PP-30

Increasing the Percentage of Good Quality Adverse Drug Reaction (ADR) Report at Hospital Tuanku Ampuan Najihah

Suriani M, Maryam Sakinah S, Safwah Nadzirah Alia S, Ruzanna Aini Z, Sandrika S

Pharmacy Department, Hospital Tuanku Ampuan Najihah, Kuala Pilah, Negeri Sembilan

1. SELECTION OF OPPORTUNITIES FOR IMPROVEMENT

1.1 Problem Prioritization

NO.	Problems	S	M	A	R	T	TOTAL
1.	**Poor reporting of ADR in HTAN**	**14**	**13**	**11**	**10**	**13**	**61**
2.	High percentage of discharge prescriptions received by discharge pharmacy out of office hour.	10	12	10	9	10	51
3.	Incomplete antibiotic request forms from wards	12	9	10	8	9	48
4.	Incomplete request form for medication usage out of formulary.	13	10	11	9	9	52
5.	High demand of extemporaneous preparation received by discharge pharmacy out of office hour.	9	9	8	9	10	45

Score 1-5 (Group Members : 5)	SCORE	1	2	3	4	5
	INDICATION	Very Low	Low	Fair	High	Very high

1.2 Justifications

S M A R T

SERIOUSNESS — High quality ADR reports are essential for conducting drug safety monitoring in pharmacovigilance.

MEASURABLE — Data related to the problem are readily available and can be retrieved.

APPROPRIATENESS — The project is related to core business of pharmacy and is consistent with the organization goals and values in improving medication safety.

REMEDIAL — Remedial action could be implemented to improve the work process with multidiciplinary approach.

TIMELINESS — This study can be completed within intended period of time.
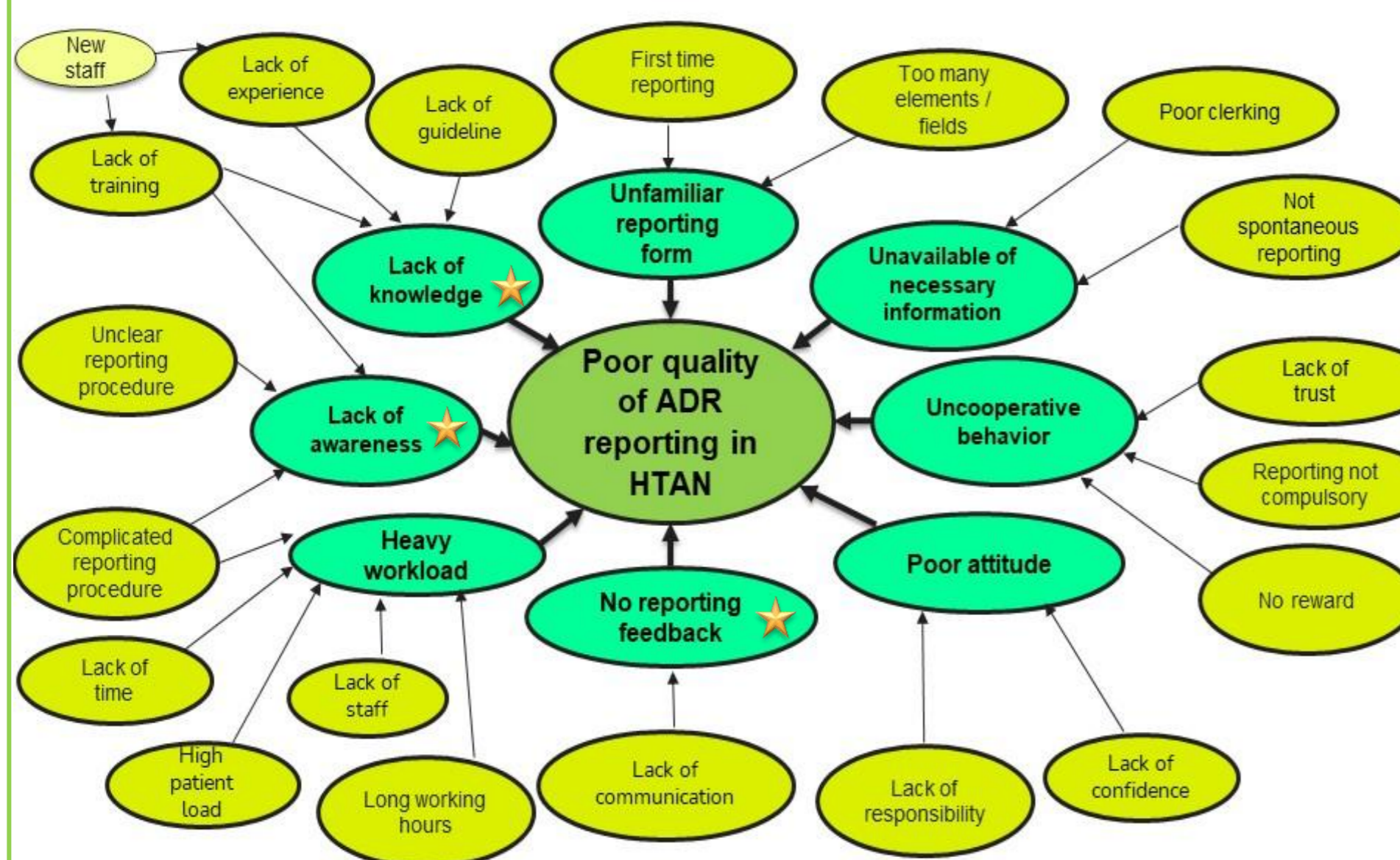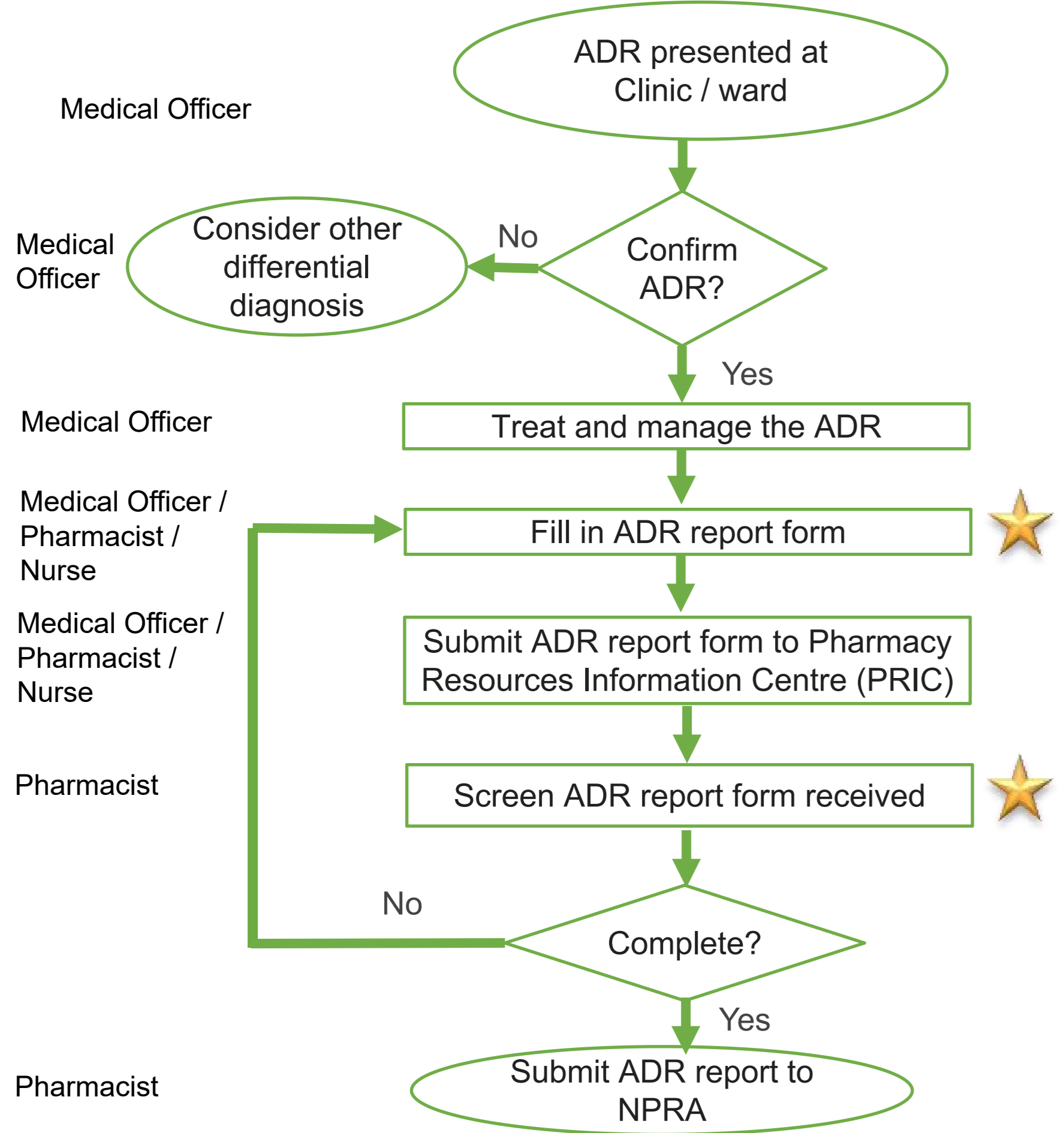
1.3 Literature Review

Adverse drug reaction (ADR) is defined as a response to a drug that is noxious and unintended and occurs at doses normally used in human for the prophylaxis, diagnosis, or therapy of disease, or modification of any physiological function[2]. A successful pharmacovigilance program is not only determine by amount of ADR reports but also by high-quality reports[4].

2. KEY MEASURES FOR IMPROVEMENT

2.1 Problem Analysis

2.2 Process of Care

Medical Officer — ADR presented at Clinic / ward

Medical Officer — Confirm ADR? — No → Consider other differential diagnosis

Yes ↓

Medical Officer — Treat and manage the ADR

Medical Officer / Pharmacist / Nurse — Fill in ADR report form ★

Medical Officer / Pharmacist / Nurse — Submit ADR report form to Pharmacy Resources Information Centre (PRIC)

Pharmacist — Screen ADR report form received ★

Complete? — No (loop back) / Yes ↓

Pharmacist — Submit ADR report to NPRA

2.3 Study Objectives

General Objective

To increase the percentage of good quality ADR report.

Specific Objectives

1. To verify the percentage of poor quality ADR reporting.
2. To identify the contributing factors to poor quality ADR reporting.
3. To formulate and implement appropriate remedial measures.
4. To evaluate the effectiveness of remedial measures.

2.4 Indicator & Standard

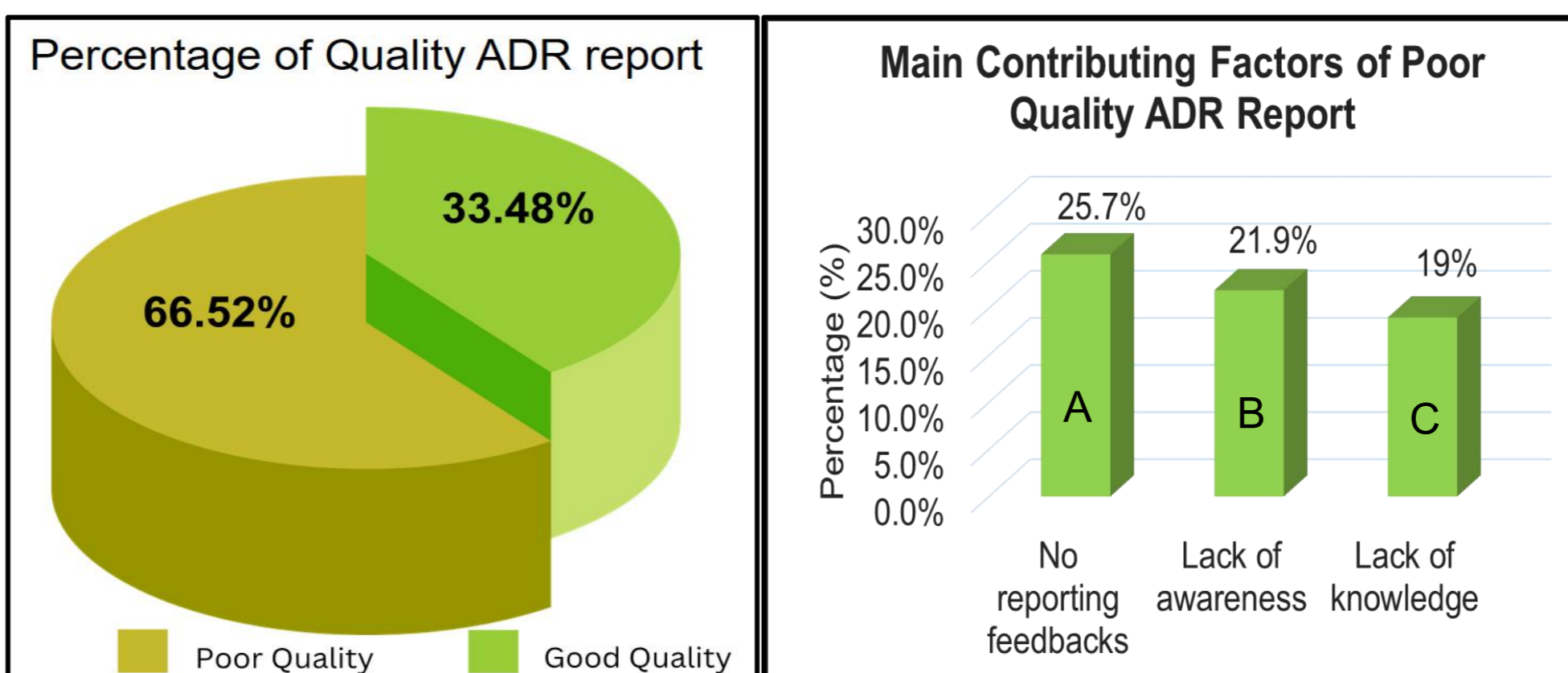| INDICATOR	Percentage of good quality ADR* reports received by Pharmacy Department
FORMULA	= $\frac{\text{Number of good quality ADR reports received}}{\text{Total number of ADR reports received}} \times 100\%$

*A good quality ADR report was defined as score of ≥ 10 based on the Adverse Drug Reactions reports Quality Algorithm (AQUA-12) quality assessment tool.[1]

STANDARD	100%** **based on requirement set by National Pharmaceutical Regulatory Agency (NPRA)[2]

3. PROCESS OF GATHERING INFORMATION

Study Design	Cross-sectional study
Study Setting	Hospital Tuanku Ampuan Najihah
Sampling technique	Universal Sampling
Data collection Tool	Questionnaires (use to investigate contributing factor of poor quality report) Data collection form (use to obtain percentage of good quality report)
Study Period	Verification study: June 2022 until September 2022 Cycle 1: October 2022 until February 2023 Cycle 2: March 2023 until July 2023 Cycle 3: August 2023 until December 2023
Inclusion Criteria	All ADR reports
Exclusion Criteria	involving vaccine, diagnostic substances, supplements, over-the-counter (OTC) and traditional medicines.

4. ANALYSIS AND INTERPRETATION

4.1 Verification Results

Percentage of Quality ADR report: 33.48% Good Quality, 66.52% Poor Quality

Main Contributing Factors of Poor Quality ADR Report: A — No reporting feedbacks 25.7%, B — Lack of awareness 21.9%, C — Lack of knowledge 19%

5. STRATEGIES FOR CHANGE

5.1 Attaching Reporting Guide to the ADR Reporting Form

Front Page: ADR Report Form / Back Page: ADR Reporting Guide

Cycle 1

ADR Reporting Form is printed at the back of ADR Reporting Form to assist the reporter when writing an ADR Report.

5.2 Providing ADR Hotline Number

ADR HOTLINE NUMBER EXT: 8013

Cycle 1

A specific phone number is assigned to receive any queries from the reporter on how to write the ADR report.

| Strategy	Problems	Outcome
5.1	Based on reviewing previous reports, most poor ADR report received had missed information. Some negative reporting was not reported.	Most of empty negative information problem was resolved. Reporter's knowledge on this issue resolved. (This strategy target factor C)
5.2	The guide written and attached at the ADR are common mistakes and some ADR reporting need specific guide. Some ADR information were reported to be contradicting with another information due to misunderstanding of the report form.	The hotline provided direct guidance for specific ADR event. All calls entertained succesfully to provide good ADR reports and reduce contradicting information in the reports. (This strategy target factors B & C)

5.3 Organising HTAN ADR Webinar Series

Cycle 2

HTAN ADR Webinar series is conducted monthly at HTAN level discussing any topics related to ADR.

5.4 Publishing HTAN ADR Newsletter

Cycle 2

HTAN ADR Newsletter is monthly publication that provides articles discussing any topics related to ADR and feedback on ADR reports received.

Strategy	Problems	Outcome
5.3	The previous strategies only involved healthcare's providers that plan to write ADR report. Thus, this strategies was done to widen the knowledge and awareness of ADR reporting to all healthcare's provider in HTAN.	The webinars were done with more than 15 attendees per session which discussed on basic principle of ADR, sharing common report in malaysia/HTAN and emphasis the important of reporting. (This strategy target factors A, B & C)
5.4	Some healthcare professional in HTAN had problem with attending programme due to the nature of work.	The newsletters were circulated by hard and soft copy to expand the feedback mechanism and improve knowledge and awareness of ADR reporting. (This strategy target factors A, B & C)

5.5 Conducting ADR Awareness Online Quiz

Cycle 3
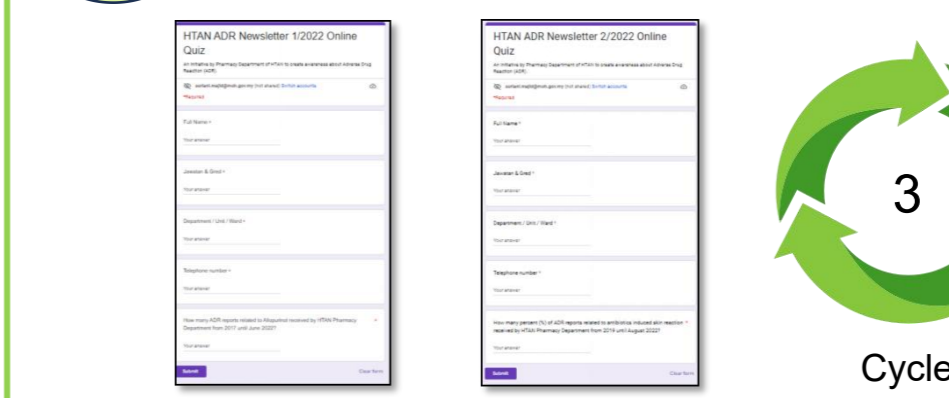
ADR Awareness Online Quiz is conducted monthly to create awareness on ADR reporting. The winners will be awarded with the certificate of excellence.

5.6 Continuous Education & Briefing Session during Orientation

Continuous ADR Education is conducted time to time to all healthcare providers and an ADR briefing also conducted during new staff orientation.
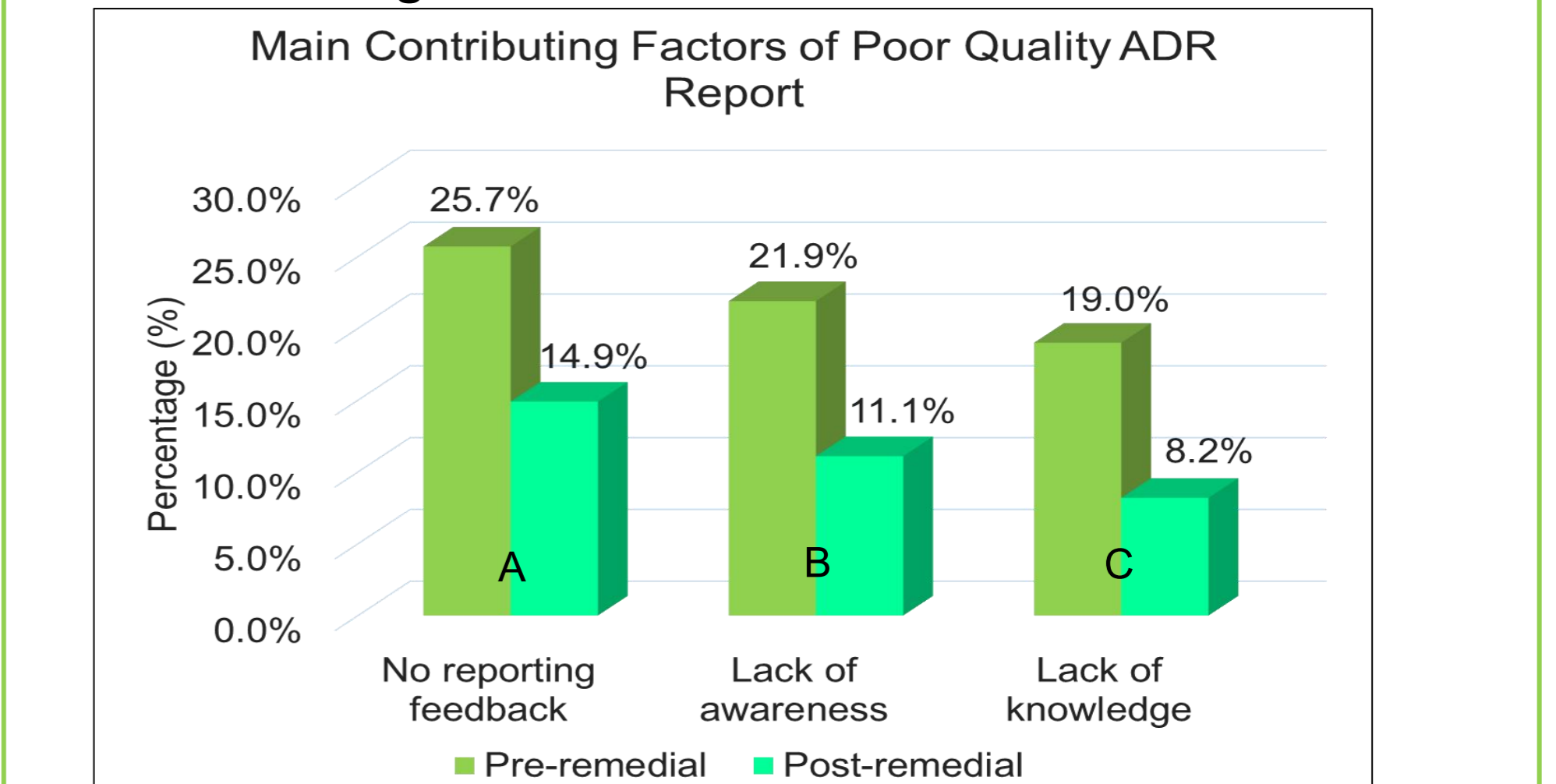
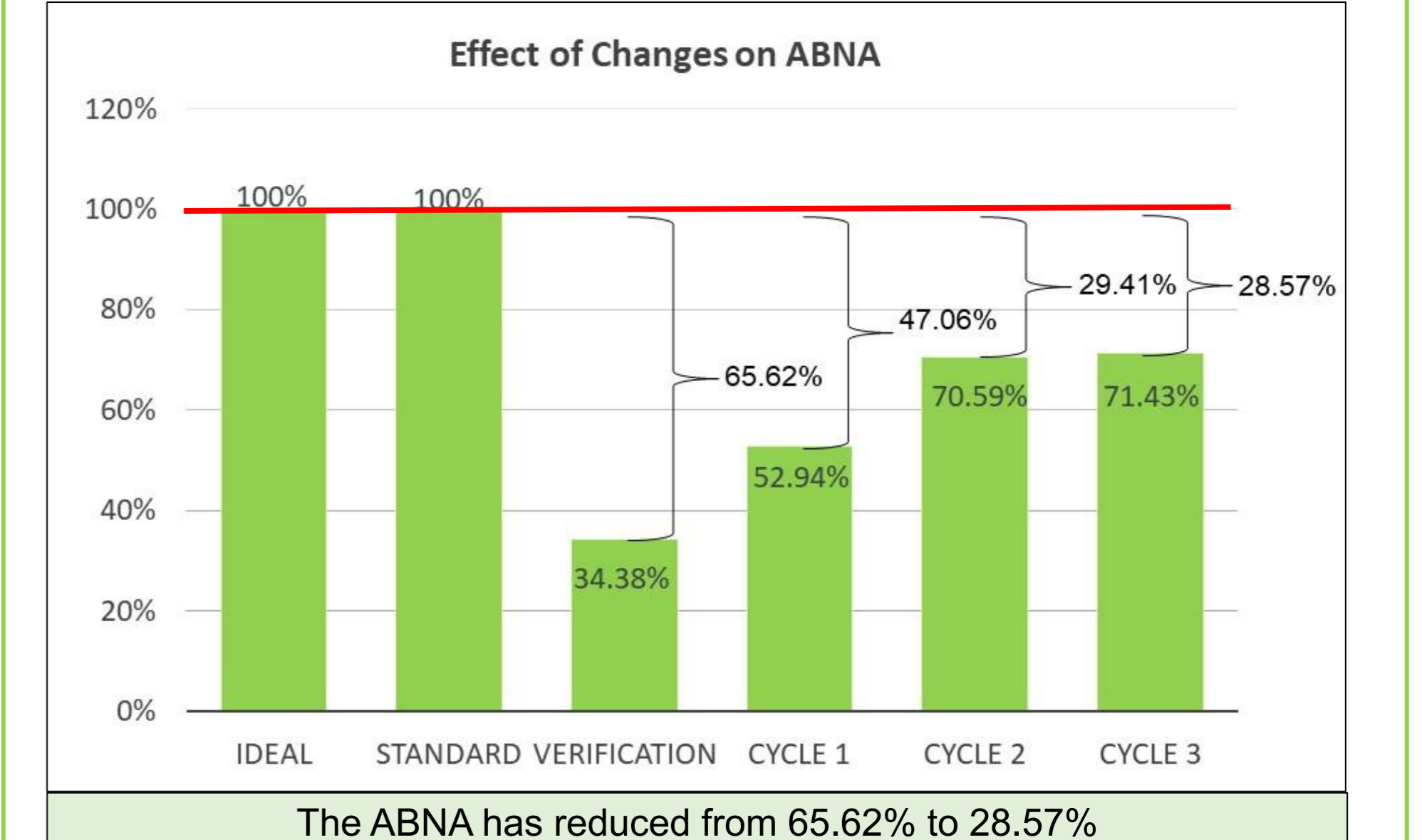| Strategy	Problems	Outcome
5.5	Previous strategies did not give any feedback to us regarding the understanding of healthcare professional towards ADR reports.	The quizzes paired with ADR webinar and knowledge and awareness of healthcare professional in HTAN were portrayed. (This strategy targets factors B and C)
5.6	HTAN had high rate of staffs exchange. The influx of new staffs might reduce overall HTAN healthcare provider's knowledge and awareness in ADR reports. Thus, this strategy was design to prevent expected event.	Result of questionnaire on contributing factor indicate improvement in the 3 factors compare to verification study result eventhough there are influx of new staffs. (This strategy improves factors A, B & C)

6. EFFECT OF CHANGE

6.1 Model of Good Care (MOGC)

Process	Criteria	Standard	Verification	Cycle 1	Cycle 2	Cycle 3
Fill in ADR report form	ADR reporting form is completely filled with: • Patient information • ADR Description • Suspected drug details • Concomitant drug details • Reporter details	100%	77.75%	82.61% ↑	83.5% ↑	87.08% ↑
Screen ADR report form received	ADR reporting form is completely filled with: • Patient information • ADR Description • Suspected drug details • Concomitant drug details • Reporter details	100%	100%	100%	100%	100%

6.2 Contributing Factors

Main Contributing Factors of Poor Quality ADR Report (Pre-remedial / Post-remedial):
- A — No reporting feedback: 25.7% → 14.9%
- B — Lack of awareness: 21.9% → 11.1%
- C — Lack of knowledge: 19.0% → 8.2%

6.3 Achievable Benefit Not Achieved (ABNA)

Effect of Changes on ABNA: IDEAL 100%, STANDARD 100%, VERIFICATION 65.62% (34.38%), CYCLE 1 47.06% (52.94%), CYCLE 2 29.41% (70.59%), CYCLE 3 28.57% (71.43%)

The ABNA has reduced from 65.62% to 28.57%

6.4 Impact

- Reduce process time from 24 hours to 1 hour
- Improve healthcare approach in pharmacotherapy; Thus, improve patient safety
- Effective report leads to identify and detect ADR early - Reduce healthcare cost

Lesson learnt:

1. Through this study, interventions implemented has proven beneficial in improving quality of ADR reports. However, it has yet to achieve its target of 100%.
2. Despite the success, this study has challenges on ensuring the interventions implemented reaching all HTAN healthcare providers.

6. THE NEXT STEP

We plan to:

1. Continue monitoring of ADR reporting.
2. Sustain the remedial measures.
3. Create ADR Online Training Module.
4. Expand the study to other healthcare facilities.
5. Publish the study in Q Bulletin.

References:
1. Aung, A., Zubrinich, C.M., Goh, M.S.Y. et al. (2023). Eur J Clin Pharmacol 79, 513–522.
2. National Pharmaceutical Regulatory Agency (NPRA). (2015, April). Bulletin_MADRAC_April_2015.pdf.
3. Salvador, M.R.; Monteiro, C.; Pereira, L.; Duarte, A.P. Int. J. Environ. Res. Public Health 2022, 19, 3754.
4. Chen, Y., Niu, R., Xiang, Y., Wang, N., Bai, J., & Feng, B. (2019). Biological and Pharmaceutical Bulletin, 42(12), 2083-2088
5. Patel, P. B., Patel, T. K., Anturlikar, S., Khatun, S., Bhabhor, P., & Saurabh, M. K. (2017). Perspectives in Clinical Research, 8(3), 137.
6. Alshammari, T. M., Wa'ad. H., Le Louet, H., & Aljadhey, H. S. (2015). Saudi medical journal, 36(7), 821.
7. Elkalmi RM, Elnaem MH, Sapar NM, Blebil A. J Pharm Bioall Sci 2021;13:325-30.
8. Robertson, J., & Newby, D. A. (2013). Medical Journal of Australia, 199(10), 684-686.
9. Terblanche, A., Meyer, J. C., Godman, B., & Summers, R. S. (2017). Hospital practice, 45(5), 238-245.
10. Abena, A. Y., Walker S., Khu, Y.L. et. al. (2022). Eur J Clin Pharmacol 78(5), p781-1791.