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Evaluation of reprocessing medical devices in 14 German regional hospitals and at 27 medical practitioners' offices within the European context – consequences for European harmonization

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Abstract

Safe reprocessing of medical devices through cleaning, disinfection, and sterilization is essential for the prevention of health care associated infections (HAI) and to guarantee patient safety. Several studies detected residual contamination and even severe infections of patients, despite carrying out reprocessing. To develop appropriate solutions, the existing situation in Germany and selected European countries was analyzed. Additionally, in 27 medical practitioners' offices and 14 hospitals, the true practice of reprocessing was analyzed using a questionnaire, a checklist, and inspection on site. A structured analysis of potential alternatives to the internal reprocessing was conducted within the German and European context.

The results indicate that the conditions for the execution of the reprocessing process in the analyzed health facilities in southern Hesse (Germany) do not satisfy legal requirements. The detected deficiencies were consistent with other reports from Germany and Europe. The analysis gave insight into several reasons for the detected deficiencies. The three main reasons were the high costs for proper implementation, the subjective value assigned to the reprocessing unit in health care facilities, and deficits in monitoring by the health authority.

Throughout the European Union, a similar regulatory framework for the performance of the reprocessing process exists, while the environment, structures of the health systems and administrative supervision vary significantly. The German states as well as selected European countries are currently discussing the challenges of increased quality-assured execution of the reprocessing process. For instance, the same supervisory system for hospitals and medical practitioners should be established at an equal standard. Alternatives such as the use of single-use medical devices, outsourcing the decontamination processes, or the cooperation of health facilities may be considered. This paper also discusses economic and ecological aspects. Finally, different options are recommended to ensure the exclusive use of reliable medical devices for surgical procedures that guarantee an adequate standard of patient safety within economic constraints.

Keywords: reprocessing, medical devices, patient safety, legal basis in Europe, analysis in medical practitioners' offices, analysis in hospitals, harmonization

1 Introduction

The reprocessing of medical devices for surgical procedures is a key element of quality assurance in health care facilities. Deficiencies in the implementation of this process involve the risk of health consequences for the patient. A double-blind study conducted in a hospital in England demonstrated that 56% of 23 monitored surgical instruments remained contaminated after reprocessing [1]. The decontamination of flexible endoscopes is always in focus, as the prevention of residual contamination is problematic and requires a validated method [2], [3], [4], [5], [6]. Moreover, a poorly designed endoscope can impede the decontamination process and may cause infections of patients [7]. Deficiencies were found in the implementation of the process, the spatial and technical requirements, as well as in personnel management and quality assurance [8], [9], [10], [11].

Through the establishment of the European Directive 93/42/EEC, requirements for the reprocessing of medical devices are upheld by the law. To ensure the quality of a sterile medical device, the standardized implementation of the entire reprocessing process using validated methods remains crucial. An important aspect to avoid errors in the reprocessing process is compliance with the cleaning, disinfection, and sterilization guidelines as well as the manufacturer's instructions.

In the present study, the reprocessing process in hospitals with a Central Sterile Supply Department (CSSD) and at medical practitioners’ offices was analyzed. The results are compared with the situation in selected European countries.

2 Methods

The monitoring of hospitals and medical practitioners’ offices was based on the nationally uniform checklist “Hygiene treatment” in Germany [12]. For the study, 27 medical practitioners of different specializations (gynecology, dermatology, surgery, orthopedics) and 14 regional hospitals were reviewed. For statistical analysis, all relevant deficiencies were merged into 4 groups, each with six individual features for the medical practitioners and the hospitals (Table 1 (Tab. 1)).

Classification of deficiencies into groups (main characteristics)	Medical practices	Hospitals
Decontamination process	• Sterilizer • Cleaning and disinfection • Packaging • Surface disinfection • Hand disinfection • Not legally compliant external decontamination	• Sterilizer • Washer-Disinfectors (WDs) • Pre-cleaning/ultrasound • Visual control • Packaging • Not legally compliant external decontamination
Personnel requirements	• Qualification • Release of instruments • Annual training • Staff rooms • Protective clothing • Cleaning staff	• Personnel planning • Technical qualification I (based on the training course of the German Society for Sterile Supply "DGSV", required for all CSSD employees) • Technical qualification II and III (based on the training course of the "DGSV" for management positions) • Staff rooms • Sluice/protective clothing • Cleaning staff of Central Sterile Supply Department (CSSD)
Space requirements	• Floor/ceiling/walls • Radiator/dirt traps • Area separation impure/pure • Separation surgery/decontamination • Storage • Insect screen	• Floor/ceiling/walls • Radiator/dirt traps • Spatial separation of cleaning/packing/storage • Transport routes/elevators • Storage • Ventilation
Quality assurance	• Complete process validation • Maintenance • Standard operation procedures • Batch control/process indicators • Hygiene plan • Skin care plan	• Complete process validation and Quality Management System • Process validation equipment • Maintenance • Standard operation procedures • Batch control/process indicators • Logistics

Table 1

Analyzed issues

3 Results

Two of the 27 analyzed medical practitioners' offices were not considered for the analysis because they only used single-use instruments. The most observable deficiencies at the 25 medical practitioners' offices were the following:

- 96% lacked experienced staff
- 92% had no system to release the instruments
- 60% no separate protective clothing was worn in the unclean sector
- 64% deficiencies were found in the packaging of the instruments
- 40% no suitable separation of clean and unclean areas was available
- 100% of the practitioners' offices had no validated reprocessing process implemented.

In the 14 hospitals, the following deficiencies were found:

- 57% basic qualification of staff was not completed
- 79% visual inspection was not performed correctly
- 50% sterilizers were obsolete or not suitable for performing a validated process
- 57% of the washer-disinfectors (WD) were obsolete or not suitable for performing a validated process
- 64% of the rooms were in need of renovation
- 100% demonstrated a lack of a validated reprocessing process in all sub-steps.

The date of establishment of a medical practice (Figure 1 (Fig. 1)) or the renovation of a CSSD (Figure 2 (Fig. 2)) has a significant impact on the quality of the treatment process. In particular, the spatial situation met the requirements better in newer or renovated facilities.

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Figure 1

Figure1: Deficiencies (mean of 6 features per deficiency group) at medical practitioners' offices depending on the date of establishment

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Figure 2

Deficiencies (mean of 6 features per deficiency group) in the CSSD, depending on the date of establishment

4 Discussion

4.1 Assessment of the reprocessing situation analyzed

Generally, a risk of contamination remains possible if the reprocessing process is not correctly performed.

Personnel requirements: Appropriate education and training is essential for performing the professional reprocessing process.

The official requirements for the staff responsible for reprocessing, described in the German Medical Devices Operator Ordinance (MPBetreibV), the Joint Recommendation of the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO), and the German Federal Institute for Drugs and Medical Devices (BfArM) from 2001 use the term "necessary expertise" [13], which is quite unspecific. With revision of the KRINKO-BfArM recommendation [14],

an additional appendix describes the necessary content for educational curriculum items, and it should preferably be included in addition to vocational training, which as yet is not available for work positions in the CSSD. For the medical practices, the Federal State of Hesse has established an optional course on decontamination education for the training of medical assistants.

A report in the Netherlands explained that although trained staff for the decontamination process is required by law, the personnel qualification in hospitals is very different, because there are no concrete, definitive training standards [15].

Inadequate hygiene conditions for the staff can lead to the transmission of pathogens between the immediate area of the health facility and the processing unit. Color coding the clothes for the different areas is already required in operating rooms [16] and has proven successful in some reprocessing units in southern Hesse. This would ensure that standard area and protective clothing is always worn only at the intended location.

In medical practices, standard area clothing is often worn without additional protective clothing for cleaning potentially contaminated surgical instruments. Generally, staff cleans their clothing themselves at home. Unprofessionally laundered clothing, for example in conventional domestic washing machines, can lead to microbial accumulation in the washing machine or insufficient inactivation of certain pathogens on the laundered clothes [17]. Pathogen transmission to immuno-compromised patients or to family members of employees has not been established, but cannot, however, be excluded [18].

Space requirements: The rooms of the CSSD in hospitals are often cramped, where high-quality and standardized work is hardly possible. Without the separation of the aseptic and unclean rooms, it must be assumed that the risk of cross-contamination is given.

In Germany, medical practitioners' offices generally occupy rented space. One problem is the building's common washbasin overflow. This direct access to the contaminated siphon poses a high risk to technical hygiene [19]. Architectural design in hospitals and medical centers usually corresponds to relevant RKI guidelines.

Quality assurance: The proper execution of a qualified quality management system is a vital aspect of standardizing decontamination procedures. The appropriate documentation also provides the operator with the necessary legal certainty. Process validation is indubitably required, also in terms of physicians and dentists [14].

The presence of a quality management system according to the German social code [20] leads to fewer deficiencies in medical practice, based on the deficiency-group analysis of space requirements and quality assurance (Figure 3 (Fig. 3)). In contrast, the effects of a quality management were only slight on decontamination process and personnel requirements. Apparently, the introduction of a quality management system for medical practices does not include the specific requirements for decontamination.

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Figure 3

Deficiencies (mean of 6 features per deficiency group) of medical practices, depending on implementation of a quality management system (QMS)

In addition, a considerable need for advice is required in hospitals to carry out the validation of all reprocessing steps. A widespread belief is that the validation of the sterilization process in accordance with EN ISO 17665 [21], [22] and the wash and disinfection process according to EN ISO 15883 [23] are sufficient. A standardized process flow can be ensured only on the basis of a quality management system with the correct classification of medical devices, detailed standard operating procedures, and packing lists (illustrated, if possible), as well as professional risk assessment. Employees must be involved in the organization of the working process.

Despite the validation of the "most difficult load", each charge has different requirements and thus is subject to other conditions. The use of indicators for daily charge control is essential and is used according to the results of monitoring in 44% of the 25 medical practitioners' offices and in 95% of the 14 hospitals. However, studies show that both biological and chemical indicators do not always reliably reflect the quality of the technical process. Therefore, a combination of different types of indicators is recommended [24], [25]. For checking the cleaning performance of a washer-disinfector in Europe, different biological media are used for the indicator.

External reprocessing: Although outsourcing of reprocessing is becoming more important, it is still controversial. For private practices or small hospitals, two outsourcing options exist:

1. reprocessing in an independent regional or even global CSSD company which supplies several other health care institutions, or
2. in the CSSD of a large hospital with its own CSSD.

The theories of transaction cost economics, founded by Ronald Coase [26], explain this by the ever-growing network of the world economy. Today, companies are less dependent to integrate interactions and transactions in companies that do not belong to the actual "core competence" [27], [28].

The prerequisites for the provision of an external reprocessing service are the validation of all sub-processes, a quality management system, and a well-qualified staff. Many hospitals in southern Hesse, Germany, met the requirements only after official monitoring and adaptation to the legal demands. The same situation was found in CSSDs within a Germany-wide hospital network [29].

In 1999, official monitoring of sterilization units in hospitals in the United Kingdom found that they do not always comply with the standards required. This led to the decision to build increasingly central sterilization units in the country [30]. Similarly, in the Netherlands in recent years, large central sterilization companies have been established. In Germany, however, there are few comparable institutions that offer only the reprocessing service. These central systems have advantages and disadvantages. A survey in the UK in 2008 with a very low number of responses showed problems such as a lack of instruments, wrong labeling of sets, and delayed delivery. In conclusion, it is recommended that these deficiencies, if identified by the customer, should be reported to the authority [31].

Single-use medical devices: On the German market, the supply of disposable instruments is continuously growing. Most are plastic products; metal products are offered only sporadically. The variety of instruments is limited. To date, the emergency and rescue services and primary care predominantly use disposable instruments.

Some doctors, mostly general practitioners and dermatologists, use disposables in their daily routine. The two most common arguments against the use of single-use instruments are:

- Environmental concerns due to the increased amount of waste [32]
- Subjective perception of lower quality due to the significantly lower weight.

The medical practitioners monitored who already only use disposable instruments do so based on the financial benefit, the safety of sterility, and at least the same quality of interventions. These statements were also described in a study by Puttaiah [33]. Another study on the use of forceps for endoscopy concludes that for reasons of quality, single-use medical devices should be preferred [34].

In the UK, disposable instruments have been increasingly used in recent years, due to the risk of vCJD infection in certain high-risk surgery [35]. Disposable metallic instruments for tonsillectomies and adenotomies are expensive; therefore, a study was conducted with disposable plastic instruments that were manufactured for that purpose. The quality of the interventions was equivalent with both kind of devices, but a familiarization phase of the doctors was necessary [36].

According to a market analysis by two independent institutes, in the future, the quality and innovations in the plastics industry are likely to improve; thus, it will be possible to offer single-use devices as alternatives to reusable medical devices that are particularly difficult to clean [37]. On the other hand, a cost-benefit analysis shows that decontamination of selected single-use medical devices, for example, ablation catheters, without increased patient risk can amount to savings of up to € 23 million per year in Germany [38].

It is necessary to review the impact on the environment due to the increased use of disposable instruments in the scope of a Life Cycle Assessment (LCA). Both processes, the new production and the reprocessing of surgical instruments, require a high level of energy and resource use. In 1999, disposable liners were compared with reusable liner fabrics in surgical interventions in hospitals. As a result, disposable fabrics were rated as more ecologically sound [39]. In 2000, the Austrian Institute for Applied Ecology conducted an LCA for the use of liners. The study summary explains that an LCA on its own does not show the appropriate method for each user; rather, the local conditions must also be taken into account for each product [40]. In a comprehensive evaluation of liners by the University of Dresden in 2005, it was found that the production of both materials was conducted using new procedures and increasingly improved ecological conditions [41].

In Italy it was found that the very high demands placed on in the reprocessing single-use instruments can hardly be met by small- and mid-scale health care institutions [42]. The health authority in UK warns of reprocessing single-use medical devices due to the occurrence of events with negative consequences for the patient [43]. The last proposal for the Medical Device Directive [44] foresees the reprocessing of single-use medical devices. This would allow the process in principle, but it must be subject to strict conditions and would define the re-use of disposable instruments as a return to the market. With these changes, a unified European legal basis will be implemented. It should be noted that the surgeon must easily recognize whether he uses a real single-use device or a reprocessed single-use device.

Cooperation of health facilities: Historically, primary health care in Western Europe is based on medical treatment. Finland founded the first community health centers in 1972, with other services such as check-ups included [45]. Other countries later adopted this model of general health care provision. Surgical procedures were carried out for many years exclusively as outpatient treatment. Within a few years, the inpatient treatment rose in Europe and the US, primarily due to legal and financial arrangements [46].

From a health policy perspective, performing outpatient surgery places a smaller burden on the health care system. Both patient waiting time and economic costs can be reduced [47]. Especially for underdeveloped regions, where only a very low density of physicians exists, alternative models should be considered.

In 2005, it was found that a structured, organized cooperation of physicians in Germany is largely absent [48]. Today, in southern Hesse, Germany, a different kind of medical practitioner cooperation is on the rise, including collaborations in highly specialized areas, close professional cooperation, and joint use of surgical and reprocessing facilities. The joint reprocessing unit provides logistic and financial advantages. It is important to consider the difficulties faced by small CSSDs in complying with all legal requirements. Training of staff, the current state of technology, and quality assurance are easier to implement in practices with a higher capacity of surgical procedures (Figure 4 (Fig. 4)).

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Figure 4

Deficiencies (mean of 6 features per deficiency group) of medical practices, depending on the frequency of the decontamination process

4.2 Prospects for the reprocessing of surgical medical devices

Reprocessing of medical devices is a complex technical process that needs to adapt to the development of innovative medical devices and the constant changes of the microorganisms [49]. These challenges are met in different ways within Europe.

- Due to the frequent occurrence of transmissible spongiform encephalopathy (TSE) in the UK, in UK is prohibited from reusing instruments of patients with an increased risk of variant Ceutzfeld Jacob Disease (vCJD). Therefore, more disposable instruments are used [50], [51]. A meticulous cleaning and disinfection process is required in the alkaline range to minimize the risk of transmission of vCJD [52].
- According to some experts, the statutory SAL value of 10^{-6} pathogens can be reduced due to the scientifically calculated probabilities of contamination [53], [54].
- The use of robotic surgical systems has increased rapidly in the last few years [55]. Because the instruments are complex, reprocessing is problematic for these medical devices [56].

The analysis of a total of 39 health care facilities and the review of relevant European literature can identify three major causes of shortcomings in the reprocessing process:

- High costs for proper implementation of the reprocessing process

- Little importance placed on the reprocessing unit in health care facilities
- Potential deficits of official monitoring.

Costs: The standardized implementation of the entire treatment process in appropriate areas with modern equipment and trained personnel is costly. Failure to comply with the rules provides a potential for cost reduction. For small health facilities with only a few surgical interventions per week, it is expensive to implement a functioning reprocessing regime (Figure 5 (Fig. 5)). Nevertheless, the conditions for reprocessing are required according to the KRINKO-BfArM recommendation [14], even in small facilities. Therefore, it is foreseeable that in the mid- to long-term, washer-disinfectors will replace manual cleaning and disinfection in the performance of reprocessing. It is expected that in the future, medical practitioners' offices with few surgical interventions will resort to an alternative instead of their own decontamination unit, for instance, the use of disposable instruments, an external reprocessing service, or cooperation with other medical practitioners.

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Figure 5

Cost estimation depending on the number of items for medical devices without special requirements for the reprocessing process

Düwel [57] used the example of University Medicine Greifswald to show that the introduction of a quality management system improved the quality and reduced the costs of the hospital. In addition, it is indisputable that the prevention of HAI affects the length of hospital stay and positively influences the recovery of patients. The incidence of HAI results in significantly higher treatment costs [58], [59], [60], [61], [62]. A direct causal relationship to the proper implementation of the decontamination process has not yet been demonstrated, although the increased infection risk posed by non-sterile instruments is internationally incontrovertible [21], [35], [63], [64], [65].

It should be emphasized that cost savings in the implementation of the reprocessing process must not lead to deterioration of performance, and thus to an increased risk for the patient. Funding must take into account the essential requirements of the entire health system.

Importance of the reprocessing unit: The target of any health facility is to heal the patient. The central figure is the doctor. In Germany, the reprocessing unit was at the bottom of the hierarchy in the past [66], [67]. The involvement of well-trained employees is important for the integration of the reprocessing unit in the existing structures of the institution. However, the salaries of such employees often correspond to those of untrained personnel. The German Society for Sterile Supply (DGSV) demands a specific job profile for this activity [68].

For physicians' staff, additional specialized training is offered optionally as part of medical-assistant training in Hesse. The goal is to achieve a high level of training coverage [69]. An equivalent system will probably also be established in other German states. At present, even within the university medical schools, the course modules on hygiene and in particular the decontamination process are only available in small numbers.

The organization of a functioning CSSD is a management task. Close cooperation with various departments/staff, such as purchasing, the end users (operators), the nursing service, hygiene and technical departments is essential [70]. In case of technical disputes, all stakeholders, including the head of CSSD, need to be able to take equal positions. Based on the Hesse-ASCA Guide [71] for the development of a systematic occupational safety organization, a guideline for the organization of the CSSD was created (Table 2 (Tab. 2)).

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Table 2

Organization guideline for CSSD

Official monitoring: There is no standard European procedure for monitoring the reprocessing units in health care facilities [72]. The conditions and structures are all different. However, there is consensus about the fact that official monitoring plays a central role. The presence of a regulatory authority ensures that standards are maintained in the health facilities. Due not only to the mentioned reasons (costs and importance) few health care facilities meet the necessary legal requirements without governmental intervention.

In the UK and in the Netherlands, a central commission is responsible for the coordination of monitoring and cooperation with other health inspectors. The Italian policy for the reprocessing process distinguishes between large and small hospitals, whereas the German KRINKO-BfArM recommendation [13] separates hospitals and medical practices. In the past, Finland predominantly monitored hospitals, and due to a change in requirements, has increasingly monitored medical practices since the 1990s [73]. In the Netherlands, it was decided to include the outpatient area in monitoring activities to ensure equivalent protection of patients. The consequences of official monitoring in this area are that not only will practitioners and health centers cooperate in running their reprocessing units at a good quality level, but also that medical practitioners rely increasingly on disposable instruments [15]. This paradigm shift to increasingly monitor the medical practices is desired in Germany [74]. However, it did not achieve coverage in the existing structures of the state authorities due to the lack of trained staff. Germany has a uniform federal checklist for implementing the MPBetreibV (German Medical Devices Operator Ordinance) [75] as well as a binding recommendation for the authorities [12]. On this basis, in some federal states, such as Mecklenburg-West Pomerania, North Rhine-Westphalia and Hesse, "special monitoring" for the decontamination process has been performed [11], [76], [77]. For a uniform implementation of the Directive for Operators of Medical Devices in all federal states, further specifications of the monitoring activities as well as a clear delineation of responsibilities between state and health authorities are required. In the new German Medical Devices Administrative Regulation, inspection and personnel requirements are described, which are currently discussed in the Working Group Medical Devices.

To enable Europe-wide implementation of the Medical Device Directive (MDD), it would be useful for a common body, such as the European Central Management Committee on Medical Devices (CMC) – first convened in December 2010 – to establish uniform frameworks for monitoring authorities.

Harmonization of approaches: Basically, the reprocessing process of medical devices must be executed in accordance with the legal provisions and the respective manufacturers' manuals. Due to the constant development of minimally invasive and complex medical devices, the manufacturer's instrument-specific decontamination instructions are increasingly important.

The present study shows that the structured administrative monitoring of the processing units is an important pillar of patient safety. The monitoring practices differ across Europe, as national health systems and legal bases are inhomogeneous. However, this fact does not allow any conclusion to be drawn regarding the quality of the reprocessing process of medical devices.

During on-site visits, some CSSD managers noted inadequate manufacturer's instructions. In addition, in the context of a COEN (Compliance and Enforcement Group) meeting, some countries reported deficiencies in the instruction manuals' description of the reprocessing processes. In Europe, each manufacturer is obliged under Directive 93/42/EEC and EN ISO 17664 to specify a validated treatment process if the medical product is intended for re-use after reprocessing.

Representatives from some countries (Ireland, UK, Portugal, France, Netherlands, Switzerland and Germany) are planning a COEN project. The aim of this IFU (Instruction for Use of Reusable MDs) working group is to improve descriptions of the decontamination process in the instruction manual. Thus, deficits would be reduced, and the treatment process would be raised to a better standard throughout the EU. The group has developed standardized checklists, and is planning a joint evaluation of the monitoring of all participating countries. With a solid legal basis, a standard is set that is to be respected in all participating countries.

Despite the different structures of the individual countries, a harmonized approach is possible due to the common checklist and the subsequent evaluation. The minimum standard demanded by each of the participating countries is crucial, and should thus provide safety for all countries and ultimately all patients.

5 Conclusion

The development of new surgical techniques and medical devices, as well as the changes of pathogens, require ongoing adjustment of the reprocessing process. Consistent standardization, extensive quality assurance measures, and good personnel training are necessary across Europe. Likewise, ecological and economic evaluation is important in the planning phase of a new reprocessing unit. Noncompliance with legal requirements poses a risk to patient safety and should not be tolerated. The three main causes of poor performance of the reprocessing process are: cost savings by reducing quality, low importance of the reprocessing unit in health care facilities, and the insufficient frequency of monitoring by the authorities.

Important approaches to improving and harmonizing the decontamination of surgical medical devices are as follows:

- Consideration of alternatives using environmental and economic assessment of the in-house reprocessing, including the type and frequency of surgical interventions in a health care facility
- Establishment of accepted and standardized training programs with adequate remuneration for performing reprocessing
- Development and adaptation of medical devices, cleaning, disinfection and sterilization appliances and of the reprocessing instructions to the needs of health care facilities in Europe
- Europe-wide standardized framework for the authorities for monitoring activities

- Europe-wide standardized framework for the implementation of the decontamination process, personnel requirements, quality assurance measures, and the spatial and technical requirement.

Notes

Competing interests

The authors declare that they have no competing interests.

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