European working time directive

The European working time directive

P Nucci

An Italian ophthalmologist's view

The European working time directive (EWTD), written by the Council of the European Union (93/104/EC) to protect the health and safety of workers in the European Union, is an excellent opportunity for the British NHS to modernise its services. It lays down minimum and maximum requirements regarding working hours, breaks, annual leaves, and schedules/arrangements for night workers. The directive was enacted in 1998 in Great Britain as the working time regulations. Since 2004, this health and safety legislation has been extended to doctors in training who have traditionally worked long hours and overtime and who are essential to any health system in providing complete medical coverage to patients. These regulations are directed at employers, building on the progress already made through the "new deal." They are part of a broader plan, which includes existing initiatives such as *Improving Working Lives* and the *Changing Workforce Programme*, to improve the work/life balance of NHS employees.

For numerous reasons, in Italy there is little awareness of these European directives. Although it is fully recognised that doctors in training are often inappropriately employed at a clinical level their experience and training should not allow their workload rarely

exceeds 58 hours per week. I recently compiled a survey for our scientific community (SOU, Società Oftalmologi Universitari) that identified the major grievances of doctors in training: hardship related to the hourly workload was, in eighth place, a long way from the first three grievances of overall inadequate surgical training, a routine and non-educational use of their time and energy, owing primarily to their employment in overflowing and ungratifying outpatient services, and inadequacy of even their classroom preparation.

The most obvious reason that the workload is not a problem for Italian doctors in training in ophthalmology is that it does not exceed 40 hours. Additionally, the problem of making up hours after being on call is no longer relevant in ophthalmology since this type of service is utilised less than in other departments. The overtime put in by junior doctors reflects more their personal availability aimed at convincing their tutors or physicians in charge of their competence, prompted by career ambition or simply by a desire for greater opportunity in training.

The second reason that these directives do not have an impact is the tendency for Italians at various levels to not perceive European legislation as binding. The national health system and the university

are notorious sectors in which the disaccord is so great that there is almost the perception of immunity from legislation, associated with the complex and anarchic condition that defines both organisations. The notion is rife that the equilibrium they have achieved, like a house of cards, cannot and must not be disturbed by a Europe that presumes much but does not give in return. The plethora of physicians in Italy, the resistance to a handover from generation to generation, the positions of untouchable privilege in a still mediocrally managed university all contribute to the deaf ear given to European dictates.

The fact that the EWTD will indeed challenge the entire hospital-university system, critically analysing how training is delivered in Italy, is another reason for concern in the minds of many university professors and hospital administrators. This challenge heralds the fear of a complex upheaval of training systems and methods, perhaps without resulting in a better trained physician, yet surely with much more work for those in charge of training. Nevertheless, I strongly believe that a better managed, better structured and more in-depth training programme will lead to a more meaningful and focused training of physicians. This is exactly what is required in addressing the EWTD.

Although the EWTD was conceived as a means of improving working lives and patients' safety, I would suggest an additional directive that goes further, requiring junior doctors to give an anonymous evaluation of the quality of their work time in their training environment.

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Surgery

Wrong site surgery

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A great deal of work needs to be done to reduce and potentially eliminate this most basic of errors

Wrong site surgery (WSS) is likely to be as old as surgery itself. Within ophthalmology Traquair, in 1947, described the "important and very pertinent disaster of wrong site surgery where enucleations of the wrong eye have been performed."¹ Although among the

pantheon of medical errors it is relatively rare, the consequences can be disastrous—for example, removing the wrong eye when its fellow is blind. Because of the potentially serious nature of this error, a number of organisations have focused their efforts in reducing the occurrence. Unusually, in the field of

medical error, WSS errors are thought to be entirely preventable. This has led to the adoption of a number of broadly similar protocols and guidelines to try to remove this most devastating of mistakes.

WHAT IS WRONG SITE SURGERY?

Wrong site surgery can be simply defined as "the performance of an operation or surgical procedure on the wrong part of the body."² Within this particular definition there are a number of subcategories:

- Incorrect side (for example, left eye rather than right), which can obviously only occur with paired structures such as kidneys, ovaries, or eyes

- Correct side but incorrect location—occurs where there is more than one similar anatomical structure to choose from (for example, incorrect finger on the correct hand or incorrect eye muscle on correct eye)
- Correct side and correct anatomical site but the incorrect operation (for example, resection of a muscle rather than recession).

The American Joint Commission on Accreditation of Healthcare Organizations (JCAHO) includes the above but also extends the definition to include²:

- Wrong patient surgery
- Wrong procedures.

Ophthalmology is one branch of surgery that is liable to any of the wrong site errors described above. The stakes are further raised in eye surgery as certain mistakes—for example, removal of the wrong eye, are irreversible.

HOW OFTEN DO WRONG SITE ERRORS OCCUR?

Like many types of medical error, under-reporting makes it difficult to be absolutely sure how often they occur. A pilot study conducted by the UK National Patient Safety Agency (NPSA) in 28 acute trusts between September 2001 and June 2002 recorded 44 patient safety incidents related to “wrong procedure surgery.”³

Unfortunately, one of commonest sources of data is the number of legal claims. Figures from the American Academy of Orthopaedic Surgeons suggest that 84% of cases involving wrong site orthopaedic surgery claims resulted in payments suggesting that these data are a relatively good measure of the number of errors (at least in the United States).⁴ The Physician Insurers Association of America reported 331 closed claims for WSS between 1985–6.⁵ In the United Kingdom figures from the Medical Defence Union from 1990–2003 show 119 cases related to operations carried out on the wrong side.⁶

Both in the United States and the United Kingdom the highest number of claims for WSS are within orthopaedics—with general surgery, neurosurgery, and dental surgery also being high. Ophthalmology is less than these higher risk areas but is still higher than a number of much larger specialties.⁷

WHY DO WRONG SITE ERRORS HAPPEN?

WSS errors occur for the same reasons as the overwhelming majority of adverse events within health care—not because of bad people but good people working within bad systems. The American

Academy of Ophthalmology states that WSS is caused by two main factors⁸:

- (1) lack of a formal system to verify the site of surgery, or
- (2) a breakdown of the system that verifies the site of surgery.

In any system, numerous factors can act to disrupt its smooth running and increase the potential for harm. These factors may be within the system (poorly designed systems having more) or act from outside it. At any point in the process—from listing the patients to their positioning in theatre, the elements that lead to WSS can surface and often compound each other. Some of the commonest include:

- Similar patient names
- Use of abbreviations
- Using “right” for correct
- Patients not “labelled” (usually a wristband) on admission
- Hospital beds being moved around
- Failure to include the patient (or their relatives or carers) in the process of identifying the correct site
- Operation site not marked or unclearly marked (for example, using an “X” to mark may suggest that this is the side to be done or equally the side *not* to be done)
- Late changes to operating lists
- Lack of a final check in the operating theatre
- Lack of involvement of all theatre staff in the identification process
- Not bringing patient notes or investigations to theatre (and conversely removing the notes from theatre of the previous patient to avoid confusion)
- Surgeon not rechecking patient details before starting the operation
- Lack of a checklist to make sure every check had been performed
- Involvement of more than one surgeon
- Time pressures (for example, unplanned emergencies or larger volume lists)
- Performance of multiple procedures in the same patient
- Patient characteristics, such as obesity or unusual anatomy, that lead to alterations in the usual positioning of the patient.

This long, but not exhaustive, list contains factors that are present in many theatres. As in so many of these situations in which adverse events occur, the more contributing factors that are present, the more likely it is that WSS will occur.

HOW CAN THESE ERRORS BE PREVENTED?

It was mentioned in the section above, that WSS errors occur because of the lack of a system to verify the correct site or if a system is established then a breakdown within it. It is therefore obvious that reducing or eliminating these types of errors involves setting up robust systems. This has been recognised by a number of national organisations that have thought that WSS was a preventable occurrence and that robust checking systems were the best method of prevention.

The US Joint Commission on Accreditation of Healthcare Organizations (JCAHO) listed the elimination of WSS as one of the national patient safety goals for 2003.⁹ The American Academy of Ophthalmology document “Eliminating wrong site surgery” stated that “Wrong site surgery is preventable with appropriate procedures for verification.”⁸ The American Academy of Orthopaedic Surgeons (AAOS) developed an awareness campaign to encourage marking of the surgical site “Sign your site.”¹⁰ Orthopaedic organisations (especially in the United States) have generally been at the forefront of recommendation for avoiding WSS but healthcare organisations all over the world and among many specialties are increasingly producing guidelines for their members.

There is a general agreement between these organisations that reducing WSS errors involve two elements:

- Creation and use of a preoperative verification process
- Implementation of a system for marking the surgical site.

More specifically, there are a number of important components that make up these two goals:

- Involvement of the patient in the consent and surgical site marking process. It has even been suggested that the patient makes his or her own mark¹¹
- Participation of *all* the surgical team in verifying the operative site—the JCAHO suggests an oral verification between team members of the correct site. It is important that all members of the team have an equal voice as it may be the “lowlier” members who notice any verification errors (<http://news.bbc.co.uk/1/hi/wales/2042228.stm>)
- Ensuring the entire patient’s records/investigations (for example, computed tomography scans) are available in theatre and that the preoperative checklist includes this
- A “time out” immediately before the start of the procedure has been suggested by some organisations.

This involves a few minutes in which all members of the team make a final verification of the correct patient, procedure, site, and any other components applicable to the surgery (for example, the intraocular lens power or examining the fundus of the eye to be removed)

- Rules for marking of the operative site:
 - Unambiguously identify the site of incision or insertion
 - Non-operative sites should not be marked
 - Be made with an indelible pen so it is not rubbed off or transferred to a different site
 - Be visible once the patient had been prepared and draped
 - Be done by the person performing the procedure (who also, ideally, has taken the consent)
 - Be done, if possible, with the patient awake, aware and involved
 - Having a relative involved can be additionally helpful
 - Marking is *not* always necessary—for example, teeth or mucous membranes, bilateral surgery, or situations where the laterality of the surgery needs to be confirmed following examination under anaesthesia, such as revision of squint corrections.

Other suggestions for making errors less likely include:

- Health organisations fostering an atmosphere in which errors are openly reported and discussed
- Avoiding using abbreviations for left and right and for structures—for example, LR or MR.
- Make sure all implants are obtained and checked *before* starting the procedure rather than during it.

As human beings are, and always will be, fallible, electronic systems have been devised that can reduce the potential for human error:

- Bar coding¹²—this has been used in a number of areas within health care when identification needs to be robust. Examples include blood transfusions, medications, and surgical instruments
- Surgichip (AMTSys) —this is a system that uses radio frequency identification technology. Patient details including name, operative location, date of surgery, and the operative procedure are fed into the system and adhesive labels are produced containing a computer chip

with this information. The labels can be attached to the patient and/or notes and are then read with a handheld scanner.¹³

Perhaps one of the most important methods of reducing WSS is to have a consistent and robust protocol that is universally followed. The ultimate goal is to produce a single national (or even international) system for identifying and marking operative sites. The more widely used a system is the more familiar staff and patients become within it (even when they move between hospitals or healthcare systems) and therefore the more likely it is to be successful.

In the United Kingdom the NPSA has attempted to do this. In March 2005 it produced a "Patient safety alert (No 6)" (reserved for high risk safety problems) with standardisation procedures both for preoperative marking and marking verification checklist.³ It seems likely that these templates will eventually be used throughout the United Kingdom unless—as the NPSA state—organisations and healthcare personnel choose not to follow these recommendations.

WHAT TO DO WHEN IT HAPPENS

The underlying principle when WSS has occurred is to act in the patient's best interest.⁸

The error may be discovered during the operation. If the patient is under general anaesthesia, the appropriate steps to return the incorrect operation to as near the preoperative situation should be undertaken. Unless there are medical reasons the correct operation should then be performed. If under local anaesthesia the patient should be informed of what has happened and have the steps that you will undertake explained (as for general anaesthesia) unless the patient disagrees with this course of action.

If the error is discovered postoperatively, after full explanation, remedial action should be undertaken as above—unless, once again, the patient's medical condition prohibits this.

A senior member of staff should give a full explanation and apology to the patient and relatives/carers. The incident needs to be reported to the appropriate local and national bodies when a root cause analysis should be undertaken to identify any learning issues.

SUMMARY

WSS is an uncommon but potentially catastrophic event. It can occur in a number of circumstances but is most common in surgery that involves paired organs or multiple sites. Certain factors

have been shown to make it more likely and these have been used to create guidelines and protocols to reduce the occurrence of WSS. As is so often the case, recognition of the possibility of the problem and the implementation of robust but user friendly systems are the keys to reducing the adverse event.

Within ophthalmology this complication has long been described and its consequences feared. Traquair himself referenced a quote from 1881 (Mauthner) advising against relying on memory alone rather than checking of the notes. Over 120 years later, there remains a great deal of work to be done by healthcare organisations to reduce and potentially eliminate this most basic of errors.

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