

Cosa conosciamo della stabilità dei vaccini a mRNA in nanoparticelle lipidiche?

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December 27th represents a milestone in the current emergency period since, after the EMA approval of the first COVID-19 vaccine candidate (Pfizer-BioNTech COVID-19 Vaccine in the US or Comirnaty® in EU), a mass vaccination campaign has been started. For a pharmaceutical perspective, this vaccine presents a great innovation because it is the first mRNA-based vaccine formulated as lipid nanoparticles approved for human use. In the context of COVID-19, healthcare professionals involved in the preparation of the doses, are posing some questions on the compatibility and stability of nanoparticles in the syringe as well as timing and transport. Due to the intrinsic innovative aspects of both the active ingredient (i.e., mRNA) and drug delivery system (i.e., lipid nanoparticles), limited information can be retrieved in the “Summary of Product Characteristics” or literature [Comirnaty®, EPAR product information. <https://www.ema.europa.eu>, Int J Pharm. 2021, 601]. Aiming to find an answer, an orthogonal approach was applied to evaluate the stability of the lipid nanoparticles and the encapsulated mRNA in a “real-life” scenario. Specifically, we investigated the effects of different storing materials (e.g., syringes vs glass vials), as well as of temperature and mechanical stress on nucleic acid integrity, number and particle size distribution. These experiments support the hypothesis that vaccine doses can be safely prepared in a dedicated area using an aseptic technique, and transferred without affecting their stability. In a more comprehensive perspective, these data have advanced the understanding of the features of these innovative delivery systems which would accelerate the pace towards new clinical applications.