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## Original article

# Construction of a manual of work processes and techniques from Centro de Dispensação de Medicamentos de Alto Custo (CEDMAC), Hospital de Clínicas, Unicamp

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## ABSTRACT

The Centers for High Cost Medication (Centros de Medicação de Alto Custo, CEDMAC), Health Department, São Paulo were instituted by project in partnership with the Clinical Hospital of the Faculty of Medicine, USP, sponsored by the Foundation for Research Support of the State of São Paulo (Fundação de Amparo à Pesquisa do Estado de São Paulo, FAPESP) aimed at the formation of a statewide network for comprehensive care of patients referred for use of immunobiological agents in rheumatological diseases. The CEDMAC of Hospital de Clínicas, Universidade Estadual de Campinas (HC-Unicamp), implemented by the Division of Rheumatology, Faculty of Medical Sciences, identified the need for standardization of the multidisciplinary team conducts, in face of the specificity of care conducts, verifying the importance of describing, in manual format, their operational and technical processes. The aim of this study is to present the methodology applied to the elaboration of the CEDMAC/HC-Unicamp Manual as an institutional tool, with the aim of offering the best assistance and administrative quality. In the methodology for preparing the manuals at HC-Unicamp since 2008, the premise was to obtain a document that is participatory, multidisciplinary, focused on work processes integrated with institutional rules, with objective and didactic descriptions, in a standardized format and with electronic dissemination. The CEDMAC/HC-Unicamp Manual was elaborated in 10 months, with involvement of the entire multidisciplinary team, with 19 chapters on work processes and techniques, in addition to those concerning the organizational structure and its annexes. Published in the electronic portal of HC Manuals in July 2012 as an e-Book (ISBN 978-85-63274-17-5), the manual has been a valuable instrument in guiding professionals in healthcare, teaching and research activities.

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## Construção do manual de processos de trabalho e técnicas do Centro de Dispensação de Medicamentos de Alto Custo (CEDMAC) do Hospital de Clínicas da Unicamp

### R E S U M O

#### Palavras-chave:

Reumatologia  
Terapia biológica  
Administração hospitalar  
Garantia da qualidade dos cuidados de Saúde

Os Centros de Medicação de Alto Custo (CEDMAC) da Secretaria de Saúde do Estado de São Paulo foram instituídos por projeto em parceria com Hospital das Clínicas da Faculdade de Medicina da USP, patrocinado pela Fundação de Amparo à Pesquisa do Estado de São Paulo (FAPESP), visando à formação de rede estadual para atendimento integral dos pacientes indicados ao uso de agentes imunobiológicos nas doenças reumatológicas. O CEDMAC do Hospital de Clínicas da Universidade Estadual de Campinas (HC-Unicamp), implementado pela Disciplina de Reumatologia da Faculdade de Ciências Médicas, identificou a necessidade de padronização das condutas da equipe multidisciplinar, frente à especificidade da assistência, verificando a importância da descrição, em formato de manual, dos seus processos de trabalho e técnicas. O objetivo do estudo foi apresentar a metodologia de construção do manual do CEDMAC/HC-Unicamp como ferramenta institucional, visando à qualidade assistencial e administrativa. A metodologia para elaboração dos manuais no HC-Unicamp, desde 2008, tem como premissas ser participativo, multidisciplinar, focado em processos de trabalho, integrado às normas institucionais, com descrição objetiva e didática, formato padronizado e divulgação eletrônica. O Manual do CEDMAC/HC-Unicamp foi construído em dez meses, com o envolvimento de toda equipe multidisciplinar, tendo 19 capítulos sobre processos de trabalho e técnicas, além dos relativos à estrutura organizacional e anexos. Publicado no portal eletrônico dos Manuais HC, em julho de 2012, como e-book, com registro ISBN 978-85-63274-17-5. O Manual tem sido valioso instrumento na orientação dos profissionais da área nas atividades assistenciais, de ensino e pesquisa.

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## Introduction

The treatment of rheumatic diseases has changed markedly in the last 10 to 15 years, with the emergence of new drugs, the so-called biological therapies.<sup>1</sup>

Disease-modifying drugs (DMDs) are conventional therapies that can control about 20% of symptoms in approximately 55%-60% of patients; only 10%-20% attain a response of 70% of development of arthritis.<sup>2-4</sup> However, there is a niche of patients who, even in association with conventional DMARDs,<sup>5</sup> do not achieve a good response or are intolerant (e.g., nausea with methotrexate, diarrhoea with leflunomide, maculopathy to antimalarials), requiring another pharmacological agent to improve symptoms and return to their productive lives.

Biologic therapies are so named because they are organic molecules of high molecular weight and have biological origin, i.e., produced by living beings and containing carbon atoms in their molecular structure. In general, the organic molecules used as substrates are immunoglobulins or antibodies.

However, their greater efficacy with greater specificity justifies the high cost, since the patient will be again a productive member of society. This will be possible after research on the physiopathogenesis, with biomolecular foundation, and on the activity in specific and critical points for a particular disease.<sup>6-10</sup>

In general, patients are lay people in the medical field, or even have a low level of education; thus, most of them are not equipped to handle (storage, application and disposal) self-

administered subcutaneous drugs or would not have a proper place for infusion of intravenous medications, and also do not have proper supervision. Being organic molecules, these drugs are very exquisite, requiring special care in their handling or transport.

This can be observed in medical consultations, considering that it is the responsibility of the rheumatologist to evaluate the patient response to the prescribed medication. It is known that a closer monitoring of patients with rheumatologic disease results in a better response to treatment, compared with patients in routine visits every 3 to 6 months, as that strategy enables an earlier intervention.<sup>3-5,11</sup>

Initially, this conduct of a more rigorous and closer follow-up may seem more difficult and costly. However, in the study TICORA, a survey on costs was also done, showing no increase in financial costs and a better quality of care and improved response.<sup>5</sup>

This strategy is practiced at CEDMAC, Health Department, São Paulo, considering that the visits take place with a shorter time interval and with the possibility of extra visits to check for effects and adverse events.

CEDMAC was established from a project developed in partnership between Hospital das Clínicas, Faculty of Medicine, USP, and Health Department of the State of São Paulo, and is sponsored by the Foundation for Research Support of the State of São Paulo (Fundação de Amparo à Pesquisa do Estado de São Paulo, FAPESP), aimed at the formation of a statewide network for dispensing costly medication. CEDMAC serves patients with an indication for use of immunobiological agents

in rheumatological diseases, and accompanies the indication, dispensing and application of these medications. Another important function of the Centers is the registration of users for reporting side effects; thus, CEDMAC can feed data into Brazilian Registry of Biological Rheumatology (BiobadaBrasil).

The role of specialist nurses is also crucial, because in addition to being familiar with terms and conditions, these professionals are also aware of the conventional drugs and, in the case of CEDMAC, of this new class of antirheumatic drugs. Thus, the specialist nurses interfere in the patients' education – on what is the disease, treatment options, the proper use of medication, and improvement in the degree of fidelity to its use. Thus, these professionals help increase the response to therapy. In some countries, these professionals even count joints and advice on contraception.

Another important role of CEDMAC is to establish innovative conduct protocols on biologicals, following the most current recommendations. By being in the public university scenario, the scientific knowledge is considered an essential factor, together with the reduction of costs. One of the main terms that enter into discussion in the context of biological drugs, particularly in the use of infusion drugs, is how to reduce the infusion time for each patient, increasing vacancies and obtaining full efficiency of the service with the highest quality possible.<sup>9,10</sup>

Since this is a statewide network of centers for dispensing and infusion of high-cost drugs (especially biologicals) in the field of rheumatology, there is the possibility of exchanging information with other centers, with the aim of standardizing the care in the State of São Paulo, with sharing of experiences.

The CEDMAC/HC-Unicamp was implemented by the Department of Rheumatology, Faculty of Medical Sciences. Its main goal is to benefit rheumatological patients with the use of biological drugs, with respect to guidance on this type of medication, its proper use and supervision as to their doubts and responses to therapy. Thereby, the CEDMAC also interferes to avoid the improper use or misuse of medications, as well as their loss.

Moreover, CEDMAC also must train specialized teams that will deal with this type of patient and drug, offering appropriate multidisciplinary care and providing more welfare to the rheumatic patient. In addition, data are generated from standardized consultations, with production of clinical research and exchange of information and experiences with other CEDMACs of São Paulo.

Considering the specificity of the assistance offered and the need for a clear standardization of conducts for the multidisciplinary team, it became important to develop and describe, in manual format, the work processes and techniques of CEDMAC/HC-Unicamp.

In the literature and in all certification programs adopted by healthcare institutions, there is consensus on the need of elaboration of operational manuals, even if the nomenclature of these documents may vary according to the source consulted: manuals of routines, norms, procedures, techniques, processes, or of standardized operating procedures.<sup>12,13</sup>

The manual is an administrative instrument that allow the organization and standardization of service guidelines in a health care institution, systematizing activities and their execution by different professionals; moreover, this document

establish points of process control and of measurement of results.<sup>14</sup> Manuals give subsidies for training and supervision of procedures, reducing the risk of adverse events, facilitating the revision of processes, meeting the requirements of regulatory agencies and offering protection against lawsuits generated by patients or labourers.

It is known that people produce better when following a standardized routine. This standardization reduces the variability of offered products or services, and this translates into predictable and reliable processes. The manual should serve as a reference document, being used for training teams to operate the work process. Moreover, the manual can function as a tool which facilitates the dissemination of institutional knowledge, as a benefit within reach of all interested.<sup>12,15</sup>

A discussion that still occurs in the healthcare scenario relates to the supposed difficulty in developing manuals for this sector, in which every patient is an unique being, with an absolutely peculiar clinical picture. In reality, what are intended to standardize are the processes likely to be used, and not the assistance to be provided.<sup>16</sup>

A good standardization must demonstrate essential characteristics: it must arise from those professionals who perform the tasks, be the result of consensus, be simple and based on institutional practice, should address more frequent and higher risk/complexity situations, be consistent with the recommendations and literature, follow a standard format and be accessible to all members of the institution. No single model exists for a manual elaboration. These documents may vary as to content, level of detail and format, according to the needs of each institution. Manuals are flexible, never complete or finished works, and depend on constant review and updating.<sup>17</sup>

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## Objective

To present the methodology of elaboration of the manual of work processes and techniques for CEDMAC/HC-Unicamp as an institutional tool, aiming to the best care and administrative quality.

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## Material and methods

The HC-Unicamp develops, since 2008, a program of institutional elaboration of manuals, entailed to and supported by, Hospital Superintendence, with clearly defined premises and logistical support for elaborating and formatting manuals, favoring the adhesion of multidisciplinary teams and the project success.<sup>18</sup>

The premises of HC-Unicamp Manuals are:

- Participative elaboration – to involve professionals from different hierarchical levels in the processes' description in the area.
- Description by processes, where possible, with multiprofessional, interareas and multidisciplinary approaches – to involve all professional categories in the preparation of the manual, and to describe the processes, allowing the dem-

onstration of the interrelationship of the multidisciplinary team and the different areas of the institution.

- Address liability processes of the area – to describe only proper and specific processes of the area.
- To reflect the reality and current practice – the manual must not describe idealized processes, but those that, in fact, are practiced; thus, in practice the motto prevails: *Write what you do and do what is written!*
- Depth and detail are determined by demand and interest in the area – due to its specificity, each area determines what are the important processes to be described and what level of detail is necessary to their reality.
- Objective, didactic and attractive description, with a focus on target audience – to avoid excessively detailed descriptions that make the reading process a tiresome thing. Use simple and direct language, favouring clarity.
- A standardized format – operational help for manual formatting and configuration of an institutional document, in accordance with the recommendations of certification programs and literature: standardized header and footer containing institutional logos, authors, implantation date, revision date, revision number, author and signature of the professional in charge of the area in question; use of documents and descriptive papers of activities already existing in the area, with its conversion to standard format.
- Compatibility and integration with manuals from other areas – to avoid repetitions and contradictions among manuals of different areas.
- Priority in dissemination and electronic use – to create, in the community, the habit of searching for information in the manuals in electronic format, avoiding the use of printed copies.<sup>18</sup>

The content of the manual covers:

- Mission and/or objectives of the area;
- Area relationship map – consists in a model that represents the relationship between supplier, input, process, output and customers;
- Macroflow of operational process of the area;
- Description of the various processes of the areas, highlighted in the analytical index;
- Description of the standards of occupational safety in each specific operational process;
- Annexes relevant to each area, such as: regulatory standards, bibliographies, used documents and guidance booklets.

After all processes were described in a certain area, the manual is referred to the Committee on Hospital Infection Control, that will analyze all procedures and techniques with which this document interfaces, assessing its compliance to standards and guidelines established for the infection control in the institution. If there is any non-compliance, a meeting is scheduled with the participation of members of the area of the manual in question and the HC-Manuals project coordinator, besides professionals of CCIH, for the needed conducts' agreement. After the arrangements, the president of CCIH signs the processes with which he/she has interface.<sup>18</sup>

In parallel, the manual is also forwarded to the Labor Safety Service that performs the analysis of the activities and

prepares technical recommendations for occupational safety. Regarding the use of individual protection, collective protection and protection barriers' equipment, as prescribed by legislation, in particular the Regulatory Standards of the Ministry of Labor and Employment and those issued by the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária, ANVISA) and the Brazilian Association of Technical Standards (Associação Brasileira de Normas Técnicas, ABNT). After the analyses, utterance of technical recommendations, and alignment of occupational safety conducts, the manual is signed by the labor safety technician in charge.<sup>18</sup>

With the final approval and signature of the professional in charge of the area in question, the document is converted to pdf, using a security system that prevents changing contents, printing and text fragments copying. This measure aims to prevent misuse of the document, especially unnecessary copies and plagiarism. Moreover, in order to improve the institutional control of all manuals issued, these are registered in the *International Standard Book Number (ISBN)* in e-Book format.<sup>18</sup>

Subsequently, the manual is forwarded to the Division of Informatics for allocation to a specific directory on the hospital's central server. In this directory, all books available for consultation can be found at a portal accessed by care network and intranet (Fig. 1). The access is free throughout HC-UNICAMP in more than 1.700 computers. Currently, there are 79 manuals of support, care areas, and management available for consultation.

Although each area has a printed copy of its manual, the electronic access is highly encouraged because of its advan-



Fig. 1 – Images from the manual's Portal, HC-Unicamp.



tages: less paperwork, continuous and simultaneous access to manuals, frequent updating of content, access to all manuals and not only to that of a specific area, quick identification of the desired process and easy consultation.

**Results**

The manual of work processes for CEDMAC-HC-Unicamp was elaborated in a period of 10 months, in a participative manner with involvement of the entire multidisciplinary team, and published in the electronic portal of HC-Manuais in July 2012 in form of e-Book (ISBN 978-85-63274-17-5).

The organizational structure of CEDMAC was addressed through:

- Description of the objectives of the area in question, encompassing the intervention in care, teaching and research.
- Map of supplier/process/client relationship that presents the interrelationships of the area with its key suppliers and internal and external customers (Fig. 2).
- Macroflow of the operational process that summarizes, in graphic presentation, the care process (Fig. 2).

In order to provide a basic technical knowledge indispensable to a good care practice by non-specialist professionals

of major and secondary levels, a chapter has been prepared addressing the biological drugs used in CEDMAC (Fig. 3) with respect to:

- Differences between traditional and biological medicines.
- Classes of biologicals used in rheumatology.
- Major biological drugs used; their characteristics, indications, contraindications and usual dosage.

The structure and operating rules of CEDMAC were described, as well as the duties of the professionals involved, specifying their accountability for tasks and hierarchical bonds. The profile of patients and their flow of access to the service were detailed. The origin of the administered medications, acquisition routine, control and care for their preservation were also described.

Chapters on the technique of preparation and administration for each biological medicine used in CEDMAC were elaborated: infliximab, adalimumab, etanercept, abatacept, rituximab, tocilizumab (Fig. 3). Chapters were also prepared for zoledronic acid and cyclophosphamide that, although not biologicals, are eventually prescribed and require special care in their preparation and administration. The most frequent adverse events in the administration of these drugs and the recommended actions were also highlighted.

Specific chapters detailed medical procedures and the systematization of nursing care performed in CEDMAC, as well as for administrative, teaching and research activities.

A total of 19 chapters describing the work process and techniques were elaborated, besides those relating to the organizational structure and annexes (references, documents used in the area, a chronological table of educational documents and folders).

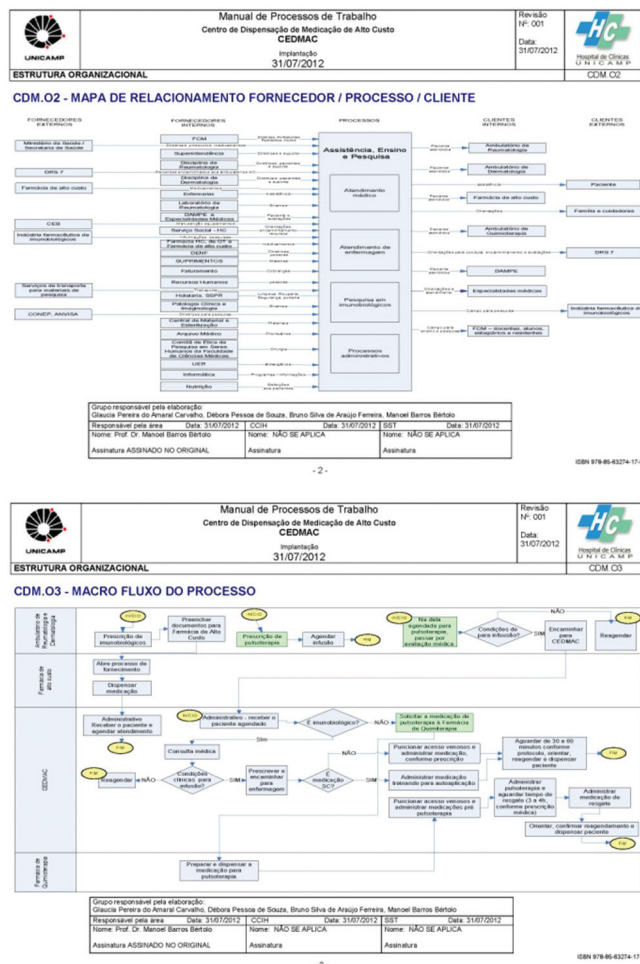
**Discussion**

Despite the hard work represented by the elaboration of the manual and of the required dedication of the multidisciplinary team, the results clearly justify it. Throughout the preparation process, care practices can be revised according to the literature and manufacturers' guidelines for their own drugs, in relation to precautions in storage, preparation, application and user assistance. Small variations in practice between practitioners of CEDMAC regarding the handling of products were observed; this way, there is opportunity for adjustments of conduct.

The possession of work processes and of described and accredited techniques facilitates the dissemination of specific technical knowledge of the area, the integration of new professionals, a continuing education for the multidisciplinary team and supervision of procedures.

Due to its teaching and research activities (characteristics of HC-UNICAMP), the manual can also function as a guidance tool for trainees, including medical residents and graduate students.

In addition to these benefits, with the manual of work processes and techniques from CEDMAC HC-Unicamp, there is a possibility of exchanging of information and experiences with other centers of infusion of biologic medicines in the area of rheumatology.



**Fig. 2 – Map of relationship and macro flow of the operational process of CEDMAC HC-Unicamp.**

	Manual de Processos de Trabalho Centro de Dispensação de Medicação de Alto Custo <b>CEDMAC</b> Implantação 31/07/2012	Revisão Nº 001 Data: 31/07/2012	
	PROCESSOS DE TRABALHO OU PROTOCOLOS DE COMPETÊNCIA DA ÁREA		

### CDM.P4 - INTRODUÇÃO SOBRE MEDIÇÕES BIOLÓGICAS

#### MEDIÇÕES BIOLÓGICAS

O tratamento das doenças reumatológicas, em especial a artrite reumatoide e a espondoartrites, mudou de forma acentuada nos últimos 10-12 anos, com o surgimento das novas terapias chamadas biológicas. (1)

As terapias convencionais (chamadas DMARD – do inglês disease-modifying antirheumatic drug, que significa droga modificadora de curso de doença) conseguem controlar cerca 20% dos sintomas em cerca de 55-60% dos pacientes, e somente 10-20% atingem reposta de 70% de evolução da artrite. (2) (3) (4) Entretanto existe um nicho de pacientes que, mesmo com associação de DMARDs convencionais (5), não apresentam boa resposta ou apresentam intolerância (p.ex: náuseas ao metotrexate, diarreia a leflunomida e maculopatia a antimetabólicos), que necessitam de outro medicamento para melhorar os sintomas e voltar a ter vida produtiva.

As terapias biológicas são assim denominadas por se tratarem de moléculas orgânicas de alto peso molecular de origem biológica, ou seja, produzidas por ser vivo, contendo átomos de carbono em sua estrutura molecular. Em geral as moléculas orgânicas utilizadas como substrato são as imunoglobulinas ou anticorpos. As bactérias e os ratos são os principais seres vivos usados na produção, sendo modificados geneticamente (normalmente com introdução de plasmídeos) para gerar uma molécula específica. (6)

**Tabela 1. Pesos moleculares de medicamentos tradicionais e biológicos**

Medicamentos Tradicionais	Peso Molecular (daltons)	Medicamentos Biológicos	Peso Molecular (daltons)
Fluoxetina	166	Etanercepte	75.000
Sinvastatina	419	Rituximabe	145.000

Fonte: EuropaBio Abril, 2009 (6)

O processo para obtenção de uma medicação biotecnológica requer muitos cuidados e técnicas complexas de produção e distribuição, tornando-o muito oneroso e exigindo mão de obra qualificada para manuseio. As etapas desse processo são as seguintes: (6)

- Identificação da molécula terapêutica;
- Sequenciamento genético;
- Tratamento da molécula para deixá-la estável, ativa e reprodutível;
- Distribuição e armazenamento em locais adequados para que não ocorra perda de função.

Grupo responsável pela elaboração: Bruno Silva de Araújo Ferreira, Manoel Barros Bertolo			
Responsável pela área	Data: 31/07/2012	CCIH	Data: 31/07/2012
Nome: Prof. Dr. Manoel Barros Bertolo	Nome: NÃO SE APLICA	Nome: NÃO SE APLICA	Nome: NÃO SE APLICA
Assinatura ASSINADO NO ORIGINAL	Assinatura	Assinatura	Assinatura

- 1 -

	Manual de Processos de Trabalho Centro de Dispensação de Medicação de Alto Custo <b>CEDMAC</b> Implantação 31/07/2012	Revisão Nº 001 Data: 31/07/2012	
	PROCESSOS DE TRABALHO OU PROTOCOLOS DE COMPETÊNCIA DA ÁREA		

### CDM.P11 – ADMINISTRAÇÃO DE TOCILIZUMABE: TÉCNICA E CUIDADOS

#### DEFINIÇÃO

O tocilizumabe é um anticorpo monoclonal humanizado antirreceptor de interleucina-6 humana (IL-6), da subclasse das imunoglobulinas (Ig) IgG1.6 Tem como alvo a inibição da interleucina-6 (IL-6). A produção anormal desta substância provoca inflamação, edema, dano articular, fadiga e anemia.

#### INDICAÇÃO

Tocilizumabe está indicado para tratamento da Artrite Reumatóide (AR) ativa moderada a grave, em pacientes maiores de 18 anos, isoladamente (monoterapia) ou em combinação com metotrexate e/ou outros DMARDs seguindo o Consenso 2012 da Sociedade Brasileira para o Tratamento da Artrite Reumatóide (<http://www.scielo.br/pdf/rbr/v52n2/v52n2a02.pdf>).

#### CONTRAINDICAÇÃO

- Hipersensibilidade ao ingrediente ativo ou a qualquer um dos excipientes.
- Tocilizumabe não deve ser utilizado em combinação com outras drogas biológicas para artrite reumatóide.
- Infecções graves como tuberculose, sepsse, abscessos ou infecções oportunistas.

#### NORMAS

O medicamento deve ser armazenado em temperatura de 2 a 8°C.

#### ENFERMAGEM

- Realizar atendimento de enfermagem conforme processo CDM.P16 – SISTEMATIZAÇÃO DA ASSISTÊNCIA DE ENFERMAGEM (SAE) e encaminhar o paciente para avaliação médica, aguardar a conduta e a prescrição para o preparo da medicação.

#### MÉDICO

- Realizar consulta médica conforme descrita no processo CDM.P15 – PROCEDIMENTOS MÉDICOS e a conduta medicamentosa (liberação ou não para infusão).

Grupo responsável pela elaboração: Gláucia Pereira do Amaral Carvalho, Débora Pessoa de Souza, Bruno Silva de Araújo Ferreira, Manoel Barros Bertolo			
Responsável pela área	Data: 31/07/2012	CCIH	Data: 31/07/2012
Nome: Prof. Dr. Manoel Barros Bertolo	Nome: Dr. Luis Gustavo O. Cardoso	Nome: Jacques Gama	Nome: Jacques Gama
Assinatura ASSINADO NO ORIGINAL	Assinatura ASSINADO NO ORIGINAL	Assinatura ASSINADO NO ORIGINAL	Assinatura ASSINADO NO ORIGINAL

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**Fig. 3 – Content images of the work manual processes, CEDMAC HC-Unicamp.**

## Conflicts of interest

The authors declare no conflicts of interest.

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