

16 September 2020

Dear Consultation team

Re: RCN response Consultation document: changes to Human Medicine Regulations to support the rollout of COVID-19 vaccines.

The RCN are pleased to have the opportunity to respond to this consultation and sets out some key issues that should be considered.

1. Background

1.1 With a membership of around 450,000 registered nurses, midwives, health visitors, nursing students, nursing support workers and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world.

1.2 Nursing teams are fundamental to the safe delivery of vaccination in the UK and vaccine clinics are primarily a nursing service. RCN members work in a variety of primary care, community settings and across the NHS and the independent sector delivering and supporting the delivery of vaccination and immunisation services.

2. Overview

2.1 We recognise that the purpose of this consultation is to consider the broad principles, regulatory context and policy recommendations proposed to the UK regulatory framework for human medicines.

2.2 The consultation acknowledges that the detail regarding the operating models and logistical planning will be decided by the NHS in each of the 4 nations of the UK. The RCN recommend that this should also involve the lead public health and health protection agencies and have parity with management of the annual flu vaccination programmes. There is already a wealth of experience in managing mass vaccination in the form of the annual influenza programme and this should be utilised to support the rollout of COVID-19 vaccines. The operating models and planning should use the same processes wherever possible.

2.3 While we acknowledge that the consultation is seeking views on the principles, we believe there is a need to differentiate between the delivery of a novel COVID-19 vaccine and the expansion of the influenza vaccination programme.

2.4 The expansion of the influenza programme will require larger numbers of people to be vaccinated than ever before. This will potentially require the need for different supply routes to obtain additional vaccine to meet the demands for the expanded programme. Influenza vaccine is however, a known vaccine, which comes in pre prepared doses, in a syringe ready for administration. It has known safety and efficacy data across different countries and health care practitioners already have a wealth of experience in administering it.

2.5 The administration of a COVID-19 vaccine will require additional and varied considerations. As a new vaccine it may require a unique and more complex process for preparation and administration. Alongside the physicality of vaccine preparation, there will be an increased demand for information and support to ensure high levels of public uptake, it is vital to instil public confidence and a feeling of safety. Health care professionals will also need to have knowledge of and assurance of the safety of administering un licenced vaccines.

2.6 Maintaining safety is fundamental and it is welcoming to see this acknowledged throughout the consultation. Alongside this there needs to be an explicit and ongoing need to maintain public confidence and trust in vaccination programmes. This will require that there are specific, transparent and robust governance process to support the programme. Nursing staff will be crucial in supporting public trust, leading teams in the delivery of this programme and in direct vaccine administration. There will need to be investment in training and guidance to support the workforce to do this.

2.7 The RCN have developed guidance to support the practical implementation of mass vaccination; Immunisation services and large-scale vaccination delivery during COVID-19.. This guidance is for all vaccinators not just the nursing workforce.

2.8 The RCN's view is that we already have legislative framework which supports the delivery of influenza vaccines. We acknowledge that further changes may be required for vaccine administration in some cases, for example, for unlicensed vaccines providing there is a clear rationale for their use. There may also be justification for wholesale movement of vaccines to maximise stocks and supplies. We would however, caution against the introduction of specific protocols where current mechanisms, such as Patient Specific Directions or Patient Group Directions, would serve.

2.9 In principle we would support legislative changes to facilitate the administration of a COVID-19 vaccine under a protocol. However, these should only be implemented for that specific vaccination programme. It is also essential that these changes are considered for these exceptional circumstances and only for the delivery of this COVID-19 vaccine.

Comment against the specific areas within the consultation;

3. Temporary authorisation of the supply of unlicensed products

3.1 In principle, the RCN would support temporary authorisation, if this is necessary to allow timely and safe administration of vaccines to those who need it.

3.2 However, we would welcome a strong commitment to ensuring that wherever possible vaccines are licenced.

3.3 The use of unlicensed products is not new for vaccines but has previously been advised after close scrutiny of available evidence and data. The RCN would therefore expect that the Joint Committee for Vaccination and Immunisation (JCVI) and Medicines and Health care products

Regulatory Agency (MHRA) provide clear and transparent scrutiny of the evidence for the vaccine and governance advice on the authorisation of unlicensed vaccines.

3.4 Having this clear evidence will support prescribers in issuing prescription for unlicensed products. This will also provide assurance for health care staff administering these vaccines and for the public in accepting and consenting to vaccination.

4. Civil liability and immunity

4.1 It is essential that all staff involved in the process have assurance that they will be protected to deliver the vaccines recommended. All staff will need to have the necessary training and education to fulfil their role within the process and are reassured that they will have the necessary indemnity.

4.2 It is also important that all those involved understand their role in relation to undertaking vaccination and know where their accountability lies. This relates to registered health care professionals and the unregistered, trained immunisers.

4.3 Unregistered practitioners have been involved in vaccine administration in many areas, however, this does not apply in all countries in the UK. In Northern Ireland unregistered practitioners are currently not supported in vaccine administration, so this will need careful consideration.

4.4 Education and training on accountability, delegation and supervision is essential to ensure clarity within the roles and functions of those involved and when, how and who to escalate issues and concerns to, see RCN resources on accountability and delegation .

4.5 All staff need to have access to education and training in line with the recommendations with the immunisation training guidance . They will also require ongoing supervision and support in practice.

4.6 All those involved will require a clear statement of support for following the legislation alongside clear and transparent protocols and local service agreements. The RCN would like to see a statement of support from the health care professional regulators, and a similar statement of support for the unregistered workforce working under delegation.

5. Proposed expansion to the workforce eligible to administer vaccinations

5.1 The consultation document states that under the Human Medicine Regulations (HMR) only 'appropriate practitioners' (doctors and other prescribers) administer vaccines. The RCN would like to be clear that most vaccines in the UK are already given by nursing staff. Within the HMR as they stand already there is provision for those who are not prescribers to administer vaccines. A prescriber can delegate the administration of a Prescription only Medicines (POMs) to another trained practitioner, providing they are confident that the person they are delegating to has the skills and competence in the administration of the medicine under a prescription or Patient Specific Direction (PSD). Registered nurses and midwives, and increasingly pharmacists and other registered health care professionals, are also specifically named within the legislation to be able to administer POMs, including vaccines, under a Patient Group Direction (PGD). This is the mechanism for authorisation for the majority of vaccines given in the UK.

5.2 These processes have been built into the legislation to maintain public safety and robust governance around vaccination programmes. It means that vaccinators know who needs to be vaccinated, exactly what vaccine they are giving, and why. This helps to maintain public trust and

confidence in the vaccination programmes, encourages high uptake of the vaccines and thereby helps stop transmission of infections. It is imperative that these processes continue for any expansion of the influenza programme and as far as possible for the introduction of a COVID-19 vaccine.

5.3 In principle, the RCN would welcome the proposals to expand the immuniser workforce to support this specific situation and supports the delivery of a COVID-19 vaccine. The use of a protocol, with clear direction for each part of the procedure, would support safe delegation of various parts of the process required for vaccine administration. However, we would note that this is unlikely in all areas of the UK, in Northern Ireland particularly it is unlikely that the NHS will support the use of unregistered staff to administer the vaccine.

5.4 The RCN would expect however that all vaccinators for any part of the process are sufficiently trained. This must include the vaccination and injection process, importance of informed consent, recognition of adverse events. It must also include information about communicating with patients effectively, and as previously stated clarity on the different roles and responsibilities and how to escalate concerns.

5.5 All staff need to understand the principles around accountability and delegation and scope of competence. Where staff are being asked to take on the vaccination role they should have some clinical skills and experience and immediate access to registered health care professional vaccinators who can provide support and supervision.

5.6 It is essential that any plans consider potential unintended consequences of undermining public trust in vaccination programmes. Critical to vaccination programmes are sufficient nursing staff being available to lead such programmes, particularly in light of the public trust in nursing.

5.7 It is important that the public feel comfortable having a vaccination and assured that the person administering it is trained, skilled, knowledgeable, empathetic and understanding. Conversely, people also need to be able to refuse vaccination without prejudice. This is a role that nursing teams already have a wealth of experience in.

6. Vaccine promotion

6.1 The consultation is focused on legislative changes to support vaccine promotion. The response given in relation to having transparent scrutiny of any vaccine authorisation would apply. The RCN would recommend that JCVI and MHRA are clearly involved in this process in order to support ongoing vaccine promotion and help to ensure public confidence in vaccination.

6.2 There will need to be some clear plain English frequently asked questions and explanations for the public on the governance process as well as on the vaccine itself. Information must be accessible and available in range of formats to enable diverse audiences/communities to access, for example, in an easy read format and a range of languages.

7. Make provisions for wholesale dealing of vaccines

7.1 We welcome the recommendations in this section of the proposals focusing on lessons learnt from previous vaccine campaigns which support having clear process for safe movement of vaccines.

7.2 As for other elements of the consultation, however, there will need to be clear and transparent governance processes to support this in order to maintain both public trust in the programme and the trust and confidence of health care staff in the vaccines they are administering.

7.3 It should also be specific for the supply of vaccines in these exceptional circumstances.

8. Conclusion

8.1 The RCN promotes patient and nursing interests on a wide range of issues by working closely with the UK Government, the UK devolved administrations and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

8.2 Nursing staff are essential to the delivery of vaccination programmes currently and they will also be crucial for the safe delivery of the expanded influenza programme in 2020 and the potential COVID-19 vaccine programme. The RCN is keen to engage with NHS and public health teams for the further development of operational plans.

For future correspondence or queries to the RCN on this consultation, please contact;
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Yours sincerely



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