

# A SYSTEMATIC LITERATURE REVIEW OF ANTIMICROBIAL STABILITY DATA IN ELASTOMERIC DEVICES

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## Background

Outpatient Parenteral Antimicrobial Therapy (OPAT) is an established approach to patient care, the benefits of which are clinical, financial and preferred place of care for patients. In order to maximise these benefits 'once-daily' antimicrobials should be used.

Antimicrobial stewardship principles state that, where possible, narrow spectrum, organism-specific agents should be used for infection management. Commercially available narrow spectrum agents frequently require administration two, three or more times each day.

- Use once daily broad spectrum antimicrobials going against stewardship principles
- Administer narrow spectrum agents as a continuous infusion via a portable medical device.

## Purpose

Medicines administration via a portable device requires appropriate stability data. The Yellow Covered Document (YCD) stipulates the minimum dataset for assessment of stability.

In order to facilitate OPAT services to adhere to stewardship requirements and access stability data for narrow spectrum agents a comprehensive literature review was undertaken. This review assessed the published antimicrobial stability literature available and its compliance with the dataset required by the YCD.

## Materials/Methods

Searches were conducted in Medline, EMBASE, Global Health, International Pharmaceutical Abstracts and Biomedical Research Database in April 2014 and November 2015.

## Results

A total 420 records were identified, 299 of which were excluded following title and abstract review. Full-text review of 121 citations identified no papers that **fully** met the dataset requirements of the YCD.

**Table 1: References that Comply with YCD Standards**

Yellow Covered Document Standard	No. Papers (n=121)
Testing under relevant storage conditions (37°C for elastomeric devices).	10
95-105% of API	10
All samples tested in duplication	46
Low and high 'clinically significant' concentrations	49
Complete physical stability testing	58
Three samples at each time point	70
At least four time points plus time zero.	79
Use of a stability indicating assay	108
All standards	0

Access to stability data in administration devices is a barrier to service expansion within the antimicrobial stewardship agenda. This review found no published studies that fully comply with YCD standards for shelf-life extension.