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)

First published: 09/05/2017

Last updated: 09/05/2017

Study Planned

Administrative details

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

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Kieran Hand k.hand@soton.ac.uk

Study contact

k.hand@soton.ac.uk

Primary lead investigator

Amazigom Mayes

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

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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