcome (Table 1, Fig. 1).

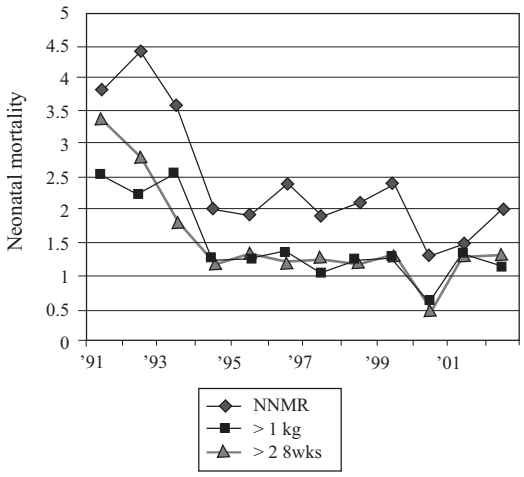

Fig. 1. Trend of neonatal mortality rate, KKH, 1991-2002.

International Benchmarking also showed us up favourably, with a neonatal mortality rate (NNMR) of 2/1000 live births. The corresponding figures for Germany (1997) was 3.5/1000 live births and for the United States (1998, Maryland), 4.8/1000 live births.

Down Syndrome Screening – Changing Expectations

In Down syndrome pregnancies at 10 to 14 weeks, the level of maternal free beta-human chorionic gonadotropin (β-hCG) is higher than average and the level of pregnancy-associated plasma protein A (PAPP-A) is lower. In Down syndrome pregnancies at 15 to 20 weeks, the levels of maternal free β-hCG is higher than average and the level of alpha-fetoprotein (AFP) is lower. For a given gestation, each relative β-hCG and PAPP-A or AFP level represents a likelihood that is multiplied by the background risk to

Table 1. Comparing KKH Neonatal Mortality Rate of 1993 and Earlier with 1994 and Later

KKH	'91	'92	'93	'94	'95	'96	'97	'98	'99	'00	'01	'02
NNMR	3.8	4.4	3.6	2	1.9	2.4	1.9	2.1	2.4	1.3	1.46	1.99
>1 kg	2.5	2.2	2.5	1.2	1.2	1.26	1	1.2	1.2	0.6	1.26	1.1
>28 wks	3.37	2.79	1.8	1.2	1.35	1.19	1.25	1.21	1.31	0.5	1.26	1.3

Comparing NNMR of 1993 and earlier with 1994 and later, P <0.0001; odds ratio (OR) 1.1; 95% confidence interval (CI) 1.08-1.15
Corrected NNMR of neonates >1 kg, P <0.0001; OR 1.14; 95% CI 1.096-1.189
Corrected NNMR of neonates >28 weeks, P <0.0001; OR 1.13; 95% CI 1.09-1.18

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calculate the newly derived risk. This is the principal of serum screening. Over the last 5 to 10 years, the triple test, the double test, the "quad" test and various combinations with age or age alone have influenced amniocentesis' policies implemented in Singapore. The efficacy of a policy is balanced by the degree of personal choice of a pregnant mother. In its many forms of freedom of practice and patient choice, much is left to the professionalism of the doctors.

The awareness of a differentiated clinical service in the form of Down syndrome screening has evolved over recent years. More than 10 years ago, Down syndrome screening was just an offer of amniocentesis to mothers 35 years and older; if discussed at all. Today, informed patients demand an individualised risk assessment, a complicated deliberation for the discerning patients looking for a differentiated antenatal service.

For the last 10 years in Singapore, the incidence of Down syndrome births has shown a significant downward trend despite the ageing pregnant population.[3] The National Birth Defect Registry (NBDR) published its findings on Down syndrome births and demonstrated a gap between the predicted Down syndrome births (projected from the age structure of our pregnant population) and the actual Down syndrome births existed for many years (Fig. 2). This gap represents an increased awareness of Down syndrome, effective communication of information, availability of screening and facilitation of choice leading to some degree of selective procreation.

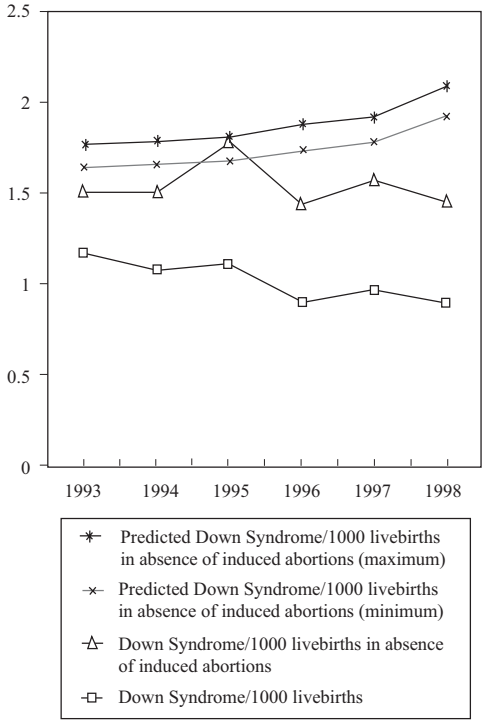


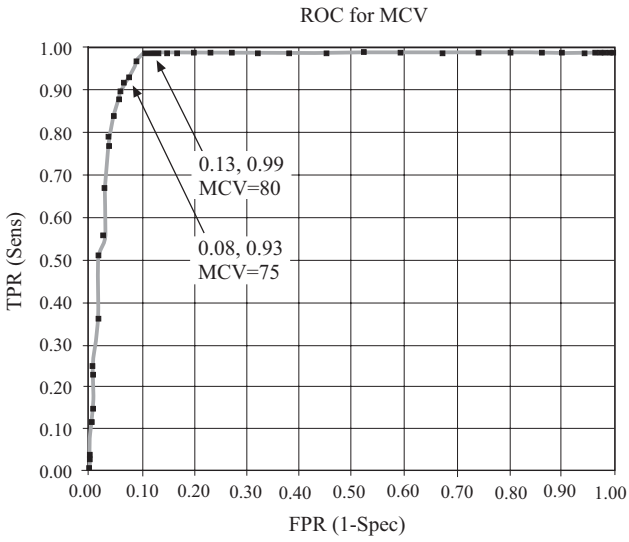
Fig. 2. Down syndrome per 1000 live births in Singapore from 1993 to 1998.

The National Institute for Clinical Excellence (NICE), United Kingdom has recommended that pregnant women should be offered screening for Down syndrome and proceeds to spell out that the test should provide a detection rate of above 60% and a false positive rate of less than 5%. NICE further defined the future by expecting that by April 2007, pregnant women should be offered screening for Down syndrome with a test which provided 75% detection with a false positive test of less than 3%; a tall order by today's standards and a paternalistic stand assuming the women's informed choice.[4]

The ever-increasing expectations of higher antenatal care standards are going to be hard to meet at some point. Society has to strike a balance between individual demands, community resource affordability, medical ethics and the endless Down syndrome screening technology provided by the industries. The role of the obstetrician is being defined not only by our pregnant mothers but also by the needs of the nation. The College will have a big share of tackling the burden of the profession in this aspect.

Antenatal Screening for Thalassaemia

A research project on Screening for Thalassaemia was started in Singapore General Hospital (SGH) in February 1988 with a grant from the then Science Council RDAS Grant BM/87/02. The principal investigator was Dr George SH Yeo and the secondary investigator was Professor Wong Hock Boon. Thalassaemia screening algorithms were identified from published equations, combinations of the various parameters of the routine full blood count (FBC), peripheral blood films, Hb electrophoresis, and tests for iron and its binding proteins. The efficacy of each



TPR (sen): true positive rate (sensitivity); FPR (1-spec): false positive rate (1-specificity)

Fig. 3. The receiver operator characteristic (ROC) of using mean corpuscular volume (MCV) for β thalassaemia screening.

parameter was tested for suitability as an antenatal screening tool and the goodness of the tests defined. Subsequent funding from a Singapore Totalisator Board Grant allowed the antenatal screening scheme to be tested. The MCV alone proved superior as the screening tool in 10,188 individuals with FBC done. Among them were 1477 female individuals and 1575 male individuals with peripheral blood films, Hb electrophoresis, tests for iron and its binding proteins done. Using the MCV as the screening parameter yielded a sensitivity better than 99%, with a false positive of 13%.[5] The simplicity of the scheme has enabled the screening test to be incorporated into the laboratory report with the routine antenatal blood tests at no added cost to the system for the last 10 years (Fig. 3).

Clinically, the effect of antenatal thalassaemia screening has been dramatic, reducing the incidence of blood transfusion-dependent thalassaemia individuals from an average of 15 to 20 cases a year to the current 0 to 1 case a year (Fig. 4).[6]

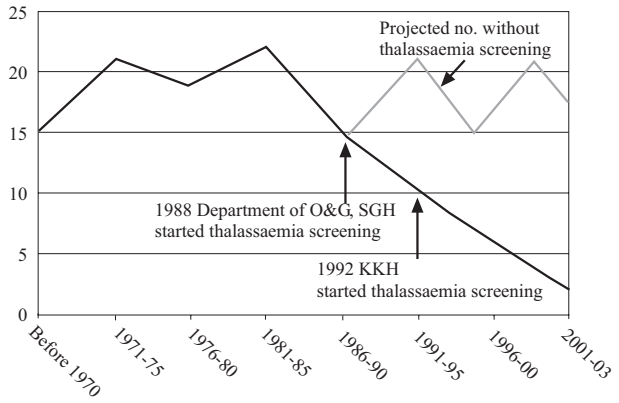


Fig. 4. Number of β thalassaemia major births in Singapore, 1997-2003.

Systems and Processes – It Has Been There but Existed Under Other Names

In obstetrics, there were many systems created locally and more will evolve with healthcare economics. To the clinicians who are passionate about improving prenatal care, a problem has first to be defined and its components resolved before a solution can be proposed. Most solutions are but about engineering the system and creating the processes to deal with each resolved component of the problem.

The organisation of the antenatal care systems in KKH is represented by the various specialised clinics created in the last 10 years. They are the all-familiar Birth Defect Clinic, Fetal Growth Clinic, High Risk Consult, Diabetic Clinic, Medical Disorder Clinic, Obstetric Day Care (ODAC) and the late arrival, the Obstetric High Risk Clinic.

Examples of recommended processes abound. Part of the routine antenatal care which evolved included the dating scan and routine blood at 10 week, screening scan at 20 weeks, growth scan at 30 weeks and glucose tolerance test when risk is present. In the high-risk group, these included serial biochemistries, serial growth studies, serial Doppler studies, serial amniotic fluid index (AFI) with cardiotocogram (CTG), just to list some common recommendations. There were also major changes in the management of obstetrics medical disorders, preterm labour, pre-eclampsia and intrauterine growth restriction in the last 10 years.

The use of common sense to identify problems and breaking down problems into its components is a rare quality in people. Clinicians are educated to see sickness as an entity and think in a "case to case" way. This "case to case" success seldom leads to any demonstrable degree of improvement in clinical outcome in an institution. It is for the healthcare leaders with the authority to engineer the systems and construct the processes to be accountable for a difference in clinical outcome. To create the systems and processes in accordance with clinical guidelines and evidence-based knowledge, the leader has to come from the clinicians. The manifestation of good clinical outcome is often serendipitous.

Medical Indemnity

There has been a lack of openness in the medico-legal claims made and the amount of litigation suits in Singapore for many years. The only certainty we have is that the amount of medical insurance premium paid has been increasing over the years (Fig. 5).

The total annual charge to NHS's income and expenditure accounts for provisions for settling claims has risen 70 folds from 1995 to 2000.

For claims closed from 1999 to 2000 with settlement costs in excess of £10,000, the average time from claim to payment of damages was five and a half years. In 65% of settlements below £50,000 from 1999 to 2000, the legal and other costs of settling claims exceeded the damages awarded, and damages awarded were usually not small.

In the States, the picture has never been better. Advertisements on the web soliciting for clients hitherto

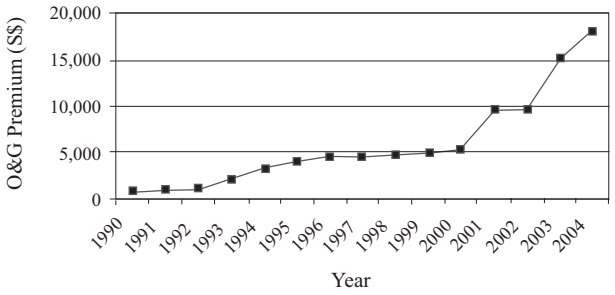


Fig. 5. Trend of obstetrics and gynaecology medical indemnity premium for the Medical Protection Society (MPS), 1990-2004.

not unhappy with their clinical outcome were particularly alarming. Closer to home, the Australian court awarded $12 million in 2001 to Calandre Simpson, a cerebral palsy victim, 22 years after caesarean birth following a failed forceps delivery. The subsequent cascade led to the folding up of UMP, a dominant medical insurer in Australia and a major crisis in the perinatal healthcare system in Australia.[7]

The medical profession needs a body which can represent us to see to it that the state of undesirable medico-legal affairs in other parts of the world does not become our destiny. At the same time, we must be able to demonstrate self-regulation, accountability and professionalism in our practices. Bolam is good until we fail to demonstrate the quality of practise upon which the society builds its trust in us. In the English case of Bolitho v City and Hackney Health Authority (1998) AC 232, the court required a test of logic before accepting an expert's position:

> *"...a defendant doctor cannot escape liability. . . simply because he leads evidence from a number of medical experts who are genuinely of the opinion that the defendant's treatment or diagnosis accorded with sound medical practice because what is required is that the practice must be accepted as proper by responsible, reasonable and respectable professionals and ...that such an opinion has a logical basis..."*

It is the judge who will decide whether the opinions are logically drawn in this case. Truly, professionalism and respect has to be earned and the formation of an autonomous College is just the beginning.

Clinical Governance

Clinical governance is defined by the Department of Health, UK as:

> *"A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish."*[8]

Concepts like organisational accountability, improving quality of services, and a supervisory framework to safeguard high standards of care are unheard of by most healthcare professionals 10 years ago. Clinical quality measurements have emerged as the requisite for accreditation only in recent years. Patient safety and risk management have emerged as major issues because of medical litigation and healthcare economics considerations. Measurements of quality and clinical indicators are created or imported constantly to allow quality to be measured. Evidence-based medicine, clinical protocols, practice audits and clinical risk management are now common words we hear daily as a result of efforts to bring safety to clinical practice and compliance to clinical guidelines. Patient safety and risk management are central to the issue of clinical governance. It is now widely accepted that creating an environment in which patient safety can be assured is the core issue in clinical governance (Fig. 6).[9]

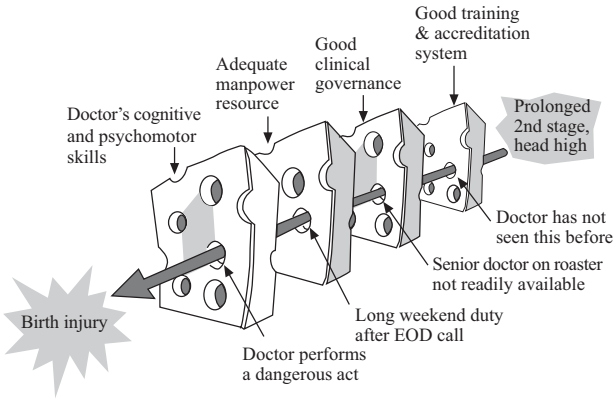


Fig. 6. An example of the human error model for accidents.

In most hospitals, there are clinical indicator audits, medical reviews, and sentinel events reports among other clinical governance tools. Professional standards are upheld with various mechanisms operating in the form of accreditation in the hospitals like basic and advanced ultrasound accreditation, CTG accreditation, surgical procedure accreditation like lower segment caesarean section (LSCS), instrumental deliveries, episiotomy repair, evacuation of uterus and D&C. Many of these are audited regularly and some on an ad hoc basis. Medical reviews are conducted to discuss cases with potential medico-legal implications or in response to complaints to improve clinical practice standards. Clinical Indicator Audit Forms or similar audit track system to track and audit adverse outcome management are important in keeping patient safety a priority in the hospitals.

Over and above these clinical quality assurance systems, individual clinicians' innovation have created systems and processes according to the needs of each specialty. Thalassaemia screening, Down syndrome screening and the evolution of prenatal diagnosis, as a whole, have changed the whole landscape of perinatal medicine.

Self-regulation

Some time in 2000, there was a cluster of scandalous medical misbehaviour surfacing in the UK.[10-15] Names like Harold Shipman and Richard Neale quickly became familiar among clinicians and healthcare authorities.

> *"…former mayoress of Hyde Kathleen Grundy dies suddenly at the age of 81. In her new will, she left £350,000 to her GP Dr Harold Shipman.…Harold Shipman issued a total of 521 death certificates,…A comparison between Shipman and others shows*

that he issued 297 excess death certificates. The excess death certificates were evident from the beginning of his practice in Hyde."

"…Separate reports into ..disgraced doctor Richard Neale called for changes to medical protocol to ensure the safety of female patients…Mr Neale, a gynaecologist from North Yorkshire, was banned from operating or treating patients in 2000 after being found guilty of 34 charges of botching women's care, leaving 15 patients in pain, incontinent or unable to bear children. …a "perplexing" decision by the General Medical Council to allow him to practice in Britain after being struck off in Canada"

The blatant blind reliance on the assumed integrity of clinicians and the lack of a regulatory framework became a grave concern in the UK. It was questioned that investigation into routine data, such as general practitioners associated with high patient mortality, would have flagged Shipman as a serial murderer. Routine data collected from hospital clinical indicator audits, medical reviews or sentinel events reports could have easily identified the Richard Neale in our hospitals.[13,14,16]

As clinicians are entrusted with a profession that makes them the providers as well as the advisors of demand, a high level of integrity is needed for the job. Regulatory framework is needed to help clinicians cope with this heavy responsibility. In practise, the aggregated appraisal of clinicians in the institutions for career development is already common practice. Outcome variance study is already a common tool for the assessment of outliers.[14,16] With the recent development in the call for reform in the healthcare services in other countries to ensure the safety of patients, self-regulation and good clinical governance are perhaps less painful ways to fulfill the needs of professionals. With this opportunity to deliver the Inaugural Lecture of the College of Obstetricians and Gynaecologists, Singapore, I hope that we will strive together and muster the courage to nurture professionalism and self-regulation.

Some Recent Milestones in the Past 20 Years

Local MFM-related Training

Dr Yeoh Swee Choo (NUH - UK '86 -'90)
Dr Henry H Cheng (SGH - UK '90)
Dr Chang Tou Choong (SGH - UCH '92)
Dr John CS Tee (KKH - USA '91)
Dr Selina Chua (NUH - UK '91)
Dr Kelvin KH Tan (KKH - UK '94)
Dr Ann SA Tan (SGH - USA '95)
Dr Lai Fon Min (KKH - UK '96)
Dr Kenneth YC Kwek (KKH - Australia '99)
Dr Mahesh Choolani (NUH - UK '99)
Dr Tan Hak Koon (SGH - UK '01)
Dr Tan Lay Kok (SGH - UK '01)
Dr Tony YT Tan (KKH - UK '02)
Dr K Vanaja (NUH - UK '02)
Dr K Devendra (SGH - UK '03)
Dr June Tan (KKH - EU '05)

Preludes to Some Current MFM Programmes in Singapore

- Medical disorders clinic for diabetes and other medical problems started in KKH in the 1970s
- Antenatal diagnosis clinic was set up in 'U' unit, KKH in 1979
- Perinatal concept evolved in 1986
- Prenatal diagnosis of β thalassaemia with fetal blood sampling and globin chain biosynthesis in 1987
- The Perinatal Society was formed in 1987 to reach out to the public
- SGH set up the Birth Defect Clinic in 1988
- Antenatal screening for β thalassaemia in 1988
- The Ministry of Health (MOH) shared antenatal care concept emerged in 1990
- High Risk Consult (perinatal clinic) in KKH, 1992
- Maternal serum screening for Down syndrome established in National University Hospital (NUH), 1992
- KKH enhanced subspecialty of MFM, 1993
- Establishment of NBDR in MOH, 1993
- Successful therapeutic fetal blood transfusion 1994
- Magnesium sulphate for management of eclampsia in KKH, 1995
- Activation codes (code GREEN) for obstetric emergencies in labour ward in KKH, 1997
- Identification of fetal cells in maternal blood with de novo staining technique, NUH, 2000

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