The risk of deep venous thrombosis with oral contraceptives containing drospirenone

Data are inconclusive, but alternatives may be preferable unless specifically contraindicated

SATURN STILLS/SPL

RESEARCH, pp 961, 962

Nick Dunn senior lecturer in medical education, Faculty of Medicine, University of Southampton, Southampton SO17 1BJ, UK
nick.dunn@soton.ac.uk

Competing interests: The author has completed the Unified Competing Interest form at http://www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declares: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Provenance and peer review: Commissioned; not externally peer reviewed.

Cite this as: *BMJ* 2011;342:d2519
doi: 10.1136/bmj.d2519

Drospirenone is a synthetic progestogen, derived from the aldosterone blocker spironolactone. It is structurally related to progesterone and has antiandrogenic and antimineralocorticoid properties. It has been marketed in oral contraceptive preparations, combined with 30 mg of ethinylestradiol, since about 2000. The contraceptive efficacy of such pills is undoubted, but their adverse effect profile is the subject of controversy, particularly the potential to cause venous thromboembolism. Two linked studies add to this debate.[1 2] Both are observational database studies and produce remarkably similar results, which support another two studies published in the *BMJ* in 2009.[3 4] All of these studies suggest that drospirenone increases the risk of venous thromboembolism compared with the progestogen, levonorgestrel. However, at least two other studies disagree.[5 6]

The two new papers analyse data taken from the UK General Practice Research Database (GPRD) and Pharmetrics, a medical claims company in the United States. They both show a twofold to threefold increased risk of venous thromboembolism in women taking oral contraceptives containing drospirenone rather than levonorgestrel. This compares with 1.5-fold to twofold increased risk in the earlier *BMJ* studies.[3 4]

Although the new papers were well planned and executed, they have weaknesses. The GPRD study had comparatively low numbers (61 cases and 215 controls), and there were 27 cases of deep venous thrombosis and 34 cases of pulmonary embolism (a case mix that does not reflect clinical practice).[1] Data were missing (for example on obesity, a risk factor for venous thromboembolism, and thus a potential confounder) and had to be imputed into the mathematical models; in addition, some subgroup analyses are not justified because of the low case numbers. In the Pharmetrics study, data on obesity were incomplete—height and weight measurements were not available,[2] and the data on duration of exposure to all contraceptives may not be reliable. This is important because first time users with short duration of exposure are at increased risk of venous thromboembolism compared with those who have used the drug for a long time.[1]

Faults can be found with any observational study, and those that use routinely collected data are more prone to error than those that use data collected specifically for the study. Nonetheless, the concurrence in risk estimates between the papers is compelling. A random effects meta-analysis of results from studies with suitable data[1 2 4 5] found an increased risk (although not statistically significant) for drospirenone preparations compared with levonorgestrel preparations (odds ratio 1.75, 95% confidence interval 0.84 to 2.67). There is also some supporting biological evidence that drospirenone can precipitate unfavourable changes in blood clotting factors.[7]

Prescribing practice should reflect available evidence on benefits and risks. Drospirenone contraceptives are said to improve acne, but there is little evidence to support their superiority over other low dose oral contraceptives.[8] They may be therapeutic for women who have premenstrual dysphoric disorder—a severe form of premenstrual tension that affects 3-8% of menstruating women, but the causes of this condition are multifactorial, and other drugs are available (for example, antidepressants).

When prescribing oral contraceptives, the patient's individual risk-benefit profile should be carefully considered, because such patients are often young, healthy, and may take the chosen pill for a long time. Of note, none of the published studies shows a significantly lower risk of venous thromboembolism for drospirenone than for levonorgestrel. Although the evidence for increased risk from drospirenone is inconclusive and the absolute risk of venous thromboembolism for women on low dose oral contraceptives is small (about 20-30/100 000 women years of use), it seems sensible to prescribe an oral contraceptive with a well known favourable safety profile (one that contains levonorgestrel) unless there is a persistent reason to use another type. The number of patients with such a specific indication for drospirenone is likely to be small.

1 Parkin L, Sharples K, Hernandez RK, Jick SS. Risk of venous thromboembolism in users of oral contraceptives containing drospirenone or levonorgestrel: nested case-control study based on UK General Practice Research Database. *BMJ* 2011;342:d2139
2 Jick SS, Hernandez RK. Risk of non-fatal venous thromboembolism in women using oral contraceptives containing drospirenone compared with women using oral contraceptives containing levonorgestrel: case-control study using United States claims data. *BMJ* 2011;342:d2151.
3 Lidegaard Ø, Løkkegaard E, Svendsen AL, Agger C. Hormonal contraception and risk of venous thromboembolism: national follow-up study. *BMJ* 2009;339:b2890.
4 Van Hylckama V, Helmerhorst FM, Vandenbroucke JP, Doggen CJM, Rosendaal FR. The venous thrombotic risk of oral contraceptives, effects of oestrogen dose and progestogen type: results of the MEGA study. *BMJ* 2009;339:b2921.

5 Dinger, JC, Heinemann LAJ, Kuhle-Habich D. The safety of drospirenone containing oral contraceptive: final results from the European active surveillance study on all contraceptives based on 142 475 women years of observation. *Contraception* 2007;75:344-54.
6 Seeger JD, Loughlin J, Eng PM, Clifford CR, Cutone J, Walker AM. Risk of thromboembolism in women taking ethinylestradiol/drospirenone and other oral contraceptives. *Obstet Gynecol* 2007;110:587-93.
7 Van Vliet HAAM, Winkel TA, Noort I, Rosing J, Rosendaal FR. Prothrombotic changes in users of combined oral contraceptives containing drospirenone and cyproterone acetate. *J Thromb Haemost* 2004;2:2060-2.
8 Arowogulu AO, Gallo MF, Lopez LM, Grimes DA, Garner SE. Combined oral contraceptive pills for the treatment of acne. *Cochrane Database Syst Rev* 2009;3:CD004425.

Do calcium plus vitamin D supplements increase cardiovascular risk?

Insufficient evidence is available to support or refute the association

RESEARCH, p 962

Bo Abrahamsen professor, Department of Medicine F, Gentofte Hospital, Copenhagen DK-2900, Denmark
b.abrahamsen@physician.dk
Opinder Sahota professor of orthogeriatric medicine, Department of Elderly Medicine, Queen's Medical Centre, Nottingham University Hospitals, Nottingham, UK

Cite this as: *BMJ* 2011;342:d2080
doi: 10.1136/bmj.d2080

Calcium supplements are widely used in the prevention of osteoporosis and as an adjunct to specific osteoporosis treatment but have been associated with a possible increase in the risk of adverse cardiovascular outcomes.[1] In the linked study,[2] Bolland and colleagues investigate the effects of personal use of calcium supplements on cardiovascular risk in the Women's Health Initiative Calcium/Vitamin D (WHI CaD) study and update their meta-analysis of calcium supplements and cardiovascular risk.[3] This new analysis is particularly relevant because it includes calcium supplements given with vitamin D.

The meta-analysis extends one previously undertaken by the same group in which calcium supplementation was associated with a significantly increased risk of stroke and myocardial infarction.[1] That study was followed by a lively debate on the *BMJ* website and elsewhere, when it was criticised for reporting individual outcomes when the global end point was not significant, for counting events rather than people with events, and for building on studies that were not designed for cardiovascular outcomes and adjudicated accordingly.

In the current study Bolland and colleagues explore the possibility that findings in the WHI study may have been masked by the widespread use of personal calcium supplements.[2] In 16 718 women, 46% of whom were not taking personal calcium supplements at randomisation, the hazard ratios for cardiovascular events with calcium and vitamin D supplements ranged from 1.13 to 1.22 (P=0.05 for clinical myocardial infarction or stroke, P=0.04 for clinical myocardial infarction or revascularisation), whereas in women taking personal calcium supplements, calcium and vitamin D supplements did not alter cardiovascular risk. In the meta-analyses of placebo controlled trials of calcium supplements or calcium plus vitamin D supplements, complete trial level data were available for 28 072 participants from eight trials of calcium supplements and WHI CaD participants not taking personal calcium supplements. One thousand three hundred and eighty four people had an incident myocardial infarction or stroke. Calcium supplements and calcium plus vitamin D supplements increased the risk of myocardial infarction (relative risk 1.24, 95% confidence interval 1.07 to 1.45; P=0.004) and the composite of myocardial infarction or stroke (1.15, 1.03 to 1.27; P=0.009).

CRISTINA PEDRAZZINI/SPL

The jury is still out on whether calcium plus vitamin D supplements increase cardiovascular risk

Although this clearly suggests that calcium and vitamin D supplements increase the risk of cardiovascular events, there are caveats, as the authors discuss. Although for the WHI study as a whole, randomisation can be assumed to have been equal across the two arms in terms of confounders, measured and unmeasured, this may not have been true for the additional strata created in the post hoc analysis. This could have contributed to the surprising findings of a 16% increased risk of clinical myocardial infarction or stroke in women allocated to calcium plus vitamin D supplements who did not use personal supplements and a 16% reduction in mortality in women given the same intervention who did use such supplements. The decision to focus on the WHI participants who did not use calcium supplements is reasonable given that the effects would be difficult to discern if both study arms had access to what was intended to be a randomised intervention. Unfortunately, although it is straightforward to remove those who were taking their own supplements from the cohort when they make up uneven parts of the randomised arms, interpreting the results is difficult because of the loss of equal randomisation.

The findings of extended survival are interesting, although they were significant only in participants who had elected to take calcium supplements before randomisation. To complicate the interpretation further, a recent meta-analysis from the group showed that the increased risk of cardiovascular events with calcium supplements

was present only in subjects with baseline dietary calcium intake above the median. It may seem counterintuitive that this study identifies one group who do not take supplements at baseline as being at increased risk of myocardial infarction if allocated to calcium and vitamin D supplements, whereas their previous study identified the group with adequate dietary calcium intake as the high risk group.

What are the implications of current evidence in clinical practice? The evidence for using calcium and vitamin D supplements as an adjunct to bisphosphonates in the treatment of osteoporosis is reassuring, both in terms of cardiovascular safety[4 5] and improved survival.[6-8] In a retrospective cohort of 23 615 patients, calcium plus vitamin D or vitamin D supplements used in combination with anti-osteoporotic drugs reduced mortality in men by 28% (hazard ratio 0.72, 0.50 to 1.03) and women by 38% (0.62, 0.50 to 0.76).[7] Because of limitations in the cardiovascular adjudication or study design of the underlying trials, it is not possible to provide reassurance that calcium supplements given with vitamin D do not cause adverse cardiovascular events or to link them with certainty to increased cardiovascular risk. Clearly further studies are needed and the debate remains ongoing.

Competing interests: The authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: No financial support for the submitted work from anyone other than their employer; BA has received consultancy fees from Novartis, serves on advisory boards for Amgen and Nycomed, and receives lecture fees from Eli Lilly and Proctor and Gamble; OS has received consultancy fees from Shire, serves on advisory boards for Amgen and Medtronic; and has received lecture fees from Eli Lilly and Amgen; no other relationships or activities that could appear to have influenced the submitted work.

Provenance and peer review: Commissioned; not externally peer reviewed.

1 Bolland MJ, Avenell A, Baron JA, Grey A, MacLennan GS, Gamble GD, et al. Effect of calcium supplements on risk of myocardial infarction and cardiovascular events: meta-analysis. *BMJ* 2010;341:c3691.
2 Bolland MJ, Grey A, Avenell A, Gamble GD, Reid IR. Calcium supplements with or without vitamin D and risk of cardiovascular events: reanalysis of the Women's Health Initiative limited access dataset and meta-analysis. *BMJ* 2011;342:d2040.
3 Jackson RD, LaCroix AZ, Gass M, Wallace RB, Robbins J, Lewis CE, et al. Calcium plus vitamin D supplementation and the risk of fractures. *N Engl J Med* 2006;354:669-83.
4 Camm JA. Review of the cardiovascular safety of zoledronic acid and other bisphosphonates for the treatment of osteoporosis. *Clin Ther* 2010;32:426-36.
5 Christensen S, Mehnert F, Chapurlat RD, Baron JA, Sørensen HT. Oral bisphosphonates and risk of ischemic stroke: a case-control study. *Osteoporos Int* 2010; online 13 October.
6 Center JR, Bliuc D, Nguyen ND, Nguyen TV, Eisman JA. Osteoporosis medication and reduced mortality risk in elderly women and men. *J Clin Endocrinol Metab* 2011; online 2 February.
7 Nurmi-Lüthje I, Sund R, Juntunen M, Lüthje P. Post-hip fracture use of prescribed calcium plus vitamin D or vitamin D supplements and anti-osteoporotic drugs are associated with lower mortality. A nationwide study in Finland. *J Bone Miner Res* 2011; online 23 February.
8 Bolland MJ, Grey AB, Gamble GD, Reid IR. Effect of osteoporosis treatment on mortality: a meta-analysis. *J Clin Endocrinol Metab* 2010;95:1174-81.

Medical abortion for adolescents

Seems to be as effective and safe as in older women

JIM VARNEY/SPL

RESEARCH, p 963

David A Grimes clinical professor, Department of Obstetrics and Gynecology, University of North Carolina School of Medicine, NC 27599-7570, USA
dgrimes@fhi.org
Elizabeth G Raymond senior medical associate, Gynuity Health Projects, New York, USA

Cite this as: *BMJ* 2011;342:d2185
doi: 10.1136/bmj.d2185

Decades of experience have established that surgical abortion is safe for adolescent women.[1] Because young women are generally healthier and have less comorbidity than adults, they fare better. However, few studies have specifically assessed the risks of medical abortion in adolescents. In the linked retrospective cohort study, Niinimäki and colleagues assessed outcomes in 3024 adolescent women and 24 006 adults who underwent medical abortion between 2000 and 2006.[2]

The development of modern methods for medical abortion began in the 1970s.[3] Initial approaches used prostaglandins alone. When given at any point in pregnancy, prostaglandins induce uterine contractions that can lead to expulsion of the embryo or fetus. However, the effectiveness of medical abortion with early prostaglandin compounds alone was suboptimal. Moreover, gastrointestinal side effects limited their acceptability.

Medical abortion improved in the 1980s with the development of mifepristone. Early in pregnancy, this antiprogestin causes the trophoblast to detach from the uterine wall and softens the cervix. Mifepristone also increases endogenous prostaglandin release while sensitising the uterus to uterotonic prostaglandin effects. Although mifepristone alone is not effective enough for routine clinical use in abortion,[3] success rates are high when it is used in conjunction with a prostaglandin; between 92% and 99% of women treated with this combination in the first trimester of pregnancy will abort without need for vacuum aspiration.

The most common contemporary regimen for medical abortion is a single oral dose of mifepristone 200 mg, followed in one to two days by administration of misoprostol, a prostaglandin E_1 derivative. Misoprostol is usually swallowed or placed in the vagina, under the tongue, or against the cheek. In some countries such as Canada, where mifepristone is not registered, clinicians use methotrexate (which is toxic to the trophoblast), followed by misoprostol or misoprostol alone as alternative regimens.[4 5]

Mifepristone and misoprostol have an excellent safety record. In typical clinical use (not in research studies), only about two women per 1000 experience a complication requiring inpatient or outpatient hospital treatment.[6] The most common complication is heavy bleeding. In early pregnancy the risk of mortality is similar to that with surgical abortion, about one per 100 000.[6 7]

Data on the efficacy and safety of medical abortion in adolescents are scarce. Several studies suggest that the procedure is more effective in younger women. Nulliparity is associated with success, and most adolescent women have not given birth.[8] A small study of 28 patients aged 14-17 years undergoing early abortion with mifepristone and misoprostol found no medical or psychological

complications.[9] Most larger clinical trials of medical abortion excluded adolescents. Younger women may have more pain than other women during medical abortion.[10] The alarmingly high "adverse event" rates in both adolescents and adults reported by Niinimäki and colleagues,[2] which range from 20 to 100 times higher than recent large studies with more specific outcome definitions,[6] should be interpreted with caution because the reported outcomes were mainly office visits by the worried well and not validated complications.[11] For example, the outcome of "haemorrhage" was neither defined nor measured because clinicians and patients are notoriously inaccurate at estimating vaginal blood loss.[6] A more useful outcome measure would have been haemorrhage requiring transfusion.[7]

Currently, medical abortion is more common than surgical abortion in some European countries. A recent randomised controlled trial from the United Kingdom compared mifepristone-misoprostol abortion with suction curettage under general anaesthesia in women who were no more than 13 weeks' pregnant. Medical abortion was more cost effective than surgical abortion, although its complication rate was higher and acceptability lower, especially in women who were at a later stage of pregnancy.[12]

Having a choice of abortion methods is important to women. No evidence suggests that medical abortion is more risky or less successful in adolescents than in older women. Indeed, women who have not previously given birth seem to have higher success rates with medical abortion. Hence, all women, independent of age, may be offered the full range of abortion services.

Competing interests: The authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; DAG performs, teaches, and studies abortion; Gynuity Health Projects studies medical abortion as part of its research; no other relationships or activities that could appear to have influenced the submitted work.

Provenance and peer review: Commissioned; not externally peer reviewed.

1 Cates W Jr, Schulz KF, Grimes DA. The risks associated with teenage abortion. *N Engl J Med* 1983;309:621-4.
2 Niinimäki M, Suhonen S, Mentula M, Hemminki E, Heikinheimo O, Gissler M. Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study. *BMJ* 2011;342:d2111.
3 Bartz D, Goldberg A. Medication abortion. *Clin Obstet Gynecol* 2009;52:140-50.
4 Wiebe E, Dunn S, Guilbert E, Jacot F, Lugtig L. Comparison of abortions induced by methotrexate or mifepristone followed by misoprostol. *Obstet Gynecol* 2002;99:813-9.
5 Blanchard K, Winikoff B, Ellertson C. Misoprostol used alone for the termination of early pregnancy. A review of the evidence. *Contraception* 1999;59:209-17.
6 Henderson JT, Hwang AC, Harper CC, Stewart FH. Safety of mifepristone abortions in clinical use. *Contraception* 2005;72:175-8.
7 Grimes DA. Risks of mifepristone abortion in context. *Contraception* 2005;71:161.
8 Chien LW, Liu WM, Tzeng CR, Au HK. Effect of previous live birth and prior route of delivery on the outcome of early medical abortion. *Obstet Gynecol* 2009;113:669-74.
9 Phelps RH, Schaff EA, Fielding SL. Mifepristone abortion in minors. *Contraception* 2001;64:339-43.
10 Teal SB, Dempsey-Fanning A, Westhoff C. Predictors of acceptability of medication abortion. *Contraception* 2007;75:224-9.
11 Fjerstad M, Westhoff C, Lifford KL. Immediate complications after medical compared with surgical termination of pregnancy. *Obstet Gynecol* 2010;115:660; author reply 660-1.
12 Robson SC, Kelly T, Howel D, Deverill M, Hewison J, Lie ML, et al. Randomised preference trial of medical versus surgical termination of pregnancy less than 14 weeks' gestation (TOPS). *Health Technol Assess* 2009;13:1-124, iii-iv.

Chernobyl 25 years on

Lessons have not been learnt and the full public health implications are unknown

Keith Baverstock docent, Department of Environmental Science, University of Eastern Finland, Kuopio, Finland
keith.baverstock@uef.fi

Competing interests: The author has completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declares: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Provenance and peer review: Commissioned; not externally peer reviewed.

Cite this as: *BMJ* 2011;342:d2443
doi: 10.1136/bmj.d2443

On 26 April 1986, a nuclear incident occurred in the then Soviet Union in a place called Chernobyl. Radiological data garnered after the United Kingdom's Windscale (Sellafield) nuclear incident in 1957 had been used a decade earlier to set emergency reference levels to protect the UK public after such events.[1] These would be used to determine evacuation and food control policies in the immediate aftermath of an incident. In 1979, the Three Mile Island incident in the United States did not pose a threat to the UK, but it was clear in 1986 that Chernobyl might. Unfortunately, not all the UK authorities recognised this possibility, so when Cumbria and southern Scotland received fallout about a week after the incident the state of preparedness was less than optimal—the first radiological assessment appeared 20 days later,[2] but it contained errors that went uncorrected for three years.[3]

The situation was much worse closer to Chernobyl: the fallout was serious and extensive, but the Soviet authorities initially denied that an incident had occurred, then acknowledged a small one, and finally—by evacuating more than 100 000 people from their settlements—acknowledged the full seriousness of the situation. Throughout Europe chaos reigned for several weeks: bans on milk were enforced in some places but not others, suspicion of contamination was enough to prevent trade in commodities, and conflicting official advice about travel was rampant. The European Regional Office of the World Health Organization (WHO/EURO) quickly evaluated the available data to formulate rational risk based advice to member states. In the immediate aftermath a programme was developed recognising the need for harmonisation and rapidity of response. An early visit made to the worst affected areas by Professor Lennart Levi of the Karolinska Institute identified an epidemic of stress related disease attributable to public anxiety. This subsequently became known as the psychosocial effect,[4] and is arguably Chernobyl's most serious health detriment to date, notwithstanding more than 6000 thyroid cancers in those exposed to iodine-131 as children and more to come.[5] A lack of trusted and timely information in the public domain exacerbates the public health effects of such incidents.

The events taking place at Fukushima in Japan over the past weeks are similar to the situation immediately after Chernobyl. Although information abounds, little of it is usable,[6 7] especially in terms of determining the potential effect on public health, and its truthfulness is doubtful. In

HELMUT FOHRINGER/EPA/CORBIS

Deserted: a ferris wheel in the town of Pripyat, near the Chernobyl power plant

the first days the engagement of the international organisations (WHO and the International Atomic Energy Agency) to ensure harmony in response to the incident was notable by its absence, the dedicated Nuclear Emergency Project Office in Helsinki set up in 1998 as part of EURO's post-Chernobyl response having been closed in 2000.

Institutional failure aside, attempts by the international research community to learn and implement the public health lessons of Chernobyl have been less than effective. Although useful information on the sensitivity of a child's thyroid to iodine-131 has been collected (and stable iodine prophylaxis was used at Fukushima), more knowledge is still needed.[8] Recently, an in-depth review of health related research carried out by experts under the auspices of a European Commission project (Agenda for Research on Chernobyl Health (ARCH); http://arch.iarc.fr) referred to the coverage at the international level as "uncoordinated . . . forming a patchwork rather than a comprehensive, structured attempt to delineate the overall health consequences of the accident."

Looking forward, the ARCH group's strategic research agenda recommends that a lifespan study—in part bringing together cohorts already under study in the most affected countries, Belarus, Russia, and Ukraine—is funded by the European Commission.[9] Latency periods for diseases caused by radiation generally extend from 10 to 60 years, so much could still be learnt and "no evidence of health damage" after comprehensive investigation would be a valuable result.

The health implications of Chernobyl have, since the incident occurred, been the "battle ground" for the lobbies for and against nuclear power, which seek to interpret the effects or absence of effects to their own advantage and are apparently unwilling to find the truth. Apart from exacerbating the psychosocial effects on those directly affected, this situation has prevented a comprehensive evaluation of the importance of the event to public health. A determined attempt to "close the Chernobyl book" was made in 2006, which sadly some UN agencies signed up to.[10]

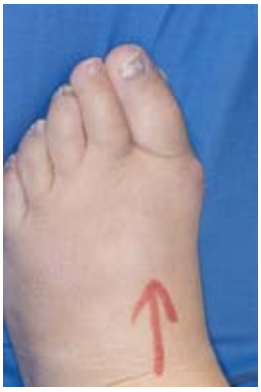
Chernobyl can still help us understand the public health consequences of radioactive fallout and the consequent exposure to low doses of ionising radiation over prolonged periods. It represents the other side of the coin from the information gathered from the atomic bombings in Japan in terms of the consequences of exposure to high doses over extremely brief periods. The Japanese and American governments are supporting long term ongoing studies of a lifespan cohort of people who were exposed.

Many have been unconvinced by arguments that Chernobyl would be the final nuclear incident, and they have been proved correct. Now it is time to act, both to ensure that the protection of the population exposed to fallout from Fukushima benefits from the experience of Chernobyl, and that the long term health effects of Chernobyl are subject to appropriate and ongoing study.

1 Baverstock KF, Vennart J. Emergency reference levels for reactor accidents: a re-examination of the Windscale reactor accident. *Health Phys* 1976;30:339-44.
2 Fry FA, Clarke RH, O'Riordan MC. Early estimates of UK radiation doses from the Chernobyl reactor. *Nature* 1986;321:193-5.
3 Baverstock KF. Cleaning up after Chernobyl. *Nature* 1989;342:744.
4 Bromet EJ, Havenaar JM, Guey LT. A 25 year retrospective review of the psychological consequences of the Chernobyl accident. *Clin Oncol* 2011; online 16 February.
5 United Nations Scientific Committee on the Effects of Atomic Radiation. Sources and effects of ionizing radiation: UNSCEAR 2008 report to the General Assembly with scientific annexes. Volume II: annex D. Health effects due to radiation from the Chernobyl accident. 2011.
6 Butler D. Fukushima update: Data, data, everywhere [blog]. *Nature* 2011. http://blogs.nature.com/news/thegreatbeyond/2011/04/fukushima_update_data_data_eve.html.
7 Editorial. A little knowledge. *Nature* 2011;472:135.
8 Baverstock K. Chernobyl and public health. *BMJ* 1998;316:952-3.
9 Agenda for Research on Chernobyl Health. Strategic research agenda: the health consequences of the Chernobyl accident. 2010. http://arch.iarc.fr/documents/ARCH_SRA.pdf.
10 Peplow M. Special report: counting the dead. *Nature* 2006;440:982-3.

Improving patient safety through education

A window of opportunity exists to include training in human factors in undergraduate and postgraduate training



DR P MARAZZI/SPL

Simon Paterson-Brown
chairman, Patient Safety Board, Royal College of Surgeons of Edinburgh, Edinburgh EH8 9DW, UK
simon.paterson-brown@luht.scot.nhs.uk

Competing interests: The author has completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declares: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

Provenance and peer review: Not commissioned; externally peer reviewed.

Cite this as: *BMJ* 2011;342:d214
doi: 10.1136/bmj.d214

The recent abolition of the National Patient Safety Agency[1] is hardly reassuring news following a series of reports that have unveiled levels of inadequacy in the provision of healthcare that shame us all, even if only by proxy. Around one in 10 patients admitted to hospital experiences an adverse event not directly related to their condition,[2] and with an estimated 234 million operations carried out worldwide each year,[3] the scale of the problem, not just from a surgical perspective, is huge.

There is little hope on the horizon of any further investment, and morale in many areas of the UK healthcare system remains low. Clinical and financial targets now dominate the horizon, with education and training forced into the back seat. The previous long hours and fatigue felt by many trainees have been reduced by the European Working Time Directive. Instead they have been replaced by more intense shiftwork patterns, which in themselves have been unpopular and not conducive to continuity of care and training, especially in many of the surgical specialties.

The past five years have seen unprecedented investment in the NHS, so that compared with many other countries hospital buildings, staffing, equipment, and facilities are of a standard that should facilitate high quality outcomes. Productivity has increased and waiting times have fallen, but multiple institutional and departmental failures remain. The associated public outrage is entirely understandable and the rising costs of preventable errors unsustainable. Such errors include wrong side surgery; failure to ensure the provision of antibiotic and thromboembolytic prophylaxis; persistently high meticillin resistant *Staphylococcus aureus*, *Clostridium difficile*, and central line infection rates; and drug errors. These primarily relate to a failure of human factors, and until this area of medicine is properly tackled, patient safety will continue to be compromised and unacceptable errors will occur.[4]

The National Patient Safety Agency (www.npsa.nhs.uk) and the Scottish Patient Safety Alliance (www.patientsafetyalliance.scot.nhs.uk) have both adopted methods from the Institute for Health Improvement (www.ihi.org/ihi) programmes for introducing "bundles of care" to reduce complications in specific areas, such as central line sepsis, prophylaxis for deep vein thrombosis, wound infections, and intraoperative errors. These collaborative efforts based on shared learning, transparency, and openness have led to remarkable improvements in patient care.[5]

Although effective and successful in their own specific areas, these programmes are not the whole answer. Poor practice and medical errors occur mainly because of failings in organisational culture and the non-technical skills that underpin good clinical practice, rather than a lack of knowledge or technical ability. These non-technical skills have now been identified for surgery,[6] anaesthesia,[7] and nursing.[8] Lessons learnt from other domains have also influenced safety and quality in medicine. Improvements include more robust reporting systems; understanding the importance of human factors; and team training to develop and sustain honesty, resilience, and cultural change.[9]

Improvements in patient safety across the board require a radical change to the culture and teaching of medicine. As highlighted in a previous *BMJ* editorial[10] and by the Clinical Human Factors Group (www.chfg.org), the importance of human factors in the safe practice of medicine in its broadest term must be imbedded in both undergraduate and postgraduate curriculums. Dedicated and enthusiastic teachers are needed within all parts of the hospital system, as is a huge cultural shift in every area of clinical practice towards open reporting and a willingness to work together in a supportive environment to reduce variations in clinical practice.

Two major changes currently occurring within postgraduate medicine offer a real opportunity to achieve many of these goals. The Postgraduate Medical Education and Training Board (PMETB), albeit now incorporated within the General Medical Council (GMC), has a unique position in being able to approve the content of all curriculums in postgraduate medicine, and this process is nearing completion of its current cycle. Similarly, the process of revalidation by the GMC is currently under construction. A window of opportunity therefore exists to incorporate those human factor elements of performance that are key to ensuring better standards of care into the core of medical education and assessment. Unfortunately, no evidence exists to suggest that these opportunities are being realised, so there is a very real danger that one of the greatest chances to radically change medical culture and practice in the United Kingdom might be lost for the next generation. Those currently tasked with the education, training, and assessment of doctors in the UK must rise to this challenge now or patients will continue to experience unnecessary and often life threatening complications from their medical treatment.

1 Roberts M. Health watchdogs "are to be axed." *BBC News* 2010. www.bbc.co.uk/news/health-10762043.
2 Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001:322:517-9.
3 World Alliance for Patient Safety. WHO guidelines for safe surgery. 2008. www.who.int/features/factfiles/safe_surgery/en.
4 Scanlon MC, Karsh B. Value of "human factors" to medication and patient safety in the intensive care unit. *Crit Care Med* 2010;38(suppl):S90-6.
5 Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S, et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *N Engl J Med* 2006;355:2725-32.
6 Yule S, Flin R, Paterson-Brown S, Maran N, Rowley DR, Youngson GG. Surgeons' non-technical skills in the operating room: reliability testing of the NOTSS behaviour rating system. *World J Surg* 2008;32:548-56.
7 Fletcher G, Flin R, McGeorge P, Glavin R, Maran N, Patey R. Rating non-technical skills: developing a behavioural marker system for use in anaesthesia. *Cogn Technol Work* 2004;6:165-71.
8 Mitchell L, Flin R. Non-technical skills of the operating theatre scrub nurse: literature review. *J Advanc Nursing* 2008;61:15-24.
9 Battles J, King H, Salas, E., Barach, P. The role of teamwork in the professional education of physicians: current status and assessment recommendations. *Joint Comm J Qual Safe* 2005;31:4:185-202.
10 Flin R, Patey R. Training in non-technical skills to improve patient safety. *BMJ* 2009;339:b3595.