patient outcomes. Pre-Hospital and Emergency Department (PHED) Data is a two-year mixed-methods observational study of the process and potential benefits of linking ambulance and ED data to allow analysis of patient outcomes. We report on our first aim, to examine the potential opportunities and challenges of this data linkage initiative.

### METHODS:

We approached six hospital trusts in an English metropolitan area. We used a structured learning log to collect data on the process, time input and reflections. We analyzed these data with descriptive statistics, and qualitatively for themes.

### RESULTS:

All six trusts agreed to participate. We used an algorithm based on date, time and patient demographics to link data. We achieved a dataset of 775,018 records covering 2012 – 2016, and a linkage rate of 81 percent.

Initial set up tasks within the ambulance service took 30 hours 20 minutes. We then identified five stages of tasks with each hospital trust: negotiating senior approval; exploring data availability; information governance agreement; data transfer; and linking. Mean time spent by the research team on these processes was 30 hours 30 minutes per trust (range: 17 hours 20 minutes to 43 hours 10 minutes), plus additional time from staff of hospital trusts. The most intensive phases were: negotiating senior approval (mean: 8 hours 5 minutes), and data linking (mean: 12 hours 40 minutes). The stage which took the longest was information governance (mean: 19 weeks).

Key themes included the positive attitudes of trusts to participating, the range of decision makers involved, and the need for sustained input from the research team.

### CONCLUSIONS:

We found the process of data linkage was feasible, but requires dedicated time from research and trust staff, over a prolonged period, to achieve set up. Linked data are now being analyzed.

## PP117 Isosorbide And Nifedipine In Chagas Patients: A Systematic Review


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### INTRODUCTION:

Chagas disease, caused by the parasite *Trypanosoma cruzi,* affects more than seven million people worldwide and it is considered by the World Health Organization (WHO) a neglected tropical disease (1). About one third of Chagas patients develop gastrointestinal disorders, such as dysphagia and achalasia. Management of the disease focuses on symptom improvement and drugs that relax the lower esophageal sphincter pressure (LESP), such as isosorbide and nifedipine. However, the use of these therapies is doubtful because of their side effects and palliative approach (2). The objective of this systematic review is to assess the effectiveness of isosorbide and nifedipine on gastrointestinal manifestation of Chagas disease.

### METHODS:

We searched MEDLINE, EMBASE and LILACS databases to retrieve potentially relevant articles from inception to December 2016. Inclusion criteria: clinical trials, cohorts or cross-sectional design; adults (>18 years old); assessment of effects of isosorbide or nifedipine on gastrointestinal symptoms in Chagas patients. Two reviewers independently screened titles and abstracts, selected eligible studies and extracted data from each study. PROSPERO registration number: CRD42017055143.

### RESULTS:

Eight studies were included (two case series, two clinical trials and four crossovers). Three studies evaluated the effect of isosorbide in LESP and three in esophageal emptying. All of them found that isosorbide rapidly reduces LESP and increases esophageal emptying rates, improving dysphagia. However, several patients



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reported collateral effects, such as gastroesophageal reflux, headaches and dizziness. One study evaluated the effect of nifedipine on LESP and one on esophageal emptying. Nifedipine decreased LESP, but there was no effect on esophageal emptying.

## CONCLUSIONS:

The available evidence shows isosorbide is effective in the management of gastrointestinal symptoms. Frequently health care of Chagas disease patients is delivered by primary care physicians. So, information on effectiveness of interventions can be aggregated to clinical guidelines, having an important value to inform general practitioners on the decision-making process regarding treatment of this group of patients, avoiding referencing to a specialized care.

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# PP120 Health Technology Assessment Framework To Capture The Full Value Of Value Added Medicines

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## INTRODUCTION:

Value added medicines (VAM) are medicines based on known molecules that address healthcare needs and deliver relevant improvements for patients, healthcare professionals and/or payers through drug repositioning, drug reformulation or drug combination (1-3). Recently, the European Commission, through the Safe and Timely Access to Medicines for Patients (STAMP) program, considered the issue of VAM development and regulatory process. Current Health Technology Assessment (HTA) tools may not fully capture the benefits of VAM, which could lead to obstacles for patient access to VAM in several European countries (1). The study objective was to identify how HTA frameworks should evolve to reflect VAM value.

## METHODS:

HTA expert interviews were performed as a preparatory step to an advisory board meeting. The following topics were addressed: (i) Eligibility for HTA and early HTA dialogues; (ii) Attributes that should be considered in HTA; (iii) HTA methodology; and (iv) Involvement of stakeholders in HTA.

## RESULTS:

VAMs bring additional benefit to patients and society. Therefore, the possibility for VAM assessment on a voluntary basis and within the appropriate assessment patterns/tools should be, in principle, included into HTA frameworks, as well as into early HTA dialogues. HTA should be patient-centric, and attributes such as patient preference, adherence, and patient reported outcomes should be considered where relevant. Unmet patient needs and disease burden should be used in a transparent and reproducible deliberative process. All these attributes should be used as explicitly and meaningfully weighted appraisal modifiers. HTA methodology should be comprehensive and should integrate societal perspectives. Patient representatives should take part in the decision-making process.

## CONCLUSIONS:

Current HTA frameworks should evolve to enhance VAM value recognition and encourage industry investment in medicines with high potential value for society.

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