

Small Changes are Big Steps: Making Nanotechnologies Ethically Affordable in Pediatric HIV Pharmacotherapy

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A recent report on the global situation of the Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS) indicates that about 40 million infected people live worldwide. About 2.5 millions are children (<15 years). This group shows especially high mortality tolls and represents a high-risk population. A novel treatment combining at least three drugs, the High Activity Antiretroviral Therapy (HAART), was introduced more than a decade ago. Antiretroviral (ARV) doses are high and complicated regimes impact patients' lifestyle. According to epidemiological investigations, adherence levels below 95% dramatically reduce the chances of therapeutic success to about 50%. However, high adherence to HAART does not lead to the complete elimination of the virus from the host. Paediatric HIV has been almost eliminated in developed countries by limiting both maternal to fetus and breastfeeding transmission. In contrast, the situation is dramatically different in developing countries where ~90% of the infected children do not have access to medication. Paediatric HAART implementation is even more challenging due to the reduced number of drugs clinically evaluated and approved for use in children. Adult-approved ARV drugs are available only in solid form and have no paediatric equivalents because companies in the U.S. and the E.U. were compelled to clinically test anti-HIV/AIDS medicines in children since very recent years. To make adult medicines appropriate for children, solid forms are often processed to adjust dose and ease swallowing. Approximately 40 million children are administered unlicensed medicines every year in Europe. Regardless, quality, safety and effectiveness concerns, extemporaneous liquid formulations are the first alternative to treat HIV-infected neonates and infants. The last World Health Assembly (WHA) recognized the right of paediatric patients to access safe, effective and proven medicines, approving the resolution "*Best medicines for children*" and launching the global campaign '*Make medicines child size*'. Prevalence of the disease is extremely higher in resource-constrained countries and there exist a need for the development of scalable and cost-effective anti-retroviral medicines.

A remarkable technological gap between the commercially available ARV formulations and the optimal features envisioned for a highly compliant ARV medication is found. Thus, a new research has focused on the design and development of ARV encapsulation and delivery strategies. With the aim to reduce dosing frequency and to improve the compliance of the existing pharmacotherapy, the design of drug delivery systems (DDS) is becoming complementary to new drug discovery.

Our research group investigates different micro and nanotechnological approaches to optimize the biopharmaceutical properties of anti-HIV drugs. This presentation will primarily discuss the main challenges in the development of medicines with enhanced biopharmaceutical properties and will briefly describe the different strategies conceived in our laboratory.