Using a Clinical Practice Guideline for Making Clinical Decisions

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Clinical practice guideline is defined as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options". It includes recommendations that are intended to optimize patient care. They are the best source of evidence for busy clinicians and may be the most efficient type of evidence to guide decision making in family practice.

Critical Appraisal

Relevance

1. Does the objective of the clinical practice guideline address to the clinical question?

Validity

1. Was an explicit and sensible process used to identify, select, and combine evidence?
2. Were all important options and outcomes considered?
3. Is the guideline likely to account for important recent developments?

Results and Recommendations

1. Are practical, clinically important, recommendations made?
2. How strong are the recommendations?

Applicability

1. Are the recommendations applicable to family practice and preferred by your patient?
2. Has the guideline been subjected to peer review and testing?

Key words: Evidence-based family practice, clinical practice guideline

Introduction

Family physicians cater to undifferentiated cases of patients and often faced with dilemmas in making multiple clinical decisions in a short period of time. For a patient with a diagnosed disease, the family practitioner may contemplate on what drug to prescribe, advice on what to avoid, patient and family directed health education, information about prognosis etc. In this case looking for evidence in every decision may be time consuming. There is a need for means of facilitating easy access to evidence to give answers to complex decisions for busy clinicians. Clinical practice guidelines, consensus statements and clinical pathways can be a useful tool for this.

Clinical practice guideline is defined, by the Institute of Medicine, as "statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options".[1] It includes recommendations that are intended to optimize patient care. A panel of experts formulates recommendation questions that guide the retrieval of evidence that is used to inform the recommendations.[2] It is an important vehicle for collating evidence examining the effectiveness and cost-effectiveness of practice, and for making recommendations for decision-makers.[3] Clinical practice guidelines and systematic reviews may be the best source of evidence for busy clinicians. Unlike treatment protocols that is usually based on consensus, clinical practice guidelines are developed by multidisciplinary teams who systematically review and evaluate the evidence and propose recommendations on what to do in specific clinical situation.[4] Thus, clinical practice guidelines are the most efficient type of evidence to guide decision making in family practice.

Scenario

Let us again consider the 55-year-old male patient discussed in the previous section was already diagnosed to have stable angina.

Because of the danger of worsening into AMI, the family physician must provide a comprehensive outpatient management plan. This includes clinical decision on what drugs to prescribe, advice on what to do and what to avoid, what is going to be the prognosis if he adheres or not to the management plan etc.

The Centre for Evidence Based Medicine (CEBM) mentioned that "one of the fundamental skills required for practicing EBM is the asking of well-built clinical questions". The PICOM Framework can guide the physician order to come up with a well-focused clinical question. PICOM stands for: Population or Patient Problem, Intervention, Comparison or Control, Outcome and Method. For this scenario, a comparison or control is not needed to be identified since we are not comparing an intervention with another alternate. The scenario can therefore be broken into the PICOM format as seen in Table 1 below.

Searching for the Clinical Guidelines

Reliable search engines for searching databases of archived published medical literature or journals are the following: PubMed, EMBASE, Cochrane Databases of Systematic reviews, and guidelines. gov. If the initial search from these search engine does not yield the intended results, the physician may use Google scholar search. Based on the clinical question, a PubMed search was done using the combination of the terms "stable angina" or "ischemic heart disease", "management", "primary care" and "clinical practice guideline". The best yield in PubMed search was the article by Snow V, et al. However, there are no updates for this guideline hence not considered by the family practitioner. Other sources can also be search for articles not found in PubMed or EMBASE. Google scholar was also search using the combination of the same terms and yielded the article by Knuuti J, et al. 2019 ESC Guidelines for the diagnosis and management of chronic coronary syndromes. European Heart Journal (2020) 41, 407477.[5] The word "Philippines" may also be added to the search term to find locally developed guideline. Google scholar search revealed this CPG: Lazaro, V. 2014 PHA Clinical Practice Guidelines for the Diagnosis and Management of Patients with Coronary Heart Disease. Asean Heart J 24, 3 (2016).[6] The family practitioner may decide to appraise all the guidelines and if all are valid may adapt decisions from them.

Critical Appraisal

Clinical practice guidelines should be developed using rigorous methodology based on a systematic review of the best available evidence for specific clinical questions and provide a rating of the quality of evidence.[7] To be trustworthy, guidelines should result from a rigorous, inclusive, and transparent process, informed by the best available research evidence and safeguarded against biases and conflicts of interest.[8] To be trustworthy, guidelines should:

- be based on a systematic review of the existing evidence
- be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups
- consider important patient subgroups and patient preferences, as appropriate
- be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest
- provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of the recommendations
- be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations

Several tools exist to appraise clinical practice guidelines.[9] The IOM developed a tool which uses 7 attributes which includes: Clinical applicability, clinical flexibility, reliability/reproducibility, validity, clarity, scheduled review and multidisciplinary process. The Appraisal of Guidelines for REsearch & Evaluation (AGREE) Instrument is the most widely used and is accepted and validated instrument to assess the guideline quality to assesses the methodological rigor and transparency in which a guideline is developed.[10] The AGREE II is the latest version of the tool and consists of 23 key items organized within 6 domains followed by 2 global rating items ("Overall Assessment"). Overall assessment includes the rating of the overall quality of the guideline and whether the guideline would be recommended for use in practice. The different tools mentioned above, though thorough and comprehensive, may be lengthy and time consuming for the busy family practitioner.

Table 1. PICOM framework.

PICOM Framework	Think:	Case Application
Population	What is the population of interest? Or patient's demographics such as age, gender or ethnicity?	Adult patients with stable angina
Intervention	What type of intervention is being considered? For example, is this a pharmacologic such as beta blocker or non-pharmacologic management such as diet or exercise?	Pharmacologic and non-pharmacologic management
Outcome	What is the desired outcome or effect that you would like to see?	Resolution of symptoms, avoidance of complications, or disease progression
Method	This refers to the design /type of research that you intend to search.	Clinical guidelines / Clinical Practice Guidelines

Based on this scenario and the framework, the clinical question can be – "Among adult patients with stable angina in the primary care setting, what is the recommended management using clinical guidelines"?

The PAFP committee proposes the following guide questions to be used when appraising clinical guidelines.

Relevance

1. Does the objective of the clinical practice guideline address to the clinical question?

Sometimes we have a tendency to proceed directly to the recommendations. But before we proceed to the recommendations, the family practitioner must first assess whether to scope and coverage of the clinical guideline is in line with your patient or clinical scenario. Afterall, how will the guideline be relevant to you in the first place, you are reading a guideline for pediatric patients but the case you are appraising is adult or geriatric patient?

Your formulated clinical question must be addressed by the objective of the clinical practice guideline. Guideline objectives are broad i.e., answers questions about the best diagnostic test, the recommended drug and non-drug interventions, the expected outcome or prognosis etc., in other words the comprehensive management for a particular disease.

The purpose of the guideline developers for coming up with recommendations may vary from the family physician's objective. Guidelines may be disseminated to assist physicians in decision making (clinical algorithms), to evaluate practice and determine the standard of care (quality assurance) or to set limits for physician choices by regulatory agencies (reimbursements, recertification). In any case, in order to find recommendations most suited to your needs, the purpose of the guideline should be in line with your clinical question. This is where clinical question that you generated in the beginning comes in handy. You make a comparison whether the guideline you are appraising has the same "PIO" with your clinical question. Does the guideline you are appraising have the same population, intervention and outcome with your patient? The guidelines have the same objective of providing evidence-based recommendations in the management of stable angina in primary care.

The Philippine and European guideline presented the key questions to which they want to make evidence-based recommendations which included evaluation, diagnosis, pharmacologic and non-pharmacologic interventions.

Validity

1. Was an explicit and sensible process used to identify, select, and combine evidence?

The guideline should describe in detail on how they have obtained evidence and how the recommendations were developed. Systematic methods in searching for evidence and the criteria for selecting should be described. Explicit link between the recommendations and the supporting evidence should be stated as well. Clinical practice guidelines are valid if, when followed they lead to the health and cost outcomes projected for them, with other things being equal.[1]

Guideline developers must allow the reader to know how the evidence has been tracked, reviewed, appraised and combined in order to allow them to ascertain the validity of the gathered evidence. Developers should specify a focused question, search the literature for available evidence, critically appraise this evidence and summarize the results in an easy-to-understand material. It must also be explicit on how the developers decided to include or exclude the evidence and how they graded the included evidence.[9]

Both guidelines specified in their methodology their method of literature search, appraisal and combining of the evidence. Both created task force groups in coming up with the recommendations which were later presented to their respective organizations.

2. Were all important options and outcomes considered?

Guidelines aid in decision-making and making better judgment calls. The alternative options, benefit and relative harm of the options must be elaborated.[9] In most cases guideline developers already present the most reasonable options and their corresponding outcomes. Outcomes such as morbidity and mortality data, prevention of complications and other measures that improve health related quality of life should be reported.

The Philippine and European guidelines have extensive recommendations for evaluation, diagnosis, drug and non-drug treatment and management of special population.

3. Is the guideline likely to account for important recent developments?

There are two important dates that determine this i.e., the most recent evidence considered in the list of reference in the guideline and

Table 2. Comparison of case applications and guidelines using PICO framework.

PICO Framework	Case Application	PHA Guideline	ESC Guideline
Population	Adult patients with stable angina	Yes	Yes
Intervention	Pharmacologic and non-pharmacologic management	Both Pharmacologic and Non pharmacologic management	Both Pharmacologic and Non pharmacologic management
Outcome	Resolution of symptoms, avoidance of complications, or disease progression	Yes	Yes

the publication date of the guideline.[9] Ideally, the evidence should be within the last 5 years before the guideline was published. Since medical knowledge rapidly transforms, this will ensure that the recommendations will not be outdated. Hence, there is a need to revise guidelines periodically.

The Philippine guidelines was published in 2014 while the European guideline was published in 2019.

Results and Recommendations

1. Are practical, clinically important, recommendations made?

Guidelines should be clear in presenting their recommendations. Practice guidelines should use unambiguous language, define terms precisely, and use logical, easy-to-follow modes of presentation.[1] To be useful, guidelines should give practical, unambiguous advice addressing a particular clinical situation. Recommendations should be simple and specific at the same time comprehensive enough to allow the reader a chance to assess the benefits and costs of following the recommendation.

Both guidelines gave practical recommendations in terms of evaluation, risk stratification, diagnosis, drug and non-drug treatment, and follow-up.

2. How strong are the recommendations?

The "strength,""grade,""confidence," or "force" of a recommendation should be informed by multiple considerations: 1) the quality of the investigations which provide the evidence for the recommendations, 2) the magnitude and consistency of positive outcomes relative to negative outcomes (adverse effects, burdens to the patient and the health care system, costs), and 3) the relative value placed upon different outcomes as determined by the developers or patient groups. Thus, grading of the recommendations is based on the methodological soundness of the available evidence, the number of positive outcomes in relation to negative ones and the consistency of findings across different evidence available. It is not enough to look into the fact that randomized controlled trials were used as evidence but also if findings across different trials were consistent. Inconsistent findings are at times the reason why different guideline developers have different recommendations regarding certain clinical issues. It is also important to note that different guideline developers use different standards for grading their recommendations and that this should explicitly be placed in the guideline for ease of understanding.[1]

Both the PHA and ESC guidelines graded their recommendations based on the strength of the evidence. The Philippine Guidelines utilized the following recommendation system which combines both the level of evidence and strength of recommendation. The recommendation ranges from recommended, may be recommended, not recommended or contraindicated. The statement "strongly recommended" means that the procedure or treatment should be performed or administered based on sufficient evidence from multiple, randomized trials or meta-analyses. The statement "is recommended" means that the procedure or treatment is beneficial or effective based on sufficient evidence from single randomized/non-randomized trial/s, meta-analyses, or expert opinion. The statement "may be recommended" means that the procedure or treatment is useful or effective although with some conflicting evidence from one trial to another. The statement "not recommended or contraindicated" means that the procedure is not useful or effective, and may be harmful based on sufficient evidence from multiple/single, randomized/non-randomized trial/s or meta-analyses

The European Guideline used the Class recommendation system which ranged from Class I (recommended or indicated), Class IIa (should be considered), Class IIb (may be considered), and Class III (not recommended). They also utilized different levels of evidence which ranged from Level A (multiple RCTs or meta-analysis, Level B (single RCT or large non-randomized studies), and Level C (consensus of opinion of experts and/or small studies).

Applicability

1. Are the recommendations applicable to family practice and preferred by your patient?

Guideline developers usually specify the intended users and the target patients.[10] The family physicians must determine the kind doctors and type of practice is the target user of the guideline. You must determine if the kind of patients you have are similar with those patients targeted by the guideline. If your patients have a different prevalence or risk of disease, if the diagnostic and therapeutic options recommended are not available in your area, the guideline might not apply.

Practice guidelines should be as inclusive of appropriately defined patient populations as scientific and clinical evidence and expert judgment permit, and they should explicitly state the populations to which statements apply.[1] It is important first to understand what the guidelines are trying to say and consider the clinical situation of the patient. For example, if a recommendation is 'strong', this means that the guideline researchers have judged that most users would want to follow the recommended action. For Weaker recommendations that contain greater uncertainty, the advantages and disadvantage of different options should be more carefully considered before a decision is reached.

There may be good reasons why a strong recommendation is not the right option. For example, the patient may be quite different from the participants in the research recommendation in terms of age or co-morbidities. Patient-centered approach should be given to our patients with consideration of their values and preferences. Some patients may have multiple comorbidities, interventions for other health problems may need to be prioritized. Achieving a balance between the health benefits and avoidable harms of polypharmacy should be aimed.[3]

Both guidelines were developed to be used by clinicians in primary care and for patients with stable angina.

2. Has the guideline been subjected to peer review and testing?

Guideline developers may belong to different specialty groups and they may interpret evidence differently and their values as to what

Table 3. Grading of recommendations commonly used by different organizations .

System	Systems for Rating Evidence Quality	System for Rating Clinical Recommendations' Strength
Grading of Recommendations, Assessment, Development and Evaluation (GRADE)	Grades of evidence Randomized trial: High Observational study: Low Any other evidence: Very low	Strong: Desirable effects clearly outweigh the undesirable effects, or clearly do not. Quality of evidence is high and other considerations support a strong recommendation. Weak: Trade-offs are less certain—either because of low-quality evidence or because evidence suggests that desirable and undesirable effects are closely balanced. The quality of evidence is high and other considerations support a weak recommendation.
Strength of Recommendation Taxonomy (SORT)	Level 1: Good-quality, patient-oriented evidence: Level 2: Limited-quality, patient-oriented evidence Level 3: Other evidence: Consensus guidelines, extrapolations from bench research, usual practice, opinion, disease-oriented evidence (intermediate or physiologic outcomes only), or case series for studies of diagnosis, treatment, prevention or screening	A: Consistent and good-quality, patient-oriented evidence.* (Level 1) B: Inconsistent or limited-quality, patient-oriented evidence. (Level 2) C: Consensus, usual practice, opinion, disease-oriented evidence, or case series for studies of diagnosis, treatment, prevention, or screening. (Level 3)
American Academy of Pediatrics (AAP)	A: Well-designed, randomized controlled trials or diagnostic studies on relevant populations. B: RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies. C: Observational studies (case control and cohort design). D: Expert opinion, case reports, reasoning from principles. X: Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm.	Strong recommendation: The benefits of the recommended approach clearly exceed the harms (or in the case of a negative recommendation, the harms clearly exceed the benefits) and the quality of the evidence is either excellent or impossible to obtain (A, sometimes B, or X). Recommendation: The benefits exceed the harms or vice versa, but the quality of evidence is not as strong (sometimes B, C, or X). Option: The evidence quality that exists is suspect or not that well-designed; well-conducted studies have demonstrated little clear advantage of one approach versus another (A, B, C, or D). No recommendation: There is both lack of pertinent evidence and an unclear balance between benefits and harms (D).
Infectious Diseases Society of America	I: Evidence from >1 properly randomized, controlled trial. II: Evidence from >1 well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from >1 center); from multiple time-series; or from dramatic results from uncontrolled experiments. III: Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.	A: Good evidence to support a recommendation for use. B: Moderate evidence to support a recommendation for use. C: Poor evidence to support a recommendation for use.

important options and outcomes may differ i.e., secondary/tertiary care vs. primary care. As such, a guideline that has been subjected to scrutiny by external reviewers from different levels of clinical practice and tested in an actual family practice setting and found acceptable might be easier to use.

Only the European guideline mentioned external review and pilot testing of the guideline after its development.

Resolution

Based on the critical appraisal, the two guidelines were well constructed and had good validity. The recommendations can be adapted and presented to the patient for mutual decision making. Since the patient in the scenario is already diagnosed to have stable angina, the recommendations for the drug and non-drug treatment and follow-up procedures were presented to the patient for shared decision making.

Patient-centered Communication

After searching and critically appraising a guideline, the next step is to share the recommendations to your patient. The language that family practitioner should use must be simple and easy to understand. We should avoid using medical jargon and analogies in order to facilitate understanding. A particularly important issue in primary care is the

impact of clinical guidelines on relationships between practitioners and patients. Cultural values might be overlooked by clinical guidelines. Over-emphasis on guidelines and clinical decision making might marginalize an important dimension of medical care: the role of the physician, in which we act as witnesses to our patients' experiences and work with them to make sense of their illnesses in the context of the rest of their lives.[11] Experts recognize the critical role that factors other than research evidence have in forming plans of care, including the experience and expertise of patients, their priorities, and the particulars of their situation, such as comorbidities, existing burdens of illness and treatment, social support, and personal capacity to safely enact the care plan.[12]

Sharing the whole content of the guidelines may not be feasible as it is time consuming, and patients may not understand the medical language. This is where Patient Decision Aids, Algorithm, and Clinical Pathways may come in handy. The National Institute for Health Care Excellence (NICE) produces patient decision aids that may be used in help in the patient make a decision with regards to their medication for example. This patient decision aid by NICE presents the different approaches showing the advantages and disadvantages involved in each approach.[13]

The Algorithms of the guidelines can be used as tools to the shared decision-making process. It may be shared to patients to provide a visualization or overview of the clinical guideline. The family physician may direct the patient at what point he is at the algorithm in order to envision what needs to be done immediately as well as possible future actions that may be taken.

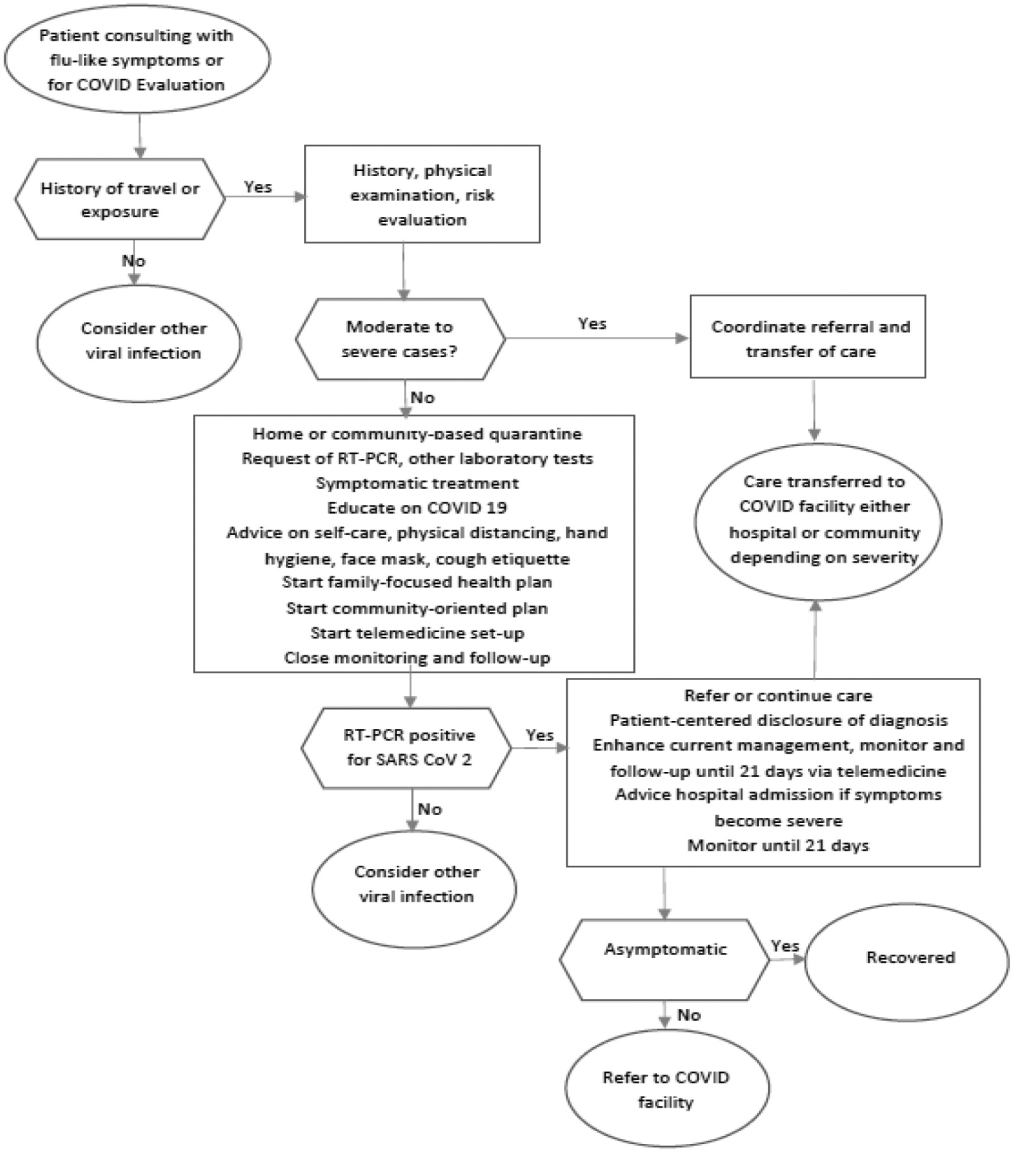

Figure 1. Sample algorithm to communicate guideline recommendations to patients.

Clinical Pathways may also be used to supplement in SDM. Clinical pathways, most specifically from the PAFP, contain summary of recommendations for the history, physical examination, diagnostics, pharmacologic and non-pharmacologic aspects that are arranged in time bound manner (first visit, second visit, continuing visit). The physician may share this table to patients in order to describe the possible plan of management for the patient.

Shared Decision Making

Guidelines, even if designed for more specific patient populations, they may not necessarily remain a 'one-for-all' type of recommendation. They cannot take into account all the individual differences in patient characteristics and preferences.[14] Patient centered approach should be given to our patients by doing shared decision making. Shared decision making (SDM) is an approach that aims to share the evidence of risks and benefits of recommendations to the patient with consideration of patient preferences.[15] The patient should be well informed on the advantages and disadvantages of a medication/procedure, its alternate options and consequences of doing nothing at all. Both the patient and the family practitioner should communicate with each other and arrive in an agreement in the plan of management of the patient. The following patient-centered questions may be: 'How can I help you to improve your quality of life?', 'What is important to you?', or 'How do you see this decision?' The patient's response to these questions should be considered which of the guideline recommendations will be adopted.

Summary Key Points

- Clinical guidelines or clinical practice guidelines are important source of recommendations for clinical decision making
- Formulating clinical questions can help guide you in the searching available evidences
- Appraisal of guidelines should be done due to varying methodology and quality
- Level of evidence and strength of recommendations are important factors that should be considered by decision makers
- Recommendations are not rules or laws that should be followed but rather should serve as a guide in the decision-making process
- Patient centered care approach and shared decision making is recommended with careful consideration of the patient's values, beliefs, preferences and resources

Visit	Pathway Tasks				Patient Outcomes
	History and Physical Examination	Laboratory	Pharmacologic Intervention	Non-pharmacologic Interventions	
First Visit	__Implement triaging system for patients with flu-like symptoms (A-III) __Take a history focusing on fever respiratory and gastrointestinal symptoms (refer to checklist) (A-II) __Take a history of travel or exposure to confirmed COVID area or patient (A-II) __Elicit risk factors smoking, diabetes, cardiovascular, respiratory and other chronic disease (A-II) __Physical examination focusing on vital signs, respiratory, cardiac and O2 sat when available (A-II) __Evaluate family genogram and SCREEM (A-II)	__Request for RT-PCR testing (A-II) __Rapid antibody test may be Requested as an alternative if on day 5 onwards of symptoms (C-II) __Request for other laboratories to evaluate status of concomitant illness or differentials i.e. CBC if bacterial infection is considered (A-II)	__Symptomatic treatment, antipyretics, metered-dose inhaler if necessary (A-I) __Delayed antibiotic prescription if warranted (A-I) __Continuation of treatment for other existing medical condition (A-I)	**Patient Intervention** __Provide balanced information on COVID-19 (A-II) __Educate on cough etiquette, use of appropriate PPE, hand hygiene, physical distancing and quarantine (A-II) __Advice on adequate nutrition, hydration and rest (A-II) __Offer psychological support, self-care advice and monitoring of symptoms (A-II) **Family Intervention** __Assist to develop and implement a Family Health Plan (A-II) **Community-level Intervention** __Refer for contact tracing and coordination of care with the municipal/city health office (A-II) **Follow-up Visit** __Set-up telemedicine for monitoring and follow-up (A-III)	__Adequate knowledge on COVID-19 (A-III) __Agree to comply with management plan (A-III)
Variations	__Consider referral to COVID 19 facility right away if the patient agree (A-III) __Patients who consult with history of exposure or contact but no symptoms may still follow this pathway (A-III)				

Figure 2. Sample clinical pathway of PAFP.

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