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bmj.com Editorial: Opioids in the UK: what's the problem? (BMJ 2013;347:f5108)

Prolonged use of opioids after surgery

Surgeons, anaesthetists, and primary care doctors can all help patients avoid it

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In a linked paper, Clarke and colleagues present the results of a large retrospective cohort study conducted in Canada in 39 140 patients aged 66 or more who underwent major elective surgery and had never taken opioids before the procedure.¹ Nearly half of the patients were discharged from hospital with an opioid prescription, illustrating that anaesthetists and surgeons no longer hesitate to use major analgesics beyond the immediate postoperative period. Although this trend has a positive effect on patient comfort and rehabilitation, concern has been raised by another important result from this study—that 3.1% of the patients were still taking opioids more than 90 days after surgery.

Similarly, a 7.7% rate of opioid prescription has been reported at one year after low risk day surgery,² and a follow-up study recently showed that 15% of women started or increased their purchase of analgesics after hysterectomy for benign disease.³ The medical profession therefore needs to ask whether long term opioid use is a real problem, and, if so, how it could be avoided.

Some may argue that 3.1% is quite a low rate of prolonged use for patients who have undergone major, invasive surgery, and that this figure may simply represent an appropriate response to patients' need for pain relief. However, use of opioids several months after surgery is not in accordance with the expected time course of postoperative healing. Also, as the authors discuss, once these figures are extrapolated to the whole population, a large number of people may be affected. Although there is no direct evidence from the current study, we can assume that some of these patients are at risk of inappropriate long term use of opioids.

This situation should be considered in the broader context of an increase in prescriptions for opioid drugs in Western countries. First observed in the United States in the early 2000s, and now identified in statistics on European populations, this trend results from a change in attitudes about the management of pain.^{4 5} Long term opioid use is, however, becoming a public health problem, with growing reports of tolerance, addiction, cognitive effects, misuse, and acute toxicity. Also, clinical manifestations of opioid induced hyperalgesia (hypersensitivity to pain), although masked by the intake of opioids, may be revealed at times of the day when blood levels are low. This effect may have direct and adverse consequences for the health of long term opioid users, increasing their risk of pain disorders and mental health problems.⁶

It is currently thought that surgery can induce central sensitisation of the nociceptive pathways, leading to a predisposition to pain disorders.⁷ The high doses of opioids given intraoperatively by anaesthetists are also suspected of inducing long term hyperalgesia and tolerance.⁶ However, although these processes are well documented, they may not fully explain the need for analgesics months after surgery.

In addition, evidence is growing that some types of surgery are harmful to nerve endings and may induce neuropathic pain.^{8 9} Interestingly, the current study found that thoracic procedures were a risk factor for long term opioid use,¹ as

three conditioning processes are combined in these patients: central sensitisation (from major surgery), opioid induced hyperalgesia (from high doses of intraoperative opioids), and neuropathic pain (from damage to intercostal nerves).

The prolonged use of opioids by certain patients after surgery can, however, be avoided. Firstly, anaesthetists should be encouraged to use analgesic strategies that help prevent central

Long term opioid use is becoming a public health problem, with growing reports of tolerance, addiction, cognitive effects, misuse, and acute toxicity

sensitisation and reduce doses of perioperative opioids, such as nerve blocks or drugs acting at the spinal level, such as ketamine.⁷ Secondly, opioids are a second line recommended option to manage peripheral neuropathic pain, the first line option being antidepressants or gabapentinoids.¹⁰ To avoid inappropriate use of drugs, doctors should look for signs of neuropathic pain in any patient still reporting pain three months after surgery. Screening tools have been developed for this purpose¹¹ as well as precise guidelines to confirm the diagnosis.¹²

Taper or withdraw

Finally, opportunities must be created to taper or withdraw opioids as soon as possible after surgery. A detailed conversation with patients about the benefits and risks of prolonged treatment would be a good place to start. Patients with a low socioeconomic status seem to be particularly vulnerable to prolonged use of opioid agents,^{1 3} and education about treatment could be particularly important for this group.

More research must be done to explore the time course of postoperative pain, including any neuropathic features. Better and longer follow-up studies of patients having major surgery are also needed. Both surgeons and anaesthetists need to collaborate better with general practitioners, who manage the postoperative period. The months after major surgery are a tricky time during which medical problems are not always resolved, but it should be possible to reduce the incidence of prolonged use of opioids if optimal care pathways are developed, including a smooth transition from secondary to primary care.

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Not Smarties

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- Editorial: Treating prostate cancer (*BMJ* 2012;345:e5122)
- Practice: Prostate cancer: summary of updated NICE guidance (*BMJ* 2014;348:f7524)
- Podcast: Screening and treating clinically localised prostate cancer

Surgery or radiotherapy for prostate cancer?

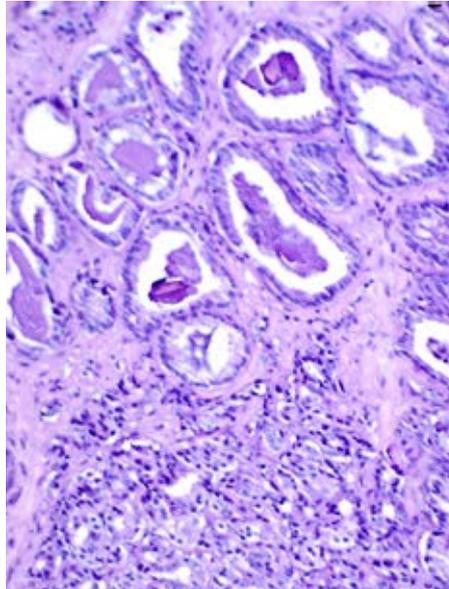
Surgery appears to be associated with better survival for men with localised disease

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Prostate cancer is the commonest malignancy in males in the Western world, accounting for over a quarter of all cancer diagnoses in men in the United Kingdom; more than 90% of new diagnoses of prostate cancer are of localised disease.¹ Surprisingly, we do not objectively yet know the best form of treatment for this prevalent disease. In a linked paper, Sooriakumaran and colleagues present some of the best quality evidence so far by comparing radical prostatectomy and radiotherapy, the two most widely used treatments.² Although previous investigators have evaluated the comparative effectiveness of treatments, most such reports were arguably flawed by lack of complete and accurate data on certain key variables that would help predict mortality. Indeed, guidelines from England's National Institute for Health and Care Excellence, updated just last month, make no suggestion as to which treatment is preferred and simply encourage decision making to be based on differences in adverse event profiles.³

The only two completed randomised studies in the specialty compared surgery with observation (not radiotherapy) and found in favour of surgery, especially for younger men and those with intermediate or high risk tumours.^{4 5} The only randomised trial comparing surgery with radiotherapy is still ongoing in the United Kingdom, and it will not report for some years.⁶

Sooriakumaran and colleagues took a complete and thorough dataset from Sweden, where virtually all predictors of mortality were available, and compared over 34 000 men with prostate cancer who had initially been treated by surgery or radiotherapy and followed them for up to 15 years.² The authors examined cancer specific mortality (after adjustment for competing risks) and found a survival benefit from surgery, which was differentially greater in younger, fitter (those with fewer comorbidities) men, and those with intermediate or high risk prostate cancer. They found that the benefit from surgery over alternative treatments might be greatest in those at greatest risk of succumbing to the disease (men with the greatest burden of disease, the longest life expectancy, or both).



Call the surgeon

Although this is probably one of the better studies to date, it still has limitations. Although there are excellent data on most of the important predictors of mortality, lack of data on tumour volume, lymph node status, and Gleason score (for the earlier cases), means that residual confounding might still have been present. The authors seem to have examined this variable in their sensitivity analyses to evaluate the potential impacts on results of a differentially distributed residual confounder, and performed propensity score matching and inverse probability of treatment weights to balance the two groups as far as possible. These analyses enable a comparison of men who had surgery with otherwise similar men who had radiotherapy. Interestingly, the hazard ratio for radiotherapy versus surgery decreased with all sensitivity analyses but remained high. The authors' take-home message was that men who first underwent radiotherapy were between 1.5 and 1.7 times more likely to die from prostate cancer than men who initially had surgery. Another criticism of the study is the lack of information (and therefore adjustment) on radiotherapy dosing. The new European Association of Urology guidelines recommend radiotherapy dosing of 78 Gy for intermediate

and high risk prostate cancer,⁷ a standard not reached by most of the Swedish centres during the course of this study. The authors attempted to quantify this by performing an analysis stratified by year of treatment; they argued that if improvements in radiotherapy dosing had an effect on comparative outcomes, then the results favouring surgery would be expected to diminish for men treated more recently. This was not the case, again suggesting that inadequate radiotherapy dosing was not responsible for the apparent benefit obtained with surgery in localised prostate cancer.

The authors also decided to investigate the comparative effectiveness of surgery and radiotherapy in men with non-localised (metastatic or possibly metastatic) prostate cancer; they found non-significant results in favour of radiotherapy. This group was, however, small and heterogeneous; interpretation of these data therefore remains uncertain, and further studies are required in this patient population. Recently, investigators have started to evaluate the role of radical therapy (surgery or radiotherapy) in distant metastatic disease,⁸ and this certainly would be an area worthy of exploration with the current Swedish dataset.

Awaiting confirmation by RCT

The bottom line is that the study by Sooriakumaran and colleagues shows that surgery is likely to be superior to radiotherapy, in purely oncological terms, for most men with localised prostate cancer.² The benefits from surgery might be greater in those men with intermediate and high risk disease or with fewer or no comorbidities, whereas those with locally advanced or distant metastatic disease may fare better with radiotherapy. The urological fraternity await confirmation of these results by randomised trial evidence in future years, and suggest that other studies should also investigate the quality of life and health economic differences between surgery and radiotherapy as these will be crucial to inform policy and practice changes.

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Practice: Accidental hypothermia (*BMJ* 2006;332:706)

Endgames: The management of accidental hypothermia (*BMJ* 2009;338:b2085)

Severe accidental hypothermia

Few UK emergency departments have a hypothermia protocol. This must change

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"Failure to prepare is preparing to fail"

Benjamin Franklin

Rarely, does a British winter go by without a headline such as "Stranded climber dies from hypothermia." However, only about five cases of severe hypothermia occur each year on British mountains. Hypothermia is more common in urban areas and was an important factor in the deaths of 166 people in the United Kingdom in 2012. In these cases, other factors often included alcohol intoxication, drug overdose, and mental illness.

Although cardiopulmonary bypass, and more recently extracorporeal membrane oxygenation (ECMO), have been used in many countries since the late 1960s to rewarm people with hypothermic cardiac arrest,¹⁻² these techniques have rarely been used for this purpose in the UK.³ In 2005, the European Resuscitation Council (ERC) guidelines recognised cardiopulmonary bypass as the preferred method of active rewarming in hypothermic cardiac arrest. The remarkable survival of a patient from a core temperature of 13.7°C showed what is possible.⁴

"Not dead until warm and dead"

The phrase "not dead until warm and dead" is well known and often quoted as a guiding principle. Management has improved internationally, but can the same be said for the UK? Few British hospitals have a hypothermia protocol, and with limited availability of ECMO and cardiopulmonary bypass and little integration between the prehospital and hospital phases of care, a streamlined pathway to the appropriate facility has never been established in this country.

Severely hypothermic patients with cardiac stability can be externally or minimally in-

sively rewarmed with an almost 100% chance of success. For those in cardiac arrest, the growing evidence base has produced greater awareness of the problems related to diagnosis and treatment. The 2010 ERC guidelines identified ECMO and cardiopulmonary bypass as important modalities for rewarming patients,⁵ with an expected survival rate of around 50%.⁶ In a Danish case report series of seven patients with hypothermic cardiac arrest, the survival rate with ECMO was 100%.⁷

Survival rates are better with ECMO than with cardiopulmonary bypass, largely because it can provide continued support during acute respiratory distress syndrome, which often occurs after the return of spontaneous circulation.² However, cardiopulmonary bypass may be the only option in the UK because ECMO is not widely available. The increased availability of mechanical cardiopulmonary resuscitation devices has improved the ability to maintain effective chest compression for hours during transport to a specialist centre,⁸ unlike manual resuscitation, which degrades rapidly.⁹

In the absence of signs of life, the key to appropriate case selection for extracorporeal rewarming is to identify patients in whom asystole was caused by hypothermia—"cold" hypoxia (and hence cerebral protection) rather than "warm" hypoxia due to asphyxia with subsequent hypothermia, as in drowning. Serum potassium may be used to differentiate between these two entities and for prognostication,⁶⁻¹⁰ especially in patients who have been involved in an avalanche, in whom warm hypoxia is more prevalent.¹¹

Measuring core temperature at the incident site may be impossible or unreliable. Therefore, many guidelines have moved to the Swiss staging of hypothermia, which relies on a situational awareness that hypothermia is possible, and an assessment of consciousness and the presence of vital signs (box).¹² Cooling during extrication and evacuation generally occurs and measures should be taken to prevent further heat loss with insulation and heat packs.⁶⁻¹² Modern algorithms emphasise the importance of an early decision on the need for extracorporeal rewarming in patients with cardiac arrest, and the recognition that this

Taking a patient with hypothermic cardiac arrest to the nearest emergency department could prevent transfer to definitive care and cost the patient his or her life

might be needed in patients with cardiac instability (systolic blood pressure <90 mm Hg, ventricular arrhythmias, or core temperature <28°C).⁶

A flexible pathway from the incident site to the rewarming facility must be agreed in advance. Flexibility is a key word. Each case will have unique geographical, chronological, meteorological, and human factors. Taking a patient with hypothermic cardiac arrest to the nearest emergency department could prevent transfer to definitive care and cost the patient his or her life. With the use of a mechanical cardiopulmonary resuscitation device, the extra time taken to transport the patient directly

to an ECMO or cardiopulmonary bypass centre will not be a disadvantage. Such a protocol has been agreed, for instance, between the Lake District Search and Mountain Rescue Association and the ECMO team at the University Hospital of South Manchester.

As far as we are aware, no country has yet developed a

national hypothermia protocol. Therefore, the onus is on prehospital and hospital teams to work together to develop a protocol for their setting, which should include the following:

- Education to ensure that staff understand the problems and to prevent cessation of resuscitation prematurely
- Clear protocols to ensure smooth mobilisation of established treatments
- Involvement of cardiac centres to provide ECMO or cardiopulmonary bypass (find your local ECMO centre: www.elseo.med.umich.edu/Member.asp)
- Ability to phone the centre directly from the casualty site
- Preparedness of transport agencies to deliver the patient directly to a cardiac centre, thereby avoiding a secondary transfer
- Commitment to share experiences with the International Hypothermia Registry (<https://www.hypothermia-registry.org/>)

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Chris Ham: Making general practice fit for the future

Strengthening leadership in the NHS

The Rose and Dalton reviews are welcome, but there are no easy answers

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The appointment of Stuart Rose (right), former boss of Marks and Spencer, to advise the government on leadership is the latest in a long line of attempts to make use of private sector expertise in the NHS. Rose's brief is to explore how the 14 NHS trusts placed in special measures can be helped to tackle concerns about their performance.¹ Like Roy Griffiths, Adair Turner, and Gerry Robinson before him, Rose faces the challenge of using experience in a very different sector to enable NHS organisations to put in place the leadership that can provide improved care for patients.

Arguably, the NHS has most to learn from the private sector about how to treat patients as valued customers rather than as grateful recipients of care. Despite progress in improving patients' access to care, much remains to be done to tackle relational aspects of care, including ensuring that patients are treated with dignity and respect and are able to communicate effectively with doctors and other staff. NHS organisations could also do more to support patients to manage their own health and wellbeing and involve them as genuine partners in care. If Rose can help support NHS leaders to introduce the changes in culture needed to improve these aspects of care, then he will have indeed performed a valuable service.

Rose will find that part of the answer to improving patient experience is to ensure that staff are supported to do the job for which they trained. There is a close correlation between staff experience and patient experience, sometimes expressed as "happy staff mean happy patients." Patients receive better care when it is delivered by staff working in teams that are well led and where staff report they have the time and resources to care to the best of their abilities. This highlights the crucial role of team leaders, often experienced nurses, who develop a culture in which patients are treated with dignity and respect, and motivate their colleagues to do the same.²

Another part of the answer can be found in studies of how high performing healthcare



Could patients ever become valued customers?

organisations in other countries deliver great care to patients. These organisations benefit from continuity of leadership, organisational stability, and consistency of purpose—characteristics that are in short supply in many parts of the NHS. This purpose is often expressed as providing the best care possible with the resources available, with quality and outcomes being at the forefront. High performing organisations pursue this purpose by setting ambitious goals, measuring progress towards their achievement, and providing staff with the skills to improve care.³

Analysis undertaken by the King's Fund concludes that leadership in NHS organisations needs to be collective and distributed rather than located in a few people found at the top of these organisations. The involvement of doctors, nurses, and other clinicians in leadership roles is also essential, particularly in the clinical microsystems that comprise the basic building blocks of hospitals and other healthcare providers. Organisations in which skilled clinical leaders work with experienced managers draw on different sources of expertise as they aspire towards higher standards of performance. The size and complexity of healthcare organisations suggest the need for caution in adapting approaches used in other sectors, such as the appointment of "superheads" to run several schools, in the NHS.⁴

This caution is directly relevant to the review led by David Dalton, chief executive of Salford Royal NHS Foundation Trust, to explore how NHS providers can collaborate in networks or chains. The government established this review to build on an initiative last autumn in which high performing NHS hospitals were invited by health secretary, Jeremy Hunt, to provide support to hospitals placed in special measures.¹ The interest in developing chains takes this idea much further to explore what incentives are needed to persuade high performing hospitals to work across different parts of England. Although it is too early to form a judgment, buddying successful hospitals with those that are struggling carries a substantial risk that standards in high performing NHS organisations will fall if their leaders are distracted by the work involved in lending support to others.⁵

The neverending talent quest

The decision by the government to set up these reviews is a welcome, albeit belated, recognition of the crucial role of leaders in improving NHS performance. At a time when there are growing difficulties in recruiting experienced people to top leadership roles in NHS organisations, it is hoped that the reviews will report expeditiously on what needs to be done to attract more talent into the NHS and how existing expertise can be used more effectively. A good start would be to redouble efforts to attract clinicians into leadership roles at all levels, as Roy Griffiths advocated in 1983, and to value the role of managers instead of constantly criticising them.

Ministers must play their part by bringing an end to constant reorganisations, which serve only to distract leaders from their core purpose of improving patient care. The leadership role of politicians also needs to be recognised through an unwavering focus on patient safety and quality as the real priorities for the NHS. Understanding that there are no easy solutions either in the private sector or the NHS is the first step on the road to strengthening leadership in the NHS for the longer term.

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