A mixed methods observational study to evaluate the implementation of a smartphone software application (App) and computerised decision-support system (CDSS) for antibiotic treatment guidelines in 50 NHS hospitals and to explore its potential impact on trends in antibiotic prescribing, resistance and inpatient clinical outcomes using interrupted time series analysis (The MicroGuide Study)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/19014

EU PAS number

EUPAS19013

Study ID

19014

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

Mixed methods design to include survey and qualitative interviews with NHS staff and exploratory analysis of quantitative outcome variables pre- and post-implementation of the intervention using time series analysis of hospital-level data

Study status

Planned

Research institutions and networks

Institutions

University of Southampton

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Institution

Contact details

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/06/2017

Study start date

Planned: 31/07/2017

Date of final study report

Planned: 28/09/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MSD

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To explore whether there are changes in trends of antibiotic prescribing after implementation of the MicroGuide App.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Mixed methods observational (survey & qualitative interviews, exploratory analysis of quantitative outcome variables)

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Infants and toddlers (28 days – 23 months)

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

0

Study design details

Data analysis plan

Quantitative variables will be analysed by comparison of trends during the two years before and two years after implementation of the App to identify statistically significant changes in slope and/or level, potentially associated with App implementation, using segmented regression analysis of interrupted time series (SRA-ITS). A meta-analysis of participating hospitals will be carried out by comparing relative changes in efficacy and safety variables at fixed time points

of 6 months, 12 months and 24 months following App implementation.Qualitative interview data will be analysed by thematic analysis according to the methods described by Braun and Clarke.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Clinical outcome data will be obtained for common infections (primary codes: pneumonia, urinary tract infection, skin/skin structure and intra-abdominal infection), from participating hospitals via the NHS Business Services Authority and Public Health England (PHE).

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No