LIST OF ESSENTIAL MEDICAL DEVICES IN THE EVENT OF A MAJOR HEALTH CRISIS: INFLUENZA PANDEMIC SCENARIO

Report

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LIST OF ABBREVIATIONS

Afssaps	**A**gence **f**rançaise de **s**écurité **s**anitaire des **p**roduits de **s**anté (French health safety products agency)
LTI	**L**ong-**T**erm **I**llness
AMELI	**A**ssurance **M**aladie **E**n **LI**gne (On-line Health Insurance Fund)
APPAMED	Medical Treatment Device Industry Association
CLADIMED	Medical Device Classification development association
CNDM	**C**ommission **N**ationale des **D**ispositifs **M**édicaux (National Medical Device Commission)
CNDMDIV	**C**ommission **N**ationale des **D**ispositifs **M**édicaux de **D**iagnostic **I**n-**V**itro (National In-Vitro Diagnosis device Commission)
DILGA	Inter-ministerial Avian Influenza Control Delegate
MD	**M**edical **D**evice
IVDMD	**I**n **V**itro **Diagnosis** Medical **D**evice
GMDN	**G**lobal **M**edical **D**evice **N**omenclature
InVS	**In**stitut de **V**eille **S**anitaire (Health Monitoring Institute)
NABM	French nomenclature of accredited medical pathology procedures
WHO	**W**orld **H**ealth **O**rganization
SFRL	**S**yndicat des **F**abricants de **R**éactifs des **L**aboratoires (Laboratory Reagent Manufacturers' Association)
SNITEM	**S**yndicat **N**ational de l'**I**ndustrie des **T**echnologies **M**édicales (National Medical Technology Industry Association)
TNB	**T**able **N**ationale de **B**iologie (National Biology Chart)

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SUMMARY

In 2006, the French General Health Directorate assigned Afssaps with the task of drawing up a list of essential medicinal products in the event of an avian influenza pandemic. This request was made within the scope of the Governmental Plan particularly intended to ensure a sufficient supply of healthcare products in the event of a major health crisis. Afssaps made this list available in early 2008. Following on from this project, the Agency has initiated a project to try to draw up the list of medical devices deemed to be essential in the event of a major health crisis.

The device sector (medical devices – MD – and in vitro diagnostic medical devices – IVDMD) is characterised by a wide diversity of products, such as consumables, implants, equipment and IVDMDs. The French market is estimated to amount to the order of several hundreds of thousands of products.

In view of the variety and the number of devices on the market, the approach adopted by Afssaps consisted of:
1) selecting the diseases requiring urgent care and chronic diseases requiring continuous treatment (i.e. almost 250 diseases selected, broken down into 19 medical or medico-technical specialties);
2) drawing up an inventory of standard devices for the treatment of these diseases;
3) selecting the essential devices in this inventory, with the assistance of experts in each specialty.

An essential device has been defined as a device for which an interruption in supply may have an irreversible clinical impact, either directly due to its specific action on the patient or indirectly as it is a tool required for a vital procedure in patient care.

To date, this project has resulted in three different lists being drawn up:

- the list of essential devices by medical or medico-technical procedure and by specialty, which is the most illustrative of the approach adopted,
- the list of essential devices in alphabetical order linked with the medical and medico-technical specialties in which they are used, enabling healthcare establishments to select devices according to their specialties;
- and finally the list of essential devices in alphabetical order linked with the various classification codes, providing the information required for their acquisition (please note that this list is not standalone, but is a supplement to the two other lists).

In total, 524 devices have been identified.
It is recommended to focus more on consumables and implants than equipment with a view to medical device procurement in the event of a crisis, since the equipment is already in place in healthcare establishments.

If an evaluation of the stock available or to be provided is envisaged, it should account for the specificity of the device production and distribution circuit (manufacture outside France, central purchasing body). Finally, the distribution channels for device also involves non-hospital structures which may be prioritised in the event of a major health crisis (home care).

BACKGROUND

I. Context

Influenza H5N1 and A/H1N1 have crossed the species barrier and contaminated humans, the victims essentially being children and young adults.

The kinetics and impact of a pandemic have been modelled by Institut national de veille sanitaire (InVS) on the basis of previous pandemics. Failing healthcare intervention, the impact in France could amount to several million infected subjects and tens of thousands of deaths by the end of the pandemic. Furthermore, a large number of subjects would be liable to develop complications requiring hospitalisation [(1)].

A pandemic conventionally spreads in successive 8 to 12-week waves, at intervals consisting of several months or even longer periods. However, due to the globalisation of exchanges, a scenario whereby the pandemic would spread without successive waves but with peaks associated with an ongoing background would be possible.

Besides its major healthcare impact, in the long term, a pandemic could give rise to:

- disturbances in the healthcare system due to the rapid saturation of healthcare services;
- social and economic disorganisation with, in particular, partial paralysis of essential services required for society and the State to function.

These societal and economic risks could particularly be caused by a shortage of essential products due to national and/or international disorganisation.

The government has drawn up a pandemic prevention and control plan, which has been updated several times since the first version in October 2004. An Inter-ministerial avian influenza control delegate (DILGA) was appointed in August 2005 to deal with response or intervention strategy organisation issues.

In early 2006, the DILGA assigned Afssaps with the task of drawing up a list of essential medicinal products in the event of an avian influenza pandemic. This request was particularly intended to ensure a sufficient supply of healthcare products in the event of a major health crisis. A report was returned in early 2008 containing the list of essential medicinal products in the event of a major health crisis.

II. Purpose of project

Afssaps was subsequently requested to draw up a list of medical devices (MD and IVD-MD) deemed to be essential in the event of an avian influenza pandemic. The purpose of this list is to anticipate healthcare requirements in the event of a crisis.

III. Data available

1. Rationale

To date, no study of this type has been identified, probably due to the specific nature of the device sector. Indeed, this sector is characterised by a wide diversity of products, such as consumables, implants, equipment and IVDMDs, ranging from dressings to complex medical imaging devices, and including all implantable items. The French market is estimated to amount to the order of several hundreds of thousands of products.

This sector is not suitable for a systematic approach consisting of conducting an exhaustive review of existing devices, as was the case for medicinal products, in view of their diversity, number and also due to the lack of an available exhaustive list of products on the market in France.

2. World Health Organization (WHO)

A template list of essential medical devices has been envisaged [2] [3] by WHO, but this project has not yet been finalised. However, WHO has drawn up lists of medical items for specific situations, but these lists tend to focus on medical issues associated with war and items intended for developing countries [4].

3. White, red or Orsec plans

The white, red and Orsec plans were a potentially interesting source of information for this study. The white plan, in particular, is a response of the healthcare system to a crisis. It is defined for each healthcare establishment, enabling planned organisation to deal with exceptional circumstances giving rise to high victim levels. Nevertheless, this plan tends to respond to hospital facility organisational issues in an emergency situation (alert, reception of victims in emergency department, personnel management, etc.) than long-term medical device management.
The Orsec plan is part of the general civil defence and safety planning system. It organises the mobilisation, implementation and coordination or actions by all public and private parties involved in the general protection of the population.
The red plan is activated in the event of a catastrophic accident of limited scope, causing or liable to cause large numbers of victims, such as a fire, criminal acts or natural disasters.

4. Other European bodies

To our knowledge, no other European body has initiated this type of project.

5. National "Influenza pandemic" plan

The national "Influenza pandemic" plan [1] defines at-risk categories requiring increased medical attention to establish present or future signs of severity:

At-risk children:
Children suffering from chronic respiratory disease:
- Asthma

- Cystic fibrosis, bronchial ciliary disease
- Bronchopulmonary dysplasia in the context of premature birth
- Recurrent bronchitis
- Severe after-effects of virosis (adenovirus, measles).

Children presenting associated co-morbidity:
- Congenital heart disease
- Drepanocytosis
- Immunocompromised state
- Kidney failure and/or nephrotic syndrome
- Neuromuscular disease.

At-risk adults:
Subjects over 65 years of age
Institutionalised patients
Underlying bronchopulmonary or cerebrovascular disease
Heart failure
Underlying neoplasia
Liver disease
Chronic kidney failure
Diabetes
Immunocompromised state (including transplant patients)
Pregnancy (particularly in the third trimester)
Cystic fibrosis and haemoglobin diseases.

6. Armed forces medical service

The Armed forces medical services have drawn up lists of standard medical items for a front-line backup station and surgical unit in the event of a crisis. They are updated over time.

7. Medical devices for the treatment of patients suffering from avian influenza in the event of a pandemic

The list of essential medical devices to treat influenza complications has been drawn up. It has been restricted to disposable or single-patient intensive care consumables and includes three types of categories: respiratory system, infusion, digestive system. It has been validated by the working group for anaesthesia / intensive care medical devices. This list can be consulted in appendix 1.

The medical devices used to treat avian influenza or its complications do not fall within the scope of this report.

METHODOLOGY

In this study, the approach was based not on the products but on the diseases to be prioritised in the event of a health crisis.

Therefore, the methodology consisted of:
- selecting the diseases requiring urgent care and chronic diseases requiring continuous treatment;
- drawing up an inventory of standard devices for the treatment of these diseases;
- selecting the "essential" devices in this inventory.

MD and IVDMD manufacturer associations were consulted from the methodology definition phase (SNITEM, SFRL, APPAMED).

I. Selection of diseases

Two types of diseases were identified: "emergency" diseases and "chronic" diseases.

1. "Emergency" diseases

It was agreed to refer to the emergency diseases identified in the book "Protocoles 2007 – Urgences – Plans et schémas thérapeutiques" written under Mr. Pierre Carli [(5)]. This book concerns 133 diseases covering 19 medical fields (see list of emergency diseases in appendix 2).

2. "Chronic" diseases

It was agreed to refer to those requiring continuous treatment. Indeed, they represent risk factors for complications and death; for this reason, their care cannot be assigned a lower priority. The diseases deemed to be LTI (Long-Term Illnesses) according to the French National Authority for Health (HAS) [(6)] were selected (see list of chronic diseases in appendix 3).

3. Other diseases included

Other diseases were subsequently added, following discussions with the experts appointed to Afssaps consulted for this project.

In total, almost 250 diseases were included. It should be noted that the aim was not to structure the severity of the diseases to be included in the event of a crisis, thus excluding patients suffering from less common diseases, but to identify a wide range of diseases to select a common base of devices to ensure the continuity of care in a crisis context.

II. Inventory of standard medical devices for the treatment of diseases

1. Bibliographic search

The inventory of medical devices was prepared on the basis of a bibliographic search for each disease. This search was essentially based on the publication by Mr Pierre Carli [(5)], on the Rouen hospital library website [(7)], on medical association websites, on the HAS site [(6)] and on various Internet publications.

Each disease was included, from diagnosis to treatment, including long-term treatment if required.

2. Summary of data obtained

2.1. Device terminology and classification

For the purposes of the terminology and harmonisation of the data obtained, the devices were organised on the basis of a classification:

MDs:

There is no official therapeutic classification of MDs. The international classification, GMDN (Global Medical Device Nomenclature) [(8)], does not include a therapeutic structure as it consists of a nomenclature and not a classification. Furthermore, it has not yet been translated into French, which poses comprehension and interpretation problems. This classification is known to most device manufacturers, but is not generally known to healthcare professionals.

The other structured therapeutic classification available in France is that drawn up by CLADIMED (medical device classification development association) [(9)], drawn up on the basis of the ATC (Anatomical, Therapeutic and Clinical classification) medicinal product model, which is known to and used by MD manufacturers and a large number of healthcare establishments in France. This classification is updated annually by hospital research working groups.

The study data is summarised on the basis of this classification to apply two classification levels: MDs considered to be general (infusion items, intubation items, etc.) and a more detailed level of these general MDs (catheters, cocks, manifolds, etc.).
Correspondence with the CLADIMED and GMDN classifications is specified whenever possible.

IVDMDs:

As for MDs, there is no therapeutic classification of IVDMDs. The approach adopted consisted of selecting the laboratory medicine procedures associated with the diseases. These laboratory medicine procedures are those taken from the National Biology Chart published by AMELI (On-line Health Insurance Fund) [(10)].

Example: "Troponin (assay) (blood)": NABM code = 7335.

Each IVDMD is thus defined with respect to the procedure defined in the nomenclature, in terms of reagent or assay kit.

Example: troponin kit (assay) (blood).

However, some procedures are not included in the TNB classification, as they are not in the nomenclature (e.g.: PCR, rapid test, etc.). They were selected if deemed essential.

2.2. Device categorisation

Once identified and classified, the devices (MD and IVDMD) identified for each disease were categorised by medical and medico-technical specialty (e.g. cardiology devices).

Nineteen specialties were defined (see Table 1).

Table 1: List of medical and medico-technical specialties

Cancerology
Cardiology
Diabetology / Endocrinology
Gastroenterology / Proctology
Gynaecology / Obstetrics
Infectious disease
Neurology / Neurosurgery
Ophthalmology
ENT
Orthopaedics / Traumatology
Paediatric
Pneumology
Psychiatry
Radiology / Medical imaging
Intensive care
Rheumatology
Sterilisation
Urology / Nephrology
Laboratory medicine

2.3. Data management

2.3.1. Data description

The data studied comprise:

- approximately 250 diseases broken down into 19 medical and medico-technical specialties;
- two classification levels for MDs: one level considered to be general (72 different categories, e.g. infusion item, intubation item, etc.) and a more detailed level of these MDs (e.g. central catheter, manifold, cock).

These devices may be used for diagnostics, treatment of diseases or prevention.

Whenever possible, the devices identified were linked with various nomenclatures available (CLADIMED, GMDN, etc.) and defined in terms of implants, equipment, consumables or IVDMDs.

2.3.2. Database creation

All the data was entered in a dedicated Access application, using an input form and exported to Excel file format. The list of devices can be handled using the dynamic cross-referenced table function which gives a large number of list presentation options (by device type, by specialty, by procedure, etc.).

II. Selection of essential medical devices

1. The term "essential"

An essential medical device has been defined as a device for which an interruption in supply may have an irreversible clinical impact, either directly due to its specific action on the patient or indirectly as it is a tool required for a vital procedure in patient care.

The term "clinical impact" refers to the clinical consequence for a patient associated with the use of a device, accounting for the role of the device in the treatment strategy.
The clinical impact may be "vital" and/or "functional" for a patient. For example, in the field of limb traumatology, the vital clinical impact issue may be resolved by amputation, which only requires a bistoury, forceps and a saw. On the other hand, the functional impact is significant in this case.

The term "irreversible" in this context refers to a death, permanent injury, a reduction in life expectancy, an irreversible deterioration in health, permanent weakening, permanent vital function and/or vital structure damage.

2. Selection of essential devices

From the list of standard devices previously identified for the care of diseases, a selection of essential devices was made by experts appointed to Afssaps, for the majority of medical and medico-technical specialties. This selection was made via questionnaires sent to experts. A sample questionnaire, relating to cardiology, is given in appendix 4.
The experts had the option of adding devices not cited in questionnaires.

RESULTS

I. List of essential devices by medical or medico-technical procedure and by specialty

This list (appendix 5) is the most illustrative of the approach adopted. It is particularly aimed at healthcare professionals. Establishments can thus adapt the list according to the procedures carried out. For example, all digestive endoscopy MDs are in the same category.

II. List of essential devices in alphabetical order linked with the medical and medico-technical specialties in which they are used

This list is given in appendix 6. This format enables healthcare establishments to select devices according to their specialties, since not all specialties are applicable in all establishments.

As a reminder, the 19 specialties were listed in table 1. The disease of devices by specialty is given in Table 2.

Table 2: Disease of essential devices according to medical or medico-technical specialty

Medical or medico-technical specialty	Number of devices
Cancerology	152
Cardiology	156
Diabetology / Endocrinology	94
Gastroenterology / Proctology	155
Gynaecology / Obstetrics	131
Infectious disease	91
Neurology / Neurosurgery	157
Ophthalmology	110
ENT	143
Orthopaedics / Traumatology	170
Paediatric	284
Pneumology	112
Psychiatry	61
Radiology / Medical imaging	132
Polyvalent intensive care	118
Rheumatology	68
Sterilisation	16
Urology / Nephrology	161
Laboratory medicine	114

The number of essential devices by specialty is very variable (ranging from 16 to 284). This is essentially due to variety and technical nature of the procedures performed in the specialty. For example, specialties involving surgical procedures, endoscopic or intensive care procedures include a greater number of devices.

Furthermore, a large number of devices are common to several specialties (e.g. infusion, intubation items, etc.).

III. List of essential devices in alphabetical order linked with the various classification codes

This list, given in appendix 7, provides the information required for device acquisition. It is particularly aimed at healthcare professionals and manufacturers within the scope of device purchasing/supplying in healthcare establishments. However, this is not a standalone list, but a supplement to the two other lists.

In total, the list includes 524 devices. The distribution according to device type is given in Table 3 and the distribution according to the purpose of the device in Table 4.

Table 3: Distribution of essential devices according to device type

Device type	Number of devices
Consumable	225
Consumable / IVDMD	3
Consumable / Equipment	8
IVDMD	122
Equipment	102
Implant	64
Total	524

Table 4: Distribution of essential devices according to purpose of device

Purpose of device	Number of devices
Diagnostics	188
Diagnostics / Treatment	25
Prevention	28
Treatment	283
Total	524

DISCUSSION

Afssaps was requested to draw up a list of essential medical devices (MD and IVDMD) in the event of an influenza pandemic. The medical devices used to treat avian influenza and its complications do not fall within the scope of this request.

Selecting the diseases requiring guaranteed care in the event of a major health crisis was considered to be the best way to draw up this list. These diseases were selected in conjunction with the experts consulted.

However, common devices may be used for the care of different diseases, such as for example infusion and injection items used in practically all medical specialties.

The aim was not to structure the severity of the diseases to be covered in the event of a crisis, thus excluding patients suffering from rare diseases, but to identify a wide range of almost 250 diseases to identify a common base of devices to ensure the continuity of care in a crisis context. Within the same medical specialty, common devices are frequently used to treat various diseases selected. Furthermore, if a disease were to be added or removed, the list of devices for the specialty would frequently remain unchanged. For this reason, list of essential devices has been presented by specialty and not by disease.

The medical device sector is characterised by a wide diversity of products, such as consumables, implants, equipment and IVDMDs, ranging from dressings to complex medical imaging devices, and including all implantable items. The French market is estimated to amount to the order of several hundreds of thousands of products.

Therefore, this sector is not suitable for a systematic approach consisting of conducting an exhaustive review of existing devices, as was the case for medicinal products, in view of their diversity, number and also due to the lack of an available exhaustive list of products on the market in France. For this reason, our methodology consisted of selecting diseases and, in a second phase, identifying the devices associated with their care to make up for the lack of exhaustive knowledge of the device market.

The sector is recent in terms of regulation and data harmonisation and subject to ongoing development. Afssaps does issue marketing authorisations for devices, as the CE mark is under the responsibility of the manufacturer (cf. Council Directive 93/42/EEC of 14 June 1993, on medical devices [(11)], European Parliament and Council Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices [(12)] and Council Directive 90/385/EEC of 20 June 1990, on the approximation of the Member States relating to active implantable medical devices [(13)]).

The concept of "essential" devices was debated with the experts consulted. Initially, a distinction was envisaged between "essential" versus "necessary" devices on the basis of clinical impact criteria, the duration of stock available or severity criteria (mortality, morbidity). Note that, in list of essential medicinal products, the medicinal products were broken down into "essential" and "necessary" medicinal products according to the following definitions:

"Essential" medicinal product: Medicinal product for which an interruption in supply *lasting for not more than 15 days** would result in a short-term or medium-term public health risk in the general population.

"Necessary" medicinal product: Medicinal product for which an interruption in supply lasting from 15 days to 3 months would result in a *medium-term* public health risk in the general population.

**: This 15-day period was determined according to a timeframe on the basis of an assumption based on the average duration of stock available in France.*

This approach was not adopted for medical devices as we are not in a position to estimate an average duration of the stock available in France, at healthcare establishment, distributor or manufacturer level.

In this project, we have not made a distinction between "essential" versus "necessary" devices according to a severity criterion as it was not deemed to be clinically significant.
The following definition was adopted for MDs and IVDMDs: "a device for which an interruption in supply may have an irreversible clinical impact, either directly due to its specific action on the patient or indirectly as it is a tool required for a vital procedure in patient care".

MDs or IVDMDs not cited in this list of essential devices may nevertheless prove to be "important" for public health, in a "normal", i.e. non-health crisis, context.
Furthermore, the presence of a device in the list does not prejudge its qualification as a medical device or in vitro diagnostic medical device. For example, shoe covers are cited in the list although this product is not considered as a medical device by Afssaps. However, other European authorities competent in medical devices consider it as a medical device. For this reason, shoe covers with the CE mark as per the directive 93/42/EEC [(11)] and other non-marked shoe covers co-exist on the European market.
Finally, a large number of products which do not have medical device or in vitro diagnostic medical device status are essential for the care of diseases, particularly in health crisis periods. They have not been included in this list Examples include patient identification wristbands, sample or product traceability labels, and also biocidal products and washing machines used before sterilisation.

Each of the main types of devices identified in the list may consist of dozens of sales references, but these references should be easily identifiable via the nomenclature applied and the associated CLADIMED and GMDN codes. Furthermore, the devices may be grouped into marketed kits or cases.

The range of devices used in healthcare establishments varies according to the size of the hospital facility, its resources and the medical and medico-technical specialties practiced (cancerology, severely burned patients, paediatrics, sterilisation, etc.). It should also be noted that the items may be dependent on the specific operating techniques of each practitioner. For example, it was not deemed to be appropriate to specify the items used for angioplasty, restricting the reference to "angioplasty item". Nevertheless, any medical team performing this procedure would be perfectly aware of the items required for these procedures, without the need for exhaustive details.

It is relatively difficult to compare this study with other studies from the literature as, to our knowledge, this type of study has never been conducted for this specific purpose.
The list was submitted to two national commissions responsible for these products, i.e. the French National Medical Device Commission and the French National In-Vitro Diagnostic Medical Device Commission. In parallel, some manufacturer associations (SFRL, SNITEM, APPAMED) were informed of the procedure once the methodology was in place. They were recipients of the list and helped finalise it.

The list of essential medicinal products in the event of a major health crisis previously drawn up includes 20 to 25% of existing active substances. The list of essential devices would appear to have been more selective in proportion.

While drawing up this list represents the first phase of the governmental plan intended to ensure a sufficient supply of healthcare products in the event of a major health crisis and set up stocks of identified devices on a national level, it is important to note the following points:

. It is recommended to focus more on consumables and implants than equipment. Indeed, the equipment is in place and in use in healthcare establishments in the event of a pandemic. Equipment maintenance remains to be organised and provided particularly in the event of global blockages. On the other hand, a shortage of implants or consumables could have repercussions on the organisation of care.

. It is difficult for Afssaps to identify the manufacturers of the devices selected, as there is no database linking devices with manufacturers to date. The European database EUDAMED is currently being developed and will eventually contain registration data for all manufacturers and devices on the European market.

. The majority of devices are manufactured outside France, with distributors acting as an interface between manufacturers and users in France. Furthermore, a large number of raw materials required for device manufacture are imported (latex, cotton, etc.), which could impede or interrupt production in the event of the closure of borders, following a national decision. However, a large number of manufacturers would appear to have developed organisations in the event of an influenza pandemic (staff, production management, etc.).

. A large proportion of device stock and orders are handled by central purchasing bodies or central pharmacies, following public contracts signed between the buyer and manufacturers. The organisations contacted highlighted that the stock available varies according to the devices and that a study would be required to provide an estimate of the period of time covered by the stock available in France.
For some devices, there are a large number of products with the same characteristics and performances, whereas, for others, few or no alternatives are available. In this way, any failure to procure a device would be liable to disturb healthcare establishments in terms of patient care until the device becomes available again.

Finally, the distribution channels of device also involves non-hospital structures such as dispensaries, private physicians or home care structures, with these options being prioritised in the event of a crisis, to enable at-risk patients to have access to treatment without being hospitalised and restrict travel and hospital congestion.

Following the drafting of this list of essential devices, it is now necessary to define the terms of its distribution. The target recipients of this list are essentially healthcare establishments located on national territory and MD and IVD-MD manufacturers and distributors. These terms will need to be discussed, particularly to define the role and support to be provided by Afssaps.

Furthermore, when setting up the work method, Afssaps was required to contact the World Health Organization (WHO) who have shown considerable interest in this project. Therefore, communicating the list to WHO and possibly to other competent European and international authorities could be envisaged and an English version should thus be envisaged.

CONCLUSION AND PROSPECTS

This study identified the essential devices in the event of a major health crisis, in response to the request made by the DILGA. Conducted by Afssaps in conjunction with experts, it accounts for both the specific nature of the device market and the degree of urgency associated with a crisis situation.

This project should also be of interest to other health organisations such as WHO or the Armed forces medical service regularly faced with this type of problem. Moreover, it is not restricted to the influenza pandemic scenario but could be of use in other major health crisis circumstances.

If the set-up of a device stock is envisaged on the basis of this list, there are several possible scenarios:

The list of MDs and IVDMDs by medical and medico-technical specialty could be sent to the directors of healthcare facilities or medical item management organisations (internal pharmacies, economic departments, biomedical departments), requesting them to estimate the period of time covered by their stock and to provide for a sufficient reserve for a predetermined period. According to their normal consumption, they could provide for the quantities to be ordered.

It may be proposed to identify manufacturers offering alternative products and organise a backup supply source.

On the basis of these data, manufacturer associations (SNITEM, SFRL, APPAMED, etc.) could conduct a concerted study to identify the items manufactured inside or outside France and make production estimates in the event of a long-term crisis such as an influenza pandemic.

It could be suggested to create a national database containing essential devices and their manufacturers, on the basis of the data previously retrieved. This base would make it possible to be responsive in the event of an influenza pandemic (or another major health crisis scenario) causing a targeted shortage of devices.

These lists are intended to reflect the state of the art in medicine and are thus subject to change with techniques and knowledge.

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http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0079:FR:HTML

(13): Council Directive 90/385/EEC of 20 June 1990, on the approximation of the Member States relating to active implantable medical devices
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0385:FR:HTML

APPENDIX 1: LIST OF ESSENTIAL MDS TO PREVENT INFLUENZA OR TO TREAT ITS COMPLICATIONS

Prevention devices

List of essential medical devices
Prevention
MDs worn by medical staff or by visitors: Protective breathing masks intended to protect the wearer Head covers Protective goggles Gloves Coats / gowns Shoe covers **MD worn by patients** § Surgical masks intended to protect the environment from the wearer

Intensive care devices

List of essential disposable or single-patient medical devices for intensive care
Respiration
Laryngoscope blade Endobronchial and endotracheal intubation tube Tracheobronchial aspiration tube Respirator circuit High-concentration oxygen masks Oxygen goggles
Blood circulation
Short peripheral catheter Infusion: infusion kit, extension, cock manifold, infusion flow rate regulator Long central catheter
Digestive
Aspiration tubing Enteral feeding tubing Lavage and bladder irrigation tubing

APPENDIX 2: LIST OF EMERGENCY DISEASES

Cancerology:

Oncological emergencies:

- Chemotherapy complications: haematological complications
- Chemotherapy complications: digestive complications
- Metabolic emergencies: hypercalcaemia, lysis syndrome
- Neurological emergencies: medullary compression, intracranial hypertension
- Haematological emergencies: disseminated intravascular coagulation, acute leukaemia (AML3, ALL, etc.)
- Haemorrhagic emergencies: haemoptysis
- Infectious emergencies: febrile neutropenia, interstitial pneumpathy

Chronic diseases:

For all forms of cancer: items for chemotherapy, radiotherapy, curietherapy or a surgical procedure (according to specialty, see specific item).

Cardiology:

Anticoagulant accident
Adult circulatory arrest
Complete arrhythmia induced by atrial fibrillation
Haemorrhagic shock
Hypertensive attack
Acute aortic dissection
Pulmonary embolism
Acute endocarditis
Lower limb acute ischemia
Malaise
Acute myocarditis
Acute cardiogenic pulmonary oedema
Acute pericarditis
Lower limb phlebitis
Acute coronary syndrome with persistent ST up-shift
Acute coronary syndrome without persistent ST up-shift
Tachycardia

Diabetology-endocrinology:

Diabetic acidoketosis
Diabetic lactic acidosis
Hyperosmolar coma
Hyperthyroïdism
Hypoglycaemia
Hypercalcaemia

Gastroenterology:

Angiocholitis

Hepatic coma
Acute cholecystitis
Lower digestive haemorrhage
Upper digestive haemorrhage
Swallowing of foreign body/caustic substances
Colonic occlusion
Small bowel occlusion
Acute pancreatitis
Peritonitis
Gastroduodenal ulcerous flare-up

Gynaecology-obstetrics:

Breast abscess
Extra-uterine pregnancy
Extra-uterine pregnancy, twisted adnexa, pelvic abscesses
Miscarriage
Post-partum fever
Genital haemorrhage
Acute salpingitis
Toxaemia of pregnancy or pre-eclampsia
Injury in pregnant women

Other forms of care: Pregnancy follow-up, emergency delivery

Infections:

Blood or genital exposure accident
Malarial attack
Botulism
Septic shock
Acute respiratory distress
Acute diarrhoea with signs of dehydration
Septicaemic states
Fever on returning from travel to tropical region
Haemorrhagic fever
Influenza
Anaerobic soft tissue infections
Legionnaires' Disease (respiratory form)
Bacterial or viral meningitis and meningo-encephalitis
Severe pneumopathy
Primary HIV infection
Rabies
Tetanus
All severe septic states
All complicated forms of infectious disease, regardless of the origin
Infectious endocarditis
Long-term fever of unexplained origin

Polyvalent intensive care:

Diving accident
Anaphylactic shock
Heat stroke
Electrification
Ecstasy and amphetamine poisoning
Cocaine poisoning

Nivaquine poisoning
Acute aspirin poisoning
Paracetamol poisoning
Carbon monoxide poisoning
Betablocker poisoning
Viper bites in France
Drowning
Opiate overdose
Hymenoptera sting
Chemical dependence
Urticaria and Quincke's oedema

Neurology/Neurosurgery:

Intracranial hypertension (due to hypoxia or other)
Acute poly radiculo neuritis
Swallowing disorders
Transient ischemic accident caused by carotid stenosis
Ischemic stroke
Acute headaches
Migraine attacks
Epileptic seizure
Epileptic state
Cerebromeningeal haemorrhage
Urgent surgical radicular sciatica treatment (if deemed necessary)
TRAUMA:
. Chronic subdural haematoma
. Extradural haematomas
. Cranial trauma
. Medullary trauma and medullary compression
Tremors, dystonia

Ophthalmology:

Eye burns
Detached retina
Endophthalmitis
Acute angle-closure glaucoma
Chronic open-angle glaucoma
Keratitis and abscess
Eyelid and lacrimal passage wound
Eyeball wound, with or without intraocular foreign body
Uveitis

ENT:

Angina
Foreign body (external auditory canal - nasal cavities)
Dizziness
Adult laryngeal dyspnoea
Epistaxis
False passage of food
Fracture of the bridge of the nose
Swallowed foreign body
Inhaled foreign body
Acute otitis media
Acute adult sinusitis

Paediatrics:

Acute appendicitis in childhood
Cardiac arrest in childhood
Infant bronchiolitis
Infant febrile convulsions
Tracheobronchial foreign body in childhood
Asthma attack in childhood
Infant dehydration
Acute diarrhoea in childhood
Urinary tract infection in childhood
Acute intestinal invagination in childhood
Childhood meningitis
Childhood purpura fulminans
Childhood skull trauma

Neonatal medical emergencies:
Foetal distress
Mother-foetus infection
Premature birth
Obstetrical trauma
Icterus
Malaises (cot death, gastrooesophageal reflux, heart rate disorders, etc.)
Respiratory distress
State of shock
Enteropathy, etc.

Neonatal surgical emergencies:
By specialty: Neurology, Ophthalmology, ENT, Cardiology, Visceral, Orthopaedics.

For example:
Curable congenital heart disease: ECC closed-heart or open-heart surgery.
Curable visceral malformations such as:

- Oesophageal atresia
- Digestive atresia
- Anal imperforation and anorectal malformations
- Ante or peri-natal small bowel volvulus
- Diaphragmatic hernia
- Adenomatoid dysplasia of the lung
- Pulmonary sequestration
- Laparoschisis
- Omphalocele
- Exstrophy of the bladder, etc.

Acquired neonatal surgical diseases:
Ulceronecrotic enterocolitis
Pyloric stenosis
Small bowel volvulus on common mesentery, etc.

Paediatric medical diseases:
Acute respiratory failure
Epiglottitis
Asthma
Pneumopathy
State of shock
Heart rate disorder
AHT and PAHT
Kidney failure
ICHT coma

Encephalopathy
Guillain-Barré syndrome
Liver failure
Metabolic diseases, etc.

Visceral and/or orthopaedic paediatric surgical diseases:
Multiple trauma (all paediatric specialties)
Cranial, chest, abdominal trauma
Acute intestinal invagination
Appendicitis
Peritonitis

Pneumology:

Severe acute asthma
Acute decompensation COPD
Acute adult bronchitis
Pleurisy
Community-acquired acute pneumpathy (excluding HIV infection)
Acute tuberculosis

Proctology:

Anal margin abscess
Anal fissure
Haemorrhoidal thrombosis

Psychiatry:

Agitation and aggression in elderly subjects
Depression in elderly subjects
Acute delirium
Emergency in subject suffering from depression

Rheumatology:

Infectious arthritis
Gout attack
Non-complicated sciatica, lumbago
Urgent radicular sciatica

Traumatology:

Blast
Serious road accident injury
Severe burn
Fracture complications: compartment syndrome
Leg fracture
Pelvic fracture
Femoral fracture
Open limb fracture
Shoulder dislocation
Minor burns
Finger and hand wound
Limb wound

Limb section
Cranial trauma
Closed chest trauma
Long bone trauma

Urology-nephrology:

Renal colic
Acute simple cystitis in women between 15 and 65 years of age
Acute hypercalcaemia
Prostatitis
Acute pyelonephritis
Acute urine retention
Male acute infectious urethritis

APPENDIX 3: LIST OF CHRONIC DISEASES

The diseases from the "LTI 30" list published by the HAS are as follows:

01 – Disabling cerebral vascular accident

02 – Medullary failure and other chronic cytopenia

03 – Chronic arteriopathy with ischemic signs

04 – Complicated bilharziosis

05 – Severe heart failure, severe rhythm disorders, severe valvular cardiopathy, severe congenital cardiopathy (Pulmonary arterial hypertension, chronic symptomatic systolic heart failure, chronic symptomatic heart failure with preserved systolic function)

06 – Active chronic liver disease and cirrhosis (Chronic hepatitis B, chronic hepatitis C)

07 – Severe primary immune deficiency, HIV infection

08 – Type 1 diabetes and type 2 diabetes

09 – Severe forms of neurological and muscular diseases (including myopathy), severe epilepsy (Severe epilepsy, amyotrophic lateral sclerosis)

10 – Constitutional chronic and severe acquired haemoglobinopathy, haemolysis (major and intermediate thalassaemic syndromes)

11 – Hemophilia and severe constitutional haemostasis diseases

12 – Severe arterial hypertension

13 – Coronary disease

14 – Severe chronic respiratory failure (Asthma-induced chronic respiratory failure, severe adult chronic respiratory failure induced by obstructive bronchopneumopathy)

15 – Alzheimer's disease and other forms of dementia

16 – Parkinson's disease

17 – Hereditary metabolic diseases requiring specialised long-term treatment (Wilson's disease, Gaucher's disease, mucopolysaccharidosis type I)

18 – Cystic fibrosis

19 – Severe chronic nephropathy and primary nephrotic syndrome

20 – Paraplegia

21 – Periarteritis nodosa, systemic lupus erythematosus, diffuse scleroderma

22 – Severe progressive rheumatoid arthritis

23 – Long-term psychiatric diseases (Severe anxiety disorders, schizophrenia)

24 – Progressive ulcerative colitis and Crohn's disease

25 – Multiple sclerosis

26 – Progressive structural scoliosis (with angle greater than or equal to 25 degrees) until spinal maturation

27 – Severe ankylosing spondylarthritis

28 – Post-organ transplant period

29 – Active tuberculosis, leprosy

30 – Malignant tumour, malignant lymphatic or haematopoietic tissue disease (colorectal cancer, skin melanoma)

31 – Marfan and related syndromes, Xeroderma pigmentosum

APPENDIX 4: SAMPLE QUESTIONNAIRE SENT TO EXPERTS TO SELECT ESSENTIAL DEVICES (CARDIOLOGY)

LIST OF MEDICAL DEVICE IN THE EVENT OF AN INFLUENZA PANDEMIC IN CARDIOLOGY

WORKING DOCUMENT TO BE COMPLETED AND FAXED TO +33 (0)1 55 87 37 62 BY 30/09/08

Recipients:

- M. [redacted]
- M. [redacted]
- M. [redacted]

[redacted]

Projet DM/Grippe aviaire = Attention Véronique : est-ce bien l'adresse de l'entité concernée à l'Agence ?
Agence Française de Sécurité Sanitaire des Produits de Santé
143/147, bd Anatole France
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CARDIOLOGY

This document is a summary of the medical devices used in cardiology disease care. It follows on from the methodology document on the compilation of a list of essential medical devices in the event of an influenza pandemic and was prepared on the basis of a bibliographic study.

This document divides medical devices into two categories: medical devices intended for diagnostics and those intended for treatment (emergency or more long-term treatment).

All these items should enable the care of the following diseases:

1. **Emergency diseases:**

- Anticoagulant accidents
- Adult circulatory arrest
- Complete arrhythmia induced by atrial fibrillation
- Severe congenital heart disease
- Haemorrhagic shock
- Hypertensive attack
- Acute aortic dissection
- Pulmonary embolism
- Acute endocarditis
- Lower limb acute ischemia
- Malaises
- Acute cardiogenic pulmonary oedema
- Acute pericarditis
- Lower limb phlebitis
- Acute coronary syndrome with persistent ST up-shift
- Acute coronary syndrome without persistent ST up-shift
- Tachycardia

2. **Chronic diseases**

- LTI No. 1: Disabling cerebral vascular accident
- LTI No. 3: Obliterative arteriopathy of the lower limbs
- LTI No. 5: Chronic symptomatic systolic heart failure
- LTI No. 5: Chronic symptomatic heart failure with preserved systolic function
- LTI No. 5: Pulmonary arterial hypertension
- LTI No. 13: Coronary disease

The associated devices have been categorised and classified (wherever possible), after a bibliographic study. For each disease, the various procedures used to identify these medical devices are given in appendix 1 (see page 23).

Three important remarks:

- **The aim is not draw up an exhaustive list of all the MDs** used in cardiology, but to identify the main types.
- **It is likely that some MDs have not been cited (incorrectly). Please include them if required.**
- Items which are not specific for cardiology but sometimes useful for diagnostic or treatment purposes are not included in this document as these items may be linked with another specialty (e.g.: Electroencephalograph, nasogastric catheters, etc.)

What is expected of you:

For each item category:

1. Identify "essential" items

   In the selected medical devices, check those that you deem to be "essential" or "non-essential". This should always be viewed in terms of a crisis context. In the event of a influenza pandemic crisis spread out over time (waves of 8 to 12 weeks), only devices which are absolutely necessary should be selected.

   "Essential" device: "Device for which an interruption in supply may have an irreversible clinical impact for patients."

2. Add any omitted MDs or remarks

   In the "Other, Details" section, note any remarks you may have or request further details. **Add any omitted MDs** you deem necessary. Suggestions are already included in the section pending your comments.

The purpose of the final page of the document (excluding appendices) (p22) is to add any diseases not included in the above list which you feel must be included. If possible, specify the associated MDs not included in this document.

DIAGNOSTICS

1. Electrocardiography

ECG ITEM	Essential	Non-Essential
Electrocardiograph		
ECG electrode		
ECG Holter		
ECG paper		

Other, Details: …….

2. Ultrasonograph

Items used to perform echocardiography, transthoracic, transoesophageal ultrasonography, abdominal ultrasonography, etc.

ULTRASONOGRAPHY ITEM	Essential	Non-Essential
Ultrasonograph		
Ultrasonography probe disinfectant		
Ultrasonography gel		
Ultrasonography probe protector		

Other, Details:

3. MRI

MRI ITEM	Essential	Non-Essential
MRI		
MRI contrast medium injector		
MRI injection tubing		

Other, Details:

4. Scanning (particularly spiral scanning)

SCANNING ITEM	Essential	Non-Essential
Scanner		
Scan product injector		
Scan injection tubing		

Other, Details: The majority of scanners are currently linked with tomographs.

5. Diagnostic nuclear medicine items

DIAGNOSTIC NUCLEAR MEDICINE ITEM	Essential	Non-Essential
Positron emission tomograph		
Single-photon emission tomograph		
Scintigraphy infusion tubing		
Scintigraphy product injector		
Gamma camera		

Other, Details:

6. X-ray

Items used for radiology (chest, lung, abdomen, etc.) and scintigraphy.

X-RAY ITEM	Essential	Non-Essential
Standard radiology room		

Other, Details:

7. Angiography items

Items used to perform coronarography, ventriculography, phlebography, pulmonary angiographies, etc.

ANGIOGRAPHY ITEM	Essential	Non-Essential
Angiograph		
Angiography needle		
Angiography contrast medium injector		
Angiography infusion tubing		
Cardiovascular investigation guide		
Pulmonary angiography catheter		
Aortic angiography catheter		
Coronary angiography catheter		
Peripheral angiography catheter		

Other, Details:

8. Scopy items

SCOPY ITEM	Essential	Non-Essential
Flexible (bronchial or digestive) fibroscope		

Other, Details:

9. Cardiopulmonary investigation items

GENERAL INVESTIGATION ITEM	Essential	Non-Essential
Stethoscope		

10. Exertion test

GENERAL INVESTIGATION ITEM	Essential	Non-Essential
Bicycle		

11. Pressure measurement

ANATOMICAL FUNCTION INVESTIGATION ITEM	Essential	Non-Essential
Pressure gauge		
Manual pressure cuff		

Other, Details:

12. Emergency haemoglobin measurement

BIOLOGICAL FLUID SAMPLING AND ANALYSIS ITEM	Essential	Non-Essential
Haemoglobin level measurement device		

Other, Details:

13. Temperature measurement

GENERAL INVESTIGATION ITEM	Essential	Non-Essential
Rectal probe		
Mercury thermometer		
Ear thermometer		

Other, Details:

14. Heart biopsy items

BIOPSY ITEM	Essential	Non-Essential
Heart biopsy forceps via endocavitary route		
Pericardial puncture needle		

Other, Details:

15. Biological fluid analysis sampling items

BIOLOGICAL FLUID SAMPLING AND ANALYSIS ITEM	Essential	Non-Essential
Disposable venous blood sampling item		
Disposable arterial blood sampling item		
Lumbar puncture needle		

Other, Details:

16. Pathological assay and identification kits

Item2	Essential	Non-Essential
BLOOD COUNT INCLUDING PLATELETS (FULL BLOOD COUNT, PLATELET COUNT)		
SEDIMENTATION RATE (SR)		
BASIC PREOPERATIVE HAEMOSTASIS INVESTIGATION (PT + APTT + PLATELETS)		
INR: PROTHROMBIN TIME IN CASE OF TREATMENT WITH AVK		
PARTIAL THROMBOPLASTIN TIME + ACTIVATOR (PCTT, PTTK, ETC.)		
FIBRINOGEN (FACT.I): ASSAY		
D DIMERS		
BLOOD HEPARIN BY MEASURING ACTIVE ANTI-X ACTIVITY		
ABO-RH BLOOD TYPING (D) (BG)		
RH (C, C, E, E) AND KELL (K) PHENOTYPES		
IAT (IRREGULAR ANTIBODY TEST): SCREENING		
IAT: IDENTIFICATION		
MICROBIOLOGICAL URINE TEST (CBEU)		
QUALITATIVE BLOOD CULTURE MICROBIO TEST		
NSO AID: GROUP 2 RHEUMATOID F: HUMAN IG (LATEX, etc.)		
T.S.H. + FREE T3 + FREE T4 (BLOOD)		
TRANSAMINASES (TGO + TGP, ALAT + ASAT, etc.) (BLOOD)		
CREATINE PHOSPHOKINASE (CPK) (BLOOD)		
LACTATE DEHYDROGENASE (LDH) (BLOOD)		
RPC (REACTIVE PROTEIN C) (ASSAY) (BLOOD)		
MYOGLOBIN (ASSAY) (BLOOD)		
TROPONIN (ASSAY) (BLOOD)		
NATRIURETIC PEPTIDES (BNP, NT-PROBNP)		
PROCALCITONIN (ASSAY) (BLOOD)		
BLOOD: GLUCOSE (GLYCAEMIA)		
BLOOD: CALCIUM (CALCAEMIA, CA)		
BLOOD: UREA AND CREATININE		
BLOOD: FULL IONOGRAM (NA+K+CL+CO2+ PROTEINS)		
BLOOD: BLOOD GASES		
URINE: MICROALBUMINURIA: ASSAY		

Other, Details:

TREATMENT

1. Infusion

INFUSION ITEM	Essential	Non-Essential
Peripheral catheter		
Central catheter		
Arterial catheter		
Venous catheter		
Pulmonary catheter		
Syringe-pusher device		
Infusion extension		
Catheter fitting dressing		
Shutter		
Infusion filter		
Manifold		
Manifold protector		
Infusion pump		
Continuous injection microinfusor		
Air intake		
Flow regulator		
Coupling		
Cock		
Blood pump Infusion acceleration transfusion system		

Other, Details:

2. Sampling and injection items

NON-SPECIALISED SAMPLING-INJECTION ITEM	Essential	Non-Essential
Reusable needle		
Disposable hypodermic needle (ID, SC, IM, IV)		
Glass syringe		
Disposable syringe		

Other, Details:

3. Cardio-respiratory intensive care items

3.1. Intubation

INTUBATION ITEM	Essential	Non-Essential
Tracheal intubation tube		
Laryngoscope		
Laryngoscope bulb		
Laryngoscope blade		
Guedel oropharyngeal airway		
Bronchial intubation tube		
Respirator		

Other, Details:

3.2. Tracheotomy

TRACHEOTOMY ITEM	Essential	Non-Essential
Rigid tube		
Tracheotomy breathing filter		
Tracheotomy tube		
Flexible tube		

Other, Details:

3.3. Oxygen therapy

OXYGEN THERAPY ITEM	Essential	Non-Essential
Mask with Amb type self-inflating balloon		
Oxygen tube		
Oxygen goggles		
Oxygen therapy mask		

Other, Details:

3.4 Assisted ventilation

ASSISTED VENTILATION ITEM	Essential	Non-Essential
Breathing filter for apparatus		
Ringed coupling		
Water trap		
Breathing filter for patient		
Heating humidifier		
Disposable ventilation circuit		
Ventilator		

Other, Details:

3.5. Stimulator and defibrillator

These items include defibrillation, electric cardioversion, electrosystolic entrainment procedures.

PROSTHETIC ITEM	Essential	Non-Essential
External cardiac defibrillator, stimulation electrode		
External cardiac defibrillator, defibrillation electrode		

Other, Details:

4. Items used for surgical procedures

4.1. Clothing

CLOTHING ITEM	Essential	Non-Essential
Medical glove		
Surgical brush		
Underglove		
Surgical glove		
Surgical mask		
Surgical gown		
Fingerstall		
Head cover		
Protective goggles		

Other, Details:

4.2. Surgical draping

SURGICAL DRAPING ITEM	Essential	Non-Essential
Draping kit		
Drape		

Other, Details:

4.3. Anaesthesia

GENERAL ANAESTHESIA ITEM	Essential	Non-Essential
Anaesthetic ventilator		
Intubation tube		
Laryngeal mask		
Ventilation mask		

Other, Details:

LOCOREGIONAL ANAESTHESIA ITEM	Essential	Non-Essential
Spinal anaesthesia catheter		
Spinal anaesthesia needle		

Other, Details:

4.4. Instruments

SURGICAL APPROACH ITEM	Essential	Non-Essential
Disposable bistoury		
Electric bistoury		
Neutral electrode plate for electric bistoury		
Electrode for electric bistoury		
Bistoury blade		
Adhesive		
Standard surgical instrument case		
Surgical suture		
Retractor		
Razor		
Speculum		
Different chisel types, including microsurgical		
Clamp		
Knife		
Dissection forceps		
Miscellaneous forceps		
Stapler		
Clip		
Needle holder		
Surgical razor		

Other, Details:

4.5. Tenting

TENTING ITEM	Essential	Non-Essential
Gauze tent		

Other, Details:

4.6. Drainage

SURGICAL DRAINAGE ITEM	Essential	Non-Essential
Drain and jar suitable for the specialty		

Other, Details:

4.7. Aspiration

ASPIRATION ITEM	Essential	Non-Essential
Aspiration flow rate regulator		
Mucus aspirator		
Aspiration tubes		
Mucus collector (aspiration bags)		
Aspirating tubing and connectors		
Disposable aspiration jar		

Other, Details:

4.8. Patient monitoring

MONITORING ITEM	Essential	Non-Essential
Pulse oximeter		
Electrocardioscope		
Capnograph		
Non-invasive pressure monitor		
Anaesthetic vapour analyser		
Cardiac flow meter with monitor		

Other, Details:

3. Items used for coronary or peripheral angioplasty

ANATOMICAL FUNCTION INVESTIGATION ITEM	Essential	Non-Essential
Cardiovascular investigation guide		
Catheter insertion device (= desilet)		

Other, Details:

UNCLOGGING ITEM	Essential	Non-Essential
Angioplasty guide		
Angioplasty guide catheter		
Angioplasty kit (Y valve, insertion needle, torque device, inflation system)		
Coronary angioplasty catheter		
Peripheral angioplasty catheter		

Other, Details:

PROSTHETIC ITEM	Essential	Non-Essential
Aortic endoprosthesis (stent)		
Coronary endoprosthesis (stent)		
Peripheral endoprosthesis (stent)		

Other, Details:

6. Vascular embolisation items

VASCULAR EMBOLISATION ITEM	Essential	Non-Essential
Embolisation catheter		
Catheter, embolisation guide		
Embolisation agent		

Other, Details:

7. Vascular surgery items

VASCULAR EMBOLISATION ITEM	Essential	Non-Essential
Embolectomy catheter		

Other, Details:

BLOOD CIRCULATION BLOOD ITEM, PREVENTION	Essential	Non-Essential
Vena cava filter		

Other, Details: The vena cava filter is used in surgery for pulmonary embolism after embolectomy

VASCULAR SURGERY ITEM	Essential	Non-Essential
Synthetic (Dacron) vascular implant		

8. Cardiac implants

Item2	Essential	Non-Essential
Implantable cardiac defibrillator		
Implantable cardiac defibrillation catheter		
Implantable cardiac stimulator		
Implantable cardiac stimulation catheter		
Heart valve (and accessories), valvular rings and tube with valve		
Dacron and felt patch		

Other, Details:

9. Cardiac assistance

CARDIAC ASSISTANCE ITEM	Essential	Non-Essential
circulatory assistance, aortic counter-pulse		
ventricular circulatory assistance, complete artificial heart		

Other, Details:

EXTRACORPOREAL CIRCULATION ITEM: E.C.C.	Essential	Non-Essential
ECC, oxygenator		
ECC, reservoir		
ECC, bubble traps		
ECC, filter		
ECC, pump body		
ECC, centrifugal head		
ECC, tube		
ECC, heat exchanger		
ECC, diathermy candle		
ECC tubing		

Other, Details:

GENERAL INVESTIGATION ITEM	Essential	Non-Essential
Swan-Ganz cardiac catheter		

Other, Details:

BLOOD TREATMENT ITEM	Essential	Non-Essential
Haemofiltration device		
Haemofiltration filters		
Haemofiltration tubing		
Haemofiltration device line		
Haemofiltration catheter		

10. Blood transfusion items

BLOOD TREATMENT ITEM	Essential	Non-Essential
Self-transfusion kit		
Transfusion kit (transfusion system)		
Transfer bags		

Other, Details:

11. Other specific items

11.1. In cases of haemorrhages

RETENTION AND IMMOBILISATION ITEM	Essential	Non-Essential
Anti-shock trousers		

BLOOD CIRCULATION BLOOD ITEM, PREVENTION	Essential	Non-Essential
Compression stockings		

Other, Details:

11.2. Specific tubes

ASPIRATION IRRIGATION DIGESTIVE TRACT ITEM	Essential	Non-Essential
Blackmore tube		

Other, Details:

UROGENITAL SYSTEM ITEM, DRAINAGE IRRIGATION	Essential	Non-Essential
Urinary catheter		

Other, Details:

12. Other general items

12.1. Dressings, compresses, strips

CLEANSING-CLEANING ITEM	Essential	Non-Essential
Gauze compress		
Non-woven		
Medical pad		
Cotton wool		

Other, Details:

HEALING AND WOUND PROTECTION	Essential	Non-Essential
Hydrocolloid dressing		

Other, Details:

FIXATION AND SECURING	Essential	Non-Essential
Adhesive securing strip		
Adhesive skin wrap		
Adhesive plaster		

Other, Details:

RETENTION AND IMMOBILISATION ITEM	Essential	Non-Essential
Elastic strip		
Stretchable strip		
Plaster strip		
Resin strip		
Cotton wool		

Other, Details:

12.2. Disinfection-decontamination-sterilisation items

DISINFECTION DECONTAMINATION - STERILISATION ITEM	Essential	Non-Essential
Surface disinfectant		
Instrument and equipment disinfectant		
Hand wash		
Antiseptic		

Other, Details:

OTHER DISEASES TO BE INCLUDED IN CARDIOLOGY

Name of disease:

Associated specific devices:

Name of disease:

Associated specific devices:

Name of disease:

Associated specific devices:

Name of disease:

Associated specific devices:

Name of disease:

Associated specific devices:

APPENDIX 1: PROCEDURES TO DETERMINE THE MEDICAL DEVICES FOR CARDIOLOGY DISEASES

1) Adult circulatory arrest [1] [2] [3]

Diagnostics:

ECG + echocardiography

Treatment:

- Ventilation with mask if available on site.
- Intensive care items: defibrillator + intubation items.
- Also assisted ventilation items and infusion items.
- Emergency electrosystolic entrainment probe (= external cardiac stimulator + Electrodes)

In hospital environment: surgery. If coronary cause: coronarography + angioplasty. Long-term: anaesthesia and fitting of implantable cardiac defibrillator

2) Haemorrhagic shock [1] [4] [5]

Diagnostics:

Haemoglobin measurement + MRI + Chest X-ray + Transthoracic and transoesophageal ultrasonography + ECG

Treatment:

- Emergency self-transfusion kit
- Intensive care: tracheo + defibrillator
- Anti-shock trousers to limit blood loss.
- Ventilation
- Intubation
- Infusion (central and peripheral route)
- Blackmore tube in case of digestive haemorrhage.
- Investigation with urinary catheter.
- Bio parameter measurement with Swan-Ganz cardiac catheter + pulmonary catheter
- Surgery

3) Anticoagulant accident [1] [6] [7]

Diagnostics:

- Abdominal ultrasonography + Echocardiography
- Scintigraphy
- Scan

- Fibroscopy

Treatment:
- Infusion
- Transfusion
- Items used for compression haemostasis: tents, compresses.

4) Complete arrhythmia induced by atrial fibrillation [(1) (8) (9)]

Diagnostics:

- ECG
- Transthoracic + Transoesophageal ultrasonography
- X-ray

Treatment:

- Electric cardioversion item.

5) Hypertensive attack [(1) (10) (11)]

Diagnostics:

- ECG
- X-ray
- Scan
- Intracranial pressure measurement in case of hypertensive encephalopathy? See neurology items

Treatment:

Infusion

6) Acute aortic dissection [(1) (12) (13)]

Diagnostics:

- Transthoracic + Transoesophageal ultrasonography + Ultrasonography
- ECG
- MRI
- X-ray
- Scan
- Aortic angiography

Treatment:

Surgery with fitting of stent-graft or prosthetic tube (vascular prosthesis)

7) Pulmonary embolism [1] [14] [15] [16]

Diagnostics:

- Transthoracic + Transoesophageal ultrasonography + Ultrasonography
- ECG
- MRI
- X-ray
- Angiography

Treatment:

- Infusion
- Oxygen therapy
- Embolectomy surgery and fitting of endocaval filter.

8) Acute endocarditis [1] [17] [18] [19]

Diagnostics:

- Ultrasonography
- ECG
- X-ray

Treatment:

- Infusion
- Exeresis surgery may be required.
- In the long-term: replacement of heart valve if endocarditis occurs on the valve

9) Lower limb acute ischemia [1] [20] [21]

Diagnostics:

- ECG
- Transoesophageal ultrasonography + Ultrasonography
- X-ray
- Angiography (arteriography)

Treatment:

- Embolectomy
- Angioplasty or bypass

10) Malaises [1] [22] [23] [24]

Diagnostics:

- ECG
- Scan

Treatment:

- Infusion
- Ventilation, etc.

11) Cardiogenic acute pulmonary oedema [1] [25] [26]

Diagnostics:

- ECG
- Scan
- Ultrasonography
- Lung X-ray
- Angiography

Treatment:

- Oxygen therapy ventilation item
- Respiratory assistance with expiratory pressure ventilation (AV-PEP) items.
- Intubation items if required + electric cardioversion items
- Circulatory assistance items: artificial heart.
- Long-term: intra-aortic counter-pulse balloon.

12) Acute pericarditis [1] [27] [28]

Diagnostics:

- ECG
- Scan
- Ultrasonography
- X-ray
- MRI

Treatment:

- Pericardial puncture
- Infusion + Surgery if required

13) Lower limb phlebitis [1] [29] [30] [31]

Diagnostics:

- ECG
- Phlebography
- Ultrasonography
- X-ray

Treatment:

- Infusion
- Medium or high-support elastic stockings.
- Thrombectomy surgery and fitting of caval filter.

14) Tachycardia [1] [32] [33]

Diagnostics:

- ECG

Treatment:

- Emergency: intensive care items: tracheo + external defibrillator. Followed by electric cardioversion or endocavitary item.
- Fitting of infusion + assisted ventilation.
- Surgical procedure if required and, in the long-term, fitting of implantable cardiac defibrillator.

15) Coronary disorders (angor and coronary syndrome) [1] [34] [35] [36] [37] [38]

Diagnostics:

- ECG
- Arteriography
- Ultrasonography
- X-ray
- MRI

Treatment:

Emergency: infusion + oxygen therapy + external defibrillator.
Surgery: angioplasty or bypass.

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APPENDIX 5: LIST OF ESSENTIAL MEDICAL DEVICES BY MEDICAL OR MEDICO-TECHNICAL PROCEDURE AND BY SPECIALTY

APPENDIX 6: LIST OF ESSENTIAL MEDICAL DEVICES IN ALPHABETICAL ORDER LINKED WITH MEDICAL AND MEDICO-TECHNICAL SPECIALTIES IN WHICH THEY ARE USED

APPENDIX 7: LIST OF ESSENTIAL MEDICAL DEVICES IN ALPHABETICAL ORDER LINKED WITH VARIOUS CLASSIFICATION CODES