



Introduction

- Previously published reviews highlighted low rates and poor quality of clinical trials in nephrology compared to other specialties.
- In this review we assess time trends in quality and quantity of nephrology trials.

Methodology

- We conducted a systematic review among Nephrology trials registered on ClinicalTrials.gov from inception to November 2018.
- Two independent reviewers assessed every trial and extracted data about major category, population and outcomes.
- After downloading a database of 288,515 interventional registered trials, the Nephrology data set was restricted to studies that includes one of 154 nephrology terms (both Medical Subject Headings [MeSH] and non-MeSH).
- Reviewers screened 5412 records and included 4959 studies in data analysis. We grouped the included trials into 3 eras. Era-1 [09/30-1982-08/31/2010]; Era-2 [09/01/2010-08/31/2014]; Era-3 [09/01/2014-12/31/2018].

Results

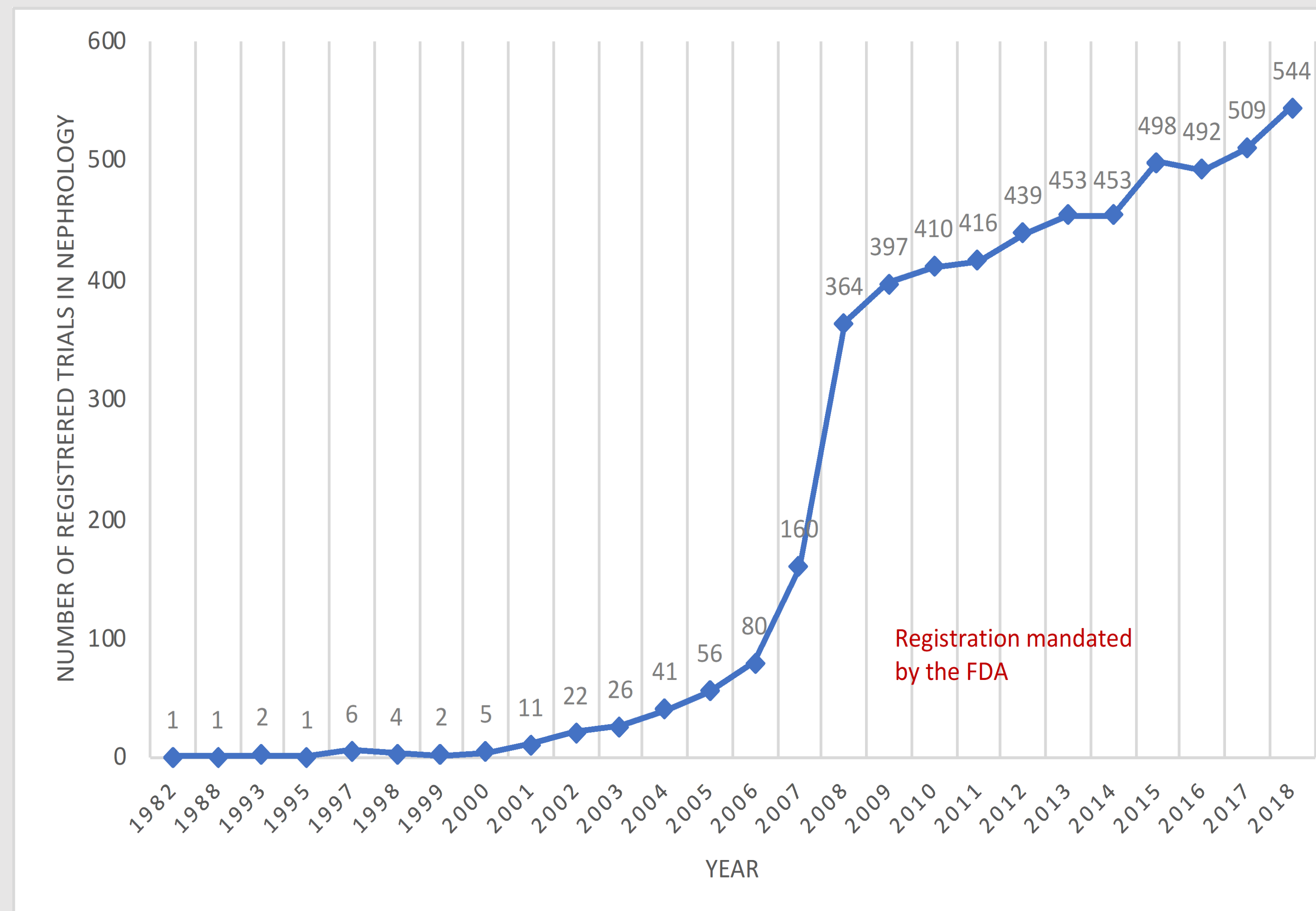


Figure 1. Number of registered nephrology trials on ClinicalTrials.gov

| | Era 1: Inception-2010 | Era 2: 2010-2014 | Era 3: 2014-2018 |
|--------------------------|--------------------------|---------------------|---------------------|
| Randomization | 77.4% | 84.5% | 82.6% |
| Blinding | 30.3% | 34.1% | 34.7% |
| >1000 Patient enrollment | 1.5% | 2% | 4.1% |
| NIH funded | 8% | 4.5% | 6.6% |
| Industry Funded | 45.3% | 42.8% | 32.2% |
| Drug Intervention | 73.5% | 64.5% | 57.2% |
| Device Intervention | 6% | 8.9% | 10.7% |
| Behavioral Intervention | 2.7% | 4% | 6.2% |
| Glomerular disease | 5.8% | 6% | 7.5% |

Table 1. Trial Characteristics

- There are less NIH and industry funded studies.
- Era 3 has more randomized, blinded and large trials.
- Drug trials per era has decreased while device and behavioral interventions increased.

Discussion

- There has been an increase in the number of nephrology trials conducted over time.
- There has been some improvement in quality and a promising trend in trials for devices, behavioral interventions
- Initiatives like the Kidney Health Initiative (KHI) are likely to have contributed to the improvement in quality and quantity of nephrology trials.
- Highlighting specific areas that are deficient in nephrology trials is likely to have increased contribution in those areas.

Clinical Trial Major Category

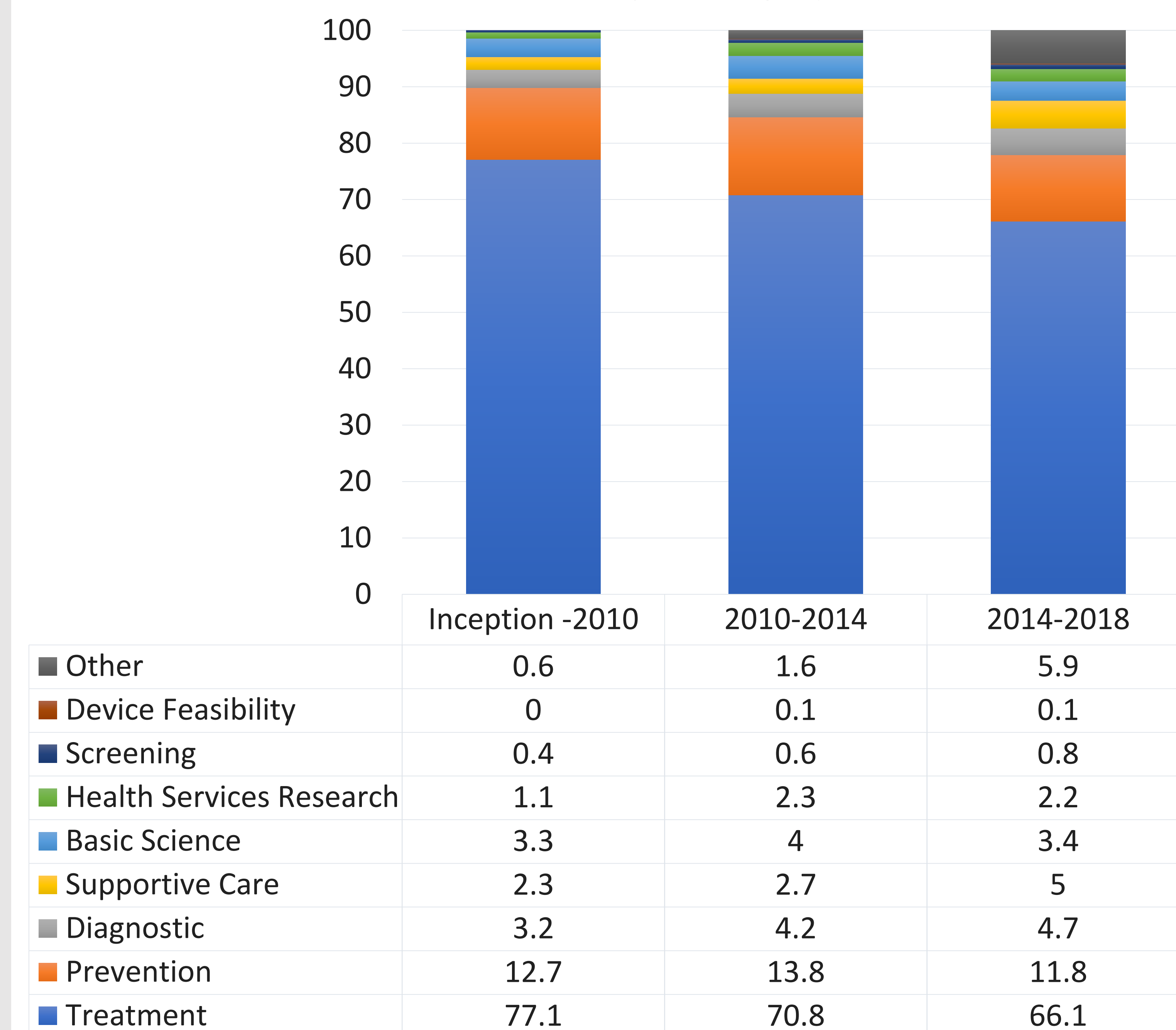


Figure 2. Major Categories for reporting on clinicaltrials.gov

Primary Population Distribution Across the 3 Eras

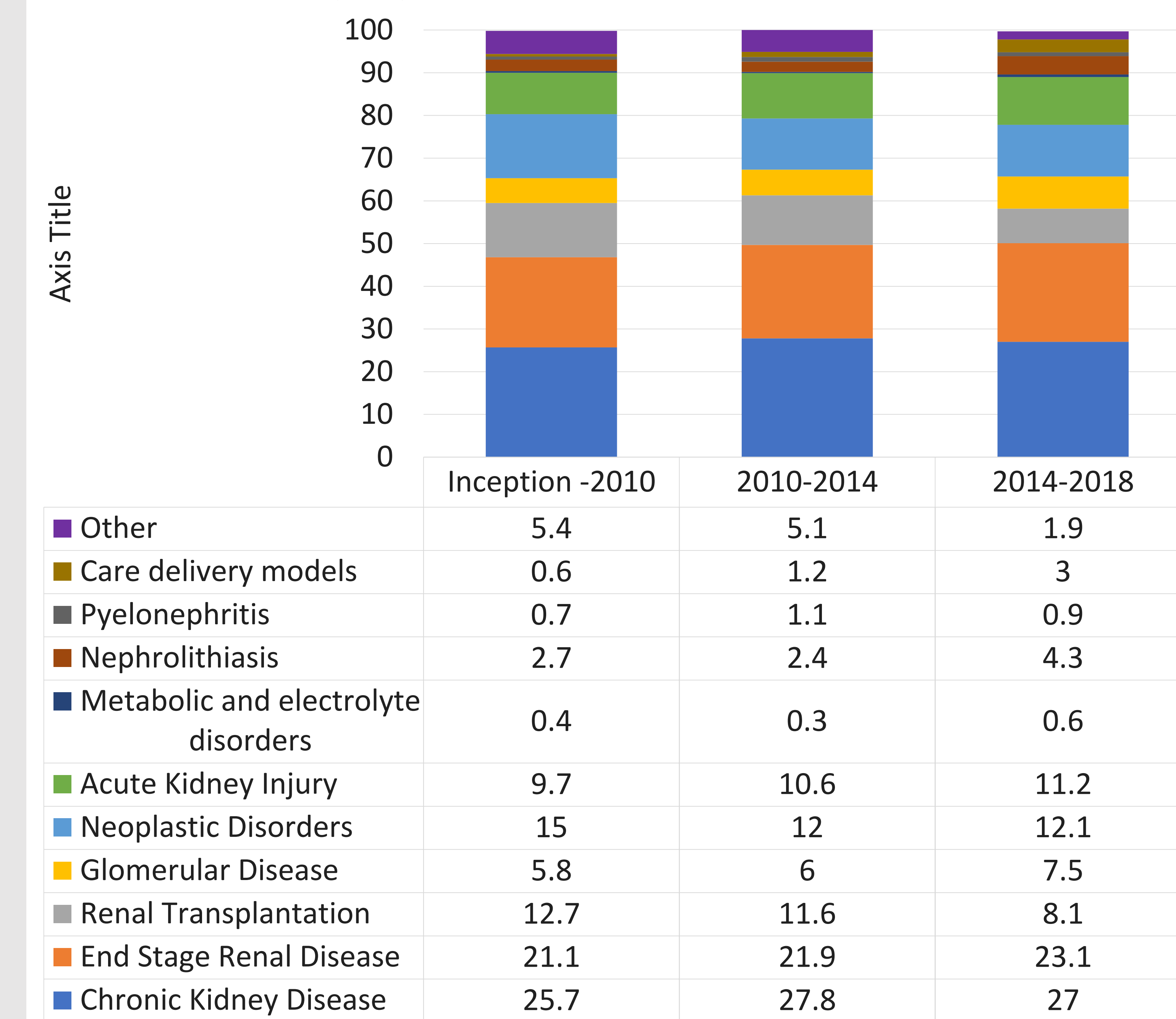


Figure 3. Distribution of nephrology trials.; While there is a decrease in transplant trials, there is an increase in living donor recipient trials [Era 1: 11.4%; Era 2: 8.6; Era 3: 23.4%]

References

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