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Background

Infections are a leading cause of death among kidney transplant recipients. An approach to improve management of infections is to ensure that infection outcomes in clinical trials are consistently reported to allow valid comparisons across interventions.

Objectives

This systematic review aimed to describe the scope and consistency of infection outcomes and outcome measures used in contemporary randomized controlled trials in kidney transplant recipients.

Methods

An electronic search using the Cochrane Kidney and Transplant Specialized Register was conducted to identify trials reporting infection outcomes in kidney transplant patients age ≥ 18 between 1 January 2014 to 31 July 2019. This timeframe was chosen to focus on contemporary outcome measures of recently published and ongoing trials. Trial characteristics, infection-related outcomes and outcome measures were extracted from included trials. Descriptive statistical analyses was performed.

Results

102 trials were identified from the electronic search

- 4,521 Participants
- 34 different countries
- Median trial duration 13 months
- Sample size 114 participants
- 92% pharmacological intervention

Outcome measures further grouped into 32 outcomes based on site of infection and organism.

- 14 sites, most commonly reported was **systemic infection** (71% trials) (Figure 1)
- 18 organisms, most commonly reported was **CMV** (62% trials)
- 1-8 different measurement definitions
- 11 different metrics, most commonly used was **number of events** (37% trials)
- 6 different methods of aggregation, most commonly **median** (46% trials)
- 55 different time points of measurements, 1-11 time points per trial
- 772 total outcome measures defined and grouped into 216 unique outcome measures (Figure 2).

Conclusion

Infection outcomes and outcome measures reported in contemporary adult kidney transplant clinical trials were **very heterogenous**. Although systemic infections, especially CMV, were most commonly reported, a multiplicity of outcome measures were used at every level extracted from the trials- definition, metric (including assays used) and method of aggregation. This **lack of harmonization** makes it **difficult to reliably compare trial evidence** designed to improve infection outcomes in kidney transplant recipients.

A **strategy to improve infection reporting** is to implement a “**core outcome set**” incorporating consensus-based “**minimum set of outcomes that should be measured and reported in all clinical trials of a specific disease or trial population**.” In 2014, the Standardized Outcomes in Nephrology (SONG) initiative was established to define core outcome sets across the spectrum of kidney disease based on shared priorities of patients and their caregivers, clinicians, researchers and policy makers². **Infection has been identified as a core outcome domain** for trials in kidney transplant recipients³.

References:

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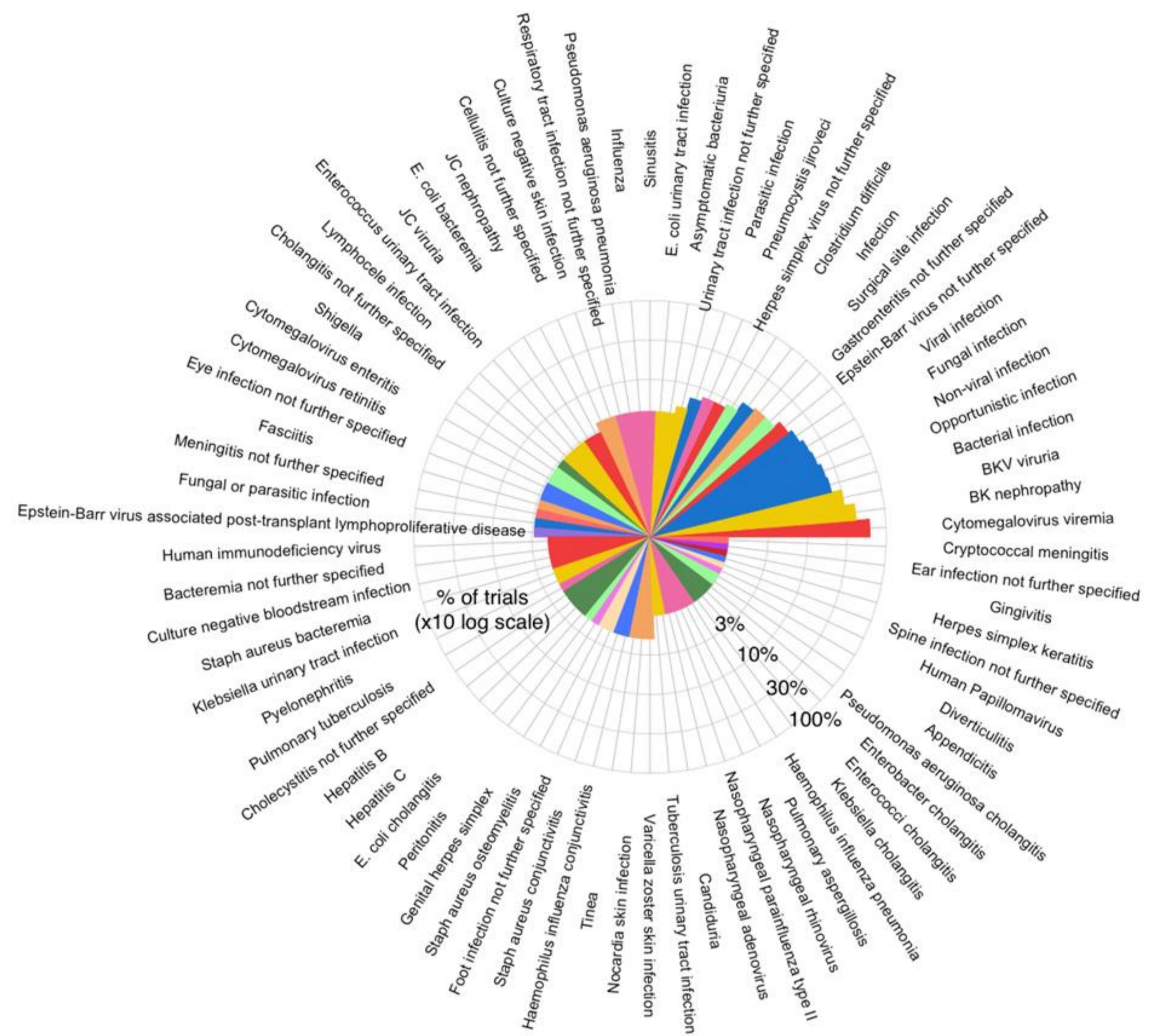


Figure 1. Chart showing the scope and frequencies of site-specific outcomes reported in 102 randomized controlled trials in adult kidney transplant recipients

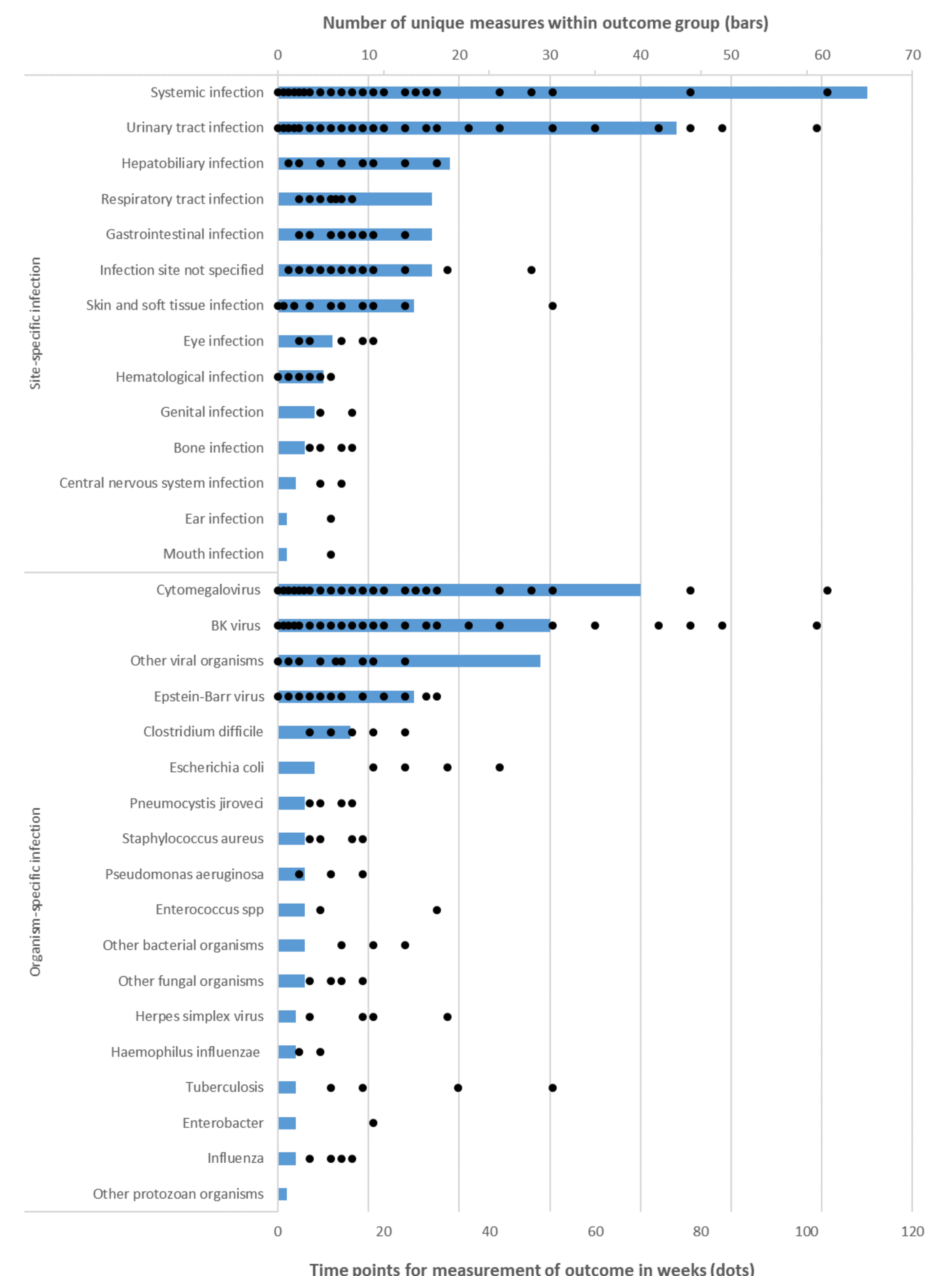


Figure 2. Bar chart showing the number of unique infection outcome measures (bars) and the different time points they were reported (dots)