**IONA Data collection sheet** *(V6, 29th July 2021)*

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| --- |
| **1. Presentation details** |
| **IONA study number**1 |  | **Age and sex**  | Age (y) \_\_\_\_\_\_\_ Male **❑** Female **❑** |
| **Participant partial postcode (exclude last 2 digits)**2 |  | **Presentation date and time** | Date : / /20\_\_\_\_ Time \_\_\_\_:\_\_\_\_ (24h clock) |
| **Criteria for severe toxicity present?** 3 | Yes ❑ No ❑ Details:  | **Suspected opioid toxicity? 4** | Yes ❑ No ❑ | **Suspected NPS toxicity?5**  | Yes ❑ No ❑ |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **2. Exposure details** | **Timing** |  |  |  | **Type (tick one)** |  | **Route (tick all that apply)** 8 | **Source (tick one)** 9 |  |
| **Substance/description**6 | **Date** **started** | **Time** **started** | **Date** **Ended**7 | **Time ended**7 | Acute | Chronic | Both | Other (specify) | Oral | Snorted | Smoked | IV | IM | SC | Multiple | Vaping | Other (specify) | Internet | Shop | Dealer | Friend | Relative | Other (specify) | Not known |
| 1 |  / /20 |  : h |  / /20 |  : h | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** |
| 2 |  / /20 |  : h |  / /20 |  : h | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** |
| 3 |  / /20 |  : h |  / /20 |  : h | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** |
| 4 |  / /20 |  : h |  / /20 |  : h | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** | **❑** |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **3. Clinical features** | **GCS** | **HR** | **SBP** | **DBP** | **Temp** | **O2 Sat** | **A / V?**11 | **FiO2**12 | **pH** | **pCO2** | **pO2** | **Bicarb** | **Base XS** | **Lactate** | **Comment** |
| **Admission results**10 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| ***General*** | **No Yes Yes** **Persisting**13 **resolved** | **Details/specify****(if abnormal)** | ***Cardiorespiratory*** | **No Yes Yes** **Persisting**13 **resolved** | **Details/specify****(if abnormal)** |
| Pyrexia/fever | **❑** **❑** **❑**  | Max Temp (oC): | Bradycardia (HR<60) | **❑** **❑** **❑**  | Min HR: |
| Hypothermia | **❑** **❑** **❑**  | Min Temp (oC):  | Tachycardia (HR>100) | **❑** **❑** **❑**  | Max HR |
| Abnormal sweating | **❑** **❑** **❑**  |  | Hypertension (SBP>160 | **❑** **❑** **❑**  | Max BP |
| Other | **❑** **❑** **❑**  |  | Hypotension (SBP<80) | **❑** **❑** **❑**  | Min BP |
|  |  |  | Dizziness | **❑** **❑** **❑**  |  |
| ***Gastrointestinal*** |  |  | Arrhythmia | **❑** **❑** **❑**  | Type:  |
| Vomiting | **❑** **❑** **❑**  |  | Palpitations | **❑** **❑** **❑**  |  |
| Abd pain | **❑** **❑** **❑**  |  | Chest pain | **❑** **❑** **❑**  |  |
| Bleeding | **❑** **❑** **❑**  |  | Breathing difficulties | **❑** **❑** **❑**  |  |
| Other | **❑** **❑** **❑**  |  | Other | **❑** **❑** **❑**  |  |
|  |  |  |  |  |  |
| ***Neurological*** |  |  | ***Psychiatric*** |  |  |
| Reduced consciousness | **❑** **❑** **❑**  | Min GCS: | Agitation | **❑** **❑** **❑**  |  |
| Seizure | **❑** **❑** **❑**  |  | Aggression | **❑** **❑** **❑**  |  |
| Mydriasis (large pupils) | **❑** **❑** **❑**  |  | Confusion | **❑** **❑** **❑**  |  |
| Miosis (small pupils) | **❑** **❑** **❑**  |  | Hallucination | **❑** **❑** **❑**  |  |
| Hypertonia | **❑** **❑** **❑**  |  | Paranoid ideation/Psychosis | **❑** **❑** **❑**  |  |
| Hyper-reflexia | **❑** **❑** **❑**  |  | Depression | **❑** **❑** **❑**  |  |
| Clonus | **❑** **❑** **❑**  |  | Suicidal ideation | **❑** **❑** **❑**  |  |
| Dystonia | **❑** **❑** **❑**  |  | Catatonia | **❑** **❑** **❑**  |  |
| Tetany | **❑** **❑** **❑**  |  | Other | **❑** **❑** **❑**  |  |
| Other | **❑** **❑** **❑**  |  |  |  |  |

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| **4. Lab findings** | **No Yes Yes not** **Persisting13 resolved known** | **Details/specify****(if abnormal)** | **5. Treatments** | **No Yes**  | **Details/comments** |
| Acidosis | **❑** **❑** **❑** **❑**  | Min pH: | Activated charcoal | **❑** **❑**  |  |
| Lactic acidaemia | **❑** **❑** **❑** **❑**  | Max Lactate: | Whole bowel irrigation  | **❑** **❑**  |  |
| Hyponatraemia | **❑** **❑** **❑** **❑** | Min Na+ | Naloxone4 | **❑** **❑**  |  |
| Hyperkalaemia | **❑** **❑** **❑** **❑**  | Max K+ | Cyproheptadine | **❑** **❑**  |  |
| Creatinine increased | **❑** **❑** **❑** **❑**  | Max Creat | Dantrolene | **❑** **❑**  |  |
| AST/ALT increased | **❑** **❑** **❑** **❑** | Max ALT/AST | ITU/HDU/CCU admission | **❑** **❑**  | Length of stay14 |
| CK increased | **❑** **❑** **❑** **❑**  | Max CK: | Intubation | **❑** **❑**  |  |
| PT/INR increased | **❑** **❑** **❑** **❑**  | Max PT/INR: | Ventilation | **❑** **❑**  |  |
| Other | **❑** **❑** **❑** **❑** |  | Cooling measures  | **❑** **❑**  |  |
| Other | **❑** **❑** **❑** **❑**  |  | Extracorporeal therapy | **❑** **❑**  |  |
| Other | **❑** **❑** **❑** **❑** |  | Sedation | **❑** **❑**  | (specify) |
| Other | **❑** **❑** **❑** **❑** |  | Therapeutic use of fentanyls15 | **❑** **❑**  | Drugs used date/time  |
|  |  |  | Other | **❑** **❑**  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **6. Outcome** |  |  | **Disposal (tick one)** |  |  |  |  |  |
| Date of outcome | Time of outcome | Length of stay16 | Discharged | Self-discharge/abscond  | Transfer medical | Transfer psych | Died | Other (specify) |
|  / /20 |  : h |  | **❑**  | **❑**  | **❑** | **❑** | **❑** | **❑** |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **7. Samples**  | **Sent?** | **Date of sample** | **Time of sample** | **Samples**  | **Sent?** | **Date of sample** | **Time of sample** | **Samples**  | **Sent?** | **Date of sample** | **Time of sample** |
| Blood 1 | Yes **❑** No **❑**  |  / /20 |  : h | Urine 1 | Yes **❑** No **❑**  |  / /20 |  : h | Oral fluid 1 | Yes **❑** No **❑**  |  / /20 |  : h |
| Blood 2 | Yes **❑** No **❑**  |  / /20 |  : h | Urine 2 | Yes **❑** No **❑**  |  / /20 |  : h | Oral fluid 2 | Yes **❑** No **❑**  |  / /20 |  : h |

 Note that participants must provide at least one sample. Provision of one blood sample (taken as soon as possible after admission) and one urine sample is ideal

|  |  |
| --- | --- |
| **8. Medicines taken in last 5 days**17 | **9. Comments/notes**18 |
|  |  |

|  |  |
| --- | --- |
| **Person completing form** |  |
| **Contact telephone number** |  | **Contact email** |  |
| **Date of completion** |  | **Date sent to Newcastle** |  |

1 copy to be kept at study site, 1 copy to be sent with samples. Copies can also be sent by email (simon.thomas@ncl.ac.uk) When completing – please refer to explanatory notes

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**Explanatory notes**

Please provide as much detail as possible and ensure that all parts of the form are completed. If the data is not available please make a comment to that effect.

1. The local lab ID number is unique to the participant and should consist of a standard letter code to identify the study site followed by a number to identify the participant (e.g. RVI-001). This same number should also be used in labelling samples from that participant so that clinical data can be linked to results of sample analysis. The number should also be retained in the local site file so that the local research team is able to link results to that individual.
2. The ‘’partial’ postcode is used for geographical mapping of exposures and refers to the participant’s home address. It is the full postcode with the final 2 letters omitted. For example the postcode SE1 7RJ would be given as SE1\_7 (n.b. *not* ‘SE17’), while the postcode SE17 4NE would be given as SE17\_4.
3. Criteria for severe toxicity are given in the protocol and in the table below. Following substantial amendments 6 in England and Wales and 4 in Scotland, these are no longer inclusion criteria but please state if severe criteria (and which) are present.

**TABLE: Criteria for severe toxicity (present at any time after exposure)**

|  |  |
| --- | --- |
| * Fever > 38.5 oC
* Clinically important hypothermia
* Glasgow coma scale < 8a
* ITU/HDU/CCU admission
* Respiratory insufficiency
* Requirement for intubation and ventilation
* Seizures
* Hallucinations/psychosis
* Extreme agitation
* Severe or prolonged (> 24 h) behavioural disturbance
* Arrhythmia
* Chest pain or ECG evidence of cardiac ischaemia or myocardial infarction
 | * Acidosis (arterial or venous pH < 7.35 or bicarbonate < 20 mmol/L)
* Severe electrolyte or fluid disturbances
* Hypoglycaemia (<1.7 mmol/L)
* Methaemoglobinaemia (>50%)
* Tachycardia > 140 /min
* SBP > 180 mmHg
* SBP < 80 mmHg
* Acute kidney injuryb
* Creatine kinase activity raised (> 1000 IU/L)
* ALT/AST activity > 300 IU/L
* PT > 15 s or INR > 1.3
* Death
* Poisons Severity Score61 of 3 (Severe) c
* Other severe manifestations of toxicity, as determined and justified by the investigator
 |

aIn the absence of likely alternative causes (e.g. severe alcohol intoxication, use of sedative drugs etc).

bDefined as a rise in serum creatinine of ≥26 micromol/litre within 48 hours, a 50% or greater rise in serum creatinine known or presumed to have occurred within the past 7 days, or a fall in urine output to less than 0.5 ml/kg/hour for more than 6 h63

cCriteria for PSS 3 relevant to recreational drug use include abnormal chest Xray with symptoms, generalized paralysis, blindness or deafness

1. Please indicate by ticking the box if the participant has been included because of suspected severe opioid toxicity. Features that might suggest this include rapidly developing unconsciousness, hypotension, pulmonary oedema, pinpoint pupils and response to the antidote naloxone. Please also note naloxone administration in section 5.
2. Please indicate by ticking the box if you suspect involvement of a new psychoactive substance. Clues to this include use a specific named NPS (e.g. mephedrone, ‘products’ (Black Mamba, Clockwork Orange etc), unidentified powders or tablets, ‘spice’ or street drugs.
3. Please give as much detail about the substances as you can, i.e. the substances the participant reports he/she has taken, e.g. heroin, Green Rolex, ecstasy, spice, unidentified white powder etc. Please use one row for each substance. Use a further sheet if more than 4 substances. It is recognised that some information may be missing or there may be uncertainty about what has been taken and the timing of that, but please provide what information is available.
4. The time and date ended is only required for chronic exposures (e.g. those taken over more than 1 hour). For an acute single exposure these columns can be left blank.
5. The route of exposure should be provided for each substance. If multiple routes are used for the same substance please tick all routes that apply and the ‘multiple’ box. If other routes of exposure please tick the ‘other’ box and write in the route next to that. Note oral = ingested, snorted = insufflated.
6. If information is available on the source of the substance in question please record that in these columns.
7. These should be results taken at (or as soon as possible after) admission, usually from the ED records.
8. Specify A for an arterial and V for a venous blood gas sample
9. Specify the inspired oxygen for the blood gas sample, e.g. Air, 100% etc.
10. Persisting symptoms or laboratory findings are defined as those that are still present at hospital discharge.
11. Please specify the numbers of days and hours in critical care.
12. Please record if fentanyl or analogues (e.g. remifentanil, sufentanyl, alfentanyl) have been given for therapeutic reasons (e.g. intubation). It is essential to rule out therapeutic use if fentanyl or fentanyl analogues are found in participant samples.
13. Please specify the numbers of days and hours in hospital in total
14. Please list medicines that may have been taken in the last 5 days, especially psychoactive medicines such as opioids, pregabalin, gabapentin, modafenil etc.

Comments and further information can be provided in section 9, but be sure not to provide anything that might identify the participant.

If you have any questions, comments or problems relating to the form, please contact the Chief Investigator as follows

|  |  |
| --- | --- |
| Prof Simon ThomasNewcastle UniversityNewcastle NE2 4HH | Tel 0191 282 4642Fax 0191 282 0288Email simon.thomas@ncl.ac.uk |