Gaps in Laboratory Quality Management Systems in the Volta Region of Ghana

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Authors' contributions

This work was carried out in collaboration between all authors. Authors EA and GKD conceived the idea. Authors EA and GKD performed on-site audit, data collection and analysis. Author EA prepared the initial draft of the manuscript. Authors EA, GKD, LQ, RAK, SYL, PA and FB were involved in the final draft of the manuscript. All authors read and approved the final manuscript.

Article Information

Original Research Article

ABSTRACT

Background and Aim: Laboratories play a key role in the control and prevention of diseases through the provision of accurate, reliable and timely results. Coordinated activities to direct and control the laboratory with regard to quality is Quality Management Systems (QMS). The study assessed gaps in the QMS of some district laboratories in Ghana.
Study Design: Non-interventional exploratory study.
Place and Duration of Study: Volta Region of Ghana, February to March 2016.

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Methodology: The Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist by World Health Organization's Regional office for Africa (WHO/AFRO) was used to assess six district laboratories in the Volta Region of Ghana. The six facilities were randomly selected to include laboratories from each of the three sectors (northern, middle, and southern) of the region. The northern sector laboratories were designated N1-HMH and N2-NDH, middle sector (M1-HMH, M2-ADH), and southern sector (S1-SDH, S2-ADH).

Results: The SLIPTA scores for the facilities were all < 55% (0-142points) which is a zero star in the 0-to-5 star rating using the WHO/AFRO laboratory strengthening tool. The S1-SDH laboratory recorded a total score of 17.4% (45points), S2-ADH 11.6% (30points), M1-HMH 17.8% (46points), M2-ADH 9.7% (25points), N1-HMH 5.4% (14points), and N2-NDH 4.7% (12points). M1-HMH had the highest SLIPTA score whilst N2-NDH reported the least score. The Quality System Essentials (QSEs) measured were below 50%. "Management Reviews", "Internal Audit", "Corrective Action", "Client Management and Customer Service" were not performed by any of the facilities whilst "Organization and Personnel" was highly performed. On the average SLIPTA score, the southern sector laboratories performed better whilst the northern sector laboratories exhibited the least performance in relation to QMS.

Conclusion: The star level recorded by the facilities is zero (0) based on 0-to-5 star rating. This implies that the total laboratory QMS is very weak and various stakeholders are encouraged to focus on strengthening district laboratories for effective healthcare delivery. This is a detailed baseline data for measuring improvement through future interventions.

1. INTRODUCTION

Laboratory quality involves accuracy, reliability and timeliness of reported test results. Laboratory Quality Management System (QMS) comprises coordinated activities to direct and control the processes, procedures and policies in the laboratory with regard to quality [1]. Health systems require quality and reliable laboratory services for effective and well-functioning systems. Routine health care, medical research, and public health systems are not serviceable without quality medical laboratory services. In many sub-Saharan African countries, medical laboratory systems are adversely affected by the absence of medical laboratories, deprived laboratory set-up and lack of professionals. Quality in the laboratory is only achieved in a logical way through the application of a quality management system [2-4].

Few developing countries have established laboratory quality standards that are affordable, easy to implement and monitor. To address this challenge, the World Health Organization Regional Office for Africa (WHO AFRO) established a stepwise approach, using a 0-to-5 star scale to fulfil ISO 15189 standard rather than pass-fail grading [1,3]. WHO AFRO's accreditation process is not intended to replace established ISO 15189 accreditation schemes, but rather to provide an interim pathway to the realization of international laboratory standards [3]. There was a recommendation that the Government of Ghana pass a law and establish a standard to regulate medical laboratories in the country in order to improve quality in clinical laboratories [2]. Before this recommendation, various advocacy meetings were held in the African region to strengthen laboratory systems. In one of these meetings, the Stepwise Laboratory Accreditation Preparation Scheme was launched by WHO AFRO. Laboratories that demonstrate outstanding performance in the WHO AFRO process will be strongly encouraged to enroll in an established ISO 15189 accreditation scheme for medical laboratories [5,3].

All activities in the laboratory is divided into twelve (12) Quality System Essentials (QSEs) captured in a model developed by the Clinical and Laboratory Standards Institute (CLSI). These include: Organization, Personnel, Equipment, Purchasing and inventory, Process control, Information management, Documents and records, Occurrence management, Assessment, Process improvement, Customer service, Facilities and safety. To achieve quality, each of the QSEs must be considered in quality improvement projects [1]. The quality model is compatible with ISO 15189 standard and WHO AFRO SLIPTA Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist for assessing laboratories [1].

Sixty-five (65) laboratories are located in the various districts in the Volta Region. No public

sector clinical laboratory had attained international standard in Ghana. At the time of this study, fifteen (15) laboratories had initiated the Strengthening Laboratory Management Towards Accreditation (SLMTA) programme in Ghana and only six (6) were with a certification with a level of quality based on number of stars. The Volta Regional Hospital Laboratory was the only facility from the Volta Region which had attained a three (3) star level during the exit assessment by the African Society of Laboratory Medicine (ASLM). QMS is uncommon in the nation's clinical laboratories which could lead to gaps (non-conformities) in the quality system of our laboratories. The present study therefore sought to identify the gaps in the QMS of selected district hospital laboratories using QSEs as indicators to provide baseline information for future interventions.

2. MATERIALS AND METHODS

2.1 Study Area

Volta Region was the study area and is one of Ghana's ten (10) administrative regions. The region is located west of Republic of Togo. An area of 20,570 square kilometers representing 8.6% of Ghana is covered by the region. It has 65 district laboratories which are involved in laboratory investigations in the various hospitals (Fig. 1).

2.2 Study Design

This was a non-interventional exploratory study to investigate the practice of QMS in district laboratories in the Volta Region of Ghana. The study was conducted between February and March, 2016 involving six laboratories. The region was divided into three sectors (northern, middle, and southern) as shown above in Fig. 1. Two district laboratories were randomly selected from each sector. The laboratories enrolled into the study were designated S1-SDH, S2-ADH, M1-HMH, M2-ADH, N1-HMH, and N2-NDH. S1-SDH and S2-ADH were laboratories from the southern sector; M1-HMH and M2-ADH from the middle belt; N1-HMH and N2-NDH from the northern sector of the region. Data collected comprised activities by laboratory staff during on-site visits and evidence of documentations (policies, processes and procedures). Permission was sought from Senior Managers for each facility and Laboratory Managers offered their consents before data was collected.
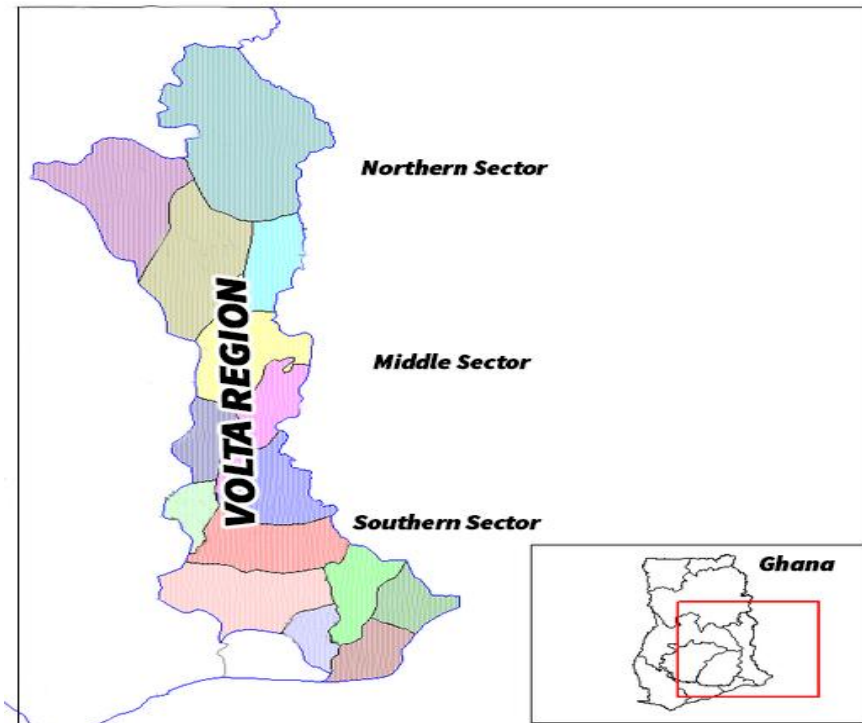

Fig. 1. Map of Ghana and the Volta Region
(*Source: Wikipedia. Accessed 15 January 2017*)

2.3 Preparation for the Assessment

Participating facilities were given notification prior to the audit through the Regional Health Director, The District Directors, The Medical Superintendents, The Administrators and the Laboratory Managements. The checklist for the assessment (WHO AFRO SLIPTA) was given to the facilities to study and prepare for the audit. Quality Manuals were requested from the laboratories on the day of assessment.

2.4 Access to the Facilities

Introductory meeting with senior management members and laboratory staff was held to introduce the audit plan on the day of assessment. The nature and expectations of the audit team were discussed.

2.5 Presentation of Findings

A brief final closing meeting was held after the preliminary audit report to present and discuss findings. Major and minor non-conformities identified were discussed at the meeting. Laboratory staff were given the opportunity to respond to the findings. After accepting the findings, a final report was submitted to the laboratory and hospital management. The laboratory staff agreed to address the non-conformities and management pledged their support to fill the gaps. Combined audit report involving all the facilities was submitted to the Regional Director of Health.

2.6 Survey Tool

2.6.1 Quality management systems in the laboratories

A checklist developed by the World Health Organization in the African Region for Stepwise Laboratory Quality Improvement Process Towards Accreditation (WHO AFRO SLIPTA) was used to collect data from the field. Data was collected through observations and interviews by a trained auditor, the first author (EA) and assisted by the second author (GK) of the manuscript. The checklist contained 12 sections with 334 questions for a total of 258 points. These sections are categorised as: "Documents and Records", "Management Reviews", "Organization and Personnel", "Client Management and customer service", "Equipment", "Internal Audit", "Purchasing and Inventory", "Process Control and Quality Assessment", "Information Management", "Corrective Action", "Occurrence/Incident Management and Process Improvement", "Facilities and Safety". Each laboratory was graded from Zero to Five stars based on total audit score. Total audit score of < 55% (0-142 points) represents Zero Star; 143-165 points (55-64%) represents 1 Star; 166-191 points (65-74%) represents 2 Stars; 192-217 points (75-84%) represents 3 Stars; 218-243 points (85-94%) represents 4 Stars and 244-258 points (≥ 95%) represents 5 Stars. The scoring system in the checklist has three sections designated as; Y = Yes, P = partial, N = No. Each item (question) has the options Y, P, or N. Each item has been awarded a point value of 2, 3, 4 or 5 points based upon relative importance and/or complexity. Some items have certain elements (sub-questions). All elements of an item must be satisfactorily present to indicate "Yes" and thus award the corresponding points. Items marked "P" and "N" receive 1 point and 0 point respectively [6].

2.6.2 Gaps using quality system essentials (QSEs) in laboratory practice

The twelve sections of the SLIPTA checklist encompassed the QSEs. Gaps were identified based on the audit report of the checklist. Gaps were the non-conforming policies, processes and procedures compared to the standard (WHO AFRO SLIPTA).

2.7 Data Analysis Plan

Data was analysed using Microsoft Office Excel 2013 and STATA software (Stata 14.0, Statacorp, Texas, USA). The scores were summarised and results presented as relative frequencies. Average scores were also generated from the data to represent the three sectors of the region. P-value less than 0.05 was considered significant.

3. RESULTS

3.1 Quality Management Systems in the Laboratories

All the facilities were not able to provide enough documents as evidence for their on-site processes or procedures. Therefore, a comprehensive laboratory policy was a new terminology for the managers. However, the six managers provided national policies in relation to certain procedures. The total SLIPTA scores for

the facilities were < 55% (0-142points) which is equivalent to zero (0) star. S1-SDH had total SLIPTA score of 17.4% (45/258), S2-ADH 11.6% (30/258), M1-HMH 17.8% (46/258), M2-ADH 9.7% (25/258), N1-HMH 5.4% (14/258), and N2-NDH 4.7% (12/258). M1-HMH had the highest SLIPTA score (17.8%) whilst N2-NDH reported the least score (4.7%). S1-SDH facility had the second highest score (17.4%) followed by S2-ADH (11.6%). This showed that none of the facilities was able to score >50% in QMS. The average score for the southern sector was 14.5%. The middle and northern sectors had average scores of 13.8% and 5.1% respectively. On the average, the southern sector of the region recorded the highest SLIPTA score (Table 1, Fig. 2).

3.2 Quality System Essentials in Laboratory Practices

Management Reviews, Internal Audit, Corrective Action, Client Management and Customer Service were not performed by any of the facilities whilst Organization and Personnel was highly performed by all the facilities. N1-HMH and N2-NDH laboratories scored 4.0% (1/25) in possession of Documents and Records for their practices. The facility S1-SDH had the highest score 28.0% (7/25) for Documents and Records followed by M1-HMH 24.0% (6/25). The highest score 45.0% (9/20) for Organization and Personnel was reported by M1-HMH whilst N1-HMH and N2-NDH both had the lowest score of 10.0% (2/20). With regards to Equipment, the highest and least scores were 16.7% (5/30) and 6.7% (2/30) respectively. S1-SDH and M1-HMH recorded the highest score and the least was N1-HMH and N2-NDH. S1-SDH and M1-HMH had the same score for Purchasing and Inventory 20.0% (6/30). This was the same for Equipment records. In terms of Process Control and Quality Assessment, the scores were not different for S2-ADH and M2-ADH 6.1% (2/33); N1-HMH and N2-NDH 3.0% (1/33); M1-HMH and S1-SDH 12.1% (433). The scores for Information Management showed slight variation in the facilities except 5.6% for N1-HMH and N2-NDH. Only three laboratories: M1-HMH, S2-ADH, and S1-SDH scored 25%, 8.3% and 16.7% respectively for Occurrence/Incident Management at the time of study. However, Facilities and Safety records vary among the participating facilities (Table 1, Fig. 2).

Table 1. Quality system essentials scores for each laboratory

Sections	Laboratories						
	Actual score	S1-SDH	S2-ADH	M1-HMH	M2-ADH	N1-HMH	N2-NDH
		Pts (%Score)	Pts (%Score)	Pts (%Score)	Pts (%Score)	Pts (%Score)	Pts (%Score)
Documents & Records	25	7 (28.0)	4 (16.0)	6 (24.0)	2 (8.0)	1 (4.0)	1 (4.0)
Management Reviews	17	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Organization & Personnel	20	8 (40.0)	7 (35.0)	9 (45.0)	5 (25.0)	2 (10.0)	2 (10.0)
Client Management & Customer Service	8	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Equipment	30	5 (16.7)	3 (10.0)	5 (16.7)	4 (13.3)	2 (6.7)	2 (6.7)
Internal Audit	10	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Purchasing & Inventory	30	6 (20.0)	4 (13.3)	6 (20.0)	5 (16.7)	4 (13.3)	3 (10.0)
Process control & Quality Assessment	33	4 (12.1)	2 (6.1)	4 (12.1)	2 (6.1)	1 (3.0)	1 (3.0)
Information Management	18	3 (16.7)	2 (11.1)	4 (22.2)	2 (11.1)	1 (5.6)	1 (5.6)
Corrective Action	12	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Occurrence/Incidence Management	12	2 (16.7)	1 (8.3)	3 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)
Facilities & Safety	43	10 (23.3)	7 (16.3)	9 (20.9)	5 (11.6)	3 (7.0)	2 (4.7)
Total	258	45 (17.4)	30 (11.6)	46 (17.8)	25 (9.7)	14 (5.4)	12 (4.7)

Key:
1. *Southern Sector Laboratories (S1-SDH, S2-ADH), Middle Sector Laboratories (M1-HMH, M2-ADH), Northern Sector Laboratories (N1-HMH, N2-NDH).*
2. *Pts = Points scored (n).*
3. *Actual Score = N*
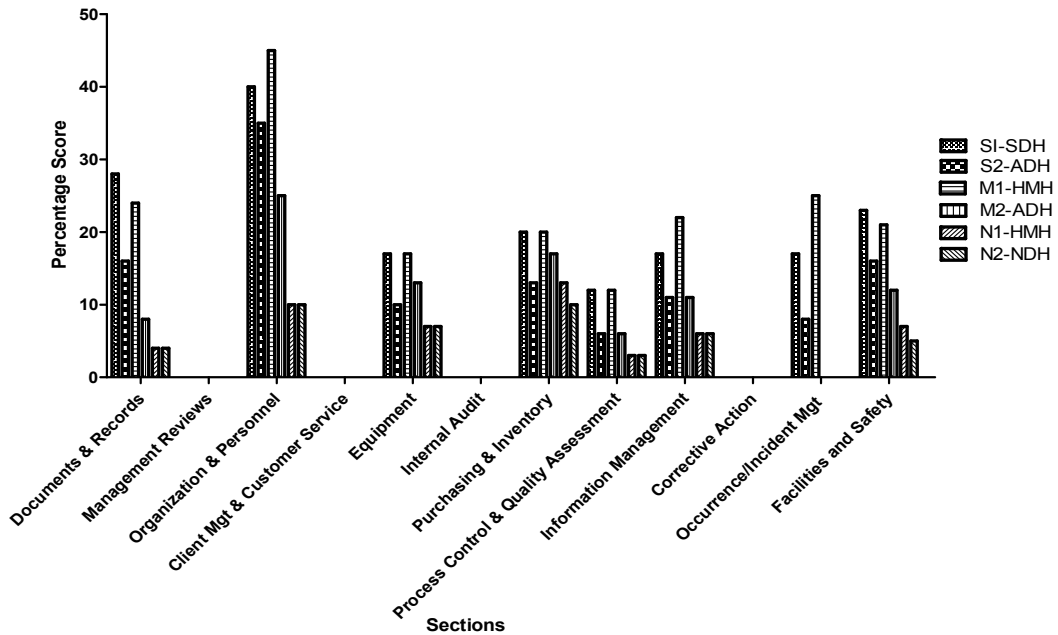4. *%Score (Percentage Score) = n / N*

Fig. 2. Percentage QSE scores for the facilities

4. DISCUSSION

This study sought to assess laboratories in the Volta Region of Ghana using QSEs as indicators, to possibly identify gaps (nonconformities) in the QMS that could be addressed to improve upon diagnosis and patient management in these parts of the country.

In the Volta Region, sixty-five (65) laboratories were located in the various districts and sub-districts at the time of this study. To build local capacity and enhance commitment to the implementation of QMS in laboratories nation-wide, the Ghana Health Service, an agency of the Ministry of Health came up with a National Laboratory Strategic Plan in 2012 [2]. Hence, the current study could justify the progress or evaluate the implementation of this five-year strategic plan. Although Ghana adopted SLMTA in 2009 with 15 laboratories enrolling, including national and regional laboratories, this study revealed that QMS implementation was relatively unknown to the facilities explored. The programme implementation excluded district and sub-district laboratories at the time for various reasons including costs. In the Volta Region, only the Regional Hospital Laboratory was involved in the programme and was graded "3 star" laboratory

through an audit by ASLM in 2014 (Unpublished data).

The SLIPTA scores for the study facilities were < 55% (0-142points). The same was reported by Nkrumah and his colleagues at a baseline audit [7]. However, compared to previous reports in the country, none of the facilities enrolled onto SLMTA programme audited by ASLM scored < 55% (0-142points). The least star level was one (1) achieved by a reference laboratory in the country, Ghana (Unpublished data). The score of < 55% also conforms to a study in Ethiopia where the average SLIPTA audit score of 41% was recorded at baseline [8]. In Ghana, the low SLIPTA score recorded could be due to lack of involvement of the district facilities in QMS. This is evident that district laboratories must also be strengthened to provide accurate, trusted and reliable results for good healthcare delivery. Earlier studies have posited that lack of laboratory QMS in educational curriculum and continuous professional development could be responsible for the low SLIPTA scores [5,9,10]. In our opinion, the Regional Hospital Laboratory can mentor other facilities to also achieve a certain standard of operation. The above opinion and other possible suggestions could however be subjected to debate by various stakeholders in educational and healthcare delivery in the region and the country. Hence, management

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engagement and commitment are critical in laboratory service delivery. Management is responsible for provision of resources for improvement projects, recruitment of well-trained certified professionals and motivating staff to accept quality. This is supported by similar studies in Tanzania [5], Uganda [11] and Ghana [7]. To establish and solidify QMS and to help laboratories achieve their quality improvement goals, mentorship and training should be emphasized [12,13]. Mentoring and training will create awareness and understanding to implement quality systems in medical testing laboratories. Evidence-based training on various aspects of laboratory activities should be implemented [12]. This can also take the form of continuous professional development programmes for the implementing facilities. The baseline information provided by this study will therefore help devise strategies for QMS implementation in the various facilities in the Volta Region.

Management Reviews, Internal Audit, Corrective Action, Client Management and Customer Service as QSEs recorded no point. This implies that none of the participating laboratories performed the above QSEs. This conforms to a previous study in Ghana where QSEs such as Internal Audit, Occurrence Management, Corrective Actions and Management Reviews scored a median of ≤ 35% at the exit audit [7]. Another study in Ethiopia revealed that at both the baseline and exit audits, lower scores were observed for Internal Audit (6% baseline and 18% exit), Occurrence Management (14% and 29%), Corrective Action (31% and 41%), and Management Reviews (32% and 44%) [8]. Others also identified Internal Audit and Corrective Action as the lowest scoring sections (<50%) [14]. These key areas in QMS are critical but are commonly low-scoring QSEs as reported in other African countries [15,16]. This may be due to lack of management commitment in the laboratories and inexperience in audit skills. Lack of planning, implementation and monitoring of laboratory policies, processes and procedures may also be a cause. Similar study reported inadequate staffing levels and lack of motivation amongst some staff members [7]. In Ethiopia, Lulie and friends also reported similar causes in addition to other relevant causes of low QSE scores through focus group discussions [17].

The overall total QMS in the facilities enrolled was very weak. The study outcome emphasizes the need to urgently strengthen and improve

laboratory service delivery at the district level. This is because laboratories test results are used in clinical and public health settings, and health outcomes depend on the accuracy of the testing and reporting. One major characteristic of test results is reproducibility. Moreover, if inaccurate results are produced, the consequences can be very significant. Delay in correct diagnosis, treatment complications, unnecessary treatment, and failure to provide proper treatment are some of the devastating consequences.

5. CONCLUSION

Laboratory QMS is very weak in the region. All the facilities were at a star level of zero (0) based on 0-to-5 star rating by WHO/AFRO laboratory strengthening checklist. This implies that, laboratory results from these facilities may not be reproducible. For future interventions, this is a valuable and detailed baseline data for monitoring improvement projects.

6. RECOMMENDATION

The study strongly recommends involvement of all district laboratories and health centre facilities in the region to gradually implement QMS. For better implementation of QMS in the laboratories, management at all levels must be committed. The laboratory staff must accept quality management in its context and own the process. The staff must also consider each process, procedure and policy as key performance indicators to achieving quality. We also recommend continuous professional development programmes in QMS for laboratory staff. The training will equip them with the fundamental skills in quality for better laboratory service delivery which is decisive for patient diagnosis. It is therefore necessary that, the Government of Ghana, Ministry of Health, Ghana Health Service, and other responsible agencies focus on strengthening district laboratories in the regions for quality healthcare delivery. Trained, qualified and certified Laboratory Technologists and Managers should be employed by the stakeholders. Furthermore, educational curricula in the laboratory sciences should be revised to include Laboratory QMS.

CONSENT

Laboratory Managers gave their consent to participate in the study.

ETHICAL APPROVAL

Prior to the study, clearance was sought from the senior management of the facilities.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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Peer-review history:
The peer review history for this paper can be accessed here:
http://www.sciencedomain.org/review-history/22952