

### Introduction

The COVID-19 pandemic has highlighted how clinical research is not representative of the population it aims to serve, limiting result generalisability. Such groups include Black adults and adult ethnic minorities, who are disproportionately affected by COVID-19 in comparison to their white counterparts. To address past disproportionalities, the INCLUDE project, launched by the NIHR in 2017, provided a strategic level overview with intervention points to aid inclusion of under-served groups; however, the degree to which this has been successfully implemented is uncertain. This systematic review aims to establish if Black adults and adult ethnic minorities were represented in UK based COVID-19 vaccination RCTs when compared to corresponding UK population proportions, based on 2011 census data.

### Methods

OVID Medline, OVID Embase and The Cochrane Central Register of Controlled Trials were screened as per PRISMA guidelines (Figure 1). MeSH terms include “Covid-19 vaccine”, “Ad26COVS1”, “BNT162 Vaccine” and keywords such as [covishield OR coronavac OR Vaxzevria OR NVX-CoV2373] were used to extract articles published between 1<sup>st</sup> December 2019 and 1<sup>st</sup> January 2022. Studies that provide (A) participant demographics and (B) full eligibility criteria were included. The following key data was extracted: number of participants analysed, number of Black adults and number of adult minority ethnicity participants to calculate the percentage presence of each group respectively. A weighted average was also calculated for extracted studies and a two-tailed, one sample t-test was conducted for statistical analysis.

### Results

Data was extracted from 7 publications. A two-tailed t-test comparing the mean percentage of Black adults enrolled (0.59%, 95% CI: 0.13%, 1.05%) against the census-recorded Black adult population (2.67%) indicates they were under-served in UK based COVID-19 RCTs ( $p < 0.001$ ). Overall adult ethnic minority presence (8.94%, 95% CI: 2.07%, 15.80%) was also lower than census data (16.30%), indicating they were also under-served ( $p = 0.039$ ) (Figures 2 & 3).

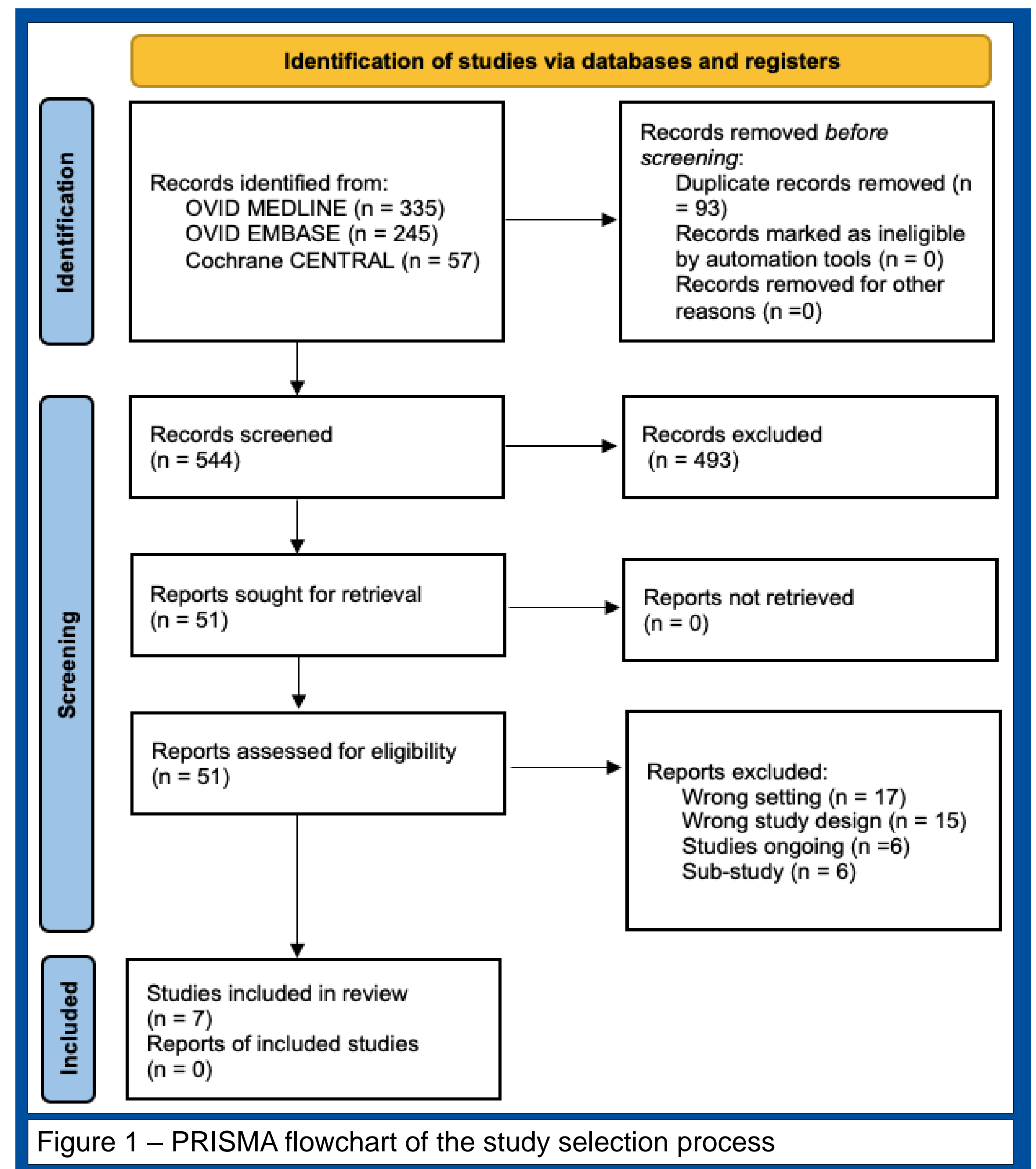


Figure 1 – PRISMA flowchart of the study selection process

### Discussion

COVID-19 has resulted in several high-profile vaccine trials being conducted over a short time. Despite the recent emergence of the INCLUDE project there was a failure to representatively recruit Black adults and adult ethnic minorities. A number of contributing factors are likely:

- Online screening tools as part of the recruitment process
- Using insufficient english language level as grounds for trial exclusion
- Feelings of distrust or racial prejudice towards vaccine manufacturers & healthcare providers.
- High volume of participating trial sites coming from regions with low black and ethnic minority populations (Figure 4)

### Conclusion

The findings provide evidence that COVID-19 vaccine trials failed to recruit a population that is representative of the United Kingdom. More inclusive practises must be developed and implemented in order to understand the true impact of COVID-19 vaccination programs (and medical research in general) on the most vulnerable groups of society and the population as a whole. Existing guidance, such as the INCLUDE project, need to be reinforced with stronger implementation practices.

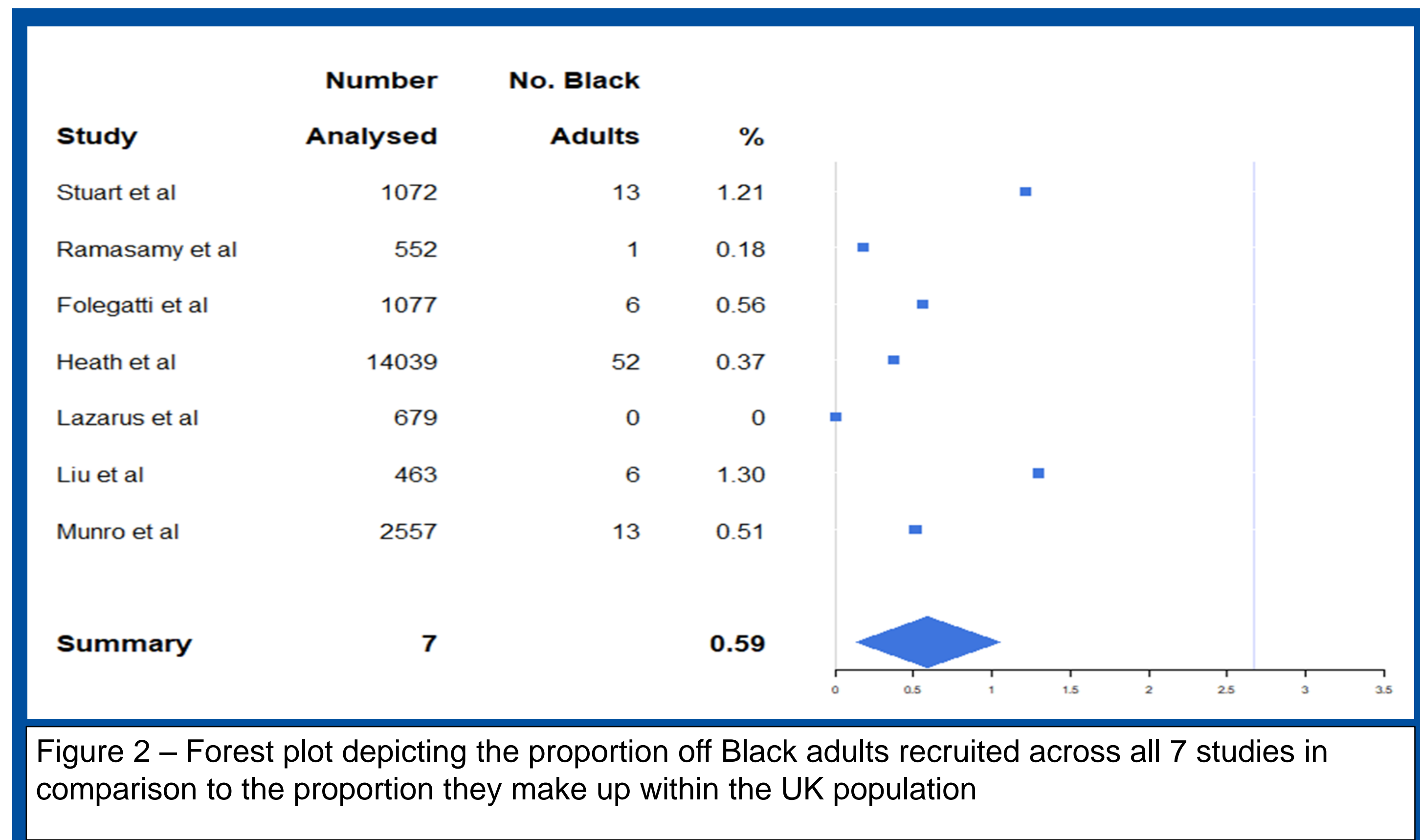


Figure 2 – Forest plot depicting the proportion off Black adults recruited across all 7 studies in comparison to the proportion they make up within the UK population

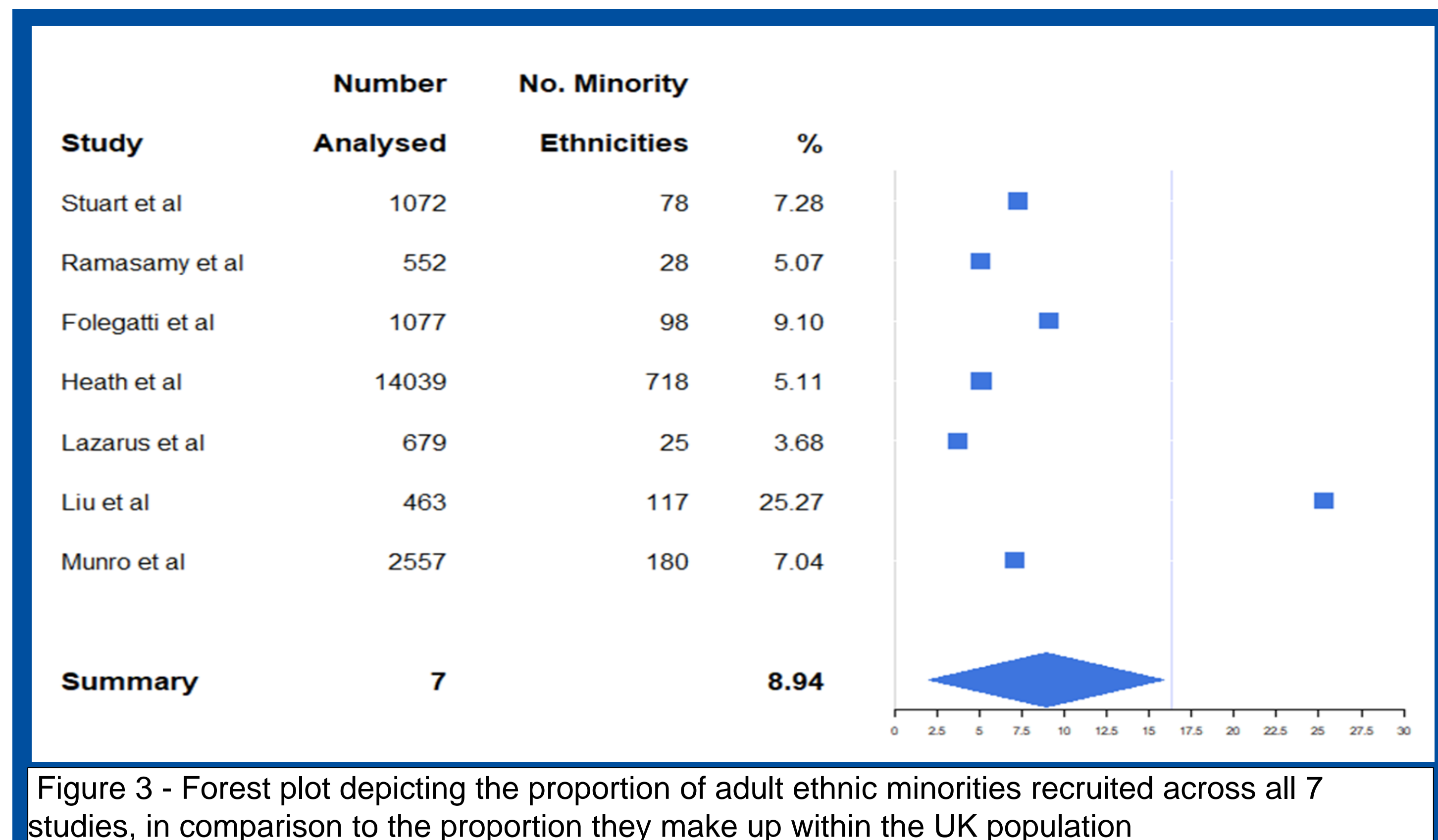


Figure 3 - Forest plot depicting the proportion of adult ethnic minorities recruited across all 7 studies, in comparison to the proportion they make up within the UK population

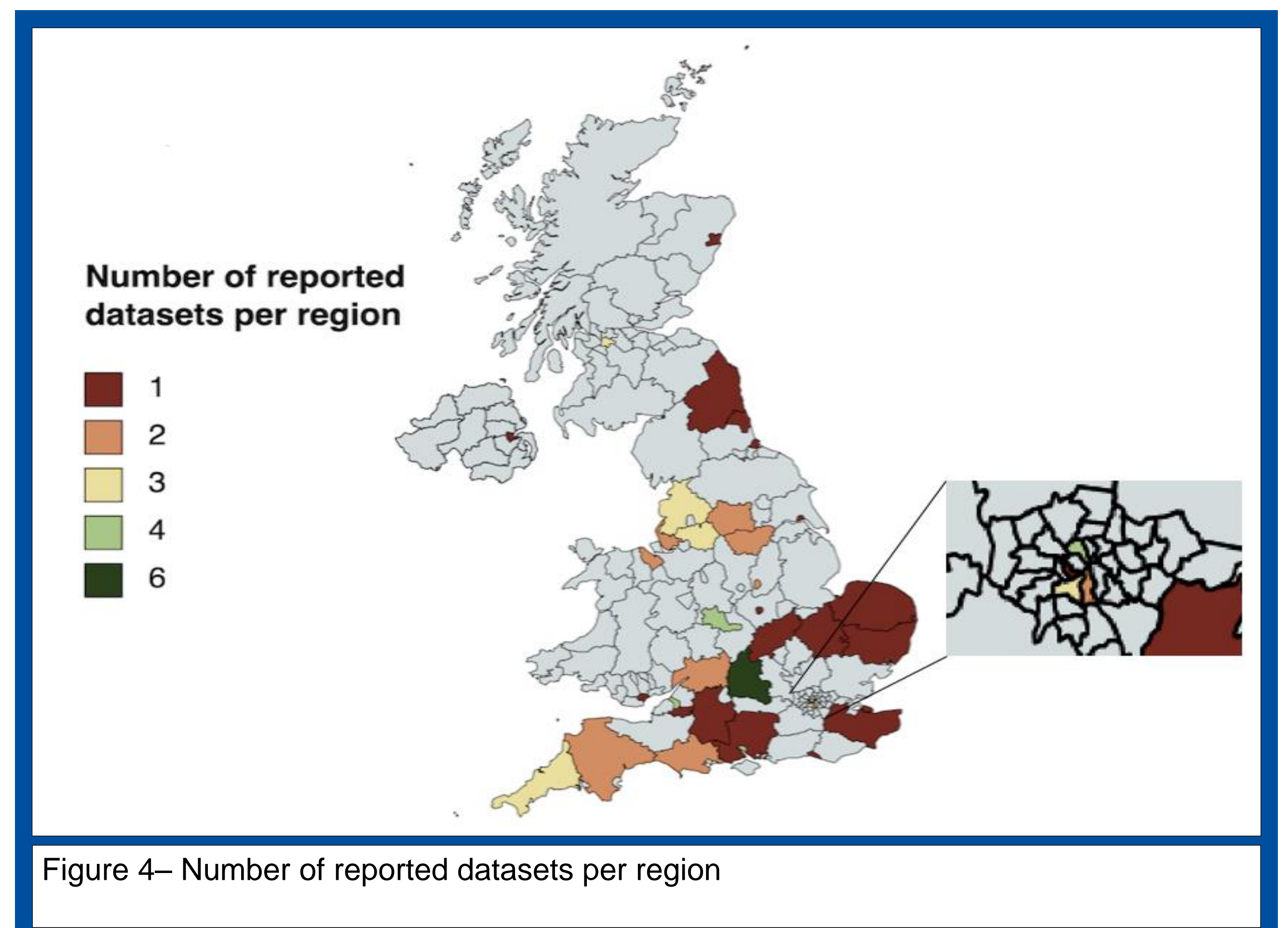


Figure 4– Number of reported datasets per region