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Challenges in Pathogen Genomic Sequencing Supply Chains in Sub-Saharan Africa: Exploring the Role of Communities of Practice

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Pathogen genomic sequencing capacity in sub-Saharan Africa is at an early stage of development with multiple initiatives that are seeking to establish broad, equitable access. Supply chains for pathogen genomic sequencing materials in sub-Saharan Africa face numerous noteworthy challenges that have received limited attention in research. In this paper, we employ a qualitative approach incorporating extensive interviews and data analysis to highlight the most salient challenges from the perspective of key stakeholders in the supply chain. We identify nine categories of challenges, including long and unpredictable lead times, need for cold chain infrastructure, and uncertain future funding. We also find evidence that stakeholders have siloed views of challenges which limits their ability to conceptualize sustainable solutions with long-term impact. Significant variability in the maturity of supply chain management practices between laboratories suggests the usefulness of a cross-organizational learning approach amongst laboratories. To this end, we develop a set of design propositions for Communities of Practice as locally-owned structures for knowledge sharing and learning on supply chain management practices considering aspects such as the focus, format, and participant selection. We also develop an example of a Capability Maturity Model that we propose to be used as a supporting tool within these Communities of Practice. We argue that improving labs' supply chain management capabilities could have positive spillovers for the entire supply chain.

Keywords: Pathogen Genomic Sequencing; Supply Chain Management; Communities of Practice

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Introduction

Pathogen genomic sequencing (PGS) is increasingly being used to support disease surveillance [1], global and local disease control programmes [2, 3], and the monitoring of antimicrobial-resistant pathogens [4]. The Covid-19 pandemic has highlighted that establishing broad, equitable access to PGS capability in parts of the world where this is lacking (e.g. Africa [2] and the Western Pacific [4]) benefits both the region where the surveillance is carried out, as well as the rest of the globe [5]. To achieve this, multiple initiatives have been seeking to establish and/or expand PGS capacity in Africa and elsewhere, including Africa CDC's Africa PGI [6], Sequence Africa SAS [7] and Tackling Infections to Benefit Africa [8].

Past research [1] has affirmed that "*the wide adoption of whole-genome sequencing […] poses new challenges for public-health agencies that must adapt to support a new set of expertise, [which] has not expanded as widely as the adoption of sequencing itself*." Similarly, establishing and operating PGS requires new capabilities from the laboratories. In particular, PGS requires not only sequencing capabilities, resources and infrastructure (including scientists, laboratory technicians/technologists, and specialist equipment) but also a host of other supporting capabilities, such as hazardous waste-disposal facilities, financing, and supply chain management (SCM). Importantly, PGS laboratories cannot function sustainably without well-functioning supply chains (SCs) for reagents and equipment.

Though PGS SC issues have been broached in trade literature, the topic has received limited attention in the academic literature (see, e.g., [9] who briefly mention challenges in procuring sequencing reagents and consumables in the Caribbean), nor has a consensus been reached on the key SC challenges for PGS. In this research, we aim to fill this gap and analyse the challenges in the SCs of reagents and equipment for PGS in sub-Saharan Africa (SSA). In doing so, we take the perspective of key stakeholders in the PGS SC into account to highlight

the most salient challenges and provide a starting point for conceptualizing sustainable solutions with long-term impact.

Our analysis shows that the SCM maturity of most PGS labs is limited and that SCM is typically not seen as a priority by the labs. We find that, in many ways, the PGS SC in LMICs is in the same state as commercial SCs in developed countries several decades ago. It took these SCs many years to reach the SCM maturity enabling the advanced SC processes we can observe today. In line with this parallel, we argue that increasing SCM capabilities is vital to sustainably improving the SCs of PGS reagents and equipment. For this, we propose using Communities of Practice (CoPs) as locally-owned structures for knowledge sharing and learning [10] in line with the recent call by [11] for investment in "learning health systems" that ultimately lead to greater resilience and self-reliance. We present a series of design propositions for such CoPs to be successful, tailored to the context of SCM capability building for PGS labs in SSA.

Our research supports Africa CDC's latest strategic plan, specifically the goal to "*strengthen Africa's clinical and public health laboratory systems and networks*" [6] by contributing to strengthening SCs for PGS in SSA, a necessary condition for operating a sustainable PGS laboratory network and ensuring equitable access to PGS capacity. We believe our findings are also of interest to stakeholders seeking the establishment of PGS laboratories in other settings where similar challenges exist.

Background: Characteristics of PGS Supply Chains in SSA

We consider four groups of stakeholders in the PGS SC in SSA: (i) laboratories (including national public health laboratories (NPHLs), academic facilities, and research centres); (ii) distributors (and/or freight carriers, freight forwarders, clearing agents, etc.) of PGS materials; (iii) manufacturers of PGS materials; and (iv) partners with a facilitating role in the PGS ecosystem such as donor agencies and laboratories based outside SSA that have assisted with setting up PGS facilities and procuring materials.

PGS capability in SSA is at an early stage of development. Although PGS capacity has rapidly expanded since 2020 [5], the market for PGS materials remains relatively small. Currently, PGS is not an established part of the healthcare systems in SSA. Donations of equipment and reagents by partners are fairly common as part of efforts to expand PGS capacity but have slowed the growth of a commercial market for PGS materials. In line with the small market, few manufacturers and distributors of PGS materials operate in SSA. For example, one manufacturer's technology is utilized for more than 50% of the sequencing carried out in Africa [5]. Given the potentially high fixed costs of distribution [12], it is common for health product distributors in SSA to act as agents for multiple companies with multiple associated product lines. Distributors need to make specific investments to cover PGS product lines, such as acquiring the technical expertise to assist laboratories with selecting appropriate PGS equipment and reagents and providing installation and maintenance, and acquiring the specialized cold-chain equipment required to preserve PGS reagents. A small market with variable demand provides little incentive for distributors to make the necessary investments to enter the PGS market.

PGS SCs differ from those of general health products in three main ways: the large number of SKUs; the fact that specific non-exchangeable equipment and consumables are required in tandem; and the funding models employed for PGS laboratories. While many of the challenges identified in health product SCs in low- or middle-income countries (e.g., financing, uncertainty, forecasting, and management/staffing [13]) are common to PGS SCs, they do not fully capture the complexity of current PGS SCs in SSA.

Background: Communities of Practice

CoPs are "*groups of people informally bound together by shared expertise and passion for shared enterprise*" [10] and have been successfully used for knowledge development, problem-solving, and the generation of new business opportunities in large organizations such as the

World Bank, O'Hare airport, and Chrysler, among others [10]. CoPs allow for cross-organization learning in different formats, with their main goal being to develop members' capabilities. CoPs have garnered much attention in the health sector at large (see, e.g., [14, 15, 16, 17]), with virtual CoPs being particularly attractive because of their potential to overcome geographical barriers, their flexibility, and ease of access to data [15]. While collaborative initiatives such as CoPs have also been identified as important tools for increasing PGS capacity [1, 2, 4, 3], the focus is typically on bioinformatics and genomics capacity, not on SCM capability, which includes skills and knowledge required to manage the existing capacity and its expansion. Similar but more general initiatives in the SCM literature (e.g., [18, 19, 20]) do not easily translate to the large research and referral labs typical of PGS. To the best of our knowledge, our research is the first to consider the design of CoPs for SCM capability development for PGS labs.

Methodology

To identify the key challenges in PGS SCs in SSA, we conducted and analysed semi-structured interviews. As our analysis indicated that lack of SCM capability is a major obstacle to improvements in the system, we drew upon the literature to develop a set of design propositions for CoPs. A summary of the methodology employed is set out below. A more detailed description is provided in Appendix A.

Interviews

We conducted a total of 54 semi-structured interviews with actors from all four groups of stakeholders in the PGS SCs in SSA between November 2021 and March 2022: 23 interviews with laboratories, 12 with distributors, 5 with manufacturers, and 14 with partners involved with different PGS aspects.

We chose semi-structured interviews to capture information on specific themes while remaining open to informants sharing new challenging PGS aspects in their own terms and language [21]. The interview guide covered three broad themes: (i) the challenges faced by the interviewee/organization in sourcing PGS materials (equipment and reagents) before/during COVID-19; (ii) the solutions they had attempted to address those challenges or that they viewed as ideal solutions; and (iii) the actors, relationships, and processes along the PGS SC, to understand the flow of products, information, and financing between the various actors.

Interviewees were selected based on purposive, snowball, and theoretical sampling [22, 23, 24]. In addition to including informants from each of the four stakeholder groups that were previously defined (i.e., laboratories, distributors, manufacturers, and partners), we took various steps to ensure the sample was representative. For example, our lab sample included national public health facilities, academic facilities, and research centres from 11 SSA countries, including larger developed countries as well as less developed, smaller, and landlocked countries, as depicted in Fig 1. The sample included labs that were conducting PGS before and during the height of the Covid-19 pandemic, some labs were recently established, while others had years of experience. More specifically, laboratory age ranged from 5 years to about 100 years, while labs' PGS experience ranged from only a few months to a maximum of 10 years (this summary of age and PGS experience excludes two labs due to a lack of data). Our sample also included informants who held different roles in the laboratories (principal investigators, laboratory technicians, and procurement officers) and who could thus provide insights based on their respective roles. We stopped the interview process when data and thematic saturation [24, 25] were reached.

Data analysis

The analysis consisted of three phases: open coding, axial coding, and content analysis [25, 26]. All interview transcripts were imported and analysed using the MAXQDA software [27].

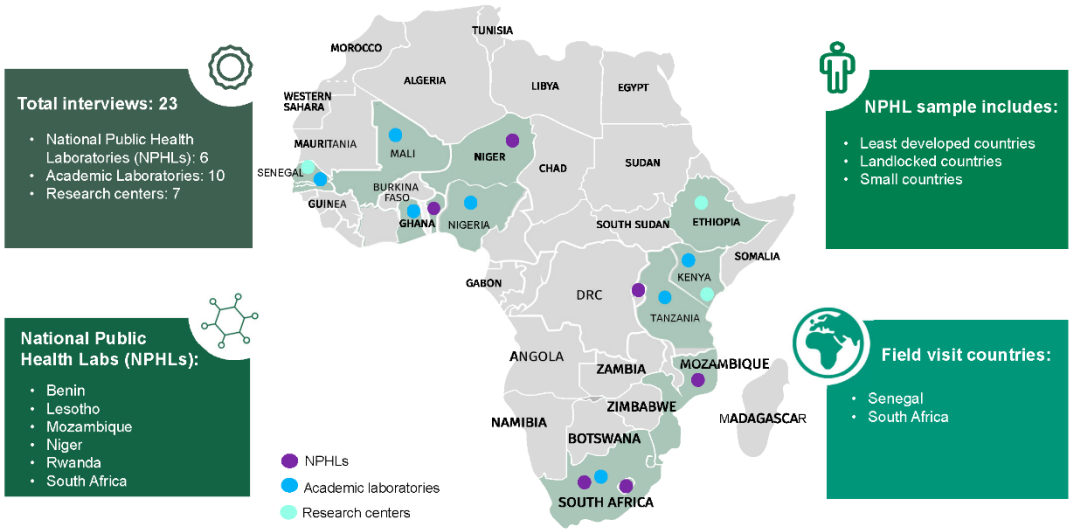

Fig 1. Country distribution of laboratories interviewed and visited.

During open coding, the coders assigned a verbatim code (exactly what the informant said) or a conceptual code (e.g., product lead time, cost of reagents) to each piece of information from the interviews. Axial coding was used to conceptualize second-order categories around the open codes. For example, challenges related to the responsibilities/capabilities of the distributor were grouped under *distributor challenges*. Table A1 in Appendix A provides examples of the progression from open to axial coding for identified PGS challenges, including quotes from different interviews. In both the open and axial coding phases, the interview transcripts were revisited, and codes and categories were constantly compared for similarities and differences [24, 25].

Using content analysis [26, 28], we quantified PGS challenges by the percentage of stakeholders who presented a PGS challenge compared to other challenges and other stakeholders. We counted challenges at most once for each interview and counted a challenge if it was mentioned as a challenge per se (e.g., cold-chain storage/cold-chain at customs) or if it was associated with a solution, implying there was a challenge and it was solved or an ideal solution would solve it (e.g., "bought more freezers"). Appendix A provides a summary of how

the axial PGS challenge categories are defined, and Appendix B provides an overview of the search guidelines used for the content analysis.

Design propositions

We drew upon four sources of information to develop the design propositions: first, the insights from our analysis; second, the literature on CoPs (e.g., [29, 10, 30, 31]); third, the literature on improving PGS capacity [1, 2, 4]; and fourth, the literature on SCM and SCM capability development in low- or middle-income countries settings (e.g., [32, 33, 13]) as well as our own experience. From our review of the relevant literature, we determined suitable formats of CoPs and then translated best practices to the context of PGS SCM capability building while verifying that the design principles were realistic (i.e., accounted for constraints) using insights from the analysis.

Stakeholder engagement

We held stakeholder meetings and discussed the research findings with experts from academia and various organizations with experience in setting up PGS laboratories and/or distributing medical products in SSA. These meetings allowed us to verify our findings and provided valuable information regarding the feasibility, impact, and sustainability of solutions which we incorporated in the CoP design propositions. The analysis was further supported by field visits to two NPHLs and two non-NPHLs, located in South Africa and Senegal (two of these laboratories also took part in the interviews at the beginning of the analysis). These visits elicited a deeper understanding of PGS challenges and offered a sounding board to guide the identification and refinement of design propositions.

Results

Nine categories of challenges emerged from our analysis of the interview data, defined below in the order of prevalence. Fig 2 positions these challenges in the SC relative to the four stakeholder groups.

- **Lead time**: The time it takes for purchased PGS material to arrive is variable and often long, which poses risks in terms of expired and damaged items and can lead to stock-outs.
- **Cold chain**: Maintaining cold chain requirements throughout the chain is difficult, especially at customs, which leads to higher costs and requires capital investments in cold chain infrastructure.
- **Technical**: There are challenges such as broken equipment, installation, repairs, service, and service contracts of PGS equipment and platforms.
- **Funding**: Budgets are limited, uncertain, unsustainable, and dependent on external support.
- **Demand**: Demand for PGS is low (during inter-pandemic periods) and varies considerably.
- **Customs**: Customs clearance is cumbersome (in terms of time and requirements) and very variable. This can lead to long lead times and concerns about breaking the cold chain.
- **Distribution**: Distributors are seen as inflating prices, inefficient, difficult to communicate with, and of variable competency.
- **Costs**: Issues include the high cost of equipment, reagents, service contracts and maintenance, import and customs, and shipping; as well as cost transparency.
- **Planning/forecasting**: It is difficult to estimate PGS needs, and no (or weak) systems are in place for planning or forecasting.

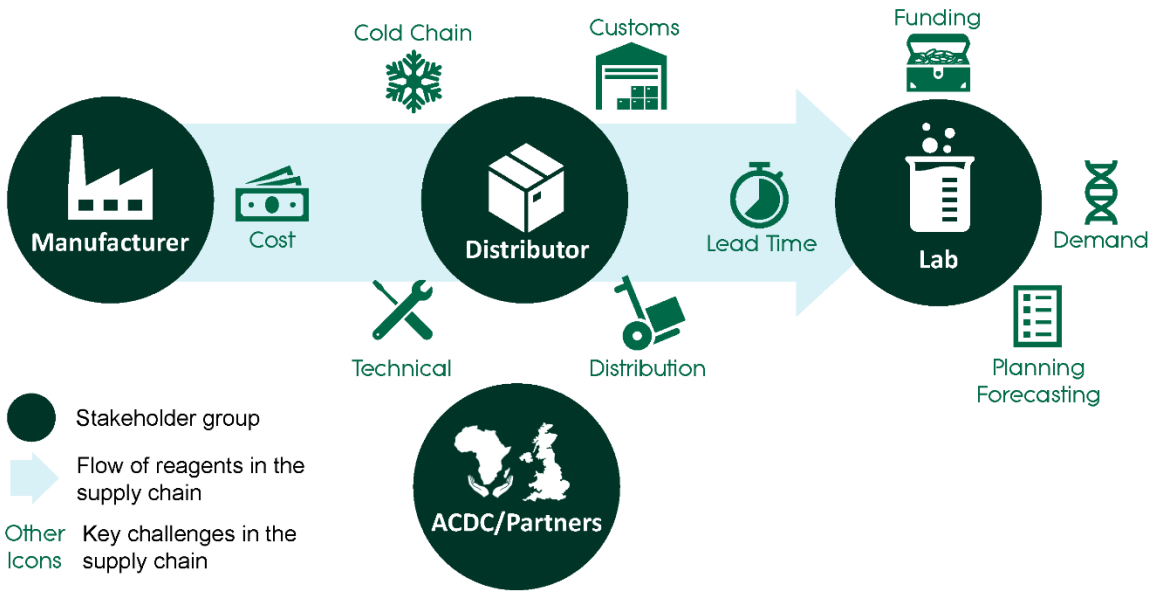

Fig 2. Key challenges and stakeholder groups.

To summarize the perspectives of each stakeholder group, we conducted a content analysis. The results, reported in Fig 3, clearly indicate striking differences in stakeholders' views of what the challenges in the SC are. Challenges mentioned by at least 80% of respondents are marked most critical; those mentioned by between 60% and 80% are marked critical. In the content analysis, we distinguish between national public health labs (NPHLs) and non-NPHLs and exclude entities that did not directly interact with laboratory operations (6 of the 14 partner-stakeholder interviews and the 5 manufacturer-stakeholders).

The content analysis shows that perspectives are broadly aligned with the roles played by the different stakeholders in the SCs. For example, distributors, who view the cold-chain as a most critical issue, are primarily responsible for ensuring the cold-chain is maintained throughout the shipping of reagents; laboratories, who are most concerned about lead times, are the most significantly impacted if reagents and consumables are not available on time (Fig 2).

Fig 3 also highlights that NPHLs and non-NPHLs view the main issues differently. Non-

Stakeholder categories	# of informants	Frequencies (%)								
		Lead time	Cold chain	Technical	Funding	Demand/volume	Customs	Distribution	Cost	Planning/ forecasting
Non-NPHLs	17	94%	71%	76%	64%	64%	53%	76%	71%	76%
NPHLs	6	83%	50%	50%	100%	50%	33%	50%	50%	67%
Distributors	12	58%	100%	75%	58%	67%	92%	58%	75%	25%
Partners	8	63%	75%	88%	63%	88%	88%	75%	63%	50%

Key: Most critical — Challenge mentioned by more than 80% of respondents in category.
Critical — Challenge mentioned by 60--80% of respondents in category.

Fig 3. Challenge frequencies by stakeholder group.

NPHLs are generally more experienced and have engaged with PGS for a longer time (from 3 to 10 years in our sample), whereas NPHLs are generally less mature, and their engagement started recently (from a few months to 6 years in our sample), predominantly to strengthen the countries' PGS response to COVID-19. Less experienced labs have a more local view of the issues; they are mainly concerned about funding and lead times. In contrast, their more experienced peers also consider issues regarding distribution, cold chain, and customs, i.e. they have a broader SC perspective.

It is evident from the preceding discussion that the PGS SC in SSA is a complex, interdependent system. Siloed views of challenges, as uncovered via the content analysis, are particularly problematic in complex, interdependent systems as they constrain efforts to conceptualize sustainable solutions with long-term impact.

Towards Communities of Practice

Laboratories that hold a more local view of the challenges in the SC have a limited ability to recognize how these are caused or influenced by inadequately proficient SCM practices on the part of laboratories. Failing to recognize this causal link leads laboratories to resort to short-term coping mechanisms. On the other hand, labs that have been involved in PGS for a longer

time and have worked with multiple distributors are better able to understand the value of SCM. This observation strongly suggests the usefulness of CoPs, as communication between labs with different levels of maturity can lead to more emphasis on SCM capabilities in all labs.

Enhancing the supply chain management capabilities of each lab separately would require significant allocation of resources. Currently, some labs are recognized as regional 'knowledge hubs' based on their laboratory technical capabilities. However, to the best of our knowledge, there are no structures to facilitate knowledge sharing or collaboration in SCM. We posit that CoPs that facilitate the sharing of knowledge, standard processes, and SC best practices among labs could be a sustainable, less resource-intensive, self-governed solution to improve their SC capabilities. Labs with high SCM maturity would take a leadership role within the CoP and function as *community leader labs*, actively shaping and guiding the learning process [31]. Less mature labs could then learn from community leader labs regarding the SC challenges beyond their local views, solutions to challenges, and best SCM practices. Our interviews and visits indicated that labs at different levels of SCM maturity are open to participating in such CoPs and show explicit interest in implementing the tools associated with CoPs.

Design propositions

For any CoP to succeed (e.g., to facilitate learning yet not overburden the mature labs functioning as community leaders), it is imperative to design the CoP carefully and use effective support tools. Below, we therefore provide 10 propositions for designing a CoP for SCM capability development for PGS labs (summarized in Table 1). These 10 propositions cover four aspects of CoP design: supporting tools, the focus of the CoP, participant selection, and format selection and support. These design propositions are based on multiple streams of literature and our interviews and analysis.

Table 1. Design propositions and their reasoning.

Aspect	Design Proposition	Reasoning
Supporting Tools	Use a Capability Maturity Model (CMM) to support various aspects of establishing and operating the CoP.	CMM enables the CoP to assess labs' SCM capabilities, set improvement priorities, and identify community leader labs.
	Use the CMM as a live document that captures contemporary best practices and is refined over time.	Labs and their environment evolve over time, and the CMM should be refined accordingly.
	Use the CMM to develop individualized transition paths towards SCM maturity, without being rigorously prescriptive.	To evaluate the effectiveness of the CoP and to incentivize continued participation.
Focus of the CoP	Use a CMM to specify one (or a few) of the most promising areas for improvement as the focus.	Having a limited focus makes the CoP cost-effective and easier to implement.
	Expand the focus and leverage existing CoP structures or general collaboration initiatives where possible.	Look for economies of scale and avoid redundancies and parallel networks.
Participant selection	To facilitate cross-learning among participating labs, where possible, select labs that share the same purpose and day-to-day challenges.	To motivate participation in the CoP, as different contexts, e.g., countries, may face different challenges.
	Use a CMM to identify mature labs to function as community leaders and ensure that all CoP members have the minimum maturity to enable learning.	Sufficient potential for learning and teaching requires a minimum level of maturity. Community leader labs should be sufficiently mature to teach others.
	Aim for a small CoP, and let the CoP grow organically where possible.	The complexity and coordination required to maintain the CoP increase with its size.
Format selection and support	Select a format in which the labs (especially community leader labs) have sufficient incentives to take on their respective roles.	Labs, especially community leader labs, take on their roles if they see benefits in the CoP. Formats at higher levels of value creation require more effort and thus need more incentives.
	Ensure other stakeholders take on an active role and complement community leader labs where necessary to cover all tasks, especially in the early stages.	CoP requires substantial time investment from community leader labs.

Supporting tools

Design proposition 1: *Use a Capability Maturity Model (CMM) to support various aspects of establishing and operating the CoP.*

CMMs are frequently used, especially in the information industry and software development (see, e.g., [34, 35, 36] for discussions and examples). CMMs comprise a matrix that includes

defined *levels of maturity* and a set of *dimensions* (in this case, SCM practices or processes). The matrix is populated with *range statements* that describe increasingly mature capabilities for each dimension. At the lowest level of maturity, processes are typically ill-defined, poorly controlled, and reactive, whilst at the highest level of maturity, processes are typically standardized, measured, and highly integrated across various dimensions. For example, a lab at the lowest level of maturity in procurement relies exclusively on the distributor for knowledge of import/export regulations. In contrast, a more mature lab uses a formal inventory management system that monitors real-time inventory levels based on which orders are placed and incorporates defined base stock levels/reorder points.

CMMs are versatile frameworks that can be used to assess a laboratory's SCM maturity and to provide insight into the operationalization of successive levels of maturity in different domains. This insight can be used to develop bespoke developmental roadmaps.

An example of a CMM is displayed in Fig 4 (see Appendix C for an expanded version). This example includes two dimensions, *demand planning* and *procurement*, with a definition adapted from the SCOR framework [37]. This framework provides a structure linking business processes, metrics, and best practices to support communication in SCs and to improve SCM activities [37]. In the CMM, the five maturity levels proposed by [38] are employed: *initial, managed, defined, quantitatively managed*, and *optimizing*. The CMM is populated with range statements formulated based on the insights developed throughout this research. Within each dimension, it is assumed that the capabilities defined at subsequent levels of maturity are cumulative; thus, capabilities defined at lower levels of maturity are assumed to be in place even when these are not mentioned again in the range statement. This aligns to an approach of systematically building up capabilities over time. A CMM can be used to analyse laboratories' SCM capabilities at a more granular level. For example, a laboratory may employ a very advanced and comprehensive approach to demand planning that is assessed as being at the

optimizing level of maturity, whilst its procurement practices may be assessed as being at the *defined* level of maturity. As such, a CMM can be used to set priorities for improvements so that the labs develop along all the dimensions of the CMM, and hence all relevant supply chain management capabilities.

		DEMAND PLANNING	PROCUREMENT
		Demand Planning is the process used for combining statistical forecasting techniques and judgement to construct demand estimates for products and services ([37], p. 590)**.**	**Procurement** involves the working knowledge of the process for acquiring goods and/or services at the best possible total cost, in the right quantity and quality, at the right time and in the right place, with all required documentation ([37], p. 804).
MATURITY LEVEL	1. INITIAL	Little or no sequencing demand planning, processing sequencing samples ad hoc.	The laboratory relies exclusively on the distributor for knowledge of import/export regulations.
	2. MANAGED	At least one staff member who possesses some demand planning experience is responsible for estimating demand for service and/or research work. This activity is triggered at their own discretion. The staff member shares demand estimates with the colleague responsible for material forecasting.	At least one staff member who possesses some procurement experience is responsible for placing orders. There is no consistency in how the inventory level or forecast need for items on the bill of material triggers order placement, and there is sometimes the need for placing urgent orders. At least one staff member has some knowledge of import/export logistics and regulations and can manage these processes for the lab independently if required.
	3. DEFINED	At least one staff member who possesses the required knowledge, skills, and abilities is responsible for estimating demand for service and/or research work: at set intervals (and more frequently, at their discretion); and taking at least a standardized set of information into account. For service work: at least historical demand is considered. For research work, demand planning is practiced at the project level, aggregating demand from different awarded grants. An SOP includes a trigger to review material forecasting when demand estimates change.	At least one staff member who possesses the required knowledge, skills, and abilities is responsible for placing orders correctly using standard order procedures. Order placement is triggered either by a periodic (e.g., weekly) review of the inventory level or by an update to the forecast need for an item on the bill of material. The laboratory has a standard operating procedure that sets out import/export documentation and application processes to be followed when these are required.
	4. QUANTITATIVELY MANAGED	For service work, relevant sources of public health / epidemiological information are regularly monitored with a view to triggering an update to demand estimates. For research work, demand projections are based on contracts or grants that have been confirmed or are being negotiated.	Real-time inventory levels, as recorded in the fit-for-purpose IT system, trigger order placement in line with the defined base stock levels / reorder points. A specific staff member or team, who possesses the required knowledge, skills, and training, is responsible for placing orders and arranging the relevant documentation for order/delivery. The laboratory keeps procurement performance metrics (such as order placement lead time).
	5. OPTIMIZING	Demand planning improvement is based on current calculated demand and projected demand through public health/epidemiological tools and/or includes expert consultations that could offer more accurate insights into demand planning for sequencing across disease areas as well.	Procurement performance metrics are periodically reviewed, and changes to the procurement process, as well as processes/practices in other dimensions, are conceptualized with a view to continuous process improvement.

Fig 4. Example CMM with demand planning and procurement dimensions.

Design proposition 2: *Use the CMM as a live document that captures contemporary best practices and is refined over time.*

The CMM in Fig 4 is merely intended as a proof of concept. Further work would be required to develop a CMM that is ready for use within a specific CoP. The CoP should take ownership of the CMM that is used and continue to refine and adapt the tool as the laboratories and the context within which they operate evolve. However, it is important to avoid being too prescriptive in terms of best practices, as these may differ depending on the circumstances of individual laboratories.

Design proposition 3: *Use the CMM to develop individualized transition paths towards SCM maturity, without being rigorously prescriptive.*

To evaluate the effectiveness of the CoP and as a means to incentivize continued participation, the CMM should be used to measure each laboratory's progress over time. Especially for non-community leader labs, the systematic progression in SCM maturity captured in the CMM can inform the development of individualized transition paths. Thus, the CMM in itself can be an attractive tool for labs to improve their SCM capabilities, as indicated to us by lab managers during stakeholder engagements. This can be done with the help of a small independent committee in collaboration with each lab.

Focus of the Community of Practice

Design proposition 4: *Use a CMM to specify one (or a few) of the most promising areas for improvement as the focus.*

An integral step in designing a CoP is determining the goal and the challenge(s) it seeks to address [31]. Since many of the products moving through the PGS SCs have low volumes, investing in *all* improvement areas for *all* labs may be uneconomical. A cost-effective approach is to specify one (or a few) key improvement areas as a focus. For this, it is imperative to

understand the current capabilities of the labs, beginning with a rigorous assessment using the CMM, which allows a lab's SCM capability maturity to be differentiated from its overall maturity (i.e., age) and its technical maturity in PGS – three aspects that are not necessarily aligned. In other words, it is not because a lab has been operational for a long time or has excellent technical skills that it is also mature in its SCM practices. The CMM will help identify the most promising improvement areas. For instance, if all of the labs have similar levels of maturity in supply planning, it is unlikely for a CoP focused on supply planning to lead to significant improvements.

> ***Design proposition 5:*** *Expand the focus and leverage existing CoP structures or general collaboration initiatives where possible.*

It is important to look for economies of scale when setting up the CoP. This can be achieved by broadening the scope where appropriate. For instance, if multiple areas of improvement overlap sufficiently, the focus of the CoP can be expanded. As a specific example, if a subset of labs is interested in sharing planning information and some other labs are interested in better forecasting, it is recommended to combine both in a single CoP. This allows for a cost-effective approach as it avoids parallel networks.

Participant selection

> ***Design proposition 6:*** *To facilitate cross-learning among participating labs, select labs with the same purpose and day-to-day challenges where possible.*

The next step is to identify the right labs for the CoP. First, it is important to ensure labs share the same purpose (i.e., role, similar environment, overall goals) and day-to-day challenges [30, 31]. Without sufficient alignment on these dimensions, they are unlikely to be motivated to participate in the CoP. A salient factor in this respect can be the country or region the labs are located in, as the external context in which labs operate may have a significant

impact. In other words, geographical proximity can allow for higher motivation, especially in the early stages of setting up CoPs.

Design proposition 7: *Use a CMM to identify mature labs to function as "community leader labs" and ensure that all CoP members have the minimum maturity to enable learning.*

It is important to ensure sufficient potential for learning (i.e., is the lab able to learn things from other labs in the CoP?) and teaching (i.e., would other labs in the CoP be able to learn things from the lab?). This requires sufficient heterogeneity in the maturity levels of labs. Community leaders should be labs with high maturity in the focus areas, while all other labs should have reached the minimum maturity required to enable learning from the community leader labs. For instance, we observed that while one mature lab used a laboratory information management system to monitor stock levels in real-time, another significantly older but less mature lab was unaware that such a system could be used for such purposes. In this case, the less mature lab might require additional training before joining the CoP to ensure cross-learning can take place.

Design proposition 8: *Aim for a small CoP, and let the CoP grow organically where possible.*

The complexity and coordination required to maintain the CoP increase with its size and is notably higher during the setup of the CoP when community leader labs have to take on new responsibilities. It is therefore advisable to start with a small CoP. Over time, the existence of the CoP and the improvements achieved by its members will incentivize other labs to achieve the minimum levels of maturity required to join the CoP, leading to an organic increase in size.

The selection of participants is also closely related to the focus of the CoP. First, if different labs can be the leaders for different areas of improvement, this decreases the burden on each.

Second, if labs within a CoP are mature in different areas, they can share their knowledge with others while learning along other dimensions. This increases motivation and engagement.

Format selection and support

Selecting a suitable format for the CoP is not evident. For example, labs are likely to improve their supply planning processes by joining a CoP where members share best practices for supply planning along with information about aspects such as suppliers and their requirements. In the case of demand planning, not only are shared insights on demand management best practices useful, but tools (and information on how to use them) can be shared in a CoP. Importantly, some supplier and demand information will be lab-specific, hence joint *supply planning* and joint *demand planning* are unlikely to work. On the other hand, joint *procurement*, where a mature lab takes on the procurement for a set of labs in the CoP, could be of interest to labs at different levels of maturity since benefits such as volume discounts could be negotiated.

We propose three CoP formats based on three levels of value creation, loosely based on the communities of practice typology presented in [31]:

- ***Information (Level 1):*** The focus is on information sharing. Community leader labs and external experts share best practices.
- ***Tools (Level 2):*** The focus is on information sharing and dissemination of tools. Community leader labs provide less mature labs with tools and knowledge on how to use them.
- ***Service (Level 3):*** The focus is on providing complete services. Community leader labs head a sustainable collaboration system for service provision.

In terms of the above examples, Information (Level 1) can be an appropriate format for supply planning, Tools (Level 2) is likely the best format for demand planning, and Service (Level 3) would be the right format for joint procurement.

Design proposition 9: *Select a format where the labs (especially community leaders) have sufficient incentives to take on their respective roles*.

The responsibilities of community leader labs increase with the level of value creation. It is therefore important to engage community leader labs and discuss potential benefits to them (e.g., improvements in capabilities and bargaining position, stronger ecosystem). For example, our lab visits confirmed that increased bargaining power could be an incentive for mature labs to join a CoP focused on joint procurement. In the case of sharing demand-planning tools, the long-term conversion of the CoP to an information network could be a significant incentive. In such a network, all the labs have demand-planning systems in place and can benefit from the input shared by others. In general, one should be realistic about the level of value creation that can be achieved; higher-level formats require an increasing time investment from community leader labs.

Design proposition 10: *Ensure other stakeholders take on an active role and complement community leader labs where necessary to cover all tasks, especially in the early stages.*

Given the substantial time investment necessary from community leader labs [31, 39], it is unlikely that mature labs can act as sole leaders, especially if the CoP is at higher levels of value creation. Therefore, it is crucial that they receive support to carry out their role effectively. External stakeholders (such as Africa CDC or smaller capacity-building organizations) will likely need to take on an active role and complement community leader labs where necessary to cover all tasks, especially in the early stages.

Conclusion

Given the unique characteristics of the pathogen genomic sequencing supply chains in sub-Saharan Africa and a lack of rigorous peer-reviewed analysis of the prominent challenges therein, we have applied a rigorous qualitative approach comprising extensive interviews with stakeholders along the supply chain to identify these challenges. We find that long lead times, along with limited and unstable funding, are among the key challenges in the pathogen genomic sequencing supply chains. These are particularly important given the cold chain requirements of reagents and are exacerbated by the distributors' lack of investments in required capabilities. Low and unstable demand and lack of demand management and other supply chain management capabilities at the labs are underlying factors that contribute to these challenges. We therefore argue that improving labs' supply chain management capabilities is key to sustainably improving these supply chains.

We observe that stakeholders hold divergent and siloed perspectives on challenges, and there is a considerable disparity in the level of supply chain management maturity across laboratories. We therefore propose a coherent set of design propositions for setting up Communities of Practice to create and disseminate knowledge among labs with different levels of maturity in supply chain management. Setting up Communities of Practice is a resource-efficient approach that facilitates improvements throughout the supply chain by helping the labs to improve their individual supply chain management capabilities to become strong and savvy customers. Our interactions with existing labs confirmed that the proposed approach is viewed favourably and that the labs see potential value in collaborating within such Communities of Practice. For instance, the lead of one of the most prominent pathogen genomic sequencing labs in the sub-Saharan African region expressed their willingness to use our proposed tool to evaluate their supply chain management maturity and to join a Community of Practice to teach to and learn from others. Through our clearly laid out design propositions,

we believe the implementation of supply chain focused Communities of Practice at pathogen genomic sequencing labs in sub-Saharan Africa can be relatively smooth. Enablers of such implementation are concentrating on essential areas of improvement with adequate support, fostering engagement, and providing incentives for the labs to organically nurture the growth of Communities of Practice.

Our approach has certain limitations that can be addressed in future research to derive additional insights. First, our aim was to identify the key challenges specific to pathogen genomic sequencing supply chains in sub-Saharan Africa to serve as a starting point for systematic and sustainable solutions that improve the overall system. Future research can investigate the differences in the prevalence of the challenges in different settings (e.g., countries) and key factors that contribute to these differences. For instance, landlocked countries may face specific challenges that are not a concern for other countries. Second, we proposed a collaborative network between labs as a pathway to improving the system. We view labs at the core of the pathogen genomic sequencing supply chains and hence argue that improving their supply chain management capabilities could spillover benefits that go beyond the labs throughout the supply chains. For instance, better supply chain management at the lab level translates to more consistent and predictable demand for distributors and more certainty in demand for manufacturers. However, given the diversity of actors, improvements in one group of stakeholders may not necessarily lead to sustainable improvements in the entire system. Future research could take this a level further and consider the interrelationships between multiple stakeholders across the supply chain and study potential synergies and conflicts that may arise as stakeholders change their practices. Third, we developed a set of design propositions for Communities of Practice as a viable way to tackle existing challenges. Researchers, practitioners, and donors can take these propositions forward by designing and

implementing such Communities of Practice and the tools required, such as the Capability Maturity Model.

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Appendix A. Methodology

Between November 2021 and March 2022, we conducted the initial phase of our study, which consisted of semi-structured interviews with stakeholders involved with Pathogen Genomic Sequencing (PGS) in laboratories in sub-Saharan Africa (SSA).

Project approval and informed consent

The study was reviewed and approved by the applicable Institutional Review Board. Informed consent to participate in the study was obtained orally from all participants prior to the start of each interview. It involved informing the participants about the purpose of the study, the potential benefits of participation, its confidential nature (they could not be personally identified), and securing their permission for the interview to be recorded for the purposes of the study.

Selection of interviewees

The selection of interviewees was based on purposive, snowball, and theoretical sampling [1, 2, 3]. We sought to engage with various actors who shared their perspectives on the PGS space in SSA. These included National and non-National Public Health Laboratories (NPHLs and non-NPHLs), PGS manufacturers, distributors/freight carriers, donor agencies, and lab partners who collaborated with local laboratories to set up PGS capabilities in SSA. As far as possible, we targeted SSA labs that conducted PGS before and during COVID-19 to capture possible differences under surge and non-surge conditions. In the non-NPHL sub-sample, we included academic laboratories and research centres. In our laboratory sub-sample, regardless of the type of institution, we sought to include informants who held various roles, including laboratory principal investigators/managers, procurement officers, and technicians with less and more PGS experience. In addition, we sought to ensure a representative sample by including laboratories in large and

more developed nations (Ghana, Kenya, Nigeria, Senegal, South Africa, Tanzania) as well as less developed, landlocked, and the smallest countries (Benin, Ethiopia, Mali, Mozambique, Niger, Rwanda). As far as possible, we sought a representative sample of laboratories from the different regions (East, South, and West).

In the "distributor/freight carrier" sub-sample, we sought to include shipping/freight carriers, PGS-specific distributors, and distributors who carried materials needed upstream to sequencing. We aimed to include distributors who served the national laboratories we spoke to, as that would enable us to hear both laboratory and distributor perspectives in the same country.

During the interviews, we asked participants to recommend and/or connect us with colleagues with other PGS roles in the same institution or other institutions that could provide insights.

The implementation of theoretical sampling is described in the next section.

Study methodology

Semi-structured interviews

We chose semi-structured interviews as they allowed us to capture information on specific themes relating to the challenges with sourcing PGS materials while remaining open to informants sharing new, challenging PGS aspects in their own terms and language [4]. We conducted a total of 54 semi-structured interviews. The resulting interviewee sample is described in the results section of the main manuscript.

Of the 54 interviews, 50 were conducted remotely via the ZOOM or Microsoft Teams platforms, depending on participant preference, and 4 were conducted in person. All interviews were recorded and lasted between approximately 40 and 70 minutes. The recorded interviews were transcribed automatically using the corresponding platform of communication. Interview transcripts were cleaned by Odetta, Inc. to enable better data analysis. Of the 54 interviews, three participants were

interviewed twice for the purpose of further clarification, triangulation, or confirmation of data. As we sought to include informants who held various roles, including laboratory principal investigators/managers, procurement officers, and technicians with less and more PGS experience, six institutions were represented by more than one interviewee. Interviews were usually conducted with one interviewee, except for eight interviews in which two interviewees participated. All 54 interviews were conducted in English, except for one where the informant was not fluent in English and asked a colleague who participated in the interview to translate.

Interview protocol

Interviewees were asked to share information about the following broad aspects:

- The challenges the interviewee/their organization faced sourcing PGS materials (equipment and reagents) before/during COVID-19;
- The solutions they attempted to address PGS challenges or 'ideal' solutions seen from their perspective; and
- The actors, relationships, and processes along the PGS supply chain (to map the PGS SC and better understand the flow of products, information, and financing between the various actors).

While each interviewee was asked the first two questions (except for the three interviewees that were interviewed twice), the interview guide was modified in an iterative approach to gain information on the actors, relationships, and processes along the PGS supply chain, building on information from previous interviews, and in line with the interviewee roles and their experiences with the PGS supply chain. In addition to the above broad aspects, we asked for information about the role of the interviewee, how long they had engaged with PGS, and requested additional information such as the bill of materials used in the lab. As mentioned above, at the end of every

interview, we asked participants to recommend and/or connect us with colleagues who had other PGS roles in the same institution or other institutions that could provide insights for our study.

Theoretical sampling

Throughout the interviews, we focused on similarities, differences, surprising facts and repeat facts, enabling us to optimize the data collection process. This allowed theoretical sensitivity (to identify elements to consider and explore) using a grounded theory approach to qualitative research [5] and allowed us to engage in more theoretical sampling as the research progressed. As the study continued, we engaged in theoretical sampling in which we sought interviewees based on themes which emerged from the collected data, including: the context of donations and the future transition to commercial PGS supply chains; lab processes such as maintenance of Bill of Materials and forecasting; sourcing specifically for each of the PGS platforms used in the laboratories; and the required equipment and reagents upstream to sequencing.

Interviews were no longer sought when saturation was reached, i.e., data saturation and thematic saturation [2, 5]. Data saturation was reached at the point when no new data emerged from the interview process. Theoretical saturation was reached at the point when no new codes or subsequent categories/themes from the analysis were encountered.

Memos

Following an interview or groups of interviews, we engaged in notetaking to capture different aspects of the informant's answers and how they compared to those of other interviewees or the study direction in general. We noted aspects that could help modify existing interview questions to better inform our study, as described in the theoretical sampling section above. Throughout the interview process, consistent with the constant comparative approach in grounded theory, interviews were compared to other interviews for similarities and differences [5, 2]. In addition,

team reports and presentation minutes on PGS challenges and their possible solutions were treated as memos to guide our methodological and theoretical decisions throughout the study.

Data analysis

All interview transcripts were imported and analysed in MAXQDA [6], a qualitative analysis software.

Open coding

Analysis of the interview transcripts began with open coding.

Two coders independently conducted open coding of a sample of three interviews that were purposefully selected to represent diverse perspectives (two laboratories with diverse expertise and PGS-focal areas and one distributor). Once coding agreement was confirmed, the 54 interviews were randomly split between two coders, who continued coding independently.

During open coding, the coders stayed close to the data by assigning a verbatim code (exactly what the informant said) or by assigning a code to describe the challenge narrated as accurately as possible to the coder's understanding (e.g., product lead time, cost of reagents). The two coders were open to all possibilities for data extraction and thus all possible theoretical directions for the research. Throughout the open coding process, consistent with the constant comparative approach in grounded theory, the interview transcripts were revisited and codes were constantly compared to already generated codes for similarities and differences [5, 2].

Axial coding

During the second phase of coding (axial coding), the different concepts broken down from the interview transcripts and identified in open coding were conceptualised into second-order categories around a core concept. For example, various challenges that are related to the responsibilities/capabilities of the distributor were grouped under *distribution challenges*. S1 Table

provides examples of the progression of coding from open to axial coding across the nine predominant PGS challenges identified, incorporating quotes from different interviews. Throughout the axial coding process, consistent with the constant comparative approach in grounded theory, the interview transcripts were revisited and categories were constantly compared to existing categories for similarities and differences [5, 2].

Qualitative content analysis

Content analysis

Through the use of qualitative content analysis [7, 8], we aimed to quantify PGS challenges by determining the approximate percentage of stakeholders who presented a PGS challenge (compared to other challenges and other stakeholders). To do so, we counted the existence of a concept across interviews versus the frequency of a concept for each interview and/or across stakeholders. To illustrate: in one interview, the informant mentioned lengthy installation challenges, challenges for repair timeliness, and distributor maintenance/technical support on three occasions. These three all relate to the "technical" challenges category and in the content analysis, this was then counted as one instance of the "technical" challenges concept being mentioned. Accordingly, we decided on the level of content analysis to encompass either specific words or broader themes to describe a challenge. This process resulted in nine concepts in total, aligned to the nine challenges (lead time, cold-chain, technical, funding, demand, customs, distribution, cost, planning/forecasting) described in the results section of the main manuscript. S2 Table provides a summary of how the axial PGS challenge categories are defined and the search considerations for each category employed for the content analysis. Fourth, we developed search guidelines for quantifying the nine concepts throughout the process of content analysis, aiming for consistency and validity of our results.

It is important to note that challenges as well as solutions/ideal solutions were regarded in the content analysis. A challenge was counted as a challenge if it was mentioned as a challenge *per se* (e.g., cold-chain storage/cold-chain at customs) and/or if it was associated with a solution (implying there was a challenge and it was solved, or there was an ideal solution that would solve it, e.g., "bought more freezers"). While some decisions on what to count/not count as challenges were easy to determine as per the search guidelines, some others were less straightforward and had to be evaluated case by case by revisiting the codes and interview transcripts for more context. Throughout the process, we carefully documented the decisions we made to classify and quantify ambivalent categories.

Consideration of actors for content analysis

The content analysis was summarised by major actors to identify the similarities and differences between their perspectives. The actors were grouped as follows: non-NPHLs (17); NPHLs (6); partners (8); and distributors and freight carriers (12). Six of the 54 informants included funders and implementing organisations that fall within our partner stakeholder category. Though their input informed our research questions and the study overall, their involvement in the PGS supply chain is at a more distal level and we therefore omitted them from the Qualitative Content Analysis, though not from the rest of the analyses. Following the same logic, we omitted the manufacturer stakeholder group (5 informants) from the Qualitative Content Analysis.

Stakeholder meetings

Following the completion of our analysis, we engaged in stakeholder meetings at two points during the course of solution development. The first meeting constituted a workshop where we discussed the preliminary research findings and potential solution avenues with experts from: PGS

laboratories located in SSA; various organizations with experience in setting up PGS laboratories in SSA (partner stakeholders); and academia. The second meeting took place as the development of the CoP solution was underway, and we discussed the ideas that were under development with a prominent partner organization. Feedback received from both of these meetings influenced our thinking in developing the design propositions by providing insights on aspects such as feasibility, impact, and sustainability.

Laboratory visits

The conceptualization and development of priority solutions were also supported by visits and interviews with laboratories. The laboratories visited in this second phase of the research included two laboratories which were interviewed in the first phase of the study. These second-phase interviews elicited a deeper understanding of four themes, namely: 1) current supply chain management and equipment management practices; 2) the performance monitoring approaches of different stakeholders in the supply chain; 3) collaboration between laboratories; and 4) development pathways for supply chain capabilities. In addition to offering more details about PGS challenges, these second-phase interviews additionally offered a sounding board to guide the identification and refinement of solution propositions. As described in this supplementary file and in the main manuscript, developing the design propositions was an iterative process, combining our data analysis, the stakeholder meetings and the second-phase laboratory visits.

Table A1. Progression from interview quotes to open and axial coding.

Interview Quote	Open Code	Axial code
"...for our second batch of equipment and reagent shipments [we have] massive delays. At this point we have 60% delivered" [I1] "... in the end, it [equipment purchase/delivery] was delayed by nine months, 10 months..." [I15] "... it takes about three to six months for things [reagents, consumables] to arrive by the time they have been ordered" [I21]	Product lead time is a challenge	Lead time
" I've had consumables being stored at the wrong temperature, and then being useless... flow cells and reagents just sit in a 40 degree warehouse in an airport…" [I7]	Cold-chain maintenance concerns at customs	Cold-chain
" The [PGS reagent] kits didn't store so well. So now the kits aren't working as well" [I9]	Damage/spoilage of reagents	
" It's about how do I transport sensitive, temperature sensitive materials and clear them at the port within x number of days…" [I29]	Cold-chain issues	
"... a lot of companies will say, we'll ship it [equipment], but we won't install it, we won't maintain it, we don't have people who can do that in-country" [I7]	Lack of in-country support	Technical
"… we have to duplicate all our equipment because [if] anything fails, it takes us around nine months to get it fixed. So it's not just a supply chain. It's also the technical support" [I9]	Lengthy installations/repairs	
" [companies] should try to capacitate the channel partners with technical skills... relying on regional or international technical support might also take a long time" [I47]		
"... the first [difficulty for laboratories] is the budget. They don't have [the budget]" [I40]	Labs have limited financing	Funding
"… in-country we don't have enough funds to purchase all these reagents" [I43]		
" The government doesn't have budget for that [reagents] . In West Africa, … our budget is not devoted to research… we are always knocking everywhere to get support" [I45]		

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Interview Quote	Open Code	Axial code
"… [putting] genomic surveillance into the spotlight has certainly helped with people understanding, and maybe the demand [for PGS] will increase in Africa" [I21]	PGS in infancy stage	Demand
" Before COVID, we didn't have to do so many sequences per day" [I30]	PGS demand pre-COVID was low in Africa	
"... I think a regional approach [for companies] is probably more viable than trying for our country… because the 'PGS] market is still quite small" [I44]		
"… the countries have different [custom/import] requirements" [I22]	Regulatory variability of processes	Customs
"… some items even may go bad... they could expire or they may be stored [at the wrong] temperature while at customs" [I37]	Customs challenges	
" It is difficult. [At customs]… they don't have refrigerators to keep [reagents] [I48]	Lack of refrigerators at customs	
" I don't know why the manufacturers always prefer to deal with us through these intermediaries [distributors]. As far as I'm concerned, some of them are just a waste of time" [I8]	Distributor and Added value/efficiency/capability	Distribution
"… it's not customs and shipping that [explain] the [higher] price. It's [because of] the suppliers and the middlemen that inflate the price… with [x manufacturer], it was almost double the price" [I13]	Distributor as Expensive	
" [Distributor Y] is very new. So we don't know if they really accumulated the knowledge and skills to [provide technical support]" [I36]	Distributor and Technical Expertise	
"...the most challenging aspect was reagents… [they are] very expensive. I'm not sure that all the different institutions in Africa can buy a lot of NGS kits for routine sequencing. It is impossible actually" [I30]	Cost of equipment and reagents	Cost
"... There are a lot of costs associated with that [a purchase]… And then you have to pay for the shipment… the cost for shipment is really huge, because it has to go [from its origin] all the way to here" [I34]	Cost of shipment	
" For the equipment, we also have the issue of maintenance. It [maintenance] is very expensive" [I41]	Cost of service contracts / technical support	

Continued on next page

Interview Quote	Open Code	Axial code
"... when we are probably halfway done [with the reagents in stock], we place another order…" [I25]	Ordering variability	Planning/forecasting
" No, there is no formula [for forecasting]… we always ensure a minimum number of kits on hand and so, we never ever run out... we know we risk kits expiring [with bigger stock on hand" [I35]	Forecasting variability	
" I will say that it [forecasting] doesn't exist. They [laboratories] don't know. That's one of the issues we have. They [laboratories] don't tell us what we [distributors] can expect" [I40]	Forecasting challenges/general	

Note: [I#] indicates the interview number from which the quote originates

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Appendix B. Search guidelines

Table B1 provides an overview of the search guidelines used for the content analysis.

Table B1. Search items considered for content analysis.

Axial code	Definition	Search considerations[a]
Lead time	Lead time refers to the time it takes for purchased PGS materials (both equipment and reagents) to reach the laboratory	lead time, slow, delay
Cold-chain	PGS has cold temperature requirements for transport and storage until use	cold-chain, dry ice, freezer, damage, spoilage
Technical	Technical challenges include broken equipment, equipment installation, repairs and timeliness of repairs, and service contracts for PGS equipment	equipment, service, installation, repair, tech, engineer, maintenance, contract
Funding	Laboratory budgets are limited, uncertain, non-sustainable and dependent on external support	funding, financing, budget, grant
Demand/volume	Demand for PGS is low and variable	demand, volume, small, market, incentive, routine, rhythm
Customs	Custom clearing processes are cumbersome (in terms of time and requirements) and these vary considerably	customs, clearance, import, regulatory, tariff
Distribution	Distributors are predominantly perceived as inflating prices, inefficient, difficult to communicate with, and of variable ability	distributor, channel partner, seller
Cost	Issues include the high cost of equipment, reagents, service contracts and maintenance, import and customs, and shipping, as well as cost transparency	cost, price, inflate, profit, margin
Planning/forecasting	It is difficult to estimate PGS needs and there are either no/weak/variable systems in place for planning or forecasting for the laboratories	plan, forecast, order, collaboration, communication, feedback

[a] Search considerations that reflect organizational identities are not presented in this table to maintain informant and organizational anonymity

Appendix C. Concept demonstrator: Capability Maturity Model

Introduction

The paper proposes a Capability Maturity Model (CMM) to support various aspects of establishing and operating Communities of Practice (CoPs) for supply chain management (SCM) capacity building for pathogen genomic sequencing (PGS) labs in sub-Saharan Africa (SSA). Uses of the CMM include: defining the focus of such a network; identifying potential hubs and participants; incentivizing participation by demonstrating how the capabilities of both participants and hubs mature over time; and developing bespoke developmental roadmaps.

As a proof of concept, an example of a CMM is presented in this supplementary file. It is important to bear in mind that further development and refinement are required before it can be considered ready for use within a specific collaborative network. It is envisaged that the CMM will be reviewed and updated throughout its lifespan to ensure it remains relevant as the labs and the context within which they operate evolve.

The CMM integrates the process/practice maturity of the supply chain as embedded within the Supply Chain Operations Reference (SCOR) [1]. The draft CMM illustrates six supply chain practices/processes (referred to as dimensions in the CMM) whose maturity can be evaluated: demand planning, forecasting, inventory management, procurement, procurement management, and supply planning.

SCOR [1] considers process/practice maturity as part of a comprehensive approach to understanding supply chain performance: immature processes are characterized by little to no consistency and ad hoc decision-making; mature processes by higher degrees of consistency that allow the integration of supply chain processes across the organization and with supply

chain partners [1]. The draft CMM uses a set of five defined maturity levels, with range statements describing each level's operationalization for each dimension.

Methodology

The development of the CMM followed an iterative process. The five maturity levels (i.e., initial, managed, defined, quantitatively managed, optimizing) are adopted from the Capability Maturity Model Integration (CMMI) [2], which is commonly used in the literature. The six dimensions were inductively derived by considering information from the SCOR [1], as well as insights from the interviews/lab visits, from the literature on SC practices in healthcare, and from the literature on laboratory supply chains. The definitions of the six dimensions were adapted from the SCOR [1]. The definitions of the range statements were also informed by the aforementioned list, as well as by various KPIs discussed in the literature and/or implemented in the labs visited.

Draft CMM

The draft CMM is presented as a series of tables. Table C1 provides a definition of the five maturity levels, adopted (and in some cases adapted) from the work of [2]. Tables C2 – C7 provide a definition as well as range statements for each of the six dimensions. It is assumed that within each dimension, the capabilities defined at subsequent levels of maturity are cumulative, even though capabilities defined at lower levels of maturity are not mentioned again in the range statement. For example, in the "Procurement management" dimension, an up-to-date bill of material (BOM) is achieved at the “managed” level of maturity; the BOM is not mentioned in the range statement for the “defined” level of maturity but is assumed to be in place. In transfer media, the CMM would typically take a matrix form where the rows denote successive levels of maturity and the columns denote dimensions for which the capability maturity has been defined.

Table C1. Definition of maturity levels (adapted from [2])

1. INITIAL
Little or no process structure or consistency, ad hoc. / Processes are not repeatable, poorly controlled, and reactive.
2. MANAGED
Builds on level 1 practices. Basic functional capabilities, with limited cross-functional alignment and integration. / Processes are dependent on individuals and are not standardized.
3. DEFINED
Builds on level 2 practices. Some integration across supply chain functions but limited integration with other functions and with supply chain partners. / Processes are defined and standardized.
4. QUANTITATIVELY MANAGED
Builds on level 3 practices. Highly integrated supply chain processes across the enterprise, with selective integration with supply chain partners. General alignment to business strategy and goals. High use of IT and digital enablement. / Processes are measured and controlled.
5. OPTIMIZING
Builds on level 4 practices. Highly integrated supply chain processes across the enterprise and with supply chain partners. Closely aligned to business strategy and goals. Extensive use of IT and digital enablement and related best practices. / Focus on process improvement.

Table C2. Definition and range statements of demand planning dimension

DEFINITION OF DIMENSION
Demand Planning is the process used for combining statistical forecasting techniques and judgement to construct demand estimates for products and services [1, p. 590].
1. INITIAL
Little or no sequencing demand planning, processing sequencing samples ad hoc.
2. MANAGED
At least a staff member, who possesses some demand planning experience, is responsible for estimating demand for service and/or research work. This activity is triggered at their own discretion. The staff member shares demand estimates with the colleague responsible for material forecasting.
3. DEFINED
At least a staff member, who possesses the required knowledge, skills, and abilities, is responsible for estimating demand for service and/or research work: at set intervals (and more frequently, at their discretion); and taking at least a standardized set of information into account. For service work: at least historical demand is considered. For research work: Demand planning is practised at the project level, aggregating demand from different awarded grants. An SOP includes a trigger to review material forecasting when demand estimates change.
4. QUANTITATIVELY MANAGED
For service work, relevant sources of public health / epidemiological information are regularly monitored with a view to triggering an update to demand estimates. For research work, demand projections are based on contracts or grants that have been confirmed or are being negotiated.
5. OPTIMIZING
Demand planning improvement is based on current calculated demand and projected demand through public health/epidemiological tools and/or expert consultations that could offer more accurate insights into demand planning for sequencing across disease areas.

Table C3. Definition and range statements of forecasting dimension

DEFINITION OF DIMENSION
Forecasting is the process of predicting material requirements to meet estimated sequencing demand in a particular forecasting period [1, p. 747]. Forecasting involves the use of qualitative and quantitative forecasting processes and tools to improve material needs forecast, typically at SKU level [1, p. 598].
1. INITIAL
Little or no formalized forecasting activity; instead, orders are based on personal judgement, experience, and/or tacit knowledge.
2. MANAGED
Forecasting of reagent, consumable and equipment needs is done from time to time; however no SOP governs either when forecasting takes place or how it is executed. A base stock level/reorder point may be defined for some (i.e., prioritized items on the BOM, but this is based on personal judgement, experience, and/or tacit knowledge alone. The forecast includes needs for quality assurance and control activities, loss and wastage rates, and needs for planned training activities.
3. DEFINED
The forecasting considers all reagent, consumables, and supplies needs as outlined in the BOM. An SOP governs when forecasting takes place, and this includes a trigger to update the forecast in line with a change to the expected sequencing demand. The SOP also governs how the forecast needs are used for decision-making when placing orders. At least one staff member who possesses the required knowledge, skills, and abilities is responsible for forecasting. A base stock level/reorder point is defined for all items on the BOM.
4. QUANTITATIVELY MANAGED
The SOP that governs the auditing and maintenance of the BOM includes a review of base stock levels/reorder points. The effort expended on achieving an accurate forecast is aligned with the priority classification of items on the BOM. There is communication between the laboratory technicians and the procurement team for better integration and planning of projected needs, considering the procurement cycle time. Information on the availability of supplies that are shared by suppliers also informs order planning. An SOP also governs periodic forecasting of equipment needs. Forecasting accuracy metrics are recorded.
5. OPTIMIZING
Forecasting accuracy is retrospectively evaluated at set time intervals, and based on this evaluation, adjustments may be made to the SOP that governs how forecasting is executed for better process improvement. Information on the lead time, including the time to import goods, that is shared by suppliers also informs order planning. Forecast errors can additionally be used for safe stock planning.

Table C4. Definition and range statements of inventory management dimension

DEFINITION OF DIMENSION
Inventory Management is the formal management of the timing and quantities of goods to be ordered and stocked by an organization in order that demand can always be satisfied without excess expenditure [1, p. 758].
1. INITIAL
Little or no use of an inventory management system (manual or IT tools).
2. MANAGED
An existing (manual or IT-based) system is used for basic inventory management for all items on the BOM (e.g., keeping track of stock levels and ensuring that items closest to their expiry date are used first). If inventory levels are not monitored in real-time, they are at least monitored on a reasonably frequent basis (e.g., every two weeks / monthly).
3. DEFINED
A (manual or electronic) inventory system monitors stock purchased, stock received, stock used, and expiry dates, and ensures that stock is used on a "first in first out" (FIFO) basis or that stock closest to its expiry date is used first. If stock levels are not monitored in real-time, this is done at least once per week. Quality of existing inventory is periodically inspected. Test kits, reagents, supplies and/or equipment that are no longer fit-for-use are discarded to enable better inventory visibility/accuracy. An SOP governs how inventory management is executed and how often.
4. QUANTITATIVELY MANAGED
Inventory records are maintained in real-time using fit-for-purpose IT. An SOP exists for practising characteristics-based/ABC inventory classification for use in the BOM. The laboratory keeps inventory management performance metrics (such as supply wastage, inventory accuracy, and stock-outs).
5. OPTIMIZING
Inventory management performance metrics are periodically reviewed, and changes to inventory management process, as well as processes/practices in other dimensions, are conceptualized with a view to continuous process improvement.

Table C5. Definition and range statements of procurement dimension

DEFINITION OF DIMENSION
Procurement involves a working knowledge of the process for acquiring goods and/or services at the best possible total cost, in the right quantity and quality, at the right time and in the right place, with all required documentation [1, p. 804].
1. INITIAL
The laboratory relies exclusively on the distributor for knowledge of import/export regulations.
2. MANAGED
At least one staff member who possesses some procurement experience is responsible for placing orders. There is no consistency in how the inventory level or forecast need for items on the BOM triggers order placement, and there is sometimes a need to place urgent orders. At least one staff member has some knowledge of import/export logistics and regulations and can manage these processes for the lab independently if required.
3. DEFINED
At least one staff member who possesses the required knowledge, skills, and abilities is responsible for placing orders using standard order procedures. Order placement is triggered either by a periodic (e.g., weekly) review of the inventory level or by an update to the forecast need for an item on the BOM. The laboratory has an SOP that sets out import/export documentation and application processes to be followed when these are required.
4. QUANTITATIVELY MANAGED
Real-time inventory levels, as recorded in the fit-for-purpose IT system, trigger order placement in line with the defined base stock levels/reorder points. A specific staff member or team who possesses the required knowledge, skills, and training is responsible for placing orders and arranging the relevant documentation for order/delivery. The laboratory keeps procurement performance metrics (such as order placement lead time).
5. OPTIMIZING
Procurement performance metrics are periodically reviewed, and changes to the procurement process, as well as processes/practices in other dimensions, are conceptualized with a view to continuous process improvement.

Table C6. Definition and range statements of procurement management dimension

DEFINITION OF DIMENSION
Procurement Management involves identifying procurement requirements, developing the strategy, identifying qualified suppliers, issuing/evaluating Invitations to Tender (ITT)/ Requests for Quotes (RFQ), evaluating bids/proposals from suppliers, and negotiating/signing contracts [1, p. 440].
1. INITIAL
The lab does not hold a Bill of Materials (BOM) for consistent procurement management. No staff member takes responsibility for the management of procurement contracts.
2. MANAGED
The lab maintains a BOM. At least one staff member is responsible for managing procurement contracts with key suppliers.
3. DEFINED
At least one staff member, who possesses the required knowledge, skills and abilities, is responsible for basic management of all procurement contracts.
4. QUANTITATIVELY MANAGED
A specific staff member or team, who possesses the required knowledge, skills and training, is responsible for PO/contract management, development of tenders and negotiation of prices. Procurement management is assessed by measuring the procurement cycle time (the aggregate time required to identify procurement requirements, develop the strategy, identify qualified suppliers, issue/evaluate ITT/RFQ, evaluate bids/proposals from suppliers, and negotiate/sign contracts).
5. OPTIMIZING
A specific staff member, who possesses the required knowledge, skills and abilities, is responsible for: developing and maintaining a purchasing/procurement strategy that takes the strategic goals of the laboratory into consideration; managing contracts with suppliers; reviewing these contracts and negotiating more advantageous procurement terms; and issuing RFPs/RFQs. The procurement order cycle is systematically collected and regularly reviewed. Based on this evaluation, adjustments may be made to the institutional procurement processes such as issuing/evaluating ITT/RFQ, evaluating bids/proposals from suppliers, and negotiating/signing contracts.

Table C7. Definition and range statements of supply planning dimension

DEFINITION OF DIMENSION
Supply Planning is the process of identifying, prioritizing, and aggregating, as a whole with constituent parts, all sources of supply that are required and add value in the supply chain of a product or service at the appropriate level, horizon and interval [1, p. 859].
1. INITIAL
Limited local know-how to place an order/know which distributor is in-country.
2. MANAGED
Maintain a database of suppliers used, ideally indicating vendor name, catalogue number, and price. At least one staff member is responsible for developing and maintaining a relationship with high-priority suppliers.
3. DEFINED
An SOP governs the maintenance of the supplier database and dictates that, as far as possible, more than one supplier should be identified for each item on the BOM. The BOM is integrated with the list of suppliers so that it shows at least one, but preferably more than one, supplier for each item.
4. QUANTITATIVELY MANAGED
Long-term supplier agreements/partnerships are negotiated for prioritized items on the BOM based on supplier performance and financial and operational considerations. Laboratory and suppliers have a relationship that allows communication about the availability of supplies with a view to informing order planning. Supplier performance is assessed, including at least the following metrics: order lead times; % of orders delivered in full; and delivery performance to customer commit date.
5. OPTIMIZING
Laboratory and suppliers have a relationship that enables them to understand lead time, time to import goods etc. Suppliers are preferentially selected based on performance (including order lead time). Supplier performance metrics are systematically collected and regularly evaluated. Based on this evaluation, adjustments may be made to proposals/contracts with suppliers.

Illustrative application

To illustrate how the CMM could support collaborative networks for knowledge sharing, learning and change within PGS laboratories, two examples are provided based on information gathered during lab visits. These are not intended to be an assessment of a specific laboratory's capability maturity, but to illustrate that the CMM can be effectively used to distinguish between labs at different levels of maturity in terms of SCM capabilities. They illustrate that the CMM can be used to identify areas (i.e. dimensions in the CMM) in which a particular laboratory has more mature capabilities and where there are opportunities for improvement.

Figure C1 provides a graphical depiction of the CMM for two laboratories based on information gathered from two existing labs. Although the two seem comparable in terms of the maturity of their technical capability, they differ significantly in terms of their SCM capability maturity. Laboratory 1 has been in existence for longer than Laboratory 2, but neither the age of the laboratory nor its technical capability maturity is correlated to the SCM capability maturity.

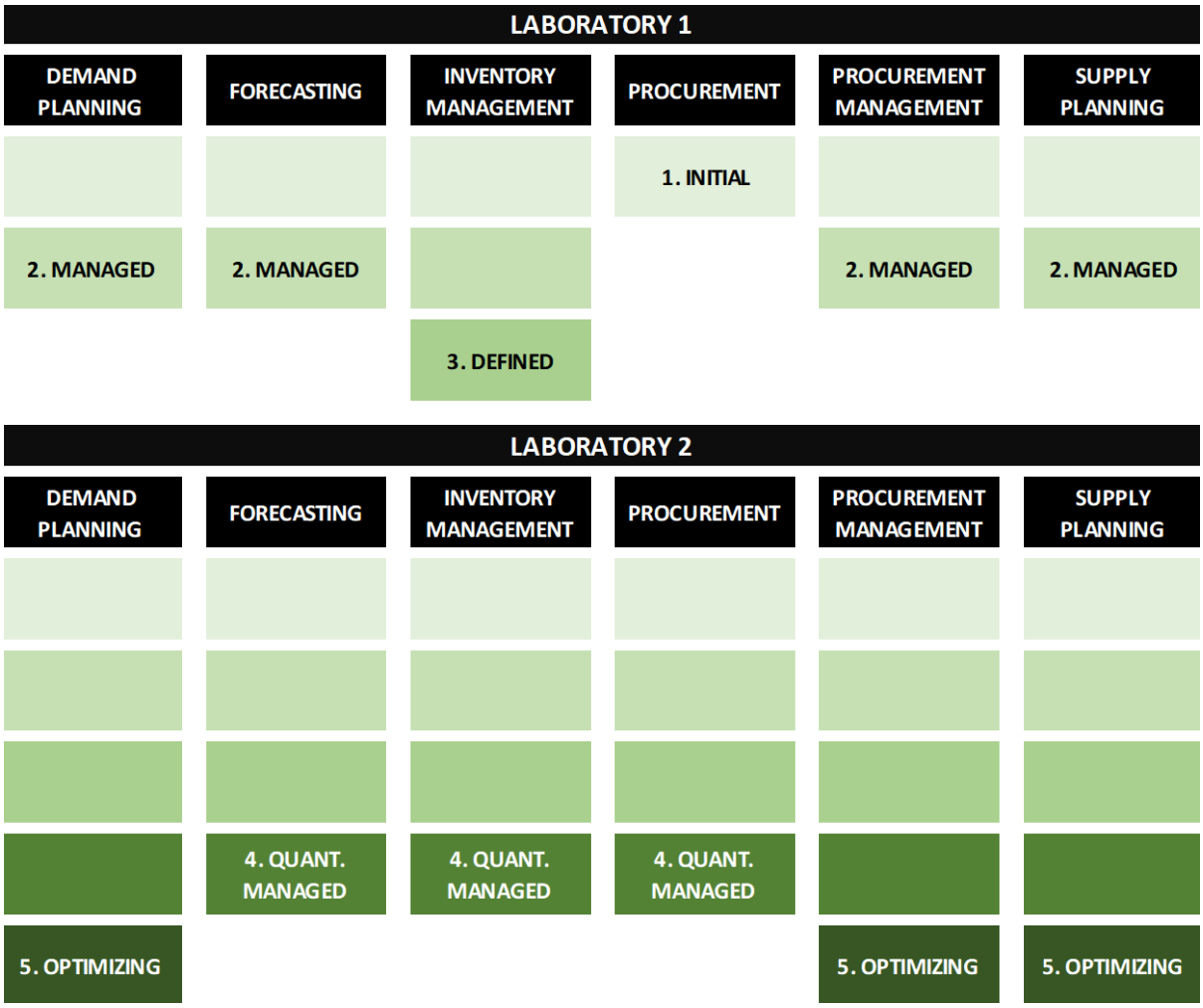

Figure C1. Illustrative comparison of two laboratories' SCM capability maturity

Table C8 shows a comparison of the applicable range statements for each of the six dimensions to illustrate the disparity between the two laboratories' SCM.

Table C8. Side-by-side range statement comparison to accompany illustrative application

LABORATORY 1	LABORATORY 2
DEMAND PLANNING	
2. MANAGED At least a staff member, who possesses some demand planning experience, is responsible for estimating demand for service and/or research work. This activity is triggered at their own discretion. The staff member shares demand estimates with the colleague responsible for material forecasting.	5. OPTIMIZING Demand planning improvement is based on current calculated demand and projected demand through public health/epidemiological tools and/or includes expert consultations that could offer more accurate insights into demand planning for sequencing across disease areas as well.
FORECASTING	
2. MANAGED Forecasting of reagent, consumable and equipment needs is done from time to time; however no SOP governs either when forecasting takes place or how it is executed. A base stock level/reorder point may be defined for some (i.e. prioritized) items on the BOM, but this is based on personal judgement, experience, and/or tacit knowledge alone. The forecast includes: the need for quality assurance and control activities; loss and wastage rates; and planned training activities.	4. QUANTITATIVELY MANAGED The SOP that governs the auditing and maintenance of the BOM includes a review of base stock levels/reorder points. The effort expended on achieving an accurate forecast is aligned with the priority classification of items on the BOM. There is communication between the laboratory technicians and the procurement team for better integration and planning of projected needs, considering the procurement cycle time. Information on the availability of supplies shared by suppliers also informs order planning. An SOP also governs periodic forecasting of equipment needs.
INVENTORY MANAGEMENT	
3. DEFINED A (manual or electronic) inventory system monitors stock purchased, stock received, stock used, and expiry dates, and ensures that stock is used on a "first in first out" (FIFO) basis, or that stock that is closest to its expiry date is used first. If stock levels are not monitored in real-time, this is done at least once per week. Quality of existing inventory is periodically inspected. Test kits, reagents, supplies and/or equipment that are no longer fit-for-use are discarded to enable better inventory visibility/accuracy. An SOP governs how inventory management is executed and how often.	4. QUANTITATIVELY MANAGED Inventory records are maintained in real-time using fit-for-purpose IT. An SOP exists for practising characteristics-based/ABC inventory classification for use in the BOM. The laboratory keeps inventory management performance metrics (such as supply wastage, inventory accuracy, and stock-outs).

	LABORATORY 1	LABORATORY 2
PROCUREMENT		
	1. INITIAL The laboratory relies exclusively on the distributor for knowledge of import/export regulations.	4. QUANTITATIVELY MANAGED Real-time inventory levels, as recorded in the fit-for-purpose IT system, trigger order placement in line with the defined base stock levels/reorder points. A specific staff member or team who possesses the required knowledge, skills and training is responsible for placing orders and arranging the relevant documentation for order/delivery. The laboratory keeps procurement performance metrics (such as order placement lead time).
PROCUREMENT MANAGEMENT		
	2. MANAGED The lab maintains a BOM. At least one staff member is responsible for managing procurement contracts with key suppliers.	5. OPTIMIZING A specific staff member who possesses the required knowledge, skills, and abilities, is responsible for developing and maintaining a purchasing/procurement strategy that takes the strategic goals of the laboratory into consideration; managing contracts with suppliers; reviewing these contracts and negotiating more advantageous procurement terms; and issuing RFPs/RFQs.
SUPPLY PLANNING		
	2. MANAGED Maintain a database of suppliers used, ideally indicating vendor name, catalogue number, and price. At least one staff member is responsible for developing and maintaining a relationship with high-priority suppliers.	5. OPTIMIZING Laboratory and suppliers have a relationship that enables them to understand lead time, time to import goods etc. Suppliers are preferentially selected based on performance (including order lead time). Supplier performance metrics are systematically collected and regularly evaluated. Based on this evaluation, adjustments may be made to proposals/contracts with suppliers.

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