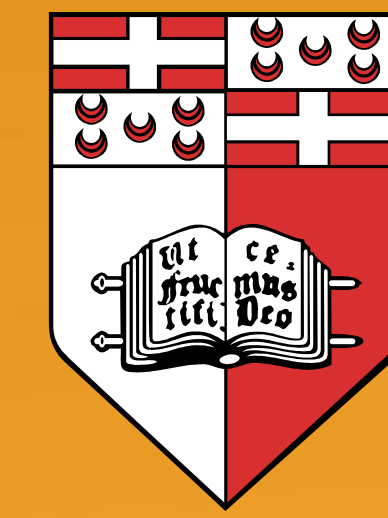# PROPOSING A FRAMEWORK FOR INR TESTING AND ANTICOAGULATION MANAGEMENT IN COMMUNITY PHARMACIES

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INTRODUCTION

The dramatic increase in the requests for International Normalised Ratio (INR) monitoring is resulting in overburdened outpatient clinics. Point-of-Care testing (POCT) devices that measure the INR are adequate alternatives to the laboratory based INR testing system.

AIMS

- To propose and investigate the acceptability and feasibility of a structured community pharmacist-led anticoagulation service, which combines INR monitoring and warfarin dose adjustments.

- To evaluate the accuracy and clinical usefulness of the CoaguChek®XS monitor compared to the anticoagulation laboratory procedure.

METHOD

Patients

- Fifty patients taking warfarin were recruited by convenience sampling from 8 community pharmacies.

- The patients were asked to visit the pharmacy on the same day that their venous plasma INR was to be monitored at the outpatient clinic. For each patient, INR monitoring was performed using the CoaguChek®XS testing device (Figure 1).

- All the patients were asked to complete a questionnaire which was delivered as a semi structured interview, with the objective being to evaluate the patients' acceptance of the proposed INR testing system.

Figure 1. INR testing procedure with CoaguChek®XS

Analysis of the accuracy of CoaguChek®XS

- The level of accuracy between the CoaguChek®XS and laboratory methods was analysed using the Pearson Correlation Co-efficient and the Bland-Altman plot.[1] Clinical significance of the discrepancies between the two methods was assessed using a previous reported criteria.[2]

Development of the proposed framework guidelines

- A clinical guideline was developed and validated by 8 health professionals to set out an effective framework for the implementation of a robust structured INR testing service within community pharmacies.

RESULTS

- Out of the 50 INR tests performed with the CoaguChek®XS, 47 INR results were obtained. The average time to perform an INR test was found to be 1 minute and 55 seconds.

- Twenty-eight out of the 47 POCT INR results issued were within 0.2 units of the laboratory INR value and only 2 dual results had a difference of more than 0.7 INR units.

- Correlation analysis demonstrated a significant positive relationship between the INR values generated by the two testing methods, with a Pearson correlation coefficient of 0.968, which was found to be statistically significant p=0.00 (Figure 2), demonstrating the reliability of CoaguChek®XS.

- The Bland-Altman plot also illustrated good agreement between the 2 methods but with increasing disagreement as INR rose above 3.5 (Figure 3).

- Clinical agreement occurred in 100% of the cases by expanded criteria and 97.9% of the cases by narrow criteria.
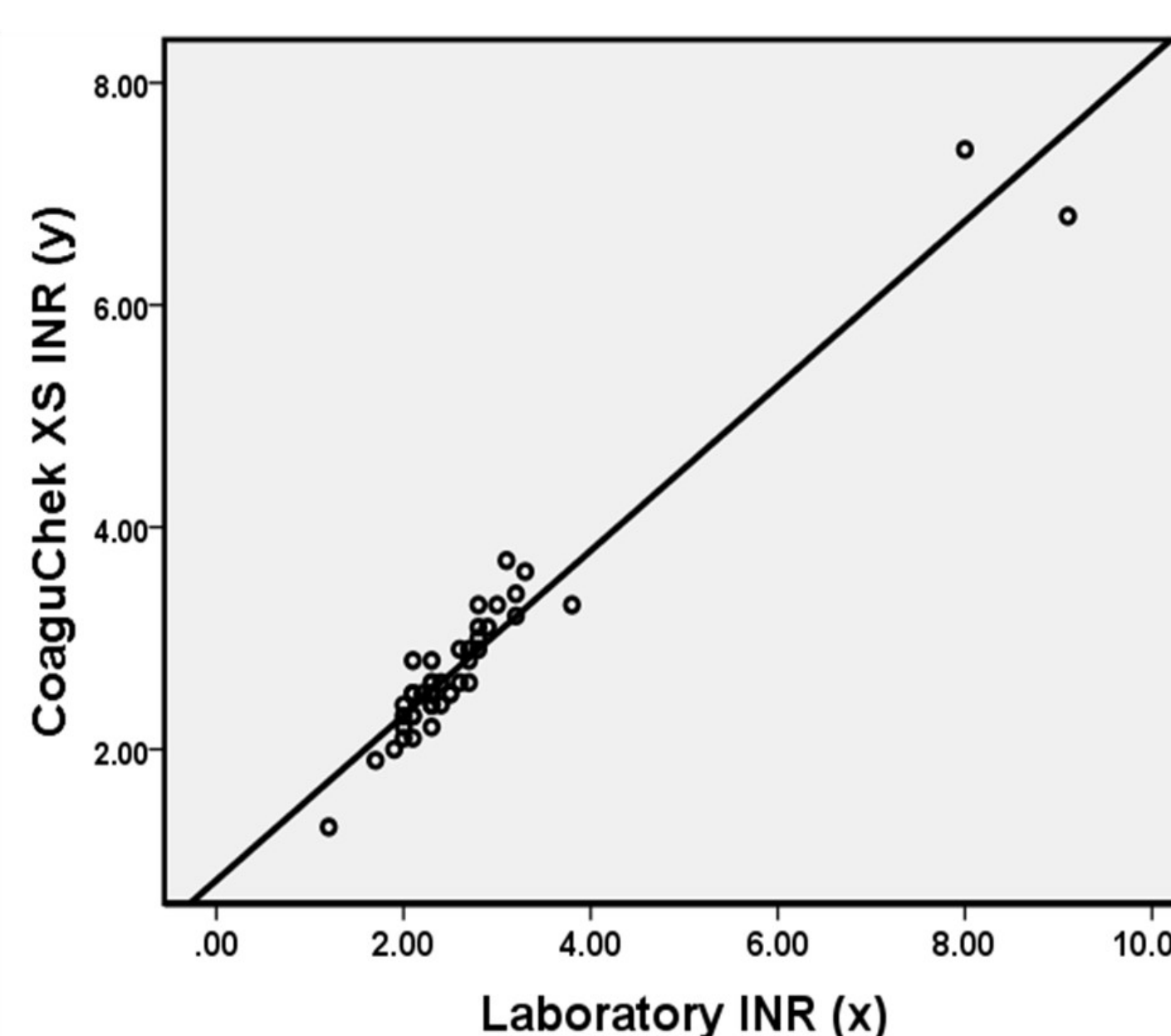

Figure 2. Linear regression analysis of paired INR results obtained using the POCT device and the laboratory method (n=47)
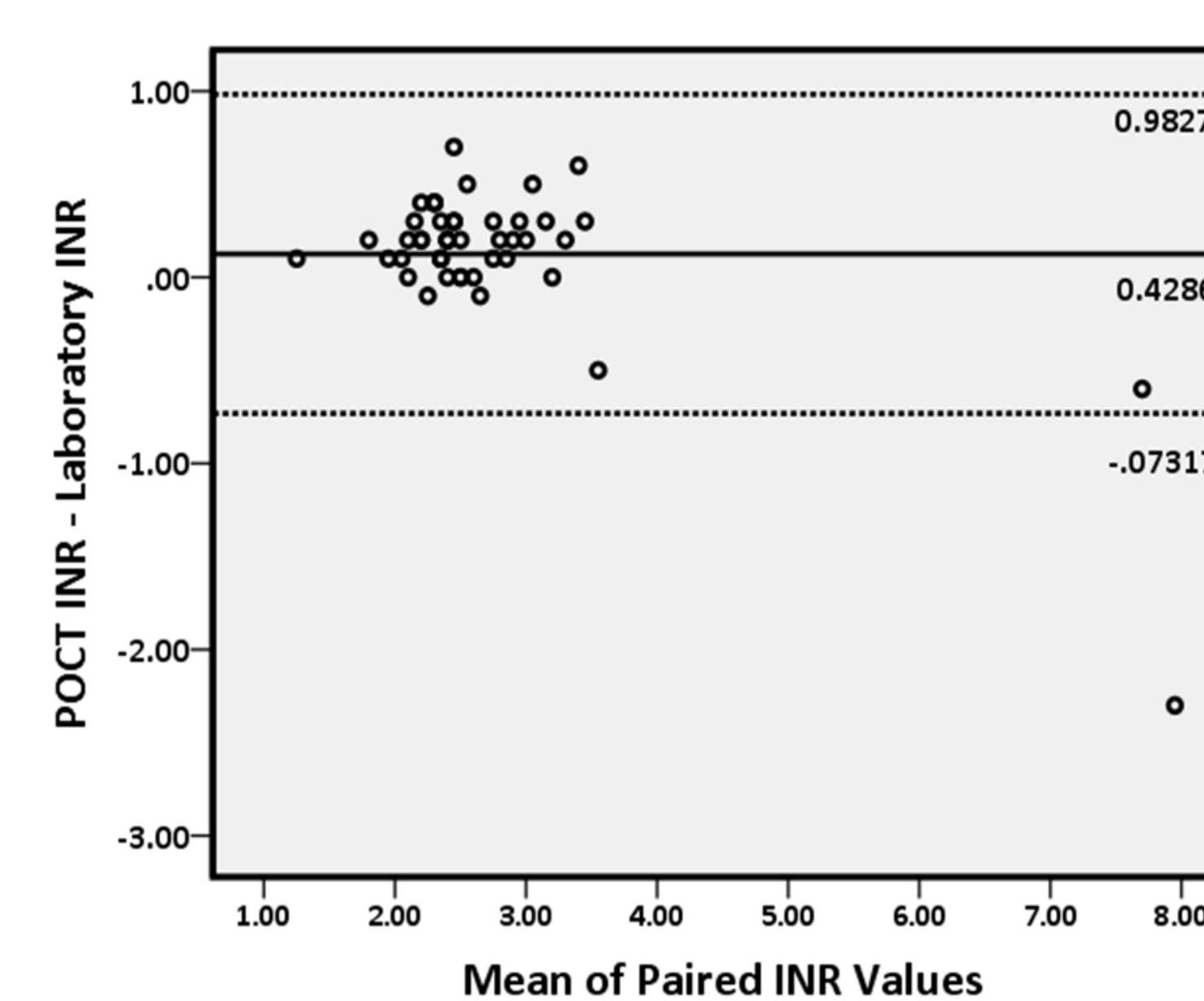

Figure 3. Bland-Altman plot of the INR results obtained with the POCT and laboratory method (n=47)

- All patients had an overall good perception of the proposed framework, with 41 participants expressing interest in using the service following implementation, with 29 of the patients also accepting that pharmacist performs warfarin dose adjustments.

- The appointed reviewers described the developed guidelines as comprehensive since they deal with all the aspects of the service to ensure that it is carried out safely and effectively. Copies of the guidelines were disseminated to promote the decentralisation of the proposed system.

CONCLUSION

The introduction of a community pharmacist-led anticoagulation monitoring service will improve the current anticoagulation management by, reducing the provision of fragmented care and by improving INR testing accessibility, patient satisfaction, clinical reliability and therapeutic effectiveness. The recommendations from this study are being taken up to drive a policy change within the public pharmaceutical service in Malta.

References

1. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986;i:307-310.

2. Douketis JD, Lane A, Milne J, Ginsberg JS. Accuracy of a portable International Normalization Ratio monitor in outpatients receiving long-term oral anticoagulant therapy: Comparison with a laboratory reference standard using clinically relevant criteria for agreement. *Thromb Res* 1998;92(1):11-7.