Medicine for Managers

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When Medicine Gets It Wrong . . .

Medicine has achieved remarkable developments from the days of Hippocrates and Galen, over the centuries to the present day. However, it hasn't always been as easy as one might think to convince the establishment of the wonders of modern healthcare and doctors, pharmaceutical companies, regulators and competing scientists have all made decisions which have delayed, frustrated or actively promoted poor decisions about health and treatment.

Adverts like these are hard to believe now but, in 1946, a campaign was launched to encourage smoking by using doctors as the medium through which its benefits could be advertised.

To be fair, there was really no definitive evidence of the damage caused by smoking until around 1950.

Medical practitioners were still regarded as demigods who could do no wrong, a status that was probably assisted by the fact that so little was known about disease generally that there really wasn't that much to get wrong.

During the 1950s many doctors, particularly in the United States, were complicit in promoting smoking, and the first US advertisement for smoking appeared in the *Journal of the American Medical Association* in 1933 and regularly thereafter for two decades. One medical journal advertised one brand of cigarette with the slogan:

"Just as pure as the water you drink"

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The ***Thalidomide*** disaster is a tragic example of a medical catastrophe. The drug was first marketed in Germany in 1953, by Grunenthal for anxiety and insomnia. It was also recommended for the treatment of morning sickness in first trimester pregnant women, ***although it was never tested on pregnant women before release***. Over the following years

an increased number of birth defects were identified in children of women who used the drug between 3 and 6 weeks of pregnancy.

By the late 1950s, it was being marketed by fourteen pharmaceutical companies in 46 countries under 37 different trade names.

In the UK, it was sold by the ***Distillers Company*** and the best known brand name was ***Distaval***. By 1961 the concerns were widespread and the drug was withdrawn the same year. It is estimated that up to 20,000 infants were born with severe defects, many of whom died.

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Another drug with disastrous consequences was ***Vioxx***.

The pharmaceutical company Merck received approval from the US Food and Drug Administration for its release in the United States in May 1999.

Prescribed as a painkiller, it was considered to be better than traditional pain killers because it caused less gastric irritation. In October 1999 a trial comparing it with ***naproxen*** showed fewer ulcers and less gastrointestinal bleeding.

However, it appeared that about 2% of patients suffered serious heart attacks or died during the study. Further heart attacks after the study were not included in the analysis and neither were a variety of other heart complications which arose.

The drug was defended vigorously but, by 2004, multiple studies showed that the risk of heart disease was significant. The drug was withdrawn by Merck. Research done in the USA revealed that at least 88,000 Americans had suffered heart attacks related to Vioxx and some 38,000 of them had died. During the period that it was used, it became very popular globally and Merck received at least 2.5 billion dollars from its sales worldwide.

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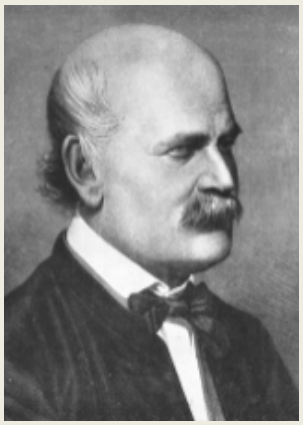
It is hard to believe that ***handwashing*** was rejected by members of the medical profession.

Ignaz ***Semmelweis,*** a Hungarian obstetrician, noted in the 1850s that ***puerpural sepsis*** (childbed fever) was much less frequent in women delivered by midwives than by doctors. He introduced a handwashing regime in his maternity ward and death rates declined by nearly 90% in less than six months.



His colleagues dismissed his findings and vilified him and he was attacked by medical professionals throughout Europe.

His mental health status was brought into question and his medical colleagues had him admitted to a mental hospital where he was beaten. He died of his injuries a few days later.

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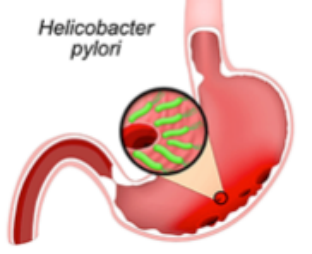
Barry ***Marshall***, an Australian gastroenterologist identified the bacterium ***Helicobacter pylori*** as the cause of stomach and duodenal ulcers in the mid-1980s. His findings were roundly dismissed by the medical profession in Australia and

abroad, and the conventional wisdom was that they were the result of stress, spicy foods and too much stomach acid. Marshall was so convinced about his discovery that in order to demonstrate it, he swallowed a culture of H pylori and, within a week, he had developed severe gastritis and early ulceration. Subsequently, the infection was also found to predispose to cancer.



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Gregor ***Mendel*** was an Austro-Czech, who was an Augustinian Friar and later Abbot. He was a biologist and lived from 1822 – 1884. He is regarded as the father of genetics, identified principally through experiments on ***peas***. He identified specific characteristics of pea plants.

For example, he established that, if true bred yellow peas are cross-bred with true bred green peas, all the offspring are yellow. Yet in the next generation, green peas reappear in a ratio 1:3 with yellow peas.

He coined the term “dominant” and “recessive” in respect of traits observed. His work on what would become genetics was dismissed and ridiculed in Europe and America. Doctors believed that characteristics from the parents were ‘merged’ and Mendel’s findings were ignored where they indicated a different situation.

More bigoted medical professionals dismissed his work as the ramblings of a simple Monk who did not understand that biology and mathematics could not be reconciled!

Dismissal of genetics occurred until his work was duplicated and published at the turn of twentieth century, 35 years after he expounded his ideas and over 15 years after his death.

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Cocaine was seen as a wonder drug by the medical profession for decades leading up to the first world war. It was routinely prescribed for a wide range of diseases and disorders including everything from headache to cancer.

Products were advertised suggesting that the drug “invigorates and stimulates the brain, muscles, nerves, stomach and heart”.

The medical profession used it in all formulations from powders to cough medicine. However, cocaine tooth drops probably stopped children making a fuss!

Its true dangers were recognised in the early part of the twentieth century.

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Medical Implants have had a profound effect on the management of disorders such as cardiac arrhythmias, where pacemakers implanted into

the chest have normalised heart activity, restoring affected patients to good health and able to undertake normal activities.

Similarly the modern implantable drug-release devices have made medication administration so much more simple and reliable.

Not all implants have been as successful. Synthetic vaginal mesh implants, hailed as a means of providing extra support in the repair of the vagina which had been damaged or weakened, were introduced in the late 1990s.

However, in the following twenty years, it became increasingly apparent that some women encountered a range of problems with such mesh, including pain or inability to have intercourse, bowel and nerve trauma, pelvic and back pain and even difficulty walking.

The use of the mesh was paused for some indications in 2018.

Another implant issue where problems have arisen after reassurances of safety, was associated with the use of the French-made PIP breast implants.

Introduced in 1991, it is estimated that 2,000,000 were sold, principally in Europe,

North and South America and Australia. They were withdrawn from use in the UK in 2010, when it was discovered that they had been fraudulently manufactured because they were made using a cheap industrial-grade silicone gel which was not approved for medical use.

They are believed to be 2-5 times more likely to rupture than standard silicone implants.

It is estimated that about 47,000 women in the UK had PIP implants and most of them are still in place.

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The ***Contaminated Blood Scandal*** continues to receive much publicity to this day because of compensation issues. In the 1970s and 1980s over four-and-a-half thousand haemophiliacs were infected with hepatitis C and HIV after being treated with contaminated blood products used in the NHS. Over half have since died.

The issue arose largely because the NHS approved purchase of blood products from American drug companies.

Much of the blood sold to British Hospitals came from American prisoners, a high proportion of whom were infected with hepatitis C and HIV.

In the UK blood is provided on a voluntary basis whereas, in the USA, donors are paid. People like sex workers, drug addicts and other risk groups with a high incidence of blood-borne diseases, needed money, hence blood donations. A single batch of Factor VIII could include blood from up to 20,000 donors,

resulting in contamination of the whole batch even if only one donor was infected.
In the early 1990s, blood Factors started being synthesised in laboratories, virtually eliminating the risk of disease transmission. Sadly, it was too late for many patients.

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These failures in healthcare stand out because, fortunately, they are relatively rare and are therefore noteworthy.

However, they do emphasise important lessons in terms of the quality of research and its critical evaluation, the need to avoid blind dismissal of findings because they do not fit the accepted norm, or the enthusiasm to accept something new because it is exciting, wonderful or simply 'fills a gap'.

The importance of adequate clinical testing is essential to ensure a new technique or equipment is of the highest quality and to ensure that the materials associated with its fabrication are of an appropriate quality and safe to use.

The disastrous events documented have informed and powerfully influenced changes to eliminate or minimise the risk of anything similar happening again, both at a professional and technical level or because of petty jealousies and fallacious assessment.

Thank goodness for British Medical Standards.

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