# A clinical audit of sterile medical devices: a French experience of quality and safety improvement in hospital services

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## ABSTRACT

**Objectives** To audit the quality and safe management of sterile medical devices (SMDs), to examine the pharmacist's role in a multidisciplinary team, and to provide an example of hospital staff assessment of SMDs.

**Methods** SMD management was assessed using the National Agency for Support to the Performance of Health and Medical-Social Establishment tool in the Hospital Centre of Cannes, France, in August 2013. Safety policy in the healthcare establishment, and the SMD cycle in the hospital pharmacy, SMD cycle and care practices in the visceral–vascular–urological surgery care unit were evaluated by four health professionals and three hospital pharmacists. A total of 1850 references to SMDs for the hospital pharmacy and 1110 references to SMDs for the care unit were analysed. The percentage of risk control was defined as: 0–33% 'low', 34–66% 'medium', 67–100% 'high'.

**Results** Risk control was 'high' (67%) for the safety policy in the health establishment, 'high' (68%) and 'medium' (64%) for the SMD cycle in the hospital pharmacy and the care unit, respectively, and 'high' (88%) for the care practices. Good scores were obtained in both services.

**Conclusions** Safety and quality standards were investigated, and satisfied. Training of health professionals and information about, and the presence of, detailed procedures for safety policy and care practices showed good results. The main weak points were a deficit in IT support and a lack of procedures in the SMD cycle. The hospital pharmacist was shown to be a key figure in the multidisciplinary team.

## INTRODUCTION

In the European *Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices*, a medical device (MD) is "any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means".[1]

Sterile medical devices (SMDs) include devices such as dressings, implantable devices and surgical instruments. Owing to their peculiarities, their management is complex, and requires good knowledge.

SMD management presents both inherent and external different risk factors. The former depend on the product characteristics; the latter include SMD use non-compliant with good health professional practices, and/or poor communication or organisation, which might cause adverse events.[2]

Every step in the SMD cycle—analysis of the request, purchase, order, reception, storage, distribution, transport, reception, use, return and monitoring—is a key factor that might affect the good management of SMDs.[2–4]

The complexity of SMD management, non-adherence to professional and/or good organisational practices, communication problems[2] and the involvement of several health professionals[2–4] contribute to an increased risk. In France SMDs used in hospitals are managed by the hospital pharmacy.

The high possibility of errors requires evaluation of the management methods to find the gaps and to propose solutions, and for this a clinical audit might be effective.[5] It has been shown that patient care is improved by the use of clinical audit,[6 7] that regular audits should be carried out,[8] and that critical points in specific processes are highlighted through such an audit when various health professionals are involved.[6 9] In particular, pharmacists have been shown to be a key participant in multidisciplinary audits.[9 10]

In France, the National Support Agency for the performance of health and medical-social establishments (Agence Nationale d'Appui à la Performance des établissements de santé et médico-sociaux—ANAP) has devised tools to enable health professionals to improve hospital performance, such as the Diagnostic SMDs Tool (Outil Diagnostic Dispositifs Médicaux Stérile).[2] This tool is an audit, which allows staff to assess the SMD cycle, both in the hospital pharmacy and in the care unit.

The self-assessment includes the following points:

1. To determine the safety of the process in order to close any gap found.
2. To encourage an exchange of information among professionals in a multidisciplinary team.

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3. To promote a culture of shared safety techniques.
4. To provide those involved with feasible action plans, aiming to have a bottom-up approach.
5. To establish priorities for improvements.[2 4]

In this study we applied the five main points of self-assessment in the Hospital Centre of Cannes, France (Centre Hospitalier de Cannes), following the ANAP indications. The aims were to demonstrate the importance of the pharmacist's role both in SMD management, and in multidisciplinary teams, and illustrate the ANAP audit, since few studies of audits in the MD field have been published.

## METHODS

The ANAP methodology was used for self-assessment. Full details can be accessed from the Diagnostic SMD tool.[2] ANAP has granted permission for publication of the data used.

### Description of the questionnaire

Two types of audit are available: one in the hospital pharmacy, another in the specific care unit in which SMDs are commonly used. The list of questions is available on the ANAP website.[2] Figure 1 shows an extract of the questionnaire structure.

The questionnaire dedicated to the hospital pharmacy consists of two parts: *Sterile medical device cycle safety policy of the establishment* and *Sterile medical device cycle in the care unit*. The questionnaire dedicated to the care unit, also consists of two parts split into: *Sterile medical device cycle in the care unit* and *Care practices and practices evaluation*. Each part of the two audits corresponds to a topic. Every topic has a subtopic, which describes a step in the SMD cycle. The entire process is shown in detail in table 1.[2] A description of topics and subtopics is given in the footnote to the table.

The format of the audit is suitable for recording in Microsoft Excel.

Four answers are possible: 'yes totally'; 'yes partially'; 'no'; 'NA (not applicable)'. Each response carries a different score, determined by a mathematical formula. In particular, 'yes partially'=0.5 and 'NA'=0 points. Its use must be strictly limited and justified.[2]

Once the fields have been completed, a score is automatically generated and total scores given numerically and as relative percentages. Additionally, a radar chart graph is used to show the data. Different quantitative variables are represented on axes starting from the same point, and cartography of the weak and strong points are generated in the same sheet, immediately highlighting the trend in management of the SMDs.

The audit levels establish these values for risk control as: 0–33% 'low', 34–66% 'medium', 67–100% 'high'. The following points were identified:

- verifying the comprehensibility of the questionnaire items, so as not give rise to misinterpretations;
- enriching the questionnaire content with other items, if necessary;
- evaluating adherence to this process;
- ensuring application of the process.[2]

### Practical application of the audit

The audit was carried out in August 2013 in the Hospital Centre of Cannes,[11] France, an 827-bed general hospital, with 8 medical centres, 39 hospital services and 1800 staff.[12]

A total of 1850 references to SMDs were managed in the hospital pharmacy in 2013.

For the audit application the following personnel were involved: (1) in the hospital pharmacy: the pharmacy head, another pharmacist, an intern, two pharmacy assistants, who are qualified pharmaceutical professionals and one warehouse worker; (2) in the care unit: the hospital pharmacy head, the hospital pharmacy intern and the matron of the visceral–vascular–urological surgery care unit.

This care unit treats patients undergoing surgery for arteries and veins, and undergoing haemodialysis. Interventions such as abdominal aortic aneurysm, femoropopliteal bypass, carotid iliac or femoral expansion, interventions on varicose veins, endoluminal expansion techniques and stent application on arteriovenous fistulas for the management of chronic renal failure are normally carried out.[13] In 2013 the number of patients hospitalised for surgery in the visceral–vascular–

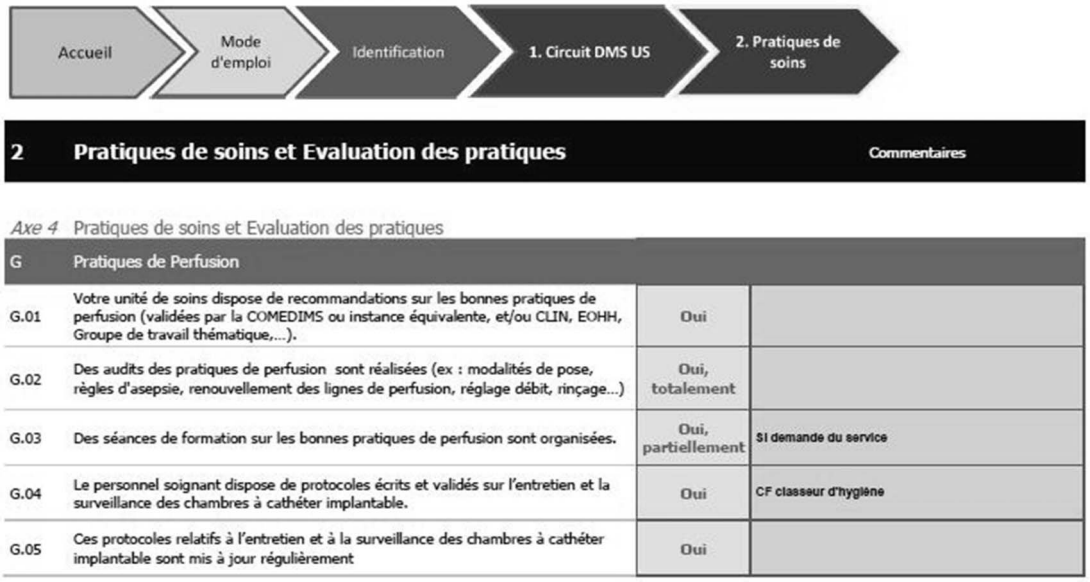


**Figure 1** Extract of the ANAP audit for the care unit. ANAP, Agence Nationale d'Appui à la Performance des établissements de santé et médico-sociaux.

**Table 1** Tree view of the ANAP tool[1]*

| Questionnaire | Hospital pharmacy/institutional instances concerning the SMD policy | | Care unit | |
|---|---|---|---|---|
| Topic | SMD cycle safety policy of the establishment | SMD cycle in the care unit | SMD cycle in the care unit | Care practices and evaluation of these practices |
| Axis/subtopic | Quality and safety management of the SMD cycle—10 questions.<br>IMDs—10 questions.<br>Agreed loan—deposit of the IMD—4 questions | Premises—7 questions.<br>Request—10 questions.<br>Order–reception—7 questions.<br>Storage—4 questions.<br>Distribution—6 questions.<br>Transport—6 questions.<br>Returns-disposal—6 questions | Request—9 questions.<br>Reception—4 questions.<br>Storage—8 questions.<br>Use of SMDs—4 questions.<br>Monitoring of SMDs—7 questions.<br>Returns-disposal—5 questions | Infusion practices—6 questions.<br>Prevention of BEA—4 questions.<br>Bedsores care—4 questions.<br>Other care practices—2 questions |
| Number of items | 24 | 46 | 37 | 16 |
| Total items in the questionnaire (n) | 70 | | 53 | |

**Sterile medical device cycle: safety policy of the department**
Quality and safety management of the SMD cycle: concerns the effect of health establishment policies from the committees in charge. It includes questions about the presence, the adherence to practices and material related to health policies in the establishment.
IMDs: an IMD is a "medical device to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and is intended to remain after the procedure."[1] The policy includes general questions about the management of IMDs.
Agreed loan—deposit of the IMD: includes questions about procedures and monitoring of IMDs.
**SMD cycle in the hospital pharmacy and/or in the care unit**
Premises: includes questions about the descriptions, typology and management of the premises where SMDs are stored in the hospital pharmacy.
Request: includes questions about how requests are made, received and managed by the care units to the hospital pharmacy, and the personnel involved.
Order-reception: includes questions about where and how order and reception take place in the hospital pharmacy and in the care unit, and about the personnel involved.
Storage: includes questions about where and how SMDs are stored in the hospital pharmacy and in the care unit, and about the personnel involved.
Distribution: includes questions about how personnel in the hospital pharmacy are involved in this step, if they are trained and adhere to procedures.
Transport: previews the SMD reception by the companies, the SMD management in the hospital pharmacy and the SMD deliverance to the care unit. It includes questions about training of personnel in the hospital pharmacy.
Returns-disposal: refers to the return and disposal of defective SMDs. It includes questions about the procedures, their availability and the training of personnel.
Use of SMDs: it includes questions about the training of personnel, the procedure availability and adherence, and the control of the expired SMDs.
Monitoring of SMDs: consists of all steps of SMD monitoring, from the patient information to the SMD traceability. It includes questions about the procedure availability and adherence to procedures.
**Care practices and evaluation of these practices**
All the subtopics include questions about the training of personnel, the procedure and availability of good practices, and adherence, and/or specific information (prevention of BEA—use of the SMD for the prevention of BEA, bedsores' care—correct use of equipment, other care practices—prescription practices, indications).
*Adapted from the Outil Diagnostic Dispositifs Médicaux Stérile of the Nationale d'Appui à la Performance des établissements de santé et médico-sociaux (ANAP).
BEA, blood exposure accidents; IMD, implantable medical device; SMD, sterile medical device.

urological surgery care unit was 2393 (vascular surgery=432, urological surgery=849, visceral surgery=1112), and hospital stays comprised 3068 patients (vascular surgery=541, urological surgery=1228, visceral surgery=1299). The number of SMD references managed was 1110 (surgical SMDs=230, SMDs for the operating room=880).

Results were automatically generated on a Microsoft Excel sheet.

## RESULTS

Data were first collected in the pharmacy, and then in the care unit. Answers to all the questions were given.

### Questionnaire dedicated to the hospital pharmacy

There are 70 questions on the 123 total items (57%) in the hospital pharmacy's questionnaire of which 24 concern the sterile medical device cycle safety policy of the establishment and 46 the sterile medical device cycle in the hospital pharmacy.

Table 2 describes the risk value for every topic and subtopic, the level of adherence to the audit standards, and the global score achieved for every field. Figure 2 represents the radar chart, with all the scores achieved for each topic and subtopic. The relative percentages are shown in table 2. In the hospital pharmacy the global risk control reflects the level of adherence to the audit (average score 67%), according to the score obtained in the two topics (SMD cycle safety policy of the establishment 67%, SMD cycle in the hospital pharmacy 68%; table 2). Thus the safety scores reflect the degree of adherence to the audit standards.

In particular, a high risk control was obtained for the topic 'sterile medical device cycle safety policy of the establishment' (68%); notably, the score was 'high' for the 'quality and safety management of the SMD cycle' (78%) and the implantable medical devices (IMDs; 71%), but 'medium' for the 'agreed loan—deposit of the IMD' (43%), which markedly reduces the overall score.

For the topic 'sterile medical device cycle in the hospital pharmacy' (68%) the following results were achieved: hospital pharmacy premises (100%) 'high', request (86%) 'high', order—reception (70%) 'high', storage (40%) 'medium', distribution (75%) 'high', transport (25%), 'low', returns—disposal (50%) 'medium'. Thus the better points in the SMD cycle are the request and order—reception. A high score was also achieved for the premises but not for storage. Good storage is linked to suitable premises but despite the good standards of the latter, the procedures for storage were poor (two questions out of four were negative). Two of six questions on transport were negative due to a lack of procedures and the absence of any analysis of the anomalies. In transport, returns–disposal lackEd good procedures.

The biggest faults do not relate to non-adherence to professional good practices, or to organisation and communication, but rather to incomplete availability of tools to avoid external risks.

### Questionnaire dedicated to the care unit

Fifty-three out of the 123 (43%) questions related to the care unit: 37 for the *Sterile Medical Device cycle in the care unit* and 16 for the *Care practices and practices evaluation*.

**Table 2** Score achieved from the hospital pharmacy

| Score for item, axis and sub-item | | Risk number | | | Percentage of risk control | Audit levels | Score achieved |
|---|---|---|---|---|---|---|---|
| | | No control | Control | Total | | | |
| 1 | SMD cycle safety policy of the establishment | 6 | 22 | 33 | 67 | High | 3 |
| A | Quality and safety management of the SMD cycle | 2 | 7 | 9 | 78 | High | 3 |
| B | The implantable medical devices | 2 | 12 | 17 | 71 | High | 3 |
| C | Agreed loan—deposit of the implantable medical device | 2 | 3 | 7 | 43 | Medium | 2 |
| 2 | SMD cycle in the hospital pharmacy | 13 | 38 | 56 | 68 | High | 3 |
| *Axis 2* | *Premises* | *0* | *7* | *7* | *100* | High | *3* |
| D | Premises hospital pharmacy | 0 | 7 | 7 | 100 | High | 3 |
| *Axis 3* | *Request—order—reception* | *4* | *19* | *24* | *79* | *High* | *3* |
| E | Request | 2 | 12 | 14 | 86 | High | 3 |
| F | Order—reception | 2 | 7 | 10 | 70 | High | 3 |
| *Axis 4* | *Storage, distribution, transport* | *7* | *10* | *21* | *48* | *Medium* | *2* |
| G | Storage | 2 | 2 | 5 | 40 | Medium | 2 |
| H | Distribution | 1 | 6 | 8 | 75 | High | 3 |
| I | Transport | 4 | 2 | 8 | 25 | Low | 1 |
| *Axis 5* | *Returns—disposal* | *2* | *2* | *4* | *50* | *Medium* | *2* |
| J | Returns—disposal | 2 | 2 | 4 | 50 | Medium | 2 |

SMD, sterile medical device.

Table 3 describes the risk control number and percentages, and the score achieved for every topic and subtopic. The score for the management of the 'SMD cycle in the care unit' (64%) was lower than that for the hospital pharmacy (2 vs 3), while scores were high for the 'care practices and practices evaluation' (88%).

Figure 3 represents the radar chart.

For the 'sterile medical device cycle in the care unit' audit showed a medium score, obtained as follows: request (70%) 'high', reception (50%) 'medium', storage (46%) 'medium', use of SMDs (67%) 'high', monitoring of SMDs (86%) 'high', management of the returns and disposal of SMDs (57%) 'medium'. The variability in the scores for different steps is evident. The absence of procedures is one of the most important deficiencies (1/7 questions in monitoring of the SMDs, 2/5 questions in management of the returns and disposal of SMDs), but there is also some organisational defect, such as the irregular control of disposal. But there is good communication between care unit and hospital pharmacy.

A high score was obtained for the 'care practices and practices evaluation'; in detail the score was broken down as infusion practices (89%) 'high', prevention of blood exposure accidents (BEAs—83%) 'high', bedsore care (100%) 'high', other care practices (50%) 'medium'. The good findings for these subtopics were achieved by high adherence to good professional practices.

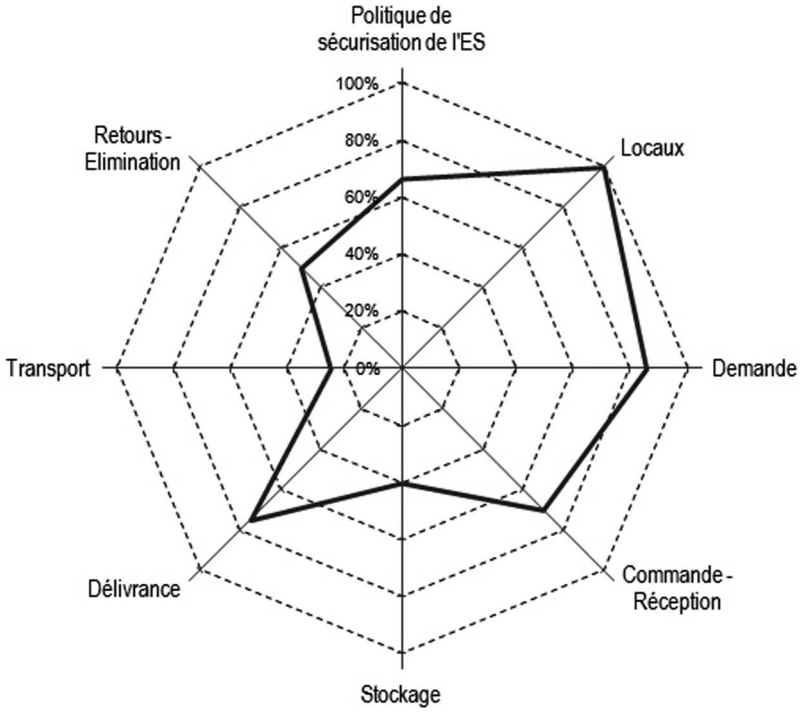


**Figure 2** Score synthesis on the radar chart for the hospital pharmacy. Politique de sécurisation de l'ES=Security policy of the establishment, Locaux=Premises, Request=Demande, Commande–Réception=Order–Reception, Stockage=Storage, Délivrance=Issuance, Trasport=Transport, Return–elimination=Returns–Disposal.

**Table 3** Score achieved by the care unit

| Score for item, axis and sub-item | | Risk number | | | Percentage of risk | Audit levels | Score achieved |
|---|---|---|---|---|---|---|---|
| | | No control | Control | Total | | | |
| 1 | SMD cycle in the care unit | 12 | 36 | 56 | 64 | Medium | 2 |
| *Axis 1* | *Request—reception—SMD storage* | *8* | *16* | *29* | *55* | *Medium* | *2* |
| A | Request | 2 | 7 | 10 | 70 | High | 3 |
| B | Reception | 2 | 3 | 6 | 50 | Medium | 2 |
| C | Storage | 4 | 6 | 13 | 46 | Medium | 2 |
| *Axis 2* | *Use—SMD monitoring* | *2* | *16* | *20* | *80* | *High* | *3* |
| D | Use of SMDs | 1 | 4 | 6 | 67 | High | 3 |
| E | Monitoring of SMDs | 1 | 12 | 14 | 86 | High | 3 |
| *Axis 3* | *Management of returns and disposal of SMDs* | *2* | *4* | *7* | *57* | *Medium* | *2* |
| F | Management of returns and disposal of SMDs | 2 | 4 | 7 | 57 | Medium | 2 |
| 2 | Care practices and practices evaluation | 0 | 21 | 24 | 88 | High | 3 |
| *Axis 4* | *Care practices and practices evaluation* | *0* | *21* | *24* | *88* | *High* | *3* |
| G | Infusion practices | 0 | 8 | 9 | 89 | High | 3 |
| H | Prevention of BEA | 0 | 5 | 6 | 83 | High | 3 |
| I | Bed-sore care | 0 | 7 | 7 | 100 | High | 3 |
| J | Other care Practices | 0 | 1 | 2 | 50 | Medium | 2 |

BEA, blood exposure accident; SMD, sterile medical device.

## DISCUSSION

After the audit a review of SMD management was carried out.

### SMD cycle safety policy of the establishment

Results showed that the safety policy was satisfactory, and was slightly better than for other French health establishments, which also used the ANAP audit.[4]

The strong points were characterised by the presence of several committees, the risk management activity and the management of IMDs.

Committees have different responsibilities: writing procedure for the correct use and disposal of the SMDs, information to the prescribers on monitoring the consumption of IMDs, writing of specific protocols on the expiration of IMDs. Table 4 describes the main committees in French Hospitals and their SMD expertise.

Risk management has proved extremely important, and to develop it further, a system of advisories and a collection of undesirable events related to the SMDs used has been set up. All the warnings have been discussed in multidisciplinary meetings.

Furthermore, MD vigilance has been an active part of health risk management. To extend this, a reporting and collection system of adverse events, related to the SMD cycle, has been implemented. This system has been integrated into the care risk global policy and IMDs have been considered especially important.

The management of IMDs is a key factor in the training of physicians on authorised and unauthorised SMD use, which has been regulated by an IT system, not used in the other SMDs. Possible IMD installation failure has also been pointed out to the hospital pharmacy. Every operation related to IMDs use has been recorded and monitored both in the hospital pharmacy and in the care unit.

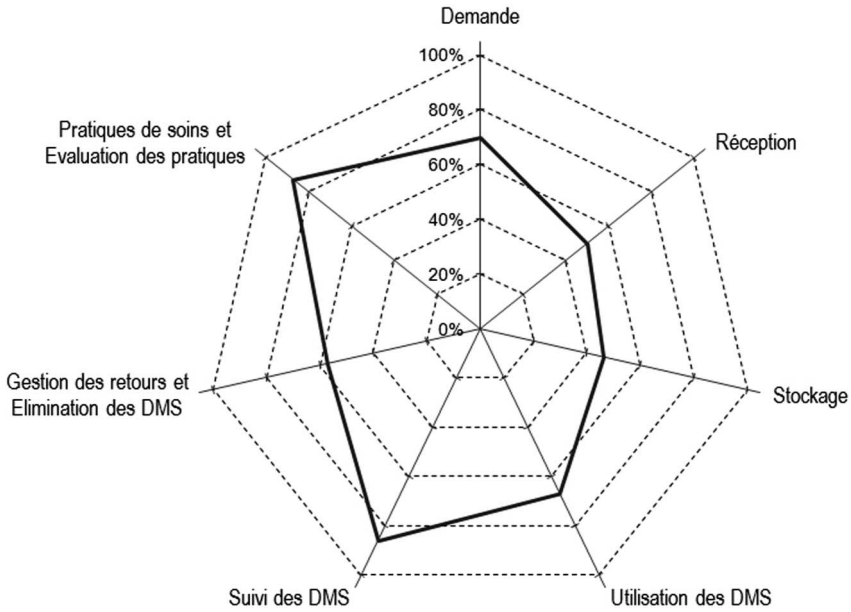


**Figure 3** Score synthesis on the radar chart for the care unit. SMDs, sterile medical devices. Demande=Request, Réception=Reception, Stockage=Storage, Utilisation des DMS=Use of SMDs, Suivi des DMS=Monitoring of SMDs, Gestion des retours et Elimination des DMS=Management of the returns and disposal of SMDs, Pratiques de soins et Evaluation des pratiques=Care practices and evaluation of these practices.

**Table 4** Main committees in French public health establishments

| Committee | Competence |
|---|---|
| Committee for the prevention of hospital infections (Comité de Lutte contre les Infections Nosocomiales—CLIN) | Responsible for giving information on the correct use of products, carries out audits and disseminates information |
| Committee of Medicines and SMDs (Commission du Médicament et des Dispositifs Médicaux Stériles—COMEDIMS) | Realises, develops and updates the drug and SMD handbook, drafts the recommendations for the correct prescription of drugs and SMDs, defines, in co-operation with health professionals, therapeutic priorities to increase coherent drug policies |
| Medical Establishment Committees (Commission médicale d'établissement—CME) | Develops quality and safety care programmes, also including SMDs |

SMD, sterile medical device.

The main weak points are the absence of procedure-regulating returns, the disposal of SMDs, and SMD and IMD management, in general.

Other important activities include the standardisation of biomedical equipment for infusion, and also the advisories system and the processing of the BEAs.

### Cycle of SMD in the hospital pharmacy and in the care unit

Findings obtained were comparable to data shown in the 2012 summary, where the findings of 21 French health establishments that used the ANAP audit were presented.[5]

The audit provided an immediate and clear diagnosis that reflected the practical situation and produced an immediate and clear map of procedures that help multidisciplinary work.[2 4]

For the hospital pharmacy, scores on the order—reception and storage were higher than results reported for other hospitals, while lower scores were obtained for transport and returns. For the care unit for the reception and the monitoring of the SMDs, there appeared to be no difference from other hospitals, while for the request and the use of SMDs results were higher for storage and lower for returns.[4]

Higher scores might have been obtained owing to the availability of premises situated in a supervised access zone—in particular, monitored entry into the hospital pharmacy, and to dedicated areas in which the baseline activities (ie, reception, storage, distribution) were routinely carried out. Correct reception and storage of SMDs was possible owing to suitable premises (both in the hospital pharmacy and in the care unit), which guaranteed good conservation and maintenance of all the products. This was important also for return operations to the suppliers: SMDs to be returned must be kept separate from all other MDs.

In addition, to ensure good quality storage of products, checks by specific personnel were carried out periodically in the hospital pharmacy, while the standards of correct storage were respected in the care unit.

The existence of a handbook of SMDs was a fundamental tool for physicians and nurses in ordering products. Additionally, any market changes were consistently communicated to the care unit by the hospital pharmacy.

Negative results were primarily due to the lack of procedure and to insufficient computerisation, both in the hospital pharmacy and in the care unit. This gap is similar in other French health establishments.[11]

An important role was played by continuing training and information both in the hospital pharmacy and in the care unit. It facilitates the correct restocking and use of SMDs by health professionals. Refresher courses have been periodically organised for hospital pharmacists, assistants, health workers and nursing staff.

The hospital pharmacist played a key role, thanks to essential and up-to-date information and correct control of SMD use.

In addition, centralisation of the management of SMDs by the hospital pharmacist produced better risk control and improved cooperation among staff. The participation of the hospital pharmacist in clinical audit was important, and should be reorganised in multidisciplinary teams (eg, the quality evaluation committee).

### Care practices and their evaluation

Local scores were higher than for other French institutions.[4] Contrary to previous audit data, higher scores are due to the presence of specific procedures and protocols relating to good perfusion practices, prevention of BEAs, bedsore care and other care practices, such as urinary probes, tracheal aspiration, gastrostomy, haemostatic perioperatory practices, and all practices related to the specific type of care unit.

Information on the management of the implantable devices was given to the patients, with the IMD identification chart.

Evaluation of the best use of off-label IMDs when needed was considered not applicable.

### Limitations

One of the drawbacks of the analysis was the relatively small amount of data.

Another limitation was the comparison with results of other French hospitals, because complete information was unavailable.

## CONCLUSION

The clinical audit was effective, and consistent with the main ANAP objectives.[2 4] Thanks to the self-assessment procedure,

### What this paper adds

**What is already known on this subject**

- Improvements in patient care are achieved by clinical audits.
- Audit should be used in hospital services.
- Management of medical devices is complex and presents many risk factors.

**What this study adds**

- The advantages of the sterile medical device (SMD) management audit are described.
- An example of SMD cycle analysis is given, in view of the lack of published reports on this topic.
- Multidisciplinary cooperation is illustrated.
- The hospital pharmacist is shown to be a key health professional.
- An interesting international working experience is shown.

the most critical issues of the SMD cycle were identified and multidisciplinary cooperation was favoured.[6 7]

Moreover, the hospital pharmacy proved to be a reference for all health professionals and committees, and a link between the different participants. The hospital pharmacist's role was fundamental in satisfying various needs and controlling the procedure.

Our future goals include improving the management of SMDs and bridging all the gaps, and verifying the present data by a further audit. Extension of the audit to other care units is also being considered.

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**Competing interests** None declared.

**Provenance and peer review** Not commissioned; internally peer reviewed.

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