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Introduction

The 1906 "Universal Exhibition" - the world's fair celebrating the achievements of human talent in science, technology and arts - was organized in Milan, Italy. That exhibition was marked by a special event: the official opening of the Simplon tunnel linking Milan to Switzerland and France, an astonishing success of the work of man, which however took a heavy toll in terms of number of deaths, injuries and diseases among the workers. A group of physicians and scientists, concerned of these consequences, decided to convene an international meeting on occupational health and safety devoted to three main issues: work-related physiology, pathology and hygiene; prevention of work-related diseases and social assistance. Three hundred delegates attended the Congress which was closed on 13 June 1906 with the creation of the International Permanent Commission on Occupational Health, currently known as the International Commission on Occupational Health, ICOH. Aim of the Commission was to promote research on occupational diseases worldwide and disseminate the available knowledge to the entire scientific community, to physicians, employers and workers. To achieve these goals it was further decided to regularly hold a congress every three years. In 2006, a century after its foundation, the ICOH will organize, on the very same dates (11-16, June), its 28th International Congress back in its birthplace, Milan, Italy. During these one hundred years, significant improvements in working conditions have been achieved, and certainly occupational health professionals have contributed thereto. At present however, the occupational health community must tackle new problems, the solution of which requires new research, new methods and new practices. Changes in the world economy, the process of globalization, new technologies, different types of employment and work contracts constantly affect health and safety at work. Small and medium-sized enterprises and the self employed do not often have the necessary financial and technical resources to adequately assess risks and ensure appropriate protection. Developing countries and countries in transition lack access to those services that would be required to assess and control occupational hazards. Against this background, and given the current scenario, for its 2006 Centennial Congress the ICOH coined the motto "Renewing a century of commitment to a healthy, safe, and productive working life", thereby emphasising its dedication to responding to the new century's challenges. ICOH members are determined to co-operate in the field of research and in practice to ensure healthy and safe work environments to the workers throughout the world and intend to do so by following the principles of sound science, excellent practice and highest professional and ethical standards. We believe that, in so doing, we will also contribute to eliminate poverty caused by unnecessary, preventable occupational diseases and injuries, promote the development of work ability and improve productivity.

In the previous issue (no. 2, March-April 2006) of *La Medicina del Lavoro*, the invited lectures delivered in plenary and semiplenary sessions of the Congress are hereby collected and offered to our readers and to all the participants of the 28th ICOH Congress. In such a way they will represent a point of reference, dated 2006, of each up-dated theme which were discussed during the entire week of work.

In this issue are included the speeches of the sessions organized by the Italian Society of Occupational Medicine and Industrial Hygiene (SIMLII) within the 28th ICOH Congress.

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President of 28th ICOH Congress

Jorma Rantanen
President of ICOH

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PREFACE

In this special issue of "La Medicina del Lavoro" are presented the papers regarding the main oral presentations from sessions organized by the Italian Society of Occupational Medicine and Industrial Hygiene (SIMLII) during 2006 Centenary ICOH Congress in Milan.

The need for continuing education for Occupational Medicine physicians is supported by many considerations, starting from its essence, and aims of Occupational Medicine lead to differences with other medical specialties: this field is not confined to clinical areas but ranges from ergonomics, to toxicology, to epidemiology and technology. Moreover the occupational physicians must interact with other professionals keeping up specific competence in the prevention context. It must also be taken into account the rapid changes in the workplace and in production processes; the emergence of new risks and new pathologies; the changing regulatory framework.

In this context SIMLII planned from 2001 a specific project, together with the Maugeri Foundation defined as "Continuing Education and Accreditation of Excellence" and to standardize and homogenize the educational part of the accreditation scheme, our Scientific Society promoted a parallel project for editing a corpus of guide-lines for updating the arguments that are major concerns for Italian occupational physicians.

The four themes suggested largely derive form this experience and today represent objects of theoretical and practical concern for Occupational Physician: what health surveillance for former exposed to carcinogens? What the references when dealing whit complex job fitness? What is the role of occupational physician in risk assessment for UEWRMSDs? And finally, are there new aspects and trends in industrial toxicology to deal with?

Regarding risk assessment for UEWRMSDs we suggested to Occupational Physician a multiple phase procedure, in which the first level aims at identification and early assessment of risk (presence/absence of a problem). This stage could be regarded as an early approach to a more complex subsequent evaluation. All occupational physicians should acquire sufficient knowledge to accomplish this level of evaluation, which consists of checking for the presence of "risk markers". The assessment design for risk factors has been adapted from OSHA guidelines for ergonomic standards and from state of Washington method.

Therefore, we believe that a preliminary analysis should assess only the presence/absence of common risk factors (strain, repetitive motion, posture) leaving the time factor and sequence analysis to a later step. Check lists for the information gathering and elaboration (OSHA, OCRA, Keyserling, Baracco) allow the occupational physician to manage a simple, first level analysis beginning with direct knowledge of the job cycle and work facilities.

Moving to health surveillance for former exposed to carcinogens , as health surveillance is a legal requirement, there are generic indications as to how to proceed. Primary rather than secondary prevention is the main goal. When working surveillance is recommended at least annually, and should be supplemented with further tests when necessary. This procedure is a good opportunity to inform workers on the significance and limitations of health surveillance and on preventive measures.

However, if what stated above is applied too strictly no account would be taken of ethical questions asking for the best possible scientific surveillance, once exposure to carcinogens, in particular at high doses, has been defined. It would seem rather reductive in this case not to adopt early effect tests allowing an early diagnosis.

For former workers significance of clinical and anamnestic issues have to be evaluated before carrying out further diagnostic examinations useful for subjects at high risk, where, by high risk, it is meant a prolonged exposure to high carcinogens doses, and their possible interaction with individual risk factors whether congenital or acquired, that may be associated with habits such as smoking. Another crucial point appears to be the identification of responsibility (for organizing and paying) of controls after retirement.

We hope that the contributions reported in this issue will be useful to discussion among Occupational Physician and to the improvement of their field activities

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Point of view of Italian Regions

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Key words

Mesothelioma; asbestos; guideline

Summary

The tragic chain of mortal events, that have happened to workers and people who have been exposed to asbestos, proposes clearly an accentuation of the efforts that have been undertaken up to now, even in absence of precise national directives, in order to give an answer to worries and, sometimes, to real consequences of citizens' and workers' asbestos exposure. Region of Tuscany, following the initiatives which have been carried out in national and regional field for the formerly asbestos-exposed or other carcinogenic agents workers, performed a guideline that was just titled "Guidelines on sanitary surveillance of formerly exposed to occupational carcinogens workers". The debate, which had risen around the sanitary surveillance of the formerly-exposed to occupational carcinogenic agents workers, had induced indeed many institutions to take decisions on issues which were not yet explicitly regulated by the national law. For example the guidelines provided suggestions regarding what bodies – either public or private – should be appointed to this task, or the kind of protocols should be adopted with all the related collective and individual consequences.

Riassunto

«Il punto di vista delle Regioni». *La tragica catena di eventi mortali accaduti a lavoratori ed a persone che sono state esposte ad amianto propone con evidenza un'accentuazione degli sforzi finora intrapresi, pur nell'assenza di puntuali direttive nazionali, per favorire una risposta alle preoccupazioni ed a volte, alle reali conseguenze dell'esposizione ad amianto di lavoratori e cittadini. In tal senso la Regione Toscana ha predisposto delle Linee di indirizzo su sorveglianza sanitaria dei lavoratori "ex-esposti" a cancerogeni occupazionali rivolte a Servizi di Prevenzione delle Aziende USL che rappresentano un atto di indirizzo coordinato, organico e uniforme per assicurare a tutti i lavoratori che rientrano nelle condizioni di esposizione, il più appropriato e qualificato livello di assistenza, tramite un percorso assistenziale che comprenda campagne informative, controlli periodici dello stato di salute, counseling per la riduzione del rischio e la ricostruzione delle coorti di lavoratori ex-esposti. La Regione Toscana, a seguito delle iniziative svolte in campo nazionale e regionale verso gli ex esposti ad amianto o ad altri agenti cancerogeni ha messo a punto una linea di indirizzo con la deliberazione del 26 giugno 2001, n. 692, titolata appunto Linee di indirizzo su sorveglianza sanitaria dei lavoratori "ex esposti" a cancerogeni occupazionali. Il dibattito sorto intorno alla sorveglianza sanitaria degli ex esposti ad agenti cancerogeni occupazionali aveva indotto, infatti, molte strutture a prendere decisioni su questioni non esplicitamente previste dalle norme, come ad esempio quali soggetti - pubblici o privati - fossero deputati alla sua attuazione, oppure quali protocolli adottare e con quali possibili conseguenze collettive e individuali.*

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Introduction

As it is known, asbestos is a natural fibrous-structure mineral, that in the past was used massively for its excellent technological properties. Indeed it has a good resistance to heat and fire, to the action of chemical and biological agents, to abrasion and wear: furthermore it has a considerable mechanical resistance, a high flexibility, it easily binds itself to building materials and has good sound absorbent and heat-insulating properties.

For these excellent qualities and for being cheap it has been used in several materials in industry, building trade, means of transport and so on. In these products, handmade articles and applications, the fibres can be both loose or weakly bound and tightly bound; in the first case we talk of asbestos with friable matrix, in the second one, instead, of asbestos with a solid matrix.

Yet we know that it has turned out to be injurious for man's health, because asbestos materials are able to release fibres which are potentially inhalable. And the exposure to such fibres is responsible of serious and irreversible pathologies, mostly of the respiratory apparatus.

Friable materials are the most dangerous ones, because they can be reduced in dust through a simple manual action and, because of their insufficient inner cohesion, they can spontaneously release fibres (above all if they are subjected to vibrations, draughts, seepages of water) or if they are damaged in the course of maintenance operations. Solid asbestos, instead, for its nature, doesn't tend to release fibres (there is a danger only if it is cut, abraded or deteriorated).

In this context, Tuscany Region has always carried out policies that tend to oppose asbestos-related risks, so that a series of initiatives have been taken for the mapping of companies that used asbestos even before the issuing of national regulations.

These problems, which are closely connected to the industrial development, the evolution of technical-scientific knowledge, let alone the taking of awareness of the workers themselves.

The Regional Plan about Asbestos of 1997 has represented a fundamental moment for an organic treatment of the problem, in order to outline quantitative dimensions and characteristics of the presence of the substance in this region, to decree obligations and duties of the enterprises and the other interested organizations, to define technical-operative aspects and to put into effect organizational and procedural measures against asbestos-related risks.

Within "Asbestos Plan" a significant importance has been given to activities of information, formation and assistance. And it is just on this side that public administrations, prevention healthcare workers and above all workers have lately concentrated more attention.

The tragic chain of mortal events, that have happened to workers and people who have been exposed to asbestos, proposes clearly an accentuation of the efforts that have been undertaken up to now, even in absence of precise national directives, in order to give an answer to worries and, sometimes, to real consequences of citizens' and workers' asbestos exposure.

In such sense Tuscany Region has planned some Guidelines about sanitary surveillance of "formerly exposed" to occupational carcinogen workers (Decree n. 692/2001). These guidelines, addressed to the Services of Prevention of National Health Agencies, represent an action of coordinated, organic and uniform policy in order to guarantee to all workers who have been exposed, the most appropriate and qualified level of assistance, through an "assistential approach" that comprises advertising campaigns, periodical check-ups, counselling for the reduction of the risks and reconstruction of cohorts of formerly-exposed workers.

This document has been largely widespread among workers through public initiatives, that have been organized by unions and in which the operators of Departments of Prevention of the Local Health Units (USL) have participated.

The Local Health Units (USL) of Toscany have taken some initiatives, addressed to formerly- exposed workers, which consist in plans that are based on medical surveillance and epidemiological researches (studies of death-rate on individuals exposed to carcinogenic agents).

From 1987 the function of registration of malig-

nant pleural mesothelioma cases has been started at the Centre for the Study and Oncological Prevention (CSPO) for the entire regional territory. From this date all the cases that have occurred in the regional territory have been collected and retrospectively reconstructed beginning from 1970 for the town of Florence.

The Prime Ministerial Decree (DPCM) 12/10/2002 n. 308 "Regulation for the determination of the model and modalities of registration about the cases of asbestos-correlated mesothelioma pursuant the article 36, paragraph 3 of the legislative decree n. 277 of 1991" has instituted at the ISPESL (Superior Institute for the Prevention and Safety at work) a national registry for the cases of asbestos-correlated mesothelioma. In this registry the information concerning the cases of mesothelioma has been collected with the aim to estimate the incidence of such cases, to analyze the previous asbestos-exposure of the registered cases and to promote plans of research in order to evaluate the connections between asbestos-exposure and cases of mesothelioma. With regard to this a decree n. 12521 of 24.11.2003 Tuscany Region has singled out the Operative regional Centre in the CSPO (Centre for the Study and Oncological Prevention).

On March 20, 2002 one day-study on malignant mesothelioma was organized in Toscany by the Regional General Directorate of the Right to the Health and by the CSPO with a presentation of the report on the registered cases of the Regional Record Office of Tuscany 1988-2000.

From the system-data of regional survey on the cases of professional diseases, that have been pointed out to the Functional Units PISLL (Hygienic Prevention and Safety at Work) of the Tuscan Local Health Units Agencies (Aziende USL), it turns out that the cases for pleural mesothelioma have been 56 in 2000, 78 in 2001 e 51 in 2002. Among the 51 cases, recorded in 2002, we confirm the prevalence of exposures in metal and mechanical sectors, as expected if we consider the previous risks for these sectors, while 7 cases have been recorded in the textile sector. The latter was studied in the past for its unsuspected sources of asbestos-exposure.

Sanitary Surveillance: Guidelines

Tuscany Region, following the initiatives which have been carried out in national and regional field for the formerly-exposed to asbestos or other carcinogenic agent workers, performed a guideline with a decree of 26 June 2001, n. 692, that was just titled Guidelines on medical surveillance of "formerly exposed" to occupational carcinogen workers. The debate, which had risen around the medical surveillance of the formerly-exposed to occupational cancerogenic agent workers, had induced indeed many institutions to take decisions on issues which were not yet explicitly regulated by national law. For example the guidelines provided suggestions regarding what bodies – either public or private – should be appointed to this task, or the kind of protocols which should be adopted with all the related collective and individual consequences.

The regional deliberation has and had the aim to point out possible assistential approaches that would be necessary on the territory, both for the request of particularly asbestos-exposed categories in the past or other carcenogenic agents, and for the initiative of the sanitary service, that has been pressed from epidemiological observations either from events " sentry" or from the presence of risks which are still currently present.

The most important points of the regional guideline regard:

– *Definitions of:* exposed workers or "formerly-exposed" workers; medical surveillance; epidemiological surveillance; counselling.

– *Actions and assistential approaches:* informative campaigns; regular medical examinations; counselling for the reduction of additional risks; epidemiological studies.

– *Bodies involved in these approaches:* Region; Public services of prevention and of epidemiology; Company doctors; General medicine doctors; Public and private medical facilities.

– *Protocol of intervention.*

After some years from this guideline it seems adequate to record and evaluate the activities that have been carried out and the difficulties that have emerged. This analysis will be useful to us in order to foresee modifications to the organization and

the possible improvements of the service. In order to do this a questionnaire has been predisposed and which has been sent to all the Departments of prevention of the region. The initiatives, regarding the sanitary surveillance, have been accomplished inside the regional territory and they have taken the starting-point from these guidelines, allowing to conform the plans of sanitary surveillance to a regional level. The revision and the possible updating of these guidelines are currently under study.

Specific sanitary interventions (participations)

Between the protocols for specific sanitary interventions there is a document for the professional category of the National Fire Department (VF): firemen's working activity implies, indeed, exposure to numerous toxic agents like smokes, exhalations, in particular Polyclyclic Aromatic Hydrocarbons (IPA), but also dusts which contain, in some circumstances, asbestos fibres. Some data have been published about the exposures of the firemen, even if the studies, that have measured or estimated the levels of polluting substances developing after the fire of various materials and during the activities of putting out, are very few. Some recent issues have illustrated the monitoring environmental activities which have been carried out soon after the fire of the buildings.

Such studies have pointed out both the necessity to use individual respiratory protective devices (Boldstad-Johnson, 2000) and the necessity to provide behavioural guidelines regarding the monitoring environmental activities in case of fire, particularly focusing on the necessity of monitoring exposure to asbestos fibres (Bridgman, 2001). In a study, that was carried out in England, it was estimated however that the contamination from asbestos fibres that was found during the operations of cleaning following the fire of a warehouse, that had a roof in asbestos cement , was modest and the risks for the cleaners' health were very low (Lewis, 1990).

Recently, after the environmental disaster caused by the terroristic attack to the Twin Towers and the consequent destruction of the World Trade Center (New York), a particular attention has been paid to the risks deriving from elevated environmental exposures to chemical substances and dusts (MMWR=Morbidity and Mortality Weekly Reports, 2002). A recent work has put in evidence that the dusts, that have been developed and diffused, mostly consisted of (for 95%) rough particles containing cement, glass fibres, asbestos, lead, IPA, policlorats Bifenils (PCB), furans and policlorats dioxins. It has been pointed out that there is a risk of mesothelioma for those who have carried out aid-activity so that there is the need to carry out a follow-up in order to keep under observation long-term risks (Ladrigan, 2004).

Asbestos-exposure for firemen can be also derived from the use of individual means of protection which contain asbestos. Surely in the past job conditions could be worse than the current ones, also because of the incomplete knowledge of the risks deriving from asbestos exposure.

Regarding the knowledge from literature on long-term effects on firemen's health we must say that, first of all, in the cohorts of firemen, which have been studied, we have recorded a reduced mortality for the whole causes and particularly for cardiovascular diseases (due to the known "healthy working effect"). Yet some excesses of cancer of the lung, brain, digestive apparatus, emolinfopoietic system and in particular of urinary tract and testicle, have been pointed out (Vena, 1987; Grimes, 1991; Aronson, 1994; Tornlig, 1994; Guidotti, 1995; Deschampes, 1995; Golden, 1995; Baris, 2001; Bates, 2001); the reasons of these excesses still remain unexplained also in relation to the fact that other studies have not pointed out any excess of cancer (Eliopulos, 1984; Heyer, 1990). A study has also described two cases of mesothelioma (Golden, 1995).

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Point of view of Occupational Health Prevention Units

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Key words

Asbestos; health surveillance; public services

Summary

The regulations pertaining to the obligation of continuation of health surveillance of workers formerly exposed to asbestos are also examined from the point of view of clinical epidemiological usefulness. The outcomes of some types of campaigns of health surveillance of formerly exposed workers organized by the SSN (National Health Service) are also examined.

Riassunto

«Il punto di vista delle unità di prevenzione della salute occupazionale». *Le normative concernenti l'obbligo del proseguimento della sorveglianza sanitaria di lavoratori con pregressa esposizione all'amianto vengono esaminae anche dal punto di vista dell'utilità clinico-epidemiologica. Vengono discussi i risultati di alcune tipologie di programmi di sorveglianza sanitaria di lavoratori esposti nel passato organizzati dal SSN.*

The regulations on prevention of asbestos-derived risks and risks due to carcinogenic agents also provide for the obligation of recording workers' exposure (art. 35 Legislative Decree 277/91). In the case where workers' exposure exceeds the levels established in Art. 24 of the said decree, i.e., greater than 0.1 fibres/ml, a registry must be established so that the names of the workers and the levels of exposure can be registered.

The levels of exposure are to be measured periodically, focussing attention on the concentration of airborne respirable fibres, using the methodology provided in Enclosure V if the levels of exposure exceed the limit of 0.1 fibres/ml. This obligation renders the registry and the registration a dynamic tool which can contain a workers' full occupational history.

The Registry reports to National Institute for Occupational Safety and Prevention (ISPESL) and the supervisory organ when initially set up and every three years on the variations occurring, and finally when work subject to risk ceases. ISPESL receives medical and risk records and individual reports that are contained in the registry for every single worker who ceases work subject to risk; ISPESL also receives all medical and risk records when a firm's operations cease.

It must be remembered that even the National Institute of Health can demand to consult and examine the registries.

Undoubtedly, the regulation that banned the use of asbestos, Law 257/92, contributed to establishing the system of preventive obligations for asbestos exposure which is, today, predominant in

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de-insulation activities. What remains to be done regarding the requirements of protection of asbestos-exposed workers is the obligation of recording exposure: this obligation can be best satisfied only if all the essential prevention activities are accomplished, these activities being the basis of the registration of exposure itself and including:

– risk assessment of exposure;

– notification to the supervisory organ in case of exposure exceeding statutory limits;

– obligation to inform workers;

– procedural, organizational technical measures;

– hygiene measures;

– health surveillance.

The employer is the person who has the obligation of recording exposure via:

– registry keeping;

– compilation: in this case the employer is assisted by the competent occupational health physician;

– communications with the Local Health Authority (ASL) and ISPESL.

The purposes of this registration are not fully explained in the regulations, but they can be assumed to cover the following types:

– preventive, collective and individual;

– epidemiological;

– compensatory and social security.

There are neither studies that demonstrate the validity of the obligation of recording nor experience of its use over time. It also seems to be very difficult to find local, general and total data on the communications received by ISPESL and ASL.

The studies related to health surveillance of workers formerly exposed to asbestos report difficulties in the recruitment of a sample of exposed workers and many judgements are made on the basis of information obtainable from data on people formerly employed in jobs involving different levels of asbestos exposure (8, 12).

We can presume that the asymmetry between the obligation to register the workers and the lack of any subsequent pertinent regulations has contributed to relapses of this obligation as foreseen in the regulation.

The first delay was due to the fact that no guidelines were issued for a registry model. Such delay has been in part compensated by the proposal drawn up by ISPESL and by a coordination of the Regions, which can be found on www.ispesl.it, which is currently available to all users.

It should also be noted that even on occasion of important national conferences, the various social partners have complained about this delay (non-governmental conference, Monfalcone, 12-13 November 2004, and the Governmental Conference on Asbestos, Rome, 1999).

As regards workers formerly exposed to asbestos, standardization features need to refer to the various temporal and occupational conditions.

A first watershed is related to the period prior to the introduction of Law (D.L.) 277/91 – presence or absence of the obligation of recording exposure. It must be remembered that during the previous period there were partial limitations of asbestos use (Ministerial Decree on Health (DM) of 26/6/86 which limited the use of crocidolite, and Presidential Decree (DPR) 215, 1988, which prohibited use of asbestos of whatever kind in the production of toys, articles for smokers, paints and varnishes).

A second period is related to Law 257/92 – with the obligation to ban asbestos use in manufacturing.

Therefore the category of formerly-exposed asbestos workers can be subdivided into various macro-categories:

– between " before" and "after" the obligation of exposure recording;

– between formerly-exposed intended as ceased exposures but continuing work in the same company and ceased exposure when there is an exposure in another firm which is not, however, involved in asbestos use.

It must be remembered that asbestos has been prohibited in manufacturing and has also been partially banned in systems or installations due to the effects caused by de-insulation.

Law 257/92 provided for a census of asbestos presence, which some authors believe has been only partially accomplished in some regions (5) and imprecise evaluations lead us to believe that asbestos is still present in some situations.

The situations where asbestos is thought to be probably present are particular systems which used asbestos for thermal and acoustic insulation:

– national and foreign maritime and rail transport;

– industrial systems in general;

– structural elements of building pipes and panelling;

– cover slabs/plates.

On this basis possible asbestos exposure at the present time can be presumed as:

unknown

– since no recording for assessment is made in plant engineering works, repairs, building construction and renovations

known

– in the case of current processes of insulation removal with possible and typical occupational and environmental exposure;

– in the global waste cycle and the "planting out" of materials deriving from de-insulation activity (as provided for in paragraph 34 and related obligations of Law (D.L.) 277/91)

The time limits of recording of asbestos exposures and of health surveillance tend to overlap, but they are two kinds of distinct obligations even if they are correlated.

In the case of health surveillance for formerly exposed workers, which is the duty of the competent occupational physician, and provided by law, pursuant to the paragraph 29 of Law (D.L.) 277/91, at the end of exposure we are have an obligation that is consistent with the general regulations for carcinogenic agents which, in the same way, provide for the continuation of health surveillance, and find that paragraph 29 of Law (D.L.) 277/91 and paragraph 69 of Law (D.L.) 626/94 are superimposable.

The law has not specified which organizations (public or business) will be responsible operatively and economically for such health measures.

It is evident that health surveillance of formerly exposed workers, who are still working, is the responsibility of the competent occupational health physician both in the case of permanence in the company where the worker has been exposed to asbestos and has been employed in different jobs, and in the case he changes company and job: the competent occupational health physician must receive both data on the previous asbestos exposure and data on health surveillance.

What remains to be defined is the scope of competences and legal responsibility of continuation of health surveillance for those workers who no longer work and who are in a condition which is objectively outside the occupational context, which is by definition collective.

The absence of national guidelines has led to a situation in which the experience that has been achieved in our country is restricted to a few Regions, and even here the experience differs from one to another.

All these experiences where attention has been focussed on the difficulties in identifying formerly exposed workers, confirm a limited availability of exposure recording, due to time-related problems concerning the year of implementation of the obligation of exposure recording.

Two types emerge from the different contributions that have produced real experience of formerly exposed workers health surveillance:

Local territorial experience which is important in setting up cohorts of workers

Regional experience based on programmed and tested principles of formerly exposed workers health surveillance, which may be considered as health planning .

In the case of planned regional experience, the organizational premises, motivations and principles can be found on the Internet.

The activity is carried out under the supervision and coordination of the Regional Health Departments: Friuli Venezia Giulia (4), Piedmont (1), Emilia Romagna (13), Veneto (8, 12), Tuscany (2, 6, 7), Lombardy (11).

As regards the preliminary planning, we not only considered possible details obtainable through tracing of employees in companies with jobs involving exposure to asbestos, but also assessments such as those deriving from the company Carex. An assessment of the prevalence of workers exposed to carcinogenic agents can be made according to criteria adopted in the Carex company. This is an international information system on occupational exposures to carcinogenic agents, backed by the European Union which provides the number - certain or questionable – of workers exposed to carcinogenic agents for every country and industri-

al activity. It is based on the composition of the labour force during the period 1990-1993.

We examined 55 branches of economic activity; these branches are classified according to the United Internal Standard Industrial Classification (UN-ISIC Rev 2) and we considered 139 agents, which have been classified by the International Agency for Research of Cancer (IARC) as "certain", "probable" and "possible" (IARC groups 1, 2A, 2B).

Health surveillance for formerly exposed workers has substantial in the phases of:

– planning of studies;

– recruitment of subject according to to a previously defined method of recruitment;

– management of meetings;

– implementation of health controls, which vary among area Services of Prevention in Workplaces and as regards medical specialists, pneumologists and radiologists;

– different forms of communication of results.

The continuation of (different) forms of health surveillance is generally obscure, moreover such forms are not numerous and there are generally different forms of involvement and participation of family doctors.

It must be borne in mind that health surveillance of formerly exposed workers does not come within the Essential Assistance Levels (LEA), as foreseen by the National Health Service.

Cost-analyses of these activities presume some quantifications relating to the cost of different health protocols which are both assigned to the surveillance project and to use by staff during contractual hours or during additional hours (3).

Management of formerly exposed workers health surveillance as provided by Law 277/91 requires monitoring methods of workers' health conditions and early diagnosis of a long-term disease (mesothelioma): however an early diagnosis of this disease does not usually lead to a significant rise in survival rate following diagnosis and this has not been proved in the literature.

A possible dual attitude has been observed:

– triggering of problems linked to fear of diagnosing a disease in workers with anxiety syndrome;

– a paradoxical emergence of a falsely induced security of being supervised.

Therefore, in the public health plans, the reasons for the study's usefulness from a social and health point of view need to be better defined:

– reasons of legal and medical nature of support also for recognition of an occupational disease;

– clinical reasons (possibility of an efficacious early diagnosis);

– public health reasons (reduction of additional risk);

– ethical-social reasons (possibility of information via individual contact);

– epidemiological reasons (a better knowledge of the cause/effect relationship).

The disadvantages which have been observed are:

– a substantial public economic commitment, with no certainties about the benefits for the individual and the community;

– risk of excessive medicalisation;

– possibility of raising inappropriate expectations of compensation and excessive worry on the state of health both in individuals and in community;

– failure to give up of harmful habits (for example smoking) which is motivated by the fact of being included in a health surveillance programme.

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Diagnosis of asbestos-related pleuropolmonary diseases

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Key words

Asbestosis; interstitial fibrosis; mesothelioma

Summary

A revision of criteria for diagnosis of asbestos-related pathological conditions was performed studying specially asbestosis, pleural plaques and malignant mesothelioma, also taking into account the problems connected with histopathology. As regards the histological diagnosis of asbestosis, it requires the presence of diffuse interstitial fibrosis in a well inflated tissue remote from the site of a tumour or other large lesion, plus the presence of two or more asbestos bodies in a 1 cm^2 section. As regards the imaging diagnosis, the HRTC 4-point scale proposed by Paris et al. (2004) has been adopted: - 0 images not suggestive of interstitial pneumonia; - 1 modest unilateral or bilateral interstitial abnormalities, involving restricted areas if bilateral; - 2 interstitial abnormalities of limited extent, but consistent with a diagnosis of asbestosis, i.e. honeycombing, even without other parenchymal changes and even though unilateral, or else any two abnormal findings among thickened interlobular septa, intralobular lines or subpleural curved lines; - 3 numerous bilateral changes on several slices involving more than 2/3 of the posterior third of each hemi thorax. Only points 2 and 3 were considered consistent with the diagnosis of lung fibrosis. Such HRCT findings are not specific for asbestosis, changes in the pleural wall such as diffuse plaques and thickenings contribute to the diagnosis of asbestosis. As regards the pleural plaques and asbestos bodies we remark that they are merely exposition markers. We also discussed the problems the pathologist may encounter in diagnosing mesothelioma; in this field the prospects are encouraging as microarray analysis are beginning to identify new molecular markers for mesothelioma.

Riassunto

«Diagnosi delle malattie pleuro-polmonari da amianto». *È stata compiuta una revisione dei criteri per la diagnosi delle patologie da amianto, con particolare riguardo all'asbestosi, alle placche pleuriche e al mesotelioma maligno, tenendo in conto anche i problemi di diagnostica istopatologica. I criteri per la diagnosi istologica di asbestosi sono delineati dal "Consensus report" (Helsinki, 1997) che richiede la identificazione di una fibrosi interstiziale diffusa in un tessuto ben aerato, lontano dalla sede di un tumore o di altra lesione massiva, plus la presenza di 2 o più corpuscoli dell'asbesto in una sezione di 1 cm^2. Recentemente, Attanoos e Gibbs (2002) hanno precisato che le aree di parenchima polmonare sottostanti ad ispessimenti pleurici con diffusa fibrosi interstiziale non debbono essere interpretate come asbestosi. Concordiamo con questa affermazione, ma accettiamo l'ulteriore precisazione che questa "fibrosi interstiziale diffusa" debba essere almeno una fibrosi di grado 3 della scala adottata dal College of American Pathologists, perché verrebbero lasciati fuori dal computo i casi di asbestosi minima. La HRCT nell'identificare la*

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fibrosi parenchimale, è una delle tecniche più sensibili e specifiche. Abbiamo adottato la scala proposta da Paris et al. (2004): - 0 non immagini interpretabili quali espressione di interstiziopatia; - 1 modeste anormalità interstiziali unilaterali o bilaterali, e se bilaterali visibili solo in aree molto limitate; - 2 anormalità interstiziali limitate per estensione, ma compatibili con la diagnosi di asbestosi, cioè aspetti a nido di ape, anche se non accompagnato da altre modificazioni parenchimali e anche se monolaterale, ovvero due aspetti abnormi, a scelta tra ispessimenti dei setti interlobulari, linee intralobulari o linee curve subpleuriche; - 3 profuse anormalità bilaterali visibili su parecchie sezioni interessanti più dei due terzi del terzo posteriore di ciascun emitorace. Solo se si sono osservate anormalità quali quelle indicate ai punti 2 o 3 si può porre diagnosi di fibrosi polmonare Questi reperti HRCT non sono specifici per asbestosi; se sono presenti alterazioni delle pleura parietale, quali placche e ispessimenti diffusi, queste sono di estremo conforto alla diagnosi di asbestosi. Le placche pleuriche e i corpuscoli dell'asbesto sono semplici indicatori di esposizione. Abbiamo pure illustrato le difficoltà che può trovare il patologo nella diagnosi di mesotelioma; in questo campo le prospettive sono incoraggianti, iniziando le tecniche sull'espressione genica a trovare nuovi indicatori per i mesoteliomi

Introduction

Owing to the increasingly wide scope of preventive medicine and also in relation to legal and insurance considerations, the diagnosis of asbestos-related pathological conditions (table 1) seems to require a revision of some concepts and criteria. We will focus on those conditions for which diagnostic methods appear to need it the most, i.e. asbestosis, pleural plaques and malignant mesothelioma, also taking into account the problems connected with histopathological diagnosis, which is widely and consistently employed.

In 2004 the American Thoracic Society (5) formulated a series of criteria for the diagnosis of non-malignant asbestos-related diseases. The main three criteria are: 1) evidence of structural pathology consistent with asbestos-related disease as documented by imaging or histology; 2) evidence of causation by asbestos as documented by the professional and/or environmental history, markers of exposure (e.g. asbestos bodies, uncoated mineral fibres, pleural plaques); and 3) exclusion of other plausible causes. The demonstration of functional impairment is not required for the diagnosis, but where present should be documented as an important element in the evaluation.

Table 1 - *Pleuropulmonary Manifestations Associated With Asbestos Exposure*

- Asbestosis
- Pleural plaques and thickenings
- Round atelectasia
- Pleural effusion
- Mesothelioma
- Pulmonary carcinoma

After a brief review of the histogenesis of asbestosis and pleural plaques, we will address the histological criteria that underpin the diagnosis of asbestosis; we will then illustrate the diagnostic potential of imaging techniques; we will analyse critically some data on the significance of pleural plaques and asbestos bodies; finally, we will discuss the diagnostic criteria of mesothelioma, also in relation to immunohistochemistry.

Histogenesis

Asbestos-induced lesions have been seen experimentally to arise at alveolar duct bifurcations where long fibre deposition occurs: here, they elicit a reaction involving granulocytes, alveolar macrophages, pneumocytes and lymphocytes. The resulting inflammation then spreads centrifugally in the alveoli and eventually to the adjacent interstitium. The mobilization of so many cells – especially macrophages - is related to the phenomenon of frustrated, ineffective phagocytosis, whereby long asbestos fibres tend to be phagocytosed by multiple macrophages and/or pneumocytes. By contrast, short fibres are wholly phagocytosed by macrophages and their toxic effects

are thus neutralized[1]. Interstitial involvement is favoured, as in silicosis (47), by lesions arising in the alveolar wall that may even become necrotic and that allow plasma proteins to filter through the wall. This may give rise to fibrin formation in the distal airways; fibrin degradation enhanced by production of plasminogen activator (PA urokinase) by the pneumocytes themselves subsequently gives rise to biologically active products that in turn favour inflammation.

Current theories on the pathogenesis of asbestosis and other lung fibroses hold that mediators and growth factors released from inflammatory cells and cells resident in the lower airways stimulate the uncontrolled deposition of excessive amounts of collagen. There is experimental evidence that numerous mediators stimulating the proliferation of lung fibroblasts participate in causing asbestosis. In rats, inhalation of crocidolite induced alveolar macrophages at the level of alveolar ducts (where the fibres were deposited) to produce cytokines and growth factors (24). γ-interferon also has a role in modulating asbestotic fibrosis via generation of nitric oxide (73, 64). Although it is unclear how asbestos fibres interface with the diverse cells involved in producing fibrosis, a mounting body of experimental evidence supports to the hypothesis that the biological effects of asbestos are due to reactive oxygen species generated through Fenton or Haber-Weiss reactions that also involve nitric oxide (40, 23). In the earliest phases of asbestosis, neutrophils predominate in alveolar cavities (24, 63), to which they are chemoattracted by the activity of C5aOH molecules formed from the action of asbestos on C5 produced by alveolar cells. After interface with biomolecules, on surface of asbestos fibres hydroxyl radicals were generate through Haber Weiss cycles that converted native C5 into an oxidized C5-like form, C5(H_2O_2). Finally, C5(H_2O_2) is cleaved by the action proteases (also physiologically present in alveoli and activated by the same mineral fibres) yielding two products, C5aOH and C5bOH, with the same functional characteristic as C5a and C5b (30). The accumulation of neutrophils in the alveolar cavities is clearly evident in experimental asbestosis induced by exposure to asbestos fibres of a single type over a limited amount of time, but is not always easy to detect in human asbestosis, which is induced by complex, prolonged exposure, often to different types of asbestos fibres. The mediators released by granulocytes and the asbestos fibres themselves soon attract into the alveoli an increasing number of macrophages, which are a hallmark of the early human disease and characterize morphologically the alveolitic process.

In synthesis, the asbestos-induced inflammation process involves first the lung alveoli and then the surrounding interstitium; this leads to fibrotic changes in respiratory bronchioles with peribronchiolitis of a more severe nature than the one induced in the small airways by other, non-sclerogenic, mineral dusts.

The interstitial fibrosis associated with asbestos exposure are found in the whole lung, are bilateral, and are commonly more evident in the inferior lobes. There is a significant correlation between severity of the fibrosis and cumulative asbestos exposure (31).

As regards the histogenesis of pleural parietal plaques, submesothelial fibroblasts were previously believed to play a crucial role; however, more recent data (37) suggest a greater involvement of mesothelial cells, which would be directly affected by the toxic action of the asbestos fibres in the pleural cavity (14). The inflammatory response would then ensue with production of fibrous matrix components (56) and altered fibrin turnover involving both increased formation and decreased dissolution. Fibrous matrix formation would be favoured by the production of cytokines such as TGFβ, and TNF-α (37, 14).

[1] In this particular context, *long fibres* are those with a length exceeding 5-8 μm and *short fibres* those 3-5 μm. Animal experiments performed to establish the role of fibre length in causing the disease found morphological evolutions substantially similar to those of human asbestosis with fibres exceeding 5-8 μm, both amphiboles (anthophyllite, amosite and crocidolite) and chrysotile. In some experiments, fibres measuring 3-5 μm failed to cause fibrosis, whereas in others nodular fibrosis did develop in the alveoli, while the tracheobronchial lymph-nodes exhibited foci rich in macrophages filled with mineral particles, some necrotic, with signs of reticulosis or fibrosis

At the light microscope, plaques appear to be constituted of strands of dense, non-vascular partly hyalinized collagen exhibiting a wicker basket arrangement; inflammatory cells may be detected below the plaque and mesothelial, often metaplasic cells at its edges.

Histological criteria

The current debate focuses mainly on the criteria defining minimal or grade 1 asbestosis, particularly those relative to fibrosis and number of asbestos bodies in histological sections. In case of lung carcinoma in exposed subjects, the diagnosis of asbestosis is a decisive element for the recognition of the pathology as an occupational disease.

The College of American Pathologists (21) has developed histologic criteria for asbestosis and a grading system to describe the severity and extent. In grade 1 the inflammation may involve one to a small number of respiratory bronchioles and alveolar ducts, but not the interstitial septa; in grade 2 a greater number of respiratory bronchioles, ducts and alveoli are involved, in grade 3 the fibrotic changes coalesce, with all the alveoli between at least two adjacent bronchioles exhibiting thickened and fibrotic walls and some alveoli being completely obliterated; grade 4 envisages the collapse of alveoli with fibrosis and remodelling of affected areas with formation of honeycombing giving rise to new dilated spaces lined or unlined with epithelium. As regards its extension, the process is classified as A-1 if several respiratory bronchioles are free of lesions at histology (fibrotic bronchioles being uncommon); B–2 if many but less than 50% of bronchioles are affected, and C-3 when more than 50% are involved[2]. Then interstitial fibrosis does not in itself differ from the one observed in other forms of interstitial pneumonias, like idiopathic pulmonary fibrosis (34).

According to Churg and Green (15), the terms mild, moderate and severe are sufficient to define the grade of asbestosis based on macroscopic and microscopic observation, but of course this is only feasible in autopsy specimens. The diagnosis of asbestosis is however increasingly made on biopsies obtained from open surgery, thoracoscopy, lobectomy or pneumonectomy, whereas transbronchial biopsy is absolutely inadequate.

The significance and diagnostic classification of asbestos-induced lesions in the small airways is still debated (9, 76). Their morphological appearance is similar to that reported for other mineral dusts, and under some respects for those induced by cigarette smoking. Although held by some to be the early phase of asbestosis, these lesions should be kept separate from frank asbestosis, given their unclear evolutionary potential towards a more severe form of fibrosis.

The finding of asbestos bodies in an important criterion for diagnosis.

The widely accepted criteria for the histological diagnosis of asbestosis are listed in the Consensus report (19) of the findings of a work group of 19 experts from 8 countries that met in Helsinki. They established that the diagnosis of asbestosis requires the presence of diffuse interstitial fibrosis in a well inflated tissue remote from the site of a tumour or other large lesion, plus the presence of two or more asbestos bodies in a 1 cm^2 section. These criteria have recently been confirmed by Attanoos and Gibbs (6), who added that even in the presence of asbestos bodies the areas of parenchyma underlying pleural thickenings with diffuse interstitial fibrosis should not be interpreted as asbestosis. While we do agree with this position, we do not feel that Attanoos and Gibbs are right in requiring diffuse interstitial fibrosis to be at least grade 3 on the College of American Pathologists scale, because all cases of minimal asbestosis would be left out. These are far from few: in 199 consecutive autopsies, 30 cases were found to have asbestosis grade 1 in 15 subjects (minimal fibrotic lesions on the walls of respiratory bronchioles associated with more than two asbestos bodies in the section) and 15 had a higher grade (9).

[2] In each section, the assessment is performed by multiplying the grade by the extension of the involvement: when several sections are examined, the sum of the points attributed to each section is divided by the number of sections examined

IMAGING TECHNIQUES

In this context, the high rate of false-negative results should not be surprising. As recently as 1986, the American Thoracic Society (4) recommended standard thoracic X-rays as one of the main diagnostic examinations, as the presence of small, irregular opacities (profusion ≥1/1 according to the ILO classification) was already significant. However, this examination has considerable sensitivity limitations, given that in 10-20% of subjects with histopathological findings of frank asbestosis, chest X-rays can be unable to demonstrate some interstitial lesion (42, 65).

HRCT is more sensitive than and has long superseded CT in detecting parenchymal fibrosis (33, 46, 52-54): in a cohort of exposed subjects with essentially negative radiographic findings (ILO 0/0 or 0/1), it detected interstitial abnormalities consistent with asbestosis in 34%; such data correlated with a significant respiratory function impairment including a reduction in alveolo-capillary diffusion (71). However, a negative HRCT for parenchymal changes does not allow to exclude asbestosis with certainty.

The study of asbestosis benefits from scans performed with the subject lying prone, with at least one acquisition through the right hemidiaphragm, so that the diaphragm occupies less than half of the right hemi thorax. Accuracy increases with increasing number of slices (75). It should be noted that the inferior lobes are preferential sites of asbestosis; as highlighted by Murray et al. (55), prone acquisitions enable easier differentiation of fibrosis from areas of atelectasia that may be found in posterior lung areas. Paris et al. (60) described a protocol envisaging six prone scans, five scans equally distributed between the carina of the trachea and the bottom part of the costophrenic angles, and the sixth being halfway between the carina of the trachea and the extreme pulmonary apices.

In asbestosis HRCT findings (table 2) are typically bilateral and prevalently involve cortical and posterobasal regions.

Peribronchiolar nodular thickening, subpleural dot-like opacities and ground-glass opacities (less common) may be early signs; subpleural dot-like opacities tend to confluence and give rise to subpleural curved lines.

Table 2 - *HRCT findings of asbestosis*

- Peribronchiolar nodular thickening
- Intralobular thickening
- Interlobular septal thickening
- Subpleural dot-like opacities
- Subpleural curved lines
- Parenchymal bands
- Ground-glass opacities
- Honeycombing

Ground-glass opacities reflect areas where the alveolar cavities are rich in inflammatory cells and have moderately thickened walls, corresponding to grade 3 of the classification of the American College of Pathologists. They should not be confused with hyperdense opacities, which are found in supine subjects in the subpleural costovertebral grooves and disappear when the position is changed.

Subpleural curved lines reflect fibrotic thickening around the bronchioles associated with collapsed alveolar structures contiguous to the fibrosis (3), corresponding to grades 3-4 of the American College of Pathologists. They are significant only if persistent since they can be found in healthy subjects, but, in this case, they disappear if patient position is changed.

Thickened intralobular septa are in relation to the peribronchiolar fibrosis and consequent involvement of alveolar ducts.

Thickening of interlobular septa and parenchymal bands are found with oedema and/or fibrosis.

HRCT findings can be summarized (60) on a 4-point scale:

0. images not suggestive of interstitial pneumonia;

1. modest unilateral or bilateral interstitial abnormalities, involving restricted areas (e.g. less than 1/3 of the posterior third of each hemi thorax) if bilateral;

2. interstitial abnormalities of limited extent (e.g. between 1/3 and 2/3 of the posterior third of each hemi thorax) but consistent with a diagnosis

of asbestosis, i.e. honeycombing, even without other parenchymal changes and even though unilateral, or else any two abnormal findings among thickened interlobular septa, intralobular lines or subpleural curved lines;

3. numerous bilateral changes on several slices involving more than 2/3 of the posterior third of each hemi thorax.

Only points 2 and 3 were considered consistent with the diagnosis of lung fibrosis.

Clearly, such HRCT findings are not specific for asbestosis, being compatible with other lung interstitial pneumonias (32, 53) or even cardiovascular disease (11). Changes in the pleural wall such as diffuse plaques and thickenings contribute to the diagnosis of asbestosis.

Pleural plaques present as circumscribed thickened areas (1 to 10 mm) and variable length, prevalently at the level of posterolateral areas and the diaphragm, the inferior lobes and less commonly the fissures, costophrenic sinuses and apices. Plaques are bilateral, multiple and may be calcified in 10-15% of cases.

Diffuse pleural thickenings are usually about 3 mm in thickness, 5 cm in height and 10 cm in width, and do not exhibit calcification.

Rounded atelectasis appears as a round or oval mass that abuts the pleura, with a "comet tail" of bronchovascular structures going in the mass and thickening of the adjacent pleura.

A HRCT-ILO classification has been devised but is not widely adopted (44).

HRCT has an important role in the diagnosis of asbestosis when radiographic findings are equivocal, extensive overlying pleural abnormalities do not allow a clear interpretation of parenchimal markings, or in presence of a normal radiogram with impaired respiratory function. HRCT is also more specific than chest X-rays and dispels all doubts regarding emphysema, vessel prominence, pleural involvement, and bronchiectasis. It is also more sensitive than X-rays in detecting pleural plaques and thickenings and can differentiate them from subpleural fat and intercostal muscles and veins.

Use of HRCT has been advocated to establish the presence of asbestosis in subjects with occupational exposure to asbestos who have a negative chest X-ray but significant changes in respiratory function (58, 57), or basilar crackles on physical examination (39). By contrast (19, 38), others recommend HRCT for workers with occupational exposure with irregular opacities ≥1/0 according to ILO, or pleural plaques. In France, systematic HRTC screening with a 6-year periodicity was recommended in subjects older than 50 years with severe occupational exposure to asbestos (20), while it does not seem warranted for people with low occupational exposure (60). The SIMLII guidelines for the health surveillance of subjects exposed to carcinogenic and mutagenic agents in the work environment (62) considering that there is an algorithm of European Institute of Oncology, which overcomes at least partly the problem of the large number of false positives, proposes diagnostic imaging for screening directed at the early diagnosis of exposure-related diseases, among which lung cancer and mesothelioma in formerly exposed workers. Moreover suggests that the request of screening is evaluated by the occupational physician or general practitioner after informing the subject about the usefulness and limitations of the method and obtaining his/her consent in line with regulations on periodical radiological screening examinations.

Pleural plaques

Pleural plaques do not require severe exposure to arise and appear in chest films 20-30 years from the beginning of exposure. For a long time they have been considered as mere indicators of remote exposure even to low asbestos concentrations (61). However, according to the guidelines of the American Thoracic Society (5) their presence is associated with a greater risk of mesothelioma or lung cancer than subjects with comparable exposure without plaques, in line with Hillerdal's opinion (35, 36). We cannot share this view, because the researches of Hillerdal are methodologically flawed. Hillerdal followed 1588 patients with pleural plaques diagnosed radiologically, 88.7% of whom had had occupational exposure to asbestos in the Uppsala area; he recorded the cases of lung cancer

and mesothelioma in this cohort and compared them with expected incidence from the official cancer registry of Sweden. 50 bronchial carcinomas occurred, while 32.1 were expected after correction for smoking habits. The risk for subjects with pleural plaques without asbestosis was increased 1.4 times. There were 9 mesotheliomas, while only 0.8 were expected. The author concluded that pleural plaques carry an increased risk of mesothelioma and possibly also of bronchial carcinoma. His cohort was made up of otherwise healthy subjects, most of whom had been exposed to asbestos, but he did not study a control group of exposed individuals without plaques. In addition the expected incidence was calculated in the general population. Commenting on this work, Smith wrote an editorial that ended as follows: "*This study is just another study that has failed to demonstrate convincing evidence of a significant risk of lung carcinoma associated with pleural plaques without asbestosis.*" (69).

Asbestos bodies

Asbestos bodies have long been considered as an important index of exposure to asbestos fibres (66, 51, 74). In vitro experiments (45) have demonstrated that the iron molecules on their surface are capable of triggering hydroxyl radical reactions that can induce DNA damage. More recently Ghio, Churg and Roggli (25) advanced the hypothesis that asbestos bodies are the expression of the sequestration of the iron on the surface of asbestos fibres, which is stored in ferritin in a less catalytically active state. Part of this iron remains catalytically active, since during body formation ferritin turns into haemosiderin. Asbestos bodies could thus trigger Fenton-type reactions capable of damaging lung structures and thus concur with asbestos fibres in giving rise to asbestos-induced fibrosis. Although the hypothesis is highly suggestive, it should be noted that in vivo, particularly in alveolar cavities, asbestos bodies are closely associated with polymorphonuclear leukocytes and macrophages, on whose membrane are found lactoferrin molecules capable of chelating iron (2, 8). In an in vitro experimental system where the data reported by Lund et al. were confirmed (45), generation of radical species by the bodies was prevented by addition of polymorphonuclear cells (29).

Whether asbestos bodies decompose in tissues after death, a problem of considerable medico-legal interest, has not yet been established with certainty. Mollo et al. (50) who studied unfixed lung fragments kept in containers for up to 18 months, believe that decomposed lungs from cadavers exhumed months after burial may yield false-negative results. By constrast, Dodson et al. (22) reported non significant reductions in the number of asbestos bodies in lungs exhumed up to 8 and a half months after death; however, some of the corpses had been embalmment The need for further studies is obvious given the importance of this question.

Additional information should also be sought better to define the role of mineralogical analysis in light and electron microscopy in detecting asbestos bodies and mineral fibres after chemical digestion of tissues (10) and in establishing pulmonary burden thresholds between individuals with occupational exposure and unexposed subjects. According to the 1991 consensus statement (26), a concentration of 1000 bodies/gram of dry lung tissue is "highly suggestive" for occupational exposure, even though lower concentrations do not allow to exclude an occupational risk.

Mesothelioma

The reliability of the pathological diagnosis of mesothelioma (and non mesothelioma) in a serous malignant tumour does not differ from that of other tumours (49). Diagnostic problems may arise in the differentiation of growths reflecting mesothelial reactions or findings of fibrosing pleuritis from malignant mesothelioma; in this respect Churg (17, 16) has recently given a number of useful suggestions.

In addition, even though in several cases the diagnosis of mesothelioma can be made on haematoxylin and eosin-stained sections (12), in other cases histochemical and immunohistochemical techniques are extremely useful, for instance to dis-

tinguish an epithelioid mesothelioma from adenocarcinoma. Conventional histochemistry may demonstrate the presence of hyaluronate in mesothelioma and mucinous glycoproteins in adenocarcinoma. Cationic stains like alcian blue bind characteristically to mesothelial cell membranes; this reaction is even more specific if it is performed before and after digestion with streptomyces-derived hyaluronidase. PAS-diastasis or mucicarmine can be used to demonstrate glycoproteins produced by adenocarcinoma or primary and metastatic mucinous carcinoma of the lung. Several batteries of antibodies have been proposed for immunohistochemical analysis, some of which stain mesothelial cells and others bind to antigens commonly expressed in adenocarcinoma cells; however, none of these markers is specific for mesothelioma or adenocarcinoma. The literature on the subject is quite vast, since the earliest applications of immunohistochemical methods to the diagnosis of mesothelioma date back to the end of the 1970s. Very few data are sufficient to account for the lack of consensus found among laboratories on the most useful markers; however, this is also due to the fact that new antibodies are continuously being tested to achieve specific and sensitive tools. Comin et al. (18) examined 42 epithelial mesotheliomas and 23 peripheral lung adenocarcinomas and suggest that calretinin and thrombomodulin are the best positive mesothelioma markers, whereas CD44H seems to be insufficiently specific for practical use, and HBME-1 appears to be of no any value. CEA and CD15 resulted the most specific for separating mesothelioma from adenocarcinoma. In a study of 44 pleural mesotheliomas and 23 pleural metastases of carcinomas (27), HBME-1 and vimentin were found to have high sensitivity (90% and 100% respectively) and specificity (91% and 60%, respectively) for mesothelioma, while MOC.31 and Ber-EP4 were highly sensitive (94% and 84% respectively) and specific (both 86% both antibodies) for carcinoma. The mesothelial cell markers that yielded the best specificity in a study by Kobashi, Matsushima and Irei (43) were cytokeratin 5/6 (100%), calretinin (88%), EMA (88%), thrombomodulin (58%) and vimentin (58%), whereas TTF.1, CEA, and LeuM1 yielded negative results. According to Soomro et al. (70), epitheliod and biphasic mesothelioma can be distinguished by positivity for calretinin, thrombomodulin, cytocheratin 5/6 and HBME-1, and negative immunostaining for CEA and Ber-EP4. In an assessment of the sensitivity and specificity of 10 monoclonal and 2 polyclonal antibodies for the differential diagnosis between mesothelioma and adenocarcinoma, Yaziji et al. (77) found that calretinin was the most sensitive to mesothelioma (95%), followed by HBME-1 (84%), WT-1 (78%), cytokeratin 5 (76%), mesothelin (75%) and vimentin and thrombomodulin (68%). The latter was the most specific for mesothelioma (92%), followed by cytokeratin 5 (89%), calretinin (87%), vimentin (84%) and HBME-1 (45%).

Two new monoclonal antibodies, podoplanin and D2-40, have recently proved useful to distinguish epithelioid mesothelioma from adenocarcinoma (59). To test the usefulness of immunohistochemistry in distinguishing peritoneal mesothelioma from serous papillary carcinoma, which involve different therapeutic approaches and carry different prognoses, Barnetson et al. (7) studied 20 peritoneal mesotheliomas and 14 serous ovarian carcinomas with a panel of 16 antibodies. Positive staining for calretinin was identified in 17 (85%) of 20 mesotheliomas, and all carcinomas were negative; Ber-EP24 stained 27 (96%) of 28 carcinomas and 2 (10%) of 20 mesotheliomas. In addition, the antibodies directed against estrogen receptors immunostained 26 (93%) of 28 carcinomas, while those directed against progesterone receptors stained 8 (29%) of 28 carcinoma. The latter two antibodies gave consistently negative results with mesotheliomas.

While stressing the fact that there exist no markers for sarcomatoid mesothelioma, which however accounts for a small proportion, and that there is no absolutely specific marker for epithelioid mesothelioma, as recently highlighted by Suster and Moran (72), we report below the results obtained by Samuel and Hammar (67) with a number of markers using epithelioid mesothelioma and adenocarcinoma (table 3).

Finally, King et al. (41) have recently carried out a systematic analysis of the results of 88 pub-

Table 3 - *Reactivity of some markers to epithelioid mesothelioma and adenocarcinoma*

Antibody	Reactivity for mesothelioma	Reactivity for adenocarcinoma
Keratin 5/6	+-	R
CEA	R	+
CD.15/LeuM.1	R	+-
B72.3	R	+-
Ber-EP-4	-+	+-
TTF-1	N	+-
Calretinin	+-	R
HBME-1	+-	R

+- : variable staining mostly positive
-+ : variable staining mostly negative
R : rare cells positive
N : almost always negative

lished papers comparing immunohistochemical staining of a panel of antibodies in mesothelioma with epithelioid area, and pulmonary adenocarcinoma metastatic to pleura. Results of a total of 15 antibodies were analysed and expressed in terms of sensitivity and specificity. The most sensitive antibodies for identifying pulmonary adenocarcinoma were MOC-31v and BG8 (both 93%), whilst the most specific were monoclonal CEA (97%) and TTF-1 (100%).The most sensitive antiboidies to identify epithelioid mesothelioma were CK5/6 (83%) and HBME-1 (85%). The most specific antibodies were CK5/6 (85%) and WT1 (96%). Where the results are equivocal by immunohistochemistry, electron microscopy helps distinguish mesothelioma from adenocarcinoma and is also occasionally necessary to distinguish desmoplastic or sarcomatoid mesothelioma from fibrous pleuritis (68).

Conclusion

We have illustrated the ability of HRCT in recognizing asbestos-related pulmonary fibrosis and pleural plaques as well as SIMLII's suggestions regarding its use in the health surveillance of individuals with previous asbestos exposure. Several studies are under way to address the problem of false-positive nodules: if the results obtained by Buck et al. (13) with PET, whose important role has been stressed by the American College of Radiology Imaging Network (1), are confirmed, this technique will become a useful adjunct to currently used tools.

We also discussed the problems the pathologist may encounter in diagnosing mesothelioma; also in this field the prospects are encouraging as microarray analysis are beginning to identify new molecular markers for mesothelioma (48; 28).

As regards the diagnostic criteria of the American Thoracic Society (5) for asbestos-related diseases, the important role of patient history cannot be neglected both in cases of pulmonary fibrosis and pleural cancer. In either, patient history, signally occupational history, can contribute to guide the diagnostic workup. If the history highlights occupational exposure to asbestos, the occupational physician may perform an accurate reconstruction of this exposure and the pathologist may determine the pulmonary asbestos body burden and/or investigate signs of even minimal asbestosis.

Finally, clinical history should not only be considered in view of the immediate pathological and clinical diagnosis, as its evolution may also be extremely important (or even crucial) in the final legal assessment, which is not infrequently made several years from the first diagnosis of asbestosis or malignant mesothelioma, when the patient may have already died.

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Medical surveillance of workers previously exposed to asbestos

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Key words

Mesothelioma; health surveillance; asbestos; osteopontin; mesothelin

Summary

According to current Italian law health surveillance of workers exposed to asbestos in the past must be maintained even after cessation of asbestos exposure (D.Lgs. 277/91). The law, however, makes no reference to timescales or time limits for clinical monitoring, nor to who is responsible. The main aims of health surveillance of individuals formerly exposed to asbestos can be summarized as follows: early diagnosis of the principal diseases associated with asbestos; counselling for workers; work-related disease certification; epidemiological studies. Medical check-ups entail a complete personal and work history, Chest X-Ray, respiratory function tests, TLCO. In all cases the worker must undergo a LDCT. We propose two new possible biological markers for the health surveillance of past-exposed patients: serum mesothelin and osteopontin.

Riassunto

«Sorveglianza sanitaria di lavoratori con pregressa esposizione ad amianto». *L'attuale legislazione italiana prescrive che la sorveglianza sanitaria dei lavoratori esposti all'amianto nel passato sia mantenuta attiva anche dopo la cessazione dell'esposizione (D.Lgs. 277/91). Tuttavia, la legge non fa riferimento alla frequenza o ai limiti temporali del monitoraggio clinico, né a chi compete tale dovere. Gli scopi principali della sorveglianza sanitaria di soggetti con pregressa esposizione ad amianto possono essere così riassunti: diagnosi precoce delle principali patologie associate all'amianto; assistenza sociale e psicologica per i lavoratori; certificazione della malattia professionale; costruzione di coorti per studi epidemiologici. Il controllo medico comprende l'anamnesi personale e lavorativa completa, radiografia del torace, prove di funzionalità respiratoria, TLCO, nonché LDCT in tutti i casi. Si propongono due nuovi marcatori per la sorveglianza sanitaria di soggetti con pregressa esposizione ad amianto: mesothelina e osteopontina serici.*

Introduction

The first problem encountered when dealing with health surveillance of individuals who have been exposed to asbestos in the past is related to the definition of *exposure*.

The contribution of Prof. Piolatto, who spoke about this in the previous speech, is undoubtedly important as a reference point for guidance on this topic.

One error, for example, would be to consider as *exposure* even the mere and general presence of asbestos in the working environment, without measuring the effective or estimated inhalation of fi-

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bres. It is always necessary to evaluate, or at least estimate, whether or not one is dealing with true exposure.

Another important aspect to consider prior to the arrangement of a health surveillance programme for individuals who have been exposed to asbestos, are the aims one wants to achieve thereby.

One cannot embark on health surveillance of the population of formerly exposed patients without taking into account the aims one wants to achieve and evaluating the costs (also and especially in terms of radiation exposure) in direct relationship with real usefulness of the latter (7). For this reason also, an ideal surveillance programme cannot avoid taking evidence-based medicine into account.

Of all possible diseases due to exposure to asbestos, cancer (of the pleura and the lung) is definitely of most concern because of the difficulties encountered in trying to determine their origin and the attribution of responsibility resulting thereof. However, we also know that the possible health effects of asbestos can also be non-cancerous, as with benign pleural pathologies and asbestosis.

Up to now there have been few contributions to the development of a methodology specifically aimed at the health surveillance of individuals formerly exposed to asbestos.

Even the qualified contributions of the Regional Technical Coordination (5) and of SIMLII (16), who have diverging schools of thought with regard to the surveillance of individuals exposed to carcinogenic substances in the past, do not provide clear, operational proposals for the surveillance of past-exposed individuals , in particular to asbestos.

Many different sources have stressed the necessity of favouring the development of shared guidelines regarding post-work and post-exposure surveillance practices, with the Public Services covering this role of assistance. The Region of Tuscany Work Group, as well as other regional working groups, has proposed guidelines for health surveillance of "past asbestos-exposed" workers, an the steps for intervention (4, 12).

Useful suggestions, (both general and specific for the preparation of this report) are found in the reports of experience of the various units operating in the area (13, 14).

Aims of health surveillance of past-exposed patients

Periodic surveillance of past-exposed individuals can have a number of aims of a preventive nature, for example.

In some cases, (as is the case of lung tumours) the data resulting from analyses give encouraging results in this sense.

Health surveillance can identify other (non-asbestos) work-related diseases in a population which has definitely worked in hazardous conditions.

Health surveillance can, moreover, be a an excellent means of promoting good vehicle for promoting healthy lifestyles in individuals who are undoubtedly subject to risk.

The main aims of health surveillance of individuals formerly exposed to asbestos can be summarized as follows:

1. Early diagnosis of the principal diseases associated with asbestos

The detection of bilateral pleural plaques can be useful both from a medical and medical-legal point of view, for example for the recognition of a work-related disease status. However, it can also affect the patient's quality of life, as a result of the often unjustified fear generated by the disease. Nevertheless, according to the ATS Guide Lines (2, 3), at the same levels of exposure, the risk of mesothelioma and lung tumour appears to be higher in patients with pleural plaques than in patients without plaques.

Through health surveillance, it is possible to achieve early diagnosis of asbestosis, thus allowing measures to be taken to delay the progression of the disease (for example by persuading smokers to stop smoking) (6).

Moreover, this kind of diagnosis has medico-legal implications for the recognition of work-related disease status.

For mesothelioma, the principal aim of health surveillance has up to date been to identify work-related diseases since, as is well-known, no efficacious treatment that could positively alter the prognosis have been available. However multimodal treatment programmes that combine surgical cytoreduction with new forms of radiation therapy and more effective chemotherapy

combinations may result in significant increases in survival rates for certain subgroups of mesothelioma patients. The possibility, therefore, of initiating treatment at an earlier stage of the disease predicts improved results in the future.

2. Counselling for workers

Counselling consists of supplying the worker with various kinds of information:

– on diseases related to asbestos exposure

– on the possibilities of primary prevention: cessation of smoking, cessation of exposure to dusts or materials which may in any way irritate the respiratory tract

– on the possible medico-legal recognition of the diagnosed disease and the stage of the same

– on the need to go to a trusted general practitioner, if respiratory symptoms were to appear, and report past exposure in order to have a complete history and undergo further tests if needed.

3. Work-related disease certification

It is necessary to send a report and first certificate for all asbestos-related diseases to the competent authorities.

Whilst for some of these diseases the relationship is well established, (benign pleural diseases, round lung atelectasis, asbestosis, malign mesothelioma, lung cancer) for others there are still doubts (chronic bronchiolitis, cancer of the colon, cancer of the bladder, cancer of the larynx) (2).

4. Epidemiological studies

Apart from reasons cited above, medical surveillance for patients formerly exposed to asbestos is required by Italian law (D.Lgs 277/91).

MESOTHELIN AND OSTEOPONTIN: POSSIBLE BIOLOGICAL MARKERS IN THE HEALTH SURVEILLANCE OF PAST EXPOSED PATIENTS

In an article published in 2003, a group of Australian and American research scientists (6) devised a method called ELISA, which proved to be effective in dosing the serum concentration of proteins of the Mesothelin family (SMR). The test proved to have an 80% sensitivity rate for MM and a 99% precision rate in healthy controls. The most surprising result of the research, which validates a predictive feature of this test, is the fact that 3 out of 7 past asbestos-exposed patients with high SMR levels had developed MM, and a fourth worker developed lung tumour within the 5 year time-span following the test, whilst none of the 33 past exposed patients with normal SMR concentrations had developed a tumour in *exactly* the same time-span. This study aroused remarkable interest and offers much hope.

SERUM OSTEOPONTIN

Osteopontin (OPN) is a phosphorylated acid glycoprotein that has been implicated in a number of physiological and pathological events, including maintenance or reconfiguration of tissue integrity during inflammatory processes.

In order to evaluate osteopontin as a potential marker for mesothelioma, researchers from several institutions conducted a clinical study to compare osteopontin levels in patients diagnosed with mesothelioma and patients with benign (non-cancerous) lung conditions. This study included 76 patients who had been diagnosed with Mesothelioma, 69 individuals who had asbestos-related benign lung conditions and 45 healthy individuals who had not been exposed to asbestos. All individuals had blood tests for osteopontin levels.

Overall, osteopontin levels were strongly associated with mesothelioma:

– osteopontin levels were significantly higher in the group of patients diagnosed with mesothelioma compared to those individuals with asbestos-relat-

ed lung complications (133 ng/ml versus 30 ng/ml, respectively);

– osteopontin levels did not differ significantly between individuals with asbestos-related lung conditions and those who were never exposed to asbestos;

– osteopontin levels correctly identified nearly 78% of patients with mesothelioma, and accurately distinguished between mesothelioma and benign lung conditions at a rate of 85.5%;

– osteopontin accurately identified individuals with stage I mesothelioma (earliest stage - prior to spread), as well as those with advanced disease.

The researchers concluded that osteopontin could be a promising marker for the detection of mesothelioma. Furthermore, osteopontin identified patients with early-stage mesothelioma, a stage at which surgical removal may be possible. However, further studies are necessary to confirm these findings, and also determine whether early detection via measurement of osteopontin levels can improve survival rates.

Initial results from studies performed at our research centre on mesothelin and osteopontin

Within the framework of a specific research activity, our group is analysing mesothelin and serum osteopontin levels in individuals diagnosed with malignant pleural mesothelioma, lung tumour, non-malignant pulmonary diseases, and healthy individuals, both past-exposed and non-exposed to asbestos (10).

Several hundred cases and controls have been analysed.

From the initial results, which are soon to be published, it can be seen that these indicators are extremely useful health screening tools, with high sensitivity and specificity levels (especially mesothelin) in relation to malignant mesothelioma and, used together (in view of the various different sensitivities and specificities of each indicator) are an effective monitoring device for other types of diseases, like lung tumour and other non-neoplastic respiratory diseases. On the basis of the data available, it can be affirmed that determination of both SMR and OPN could also be useful markers for screening asbestos-exposed individuals.

Strategies in health surveillance of past exposed individuals

According to current Italian law, health surveillance of workers exposed to asbestos in the past must be maintained even after cessation of asbestos exposure (D.Lgs. 277/91). The law, however, makes no reference to timescales or time limits for clinical monitoring, nor to who is responsible.

In any case, it seems evident that in this kind of programme the amount of invasive diagnostic procedures should compatible with the level of risk the individual has been exposed to (extent and duration of exposure), and/or the presence of synergic factors, and/or evidence of sub-clinical alterations that can be ascribed to the specific risk, based on identification and characterization of the risk, both at individual level and at group level. For this purpose two different types of research are necessary, epidemiological and clinical, the results of which must be integrated in order to set up a correct health surveillance that is adequate for each single worker's risk level. If, on the one hand, it is unacceptable that individuals at risk of neoplastic and non-neoplastic asbestos-related diseases are not under a health control programme, on the other hand, the inclusion of workers with merely potential or irrelevant exposure in follow-up practices will create a risk of a falsely positive attitude requiring invasive and costly integrative medical tests, unacceptable both on an economical and on a human level.

It is important that past-exposed workers be assessed in an initial clinical control in global terms (namely, both clinical/radiological and functional) for diagnosis and recognition of possible neoplastic and non-neoplastic asbestos-related occupational diseases, as well as for classification of the type of exposure. Once the investigations have taken place, also in relation to epidemiological data and the existence of possible non-occupational risk-factors (tobacco smoking, familiarity, etc.), it will be possible to define an individual risk profile which will

enable health surveillance to be planned from a risk/benefit and cost/benefit outlook.

Generally speaking, periodic yearly controls are justifiable only for workers with the highest risk levels and for those who present benign diseases associated with asbestos, whereas for medium/low exposure and in the absence of other risk factors, 3-yearly control periods could be proposed.

The general approach. as regards imaging tests, is for these workers to undergo chest X-Ray and at a subsequent, a spiral low dose CT (LDCT) (9) to minimize radiological risk whilst still obtaining sensitivity and specificity levels superior to traditional screening with just chest X-Ray.

To schedule HRCT at the first diagnostic screening does not appear to be very useful and furthermore exposes the patient to significant radiological risk and ought only to be used in more profound diagnostic examinations when a neoplastic disease is suspected. Such methodology appears to be similar to the health surveillance project recently proposed for workers exposed to silica dust (13).

A useful contribution can be found in the ATS documents (1-8) and in the Helsinki Consensus Report (1-3, 5, 11, 16, 17).

Operative proposal for health surveillance of past-exposed individuals

It is important to establish the criteria whereby health surveillance of past-exposed individuals will minimize costs and invasive tests and optimize the results.

The following methodological proposal is based on the literature and the authors' experience.

As far as we know, according to currently available data, mesothelin and osteopontin still have the status of scientific research and therefore it is necessary to obtain informed consent from the workers.

A. Initial screening of past-exposed workers

The first contact with the worker who has had previous exposure to asbestos must be aimed first of all at focussing on the main medical history and clinical aspects. The following protocol is proposed:

1. medical check-up with a complete medical history, chest X-Ray, respiratory function tests, TLCO, mesothelin and osteopontin analysis;
2. where chest X-Ray reading or re-reading suggests the presence of a pleural or pulmonary disease, or if the mesothelin and osteopontin dosage is high, the worker must undergo a LDCT;
3. if the LDCT proves negative or shows alterations of a benign pleural type, or asbestosis, the protocol would end with carrying out medico-legal procedures;
4. if the LDCT suggests the presence of alterations of a neoplastic nature of the lung or pleura, the patient must immediately be sent to a chest specialist for more in-depth examination.

During the medical check-up the occupational physician must inform the worker, without alarming him, with regard to the occupational risk that has been certified, on the importance of a preventive life-style and on the importance of a medical follow-up. Once the check-up has taken place, the occupational physician must give a copy of the medical records to the worker, with the details ensuing from health surveillance.

The worker must be informed of the fact that the onset of dyspnoea and/or chest pain - not to be mistaken for seasonal and common infectious diseases - require further evaluation of the symptoms as well as dosage of serum indicators (mesothelin and/or osteopontin), and a chest X-Ray, after which, the procedures described in A2) and A4) can be followed.

B. Subsequent controls

If during the first screening the worker does not present pulmonary and pleural diseases and the indicators (mesothelin and/or osteopontin) give negative results, the following measures should be taken:

1. once every three years a medical check-up including a medical history update, chest X-Ray, respiratory function tests and TLCO; annual mesothelin and osteopontin analysis.

If, during the first screening, any X-ray alterations are observed associated with to asbestos-related diseases, and/or alterations in the indicators (mesothelin and/or osteopontin), an annual medical check-up must take place, with respiratory function tests and TLCO, mesothelin and osteopontin analysis, with a 3-yearly chest X-Ray.

If the results indicate, even only in the medical history, signs of dyspnoea, chest pains, signs of pleural fluid (also observable by ultrasonography), alterations in the serum indicators (mesothelin and/or osteopontin), a chest X-Ray must be performed, after which, procedures as in A2) to A4) can be followed.

In both cases, if the X-Ray reading and the rereading were to suggest the presence of pleural and pulmonary pathologies or if the mesothelin and osteopontin analysis' were to have altered, the worker should undergo LDCT; further exams (including HRCT) would only be necessary if Chest X-R and LDCT results were to indicate the presence of asbestos-related diseases and/or with concomitant alterations of the markers (mesothelin and osteopontin).

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National epidemiologic surveillance systems of asbestos-related disease and the exposed workers register

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Key words

Asbestos; mesothelioma; epidemiology

Summary

Introduction: *Italy was the main European producer of asbestos for most of the 20th century and raw asbestos imports wee also significant until the 1990's; there was a mean delay of about ten years in the pattern of asbestos consumption in Italy compared with the USA, Australia, UK and Scandinavian countries.* **Methods:** *A national surveillance system (ReNaM) was implemented to identify cases of mesothelioma and investigate the modalities of asbestos exposure. A register of exposed workers and a database of companies presumably involved in the asbestos exposure problem was also developed. ReNaM has a regional structure and an operative centres (COR) have been established in 16 Italian regions.* **Results:** *The ReNaM database currently contains more than 5,000 mesothelioma cases and for 3,500 of these exposure modalities have been defined. Cases of pleural mesothelioma represent 93% of the total but there were also 334 cases of peritoneal mesothelioma, 15 of the pericardium and 14 of the tunica vaginalis of the testicle. Cases with ascertained exposure are thus distributed: 67.4% occupational exposure (ascertained, probable, possible), 4.3% domestic, 4.2% environmental and 1.3% hobby-related exposure, totalling 77.2%; 22.8% had unlikely or unknown exposure. The latency period is very long: on average 43.6 years. The register of asbestos-exposed workers contains figures on exposed workers notified to ISPESL up to 2004 and refers to the exposure period 1993-2003. The data registered cover 160 firms and about 700 workers.* **Conclusions:** *A national, coordinated and uniform epidemiological surveillance system of cases of mesothelioma and the definition of asbestos exposure through active research is extremely important in identifying unexpected contaminating sources. The register of asbestos-exposed workers allows risk to be monitored and protection measures to be implemented.*

Riassunto

«Il sistema nazionale di sorveglianza delle malattie da amianto e registro degli esposti». **Introduzione:** *L'Italia è stata il più importante produttore di amianto dell'Europa occidentale nel corso degli anni '60, '70 e '80 e le importazioni di amianto risultano consistenti fino in prossimità del bando del 1992. L'andamento del consumo di amianto nel tempo mostra un ritardo medio di circa 10 anni rispetto ad Australia, Stati Uniti, Regno Unito e Paesi Scandinavi.* **Metodi:** *È stato realizzato un sistema nazionale di sorveglianza per individuare i casi di mesotelioma e per indagare le modalità di esposizione ad amianto. Inoltre, è stato implementato un registro dei lavoratori esposti ad amianto e una banca dati di aziende con possibile presenza di amianto. Attualmente i Centri Operativi (COR) del Registro Nazionale dei Mesoteliomi sono stati istituiti in 16 regioni italiane.* **Risultati:** *Sono*

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stati registrati nel ReNaM più di 5.000 casi di mesotelioma e per 3.500 casi sono state definite le modalità di esposizione. I casi di mesotelioma pleurico rappresentano il 93% del totale ma sono presenti anche 334 casi di mesotelioma del peritoneo, 15 del pericardio e 14 della tunica vaginale del testicolo. I casi con esposizione definita sono così distribuiti: il 67,5% lavorativa (certa, probabile o possibile), il 4,3% domestica, il 4,2% ambientale e l'1,3% relativa ad attività eseguite durante il tempo libero; il 22,8% del totale dei casi presenta un'esposizione improbabile o indefinita. Il periodo di latenza risulta essere molto lungo: in media è uguale a 43,6 anni. Il registro degli esposti ad amianto raccoglie dati sui lavoratori e sui livelli di esposizione notificati all'ISPESL fino al 2004 e che fanno riferimento al periodo espositivo 1993-2003. Sono presenti circa 160 cantieri con 700 lavoratori. **Conclusioni:** *Un sistema di sorveglianza epidemiologica uniforme, standardizzato e distribuito su tutto il territorio nazionale dei casi di mesotelioma e la definizione dell'esposizione ad amianto è di fondamentale importanza per identificare possibili nuove ed inaspettate fonti di contaminazione. La registrazione dei lavoratori esposti può contribuire a monitorare il rischio ed a predisporre misure di protezione.*

Introduction

Italy was a main producer of asbestos for most of the 20th century and raw asbestos imports were also significant until the 1990's; there was a mean delay in the pattern of asbestos consumption in Italy of about ten years compared with the USA, Australia, UK and Scandinavian countries. Since association with asbestos exposure is well established and the growing trend in mesothelioma incidence/mortality rates follow the asbestos consumption curve in many countries with a mean lag time of 30-40 years, the trend of mortality from pleural mesothelioma will still be rising and the peak will presumably be reached in the second decade of this century, around 2010-2020 (13, 24).

Taking into account that the situation in Italy has become particularly alarming, the Italian National Mesothelioma Registry (ReNaM) was set up at the National Institute for Occupational Safety and Health (ISPESL) in accordance with Art. 36 of Italian Legislative Decree N. 277 introduced in 1991. In 2002 methods to collect and record data with standard operating procedures were fixed by law.

The methods and results obtained by ReNaM are briefly reported here. The asbestos- exposed workers registration system and the register of enterprises probably involved in asbestos exposure are also described.

Methods

National mesothelioma register

ReNaM's main objectives are: to estimate the incidence of malignant mesothelioma (MM) in Italy, to define and record exposures to asbestos for each mesothelioma case, to assess the impact and diffusion of the disease in the population, and to identify unknown sources of environmental contamination with asbestos or other potential causes of mesothelioma. Regional Operating Centres (COR) in 16 Italian regions have been set up to identify and to investigate all cases of MM diagnosed in each region, applying national guidelines (17). The ReNaM currently covers more than 80% of the Italian population and, considering pleural mesothelioma deaths, accounts for about 91% of the national case-list.

Each COR directly collects cases diagnosed and treated by regional health care institutions, namely pathology and histology units, lung diseases and chest surgery wards. Hospital discharge records and death certificates are also examined to check if all available information has been collected. Guidelines are used to standardize the diagnostic criteria for mesothelioma, and cases are classified as definite, probable, possible and non-mesothelioma, depending on the level of diagnostic confidence achieved. Occupational history, lifestyle habits and areas of residence for each case are obtained by direct inter-

view using a standard questionnaire, administered by a trained interviewer. When a subject is not available, next-of-kin can be interviewed on the case's work and life history (indirect interview). To obtain information on occupational and/or residential exposure, each COR can also consult local health and public hygiene offices, and regional occupational prevention, hygiene and safety agencies. Exposure is then classified by an industrial hygienist, checking available documents and applying his own knowledge on industrial conditions to establish whether the patient's work, private life or any particular environmental conditions could have any association with exposure to asbestos.

Data presented in this study refer to MM cases notified to ReNaM by COR with a diagnosis in the period between 1993 and 2001. Currently, operating centres exist in Piedmont, Val d'Aosta, Lombardy, Veneto, Autonomous Province (P.A.) of Trento, Friuli-Venezia Giulia, Liguria, Emilia-Romagna, Tuscany, Marche, Umbria, Abruzzo, Campania, Puglia, Basilicata, Calabria and Sicily. Val d'Aosta, P.A. Trento, Umbria, Abbruzzo, Calabria have not yet sent data to the National Register due to the fact that they were only recently established.

Enterprises register

The Presidential decree of 8 August 1994 "Concerning recommendation and coordination for Regions and Autonomous Provinces of Trento and Bolzano for the adoption of protection, contaminated land clearance, removal and disposal plans in order to protect from dangers rising from asbestos" identified economic sectors, (classified according to ISTAT ATECO81), as regards a possible use of asbestos in industrial activity. The economic sectors listed were divided into two groups: the first represents the "major involved", the second the "probably involved" sectors.

On the basis of these laws, ISPESL drew up and provided to all Regional Health Council Offices a register of enterprises probably involved in asbestos exposure.

The register refers to 1991, just before the banning of asbestos, and was set up through linkage procedures between enterprises registered at Chamber of Commerce (CERVED) and information gathered by the National Institute of Social Security (INPS). The Register is organized on different reliability levels created according to the accuracy of merged data [Erba, 1996]. The register includes enterprises whose activity had not ceased at 31 December 1990 and for which the reliability level was up to three (e.g. certainly present in both INPS and CERVED archives). Workers are grouped by job title: employees or manual workers. Economical sectors of Commerce, Transport and Renting were not considered at the first step.

Asbestos-exposed workers register

The current asbestos and carcinogenic substances exposure registry is governed in Italy by Laws (D.Lgs.) No. 277/1991 and No. 66/2000.

The lack of a DPCM (Prime Minister's Decree) establishing reference forms and collection methods has thwarted the practical application of the law. However, pending the issue of this decree, ISPESL has established a reference model, available on web site www.ispesl.it, including four forms, one of which is used to gather information on worker exposure, in particular: personal data, job title, starting and ending exposure date, exposure value of asbestos fibres and measuring date (25).

Information collected via this model together with any other type of notification is recorded in the asbestos exposure registry established at ISPESL (24). Following the introduction of law No. 257 issued on 27 March 1992, which concerned the ban of asbestos for industrial and civil purposes in Italy, recorded data refer to enterprises operating in the sector of removal and disposal of asbestos.

Results

National mesothelioma register

The National Mesothelioma Register contains information related to 5,173 cases of malignant mesothelioma (MM). For 3,945 cases (equal to 76,3%) the diagnosis is definite MM, probable MM for 15% and possible MM for 8,7%.

The gender ratio is 2.62 which means 2.6 cases of mesothelioma in males for each female. Such ratio is highly correlated with the territory of reference. In particular, the ratio of female cases (27,6% in the national register) varies from 8% in Friuli-Venezia Giulia up to 37% in Piedmont. Pleural Mesothelioma cases represent 93% of the total but 334 cases of mesothelioma of the peritoneum, 15 of the pericardium and 14 of the tunica vaginalis of testicle are also worthy of note. The ratio of female cases is particularly high (41.6%) for peritoneal mesothelioma. The percentage of cases with age at diagnosis lower than 35 years is extremely low (28 cases, equal to 0.6% of the total), while more than 50% of cases are aged between 55 and 74 years. The average age is 67.4 for the whole set of recorded cases but varies by anamnestic code from 65.5 as "ascertained" to 72.7 as "probable" and 74.4 as "possible", and by site of pathology varies from 67.6 years for pleural mesothelioma to 64.2 for peritoneum and 61.6 for pericardium and 58.9 for tunica vaginalis of the testicle. The morphology of almost half of the notified cases is defined as epithelioid (50%), 7% as biphasic and 12% as fibrous. Such distribution is steady by sex and without significant differences by site of pathology.

Analysis of data by exposure type refers to the whole set of cases diagnosed from 1993 to 2001 (5,173 cases). Exposure type was studied in depth for 3,552 cases (68.7%) while for 1,621 (31.3%) this process is still on-going. The method for reconstructing exposure is through direct interview with patient or next of kin (46.8% and 45.6% respectively).

Cases with defined exposure are thus distributed: 67.4% occupational exposure (ascertained, probable, possible), 4.3% domestic, 4.2% environmental, 1.3% hobby-related exposure, totalling 77.2%; 22.8% present unlikely or unknown exposure. Latency, defined as the difference between diagnosis date and starting date of exposure, was measured on 2,544 mesothelioma cases. The latency is on average equal to 43.6 years and the median time since first exposure is 44 years with a standard deviation of 12 years and the statistical distribution is clearly normal.

Enterprises register

The number of potentially exposed workers (referring to 1991) employed in the enterprises with a possible use of asbestos, as listed in Law (DPR) of 8 August 1994 for the "principally involved" economic sectors is about 120,000 workers in more than 19,000 firms. The economic sector with the highest number of workers is the "installation of heating, air conditioning and water systems and distribution of gas and hot water supply" (Ateco81 code n. 503.1), followed by "shipyards, buildings for metal engineering" (Ateco81 code n. 361.1). Considering the number of enterprises, however, the largest sector is the "installation of heating, air conditioning and water systems and distribution of gas and hot water supply" (Ateco81 code n. 503.1), followed by the "shaping and processing of flat glass" (Ateco81 code n. 247.4). The register has been recently updated as at 1999, eliminating the economic sectors with a "direct use" of asbestos, which was banned by Law (D.Lgs.) No. 257/1992, and including new sectors such as removal and disposal of asbestos-containing materials. The economic sectors selected are those in which asbestos is present as an environmental contaminant both in building structures and in manufacturing processes.

Asbestos exposed workers register

The asbestos exposure register contains records on exposed workers received by ISPESL up to 2004 and refer to the exposure period 1993-2003. Recorded information includes: name of the firm, location of the yard or factory (giving at least the province) where workers are employed, personal data of each worker (surname, name, sex, date of birth), job title, measurement and duration of exposure. The data registered covers 160 yards/factories and about 700 workers with more than 2,000 type of exposures. Unfortunately the quality of information is not very accurate and frequently records contain data which is incomplete and different from the standard proposed by ISPESL. One of the most recurring mistakes is a wrong or missing code for economic activity, job title and the

town code. Moreover, the occupational exposure section is the one with the most missing data.

Discussion

A coordinated and uniform activity covering the entire national territory of epidemiological surveillance of mesothelioma cases and definition of asbestos exposure via an active data research system is extremely important in identifying contaminating sources which were up to now unknown and unexpected, and thus make available mass of valuable information on occupational risks due to asbestos.

The identification of mesothelioma cases with exposure in unexpected economic sectors such as textiles and agriculture is the most reliable proof of the positive role of an epidemiologic surveillance system of asbestos- related diseases.

The development of the asbestos enterprise register and related exposure registry is a valid tool in identifying exposed workers, in providing a detailed estimate of the same and in monitoring the ban of such a dangerous substance.

Identification of enterprises by name and estimation of the number of workers makes it possible to define the scenario of exposed workers in Italy before asbestos was banned and to start verification of information on removal and disposal plans and render any new hazardous situations safe. Moreover, the ISPESL enterprises register was used to implement the results of the census carried out by Emilia-Romagna, Veneto and Lazio regions.

At present, the CAREX database (a European study to estimate the number of workers exposed to carcinogenic substances) estimates that there are about 76,000 workers exposed to asbestos, above all in the construction industry (over 90%), and in manufacture of transport equipment (3.5%), land and water transport (3.3 %), electricity, gas and steam (1.3%) (15). The asbestos-exposed workers register is today the best instrument to asses the number of workers currently exposed insulation removal activities.

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Evaluation of fitness for work: the most challenging situations

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Key words
Health surveillance; fitness for work

Summary
Evaluation of fitness for work (FW) is the final task of both health surveillance and risk evaluation. It's aim is to protect the physical and psychological health of workers and respect their professional skills. The Occupational Physician faces several difficulties in the evaluation of FW. Moreover, Italian legislation on this topic can be variously interpreted and this can cause conflicting evaluations. In this session, the most challenging situations in FW evaluation will be taken into consideration.

Riassunto
«La valutazione dell'idoneità al lavoro: una sfida per il medico del lavoro». *La valutazione della idoneità lavorativa costituisce l'atto finale della sorveglianza sanitaria e della valutazione dei rischi, ed è finalizzata a proteggere la salute fisica e mentale dei lavoratori nel rispetto delle loro capacità professionali. Le difficoltà che il Medico del Lavoro deve affrontare quando valuta l'idoneità lavorativa sono numerose. A ciò si deve aggiungere che le leggi italiane sulla prevenzione occupazionale possono frequentemente essere interpretate in maniera non univoca. In questa sessione vengono esaminate le più frequenti e più importanti situazioni che possono creare difficoltà nella formulazione del giudizio di idoneità lavorativa specifica.*

Introduction

The evaluation of fitness for work is the responsibility of the Occupational Physician (OP) entrusted with health surveillance (HS) programmes. For the OP, this is one of the most important and most demanding tasks, being the equivalent of treatment for General Practitioner (GP).

FW evaluation is the final task of both risk evaluation and HS. Therefore, HS programmes are the result of detailed knowledge of the workplace and, consequently, careful risk evaluation. This activity must be based on close cooperation between the various Occupational Health Professionals (OHPs), and the OP should interpret the results from a health-based point of view.

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The Italian Society of Occupational Medicine and Industrial Health (SIMLII) in its specific guideline published in 2004, defines HS as "the combination of medical actions aimed at increasing health and safety protection, in relation to the various occupational risk factors, at improving safe practices of carrying out work activity, and at promoting a proper evaluation of fitness for work, considering the specific tasks of the job" (5).

The OP should examine the functional state of the various target organs and identify those health conditions that may interfere with normal performance of job tasks, and that may be aggravated, although not directly caused, by working activity. The importance of this latter issue is progressively increasing, due to the fact that traditional risks and classical occupational diseases are progressively decreasing.

Therefore, the main aims of HS are the identification of all conditions, congenital or acquired, that can cause individual hyper-susceptibility and the diagnosis of the earliest health effects caused by working activity (2, 3).

In practice, the evaluation of FW requires that the OP respect one of the main principles of the ICOH Code of Ethics: "to promote the adjustment of work to the worker" (4).

Thus, FW evaluation can be a very complex activity involving great responsibility. The adequacy and efficacy of FW evaluation should be also verified periodically (1).

Another important aspect is related to the fact that congenital alterations and acquired diseases, which can be caused by work activity or might potentially be the cause of an increased susceptibility to occupational risk factors, can involve all biological organs and systems. The clinical assessment of these conditions generally involves other specialists (orthopaedists, dermatologists, neurologists, haematologists, etc.). Therefore, it is necessary for OPs to constantly update their knowledge of general medicine almost in a similar way to GPs. At the same time, OPs must be able to establish a dialogue with all the various specialists. An accurate clinical diagnosis and knowledge of working conditions will allow OPs to protect workers' health and well-being through a proper evaluation of FW. This will be achieved also by respecting the workers' professional skills.

Another challenge in this process is related to the fact that FW cannot be easily applied in the workplace because a concrete possibility of adapting the job to the workers may not be feasible. This occurs more frequently in small firms due to a lack of possible alternatives for job tasks and positions. Moreover, FW evaluation may not be accepted by the workers, especially when a judgement of unfitness might be in conflict with job skills and might hamper economic and career expectations.

To the various above-mentioned challenges, we may add others, that are typical of the situation in Italy since they are related to Italian legislations that can be differently interpreted and may influence the FW evaluation, to the extent that HS, and therefore, FW evaluation may be illegal in some situations.

On this subject, the following questions should be raised:

– is preventive examination (i.e., medical examination before the beginning of a certain work activity) ethical and legal before formal engagement of the worker?;

– is it possible to assess the general health status considering also non-work-related risk factors (e.g. checking blood sugar, cholesterol), based only on individual agreements with the workers?;

– should FW evaluation also protect third parties (e.g., in the case of epileptic drivers of public transport)?

The five presentations in this session will deal with the most challenging situations that may cause difficulties in the evaluation of FW. We asked the speakers to address these issues, which may also be an interesting topic of discussion with the international experts.

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Fitness for work: the SIMLII Health Surveillance Guidelines

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Key words
Fitness for work; health surveillance; guidelines

Summary
Italian legislation on prevention in occupational hygiene and safety, which is based largely on European Union Directives, requires health surveillance when risk assessment has identified a risk for workers' health. Health surveillance must be carried out by the occupational physician and concludes with the issue of a fitness for work certificate for the specific job. The guidelines produced by the "Italian Society of Occupational Medicine and Industrial Hygiene" (SIMLII), through the "Consortium for Accreditation and Updating in Occupational Medicine" founded by the "S. Maugeri Foundation of Pavia", Italy, focus firstly on the definition of judgment of fitness for a specific job. They outline the theoretical basis of the medico-legal terminology for fitness for work, which is founded on the concepts of suitability, fitness, capacity, ability, representing successive degrees of qualification and specific potential that the worker may attain during accomplishment of the tasks involved in the job. To assess fitness for a specific job, the occupational physician must consider whether the worker possesses the psycho-physical requisites normally needed to do the job, not the top levels of such requisites. The intrinsic characteristics of any judgment of fitness for work, namely its individual, probabilistic and time-dependent nature, are illustrated. The operative methodological model for making a judgment must include: assessment of the job and work environment, assessment of the worker through health surveillance, comparison and correlation of the two terms of the equation: human subject-work environment, the judgment thus made and the choice of any necessary measures and/or intervention. The methods for conducting the assessment process culminating in a judgement are presented, as stipulated in the pertinent legislation, and include the following conclusions: fitness, partial or total unfitness, temporary unfitness, fitness provided suitable prescriptions are observed, fitness provided some conditions are met. These definitions are analyzed in greater depth, especially the possible confusion between partial unfitness and fitness provided suitable prescriptions are observed. The employer or worker may lodge an appeal with the local health service inspection service against certain judgments of unfitness for work. Finally, as health surveillance is governed by different legal norms, the contents of which appear to be to some extent contradictory, even though aimed at safeguarding the dignity and freedom of the worker, the reasons why the occupational physician should take into account diseases apart from those of the organs exposed to specific risk are discussed. These should be borne in mind when issuing the specific fitness for work certificate at the end of preventive and periodical medical examinations.

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Riassunto

«L'idoneità nelle linee guida SIMLII sulla sorveglianza sanitaria». *La legislazione preventiva italiana di igiene e sicurezza sul lavoro, che deriva quasi tutta da Direttive dell'Unione Europea, prevede la sorveglianza sanitaria quando la valutazione del rischio ha evidenziato la presenza di un rischio per la salute dei lavoratori. Essa richiede che la sorveglianza sanitaria sia effettuata dal medico competente, tra cui lo specialista in medicina del lavoro, e si concluda con la formulazione del giudizio di idoneità alla mansione specifica. Le Linee guida prodotte dalla Società Italiana di Medicina del Lavoro ed Igiene Industriale (SIMLII) attraverso il "Consorzio per l'accreditamento e l'aggiornamento in Medicina del Lavoro", costituito con la Fondazione Maugeri di Pavia, forniscono innanzitutto la definizione del giudizio di idoneità alla mansione specifica. In esse è riportata la base teorica cui si ispira la terminologia medico-legale dell'idoneità al lavoro, fondata sui concetti di validità, idoneità, capacità, abilità, che esprimono gradi successivi nella possibilità del lavoratore di espletamento delle operazioni che compongono una mansione lavorativa. Nel valutare l'idoneità alla mansione il medico del lavoro deve prendere in considerazione il possesso da parte del lavoratore dei requisiti psico-fisici comunemente indispensabili per lo svolgimento della mansione e non il possesso dei migliori requisiti psico-fisici necessari per lo svolgimento della stessa. Sono illustrate le caratteristiche intrinseche del giudizio di idoneità, consistenti nell'essere individuale, probabilistico e temporale. La metodologia dell'idoneità al lavoro si articola attraverso fasi successive che prevedono: la valutazione del lavoro e dell'ambiente di lavoro, quella dal lavoratore attraverso la sorveglianza sanitaria, il confronto ed interazione del binomio ambiente di lavoro-uomo, la formulazione del giudizio e la scelta dei provvedimenti e/o degli interventi. Sono presentate le modalità di formulazione del giudizio di idoneità alla mansione specifica, come previsto dalla legislazione preventiva, che prevedono le seguenti possibilità: idoneità, non idoneità parziale o totale, non idoneità temporanea, idoneità con prescrizioni, idoneità a determinate condizioni. È riportato un approfondimento sulla differenza del significato di non idoneità parziale e di idoneità con prescrizioni. Per alcune tipologie di definizione del giudizio di idoneità è previsto il ricorso sia da parte del datore di lavoro che del lavoratore all'Azienda Unità Sanitaria Locale, preposta alla vigilanza sull'applicazione della normativa preventiva nei luoghi di lavoro. Infine, poiché la sorveglianza sanitaria è prevista da diverse norme legislative con contenuti che per alcuni aspetti appaiono contraddittori, pur salvaguardando la dignità e la libertà del lavoratore, sono indicate le motivazioni che devono spingere il medico del lavoro competente, nel momento della definizione del giudizio di idoneità alla mansione specifica, emesso a conclusione sia della visita medica preventiva che di quelle mediche successive, a tenere conto anche delle patologie che riguardano gli organi diversi da quelli esposti a rischio specifico.*

Introduction

In the field of Occupational Medicine, health surveillance is considered as a preventive activity that must be accomplished by means of thorough, complete medical examinations of workers. This requires the occupational medicine specialist to possess an in-depth knowledge of the technical aspects of the production cycle and work set-up, as also of the qualitative and quantitative aspects of exposure to occupational hazards and their specific effects on workers' health. The main aims are to prevent occupational and work-related diseases, to avoid work-related exacerbation of any pre-existing diseases of whatever aetiology, and to contribute to reducing the rate of accidents at the workplace (3, 4, 6, 8, 19, 22-27).

The Italian legislation safeguarding workers' health and safety is mostly contained in the following laws: Law (Legislative Decree - D.Lgs.) 277/91 (noise and asbestos), D.Lgs. 626/94 modified and integrated by D.Lgs. 25/02 (general norms safeguarding workers' health, activity at video-terminals, carcinogenic agents, chemical agents, biological agents, manual transport of loads), D.Lgs. 230/95 modified and integrated by D.Lgs. 241/00 (ionizing radiations), D.Lgs. 532/99 (night shifts), D.Lgs. 187/05 (vibrations), and is based almost entirely on European Union laws. According to these laws, health surveillance is

mandatory when risk assessment of exposure to a given occupational agent of chemical, physical, biological type or linked to the work set-up or special circumstances, as reported in a risk assessment document, demonstrates this agent to be harmful to human health. The risk assessment probes all risk factors, both those covered and those not covered by law. The responsibility for accomplishment of health surveillance is assigned by the above laws to the "competent physician" (medico competente) and those medical specialists who may carry out this activity are defined in these laws; they include the Occupational Physician (O. Ph.) (5, 10-15).

The O. Ph. is the only physician currently in possession of the necessary skills to carry out preventive activities and screening in the workplace, and especially health surveillance and risk assessment.. The O. Ph acquires these skills through specific education and training in targeting disease prevention in the workplace, and through periodical updates during the professional career (1, 26). The Occupational Medicine skills described in the "Guidelines for health surveillance", produced by the "Consortium for Accreditation and Updating in Occupational Medicine" with the contribution of the "Italian Society of Occupational Medicine and Industrial Hygiene (Società Italiana di Medicina del Lavoro ed Igiene Industriale, SIMLII)" and the "S. Maugeri Foundation of Pavia, Italy", are defined as "the possession of knowledge, abilities-skills, aptitudes for medical practice in the field of occupational medicine such as to guarantee efficacious primary and secondary prevention with the goal of preserving health, considered as a state of physical and psychological wellbeing that allows working activities to be carried out in optimal conditions by those workers undergoing health surveillance" (27).

According to these guidelines, health surveillance obliges the O. Ph. to perform:

a. preventive medical examinations to ascertain the absence of any contraindications for specific tasks, ensure fitness for the job (D.Lgs. 626/94 as revised, Art. 16, par. 2/a);

b. periodical medical examinations to assess the state of health of workers and confirm the judgment of fitness for the job (D.Lgs. 626/94 as revised, Art. 16, par. 2/b);

c. medical examinations as requested by the worker, if an occupational risk is involved (D.Lgs. 626/94 as revised, Art. 17, par.1/i);

d. a medical examination at retirement from the job; on this occasion the O. Ph. must supply the worker with any recommendations for medical prescriptions to be taken henceforth (D.Lgs. 626/94 as revised, art. 72-decies, par. 2/c) (11, 14).

As can be seen from the above, making a fitness for work assessment, evaluating the individual worker's physical and psychological fitness for the overall job and all specific tasks involved, is clearly foreseen in the relative legislation only for health surveillance of a preventive or periodical type. It is not foreseen for medical examinations requested by the worker, but is legitimate at the end of the medical examination at retirement. However, the issue of a fitness for the job certificate by the O. Ph. is compulsory according to the hygiene and safety in the work place regulations.

In those cases in which it is compulsory, issue of a fitness for work certificate is the final part of the medical examination carried out during health surveillance. It summarizes the O. Ph.'s conclusions about the risks in the working situation and the current medical knowledge concerning the worker's state of health or disease. Apart from the preventive aims, the ethical and social implications cannot be ignored. On these grounds, the SIMLII guidelines define the judgment of fitness for the job as the "Assessment of possession of the necessary psychophysical requisites and absence of contraindications for carrying out the specific tasks, related above all to the presence of occupational risks ascertained and reported in the risk assessment document, but also related to any aspects of the tasks that could exacerbate pre-existing particular states of health in the individual, with the aim of safeguarding the health and safety of the worker" (2, 27).

FITNESS TERMINOLOGY

The medico-legal terminology used to certify fitness for work derives from social insurance terminology, as adapted by Gerin in the 1950s. It is based on the concepts of suitability, fitness, capaci-

ty and ability that represent successive degrees of qualification and specific potential that the worker may achieve during accomplishment of the operations making up a task. By suitability, Gerin meant the "psycho-somatic efficiency in carrying out any activity"; by capacity, "the set of specific aptitudes and special training" and by ability, the presence of "special, particularly pronounced aptitudes of the subject". He did not provide a definition of fitness but it can be deduced from the context that the term is taken to mean an intermediate condition between suitability and capacity (17).

The concepts of suitability, fitness, capacity and ability were later developed with reference to specific working activities and correlated risks, and can be interpreted in specific contexts (7, 21).

The concept of suitability, in the sense of biological integrity, has maintained its original validity. The subject is suitable when he/she can undertake any occupational or non-occupational activity.

Fitness can be considered as suitability with precise reference to a particular activity or specific task. It is at this level that the term is correlated with work, and refers to a logical evaluation of how well the worker's degree of psychophysical integrity fits the work to be done. It is clear from this that for a given subject there must be the same number of potential evaluations of fitness as there are tasks or activities that he/she may be asked to do in the accomplishment of the job. According to Gerin, fitness, like work capacity, cannot be considered in a generic sense because otherwise it would be indistinguishable from suitability, but must be specifically related to each precisely defined working activity making up the myriad tasks involved in the job description. The terminology "fitness for the specific job", as reported in the pertinent Italian legislation, stresses the fact that this specificity is essentially an attribute of the work set-up not of the subject who should do the work.

To assess fitness for the specific job, the O. Ph. must consider whether the worker possesses the psychophysical requisites normally needed to do the job, not top levels of these requisites. This concept is stated in an Italian High Court ("Corte Costituzionale") sentence of 7.7.1987: "The worker's physical fitness, already present or in course of acquisition, must in accordance with safety requirements and the freedom and dignity of the person safeguarded by Art. 41 of the Italian Constitution, be referred to the worker's possession of those abilities commonly regarded as indispensable to accomplish the material actions, not to the employer's presumed expectation to be able to rely on high level performance yielding maximum profit" (27).

Capacity refers to the subject's ability to perform a given activity, as a result of innate qualities, special education and theoretical-practical training. Finally, ability expresses particularly good levels of capacity and skill-dexterity in carrying out a certain job. As such, neither of these pertains to the O. Ph.'s assessment of fitness for work.

It can be seen from the above that to achieve an overall judgment of fitness for a specific job, apart from medical skills, the O. Ph. must possess an in-depth knowledge of technical science and psychosocial aspects, so as to assess the worker's level of training, culture and aptitudes. Nevertheless, as stated above, in accordance with current Italian regulations on occupational hygiene and safety, the O. Ph. is called upon to express only a judgment of fitness, and hence "suitability for the specific job" and not of her/his innate capacity or ability to do the job.

Definition of the judgment of fitness

The formulation of a judgment of fitness for the job is one of the most complex and qualified tasks the O. Ph. is called upon to make, and also one of the most delicate, in view of the underlying ethical and socio-economic implications (2, 27). The adjective "complex" must not necessarily be interpreted as a synonym of "difficult" because in this case it refers to the fact that the task is conditioned by a high number of interacting variables of different nature.

In fact, the judgment of fitness for work requires an in-depth knowledge of the job description, including the sensory, energy, biomechanical requirements, etc., that the workers should possess, as well as of the correlated risks, and lastly of the individual state of health of the subject called upon to do

the job. In other words, the O.Ph. should not only have an excellent clinical background but also a specific knowledge of other disciplines such as occupational hygiene, industrial technology, ergonomics, industrial toxicology, occupational epidemiology, occupational psychology. Thus, a correct judgment of fitness for work must focus on both terms of the equation on which the judgment is founded, i.e. the human subject and the work environment. The complexity and difficulty of the judgment are related to the wide variability of the two terms. We need only consider, regarding the human person, of the variability among individuals and even in the same individual over the course of time, of the different anatomical and clinical, functional, socio-economic, and psychological aspects or even the different daily habits and lifestyles. As to the environment, there may be huge variations in the environment, facilities, plants, machinery, technological cycle, substances used and work set-up.

The judgment of fitness always has a preventive function and must be based on the individual, on probability and on time factors.

It is preventive because it must guarantee the psychophysical safety of the worker doing the job. In short, it aims to safeguard health, considered in accordance with the WHO declaration, as "a state of complete psycho-physical wellbeing and full enjoyment of social relations". Safeguarding the state of health of the individual worker also has favourable repercussions on work colleagues and, according to some authors, even has a dual value: it safeguards above all the health of the worker but also the employer's legal responsibility deriving not from technical or organizational failures but from particular predispositions of the individual worker (27).

It is individual because the judgment is valid only for the specific subject, although it can provide useful indications for a homogeneous group of exposed workers.

The judgment is almost always probabilistic and based on a combined judgment of the subject's state of health in conjunction with the job conditions, and can thus range from fit (healthy subject and/or suitable environment) to unfit ("diseased" subject and/or unsuitable environment). Obviously, temporary and above all permanent total unfitness, due to an altered state of health of the individual, are judgments based on certainty not probability.

The judgment is based on time factors in the sense that it is valid for a limited period of time, generally the interval between two periodical medical examinations, with the exception of a judgment of absolute permanent unfitness due to irreversible "disease" making the specific tasks incompatible with the subject's capacities. The greater the specialist's experience and skills, and hence the accuracy and depth of any supplementary investigations, as also knowledge of the environment and work set-up, the more valid the judgment of fitness for work will be.

Apart from these pre-eminently "medical" aspects, the judgment also carries ethical and legal implications. The ethical content applies to the physician's conscience when making a decision of unfitness for work, especially for a role requiring experience and skills that the worker has developed over time. The legal content lies in the precise legal norms with which the formulation of the judgment must comply.

Methodology for assessing fitness

No validated models are yet available on which to base how a judgment of fitness for work should be made, or on which to build a scientific basis of reference criteria. In any case, any operative methodological model for making this judgment must include the following steps:

1. Assessment of the job and work environment;
2. Assessment of the worker;
3. Comparison and correlation of the two terms of the equation;
4. Making the judgment;
5. Choice of measures and/or intervention.

The judgment must thus stem from two distinct investigation phases followed by a logical evaluation of their relations. Knowledge of the human subject-environment equation can only be gained by close analysis of the work set-up and by health surveillance.

Making the fitness for work judgment

The assessment process culminating in expressing a judgment can be performed in various ways that can be summarized, in accordance with the content of D.Lgs. 626/94 as revised, Art. 17, par. 1/c, and par. 3, as follows:

- fitness for the specific job;
- partial unfitness for the specific job;
- total unfitness for the specific job;
- temporary unfitness for the specific job;
- fitness, provided suitable prescriptions are observed, for the specific job (only for workers at video terminals, see D.Lgs. 626/94, as revised, Art. 55, par. 1/a);
- fitness provided some conditions are met (for workers exposed to ionizing radiation, see D.Lgs. 230/95, as revised, Arts. 84, par. 4, and Art. 85, par. 2) (9, 11, 12, 27).

A certain degree of uncertainty still surrounds the issue of precisely how the individual cases of fitness should be defined, due to the generic wording of the legislation. In particular, the concepts of "partial unfitness" and "fitness provided suitable prescriptions are observed" are often confused and regarded as interchangeable. Instead, the differences between these two concepts have important practical implications as regards prevention and the medico-legal consequences of the judgments. It therefore seems useful to attempt to differentiate the meaning and implications of the different levels of judgment of fitness.

A close analysis of the different levels, integrated by an in-depth knowledge of the fields of Occupational Medicine and by practical experience gained in the specific sectors, allows the following specific meanings to be attributed:

- fitness for the specific job: complete fitness;
- partial unfitness for the specific job: the fitness is limited to some of the operations numbered among those involved in the job description (not solvable by the adoption of suitable prescriptions);
- total unfitness for the specific job: the total unfitness (not solvable by the adoption of suitable prescriptions) applies to all the operations involved in the job description (or almost all of them, so that it is impossible to make an advantageous use of the worker in that job);
- temporary unfitness for the specific job: the unfitness (partial or total, as defined above) will predictably last for a limited time;
- fitness provided suitable measures are adopted, for the specific job: there is complete fitness for the job provided that specific precautions are taken.

A judgment of unfitness (total or partial) must also take into account the possible toll of wear the job may have on the given worker, with a time prediction that will probably be short term, regardless of whether the disease the worker is found to suffer from might allow continuation in the same role. Judgment of unfitness may be permanent or temporary. It is permanent when the disease dictating the judgment is of a chronic and hence permanent nature, and limited when the subject will presumably recover from the disease.

As stated above, fitness for the job provided suitable prescriptions are observed is formally stipulated in D. Lgs 626/94 only for workers at video terminals. It is most likely that the legislator was implicitly referring – even if this is not specifically stated – to the use of special spectacles during work. Other similar situations frequently arise, however, and the O. Ph. is often faced with such cases, in which the question of work at video terminals does not apply. For the reasons considered above, these situations are different, from both a conceptual and a practical point of view, from those giving rise to a judgment of "partial unfitness for the job". In fact, fitness "with prescriptions" expresses a case of total fitness for a specific job provided that precise prescriptions are observed. The conditions posed are associated with factors inherent to the subject, that have a bearing on the characteristics of the tasks to be carried out. These may consist of the use of special spectacles for workers at video terminals, but also masks, gloves, ear mufflers, etc., in other working activities.

The medico-legal aspects differentiating the two types of judgment refer, only in the case of a judgment of "partial unfitness", on one hand to the O.Ph.'s obligation to send a written communication of the judgment to the employer and the worker, and on the other hand, to the possibility

for the employer or the worker to lodge an appeal against the judgment within 30 days of receipt of the communication. The appeal should be made to the local health service inspection team (Organo di Vigilanza dell'Azienda Unità Sanitaria Locale), which has the task of verifying the correct application of preventive norms in the workplace, as expressly stipulated in D. Lgs. 626/94. This obligation of written communication of the judgment by the O. Ph. applies not only in cases of partial unfitness but also of total unfitness or temporary unfitness, and in these cases, too, the employer or worker can appeal against the judgment as described above.

As regards the judgment of "fitness provided some conditions are met", which applies to workers exposed to ionizing radiations as stipulated in D.Lgs. 230/95 (revised), the meaning of this wording is not clear. In any case, we believe it may refer to tasks involved in the job description that may require some limitations in the case of that specific worker, and should therefore be taken to mean a "partial unfitness for the specific job". It could also, however, be taken to apply to situations in which the worker may carry out specific tasks provided use is made of suitable protection measures: in this case it would come under the heading of fitness "with prescriptions".

Moreover, it should be noted that the judgment of "full fitness" does not formally carry the right for the worker to lodge an appeal (evidently because the legislator considered that this judgment does not place the worker's job tenure at risk). Instead, worker disagreement with the judgment of full fitness is much more frequently observed in practice than disagreement with the judgment of limited fitness.

The health condition determining a judgment of the specific worker's unfitness for the job in question must not, of course, be communicated to the employer as it is covered by the laws of confidentiality, as indicated in the deontological code and expressly stipulated in the Italian Penal Code (27).

In any case, a correct use of the different types of judgment of fitness, based on judiciously weighed scientific evidence, as well as a correct and meticulous observation by the employer of the prescriptions contained in the judgment, should only in very exceptional cases give rise to an appeal by the worker.

It should also be pointed out that the O. Ph. must base the judgment of fitness on the specific characteristics of the job, avoiding generic limitations such as "unfit for tasks requiring excessive physical effort". In practice, the latter judgment transfers to the employer, who does not possess the requisite technical knowledge, the burden of converting the generic judgment into an applicative prescription for the specific job. On the other hand, if the O. Ph. identifies any tasks involved in the job that the worker cannot carry out, a judgment of partial unfitness for the job must be issued, including a list of all those tasks that are precluded.

Discussion

The preventive norms aiming to assure hygiene and safety at the workplace in force in Italy seem to place limits on the role of the O. Ph's powers/possibility of making a clinical/diagnostic assessment of the worker's general state of health when performing both preventive medical examinations to exclude contraindications for the work included in the job description and periodical medical examinations to verify the continuing state of health of the employee limited to those organs exposed to risk factors. This is because the legislation stipulates that the medical investigations must include clinical and biological tests and diagnostic procedures exclusively targeting the specific risk factor, as considered necessary by the O. Ph. (11, 27).

This limitation stems from the fact that the preventive norms, and especially art. 16 of D.Lgs. 626/94, seem to be in conflict with art. 5 of Law n. 300 of 1970, otherwise known as the "Worker's Statute". This article stipulates that "the employer is forbidden to check up on the worker's fitness for work, or unfitness due to ill health or accidents at the workplace. The legitimacy of absence due to ill health can be ascertained only by the inspection services of the state health insurance agencies, which are obliged to carry out such controls when requested to do so by the employer. The employer

is free to request a check of the worker's fitness for the job by public specialist institutions" (20).

In other words, in order to safeguard the worker's health while respecting her/his dignity and freedom, the O. Ph. must make medical tests investigating only the specific organ exposed to the risk factors, in accordance with the preventive norms, and must not make medical examinations aiming to ascertain the overall state of health of the worker, in compliance with art. 5 of Law 300/70. Thus, the O. Ph. is asked to screen the human subject-worker only in this context, despite the fact that subjects are not sets of separate, distinct organs that can be investigated separately, but are beings whose organs are intimately linked, both anatomically and functionally (16,18).

A principle that must always be respected by the O.Ph. when subjecting a worker to medical tests, within the limits of compliance with the legal norms currently in force, is the clinical/diagnostic principle. In other words, medical examinations should always conclude, in line with the principles of the art of medicine, with a diagnosis on the state of health of the worker, both overall and with respect to the target organs. It is in reference to this state of health that a valid judgment of fitness for work must be founded. A job that exposes workers to noise, for instance, the risk factor that imposed the obligation of health surveillance, may involve tasks that have nothing to do with noise but may require a good function of the dorso-lumbar region of the spine, as when required to climb steps in industrial plants, for example. In the presence of impaired function of the spine, in our view the O. Ph. should make a diagnosis of this alteration and take it into account in addition to the worker's state of hearing, when making a judgment of the worker's fitness for the specific job (27).

The limits on the specialist's clinical/diagnostic powers/possibilities during preventive medical examinations are not found in the legislation concerning radioprotection. In fact, Art. 84, par. 3, of D. Lgs. 230/95 (as revised), stipulates that "the preventive medical examination must include a complete medical history, including any previous exposure, due both to tasks carried out and to prior medical investigations and treatments, and a complete overall clinical examination including any necessary specialist and laboratory tests required to assess the overall state of health of the worker" (12, 13).

While taking into account the difficulties posed by art. 16 of D.Lgs. 626/94 for preventive medical examinations, SIMLII maintains that the O. Ph. possesses all the specialist and basic medical skills necessary to be able to assess, in line with the art of medicine, the overall state of the health of the worker during preventive medical examinations as well as the state of the specific organ/s exposed to risk factor/s when making a judgment of fitness for the specific job. This is in line with what is stipulated in art. 84 of D.Lgs. 230/94 on radioprotection, which allows and indeed requires the O. Ph., denominated "authorized physician" and listed in a National Register, to examine workers exposed to ionizing radiation in accordance with the prescribed norms. This would avoid the inconvenience deriving from a restrictive reading of art. 16 of D.Lgs. 626/94, whereby the worker must undergo medical examinations in two different medical facilities and twice over, i.e. at a public health facility to assess the "overall state of health", a knowledge of which is obviously necessary in order to be able to issue a correct certificate of fitness for work, and by the O. Ph. in order to assess the state of health of the specific organ, and thus obtain a judgment of "fitness" for the specific job (27).

Another aspect limiting the O. Ph.'s activities is the possible presence of a risk situation that is not statistically foreseeable *a priori* for any worker and thus in practice cannot be included in the risk assessment document. This will concern only particular groups of workers in whom a specific disease could be exacerbated by carrying out tasks included in the job description or render these tasks unsafe or impossible. In such situations, which can be observed during preventive medical examinations, periodical examinations made for risk factors, and medical examinations requested by the worker, it does not seem reasonable or ethically correct for the O. Ph. to refrain from carrying out the necessary medical tests and making a fitness for work judgment on the basis of these findings. Nor would it be reasonable to invoke art. 5 of Law 300/70 to

justify the formal exclusion of the risk identified in the risk assessment document. By its very nature, this could not include all the specific risk situations associated not with the job itself but with the worker under examination (27).

One example of such a situation could be the identification of a chronic non occupational disease (e.g. cancer or ischemic heart disease), which will not be affected by any specific occupational risk factor, but which will cause the O. Ph. to consider the worker not sufficiently fit for the job in view of the physical effort the job will entail. This could apply in the case of a builder. In this case, the problems the O. Ph. must face during a preventive or periodical examination or on request by the worker concern the question of whether the worker will be able to withstand a normal daily work rhythm. Obviously, this cannot be considered a specific risk factor to be included in the risk assessment document. Another example could be that of a machine tool worker under treatment with anticoagulant drugs, for whom the risk of accidents at the workplace would be critical, although not relevant for co-workers and hence not such as to require targeted health surveillance. In this situation, it is not in our view necessary to invoke, as is commonly done, art. 5 of Law 300/70, although the worker can always invoke this law if se/she considers the judgment issued by the O. Ph. to be damaging to his/her interests.

It is highly desirable that the planned reform of national legislation safeguarding the health and safety of the worker, which is obviously urgent and can no longer be justifiably postponed, should take into account all the aspects described in the present study, thus resolving all the controversial questions posed by the current norms.

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Disability and work: fitness for work judgement

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Key words

Disability; work; occupational health physician; work fitness judgement

Summary

Background: *The role of physicians, in particular those dealing with health promotion in the workplace, takes on a specific meaning in relation to the difficulties that disabled people encounter both in order to reach the workplace and to reconcile their working activity with the difficulties that result from their condition. Observing the data concerning employment of disabled persons in Italy, it becomes dramatically evident that among the disabled subjects of working age only 17% are employed.* **Objective:** *The objective of the occupational health physician is to recognise the impairment, study the disability and, possibly, eliminate or reduce the handicap. Achieving this target is difficult, and there is often a lack in understanding the discomforts experienced by disabled people in their working activity. Expression of a judgement of work fitness for a specific task is a particularly delicate matter, all the more so if the worker is a disabled person. A judgement of work fitness of a disabled person should include evaluation of the person's ability and an analysis of the working task and the workplace.* **Conclusions:** *Based on our experience, one can safely say that working inclusion and integration in work is possible, without any decrease in productivity, if an appropriate position is found for disabled workers. The occupational health physician has a primary role in the entire process of inclusion of disabled people at work, since he/she knows the company, the tasks, and the associated risks, and furthermore is able to assess the capabilities and abilities of the worker and can thus identify the most suitable and safe working situation.*

Riassunto

«Disabilità e lavoro: il giudizio di idoneità». **Introduzione:** *Il ruolo dei medici e in particolare dei colleghi che si occupano della tutela della salute negli ambienti di lavoro assume un significato particolare in considerazione delle difficoltà che i lavoratori disabili incontrano sia per raggiungere una stabile occupazione sia per conciliare l'attività lavorativa con le difficoltà proprie del loro status. Osservando i dati relativi all'occupazione dei disabili in Italia emerge la drammatica evidenza che i soggetti occupati tra i soggetti con disabilità in età lavorativa risulta utilmente impiegato solo il 17%.* **Obiettivi:** *L'obiettivo del Medico Competente è quello di riconoscere la menomazione, studiare la disabilità e, possibilmente, annullare o ridurre l'handicap. Il raggiungimento di questo obiettivo è difficoltoso e spesso nella realtà assistiamo ad una scarsa comprensione dei reali disagi vissuti dai disabili durante l'attività lavorativa. L'espressione del giudizio di idoneità alla mansione specifica è un momento molto delicato nell'attività del medico competente nei confronti dei lavoratori, a maggior ragione se disabili per i quali è stata individuata una esposizione a rischio nel Documento di Valutazione. Il giudizio di idoneità di una persona disabile dovrebbe prevedere da un lato la valutazione delle capacità della persona in generale ed in relazione alla specifica attività lavorativa, e dal-*

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l'altro un'analisi del compito lavorativo e del posto di lavoro, che dovrebbero essere comunque adattabili alle capacità operative della persona stessa. **Conclusioni:** *Anche in base alla nostra esperienza, si può affermare che è possibile l'inserimento e l'integrazione lavorativa, senza cali di produttività, collocando le risorse disabili nei posti adeguati. Il Medico del Lavoro svolge un ruolo determinante in tutto il processo di inserimento lavorativo della persona disabile in quanto conosce l'azienda, le mansioni, i rischi ad esse connesse ed inoltre è in grado di valutare le capacità, le abilità del lavoratore ed individuare la situazione lavorativa più idonea e sicura.*

Introduction

The role of physicians, in particular those dealing with health promotion in the workplace, takes on a specific meaning in relation to the difficulties that disabled people encounter both in order to reach the workplace and to reconcile their working activity with the difficulties that result from their condition. If for everyone work is a necessity and a source of satisfaction, for disabled people it often also means social inclusion and integration. Nevertheless, the great difficulties in terms of inclusion cannot be underestimated when dealing with disabled people.

In particular, observing the data concerning employment of disabled people in Italy, it is dramatically evident that among the able population, the percentage of employment is 54%, while among the disabled of working age only 17% are employed. The situation in Europe is better, albeit not quite satisfactory, since the employment rate among the able population is 66%, while the equivalent for "slightly" disabled people reaches 47%, dropping to 25% for people with serious disabilities.

It should be noted that a comparison of data concerning employment percentages is difficult due to the different collection methods, as well as to the different social characteristics present in the different countries of the European Union. However, in Italy there is a dramatically low level of unemployment of the disabled population.

Definitions and types of disability

In order to consider the disabled person as a resource to be inserted and integrated into the working world, it is necessary to overcome the cultural resistance linked with the commonly held opinion that the disabled person is incapable and unproductive. This conviction is also derived from the fact that the criteria of ascertainment of the psychophysical conditions of people with disabilities pose the problem of quantifying the degree of impairment, in order to assign financial and other benefits. Therefore, evaluation of the abilities of the subject under examination was right from the beginning considered in terms of the percentage of disability suffered. That is how the idea that the percentage of disability was associated with working ability. Furthermore, the rather different psychophysical conditions were described using the same percentage parameter.

In recent years, thanks to the introduction by OMS of the ICIDH (International Classification of Impairment, Disability and Handicap) (9), an attempt was made to focus attention on *disabilities* (as inabilities to carry out specific actions), and on the impact between *disability and environment* that could generate *handicap*. As a matter of fact, even though the words "disability" and "handicap" are used as synonyms, it is important to remember that they have different meanings and implications.

First of all, it is important to clarify the meaning of *impairment* and *disability*. The word impairment indicates any loss or abnormality in a psychological, physiological or anatomical structure or function. The word disability indicates any limitation or loss (resulting from impairment) in the ability to carry out an action in the way and to the extent considered normal for a human being. The word handicap indicates the disadvantageous condition resulting from an impairment or disability which, in a certain subject, limits or prevents fulfilment of

the subject's "normal" role in relation to their age, sex, and socio-cultural factors.

A further distinction must be made between illness and disability. Disability, in fact, may be the result of an illness or an accident, but must not be confused with the concept of illness. Two people with the same illness may have different disabilities, while two people with the same disabilities do not necessarily suffer from the same illness.

A further step forward was achieved thanks to the new classification model introduced by the WHO: ICF (International Classification of Functioning, Disability and Health) (10), which "intends to describe what a person in any condition of health *can do*, not what they *cannot do*". In this case, the key element is the residual health and ability rather than the disability. As a matter of fact, the ICF classifies health with all its related conditions. While traditional indicators are based on mortality rates, the ICF overturns this point of view focusing on the quality of the unhealthy person's life, and trying to understand the way they feel their condition and how to improve their life. (7)

At this point, it is useful to supply some other definitions:

Handicapped Person: "He/she who has a stabilised or progressive physical, psychic or sensorial defect, which causes difficulties in learning, and in relation to integration in the workplace, to such an extent as to determine a social and alienating disadvantage." (Law n°104/92, article 3).

Civil disabled: "Civil disabled persons are those persons who are affected by physical defects, which reduce their working ability by no less than 1/3, … except for persons disabled in the course of service at war or in the workplace, or deaf-mutes ..." (Law n° 482/1968, article 5). "Mutilated persons and civil disabled persons are citizens affected by congenital or acquired defects, even of a progressive nature, including psychic irregularities which, due to organic or metabolic disorders, mental subnormality, mental insufficiencies deriving from sensorial defects, which reduce working ability by no less than 1/3 or, if under the age of 18, who have persistent difficulties in carrying out the tasks and functions typical of their age group. This does not include disabled persons due to war, work or service, as well as blind or deaf-mute persons, to whom other laws apply…" (Law n° 9118/1971 article 2).

Disadvantaged people (Law n°381/91 article 4). The following categories of people are considered disadvantaged: people with physical, psychic and sensorial disabilities; psychiatric patients or past patients of psychiatric hospitals; drug-addicts or alcoholics; minors of working age; convicts. Disadvantaged people must make up at least 30% of the workforce of the cooperative societies.

Legal references

In Italy, starting from the 1950s, numerous laws were passed for the protection and assistance of socially disadvantaged subjects (such as disabled and mutilated persons, deaf-mutes, and the blind), up until law n° 68 of 1999. This law brought in new regulations concerning the right to work of disabled subjects, and it introduced the concept of the "dedicated employment". "Dedicated employment" means that the assignment of the disabled must take place considering his real working ability, in relation to the characteristics of the workplace. The law therefore considers the disabled not as a burden but as a resource and an opportunity. Table 1 shows a comparison between law 482/68 and law 68/99 concerning the subjects involved.

The first quantitative results of the application of the new legislation are contained in the recent report from the Institute for the Development of Professional Training of Workers (ISFOL 2002), where the data concerning the results of "dedicated employment" is found. In particular, the employment rate for disabled people, 20.8%, increases to 22.9% for people with sensory disabilities (3).

In the 2004 Report from the Ministry of Welfare on the degree of application of Law 68/99 regarding employment of persons with disabilities, the percentages encountered were: 51.6% in the North, 18.4% in the Central regions, and 35.6% in the South of Italy. Research shows that at the end of December 2003, 471,059 disabled workers seeking employment were engaged in obligatory employment, with 102,922 new engagements in 2003.

Table 1 - *Comparison between Law 482/68 and Law 68/99*

Law 482/1968	Law 68/1999
• War, military and civilian disabled • Service disabled • Work disabled • Civil disabled • Blind • Deaf-mutes • Orphans and widows of men killed in action or in service at work • Past tuberculosis patients • Refugees	• People of working age affected by physical, psychic or sensorial impairments and people with intellectual handicaps, which cause a reduction in working abilities exceeding 45%. • Persons disabled as a result of work, with a degree of disability exceeding 33%. • Blind or deaf-mute persons • Disabled from war service • Civilian disabled at war or in service with impairments from 1st to 8th categories. • Blind switchboard operators, blind or deaf-mute therapists (special regulations)
To be excluded: Those over 55 years of age, those who have lost any working ability or who may cause damage to the health and safety of their work colleagues or to the security of the systems, because of the nature and degree of their disability	

Thanks to the new law, 26,760 workers found employment (2).

Epidemiological data

In an attempt to quantify and describe the phenomenon of disability in Italy, numerous difficulties are encountered due to the complexity of the phenomenon and to the nature of the available tools, some of which are still in the process of being tested and perfected. A recent ISTAT survey on the characteristics of the population with disabilities contributed to defining a phenomenon that is generally still managed on the basis of a number of stereotypes (Survey on health conditions and use of health-related services, 1999-2000) (5).

The partial estimates obtained from the ISTAT survey show that in Italy there are about 2,800,000 people with disabilities, equal to about 5% of the population, most of whom still live with their families. It is important to point out that these are only estimates, which presumably negatively distort the actual number of disabled persons in Italy. Since disabled persons in families are identified via the sample method of interview, an underestimate cannot be ruled out. The data from this survey show a development rate of disabilities of 1%. It is important, however, to note that this value increases with age. This phenomenon can be explained by the fact that some disabilities cannot be diagnosed at birth, some conditions that lead to disability are acquired during life and, finally, health conditions usually deteriorate with age. The ISTAT survey, furthermore, revealed that 66% of disabled persons in Italy are women, while only 34% are men. Also, in relation to the total population, disability is 6.2% in women and 3.4% in men.

As regards the territorial distribution of disabled persons in Italy, there is a disability rate of 5.2% in southern Italy, while this figure drops to 4.4% in north-eastern Italy and to 4.3% in north-western Italy. In central Italy the disability rate is 4.8%.

Other interesting data concern the level of education of disabled persons, which is generally lower than that of persons with no disability (no qualifications: about 33% among disabled persons, less

than 5% among non-disabled; primary or junior high school levels: about 56% among disabled persons, 55% among non-disabled persons; university degree: 10.4% among disabled persons, 40% among non-disabled persons). This phenomenon can partially be traced to an "age" factor. In fact, older people, many of whom are disabled, have a lower level of education compared to younger people. Another possible explanation is that there are fewer opportunities for access to schools for subjects with some types of disability.

A recent survey carried out by the University of Bologna considered, besides persons who declared the "maximum level of disability" in carrying out at least one of the activities of everyday life, also all those who simply had "significant difficulty" in carrying out activities of everyday life, thus bringing the number of disabled people to 6,980,000 persons (7).

The currently available data on the employment of disabled persons show low levels of employment for disabled persons compared to the non-disabled. The total number of disabled persons of working age is 584,000. Of these, 99,280 (17.1%) are regularly employed, while about 146,000 (25.2%) are seeking employment. (www.disabilitaincifre.it)

A European survey found that 17% of the European population (about 37 million) of working age have a more or less serious form of disability; almost half of these belong to the 50-64 age group (4).

Furthermore, the data show significant differences between the various countries of the European Union. The lowest rates are found in Spain, Italy and Greece (<10%), while the highest rates are in Finland (23%), followed by the UK, Netherlands, Portugal, Belgium and Sweden. The employment rate among disabled persons is 44%, 19% lower than the general figure. It is also necessary to stress the difficulties in providing a clear picture of the employment situation of the disabled in the European Union, mainly because the member states use different definitions of disability, but also because not all countries make regular surveys supplying information on the level of employment of disabled people.

Relation between disability and working context

It is a common experience for all physicians who practice occupational medicine to have to face, on a daily basis, the employment problems concerning disabled workers. The aim of the occupational physician is to recognise the impairment, study the disability and, possibly, eliminate or reduce the handicap. Achieving this target is difficult, and there is often a lack of understanding of the discomforts experienced by disabled people in their working activity. The critical elements underlying the problem of insertion in the workplace are multiple and not exclusively linked with the situation of the labour market. Figure 1 shows some of the critical issues encountered in the daily management of health and safety of workers with disabilities.

An "adverse" workplace, in terms of accessibility, safety and acceptance, can lead to an increase in the handicap and unfitness for the job. In this sense, it is important to carry out a careful analysis of the occupational risks, also including aspects concerning work organisation, company environment, possible architectural limits (not only of the building but also of the facilities) and hygiene and safety aspects. Risk evaluation, in this specific case, is a central point in the creation of a working environment which fully complies with the criteria of hygiene and safety in the workplace, not only for disabled persons but also for "healthy subjects" (6).

Ensuring that employers and co-workers are aware of a disabled condition is an extremely important factor for the inclusion of the disabled worker in the workplace, in order to improve social integration. Supplying the employer with essential information on the disability, the capabilities and the reasons for engaging a potential disabled worker is a crucial stage in the process leading to inclusion and integration at work. In the same way, it is essential to supply the disabled worker with training and information concerning the assigned task, the machinery and the equipment to be used, the organisational procedures and the workplace where he/she will work.

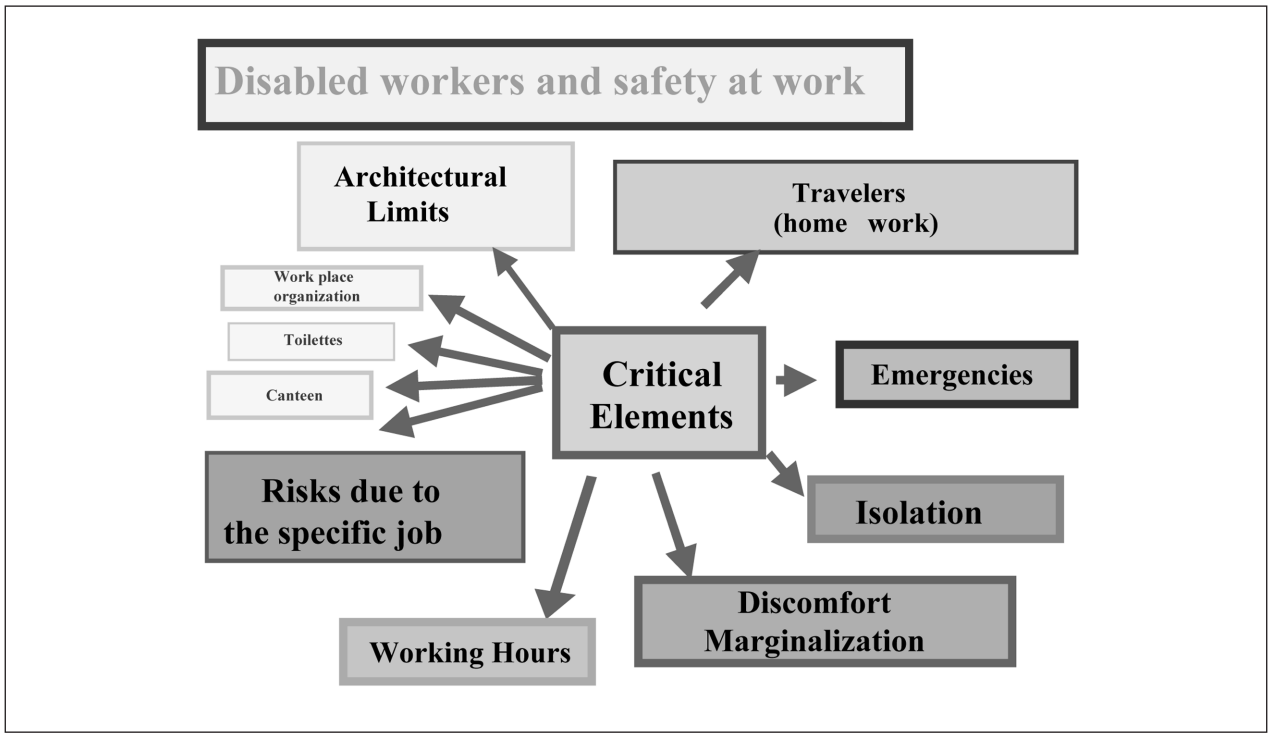

Figure 1 - Critical aspects derived from the daily management of themes concerning the health and safety of workers with disabilities

Health Surveillance

The subsequent step, after identifying risk, evaluating specific risks and analysing the job tasks, is health surveillance through periodic medical examinations aimed at monitoring the health conditions of workers exposed to specific risks.

This periodic examination is a very delicate step in the case of a handicapped subject.

It is very important that occupational health physicians be able to understand the disability of this special category of workers, paying particular attention to the verbal and non-verbal language of these subjects, and to physical contact with them during the medical examination, showing understanding and sympathy regarding their condition. If the main aim of health surveillance is to establish, promote and prolong in time a condition of global balance of the existing relationship between the level of psychophysical health of the working individual and the environment in which he/she passes their working day, in the case of disabled persons the approach must be no different from that taken with other workers in the company, defined as "normal". If this were not so, there would be a great risk of further segregating this category of workers, whereas this should be an occasion to achieve better integration for them in the working environment.

Legislative Decree 626/94 (article 17 para. 2), states that the occupational health physician may "avail himself, if needed, of the collaboration of other appropriate specialists (of accredited structures), and chosen by the employer", for the diagnosis of certain diseases and for expressing the subsequent judgment of fitness for work for the specific task. This possibility would be particularly useful for disabled workers with problems of a mental and psychic nature, which are fields with which the occupational physician is not generally familiar. In conclusion, it would be useful for occupational health physicians to be better trained in these problems.

Work fitness judgement

The "dedicated employment" of a disabled person in a specific situation implies a combination of two actions: one is the expression of the "judgement of semi-specific work fitness", at a pre-employment examination, in compliance with law 68/99, by occupational physicians of the Local Health Department. The other one when the disabled person is entrusted to the care of the occupational health physician of the company. In the latter case, the occupational health physician can evaluate more specifically the workplace/position and the subject's exposure to risks, expressing a judgement of compatibility of the person with the job/environment, and can propose to the employer to apply the necessary and specific safety and hygiene measures.

The expression of a judgement of work fitness for the specific task is a particularly delicate matter for the occupational physician, especially if the workers are disabled persons for whom exposure to risks has been identified in the Evaluation Document.

The judgement of work fitness of a disabled person should include the evaluation of the person's ability and an analysis of the task and the workplace, which should anyway be adaptable to the worker's capabilities (1).

The process that leads to the judgement of work fitness must be extremely flexible and must be the result of contribution by different professionals, not only in the medical field but also in the technical and psychosocial fields.

The judgement of compatibility must be based on the following points:

a) The working handicap is not necessarily linked to the disability of the person, but is more often derived from incongruence in the interaction between the individual and the environment.

b) The definition of working ability must be of a "specific" kind, based on analysis of the individual residual functional capacities, associated with their cultural and professional level of training, compared with the operational requirements (physical, mental, and relational) of the task (consider the case of blind people who work as, switchboard operators without any impediment).

c) The judgement of work "fitness" for the specific task, in order to be really effective, cannot be limited to a mechanical comparison between the requirements of the task and the functional characteristics of the person, but must be supported by a series of activities aimed at optimising interaction between the individual and the organisation of the job.

The judgement of compatibility with a specific task, in spite of conflicting sentences of the Supreme Court, might include evaluation by the occupational health physician, of the possibility of obtaining some "task cuts" for the disabled person, wherever possible, without creating any significant problems either for the disabled person or for the company.

This option might be very useful, for example, in the case of workers who "become" disabled (during their working activity), or in whom disabling diseases are detected during a periodic medical examination and who therefore need to be assigned and/or re-assigned to a job that is compatible with their health condition; if the subject still has some working capabilities, he/she should be used in the best way possible.

Conclusions

The main characteristic of the critical factors in the assignment/maintenance on a job for subjects with disabilities is to exercise a strong sense of conservation of health and professional skills, so as to avoid the disability becoming even more of a disadvantage by trapping the worker in tasks that are scarcely gratifying in relation to his/her real professional qualifications.

Based on our experience, it can be safely said that inclusion and integration in work is possible without any decrease in productivity, if an appropriate job is found for disabled workers. In order to do this, a close and continuous cooperation is required between the company, the "Dedicated Employment Centres" and the Medical Commission of the Local Health Authority. This cooperation should take place with the occupational health physician acting as an interface with the company

itself. In this case one could define the occupational health physician as a "mediator" between the realm of disability and the productive system. The occupational health physician has a primary role in the entire process of inclusion of disabled people at work, since he/she knows the company, the tasks, and the associated risks, and furthermore he/she is able to assess the capabilities and abilities of the worker and thus identify the most suitable and safe working situation. Beyond assigning tasks based on abilities, the occupational health physician can assist the employer in preventing, managing and solving employment problems linked with the presence of disabled workers in the productive unit, as well as providing counselling and support for the workers.

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Protection of third parties in current legislation and preventive practice

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Key words
Collective health, Italian legislation

Summary
The problem of safety and the management of risks to third parties, which may be caused by a change in the mental or physical health of an employee, is one which affects a number of different areas (infectious diseases, psychiatric illnesses, conditions of drug and alcohol abuse, etc.). Italian legislation deals with the issue of fitness for work through a variety of laws, decrees and regulations which, because many of them were issued in different historical circumstances, are not always mutually harmonized. The growing complexity of the workplace makes the role of the Occupational Physician more complex, and to this person the law assigns the exclusive task of monitoring the health of employees in the cases covered by the current regulations. In our opinion, the Occupational Physician, to the best of his knowledge and conscience, having taken into consideration all the aforementioned factors, must take each case on its merits, in the most responsible manner possible, weighing up the complexity and delicacy of the aspects discussed earlier, and decide to deliver a verdict of fitness and/or to break or not to break the obligation of confidentiality, tending, in our view, to favour the need to safeguard collective health, or that of third parties, should there be a conflict of interest.

Riassunto
«Gestione del rischio per i terzi nell'attuale legislazione e nella pratica preventiva». *Il problema della gestione del rischio per i terzi, derivante da una alterazione dello stato di salute psico-fisica di un lavoratore, investe numerosi ambiti (malattie infettive, psichiatriche, stati di tossicodipendenza, etc.). La legislazione italiana affronta il tema dell'idoneità al lavoro in un insieme di leggi, decreti, provvedimenti che, elaborati in momenti storici diversi, non sono sempre armonizzati tra loro. L'accresciuta complessità del mondo del lavoro rende estremamente complesso in Italia il ruolo del Medico Competente, al quale la legge affida in via esclusiva il compito di effettuare la sorveglianza sanitaria dei lavoratori nei casi previsti dalla normativa vigente. A nostro parere il Medico Competente, in scienza e coscienza, dovrà decidere caso per caso con estrema responsabilità di formulare il giudizio di idoneità e/o derogare o meno dall'obbligo della riservatezza, tenuto conto a nostro parere di tendere o far prevalere la tutela della collettività e/o terzi in caso di conflitto tra opposti interessi.*

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Introduction

The problem of the safety and management of risks for third parties, which may be caused by a change in the mental or physical health of an employee, is one which affects a number of different areas. Indeed, as well as infectious diseases transmitted via the blood or air or personal contact, which were prevalently discussed in recent years, the present scenario has broadened to include some mental illnesses (schizophrenia, epilepsy, etc.), certain behavioral disorders (impairment due to stress, mobbing, etc.), serious disabilities (visual, auditory, motor etc.), neurological diseases (dementia, Parkinson's disease, etc.), late-onset genetic diseases (Huntington's Chorea, multiple sclerosis, etc.), conditions of drug abuse, alcohol and drug dependence, etc.

Italian legislation deals with the issue of fitness for work through a variety of laws, decrees and regulations which, because many of them were issued in different historical circumstances, are not always mutually harmonized.

The growing complexity of the workplace makes the role of the Occupational Physician more complex, and to this person the law assigns the exclusive task of monitoring the health of employees in the cases covered by the current regulations.

Occupational Physician, evaluation of fitness for specific tasks and protection of third parties

One of the most challenging and demanding aspects of an Occupational Physician's professional activity is when he/she is called to express a judgement on the fitness of an employee for a specific job. Such evaluation is the final step in a process of health monitoring, and involves checking compatibility between assessment of the occupational risk of the specific job resulting from an evaluation of the risks, and assessment of the health profile of the employee, in terms of any current disease and previous conditions, individual hyper-susceptibility, physical and psychological state, habits and lifestyle, etc.

Medical investigations requested by the Occupational Physician (clinical, biological and instrumental tests) and carried out during regular check-ups are essential if the occupational risks are to be properly evaluated; their objective is to safeguard the health and safety of employees in such a way as to enable them to be actively engaged in the working environment, rather than excluded from it.

According to the opinion of the "Italian Group for the Study of Inter-Hospital Management of Employees with Diseases considered Dangerous to the Public" (GIS GILMaPP) (13), which includes experts from various disciplines and which has the support of a number of trade union organizations, "the activities conducted by the Occupational Physician should have, as their primary objective, the protection of the health of the employee. Other objectives, such as the protection of public health, are not the task of the Occupational Physician, as defined by the laws in force and by the Code of Ethical Behaviour (which states that the prescription of investigations which are not directly related to the health risk of the employee is not considered to be ethical, and that the investigations must be chosen on the basis of the role they could play in protecting the health of the employee), unless the characteristics of a disease in the employee alters the integrity of the target organs affected by occupational exposure". Examples of this kind include employees with visual defects whose activities could lead to a higher risk of accidents and who, for this reason, should be exempted from carrying out certain tasks. Another example includes health care professionals suffering from a state of immune depression who, since they are more susceptible to infection, should not be assigned to treating infected patients. Situations of this kind are implicitly covered by the regulations in force.

Given that the Occupational Physician is bound by a duty to protect the health of the employee with regard to specific risks, with the provision that "third parties" may also be protected as an indirect result, the Occupational Physician's role should be considered under circumstances where the risk is exclusively related to third parties. In this regard, it is then necessary to establish how to view, interpret and apply Article 4, Subsection 5, letter n of Law

Decree n°. 626/94, which states that: "*the employer should adopt appropriate actions to assure that the technical measures taken do not cause any risk to public health or cause damage to the external environment*" and to Article 5, which states that "*Each employee must look after his/her/her own safety and his/her/her own personal health, as well as that of other persons present in the workplace, who could be affected by his/her actions or omissions, in accordance with his/her training and with the instructions and resources supplied by the employer.*"

The case of health care professionals suffering from diseases which may be transmitted to patients is a circumstance which, by analogy, may be adapted to other situations in which the risk evaluation document reveals the presence of a risk, not just for the employee concerned but also for the health and safety of third parties. In these situations, the Occupational Physician must express an evaluation of job fitness, which may involve prescriptions and limitations (8, 12). In these cases, the Occupational Physician is obliged to adequately inform and train the employees as to the measures required for avoiding contagion of patients, and the health care professional will have the professional obligation to inform patients undergoing a surgical operation about the risk that he/she could transmit biological agents present in case of accident and obtain a statement of informed consent which acknowledges that this risk exists. Likewise, in planning a vaccination programme, the Occupational Physician cannot abstain from requesting a statement of informed consent from the employees. The evaluation of the extent of the risk for the health of the person exposed to biological agents will be the subject of a subsequent judgement of fitness or non-fitness for any persons who may refuse to be vaccinated or who fail to respond. Any employee anxious not to run the risk of proving contagious for other persons should ask to be referred for a medical examination, according to Article 5, Act no. 300/70 and specific related regulations, for example, Presidential Decree n°. 384/90, and Presidential Decree n°. 461/2001, etc. In cases where all the possible general and specific measures of prevention and protection have been adopted without obtaining any true benefit for the safeguarding of third parties in the aforementioned cases, the Occupational Physician could declare the employee unfit for specific tasks. According to the opinion expressed by the Italian Society of Occupational Medicine and Industrial Hygiene (SIMLII), to express a judgement of unfitness in order to protect third parties is not only counter-productive from a technical viewpoint, but could also give rise to civil or criminal action against the workplace physician, given the lack of a clear guidance in the legislation in force (21).

On the other hand, in circumstances where the protection of the health of a single employee is not compatible with the protection of collective health, a situation which occurs frequently, and where the risk only concerns the health and safety of third parties, the role of the Occupational Physician becomes more complex in the light of the responsibilities and the persons involved; it should however be added that it is unlikely that an employee who represents a danger for other persons (for example someone suffering from a psychiatric disorder) will obtain, during the pre-employment medical examination, a clearance for fitness to carry out general tasks from the relevant bodies having the task of making such decisions under the aforementioned regulations.

The principle of objective protection of health in the workplace, once again, falls directly on the employer who is deemed responsible for general safety obligations, under the terms of the Italian Civil Code, Article 2087, which states that: "*he/she should safeguard the working conditions*", and that, according to Law n°. 626/94, Article 4, Subsection 5, letter c: "*in assigning tasks to employees, it is his/her duty to take account of the abilities and conditions of these persons in relation to their health and safety*" and, according to the opinion of some experts in the field of employees' rights, "*it is the employer who must adopt all the preventive measures technically possible in order to assure the physical safety of the employees and that health be safeguarded, even under circumstances where the behavior of these persons is careless.*" (6). It should be emphasized, in this regard, that the responsibility for any dangerous behaviour of employees that could make such persons eligible for disciplinary or legal sanctions will not automatically involve or become the responsibility of the Oc-

cupational Physician, but should be resolved by the competent authorities. The problem of managing the fitness assessment of employees performing tasks which entail risks for the health and safety of third parties has so far failed to meet with a satisfactory response, either with legislation or by research bodies which ought to supply the scientific knowledge needed to develop suitable legislative guidelines (16). The issue has, for example, been approached regarding health investigations concerning alcohol and alcohol-related problems, as stipulated by "Legge Quadro" (Framework Act) no. 25/2001, as well as regarding drug abuse and use of psychotropic substances, as stipulated by Presidential Decree n° 309/1990, covering categories of employees carrying out tasks which entail risks for the health and safety of third parties, which had not yet been identified by the Ministry of Labour or the Ministry of Health. Act n° 125/2001 assigns to the Occupational Physician the duty of safeguarding the health of third parties, together with that of individual employees.

Under current conditions, in the absence of any regulations for implementation in order to identify the work categories that involve a high risk of accidents, or where it is necessary to protect the health and safety of third parties, the tendency in assessing fitness for work is to avoid programming specific tests and investigations and instead to view each individual case, evaluating the implications for the employee of continuation or removal from his/her tasks, including the possible impact on the population (7). Clearly, if another work area is satisfactory for the employee, and acceptable for work organization, the problem may be resolved to the satisfaction of all concerned parties (1).

The Ombudsman for the protection of personal data has expressed an opinion on this issue, in response to a question raised by the Ministry of Labour and Social Policies on the identification of categories of employees who should be subjected to tests to establish the absence of drug dependence, given that they are involved in tasks that entail risks to the health and safety of third parties. The categories in question include transport, health and building sector employees, to name but a few. The Ombudsman declared a ban on "*generalized investigations, with no specific reasons*" and that the investigations in question should be conducted only in cases where symptoms of drug dependence are evident. The results of such tests must be used exclusively for the purpose of safeguarding the safety of the population (www.garanteprivacy.it).

At this stage, we need to take a few details into account. The first concerns the legitimacy of an employee's constitutional right to refuse to undergo medical tests, as foreseen in Article 32 "…*nobody can be forced to undergo a specific health treatment, unless this is dictated by law. The law cannot in any circumstances violate the limits imposed by respect for the human person*"; the second point concerns the right of an employer to dismiss an employee who refuses to undergo obligatory health monitoring, in circumstances where it proves impossible to reassign the employee in question to other tasks. In other words, the Occupational Physician cannot oblige an employee to undergo medical investigations, while the employer has the duty to take all measures that the law requires, including, in extreme circumstances, that of fair dismissal the employee in question.

Regarding activities which pose a risk to the health of third parties, the Constitutional Court delivered its verdict in Sentence n° 218/1994 declaring that Article 5, Subsections 3 & 5, of Act n° 135/1990 is constitutionally illegitimate in that it does not stipulate health checks to determine the absence of HIV-positive infection as a prerequisite for employees engaged in activities which carry a risk for third parties. The rationale for the sentence was inspired by "…the duty of the individual to abstain from damaging or putting at risk the health of others through his/her own behavior…"(9).

Finally, in formulating a fitness assessment, it is appropriate to point out that the problem is not of evaluating fitness to carry out general work tasks (1), but rather that the specific tasks need to be examined in all their complexity. Indeed, in cases where the psychic and physical level of fitness of an employee for generic reasons must be ascertained in relationship to the health of the employee him/herself, the provisions of Article 5, Subsection 3, of the Workers' Statute (Act n° 300/70) must be complied with and the public health structures

charged with this task must be consulted. Under such circumstances, health investigations may be ordered for various reasons; for example, to establish fitness for work of the employee after a long period of absence due to illness, or to exempt someone from service, etc. In these cases, the medical examination is carried out by the Medical-Forensic Commission of the local public health authority (ASL) or by public agencies considered to be impartial in the matter. In such cases, the medical-forensic evaluation refers generically to the ability to work (generic fitness for work) but does not evaluate the risks involved and cannot therefore automatically be considered to be an evaluation of specific fitness such as those issued by the Occupational Physician.

Finally, it is important to emphasize the significance of identifying, in the Risk Evaluation Document, all the factors pertaining to the work-related risk that could exist, and their reciprocal interactions, including safeguarding third parties (5, 12), and also evaluate their extent, where necessary, with the aid of analytical or instrumental methods. The Risk Evaluation Document becomes the point of reference for the employer and for all the other corporate personnel involved in the issue of work safety. Assuming that the identification and adoption of the criteria to be used in carrying out risk evaluations remain within the discretional area of the employer, who directly accounts for any actions he/she takes (Ministry of Labour, Circular Letter n° 102, of August 7, 1995 - Law no. 626, of September 19, 1994, directives for application), the employer must draw up the document along with the official responsible for accident prevention and health safety and with the Occupational Physician, in cases where health monitoring is mandatory, subject to consultation with the safety representative (Article 4, Subsection 6, Decree Laws n° 626/94 and subsequent amendments).

Occupational Physician and Professional Confidentiality

In the physician-patient relationship, it is necessary to distinguish between the public area, that is to say the field where the physician is called upon to comply with legal obligations and therefore to be aware of, and comply with laws and regulations, and the private area, which only concerns the two persons involved in the contractual relationship: physician and patient. All matters related to this last field must remain in the private area, a fact which is first and foremost a question of professional ethics, as opposed to a judicial consideration. Indeed, Article 9 of the Professional Medical Code states that: "*the physician must maintain confidentiality regarding any information confided to him, or of which he/she becomes aware through his/her profession…*".

On the other hand, the aforementioned Article 32 of the Italian Constitution sanctions the concept of "*safeguarding health as the right of the individual and in the collective interest… nobody can be forced to undergo a specific health treatment, unless this is dictated by law. The law cannot in any circumstances violate the limits imposed by respect for the human person*".

The physician has the difficult task of choosing between a duty to respect professional confidentiality and a duty to inform, for example, the competent authorities in the event that he/she considers his/her patient may compromise the well-being of other persons.

The physician must in the most categorical fashion respect the person he/she is treating, at the same time respecting his/her own conscience and observing the laws in force. Which means that he/she must be aware of the just reasons for revealing a professional secret as laid down by the aforementioned Professional Medical Code and Criminal Code.

Revealing a professional secret is only legitimate if a just cause exists. Just causes can be either of an imperative or permissive kind. Imperative causes are those which impose revealing a professional secret on the grounds that this has been expressly ordered by the judicial authorities. This is the case for mandatory health notifications, mandatory certificates, reports, judicial statements, physical examinations ordered by a judge, expert appraisals and technical consultations, arbitrations and medical-forensic examinations requested by public

health authorities and conducted on their behalf. This category does not include assessments of fitness to work expressed by the Occupational Physician. It should, however, be emphasized that, even in these cases, although a physician may be required to reveal a professional secret, he/she is nevertheless bound to observe the strictest possible confidentiality regarding any information deemed irrelevant to the satisfactory conclusion of the matter in question, and concerning which the authorities have not made any specific reference or order. Permissive causes are those which enable or permit (but do not oblige) a physician to reveal a secret, provided there is the consent of parties having the right to do so, as contemplated in Article 50 of the Criminal Code: "*anyone causing detriment to a right is not punishable, provided that consent was obtained from the person eligible to give it.*" This is based on the logic that maintaining a secret is the personal right of the patient, who can therefore do with it what he/she will, thereby nullifying any negative judicial implications of such an action. As it is known, the validity of any consent given by the person who has a right to it presupposes that the consent is informed, in good faith, explicit, free and without malice. Ultimately, the patient can only consent to the revelation of such secrets of which he/she really and truly has full knowledge. All such considerations are also in keeping with the regulations regarding informed consent in the field of medical treatment which a patient may be required to undergo (2).

Occupational Physician and Code of Ethics

An important reference for the specific role of the Occupational Physician in safeguarding the health and safety of employees consists in the stipulations laid down in the Code of Professional Ethics for occupational healthcare workers drawn up by the International Commission on Occupational Health (ICOH) (14) which states that the prescription of medical investigations which do not have a direct influence on the risk for the health of the employee should be considered unethical and that medical investigations must be selected on the basis of their validity in protecting the health of the employee concerned (Article 12).

In the aforementioned code, the only reference to third parties appears in Article 11, which points out that: "*under circumstances where the health conditions of the employee and the nature of the work performed are such as to put the safety of other parties in danger, the employee must, of course, be informed of the situation*". As a consequence, the Occupational Physician is obliged, under the terms of Article 6, to dedicate as much time as it might be necessary to inform the employee of the significance of the various tests included in the health monitoring programme, as well as of the significance of the health conditions and any diseases which may be revealed during the monitoring process, using terms and concepts that are readily understandable for the employee, albeit bearing in mind that the content of the information is bound by specific legislative rules (Decree of Law n°. 626/94 Article 17, Subsection 1, letters e, f, m) and, in our own opinion, involving the general practitioner in consultations. At the end of the day the responsibility for revealing the existence of a serious health condition which could pose a potential health risk for third parties rests primarily with the "sick" employee, even if the latter may often be reluctant to do so for a series of reasons (fear of being marginalized, demoted, etc). The staff employed in the health sector are expected to report any such conditions involving their own health, with the prospect of serious consequences and sanctions, given that they are public service officials, should they fail to report such conditions or refuse to undergo medical investigations.

Article 11 of the ICOH Code points out that: "*in the case of particularly dangerous circumstances, the management and, if so required by national regulations, the Competent Authorities must be informed of the measures needing to be taken in order to safeguard third parties*." Clearly, in order to avoid all forms of discrimination, the existence and severity of the danger for third parties should first be adequately assessed and documented. For example, evidence given by colleagues who have witnessed episodes, or who are aware of dangerous conditions affecting

an employee, which is almost always made in a verbal form, could be recorded in a written form.

Occupational Physician and Protection of Privacy

Law n° 196/2003 called "Code for protection of personal data", which came into force on January 1, 2004, is the new code for the protection of privacy. Article 23 establishes that all sensitive data may only be processed upon the written consent and knowledge of the person involved. Such consent could concern the whole management process, or just one or several parts of this process. Article 24 defines "*cases in which management may be carried out without consent*" stipulating in point e) that consent is not required when the management of data is deemed necessary for saving life or safeguarding the physical safety of a third party. In particular, heading V of Decree of Law no. 196/2003 makes specific provisions for the handling of sensitive data in the field of health.

The authorization of the Ombudsman is given via the Consiglio Superiore di Sanità or Upper Health Council, unless it is a matter of particular urgency. A provision introduced on December 21, 2005, and published as a Supplement in the second issue of Gazzetta Ufficiale (Official Gazette), dated 03/01/2006, stated that: "*Authorization for the management of sensitive data in labour relations*" (Authorization no. 1/2005) (3), the Ombudsman for the Protection of Personal Data authorizes the management of sensitive data, defined in Article 4 of the Code and relating to labour relations; the authorization also covered activities carried out: "*by the Occupational Physician in the fields of hygiene and safety on the workplace, in his/her capacity as a consultant or member of staff…relating to data which may reveal the state of health, …the physical and mental fitness to carry out certain tasks…*". With the "*Authorization for management of data likely to reveal the state of health and the sex life*" (Authorization no. 2/2005) (4), the Ombudsman for the Protection of Personal Data authorizes "*professional health professionals to manage data likely to reveal the state of health, provided that the data and the management are indispensable for safeguarding the physical safety or the health of a third party or the collective physical safety or health, and consent has not been given, or cannot be given since it is to all intents and purposes unavailable.*"

Preventive practice

A first example concerns the problem of the risk of transmitting infectious diseases, such as hepatitis B and C, from health professionals to the public. The "Italian Group for the Study of Inter-Hospital Management of Employees with Diseases considered Dangerous to the Public" (GIS GILMaPP) (13, 15), an association that includes physicians, judiciary officials and experts in bioethics, has proposed a model for managing such employees. In this regard, according to recent provisions which we highlight in the conclusion of the present report, an obligation exists to report an occupational disease, as mentioned by the Decree of April 27, 2004, issued by the Ministry of Labour and Social Policy, as follows: "List of diseases for which there is an obligation to report, in compliance with Article 139 of the Bill approved by Presidential Decree no. 1124 of June 30, 1965, no. 24, along with subsequent changes and additions" and in which hepatitis B and C virus infections are also mentioned.

The main prescriptions for managing health care professionals who are HbsAg-positive and/or anti-HCV positive were intended to update the previous prescriptions concerning public health (8, 13, 15, 18, 21).

A recent "Consensus Document", agreed at European level, recommends that health professionals who are HbeAg-positive or who have a level of HBV DNA > 10^4 genomes equivalent/ml, should not carry out exposure prone activities of the type already described. However, it is up to each country to establish the "cut-off" level on an individual basis, weighing up the risk of transmission of infection to patients against the loss of expert health professionals. The level of HBV/DNA must be checked on an annual basis for anyone found to have a level lower than the cut-off point established. Any health professional found to be a

source of transmission must be removed from exposure-prone tasks, regardless of the level of HBV/DNA. No consensus has yet been reached on the management of HCV-positive health professionals. Lastly, the problem of the informed consent has been addressed and it has been established that a health worker who is HBV/DNA-positive should, in order that he/she may continue to carry out exposure-prone tasks, have the option of revealing his/her positive condition to the patient, who in turn must receive accurate and comprehensible information on the subject.

A second example concerns fitness for specific tasks of employees engaged in driving motor vehicles, in cases where such employees have a clinical history of epileptic disease, which could prove dangerous to third parties as well as to themselves. (10). In this case, it is necessary to establish the type, frequency and severity of the crises in the staff member in question, as well as establishing how regularly any therapy is received. It is extremely important to ascertain the date that the last crisis began, since a person may be considered cured if he/she suffers no attacks for more than 5 years and he/she has an electroencephalogram as defined by the regulations.

A health protocol has been proposed for employees engaged in driving motor vehicles who have a clinical history of epilepsy, which would establish down provisions for obtaining accurate knowledge of the various activities carried out, as well as the type of vehicle driven, the routes taken and the chemical and physical agents present in the workplace. (10) This would be in addition to the medical examination involving the collection of medical history data, blood testing, urine analysis and cardiological examination, aimed at evaluating the general condition of the employee. The employee would also be subject to a neurological examination with an electroencephalogram, both the basic type and type "activated" by epileptogenic stimuli (hyperpnoea, photo-stimulation, sleep deprivation, etc.).

In these cases expression of a fitness assessment must also take into account the provisions of the Italian laws in terms of issuing and renewing driving licenses. The Highway Code Test, which came into force in January 2003, allows the issue of a category A and B driving license to individuals with a clinical history of epilepsy, provided that they have displayed no accompanying symptoms for more than two years, regardless of the administration of any therapy. The certificate of ability to drive is issued by a special Local Medical Commission on the basis of health certification supplied by the individual's general practitioner or by a specialist belonging to the public health services, and it is valid for two years. Under no circumstances can a person suffering from epilepsy receive a category C, D, and E driving license.

An Occupational Physician who observes that an employee is unfit to drive may ask him/herself if he/she should report the fact to the agencies authorized to issue and renew driver licenses. At present, in Italy, there is no legislation which makes such action mandatory. As a result, the possibility of avoiding injury to third parties or of reducing the exposure of an employee to a greater risk of accident, are not considered sufficient reasons for obliging the Occupational Physician to violate professional secrecy. The Occupational Physician may express an assessment of unfitness when safeguarding the health of third parties coincides with that of the employee in question.

We hope legislative measures will be introduced to give some clear guidance as to the tasks of an Occupational Physician vis-à-vis the competent authorities in the case that in the course of duty he/she receives notice of a disease which may impair the person's ability to drive a vehicle.

In conclusion, the question of disabled and partially disabled employees needs to be addressed. Article 10 of Law No. 68/1999 states that in cases where a disabled person falls under a category of an employee subject to regulations covering health monitoring, the Occupational Physician must not only take into account the outcome of the investigation into the disability carried out by the special medical commission as laid down in Article 4 of Law no. 104/92 but, during regular preventive medical examinations, he/she must also express a judgment on the compatibility between the state of health of the disabled employee and the tasks he/she will be expected to carry out. In accordance

with Article 17 of Law No. 626/94, both the disabled employee and the employer have the right to lodge an appeal against the verdict of the Occupational Physician with the supervisory authority that has jurisdiction in that area. Should the verdict continue to be controversial, an appeal can be made to the medical commission mentioned earlier, whose opinion will represent the final verdict on the matter (11). Previous legislation on the issue, Act no. 68/1999 does not contain any ruling on verifying that the presence of the disabled employee is not prejudicial to third parties (5, 12).

Conclusions

Taking into account the professional, ethical, legal and judicial aspects analyzed thus far, it can be concluded that it would be appropriate to introduce rules which, in order to improve the efficiency of the Occupational Physician in cases where he/she has to exclude an employee who represents a danger exclusively to third parties, imposes a "virtuous" behaviour on employees, while prohibiting behaviour of a risky nature (19), in accordance with Article 5 of Law 626/94 and subsequent amendments.

The key points that have emerged thus far would appear to be the following:

1. the activities of the Occupational Physician, the medical investigations and the assessment of fitness for work are all aimed at safeguarding the individual employee (1);

2. the medical investigations which employees must undergo during the health surveillance activities must be deemed necessary and aimed at evaluating risk; the latter should, insofar as possible, be a "specific known risk", current and future;

3. in safeguarding the health of the individual employee, an exercise which is carried out using all the tools available, including protective and preventive measures, both of a general and a specific nature, there are automatically positive repercussions on the collective health, in this way enabling "third parties" to be protected as well.

In this context, the role of two of the many persons involved – apart from the Occupational Physician – becomes critical. These are the employer and the employee. In our opinion, the employer must take all the appropriate measures in order to effectively safeguard the health of employees, including protecting them under circumstances where they display rash behaviour, and must also take into account the existence of risks for collective health (meaning that of both employees and service users) as well as for the individual, and must make provision for these in the risk assessment document; the employee must take care not to engage in behaviour that could prove dangerous either to him/herself or to others, respect the rules and the protective and preventive measures and be aware of potential risk situations and the correct behaviour in such circumstances, in accordance with Article 5 of Law 626/94 and subsequent amendments, including a willingness to take part in appropriate information and training initiatives, which must be made available by the employer, who may if necessary call on the Occupational Physician to assist in this respect.

In practice, safeguarding the health and safety of the individual employee generally coincides with safeguarding that of third parties; as a result, under circumstances where there is a risk both for the employee and for a third party, the expression of judgment of work fitness on the part of the Occupational Physician will prove useful for protecting both these categories. Indeed, the expression of a judgement of fitness to carry out specific tasks in respect of an individual employee will enable the employee to be assigned, where possible, to different tasks, in such a way that no danger will be caused to other parties. The employer should make the decisions deemed necessary for preventing risks to third parties; but he/she must not in any way fail his/her obligation to maintain the confidence of the employee, nor, worse still, should he/she adopt any discriminatory behaviour with regard to the employee in question.

In cases where safeguarding the health of the individual employee does not coincide with safeguarding collective health, and there is only a risk for the health and safety of third parties, the role of the Occupational Physician becomes more complex. In expressing judgment on the fitness of the

employee to carry out specific tasks, the Occupational Physician may decide, after carefully evaluating each case on its own merits, to express a judgement of unfitness for work, or qualified fitness, or he/she may decide to inform the employer, ignoring the obligation of confidentiality in accordance with the clause covering just cause foreseen by the penal code, with the justification of urgent need to safeguard the health and safety of third parties, as stipulated in the professional code of the National Federation of Medical Surgeons, and referring to the recent authorization by the Ombudsman for the Protection of Personal Data on the subject of handling data which may reveal the state of health (Authorization no. 2/2005 of G.U. 3/01/2006 S.O. no. 2). As far as the issue of urgency is concerned, the Criminal Code refers to the concept of "*present danger of severe injury for the person*" which may not be avoided by other means, assuming that revealing a professional secret is proportional to the level of danger (Article 54); in seeking to define the meaning of urgency, the professional code of physicians and surgeons also interprets the concept in terms of imminent danger. By assuming a broader interpretation of the concept of urgency, one can, in our opinion, refer to the possibility of the work tasks carried out by the employee being effectively performed (for example, will he/she be immediately able to carry out these tasks?); in the latter case, the reference is not just to risk of death, but to risk of injury as well, the existence and frequency of which should not be random, in such a way as to justify, in extreme cases, resorting to a judgement of qualified fitness or unfitness of the employee to carry out specific tasks.

Some authors have reported (17) that one can only inform the employer about an employee in the strictly limited case that this is necessary in order to allow urgent steps to be taken to safeguard the health of work colleagues.

With regard to this possibility that an employee may only prove dangerous to third parties, it should be remembered that the physician has an obligation to make a health report for many diseases. The health report is the document which the health officer uses to communicate the information to the competent authority (health authority) based on facts which have been directly observed as a result of, and through the practice of his/her profession, and which the Authority needs to know about. This has a clinical, statistical and preventive function, and is therefore a highly valuable tool for enabling preventive measures to be put in place by the competent bodies. Such measures may be primary, secondary or tertiary in nature. Primary prevention includes all measures put in place in the absence of symptoms in the patient and which therefore concentrate on the cause of the situation that needs to be prevented. Secondary prevention focuses on the symptoms with the aim of identifying the disease at an early stage. Tertiary prevention applies to conditions where one can only hope to influence the degree of severity of the disease, and not the baseline conditions.

Obligatory health reports include reports of infectious and transmittable diseases (D.M. 5/07/1975 and subsequent amendments), accidents in the workplace, occupational diseases, cases of injury leading to invalidity, cases of pesticide poisoning, etc. With respect to occupational diseases, the Decree issued by the Ministry of Labour and Social Policy on 27/04/2004 updated the list of occupational diseases for which it is mandatory to submit a report to the authorities - ASL, INAIL and the Labour Inspectorate, as established by Article 139 of DPR 1124/65.

In conclusion, although we are aware that oversimplification may detract from accuracy, we believe the situation may be summarized as follows.

1st Case. Safeguarding the health and safety of the individual employee coincides with safeguarding the health of third parties; each person must adhere to the legal obligations covering health and safety issues and it is the task of the Occupational Physician to deliver a judgment as to the fitness, qualified fitness or unfitness of an employee to carry out specific tasks.

2nd Case. Safeguarding the health and safety of the individual employee does not coincide with safeguarding the health of third parties; such circumstances, although rare in our opinion, may nevertheless occur in a work setting and complicate the position of the Occupational Physician who works in a relationship seen as exclusive with the

individual employee whose health is being monitored, based on the trust of the individual concerned, even though the physician is responsible to the employer. Faced with such an eventuality, the Occupational Physician must choose among various options:

A. The situation endangering third parties falls into the following categories:

1) Diseases for which there is a duty to make a mandatory health report for infectious and transmittable diseases. In this case, the Occupational Physician discharges a legal obligation, delegating to the authorities appointed to deal with the notification the task of putting measures in place to safeguard collective health.

2) In cases of accident or occupational disease, the Occupational Physician must send a mandatory report to the competent Authority.

In both cases, in our opinion, the Occupational Physician should take it upon him/herself to evaluate the urgency of the specific situation and verify that notification is given to the authorities concerned, in the time scale and with the means considered appropriate to the circumstances.

B. In situations not covered by the previous point and in which there is only a danger for third parties, the Occupational Physician, taking into due consideration the provisions of the Italian penal code, the professional code of the National Federation of Physicians and Surgeons and the privacy code regarding the communication of data concerning a person's state of health, must take each case on its own merits, evaluating whether or not a just cause exists, or whether there is a case for an urgent need to safeguard the health of third parties. In the preliminary stages of this process, the Occupational Physician must view the cost/benefit ratio of any decision he/she may take to reveal information about the employee, in so doing, violating professional secrecy, and taking into account the possible repercussions this may have on the bond of trust he/she has with the patient. The first problem regards evaluating the degree of urgency, for which different interpretations may well exist. A narrow interpretation could define urgency as a situation where there is an imminent danger (e.g. risk of death), and therefore would not enter into the realm of a potential risk, whilst a broader interpretation would look at the possibility of the work tasks carried out by the employee being effectively performed (for example, will he/she be immediately able to carry out these tasks?). In all events, before deciding to violate professional secrecy, the Occupational Physician must take it upon him/herself to verify, at the workplace, using a variety of methods (verbal, written notifications etc.) that:

1) the employer has adopted all the necessary protective and preventative measures, of both a general and specific nature, in order to safeguard all the employees and service users as well as individuals, and evaluate if these are sufficient, and if they are not, urge the employer to put such measures in place, if technically feasible;

2) the employee is aware of all the obligations that exist in his/her regard (Article 5 of Law no. 626/94 and subsequent amendments) including those of ensuring his/her own and others' health and safety and invite the employee to do so, for example by authorizing the Occupational Physician to violate professional secrecy.

The Occupational Physician must, furthermore, consider whether it might be appropriate to involve the general practitioner as a central figure in the task of persuading the employee, for example, to disclose information about his/her own state of health where this may have repercussions on the health and safety of third parties, before deciding to violate professional secrecy.

Once all the resources available have been evaluated and applied, the Occupational Physician may decide to violate professional secrecy on the grounds of just cause and urgency and inform the employer, refraining, in our opinion, from supplying information that may not be strictly necessary (for example, diagnosis) and in a manner which assures respect for the dignity and confidence of the person concerned, not least so as to prevent the employee being subjected to unjustified discrimination or marginalization in his/her working and relations environment. He/she could, for example, invite the employer to send the employee for a joint medical examination, in compliance with Article 5 of Act no. 300/70.

In our opinion, the Occupational Physician, to the best of his knowledge and conscience, having taken into consideration all the aforementioned factors, must take each case on its merits, in the most responsible manner possible, weighing up the complexity and delicacy of the aspects discussed earlier, and decide to issue a judgement of fitness for work and/or to violate or not to violate the obligation towards respecting confidence, and tend in our view to favour the need to safeguard collective health, or that of third parties, should there be a conflict of interests.

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Fitness for work in difficult cases: an occupational medicine experience in a University Hospital

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Key words
Occupational physician; fitness for work; clinical cases

Summary
Background: *Fitness for work (FW) in certain clinical cases poses significant professional challenges for Occupational Physicians (OPs).* **Objectives:** *to discuss the role of a public Institute of Occupational Medicine (IOM) in FW, thorough description of clinical cases.* **Methods:** *the IOM at the University of Brescia is a public clinic available to general practitioners, OPs, other specialists, insurance companies, health authorities, employers, trade unions. IOM expert opinion on FW may be requested by OPs, employers or workers. In each case, occupational and clinical histories are taken, physical examinations, laboratory and instrumental tests might be performed, and technical and clinical documentation is acquired; expert opinions from other specialists might also be sought. Risk assessment (RA) stems from worksite inspections and information from company health and safety representatives, or health authorities.* **Results:** *a few peculiar clinical cases are reported: tremors in a dental hygienist trainee, chorioretinitis in a welder, spasmofilia in a nursing aide, obstructive sleep apnoea in a steel worker, epilepsy in a metal engineering worker, as well as a number of cases from the same workplace.* **Conclusions:** *FW judgement made by a IOM had several advantages from clinical and RA aspects. Work restrictions may not always be evidence based and it might be difficult to balance rights and duties of patients, employers and OPs; the IOM's wider experience, case discussion with the relevant parties, scientific and technical documentation of diagnostic and FW processes, strengthen the role of the IOM in dealing with difficult cases and as a guarantee from technical and ethical viewpoints.*

Riassunto
«Idoneità lavorative difficili: una esperienza di Medicina del Lavoro in un ospedale clinicizzato». *Il giudizio di idoneità al lavoro specifico (GI) pone significative problematiche professionali al Medico del Lavoro (ML), specialmente in riferimento a certi casi clinici e a determinate situazioni lavorative. Scopo del presente lavoro è presentare e discutere il ruolo di una struttura pubblica di Medicina del Lavoro (IOM) nel GI, attraverso la descrizione di alcuni casi clinici. Il Servizio di Medicina del L avoro degli Spedali Civili di Brescia, convenzionato con l'Università, è l'unico ente pubblico che effettua attività di sorveglianza sanitaria e formulazione di giudizi di idoneità disponibile per i medici del lavoro che operano nel territorio, medici di famiglia, altri specialisti, istituti assicurativi, autorità sanitarie, datori di lavoro e patronati sindacali. Il parere dell'IOM può essere richiesto, a norma di diverse leggi italiane, sia dal medico del lavoro che opera nel territorio, sia dal lavoratore sia dalle aziende. Per ogni caso, vengono effettuati un'anamnesi lavorativa e clinica completa, un esame obiettivo, eventuali esami di laboratorio e strumentali; viene acquisita tutta la pertinente documentazione tecnica e clinica, e possono*

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anche essere richieste consulenze presso altri specialisti. La valutazione del rischio (RA) è condotta attraverso sopralluoghi presso i singoli ambienti di lavoro, nonché attraverso la raccolta di varie informazioni fornite dal datore di lavoro, dai responsabili della prevenzione e protezione delle singole aziende, dai medici del lavoro, dai rappresentanti dei lavoratori per la sicurezza e dalle autorità sanitarie. Ogni caso viene concluso con una relazione sanitaria, che illustra il processo diagnostico e del GI, discutendone le motivazioni ed allegando, quando ritenuto opportuno, appropriati riferimenti bibliografici. Vengono descritti alcuni casi particolari, tra cui: tremori essenziali in uno studente del corso per Igienisti dentali; corioretinite in un saldatore; spasmofilia in una operatrice socioassistenziale; il caso di una sindrome delle apnee ostruttive nel sonno in un lavoratore di acciaieria; un caso di epilessia nel settore metalmeccanico; numerosi casi provenienti dallo stesso ambiente di lavoro (un'azienda metalmeccanica ed un istituto di vigilanza). GI formulati nell'ambito delle attività di un IOM possono portare a numerosi vantaggi, sia sul versante clinico, sia sul versante del RA, sia nella gestione del caso. E' certamente da riconoscere che non è sempre possibile formulare GI basati sull'evidenza ed è spesso difficile conciliare e bilanciare diritti e doveri di datori di lavoro, lavoratori e ML. Tuttavia, è altrettanto necessario sottolineare che la più vasta esperienza sviluppata nell'ambito degli IOM ospedalieri ed universitari, l'accesso a servizi più qualificati, l'abitudine a discutere i casi con tutte le parti in causa, l'approfondimento tecnico e scientifico attraverso varie fonti, la discussione epicritica del processo diagnostico da un alto e della formulazione del GI dall'altro, rafforzano il ruolo degli IOM nel trattare e gestire casi difficili di idoneità al lavoro specifico, coniugando sia il rigore tecnico e scientifico con l'applicabilità pratica, nel rispetto delle linee guida tecniche ed etiche dei professionisti della salute occupazionale.

Introduction

The definition of fitness for specific work (FW) is a fundamental aspect of health surveillance (HS) in workplaces, and is the most important and demanding activity of occupational physicians (OPs).

In individual cases, FW may represent a significant professional challenge to OPs in their daily practice. On the one hand, workers might in fact be exposed to a variety of occupational risk factors (biological, physical, chemical, ergonomic, psychosocial, etc.), and on the other, there are very many important clinical illnesses or conditions which may affect various organs and apparatuses, and which in turn may render the worker more susceptible to various risk factors and interfere with regular working life and activities.

Such clinical cases may often require thorough investigations, in risk assessment (RA) as well as in diagnosis and prognosis, in order to achieve in the first case an in-depth risk profile tailored to each individual worker, and in the second the most accurate and updated clinical diagnosis together with therapeutic options and prognosis.

Moreover, case management and its follow up in a particular working environment can be really difficult for the OP, and several ethical and technical aspects can be especially important, such as respect of workers dignity and professional competence, protection of health and safety of third parties, confidentiality, real applicability of the specific FW judgement in current organizational contexts, relationship and communication with employers and trade unions. Therefore, high professional commitment is often demanded of the OP, who must take into account all the relevant issues before making a judgement of FW.

Sometimes, the single occupational physician practising in a specific situation will not be able to obtain or manage all the relevant data, for a variety of reasons, e.g. from scientific and technical, as well as logistic and organizational standpoints. In such cases, OPs may require expert advice from medical specialists belonging to other branches and/or from occupational health clinics, whose expertise might be required in order to assess FW in specifically difficult cases or complex situations (2, 4, 5).

The aims of this article are to describe a number of particular clinical cases or conditions with spe-

cial reference to the complexity of certain diagnostic procedures and case management; to highlight the role of an occupational health clinic in expressing FW, and to underline the importance of occupational health clinics in cooperating with OPs practising in specific working environments.

Methods

The Institute of Occupational Health (IOM) of the University of Brescia operates at a large regional hospital (Spedali Civili), and serves as the only public occupational health clinic in the Province of Brescia, a highly industrialized area in Northern Italy with agriculture and service sectors also well represented. In general, company occupational health services are run by private OPs, who are often hired by larger structures offering a variety of services in the field of occupational health.

The IOM is a specialized occupational health services, and access to it is available, as an out-patient clinic, to general practitioners, occupational physicians, specialists from other disciplines, insurance companies, local public health authorities, employers; it is also available for referrals requested by medical staff belonging to any general or specialist hospital departments, or for any other body requiring occupational health and safety advice. The IOM may also operate as the corporate occupational health service in very specific working situations (1).

As regards the specific item of FW, workers have access to the IOM in two main ways:

– an Italian law issued in 1970 (L.n. 300/70) enables the worker or the employer to request a public health authority to make a FW assessment in the case of specific job tasks. Such an assessment is charged to the employer and it is regularly performed at an IOM. The employer is required to submit a specific statement where job tasks are described in detail; the assessment is mandatory for the worker. Both employer and employee are then obliged to apply the final judgement expressed by IOM in the workplace;

– the Italian legislative decree n. 626/94 specifically states that only OPs are entitled to express FW judgements, which are mandatory in preventive and periodic HS examinations. The OPs may seek expert advice in order to reach better diagnostic conclusions that can assist them in expressing a FW judgement; such expert opinion is often requested from IOM.

In every case, thorough occupational and clinical histories are taken and physical examinations are performed by trained occupational physicians on the staff of the IOM; laboratory and instrumental tests might be performed, technical and clinical documentation is acquired; expert opinions from other medical specialists belonging to the hospital might also be requested.

Worksite inspections are sometimes needed and information on job tasks and RA is often collected directly from employers, company health and safety representatives, or local health authority; a constant relationship in maintained with company OPs. At the end of the process, a detailed clinical report is issued, including discussion of the process leading to clinical diagnosis and to FW. The full report is sent to the OP, whereas the FW is sent to the company.

Case reports

Case Number 1

A 21 year-old male, right handed, moderate alcoholic and coffee drinker, light smoker, underwent preventive medical examination as a first year training student at the university school for dental hygienists. The clinical history was apparently without note. Physical examination showed intentional tremors, localized in both hands. The clinical history was taken again, and it showed that tremors had been present for a few years and were enhanced under “stress conditions”; his brother was also affected. The patient was referred to the neurologist, whose examination confirmed tremors with clinical characteristics of essential familial tremor. Tremorimetry was performed at the IOM, in order to measure tremor intensity and frequency, which were greater in the left hand. Thyroid function was normal.

Based on legislative profile, the training activities of dental technicians specifically requires execution of various manoeuvres inside the oral cavity of the patient, which are also considered exposure-prone procedures, when biological risk is considered. Workers' hands should therefore be very firm, in order not to cause any harm to the patient or the worker.

The trainee was judged unfit for job tasks entailing fine movement control of the hands and, in particular, unfit to perform manoeuvres inside the oral cavity of the patient. The main problems encountered in this case were the clinical evaluation of hand tremor and its significance as regards specific job tasks; however, the most significant effort was dedicated to convey proper information and counselling to the young technician, especially about his further professional developments. Eventually, the student dropped out.

Case Number 2

A 43 year-old male had worked since the age of 25 at a small firm, mainly as a welder (various types, various levels of quality and precision required), partly as a grinder and shearer of metal parts. At the age of 33, an ophthalmologist diagnosed, through fluoro-angiography, a serous central chorioretinopathy of the left eye. At 38, pigment dispersion was detected, with normal visual acuity using proper lenses. The worker then complained about distortion of images; fluoro-angiography showed, in left eye, a relapse of chorioretinitis, leakage in the parafoveal region, visus 8/10; on the right eye, a few areas of pigment rearranging. After therapy, he then performed yearly eye checks. He presented to the OPs with constant bilateral distortion of images, particularly straight lines, during welding too. Eye check showed mild hypermetropic astigmatism, alteration of Hishihara test, irregular, diffuse non symmetric defects in retinic pigmentation, and pigment mobilization in paramacular (right eye) and macular (left eye) regions, compatible with chronic serous central chorioretinitis. Direct retinic fototoxic effect was excluded on the basis of the site, type and evolution of pigment alterations, fluoro-angiography patterns and symptoms (no central scotoma).

Chronic bilateral serous central chorioretinitis was the OPs final diagnosis. FW judgement considered the worker fit for his work; a detailed prescription of personal protective devices (mask, with automated filter for welding) was issued. Moreover, since the new eye protection could be uncomfortable to wear all the time owing to its weight, a follow-up evaluation of compliance was suggested.

The problems in this case were mainly: evaluation of personal protective devices, which, after thorough assessment of current equipment and a literature search, were judged inadequate and eventually replaced; differential etiological diagnosis, with exclusion of welding fototoxic effects (caused by infrared and ultraviolet radiations); evaluation of worker's susceptibility determined by chorioretinitis, which required assessment of efficacy of protection devices and welding procedures; preservation of worker's skill and competence, with the aim of maintaining the worker at his job in a small firm with no practicable alternative duties.

Case Number 3

A 47 year-old male worked at a steel foundry, in the furnace and ladle furnace areas, over three shifts, including nights. For a few years he had complained of asthenia and diurnal sleepiness, headache. Admission to a pneumology department showed obstructive sleep apnoea (OSA), ptosis of soft palatum, snoring. He then underwent plastic surgery of uvula and palatum, without benefit. Continuous Positive Airway Pressure (CPAP) therapy then begun, with facial mask. In the last few months, symptoms had worsened, with constant sleepiness, difficulties in wearing the mask during diurnal sleep, loss of memory and concentration. He also followed antihypertensive treatment; a 10 Kg weight gain in the last 2 years was also observed. No working accidents were reported. Physical examination showed borderline hypertension, BMI 27.7. All lung function tests were normal. Simple reaction times were remarkably slow. Neurophysiological and pneumological specialist assessment showed OSA, with significant worsening of hypersomnia, mainly during night shifts (Epsworth Scale 16, confirmed by Multiple Sleep

Latency Test), snoring, and asthenia. An incorrect use of CPAP was also documented. The OPs then concluded with the following diagnosis: OSA, with moderate-severe hypersomnia. Hypertension. Advice was given as regards regular and proper use of CPAP, weight loss, circadian rhythm stabilization. FW excluded night shifts and working at the ladle furnace area. The patient was fit to work in the furnace area, since this task was not performed alone, mainly in closed areas with automatic systems, and with no relevant risk of accidents.

The main problems in this FW judgement were to evaluate the risk of accidents, the organization of proper shifts, the possibility of team work, and to increase the worker's compliance with treatment.

Case Number 4

A 49 year-old male, non-smoker, non-drinker, had worked since the age of 39 at a company producing metal parts for furniture, attending, on daily shifts, the semi-automatic shearing machine; he was also supposed to use a forklift. The clinical history showed febrile seizures at the age of 2 and at 16 diagnosis of temporal epilepsy; therapy was continued for 5 years. The patient reported the last generalized seizure at 20 and, after that, 2-3 partial seizures/year, characterized by sensory, motor and autonomic symptoms, occasionally with short absence, with no falls and no particular triggers; he stated that the seizure was always preceded by a sensation of warmth, that allowed him to refrain from activities. At 45, he was admitted to a neurology department and discharged with a diagnosis of "Partial temporal epilepsy. Possible ischemic episode in the area of the left posterior inferior communicating artery." Further assessments showed vertiginous syndrome, atheromatosis of left carotid artery. NMR showed a large stabilized infarct area at left cerebellum, whereas more recent ischemic lesions could be recognized at right cerebellum and frontal cortex levels. Very recently, the patient had complained about diurnal sleepiness; neurological examination was normal, polysomnography showed OSA of mild entity; CPAP therapy then begun. Epilepsy was treated with several drugs, and no further seizures were reported for 1.5 years, when treatment was changed, 3 working accidents were registered at ages 30, 34 and 43, one of which while using a forklift.

The diagnostic conclusion were: partial epilepsy. Multi-infarct encephalopathy. Obstructive sleep apnoea. The worker was fit for work at the shearing machine, but unfit to use forklifts. A prescription to adopt specific barriers and sensors for the shearing machine was issued to the company.

The problems in this case were the evaluation of all the safety features of the shearing machine, danger to third parties, compliance with treatment, time since last seizure, organization of job tasks.

Case Number 5

A 25 year-old female had worked since the age of 16 as a nursing aide at a nursing home, with the task of assisting dependent, non-cooperating patients. For a few years she had complained of severe asthenia, loss of weight, tachycardia, nocturnal cramps, sudden change of mood; she also described 4-5 episodes/month of palpitation, dyspnoea, sweating, paresthesias of face and extremities, general muscle contractions and loss of consciousness for a few minutes. Almost once a week, she reported sudden onset of muscular spasms of extremities and face, hyperventilation, anxiety, followed by intense myalgia and asthenia, forcing her to stay off work for several days. She followed a treatment based on calcium, various saline integrators, and, occasionally, benzodiazepines. She avoided driving, sports and being alone, but maintained social relationships. Electromyography showed a pattern of spasmophilia. Electrolytes and hormonal levels were normal, with the exception of basal cortisole (slightly above normal values). Physical examination was negative. Neurologic referral confirmed absence of neurological findings, but, suspecting a panic disorder, suggested specific pharmacological support and psychotherapy. The psychiatric consultant's report showed slight anxiety, mainly anticipating the spasmophilic fit, and some modifications of personality traits related to the disease; only psychological support was recommended. Apart from absenteeism, no particular problems in assisting patients was reported; pending FW judgement,

she was moved to administrative tasks. The final diagnosis was Anxiety Disorder. Spasmophilia; the patient was judged fit for her specific work, not to be performed alone.

The main problem in this case was the diagnostic process, since spasmophilia is a ill-defined clinical entity, often associated with panic disorders; psychiatric assessment was important in order to evaluate personality, cooperation, thoughts and behaviours, treatment options, and risk of danger to third parties. Furthermore, specific counselling was directed to the problem of absenteeism and coping with patients.

Cases from the same workplace

a) A metal engineering factory producing automotive steering equipment and employing about 300 workers, requested IOM intervention and expert opinion in order to evaluate FW for a number of workers, previously judged unfit for certain job tasks and night shifts as a result of medical assessments that were judged incomplete and difficult to manage by the plant OPs. The main reasons for such re-evaluation were changes in production schedules with more night shifts required. The main activities of these workers were similar and included setting and operating various semiautomatic and automatic machines (torsion bar placing, input shaft buffing, sleeve assembling, pinion machining, etc.), over three 8-hour shifts, including nights, with weekly rotations. Risk assessment showed noise levels ranging from 80-85 dBA, NIOSH index for manual load handling ranging from 0.5 to 1.5, exposure to mineral oils, a mild-moderate risk of injury, organizational problems related to shifts. A worksite inspection was also performed, specific documentation regarding job tasks was obtained as well as clinical records from plant OPs. All together, FW assessment was performed in 10 subjects, aged from 27 to 37, who had been working at the company for several years. The main ailments to deal with were sleeping disorders, headache/migraine, anxiety, depression, eating disorders, tremors, hypertension, vagal syndrome, back and shoulder pain; 8 out of 10 workers were judged fit for their job tasks, including night shifts; one subject with eating disorder was judged unfit for shiftwork in order to be able to comply with psychopharmacological treatment initiated after IOM assessment. One worker was also unfit for shiftwork owing to pharmacological treatment required for anxiety and depression.

Every worker was followed up over the next few months, and their compliance was good.

Overall, the main problems in this peculiar situation were the diagnostic assessments which, for example in cases of headache, eating or sleeping disorders, required careful clinical assessment. Moreover, risk communication and counselling with workers was also delicate, as well as relationships with trade unions.

b) The IOM served as the OPs for a company employing about 250 people performing security services. Activities included money counting, transport of valuables, guarding and protection, inspection and patrol, alarm surveillance, with a high turnover of job tasks. The main risk factors were night- and shiftwork, long working hours, psychosocial factors, assaults, robberies, whole body vibrations, weight lifting, repetitive movements of upper extremities. Workers also had to be fit to carry firearms. Turnover was very high (15-20%/year). Health surveillance enabled us to diagnose many common diseases relevant to FW, such as hypertension, diabetes, coronary heart diseases, arrhythmias, chronic liver and kidney disorders, neuropsychological disorders such as epilepsy, sleeping disorders, anxiety and depression, toxic substance abuse. Overall, about 10% of workers were not fit for their work and were assigned to other duties. Among the diseases identified, a case with delayed sleeping phase should be mentioned, which was diagnosed after a number of neurological assessments and which enabled to a FW assessment to be made requiring only evening and night shifts; also of note are the 2 Berger nephropathy cases, which were discovered only after health surveillance performed by the OPs, who then prescribed specific working schedules in order to cope with regular eating and drug treatment compliance. Five subjects with insulin-dependent diabetes were all treated by excluding early morning and night shifts and prescribing proper schedules and activi-

ties allowing regular eating and drug treatment. Six coronary heart disease cases posed several problems not only from the clinical standpoint, but also as regards the occurrence of high stress circumstances such as assaults, robberies, etc. Each case was judged unfit to work in transport of valuables, patrolling, or safety services for high risk buildings and were assigned to office work, money counting or light caretaking duties.

The main problems to deal with in this workforce were first of a clinical nature because many workers had never undergone a thorough clinical examination and were diagnosed for the first time. In second place were the difficulties in RA which pertained mainly to work organization. In fact, the company was receiving HS activities for the first time; therefore, the first FW round had to change a number of established situations and had to find solutions in order not to penalize either the worker or the company. Meetings were held with employer and workers' representatives; risk communication was an important part of HS, shift schedules rearrangements were discussed. Every worker was finally able to find an appropriate job task.

Discussion

FW is the specific responsibility of the OPs and the final step after RA e HS activities. The process of FW necessarily requires specific competence in several disciplines, such as industrial technology, hygiene, ergonomics, toxicology, epidemiology, psychology, accident prevention, as well as in several clinical branches, such as internal medicine, cardiology, neurology, allergology, etc. The OPs should in fact be able to evaluate all the different perceptive, biomechanical, physical, ergonomic and psychological demands and requirements posed by the workplace and the job tasks for the individual worker, and combine this information with all the relevant clinical data, for both clinical diagnosis and risk assessment. This multidisciplinary competence is the true framework of OPs practice and is the fundamental tool for making FW assessments, which are necessarily on a case-by-case basis, given the ample variability of clinical conditions and RS results (3, 8, 9). The methodological process of FW assessment is then important as it may change in the case of single practitioners or when second level IOM structures are involved. We have reported the particular experience and viewpoints of a public occupational health clinic and we believe that a number of advantages are available when an IOM participates in FW judgement, either requested by the worker, or the OPs, or the company.

First, the clinical role is very important. In fact, such units have wider experience than the single OP practitioner; they also have easy access to other medical and non-medical specialists, whose competence might often be required before a FW judgement can be made (6); such referrals are more effective and efficient when dialogue with OPs is constant, when competence is acquired through evaluation of many single cases and above all, discussed in detail with the OPs; such an approach is currently carried out at the IOM. Moreover, direct access to various resources such as instrumental or laboratory facilities should also be stressed as this can reduce costs and the time allotted to case definition and also be more quality oriented. Finally, the reliability of clinical diagnosis performed at IOM is generally better. Systematic efforts can also be easily conducted to formally acquire all the pertinent documentation regarding risk assessment (e.g. job descriptions and procedures, technical safety data sheets, personal protective device features, industrial hygiene measurements, ergonomic data, clinical records, original X-ray films, etc.) directly from the OPs, the employer or the worker. In some cases, trade unions can be involved.

All these activities contributed to effectively assessing and managing, from a third party stand point, many difficult cases of FW as well as reducing the level of conflicts that arose in such cases, especially when several cases were examined in a short period of time.

FW judgement may entail restrictions and limitations to some job tasks and may significantly affect the skill and capacity of individuals, as well as having consequences for work organization.

It should also be clearly stressed that work restrictions may not always be evidence based and that it might be difficult to balance the rights of

patients and employers, evaluate scientific uncertainties, and comply with duties and obligations of employers, workers and OPs too (6, 7).

However, the IOM second level experience acquired through evaluation of several cases, the habit of discussing every single case with all the relevant parties, the attempt to make a detailed examination of every case from the scientific and technical standpoint, the documentation of diagnostic and FW processes, with appropriate bibliographic references supporting decisions, strengthen the role of IOM in dealing with difficult cases and is a guarantee both from technical and ethical viewpoints.

In conclusion, the experience of the IOM was able to combine scientific principles with practical feasibility, while fully respecting the international code of ethics for occupational health professionals (4).

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Occupational (and non-occupational) risk factors for musculoskeletal disorders

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Key words

Musculoskeletal disorders; occupational diseases; occupational risk; non-occupational risk-factors

Summary

Background: *Musculoskeletal disorders are an important cause of disability and absence from work in industrialized countries. A number of studies reported the importance of occupational, personal and psycho-social factors in the aetiology of these work-related disorders.* **Objectives and Methods:** *To stress the complex relationships existing between risk factors, reporting findings from reviews and original studies regarding two of the most significant musculoskeletal disorders: carpal tunnel syndrome (CTS) and low back pain (LBP).* **Conclusions:** *More detailed epidemiological studies are needed to explore the interactions between risk (and protective) factors, since these can play the role of determinants, confounders or effect modifiers.*

Riassunto

«Fattori di rischio lavorativi (e non) per la patologia muscolo scheletrica». *Le patologie muscoloscheletriche dovute a sovraccarico biomeccanico sono un'importante causa di inabilità e di assenteismo, nei paesi industrializzati. Diversi studi mettono in evidenza l'importanza di fattori di rischio professionali, personali e psicosociali nella genesi di queste malattie correlate al lavoro. Per mostrare la complessità delle relazioni esistenti tra patologie muscoloscheletriche ed i loro fattori di rischio legati al lavoro e non, vengono presentati i risultati di alcune revisioni e di alcuni studi originali, riguardanti mal di schiena e sindrome del tunnel carpale. Risulta necessaria l'esecuzione di studi epidemiologici informativi che esplorino le complesse interazioni tra fattori di rischio (e fattori protettivi), potendo essi rivestire, di volta in volta, il ruolo di determinanti, confondenti o modificatori d'effetto.*

Introduction

Musculoskeletal pathologies due to biomechanical overload play a significant socioeconomic role, as they represent one of the major causes of disability and consequent absence from work in industrialized countries (34). The etiopathogenesis of these disorders is multifactorial and presents aspects which have not been fully clarified and explored. The interaction of different etiopathogenic factors represents the "stress process" affecting the worker's health and working efficiency. It is therefore necessary to identify the possible occupational and non-occupational risk factors (or protective factors), in

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order to evaluate their role and reciprocal interaction in the onset of "Work Related Musculo-Skeletal Disorders" (WRMSDs), so as to accomplish surveillance and preventive measures.

Among musculoskeletal disorders, the most important from a social perspective are probably Carpal Tunnel Syndrome (CTS) and Low Back Pain (LBP) (17, 21). The following examples refer to these two disorders: findings from reviews and original studies are presented, in order to underline the complex relationships existing between their risk factors.

Carpal tunnel syndrome

CTS has a complex and multifactorial etiology, resulting from the interaction of personal/psychosocial factors and occupational factors.

As regards occupational factors, the NIOSH systematic review made in 1997 by Bernard et al. is still considered to be of fundamental importance (1). What emerges from this review is a positive association between CTS and repetitiveness, force and vibrations transmitted to the hand-arm system. In addition, strong evidence of association was observed out between the onset of the disease and simultaneous exposure to different risk factors.

In his review, Malchaire points out how half (12 out of 24) of hand and wrist disorders were associated with occupational risk factors (22). This suggests that, as well as dealing with biomechanical (occupational) factors, personal and psychosocial factors should be also taken into account in order to lower the risk for these disorders (15).

Therefore, CTS may have non-occupational determinants that are sometimes only assumed and should be taken into consideration in epidemiological studies as possible confounders. Among these are age, gender, anthropometric factors, systemic illnesses and familiarity. As regards psychosocial factors, although their association with high job-stress and high job demands has already been pointed out, it is not possible to draw definite conclusions about their role in the etiology of upper extremity disorders, due to the cross-sectional character of most studies (3).

In order to highlight the peculiarity of the relationship between working activity and CTS, the *MODS (Musculoskeletal Occupational Disorders Studies) collaborative group* carried out a wide descriptive multicentre study in seven Italian regions based on the analysis of hospital discharge files and data from the national census (24). To explore the possible influence of housework on CTS incidence, the possible relationships with civil status, age and gender have been also investigated.

The general incidence rate, standardized by age, of hospitalized CTS cases was 106 out of 100.000 subjects/year; in line with previous studies (2, 26), the highest prevalence was found in women, where the rate was 3-4-fold higher compared to males. Notably, the disorder showed a more frequent development among women in the age range 40-49 (11). According to the most reliable hypothesis, the higher prevalence in women could depend on hormonal factors (9, 29). Married subjects show, as compared to their counterparts, significantly higher rates according to age (around 60% in women and 40% in men). In confirmation of the results of the study by Tang et al (32), housekeeping can be included in the list of relevant risk factors.

In a large case-control study recently conducted by the same MODS collaborative group (25), occupational and non-occupational risk factors were considered in order to highlight the peculiarity of the relationship between CTS and working activity.

The results of the study stressed the relevance of manual work, apart from gender and age, in the etiology of CTS and the possible influence of non-occupational factors.

What emerged from our analysis is a correlation between Body Mass Index (BMI) and the development of CTS: obesity (BMI>30) seem to predispose for a more frequent development of such disorder, compared to data from the general population. These results confirm those reported by previous studies (4, 18, 19, 30, 38). A significant, negative association also emerged between height and CTS; the results obtained confirm the findings of two previous studies (6,8) affirming the protective role of height, probably related to the features of forearm, wrist and hand.

As already observed by Stevens and Solomon (29, 31), our study demonstrated a positive association with rheumatoid arthritis and flexor digitorum tenosynovitis, whereas, according to our analysis, wrist fractures, usually reported among risk factors (6, 31), do not seem to have any influence on the development of CTS.

As regards CTS familiarity, the genetic component is considered an important risk factor in the onset of CTS, though the literature reports only few studies investigating this aspect (12, 27). Our results showed a significant association with brothers/sisters who underwent surgery for CTS but not with parents.

The possible outcomes deriving from the interaction between occupational and non-occupational determinants deserve further investigation. It is reasonable to suppose that specifically designed analytical studies will further analyze this problem, taking into account factors like the quantity/kind of domestic activities and family size and composition (28), as well.

Low back pain

Among musculoskeletal disorders due to biomechanical overload, a significant role is played by low back pain, which represents the most common and serious musculoskeletal disorder (23).

About 80% of the general population experience low back pain at least once in a lifetime, 50% of the cases recover within 4-8 weeks, and the relapse trend reaches 85% (14). This disorder is still one of the most significant "non-lethal" health problems; it is indeed the second cause of absence from work and the major cause of disability under age 45 (21).

In the Netherlands, the social cost of low back pain due to occupational, biomechanical and psychosocial risk factors has been estimated at 1,7% of the gross domestic product, and half is due to absence from work (36). In the USA, the annual cost for LBP has been estimated around 100 billion dollars (23). Given the socioeconomic relevance of LBP, increasing importance is being placed on the prevention of occupational risk factors, though without leaving out the non-occupational ones, like age, gender, anthropometric factors, training conditions, smoking, genetic or acquired pathologic conditions and psychosocial factors.

In the relationship between occupational risk factors and LBP, the NIOSH review (1) reports strong evidence of association with Whole Body Vibration (WBV) and other occupational factors like weightlifting, frequent back bending and twisting, forceful exertions and/or wrong posture, which are found to be important in the development of LBP.

As regards psychosocial factors, including low professional satisfaction, workload perception, organizational aspects, social support at work and stress, it is difficult to fully evaluate their association with LBP given the conflicting results reported in the literature. Most recent studies focusing on the possible relationships between psychosocial factors and LBP (10, 15, 33, 35) have produced contradictory results. In a systematic review, Hoogendoorn (16) concluded that "low professional satisfaction is a relevant risk factor for low back pain". Conversely, in a further critical systematic review, Hartvigsen (13) did not find significant evidence of the association between low back pain and occupational stress.

Among personal factors, age and gender seem to play a more relevant role for LBP, e.g. studies conducted on the general population show an increased risk (40-57%) in women (7).

Tobacco smoking, the presence of predisposing diseases and anthropometric factors like height and BMI were also considered relevant. As concerns height, a few studies have reported an increased risk for taller subjects, but most research does not confirm this result; as for BMI, a considerable risk increase is evident for definitely obese subjects (7). As far as tobacco smoking is concerned, it must be specified that if until recently it was considered as a possible risk factor, according to Leboeuf-Yde's review (20) it should be considered as a weak marker of risk rather than as a real causative factor (many factors, if associated with smoking, could actually affect the onset of such disorder: socioeconomic class, lifestyle, etc.).

In 2004, a cross-sectional study was conducted (37), baseline for a perspective study, on 3702

workers of a big chain of super- and hyper-markets. We evaluated the prevalence of low back pain according to its different definitions (acute, recurrent and chronic) and the possible occupational, personal and psychosocial factors. In the 12 months analyzed, general (aspecific) low back pain prevalence in the study population (82% of the subjects participated in the study) was 34,5% (36,6% in women and 30,7% in men). The prevalence of acute, recurrent and chronic LBP was 5,0% (186/3702), 24,7% (913/3702) e 4,8% (177/3702), respectively. The biomechanical risk factor was higher for workers of the "fruit and vegetables" department, due to uninterrupted lifting of crates and boxes (mean weight per crate: 8 kg; maximum weight: 14 kg) and prolonged 30 γ bending. The general lack of significant differences in LBP prevalence among groups with different biomechanical risk levels could be attributed to workers' mobility between different departments.

Data suggest a potential relationship between LBP and stress-related psychosomatic symptoms, with the exception of professional satisfaction (the level of which seems to be high in the study population, probably due to the company's policy).

As regards the distribution of personal factors, significant differences were found for practice of sports, age, BMI and cumulative occupational exposure. Sports activity was found to be protective for both genders, whereas obesity and a long occupational exposure were significant risk factors.

Discussion

Like other research on the determinants of musculoskeletal disorders, the results of these studies demonstrate that the different disorders, in their different manifestations (acute, recurrent and chronic) show independent relationships with a variety of occupational, and non-occupational factors, thus having a different influence each time on the onset of these disorders.

Dealing with Carpal Tunnel Syndrome (CTS), You et al. (39) pointed out that the presence of occupational, personal and psychosocial factors is essential in causing the onset of the disorder; this can also apply to other musculoskeletal disorders. According to You's results, a subject with personal susceptibility to CTS, exposed to a low occupational and psychosocial risk, has a higher probability of developing CTS as compared to a subject exposed to a moderate occupational risk but presenting low personal susceptibility and low psychosocial risk.

There are different hypotheses concerning the possible association between occupational and non-occupational factors, but the lack of methodological homogeneity in the different studies has hampered reaching definite conclusions.

Moreover, most international epidemiological studies are cross-sectional and are limited by the poor population sample considered, by inadequate control of major confounders and by the lack of standard diagnostic criteria; hence the difficulty in establishing causative relationships (5).

This presentation shows that a complex mixture of interactions between occupational and non-occupational risk (or protective factors) is implicated in the onset of musculoskeletal disorders and that, although much has already been done to identify the single factors, much remains to be done to understand their interaction mechanisms.

Hence, more detailed epidemiological studies are needed to explore the interactions between risk (and protective) factors, since they can play the role of determinants, confounders or effect modifiers.

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Health risks from occupational exposures to mechanical vibration

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Key words

Human vibration; health effect; risk assessment

Summary

Health effects of occupational exposure to hand-transmitted vibration (HTV) and whole-body vibration (WBV) are reviewed. Excessive exposure to HTV from powered processes or tools is associated with an increased occurrence of symptoms and signs of disorders in the vascular, neurological and musculoskeletal systems of the upper limbs. This complex set of disorders is called hand-arm vibration syndrome. Long-term occupational exposure to intense WBV is associated with an increased risk for disorders of the lumbar spine and the connected nervous system. With a lower probability, the neck-shoulder, the gastrointestinal system, the female reproductive organs, the peripheral veins, and the cochleo-vestibular system are also assumed to be affected by WBV. However, there is weak epidemiological support for WBV-induced disorders of organ systems other than the lower back. In addition to the health effects of human vibration, this review provides information on methods for the protection and health surveillance of vibration-exposed workers according to the European Directive 2002/44/EC on mechanical vibration.

Riassunto

«I rischi per la salute da esposizione professionale a vibrazioni meccaniche». *In questo studio vengono discussi i sintomi e le patologie derivanti dall'esposizione professionale a vibrazioni trasmesse al sistema mano-braccio (hand-transmitted vibration, HTV) e a vibrazioni trasmesse al corpo intero (whole-body vibration, WBV). Un'intensa e prolungata esposizione a HTV generata da utensili vibranti è associata ad una elevata occorrenza di disturbi e patologie a carico degli apparati vascolare, neurologico e muscolo-scheletrico degli arti superiori, definiti, con termine unitario, sindrome da vibrazione mano-braccio. Un'esposizione prolungata a WBV in conducenti di veicoli pubblici e macchine industriali ed agricole è associata ad una aumentata occorrenza di lombalgie, lombosciatalgie ed alterazioni radiologiche a carico del rachide lombare. Vi è una scarsa evidenza epidemiologica di un aumentato rischio di patologie a carico di altri organi o apparati negli esposti a WBV (es. distretto collo-spalla, apparati gastrointestinale, circolatorio periferico e riproduttivo femminile). Vengono, infine, discussi gli aspetti connessi con la sicurezza e la sorveglianza sanitaria dei lavoratori esposti a vibrazioni meccaniche nel contesto della Direttiva Europea 2002/44/CE.*

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Introduction

Mechanical vibration arises from a wide variety of processes and operations performed in industry, mining and construction, forestry and agriculture, and public utilities.

Hand-transmitted vibration (HTV) occurs when the vibration enters the body through the hands, e.g. in various work processes where rotating or percussive power tools or vibrating workpieces are held by the hands or fingers. Whole-body vibration (WBV) occurs when the human body is supported on a surface which is vibrating, e.g. in all forms of transport and when working near some industrial machinery (7).

Article 2 of the Directive 2002/44/EC of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (vibration), defines "hand-arm vibration" as "*the mechanical vibration that, when transmitted to the human hand-arm system, entails risks to the health and safety of workers, in particular vascular, bone or joint, neurological or muscular disorders*", and "whole-body vibration" as "*the mechanical vibration that, when transmitted to the whole body, entails risks to the health and safety of workers, in particular lower-back morbidity and trauma of the spine*" (5).

According to the 3rd European Survey on Working Conditions (10), about 23.6% of all workers interviewed during the survey reported being exposed to mechanical vibration in the workplaces of the European Union (EU).

In Europe, construction, agriculture, forestry and fishing, public utilities, mining, quarrying and manufacturing, transport, storage and communications, are the sectors with the greatest exposure to vibration from hand tools, machinery, and vehicles.

This paper provides an overview on the evaluation and assessment of vibration exposure at the workplace, as well as on the long-term health effects caused by occupational exposure to HTV and WBV. Protection and health surveillance of vibration-exposed workers are discussed in the context of the Directive 2002/44/EC.

Evaluation and assessment of vibration exposure

The human response to vibration depends mainly on the magnitude, frequency and direction of the vibration signal (7). For practical convenience, the magnitude of vibration is expressed in terms of an average measurement of the acceleration, usually the root mean square value (ms^{-2} r.m.s.). The r.m.s. magnitude is related to the vibration energy and hence the vibration injury potential. The frequency of vibration is expressed in cycles per second and is measured in Hertz (Hz). Biodynamic investigations have shown that the response of the human body to vibration is frequency dependent (7). The adverse health effects of whole-body vibration can occur in the low frequency range from 0.5 to 80 Hz (one-third octaves). For hand-transmitted vibration, frequencies from 6.3 to 1250 Hz (one-third octaves) can provoke disorders in the hand-arm system. Frequencies below about 0.5 Hz can cause motion sickness. To account for these differences in the response of the body to vibration frequency, current standards for human vibration recommend to weight the frequencies of the measured vibration according to the possible deleterious effect associated with each frequency (8, 9). Frequency weightings are required for three orthogonal directions (x-, y- and z-axes) at the interfaces between the body and the vibration, in accordance with international standard ISO 5349-1 for hand-transmitted vibration (9) and ISO 2631-1 for whole-body vibration (8).

According to the European Directive 2002/44/EC (5), daily exposure to hand-transmitted vibration is assessed in terms of 8-h energy-equivalent frequency-weighted vibration total value ($A(8)$ in ms^{-2} r.m.s.), calculated from the magnitude of the vibration total value $[a_{hv}=(a_{hwx}^2+a_{hwy}^2+a_{hwz}^2)]$ and the daily exposure duration (hours). Daily exposure to whole-body vibration is also based on $A(8)$ (ms^{-2} r.m.s.), but calculated from the highest (r.m.s.) value of the frequency-weighted accelerations ($1.4a_{wx}$, $1.4a_{wy}$, or a_{wz}). Moreover, the EU Directive suggests the highest *vibration dose value* (VDV) of the frequency-weighted accelerations as an alternative measurement of WBV exposure

Table 1 - *Daily exposure action values and daily exposure limit values for hand-transmitted vibration (HTV) and whole-body vibration (WBV) according to the European Directive 2002/44/EC on mechanical vibration. A(8) is the daily vibration exposure value normalised to an eight-hour reference period, and VDV is the Vibration Dose Value (see text for definitions)*

	HTV	WBV
Daily exposure action value	A(8)=2.5 ms^{-2} (r.m.s.)	A(8)=0.5 ms^{-2} (r.m.s.) VDV=9.1 $ms^{-1.75}$
Daily exposure limit value	A(8)=5 ms^{-2} (r.m.s.)	A(8)=1.15ms^{-2} (r.m.s.) VDV=21 $ms^{-1.7}$

(1.4VDV_{wx}, 1.4VDV_{wy}, or VDV_{wz}). The VDV is a cumulative dose, based on the fourth power averaging of the acceleration time history (units=$ms^{-1.75}$), and is considered a better indicator of the risks arising from exposures to vibration peaks or shocks.

The EU Directive 2002/44/EC establishes "daily exposure action values" and "daily exposure limit values" for both hand-transmitted vibration and whole-body vibration (table 1). Workers must not be exposed above the exposure limit values. If the exposure action values are exceeded, the employers must implement administrative, technical and medical measures with the aim to protect workers against the risks arising from vibration exposure.

Health effects of vibration on the human body

Hand-transmitted vibration

Excessive exposure to HTV from powered processes or tools is associated with an increased occurrence of symptoms and signs of disorders in the vascular, neurological and musculoskeletal systems of the upper limbs (1, 2, 7). This complex set of disorders is called *hand-arm vibration syndrome*. The vascular and osteo-articular components of the syndrome are included in a European schedule of recognised occupational diseases (4).

Neurological disorders

There is epidemiological evidence for a greater occurrence of digital tingling and numbness, deterioration of finger tactile perception, and loss of manipulative dexterity in occupational groups using vibrating tools than in control groups not exposed to HTV (2, 6).

Neurophysiological studies have suggested that sensory disturbances in the hands of vibration-exposed workers are probly due to vibration-induced impairment of various skin mechanoreceptors (Meissner's corpuscles, Pacinian corpuscles, Merkel cell neurite complexes, Ruffini endings) and their afferent nerve fibres. Electron microscopic studies of human finger biopsy specimens suggest that hand-transmitted vibration can provoke perineural fibrosis, demyelination, axonal degeneration and nerve fibre loss.

The neurological component of the HAV syndrome is currently staged according to the scale proposed at the Stockholm Workshop 86 (11). The sensory-neural (SN) scale consists of three stages (SN1, SN2, SN3) according to the symptoms complained of and the results of clinical examination and objective tests.

Clinical and epidemiological surveys have revealed an increase in sensory-neural disorders with the increase of daily vibration exposure, duration of exposure, or lifetime cumulative vibration dose.

Some epidemiological studies have shown an increased occurrence of signs and symptoms of entrapment neuropathies, mainly carpal tunnel syndrome (CTS), in occupations involving the usage of vibrating tools (6). CTS is also common in job categories whose work tasks involve high-force and repetitive hand-wrist movements (1). The independent contribution of vibration exposure and physical work load (forceful gripping, heavy manual labour, wrist flexion and extension), as well as their interaction, in the etiopathogenesis of CTS

have not yet been established in epidemiological studies of workers who handle vibratory tools. It is likely that ergonomic risk factors play the dominant role in the development of CTS.

Musculoskeletal disorders

Vibration-induced bone and joint disorders are a controversial matter (2, 6, 7). Early radiological investigations had revealed a high prevalence of bone vacuoles and cysts in the hands and wrists of vibration-exposed workers, but more recent studies have shown no significant increase with respect to control groups made up of manual workers. An increased risk for wrist osteo-arthrosis and elbow arthrosis and osteophytosis has been reported in coal miners, road construction workers and metal-working operators exposed to shocks and low frequency vibration (<50 Hz) of high magnitude from percussion tools (pick, riveting and chisel hammers, vibrating compressors). It is thought that, in addition to vibration, joint overload due to heavy physical effort, awkward postures, and other biomechanical factors can account for the higher occurrence of skeletal injuries found in the upper limbs of users of percussion tools.

Workers with prolonged exposure to HTV may complain of muscular weakness, pain in the hands and arms, and diminished muscle force (6, 7). Vibration exposure has also been found to be associated with a reduction of hand-grip strength. In some individuals muscle fatigue can cause disability. Direct mechanical injury or peripheral nerve damage have been suggested as possible etiologic factors for muscle symptoms. Other work-related disorders have been reported in vibration-exposed workers, such as tendinitis and tenosynovitis in the upper limbs, and Dupuytren's contracture, a disease of the fascial tissues of the palm of the hand. These disorders seem to be related to ergonomic stress factors arising from heavy manual work, and the association with HTV is not conclusive.

Vascular disorders (white finger)

Vibration-induced white finger (VWF) is recognised as an occupational disease in many industrialised countries. Epidemiological studies have pointed out that the prevalence of VWF is very wide, from 0-5% in workers using vibrating tools in geographical areas with a warm climate to 80-100% in the past among workers exposed to high vibration magnitudes in northern countries (1, 2, 6, 7).

It is believed that vibration can disturb the digital circulation making it more sensitive to the vasoconstrictive action of cold temperature. Clinically, VWF is characterised by episodes of white fingers caused by spastic closure of the digital arteries. A blue discoloration of the fingers (cyanosis) may follow. The attacks are usually triggered by cold and last from 5 to 30-40 minutes. In the recovery phase, commonly accelerated by warmth or local massage, redness (hyperaemia) may appear in the affected fingers as a result of a reactive increase of blood flow in the cutaneous vessels. In the rare advanced cases, repeated and severe digital vasospastic attacks can lead to trophic changes (ulceration or gangrene) in the skin of the fingertips.

A grading scale for the clinical classification of VWF was proposed at the Stockholm Workshop 86 (11), consisting of four symptomatic stages, from mild (stage 1) to very severe (stage 4). VWF symptoms are staged according to the frequency of finger blanching attacks, the number of affected fingers and the number of affected phalanges in a given finger.

The prognosis of VWF is still uncertain. Studies have reported that VWF may improve, persist or worsen in workers with current or previous exposure to hand-transmitted vibration. It has been suggested that cessation or reduction of vibration exposure may be associated with some reversibility of VWF, but the rate of remission of vasospastic symptoms over time is not well known (2, 6). However, since the late 1970s a decrease in the occurrence of VWF has been reported among active forestry workers in both Europe and Japan after the introduction of anti-vibration chain saws and administrative measures curtailing saw usage time together with endeavours to reduce exposure to other harmful work environment factors (e.g. cold and physical stress). Recovery from VWF has also been reported among retired forestry workers. In

general, there is evidence for a decrease in the occurrence of VWF in the last two decades, at least among occupational groups who started to work with modern vibrating tools.

Whole-body vibration

Long-term occupational exposure to intense WBV is associated with an increased risk for disorders of the lumbar spine and the connected nervous system (1, 3). With a lower probability, the neck-shoulder, the gastrointestinal system, the female reproductive organs, the peripheral veins, and the cochleo-vestibular system are also assumed to be affected by whole-body vibration (6). However, there is weak epidemiological support for vibration-induced disorders of organ systems other than the lower back. In some countries (e.g. Belgium, France, Germany, The Netherlands), (low) back disorders occurring in workers exposed to WBV are, under certain conditions regarding intensity and duration of exposure, considered to be an occupational disease which may be compensated.

Low back disorders and WBV exposure

There is strong epidemiological evidence that occupational exposure to WBV is associated with an increased risk of low back pain, sciatic pain, and degenerative changes in the spinal system, including lumbar intervertebral disc disorders (1, 3, 6). Several epidemiological studies have suggested a trend to increasing risk of low back pain with increasing exposure to WBV (3).

The role of WBV in the etiopathogenesis of low back injuries is not yet fully clarified, as driving motor vehicles involves not only exposure to harmful WBV but also to several ergonomic factors which can affect the spinal system, such as prolonged sitting in a constrained posture, bending forward and frequent twisting of the spine. Moreover, some driving occupations involve heavy lifting and manual handling activities (e.g. delivery truck drivers), which are known to strain the lower part of the back. Individual characteristics (age, anthropometric data, smoking habit, constitutional susceptibility), psychosocial factors, and previous back traumas are also recognised as important predictors for low back pain. Therefore, injuries in the lower back of professional drivers represent a complex of health disorders of multifactorial origin involving both occupational and non-occupational factors (3). As a result, it is hard to separate the contribution of WBV exposure to the onset and the development of low back disorders from that of other individual and ergonomic risk factors.

However, biodynamic and physiological experiments have shown that seated vibration exposure can affect the spine by mechanical overloading and excessive muscular fatigue, supporting the epidemiological findings of a possible causal role of whole-body vibration in the development of (low) back troubles (7). Nevertheless, owing to the cross-sectional design of the majority of the epidemiologicalal studies, this epidemiological evidence is not sufficient to outline a clear exposure-response relationship between WBV exposure and (low) back disorders (3).

Protection and health surveillance of vibration-exposed workers

The prevention of injuries or disorders caused by mechanical vibration at the workplace requires the implementation of administrative, technical and medical procedures.

Administrative measures include adequate information and advice to employers and employees, organisational changes in work, and training to instruct the operators of vibrating machinery to adopt safe and correct work practices. Since continuous exposure to vibration is believed to increase vibration hazard, work schedules should be arranged to include rest periods.

Technical measures include the choice of tools with the lowest vibration and with appropriate ergonomic design. Maintenance conditions of machinery should be periodically checked and personal protective equipment, when available, should be provided for employees exposed to mechanical vibration.

Health surveillance consists of pre-employment medical screening and subsequent clinical exami-

nations of vibration-exposed workers at regular intervals. Medical preventive programmes should be managed by certified occupational health personnel.

In most cases only a combination of administrative, technical and medical actions will lead to an effective prevention of vibration-induced disorders.

According to the EU Directive 2002/44/EC (article 8, para. 1), health surveillance is intended to prevent and rapidly diagnose any disorder linked with exposure to mechanical vibration. Health surveillance is appropriate where: (i) the exposure of workers to vibration is such that a link can be established between that exposure and an identifiable illness or harmful effects on health; (ii) it is probable that the illness or the effects occur in a worker's particular working condition; and (iii) there are tested techniques for the detection of the illness or the harmful effects on health". In any event, workers exposed to vibration exceeding the daily exposure action values (table 1) are entitled to appropriate health surveillance (5).

The aims of health surveillance are to inform the workers of the potential risk associated with vibration exposure, to assess health status, to diagnose vibration-induced disorders at an early stage, and also to check the long-term efficacy of preventive measures. The employers must provide a health-monitoring programme for all workers occupationally exposed to vibration according to the EU legislation and that of the country. Appropriate facilities for health surveillance of the vibration-exposed workers must also be provided by the employers. The management of a health surveillance programme for workers exposed to vibration must be under the supervision of a physician with specialization in occupational medicine or at least with certified training in occupational health. The workers must be informed by the health care staff that their personal and health data are confidentially treated and stored.

Pre-placement medical assessment and periodic clinical examinations at regular intervals must be conducted for each worker who is exposed to mechanical vibration at the workplace. It should be noted that no one symptom or sign is specific of vibration-induced disorders and that the clinical features of the syndrome may be found in several other diseases. As a result, the occupational health physician must consider various clinical and laboratory tests in order to perform a differential diagnosis when the case history and the physical examination suggest the presence of symptoms or signs of vibration-induced disorders.

A pre-placement medical examination must be offered to each worker who is to handle vibrating tools on the job. The main purposes of pre-placement health assessment are to make the worker aware of the hazards connected with exposure to vibrating, to obtain baseline health data for comparison with the findings of subsequent periodical health examinations, and to verify the presence of pathological conditions which may increase the risk of adverse health effects due to vibration exposure. The pre-placement medical evaluation must be performed according to the principles and practice of occupational medicine and must include the case history, a complete physical examination and, if necessary, special diagnostic investigations according to the clinical judgement of the physician.

The pre-placement examination must be followed by periodic health re-assessment at regular intervals. At the periodic medical examination, any change in work practices with vibrating tools must be reported. Moreover, any illness or injury occurring since the last examination, any symptom possibly related to vibration exposure, as well as the findings of the physical examination, must be reported. The reported findings for the individual must be compared with those of previous examinations.

Special diagnostic investigations must be decided by the physician on the basis of the worker's symptoms and the results of the clinical examination. For hand-transmitted vibration, vascular investigations (cold test with measurement of finger skin temperature and/or finger systolic blood pressure), neurological investigations (tactile sensitivity, thermal and vibrotactile perception thresholds, fingertip dexterity, electroneurophysiological testing), muscle strength investigations (pinch and hand grip strength), and radiological investigations of the upper limbs should be considered. For whole-body vibration, special investigations include X-ray

of the lumbar spine, CT-scan, or MRI. However, these radiological procedures are not acceptable in the absence of positive signs and symptoms of spinal disorders.

Avoidance or reduction of vibration exposure for workers affected with disorders caused by HTV or WBV should be decided after considering the severity of symptoms, the characteristics of the entire working process, and other aspects related to the company's medical policy and the legislation of the country. Since there is clinical and epidemiological evidence that some vibration-induced disorders, mainly the vascular component of the hand-arm vibration syndrome, may be reversible when vibration exposure has ceased, the physician shall discuss with the employee the possibility of his/her re-employment in work with vibration exposure if previous symptoms and signs have improved sufficiently according to well-established medical criteria.

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Clinical and diagnostic features of upper extremity work-related musculoskeletal disorders

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Key words

Musculoskeletal disorders; upper extremity; carpal tunnel syndrome; rotary cuff tendinopathy

Summary

Upper extremity work-related musculoskeletal disorders, (UE-WMSDs) are one of the major causes of work-related disability in industrialized countries. Diagnostic criteria for many UE-WMSDs are still under debate, and several different national and international studies have attempted to reach a consensus agreement on the minimum criteria for case definition of UE-WMSDs. This paper describes clinical and diagnostic features of UE-WMSDs, focussing on carpal tunnel syndrome and rotary cuff tendinopathy.

Riassunto

«Criteri clinici e diagnostici nei disturbi musculo-scheletrici dell'arto superiore». *I disturbi muscoloscheletrici dell'arto superiore lavoro-correlati (upper extremity work-related musculoskeletal disorders, UE-WMSDs) costituiscono una delle principali cause di invalidità lavorativa nei Paesi industrializzati. I criteri diagnostici per molti UE-WMSDs sono tuttora oggetto di discussione e diversi studi hanno proposto dei criteri minimi per la definizione dei casi di UE-WMSDs. Questo articolo descrive le caratteristiche cliniche e diagnostiche dei UE-WMSDs, con particolare riferimento alla sindrome del tunnel carpale ed alla tendinopatia della cuffia dei rotatori.*

Introduction

Upper extremity work-related musculoskeletal disorders, (UE-WMSDs), also known as cumulative trauma disorders, repetitive strain injuries, occupational cervico-brachial diseases and occupational overuse syndromes, group diseases, syndromes and disorders of the arms in which work is recognised as a major, although not the only, risk factor (19, 25). Work activities related to UE-WMSDs are characterised by a biomechanical overload in the upper limbs, due to repetitive movements, intense efforts and/or strained posture over long periods of time at work.

Defining the aetiology and pathogenesis of UE-WMSDs is arduous for several reasons:

– there is no gold standard for the diagnosis of most of these conditions and consequently no con-

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sensus on clinical and epidemiological criteria. The many classification systems that have been proposed differ greatly in the disorders they include, the definitions they adopt and the criteria they use to establish that the patient is affected (21);

– it is difficult to estimate the type and extent of exposure to work-related risks;

– unravelling the roles of concomitant causes and confounding factors is a complex task (16). Age, gender, life-style, activity outside work, and concomitant systemic diseases all need to be considered and recent studies have also proposed including psycho-social factors in the analysis (3).

On 27/04/2004 the Italian Ministry of Labour and Welfare recognised micro-trauma and postural strains of the upper limb due to repetitive movements continuing for at least half the work-shift as responsible, with varying degrees of probability, for different UE-WMSDs., which by law must be reported to Health Surveillance Services. Syndromes that are most probably work-related are those linked to biomechanical overload of the shoulder (rotary cuff tendinitis, bicipital tendinitis, calcified tendinitis, and borsitis), elbow (lateral and medial epicondylitis, and olecranon borsitis), wrist and hand (tendinitis of the flexor-extensor muscles, De Quervain's syndrome, "trigger finger", and the carpal tunnel syndrome). Disorders that are less likely to be work-related include ulnar nerve entrapment syndrome in the elbow or the wrist (Guyon's canal syndrome) and triceps tendinitis. Finally the thoracic outlet syndrome except for the vascular form and Dupuytren's disease could possibly have a work-related aetiology.

Diagnostic criteria for UE-WMSDs are influenced by the setting. Sensitive criteria are needed in health surveillance of workers exposed to biomechanical overload of the upper limbs so as to identify the maximum number of subjects with UE-WMSDs. On the other hand, a definitive and, as far as possible accurate, clinical diagnosis with all its legal and therapeutic implications, must rest on highly specific tests or criteria (19).

Several different national and international studies have attempted to arrive at a consensus agreement on the minimum criteria for case definition of UE-WMSDs in epidemiological studies and/or for clinical diagnosis (5, 12, 10, 19) (table 1). Although there is widespread consensus on diagnostic criteria for the rotary cuff syndrome, epicondylitis, De Quervain's disease, the carpal tunnel syndrome and the hand-arm vibration syndrome, agreement is limited on disorders such as radial tunnel syndrome, Guyon's canal syndrome, and thoracic outlet syndrome. Furthermore, disorders of the upper limbs often present with symptoms (pain for example) and signs of chronic processes that are not included in any specific diagnostic category (19).

Table 1 - *A comparison of case definition criteria for some UE-WMSDs*

Anatomical site	Reference (10)	(19)	(12)
Shoulder disorders	**Rotator cuff tendinitis** History of pain in the deltoid region and pain on resisted active movement (abduction – supraspinatus; external rotation – infraspinatus; internal rotation – subscapularis)	**Rotator cuff syndrome** At least intermittent pain in the shoulder region without paraesthesia which is worsened by active elevation of the upper arm for >4 days out of the past 7 days and at least one of the following tests positive: (a) pain on resisted shoulder abduction, external rotation or internal rotation; (b) resisted elbow flexion; or (c) painful arc	**Shoulder tendonitis** Limitation of abduction of the shoulder, painful arc on abduction of the shoulder, shoulder pain, sleep disturbance

(continued)

Table 1 - *continued*

Anatomical site	Reference (10)	(19)	(12)
Elbow disorders	**Lateral epicondylitis** Epicondylar pain and epicondylar tenderness and pain on resisted extension of the wrist **Medial epicondylitis** Epicondylar pain and epicondylar tenderness and pain on resisted flexion of the wrist	**Lateral and medial epicondylitis** At least intermittent, activity dependent pain localised around the lateral or medial epicondyle for >4 days out of the past 7 days and local pain on resisted wrist extension (lateral) or wrist flexion (medial) **Cubital tunnel syndrome** At least intermittent paraesthesia in the 4th and/or 5th digit or the ulnar border of the forearm, wrist or hand for >4 days out of the past 7 days and a positive combined pressure and flexion test	**Lateral epicondylitis** Pain or tenderness or pain on loading relevant muscle at lateral epicondyle
Wrist/hand disorders	**De Quervain's disease** Pain over the radial styloid and tender swelling of the extensor compartment and either pain reproduced by resisted thumb extension or positive Finkelstein test	**Tenosynovitis of the wrist** Pain on movement localised to the tendon sheaths of the wrist and reproduction of pain by resisted active movement **De Quervain's tenosynovitis** Intermittent pain or tenderness localised over the radial side of the wrist, which may radiate proximally to the forearm or distally to the thumb for >4 days out of the past 7 days and at least one of the following tests positive: (a) Finkelstein's test; (b) resisted thumb extension; (c) resisted thumb abduction **Peritendinitis/tenosynovitis of the wrist** Intermittent pain/ache in the ventral or dorsal forearm or wrist region for >4 days out of the past 7 days and provocation of symptoms during resisted movement of the muscles under the symptom area and reproduction of pain during palpation of the affected tendons or palpable crepitus under symptom area or visible swelling of dorsum wrist/forearm	**Tenosynovitis** Pain on movement of tendon or swelling of tendon sheath or triggering/locking/nodule on tendon located in finger flexor or extensor tendon, or thumb flexor, extensor or abductor tendon

(continued)

Table 1 - *continued*

Anatomical site	Reference (10)	(19)	(12)
		Guyon's canal syndrome Intermittent paraesthesia in the palmar ulnar nerve distribution of the hand distal to the wrist or pain in the ulnar innervated area of the hand, which may radiate to the forearm for >4 days out of the past 7 days and at least one of the following test positive: (a) weakness or atrophy in the ulnar innervated intrinsic hand muscles; (b) Tinel's sign; (c) reversed Phalen test; (d) pressure test over the Guyon's canal	
Carpal tunnel syndrome	Pain or paraesthesia or sensory loss in the median nerve distribution and one of Tinel's test positive, Phalen's test positive, nocturnal exacerbation of symptoms, motor loss with wasting of abductor pollicis brevis, abnormal nerve conduction time	Intermittent paraesthesia or pain in at least 2 of digits, I, II, or III which may be present at night as well (allowing pain in the palm, wrist, or radiation proximal to the wrist) for >4 days out of the past 7 days and at least one of the following tests positive: (a) Flexion compression test (b) carpal compression test (c) Tinel's sign; (d) Phalen's sign; (e) 2 point discrimination test; (f) resisted thumb abduction or motor loss with wasting of adbuctor pollicis brevis	Paraesthesia or numbness in median nerve distribution, pain at night, paraesthesia in a peripheral nerve distribution, diminished power related to a peripheral nerve at the wrist

From: (24), modified

Clinical and Diagnostic Features

Symptoms related to UE-WMSDs are often aspecific and perception may be influenced by psycho-social factors. They usually have a gradual onset. In the early stages they often regress when the patient refrains from manual activity. In advanced stage disease they persist even when the patient is at rest. Disease progression is unpredictable and may occur after days, weeks or months of exposure.

In illustrating some clinical and diagnostic features of UE-WMSDs this paper will focus on the carpal tunnel syndrome, the most common nerve entrapment pathology of the upper limbs in the general population and rotary cuff tendinopathy, the most frequent cause of shoulder pain.

Case History

An accurate case-history is essential for diagnosis. In order to assure precise and detailed case history information, data should be collected by means of standard questionnaires investigating:

– family history (e.g. musculoskeletal pathologies and diabetes mellitus);

– personal habits (e.g. sports and hobbies, contraceptive therapy, smoking);

– occupational history (e.g. prolonged strained upper limb postures, highly repetitive movements, marked strength requirement, use of vibrating tools);

– disease history (e.g. fractures of the upper limb bones, diabetes mellitus and other endocrinological disorders).

An accurate case history helps to eliminate many diseases which would otherwise be included in the differential diagnosis of specific UE-WMSDs. Katz et al. (6) proposed a questionnaire to elicit details of pain, numbness, strength and disturbances in the autonomous nervous system of the upper limbs. The questionnaire assesses the localisation, type of onset, duration and irradiation of pain and numbness and any therapy received.

It is also essential to ascertain the pattern of symptoms over time. Consensus documents indicate minimum time criteria for considering a symptom as indicative of a specific UE-WMSD (5, 19).

The *carpal tunnel syndrome (CTS)* is caused by compression of the median nerve inside the carpal tunnel. Characteristic features are sensory changes along the median nerve distribution of the hand, pain, and loss of grip strength with difficulty in performing tasks (e.g. opening bottles). Symptoms usually involve the dominant hand, pain but not numbness irradiates to the forearm and upper arm, symptoms recur intensely during the night and shaking the hand relieves them. Onset is often progressive and symptoms worsen over months or years. In some cases onset is acute due to intense physical labour without training.

Katz et al. (13) proposed a self-administered diagram to investigate the nature and distribution of CTS symptoms. The diagram depicts the back and front of the hand and arm and the patient can indicate the exact location of the disturbances. The results are classified according to correspondence with typical CTS symptom pattern (classic, probable, possible, improbable CTS).

CTS needs to be differentiated from cervical radiculopathy, thoracic outlet syndrome, proximal median nerve compression, lateral epicondylitis and other forearm musculoskeletal disorders.

Pain is the characteristic symptom of several shoulder disorders, including *rotary cuff tendinopathy (RCT)*. In RCT pain is typically felt in the antero-lateral shoulder area and can irradiate to the deltoid area. Pain increases with, and limits, certain movements, e.g. combing hair or putting on a pullover, and is present at night. Concomitant cervical or thoracic pain and pain in the other arm should be assessed.

Previous trauma, hobbies and sports, symptoms in other joints, fever, weight loss, rashes, respiratory symptoms, and current illnesses (diabetes, cancer, respiratory, cardiovascular and gastro-intestinal diseases, and psoriasis) and therapy all need to be documented.

Family history of RCT should be ascertained as susceptibility may have a genetic basis (11).

RCT and other rotary cuff disorders share clinical features with other diseases of the glenohumoural and acromium-clavicular joints, the cervical spine, cancers, and rheumatic polymyalgia, making differential diagnosis difficult. The difficulty is increased by frequent concomitant diseases (17).

Clinical Examination

Should the case history lead to a suspicion of UE-WMSDs, a specific clinical examination should be performed, bearing in mind that two or more UE-WMSDs may be concomitant in any patient and give rise to clinical pictures which are difficult indeed to diagnose and that some clinical information may depend on the patient's cooperation and subjective response. In fact many signs depend upon eliciting a symptom in response to specific manoeuvres or stimuli (the so-called provocative tests).

Even though countless studies have investigated the accuracy of many clinical tests in diagnosing specific arm and shoulder pathologies, gaps in knowledge are still evident and doubts persist about the efficacy of most tests, particularly in the setting of occupational medicine. Several factors are involved:

– subjects recruited to the diverse studies assessing test accuracy often present with disease characteristics that differ from those found in subjects, such as workers undergoing health surveillance, on whom the test will eventually be used;

– diagnostic criteria are not clearly defined;

– information on sensitivity, specificity, positive and negative predictive values, likelihood ratio (LR) and confidence intervals, is insufficient for evaluating the diagnostic accuracy of the tests. In

clinical practice the predictive values and LR are more helpful than sensitivity and specificity. The advantage of LR over predictive values is that it is not influenced by disease prevalence in the cohort undergoing the test. LR expresses the ratio between two probabilities – probability of a given test result in patients with the disease and probability of obtaining the same result in patients without the disease (14).

In *CTS* the clinical examination may show reduced superficial sensation in the hand area innervated by the median nerve. In advanced stage disease, trophism and strength of the abductor pollicis brevis and other thenar muscles may be compromised.

Many tests have been proposed for diagnosing CTS (2) but due to poor sensitivity and specificity some are of limited use. Sensitivity and specificity vary greatly in different studies. In Phalen's test for example they range respectively from 28% to 61% and from 80% to 94%; in Tinel's test sensitivity ranges from 25% to 60% and specificity from 67% to 87% (9).

A review showed that the clinical symptoms and signs most probably associated with electrophysiological signs of CTS are: the classic/probable pattern in the Katz diagram, reduced response to pain in the median nerve innervation area, reduced strength in thumb abduction (7). In a recent study designed to establish a clinical prediction rule for CTS, the highest LR (18.3) was associated with concomitance of the "flick sign" (i.e. shaking hands to relieve symptoms), a wrist-ratio index over 0.67, a score over 1.9 on the "Symptom Severity Scale", hypoesthesia in the median nerve innervation area of the first finger and an age of over 45 years (22).

When *RCT* is suspected, the clinical examination should focus on both shoulders, the neck, the chest and the axilla. trophism, muscle strength, tumefactions, joint crepitus and other signs of inflammation in the shoulder joints as well as shoulder stability and range of motion all need to be assessed. When RCT is present, passive, active and, particularly, resisted, shoulder movements cause pain and are restricted except for passive movement.

Many clinical tests have been proposed for diagnosing RCT and other shoulder UE-WMSDs and each may be positive in several different disorders (8, 18). The best known is the painful arc, i.e., onset of pain during 70°-120° abduction. Although neither highly specific nor sensitive for RCT, a positive result reinforces diagnosis (4).

Overall, present evidence is not solid enough to assume that a positive result of any one clinical test or of two or more combined accurately diagnoses a specific shoulder UE-WMSD (8).

Instrumental tests

Imaging systems such as ultrasound scans or magnetic resonance imaging (MRI) serve to confirm the diagnosis of UE-WMSDs and assess severity. If nerve entrapment is suspected an electrophysiological study is recommended (5).

Ultrasound scanning of the soft tissue in the upper limbs is non-invasive, does not expose the patient to ionising radiation, and is easy to repeat. Unlike other imaging techniques functional assessments are possible. An ultrasound scan of any given area of the upper limbs should always be compared with images of the contra-lateral area. Scans are useful when acute or chronic tensynovitis of the arms is suspected e.g., lateral and medial epicondylitis or finger flexor tendinitis.

Ultrasound studies are becoming more widespread in cases of suspected CTS. Increased cross-sectional area of the median nerve at its entrance into the carpal tunnel is the most specific finding (26). Other signs are: marked median nerve narrowing beneath the flexor retinaculum; reduced echogenicity in the broadened part of the nerve; reduced nerve mobility (23). Because of its costs and limited availability, wrist MRI is rarely used to diagnose CTS. It is indicated when a growth is suspected inside the carpal tunnel or when symptoms persist after carpal tunnel release. Cross sectional areas of the median nerve, flexor tendons, and carpal tunnel, and the palmar bowing of the transverse carpal ligament were found to be greater in subjects with idiopathic CTS (diagnosed by means of nerve conduction studies) than in healthy controls (20).

Many studies have evaluated the validity of ultrasound scanning and MRI in detecting **RCT** and other musculoskeletal shoulder disorders. Sensitivity and specificity vary in the diagnosis of RCT but are considered reliable for full-thickness tear, the diagnostic criteria of which appear better defined (8).

Electrophysiological tests are crucial for diagnosing nerve entrapment in the upper limbs. Besides confirming diagnosis as hypothesized from the case history and the clinical examination, they may provide information on:

– the site of the lesion;

– the type of nerve fibres that are involved (sensory and/or motor), on-going pathological processes (demyelinisation and/or axon loss, re-innervation, acute or chronic nerve damage);

– the severity of nerve damage.

In early stage CTS distal sensory or motor latency is increased and sensory conduction velocity is reduced in the median nerve at the wrist. When CTS is more severe, fasciculation potentials and other signs of denervation are present. The manner and completeness of motor unit recruitment is impaired.

Although electrophysiological studies are considered by most physicians as the gold standard in the diagnosis of CTS, false negatives and false positives do occur (7). A normal nerve conduction time does not exclude nerve compression which may be concomitant with slight nerve conduction slowing or presence of some fast conducting fibres. The American Association of Electrodiagnostic Medicine (1) has drawn up specific guidelines on performing electrophysiological studies in CTS in order to guarantee maximum sensitivity and specificity. In testing median nerve conduction velocity, the short-segment, onset latency-based transcarpal nerve conduction velocity was most sensitive in diagnosing CTS (15).

Conclusions

UE-WMSDs are one of the major causes of work-related disability in industrialized countries and cause marked health and social problems and financial cost (19).

In Italy, the specialist in Occupational Medicine is the only licensed practitioner of Health Surveillance who has been trained in depth to recognise and assess work-related disorders of the hand, arm and shoulder. During Health Surveillance at the workplace he/she frequently encounters the most common UE-WMSDs, which he/she can diagnose clinically, instrumentally or in consultation with other specialists.

As diagnostic criteria are undefined for many UE-WMSDs, specialists in Occupational Medicine should always update their knowledge on consensus criteria. Besides formulating more accurate diagnosis they will be able to establish relationships between disorders, work activities and other risk factors and will be better equipped to judge fitness for work, to propose ergonomic interventions to reduce risk and to fulfil their legal obligations in Health Surveillance.

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Work-related musculoskeletal disorders with reference to the revised occupational diseases list

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Key words

Occupational diseases list; work-related musculoskeletal disorders

Summary

Due to the different compensation schemes, compensated musculoskeletal disorders vary widely between countries. In Italy, following the Constitutional Court Decision no.179/1988, these disorders were treated as "non-listed" diseases and workers must prove their occupational origin by submitting a compensation claim for musculoskeletal disorders to INAIL. The Italian Workers Compensation Agency (INAIL) supplied guidelines for the management of these claims. Recently, a new occupational diseases list has been submitted to the Labour Ministry for approval. This list includes musculoskeletal disorders of the upper limb, back and knee.

Riassunto

«I disturbi muscoloscheletrici lavoro-correlati e la nuova lista delle malattie professionali». *A causa dei diversi sistemi di indennizzo, i disturbi muscoloscheletrici indennizzabili variano molto fra i vari Paesi. In Italia, a seguito della sentenza della Corte Costituzionale No. 179/1988, tali disturbi sono stati considerati malattie "non tabellate", cosicché ai lavoratori spetta l'onere di dimostrarne l'origine professionale mediante presentazione all'INAIL di una domanda di indennizzo per disturbi muscoloscheletrici. L'INAIL ha fornito linee guide per la gestione di tali domande. Recentemente, è stata sottoposta per approvazione al Ministero del Lavoro una nuova lista delle malattie professionali, che comprende i disturbi muscoloscheletrici degli arti superiori, del rachide e del ginocchio.*

Introduction

In Italy, occupational diseases are listed, as required by law (Accident at Work and Occupational Diseases Regulations 1965). The Constitutional Court Decision no. 179/1988 established that any work-related ill-health condition can be compensated if workers can prove the occupational origin of the disease, even if this is not listed as occupational in the annexed tables of the Accident at Work and Occupational Diseases Regulations 1965.

Work related-musculoskeletal disorders are included in most European countries' lists and in the "Information notice on diagnosis of occupational diseases" issued by the European Commission on 19th September 2003. In Italy, these disorders are still considered as "non-listed" diseases.

Data

The incidence of work-related musculoskeletal disorders was examined using the data bank of the Italian Workers Compensation Authority (Technical

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Directorate for Actuarial and Statistical Research).

Data concerned musculoskeletal disorders from 1994 to 2004 and were codified as follows:

386: disorders of intravertebral disks

387: disorders of synovia, tendons and cavities

388: disorders of muscles, ligaments, aponeurosis and soft tissues

388: approximately codifies Carpal Tunnel Syndrome and 387 is used to indicate Tendonitis

Data on occupational diseases were drawn from the Annual Report 2004.

These data show an opposite trend for listed and non-listed disease claims. "Listed disease" claims decreased from about 50000 in 1960, to 10112 in 2000 and 5127 in 2004. "Non-listed" diseases amounted to 15202 in 2000 and 16902 in 2004 (table 1), and currently represent more than 60% of total claims (figures 1 and 2).

Table 1 - *Tavola n. 27. Malattie professionali manifestatesi nel periodo 2000-2004*

Tipo di malattia	2000	2001	2002	2003	2004
Agricoltura					
Malattie tabellate di cui:	295	197	197	2003	2004
26-ipoacusia e sordità	100	81	83	59	54
24-asma bronchiale	87	58	51	54	40
25 alveoliti allergiche	63	29	29	20	13
99 - Malattie non tabellate di cui:	639	729	756	828	808
Ipoacusia	285	218	180	154	144
Tendiniti	23	49	52	94	99
Sindrome del tunnel carpale	29	28	45	67	77
Artrosi	25	31	45	27	48
Bronchite cronica	27	25	20	12	12
Dermatite da contatto	14	13	15	12	12
Indeterminate	10	38	76	80	95
Totale agricoltura	944	967	1029	1068	1030
Industria e servizi					
Malattie tabellate di cui	9817	9512	7630	6094	5032
50-ipoacusia e sordità	5279	4735	3558	2572	2124
42-malattie cutanee	1050	1024	830	657	536
91-asbestosi	629	771	673	512	495
56-neoplasie da asbesto	449	625	659	635	562
90-silicosi	664	568	452	428	312
52-malattie osteoarticolari	358	373	340	264	213
40-asma bronchiale	272	257	190	182	176
43-pneumoconosi da silicati	223	176	131	104	74
99 - Malattie non tabellate di cui	14563	16609	15680	15578	16094
Ipoacusia	6089	5725	3518	3509	3581
Tendiniti	801	1059	1105	1155	1317
Malattie dell'apparato respiratorio	1167	1157	1212	706	607
Sindrome del tunnel carpale	835	890	660	727	864
Tumori	381	458	39	404	422
Indeterminate	379	1002	2086	2002	3208
Totale Industria e Servizi	24759	27123	25396	23644	24334
Totale in complesso	25703	28087	26425	24712	25364

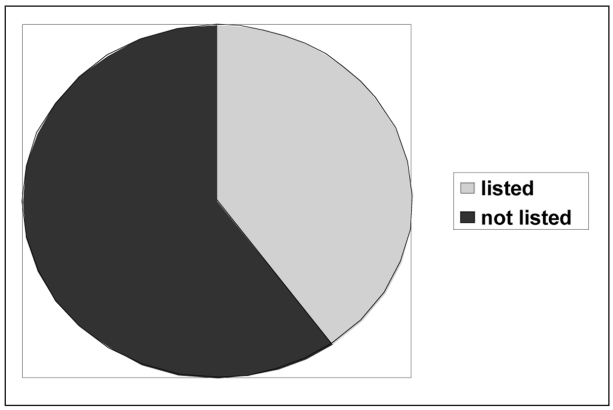

Figure 1 - "Listed" and "not listed" diseases: claims in 2000

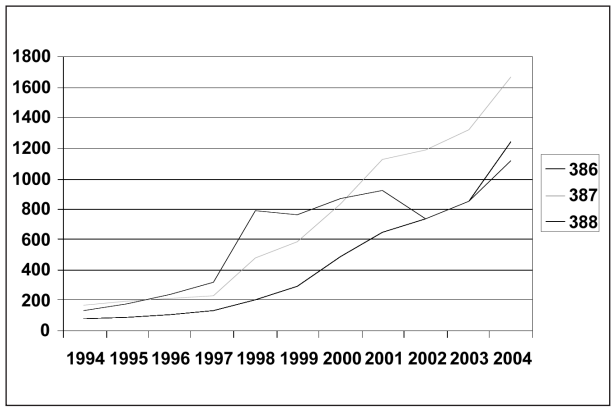

Figure 3 - Musculoskeletal disorders: claims 1994-2004

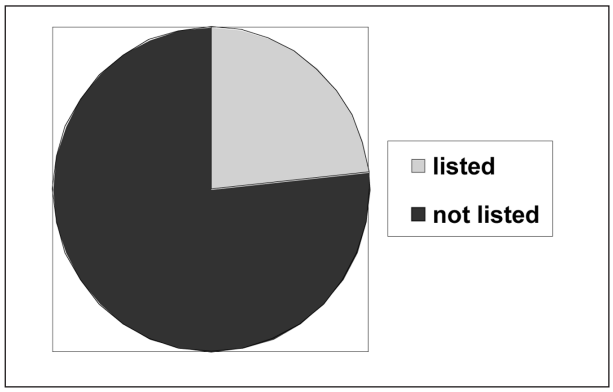

Figure 2 - "Listed" and "not listed" diseases: claims in 2004

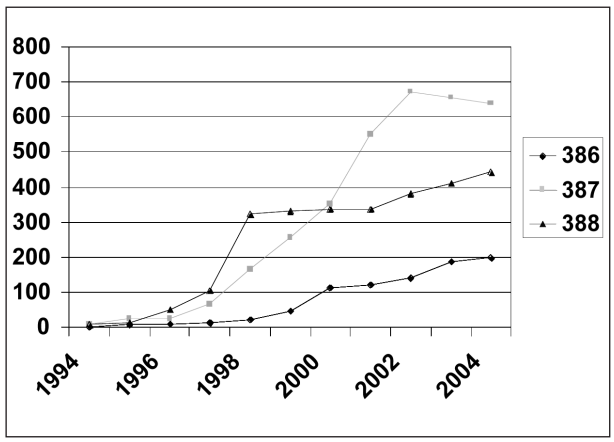

Figure 4 - Musculoskeletal disorders: accepted cases from 1994 to 2004

In the last ten years, a progressive increase in claims for musculoskeletal disorders has occurred with repercussions on the number of accepted cases (figures 3 and 4).

Musculoskeletal disorders of the upper limb and back are the most frequent "non-listed" diseases after noise-induced hearing loss (figure 5).

Between 1994 and 2004, claims increased as follows (figure 3):

– Back Disorders from 81 to 1245

– Tendonitis of different segments of the upper limb from 165 to 1667

– Carpal Tunnel Syndrome from 138 to 1123

The same trend was observed for accepted cases (figure 4); Back Disorders were 4 in 1994 and 199 in 2004; Tendonitis cases were 11 in 1994 and amounted to 639 in 2004; the cases of CTS were 8 in 1994 and amounted to 443 in 2004.

Table 2

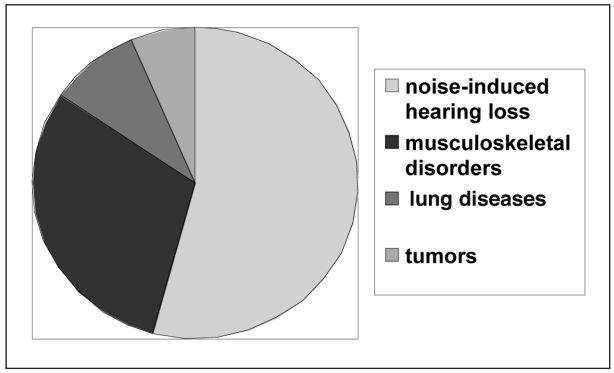

Figure 5 - "Not listed diseases" 2004

According to Eurostat, diseases due to physical agents in the European Union are 70% of occupational diseases, some of the most frequent being wrist and hand tendonitis (table 2) .

Table 2 - *Malattie professionali denunciate e riconosciute dall'INAIL per alcuni codici sanitari e anno di manifestazione. Gestioni: Industria e Servizi, Agricoltura. Dati aggiornati al 31.10.2005*

MP non tabellate	Codice M					
	386		387		388	
Anno di manifestazione	Den.	Ricon.	Den.	Ricon.	Den.	Ricon.
1994	81	4	165	11	138	8
1995	91	7	192	24	179	14
1996	107	11	217	24	243	52
1997	135	14	231	87	325	104
1998	202	21	481	165	787	323
1999	293	48	587	258	763	332
2000	487	113	830	351	870	338
2001	644	123	1127	552	925	338
2002	735	140	1183	874	737	383
2003	855	187	1325	667	853	412
2004	1245	199	1667	639	1123	443

MUSCULOSKELETAL DISORDERS AND THE ITALIAN COMPENSATION SYSTEM

The recognition of work-related musculoskeletal disorders for purposes of insurance was introduced in Italy by Constitutional Court Decisions Nos.179/1988 and 208/1988. However, an increase in claims number was observed only after 1994, when INAIL circular no. 35/1992 supplied the first guidelines for the management of such claims.

With Presidential Decree No. 336/1994, hand-arm vibration syndromes caused by prevalent use of power hand-tools was introduced in the list, whereas "non-listed" diseases were:

– Hand-arm vibration syndrome not due to prevalent use of power hand-tools

– Neurological component of the vibration syndrome without osteoarticular and vascular component

– Whole body vibration disorders

– Repetitive manual work and biomechanical overload disorders

Since 1998, a clinical diagnostic protocol has been in use in different INAIL departments to manage carpal tunnel syndrome claims.

Originally, every relevant musculoskeletal disorder claim was submitted to the Chief Medical Office of INAIL, but the new circulars Nos. 81/2000 and 25/2004 concerning back, upper limb and knee musculoskeletal disorders allowed local offices to decide on claims. In any case, claims have to be processed using the guideline supplied by the two circulars.

These guidelines are based on the analysis of 3000 musculoskeletal disorders cases submitted to the Chief Medical Office of INAIL.

They define both the diagnostic procedures (anamnesis, objective examination and instrumental assessment) and the medico-legal criteria that must be followed to compensate work-related musculoskeletal disorders.

Accordingly, back disorders can be accepted and compensated by INAIL if they are caused by whole body vibrations and manual material handling.

In both cases, the lumbar spine must be the anatomic region involved.

The most common activities involving exposure to whole body vibration risk are connected with driving heavy trucks and earthmoving machinery. The evaluation of exposure is performed according to ISO 2631 – 1: 1997 and Directive 2002/44/EC. An exposure limit of 1,15 m/sec2 for five years is required to judge whether the disease is work-related.

The most common occupations involving manual material handling are:

– Porterage

– Storage

– Health care workers in hospital wards where manual patient handling is required

– Building labourers with prevalent manual material handling

"Revised NIOSH equation for the design and evaluation of manual lifting tasks" (1993) and Snook Ciriello "Liberty Mutual tables for Lifting, Carrying, Pushing, and Pulling" and Mapo index are applied for the assessment of occupational risk.

An exposure duration of over 5 years with NIOSH Risk Index and Snook Ciriello >3 and MAPO Risk Index > 5 is required to judge the disease as work related.

Among the cases examined by the Chief Medical Office, carpal tunnel syndrome covers almost 50% of upper limb disorders and is often associated with wrist, elbow and shoulder tendonitis.

Among upper limb disorders, the circulars deal with tendonitis of the shoulder (supraspinal, biceps tendonitis), Duplay's disease, medial and lateral epicondylitis of elbow and De Quervain's disease.

2-3% of musculoskeletal disorders examined by the Chief Medical Office involved knee bursitis

Recognised risk factors of upper limb disorders are repeated exertions, force, postures, duration of recovery and contact strain, low temperature and vibration.

Circular 81/2000 lists the activities most involved:

– Line installation, assembly, micro-assembly and wiring at pre-established and/or high rates in the engineering and electromechanical industry with or without manual, electric or pneumatic instruments

– Supplying and/or unloading of machines (lathes, cutters, presses) when work pace if fixed and/or fast

– Line manufacturing and packaging at pre-established and/or high rates

– Selection operations at pre-established and/or high rates (for example the ceramic and food industry)

– Smoothing by hand and/or orbital sander in the processing of wood, car bodywork etc

– Plastic products (trimming and burring operations)

– Papering and covering operations in the industrial and handmade setting.

– Textile industry (spinning and warping etc)

– Clothing industry, shirt factories, knitwear industries, jeans industries, hosiery factories, etc (cutting, hand or machine sewing, hemming and other finishing touches, hand or press ironing)

– Footwear and leather industry (cutting, assemblage, sewing, sizing etc. at pre-established and/or high rates)

– Building jobs (floor and covering layers, decorators, plasterers) performed without interruption for most of the work-shift

– Marble, stone, wood and metal manufacture (engraving, cutting, carving etc.)

– Carpentry jobs using tools like hammer and mallet for at least a third of a work-shift

– Meat processing (poultry, pork): slaughtering (skinning, evisceration, boning), sausage-making at pre-established and/or high rates

These two circulars constitute a reference point and guarantee the homogenous management of cases.

THE NEW LIST

On 11 August 2005, the commission of the Accidents at Work and Occupational Diseases (Amendment) Regulations 2000 requested the Ministry of Labour to examine the new list with regard to legislation.

The proposed list includes musculoskeletal disorders of the upper limbs, back and knees, listed under five categories in items 81 to 85. The addition of these disorders is one of the most important changes in the proposed list.

According to available data, these disorders are the most common "non-listed" diseases after occupational hearing loss. Despite their multifactorial origin, the etiologic fraction due to work can be assessed in some particular activities.

Among the 3000 cases processed by INAIL Chief Medical Office from 1998 to 2003, the most frequent conditions were: Lumbar slipped disk, tendonitis of the shoulder (supraspinal, biceps tendonitis), Duplay's disease, shoulder bursitis, medial

and lateral epicondylitis of elbow, olecranon bursitis, De Quervain's disease, carpal tunnel syndrome; knee bursitis, quadriceps femoris tendonitis, meniscopathy.

Each of these conditions is included in the proposed list and associated with ICD 10 code.

In item 81, "lumbar slipped disk" is related to habitual manual material handling without mechanical devices for at least five years, and to whole body vibrations above the daily exposure limit of 0,5m/sec2.

In items 82 to 85 of the Industry List, biomechanical overload disorders of the shoulder (82), elbow (83), wrist and hand (84) and knee (85) are described as caused by activities normally involving repetitive movements, without reference to specific activities.

Musculoskeletal diseases of the upper limb and back due to biomechanical overload must not be considered "occupational diseases", but "work-related diseases", because they are frequent in the general population and cannot therefore be exclusively caused by work.

For this reason, it is important to identify a series of jobs and working conditions for which risk may be reasonably presumed and for which a list system can be adopted.

The use of general terms such as "habitual", "prevalent" or "prolonged" may not be clear and may lead to ambiguous interpretations.

As regard item 81, a certain limit of exposure should be reached (0,5 m/s2) for lumbar disk hernia to be considered induced by vibration. However, this limit is certainly useful for preventive purposes, but it may be misleading if used as a discriminatory value between scheduled and non-scheduled diseases

There are no exposure limits for manual material handling, but a time limit of ten years of activity for vibration and five years for manual material handling is required. This temporal limit does not affect individual susceptibility to risk factors.

Lastly, the same commission that included musculoskeletal disorders of the back due to whole body vibration in the occupational diseases list, includes them in List II - second group of Ministerial Decree of 27 April 2004, which is a list of diseases that cannot be included in the first list taking into account previous scientific evidence.

This is in contrast with the complementary role of the two lists required by law.

Discussion

According to Italian Workers Compensation Agency data, musculoskeletal disorders of the upper limbs and back are the most frequent "non-listed" diseases after noise-induced hearing loss. Claims for recognition of these disorders have gradually increased over the last ten years and consequently their compensation.

This change has been encouraged by a growing awareness of musculoskeletal disorders at the workplace and by the establishment of medico-legal diagnostic criteria by the Workers Compensation Agency.

For this reason, such disorders have been included in the proposed occupational diseases list.

A legal list should include diseases minutely described and carefully evaluated on an individual basis with respect to work. This is because the occupational origin of a listed disease is a legal presumption.

A generic description of activities and exposure and time limit does not ensure an adequate protection of workers.

Subsequent to the Accident at Work and Occupational Diseases (amendment) Regulation 2000, a vicious circle now exists between the list of 27 April 2004 and the Occupational Diseases List.

The Ministerial Decree of 27 April 2004 includes diseases with a possible work-related origin that must be reported by law in accordance with Art. 139 of the Accident at Work and Occupational Diseases Regulation (1965). It also has a specific epidemiological and statistic aim. Cases reported by law are then included in the "National Work Related Diseases Register" with free access to all organisations dealing with health and safety in the workplace.

As required by section 10 of the Accident at Work and Occupational Diseases (Amendment) Regulations 2000, the scientific commission exam-

ines the register to update the Occupational Diseases List as required by law.

Finally, when an ill-health condition has been included in the list it can be more thoroughly verified and prevented thanks to information on risk factors.

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RECENSIONE

Lezioni Magistrali di Medicina del Lavoro dal 68° Congresso Nazionale della Società Italiana di Medicina del Lavoro ed Igiene Industriale (Parma, 5-8 ottobre 2005)

Prodotto da FORMMA (Fondazione Onlus per la Ricerca in Medicina Molecorare Applicata) ed in vendita contrassegno a 100 €, incluse IVA e spese di spedizione, presso Meneghini & Associati, Via Trieste 56[F], Vicenza (tel. 0444/322377 - fax 0444/320321 - e-mail: meeting@meneghinieassociati.it)

Questo maneggevole cofanetto racchiude tre DVD ed un volume con i testi di alcune lezioni magistrali tenute al 68° Congresso Nazionale della Società Italiana di Medicina del Lavoro ed Igiene Industriale, svoltosi a Parma dal 5 all'8 ottobre 2005.

Nel primo DVD sono state raccolte quattro letture magistrali relative al contributo dato dalla Medicina del Lavoro alle conoscenze mediche: anni di ricerche hanno infatti permesso di comprendere i meccanismi patogenetici implicati non solo nell'insorgenza di malattie professionali, ma anche di patologie rilevanti per altre discipline mediche. In particolare, il prof. Pernis illustra il ruolo della risposta immunitaria nella patogenesi della Silicosi e come questi meccanismi patogenetici siano alla base delle più comuni malattie del collageno, quali la Sclerodermia, il Lupus Eritematoso Sistemico e l'Artrite Reumatoide. Il prof. Richeldi descrive la berilliosi come modello per lo studio della sarcoidosi polmonare, dimostrando come queste patologie siano istologicamente molto simili e come siano analoghi i fattori di aumentata suscettibilità individuale. La lezione della prof. Mapp tratta dell'asma professionale indotta da isocianati come modello per capire i meccanismi patogenetici che sono alla base dell'asma ad insorgenza in età adulta, con patogenesi non IgE mediata. Infine, il prof. Costa indica come le conoscenze sul ruolo del polimorfismo di enzimi deputati alla biotrasformazione dei tossici occupazionali abbiano aperto nuove linee di ricerca sulla possibile importanza di tali genotipi anche nelle patologie non occupazionali e molto comuni, come l'aterosclerosi.

Più pratico è il taglio della presentazione del prof. Mutti, che nel secondo DVD illustra le Linee guida sul Monitoraggio Biologico della Società Italiana di Medicina del Lavoro ed Igiene Industriale, con lo scopo dichiarato di orientare il Medico Competente nella scelta degli indicatori biologici più appropriati nell'esercizio della professione. La presentazione illustra i principali fattori da considerare non solo nella scelta dell'indicatore, ma anche nella scelta del momento in cui effettuare il prelievo. Vengono poi illustrati i criteri interpretativi e le filosofie sottese alla definizione di valori di riferimento o valori limite applicabili a livello individuale o di gruppo.

Il terzo DVD contiene le presentazioni della Tavola rotonda sui Criteri per il riconoscimento delle malattie professionali. Il prof. Pira espone i criteri per individuare il nesso causale in presenza di associazioni tra esposizione professionale a fattori di rischio e sviluppo di malattia, integrando criteri epidemiologici con quelli sperimentali. Il prof. Cimaglia definisce i criteri per il riconoscimento e l'indennizzo delle malattie professionali in ambito assicurativo, segnalando la necessità di una tutela privilegiata del rischio lavorativo rispetto alle patologie non lavoro correlate. Il prof. Maroni, infine, riassume le attuali revisioni internazionali nell'ambito della criteriologia per il riconoscimento delle malattie professionali.

Gli argomenti trattati sono ben organizzati ed i contenuti sono esposti chiaramente ed in modo razionale. I suggerimenti dati dagli autori sono rilevanti e le esperienze originali sono frutto di ricerche ben condotte. Ad arricchire il cofanetto, un volume che riassume le presentazioni con appropriate voci bibliografiche e tre questionari a scelta multipla per la valutazione dell'apprendimento. La restituzione dei questionari, debitamente compilati e con una percentuale di risposte esatte pari ad almeno il 70%, darà diritto a n. 5 crediti formativi per ciascuno dei tre questionari. I crediti così ottenuti potranno essere cumulati con quelli relativi agli eventi facoltativi previsti nell'ambito del Programma di accreditamento di eccellenza per Medici del Lavoro.

Complessivamente, questa tempestiva iniziativa editoriale integra bene la pubblicazione degli atti, con la traduzione in italiano dei testi disponibili solo in lingua inglese e con la possibilità di rivivere significativi momenti congressuali, attraverso DVD fruibili sia mediante personal computer che con comuni televisori dotati di lettore.

Un aspetto sicuramente innovativo è appunto la digitalizzazione delle presentazioni, che ne favorisce la diffusione e l'accessibilità. Soprattutto, è un modo per fissare momenti congressuali che sarebbero altrimenti destinati a sfumare nella memoria, consentendo inoltre a chi non sia stato in grado di partecipare al 68° Congresso Nazionale della SIMLII di apprezzarne alcuni dei contenuti più significativi.

L'iniziativa sarà sicuramente utile non solo per l'aggiornamento dei professionisti, ma anche per la formazione dei Medici del Lavoro, grazie ad un equilibrato dosaggio dei contenuti a carattere più accademico e di aspetti pratici, di immediato interesse per l'esercizio della disciplina.

V.F.

NORME PER GLI AUTORI

«LA MEDICINA DEL LAVORO» pubblica lavori originali, rassegne, brevi note e lettere su argomenti di medicina del lavoro e igiene industriale. I contributi non devono essere già stati pubblicati o presentati ad altre riviste. I dattiloscritti, in lingua italiana o inglese, devono essere inviati in duplice copia alla *Redazione de «La Medicina del Lavoro» - Via S. Barnaba, 8 - 20122 Milano*. I lavori saranno sottoposti a revisori; sulla base dei loro giudizi la Redazione si riserva la facoltà di suggerire modificazioni o di respingerli. Gli autori verranno informati delle motivazioni che hanno portato la Redazione a formulare suggerimenti o giudizi negativi. Le opinioni espresse dagli autori non impegnano la responsabilità della Rivista.

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FIGURE – Le figure devono essere numerate in successione con numeri arabi a matita sul retro; le didascalie in entrambe le lingue, italiano ed inglese, devono essere separate dalle figure. *Formato cartaceo*: fotografie, disegni, grafici, diagrammi devono essere inviati in bianco e nero con dimensioni 10x15 cm. *Supporto informatico*: i files devono essere salvati su dischetto o CD formattati PC o MAC. Le immagini vanno salvate come singolo file in formato di 10x15 cm e devono avere una risoluzione di 300 dpi ed essere salvate in formato JPEG con compressione media. I disegni, grafici e diagrammi (tratti in bianco e nero) devono avere una risoluzione di 800 dpi ed essere salvati in formato BMP (bit map) o TIFF. Nel testo la figura deve essere citata per esteso (es.: figura 1). Nel caso che gli autori intendano pubblicare figure o grafici tratti da altre riviste o libri, dovranno previamente ottenere il permesso scritto dall'autore e dalla casa editrice, copia del quale deve essere inviata alla redazione della rivista; nell'articolo gli autori dovranno indicare le fonti da cui il materiale stesso è tratto.

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– Mc Mahon B, Pugh TF: *Epidemiology. Principles and methods.* Boston (MA): Little Brown and Co, 1970
– Fogari R, Orlandi C: Essential hypertension among workers of a metallurgical factory. In Rosenfeld JB, Silverber DS, Viskoper R (eds): *Hypertension control in the community.* London: Libbey J, 1985: 270-273
– Galli DA, Colombi A, Antonini C, Cantoni S: Monitoraggio ambientale e biologico dell'esposizione professionale a pigmenti e coloranti azoici. In Foà V, Antonini C, Galli DA (eds): Atti del convegno *Materie coloranti ed ambiente di lavoro.* Milano, 14-15 marzo 1984. Fidenza: Tipografia Mattioli, 1985: 129-137
– Ranofsky AL: *Surgical operations in short-stay hospitals: United States 1975.* Hyattsville (MA): National Center for Health Statistics, 1978 (DEHW publ no PHS 78-1785; Vital and health statistics, series 13, no 34)
– International Agency for Research on Cancer: *Some chemicals used in plastics and elastomers.* Lyon: IARC, 1986 (IARC monographs on the evaluation of the carcinogenic risk of chemicals to humans no 39)
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