L-Università ta' Malta
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COMMUNITY PHARMACIST-LED VITAMIN D POINT-OF-CARE TESTING

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SERVICE OR PROGRAM

To establish a framework for community pharmacist-led Vitamin D point-of-care testing (POCT).

Process

1. Appraisal of Vitamin D POCT devices
2. Validation of selected Vitamin D POCT by comparing results with gold standard (Table 1)
3. Development of Vitamin D POCT framework including **risk assessment** and **action plan** for **patient management**
4. Feasibility testing of developed framework in a community pharmacy setting on 80 participants recruited by convenience sampling (Figures 1-3)

SIGNIFICANCE

The community pharmacist-led service developed responds to an identified health service need with respect to Vitamin D POCT. This pharmacist-led approach to Vitamin D POCT aims to:

- **Reduce economic burden** on healthcare facilities
- **Add value to clinical pharmacy provision in primary care**
- **Benefit patients** through harmonisation of Vitamin D analysis, coupled with identification of risks and a personalised action plan (Figure 4).

Table 1: POCT vs. Gold standard (N=20)

Vitamin D Test Result	POCT	Gold Standard
Deficient	1	2
Insufficient	17	16
Sufficient	2	2

Cohen's kappa (K) = 0.84

Figure 2: Vitamin D Levels Tested Previously (N=80)

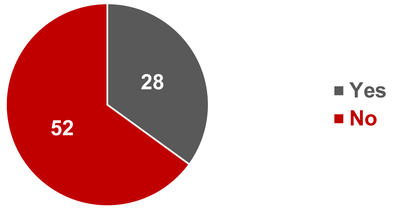


Figure 1: Vitamin D POCT Results (N=80)

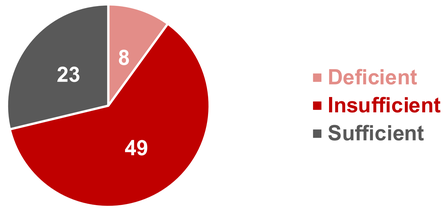


Figure 3: Presence of Metabolic Disorder vs. Vitamin D Level (N=80)

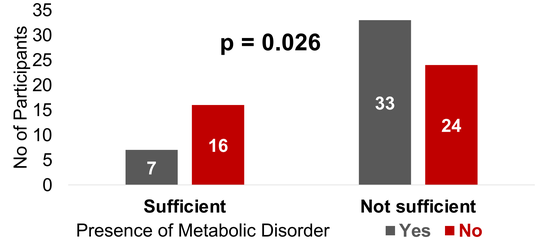
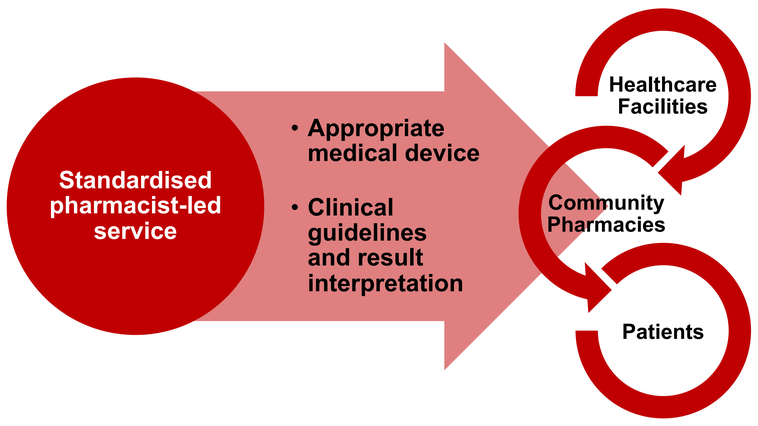


Figure 4: Significance of framework



JUSTIFICATION

- With increased awareness on the relevance of Vitamin D to immunomodulation, patient and general practitioner requests for access to Vitamin D testing increased. A need was identified for service provision in primary care that **ensures patient safety, quality** and **reliability** in the testing process.
- The service developed identified a semi-quantitative POCT to assess Vitamin D (sensitivity 4ng/ml, cost US$6 per kit) which conforms with EU Medical Device Regulations and is feasible to be applied within community pharmacy.
- The POCT results were **validated** against the laboratory-driven test (gold standard) for 20 patients. Concordance was observed between the two methods (κ=0.84) (Table 1).
- Figure 1 presents the Vitamin D POCT results undertaken in community pharmacy, with 57 participants showing deficient or insufficient Vitamin D levels (Figure 1). Statistical significance was observed between presence of metabolic disorders and deficient or insufficient Vitamin D level (p=0.026) (Figure 3).

ADAPTABILITY

Development of the **Vitamin D POCT framework** enables **standardisation** of **pharmacist-led** Vitamin D POCT testing and is **feasible** to be implemented as a **service** in community pharmacy.

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