May 19, 2021

COVID-19 Vaccine Label: User Evaluation

Living Labs Activity Summary

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1 Project background, process and tools

2 Findings and implications

3 Other Living Labs activities

4 Zambia Ministry of Health remarks

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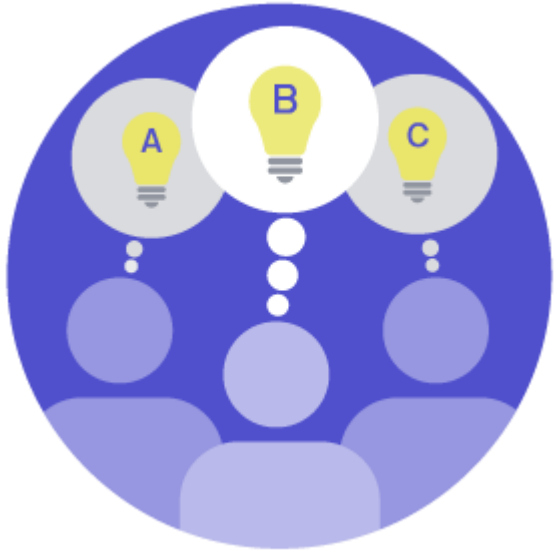
PATH's Living Labs initiative

We accelerate the pace of health innovation by using human-centered design methods to co-create, test, and scale solutions to long-standing health challenges.

Designing Solutions



Exploring Concepts

Testing Prototypes

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Project background, process and tools

Design challenge

Background

In partnership with the World Health Organization (WHO) and Coalition for Epidemic Preparedness Innovations (CEPI), the Living Labs conducted **a rapid assessment of usability and acceptability of the proposed universal draft models for COVID-19 vaccine labels and packaging.**

Health care workers provided feedback on the design of the labeling prototypes and insights on how they would improve the labels.

Purpose of findings

1. Create training programs for health workers on delivery and use of COVID-19 vaccines.

2. Inform updates to label designs for future batches of vaccines produced by manufacturers.

User profiles

65

Users engaged

28

Health facilities engaged

18

Rural facilities

10

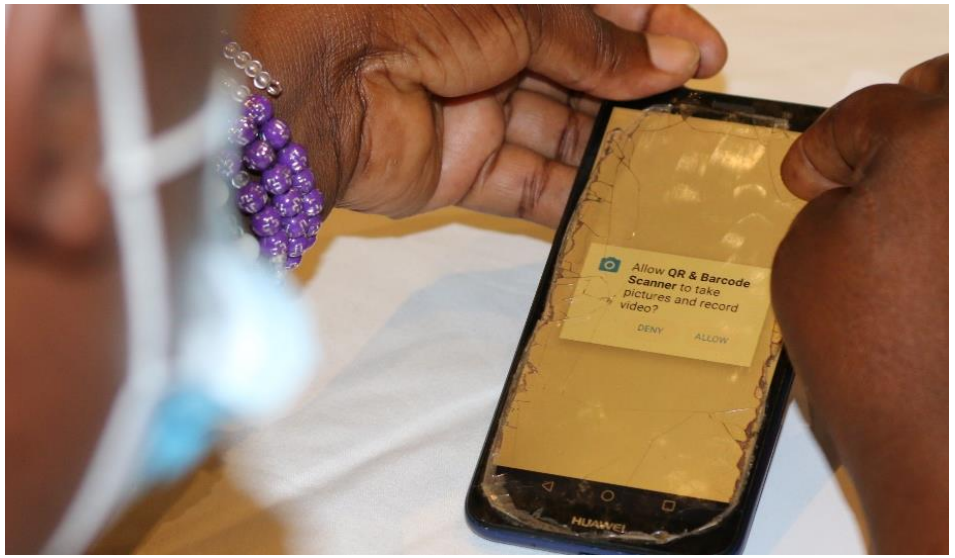
Urban facilities

We engaged users in **Kenya & Zambia** 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 Ministry of Health stakeholders

4D approach overview: Dec. ‘20 - Feb. ‘21

Phase 1:
Discover & Define



- Sent an online survey to all participants.
- Integrated insights from the online survey into a focus group discussion guide.
- Created label prototypes to use in focus groups.

Phase 2:
Discover, Define, Dream & Design

- Led a series of focus group discussions.
- Conducted follow-up interviews.
- Synthesized and analyzed results in Miro (a virtual collaboration tool).

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Focus groups scenarios

….Vaccines lacked vial monitors?

….Expiry dates were not established on vaccine vials/packaging?

….Expiry dates were handwritten or looked up on a site rather then labelled on the vial?

….QR codes were established on the labels instead of an expiry date?

….The label stated that the vaccine expires three months after the manufacturing date?

Findings and implications

Priority features

- Name of vaccine
- Vaccine Vial Monitor (VVM)
- Dose per vial
- Number of milliliters
- Manufacturer
- Expiry date
- Route of administration
- Batch number/lot number (packaging)
- Side effects (packaging)
- Storage

Per evaluation findings, inclusion of these details as part of the COVID-19 vaccine label will assist in:

- Safe handling and administration of vaccine.
- Easy tracking should there be an issue or unwanted reactions.
- Easy identification of vaccine.

Insights: Vaccine vial monitors

- Health care workers (HCWs) consistently stated **that the VVM must be included on the vial labels** to ensure vaccine potency and safety.
- The older and experienced **respondents would neither pick nor administer vaccines without VVM regardless of directive**. VVM have become an important standard operating procedure, and providers would not want to revert to old practices.
- Most HCWs have reservations to receive the vaccine, some citing missing VVM as the reason.
- Increase in wastage as vaccine have to be discarded every six hours

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

Vaccine Vial Without VVM and Manufacturing Date

Insights: Expiry date

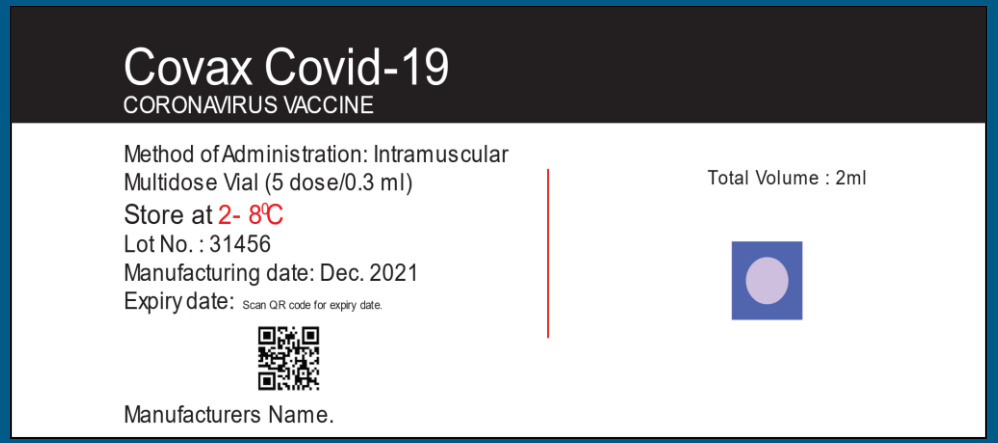
- HCWs indicated that if the **vaccine had a missing, handwritten or confusing expiry date** they would try to seek clarity from their supervisors or they would simply not administer the vaccine resulting in missed opportunities to vaccinate.

- **Handwritten expiry dates are a problem**, as HCWs would assume it was not done by the manufacturer and thus not approved for use.

- The **expiry date is standard operating procedure that cannot be omitted**; it is used to ascertain if the vaccine is safe and as a defense in case of complaints.

Insights: QR code, website and accessing vaccine information

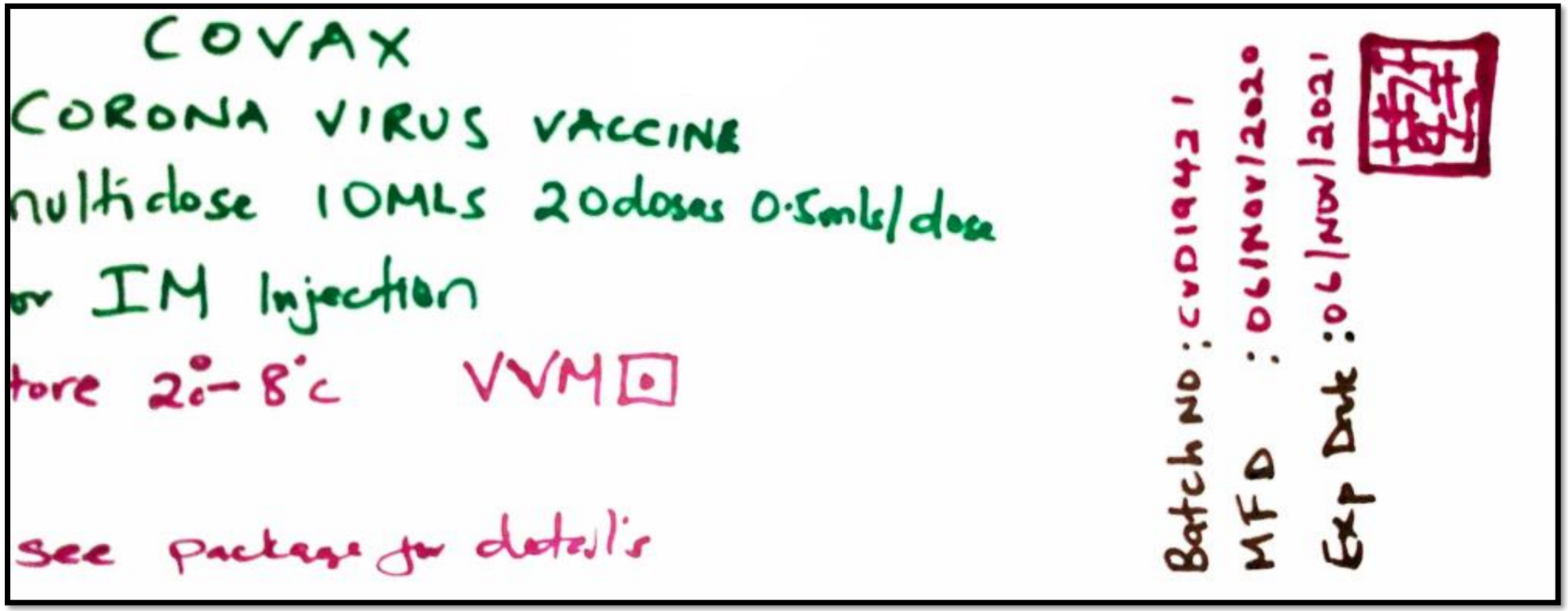
- **HCWs are willing to access external resources** (i.e., website or barcode) but primarily as a secondary source of data.
- HCWs expressed **they do reference and use the batch/lot number** to trace vaccines in case of problems.
- QR codes are considered important but secondary to an expiry date.
- **Potential barriers** to utilizing QR codes or websites include **lack of a device** that can scan barcodes, **lack of interact access** in their health facility or **lack of data bundles** for their mobile phones.



Sample label with QR code used during focus groups to gather feedback

Ideal vaccine label

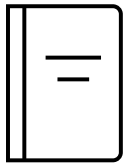
Focus group participants designed their ideal vaccine vial label.



Critical factors for a successful COVID-19 vaccine roll out

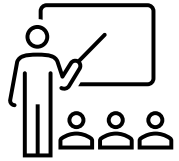
Strong government support

HCWs can and have adapted to new vaccine introductions **with the support of strong public communications and public policy**.



Compendium of “explainers”

With the expectation that there may be different vaccines from different manufacturers with different handling requirements, it would be preferable to **provide one holistic reference guide for all vaccines** HCWs may encounter.



Training adapted to the context

While eLearning modules could seem appropriate to quickly provide training, **online training efforts have failed recently** especially with remote workers and when there is insufficient support for HCWs to purchase mobile data.

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Implications of our insights

- Sharing with the Ministries of Health in Kenya and Zambia to help inform COVID-19 vaccine roll out plans
- Sharing results with the immunization community
- Global discussions around label standardization are still ongoing and compete with other pressing COVID-19 priorities, engagement to date with National Regulatory Agencies has been inconclusive

Other Living Labs activities

Gathering HCW and MOH views on current vaccine rollout

• The current vaccine has no VVM, and HCWs have concerns about its safety.

• HCWs depend on instruction of discarding the vaccine after 6 hours from the time the vial is opened.

• The presence of the expiry date provides HCWs assurance that the vaccine is potent and approved for use.

• HCWs highlighted the missing manufacturing date, which poses question around the shelf life of the vaccine.

• HCWs recommend that in the next roll out, they should be involved with full community engagement to increase vaccine acceptability.

"I got vaccinated because I am a health care provider who is at high risk of getting infected with COVID-19 and I want to be an ambassador for other health care workers and my family".

HCW in Zambia

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Related Living Labs immunization activities

	Project	Challenge	Approach
1	**Co-creating motivational solutions for frontline immunization workers**	Frontline immunization workers have a demanding job, but often have limited resources and support. This can lead to demotivation and ultimately a decrease in vaccine coverage.	Tested prototypes that build on HCWs own desire to learn, improve, and achieve increased uptake of immunization services.
2	**Managing routine immunizations with a client scheduling app**	Managing progress toward the 90% immunization target is difficult when providers don't know how many children are coming for vaccinations daily and do not have easy tools for reminding caregivers of scheduled immunizations.	Engaged HCWs to design, prototype and test a client scheduling app. The app would allow HCWs to trace clients, plan for supply needs, and contact caregivers about appointments.
3	**Usability test of a Covid-19 Paper Based Information System.**	Documenting Covid-19 vaccination and scheduling for next vaccination appointments is challenging without the right set of tools. Regardless of the type of the facility, proper documentation is paramount for tracking and referencing.	Conducted usability test of a paper-based Information tool with 16 HCWs to evaluate their experiences using the tool and the overall acceptability of the tool.

*The Living Labs also engage in non-immunization activities and projects. Please visit path.org/livinglabs to learn more.

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Zambia Ministry of Health remarks

Discussion

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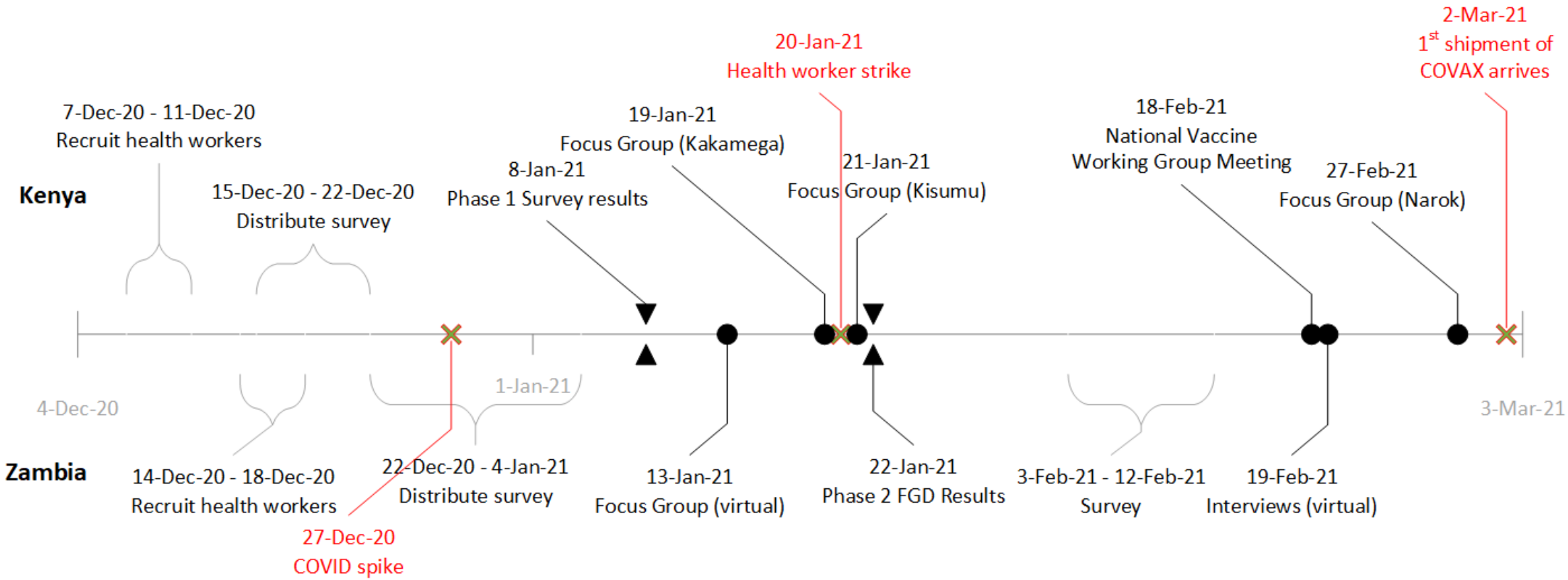
Annex

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.

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