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Safety Concerns in Reproductive Technology

The following article is the first to appear in our study of the safety of established (Part I) and emerging (Part II) Assisted Reproductive Technologies.

Over 25 years ago the first IVF baby, Louise Brown, was born on July 25, 1978. Worldwide there have now been over 1 million babies born as a result of assisted reproductive technology (ART), and services are rapidly expanding in many countries.[1] The desire to have children runs deep, and thus reproductive failure can be a great disappointment, bringing pressure to bear on ART centres and their relative pregnancy rates. Moreover, the number of couples in the developed world experiencing infertility is expected to increase in the next 20 years due to women delaying child-bearing, further increasing demand for infertility treatment.[2] Despite the apparent safety of ART, new studies have emerged raising important questions about the safety of standard procedures.

ART covers a range of interventions aimed at overcoming infertility. Predominantly, sperm and eggs, collectively known as gametes, are manipulated in a variety of ways (such as in vitro maturation or ovarian stimulation) before fertilisation is attempted. Although IVF remains the mainstay, intracytoplasmic sperm injection (ICSI), a technique where the sperm is injected into the egg, is fast gaining ground. Gamete Intra-Fallopian Transfer (GIFT) also has good success rates, the difference being fertilisation is achieved in the woman's body.

Previous studies on young children conceived after IVF, embryo freezing, and ICSI have been generally reassuring.[3] Outcome studies, however, 'are relatively few to date and hampered by difficulties such as high cost, ethical considerations, recruitment of appropriate controls (in that no naturally-conceived children were included as a control group), and unwillingness of some parents even to tell their children how they were conceived, let alone bring them for assessments.'[4]

There have been a spate of recent reports about the health of ART children that have caused widespread concern. In particular, studies have been published showing a risk of low birth weight, even among singletons, an increase in major birth defects, the longer term risk of neurodevelopmental disadvantage, and the postulated risk of the in vitro environment causing an increase of certain rare diseases and possibly cancers.[5] Far and away the greatest problems, though, arise due to multiple pregnancy.

Low Birth Weight

A recent study compared the incidence of low birth weight (LBW) among liveborn ART babies with that found in the general population.[6] This most comprehensive study of its kind found some troubling trends in ART. As expected, multiple births lead to LBW babies, and this issue is addressed below. Of particular note was the finding among the singletons examined. Regardless of the cause of infertility, the risk of LBW among term singletons conceived through ART was 6.5%, over two and a half times that found in the general population.[7] Although no cause was identified, other factors such as the mother's health had been taken into account. It is not clear whether the underlying condition causing infertility or the techniques utilised in ART is the primary cause.

Low birth weight has serious implications for the child's health, not just at birth but because it predisposes the in-

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fant to later sequelae. A German study just released compared the cognitive and behavioural level of normal weight and LBW children at 11 years of age. In particular, children were assessed on scholastic, motor, cognitive and behavioural criteria, excluding children with severe neurological disability from the study. Psychometric measures were used to determine a range of diverse abilities including arithmetic, spelling, concentration, non-verbal intelligence and motor skills. Scholastic aptitude was gauged mainly by teacher and parent reports, while behavioural problems were identified by the standard Child Behaviour Checklist. LBW children performed significantly less well than those of normal birth weight on all counts. The poor outcome could not be attributed to other, confounding obstetric risk factors.[8] If this finding is confirmed, prospective parents should be informed of such long-term risks associated with ART procedures.

Multiple Embryo Transfer

There is little doubt that ART has increased the incidence of multiple births. Throughout Europe and the US the twinning rate has increased 50 to 60% over the last thirty years. The triplet rate has increased even more dramatically, with a 430% increase in the UK and a 696% increase in the US over the same period. In real terms, this translates to 40,500 more twins and 6,500 more triplets born annually in the US alone.[9] Of particular note is that, within the group of mothers aged 35-39, the ratio rocketed from 48 to 403 triplet or higher order births per 100,000.[10] Multinational studies have attributed up to 24% of twin pregnancies and up to 59% of all triplet and higher order pregnancies to ART treatments, particularly ovulation inducing drugs and the routine practice of multiple embryo transfer.[11]

This may not seem too serious but these pregnancies can have serious health consequences for both the mother and child, as well as increasing the burden on health care resources. Multiple pregnancy is the main risk factor for adverse outcomes in ART treatments. Multiple births almost always lead to babies being born earlier and less well developed, resulting in higher infant morbidity and mortality.[12] For example, the prevalence of cerebral palsy increases exponentially: 0.23% for singleton births, 1.3% for twins and 4.5% for triplet births.[13] And even with advanced neonatal intensive care, perinatal mortality is four times higher in triplet births than that found in singleton births.[14] There are also significant obstetric risks for the mother such as preeclampsia. Despite clear evidence for years now that the transfer of three embryos increases only the risk of multiple births but not the overall pregnancy rate, the practice still persists.[15]

Even the transfer of two 'good quality' embryos in patients with a good prognosis leads to an unacceptable frequency (around 40%) of twin gestations,[16] thus increasing health problems for both the newborn infant and the mother.[17] Although Australian guidelines limit the replacement of embryos to two, which is certainly preferable to US guidelines, there is no rationale in most infertility cases to transfer more than one embryo. Risks must always be weighed against the advantages, and when alternative solutions with minimal risks are available, the risky procedures should be shelved. It is unethical to do harm when safer techniques are available. In the context of infertility treatment today, it is unethical to apply clinical procedures likely to result in higher multiple pregnancy rates when it is possible to produce a singleton pregnancy. 'The long-term welfare of the family should take precedence over the short term goal of achieving a pregnancy and ambiguous preoccupation with clinical success figures. Indeed, a healthy child is the ultimate goal of IVF treatment... the professional competence of an IVF center should be measured in terms of ongoing singleton pregnancies per cycle' [18]

Increase in Birth Defects

A study analysing combined data from three Western Australian registries detected further disparity between babies conceived through ART and those conceived naturally. The researchers looked at the rate of major birth defects at one year of age for three different groups: those infants born after IVF, those born after ICSI and those naturally conceived. Data used from the West Australian Births Defect Registry defined major birth defects as 'abnormalities that are probably of prenatal origin, including structural, chromosomal and genetic defects.' After taking into account factors that could have influenced the rate of birth defects (such as the mother's age and the baby's sex), the researchers found that children conceived through ART were twice as likely to have a birth defect. By the age of one, 8.6% of the infants in the ICSI cohort and 9% of those conceived using IVF had one or more serious defects detected. Birth defects among the infants conceived through ART covered the full range found in newborns, including brain abnormalities, holes in the heart, one kidney, undescended testicles, and cleft lips and palates. Even when the investigating scientists considered only singletons, infants conceived through ART were still more likely to have single and multiple birth defects.[19]

Although the cause(s) for an increase in birth defects was not identified, several possible explanations were proposed by the researchers involved. It is possible that the underlying cause of infertility affects the risk. Drugs taken to encourage ovulation or to maintain a pregnancy in the early months could also be involved; alternatively, some aspect of the ART techniques themselves may be harmful. One of the authors, Dr Kurinczuk, said the increased risk of birth defects 'should not necessarily deter people from having the procedures, but they need to take them into consideration when making a fully informed choice.' Although experts in fertility cautioned that these findings do contradict smaller studies, they agreed new studies would be needed to confirm the elevated risk.[20] And with a steadily increasing number of women having children via ART, the cause of these increased birth defects

should be investigated and determined expeditiously.

Increase in Rare Disorders

When doctors in Holland recently diagnosed a rare form of eye cancer in five children within a fifteen month period, alarm bells rang. Known as retinoblastoma, the expected incidence is 1 in every 17,000 children born: researchers found the incidence in IVF-conceived children to be about 5 in every 17 000. Though the disease is still rare, the increased risk is of concern, particularly because all new cases were children conceived by IVF. Dr Moll, the lead researcher, believes the ovulation inducing drugs used in IVF treatment could be a possible cause. Other possibilities include a genetic link between infertility and this type of cancer, or perhaps imprinting problems arising from culture conditions.[21]

An American and UK study both found an association between a rare disorder and children conceived through IVF. The investigators found children conceived through IVF had an elevated risk of Beckwith-Wiedemann syndrome (BWS), usually caused by incorrect imprinting.[22] Epigenetic mechanisms control gene activity, and thus cell function, without changing the sequence of the DNA itself. Genomic imprinting, a form of epigenetic modification, describes the processes by which genes are turned 'on' or 'off' , ensuring the correct level of gene expression within an individual's cells. It is poorly understood but is known to occur at two critical points: during the formation of sperm and eggs, and in very early embryonic development. ART treatments occur precisely at both these time points in development. Thus crucial events that are easily disrupted occur at the very stages gametes and embryos are being manipulated in the ART laboratory. The researchers believe 'that some aspect of the ART procedure increases the frequency of epigenetic abnormalities leading to congenital malformation syndromes.' [23]

The British Fertility Society, in rejecting such statements, asserted that if the results were true, the risk of the syndrome would be raised from about one in 30 000 births to about only four in 30 000, apparently acceptable figures. Such a correlation, if confirmed, ought not to be dismissed lightly. Dr Reik, lead author for the UK study, has pointed to other research which suggested an increased risk of Angelman's syndrome, an imprinting disorder that causes neurobehavioural symptoms, in children born after IVF.[24] He argues that children conceived by artificial techniques should be carefully followed up. 'Obviously, the vast majority of IVF babies are born healthy and happy, but we published our findings because parents should be informed of all potential risks. I also feel that the IVF community has not taken on board the need for study of these children's long term health. For example, I know of no study of cancer rates among artificially conceived children. Research on such basic questions is sorely needed.'[25]

Monitoring and Regulation

Evidence is gathering that the various ART techniques may not be altogether as innocuous as first supposed. The long-term sequelae of IVF and associated ART practices needs closer examination, and in more longitudinal studies. Unfortunately, much of the research into assisted reproduction has concentrated more on the needs and dilemmas of the parents.[26] Set against this is the fact that the pace of advances in the treatment of infertility has been extremely rapid over the last decade.[27]

'We do not have an effective system for monitoring the health, development, and outcomes of these children,'[28] said Dr Hudson, director of the genetics and public policy centre at Johns Hopkins University. Large, prospective studies should be able to identify problems and clear up much of the uncertainty. Perhaps clinicians are tending to place clinical success, in terms of the number of livebirths per treatment cycle, above safety when utilising ART. It is indeed tragic if the long-term health of the child has been compromised at the expense of success rates.

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Is Population Mass Screening for Certain Cancers Always Beneficial ?

The prevailing attitude in Western Society is that all efforts should be expended to reduce mortality from certain cancers through early detection and treatment. Some cancers have recognised pre-clinical stages and changes, which may (but not absolutely or inevitably) lead to cancer. Herein lies the predicament. Should whole populations of asymptomatic people be screened for cancers, which they may never get? In screening, are people given accurate predictions about risks and probabilities associated with the cancer screened for, the screening test itself and the aftermath should the screening test be negative or positive? Does screening lead to over diagnosis and over treatment of non-cancer abnormalities? Are all populations equally targeted? Are the benefits equally distributed? Who carries the burden? New screening technologies may help the individual, but at what cost to the community as a whole. Are we becoming too intent on looking at ways to prevent inevitable death rather than actually living? Screening for five common cancers will be discussed.

What is Screening ?

Screening is the examination of asymptomatic people in order to classify them as likely or unlikely to have the disease. The disease must pass through a preclinical phase during which it is undiagnosed but detectable. Early treatment must offer some advantage over later treatment.[1] Screening is usually directed at diseases that progress to an increasingly serious stage unless treated successfully. The proportion of a population that has detectable preclinical disease is an important determinant of the utility of screening in controlling the disease. Screening for rare diseases is not rewarding.

The sensitivity of a screening test refers to the probability that a test correctly classifies people with preclinical disease as positive. Specificity refers to the probability that the test classifies as negative people who are not diseased. Test reliability is its capacity to give the same result on repeated application in a person with a given level of disease. Of particular importance is the predictive value positive (PVP) of a screening program. That is, the proportion of people with a positive test who have the disease in question. High PVPs indicate that a high proportion of screening program costs are being expended for the detection of disease during its preclinical phase, whereas low PVPs indicate that some costs are being wasted on detection and diagnostic evaluation of false positives- people who have a positive screening test but not the disease.[2]

Whilst screening for disease and cancers in individuals may benefit the individual there are also potential harms.

Every cancer screen brings the likelihood of potential adverse effects from complications and additional diagnostic procedures, identification and treatment of clinically insignificant cancers, and anxiety and distress from the screening process regardless of the result.[3] In an era of escalating health costs and fewer resources, along with growing waiting lists, the costs of mass screening asymptomatic populations is ethically questionable. Could the 'savings' be diverted to treatment and care options for those actually diagnosed with cancer.

Breast Cancer Screening

The risk of breast cancer for Victorian women is 1 in 12 with the median age of development the late 50s. Factors strongly associated with the risk of breast cancer include female sex, increasing age and a strong family history. Those with a hereditary risk may have a genetic mechanism for their breast cancer, that is, mutated BRCA1 or BRCA2 gene.[4] The BRCA genes act as tumour suppressors. Mutated genes lead to increased susceptibility to certain cancers.[5]

The only factor shown to have a major effect on the mortality due to breast cancer is early detection by screening mammography (not diagnostic mammography). Mammography screening for breast cancer has become controversial since a Cochrane Review (2002) suggested that currently available reliable evidence does not show a survival benefit of mass screening for breast cancer.[6] Women are perhaps reassured by the familiarity of the national mammography program. Certainly, diagnostic mammography should be available for any fully informed individual.

Cervical Cancer Screening

Australian women are currently encouraged to have cervical smears every two years, despite scientific evidence suggesting 3 years is the better interval, detecting about 90.8% of squamous cervical cancer compared to 92.5% with 2 yearly intervals. However, in the absence of screening, it is suggested that, perhaps at worst, only one in 50 Australian women would get cervical cancer over their lifetime, so the 98% who would not get this cancer will never benefit from screening.[7]

A United Kingdom review suggests that cervical cancer screening is labour and resource intensive for women not destined to develop invasive cancer. They suggest that around 1000 women need to be screened for 35 years to prevent one death. For each death prevented, over 150 women will have an abnormality found, over 80 will be referred for investigation, and over 50 will have treatment. Over 80% of certain abnormalities do not progress to invasive cancer, yet all will be treated exposing women to risks from surgical procedures.[8] It is questionable to assume that every woman needs to be screened and then carry the burden of knowing that they do or don't have some perceived cervical abnormality that could, but probably won't, statistically, be the cause of their eventual death. It is not a question of denying access to women, but they should be fully informed before making their decision.

Prostate Cancer Screening

Many men diagnosed with prostate cancer eventually die with the disease rather than from the disease. Current data does not prove that screening reduces mortality from prostate cancer. A man's lifetime risk of having microscopic prostate cancer is estimated at 42%, but the risk of his dying of prostate cancer is only about 3%. Radical prostatectomy for localised prostate cancer, whilst removing the risk of death from the disease, is controversial for healthy men.[9] Prostate-specific antigen (PSA) is a tumour marker used to detect, stage and monitor men with prostate cancer. Sensitivity tests suggest that 20-30% of tumours are missed with this screening, and the false-positive rate is as high as 60%[10]

Positive screening results cause patient anxiety and mandate a prostate cancer biopsy. A negative biopsy report also causes anxiety because the false negative rate of biopsy findings is relatively high.[11] Frankel et al, (2003) suggest, 'The balance of proof must be high to justify exposing men older than 50 years to a process where, of 1 million men, about 110,000 with raised PSA's will face anxiety over possible cancer, about 90,000 will undergo biopsy, and 20,000 will be diagnosed with cancer. If 10,000 of these men underwent surgery, about 10 would die of the operation, 300 will develop severe urinary incontinence, and ....4000 will become impotent.'[12] Population screening of asymptomatic men is not currently recommended, though diagnostic testing for fully informed individuals is supported.

Colorectal Cancer Screening

Colorectal cancer (CRC) is the second most common cause of cancer death in Australia. Early detection of polyps and cancers are the main benefits of undertaking screening programs for CRC.[13] If 2/3 of people offered a biennial haemoccult screening program attended for at least one haemoccult test, it is estimated that 8.5 deaths from colorectal cancer per 10,000 people offered screening would be prevented over a period of ten years.[14]

The Federal Government is currently funding a project to implement the Bowel Cancer Screening Pilot Program, using a Faecal Occult Blood Test (FOBT), which may be expanded into a national campaign.[15] There is also a mechanism for a genetic predisposition for certain bowel cancers, with targeted screening of at-risk populations recommended. Certainly, individuals with strong-family history of bowel cancers should be encouraged to have early screening. Until long-term benefits of screening asymptomatic masses is shown, the money saved by tar-

geted rather than mass screening could surely benefit those needing treatment.

Ovarian Cancer Screening

One woman, every 10 hours, is diagnosed with ovarian cancer, often referred to as a 'silent' killer as it often remains undetected until in its advanced stages.[16] Ovarian cancer is the eighth most commonly occurring cancer in Australian women. There is no reliable screening test used to detect pre-clinical disease in asymptomatic women, though trials using experimental technologies are currently progressing. These include ultrasonography and the measurement of a tumour marker called CA-125. CA-125 is an antigen produced by the majority of ovarian cancers and can be measured by a simple blood test, though it is not specific for ovarian cancer.[17]

Inhibin, a hormone involved in regulating fertility, in conjunction with CA-125, has been found to detect the majority of ovarian cancers in research conditions.[18] Individuals in high-risk groups, or with symptoms, are encouraged to seek diagnostic testing if they choose. Recommending population screening for all women is unwarranted given that even with early detection and treatment prognosis is often poor.

Cancer Control versus Costs of Mass Screening in an Era of Scarce Resources

One important aspect of proving the benefit of screening is the economic evaluation of screening programs. It is suggested that there is no evidence of any systematic tendency for screening programs to be more or less cost-effective than other prevention or treatment programs.[19] Various formulas to calculate risks are used to justify screening. To put perspective into the picture it has been estimated that more potential years of life lost would be regained by enforcing a smoke-free Australia than by any other possible scenario based on proven effectiveness, or in other words 'the greatest potential for health gain lies less in cancer screening than fully funded tobacco control'.[20]

Can Cancers be Prevented?

1. Predictive Genetic Testing

Predictive genetic testing is the use of a genetic test in an asymptomatic person to predict future risk of disease. Supporters argue that its potential is in accurate risk assessment and appropriate targeting for screening. However, these tests cannot definitely predict when a condition will develop, its severity, or whether it will develop at all.[21] Even if a mutation is found, this only indicates that there is a greater risk that this person will eventually develop a cancer, not that they actually will. Knowing about a mutation does not mean a cancer can be prevented.[22]

At present predictive genetic technologies are not widely used. Their potential to cause benefits is undeniable. Unfortunately their predictive value is not absolute. Debate continues about the potential for these therapies to be exploited and used in a negative way, getting close to what some consider the 'new Eugenics'.[23] Others predict that potential employers and insurers may use this technology in discriminatory ways.[24] The burden of knowing is not necessarily beneficial. Before any decisions about population genetic testing are made, public debate about its medical, ethical, and legal pros and cons is required.

2. Chemoprevention

Chemoprevention is also promoted although it is not a new concept, eg, chemopreventers in the form of medications to reduce cholesterol with the aim of preventing future cardiovascular disease. They can also be derived from food and drinks, eg. the antioxidents found in some tea beverages. Chemoprevention of cancer aims to prevent, arrest, or reverse either the initiation phase of carcinogenesis or the progression of neoplastic cells to cancer. There are many naturally occurring and synthetic agents, which show promise in this area. However, these agents must have low toxicities compared with chemotherapeutic agents used to treat cancer.[25] However, lifestyle changes, in their own right, may enhance one's health and negate the need for expensive detecting and treatment technology.

3. Prophylactic Surgery

Prophylactic surgery is also proposed as a cancer preventative. This involves the removal of certain organs or body parts, in asymptomatic people to avoid the risk of developing certain cancers. This type of prevention is an option some people take if they have a strong family history of certain cancers, and/or show genetic markers for the said cancers. This type of prevention is risky, given that estimating probabilities is not an exact science, and the individual's lifetime risk of developing the cancer they aim to prevent may become skewed in statistical analysis.[26] Is it justifiable to predict that, for example, women who have prophylactic mastectomy will not develop breast cancer, compared to those that do not have prophylactic surgery? Of course they will be less likely to develop breast cancer, given that they have had their breasts removed before they may have (not would have) developed the cancer. Even so, this type of prevention at any cost seems extreme and presumptuous.

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Postponing Mortality

What are the limits of medical technology in a society where the benefits are not equitably distributed? Population mass screening that benefits the few is a considerable economic burden for the many. Is the main impera-

tive to reduce morbidity or mortality? A person's lifetime risk of mortality (unlike morbidity for certain diseases, conditions and injury) is currently 100%. Diagnostic screening to detect cancer in its early stages is useful for the individual but no program can categorically prove that there is a long-term benefit for doing mass screening in asymptomatic populations.

Screening for cancer cannot prevent cancer, but it does offer hope for early intervention. The problem inherent in screening asymptomatic populations is that it engenders a belief that should something abnormal be found, cancer will be prevented. Not every abnormality will be cancer, yet most will be treated and all will cause some degree of psychological stress and anxiety. Any treatment carries risks. Individuals should always be self-determining in their choice to screen for early detection of cancer. The consequences of either choice is that in knowing they may start dying awaiting their more certain death, or take their chance not knowing and keep living until death overtakes them.

There is something referred to as the Cascade Effect, where a process once triggered into motion, proceeds to a seemingly inevitable conclusion. This, when applied to medical technology, has been described as, 'a chain of events initiated by an unnecessary test, an unexpected result, or patient or physician anxiety, which results in ill-advised tests or treatments that may cause avoidable adverse effects and/or morbidity.'[27] People should be able to make informed choices about whether they wish to be screened or not. They should not be compelled to do so, either through coercive media campaigns or alarming statistics. Individuals at higher risk for developing certain cancers should certainly be offered diagnostic testing. Mass population screening of asymptomatic people is costly and the long-term benefits difficult to justify when people with proven disease may be missing out on treatment due to scarce resources.

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Medical Journalism - Benefits, Rights and Responsibilities

This article will consider the valuable role the media plays in disseminating health information and how the press has the right to investigate and report on any health issue that it chooses. With this right should come a

The Value of Medical News in the Media

Newspapers, and the media in general, play a very important role in disseminating medical information. In particular they have an invaluable role in relaying news regarding new treatments, breakthroughs and recently discovered complications or side effects. The media has the ability to capture the attention of both the general public and patients who are suffering particular conditions. This enables them to convey information that relates to public health issues and news that relates to potential therapies for specific conditions. These features ensure the media has a unique position of influence. How this position is used, or perhaps more importantly, how this position of influence should be used will be the subject of this article.

The media in all its forms has a primary responsibility to its shareholders. That means the primary role of newspapers is to sell. What makes newspapers sell and current affairs programs rate well on television are topics and stories considered highly 'newsworthy'. Generally speaking, health and medical issues rate well on the newsworthiness scale making health a hot topic. Later in this article I will look at how 'bad' news stories appear to rank higher than 'good' news stories. Health related articles can influence policy makers, consumers of health services and the population in general. This can as a result influence the provision of, and demand for, health services.[1] Put simply the role the media plays in the health sector and the influence this can create should not be underestimated.

What Makes the News?

Before commenting on how journalists should deal with health information it will be helpful to identify how they currently report medical issues and which medial issues they report on. Newspapers reporting of health issues has been criticised for attributing too much certainty to research findings, premature representation of findings as breakthroughs and for being alarmist, incomplete, or inaccurate.[2] It has also been suggested that articles in the media about new medications may fail to properly disclose any financial ties that study groups or experts have with the pharmaceutical manufacturers.

Perhaps some examples may be the most appropriate way of demonstrating the perils of failing to accurately and completely report on medical issues. Alendronate, a bisphosphonate for the treatment and prevention of osteoporosis, has received media attention because it plays an important role in preventing a major disease. On one particular evening, 22 May1996, in response to results released at a conference of a randomised controlled clinical trial, three major US television stations ran stories related to alendronate. All three stories gave only the relative risk reduction, ie that the new osteoporosis drug could reduce the incidence of hip fractures by 50 per cent, this statistic obviously making the drug sound impressive. One reporter described the results as 'almost miraculous'. What all of the stories failed to mention were actual event rates (hip fractures). The drug does not sound quite as 'miraculous' when its success is put this way. Event rates in treated patients were 1 per cent and in non-treated patients 2 per cent. Only one of the three articles mentioned gastrointestinal distress as a possible adverse effect and none of the stories disclosed that the study investigator being interviewed had received funding for the study from the manufacturer of the drug.[3] While this is only one example it does demonstrate the possible pitfalls associated with media reports of medial research.

Misreporting of medical issues can cause greater potential harm than merely creating undue excitement about a medication. In June last year the Sydney Morning Herald ran a story with the headline, 'Doctors warn: just one tablet of aspirin a day may be enough to do you serious harm'.[4] The story related that a study in a Sydney hospital had found that where any drug was implicated in gastrointestinal bleeding, low dose aspirin was consistently the most likely culprit, ahead of anti-inflammatory drugs, which were more often blamed for the condition.[5] Before the end of the day the 'blood and guts' story proved irresistible to the television news, which all ran similar stories one even stating that "new research shows that even small doses of aspirin can cause potentially fatal stomach bleeding"[6]. The process of transferring the medical information in to stories carried by at least 20 media outlets had transformed an observational retrospective study of 20 patients presented as a poster at a conference into

'sensational' medical news.

While this kind of sensationalism or inaccuracy may occur frequently in the media we as a community can ill afford this kind of treatment of important medical information. Imagine the people who sat in their homes that night concerned and distressed that the medications they were taking for serious medical conditions such as heart or cerebrovascular disease may pose fatal risks. Should they take their aspirin in order to prevent a heart attack or stroke or should they cease their medication in order to prevent a fatal stomach bleed? Before examining the ethical implications of both these examples it is important to note that the information published in the newspapers regarding aspirin has still yet to be published in a peer reviewed journal. This raises the question of when research findings become scientific 'facts'. Media coverage of issues prior to publication may well do the community a disservice, as the imprimatur of the press can convey a sense that the information is valued, accurate and widely accepted, when the truth is very different.

Bad Versus Good News

It is also important to consider whether or not the media present a balanced coverage of all health-related topics. A research project in the United Kingdom set out to assess the characteristics of medical research that is press released and consequently reported in the newspapers. The project discovered that of 1193 original research articles that were published in Lancet or British Medial Journal, 517 were highlighted in press releases and 81 were reported in one or both of the UK's top selling newspapers (one broadsheet the other tabloid). The study found among other things that while good news and bad news stories were equally likely to be press released it was bad news stories that were more likely to be reported in newspapers.[7] With such a skewed presentation of medical research findings it should come as no surprise that people in general over estimate their chances of developing most major diseases, especially cancer. Along with the disproportionate reporting of bad news medical stories comes a saturation of public health messages contained in news stories. These stories, promoting particular public health issues, often fail to disclose that the expert who is making the comment may have conflicts of interest. This kind of reporting and publicity gives issues a kind of credibility that they cannot get from paid advertisements. This state of affairs led Hilda Bastian, convenor of the Cochrane Collaboration's consumer network, to make the following observation, "Public health experts are making us all paranoid, that at any time your body could be turning against you"; she also says, "we are healthier than we've ever been if you're in a developed country, and yet people are more scared than they've ever been about illness".[8]

The Rights of Journalists

It has long been accepted that a basic tenet of journalistic ethics is that journalists should be independent. They have a right to report and investigate any issue they choose without fear or favour. They frequently claim freedom of the press and resist moves to restrict or regulate their voice. Most journalists also acknowledge that although they have rights they must also abide by ethical standards. The Sydney Morning Herald has such ethical principles as honesty, impartiality, fairness and independence listed on its website under the title 'Ethics Code'.[9] These values are important for journalists to uphold not only because they should but also to ensure that a newspaper or current affairs program appears to have credibility. It is not sufficient to be abiding by such a code but in the media it is also crucial to be seen to be working within such ethical guidelines. Meeting the ethical standards required by journalistic ethics may not be adequate when dealing with medical and health information. Journalists have on numerous occasions stressed that their right and responsibility to report medical matters takes precedence over scientific or evidential rigour.[10] While this may be true they also have a responsibility to report information that is, or should be, in the public domain. They must acknowledge the power of medical information and consider how it is different from other information they may be reporting. They should ensure that all opinions are given a fair hearing and acknowledge that misrepresenting medical information could have fatal consequences.

It is not only journalists who influence what the media tells us. Sub-editors, editors and media owners can also play a role. This article focuses primarily on the reporting of journalists but it is essential to note that the decisions made by others influence the finished news item. The decisions made by editors and others can be based on factors of space, appeal and relevance. Articles can be shortened, reworded or substantially rewritten to change their size, focus or newsworthiness, however, this should not risk altering their original message. The decisions of these parties should be held to the same standard of ethics as the journalists themselves.

Trial by Media

Not only has the media misrepresented research findings, they have also on at least one occasion influenced the research before it was even conducted. Articles in the Sydney Morning Herald raised concerns about the safety and ethics of a proposed clinical trial of the management of acute myocardial infarction (AMI or heart attack). The aim of the trial was to improve the outcomes for patients suffering AMI and to identify the possible need to develop cardiac interventional units in local hospitals.[11] The proposed trial was going to compare two treatments of AMI, one available at a major city hospital and the other at local district hospitals. Patients presenting to the ambulance service were to be randomly assigned to each group. In any kind of research involving emergency medicine, questions can be raised about patients and informed consent but the newspaper made it sound as though this was the

first time research of this kind was to be conducted. This was not the case. The newspaper articles also raised questions about delaying treatment because of the increased travel time it would take for patients to receive treatment in a city hospital.

I do not need to comment on the actual safety or ethical aspects of the trial because my opinion on those issues is not what is relevant. What is important is that the trial had been put before the appropriate ethics committee. The committee required that a small pilot study be conducted before they approved the complete trial. The pilot study was completed to the satisfaction of the ethics committee and after being questioned by numerous other committees final approval was eventually granted. The Sydney Morning Herald article was then published raising public fears because the article failed to properly describe the trial, or acknowledge previous trials conducted with the same consent issues, or to detail the results of the pilot study. The NSW Health Minister then stepped in to establish yet another committee to consider the trial and huge delays have resulted. As a result of newspaper articles which, 'misrepresented the trial's rationale, risks and important ethical issues'[12] important medical research has been unduly delayed perhaps costing lives.

Conclusion

As I detailed earlier misrepresenting health information or inaccurately or incompletely covering a medical issue can have disastrous consequences for people affected by the issues. The influence that health related topics has on both the community and decision-makers requires that higher standards of honesty and integrity be met. It is not sufficient when dealing with health information just to make sure that what is said is not incorrect. What is included in the article or television story should be accurate, complete, easily understood and in cases where medical opinion is not in agreement both positions should be treated equally. People, especially patients, should not be left feeling scared or unsure upon reading about health issues. Nor should we be presented with unrealistic expectations of illness.

We as a community need to be reassured that when we encounter a health-related topic in the media we are not merely being exposed to unpaid publicity for a disease, medication, medical opinion or research centre. If this is not achieved the public will be very quick to add health issues to the other topics in the media they already view with very cynical eyes. We are rightly very quick to disapprove of conflicts of interest in business, including medicine, but we need to be just as eager to condemn the failure to disclose such conflicts in any media reporting.

Experience allows many people to understand the media and how it operates. We, as a community, should endeavour to educate young people and those in other vulnerable positions about how the media, including newspapers and television, operate. This would include making them aware of media ownership, sensationalism, advertising and reporting. Although the media should improve the way it handles health information, we should not leave it up to them alone. If we understand health reporting and what we should be told then we can begin to demand better.

Health information is not like any other information. It has a special power and influence that require it to be treated with an increased sense of respect and transparency. If this is done, it will be a win win situation. If people can trust what they read or see on television, and loose their cynicism, the likelihood of them buying a newspaper or watching the television will increase.

ENDNOTES

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Destruction of Human Embryos, Fetuses and Ethics

This article is an abridged version of a paper given on 16-9-2003 in Marseille at an international Conference on "Procreation and the Rights of the Child".

The fact that many embryos and fetus are lost naturally does not imply that this may be done deliberately for any reason.[1] This often takes place following routine assisted reproductive technology(ART) procedures when some embryos are thought to be sub-optimal: they may be discarded, donated for destructive research or simply allowed to die in the laboratory. In more recent times Preimplantation genetic diagnosis (PGD) enables a couple at risk of transmitting an inheritable disease to have recourse to ART so that their embryos may be tested for it. Embryos found to be free of the disease are selected for implantation. The remaining embryos are discarded.[2] Multiple pregnancies usually occur as the result of infertility treatment, eg ovulation induction or routine multiple embryo transfer during ART treatment. Higher order multiple pregnancies put the whole pregnancy at risk. To enhance the birth of only one or two viable infants the number of embryos or fetuses in a multiple pregnancy may be reduced by a lethal ultrasound-guided intracardiac injection of potassium chloride into one or more embryos/ fetuses. This is known as multi-embryo or multifetal pregnancy reduction, which occurs at 8-12 weeks gestation, usually to achieve a twin pregnancy.

Traditional Concept of the Human Person, Embryos and Ethics

From early Christian times it was held that human life should be cherished and shown absolute moral respect from conception because human life is an inviolable divine gift.[3] The Second Vatican Council confirmed this living tradition on the moral status of human embryos: 'Life once conceived must be protected with the utmost care...'[4] I believe this theological insight expresses a widely shared value for human life, held also by many who do not believe in the Bible.

There are also sound philosophical, ie, rational, arguments that support the biblical and Christian tradition on absolute respect for the human embryo based on its natural actual and proximate potential, inherent in its formative process from conception, to form a human individual and person. The recognition of the need of moral respect for human life from conception reflects humanity's high regard for life that from time immemorial has taken its origin from a couple's mutual self-giving in love. It arises in the heart and not from religious sources alone. There is no justification for the reductionism that views human embryos as no more than genetic products, devoid of inherent value. Secular views on the value of human embryos rest on the questionable metaphysical assumption that only matter really exists, thereby excluding God and any immaterial human soul. Once a human individual is conceived and is creatively animated by an immaterial soul, a human person would be constituted a subject of a rational nature with intrinsic and inviolable dignity.[5]

Michael Panicola, Germain Grisez and William May have given solid and credible arguments to support that the zygote from fertilisation already is a human individual and so a person.[6] The zygote is a totipotent cell whose newly constituted genetic package, in conjunction with exchanges of signals from the maternal reproductive tract, continuously directs, in a coordinated process, the multiplication of cells with unidirectional purposeful development. At the same time, the differentiation of tissues required for the growth of the one and the same living individual proceeds. The embryo possesses the potential to develop and grow into an adult from the beginning. This argues that the zygote and the adult are the same living individual. Once the human embryo is formed, naturally or artificially, it is owed a duty of unconditional moral respect and protection, regardless of benefits their destruction may bring to third parties.

Pope John Paul II in his 1995 Encyclical Letter Evangelium Vitae rightly leaves no doubt that from conception the embryo is to be treated as a person:

> What is at stake is so important that, from the standpoint of moral obligation, the mere probability that a person is involved would suffice to justify an absolutely clear prohibition of any intervention aimed at killing a human embryo. The Church has always taught and continues to teach that the result of human procreation, from the first moment of its existence, must be guaranteed that unconditional respect which is morally due to a human being in his or her totality and unity as body and spirit: 'The human being is to be respected and treated as a person from conception.'[7]

Ethical Evaluation of Destroying Embryos

Those who hold that human embryos should be protected as persons from conception rightly believe that the deliberate destruction of embryos in any situation is unethical. This applies to excess ART embryos, to embryos donated for research or to embryos found by PGD to be affected by an abnormality, even if this means avoiding subsequent abortions and less suffering for disabled offspring and their carers.[8] Clearly, PGD is eugenic since its purpose is to reduce the number of children born with congenital abnormalities.[9] The practice of discarding embryos for social

sex-selection is likewise unethical: it also shows how low the value of human life has fallen in our culture when life is taken even for non-life saving and non-therapeutic purposes.

In a case of multiple pregnancy where it is most likely that some or all embryos would be lost if the pregnancy is left to continue, it would be unethical to perform multi-embryo or multifetal reduction. This would be the deliberate killing of some embryos to save others. As such it would be direct abortion. Unethical actions may not be done to prevent suffering or to save innocent lives. Obviously it is ethically imperative for ART practitioners to change their protocols by implanting one or at most two embryos and to fully inform prospective parents of the risks of multiple pregnancy. Likewise the initial dose of fertility drugs for ovulation induction needs to be conservative, women's follicles monitored and the dosage adjusted accordingly to minimise the risk of more than twin pregnancies resulting from sexual intercourse.

Human embryos should not be subjected to unjust discrimination as if only embryos free of genetic defects are worthy to be born alive. Liz Hepburn wisely commented: 'Paradoxically, we seem to be prepared to eliminate the very people before birth whom anti-discrimination legislation seeks to protect after birth'.[10] This is an ethical challenge that the international community must not ignore.

ENDNOTES

1 Norman Ford, *The Prenatal Person. Ethics from Conception to Birth*, Oxford; Blackwell Publishing, 2002, 76-77, 102-3, 56-59, 61-62,152 and 166.

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