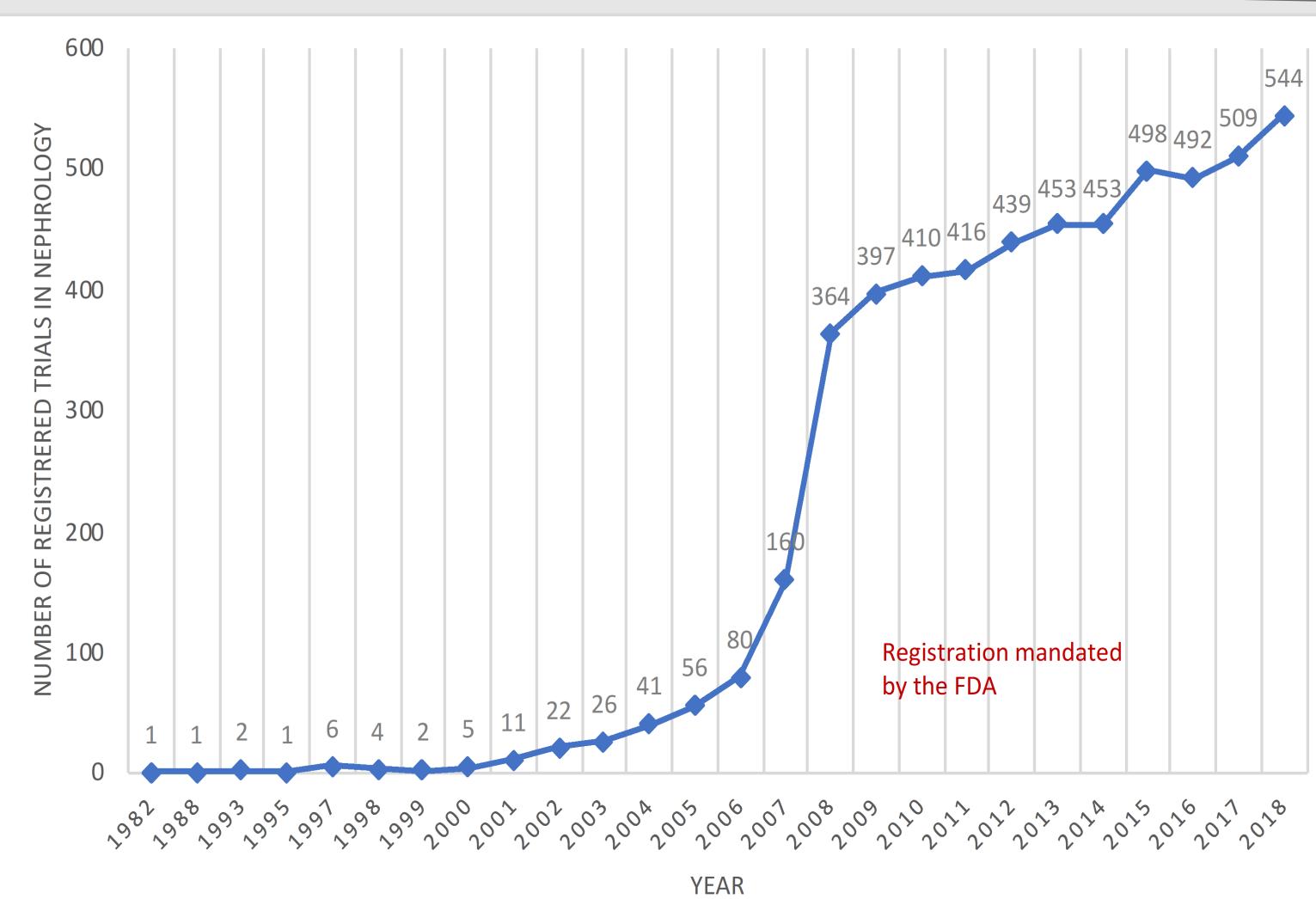


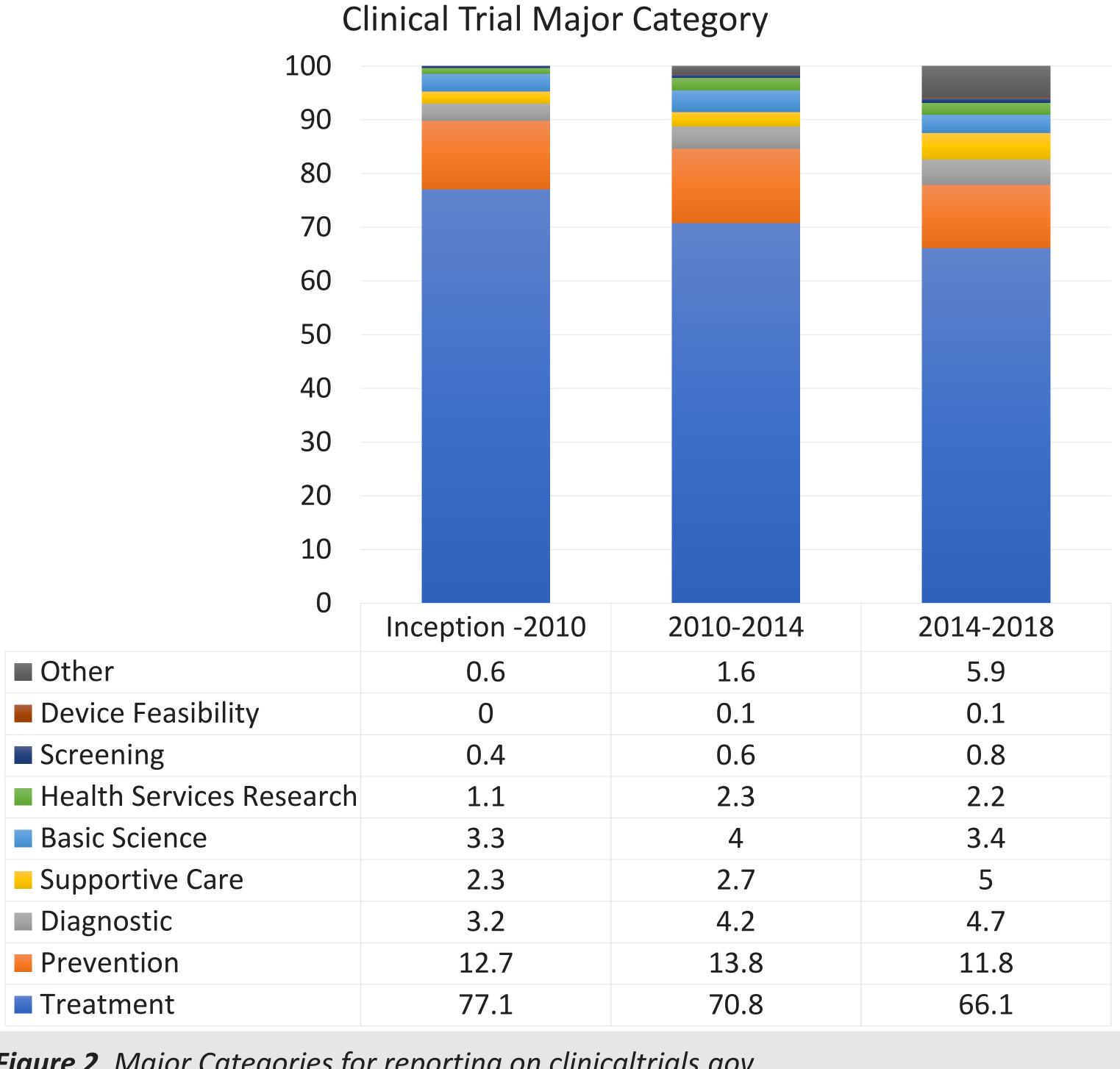
Introduction

- 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].





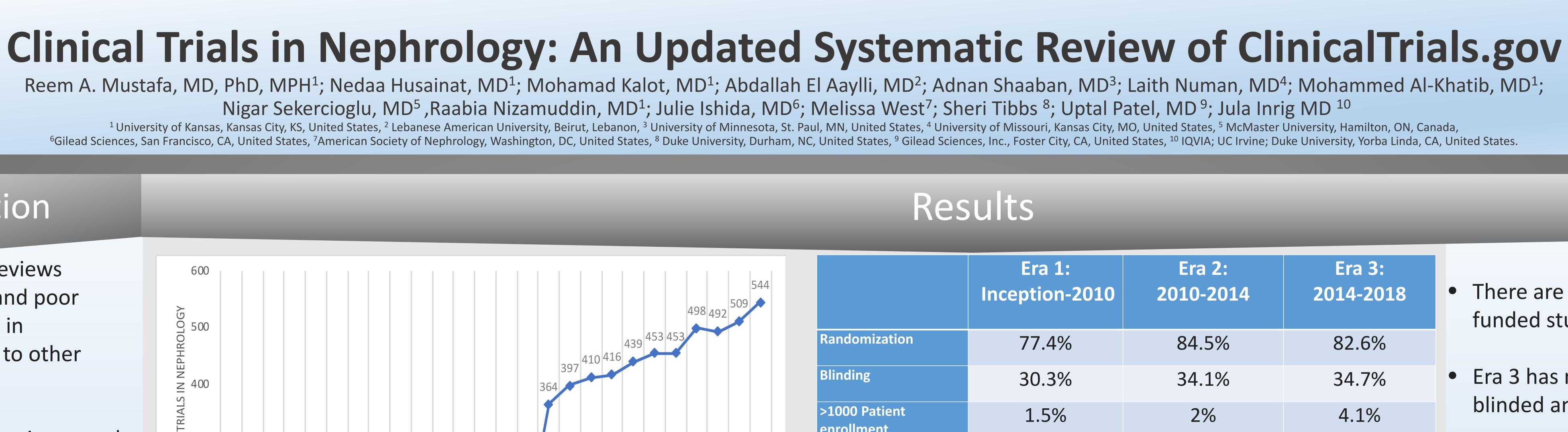


Figure 2. Major Categories for reporting on clinicaltrials.gov

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Results

	Era 1: Inception-2010	Era 2: 2010-2014	
Randomization	77.4%	84.5%	
Blinding	30.3%	34.1%	
>1000 Patient enrollment	1.5%	2%	
NIH funded	8%	4.5%	
Industry Funded	45.3%	42.8%	
Drug Intervention	73.5%	64.5%	
Device Intervention	6%	8.9%	
Behavioral Intervention	2.7%	4%	
Glomerular disease	5.8%	6%	

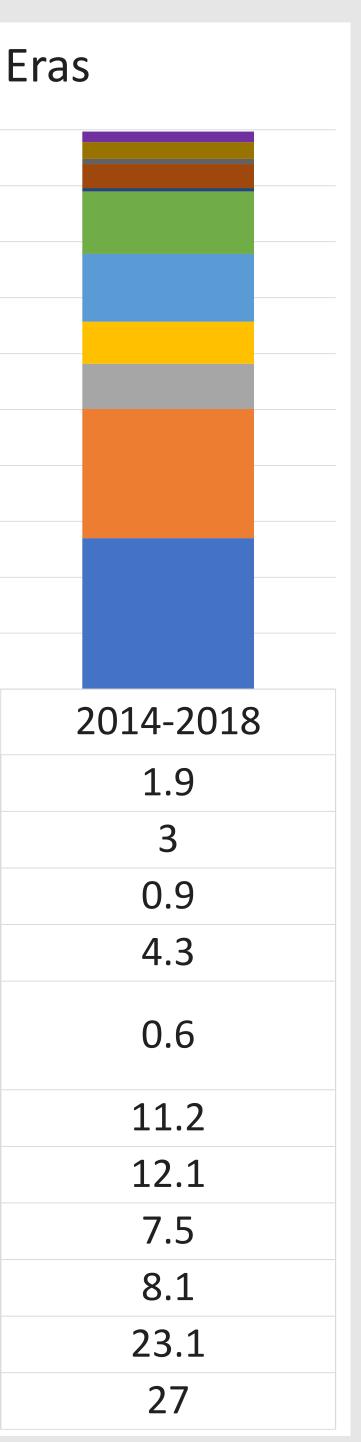
 Table 1.
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Renal Transplantation12.711.6End Stage Renal Disease21.121.9	Neoplastic Disorders	15	12
End Stage Renal Disease 21.1 21.9	Glomerular Disease	5.8	6
	Renal Transplantation	12.7	11.6
Chronic Kidney Disease 25.7 27.8	End Stage Renal Disease	21.1	21.9
	Chronic Kidney Disease	25.7	27.8

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%]



Era 3: 2014-2018
82.6%
34.7%
4.1%
6.6%
32.2%
57.2%
10.7%
6.2%
7.5%



- 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.

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