End-to-end process review

25/03/2020

Purpose of the session:

- Communicate current end-to-end process
- Highlight open decisions and critical assumptions for escalation

Following the session, this document captures:

- The updated end-to-end process
- Assumptions and the associated rational
- Open design questions and the associated implications

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End-to-end testing process flows

The below is the end-to-end flow of the proposed end-state process



PROPOSAL: End-to-end testing approach

Step 0: Testing protocol for key workers communicated (PHE) Step 1: Verified person (or family member) requests test (NHSX)



PROPOSAL: End-to-end testing approach

Step 2: Testing kit consumables sourced (Manufacturer)



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PROPOSAL: End-to-end testing approach

Step 2g and 2d; Step 3: Individual delivery of packaged testing kit distributed to individuals at home (Manufacturer/ Delivery Partner) Step 3b: Bulk delivery of testing kit to centre (Delivery Partner)



Assumptions	Rationale
l. Labs will serve regions as a base case	 Defines which returns labels / packaging is sent out to who
1. Randox kits are nationwide	 Defines who these are shipped to at point of order
. Thermofisher kits are mainland nly	 Return times and flight transport requirement compliance in the design
7. There will be bulk delivery to est centres, but only for exception nanagement and base case is home lelivery	 Amazon delivery model / alternative shipping options and test centre process design, storage facilities etc. Scale of stock management and ordering process required at test centres
Open questions	Implication
Y. Will there be capacity to ship est centres directly?	 Flexibility of system to manage errors and exceptions
. At what point is return route lecided – i.e. courier or Royal 1ail?	 Post delivery needs to be from post office drop off – max 2km walk for symptomatic individuals
. How do we manage lab capacity It this stage?	 Labs operating at capacity will continue to receive tests if incorrectly managed

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PROPOSAL: End-to-end testing approach

Step 4: Person conducts self-test at home following agreed protocol (Patient)



PROPOSAL: End-to-end testing approach

Step 4b: Test conducted at a centre following agreed protocol (e.g. Boots / test centre), bulk NHS testing



PROPOSAL: End-to-end testing approach

Step 5: Tests collected and delivered to central testing laboratories following agreed protocols (Delivery Partner)



PROPOSAL: End-to-end testing approach

Step 6: Central laboratories run the tests (Multiple lab sites)

st ع	Step 5 Central laboratories run the test Step 7						Assumptions	Rationale	
rmoFisher Kit L	1. Sample processing machine	2. Preparation re-agent	3. Extraction of DNA	4. Sample processing machine PCR (testing)	5. PCR (testing)	6. Results uploaded to internal system (LIMS)	6. Results uploaded to internal system (LIMS)	6. Results data loaded into LIMS by TFS labs, but they do not hold patient data	 Simplifies data management and GDPR requirements. Need to develop data platform that links test results with patient data
The	(Central lab)	(Central lab)	(Central lab)	(Central lab)	(Central lab)	(Central lab)	(Central lab)	13. Randox hold patient data in their system as entered into their portal	 Per established system architecture GDPR approval required (being progressed)
								Open questions	Implication
SHN									
Digital Platform(s)									
Step 5 Randox laboratories run the test Step 7									
xopu	8. Sample processing	9. Preparation	10. Extraction	11. Sample processing	12. PCR (testing)	13. Results uploaded to	14. Results compiled into		
Ra	machine	machine (testing) (testing) (testing) (LIMS)		required		9			
	(Randox)	(Randox)	(Randox)	(Randox)	(Randox)	(Randox)	(Randox)		
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DR	RAFT: SUBJECT TO CHANGE	PROPOSAL: End-to-end testir	ng approach	
	Step 7: Test results collected and aggregated (NHSX)	Step 8: Results distributed to patients (NHSX)Step 8b: Results analysed for surveillance purposes		
Kits			Assumptions	Rationale
moFisher			4. NHS responsible for deciding action for test results – i.e. advice to positive tests	Correct medical advice / decisions
Ther			Open questions	Implication
	 Results provided to NHSX 4. NHS evaluates 	Gradients Gradients Step 8 5. Patient 6. Individual can call registers/logs in to	1.&3. How does Randox test result data get shared with NHS / NSHX?	 Architecture of common data platform to align across multiple sources (common patient inputs at front end simplifies this)
SHN	test result and determines	results portal enquiries (existing 111) (Individual) (Individual)	5. Does the portal provide a login to access your results?	Who develops and designs this?
	appropriate patient communicati	7. Aggregated results provided to	5. How would it be communicated that results are ready?	Who develops and designs this?
Step 7	ON (NHS)	(NHS) (PHE)	8. What requirements are there for ongoing analysis?	Data requirements captured upfront
tform(s)	Test results collected and aggregated - 1. TFS LIMS 3. NHSX test data uploads		3. What is the process for a `VOID' result?	 Patient may need to go through the process and additional time
Digital Pla	aligned to patient data in common data platform (TBC)			
J	2. Randox			
Rando	common data platform			10
	(ndiluox)			INQ000587598_0010