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TIME
Take home naloxone Intervention
Multicentre Emergency setting feasibility trial

NHS
National Institute for
Health Research

Patient Privacy Notice

This patient notification contains information about our research study **"Take Home Naloxone Intervention Multi Centre Emergency Setting Feasibility Trial (TIME)"** and how it will use patient data.

1. What is the study about?

People who take opioid drugs such as heroin can overdose. The number of people who die this way is increasing. Naloxone is a drug that can reverse the effects of opioid overdose. Emergency ambulance staff and doctors in the Emergency Department regularly administer naloxone, but some people die before they reach emergency medical services.

There are schemes in where naloxone is given to drug users to administer to others in an emergency, this is called 'Take Home Naloxone' (THN). But we don't know whether THN saves lives and there are some concerns that it could encourage risk-taking behaviour

We will carry out this initial study to see:

1) whether it is possible for ambulance paramedics and Emergency Department staff to give out THN kits to drug users they see, and;

2) if we can collect data about this new way of distributing naloxone to find out whether it reduces deaths from overdose. We included people who have overdosed and drug users who presented with other drug-related problems such as an abscess.

We will carry out this study in two areas where THN was given to patients who have overdosed or who are at risk of overdose (Emergency Department and the ambulance paramedics who serve that hospital) and two other areas where THN kits were not given out.

In this study we will follow what happens to patients using the routine information which health services already collect. We will collect information about deaths, overdoses, emergency ambulance calls and emergency department attendances and admissions up to 1 year after patients are seen. We will compare these figures between the area which give out THN and the areas which are not. To find out about the experiences and views of patients receiving THN and staff who give out the kits, we will carry out interviews.

Our research is funded by the National Institute of Health Research.

2. What data will be collected and how it will be used?

We will conduct the study in the Emergency departments and their catchment areas within the local emergency ambulance service and collected trial data between 10/10/2019 to 02/06/2021. The following sites were allocated to the intervention group: Hull Royal

Infirmary (HRI) and Yorkshire Ambulance Service (YAS), Bristol Royal Infirmary (BRI) and South West Ambulance Service Foundation Trust (SWASFT). The control group comprised: Great Northern Hospital Sheffield (GNH) and Yorkshire Ambulance Service (YAS), Wrexham Maelor Hospital (WMH) and Welsh Ambulance Service NHS Trust (WAST). We intend to use routinely collected data of opioid users attending ED or attended to by ambulance services in the 24 months previous to our recruitment phase to identify those at risk of death from opioid overdose.

Primary data sources will include HES (Hospital Episode Statistics) datasets from NHS Digital for study sites in England, and the Emergency Department Data Set (EDDS) and Patient Episode Dataset Wales (PEDW) from the SAIL Databank for study sites in Wales.

Data processing is carried out under Articles 6 (1) (e) and 9 (2) (j) of the General Data Protection Regulations (GDPR). Data will be stored in a secure environment within Swansea University and only accredited researchers will have access to this data. Patient-level data will not be shared with any other person or organisation. Study outputs will only report grouped data, and we will ensure that individuals cannot be identified in them. Data security arrangements within Swansea University conform to standards specified by the Health Research Authority, NHS Digital, Digital Health & Care Wales and UKSeRP. Data will be archived for 5 years following the study.

3. Who has reviewed the study?

Our research has been approved by the Health Research Authority, following review by an NHS Research Ethics Committee.

4. How we will report our findings?

At the end of the study, we will publish our results in peer-reviewed, Open Access academic journals, ensuring that anyone who wishes to can access the results free of charge. We will also present the study at relevant conferences. In addition, we will produce an end of study report for interested parties including: our funder; clinical staff who participated in the study; and other stakeholders, including patient and public involvement representatives. It will not be possible to identify any patient from the published results.

5. Your rights

You can use the national data opt-out service; this allows people to prevent their confidential patient information being used for research and planning. More information on this is available on the NHS Digital website: https://digital.nhs.uk/services/national-data-opt-outprogramme

6. What if there is a problem?

Please contact:

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Thank you for taking the time to read this patient notification and for taking an interest in this research study