Why you should read this article:

- To be aware of the importance of safe vaccination practice in avoiding vaccine-related adverse events
- To understand the principles of safe vaccination practice
- To enable you to use the '8Rs' checklist to avoid vaccine-related adverse events

Using the '8Rs' checklist to support safe vaccination practice

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Abstract

Safe vaccination practice is essential to reduce the risk of vaccine-related adverse events, ensure vaccines are administered safely and maintain a high level of confidence in vaccination programmes among the general public and healthcare practitioners. This article focuses on safe vaccination practice in relation to the routine vaccination programme, as well as considering vaccination against coronavirus disease 2019 (COVID-19). It provides examples of vaccine-related adverse events and explains how using the '8Rs' checklist can promote patient safety and reduce the risk of such events.

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Keywords

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VACCINES PROVIDE protection against certain infectious diseases, as well as reducing the risk of associated complications, hospital admissions and death from these diseases. The first vaccine was developed for smallpox in 1796, and vaccines have subsequently been introduced for a range of other diseases, including polio, cholera, tuberculosis, measles, tetanus, influenza and human papillomavirus (UK Health Security Agency (UKHSA) 2020), as well as coronavirus disease 2019 (COVID-19). Since then, many new vaccines have been developed and a national vaccination programme known as the Complete Routine Immunisation Schedule has been put in place in the UK (UKHSA 2022a). This programme is lifelong, although most routine vaccines are administered in childhood.

Some people may be at higher risk of exposure to specific vaccine-preventable infectious diseases due to their lifestyle, occupation and/or the countries they travel to, or they may have a medical condition that increases their risk of complications from certain diseases or be prescribed medicines that affect their immune system, leaving them vulnerable to preventable diseases (UKHSA 2022b). In such instances, additional vaccines may be recommended or certain vaccines, such as live vaccines, may be contraindicated.

As people age, their immune system gradually deteriorates and has a decreased capacity to respond effectively to infections or vaccines (Crooke et al 2019). This has led to the development of vaccines such as the adjuvanted quadrivalent influenza vaccine, which is specifically recommended for those aged 65 years and older because it can provoke a stronger immune response in this age group (Centers for Disease Control and Prevention 2021).

Nurses are required to have the knowledge, skills and competence to deliver safe and effective vaccinations (Public Health England (PHE) 2018). This means that an understanding of the different vaccines available, their

indications for use and how to store them correctly to avoid compromising their quality is essential to ensure that patients receive effective protection against certain diseases.

Vaccine-related adverse events

The Health and Safety Executive (1999) described human factors such as time pressures, competence levels, resources, workload and communication issues that can result in unintended actions or mistakes occurring in the workplace. In a vaccination clinic, examples of unintended actions or mistakes may include errors in vaccine selection, preparation, checking a patient's history, scheduling or administration. Although such incidents may occur due to a healthcare practitioner's lack of knowledge or experience, they can also occur during routine procedures that are familiar or when a lapse in concentration occurs.

The World Health Organization (WHO) (2013) developed five categories to describe adverse events following vaccination:

- Vaccine product-related reactions – caused by an inherent property of the vaccine.
- Vaccine quality defect-related reactions – caused by defects in the quality of the vaccine as supplied by the manufacturer, including the administration device.
- Immunisation error-related reactions – caused by inappropriate handling, prescribing or administration.
- Immunisation anxiety-related reactions – where symptoms are related to anxiety about the vaccine rather than the product itself.
- Coincidental events – which appear to be side effects of the vaccine but are caused by something else.

Some vaccine responses may appear to be an adverse event but are actually expected reactions, such as pain, redness or tenderness at the injection site, fever or headache. These reactions are usually mild and last for only a few days. For example, an expected reaction to the Bacillus Calmette-Guérin (BCG) vaccine is a small blister at the injection site that may be painful and might ooze for several days, then eventually heal and leave a scar.

A systematic review of vaccination incidents by the National Patient Safety Agency* (NPSA) (2008) identified that in 2007 there were 949 incidents relating to children aged under 18 years. Following a detailed analysis, the NPSA (2008) recommended that improvement was required when checking whether a patient had previously received the vaccine being given and when documenting the vaccines administered in patient records.

Lang et al (2014) analysed 4,301 calls to a vaccine advice service in England, finding that around 4% (*n*=158) of calls concerned vaccine errors and 92% (*n*=145) of those calls concerned immunisations delivered in primary care. Analysis revealed that 51% (*n*=80) of errors occurred during either vaccine selection or preparation, while 41%, (*n*=64) occurred during history checking and scheduling. The most frequent error recorded was administering the wrong vaccine (33% of reports, *n*=52), 13 of these errors were a result of mixing up vaccines that shared the same first letter. Other errors occurred during consultations with pairs of siblings (*n*=7) and when healthcare practitioners failed to revaccinate the patient following a vaccine spillage (*n*=7).

Between April 2019 and March 2020, patient safety incidents related to medication accounted for around 10% (*n*=222,494) of reports made to the National Reporting and Learning System in England and Wales. However, the most commonly reported degree of harm resulting from the incidents related to medication was 'no harm' (88%) (National Reporting and Learning System 2020, NHS England and NHS Improvement 2020).

For vaccine-related incidents, the potential for harm from administering an incorrect vaccine depends on the individual and which vaccine has been administered (UKHSA 2017). Although administering an incorrectly stored vaccine is unlikely to cause harm, an individual may have a suboptimal response to it and their risk of disease may subsequently be increased because they may not develop the expected protection from the vaccine. However, administering a live vaccine to an immunosuppressed patient could have severe consequences as the virus or bacteria could replicate unchecked, causing severe infection (UKHSA 2017).

Safe vaccination practice and the '8Rs' checklist

The Code: Professional Standards of Practice and Behaviour for Nurses, Midwives and Nursing Associates (Nursing and Midwifery Council (NMC) 2018) requires all nurses to prioritise people and preserve their safety by ensuring that they, and any staff they are responsible for, have the knowledge, skills and competence to deliver safe and effective practice.

To reduce the risk of common vaccine errors, the Royal College of Nursing (RCN) (2021) has updated its best practice guidelines to provide a practical approach

Key points

- It is essential that nurses understand the different vaccines available, their indications for use and how to store them correctly to ensure that patients receive effective protection against certain diseases
- The '8Rs' checklist supports safe vaccination practice, and comprises: right patient; right to give the vaccine; right dose; right vaccine (and diluent if required); right time; right route; right site; and right documentation
- Before vaccinating patients, healthcare practitioners need to ensure there is a safe clinical environment for the consultation, personal protective equipment is available and used as required, and all relevant policies and procedures are followed
- Strict adherence to vaccine storage recommendations is required because non-adherence can compromise the quality and effectiveness of the vaccine and fail to deliver the expected immune response

that healthcare practitioners can use before administering a vaccine at childhood immunisation clinics. These guidelines can also be applied in other settings, such as when vaccinating adults against COVID-19. The RCN (2021) guidelines include a checklist comprised of '8Rs':

- Right patient.
- Right to give the vaccine.
- Right dose.
- Right vaccine (and diluent if required).
- Right time.
- Right route.
- Right site.
- Right documentation.

Checking these 8Rs before administering a vaccine may assist healthcare practitioners to adhere to safe vaccination practice.

Right patient

Verifying the patient's identity and the vaccines that they are attending the clinic to receive is a crucial part of the vaccination process. It is important to avoid any confusion when siblings are seen together, as this has been identified as a cause of errors (Lang et al 2014).

Right to give the vaccine

The Immunisation Against Infectious Disease document – commonly referred to as The Green Book – advises that 'almost all individuals can be safely vaccinated with all vaccines' (UKHSA 2017). However, although a vaccine may be recommended for a specific age or population group, it would be contraindicated if an individual has a history of a previous anaphylactic reaction to it or to any of its components. Specific vaccines may need to be deferred or avoided in certain patient groups.

Live attenuated vaccines are contraindicated for pregnant women and for patients with immunosuppression caused by an underlying medical condition or treatment. In patients who are immunosuppressed, live vaccine strains, although attenuated, can replicate once administered and may cause an infection that can be extensive, severe or in some cases fatal (Medicines and Healthcare products Regulatory Agency (MHRA) 2016).

In 2016, the MHRA received four reports of neonatal deaths from disseminated BCG or tuberculosis infection after exposure to a tumour necrosis factor-alpha antagonist in utero. As a result, they published an update stating that 'any infant who has been exposed to immunosuppressive treatment from the mother either in utero during pregnancy or via breastfeeding should have any live attenuated vaccination deferred' (MHRA 2016). In the same year, notifications were made following the administration of shingles vaccine to older patients with immunosuppression who experienced possible disseminated viral infection caused by the vaccine, prompting a reminder to be aware of the 'special precautions associated with the shingles vaccine before proceeding with immunisation' (MHRA 2016). Two reports of fatal adverse reactions to yellow fever vaccines in 2019 led to warnings that 'yellow fever vaccine is contraindicated in any person who is immunosuppressed' (MHRA 2019a, 2019b).

An evaluation of newborn screening to identify severe combined immune deficiency has been introduced for babies born in certain regions of England (UKHSA 2021). Although it is important that babies with severe combined immune deficiency are appropriately vaccinated, they should not receive live vaccines such as the BCG and rotavirus. The UKHSA (2021) has published an algorithm for the process of checking for severe combined immune deficiency screening results at the routine eight-week vaccination appointment.

The Complete Routine Immunisation Schedule (UKHSA 2022a) details who should receive vaccines, what diseases these protect against, at what age they should be given, and the site and route of administration. The healthcare practitioner also needs to check that vaccines are not contraindicated for each patient by consulting The Green Book and any patient group directions (UKHSA 2020, 2022c).

Right dose

All vaccinations offered as part of the UK's routine vaccination programme are presented as a standard dose, usually in a single-use pre-filled device such as a syringe for injection or an applicator for oral or nasal administration. When using such devices, the full dose should be administered and it is unusual for an incorrect dose to be given unless the healthcare practitioner inadvertently administers a partial dose. Some vaccines such as the BCG and COVID-19 vaccines are presented in multi-dose vials and healthcare practitioners must be familiar with the correct dosing schedule for children and adults, as described in the national protocols in The Green Book (UKHSA 2022b) or in patient group directions.

While the administration of a greater than recommended dose will not usually affect the patient's immune response or their protection against a disease, it may increase

the risk of an adverse reaction. When a lower than recommended dose is administered, for example if vaccine leaks out at the injection site during administration, it may be recommended that the dose is repeated as an incomplete dose may not elicit the required immune response. Healthcare practitioners should seek further advice before revaccinating as repeat doses of specific vaccines may not be recommended due to the risk of significant local reaction and because some vaccines, such as the BCG, may lead to keloid scarring. Further information on responding to vaccine errors is included in the vaccine incident guidance published by PHE (2021a).

Right vaccine (and diluent if required)

In Lang et al's (2014) study, the most common error recorded was the administration of the wrong vaccine, with errors occurring during vaccine selection and preparation. This can occur when there are vaccines in the medical refrigerator with similar packaging, with similar names or with names that share the same first letter.

The Visual Guide to Vaccines poster (UKHSA 2022d) shows images of the vaccines used in the routine vaccination programme in the UK. The images show four vaccines in similar blue and white packaging, four with a name ending in 'rix' and two different vaccines that protect against pneumococcal disease with different age indications. There are several influenza vaccines available, also with different age indications. To minimise the risk of the wrong vaccine being selected, Lang et al (2014) suggested separating paediatric and adult vaccines in the fridge and labelling vaccines with a warning to check that the dose is age appropriate.

Some vaccines will require reconstitution. All parts of these vaccines should be correctly reconstituted and only the diluent supplied with the vaccine should be used. An example of such a vaccine is Infanrix hexa, which is given to infants to protect them against six childhood diseases: diphtheria, tetanus, pertussis (whooping cough), polio, *Haemophilus influenzae* type b and hepatitis B. Failure to use the correct diluent would mean that the infant does not receive protection from *Haemophilus influenzae* type b as this is contained in the powder component of the Infanrix hexa vaccine.

Right time

Healthcare practitioners must follow the age-based recommendations of the routine vaccination programme, which are informed by several factors, including (UKHSA 2020, 2022b):

- Age-specific risk for a disease.
- Risk of complications from the disease.
- Ability of the individual to respond to the vaccine.
- Effect on population transmission.

To optimise protection against certain diseases, routine vaccines are administered before the age of greatest risk. Although the routine childhood programme begins at eight weeks of age, maternal vaccination provides the unborn baby with protection against disease in the first weeks of life (Campbell et al 2015).

Pertussis, influenza and COVID-19 vaccines recommended for pregnant women are to protect the woman herself, to protect the unborn baby as it develops passive immunity from the transfer of maternal antibodies, and to protect the infant from transmission of infection from the mother following birth. Maternal vaccinations should be administered at the recommended stage of pregnancy. It is recommended that pregnant women are vaccinated against COVID-19 as soon as possible (UKHSA 2022e), while an influenza vaccine can be administered at any stage of pregnancy and the pertussis vaccine is recommended from 16 weeks of pregnancy (NHS 2019a, 2019b). Delaying vaccination leaves the pregnant woman at risk of infection and may compromise the passive immunity given to the infant if it is born before optimal transfer of maternal antibodies has taken place.

Some of the vaccines in the routine programme require a series of doses with recommended intervals between them. This is to enable a primary response to develop so that future doses stimulate the immune system to produce a secondary response. Administering a vaccine with less than the recommended interval from the previous dose may lead to a reduced response to the vaccine. Booster doses should also be given at the correct intervals to ensure optimal and long-lasting protection (PHE 2021a).

It is important to ensure that a vaccine is used before it reaches its expiry date, which is usually determined by adding the shelf-life period to the date of manufacture. Although it is unlikely that a vaccine would lose all potency on reaching its expiry date, revaccination may be recommended for a patient if an expired dose was inadvertently administered to them. Since most vaccines tend to have a shelf life of a few years, those that have reached their expiry date will have had a prolonged time in storage and may be more vulnerable to degradation (PHE 2021a).

Right route

A vaccine can be administered via the intramuscular (IM), subcutaneous, intradermal, oral or intranasal route. If administered via an incorrect route, the vaccine may not elicit an optimal immune response. If vaccines containing adjuvants are administered subcutaneously, there may be an increased risk of a local reaction or formation of a granuloma at the injection site (Plotkin et al 2008).

All injected vaccines given as part of the routine vaccination programme are recommended to be given via the IM route, so healthcare practitioners should check the site of administration and the needle length before administration (Plotkin et al 2008, UKHSA 2022a).

A Cochrane review by Beirne et al (2018) explored the effect of needle size and gauge on immune response to a vaccine, pain experienced during the vaccination procedure and occurrence of reactions after vaccination. The authors advised that 'choosing an appropriate length and gauge of a needle may be important to ensure that a vaccine is delivered to the appropriate site and produces the maximum immune response while causing the least possible harm'. They concluded that for IM injections, using 25mm needles (23G or 25G) 'probably reduces the occurrence of local reactions while achieving a comparable immune response to 25G 16mm needles' (Beirne et al 2018).

Right site

A full assessment of the area that the vaccine will be administered into should be conducted to find the anatomical markers that will help to identify the correct injection site. The deltoid muscle in the upper arm is the recommended site for those over the age of one year because this muscle is usually sufficiently developed by this age. If there is insufficient muscle mass at the site of the deltoid then an alternative site, such as the anterolateral aspect of the thigh, may be used. The recommended site for infants under the age of one year is the vastus lateralis muscle in the anterolateral aspect of the thigh.

Using the correct technique and landmarking the injection site for the administration of an IM injection can optimise the response to the vaccine and help to avoid bruising, shoulder injury, pain and reduced range of motion at the joint (Bancsi et al 2018). If the vaccine is administered at the wrong site, then a more severe or prolonged reaction may be experienced (Plotkin et al 2008).

Occasionally, there may be challenges accessing the correct site for vaccination, for example when vaccinating an infant in a hip spica cast. It may be possible for vaccines to be administered when the infant's cast is being changed, or a window could be cut in the cast for the injection and then reapplied. If that is not possible and vaccines are administered in the deltoid muscle, consideration will need to be given to the needle size, the location of the radial nerve (since it is more superficial in infants), and the injection technique. If more than two vaccines are to be administered into a single muscle, a gap between injection sites of 2.5cm is recommended to enable vaccine identification in the event of a local reaction (Australian Government Department of Health 2021).

Right documentation

Vaccines are prescription-only medicines and a legal framework for their supply and administration is required to be in place. This may be in the form of an individual prescription, a patient-specific direction, patient group directions or a national protocol.

National patient group directions templates are published for vaccines recommended as part of the national vaccination programme. These documents require local sign-off by an appropriate authorising person before use. They contain full details of the vaccine and outline inclusion and exclusion criteria for each of them. Assessing patients against the exclusion criteria in the patient group directions should identify those who are not eligible to receive the vaccine and those with clinical contraindications.

Once administered, details of the vaccination should be carefully and accurately recorded in the digital clinical care system using the correct codes and in the personal child health record (the red book). This can help to avoid duplicate doses being administered, identify the cause of any local reaction that may occur and facilitate patient identification in the event of a product batch recall.

All patients should be informed about expected reactions following vaccination, advised on actions to take if they have any concerns, and receive or be signposted to further information. Information for healthcare practitioners and leaflets for patients and parents are available to download at: www.gov.uk/government/collections/immunisation.

Any adverse events following vaccination should be documented and can be reported by patients or healthcare practitioners via the MHRA's (2021a) Yellow Card scheme. Side effects are usually mild and quickly resolve but rarer serious effects, such as

anaphylaxis, may require hospital treatment and would mean that future doses of the same vaccine are contraindicated. The COVID-19 Yellow Card reporting site (coronavirus-yellowcard.mhra.gov.uk) should be used to report any side effects from COVID-19 vaccination (MHRA 2021b).

Training and competence in administering vaccines

There are various factors that healthcare practitioners need to consider before vaccinating patients. These include ensuring that there is a safe clinical environment for the consultation, personal protective equipment (PPE) is available and used as required and all relevant policies and procedures are followed. There should also be a safe system to store vaccines and manage waste, for example expired vaccines and equipment used to administer vaccines, such as vials, syringes, sharps and packaging.

The national minimum standards and core curriculum for immunisation training for registered healthcare practitioners (PHE 2018) and healthcare support workers (PHE 2015) describe the minimum training that those involved in any aspect of vaccination should receive. Further recommendations have been published to support the delivery of the influenza vaccination programme amid concerns about co-circulation of influenza and COVID-19 (PHE 2021b, 2021c, UKHSA 2022f).

A range of immunisation e-learning courses have been developed and are available at: www.e-lfh.org.uk. It is recommended that healthcare practitioners who are new to administering vaccines work with a supervisor or trainer until they feel confident that they have the necessary knowledge and skills.

The training recommendations include a competency assessment tool and it is recommended that healthcare practitioners who are experienced in vaccination self-audit against the competencies described, although additional competencies may be required depending on the locality or service area (PHE 2018).

Vaccine storage and handling

All healthcare practitioners with a role in vaccination have a responsibility to ensure these products are correctly stored and handled before use. On receipt of a vaccine delivery, strict adherence to storage recommendations – usually within the temperature range of 2°C to 8°C – is required because non-adherence can compromise the quality and effectiveness of the vaccine and fail to deliver the expected immune response (PHE 2021a). If revaccination is required, there may be an increased risk of adverse reactions with additional doses of the vaccine (PHE 2021a).

Incorrect storage and transportation of vaccines leads to increased waste and unnecessary costs. During 2019, vaccine wastage in England voluntarily reported via ImmForm was estimated at £5.8 million based on list price (PHE 2020). Most of the reported incidents were avoidable and more than half of them occurred due to the failure of refrigeration equipment or from the influenza vaccine Fluenz Tetra expiring before it could be used. Regular deliveries and stocktaking ensure there is a sufficient supply of the correct vaccines and should minimise the risk of administering expired stock.

COVID-19 vaccines have vaccine-specific storage recommendations and although most of them continue to be stored and handled correctly, cold chain breaches have occurred. All vaccination sites and GP surgeries should ensure that the following best practice procedures for cold chain management are in place and being adhered to (PHE 2021a):

- Vaccines should be stored in an electric-powered medical refrigerator as these have an inner lining designed to maintain the recommended 2°C to 8°C temperature range.
- The fridge temperature should be recorded before clinics start and at the end of the day to ensure vaccine storage breaches can be identified before any potentially compromised vaccines are administered.
- All fridges should have two thermometers, one of which is a maximum and minimum thermometer independent of the mains power to enable recording in the event of a power cut. If only one thermometer is used, a monthly check should be undertaken to confirm that the calibration is accurate.
- All healthcare practitioners involved in vaccinations should know how to access the fridge temperature history. Any deviations from the recommended range should be acted on immediately.
- Fridge servicing and calibration should be undertaken annually.

PHE (2021a) has published guidance on how to respond to vaccine storage and handling incidents and errors in vaccine preparation and administration. Where there is any uncertainty, for example regarding new vaccines, incident-specific or vaccine-specific advice should be sought. Chapter three of The Green Book also includes further guidance on the storage and management of vaccines (UKHSA 2013).

Conclusion

Adhering to safe vaccination practice reduces the number of adverse events and maintains confidence in vaccination programmes among the general public and healthcare practitioners. Safe vaccination practice includes an assessment of the patient and their eligibility to receive the vaccine, confident and competent healthcare practitioners who are familiar with the programme, and vaccines that have been correctly stored and managed so as to not compromise their potency.

It is essential for all healthcare practitioners involved in vaccination to maintain their knowledge and skills and keep up to date with relevant practice and training. Using the 8Rs checklist during vaccination appointments can enable healthcare practitioners to reduce the risk of errors and protect patients from various diseases.

*The patient safety functions of the National Patient Safety Agency are now undertaken jointly by NHS England and NHS Improvement

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