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Introduction

This is our second guide in response to issues concerning vaccination and Covid-19. It documents the key learnings we have gained from the human factors assessment of the vaccination system implemented by NHS Ayrshire & Arran (NHSAA).

Its purpose is to share success, recommend design and safety improvements and offer a universal template for future safe and effective rollouts of time-critical vaccination programmes.

The guidance will also be useful for the design and delivery of any public health vaccination programmes post Covid-19.

The Keil Centre, NHS Ayrshire & Arran, NHS Education for Scotland and the Chartered Institute of Ergonomics and Human Factors have collaborated to produce the key learnings documented in this guidance.

The full human factors assessment is presented in The Keil Centre Limited – Human Reliability Assessment for the Covid-19 Service Delivery for NHSAA on behalf of NHS Education for Scotland (NES). Version 1.1, 14th May 2021. The full technical report can be downloaded here: https://bit.ly/3vOL0cL

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The Chartered Institute of Ergonomics & Human Factors (CIEHF) received its Royal Charter in 2014 to recognise the uniqueness and value of the scientific discipline and the preeminent role of the Institute in representing both the discipline and the profession in the UK. This includes the protected status of "Chartered Ergonomist and Human Factors Specialist" with the post-nominal C.ErgHF awarded to practising Registered Members/Fellows who are among a group of elite professionals working at a world-class level.

Methodology

Vaccinating a nation: the challenges

The size of the vaccination programme for Covid-19 is unprecedented. Within Scotland alone, approximately 4.4 million people had to be vaccinated as quickly as possible, with each person receiving two separate doses of the vaccine followed by a 'booster' dose at least six months after the second dose. With this level of urgency being repeated worldwide, the challenges of delivering a successful vaccination programme were exceptional, and included:

Supply

Vaccines were being newly (and rapidly) developed, with global demand for delivery. High simultaneous demand across the world also affected the supply of other equipment and medical consumables.

Restrictions and guidance

Aspects of the vaccine were, and are, still being analysed even as the roll-outs began. As more is learned about each vaccine, restrictions and guidance are and will be subject to sudden change.

Storage and transportation

The Pfizer vaccine has specific cold temperature storage requirements, and the cold chain needs to be maintained for all vaccines.

Staffing

Delivering a mass vaccination programme requires significant staffing resources, while other health services must still be provided. For NHSAA, this was required in a short space of time due to the urgent need to provide population protection. Staff also need to be vaccinated.

Safety

Vaccination centres need to enable social distancing to mitigate the potential for virus transmission.

At the time of writing (October 2021), global vaccination programmes are under way and good progress is being made in countries such as UAE, Iceland, Chile, Bahrain, UK, Israel and Uruguay. Other countries and regions, however, still have some way to go and vaccination programmes will be a feature of life for many for the foreseeable future.

Methodology

This guidance is a potentially valuable learning and reference resource for those leading and advising on the safe design and implementation of mass vaccination programmes for Covid-19 protection, as well as other diseases that require immunisation.

We used a combination of study methods that are reported in this guidance, including:

Human reliability analysis (HRA)

The specific technique used for our analysis of the mass vaccination roll-out is called systematic human error reduction and prediction approach (SHERPA).

Hierarchical task analysis (HTA)

In the first stage we analysed the tasks undertaken within the system, according to the scope of the assessment. We used a hierarchical task structure (known as hierarchical task analysis or HTA), through which tasks were described and re-described in more detail as the analysis progressed.

Performance shaping factors (PSFs)

PSFs are the background conditions within a system that can make failures more likely. We analysed each task as follows:

- Relevant PSFs were identified for the task.
- Eight categories of PSF were used, examples of these are shown in table 1.

· Site visit

The purpose of the site visit was to clarify with healthcare professionals how tasks are undertaken in practice, and to identify relevant PSFs.

HRA workshops

HRA workshops were conducted via Microsoft Teams, due to the need for social distancing. Eight workshops were conducted over a six working day period.

· Risk ranking of the actions

NHSAA performed a risk ranking for the action themes using a well-established NHS risk matrix.

Presenting our learnings

We have presented our learning according to the principles laid out in *Vaccinating a nation: Ten human factors and ergonomics principles*, published earlier this year and available in various languages at covid19.ergonomics.org.uk.

It provided guidance over a number of work systems, such as manufacturing, filling and packaging for distribution, testing and approval, cold chain delivery, booking systems for vaccination appointments, local administration of the vaccine, and patient follow-up.

Whilst recognising that operational complexities vary from country to country, it offered ten core principles for systems thinking in vaccination programmes that apply across all settings, (as shown in Figure 1). We have used those same core principles as the basis for the structure of this follow-up guidance.

Performance shaping factors	Examples and explanations where factors can make error more likely
Task	Factors may include excessive demands of the task, excessively high (or low) workload, working under time pressure, complex tasks demanding high levels of concentration, tasks which are very monotonous and repetitive, situations with many distractions, interruptions or divided attention, or non-standard activities.
Procedures	Work procedures or instructions can make error more likely through absent or highly variable task method, or by being inaccurate, inadequately presented, unintelligible, overly complex and/or unclear.
Ambient environment	The ambient environment can present significant challenges to performance and may include the weather, thermal environment, lighting, noise, air quality and/or the presence of health hazards.
Human- technology interactions	The equipment that people interact with, the conditions of that interaction or the workspace can induce failure. There are several examples, including information presentation issues or a lack of information, too much automation, alarm issues including overload/fatigue, inadequate equipment positioning, equipment issues, inappropriate work tools for the task, unclear signs and signals, inadequate workplace access or workspace arrangement, or factors that make the task more difficult, such as the use of personal protective equipment.

Table 1. Examples of PSFs

IDENTIFY



1. Understand people's needs and capabilities.



2. Consider tools and equipment.



3. Assess the physical environment.



4. Describe the tasks people do.



5. Evaluate potential vulnerabilities.

IMPROVE



6. Re-design physical spaces, tools and tasks to enhance performance and reduce risk.



7. Develop usable work instructions.



8. Design and deliver suitable training.

ADAPT



9. Monitor work-as-done and adapt to achieve sustainable change.



10. Record and learn from incidents.

Figure 1: Principles from Vaccinating a nation: Ten human factors and ergonomics principles.

IDENTIFY

1. Understand people's needs and capabilities

The vaccination programmes running across the country tie together different work systems and people, for example patients, their carers or family members, front line staff in vaccination centres, managers, administrators and so on, all of whom have a diverse range of needs and capabilities. These need to be properly understood so systems can be designed to meet them. Some of the key learnings that arose from our study were:

Define patient groups

Understanding the target audience for communications around the vaccination programme should be vital. Patients vary in their IT literacy and access to online information and appointment booking tools. Some are hard to reach, such as those who are homeless, have drug or alcohol issues or are within a traveller community. This can create health inequality. It's important to consider patient needs even before they arrive at the vaccination centre, for example by:

- Taking account of the local geography and how patients travel to the vaccination centres.
- Understanding the demographic and the availability and suitability of public transport.
- Considering providing help with public transport costs, for example by proactively providing tickets.

Define staff profiles

There are likely to be many different people and roles operating in the vaccination programme at different times and stages. It's important to try to identify them and map out their requirements and capabilities, particularly when it comes to managing performance. Our study showed that flexible communications are vital, because staff complement in vaccination teams can be fluid, dependent on individual working hours. That creates complexities in rostering, which mean that a single shift briefing may not reach all staff.



2. Consider tools and equipment

In *Vaccinating a nation: Ten human factors and ergonomics principles*, we highlighted the need for tools and equipment to be appropriate for the task, to be usable, and to be properly maintained. We also noted the need to consider, for every tool and piece of equipment, why it would be used, how it would be used and who would be using it, as well as how easy it would be to understand and use it. In our study, that translated directly into:

Checking Wi-Fi and mobile signals

Much of the communication between vaccination organisers and staff and patients may be via mobile phones. If a digital patient scheduling system is being used by many people at once it can compromise data speeds, which in turn can affect patient throughput and social distancing and may lead to data loss. It's therefore vital to undertake volume testing of Wi-Fi at new centres.

Creating usable scheduling and recording tools

Patient details must be accurate. Scheduling errors can create major operational difficulties in any programme, and on this scale have the potential to cause significant disruption. It is therefore essential that the patient details held by organisers are accurate and that patients are assigned to their most accessible vaccination centre – which may not be the one nearest their home.

Similarly, the vaccination management tool must record the correct patient information, make that information easily retrievable and require minimal training. The clinical assessment step (i.e. assessing a patient's suitability to receive the vaccine) includes a review of their vaccination history and reaction to allergens as well as other specific medical issues. A checklist aids the clinical assessment, and tools used should incorporate error flagging, for example when a patient has already received both initial vaccine doses.

We recommend involving usability experts in the design of scheduling and recording tools, and significant user testing prior to roll-out.

Avoiding common vaccination errors

Rather than relying solely on the skill and competence of the people administering the vaccine, there is a need to ensure the design and set up of vaccination centres is optimised to support error-free performance, by putting in place simple measures such as:

- Setting up separate clinics for different types of vaccine.
- Differentiating vials, syringes, and requisition forms for different types of vaccine (in addition to the labelling).
- Using syringes with specific maximum point markings and tactile feedback.
- Separating the storage of different types of vaccine.

3. Assess the physical environment

The vaccine is delivered via several different models, including vaccination centres, drivethroughs, roving services and specific venues such as care homes. In each case, the physical space needs to support check-in, clinical assessment, vaccination stations, clinical support, staff rest areas and material storage, which means assessing the following aspects of the physical environment:

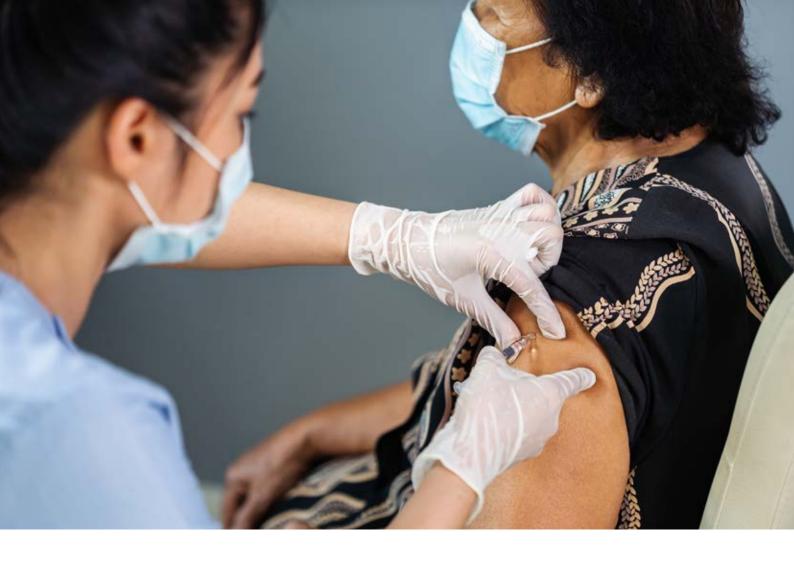
- Infection control, cleaning requirements and facilities.
- · Building heating (or facilities to keep warm).
- · Fire safety and emergency response.
- Staff welfare and hand washing facilities.
- Covid security according to venue size and layout and other considerations, such as separation from other activities..
- · Vaccine, equipment and staff security.
- Clean preparation areas.
- · Waste management facilities and waste collection.
- Post vaccination space due to the need to monitor patients for 15 minutes after the vaccine has been administered (may require a bigger venue or the reduced throughput).
- Marshalling. Requirements differ by venue regardless of the number of vaccinators and is driven by venue layout. (Areas with corners and stairs, for example, are more complicated).

Other location-specific risk controls may include the need to grit paths in icy conditions, flush water systems to avoid legionella issues, and organising hi-vis garments for low light or low visibility conditions.

NHS Ayrshire & Arran also considered the amount of footfall into hospitals and the need to avoid introducing infection.

Our learnings suggest the need to consider these additional contingency measures:

- Power failure (fridges and digital devices).
- Escalation protocols and facilities for emergency situation recording.
- · Spares for digital devices.
- Lighting, heating, ventilation, staff phones, chargers and having sufficient power sockets where they are required.



4. Describe the tasks people do

Vaccinating a nation: Ten human factors and ergonomics principles explained how to create task inventories by breaking down large scale tasks – such as managing appointment bookings – into their component parts, like so:

- · Inviting the patient.
- Booking in the patient.
- · Managing changes to bookings.
- · Managing scheduling across diverse settings (e.g. vaccination centres, hospitals, care homes).

Doing so enables reflection on potential process vulnerabilities, factors in the ways that work systems that might affect task performance, and highlights the types of training and support people might need.

5. Evaluate potential vulnerabilities

Once tasks have been identified and described thoroughly, it's possible to begin considering the wide range of performance shaping factors (PSFs) that might make errors more likely. These are the situations and circumstances, internal and external, that could have an impact on how people are able to perform their tasks. Our study identified examples such as:

- Pressure to maintain a high throughput of vaccinations.
- Not having an accurate patient list or record.
- Working a long shift.
- Starting work after the shift team briefing.
- Vaccination teams changing by shift.
- Having insufficient staff.
- 1 Lack of pre-warning on vaccine delivery dates.
- Change in national strategy.



IMPROVE

6. Re-design physical spaces, tools and tasks to enhance performance and reduce risk

An analysis of proposed work systems and set-ups within a physical space, as well as of the tools and tasks involved, will highlight weaknesses and allow for improvement before problems arise. Involving the people who are delivering the tasks using the tools within the spaces will not only help to identify weaknesses, but will also help find potential solutions. Some of the key improvements our study identified include:

Making vaccination centres Covid-secure, for example by:

- Setting up patient journey points for social distancing, e.g. entry areas, traffic routing, and waiting areas.
- Providing way pointers/signage, demarcation of areas and routes, seat labelling, patient information/instruction and separate dedicated sanitisation stations/ handwash facilities for patients and staff.
- Reinforcing marshalling. The requirements for marshalling will differ by building, but will
 involve using different access points, including fire exits, to support one-way routing.
 Marshalls will help to manage patient flow. Additional staff will be required to support that
 management during breaks or shift changeovers.
- Using external barriers/queue management systems for larger pedestrian centres.

Ensuring the usability and accuracy of tools

As we identified in section 2 above, assessing tool usability is essential. That means understanding end user needs, defining requirements, developing designs that meet those requirements and evaluating the design through user testing and compliance with requirements (see Figure 2¹).

For example, we know that inaccurate patient records create complications and potential for larger errors, which is why scheduling and recording tools should allow in-situ updating. Identity checks are also important — errors have been reported where family members with the same name have been mistaken for one another, where appointments have (or have not) been rescheduled or cancelled when required. Situations like these create vaccination errors, reduced throughput, bottlenecks and loss of social distancing.

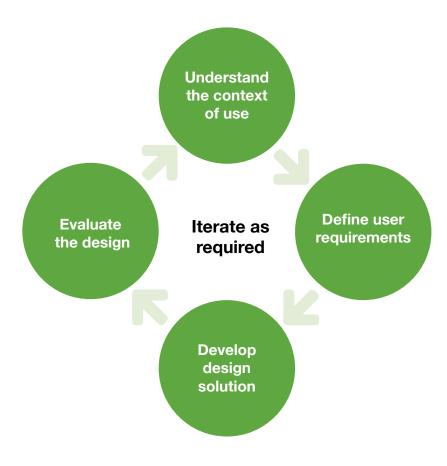


Figure 2: Usability Engineering

7. Develop usable work instructions

A **work instruction** is a simple, step-by-step description of how to do a task, supported by **job aids**, designed to support specific elements of that task. Analysing tasks, as outlined earlier in this document, delivers a hierarchical breakdown of each task, which in turn provides the structure for work instructions. Further analysis of vulnerabilities and risks for each task then highlights critical steps where a job aid might be helpful.

Both work instructions and job aids should be developed in collaboration with the people who are doing the work. The level of technical detail they provide should be proportionate to the level of experience and the complexity and risk profile of the task.

Layout, presentation and usability aspects are as important as content. They should be consistent and formulated to be accessible to as many users as possible. We suggest:

Preparing template work instructions

Prepare a template for standard operating procedures (SOPs) and guidance at a national level, for the whole system from set up, bookings, vaccinations and logistics to patient management, marshalling and cleaning and infection control.

Supplement work instructions

Supplement SOPs with posters and other stationary media. For example, a poster at the vaccination stations might show the correct vaccination method, useful for mentoring trainees. A roller banner at the exit point will remind patients to wait for 15 minutes before they leave.

Provide job aid flow charts for specific events

Anticipate events that could happen at vaccination centres, like fainting or anaphylactic reaction, and prepare and provide easy-to-follow job aids setting out the correct responses.

Simplify patient information

Patient information leaflets should follow a simple format with infographics and visual content to support patients who may be have difficulty reading. Make sure all information caters for a wide range of literacy/language comprehension and IT capability and access.

More detailed guidance on the human-centred design of work procedures can be accessed here: https://bit.ly/3jEJiGe

8. Design and deliver suitable training

Service delivery teams will include staff from various backgrounds and with varying skills and knowledge. That means training must provide standard elements, but also vary according to individual need. It may need to include varying levels of IT familiarisation and the use of scheduling, vaccination management recording, stock management and ordering tools.

The task analysis described in section 4 and the evaluation of vulnerabilities described in section 6 must feed into the training design. Work instructions (section 7) must align with and be used during the training.

It's also important to:

Reinforce training

by providing mentoring, supervision, and competence assessment.

Provide access to competence records

to those in charge of recruitment and rotas. Teams may vary from shift to shift and include staff coming and going at different times.



ADAPT

9. Monitor work-as-done and adapt to achieve sustainable change

As previously identified in *Vaccinating a nation: Ten human factors and ergonomics principles*, the scale of the challenge of delivering a national vaccination programme, together with the development of new vaccines and the threat of new variants of the virus, mean health systems have to be adaptive and agile in order to vaccinate the population safely and efficiently.

That means planning every step in advance is not only unlikely, it's also probably unhelpful. We must be able to adapt as circumstances change. Part of that will come from monitoring how tasks are actually being carried out by the people on the ground. Staff usually find good solutions to everyday challenges. These need to be documented, both so they can be analysed to ensure they don't introduce new risks, and so that the lessons they teach us aren't lost.

We would suggest that involves:

Coordinating lesson capturing

Lessons need to be captured and linked at all levels of the service delivery hierarchy. Daily meetings of the governance team will enable capturing of issues and identification of changes to work-as-imagined. Daily team briefings and de-briefings (also known as safety huddles) within delivery teams enable capturing of issues and changes in work-as-done. It's essential that there is a strong and coherent link between the frontline and governance teams.

Embed the learnings

Lessons can be captured and embedded in work procedures and instructions, through training, and in regular communications such as briefings, huddles, job aids and public communications.

10. Record and learn from incidents

Systems with the size and complexity of that required to vaccinate a nation are extremely unlikely ever to be delivered without incident. Even the best planning and the best system design is subject to factors like unintentional 'human error', IT failure, information shortages and more. However, each incident we encounter gives us valuable insight and learnings to take forward into future planning and adaptation, which is why it is vital to ensure we record, analyse, learn from and share these, every time.

The governance team of the operation will provide the central point of coordination between service delivery teams in individual healthcare organisations and the national NHS team (figure 3). That ensures lessons can be collated and shared in both directions.

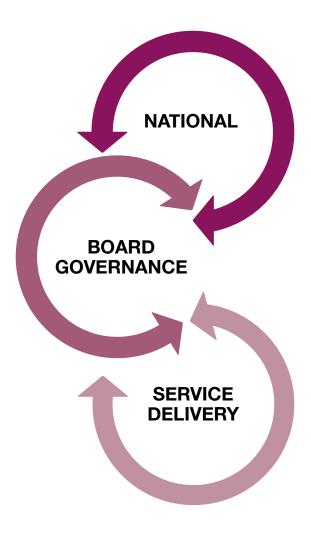


Figure 3: Two-Way Communication of Lessons

What we've learned

In the UK, the order of the vaccination roll-out was based on patient risk according to age and underlying health conditions. The Scottish Government published a Service Delivery Manual, which also classified patients in four groups: care home residents, health and social care workers, patients over 80 years old, and the general population.

The intention was to capture the different delivery requirements of each patient group, and to create a national strategy that would guide the roll-out of the vaccination programme.

While there is an advantage to having a national strategy, it is equally important to remember some key additional considerations:

- We must recognise that patients and staff in different regions, even different communities, will have different requirements. Service delivery cannot possibly be uniform across an entire nation. The model of delivery must be adaptive and flexible.
- Service delivery is, ultimately, dependent on vaccine supply. Patient scheduling and other logistics can only be implemented once supply is understood at a local level.
- Changes to the strategy (such as changing patient cohorts or altering the interval between the first and second vaccine) can have huge impacts on roll-out, and increase the risk of things going wrong.
- It's vital to set up governance teams who will oversee the roll-out at local and national levels and take responsibility for ensuring delivery of principles and practical efforts that create a successful vaccination programme.

The key learnings we have identified for the start of a national vaccination programme are:

- Appoint a dedicated, multi-disciplinary governance team to scope, define, implement, and test the vaccination system. Include user acceptance testing (i.e. verifying that solutions work for users) for every part of the system.
- Ensure the correct specific roles are represented in the governance team: clinical, logistics, pharmacy, IT, health & safety and centre set-up. Involve estate management from individual healthcare agency partnerships (e.g. to review leasing agreements) and consult with local people.
- Have the governance team meet routinely, e.g. daily.
- Clearly define the command and control structure, as well as the roles and responsibilities of the various service delivery teams (e.g. booking, vaccination, logistics, infection control). This includes establishing and defining the authority of team leaders at the vaccination centres.
- Start recruitment early and ensure expectations for the roles are clearly stated and defined. A multi-area service requires flexible service delivery and specific hours of work. Candidates need to be able to meet those. Appoint staff well in advance of the roll-out to allow time for training and competence development. Large-scale training and mobilisation of staff requires significant time and resources.

- Maintain communication between national government and health board teams, ensuring specific delivery requirements are understood and accurately documented for effective handover between representatives at both levels.
- Develop internal and external communications strategies. Set up a call centre at the onset of the programme to manage high volumes of calls from the public.
- Identify and review the best locations to administer vaccines. Clarify the different requirements for different types of venue.
- Implement, test, and improve scheduling tools prior to roll-out.
- Ensure patient lists are accurate and provide the means to update records/improve accuracy in situ. (NHSAA used Community Health Index (CHI) numbers to identify patients).
- Develop a management plan for logistics, stock management and backup supplies as well as centre set up and pharmaceutical and equipment consumables.

One final lesson

Human Factors and Ergonomics specialists offer services and support at every stage of planning and delivery of your projects, whether they're national vaccination programmes or individual projects for single organisations. CIEHF will help you to connect with suitably qualified specialists for your project, and you can contact them via their website at ergonomics.org.uk.

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