



Received: 02 October 2018
Accepted: 15 May 2019
First Published: 21 May 2019

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Reviewing editor:
Amr Elshaer, United Kingdom

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PHARMACEUTICAL SCIENCE | RESEARCH ARTICLE

A comparative evaluation of written medicine information of antidiabetic medicines from Qatar, Australia and Europe

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Abstract: Background: Written medicine information (WMI) is valuable for health communication and encouraging the appropriate use of medicines by patients. Medicine regulations differ between countries, reflecting variations in WMI in terms of content and quality. The World Health Organization has recommended the provision of unbiased drug information to serve consumers. The objective of this study was to compare WMI of antidiabetic medications authorized for marketing in Australia, Europe, and Qatar using different quality criteria.

Methods: Twelve WMI that were approved by respective regulatory agencies (RAs) in Australia, Europe, and Qatar were selected for quality evaluations. The evaluation tools used in this study were the DISCERN instrument and the Ensuring Quality Information for Patients (EQIP) tool in addition to the Flesch reading ease (FRE) score, and the Flesch-Kincaid grade level (FKGL) formula.

Result: WMI from Qatar do not follow a specific format while those from Australia and the Europe follow the CMI and PIL formats, respectively. The best FRE and FKGL scores were achieved using WMI from Australia and Europe, respectively. There are significant differences ($p \leq 0.001$) between the EQIP scores of WMI from Qatar vs. Australia and the EMA, while there are no significant differences ($p = 0.134$) between the EQIP scores of WMI from Europe and Australia.

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PUBLIC INTEREST STATEMENT

The leaflet which accompanied the medicine is very important for the user to recall the important facts about the medicine and to effectively communicate with the pharmacist and physician. These leaflets are different in each country because of the governing laws and regulation; the difference can be in term of language, layout and formatting. We compare the quality of these leaflets which are available in Qatar against the ones from Europe and Australia. The leaflet from Western region and Australia were superior to those from the state of Qatar. The guidance for developing these documents were clear and tailored to the targeted users; while the law in Qatar didn't specify the quality and layout requirements for these leaflets. This kind of studies will help in making unified global guidelines that help patients to receive appropriate information about their medications(s).

Conclusion: The quality and content of WMI are highly variable between different sources with some countries exhibiting best practices. The findings suggest the need for harmonization of guidelines for development or format to ensure global standardization of patient friendly WMI.

Subjects: Research methods; Health Education and Promotion; Pharmacy & Dispensing

Keywords: Evaluation; written medicine information; Australia; Europe; Qatar

1. Introduction

Written medicine information (WMI) is valuable for encouraging the appropriate use of medicines by patients and assists in communication with health care providers; WMI is available as printable documents and package inserts (Luk, Tasker, Raynor, & Aslani, 2010). WMI is also referred to as patient information leaflets (PILs) or consumer medicine information (CMI) (Koo, Krass, & Aslani, 2005; Tong, Raynor, & Aslani, 2014). For the purpose of this paper, we use the term WMI to represent both PILs and CMI. WMI is developed and approved in accordance with guidelines, recommendations, and/or regulations specific to each country. Health care systems and medicine regulations differ between countries, which subsequently reflects the substantial variations in WMI in terms of content, terminology, design, layout, and quality (Luk et al., 2010). Countries such as New Zealand have stipulated mandatory regulations about the necessity of providing patients with appropriate drug information for their prescribed medicines (PHARMACY COUNCIL OF NEW ZEALAND, 2011). Other countries have no such legal regulations to provide such medicine information and hence no guidelines for manufacturers to develop these important documents (Young, Tordoff, & Smith, 2017). The implementation of the regulatory guidelines for WMI in different countries exhibits inconsistencies, partially due to limited resources and non-compliance (Reggi et al., 2003). For example, in Malaysia, the majority of dispensed medications in community pharmacies are not labeled adequately due to regulatory non-compliance, which exposes patients to the risk of medication errors (Neoh, Hassali, Shafie, Awaisu, & Tambyappa, 2009).

The World Health Organization (WHO) has recommended the provision of unbiased and reliable drug information on the website of each National Regulatory Authority (NRA) with the intention of serving both consumers and health care professionals (WHO, 2017a). The drug manufacturers and marketing authorization holders (MAHs) produce WMI in accordance with each country's requirements and regulations, which vary according to the scope of each manufacturer (Luk et al., 2010). The WMI guidelines vary between the regulatory agencies of different countries, which warrants the need for regular updates and modifications to meet patients' needs (Young et al., 2017). As a result of these regulatory variations across countries and the recognition of some by the WHO as "stringent regulatory authorities" (SRAs) (WHO, 2017b), it is worthwhile to assess the quality of WMI available in the State of Qatar compared to countries with established regulatory requirements. Our previous research evaluating the readability and comprehensibility of PILs for antidiabetic medications in Qatar revealed the inappropriateness of the evaluated PILs for the targeted patients and hence suggested the necessity of comparing Qatar's PILs to international counterparts (Munsour, Awaisu, Hassali, Darwish, & Abdoun, 2017).

2. Objective

The objective of this study was to compare WMI of antidiabetic medications authorized for marketing in Australia, Europe, and Qatar using different quality criteria.

3. Methods

3.1. Selection of written medicine information

The WMI of antidiabetic medications selected for this evaluation study were approved by the respective regulatory agencies (RAs), that is: the Ministry of Public Health (MoPH) in Qatar, the

Therapeutic Goods Administration (TGA) in Australia, and the European Medicines Agency (EMA). The EMA body composed of the 28 European Union (EU) member states and the 3 European Economic Area (EEA) member states. The selected WMI from Qatar are available along with the commercially dispensed antidiabetic medications in a tertiary care hospital setting; the hospital has no official policy or guidelines on the provision of WMI. Qatar has a multi-ethnic population, and all of the medicines for diabetes mellitus (DM) are imported from foreign countries (Awaisu et al., 2014). On the other hand, WMI from Australia and Europe were obtained from their respective website repositories. The selection criterion for WMI was based on the availability of the same brand name antidiabetic medications from the three sources to avoid variations within the generic WMI. Of 45 antidiabetic medications approved by MoPH-Qatar, only 12 similar brand names were approved by the TGA-Australia and the EMA-Europe. The 12 WMI hardcopies of antidiabetic medications from tertiary care hospitals were representative of Qatar's WMI. Qatar's WMI was verified for current regulatory status with their regulatory agency MoPH-Qatar.

The source of Europe's WMI is the EMA website, which in 1995 started operation in maintaining the efficacy, safety, and high quality of medicines in EU member states and member countries of the European Economic Area (EMA). The printable versions of WMI documents were retrieved from a searchable box under the subtitle "Find medicine" (EMA). The section "Package leaflet: Information for the user" of the downloaded document was considered in this study. Europe's WMI was selected on the grounds that antidiabetic medicines are among those that require centralized authorization by the agency and hence their WMI are representative of EU countries (EMA, 2017a). Australia's patient-targeted WMI is known as consumer medicine information (CMI) and was introduced in 1993 as a standardized document (Hamrosi, Raynor, & Aslani, 2014). Australia's CMI exhibited superior quality following the guidelines and templates outlined by the regulatory authority considering the production of appropriate content and layout (Jay, Aslani, & Raynor, 2011).

3.2. Evaluation tools

This evaluation tools used in this study were the DISCERN instrument and the Ensuring Quality Information for Patients (EQIP) instrument. In addition to the aforementioned tools, we recorded additional information related to the evaluated WMI such as the number of words, readability, and comprehensibility as measured by the Flesch reading ease score (FRE) and the Flesch-Kincaid grade level (FKGL) formula.

3.3. DISCERN instrument

DISCERN is a reliable and validated instrument for assessing the quality of written information on treatment choices developed by a group from Oxford University (Charnock, Shepperd, Needham, & Gann, 1999). It has been used since 1999 for the assessment of documents related to chronic conditions; it was expanded in 2008 to also assess online resources (Matsoukas et al., 2008). The DISCERN tool consists of 15 key questions, and a sixteenth question that indicates the document's overall quality score as evaluated by rater(s). The instrument's items are classified into three sections as follows:

- Section 1 (Questions 1 to 8): Assesses the reliability of the document to confirm if it is from a trusted information source.
- Section 2 (Questions 9 to 15): Focuses on information details as follows:
 - (a) Questions 9 to 11: Related to active treatment including self-care.
 - (b) Question 12: Related to no treatment option(s).
 - (c) Questions 9, 10, 11, 12, 13, and 15: Related to treatment mentioned in the document under evaluation.
- Section 3 (Question 16): Indicates the overall quality score as judged by the rater.

The response to DISCERN questions is on 5-point rating scale that ranges from “Yes” to “No” as follows:

- A score of 5 is awarded if the answer is definitely “Yes” and the quality criteria are completely met.
- A score between 2 to 4 is awarded if the question is partially answered and the document meets the quality criteria to some extent.
- A score of 1 is awarded if the answer to the question is definitely “No” and the quality is not fulfilled by the document.

3.4. The EQIP instrument

The EQIP is a reliable and validated tool to assess the quality of the written health care information and recommends a subsequent action for that particular document (Moult, Franck, & Brady, 2004). The EQIP is a 20-item checklist with four choices (“yes,” “partly,” “no,” and “does not apply”) (Promislow, Walker, Taheri, & Bernstein, 2010). Each item produces a score between 0 and 1 and an overall score ranging from 0 to 100 can be calculated using the below EQIP algorithm (Charvet-Berard, Chopard, & Perneger, 2008):

$$\% \text{ score} = ((\text{Yes} \times 1) + (\text{Partly} \times 0.5) + (\text{No} \times 0) / 20 - \text{Does not apply}) \times 100$$

The recommended action for the evaluated document considers the 75th quartile as a cut-off point for segregating the EQIP scores as follows (NHS, 2005):

- 76% and above: review in two to three years
- 51% to 75%: review in one to two years
- 26% to 50%: begin the review now and replace within six months to one year
- 0% to 25%: remove from circulation immediately

3.5. Evaluation process

The evaluation team comprised a drug information specialist, a drug regulatory pharmacist, two clinical pharmacists currently employed by the National Diabetes Center in Qatar, and two university professors who are experts in pharmacy practice research. Each of the 12 WMI used were approved by the respective regulatory authorities and were included in this evaluation exercise. All of the evaluators were thoroughly briefed about the EQIP and DISCERN instruments using their original guidelines and user manuals. Each WMI was independently evaluated by a panel consisting of two raters. We adapted the Delphi technique as the method of reaching consensus between the experts as explained by Keeney, Hasson, and McKenna (2006). The university professors approved the awarded score and finalized the findings of the two raters.

3.6. Ethical approval

Ethical approval was not required for this study and hence it was not sought.

3.7. Statistical analyses

The data analyses were performed using the IBM Statistical Package for Social Sciences (SPSS) program for Windows, version 21 (IBM, Armonk, NY, USA). Inferential and descriptive statistics were mainly used for the data analyses and the results were presented as the mean, standard deviation, frequencies, and percentages. One Way ANOVA, Kruskal-Wallis test and correlation analyses were used to compare between the three countries/regions. $P \leq 0.05$ was considered statistically significant.

4. Results

4.1. Characteristics of the evaluated WMI for antidiabetic medications approved in Australia, Europe, and Qatar

Thirty-six WMI documents were considered for evaluation from the three sources; each source was represented by 12 WMI with the same brand names to avoid inter-generic variability as discussed in a previous study (Munsour et al., 2017). All of the evaluated WMI documents described brand-name products, namely: Galvus® (vildagliptin), Januvia® (sitagliptin), Lantus® (insulin glargine) vial, Lantus® (insulin glargine) SoloSTAR®, NovoRapid® (insulin aspart) FlexPen®, NovoRapid® (insulin aspart) vial, NovoMix® (insulin aspart) FlexPen®, Humalog® Mix 75/25 (75% insulin lispro protamine suspension and 25% insulin lispro injection) KwikPen®, Actrapid® (human insulin) vial, Victoza® (liraglutide) injection, Levemir® (insulin detemir) FlexPen®, and Actos® (pioglitazone). We considered only the English version of the evaluated WMI. The 12 WMI from Qatar do not follow a specific format, while those from Australia and the EMA follow the CMI and PIL formats, respectively. The mean number of words of the 36 WMI was 3461.69 ± 1092.43 ; the minimum and maximum number of words were 1429 (Januvia-Qatar) and 6605 (Victoza-Qatar), respectively. A One Way ANOVA test of the evaluated WMI showed no significant effect of the source on the number of words ($F = 0.39$, $p = 0.675$). The details about the number of words from the different sources are described in Table 1.

4.2. Readability and comprehensibility of written medicine information

WMI for the accompanying DM products were tested for readability and comprehensibility as measured using the FRE and FKGL, respectively. The Kruskal-Wallis test indicated a significant effect of the source (Qatar vs. Australia vs. the EMA) on the readability ($H = 6.09$, $p = 0.048$) and similarly on the comprehensibility ($H = 6.41$, $p = 0.041$) of the 36 evaluated WMI. Table 2 presents the readability and comprehensibility scores of WMI from Qatar, Australia, and Europe.

4.3. EQIP evaluation

The mean EQIP for the 36 WMI was $61.60\% \pm 14.63\%$, the minimum EPIQ score was 22.50% (Humalog Mix 75/25 KwikPen-Qatar), and the maximum score was 85.00% (NovoRapid FlexPen-Australia). The mean EQIP scores for each country are shown in Table 3. The EQIP is expressed as a percentage score, where 100% is the highest quality document.

Table 1. Number of words of written medicine information from Qatar, Australia, and Europe

Source	Qatar	Australia	Europe
Galvus®	3472	2391	1925
Januvia®	1429	1868	1709
Lantus vial	3727	4092	3853
Lantus® SoloSTAR®	5011	4092	4046
NovoRapid® FlexPen®	3379	4495	4174
NovoRapid® vial	2771	4472	3499
NovoMix® 30 FlexPen®	3600	4777	4518
Humalog® Mix 75/25 KwikPen®	2616	3377	3005
Actrapid®	2069	4306	3117
Victoza®	6605	3115	3040
Levemir® FlexPen®	3299	4721	4205
Actos®	3245	2407	2194
Mean ± SD	3435.25 ± 1338.45	3676.08 ± 1012.92	3273.75 ± 943.56

Table 2. Readability and comprehensibility of written medicine information from Qatar, Australia and Europe

Source	FRE			FKGL		
	Qatar	Australia	Europe	Qatar	Australia	Europe
Galvus®	36.4	57.1	58.6	9.5	9.8	8.8
Januvia®	55.7	63.0	63.6	8.6	5.2	6.4
Lantus® vial	52.0	61.0	60.6	9.8	5.5	6.7
Lantus® SoloSTAR®	57.3	60.2	59.2	8.8	5.6	7.0
NovoRapid® FlexPen®	59.4	48.0	60.2	8.3	11.1	8.0
NovoRapid® vial	56.5	60.2	57.2	8.7	5.7	8.5
NovoMix® 30 FlexPen®	60.4	64.0	60.1	8.0	5.4	8.1
Humalog® Mix 75/25 KwikPen®	25.4	52.0	66.1	13.9	9.8	6.1
Actrapid®	62.0	50.9	58.0	7.2	10.4	8.2
Victoza®	25.0	59.8	64.1	14.1	8.0	7.6
Levemir® FlexPen®	60.8	61.8	59.3	7.9	7.9	8.2
Actos®	16.0	57.8	60.4	15.7	9.6	6.8
Mean ± SD	47.2 ± 16.7	58.0 ± 5.0	60.6 ± 2.7	10.0 ± 2.8	7.8 ± 2.3	7.5 ± 0.9

A one-way ANOVA test of the WMI EQIP scores indicated the significant effect of the source (Qatar vs. Australia vs. the EMA) on the EQIP scores ($F = 29.31, p < 0.001$). Tukey's post hoc test revealed that there was a significant difference ($p < 0.001$) between the EQIP scores of WMI from Qatar vs. Australia and Europe, while there was no significant difference ($p = 0.134$) between the EQIP scores of WMI from Europe vs. Australia.

4.4. DISCERN evaluation

The mean DISCERN score for the 36 evaluated WMI was 5 (mean = 4.39, SD ± 1.34) and the minimum and maximum DISCERN scores were 1 and 5, respectively. WMI from different sources exhibited variable DISCERN scores as determined by the Kruskal-Wallis test, $H = 16.70, p < 0.001$. We conducted pairwise comparisons with adjusted p -values that showed significant differences between Qatar's WMI vs. those from Australia and Europe (adjusted $p = 0.001$); no significant difference between WMI of Australia and Europe (adjusted $p = 1.000$) between them. The results of the quality evaluation using the DISCERN tool are shown in Table 3.

4.5. Correlation analysis

The linear correlation of the quality scores using the EQIP and DISCERN tools was analyzed using Pearson's correlation coefficient. There was a significant relationship between the DISCERN and EQIP scores of the evaluated WMI ($r = .811, p < 0.001$).

5. Discussion

WMI formats from the different sources (Qatar, Australia, and the EMA) varied. A previous study indicated international variations in the format, presentation, and quality between WMI from 6 English-speaking countries: New Zealand, the US, Canada, Australia, the UK, and Ireland (Luk et al., 2010). The WMI format from Qatar was heterogeneous in terms of content, layout and quality measure by EQIP and DISCERN tools. This may be due to the absence of guidelines by the regulatory authorities in Qatar. (MOPH-QATAR, 2017). WMI from Australia and the EMA followed a standardized

Table 3. EQIP and DISCERN evaluation of written medicine information from Qatar, Australia, and Europe

WMI	EQIP			DISCERN		
	Qatar	Australia	Europe	Qatar	Australia	Europe
Galvus®	40	65	62.50	1	5	5
Januvia®	52.50	67.5	65	3	5	5
Lantus® vial	52.50	75	57.50	5	5	5
Lantus® SoloSTAR®	57.50	72.5	67.50	5	5	5
NovoRapid® FlexPen®	50	85	70	5	5	5
NovoRapid® vial	55	77.5	67.50	5	5	5
NovoMix® 30 FlexPen®	55	77.5	72.50	5	5	5
Humalog® Mix 75/25 KwikPen®	22.50	62.5	62.50	1	5	5
Actrapid®	47.50	77.5	60	3	5	5
Victoza®	30	77.5	70	1	5	5
Levemir® FlexPen®	60	80	72.50	3	5	5
Actos®	27.50	60	62.50	1	5	5
Mean ± SD	45.83 ± 12.71	73.12 ± 7.70	65.83 ± 4.92	3.17 ± 1.80	5	5
Minimum	22.50	60	57.50	1	5	5
Maximum	60	85	72.50	5	5	5

format (EMA, 2016; TGA-AUSTRALIA, 2014). The number of words of the evaluated WMI across the varying countries exhibited no significant differences. Some individual WMI demonstrated substantial differences in the number of words among the countries. For example, the number of words of Galvus (vildagliptin), NovoRapid (insulin aspart) FlexPen, NovoRapid (insulin aspart) vial, Actrapid (human insulin) vial, Victoza (liraglutide) injection, and Levemir (insulin detemir) FlexPen had a difference of more than 1000 words across the countries as shown in Table 1.

The readability of WMI from Qatar and the two regulated markets exhibited statistically significant differences in their FRE and FKGL scores. The most readable WMI documents were from Europe as demonstrated by the mean FRE score of 60.6 (± 2.7), while the scores from Australia and Qatar were 58.0 (± 5.0) and 47.2 (±16.7), respectively. The minimum acceptable FRE score is ≥ 60 (Mason & Williamson, 2018). Hence, only WMI from the EMA achieved this standard score. A systematic review revealed that WMI had various readability issues such as complex text, inadequate font size, and a lack of relevant pictograms (Pires, Vigario, & Cavaco, 2015). A study involving the evaluation of randomly selected WMI in Australia reported a mean FRE score of 51 (± 6.8, range 37–60) (Baker, 1997); this score indicates that the readability was “fairly difficult,” which was similar to our finding with respect to Australian WMI, that is, 58 (± 5.0). Furthermore, the acceptable comprehensibility range was the sixth to eighth grade levels of the US educational system (Luk et al., 2010). The mean FKGL scores were 10 (± 2.8), 7.8 (± 2.3), and 7.5 (± 0.9) for Qatar, Australia, and the EMA, respectively. This implies that the WMI from Australia and Europe required eighth grade level comprehension, while Qatar’s WMI required tenth grade level comprehension. A previous study of WMI from six English-speaking countries (Luk et al., 2010) reported that Australian WMI exhibited the lowest FKGL score and hence was the best understood. A comparative study of WMI from the US, the UK, and Australia using US keystone criteria reported the Australian WMI to be superior (Raynor et al., 2007).

Similar to our findings, the UK antidepressant WMI presented an acceptable FKGL score of 7.3 (Haw & Stubbs, 2011). The European WMI for biological medicine evaluated between 2007 and 2013 exhibited no comprehensibility improvement as measured by the FKGL (range 13.3–18.6) (Pinerolopez, Modamio, Lastra, & Marino, 2016), which was contrary to our findings that reported the mean FKGL score of the European WMI of 7.5 (\pm 0.9).

The advantage of the EQIP score is its ability to be converted into an “action recommendation” for the evaluated document and is interpreted as follows (NHS, 2005):

EQIP score	Recommended action
\geq 75	Continue to stock; review in 2 to 3 years
51 to 75	Continue to stock; review in 1 to 2 years
26 to 50	Continue to stock; begin review now and replace within 6 months to 1 year
0 to 25	Remove the document immediately

The recommended action for the evaluated WMI is as follows:

Source	EQIP score	Recommended action
Australia	73.12	Continue to stock; review in 1 to 2 years
EMA	65.83	Continue to stock; review in 1 to 2 years
Qatar	47.08	Continue to stock; begin review now and replace within 6 months to 1 year

The aforementioned EQIP scores indicate the superiority of WMI from Australia and the EMA compared to Qatar’s WMI. The difference in EQIP scores among the three regions is statistically significant; Qatar’s WMI was of low quality compared to counterparts from Australia and Europe as measured using the EQIP tool.

The median DISCERN scores of the evaluated WMI from Qatar, Australia, and Europe were 3, 5, and 5, respectively. The DISCERN scores indicated the better quality of WMI from Australia and Europe over Qatar’s WMI. Furthermore, the pairwise comparisons indicated a statistically significant difference between Qatar’s WMI and Australian and European WMI, while European and Australian WMI showed no statistically significant difference. A study comparing WMI from the US and Europe reported inconsistencies in the ADR data of the evaluated brand-name drugs in these countries (Cornelius, Liu, Peacock, & Sauzet, 2016). There were substantial variations in warning information contained in WMI from the US, Canada, the UK, and Australia that negatively affected patient safety and this mandates the international standardization of these leaflets (Kesselheim, Franklin, Avorn, & Duke, 2013). Boxed warnings of drug labels along with contraindications, precautions, warnings, and pregnancy categories from Australia, the US, and the UK vary; boxed warnings from the US are approximately 10 times longer and more detailed than those from Australia (Buckley & Rossi, 2011).

Approximately 93% of WMI accompanying imported drugs were of lesser quality compared to those locally produced as reported by a comparative study in Palestine (Qatmash et al., 2017). The package insert of drugs marketed in Saudi Arabia had limited and incomplete information compared to the corresponding brand drugs marketed in the US (Bawazir, Al-Hassan, Al-Khamis, Abou-Auda, & Gubara, 1991). An international comparative study involving 26 countries reported substantial inter-country and intra-country differences that can affect patients and prescribers (Reggi et al., 2003). The drug information contained in leaflets produced by pharmaceutical companies and approved by the NRA exhibited better quality than those from the Internet according to a study conducted in Spain (Mira et al., 2013). The differences in prescribing information between countries affects international

patients and health care providers concerning drug utilization and the development of treatment guidelines (Reggi et al., 2003).

6. Conclusion

The inter-country variations in the quality of WMI may be partly explained by different legislative frameworks and implementation due to resource limitations (Reggi et al., 2003). Australia and Europe's WMI performed better than Qatar's WMI in terms of quality, readability, and comprehensibility criteria. There are shortcomings in the legislative framework for the development and quality requirements for WMI in Qatar. The findings suggest the need for harmonization of guidelines for development of patient friendly WMI or format to ensure global standardization of patient friendly WMI.

Funding

The authors received no direct funding for this research.

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Citation information

Cite this article as: A comparative evaluation of written medicine information of antidiabetic medicines from Qatar, Australia and Europe, Emad Eldin Munsour, Ahmed Awaisu, Mohamed Azmi Ahmad Hassali, Hamda Ali & Zeinab Dabbous, *Cogent Medicine* (2019), 6: 1620904.

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