

## Health Technology Assessment and patient safety

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### ABSTRACT

Health Technology Assessment (HTA) is a process used to evaluate the clinical effectiveness and cost-effectiveness of health technologies by a systematic review of clinical, economic, and utilization research. Despite widespread investment in patient safety technologies in the U.K., U.S., and elsewhere, little HTA has been done to establish the clinical or cost-effectiveness of these technologies. The HTA and patient safety literature suggests there are four categories of patient safety HTA, including HTA for existing safety technologies, underutilized safety technologies, emerging safety technologies, as well as safety aspects of technologies with a non-safety primary purpose. Recent HTA and other research, including a 2002 evidence-based evaluation of patient safety technologies from the U.S. Agency for Health Research and Quality, provide an important foundation for a more comprehensive approach to patient safety HTA. However, HTA programs must address prioritization, methodology, and dissemination challenges introduced by patient safety technologies before significant progress can be made.

*Key words: Health Technology Assessment, patient safety, prioritising*

### Introduction: what is Health Technology Assessment?

Health Technology Assessment (HTA) is the process of evaluating the clinical and economic effectiveness of existing or new health technologies, usually by the synthesis of evidence from randomized controlled trials (RCTs), and from the best available, "real world" data on utilization, effectiveness, and cost [1-3]. HTA is distinct from regulatory processes, which often establish efficacy and safety in ideal circumstances rather than clinical and economic effectiveness in everyday clinical practice. In the UK, HTA is also distinct from appraisal, which involves the translation of HTA and other evidence into policy and practice decisions [3,4].

HTA is commonly applied to "traditional" biomedical technologies including pharmaceuticals, medical devices, and diagnostic technologies, but it can also be applied to any other effect of a health service on patients, including practice, health system, and organizational technologies [5]. Many technologies to improve patient safety could therefore be evaluated by HTA, but in practice this has not happened as often as might be expected.

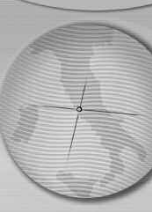
Early HTA efforts in the United States and United Kingdom in the 1980's drew from research in health economics and evidence-based medicine to develop assessment methodology [4]. In the past twenty years, a rapid expansion in the scope and methods of HTA catalyzed the

development of an international HTA community which today includes 42 public organizations in 21 countries plus countless private and nonprofit organizations [3,6].

Many of the "HTA-rich" western countries have developed HTA systems tailored to their national healthcare environment [3]. In the United States, for example, the Agency for Healthcare Research and Quality (AHRQ) and Veteran's Administration Technology Assessment Program, and a multitude of private healthcare organizations and companies each conduct their own HTA, contributing to the often fragmented, duplicative, and highly variable quality of HTA in that country [6]. In the United Kingdom, where healthcare costs and outcomes quickly reflect on government, a centralized National Health Service (NHS) HTA program was established in 1993 [4]. The UK program is unusual amongst national HTA programs in that most of its budget (80%) funds new randomized clinical trials. The UK program is also noted for its strong relationship with the UK appraisal organization, the National Institute for Health and Clinical Excellence (NICE), which uses HTA as the basis for its guidance for the NHS and which also proposes topics for HTA (see Box 1).

### Defining Patient Safety

The patient safety literature is replete with definitions of "adverse event," "medical error," and "preventable injury," as well as descriptions of



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**Box 1: Key Activities of the UK NHS HTA Program**

**Choosing priorities:**

- 1.) A “formal and explicit process of agenda-setting” begins each year with the identification of 1,000 potential research topics collected from consultations, horizon scanning and past HTA research
- 2.) Expert panels for diagnostic technologies, pharmaceuticals, therapeutic procedures, and disease prevention select about fifteen research topics each based on the burden and cost of the health problem, the urgency of the research, research cost, and other criteria
- 3.) The Prioritization Strategy Group reviews and finalizes scientific and cost priorities to select a final fifteen research topics [1]

**Collecting and evaluating data:**

HTA evaluations are based on three major research categories: new randomized clinical trials (primary research), systematic reviews to evaluate an existing body of evidence (secondary research), and disease-wide guidelines or synthesis of evidence (tertiary research)<sup>1</sup>. Research is contracted to academic researchers and investigation centers

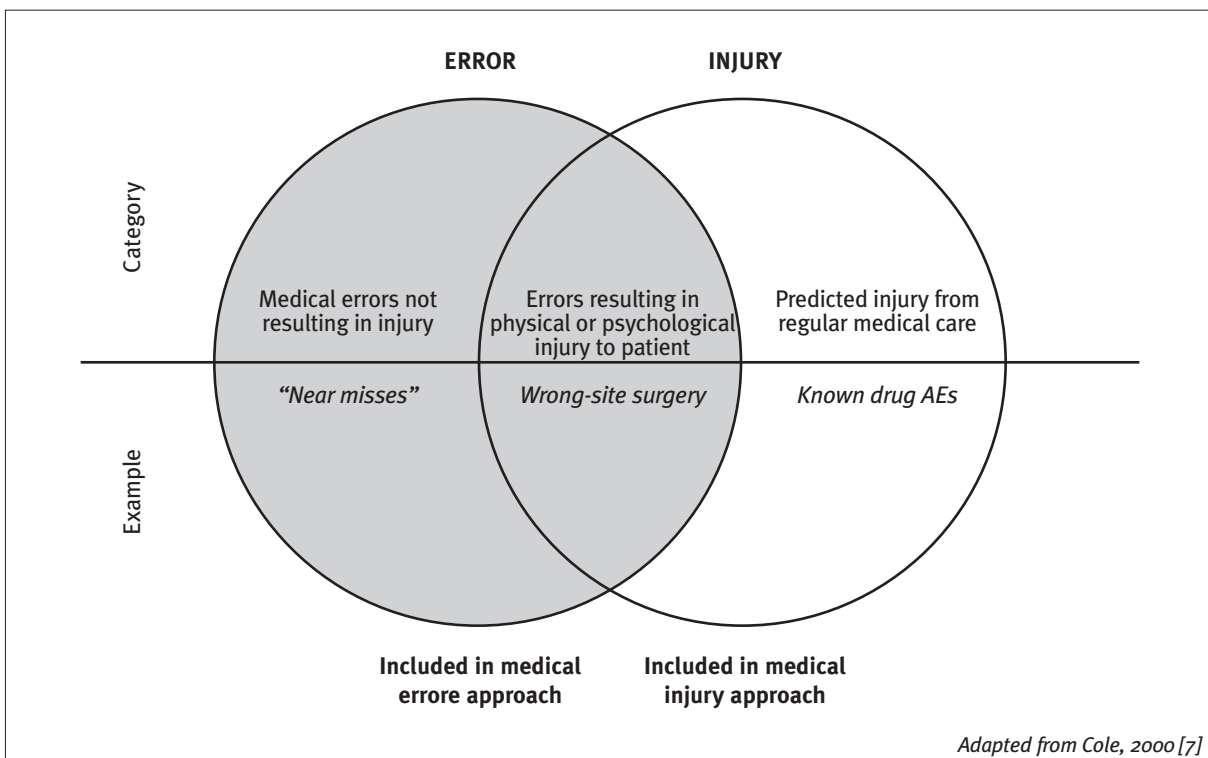
**Applying and transferring findings:**

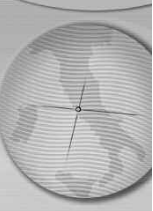
HTA monographs are published by the HTA program and are included in the Cochrane Library and other worldwide HTA databases. The HTA program’s clinical and economic efficiency findings are usually key factors in the formulation of NICE coverage decisions

how these concepts interact to form definitions of patient safety [7-11]. The most straightforward patient safety issues involve both an error and physical or psychological harm. Apart from these clear cases, the patient safety literature distinguishes between two approaches to patient safety: one emphasizing minimizing injury and the other minimizing error (Figure 1). The injury approach considers injuries caused by error as well as expected injuries from receiving appropriate medical care (e.g., adverse drug reactions which may be anticipated in a

proportion of patients). The error approach considers errors which result in injury as well as “near misses”. The recent controversy surrounding the absence of technologies highlighted by the error approach in a recent AHRQ injury-focused report suggests patient safety experts and researchers are far from agreement [12]. It seems clear, however, that healthcare should strive to minimize as many injuries and errors as possible [7]. This paper will consider patient safety in the broadest sense, including errors that do not result in injury (“near misses”)

**Figure 1. Approaches to patient safety**





and injuries not due to error (accepted adverse events).

In the context of patient care, safety issues can emerge in traditional clinical areas like adverse drug events and complications of surgery, less traditional clinical areas like provider fatigue and information transfer, and from non-medical approaches to safety, like information technology and human factors research [12]. This broad range of patient safety domains suggests an equally broad range of technologies employed in healthcare to address these issues (Table 1). Patient safety technologies are any which reduce the risk of adverse events related to exposure to medical care, either by directly reducing the probability of injury or by reducing errors that may lead to injury [12,13].

Patient safety technologies are often closely linked to those which can improve quality of care [12,13]. An Institute of Medicine (IOM) patient safety committee went so far as to claim patient safety and quality of care are "indistinguishable" [14]. In general, technologies applied to only one particular circumstance are often considered quality interventions while those can be applied over several diseases or circumstances are safety interventions.

Many non-safety health technologies can indirectly impact patient safety by raising or lowering the risk of injury or error in health care. Most technologies with a therapeutic or diagnostic primary purpose can affect patient safety through opportunities for error (e.g., in misdiagnosis, misuse, or interaction with other technologies), and by an accepted risk of injury

(e.g., adverse events). While these other technologies undoubtedly influence patient safety, the term "patient safety technology" is reserved for technologies with patient safety as their primary purpose.

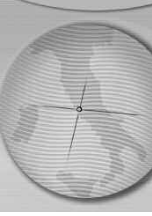
### What is Patient Safety HTA?

The rapid rise of patient safety to the attention of policymakers and the public [15] after the 2000 IOM [9] and UK Department of Health [16] reports left healthcare providers and researchers little time to evaluate the effectiveness of many patient safety technologies. Intuitively attractive and available technologies like bar code and computer order entry systems, regulated resident work hours, and increasing the prescription of beta-blockers to prevent perioperative cardiac events were quickly adopted in some settings, even though their effect on patient outcomes and safety had not been comprehensively studied [17,18]. The real costs of these interventions, both actual purchase and implementation costs as well as hidden costs from delays, forgone opportunities, and new opportunities for patient harm, had almost never been studied. While five years after the reports we know more about the prevalence and costs of patient safety [15], we still know relatively little about the benefits and costs of the range of ideas and tools used today to address patient safety issues [19].

The need for objective evaluation of technologies is exactly what drives HTA programs around the world. In the case of patient safety technologies, many of which are already used, HTA is urgently needed to evaluate the clinical and economic effectiveness of existing technologies and to

**Table 1. Examples of Patient Safety HTA: Technologies and assessment types**

Assessment Title	HTA organization	HTA form	Technology Type	Evidence Considered
Coronary artery stents: a rapid systematic review and economic evaluation	UK HTA Programme	Modified systematic review (rapid)	Emerging/Patient safety aspect of a non-safety technology	Randomized trials (some short-term data), economic model
Making Health Care Safer: Prevention of Misidentifications: Bar Coding	U.S. Agency for Health Care Quality and Research	Evidence-based assessment	Existing/Implemented	Anecdotal
Making Health Care Safer: Ultrasound Guidance of Central Vein Catheterization	U.S. Agency for Health Care Quality and Research	Evidence-based assessment	Underutilized	Randomized trials
Medicines for Children Research	UK HTA Programme	Primary research (pending)	Patient safety aspect of a non-safety technology (pharmaceuticals)	Original randomized trials (pending)



prioritize their implementation in health care practice. Experience with other medical technologies adopted without assessment suggests the very real possibility that current patient safety technologies could be ineffective, wasteful, or even harmful [17]. Even technologies that ostensibly improve patient safety can introduce new possibilities for injury and harm that may not be detected without effectiveness evidence [18,20]: computerized physician order entry systems, for example have been implicated in creating new threats to patient safety [17,21]. Inadequate effectiveness evidence deprives decision makers already swayed by media attention, government and professional guidelines, and the threat from liability of an important parameter for prioritizing safety practices [11,17].

### The Extent of Patient Safety HTA

Recently, there has been some progress in patient safety HTA, notably a 2002 AHRQ report summarizing the evidence supporting over 80 patient safety technologies using an evidence-based approach [12]. Despite the controversy surrounding this report [11,17], it and subsequent discussion serves as a foundation for future patient safety research by outlining the breadth of patient safety technologies and the challenges faced by patient safety HTA. The AHRQ report and other patient safety HTA literature confirms that little is known about many patient safety technologies, especially organizational and systems changes that are considered the most likely to significantly improve patient safety. Overall, however, HTA focusing on patient safety technologies remains scarce and patient safety is rarely considered in HTA for other technologies. The paucity of patient safety HTA can be attributed both to the rapid introduction of patient safety technologies as well as methodological differences between HTA for 'typical' biomedical technologies and HTA specific to patient safety technologies [11].

Patient safety assessments completed to date include systematic reviews, expedited 'rapid' reviews, and primary research. Existing patient safety HTA has targeted implemented, emerging, and underutilized safety technologies as well as the safety aspects of non-safety technologies. Table 1 lists examples of patient safety HTA from a variety of sources. Several summaries of patient safety research, especially Shojania et al, report the current state of evidence for a wide range of patient safety technologies [12].

Four categories of patient safety HTA can be identified in the literature: HTA for established technologies which specifically target patient

safety, HTA for understudied or underutilized technologies, HTA for emerging patient safety technologies, and HTA to identify patient safety issues in technologies with a primary purpose other than patient safety. In addition to these categories, HTA programs can produce important methodological research on patient safety HTA tools, indicators, and review/evaluation methods.

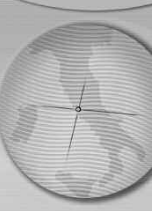
**Implemented patient safety technologies** include many "popular" responses by hospitals and practitioners following the US and UK patient safety reports, including drug bar coding, computerized order entry, and work hour regulations. These technologies are already used in some health care settings, and in most cases are not supported by evaluations of clinical or cost effectiveness. Widespread investment in many of these technologies introduces challenges in the HTA prioritization process.

**Underutilized patient safety technologies** include existing technologies that will probably effect patient safety, but have not been studied or implemented. These technologies may be underutilized because they are unappealing (e.g. how best to assess whether a nasogastric tube is in place) or methodologically difficult (e.g. systems technologies) for researchers or health care experts. They may also be underutilized due to a lack of health care provider expertise or knowledge, high capital cost (e.g. standardization of medical equipment), or simply because investment in other technologies preclude their use. Technologies in this category challenge HTA programs to weigh the cost of an economic evaluation specifically addressing the reasons for underutilization against the potential patient safety and quality benefits from the technology [22].

**Emerging patient safety technologies** include technologies on the horizon that will probably improve patient safety. Emerging technologies require a different approach from HTA programs to maximize the evidence and evaluation available when the technology becomes available. For example, a recent UK assessment of a rapidly evolving technology, drug-eluting coronary artery stents, adapted the standard methodology to include short-term data [23,24].

**Technologies for non-patient safety purposes** include all technologies with a primary function other than patient safety. In some instances HTA plays a role in identifying the patient safety implications of these technologies in the course of clinical and cost-effectiveness assessments. This category often includes technologies where HTA can review data used for





regulatory approval, usually in cases where approval was based on short-term data (e.g., aortic endovascular grafts), or where the regulatory process requires minimal empirical data (e.g., most medical devices) [25]. Routine HTA which identifies ineffective or duplicative technologies may play a role in patient safety by decreasing the risk faced by patients. Identifying patient safety issues in routine HTA will require HTA programs to include patient safety in their evaluations more formally.

### **How to Do Patient Safety HTA**

The examples listed above give a sense of the breadth of technologies and approaches in patient safety HTA, but also hint at the challenges facing patient safety HTA, both in terms of the quantity and diversity of technologies that require assessment and in terms of the particular challenges presented by patient safety technologies. Some challenges of patient safety HTA can be at least partially addressed by modifying the prioritization, data collection and synthesis, and dissemination activities of HTA programs. Other challenges to comprehensive patient safety HTA will only be addressed by broader changes in the fields of patient safety, health policy, and HTA in general. Several approaches to facilitating and strengthening patient safety HTA are considered below.

### **Create a patient safety HTA prioritization process**

The proliferation of patient safety technologies challenge HTA programs to determine whether assessing “popular” technologies like computerized physician order systems is a more efficient use of limited resources than assessing emerging or underused technologies [4]. HTA programs must also choose whether to assess technologies in the “high risk” patient safety areas of hospitalization, critical care, and surgery, or in understudied but widespread primary and home care settings which might present even greater opportunities for improvement [14]. These decisions can only be made if HTA programs have basic information about the extent of the patient safety problem and the lifespan of the technology, in addition to basic clinical and economic data [26]. Since information has a cost, HTA programs must develop new methods to obtain information about patient safety technologies to complement existing measures used in prioritization [18].

HTA programs must also determine which patient safety technologies are not in need of assessment. Some patient safety interventions like removing concentrated electrolytes from patient

wards, hand washing guidelines, sponge counts in surgery, and standardizing prescribing to require the use of leading zeroes (e.g. 0.25 mg Digoxin and not .25 mg, which might be mistaken for 25 mg) are simple, low cost and “common sense.” These interventions do not require usually even a brief assessment. But HTA programs and healthcare providers should monitor the effect of these “common sense” interventions and be prepared to conduct an assessment. In one example, a hospital adopted the seemingly “common sense” intervention of reducing verbal orders in favour of written orders - but increased the error rate fourfold [27].

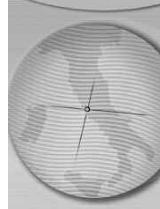
### **Change the focus of HTA to include patient safety**

A concerted effort is needed to introduce a focus on patient safety into HTA programs so closely focused on clinical and economic effectiveness. Currently, most HTA assessments indirectly count patient safety as a factor in clinical effectiveness (adverse events and errors impact clinical outcomes) and in cost effectiveness (costs of injury or adverse event). There are encouraging signs that HTA programs are increasingly accepting patient safety as an important outcome in itself: the UK HTA program, for example, has planned a study of the clinical effectiveness and safety of pharmaceuticals for pediatric patients.

It is often lamented that HTA rarely considers the social, political, and ethical aspects of technologies, despite their inclusion in many definitions of HTA [12]. These factors are particularly critical in the assessment of patient safety technologies where ethical [28], legal [29], and political [30] dimensions of technologies and the concept of patient safety closely guide decision makers.

### **Adapt HTA methods to patient safety technologies**

Methodological difficulties complicate the assessment of some patient safety technologies. Patient safety technologies are more likely to be multidimensional system, organizational, or practice changes with low generalizability than non-safety technologies. Many of the most serious patient safety concerns are uncommon enough to prohibit achieving statistical power in clinical trials at a reasonable cost [11,12]. Where a study is possible, capturing patient safety outcomes (e.g., near misses or determining if an injury is due to error) is more difficult than is the case with many clinical outcomes [12]. Developing new patient safety data standards [14] and indicators seems to be a critical first step in addressing many of the



methodological issues hindering patient safety technology assessment.

### Develop innovative ways to apply patient safety HTA

The current political interest and investment in unevaluated patient safety technologies could complicate translating future patient safety HTA into policy and practice. It is unlikely that major patient safety technologies like computer order entry systems will simply be abandoned if an HTA assessment does not show the technology to be effective. At the least, ignoring or downplaying patient safety HTA evidence risks adopting improvements which are not cost-effective [18], which in turn will prevent investment in other patient safety interventions and limit resources available for actual patient care and services [17]. Linking HTA evidence to patient safety guidelines like the US National Quality Forum's Patient Safety Practices [31] may be the best way to provide healthcare providers with reliable HTA information to decide which patient safety technologies to implement [16].

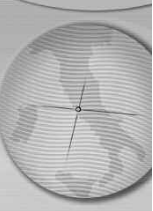
### Conclusions

Despite the assertion of one patient safety expert that healthcare providers have the tools they need in the form of tested and effective safe practices awaiting implementation, it remains true that very little effectiveness evidence supports most patient safety technologies [15]. HTA is capable of producing clinical and cost effectiveness evidence for patient safety technologies. HTA programs should build off an encouraging foundation of patient safety HTA while addressing challenges introduced by the current use and methodological issues surrounding patient safety technologies. First, HTA programs need to adapt their prioritization processes to reflect the current extent of patient safety technology use and the generally small evidence base for these technologies. Second, HTA programs must incorporate patient safety in their assessment of non-safety technologies. Third, new methods to evaluate patient safety effectiveness must be developed. Fourth, HTA programs, health care providers, and policymakers must recognize the challenges of applying patient safety HTA in a politically charged environment. These steps are necessary to enable the comprehensive assessment of patient safety technologies by HTA.

### References

1) OTA. Identifying health technologies that work: searching for evidence. Washington, DC: Office of Technology Assessment For sale by the U.S. G.P.O., Supt. of Docs., 1994.

- 2) Siebert M, Clauss LC, Carlisle M, et al. Health technology assessment for medical devices in Europe. What must be considered. *Int J Technol Assess Health Care* 2002;18(3):733-40.
- 3) Lehoux P, Blume S. Technology assessment and the sociopolitics of health technologies. *J Health Polit Policy Law* 2000;25(6):1083-120.
- 4) Stevens A, Milne R. Health technology assessment in England and Wales. *Int J Technol Assess Health Care* 2004;20(1):11-24.
- 5) Sinclair A. Assessing health technology assessment. *CMAJ Can Med Assoc J* 2001;164(13):1881.
- 6) Perry S, Thamer M. Medical innovation and the critical role of health technology assessment. [see comment]. *JAMA* 1999;282(19):1869-72.
- 7) Cole T. Medical errors vs medical injuries: physicians seek to prevent both. *JAMA* 2000;284(17):2175-7.
- 8) Cooper J, Blim J, Blum L, Anderson S, Zipperer L. Current Research on Patient Safety in the United States. Washington, DC: National Patient Safety Foundation, Health Systems Research, Inc., 2001.
- 9) Kohn LT, Corrigan J, Donaldson MS editors. To err is human: building a safer health system. Washington, D.C.: National Academy Press, 2000.
- 10) Layde PM, Cortes LM, Teret SP, et al. Patient safety efforts should focus on medical injuries. [see comment] [erratum appears in *JAMA* 2002 May 8;287(18):2363 Note: Maas Leslie A [corrected to Cortes Leslie M]]. *JAMA* 2002;287(15):1993-7.
- 11) Leape LL, Berwick DM, Bates DW. What practices will most improve safety? Evidence-based medicine meets patient safety. [see comment]. *JAMA* 2002;288(4):501-7.
- 12) Shojania KG, Duncan BW, McDonald KM, Wachter RM, Markowitz AJ. Making health care safer: a critical analysis of patient safety practices. Rockville, MD: Agency for Healthcare Research and Quality, U.S. Dept. of Health and Human Services, 2001.
- 13) Lilford R. The Director's Statement: Patient Safety Research Programme in England and Wales. Birmingham, UK: Patient Safety Research Programme, 2004.
- 14) Aspden P, Institute of Medicine (U.S.). Committee on Data Standards for Patient Safety. Patient safety: achieving a new standard for care. Washington, D.C.: National Academies Press, 2004.
- 15) Leape LL, Berwick DM. Five years after To Err Is Human: what have we learned? *JAMA* 2005;293(19):2384-90.
- 16) Great Britain Dept. of Health. An organisation with a memory: report of an expert group on learning from adverse events in the NHS. London: Stationery Office, 2000.
- 27) Shojania KG, Duncan BW, McDonald KM, Wachter RM. Safe but sound: patient safety meets evidence-based medicine. [see comment]. *JAMA* 2002;288(4):508-13.
- 18) Warburton RN. Patient safety—how much is enough? *Health Policy* 2005;71(2):23-32.
- 19) Arah OA, Klazinga NS. How safe is the safety paradigm? *Qual Saf Health Care* 2004;13(3):226-32.
- 20) Battles JB, Keyes MA. Technology and patient safety: a two-edged sword. *Biomed Instrum Technol* 2002;36(2):84-8.
- 21) McNutt RA, Abrams R, Arons DC. Patient safety efforts should focus on medical errors. [see comment]. *JAMA* 2002;287(15):1997-2001.
- 22) UK NPSA. Making the NHS a safer place for patients. London: UK National Patient Safety Agency, 2004.
- 23) Hill R, Bagust A, Bakhai A, et al. Coronary artery stents: a rapid systematic review and economic evaluation. *Health Technol Assess* 2004;8(35):iii-iv, 1-242.
- 24) Hill RA, Dundar Y, Bakhai A, Dickson R, Walley T. Drug-eluting stents: an early systematic review to inform policy. *Eur Heart J* 2004;25(11):902-19.
- 25) Lieberman JR, Wenger N. New technology and the orthopaedic surgeon: are you protecting your patients? *Clin Orthop Relat Res* 2004;(429):338-41.
- 26) Great Britain Dept. of Health. Building a safer NHS for patients: implementing an organisation with a memory. London: Department of Health, 2001.



27) West DW, Levine S, Magram G, MacCorkle AH, Thomas P, Upp K. Pediatric medication order error rates related to the mode of order transmission. *Arch Pediatr Adolesc Med* 1994;148(12):1322-6.

28) Sharpe VA. Promoting patient safety. An ethical basis for policy deliberation. *Hastings Center Report* 2003;33(5):S3-18.

29) Sage WM. Unfinished business: how litigation relates to

health care regulation. *J Health Polit Policy Law* 2003;28(2-3):387-419.

30) Shuren AW. Health care delivery errors: patient safety falls prey to politics. *J Pediatr Health Care* 2001;15(1):42-4.

31) Kizer KW. Patient safety: a call to action: a consensus statement from the National Quality Forum. *Medgenmed [Computer File]: Medscape General Medicine* 2001;3(2):10.