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Workshop Report

Methodological developments in nucleic acid diagnosis II*

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Introduction

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Introduction

Timely diagnosis of infectious diseases depends on early and accurate detection of the causative agent, and is crucial for efficient therapy and prevention of further spread of the disease. Based on Pasteur's and Koch's achievements, the field of medical microbiology has made significant contributions to the fight against infectious diseases, which were major causes of morbidity and mortality in industrialized countries at the turn of the century. In the 'golden era' '... media, staining procedures, chemical tests to detect end products of metabolism, and serologic tests to identify microbial antigens were developed and adopted by medical microbiologists ... for research and diagnostic purposes'[1]. Recent years have witnessed a dramatic change from traditional culture-based analysis towards molecular detection based on the identification of nucleic acid sequences specific to the appropriate microorganism. This development has been fostered by breathtaking advances in molecular biology such as hybridization, synthesis, sequencing, and in vitro amplification of nucleic acids. Fueled by dozens of initial glowing reports of the power of these novel techniques, many microbiologists and infectious disease specialists were tempted to speculate that nucleic acid hybridization and amplification might supersede conventional microbiological diagnosis. This enthusiasm has been replaced by a more realistic view of the possibilities and limitations and the practical value of nucleic acid-based diagnostics.

Many issues have to be addressed before the true value and benefit of these novel technologies can finally be determined. Open questions range from technical problems, e.g. sample preparation or contamination control, to the clinical relevance of new tests. Setting quality standards is of highest priority and involves the laboratory's infrastructure, personnel, workflow and logistics as well as test evaluation, standardized procedures and materials, and proficiency testing. First attempts have been made. The results, however, were discouraging[2,3]. At present it is dangerous and costly to provide routine molecular genetic testing before the standardization problem has been solved. With the current uncritical application of molecular genetic diagnosis we may soon find ourselves considering gene therapy. In a recent editorial D. S. Greenberg stated 'Gene therapy has been oversold to the public by zealous researchers and gullible journalists, leading to the widely held, but mistaken, perception that clinical gene therapy is already highly successful. It isn't, and while clinical trials should continue, research should be reoriented toward fundamental studies ...'[4].

To provide a critical forum for the discussion of all aspects of nucleic acid diagnosis in microbiology and infectious diseases, three scientific societies (Deutsche Gesellschaft für Hygiene und Mikrobiologie [DGHM], Gesellschaft für Virologie [GfV], and Vereinigung für Allgemeine und Angewandte Mikrobiologie [VAAM]) decided to organize a workshop, which was first held in Berlin on November 6, 1993*. The great success of this meeting encouraged the organizers to have a second workshop (II) on this topic, held in Berlin on December 3, 1994. The continued great interest in exchanging ideas and experience in a forum of experts working in this field was mirrored by a significant increase (20%) in the number of posters presented. There were 15 posters dealing with several issues of viral diagnosis covering

* The abstracts of the first workshop held in 1993 were published in September 1994 in Experientia vol. 50 (9), pp. 789–807.

Cytomegalo- (CMV), Entero-, Hanta-, Hepatitis B- (HBV), Herpes Simplex- (HSV), Human Immunodeficiency- (HIV) and Poxviruses. The main topics were quantitative amplification and molecular typing by various methods for detection, therapeutic monitoring, and epidemiology. Another 13 posters covered aspects of purifying nucleic acids from clinical specimens, molecular typing, detection of virulence genes, molecular taxonomy and description of microbial diversity of bacteria ranging from fastidious bacteria, e.g. *Borrelia burgdorferi*, *Helicobacter pylori*, *Mycobacterium tuberculosis*, to complex environmental microbiota, e.g. activated sludge. Only two posters dealt with the detection of parasites, *Entamoeba histolytica* and trypanosomes, and only one poster discussed the detection of the fungus, *Aspergillus fumigatus*.

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