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Remdesivir
Adverse Events and Clinical Outcomes Report Form

It is recommended that this report form is completed within 2 weeks of remdesivir cessation, discharge or death

1. *Enter a 'code' unique to this patient

(use the same code that was selected in the prescribing declaration form / IPU submission with the suggested template Remdesivir_LHD_MRN_DATEofADMISSION or refer to the email from the DTC for the unique code)

2. *What is today's date? (date format: dd/mm/yyyy)

Section A. Clinician's details

3. *Full name of clinician providing this report

4. *Are you the same clinician who made the original remdesivir prescribing declaration / IPU?

- O Yes (jump to question **9**)
- O No (jump to question **5**)

5. Clinician's email address

6. Clinician's contact number (pager and/or extension and/or mobile number)

7. Clinician's specialty

- O Infectious Diseases Physician (jump to question **9**)
- O Intensivist (jump to question **9**)
- O Respiratory Physician (jump to question **9**)
- O Emergency Medicine Physician (jump to question **9**)
- O Other, please specify (jump to question **8**)

8. If other specialty, please specify [Question ID: 26947]

Section B. Patient Demographics

9. *Patient's initials

10. *Patient's MRN

11. *What date was the patient admitted to hospital? (date format: dd/mm/yyyy)

12. *Please select any pre-existing poor prognostic factors for COVID-19 (more than one answer may be selected)

☐ Age equal to or greater than 65 years

☐ Smoker, current and former

☐ BMI equal to or greater than 30 kg/m2

☐ Vascular (e.g. cardiovascular disease, cerebrovascular disease, hypertension - please specify in next question)

☐ Diabetes (please specify diabetes type in next question)

☐ Chronic respiratory disease (please specify in next question)

☐ Immunocompromised (e.g. HIV, transplant recipient, use of immunosuppressant(s) - please specify in next question)

☐ Cancer

☐ Neurologic conditions, including dementia

☐ Substance use disorder or mental health diagnosis (e.g. depression, bipolar disorder - please specify in next question)

☐ Other (please provide details in next question)

☐ No poor prognostic factors for COVID-19 identified

13 Please provide further details about any selected pre-existing poor prognostic factors

Section C. Remdesivir Details

14. *What date was remdesivir commenced? (date format: dd/mm/yyyy)

15. *Actual duration of remdesivir treatment

○ 5 days (jump to question **17**)

○ 10 days (jump to question **17**)

○ Other (please provide details in next question) (jump to question **16**)

16. If other, please specify dosing duration and reason

17. *If the actual dosing was different to that initially proposed, provide details (use N/A if dosing not different)

Also include information if:

- **infusion incomplete/ceased early**
- **still ongoing/additional doses planned**
- **dose was adjusted and why**
- **consent to treatment withdrawn**
- **contraindication identified**
- **adverse drug effect experienced (identify here and provide details in section E)**
- **death occurred**

Section D. Other Therapy

18. *Was the patient acutely commenced on any of the listed therapies as a result of treatment for COVID-19? (more than one answer may be selected)

☐ Other antiviral therapy

☐ Corticosteroid (not topical)

☐ Immunomodulator

☐ Antibacterial therapy

☐ Antithrombotic therapy

☐ Antifungal therapy

☐ ACE inhibitor

☐ Sartan

☐ Statin

☐ Other COVID-19 modifying therapy (including pre-hospital therapy; specify in next question)

☐ Other therapy (specify in next question)

☐ The patient was not commenced on any of the listed medicines above

19. Provide details of relevant therapies selected in the previous question, including if it was COVID-19 specific therapy and/or part of a clinical trial

20. *Did any potential or actual drug interactions impact the management of COVID-19 in this patient? (e.g. required change in choice of therapies / dose changes)

○ No relevant drug interactions identified (jump to question **22**)

○ Yes, interaction(s) involving remdesivir (jump to question **21**)

○ Yes, interaction(s) involving other relevant COVID-19 therapies (jump to question **21**)

21. Provide details of drug interaction(s)

Section E. Possible or Likely Adverse Effects Due to Remdesivir

22. *Did the patient experience any adverse effects (possible or likely) due to remdesivir use?

- O Yes (jump to question **23**)
- O No (jump to question **46**)

23. Select the adverse effects, which were possible or likely due to remdesivir use (more than one answer may be selected)

- ☐ Increase(s) in LFTs
- ☐ Possible allergic reaction, including anaphylactic reactions and angioedema
- ☐ Infusion-related reactions (within 24 hours of IV infusion; including but not limited to hypotension, nausea, vomiting, diaphoresis and shivering)
- ☐ Bradycardia (including severe bradycardia and sinus bradycardia)
- ☐ Cardiac failure
- ☐ Hypotension
- ☐ Gastrointestinal symptoms not related to infusion reaction (e.g. nausea, vomiting, diarrhoea)
- ☐ Headache
- ☐ Rash
- ☐ Prolonged prothrombin time
- ☐ Death
- ☐ Other (please provide details in next section)

You are required to provide details for each adverse effect identified. If there are more than TWO adverse effects, a free text field to provide details of additional adverse effects follows.

Section E continued. Details of Possible/Likely Adverse Effects Due to Remdesivir

First adverse effect

24. What was the adverse effect?
(Name the adverse effect only, further details to be provided below)

25. What was the likelihood that this adverse effect was due to remdesivir use?

- O Possible
- O Likely
- O Don't know

26. What was the timing of onset of the adverse effect after the initial remdesivir dose was administered (in hours/minutes as applicable)?

27. What was the severity of the adverse effect?

- O Mild, no treatment required (jump to question **29**)
- O Moderate to Severe, treatment required (jump to question **28**)
- O Life-threatening (jump to question **28**)
- O Don’t know, no treatment required (jump to question **29**)

28. Provide details of administered treatment for adverse effect including relevant laboratory results and/or diagnostic procedures

29. Has the patient recovered from the adverse effect?

- O Yes (jump to question **30**)
- O No (jump to question **31**)
- O Don't know (jump to question **31**)

30. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)?

31. Did the adverse effect prolong the hospitalisation or cause death?

- O Yes
- O No
- O Don't know

32. Provide further details of the adverse effect
(Please provide as much detail as possible and include any results of relevant laboratory data and other investigations, monitoring required etc.)

33 Do you have a second adverse effect to provide information about?

- O Yes (jump to question **34**)
- O No (jump to question **45**)

Section E continued. Details of Possible/Likely Adverse Effects Due to Remdesivir

Second adverse effect

34. What was the adverse effect?
(Name the adverse effect only, further details to be provided below)

35. What was the likelihood that this adverse effect was due to remdesivir use?

- O Possible
- O Likely
- O Don't know

36. What was the timing of onset of the adverse effect after the initial remdesivir dose was administered (in hours/minutes as applicable)?

37. What was the severity of the adverse effect?

- O Mild, no treatment required (jump to question **39**)
- O Moderate to Severe, treatment required (jump to question **38**)
- O Life-threatening (jump to question **38**)
- O Don't know, no treatment required (jump to question **39**)

38. Provide details of administered treatment for adverse effect including relevant laboratory results and/or diagnostic procedures

39. Has the patient recovered from the adverse effect?

- O Yes (jump to question **40**)
- O No (jump to question **41**)
- O Don't know (jump to question **41**)

40. How long did it take before the patient recovered from the adverse effect (minutes/hours/days)?

41. Did the adverse effect prolong the hospitalisation or cause death?

- O Yes
- O No
- O Don't know

42. Provide further details of the adverse effect
(Please provide as much detail as possible and include any results of relevant laboratory data and other investigations, monitoring required etc.)

43. Were any other adverse effects due to Remdesivir (possible or likely) experienced by the patient?

- O Yes (jump to question **44**)
- O No (jump to question **45**)

Section E continued.Details of Possible/Likely Adverse Effects Due to Remdesivir

Additional adverse drug effects (three or more)

44. Please provide a free text description of all additional adverse effects identified. Include the following information:
(If helpful, copy and paste the dot points below in your response)

- Name the adverse effect
- Likelihood that this adverse was due to remdesivir: [possible/ likely/ don't know]
- Timing of onset of the adverse effect after initial remdesivir administration: [hours/minutes, as applicable]
- Severity of the adverse effect: [mild, no treatment required; moderate to severe, treatment required; life-threatening; don't know, no treatment required]
- Provide details of administered treatment for adverse effect including relevant laboratory results and/or diagnostic procedures: [provide details or N/A]
- Recovery from the adverse effect? [yes/ no/ don't know]
- Time to recovery from the adverse effect: [minutes/hours/days]
- Prolongation of hospitalisation or caused death by adverse effect: [yes/ no/ don't know]
- Any other relevant details of the adverse effect (include results of relevant laboratory data and other investigations, monitoring required etc.)

Section E continued. Possible/Likely Adverse Effects Due to Remdesivir

45. *Were adverse effect(s) reported elsewhere?

- O No
- O Yes, reported to both the TGA and the hospital's adverse events reporting system
- O Yes, reported within the hospital's adverse events reporting system
- O Yes, reported to the TGA
- O Not sure

Section F. Clinical Outcomes

46. *Select the current clinical status of the patient

Refer to National COVID-19 Clinical Evidence Taskforce Living Guidelines https://covid19evidence.net.au/ for definitions of respiratory support requirements for

- Adults
- Neonates, children and adolescents

- ◯ Not hospitalised, no limitations on activities (jump to question **51**)
- ◯ Not hospitalised, limitations on activities, home oxygen requirement, or both (jump to question **51**)
- ◯ Hospitalised, not requiring supplemental oxygen and no longer requiring ongoing medical care (used if hospitalisation was extended for infection-control reasons) (jump to question **52**)
- ◯ Hospitalised, not requiring supplemental oxygen but requiring ongoing medical care (COVID-19–related or other medical conditions) (jump to question **52**)
- ◯ Hospitalised, requiring supplemental oxygen via low flow oxygen devices (jump to question **52**)
- ◯ Hospitalised, requiring supplemental oxygen via High Flow Nasal Oxygen (HFNO) or other high flow oxygen devices (jump to question **52**)
- ◯ Hospitalised, on non-invasive ventilation (NIV) (jump to question **52**)
- ◯ Hospitalised, on invasive mechanical ventilation (jump to question **53**)
- ◯ Hospitalised, on Extracorporeal Membrane Oxygenation (ECMO) (jump to question **53**)
- ◯ Death (jump to question **48**)
- ◯ Other (please provide details in next question) (jump to question **47**)

47. If other clinical status, please provide details

48. Date of death (date format: dd/mm/yyyy)

49. Cause of death (as documented on death certificate)

- O COVID-19 (jump to question **51**)
- O Other (jump to question **50**)

50. If other, specify cause of death as per death certificate

51. *Specify the total hospital length of stay (LOS) in days (numeric field)

52. *Did the patient require intensive care?

- O Yes (jump to question **53**)
- O No (jump to question **54**)

53. Specify the ICU/PICU/NICU LOS in days (numeric field)

Section G. Additional Information

54. Optional: please include any other information relevant to this report if not captured elsewhere.

E.g. consider including:

- requirements and duration of intubation or ECMO
- scores on admission to and discharge from ICU such as SOFA or APACHE 2 etc.
- development of respiratory failure
- development of multiorgan failure

55. What was the patient's COVID-19 vaccination status on admission?

- ◯ Not vaccinated against COVID-19 (questionnaire finished)
- ◯ Partially vaccinated, received part of the vaccination course (jump to question **56**)
- ◯ Fully vaccinated, however second vaccine dose was within 2 weeks of admission (jump to question **56**)
- ◯ Fully vaccinated, however, patient was immunosuppressed prior to admission (jump to question **56**)
- ◯ Fully vaccinated (jump to question **56**)
- ◯ Other (please provide details below) (jump to question **56**)

56. If known, provide details of:

- which vaccine they received,
- dates of any doses,
- details of immunosuppression if applicable

Submission

- You are now ready to submit the Remdesivir Adverse Events and Clinical Outcomes Report data.
- Please ensure you have completed all the questions marked with an asterisk*.
- Your local DTC will contact you if any further information is required.

Thank you for your contribution.