**HSC-PBPP End of Project Reports – October 2024**

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| **Application Reference**  **(click on reference for EPR Summary)** | **Applicant** | **Applicant Organisation** | **Title and Purpose of study** | **Date of Approval** |
| [2223-0047](#_2223-0047_Mohamed_Shoaeir) | Mohamed Shoaeir | SICSAG | Improving the identification of sepsis in SICSAG data | 09/08/2023 |
| [2223-0033](#_2223-0033_Dr_Natalia) | Dr Natalia Matveyev | University of Edinburgh | Characteristics and outcomes of high-risk COVID-19 patients treated with Sotrovimab, oral anti-virals, or no treatment in Scotland | 06/10/2022 |

**END OF PROJECT REPORT SUMMARIES**

## 2223-0047 Mohamed Shoaeir

**Improving the identification of sepsis in SICSAG data**

**The Public Benefit Impact Summary**

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| 1 | **Aims** |  |
|  | What did the study set out to achieve? | To develop a case definition for sepsis aligned with the Sepsis-3 definition in the SICSAG database and evaluate its accuracy against clinically defined sepsis |
| 2 | **Public Benefit Impact** |  |
|  | How will these outcomes directly result in benefit for the public? Please give details. This should be the main section answered. | A validated definition of sepsis which can be operationalised within the SICSAG dataset will allow national reporting of processes and outcomes for patients who are critically ill with sepsis. This will enable targeted quality improvement initiatives to improve care and outcomes for patients affected by sepsis. This would be to improve the recognition of patients with sepsis and so will aid in understanding and treatment of sepsis. The QI project recommendations will be discussed with PHS/SICSAG who are responsible for management and maintenance of WardWatcher. |
| 3 | **Data** |  |
|  | What data were received/processed/collected?  Was it as expected? Please give brief details. |  |
| 4 | **Methodology** |  |
|  | How did you collect the data? | Data has been collected from patients at different ICUs in Scotland through local data collector.  Another set of data related to those patients has been collected from SICSAG data base. |
| How did you process the data? | Data from local case note reviewers has been sent to me through NHS emails following the data protetion policy.  Data from SICSAG has been sent through NHS emails.  Data has been kept securely in NHS lothian computers protected by password known to me only. |
| How did you provision/publish the information? | Results have been discussed at SICS internation conference. Academic paper will be published in an internation journal. |
| Did your study scope change from its original aims? Please give brief details. | No |
| 5 | **Outcomes:** |  |
|  | The outcomes / results of your proposal. Please give brief details. | Sepsis is underrecoreded in SICSAG database and this database can not be used as source to quality improving projects or research. We do recommend also to make admission diagnostic codes more explicit. |
| 6 | **Future Questions:** |  |
|  | Have the processes / results raised further questions for future exploration? Please give brief details. | Admission diagnosis in SICSAG data base can be more detalied to accomodate and identify sepsis accuratley. |

## 2223-0033 Dr Natalia Matveyev

**Characteristics and outcomes of high-risk COVID-19 patients treated with Sotrovimab, oral anti-virals, or no treatment in Scotland**

The Public Benefit Impact Summary

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| 1 | Aims |  |
|  | What did the study set out to achieve? | To describe characteristics and clinical outcomes of highest risk patients with COVID-19 receiving early COVID-19 treatments in Scotland. |
| 2 | Public Benefit Impact |  |
|  | How will these outcomes directly result in benefit for the public? Please give details. This should be the main section answered. | Since the start of the pandemic, new vaccines and treatments have been developed to reduce the risk of people becoming very unwell with COVID-19. People who were particularly at risk included those who are 65 years of age or above, living with an immune disorder and/or with high-risk conditions or treatments. The new treatments, including monoclonal antibodies and antivirals, have all been shown (in clinical trials) to reduce severe disease in high-risk patients. By monitoring them at a national population level, we were able to look at patterns of treatment benefit that might not be obvious in clinical trials.  We studied groups of high-risk COVID-19 patients in Scotland who had these treatments after they were diagnosed, and whether they became unwell. We compared these patients to people who were eligible, but did not receive treatment (or were only treated when they started to become even more unwell).  Our findings showed that among patients who received early COVID-19 treatment with sotrovimab or antivirals in Scotland, low proportions were hospitalised or died within 28 days of treatment. These results are supported by other real-world studies. We noted that sotrovimab was frequently given to patients aged below 75 years old in. Most treated patients had missing data for their high/highest-risk status and conditions, which reduced the feasibility of conducting a comparative effectiveness analysis to assess the impact of sotrovimab in preventing severe COVID-19 among this population.  While the benefits of early treatment in high-risk COVID-19 patients have been demonstrated within a clinical trial setting, before our study there was a limited data available on the effectiveness of these treatments in a real-world setting. |
|  |  | Additionally, we were able to see which specific sub-groups of high-risk patients are most at risk of developing severe disease with respect to factors such as early treatment received, vaccination status, and frailty. The insights from this study have contribute towards the improvement in management of high-risk COVID-19 patients and in identifying sub-groups of patients who are at highest risk of severe disease. |
| 3 | Data |  |
|  | What data were received/processed/collected?  Was it as expected? Please give brief details. | We used data from administrative health datasets managed by Public Health Scotland and National Records of Scotland, linked and pseudonymized by the electronic Data Research and Innovation Service. |
| 4 | Methodology |  |
|  | How did you collect the data? | All the data is collected as part of routine healthcare provision. |
| How did you process the data? | Data were linked and pseudonymized by the electronic Data Research and Innovation Service.  We identified adults (aged ≥18) who were diagnosed and treated for COVID-19, in either a community or outpatient setting, because of a high-risk comorbidity which increased their risk of poor outcomes from COVID-19.  The study cohort was drawn from the Scottish general practitioner-registered population living within six health boards (i.e. Ayrshire & Arran, Dumfries & Galloway, Forth Valley, Greater Glasgow & Clyde, Lanarkshire and Lothian) that used the Hospital Electronic Prescribing and Medicines Administration (HEPMA) system for recording administration and prescription of COVID-19 therapies.  We then reviewed hospital admissions, critical care unit admissions, and mortality records, to estimate the risk of each outcome within 28 days of treatment. |
| How did you provision/publish the information? | Data for this study (study ID: 2223-0033) are held by the National Services Scotland electronic Data Research and Innovation Service in the National Safe Haven. Restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available.  Results were published at:  Drysdale, Myriam, Holly Tibble, Vishal Patel, Daniel C. Gibbons, Emily J. Lloyd, William Kerr, Calum Macdonald, Helen J. Birch, and Aziz Sheikh. "Characteristics and outcomes of patients with COVID-19 at high risk of disease progression receiving sotrovimab, oral antivirals, or no treatment: a retrospective cohort study." *BMC Infectious Diseases* 24, no. 1 (2024): 670. |
| Did your study scope change from its original aims? Please give brief details. | No |
| 5 | Outcomes: |  |
|  | The outcomes / results of your proposal. Please give brief details. | In total, 2548 patients were included (492: sotrovimab, 276: nirmatrelvir/ritonavir, 71: molnupiravir, and 1709: eligible highest risk untreated). Patients aged ≥75 years accounted for 6.9% (n=34/492), 21.0% (n=58/276), 16.9% (n=12/71) and 13.2% (n=225/1709) of the cohorts, respectively. Advanced renal disease was reported in 6.7% (n=33/492) of sotrovimab-treated and 4.7% (n=81/1709) of untreated patients, and ≤5 nirmatrelvir/ritonavir-treated and molnupiravir-treated patients. All-cause hospitalizations were experienced by 5.3% (n=25/476) of sotrovimab-treated patients, 6.9% (n=12/175) of nirmatrelvir/ritonavir-treated patients, ≤5 (suppressed number) molnupiravir-treated patients and 13.3% (n=216/1622) of untreated patients. There were no deaths in the treated cohorts; mortality was 4.3% (n=70/1622) among untreated patients. |
| 6 | Future Questions: |  |
|  | Have the processes / results raised further questions for future exploration? Please give brief details. | The data indicated that some eligible patients (based on COVID-19 diagnosis and high-risk comorbidities) were untreated; the reasons for this were not ascertained as part of this study but are of interest for future research. |