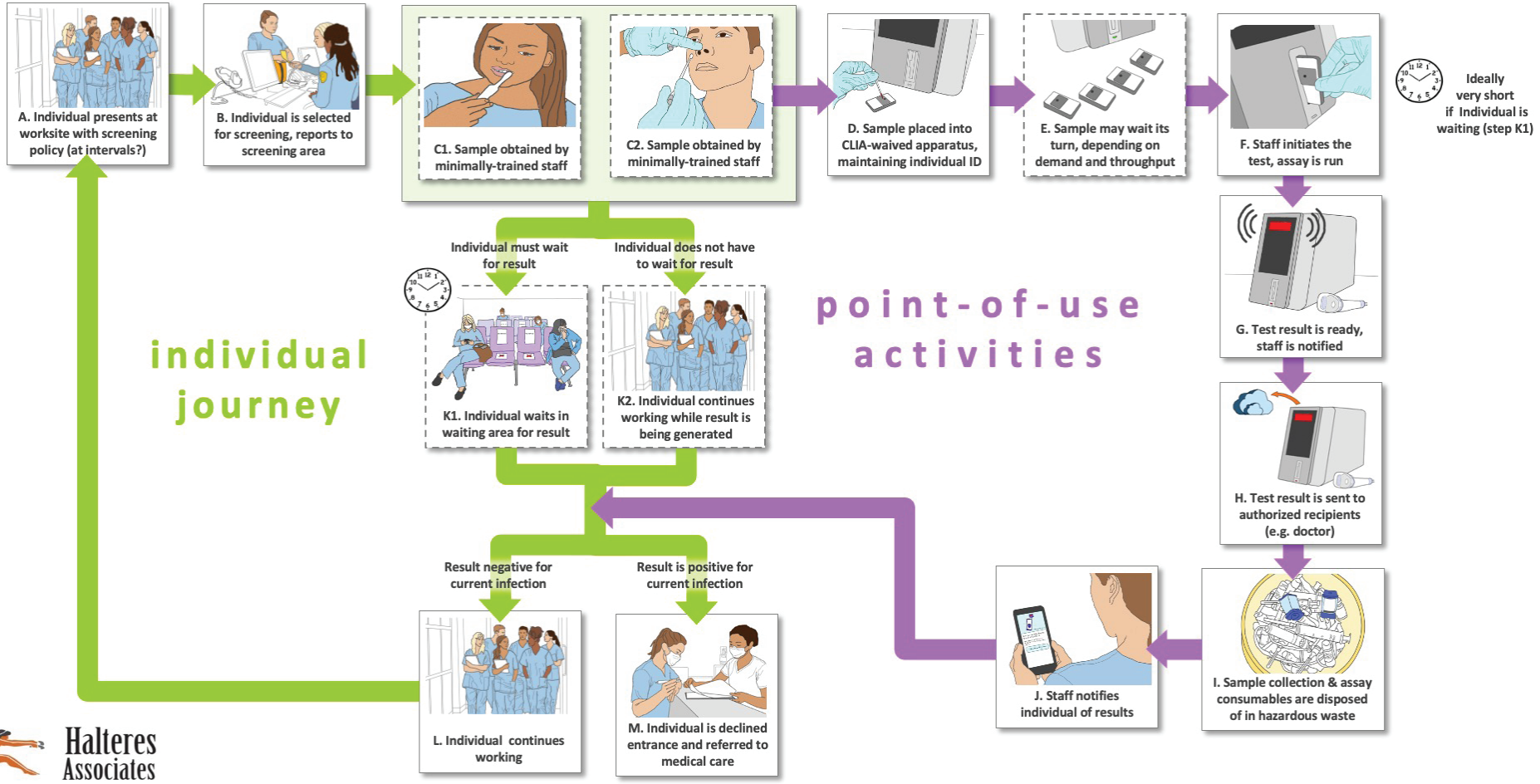
Storyboard H: Workplace SCREENING of Individuals On-Site for Non-symptomatic Infection



Description: Storyboard H is related to a new Use Case 11, which we have called Screening of Non-Symptomatic Individuals. There has been a great deal of discussion in many quarters about this Use Case. See the updated Use Case tables. In contrast to Storyboard G, we are now showing the screening of individuals (not populations) to enable decisions about their suitability to continue in a work environment. There are two intended uses for this Use Case: 1) determine if an asymptomatic or pre-symptomatic individual has a current SARS-CoV-2 infection and 2) determine if an individual has been previously exposed. We assume symptomatic persons will be dealt with independently. The type of test that would be used for intended use 1 could be either an RNA tests or possibly an antigen test (depending upon the performance) (see Use Case 5: diagnosis). It is conceivable that the tests would could be designed to detect other respiratory diseases as well (see Use Case 6: differential diagnosis). For intended use 2 it is likely that a serology test would be employed (IgG alone or potentially in combination with IgM and IgA), but the issues of performance for determination of immune status remain unresolved. Storyboard H is best suited to intended use 1, where more frequent testing would be required than intended use 2. For previous exposure, an individual would likely be tested when applying for a job or after recovery from flu-like illness. If there are studies which demonstrate that monitoring of the titer of an individual would be useful to indicate the loss of immunity, there could be additional tests scheduled based upon the results.

In Storyboard H, we assume that the testing is conducted on-site, very nearby or in a mobile unit at the site of employment. We now refer to the green path as the "Individual Journey", as opposed to the "Patient Journey" used in other Storyboards. Individuals present at their

worksite (Step A). In this example storyboard, we chose to illustrate healthcare workers being tested at their place of work. In Step B, based on an algorithm which specifies the desired frequency of testing (to be determined), we show workers reporting to a scheduling area. Frequency of testing could be determined by last test date, known recent exposure to infected persons or the nature of their job. Risk assessment will be key to select the appropriate frequency of testing.

Given that this is not likely to be a sophisticated lab environment, we show sample collection by minimally trained staff (Steps C1 and C2). This will limit the practicality of the sample type and form of collection. An exception could be instances in which a mobile lab is used, which might be manned by more highly-trained professionals. Although we show staff collecting the samples, it would be far preferable for the employee to collect their own sample (see Storyboard I). This is common in HIV self-tests which use finger-prick blood or oral fluid, both of which are under investigation for SARS-CoV-2 tests. While the test is being performed, the employees could wait for the result or, depending upon the nature of their work and the pre-test probability of a positive test, they could begin work (see new Use Case 11 Screening of Non-Symptomatic Individuals)

Steps D through J are very much like Storyboards C and E along the "Point-of-Use Activities" track. After processing in a small instrument with the ability to test cartridges one at a time, the results are available within an acceptable time frame, probably less than 30 min. Note that with a large number of employees to test, this process might be difficult to implement and could require off-site testing, which although possible, is not ideal due to the added turn-around-time involved.

When the results are available, the "Individual Journey" meets the "Point of Use Activities", which enables the decision that the tested person is either able to go to work (Step L) or is referred to medical care (Step M). Once antiviral therapy is available, the individual could be treated in isolation, retested and then allowed to return to work.

Observations: For intended use 1, there are issues concerning the quality of the existing RNA tests. There have been reports of false negative results due to poor sampling (e.g., nasopharyngeal, mid-turbinate, nasal swabs, etc.) or poor test design (e.g., insufficient LOD). These issues are not surprising in the early phases of new infectious diseases and will likely be worked out with time in the crucible of the diagnostics marketplace. But the lack of accepted gold standards and high-quality validation sample panels has been limiting to date.

For intended use 2, although several serology immunoassays have been developed, few are adequate, and none is without issues. Over the last few months, the FDA has removed more than 70 immunoassays from the market. There are two major issues: false positivity and lack of correlation to immunity. We have discussed this in our post "Primum non nocere."

Legend: The Storyboards are meant to be approximate descriptions of the overall testing ecosystem. They are organized as flow charts containing sites of activity, people involved (e.g., patients, medical practitioners and laboratorians) and pathways for tested individuals, healthcare professionals (or other testers in some cases), sample collection and transport, testing, result generation and information flow. They also show key decisions informed by the test results.

There are three types of "journeys" in the Storyboards: 1) the tested individual's (usually patient) journey which are shown using green arrows, 2) point-of-care or point-of-use activities which are shown with purple arrows (e.g., sample collection, sometimes testing) and 3) the sample and data journey through a laboratory, which is shown with blue arrows.

The letters that label each step are not meant to indicate an order for the steps, they are simply there to facilitate discussion about the storyboard. Optional steps have a dashed outline, and examples of possible variations in a step are labeled with the same letter followed by differentiating numbers e.g., B1, B2 and B3)

There are a number of clocks and calendars pictured near specific steps to indicate time-consuming steps and those that could vary in total time depending upon the workflow efficiency of the healthcare site and the characteristics of the testing platform (e.g., batch analysis, time to results).