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The mission of the Journal of the Malta College of Family Doctors (JMCFD) is to deliver accurate, relevant and inspiring research, continued medical education and debate in family medicine with the aim of encouraging improved patient care through academic development of the discipline. As the main official publication of the Malta College of Family Doctors, the JMCFD strives to achieve its role to disseminate information on the objectives and activities of the College.

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Global warming to global warning

Prof. Pierre MALLIA

There is no doubt that the amount of air pollution in countries struck by the COVID-19 virus went down considerably. The lockdown decreased the amount of cars for starters and even industry was affected according to sources. But the real question is whether this is temporary. Are we going back to square one once things return to normal? Are we going to take this as a 'global warning'?

The answer, I believe, lies not in individual decisions. Left individually we all buy the necessary products, we all use cars daily, we continue to go to places, such as school meetings, after which we ask why we attended. The word 'solidarity' was thrown around a lot – perhaps with wrong timing – but solidarity has to come with together starting somewhere to reduce our air pollution and in turn reduce traffic congestion, time of travelling, expenses of diesel and petrol, and indeed waste of time. The answer, again, in my opinion, is to use what we have learned to reduce the amount of traffic and air pollution. Here are some ideas:

1. Children have been receiving lessons at home, and university students got used to virtual learning and 'Zoom' meetings. Adults also worked from home. If we assess the success of these endeavours in a crisis and see how they can be improved in more normal times, can we not make the jump of dividing our office ours, where possible, into two or three days physically at work (to meet clients, have social contact, and maintain the working environment), but also have one or two days a week in which work can be done electronically from home. Probably meetings will have less confrontation. Children are facing a virtual world anyway and this will serve them as good training. It was a first for me to use virtual meetings for both local and international meetings. They waste less time and avoid local and international travel.
2. Can we do away with useless meetings such as crowded parents' days? If need be we can have virtual meetings here too, spread over some time or by appointment.
3. Do we really need to deliver that car application, or passport application for that matter, in person? Why cannot these be done online? We would certainly reduce a considerable amount of travel especially during traffic hours.
4. Even hospital appointments have been shown to be able to withstand a little reduction. Cardiology doctors were personally calling patients to see how they were doing and giving them advice. Rather than having two or three appointments a year, people can have one when they are outside the danger zone. It saves a considerable amount of time and avoids a lot of people sitting together in waiting rooms.

I am sure that working together many people can come up with many other ideas. We once generated twenty ways on how to reduce traffic. But small steps at a time will definitely help. Do we really need all these cars in the country – what incentive can we give to use public transport? Perhaps a tax reduction? A look at balance sheets could show that this may just be possible.

On an international level the EU has come under attack. It was certainly not prepared and countries showed how divided they are when it comes to the introduction of emergency measures, shutting down airports, and now supporting each other financially. Can our parliamentarians reduce the amount of travel and waste they carry out at EU level? They all complain about the futility and extra travel resulting from meeting in Strasbourg. Moreover, travel by air to and from countries does not really set an example. Let's face it, our habits of increased travel, low cost airlines, and travelling further and further away have given nature more vectors on which such viruses can travel. But imagine the carbon emissions being added to the atmosphere.

Let's face it, we are not about to give up our luxuries without incentives unfortunately. We are all going to buy cars and go for perhaps more than one holiday a year. Don't even mention giving up on our mobile phones and changing them every two or three years. Luxury is very difficult to give up. But what we can do is change the way we do things without giving up anything else really. If COVID-19 has taught us anything in this regard, it is that besides the initial 'survival of the fittest' instinct of buying and hoarding groceries, we can all use the internet to greater advantage and we all appreciated the lack of congestion on roads and the news that our air is cleaner. So are we simply going to go back to the original state of affairs?

Natural events have given us a warning. It does not take a tsunami to kill many people. A disaster situation can be caused by a virus. We knew this. The WHO knew this. And yet we were still unprepared. Internationally at least we did not have a contingency plan.

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RESEARCH ARTICLE

Is a pneumococcal vaccine for the elderly appropriately recommended by Maltese geriatricians and general practitioners?

Dr Nicole Marie ZERAFA, Dr Daniela BONELLO, Dr Marco GRECH and Dr Antoine VELLA

ABSTRACT

Background and objectives

The Centre for Disease Control and Prevention, the World Health Organization, and the National Institute for Health Care and Excellence recommend the pneumococcal vaccine to patients aged 65 years and over, patients with chronic lung disease and patients suffering from a number of other listed chronic conditions. This study aimed to assess whether geriatricians and family practitioners in Malta recommend the pneumococcal vaccine to the above mentioned populations.

Method

A questionnaire was formulated by the authors to collect demographic data about the respondents, inquire whether respondents knew about the pneumococcal vaccine, its availability in Malta, its properties, which groups of patients are recommended for administration of this vaccine, and whether these patients were being identified in the respondents' practice. The questionnaire was circulated via electronic email to family practitioners and geriatricians in Malta. All responses were then compiled, and the results formulated and analysed.

Results

A total of 47 responses were collected: 28 were family practitioners (60%) and 19 were geriatricians (40%). Forty-four (94%) respondents recommend vaccines in their daily routine, but only 37 (79%) of respondents are aware of the guidelines on the pneumococcal vaccine. Ten (23%) respondents always include the vaccine as part of their management of pneumonia, 25 (54%) occasionally do so and 10 (19%) never do. Twenty-six (55%) respondents recommend the vaccine in patients aged 65 years and over, 44 (93%) recommend it in chronic lung disease, 23 (48%) recommend it in post-splenectomy patients, 29 (62%) in immunocompromised patients and 32 (67%) in congestive heart failure.

Conclusion

There is a need for geriatricians and family practitioners in Malta to be reminded of the guidelines surrounding the pneumococcal vaccine and in which groups of patients it should be recommended.

Key Words

Pneumococcal vaccines; aged; geriatricians; general practitioners; Malta.

INTRODUCTION

The pneumococcal vaccines

The pneumococcal vaccines (PCVs) are inactivated or 'killed' vaccines that do not contain live organisms. As explained by the Centre for Disease Control and Prevention (CDC), such vaccines help prevent pneumococcal disease, which is any type of infection caused by *Streptococcus pneumoniae* bacteria (pneumococcus) (CDC, 2018a).

The World Health Organisation (WHO) mentions that this bacterium can cause a spectrum of disease including otitis media, upper respiratory tract infection (URTI) as well as more serious infections such as pneumonia, meningitis and bacteraemia (WHO, 2017; Daniels, Rogers and Shelton, 2016). It is a leading cause of illness in young children, and of death in elderly people and people with immune deficiencies and chronic illness (Jefferson and Demicheli, 2002). It is spread from person to person by direct contact with respiratory secretions like saliva and mucus (Daniels, Rogers and Shelton, 2016; CDC, 2018b).

Two types of pneumococcal vaccines are available. The pneumococcal conjugate vaccine (PCV 13 or Prevnar 13) protects against 13 strains of pneumococcal bacterium. It is recommended for all children younger than 2 years old, all adults who are 65 years or older, and those from 2 to 64 years old with particular medical conditions (see next section). The pneumococcal polysaccharide vaccine (PPSV23 or Pneumovax 23) protects against 23 strains of pneumococcal bacterium (CDC, 2019a). It is recommended for all adults who are 65 years old or over, those from 2 years old to 64 years old with certain medical conditions, and adults 19-64 years old who smoke cigarettes.

Who and how to vaccinate?

The CDC compiled a list of medical conditions and recommends that any patient suffering from any one or more of these conditions gets vaccinated against pneumococcal bacteria. These include alcoholism, chronic heart disease, chronic liver disease, chronic lung disease (including chronic obstruction pulmonary disease (COPD) and asthma), diabetes mellitus, any immune compromising conditions, nephrotic syndrome, human immunodeficiency virus (HIV) infection, sickle cell disease, malignancy, and congenital or acquired asplenia. Smokers are also listed among those at increased risk for pneumococcal disease, and therefore it is recommended they take the pneumococcal vaccine too (CDC, 2019b).

The recommended method for administration according to the CDC is as follows: a dose of PCV13 should be given to adults 65 years or older (if they have not received a dose before) and then a dose of PPSV23 is administered at least 1 year later. In patients who have already received PPSV23, a dose of PCV13 should be given at least 1 year after the most recent dose of PPSV23 (CDC, 2019b).

Additionally, the National Institute for Health Care and Excellence (NICE), along with Public Health England, have updated their local guidelines on the vaccination of children to include the PCV13 as part of the national immunisation schedule (NICE, 2019).

Campaigning and raising awareness of the vaccine by physicians

It has also been demonstrated that an effective campaign in a general practice setting is an effective way for increasing the uptake of pneumococcal vaccine (McDonald, et al., 1997).

This also applies to paediatricians and geriatricians. Two particular studies which focus on the paediatric population in Jordan and Singapore have concluded that strengthened efforts by health care providers, which include prioritizing distribution of key messages on PCV, its benefits and side-effects, can motivate parents and encourage the uptake of the PCV amongst their children (How, et al. 2016; Masadeh, et al. 2014).

The availability of the pneumococcal vaccine in Malta

Currently, there are 2 brands of conjugate pneumococcal vaccine on the Maltese market – Synflorix and Prevnar-13. These vaccines can be given to children from the age of 6 weeks, with a second dose at 4 months and a booster dose during the second year of life. The 10-valent vaccine (Synflorix) was introduced on the National Immunisation Schedule in May 2020 (Primary Child & Youth Health & Immunisation Unit, 2020).

Aim

This study aimed to evaluate and demonstrate in a descriptive way whether family practitioners and geriatricians in Malta are aware of the pneumococcal vaccine, its properties, and in which populations it is recommended.

METHOD

The CDC, NICE and WHO guidelines on the pneumococcal vaccine were researched. A literature review on the pneumococcal vaccine and its use among elderly populations and the community was also conducted.

A questionnaire was formulated by the authors using the Google Forms software. Its purpose was to collect data on whether family practitioners and geriatricians are aware of and are following the guidelines researched. It included a total of 29 questions divided into two sections. The first section requested demographic data such as age, gender, speciality, years in practice, public or private sector of medical practice, and region of Malta where practice is held. The second section comprised of 23 questions all relating to the properties of the vaccine, the guidelines surrounding its use, whether respondents included vaccination in their daily practice, and whether respondents were aware of the pneumococcal vaccines available in Malta. Finally, respondents were asked for their feedback on why uptake of this vaccine may be hindered in Malta, and what improvements could be made if any.

Ethics committee permission was not required as no human subjects were involved in the research. However permission was sought from the Head of the Geriatrics Department at Karin Grech Hospital, the Secretary General of the Geriatric Medicine Society of Malta, the Principal General Practitioners of the public Primary HealthCare service of the three regions in Malta, and the Secretary Generals of the Malta College of Family Doctors and the Association of Private Family Doctors for circulation of a special link to the survey software via electronic mail (Microsoft Outlook) to all family practitioners and geriatricians working or affiliated with these entities. Prior to its distribution a pilot questionnaire was circulated for a preliminary test.

The link was distributed through electronic mail a total of five times to all of these entities until a substantial number of responses were collected. Once a suitable number had been reached, the responses were analysed in a descriptive fashion.

RESULTS

As this study intended for Family Practitioners and Geriatricians working in Malta was circulated to a these specialists with the purpose of recording data from a variety of practices (public or private), regions in Malta, years in practice etc., this enabled the data to be more representative of the practices of respondents from all over Malta, at all stages of training, and in public and private sectors of health.

A total of 47 responses were collected. Table 1 demonstrates the demographic data collected from the respondents.

Table 1: Table showing distribution of demographic data from respondents in numerical and percentage form

	Number of responses	Percentage of total responses (%)
Family Practitioners	28	60
Geriatricians	19	40
Female	20	42.6
Male	27	57.4
Aged 20-30 years	11	23.4
Aged 31-40 years	7	14.9
Aged 41-50 years	10	21.3
Aged 51-60 years	18	38.3
Aged 61-70 years	1	2.1
Less than 10 years in practice	15	31.9
10-20 years in practice	6	12.8
20-30 years in practice	18	38.3
More than 30 years in practice	8	17
Work in the public sector only	30	63.8
Work in the private sector only	9	19.1
Work in both private and public sectors	8	17
Work in central region of Malta	18	38.3
Work in north region of Malta	1	2.1
Work in south region of Malta	17	36.2
Work in two regions of Malta	2	4.1
Work in all regions of Malta	7	14.9
Work in other regions of Malta not mentioned above	2	4.1

Table 2 demonstrates the data collected pertaining to whether the respondents include the pneumococcal vaccine in their practice, both in general daily practice and in the treatment of diagnosed pneumonia disease.

Table 2: Table showing data collected regarding the inclusion of the pneumococcal vaccination in the respondents' medical practice

	Number of responses	Percentage of total responses (%)
Aware of the CDC and NICE guidelines on pneumococcal vaccination	37	78.7
Actively encourage vaccination in practice	44	93.6
Keep vaccination records in their practice (family practitioners)	17	36.2
Keep vaccination records in their practice (geriatricians)	8	17.0
When pneumonia diagnosed, enquire on pneumococcal vaccination status - always	8	17.0
When pneumonia diagnosed, enquire on pneumococcal vaccination status - sometimes	23	48.9
When pneumonia diagnosed, enquire on pneumococcal vaccination status- rarely	7	14.9
When pneumonia diagnosed, enquire on pneumococcal vaccination status - never	9	19.1
Actively recommend patients over 65 years of age to take the pneumococcal vaccine	26	55.3

Include pneumococcal vaccine in management of pneumonia in 65-year-olds or older patients - always	11	23.4
Include pneumococcal vaccine in management of pneumonia in 65-year-olds or older patients - sometimes	23	48.9
Include pneumococcal vaccine in management of pneumonia in 65-year-olds or older patients – rarely	9	19.1
Include pneumococcal vaccine in management of pneumonia in 65-year-olds or older patients - never	4	8.5
Recommend the pneumococcal vaccine to patients with specifically listed medical conditions listed in the guidelines - always	22	46.8
Recommend the pneumococcal vaccine to patients with specifically listed medical conditions listed in the guidelines - sometimes	17	36.2
Recommend the pneumococcal vaccine to patients with specifically listed medical conditions listed in the guidelines - rarely	3	6.4
Recommend the pneumococcal vaccine to patients with specifically listed medical conditions listed in the guidelines - never	5	10.6

Respondents were asked whether they were aware of certain properties about the vaccines in Malta – which types are available, how much they cost and where they may be acquired. The results are shown in Table 3.

Table 3: Results of respondents' answers about the pneumococcal vaccines available in Malta

	Number of responses	Percentage of total responses (%)
Aware of where patients may acquire the pneumococcal vaccine in Malta	29	61.7
Aware of how much the vaccine costs in Malta	33	70.2
Aware of the two types of vaccine available in Malta	35	74.5

Furthermore, respondents were questioned about their knowledge on the various properties of the pneumococcal vaccine, such as number of doses, contraindications and target organisms (among other properties). The results of the answers to these questions are shown in Figure 1.

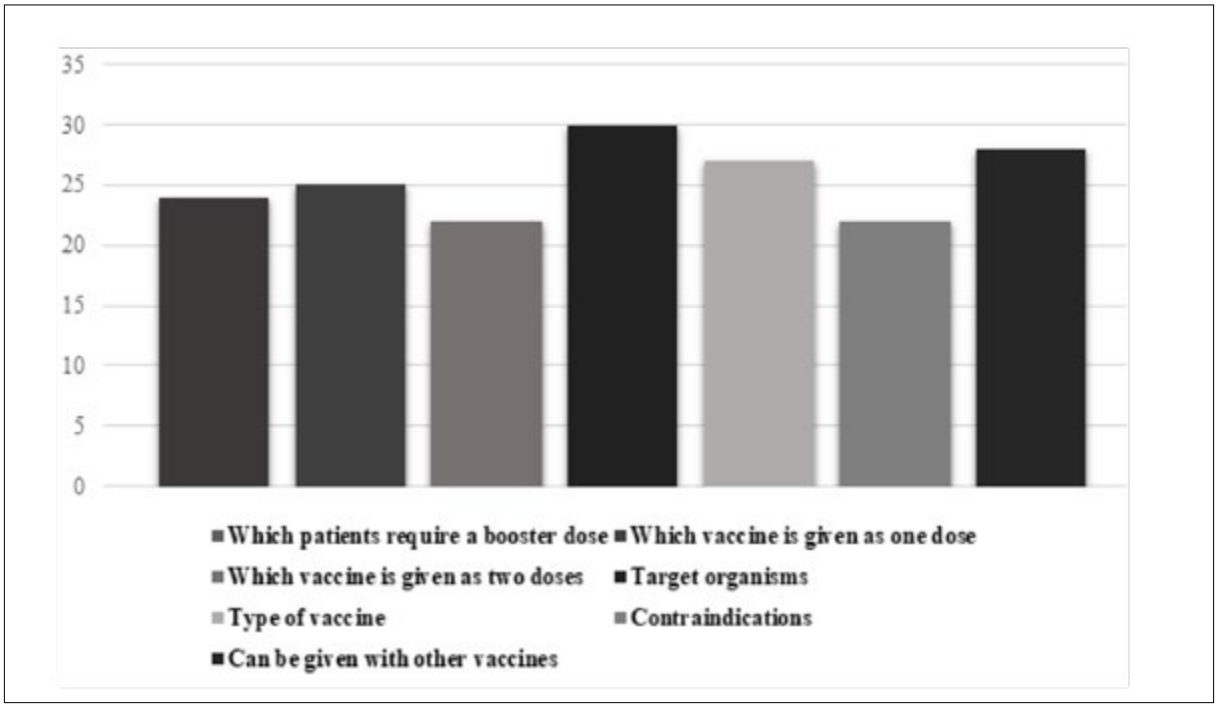

Figure 1: Respondents' answers to questions about the pneumococcal vaccine's properties

The guidelines researched list a number of chronic medical and immunosuppressive conditions; patients suffering from these conditions, without an episode of pneumococcal infection, are to be prescribed the pneumococcal vaccine. Respondents were asked if they were aware that patients suffering from these conditions were recommended to take the pneumococcal vaccine, and whether they had ever prescribed the vaccine to patients suffering from these conditions. The results are shown in Table 4.

Table 4: Table demonstrating how many respondents were aware that medical conditions listed were recommended to take the vaccine, and how many respondents have prescribed the vaccine to these patients.

Medical condition	Number of respondents who knew this condition merited prescription of the pneumococcal vaccine	Percentage (%)	Number of respondents who have prescribed the pneumococcal vaccine to patients suffering from this condition	Percentage (%)
Post-splenectomy	38	86.4	20	47.6
Diabetics	33	75.0	26	61.9
Immunocompromised patients prior/during/ post-treatment	34	72.3	26	61.9
Chronic liver disease and alcoholism	31	70.5	13	31.0
Congestive heart failure	38	86.4	28	66.7
Chronic renal disease	34	77.3	18	42.9
Chronic lung disease	43	97.7	39	92.9

Respondents were then questioned on whether they have noted that vaccination has been effective in their practice, whether they wish for the pneumococcal vaccine to be included in the National Health Service (NHS), and whether they are likely to recommend the vaccine in future after completing this questionnaire, as well as other questions pertaining to their practice. The results are shown in Table 5.

Table 5: Table showing results of respondents pertaining to the pneumococcal vaccine in their current and future practice

	Number of respondents out of 47	Percentage (%)
Noted that patients who get vaccinated suffer less from preventable disease	31	66.7
Noted that patients who took the pneumococcal vaccine suffered less from pneumonia thereafter	20	42.2
Feel that the pneumococcal vaccine should be offered on the NHS to those patients in whom it is recommended	45	95.7
After going through the questionnaire are more likely to recommend the pneumococcal vaccine in future practice	45	95.7

Finally, respondents were asked for their feedback on what may be obstacles in Malta to patients receiving the pneumococcal vaccine. The results are shown in Figure 2.

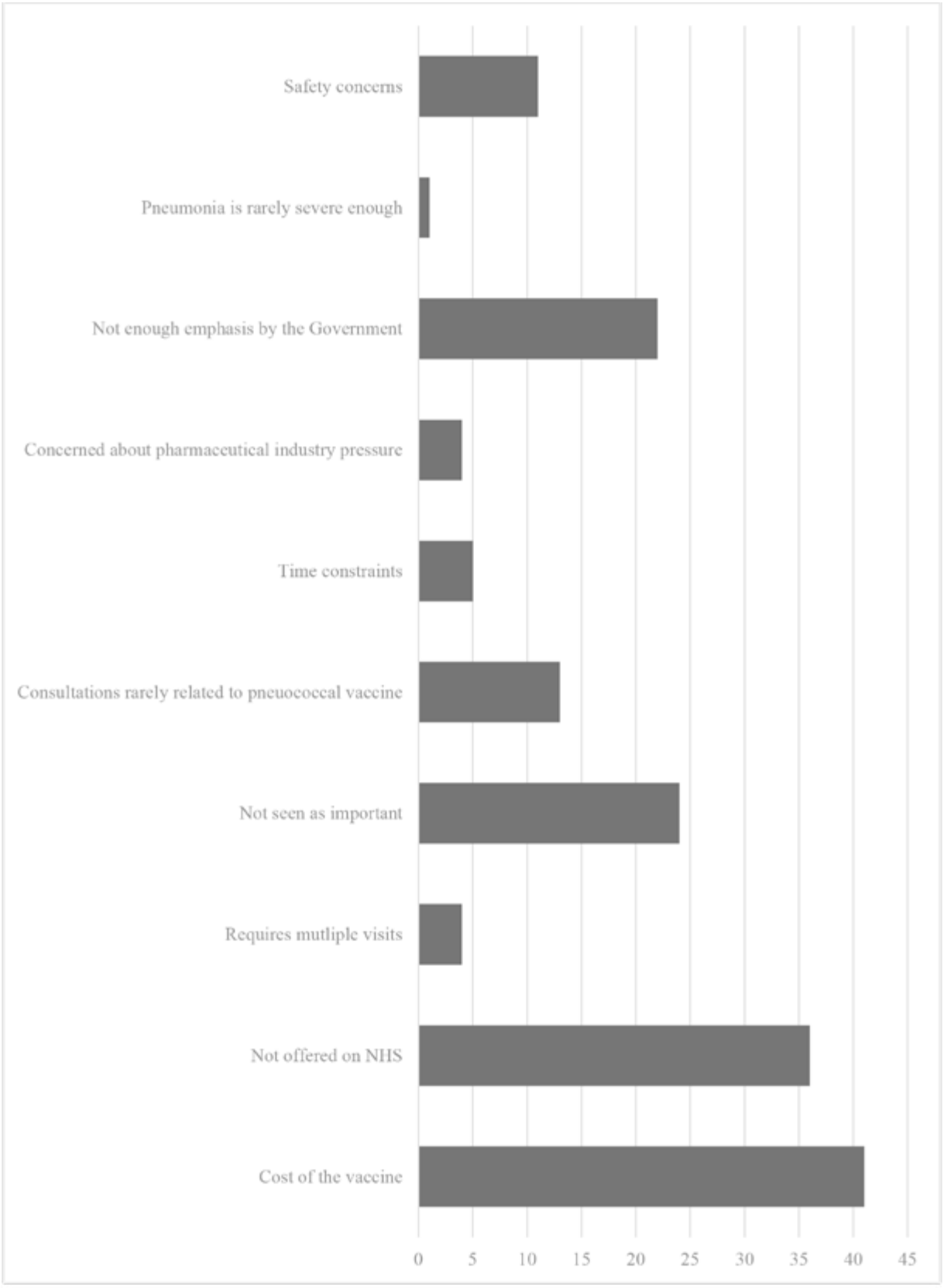

Figure 2: Reasons given by respondents to what barriers may exist in Malta to prevent patients accessing the pneumococcal vaccine

DISCUSSION

During analysis of the results, it was noted that a higher number of respondents were family practitioners (28) rather than geriatricians (19). Therefore the results may be more representative of what goes on in the family practice and primary care sector than in the practice of geriatrics in Malta. Moreover, the data in Table 1 demonstrates that the respondents worked mainly in the public sector rather than private sector, and that the majority had been practicing medicine for more than 10 years. This means that the information gathered is representative of the situation in a number of public health care services and of medical practitioners who have been working in the health care system for more than 10 years.

It is encouraging to note that the majority of respondents actively promote vaccination throughout their practice, and that they are aware of the guidelines surrounding the pneumococcal vaccine. However, as the results in Table 2 demonstrate, few respondents kept records of vaccination in their practice. When diagnosing pneumonia, while it was noted that 23.4% of respondents always inquire on the pneumococcal vaccination status of a patient, and 44.8% sometimes do so, the others admit that they rarely or never do so. Interestingly the respondents who answered in the affirmative to always checking the pneumococcal vaccination status tended to be geriatricians. This may be because geriatricians are trained to deal with patients who have a number of chronic conditions simultaneously, and also because there exist a number of obstacles when primary care physicians treat elderly patients, such as administration issues or medical complexity in treating multimorbid patients (Adams, et. al, 2002; Kane, 2002). Finally, Table 2 also shows how more often than not respondents did not include the pneumococcal vaccine as part of their long-term management of pneumonia. The reasons for this could be several, especially when concerning the public service of primary care in Malta. There was no established electronic record system of patients available in all primary care centres when the study took place, patients often do not meet the same doctor when attending follow-up appointments in the health centres, and time constraints are also a factor. Unfortunately, it has been demonstrated that primary care physicians failing to promote the pneumococcal vaccine is a cause of future preventable pneumonia (Kyaw, Nguyen-Van-Tam and Pearson, 1999).

Table 3 and Figure 1 detail the respondents' answers to questions about details of the vaccine's availability in Malta and on more of its properties as detailed by its developers. The majority of respondents knew about the cost and availability of the vaccine in the Maltese market, but it was noted that there was a lack in knowledge on some of the other properties of the vaccine, particularly which vaccine is given as two doses, and the vaccine's contraindications. This highlights how consistent revision of knowledge about these vaccines' properties is essential in promoting uptake.

With regard to recommending the vaccine outside the management of pneumonia and rather in the management of long-term chronic disease, Tables 2 and 4 demonstrate that less than half of respondents (46.8%) always include this vaccine in their management. When asked if they have prescribed the vaccine in the past to patients with some of these conditions, Table 4 shows that the majority of the respondents have included it in management of chronic lung disease. Despite this the results were less so for other chronic conditions, the lowest for chronic liver disease. One may note however that some of the literature points to more demonstrations of the efficacy of the vaccine in preventing pneumonia in patients with chronic lung disease rather than in patients with other chronic conditions, including multimorbidity. Therefore while the guidelines should be kept in mind in future practice, the research currently being carried out into demonstrating the efficacy of the pneumococcal vaccine in other populations apart from chronic lung disease needs to be closely monitored (Jackson, L.A., et al. 2003; Simberkoff, M.S., et al. 1986; Sims, R.V., et al. 1988).

Finally, Table 5 and Figure 2 include data about how respondents feel the uptake of the vaccine could be improved in Malta. After completing this questionnaire respondents

reported that they are more likely to include the vaccine in their future practice, as shown in Table 5. The same table also shows how respondents would prefer to have the vaccine offered on the NHS in Malta, as the fact that it requires to be purchased is seen as a barrier to promoting its uptake. However the authors note that this study was carried out prior to May 2020 when the pneumococcal vaccine was introduced onto the Maltese National Immunisation Schedule. Figure 2 also demonstrates that another obstacle to promotion of the pneumococcal vaccine is a feeling that 'it is not important'. The fact that the literature currently does not seem to prove the efficacy of the vaccine in a number of more recent studies can be a contributor to this (Conaty, et al. 2004; Kraicer-Melamed, O'Donnell and Quach, 2016; Ochoa-Gondar, et al. 2008). Therefore, further studies need to be carried out both locally and abroad on the vaccine's efficacy for a more informed decision.

This study provides a basic idea of the awareness among family practitioners and geriatricians on the guidelines and promotion of the pneumococcal vaccine, but the study has its limitations and weaknesses. These include:

1. The total number of respondents in this study was only 47. The questionnaire formulated to gather the information was an electronic version and was circulated using digital forums and electronic mailing systems. It was therefore subject to the participants dedicating the time to complete the questionnaire. The results would have been more representative had the number of respondents been greater.
2. The responses collected might not be accurate. In such surveys / studies one has to consider the possibility of respondents providing responses that are considered desirable for the named study.
3. The questionnaire which was formulated included both open-ended and closed questions and therefore it provides a level of detailed and valuable information. The questionnaire manages to cover the most-wanted information.
4. A response rate cannot be calculated, as the exact number of family practitioners and geriatricians to whom this questionnaire was sent is unknown. This was because the link to the questionnaire was initially sent to the Head of the Geriatrics Department, the Principal General Practitioners of the public Primary HealthCare service of the three regions in Malta, and the Secretary Generals of the Malta College of Family Doctors and the Association of Private Family Doctors for circulation, who themselves circulated the questionnaire to the physicians concerned. The authors were only aware of the responses which were completed.

This study suggests that there are gaps in the information and education about the pneumococcal vaccine in Malta among the family practitioners and geriatricians in Malta. Moreover, the results demonstrated that a significant number of the candidates fail to promote the uptake of the vaccine in their daily practice. The reasons for this are various and have been discussed, and ultimately more research into the efficacy of this vaccine in preventing disease is required to shape future practice, particularly in patients with other chronic diseases other than chronic lung disease. Until then the guidelines continue to recommend that the vaccine be promoted in the mentioned patients, and to improve the uptake of this vaccine in Malta, the researchers have compiled a list of recommendations. These are detailed in the Recommendations section.

This study is, as far as the authors are aware, the first study to be carried out locally to demonstrate the awareness among family practitioners and geriatricians on the guidelines about the pneumococcal vaccine. While the aim to have an idea of the situation of local family practices and geriatrics departments has been met, this study highlights the need for more education on this vaccine and all of its properties, including the guidelines to which patients it ought to be recommended.

RECOMMENDATIONS

Following this study, the following recommendations are being put forward:

1. A series of newsletters and reminders (electronic or otherwise) would serve to promote the recommendation of the pneumococcal vaccine to those for whom it is recommended according to the guidelines. These should be targeted towards all medical staff, but family practitioners and geriatricians are in primary positions to promote uptake of this vaccine.
2. Organised workshops should be held for medical professionals to remind them about the properties of the vaccine, including how it is to be administered and other relevant information. There is no need for these to be lengthy or time-consuming. Quick and frequent reminders may be enough to increase this vaccine's uptake.
3. Moreover, it is recommended that the information mentioned in the previous recommendation should be made available to patients using methods and language easy for them to comprehend so that they too may approach their doctors to ask about the vaccine.
4. Finally, a repeat of this study should be carried out after these recommendations have been put forward to study their effect on the vaccine's uptake. This is with particular reference to an adult and geriatric population now that the vaccine is included in the national immunisation schedule for children in Malta as of May 2020.

CONCLUSION

The results of this study demonstrate that a number of doctors from the family medicine and geriatric medicine specialities in Malta fail to include the pneumococcal vaccine in their daily practice, for a number of reasons discussed. Despite this, the majority demonstrated that, after being made aware of it through this questionnaire, they were more likely to include it in their management in the future. The researchers therefore feel that by increasing education and awareness of this vaccine in the Maltese medical community the local uptake of the pneumococcal vaccine will increase significantly.

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Quality improvement through evaluation of GP trainers' continuing professional development in Malta

Dr Mario R SAMMUT and Dr Günther ABELA

ABSTRACT

Background

Mandatory trainer continuing professional development (CPD) sessions were held during 2019 for each GP trainer actively involved in the Specialist Training Programme in Family Medicine – Malta.

Objective

GP trainer CPD sessions were evaluated to improve the quality of the provided CPD that was intended to refine their assessment skills.

Method

Participants were sent a link to an electronic feedback form to complete anonymously using Google Forms. The responses were exported into Microsoft Excel to enable analysis, both quantitatively and qualitatively using item content analysis.

Results

Twenty-six GP trainers completed the feedback questionnaire, giving a response rate of 46%. Positive comments were made regarding the relevance and group dynamics of the sessions (marked as 3 or more out of 5) and the ensuing discussion and interaction (81%). Moreover, 42% stated that they would not change anything about the CPD sessions, while 23% gave different comments about their timing. Educational needs identified by participants ranged from technical help (42%) to providing trainee guidance (35%) and self-development (12%). While 38% of respondents wanted further training in assessment and marking, 27% wished to broaden training to include other teaching topics.

Conclusion

Since the 2019 trainers' CPD sessions were well-received, it was proposed that in 2020 the topic of assessment should be tackled in more depth, with fine-tuning made of the sessions' facilitation and timing. Trainer CPD sessions to be held after 2020 could incorporate further recommended topics that are set at different levels for participants with varying levels of knowledge and skills.

Key Words

Quality improvement, general practice/education, continuing medical education, Malta

INTRODUCTION

Background

Malta's Specialist Training Programme in Family Medicine (STPFM) was launched in 2007 after the training document drawn up by the Malta College of Family Doctors (MCFD) was approved in 2006 by the Specialist Training Committee within the Ministry for Health (Sammut, et al., 2006). Since then, 83 doctors have successfully completed the programme to become specialists in family medicine, with another 63 undergoing training

during 2019-20 within the Department of Primary HealthCare (PHC) (Sammut, 2017; Sammut and Abela, 2019a).

During the three-year training programme, each trainee is supervised on a one-to-one basis by a GP trainer while practicing on a 50-50 basis in family medicine and in other appropriate specialities, with the latter also being supervised by relevant specialists (Sammut and Abela, 2012). In 2018 PHC and the MCFD agreed to allow contracted GP trainers to take on another GP trainee if there are not enough available trainers (Sammut & Abela, 2018). After having undergone training as teachers in family medicine, GP trainers are expected to keep updated on educational methodology by undergoing regular training in teaching/medical education and continuing professional development (CPD) as assessors/examiners (Sammut, et al., 2006; Specialist Accreditation Committee, 2003).

As such trainer CPD meetings did not take place during the initial years of the STPFM, an assessment of the educational needs of trainers and their practices was carried out in 2015 by the postgraduate training coordinators in family medicine which resulted in an introductory CPD meeting in 2016 for new GP trainers (Sammut and Abela, 2017). Subsequently, in 2017 GP trainers were mandated to attend yearly GP trainers' CPD meetings by the inclusion of a requirement in their contracts with PHC following a recommendation by the Specialist Training Committee in Family Medicine (Sammut and Abela, 2017).

The yearly theme for GP trainers' CPD sessions is discussed and agreed between the postgraduate training coordinators and the MCFD, following which a number of sessions are then organised with each GP trainer required to attend at least one. The theme for the 2019 sessions was based on the recommendation of the Royal College of General Practitioners' International Development Adviser for Malta that GP trainers refine their assessment skills by undertaking educational activities involving double marking of video consultations and case-based discussions (Sammut and Abela, 2019a). This suggestion was consistent with the findings of an assessment of the educational needs of GP trainers in Malta carried out in 2015 where the most important and urgent recommendation included more exam-oriented training (Sammut and Abela, 2017).

Objective

A fundamental part of any educational course is evaluation, with the aim of improving the quality of the education delivered (Karim, et al., 2013). An evaluation was carried out of the trainer CPD sessions on assessment skills held during 2019 to improve the quality of the CPD training that was provided.

METHOD

The study made use of a descriptive, cross-sectional retrospective method. GP trainer CPD sessions were organised as follows:

1. The contracted GP trainers were invited to choose a date when they could attend from a prepared list. The number of attendees per date was set at a maximum of seven. As there were 57 GP trainers who needed to attend these sessions, this resulted in the formation of 9 groups.
2. Each group nominated a coordinator and, through such coordinator, they were asked to select 2 video consultations and 2 case-based discussion write-ups. The necessary consent was obtained from the patients as well as from the GP trainees. Alternatively, the GP trainers could use video consultations and case-based discussions already available from other sources such as books.
3. The CPD session consisted of a review of the videos/case write-ups, followed by blind marking by all the GP trainers in the group using the relevant assessment forms developed by the MCFD. After the blind marking was concluded, the trainers discussed their markings accordingly with the scope of learning from each other's point of view.

Following each session, feedback from participants was collected and analysed as follows:

1. At the end of the session, the GP trainers were sent a link to an electronic feedback form to complete (Figure 1) using Google Forms, reassuring them that their replies would remain anonymous. The form was adapted from one devised by Sammut, et al. (2007).
2. The responses from the completed forms were exported into Microsoft Excel to enable analysis, both quantitatively and qualitatively using item content analysis (Krippendorff, 1989).

Ethical considerations

No ethical approval was needed since sensitive personal data were not gathered.

RESULTS

Response rate

All the 57 GP trainers that at the time were involved in the STPFM attended the sessions. Out of these, 26 GP trainers completed the feedback questionnaire, giving a response rate of 46%.

Relevance of the topic and group dynamics

Figures 2 and 3 outline the responses received to the first two questions of the feedback form regarding the relevance of the topic and the dynamics during the group sessions. Both topics were scored as 3 or more out of 5.

Positive aspects

All the GP trainers' replies to the question 'What I liked' are shown in Table 1. Grouping the replies into themes, no less than 21 trainers out of the 26 responders (81%) appreciated the discussion/ interaction within the meetings that enabled sharing and comparing of different points of view. Six trainers (23%) also highlighted the fact that the topic was practical/relevant.

Areas for improvement

Table 2 shows the GP trainers' answers to the question 'What I would change'. Eleven participants (42%) stated that they would not change anything. Another six (23%) gave different comments about the time, including duration, time of day, punctuality and protected time.

Area/s where further development needed in role of educator

The GP trainers' comments in reply to the question 'Which area/s in your role as an educator do you feel needs further development' may be seen in Table 3. Eleven participants (42%) requested help of a technical nature such as with the ePortfolio, new teaching methods, time management, appraisal of data, information technology (IT) skills, sharing resources and grading. While three trainers (12%) wished to develop their own assertiveness or confidence, ten respondents (38%) wanted to improve the guidance they provide to their trainees such as feedback, validation, encouragement, motivation, helping difficult trainees and exploring concerns.

Topics for future discussion

Table 4 lists the GP trainers' replies to the question 'Mention one topic which you would like to be discussed in next year's Trainer CPD'. Ten respondents (38%) wished further training in assessment and marking, with a couple suggesting a link to or focus on summative assessment. Another seven participants (27%) wanted to broaden training to include other teaching topics, such as handling difficult trainees (and trainers), one-to-one mentoring and giving feedback. A number of clinical topics were also suggested for future CPD meetings (see Table 4).

Comments/suggestions

Six GP trainers (23%) gave favourable comments regarding the CPD sessions, while three others made organisational suggestions for improvement (see Table 5).

DISCUSSION

Response rate

The fact that only 46% of participants completed the feedback questionnaire might be seen as discouraging if one uses this as a gauge of the GP trainers' interest in improving on these CPD sessions. However, as response rates to online surveys are lower than of paper-based questionnaires (Cho, et al., 2013), this 46% rate can be regarded as acceptable, especially as the

Figure 1: Feedback form

Trainer CPD Feedback Form 2019

Session held on

* Required

Session held on

1. **Relevance of topic to your trainer (educational) CPD needs** *
   Mark only one oval.

	1	2	3	4	5	
Least	◯	◯	◯	◯	◯	Best

2. **Way topic was dealt with (group dynamics)** *
   Mark only one oval.

	1	2	3	4	5	
Least	◯	◯	◯	◯	◯	Best

3. **What I liked** *

4. **What I would change** *

5. **Which area/s in your role as an educator do you feel needs further development** *

6. **Mention one topic which you would like to be discussed in next year's Trainer CPD** *

7. **Comments / suggestions**

Figure 2: Relevance of topic to trainer's educational CPD needs (score: 1 – least, 5 – best)

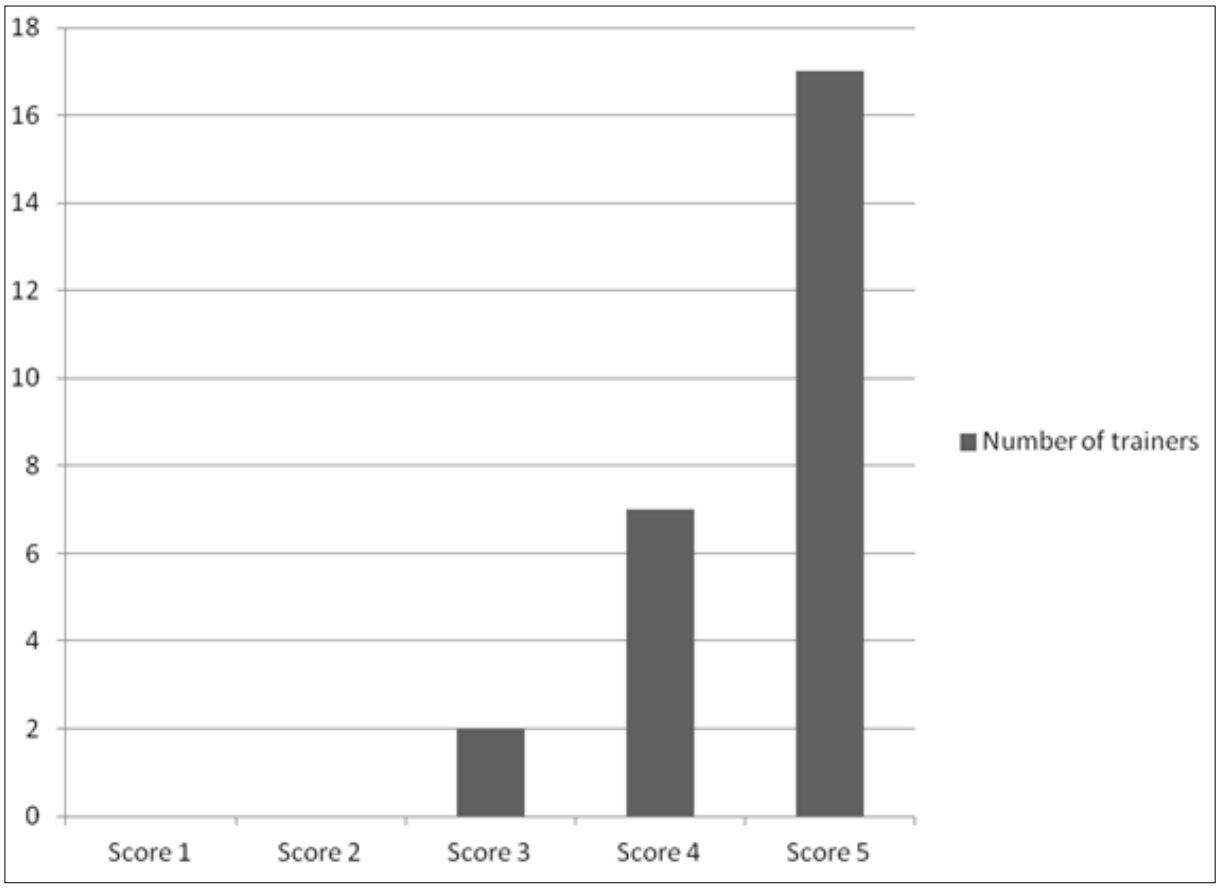

Figure 3: The way the topic was dealt with (group dynamics) - score: 1 – least, 5 – best

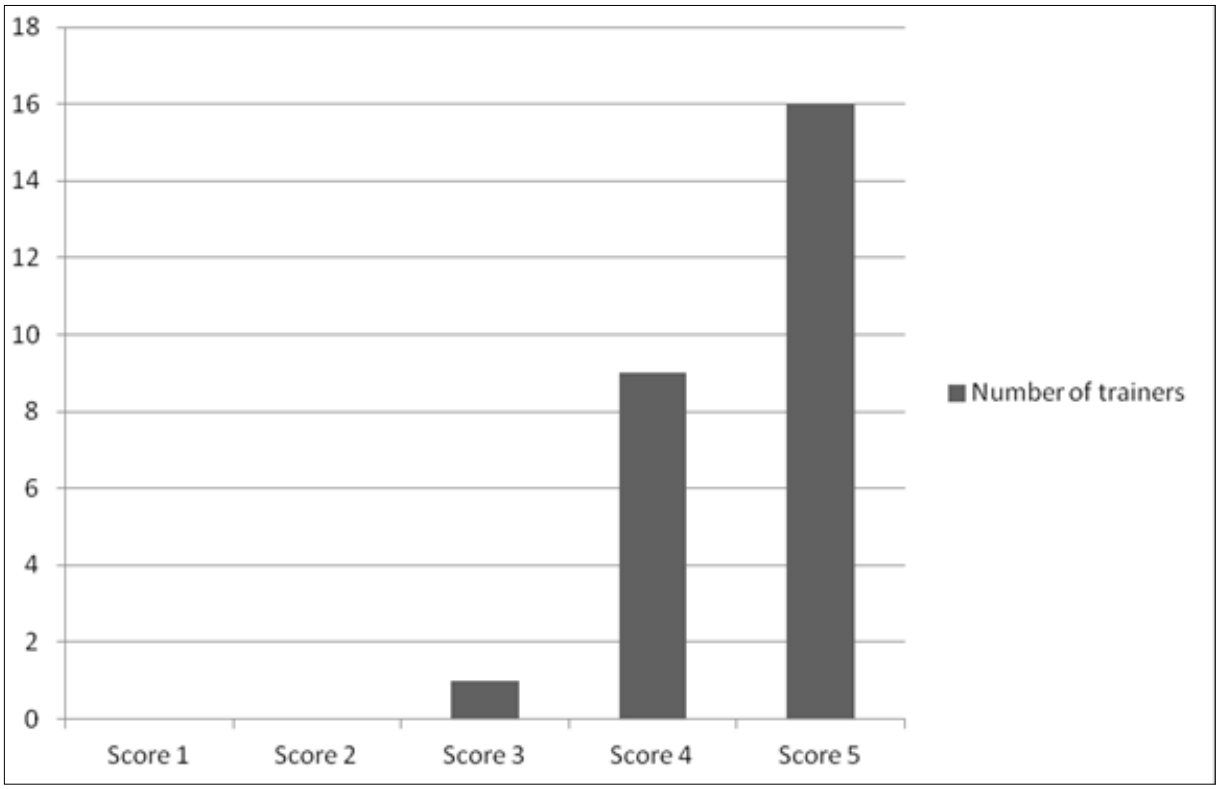

Table 1: Replies to the question 'What I liked'

Frank discussion with peers
Input from other trainers; discussion
Group interaction
Video Setup
Good interaction with frank discussions on approach in dealing with subject matter and trainee.
The very interesting and productive discussions.
Doctors with more experience had a different outlook from us younger doctors
Discussion
Sharing of different opinions and approach but reaching the same conclusions overall.
Being able to get practical feedback and seeing how and why colleagues mark in a particular way
Discussing feedback on how colleagues mark trainees.
Topic which we use daily, good to compare with peers
Interactivity and feedback from other trainers
CPD was practical and relevant and I also liked the group interaction.
Group discussion of things to look out for in COT and CBD scoring
Frank interaction between colleagues about various issues. Congruence between markings between trainers.
A very good experience. if only we can have them more frequent because its a learning experience. discussion with other doctors and learning from each other
Practical topic that will definitely come handy
Discussing scoring and appraisal with my peers. Very relevant
Relevance of topic...CBD + COT
Practical and useful to compare ideas
Possibility to discuss with colleagues
The open discussion on grading the Trainee
See different point of views; learn from others
Discussion with other trainers about common issues, different perspectives.
Group discussion

Table 2: Replies to the question 'What I would change'

Perhaps the food
Nothing regarding the session, but the quality of food could be improved
Nil
Not much.
Session format is fine
I would like to see some standardised scores especially of videos.
Punctuality
None
Presence of administrator missed.
Number of cases needed to discuss in one session as we had to rush to discuss cases.
Number of cases that need to be discussed. We had to rush through some cases since feedback given was quite significant and relevant.
Nil
Nothing from session except healthier food options
The time: late morning to early afternoon rather than all afternoon
Two step process of first scoring individually without discussion and then comparing scores!
Start at 1.00pm and end earlier to avoid traffic afterwards. Choose hot topics to discuss
The time when it was scheduled, has to be protected time catered for and covered
Possibly assessing material of either anonymous trainees or material off the internet
Nil
Nothing. Certainly not the boring format we had in previous years.
Good session. Nothing to change
Having the possibility to project the videos rather than see them on computer
The group size.
Twice a year; Health Centre based
Nothing
Smaller groups (3-4)

Table 3: Replies to the question 'Which area/s in your role as an educator do you feel needs further development'

Confidence
How to formulate and write reports of feedback in COTs and CBDs
Exposure to hospital specialities
Validating trainee work.
I had been away as a trainer so basically use of new portfolio and adapting to the new requirements
Guiding the trainees through the video consultations.
Alternative methods of teaching
Assertiveness
Researching new methods to make tutorials more dynamic and interesting.
How to encourage or motivate students
How to motivate students
How to help the trainee identify the his needs and guide him
Use of ePorfolio
Dealing with difficult trainees.
The e portfolio
How to interpret data, how to appraise journals or studies
More teamwork
Providing negative feedback. Sometimes I tend to sugarcoat things or worry about pointing out negative behaviors, which ultimately wouldn't benefit the trainee.
IT skills
Feedback in CBD.
Practical sessions - i feel time limitations do not allow us enough time to teach practical things to the trainees
Sharing resources that are used by Trainers in their training
Grading the CBDs
Timing
I would like to be more assertive at times.
Exploring trainees' concerns

Table 4: Replies to the question 'Mention one topic which you would like to be discussed in next year's Trainer CPD'

Same again
Discipline for truant GP Trainees and carefree supervisors
One to one mentoring
Consultation skills.
Same topics should be maintained
More on assessment.
As above
Depression
Medical legal
The above
The above
A topic related to coping with trainees problems
Contrast between marking of COT(Needs further dev, competent, excellent) and marking of Cases in final exit examine (Clear pass - Marginal pass - Marginal fail - Clear fail)
Social services available in Malta
Further ePortfolio training
Complex ethical issues when dealing with children and their carers
More video and CPD discussions
How to give constructive feedback
Guidance regarding assessments - going over difficulties experiences when filling out portfolio
Just a repeat of the same topic.
Same as this years
Sharing resources that are used by Trainers in their training
As this year. I felt that I learnt a lot from this session.
Preparing for summative assessment
Guidelines to trainers and trainees in difficult scenarios in clinic and home visits.
Metabolic syndrome

Table 5: Replies to the question 'Comments/suggestions'

Better than last year
Should the items for assessment have a description of what is meant by them to dispel uncertainties of meaning?
Good outcome
CPD's should not be too long as participants tend to lose interest and concentration when longer than 2 hours.
Very good initiative
Very useful session. Thank you
Found today's session extremely helpful - the most useful session so far . Would be happy to repeat it in a year or two's time
Very good meeting
A moderator would have helped the group reach the aims of the CPD, namely that marking of videos and CBDs become more consistent

survey targeted the whole population of trainers and not just a sample of them.

Favourable comments

Those participants that completed the questionnaire had positive comments regarding the relevance and group dynamics of the sessions (scoring 3 or more out of 5) and the ensuing discussion and interaction (81%). Moreover, 42% stated that they would not change anything about the CPD sessions, with 23% making favourable comments regarding them. This positive feedback regarding trainers' CPD resonated with previous studies in the UK and Malta, where educational CPD was found to be very important to GP trainers (Waters and Wall, 2007; Sammut and Abela, 2017).

Proposed organisational changes

Regarding areas for improvement, the most common comments (23%) were related to time concerns, specifically better timing of the sessions according to participants' availability and improving the schedule of topics to be tackled to avoid rushing through them. However, putting these comments into perspective, the afternoon timing of the sessions was mentioned by only two of the 26 participants, with the other respondents presumably happy with the time-slot allocated.

As regards the comments on the duration of the session and the speed with which the cases were covered, the direction given was to cover 2 video consultations and 2 case based discussions per session – this translates to 45 minutes per case which the coordinators believe was sufficient. Arising from a remark that the "presence of (an) administrator (was) missed" during the session, it is presumed that the problem arose when the identified coordinator of the group failed to act as moderator of the meeting.

Three observations were made regarding the quality of the food, which topic was promptly tackled by the coordinators, whose efforts were however limited by organisational and financial constraints. Another respondent commented that "the time when (the CPD session) was scheduled, has to be protected time catered for and covered". This challenge of protected time has also been identified by trainers in the UK (Waters and Wall, 2008) and is an ongoing problem faced in Malta due to staff shortages within state primary health care services (Sammut and Abela, 2013; Sammut and Abela, 2017; Sammut and Abela, 2019b).

Trainers' educational needs

A whole breadth of educational areas was identified by respondents as needing development. Some needs may be classified as basic (self-confidence, teaching methods, grading trainees' work) and organisational (developing IT skills, using the ePortfolio, managing time effectively, accessing resources and appraising data).

Other trainers said they needed to improve the guidance they provided to their trainees by enhancing their training skills, including:

- Giving feedback (4 participants);
- Motivation of trainees (2 respondents);
- Validating work;
- Providing guidance;
- Exploring concerns;
- Dealing with difficult trainees.

The development of teaching skills had similarly been identified as the top development need in an assessment of Maltese GP trainers' educational needs carried out during 2015 (Sammut and Abela, 2017).

A study of European GP trainers found that "experienced teachers were much more concerned about programme development, institutional support, methods of enhancing teaching and learning, while the emphasis for novice trainers was much more in relation to dealing with time constraints, putting theory into practice, and teaching while taking care of patients" (Guldal, et al., 2012).

Considering these conclusions of Guldal, et al. (2012), the two levels of educational needs identified by Maltese GP trainers (basic/organisational versus training skills enhancement) may have been proposed by different levels of trainers, namely those who are still new to the job and want to learn more in contrast to others who more experienced but feel they can do better.

Proposed topics for future sessions

A few specific topics were suggested for trainers' future CPD sessions, ranging from clinical (depression and metabolic syndrome), through social services availability, to medico-legal and ethical issues and problem cases. However, nearly two-thirds (65%) of participants requested topics related to teaching in general, with a special focus on assessment and marking.

The STPFM Quality Management Report for annual appraisals carried out in 2018 (Abela and Sammut, 2019) once again 'recommended that the theme of assessment and score allocation continues to be given its due importance and periodically discussed in the Trainer CPD sessions which are now being held regularly'. Thus, since the 2019 trainers' CPD sessions were overall well-received, it was only logical to propose that the same topic of assessment was tackled further during the sessions held in 2020. This proposal is consistent with a qualitative study of GP trainers in the UK which concluded that "achievable personal development plans can be constructed through an appraisal process" within an educational course (Pitts and Curtis, 2008).

Limitation of study method

Although the questions used in the feedback form were not passed through the process of validation, they were adapted from an evaluation form that has been used reliably for over ten years by GP trainees to evaluate half-day release course sessions they attended. Recall bias was avoided as the GP trainers were sent a link to an electronic feedback form promptly at the end of the session.

As just under half the GP trainers completed the feedback form, the opinions of the other 54% are unknown. The non-response may be due to participants being either happy with the training sessions or not being interested in providing feedback. Ideally non-respondents should have been contacted regarding their reasons for not replying, but this was not possible as the survey was anonymous. However, as the invitation to complete the survey was sent to all participating GP trainers and not just a sample, this effect of this bias was minimised.

While it would have been ideal to compare and contrast this local study with other international studies, such studies were found to be sparse; this finding highlighted the topic as a knowledge lacuna.

Recommendations

In the light of the feedback received, the following recommendations were proposed for discussion with the MCFD:

1. The same topic of assessment should be considered for 2020, while topics for trainer CPD sessions to be held after 2020 may include those suggested by the survey participants in their replies. These sessions could incorporate topics that are set at different levels for trainers with varying levels of knowledge and skills (Guldal, et al., 2012).
2. Organisationally, the same format used in 2019 could be used in 2020, however ensuring that the coordinators of the groups act as moderators during the sessions, making it a point that sessions start on time and keep to the time schedule allotted. Also, some worked examples could be used in these sessions.
3. In future, the use could be considered of any available face-to-face or online modules prepared by reputable institutions (such as the Royal College of General Practitioners and the European Academy of Teachers in General Practice/Family Medicine) that are approved by the MCFD as equivalent to or as a substitute for the trainer CPD meetings.

CONCLUSION

Since the 2019 trainers' CPD sessions were well received, it was proposed that in 2020 the topic of assessment should be tackled in more depth, with fine-tuning made of the sessions' facilitation and timing. Trainer CPD sessions to be held after 2020 could incorporate further recommended topics that are set at different levels for participants with varying levels of knowledge and skills. It is hoped that GP trainers' CPD activities will continue to develop their educational skills and thus benefit the quality of training provided to GP trainees.

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RESEARCH ARTICLE

Warfarin dosing and follow-up: adherence to the local guideline at a health centre in Malta

Dr Gabriel DE GIORGIO, Dr Naomi PISCOPO and Dr Anton BUGEJA

ABSTRACT

Background

Point-of-care testing (POCT) describes any test performed outside hospital where the result influences patient management.

Objective

This study aimed to establish whether warfarin dosing and follow-up at the local point-of-care (POC) clinic at Cospicua Health Centre (CHC) was performed in adherence to the locally provided 'Clinical Standard Operations Procedures for Health Centre POC-Based ACC Guideline' which is based on previous guidelines as published by the British Committee for Standards in Haematology (BCSH) on POCT.

Method

A set of five random consecutive entries for each of 50 randomly selected patients attending the POC clinic at CHC between January and September 2019 were analysed. The data collected included indication for anticoagulation, International Normalised Ratio (INR) result on date of dosing, new warfarin dose prescribed and follow-up given in days/weeks. Eligibility criteria included records of a minimum of five consecutive uninterrupted visits and a target INR range of 2-3, 2.5-3.5 or 3-4.

Result

A total of 250 entries were studied, and found to be mostly female patients (60%). The most common indication for anticoagulation in the population was atrial fibrillation (70%). Warfarin dosing was performed according to the local guideline in 80.4% of recorded entries. However, follow-up date given was only according to the local guideline in 42.8% of cases.

Conclusion

The lack of guideline adherence to local dosing and follow-up recommendations may lead to unsafe warfarin prescribing, increased healthcare resource expenditure and unnecessary appointments at busy POC clinics. Stricter adherence to the local guideline and implementation of an improved system of documentation remains desirable. The reasons behind this needs to be studied further when dedicated software was made available to doctors to aid in warfarin dosing.

Keywords

Point-of-care testing, warfarin, International Normalised Ratio.

INTRODUCTION

Community point-of-care testing (POCT) has greatly facilitated the means by which patients requiring anticoagulation are tested in a comfortable, fast and streamlined manner. Not only does this achieve moderate-to-high time in therapeutic range (TTR) more readily (Mooney, et al., 2019) but it also results in an increased patient satisfaction (Riva, et al., 2020) and longer TTR from POCT (Okuyama, et al., 2014). Similar results were also shown in other point-of-care (POC) tests, such as haemoglobin A1c (HbA1c), lipid profile and comprehensive metabolic panels (Crocker, et al., 2013). In Malta, POCT is cheaper than the laboratory-centralized system for INR testing (Zammit, et al., 2011) and is equally accurate (Riva, et al., 2017).

The POC service was extended to Cospicua Health Centre (CHC) in July 2014, complementing the previous method of venous sampling. The machine provides an immediate result within a matter of seconds, enabling the attending doctor to issue a prescription for warfarin dose and duration for follow-up at the time of testing. Records of the result and prescription are recorded in the patient's file and on a dedicated booklet which are kept by the clinic and patient respectively. This novel means of INR testing has improved the quality of life for many of the local citizens and service users as it does not necessitate visits to the island's general hospital and there is no delay for warfarin prescriptions. It also enables further assessment of the patient at the time of testing in scenarios where the INR result is grossly outside the therapeutic range.

When prescribing warfarin and advising follow-up, the doctor may refer to the easily accessible local guideline 'Clinical Standard Operation Procedures for Health Centres POC Based ACC' [hereafter local guideline] (see Table 1) which is based on the guidelines published by the British Committee for Standards in Haematology (BCSH) on POCT (Keeling, et al., 2011). Alternatively doctors may use the DAWN AC Anticoagulation Software which guides dosing. The programme is available at CHC and doctors received training in its use by the end of 2018.

During the authors' assignment to this clinic it was noted that this local guideline was not always being adhered to and that the relevant software was not in use. Furthermore there appeared to be issues with the dedicated POC documentation section in the patient's file. In view of this, the authors decided to conduct a formal study with the primary aim of assessing the adherence of doctors prescribing warfarin dose and follow-up duration at the CHC POC clinic with the local *'Clinical Standard Operation Procedures for Health Centres POC Based ACC'* guideline. Secondary aims included identification of possible limiting factors to local guideline adherence.

Table 1: Algorithms for warfarin dosage changes according to local guideline

Goal INR Range	Current INR	Adjustments	Recommended Follow-Up
2 - 3	< 1.5	Seek provider input to assess need for low molecular weight heparin (LMWH)	Twice weekly until INR in goal range
	1.5 – 1.7	Increase next dose by 50%, weekly dose to increase by a total of 10%	Weekly until INR in goal range
	1.8	Increase next dose by 50%, then resume normal dosing pattern	10-14 days
	1.9 – 3.2	No change	4-6 weeks
	3.3 – 3.5	Decrease next dose by 50%, then resume normal dosing pattern	10-14 days
	3.6 – 4.0	Decrease next dose by 50%, weekly dose to decrease by a total of 10%	Weekly until INR in goal range
	4.1 – 5.0	Decrease dose by 50% today and tomorrow, weekly dose to decrease by a total of 15%	Within 5 days
2.5 – 3.5	<2.0	Seek provider input to assess need for LMWH	Twice weekly until INR in goal range
	2 .0 – 2.2	Increase next dose by 50%, weekly dose to increase by a total of 10%	Weekly until INR in goal range
	2.3	Increase next dose by 50%, then resume normal dosing pattern	10-14 days
	2.4 – 3.7	No change	4-6 weeks
	3.8 – 4.0	Decrease next dose by 50%, then resume normal dosing pattern	10-14 days
	4.1 – 5.0	Decrease next dose y 50%, weekly dose to decrease by a total of 10%	Weekly until INR in goal range
3 - 4	<2.0	Seek provider input to assess need for LMWH	Twice weekly until INR in goal range
	2 – 2.4	Increase next dose by 50%, weekly dose to increase by a total of 10%. Seek provider input to assess need for LMWH	Weekly until INR in goal range
	2.5 – 2.8	Increase next dose by 50%, then resume normal dosing pattern	10-14 days
	2.9 – 4.2	No change	4-5 weeks
	4.3 – 4.5	Decrease next dose by 50%, then resume normal dosing pattern	10-14 days
	4.6 – 5.0	Decrease next dose y 50%, weekly dose to decrease by a total of 10%	Weekly until INR in goal range

(NB: INR - International Normalised Ratio)

METHOD

Study Design

A preliminary literature review was carried out prior to determine the data to be collected for a descriptive, cross-sectional, retrospective study. Approval was sought and obtained from the Data Protection Officer of the Primary Health Care Department. The research study was found to present no potential issues in the domain of research ethics and data protection.

Subsequently, a spreadsheet was created whereby data collected included entry number, hospital number, age, sex, indication for warfarin, target range, date of dosing (DOD), current dose (i.e. dose prior to testing) in mg, INR result on DOD, new dose (i.e. dose prescribed on DOD) in mg, follow-up given in days/weeks and resultant INR. A drop-down menu was included for both dose and follow-up to indicate whether this was done according to the local guideline (Yes/No).

Patient Population and Data Collection

Patients were randomly selected from the population with an appointment at the POC-clinic at CHC within a 9-month period between January and September 2019. Data was retrospectively collected primarily from the patients' clinical files and from the patients' anticoagulation booklets. Eligibility criteria included a clear record of a minimum of five consecutive uninterrupted visits and having a target INR range of 2-3, 2.5-3.5 or 3-4 (these ranges are covered by the local guideline). Interrupted entries, that is failure to attend a follow-up appointment or interim changes to the original dosing and follow-up plan, were excluded from the study. From the eligible patients, 50 random patients were selected and for these a random set of five consecutive entries of POC testing were identified (n = 250). At no point in the study did the authors encounter evidence for use of DAWN software.

RESULTS

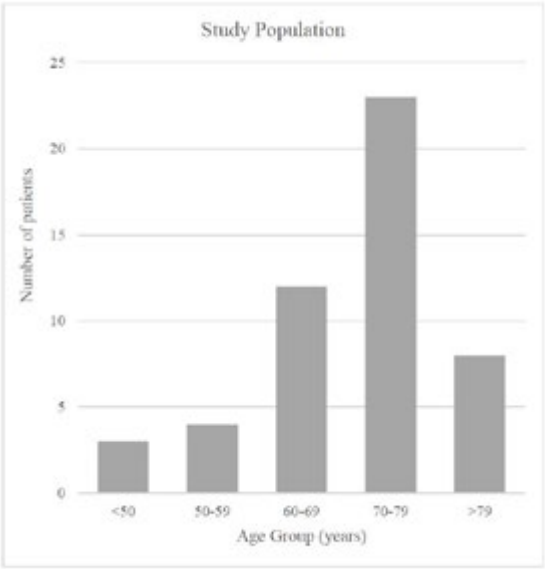
Demographics

Fifty patients were included in the study, of which 30 (60.0%) were female and 20 (40.0%) were male. Table 2 demonstrates the subject population's age statistics and Figure 1 shows the age group distribution.

Table 2: Tabulation of age statistics for subject population

Descriptive statistic	Age (years)
Range	47 - 84
Mean	70.18
Median	72
Mode	72

Figure 1: Column graph showing distribution of age groups in subject population



Indication for anticoagulation

The majority of subjects (70.59%) were on warfarin for atrial fibrillation (AF) whilst the least common conditions requiring anticoagulation were aortic valve replacement (AVR – 3.92%) and mitral stenosis (MS – 3.92%). Other conditions encountered in the subject population included deep vein thrombosis (DVT – 9.8%), mitral valve replacement (MVR – 5.88%) and pulmonary embolism (PE – 5.88%). One patient was being anticoagulated simultaneously for MS and AF (see Table 3).

A therapeutic INR range of 2-3 was indicated in 46 patients (92%), whilst the desired range for the remaining 4 patients (8%) was 2.5-3.5 (one AVR and three MVR). None of the patients in the study had a desired INR range of 3-4.

Table 3: Indication for anticoagulation for the subject population

Indication for Anticoagulation	Number of Patients with condition
Atrial fibrillation (AF)	35
Mitral valve replacement (MVR)	3
Aortic valve replacement (AVR)	2
Deep vein thrombosis (DVT)	5
Pulmonary embolism (PE)	3
Mitral stenosis (MS)	1
MS + AF	1

Adherence to local guideline

When dosing warfarin at POCT, almost one fifth of prescribing doctors (19.6%) diverged from the respective local guideline according to the patient's desired INR range, with a tendency towards under dosing. For the remaining majority, i.e. 201 of 250 entries (80.4%), the dose of warfarin given was according to the local guideline's recommendations (see Figure 2). When the Rosendaal method of calculating therapeutic time in range (TTR) was used to assess the result (Rosendaal, et al., 1993), patients who were given warfarin according to local guidelines had a higher TTR (74.9%) when compared with those for which the local guideline were not observed (41.1%).

Only 42.8% of all entries had a follow-up appointment scheduled according to the local guideline. Out of the remaining 57.2%, the great majority opted for an earlier appointment (see Figure 3). Indeed 92% of the latter had an earlier appointment; if these were given a correct appointment these patients would have been spared a total of 150 days, one of whom was brought earlier by 28 days. In contrast, the remaining patients were given a later appointment for a total of 30 days, with one given an appointment 14 days later than was indicated. The TTR in patients given warfarin according to local guideline and those in which the local guideline was not observed was comparable at 68.2% and 68.1% respectively.

Figure 2: Pie chart showing the proportion of doctors who adhered to the proposed changes in warfarin dosing as per the algorithms for warfarin dosage changes according to local guideline (see Table 1)

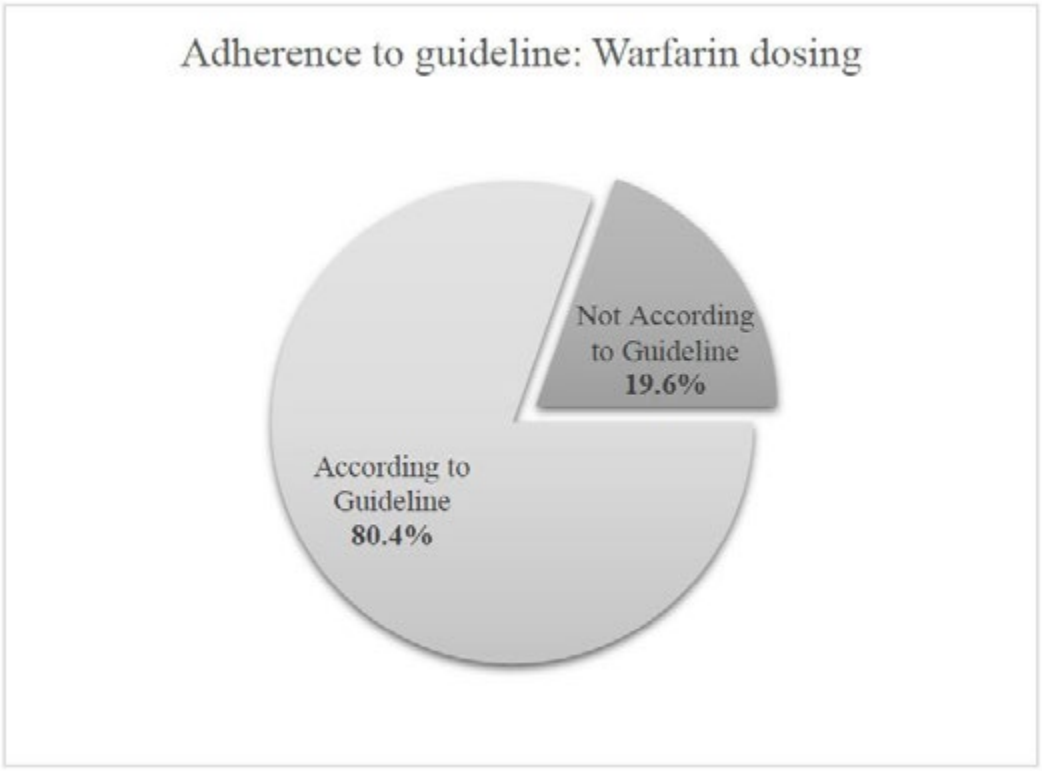
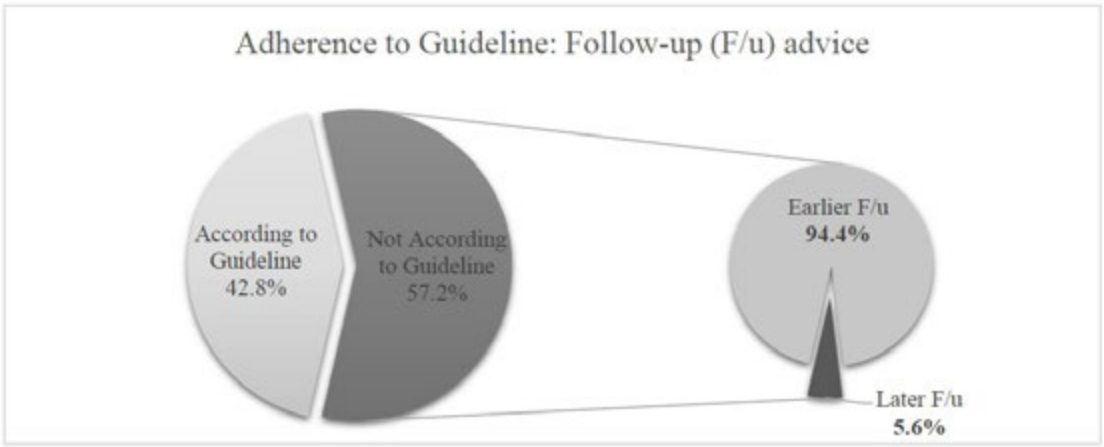


Figure 3: The pie chart on the left shows the proportion of doctors who adhered to the proposed changes in providing follow-up as per the algorithms for warfarin dosage changes according to local guideline (see Table 1). The pie chart on the right shows the proportions of earlier / later follow-ups given by the doctors who did not adhere to the follow-up advice proposed by the local guideline



DISCUSSION

The study highlighted the fact that doctors' adherence to the local standardized method guiding warfarin dosing (80.4%) and especially follow-up (42.8%) is lacking. A tendency towards under-dosing and advising earlier follow-up appointments emerged. The general tendency to offer earlier follow-up advice was however clear, with only 5.6% of the proportion of doctors not adhering to the local guideline offering follow-up appointments later than advised. This seemingly 'safer' approach did not result in better outcomes. Indeed, under-dosing decreased TTR and earlier follow-ups did not result in any benefit, with its unnecessary inconvenience for the patient, increased workload on POC clinic staff and improper allocation of healthcare resources. This is in line with the findings of Franke, et al. (2008) who had shown that adherence of doctors to a standardized protocol guiding warfarin dosing increases the percentage of patients being found within the desired INR range on follow-up testing.

Various factors might be considered for earlier appointments, including the individual patient's ability to maintain a moderate-to-high TTR, current or recent use of medications such as antibiotics and/or other drugs which interfere with the mechanism of cytochrome P450 (CYP450) enzymes, seasonality, diet and alcohol intake. Some of these factors may be indirectly related to each other, such as the seasonality with diet and alcohol intake. To address this limitation, entries considered in the study spanned from January until September of 2019.

These confounding factors, however, should prompt the attending doctor to refer the patient for central laboratory testing (i.e. to the central ACC) at Mater Dei Hospital (MDH) especially in the presence of 3 consecutive INRs outside the therapeutic range of 1.9-3.2 as stated in the 'Non-eligibility criteria for patient transfer from the current system to the HCPOC ACC' in the local guideline (see Table 4). When analyzing the data, it transpired that 4 of the 50 patients (8%) with INRs outside the range of 1.9-3.2 were followed-up at CHC POC clinic instead of being seen at the MDH ACC.

Table 4: Non-eligibility criteria for patient transfer from the current system to the health centre point-of-care anti-coagulant clinic (HCPOC ACC) according to the clinical standard operation procedures for HCPOC-based ACC

1	Unstable International Normalised Ratios (INRs) as defined by 3 consecutive INRs outside the therapeutic range of 1.9 – 3.2
2	Patients with a target INR >3.0
3	Patients with antiphospholipid syndrome
4	Patients with liver disease
5	Patients with severe renal failure
6	Patients on other anticoagulants including those on dual antiplatelet agents
7	Patients suffering from active cancer (receiving treatment with chemotherapy or radiotherapy)

Patients who regularly attend POC clinic at their respective health centre (HC) should not simultaneously attend the MDH ACC as the two modalities of measurement are not entirely interchangeable. Studies show that there is a positive bias of around 0.24-0.35 INR units for POCT when compared to conventional central laboratory instrumentation for INR monitoring, which becomes more significant with increasing values of INR (Dorfman, et al., 2005), thus highlighting the need to refer the patient to MDH ACC in case of unstable INRs.

The POC clinic's current documentation system can be improved. In most cases, successive entries were jotted down in random, untitled sections of the patient's file, making continuity of care difficult. A dedicated form should be used for POC clinic entries, preferably using that provided by the DAWN software, thus enabling the prescribing doctor to rapidly find the previous entry and dose accordingly and help avoiding confusion and prescribing errors. Such a form would include:

(i) *Patient details*: name, hospital number, age, indication for warfarin, target INR range
(ii) *Date of POC clinic appointment*
(iii) *Last warfarin dose prescribed and follow-up advice in days/weeks*
(iv) *Today's INR result*
(v) *New warfarin dose and follow-up advice in days/weeks*
(vi) *Tick-the-box option to indicate whether local guideline was adhered to*
(vii) *Remarks section:* to include any concurrent CYP450 enzyme-inducers/inhibitors along with a justification for not following the local guideline in the respective cases
(viii) *Name, signature and registration number of prescribing doctor*

The small sample size and performance of the study in only one out of eight public health centres in Malta are limitations to this study. This did not allow analysis of the effect of training and level of expertise on quality of care.

Nonetheless the random selection of 50 patients who regularly attend the POC clinic at CHC for warfarin dosing remains a good representation of the regional population (when considering that 15 to 20 appointments are given daily with a maximum follow-up of no more than at 6 week intervals). The results highlight challenges in the regional adherence of the local guideline as well as identified factors influencing outcomes. Conspicuous is the lack of use of the DAWN software which would have addressed many issues highlighted above, namely correct dosing and setting of an appropriate follow-up appointment. The reasons behind the lack of use of this software remain unknown, requiring separate study and eventual implementation.

CONCLUSIONS

This study at CHC has shown that warfarin dosing in the majority of cases is in line with the provided local guideline, but improvements are necessary in the advice for follow-up. This may be achieved if local protocols are more strictly adhered to so as to ensure better TTRs, decreased patient inconvenience and increased efficacy of healthcare resources. Non-eligibility criteria for POCT should be kept in mind and patients should be referred to central laboratory instrumentation monitoring at MDH when appropriate. The implementation and use of DAWN software should facilitate the chronological recording of the patients' warfarin dosing history, with a subsequent decrease in the chance of errors in prescribing.

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