

Romania plans changes to clinical trials system

Doctors in Romania are up in arms about draft government legislation that would see their payments for undertaking clinical trials in the country severely cut. Ed Holt reports.

Romanian doctors have warned new legislation being drawn up by the government could spell an end to clinical trials in the country.

The health ministry is drafting a bill which would change the current system of clinical studies under which, it claims, money for the studies goes exclusively to doctors while the hospital expenses of patients in the studies are covered by the state.

But doctors say that such a change will leave highly qualified specialists with little incentive to do clinical research. Ovidiu Bedreag, who works at one of the largest hospitals in the country, the County Emergency Hospital in Timisoara, told *The Lancet*: "It is completely wrong for the health ministry to take aim at whatever money the doctors who run clinical trials get. It will only kill what clinical trials there are in Romania since no doctor would accept working so hard—and clinical trials are hard work—and not get paid reasonably."

"We doctors work for small salaries and wages from clinical studies only make our earnings decent."

The Romanian health ministry says that the dispersion of funds for trials at stages where patients are hospitalised is unfair and that state hospitals—where the trials are done treat patients at their own cost and receive nothing from the companies funding the research.

The Romanian health-care system is on the brink of collapse as it struggles with mountainous hospital debt, striking workers, a brain drain of doctors and nurses, and underfunding by the state. State spending on health care has already been comparatively low for years and in 2009 was 3% of gross domestic product (GDP). The western European average is about 8% of GDP. Almost all hospitals are deeply

in debt with official figures showing total hospital debt to drug and medical equipment suppliers running into hundreds of millions of Euros.

There are also severe staff problems. Hospital staff say expensive high-tech equipment is being left to rust in storage rooms because specialists have moved abroad for salaries at least ten times those at home. According to the Romanian College of Physicians almost 10% of all doctors have emigrated since 2007.

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Doctors warn that the new legislation on clinical trials will only fuel discontent among medics already despondent at salaries of as little as €200 per month in some cases—less than the national average of €350. But just as importantly, doctors working in clinical trials argue, the draft legislation would also rob some patients of the opportunity to receive potentially life-saving treatment, which they could never get as part of normal state health care.

Sorin Paveliu, who runs a health-care facility in Bucharest specialising in clinical trials, told *The Lancet*: "Being a doctor in Romania is very traumatic because sometimes you look at a patient, you know how sick he is, but you cannot do anything for him. I see patients in trials being offered a second chance."

"In state health care a patient only gets 3 to 4 minutes with a doctor every 9 months. But if they are in a clinical trial they get 2 hours every 2 weeks with a doctor and are treated like a VIP, or rather, like any other normal patient in New York or Paris. Cutting a doctor's

pay [for clinical studies] is a crime since it would kill off clinical studies."

The exact details of the legislative changes being planned are unclear. The draft legislation is being kept under close wraps by the health ministry and when contacted by *The Lancet* the ministry declined to answer any questions on the bill. One idea which was floated already last year was a stipulation that all clinics doing clinical research would have to have an emergency ward—a condition doctors said would effectively liquidate smaller clinics involved in research.

But health minister Cseke Attila told local media: "We'll draft a bill this year because it's not fair that money for these clinical tests goes exclusively to doctors while the hospital expenses of patients in the studies are paid by the health ministry or local authorities."

This is hotly disputed by doctors involved in research. They say that 20% of the value of a contract for a clinical trial signed between a hospital and, for instance, a drug company goes to the hospital and a further 40% is paid in tax to the state. The remainder goes to the doctor running the trial.

According to the European Medicines Agency 240 clinical trials took place in Romania in 2010. "Hospitals benefit significantly from these trials", said Bedreag. "We get good equipment delivered by the pharmaceutical companies, doctors are kept up to date with the latest research in their fields and they get to interact with foreign colleagues and learn from them."

He added: "In fact, the whole debate should not be about how to cut doctors' earnings but on how to encourage bringing more clinical trials to Romania."

Ed Holt