16-March-2021

COVID-19 Vaccine Label User Evaluation

Living Labs Activity Summary

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Living Labs overview

We envision a world where all communities have the solutions they need to live healthy lives.

We accelerate the pace of health innovation by co-creating with users to rapidly design, test, and scale solutions to their long-standing challenges

We partner with product developers, program designers, donors, and others to design solutions, explore concepts and test prototypes.

Since 2019, the Living Labs has been establishing trusted relationships with 500+ healthcare workers to speed insight generation on vaccine service delivery.

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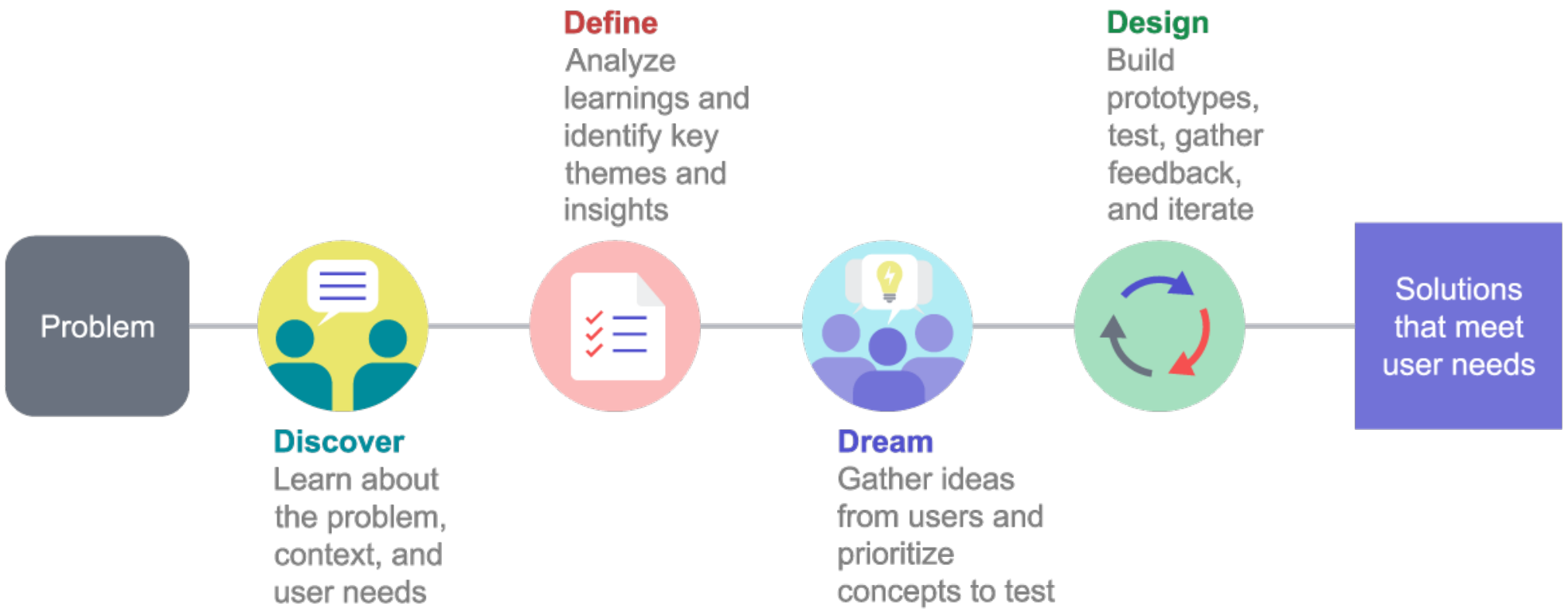
Our ‘4D’ approach to human-centered design



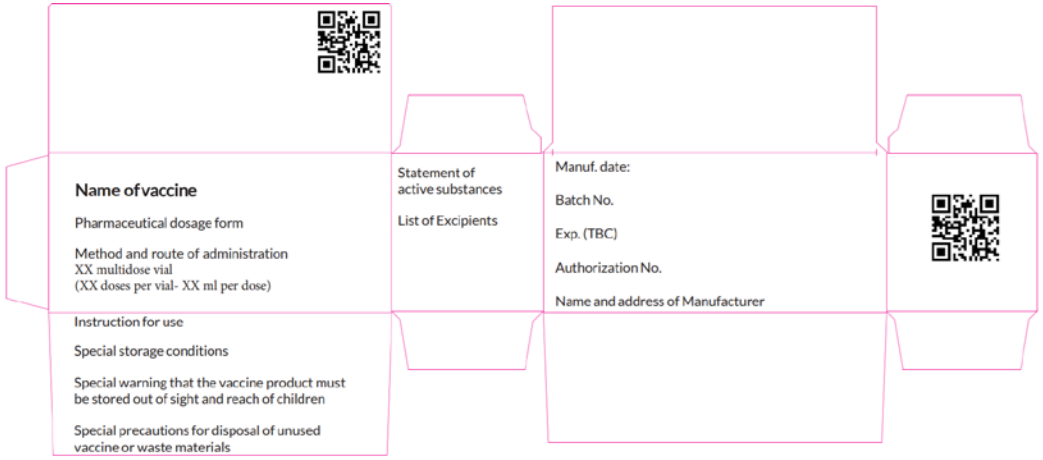
Project Background

Design challenge

In order to unify the labeling requirements for COVID-19 vaccines that will be supplied through the Access to COVID-19 Tools (Act) Accelerator, the Regulatory Advisory Group (RAG), which is co-led by the World Health Organization and Coalition for Epidemic Preparedness Innovation (CEPI), has proposed universal draft models for vials and packaging.

The model label for vials include the following: name of the product, date of manufacture, method of administration, dosage form and storage conditions.

Due to the urgent need of access to COVID-19 vaccine post-approval, the labels and packaging may be in a dynamic state as distribution begins.



Project objectives

The Living Labs sought to rapidly provide insight into the proposed labels to:

1. **Inform healthcare worker training on delivery and use.**
2. **Inform updates to label designs for future batches of vaccines produced by manufacturers.**

Living Labs leveraged existing relationships with immunization service providers in Zambia and Kenya to conduct the research study.

Evaluation Approach

Protocol summary

Ethics review: The Living labs has received exempt approvals from the Western Institutional Review Board (WIRB) IRB Affairs Department under the Common Rule and applicable guidance under 45 CFR § 46.104(d)(2) with local approvals by the ERES Converge Institutional Review Board in Zambia and Maseno University Ethics Review Committee (MUERC) in Kenya.

COVID-19: PATH institutional review for conducting research during the coronavirus pandemic was completed including (1) compliance with local regulations, and (2) protecting the health and safety of the evaluation participants and study team. [***Note***: Confirmed infections in Zambia greatly increased in late December, causing a change to utilize a virtual focus group sessions and interviews.]

Consent: Informed consent was obtained from participants for study activities and photo and video documentation during simulated use.

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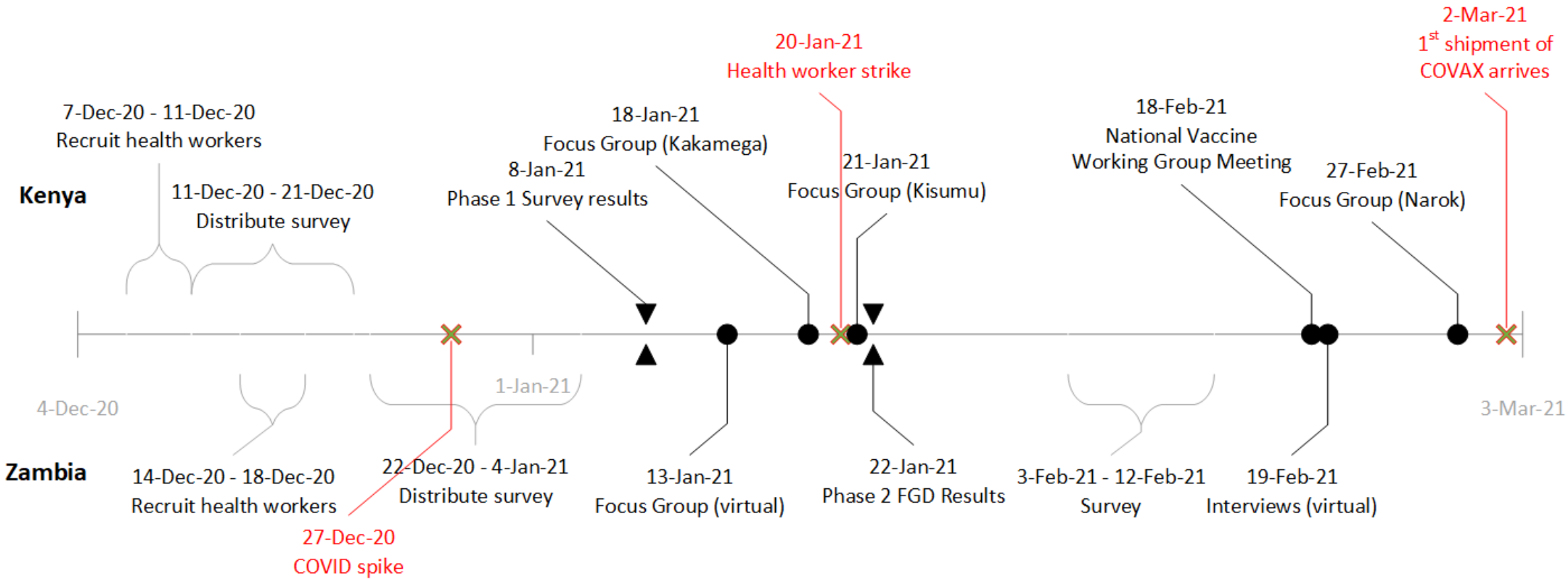
Timing

Phase one consisted of online surveys that were conducted in December 2020 through early January 2021. Phase two consisted of focus group discussions that took place in mid to late January 2021. Additional questions were posed during interviews and meetings during the month of March.



Approach overview

Planning

Selected a convenience sample drawing on frontline immunization workers and ministry of health officials who had previously engaged with the Livings Labs.

Phase 1

Sent a short online survey using Google Forms to all participants.

Integrated insights from the online survey into a focus group discussion guide.

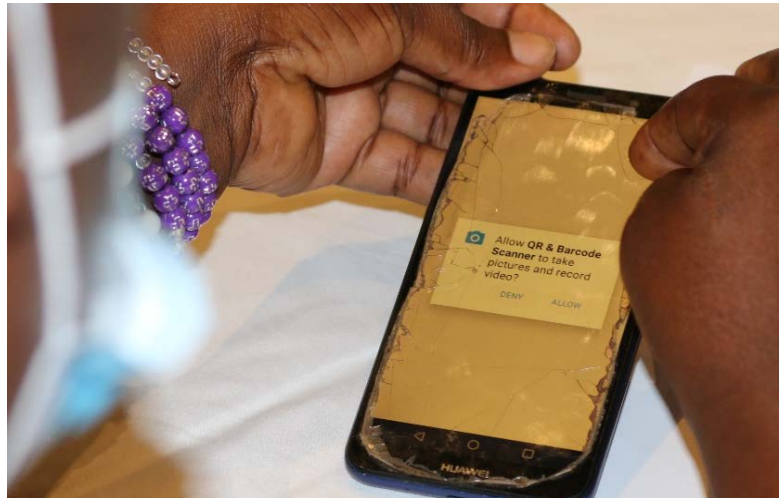
Created a set of label prototypes to use during focus groups.

Phase 2

Led a series of focus group discussions.

Held a series of follow-up interviews.

Synthesized, analyzed, reviewed findings with country and global working groups..

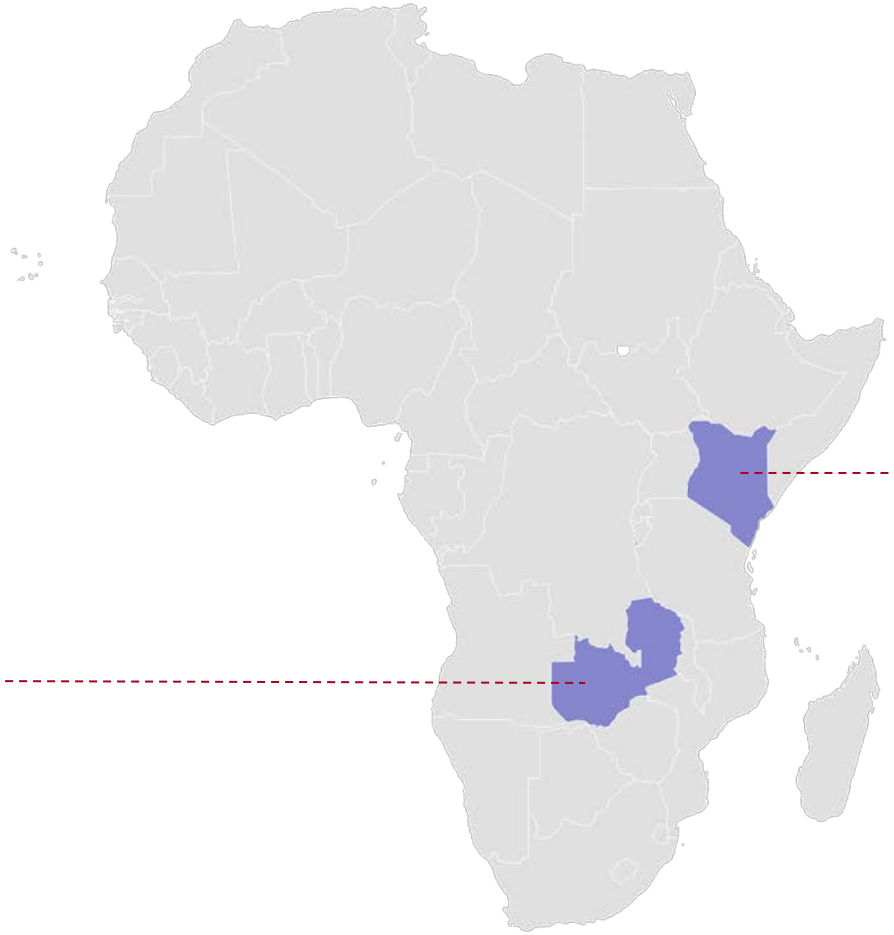


Results and Recommendations

Profiles of countries engaged

Zambia

- Users engaged in 3 provinces (Northern, Southern and Lusaka)
- Will receive COVID-19 vaccines through COVAX
- Has had more than 80,000 confirmed COVID-19 cases including more than 1,100 deaths.



Kenya

- Users engaged in 4 counties (Kisumu, Kakamega, Migori, Nakuru)
- Received its first 1 million doses of the COVID-19 vaccine on March 3, 2021 through COVAX
- Has had more than 106,000 confirmed COVID-19 cases including more than 1,800 deaths.

COVID-19 statistics accessed March 3, 2021.
Source: CSSE at Johns Hopkins University

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User profiles*

65

Users engaged

28

Health facilities engaged

18

Rural facilities

10

Urban facilities

We engaged individuals in the following roles:

- Nurse
- Nurse-in-charge
- Health promotion officer
- Expanded Programme on Immunization (EPI) Logistician
- Reproductive, Maternal, Newborn and Child Health (RMNCH) Coordinator
- National MoH stakeholders

- Of these individuals, 47 were female and 18 were male.

*Represents user input from Kenya and Zambia as of 3-Mar-2021

Overcoming barriers in the face of COVID-19

Both Kenya and Zambia face challenges in managing the distribution vaccines.

Inconsistent or no **electricity in health facilities** causes challenges for maintaining proper cold storage.

No **connectivity** in their facilities or health facilities must cover internet **fees** themselves, making it challenging to digitally collect and access health data

Health workers must travel **long distances** to gather vaccines for distribution or to get to health facilities or communities where they will distribute vaccines

PATH/Trevor Snapp

Frontline immunization workers are well-trained on operating procedures

Through its engagement with health care workers, the Livings Labs learned that frontline immunization workers in Kenya and Zambia feel well-trained in vaccine delivery including the following areas:

- Checking the vaccine vial monitor (VVM) to ensure vaccines have been maintained in proper cold storages
- Checking vaccine vials and/or packaging for expiry dates
- Managing vaccine cold chain
- Preventing and responding to adverse events following immunizations (AEFIs)

Importance of vial labeling

Nearly all respondents indicate that vaccine package labels are very important for their work (94%)

In Kisumu, Kenya, 10 of 11 providers in the focus group all had over 5 years of immunization experience. In their opinion, labels should only have details that assist in administration.

"*During training we get some information such as five doses per vial or total volume per vial, as such we have them in mind and don't need them on the vial label…*"

Less-experienced nurses seek more information such as the VVM, safety profile, vaccine composition, and special handling instructions

Key needs

Means of accessing additional vaccine information

- Nursing staff are willing to access external resources by navigating to a website or scanning a vaccine barcode however sometimes they do not have internet access in their facility location.

Support of public officials

- Health workers can and have adapted to new vaccine introductions, but these usually are supported by strong advocacy and public policy. This includes feeling like the government has helped secure public confidence in the vaccine so they don't have to "push" the vaccine and that policies are in place to protect them in the cases of Adverse Events Following Immunization (AEFIs).

Training that is appropriate to the context and comprehensive

- While eLearning modules have been proposed, online training efforts have failed recently because they are inaccessible to some rural health workers. With the expectation that there may be different vaccines with different handling requirements, training should cover the various vaccine product characteristics together and reference materials should be provided that cover all possible vaccines.

In response to vials missing an expiry date or VVM…

"[I would] hold suspect of the viability of the vaccine and would reach out to my coordinator for clarification."

– Nurse, Kenya

"The online training is easy—has a lot of options for videos and slides—but the only challenges are network and skills. Because someone without computer skills can't manage."

– Nurse, Zambia

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Recommendations for training programs for healthcare workers on COVID-19 vaccine delivery and use.

Recommendation 1

Enable offline training programs that do not require data connectivity.

Provide print-based materials for local adaptation and in-person training where network challenges exist.

Recommendation 2

With elevated concerns regarding vaccine safety, provide additional training topics regarding:

- Mechanism of action for side effects
- Pathophysiology and safety issues

Recommendation 3

Considering the expected changes from the standard data on vaccine labels, additional training and sensitization regarding the absence of VVM or expiry data will be necessary, and may also require policy changes in some instances.

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Recommendations for manufacturers for future vial development

Recommendation 1

As soon as feasible, include expiry date and VVM on vial label to reduce hesitancy and retraining.

Both are considered key to confirm potency.

Recommendation 2

Limit the amount of information contained on the vial to essential information (dosage, route of administration, cold chain requirements, batch/lot number) that can be prominently identified in low-light conditions and core to the immunization delivery process.

Providers may not have access to a leaflet and the secondary package thus the necessity for the stated information on the vial.

Recommendation 3

Print (serialized?) GS1 DataMatrix barcodes on secondary packaging along with website for additional information that can be managed by cold chain officers and district/county personnel.

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Next Steps

- Roll-out readiness planning with national EPI programs
  - Identify potential COVID-19 vaccine delivery and outreach strategies leveraging on existing vaccination platforms
  - Develop a training plan for all participating facilities
- Focus group discussions with health care workers in Senegal

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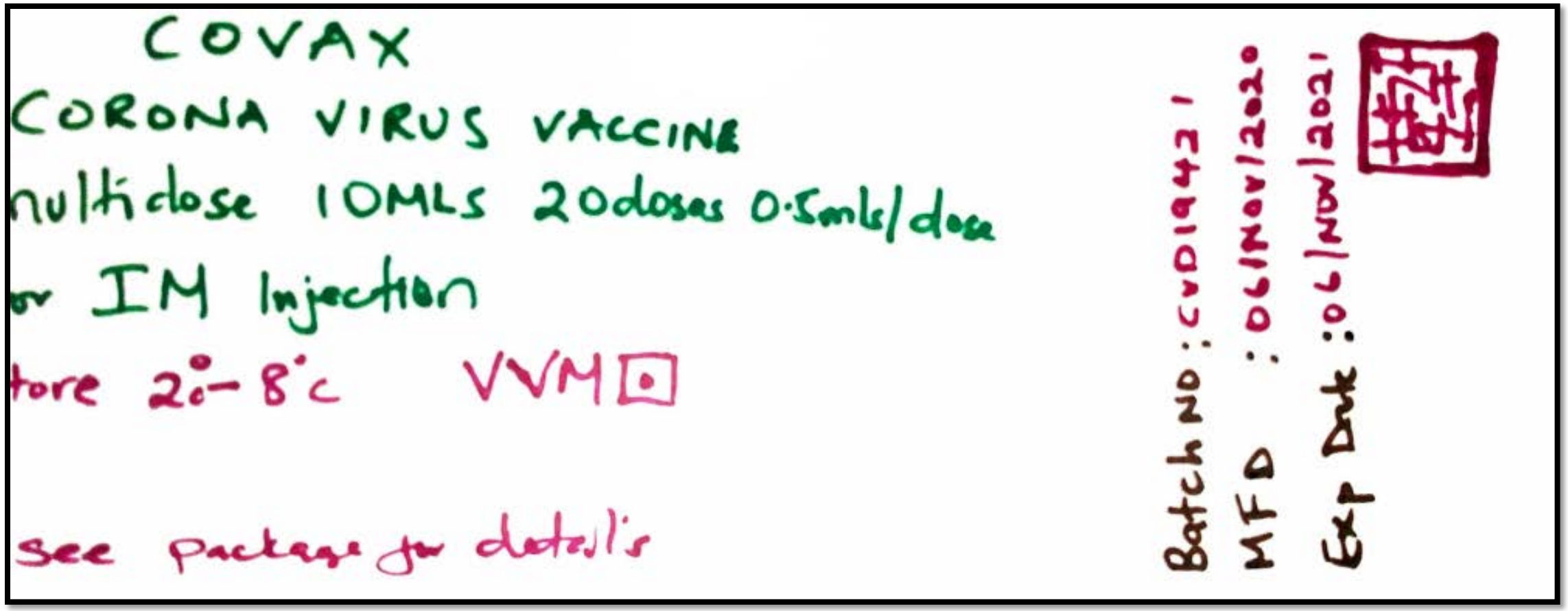
Ideal vaccine label

Focus group participants design their ideal vaccine vial label.



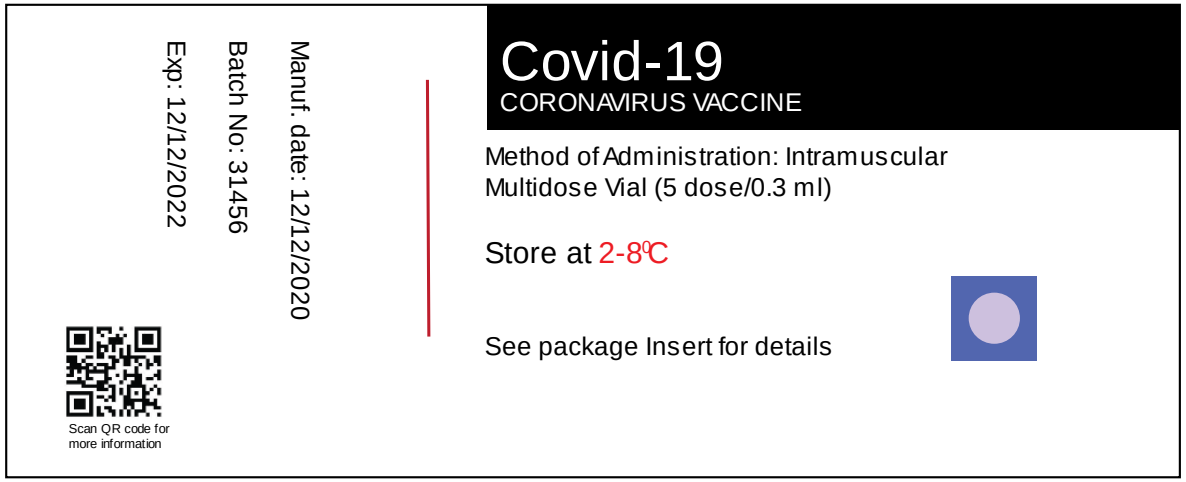
VVM and expiration data

Respondents were consistent in stating that **both the VVM and expiry date must be included in the vial labels to ensure that the potency and safety of the vaccine is assured**

The older and experienced respondents would neither pick nor administer vaccines without VVM regardless of whatever directives to do so. **Since having VVM is an important SOP and would not want to go back to the old practices.**

Experienced providers consider provision of expiry dates and VVM as the gold standards while equating the contrary to “practicing witchcraft.”

Sample label used to elicit feedback from frontline immunization workers



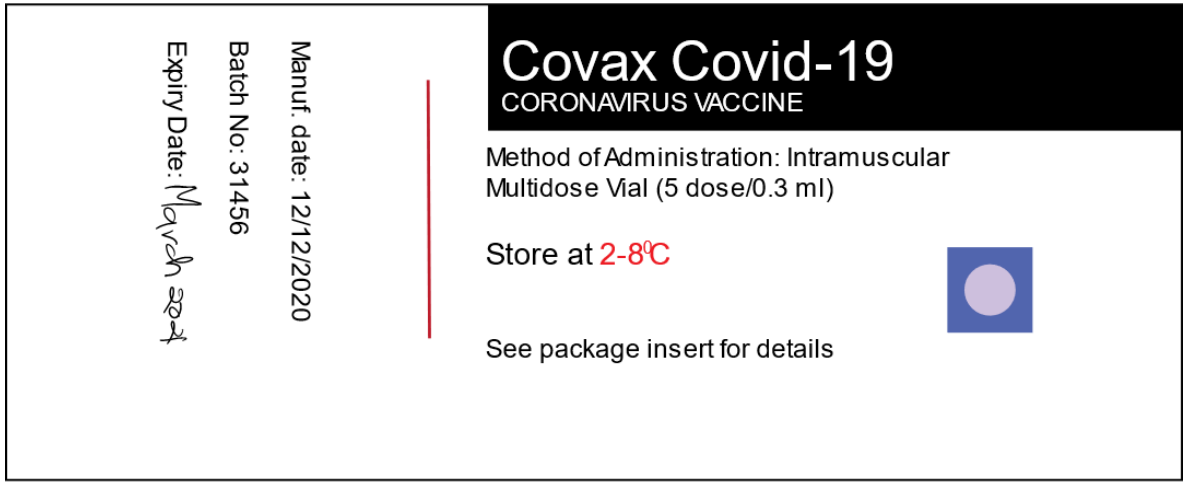
Design Challenge: How might we… modify training and communication if VVM and Expiry is not available on the label?

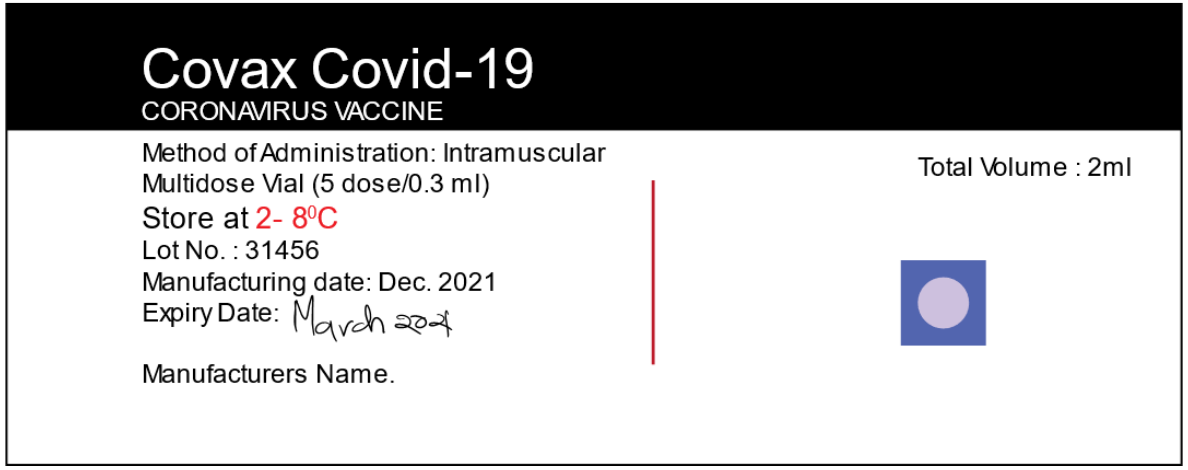
Handwritten expiry date

Less visible label writings on vaccines labels as a major cause for vaccine administration errors.

Respondents acknowledged that inclusion of on expiry date on a label is paramount; missing, confusing or handwritten expiry date would result into rejection of the vaccines.

Nurses with under 5 years experience would not administer the vaccine with handwritten expiry date due to the fear of scam and malice. However, they would administer if it were clearly communicated and gazetted by the Ministry of Health.





Website and barcodes

Healthcare workers perceive the inclusion of a website or barcodes useful as they will aid in authenticating the vaccines to avoid using counterfeits, and in accessing more information the vaccine.

All respondents emphasized that having a website cannot be an alternative to the printed expiry date and all would reject such a move.

Similarly, the use of a barcode was also not a sufficient alternative for authentication as access to and use of barcode readers as part of the workflow presented challenges.