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An evidence-based practice for the implementation of whole genome sequencing at a national reference laboratory in Colombia

Una práctica basada en la evidencia para la implementación de secuenciación de genoma completo en un laboratorio nacional de referencia en Colombia

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Abstract

The evidence-based practice (EBP) in health has been described previously in health approaches. The technologies applied to health, such as whole genome sequencing (WGS), provide a better understanding of emerging risks as antimicrobial resistance in priority pathogens due to the massive data generation and the increased resolution in public health investigations. The information related to WGS implementation in low- and middle-income countries (LMICs) is scarce, and the cost and complexity have been described as challenges for the formal implementation. The strengthening of epidemiological surveillance and the incorporation of new technologies in the public health system are described in the health plans in Colombia. Therefore, this study aims to provide an EBP for the WGS implementation in pathogen laboratory surveillance at a national reference laboratory in Colombia. To accomplish this goal, a concept model resulted from the integration of implementing science elements contained in the Iowa model, the PRACTIS step-by-step framework and the end-user behaviors, the review of information, local research implementation, and previous experiences in WGS, were used to build a structured EBP as a theoretical proposal. The results evidenced a positive perception of the commitment in strategic stakeholders for future implementation of WGS as routine in pathogen surveillance in Colombia. The resulting structure of the EBP was built on strata, distributed in action levels, categories and parameters. The theoretical EBP was recognized, criticized and evaluated by groups of people from two national reference laboratories, in two different roles, as developers and as end-users. An advisor groups of experts were involved looking for the addressing of local barriers and recommendations. The EBP proposed in this study improved the knowledge and understanding of all the strategic audiences of the national action plan on WGS implementation requirements in a local context in Colombia. The EBP for WGS could be set as the first step to the formal implementation planning in a national reference laboratory in Colombia due to the synthesis and intuitive structure for all audiences. Additionally, the EBP also promotes quick and strategic driven WGS for all audiences on novel health initiatives locally. The EBP in LMICs could be an essential resource on health knowledge translation in local action and policies, overcoming access barriers and promoting the evidence-based decisions in health.

Keywords

Implementation, Antimicrobial resistance, whole genome sequence, Low- and Middle-Income Countries, Evidence based practice.

Introduction

In May 2015 the 68th World health assembly, at the general United Nations (UN) meeting launched the global action plan on antimicrobial resistance (AMR), recognized as one of the greatest emerging risks for global public health. Global burden of antimicrobial resistance in 2019 was estimated in 1.27 million (95% UI 0.911–1.71) of attributable deaths and an economic impact of $100-210 USD trillions, especially on health systems in developing countries by 2050 (1,2). UN member countries were urged to take local action to tackle antimicrobial resistance following the five strategic objectives from global action plan: Awareness, surveillance, reduce disease burden, optimizing antimicrobials use and investment in research and innovation (3). In Colombia, antimicrobial resistance actions were also defined in five strategic lines at National action plan, as example the strategic line 2: The improvement of the current surveillance and research on AMR (4). Inter-sectorial commission for AMR, which include agriculture, environment, food and clinical interfaces as one health approach, developer of the National action plan recognized the complex epidemiology of pathogens and the AMR of zoonotic diseases locally and outlined the urgency to promote the risk assessment from the one health approach in Colombia.

Integration of genomic innovations and technologies in low and middle-income countries (LMICs) health systems are critical to improving the capacity to address disease, treatment and diagnosis in the population, and to allow early detection and precise monitoring of emerging risks, such as COVID-19 (5). In the case of COVID-19, it has been shown that the innovation and adoption of genomic technologies in LMICs health systems have made it possible to better address the disease to accurately monitor emerging risks and make real-time health policy decisions (6). In Colombia, the COVID-19 response coordinated by the public health institute (INS) allowed to build a national genomic network, which involved diverse national and international academic, governmental, and private organizations with genomic capacity. The National response to COVID-19 accelerated the understanding and the incorporation of genomic in public health system in Colombia (7). The experiences in genomics during the implementation of the national COVID-19 genomic sequencing network have demonstrated the higher power of resolution of this technology, which has allowed public health authorities to the identification of variants of interest, viral transmissibility, association with severity and the estimation of vaccine effectiveness (8,9). In 2022, the national reference laboratory in Colombia was designated as regional reference sequencing laboratory for COVID-19 in the Americas (7). Nevertheless, the genomics in the Colombian public health system is at its early stages and most of the previous whole genome sequencing initiatives in Colombia have been related to independent research and private services with reduced access to wider population surveillance, and frequently, benefits are not truly translated to the local health system and to the population´s health. The incorporation of genomics in the health system in Colombia remains as being seen as non-essential from the perspective of the one health agenda, resulting in the absence of current health plans, actions, guidelines, as well as reference technology in all official institutes (10,11). The Pan American health organization (PAHO) recognized the gap between the knowledge and the know-how in public health practice, especially in new technologies, and advised that this gap is a contributory factor on deep sanitary inequities in countries (11). Nonetheless, the public health decennial plan 2022-2031 in Colombia highlighted the great advances in the last decades in knowledge, technology and innovation in health, elsewhere, also recognized the limitations in the incorporation of these technological advances in the practice in public health (11). Therefore, the knowledge management in Colombian public health and the transformation of data to useful information to take evidence-based decisions was proposed as part of the process of territorial implementation process. Likewise, the statutory law 1751 from 2015 in Colombia establishes the need of an innovation, science and technology policy in health to support among others, the promotion of new knowledge from research and the acquisition of sufficient technologies for high quality services and surveillance in health (12). The legal frameworks for the incorporation of technologies in health are described well, however, the know-how in real-life scenarios is less developed in Colombia.

Whole genome sequencing (WGS) and bioinformatics of infectious diseases have been incorporated successfully as gold standard method in public health laboratory surveillance in high income countries, providing intelligent genomic data to monitor health trends, high resolution outbreaks detection, and real-time investigations and response (13). WGS data generation should resulted in strengthen of knowledge, better understanding of biological risks, improving laboratory response and providing support to plans and actions in local and global public health context (14,15). However, the integration of WGS to laboratory surveillance in LMICs has multi-factorial challenges focused on high cost, complexity, quality assurance and scarce trained human resources (16). In LMICs, the accessibility to training, infrastructure, and communication for a laboratory of genomic surveillance of infectious diseases has been fostered by global sequencing consortia initiatives and by national authorities, especially, during the COVID-19 pandemic (15,16). As standard, the National Institute for Health Research in the United Kingdom is funding a Global health research unit in antimicrobial resistance (GHRU-AMR), initiative created by the Centre for Genomic Pathogen Surveillance (UK) and four institutions in Asia (Philippines), Indo-Asia (India), Africa (Nigeria) and the Americas (Colombia), as one of the broadest consortia in genomics building capacities and sequencing laboratory surveillance in LMICs. This initiative described the first roadmap for incorporation of WGS into the existing National AMR *Klebsiella pneumoniae* (KPN) laboratory surveillance framework in LMICs. KPN is an emerging priority pathogen than cause community and hospital-acquired infections, worldwide, listed by WHO as a critical pathogen for the extremely resistant behavior exhibited. In Colombia, KPN resistant to the last treatment resource the carbapenems, is the most frequent pathogen reported in intensive care units, up to 15.6% of all isolates (16).

Despite the translation from the implementation research to real practice in health has been described extensively on theories, models and frameworks, and evidence base practices to the best of our knowledge, an evidence-base practice (EBP**)** for WGS implementation in National reference laboratory in LMICs has not been described (17). However, some references in the United Kingdom and the United States proposed essential elements of genomic implementation as costing, infrastructure, human resources and training, laboratory services, quality assurance and sustainability (18–20). From the implementation sciences, the Iowa model and the PRACTIS guide were used in this study to explain the translation process from uptake implementation research on WGS in Colombia, during the GHRU-AMR initiative and other previous experiences, to an EBP for implementation of WGS in a reference laboratory. Adapted concepts from the Iowa model to identify the issue or the opportunity, stating the purpose, synthesizing the body of evidence, promoting stakeholder commitment, and designing and piloting the practice were incorporated in this study (21).

Therefore, this work aims to provide a synthetic EBP for implementation of WGS in pathogen laboratory surveillance at a national reference laboratory in Colombia. This work contributes to the rapidly and effective assimilation by other reference stakeholders of the WGS concepts, action levels on implementation, commitment measures and sustainability requirements. This work should also promote a fastest and strategically driven of WGS technology in public health initiatives and policies in Colombia.

Methods

A systematic step by step translation study was developed to accomplish an EBP for implementation of WGS in Colombia. The roadmap for the implementation of WGS as part of AMR surveillance in LMICs, the WGS implementation experiences and the case of *Klebsiella pneumoniae* (KPN) was used as local reference in the implementation research. The Colombian GHRU-AMR initiative had integrated WGS and bioinformatics to the KPN surveillance of AMR program between 2018-2021, as a part of a WGS implementation research at the National reference laboratory in Colombia.

The phases of this study were defined using concept elements of end-user commitment, the Iowa model and the structure of the PRACTIS guide, as described below:

i) Commitment of stakeholders

Klein unidimensional target-free (KUT) measure was used to assess the commitment across multiple audiences from the inter-sectorial antimicrobial resistance commission for the National action plan in Colombia (22). The four KUT question items were oriented to the implementation of genomic surveillance of pathogens as routine in Colombia. Three strategic target audiences described in the National action plan were defined: i) Policy makers, ii) National reference laboratories and iii) Academic/Research institutions (Table 1). A short survey containing the KUT standard questions was developed on survey monkey platform, and it was delivered using the communication channel of the Inter-sectorial antimicrobial resistance commission by e-mail. Descriptive statistics, alpha reliabilities, and distribution for the commitment assessment data were determined.

ii) Review of existing literature

A non-systematic literature review was conducted to identify, integrate and synthetize concepts, procedures and experiences on implementation of WGS in pathogen laboratory surveillance. The indexed publications and government documents until 23rd of March 2022 were included into the analysis. Three reference computational engines were used to search the available literature: a) Web of Science, b) PubMed and c) Google. The search terms were (pathogen, surveillance, implementation) AND genomics OR whole genome sequencing OR WGS), in two languages Spanish and English. The first fifty titles and abstracts resulting from each query search were explored and selected manually ensuring that the literature has pointed to our objective and the implementation scope. Selected literature was classified into three action levels: laboratory, bioinformatics, and communication. Data from selected literature was synthetized in tables for the theoretical construction of the EBP, defining variables as reference, type of evidence, scope, main and additional information (23).

iii) Design of a local evidence-based practice (EBP) for implementation of WGS

The design of the EBP for implementation of WGS in Colombia was developed using the PRACTIS step by step structure (24). Initially, a theoretical proposal for the EBP was constructed on three action levels resulted from our previous study (16). Other two strata categories and parameters were developed in this study from the review of literature, the local implementation research and other previously affirmed experiences. The theoretical proposal was initially challenged and scored by the group of people involved in KPN GHRU-AMR implementation research in the national reference laboratory at National health institute (INS) in a series de workshops. Subsequently, other group of people from the national reference laboratory at the Colombian agriculture institute (ICA) in Colombia also criticized and enriched the EBP in a series of workshops. Finally, the local barriers definition and the addressing recommendations involved the advisor expert group. The development of the EBP followed four steps:

Step 1. Characterization of action levels, categories and parameters of local implementation. An initial basal structure of the EBP was described in our previous study, where specific action levels on incorporation of WGS in AMR national surveillance during GHRU-AMR initiative were established (16). Three levels (laboratory, bioinformatics and communication) were used in this study, and the quality assurance was included as category. Additional categories and parameters strata were included in the structure of the EBP based in the PRACTIS guide conceptual elements for an implementation process. Five "Ps" for effective implementation (People, Place, Process, Provisions, Principles) were incorporated in the rational for the parameter's characterization (24). A set of simple questions for each variable in the parameter's stratum were developed for the orientation of EBP developers and the end-users.

Step 2. Strategic stakeholder participative construction: Critiquing and adjusting. Stakeholders belonging to the inter-sectorial AMR commission from the national reference laboratories institutions were involved in the construction process of the practice to generate sense of appropriateness in future WGS implementation. The selected stakeholders participated in a series of workshops to capture their opinion, preferences, perspectives, and recommendations on the EBP proposal. The incorporation or exclusion of the variables in the structure were defined by the participants of the workshops based on a scoring assessment as a measure of the applicability of most relevant items in the local context. Values from 1 to 10 points were assigned to the variables using a weighting method suggested by Glasgow (25): 1–4 = low application, 5–6 = medium application, 7–8 = high application, and 9–10 = very high application of the parameters. A meeting was planned with coordinators of the national reference laboratories to introduce the study and activities. Initially, two workshops for critique and adjust the parameter's strata and orientation questions was undertaken with a strategic implementation group from the GHRU-AMR at INS. A second round of workshops were held with the bacteriology and molecular biology departments from the national reference laboratory at ICA for critique and adjust the parameter's strata and orientation questions at the version one of EBP, including preferences, perspectives and recommendations. Once the parameters and orientation questions were critiqued and adjusted, the strategic working group was feedback providing the last version of the EBP.

Step 3. Identify implementation barriers and facilitators. A workshop for identification of the potential barriers in the implementation of WGS was developed with the strategic working groups in the national animal health reference laboratory. The ecological model proposed in the PRACTIS guide for implementation was reviewed and internalized by the working group focusing on three levels: organizational, provider and individual. Specific construct elements from the PRACTIS ecological model were extracted and used as reference influences in a participative analysis on the local context.

The concerted barriers were centralized on the EBP document as additional strata.

Step 4. Addressing potential barriers and recommendations to implementation. Once potential barriers to local implementation practice were identified and described in the EBP, the experts from national and international board were requested to generate possible addressing of the barriers. Afterwards, the complete structure compiled in a datasheet were shared previously with the international experts for contextualizing and an additional working session was held to recover the addressing proposal to the defined local barriers. Additional strata integrated the expert concepts on barriers addressing and recommendations. The last version of the EBP for implementation of WGS in Colombia was presented at a working session to each national reference laboratory and with the Inter-sectorial antimicrobial resistance commission in a general session.

Ethical considerations. The open access literature, thoughts and experiences used to design, improve, and generate the EBP for implementation of WGS in Colombia do not use sensible data from patients or institutions. The results of this study will be an open-access educational material for all committed and general audiences. Here, the author declared a labor agreement for AGROSAVIA, due the high interest of the Institute on WGS application to AMR research for the National action plan activities. The ethics research committee of medicine faculty of Andes university in Bogota, Colombia approved this study on the act Nº 20210803.

Results

The EBP for implementation of WGS at a national reference laboratory represents a structured initiation process for interpreting and planning a formal process at other national reference laboratories in Colombia. The EBP developed in this study improved the awareness and the commitment of all stakeholders, due the health research knowledge management. The theoretical structure of the EBP was built on a strata framework including action levels, categories, and parameters. The EBP was developed and criticized in a participative process by the implementation working groups at two national reference laboratories in Colombia and the addressing of local barriers were supported by the national and international WGS advisor group. The EBP applied to one national reference laboratory allowed to understand the level of development for the implementation of WGS. The EBP could promote the well use of the resources in the end-user laboratory due the clear recognition of all essential implementation requirements and the prior resolution of barriers in a local context. The EBP for WGS allowed any level of decision to understand the general concepts and the overall process of WGS in a structured approach. The results from this step-by-step study are described below.

Assessment of stakeholder's commitment. The survey was delivered to 65 members of institutions belonging to the inter-sectorial antimicrobial resistance commission for the National action plan in Colombia. The 32.3% (n=21) of the responses were retrieved from 1 supranational institution and 8 national institutions (Table 1). In general, the responses in the KUT survey were frequently rated as "the Quite a bit" and "extremely" options. The items "what extent have you chosen to be committed" and "what extent do you care about" were the most highly scored in all audiences (fig.1). However, strategic stakeholders from the policy makers audience exhibited a non-participation in the actual implementation process and a low grade of importance about WGS implementation. These results should be evidence of a gap for the ahead implementation process of WGS in the framework of the National action plan. Likewise, the results from the actual grade of dedication in the implementation of genomic surveillance of pathogens as routine in Colombia exhibited a wide distribution across all grade options. These results could stem differential advances in genomics at the national reference institutions as one health approach. A participative process of communication of previous WGS implementation advances in national reference laboratory with the AMR inter-sectorial commission stakeholders in Colombia is required to generate commitment. However, academic/research and national reference laboratory audiences showed a higher commitment in the actual process of implementation of genomic surveillance of pathogens as routine in Colombia (fig.2). The overall results obtained in the survey suggested a positive attitude of the respondents to the commitment, due a high level of importance, as well as a high dedication grade intention in the implementation of genomic surveillance of pathogens as routine in Colombia.

Design and evaluation of EBP for local WGS implementation.

Of the 300 items that resulted from the literature search, the 8.3% (n=25) of the documents were selected as relevant for the research scope of this study. The low number of documents found related to the implementation of WGS in LMICs, especially in Spanish, evidenced the lack of access to the knowledge on the implementation of this new technology in the health systems. The twenty-five documents were classified in the three action levels, taking into the account the main scope, topics and results. Additional categories defined as general scope and quality assessment must be included for those relevant documents where the main scope does not fit exactly into the three action levels defined previously. The distribution of the documents was described in the laboratory (n=8), following by the communication (n=4), bioinformatics (n=1) and the general scope (n=9) plus quality assessment (n=3). The results were compiled in a table, describing the type of evidence, scope, main and an additional information relevant to the scope of this study.

The synthesis of the literature, the concept model, the affirmed experiences during GHRU-AMR implementation research and other previous experiences were seized to describe most relevant categories and parameters on three action levels for a WGS implementation process in a national reference laboratory in Colombia. The infrastructure, equipment-consumables, human resource-training, costing and quality assessment were set as categories in the second strata of the EBP for implementation of WGS. Likewise, relevant parameters were defined for each category following the synthesis of the literature, the PRACTIS ecological model and WGS previous experiences as the third strata of the EBP (fig3). The total number of parameters defined (n=129) for each action level were 46, 47 and 36 in laboratory, bioinformatics and communication, respectively. A set of short questions on implementation context linked to the parameters were formulated to orientate the responders during all scoring process.

The theoretical proposal of the EBP for implementation of WGS was criticized and adjusted by the implementation group at INS in Colombia. This first scoring challenge was made from the developer rationalism, encouraging the participants also to provide on the paper any opinion, recommendations or comments on the EBP experience. Parameter and questions scores in all the action levels of the EBP evidenced a general acceptance of the proposal by the implementation group, the 74,4% (n=96) of the variables were rated up of the limit acceptance value of 42/70 points; however, the lowest punctuations were assessed to the communication action level (fig.4). The resulted capture formats were explored to recover the scoring and the suggestions made by the implementation group into the EBP structure. New version of the EBP was accomplished following the feedback from health reference laboratory and the re-structuring of the low scored parameters and question.

The second scoring challenge of the EBP was held with the molecular biology and bacteriology groups in the national reference laboratory at ICA, similarly as it was described above, the EBP structure was introduced, the end-user rationalism was defined and the scoring procedure for parameters and questions was performed. Twelve new parameters were included as recommendations from the challenge. The parameter and the questions scores in all the action levels of the EBP evidenced a general acceptance of the proposal by the implementation group, the 93,6% (n=132) of the variables were rated up of the limit acceptance value of 36/60 points (fig.5). The physical capture formats were explored recovering any suggestions made by the implementation group and a new version of the EBP was generated. For the identification of barriers on WGS implementation in a reference laboratory, the PRACTIS implementation influences from the ecological model were used as theoretical reference to orientate the definition of the own experienced barriers in a local context. A list of barriers for the implementation of WGS following the EBP strata structure was captured from the implementation group at the national reference laboratory, with a briefly description. The set of barriers was integrated in a consolidated spread sheet (Table 2).

Finally, the advisor group were invited to address the potential barriers defined by the implementation working group in the end-user national reference laboratory, providing recommendations and suggestions in a new stratum of the EBP. All local barriers were addressed based on the experience of the advisor group. The final EBP with all the contributions from all participative sessions was presented to the stakeholders in a general session of the inter-sectorial AMR commission for the National action plan. A simple measure of knowledge in general concepts in WGS was performed with the assistants on *pre* and *post* evaluation at the final session.

Discussion

The EBP is described as the application of research approach in combination with real-life expertise, and end-user's preferences at specific local context (17,26). Synthesis of the EBPs orientated to improve the knowledge and the commitment of stakeholders had been applied in scenarios where a problem is identified, the data and resources are scarce and the lack of access to knowledge occurred (17,27), as the local implementation of WGS in LMICs. In general, creating awareness and commitment in target audiences related to the implementation of a EBP is an initial point for the formal implementation process (27). The communication process of the WGS relevance in pathogen bacteria AMR research and surveillance from the one health approach in Colombia was initiated in 2015, at the national inter-sectorial commission and leader by the Colombian agriculture research Institute – AGROSAVIA (28,29). This study generated a measure of the current commitment of stakeholders of the NAP to the implementation of genomic surveillance of pathogens as routine in Colombia. The measure revealed a high level of commitment in all audiences, especially those national reference laboratories and Academic/Research institutions who has been developing the awareness and the commitment of the AMR in Colombia. In contrast, a lack of participation of the policy makers audience on previous WGS approaches in Colombia was recognized, and the reduced grade of importance for the WGS implementation exhibited the need for the improvement of the awareness and commitment on WGS as technological alternative to strength the fight with AMR. However, the overall high level of commitment for the future WGS implementation process in all audiences from the National commission for AMR suggested a positive perception to the initiative. If the stakeholders comprehend the core structure for WGS implementation and the capabilities of the third-generation surveillance as that based on WGS, the improvement of the commitment in strategic stakeholders to the implementation of genomic surveillance of pathogens as routine in Colombia could occurred (16,30–32).

The translation process from implementation research to formal implementation using EBP approach has been described in educational and quality assessment processes in health, especially in nursing practitioners (17,27). EBP is a complex phenomenon and the direct causal relationships between the structure of EBP and specific outcomes on implementation are difficult to probe. Nevertheless, EBP has the potential to improve the knowledge and the know-how practices in health (17). In Colombia, the actual decennial public health plan recognized the lack of local evidence data and the gap between the knowledge and the know-how practices in health, therefore, EBP approach could address those gaps as a strengthen mechanism in knowledge management (11). Some barriers in EBP approaches are previously described, the most relevant to this study was the requirement of several strategies to translate knowledge into the practice, the differences in the languages used by the stakeholders in the practice and the long term of the implementation phases (21,33). Stakeholders belonging to the National commission for AMR in Colombia, where WGS has proposed as the innovative technology in the National action plan activities to integrate pathogen and AMR data from National reference laboratories (animal, food and clinical) as one health approach, could adopt the EBP to standardize the technical concepts and the understanding of formal WGS implementation implications in local context at all levels of decision. The commitment across the stakeholders in the national AMR commission observed in this study resulted favorable for a future implementation of WGS as routine into the Colombian public health system. The EBP for implementation of WGS in Colombia also addresses the knowledge management to the known-how practices, demonstrating in a step by step, how to capture the most influent parameters in a particular implementation context, anticipating and addressing potential barriers and facilitators, as well as promoting the sustainability throw a conscientious planning process (24). The application of this EBP in a national reference laboratory in Colombia allowed in real-life with low resources to identified strengths and weaknesses for the well planning of the implementation of WGS in a particular context.

The participative construction process on the EBP involved developers, end-users and expert stakeholders from the national commission for antimicrobial resistance allowed the networking and the appropriateness of the EBP in future WGS implementation at national reference laboratories. A decision make process involving all stakeholders using an inter-disciplinary perspective, increase the appropriateness of the EBP in local context (34). The EBP structure also could be used by the end-users as progress monitoring instrument and as core structure for other technologies implementation (27). The EBP proposed in this study is the first stepping-stone to the formal implementation of WGS plan in a specific local context at National reference laboratory in Colombia.

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Tables and figures

Table 1. Description of KUT survey participant stakeholder's institutions belong to the national commission for AMR in Colombia.

Audience	Institutions
Policy makers	- Epidemiology and demography, and medicines and technology directions of Colombian public health ministry (MSPS). - Livestock, innovation and technology and animal health directions of Colombian Agriculture Ministry (MADR). - Pan-American health organization (PAHO). - The National planification agency (DNP).
National reference laboratories	- The National health Institute (INS). - National Drugs and Food administration Institute (INVIMA). - National Colombian Agriculture Institute (ICA).
Academic/Research institutions	- Colombian agriculture research corporation (AGROSAVIA). - Colombian public health association.

Table 2. Barriers in the local context and addressing by the national experts

Local barriers	Experts addressing
Costing	- The formalization of the inter-sectorial RAM commission for the National action plan. - National / International funding calls for the improvement of National action plans. - International health authorities financial support (PAHO-CDC-NIH).
Human resource	- Promote personnel training and local train of trainers. - External human support with specific technical skills - Human seedlings on the academy and research institutions focused on WGS, mainly on bioinformatics skills.
Sustainability	- Increased and intelligent risk communication to decision makers. - Communicate the cost-benefit of WGS in a specific context to all stakeholders - COVID-19 pandemic allowed to understand the relevance of WGS for public health in all audiences
Communication	- Promote an effective WGS results communication for all audiences - Design a timely, clear and synthetic report for WGS initiatives - The data and the results should be reported to the national and global level.

Fig 1. Frequencies of all participants responses by KUT commitment survey questions

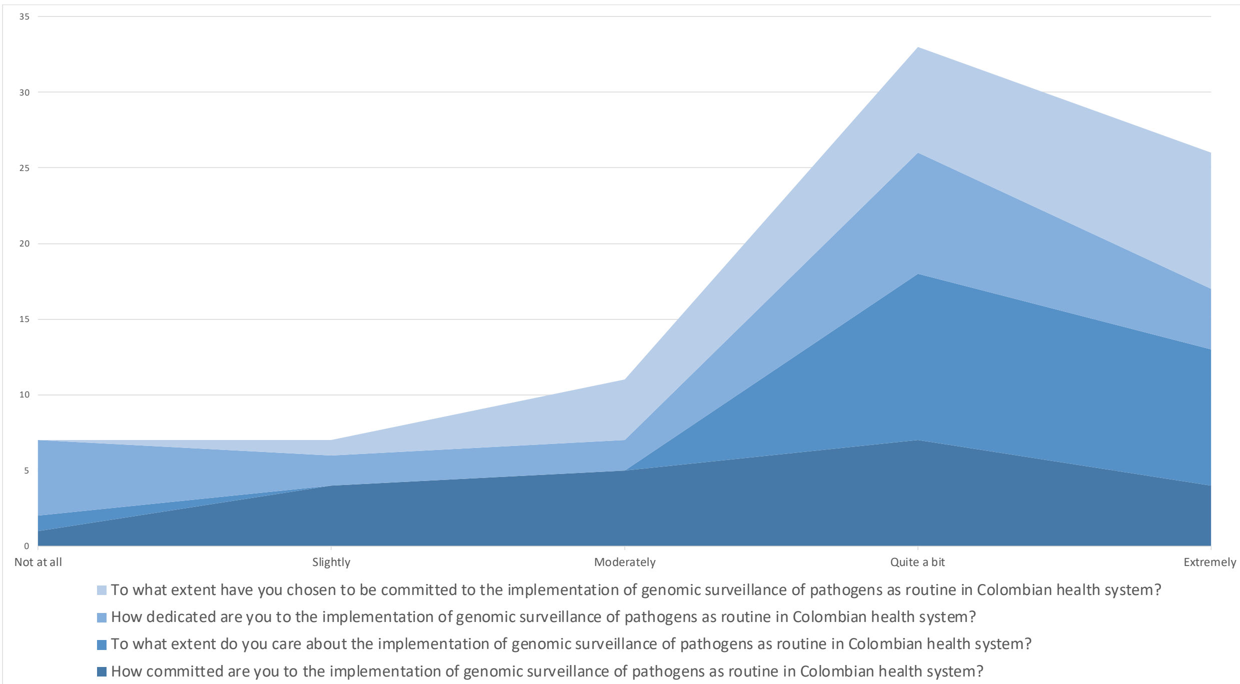


Fig 2. Distribution of the KUT survey responses by strategic audiences

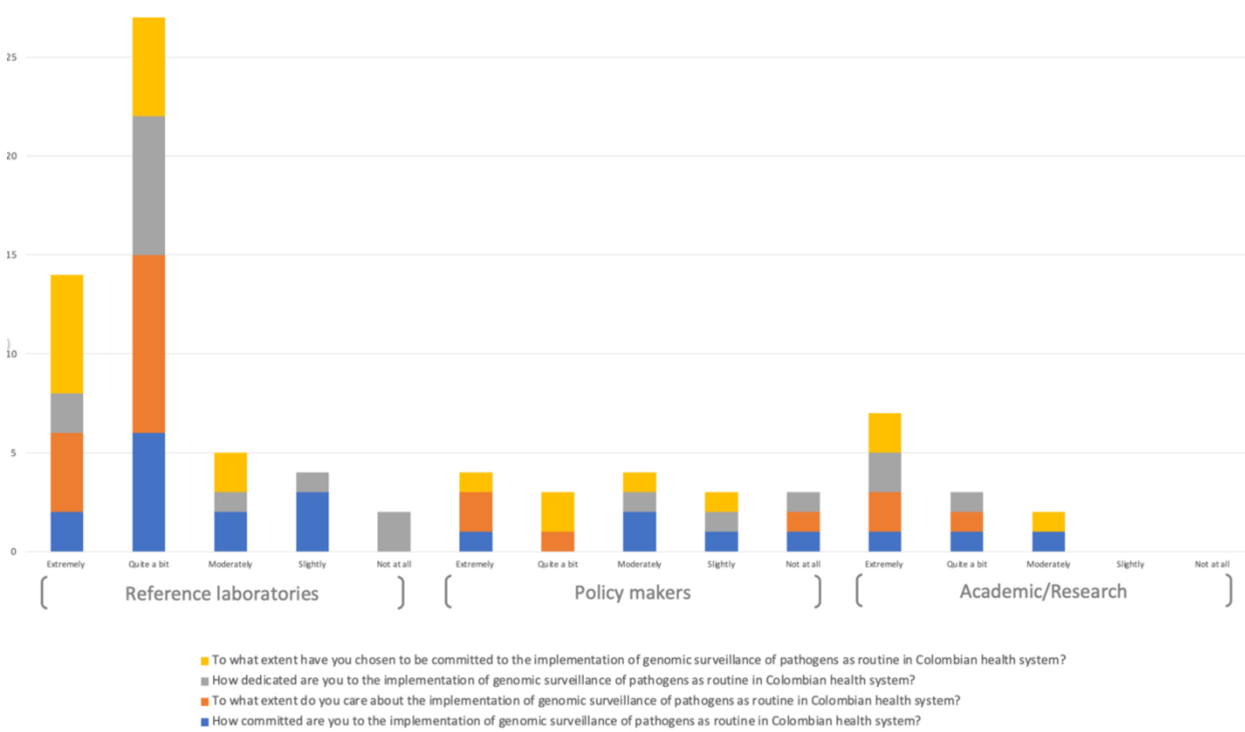


Fig 3. EBP core and variable structure for the implementation of WGS

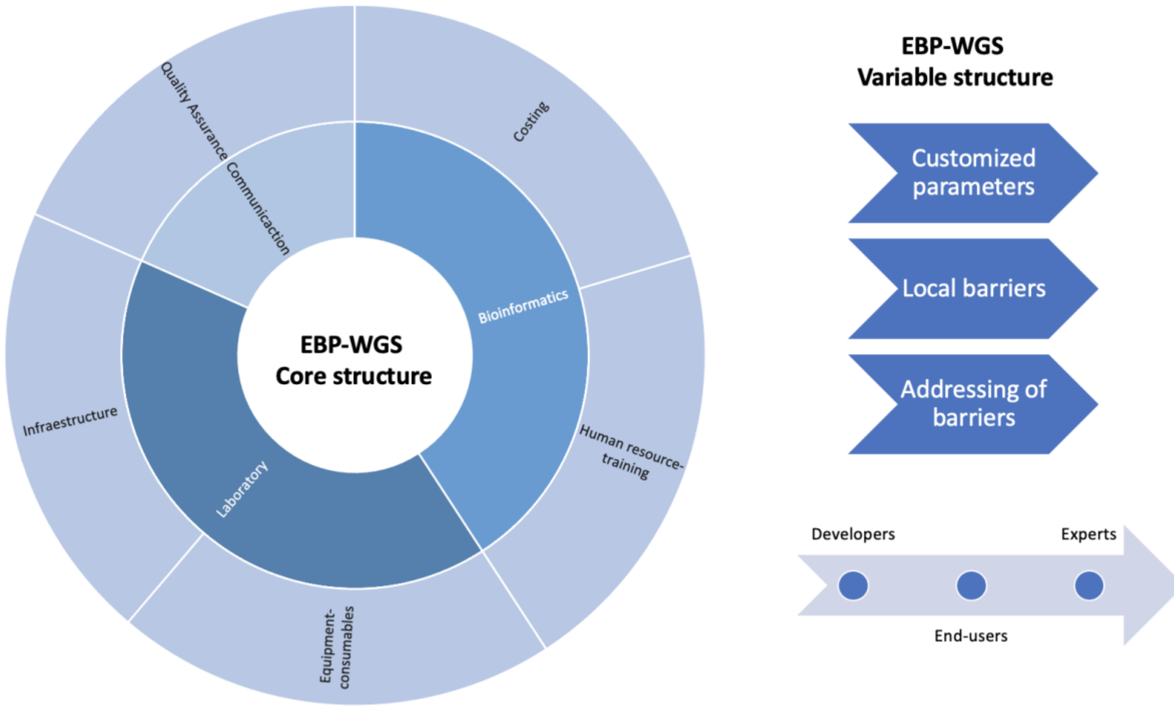


Fig 4. Distribution of scores from EBP categories and questions in the three action levels at the National health institute. The scoring results for laboratory parameters (BLUE), laboratory questions (ORANGE), bioinformatic parameters (GRAY), bioinformatic questions (YELLOW), the communication parameters (LIGHT BLUE), the communication questions (GREEN) were accepted following a cut-off line at the sixty percent.

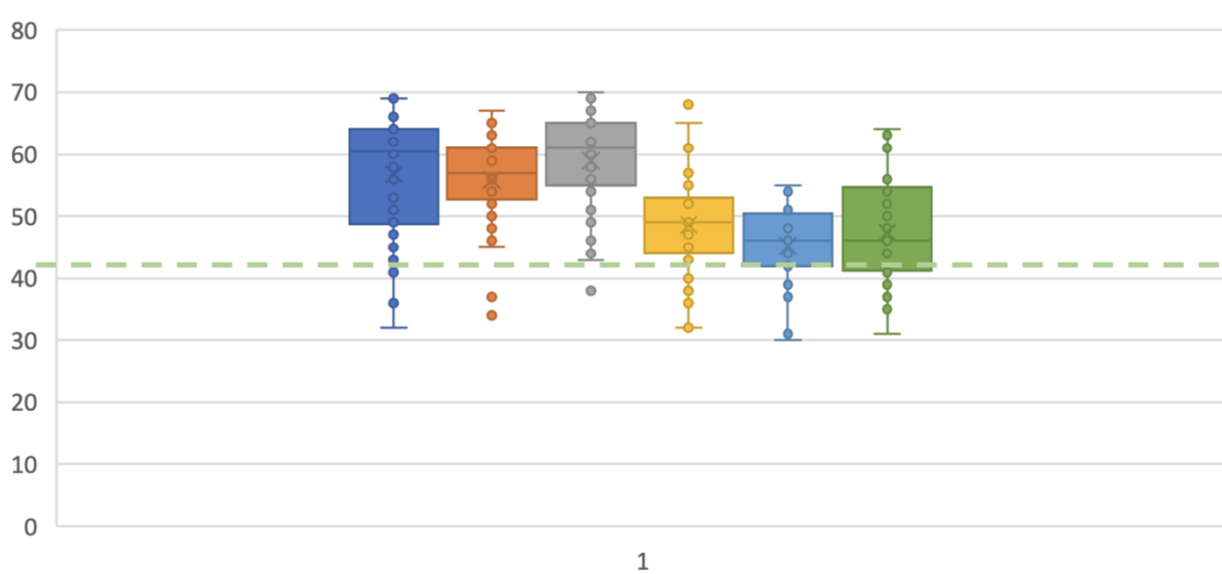
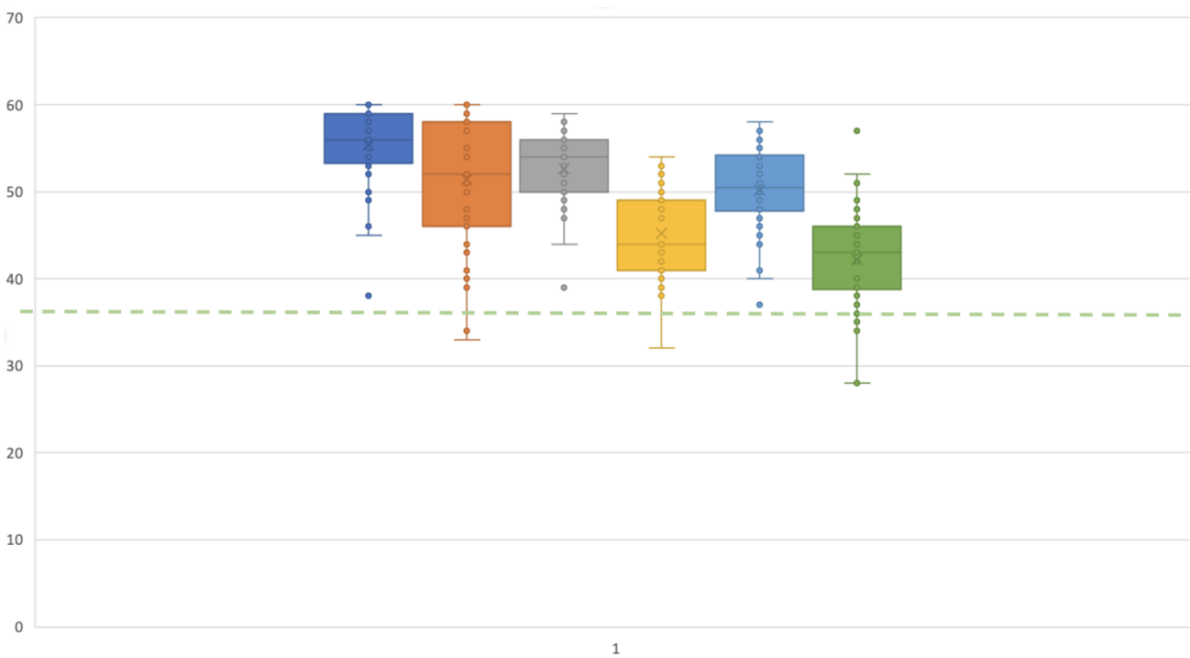


Fig 5. Distribution of scores from EBP categories and questions in the three action levels at the Colombian agriculture institute. The scoring results for laboratory parameters (BLUE), laboratory questions (ORANGE), bioinformatic parameters (GRAY), bioinformatic questions (YELLOW), the communication parameters (LIGHT BLUE), the communication questions (GREEN) were accepted following a cut-off line at the sixty percent.



Resumen de Política

Las prácticas basadas en la evidencia para la gestión del conocimiento en nuevas tecnologías en Colombia

Existe una brecha entre la generación del conocimiento en investigación y su aplicación en las prácticas, reconocida como un factor contributivo a las inequidades en salud, que puede ser abordada desde las prácticas basadas en la evidencia para la gestión del conocimiento y de las tecnologías en salud.

Las prácticas basadas en la evidencia (PBE) son alternativas costo-efectivas para la gestión del conocimiento y de las tecnologías en salud, especialmente en contextos de recursos limitados. Las tecnologías usadas en las vigilancias de tercera generación, como la secuenciación de genoma completo (SGC), han demostrado su alto valor informativo para la toma de decisiones en salud pública. SGC ha sido incorporada como "gold standard" en las vigilancias de países de altos ingresos, permitiendo determinar riesgos y las rutas de diseminación de patógenos emergentes o re-emergentes con potencial epidémico y pandémico de manera más precisa y oportuna. No obstante, se reconocen brechas multifactoriales durante su implementación, que representan una barrera en la gestión de esta tecnología en países de bajos y medianos ingresos. Es por esto, que esta iniciativa busca a partir de una PBE desarrollada desde los modelos teóricos de la implementación y de usuario final, gestionar el conocimiento para la implementación de la SGC, desde un laboratorio nacional de referencia que cuenta con múltiples experiencias previas y otro laboratorio que requiere de la actualización en estas tecnologías para su aplicación en contextos locales de interés en Colombia. Además, se busca mejorar los conocimientos en estas tecnologías con audiencias estratégicas del plan nacional de acción para la resistencia antimicrobiana en Colombia. La síntesis de esta PBE se desarrolló en tres niveles de acción, compuestos por cinco estratos y sus respectivos parámetros. La pertinencia de la síntesis fue retada con los grupos de dos laboratorios nacionales de referencia y los expertos. El desarrollo participativo, interdisciplinar e intersectorial de esta práctica y sus insumos podría tener un efecto positivo sobre el conocimiento, el buen uso de los recursos, los procesos de gestión interna, la comunicación asertiva, consecución de recursos y el trabajo en redes asociado a las tecnologías de SGC en los laboratorios nacionales de referencia. La gestión del conocimiento de nuevas tecnologías soportada por las PBE se constituye en un recurso importante de bajo costo que puede ser aplicado a diversos contextos locales, generando datos que puedan apoyar la toma de decisiones basadas en la evidencia en salud pública.

I*ntroducción*

Las vigilancias de tercera generación, como la basada en las tecnologías de secuenciación de genoma completo (SGC) han sido incorporadas exitosamente como "gold standard" en las vigilancias de los sistemas de salud de países de altos ingresos (1–3). Estas experiencias en SGC han demostrado un mayor poder de resolución, la obtención masiva de información útil, y la reducción de procesos, y tiempos de respuesta en el diagnóstico de enfermedades y de las investigaciones en salud pública (4,5), en comparación con las metodologías tradicionales compuestas de múltiples procesos, con tiempos amplios de respuestas, que requieren un mayor número de personas y la armonización e integración de los reportes individuales dentro de los sistemas de información en salud. Sin embargo, se reconocen algunas brechas en países de bajos y medianos ingresos para la implementación sostenible y universal de esta tecnología como los altos costos, el escaso talento humano calificado, los estándares de calidad, la complejidad de los procesos, el análisis de la información y la comunicación efectiva a los tomadores de decisiones (4,6). Adicionalmente, la información disponible para la implementación de la SGC en países de bajos y medianos ingresos son escasos, y los datos disponibles podrían tener barreras de acceso para su aplicación local, por estar diseñados en contextos propios de países de altos ingresos y por el lenguaje dirigido a audiencias específicas (7).

De la misma manera, la SGC ha sido aplicada en la vigilancia de la resistencia antimicrobiana principalmente en la integración de datos en contextos complejos, aportando información útil para la definición de las rutas de diseminación, la severidad de las variantes de interés, y la disminución de la susceptibilidad a terapias clínicas (6,8). La resistencia antimicrobiana en bacterias patógenas prioritarias es reconocida actualmente por la OMS como uno de los retos más importantes para la salud publica global. Actualmente, el abordaje más aceptado en contextos donde la epidemiologia de los patógenos es compleja como en Covid-19 y la resistencia antimicrobiana, es la visión de "Una salud" (animal, alimento, humano y ambiente), donde se integran los grupos de personas involucradas, en los sistemas productivos, en el monitoreo ambiental y en el sector de la salud pública, para comprender su interacción y responsabilidad en la propagación de los riesgos en salud (9).

En Colombia se ha establecido que la resistencia antimicrobiana es un problema de salud pública y que las dinámicas de diseminación entre los sectores involucrados desde la visión de "Una salud" son complejas, sumado a la escaza disponibilidad de datos integrados locales, representa una importante brecha que limita el diseño apropiado de acciones en salud, para la contención de esta problemática en el país (10–12). En 2018, se publicó el plan nacional de acción para la resistencia antimicrobiana, que contiene acciones intersectoriales encaminadas a abordar la problemática de la resistencia antimicrobiana en el país, y SGC ha sido la propuesta multisectorial (OPS/OMS, FAO, OIE entre otros) como una metodología integradora de datos de patógenos entre los diferentes sectores (13). Como una de las iniciativas más importantes en la lucha contra la resistencia en Colombia, el Instituto nacional de investigación en salud (NIHR) del Reino Unido financia la unidad de investigación en salud global para la resistencia antimicrobiana (GHRU-AMR). Esta iniciativa ha implementado tecnologías de punta como la SGC en las vigilancias nacionales de patógenos prioritarios para la OPS/OMS en Colombia (14). Como parte de los resultados de la unidad de investigación en salud global para la resistencia antimicrobiana se ha descrito el primer mapa de ruta para la incorporación de SGC en las vigilancias de la resistencia antimicrobiana en países de bajos y medianos ingresos.

Recientemente, la pandemia por COVID-19 aceleró la implementación de una red nacional de vigilancia genómica en el país, que involucró diversas instituciones académicas, gubernamentales y de investigación nacionales con capacidades genómicas instaladas, como parte de la respuesta nacional coordinada por el Instituto Nacional de Salud (5,15–17). Estas experiencias en la aplicación de la SGC en Colombia han demostrado además el alto valor epidemiológico de los datos genómicos para la toma de decisiones en salud. La pandemia ha permitido un momento único para las tecnologías genómicas en el país, pues ha hecho de conocimiento general la importancia de las vigilancias de tercera generación, mediante la comunicación asertiva y el uso del lenguaje asociado. Sin embargo, se reconocen también diferencias profundas entre los conocimientos y capacidades de los laboratorios nacionales de referencia y la red de laboratorios de salud pública frente a la implementación sostenible y rutinaria de la SGC, lo que es una barrera para la gestión de esta tecnología desde la visión de "Una salud" en Colombia.

Estas brechas en los laboratorios nacionales de referencia pueden ser abordadas desde un trabajo intersectorial participativo, donde las evidencias, las experiencias y los aprendizajes de los laboratorios nacionales de referencia más desarrollados sirven como insumo en la planeación de la implementación, en aquellos laboratorios nacionales de referencia donde no se haya iniciado el proceso o se encuentre en estado de desarrollo.

Enfoque

Las practicas basadas en la evidencia (PBE) han sido desarrolladas y aplicadas ampliamente en procesos educativos y de calidad en salud, describen en contextos específicos la aplicación de la evidencia disponible, las experiencias en la vida real y las preferencias de los usuarios finales, para el mejoramiento de los servicios en salud (18–20). El uso de las PBEs para la implementación de nuevas tecnologías, es una alternativa poco explorada, pero que puede ser factible para el fortalecimiento de los sistemas de salud y sus tecnologías en países en desarrollo donde los datos en salud son escasos (21). La PBE para la implementación de la SGC en un laboratorio nacional de referencia es una aproximación innovadora que busca a partir de la evidencia disponible, los resultados en una investigación de implementación local y de las experiencias sentidas de los actores de dos laboratorios nacionales de referencia, generar la síntesis estructurada de una implementación de SGC en Colombia. Esta práctica se desarrolló en el marco del plan nacional de acción para la resistencia antimicrobiana, donde de manera participativa con los actores estratégico se realizaron sesiones grupales de trabajo presenciales y remotas, en donde se dio espacio a la construcción interdisciplinar desde los roles definidos: desarrollador, usuario final y experto. Se evaluó el nivel de compromiso de las audiencias estratégicas del plan nacional de acción para la resistencia antimicrobiana, frente a la implementación de la SGC en la vigilancia de patógenos de interés en salud pública. Posteriormente, los modelos teóricos IOWA (18), PRACTIS (22) y del comportamiento de usuario final (23) fueron usados para la estructuración metodológica de la práctica, estableciendo paso a paso la definición del problema, la medida del compromiso de los actores frente a la tecnología en las audiencias estratégicas , la conformación de los equipos de implementación en los diferentes roles, el diseño y evaluación participativa del instrumento de síntesis, y el pilotaje en un contexto local en Colombia.

Resultados

Esta síntesis de una PBE para la implementación de SGC en un laboratorio de referencia en Colombia se estructuró en cinco estratos: 1) Niveles de acción, 2) Categorías, 3) Parámetros, 4) Barreras locales y 5) Recomendaciones. Adicionalmente, se generaron preguntas orientadoras específicas para cada parámetro evaluado con el objetivo de enfocar la intencionalidad durante la evaluación de pertinencia. Las actividades intersectoriales y multidisciplinarias desarrolladas también permitieron la evaluación participativa del instrumento, la definición del contexto local de un laboratorio nacional de referencia, el aumento del nivel de apropiación de los actores estratégicos y el trabajo en redes. Además, los actores del plan nacional de acción para la resistencia antimicrobiana en Colombia mostraron una posición favorable frente el compromiso de una futura implementación de tecnologías de precisión como la SGC en las vigilancias rutinarias de enfermedades infecciosas desde el enfoque de "Una salud" en Colombia.

C*onclusiones*

- La gestión del conocimiento en nuevas tecnologías a partir de las PBEs permite mejorar **el nivel de conocimiento, del entendimiento y del compromiso** de actores estratégicos frente a la futura implementación local de estas tecnologías.

- La **gestión del conocimiento** a partir de PBE también puede **promover** el buen uso de los recursos, acelerar los procesos de gestión interna en las instituciones, aumentar la consecución de recursos, mejorar la comunicación asertiva, e incentivar el trabajo en redes.

- Promueve el **manejo rápido y estratégico** de la implementación de SGC por parte de los tomadores de decisores en iniciativas de salud y de políticas públicas en Colombia.

- Esta síntesis de una PBE para la gestión del conocimiento en nuevas tecnologías podría ser **ajustada** para la planeación de la implementación de **SGC** en otros **contextos particulares**.

- Las PBE se pueden constituir en **un recurso esencial** para **la acción en salud pública**, en escenarios donde los datos y recursos en salud son escasos, y las tecnologías tienen barreras de acceso.

RECOMENDACIONES DE POLÍTICA

- El plan decenal de salud (PDS) 2022-2031 define que se deben realizar esfuerzos para la generación y transformación de los datos en salud en información útil que soporte las decisiones basadas en la evidencia, como parte de la gestión del conocimiento. Sin embargo, existen debilidades conceptuales en el plan decenal en la definición de cómo lograr esto en la vida real en el contexto colombiano, es por esto, que las prácticas basadas en la evidencia pueden ser un recurso esencial en el proceso de traducción dentro de la futura gestión del conocimiento.

- La ley estatutaria 1751 de 2015, establece la necesidad de una política de innovación, ciencia y tecnología en salud, que permita entre otros, la promoción del nuevo conocimiento desde la investigación y la adquisición de tecnologías suficientes para proveer servicios de salud de calidad y para mejorar las vigilancias epidemiológicas. Por lo que es fundamental alcanzar este objetivo puesto que dará un marco legal para la incorporación oportuna y sostenible de nuevas tecnologías como la SGC en sistema de salud en Colombia.

- La aplicación de esta práctica basada en la evidencia debe ser el primer paso en la planeación de la implementación de SGC en los laboratorios nacionales de referencia en Colombia, debido su alto valor como insumo en una correcta planeación de tecnologías de alto costo. Pero se debe continuar con la validación y el perfeccionamiento de esta práctica con grupos más amplios de actores y con escenarios más diversos, como la red de genómica COVID-19 en Colombia o la red PulseNet LA&C en las Américas.

- Para la salud pública y la seguridad alimentaria en Colombia es fundamental que los laboratorios nacionales de referencia (Instituto Nacional de Salud - INS (humano), Instituto Nacional de Medicamentos y Alimentos – INVIMA (alimentos) y el Instituto Colombiano Agropecuario - ICA (animal) modernicen, armonicen e integren las nuevas metodologías aplicadas a las vigilancias nacionales de patógenos. Esto permitirá responder a los retos sanitarios locales y globales, como las epidemias y pandemias, de una manera adecuada y rápida protegiendo la salud de la población.

- La aplicación de tecnologías de precisión desde la perspectiva de "Una salud" representa una de las posibles estrategias de fortalecimiento de los sistemas de vigilancia para la contención de la resistencia antimicrobiana y otros riesgos prioritarios en salud global, pero es necesario continuar con múltiples abordajes de manera sistemática que permitan responder a la complejidad de estos fenómenos en Colombia.

- La sostenibilidad de las nuevas tecnologías en salud, como la SGC, se reconoce como una de las principales barreras para la implementación rutinaria en Colombia. Es por esto, que se debe promover la comunicación efectiva con los tomadores de decisión, que permita posicionar este tema fundamental en la agenda de salud pública para la obtención de recursos permanentes. Sin embargo, temas prioritarios como la resistencia antimicrobiana y COVID-19 han resultado ser una plataforma para el soporte técnico y la financiación externa a corto y mediano plazo en Colombia.

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