

A Clinical Investigation of an Autonomous Phone Conversational Agent for Cataract Surgery
Follow-up

NCT05213390

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Statistical analysis plan

Using the variables:

- doraoutcomeupdate (0 = pass, no review, 1 = fail, needs review)
- supervisoroutcomeupdate (0 = pass, no review, 1 = fail, needs review)

Primary outcome: Agreement between Dora and clinician for overall outcome decision and each symptom (x5)

- Inter-rater reliability (kappa)
- Accuracy (%)
- Data regarding true/false negatives/positives

	Clinician: follow-up (1)	Clinician: no follow-up (0)
Dora: follow-up (1)	TP	FP
Dora: no follow-up (0)	FN	TN

- Sensitivity, specificity, AUC

Secondary outcomes

Clinical safety: Comparison with real complication rate

**Note: please do this analysis three times, once for each of the three complication measures*

- Data regarding true/false negatives/positives (**Tables 2-3**)

	Complications: 3 month audit	No complications: 3 month audit
Dora: follow-up	TP	FP
Dora: no follow-up	FN	TN

- Sensitivity, specificity, AUC
- Variables
 - Dora follow up: “**doraoutcomeupdate**”
 - Complications:
 - “**hospital-review-within-3-months**”
 - 0 = no hospital review, 1 = hospital review
 - “**unexpected-change-management**”
 - 0 = no unexpected change management, 1 = unexpected change management



- “unplanned-hospital-rev”
 - 0 = no hospital review, 1 = hospital review