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Fitness for work in health care workers: biological risk

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Summary
The aim of this contribution is to propose good medical practice in formulating and managing fitness for work (FFW) for health care workers exposed to biological agents. A literature review was conducted, together with a critical analysis of available scientific evidence and presentation of practical examples taken from the Italian multicentric study in which the authors have been participating since 2008. Within the health care sector and with special reference to biological risk, making and subsequently managing a FFW for a specific job is in fact a particularly arduous task for the occupational physician and for the entire hospital management system. The process that leads to issuing a FFW needs to follow the appropriate guidelines and good technical and scientific practice and also take into careful consideration current legislation (national, regional, etc); it is the result of a well grounded balance between professional ethics, rights and duties of the worker and patient, but also of the employer and of all those involved. All these aspects need to be adapted to the single work situations, applying the principle of precaution and careful flexibility in management, with accurate evaluation of each individual clinical case with its peculiarities and referral, where necessary, to expert opinion. It is also indispensable to have in place a clear and jointly agreed hospital management policy where co-responsibility is taken by each single actor, always with due respect for specific roles, so that the Occupational Physician and employers are not left to manage the issue alone.

Riassunto
«Giudizio di idoneità e rischio biologico negli operatori sanitari». *Scopo di questo contributo è proporre buone prassi nella formulazione e gestione del giudizio di idoneità negli operatori sanitari esposti ad agenti biologici.È stata condotta una revisione della letteratura, congiuntamente ad un'analisi critica delle evidenze scientifiche disponibili, valutazione indicazioni dalla pratica sul campo, con riferimento allo studio multicentrico italiano cui gli autori da tempo contribuiscono. Nel settore della sanità, con particolare riferimento al rischio biologico, la formulazione e la successiva gestione del giudizio di idoneità alla mansione specifica è infatti particolarmente impegnativa per il medico del lavoro/competente e per l'intero sistema gestionale aziendale. Il processo che porta alla formulazione del giudizio di idoneità deve essere indirizzato da linee guida e da buone prassi tecnico-scientifiche*

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ed attento a quanto previsto dalla legislazione (nazionale, regionale, ecc.), frutto di un bilancio motivato tra etica/deontologia professionale, diritti e doveri del lavoratore/paziente, ma anche del datore di lavoro e di tutti gli attori coinvolti a vario titolo nel processo e tutela della riservatezza. Tali aspetti dovranno essere adattati alle singole realtà operative, applicando il principio di precauzione e con attenta flessibilità gestionale, valutando sempre accuratamente il singolo caso clinico con le sue peculiarità, ricorrendo ove necessario al parere di esperti. È inoltre indispensabile una chiara e condivisa politica aziendale, in cui vi sia un'assunzione di co-responsabilità dei singoli protagonisti, nell'indispensabile rispetto degli specifici ruoli, affinché il medico del lavoro/competente e i datori di lavoro non siano lasciati soli a gestire la tematica.

Introduction

In every sector where the Occupational Physician carries out his/her duties, the tasks assigned to him/her cover a wide range: from application of the appropriate regulations to training, in cooperation with the different actors involved in protecting workers' health and safety. The Occupational Physician plays a fundamental role in contributing to assessment and management of risk, draws up and puts into practice the health surveillance programme and, as a final result issues a fitness for work (FFW) for the specific job. The FFW, in addition to the primary aim of protecting the worker's health against specific risks present at the workplace, increasingly – and especially in contexts such as health care – must also take into account the health of third parties, meaning all the problems involved in transmission of biological agents from health care worker to patients or work colleagues.

The topic of FFW in the health care sector, with particular reference to biological risk , is therefore a true test of competence for the Occupational Physician, who must always bear well in mind the ethical and scientific aspects as well as good management practices (1, 17, 10).

The special interest in this topic is due above all to the high number of workers employed in health care who are exposed to biological risk (in Italy INAIL – National Insurance Institute for Occupational Accidents and Diseases – estimates the number at about 5% of the workforce, i.e. about 862,000 health care workers), to the significant prevalence of potentially communicable infectious diseases among health care workers, to the impact of these diseases on health, to the high number of accidents with biological risk, to the consequent direct and indirect socio-economic costs (9, 12, 16). Clearly, safeguarding "rights" is mandatory, even though complex. The tasks cover protection of workers, and patients (in the case of health care workers with diseases that can be communicated via the blood these tasks become particularly onerous for the Occupational Physician, especially in a legislative context that does not lend itself to unequivocal interpretation as regards the protection of third parties), but also safeguarding confidentiality. It should be stressed that this is a field which by its very nature poses particularly delicate problems such as the safeguard of the Occupational Physician's professional status, which is often at a high level and which cannot be restricted without valid scientific assumptions (so-called "evidence-based occupational medicine"), which are available via guidelines, good medical practice, best available technologies, consensus documents by experts, etc.

Over the last few years various national and international initiatives have transformed these topics into regulations, guidelines and/or good practice norms (e.g. the 2002 ICOH Code of Ethics, Legislative Decree 81/08 in Italy, the Recommendations of the Society for Health care Epidemiology of America, 2010).

The Italian Society of Occupational Health and Industrial Hygiene (SIMLII) Guidelines in 2005 addressed these different topics with the aim of assisting the Occupational Physician in all aspects regarding biological risk (2). The Guidelines especially addressed the question of management of

health surveillance and FFW for specific jobs, which were largely reviewed and updated in 2010 at the meeting "Rischio biologico, psicosociale e biomeccanico per i lavoratori della Sanità" (Biological, psychosocial and biomechanical risk for health care workers) (23).

The aim of the present paper is to propose good practice norms in making and managing FFW of health care workers exposed to biological agents via literature review, critical analysis of available scientific evidence, and use of practical examples from the Italian multicentre study in which the authors have been contributing since 2008 (14).

National and International Guidelines

Over the last few years the scientific literature has provided many suggestions for the management of health surveillance of workers exposed to biological risk and has addressed topics such as ethics, issuing and management of FFW, also in cases where there is a danger for third parties. All these topics are extremely important in view of the ethical, technical/scientific and management implications.

In Italy, following the impact of the HIV epidemic, the topic of transmission of infectious agents via the blood in the health care context had already been addressed in 1994 by the National Commission for the Fight against AIDS set up by the Ministry of Health (Commissione Nazionale per la lotta contro l'AIDS, 1995), which drew up guidelines for the prevention of transmission of only HBV and HIV viruses, also from health care workers to patients. The recommendation made at that time was to exclude from performing invasive procedures that posed a risk of exposure for patients those health care workers with any of the following serological statuses: HBsAg+ HBeAg+, HBeAg- HBVDNA+, HIV+. In those cases where the provider was not required to perform procedures associated with risk the recommendation was to make an assessment case by case through an expert committee.

Subsequently in 1999 the Italian Istituto Superiore di Sanità (High Institute of Health) organised a Consensus Conference to address the problems concerning HCV transmission (4). Basically, it advised against screening all health care workers and recommended obtaining data on the serological status and report it to the competent authorities only for providers who performed procedures associated with risk. In the case of proven contagiousness it was recommended to exclude the provider from carrying out only exposure-prone procedures (EPP) performed personally. HBeAg+, HBsAg+ e HBVDNA+, antiHCV+ e HCVRNA+ subjects were considered to pose a risk of transmission of infection. No restrictions were foreseen in all the other cases. These guidelines, which at the time were deemed to be the best possible synthesis of all the experience reported in the infectious diseases literature, did not however address in detail the complex juridical, bioethical and medico-social aspects of FFW in health care work.

In 2005 the SIMLII published the above mentioned Guidelines for health surveillance of health care workers exposed to biological risk where all these different topics were addressed with the aim of providing support and assistance to the Occupational Physician in managing all aspects of biological risk and FFW (2). For health surveillance, protocols were proposed that included the appropriate vaccinations and set intervals for serological testing and medical examinations, according to the actual risk level to which the health care worker was exposed. The Guidelines stated that the Occupational Physician should have a leading role in the management of these issues and should assess each single case taking into consideration all of the following factors: the provider's specific job, type of invasive procedures that he/she is required to perform, surgical techniques used, type of patients attended, form of work organization, personal protective devices, available and actually used, occurrence of any previous accidents or transmission of infection by the provider, clinical status of the provider, referral to expert opinion where appropriate. Only after careful consideration of all these factors can the Occupational Physician reach a decision as regards FFW and for this reason the Guidelines strove to provide all the various methodological references as well as a number of practical examples. Above all

the guidelines state that the problem arises only when the health care worker is required to personally carry out procedures involving transmission risk, otherwise there is no reason to apply any restrictions. In any case there is an obligation to take standard precautions to prevent biological risk, an obligation which is explicitly stressed, recommending more specific measures where appropriate (e.g., use of double-gloving). However, in cases where the provider is required to perform invasive procedures associated with risk the problem arises in situations where there is proven possibility of communicability, that is, HBeAg+, HBsAg+ e HBVDNA+, HCVRNA+, HIVAb+ subjects. For all these cases, the Guidelines suggest two possibilities:

a) Certification of non-fitness to personally perform EPP;

b) Certification of fitness but with constant use of double-gloving when personally performing EPP. In particular situations (e.g., placing sternal wires, exposed fractures, multiple traumas) cut-resistant gloves should be used.

The choice between the two alternatives is left to the Occupational Physician who decides case by case once he has made the above assessments. The need to take the standard precautions is however always stressed. No further restrictions are foreseen for other serological conditions different from those already cited. In the case of a health care worker undergoing antiviral treatment it is suggested that the individual be considered temporarily unfit to personally perform invasive procedures with risk of exposure. If HCVRNA or HBVDNA stay negative for at least 6 months after completion of treatment, all restrictions may be removed. In this case, too, the need to take the standard precautions is always valid. Suggestions are also made on how to manage all these problems in a comprehensive manner, including the possibility of setting up an expert committee at hospital or inter-hospital level; this committee would act as support for both the Occupational Physician and the employer and also the health care worker, each according to his particular role and competence. In conclusion, it is advised that the forms used to obtain informed consent of patients who need to undergo invasive procedures make explicit mention also of the risk of transmission of infections with such procedures. These Guidelines, which are complete with tables of practical examples of FFWs for all other infectious diseases, are still considered a valid reference for overall good practice as regards methods, approach, type of verification, and general method of formulating a FFW. Nevertheless, it is now necessary to take account of the most recent technical and scientific innovations, such as the analytical techniques currently available for the diagnosis of HBV, HCV e HIV diseases, which are increasingly more sensitive and permit identification of new seropositive subjects (previous false negative), or early identification (even after 12 days for HIV and HCV) of effective seroconversion following a biological accident, and therefore the possibility of early treatment of HCV infection and with good results. All these aspects, a more accurate assessment of contagiousness of health care workers (using the genome equivalents - GE) and management of infected workers also from a prognostic point of view, are clearly of interest to the Occupational Physician, especially with regard to deciding any restrictions in the FFW. The evolution in our knowledge of infectious diseases and the recently introduced possibilities of treatment of viral infections have suggested the advisability of including in the requirements for issuing a FFW that of maintaining a number of viral copies below the infection threshold; in fixing this threshold, however, different opinions have been expressed by experts from the different countries.

In 2003 a European Working Group issued a document concerning risk of transmission of HBV and HCV (7). It consisted of recommendations (on which moreover, in some cases there was not full agreement between all the members of the expert panel) which were essentially based on evaluating the serological status of the health care worker. In the case of HBV risk, a condition of contagiousness, defined on the basis of quantitative measurement of HBVDNA, implies suspension of tasks with greatest risk. However no cut-off level was defined that could be applied to all cases. Practically, it was proposed to exclude workers from performing EPP in the following conditions:

- HBeAg+ worker: it is however foreseen that an Expert Panel may assess the case and, if HBVDNA measurement is below the cut-off established by national regulations, the worker could avoid exclusion from EPP, with the obligation to repeat HBVDNA measurement every three months;
- HBeAg- worker with HBVDNA >10^4 GE/ml: if HBVDNA falls below the cut-off used the case may be re-assessed with the obligation of yearly measurement of HBVDNA;
- Workers who have caused transmission of HBV to patients independently of HBV serological status.

It is advised to obtain informed consent of the patient, although this is not considered mandatory. However, no consensus was reached for cases of workers with HCV infection. It is to be hoped, as a minimal condition, that each worker be aware of his/her serological status for HCV, that the worker be referred to a specialist so as to undergo specific treatment if appropriate, and that, in case of injury of the worker with significant bleeding into a cavity of the patient during a surgical operation, both the Occupational Physician and the patient be informed.

The UK has over the years issued a number of documents on this topic (20-22). The basic assumption is that the serological status be known before the health care worker is assigned to risk procedures and that this status be regularly checked over time. In this case, too, detection of a condition of contagiousness implies abstention from high risk procedures. In this process particular importance is given to the role of the Occupational Physician, who is the central figure in each stage of the process. In the latest update (15) it is advised to exclude from performing EPP those health care workers presenting the following conditions:

- HBeAg+;
- HBeAg- HBVDNA+ (with baseline value >10^5 GE/ml, tested in 2 laboratories, or with pre-treatment baseline value of 10^3-10^5 GE/ml, but which under oral treatment stays at >10^3 GE/ml);
- if treatment or controls are interrupted or if a control is refused;
- HCVRNA+;
- HIVAb+;
- currently undergoing antiviral treatment;
- non-responders to HBV vaccination.

Performance of EPPs is permitted however for health care workers with HBeAg- HBVDNA+ with base value ≤10^3 GE/ml in two consecutive tests carried out after an interval of one month (in this case they must undergo annual controls) or if the pre-treatment base value is 10^3-10^5 GE/ml but under oral treatment stays at <10^3 GE/ml (in this case they must undergo 3-monthly controls). If, after a year from completion of treatment HBVDNA <10^3 GE/ml, controls must be annual. It should be noted that these Guidelines are similar to those that have for some time been followed in Canada (19).

In the USA, SHEA (Society for Health care Epidemiology of America) recently updated and significantly revised its opinions (8), proposing specific recommendations that set out different strategies according to the type of infection (HBV, HCV e HIV) and a new classification of the procedures involving risk. Practice restrictions are applied only in special cases, according to the viral burden of the infected health care worker and the tasks that are to be performed (differentiated and specific evaluation for each single case). It is also mandatory in these cases to include the Occupational Physician and the specialist in infectious diseases who is treating the patient on the expert review panel, with a consensus document signed by the Expert Review Panel and the health care worker in question who undertake joint responsibility.

In particular the procedures associated with risk are classified and divided into three categories according to the level of probability of transmission of blood-borne pathogens.

Category 1: procedures with *de minimis* risk of blood-borne virus transmission;

Category 2: procedures for which blood-borne virus transmission is theoretically possible but unlikely;

Category 3: procedures for which there is definite risk of blood-borne virus transmission or that have been classified as EPP.

On the basis of this classification recommendations are made for management of HBV-, HCV-

or HIV-infected health care workers, which can be summarized as follows:

1) No restrictions for category 1, 2 and 3 procedures for health care workers whose status is one of the following: HBeAg+ or HBeAg- with viral burden < 10^4 GE/ml; HCV+ with viral burden <10^4 GE/ml; HIV+ with viral burden <5 x 10^2 GE/ml. The health care worker undergoes six-monthly controls and a FFW without restrictions is confirmed provided that:
   a) there is no evidence of having transmitted infection to patients;
   b) the health care worker obtains advice from the Expert Review Panel about continued practice;
   c) the health care worker undergoes routine follow-up by the Occupational Physician (or appropriate public health official) with six-monthly checks to confirm that the viral burden is maintained below the recommended threshold;
   d) the health care worker is seen regularly by his personal physician, who will have expertise in managing the infection and is authorised by the health care worker to discuss his/her clinical status with the Expert Review Panel;
   e) the health care worker regularly seeks advice from an expert regarding optimal infection control procedures and strictly complies with the recommendations he receives (including routine use of double-gloving when performing procedures classified under categories 1 and 2; change of gloves every 2-3 hours if performing technical tasks known to compromise glove integrity, avoid touching or fingering needle points or working in "blind situations"; in case of injury immediately check any bleeding, contact an expert, report the exposure of the patient and carry out prophylactic measures where necessary);
   f) the health care worker agrees with the contents of and signs a contract or letter proposed by the Expert Review Panel, that characterizes his/her responsibilities.
2) Categories 1 and 2 procedures may be carried out by health care workers with the following statuses: HBeAg+ or HBeAg- with viral burden ≥10^4 GE/ml; HCV+ with viral burden ≥10^4 GE/ml; HIV+ with viral burden ≥5 x 10^2 GE/ml, but they cannot carry out procedures under Category 3 (not even if they observe the appropriate procedures for control of infection). These health care workers must always use double-gloving for all invasive procedures, for all procedures involving contact with mucous membranes or damaged skin, and in all patient care manoeuvres where use of gloves is required. Also for these health care workers authorisation to perform such procedures is granted and confirmed only if the above conditions are complied with.

The tasks assigned to the Expert Review Panel are also of interest:

- assessment of the clinical status of the infected health care worker;
- assessment of the data concerning viral burden;
- assessment of the skills, expertise and experience of the health care worker;
- assessment of the procedures carried out by the health care worker and the specific techniques used;
- assessment of the degree of the health care workers compliance with the precautions necessary to prevent transmission of infection;
- issuing of specific recommendations for prevention of infections when performing particular procedures and assessment of the health care workers readiness and willingness to comply with such recommendations;
- counselling with health care worker about his ethical obligation to report any exposure of a patient (if this should occur) and the appropriate procedures to follow in such cases;
- develop and execute a contract between the infected health care worker and the Expert Review Panel (an example of a possible contract is proposed);
- where transmission of infection is suspected attention should be give to the possibility of drug abuse;

- reporting to the office in charge of clinical risk management if non-compliance in carrying out procedures or exposure of a patient is detected;
- reporting to the competent administrative authorities any infringement of the contract signed between the health care worker and the Expert Review Panel (if required by law or by regulations).

Italian Multicentre Study on Biological Risk in Health Care

The multicentre study involved a group of nine large Italian hospitals, 38 Occupational Physicians, various specialists in other disciplines besides occupational medicine (e.g., head of prevention and protection, epidemiology, infectious diseases, forensic medicine, hygiene, respiratory diseases, etc.). Data from about 32,000 health care workers exposed to biological risk were collected and analysed (13). For each hospital data were processed regarding health surveillance protocols, risk of blood-borne biological agents and the results of health surveillance; assessment was made of the prevalence of health care workers testing positive for blood-borne diseases (HBV, HCV, HDV, HIV), comparing this prevalence with literature data; the FFW were analysed and data were collected and evaluated concerning the analytical techniques used for diagnosis of blood-borne diseases and the mode of management of vaccinations and non-responders (3).

Table 1 summarizes the data on prevalence of HBV, HCV and HIV, HDV markers in health care workers exposed to biological risk: it can be seen that subjects who tested positive for HBV and HCV were less than the 2% reported in the literature as an estimated prevalence of these viruses in health care workers (0.8% for HBV and 1.1% for HCV), whereas for HIV the result was practically identical (0,09%).

The results overlap those of the general population as regards HBV and HIV, thus confirming a known trend. In fact occupational infection by HBV is now a rare event thanks to the availability of an efficacious vaccine which in Italy has been obligatory for school-age children for almost 20 years now, and which is also useful in the post-exposure phase.

Regarding HIV, the data that emerge are very likely to be due to the availability of efficacious treatment of HIV patients who therefore access hospital treatment less frequently and whose clinical status is less serious, and also to the availability of post-exposure prophylaxis for health care workers who have accidents with biological risk with an HIV-positive patient as source, and also to the re-

Table 1 - Multicentre study in 9 Italian hospitals: prevalence of markers for HBV, HCV e HIV, HDV in health care workers exposed to biological risk. Data from about 32000 health care workers

	HBsAg+	HBsAb	HBeAg	HDVAb	HBVDNA	HCVAb+	HCVRNA	HIVAb+
Total No. (%)	251 (0,8)	15157 (47)	25 (0,08)	3 (0,01)	69 (0,2)	362 (1,1)	177 (0,5)	32 (0,09)
Range (%)	0,3-1,6	43-87	0,03-0,3	0,02-0,05	0,03-0,7	0,5-2	0,1-1,4	0,02-0,5

Table 2 - Multicentre study in 9 Italian hospitals: Fitness For Work in 373 seropositive health care workers

Virus	No. (%) of positive health care workers performing invasive procedures	No. (%) of positive health care workers providing assistance to patients	No. (%) of positive health care workers handling only biological material	Others	No.(%) (total=373)
HBV	11 (2.9)	67 (!8)	8(2.1)	11(2.9)	97(26)
HDV	1 (0.26)	2(0.53)	0	0	3(0.8)
HCV	29 (7.7)	143 (38)	22 (5.8)	35(9.3)	229(61)
HIV	2 (0.53)	18 (4.8)	9 (2.4)	15(4)	44(12)

ported low response to undergo testing in certain situations.

Table 2 reports the data concerning FFW which in the 9 hospitals studied were issued for health care workers testing positive for HBV, HCV, HIV, HDV. The majority of the FFWs concerned health care workers assigned to patient care: they included health care workers testing positive for HCV (229 assessments), HBV (97 assessments) and HIV (44 assessments). In only one case was an assessment of non-fitness made, which concerned a health care worker who worked in surgery but did not perform invasive procedures: the assessment was made on the basis of HIV disease and was in agreement with the SIMLII Guidelines.

As regards FFW with restrictions or recommendations some peculiarities in management were observed between and within hospitals, even with respect to the SIMLII Guidelines, which recommend issuing a certification of non-fitness or fitness with recommendations (e.g., use of double-gloving) for subjects positive for HBeAg, HBV-DNA, HCV-RNA and HIV only for health care workers who personally perform EPP.

Restrictions included exclusion from night-work, from tasks with a high level of biological risk and exclusion from exposure to hepatolesive agents; in only two hospitals did the restrictions concern exclusion from carrying out invasive procedures with high biological risk or from tasks with high biological risk. The majority of recommendations concerned the use of personal protection devices (PPD) and observation of standard precautions; two hospitals recommended constant use of double-gloving when carrying out invasive procedures, as is recommended in the SIMLII Guidelines. Analysis of the data also showed that some hospitals managed in a uniform manner all health care workers who tested positive for blood-borne diseases, regardless of the level of risk.

On the question of vaccination against hepatitis B virus, it was found that vaccination coverage was certainly not optimal (about 30% of the workers were not vaccinated). As regards non-responders the data agreed with literature data which report an estimate of between 5 and 10% of the adult population (11, 18). Considering the non-responders and the non-vaccinated, in the hospitals studied there were in any case hundreds of workers who were still not protected against HBV risk.

Regarding the practice of vaccinating non-responders, differences in management were observed in the hospitals studied. Some hospitals provided a single complete vaccination cycle and sometimes a fourth dose, which is what Italian legislation has prescribed since 2000, whereas other hospitals follow the CDC or Health Canada recommendations and therefore provide a second vaccination of three doses (6, 11, 18, 19).

In conclusion, in the hospitals studied there was a general tendency to follow the SIMLII 2005 Guidelines (2) and the recommendations in the literature, even though peculiarities between and within hospitals were observed regarding management of health care workers testing positive for blood-borne diseases, and in vaccination practice of non-responders.

Proposal for the formulation and management of fitness for work

As in all cases, but especially so for biological risk, there are factors that constitute the basic requirements that are indispensable to be able to make a FFW.

Some requirements concern good practices in evaluating individual risk that must be applied integrally with the active participation of the Occupational Physician, via an integrated and multidisciplinary approach. The following are the main factors that should be considered:

- general features of the workplace and work organization;
- use of best available safe technological tools:
  - the presence of suitable collective and individual safety and protective devices, with checks on how they are used, as well as fit test;
  - the existence and distribution of and compliance with standard precautions, procedures for handling biological risk accidents and any post-exposure prophylaxis, management of "close contacts" with patients with infections that are communicable via the respira-

tory route and/or blood, isolation measures, protection of pregnant and/or breastfeeding female workers;
- efficient contact with the Hospital Infections Committee;
- a specific information, training and permanent education programme;

- methods for identification of biological agents and assessment of individual risk of transmission of biological agents;
- prevalence of infectious diseases in the patient population;
- analysis of anonymous collective data on health surveillance and biological risk accidents.

Through these evaluations it will be possible to accurately identify the health care workers assigned to the various wards/departments, their jobs, tasks and how tasks are carried out, and therefore the biological risk category they can be assigned to.

The FFW cannot then be derived from an automatic application of a predefined model but will be the result of a logical process through a series of steps, each of which can influence the final result, which reflects the highest degree of professional responsibility of the Occupational Physician. For each individual health care worker the following aspects must be evaluated:

- Type of infection (HBV, HCV, HIV), degree of infectiousness, analytical methods used to measure the viral burden;
- Clinical status, presence of hypersusceptibility conditions (protected by vaccination, etc.), any treatment already carried out and/or recommended;
- If the health care worker has previously caused transmission of infection to third parties;
- If the health care worker has previously had a biological risk accident during practice;
- Which specific tasks are carried out, which risk procedures are performed and with which techniques, the degree of technical expertise and experience in such procedures, which prevention measures are to be taken (standard and specific precautions, PPD), the level of compliance with infection prevention recommendations;
- Type of work organisation.

These evaluations will make it possible to define the treatment and/or preventive measures (restrictions/recommendations) that are necessary to safeguard the worker's health.

Thus every case must be evaluated separately, using reference criteria for each of the items considered. It is obviously advisable to take advantage of expert advice and opinions (specialists in infectious diseases, forensic medicine, a worker having the same status and specialisation), always ensuring maximum confidentiality regarding the case in question and aspects connected with informed consent (5).

It may also be advisable to consider, case by case, whether it will be useful to explicitly recommend the obligation to comply with standard precautions for preventing infections or particular safety measures when these are supported by scientific evidence such as, for example, the obligation of using double-gloving (or other types of gloves, for example, cut-resistant gloves) when carrying out procedures associated with risk, use of "hands-free" or "no-touch" techniques, retracting needles, blunt instruments, etc.

In this way, conditions are also created indirectly for the protection of third parties. All the measures taken to protect the health of an infected health care worker will in fact indirectly, but with equal efficacy, also be measures to protect the health of the patients and work colleagues. A FFW for a specific job that the Occupational Physician issues is in fact aimed in the first place at protecting the health of an infected health care worker due to his/her greater susceptibility caused by the infection (greater susceptibility to superinfections by other viruses or by other genotypes of the same virus, to exposure to toxic substances (anaesthetics, solvents, drugs), to work overload (stress, shifts, hours). For example, an HIV-positive worker needs to be protected against all occupational risks that might accelerate the process towards a state of acquired immunodeficiency (AIDS). At this point, there seem to be only very few situations where, although there is no need for prescriptions to safeguard the health of the worker, there is still however the possibility of risk for third parties. In these cases the Occupational Physician cannot renounce

his ethical obligation (and responsibility) of protecting the health of everyone, and therefore also of third parties.

The Occupational Physician is the ideal and most suitable person, since he/she is professionally and legally competent, to act in a direct manner as consultant to both employer and health care worker because of the latter's duty not to cause impairment to the health and safety of patients and work colleagues. It is nevertheless necessary that the role of the Occupational Physician be explicitly declared and recognised, thus putting him/her in a position to exercise such role with transparency and efficiency: this could be achieved, for example, by implementing the measures proposed as follows.

It would be appropriate that the complex series of ethical dilemmas that the management of each single case poses be addressed not *"ex post"* after identification of the case in an improvised manner, but that the whole question be carefully considered *"ex ante"* by all the actors responsible for health and safety in a hospital and that these reflections take the form of a written policy (10). It is clear therefore that it is necessary to define *a priori* a form of management of these problems that is formally agreed upon by employers and health care worker right from the start of the contractual relationship; this will then set the path whereby, with all the appropriate personal guarantees, it will be possible to safeguard the rights of all concerned with each and everyone taking full responsibility. The Occupational Physician constitutes the mainstay of this process, with the support of specific professional expertise and with the possibility of liaising with a third party/panel that, being restricted to a purely professional role, may act as a means of evaluation and guarantee that goes beyond the local context and the specific health care setting.

It could be advisable to include the preparation of a "Document for the management of risk of communication of infection to third parties consequent on health care activities", to be signed at the beginning of the health care worker's employment, that clearly states and ratifies the hospital management's policy in this respect, the actors involved (employer, health care worker, Occupational Physician, group of experts supporting the Occupational Physician), their responsibilities, roles, and tasks, operating procedures for overall management of the issue.

The responsibilities of the employer include: identification of the procedures deemed to pose a risk of transmission of infections (in cooperation with the Occupational Physician and the health care worker prevention and protection service); guarantee that the risk conditions are properly evaluated and controlled; guarantee awareness and application of the measures necessary to prevent infections; ensure maximum awareness of the procedures involving biological risk; guarantee confidentiality for the worker; guarantee the rights of the patient to receive information (on exposure to biological agents, prevention, treatment, counselling, inclusion in the informed consent document a notice on risk of transmission of infections during procedures the patient will undergo); management of communication with the patient and preventive measures taken concerning the patient.

The responsibilities of the health care worker are, in particular: awareness of his/her serological status and of the obligation/requirement to inform his head of health and safety; apply the measures necessary to prevent infections; undergo health controls aimed at safeguarding the patient's health; duly report all accidents with biological risk and obviously accidents with risk of contaminating a patient.

The responsibilities of the Occupational Physician are: to inform the health care worker with communicable diseases of the risks to which he/she exposes him/herself and the patients under their care; carry out the health checks prescribed also for the protection of third parties; issue FFW for the specific job so as to protect the worker and third parties. In the latter case, the Occupational Physician may opt for referral to previously identified experts (specialists in infectious diseases, forensic medicine, worker with the same work status and specialisation as the infected worker); in particular the Occupational Physician may avail himself of the support of this group of experts (who may be identified also at a level beyond that of the hospital, at least local/regional) for the following tasks for which he/she is anyway responsible:

a. Consultation with the worker's personal physician
b. Assessment of clinical status of the infected worker and his/her viral burden
c. Assessment of expertise, skill and experience of the worker, procedures performed and specific techniques used
d. Assessment of degree of worker's compliance with the preventive measures that must be taken
e. Make specific recommendations for the prevention of infections in performing particular procedures
f. Definition of any need/usefulness of carrying out a retrospective investigation

Lastly, it is to be hoped that an official pronouncement be made on this issue (regulations?, good practice?), which should cover both scientific and professional aspects (guidelines, consensus document) suggesting criteria for decision-making in the light of current knowledge and updates of the same, as well as aspects of management (explanatory circulars issued by Ministries or Regional authorities) that will indicate the policies to adopt also at levels above that of the hospital.

Conclusions

The issue and subsequent management of a FFW for a specific job is always a demanding task for the Occupational Physician and for the entire management system of an enterprise.

In the health care sector, with special reference to biological risk, the difficulties are further accentuated by multiple factors that must be simultaneously considered, including the ethical and scientific aspects as well as good medical/technical practice.

Daily practice must of necessity incorporate the latest and most advanced scientific knowledge and opinions (the SHEA Recommendations are of particular importance). Such scientific knowledge, making due allowance for its intrinsic and time limits, must however be used and applied to each single situation, applying the principle of precaution and flexibility in management, always with careful assessment of each single clinical case with its peculiarities and with referral, where necessary, to expert opinion.

As we have already stressed, thorough multidisciplinary competence is required in the fields of microbiology, infectious diseases, hygiene, epidemiology, forensic medicine and safe technology, all of which must be coordinated and guided by the experience of the Occupational Physician who will apply the criteria typical of occupational medicine.

The process that leads to issuing a FFW will thus be constantly aware of legal requirements, whether national, regional o otherwise, and will be the result of a well grounded balance between professional ethics, rights and responsibilities (first and foremost of the worker and patient, but also of the employer and of all other actors variously involved in the process), and confidentiality (in this contest the data in question are especially sensitive), following the most recent guidelines and good technical and scientific practice (1).

It is all the more important in this specific sector to have a clear and jointly agreed hospital management policy, whereby each single actor takes co-responsibility, always necessarily respecting the specific roles of each, so that the Occupational Physician (and the employer) is not left to manage the issue alone.

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