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Experimental phage therapy in humans as seen from a medical, legal, and administrative perspective

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According to Polish law, phage therapy is considered an experimental treatment which is carried out on the basis of the respective legislation (pharmacological law, regulations of the Minister of Health). Experimental treatment occurs when a physician introduces new or only partially tested diagnostic, therapeutic, or prophylactic methods for the direct benefit of the person being treated. In contrast, an investigational experiment has the primary purpose of broadening medical knowledge (and is tantamount to clinical research). To satisfy the existing requirements, two basic items are prerequisites for experimental therapy: a) the written informed consent of the patient and b) approval by an institutional review board (bioethics commission). In addition, the patients, staff, and institution are covered by a health insurance company. Furthermore, the treatment may be implemented only by a qualified doctor and when available treatment has failed (arts. 29/1, 21/2, and 21/3 of the law on the physician’s profession). Hence our current phage therapy program involves cases in which prior antibiotic treatment did not lead to the eradication of infection. In the fall of 2005 we opened at our Institute a phage therapy center, an outpatient clinic which accepts patients from the whole country and is also open to qualified patients from abroad. According to the Polish regulations, expenses related to experimental therapy cannot be reimbursed by the national healthcare insurance, so the patients (and referring hospitals) are expected to cover the costs of phage therapy (which are only a fraction of the actual costs of antibiotics treatment). All patients undergo a careful medical examination including laboratory tests (and other diagnostic tests, if necessary). In addition, patients are monitored for the effects of phages on immune parameters. The standard phage treatment usually lasts for three weeks, and the patients are seen after the first week of therapy and thereafter. Our therapeutic approach fulfills current requirements of patient protection and enables the generation of valuable data which could throw more light on the value of phage therapy in various clinical settings.