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Review of Training and Education Standards Applied to Pharmacy Based Travel Medicine Services in the UK

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Abstract

Background: The history of pharmacy based travel medicine services was originally published in 2018. This article reviews the current training and education standards against the regulators and professional standards.

Professional standards: The provision of travel health services standards were assessed by different regulators for the professions giving rise to variances in the inspection processes and a dependence on self-assessment. The principal of self-assessment had been criticised due to practitioner's inaccuracy in the determination of competency.

International and National Training Standards: The International Society of Travel Medicine (ISTM) offers an education course with guidance on the proportioned time for study in the key areas. This was compared to the provision by the UK agency responsible for of PGDs and the NHS providers of travel health advice to identify the areas of variation from an international standard. A review of PGD providers showed a wide variation in the length of time for self-determination and assessment when compared to the specialist providers.

Discussion: The training time for a single study was suggested as a 50 hours modular course and the key areas needed to include pretravel risk consultation and immunology/vaccinology. When considering the travel consultation process in the UK, the immunisation technique was the only identified area with formal assessment; however this was only 5% of the suggested international standard and was not mandatory. This was unlike other high income countries which have defined mandatory training and licensing before a travel health service can be supplied by a pharmacists. The potential for increased patient risk continues to rise without any formal education or assessed pharmacy standards. To provide uniform consistent standards the same standardised education and inspection should be provided by all the regulatory agencies. These standards should follow a similar pathway to the national immunisation standards involving education and have a mandatory standard of competence assessed externally before independent practice is allowed. The pharmacy regulator is introducing new inspection standards but it is unknown if these will involve mandatory assessment before practice in the future.

Conclusion: The current pharmacy system is not fit for purpose for use of PGDs without additional training. This assessment/inspection should involve all the areas of the service provision including vaccination technique, education and training and an external level of assessed competence. Both the PGD regulating authority and the pharmacist regulator have the authority to commit to uniform practice across all professions.

Keywords: Pharmacy; Patient group direction; Prescriptions

Introduction

The practice of pharmacy based travel medicine services in the UK has continued to grow since the early 2000s when changes in legislation were made to the supply function. At this time the creation of the Patient Group Direction (PGD) allowed any pharmacist to supply a prescription only medicine (POM) without the need of a prescription, to any patient that came within the inclusion list of allowable conditions [1].

This supply function, was originally intended for the provision of influenza vaccination, and naturally evolved to include other vaccination based services such as travel medicine. The original paper investigated the need for mandatory advanced level education only advanced level practical training (i.e., vaccination technique, basic life support skills and anaphylaxis) was externally assessed before practice commenced.

Literature Review

This review looks at the variation in advanced level training between PGD suppliers and specialist providers to determine the variations in time and knowledge in the training support and the inspection powers of the regulators. Pharmacy travel health services can be provided as a NHS or non-NHS (private) service in the primary healthcare sector and hence this review is produced for this journal as the service can be supplied by other healthcare professionals.

For the purposes of this review the term of travel health and travel medicine are used individually, the author acknowledges there is no legally defined standards for the use of these titles, but professionally a differential exists.

- **Travel medicine**

It is a branch of medicine that specialises in diseases and conditions that are acquired during travel [2].

- **Travel health**

It discusses about what to think about before travel [3].

From the above definitions a range of services can be provided, under either heading, for travel within community pharmacy. It is usual

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to consider the natural extension from flu vaccination into a travel vaccination service. When this is combined with a detailed pre-travel risk assessment to develop a risk management plan then a travel health service is started [4]. Following the first definition when post-travel diagnosis and screenings are involved then a full travel medicine service is being provided, which is outside the range of the many community pharmacies.

It is important to realise that the levels of clinical training and education will vary according to the range of services supplied. This will extend as a spectrum, from supplying anti-malarials to providing some travel vaccinations, through to a service supplying extensive specialist knowledge in travel medicine. The impact of the amount of time given to training and education therefore should reflect the service levels that can be provided.

Professional Assessment

The approach to practitioner self-assessment was discussed in a systematic review of doctors which concluded, "The preponderance of evidence suggests that physicians have a limited ability to accurately self-assess. The processes currently used to undertake professional development and evaluate competence may need to focus more on external assessment" [5].

From this proposal comes the conclusion that an external system of evaluators and assessors should be in place rather than a reliance on self-assessment. The obvious choice of assessors should be the commissioners of service (if contracted by a public body) or by one of the regulatory bodies (if a private service).

Within the UK the pharmacy professional standards are assessed by a the Inspectorate of the General Pharmaceutical Council (GPhC) and the other health care professions by the Care Quality Commission (CQC) for both public and private bodies.

Pharmacy Professional Standards

Within the UK the professional practice standards are set and regulated by the General Pharmaceutical Council (GPhC). The new professionals standards set in 2018 [6] place the emphasis of competence and assessment to practice on the individual pharmacist and their personal interpretation.

This is demonstrated in the following:

Standard 4 - Pharmacy professionals must maintain, develop and use their professional knowledge and skills

People receive safe and effective care when pharmacy professionals which include:

- Recognise and work within limits of their knowledge and skills, and refer to others when needed
- Carry out a range of continuing professional development (CPD) activities relevant to their practice
- Record their development activities to demonstrate that their knowledge and skills are up to date
- Use a variety of methods to regularly monitor and reflect on their practice, skills and knowledge

Standard 5 - Pharmacy professionals must use their professional judgement

People receive safe and effective care when pharmacy professionals which include:

- Use their judgement to make clinical and professional decisions with the person or others
- Have the information they need to provide appropriate care
- Recognise the limits of their competence

Care Quality Commission

The provision of travel medicine services to other health care professions in the UK is regulated by a division of the Medicines Health Regulatory Agency (MHRA) called the Care Quality Commission [7] (CQC). The key lines of enquiry (KLOEs) sets out to find evidence that answer 5 key questions. One of these is that staff is assessed and their needs are supported by others with the right skills and knowledge.

Historically, when the Health and Social Care Act 2012 was introduced part 3 detailed the provisions for registration by the CQC and part 8 established the National Institute for Health and Care Excellence (NICE) to develop healthcare standards. Importantly this legislation indicated that "community pharmacies will not have to register with the CQC provided that they are engaged only in dispensing and associated activities, nor will registration be required for diagnostic testing of the simplest kind. However, prescribing, clinical services or services designed to promote health and wellbeing may become subject to registration requirements." (Table 1) [8].

As the CQC have no legal jurisdiction in pharmacies, these are inspected by the (GPhC) inspectorate team. With no legal requirement for same standards, the 2 inspecting agencies have evolved differently for the monitoring, supply and provision of the same healthcare

CQC [7]	GPhC [9]
KLOE are the services Well-led: The leadership, management and governance of the organisation make sure it's providing high-quality care that's based around your individual needs, that it encourages learning and innovation, and that it promotes an open and fair culture.	'Governance arrangements' includes having clear definitions of the roles and accountabilities of the people involved in providing and managing pharmacy services. It also includes the arrangements for managing risks, and the way the registered pharmacy is managed and operated. 'Pharmacy services' covers all pharmacy-related services provided by a registered pharmacy including the management of medicines, advice and referral, and the wide range of clinical services pharmacies provide.
Do staff have the skills, knowledge and experience to deliver effective care and treatment?	There are enough staff, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided
Do people have their assessed needs, preferences and choices met by staff with the right skills and knowledge?	Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training
How are the learning needs of all staff identified? Do staff have appropriate training to meet their learning needs that covers the scope of their work, and is there protected time for this training?	Pharmacy services are managed and delivered safely and effectively

Table 1: Comparison of inspection processes between CQC and GPhC relating to skills and training.

service. The variance between the two agencies of inspecting processes highlights the difference in the culture of reviewing training of skills and knowledge [9]. The CQC focus is upon the establishment of skills and knowledge of the individual staff when compared to the GPhC who views the amount of staff with appropriate skills and the service delivery is safe and effective.

Comparatively, the GPhC [10] inspection decision making framework focuses on the operational provision of pharmacy practice and references to the training of employed staff. There is currently no clinical assessment of practice, training or education. The recently announced change to the types of inspection indicates that in the second half of 2019 the GPhC plan to introduce themed inspections that will focus on specific issues in more depth to produce a report that identifies learning or good practice that can be shared [11]. At the time of writing there is no indication is these would be advisory or have any mandatory implications.

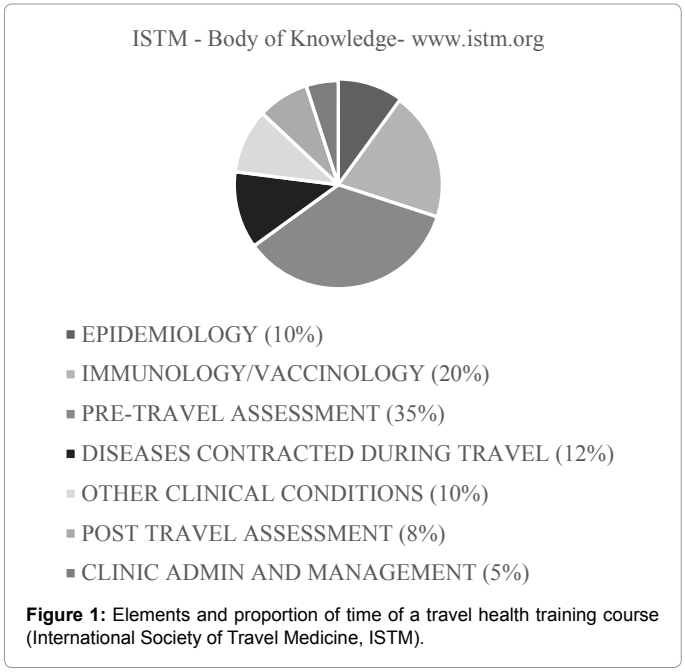

Figure 1: Elements and proportion of time of a travel health training course (International Society of Travel Medicine, ISTM).

International and National Standards

The International Society of Travel Medicine (ISTM) offers a travel health course covering the essential elements of knowledge and practice. This is known as the Body of Knowledge and the essential elements, along with the percentage of emphasis for examination, are show in Figure 1 below.

Each of the headings is studied by the individual practitioner and then assessed in a single formal examination. A minimum pass mark of around 75% is required as necessary to be awarded the Certificate in Travel Health, which is mandatorily required in some countries and states of the USA before practising travel health or medicine.

Within the UK the national regulators refer to phrases such as "appropriate skills and training". A web search for a national standard for travel health services was conducted of the public health and professional bodies. These included the PGD regulator, MHRA NICE and NHS funded bodies. The results of the NICE clinical knowledge are listed below [12].

- Immunizations that are required to be supplied and managed
- Prevention of traveller's diarrhoea
- Malaria prophylaxis
- Insect bites and stings

The regulatory bodies produced recommendations but no formal guidelines of minimum standards.

Figure 2 below highlights the key areas of the travel health

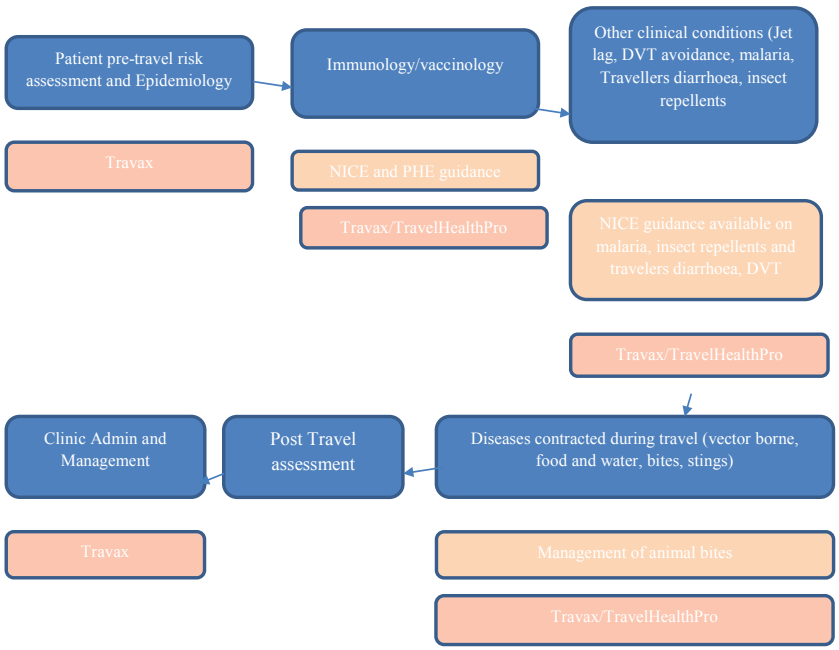

Figure 2: The Travel Health Assessment process - A Comparison of Body of Knowledge elements with information available from NICE Clinical Knowledge Summary (CKS) and NHS specialist services (Travax, TravelHealthPro).

assessment process for a patient consultation compared with the information available from the PGD regulator and PHE and specialist NHS sites Travax (www.travax.nhs.uk) and TravelHealthPro (www.travelhealthpro.org). This confirms that some of the key information in the process is not covered by the PGD regulator and further information has to be sought from specialist web sites; not all of which covers the Body of Knowledge.

Training and Standards

The provision of a travel health service may involve the supply and administration of vaccines against diseases. The process of the correct immunisation technique is outlined in a Public Health England (PHE) document [13].

This document suggests for the purposes of immunisation "Any practitioner must have received specific foundation training and have been assessed as competent by an experienced registered practitioner. The requirement of what needs to be assessed includes both knowledge and clinical competence. For the service to be supplied then a support network should be available that includes access to an experienced supervisor in immunisation".

This supports the outcome of a study of American travel health practitioners providing travel health advice. This concluded that creating easily accessible travel medicine education programs for providers, from a wide range of disciplines was needed to improve the management of travellers [14].

An earlier study into education indicated that the most important correlations of baseline knowledge were the profession of the provider and their experience in travel medicine. All practitioner groups improved their knowledge after completing a training course [15]. Highlighting that multidisciplinary assessments of practice are required with additional training.

The PHE document covers the section of travel health provision relating to vaccine administration; however this level guidance does not extend to cover other elements of a travel health service such as the education and knowledge of the subject or the minimum levels of competence.

Without any regulations in the UK regarding the content of training then individual companies have provided their own supporting information when supplying the legal documents (PGDs). These were evaluated following an online search, as seen in Table 2.

Of the suppliers 5 from 7 allowed self-assessment to be completed as an indicator of competence to practice. The training time to support the delivery of a travel service ranged between 4 and 20 hours for knowledge education. Other skills required for travel vaccination service were sub-contracted to other suppliers by the PGD suppliers, with only 2 providers supplying all the services in-house. Feedback from of the PGD suppliers raised concern about the bias of pharmaceutical industry and emphasis of training on their products in the short time periods of training.

By comparison the formal travel health specialist providers (Table 3) did not provide any PGD documents and focussed attention on the academic knowledge element of training.

The specialist providers did not supply any other services except for knowledge training which ranged between 4 days to 15 months. (The short course from London School was the only one available to pharmacists as the diploma was only open to physicians in the London area).

For diploma training, this was formally assessed externally before an award of competence was issued. None of the courses included training or education in the other elements of travel service provision.

Comparison with Pharmacists in California

For comparison with other pharmacist travel health services, the Californian model was reviewed. Californian pharmacists are registered following a 7 year academic training period and registration examinations set by the state board. Pharmacists supply vaccinations by following a prescriber's protocol or vaccines which are listed on the routine vaccination schedule. This service is subject to pharmacists being registered with the Californian Code of Regulations (CCR) which includes standards of training, basic life support and record keeping [16]. Practising without the CCR is subject to penalties of immediate closure and censorship.

Suppliers	PGD supplier	Training provided and time	Training mandatory to use PGD	Self-certification of competence	Other training offered Basic Life Skills, Immunization
Pharma Doctor	Y	N- referred to Valneva or GSK	Y	Y	Referred: BLS Immunization technique
Valneva	N	Y (4 hrs)	N	Y	None
GSK	N	Y (Estimate 8 hrs)	N	Y	None
Voyager	Y	Y (1 day)	Y	Internal assessment	Own: BLS Immunization technique
Sonar Informatics	Y	Y (3 hrs)	Y	Y	Referred
National Pharmaceutical Association	Y	Y (Unknown)	Y	Y	Referred: BLS Immunization technique
IncaHealthcare	Y	Y (Estimated 20+ hrs)	Y	Internal assessment	Own: BLS Immunization technique. Own: Competency standards

Table 2: Comparison of travel health training supplied by providers for pharmacists.

Suppliers	PGD supplier	Training provided and time	Training mandatory to use PGD	Self-certification of competence	Other training offered Basic Life Skills, Immunization
Foundation course- Royal College Physicians Surgeons (Glasgow)	N	6 months	N	N- assessed	N
Diploma in Travel Medicine- Royal College Physicians and Surgeon (Glasgow)	N	12 months	N	N- assessed	N
Professional Diploma in Travel Health (Liverpool)	N	7-15 months	N	N- assessed	N
Travel Medicine- short course. London School of Tropical Medicine and Hygiene	N	4 days	N	N- attendance certificate given	N
Certificate In Travel Health	N	Unlimited	N	N-assessed	N
ABC of travel- British Global Travel Health Association	N	Y (Self-paced)	N	Y	N

Table 3: Comparison of travel health training supplied by specialist providers for pharmacists.

The minimum standards of travel health service provision include a mandatory completion of an immunisation training programme; training programme that includes International Society of Travel Medicine (ISTM) Body of Knowledge; CDC Yellow Fever Vaccine Course and basic life support certification [17].

Discussion

The evidence highlights that in the UK the supply and use of PGDs utilising only undergraduate training is considered adequate to provide an unrestricted travel medicine service.

Internationally it is recognised that vaccination and travel medicine are advanced level services and there is a requirement to develop a formal accreditation and assessment to provide standardised levels of competency across all healthcare professions.

Training time

The question of how much and how long training should be considered as a minimum, is dependent on several determinations that include the range of the services being provided (e.g. a part time supply service for anti-malarials or full time travel health clinical services). The ISTM Body of Knowledge highlights that the proportion of training time that should be spent on the skills relating to the pre-travel risk assessment. As shown in diagram 2 the largest proportion of time should be given to the pre-travel consultation and immunology/ vaccinology. Although some of these steps in the process are mentioned in the UK guidelines there is no suggestion to the minimum requirements for training times.

The necessary length of time relating to training varied widely especially between the PGD providers and the specialist educators. Within the UK there remains no defined standard either from the NHS or in the non-NHS market. A recent study suggesed that the minimum level of training of these standards could vary from 2 day course for practitioners with some experience, to 10 week (50 hour) modules as used by medical students [18]. The underlining point being that some form of training is beneficial to the service and to the patient receiving it.

Training and education

The training and course curricula will vary between providers, however the key elements appear in a in the ISTM Body of Knowledge list, with some of these covered by NHS provider services. Within the UK there are few national references to the minimum training standards and there is no mandatory training or assessment before commencing to supply a travel health service. The Public Health England (PHE) guidelines however, do suggest assessment of the administration and management of vaccines, which would correspond to only 5% of the assessment time of the ISTM Body of Knowledge. The PHE guidelines, although produced by the NHS, do not extend further to cover the other elements of the travel health assessment and supply process nor do they suggest the use of external assessors.

Therefore it appears that the absence of an overall national standard for travel health in the UK omits to cover some of the major areas of specialist education and allows pharmacist competency to be measured using self-assessment which has been suggested as having limited ability to be accurate.

The inference and impact of commercialism was not investigated into the reasons why pharmacists were starting travel health services due to the levels of anticipated bias. However several of the major PGD suppliers have recently increased the promotion of their services, without an increase in the levels of supportive training.

Patient risk

The impact of the identified shortfalls in practice areas increases the risk of incorrect or inappropriate advice. In the event of a patient attending with co-morbidities and the supplying pharmacist having non-assessed competencies to advise correctly, there is an increased risk to the patient for contracting vaccinable and non-vaccinable diseases. With an increase in the number of malaria cases within the UK (PHE- Malaria imported into the UK, 2017) and the recently reported deaths following yellow fever vaccination there is requirement for have increased professional awareness to reduce the risk to patients from the advice they are given by pharmacists.

With increasing numbers of UK pharmacists providing immunisation services (including flu, travel health and national immunisation vaccines) the results of adverse events was assessed by reviewing reported error data. The MHRA adverse reporting statistics for 2017 [19] showed no deaths recorded due to vaccination by any health care professional, however this list does not disclose non-death errors. The question remains unanswered of how many errors or near misses could be prevented with improved education?

Inspection and regulation

The values of the GPhC professional standards in the UK to demonstrate competency are self-assessed without any external assessment. This is contrary to the principles of the PHE assessment of immunisation practice, and advice from the medical community. As previously discussed self-assessment is not identified as the best choice and therefore it can be argued that a form of external assessment of knowledge before practice is advantageous, which should be the subject of a formal inspection process by the regulator. This level

of inspection would provide improved patient and other healthcare practitioners confidence in the standards of pharmacy led travel health services.

To consider in more detail, standard 4 states that pharmacists are to record and list training to ensure their skills are up to date and their activities are relevant to their practice. Without defined standards in travel health it can be argued that these cannot be demonstrated satisfactorily. Likewise standard 5 requests pharmacists to know the limits of their competence. With the largest study areas (pre-travel assessment and immunology/vaccinology) not having any defined competencies then again this is standard can be arguably challenged as indeterminable.

The inspectorate division of the GPhC follow guidelines that do not include any clinical service review or whether the clinical levels of training are relevant to the level of service supplied. However when the CQC inspect, they include an evaluation of the levels of training and education such they are fit for the service delivery and assessment is made by another professional. The disparities between the GPhC and CQC does not support uniform quality delivery of the same clinical services. The consultation paper on the regulation of health professionals by the Department of Health and Social Care [20] recognises the regulation models are outdated and concluded its consultation in January 2018. The new proposals for change in the manner of inspections do not indicate the use of minimum standards for service provision.

In the short term, the licensing authority for the supply of PGDs, the MHRA (Medicines Health Regulation Authority) should consider mandatory levels of training and an external assessment to be provided with the purchase, prior to the use of PGDs. This would provide improved patient safety whilst the professional bodies decide on regulation and registration standards.

Other countries

By comparison, other countries demonstrate that a formal external examination and assessment processes need to be completed before being able to supply medication without a medical intervention. Travel health pharmacists are licensed and registered to practice according to defined education courses, basic life support, and anaphylaxis and vaccination techniques. From private communication this is now a focus point for the International Pharmacy Federation (FIP).

UK travel market

The travel health market continues to expand and the ABTA report of 2019 (www.abta.com) estimates an increase of 5% in the holiday market. The website continues to advise travellers to seek advice about vaccination and malaria preparations before travel. The PHE 2017 review into the continued supply of travel vaccinations on the NHS remains unpublished with many general practice surgeries opting not to supply vaccinations for travel purposes. The supply of vaccinations and medication for travel is moving from the NHS towards the private sector where pharmacies are filling the increasing gap in the travel health market.

Conclusion

The pharmacist exclusion from the original CQC inspection process is no longer fit for purpose when providing the same services as other healthcare professionals. The pharmacist use of PGDs excludes the need to mandatory complete any specific advanced level education or external assessment before practising travel health. This is at difference to the advice within the national guidance for vaccination technique; other countries mandatory licensing and the report that improved service provision is provided following training, irrespective of the levels of experience of the practitioner. To rectify the situation and reduce the risk to the public in the short term the MHRA could require all PGD suppliers to supply mandatory training and assessment before their use to a defined minimum standard. The GPhC inspectorate division has the opportunity to manage the clinical standards in the interim until universal national standards are agreed.

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