



Development of a next-generation mock-up vaccine using an intradermal needle-free vaccination device

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The COVID-19 pandemic revealed the urgency and importance of vaccine development. Therefore, it is extremely important to develop a modality that can be applied to various infectious disease vaccines in preparation for unknown infectious disease contingencies, even in peacetime. The Vaccine Development Research Center (VDRC) of Kumamoto University is building a "Research and Development Platform for Administration Devices" aimed at maximizing vaccine efficacy and convenience of use.

Seasonal influenza vaccines are mainly administered by subcutaneous or intramuscular injection. However, subcutaneous and intramuscular injections are associated with pain during and after inoculation, swelling of the inoculation site, and fear of injections, which are challenges for large-scale inoculation. The needle-free intraepidermal delivery device (PassPort™) is novel administration technology that effectively delivers vaccines into the epidermis and is expected to induce superior immunity compared to subcutaneous or intramuscular injection, because it targets epidermal Langerhans cells. Furthermore, the needle-free system enables painless administration and easy handling without problems such as disposal of needles and needle-stick accidents. In addition, unlike injectable solutions, this formulation is a patch containing the antigen in a dry patch, which is superior in terms of stability, manufacturing, and distribution.

Based on the above background, the objective of this study is to develop a seasonal influenza vaccine-encapsulated dry patch formulation using an intraepidermal administration device targeting epidermal Langerhans cells. This technology is simple and versatile, leading to the development of mock-up vaccines that can be quickly manufactured and distributed in an emergency. Through this research, we expect to achieve the following: (I) increased efficacy of the vaccine formulation (reduced dosage); (II) reduced side effects (local irritation and pain) due to reduced dosage; (III) simplified administration; (IV) improved stability, which may enable storage at room temperature, eliminating the need for refrigerated or frozen storage facilities; and (V) superior distribution due to individually packaged dry patches that can be easily manufactured. This device technology will also open the possibility of vaccines for priority infectious diseases as an intradermal administration platform that can be used for various vaccine modalities.