Pressure Relieving Support Surfaces: a Randomised Evaluation 2

National Institute for Health Research Health Technology Assessment Programme

ctru University of Leeds

UKCRC Registered Clinical Trials Units

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Polite request

- No social media postings please

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Research Design: Multicentre, open, randomised, double triangular group sequential, parallel group trial, with two planned interim analyses.

Research Aim: determine clinical and cost effectiveness

Population:	Secondary and community in-patients Evidence of acute illness High risk PU development
Intervention:	**alternating pressure mattresses (APM)**
Comparator:	**high specification foam (HSF)**
Outcome:	Category 2 (and above) pressure ulcers

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Objectives – to compare

Primary: Development new category ≥2 to ***trial completion***

2. new category ≥2 ***treatment phase***
3. new category ≥ 1 to ***trial completion***
4. new category ≥ 3 to ***trial completion***
5. time to healing of pre-existing Category 2 PUs to ***trial completion***

6. health related quality of life (SF12, PUQOL)
7. incremental cost-effectiveness
8. compliance

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Setting: acute secondary and community NHS Trust in-patients

Inclusion:

1. **Evidence of acute illness**

2. **At high risk of PU development:**
    a) bedfast/chairfast AND completely immobile/very limited mobility AND/OR
    b) Category 1 PU on any pressure area skin site AND/OR
    c) localised skin pain on a healthy, altered or category 1 pressure area skin site.

3. **Expected total length of stay of 5 or more days**

4. **Consent**
    a) written informed consent
    b) witnessed verbal consent
    c) consultee agreement

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Interventions

HSF

APMs

Treatment phase maximum 60 days defined as from randomisation to:

a) 60 days or
b) discharge from an eligible in-patient facility or
c) when the patient is considered no longer at high risk, whichever is soonest.

Trial completion 30 days after end of treatment phase

Maximum total time in trial 90 days

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Sample size: 2954 patients

Primary Endpoint: Time to developing a new Category ≥2

Assumptions:

- APM: 18% new ≥ Category 2 (PRESSURE 1)
- HSF: 23% new ≥ Category 2 (literature)
  - corresponding to a hazard ratio of 0.759
- 90% power
- 2-sided 5% significance level
- 6% loss to follow-up (PRESSURE 1)

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Baseline Characteristics

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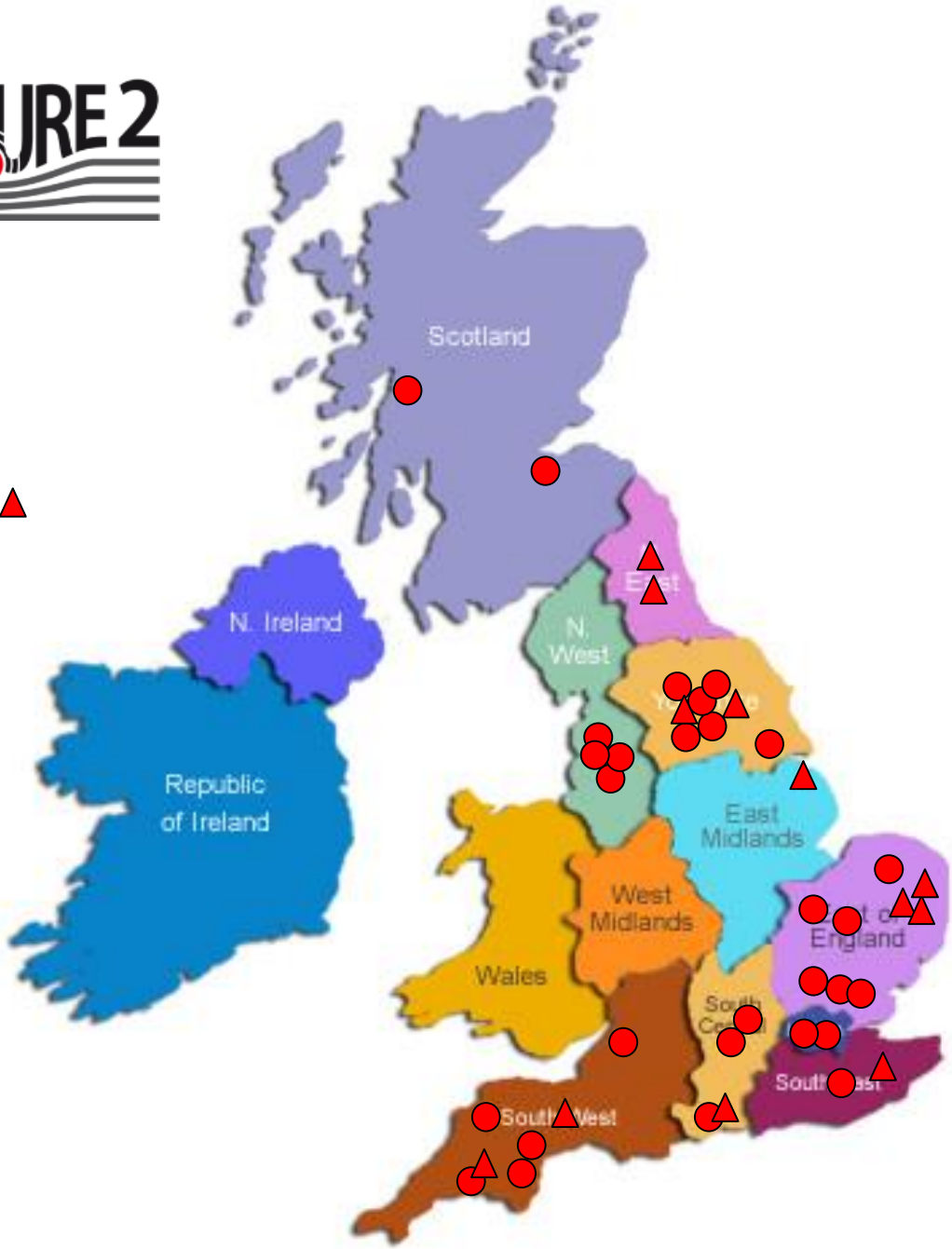
Key
Acute ●
Community ▲



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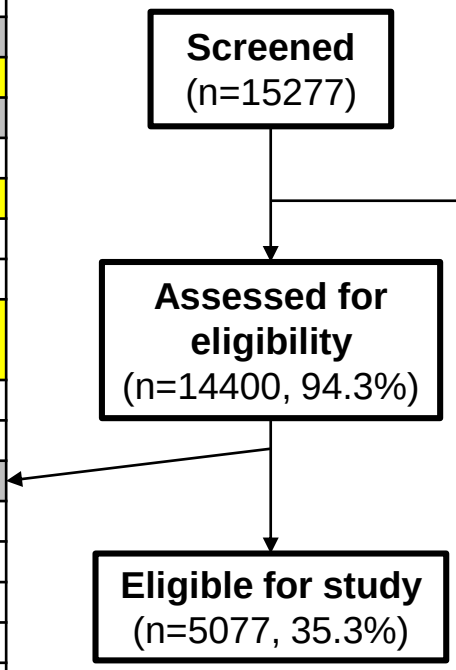
Not eligible for study 9323 (64.7%)	
Intervention not required	
Not at high risk of PU development	2180 (23.4%)
Patient factors	
Not got evidence of acute illness	142 (1.5%)
Current or previous category 3 or above PU	881 (9.4%)
Unable to receive intervention as not able to go to bed	44 (0.5%)
Unable to receive intervention as too unwell	709 (7.6%)
Unable to receive intervention as patient unwilling to change mattress	938 (10.1%)
Weight is lower than 45 kg	424 (4.5%)
Weight is higher than 180 kg	38 (0.4%)
Protocol factors	
Is aged <18 years	20 (0.2%)
Not expected to have a total length stay of 5 days or more	1640 (17.6%)
Not expected to comply with follow-up schedule	691 (7.4%)
Not on electric profiling bed frame	200 (2.1%)
Has previously participated in the trial	66 (0.7%)
Planned admission to ICU	24 (0.3%)
Logistical factors	
Unable to receive intervention as trial mattress unavailable	4 (0.0%)
Unable to receive intervention as staff unwilling to change mattress	1116 (12.0%)
Miscellaneous	
Other reason	72 (0.8%)
Missing	134 (1.4%)



Not assessed for eligibility 877 (5.7%)	
Missed by TVTM	68 (7.8%)
Patient died	25 (2.9%)
Patient discharged	157 (17.9%)
Ethically inappropriate	482 (55.0%)
Patient not interested	14 (1.6%)
Research team unable to visit due to ward closure	20 (2.3%)
Language barrier	15 (1.7%)
Other	18 (2.1%)
Missing	78 (8.9%)

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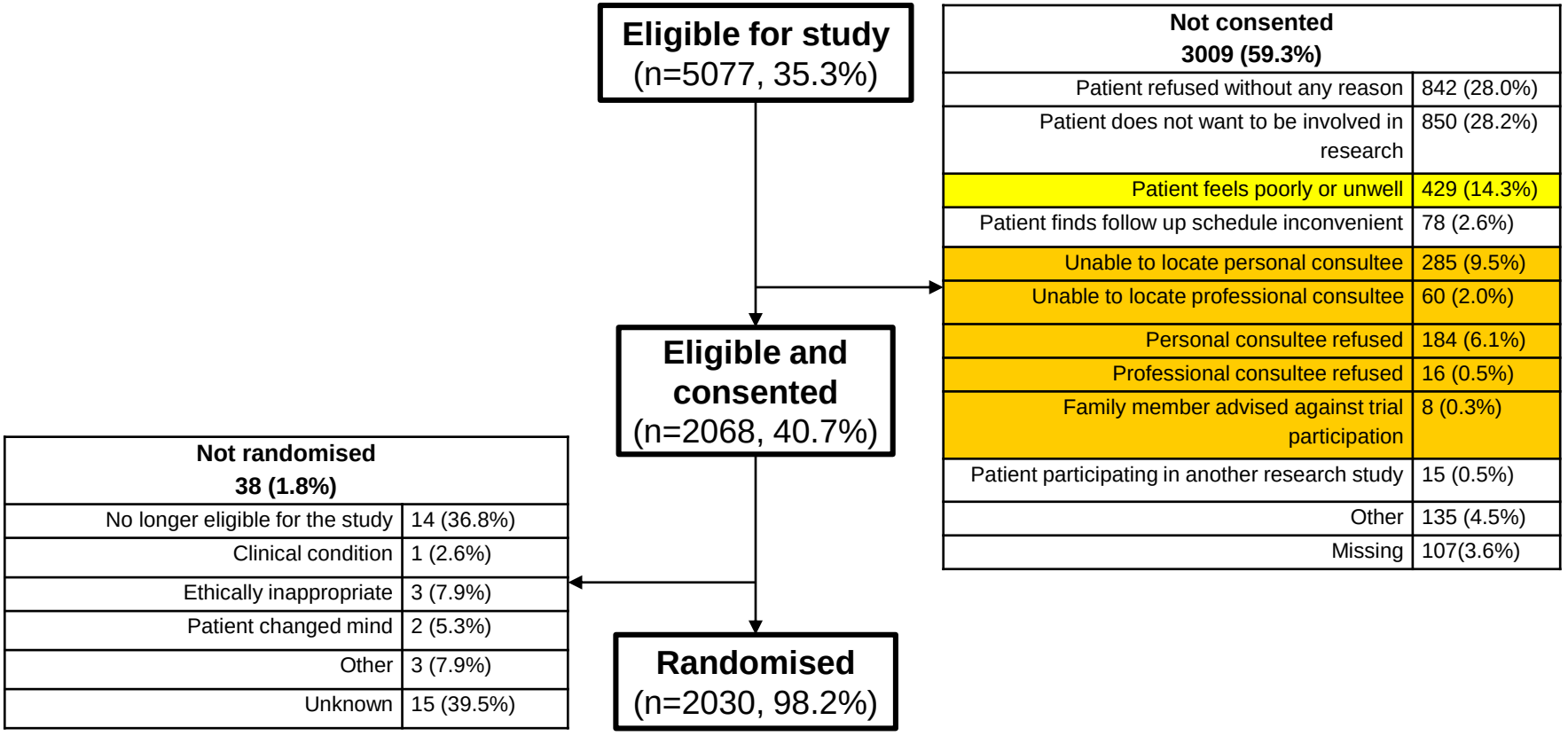

Not consented 3009 (59.3%)	
Patient refused without any reason	842 (28.0%)
Patient does not want to be involved in research	850 (28.2%)
Patient feels poorly or unwell	429 (14.3%)
Patient finds follow up schedule inconvenient	78 (2.6%)
Unable to locate personal consultee	285 (9.5%)
Unable to locate professional consultee	60 (2.0%)
Personal consultee refused	184 (6.1%)
Professional consultee refused	16 (0.5%)
Family member advised against trial participation	8 (0.3%)
Patient participating in another research study	15 (0.5%)
Other	135 (4.5%)
Missing	107(3.6%)

Not randomised 38 (1.8%)	
No longer eligible for the study	14 (36.8%)
Clinical condition	1 (2.6%)
Ethically inappropriate	3 (7.9%)
Patient changed mind	2 (5.3%)
Other	3 (7.9%)
Unknown	15 (39.5%)

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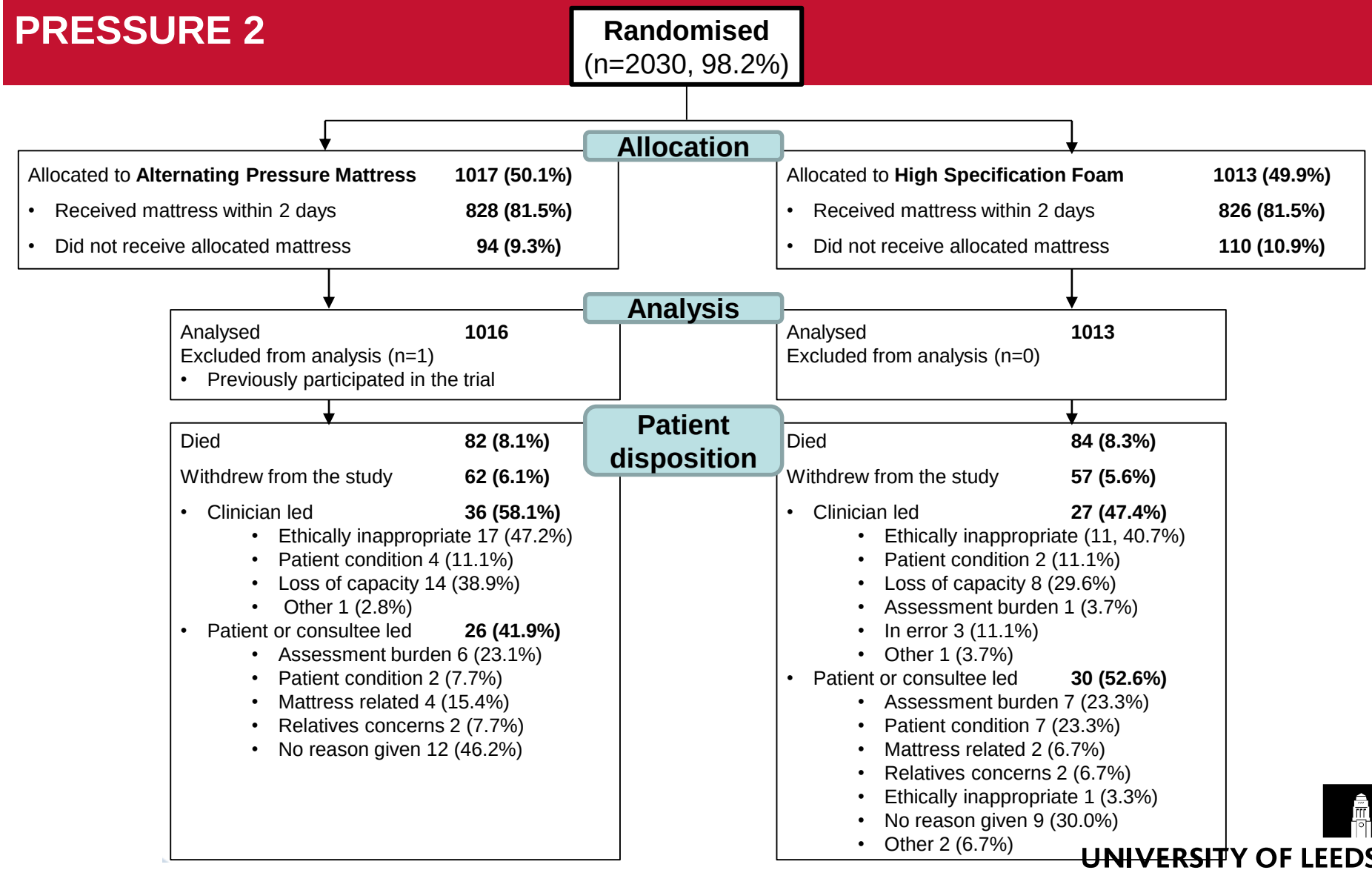
Randomised
(n=2030, 98.2%)
Allocation
Allocated to Alternating Pressure Mattress 1017 (50.1%)
• Received mattress within 2 days 828 (81.5%)
• Did not receive allocated mattress 94 (9.3%)
Allocated to High Specification Foam 1013 (49.9%)
• Received mattress within 2 days 826 (81.5%)
• Did not receive allocated mattress 110 (10.9%)
Analysis
Analysed 1016
Excluded from analysis (n=1)
• Previously participated in the trial
Analysed 1013
Excluded from analysis (n=0)
Patient disposition
Died 82 (8.1%)
Withdrew from the study 62 (6.1%)
• Clinician led 36 (58.1%)
• Ethically inappropriate 17 (47.2%)
• Patient condition 4 (11.1%)
• Loss of capacity 14 (38.9%)
• Other 1 (2.8%)
• Patient or consultee led 26 (41.9%)
• Assessment burden 6 (23.1%)
• Patient condition 2 (7.7%)
• Mattress related 4 (15.4%)
• Relatives concerns 2 (7.7%)
• No reason given 12 (46.2%)
Died 84 (8.3%)
Withdrew from the study 57 (5.6%)
• Clinician led 27 (47.4%)
• Ethically inappropriate (11, 40.7%)
• Patient condition 2 (11.1%)
• Loss of capacity 8 (29.6%)
• Assessment burden 1 (3.7%)
• In error 3 (11.1%)
• Other 1 (3.7%)
• Patient or consultee led 30 (52.6%)
• Assessment burden 7 (23.3%)
• Patient condition 7 (23.3%)
• Mattress related 2 (6.7%)
• Relatives concerns 2 (6.7%)
• Ethically inappropriate 1 (3.3%)
• No reason given 9 (30.0%)
• Other 2 (6.7%)

Baseline demographics

Gender

Male 907(44.7%)	Female 1119(55.2%)

Age (years)

Mean 78.0(13.1), Range 21-105

Ethnicity

White 1992(98.2%)	Mixed race 6(0.3%)	Non-white 28(1.4%)

Consent type

Written 1402(69.1%)	Witnessed verbal 303(14.9%)	Consultee agreement 322(15.9%)

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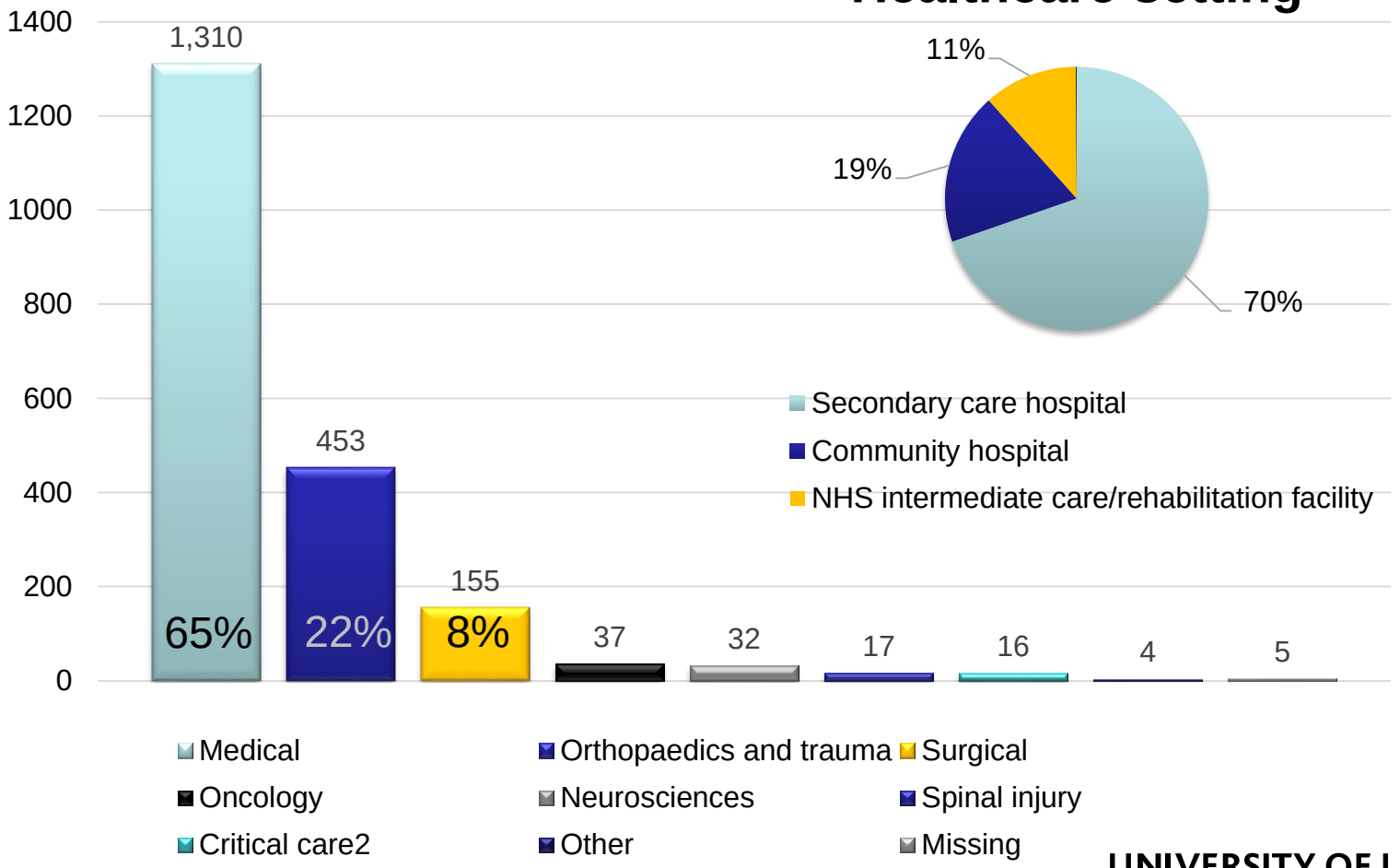
Medical specialty



Healthcare setting

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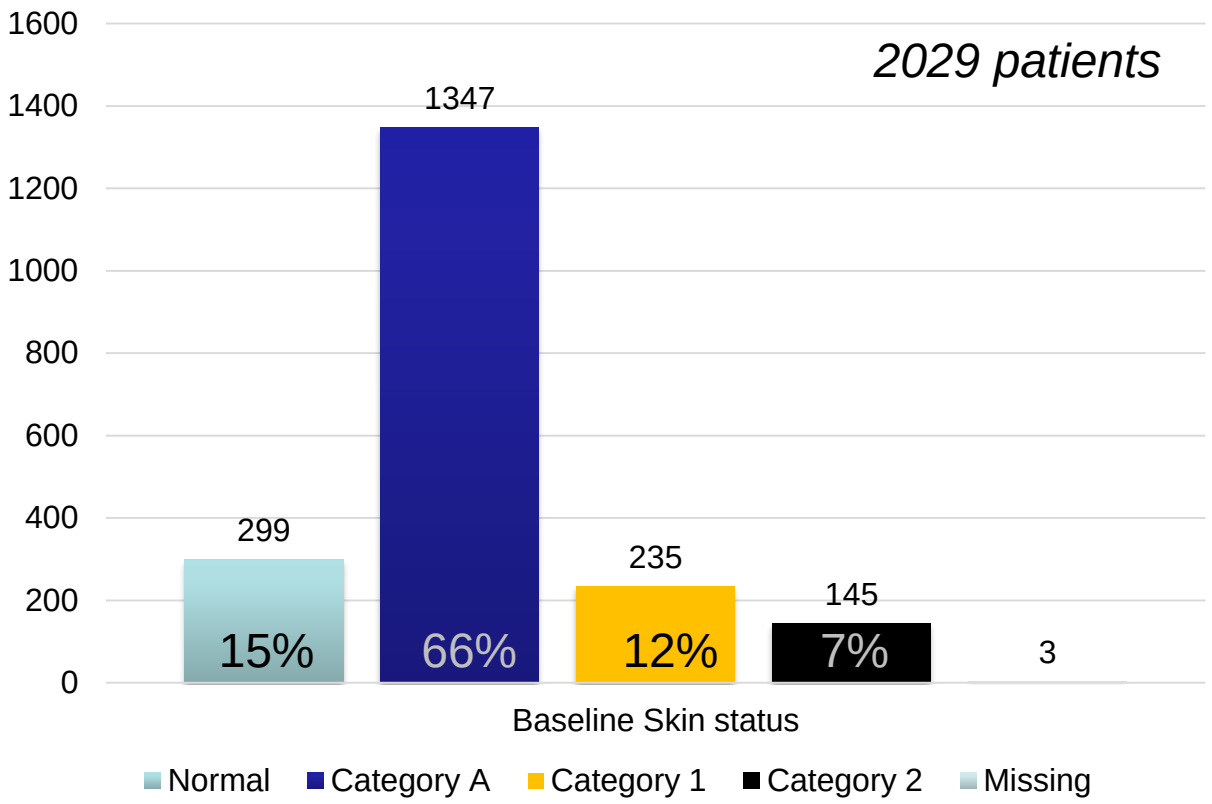
Baseline skin status (patient level)



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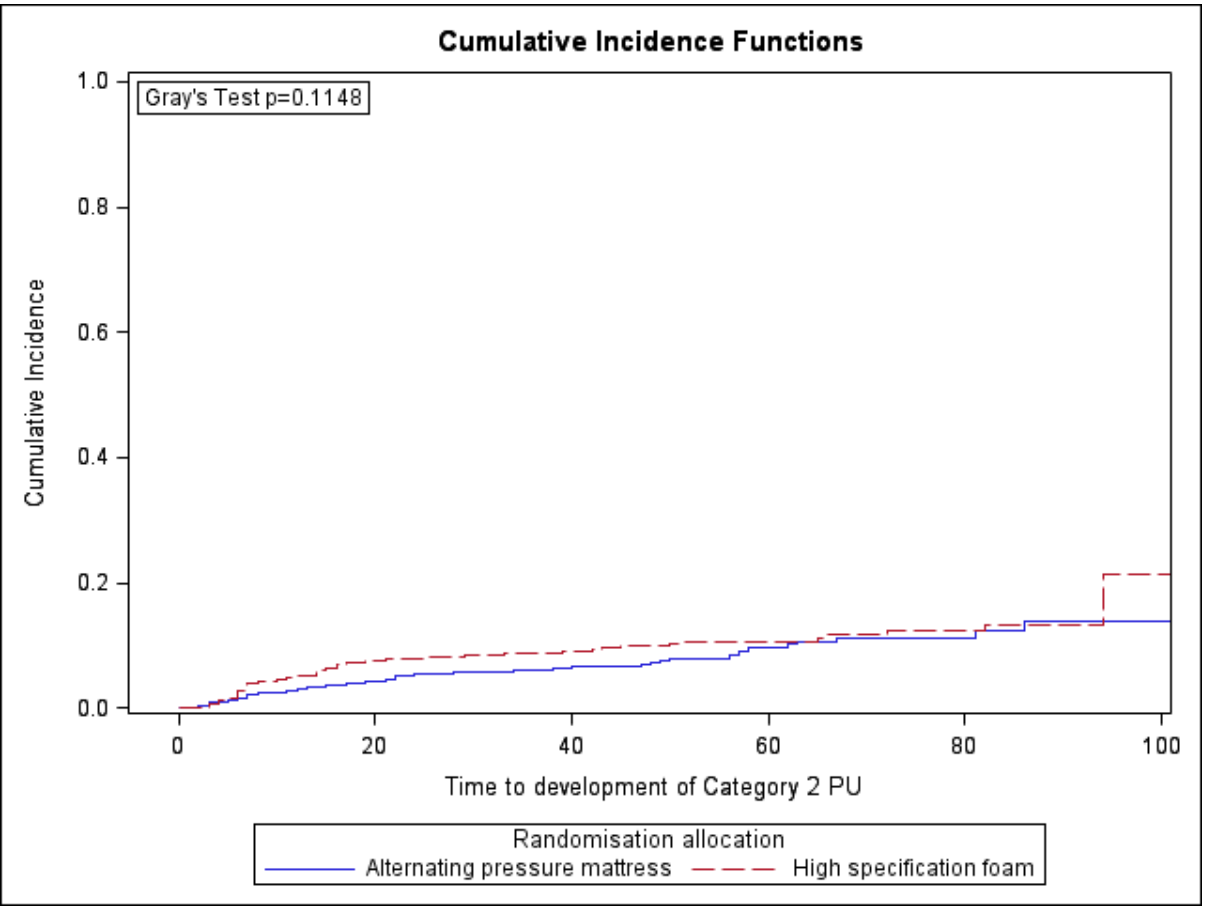
Main Results

Primary endpoint – new Cat ≥2 trial completion

Overall	APM	HSF	P-value
160 (7.9%) patients	70 (6.9%)	90 (8.9%)	0.0890
213 PUs	89 PUs	124 PUs	



Absolute difference=2%

Non-significant

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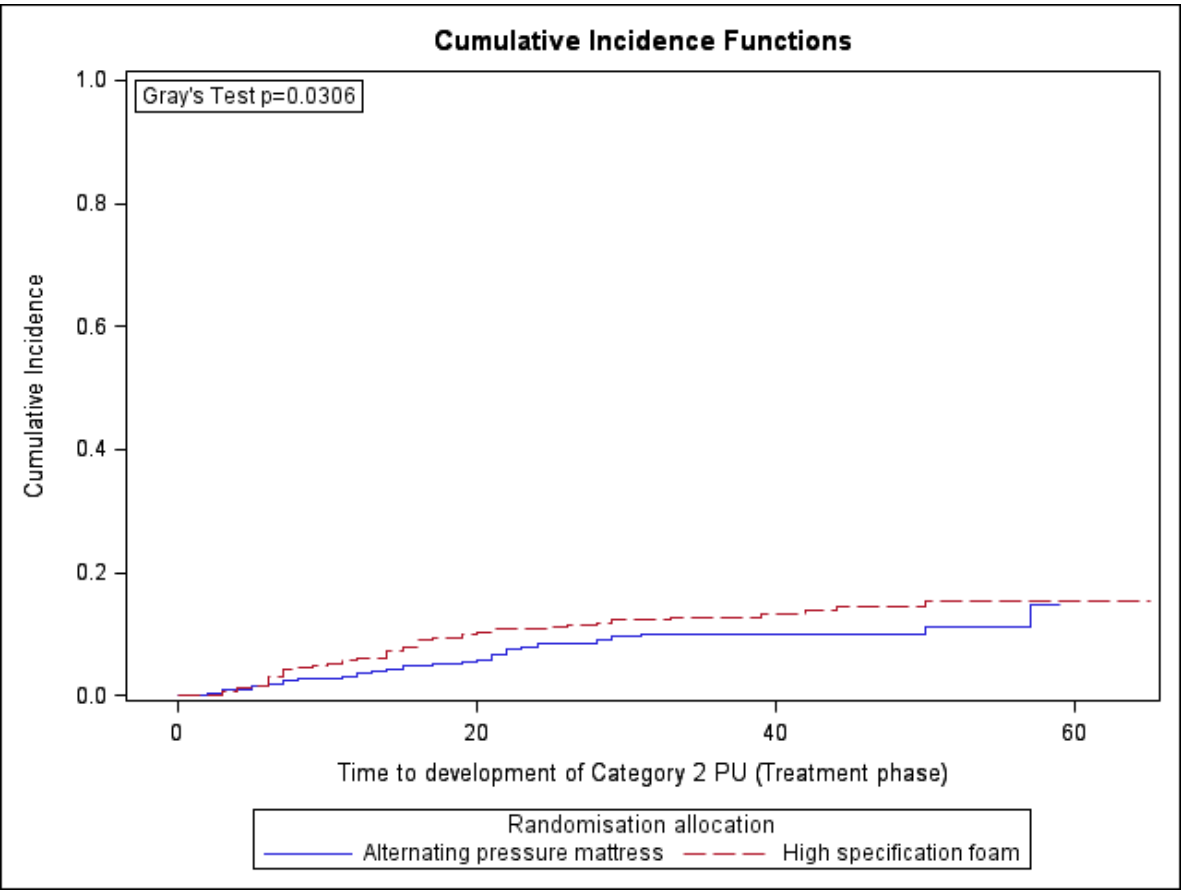
Sensitivity analysis - new Cat ≥2 treatment phase

Overall	APM	HSF	P-value
132(6.5%)	53(5.2%)	79(7.8%)	0.0190

Absolute difference=2.6%

Clinical Significance?



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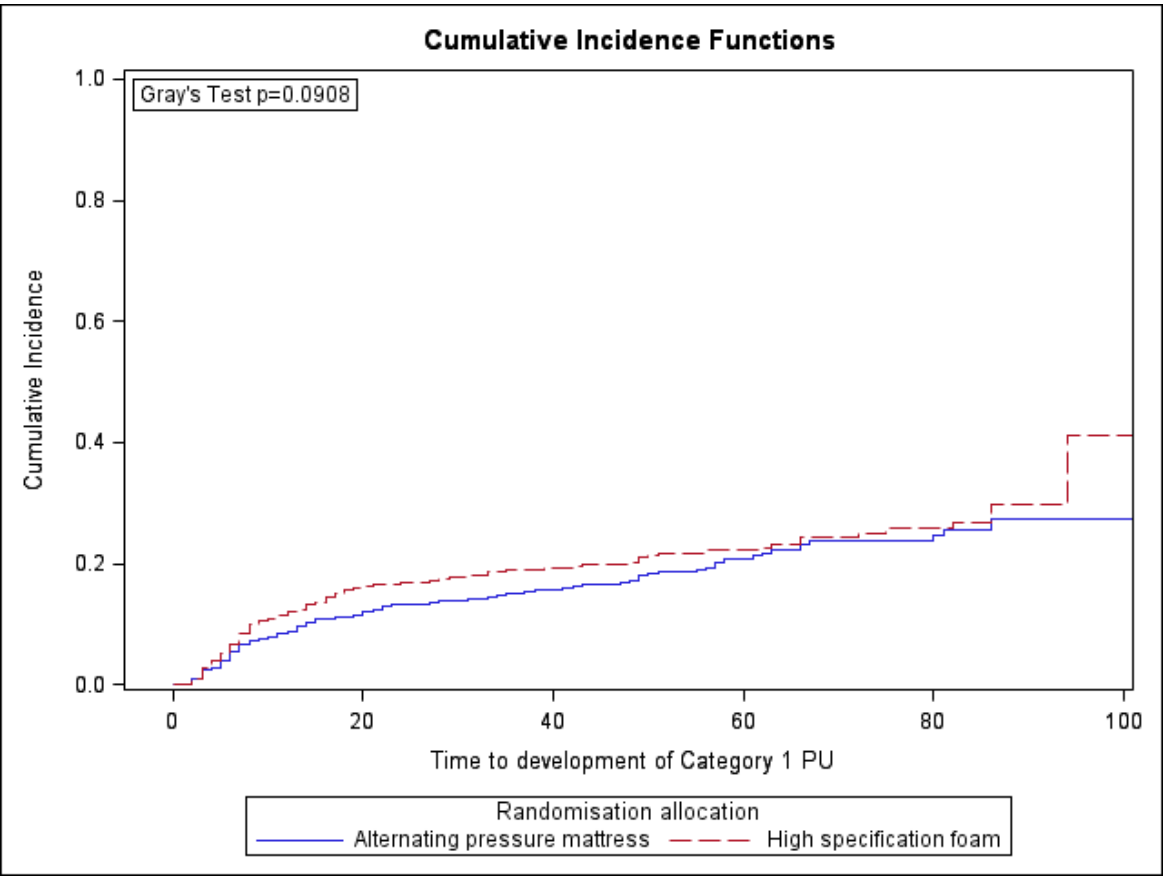
Secondary endpoint - new Cat ≥1 trial completion

Overall	APM	HSF	P-value
350(17.2%)	160(15.7%)	190(18.8%)	0.0741

Absolute difference=3.1%



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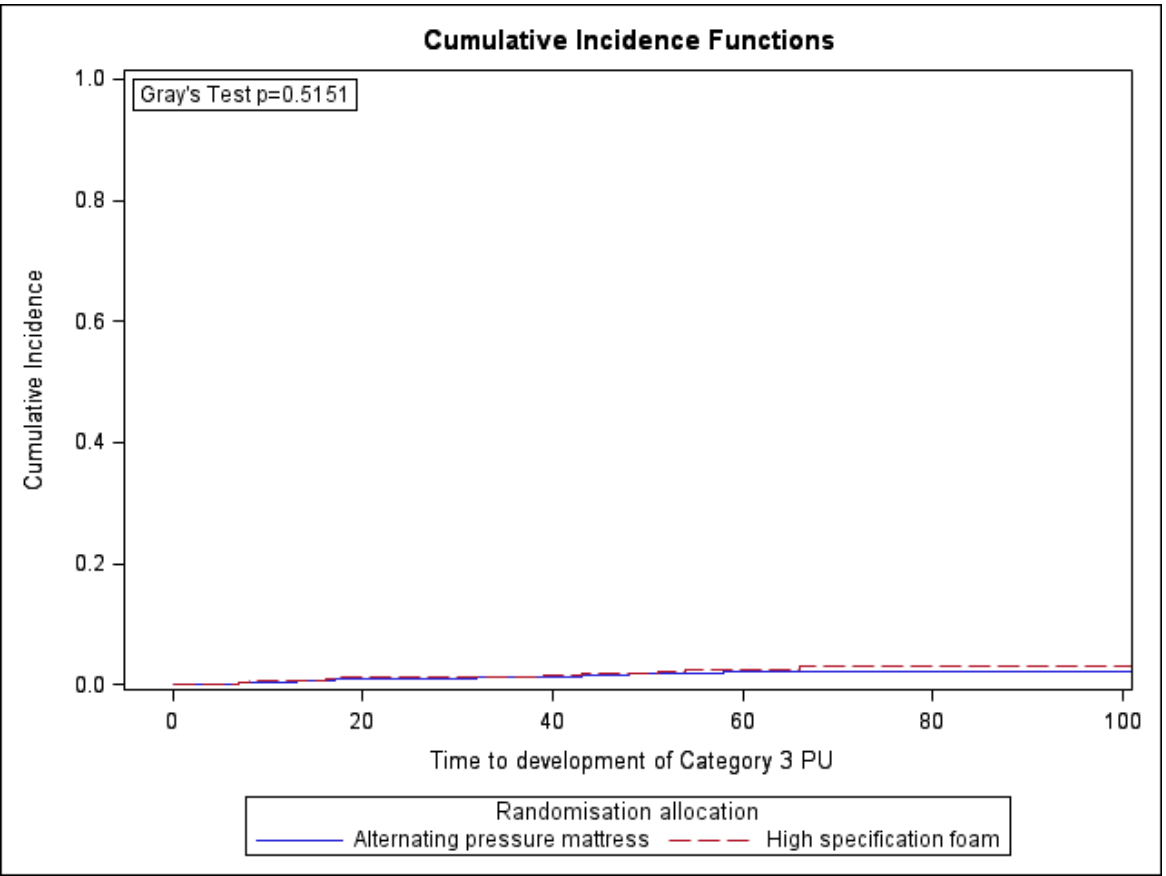
Secondary endpoint – new Cat ≥ 3 trial completion

Overall	APM	HSF	P-value
32(1.6%)	14(1.4%)	18(1.8%)	0.5498

Absolute difference=0.4%



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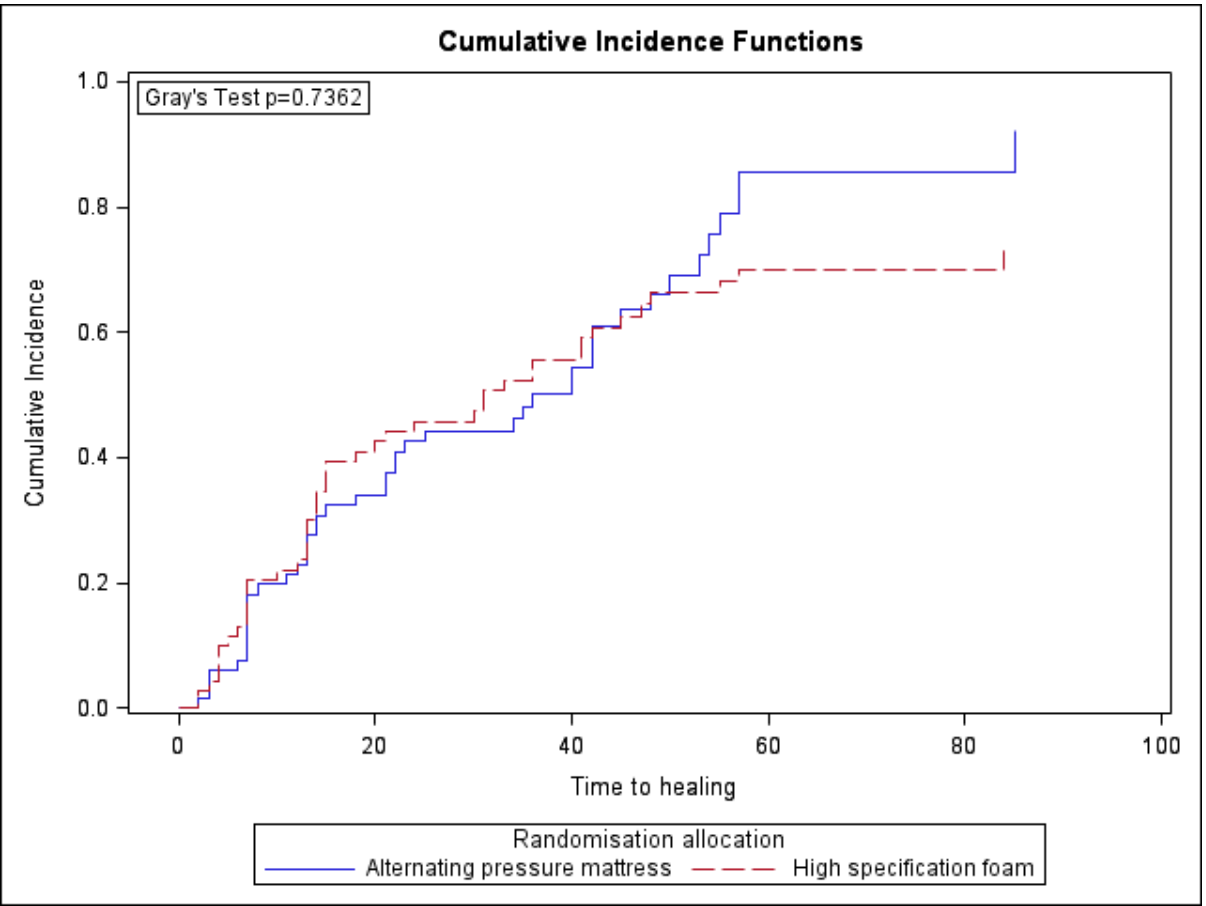
Secondary endpoint - healing of pre-existing Category 2 PUs

Overall	APM	HSF	P-value
75 (61.4%)	44 (62.9%)	45 (60.0%)	0.5990



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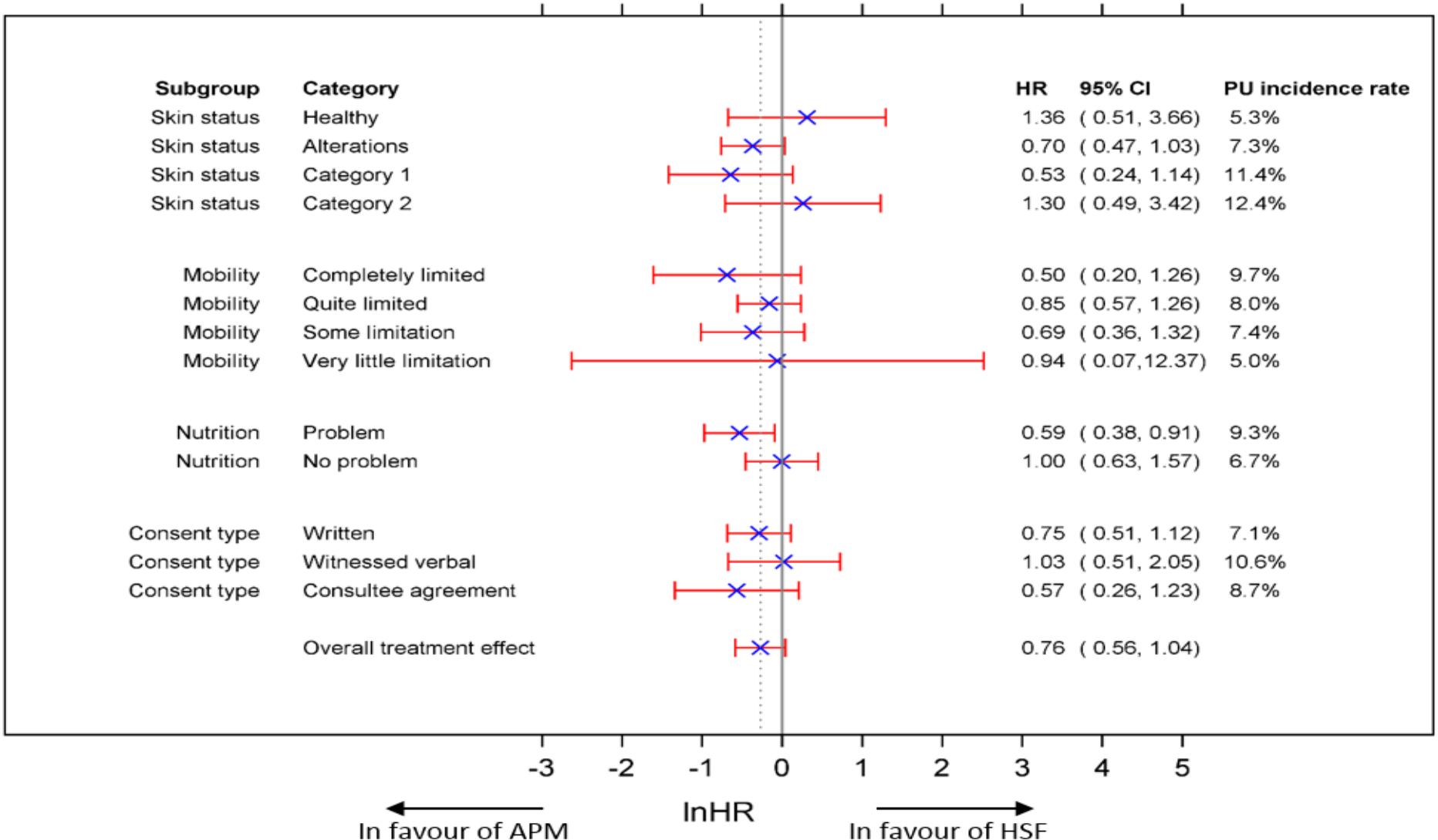
Primary endpoint: adjusted analysis: which patients most likely to develop PU?

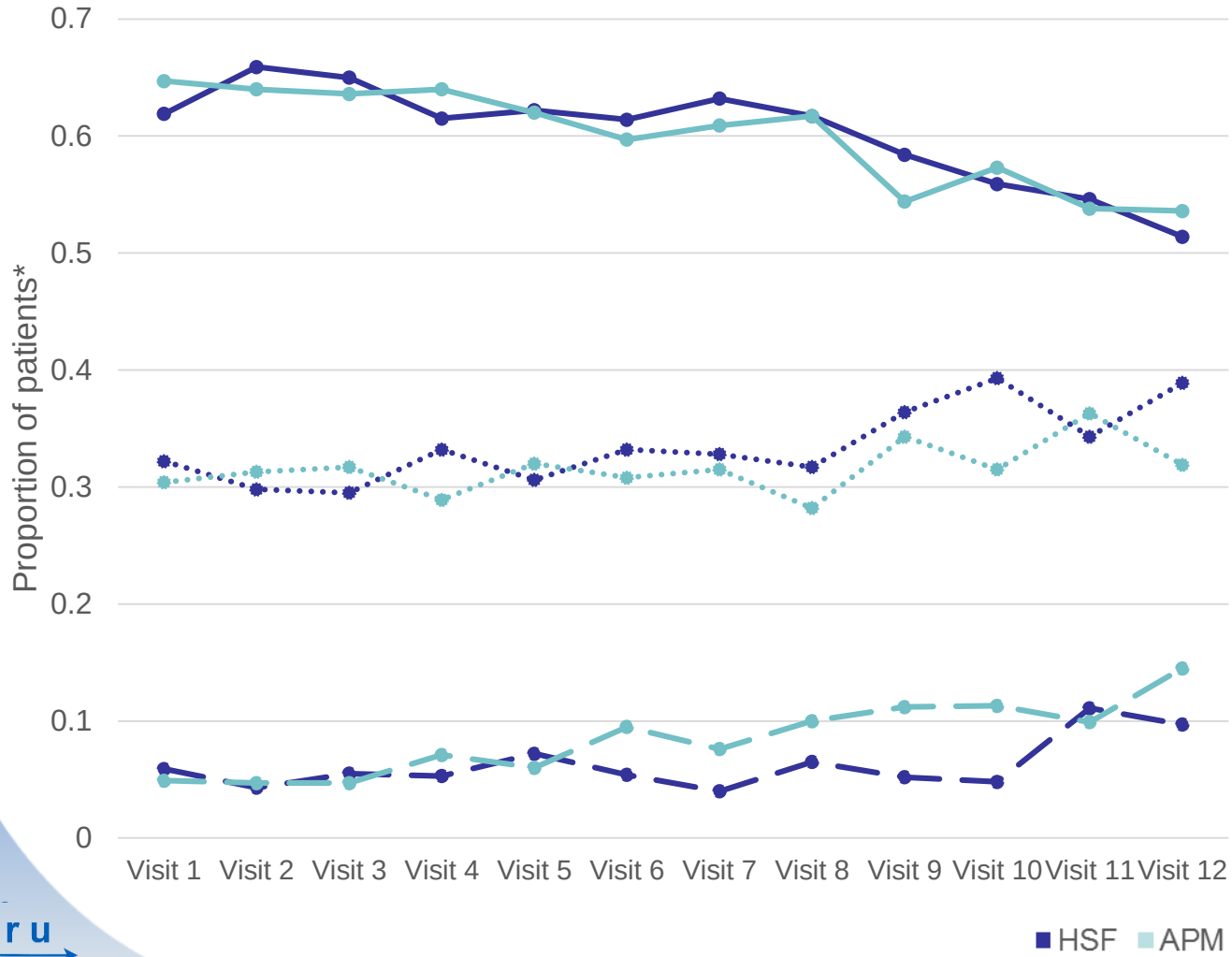
Covariate	Level of covariate	HR point Estimate	HR 95% Wald Confidence limits		Wald P-value
Treatment	HSF	-	-	-	0.0890*
	APM	0.76	0.56 to	1.04	
Skin status	No PU	-	-	-	0.0057
	PU Category 1	1.83	1.17 to	2.87	
	PU Category 2	1.83	1.09 to	3.09	
Consent type	Written	-	-	-	0.3025
	Witnessed verbal	1.34	0.90 to	1.99	
	Consultee agreement	1.23	0.79 to	1.91	
Setting	Secondary care hospital	-	-	-	0.6182
	Community hospital	1.06	0.71 to	1.58	
	Intermediate/ rehabilitation	1.26	0.79 to	1.99	
Pain	No	-	-	-	0.5070
	Yes	1.14	0.82 to	1.61	
	Unable to assess	0.38	0.05 to	2.94	
Peripheral circulation	No	-	-	-	0.5688
	Yes	1.09	0.75 to	1.57	

Moderator analysis: Which patients benefit most?

a) Forest plot of effect sizes within subgroups, primary endpoint



Repositioning over time by mattress type



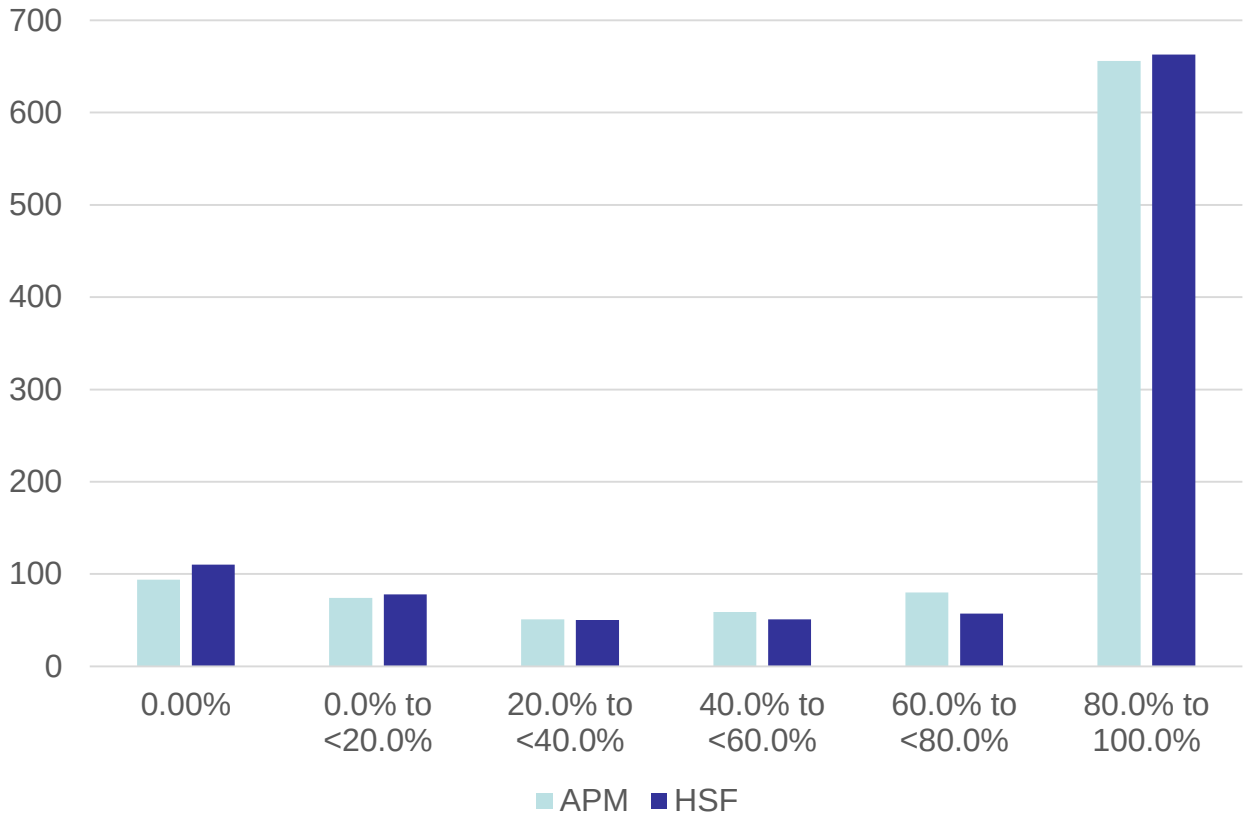
2 to 3 hourly or more frequently

4 to 5 hourly

6 to 7 hourly or less frequently

Preferences and Compliance

Mattress Compliance



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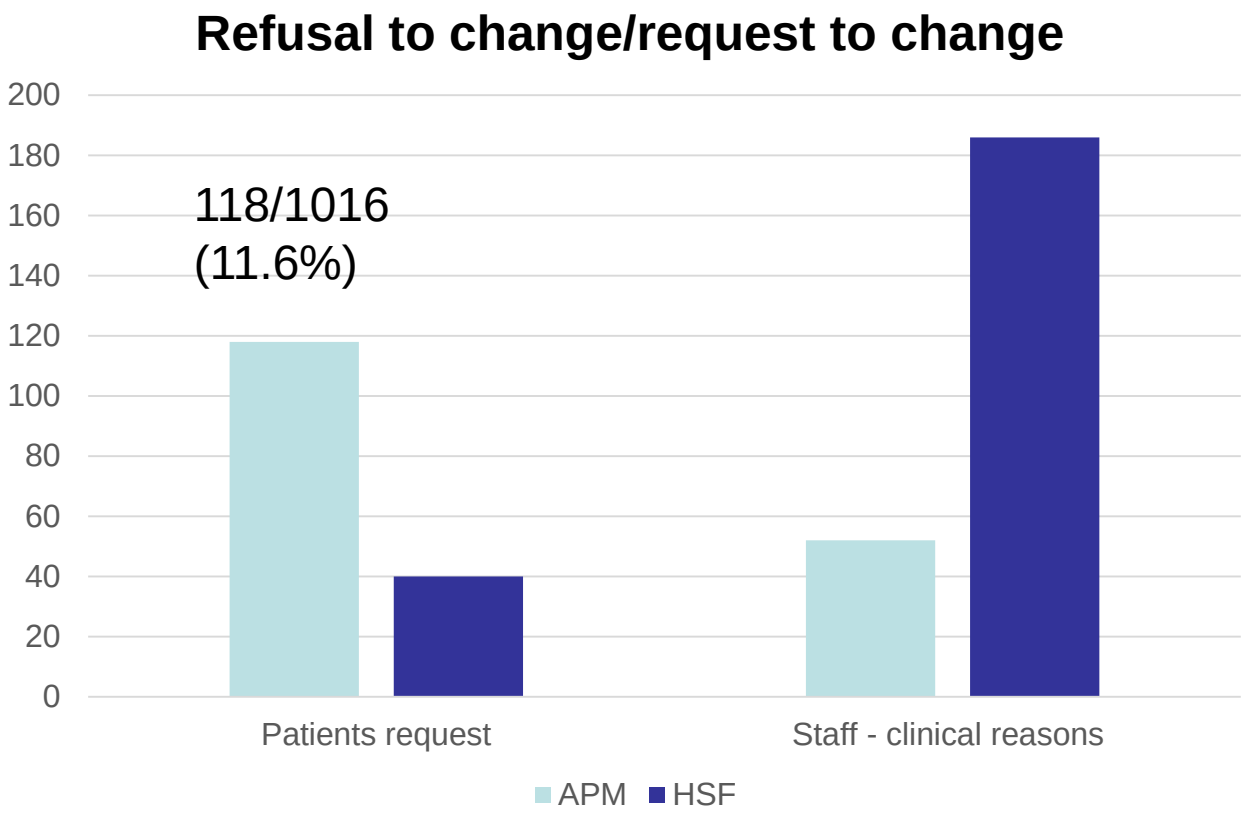
Mattress changes



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Health Economics

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Cost effectiveness:

Within trial analysis:

- QALYs & PUQoL differences negligible

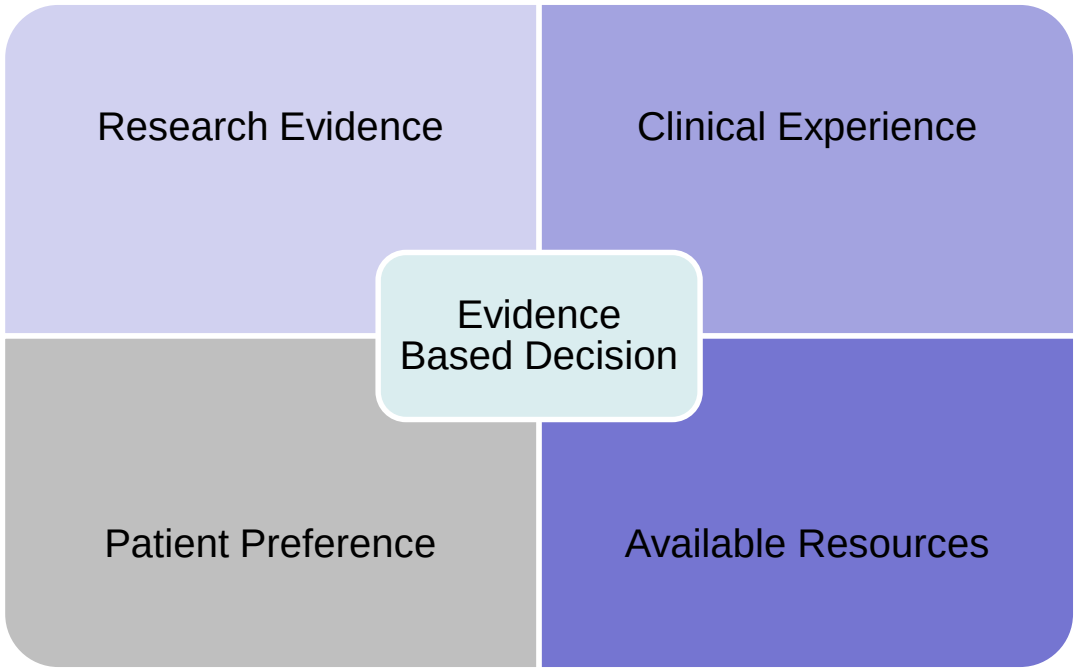
	EQ-5D	PUQoL
APM	0.128	0.1824
HSF	0.127	0.1815
Incremental	**-0.0011**	**-0.0009**

- HSF more costly (£113), but small

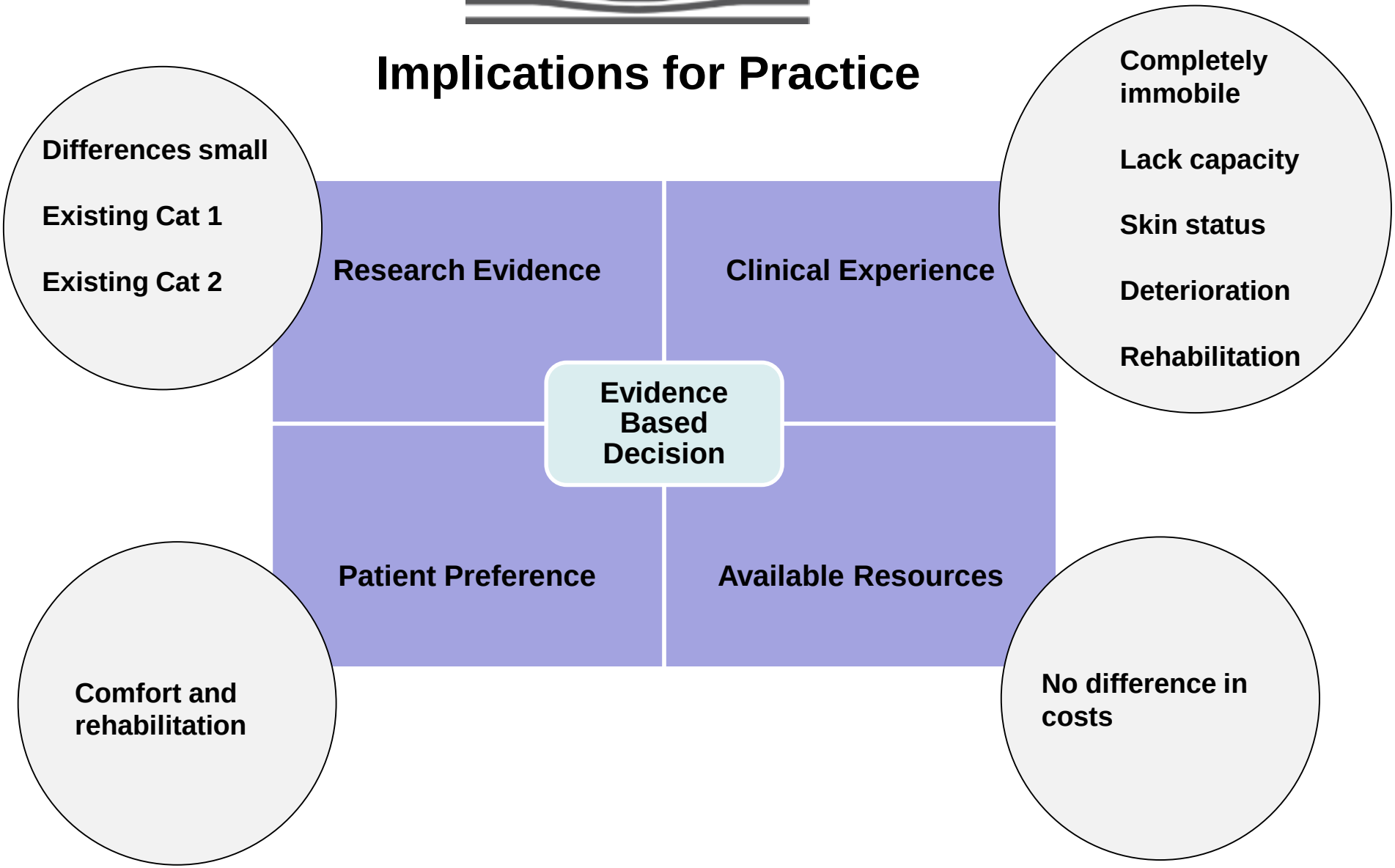
	Costs
APM	£4,533
HSF	£4,646
Incremental	**£113**

- Model - APM is the most cost-effective alternative BUT the results were not robust to sensitivity analysis

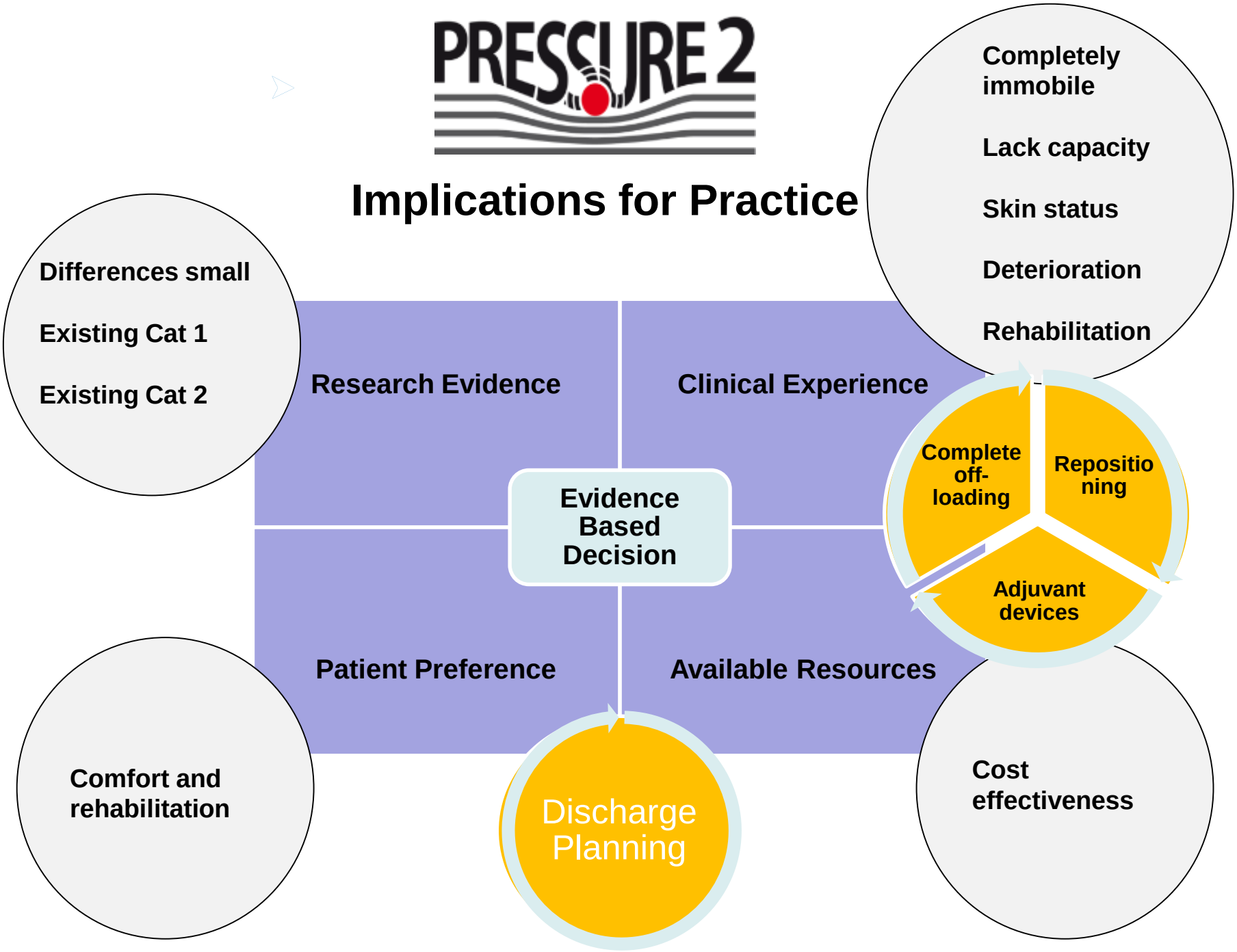
Implications for Practice



Implications for Practice



Implications for Practice



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Disclosure

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The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR, NHS or the Department of Health.

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Safety

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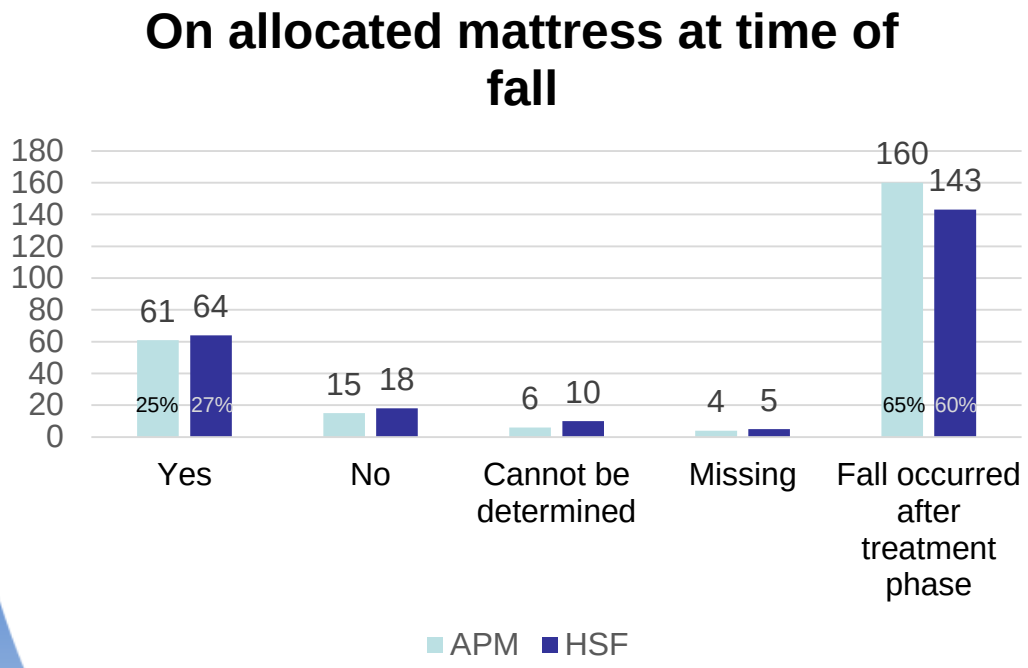
Safety



- 22 Device ulcers observed
  - 12 APM, 10 HSF
  - None were serious
- 3 other related AEs
  - 1 APM, 2 HSF
  - None serious