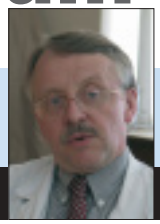
The Belgian health system



Jean-Daniel Hecq

The Belgian health system works by means of obligatory health insurance schemes that cover almost all of the population. It is related to the French system. The patient advances the money to the doctor then the insurance company (the equivalent of the Social Security) reimburses the part for which the patient is covered. However, the coverage is less complete in Belgium than in France. Cancer and childbirth, for example, are not covered 100%. The insurance companies partially reimburse most people for medicines and hospitalisation. To top up the standard cover, a private insurance policy can be taken out.

Since 1995, hospital budgets have consisted of three components: basic financing (depending on the type of institution), a fixed price is set in advance (depending on what is being done), and partial financing depending on the number of days and interventions.

The classification of All Patient Refined Diagnosis-Related Groups (APR-DRGs) has been set up as the basic method for reimbursement because it was well documented, operational, used in many countries and enables international comparisons to be made. The use of APR-DRGs for the allocation of the budget to public hospitals has met with much resistance. In 1992, the public authorities decided to adopt it: the budget is scaled up or down depending on the performance of the establishment measured by the duration of each admission classed in a APR-DRG by comparison with the Average Duration of Stay (ADS) for this APR-DRG. If the time spent in hospital is too long compared with the ADS of the group, part of the fee tied to these days is not paid. Hospitals that have a duration of stay longer than the national ADS for a DRG must give back part of the budget corresponding to these extra days. There is an equivalent calculation on the rate for replacing complete stays in hospital by outpatient attendance (a calculation of the number of extra days or days saved).

This system of finance in now being replaced by a new system of "justified bed" (by activity) and finance is awarded per admission (flat-rate APR-DRG based on the national average, regardless of the real length of admission).

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Hospital pharmacy in Belgium

Jean-Daniel Hecq

On 10 May 2003, the Belgian Association of Hospital Pharmacists (ABPH) celebrated 50 years of existence. Created in 1953, this professional and scientific association represents all pharmacists who work in Hospital Institutions, whether private or public, university, general or psychiatric.

The professional life of a Belgian Hospital Pharmacist is regulated by different Royal Decrees (AR). In 1978 the obligation appeared in the "Moniteur", the official journal that publishes all laws and Royal Decrees, requiring the presence of a pharmacist in all hospitals of the Kingdom (AR of 19/10/1978).

It was about the same time that the Belgian Universities introduced a programme of specialisation in Hospital Pharmacy and that the profession started to differentiate itself from that of pharmacists working in dispensaries open to the public.

Belgium

The possession of this additional qualification for the right to practice in a hospital environment became compulsory in 1986.It was in 1989 that, following the federal trend within the country, 2 regional Associations were created: one for Dutch speakers (the Flemish Association of Hospital Pharmacists - VVZA) and the other for French speakers (the French-speaking Association of Belgian Hospital Pharmacists - AFPHB). These Associations are represented within the ABPH. And it was the AR of 04/03/1991 that fixed the standards which a hospital pharmacist must satisfy to be approved that went on to significantly regulate the general and specific tasks of the pharmacist within his/her Hospital Institution, creating on the same occasion the term "Fonction hospitalière" in order to classify Hospital Pharmacy within it.

In Belgium, Hospital Pharmacists are responsible for pharmaceutical specialties, extemporaneous preparations, antiseptics and disinfectants, registered dietary products, medical and surgical equipment, implants and prostheses, radio isotopes, medical gases and products that are under investigation by clinical trials.

The general duties of the Hospital Pharmacist are standard:

- the individualised distribution of medicines;
- the preparation of non sterile and sterile medicines;
- the supply, keeping in stock permanently and appropriate storage of medicines;
- the analysis and quality control of raw materials and medicines.

The specific tasks are very numerous:

- the organisation of an effective, safe and economic system of distribution in the various hospital units;
- integration into multidisciplinary teams in order to optimise therapeutic efficacy and safety;
- the collection, processing and distribution, in a structured manner, of all the necessary pharmacological, toxicological and pharmaco-technical information concerning the medicines used in the hospital;
- active collaboration with the nursing staff regarding the use of medicines;
- the organisation and promotion, in collaboration with the medical team, of pharmacovigilance activities;
- partial responsibility for the sanitary arrangements for hospitalised patients and discharged patients, in collaboration with the medical and nursing staff;
- making available for the hospital departments antiseptic and disinfectant solutions of an appropriate quality for the therapeutic necessities;
- to guarantee at a qualitative level the daily activities of the sterilisation unit;
- supervision of the galenical preparation of injectable solutions of radio-pharmaceuticals;
- drawing up, in collaboration with the doctor in charge of the hospital, an annual report, of the hospital as a whole and by department, of the consumption and cost of the medical treatment, and a report on the relation between the consumption of medicines and the pathologies treated in the hospital;
- contribution to clinical trials whenever they are performed in the hospital;
- contribution to the rapid and suitable treatment of cases of poisoning.

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The distribution of medicines in Belgian hospitals

Arnout Verlinden

The legal position

The distribution of medicines in hospitals is tightly regulated in comparison to the situation in public pharmacies. The various legal documents state that before any medicine is given to a patient on a medical prescription the name of the patient is required and that the distribution must be done on a named patient basis, in other words the principle of unit dose distribution is enshrined in law. Exceptions to this are the distribution of medicines to operating theatres, the casualty department and intensive care units. For urgent situations a limited stock of medicines is allowed on the various wards.

The present situation

By comparison with this very detailed legislation the reality in hospitals is very different. In real life, medicines distribution can take the form of very comprehensive stocks of medicines being kept on the wards, supplies being made for a defined period from the pharmacy for named patients and we even have the strict unit dose distribution for 24 hour periods. All hospital pharmacists operate an on-call system to ensure that medicines are available outside the opening hours of the pharmacy.

To improve the distribution of medicines a number of hospital pharmacists repack medicines in unit doses. In addition automatic dispensing units with limited access have also been introduced in hospitals over the last few years as an alternative to the more accessible medicines store cupboards.

Important reasons for these wide variations in practice are the reluctance of the authorities and hospital managements to make available the necessary resources for hospital pharmacies to operate as they are legally required to do so and the very limited introduction of standards within hospital pharmacy.

What would we like to happen?

The professional association of hospital pharmacists is naturally a proponent of strongly patient-oriented distribution of medicines. It states that in this model the hospital pharmacist can contribute significant added value in the optimisation of drug therapy such as evaluating the prescription and supplying the medicines ready for administration. If this were to happen and a number of activities currently performed by the nursing staff were taken over by the hospital pharmacy, the nurses would be able to concentrate more on nursing the patients.

Additional resources from the authorities and redistribution of the resources within the hospitals will be necessary if hospital pharmacists are to be able to meet their legal obligations. The implementation of electronic communication between doctors, hospital pharmacists and the nursing staff will also contribute to it in due course.

So this means that medicines always having to be supplied by the hospital pharmacist sets a logistic challenge for administration and makes electronic communication almost imperative. As the authorities are not providing additional resources to enable us to comply with the legislation it is very difficult for hospital pharmacists to meet their legal obligations.

One of the possible distribution systems, widely used in the United States of America, is unit-dose distribution per patient per 24 hours. This model shifts the work from the ward to the pharmacy and this has very little effect on the total staffing level of the hospital. This model requires electronic communication between wards and the pharmacy in the contemporary hospital scenario, where a rapid response to changing treatment is necessary.

In addition it requires far-reaching flexibility as regards hours of work of both hospital pharmacists and specialist physicians and a presence even during the weekends.

As the professional association of hospital pharmacists we are satisfied with the legislation in place but in order to do as it directs we have got to find creative solutions to a number of problems. These problems are: the shortage of resources and the reorganisation of the workforce.

In Belgium it is always the case that the hospital pharmacy does not generate revenue and therefore no additional income will be obtained for the additional activities referred to above.

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Clinical pharmacy

Ludo Willems and Dominique Wouters

Clinical pharmacy started several decades ago in the Anglo-Saxon countries. In this system hospital pharmacists work on the wards and the main aim is to optimise the use of medicines. This focus by hospital pharmacists on clinical work has so far not become generally established on the European mainland and the Belgian situation is no exception. In practice most Belgian hospital pharmacists devote their working time primarily to standard pharmaceutical duties.

Nevertheless in Belgium clinical pharmacy can be regarded as a legal requirement. Alas, and this is the case for the very many duties in this Royal decree, the resources needed to fulfil these obligations have never been allocated and for a long time clinical pharmacy never came to life in the hospitals.

In recent years Belgian hospital pharmacists have to an increasing extent became aware of their opportunities as providers of pharmaceutical care. This has already led to small-scale projects in which hospital pharmacists have become partners on the wards to doctors and nurses in drug treatment. A number of hospital pharmacies regularly perform drug use evaluations and inform the doctors about the consumption of medicines linked to information about the pathology.

After all because of complex reimbursement rules for administered medicines Belgian hospital pharmacists have a mine of information at their disposal.

But it is these very reimbursement rules, whereby all administered medicines can be invoiced to the patient or his/her health insurance company, that ensure that hospital managers derive no financial benefit from the rational use of medicines. In other words the consumption of medicines is not included in the hospital's budget. Precisely this argument, the medicines budget, was in the past one of the drivers for the development of clinical pharmacy.

In addition to these early initiatives the relation between medicines and the patient is increasingly finding a place in university courses, both in the training to become a pharmacist and in the specialisation year for hospital pharmacist. Periods of training on wards are bringing pharmacy students into direct contact with doctors and patients and are making them more familiar with the possibilities of clinical pharmacy.

Recently some universities have developed specific programmes to encourage clinical pharmacy in hospitals.

One programme, part theoretical, part practice-oriented, prepares hospital pharmacists for their tasks as clinical pharmacists. The rational use of medicines, drawing up plans for the provision of pharmaceutical care and working in partnership with doctors form part of this course. A certificate in clinical pharmacy is associated with this course. Additional information can be found on the website www.md.ucl.ac.be/pharma/pharmacie-clinique

Another university is offering a restricted number of hospital pharmacists the possibility of practising clinical pharmacy in their daily work, supported by specific courses about the pathology being treated. This practice-oriented training is also rewarded with a specific certificate.

The next few years will be crucial for the development of clinical pharmacy in Belgian hospitals.

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Computerised medical prescribing in Belgium

Philippe Goulard and Dominique Wouters

For more than 20 years, computerised communication has been becoming a fact of life despite developing faster than the legislation. Continual changes of technology have an enormous impact on the costs and quality of work. The principal advantage of the electronic revolution is rapid accessibility to good quality information. Meanwhile, a legal framework is being erected for electronic prescribing.

Historical background

Since the end of the 1970s the administrative departments have started to computerise patient admissions and their invoices. Our hospital pharmacies were involved

from the start. Our colleagues thus became familiar in particular with the first computers and their databases.

Later, all the medical departments developed their own applications, thereby creating a veritable Tower of Babel within each hospital; a great store of data was accumulated by each department separately. The duplication of information persuaded all those in charge to organise a reaction to this problem.

The administrative rules in Belgium

In Belgium, the administrative duties of hospital pharmacists grow more onerous from day to day. For example, many prescribed specialties are reimbursed according to criteria submitted for approval to the Public Health authorities. So, during the last "Health dialogues" of Sunday 25 January 2004, the Minister of Public Health promised to relax the procedures.

Evolution

During the 1990s "client-server" technology gave us a way round the problem of exchanging information between departments. The information available on a server became available to any departments with read or write access rights as the computers became attached to networks. The possibility of exchanging information, the fear of the year 2000 bug and the increased capacity of hard discs at ever-reducing prices pushed many hospitals to re-write their applications.

Therefore some hospitals succeeded in developing systems for the electronic prescribing of medicines.

Others chose to re-write a more powerful management application that is now well suited for the current administrative workload.

In 2001, hospital pharmacists and the computerised systems were monopolised by further changes, in particular the entry of generics onto our market together with changes in the mechanisms of reimbursement. Furthermore, the preparation of reports of consumption by ATC code in terms of DDD and DDA by prescriber has become obligatory. These reports have to be sent to the members of the Medico-Pharmaceutical Committee in order that rational measures aiming to reduce the hospital's consumption of drugs may be taken.

The effort required to keep up with this turn of events has therefore significantly curbed the development of electronic medical prescribing systems, which explains why today, only a few hospitals in fact have them.

The case for electronic prescribing

In the last the few years electronic medical and nursing records have become established. Being able to consult digitalized images in the medical record has aroused the interest of prescribers who in turn have started to ask for prescriptions to be computerised.

Data from the international literature demonstrates that medication errors are responsible for 20% of complications with treatment. The setting up of a computerised prescribing system would reduce this error rate significantly.

This system also enables the doctor to be informed of the limited range of articles available in the hospital's therapeutic formulary, alternatives to them and their cost. Finally it offers the advantage of a full and clear view of the treatment, enables the stocks held in emergency cupboards to be reduced and facilitates writing the patient discharge letter. In the near future, data capture at the patient's bedside will become possible with the introduction of wireless technology.

Pre-requisites

A worthwhile prescription system must be able to check the doses prescribed (lethal doses and maximum daily doses), analyse the pharmacological interactions between the various drugs, give the prescriber and the nursing staff complete information about the medicine (contraindications, side effects, recommendations for usage, etc.). It must have a functional way of checking the dose in terms of parameters entered in the medical or nursing records (allergies, dose/weight, etc.). Finally, it has to master the physico-chemical incompatibility of certain combinations.

Today in Belgium

Many groups of hospitals and commercial companies are actively studying the incorporation of prescribing upstream of the management software. Over the next five years, a large number of hospitals will start to use such systems.

This computerisation will then enable the Medico-Pharmaceutical Committee in any institution to conduct an enquiry into the quality of the prescribing.

At the present time there are no studies in Belgium that analyse the frequency, the aspects, and the determinants of the quality of prescribing. Such a tool would also enable doctors to asses their own prescribing information. This knowledge is really indispensable if we want to improve or rationalise the prescription of medicines whether the intention is to improve Health Public or to control the budget, for example if fixed prices are introduced.

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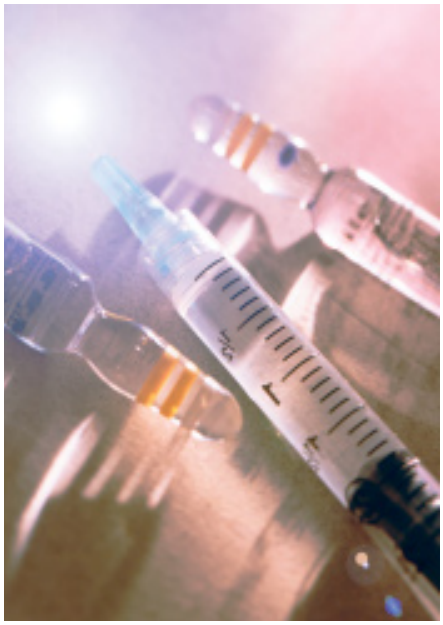
Central Intravenous Additive Services CIVAS

Jean-Daniel Hecq

In the hospital environment, a large proportion of medicines are administered by the intravenous route. Even today, the majority of these injectables are prepared extemporaneously by the nursing staff. On the other hand, the operating theatre is generally the only aseptic area of the hospital institution apart from possibly an aseptic unit for cancer patients.

The progressive growth in preparation of injectables

At the end of the 70s the preparation began of standardised parenteral nutrition formulations under horizontal laminar air flow hoods or in isolating units. The first solutions to be made were 2-component mixtures (amino acids + glucose) then these were followed by 3-component mixtures (amino acids + glucose + lipids). The factors that drove this new undertaking by hospital pharmacies were a need to improve the bacteriological quality of the finished product, improve its physico-chemical quality and reduce the workload of the nursing staff.



During the 80s the anti-cancer drugs in turn came within our remit and were prepared under vertical laminar air flow hoods or in isolating units. The desire to protect the operator, whether that was a hospital pharmacist or pharmaceuticals technical assistant, was another argument in addition to those used to justify the preparation of solutions for parenteral nutrition, as these substances were obviously toxic to handle. First to be taken on were courses of chemotherapy for hospitalised patients. Then the service extended to treatment for day patients. Progressively, these preparations prepared extemporaneously were transformed into the production of stock. This was quite an easy step for solutions for parenteral nutrition but the development of standardised doses for courses of anticancer chemotherapy took more time.

However, there remained the body of other injectables namely the antibiotics, the antiemetics and the analgesics. The stimuli to prepare these medicines were identical to the previous reasons with the addition this time of an economic aspect. This is because we were now talking of preparations in larger quantities, of standardised doses prepared more rapidly and at a lower cost in terms of the equipment used and the personnel. Gradually the concept developed of a Centralized Intravenous Additive Services (CIVAS).

The advantages of a CIVAS hinge on the reduction in medication errors, the administration of medicines at the right speed and the right time and a reduction in the risk of microbiological contamination together with the risk of phlebitis without mentioning the protection of the hospital personnel from dangerous substances.

These different steps were marked by publications about good practice distributed to the members of the ABPH-BVZA. These included

- "Practical recommendations for the preparation of parenteral nutrition mixtures" .ABPH - BVZA 1988
- "Cytostatics" VZA 1986 & "Cytostatics in Hospital Pharmacy ", AFPHB, CD-ROM 12.2002
- "Centralised intravenous additive service (CIVAS). Implementation manual for Belgian Hospital Pharmacists. ABPH-BVZA 1999"
- "The stability of injectable medicines in Infusion" CD-ROM 2004 edition

Conclusion

In addition to the guarantee of physico-chemical and bacteriological quality, the principal advantage of a CIVAS is to free the nursing staff of the tasks of preparation of injectables so that they can spend more time caring for the patients. The establishment of a CIVAS contributes to the rational management of healthcare institutions.

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Sterilisation in Belgium

Chantal Faber

The legal position.

In Belgium, a number of official documents are concerned with sterilisation.

The Royal Decree (A.R.) of 4 March 1991 fixes the functional standards that a hospital pharmacy must satisfy to be approved. One of these concerns the responsibility of the hospital pharmacist in matters of sterilisation.
This is because it falls to hospital pharmacists to guarantee the level of quality of the daily activities of the sterilisation department. This responsibility lies particularly in validating the procedures, in giving advice concerning the equipment and the methods of sterilisation, by monitoring preliminary stages such as cleaning, disinfection or the packaging as well as approving the conditions under which and the time for which the sterile materials may be stored.

The High Council for Public Hygiene has drawn up two series of Recommendations:

- Recommendations regarding the techniques of sterilisation (1993) the purpose of which is to provide a good practice guide for the managers of healthcare institutions and for the personnel responsible for sterilisation, to assist them in their work.
- Recommendations formulated to prevent the transmission of Transmissible Spongiform Encephalopathies (TSEs) in a hospital environment were published in February 2001.

These Recommendations do not constitute legal requirements. Nevertheless they are regarded as good practice guides to be followed by the users.

For its part, the Ministry of Public Health seeks to elaborate specific Sterilisation Standards and, by the same token, poses the crucial problem of the resources that will need to be found both in terms of personnel in charge of applying these standards and to finance the inspectors whose responsibility it is to verify their application.

Directive 93/42/CEE imposes the duty of vigilance for medical devices on the Ministry of Public Health and in particular the Pharmacy Inspectorate.
The consequences of these legal documents are clear: if equipment for single use is used more than once in a healthcare institution, everyone involved, in other words not only the pharmacist responsible for the sterilisation but also the doctor who reuses the disposable medical device and the hospital managers, may be held responsible by the civil and criminal courts if any injury ensues.

The Pharmacy Inspectorate for its part considers that single use medical devices represent the way of avoiding transmitted infections. Following the example of the French Health Products Safety Agency (AFSSAPS) it would like to see the banning of medical devices for multiple usage if their reuse is risky, for example, if they are difficult to clean.

Traceability: a precious tool

Traceability is, according to the ISO 8402 standard, the ability to recover the history, the use or the location of an article or an activity, or of similar articles and activities, by means of a recorded identification.
In some hospitals, the manager of the Sterilisation Department will be able to use software that enables the equipment to be traced.

Each item to be sterilized receives at the start of reprocessing, a unique sterilisation number that will also appear in the patient's records. All the stages of the reprocessing (cleaning, disinfection, packing, sterilizing equipment) are regularly validated. Thus, in the event of a legal investigation, each of the different areas of sterilisation is able to furnish evidence that it has followed the procedures in force at each step of the process.

Like all hospital departments, the sterilisation department must possess tools so that it can be assessed and any changes in productivity (volume and ratio) and production costs (per product and per client) can be monitored.
Traceability enables the consumption of resources to be determined by cost centre and this to be compared with that of other equivalent institutions. The comparison of costs with those of the industry or of subcontractors must also be possible. Traceability software provides an appreciation of the extent and the condition of the stock of instruments available, in stock, being repaired, together with a follow-up on any losses.
Traceability may yield some information for deciding the best financial strategies in the light of the facts it reveals (this or that device is used rarely or frequently, needed urgently, etc.).

In the end advantages will be structural, because with the help of the computer system each person finds the reference points necessary to perform his/her own activity in addition to information relating to production as a whole: the urgency with which the item is needed, the washing procedure, information on where the item is in the reprocessing sequence or if it has already been sterilised and the quantity and the availability of the instruments of which it is composed, their packaging, their mode of sterilisation, the content of any loads in the sterilizing equipment, etc.

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Hospital hygiene

Jozef Goossens

To further hospital hygiene a Hospital Hygiene committee is required to be established in every hospital. This is a advisory body that reports to the Medical Director, on which in addition to the Hospital Manager, the Medical Director, the physician with the post of Hospital Hygiene Officer, the microbiologist, the Chief Nursing Officer, the nurse in charge of hygiene and three physicians from the institution, a hospital pharmacist also has a seat. This committee is charged with a number of tasks, but the contribution of the hospital pharmacist will be primarily focused on the following domains:

- sterilisation
- disinfection and general hygiene (kitchens, hand disinfection, controlling Legionella, etc.)
- the antibiotics policy.

Sterilisation.

In Belgium the activities of the central sterilisation department fall under the responsibility of the hospital pharmacist.
The hospital pharmacist takes joint responsibility for which cleaning and sterilisation techniques will be used in the central sterilisation department and advises on the purchase of the equipment.
The processes and the standards by which the sterilised materials are passed for use are developed in consultation with the hospital hygiene officer and the bacteriologist.
They are submitted for evaluation to the committee for hygiene and implemented following approval by this committee.

Disinfection and general hygiene

Belgian Hospitals strive for a common policy in the choice and the use of disinfectants. The range of products is consciously kept restricted to simplify the use and supervision of these products.
Hospital pharmacists employ discussion with the consumers to estimate the needs and the objectives for the use of these disinfection products.
In the hygiene committee they jointly determine the choice of disinfectant after studying the literature. The correct indications for use, the concentrations to be used and the contact times are laid down in procedures. These procedures are explained and introduced via in-service training.
The introduction of these products is followed by a check and monitoring of the disinfection techniques in the departments.
The impact on the skin, the mucous membranes, wounds, the instruments and the equipment used in care is evaluated and if necessary corrected.

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Antibiotics policy specialists

Ludo Willems

In the mid-90s a general consciousness emerged in Belgium to an increasing extent both from those working in the health care sector and the authorities concerning the use of medicines in general and antibiotics in particular. Doctors, pharmacists and patients were made aware of the dangers that are associated with the injudicious use of antibiotics via the professional literature and the media.
In an effort to optimise the use of antibiotics in hospitals it was decided in 2001 to work with specialists in antibiotics policy. The authorities provided the hospitals with the financial means to pay for these specialists. The scientific associations of medical specialists and hospital pharmacists, together with the universities, prepared a training programme that consisted of lectures and practical training courses in different departments of the hospital. Subjects such infectious diseases, microbiology, hospital hygiene, monitoring the consumption of antibiotics and Evidence Based Medicine are taught.
With this project the authorities have placed hospital pharmacists together with medical specialists in the field of antibiotics. Hospital pharmacists are after all the pharmaceutical care providers who are associated with very many aspects of the use of antibiotics, ranging from the selection of these medicines in the Medical Pharmaceutical Committee and their prescription to the collection of data regarding their use as regards the patient, prescriber and department. In this project hospital pharmacists work closely with specialists in infectology, microbiologists and the hospital hygiene officer. The authorities hereby also recognise the clinical role that hospital pharmacists are required to perform in the hospital.
The participating hospitals are financed for this if they provide proof of the activities of the antibiotics policy specialists in promoting the rational use of antibiotics. Hospital pharmacists are playing a determining role in this in most hospitals.
It is the intention of the authorities in the future to appoint antibiotics policy specialists in all general and University hospitals.

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The Medical Pharmaceutical Committee

Jean-Luc Taziaux

The creation of a Medical Pharmaceutical Committee (MPC) was made a requirement by the royal decree of 4 March 1991 amended by that of 20 August 2000 that has to be complied with in full by every hospital to gain the licence approving the hospital pharmacy.

The committee is composed of the Hospital Manager or his representative, the Chief Pharmacist and one or several other hospital pharmacists, the Medical Director, doctors designated by the Medical Committee and, as the case may be, other specialist doctors and the Chief Nursing Officer.

The hospital pharmacist occupies a dominant position on it as he or she prepares the agenda and chairs the meeting.

The most important mission of the MPC is the establishment and keeping up to date of the Therapeutic Formulary, an obligatory list of medicines selected in a reasoned and financially justified manner; these medicines should always be available to satisfy diagnostic and therapeutic needs. This is an essential tool with which the pharmacist manages the hospital pharmacy and places intelligent restraints on the stock of medicines. He/she must ensure that this Formulary is strictly followed in his/her hospital.

The other missions of the MPC are the standardisation of procedures relating to the use of medicines, the analysis of their consumption in the hospital by department and by doctor, and a comparison of this with national and international figures, more particularly in terms of comparable pathologies, and reporting on this to the Minister of Public Health and Social Affairs and to all the doctors in the institution,.

It goes without saying that this committee must work in harmony with the Medical Equipment Committee, the Hygiene Committee, the Transfusion Committee (RD 16/04/2002) and lay the ground rules for the Antibiotic Therapy Committee.

It is an undeniable fact that hospital pharmacists at present occupy a central position, by virtue of their expertise and view of all the hospital activities, and are therefore well placed to control the movements of medicines.

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Quality in Belgian hospital pharmacies

Constant Smets

The Belgian hospital pharmacist is responsible for a very wide range of products and complex, continually changing, processes. Monitoring these is a day-to-day concern. The distribution of medicines is a striking example of this.

The authorities have brought in a quality decree in accordance with which the hospital is required to pursue a number of quality exercises. The most important goal is the implementation of electronic prescribing as a quality-enhancing element and delivery of medicines in unit dose form.

Different hospital pharmacies have set up quality systems of their own initiative.

When deciding between the different quality systems the ISO9001 standard was selected because this appears most suitable for hospital pharmacies: the ISO system covers all the processes of hospital pharmacy: administration, production, distribution, sterilisation, purchasing, etc.

The first hospital pharmacy obtained ISO certification in 2001. Subsequently a number of hospital pharmacies throughout Belgium have obtained this certificate.

Quality is a system in which an upwards quality spiral is achieved by continual effort: a process of planning, executing, evaluating and making readjustments.

An essential component of this system is assessment: performing audits. ISO requires both internal audits (self checking) and external audits (by certificating bodies).

To generate added value from the internal audits it was decided to inaugurate a system of peer review. Use is made of an evolving review list as a neutral tool: hospital pharmacists from one hospital evaluate another hospital pharmacy. Enormous added value is created by passing on our knowledge and sharing our experiences.

Through using ISO certification Belgian hospital pharmacists have succeeded in greatly improving the quality of pharmaceutical care.

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Traceability of implants

Dominique Wouters

The monitoring of implants and medical devices in the hospital is a complex undertaking that requires a tripartite collaboration between doctors, nurses and pharmacists.

Traceability means the ability to retrace the history, the use or the location of an entity by means of identification records.

Traceability in the health system enables the patients and the healthcare professionals to be protected, to help in the determination of their respective responsibilities and to facilitate the modalities of execution.

Traceability consists essentially of managing the information in a completely rigorous manner so as to ensure health is safeguarded. The traceability of implants and sterile medical devices is ensured by collecting the following information: origin and supplier of the product, date of entry of the product to the pharmacy, a record of the serial number and the expiry date of the product received by the pharmacy, locating the implant in the hospital, implantation or implant-patient liaison, invoicing the patient and managing any problems.

There is a requirement to trace active implants; the others are left to the free appreciation of the hospital pharmacist.

In some hospitals computer programs are being considered to improve the system by tracing the implants and medical devices using a barcode assigned upon entry of the implant to the pharmacy. This barcode will be read in the operating theatre during the intervention and the pharmacy will process the data. A relation with the operations protocol is also envisaged.

These new computer programmes will enable the traceability and the logistics to be of high quality; they help share the information by making data about the implants available to the surgeons and nurses. This allows the much more rapid access to the information in case of difficulties, particularly when it comes to recalls of equipment or if there are lists of patients to contact to check the devices or the implants.

Traceability is becoming a major imperative and demands close collaboration between those who contribute to it within the hospital, doctors, nurses, hospital pharmacists but also a partnership with the industry and the Public Health Authorities.

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The Medical Equipment Committee

Fabienne Snackers

The Royal Decree of 04/03/1991 requires all hospitals to create a Medical Equipment committee (MEC). This is composed of the Hospital Manager, one or more pharmacists, of the Medical Director, doctors designated by the Medical Committee, the Chief Nursing Officer, a nurse designated by the Chief Nursing Officer and the hospital Hygiene Nurse. This committee was created at the same time as the Medical Pharmaceutical Committee (MPC) and its aims are the same only in the area of sterile medical-surgical equipment, implants and prostheses.

This committee is responsible for drawing up the list of sterile medical-surgical equipment available together with that of implants and prostheses. It standardises the procedures relative to the use of the products selected.

This committee has to arrange the different steps of choosing the equipment: from deciding what is needed taking into account what is commercially available, conducting trials, and the final decision, followed by drawing up a suitable protocol for the use of the new product.

At the conclusion of this process, the MEC frequently takes an active part in vigilance for medical devices, either in the monitoring of incidents or risks of incidents relating to the use of medical devices. Vigilance for medical devices is a requirement of the AR of 18/03/1999 relating to medical devices.

This is because, any malfunctioning or any alteration in the characteristics and/or performance of a device together with any shortcoming in the labelling or in the instructions that might lead to death or a serious deterioration in the patient's state of health must be reported to the Pharmacy Inspectorate.

The MEC plays an important role along the same lines by documenting any difficulties with the use of a selected product within the hospital. These observations may lead to the necessity of additional training of the caring personnel, exchanging a faulty piece of equipment or the reconsideration of a poor choice. It is clear that hospital pharmacists are a key element of this MEC when it comes to the choice of products and follow-up of their use because pharmacists know what is commercially available, are technically competent and take the main responsibility for hospital purchases.

It is certain that the quality of the medical equipment has a direct bearing on the quality of the care accorded the patient.

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