



ACST-2 Update

Alison Halliday and Richard Bulbulia

5th May 2020

Recruitment will end 31st Dec 2020

**Mean days from randomisation to procedure,
mean person-years follow-up from entry
to 04/05/2020**

Of 3125 procedures

1587 allocated CEA: 24 days

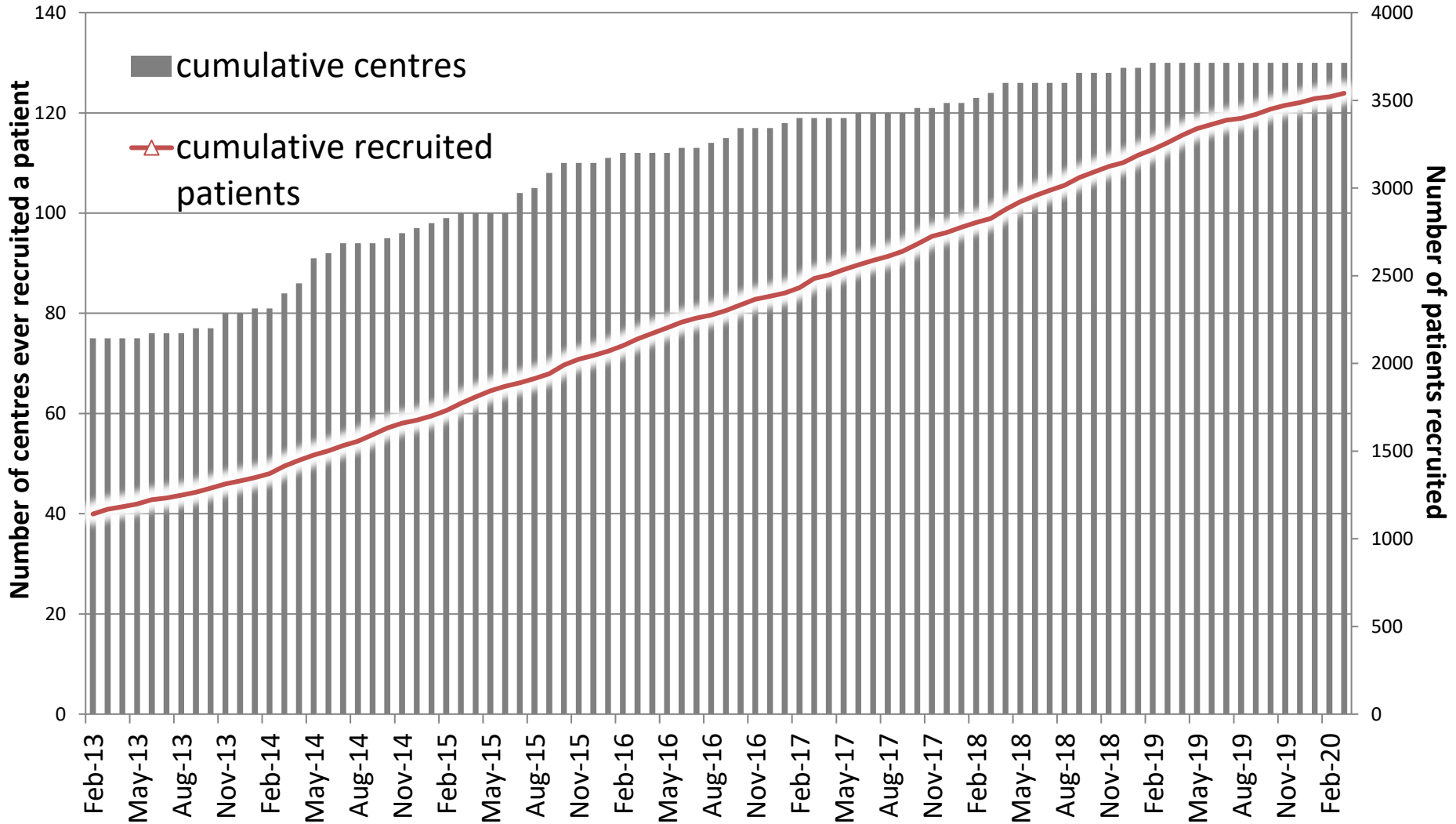
1538 allocated CAS: 29 days

Those allocated CEA: mean follow up 4.7 p-y

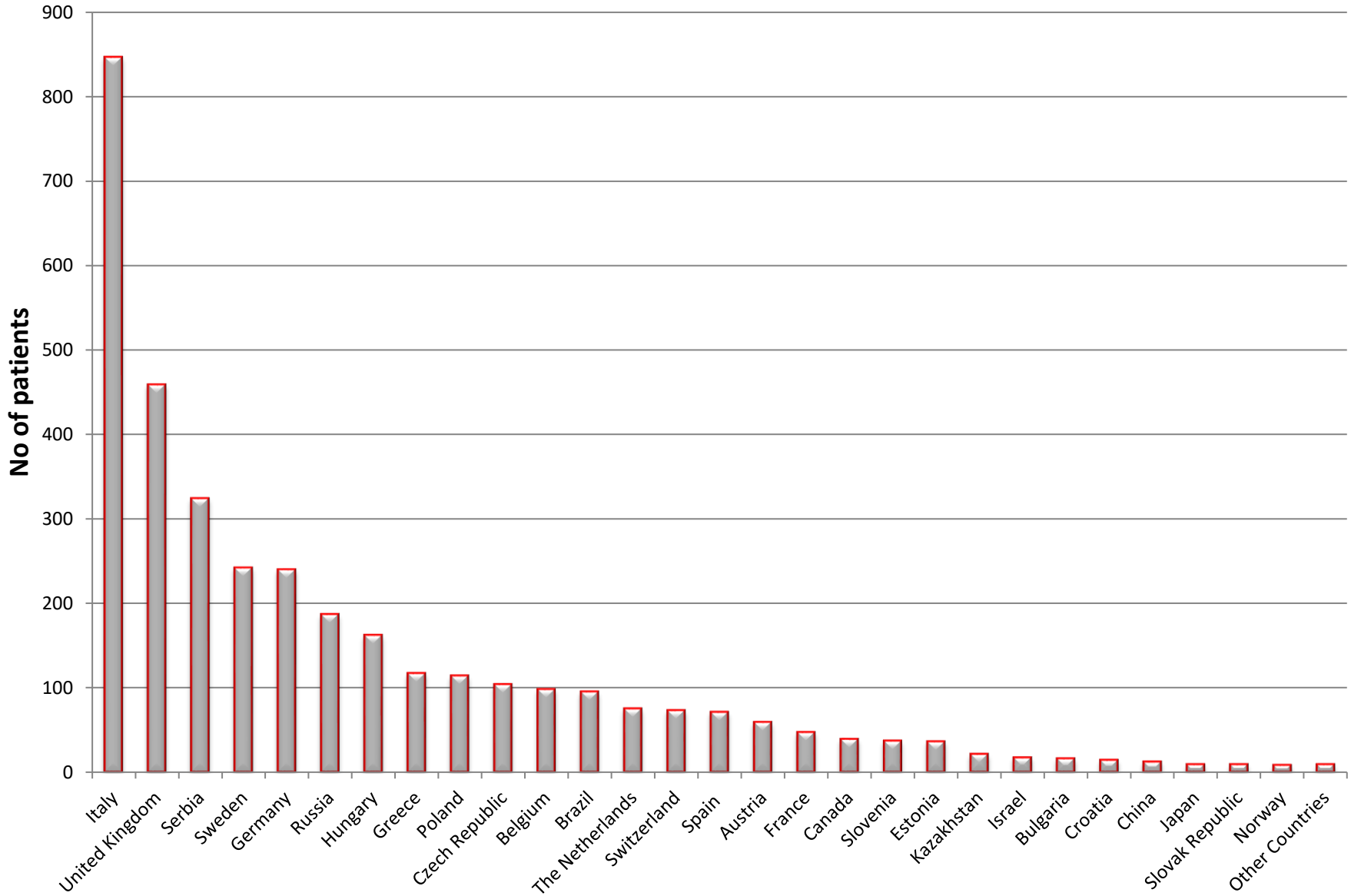
Those allocated CAS: mean follow up 4.7 p-y

(Treatment cross-over 3.8%)

No. of centres ever recruited a patient, and cumulative recruitment March 2020



Recruitment by country March 2020



ACST-2 Patients

Men	70%
Atrial Fibrillation	6%
Coronary artery disease	35%
Diabetic	30%
Renal impairment	8%
Previous stroke symptoms or infarct*	26%
Ipsilateral Echolucent plaque	30%
Operated stenosis (70-99%)	97%
Contralateral severe (80-100%) disease	11%

*% with previous symptoms from either CT/MRI or reported at randomisation (not as % of those who have had a CT/MRI scan)

ACST-2: Age at Randomisation

	CEA (n)	CAS (n)	%
Under 65 years	493	496	28
65 - 75	808	804	46
Over 75	469	472	27
Youngest	45	42	
Oldest	92	89	
Median Age	70	69	

ACST-2: Medical Treatments at entry:

BP drugs	89%
Lipid-lowering	85%
Anti-thrombotic	99%

+ good long-term compliance

ACST-2 and modern CAS therapy

Stents used

<i>Closed 45%</i>	678
<i>Open 32%</i>	483
<i>Hybrid 13%</i>	187
<i>Membrane 10%</i>	148
<i>Total</i>	1496

CPD use

<i>Filter 69%</i>	1031
<i>Proximal occlusion 16%</i>	232
<i>Distal balloon 0.5%</i>	8
<i>None 15%</i>	228
<i>Total</i>	1499

ACST-2 and modern CAS therapy (Brand details)

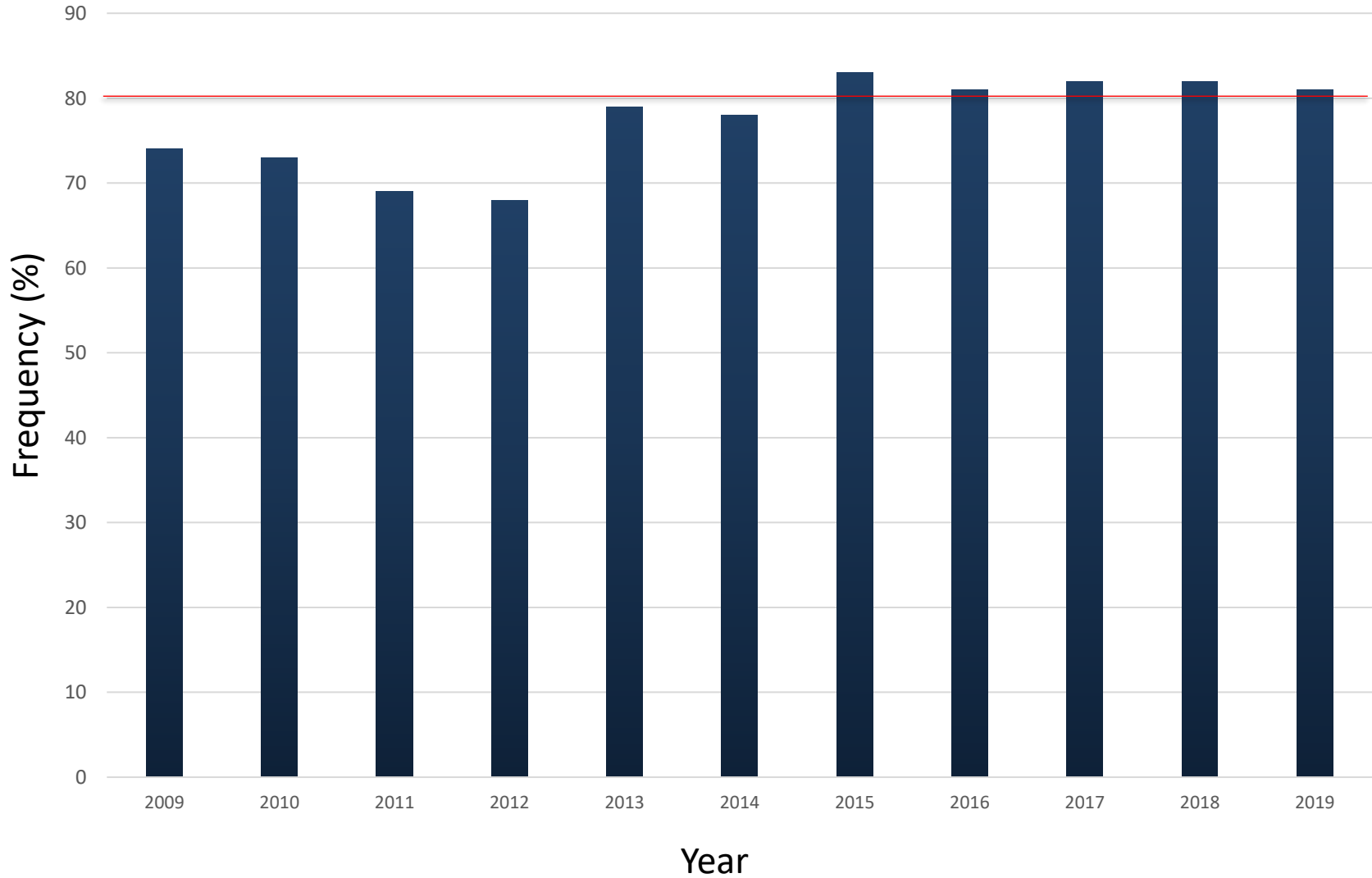
Stents used

<i>(Closed 45%)</i>	
Wallstent	431
Xact	237
Adapt	10
<i>(Open 32%)</i>	
Precise	201
Protégé® RX	141
RX Acculink	125
ViVEXX	9
Zilver	7
<i>(Hybrid 13%)</i>	
Cristallo Ideale	175
Sinus Carotid RX	11
Mer	1
<i>(Membrane 10%)</i>	
Roadsaver	92
CGuard	56
Total	1496

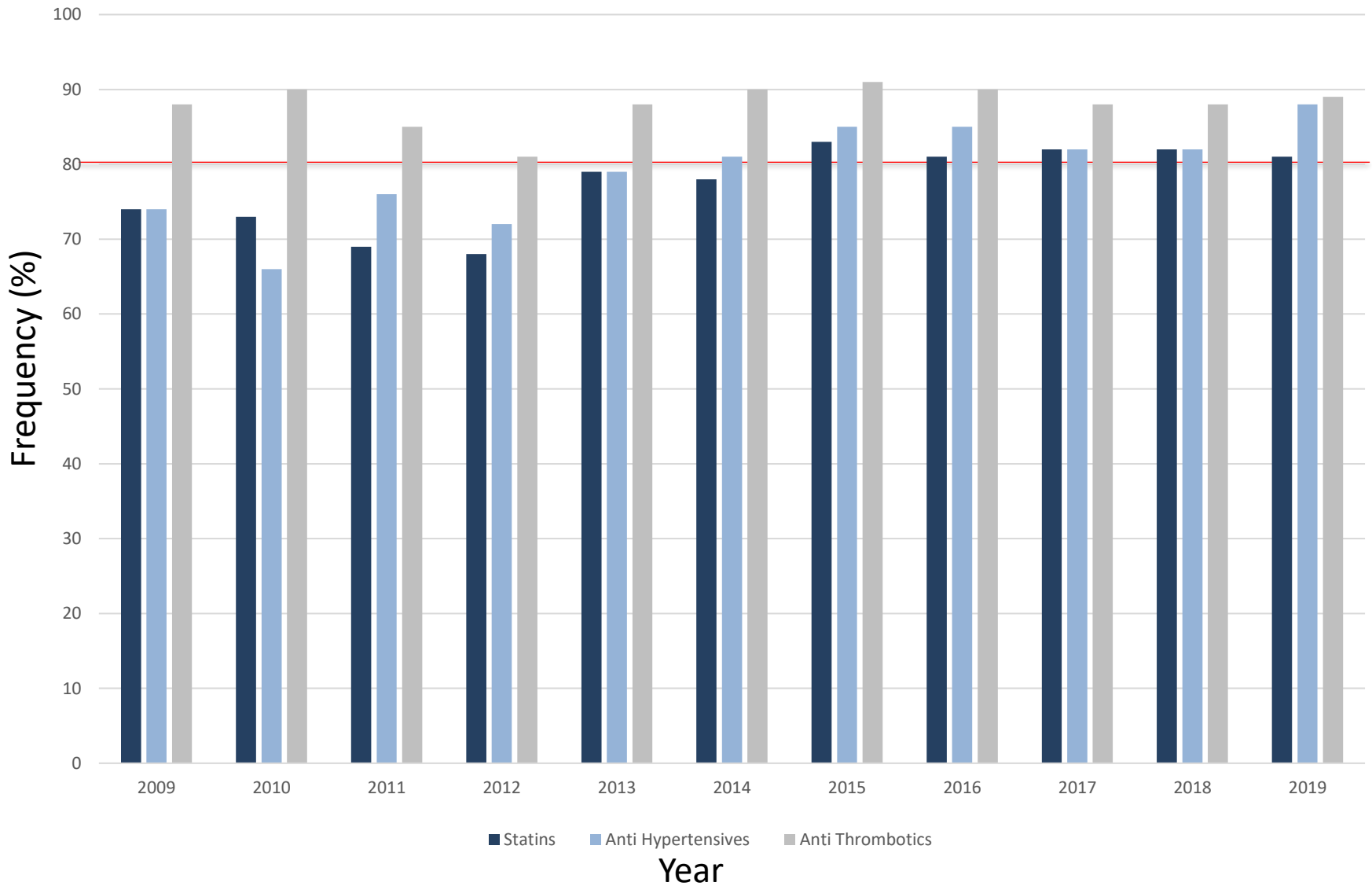
CPD use

<i>Filter (69%)</i>	Filterwire	357
	Emboshield	311
	Spider	232
	Accunet	79
	AngioGuard	50
	FiberNet	1
	Wirion System	1
<i>Proximal occlusion (16%)</i>	Moma	203
	Flow Reversal	28
	TCAR	1
<i>Distal balloon (0.5%)</i>	Twin One	6
	Viatrac	2
<i>None (15%)</i>		228
Total		1499

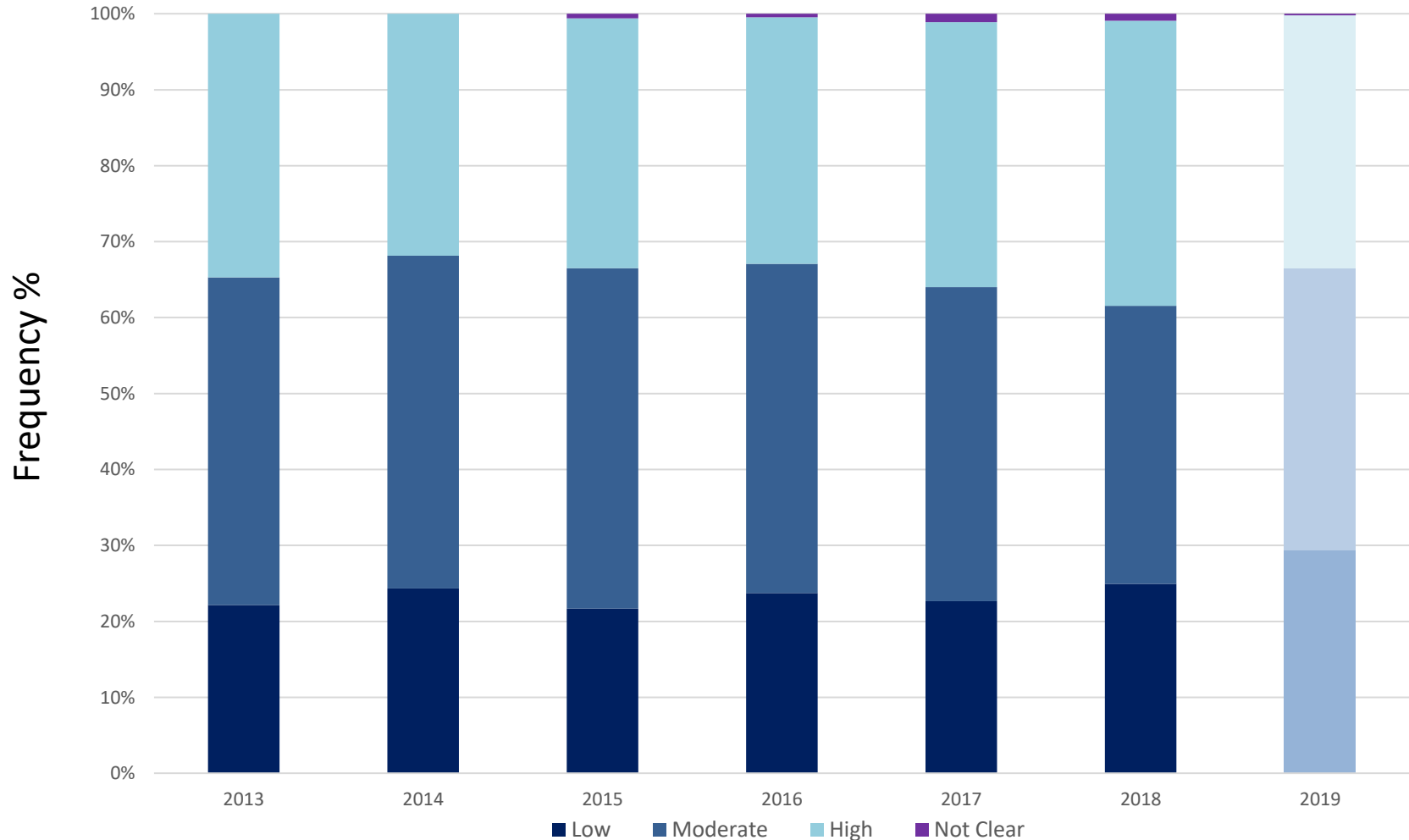
Long-term statin use >80%



Long-term Medication use



Annual follow up ACST-2: >75% on moderate or high statin regimens





Asymptomatic Carotid Surgery Trial (ACST-2)



Aiming for complete data

Andrea Craddock-Bamford & Vasha Bari





Where are we?



- As of today (5th May 2020) 3542 patients recruited
- Recruitment continues until 31st Dec 2020
- 128 active centres from 33 countries
- Some patients are now in their 10th year of follow-up

Quality of data looks good!

All Initial Forms as of 5th May 2020

Total Randomised patients	Consent Form Received	Randomisation Form Received	1-month Follow-up Received
3542	3487 (98.4%)	3495 (98.7%)	3432 (97.0%)



Annual Forms



Year	Forms sent	Forms received
2017	1912	94.3%
2018	2176	95.1%
2019	2696	65.5%*

2020 Aim - to receive at least **95%** of Annual Follow-up forms

Please send Annual Forms via email

*Underestimates total forms received for 2019



Missing Data



- **Consent Forms:** 43 missing out of 3542 from 27 sites
- **Randomisation Forms:** 35 missing out of 3530 from 26 sites
- **1 Month Follow up Forms:** 89 missing out of 3517, from 17 sites
- **Annual Follow Up Forms:** 911 missing out of 2627 from 87 sites
- **Please continue to send the missing forms!**

With missing forms we have incomplete data!

Please answer our emails

Only forms with complete data are being processed!!!



Please remember...



- Patient sign the consent form before randomisation
- Both patient and collaborator sign and date the consent on the same day
- Only clinicians with approved track record can operate ACST-2 patients
- Fill in all required information
- Date the post-procedure follow up
- List drugs and doses clearly on annual follow up forms
- Provide patient's and relative/friend's full address



Major Events

Primary Outcomes:

➤ Periprocedural risks within 30 days:-

Stroke

MI

Death

➤ Long term prevention of disabling and fatal strokes

Currently the peri-procedural disabling stroke and death rate within 30 days is around 1.0 %



Major event data



For patients that report having a **stroke**, send us:

- Imaging reports
- Hospital discharge reports
- 6 month modified Rankin Score

For patients who have **died**, send us:

- Date of death
- Cause of death
- Did they have a stroke prior to death?



Quality of data looks good!

For everyone answering queries that we have sent out about Major Events:

THANK YOU!

If you still have information to send to us, please do so as soon as you are able to.

Remember we are Missing Data

- **Consent Forms:** 49 missing out of 3542 from 27 sites
- **Randomisation Forms:** 41 missing out of 3530 from 26 sites
- **1 Month Follow up Forms:** 46 missing out of 3517, from 17 sites
- **Annual Follow Up Forms:** 952 missing out of 2627 from 87 sites

With missing forms we have incomplete data!

Please answer our emails

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