



Structure and function of anticoagulation clinics in the United States: an AC forum membership survey

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Abstract

Many anticoagulation clinics have adapted their services to provide care for patients taking direct oral anticoagulants (DOAC) in addition to traditional warfarin management. Anticoagulation clinic scope of service and operations in this transitional environment have not been well described in the literature. A survey was conducted of United States-based Anticoagulation Forum members to inquire about anticoagulation clinic structure, function, and services provided. Survey responses are reported using summary or non-parametric statistics, when appropriate. Unique clinic survey responses were received from 159 anticoagulation clinics. Clinic structure and staffing are highly variable, with approximately half of clinics (52%) providing DOAC-focused care in addition to traditional warfarin-focused care. Of those clinics managing DOAC patients, this accounts for only 10% of their clinic volume. These clinics commonly have a DOAC follow up protocol (75%). Clinics assign a median of 190.5 (interquartile range 50–300) patients per staff full-time-equivalent, with more patients assigned in phone-based care clinics than in face-to-face based care clinics. Most clinics (68.5%) report receiving reimbursement, which occur either through a combination of patient and insurance provider billing (78.2%), insurance reimbursement only (19.5%) or patient reimbursement only (2.3%). There is wide heterogeneity in anticoagulation clinic structure, function, and services provided. Half of all survey-responding anticoagulation clinics provide care for DOAC-treated patients. Understanding how changes in healthcare policy and reimbursement have impacted these clinics remains to be explored.

Highlights

- Anticoagulation clinics have highly variable structure and staffing models
- While half of anticoagulation clinics provide DOAC-focused care, these patients represent a small minority of the anticoagulation clinic population
- Future studies should examine how changes in healthcare policy and reimbursement may impact anticoagulation clinic structure and function

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Introduction

Warfarin is a notoriously difficult medication to manage [1]. Although effective for the prevention of thromboembolism, it has a long onset and offset of action in addition to numerous drug and food interactions. Lastly, it has a narrow therapeutic window in which the benefits of preventing thromboembolism and the risks of bleeding are optimally balanced. Helping patients achieve that balance and keeping them within a narrow therapeutic window is a constant challenge.

Anticoagulation clinics were introduced over two decades ago to centralize, standardize, and improve the care of patients on warfarin, usually for the prevention of stroke associated with atrial fibrillation [2]. Since that time, these clinics have grown and evolved to care for patients with a wide variety of conditions, clinical needs, and newly introduced medications [3]. Most significant is the introduction of direct oral anticoagulants (DOACs) in 2010.

Despite the longstanding presence of anticoagulation clinics, a robust review of existing clinic structure and

function has not been undertaken since the introduction of DOAC medications. In this survey, we describe the diversity of anticoagulation clinics across the United States with a focus on their clinic structure and services provided.

Methods

A team of clinical and research experts developed a web-based survey aimed at characterizing anticoagulation clinic structure and services. This survey was piloted and refined based on feedback from six diverse anticoagulation clinics associated with the Michigan Anticoagulation Quality Improvement Initiative, a Blue Cross Blue Shield of Michigan-sponsored collaborative [4, 5].

All current members of the Anticoagulation (AC) Forum were invited to participate in the survey (online supplement). An e-mail invitation was sent to the AC Forum listserve with two reminder e-mails between March and April 2017. Social media was also used to promote participation in the survey to the AC Forum membership and followers. Survey respondents were offered a chance at one of four \$50 gift cards in exchange for completing the survey.

This project was reviewed and deemed exempt from regulation by the University of Michigan institutional review board (HUM00126169). Funding for this survey and analysis was provided by Pfizer. Pfizer medical affairs authors provided input to study question development and design, but University of Michigan investigators made all final decisions regarding survey design, data analysis, and results reporting.

The survey respondents were limited to those residing and working within the United States; all respondents from outside the United States were excluded from final analysis. Additionally, we screened for any duplicate responses based on clinic zip code, hospital affiliation, patient population served (inpatient vs. outpatient), training level (e.g. nurse, pharmacist), and role (front-line provider vs. clinic manager) of the survey respondent. We also excluded any clinics that provided only inpatient care ($n = 2$), as our focus was on chronic anticoagulation management.

All survey respondents were invited to complete the first half of the survey, focused on details of clinic function that any staff member is likely to know (e.g. types of patients managed, services provided). The second half of the survey was administered only to respondents who self-indicated detailed knowledge of the clinic's staff model, structure, and policies (51/159, 32.1%). These questions focused on more detailed information, such as number of staff full-time-equivalents (FTE) by training level, staff reimbursement for after-hour coverage, and patient distribution based on indication and insurance. The survey design employed a logic mechanism intended to limit the number of questions any survey respondent had to complete. For example, a question

about the types of DOAC services offered in a clinic was limited to respondents who expressed detailed knowledge of the anticoagulation clinic/service insurance, diagnosis, and drug treatment breakdown as well as reported care of DOAC patients in their clinic. Results are reported both for the number of survey respondents and the percent of survey recipients who were shown individual questions. Missing values were excluded from the denominator when calculating percentages.

Statistical analysis was performed using Stata version 14.2 (StataCorp, College Station, TX). Summary statistics (mean \pm standard deviation [SD] or median and interquartile range [IQR]) are presented for all analyses. Analysis of staff FTE are based only on clinics employing each specific category of staff member. Spearman's rho was calculated for the association between clinic size and number of patients assigned to each FTE staff. The Kruskal–Wallis test was used to compare the association between clinic structure (e.g. phone-based or face-to-face) and the number of patients assigned to each FTE staff. Comparisons of clinic reimbursement and point-of-care INR testing were performed using chi-squared analysis.

Results

Survey responses were collected from 166 anticoagulation clinic providers. Four responses from outside the United States, one duplicate response, and two responses from inpatient-only services were excluded, leaving 159 unique surveys from 36 states for further analysis. The majority of clinics provided only outpatient care (114/159, 71.7%), followed by both inpatient and outpatient care (45/159, 28.3%). The majority of clinics were not affiliated with academic institutions (125/159, 78.6%). The most common form of patient interaction by clinics involved a combination of face-to-face and telephone-based care (75/158, 47.5%), followed by face-to-face only (54/158, 34.2%) and phone-based only (29/158, 18.4%).

Nearly all clinics (158/159, 99.4%) provided care for patients treated with warfarin while just over half (83/159, 52.2%) provided care for patients taking DOAC medications. Clinics that manage both warfarin- and DOAC-treated patients estimated that 90% (IQR 65–93%) of patients are on warfarin while 10% (IQR 5–30%) are on DOAC medications. At the time of anticoagulation clinic enrollment, most clinics (146/159, 91.8%) provided advice about anticoagulant dose selection while fewer provided advice about anticoagulant drug selection (83/159, 52.2%), INR target range selection (106/159, 66.7%), and duration of therapy (80/159, 50.3%). For warfarin-treated patients, clinics used a combination of different INR laboratory testing methods (Fig. 1). For clinics that care for DOAC patients, use of

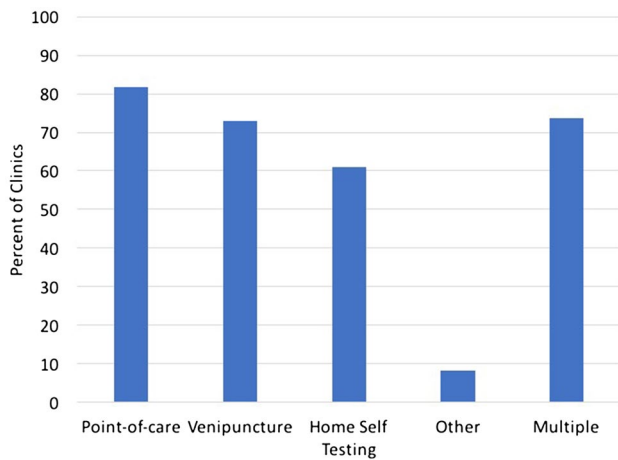


Fig. 1 Clinic Utilization of INR Testing Methods. Clinics may use multiple forms of INR testing and, therefore, be represented in multiple categories

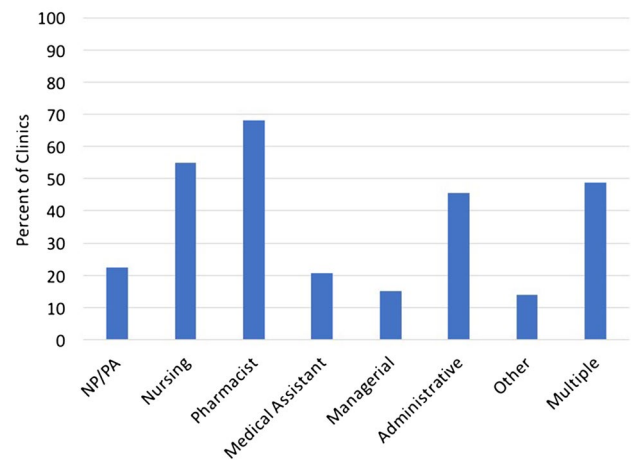


Fig. 3 Staff Utilization by Anticoagulation Clinics. Clinics with multiple staff types are represented multiple times in this figure. NP/PA nurse practitioner/physician assistant

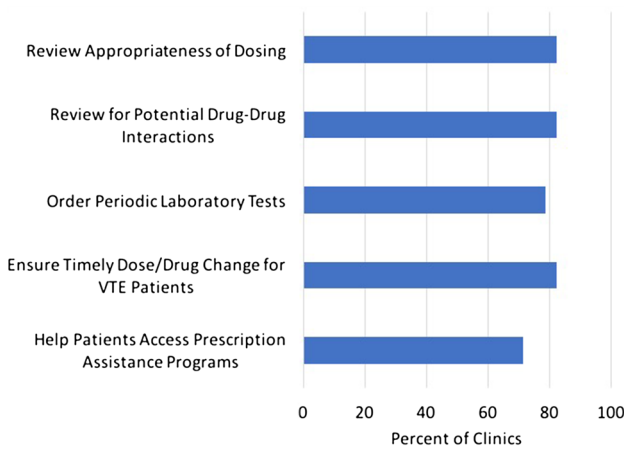


Fig. 2 Services Provided by Clinics for DOAC Patients. Percent of clinics reporting each service among surveyed clinics reporting care of patients treated with direct oral anticoagulants. DOAC direct oral anticoagulant, VTE venous thromboembolism

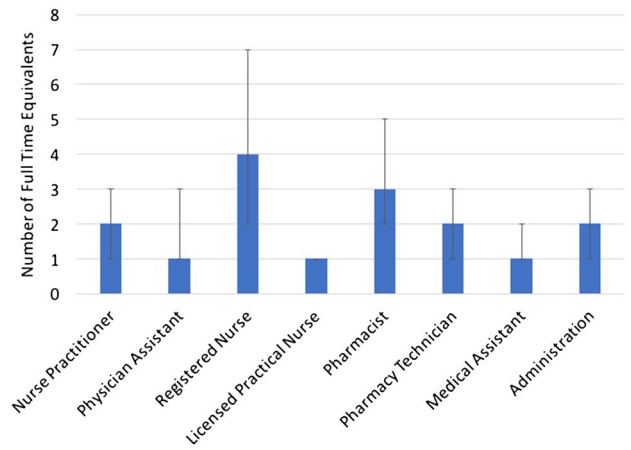


Fig. 4 Number of Clinical FTE by Staff Type. Clinics may have multiple staff member types. Median number of full time equivalent staff calculated among clinics reporting use of that specific staff type. Error bars indicate interquartile ranges. FTE full-time-equivalents

follow up protocols were common (21/28, 75%). Specific services were routinely provided, with at least 25/28 (89.3%) providing one or more of the services asked about in the survey (Fig. 2).

Nurses and pharmacists were the most common staff in the anticoagulation clinics (Fig. 3). Seventy-eight of 159 (49.1%) clinics reporting a combination staff with different training skills (e.g. nursing, pharmacist, medical assistants). Among the 88 clinics using nurses to deliver care, 47 (53.4%) did not employ any pharmacists. Similarly, among the 109 clinics using pharmacists to deliver care, 68 (62.4%) did not employ nurses. Forty-one out of 159 (25.8%) used both nurses and pharmacists to care for patients. Combined use of face-to-face and phone-based care was more common

in the nurse-only clinics (29/46, 63.0%) as compared to the pharmacists-only clinics (27/68, 39.7%) while face-to-face care was more common in the pharmacists-only clinics (30/68, 44.1%) as compared to nurse-only clinics (11/46, 23.9%, $p=0.042$).

As shown in Fig. 4, clinics were most heavily staffed with nurses (median 4 FTE) and pharmacists (median 3 FTE). Clinics managed a median of 925 patients (IQR 400–2000). The median number of patients assigned to one clinical FTE was 181 (interquartile range 50–300). There was a modest positive association between clinic size and number of patients assigned to each clinical FTE (Spearman's rho 0.606, $p<0.001$). Phone-based clinics had a higher median number of patients assigned to each clinical FTE

than face-to-face clinics (350 vs. 117.5, $p < 0.001$, Fig. 5). Collectively, the 130 clinics reporting their patient volume managed 209,096 patients on chronic anticoagulants.

Most often, patients managed by the anticoagulation clinics were treated for stroke prevention in atrial fibrillation ($54.2\% \pm 16.4\%$), followed by venous thromboembolism ($27.7\% \pm 16.0\%$), mechanical valve replacement ($10.7\% \pm 6.9\%$), and prophylaxis following orthopedic surgery ($2.5\% \pm 3.6\%$). Most patients were insured through Medicare ($51.9\% \pm 24.2\%$), followed by private insurance ($23.0\% \pm 17.6\%$) and Medicaid ($13.0\% \pm 13.9\%$). A majority of respondents (88/128, 68.8%) reported being reimbursed for the services provided by their anticoagulation clinic. These clinics were most commonly reimbursed through a combination of insurance and direct patient payment (68/88, 77.3%), followed by insurance reimbursement only (18/88, 20.5%) and patient reimbursement only (2/88, 2.3%). Of clinics who reported reimbursement for their services, 82/88 (93.2%) used point-of-care INR testing while non-reimbursement clinics are less likely to use point-of-care INR testing (23/40, 57.5%, $p < 0.001$). There was no significant association between anticoagulation clinics receiving reimbursement for their services and the number of patients managed (OR 1.0, $p = 0.12$) or the number of clinic FTE staff (OR 0.98, $p = 0.43$).

Discussion

Our survey of 159 anticoagulation clinic providers across the United States demonstrates important variation in clinic structure and function. While nearly all clinics manage patients on warfarin, only half have begun to manage patients taking DOAC medications. Additionally, the staffing of these clinics is quite varied, with only one quarter of

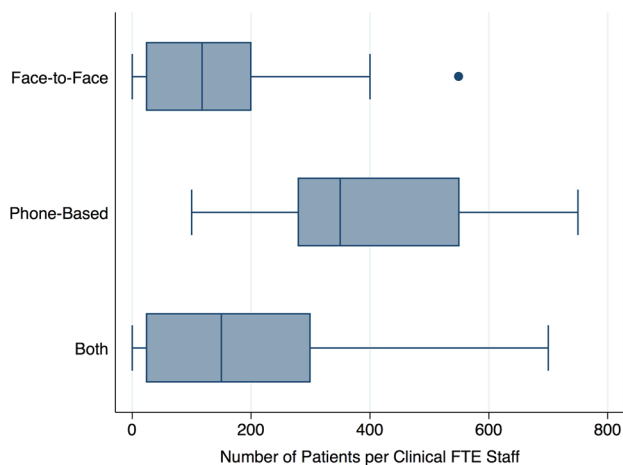


Fig. 5 Number of Patients Assigned to Clinical Staff. *FTE* full time equivalent

clinics employing both nurses and pharmacists. More clinics who responded to our survey have pharmacist staff than nursing staff. Finally, phone-based care was associated with lower resource use than face-to-face clinics, as evidenced by larger patient-to-staff ratios.

Numerous published reports have compared anticoagulation clinic care to usual care [6–10]. In general, they find benefit to care delivery in a dedicated anticoagulation clinic model. However, very few reports have examined the structure and function of these clinics, and none have explored the role anticoagulation clinics are playing for DOAC-treated patients.

Recent guidance documents from the European Heart Rhythm Association and the AC Forum recommend a series of care steps for every patient treated with DOACs [11, 12]. These include checking for medication adherence, monitoring for adverse events (e.g. bleeding or thromboembolic events), assessing for any change in medications (particularly medications known to interact with DOACs) and reviewing lab tests (e.g. renal function). These are activities currently performed by most anticoagulation clinics for their warfarin-treated patients. It makes logical sense that similar activities should be provided for DOAC-treated patients. This may be of particular importance given the complexities in DOAC dosing (e.g. different doses for different indications and renal function level). In fact, a recent report suggests that nearly 10% of patients are prescribed inappropriate DOAC doses [13]. Inappropriate dosing of DOACs was linked to an increased risk of all-cause mortality and hospitalizations. Therefore, review of dosing by anticoagulation experts in the anticoagulation clinic could be a potentially life-saving intervention [3].

As anticoagulation clinic staff face changing patient demographics, reimagining the role of the clinic is critical [3]. Central to that will be the model of care delivery and how that ties to reimbursement. Our data suggest that a majority of these are reimbursement-based clinics, although nearly one-third do not generate any reimbursement. Clinics that are reimbursement-based are also more likely to use point-of-care INR testing for at least part of their patient population.

Our study has a number of important strengths. This is the largest survey of anticoagulation clinic providers to report on the structure and function of anticoagulation services with robust responses from clinic in more than two-thirds of US states representing a wide variety of clinic models and sizes. There are also a few limitations that should be considered. First, we are unable to report a response rate since the survey invitation was open to anyone on the AC Forum e-mail list or who connected via social media. This was done to increase response quantity and diversity. Second, we are unable to verify any of the survey responses to individual questions. However, given the large sample size

and the general familiarity of clinic staff with their daily operations, we believe these results to be as truthful as possible. We also limited more detailed questions (e.g. number of FTE) to respondents who reported having in-depth knowledge of clinic operations and management. As with any survey, the reported findings are based on respondent self-report. We were unable to objectively verify any of the survey responses. Finally, while our large sample size allows for some generalization of the findings, we did not specifically gather a nationally representative sample of anticoagulation clinics.

Given the diversity in anticoagulation clinic structure and function, a one-size-fits-all approach to DOAC care is unlikely to be successful. Rather, implementation of DOAC care must address the contextual factors that vary between each clinic, their patients, and resources. Future studies should explore different approaches to DOAC care and address ability to scale across a diverse range of anticoagulation clinics, including face-to-face, phone-based, and population-based care models.

In summary, anticoagulation clinic care is diverse across the United States, but has evolved to incorporate care of DOAC patients in numerous sites. With different staffing and reimbursement models, future care interventions that incorporate the anticoagulation clinic must account for this variation in personnel, structure, and services provided.

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Compliance with ethical standards

Conflict of interest GDB has received consulting fees from Pfizer, Bristol-Myers Squibb, Janssen, and Portola along with research support from Pfizer, Bristol-Myers Squibb, and the National Heart, Lung, and Blood Institute. EKR has received consulting fees from the American College of Physicians. JBF has received consulting fees from Pfizer, Bristol-Myers Squibb, and Janssen along with research funding from Pfizer and Bristol-Myers Squibb.

Ethical approval This project was reviewed and deemed exempt from regulation by the University of Michigan institutional review board (HUM00126169).

Informed Consent Consent was implied when survey respondents elected to complete the survey.

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