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Guideline for the implementation of medical products using small bore connectors specified in the ISO 80369 series

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ISO Lignes directrices pour la mise en œuvre de dispositifs médicaux utilisant des raccords de petite taille conformément à la série de normes ISO 80369

(White paper)

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Introduction

This TC 210 White Paper was developed based on a guideline document drafted by the German APS[1] group. It contains guidelines intended for all parties involved with the complex changeover to ISO 80369 connectors and it aims to contribute to patient safety across the different healthcare applications.

Manufacturers of medical products are being encouraged to adopt ISO 80369 connectors in order to minimise the unintentional risks of misconnection between different applications. The first of these new connectors were placed on the market in 2016 and introduced into health care facilities. Background on the development of the ISO 80369 series is provided below.

Over a certain transitional period it is anticipated that product systems that currently use a Luer or Luer style connector, and are not intended for intravascular or hypodermic use, will need to connect with a part of the product system that uses the new connector, which will be incompatible with the current system. This is expected to occur not only within a specific health care facility but also across health care sectors such as doctor's practices, out-patient and stationary care/rehab facilities, pharmacies, and homecare among others.

As a consequence, the health care facilities should plan for and execute the changeover, i.e. the transition from medical products and accessories using Luer or Luer style connectors to medical products using the new connectors, into their normal care processes. The changeover primarily impacts consumable, single use medical products. However, these new connectors will also be used on capital medical equipment such as anaesthetic workstations.

The complex changeover process poses considerable risks for the patients such as:

- interruption/delay of care;
- new chances for misconnections;
- use and availability of adapters.

To avoid these and other adverse effects for the patient(s), the management should administer and supervise a well-planned changeover process. It will be necessary to establish a changeover team (referred to throughout the document as COT) to bring together the knowledge from the various departments that will be impacted by the change.

Background on the development of the ISO 80369 series:

The Luer connector[2] has become a universal connection system on medical products used in quite different applications. Originally, Luer connectors were intended to be used for the connection between an intravenous cannula and a hypodermic syringe. However, due to its simple design, size and ease of use, it has become ubiquitous and is used on applications such as: spinal and epidural syringes and needles, blood pressure cuff inflation systems, enteral feeding tubes, anaesthetic breathing systems etc. Their simple and effective design means that they can be used for almost any connection to and from the patient. Their dimensions were standardized in International standards ISO 594-1 and ISO 594-2 (now withdrawn and replaced by ISO 80369-7) which means they are compatible between different manufacturers and different medical products and are used in the millions throughout the world.

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1 APS stands for Aktionsbündnis Patientensicherheit, which translates to Action alliance patients' safety

2 The conical connection type was invented by the instrument maker Hermann Wülfing Lüer living in Paris. The Anglo-Saxon name "Luer" is now internationally accepted and therefore used herein.

It is, however, the universality of these connectors which poses a high risk for patient safety. Use of the Luer on different, incompatible medical equipment is virtually predestined to abet unwanted misconnections which may lead to fatal consequences. Such misconnections occur frequently and often involve products used for enteral feeding. There have also been misconnections involving infusion products and respiratory products that have led to fatal patient outcomes.

In order to prevent such misconnections between different applications in the future, a joint working group of ISO/TC 210 and IEC/SC 62D developed the ISO 80369 series of International Standards under the title "*Small-bore connectors for liquids and gases in healthcare applications*." This series defines new standardized connectors that reduce the risk of misconnections for respiratory, enteral, cuff inflation and neural applications. The series includes a redefined Luer connector that is specified for intravascular and hypodermic applications only.

Guideline for the implementation of medical products using small bore connectors specified in the ISO 80369 series

1 Scope

This White Paper contains implementation guidelines for the introduction of medical products that incorporate the new small-bore connectors specified in the ISO 80369 series of standards.

It is addressed to health care facilities, service providers and any other entity or person carrying out or involved in the changeover from medical products using Luer connectors to medical products using the new non-interchangeable connectors within the ongoing health care facility patient care processes. It is also addressed to manufacturers of the medical products concerned.

This guideline elaborates on the following aspects and steps which are considered to be essential for the changeover:

1) management responsibility;
2) approval of Phase I;
3) analysis;
4) planning;
5) approval of Phase II;
6) logistics;
7) procurement;
8) planning review;
9) preparation of checklists;
10) approval of Phase III;
11) changeover process;
12) exchange of experiences.

NOTE: These guidelines are intended to be continually updated based on the experiences gained during the actual changeovers.

2 Initial situation

2.1 Background information

Luer connectors are used in all areas of medical technology thereby enabling incompatible medical products to be unintentionally connected increasing the risk of harm to patients. Connections between two incompatible medical products are considered to be unintentional connections.

Such occurrences were recorded as early as 1968 and have regularly continued ever since [1]. In their paper “Tubing Misconnections: Normalization of Deviance” Simmons et al. describe the results of a literature research on studies between 1972 and 2010. 116 cases of unintentional connections were found in 34 publications. Out of those 34, 21 resulted in death and the remainder had no detrimental effects or the outcome was unknown [2].

In 2007, the World Health Organization (WHO) recognized unintentional connections as a risk to patients and Avoiding Catheter and Tubing unintentional connections ranks at No 7 of the 9 Patient Safety Solutions. Despite this, Luer connectors are still those most commonly used connectors on medical products [4].

The European Committee for Standardization CEN published a study in the year 2000 whose purpose was to analyse the risk caused by Luer connections. As a consequence EN 15546-1 “Small-bore connectors for liquids and gas in healthcare applications — Part 1: General requirements” [7] was published in 2008. Since the publication of this European standard this topic became increasingly focussed internationally and as a result an international joint working group of ISO TC 210 and IEC TC 62D was established to work on this issue and the ISO 80369 series of standards was developed.

This series of standards aims to eliminate or reduce risks of unintentional connection by means of safe design. The connectors are designed so that connectors from each application are no longer compatible with the connectors of a different application. The 80369 series also specifies general requirements for small-bore connectors carrying fluids or gases in applications of medical care and includes the methodology to ensure non interconnectability between connectors from different applications

The plan is for the medical products incorporating the new small-bore connectors of the individual areas of application to be replaced step by step. This process has already started in the field of enteral products.

The implementation of the new connectors and the changeover process can pose new risks of their own e.g.:

- What happens if a patient is transferred to another health care facility that has not converted to the medical products with the new connectors?
- How to avoid delays in therapy, if connections cannot be made?
- Who is affected by the changeover?
- How to inform and train the people concerned?

Risks should be identified and analysed in the run-up and then measures should be developed for their control in order to perform the implementation of the new connectors as smoothly as possible.

The following health care facilities particularly are affected by the changeover processes:

- hospitals, clinics;
- outpatient surgery clinics;
- outpatient or stationary care facilities;

- preventive and rehabilitation facilities;
- rescue services;
- dialysis facilities;
- day clinics;
- maternity facilities;
- other treatment or care facilities;
- doctor's practices/dental practices;
- practices of other human health professions;
- pharmacies;
- purchasing communities/cooperatives;
- clinic service providers;
- homecare sector;
- centres for laboratory medicine;
- medical supply stores.

Examples of hazardous unintentional connections

The risk caused by unintentional connections is particularly high in intensive care. The events are often multi-causal and arise from a concatenation of different circumstances increasing the risk(s). These may include e.g. bad visibility due to subdued illumination, a multitude of unmarked tubes in close proximity (see Figure 1) and/or high workload.

The U.S. Foods and Drug Administration provides an overview and risk assessment of some misconnections [3].

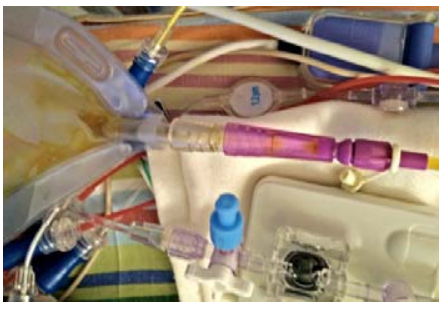

Figure 1 — Different small-bore connectors in close proximity to each other

2.2 Standardization of safe and secure small-bore connectors

In order to protect patients from unintentional connections in future the ISO 80369 standard series, “Small-bore connectors for liquids and gases in healthcare applications” was developed:

- Part 1: General requirements;
- Part 2: Connectors for breathing systems and driving gases applications;
- Part 3: Connectors for enteral applications;
- Part 5: Connectors for limb cuff inflation applications;
- Part 6: Connectors for neuraxial applications;
- Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications.

Connectors for other applications may be standardized in future. Manufacturers will be under pressure to produce their medical products with these new non-interchangeable connectors. Therefore, many medical products with Luer connectors will be withdrawn from the market by the industry in the near future and the health care facilities will, in time, have to change over to the new non-interchangeable medical products and retrofit existing medical products. The transition process is complex for the health care facilities and requires considerable organizational effort.

3 General considerations with regard to transition to the new small-bore connectors

Manufacturers of non-disposable medical products or long term use products fitted with Luer connectors and that connect to disposable medical products that use the new connectors will need to consider measures to facilitate continuity of treatment. While adapters, i.e., transition connectors, or conversion kits may be one option for addressing this issue, manufacturers and health care providers must work together to mitigate and control additional risks posed by the use of such accessory components. For example, a potential risk may be the re-introduction of misconnection between products intended for different purposes based on the assumption that the products will no longer misconnect.

The risk assessment for the universal adapters shows that, in general, they should neither be procured nor used. However, special adapters could be permitted under very special conditions as accessories to the medical product concerned for a very limited period of time. If an adapter is found to be necessary, manufacturers should consider the use of one that must be detached using a tool in order to maintain the safety intended by the ISO 80369 series of standards.

Possible approaches:

1) **Exchange:** Replacement of a medical product already in operation by a medical product with connectors complying to the new standards:

   Replacement is primarily done for medical products not intended for reuse (e.g. single-use tubes replaced with comparable tubes using connectors in compliance with the new standards). Replacement may occasionally be appropriate for medical products which cannot be converted.

2) **Adaption:** Modification of a small bore connector on a medical product from a Luer connector to a connector in compliance with Parts 2 to 6 of the ISO 80369 series of standards by:

   a. adapter / transition piece that are intended by the manufacturer and that require the use of a tool to convert Luer connectors to connectors in compliance with Parts 2 to 6 of the ISO 80369 series of standards.

   b. adapter / transition (universal adapter) piece for use by the operator to convert Luer connectors without the use of a tool to connectors in compliance with Parts 2 to 6 of the ISO 80369 series of standards.

3) **Retrofitting:** Modification of a medical product already in operation that is deemed suitable for reuse by the manufacture by replacing the current connectors with connectors that comply with the new standards.

   Retrofitting should only be done based on the manufacturer's provisions and by either the manufacturer or by qualified persons acting in consultation with the manufacturer. Retrofitting should always require the use of appropriate tools.

   In general, medical products suitable for retrofitting are capital goods, e.g. equipment such as anaesthetic machines, lung ventilators, and monitors, that are equipped with connectors for gases. For such durable medical products the manufacturers should offer corresponding retrofitting or conversion sets so that competent specialist staff can perform the conversion to the new connectors at the scheduled time. To this end, it is essential to take into account the accessories required in conjunction with the retrofitting. For example, connecting tubes not intended to be reused should be replaced with similar connecting tubes using connectors that comply with the new standards.

4 Recommendations for action

4.1 General

Figure 2 outlines the 12 process steps that are discussed in the section 4.

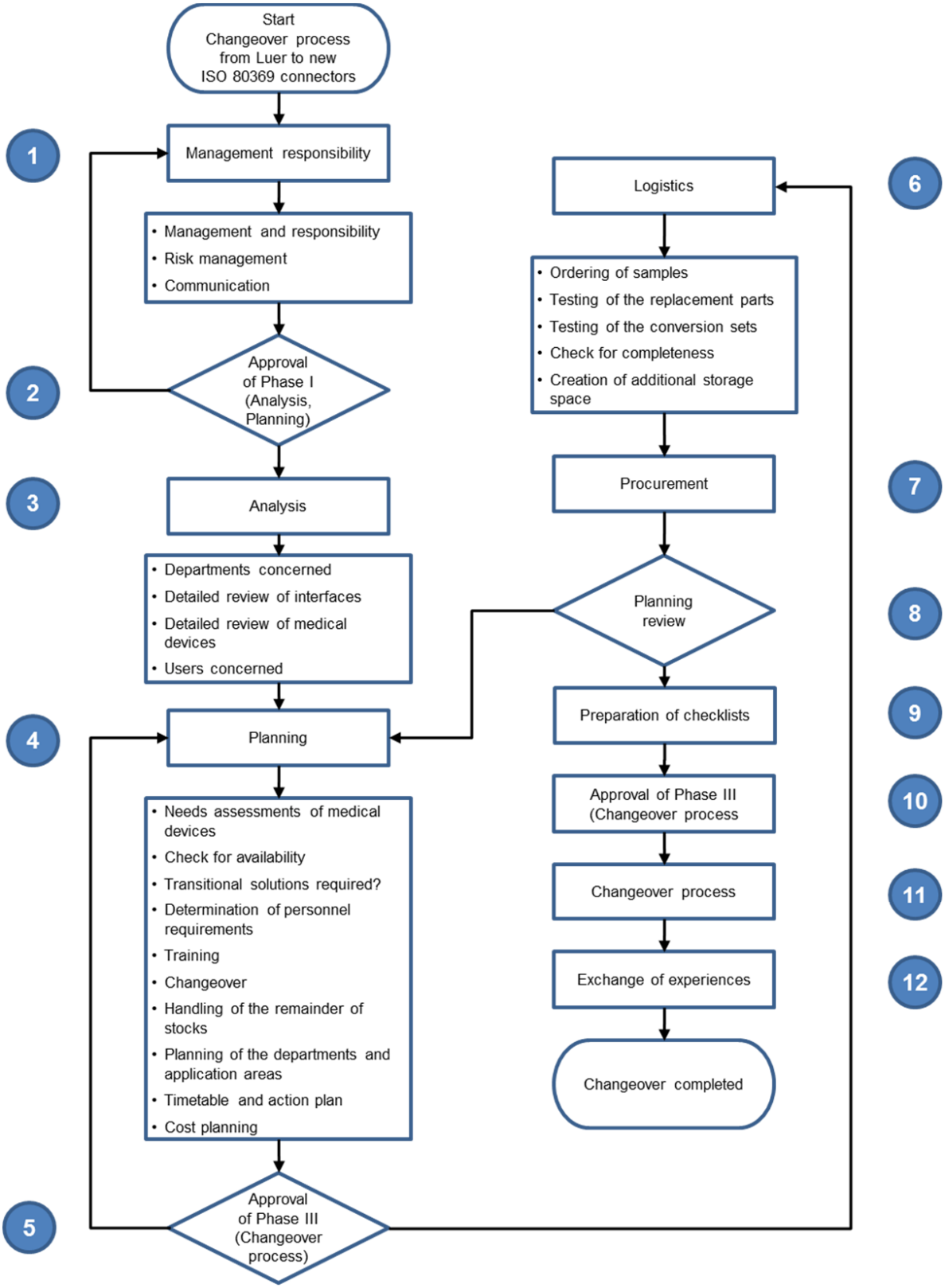

Figure 2 — 12 Aspects and process steps for a successful implementation

4.2 Management responsibility

4.2.1 General

The facility's top management has the overall responsibility for the changeover process, e.g. the executive board. Top management should establish a team of responsible and motivated persons to, to prepare, coordinate, supervise and audit the changeover process. It is essential that the members of the changeover team (COT) understand the necessity of changeover and that they are ready to play an active role in the process. It is important to form such a team as early as possible. It is imperative for the top management to be involved in this COT.

4.2.2 Organisation

The changeover for all types of connectors can be managed by either a cross-institutional team or by department or application specific teams.

COT's should be authorized to make decisions and give directives regarding the changeover process. They should be comprised of representatives from the departments/wards impacted by the changeover, including, but not limited to, hospital hygiene, quality and risk management, medical engineering, and procurement representatives. Ideally, the COT is led by a person (COT leader) who can provide support for the project from the medical staff and the administration. It is beneficial for the persons involved to hold a leading position in their respective departments.

It should be determined on a case-by-case basis whether it makes sense to include cross-institutional representation on the COT (e.g. involving representatives of the nearby care facilities in the changeover for enteral applications).

The size and composition of the team should reflect the size and complexity of the health care facility. The composition of application-specific teams in a hospital could be as follows (examples taken from UK hospitals where the changeover process has already been completed in an application area):

Team Enteral Applications:

- Medical staff
- Risk management staff
- Procurement staff
- Medical engineering staff
- Representatives from General Practitioners
- Representatives from care facilities
- Discharge planners or those responsible for transition of care to long term care or home care settings

Operations were headed by a chief dietician.

Team Neuraxial Applications:

- Staff from anaesthesia, oncology, haematology, neurology
- Pharmacy staff
- Risk management staff

- Procurement staff
- Medical engineering staff

The prime person responsible for the decision as to which products should be introduced was with an anaesthetist.

4.2.3 Risk management

The management of the health care facility is required to establish the risk management plan for the changeover process and provide the necessary resources.

The risk management plan should:

1) identify and analyse the risks prospectively;
2) develop, plan, initiate, and implement risk control measures;
3) communicate the risks and risk control measures through education, training, and other methods;
4) regularly audit the safe handling of the new medical products; and
5) provide for public access to relevant patient safety findings related to the changeover process and the use of the new medical products.

The management of the health care facility concerned should instruct each COT to:

1) carefully analyse the need for conversion kits and plan their procurement and installation;
2) critically examine the need for special adapters as accessories to the medical product in cooperation with the risk management team;
3) if use of an adapter is found to be indispensable, create a deployment plan and timetable for each special adapter, which describes:
    a. the duration the special adapters may be used in each area it is deployed,
    b. how the adapters are to be completely withdrawn from use and disposed of/destroyed after the transition;
4) carefully justify and document the timeframe for use of a special adapter in a specified but limited area
5) supervise the application of the special adapters; and
6) ensure the decommissioning and the disposal of the special adapters.

4.2.4 Communication

The management of the health care facility is required to inform all impacted employees of the changeover, the COT's established for this purpose, and their tasks and responsibilities at an early stage.

They should authorize the COT to openly circulate safety information regarding the transition to and use of the new medical products.

In the case of continuous patient care, e.g. in the event of a transfer or discharge, the COT should be responsible for communicating with external organizations such as registered General Practitioners, home-care facilities, and rescue services.

4.3 Approval of Phase I (Analysis, Planning)

The COT is responsible for analysing and planning for the changeover within their health care facility – this constitutes phase I of the changeover process. Before beginning this phase, the COT should provide a proposed strategy for conducting the analysis and planning phase to management for approval. The analysis and planning activities are to be documented and provided to top management once completed. The COT may also consider providing periodic updates to management based on their facility's policy and procedures. Sections 4.4 and 4.5 outline elements that should be included as part of the analysis and planning phase

4.4 Analysis

4.4.1 Differentiation between old and new medical products

A clearly defined name to differentiate the old and the new medical products should be used in all verbal and written communication.

4.4.2 Departments concerned

In the various types of facilities within the health services, the following wards/departments are typically affected:

- All patient care units/wards;
- Operation theatre;
- Intensive care unit;
- Functional wards;
- Emergency unit;
- Purchase/procurement;
- Stock-keeping;
- Pharmacy;
- Laboratory;
- Processing/sterilization;
- Medical engineering;
- Logistics.

4.4.3 Documentation of department and facility interfaces

The transfer of patients, medical products, information, services, and personnel between departments within a health care facility and between different health care facilities results in important interfaces between these entities.

These internal and external interfaces must be identified, documented, and addressed as part of the changeover process.

4.4.4 Inventory of medical products

4.4.4.1 General

A comprehensive inventory of medical products concerned should be carried out and properly documented.

When conducting the inventory, take into account that the nomenclature used for the different health care applications included in the ISO 80369 series of standards are generic. The specific products for each health care application impacted by the changeover may not be easily deduced. For example, even the title of ISO 80369-7 implies that this connector is for intravascular or hypodermic applications only, but it is reasonably foreseen that there are some other applications such as inflating tubes for cuffs for fixing invasive medical products, such as tracheal tubes, laryngeal masks, percutaneous endoscopic gastrostomy tubes and urinary catheters that will continue to use the 80369-7 Luer small-bore connector for an undefined period of time. It is therefore advisable to carefully review the scope of the relevant medical product standards that specify use of the ISO 80369 series connectors as well as information available from the manufacturers.

It is imperative to document the inventory of medical products impacted by the changeover so that the terms and code numbers used in the procurement system can be appropriately referenced back to the inventory list.

4.4.4.2 Replacement /changeover

All medical products/accessories not intended to be reused that are presently equipped with Luer connectors and therefore potentially required to be replaced should be identified. Stock registers, which also cover accessories, may be used for the registration and documentation of these medical products. Accessories are regarded as part of the medical product.

Where stock registers are not available, corresponding lists should be created. These lists should at least be differentiated according to the application areas (respiratory, enteral, etc.) and according to manufacturers/suppliers.

These lists should also note who is generally responsible for procurement/provision (regular procurement operator). The regular procurement operator could be e.g.:

- the party (e.g. a legal entity or a person) responsible for the use of the medical products/accessories;
- the health insurance company providing the patient with the products/accessories as required in the context of medical product use;
- the service/homecare provider providing the patient with the products/accessories as required in the context of medical product use (e.g. lump-sum payment/reimbursement);

- an organisation that provides the patient with the products/accessories as required in the context of a medical product leasing or rental contract; or
- the patient.

Note: It is important that the COT has information regarding the regular procurement operator in order to coordinate the ordering of products and assumption of costs during the replacement/changeover process.

4.4.4.3 Retrofitting

Clearly identify the products in the stock register or list that need to be retrofitted. Once these products have been identified, clearly document the owner, responsible organisation, or the person responsible for the status of these medical products or (for possible categories of the regular procurement operator see the paragraph above).

4.4.5 Users concerned

The COT should determine and document all users within the health care facility who will be impacted by the changeover to facilitate information dissemination and coordination of training during the implementation process. The documentation should include their organizational affiliation (e.g. ward, function, and department).

4.5 Planning

4.5.1 Determination of the medical products demand

The COT should determine the demand or supply needed for each medical product impacted by the changeover, which in turn should yield specific information on the number of:

a) each medical product needed, including,

   1) disposables,

   2) reusable medical products,

   3) accessories

   4) conversion kits;

b) departments;

c) applications/processes

The COT should also take into account the following factors:

- cross-department use (e.g. for syringes);
- stock level/effective reach;
- criticality, if not available; and
- the number of sample sets needed for communication and training.

4.5.2 Check for availability

4.5.2.1 General

In order to avoid supply bottlenecks, the internal suppliers (e.g. buying groups) and external suppliers (e.g. manufacturer) should be involved in the changeover planning at an early stage. The changeover should only be implemented when availability of the new products are assured.

4.5.2.2 Replacement parts

For products already in operation that require replacement of parts, consult the manufacturer and supplier for information on the availability of comparable medical products or parts with the new connectors. This inquiry should comprise the following details:

- reference number;
- price;
- detailed description of the comparable medical product, if necessary;
- availability or delivery time of the quantity required for the facility.

4.5.2.3 Conversion parts

For products that require retrofitting, consult the manufacturer and supplier for information on the availability of appropriate retrofitting conversion sets. This inquiry should, as a minimum, comprise the following details:

a) reference number, price and, if necessary, a detailed description of the conversion set;

b) details on whether assistive products or tools are required for the retrofitting process by the facility's own staff;

c) allocation of who can/should perform the retrofitting process of the products concerned;

d) reasonably foreseen time necessary for the retrofitting process per product;

e) costs for the retrofitting per medical product if carried out by the manufacturer/supplier or working hours if carried out by the facility's own staff;

f) downtime of the medical product caused by the retrofitting process (e.g. drying of adhesives);

g) checks to determine whether the retrofitting was successful;

h) feasibility of checks to be performed by facility's own staff (e.g. availability of the control provisions, requirement of special measuring tools);

i) availability or delivery time of the quantities of conversion set, parts, tools, etc. required by the facility;

j) availability of staff required for the retrofitting action at the manufacturer/supplier facility or lead time required when performing the retrofitting process in the health care facility;

k) if several products of a manufacturer/supplier are concerned: check whether all products can be retrofitted by the same staff;

l) check whether the staff required for retrofitting process at the manufacturer/supplier are also available for a weekend retrofitting action;

m) results of tests performed by the manufacturer/supplier to verify the continued safety and proper functioning of the product after the retrofitting has been performed.

4.5.2.4 Resources for the retrofitting process

For all products to be retrofitted, specify who carries out the retrofitting (e.g. the manufacturer or the facility's own staff). If the retrofitting is carried out by the facility's own staff, the timetable to perform this work in addition to the daily routine activities should be taken into consideration.

4.5.3 Necessity of provisional solutions

4.5.3.1 General

In principle, retrofitting and changeover should be started and executed only when the corresponding conversion sets, assistive products, tools, and measuring equipment as well as the staff resources required for the changeover process are available.

4.5.3.2 Risk management

If it is, impossible to perform the retrofitting or the replacement of the necessary accessory parts at the same time, the following information should be available to assess the risk of performing a non-contemporary retrofitting:

a) reference number, price and a detailed description of the required "adapters", if necessary;

b) availability or delivery time of the quantity required for the facility;

c) time schedule for the transition period using adapters;

d) risk assessment of and acceptability to the staff in the department concerned:

   1) to work with adapters during a transition period,

   2) to prevent the transfer of adapters into other areas not authorized by the COT;

e) planning of additional training activities.

Based on this information, a risk assessment should be carried out to determine, whether the increased risk during the "adapter transition period" is less or greater than the risk which would arise from the lack of an adapter. If required, an external expert opinion should be sought. In cases where the risks are unclear, the "adapter transition period" should be omitted and either a replacement carried out or the retrofitting/changeover process postponed until later.

This risk assessment and the additional measures resulting from it should be documented carefully.

4.5.4 Determination of personnel resources

4.5.4.1 Communication planning

The information about the new connectors should be issued by a combination of all available communication channels (personally, intranet, e-mail, and poster). Approximately four months should be allotted to prepare for the changeover in large health care facilities. Communication should first be

directed to those persons most directly affected by the changeover. The reason and justification for performing the changeover should be clearly conveyed. The following information should also be communicated to better explain what the changeover means for the staff involved:

- There is generally no need to learn new processes.
- Changes will mainly focus on assuring in advance that the right materials are available in the locations they are needed.
- Staff will need to be aware that impacted products will have new connectors that will not interconnect with Luer connectors or products using other connectors in the ISO 80369 series of standards

By means of sample sets, the employees should be given the chance to see, touch and try out the connectors. The COT should make such sets available in various areas in the health care facility, e.g. in the canteen, in the wards or units, and in the operating room.

Best practice example:

E-mails can be sent regularly (in three different levels) to all the persons concerned. The first level will inform about the fact that a change is due (these emails should be repeated several times, if required). The second level reiterates (or restates) information from the first e-mail, summarizes the implementation plan, and provides a rough implementation date. The third level e-mails should state the concrete changeover date and provide other important facts about the changeover process.

Information about the changeover process can also be displayed on the facility's intranet under the heading such as "News of the day". This heading, or one similar, should be shown on the initial screen and appear every time the intranet is opened.

Posters can be hung or displayed throughout the hospital and used as attachments to the e-mails.

Timelines should be handed out in all departments concerned documenting the current state of the planning and implementation processes. It should be clearly communicated when the new materials will arrive and be available for use.

You may also consider providing information on the menu pages for material order. If an old product is ordered, the software may be programmed to alert the user, e.g. using a pop-up window, that this product will soon expire and the reason for the expiration. The information provided should be concise.

4.5.4.2 Education/training

The instruction/education activities required for all users should:

- be held prior to the beginning of the changeover process;
- be executed close to the scheduled changeover process; and
- include practical handling of the new medical products.

It can be advisable to integrate these measures into further education, training or information events already in existence. Participation in these events should be documented.

Additional individual training should be held in the departments concerned when required.

Best practice examples:

In the UK, an e-learning tool was created to support the training. Names of the employees that had worked it through were registered and they were allowed to use the new products. New employees also had to work their way through the e-learning tool.

In cooperation with a manufacturer a video could be made which shows the new connectors in their application. This video could be distributed either on DVD or provided online. The chance to register who has seen the video should also be provided.

For the instruction/education measures of the nursing staff it should be ensured that:

a) qualified coaches/instructors are available;

b) a sufficient number of coaches/instructors are available at the scheduled training times;

c) **all** employees take part in these instruction/education measures;

d) absent staff members will be trained prior to handling retrofitted/converted products;

e) all instruction/education measures are completed with a performance check to ensure that the qualification for safe handling is given during and after the retrofitting/changeover process.

Information for the homecare sector:

It should be ensured that external nursing services, voluntary community services, and family members taking part in the changeover process are involved in these instruction/education measures in a suitable way.

It is recommended to have qualified coaches/instructors available during and subsequent to the changeover process in order to give guidance on the practical application of the retrofitted systems and the replaced medical products. A telephone hotline can also be a useful information tool. This longer-term support is necessary to reach persons who were absent on Day X, e.g. employees who have fallen ill, external nursing services, voluntary community services, and family members.

4.5.4.3 Changeover process

The changeover procurement and ordering should be subdivided in at least two areas:

1) Retrofitting process

- procurement of the conversion sets and ordering of the internal or external service for the retrofitting processes on site at the scheduled time; and/or
- ordering of the retrofitting service including delivery of the conversion sets on site at the scheduled time.

During this step it is essential to ensure that other persons responsible for the equipment status/the retrofitting of the individual medical products (other than the facility itself) are asked to carry out or have carried out the retrofitting at the same time (regular procurement operator, see clause 4.4.4.2).

2) Replacement process

- procurement of suitable single-use medical products/accessories needed for the retrofitted medical products;
- at a delivery time prior to the scheduled retrofitting date of the products concerned in this context.

NOTE 1 For reasonably foreseeable delivery delays a safety period should be allowed.

NOTE 2 If required, internal or external logistics services should be engaged for the replacement of the single-use medical products/accessories at a time immediately prior to the appointed retrofitting date of the medical products concerned.

It is essential to ensure during this step that the other persons responsible for the equipment status / changeover of single-use medical products (other than the facility itself) are asked to carry out or have carried out the changeover process at the same time (see regular procurement operator, see clause 4.4.4.2).

Procurement should ensure that only systems in conformity with the standard are tendered and ordered before and after the changeover process.

Best practice example (from the UK):

To avoid problems when handling the new medical products, they should be tested by users before ordering.

Suitable measures should be taken to avoid mix-ups during the changeover process, e.g.:

- Ensuring that the new and old variants are always separately stocked;
- removing incorrectly sorted products immediately after discovery and informing the employees of the department concerned;
- assigning new internal reference numbers, focussing on marking the new products in a special, uniform, and consistent manner (unless that has already been done by the manufacturer) and fixing this marking in all places where these products are mentioned (e.g. on the products themselves, in storage places, packaging, documents).

Products that are not clearly described should not be used and instead be removed to a storage area for quarantined stock.

Persons, departments, and institutions downstream of the flow of goods should be informed at an early stage; e.g. by the adaption of the letters of dismissal or patient transfer documents. This should include explicit information on which connector system, old or new, was used and, if required, suitable adapters should be kept available for a transition period and handed over to the facilities/patients in order to ensure compatibility.

4.5.5 Handling of remaining stock quantities

It should be specified how to handle remaining stock quantities of old products and the respective scheduling be adjusted accordingly.

a) Does the manufacturer possibly offer an exchange or do they take back old items?

Note 1: For enteral feeding products, a methodical plan including the use of transition connectors has been made available to work through old/legacy feeding tubes until inventory/supply is depleted. At which time, feeding tubes with new connectors should be placed.

Note 2: For neuraxial products, transition connectors or adapters are strongly discouraged to avoid potential misconnections. Facilities are advised to deplete old/legacy inventory and replenish products supplied with new connectors.

b) Are they to be used up?

c) Will new storage space be required or are remaining stocks allowed to run out first?

d) Are reserves to be kept available for emergencies?

e) “Unofficial” storage at workstations should also be taken into account.

4.5.6 Planning of the departments and application areas

It is recommended that the changeover process is organized step by step (e.g. first connectors from the respiratory department then from the nutrition department, etc.) in order to:

a) not create new connection problems within the health care facility;

b) reduce the complexity;

c) maintain clarity;

d) minimize errors; and

e) be able to learn from the errors identified for the next changeover process.

The changeover process can be carried out in different ways, e.g.:

- individual departments within the health care facility change over one after the other;
- the entire facility changes over to one new connector at a time.

Whenever procurable the conversion of a connector from one application area should only be started after the conversion of a connector from another application is completed.

Important information: If individual departments within a health care facility are to change over consecutively it should be ensured that these departments do not exchange materials in an unplanned manner.

4.5.7 Timetable and action plan for the conversion of a connector in one department

For every application area and each new connector type an individual timetable for the changeover process should be created. In that timetable the time frame in which the old products are used up and the new ones are introduced should be specified. A changeover should only be started after the

manufacturers have delivered all the medical products concerned, for all the departments of the health care facility affected by the changeover.

The time period of the changeover process should be as short as possible (e.g. one day) so that old and new systems are used in parallel only briefly or not at all. Correspondingly, the departments to change over in one step should be limited as a function of the resources available.

If, in exceptional cases, a temporary use of adapters is necessary, then the transitional periods should be stipulated in the timetable of the changeover process.

Important information: One possibility that must be taken into account is that, after a changeover process, patients might come in from another (internal or external) department bringing their “own” medical products with old connectors. Examples are PEG tubes which are normally in use for several years and can only be replaced by surgery.

The timetable should take into account that the users of the medical products are to be informed about the changeover process and properly instructed in a timely manner.

The timetable and action plan should contain the following details:

a) a list of all identified product types which are affected by the retrofitting:

   1) all serial numbers of this product type including their exact locations;

   2) owner/competent organisation or person responsible for the status/the retrofitting of these medical products;

   3) way of access to the product and, if necessary, access conditions;

   4) if required, specific characteristics of the site, operational environment or application conditions;

   5) necessity of a replacement product for the duration of the planned retrofitting;

   6) necessity of conversion sets independent of the ordering of the retrofitting service, or the ordering of the retrofitting service including procurement of the required conversion sets;

   7) provider of the retrofitting service;

   8) time required for retrofitting the individual product, possibly including necessary waiting periods until further use;

   9) list of the single-use medical products which have to be immediately converted during the context of the retrofitting concerned;

   10) required lead times for the procurement and/or ordering of the retrofitting service.

b) a list of the product types which need to be modified simultaneously including the cause/rationale for this necessity, e.g.:

1) the single-use medical products/accessories need to be replaced in the context of the product retrofitting;

2) access to these products is possible/appropriate only when done simultaneously;

3) the retrofitting service is provided by the same company.

c) a list of the products for which retrofitting and conversion of the required accessories cannot be done simultaneously, i.e. which require the use of adapters, with the following additional information:

1) safety measures;

2) training arrangements for the staff concerned;

3) markings;

4) reasonably foreseeable duration of necessary transition periods;

5) number of necessary adapters;

6) strategy, timetable and persons responsible for the disposal of the adapters.

d) details on the lead times to be expected for the procurement of the single-use medical products/accessories.

e) details on how the other owners/persons/organisations responsible for the status/retrofitting of these medical products from outside the health care facility can be:

1) informed about the necessity of retrofitting;

2) involved in the retrofitting planning of the facility, i.e. in what manner can retrofitting of the medical products be “synchronized” with the retrofitting of the other products in the facility.

f) size of the departments and/or details on which departments can be processed “simultaneously” in a single retrofitting/changeover process;

g) product groups/product ranges which can, or should reasonably, e.g. for cost minimization reasons, be processed “simultaneously” in a single retrofitting/changeover process;

h) possibility of executing retrofitting/changeover measures during regular operations including applicable conditions;

i) potential time windows for the retrofitting/changeover measures;

j) staff resources and time windows required for the necessary training arrangements.

4.5.8 Cost planning

In the context of changeover process a cost planning should be prepared. This should help to calculate the costs for the medical products needing new connectors, for the conversion sets, for the overtime to be done by the facility management, for training and instructions, etc.

For clarity reasons and as new connectors are introduced, an individual cost plan should be prepared for each connector type.

Note: Those evaluating the transition and considering the cost of changeover as well as the potential incremental cost of each product should be reminded that the total costs should be compared to the potential cost of a misconnection. It is hard to calculate but facilities should keep in mind why the transition is in place.

4.6 Approval of Phase II (Logistics and Procurement)

After preparation of the timetables and cost plans these should, together with the other documents (e.g. inventory-taking) be presented to the executive board. Approval of procurement is given by the management of the health care facility and should be documented in writing.

4.7 Logistics

4.7.1 Procurement of samples

To be able to assess the future constellations in advance, they should be tested before starting the next phase.

4.7.2 Testing of the replacement parts

Prior to putting the medical products to be replaced into service they should, among other things, be subjected to a test for the following:

a) usability in connection with the other (possibly new) medical products, conversion sets, etc.:

   1) manageability;

   2) identifiability;

   3) differentiability.

b) hygienic aspects;

c) training needs.

The results need to be documented and presented to the COT.

4.7.3 Testing of the conversion sets

Prior to the assembly of the conversion sets, they should be subjected to tests for the following:

a) assembly:

   1) retrofitting, assembly, and test instruction;

   2) prerequisites for assembly, preparation;

   3) time necessary;

   4) necessary tools, excipients, measuring equipment;

   5) documentation;

6) marking;

7) tests, approval.

b) usability in connection with other (possibly new) medical products:

1) manageability;

2) identifiability;

3) differentiability.

c) hygienic aspects.

d) training needs.

The results should be documented and presented to the COT.

4.7.4 Check for completeness

Approval should be given only after completeness of all accompanying materials is confirmed according to the lists previously prepared (see 4.5) for all applications and configurations.

4.7.5 Creation of additional storage space (temporary)

Storage space for the medical products with Luer connectors is required to be available to its full extent until the changeover process is completed. Extra storage space for the replacement products with the new connectors needs to be created.

Important points for the extra storage space that need to be considered should include the following:

a) quick accessibility;

b) usability;

c) identifiability;

d) differentiability;

e) unambiguous marking;

f) securing, locking capability.

4.8 Procurement

The main problem for the procurement of a health care facility is that a changeover process can only be carried out when the medical products and conversion sets are available at the same time. Manufacturers should list and manufacture the new products; but it is reasonably foreseen that they will control their manufacturing as a function of the demand from the market. Conversion sets will most likely not be general stock articles but be manufactured on request only. This can result in unusual delivery times.

The communication required between health care facilities and manufacturers in this context is not altogether common and will have to be practiced on both sides for the upcoming changeover processes.

In some cases, if only a few parts are involved, the procurement for a changeover process may be simple. However, if many medical products are affected at the same time, then the need for communication will be considerable and require some time. In addition to that, the communication can be hindered by manufacturers and health care facilities using different terminologies.

Points to be taken into account:

a) new reference numbers for:

   1) replacement parts;

   2) conversion sets;

b) price lists;

c) delivery times;

d) second sources suppliers;

e) differentiable packaging;

f) unknown storage volume.

In many of the larger health care facilities the procurement processes are carried out in the context of e-commerce. This needs to be taken into account.

4.9 Planning review

The person charged by the legal operator of the facility with the coordination and performance of the changeover process should introduce the plans prepared to all the persons concerned/involved and put them forward for discussion. The circle of persons concerned/involved should include the following departments/persons:

a) nursing services;

b) clinicians involved;

c) staff from the functional departments;

d) internal or external medical engineering, depending on the circumstances;

e) internal or external purchasing and procurement agencies responsible for the facility;

f) internal or external goods distribution logistics;

g) social services working in the facility;

h) external enterprises involved in the changeover process and retrofitting.

After a first presentation of the overall draft plan and the initial discussion, the parties involved should be given sufficient time to discuss the draft plan internally and, if required, to comment on special aspects or on points not yet included in the draft.

After that, the planning should be improved and amended in line with the comments received. In individual cases, this process may require several passes to reach consensus with the persons involved.

In large or complex facilities it can be advantageous to have the changeover implemented in a phased manner for clinics, units/wards, functional departments or divisions. This also has the advantage that the temporary required additional storage spaces in cabinets, etc. can be reused

4.10 Preparation of checklists

To ensure that all planned details are carried out during the changeover process, checklists should be created. Examples of such lists can be found e.g. on the websites of the Global Enteral Product Supplier Association [5].

4.11 Approval of Phase III (Changeover process)

Upon consensus being reached by the persons concerned/involved, the planning and the checklists should be stipulated and approved by the management of the health care facility.

The approved plan should be published on the facility's intranet and be accessible to everyone. The published timetable should be updated throughout the entire process. Postponements should be communicated as quickly as possible.

Furthermore, a prominent note should be shown on the initial intranet page to make the reader aware of the forthcoming changeover process and there should be a link to an information page giving the details on the changeover process (the Why, How & When). In smaller facilities (e.g. care facilities) which do not have an intranet of their own, awareness of the changeover process and the respective timetable should be raised by means of prominent notices on noticeboards etc.

4.12 Changeover process

4.12.1 Making new replacement medical products available

All new replacement medical products should be sorted into the additionally created store shelves. The conversion sets should preferably be stored in the medical engineering department. Precautions should be taken to ensure that the replacement parts and conversion sets are not touched up to day X.

4.12.2 Check for completeness

The completeness of the replacement parts and conversion sets should be checked using the checklists.

4.12.3 Instruction/training

It should be conveyed how to designate and distinguish the old and the new medical products in verbal and written communication.

In accordance with the planning, the users should be instructed in the practical handling of the new medical products. In addition they should be shown the new additional stock locations.

4.12.4 Day X

4.12.4.1 General

The retrofitting of the medical products as well as the replacement of the medical products should be executed in as short as possible a time (for example in one day).

If possible, the changeover should be carried out in a “non-operational phase”. If this is impractical due to operational or organizational reasons, then a changeover can also be carried out in the regular mode; however, this creates a higher risk.

4.12.4.2 Storage spaces

New and old storage spaces (see 4.7.5), shall be clearly marked so that it is clear for all people involved that products are different and should not be mixed.

4.12.4.3 Supervision

The COT leader is responsible for supervising the retrofitting and replacement processes, verifying successful completion, and approving the converted department.

The approval process should be carried out by at least two experts / specially trained persons according to the “dual observer principle”/the “four-eye principle”

For support with the necessary checks the COT leader can appoint qualified internal and external experts for the examination of subdivisions or entire departments.

The converted department can return to normal operation only after the changeover process has been completed and approved.

4.12.4.4 Individual approvals

Approval of a retrofitting can only be given by the responsible person, e.g. by medical engineering staff.

If the changeover process is carried out during regular operation, then the checks and approval should be performed immediately after or, in individual cases, in parallel with the changeover process. At the same time, the successful retrofitting and the availability of the new products should be ensured for all functional departments.

4.12.4.5 Documentation

The changeover process should be documented giving the dates, times, and names for:

a) training of the employees (by which measures);

b) all individual approvals;

c) the general approval of departments / divisions;

d) disposal of the old medical products with Luer connectors.

4.12.4.6 Coaching

It is recommended that qualified coaches/instructors will be available during and subsequent to the changeover process in order to give guidance on the practical application of the retrofitted systems and the replaced medical products. A telephone hotline can also be a useful arrangement. This longer-term support is necessary to reach persons who were absent on Day X, e.g. employees who have fallen ill, external nursing services, voluntary community services, and family members.

4.12.4.7 Communication of hazards identified

All findings of hazards related to the changeover processes and the application of the new medical products should immediately be reported to the COT leader.

For hazards related to the changeover processes it is advisable to establish a separate reporting channel or a new category in an existing internal adverse event reporting system, e.g. Critical Incident Reporting System (CIRS). As e.g. with the CIRS reports, it should be possible for these reports to be handed in anonymously and the reporters should be assured, in writing, that they will not be sanctioned in any way because of their report. Such reports should also be given irrespective of the fact that an incident was a “near miss” only. For emergency cases the COT should be available by telephone and e-mail 24 h a day. It is advisable to set up a special e-mail address for the changeover process.

The COT should review the reports continually, identify and examine the causes, assess the identified risks and, if necessary, initiate appropriate risk control measures.

For the reporting of incidents to the relevant national authorities, regional or national legal or regulatory requirements need to be taken into account.

4.13 Exchange of experiences

After a department has completed the changeover process, the COT should hold a debriefing with the staff involved in order to address and document problems or weaknesses detected during the changeover process. The identified problems should be used to improve the changeover process in other departments or areas of the health care facility.

Facilities that have successfully adopted new ISO 80369 standard connectors should also consider sharing their experience and lessons learned with other facilities throughout the country, region and globe. One possible outlet to share the facilities experience would be at secretariat of Joint working Group 4 ISO/TC 210 and IEC/SC 62D: Small bore connectors, Email: standards@aami.org.

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ISO 80369-5, Small-bore connectors for liquids and gases in healthcare applications Part 5: Connectors for limb cuff inflation applications;

ISO 80369-6, Small-bore connectors for liquids and gases in healthcare applications Part 6: Connectors for neuraxial applications;

ISO 80369-7, Small-bore connectors for liquids and gases in healthcare applications Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications