

## **I. Introduction**

The right for access to high-level health care is declared to be basic right of EU citizens. The clients receiving care have the justifiable expectation towards the health care providers to do their utmost to ensure safe health care for their patients.

Patient safety is the primary field in quality of patient care that applies to immunity from accidental damage during medical treatment. It calls for activities to avoid, prevent and correct adverse events, care failures, to define and analyse risks and events related to patients for a safer treatment and care and to prevent and decrease the patients' health damages.

Nosocomial infections are stated first amid the most frequent mistakes occurring in health care.

The average incidence of hospital infections is 5-15 per cent showing a lower rate than the average in some hospital profiles e.g. obstetrics, paediatrics, neonatal unit, internal medicine; (obstetric unit – 1.3%, neonatal unit - 0,5-2%, unit of internal medicine - 2-5%). However, their development can be reckoned with a higher frequency in the manual departments, e.g. surgery – 3-10%; ICU – 10-20%; PIC, NIC 3-40%; chronic care unit – 5-15%. The average mortality of hospital infections is 1 per cent, though in certain clinical forms, e.g. in blood stream infections, the mortality can be 30-70-90 %.

According to the Report of European Centre for Disease Prevention and Control in 2008, in the health care institutions providing acute care of developed countries the average rate of Health Care-Associated Infections (HCAI) is 7.1%, with extreme values of 3.5 % (Germany 1999) and 10.5% (Canada 2002).

In EU countries, annually 3 million persons are affected by infections related to hospital care, and every tenth EU citizen receiving hospital care will suffer hospital infection. About fifty thousand from them have a fatal outcome of their infections.

Taking the estimated 5 per cent of incidence of hospital infections in Hungary as the basis, according to my calculations the number of hospital infections is 90 000 counted on 1 800 000 discharged patients in 2006; the estimated number of death cases due to infections is 900 viz., 1 per cent!

The calculated data show that annually, in Hungary, the lives of 900 persons could have been saved (nearly double the number of death cases caused by cervix cancer due to the defect of screening) with the efficient use of infection control, one of the important tools of primary prevention. Hereby, not only the mortality due to nosocomial infections belonging to preventable deaths within surplus deaths will be decreased, but also on this track both the mean expectation at birth and quality of life can be improved. Currently, to improve the citizens' quality of life is one of the priority targets of EU, including the general improvement of the quality of hospital care. The incidence of nosocomial infections is the quality indicator of hospital care within health care.

Hospital infections caused by pathogens resistant to one or more antibiotics should be highlighted. In addition to their threat to patients, their treatment burdens a significant surplus cost for the budgets of institutions. Such is the methicilin resistant *Staphylococcus aureus* (MRSA) that causes about 5% of nosocomial infections in Europe. The multi- and pan-resistant enterococci, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Acinetobacter* species cause increasingly more concerns. The imprudent use of antibiotics provides the main factor for the development of resistance.

In 1950s and 1960s, the issue of hospital infections received attention, and surveys were performed to explore their morbidity, mortality and lethality relations and the related costs. However, these examinations were performed by various aspects and methods. As lacking the common assent, even it was non-evident what notion was connected to the different designations by the various authors. Even now, it is hard to establish accurately the international rates and trends.

In the recent years, several, current surveys and surveillance examinations in Hungary and abroad have been performed with definitions using the nearly same content. They provide useful data and are suitable to evaluate the real burden of HCAs and to plan effective preventive measures with special attention to the fact that it is proved on the high level of scientific evidences that 30-50% of hospital infections (depending from manifestation) can be prevented with the use of appropriate tools of hospital hygiene/infection control.

## II. Target

In Hungary, appropriate infection control system, development of IT system, exact definition of tasks of health care providers and authority are required for the achievement of data collection and analysis with uniform content and interpretation, for the performance of adequate measures and the control of their accomplishment, and for making the necessary modifications.

The target of my paper is to collect the currently main characteristic factors causing the development of nosocomial infections and outbreaks, using these factors to show all the possibilities and necessities that can be introduced and applied for the improvement of present situation in hospital hygiene within Hungarian health care, and for the prevention and decrease of HCAs. In the interest of all that, with the definitions hereinafter and analysis of our collected characteristic data we achieved our outcome, the issuing of ministerial decree that regulates the activity in this field:

- notion, aim, system, and economic impact of infection control
- content of infection control, and within it the epidemiological features of nosocomial infections
- evaluation of data generated by the Epidemiological Control System and Information System (EFRIR), and by its part, the National Nosocomial Surveillance System (NNSR)
- collection and evaluation of data generated by the Complex Control System

I had in view to achieve the new legal regulation, the issuing of **Decree 20/2009.(VI. 18.) EüM** on the prevention of Health Care-Associated Infections and on the minimum conditions of these activities; this regulation became essential as verified by the collected data.

As a further result of our exploration, **I made suggestions** with which the development and spread of hospital infections, occurrence of outbreaks, further unjustified sufferings of patients can be prevented, and the surplus costs of patients' treatment and nursing due to all these can be saved; favourable changes can be achieved in the morbidity and mortality rates of the country, and in the mean expectation of life at birth.

### **III. Materials and method**

For the analyses, I applied mainly the data of various volumes of Hungarian Central Statistical Office (KSH) and National Population Health Survey (OLEF). Within this area of my work I relied on Péter Józán's work with the title of "Crisis and renewal in epidemiological development in Hungary after the World War II" published in 2008.

The international data are mainly from the database of World Health Organization and of the European Centre for Disease Prevention and Control (ECDC).

My direct aim was the data collection and analyses to verify the need for legal regulation based on in addition to the above-mentioned, partly on data from the Epidemiological Control System and Information System (EFRIR), and its part, the National Nosocomial Surveillance System (NNSR), and partly from the so-called Complex Control System.

The "National Nosocomial Surveillance System" (NNSR) started as a part of the Epidemiological Control System and Information System (EFRIR) in Hungary, November 1, 2004. NNSR has been a participant in the EU data collection system: it has participated in the programme of Hospitals in Europe Link for Infection Control through Surveillance (HELICS) since 2003, a surveillance-based infection control network of European hospitals, and in the programme of Improving Patient Safety in Europe (IPSE) since 2005.

The NNSR includes surveillances based on microbiology, patients and units; the efficiency of surveillances is ensured by the use of standardized methodology and identical definitions (case definitions elaborated by CDC in 2002 and 2004 for nosocomial infections in active institutions of inpatient care and HELICS definitions, respectively).

The NNSR is a web-based surveillance system, not having a paper-based form. In the beginning, the hospitals joined to it on a voluntary and anonym basis. NNSR is divided into two parts of reporting: compulsory reports and voluntary reports.

In NNSR, the reported data are available for the period of 2005-2007.

In my work, I used the results of wound infection surveillance operated by uniform definitions and methodology – accepted also in Hungary - applied by the National Nosocomial Infection System (NNIS) operated by the Center for Disease Control and Prevention (CDC).

The National Nosocomial Infection System equals to the surveillance recommended by the surveillance system of the European Union (HELICS), the source of which I also considered data.

Within the frame of Hungarian wound surveillance, between 2005 and 2007, 18 categories of surgical interventions were regularly selected. I highlighted 3-3 types of operation in top number within the most and least frequently used categories of surgical interventions with the indication of validated rates of wound infection.

For the surveillance of antimicrobial resistance and antibiotics use of Intensive Care Units, I used the data of Sub-programme 5. "Improvement of Patient Safety in Europe".

The data were recorded from eight ICUs of various types in four inpatient institutes of the eight the participating countries: Czech Republic, Estonia, Croatia, Germany, Romania, Sweden, Turkey, and Hungary. Relatively, low number of samples were analysed about the state of

resistance – except Germany. The Hungarian results were obtained from the second highest number of samples amid the participating countries.

The surveillance system of infections related to instrument use in ICUs is focused on the collection of data on pneumonia, blood stream and urinary passage infections related to instrument use (respirators, vascular and urinary tract catheters), according to the profile of ICU and the adopted case definitions and methodology elaborated within the frame of NNIS, USA, and with professional supervision of the Department of Hospital Hygiene of the National Center for Epidemiology (OEK). Data generated by this manner were used in my work. The rate of infections related to instrument by 1000 care days and the non-instrumental infections by 1000 care days were divided by the unit types. The surveillance provides opportunity to introduce the instrument usage rates by single instrument and to determine the length of hospital stays. Only few institutions have joined to the surveillance of Perinatal Intensive Centres (PIC), therefore, these results are not suitable for national publication. In general, the surveillance database of infections related to instrument use is small; therefore, the national average values relating only to the Central Teaching Units can be presented.

Basic data about the situation of Hungarian hospital hygiene and infection control in 2007 were received from the hospital hygiene and infection control survey of NPHMOS health service providers that associated with the health administrative survey. **(Complex Control System)**

The preparation for the complex control was done in 2007, and the published examinations were performed in 2008 and 2009. The aim of the control series was to collect data on the current situation of hospital hygiene of health service providers giving inpatient care and on their infection control activity. The staffs of NPHMOS Regional and Sub-regional Institutes, public health controllers, medical officers, and chief medical officers were included. A pre-printed record was prepared considering the viewpoints of health administration, hospital and nursing hygiene, and infection control. In addition to this, a record of form, a so-called complementary record was made for the control of unit or activity of stressed importance like the operating theatre and room, and disinfection. Therefore, the same questions were asked in the controlled hospitals, and the evaluation of records, taking of necessary authority measures were done continuously in accordance with the regulations of administrative proceedings.

The controls covered the Units of Hub Hospitals and Field Hospitals.

We performed pre-planned controls. The authority measures were based mainly on the health administrative defects put down in the records for which the regulations of law on authorization to practice are the guiding principles.

#### **IV. Results**

- The complex control introduced and supervised by me provides an overall view about the inpatient care of Hungarian health, equally covering the fields of health administration and hygiene, and with the assiduous and professionally outstanding work of my colleagues it will provide a basis of comparison for the work of future years. These data have been missing so far.

- The smaller part of defects reveals the architectural insufficiencies in placement of health service providers that are partly inherited and partly show the need for a more circumspect planning of new investments and for the more profound specialized authority activity of the health authority (shortcomings in wash up and patients' preparation sites)
- The safety of care is highly improved by the penetration of Central Sterilization Units – its further spread could improve the safety more. (83.2%)
- The surveillances activities within infection control foster the safety of operation, and the use of Antibiotics Resistance Surveillance should be a primary development.
- The regular training of health care workers, the technical and authority supervision of law-abiding attitude, the strengthening of measures are indispensable for compelling the development of professional field. The assurance of human conditions of NPHMOS – both in number of staff and qualification - is essential for the effective operation of control.
- The new control system has contributed to the unification of hospital hygiene network and will help it in the future.
- The elaborated samples of control record will provide opportunity for control with the same viewpoints in the whole country, and for the generation of comparable, valuable data. The worked-out collection of notions will assist the unambiguous data service.
- The elaboration of controlling frequency, updating of registration code system are the basis of the controlling activity of the Service's internal infection control, assisting all levels of management.
- In the respect of infection control, the generated data are the basic documents for the Service's external quality supervision activity. With its help, also, the supervisor chief medical officers can act based on common viewpoints, therefore, the control system is the foundation for the unity of authority measures.
- In addition to information on the occurrence of nosocomial infections and the hygienic situation of health service providers, the system provides information about the infection activity of providers, the applied antibiotics policy, and the commitment of staff and management.
- The experience of controls proves the changes, the necessity of Decree 20/2009. (VI. 18.) EüM in addition, its effect on the improvement of work quality of health service providers.
- The state of affairs observed by the representatives of specialized supervision and health authority enable the right determination of tasks and priorities.
- With the achievement of promulgation of Decree 20/2009. (VI. 18.) EüM, the law gives legal basis and safety both for the infection control work of health service providers and the authorizing, control and specialized supervision activity of the health authority.

## V. Recommendations

V.1. **Recommendations including the development of situation of infection control** that are determined by the above-summed up and by the data of the Complex Survey:

- Improvement of national surveillance programmes in compliance with EU expectations
- Regulation on decree level of professional minimum conditions for hospital hygiene and infection control and its observance
- To have hospital hygiene and infection control recognized as independent professional field through the developed system of specialised supervision
- Inclusion of trainings, further education, technical training of this special field into the national inventory
- Strengthening and separation of authority and specialised supervision activities

V.2. **Factors facilitating the accomplishment of recommendations are the following:**

- The Decree 63/1997 (XII. 21.) NM and the Decree 18/1998 (VI. 3.) NM on the reporting order of communicable diseases and the Decree 63/1997 (XII. 21.) NM provides the **legal background for the surveillance programmes** on the one hand. According to the amendment effective since November 1, 2006, within the electronically (EFRIR) operating NNSR mandatory reporting system, the infections of multi-resistant pathogens (MRK) and nosocomial blood stream infections are notified.

On the other hand, the legal background for the surveillance programmes is provided by the Decree 20/2009. (VI. 18.) EüM with the determination - by levels of care- of required minimum surveillance, nosocomial surveillance, microbiological surveillance, antimicrobial resistance surveillance, surveillance related to the use and utilization of antibiotics that are required in the background of voluntary reports. My most important recommendation is the strengthening of surveillance activity.

- The Decree 20/2009 (VI. 18.) EüM constitutes the recognition of prevention of HCAs as independent health activity, and the Decree determines both the **minimum professional conditions** and the supervision system.

Further recommendation is to describe the minimum conditions for hospital hygiene and infection control, theatre unit, and sterile material supply in the amendment of Decree 60/2003 (X. 20.) ESzCsM on the minimum professional conditions for the provision of health services.

- **My recommendation for the representation of the activity as independent special field means the strengthening of infection control system** that will be fostered by the prospective passing of amendment of Decree 2/2004 (XI. 17.) EüM. In the Draft Decree on health service providers and registration on their licence to practice, and health professional inventory, the activity of hospital hygiene and infection control, hygiene of institute, and sterile material production will be represented with independent profession codes.

According to 10. § of Decree 15/2005. (V. 2.) EüM on professional supervision of health service providers, NPHMOS performs the control of hospital hygiene as independent special field that also confirms the independent representation and indication of the special field within epidemiology.

- The inclusion of trainings, further education, professional education of the special field in the adequate national inventory will further strengthen the activity of this field.

Therefore, the specialized epidemiological nurse, disinfecting sterilizing technician is represented in the Decree 32/2008. (VIII. 14.) EüM on publishing of the professional and examination requirements for qualifications within the competence of Minister of Health.

- **Authority and special supervision duties of infection control form the part of NPHMOS' activity.** In accordance with the XI. Act of year 1991 and the Governmental Regulation 362/2006 (XII. 28.), **within performance of the authority duties**, and pursuing authorization and control the Service investigates the implementation of legal regulation about the operation and setting into operation of health services; as circumstances require measures will be taken.

It is the task of the authority of public health-epidemiology to provide the control and external quality supervision of the activity of hospital hygiene. As circumstances require the Service uses the weapon of authority measure to improve prevention and patient safety and to ensure the satisfactory situation of public health- epidemiology. The measures of the Service are based on the Decree on the prevention of infections, and professional minimum conditions and supervision of the activity. In long term, the authority work as a primary prevention – with the moderation of effect of factors leading to the development of infections – will probably decrease the occurrence of HCAs, outbreaks.

The strengthening of authority activity is the token for the efficiency of infection control.

### **V. 3. Factors fostering the realization of recommendations**

Several EU regulations and programmes indicate the directions and tools for development of infection control (Decision 2119/98/EC: Council Recommendation improvement patient safety by infection control draft, Public Health Program 2008-2013); on the basis of them and considering the Hungarian experiences gained during our work, I recommend the following:

With the consideration of factors contributing to the development hospital infections, national infection control data, operation conditions of Hungarian infection control, and experiences of Complex Control, I have drafted the factors fostering the improvement of national infection control:

- The efficient prevention of health care associated infections can be achieved only under **legal regulation**. The regulation includes the determination of structures, human and material conditions, tasks of infection control for every level of health care system, and the strengthening of the service provider's responsibility. The Decree 20/2009 (VI. 18.) EüM – as the result of work for several years – provides the professional legal regulation.

Its consistent implementation is a guarantee for the development of infection control activity.

- The HCAs affect every level of care system, however, in different measure. In Hungary, following the change of health care systems the focal points have been transferred to outpatient care. On the one hand, the processes of changing have not finished yet, and on the other hand, the risk for health damage for both patients and staff is the highest in inpatient care. Therefore, mainly the infection control of inpatient institutes should be developed. It helps the successful work that the data on nosocomial infections, outbreaks are available still from inpatient care. Probably, and this process has already started, the importance of long-term care will increase amid the health services. Therefore, it is important to strengthen the infection control activity of this area gradually.
- Infection control is only the one but significant element in the tool-kit for fighting off antimicrobial resistance. The prevention and decrease of development and spread of multi-resistant pathogens, working out of efficient strategy are based on the collaboration of several ministries and various organizations. Therefore, it has been needed to set up and operate the inter-sectoral mechanism that the European Union has urged on since 2001. The result of national improvement in this field was the operation of National Committee of Infection Control and Antibiotics (OIAB) officially started in August 2009; the strengthening of the work of OIAB will be the task in the near future.
- The law [Decree 20/2009 (VI. 18.) EüM) has enforced the forming of national (OTAB) and regional Committees (RIAB). The Committees are the embodiment of the inter-sectoral system, their structures should be filled with right professional content. The establishment and operation of an inter-sectoral system in regional and national level was done – with the governance of NPHMOS – that has the task to develop, coordinate and control the national and local strategies for the prevention of HCAs, and for the pressing back of multi-resistant pathogens and antimicrobial resistance. The strategy is the indispensable factor for development in addition to the elaboration of action plan and national policy of antibiotics. .
- It is necessary to develop the surveillances (NNSR, microbiological) operated by the National Center for Epidemiology, and to start new programmes.
- The spread of multi resistant pathogens has been connected to the inadequate use of antibiotics. Therefore, it is essential **to operate an antibiotic-use monitoring covering all levels of health care** (collection of data on antibiotic use in DDD – in determined unit of daily dosage- and their analysis in primary, outpatient and inpatient care in local, regional and national level). Monitoring is essential for the development of efficient strategy. The EU financed surveillance projects, in which Hungary has also participated, will provide opportunity for international comparison within the country with their methodology.
- **The strengthening of microbiological testing** provides a direction for further development.
- The result of microbiological testing is the basis of prudent use of antibiotics and cost-efficient antibiotic therapy. In Hungary, the rate of relevant microbiological tests like haemo-culture or broncho-alveolaris lavaege is small. **Algorithms have to be worked out to determine the scope of mandatory microbiological tests for certain diseases.**
- Knowing the colonization is indispensable for the prevention of spread of multi-resistant pathogens within the institution, therefore, **the system for performance of compulsory screening tests have to be determined.**
- Continuous work is required for the **review and unification of therapy guidelines** for the patients requiring **antibiotic** therapy.



- I believe that a further task is to elaborate and publish national mandatory guidelines for infectious disease caused by multi-resistant microbes.
- It deserves special attention that the procedure of making reusable the medical devices used in health care should be in accordance with the Medical Devices Directive (93/42 EEC), the EU guideline for medical devices.
- With a view to the development of HCAs, the so-called institutes of long-term nursing care have become more significant with the aging of population. It is justified to initiate negotiations with the Ministry of Social and Labour Affairs regarding the infection control of social institution providing primary nursing care outside the health care system. The situation of infection control in these institutes has an influence on the situation of infection control of institutes under the control of Ministry of Health; this influence exists inversely.
- Training and further education is of basic importance as this special field can be successful only with professionals having adequate expertise.

The efficient prevention of HCAs can be realized only with trained staff; therefore, the education for specialized clinical nurses should be reinforced by ICP (infection control practitioner) curriculum worked out within the frame of IPSE.

As a mandatory module for the special examination of preventive medicine and public health, I recommend the training module based on the IPSE ICD (infection control doctor) curriculum.

The spread of pathogens within the institutions depends from the health care workers; therefore, the knowledge related to HCAs is important for every health care worker. **A material including infection control knowledge has to be worked out for the health care staff; and it would be the part of occupational basic training at employment in health institute**

- The population does not have proper knowledge on either HCAs or the possibility of prevention of infections. Therefore, it is necessary to develop the knowledge of public in this field.
- It is the requirement in our age to develop communication strategy, to provide planned, conscious communication also in this field and in national, regional, and institutional level. The accomplishment of informing and attention-attracting function of communication for the public and health will help **the realization of aims of infection control.**

**VI.** I believe that it is **a result to be expected** that the preventable deaths and sufferings due to HCAs will decrease under the influence of my and my colleagues' work. .

In our work, in addition to the determination of definitions required for the unified Hungarian infection control we have proved the necessity of new legal regulation with the system of data collection and control developed and used by us. As a result, the published ministerial Decree determines the structure, persons involved in infection control activity, their tasks, in addition to the clarification of notions. The suitability and efficiency of the new control system was proved.

Improvement can be reached with help of the achieved result: veritable detection of number of nosocomial infections and outbreaks and their efficient prevention. It is the duty of the health service provider to prevent and minimize HCAs and to ensure the determined human and material conditions and necessary resources. Currently, full scope of data is not available yet for the profile of Hungarian situation of infection control. The results of National Nosocomial Surveillance System and National Resistance Surveillance operated by the National Center for Epidemiology (OEK) show that the HCAs are heading in the mortality due to infectious diseases in Hungary. (Table 4.)

**Table 4.**

**Mortality due to non-nosocomial and nosocomial infectious diseases, 2005-2007**

<b>Number of death cases</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>
Due to non-nosocomial infectious diseases	213	200	183
Due to nosocomial infectious diseases	314	270	394

The future picture is darkened by the fact that the frequency of multi-resistant pathogens (MRP) has rapidly increased. While in 2005, 695 MRP infections were recorded, 1620 infections were reported in 2008.

Unfortunately, even with an incomplete surveillance activity this number shows that a higher frequency of nosocomial outbreaks has to be reckoned with (partly, as the result of improvement in reporting discipline, and partly, for the numerical increase of infections, outbreaks) (Table 5.).

**Table 5.**

**Number of nosocomial outbreaks in years 2004-2008**

<b>Year</b>	<b>Total number of outbreaks</b>	<b>Non-specific outbreak</b>	<b>Specific outbreak</b>
2004	108	74	34
2005	112	57	55
2006	140	114	26
2007	128	98	30
2008	199	164	35

In the background of this trend, the social-economic and life style characteristics, the health culture of population, and the human, material, financial conditions of health care system can be found in addition to the demographic features of population.

**Further results to be expected are the following:**

1. Reduction of frequency of HCAs with the prevention of avoidable infections in all levels of health care
2. Prevention and pressing back of development and spread of infections caused by multi-resistant pathogens
3. Improvement of professional quality of patient care and safety with the decrease of adverse events related to care (infections, outbreaks)
4. Contribution to the decrease of health expenditures in the long run
5. Living up to the expectations jointly drafted by EU Member States

On the basis of all these, the expected result of our work still seems to be significant.

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