EMBED: *A Pragmatic Trial of User Centered Clinical Decision Support for **EM**ergency Department Initiated **B**uprenorphin**E** for Opioid Use **D**isorder*

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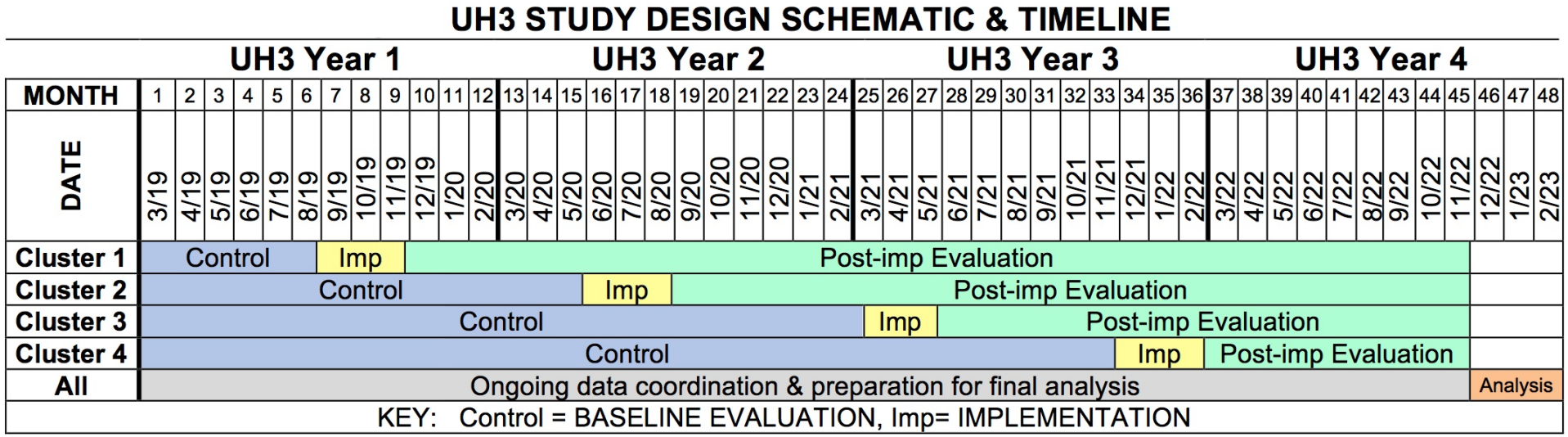
Original stepped wedge study design plan

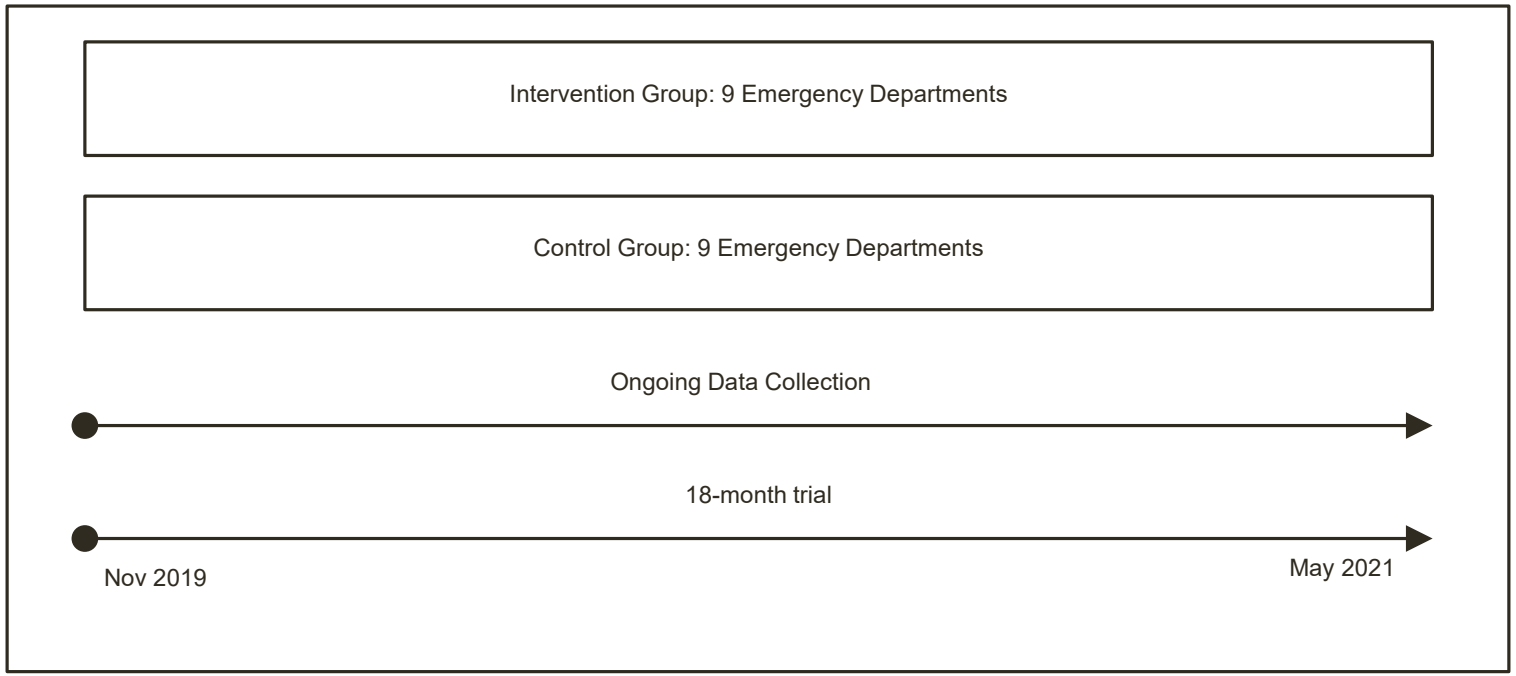


Study Design Change

Feature	Stepped Wedge	Group Randomized
Length of trial	Longer trial period due to baseline and post-implementation phases	Shorter trial period
Control for temporal trends	Weaker, more vulnerable due to longer trial period	Stronger, due to shorter trial period
Control of heterogeneity by site	Yes, sites serve as their own control	Not as good, compensate for this weakness by employing constrained randomization
All sites get intervention	Yes	No, but can offer at end of shorter trial
Number of clusters (ED sites)	Fewer	More – increased budget
Go-live of IT intervention	Staggered, later implementations can learn for issues in earlier ones	Synchronized, requires more lead time and coordination
Additional time for IT build, pilot testing, and dissemination	No, due to longer trial period	Yes, shorter trial period permits additional time for IT build and dissemination in later UH3 years

Methods

- 18-month pragmatic, parallel, group randomized trial
- 18 ED clusters (21 sites) in 5 healthcare systems randomly allocated in 1:1 ratio to intervention versus usual care arm with stratified covariate constrained randomization
- Intervention: CDS to support diagnosis & withdrawal assessment & automate orders, notes, Rx, AVS, referral
- Primary outcome: initiation of BUP in ED at patient level
- Protocol approved by Western IRB (**WIRB**)



EMBED Trial Protocol.
BMJ Open, 2019

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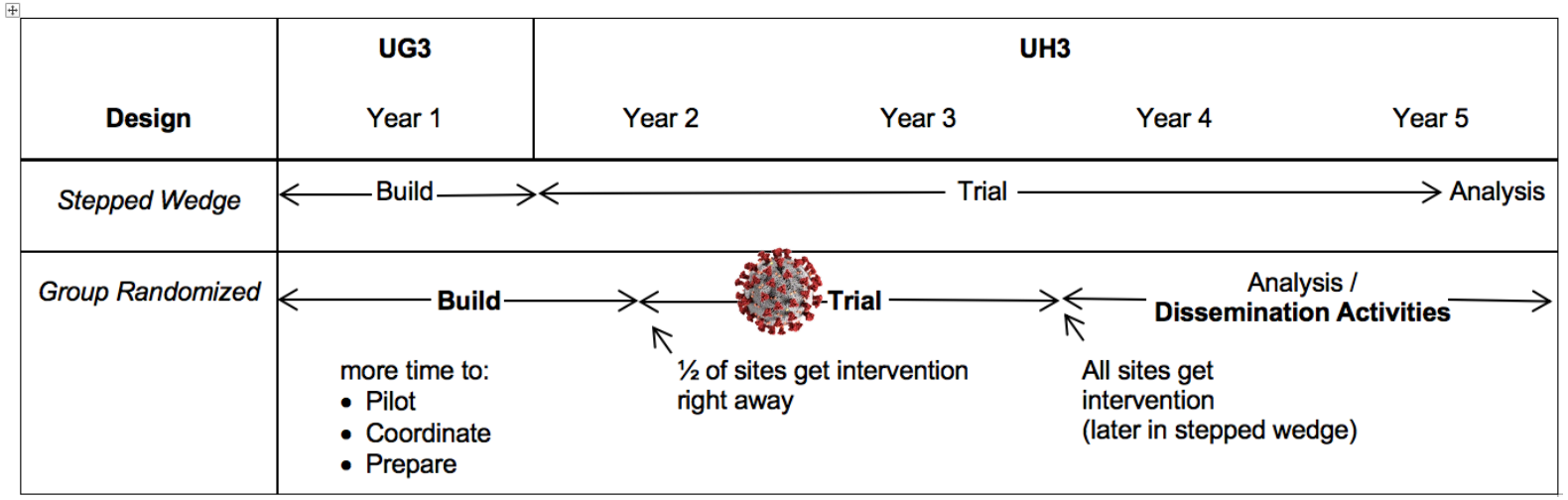
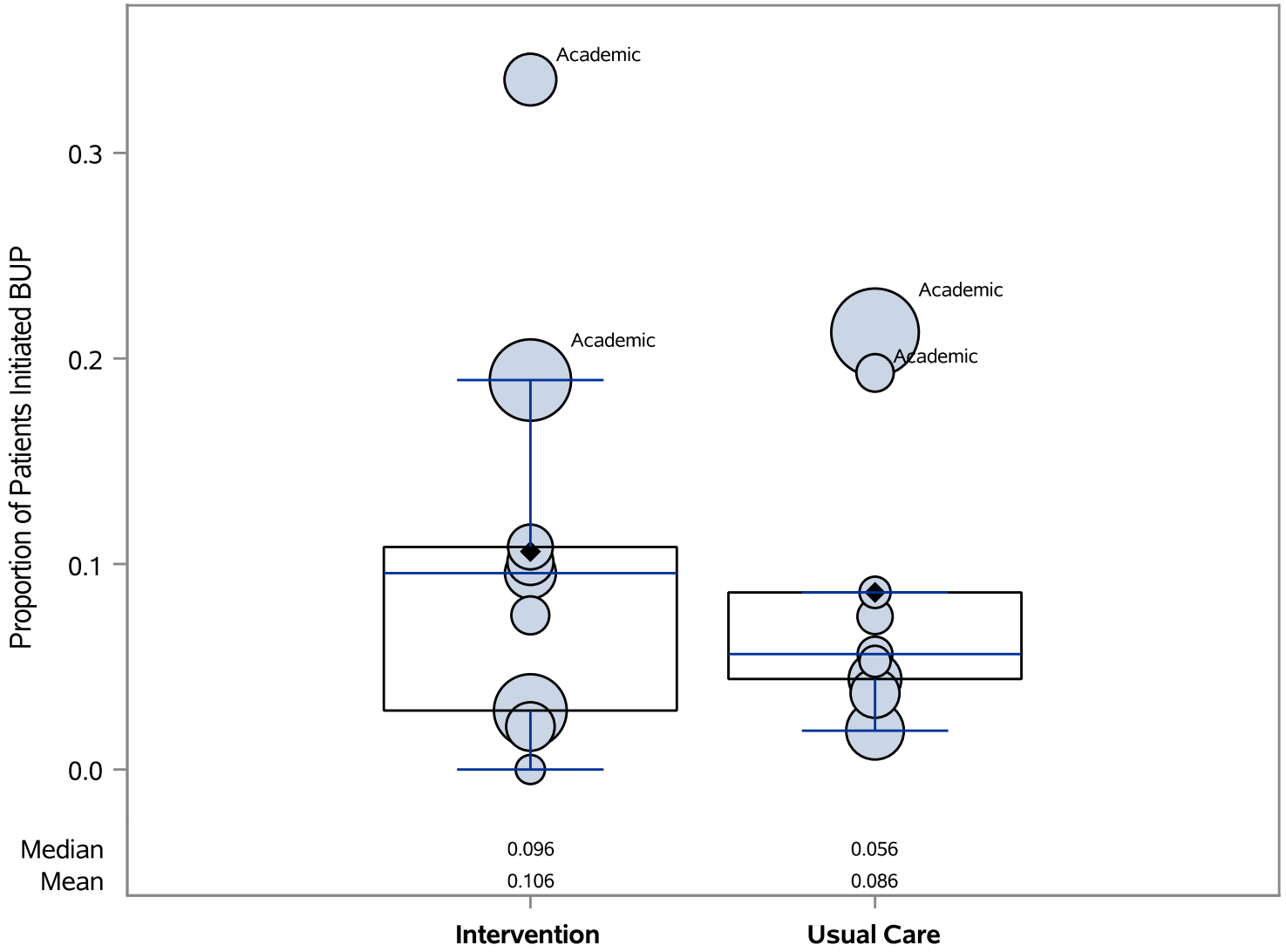
Study Design Change

- Increasing the CDS build and integration period allowed for the switch to a group randomized CRT
- Better control of temporal trends
- Shorter overall trial period
- Larger number of EDs required to maintain power
- Covariate constrained randomization used for balance across sites/clusters
- Offer intervention to all EDs at end of trial



Proportion of OUD patients receiving BUP by study arm



* Bubble size indicating OUD cluster patient volume

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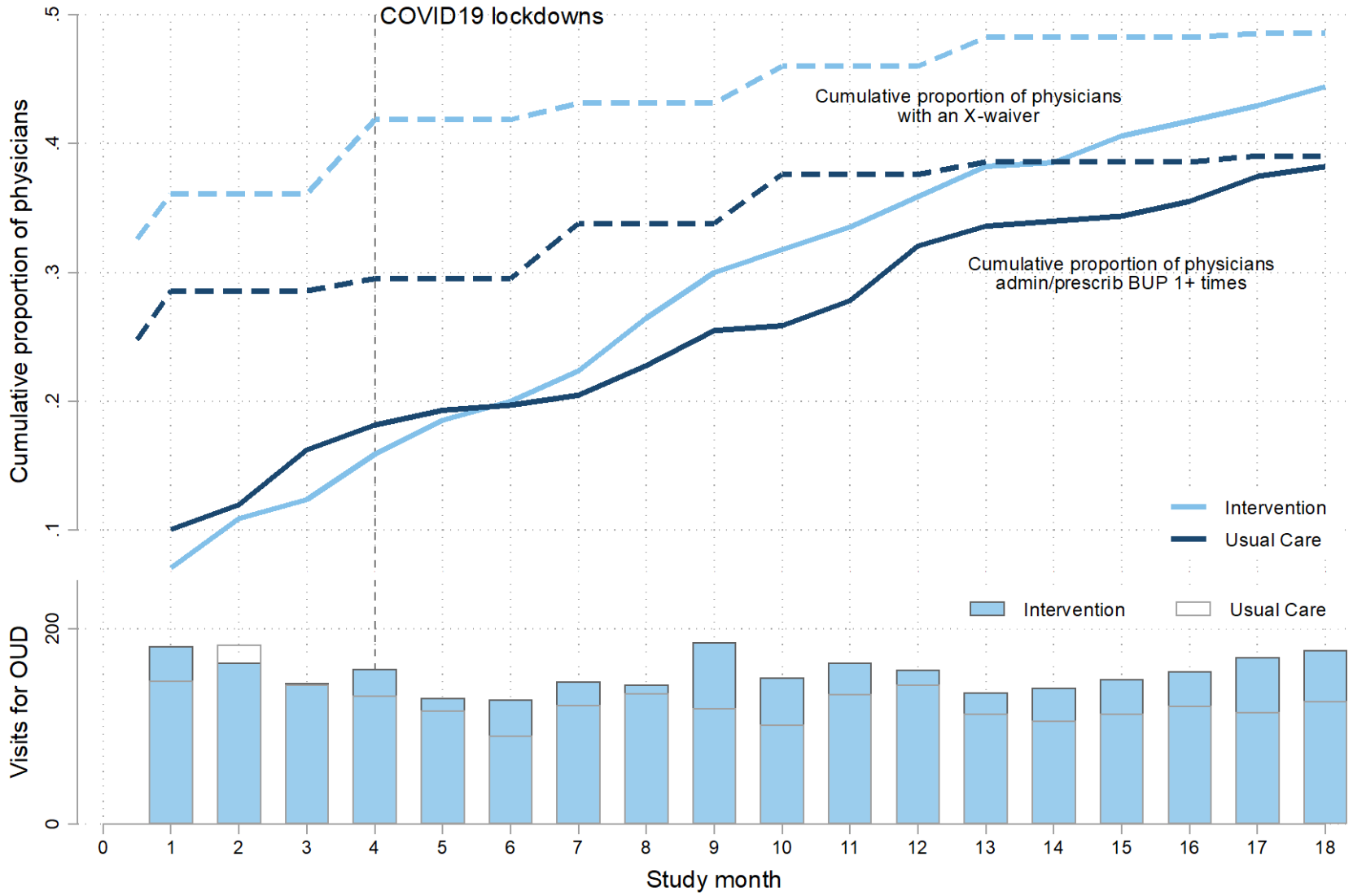
Temporal trends of physicians initiating BUP and X-waiver (cumulative)



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