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# **Q** Bulletin

Institute for Health Systems Research Ministry of Health, Malaysia

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# Q Bulletin Ministry of Health Malaysia

# INTRODUCTION

The Q Bulletin of the Ministry of Health Malaysia is a peer-reviewed journal addressing quality assurance/improvement study related to health care. The journal welcomes original contribution from representatives of all health professions from health-related backgrounds in the discipline of quality assurance/quality improvement.

Your manuscript should include abstract (up to 300 words), main text (up to 4000 words; excluding abstracts, tables and figures) and maximum of 5 tables and/or figures.

#### 1. Title

#### 2. Author's Name & Affiliation

Full name of authors and clearly indicated corresponding authors with contact email.

#### 3. Abstract

Summarise your work, including a brief background to the problem, the method for your quality improvement project, overall results and conclusion. Please include 3-5 appropriate keywords.

#### 4. Problem

Summarise the problem and focus of your project. Give some details about your local context. Include here the SMART aim of your project.

#### 5. Background

Give background information about the problem and summarise the literature on existing evidence that this problem exists, factors contributing to the problem and strategies that has been done in the past.

#### 6. Measurement

Describe measures that you have selected for studying processes and the outcomes of the intervention(s). Describe plan for data collection and include the results of your baseline measurement (verification study).

#### 7. Initial assessment of the problem

Describe what processes are involved in your problem including the critical steps that in the processes that will contribute to the achievement of your final goal. Describe the perceived factors that could contribute to the problem and how you quantify them. Include here the results of the study that you conducted to identify the contributing factors to the problem.

#### 8. Strategy

Explain your strategy for improvement to the reader and discuss how you implemented your improvement cycles. For each PDSA cycle you should describe your aim, your change hypothesis and strategy for change. Describe how you implemented the change and the data you collected. Describe your key learning from each cycle of change, and discuss how this learning impacted on your change process. How well did your predictions of what change was needed match your outcomes? What worked more effectively than anticipated and what had less effect than predicted?

#### 9. Results

Provide a summary of what your results using appropriate chart or diagram. Compare your results to your baseline measurement.

#### 10. Lessons and limitations

Discuss the lessons, the strengths and limitations of the project. If you were to undertake this project again, what would you do differently?

## 11. Conclusion and the next steps

Reflect on your aims statement – did your project achieve its aims? Did you adjust your aims as you went along? Was it a useful project? Were your measures appropriate and did you use balancing measures?

#### 12. References

Use the Vancouver style for referencing.

#### 13. Acknowledgements

Please include here the names of anyone who is not on the author list but whose input you wish to acknowledge.

#### 14. Communication

Full version of the guideline can be found at the last section of this journal. For submission purpose, please contact ihsrqa@moh.gov.my

# **EDITORIAL**

# Editorial Introduction to the First Issue of the New Q Bulletin of the Ministry of Health Malaysia: Getting QA Studies Heard and Used

Dear Readers,

On behalf of the Q Bulletin's Editorial Committee, I am delighted to announce the publication of the inaugural issue of Q Bulletin facelift; the official Journal of Quality Assurance/Quality Improvement in Healthcare for the Ministry of Health Malaysia (MOH), which endeavour to be published twice a year. The launch of this new version marked another significant milestone in the roadmap of the Quality Assurance Programme (QAP) of the MOH. Being a "social" bulletin previously, the bulletin is now uplifted to a peer-reviewed journal featuring commendable QA studies.

Since the inception of QAP in 1985, numerous QA studies had been conducted in various healthcare facilities. We recorded more than 500 QA studies presented at the National QA Conventions, which commenced in 2001. Most of the projects addressed relevant quality problems that adopted replicable remedial measures. Yet, the dissemination of projects in the form of publication was scanty; thus, limiting the sharing of the best practices to a broader audience. Throughout the years, considerable efforts had been made to facilitate the publication of QA Projects. Since 2007, the QA Secretariat without failed had organised Writing for Publication workshops; however, the number of projects that got published in any journal were minimal.

This new version has been in the making for more than a year. The idea sparked in June last year when Dr. Sondi Sararaks reviewed the draft of the best practices in Malaysia for the ASEAN initiative compiled by the QA Secretariat. Upon discussion, we decided that the time is appropriate to promote and disseminate our many best practices of QA studies using our existing Q Bulletin as the vehicle.

We foresee that establishing a journal is indeed a daunting task. Nevertheless, our passion pushed us to reach our goal and taught us invaluable lessons along the journey. Yet we ardently embraced the belief that "where there is a wail, there is a way".

We took up the challenge and started the groundwork, including:

- (i) Developing the overall plan of action
- (ii) Developing and outlining the scope of the bulletin, roles, and responsibilities of the editorial committee, reviewers, and the flow process of the manuscript publication
- (iii) Nominating editorial committee members to attend a workshop on journal management
- (iv) Searching for examples on the instruction for authors to adopt and adapt
- (v) Identifying potential projects to be included in the first volume this was done by reviewing the list of QA projects presented at the previous National QA Conventions
- (vi) Communicating with potential authors of the identified projects and requesting for their commitment to writing the draft of manuscripts
- (vii) Disseminating information about the new bulletin and calling for authors by sending official letters to all MOH Head of Programmes and State Health Directors, publication of Q Bulletin Vol.1, No.27, Jan-Dec 2018, e-pamphlet, and promoting it during QA training
- (viii) Conducting a series of writing workshop, followed by virtual communication to assist the authors in improving and refining their manuscripts
- (ix) Engaging a group of reviewers to help us improve the quality of the manuscripts

Today, the hard work paid off. The release of this Bulletin's new look rendered us a sense of fulfilment.

This inaugural issue owes so much to many people. Thanks are due first to Dr Nor Izzah Hj Ahmad Shauki, the Director of IHSR, for her unfailing support in the publication of this first issue and Dr Sondi Sararaks, the

Head of Centre for Health Outcomes Research, IHSR, from whom the idea originates. Thanks are also due to my Associate Editor, Dr Izzatur Rahmi Mohd Ujang and the editorial committee members who worked arduously for the past one year to realise this mission. This Bulletin would not be timely published without the assistance of our assigned reviewers who had tirelessly reviewed the manuscripts and provided critical comments. On top of that, our heartfelt appreciation goes to all authors of the six projects, who have shown high commitment and a deep passion for completing the first draft and refining the manuscripts despite numerous rounds of reviews. Congratulations!

This first-ever new version Bulletin is far from perfect. We are committed to bring this Bulletin to a greater height and to sustain the publication of this Bulletin by pursuing the following strategies:

- (i) More aggressive promotional strategies to attract authors to submit their manuscript
- (ii) Create/attract a pool of diverse topic of manuscripts
- (iii) Create/attract a pool of reviewers
- (iv) A more effective and efficient editorial team and editorial process

We hope that one day our beloved Q Bulletin will:

- (i) Be published in the form of e-bulletin/open access
- (ii) Be the journal of choice for the QA studies
- (iii) Adopt efficient publication process using available journal management system (e.g. MyJMS)
- (iv) Be able to attract papers beyond Malaysia

As the saying goes, the first step is always the hardest. Each process that we went through to come up with this first issue was indeed a remarkable and exceptional learning experience. We hope that this notable effort will serve as a platform for the sharing of local QA studies, and able to contribute to the translation of QA study into policy and practice. Thus, serving the purpose of conducting a QA study.

We eagerly welcome your feedback and comments to help us improve in the future.

Thank you.

Dr Samsiah Awang

Editor-in-Chief

# MEDICATION STOCKPILING: A RED ALERT TO COMBAT FOR QUALITY, SAFETY, AND EFFICACY OF MEDICATIONS

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# **Abstract**

Medication Stockpiling (MS), in the Ministry of Health, Malaysia, resulted in the disposal of MYR 2 million worth of expired or spoilt medicines between 2014 and 2016. MS is an alarming issue that causes healthcare resources wastage and potentially harmful and toxic to patients. This study aimed to reduce MS in Hospital Selama, beginning with the medical wards within one year.

A situational analysis from the year 2013 to 2014 showed a 9.4% increase in MS. A four-month pre-intervention study from November 2014 to February 2015 revealed a 28% MS. The standard of the study was set based on the team members' consensus. The aim was to reduce 50% of MS after four-month of intervention. The cause-effect analysis identified the main contributing factors of MS. The questionnaire was distributed to nurses in the wards and pharmacists to pinpoint the MS antecedent. The results indicated a lack of routine ward audit by the clinical pharmacists, overindent by ward nurses and oversupply by the pharmacy unit. A flow-chart of the good care process comprises the steps of medications indent and supply was developed. It involved assigning the nightshift nurses for checking and indenting the wards' medication stock, developing the ward stock indent (WSI) form, ensuring the pharmacy staff supply sufficient medication and enforcing a monthly ward audit by the clinical pharmacists and cross-audit by other pharmacists. Each indicator in the model of good care was then measured.

The post-intervention period successfully achieved a 3.5% MS; an 87.5% reduction (exceeded the target). Additionally, a cost reduction in the medication wastage from MYR 1,273.97 to MYR 654.44 was noted. The study successfully achieved less than 6% of MS from 2015 to 2018.

In conclusion, the study facilitated a successful collaboration among the hospital different units towards MS reduction.

**KEYWORDS**: Medication stockpiling, medication wastage, quality study

# Problem

Medication stockpiling (MS) is the inappropriate accumulation of medication to prevent a shortage of medications when Routine quarterly ward-check needed. reports by pharmacists showed that almost all units kept excess medications for after office hour use. Extra workforce and time were needed to screen all the returned, unused medications to determine if they were still redispensable or re-usable by considering proper storage and expiry date. MS has been highlighted as a serious issue when a situational analysis in two medical wards of Hospital Selama showed an increase of 9.4% MS, from 40% (Year 2013) to 49.4% (Year 2014). It triggered a red alert when two fastmoving medications; Amoxycillin capsule and Captopril tablet were found expired in the ward due to MS. This has led to medication wastage and caused ineffective treatment or toxic effect to patients.

Hospital Selama is a district, nonspecialist hospital located in Selama, Perak, a state in the northern part of Peninsular Malaysia. It served a population approximately 300,000 people. It consisted of three wards, namely Male, Female and Pediatric, and Obstetrics and Gynaecology (O&G) Ward, giving a total of 90 beds. The hospital's bed occupancy rate (BOR) ranged from 35% to 45%. Other units include the Emergency Unit, Outpatient Unit, Pathology Service Unit, Physiotherapy and Pharmacy Rehabilitation Unit, Unit. Hemodialysis Unit, and others. Pharmacy is one of the critical clinical support units with the role of thoroughly screening prescriptions, filling, dispensing of medications, suggesting recommendations or interventions, counselling the patients. Pharmacists are imperative to ensure medication safety, quality, and efficacy by safeguarding the precise choice of drug, dose, frequency, duration of medication. They also ensure no contraindication, polypharmacy, and drugdrug interaction for the patients. Operational hours of the Pharmacy Unit started from 8 am to 5 pm, and any emergency cases are handled by the on-call pharmacist. Ward Supply Pharmacy Unit (WSPU) consisted of a pharmacist and a pharmacist assistant, in charge of supplying the ward stock medications to all units. Each medical ward is made up of 15 to 20 ward staff, and one of the ward staff's responsibilities is to indent the ward stock medications. Each ward kept up to approximately 80 types of medications.

Although the initial verification phase of the problem indicated only 9.4% MS, the percentage of MS during the four months preintervention period study of November 2014 to February 2015 was 28%. The figures highlighted the urgent need to solve this problem and thus, upon a consensus among the group members, this study was formulated aiming to achieve a 14% MS (a 50% reduction) by the end of the one-year study.

# Background

According to The Academy of Manage Care Pharmacy (AMCP), MS is an unnecessary, wasteful, expensive, dangerous circumvention of potentially appropriate healthcare resources (1). The disposal of expired medications had been a concern in many countries as proper and safe disposal were costly (2). On the other hand, if disposed of improperly, the waste may enter the ecosystem, negatively impacting on human health and the environment (2). The Stars Online reported that the Ministry of Health Malaysia had disposed nearly MYR 2 million worth of expired or spoilt medicines over a two-year period, from 2014 to 2016 (3). The report stated that most of the expired medicines were stockpiled by patients and returned to government pharmacies under the Ministry's "Return Your Medicines" program. Total medication disposed of in 2014 was worth MYR 1.8 million, which equaled to 0.075% of the budget of the year (3). This is an alarming issue as MS led to medication and financial wastage.

A study conducted in Gondar University, a teaching and specialist hospital in Ethiopia, showed that expired medications increased toxicity risk as the active ingredient of medication underwent degradation and might lead to the formation of toxic products (4). This endangered patients' health.

Besides, MS for extended periods may reduce the drug potency as the storage was beyond the manufacturer's recommendations. The poor storage condition medications were exposed to heat, light, humidity, and air may cause the medication to lose its potency. Moreover, MS may also cause a shortage of medications in the drug distributing system (5). The disruption in the supply chain can significantly decrease the quality of service and care provided to patients, affect the patients' satisfaction and their well-being. In conjunction with the application of Government Service Tax (GST) in 2015, the budget allocated for purchasing medication in the government sectors was reduced by 2.58%, or MYR 3.1 million (6). Despite the hike in the number of patient visits to government facilities by 20%, the budget allocation was continuously decreased in trend by 9.28% as noted in the 2016 Budget and was further reduced to 3.78% in 2017 (6). This caused the populations to have a negative perception or assumption of drug shortages due to budget cuts. The Ministry of Health holds the ground that the government health facilities were not facing a shortage of fund whilst encouraging staff of the government sectors to work around the budget constraint. The situation can be improved by seeking for innovative cost-saving effort, one of which is by reducing MS and ensuring systematic ward stock management system. Reducing MS would allow short expiry medications to be offered to other hospitals or clinics on time for patients use, and the amount of expired medications and cost for proper drug disposal can be reduced.

The of Huddersfield University conducted a study that aimed at identifying the root causes contributing to medication wastage in a hospital pharmacy in the UK and its potential solutions (7). The results of the that most studv revealed medication wastages happened in the ward. The root cause of medication wastage was most likely due to unknowingly expiring stockpiled medications as pharmacists failed to perform routine ward checks and tended to supply whatever amount of medications requested by the ward staff (7). Moreover, another important cause was the unnecessary stock ward holding by ward staff. Ward staff might not realize the actual value of the medications kept in the ward, failed to return the excessive medicines to the pharmacy, requested more medications than necessary, and operated a 'just in case' system. In addition, staff in the ward might not perform stock ward checking accordingly or check the expiry date of medications routinely. Last but not least, poor communication between staff ward and pharmacists might also lead to MS and medication wastage.

The study in the UK came up with solutions that emphasising on ward staff inspecting their own ward's medication stock and checking the expiry date to ensure no expired medications in the ward (8). Besides, ward staff should return the excessive medication after a patient was discharged or deceased to the pharmacy on the same day during office hour or early the next day. A series of facilitated workshop or seminars on the Standard Operating Procedures (SOPs) or the process of care and improved communication among the units were also the solutions to this issue.

An international survey in the Netherlands highlighted that pharmacists had some essential roles in reducing medication wastage throughout the pharmaceutical supply chain (7). In the survey, 86.4% of nineteen developed countries reported stock ward management as the most frequently implemented activity to reduce medication waste. Thus, pharmacists play an essential role in the whole process of medicine usage, from avoiding unnecessary supply to recycling medicines that were no longer needed.

# Measurement

The primary outcome of this study is the percentage of MS. It is calculated as the quantity of unused medication return (MR) over the total quantity of medication supplied. The quantity is irrespective of the types of medications. For example, if the medication returned consists of two vials of Ceftriaxone injection, three tablets of Bisoprolol tablet

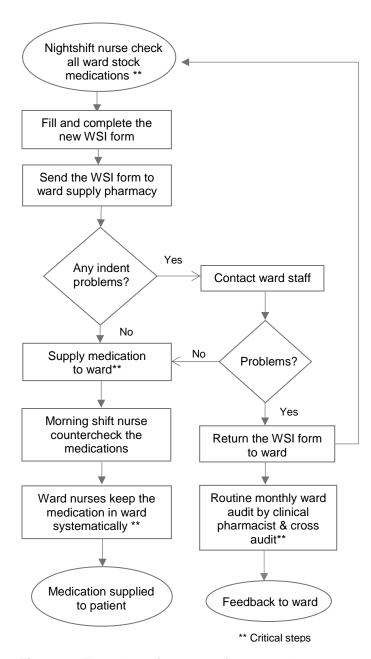
5mg and four bottles of Cloxacillin syrup, the quantity counted for unused MR is nine. Initial data collection involved only two medical wards (Male Ward and Female and Paediatric Ward). All oral and injection medicines supplied to medical wards were included. Data were collected daily at the WSPU through ward stock indent (WSI) form and the pharmacy MR record. Pharmacists or pharmacist assistants of the WSPU counted the quantity and cost of MR from each ward every month and identified the medication that could be reused. A pre-intervention study showed 28% MS within a four-month period. starting from November 2014 to February 2015. A 50% reduction of MS is aimed to be achieved at the end of this study.

# Initial Assessment of the Problem

After reviewing the current process of care of drug indent and supply to the ward (Figure 1), the critical steps that aided in reducing the percentage of MS were listed First, night shift ward nurses were responsible for the indent of ward stock medications. They must check medications kept in the ward and identify the types and quantity of medications that have reached below the minimum level of ward stock. The minimum level of ward stock is the minimum quantity of medications that must be kept in the ward that is sufficient to spare for after office hour use. Also, they must return the excessive medications, if any, or exchanged medications with short expiry. Short expiry medications are medications that will be expired in one week based on the expiry date. Then, the WSI form must be duly filled before submitting to WSPU. The WSI would be updated from time to time accordingly upon the request of the ward's nursing manager and after a discussion with the pharmacist-in-charge.

Next, the pharmacist or assistant pharmacists in WSPU must supply the correct quantity of medications to avoid exceeding the maximum level of ward stock level and ensure all medication supply were labelled, in good condition and unexpired.

The ward nurses working in morning shift would countercheck the medications supplied and collected back to the ward and place the ward stock (WS) medications into their respective shelves systemically.



**Figure 1:** Flow-chart of process of care on drug indent and supply.

Besides, clinical pharmacist units also lend cooperation to reduce MS. All clinical pharmacists in charge of the respective wards must carry out routine monthly ward audit to inspect the ward stock medications. Audit marks are deducted for any expired medications, improper storage of medications, medications that fall below minimum quantity, or excessively stored medications. The audit report would then be

forwarded to the nursing manager for his or her attention. A routine cross audit would be conducted by other pharmacists every three months.

Before suggesting the implementation, a cause and effect analysis technique was performed to analyse the probable contributing factors (Figure 2).

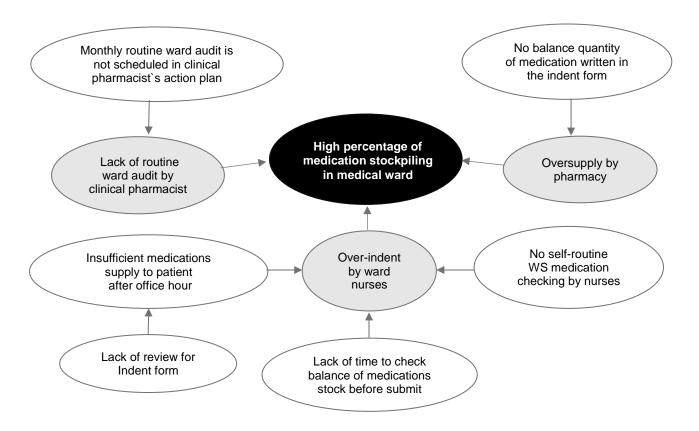


Figure 2: Cause-effect analysis chart of high percentage of medication stockpiling in medical wards.

Two separate sets of questionnaires were developed to identify the factors contributing to MS. One was targeted at nurses, on the reasons of over-indent, whereas the other is for pharmacists on the factors of oversupply. Both the nurses and pharmacists can select more than one reasons from the list in the questionnaire. The main contributing factors were identified by ward nurses (n=30) namely lack of time to check stock balance before indent (80%), insufficient medication to fulfil patients' need after office hours (63%) and no self-routine WS medication checking by nurses (50%).

On the other hand, the questionnaire was distributed to the pharmacists and pharmacist assistants (n=16) to determine the factors of oversupply of medication to the wards and no routine ward audit by the clinical pharmacists. All respondents claimed that the reason for oversupply was because they did not know the quantity balance of medications in the ward. Hence, they tended to supply whatever was requested. All respondents agreed that clinical pharmacist did not perform ward audits because ward audit was not included in the clinical pharmacists' action plan.

# **Strategy**

This study's SMART aim was to reduce the percentage of MS by 50%, from the pre-intervention phase by the end of a 1-year period. Few strategies were implemented, aiming at improving the model of good care in the post-intervention period.

The initial intervention was to tackle the problem of over-indent by ward nurses and supply pharmacy staff who tend to oversupply the medications. A new format of WSI form to replace the previous indent form, which is called *Buku Kimia* was developed. This format was developed in a partnership between the medical ward and ward supply pharmacy staff. The new WSI form consisted of the list of ward stock medications of each ward with the minimum and maximum quantity of medications that are allowed to be kept. There were three additional columns to be filled upon a ward stock indent, namely the quantity of left-over medications, the expiry

date of the medications, and the quantity of medications to be indented. The new format of WSI form (as shown in Appendix) was approved to be used in Hospital Selama by the Hospital Director.

Additionally, the schedule of pharmacists, on-call pharmacist and their contact number were distributed to the wards at the beginning of each month. This was done to tackle the problem of over-indent for 'just-in-case' use and to reassure ward staff that stockpiling was unnecessary as an on-call pharmacist was readily available if there is an urgent need for medications.

Besides, the WSI list in each ward was also revised and updated according to the prescribing trends. Ward supply pharmacists allowed the nursing manager to submit the application form to update the WSI list as and when needed instead of making a yearly request. This was done to overcome the problem of over-indent of WS medications, which arise from the lack of medications supply for patients after office hour.

Another intervention was to come up with the SOP of indent ward stock from the pharmacy. The SOP was initially drafted by the head of Ward Supply Unit and then revised by sisters in the ward. This effort aims to compel all ward staff to follow the SOP, which is applicable and agreed by both the ward staff representatives and reduce the over-indent problem of WS medications. The discussion's results also determined that night shift nurse is responsible for doing a routine ward stock check and filling in the WSI form, whereas morning shift nurses are counterchecking responsible for medications supplied by the ward supply pharmacy and placing them into the corresponding slot systemically according to the 'First In First Out' rules.

Furthermore, clinical pharmacists were obligated to perform a routine audit of WS medications every month. The Head of Pharmacy Department had set the WS medications audit as one of the key performance indicator (KPI) for the pharmacists. This is to solve the problem of clinical pharmacists who did not routinely perform a ward audit, which led to a high

percentage of medication stockpiling. The KPI was set to be 100%. Clinical pharmacists must include ward audit in their tentative action plan, and upon the completion of the ward audit, a report must be sent to the nursing supervisor of the ward. Meanwhile, other pharmacists must take a turn to do a cross-audit on the wards every three months. The head of the ward supply unit arranged the schedule and pharmacists in charge of the cross audit.

In addition, continuous medication education (CME) of the SOP of WS management was provided to all Pharmacy's staff and ward staffs. CME, in collaboration with the nursing unit and ward supply pharmacy unit was carried out twice a year.

## Results

The post-intervention analysis indicated that all criteria in the model of good care (Table 1) showed an improvement after the intervention. The post-intervention study revealed an 87.5% reduction of MS, from 28% (November 2014 – February 2015) to 3.5% (July – October 2015). The subsequent monitoring phase (November 2015 – Feb 2019) showed that the MS percentage was sustained around 3.3%, which was higher than the standard set (Figure 3). The yearly MS analysis indicated that MS was reduced from 49.4% (2014) to 5.5% (2015). The total

cost of unused medication returned was reduced by 48.6% after the intervention.

In general, all of the approaches implemented were indeed a success. However, the ward audit by pharmacists suggested that there was still a 10% ward stock falling below the minimum level and not indented by ward nurses and 3% of medications were found to have a short expiry date but were not returned to the pharmacy unit. Upon investigation, this was mainly due to two reasons. First, the new ward nurses were not familiar with the WS indent system and SOP. Second, the high workload of the night shift nurses, such as when one of the nurses needed to escort or transfer out a case and has to leave the other staff nurses to be in charge and take care of the patients.

This was overcome by adding the briefing on the WSI system in the echo training checklist for every new staff nurse. Besides, the wards' nursing supervisors had instructed staff nurses of the morning shift to take over the responsibility of checking WS and filling in the WSI form in case the night shift staff nurses are unable to do so due to high workload.

However, the post remedial survey showed that 100% of clinical pharmacists performed the ward stock audit.

Table 1: Model of good care for reducing MS in medical ward.

No	Procedure	Criteria	Standard	Pre- remedial	Post- remedial	February 2019
1	Night shift nurses identify the types and	Indent WS medications when quantity below minimum level (refer WSI list)	100%	75%	90%	98%
	quantity of WS medications to be indented	<ol> <li>Replace medications that easily change colour due to humidity, e.g. Ascorbic Acid, Cap Phenytoin</li> </ol>	100%	86%	100%	100%
		<ol> <li>Exchange WS medications with short expiry date (at least one week before the expiry date)</li> </ol>	100%	80%	97%	100%
		4. Regularly update the WSI list	100%	50%	100%	100%
2	Pharmacy supply medications to ward	Supply the correct quantity of WS medications and do not exceed the maximum stock level	100%	70%	100%	100%
		Supply WS medications that are not expired	100%	100%	100%	100%
		Supply each oral tablet of WS medications with label name and expiry date	100%	40%	100%	100%
3	WS medications are kept systematically	WS medications kept systematically in labelled location by morning shift nurses	100%	50%	95 %	100%
	in ward	Medication stored according to Standard Operating Procedure in ward	100%	100%	100%	100%
		Monthly routine WS medications audit by a clinical pharmacist	100%	25%	100%	100%
		Quarterly cross audit by other pharmacists	100%	100%	100%	100%

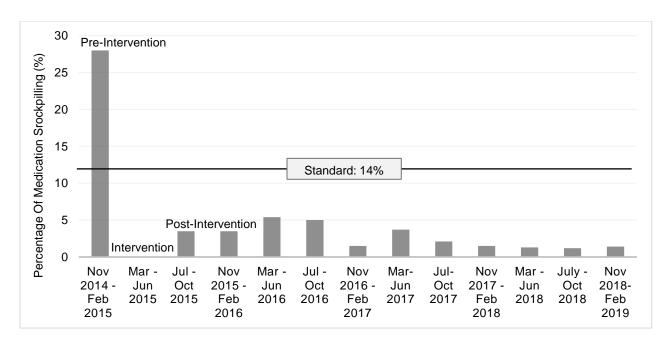


Figure 3: Achievement on percentage of medication stockpiling (ABNA analysis).

# **Lessons and Limitations**

This study showed that the implementation of a systematic WSI system helps to reduce the percentage of medication stockpiling, and it yields a sustainable result. An additional achievement of this study is the cost-saving of medication wastage. During the pre-intervention study, the cost of the medication wastage resulted from medication stockpiling was MYR 1,273.97, but it was reduced to MYR 654.44 during the post-intervention study period, which showed a cost reduction of 48.6%.

Multidisciplinary communication and teamwork are the key success factors of this study. This study would never have achieved its goal without the full support of the hospital director and the commitment from everyone involved, directly or indirectly. Since this study ensured the involvement of all related parties throughout the process, group discussion sessions, and considered the collective views of the team members when designing the WSI system, it yielded a sustainable and user-friendly WSI system.

However, despite the initial enthusiasm, the study encountered several teething problems when the WSI system was

extended to other units, such as the Emergency Unit and Outpatient Unit. The most challenging part was that the other units did not have any clinical pharmacist who could assist in the medications monthly audit. Moreover, it was rather difficult to convince the senior staff to embrace the new WSI system as they were so used to the existing deep-rooted routine. Nevertheless, there was a positive change when the impact of the new WSI system to medical wards was presented in multiple presentations, focusing on the reduction of medication wastage and the costs saved.

This study can be applied to other bigger hospitals with 600 beds and BOR >80%. It can be done by implementing the WSI format, which consisted of the column for minimum quantity, maximum quantity, and the medications' expiry date. The types of WS medications stored and the maximum quantity allowed should be tailored accordingly based on the facility. The flowchart of the process of care can be adopted as well, with minimal revision. There is no doubt that it will result in a higher reduction of MS and a more significant impact on the hospital.

# **Conclusion and the Next Steps**

In conclusion, this study had revealed the contributing factors that might have led to medication stockpiling. Interventions were suggested and implemented in order to tackle each factor. This study had successfully reduced the percentage of medication stockpiling in both medical wards, and the WSI system was then implemented in all other units. The results of MS for both medical wards were presented to the Hospital Director and head of all units. This was done to convince other units to embrace the change as reducing MS brought positive impacts especially in ensuring the quality, safety, and efficacy use of medications. The flow-chart of the process of care for other units was revised accordingly following a discussion with the respective head of unit, taking into account the staff's workload and working schedule.

Continuous efforts and teamwork among the wards, units, and pharmacy unit are critical in order to ensure the sustainability of the interventions. The monitoring of these indicators and the saving of cost are an ongoing process, and prompt actions are to be taken if the percentage of medication stockpiling increased or failed to reach the initial target set. Besides, this study allowed all parties involved to contribute suggestions as a proactive approach in addressing issues promptly to give better outcomes, with the hope of achieving zero medication stockpiling in all units of Hospital Selama. This is further supported by a monthly and quarterly scheduled audit on medications by dedicated Strong support from the pharmacists. Hospital Director continues to motivate this study through yearly conferment of a certificate of achievement to the respective units with the best WSI management. Continuous efforts are underway to sustain and improve the MS results, striving towards achieving a zero-medication stockpiling in all units of this hospital.

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# **Conflict of Interest**

None

# **Funding**

None

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**Appendix**WSI form for Male Ward

# SENARAI INDEN UBAT FLOOR STOCK - UBAT LIST A & TROLI KECEMASAN **WAD LELAKI**

# **TARIKH:**

DII	NAMA UDAT	BI	BIL		EXP	В	IL
BIL	NAMA UBAT		MIN	BAKI	DATE	INDEN	BEKAL
UBA	T SUNTIKAN (FLOOR STOCK) - LIST A						
1	Amoxicillin 1g & Clavulanate 200mg inj. (Augmentin)	5	2				
2	Ampicillin & Sulbactam 1.5g inj. (Unasyn)	5	2				
3	Cefoperazone sodium 1g inj. (Cefobid)	5	2				
4	Ceftazidime 2g IM/IV inj. (Fortum)	5	2				
5	Ceftriaxone 1g inj. (Rocephin)	3	2				
6	Cefuroxime 1,500mg IM/IV inj. (Zinacef)	5	2				
7	Diclofenac sodium 75mg/3ml inj.	20	10				
8	Digoxin 0.25mg/ml inj.	5	2				
9	Dobutamine HCL 250mg/20ml inj.	5	2				
10	Isosorbide dinitrate 1mg/ml 10ml inj.	5	2				
11	Metronidazole 500mg/100ml inj.	5	2				
12	Noradrenaline acid tartrate 4mg/4ml inj.	5	2				
13	Omeprazole 40mg inj.	4	2				
14	Streptokinase 1,500,000 IU inj. (*)	2	1				
15	Tramadol HCL 50mg/ml inj.	20	10				
16	Verapamil HCL 5mg/2ml inj.	5	2				
LIST	A MISCELLANEOUS	•					
1	Calcium polystyrene sulfonate powder (Kalimate)	10	5				

# (\*) UBAT TERSEBUT PERLU DISIMPAN DALAM PETI SEJUK (SUHU SIMPANAN : 2°C - 8°C)

# **TROLI KECEMASAN**

BIL	NAMA UBAT	BIL	BAKI	EXP DATE	INDEN	BEKAL
1	Adenosine 3mg/ml inj.	5				
2	Adrenaline 1mg/ml inj.	10				
3	Amiodarone 150mg/3ml	10				
4	Atropine sulphate 1mg/ml inj.	5				
5	Aminophylline 2.5% inj.	5				
6	Calcium gluconate 10% 10ml inj.	5				
7	Chlorpheniramine 10mg/1ml inj.	5				·
8	Dexamethasone 8mg/ml inj.	5				

9	Dextrose 50% 10ml inj.	5		
10	Dopamine 200mg/5ml inj.	5		
11	Flumazenil 0.5mg/5ml inj.	3		
12	Furosemide 20mg/2ml inj.	10		
13	Heparinised saline 50 IU/5ml inj.	5		
14	Hydrocortisone 100mg inj.	5		
15	Lignocaine HCL 200mg/10ml inj.	5		
16	Naloxone 0.4mg/ml inj. (adult)	3		
17	Phytomenadione BP10mg/ml inj.	5		
18	Promethazine HCL 25mg/ml inj.	5		
19	Sodium bicarbonate 8.4% 10ml inj.	5		
20	Water for injection 10ml	10		

Hospital Selama (Jan 2019)

# IMPROVING THE PERCENTAGE OF PLATELET CONCENTRATES THAT MEET PLATELET COUNT STANDARD

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# **Abstract**

The platelet concentrates (PCs) is used for the treatment and prevention of bleeding in patients with reduced platelet number or function. The prepared platelet concentrates (PCs) must meet the specified quality control (QC) test standards. PCs that do not meet QC standards will reduce the efficacy of patient care and increase the need of repeated PC transfusion. According to the standards, at least 75% PCs tested should contain more than 60 x 10<sup>9</sup> per platelet count units. Hence, the objective of this study was to increase the percentage of PCs that meet the platelet count standard to more or equal to 75%.

A cross sectional study was conducted from May 2015 to March 2016. Data were collected and analysed through monthly PCs QC test results. A retrospective QC data review in March and April 2015 showed only 30% PCs achieved the platelet count standard for QC tests. Intervention package was implemented to tackle the identified risk factors that lead to platelet count problems that do not meet the standards.

The post remedial results showed an increase to 90% of PCs that meet platelet count standards in January to February 2016. The study also found that the rate of platelet count increment in patients after PCs transfusion increased from 5 x 10<sup>9</sup> per ml to 9 x 10<sup>9</sup> per ml after the study. Additionally, the repeated PC transfusion rate decreased from 22% to 18%. Achievements were successfully maintained after the study which was 89% in March to April 2017. Continuous monitoring need to be carried out to ensure the achievement remains in compliance with the established standards. This quality improvement method has facilitated successful platelet transfusion to patient by improving the quality and performance of PCs. The improvement strategies of this study have the potential to be implemented at other blood collection centers in order to improve the quality of healthcare services.

**KEYWORDS:** Platelet concentrate, cold chain, quality improvement

# Problem

In our Blood Transfusion Unit, QC tests were conducted every month to assess the quality of PCs. These QC tests illustrate function and effectiveness of PCs transfusion to patients. Among the parameters evaluated were platelet count, residual leukocyte, pH value and sterility. All quality parameters of the PCs in our Blood Transfusion Unit had achieved the minimum standards except for platelet count parameter, which repetitively did not meet the standard since 2010. Only 30% of PCs had achieved the standard platelet count for QC tests in March and April 2015. A verification study conducted in May 2015 also found that only 40% of PCs achieved specified platelet standard count of more than 60 x 109 per unit. According to the "Transfusion Practice Guidelines for Clinical and Laboratory Personnel" 3rd Edition by the National Blood Centre, at least 75% of the tested platelets must contain platelet count more than 60 x 10<sup>9</sup> per unit (1). Average platelet count increment per unit PC transfused was at minimum level which is 5,000/mL only.

Our Blood Transfusion Unit is a clinical support unit in the Sultanah Nur Zahirah Hospital (HSNZ) located in the district of Kuala Terengganu on a 21.09 hectare with population of 343,284. HSNZ is a state general hospital and acts as a reference hospital for district hospitals and health clinics throughout the state of Terengganu with a total population of 1,207,700.

The Blood Transfusion Unit play an important role in supplying blood and blood components to patients who were in need. Our Unit processed about 4,500 units of PCs per year. We provided PCs not only for HSNZ patients, but also for all district hospitals in Terengganu. The Blood Transfusion Unit consisted of 43 members led by a transfusion physician and assisted by medical officers, science officers. medical laboratory technologists, assistant medical officers, trained nurses, assistant information officers and other support officers. Additionally we provided clinical and consultative diagnostic services pertaining to transfusion service in ensuring accurate treatment was given to the patients.

The aim of this study was to increase the percentage of PCs that meet the platelet count standard to more or equal to 75% within a year.

# **Background**

The normal concentration of platelets in the blood is between 150 to 400 x 10<sup>9</sup>/L and their main function is to promote a haemostatic surface in blood vessels (primary haemostasis) following the events of vasoconstriction, adhesion, secretion, and platelet aggregation. The PCs are used for the treatment and prevention of bleeding in patients with reduced platelet number or function for example in acute treatment of thrombocytopenia. PCs transfusions are a lifesaving adjunct to control and prevention of bleeding in cancer, hematologic, surgical, and trauma patients.

The PC supplied must meet the specified quality control (QC) test standards to ensure its therapeutic effects. PCs that do not meet QC standards will reduce the effectiveness of treatment and increase repeated PCs transfusion. Therapeutic effects were determined by the quality of PCs which were largely affected by preparation method and storage conditions such as duration taken from collection to processing. type of storage container, and storage solution (plasma or an additive solution) (2). The recommended shelf life of PCs in presently available platelet storage bags is 5 days. The yield of platelet also depend on the donor's platelet count. However, at the time of the study, there was no policy requiring platelet count measurement before blood donation, so the donor platelet count factor would not be addressed in this study (3).

It is important to understand the standard method of platelet preparation for clinical use and how they differed from the preparation for use as research samples in clinical chemistry. The separation of platelets from whole blood was based on the differential densities of the various cellular elements when blood was subjected to defined centrifugation forces. The protocols for the preparation of platelets relied on this characteristic, including those used by blood transfusion services for the preparation of platelet concentrates (PCs) for clinical use. A quality monitoring programme (QMP) for PCs was implemented to improve standards and to better understand platelet products by performing routine quality control (QC). Randomly selected PCs were sent to a laboratory and tested on platelet count, residual leucocytes, pH, and sterility preferably on the day after the expiry date of the PCs. This quality check on components prepared from whole blood donations focused on the product's safety and compliance with regulatory standards (4).

#### Measurement

The general objective of the study was to increase the percentage of PCs that met the platelet count standard to more or equal to 75% within one year. The standard of 75% was in accordance with the Transfusion Practice Guidelines of Clinical and Laboratory Personnel (3<sup>rd</sup> edition 2008) by the National Blood Center. The specific objective was to identify the causes of platelet count not meeting the standards set. The study was also conducted to suggest and implement improvement strategies and subsequently evaluate the effectiveness of the strategies.

The indicator in this study was the percentage of PCs that met the specified platelet count standard (more than 60 x 10° per unit) calculated using the following formula:

The percentage of PCs that met the standard platelet count

 $\begin{aligned} & \textit{Number of PCs containing} \\ &= \frac{\textit{more than } 60 \ \textit{x} \ 10^9 \ \textit{per unit platelet count}}{\textit{Number of PCs sampled in monthly QC test}} \ \textit{x} 100\% \end{aligned}$ 

This indicator was collected monthly by our science officer using a standard QC format. Any expired PCs can be sampled for the monthly QC test but PCs with visible red blood cell contamination or leaked blood bags were excluded. A minimum 10 PCs were selected for the monthly QC check and full blood count (FBC) test was performed preferably on the day after the expiry date of PCs. The specified standard for platelet count was the count must be more than 60 x 10<sup>9</sup> per unit.

Verification study conducted in May 2015 found that only 40% PCs achieved specified platelet standard count of more than 60 x 10° per unit.

# Initial Assessment of the Problem

Blood collected from blood donation mobile session or walk-in donor at HSNZ were brought to the laboratory for processing. Upon arrival at the laboratory, the blood bag was weighed. If it met the criteria of weight (within the normal range) and the blood collection time did not exceed 12 minutes, the PCs were produced. Otherwise, PCs will not be produced from the blood bag. The resulting PCs were weighed and stored until used or expired.

The processes involved in platelet concentrate production were as in Figure 1. Some contributing factors had been identified such as less efficient blood temperature monitoring system (blood cold chain system), non-optimal equipment performance such as blood bags spring scales and refrigerated centrifuges machine as well as under competent staff.

The results from preliminary study found that there were some problems in certain processes such as:

1. The blood cold chain is a system for storing and transporting blood and blood products within the correct temperature range (20-24°C) and conditions, from the point of collection from blood donors to the point of transfusion to the patient. Among the problems identified in cold chain implementation were inconsistent blood box temperature monitoring, inadequate storage due to blood

- collection exceeding the target, suboptimal ice packs preparation during blood donation session, improper transportation and storage of triple and double bags blood and untrained staff.
- 2. The condition and performance of the refrigerated centrifuged machine used to produce PCs was non optimal.
- 3. Only 50% of spring weighing scale verification activities were carried out.
- The spring weighing scale used for weighing blood bag should be verified every 3 months and standard performance was at least 90%.
- Non-standardised PCs processing methods and QC test sampling techniques were also found contributing to this problem as it relied on the staff's skill.

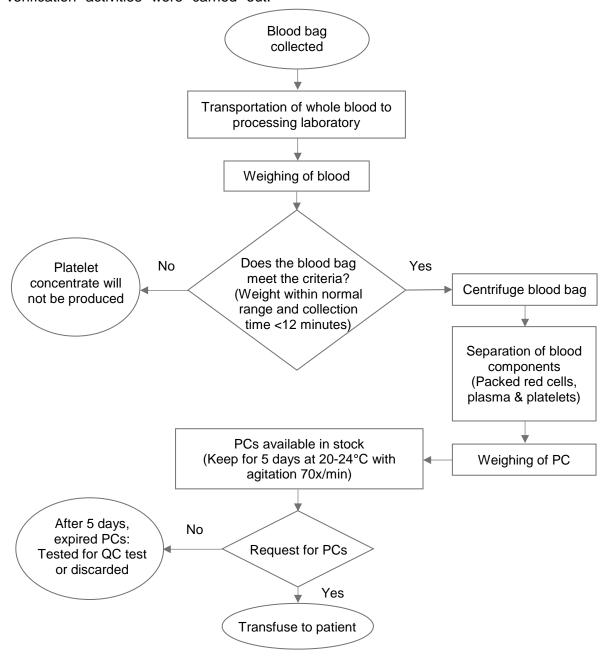


Figure 1: Process of platelet concentrate production.

# **Strategy for Change**

Two phases of remedial actions had been implemented from June until September 2015 (first phase) and in December 2015 (second phase). Each strategy was implemented to address the identified contributing factors.

#### a) First phase:

The first step was to improve the blood cold chain monitoring system during the blood donation session and transportation to the laboratory. Transportation for triple blood bags blood collection for platelet processing and double blood bags for whole blood were separated in different blood boxes for proper temperature monitoring. The blood box temperature was strictly monitored for at least every 30 minutes. The type of ice pack used was also changed to a more durable and cold resistant one. Additionally, the Blood Box Temperature Monitoring Record Form had been modified to be more user-friendly, improving staff compliance to temperature monitoring requirement.

Secondly, to improve the accuracy of measured donated blood weight, the spring weighing scale was verified every 3 months. Verification training was conducted to all respective staffs which emphasised on the importance of equipment verification and the correct method of performing verification activities.

The third step of remedial action was to reorganise and optimise manpower involved during blood donation activities. The ratio of blood donor beds to phlebotomist was limited to 2 beds to 1 phlebotomist. If the blood collection target for the mobile session was high, additional staffs from another department would be requested as an additional phlebotomist. In addition, a skilled Medical Laboratory Technologist (MLT) had also been privileged as a phlebotomist. In this way, there were more human resource and less workload during the blood donation process and therefore could maintain the quality of donated blood.

Fourthly, the functional calibration of the refrigerated centrifuge for PCs processing was carried out to ensure it functions optimally and consistently. This was crucial in ensuring good quality PCs preparation. Functional calibration of the refrigerated centrifuge was usually performed in case of machine damage, machine relocation or when poor quality of PCs being produced. The calibration was carried out with several programme settings attempted. Post calibration, the programme on the centrifuge machine had been changed to the new settings and configurations that will give higher platelet count yield.

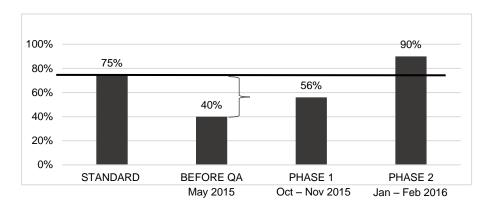
## b) Second phase

A validation test for the ratio of ice packs number to blood bags in the blood box was also carried out. The test was carried out with different number of blood bags, ice pack and temperature logger during the validation process. The result showed that the best sufficient ratio of ice pack ratio to the blood bags was set to 2:1. This information was very crucial in ensuring optimal management of blood bag temperature monitoring during blood donation mobile sessions transportation to the processing laboratory. Staffs on duty can plan quantity of ice packs needed according to the estimated number of blood donors.

In addition, CME, training and briefing sessions were held regularly to make sure all the strategies and actions were implemented by our staff. A briefing before the blood donation session began was given by a Blood Transfusion Unit staff to any additional staffs involved during blood donation session.

## Results

The post-remedial PCs quality control test results had shown that the percentage of PCs that met the platelet count standards had increased from 46% to 56% (Oct – Nov 2015) and to 90% subsequently (Jan – Feb 2016) as shown in Figure 2. This showed that the interventions were successful in increasing the quality of PCs produced in the Blood Transfusion Unit. All other critical steps involved in processing of PCs that were identified in the Model of Good Care had also improved with the implementation of the remedial actions (Table 1).



**Figure 2:** Pre and post-remedial achievements: Percentage of PCs that reached the platelet count standard (more than 60 x 10° per unit).

 Table 1: Improvement results on MOGC.

Step	Process of Care	Criteria	Standard	Pre - Remedial	Post- Remedial
1.	Blood donation	All donors met the blood donation criteria	100%	100%	100%
		Blood collection time does not exceed 12 minutes	100%	100%	100%
		The blood box temperature at the blood donation site was 20-24°C	90%	81%	91%
2.	Transportation to the processing laboratory	The transportation temperature from the collection site to the processing laboratory was 20-24°C	90%	81%	91%
3.	Weighing the blood bags	Blood bags' weight falls within the normal range.	95%	89%	92%
	-	The verification of spring weighing scale was carried out every 3 months	100%	50%	100%
4.	Component processing	<ol> <li>Processing done within 24 hours after donation (preferably within 12 hours)</li> </ol>	100%	100%	100%
		Using refrigerated centrifuge		Not	
		machine that has been validated on the optimum program setting	Optimum	optimum	Optimum
		Separation of blood components:     Platelets were separated into     satellite bag	95%	90%	95%
5.	Weighing the platelet	Complied with specified weight/volume range (50-70ml)	95%	93%	98%
6.	Storage of platelet bags	Storage temperature at 20-24°C, agitation 70x/min, arranged on a single layer (no overlapping) and kept for 5 days only	100%	100%	100%

This notable improvement was also demonstrated in increment of patients' platelet count post PCs transfusion. The expected platelet count increment after transfusion of one unit of PC was from 5 to 10 x 10°/ml. Analysis on the increment of platelet count in post-PCs transfusion patients before and after remedial actions were taken had increased from 5 x 10°/ml to 9 x 10°/ml. This illustrated that the quality of the PCs had improved hence improving therapeutic effect of PCs transfusion in reducing patient's morbidity. Repeated transfusion rate for PCs components had also decreased from 22% before the remedial actions to 18% postremedial. The reduction of repeated PCs transfusion rate benefited the patients as it can reduce the risk for infection of infectious diseases (HIV, Hepatitis B, Hepatitis C and Syphilis) and transfusion reactions such as allergy and others. The staff workload in the blood transfusion unit could also be decreased with the reducing number of repeated request of PCs. In addition, high platelet quality would be expected to result in improved clinical efficacy, determined by count increment, improved haemostasis, and lower risk for adverse reactions in recipients.

# **Lessons and Limitations**

It was evident from this study that proper management of blood cold chain system and standardisation of all procedures involved in preparation and processing of PCs were very crucial in ensuring quality of PCs. Besides, full commitment from the staffs and top management in achieving organisation's target was a foundation in overcoming long standing problem.

We still did not manage to ensure more than 95% of collected blood bag in mobile session within the desired weight. The mechanical spring scales that were being used to weigh the blood bag during blood donation might not accurate enough and subject to user handling variance. Delay in clamping the blood bag tubing especially in crowded and big target mobile session will also lead to overweight blood bag. A better option to prevent overweight blood bag is by using automated blood mixer. The machine

will mix and weigh the blood bag continuously and will clamp the blood bag tubing automatically once the desired weight is achieved.

# **Conclusion and the Next Steps**

From the study, it can be concluded that the implementation of appropriate and effective improvement measures could result in better output. All members of the unit need to be committed in ensuring the continuity of the improvement measures. Achievements were successfully maintained after the study which was 89% in March to April 2017 (mean  $78 \times 10^9$  per unit).

Despite not all remedial actions achieved the pre-determined standard, the QC of PCs has been met. The use of automated blood mixer may help to overcome the remaining hurdle. Proposal to purchase additional automated blood mixers will be submitted to the hospital management.

With such good results and performance, Blood Transfusion Unit HSNZ would become more confident in providing PCs to help care for patients in need. However, in order to improve and maintain achievement, continuous monitoring would be carried out as well as updating procedural guideline with the latest technique. The improvement step of this study had the potential of being shared and implemented at other blood collection and processing centers of PCs to improve the quality of health services.

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# **Conflict of Interest**

None

# **Funding**

None

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# IMPROVING IUCD USAGE AMONG REPRODUCTIVE WOMEN WITH DIABETES MELLITUS IN HEALTH CLINICS OF PERLIS

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# **Abstract**

Pregnant women with diabetes mellitus pose an increased risk of maternal and infant morbidity and mortality. In Perlis, for the year of 2016, only 3 (0.3%) out of 1,114 reproductive women with diabetes mellitus were using an intrauterine device (IUCD) as their main contraceptive measure. This project aims to improve the usage of IUCD to 10% among reproductive women with diabetes mellitus in nine health clinics of Perlis.

A retrospective contraception card review was undertaken to determine the baseline in providing IUCD services. Two sets of validated questionnaires were distributed to patients and healthcare providers in the pre and post-remedial period.

Customised training sessions were organised for both doctors and nurses' group. A quick reference for IUCD was developed to guide the healthcare providers during counselling sessions. The Model of Good Care (MOGC) was integrated into the Maternal and Child Health State Plan of Action 2016 to ease the supervision of quality improvement.

Of the 244 diabetic women who had undergone counselling, 44 (18%) agreed to use IUCD and 38 (16%) of them inserted the IUCD within two weeks. Our project was able to increase the usage of IUCD among diabetic women in nine Perlis health clinics from 3 (0.3%) to 38 (3.4%) within six months. There was a gap reduction in achievable but not achieved (ABNA) from 9.7% to 6.6%. [ABNA = Achievable benefit not achieved]

Low usage of IUCD among diabetic women is a challenging issue and patient refusal to use IUCD, lack of husband support and comfortable with the previous contraception method were among the main contributing factors. However, providing continuous awareness and new process of effort in promoting the usage of IUCD among diabetic women do improve the uptake of the approach.

KEYWORDS: IUCD (intrauterine contraceptive device), reproductive diabetic women, contraception

# **Problem**

Pregnant women with diabetes mellitus pose an increased risk of maternal morbidities such as pre-eclampsia, placenta abruptio, polyhydramnios and preterm labour. Such cases had been identified in our monthly maternal and perinatal mortality review at the Perlis state level from January to December 2016. One of the proven interventions for this problem is patient empowerment through the usage of long-term contraception until the patient diabetic parameter improved prior to their conception (1).

Based on the contraception card review, only 3 (0.3%) women with diabetes in Perlis were using IUCD in 2016. The remaining 1,111 (97.7%) diabetic women practised other methods either contraception or did not use any contraception. This showed that IUCD usage among diabetic women in Perlis was very low and an intervention is needed. Multiple factors can contribute to the low IUCD usage among diabetic women such as lack of knowledge among healthcare providers, lack of referral by nurses to medical officers, and patient refusal of IUCD insertion.

According to the World Health Organization Medical Eligibility Criteria (WHO MEC 2008), IUCD is a well-known first line recommendation for contraception among diabetic women. IUCD is a non-hormonal contraception method that had been proven to not affect lipid metabolism and glucose homeostasis in diabetic women unlike hormonal contraception (2).

Unfortunately, in Perlis. most women with diabetes mellitus were not using IUCD as their main contraceptive measure. According to the National Diabetic Registry System (NDR) data in 2016, 15,868 registered diabetic women had attended health clinics in the past seven years in Perlis (2009-2016). In 2015, of those who registered, only 6,545 (41.2%) diabetic women were still on an active follow-up of which 1,114 (17%) were of reproductive age of 15 - 45 years, distributed unequally in all nine of Perlis health clinics.

This project aims to improve the percentage of IUCD usage among diabetic women to 10% within the 1-year period and ultimately reduce maternal diabetic morbidity and mortality.

# **Background**

Globally, the average percentage of women of reproductive age who used IUCD was 14.3%. However, in some countries, the percentage of women using IUCD is less than 2%, whereas in other countries, it is more than 40% (3). Good knowledge and skills among healthcare providers, positive religious belief towards IUCD, and local guidelines that prioritised the usage of IUCD were among the main contributing factors reported in countries with high usage of IUCD.

Another systematic review in 2007 by Kai J Buhlinga et al. showed that healthcare providers' attitude and knowledge had a strong influence on the rates of IUCD usage (3). The likelihood of a healthcare provider prescribing IUCD depended on many factors including the providers' knowledge base and whether they had received appropriate training on placement or removal techniques patient counselling. Several and misperceptions remain among healthcare providers regarding the efficacy and safety of IUCD and the types of women for whom it is unsuitable. The degree to which these misperceptions curtail IUCD usage in individual countries may depend on the persistency of these misperceptions and the success of the educational programmes in dispelling them. Family planning experts in the US, for example are actively addressing the misperceptions among women and healthcare providers regarding IUCD safety and the unsuitability of this method for certain groups of women. This review also showed that in practice, factors such as geographic differences, government policy, and the healthcare providers' educational influenced the use of IUCD more than medical eligibility criteria (3).

Another study cited that the main reasons married women were not using IUCD include the usage of another method of contraceptive (93.3%), development of side

effects (3.9%), absence of husband's permission (1.6%), medical problems and non-availability of service (1.3%) (4). The study found out that 126 (45%) of the married women were in the category of low knowledge, followed by high knowledge 137 (31.1%) of IUCD, whereas the remaining (23.7%) had moderate knowledge. The results of regression analysis also showed that women who had high knowledge of IUCD were eight times more likely to practice IUCD as compared to those with low knowledge.

There are several methods of contraception appropriate for diabetic women and the selection should be based on the criteria such as patient diabetic status, complications and diabetic age up to date as outlined by WHO Medical Eligibility Criteria (MEC 2008) (2).

A systematic review conducted in the US in 2013 concluded that at that time, IUCD was the most effective method to reduce the rates of unwanted pregnancy (1). The review also confirmed that there were sufficient well-controlled studies to conclude that both the copper-bearing and Levonorgestrel IUCDs are effective and safe for women with DM1 or DM2.

The US and the UK have already recognised the need to increase IUCD use and had developed national evidence-based guidelines and training on IUCD to healthcare providers. Following the implementation of the strategies, the IUCD use in these countries increased to 40% in 2013 (3).

# Measurement

The verification study took place from December 2015 to March 2016. Identification of reproductive diabetic women was based on the National Diabetic Registry (NDR) where their contraception cards were retrieved from the respective clinics to obtain information on the IUCD usage. We found that of the 1,114 reproductive diabetic women registered in Perlis, only three of them used IUCD as a contraception method. We also found out that

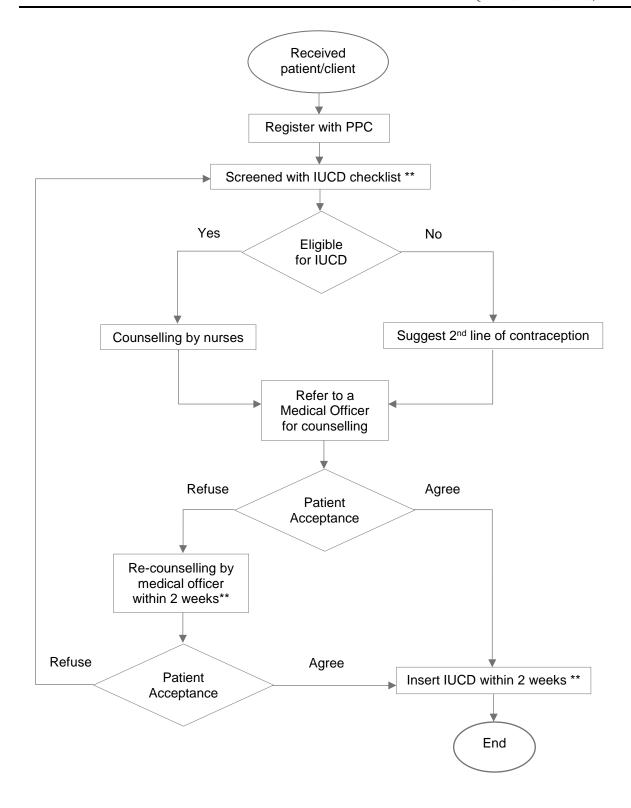
the percentage of diabetic women registered with PPC was low at 379 (34%) with those referred to the medical officers for IUCD counselling being even lower at 28 (7.3%).

To meet the aim of our project in improving IUCD use among diabetic women, we set a target of 10% based on a study carried out in the US (2012), where 12% of women using IUCD in which maternal morbidity or mortality had been markedly reduced (5).

The referral and screening standards of data were collected monthly and the final target achievement of data was calculated every six months.

# Initial Assessment of the Problem

The existing process of care was reviewed and a few critical steps were identified and added to emphasise on the importance of screening all diabetic women using a new comprehensive IUCD checklist (Figure 1). The IUCD checklist had two major components with eight questions component A (history-taking) and two questions in component B (speculum examination) to be used during the screening process by a medical officer. Next, the women will undergo speculum examination (component B) to look for any abnormality of the cervical or adjacent area. Eligible women were those with no contraindications as listed in component A and component B. Then, the women accompanied by their husbands will be referred to nurses and medical officers in the clinics for further counselling. IUCD procedure would be carried out on the same day or within two weeks' time for women who agreed to the procedure. For those who refused, a follow-up session will be arranged in two weeks whereby another counselling session will be given to convince the women of the benefit of IUCD.



\*\* added critical steps

Figure 1: Process of care of IUCD intervention in diabetic women.

We performed a cross-sectional survey using structured questionnaires among 100 reproductive diabetic women who enrolled in the National Diabetic Registry and on active follow-up from 2015 to 2016 to assess their knowledge, attitude and practice of the contraception methods. questionnaire was developed in April 2016, which was validated by two experts. Following this, a pilot study was carried out among 30 diabetic women from a health clinic in Perlis. The questionnaire was divided into two main sections, which included 13 questions on Knowledge, Attitude and Practice (section A) and 10 questions on factors contributing to low IUCD usage (section B). In both sections, two points were awarded for each correct answer and 0 point for incorrect answers. SPSS version 21.0 was used to analyse the data.

The majority (83%)of respondents were at the age of 24 – 40 years old, with the median age of 37.0 years and three-quarters of the respondents (74%) were Malays (Table 1). Fifty four (54%) subjects were housewives. Most of the participants, or 97 (97%) had formal education and only three (3%) did not receive any formal education. Nearly half (48%) of the women were employed, mostly as government workers. From this study, about nine (9%) of the respondents had good knowledge (score >12), 34 (34%) of them had moderate knowledge (score 8-12) and 57 (57%) of them had poor knowledge of IUCD (score <8). Knowledge level among respondents for individual questions was shown in Table 2. We also found that 86 (86%) of the women who refused IUCD were due to lack husband support, 23 (27%), issued with religious belief, 17 (20%), and comfortable with the current contraceptive method, 46 (53%).

**Table 1:** Characteristic of respondents (n=100).

No	Characteristics	Frequency (%)
1	Occupation	
	Government Worker	30 (29.7%)
	Non-Government Worker	16 (15.8%)
	Housewife	54 (52.5%)
2	Educational Level	
۷		2 (2 250()
	No Formal Education	3 (2.25%)
	Primary School	16 (15.8%)
	Secondary School	61 (59.7%)
	University/College	21 (18.8%)
3	Age of Marriage	
	1-2years	16 (15.8%)
	3-4years	8 (5.9%)
	>5years	77 (76.2%)
4	Race	
	Indian	5 (5.0%)
	Chinese	10 (9.9%)
	Malay	77 (74.3%)
	Other	9 (8.9%)
5	Age	Median 37.0

**Table 2:** Knowledge level among respondents (n=100).

Questions	Correct Answer	Incorrect Answer	Unsure
	n (%)	n (%)	n (%)
IUCD is not suitable for women with pelvic inflammatory disease	21 (21%)	10 (10%)	69 (69%)
IUCD can cause cancer	37 (37%)	53 (53%)	10 (10%)
Fertility of Diabetic Women who use IUCD will not be affected after IUCD removal	29 (29%)	19 (19%)	52 (52%)
IUCD usage will not affect sexual activity	36 (36%)	12 (12%)	52 (52%)
IUCD will be able to prevent unwanted pregnancy for 3 years	16 (16%)	8 (8%)	76 (76%)

The second part of the study involved the assessment of the quality of treatment given and case management. This was done through a review on the documentation of the contraception care by a medical officer to a sample of 10 contraception cards for each clinic using the checklist guide developed by a family medicine specialist on April 2016. From this review, 56 (56%) contraception cards with non-optimised case management were detected.

The third part of the study involved a survey on the knowledge of IUCD among 135 healthcare providers using the validated questionnaires. From this study, we found that 22 (22%) of the total respondents had good knowledge (score >8), 71 (71%) of them had moderate knowledge (score 4–7), and

only 7 (7%) of them had poor knowledge about IUCD (score <4).

# Strategy

Two separate customised training sessions were organised, tailored for nurses and doctors. This strategy was implemented to ensure that all healthcare providers are equipped with the essential knowledge and skills on IUCD insertion.

Two workshops for doctors were conducted in early June 2016, which were attended by 46 doctors from nine health clinics. The focus of the workshops was on knowledge enhancement and also the IUCD insertion skill-building. The evaluation of IUCD insertion procedure (OSCE-oriented) was led by two obstetricians. During the workshops, all doctors were also taught on the best counselling method for the husbands.

The second training session comprised three workshops begun in mid-June 2016. The project team, a matron and three staff nurses assembled a group of 235 nurses who were responsible for delivering personalised care at their respective health clinic. They were briefed on the proper IUCD counselling, the importance of diabetic women to be registered in a pre-pregnancy programme or contraception care and referral cases to medical officers.

For the second strategy, a quick reference for IUCD was developed by a team that consisted of eight team members who were doctors, matrons and nurses with additional two specialists of family medicine in June 2016. This guick reference for IUCD highlighted counselling three major components including the impact of diabetes on pregnant women and babies, benefit of IUCD during pre-pregnancy, and correction of misconception towards IUCD. This quick reference was disseminated to all healthcare providers (nurses and doctors) in early August 2016. Trained nursing manager and supervisor from each health clinic monitored and supervised the use of this reference. Briefing about the new quick reference was carried out for both nurses and doctors in the training sessions as mentioned earlier. Continuous briefing sessions were conducted

weekly within two months to cover all healthcare providers. The training sessions provided adequate knowledge for the staff to counsel the mothers during individual counselling and open talk at the clinic's waiting area.

Finally, the revised process of care was integrated into the Maternal and Child Health State Plan of Action 2016 to standardise the practices in contraception care in Perlis, assisted in data collection and eased the supervision of quality improvement initiative.

### **Results**

Remedial measures were completed in December 2016 and were evaluated in January 2017. The registration of diabetic women into PPC had markedly increased to 610 (54%) within six months from the previous 379 (34%) of PPC registration. IUCD counselling referral to medical officer also increased to 244 cases (79%) compared to only 28 cases (7.3%) in the pre-remedial phase.

Further analysis showed that out of 244 diabetic women who had undergone counselling, 44 (18%) of them agreed to use IUCD and 38 (86%) of them inserted IUCD within two weeks. Our project was also able to increase the use of IUCD among diabetic women in the nine Perlis health clinics from three diabetic women (0.3%) to 38 diabetic women (3.4%). Our team project reduced ABNA (achievable but not achieved) from 9.7% to 6.6% (Figure 2).

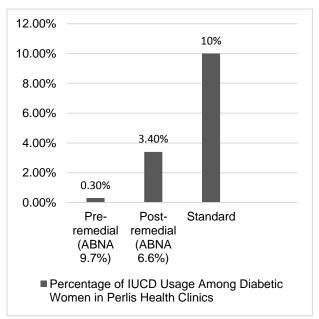
In the post remedial phase, similar KAP questionnaires were distributed to another 100 respondents who received interventions. From the post-remedial study, patient refusal to the IUCD insertion, 86 (86%) was

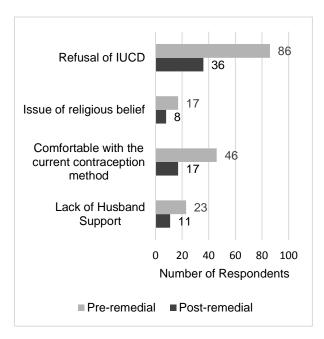
noticeably reduced to 36 (36%). Factors for patient refusal of IUCD among the 36 respondents (Figure 3) included lack of husband support, 11 (31%), comfortable with the previous contraception method, 17 (47%), and the issue of religious belief, eight (22%). With regards to their knowledge of postremedial, we found that about 49 (49%) of the respondents had good knowledge (score >12), 28 (28%) of them had moderate knowledge (score 8–12) and 23 (23%) of them had poor knowledge of IUCD (score <8).

In addition, we also found that post remedial non-optimised case management issue for all diabetic women who visited the clinic decreased from 56 (56%) to 17 (17%).

Furthermore, post-intervention survey among 112 healthcare providers on their knowledge of IUCD shows an improvement with 90 (80%) of the respondents had good knowledge (score >8), 16 (14%) of them had moderate knowledge (score 4–7) and only 6 (5%) of them had poor knowledge of IUCD (score <4).

**Figure 2:** IUCD use among diabetic women in Perlis.





**Figure 3:** Contributing factors for low usage IUCD (pre and post-remedial).

### **Lessons and Limitations**

This project aims to improve IUCD use among diabetic women in Perlis. Continuous and effective communication about family planning and IUCD between healthcare providers and all diabetic women attending health clinics is the main focus. For this to be achieved, we successfully designed and implemented a quality improvement measure and system that suited the health clinic environments and for better patients' cooperation for IUCD counselling, insertion and follow-up.

Our project also emphasised on continuous monitoring and staff supervision for practices in IUCD counselling. A target has been given to each healthcare provider for IUCD insertion and counselling in order to continuously motivate them. We also focused on periodic healthcare provider training sessions and the application of skills with knowledge.

However, despite the initial enthusiasm, we encountered some problems during the implementation of the new system. Monitoring the husbands' participation and support is another challenge that we had not addressed in this project.

Besides that, we did not assess diabetic women comprehension after they received counselling from healthcare providers by using the new quick reference guide. The level of comprehension of these diabetic women should be studied in the future and further review of the quick reference and counselling context might be needed.

# **Conclusion and the Next Steps**

Low usage of IUCD among diabetic women is a problem, and patient refusal of IUCD was identified as the main reason. With continuous training for the healthcare providers, patient education and promotion, misconception correction. and enhancement of a new process of care among our nurses and doctors, the usage of IUCD have been successfully increased from three (0.3%) to 38 (3.4%). Nevertheless, there is still more room for improvement as the achievement of the first cycle was still below the standard set, which was 10%. Continuous training of the healthcare providers will improve the quality in the educational session of diabetic mothers and ultimately ensure the sustainability of better IUCD uptake among them.

The next step would be to ensure continuous training sessions to all healthcare providers through seminars and hands-on for the three health clinics identified in our study that had the most healthcare providers with low and fair knowledge. Additionally, we plan to create an IUCD teaching model on the IUCD insertion procedure via innovation in the future for a demonstration session during patient counselling. This will help to improve patients' understanding of the IUCD insertion procedure and alleviate their fear towards the procedure. Methods to monitor the husbands' participation and support also need to be explored. Also, a mechanism would be put in place to ensure proper counselling for all diabetic women at all times.

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## **Conflict of Interest**

None

# **Funding**

None

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# INCREASING THE PERCENTAGE OF APPROPRIATE TESTS CONDUCTED IN THE SEROLOGY LABORATORY, HOSPITAL SULTANAH NUR ZAHIRAH

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### **Abstract**

Wastage due to unnecessary laboratory test requests is a major problem in government hospitals because they have cost implications. Although screening of infectious marker tests such as Human Immunodeficiency Virus (HIV), Hepatitis B surface Antigen (HBsAg), Hepatitis B antibody (AHBS) and Hepatitis C Virus (HCV)) before testing have been put in place, inappropriate tests were still being carried out in the Serology laboratory, which resulted in wasted human resources and reagents, increased workload and increased maintenance costs. Based on the verification studies using the Laboratory Information System (LIS), we observed only 70% of the tests followed the ordering guidelines or test specifications. Thus, we aim to increase the standard to more than 95% of the infectious marker test requests which were appropriate according to a few guidelines.

A cross-sectional study was conducted for all infectious marker tests received at Serology Laboratory from January 2015 to June 2016 to verify the problem. A workplace audit and questionnaire survey on the staff were carried out to gain more information. Low level of knowledge, unavailability of standardised guidelines for quick and easy reference, lack of staff and inefficient work processes were among the main contributing factors. Empowering new staff to screen specimens, developing simple and informative screening guidelines, providing adequate trays and refrigerators for screening purposes and strengthening and developing a more effective process of care were the strategies taken during this study.

The appropriate tests carried out from July to September 2015, October to December 2015, January to March 2016 and April to June 2016 were 99%, 98.80%, 99.50%, 98.90% respectively. During the same period, 711, 411, 710 and 768 tests were rejected. We monitored the performance and managed to achieve 100% appropriate testing for the period of July 2016 to June 2018 and an estimation of MYR 73,437.50 cost saving was achieved.

KEYWORDS: Appropriate test, infectious marker test, serology laboratory, quality study

#### **Problem**

In programmes such as Haemodialysis, Thalassemia. and Methadone rehabilitation, regular screening of infectious marker tests for (Human Immunodeficiency Virus (HIV), Hepatitis B surface Antigen (HBsAg), Hepatitis antibody (AHBS), and Hepatitis C Virus (HCV) is important to ensure patients' safety. Besides, screening the antibody status of HBV in healthcare workers is also crucial to determine the immunisation requirement. The requisition of the above tests needs to comply with certain specification or guidelines, including those from the Ministry of Health (MOH) and state-level authority. Failure to meet the specifications or guidelines will result in inappropriate testing and wastage.

In order to ensure that clinicians' requests comply with the guidelines, screening of the requests before testing had been made compulsory in our laboratory since early 2014. However, verification study carried out in July to December 2014 showed that 30% of the requests did not comply with the specification and guidelines, particularly the request for the same test repetitively in a short period of time and failed to comply with the test algorithm.

The Serology Laboratory in the Pathology Department is one of the major laboratories in Hospital Sultanah Nur Zahirah that provides serological testing services to all health facilities in the seven districts of Terengganu. On average, our laboratory runs about 9.000 tests per month, of which 3.000 are infectious marker tests. There are eight medical laboratory technicians. scientific officers and one medical officer (on a rotation basis) working in the Serology Laboratory. However, the screening process is performed only by the medical officer resulting in heavy workload, delays and ineffective screening process. Thus, this quality project aims to increase percentage of appropriate infectious marker tests from 70% to more than 95% within six months.

# **Background**

Carrying out tests following inappropriate requests resulted in wastage of multiple resources. including funds. laboratory reagents and human resources the heavy because of workload for unnecessary tests. These circumstances might have resulted from the ineffectiveness of the specimen screening system in Serology Laboratory, heavy workload and lack of personnel. A Study conducted in Turkey reported that 12.9% test requests were not suitable for Anti-HBs test (1). Findings from another study in a tertiary hospital showed that 11% of tests were repeated, over-utilised, simply avoidable and could be excluded, while 10% of ordering physicians were responsible for the problems (2). In addition, a study carried out in Sarkaya University revealed that high test repetition rate of 87.7% resulted in a waste of USD 6,489 for a period of five years while the estimated cost of wasted tests unnecessary testing of antiretroviral, anti-HCV and HBsAg tests across Turkey was USD 1,042,215 (3). Evidence showed that single and combined interventions, such as educational initiative and guideline dissemination were effective in improving test utilisation and physician orders (4). Moreover, another study suggested that a computerised ordering system, complete with algorithms, clinical pathway analysis. and cost information could help in examining and restricting the order of test (5).

#### Measurement

Initial data were gathered using the Laboratory Information System (LIS), monthly rejection statistics, questionnaires and workplace audit. Data from LIS were used to calculate the number of requests that were appropriate for testing and the number of cases rejected in both pre and postremedial phase. Cases for inappropriate infectious marker test requests that should not have been tested, but still had been carried out were also calculated. This study used the percentages of appropriate tests request against the total tests run as the

indicator to evaluate the achievement, with a standard of more than 95%, based on our group consensus. Our baseline findings showed that only 70% of infectious marker test requests were appropriate, while 30% of the specimens should have been rejected earlier. We collected data using LIS for a period of six months.

# Initial Assessment of the Problem

According to the problem analysis, a few factors contributing to the problem in hand including a low level of knowledge on the screening process, too many specimens received daily, lack of staff to perform the screening, inefficient work process, and inadequate specimen isolation system.

We begin the study by assessing the knowledge of Serology Laboratory staff using a set of questionnaires comprising 10 questions. The questionnaires focused on whether they had performed screening of specimens or not and their knowledge about specific guidelines for infectious marker testing. The questionnaires were distributed before and after interventions to evaluate the successfulness of the educational initiative strategies.

Results showed that only 10% of the staff knew about the guideline and had performed screenings, 20% had knowledge but did not perform screenings, while 70% were not aware of the screening processes, which concluded the staff's poor level of knowledge of the screening process.

In order to understand more about the screening process, we reviewed the work process of care, the key person responsible for screening and the standard operation procedure (SOP). Photos were taken and the flow of the screening process was observed to gain more information about the existing problem. Audits finding showed that there was only one medical officer assigned for the screening process. As a state hospital that received 3,000 specimens every month, screening handled by one staff was definitely inadequate. We also found that screening was not efficient as the rejection comments,

which were supposed to be clear so as to educate the requestors on the correct guidelines, were not standardised.

In the process of care (POC) evaluation, we found that the current POC used in screening the specimens was inadequate to guide the screener, thus, resulting in the inefficient screening process. There was no guideline for reference at the receiving area. The flow of specimens and forms to be used in the stages of receiving. accepting and rejecting was unclear in the existing POC. The available refrigerator was inadequate to store all of the specimens The received. efficiently. forms specimens between the screened and unscreened were not properly sorted and labelled. These data supported all the potential factors contributing to the problem during the problem analysis phase.

# Strategy

Based on the identified contributing factors, we discussed and set up four improvement strategies to be implemented. A QA team consisting of scientific officers and laboratory technologists was established at Serology Laboratory under the supervision of a Clinical Microbiologist. The implementation team met every four weeks during the cycles to monitor the implementation of the new POC.

Staff management was the first strategy implemented to enhance the screening process. Four scientific officers were assigned as screeners in addition to the existing medical officer. They were responsible for screening all specimens received twice a day; in the morning and afternoon. This new arrangement had sped up the screening process and reduced delay in testing the samples.

We developed a simple and informative screening guideline to assist the screeners. Continuous training sessions for all staff was conducted as the second strategy. This guideline covered the category of request, appropriate detention for a repeat test, an appropriate time interval for each test, and a test algorithm based on the MOH Malaysia guideline. Training was conducted

for all serology staff based on the new guideline to increase their knowledge and facilitate the screeners in assessing the appropriateness of the requests confidently reject specimens, which did not meet the specification or did not follow the guidelines. Softcopy of the guideline was made available in each computer at Serology Laboratory for ease of access. Orientation sessions were conducted for new staff by senior staff to disseminate knowledge on the screening process and they were supervised during the screening activities. New junior doctors were also exposed to the guidelines for appropriate test request during the orientation programme. Using standardised reasons for rejection resulted in better understanding and acceptability by the requesting clinicians.

We reviewed the current process of care and found that it was inadequate to guide the staff for effective screening. Therefore, the process of care (Figure 1) was streamlined in more detail, which involved the work processes and surrounding structures according to our Model of Good Care

(MOGC). We added a few steps in the process of care that are critical to making the screening process more effective. The new POC ensures only specimens that passed the screening process were tested.

Screenings were carried out based on the new guidelines developed in which the standardised rejection criteria comments as outlined in the guideline were used to reject inappropriate specimens. This is important in order to educate the requestor on the criteria for an appropriate test request.

Systematic isolation of specimens and forms had been implemented whereby specimens and forms were separated into two different trays, which were labelled as screened and unscreened, to ensure the screening process efficiency and facilitate staff. Additional double door refrigerator had been placed in Serology Laboratory to accommodate all specimens received. Accepted and rejected specimens were segregated and properly labelled between those screened and unscreened, and stored appropriately in the refrigerator.

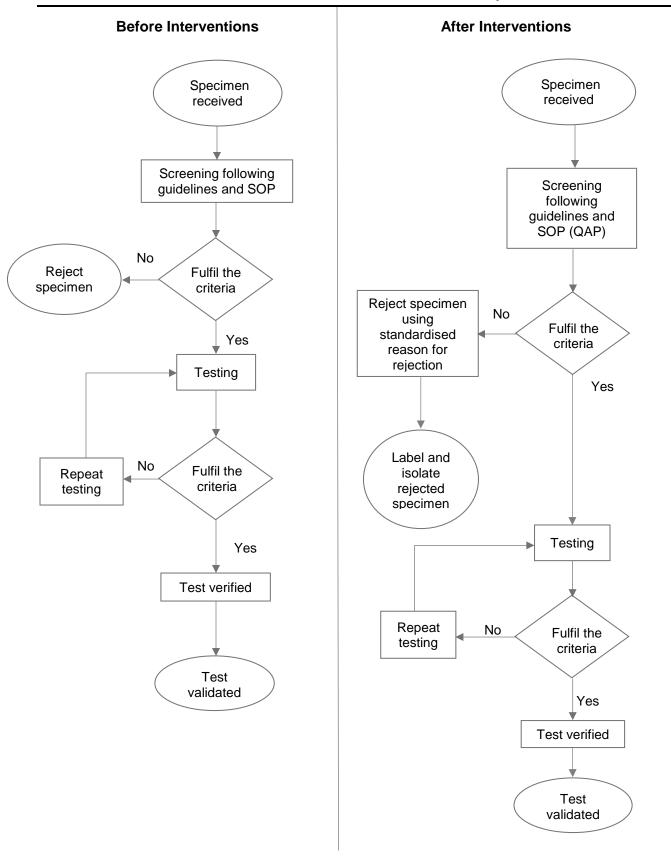


Figure 1: Improved SOP/ POC to enhance test screening in the serology laboratory.

#### Results

The post-remedial evaluation was conducted to assess the effectiveness of the measures that had been implemented. In July to September 2015, 99.2% of the tests conducted were appropriate with 711 specimens rejected, while in October to December 2015, 98.7% of tests conducted were appropriate with the rejection of 411 tests. The outcomes suggested that the measures taken were effective in overcoming the stated problems, and tests that do not meet the guidelines were rejected. In January to March 2016, 99.5% of the tests were screened and appropriately tested with a rejection of 710 tests, while in April to June 2016, the appropriate test was 98.8% with a

rejection of 768 tests. QA Standard of more than 95% was successfully achieved until June 2016, indicating that all measures taken were effective.

The monitoring continued until June 2018 to assess the sustainability of the applied measures. All specimens received were efficiently screened and appropriately tested, which in turn, achieved the QA standard of 100% (Figure 2).

After the interventions, 60% of staff knew and screened, 20% had knowledge but did not perform screening, while 20% still had low awareness of the screening processes (Figure 3).

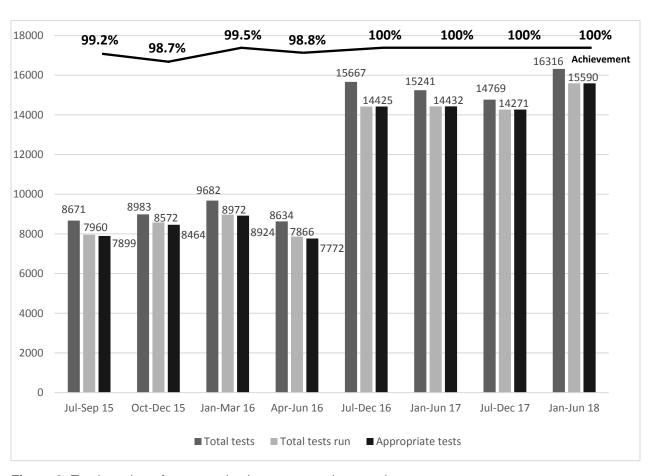


Figure 2: Total number of tests received, tests run and appropriate tests.

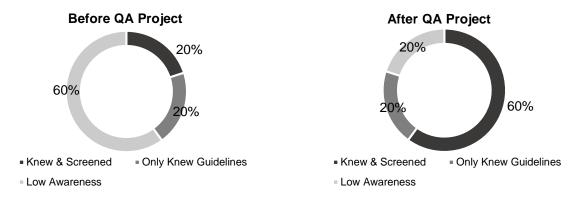


Figure 3: Staff knowledge on screening guidelines and process before and after the intervention.

We learned that after the interventions, more specimens that did not follow the guidelines were able to be identified efficiently and rejected. The rejected specimens as shown in Figure 4 reflect the efficiency of the new POC whereby all inappropriate tests were successfully screened and rejected with standardised rejection comments. We also found that rejected specimens tripled from before QA (Oct - Dec 2014), which was around 246 specimens and after the QA strategies were implemented, the rejection was as high as 1,242 specimens in July to December 2016 (Figure 4). The rejection rate from October to December 2015 decreased and more appropriate specimens were received. These findings were derived from the standardised rejection comment that has been implemented, which taught the requestors of the correct guidelines and guided them in sending appropriate specimens.

However, the rejection rate increased from January to Jun 2016, which could be due to the high turnover rate of housemen that might have contributed to unnecessary specimen sent to Serology laboratory. This is despite the training given during the orientation programme for house officers that was held at the Pathology Department from time to time. The number of rejected specimens fluctuated from July to September 2015 and from January to June 2018 and we stipulated that this has resulted from an upturn in regulatory compliance (Figure 4).

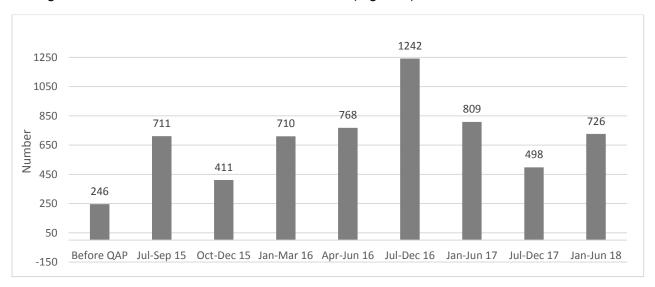


Figure 4: Number of tests rejected in post remedial phase in serology laboratory.

Through this study, we rejected 5,875 tests from July 2016 to June 2018, which did not meet the guidelines or specifications and we estimated that MYR 73,437.50 of reagent cost could be saved. This savings can be channeled to more needed tests in the routine microbiology test, such as blood culture and sensitivity test, CSF analysis, and others.

#### **Lessons and Limitations**

The QA study had opened our eyes to the causes that contributed to the problem and the implemented strategies had successfully improved the specimens' routine screening process and reduced inappropriate testing. Appropriate testing of infectious diseases' tests has increased from 70% to more than 95% in six months.

Reiected requests accompanied by uniform comments of the guideline and this has indirectly fostered positive values among clinicians to order the right test. Rejected specimens were still high compared to our department target rate of rejections, which should be less than 1.5%. Continuous training session for new staff must be maintained especially for House Officers. Besides that, this project provided the opportunity of collaborative work to improve the patients' outcome with limited resources and also enhanced the spirit of teamwork between clinicians and laboratory staff.

One of the limitations of this study was that our Hospital Information System (HIS) could not be fully utilised and synchronised with the Laboratory Information System (LIS) to assist clinicians to make decisions in ordering tests for patients. This was a challenge for both parties to maintain good practices to optimise laboratory testing requirement.

# **Conclusions and Next Steps**

This study suggests that the improvement in the screening process of infectious diseases had led to the appropriateness of testing in Serology

Laboratory. However, there are rooms for continuous improvement to ensure that the testing process is carried out in accordance with the appropriate clinical justification, such as involving medical laboratory technologist as a screener and expanding the screening process to other tests in Serology Laboratory. This will minimise wastage in healthcare which is in line with the government's aspiration to optimise the budget allocation for the Ministry of Health.

The guideline produced based on this QA project has been circulated to all hospitals and health clinics in the state of Terengganu. This QA project was in line with the recommendation by the Honorable Prime Minister of Malaysia and the Ministry of Health Malaysia for the budget-saving measure. In April 2016, a circular from Pathology Service MOH related to screening and conducting 'clinically indicated' test was issued which is in line with our guideline.

In addition, we also plan to expand the screening process to all tests in Serology Laboratory such as Leptospirosis test, Dengue test, tests from TORCHES panel (Toxoplasma, Rubella, Cytomegalovirus, Syphilis and Herpes Simplex 1/2) and Autoimmune tests, such as the Anti-Nuclear Antibody test to ensure that all tests carried out in the laboratory are appropriate. We also need to reduce the high rejection rate to the standard of our departments, besides being able to screen the clinicians' requests successfully.

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# **Conflict of Interest**

None

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# IMPROVING PRE-PREGNANCY CARE (PPC) AMONG CLIENTS WITH DIABETES AND HYPERTENSION AT HEALTH CLINICS IN KUALA MUDA DISTRICT, KEDAH

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#### **Abstract**

Pre-pregnancy care (PPC) is a set of interventions used to identify and reduce women's risks during reproductive age, especially women with chronic illnesses to achieve a healthy pregnancy. It includes optimisation of care, advice on appropriate contraception, and lifestyle modification. Our project aims to increase the PPC registration percentage of women with diabetes and hypertension from 53% to 100%, hence increasing their chances of receiving appropriate PPC intervention.

Both the cards of diabetic and hypertensive clients were reviewed using the PPC assessment form where the percentages of registered clients, completeness of registration, and aspects of interventions were calculated. We developed a new standardised guideline with a refined registration process into our routine Non-Communicable Disease (NCD) Clinic. The new PPC guideline implementation was reassessed every three months for two cycles by our district PPC team.

Post-intervention, the percentages of diabetes and hypertension clients registered with PPC has increased to 79.2%. Furthermore, proper registration helped to increase the percentages of PPC intervention from 86.6% to 95.3%. The implementation analysis showed that the completeness of five registration components had increased significantly from 1.4% to 16.8%. All elements under optimisation of care showed a positive changed, from 65.1% to 85.6% for optimisation of treatment, 48% to 52.6% for contraception advice, and 30.2% to 44% for lifestyle modifications.

We conclude based on the findings of this study that a well-structured PPC guideline with a few modifications that enhanced the process efficiency was able to increase the PPC registration percentages of eligible women with diabetes and hypertension and in turn, increase their chances of getting appropriate intervention. Continuous assessment and periodic PPC courses for healthcare workers are essential to ensure the sustainability of the implementation.

**KEYWORDS:** Pre-pregnancy care, diabetes, hypertension, quality study

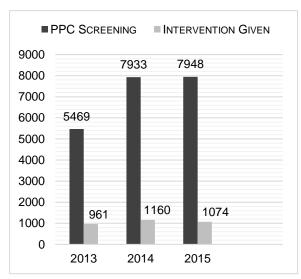
#### **Problem**

The implementation prepregnancy care (PPC) is important to ensure a planned and safe pregnancy especially for high-risk reproductive-age women, to reduce maternal and foetal morbidity and mortality. PPC service was introduced to all health clinics under the Kuala Muda District Health 2011 but Office (KMDHO) in the implementation was very poor. There were no standard guidelines; hence, every clinic has its own way of running the PPC service which mainly focuses on post-natal clients. The Malaysian Perinatal Care Manual released in 2013 provides a general guideline of the PPC service, enlightening us on other possible entry points for PPC (1).

We examined data collected for PPC from 2013 to 2015. At that time, women registered with PPC were reproductive women aged 15 to 49 years who were screened for PPC and given appropriate intervention. Based on the record, active management given to the registered clients was not well documented. The total number of women screened for PPC had increased substantially from 5,469 in 2013 to 7,948 in 2015, showing a 45% increment. However, the percentages of clients with interventions were not only small, but has been declining from 18% in 2013, 15% in 2014 and 14% in 2015 (Figure 1). Limited data and the declining trend of PPC intervention indicated that our current PPC needs to be strengthened in terms of its overall process, data collection and monitoring aspect to allow for the impact assessment of PPC.

Kuala Muda District Health Office (KMDHO) serves a large district with high-density of a population estimated at 456,605 people (2). There are seven health clinics operated by 497 healthcare workers including doctors, paramedics, and support staff.

Among many medical problems in district. the escalation of this noncommunicable diseases (NCD) in reproductive-aged women need to be addressed. When PPC was introduced in KMDHO, PPC screening was mainly



**Figure 1:** Percentages of screened PPC clients given an intervention

conducted among post-natal mothers from maternal and child health (MCH) clinic, while women with NCD were less screened and registered with PPC. We believed that PPC should focus more on NCD clients since they are facing a greater risk of uncontrolled diseases during conception. As such, PPC implementation should be improved further by shifting the main focus from MCH to NCD with the development of a well-structured process of care for all the health clinics. Since diabetes and hypertension are the main NCD representing the majority of NCD clients, focusing the PPC screening and intervention on them will render a greater effect in reducing unsafe pregnancy.

Our aim is to achieve a 100% PPC registration of eligible clients with diabetes and hypertension and provide them with at least one intervention, as outlined in our PPC. Achieving optimal control in the disease management such as having HbA1C equal or less than 6.5% (target is 30%), and blood pressure less than 140/90 mmHg (target is 50%) are considered added benefits of the PPC implementation. This project was conducted over a period of six months, divided into two PDSA (plan, do, study and act) for a cycle of three months each. The improvement was assessed by comparing the end result with the baseline findings.

# **Background**

The Ministry of Health Malaysia (MOH) implemented the PPC as an initiative to reduce maternal morbidity and mortality among high-risk clients with medical conditions, such as diabetes, hypertension, asthma, and bad obstetric history. It focuses on preconception interventions for modifiable risk factors to improve maternal health and foetal outcome (1,3-5). Early recognition of potentially modifiable risks (6,7) among these women will help them to plan a safe pregnancy, optimise their disease control, and prevent poor pregnancy outcome (1.5.8). For women with non-modifiable risk factors, such as having a genetic disorder, PPC provides a platform for counselling where the women were informed of the potential risk so they could make informed decisions about their pregnancy plan (3). The major components of PPC are risk assessment followed by education and health promotion, and medical and psychosocial intervention (8,9).

In developing countries, including Malaysia, NCD is a major disease burden and the prevalence is increasing every year, especially for diabetes (10). The prevalence of diabetes is higher among reproductiveage women of 18 - 49 years old, which is between 5.5% to 22% (10). Studies have shown that adverse pregnancy outcome in women with diabetes was 3-5 times higher than other maternal population, including miscarriages, pre-term labour, macrosomia, foetal malformation, birth injury, perinatal pre-eclampsia, mortality, urinary disorder and neural tube defect (11-13). Evidence suggested that women receiving PPC have better glycaemic control, hence reducing serious congenital abnormalities (13,14).

Despite the encouraging evidence that supported PPC role in improving the outcome of a maternal and foetal high-risk group, PPC acceptance among healthcare providers and the community is still low (1,3–6). Studies suggested that primary

healthcare played a major role in the PPC implementation (5,6,15-18), as the main healthcare providers in the community. However, the implementation of PPC is rather challenging. The barriers identified among General Practitioners regarding PPC include clients' reluctance to come during the preconception stage, time constraints for consultation, addressing multiple preventive measures at a time, clients' unwillingness to attend subsequent PPC sessions and lack of tool or checklist for PPC (5,15,19). In addition, there were also challenges in attracting women to be involved in PPC as most of the women have low awareness of PPC (19). The most likely explanation for this was that the GPs might not have given adequate PPC counselling, sexual education and contraceptive methods (17). The women held the perception that PPC should be offered actively by the GPs during their routine consultation (5,19,20).

A successful PPC implementation required the involvement of many individuals. groups, and institutions (4,17). Each level has its own role. At the national level, MOH needs to formulate a national strategy to standardise the PPC delivery system and integrate PPC intervention packages into the existing local health programme (17). The system needs to be sustained with adequate human resources, low financial burden and has constant monitoring and evaluating procedures (4–6,17). Identifying at-risk population. planning an appropriate intervention and conducting an outreach programme to deliver PPC to urban African American women with the risk of poor birth outcomes in Georgia, USA, were shown to have a beneficial impact on the target group (8). The healthcare providers' motivation to implement PPC was also an integral part to ensure PPC success as demonstrated by the GPs in the Netherlands where 93% of the GPs perceived PPC as part of their job and their planned pregnancy achieved 85% (16). Therefore, the integration of multidisciplinary level is the key to a successful PPC.

### Measurement

A pre-intervention study was carried out a month prior to the intervention implementation. The purpose is to ascertain the number of women with diabetes (DM), and hypertension (HPT) registered with PPC. A total of 649 clients' cards (334 diabetes cards and 315 hypertension cards) was randomly selected from all seven NCD clinics and reviewed using the PPC Assessment Form. Inclusion criteria were women aged 15 to 49 years with diabetes and hypertension who have not reached menopause stage or had undergone a bilateral tubal ligation (BTL) or total hysterectomy. The assessment provided data on the percentages of eligible reproductive age women with diabetes and hypertension registered under PPC and the percentage of interventions given to the PPC clients. Additional information collected was the type of interventions given, such as optimisation of care (which include either optimising medications or referral to appropriate personnel such as Family Medicine Specialist (FMS), dietician or hospital physician, advice or initiation of

contraception, and advice on lifestyle modifications. Data collected were analysed using SPSS version 21.

Of all the 649 clients' cards reviewed, 344 (53%) samples were registered under PPC and among those who have registered, 298 (86.6%) were given at least one intervention as outlined in the PPC guidelines. Clients registered under PPC received more interventions compared to the non-registered client (Table 1). Among the interventions given, optimisation of care has the highest percentages of 75.2%, while advice on contraception and lifestyle modifications showed 47.8% and 30.2% respectively. Subsequent the preintervention study, the PPC assessment form was improved and to be used in the post-intervention phase.

The post-intervention assessment was carried out every three months for two cycles by our district PPC team which comprised three doctors and three nurses from different clinics. We collected and analysed the data at the end of the first cycle and evaluated all the processes involved in the remedial measures to be taken before commencing on the second cycle.

**Table 1:** Results of PPC in the pre-intervention phase.

	Registered PPC n (%)	Non-registered PPC n (%)
Total clients' cards reviewed (n= 649)	344 (53%)	305 (47%)
Number of clients received interventions	298 (86.6%)	205 (67.2%)
Types of interventions		
<ul> <li>Optimisation of care</li> </ul>	224 (75.2%)	175 (85.4%)
Achieved target	87 (38.8%)	94 (53.7%)
HbA1C (≤ 6.5%)	8 (3.6%)	13 (7.4%)
Controlled BP	135 (60.3%)	127 (72.6%)
Referral to other specialities	41 (18.3%)	25 (14.3%)
<ul> <li>Advice/Initiation/Maintenance of contraception</li> </ul>	165 (47.8%)	15 (4.9%)
Advice on lifestyle modifications	104 (30.2%)	39 (12.8%)

# Initial Assessment of the Problem

Based on the pre-intervention data, clients registered with PPC received more interventions compared to non-registered clients, inferring that registering the NCD clients with PPC improved their chances of receiving more interventions. However, variation in the registration process of each clinic and the lack of support from medical staff were a major concern. For the first step, we improvised the existing PPC flow-chart (Figure 2) based on the MOH PPC in Perinatal Care Manual (1). The refined flowchart elaborated each step emphasising on the registration process and choices of intervention that is suitable for the client needs. Every clinic is required to form a PPC team which consists of a doctor and a nursein-charge who will liaise directly with the district PPC team.

Another step included under the registration procedures is the use of PPC registration kit to improve the clients' card traceability and proper history-taking. Following the registration, PPC clients are referred to a doctor for a quick history-taking, assessment and consultation to decide on

the appropriate interventions. We divided the interventions into three different categories, namely optimisation of care, advice of contraception and advice on lifestyle modification. Optimisation of care can be achieved through the adjustment of the current treatment or referral to the proper personnel. At the end of this process, staff nurses will update clients of their next appointment to avoid defaulter.

embarking Before on implementation of the new PPC flow-chart. we assessed the level of healthcare workers (HCWs) knowledge, attitudes and their current practice of PPC. A questionnaire was developed and validated before being distributed to a total of 157 HCWs who were involved in PPC, consisting of doctors, assistant medical officer (AMO) and nurses. The study revealed that 103 (65.6%) of the total participants had attended a PPC course in the past two years. Participants who attended the PPC courses had better results in terms of knowledge, practice and attitudes (Table 2). Therefore, a comprehensive PPC course is important to increase the level of awareness among our HCWs. Hence. ensuring a successful PPC implementation.

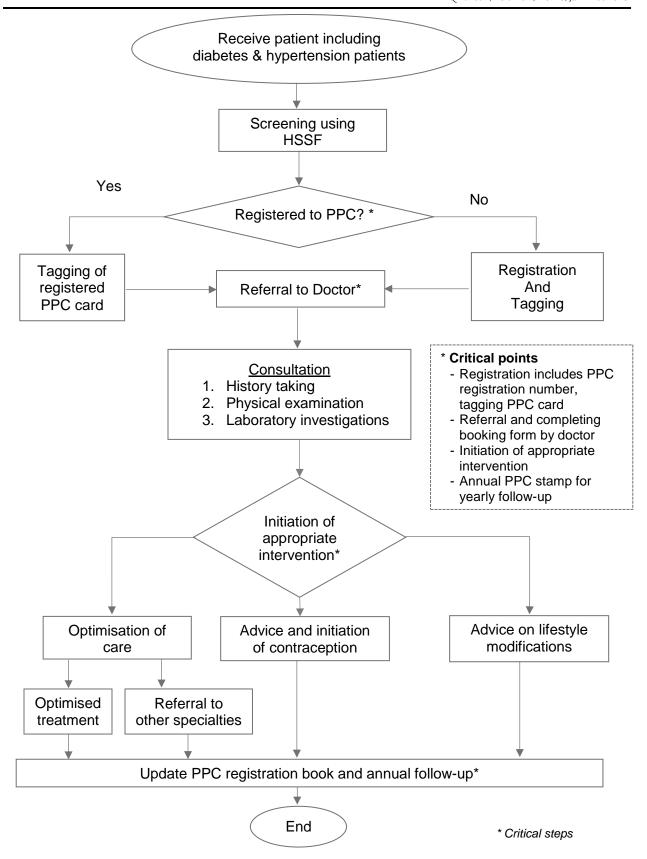


Figure 2: Improvised PPC flow-chart.

Table 2: KAP on PPC.

	Participa	ınts (n, %)	Total	<i>P</i> -Value
Training information on PPC in the past 2 years	Attended (103, 65.6%)	Not attended (54, 34.4%)	N = 157	
Scoring				
Knowledge Excellent (81-100%) Good (61-80%) Moderate (41-60%) Poor (21-40%) Very poor (0-20%)	21 (20.4%) <b>70 (68%)</b> 9 (8.7%) 3 (2.9%) 0 (0%)	7 (13%) 30 (55.6%) 15 (27.8%) 1 (1.9%) 1 (1.9%)	28 (17.8%) 100 (63.7%) 24 (15.3% 4 (2.5%) 1 (0.6%)	0.02
Practice	5 (4.9%) 65 (63.1%) 31 (30.1% 2 (1.9%) 0 (0%)	2 (3.7%) 14 (25.9%) 37 (68.5%) 0 (0%) 1 (1.9%)	7 (4.5%) 79 (50.3%) 68 (43.4%) 2 (1.3%) 1 (0.6%)	< 0.01
Attitude Positive Neutral Negative	80 (77.7%) 16 (15.5%) 7 (6.8%)	28 (51.9%) 21 (38.9%) 5 (9.3%)	108 (68.8%) 37 (23.6%) 12 (7.6%)	< 0.01

# Strategy

Our project aims to improve the PPC service by registering 100% of women with diabetes and hypertension eligible for PPC and ensuring all registered clients receive at least one intervention addressing their medical problems. The Achievable Benefit Not Achieved (ABNA) for the percentages of clients who received intervention in the preintervention study was 13.4 which we intend to reduce to zero.

Prior to this project, a meeting was held with all designated PPC in-charge including doctors and nurses from all seven health clinics with regards to the project's goal and objectives and the introduction of the new PPC flow-chart. At the end of the meeting, they were given the registration kit

to kick start the project. The person-incharge was expected to do echo training at their respective clinic to increase the awareness on the PPC project and to monitor the implementation of PPC. The district PPC assessment team used the quality assurance model of Plan, Do, Study, Act (PDSA) cycle to ensure adequate time allocation for the implementation of the modified flow-chart.

PDSA cycle 1: The first phase of our project is meant to strengthen the PPC registration process and PPC intervention by introducing the PPC Registration Kit. The PPC registration kit includes a tag sticker, a stamp and a Booking Form. Tagging sticker was introduced to improve clients' card traceability and a booking form is developed

to shorten the process of history-taking by the doctor given the limited consultation time. We hoped that by using the tagging sticker on the client's card, doctors would be more alert of the PPC components during the consultation. The Health Status Survey Form (HSSF), a general questionnaire on one's health status was used during registration process to identify any other risk factors apart from diabetes and hypertension. The PPC stamp was created mainly to ensure a continuation of the yearly follow-up for family planning and plan for optimisation of care.

At the end of the PDSA cycle one, our district PPC team did a post-intervention evaluation on clinics other than their respective clinic to avoid bias. In view of our initial plan of evaluating the adherence to PPC registration, we randomly selected 20 registered PPC cards from each clinic for the assessment. A total of 140 clients' cards were assessed and the findings were disappointing. Only 1.4% completed all five registration components and the number of interventions received by the registered PPC clients was 70%. The poor results of cycle one was due to the inconsistency in the adherence to the new flow-chart, lack of commitment from PPC in-charge and lack of awareness among doctors regarding the newly implemented PPC, especially in completing a booking form, HSSF and PPC stamp. Random interviews with the doctors revealed that most of them were still unaware of the PPC flow-chart mainly due to the lack of echo training at the clinic level, leading to poor adherence to the registration process.

PDSA Cycle 2: In the second cycle of PDSA, we conducted a PPC roadshow for all of the seven health clinics. During the PPC roadshow, the doctors were briefed on the PPC implementation by the district PPC team. Continuous reminders were given to

the clinic focal PPC in-charge. Regular surveillance was done by the district PPC team at their respective clinic to ensure the adherence to the flow-chart. At the end of the PDSA cycle two, we conducted a second post-intervention review, assessing 780 clients' cards.

#### Results

We audited 140 registered PPC clients' cards in the first cycle and 780 cards among eligible PPC clients in the second cycle. The percentage of eligible clients registered with PPC increased from 344 (53%) pre-intervention to 618 (79.2%) in cycle two. There were no data for the percentage of registered clients for PDSA cycle one since this cycle was meant to assess the adherence to the registration process. The comparison between preintervention results with PDSA cycle one showed a decline in the percentage of intervention given from 86.6% to 70% and a decline can be seen in other parameters as well. However, after the re-evaluation and corrective measures were taken, the second PDSA cycle showed an increase in the percentage of intervention given to clients, that is from 70% to 95.3%, which reduce the ABNA gap to 4.7 (Figure 3).

Completeness of registration (the 5/5 components that consist of the registration number, tagging, BSSK, booking form and PPC stamp) improved from 1.4% to 16.8%. The results comparison between the preintervention study and PDSA cycle two reveal that optimisation of care increased from 75.2% to 85.6%, advice or use of contraception, from 47.8% to 52.6% and advice on lifestyle modifications, from 30.2% to 44%. The complete results of the three studies are presented in Table 3.

Table 3: Summary of results for pre and post-intervention cycles.

	Pre-Intervention Study (N=649)	PDSA Cycle 1 (N=140)	PDSA Cycle 2 (N=780)
Total clients registered	344 (53%)	140(100%) *	618 (79.2%)
Completeness of Registration 0/5 complete 1/5 complete 2/5 complete 3/5 complete 4/5 complete 5/5 complete	Not applicable	1 (0.7%) 0 (0%) 79 (56.4%) 45 (32.1%) 13 (9.3%) 2 (1.4%)	0 (0%) 36 (5.8%) 242 (39.1%) 162 (26.2%) 74 (12.0%) 104 (16.8%)
Number of Intervention received** 1 Intervention 2 Interventions 3 Interventions	298 (86.6%) 139 (15.4%) 104 (30.2%) 48 (14.0%)	98 (70%) 56 (40%) 36 (25.7%) 6 (4.3%)	589 (95.3%) 243 (39.3%) 155 (25.1%) 191 (30.9%)
Types of interventions:  • Optimisation of care Achieved target HbA1C (≤ 6.5%) Controlled BP • Referral to other specialties	224 (75.2%) 87 (38.8%) 8 (3.6%) 135 (60.3%) 41 (18.3%)	44 (31.4%) 3 (2.1%) 3 (2.1%) 63 (45% 8 (5.7%)	529 (85.6%) 186 (35.2%) 25 (4.7%) 321 (60.7%) 40 (7.6%)
<ul> <li>Advice/ Initiation of contraception</li> </ul>	165 (47.8%)	55 (39.3%)	325 (52.6%)
Advice on lifestyle modifications  **PDSA Cycle 1 accessed 440 registered.**	104 (30.2%)	48 (34.3%)	272 (44%)

<sup>\*</sup>PDSA Cycle 1 assessed 140 registered clients' cards to analyse the adherence to PPC flow-chart.
\*\* PPC clients received any one of the interventions suggested.

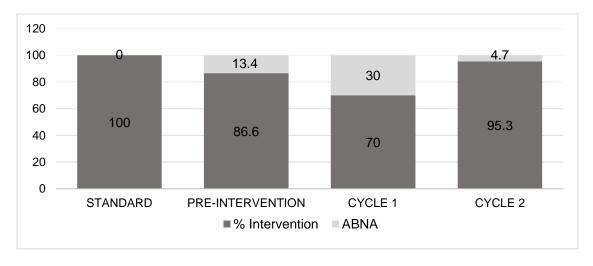


Figure 3: ABNA percentage of intervention.

#### **Lessons and Limitations**

Similar to any other projects, this project encountered several shortfalls during the implementation phase. The main lesson learnt from this project was the importance of embracing the PDSA process as it could assists in the identification of any flaw in the study design and unexpected results.

After the first PDSA cycle, we noticed that our intention to evaluate the adherence to the new PPC flow-chart by assessing only a small number of registered PPC clients led to an inconsistent of data collected, which prevent the comparison of data from pre-intervention and PDSA cycle two. The small number of samples might affect the PDSA cycle one results. Therefore, in the second cycle of PDSA, we increased the number of cards assessed to strengthen the quality of the study.

Furthermore, we learned that a strong multidisciplinary communication team need to be established before embarking on any project. This is to ensure that the trained personnel would conduct an echo training to all HCW at their respective clinics and convey any updates. Therefore, we arranged for a series of roadshows by visiting each health clinic and educating all doctors. In view of the rapid turn-over of doctors, we need to incorporate PPC in courses provided by **KMDHO** for а more sustainable implementation at the clinic.

The study also has several limitations. The lack of human resource, heavy workload and other competing tasks were among the challenges that we encountered. For some of the HCWs, the introduction of the new preventive measures in PPC added burden to their daily task. Therefore, continuous motivation is needed. Dedicated staff should be assigned to ensure the sustainability of PPC.

Our study only focused on modifying the PPC implementation and we did not look at client factors that might have influenced the success of PPC. Client willingness to participate and share information with HCWs regarding their planned pregnancy promotes the planning of a safe pregnancy and the initiation of folic acid. Community awareness programmes that promote PPC need to be organised by the clinic in conjunction with the clinic health panel (*Panel Kesihatan*) or other local non-governmental organisations (NGO).

The impact of the **PPC** implementation on reducing unplanned pregnancies with poor NCD control cannot be studied at the time due to unavailability of data on reproductive-age women with underlying NCD who became pregnant and their control status during antenatal booking. To overcome this issue, we have started collecting data on pregnant NCD patient assessing their status of PPC and their disease control prior to pregnancy. We hope that the data will give us some insight into the effectiveness of PPC implementation.

Finally, as the study was carried out at the end of the year, a refresher PPC course for our HCWs could not be done due to financial constraint. Having a scheduled refresher course will increase their knowledge, improve their practice at the health clinics and probably yield some positive attitudes towards implementing PPC.

# **Conclusion and the Next Steps**

PPC role is imperative in improving the maternal and foetal outcomes through a series of interventions aimed to achieve safe pregnancy especially for high-risk mothers. For the first step in creating a strong platform for the PPC implementation with a bigger impact, our project has shifted the focus of PPC entry point from post-natal mother to women in reproductive age with NCD. This is because women with underlying NCD pose a greater risk if they got pregnant with poorly controlled care. Therefore, we focused on diabetes and hypertensive clients as they represent the majority of NCD cases among reproductive women.

The strategies implemented managed to increase the registration percentage of diabetes and hypertension clients with PPC from 53% to 79.2% whilst PPC clients receiving intervention increased from 86.5% to 95.3%. From the study, we can conclude that a structured PPC flow-chart with a few

modifications can help us achieved the study objectives. This project could also be extended to other NCDs as well, such as bronchial asthma, thyroid disorder and heart disease. In order to ensure the 100% of registered PPC clients received any one of the interventions, strict adherence to the new PPC guideline is of utmost importance. Continuous periodic assessment on the compliance with the process of care as well as a scheduled refresher PPC course is crucial to ensure the sustainability of PPC implementation.

Further studies are needed in the future to assess the impact of the PPC implementation on the health of maternal and foetal. We might look into the trend of planned or unplanned pregnancy among women with NCD and assess their risk by looking at their disease control during antenatal booking.

Currently, KMDHO has become a reference point for the PPC implementation in Kedah and the Ministry of Health Malaysia is presently adopting our PPC flow-chart to develop a national PPC guideline for all health clinics in Malaysia.

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#### **Conflict of Interest**

None

# **Funding**

None

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# **EFFECTIVE STRATEGIES TO IMPROVE THE UPTAKE OF PAP SMEAR SCREENING IN PONTIAN DISTRICT**

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#### Abstract

Pap smear screening is proven to be an effective tool for the early detection of cervical cancer. Public Health Laboratory of the Ministry of Health Malaysia (MOH) reported that Pontian Health District achieved only 69.4% out of the 4,112 targeted Pap smear screening performed in 2014. Pontian District Health Office conducted a Quality Assurance (QA) project, aiming to increase the percentage of Pap smear screening uptake among women in Pontian district to 100%.

A cross-sectional study using questionnaires was conducted in January 2015 involving 256 women to measure their knowledge, attitude, and practice towards Pap smear screening. The results showed 93.8% of respondents have a good knowledge of Pap smear. However, only 72% agreed to do Pap smear screening while 28% refused to do the screening. The 72 women declined the Pap smear screening for various reasons, such as time constraint (27%) feeling shy (27%), perceived the procedure as painful (23%), afraid to know the result (19%) and perceived the screening as unimportant (4%). The results also revealed only 44% of the respondents received information about Pap smear screening from health staff.

Several strategies were identified to overcome the reasons; the expansion of Pap smear screening to the workplace and residences overcome time constraint issue, an innovative tool known as "Sisih Malu" to combat the shyness feeling of doing Pap smear screening, while "Celik Servik" demonstrates the procedure as simple and painless. Active promotion of Pap smear screening was also conducted by the clinics' staff who emphasised on cervical cancer early detection, which is more treatable at an early stage. These improvement strategies were conducted from February until December 2015.

Post-intervention saw Pap smear screening in Pontian district increased to 4,936 (118.9%), exceeding the 4,152 target set for 2015 and increased 130.5% in 2016. Another survey among 99 women in January 2016 showed that a 100% willingness to undergo a Pap smear screening.

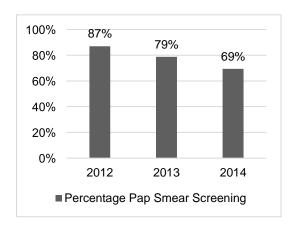
**KEYWORDS:** Pap Smear, coverage, improvement

#### **Problem**

Cervical cancer remains a major threat to the health and life of Malaysian women and there is a need for early detection and management of cervical cancer. The proven screening method for early detection of cervical cancer is cervical cytology examination, typically referred to as the Pap smear examination. Thus, in 1969, Family Health Development Division established the cervical cancer screening programme, which was incorporated into the Maternal and Child Health programme of MOH, Malaysia. The programme was planned, organised and evaluated by the Family Health Development Division. Every year MOH gives a certain target for a total Pap smear screening for each state and district level according to the estimated women population which was obtained from the Health Information Centre, MOH. At the state level, Family Health Officer plans and coordinates activities related to Pap smear screening in which each district was given a target in terms of the number of Pap smear screening to be performed in a year. The target was then divided accordingly among different health clinics in the district. Pap smear screening is carried out by the Medical and Health Officers and Public Health Nurses and the smears were read by a trained Medical Laboratory Technologist at Public Health Laboratories.

The annual target for every district was set at 40% of the 1/3 estimated sexually active women of childbearing age. It was estimated that the population of women aged between 30 and 65 years in Pontian district for the year 2014 was 39,153 of which 76.14% was sexually active. This means that 4,112 women in Pontian district were expected to be performing the Pap smear screening in 2014. The standard given by the Johore State Health Department was 100%. Pontian District Health Office was not able to achieve the target since 2012 as shown in Figure 1.

The Quality Assurance project aimed to increase the percentage of Pap smear screening from 69.4% to 100% in Pontian district within one year.



**Figure 1:** Trend of Pap smear screening (%) for Pontian district (2012 - 2014).

# **Background**

Cervical cancer remains a major threat to the health and life of Malaysian women. It remained as the second contributor to cancer-related death after breast cancer in Malaysia (1). It was estimated that two women died of cervical cancer every day and 30% of the cervical cancer cases were detected at stage 3 and 4. Women who had never been screened or who have not been screened in the past five years face a greater risk of developing invasive cervical cancer (2). The proven screening method for early detection of cervical cancer is the cervical cytological examination using the Papanicolaou's stain, which is also known as the Pap smear examination. Pap smear screening was found to be cost-effective and useful for early detection of cervical cancer in women. The slow evolvement of cervical cancer through a latent period of 10 years makes early detection of this cancer possible and practical. Population-based cervical cytology screening programme offering the Papanicolaou testing every three to four years has reduced cervical cancer incidence and increased the mortality rate by up to 80% in developed countries in the last five decades (3). It was 100% treatable if cervical cancer was detected at an early stage. Subsequently, it prevents further metastasis and mortality caused by late detection. Early detection also reduces the cost of treatment.

A study by Yeo et al. showed that the demography, women's beliefs of the

effectiveness of Pap smear in detecting cervical cancer, the desire to detect health problems early and the perception on Pap smear being painful, were found to be the factors that significantly influencing Pap smear uptake(4). Healthcare professionals need to be mindful of these factors when encouraging women to undergo this procedure.

There are a few studies on the strategy to increase Pap smear screening. Marion M et al. stressed on the importance of building awareness and motivation for cervical cancer screening through various activities, such as continuous education. hosting screening events, specifically for women, improving the attitude and service of health care providers, and promoting screening tools (5). A study by Rebecca A et al. suggested that the use of letters or physician reminders and Human Papilloma Virus self-sampling might increase cervical screening uptake in young women (6). Another study by Amelia A et al. confirmed that using individual contact method and assigning a fixed screening date notably increased the participation in screening and the response was strongly dependent on age (7).

#### Measurement

The percentage of women who underwent Pap smear was chosen as the measure for this project and was calculated as the number of women who underwent Pap smear screening per total number of women targeted for Pap smear screening. The target was set at 100% given by Johor State Health Office for all districts in Johor. The targeted Pap smear screening for Pontian Health Office was 4152 for the year 2015. The monthly data of the number of women who underwent Pap screening were obtained from reports submitted by health clinics and Public Health Laboratory Johor Bahru. assigned nursing manager of each clinic submitted the report electronically to the district office using a standardised format provided by MOH. The Public Health Laboratory was responsible for submitting the monthly statistic on Pap smear to the district health officer. Reports compiled by the district matron and

subsequently sent to the State Health Department.

# Initial Assessment of the Problem

This one year project started in January 2015 and involved all eight health clinics and 33 community clinics in Pontian district. The first evaluation was carried out in December 2015 and was subsequently monitored yearly. A cross-sectional study to identify the contributing factors was conducted in January 2015 involving 256 reproductive women aged from 20 to 60 years using a pre-developed questionnaire, which consisted of four components, namely socio demography and socioeconomic features, knowledge, attitude, practices towards Pap smear screening. The sample was taken among women attending eight health clinics in Pontian district to accommodate for any heterogeneity. There were two questions on knowledge, three questions on attitude and four questions on practice towards Pap smear screening. The study showed that 93.8% of respondents had knowledge of Pap smear screening and 72% of the respondents agreed to do a Pap smear screening. Seventy two (28%) respondents did not agree to do a Pap smear screening because of time constraint (27%), shyness (27%), perceived the procedure as painful (23%), afraid of knowing the result (19%) and perceived the screening as unimportant (4%).Only 44% respondents received information about Pap smear screening from healthcare providers. The results showed that age, educational status, duration of the marriage and the number of children were significant factors associated with Pap smear screening (p<0.05). The results also showed that the percentage of Pap smear screening was low among women aged 21 to 30 years old with high educational level. those who were married for less than five years, and have less than three children.

# **Strategy**

Group members of this project identified several strategies to overcome the contributing factors of the low

percentage of Pap smear screening uptake. These strategies were implemented from February to December 2015. The issue of time constraint highlighted by the respondents was addressed by extending the Pap smear screening programme to the respondents' workplace and residence. Pap smear screening which was previously confined to health clinics only was also offered at the community clinic level. A dedicated room for Pap smear was provided in health clinics to facilitate clients to undergo the Pap smear screening, hence reducing the waiting time significantly.

Malaysian women are known to be shy when it comes to the private part examination. An innovative device called "Sisih Malu" was created to overcome shyness of braving the procedure. An oval hole (measuring at 9 inches x 7 inches) was made at the centre of a disposable green crepe paper (measuring at 39 inches × 39 inches) which costs only MYR 0.94. During the procedure, the Paper covered the lower part of the client's body and exposed only the private part. The nurse will explain to the client how to apply the "Sisih Malu" tool and the client will be left on her own to undress and apply the cover. The client has the privilege to call the nurse once she feels ready. After applying the "Sisih Malu" the client would call the nurse and the Pap smear procedure would be performed immediately. Once the Pap smear procedure was completed, the nurse will leave the client to dress on her own and once the client is ready she will be given further advice (Figure 2). The green Paper will be disposed of after use. This innovation helped to reduce clients' shyness during Pap smear screening.

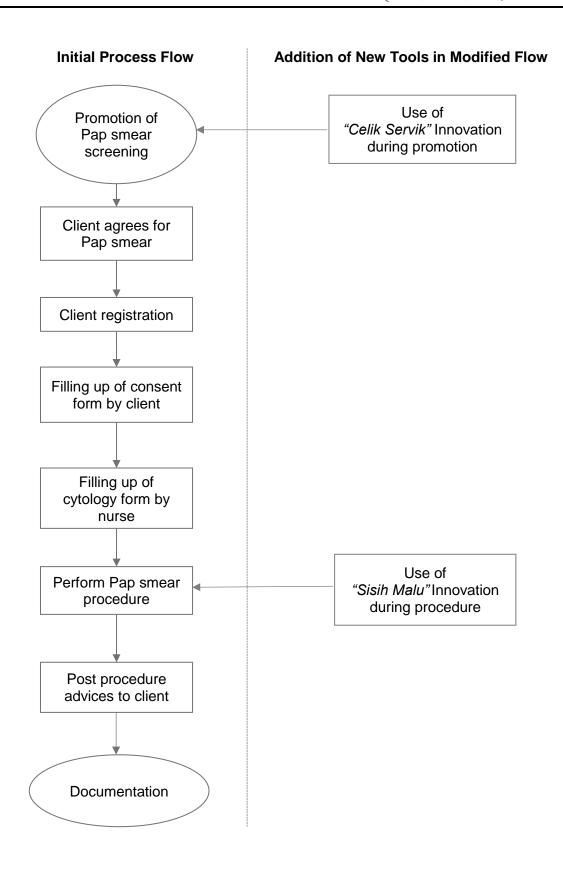
Although women can be educated, many are not aware of the benefit of the cervical cancer procedure. Thus, an innovation called "Celik Servik" was developed as an educational tool to guide women on the Pap smear procedure. "Celik Servik" is a transparent model of a cervix. It was created using a plastic cup which

represents the vagina and an inverted pacifier at the bottom of the plastic cup cervix. The cup is represents the translucent so that a client can see how the during procedure is conducted demonstration. By using this model, we are able to convince clients that the Pap smear procedure is not painful. This is a low-cost innovation that costed only MYR 5 per model. Recycled plastic cups can also be used to further cut the cost. This model can be made in various sizes and can be easily brought anywhere for demonstration purposes.

Some women were afraid to know the result of their Pap smear screening. In such cases, explanation was given to the client on the importance of Pap smear screening for early detection of cervical cancer which is highly treatable if detected early.

Another strategy was to increase the promotion of Pap smear screening as our study showed that only 44% of the respondents have received information on Pap smear screening from healthcare workers. The approach opportunistic in which advice on Pap smear screening was given in the outpatient clinic setting, during a postnatal home visit, during a community event or health camp. We focused on women aged between 21 and 30 years who have high education level, with the duration of marriage less than five years, and have less than three children. After a briefing on Pap smear screening was given, the client's card will be tagged in pink to indicate that the client has been briefed, thus, avoiding a repetition.

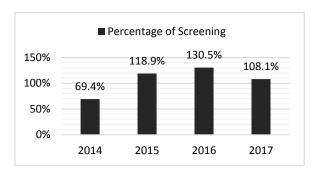
The initial and modified process flow for performing a Pap smear is shown in Figure 2. The initial process was modified by adding two activities: i) a promotion on Pap smear screening using "Celik Servik" innovative tool and ii) using the innovation of "Sisih Malu" during a Pap smear procedure



**Figure 2:** Modified flow-chart for Pap smear screening procedure using "Celik Servik" and "Sisih Malu" innovation.

### Results

An evaluation was conducted on December 2015, one year following the intervention. Pap smear screening percentage has increased to 4,936 (118.9%), exceeding the 4,152 target for the year 2015 (Figure 3). Close monitoring showed that the performance continues to increase and exceed the target in the subsequent years, which proved that the strategies are sustainable.



**Figure 3:** Percentage of Pap smear screening for Pontian district from the year 2014 to 2016.

Both the strategies of "Celik Servik" and "Sisih Malu" were able to improve the target set for Pap smear screening. The results of Pap smear screening for 2017 showed only Pontian district exceeded (108.1%) the target set while the other nine districts in Johor achieved less than 100%.

Detection of an early stage of cervical cancer has also increased concurrently with the increased number of Pap smear screening. Forty cases were detected in 2015 as compared to 27 cases in 2014 and no late-stage cervical cancer was detected in 2015 via the Pap smear screening programme. A post-interventional survey using the same questionnaire was conducted in January 2016 among women and the result is shown in Table 1.

**Table 1:** Comparison of factors affecting consent for Pap smear screening before and after interventions.

Factors	Before	After
	QA	QA
	project	project
	(n=256)	(n=99)

1.	Did not agree to undergo Pap smear screening	28%	0%
2.	No time for Pap smear screening	27%	11%
3.	Shy to undergo Pap smear screening	27%	0%
4.	Think Pap smear screening is painful	23%	0%

#### **Lessons and Limitations**

The key learning point of this project is that simple and low-cost innovation coupled with continuous promotion of the importance of Pap smear screening could be the success factor in increasing the uptake of Pap smear screening. Notably, this study is only applicable to women who seek treatment or services at the health clinic as indicated by the sampling method. Ideally, the sampling should cover the entire community so that the results can be generalised. Another major challenge of this study is the high turnover rate among nursing staff in Pontian district.

We continuously educate new staff about the interventions to ensure the sustainability of this project. If we were to undertake this project again, we plan to broaden the promotion of Pap smear screening to cover government and private hospitals and private clinics in order to reach a greater proportion of the community.

# **Conclusion and the Next Steps**

This project has shown sustainability since it started in 2015 until 2017 where the percentage of Pap smear screening for Pontian District Health Office exceeded the target of 100%. Our project team has appointed a number of champions in the team to ensure the continuation of the project and to expand it to other districts. This project might help to reduce the cost of treatment for cervical cancer patients by increasing the chance of cervical cancer early detection. In October 2017, this project was expanded to all districts in Johor. We aim to

replicate this project to other states in Malaysia.

# **Acknowledgement**

We would like to thank the Director General of Health Malaysia for his permission to publish this article and all the nursing staff of Pontian Health Office for their involvement and contribution to this project.

## **Conflict of Interest**

None

# **Funding**

None

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# Quality Improvement Report (QIR) for Q Bulletin Guideline for Authors

This guideline is the modified version of the BMJ Open Quality template for quality improvement project report. The original template can be accessed here: <a href="https://bmjopenquality.bmj.com/pages/authors/#editorial\_policy">https://bmjopenquality.bmj.com/pages/authors/#editorial\_policy</a>

Your manuscript should include:

- 1. Abstract (up to 300 words)
- 2. Main text (up to 4000 words; excluding abstracts, tables and figures)
- 3. Maximum of 5 tables or figures.
- 4. Please use Font Arial, Size 12, double spacing.

Subheading	Description
Title	Indicate that the article concerns an initiative to improve healthcare.
Abstract	This is a summary of your work and is the most important section to attract a reader's attention. Please ensure you include:
	<ul><li>a) A brief background to the problem,</li><li>b) The method for your quality improvement project,</li><li>c) The overall results and</li><li>d) The conclusion</li></ul>
	Keep it succinct and factual. Please include 3 – 5 appropriate keywords for your manuscript.
Problem	Summarise your problem and the focus of your project. Give some details about your local context including;
	<ul> <li>a) The type of organisation you work in,</li> <li>b) The size of your organisation,</li> <li>c) Details about the staff members who work there and</li> <li>d) Perhaps a little bit about your local patient population.</li> </ul>
	Include here the SMART aim of your project (for example; the aim was to reduce medication errors from 15% to 5% across six elderly care wards in three months).
Background	This section gives the reader background information about the problem and provides up-to-date, research and knowledge from the literature.
	Summarize the literature you have found on the background to your problem here.
	<ul><li>a) What existing evidence is there that this problem exists?</li><li>b) What existing evidence is there on the factors contributing to the problem?</li><li>c) What evidence is there that other people have tried to solve this problem in the past?</li></ul>
	d) Is there any evidence for what works and what doesn't to solve your problem?

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#### Measurement

Describe which measures you selected for studying processes and the outcomes of the intervention(s), including:

- a) Rationale for choosing them,
- b) Their operational definitions,
- c) Inclusion and exclusion criteria,
- d) The standard and how you determine it

Describe how you planned to collect this data throughout your project and how frequently.

Include here the results of your baseline measurement (verification study).

# Initial assessment of the problem

Describe what processes are involved in your problem including the critical steps that in the processes that will contribute to the achievement of your final goal.

Describe on the perceived factors that could contribute to the problem and how you quantify them.

Include here the results of the study that you conducted to identify the contributing factors to the problem.

#### Strategy

In this section you should explain your strategy for improvement to the reader and discuss how you implemented your improvement cycles. In most cases you will have tried a number of progressive improvement cycles, some of which will not have been successful. It is important that you also share these to help others avoid similar difficulties. Remember that data should be collected continuously throughout your project.

This is a difficult section to document and will contain a lot of information. For each PDSA cycle you should describe your aim, your change hypothesis and strategy for change.

- a) Describe how you implemented the change and the data you collected.
- b) Describe your key learning from each cycle of change, and discuss how this learning impacted on your change process.
- c) How well did your predictions of what change was needed match your outcomes?
- d) What worked more effectively than anticipated and what had less effect than predicted?

#### Results

Provide a summary of what your results using appropriate chart or diagram.

- a) Describe the variation in your data.
- b) Were the interventions you made responsible for
- c) Any improvements?
- Describe how contextual elements interacted with the intervention(s) and affected your results.
- e) Compare your results to your baseline measurement.

Comment on how you assessed whether the data was complete and accurate- was there any missing data?

Please comment on whether there were any unintended consequences such as unexpected benefits, problems, failures or costs associated with the intervention(s).

# Lessons and Limitations

In this section, discuss the lessons you learnt from the project and its limitations.

Comment on the strengths of the project.

Describe any problems you faced and how you navigated these.

If you were to undertake this project again, what would you do differently?

Reflect on your project's limitations.

For example, did you realise as the project was implemented that your results would be affected by unforeseen factors such as a small sample size or the turnaround of patients or staff?

Comment on the limits of generalize ability.

Describe whether chance, bias, or confounding have affected your results and whether there was any imprecision in the design or analysis of the project.

Are more data points required?

Were efforts made to minimize/adjust for any limitations?

Although we accept publications using different improvement approaches, we would expect you to have modified your intervention as it was implemented and undergone a process of continuous improvement, measurement and learning. If your project does not fit with this approach then we would like to see reflections and learning here about how you could have incorporated continuous improvement and measurement approaches in your project.

# Conclusion and the next steps

You should reflect on your background research, noting what is already known on this topic and what your project adds.

You should refer back to your aims statement – did your project achieve its aims? Did you adjust your aims as you went along? Was it a useful project?

Were your measures appropriate and did you use balancing measures?

Think about what your senior sponsor would like to see as an output of your work and what can help others to make the case for undertaking a similar piece of work – or for doing something differently if your project was not successful.

Please describe your cost analysis here, were there any financial savings that your project made? Being able to demonstrate that your intervention delivered savings really helps to add value.

Give an assessment of whether you think your project is sustainable – do you have enough data? What have you done to try to ensure that your work continues? Comment on how you would spread your project and whether it could be replicated elsewhere. Discuss what your next steps will be and whether further study in the field is required.

The point of the conclusion is not to rewrite the whole project, but to give an overview of how the whole project was conducted, what it achieved, and some personal reflections.

References	In this section you should record any references to published material that you refer to elsewhere in your project. This is particularly likely to include material from background reading or from your conclusions.
	Use the Vancouver style for referencing.
Acknowledgements	Please include here the names of anyone who is not on the author list but whose input you wish to acknowledge.
Conflict of Interest	Please declare any conflict of interest, if any.
Funding	Please declare any source of funding, if any.





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