

Chapter 13

Case Study – Italy

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Abstract After the peak of interest in 2001, the threat of bioterrorism is now considered just one of the diverse risks Italy's society faces endangering public health. Without major investments, the effort has been to integrate existing resources, to implement tight links among national and supranational agencies and to make plans for their most efficient involvement in case of need. The mainstay for the response to a biological attack is represented by the public health system, entrusted to Italy's national health service, centrally coordinated but put into action by the Regions. The emerging threat of emerging infectious diseases and of bioterrorism has shown the need for a change in the education curricula of sanitary professions and for specific training of first line operators. Specific courses have been activated by universities and other bodies, but attendance has been limited by the lack of ad hoc funds.

13.1 Background

In the 150 years as a unitary state, Italy has always devoted much attention to its public health, starting with the Crispi-Pagliani law of 1888 which collated the several previous sanitary systems into a single one, centrally controlled and articulated in over 90 provincial medical offices and laboratories, and sanitary officers in the over 8,000 townships, with consistent public health structures in the large cities.

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The fascist regime reordered the system in 1934, and implemented large programmes against tuberculosis and malaria. Several health care systems were activated for various working groups, and were eventually unified into the INAM (*Istituto Nazionale di Assicurazione contro le Malattie* – National Institute for Health Care Insurance).

After the war, with the advent of the Republic, its Constitution, Article 32, stated health to be a fundamental right of the individual and interest of the community [4]. In 1978, the previous health insurance system was abolished and the SSN (*Servizio Sanitario Nazionale* – National Health Service) was established on the model of the British NHS.

Again implementing the Constitution, in 1970 the autonomy of the 20 Regions had been recognized, and since 1980 they were charged with the management of health in their territories, in the frame of national sanitary programmes decided centrally by the health minister, with the assistance of various technical bodies, like the ISS (*Istituto Superiore di Sanità* – Superior Health Institute). Each Region has legislative power to implement the SSN in its territory, and provides health care through a number of hospitals, USL (*Unità Sanitarie Locali* – Local Sanitary Units) or ASL (*Aziende Sanitarie Locali* – Local Sanitary Enterprises). The SSN employs over 600,000 persons, including about 100,000 MDs and 260,000 nurses [24].

Presently the SSN is characterized by universality; it is funded by the general fiscality and it takes care both of clinical and preventive medicine. There are great efficiency gaps between Regions [18], and – although plagued by corruption, cronyism, and nepotism – Italy's SSN ranks among the best, as judged by WHO, and Italy's health profile is above regional and global averages [36].

13.2 Public Health in Italy

ASLs are responsible for the use of allotted resources in all aspects of health care; so they are also in charge of protecting and promoting public health; each has a section or department of preventive medicine that deals with hygiene and public health: epidemiology, health promotion and education, food control, veterinary surveillance, and environment protection.

Other agencies cooperate in the protection of public health, either at the regional level, like the ARPAs (*Agenzie Regionali di Protezione Ambientale* – Regional Environment Protection Agencies) or supra-regional, like the 10 IZPSs (*Istituti Zooprofilattici Sperimentali* – Experimental Zoo Prophylactic Institutes).

13.3 Coping with Emergencies

Perhaps more than other countries, Italy has suffered from a wide range of catastrophes, both natural – earthquakes, eruptions, floods (Polesine 1951; Florence 1966), landslides – and man-induced – wars, industrial disasters (Seveso 1976), railroad explosions (Viareggio 2009), terrorist massacres (Piazza Fontana 1969; Fiumicino

1973, 1985; Bologna 1980), forest fires, and epidemics. Through the centuries, the latter, especially the plague pandemics, have had an essential role in shaping the public health response that has been the basis for Italy's modern public health system, and a model elsewhere in Europe and the world [1, 5]. Of the former, the earlier ones have been met by improvisation; in time, they have driven the establishment of the present system to cope with all kinds of emergencies, mainly based on Civil Defence (*Difesa Civile* – DC), and Civil Protection (*Protezione Civile* – PC).

13.3.1 The Role of the Military

Italy used to have a compulsory military draft; the Army was a vast organization, diffuse across the territory and well structured; for decades it has been the mainstay of the response to all kinds of emergencies, with the obvious limits set by the lack of specific training [20].

In time, military service has become a specialized profession [13]. The Army has reduced its manpower and dismantled many of its territorial structures. Generally speaking, in the event of a disaster the role of the military has become subsidiary to that of the organizations whose mission is the defence and protection of the civilians. However, the specific threat posed by biological agents (and chemical or nuclear weapons) dictates that the military apparatus be ready to face it, so it maintains specialized units for NBC (nuclear, biological, chemical) defence, and a national centre for research and specific training, which is done at the Nubich grounds, near Rieti. The centre runs courses for the personnel of all the armed forces, the national and local police corps, the Italian Red Cross, the firemen, the SSN, and the railway and port authorities. The centre, which participates in international working groups, develops policies, procedures, and guidelines for the integrated response to NBCR emergencies. Although subsidiary, the role of the Army remains essential, on account of its logistics and the capacity to mobilize its manpower, including its specialized medical and engineer corps (Fig. 13.1). One particular unit, the 7th Regiment “Cremona”, is fully dedicated to NBC defence; the regiment has specialized units for the delimitation of the affected area and for the decontamination of people and materials. Regarding the biological hazards, it is equipped with a mobile laboratory capable of molecular detection of biological agents, isolator tents, and ambulances.

A limited capacity for the safe aerial transport of highly contagious patients is guaranteed by the Air Force, with a number of aircraft transit isolators which, along with specially trained and equipped teams, have been used for civilian missions on several occasions.

13.3.2 Civil Defence (DC)

The notion of DC has changed in time and it has given rise to a variety of models. At present, in Italy, DC is conceived as a hierarchy of diverse structures which are

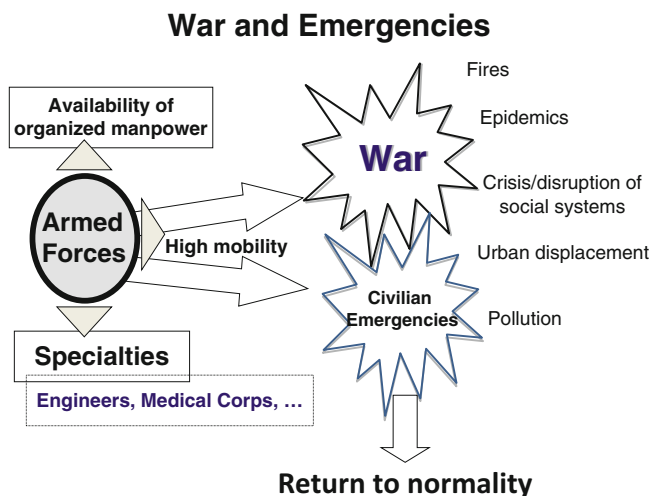


Fig. 13.1 The asset of the armed forces, conceived to face war, remains essential for the integrated response to all kinds of civilian emergencies. (Modified from [19])

coordinated to respond to intentional threats, including bioterrorism, which endanger the population. National (secret) intelligence services, in collaboration with the ones of other countries or organizations, should assess the risks of such threats.

The chain of command for DC has vertex structures at ministerial level, and provincial prefects who coordinate the efforts of municipal entities. Personnel and facilities may be drawn from the SSN, the PC structures, the military apparatus, the Red Cross, and volunteer NGOs. DC can activate emergency operational rooms at various levels and it may emanate and enforce regulations.

13.3.3 Civil Protection (PC)

The Law 225/1992 (24 February 1992) [17] has established a national department, at the highest ministerial level, with the mission to foresee, prevent, and manage extraordinary events that might endanger the population; Italy's PC is not directly aimed to face bioterrorism, but its structures may be called upon by the DC in order to activate an integrated response.

The organization of PC is diffuse on the territory, and it can rely on over 300,000 variously trained volunteers and on all the facilities available to public institutions. PC follows the so called "Augustus method", which formalizes the steps to be taken to the various ends of the mission. In particular, it links the various functions, in order to define the scenarios and to answer the questions "Who does what, where and when?" [10].

13.4 Biological Warfare

The idea that biological agents can be used as weapons dates back to pre-history [32]. In modern times several states have invested a lot for the study and development of biological weapons. There have been international agreements to ban them, which have not deterred some states, notably Japan, to use them, and others, notably the two superpowers, to prepare huge stockpiles of deadly, “weaponized” biological agents.

Italy had adhered to the Geneva Protocol of 1925, prohibiting the use in war of chemical or bacteriological methods of warfare. At the time, and until World War II, some experts were engaged in literature searches on the matter of the potential use of biological agents, and a limited amount of research was done on it. Contrary to a recent libel asserting a heavy involvement of the fascist regime in biological warfare [7], it is proven by documents from the British National Archives that the allies had investigated Italy’s activities in the field and concluded that they were very limited in scope, lightly financed, and naively conducted [3].

Rather than an active actor, Italy appears to have been the victim of an insidious kind of biological warfare, the attack by the Germans to the reclamation system of marshy lands in the Pontine area, with the introduction of salty waters to favour the breeding of *Anopheles labranchiae*. There followed an upsurge of malaria cases, which lasted for years after the end of the war [28].

13.5 Bioterrorism

Worldwide, the concept of bioterrorism is recent, as it only emerged in the 1990s of the past century. A PubMed search for the word finds nothing until 1996, when a paper was published in JAMA [31]. An editorial of 1997 recognized the unpreparedness of society to face bioterrorism, and pleaded for more attention to the threat [35], while the six papers of 1998 stressed its relevance to public health. Figure 13.2 shows how the number of papers on bioterrorism rose at first slowly, and then peaked on account of the anthrax mailings following the Twin Tower attack of 11 September 2001.

In fact, the surge of scientific interest on bioterrorism was an immediate consequence of the new geopolitical asset of the world, with the end of the superpower bipolar influence, which had been based on atomic deterrence. Biological agents were thus considered to be attractive by “rogue states” and by non-governmental groups, on account of their favourable cost/effects ratios, which allowed their economic development as weapons of mass destruction or their use as a frightening means of terrorism, capable, with a modest effort, of disrupting entire societies.

The emerging threat has been amplified by the media coverage, which has indulged in apocalyptic worst case scenarios. This in turn has had paradoxical effects, like the hoarding and subsequent shortage of ciprofloxacin in the entire USA, followed by a rise in the stock values of its manufacturer.

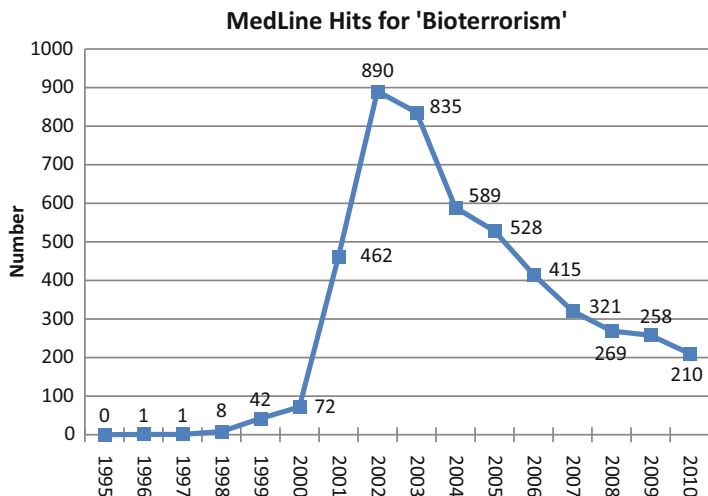


Fig. 13.2 The rise and fall of scientific interest in bioterrorism, as shown by the number of hits in the MedLine database. (Accessed 18 April 2011)

The media storm swept through the world. The anthrax scare hit the headlines and enticed the phenomenon of fake alarms: over a period of a few weeks in Italy alone there were hundreds of such alarms. Measures had to be taken immediately: A task force of experts was set up and a guideline for their management was hastily drawn. In short, the guideline instructed for a minimal and safe handling of suspicious specimens by first line operators; the heat inactivation of the material, and its referral to the national anthrax reference centre at the IZS of Foggia, where in due course the material was analyzed by PCR [8, 9, 11, 12].

Immediately after the peak of the anthrax scare, societies everywhere realized that they were unprepared to face bioterrorism. The more affluent ones allocated enormous amounts of money and implemented programmes for the early warning of biological attacks, for research on selected agents, for educating laymen and professionals, in short, for preparing for the worst. The less affluent ones, like Italy, took advantage of the growing knowledge on the threat and followed as they could.

On the judiciary side, the emergence has brought about an updating of the penal laws against the associations with the scope of terrorism in general (Law of 15 December 2001) [15], while the old penal code, Article 438, states: “Anyone who causes an epidemic through the spread of germs is punished with life imprisonment”, and Article 430 states “Anyone who poisons water or substances intended for food, before they are paid or distributed for consumption, is punished with imprisonment of not less than fifteen years. If the fact is followed by death it is punished with life imprisonment”. There are several other provisions for criminal offences which may occur in bioterrorism activities, and it may be recalled that in Italy all crimes must be prosecuted. Actually, this is the main difference in the response to natural epidemics and the bioterrorism threat.

13.6 Where Do We Currently Stand?

Before the anthrax scare we had to face a series of other biological emergencies, like the HIV pandemic and the Bovine Spongiform Encephalopathy. Each found Italy unprepared, and each had some strengthening effect on Italy's public health system. In particular, there was a renewed interest in infectious diseases (ID), a branch of medicine that had appeared to be superseded by antibiotics. *Ad hoc* investments led to the opening of many ID units, many more MDs embraced the specialty, and there was a flowering of mathematical models of epidemic spread. In general, these emergencies favoured the transfer into the health system of modern communication technologies.

In the last decade the SARS pandemic (2003) demonstrated the value of real time networks and of international collaboration: in a matter of weeks after the isolation of the agent by Carlo Urbani, the virus was fully characterized as a novel Coronavirus and PCR methods allowed for its detection. Italy reacted with health checks of incoming international flights, and guidelines for caring and isolating patients at two selected ID hospitals, located in the cities near Italy's two main airline hubs, where the Spallanzani Hospital (Rome) and the Sacco Hospital (Milan) are equipped with negative pressure isolation rooms, BSL-4 laboratories, and isolator ambulances and stretchers. Both are national reference centres for bio-emergency.

An urgent decree funded the establishment of a national centre for disease prevention and control, CCM, with the mission to prevent and control sanitary emergencies due to bioterrorism or incumbent epidemics [16].

In 2006 there was the first Italian report, in birds, of the highly pathogenic H5N1 influenza virus which had lingered since the 1990s in the Far East and had reached Turkey, East Europe, and Great Britain, with a number of serious human infections. The bird flu led to a stringent veterinary surveillance and to a network of dedicated laboratories. Italy followed the lead of the WHO 2005 pandemic preparedness plan, and adopted its own [25], which dictated that all Regions had to prepare similar plans, coordinating the efforts of the various agencies involved. At the central level, measures were taken as to the purchase of vaccines and antivirals, with *post factum* political controversies.

On the regulatory side, the national committee for biosafety, biotechnology and life sciences, under the patronage of the prime minister office, has drafted a code of conduct for biosafety [26] which stresses the importance of education and of strict adherence to caution in the handling of select agents.

The council of regional health assessors has agreed on a list of diseases deserving extreme surveillance and control, regardless of whether they occur naturally or maliciously. The list includes smallpox, botulism, plague, tularemia, multiple viral hemorrhagic fevers, yellow fever, Marburg virus disease, cholera, and any other quarantinable diseases considered by international authorities.

Other kinds of emergencies, like the garbage disposal crisis of Naples, the Aquila earthquake, the waves of clandestine immigrants and the recent global economic crisis have distracted from the threat of bioterrorism, which is now to be considered

just one of the possible, albeit improbable, catastrophic events, for which the foundation has been laid for an integrated response. The fact that the word “bioterrorism” is not present in the national plan for health [21] nor in the national plan for prevention 2010–2012 [23] attests that it is no longer considered a priority.

13.6.1 Education for Bioterrorism

At the basis of preparedness is knowledge of the risks, first and foremost by MDs. Although some information was routinely taught about specific agents, bioterrorism was not contemplated in the university core curricula and standard textbooks, until editions published after 2002. This means that most of the physicians have had to rely on continuous medical education (CME) for training in this area. Many medical societies have included sessions on bioterrorism (and other biological emergencies) in their national congresses [34]. Some have set up study groups of experts and fostered the establishment of early warning systems and laboratory networks. The CME offer has been consistent, but its fruition has been hampered by the lack of public funding.

Universities have organized updating courses on bioterrorism and biological emergencies and have devoted postgraduate public health theses, PhD curricula, and more structured Master Courses, like the one on NBCR Medicine jointly set up by the Army and the University of Florence (see <http://e-learning.med.unifi.it/didonline/anno-ii/microbiologia/MasterNBC/>) which is now running its sixth edition. This Master Course is forming a highly specialized nucleus of operators, mainly military medical officers, but also public health officers in the various branches of Italy’s SSN. More or less along the same line, there has been an education effort in the area of general disaster relief.

Other agencies, like the military corps of CRI (the Italian Red Cross), the DC and PC organizations, the *Corpo Nazionale dei Vigili del Fuoco* (CNVVF, the national firemen organization), or the “118” national emergency call system, have instructed their first line operators on safety issues, the correct use of equipment, and the basics of emergency interventions.

13.7 Issues About Specific Category A Agents

13.7.1 Anthrax

Natural anthrax has a long history as a public health problem in Italy, where it has been efficiently controlled by the local structures of Italy’s services in the first half of the twentieth century. Extended animal vaccination, careful disposal of affected animals, and stringent veterinary surveillance have almost wiped out the disease from Italy’s herds. Human cases from animal contacts have declined so much that

the basic public health curricula have given less and less attention to it, relegating anthrax to be dealt with in the occupational medicine courses. Still in the 1960s a standard treatise of hygiene [27] gave a full education of anthrax and its control. Sophomore medical students exercised with *Bacillus anthracis* culture, guinea pig inoculation, and post-mortem dissection. Veterinarians on the field could perform the Ascoli reaction to diagnose anthrax in the carrions. And all provincial public health laboratories routinely tested for it, which in the Italian language had always been named *carbonchio*. In time, provincial health laboratories were dismantled, and slowly entire cohorts of MDs were formed who only had a cursory knowledge of *carbonchio*, even less of *antrace*, as the media started to call it. Hospital and territorial laboratories gradually gave up the traditional methods of diagnosis, and when the anthrax letter scares occurred, the best that could be done was to adopt a minimal guideline to safeguard first line officers.

Presently there is reasonable attention to anthrax. Regional and local health care units have done their due diligence on it and emergency and intensive care units should be ready to diagnose and treat even the pulmonary forms. A recent outbreak of natural anthrax has shown a valid integrated response to control it [14]. Small attacks would be faced similarly. False alarms are also less of a problem – one such event recently was barely reported in the local newspapers.

A massive airborne attack is considered very unlikely, but the event would considerably strain Italy's response capacity. Italy has no human vaccine, though it should have no problems with antibiotic procurement, delivery and administration. Italy would be at a loss in regard to the decontamination of large areas, and would have to rely on general plans for disasters to deal with the mass casualties.

13.7.2 *Botulinum Toxin*

Even natural cases of botulism are considered health emergencies, imposing immediate notification, epidemiological investigation, tracing and confiscation of incriminated foods or feeds.

In late 1996, a serious outbreak due to contamination of mascarpone cheese [2] led to centralizing the stock of anti-botulinum immune globulins and to strengthening the surveillance system.

A massive aerosol attack is considered highly improbable. Smaller attempts, like the ones in Japan by the Aum Shinrikyō sect, have been unsuccessful. Attacks to the food chain could easily overcome the treatment capacity of Italy's intensive care units, and would be faced as if they were natural outbreaks.

13.7.3 *Plague*

Italy has faced plague epidemics for centuries, as attested by innumerable works of art, and by historical and literary accounts. The word itself invokes terror, and *Yersinia pestis* is rightly considered in Category A, as an agent deserving priority consideration.

Again, a massive aerosol attack is considered very unlikely, but it would cause mass casualties; very many cases could be treated effectively, hospital facilities would increase to maximum capacity, but there would still be the need for domiciliary quarantine, lazarettos, travel restrictions and the like. Limited attacks, say a number of contagious cases going through airline hubs, should be spotted by international warning networks and ensuing outbreaks be confined and controlled.

13.7.4 *Smallpox*

Universal vaccination had been compulsory in Italy. Suspended in 1977, it was definitely abrogated in 1981, but pediatricians had already discontinued it a number of years before. Perhaps those over 50 years (about half of the total population) [30] have in fact been vaccinated and might have some residual immunity to smallpox.

In 2002, following the third ministerial meeting on health security and bioterrorism, the Minister of Health announced that Italy has a national stockpile of five million doses of the traditional vaccine, that could be diluted to vaccinate twenty-five million persons. He also stated that Italy has no hyper-immune gamma globulins and announced the intention to buy a stock of the antiviral cidofovir [6] for the treatment of about 500 cases [22]. In addition, there was a pledge for an education effort, such that “every emergency room doctor or nurse will be prepared to recognize a smallpox case”.

Clearly we have to rely on the international intelligence cooperation in order to assess the risk of a return of smallpox. The remote idea that it could appear in Italy is appalling, in the light of what happened following its introduction in countries which had been free from it for decades [33], as in Yugoslavia in 1972. In the event that smallpox be reintroduced, the DC and PC structures would be alerted and emergency legislation would be passed to limit civil rights and enforce containment of the epidemic.

13.7.5 *Tularemia*

Tularemia is not enzootic in Italy, but it has been repeatedly introduced with wild game, giving rise to small human outbreaks. Of interest is the one in Tuscany, where cases were due to contamination of small spring water reservoirs.

A serious aerosol attack would be undetected until cases were taken for emergency care and would be correctly diagnosed by hospital laboratories, of which the smaller ones would not attempt culture methods, because of the lack of BSL-3 facilities. Pneumonias would be treated with an empirical antibiotic therapy, and standard isolation could be guaranteed.

13.7.6 Hemorrhagic Viral Fevers

Attention to exotic hemorrhagic viral fevers (HVF) is driven by the fear that they could be imported by the normal travel routes and mass illegal immigration rather than by the threat of bioterrorism. Two hospitals have been earmarked as appropriate to manage them, and are equipped to strictly isolate the patients and to diagnose HVF in BSL-4 laboratories.

13.7.7 Category B Agents

Italy's physicians and veterinarians are knowledgeable about Q fever and brucellosis. Hospitals and laboratories are well equipped for their diagnosis and treatment, and ASLs could perform adequate epidemiological enquiries.

Not so for glanders and melioidosis, the first having long disappeared from the medical core curricula, the second having never been seen in Italy. In the unlikely event of their malicious use, diagnosis of human cases would be delayed, and therapy would be empirical.

Of the biological toxins in Category B, the staphylococcal enterotoxin B is well known for occasional food poisoning outbreaks, which are managed routinely; somewhat less adequately when *C. perfringens* toxin is involved. An attack by aerosol is considered less feasible. In the event, Italy would be unprepared to detect it immediately.

Ricin toxin is more of a problem. The raw material is easily acquired, the toxin may be prepared by an individual or by a small organization, and attempts to prepare it have been discovered in several countries. Dispersal of the powder form, either by mailings or otherwise, would go undetected in the absence of warnings. Cases would be taken to emergency rooms, many of which are linked to poison centres.

13.7.8 Category C Agents

Viruses in this category are not present in Italy, as they are exotic and/or emergent. Cases would be managed by ID specialists, with limited laboratory help for specific diagnosis and no specific therapies. Vaccination for yellow fever is normally offered to travellers, and should be available if needed.

As to the extremely drug-resistant *Mycobacterium tuberculosis* (XDR-TB), there had been a long period of complacency, during which the traditional complex structure for tuberculosis control was dismantled in Italy, although there has been the realization that it is still a problem, as it is reintroduced by immigrants from endemic areas, and standard treatments are often ineffective. Interest in *Mycobacteria* has recently increased, and Italy has a network of reference laboratories which have

implemented modern techniques for identification and drug sensitivity assays. Attention to XDR-TB [29] is high on account of its natural history.

13.7.9 Other Agents

The official lists are not exhaustive of the agents that may be exploited for bioterrorism. Indeed, it would be easier for a malicious layman to get hold of *Amanita phalloides* and to serve it at a banquet than, say, to organize an attack with a *Brucella* or a *Coxiella* organism.

Regarding food and feed safety, the threat can only be faced by a general awareness of the risk. In Italy, the plan for crisis management in the field is the State-Regions Agreement of 24 January 2008, drawn in actuation of European directives, which provides for the establishment, in case of an emergency, of national, regional, and local crisis units. Like several similar regulations, this has a clause stating that no new funds are provided.

13.8 Closing Remarks

The threat of bioterrorism still lingers as a menace to public health and to society in general. Its emergence has had wide-ranging effects on the internal organization of advanced countries, which are now more prepared to face it, and can rely on international collaboration and mutual aid. In Italy, the mainstay for the response to a biological attack is represented by the public health system, entrusted to Italy's national health service. As elsewhere, other more recent biological emergencies have had priority consideration, strengthening the response capacity of public health, and of society in general, particularly in the areas of education, training, and integrated planning.

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