AUCKLAND WOMEN'S HEALTH COUNCIL

NEWSLETTER

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Time for one-person trials

In a recent paper in the science journal *Nature*, Nicholas Schork presents the case for precision medicine, and the need for one-person trials. Precision medicine requires a different type of clinical trial that focuses on individual, not average, responses to therapy.

"Every day, millions of people are taking medications that will not help them. The top ten highest-grossing drugs in the United States help between 1 in 25 and 1 in 4 of the people who take them. For some drugs, such as statins – routinely used to lower cholesterol – as few as 1 in 50 may benefit. There are even drugs that are harmful to certain ethnic groups because of the bias towards white Western participants in classical clinical trials." (1)

N-of-1 trials

Studies that focus on a single person – known as *N*-of-1 trials – involve collecting all sorts of relevant data for one person, as frequently as possible – perhaps every day or periodically over months or years. The usual design and statistical safeguards can still be employed, such as blinding patients and researchers to the drugs being tested, meaning neither knows which drug or placebo the patient is taking.

Classical clinical trials collect a handful of measurements from thousands of people. Precision medicine requires different ways of testing interventions with researchers investigating genetic and environmental factors, among others, that shape an individual's response to a particular drug.

Doctors have actually been undertaking *N*-of-1 trials in an ad hoc way for decades. For example a doctor may prescribe one drug for hypertension, monitor its effect on their patient's blood pressure and if it doesn't work or the side effects are unacceptable, prescribe a different drug. But, as Schork points out few clinicians or researchers have formalised this approach into well-designed trials.

Sometimes researchers discover purely by chance that an intervention works well in particular groups of patients. After getting disappointing results with a drug in large, population-based trials, they then conduct ad hoc post-trial analyses, to try to identify the factors that cause some of the people in the trial to appear to be responsive.

"For instance, the drug Gleevec (imatinib) was found to double survival rates of leukaemia patients with a chromosomal abnormality in their tumours called the Philadelphia translocation. Similarly, it turns out that Erbitux (cetuximab) improves the survival of people with colorectal cancer whose tumour cells carry a mutated EGFR gene but not a mutated KRAS gene." (1)

Precision Medicine Initiative

Recognition that doctors need to take the individual's response to drugs and other interventions into account is resulting in an increased interest in precision medicine. In January 2015 President Barack Obama announced a $US215 million national Precision Medicine Initiative. It includes, among other things, the establishment of a national database of the genetic and other data of one million people in the United States.

The *N*-of-1 approach means that various practical problems will need solving. These include using the diversity of health-monitoring devices, developing new ones and identifying appropriate disease biomarkers, such as tumour DNA circulating in the bloodstream. A cultural shift in regulatory agencies, pharmaceutical companies and in the clinic will also be needed.

Schork's paper gives an example of a study in Australia which measured reported pain levels, swelling and other symptoms associated with osteoarthritis and chronic pain in 132 people taking different drugs over three years. For each person, measurements were taken every two weeks for 12-week periods, when the patient was either off or on a particular drug. By comparing the data collected before and after the different treatments, the researchers showed that, although initially costly, the formalised *N*-of-1trials resulted in more effective prescriptions.

The barriers

There are significant barriers to implementing *N*-of-1trials. Regulatory agencies, researchers and clinicians are rightfully wary of moving away from classical clinical trials, Schork says. The pharmaceutical industry prefers to focus on drugs that are likely to be used by thousands or millions of people. And tailoring treatments to individual patients can be costly.

However, Schork believes the time is ripe for making it happen and gives three reasons for his optimism.

Firstly, there is a growing interest in what he calls 'omics' assays (tests) that expose people's unique characteristics at the molecular level. Researchers and clinicians are assaying people's blood metabolites (their metabolome) and the microbes in their bodies (their microbiome) as well as their DNA and RNA.

Secondly, cheap and efficient devices that collect health data are becoming available, such as the Apple Watch, continuous glucose monitors and portable electroencephalogram (EEG) monitors.

Finally, governments and life-sciences funding bodies worldwide are increasingly supporting a more targeted approach. *N*-of-1trials could save millions of dollars that are currently spent on inappropriate interventions, and the management and treatment of persistent or recurring diseases.

The end of patients as guinea pigs

"Key to making precision medicine mainstream is the ongoing shift in the relationship between patients and physicians. A major advantage of the *N*-of-1approach over classical trials is that patients are no longer guinea pigs whose involvement in a study may help only future generations. In *N*-of-1trials the effectiveness of different treatments are vetted for the actual participants.

Physicians are having to become more acutely aware of the unique circumstances of each patient – something most people have long called for," Schork concludes.

References

1. Nicholas J. Schork. "Time for one-person trials" *Nature* 30 April 2015

SHEILA KITZINGER

The high priestess of natural childbirth

Sheila Kitzinger was one of the most influential figures in the natural childbirth movement. She was a world renowned anthropologist, childbirth educator, and feminist. In a career that spanned more than 50 years, she oversaw a radical change in maternity care, campaigning ceaselessly for care that placed women's rights and choices at the very heart of childbirth. Sheila died at home on 11 April 2015. The British newspaper *The Guardian* announced her death in a tribute that began:

"Sheila Kitzinger, the "high priestess of natural childbirth", has died at the age of 86. She could reasonably be said to have done more than anyone else to change attitudes to childbirth in the past 50 years. It was her belief that childbirth should not be reduced to a pathological event and she waged a relentless crusade against its medicalisation. She felt obstetricians had taken control, pushing aside the hands-on experience of midwives and the personal needs and wishes of mothers.

Kitzinger believed birth should be seen and experienced as a highly personal and social event, one that was even sensual and sexual. She promoted birth practices that were far more women-centred and humanised than those followed in most hospitals in Britain, and other western societies. She suggested that women should draw up their own birth plans and decide for themselves whether, among other things, they might want to move around during labour or even give birth in water." (1)

Sheila Kitzinger wrote numerous books on pregnancy and childbirth which touched the lives of women all around the world. One of her early most popular books, "Pregnancy and Childbirth" was first published in 1980 and was revised and expanded many times in the decades that followed. Sheila's descriptions of pregnancy and birth, her encouraging words and the powerful photographs of natural birth resulted in this book becoming the bible for thousands of pregnant women in dozens of countries. Mothers who read it over and over again during the pregnancies and births of their children bought later editions for their grown up daughters and daughters-in-law when they were expecting their babies.

"Woman's experience of sex"

Likewise when Sheila's ground-breaking book, "Woman's experience of sex" was first published in 1983 it, too, became an instant best seller. As with giving birth, Sheila placed sex in the context of the continuum of life. She believed that female sexuality had for too long been oversimplified and predominantly seen through the eyes of male "experts." Drawing upon the accounts of a large number of women who talked to her, "Woman's experience of sex" explored every area of women's sexual needs – as lovers, mothers, wives and widows, but above all as women.

"*A Passion for Birth*"

In her autobiography, "A Passion for Birth: My life: anthropology, family and feminism," (2) which was completed shortly before her death, Sheila describes her unconventional child-hood and the influence that her

mother had on her. “Í had a rather unusual upbringing. Mother was both a feminist, though at that time she would not have called herself one, and a committed pacifist, and was always challenging powerful institutions.” Her mother worked in an early family planning clinic and was an active campaigner for birth control. She was also into natural healing and what is now referred to as alternative medicine.

While her mother had left school at 14, Sheila attended a girls’ school near the family home in Taunton, Somerset. After training to teach drama and voice production, she then went off to Oxford where she studied anthropology.

In 1952 Sheila married the economist Uwe Kitzinger. Her first child was born four years later when her husband was in the diplomatic service and they were living in France. After checking out the two private maternity hospitals, one Catholic and one Jewish, Sheila decided that there was no way she could simply hand her body over as both institutions expected her to do. She decided that she would give birth at home, which was highly shocking to her fellow diplomatic wives at the time.

Once back in England, Sheila went on to give birth to four more daughters, all born at home. They included her twins Tess and Nell, then Polly, and in March 1963 Sheila gave birth to Jenny who was born before the midwife arrived.

National Childbirth Trust

After the birth of Celia, her eldest daughter, Sheila started teaching for the former Natural Childbirth Trust (now known as the National Childbirth Trust) and co-created their new teacher training scheme.

During this time Sheila became a social anthropologist, specialising in pregnancy, birth and the parenting of babies and young children. She researched styles of childbearing and how women prepare for birth in many different societies, including the Caribbean, South America, Africa, China, the Canadian Inuit, the USA and – when Sheila came to Auckland in 1992 as one of the keynote speakers at the Birth in the 21st Century conference – New Zealand Maori.

“The Experience of Childbirth”

Six weeks after the birth of Polly, Sheila began writing “The Experience of Childbirth.” In her autobiography she writes “Polly was waking at 5.30am in the morning to breastfeed, and it was an ideal opportunity to write before everybody else woke up. Writing early in that precious time in the morning, in the first light of dawn, has stayed a habit.” (2) The first draft was completed within six weeks, and over the next few weeks Sheila read it through aloud, amending it to make sure she was speaking to women in her own voice.

In 1962 “*The Experience of Childbirth*” was published. Nothing like it had ever been published before. At the time it was seen as extremely radical as it signaled a change in women’s sense of themselves. It presented a powerful argument against the medicalisation of birth and strongly advocated for women to have choice and control over how they wished to give birth.

In the 2004 revision of this ground-breaking book, Sheila wrote "Rereading my words in that edition I am astonished that it could ever have been considered radical. But it was!"

Sheila had two major passions in her life – women and childbirth, and the marginalisation of people who did not fit into society. She became a prolific writer and later publications included "Birth Over Thirty" (1982) and "Birth Over Thirty-Five" (1994), "Women's Experience of Sex" (1983), "Giving Birth: How It Really Feels" (1987) which was a revised edition of her 1971 book "Giving Birth," "Breastfeeding Your Baby" (1989), "Ourselves As Mothers" (1992), "The Year After Childbirth" (1994), "Becoming a Grandmother" (1997), "Rediscovering Birth" (2000), "The Politics of Birth" (2005) and "Birth Crisis" (2006).

In 2014 Sheila was diagnosed with cancer. Her website states "After some initial investigation and treatments, she recovered well enough to finish her autobiography "A Passion for Birth." When the illness returned, she decided not to have further investigations.

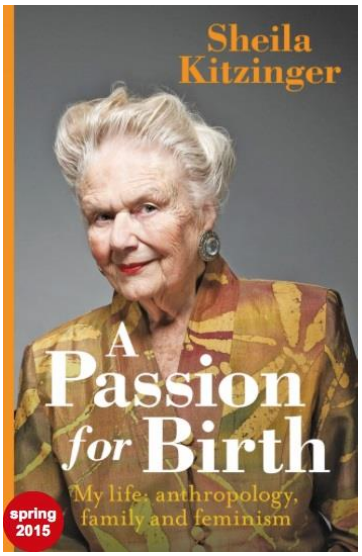
Sheila approached death with the same attitude as she did birth - questioning the need for various medical interventions and making her own choices. Just as she believed in thinking about what you would want while giving birth, she also believed in the value of thinking in advance about dying - and making plans.

Sheila set down her wishes in an Advance Decision to Refuse Treatment and gave one of her daughters power to represent her (Lasting Power of Attorney for Health and Welfare) should she lose the capacity to take decisions for herself. She specifically refused further admission to hospital.

Sheila was cared for at home, as she wished, and that is where she died. On the 12th of April her family carried her body in the brightly decorated cardboard coffin she had requested to a natural burial site for a small private ceremony. We read some of Sheila's own poetry at the graveside and scattered the coffin with earth, sprigs of rosemary and camellia blossom from our lovely garden." (3)

As Sheila wrote in one of her own poems –

After the soaring, a peace
Like swans settling on the lake
After the tumult and the roaring winds,
Silence



References

1. http://www.theguardian.com/lifeandstyle/2015/apr/12/sheila-kitzinger
2. Sheila Kitzinger. "*A Passion for Birth. My life: anthropology, family and feminism.*" Published by Pinter & Martin. 2015.
3. http://www.sheilakitzinger.com/

A NEW PILL AVAILABLE FOR FEMALE SEXUAL DISFUNCTION

First the pharmaceutical industry invented the diagnosis – hypoactive sexual desire disorder (HSDD) – and then they set about trying to find a drug for this "unmet medical need" in women. The "new" drug, flibanserin, is being hailed as the new Viagra for women, but it isn't. It is actually a drug which the FDA decided in 2010 wasn't sufficiently effective – not much better than a placebo – and the side effects far outweighed the very doubtful benefits.

Flibanserin was originally owned by Boehringer Ingelheim and had been investigated as an antidepressant. It changes brain chemistry, not blood flow, as Viagra does. The drug company tried again in 2013 and then managed to offload the lemon on to Sprout Pharmaceuticals who mounted a campaign to pressure the FDA to approve more drugs to treat female sexual dysfunction, especially this one, accusing it of having a gender bias. The FDA convened an advisory panel which has recently urged the FDA to approve the drug.

Among other things the drug has the potential for the use of hormonal contraceptives and alcohol to make its side effects – nausea, sleepiness, dizziness, fainting, and low blood pressure – worse. It is aimed at menopausal women, and would have to be taken daily on a long-term basis.

Flibanserin, the failed antidepressant, may not have measured up in the past, but buckets of money and a public relations campaign to rebrand it as libido-in-a-pill has ensured it is coming to a pharmacy near you.

AWHC GENERAL MEETING 28 May 2015

Detailed minutes of this meeting are available on request. Matters discussed included:

- Financial reports
- Grant applications
- Ethics committees
- HQSC Forum on 18 May
- HPV Screening
- 2015 Cartwright conference

Further information on some of the topics listed above is contained in this issue of the AWHC newsletter.

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UP AND COMING EVENTS

DISTRICT HEALTH BOARD meetings for June/July 2015:

Waitemata DHB (Website address: www.waitematadhb.govt.nz)
The Waitemata Hospital Advisory Committee meeting starts at 11am on Wednesday 1 July 2015 and will be followed by the DHB Full Board meeting which starts at 1.30pm. Both meetings will be held in the DHB Boardroom, Level 1, 15 Shea Terrace, Takapuna.

The **combined Waitemata DHB and Auckland DHB** Community & Public Health Advisory Committee meeting starts at 2pm on Wednesday 22 July 2015.

Auckland DHB (Website address: www.adhb.govt.nz)
The Hospital Advisory Committee meeting will be held at 9.30am on Wednesday 24 June 2015 followed by the Full Board meeting at 2pm. Both meetings will be held in the A+ Trust Room in the Clinical Education Centre, Level 5, Auckland City Hospital.

Counties Manukau DHB (Website address: www.cmdhb.org.nz)
The Hospital Advisory Committee meeting will be held at 9am on Wednesday 17 June 2015 at Ko Awatea and will be followed by the Full Board meeting at 1.30pm.

The Community & Public Health Advisory Committee meeting will be held at 1.30pm on 8 July 2015 at Ko Awatea.

ETHICS COMMITTEE meetings – dates for the four MOH ethics committees are at:
http://www.ethics.health.govt.nz/about-committees/meeting-dates-venues-minutes

The Auckland Women's Health Council and Women's Health Action will be co-hosting a Cartwright conference to mark the 27th anniversary of the Cartwright Report –

"The Future of Screening: Balancing the benefits and risks of cancer screening."

Date: Friday 7 August 2015.
Venue: Fickling Centre, Three Kings, Auckland

Please register online at http://www.eventbrite.co.nz/e/the-future-of-cancer-screening-in-new-zealand-tickets-16706180636

Or contact Women's Health Action on 09 520 5295 or info@womens-health.org.nz