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COVID-19 Vaccines: Need for Global Tracking System

As the world's first COVID-19 mass vaccination programmes are underway in the UK, the U.S. and some other countries, a new paper (Vander Stichele et al. 2020) highlights the need for global monitoring of vaccine use (who was inoculated with which vaccine product, where and when) as well as its safety and effectiveness.

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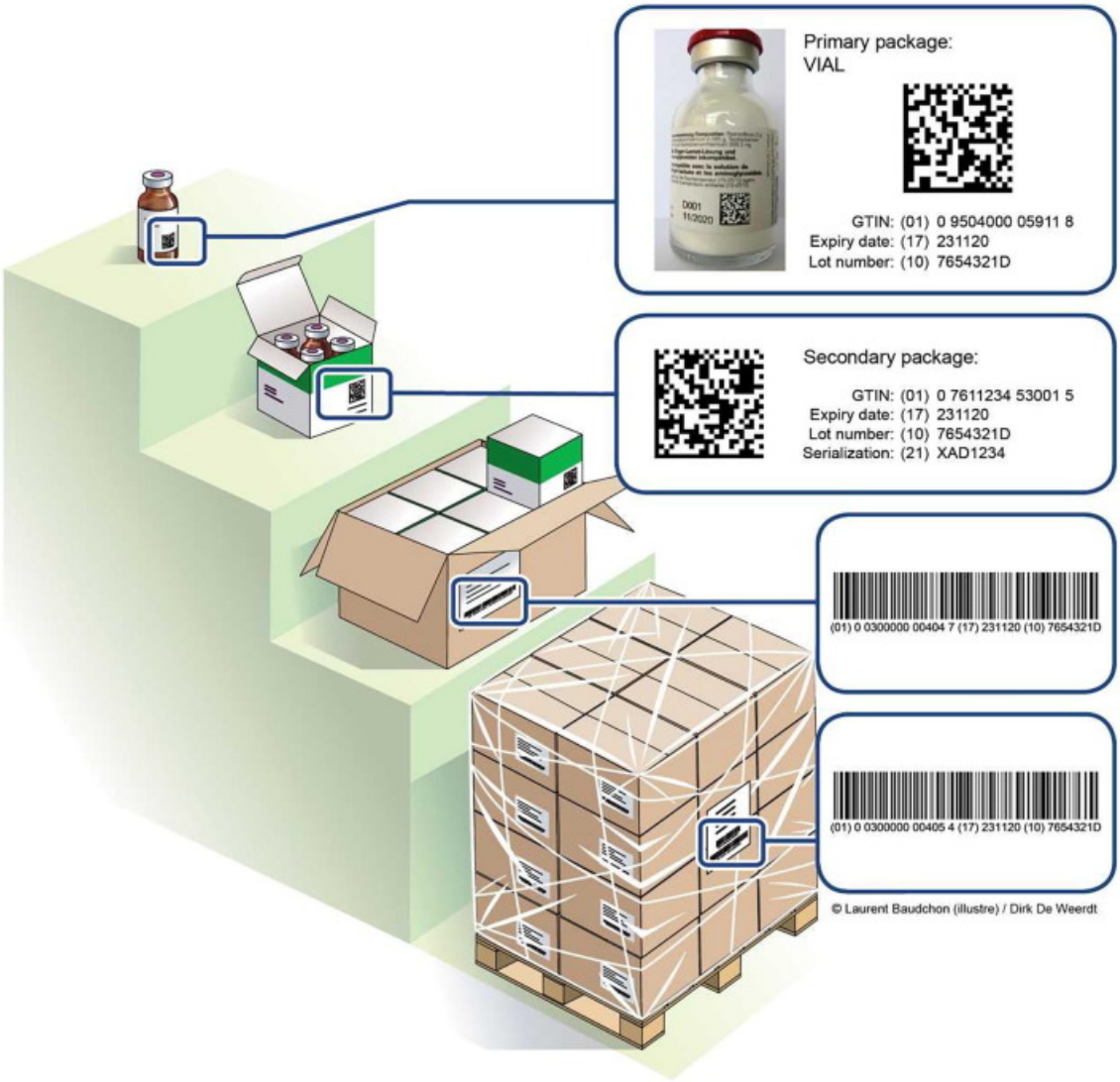
"Many COVID-19 vaccines are using novel technology platforms little or never used in clinical care previously," the report points out. "Combined with the inherent limited sample size, duration, and population heterogeneity of pre-licensure clinical trials, there is a critical need to monitor safety and effectiveness of the COVID-19 vaccines post-introduction."

Specifically, the paper cites two key elements that make for a robust pharmacovigilance strategy:

1) Unique 'univocal' global identification of COVID-19 vaccines

Each vaccine product should have its global univocal identification (named Pharmaceutical Product Identifier or PhPID), as described in the ISO/CEN suite of IDMP standards. This helps with recognising branded variations of the same global vaccine, marketed in different countries. This requirement is supported for all medical products by the FDA and by EMA, and facilitated by the EU Action Project UNICOM. The WHO Collaborating Centre for International Drug Monitoring in Uppsala (WHO UMC) is ready to assign such global identification for every unique vaccine.



Representation of Global Trade Item Number, expiry date, lot number and serialisation number on different levels of vaccine packaging with two-dimensional DataMatrix and linear barcode (Vander Stichele et al. 2020).

2) Unique detailed local market identifiers using global standards

National authorities for marketing authorisation should enforce the use of 2D barcodes (GS1 DataMatrix) on the secondary packaging (carton boxes) and on the primary packaging (vial or prefilled syringe), consistent with CEN ISO/TS 16791, including serialisation (a unique number for every outerpackage) preferably with GS1. These identifiers can trace the vaccine from production to point of immunisation on the ground and serve as protection against falsification and counterfeiting.

"By capturing product identification, including batch number, from the 2D barcode, quality of reporting improves in the standardised Individual Case Safety Report (ICSR), the basis for global pharmacovigilance," the authors write adding that each immunisation site should adapt its processes to ensure the capture of the barcode data for each vaccine accurately, aware that "this is a system potentially at great risk for error with little backup" (e.g. no way for vaccinee to take a photo of primary packaging).

The paper authors also suggest these other measures to ensure effective monitoring of the use of COVID-19 vaccines.

Digital immunisation certificates and national immunisation registry: Countries need National Immunisation Registries for COVID-19 immunisation campaigns; many but not all high-income countries already have them, but usually not for adults. Registers should be able to collect and record the supply chain identification of the administered vaccines. For low- and middle-income countries (LMICs), open source solutions for database management in national registries can be provided with current programmes under the umbrella of GAVI. The 'digital divide' – in terms of unreliable electricity or inadequate digital data storage – is a major challenge, both within and across nations, especially LMICs. Thus, non-digital solutions for COVID-19 vaccine tracking will be needed.

Apps for vaccine administrators: Certified (preferably open-source) apps can be developed for smartphones to allow vaccine administrators

(whatever their profession) to record the act of immunisation, the date, the patient's ID, and scan the identity of the product. This can result in a certificate for the patient and a recording of the immunisation act in the National Vaccination Registry. It could also facilitate compliance monitoring when administration must be repeated and protect against hazardous duplicate vaccination with different vaccines.

Smooth pharmacovigilance reporting. The same systematic approach could also facilitate precise identification and effective analysis in case of side-effects to be reported to the global pharmacovigilance monitoring system, or to study comparative effectiveness and safety in big data pharmaco-epidemiological databases.

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