The implementation and utility of screening logs in a randomised controlled trial of Peri-Operative chemotherapy or sUrveillance in upper Tract urothelial cancer (POUT – CRUK/11/027)

Michelle Snape, Rebecca Lewis, Caroline Wilson, Emma Jones, Roger Kockelbergh, Rob Jones, John Chester, Mark Johnson, Emma Hall and Alison Birtle on behalf of the POUT TMG

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Background

- Upper tract urothelial cancer (UTUC) affects the ureter and renal pelvis
- Rare tumour: estimated incidence 2-4 cases per 100,000 individuals per year in UK[1-3]
- Poor 5 year survival rates ~ 34%[4]
- Few randomised studies[5-7]
- No current international postoperative standard of care

1. SWPHO, 2010; 2. Genega, et al., 2002; 3. Raman, et al., 4. Cozad, et al., 1995 5. Hellenthal, et al., 2009; 6. Song, et al., 2010; 7. Kwak, et al., 2006

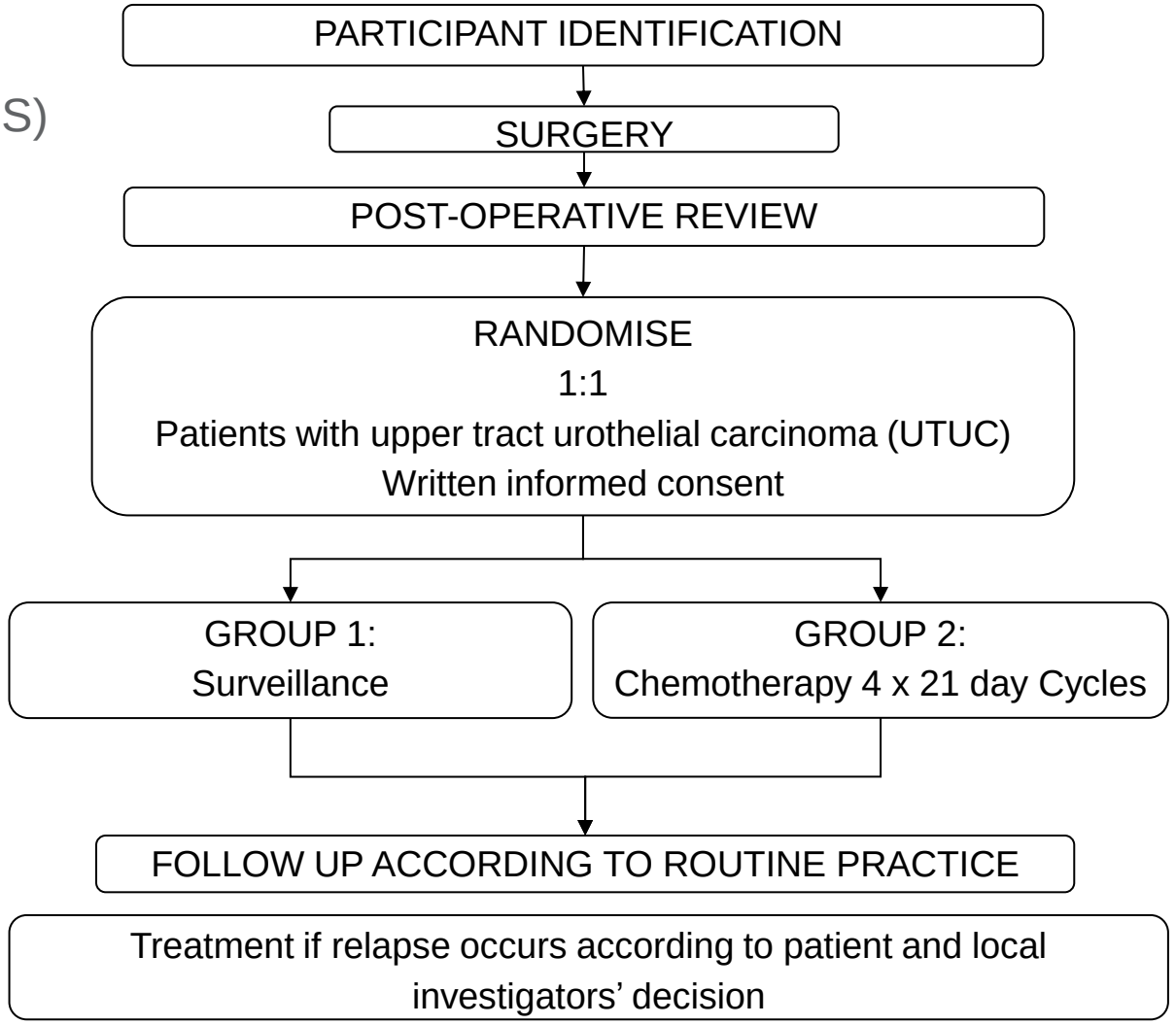
The POUT trial

PRIMARY ENDPOINT

- Disease-free survival (DFS)

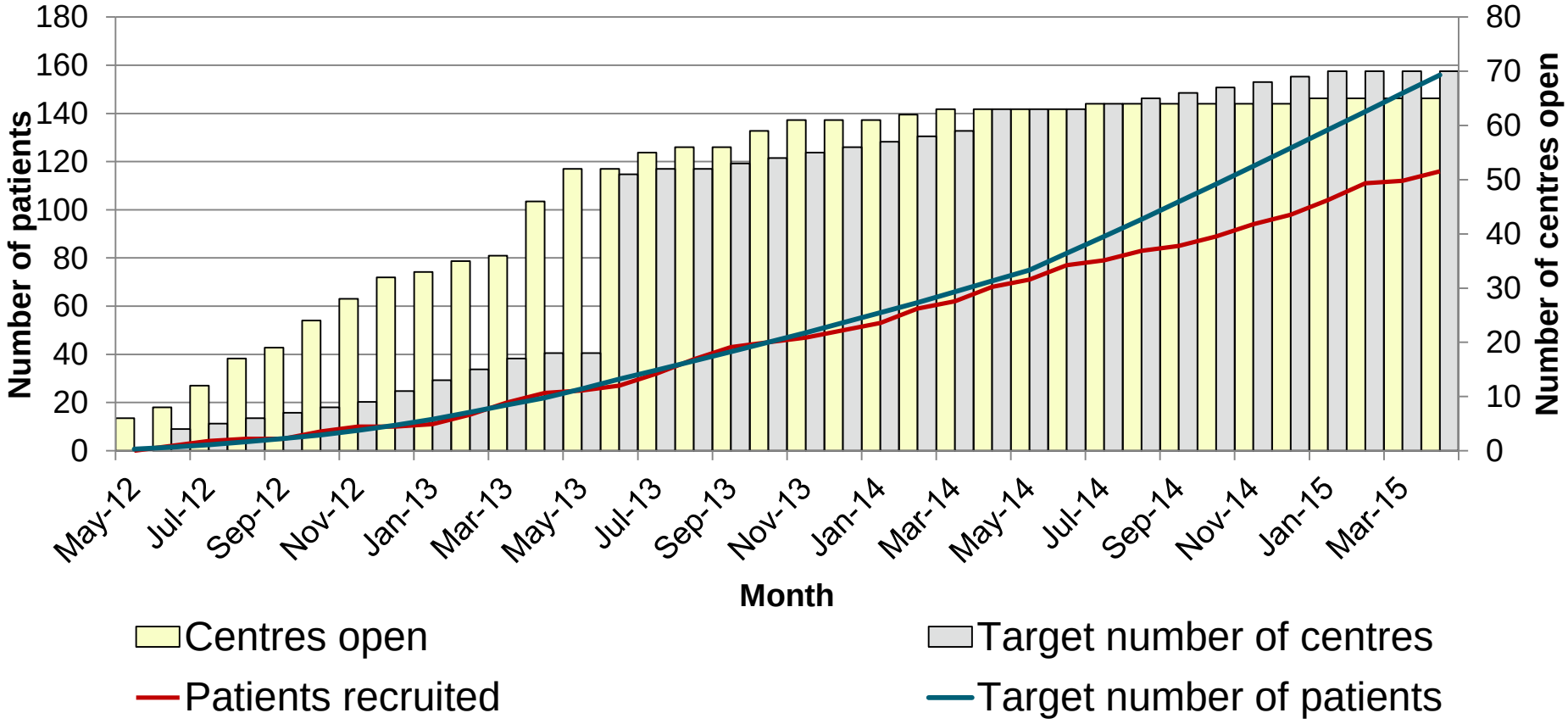
FEASIBILITY

2 year recruitment optimisation phase
Qualitative recruitment study
Stop/go recruitment targets



Study status

POUT target accrual = 345 patients in 5 years



Up to 1st May 2015:

116 patients recruited from 65 open centres in the UK

Screening logs

Screening logs are used to capture information on potential POUT participants.

We request details on all patients:

- due to undergo pre-trial surgery
- who have been referred in having had surgery

Requested by the ICR-CTSU monthly and reviewed centrally

Screening logs

1	Details NOT to be sent to ICR-CTSU (please fold)		Please record the details of **ALL patients due to undergo or referred having undergone radical nephro-ureterectomy***.							
2	Patient initials and NHS number	Screening no. (e.g. 001, 002, ...)	Date of NU* surgery	Histology (T/N/M)	Pathology (TCC, SCC, both)	Age/ Gender	Please record the DATE patient information sheet(s) (PISs) given to the patient:		Patient: Recruited (1) Declined (2) Ineligible (3) Not approached (4) Awaiting patient decision (5)	Final screening outcome (if previously recorded that patient had not yet been approached or awaiting decision): Randomised (1) Declined (2) Ineligible (3)	*If patient NOT randomised, please explain in detail the reasons why?* *If patient recruited, please provide trial ID and randomised allocation.*
3							PRE-SURG	MAIN PIS			
4		001									
5		002									
6		003									
7		004									

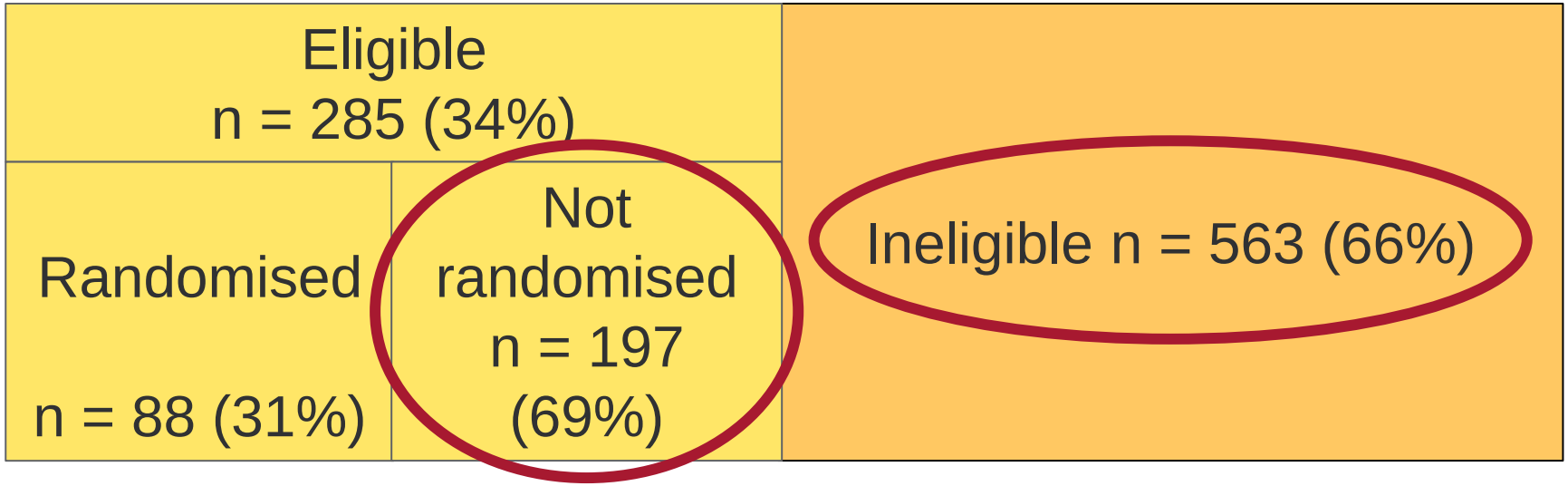
Patient: Recruited (1)
Declined (2)
Ineligible (3)
Not approached (4)
Awaiting patient decision (5)

Sheet1 Sheet2 Sheet3

Screening overview

Total patients reported = 848

Actual number randomised = 112

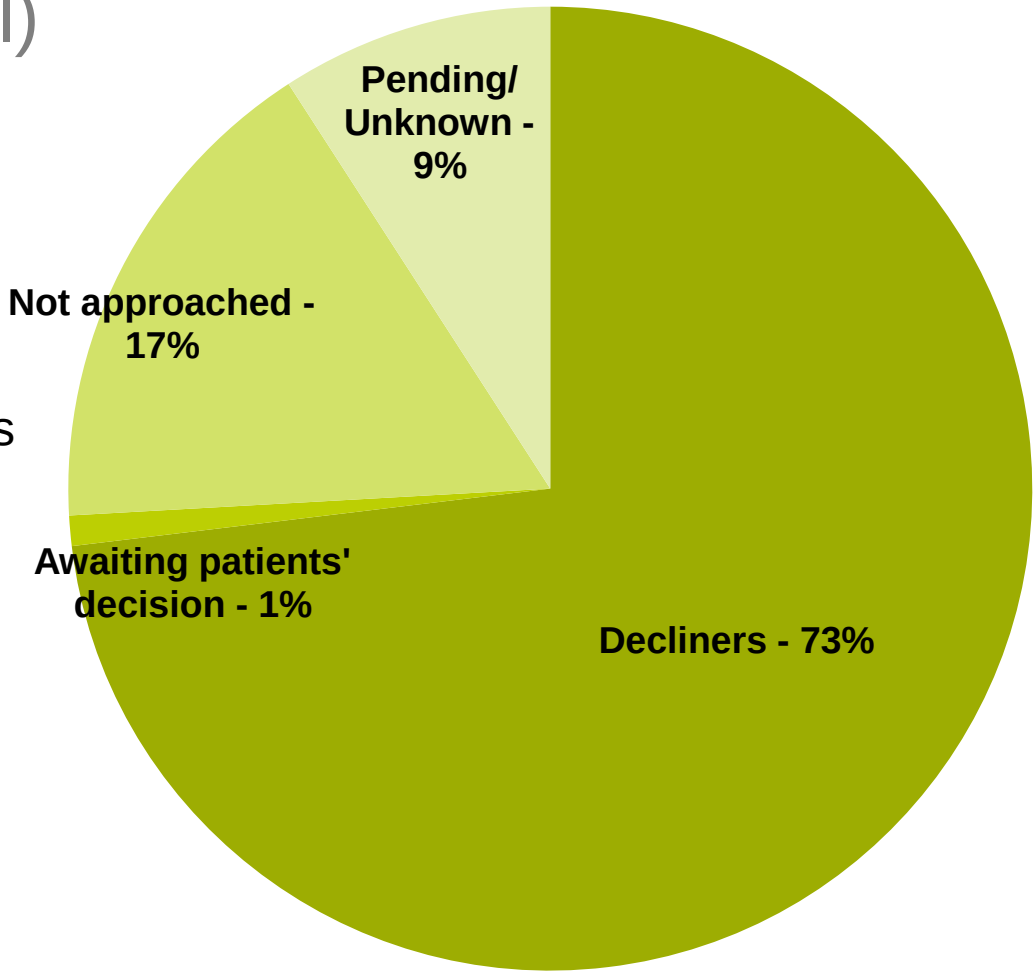


Data presented up to the end of March 2015

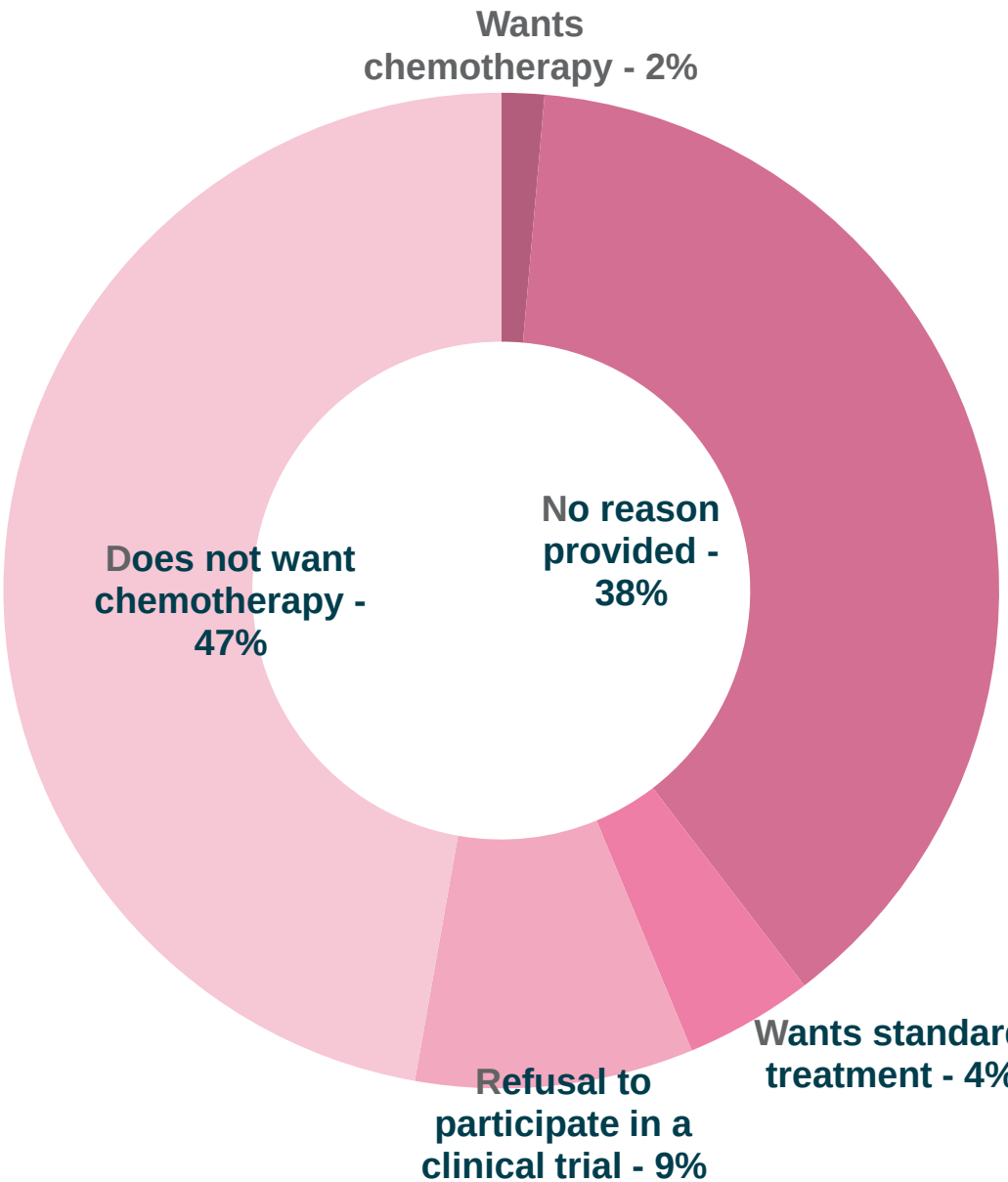
Potential participants

197 potential participants reported (23% of patients overall)

- Decliners - 144 patients
- Awaiting patients' decision - 2 patients
- Not approached - 33 patients
- Pending/Unknown - 18 patients



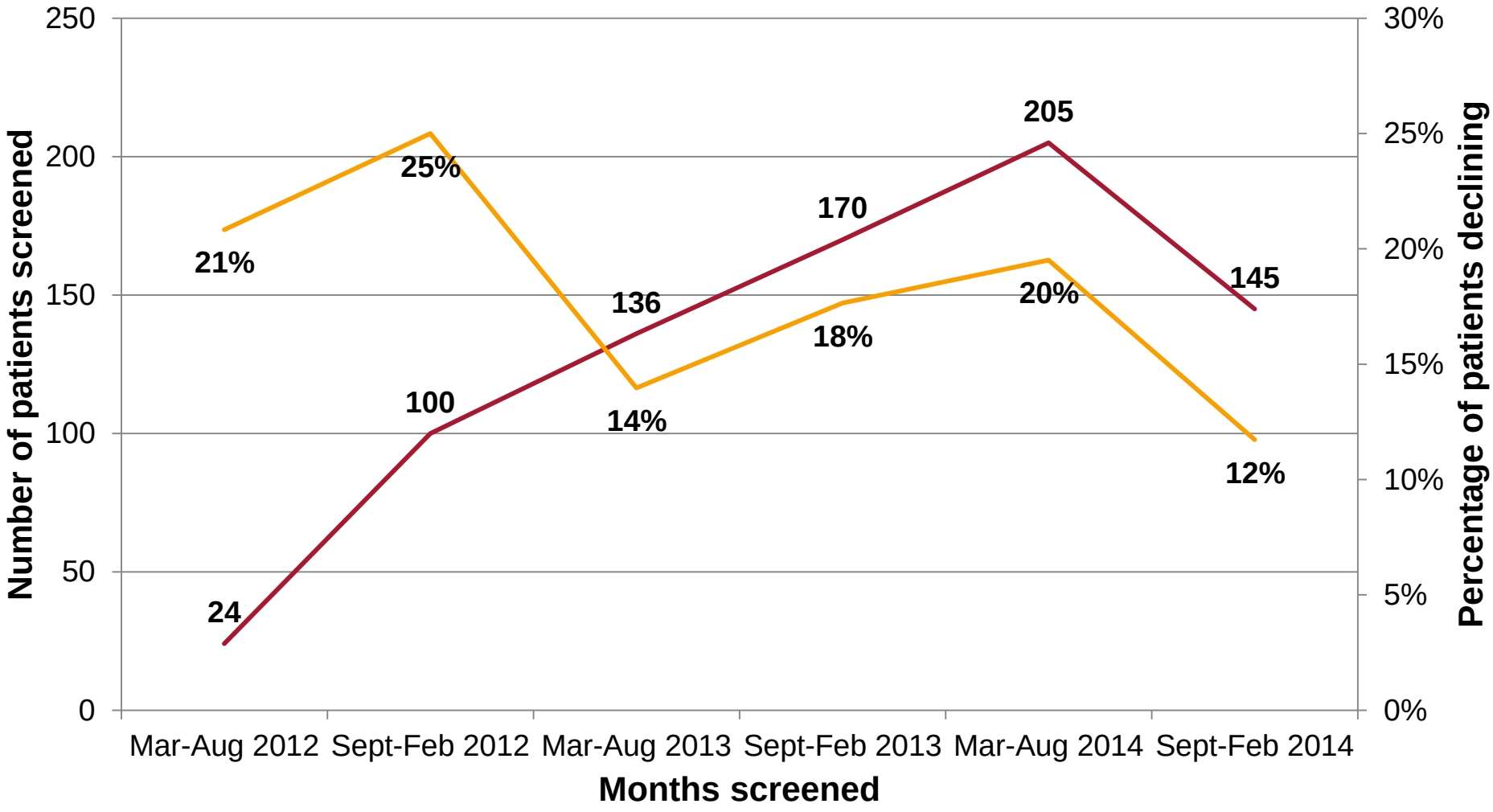
Patient preferences - decliners



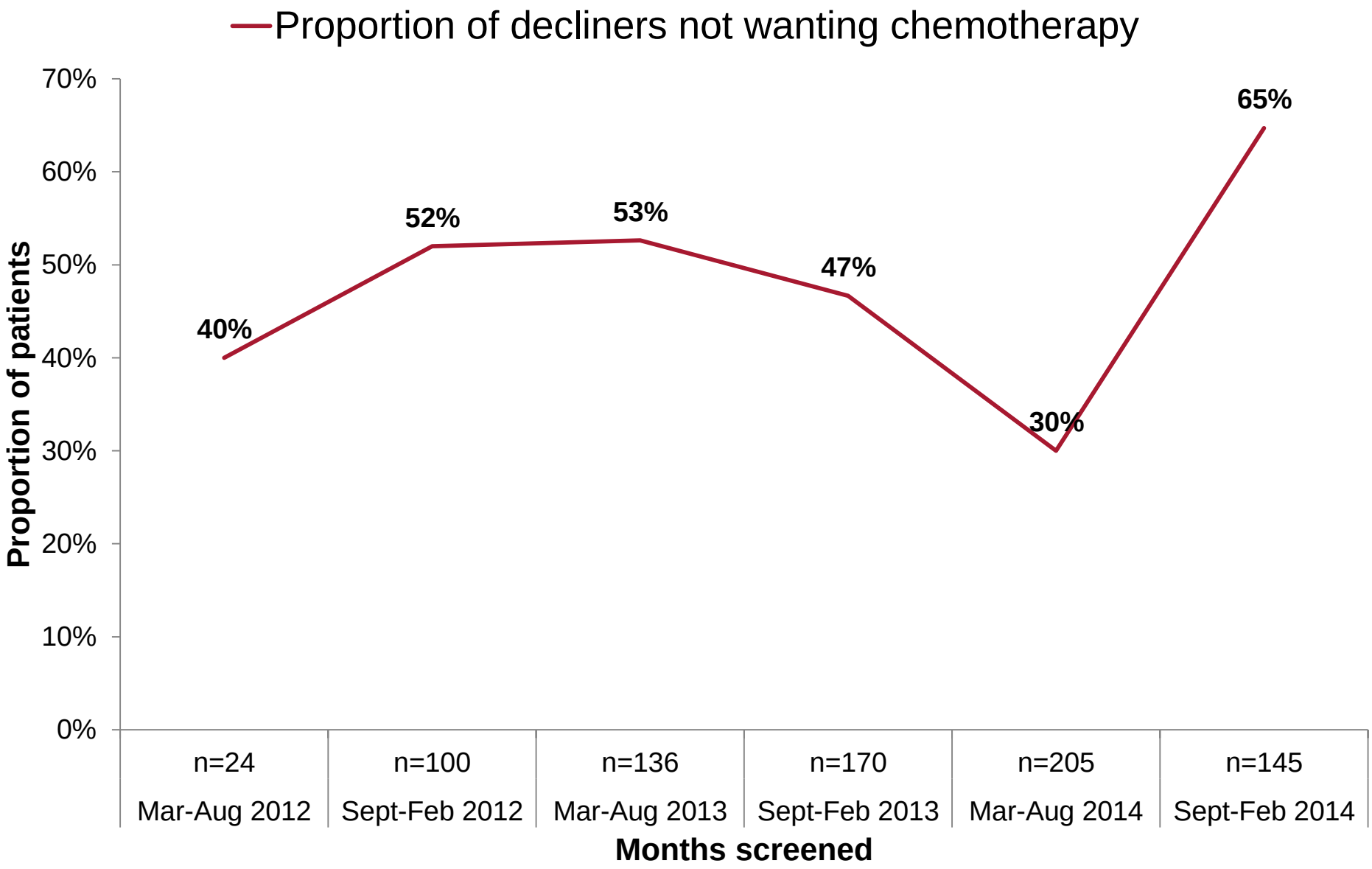
- Wants chemotherapy - 2 patients
- No reason provided - 55 patients
- Wants standard treatment - 6 patients
- Refusal to participate in a clinical trial - 13 patients
- Does not want chemotherapy - 68 patients

144 patients have declined POUT

Targeting patient preferences



Targeting patient preferences



Conclusions

Implementation of screening logs:

- is hard work and time consuming
- requires persistence

However utilisation of screening logs helps:

- to understand your patient population
- to identify barriers to recruitment
- to improve and adapt current practice and advice
- to maintain trial awareness and oversight of trial activity at centres

Particularly useful for trials with small patient populations

Acknowledgements

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Clinical Trials and Statistics Unit, The Institute of Cancer Research, London, SM5 2NG
020 8722 4288 / POUT-icrctsu@icr.ac.uk