

MEDICAL RESPONSIBILITY, INSURANCE POLICIES, NEW LAWS AND EUROPEAN DIRECTIVES. IS IT TIME TO REFORM THE STATUS OF ITALIAN MEDICAL RESIDENTS?

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ARTICLE INFO

Article history:

Received 26 May 2018

Revised 27 June 2018

Accepted 11 July 2018

Keywords:

medical responsibility, medical residents, no-blame culture, insurance policies, training contract.

ABSTRACT

In Italy there is an ongoing debate on the need to clarify the legal aspects related to the clinical activities of medical residents.

While residents attend university medical schools, specific policies should be implemented to guarantee their proper utilization in health organizations also for the direct and indirect legal responsibilities of patients health and safety.

It seems necessary to create an uniform and clearer legal framework to surmount criticism of the utilization of residents. We recommend Ministries of University and Health to change the current training contract into a job-training one, in line with experiences for residents of other European countries. This initiative could promote a no-blame culture and also help Italian specialist doctors of future generations to be trained in order to move and be competitive across European country borders and finally promote the sustainability of the Italian public NHS through a patient-centred and inter-professional integrated approach.

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1. Commentary

Female In Italy there is an ongoing debate on the need to clarify the legal aspects related to the clinical activities of doctors attending post-graduate academic training courses, namely medical residents.

In fact, both the regulatory system and the jurisprudence available in this field have been subject to different interpretations and related decisions. While residents attend university medical schools, specific policies should be implemented to guarantee their proper utilization in health organizations seeing as how they are, at the same time, fully involved in clinical practice within hospitals, health facilities and services of the National Health System in having direct and indirect legal responsibilities of patients' health and safety.

According to art. 37 of Legislative Decree n. 368/199 and the subsequent changes made [1], the law transposing the European Directives on the topic in the Italian context [2], medical residents are temporarily hired

under a specific training contract, adopted nationally on July 7, 2007 through a Decree enacted by the Council of Ministries, jointly signed by the legal representatives of universities and health regional authorities. According to the law, the contract clearly states that training is aimed at acquiring knowledge, skills and competency required to practice as a specialist in Europe. Also, hospitals and health services are in charge of guaranteeing full insurance coverage to trainee doctors under the same conditions as provided to consultants. This is important for two reasons: first of all, because it does represent, comparing the legal status of Italian trainees to other countries, a unique case in which the first years of insurance do not need a payment made upfront by the young doctor; and secondly, the impact of the recent Italian law No 24/2017. Article 10 of this provision, agreeing with what has been said in some sentences (e.g. Sentence n. 6614 - 12.14.2015 of 5th Penal Section of Palermo Court), states that "Public, private health and social health care facilities must be provided with insurance coverage or similar measures for third party and workers liability, also for damages caused by personnel in any capacity

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DOI: 10.3269/1970-5492.2018.13.21

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operating in public or private health or social health facilities, including those involved in training, updating, experimentation and clinical research” [3]. On the other hand, it is stated that some Italian regions, in recent years, have canceled or not renewed insurance policies for the protection of employee structured staff, by paying the sums for the stipulation of policies in order to create a compensation fund for public liability to be used in the event of a claim. Other regions, however, have unloaded this task to local health authorities, having to put money aside in the budget with the expectation of having coverage of damages caused to patients. This transfer of power has, in fact, bypassed the Article 41 of Legislative Decree No 368/1999.

Current legislation and contracts signed by Italian medical residents and doctors in training also stress the idea that residents cannot replace the specialist consultant under any circumstances while they are being supported within a tutorship to traineeship relationship and that insurance coverage is guaranteed to the doctors in training. Article 41 of Legislative Decree No 368/1999 states that “ Local Health Authority, in which the medical resident carries out the training activity, provides insurance coverage for occupational risk, for third party liability, for work accidents, and all under the same conditions as their own medical staff” [4].

If, on one hand, the role of university hospitals or teaching hospitals, which have been part of residency school networks since 2017 [5-6], was conceived to train residents, then on the other hand, the post-graduate doctors in training are increasingly considered a useful and low cost replacement for other health professionals or, in some cases, for the fully trained medical personnel, so reducing their time to focus in depth on improvement of their skills and general learning curve.

As a consequence of the recalled criticism, several jurisprudential cases have been raised against doctors in training and their not so well defined status exposed them to medical responsibility in legal disputes. Particularly, residents have been convicted for medical responsibility, unskillfulness and negligence in situations where they were accused of failure to reduce risk and, sometimes, also for refusing to complete the task [7-8]. Speaking to the issue, a sentence on 24/11/1999 n. 5311 of the penal section of the Italian Supreme Court has stated that, in consideration of the medical degree and the ability to practice, the trainee has the duty of preserving patients’ health, thus, ignoring the ontological limits which apply to a category composed of doctors in training. In another case, a resident was convicted as part of a guilty medical equip (18/05/2005 n.18568 of the Court of Cassation, criminal division) [9]. As a matter of fact, the Supreme Court has denied the existence of a clear regulation on the status and the role of a doctor in training.

As a matter of fact, the European Union only states general principles regarding the issue, so there’s no unanimous legislations and each Country has its own jurisprudence.

In various instances, the Court of Cassation explained that even if the trainee just acts under the guide of the tutor, they are obliged to manage, to the limits of their competency, and eventually contest and even refuse to apply the medical decisions made by the fully trained doctor if they are considered wrong or dangerous for the patient. This ambiguous role has to be enacted, of course, with respect to the principle of “gradual responsibility” ruled by the law and jurisprudence [01/08/2008 n.32424 of the Court of Cassation, IV penal section]. As a matter of fact, the true meaning of the actual legislation is the relationship, perhaps frequently used by law, within the “autonomy bound”: the autonomy of the trainee doctor cannot be underestimated, because it comes from people that have already earned a medical degree (albeit still in their training years) especially for those disciplines that require high level knowledge, their

activity is contained in very strict margins and in every moment double - checked by their tutor.

The actual Italian legislation states that if a trainee doctor, with their current capacity recognizes that a specific matter is too difficult or presents too many risks, can refuse to take care of that case considering that every mistake is surely prosecutable by law.

That being said, trainee doctors have to be, as recent years have shown, fully aware of the many risks of being in control of a patient, even under tutor surveillance, because legislation about self – responsibility is actually pretty severe. Speaking of that, for every criminal responsibility the trainee doctor is obliged to answer just for himself, like every other worker. Criminal accountability is fully personal and the legal judgement about working mistakes is based on very precise parameters of evaluation, including the aforementioned: unskillfulness, imprudence, working negligence and also the wrong usage of laws, regulations, specific orders or common prescriptions and disciplines that are recommended in each case. Generally speaking, though, the most recent studies show that, when unfortunate mistakes are made by trainee doctors, they are no different above the average line compared to the ones made by other hospital workers, even if fully trained or experienced.

This diversified jurisprudence has not been easy to live up to even for the Italian judiciary system, as the number of lawsuits against trainee and fully trained doctors has significantly increased in the last few years, especially when regarding protocol – related questions and guard duty behaviors, often leading to court battles that can last up to five years and can leave hospitals depleted of their personnel until concluded. Recent norms, especially the ones regarding the professional responsibility of doctors on duty approved by the Italian Senate on January 28th, 2016, aim to put a stop to unnecessary lawsuits against doctors and trainee doctors, but it is clear that much more needs to be done in order to make way for a new legislation.

In this scenario perhaps it seems unreasonable that, while not taking any action in order to make a clear path for the numerous responsibilities that the trainees must take care of, opening the door for the above – said lawsuits, legislators in Italy have largely clarified laws regarding potential autonomous work, which is not allowed under any circumstances. Trainee doctors are only allowed to enter their name in specific registries in order to substitute general practitioners within the primary care setting, but they absolutely cannot practice any other medical activity and, if they do so, they are immediately prosecutable by law.

These are all cases in which a clearer contract could have been fundamental to preserve the residents from any medical responsibility not related to their status, but, to date, it seems to be inappropriate or, mostly, improvable. Legislation in this field could easily apply directly to the contract, improving the general understanding of medical responsibilities by the trainee and preventing lawsuits against hospitals and their personnel, which sometimes is already lacking even at full potential.

In conclusion, it seems necessary for the legislator to create a uniform and clearer legal framework to override the previously described criticism of the utilization of residents.

We strongly recommend Ministries of University and Health to evaluate the change of the evolution of the current training contract into a job-training one, in line with experiences documented for residents of other European countries.

This initiative could promote a no-blame culture where, to cooperate and act in a safe and, above all, legitimate way, could be considered the first step in the creation of a brand new uniform regulation able to guarantee

the transition of a new medical environment in which trainees will improve their medical knowledge and skills.

These will also help Italian specialist doctors of future generations to be trained in order to move and be competitive across European country borders [10] as well as to face the new challenges of implementing genomic technologies in healthcare [11] and to promote the sustainability of the Italian public NHS through a patient-centred and inter-professional integrated approach [12-13] by spreading a *value and population-based* healthcare [14].

References

1. Implementation of Directive 93/16/EEC on free movement of doctors and mutual recognition of diplomas, certificates and other qualifications; and Directives 97/50/EC, 98/21/EC, 98/63/EC and 99/46/EC amending Directive 93/16/EEC. Legislative Decree, No 368 (Aug 17, 1999) [cited 2018 Feb 28]. Available from: <http://www.normattiva.it>.
2. Directive 2013/55/EU of the European Parliament and of the Council amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation'). (Nov 20, 2013) [cited 2018 Apr 28]. Available from: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32013L0055>.
3. Article 10 of Law No 24 of 8 March 2017, Provisions on safety healthcare and patient-safety healthcare and on healthcare professional liability (Mar 8, 2017). Available from: <http://www.gazzettaufficiale.it/eli/id/2017/03/17/17G00041/sg>.
4. Article 41 of Legislative Decree No 368/1999, Implementation of Directive 93/16/EEC on free movement of doctors and mutual recognition of diplomas, certificates and other qualifications (Aug 17, 1999). Available from: http://www.gazzettaufficiale.it/do/atto/vediListaRettifica?dataPubblicaazione=2000-02-23&codiceRedazionale=000A2006&tipoSerie=serie_generale&tipovigenza=originario&tiporettifica=rettificante.
5. Ministerial Decree No 68/2015, Reorganization of Medical post-graduate Schools (Feb 4, 2015). Available from: http://www.gazzettaufficiale.it/eli/id/2015/06/03/15A04227/sg;jsessionid=1rPtro-x-E0wndetKdeYqw__.ntc-as4-guri2a.
6. Ministerial Decree No 402/2017, Standards, requirements and indicators of training and care activities of Healthcare post-graduate Schools (Jun 13, 2017). Available from: <http://www.gazzettaufficiale.it/eli/id/2017/07/14/17A04639/sg>.
7. Ventura Spagnolo E, Mondello C, Cardia L, Ventura Spagnolo O, Bartoloni G. Odontogenic abscess complicated by descending necrotizing mediastinitis: Evidence of medical and dental malpractice. *Minerva Stomatol*. 2016 Dec; 65(6):412-415.
8. Ventura Spagnolo E., Mondello C., Indorato F., Cardia L., Raffino C., Cardia G., Bartoloni G. An unusual fatal case of overdose of Vinblastine and review of literature. *Australian Journal of Forensic Sciences* 2017 Nov; 49 (6): 704-710.
9. Sentence No 18568 of Court of Cassation, IV criminal division (May 18, 2005). Profiles of criminal liability in team medical activity.
10. Costantino C, Maringhini G, Albegiani V, Monte C, Lo Cascio N, Mazzucco W. Perceived need for an international elective experience among Italian medical residents. *EuroMediterranean Biomedical Journal* 2013, 8(3):10-15.
11. Ianuale C, Leoncini E, Mazzucco W, Marzuillo C, Villari P, Ricciardi W, et al. Public Health Genomics education in post-graduate schools of hygiene and preventive medicine: A cross-sectional survey. *BMC Medical Education* Volume 14, Issue 1, 10 October 2014, Article number 213.
12. Mazzucco W, Ricciardi W, Boccia S. Addressing the gap between genetics knowledge and clinical practice: A pilot study to implement genetics education among physicians in Italy. *Italian Journal of Public Health* Volume 9, Issue 4, 1 January 2012, Pages e8673.1-e8673.3.
13. Michelazzo MB, Pastorino R, Mazzucco W, Boccia S. Distance learning training in genetics and genomics testing for Italian health professionals: Results of a pre and post-test evaluation. *Epidemiology Biostatistics and Public Health Open Access* Volume 12, Issue 3, 22 September 2015, Article number e11516, 6p.
14. Frenk J, Chen L, Bhutta ZA, Bhutta ZA, Cohen J, Crisp N, Evans T et al. Health professionals for a new century: transforming education to strengthen health systems in an interdependent world. *Lancet* 2010. Published online Nov 29. DOI:10.1016/S0140-6736(10)61854-5.