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Evidence-Based Analysis of Field Testing of Medical Electrical Equipment

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***Abstract*- Field testing of medical electrical equipment remains a topic of debate amongst biomedical engineers. A questionnaire was circulated among members of the main professional body for Medical Engineering Departments in the UK and Ireland and in the Medical Physics and Engineering Mailbase Server. The aim of the questionnaire was to establish consensus on common practice on the frequency and type of safety tests carried out in the field and common sources of hazards and risk management. Twenty-six replies were received in total. A clear majority of 54% of the respondents reported that they carried out safety tests on hospital-based medical equipment on a yearly basis. For other equipment, regular tests were carried out by 58% on loan equipment and by 69% on medical electrical systems. Laboratory equipment on the other hand were not tested in 42% of the cases. Domiciliary and research equipment were only tested in 11% and 15% of the cases respectively. A clear majority of 93% said that they label equipment after tests, 34% said that they always record the actual values (as opposed to pass or fail) and 54% said they carry out functional test as part of the safety test. Although 61% of failures were attributed to the mains lead, only 50% of the respondents said that they had a management system in place for detachable mains leads.**

I. Introduction

Although electrocution in hospitals or any other medical environment is a rare event, the consequences can be tragic and extremely costly. This is perhaps the reason why many Medical Engineering Departments devote much time and effort into conducting thorough routine tests on medical (and sometimes non-medical) equipment in the hospital. Whilst the nature of the hazards and risk minimization methods during the design of equipment are generally well understood, there is still a lack of harmonization between different organizations with regard to field testing. Issues that surface regularly are: what tests should be done as routine and, at what frequency. Such information should be derived from evidence. Unfortunately, there are not many reports in the literature of incidents related to electrical hazards associated with medical equipment. This may either be due to fear of litigation or inadequate reporting systems or both. The problem is further compounded by the fact that International standards related to electrical medical equipment (such as the IEC 60601 series) are mainly aimed at type testing of equipment at the design stage and do not give any guidance on field testing for hospital staff. In fact, repetition of some tests described by these standards is discouraged when the equipment is in regular use. The responsibility of deciding on the number of tests and the frequency usually falls on the Hospital and a decision has to be taken locally or (sadly) the ease of performing some tests and the difficulties of others, often by the Medical Engineering staff themselves. These decisions are based on guidance documents, evidence-based practice and risk analysis.

Injury due to electrocution is often a result of many factors, usually including a combination of water, electricity and bad luck! However, poor equipment design, poor maintenance and unsafe practice with multiple portable outlets may also be implicated. Some examples in the literature include humidity in the plugs of blood and fluid heaters causing device failure [1] and an accidental toppling of a fluid container causing spillage onto a blood pressure monitor [2]. Whilst the incidents did not cause immediate danger to the patient, unfortunately the malfunction of the blood monitor in the latter case caused subsequent harm as the patient's blood pressure was being lowered for surgery at the time and no spare monitor could be located quickly. Other causes of electrical hazard are due to excessive leakage currents. Singleton et al reported 2 incidents where anesthetists received electrical shocks after touching a faulty device and the chassis of another device simultaneously. As class I equipment have deliberately good earth conductors, they can convey leakage currents from faulty devices via the operator especially if they have wet skin which is very common with anesthetists. Skin preparation makes the situation even worse in terms of lowering the body resistance to electrical current by removing the outermost layer of the skin (*Stratum Corneum*) [3]. Surgical diathermy devices are another source of electrical hazard usually manifested as burns to the skin especially if the return plate provides poor contact with the skin [2].

The most frequent and potentially serious faults occur directly at the equipment mains part since plugs and mains cords are often subjected to rough treatment and physical torture in the form tugging, twisting or simply wrong wiring. A worrying aspect about these faults is that the equipment can carry on functioning seemingly well until some unfortunate soul happens to be at the receiving end. Atkin and Orkin 1973 described an unfortunate incident where an anaesthetized patient was connected to an ECG device that had been wired wrongly with the earth and neutral connections transposed [4]. After noticing electrical interference with the ECG signal, the anesthetist instructed an assistant to plug the monitor into a 2nd wall socket. Unknown to the assistant, the 2nd socket was wired with

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reverse polarity causing the chassis of the monitor to go live and suffered a minor shock. Unfortunately the patient experienced an intense shock since she was also connected to a surgical diathermy plate. She became cyanotic and her pulse stopped but later recovered completely. Since the incident happened in the USA, the voltage that the patient experienced was limited to 110V. One wonders whether the patient would have been so fortunate had the incident happened in the UK with twice the mains voltage level.

A very unfortunate and sad incident was reported by Yamazaki et al 1997 when a 9-month old baby was found dead on a bed after admission to hospital with suspected pneumonia [5]. The patient apparently put an uncovered oval shaped lamp switch (pendant switch) into his mouth and died of electric shock after contacting the exposed wires. Routine safety testing could have in theory prevented 3 out of the 7 incidents mentioned above.

There are probably many more examples like the ones mentioned above. They all highlight the fact that routine safety testing should be part of an overall process which should include diligence. There is probably a lot of common sense in the argument that visual inspection alone would be sufficient especially for class II equipment. Moreover, electrical safety tests on equipment with detachable mains leads are meaningless if the mains lead used to carry out the test with is not the same as the one used in practice.

The aim of this article is to summarize the main findings of a survey conducted by the working party amongst a number of Medical Engineering Departments in the Great Britain and The Republic of Ireland regarding electrical safety testing of medical equipment.

II. Material and Method

In order to get an informed opinion on current practice, the working party constructed a questionnaire which was circulated to IPEM members via the newsletter and to other interested parties using the Medical Physics and Engineering Mailbase Server. The aim of the questionnaire was to establish consensus on common practice on a number of issues. On hospital-based equipment, the main issues were the frequency field safety tests, sources of hazards and risk management. Risk management related questions were frequency of safety tests failures, the proportion of mains lead failures to the overall number of failures and any mains lead management schemes used.

The questionnaire also aimed at establishing the frequency of tests carried out on equipment not owned by the hospital. These equipment include:

1- loan equipment
2- domiciliary equipment (e.g. ventilators, feeding pumps)
3- medical electrical systems (e.g. pump stacks, theatre trolleys)
4- laboratory equipment (e.g. blood gas analyzers, hemoglobinometers)
5- research equipment

The participants were also asked to add specific comments on some questions and overall comments. Participants filled and submitted the questionnaire on-line. A full list of the questionnaire can be found on the following website: http://www.liv.ac.uk/~afgt/EST_Questionnaire.htm

III. Results

Twenty-six replies were received in total. A graphical representation of the responding centers is shown in Fig. 1 illustrating a fair representation through the country.

Results of questions related to the frequency of tests of hospital-owned medical equipment showed that a majority of 53.8% carried out tests once-a-year whilst 30.8% said that it varied. Reasons for the variation were:

- departmental policies on planned maintenance
- resource management
- manufacturer guidelines
- frequency of use
- dependency
- location

Results of the number of failures uncovered by the tests and the number of failures that could have caused immediate hazard are shown in Fig. 2.

These results show that in the majority of cases, routine safety tests uncovered 1-5 failures and the majority of these failures did not constitute significant risk.

Results of tests on equipment not owned by the hospital are shown in Table 1.

These results suggest that loan equipment and systems tend to be tested on regular basis whereas domiciliary and laboratory equipment go largely untested.

Damage to the mains lead seams to be the major cause for electrical safety failure and was attributed to 61.2% of failures in the previous year. Failures due to the equipment itself was attributed to 31.8%. Although mains leads were the major cause of failure, only 50% said they had a mains lead management system in place. Management schemes for detachable mains leads include, inventory, color, frequent replacement, physical inspection and affixing to the equipment. A majority of 38.5% said that they always recorded the test results and 53.8% said they carried out functional test as part of the safety test (Fig. 3).

Fig. 1 Centres taking part in the questionnaire

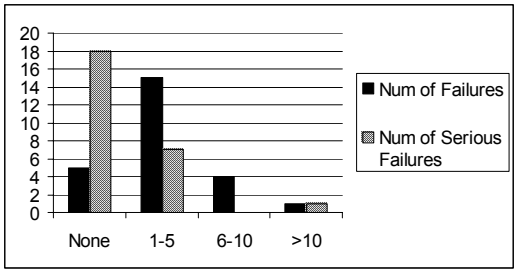

Fig. 2 The number of failures and serious failures uncovered by routine safety tests

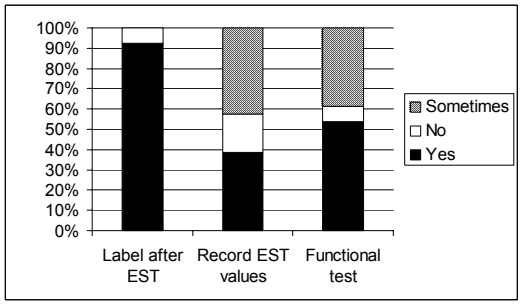

Fig. 3 Labeling, record keeping and functional tests

TABLE 1
TESTS ON EQUIPMENT NOT OWNED BY THE HOSPITAL

Equipment	Frequency of tests (%)			
	Regularly	On commission only	Varies	Never
Loan	57.7	26.9	11.5	3.8
Domiciliary	15.4	7.7	38.5	38.5
Systems	69.2	3.8	19.2	7.7
Laboratory	15.4	7.7	34.6	42.3
Research	11.5	7.7	61.5	19.2

IV. Discussion

There were a number of comments amongst the replies emphasizing the fact that electrical safety tests represent only part of an overall procedure which includes other measures such as visual inspection and routine replacement plans. In some cases, audits revealed that reducing the frequency of safety tests had little effect on the failure rate.

There is clearly a need for carrying out routine electrical safety monitoring (of which, testing is a part of) in hospitals to protect staff and patients. Patients are especially vulnerable because they might not have the ability to pull away and have their natural defenses removed. There is however a greater need to implement a common management system on a national basis. In order for such system to be cost-effective and safe, it should be evidence-based and backed up by risk analysis. It may well be that the time-honored 'testing to 601' is no longer justified or appropriate. Above all, staff vigilance and training should be high on the agenda for all hospitals to prevent rare but potentially tragic cases of electrocution in a place of care.

The European Commission have recently circulated a draft standard on routine testing for comments. The proposed standard covers testing after repair of medical electrical equipment and assemblers of systems. They have some new definitions, most notably accessible conductive parts, equipment leakage current (leakage current from all sources), recurrent test, touch current. As regards testing intervals this is suggested as "what the manufacturer says" otherwise it must be in the range 6-36 months and a list of equipment is given which should not exceed 24 months, which are mainly active treatment devices.

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