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Impacts on clinical decision making

Changing hormone therapy management after the WHI

Background
Medical news often receives intense, but distorted, media coverage, which can lead to high levels of insecurity in both patients and doctors.

Objective
To elicit general practitioners' self reported behaviour regarding hormone therapy (HT) advice and prescribing, before, immediately after, and 2 years following the release of the first results of the combined oestrogen and progesterone arm of the Women's Health Initiative (WHI) study; to elicit GPs' understanding of statistical risk terminology; and to explore their personal preferences relative to the trade offs between quality and length of life in medical treatment.

Method
In October 2004, a questionnaire was sent to all 169 GPs working on the central coast of New South Wales.

Results
The response rate was 67.5%. Before the release of the WHI study, 43.8% of GPs recommended HT; 5.9% did so immediately after, and 1.8% 2 years later. When expressed as number needed to treat (NNT), 20.8% of GPs stated that they were unable to interpret the absolute risk of HT use. Half of the 84 GPs who stated that they understood the concept of NNT were not going to reconsider the advice to give HT. General practitioners with a personal preference toward length of life over quality of life proved to be significantly more likely to advise against HT use (p=0.008 in a group comparison).

Conclusion
The sensationalising of the disease specific mortality differences in HT users had a dramatic and lasting effect on GPs' attitudes to, and prescribing of, HT. General practitioners acknowledged their poor understanding of basic statistical risk terminology. Providing absolute risk terms did not alter clinical decision making in 50% of GPs, clinical decision making may well be more powerfully influenced by a doctor's personal preferences relative to the trade off between quality and quantity of life.

The intense media coverage following the Women's Health Initiative (WHI) study[1] on the risks and benefits of combined oestrogen and progesterone hormone therapy (HT) in July 2002 alarmed patients and general practitioners alike.

The immediacy and intensity of this coverage prevented most doctors from becoming fully informed about the study's methodology, results, conclusions and implications. This situation allowed us the opportunity to study the impact dramatic news has on doctors' consulting behaviours and their understanding of scientific data. In this study, we were interested in GPs' self reported behaviour regarding HT advice and prescribing before and immediately after the release of the WHI study. Furthermore, we wanted to explore if GPs had maintained or altered their advice and prescribing of HT 2 years after the release of the study. In undertaking this survey, we postulated that changes in advice regarding the use of HT may have a relationship to a GP's personal preference regarding the trade offs between quality and length of life.

Method

We developed a self administered questionnaire that asked GPs to provide responses relative to:

- their demographic data
- their general advice on HT immediately before and after the release of the WHI study
- their current approach to HT prescribing defined by four possible clinical approaches
- their understanding of the risk figures from the WHI study
- their willingness to change their HT advice when spelling out the risks of HT use in absolute terms (calculated from the relative risk data in the original paper), and
- the importance they attach to the trade offs between quality and quantity of life when considering management options for menopause.

In October 2004, the Central Coast Division of General Practice in New South Wales distributed the questionnaire to all 169 GPs, with a follow up questionnaire being sent to nonresponders after

2 weeks. Data was analysed using the SPSS 11.0® statistical software, and results were considered statistically significant at a level of 5%. Statistical significance of continuous measures was tested by a two tailed student t-test, or ANOVA, while categorical data was tested for significance using the Chi-square test.

The study was approved by the Ethics Committee of the University of Newcastle.

Results

During the study period, eight doctors either retired or stopped practising in the area, leaving a study population of 161. Of these, 114 doctors (67.5%) responded. Seven (6.1%) blank questionnaires were excluded, leaving 107 questionnaires for analysis.

Results showed that the WHI study significantly changed the approach of doctors who had previously been supportive of combined oestrogen and progesterone HT. After the study, these GPs put the decision regarding HT into the hands of their patients – advising them either to cease HT and to see how they responded (p=0.002), or to simply decide for themselves (p=0.002) (*Table 1*). This approach was sustained over time, with 98.2% of GPs indicating that at the time of the study (2004) they only prescribed HT for symptomatic patients or patients who requested HT.

In their responses, GPs demonstrated a poor understanding of statistical terms: 20.8% of all GPs stated that they were unable to interpret the risk of HT, even after being provided with absolute risk figures. Half of the 84 GPs who said they understood the absolute risk figures said they would not reconsider the advice they were giving to their patients.

A GP's personal preference relative to the trade offs between quality and length of life significantly influenced their approach to HT advice. Irrespective of a GP's age or ethnicity, those who showed a preference toward length of life were significantly more likely to advise against HT use (p=0.008 in a group comparison). Those GPs with a stronger personal preference toward quality of life showed a trend toward reconsidering prescribing HT as a result of the additional information about the absolute increase in risk for specific causes (*Table 2*).

Discussion

Medical stories, particularly those promoting new technologies and those reporting misadventure, attract great attention in the media. Such stories have a great impact on patients, who often make immediate decisions in regards to their own health management in response.[2]

The release of the risks and benefits of combined HT from one arm of the WHI study[1] in July 2002 led to sensational headlines in the media.[3] The more reassuring findings from the second arm on the oestrogen only HT study, in contrast, received little attention.[4] Despite prompt callings from the medical profession not to panic after the first results were released,[5] many women immediately ceased taking their medication or sought their doctor's advice regarding their ongoing HT management. When asked to cite their reasons for ceasing HT, women responded that this study showed HT to be risky, confirming their initial suspicions about the treatment; or that the proclaimed benefits relative to the risks were overstated.[6] While the controversy left women feeling generally less trusting of medical recommendations,[7] by 2004, one-third of Australian women had restarted HT.[2]

Less is known about the effects of media on doctors and their clinical decision making. In this study, doctors showed that they become as overwhelmed by the reporting of 'threatening figures' in the mass media as their patients. Responses are based on three major factors:

- the lack of statistical knowledge
- the psychological impact of being confronted with relative rather than absolute risk data, and
- the impact of personal preferences on the trade offs between quality and quantity of life.

Statistical knowledge

In their responses, 20.8% of all GPs freely acknowledged their lack of understanding of the most fundamental statistical terms they encounter: relative risk, absolute risk and number needed to treat (NNT). This lack of understanding of statistical concepts directly diminishes the GP's ability to evaluate scientific papers, while also undermining their attempts to communicate risk in a balanced fashion to their patients.[8] A USA study showed doctors in general overestimated the risks associated with HT, and that general physicians did so more often than specialist gynaecologists.[9]

Appreciating risk

Risk is as much a numerical concept as it is subjective to the individual.[10] The numerical concept can become particularly dangerous if, as has been reported in most epidemiological studies, relative risk is mistakenly translated as representing the true or absolute risk for an individual. This misperception of numerical data has been shown to elicit quite bizarre personal and – at a policy level – political responses.[8,10–12]

When confronted with uncertainties, especially those associated with risk, doctors use a mix of three approaches to create certainty in the mind of their patients:

- constructing temporary certainty and offering general reassurance
- developing a coherent story of certainty despite implying uncertainty, or
- frankly acknowledging uncertainty.[11]

These findings support a nexus between knowledge about, and psychological experience of, risk data. Specifically, the study showed how the bigger figure of relative risk overrides the lower figure of true or absolute risk.[9] Even after providing the absolute risk differences in relation to four outcomes (*Table 1*), half of the GPs in this study still refused to alter their approach to HT.[8,10]

Table 1. Overview of study population and responses

Age	50.1 years (range 29–77 years)	
Ethnicity	**N (%)**	
European	79 (75.2)	
Asian	22 (21.0)	
Arabic	04 (3.8)	
Practice size		
Solo	14 (13.5)	
2 doctors	15 (14.4)	
3–4 doctors	38 (36.5)	
5 or more doctors	37 (35.6)	
Professional memberships		
Fellow RACGP	29 (27.1)	
Member of the Menopause Society	04 (3.8)	
Vocationally registered	67 (64.4)	
Number of HT patients seen per week		
Less than 5	55 (55.6)	
5–10	34 (34.3)	
More than 10	10 (10.1)	
HT advice – before/after release of study		
– to use HT	46 (43.8)	6 (5.9)
– not to use HT	01 (0.9)	3 (2.9)
– to not start HT and to see how they go	12 (11.5)	37 (36.3)
– to make up their own mind	46 (43.8)	56 (54.9)
Altered HT prescribing based on debate	84 (79.2)	
HT prescribing today		
– I actively promote HT	01 (0.9)	
– I do not prescribe HT at all	01 (0.9)	
– I only prescribe HT for symptomatic patients	80 (74.8)	
– I prescribe HT only if requested	25 (23.4)	
Understanding the additional risk posed by HT		
– I would advise to use HT	07 (6.5)	
– I would advise not to use HT	05 (4.7)	
– I would advise to not start HT and to see how they go	29 (27.1)	
– I would advise to make up their own mind	48 (44.9)	
– Nonresponses	18 (16.8)	
Would you reconsider prescribing HT if you knew that this study reported:		
– no difference in overall death rate among women taking HT compared to those not taking HT?	59 (57.3)*	
– that the difference in the number of women being diagnosed with breast cancer between the two groups is 8 in 10 000?	42 (43.8)	
– that HT treatment protects against bowel cancer and osteoporosis?	52 (53.1)	
– that the difference in the breast cancer rate in this study is 66% lower than was known from previous studies?	57 (59.4)	
Quality of life and length of life trade offs		
Personal degree of importance (0 = quality, 100 = quantity)	31.4** (SD: 18.3) (range 0–100)	

* Number (%) stating 'yes'; ** <50 indicates greater importance of quality of life; >50 indicates greater importance of quantity of life

NB: N=107; not all participants answered all questions

Balancing the consequences of accepting risk

General practitioners' decision making is further influenced by their position relative to the perceived trade offs between quality and length of life. The study showed that these personal values substantially influence clinical decision making. Those valuing quality of life over quantity of life tended to favour HT prescribing, ie. these GPs tend to accept clinically miniscule increases in disease specific risk (eg. an 8 per 10 000 absolute increase in breast cancer incidence) when overall quality of life is improved and mortality is unaffected.

Changing consulting behaviour

Most GPs are no longer actively promoting HT as a preventive treatment modality. Instead, a substantial number tend to adopt a passive role, putting the decision solely in the hands of their patients. These GPs only tend to prescribe when asked by the patient or if the patient complains about menopausal symptoms. The GPs in this study, in contrast to a USA study,[12] did not indicate that they engaged in more detailed discussion about the individual risks and benefits of HT (an observation congruent with the finding of a lack of understanding of statistical terminology).

These observations raise the question of how much media sensationalising interferes with an in depth analysis of scientific data. As Burger[13] has shown, the WHI results are of little clinical relevance considering the majority of study participants were not healthy perimenopausal women and that the decontextualisation inherent in the use of relative differences generates fear and inappropriate behaviours in consultations.

Limitations of this study

Our findings are potentially biased by recall and self reported behaviour change. These, however, are unlikely to be a major issue considering a recent study showed that the negative reporting of the WHI study on combined HT has led to a sustained decrease in HT prescribing in Australia.[14]

Table 3 contextualises our findings, contrasting the original study data where risk was expressed in relative terms with those where risk was expressed using less emotive absolute terms. This data should help those with a lesser understanding of statistical terms. Additionally, using the study figures, we calculated that the likelihood of a GP seeing an additional adverse outcome in his or her practice is dependent on the number of patients treated with HT. These considerations are important when evaluating any other research finding.

Conclusion

The media sensationalising of the disease specific mortality differences in combined HT users has had a dramatic and lasting effect on GPs' attitudes and prescribing decisions. In this study, GPs acknowledged their poor understanding of basic statistical terms, in particular the difference between relative and absolute risk reduction. There is an urgent need to remedy this deficiency. Simply providing absolute risk data did not alter clinical decision

Table 2. Doctors' preferences relative to the trade offs between quality and quantity of life and its impact on HT advice

	Mean score on the continuum scale of quality of life and quantity of life*		**Significance**
Those who self reported that they understand the additional risk posed by HT use would advise patients:			
• to use HT	24.9 (SD: 16.2)		*p*=0.008^
• not to use HT	56.2 (SD: 30.0)		
• to not start HT and to see how they go	28.0 (SD: 11.6)		
• to make up their own mind	30.7 (SD: 18.2)		
Would you reconsider prescribing HT if you knew that this study reported?	**Mean score on the continuum scale**		
	Those indicating willingness to change	Those not indicating willingness to change	
No difference in overall death rate among women taking HT compared to those not taking HT	28.3	35.1	*p*=0.07
That the difference in the number of women being diagnosed with breast cancer between the two groups is 8 in 10 000	30.3	33.6	NS
That HT treatment protects against bowel cancer and osteoporosis	27.7	36.0	*p*=0.03
That the difference in the breast cancer rate in this study is 66% lower than was known from previous studies	29.5	36.0	*p*=0.09

* Continuum scale of quality of life: 0 = total importance on quality of life; 100 = total importance on quantity of life. A figure of 50 indicates equal importance; <50 indicates greater preference for quality of life, >50 indicates greater preference for quantity of life

^ Indicates group comparisons

Table 3. Contextualising the study findings

	Risk reporting in the original WHI paper on combined HT					Absolute risk of combined HT use		Likelihood of an individual GP observing an additional adverse event		
Outcomes	**Total numbers/100 patients**		**Hazard ratio**	**Adjusted 95% CI**	**Relative risk for HT users (%)**	**Absolute risk per 100 HT users (ie. rate per 100 HT users; rate per 100 nonusers)**	**No. of patients per 10 000 experiencing an additional/ prevented event**	**Depending on caseload, number of GPs seeing an additional adverse (or prevented) outcome**		
	HT	**Placebo**						**10 patients on HT**	**25 patients on HT**	**100 patients on HT**
Cardiovascular disease										
Coronary heart disease (CHD)	1.93	1.51	1.29	0.85–1.97	+ 21.76	+0.42	42			
CHD death	0.39	0.32	1.18	0.47–2.98	+ 17.95	+0.07	7			
Nonfatal myocardiol infarction	1.56	1.18	1.32	0.82–2.13	+ 24.36	+0.38	38			
CABG/PTCA	2.15	2.11	1.04	0.71–1.51	+ 1.86	+0.04	4			
Stroke	1.49	1.05	1.41	0.86–2.31	+ 29.53	+0.44	44			
Fatal	0.19	0.16	1.20	0.32–4.49	+ 15.79	+0.03	3			
Nonfatal	1.11	0.73	1.50	0.83–2.70	+ 34.23	+0.38	38			
Venous thromboembolic disease	1.78	0.83	2.11	1.26–3.55	+ 53.37	+0.95	95			
Deep vein thrombosis	1.35	0.64	2.07	1.14–3.74	+ 52.59	+0.71	71			
Pulmonary embolism	0.82	0.38	2.13	0.99–4.56	+ 53.66	+0.44	44			
Total for cardiovascular events	8.16	6.74	1.22	1.00–1.49	+17.40	+1.42	142	1 in 7.0	1 in 2.8	1 in 0.7
Cancer										
Invasive breast	1.95	1.53	1.26	0.83–1.92	+21.54	+0.42	42			
Endometrial	0.26	0.31	0.83	0.29–2.32	–16.13	–0.05	–5			
Colorectal	0.53	0.83	0.63	0.32–1.24	–36.14	–0.30	–30			
Total for cancer events	5.90	5.65	1.03	0.86–1.22	+ 4.24	+0.25	25	1 in 40	1 in 16	1 in 4
Fractures										
Hip	0.52	0.77	0.66	0.33–1.33	–32.47	–0.25	–25			
Vertebral	0.48	0.74	0.66	0.32–1.34	–35.14	–0.26	–26			
Other osteoporotic	6.81	8.65	0.77	0.63–0.94	–21.27	–1.84	–184			
Total for fracture events	7.64	5.65	0.76	0.63–0.92	+26.04	+1.99	199	1 in 5	1 in 2	1 in 0.5
Death										
Due to other causes	1.94	2.05	0.92	0.62–1.35	+5.67	+0.11	11			
Total for death events	2.72	2.69	0.98	0.70–1.37	+1.10	+0.03	3	1 in 330	1 in 132	1 in 33

Column two shows the study findings from the original paper; column three lists the findings in terms of absolute risk; column four relates them to the level of the individual practitioner, taking caseload into account. This data is based on a time period of 5.2 years of HT

making, which suggests that government funded programs to improve GP research literacy, such as the Primary Health Care Research, Evaluation and Development (PHCRED) strategy, should be continued. Consideration should also be given to getting GPs involved in funded research networks to improve research literacy at the practice level.

Clinical decision making may well be more strongly influenced by a doctor's personal preference relative to the trade offs between quality and quantity of life than by statistical risk data. This factor was not previously identified in other studies.

Finally, we believe that the media failed in its responsibilities to objectively inform and educate in this situation. Considering there is already a great amount of uncertainty relative to issues surrounding HT, and the complexity of appropriate prescribing to women troubled by their symptoms, this failure is especially problematic. Portraying uncertainty as certainty, misrepresenting relative differences as absolutes, and failing to consider psychological factors influencing decision making, do not serve anyone well.

Conflict of interest: none declared.

References

1. Writing Group for the Women's Health Initiative Investigators. Risks and benefits of estrogen plus progestin in healthy postmenopausal women. Principal results from the Women's Health Initiative randomized controlled trial. JAMA 2002;288:321–33.
2. MacLennan A, Taylor A, Wilson D. Hormone therapy use after the Women's Health Initiative. Climacteric 2004;7:138–42.
3. Media Watch (ABC Television). Media risks of HRT. Available at www.abc.net.au/mediawatch/transcripts/120802_s3.htm. [Accessed December 2008].
4. The Women's Health Initiative Steering Committee. Effects of conjugated equine estrogen in postmenopausal women with hysterectomy: The Women's Health Initiative Randomized Controlled Trial. JAMA 2004;291:1701–12.
5. Australian Medical Association. HRT – don't panic. Available at www.ama.com.au/web.nsf/doc/WEEN-5GB4CX [Accessed 4 December 2008].
6. French L, Smith M, Holtrop J, Holmes-Rovner M. Hormone therapy after the Women's Health Initiative: a qualitative study. BMC Fam Pract 2006;7:61.
7. Schonberg M, Davis R, Wee C. After the Women's Health Initiative: decision making and trust of women taking hormone therapy. Women's Health Issues 2005;15:187–95.
8. Edwards A, Elwyn G, Mulley A. Explaining risks: turning numerical data into meaningful pictures. BMJ 2002;324:827–30.
9. Williams R, Christie D, Sistom C. Assessment of the understanding of the risks and benefits of hormone replacement therapy (HRT) in primary care physicians. Am J Obstet Gynecol 2005;193:551–8.
10. Reventlow S, Hvas A, Tulinius C. "In really great danger ..." The concept of risk in general practice. Scand J Prim Health Care 2001;19:71–5.
11. Griffiths F, Green E, Tsouroufli M. The nature of medical evidence and its inherent uncertainty for the clinical consultation: qualitative study. BMJ 2005;330:511–7.
12. Burg M, Fraser K, Gui S, et al. Treatment of menopausal symptoms in family medicine settings following the Women's Health Initiative findings. J Am Board Fam Pract 2006;19:122–31.
13. Burger HG. WHI risks: any relevance to menopause management? Maturitas 2007;57:6–10.
14. Canfell K, Banks E, Moa A, Beral V. Decrease in breast cancer incidence following a rapid fall in use of hormone replacement therapy in Australia. Med J Aust 2008;188:641–4.