EXPLANATORY MEMORANDUM TO

THE HEALTH PROTECTION (NOTIFICATION) (AMENDMENT) (NO. 2) REGULATIONS 2020

2020 No. 674

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument adds Acquired carbapenemase-producing Gram-negative bacteria to the list of causative agents which, when identified in a human sample, must be notified by the operator of a diagnostic laboratory to Public Health England (PHE). It also adds to the information required to be included in the notification of a causative agent to PHE, the results of any antimicrobial susceptibility test results and any resistance mechanism identified in respect of the sample.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

4.1 The extent of this instrument is England and Wales.

4.2 The territorial application of this instrument is England only.

5. European Convention on Human Rights

5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 The Public Health (Control of Disease) Act 1984 ("the 1984 Act") and regulations made under it provide a legislative framework for public health protection in England and Wales.

6.2 Part 2A of the 1984 Act (public health protection), as inserted by the Health and Social Care Act 2008, provides a legal basis to protect the public from threats arising from infectious disease or contamination from chemicals or radiation.

6.3 The Health Protection (Notification) Regulations 2010 SI 2010/659 ("the 2010 Regulations") created a scheme for notifying actual and suspected cases of infection and contamination in humans to specified bodies with public health responsibilities. This allows prompt action to be taken by those bodies to protect public health where appropriate.

6.4 Regulation 4 of the 2010 Regulations requires the operator of a diagnostic laboratory to notify PHE of the identification of causative agents in a human sample (from live or deceased patients) within 7 days, where causative agent means: a causative agent listed in Schedule 2 to the Regulations; or evidence of an infection caused by such an agent. This instrument amends the 2010 Regulations by adding Acquired carbapenemase-producing Gram-negative bacteria to the list of causative agents in Schedule 2.

6.5 Regulation 4(2) of the 2010 Regulations sets out what information must be included within the notification to PHE insofar as it is known to the operator of the diagnostic laboratory. This instrument amends regulation 4(2) of the 2010 Regulations by adding a requirement to include in the notification to PHE the results of any antimicrobial susceptibility test and any resistance mechanism identified in respect of the sample.

7. Policy background

What is being done and why?

7.1 The scale of the antimicrobial resistance (AMR) threat, and the need to contain and control it, is widely acknowledged by governments, international agencies, researchers and private companies alike.

7.2 Increasing levels of AMR pose a significant threat to healthcare and economic stability globally. If resistance continues to increase, more people will suffer longer infectious illnesses as they become more difficult to treat and the number of human deaths and suffering attributable to infectious disease will increase, as will the socio-economic costs associated with treating ill health in humans.

7.3 In 2018, there were over 60,000 antibiotic-resistant severe infections in England alone, equivalent to 165 new antibiotic resistant infections per day; this represents an increase of 9% on the previous year[1].

7.4 These legislative amendments will strengthen AMR surveillance in England. Reliable surveillance schemes that collect data on resistance are needed to guide treatment and prescribing, detect the emergence of AMR threats, identify populations at risk, evaluate trends, inform policy development and assess the impact of interventions. They also enable appropriate and timely action to be taken in order to protect the public's health, including the prompt notification and investigation of outbreaks.

7.5 Carbapenems are a valuable family of β-lactam antibiotics normally reserved to treat serious life-threatening multi-drug resistant Gram-negative infections in hospitals. They are commonly referred to as "antibiotics of last resort". Resistance to some or all carbapenems is an intrinsic characteristic of some Gram-negative bacteria. Others can produce carbapenemases, which are enzymes that destroy carbapenem antibiotics.

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/843129/English_Surveillance_Programme_for_Antimicrobial_Utilisation_and_Resistance_2019.pdf

7.6 Carbapenem resistance due to the emergence of acquired carbapenemases in Gram-negative bacteria is of particular concern due to the ability of these bacteria to transfer resistance to different bacterial species, both within an individual and in the environment. This ability means they can cause multi-species outbreaks of carbapenem-resistant bacteria that can be difficult to recognise or control unless the resistance mechanism is tracked in relative real-time.

7.7 Global surveillance has shown an increase in the prevalence of bacteria carrying carbapenemases. In England, detections of carbapenemase-producing bacteria have increased year-on-year since 2006: from four in 2006 to 4,028 in 2018[1].

7.8 Unless action is taken, rapid spread of these acquired carbapenemase-producing Gram-negative bacteria will pose an increasing threat to public health and medical treatment pathways in the UK. These multi-drug resistant bacteria can spread rapidly in healthcare settings, lead to poor clinical outcomes because of limited therapeutic options, and are associated with an increase in morbidity and attributable mortality. They can also have significant cost and operational implications for healthcare organisations resulting from prolonged hospital stays and the care of infected and colonised patients. Previous large outbreaks in the UK have led to substantial costs (both healthcare, staffing and other resources) given the time taken to achieve control once the outbreak is established. In some health and social care organisations in England, acquired carbapenemase producers are now endemic.

7.9 Timely notification of detections of acquired carbapenemase-producers to PHE, and distinction from bacteria with other carbapenem resistance mechanisms, will support early detection of outbreaks and rapid implementation of enhanced control measures to prevent further colonisation, carriage and spread. Further, a comprehensive overview of carbapenemase activity in England will allow PHE to estimate the burden of these infections to the population, improve understanding of these bacteria and monitor long-term trends.

7.10 An understanding of local epidemiology and context is key, as public health actions will differ depending on: the prevalence of these bacteria in patients being admitted to healthcare settings; the resistance mechanism(s) identified; prior outbreaks within the region; the patient population mix; and individualised risk assessments of areas where transmission is most likely to occur.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act.

9. Consolidation

9.1 Consolidation is not relevant to this instrument. There are no plans to consolidate the 2010 Regulations at this stage.

10. Consultation outcome

Stakeholder workshop

10.1 PHE ran a workshop on 21 August 2019 to seek views on proposals to make Acquired carbapenemase-producing Gram-negative bacteria notifiable. The workshop was attended by 27 experts, representing a range of professions, professional organisations

and geographic locations. The discussion focussed initially on the definition of the causative agent to be included in the 2010 Regulations; the proposed definition presented to delegates was 'Acquired carbapenemase-producing Gram-negative bacteria causing invasive infection'. Delegates were then split into four breakout groups to further focus discussions on aspects associated with surveillance, microbiology, infection prevention and control (IPC) and antimicrobial stewardship.

10.2 Overall, there was broad support for making the legislative change, with several participants suggesting that the definition not be limited to invasive infection; identification of colonisation with these bacteria was considered as important as invasive infection by some workshop participants. Following consideration of workshop participants' contributions, the definition of the causative agent was extended to include Acquired carbapenemase-producing Gram-negative bacteria isolated from all specimen sites.

10.3 Delegates also noted the need to produce clear guidance for identification of bacteria suspected of acquired carbapenemase production and the process for reporting.

10.4 Delegates queried whether addition to the 2010 Regulations will result in increased attention and resource required to prevent and control outbreaks. Discussion around this point highlighted the importance of surveillance and using information gathered to inform actions required to contain and control acquired carbapenemase producers. The discussion concluded with agreement that surveillance outputs be readily available; reports on all causative agents are already published weekly[2].

10.5 The revised approach was endorsed by the government's Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection.

Consultation on draft carbapenemase-producing Enterobacterales framework

10.6 PHE ran a public consultation on a draft of its *Framework of actions to contain carbapenemase-producing Enterobacterales*[3] ("CPE Framework"), which included the intention of government to add Acquired carbapenemase-producing Gram-negative bacteria to the list of causative agents to be notified under the 2010 Regulations. The consultation ran from 7 January 2020 to 14 February 2020.

10.7 Six comments were received from four respondents; comments received included clarification on whether the definition was limited to invasive infections and whether suspected cases should be reported. One comment was received regarding the potential challenges faced by organisations that do not have access to electronic surveillance systems. We are not aware of any laboratories conducting antimicrobial susceptibility testing for National Health Service ("NHS") NHS patients that are unable to report the data electronically. If there are any small, private laboratories without access to PHE's electronic surveillance system then there are alternative means by which these laboratories can report electronically, such as via PHE's Second Generation Surveillance System (SGSS) user interface.

10.8 The final version of the CPE Framework is due for publication prior to this instrument coming into force.

[2] https://www.gov.uk/government/publications/notifiable-diseases-causative-agents-report-for-2020
[3] https://www.gov.uk/government/consultations/carbapenamase-producing-enterobacterales-framework-of-actions

Email to all diagnostic laboratories in England

10.9 On 15 May 2020, PHE sent an email to the operator of each diagnostic laboratory in England setting out the proposed legislative changes and attaching a proforma through which recipients can provide comments. Recipients were given three weeks to respond. Two responses were received as a result of the consultation. One respondent made comments on how to report acquired carbapenemases to PHE's national microbiology database, SGSS; guidance on establishing reporting of acquired carbapenemases has been published previously, with detailed guidance to be published prior to the enforcement date in an update to '*Laboratory Reporting to Public Health England: a guide for diagnostic laboratories*'. One response stated that some laboratories will need to manually enter data to report acquired carbapenemases to PHE. PHE liaised with operators of diagnostic laboratories and estimates that reporting a positive result will take no longer than five minutes. Automation of reporting will be achievable subsequent to redevelopment of laboratory data reporting systems and related information systems.

11. Guidance

11.1 Operational guidance for diagnostic laboratories on reporting causative agents to PHE already exists: *Laboratory reporting to Public Health England: A guide for diagnostic laboratories*[4]. This guidance will be updated to include the new reporting requirements and will be published before this instrument comes into force.

11.2 In May 2019, PHE published guidance to support diagnostic laboratories to make an informed choice on the implementation of commercially-available carbapenemase detection methods: *Commercial assays for the detection of acquired carbapenemases*[5]. PHE will continue to maintain this guidance.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector.

12.3 Estimates on costs to the NHS (all diagnostic laboratories performing microbiology services for the NHS) have been prepared. It is estimated that the cost of establishing electronic reporting of acquired carbapenemase producers is approximately £5,000.

12.4 The estimated annual cost to the NHS will depend on the prevalence of acquired carbapenemase producers in an area and therefore the number of reports per annum. Based on the median number of reports received by PHE in February 2020, it is estimated that total annual costs will be under £5,000.

12.5 A full Impact Assessment has not been prepared for this instrument because of the low level of impact per business. Broad brush figures derived from proportionate analysis are set out in paragraphs 12.3 and 12.4.

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4 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/739854/PHE_Laboratory_Reporting_Guidelines.pdf

5 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/804995/Detection_of_carbapenemase_report.pdf

13. Regulating small business

13.1 There may be a small number of independent diagnostic laboratories which are small businesses to which this instrument applies.

13.2 It is not considered that the instrument will have a significant impact on these laboratories as they are not likely to identify many acquired carbapenemase producers. The notification requirements apply to the laboratory that first receives the sample. As most independent sector laboratories, according to our information, will usually receive samples from other laboratories, they will not be directly affected by the requirements. No new procedures or enforcement structures are needed to implement these changes.

13.3 PHE contacted the Independent Healthcare Providers Network to seek the views of independent sector laboratories. PHE did not receive any responses from this sector. The basis for the final decision on what action to take to assist small businesses is that no additional support is needed as the impact should be minimal.

14. Monitoring & review

14.1 The approach to monitoring of this legislation will be kept under regular review.

14.2 The instrument does not include a statutory review clause.

15. Contact

15.1 Jasmin Shepherd at the Department of Health and Social Care (telephone: 020 7210 5108 or email: HealthProtectionTeamPQsandGeneral@dhsc.gov.uk) can be contacted with any queries regarding the instrument.

15.2 Morwenna Carrington, Deputy Director for Health Protection Policy at the Department of Health and Social Care, can confirm that this Explanatory Memorandum meets the required standard.

15.3 Lord Bethell of Romford at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.