PAFP Clinical Pathways and Guideline Development Method

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Clinical Pathways, Guidelines and Consensus Statements

Clinical pathways, guidelines and consensus statements are essential tools to ensure quality health care. Clinical Pathways, guidelines and consensus statements are guidance statements develop to provide information to health care providers on the best care for a patient. All statements are systematically developed. Clinical practice guidelines statements are based on relevant and quality scientific literature that includes an assessment of the likely benefits and harms of a particular intervention. This will enable clinicians to select the best care for a patient.[1] A clinical pathway on the other hand is an optimal sequencing and timing of interventions not only by physicians but also nurses and other healthcare professionals. The sequencing is designed to minimize delays, optimize resource utilization and to maximize the quality of care.[2] Clinical pathways differ from clinical guidelines and protocols as they are a set of practical treatment processes detailing how to implement clinical guidelines, including both clinical and non-clinical activities. Clinical guideline provides general recommendations, while clinical pathways provide specific task recommendations i.e., who should do the task, when and what will be the expected outcome for the care of the patient. Clinical pathway can also specify the variation i.e., if the task is not feasible, what is the alternative. Consensus statements are developed by an independent panel of experts, usually multidisciplinary, convened to review the research literature for the purpose of advancing the understanding of a health care issue. The expert panel develop consensus statement recommendations based on their review.

PAFP Approach of Clinical Pathway and Guideline Development

Some guideline developers follow the GRADE Approach using software like GRADEPro.[3] GRADEPro is an evolving software and currently can be used for interventions, diagnosis and prognosis. This is usually used when developing de-novo recommendations. Others use the ADAPTE Process.[4] The process was developed to take advantage of existing guidelines and avoid duplication efforts. The process provides a systematic approach to adapting recommendations from existing and quality guidelines that may address a specific health question for a specific condition that can used and applied to a defined scope and target setting. In the PAFP, we adopted this approach to address the unnecessary duplication of work. We make sure that the adapted recommendation addresses the specific clinical issues in family and community practice. Unfortunately, not all essential family and community practice interventions can be seen in current guideline recommendations. But guidance is still needed, so a de-novo approach to development of recommendation is still necessary. We therefore developed a mixed approach suitable to family and community practice as summarized by the steps below.

- Step 1 - Formation of development team
- Step 2 - Define the scope (specific to family and community practice setting)
- Step 3 - Define and agree on review questions for key clinical decisions (specific to family and community practice setting).
- Step 4 - Search, identify and review the available evidence (first from existing clinical practice guidelines using the ADAPTE Process, then for meta-analysis, systematic reviews, randomized controlled trials and observational studies for de-novo recommendation)
- Step 5 - Develop the recommendations
- Step 6 - Consensus panel
- Step 7 – Writing the final guideline or pathway
- Step 8 - Dissemination and Implementation Process

Step 1 - Formation of Development Team

Convening an effective Development Team is one of the most important stage in producing a PAFP clinical pathway or guideline.[5] The team will develop the scope, review the medical literature and write the final document which is a work intensive process. The team should have a leader and membership that are committed and with the appropriate expertise. The team may also have an adviser to guide the whole process. The ideal size for the team is 5-10 members. The whole team need to be approved by the PAFP Clinical Pathways and Guidelines Steering Committee (currently the PAFP Research Committee). This is necessary if the PAFP organization will be the organizational endorser of the clinical pathway or guideline.

The selection criteria for inclusion into the PAFP Development Team should include commitment, expertise, appropriate conduct with declaration of conflict of interest. Commitment is a very important criteria for the team leader. Often the team leader may have to fill-in the left gap by some members. The team should have members whose clinical practice is in the area to be covered by the pathway or guideline and members who have good experience or knowledge of patient and care provider issues. The primary responsibility is to improve patient care and outcomes guided by principle of transparency and fair group decision making. Team members may have different beliefs, values and experience, so each member should have an equal opportunity to contribute to the development process.[5]

Step 2 - Define the Scope

For PAFP, the scope should be limited to issues of health care relevant to family and community practice. The scope should briefly describe the epidemiology of the disease or condition in family and community practice. The scope should specify the population or condition to be included or excluded, the healthcare setting, the main care processes and patient outcomes that will be considered. Health system and equity issues may also be considered. In defining the scope, a quick search of the medical literature to identify previous clinical guidelines, meta-analysis and systematic reviews relevant to the topic. This search may not be exhaustive but only to initially define the scope.[5] For guidelines that are updates of existing guidelines, limiting the searches to publication dates may be done. The development team may also check key clinical issues with stakeholders, but with the perspective that the clinical pathways and guidelines are for family and community practice.

Step 3 - Define and Agree on Questions for Clinical Decisions

The key clinical issues listed in the scope need to be translated into review questions. Review questions should address areas covered in the scope and should not introduce new aspects not specified in the scope. The PAFP has established a clinical pathway structure that is relevant for family and community practice. At the minimum, the review question should address five main areas, i.e., 1) assessment (clinical history, physician examination, family and community health resource assessment and differential diagnosis); 2) diagnosis (laboratory and imaging tests); 3) pharmacologic intervention (drugs, vaccines) 4) non-pharmacologic intervention (patient-centered, family-focused, community-oriented interventions) and 5) expected patient outcome (patient knowledge, quality of life, disease status). Various strategies to formulate the question for each clinical question have been published and can be used as reference.[6-8]

The assessment should include clinical history and physical examination and focused on investigating the presence of symptoms, signs and risk factors that might increase the probability of diagnosis of disease. Review questions about "risk or harm" address the likelihood of the presence of the disease from a population with the risk factor or none. Knowledge of these risk factors will lead to a more focused clinical assessment. A helpful structured approach for developing questions about risk or harm is POEM (population, outcome, exposure/risk factor and methodology) A diagnostic test is a means of determining whether a patient has a particular condition (disease, stage of disease or subtype of disease). Diagnostic tests can include laboratory or pathological examination and imaging tests. Review questions about diagnosis are concerned with the accuracy or performance of a diagnostic test i.e., the ability of the test to predict the presence or absence of disease. The PDCA (patient, diagnostic test, comparator, accuracy) framework is useful when formulating review questions about diagnostic test accuracy. A review question relating to intervention is usually best answered by a randomized controlled trial (RCT), because this is most likely to give an unbiased estimate of the effects of an intervention. A helpful structured approach for developing questions about interventions is the PICO (population, intervention, comparator and outcome). Patient-centered interventions are usually health education or counseling to improve the prognosis of the condition i.e., cure, control of progression and prevention of complication. Health education or counseling directed to the patient, family or community may be considered as intervention questions. The standard PICO structure can be used for this. Review questions about prognosis address the likelihood of an outcome for patients from a population at risk for that outcome, based on the presence of a proposed prognostic factor. A helpful structured approach for developing questions about prognosis is similar to risk questions POEM (population, outcome, exposure/prognostic factor and methodology). Case–control studies are not ideal for answering questions about prognosis. Recommendations may also include service delivery, health system and financing. The standard PICO can also be used but the type of studies my not be limited to RCT. It may include cost-effectiveness studies, uncontrolled clinical trials or community trials. The outcomes can be resource utilization, cost-effectiveness, health care providers and patient acceptability and satisfaction. The expected patient outcome in the PAFP clinical pathway structure can be derived from the effect of both the pharmacologic and non-pharmacologic intervention.

Step 4 - Search, Identify and Review the Medical Literature

In the PAFP process, the initial search will be focused on clinical practice guidelines developed for the past five years. If the guideline is more than 5 years old and without any update, there is a possibility that the recommendations may already be outdated. These guidelines will be appraised using the AGREE II criteria.[9] Recommendations developed to address review questions from existing and appraised guidelines will be adapted.

In the absence of an existing and appraised guidelines, a review question will be formulated for de-novo development of the recommendation. For each review question, we develop a brief review protocol that outlines search strategy, critical appraisal, summarizing the results and developing the recommendations. This review protocol should not be more than one page but should make it possible for the review to be repeated by others at a later date. The search strategy should identify the key terms from the review question, the search strategy and other limits used i.e., family practice setting, study design or date of publication. It should also include the database searched i.e.,

Medline, Embase and HERDIN. The grey literature like Google scholar may also be used. The titles and abstracts of the retrieved citations are then scanned for their relevance to the review questions and the full text retrieved.

To assess the quality and extract data from the evidence the full text must be retrieved. They can be obtained from free online journal articles or individual articles can be purchased from the websites of most journals that do not allow free access, but this can be expensive. Some websites provide links to medical journal web pages with freely available articles like Free Medical Journals (LinksMedicus), Genamics JournalSeek and Sci-Hub.[10-12]

To assess the quality of the evidence, the PAFP uses a combination of the AGREE, GRADEpro and EBFP. Before the quality assessment, the team will have to decide on the critical results or outcomes they expect from the study i.e., association of signs and symptoms or risk factors to disease diagnosis, accuracy of diagnostic tests, benefits i.e., decrease mortality, cure, symptom relief or quality of life and potential side effect of interventions etc. The GRADE system is an evolving development process, and currently the software can be used for questions on intervention, diagnosis and prognosis.[3] For clinical question that the GRADEpro may not apply, we used a modified Gradepro scoring but similar parameters for upgrading or downgrading the evidence.

After quality assessment, we extracted the data into an evidence table. Relevant outcome data were prioritized for decision-making, i.e., prevention of death or cure of disease was considered the most important outcome, followed by quality of life, symptom relief and lastly laboratory parameters. Trade-off between beneficial outcomes and potential harm was also assessed. If there are net health benefits from an intervention, we also consider how the implications of resource use and its cost effectiveness. Then we make short evidence statements that will be the basis of the recommendation.

Step 5 - Develop the Recommendations

After developing the summary of the evidence, we develop recommendation statements that are patient centered. We emphasize the involvement of the patient in decisions on treatment and care by using verbs such as 'offer', 'consider' and 'discuss' in recommendations, rather than 'prescribe' or 'give'.[5] The wording of final recommendations is agreed by the development team. We also include information about the quality of evidence used to develop the recommendations.

Step 6 - Consensus Panel

Some recommendation may have strong evidence, but it's applicability to family practice may not be possible. This is the role of the consensus panel. The consensus panel must be selected and of different person from the pathway or guideline development team. The panel should be active family and community medicine practitioners with adequate knowledge of the capacity and available resources in the Philippines both urban and rural setting. They should vote on each recommendation if it should be adopted for family and community practice. Prior to the voting, the panel will be oriented on evidence to decision framework to evaluate the recommendation in terms of balance of benefits and harms, respect for patient rights, acceptability, societal considerations, considerations of equity, equality and fairness, cost, feasibility and health system considerations and quality of evidence.[13,14] The quality of the evidence and the panel vote should be the final grading of the recommendation.

Step 7 - Writing the Final Guideline or Pathway

After formulating the recommendations and based on the summary of evidence, we write the full guideline format for publication which should include the full guideline/clinical pathway, clinical pathway in table form and an algorithm. The full write-up will follow the AGREE II criteria.[9] The clinical pathway is for busy family practitioners to implementation the recommendations in a continuous quality improvement activity. The clinical pathway can be used as checklist or standards of care. We also develop a simple algorithm that can be used to explain the process of care to the patient. This will promote patient-centeredness and shared decision making. We also include recommendations for dissemination and implementation and plan for evaluation and update.

Summary

The PAFP process is a mixture of adapting existing guideline recommendations and developing de-novo recommendations for family and community practice. While this process was designed to be efficient in clinical pathways and guideline development, it does not sacrifice the quality of the final recommendations. We also recognize the value of consensus by a panel of family and community practitioners by making vote on the recommendation. Their vote was also based on objective framework. Lastly, we write the clinical pathways and practice guidelines in a manner that is useful to clinicians, patients and family to promote shared decision making.

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