Current Practice and How it Links with Eugenics

Address given to the “Loving every child: Defying eugenics” seminar on 4th August 2012

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In 2004 it became medical policy to screen every pregnant woman in Australia for Down syndrome. Called “Best Medical Practice”, it is now the benchmark of care. Each mother, at her first consultation for each pregnancy, is to be invited to consider the worth of her child. She is invited to submit her child for ‘consideration’ of whether he or she is worth having. No benefit is stated to Australian children from the new consideration.

This ‘Standard of Care’ is a measure of the standard of the child. On one hand it is a medical package offered to all. On the other, it represents a biomedical vision, which has cast a net of confusion, misinformation, despair, hazard and programmed death over Australian families.

How have we come to this place?

The mystification of prenatal genetic testing obscures not only its process but also its purpose. Hiding in vague language and unspecified “best practice” marketing, its activity, results and goals are not always obvious to public opinion or indeed to parents’ consent. Society will have difficulty evaluating this commodity without removing prenatal genetic testing from its habitat of ignorance, and despair-laden counseling. We can’t make decisions about this ‘health package’ offered to every family if we don’t understand it.

‘Prenatal testing’ is a separate part of antenatal care, and the term is used to refer to prenatal genetic testing.

To demystify and grasp the issues of prenatal genetic testing, we will:

1) briefly visit its history, the abandonment of beneficence and removal of conscience.

2) understand the process: first and foremost of Down Syndrome screening, because it is both universal and opaque; its hazards and reliability; and understand its enablers: the values behind “Best Practice”, together with the skewed misinformation, promotion, low standard of genetic counseling even at a tertiary level, the poor codes of ethics and medical oaths, lack of accountability and disregard for hazard and concepts of proportionality which sustain it.

3) look at the other processes of prenatal genetic testing and

4) look at what’s new, but in the distance.
BACKGROUND AND HISTORY

The Down Syndrome net woven together over the last generation is complex and twisted with medical jargon. It has a screening layer, like no other screening test, and a diagnosis layer, with no comparison in general medicine. Its design has expressed no therapeutic purpose; no intended beneficence. Its implementation across Australia proposed no positive or improved outcomes for the children whom it will diagnose with Down Syndrome. The rationale for its introduction was economic.

Its timing, wrapped up before 20 weeks gestation, pursues its own abortion agenda. Its disinterest in the wellbeing of the child is evident from the combined peril in which it places the child, and the absence of any studies demonstrating benefit for the child.

And yet this test for Down Syndrome is overwhelmingly the commonest prenatal genetic test in Australia ¹ and in the rest of the world.

The National search for Down Syndrome is now a population test. It should not be likened to other antenatal investigations and care, which aim to protect and further the health of mother and child. In days of Hippocratic principles of medicine, to the question: ‘how will this particular antenatal investigation help me or my child’ there was an answer. However, when that question is put to population testing for Down Syndrome: ‘how is it intended to help me or my child’ the answer is an offer to destroy the child within a legally timed framework. The less stated answer is that the test’s purpose and design is to bring relief to the community².

This is the current face of genetic prenatal testing, unsafe tests with nasty mortality rates of up to one in thirty three foetal deaths³, nasty choices and a lot of spin. .

The reason for exposing unborn individuals to hazard of injury or death, to be logical, would need to confer more benefit to their health/wellbeing/life expectancy than the detriment evidenced by the tests’ mortality rates and possible complications (limb deformity, lung problems⁴ ⁵, infection, prematurity etc.)

To be regarded as therapeutic, prenatal genetic testing, like any other medical intervention, would need to meet this simple criterion:

The benefit conferred on the child would need to be more than the risk of hazard to the child.

³ A Decision Aid, RANZCOG and Murdoch Children’s Research Institute Ed. 2 2009.
⁴ NICHD National registry for amniocentesis study group JAMA 1976; 236:1471-76
To be justifiable, in the light of the known morbidity and mortality rates of its procedures, and to be in accord with all other known standards of medicine, prenatal genetic testing would need to have met this requirement.

**BENEFICENCE ABANDONED**

A major paediatric resource by Thomas Phaire in 1553 began with the promise:

> My purpose is here to do them good that have most need,  
> that is to save children,  
> And to share the remedies that God has created for the use of man.

The same promise stood its ground in the 1970’s. It appears inside the cover of the “Clinical Paediatric Surgery” a 1970 medical textbook.

Within the 40 years since then the promises and oaths that shaped obstetrics and paediatrics have changed. The Hippocratic Oath is of merely historical interest. Mentored medical students invent a new one each year. Small groups sometimes draw aside and take their own. The Obstetric College code of ethics in Australia\(^6\) no longer mentions the baby.

 Barely one generation later, in 2007, we have the Medical Journal of Australia publishing a study of the rates of Down Syndrome births across Queensland\(^7\). This study looked at the numbers of these births. It was checking whether prenatal screening and testing, over the 4 years since its widespread introduction, had successfully reduced the number of Down Syndrome live births. It looked at where this had or had not occurred. These Queensland researchers found a significant drop in the maternal age-adjusted rate of Down Syndrome births in private patients, but not in public patients. They found that rural mothers had not decreased their live births of Down Syndrome babies either.

Immediately after this study was published, the spokesperson for RANZCOG (Royal Australian and New Zealand College of Obstetricians and Gynaecologists) said this data was striking, and supported moves for a nationwide “best practice prenatal screening” policy and services\(^8\). This same spokesperson is also a partner in the multi-million dollar business “Sydney Ultrasound for Women” which performs prenatal screening and diagnostic foetal testing, and which then had eight sites around the metropolitan area. Instead of arousing a sense of purpose to ‘do them good’, this result of stable or increased numbers of live births of Down Syndrome aroused medical indignation.

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\(^8\) *Australian Doctor* 9th March 2007
A specialist in foetal maternal medicine at Prince Of Wales Hospital\(^9\) likened this to a “failure in the quality of cancer care” and recommended extra resources, so that all mothers had access to screening.

The head of maternal foetal medicine at Adelaide’s Women’s and Children’s Hospital\(^10\), said this study, showing unequal rates of Down Syndrome children’s ‘removal’ from the Queensland community

“certainly does support the argument that availability of prenatal diagnosis is something that should be uniform”\(^11\).

This same specialist very recently gave an address in Melbourne to a national colloquium of Catholic bioethicists on ‘The Need for Genetic Testing’. Citing only anecdotes, he provided no figures of such except for those on the South Australian birth defects register. This is a little unusual for a foetal maternal medicine unit, usually very rigorous with statistical outcomes. He was at pains to imply some therapeutic benefit from the invasive testing protocols for Down Syndrome but unable to substantiate this. It is bizarre for a testing protocol recommended for all pregnant women in the country and introduced at huge national expense to have no studies done whatsoever even endeavoring to demonstrate a benefit for the tested individual.

One slide was devoted to the importance of prenatal genetic testing to find Down syndrome babies before birth so as to diagnose gut problems. He omitted to say that these occur in 5% of Down Syndrome\(^12\) babies. The foetal mortality rate incurred from invasively testing 5% of all Australian mothers for Down Syndrome for this stated purpose is up to 20 times higher than the chance of finding the condition using placental biopsy, and up to 6 times higher than the chance of finding the condition for amniocentesis.

This same specialist provided miscarriage figures to bioethicists of only one half to one third those consistently stated by RANZCOG and the Murdoch Children’s Research Institute. When questioned as to how this was so, he replied that this was what he had observed and that his policy was to only count foetal deaths occurring within two weeks of an invasive test. Down syndrome miscarriages were not counted, “three probably normal babies miscarried for (x) babies with Down Syndrome detection”. He emphasized that chromosomally abnormal babies were more fragile, and more susceptible to problems in their womb environment, which would seem to suggest they may have a higher procedural mortality rate to a thinking member of his audience. Stopping counting his mortality rate on day 14 was un-referenced and opposed to evidence. In fact, the

\(^9\) ibid
\(^10\) ibid
\(^11\) ibid
\(^12\) Dunlop S, Down syndrome, an approach to children and their families, RANZCOG O&G Magazine vol 11 No 2 Winter 2009
hallmark study of foetal detriment following amniocentesis\textsuperscript{13}, a randomized controlled study, concluded that “as expected, the frequency of complications in the first 4 to 6 weeks was higher after amniocentesis than after ultrasound”.

Since ongoing amniotic fluid leak problems, such as limb deformities, lung problems etc from amniocentesis\textsuperscript{14,15,16} are noted at birth, his justification for dismissing miscarriages caused after his 2 week cut-off becomes tenuous. These babies are living evidence of sampling problems beyond the testing fortnight, one of which is sepsis, which can arise at any time in the presence of an amniotic fluid leak. An ongoing slow leak cannot be relied upon to kill the foetus within the first two weeks. Procedural cord trauma may cause death as babies outgrow blood supply through damaged vessels. He was unaware of this documentation and uninterested in following it up.

When the invasive testing programme was first introduced, a significant study “Screening for Prevention of Down Syndrome” was published in the Lancet\textsuperscript{17}. Even though openly eugenic, it advised that this programme of Down Syndrome prevention:

“would require that every woman subjected to amniocentesis be followed at least until delivery. This is an ethical requirement and what is learned from it should enhance the informed quality of the consent given by participants in the screening procedure.”

Ongoing quality control of procedural performance standards would suggest ongoing auditing of outcomes of invasively tested pregnancies. This foetal maternal specialist did not cite any such audit figures, nor any study to support his non-inclusion policy. The foetal medicine which is concerned with checking foetal quality seems less rigorous with its own quality control.

There were many errors presented as fact. 5\% of all babies he said have a major birth defect. This is not true. 5\% do have a birth defect but this can be minor or major. All Down syndrome patients he said will develop dementia. The figures are 9\% up to the age of 49 years, 18\% of those aged 50 to 54, and 35\% of those aged 55-59\textsuperscript{18}.

Advocating prenatal genetic testing on the basis of ‘psychological preparation’ he again cited no research. He particularly failed to refer to evidence which shows that prenatal

\textsuperscript{13} Tabor A, Madsen M et al Randomised control trial of genetic amniocentesis in 4606 low-risk women The Lancet June 7 1986
\textsuperscript{14} Working party on amniocentesis. An assessment of the hazards of amniocentesis BrJ Obstet Gynaecol1978; 85 (suppl 2): 1-41
\textsuperscript{15} National Registry for amniocentesis study group. Mid trimester amniocentesis for prenatal diagnosis. Safety and accuracy.\textit{JAMA} 1976; 236: 1471-76
\textsuperscript{16} ibid 12
\textsuperscript{17} Stein Z, Susser M, Guterman AV Screening programme for Prevention of Down Syndrome, The Lancet Feb 10 1973
screening is associated with disrupted bonding between mother and child\textsuperscript{19}. Nor did he refer to evidence by Queensland researchers\textsuperscript{20} of the psychological ramifications of pregnancy loss. They had found that mothers who had experienced a pregnancy loss – inevitable in the testing process – were almost three times more likely to have a lifetime illicit drug problem.

Errors continued. He claimed that possible cardiological interventional procedures for the foetus who is chromosomally diagnosed with Down syndrome are made possible by the cellular diagnosis, because the ultrasound performed at twenty weeks will likely have missed these babies’ major heart defects. The statistical chance of a baby with Down Syndrome having a congenital heart defect is around 44\% \textsuperscript{21}. The chance of a cardiac lesion \textit{of the severity and nature indicated} is rare. The chance of a cardiac lesion \textit{of the severity and nature indicated} being missed on the anomaly scan has not been quantified. This foetal maternal specialist did not appreciate or did not inform the audience that the statistical death rate for the invasive prenatal diagnostic procedures he advocated towered over the benefit he extolled to the National Colloquium of Catholic Bioethicists.

At this presentation on the ‘need for genetic testing’, there was no due regard for the incidence of conditions or for \textit{proportionality} with the procedural mortality rate. His claim of looking after Down Syndrome children more assiduously than normal pregnancies was a little pale after having deliberately exposed them to grave and high risk hazard, having referred to the inadvertent loss of ‘normal’ babies and having concurred that too many Down Syndrome births in some areas of Queensland warranted more access to prenatal diagnosis.

Within one generation obstetric and foetal medicine had moved from assistance of those most in need, to disapproval and criticism of their survival, undisciplined quality control and dissemblance. The usual ethos or \textit{telos} of medicine had been traded for a biomedical vision, a eugenic standard, \\
``tending to the production of fine offspring'.
Likening a ‘failure to remove Down Syndrome births’ to a ‘failure in the quality of cancer care’ portrays these children not merely as valueless, but as negatively valued. We have indeed ‘severed our human solidarity with them’.

\textsuperscript{20} \textit{British Journal of Psychiatry} 2008; 193:455-60.
It is worth noting at this point, that:

--it was the German Medical Association itself that had proposed the ‘compulsory sterilization law’ in 1932, which became the Law for the Prevention of Hereditarily Diseased Offspring the following year (and which specified hereditary feeblemindedness).

--In 1934 the profession most represented in Nazi Party membership was the medical profession. By 1934, 45% of doctors had joined the Nazi party. The professional group with the next highest membership were lawyers, with 25%.

--in 1947, and on the 50th anniversary of WW2 in 1996, both the BMJ and the JAMA said that the “State had manipulated medicine”.

The German Medical Association in 1996 saw it very differently. Holding their own conference on the 50th anniversary of the Nuremberg Doctors’ Trial, entitled “Medicine and Conscience” they attributed Nazi medicine – experimentation and eugenic practices – to the “separation of biological power from a moral sense”, to the “removal of conscience from medicine”.

They warned their international medical peers that the tragedy of those times was not mere happenstance, and that doctors involved had abandoned conscience and dismissed morality.

Eight years after this warning, an article in “Australian Doctor” proudly announced that Australia led the world in Down Syndrome screening. Professor Sheffield, a clinical geneticist at the Murdoch Children’s Research Institute, regretted that there was still room for improvement, since some states had not yet maximized their detection methods. He was quoted seeking a “national consensus” on Down Syndrome screening:

“We’ve been trying for years, but there is resistance from politicians, so each state has to cope with their own allocations (for screening)”.

The following year the Royal Australian and New Zealand College of Obstetricians and Gynaecologists endorsed national Down Syndrome prenatal screening as “Best Medical Practice”. This designation usually signifies things like:

- evidenced reduction in mortality rates
- demonstration of enhanced 5 year survival
- scientific data quantifying the benefit of testing for the individual tested

ie evidence based medicine.
Normally evidence-based medicine is known and respected around the world as a standard of care. In the case of Down’s detection, however, instead of beneficence with quantified scientific data, evidence-based medicine presents other figures. Denmark proudly announced in the British Medical Journal in 2008 that it had only delivered to life 31 Down Syndrome children the previous year.

The earliest amniocentesis foetal chromosome test for Down Syndrome was in 1968. It was offered to older women who have a greater chance or “incidence” of Down Syndrome births. Initially women over 40 years then women over 37 years were offered invasive testing. Openly eugenic, it declared:

“..where abortion laws permit, there is no need and no justification for delay in trying to institute a prenatal diagnostic screening programme for Down Syndrome. To effect the policy advocated here will bring relief to the community and new assurance to prospective parents.” 25

But medicine became dissatisfied. This method could only detect 70% of Down Syndrome children before birth. The other 30% occur in women under 37 years of age. Also raising concern, as was later referred to in the International Journal of Medical Sciences 2005 26, this advanced maternal age group had included a disproportional number who would not accept termination for religious reasons and it included many (eg with infertility) who would not accept the hazards of invasive diagnosis.

So, as the decades passed, techniques of detection escalated to maximize live birth prevention of Down syndrome, to produce the curly and convoluted programme of screening and its targeting we have today. Within this maze are major issues of medical transparency that affect informed consent and public opinion.

THE PROCESS

We know all pregnant women are now advised “Pre-natal Screening”. Some may say “offered” but medical magazine, peer reviewed medical and allied health articles on pre-natal testing and patient literature now refer to it as ‘recommended’, ‘essential’, ‘advised’, ‘important’, sensible and ‘routine’. 27 28 29 30 31 Screening is the first part of testing for Down Syndrome (and other more major but rarer chromosome abnormalities).

25 ibid
28 Hodgson JM, J Genetic Counsel (2010)19:22-37
30 Prenatal Diagnosis and Counselling. NSW Health.
31 Early Pregnancy Test for Down Syndrome by Sydney Genetics
This is now called Combined First Trimester Screening, because it involves a combination of multiple pieces of information, from mother’s blood tests (measuring levels of two pregnancy proteins) combined with ultrasound measurements of the foetus at 12 to 13 weeks gestation. There is about a 2 week window in the pregnancy where that information overlaps. It is then we can assess the likelihood that a pregnant mother’s growing son or daughter has Down Syndrome.

What confuses many people, and many doctors too, is that this is not a screening test for a problem, but a massive population net to see who is in the top 5 per cent bracket of risk for having the problem. Its aim is to separate out all those who are in this 5 per cent with a higher chance of having Down syndrome from the other 95 per cent of babies in the population with a lower chance of having Down syndrome. Screening locates who is in this higher risk end of the population for possibly harbouring Down syndrome. They become the target group. A line is drawn across that 95th centile.

Those above the line, those who land in this target group – and 5 per cent always do, one in twenty mothers – are offered a very different, second test. The next test is the one that actually gives the diagnosis, (i.e. more than a measure of the chance of D.S.) by either a biopsy or sampling of the placenta or of the amniotic fluid, to count the number of chromosomes. This sampling is known as invasive testing because it enters the uterus, or ‘diagnostic testing’. It has unacceptably high mortality rates, as we shall explore.

These measurements which together form the Combined Screening Test are not necessarily looking for abnormalities. Rather, they are measuring the smallest differences of blood levels or neck space widths from the median or middle values calculated for the population. In other words, how far are this baby’s, and this pregnancy’s measurements from the dead middle of the population range. These scores are known as “multiples of the median”. They are small proportionate digressions. Everyone has them - to some degree.

EVERY PREGNANCY IS GIVEN A NUMBER.

Each measurement or score is calculated for the foetal age. A software programme then calculates the likelihood ratio, or D.S. chance, from these. On top of these measurements there is the mother’s natural and expected age risk for Down Syndrome. The likelihood ratio from measurements is then multiplied by the mother’s own expected age risk. Adjustments are also made for her weight, ethnicity, smoking habit, and an approved, impervious, patented software package then prints out a mother’s individual risk factor for carrying a Down Syndrome baby.

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Scott F, Peters H, Bonifacio M. Prospective evaluation of a first trimester screening programme for Down Syndrome and other chromosomal abnormalities. ANZJOG 2004; 44 200-204.
She may be told her figure is 1 chance in 50 of having a Down Syndrome child, or 1 chance in 2000, up to 1 chance in 2.

That line which is drawn across the 95th centile of the pregnant population of Australia is drawn at a risk level of 1:300. Those under it will have a result which says the risk of Down Syndrome, trisomy 21, is less than 1:300. Those over it will be told they have a risk of more than 1:300. At that cut-off, 5% of the population will have a risk of Down which is greater than 1:300. The Royal Australian College of Obstetricians protocol is to consider any chance of Down’s that is more than a 1:300 chance a positive or high risk result. That is where the cut-off is set. It is an arbitrary cut-off.

All mothers are given their figure. Every pregnancy is given a number. Mothers who have more than a 1:300 chance of carrying a Down Syndrome child are also advised that they have screened high risk, screened positive. They are next offered an invasive test to sort things out, often counseled by specially trained genetic counselors.

With figures like this the test is obviously going to have a high false positive rate. And it does. The screening test is only screening for risk of Down Syndrome, is merely trying to determine a manageable target group. The RANZCOG and Murdoch Children’s Research Institute patient hand-out in 2008 stated that only 2% of this screen positive group will actually have Down Syndrome, i.e. 98 per cent of the screen positive group offered invasive testing do not have Down Syndrome. The screen positive rate of this population test is almost equal to its own false positive rate.

The 5% cut off was selected for the following reasons:

1) that false positive rate is considered acceptable, about all the community could accept.
2) that is the false positive rate needed to pick up around 90% of Down Syndrome pregnancies.
3) That pick-up vs. false positive rate will deliver a good benefit to cost ratio.
4) It doesn’t want the percentage of pregnancies with Down syndrome to get too far ahead of the invasive tests’ own mortality rate spent looking for them.

TESTING HAZARD

The next step is invasive testing, by chorionic villus sampling, or amniocentesis. Mortality rates of this are not nationally audited, so we go on figures assessed and compiled by the Royal Australian and New Zealand College of Obstetrics and Gynaecology (RANZCOG) and the Murdoch Children’s Research Institute. The

33 A Decision Aid Murdoch Children’s Research Institute/ RANZCOG Ed 1 Nov 2008
34 Ibid
36 A Decision aid testing in pregnancy for foetal abnormalities Edition 2, 15 Dec 2009
foetal death rate for chorionic villus sampling additional to the risk of miscarriage is consistently given as up to 1:33 (range 1% to 3%). The foetal death rate additional to the miscarriage rate of amniocentesis is consistently given as up to 1:100 (range 0.5 to 1%). A U.K. study has shown that foetal mortality rates from invasive testing are 6 to 8 times higher for specialists in training.

Invasive testing has mortality rates that would be wholly unacceptable for a test in any other field of medicine. For a non-therapeutic test this would be abhorrent. No treatment is planned or possible for having 47 chromosomes instead of 46 chromosomes. This is Down syndrome, also called “trisomy 21”.

Rarer chromosome problems, lethal ones, will also get a risk reading from this screen. Every pregnancy is assigned a number registering the chances of these also. Three in all.

DOWN SYNDROME.

What does it mean to have Down Syndrome, that so much importance is placed on it, so much money thrown at decreasing its live birth rates? Those of us with Down syndrome have an extra chromosome, that is, 3 copies of chromosome number 21 instead of having two copies, one from Mum and one from Dad.

They do have a range of problems. However, just knowing the chromosome count will not tell you which particular problems they have, nor how severe they are. Heart (40 to 50%) and gastro-intestinal malformations may be present; coeliac disease and hypothyroidism may develop; neck instability may need surgery. Later, dementia may develop. Intellectual disability is a feature of the condition, but Children with Down Syndrome learn and develop throughout life albeit at a slower pace than usual.

Literacy rates of just over 40% have been noted and are improving. early intervention programmes help to develop their potential. Symptoms of other problems can be treated.

These problems are judged to be an intolerable burden, on the individual and on society. The screening is to find where in the community to focus the diagnostic effort, and the diagnostic effort is to talk about “choices”. When eventually tracked down, in the most recent Australian report, 94.7% of Down syndrome babies are terminated. For every hundred babies invasively tested because they have screened positive, all 100 are placed at hazard, one or two may miscarry and two are marked for eugenic death.

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37 Guidelines and audit Committee of the Royal College of Obstetricians RCOG guideline no. 8 (revised) 2005 Jan. London UK Royal College of Obstetricians and Gynaecologists
38 Journal Pediatrics 2008; 152:20-4
TESTING RELIABILITY

Following a more recent Melbourne study, RANZCOG said that perhaps 4 to 6 women out of a hundred who have screened positive may have Down Syndrome. Melbourne or even Victorian women, however, may not represent the rest of the Australian population, in terms of maternal age at childbearing.

[I should add that for mothers who miss this Combined Screening test window and present late in their pregnancy there is another, less effective, maternal serum screening test offered at about 16 weeks also with around 5% false positive rate assigned it, that could lead to diagnosis of 75% of D.S.]

The overall false positive rate, affecting almost 5% of the pregnant population, is not the same for each age group. It has been adjusted to maintain a 90% pick up rate in the population, taking into account the contribution made to Down syndrome from advanced maternal age. The principles of these calculations have not changed since the advent of maternal serum screening.

At age 16 the false positive rate is around 2%
At age 30 the false positive rate is 4%
At age 36 the false positive rate is 10%
At age 44 the false positive rate is 47%

So the false positive rate increases exponentially.

At 44, 1:35 babies will have Down Syndrome. More than half the mothers at this age will be told they have screened positive, 51%. If you take 100 pregnant 44 year olds 51 will be told they have screened positive, about 4 will have a Down Syndrome pregnancy diagnosed invasively at 16 weeks by amniocentesis. One of these would have miscarried naturally before birth.

There are other issues:

-the pregnancy hormones measured change over the interval of time for collection.

-In Sheffield a few years ago there was a laboratory computer problem, and lots of mothers were given the wrong Down Syndrome risk assessment. How often does this happen?

40 Reynolds TM Down Syndrome Screening: a controversial test, with more controversy to come J Clin Pathol 2000;53:893-898
-In 1996 National External Quality Assessment Scheme in the UK sent dummy patient results to different labs. They found a huge variation in results. Co-efficients of variation were 36.5%, 31.5% and 55.6% for different methods used.

-although trained and specially accredited by the Foetal Medicine Foundation, ultrasonographers are measuring tiny foetal neck spaces of less than 2 mm, and not immune from observer error.

-software calculation is a black box, **poorly understood** by users and obstetricians alike.

It has been found that less than 10 per cent of health care professionals allied to a tertiary level maternity hospital were able to provide accurate information on the characteristics of the various screening tests. And these are the creme de la creme. In a study of obstetricians and GP’s who regularly look after pregnant women, 47% did not know that 5% of screened mothers receive a high risk result; only small correlations were found between perceived knowledge and actual knowledge; and 1/3 did not know what the false positive rate was.

A BMJ study in 2006 evaluated the knowledge of obstetricians, midwives and also patients. Of the Obstetricians’ responses regarding prenatal screening tests, 43% were correct, there were no correct answers from midwives, and 9% correct answers from patients. Despite the rate of errors, obstetricians ticked ‘confident’ in their incorrect responses.

The Professor of Biostatistics at the Australian National University’s Centre for Epidemiology and Population Health, commenting on this study, said not knowing what a positive result meant “could create more alarm than necessary. Providing patients with a leaflet containing relevant information and explaining about the probability of a patient having the condition after a positive result could be helpful” he said. The research article itself expressed concern that the impact of inaccurate estimates would be magnified if those making them were confident in them.

How do they counsel mothers?
How do these mothers give informed consent to invasive testing?
Pre-test counseling and information for mothers about prenatal procedures will shape their understanding.

-There are also commercial interests here. It’s big business. Ties exist between National Policy making and business. A major NHS report in the U.K., promoting universal Down Screening, had a lead author who also directed the company which marketed the required

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43 BMJ. doi:10.1136/bmj.38884.663102.AE
44 ‘Experts fail Down screening test’ Australian Doctor 4 August 2006
software. The frequency of pregnancy means large numbers of people tested and large incomes even with small profit margins. It is interesting to note that when Rontgen invented x-rays he waived the patent for the good of mankind. His letter is on display in the handwritten manuscripts exhibition in Canberra. The same happened with the polio vaccine. Altruism is not a feature of prenatal testing.

After the screen positive result with all its conundrums comes the offer of invasive test. Its hazards are to be considered. Its purpose is to be considered. To assist parents through this process there is:

**GENETIC COUNSELLING**

Many mothers are referred to professional genetic counselors to receive information and support to decide about subsequent diagnostic testing after a ‘High Risk’ screen result. From an ethical perspective, informed decision making is a central goal of prenatal genetic counseling.

In 2009 an Australian study explored current practice in prenatal genetic counseling in two tertiary referral public hospitals in Victoria. This study was published in the Journal of Genetic Counseling in 2010. With consents, five accredited Genetic Counselors at two tertiary referral maternity hospitals in Victoria had their de-identified client interviews audio-taped over an 18 month period, from 2003 to 2005. 52 mothers were approached to participate. With risks from 1:4 to 1:296, thirty one women declined to participate, giving the reason that they were too distressed. Twenty one agreed to participate.

The study found:

* that the majority of clients demonstrated a poor understanding of the screening test they had been given.

* counselors only offered an explanation of procedure related miscarriage in response to specific questioning. Then the figures for foetal mortality given were not RANZCOG figures, but a fraction thereof.

* couples were sometimes advised to consider whether they could cope with the uncertainty of not knowing for sure without a diagnostic test.

Normal counseling aims to help clients manage uncertainty, rather than provoke it.

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*misinformation was given:

1) a genetic counselor advised a client with a 1:82 risk of Down Syndrome:

\textit{Down Syndrome babies can also have serious heart problems. Nothing we can test in pregnancy can tell you that.}

Not true. Foetal ultrasound plus echocardiography is available, with or without chromosome diagnosis. There was no mention of foetal ultrasound/echocardiography.

2) a genetic counselor advised:

\textit{We do know that kids and adults with Down Syndrome are always dependent on their parents.}

This is incorrect. Many people with Down Syndrome are able to leave home.

* one counselor was asked what Down Syndrome could mean for a baby. The counselor replied, after mentioning the intellectual disability:

\textit{“... these children with Down Syndrome have a particular facial appearance about them...so um their eyes are sort of more slanted, they’ve got sort of loose um facial um appearance, um sometimes the tongue is bigger and sort of hanging out so there’s sort of a particular sort of appearance”}.

No proper discussion of the variable incidence and variable severity of the possible problems, literacy rates etc, being part of the family, Down Syndrome people having websites.

* Only 2 out of 21 sessions offered clients a brochure from the Down syndrome association

* The study itself observes:

\textit{“At no time did any of the counselors talk about any potential for children with Down Syndrome to contribute to family life... there was no overt encouragement of clients to deliberate about the possibility of having a child with a disability”}

and

\textit{“there was commonly a notable reluctance on the part of counselors to talk about how an abortion may be performed”}.

* genetic counselor 3 says to one client:

\textit{“your risk for Down Syndrome has come back at 1:51, which probably comes as a huge shock to you”}.

If she wasn’t particularly anxious she will be now.
only one counselor mentioned to the mother that if she would not consider an abortion there was no point in risking the baby’s life with an amniocentesis.

* Concerning the possibility of Down syndrome, induction with a “mini-labour” was mentioned, but never that it was an emotionally painful process resulting in the delivery of a stillborn baby, (whom she would not meet).

* adoption was never mentioned.

* one of the conclusions of this study of genetic counseling, was that it reflected what other studies had shown:

“That information given about Down Syndrome in prenatal settings is generally inadequate for informed consent and often emphasizes the negative aspects of the condition”

Informed consent and “choice” is often directed by
-Misinformation,
-Pressure (blue pamphlet NSW Health “The importance of checking your baby’s health before birth”),
-Negative value assigned to Down Syndrome,
-Covert values against disability and learning difficulties in particular,
-Concealment of the economic rationales behind Best Practice guidelines, and the jeopardy to the benefit-to-cost ratio feared, if participation rates are low.

MISINFORMATION ABOUT PRENATAL TESTING

Apart form Genetic counseling, there are other direct sources of poor or misinformation impacting on maternal anxiety and on informed consent:

* The W.A. Dept. of Health has a printed patient information booklet dated 2008. It was largely put together by the centre for “Genomics” and the W.A. foetal medicine unit at King Edward Memorial Hospital. The first page of writing contains a glaring error. Prenatal screening tests “Tell us if Down Syndrome is likely or unlikely”. It doesn’t. It can’t. It gives only a risk assessment up to 1:2. Being assigned to the screen positive group merely assigns you to the target group. The screen positive rate almost equals the false positive rate. Being assigned to this group cannot tell you that you are likely to have a Down Syndrome baby. You may be assigned

47 Prenatal Diagnosis and Counselling NSW Health and NSW Genetics Education Program June 2001
a high risk rating, 1: 3 or 1: 2 even but the screening test will not say that Down
syndrome is probably present.

This misinformation steers people toward invasive testing. When this mistake was
pointed out, the foetal maternal medicine specialist who advised and signed off on this
document said the correction was being “picky”. They did correct it in 2011, but it was
distributed for years and on the website.

If these mothers had then turned to a Bioethics Centre in W.A, they may have received
advice 48 that mothers who screen positive for Down Syndrome, i.e. 5%, but who don’t
have Down Syndrome, probably have another abnormality. Though notified twice of
their mistake, once through their governing body and through the chief signatory
specialist, they did not amend their misinformation until it received attention in the
secular press. They also gave mortality rates from the procedure which ranged from one
quarter to one half of the then RANZCOG stated rates.

If mothers in Victoria turn to a well known Melbourne Bioethics Centre for truthful
information, they may be given the information their director gave to a Bioethics
Colloquium in 2011. Published last year in a Christian health quarterly magazine49 as
debate, and distributed to health care agencies, he stated that because prenatal screening
and testing is Best Medical Practice it benefits the health of the mother and benefits the
health of the child. Prenatal testing, it was claimed, safeguards the pregnancy, and
safeguards the health of mother and child. He was unable to say from what. Rigor and
accountability are not the valuable tools they could be to modern bioethics.

Misinformation does matter.
‘Pregnancy Help’ were using an information booklet from Sydney Ultrasound for
Women, which performs invasive testing. Like most other resources its previous edition
overstated the Down Syndrome incidence in the screen positive group, saying a positive
screening test doesn’t necessarily mean your baby has Down Syndrome. This is a long
way from saying only a tiny percentage do. Its current edition has ‘reduced’ the foetal
mortality rate figures to a level that the community might find more palatable,
unreferenced and well below RANZCOG and MCRI figures. All mistakes are skewed in
the same direction ie toward uptake of testing.

The Federal Government has also given incorrect advice, though less so than the above.
Their Biotechnology Australia Fact Sheet number 21 spoke of screen positive mothers as
demonstrating “abnormal results”. When they were notified explaining where and why
their information was wrong they courteously replied. The then manager of Biotech
Australia arranged for someone to take the fact sheet down from the site (to their credit).

48 Nuchal Translucency Screening on Catholic Premises 2004
49 CHA Health Matters Autumn 2011
So why is this prenatal testing process Best Medical Practice?

The aim of prenatal testing is to maximize detection of Down Syndrome for secondary prevention. The stated aim is to reduce the number of live Down Syndrome births.\(^50\)\(^51\)\(^52\)\(^53\)\(^54\)\(^55\).

One recent article put together by the Royal Women’s Hospital Melbourne together with the Murdoch Children’s Research Institute looked at foetal outcomes after diagnosis of a birth defect in a Foetal Medicine Unit (FMU). In relation to Down Syndrome it spoke of an “unexpected finding” that this unit had lower figures for Down S. terminations which didn’t measure up to the 94.7% rate for the rest of the state. However, it reasoned that the majority of women who attended this unit were first seen after 18 to 20 weeks, when the diagnosis of Down Syndrome may be too late for mothers to consider a pregnancy termination.

Its conclusion did state that the issue may have been to do with the Foetal Medicine Unit counseling and support that facilitated the choice for the continuation of an affected pregnancy. This “issue”, it claimed, highlighted the importance of a multifaceted mix of health professionals.\(^56\)

Reducing Down Syndrome births is soothed with the title ‘secondary prevention’ of Down Syndrome. Another name might be Down syndrome genocide.

The “Best Medical Practice” for reducing live births is derived from determining the most acceptable balance between false positives, false negatives, detection rates, and the economic costs to the nation of lifetime care for someone with Down Syndrome vs. costs of national screening and testing programmes. These different factors have all been carefully evaluated. Applying the testing method thus arrived at is expected as a standard of care as “Best Medical Practice”. That is the focus of modern Australian studies. None attempt to show beneficence, because it is well known and accepted that there is no clinical gain that can trump the staggering death rate of prenatal genetic diagnosis

\(^{50}\) Stein Z, Susser M, Guterman A. Screening programme for Prevention of Down Syndrome The Lancet Feb 10 1973
\(^{51}\) Coory MD, Roselli T, Carroll HJ. Antenatal Care Implicationsof Population-based Trends etc MJA 186: 5 5 March 2007
\(^{52}\) Scott F, Peters H et al Prospective evaluation of a first trimester screening programme etc ANJOG 2004; 44 200-204
\(^{53}\) Chang TC, Antenatal screening for Down syndrome in NZ: time for a national screening policy ANJOG 2006 46: 92-96
\(^{54}\) Cuckle HS, Primary Prevention of Down syndrome Int J Med Sci 2005 2
\(^{56}\) Lewis S, Mc Gillivray G et al. Perinatal outcome followinf suspected foetal abnormality when managed through a FMU Prenatal Diagnosis 2010; 30: 149-155.
squeezed into the abortion time frame. There are no figures of improved well being from population screening protocols for early pregnancy Down Syndrome diagnosis.

It has been estimated that $75,000 worth of screening goes into each Down Syndrome birth avoided. Each Down Syndrome person is estimated to cost $250,000 in a lifetime. The UK estimated that 400 procedural deaths occurred to remove 660 Down Syndrome children. However, they do not count Down Syndrome miscarriages, and had only reported miscarriages to work from. There is no requirement to report miscarriages and these are usually managed in the community or local hospital. The MJA article looking at Down syndrome births in Queensland which had not reduced over a four year period of testing was disinterested in procedural mortality, concluding:

“recent economic analyses have shown that population based screening probably represents value for money. When the costs of screening are offset against the lifetime costs of caring for a person with Down syndrome, screening is less costly than no screening at all, regardless of which strategy is used.”

A journal compilation published in ANZJOG in 2006, 46:92 -96 looking at population screening policy similarly concluded:

“For consideration of national policy, cost effective screening programmes will be significantly compromised if the participation rate is low… the costs of the screening programme to detect a certain number of cases has to be balanced against the cost of managing missed or undetected cases in the population… transport to and from (termination) facilities and ongoing grief counseling as well as the emotional cost of miscarriage.”

A benefit-to-cost ratio greater than one indicates benefits are greater than costs, and this and other articles quote a benefit to cost ratio of 1.57 favouring first trimester combined Down Syndrome screening. There is no reference to clinical gain supporting this protocol. On the contrary, live Down syndrome births will significantly compromise the benefit of a national policy.

The argument in favour of prenatal testing as Best Medical Practice is economic and eugenic.

What other case can be presented here?

In the Down Syndrome higher risk group, other problems not related to Down syndrome were occasionally found retrospectively. These fall into two categories:
a) those we can do nothing about in utero and
b) structural problems which would be diagnosed later on the 20 week ultrasound.
Given the occasional occurrence of placenta praevia, miscarriage, low birth weight, diaphragmatic hernia, exomphalos, skeletal dysplasia, hypertension and preterm labour, the question was asked:

Could prenatal screening be useful for anything else?

Looking at this in 2008 a major review of data from 22,000 pregnancies was undertaken to evaluate first trimester (first 3 months of pregnancy) indicators of adverse pregnancy outcomes.

Their research concluded:

“Biochemical indicators and nuchal translucency that are measured during first trimester screening for Down Syndrome show a number of associations with adverse outcomes, but do not show appropriate performance characteristics for screening tests”, and

“it is important to note that none of the indicators for adverse outcomes other than the combined risk for down Syndrome were suitable as a screening test”

Widened nuchal translucency measurements, the width of that fluid filled space at the back of baby’s neck, have also been associated with cardiac defects. Some of these are linked with a chromosome problem and some are not. But increased width here can alert us to the presence of congenital heart disease, and the greater the width the more likely a problem is. However, the baby’s heart at this time is 11mm by 6 mm. Foetal maternal specialists remind us that “identification of all abnormalities in the first trimester is unquestionably more difficult”. Also it requires doppler ultrasound, whereas the Australia-wide combined first trimester screening test does not use doppler ultrasound, nor is it required to. Any nuchal measurement over 3 mm is recommended for foetal echocardiograph at 22 weeks or more, after the routine twenty week ultrasound which normally picks up these defects.58

THE PROCESS OF TESTING FOR SINGLE GENE ABNORMALITY.

There are no foetal screening tests for gene abnormalities. (We call them single gene abnormalities). There is only direct diagnosis by an invasive test: chorionic villus sampling or amniocentesis, or testing via IVF. If we suspect a gene problem from the family history, the question is – and will always be

“When do we need to diagnose it?”

Is there some proposed monitoring in the womb that is dependent on a documented foetal gene diagnosis?

Is there some proposed therapy in the womb that will enhance the well-being of this child and that cannot be inferred from ultrasound or other safe monitoring, and that requires an actual foetal gene diagnosis?

In justice to the foetus, the mortality and the morbidity of invasive testing require this consideration.

58 Cooper S, Parmar R, Foetal Cardiac: Diagnosis and management from the perspective of the paediatric cardiologist, O&G Magazine Vol 10 No 3 Spring 2008
If the answer is yes, a particular scenario is present and a documented foetal diagnosis is required for monitoring or therapy, then the issue becomes a proportional one. Is the proposed benefit of greater magnitude than the known hazards? Can it be delayed till a little later in the pregnancy when the risk of prematurity, is less final than the risk of death.

The ethos of medicine, the telos of Hippocratic principles is always logical beneficence. It sits well with Evangelium Vitae, which supports therapeutic testing that does not expose the child to a disproportionate risk of harm.

That said, most foetal gene diagnoses are not therapeutic. Recommended testing for muscular dystrophy, haemophilia, cystic fibrosis, fragile X tests is timed and squeezed into the laws for legal termination of pregnancy. Where some advantage may be envisaged from knowing the genetic diagnosis before birth, this can be postponed until a later, safer time in the pregnancy, that is until a stage when the benefits of diagnosis outweigh the risks and hazard of the procedure to obtain it.

Of 3,978 invasive prenatal diagnostic tests in Victoria in 2007, only 113 were done for a single gene disorder, and 91% of them were done by the 12/40 CVS, with its death rate up to 1:33\textsuperscript{59}.

Many of these mothers have instead been ushered into the 3\textsuperscript{rd} method of prenatal testing, pre-implantation genetic diagnosis.

**THE PROCESS of PRE-IMPLANTATION GENETIC DIAGNOSIS.**

This is also known simply as ‘PGD’

This requires the decision not to conceive naturally. Hyperstimulation of the mothers’ ovaries with potent hormones produces multiple eggs, which are surgically harvested and fertilized in the IVF laboratory. Some IVF centres test the embryos on day 3, and some on day 5 or 6\textsuperscript{60} when the embryo has more than 100 cells. In this latter technique 3 to 4 cells containing the genetic makeup of the embryo are removed from the trophectoderm (which goes on to form the placenta) and studied for quality.

Chromosome disorders can be detected in the newly formed embryos at this early stage and they will be discarded. Single gene abnormalities are more difficult to detect, because the technician needs to know which gene abnormality needs detection. With sufficient notice, even rare gene problems can have a test developed around them to apply to the embryo. Screening the embryo for the many, many gene defects which exist is not possible at present without foreknowledge of which ones to suspect.

\textsuperscript{60} Conceptions issue 13 May 2010
Embryos considered defective are discarded. Satisfactory embryos may be implanted or frozen for an uncertain future.

A testimonial written by parents appeared in the “Sydney IVF” newsletter in March 2009. It thanked IVF for helping them avoid “the heartbreaking decision of terminating”; We read on, and find that they -produced 8 tiny embryos (8 babies), -implanted one, -froze two, -and discarded five.

The termination doublespeak arises because of the FIGO definition of pregnancy (that our Obstetric College has agreed to), which states that pregnancy begins after day 6 of the pregnancy, ie. from implantation. So the discarded babies were not ‘terminated’ because the International Federation of Obstetricians and Gynaecologists (FIGO) had not given them living status yet.

The same pregnancy definition is used to exonerate the morning after pill and IUCD’s of causing abortion.

**THE FUTURE METHOD OF PRENATAL TESTING?**

**Non-invasive** foetal diagnosis is the latest possibility on the horizon. The entire genome of the foetus has been scanned from a sample of the mother’s blood 61. This was achieved by separating foetal DNA from the mother’s DNA, and then putting all the foetal DNA fragments together.

The science has moved fast. Foetal cells had been isolated from the mother’s blood, but in 1997 in Hong Kong fragments of actual foetal DNA were first identified in the mother’s blood. Normal, natural decay of foetal cells extrudes these fragments of DNA from the nuclei of foetal cells. Hence this DNA has become known as “cell free DNA”.

From this came an initial array of possibilities. :-

From the inquisitive [do-it-yourself testing kits of foetal sex, at 7 weeks gestation are now sold over the internet. In comparison with other tests of foetal cell free DNA, this test is relatively simple, and looks for a Y chromosome, for $25 to $150].

To the therapeutic. In 2009 the MJA published reliable rhesus blood group identification of a foetus from the mother’s blood. This test can rule out the possibility of rhesus problems for 15% of mothers who are rhesus negative, at week 12 gestation.

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To the non-therapeutic / eugenic
Looking for single gene disorders such as dwarfism;
And looking for chromosome problems such as Down Syndrome. Although this has lately been achieved\textsuperscript{62} \textsuperscript{63}, there are issues associated with it.

It has a 96.6\% positive predictive value (i.e. the odds of being affected if positive) and 100\% negative predictive value. It will not completely do away with the recommendation of amniocentesis for karyotyping if the child screens positive for Down syndrome. One in fifty families who screen positive for Down syndrome by current combined first trimester screening will still be advised invasive testing\textsuperscript{64} It is proposed to use it as a second tier test after the combined test, or as a first tier test.

For now, and probably for the next 5 to 10 years, the complexity of Down Syndrome screening and testing from the mother’s blood, and the commercial interests in the test mean intellectual property laws will place it out of reach for some time to come. Many patents are held in the USA by the companies SEQUINOM and VERINATA, and they have no current plans for the Australian market.
Professor Hyett at RPAH High Risk Pregnancy Centre says costs will be prohibitive, starting with
* $1M to equip the lab
* $2.5M to run validation studies
* $1000 intellectual property fees per test
* in addition to the material cost of the test and labour, estimated at another thousand dollars.

When these tests become future reality, they will bring into defining focus all the values which have quietly carpeted Australia’s maternity care, genetics counseling, medical colleges, graduating medical oaths, codes of ethics, HSC biology papers, our legal system’s “wrongful life”, and especially the RANZCOG slide of Best Medical Practice into deadly ideologies.

In addition to the ‘collective ethic’ of new medical values are the slogans which have groomed parents to accept these values. In their ambience of compassion and reassurance we find the language whereby ‘peace of mind’ requires consenting one’s own child to unacceptable dangers and whereby ‘psychological preparedness’ becomes a pearl at any price. Reassurance is now worth the risk of desolation.

\textsuperscript{62}Chiu RWK, Akoleka R et al. Non-invasive prenatal assessment of trisomy 21 by multiplexed maternal plasma DNA sequencing \textit{BMJ} 2011;342:c7401
\textsuperscript{64}Ibid 51
In an address to the Pro-Life Movement Pope John Paul II explained that if “a degree of risk must be undertaken”, the doctor must “ensure that it is justified by a truly urgent need for the diagnosis and by the importance of the results that can be achieved by it for the benefit of the unborn child himself”.65

The replacement of morality with ethics which derive good and bad from collective interests would sacrifice our children to its checklists. The poor application of bioethics in this setting can no longer tell eugenics from therapy, no longer does its homework on the biology, and is content to follow the easier slide of ‘Best Medical Practice’. The cold fog of prenatal testing survives on a creeping despair, on ignorance and on a cruel assumption that love is conditional.

Families have had to carve their own way out of this landscape - have had to protect themselves from obstetric medical protocols, and find their own exits, unsignposted, from the National Down Syndrome Screening Programme. Each family, on its own, has been left to challenge these protocols
- without fully understanding them
- without the language
- without facility with the factual details
- without the support of the onlooking community
- without reliable input from genetics counselors.
- without the graduating medical oaths to protect them from a medical culture that has recently adopted eugenic thinking – oaths that once protected them from us, and us from ourselves.
- without the protection of specialist medical colleges that have fallen one by one to the policy of eradicating Down Syndrome births and closed ranks against these children:
  * The Royal Australian and New Zealand College of Obstetricians
  * The Royal Australian College of GP’s
  * The Royal College of Pathologists of Australia and
  * The Human Genetics Society of Australasia.
- without the support of bioethicists; in fact misled and misinformed by centres devoted to bioethics
- and where consent is not informed consent.

This national policy is enabled by misinformation, omissions of information, coercion and betrayal of trust. All of these work together in one direction, to orientate the ‘autonomy’ of parents toward the stated goal to “bring relief to the community”. Together with the pressure from medical colleges and the negative value placed on people with Down syndrome from spokespersons of its upper echelons, they serve the cost-benefit ratio, which the Medical Journal of Australia has warned its readers will be compromised if participation rates are low. Live births of Down Syndrome babies are

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65 Discourse to Participants in the Pro-Life Movement Congress 3 December 1982
criticized for their pre-calculated lifetime cost effect on the economic ratio. Foetal maternal medicine specialists on the public record for their “certainty” that Queensland’s failure to reduce its live birth rates of Down S. in rural and public sectors supports the call for more uniform prenatal genetic testing are compromised.

No wonder parents feel they can’t outrun this. They have been left to outrun it on their own.

More than ever parents need the solidarity and the tools, the confidence and the education to challenge pseudo-science testing routines. Tests which can kill their child, but promise no benefit to the child commensurate with the hazard they impose are not therapeutic by definition. Their economic evaluation of the worth and worthiness of each child is not antenatal care but a parasite attached to it.

This test invades more than the womb and threatens more than the safety of the child, with neither proposal nor evidence of benefit, it invades the home, the family, the doctor-patient relationship and the security of society, which has a right to be protected from quasi-medical and tax-payer funded eugenic programmes.

As an article in the recent Messenger magazine pointed out, our generosity may be rather limited at times, but we have tremendous capacity to grow in love. It is this we underestimate, and it is this that Medical Colleges have lost touch with - the source of our hope, our creativity, and our potential for unconditional love.

Clearing the fog from prenatal genetic testing gives families back their autonomy and lets them breathe the free air again, as Tolkein would say. But not just free air, air lit with understanding, and enriched with the guidance of the Holy Spirit.

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