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Dear Colleague

National Framework for Vaccine Administration by Healthcare Support Workers in Scotland V2.0 (July 2021)

1. In 2018, NHS Boards requested that the Vaccine Transformation Programme Steering Group look into the use of Healthcare Support Workers (HCSWs) nationally and provide a framework to aid local decision making on the safe and legal use of this staff group for vaccination programmes in Scotland. The National Framework for Vaccine Administration by HCSW in Scotland was published in July 2020, with a one year review date.
2. The updated National Framework has now been refreshed and updated to support employers in considering the professional and legal aspects of utilising the HCSW workforce in vaccination administration in Scotland.
3. HCSWs are a vital part of the workforce and support the delivery of health and social care services as part of the multi-disciplinary team. The role of and use of HCSWs as Vaccinators has developed significantly over the past months. This has been in response to both the introduction of regulation 247A, which permits HCSWs to administer Flu and COVID-19 Vaccines during the pandemic and the need to ensure that we have a sufficiently sized multi-disciplinary workforce to deliver the future vaccination programme, including Flu and COVID-19.
4. The learning, developments and positive impacts that have arisen from the increased inclusion of HCSWs in multi-disciplinary vaccination teams was considered by the reconvened short life working group in the 2021 update of the National Framework. These have resulted in additional vaccines and additional age cohorts, coming into scope for administration by HCSWs. Administration by HCSW vaccinators who are deemed proficient and confident in the role, will continue to be under the

**From the Deputy Chief
Nursing Officer Designate**

Anne Armstrong

30 August 2021

DL (2021) 27

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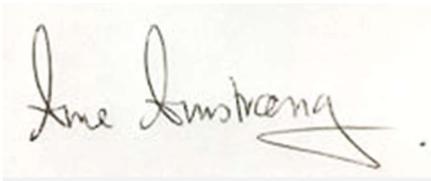
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supervision of registered healthcare professionals.

5. The legislation surrounding the supply and administration of medicines is reserved, meaning it applies across all nations of the UK. Providing the provisions of the Human Medicines Regulations are met, then the administration of medicines by HCSW is lawful from the Scottish legislative context.
6. The National Framework provides employers with information to support the use of HCSWs in administering vaccines. It does not intend to provide a definitive model for all situations, rather a set of principles to be followed. It should be used a part of the suite of resources available, including the National HCSW Vaccinator Job Description and the NES/PHS Education materials available on [TURAS](#).

Yours sincerely

A handwritten signature in black ink on a light-colored background. The signature is cursive and reads "Anne Armstrong".

Anne Armstrong
Deputy Chief Nursing Officer Designate

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**National Framework for Vaccine Administration
by Health Care Support Workers (HCSWs) in
Scotland**

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Government

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Preface

In Scotland, as part of the implementation of the new GP contract that came into force in April 2018, a Vaccine Transformation Programme was established to move the delivery of vaccinations away from a GP delivery model to one based on NHS Board/Health and Social Care Partnership (HSCP) delivery. While mixed progress has been made overall with progress towards delivering the commitments of the new GP contract, it is notable that the Pandemic has had an impact upon the implementation and transfer of services. All vaccination and immunisation arrangements that are part of the core GP contract are now to be removed from the regulations by October 2021, with full transition by April 2022.

At the initial point of implementation, the biggest challenge faced was how to deliver the annual adult flu vaccination programme which requires over 70% of the vaccine doses given in Scotland per annum to be targeted to over 2 million people, primarily within a two-month time frame in the winter. The scale of this delivery challenge led NHS Boards/HSCPs to explore the use of Health Care Support Workers (HCSWs), as part of their local vaccination teams, to ease the pressure on the registered practitioner workforce, particularly during the winter months.

HCSWs were already being used for the delivery of some vaccination programmes in England & Wales and by some primary care practices in Scotland. The Royal College of Nursing (RCN) published a helpful guidance on *Health Care Support Workers Administering Inactivated Influenza, Shingles and Pneumococcal Vaccines for Adults and Live Attenuated Influenza Vaccine (LAIV) for Children* (initially in 2015 with version 3 updated in 2019) in line with the *National Minimum Standards and Core Curriculum for Immunisation Training of Health Care Support Workers* (Public Health England, 2015) which have both been adopted in England and Wales but not in Scotland.

The role of HCSW vaccinators has developed significantly over the past months, to support delivery of Flu and COVID-19 vaccines during the pandemic. In order to ensure that the UK has a sufficiently sized workforce to deliver a COVID-19 vaccine programme, changes to the Human Medicines Regulations (The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020), brought about a new regulation (247A). While a disease is pandemic, regulation 247A permits the supply or administration of a medicinal product used for vaccination or immunisation against coronavirus or influenza in accordance with a protocol that is approved by ministers. The national protocols allow specified classes of people, which need not be limited to registered healthcare professionals, to administer COVID-19 or influenza vaccine. This includes HCSWs.

Scottish Executive Nurse Directors (SEND) issued a Framework for the administration of medicines to adults by Health and Social Care employed Support Workers in September 2020. This supports the administration of medicines by Healthcare Support Workers and refers to the administration of medicines in general. It is complementary to this guidance on vaccination.

In 2018, NHS Boards requested that the Vaccine Transformation Programme Steering Group look into the use of HCSWs nationally and provide a framework to aid local decision making on the safe and legal use of HCSWs for vaccination programmes in Scotland. The

National Framework for Vaccine Administration by HCSW in Scotland was published in July 2020, with a one year review date. The original short life working group was re-established to take this review forward to 31st March 2022, when the amendments to the Human Medicines Regulations are due to end. The review group encompassed:

- The Scottish Government Chief Nursing Officer (CNO) Directorate;
- The Scottish Government Chief Medical Officer (CMO) Directorate;
- Scottish Government Vaccine Transformation Programme Team;
- Scottish Government Public Health Policy Team (Vaccination);
- Scottish Government Primary Care Directorate;
- The Royal College of Nursing (principal UK professional body for nurses, representing the interests of nurses across the UK);
- NHS Education for Scotland;
- Health Protection Scotland;
- NHS Board VTP Business Change Managers from NHS Orkney, Fife and Greater Glasgow & Clyde (small, medium and large demographic areas);
- Scottish Partnership Forum
- NHS Board Nurse Directors

Development of this updated Framework document has been highly collaborative. Approval was sought and given by the RCN to adapt and customise their guidance document adopted in England & Wales for the context in Scotland.

Acknowledgements

The authors would like to thank all individuals and organisations that were part of the Short Life Working Group and contributed to the development and production of this publication. We would like to express our gratitude to the Royal College of Nursing for their support and for allowing us to adapt and customise their original guidance for use in Scotland. Finally, we would like to acknowledge the support and input from the Royal College of Midwives and the Scottish Executive Nurse Directors group in compiling this document.

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1.0 Introduction: Why is the framework needed?

Moving forward with the Vaccine Transformation Programme in Scotland, as originally outlined in the 2018 GMS Contract, delivery is now expected to be completed by April 2022, the time extension having been extended due to COVID-19 Pandemic. Responsibility for transition remains with Health and Social Care Partnerships and NHS Boards.

1.2 Transitioning to New Vaccination Models

COVID-19 has expedited processes and changes to workforce and skill mix as well as accommodation, IT systems and infrastructure. Amendments to the Human Medicines Regulations (2012) have also made possible the administration of Flu and COVID-19 Vaccines at greater capacity by HCSWs.

Reviewing changes and process that have occurred since the inception of COVID-19 Immunisations have led to a better understanding of how HCSWs can be part of the multi-disciplinary vaccination service and team.

Looking toward a sustainable vaccination programme for Scotland, it is recognised that there is a need to embed this role in practice, whilst acknowledging the limitations both legally and professionally.

1.3 The Scale of the VTP Workforce Challenge

The biggest challenge to the Vaccine Transformation Programme in Scotland is how to deliver its extended annual flu vaccination programme concurrently with the potential COVID-19 vaccine booster programme, and COVID-19 first and second dose vaccinations to new eligible individuals, whilst continuing to deliver Scottish Immunisation Programme Vaccines to children and adults

The scale of this challenge has led NHS Boards/HSCPs to implement, embed and grow the use of Health Care Support Workers (HCSWs) as part of their local vaccination teams, to ease the pressure on the registered healthcare professional workforce.

2.0 Purpose

NHS Boards requested that the VTP Steering Group consider the use of HCSWs nationally, to provide a framework to enable and aid local decision making on the safe and legal use of HCSWs to support delivery of vaccination programmes in Scotland.

The purpose of this document is to provide employers with a Framework and principles to help make informed decisions about implementing the use of HCSWs to administer vaccines as outlined.

The document does not intend to represent or direct a definitive model for all situations but rather it outlines a set of principles to be followed if consideration is being given to HCSWs involvement in supporting the delivery of specific vaccination programmes by employers.

3.0 Definitions

The following are a guide to the terminology used throughout this document which aligns to those used by the Royal College of Nursing:

- **Health Care Support Worker (HCSW)*** - The term HCSW is used throughout this Framework to include all non-statutory registered staff that may be involved in administering vaccinations.
- **Prescriber** - The term 'prescriber' refers to a registered practitioner who is an independent prescriber, registered medical practitioner or registered dentist who is responsible for issuing the prescription or patient specific direction (PSD).
- **Registered healthcare professionals** – This terminology encompasses all those practitioners, including registered nursing, medical practitioners; pharmacists, allied health professionals and registered dentists, who may be involved in the support and supervision of HCSWs.

* For the purposes of this framework the following healthcare professionals and non-registered practitioners are permitted to administer under the National Protocols for Flu and COVID-19 and therefore all of the following should be considered as Health Care Support Workers

- Pharmacy technicians, provisionally registered pharmacists, pre-registration pharmacists and other pharmacy support practitioners.
- Retired clinical practitioners such as doctors, dentists, pharmacists, nurses, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, Orthotists/Prosthetists, paramedics, pharmacy technicians, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered.
- Student doctors, dentists, pharmacists, nurses, midwives, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently

- registered.
- Healthcare Scientists.
- Dental nurses.
- Physician's assistants.
- Non-Registered Armed Forces staff: Combat Medical Technician – Class 1,2 &3, (CMT), Royal Navy Medical Assistant (RN MA) , Royal Air Forces Medic, Defense Medic, Healthcare Assistant (HCA), Military General Duties Vaccinators

4.0 Scope

This publication applies to Scotland within the following parameters of scope.

4.1 In Scope

Currently, the vaccines listed below are within the scope of the Framework:

Influenza Vaccine:

Live Attenuated Influenza Vaccine (Fluenz Tetra) for children (non-injectable)*
Inactivated influenza vaccine for school age children and adults.

Pneumococcal

Pneumococcal Polysaccharide Vaccine (Pneumovax®) for those aged 65 Years and older and those aged 18 to 64 Years in clinical risk groups.

Pertussis

Pertussis containing vaccine(s) for pregnant women.

COVID-19

All COVID-19 Vaccines for those of school age and over, as outlined in The Green Book.

Shingles

Inactivated Shingles Vaccines , as outlined in The Green Book

4.2 Out of Scope

The Framework supports HCSWs to administer those vaccines outlined above. It does NOT support HCSWs to administer vaccines to pre-school age children, to administer other live attenuated vaccines as part of a re immunisation or booster programme following disease or treatment or to administer Travel Vaccinations. These are individualized schedules that are dependent on pre-assessment and continuous assessment of the individuals condition up to and including the point of administration of the vaccine. *This is in contrast to LAIV which is acceptable as the live vaccine has been weakened. The Green Book informs that *“live attenuated influenza vaccine (LAIV) Fluenz® Tetra contains live viruses that have been attenuated (weakened) and adapted to cold so that they can only replicate at the lower*

temperatures found in the nasal passage. These live viruses cannot replicate efficiently elsewhere in the body but may cause mild coryzal symptoms.”

The Agenda for Change (AFC) pay scale of HCSWs to be deployed to administer vaccine is out of scope for this Framework, as this is a matter for local workforce considerations and Human Resource mechanisms within the employing organisation. A National Job Description for COVID-19 HCSW Vaccinators was developed and issued in December 2020; at time of publication of this framework, this Job Description is being updated as a generic HCSW Vaccinator JD. This will be available for employer use and reference.

5.0 The Legal Framework in Scotland

All vaccines are classified as prescription only medicines (POM). This means that they are subject to legal restrictions and in order to give them, there needs to be an appropriate legal framework in place before they can be supplied and/or administered to eligible people. Additionally, any person who supplies and administers a vaccine must have a legal authority to do so.

The legislation that governs the supply and administration of medicines is reserved to the UK Government, and it applies across all nations of the UK; therefore, the legal framework defined in the RCN guidance is applicable across the UK. However, in producing this framework, provided the provisions of the Human Medicines Regulations (2012) are met, then the administration of medicines by HCSWs is lawful from the Scottish legislative context. The legal framework for Scotland is outlined below.

The Human Medicines Regulations (2012) state that only qualified prescribers such as registered medical practitioners, dentists or other independent prescribers can administer a POM such as a vaccine unless one of the following types of instruction are in place:

5.1 Patient Group Directions

A patient group direction (PGD) is defined as a written instruction for the administration or supply of a medicine, in an identified clinical situation, to groups of patients who may not be individually identified before presentation for treatment. PGDs are not a form of prescribing but they allow a range of specified registered healthcare professionals to administer and/or supply a medicine directly to a patient with an identified clinical condition without the need to necessarily be seen by a qualified prescriber. The healthcare professional working within the PGD is responsible for assessing that the patient fits the criteria set out in the PGD.

The legislation governing PGDs specifies the registered health professionals who may supply or administer medicines under a PGD.

Health Care Support Workers (HCSW) are not one of the groups authorised to use PGDs and consequently it is not lawful for a HCSW to administer or supply medicines in accordance with a PGD.

Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same practitioner who has assessed the patient under the PGD. Therefore, registered healthcare professionals operating under a PGD cannot delegate to a HCSW the supply or administration of injectable vaccines in accordance with a PGD. Where non-injectable medicines have been legally supplied to an individual for subsequent administration, the legislation does not regulate who may administer non-injectable medicines. Therefore, there may be models where a HCSW may administer non-injectable vaccines to individuals who have been legally supplied with a vaccine with instruction as to its subsequent administration by another health care practitioner, such as a HCSW

The important proviso is that the registered health care professional takes responsibility for the clinical assessment and supply of the medicine under the PGD to an individual child or young person. The LAIV childhood influenza vaccine must be administered immediately after supply, so there is no requirement to label the vaccine.

Example scenario when a HCSW may administer a non-injectable vaccine

When a PGD only covers supply of a non-injectable medicine (for example, the LAIV), it can be given to the patient by the registered health professional named in the PGD for later self-administration or for administration by another person, such as a HCSW. The law requires that the administration of the supplied medicine is in accordance with the PGD (which needs to specify that the medicine is supplied for subsequent administration). If the subsequent administration takes place immediately after the supply (and the vaccine does not leave the clinic setting), there is no requirement to label the vaccine.

5.2 Patient Specific Directions

A patient specific direction (PSD) is a written instruction from a registered medical practitioner or dentist or non-medical prescriber (hereafter in this document referred to as 'the prescriber') for a medicine to be administered or supplied to a named patient after the prescriber has assessed the patient on an individual basis.

PSDs are a form of prescribing - the prescriber is making a decision about the clinical suitability of a named individual to receive a medicine based on an individual patient assessment. PSDs are individually tailored to the needs of a single patient and are used once a patient has been assessed by a prescriber as being suitable to receive the medicine. The prescriber must have knowledge of the patient's health and be satisfied the medicine meets the individual needs of each patient. For example, a HCSW may be

working within an influenza immunisation clinic. The prescriber must review the patients attending the clinic and sign a list of those who they authorise to be immunised.

A PSD must be written and signed by the prescriber. It could be an electronic record made in the patient notes where it is identifiable to the prescriber.

There is no standard format for a PSD for the administration of a medicine but as a minimum should include:

- Name of the patient and/or other individual patient identifiers including age if the patient is a child;
- Name, form and strength of the medicine;
- Route of administration;
- Dose;
- Frequency;
- Date of treatment and the date treatment ends as applicable ;
- Signature of prescriber.

There is no legally valid period for a PSD for administration of a medicine. The prescriber should include a start and finish date as appropriate within the direction to ensure it is acted on within a time frame following the assessment which is appropriate to the needs of the patient. See also Appendix 1 HCSW and administration of specific vaccines in accordance with a Patient Specific Direction (PSD).

5.3 PSD Prescriber Responsibilities

The Prescriber is responsible for the assessment of the patient and for the decision to authorise the administration of a medicine to that individual patient. This is a clinical decision for which the prescriber has a duty of care and is professionally and legally accountable for the decision and the care they provide.

Medicines regulations do not specify that a face to face consultation is required for a PSD to be produced for an individual patient. However, before writing a PSD remotely the prescriber must satisfy themselves that they have adequate knowledge of the patient's health, and is satisfied that the medicines serve the patient's needs, and can make an adequate assessment of the individual's clinical suitability for the medicine. It is intended that national support materials will be developed to support prescribers by highlighting the clinical contraindications for vaccines included in the scope of this Framework.

The PSD issued by the prescriber grants the authority to administer the vaccine to a specific patient directly to a person such as a HCSW and not through any third party such as team managers. The prescriber must be satisfied that the person such as a HCSW to whom the administration is delegated through the PSD has the experience, knowledge and skills and has been deemed competent by the employing organisation to provide the treatment involved.

5.4 Who can administer under a PSD

Medicines regulations do not specify who can administer medicines under a PSD and accordingly it is lawful for a HCSW to administer medicines using the authority of a PSD. NHS organisations may limit or extend those who are authorised to administer medicines under a PSD in local medicines policy and governance arrangements.

5.5 National Protocols

In order to ensure that the UK has a sufficiently sized workforce to deliver a COVID-19 vaccine programme, changes to the Human Medicines Regulations (The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020), brought about a new regulation (247A). While a disease is pandemic (or imminently pandemic) and a serious or potentially serious risk to human health, regulation 247A permits the supply or administration of a medicinal product used for vaccination or immunisation against coronavirus or influenza in accordance with a protocol that is approved by Scottish Ministers. The national protocols allow specified classes of people, which need not be limited to registered healthcare professionals, to administer COVID-19 or influenza vaccine.

In accordance with regulation 247A, the protocol specifies: the characteristics of and training required for health care workers permitted to administer vaccine under the protocol, the requirement for individuals to be designated and authorised to administer medicines under the protocol by an appropriate manager (in the employing organisation), record keeping requirements (including the requirement to record the name of the person who administers the vaccine) and requirements for the supervision, where appropriate, of the people administering the vaccine.

The protocol also includes information similar to that commonly found in PGDs, for example, who is eligible for vaccination under the protocol and who is not, actions to be taken if the patient is excluded or declines the vaccine, a description of the vaccine, route of administration, dose, frequency, reporting of adverse reactions, recording, storage and disposal. These details are set out in a clinical annex within the national protocols.

The protocol may be followed wholly from patient assessment through to post-vaccination by a single person. Alternatively, multiple health care workers may undertake stages in the patient vaccination pathway in accordance with the protocol. Where multiple person models are used, the service provider or contractor must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The service provider/contractor is responsible for ensuring that health care workers are trained and competent to safely deliver the activity they are employed to provide under the protocol. In national protocols for COVID-19 vaccine, HCSW are permitted to undertake vaccine preparation, vaccine administration and, record keeping but are not permitted to undertake assessment of the individual presenting for vaccination, provide information, obtain informed consent or provide advice to the individual.

6.0 Principles for Safe Vaccine Administration

The overriding principle is that patient safety is paramount and anyone involved in the prescribing or administration of vaccines must be suitably proficient and have the knowledge, skills and experience to protect and promote the health of patients and the public.

Professional Regulatory Bodies require their respective registrants to abide by mandatory standards of practice and behaviour. These standards support and reinforce professionalism, and require all Registrants to be accountable for the care they deliver. A core element of all of the professional bodies' standards relates to effective and safe delegation of tasks to others; this is particularly important where this relates to delegation to non-statutorily registered staff and so is of direct relevance to the issue of vaccination by HCSWs.

The respective professional regulatory bodies for medical practitioners, nursing and midwifery practitioners, pharmacists and Allied Health Professionals such as paramedics and physiotherapists, all require that the person to whom the task is being delegated must have the skills to proficiently and appropriately carry out the work in a safe and effective manner.

The following Delegation guidance has been adapted for use from The Northern Ireland Practice & Education Council for Nursing and Midwifery: Deciding to Delegate Decision Support Framework, which was adopted for use in Scotland in 2020. The NMC Delegation and Accountability Supplementary Information to the NMC Code offers further information for practitioners, managers and clinical leads.

6.1 Delegation

The Northern Ireland Practice & Education Council (NIPEC) for Nursing and Midwifery: Delegation Framework informs that "*Delegation is the process by which a nurse or midwife (delegator) allocates clinical or non-clinical tasks and duties to a competent person (delegatee). The delegator remains accountable for the overall management of practice, for example, in a clinical context: the plan of care for a service user, and accountable for the decision to delegate. The delegator will not be accountable for the decisions and actions of the delegatee.*" For the purposes of this Framework this is extended to all Registered Healthcare Professionals.

6.1.1 Accountability

In the context of healthcare delegation means that a Registered Healthcare Professional is answerable for choices, decisions and actions or inaction measured against a specified standard or standards.

For those who are delegating healthcare tasks and duties this includes accountability to consider and adhere to:

- Professional Standards
- Employment Standards
- the delegation decision making process

and for confirming

- the safety, quality and experience of outcome against the described standard.

For those individuals who are accepting the delegated task or duty (delegatee), being accountable for their own actions includes adherence to:

- the described professional standards
- employment standards
- acting within organisational policies and procedures

6.1.2 Responsibility

In the context of delegation of healthcare tasks and duties means that a Registered Healthcare Professional should be prepared and able to give an account of his or her actions for any decision to delegate. Delegators and delegatees have responsibilities to support a framework for decision making to delegate healthcare tasks and duties. They include that:

The delegator has:

- authority to delegate the task (e.g. administration of vaccination)
- competence relating to the task (e.g. administration of vaccination)
- undertaken an assessment of need prior to decision making and obtained any required consent
- undertaken a risk assessment as to whether or not the task is delegable in the particular circumstance
- provided clear direction to the delegatee checking competence and understanding to carry out the task
- provided the necessary level of supervision for the delegate
- ensured a process is in place to enable regular and ongoing review and evaluation of the outcome of the delegated task in the context of the ongoing assessment of clients changing needs.

The delegatee has:

- undertaken relevant training and development for the delegated task
- confirms acceptance of the task and agrees competence
- communicates the outcome (written and/or verbal)
- understands the factors that inform the delegation decision making process
- communicates or reports relevant changes to the delegator which may impact on safety or the outcome, taking into consideration the delegation decision making factors
- maintains his/her own competence
- works to the terms of his/her employment
- works to organisational policies and standards including raising and escalating concerns
- adheres to relevant codes of practice.

Attainment of these principles relies on following and promoting a series of common principles by everyone involved in vaccine administration as detailed in the RCN guidance and adopted in Scotland as outlined in preceding sections.

6.2 Record Keeping

Elements of the end to end vaccination process can be undertaken by more than one person. For example prescribing by an Independent or Medical prescriber, clinical assessment and consent by a Registered Healthcare Professional and administration, including checking of batch, batch expiry, dose administered by a HCSW.

The HCSW Code 4.1.2 informs that:

'it is within the code of conduct of all healthcare professionals not to delegate tasks unless they are sure that the person they are delegating to has the skills and is happy to perform the task. The person who delegates will remain professionally accountable for delegating the task. However, if you accept the task, you will be accountable for how well you perform it.'

In considering the above it is deemed acceptable for a HCSW, who has undertaken relevant training and development and has been deemed proficient, to record the vaccination event they have undertaken, without need for counter signatory of a Registered Healthcare Professional.

HCSWs will need to comply with safe record keeping principles all records must be readable, relevant and accurate, be accessed only by those who need to be secure, and involve the person in your care and/or their carer. Further to this, there must be an auditable record of clinical staff who have undertaken any element of the end to end process of vaccination. It is important to ensure that relevant documentation is available should there be any requirement for reflective checking i.e. Adverse Events, Incidents or Complaints. The patients vaccination record must allow for the recording of any Registered Healthcare Professionals and HCSWs involved in the vaccination event.

6.3 Governance and Accountability

The Employer

- The organisation (employer) providing the care must decide who is authorised to administer the vaccine within their local medicines policies and governance arrangements. In this context, the employer must also arrange indemnity insurance for the HCSW to perform the intervention.
- The organisation employing the HCSW has a duty of care to the patient and its staff. It is responsible for ensuring the staff employed are properly trained and undertake only those responsibilities specified in their agreed job descriptions.
- The employer must ensure non-statutorily regulated staff, such as HCSWs are deemed proficient to undertake their task. Immunisation knowledge and skills proficiency assessment tools have been developed to support employers. Section 6.4.1 of this Framework lays out some principles to be considered in assessment of proficiency.

The Employee

- Prescribers and HCSWs administering vaccines must ensure they adhere to local vaccination/ medical policies and clinical governance policies and procedures.
- The HCSW who administers a vaccine is responsible for their own practice, and must be trained and proficient to undertake administration of vaccines. HCSWs must act according to their level of proficiency and in accordance with the directions of the prescriber as laid out in the PSD or appropriate National Protocol.
- HCSWs must not be put in a position where they have to make standalone clinical decisions. This must remain the responsibility of the registered health care professional. HCSWs must operate as part of teams with access to registered health care professionals at all times.

Clinical Governance

HCSWs in Scotland must not take informed consent from patients for vaccination or make any clinical decision. HCSWs must always work as part of a team with registered practitioners so that any informed consent or clinical issues can be discussed quickly with a registered health professional on site. The agreed skill mix ratio in Scotland is no less than 30:70 (1:3) Registered Healthcare Professionals: Healthcare Support Workers.

6.4 Quality Assurance

Patient safety is paramount. This is achievable using HCSWs to administer those vaccines which are within the scope of this Framework by ensuring:

- Appropriate governance and accountability, including robust local processes and systems for measuring, assuring and reporting on record keeping and Vaccinator proficiency, as minimum, until such time as nationally agreed measures/ indicators are in place.
- HCSWs are trained and deemed competent with regular Continuous Professional Development (CPD) updates to maintain competence;
- CPD should be recorded in the individuals TURAS Professional Portfolio. It should include, as minimum the: title, dates, number of hours, description and key learning points of the learning activity;
- HCSWs work as part of a team with registered health care professionals within a clinical governance environment ensured by their employer;
- HCSWs have easy access to clear local policies and procedures which are in compliance with the legal framework (see section 5.0).

Further guidance is available in the preceding sections.

6.4.1 Workforce Education Development

To help ensure a safe and effective delivery of this service all staff administering vaccines, including HCSWs, should have;

- Acquired and continue to maintain the necessary knowledge and skills through access to and completion of a variety of quality assured educational resources and interventions, supported by supervisors and mentors. For example. NES PHS Promoting Effective Immunisation Practice (or equivalent) and relevant vaccine specific resources for each vaccine the HCSW is to administer.
- Demonstrated proficiency in administering these vaccines through an appropriate assessment process;
- Complied with their employers educational and clinical governance requirements.

Adherence to the above is an employer responsibility. The final proficiency 'sign off' of these vaccinators and any associated timelines related to this is undertaken and determined by the employers within their own clinical and educational governance requirements. The workforce education development including ongoing CPD for all staff (including HCSW) is essential to ensure that knowledge & skills are maintained. To support employers in this regard, NHS Education for Scotland/ Public Health Scotland (Commissioned by Scottish Government) have developed and revise as required national educational resources including proficiency documents. These are developed in close collaboration with partners including Boards, Scottish Government and RCN. Employers can use these to support HCSWs in achieving proficiency in administering vaccines. The vaccination education resources align with the National Minimum Standards and Core Curriculum for Immunisation Training of HCSWs (PHE 2015). The clinical skills aspects and any face to face training are carried out by the employers including HCSW Mandatory Induction Standards and Mandatory training.

6.4.2 Team Working: Access to a registered healthcare practitioner

HCSWs must always work as part of a team with registered healthcare practitioners as:

- HCSWS must not make stand-alone decisions;
- HCSWs must not take informed consent.

Therefore, a registered healthcare practitioner, must be available at all times to offer supervision. The agreed ratio for Scotland is no less than 30:70 (1:3) Registered Healthcare Professionals: Healthcare Support Workers, to ensure that:

- Consent is undertaken by a registered healthcare professional, in line with national guidance;
- Clinical issues can be escalated and discussed quickly with a registered healthcare practitioner on site;

- There is a registered healthcare professional on site and available for immediate direct presentation to patient in support of responding to any adverse events following vaccination e.g. anaphylactic reaction.

6.4.3 Local policies and procedures

All local policies and procedures for the utilisation of HCSWs for vaccination should ensure the following:

- HCSWs must not be asked or put in a position where they would need to make any clinical decision or to take consent for vaccination;
- HCSWs must always have access to registered healthcare professionals on site and available for immediate presentation to patient for support;
- If HCSWs are to be used for vaccinating housebound patients, they must still do so as part of a team, with support from registered healthcare professionals.

7.0 Further Reading

Nursing and Midwifery Council: Professional Standards of Practice and Behaviour for Nurses, Midwives and Nursing Associates (2018)

<https://www.nmc.org.uk/standards/code/>

General Medical Council: Good Medical Practice (2019) <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice>

General Pharmaceutical Council; Standards for Pharmacy Professionals (2017) https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf

Health and Care Professions Council: Standards of Conduct, Performance and Ethics (2018) <https://www.hcpc-uk.org/standards/standards-of-conduct-performance-and-ethics/>

The Human Medicines Regulations 2012 (UK Legislation) <http://www.legislation.gov.uk/ukxi/2012/1916/introduction/made>

Guidance on HCSW Administering Inactivated Influenza, Shingles and Pneumococcal Vaccines for Adults and LAIV for Children (Royal College of Nursing 2019) [Publications | Royal College of Nursing \(rcn.org.uk\)](#)

Northern Ireland Practice & Education Council for Nursing and Midwifery: Delegation Framework <https://nipec.hscni.net/microsites/covid-19-surge-capacity/delegation/>

Nursing and Midwifery Council: Delegation and accountability Supplementary Information to the NMC Code [delegation-and-accountability-supplementary-information-to-the-nmc-code.pdf](#)

The Role of Nursing Associates in Vaccination and Immunisation (Royal College of Nursing, 2019) <https://www.rcn.org.uk/professional-development/publications/pub-007565>

Questions About Patient Specific Directions (Specialist Pharmacy Service 2020) <https://www.sps.nhs.uk/articles/patient-specific-directions-qa/>

Medicines Matters: [A guide to mechanisms for the prescribing, supply and administration of medicines](#) (Dept of Health England, 2006)

Care Quality Commission: GP mythbuster 19: Patient Group Directions (PGDs)/ Patient Specific Directions (PSDs) <https://www.cqc.org.uk/guidance-providers/gps/gp-mythbuster-19-patient-group-directions-pgdspatient-specific-directions>

Patient Group Directions and Patient Specific Directions in General Practice (British Medical Association, 2016) <https://www.bma.org.uk/advice/employment/gp-practices/service-provision/prescribing/patient-group-directions>

Patient Specific Directions (Specialist Pharmacy Service 2018) <https://www.sps.nhs.uk/wp-content/uploads/2013/03/PSD-final-July-2018.pdf>

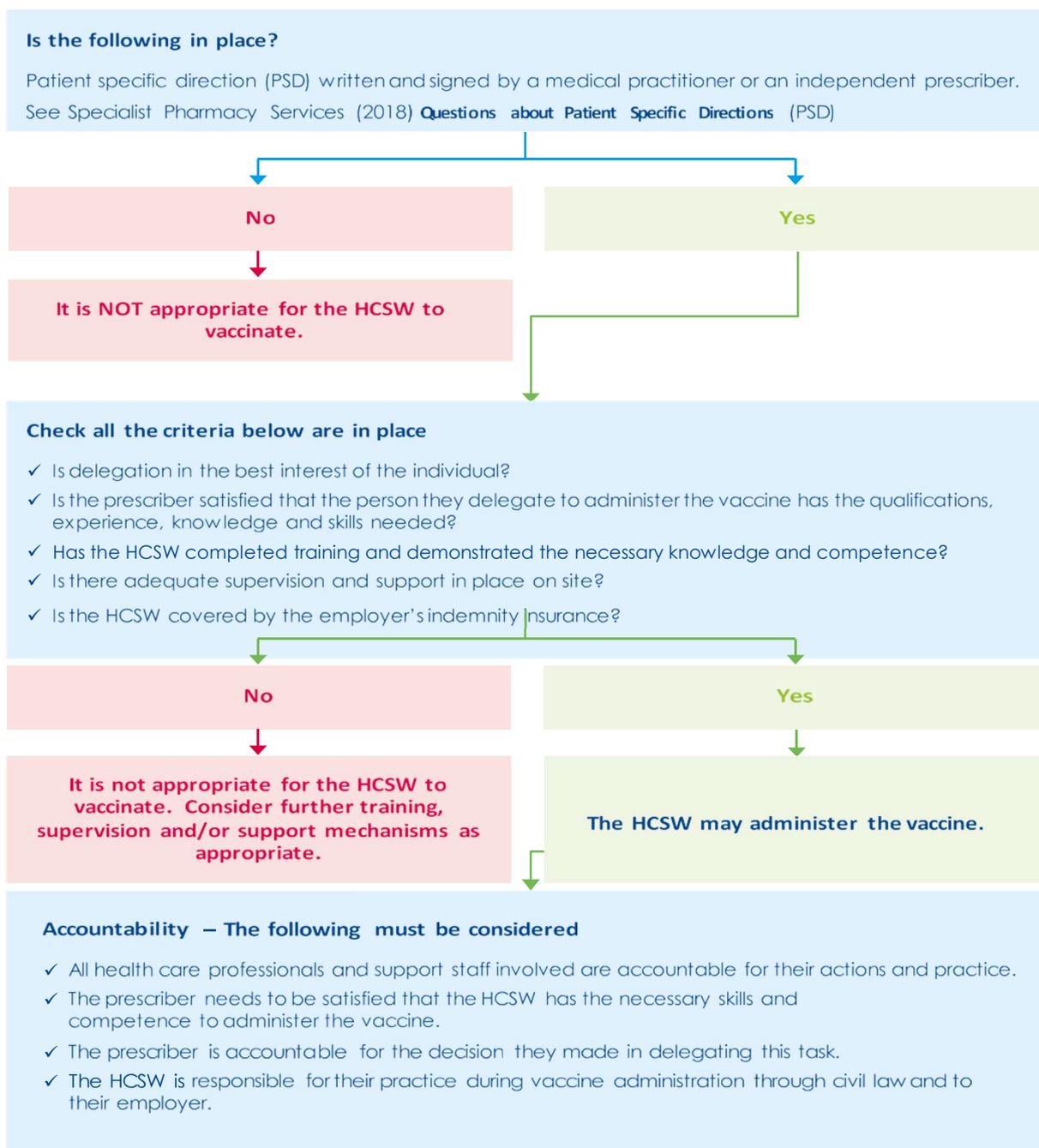
Competing interests of members: None Declared (2020 & 2021)

Appendix

1: HCSW and administration of specific vaccines in accordance with a patient specific direction (PSD)

Algorithm to clarify the administration of influenza, pneumococcal or pertussis in pregnancy vaccines to adults or the LAIV to children by a HCSW in accordance with a PSD.

Prescribing and arrangements for supply and administration





National
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2.