Trauma emergency unit: long term evaluation of a quality assurance programme

Emmanuel Gagneux, Pierre Lombrail, Philippe Vichard

Abstract

***Objective*—Long term evaluation of a quality assurance programme (after an assessment in 1993).**

***Design*—Review of medical records.**

***Setting*—Emergency area of an orthopaedic, trauma, and plastic surgery unit in a French teaching hospital (Besançon).**

***Subjects*—1187 consecutive ambulatory patients' records, from July 1995.**

***Main measures*—Occurrence of near adverse events (at risk events causing situations which could lead to the occurrence of an adverse event).**

***Results*—71 near adverse events were identified (5.9% of the ambulatory visits). There was a significant decrease in the rate of near adverse events between 1993 (9.9% (2056 ambulatory visits, 204 near adverse events)), and 1995 (5.9% (1187 ambulatory visits, 71 near adverse events)), and significant change in the proportion of each category of adverse event (decrease in departures from prevention protocols).**

***Conclusions*—Despite their limitations, the effectiveness and efficiency of quality assurance programmes seem to be real and valuable. Maintaining quality improvement requires conditions which include some of the basic principles of total quality management (leadership, participatory management, openness, continuous feed back). The organisation of this unit as a specialised trauma centre was also a determining factor in the feasibility of a quality assurance programme (specialisation and small size, high activity volume, management of the complete care process). Quality assurance is an important initial step towards quality improvement, that should precede consideration of a total quality management programme.**

(*Quality in Health Care* 1998;7:12–18)

Keywords: quality assurance; emergency; trauma surgery

Orthopædic, Trauma and Plastic Surgery Unit, Pr Vichard, Hôpital Jean Minjoz, 25030 Besancon Cedex, France
E Gagneux, consulting orthopaedic surgeon
P Vichard, university professor and consulting orthopaedic surgeon

Public Health Department, Pr Brodin, Hôpital Robert Debré, 48 Bd Serurier, 75019 Paris, France
P Lombrail, senior lecturer

Correspondance to: Dr E Gagneux, Service de Chirurgie Orthopédique et Traumatologique, Hôpital Jean Minjoz, 25030 Besançon Cedex, France. Tel: 0033 3 81 66 82 42; Fax: 0033 3 81 66 93 06.

Accepted for publication 5 January 1997

Introduction

Assessment is the first step taken in a quality programme, and it shows the great variability in current medical practice. These variations are one of the sources of adverse events. The main goal of a quality assurance programme is to reduce these variations, by identifying them and correcting them before the adverse event occurs.

Setting up and running quality assurance programmes in emergency departments is very difficult. The main reason is the difficulty of standardising the unit activities. The case mix is very broad with various injuries; the volume of care varies suddenly and considerably. Double care process is another element. The first process, ambulatory care, includes complete diagnosis and therapeutic procedures, and the second process targets seriously injured patients. These patients need rapid diagnosis and immediate transfer to a specialised care unit.

For the past few years quality assurance programmes have been criticised. The main criticisms concern the excessive standardisation of the procedures, without taking into consideration the organisation of the care process. The limits of focusing on conformity to quality standards have been pointed out.[1–3] This type of approach could reduce the quality process to a quest for minimal quality standards. "In addition, professionals must take part in specifying preferred methods of care, but must avoid minimalist standards of care . . . Quality control engineers know that such floors rapidly become ceilings, and that a company that seeks merely to meet standards cannot achieve excellence."[1] Another limit to the quality assurance approach is the difficulty in standardising the care process (particularly in emergency units). This lack of standardisation means that a large part of the medical process is left out of quality assurance programmes, and thus their efficacy is limited. For example, the studies in our emergency unit showed that although 60% of problems with the quality of care would be dealt with by prevention protocols, 40% encompassed such a variety of situations that any standardising process was impossible.[4] On the other hand, even if standardisation of all care processes were possible by developing critical pathways and algorithms[5]; such a situation is not acceptable. Standardising every process means a rigid and locked in system. These systems are well suited to technical procedures (such as biological laboratory or radiology units, which function as industrial systems), but they are not applicable to emergency units. Because of the variability of care needed and case mix, these units must permanently adapt their process to new conditions and to random events (defined as external events which interfere with the care process—for example, a phone call to a nurse, or delays for radiography due to unavailability of the radiographer[6]). If the system is too rigid, the flow of processes could slow down and bottlenecks could appear, thus producing adverse events.

Adverse events are generally defined as injuries that result from care provided in a hospital,

by contrast with injuries that stem from the patient's disease or condition.[7] This definition includes treatment complications and adverse events due to negligence, errors, or dysfunctions.[7–9] These adverse events are related to final outcome. In the case of emergency ambulatory care, systematic assessment of long term final outcome is difficult. The most usual procedure for detection of a problem in quality is the daily record, and what are named (improperly) adverse events are in fact related to intermediary outcome and to quality problems. They are at risk events creating situations which could lead to the occurrence of an adverse event. A better term for these at risk events could be near adverse events. Near adverse events are related to variations occurring in the three fields of quality described by Donabedian (structure, process, outcome), contrary to the adverse events defined as final health outcome. However, there is a direct relation between the occurrence of near adverse events and the incidence of adverse events,[10] and measuring the occurrence of near adverse events is a good indicator in technical assessment of quality of care.[4]

Few studies have been done on adverse events (or near adverse events) in emergency units,[11–13] and to our knowledge, only one has been carried out in an orthopaedic and trauma surgery unit.[4] The introduction of quality assurance measures is still experimental,[14–16] and most of the reports have a follow up of less than one year.[17–19]

In 1993, after an initial assessment of near adverse events (at risk events causing situations which could lead to the occurrence of an adverse event) in the emergency room of the orthopaedic, trauma, and plastic surgery unit of Jean Minjoz Hospital in Besançon (France) (box),[4] a quality assurance programme was initiated. This paper presents the long term evaluation of this ongoing programme. Our goal was to assess the modifications of the level of quality related to the quality assurance programme in a trauma emergency unit, and thus, to assess both the efficiency of quality assurance procedures, and the practical conditions of their implementation.

The initial assessment of near adverse events (1993)

The nature and the frequency of near adverse events in everyday functioning of the trauma emergency area, and the feasibility of their detection by means of a daily record review was assessed. A senior surgeon identified the near adverse events by reviewing the complete record with a minimal six month follow up for every patient treated in the trauma emergency area during a 10 week period. To test the reliability of this review, a blind rereview of all records which included the detected near adverse events, mixed with an equal number of controls, was carried out by two independent experts. The review of the 2604 records identified 204 medical near adverse events, 67% of them involving prevention failure (tetanus, thrombosis, and rabies). Near adverse events were detected by using the initial medical record for 97.05%, and the complete medical record for the others. The rereview evaluated the positive predictive value of the initial review at 97.5% and its negative predictive value at 96%. It was concluded that the review of the initial record by a single senior was effective in detecting near adverse events.

Materials and methods

THE SETTING

Jean Minjoz Hospital is a 729 bed teaching hospital in Besançon, a town of 120 000 inhabitants which is the regional capital of Franche-Comté in eastern France. The orthopaedic, trauma, and plastic surgery unit is set up as a trauma centre with an independent trauma emergency area. The trauma emergency area receives all the injured patients from Besançon, and the most severely injured patients in Franche-Comté. It sees more than 15 000 patients a year, some 2250 of whom are admitted to hospital in the unit.

The trauma emergency area is staffed by a junior doctor (intern in the French system) who is autonomous and responsible for the area. The junior doctor may seek help from the senior orthopaedic surgeon who is on duty 24 hours a day in the hospital during the week and on call at home during the weekend.

QUALITY ASSURANCE PROGRAMME

In 1993, the first assessment included 2056 consecutive ambulatory cases,[4] and showed the incidence of near adverse events to be 9.9% (n=204), during a period of 10 weeks, from 13 November 1992 to 20 January 1993. Failure to follow preventive procedures constituted 67% of the near adverse events, with antitetanus procedures heading the list (60% of all near adverse events). Failure to diagnosis represented 25% and misorientations 8.4% of the near adverse events. Given these results, a quality assurance programme was initiated. The main measures were:

(1) Raising staff awareness of preventive procedures by disseminating the results of assessments, posting the antitetanus preventive protocol, and regularly training the students.

Dissemination of the results of assessments was done during many informal discussions between one of us (EG) and the trauma emergency area staff members, with a special mention for tetanus prevention. This feedback was well received, and unit members agreed that it was a good opportunity for dialogue.

Writing up and conspicuously posting the protocol for prevention of tetanus on the wall was the next action taken, to standardise the prevention procedures.

Regularly training the students, by scheduling courses at the beginning of each training period, was the third action taken. The course topics included medical and administrative procedures and working rules of the trauma emergency area.

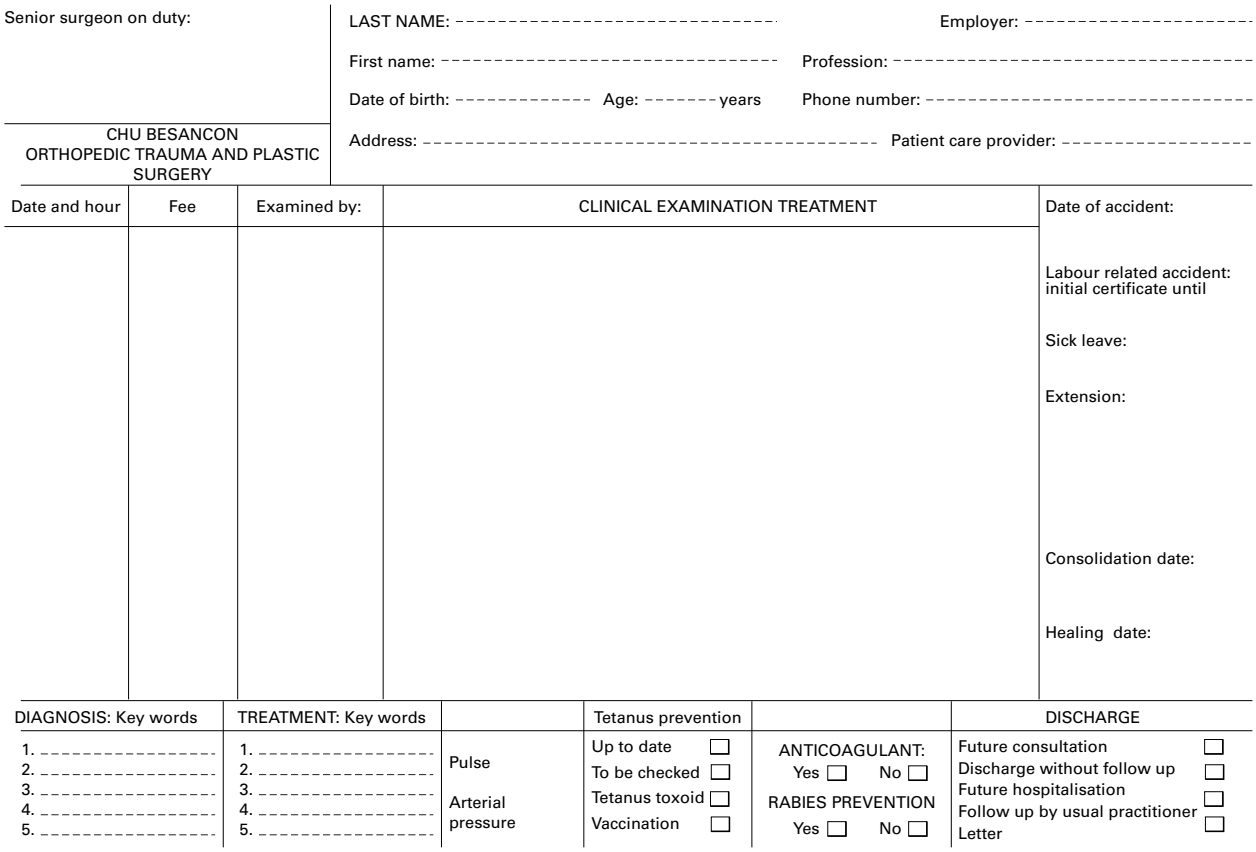

Figure 1 Medical record form.

(2) Modifying the medical record form (fig 1) by adding recapitulative headings about a patient's tetanus status, anticoagulant prescription, and rabies prevention.

(3) Automatically detecting near adverse events with the computerised medical file and prompting corrective action. For every ambulatory patient a computerised record is created during or just after the visit. This record consists of administrative and diagnostic data (using the international disease classification). In some situations, which were identified at risk for near adverse events by the previous study,[4] warnings appear on the screen during the data capture. For example, in the case of a traffic accident, the question "was the hæmodynamic check up performed?" appears, or in the case of a wound diagnosis (whatever its gravity) the warning is: "did you think of the tetanus prophylaxy?". The medical secretary must verify these points on the paper medical record, and in case of near adverse events must inform the junior doctor who is in charge of carrying out corrective action as soon as possible.

Table 1 Distribution of main diagnosis among injured patients in 1993 and 1995

	1993 (n (%))	*1995 (n (%))*
Contusions	863 (41.9)	450 (37.9)
Sprains	395 (19.2)	199 (16.7)
Fractures	404 (19.6)	175 (14.7)
Dislocations	36 (1.7)	17 (1.4)
Wounds	673 (32.5)	465 (39.1)
Miscellaneous		72 (6.1)
Unspecified	87 (4.23)	7 (0.6)

As a patient could have many injuries, the total exceeds 100%.

THE ASSESSMENT METHOD

To evaluate the efficacy of our quality assurance programme, we performed a second assessment 18 months after its initiation, with the same method as in our previous study (box).[4]

In keeping with our previous results, we modified the procedure. Only one reviewer performed a review of daily records (EG, senior consulting orthopaedic surgeon). This single review, in which a senior surgeon skilled in emergency care used clinical judgement based on implicit criteria, was effective in detection of near adverse events (with a positive predictive value of 97.5% and a negative predictive value of 96%.

As in the initial study, near adverse events were grouped into three categories: diagnosis, treatment, and orientation. Near adverse events involving diagnosis were defined as: misdiagnosis or oversight diagnosis; lack of information in the patient's examination record; paraclinical examination apparently not done or not followed up.

Treatment problems were defined as: discrepancy between the treatment and the diagnosis; departure from existing protocols; lack of thrombosis or prevention of tetanus or rabies.

Orientation problems were defined as: lack of follow up (no appointment or letter to the usual provider of health care); inappropriate decision for follow up—for example, discharge of a patient with an abdominal contusion.

Table 2 Distribution of near adverse events in the diagnosis categories, 1995

Near adverse events	*Contusions*	*Sprains*	*Fractures*	*Dislocations*	*Wounds*	*Miscellaneous*
Yes	28	18	18	1	37	2
No	422	181	157	16	428	77
Total	450	199	175	17	465	79

A patient could have many injuries and a single event may appear in more than one diagnosis category, so the total may exceed 71.
χ^2=6.71, 5 df, p=0.24.

Table 3 Comparison of new adverse events

	First study (1993)	*Second study (1995)*
Near adverse events	204 (9.9%)	71 (5.9%)
No near adverse event	1852	1116
Total	2056	1187

χ^2=15.05, 1 df, p<0.001.

In the data analysis, proportions were compared by the χ^2 test with a level of 0.05 required for significance. The rates of near adverse events and their distribution in the three categories were compared. In the previous study, we had found that one major near adverse event was the lack of tetanus prevention. We therefore compared the proportions of the occurrence of this near adverse events in relation to the number of wounds. As occurrence of near adverse events could increase with increased numbers of patients in the trauma emergency area, the number of near adverse events an hour was also compared with the volume of admissions an hour.

Results

STUDY POPULATION

This prospective study was carried out on the 1474 patients who were treated at the trauma emergency area from 1–31 July 1995. During this period 1210 injured people were sent home; 1187 medical records were available for the study and constitute the study's population.

Table 1 summarises the main diagnosis groups. There were slightly more wounds in 1995 than in 1993. Of the 1187 patients, 721 were men and 466 women. Their mean (SD) age was 35.6 (0.9) years.

The review identified 71 patients with near adverse events (5.9% of the ambulatory visits). The types of near adverse events were 36 cases (50.7%) in the diagnosis category: misdiagnosis (nine); insufficient information in the patient examination record (nine); paraclinical examination not done (nine); misevaluation or failure to evaluate the severity of the injury (nine); diagnosis oversight (one). In the treatment category there were 29 cases (40.8%) of near adverse events: discrepancy between treatment and diagnosis (six); lack of tetanus prevention (20); lack of rabies prevention (4). In the orientation category there were six cases (8.5%) of near adverse events: discharge without follow up for a serious lesion (five); discharge of patient requiring admission to hospital (one).

Table 4 Distribution of near adverse events

	First study (1993) (n (%))	*Second study (1995) (n (%))*
Diagnosis category	51 (25)	36 (50.7)
Treatment category	136 (66.6)	29 (40.8)
Orientation category	17 (8.4)	6 (8.5)
Total	204	71

χ^2=16.7, 2 df, p<0.001.

Table 5 Comparison of tetanus prevention

	First study (1993)	*Second study (1995)*
Omissions	121 (17.9%)	20 (4.3%)
Prevention	552	445
Total	673	465

χ^2=47.4, 1 df, p<0.001.

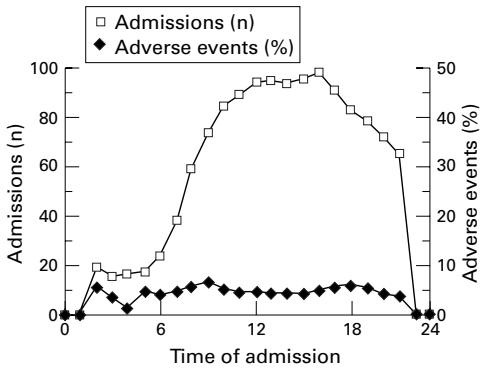

Figure 2 Rate of near adverse events during the day.

DATA ANALYSIS

As in the 1993 study, there was no correlation between the volume of admissions an hour and the number of near adverse events for each day of the week (fig 2). There was no correlation between the main diagnosis groups (table 2).

There was a significant decrease of the near adverse events rate: 5.9% versus 9.9% between 1993 and 1995 (p<0.001, table 3). Significant changes in the proportions of the types of near adverse events were found with a dramatic decrease in the treatment category (table 4). This was particularly apparent for tetanus prevention: the omissions dropped from 121 in 673 wounded patients (17.9%) to 20 in 465 wounded patients (4.3%, p<0.001, table 5).

We stress that there had been no changes in staff number, in skill mix, nor in any other aspects of organisation of the care process during this period other than the introduction of the quality assurance programme, which could interfere to vary quality.

Discussion

The analysis showed a significant decrease in the occurrence of near adverse events, and a change in the proportions of the three types. The proportion related to preventive protocol failure decreased, whereas the proportion related to non-standardisable procedures (the diagnosis category) increased. Such a result could be expected considering that the quality assurance procedures we implemented were only related to the standardisable aspects of the care process.

RELIABILITY OF THE ASSESSMENT METHOD

The main challenge of a quality assurance programme, is to eliminate near adverse events. In

our experience, these programmes refer mainly to measures such as feedback information, practice guidelines, training, and standardisation of procedures. We also used computerised medical recording as confirmation of detection for near adverse events, and we modified the medical record form to help with this.

DID THE RATE OF NEAR ADVERSE EVENTS REALLY DECREASE?

Because of the lack of references, the variation in the rate of the near adverse events should be given more importance than their absolute value. The rate of near adverse events was decreased by a factor of 1.7. This was a large decrease, but was it related to our quality assurance programme?

The method of assessment we used was similar and validated by the previous study. We had already shown that the reviewing of emergency records by a single surgeon is a reliable method for the detection of adverse events.[4]

Even if the case mixes varied between the two studies, the types of injuries were similar in the two groups, and we verified that the rate of near adverse events was independent of the diagnosis categories. We also found that the main difference between the two groups was related to the number of wounds, and that the decrease in the rate of near adverse events was mostly attributable to a much better tetanus prophylaxis prevention, despite the higher percentage of wounds in 1995.

Furthermore, we found no change in the unit, hospital, or care organisation which could explain these results. So it can be reasonably assumed that the decrease was at least in part attributable to the changes in the care process due to our quality assurance programme. The decrease was maintained in the long term as the programme was introduced 18 months previously, and continues to be maintained.

EXTERNAL VALIDITY

Most of the papers considering quality assurance and quality programmes, in admission to hospital or in emergency units, are theoretical. Very few are based on an outcome assessment (final or intermediary),[8 9 13 20] and to our knowledge our study is the only one performed in an emergency department. This reflects the difficulty in reliably assessing the technical quality of care. Most of the current indicators are related to observance of practice guidelines or specific aspects of evaluation of health status—for example, rate of infection in hospital.

PARTICIPATORY MANAGEMENT

A method such as ours requires general participation of the whole unit staff. Implementing a quality assurance programme requires not only the managerial will to initiate reflection on quality of care (asking about the current performance of the unit), but the staff must also adopt the quality project and modifications to the care process. The main difficulty found by many authors in such experiments is the generation of awareness and motivation of staff members.[21–23] To achieve these aims participatory management is necessary rather than the classic top down management. Participatory management is one of the 14 principles defined by Deming for total quality management.[24]

PARTICIPATION FROM THE STAFF

Getting support and active participation from the staff requires considerable informative and educational effort. One aspect of this effort consists obviously of technical aspects—such as instruction on procedures for prophylaxis—the other concerns the procedures used for quality assessment and their results (feedback). Complete professional openness is necessary to obtain staff trust and their acceptance of the modifications. This point is fundamental to long term maintenance of quality improvement and is stressed by Palmer.[25] In our experience, to obtain cooperation of medical staff in a quality assurance programme is more difficult than to obtain cooperation of non-medical staff. This is due to a cultural phenomenon (medical egocentricity) and to the traditional vision of quality, which is focused on individual technical performance.

PROCESS COST

Evaluation of a quality assurance programme is costly in time and energy. For example, one of us spent two hours a day reviewing the records (detecting one to four near adverse events). Quality assurance procedures generate expenses (printing of medical records, development of computer software, etc). Although these expenses can be justified by considerable quality improvement (as in our study), we must question the actual efficiency and acceptability of these programmes (the daily review of records was refused as a routine quality assurance procedure by the senior surgeons of the unit). Although it seemed efficient (and easy) to reduce the rate of near adverse events by a factor of 1.7 with simple quality assurance procedures, the residual rate of 5.9% is still too high, and the marginal cost of further improvement would probably increase exponentially. We touch here on some limitations of quality assurance programmes. When does a programme stop being cost effective, what cost level is possible or permissible, and is there an acceptable level of adverse events (even if a residual rate of near adverse events is ethically unacceptable)?

ABOUT OUR RESULTS

Given the lack of studies comparable with ours, we could not compare our rates of near adverse events. One supposition could be that because their absolute level was so high, it was easy to obtain a significant decrease, given only a quality assurance programme. We have no other emergency rooms for comparison, but it is obvious that our programme and assessment constitute one step towards quality. The challenge was not only to assess and then obtain a decrease in the rates of near adverse events, but also to maintain this quality improvement. This goal has so far been attained for 18 months.

Other studies have stated that quality assurance programmes are reliable and relevant in emergency departments,[16 26] and in other units or hospitals,[20 27] but there is a lack of statistical evidence.

The type of organisation in the trauma centre of our unit—comprising specialisation and small size of the unit, high activity volume, management of the complete care process—is probably a determining factor in the feasibility of such a quality assurance programme.

Due to the specialisation of activity and the high activity volume, whatever the diagnosis is, the care process is the same for every patient, and the number of standardised procedures is low. For these reasons the level of staff training is high. This high level of training of the staff required is a factor stressed by Donabedian, Reason, and Shortell *et al*,[10 28 29] for improving quality of care.

The small size of the unit means a limited number of hierarchical levels, and good communication between staff members. It is easier for a junior doctor to seek help from a senior doctor that he knows well and sees every day in the unit. Also the senior doctor knows the junior, and can thus keep an eye on his activities knowing what his weaknesses are.

Because of the structure of the trauma centre, follow up of the patient is done by the hospital units to which the patients are admitted or at outpatient consultation. Patients are followed up by the same surgeon from their first to last visits. Knowledge of the patient's evolution probably improves staff motivation for quality care. All the junior doctors on duty in the trauma emergency area are specialised in surgery, and most of them in orthopaedic and trauma surgery. This is another cause for motivation and the high level of training.

LIMITATIONS OF QUALITY ASSURANCE

Organisation and coordination of the care process are not considered by quality assurance programmes.[1] Professional practice assessments focus on development of therapeutic strategies, without taking into consideration the practical application of these strategies.[30] Lomas[2] states that quality assurance programmes have considered only medical expertise, disregarding other professional activity and care user participation, which are additional major aspects of the care process. Currently, one solution seems to be the application of the industrial total quality management principles as they were defined by Deming.[24] Since the beginning of the 1990s, these principles have been applied in some medical systems,[6 29 31 32] and by us in our trauma emergency area.[33] Application of the principles of total quality management demands a huge amount of time, energy, and money,[34] and in our experience its efficiency still has to be proved. Total quality management is still in the experimental stage in health organisations. Reason,[28] stressed that, whatever the organisation is, the human factor is the most important one in the occurrence of adverse events, and it is one reduction in efficacy of total quality management. He also argued that: "Effective risk management means the simultaneous and targeted deployment of limited remedial resources at different levels of the system: the individual or team, the task, the situation, and the organisation as a whole". From this point of view, quality assurance programmes are complementary to the organisational total quality management approach.

Effectiveness and efficiency of quality assurance programmes seem to be real and valuable. Although they do not contribute to a significant organisational improvement of care systems, they make the systems tighter and safer. However, implementation of a quality assurance programme requires conditions which are some of the basic principles of total quality management: participatory management and continuous feed back of information.

We think that quality assurance is an initial step on the path to quality, before consideration of a total quality management programme. Given the results of our study, quality assurance remains relevant. It allows considerable improvement in the quality of care, with a (relatively) low investment. It can also be used as training for quality programmes for the team, before the introduction of total quality management.

Conclusion

If total quality management currently seems to be the best route to quality improvement, quality assurance programmes have shown their effectiveness. They give valuable results, and they remain one important aspect of quality programmes, particularly as a first step towards implementation of total quality management.

With the quality assurance programme we were able to optimise the care process of the trauma emergency area by increasing the level of medical quality. Implementing and maintaining quality assurance programmes in medical units require the use of total quality management concepts such as participatory management, staff education and training, and professional openness. We think that practical application of these general concepts could help other clinicians involved in quality assurance policy.

Our thanks to Lois Rose for her help in correcting the English manuscript.

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