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# PUBLIC HEALTH AND PREVENTIVE MEDICINE ARCHIVE

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Predictors of treatment interruption among tuberculosis patients in public health centres in Bali, Indonesia

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Abstract

Background and purpose: Tuberculosis treatment interruption (TB TI) is one factor that leads to treatment failure, tuberculosis (TB) drug resistance and drop out. The purpose of this study is to identify the incidence and the predictors of TB TI in public health centres (PHCs) in Bali.

Methods: A retrospective longitudinal study was conducted using secondary data of 644 cohorts of TB patients on the first regimen who enrolled in 11 PHCs in Denpasar Bali during 2011-2012. Information from TB program officers in PHCs was also obtained to determine the differences within the practical implementation of TB treatment. Data were analysed using Kaplan Meier and Cox Proportional Hazard Regression.

Results: The study revealed that 378 patients experienced TB TI with the total events of 535. The incidence rate of TB TI event was 5.1 per 1.000 person days and the median time was 56 days (IQR: 56-57). Predictors of the TB TI were male (AHR=1.22; 95% CI: 1.02-1.45; p=0.027) and a more flexible schedule to take the medicine (AHR=1.47; 95%CI: 1.22-1.76; p<0.0001).

Conclusions: The implementation of fixed schedule and shortened time lapse for patients to take TB drug will enable more close contact between patients and health providers. Intensive adherence counselling especially tailored for male patients is also required.

Keywords: tuberculosis, treatment, retrospective longitudinal study

Introduction

Tuberculosis (TB) is a major public health problem worldwide and responsible for 9 million morbidities and 1.5 million deaths.1 TB treatment is still a major public health issue in Indonesia, wherein TB relapse, multi drug resistance (MDR) and defaulter (where patients do not take drugs for more than 8 weeks), continue to be problematic. In 2012, an estimated proportion of TB relapse cases in Indonesia was 2.4%, while MDR TB was 1.9% (1.4-2.5) in new cases and 12% (8.1-17) in retreated cases.² Bali Province accounted for 0.9% of the total TB cases in Indonesia,³ where the highest number of TB cases in 2012 came from Denpasar, the capital city of the province.⁴ All PHCs in Denpasar have implemented the directly observed treatment short course (DOTS) strategy and have trained TB officers related on TB treatment management. However, 11.1% of TB cases in Denpasar were re-treated, and this accounted for 47% of suspected MDR-TB cases in Bali. The MDR-TB rate had slightly decreased from 3.9% in 2012 to 3.7% in 2013; however, the percentage of defaulter of all TB patients had increased from 1.9% (2012) to 3.7% (2013).⁴,⁵

Previous studies showed that patients who did not take medication regularly or experienced treatment interruption (TI) were more likely to be default from treatment, had
MDR-TB, and had treatment failure.\textsuperscript{6-8} Several studies in Indonesia have found that among the predictors of TB TI were relapse status, availability of treatment support, time to initiate TB treatment, home visit, counseling, drug quality, transportation, distance to health facilities, family income, family support, drug side effects, knowledge levels, and health provider’s behaviour.\textsuperscript{9-12} Studies in other countries found that gender of the patient (male), ignorance about the time length of TB treatment, distance to health facilities, and smoking were also among the predictors.\textsuperscript{13-16} This study aims to confirm those findings and provide sufficient understanding on the occurrence of TB TI and its predictors, which will provide crucial insight into how to develop better management of TB treatment in the future.

**Methods**

A retrospective longitudinal study was conducted using cohorts of TB patients in eleven PHCs in Denpasar. The study population was TB patients under TB regimen category 1 during 2011-2012. The inclusion criteria were age $\geq$ 15 years old and the completion of TB treatment.

Based on the national guideline,\textsuperscript{17} TB is diagnosed by sputum and/or radiologic test, and the administration of TB treatment depends on the type of TB (pulmonary or non-pulmonary TB) and the history of TB treatment (new or re-treatment). TB treatment Category I consists of two phases: the intensive (two months) and continuation (four months) phase (one month = 28 days). Sputum is checked after the intensive phase to identify the conversion status of the TB bacilli in the sputum. Those who do not have the conversion must have an insertion phase for one month. In this study we categorized insertion and continuation phase as post intensive phase. TB TI on the intensive phase will delay the start of continuation phase.

Data of predictors extracted from the clinical record were: demographics, clinical condition and programmatic. Demographic data included: age, gender, history of TB treatment (new or referral from other PHCs). Clinical condition included: baseline sputum test result, type of TB infection (pulmonary/non-pulmonary), and HIV status. Programmatic factors consisted of: available facilities of the PHC (ability to conduct sputum test including microscopic referral and satellite PHC), and patient’s relationship to treatment observer (family/not family/N/A). We also interviewed 11 TB program officers regarding the maximum duration of providing TB drugs to the patient for each visit. We categorized the duration to be: less flexible if the drugs provided maximum of 1 week, and more flexible if the drugs provided up to 2 weeks. Other information gathered in the interview was the common reasons of TB TI, and the strategies implemented by the TB officer to overcome problems related to TB TI.

During the intensive phase, TB TI was defined as the date when patients did not pick up the drug for at least one day to a maximum of 8 weeks. During the continuation phase, TB TI was defined as the date when patients did not pick up the drug for at least 2 consecutive days to a maximum of 8 weeks. In further analysis, we expanded the TB TI definition using interruption for at least 7 consecutive days.

Based on the above definition of TB TI, we used three scenarios to define the events. The first scenario is the first TB TI as an event, the second scenario is the multiple repeated TIs occurred for each patient during the period of observation, and the third scenario is the expanded TB TI definition (7 days). First, we calculated the cumulative incidence of TB TI based on two definitions of events. For further longitudinal analysis, in the first scenario we
calculated incidence rate and its median time using survival analysis and Kaplan Meier graph. For the second and third scenario, we calculated the incidence rate and the predictors of TB TI. Cox Regression was used to unearth the hazard ratio (HR), 95% CI and the p value. TB patients who experienced default, transferred out, died, and those who did not experience TB TI during the study were censored. Multivariate Cox regression modelling was conducted for all variables with the p value <0.20 in the univariate analysis. Analysis was conducted using STATA 12.0.

This research has been approved by the Head of Health District Office of Denpasar, Bali and the Ethics Committee of the Faculty of Medicine, University of Udayana/Sanglah General Hospital.

### Results

**Table 1. Demographics, clinical and programmatic characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographic factors</strong></td>
<td></td>
</tr>
<tr>
<td>Age: Median (IQR)</td>
<td>35 (27-48)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>278 (43.2)</td>
</tr>
<tr>
<td>Male</td>
<td>366 (56.8)</td>
</tr>
<tr>
<td><strong>History of TB treatment</strong></td>
<td></td>
</tr>
<tr>
<td>New</td>
<td>610 (94.7)</td>
</tr>
<tr>
<td>Referred in</td>
<td>34 (5.3)</td>
</tr>
<tr>
<td><strong>Clinical condition</strong></td>
<td></td>
</tr>
<tr>
<td>Sputum result test before treatment</td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>216 (33.5)</td>
</tr>
<tr>
<td>Positive</td>
<td>420 (65.2)</td>
</tr>
<tr>
<td>Not done</td>
<td>8 (1.2)</td>
</tr>
<tr>
<td><strong>Type of TB infection</strong></td>
<td></td>
</tr>
<tr>
<td>Extra pulmonary</td>
<td>53 (8.2)</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>591 (91.8)</td>
</tr>
<tr>
<td><strong>HIV status</strong></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>197 (30.6)</td>
</tr>
<tr>
<td>Positive</td>
<td>8 (1.2)</td>
</tr>
<tr>
<td>Unknown</td>
<td>439 (68.2)</td>
</tr>
<tr>
<td><strong>Programmatic factor</strong></td>
<td></td>
</tr>
<tr>
<td>Patients relationship to treatment observer</td>
<td></td>
</tr>
<tr>
<td>Family</td>
<td>610 (94.7)</td>
</tr>
<tr>
<td>Family and health workers</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>Health workers</td>
<td>16 (2.5)</td>
</tr>
<tr>
<td>Others</td>
<td>9 (1.4)</td>
</tr>
<tr>
<td>None</td>
<td>8 (1.2)</td>
</tr>
</tbody>
</table>

*History of TB treatment was categorized into new patients and patients who referred into PHCs.

A total of 819 TB patients were registered in TB treatment in PHCs in Denpasar between 2011 and 2012. Among those, 175 (21.4%) medical records were ineligible due to massive incomplete data (6.8%), <15 years old (6.3%), and were on the second category of TB treatment (8.2%); resulting in 644 (78.6%) medical records that were eligible for the analysis.

Table 1 describes the patients' characteristics. A total of 366 (56.8%) were male with median age 35 years (IQR: 27-48). Almost all (94.7%) were new TB patients, had pulmonary TB (91.8%), were diagnosed based on sputum tests (65.2%). More than half (68.2%) were not tested for HIV, and almost all (94.7%) had a family member as a treatment observer.
Table 2. Univariate analysis of predictors of TB treatment interruption

<table>
<thead>
<tr>
<th>Variables</th>
<th>Multiple (TB TI ≥1 days)</th>
<th>TB TI ≥7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HR</td>
<td>95%CI</td>
</tr>
<tr>
<td><strong>Demographic factor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>1.00</td>
<td>0.99-1.00</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.20</td>
<td>1.01-1.43</td>
</tr>
<tr>
<td><strong>History of TB treatment</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>Referred in</td>
<td>0.93</td>
<td>0.61-1.39</td>
</tr>
<tr>
<td><strong>Clinical condition</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputum test result before treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>1.22</td>
<td>1.01-1.47</td>
</tr>
<tr>
<td>Not done</td>
<td>1.65</td>
<td>0.81-3.36</td>
</tr>
<tr>
<td><strong>Type of TB infection</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extra pulmonary</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>Pulmonary</td>
<td>1.16</td>
<td>0.83-1.62</td>
</tr>
<tr>
<td><strong>HIV status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>1.35</td>
<td>0.69-2.64</td>
</tr>
<tr>
<td>Not done</td>
<td>1.06</td>
<td>0.88-1.27</td>
</tr>
<tr>
<td><strong>Programmatic factor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of PHC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHC of microscopic referral</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>Satellite</td>
<td>1.10</td>
<td>0.90-1.35</td>
</tr>
<tr>
<td><strong>Patient’s relationship to treatment observer</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Family</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>Not family</td>
<td>0.56</td>
<td>0.31-0.99</td>
</tr>
<tr>
<td>None</td>
<td>1.29</td>
<td>0.61-2.72</td>
</tr>
<tr>
<td>The maximum duration to drug pick up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less flexible</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>More flexible</td>
<td>1.46</td>
<td>1.21-1.75</td>
</tr>
</tbody>
</table>

During the 6-8 months of TB treatment, more than half (58.7%) patients experienced at least one or more episodes of TB TI, leaving 234 (36.3%) patients who did not experience any TB TI, 10 (1.6%) defaulted, 14 (2.2%) died, and 25 (3.9%) were transferred out. Overall, there were 535 (83.1%) episodes of TB TI, wherein 10.1% experienced TB TI at ≥7 consecutive days. Longitudinal analysis for the first scenario resulted in the incidence of the first TB TI at 6.1 per 1,000 person days with the median time of 59 days (IQR was not reached), while for the second scenario, the incidence rate of overall incidence of TB TI was 5.1 per 1,000 person days.
Figure 1: Kaplan-Meier survival estimate

<table>
<thead>
<tr>
<th>Number at risk</th>
<th>644</th>
<th>551</th>
<th>243</th>
<th>229</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analysis time</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 3. Multivariate analysis of predictors of TB treatment interruption

<table>
<thead>
<tr>
<th>Variables</th>
<th>Multiple (TB TI ≥1days)</th>
<th>TB TI ≥7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AHR 95%CI p</td>
<td>AHR 95%CI p (g)</td>
</tr>
<tr>
<td>Demographic factor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1.22 1.02-1.45 0.027</td>
<td></td>
</tr>
<tr>
<td>Clinical condition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sputum test result before treatment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>Positive</td>
<td>1.77 0.98-3.22 0.06</td>
<td></td>
</tr>
<tr>
<td>Not done</td>
<td>4.79 1.09-21.08 0.04 0.05</td>
<td></td>
</tr>
<tr>
<td>Programmatic factor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The maximum duration to drug pick up</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Less flexible</td>
<td>1 (ref)</td>
<td></td>
</tr>
<tr>
<td>More flexible</td>
<td>1.47 1.22-1.76 &lt; 0.0001</td>
<td></td>
</tr>
</tbody>
</table>
| Secondary data: demographic factor, clinical condition, type of PHC, patient relationship to treatment observer; Primary data: the maximum duration to take drug

days with median time of 61 days (IQR: 56-215). The Kaplan Meier graph indicated that most of the first TB TI occurred within the transition between the intensive and post intensive phase (day 56th-58th).

Table 2 describes that variables of gender and sputum test results before TB treatment showed a tendency to be significant for both scenarios, but not for the variable of maximum duration to drug pick up. However, final multivariate model (Table 3) shows a different result. Incidence of TB TI with repeated event were more likely to be among males compared with females (AHR=1.22; 95%CI: 1.02-1.45; p=0.027) and among patients with more flexible duration to take TB drugs (AHR=1.47; 95%CI: 1.22-1.76; p<0.0001). While TB TI for ≥7 consecutive days was more
likely encountered among those who did not have a sputum test (AHR=4.79; 95%CI:1.09-21.08; p=0.04).

Based on the interviews with TB officers, eight of them were less flexible in providing TB drugs for only one week, while the others were more flexible by giving drugs for more than two weeks on the intensive phase. They stated that the sputum collection was often not timely done, impacted upon the speed of sputum test result dissemination. In providing a response to this, 4 officers admitted that they continued to give the drugs that was used on intensive phase, 3 officers continued to give the drug that was used in the continuation phase, and 3 officers stopped the treatment until they get sputum test result. Only one TB officer had never experienced the late sputum test result.

**Discussion**

We found that the overall occurrence of TB TI in Bali in 2011-2012 was relatively high, and mostly occurred in the transition between intensive and post intensive phases. The independent predictors of the occurrence of multiple TB TI were male and patients who had more flexible duration to access medication; while the predictor for TB TI ≥7 consecutive days were patients who were not diagnosed as TB based on sputum test.

Using the first and multiple TB TI definitions, more than half the patients experienced TB TI with the incidence rate of 6.1 and 5.1 per 1,000 person years. As this is the first published study which calculates the incidence of TB TI in Asia, limited data is available to compare this number to other similar studies in Indonesia/Asia. A longitudinal study in Kenya detailed lower cumulative incidence of TB TI among the new patients (4.5%), but higher among the retreatment patients (8.5%), however this study used a different definition of TB TI as when treatment was interrupted for two consecutive months or more. Many studies in Indonesia measured the proportion of TB TI with cross-sectional studies and put forward a variety of definitions. Our study found that the cumulative incidence of TB TI was 58.7%, while studies in Indonesia ranged from 39.2% to 86.9%, compared to studies conducted in other countries, the TB TI with TI definition was missed treatment for 2 consecutive days in the intensive phase of treatment, 14 consecutive days in continuation phase (category 1) in Nigeria, for instance, was lower (19%) than our study. Despite of TB TI definition, this study supports the fact that occurrences of TB TI in many places in Indonesia were common.

Our study found that most TB TI occurred on day 56, with a median time of the first TB TI and multiple TB TI on day 59 and on the 61th. The 56th day should be the end of the intensive phase if patients took medication regularly and without any interruption. This finding paralleled with a retrospective cohort study regarding the drop out of TB patients in South Sumatra, Indonesia, and retrospective cohort study in India. Our interviews with TB staff revealed that TB TI during the transition period was due to the slow dissemination of sputum test results. After two months of taking medication, many patients experienced improved health therefore did not return or were late for follow up sputum check. Phone call or text messages conducted by the TB staff to track and remind patients who were late or to confirm result of sputum test was not always effective. This circumstance resulted in delays in providing TB treatment following the sputum test result. Other studies in Indonesia also found that the lateness of the sputum test result dissemination is one precursor for TB TI. In addition, a study in North Sumatra found that 47.4% patients with TB TI did not understand the objective of the sputum test and 71.1% patients commit sputum test not according to
the schedule. In this setting, TB staff’s efforts to carry out a home visit were often in vain as sometimes patient could not be found or staff were provided with a falsified address. The efforts of TB staff during this transition phase also played an important role in positively influencing TB TI. When the sputum test result was not available after the intensive phase, PHC staff responded to this situation with different approaches. Some PHC staff chose to continue providing TB treatment, but some other staff decided against this. Patients who were given medication were still in contact with TB staff, therefore there was a lower possibility for treatment interruption compared with those who were being stopped for the treatment. The government tried to overcome this matter by introducing a new national policy in March 2015. In this policy, PHC staff are required to continue providing TB treatment regardless of the availability of the sputum test result after the intensive phase. As it is still preliminary, it is too early to identify the effectiveness of this policy to address the issue of TB TI.

In our study, men were more likely to experience TB TI compared with women (AHR=1.22; 95%CI: 1.02-1.45; p=0.027). This is consistent with studies in India, South Africa and Nigeria, and Russia, which discovered that males were more at risk of TB TI compared with females. Another study suggested that this was due to men’s lower adherence to DOTS treatment compared with women, and the tendency of men having a higher risky behaviour such drinking alcohol and smoking. In our study, we did not identify those behaviors, however, this information highlights the importance of possible factors related to men and TB TI, particularly because cigarette smoking was prevalent (29%) among people with age ≥10 years in Indonesia. Another predictor associated with multiple TB TI was the flexibility of schedule for medication provision. This study showed that patients with more flexible schedule for access were less likely to have regular contact with PHC, thus were more likely to experience TB TI. More studies are needed to confirm this association.

For the second scenario (TB TI ≥7 consecutive days), the predictor of TB TI was the patient who did not undergo a sputum test before treatment. There was no previous study that found the relationship between sputum test result before treatment and TB TI, thus there are difficulties in confirming this result. It might also be possible that there was bias in analysis due to the relatively small number of cases in this study.

This study is not without limitations. The definition of multiple TB TI being used in this study (one to 80 days of interruption) might be sensitive to error of recording. In addition, several survival studies which use repeated event analysis were those with recurrent disease outcome and to measure behavior which are relevant with TB TI. Expanded definition of TB TI using 7 consecutive days may therefore provide a more stable measurement of TI. However, our study also found different predictors for each TB TI definition. Using one day and calculating multiple event of TB TI was useful to provide information on the frequency of TB TI which may relate to program implementation. While using 7 consecutive day of TB TI may provide the size of severe TB TI among patients, which may lead to possibility of MDR TB. Our study emphasizes there were a problem in the duration and the frequency of TB TI. Previous studies also associated TB TI with poor outcome of TB treatment and the occurrence of TB-MDR, however, the definition of TB TI was not exactly same with our TB TI definition.

There are other variables that are evident from other studies to predict the TB TI but not included in this study such as socioeconomic factors (education, occupation, and marital status), distance to health centre, risk behaviour, and other behaviour factors. In addition, as in other studies which use
secondary data, incompleteness and error on recording data may also be a concern. This study was conducted among TB patients at PHCs which may have different characteristics from those who come from hospital setting.

**Conclusion**

TB TI are common in Denpasar, in terms of both duration of length TB TI and the frequency. Being men and patients whose pick up the drug more flexible are more likely experienced TB TI. A fixed schedule and shorten interval to take TB medicine allows more contact between patients and health care providers. Adherence counselling for men are needed to reduce TB TI on men patients.

**Acknowledgement**

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2. Title must be concise and ensure it reflects the subject matter. Title page should be no longer than 18 words.

3. Authors' name and affiliation must be placed under the title. Corresponding author’s email address must be stated to allow further discussion and interaction with the audience.

4. Abstract should be no longer than 300 words and must reflect the subject matter which includes: background and purpose, methods, results, and conclusion. It should also be accompanied by 3-5 key words.

5. Introduction must concisely address the existing gaps in the literature and state precisely study objectives.

6. Methods must clearly outline the study design, population, sample, source of data, data collection techniques, research instruments, and data analysis.

7. Results present findings of the study without opinion of the authors. Findings should be concise and can be presented using tables, graphs, and narratives. Table must be single space and must be numbered based on its occurrence in the text. The maximum of four tables and/or graphs are allowed which must contain a short self explanatory title. The title of table is placed above the table with left alignment, single space. The title of graph is placed under the graph with centre alignment, single space.

8. Discussion explains precisely findings of the study supported by sound theoretical and evidence from previous studies. Specific to qualitative studies, findings can be presented along with the discussion.

9. Conclusion should answer the research questions and can include a brief recommendation.

10. Acknowledgements should be addressed to related stakeholders who had supported the study, including respondents.

11. Reference lists It contains all references cited in the text. Referencing format must follow the Vancouver style (superscript without bracket), and should refer to the most up-to-date available evidence. Author's last name followed by the initials of their first and middle name should be consistently used. When the authors are up to six, all authors should be written, but when those are more than six, the first six authors should be written followed by et al. The title of article must be written in sentence case. If the journal acronym is used, it should confirm to Medicus Index. Examples of referencing styles of different sources can be seen in the appendix.

12. Authors should pay attention on their writing structure, including sentence structure, accuracy of the text, table or graph. All accepted manuscripts will be provided back to the authors if the format has not complied with the instruction guidelines.

13. Authors must state their full name, qualifications, corresponding address, and affiliations. They should also complete the agreement form of right transfer for publication purposes only.

14. All manuscripts are subject to peer review processes and reviewed by editors. Further revision is requested prior to publication, or rejected for publication. Editors will provide the final decision and notify the authors whether the manuscript is accepted for publication.

15. Accepted manuscript written in Bahasa Indonesia will be translated by the PHPMA production editor, with the cost of IDR 3,000,000.

16. Manuscript must be submitted electronically to the following email: jurnalmikm@gmail.com
Appendix 1. Referencing guidelines

Every cited reference must appear in the reference lists and vice versa. The citation in the text should be numbered, for example: 1 or 2. If the citation is more than two references, only the first and the last number are written separated by ‘dash’, for example 1-3 or 3-8. The citation must be superscript and must be placed after the text, for example: Nutritional assessments can be done by several methods which are anthropometric\(^1\), dietetic\(^2\), and biochemistry tests.\(^3\)

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Scientific or technical report
Example:

Thesis (PhD, Master or Undergraduate)
Example:

Electronic journal article
Example:
Appendix 2. Guidance for statistical reporting

This guidance is provided to assist authors preparing for their statistical report for publication. This guidance is not to replace the existing statistical guidelines required in a quantitative study. Each component is elaborated below.

Abstract:
Total sample and source of data must be clearly stated. Any conclusion made from statistical tests must be accompanied by descriptive statistic reports for example mean, median, mode, standard deviation, interquartile, variation coefficient percentage, 95% confidence interval, regression formula, and so forth.

Methods:
For an experimental study, sampling technique and randomisation procedure must be clearly provided. If applicable, analytical precision should also be stated. Statistical hypothesis must be clearly stated. Power of the study should be provided in relation to sample size calculation (it is recommended to use at least 80%). For a case control design, selection procedures for cases and controls must be explained in great depth. When applicable, matching procedure should also be clearly stated. For a diagnostic study or a clinical trial, it is recommended to refer to other reporting structures for example STARD, CONCORT, or STROBE.

Results:
Any insignificant precision should be avoided, especially when presenting data using table. A rounded data is easier to read and often decimal numbers are not essential. It is recommended for percentage data to report only one decimal digit (for example 27.9%). If the sample size is relatively small, it is strongly recommended to avoid decimal numbers. Data distribution must be reported in terms of mean, standard deviation, or coefficient variation percentage and must be reported as ‘mean (SD)’ instead of ‘mean ± SD’. If data are not normally distributed (after the Shapiro Wilk Test), median and interquartile range must be used to replace mean and standard deviation. A skewed data could be normalised by applying a logarithm or power transformation. All statistical analysis must use this transformed data which then must be re-transformed for data presentation. All individual values must be presented (if applicable) by deleting all overlapping values. Error bars which reflect standard error for each mean value or interquartile range for each median value can be used to guide data interpretation.

Each statistical test such as chi square test must be reported with the descriptive data, degree of freedom and p-value. Validity of each assumption prior to the test should be examined (for example data should be normally distributed when a t-test is used with the same variance for each data set). When a contingency table is used (2x2 table) for chi square test, continuity correction should be considered and if the expected count is low, the Fisher Exact value should be used. P-values should be clearly provided to show significance of such test. When the statistical test shows a very significant result and p-value from the computer program calculation is 0.0000, p-value should be presented as ‘p<0.0005’. Confidence interval must also be clearly stated, particularly for the insignificant results. As a general principle, statistical analysis should be reported as p ≤ 0.05. If another method is used, this must be clearly justified on the method section of statistical analysis.

Discussion:
A result of statistical test is not the most critical point of discussion. It is recommended that p-value should not be compared for different data set or for a different statistical analysis. Each association must not be interpreted as causal relationship without a sound supporting evidence.
Statistical issues:

Multiple Comparisons
This can cause misleading interpretation for significance values. Primary hypothesis must be clearly stated. Every association identified from a retrospective method must be interpreted with cautions. If applicable, one statistical test should be performed to all variables, for example ANOVA test. If this test is not significant, multiple comparisons thus can be applied. If ANOVA test is not applicable (or related statistical tests), multiple comparisons can be applied by referring to Bonferroni test.

Paired Data
For paired data, the difference for each pair and variability from these differences is more significant than the values of each individual. It is recommended to use graph for example plotted lines to present paired data.

Standard regression analysis
To perform this analysis, independent data are required (repeated measurements are not an independent data). Independent variables are measured without significant errors and all data must be normally distributed without outliers. These can be easily tested using a scatter plot diagram.

Method comparison
It is inappropriate to compare methods using regression and correlation coefficient. It is recommended to use the Altman and Bland Difference Plot. If regression and standard scatter plot are considered useful, it can be presented along with the Altman-Bland Plot. It should always be considered that if two methods are supposed to measure the same matter, it is highly possible that both are correlated, therefore correlation value provides limited information for interpretation. When a more complex statistical analysis is performed for example a multivariate analysis including ROC test or other tests, it is recommended that the authors should consult to statisticians.
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