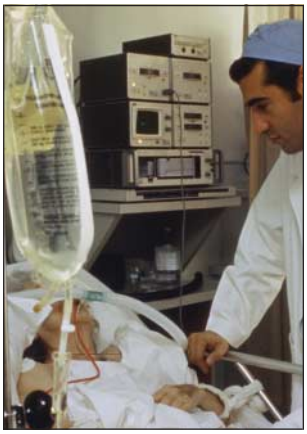
Facilitating consent for trials in dying patients

Research in palliative care settings needs novel approaches. As obtaining fully informed consent is usually impossible, research on drugs that could benefit dying patients is particularly difficult. Rees and Hardy (p 198) have developed a novel advance consent process to support a trial comparing two of the drugs commonly used for the control of "death rattle." If generally accepted, this may facilitate the research necessary to advance the care of dying patients.



JUNEBUG CLARK/SPL

POEM*

Continuous use of combined contraceptive pill minimises vaginal bleeding

Question Does the continuous use of combined oral contraceptives lead to less vaginal bleeding without an increase in adverse effects?

Synopsis Women aged 18 to 44 years were recruited by flyer for a randomised (non-blinded) controlled trial of contraception; the flyer did not emphasise the potential for reduced bleeding. There were 79 women enrolled and randomised (allocation concealed) to continuous (that is, no weeks off hormonal treatment) or standard 28 day cycles of 20 µg ethinyl estradiol with 100 µg levonorgestrel (Alesse) for 48 weeks. Women who experienced prolonged bleeding (more than 10 days) after cycle 3 (84 days) were instructed to return to the study clinic for evaluation including pelvic examination, transvaginal ultrasonography, and endometrial biopsy. Weight and blood pressure were measured every 84 days. Median days of bleeding in the first 84 days (cycles 1-3) were 3 in the continuous group and 10 in the cyclic group ($P < 0.001$). By cycles 10 to 12, 72% of women in the continuous group had no bleeding or spotting. There was a small difference in systolic blood pressure between groups at study exit among women who completed the study (116 (SD 12) mm Hg standard treatment *v* 108 (13) continuous treatment; $P = 0.02$). Otherwise there were no differences between groups for changes in blood pressure or weight or haemoglobin. There were no pregnancies and no cases of endometrial hyperplasia or neoplasia.

Bottom line Within six months, most women who take combination oral contraceptive pills on a continuous basis (without skipping hormonal treatment every fourth week) will not have any vaginal bleeding that requires the use of a pad. The results are similar to those of Depo-Provera, with the advantage that treatment can be stopped quickly if desired.

Level of evidence 1b (see www.infopoems.com/resources/levels.html); individual randomised controlled trials (with narrow confidence interval).

Miller L, Hughes JP. Continuous combination oral contraceptive pills to eliminate withdrawal bleeding: a randomized trial. *Obstet Gynecol* 2003;101:653-61.

* Patient-Oriented Evidence that Matters. See editorial (*BMJ* 2002;325:983)

Editor's choice

Death, come closer

Death gives life meaning. Without death every birth would be a tragedy. The thought that I might be editing the *BMJ* for the next 5000 years is perhaps even more awful for me than for you. Gulliver was vastly excited when he travelled to Laputa and heard of the Strudbruggs, the immortals. He imagined them with their "minds free and disengaged, without the weight and depression of Spirits caused by the continual Apprehension of Death." In fact they were the most miserable of people. One of their "prevailing Passions" was envy of the deaths of the old. Truly, where there is death there is hope, not only for those who want to follow but also for those who must die.

"The fear of death is being replaced by the fear of dying," writes Jocalyn Clark, the *BMJ* editor who has assembled this issue (p 174). I suspect that few *BMJ* readers worry about burning in hell, but many must wonder how it will be when it comes to their turn to die. Most doctors have witnessed patients die undignified, soulless, high tech deaths and hoped for something better for themselves and their patients. But what does a good death look like and how high a priority should it be for health services? If death is defeat, then it won't be a high priority. But if a good death is the culmination of a good life then it must be a priority.

What is clear from reading this theme issue on a good death is that one size won't fit all. We want to be as different in dying as in living. Different cultures, times, and religions have different concepts of a good death (p 175 and p 218). Some want it sudden, some slow. Some want a quiet death with minimal medical involvement. Others want to follow Dylan Thomas and "rage, rage against the dying of the light," squeezing every last drop from life (p 224).

A few chose to kill themselves, while others would like to be killed. We wondered about excluding euthanasia from this issue, but it wouldn't go away (p 189 and p 213). Even in countries that have legalised euthanasia few chose to die that way (p 201), suggesting that perhaps it's unimportant. But pressure to legalise euthanasia seems likely to grow and combine with people wanting increasing choices on how they die. For Ivan Illich death was the ultimate form of consumer resistance, but as the baby boomers turn their thoughts to death they are unlikely to accept the squalid end that may happen in a health service preoccupied with life at the expense of death.

The diagnosis of dying is one of the most crucial that a doctor must make. Paul Glare and others show that doctors consistently overestimate the time patients have left to live (p 195). In order to help their patients to a good death they must "recalibrate" themselves, recognising that death is closer than they think. This theme issue aims to recalibrate us all.

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