

GENERAL FRAMEWORK FOR A MULTIDISCIPLINARY QUALITY MANUAL FOR CARDIAC CARE NETWORKS





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COLOPHON

Title: General framework for a multidisciplinary quality manual for cardiac care networks

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Acknowledgements: We acknowledge the organizations that submitted examples of quality manuals for cardiac care networks to the

scientific associations of cardiologists and cardiac surgeons.

Other reported interests:

All experts consulted within this report were selected because of their role in the sector of cardiology or cardiac

surgery. Therefore, by definition, all consulted experts have a certain degree of conflict of interest to the main

topic of this report.

Layout: Ine Verhulst

Disclaimer:

• The external experts were consulted about a (preliminary) version of the scientific report. Their comments were discussed during meetings. They did not co-author the scientific report and did not necessarily agree with its content.

This report was not submitted for scientific validation since the assignment was limited to support
the colleges of physicians in cardiac pathology in a consensus process. The KCE was not asked to
underpin this process scientifically.

• Finally, this report has been approved by common assent by the Executive Board.

• Only the KCE is responsible for errors or omissions that could persist.

Publication date: 2 December 2013 (2nd print; 1st print: 20 November 2013)

Domain: Good Clinical Practice (GCP)

MeSH: Quality Assurance; Health Care; Cardiovascular Diseases

NLM Classification: WG100 Language: English

Format: Adobe® PDF™ (A4)



_egal depot:	D/2013/10.273/94

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How to refer to this document?

De Laet C, Van den Heede K, Mertens R. General framework for a multidisciplinary quality manual for cardiac care networks. Health Services Research (HSR) Brussels: Belgian Health Care Knowledge Centre (KCE). 2013. KCE Reports 213C. D/2013/10.273/94.

This document is available on the website of the Belgian Health Care Knowledge Centre.





An easy description of what quality assurance really means is:

We state what we **plan** to do; We try to **do** what we said; We **check** whether we did what we said; We **act/adjust** where needed.

It is the well-known *Plan-Do-Check-Act* quality circle launched by William Edwards Deming in 1950. The Royal Decree of July 15, 2004 defined the criteria to officially recognise the care programme for 'cardiac pathology'. When in June 2012 a new article 8 required the development of a multidisciplinary quality manual for each of those care programmes this concerned the first step of this quality circle: stating what we plan to do. In May 2013 the Minister asked KCE to support the college of physicians for cardiac pathology with the development of a general framework for this quality manual, in order to help the hospitals and networks developing their own manual. Quality in such a setting asks for more than just high quality care by individual physicians, it needs clearly formulated agreements and a joint commitment to achieve excellence. A quality manual is a key element in this process.

KCE had some experience with this subject. In 2006 we published a general framework for a quality manual for oncology care programmes. After a comprehensive literature review it was concluded that there are no scientifically validated general models available in the medical literature. Based on these experiences, and given the short timeframe allowed for this assignment we decided to proceed differently this time. Therefore, we used a kind of cocreation approach. Through the scientific societies of cardiologists and cardiac surgeons an appeal was launched to share with us their existing prototypes and models of quality manuals. This appeal proved to be very successful and we received more or less advanced examples from over 20 institutions and networks. We sincerely like to thank those institutions for their collaboration. Based on those examples and combined with our previous experiences with the oncology quality manual we tried to develop the common denominator for a manual described in this report.

Obviously the real work is only starting and the networks for cardiac pathology have now to populate this framework with their own agreements and descriptions. Not an easy task but extremely important. A well made – and regularly updated – quality manual could become an instrument to promote a network towards colleagues and ultimately also towards patients!

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■ TABLE OF CONTENTS

	FOREWORD	1
LIST (DF ABBREVIATIONS	3
	SCIENTIFIC REPORT	2
1	SCOPE AND GENERAL APPROACH	2
1.1	SCOPE	
1.2	METHOD	5
1.3	RESULTS AND CONCLUSIONS FROM THE EXPERT PANEL	5
1.4	DEFINITIONS USED	5
2	PROPOSED STRUCTURE FOR A MULTIDISCIPLINARY QUALITY MANUAL FOR CARDIA	
PART	1: VISION AND MISSION OF THE CARE NETWORK	
PART	2: DESCRIPTION OF THE CARE NETWORK	8
	3: SCIENTIFIC BASIS	
PART	4: NETWORK FUNCTIONING	8
PART	5: QUALITY ASSURANCE	11
PART	6: DEVELOPMENT AND UPDATING PROCESS OF THE MANUAL	12
	APPENDIX	13
STRU	CTURE OF THE ORIGINAL ONCOLOGY MANUAL	13
	REFERENCES	16



ABBREVIATION DEFINITION

ACE Angiotensin Converting Enzyme
ACS Acute Coronary Syndrome

AF Atrial Fibrillation

AMI Acute Myocardial Infarction

BIS Bispectral index
BMS Bare Metal Stent

CABG Coronary Artery Bypass Graft
CVA Cerebro Vascular Accident

DES Drug Eluting Stent ECG Electrocardiogram

ESC European Society for Cardiology

GP General Practitioner

IABP Intra-Aortic Balloon Pump

ICU Intensive Care Unit

INVOS In Vivo Optical Spectroscopy

NSTE-ACS Non-ST-Segment Elevation Acute Coronary Syndrome

OPCAB Off-pump coronary artery bypass
PCI Percutaneous Coronary Intervention

QERMID Quality Electronic Registration of Medical Implant Devices (RIZIV – INAMI)

QI Quality Indicator

SLA Service Level Agreement

SOP Standard Operating Procedure

STEMI ST-Elevation Myocardial Infarction

TEE Trans Esophageal Echocardiography

URL Uniform Resource Locator

■ SCIENTIFIC REPORT

1 SCOPE AND GENERAL APPROACH

1.1 Scope

In recent years the Belgian Health Authorities have set up various care programmes (zorgprogramma/programme de soins) in order to give more coherence to the healthcare system. Healthcare programmes were developed for several domains including oncology, in vitro fertilization and cardiac pathology.

Within the framework of the care programme for cardiac pathology and by Royal Decree of June 12th 2012, the medical centres with a recognised cardiology service (A, B, and also E,T,C) need to develop a compulsory multidisciplinary quality manual (multidisciplinair cardiologisch handboek/manuel cardiologique pluridisciplinaire) detailing protocols and guidelines.¹ The College of physicians for cardiac pathology has been asked to develop, with support of the KCE, a framework to try and unify the structure of this quality manual.

The aim of this short report is not to develop new guidelines or detailed clinical pathways but to propose a basic structure for this multidisciplinary quality manual. For many cardiac pathologies, guidelines have been developed in the past by relevant organisations and for these guidelines the interested reader is referred to the original sources, including the guidelines developed under the auspices of the European Society for Cardiology (ESC, www.escardio.org).

In 2006, KCE published a first report on a structure for the oncology care programme quality manual.² The aim was to propose a uniform structure for hospitals to list information on several procedures including among others guidelines to be used, quality indicators to register and procedures to perform quality audits. In order to support the College of physicians for oncology, the KCE was asked at that moment:

- To search all information concerning the utilization of quality manuals in both the scientific literature and in other sources: does it exist and if so, what is the format, the content and how is it used?
- To propose a general structure of a quality manual, based on the evidence found.

The present work only focuses on the development of a general template of a quality manual for cardiac networks according to the legal requirements.¹

1.2 Method

We used the basic structure of the oncology manual template from 2006 (see Appendix) as a basis to develop a first draft of a structure for the multidisciplinary quality manual for cardiac networks. Items that appeared irrelevant for cardiac pathologies were taken out. This draft was subsequently complemented with items specific for cardiac pathologies.

To identify items relevant for cardiac pathologies, the Colleges of physicians for cardiac pathology collected a number of existing drafts and prototypes for multidisciplinary quality manuals for cardiac networks that are being developed in several Belgian centres. Those drafts were at various stages of comprehensiveness and of various lengths. Because most of this work is preliminary, we were able to only use this material on the understanding that it would not be listed in detail and that the hospitals concerned would remain anonymous.

The combined items were subsequently scored by external experts and stakeholders to evaluate their relevance and subsequently discussed at a meeting. The final result that was agreed upon at that expert meeting is presented in the next chapter.

The literature review about multidisciplinary quality handbooks, performed in the report from 2006, did not yield useful examples from abroad. It was highly unlikely that by now, additional useful information would be available. Therefore, it was decided that updating this literature review in the context of the development of this multidisciplinary cardiology handbook was beyond the scope of this project.

1.3 Results and conclusions from the expert panel

The material we received from over 20 Belgian hospitals and networks suggests that a few hospitals are well advanced with the development of a multidisciplinary manual for cardiac networks but that the structures of those are very different, making comparisons difficult.

Much of the other material we received consisted of ad hoc therapeutic schemes, processes and flow charts for specific cardiac pathologies. Most frequently these pathologies concerned myocardial revascularisation therapy in acute coronary syndrome (ACS) and atrial fibrillation (AF). However, also other relevant pathologies were encountered such as how to handle acute thoracic pain, management of heart failure, pacemaker implantations or procedures for medical imaging.

Although all these documents are mainly based on the same guidelines (mostly guidelines from the European Society of Cardiology), the formats and graphical layouts are very different, making direct comparisons difficult, but also making it more difficult for cardiologists and paramedical personnel working in different hospitals or residents in training that change hospitals.

The items from the draft manuals were listed and potentially relevant items for cardiac pathologies chosen. We originally selected 74 individual items and these were scored for relevance by 12 participants of the expert group and afterwards evaluated during an expert panel meeting. In case of diverging opinions consensus was pursued. As a result 44 individual items were kept while some items were combined.

The basic structure of the oncology manual was also simplified by limiting the number of headings and by grouping some of the items differently, after adding some items that are specific for cardiac pathologies.

An ideal quality manual should ideally be published in an electronic format (e-book) facilitating navigation through it with direct and easy access to all chapters.

1.4 Definitions used

To reduce the unjustified variations of clinical practice, and thus to improve their quality, several models to streamline healthcare organization have been developed, including protocols, clinical practice guidelines, clinical (or critical, or integrated care) pathways, case-management, disease management and standards of care:

- Clinical practice guidelines are tools for clinical decision-making;
- Protocols are "step by step" instructions, intended to make sure that a task is carried out in a uniform way;
- Clinical pathways and disease management form part of methodologies to structure the care.

They are all tools formalizing sets of care procedures **applying to the majority of the patients**. They make it possible to better foresee the process of care and thus to plan it.

- Case-management is a **completely individualized approach** corresponding to the plan of care;
- Finally standards of care are **rules to be respected**. They include guidelines and clinical pathways. They represent the basis on which indicators to assess the quality of care are built.

2 PROPOSED STRUCTURE FOR A MULTIDISCIPLINARY QUALITY MANUAL FOR CARDIAC NETWORKS

Part 1: Vision and mission of the care network

Mission statement and strategic objectives

The first part of the manual should contain the mission statement of the network and its general strategic approach for the fulfillment of this mission. This is based on the values and the goals of the network within 5 years. This part should detail what patients and personnel can expect from the organization.

Example mission statement and general strategy from an existing manual (not the original version; translation by KCE)

The mission of our [Network Name] is to deliver high quality cardiologic care by using state-of-the-art clinical and diagnostics tools, putting the patient in the centre of the care process.

By sharing experience and knowledge its aim is to deliver high quality care for a larger region. A streamlined working process will be realised by the development of common work practices, procedures and checklists. To share patient information and to facilitate analysis and interpretation of the data, common databases are being developed.

Innovation will be stimulated by collaboration on the levels of data management, scientific research and clinical studies. Common investments will allow the network to use state-of-the-art material and instruments while delivering care.

Patient charter

The network could also spell out its commitment to patient-centred high-quality care vis-à-vis the patient and the community itself, by expressing it under the form of a patient charter. This is a document which should be produced by all involved caregivers of the different partners in the network. Its production process is an opportunity to reaffirm and reinforce their mutual agreement to actively strive for excellence in the care for their patients.

Example of a patient charter (excerpt)

Dear Patient,

In our *[Network Name]*, we commit ourselves to offering you, as a patient, the best available care, according to the state of the art, chosen in function of your personal medical needs, and not of your ability to pay, your lifestyle or any other factor. Your opinion and choices, in function of your own life project, will duly be listened to and taken into account, and the eventual treatment decision will be the result of a discussion in which we search the solution that best serves your interests.

Therefore, you are entitled to full, understandable and timely information on your treatment options, if you wish so before any treatment decision is taken (unless the urgency of your medical problem does not permit so). This information also includes a realistic estimate of the costs to be expected over and above the health insurance coverage.

In our [Network Name], you can expect to be treated with respect and dignity, and with discretion and maximum confidentiality, meaning that nobody has access to your medical information who is not directly involved in your care process. You can at any stage obtain full access to your own medical information and decide to whom access should be granted for the aftercare after your discharge.





Structure, infrastructure and staffing

The second part of the manual contains a description of the structure of the care network, including:

- Geographic location of each of the partner centres, including usefull information on travel time and distances as well as on the travel modalities between the centres:
- Available bed capacity, by type (bed index; inpatient, day-care, rehabilitation) at each of the locations;
- Available technical infrastructure and equipment at each of the locations;
- Medical and paramedical staffing, with official legally recognised specialty, job titles and training level;
- Coordinates of management, unit heads, other functional coordinators;
- Opening times, permanencies, telephone numbers and any other usefull information.

Part 3: Scientific basis

This part of the manual describes the guidelines and processes that are applied for each pathology or condition. It offers them the scientific basis, by listing the scientific groups that developed and endorsed those guidelines as well as by providing the direct links (URL) to the full original guidelines.

A disclaimer and cautionary statement should also be added explaining that, although quality manuals and guidelines are the product of extensive consultations they should not be used purely as a 'cook book', and that in individual patients there may be very good reasons to, deliberately, deviate from them.

Part 4: Network functioning

This section should describe the working arrangements within the network:

General arrangements

- Description of the available care programmes, and the multidisciplinary teams per programme;
- Identification of the multidisciplinary team(s), team coordinator(s), meeting frequency;
- Organisation of the communication with other disciplines and external communication with GPs, private cardiologists, home care and other hospitals (both within and outside the network);
- Detailed description of the items that need to be systematically registered in the patient record throughout the network. These should at least include personal and family history, complete anamnesis, results of clinical and technical examinations and the performed interventions. The patient record should also include the treatment plan for the individual patient;
- Data management and arrangements for effective communication and sharing of the electronic patient records within the network;
- Formal collaborations with other institutions (e.g. nursing homes, rehabilitation centres, tertiary referral centres) should be described in detail with the contractual arrangements and obligations, contact information and the names of the coordinators.

KCE Report 213 Cardiology Quality Manual 9

Diagnosis-specific and procedure-specific arrangements

For each of the major clinical conditions amenable to care by the network for cardiac pathologies there should be a description of the Standard Operating Procedures (SOP) and Service Level Agreements (SLA) inside the centre and between the centres for interventions, patient referral/ back-referral and patient follow-up. This includes items such as:

- Uptake procedure and diagnostic work up;
- Procedure for urgent patient admission;
- Procedure and modalities (incl. quality and safety) of between-centre patient transportation;
- Communication between referring and receiving centre;
- Detailed algorithms/clinical pathways for each of the major diagnostic categories, including:
 - Decisional processes
 - Succession of procedures
 - o Exams
 - Medication
 - o Triggers for referral, rules for back-referral
 - Detailed, timed description ('standing order') for each of the relevant basic and advanced cardiac procedures mentioned in the algorithms, defining 'who-what-when-how-with what', including required competences; required infrastructure, equipment and material
 - Safety precautions
 - Patient preparation, information, informed consent and instructions
 - medication administration instructions
 - o Recovery and aftercare
 - Risk management and complications preparedness and management
 - Relevant quality indicators

- Aftercare and rehabilitation arrangements;
- Training arrangements of the specific teams involved, and of new collaborators;
- Endorsement of the procedure by the competent hierarchy;
- Information of the GPs and other potentially referring entities.

Example of elements to be included in a clinical pathway for Acute Coronary Syndrome (ACS)

Pre-hospital management

- Pre hospital ECG: who will do the analysis/interpretation?
 Wireless transfer?
- Triage: which patient needs direct transfer to a Percutaneous Coronary Intervention (PCI) centre

Transfer protocol to PCI centre: contact person

- Medication: e.g. antiplatelet therapy antithrombotic therapy In hospital management
- Initial assessment: (short) medical history current complaints (onset) – Electrocardiogram (ECG) within 10 min – biomarkers <60 min in case of Non-ST-Segment Elevation (NSTE)-ACS
 Contact person on the emergency department
- Triage: STEMI (ST-Elevation Myocardial Infarction) vs NSTE-ACS vs other diagnosis

1.STEMI: (eg flowchart)

Indication primary PCI vs Thrombolysis

Contact person cathlab - transfer protocol

Specify antiplatelet therapy - antithrombotic therapy

Admission policy

2. NSTE-ACS: (eg flowchart)

Specify antiplatelet therapy – antithrombotic therapy

Risk stratification

Indication and timing invasive evaluation

Admission policy

Pre discharge - post discharge

- Discharge policy medication checklist
- Revalidation policy secondary prevention measures
- Follow-up consultation policy

Example of elements to be included in a clinical pathway for myocardial revascularisation

Indication CABG (Coronary Artery Bypass Graft) versus PCI

- General flowchart
- Heart team discussion: which kind of patients, required participants
- Information and consent policy: patient general practitioner

CABG

- Preparation: pre-medication, preventive measures, required preoperative tests and investigations
- Anesthesia: routine per-operative monitorings cardiopulmonary back-up
- Antiplatelet and antithrombotic treatment: What? In whom? To stop when? Postoperative thrombosis prophylaxis; Heparin management when intra-aortic balloon pump; When to restart antiplatelet or antithrombotic treatment?, Antiplatelet treatment after ACS and CABG (double?, which?)
- Technical description of the procedure
- Management of the intra-aortic balloon pump in the perioperative phase (pre, per and post)
- Post CABG monitoring on intensive care unit (ICU) and ward;
 Fluid management, patient mobilisation policy, drains and wound management
- Reporting policy
- Possible complications: prevention and treatment, e.g. schedules or protocols for atrial fibrillation, tamponnade, glycemia control, renal insufficiency, etc.
- Optimization of secondary preventive measures



- Preparation: premedication, preventive measures (contrast allergy, contrast nefropathy), required pre-operative tests and investigations
- Access site policy: radial versus femoral
- Antiplatelet and antithrombotic treatment peri-procedural
- Technical description of the procedure
- Indication DES (Drug Eluting Stent) vs BMS (Bare Metal Stent)
 Sheath removal policy: closing devices?
- Post PCI care monitoring
- Reporting policy
- Possible complications: prevention and treatment
- Optimization of secondary preventive measures

Part 5: Quality assurance

Quality assurance procedures are described at 3 levels: the network, the process level and at the patient level.

At the network level

What is the overarching approach to quality assurance at the network level?

- Appointed persons, structures; mission and objectives; meeting frequencies; reporting modalities;
- Quality evaluation procedures; process and oucome data registration and input into external databases such as national registration systems (cf QERMID, STEMI database); participation to external benchmarking;
- Data analysis & reporting;
- Continued medical education policy within the network.

At the process level

- Collection and analysis of the necessary data to compute quality indicators (QI) by specific pathology/procedure (see examples in text box):
 - o Definition of QI or selection from existing QI systems.
 - Modalities of data registration for QI computation, and participation to national registration schemes (e.g. "QERMID").
 - Data analysis and reporting.
- Regular (e.g. monthly) staff meetings for monitoring of the QI results and periodic feedback;
- Mechanisms for initiating subsequent quality improvement initiatives.



Example of potential Quality Indicators for the care program cardiac pathologies

Program A (source: STEMI database)

- ACS Time points:
- o Diagnosis to PCI hospital
- o PCI centre to balloon
- Treatment %
- % PCI/Thrombolysis/conservative
- Discharge medication (dual antiplatelet, statins, ACE-I, aldosterone receptor antagonist, betablocker)

Program B (source: PCI database)

- % successful PCI
- % urgent CABG
- % re-intervention
- Adjusted mortality (1 month, 1 year)
- % postoperative AMI
- % postoperative Cerebro Vascular Accident (CVA)

At the patient level

- Communication policy towards patients and their relatives;
- Patient information documents ([URL]);
- Policy for patient participation and clinical shared decision making;
- Informed consent procedures (roles, responsibilities, timing, written material [hyperlinks], conflict management).

Part 6: Development and updating process of the manual

Description of the development process of the multidisciplinary quality manual with data sources, authors and affiliations, number of meetings, history of updates all as legally required.



STRUCTURE OF THE ORIGINAL ONCOLOGY MANUAL

Aim of the manual

The model provides a framework allowing the care programmes to specify their institutional features. For oncology, the latter were created with help of the College of physicians for oncology. It is the task of the College to supervise the quality of care of adult cancer patients in Belgium through multidisciplinary consensus and to support the Cancer Care programs in their implementation of optimal cancer care.

The proposed structure intended to facilitate the production of local manuals, and to offer a national template. The aim for both the template and the locally produced manuals is that they eventually would be available online.

The aim is that local programs use the template as the basis for their manual by complementing this with their local data and preferences. The consultation of the manual, including the guideline sections should be free and open, both for professionals and the public, including patients.

Structure of the oncology manual

This section is a short overview of the original oncology manual structure.

Cautionary statement

Quality manuals and guidelines are the product of extensive consultation. Nevertheless it should be underlined that it may be possible that on certain aspects well-founded dissension can exist. In general, guidelines should never be interpreted as a dictate but rather as a beacon helping care givers and policymakers to orient their proper actions.

Guidelines are in general not comprehensive and local programmes are required to complement them with their own preferences, which should also be supplemented by supportive evidence and local preferences can be included.



Listing of the infrastructure - services - staff

- Available infrastructure, location, opening times, contact information;
- Available personnel, with official legal specialty, name of coordinators, day hospital activities;
- List of formal collaborations with other institutions, contractual arrangements and obligations, with contact information and name of coordinators.

Development process of the multidisciplinary manual

 Development process of the multidisciplinary manual; data sources, authors and affiliations, number of meetings, history of updates all as legally required.

General strategy of the care programme

- Mission, vision, values, goals within 5 years, quality policy;
- Working arrangements of the multidisciplinary team;
- Strategy to improve the work processes;
- Strategy and targets for minimising delays;
- Follow-up and strategies on improving follow-up and reduce side effects and recurrence;
- Review of services for screened and symptomatic patients;
- Rules for the network to achieve consistency in clinical policies, organisation and care, irrespective of the patients point of entry into the system.

General clinical approach

Detailed description of the items to be registered in the medical file:

- Personal and family history;
- Anamnesis;
- Complete physical examination;
- Staging (specific for oncology to be replaced by care programmespecific items);

- Plan of treatment following guidelines or through multidisciplinary approach if no guidelines are available;
- Communication policy.

Specific clinical approach by type of medical condition in the programme

- Reference (URL) to clinical guidelines to be applied by type of medical condition;
- Reference (URL) to specific procedures by type of medical condition.

Transversal themes

Procedures and names plus function of the individuals responsible for:

- Patient information procedures;
- Psychological approach of the patient and his/her family;
- Pain management;
- Nutritional approach;
- Specific pharmaceutical procedures;
- Clinical trials participation procedures (name of data-nurse, name of president of the ethical commission);
- Rehabilitation;
- Bedsores prevention;
- Specific cultural approach;
- Palliative care and end of life approach.

Specific approach by speciality

- Lists of specific scientific groups or societies in Belgium and abroad for specific sub-specialties;
- Reference (URL) to guidelines for each topic or sub-specialty when relevant.

KCE Report 213 Cardiology Quality Manual 15

Organisational approach

- Internal multidisciplinary coordination: multidisciplinary team:
 - o Identification of coordinator(s)
 - o Frequency of meetings
 - Communication with other disciplines
- External coordination:
 - Referral and communication policy with the general practitioners
 - Referral and communication policy with home care
 - Policy of communication with other hospitals
 - Policy of communication with other specific services / institutions with which formal agreements were made
- Policy of patient participation in the decision-making process;
- Policy for quality of care: quality evaluation procedures, risk management, quality promotion;
- Data management:
 - Indicators (with at least the percentage of observed and the number of divergences with guidelines recommendations)
 - Links with external databases
 - o Control procedures used for data management
- Policy of continuing medical education of the staff:
 - Description
 - Frequency of case reviews

Description of procedure for and frequency of updating the multidisciplinary manual

Description of the procedure and frequency for updating the multidisciplinary manual.



- FPS Health. Koninklijk besluit tot wijziging van het koninklijk besluit van 15 juli 2004 houdende vaststelling van de normen waar de zorgprogramma's 'cardiale pathologie' moeten voldoen om erkend te worden - Arrêté royal modifiant l'arrêté royal du 15 juillet 2004 fixant les normes auquelles les programmes de soins 'pathologie cardiaque' doivent répondre pour être agréés Moniteur Belge / Belgisch.Staatsblad 15/06/2012; 2012. Available from: http://www.ejustice.just.fgov.be/cgi/summary.pl
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