





Health Information System (HIS) Policy Toolkit







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Acronyms

DQA data quality assessment

HIS health information system

HMIS health management information system

ICD International Classification of Diseases

ICT information and communication technology

IT information technology

M&E monitoring and evaluation

MoH Ministry of Health

NGO non-governmental organization

SDG Sustainable Development Goal

SOP standard operating procedures

TOR terms of reference

WHO World Health Organization

How to use this toolkit:

According to the World Health Organization (WHO) a Health Information System (HIS) "collects data from health and other relevant sectors, analyses the data and ensures their overall quality, relevance and timeliness, and converts the data into information for health-related decision-making." An HIS policy specifies the principles to be used to guide decision-making of HIS stakeholders and to help achieve these HIS outcomes defined above. An HIS policy can ensure a well functioning HIS with sound data to make decisions, which is needed for the formulation of public health policy and planning of health programs. Further, a policy focused on the HIS is important to guide all stakeholders in the health sector that interact with health information to ensure individuals' rights to privacy are protected and that high quality data are collected, analysed, disseminated and ultimately used to guide decision-making at all levels of the health system.

This toolkit provides tactical and technical guidance for developing a new HIS policy. The technical guidance can also be used to update and revise an existing HIS policy.

- The first part of the toolkit consists of the Steps to develop a National Health Information System Policy, to be used as a practical guide to inform countries looking to develop a national HIS policy or related guidelines and help with the planning process. In addition to outlining the critical steps involved in developing an HIS policy, this table also includes guidance on the key stakeholders that could contribute to each step, suggested timelines in which to complete each step, available resources that can be referenced during each step, and suggested results/outputs from each step.
- The second table in this toolkit is a **Key Principle Checklist** that provides an outline of the key principles to include in an HIS policy, and a box to be marked by the authors of an HIS policy if a principle is to be included in the national HIS policy. It provides a summary of the final decisions made after the **Key Principle Matrix** is completed.
- The third part of the toolkit, the **Key Principle Matrix**, describes the key principles that can be included in a national HIS policy and provides preliminary guidance on what needs to be included. Not every principle will be appropriate for every country's HIS policy. In addition to suggesting key principles and providing guidance on how to apply them, this matrix can function as a decision tool for stakeholders that are developing the HIS policy.



Steps to develop a National Health Information System Policy

The steps below are suggestions and may differ from country to country depending on usual procedures or country needs. Similarly, the timelines and key parties are only a suggestion. Ultimately, the final HIS policy is the only required output from this process, though the other suggested outputs will help to make the process of writing an HIS Policy more effective. In this document, "authors" are the Ministry of Health officials requesting the HIS policy who will formally be recognized as the authors of the document, and who ultimately, will be charged with seeking national adoption of the policy. "Technical writers" are the individuals (consultants, external partners, Ministry of Health staff, etc.) who will draft the HIS policy, consulting extensively with the authors.

	Step	Key Parties	Time-frame	Available tools	Output
1	Policy authors identify need for policy and identify the key domains and recruit technical writers to help write the document.	MoH, technical writers	1 month	HIS Key Principle Matrix	High level outline of policy document
2	Consult with key stakeholders to map out HIS structure.	Technical writers, authors, stakeholders*	2 weeks	NA	Enterprise map or matrix of HIS
3	Decide on what areas/key principles to cover and how much guidance to provide.	Technical writers	Ongoing (initially 1 week)	HIS Key Principle Matrix	Outline of policy document
4	Review national policies, guidelines, documents related to HIS to determine what policies/procedures already exist.	Technical writers	2 weeks	 HIS Key Principle Matrix Summary of document review (Annex 1) 	Fill out HIS Key Principle Matrix with information from national documents
5	Review other countries' HIS policies to determine which formats/content could be applicable.	Technical writers	1 week	 HIS Key Principle Matrix Summary of document review (Annex 1) 	Refined policy outline
6	Review international health reporting standards and conduct literature review to fill-in gaps from 4 and 5 above.	Technical writers	1 week	HIS Key Principle Matrix	Literature review
7	Conduct needs assessment with key stakeholders from across the health sector.**	Technical writers, stakeholders*	2 months	Sample needs assessment questions (see Annex 2) Summary of document review (Annex 1)	Needs assessment report
8	Draft the policy document, gathering input from authors and other important stakeholders along the way.	Technical writers, authors	3 months	NA	HIS policy Draft 0

continued>

	Step	Key Parties	Time-frame	Available tools	Result/Output
9	Invite all key stakeholders that would be affected by/use an HIS policy to a meeting to provide feedback on the draft policy. Internal stakeholders All stakeholders	All stakeholders*	6 days	Sample agenda (see Annex 3)	2 meetings that are each 3 days long
10	Update policy document from stakeholders' meeting and send a final draft for revision to the policy authors.	Technical writers	2 weeks	NA	HIS policy Draft 1 (may require multiple iterations)
11	Solicit final approval and adoption of HIS policy as per national protocols.	Authors	1 month	NA	Final HIS Policy
12	Develop a dissemination plan for the HIS policy. Consider: • Who will develop/conduct training on the policy for key stakeholders • Who will receive training? • In which format will the HIS policy be disseminated? Print or electronic or both? • Do additional accompanying documents (SOPs, etc.) need to be developed?	Authors	1 week		 Training plan Training materials Printed HIS policy and/or Final HIS policy uploaded to appropriate national websites
13	Plan for regular updates of the HIS policy. Consider: • How frequently will the policy be reviewed and updated? • Who will review and update the policy?	Authors and other relevant stakeholders	1 week	NA	HIS policy evaluation plan

^{*} Stakeholders include all parties that are either generators of health data or users of health data. Examples include Ministry of Health (including health programs, monitoring and evaluation, epidemiology, information and communication technology); public sector agencies (such as the national identification agency, the ministry responsible for vital registration, and the department of interior amongst others); private health sector; religious and NGO health partners; National Statistics Office; academic partners, public and private health facility providers and administrators, health development partners.

^{**} Note: the needs assessment may also be an opportunity to gather additional information on the current operational practices of the HIS and any key policy or other documents missed.



Key Principle Checklist

The checklist provides a complete list of principles to be used in National HIS policy design. Some HIS policies include all of these principles, while some include a selection. The authors of the policy should review this list carefully and select the key principles they would like to include in their national HIS policy. Authors can refer to the detailed list in the **Key Principle Matrix** for more information about a principle in the checklist. The checklist provides a summary of the decisions from the Key Principle Matrix.

	Key Principle	Check if principle will
		be included in HIS policy
1	Coordination	0
1.1	Organizational roles and responsibilities of key HIS stakeholders	0
1.2	National HIS components	0
1.3	Data harmonization	0
1.4	HIS steering committee/leadership	0
1.5	Interoperable systems and data exchange	0
1.6	Coordination between HIS and other major national data collection initiatives	0
1.7	Training on how to handle health information	0
2	Data Collection and Reporting	0
2.1	Coordinated collection and reporting tools	0
2.2	Harmonized indicators and survey questions	0
2.3	Routine data collection and reporting procedures	0
2.4	Non-routine data collection and reporting procedures	0
3	Data Quality	0
3.1	Quality of routine data	0
3.2	Quality of non-routine data	0
3.3	Data integrity	0
3.4	Data management	0
4	Data Analysis and Dissemination	0
4.1	Basic HIS analyses	0
4.2	Capacity to analyze data	0
4.3	Automate/facilitate electronic data analysis	0
4.4	Data analysis standards	0
4.5	Harmonization of data formats	0
4.6	Data dissemination protocols	0
4.7	Key health information reports	Continued

#	Key Principle	Check if principle will be included in HIS policy
5	Data Use	0
5.1	Indicator tracking (including harmonizing targets)	0
5.2	When should data be used	0
6	Data Confidentiality	0
6.1	Definition of confidential health information	0
6.2	Protocols to handle confidential health information	0
6.3	Consequences for breaches of confidentiality	0
7	Data Security and Storage	0
7.1	Secure computer systems to handle data	0
7.2	Data storage and archiving	0
7.3	Confidential data disposal	0
8	Data Sharing	0
8.1	Sharing of de-identified data	0
8.2	International reporting requirements	0
9	Resource Requirements	0
9.1	Human resources	0
9.2	Financial resources	0
9.3	Information and communications technology (ICT) resources	0
10	Data Ownership	0
10.1	Who owns data	0
10.2	Data sovereignty laws	0



Key Principle Matrix

Each country developing these policies needs to decide on the level of detail to provide. Some countries create high-level policy documents that elaborate general principles but leave more detailed guidelines to be developed in associated standard operating procedures (SOPs). Other countries create guideline document and provide a higher level of specificity and detail. Furthermore, certain policies may focus more narrowly on certain domains; others may not provide details on guidelines and procedures and therefore only very high-level principles will be included. Further, the tool can also be used to analyze an existing national HIS policy to update it, and/or to ensure that it is complete in that it includes all relevant key principles. This analysis could be carried out by national HIS stakeholders in the public or private sector, or external partners with HIS and policy expertise.

While it is possible to structure the HIS policy using only the key principles, including a "background" chapter that summarizes the origins of the HIS policy and provides some historical context about the national HIS can be useful to the reader to better understand the contents of the document. In the beginning of the HIS policy document, specifying the vision (the change the policy aims to create), objectives (the specific targets the policy aims to achieve) and scope (identification of who will be affected by the policy) of the HIS policy is important to establish what the policy does and does not cover and who is subject to following it (i.e. anyone who handles any type of health data in the country, health workers, researchers, MoH staff, etc.) and/or protected by it (i.e. users of the health system, survey participants, health workers, etc.). The scope can also specify the data that is subject to the HIS policy (i.e. electronic data, paper-based data,

laboratory specimens, health records, aggregated vs. identifiable data, insurance data, etc.). Further, the scope can also specify who can enforce the policy – this could include the Ministry of Health, the national government and others.

Health information systems are comprised of population-based and institutional-based data sources. Population-based sources generate data about individuals within a defined population and can be continuous sources (i.e. civil registration) or periodic (i.e. demographic and health surveys). Institution-based sources are limited to data about individuals utilizing

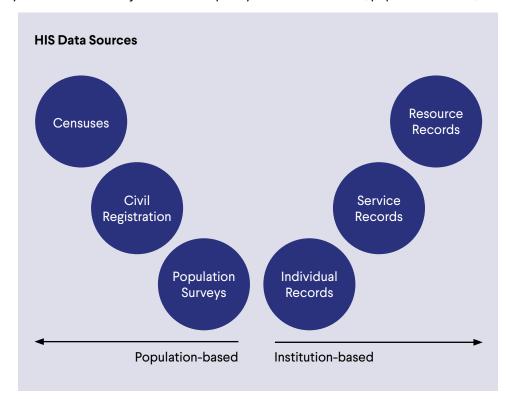


Figure 1. HIS Data sources. World Health Organization Health Metrics Network. Framework and Standards for Country Health Information Systems. Second Edition. 2012. Available online: https://www.who.int/healthinfo/country_monitoring_evaluation/who-hmn-framework-standards-chi.pdf

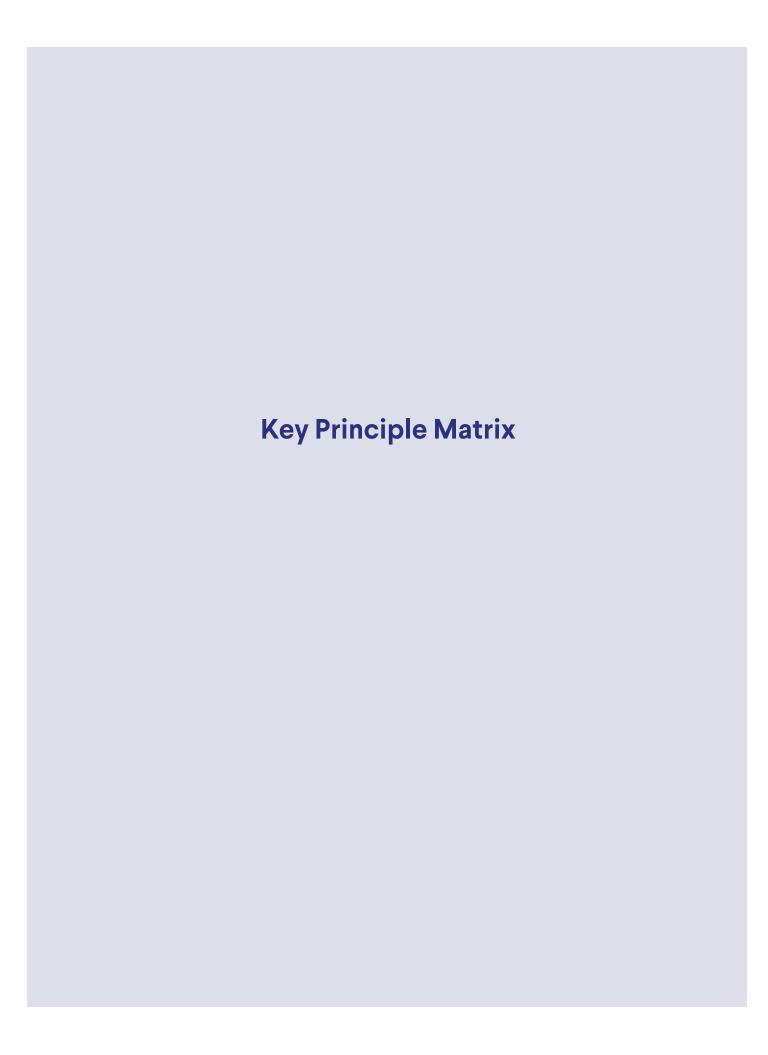
institutional services, providing information on the state of the health system's patients, resources (financial, human) and logistics. These sources can also generate routine data (i.e. health facility registers) or non-routine data (i.e. health service operational research)ⁱⁱⁱ. A Health Management Information System (HMIS) is dedicated to reporting health status, interventions and resources statistics for decision-making, on a routine basis. While drafting an HIS policy, it is important to consider the national HIS and where its components fall within this model. For example, more Ministries of Health are taking a proactive role in notifying vital events to the civil registrars. It is also critical to identify whether there is health information collected nationally that is beyond the scope of the national health ministry that should also be governed by this policy such as, school health and prison health records. These external connections raise many associated issues in relation to data security, confidentiality, archiving, and information technology (IT) interoperability across different government departments that would need to be considered in the policy.

The need for a national HIS policy could be articulated by the Ministry of Health or another government entity, the private sector, and/or external partners in the health sector. While the Ministry of Health would traditionally lead the development of this policy, many stakeholders must be actively involved in its development. The content and writing of the national HIS policy should be guided by the appropriate technical staff of the country, according to the national HIS structure. Potential members of the author team may be from the Ministry of Health monitoring and evaluation unit, the national statistics agency, national research bodies, and other experts on the national HIS, as well as external technical policy writers with HIS expertise. Experts in specific technical areas should also be consulted to provide inputs to the principles relevant to their field of knowledge. Given that most countries are moving or have moved from a paper-based routine HMIS to an electronic one, it is also critical to have policy expertise in IT, management information systems and/or IT security. Legal expertise, particularly in the area of data protection and security, is also an asset and could provide guidance on national legal precedents that can inform the HIS policy. Identifying the decision-makers for each key principle and/or data source can also simplify the list of necessary consultations when drafting this HIS policy, both to solicit buy-in, as well as to gather the requisite information. The structure of this guide is designed to facilitate this identification process.

To the right of the box with the Key Principle and the Guidance, there is a column to be completed with the author team that asks the following questions:

- 1. What is already included in existing legal/policy/operational documents relating to this key principle?
- 2. Before you decide whether to include this principle in your HIS policy, do you need to do more research? Additional research could include reviewing international best practices and current HIS practices, facilitating stakeholder discussions, etc.
- 3. Who is the decision-maker/key consultants that will determine what is included in each section/sub-section of the policy?
- **4.** Is this principle something that should be included in the policy you are drafting?

 If it is included, will you provide very detailed guidelines or procedures or simply a high-level policy statement?
- 5. What, if any, tools/supplementary documentation are required to support and/or implement the principle?



1.1

KEY PRINCIPLE

Clearly define roles and responsibilities of key stakeholders at an organizational level (unless specification is required at the individual level)

GUIDANCE

Articulating the roles of key stakeholders in the HIS and how they interact with each other is required for a high functioning HIS.

- Map out all of the key stakeholders in the HIS landscape.
- Define the roles and responsibilities of HIS stakeholders (within and outside of the MoH, other government agencies, private sector, donor partners, community-based organizations, at each level of the health system, etc.)

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Yes	◯ No	Summary:
More resea	arch needed	!?
Yes	O No	Summary:
Who is the	decision-m	naker? (i.e. who
		cluded in each of the policy)
Decision-n		
Consultant	:	
Consultant		
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nclude in	policy?	

1.2

KEY PRINCIPLE

Identify all components of the national HIS

GUIDANCE

National HIS usually consist of many data sources that can be 1) population-based (censuses, civil registration systems, population surveys)

or

2) institutional (individual, service, resource records).

 Understand what the different components of the HIS are, who implements each component, data collection and use processes and systems for each and existing guidelines/procedures for each

	l in existing al documen	ts? If yes, summarize
Yes	○ No	Summary:
		10
More rese	arch needed	
Yes	O No	Summary:
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1.3

KEY PRINCIPLE

Determine how data are harmonized so it is consistent and clear^{iv}

GUIDANCE

Harmonization is the process of aligning data to reduce duplication of collection efforts, and to ensure data from like indicators can be compared (across time, place, population) and merged, as needed. Consider how this should be done throughout the HIS (details follow in the sections below):

- Data Collection
- Data Analysis
- Data Use

Described in existing legal/policy/ operational documents? If yes, summarize.			
Yes No	Summary:		
More research needed?			
	C		
Yes No	Summary:		
Who is the decision-mal determines what is inclu- section/sub-section of the	uded in each		
Decision-maker:			
Consultant:			
Include in policy?			
Yes No			
Level of detail needed:			
Tools/Supplementary doneeded?	ocumentation		
Data Dictionary			
Yes No			
Other:			

1.4

KEY PRINCIPLE

HIS steering committee/leadership

GUIDANCE

A national body to oversee the country's HIS is often comprised of various stakeholders from the public and private sector (i.e. MoH, WHO, donors, international NGOs, faith-based organizations). In the HIS policy, it is helpful to articulate the structure of this coordinating body to highlight roles and responsibilities in relation to the policy.

- Does such a body exist?
- Who are the members?
- Is there a committee chair?
- Who oversees HIS coordination and functioning?
- Have these parties been consulted during the drafting of the HIS policy?

Described in existing legal/policy/ operational documents? If yes, summarize.
Yes No Summary:
More research needed?
Yes No Summary:
Who is the decision-maker? (i.e. who determines what is included in each section/sub-section of the policy)
Decision-maker:
Consultant:
Include in policy?
Yes No
Level of detail needed:
Tools/Supplementary documentation needed?
HIS steering committee TOR
Yes No
Other:

1.5

KEY PRINCIPLE

Focus on interoperable systems and data exchange

GUIDANCE

In many cases, the data from the HIS are fragmented and there is duplication across sources or across programs within the same source. To ensure the utility and power of the HIS:

- Integration of data sources should be pursued when possible (i.e. health facility data from different health programs should be collected and managed by the same system^{vi}).
- When full integration is not possible (i.e. survey data v. health services data), data should be managed and stored in interoperable systems, with the use of a data dictionary technology systems and software applications that have the ability to communicate, to exchange data and to use the information that has been exchanged or an integrated data warehouse.

Described in operational d	_	egal/policy/ s? If yes, summarize.
Yes (No	Summary:
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Yes () No	Summary:
	hat is inc	aker? (i.e. who luded in each the policy)
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Consultant:		
Include in pol	icy?	
Yes	No	
Level of detail	needed:	
Tools/Supple needed?	mentary o	documentation
List and/or arc		
-		nt are part of the y are connected
Yes	No	
Other:		

1.6

KEY PRINCIPLE

Coordinate surveys and other large health data initiatives with MOH timelines and other needs

GUIDANCE

Non-routine HIS data sources such as health surveys should be coordinated with major health sector initiatives such as 5-year strategic plans and reporting schedules for the Sustainable Development Goals (SDGs) and non-health sector initiatives such as the Living Standards Measurement Study.

- Timelines should correspond to major MOH initiatives.
- Indicators and questions should be coordinated with MOH reporting requirements and national health indicators.

Described in existing legal/policy/ operational documents? If yes, summarize.
Yes No Summary:
More research needed?
Yes No Summary:
Who is the decision-maker? (i.e. who determines what is included in each section/sub-section of the policy)
Decision-maker:
Consultant:
Include in policy?
Yes No
Level of detail needed:
Tools/Supplementary documentation needed?
Coordinated HIS Calendar
Yes No
Other:

1.7

KEY PRINCIPLE

Ensure that health staff and others responsible for handling health information (i.e. national statistics agencies, national civil registration and vital statistics receive the training and support needed to appropriately collect/report/ensure quality of/analyze/disseminate/use/protect and share data

GUIDANCE

Adequate training of those responsible for the functioning of the HIS, including all staff and leadership, is essential. Some ways to include this in an HIS policy are to:

- Outline a realistic capacity building plan if insufficient capacity is identified in any of the areas related to data handling or to improve existing capacity.
- Consider and refer to the training/certification programs in place/needed to enable high quality data availability and staff capabilities.

		legal/policy/ ts? If yes, summarize.
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Yes	No	Summary:
More resea	arch needed	/ ?
Yes	No	Summary:
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Consultant	:	
Include in	policy?	
Yes	No	
Level of de	tail needed	:

2.1

KEY PRINCIPLE

Ensure routine data collection and reporting tools are designed, vetted and revised via a coordinated process

GUIDANCE

In order to minimize burden on health workers at all levels, all data collection and reporting tools should be coordinated (including both routine and non-routine data).

- Clearly define who, at the central level, will manage data collection and reporting tools.
- Delineate procedures for the development and revision of data collection tools and how the key agency works with other stakeholders to ensure their needs are met.
- Delineate how (process/frequency) the central group coordinates with ICT and other groups responsible for implementing electronic data collection systems.
- Eliminate duplication.

Yes Yes	O No	Summary:
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2.2

KEY PRINCIPLE

Harmonize indicators and survey questions

GUIDANCE

To ensure that survey questions and national indicators from all programs adhere to similar standards, they must be harmonized, as follows:

- Ensure related survey questions are standardized so that concepts and definitions are similar across surveys.
- Harmonize indicators across health programs/partner agencies working in-country to avoid data duplication and make data easier to use and interpret.
- Require common terminology across all data sets, including for diagnoses (ICD-10, ICD-11), medical procedures, administrative areas, etc.

Described in existing legal/policy/ operational documents? If yes, summarize.
Yes No Summary:
More research needed?
Yes No Summary:
Who is the decision-maker? (i.e. who determines what is included in each section/sub-section of the policy)
Decision-maker:
Consultant:
Include in policy?
Yes No
Level of detail needed:
Tools/Supplementary documentation needed?
List of all national indicators and definitions
Yes No
National diagnosis coding system (e.g. ICD 10)
Yes No
Other:

2.3

KEY PRINCIPLE

Describe procedures for collecting and reporting data on a routine basis to ensure all stakeholders are aware of who to report to, when to report and how to report

GUIDANCE

Delineating procedures for data collection and reporting helps to ensure standardization and will ideally lead to higher quality data. Procedures of data collection and reporting to be outlined include:

- what and how data collection tools are made available at all levels.
- IT infrastructure requirements and procedures for collecting data electronically.
- data entry and data receipt protocols.
- frequency and timeline of data collection and reporting.
- reporting procedures for all levels of the health system.
- individuals responsible for data collection.

Described in existing legal/policy/ operational documents? If yes, summarize.
Yes No Summary:
More research needed?
Yes No Summary:
Who is the decision-maker? (i.e. who determines what is included in each section/sub-section of the policy)
Decision-maker:
Consultant:
Include in policy?
Yes No
Level of detail needed:
Tools/Supplementary documentation needed?
Standard Operating Procedures for HIS data collection and reporting
Yes No
Other:

2.4

KEY PRINCIPLE

Non-routine data collection and reporting procedures

GUIDANCE

For all health data that are collected outside of the national routine HMIS, policies on how to collect data from different sources should be articulated. Examples of policies related to non-routine data collection include:

- Whether permission must be granted to a data collector to collect health data outside the routine HMIS and if so, for what types of data and by whom.
- Vetting of non-routine data collection instruments/systems.
- Private-sector data collection and reporting requirements for non-routine data.
- Who each type of data must be reported to at the local and national level.

Yes	○ No	Summary:
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More rese	arch needed	! ?
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3.1

KEY PRINCIPLE

Ensure quality of routine data

GUIDANCE

The high data volumes and short timelines resulting from routine data collection (i.e. routine HMIS) can lead to error, which must be monitored and mitigated via data quality checks and supervision/support to data collectors. To alleviate this, the HIS policy should specify:

- frequency and method of routine data quality checks as well as data quality assessments.
- feedback process for all levels of data collection.
- common disaggregations.
- procedures and frequency for on-the-job supervision (outline).

Described in existing operational documer	legal/policy/ ats? If yes, summarize.
Yes No	Summary:
More research neede	d?
Yes No	Summary:
Who is the decision-r determines what is in section/sub-section	cluded in each
Decision-maker:	
Consultant:	
In alcoha in maliace	
Include in policy?	
Yes No	
Level of detail needed	i:
Tools/Supplementary needed?	documentation
Data Quality Assessm	ent (DQA) Guidelines
Yes No	
Other:	

3.2

KEY PRINCIPLE

Ensure quality of non-routine data

GUIDANCE

For all non-routine data that are collected (i.e. surveys) the policy should state how quality of the data will be ensured and who is responsible for ensuring quality.

Summary:
Summary:
Summary:
the policy)
ocumentation
ocumentation t (DQA) Guidelines

3.3

KEY PRINCIPLE

Ensure data integrity is maintained throughout data collection, reporting, quality checking

GUIDANCE

Data integrity is the degree to which data are complete, accurate and reliable and that these characteristics of the data are maintained throughout the data life cycle^{iX}.

- All data, paper or electronic, should be collected and stored in a secure manner.
- Any changes made to data after it's collected should be done by authorized individuals only and clearly documented.
- Specify parameters for "data locking" (to prevent data from being changed after it has been reported).
- Limit the number of people authorized to clean/modify data (in either aggregated or individual systems).
- Specify how changes to data must be documented.

Described in existing legal/policy/ operational documents? If yes, summarize
Yes No Summary:
More research needed?
Yes No Summary:
Who is the decision-maker? (i.e. who determines what is included in each section/sub-section of the policy) Decision-maker: Consultant:
Consultant:
Include in policy?
Yes No
Level of detail needed:
Tools/Supplementary documentation needed?
Data Quality Assessment (DQA) Guidelines
Yes No
National HMIS guidelines/protocols
Yes No
Other:

3.4

KEY PRINCIPLE

Data management

GUIDANCE

Ensuring high quality data is not only about how the data are collected, but also how it is managed.

- Specify which department is in charge of data management.
- Specify minimum criteria for data management software.
- Require that meta-data dictionaries be developed for all data sets

Yes	O No	Summary:
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4.1

KEY PRINCIPLE

Define basic analyses to be conducted at every level of the health system

GUIDANCE

Routine HIS collect a lot of data, much of which is not used. Further, the people collecting the data at the facilities rarely have access to completed analyses. Without a commitment to analyzing the data, disseminating the resulting information and using it, there is no point in collecting HIS data*. One way to improve the use of data is to predefine basic analyses that can help facilities, districts and national level officials make evidence-based decisions. An HIS policy should provide a list of key analyses to be conducted at each level or lay out the general principle that such a list needs to be developed. Potential analyses include:

- Assess health equity i.e. compare key indicators across geographies, socio-economic status, gender, and ethnicity (as applicable) [National].
- Identify major risk factors for mortality through attributable risk analyses [National].
- Determine major causes of morbidity and mortality [all levels].
- Determine if the health system is meeting targets [all levels].
- Project potential spending for future years [all levels].
- Determine resource allocation.

	_	legal/policy/ ts? If yes, summarize.
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More rese	arch needed	d?
Yes	No	Summary:
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Include in	policy?	
Yes	No	
Level of de	etail needed:	:
Tools/Sup needed?	plementary	documentation
	ata Analysis c programs,	
Yes	No	
	nd Use Guid c programs,	
Yes	No	

4.2

KEY PRINCIPLE

Ensure capacity and systems are in place to conduct high quality data analyses

GUIDANCE

One reason data analysis is rarely done is that staff often have neither the time nor the training to conduct the analysis. In addition to defining needed analyses, an HIS policy could be written to ensure that the system is set up to allow them to be conducted, such as:

- Allocated time to conduct in-depth data analysis.
- Regular demand from health system stakeholders for high quality analyses to drive decisions.

Yes	No	Summary:
More rese	arch needed	d?
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4.3

KEY PRINCIPLE

Effectively incorporate data analysis tools into the electronic data collection system for routine HIS

GUIDANCE

Electronic data collection systems can be programmed to include analyses so facility-level staff can easily understand what their data means and apply it to their operations. For more aggregated levels of the health system (i.e. district, region, national) more complicated analyses are often required, and thus automating them can save time and alert officials to issues closer to real-time.

- Determine who is responsible for ensuring that analyses specified in 4.1 get incorporated into electronic HMIS systems.
- Specify all reports that must be generated from data analysis.

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Yes	No	Summary:
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Yes	No	
Level of de	tail needed	:

4.4

KEY PRINCIPLE

Establish clear data analysis standards

GUIDANCE

Data analysis standards can help ensure that analysts conduct appropriate analyses, do not make conclusions that are not supported by the data, and only report results that can be replicated. The needs for standards will differ depending on the complexity of the analysis and the type of data used, however, some to consider include:

• When publishing estimates that are unreliable (large relative standard errors (>30%), small denominators (<50), large 95% CI (>10), etc), or with missing data, note that the estimate is unreliable or missing data when publishing.

Only conclude that there are differences between groups or over time if they are statistically significantly different.

- When comparing estimates across groups, they should be age-standardized.
- Do not publish estimates with a lot of missing data (e.g. less than X% reporting – threshold to be set by country, based on Data Quality Assessment guidelines).

Described in existing legal/policy/ operational documents? If yes, summarize.
Yes No Summary:
More research needed?
Yes No Summary:
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Decision-maker:
Consultant:
Include in policy?
Yes No
Level of detail needed:
Tools/Supplementary documentation needed?
National Data Analysis Guidelines (i.e. Data Demand and Use Guidelines) (for specific
programs, or HMIS)
Yes No
Other:

4.5

KEY PRINCIPLE

Harmonize data formats from different data sources

GUIDANCE

In order to analyze data from different sources (i.e. a similar indicator), they must first be converted into a common format to ensure that all of the data can be analyzed and compared, if needed.

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4.6

KEY PRINCIPLE

Ensure that protocols for data dissemination within the MOH exist and are followed

GUIDANCE

Data collected through the HMIS system, surveys or other systems may be managed by one department in the MOH, but many departments depend on that data to make decisions. Articulating clear protocols for data dissemination will ensure that high quality data are made available quickly in a way that protects the confidentiality of patients in the system.

- Specify procedures for disseminating data including:
 - quality checks and data cleaning.
 - protection of patient privacy.
 - timeliness.

Described in existing legal/policy/ operational documents? If yes, summarize.		
Yes	No	Summary:
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Yes	No	
Level of de	etail needed:	
Tools/Sup needed?	plementary	documentation
Enterprise	architecture	,
Yes	No	
Other:		

4. Data Analysis and Dissemination

4.7

KEY PRINCIPLE

Define key reports that need to be released

GUIDANCE

While in many cases disseminating raw data can be useful, health reports allow for the dissemination of data that is already analysed and packaged for use. Potential reports that should be considered include:

Routine reports:

- Annual health report
- Weekly or monthly epidemiology bulletins
- Annual vital statistics reports

Topic/Program/Evaluation-specific reports:

- Topical health reports (short)
- End-line and mid-term evaluations of strategic plans

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5. Data Use

5.1

KEY PRINCIPLE

Outline clear systems for tracking indicators, including harmonizing targets

GUIDANCE

Ensuring a process is in place to develop harmonized targets throughout the health sector is important to maintain consistency across how data can be used for decision-making. An HIS policy should specify:

- Frequency with which targets are updated.
- Process by which targets are updated, including how this is coordinated across departments and between the local and national level of the health system.
- Which department is responsible for tracking progress towards targets.
- Which department is responsible for reporting health-related indicators at an international level, e.g. SDGs.

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5. Data Use

5.2

KEY PRINCIPLE

Provide guidance on when data should be used

GUIDANCE

Using data for planning, policymaking and decision-making are the ultimate goals of an HIS. Data is most likely to be used when systems are established that allow for regular review of data. The following types of guidance may be useful:

- Defining the planning process, including what data needs to be used in the creation of annual plans and budgets.
- Outlining systems where data is regularly reviewed, such as quarterly meetings to review progress toward targets.
- Identifying technology needs to help use data more effectively and efficiently.

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Level of detail needed:	
Tools/Supplementary d	ocumentation
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Demand and Use Guidel programs, or HMIS)	ines) (for specific
Yes No	
Other:	

6. Data Confidentiality

6.1

KEY PRINCIPLE

Define and identify what constitutes confidential health information

GUIDANCE

Confidential health information is information that identifies an individual AND relates to at least one of the following (1) past, present or future health condition, (2) provision of health care to an individual, (3) payment for health care^{xi}. An HIS policy should:

- Provide a clear definition of confidential health information
- Consider the need for individual privacy and confidentiality versus the public health imperative of protection of population health.
- Incorporate any laws or regulations already existing that deal with this.

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6. Data Confidentiality

6.2

KEY PRINCIPLE

Handle confidential information according to a strict protocol

GUIDANCE

Health systems collect a lot of confidential health information and therefore it is critical that procedures are in place to protect the privacy of individuals who access the system. Some key things that should be covered in the policy include:

- Consider the ethical aspects of data collection, analysis and use.
- De-identify health information to protect patient confidentiality; this is particularly important for both survey data and data from electronic health records.
- Confidential health information should be stored securely and procedures for accessing this information should be clearly articulated, including what data can be accessed, by whom, how can it be accessed. Data logs should track each of these elements, as well to protect confidential health information.
- Identify under what circumstances eligible people can have access to confidential health information, including
 - Medical personnel providing patient care.
 - Referrals of patients to a new facility.
 - Billing for medical visits/health insurance.
 - Outbreak investigations and notifiable disease reporting.
 - Reporting of births and deaths to the civil registration authority.
 - Clinical supervision and monitoring and evaluation of programs.
 - At the written request of patients.
 - For children or unconscious patients unable to give consent (what is the national legislation/policy?).
 - Intra-agency exchange of client-level information.

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Level of detail needed:	

6. Data Confidentiality

6.3

KEY PRINCIPLE

Clearly articulate consequences for breaches of confidentiality

GUIDANCE

Identify any existing regulations around breach of confidential health information in the country and apply it to the HIS, as relevant. If none exists, this policy may be an appropriate place to indicate the repercussions of such a disclosure.

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7. Data Security and Storage

7.1

KEY PRINCIPLE

Computer systems for entering, managing and storing confidential health data should be secure

GUIDANCE

With the shift to electronic medical records, much confidential information will now be available in electronic format and ensuring security of that data is crucial. Some security-related issues to consider including in an HIS policy:

- All systems that store confidential information should be password protected to limit the possibility of unauthorized access. Users should only be granted access to data that they specifically need – for instance a doctor should only be able to see records of patients under their care/in their facility, not all patients. Development of a hierarchy structure that articulates data access rights for each relevant stakeholder can aid in this process.
- To ensure data integrity, only authorized users of the HIS can change health information once it has been entered into the paper or electronic system.
- Servers should be secure and data stored in-line with national policies (in many cases, countries do not allow storage of sensitive data on the cloud).
- Procedures should be outlined to ensure that data are backed-up regularly.

Described in existing legal/policy/ operational documents? If yes, summarize.
Yes No Summary:
More research needed?
Yes No Summary:
Who is the decision-maker? (i.e. who determines what is included in each section/sub-section of the policy)
Decision-maker:
Consultant:
Include in policy?
Yes No
Level of detail needed:
Tools/Supplementary documentation needed?
National e-Health guidelines
Yes No
MoH ICT Policy/Protocols
Yes No
Other:

7. Data Security and Storage

7.2

KEY PRINCIPLE

Provide guidelines around data storage and archiving

GUIDANCE

Guidance should be provided on archiving data in health facilities and data security for paper-based forms and electronic health data.

- Define how long paper-based registers or data should be stored on-site (perhaps 2 years); and then how long they should be stored in an offsite archive (perhaps 10 years). This could differ for different types of data (e.g. individual records versus surveillance data). National laws or policies from other government departments may already exist that are relevant here. For example, individual records from civil registration should be stored indefinitely in the national civil registration archives.
- Define how long electronic health records should be kept (some policies suggest during the life of the patient).
- Provide standards for sites where data are stored, including safety from fire, water damage, theft, vermin, etc.

Described in existing legal/policy/ operational documents? If yes, summarize.
Yes No Summary:
More research needed?
Yes No Summary:
Who is the decision-maker? (i.e. who determines what is included in each section/sub-section of the policy)
Decision-maker:
Consultant:
Include in policy?
Yes No
Level of detail needed:
Tools/Supplementary documentation needed?
MoH ICT Policy/Protocols
Yes No
Other:

7. Data Security and Storage

7.3

KEY PRINCIPLE

Specify procedures for confidential data disposal

GUIDANCE

Confidential data must also be safely disposed of to ensure that no one can access the information after disposal.

- Identify which kinds of data can be disposed of and which should be archived
- Develop procedures for disposing data that ensure that confidential data cannot be reconstructed, for example by:
 - Burning, pulping or shredding paper-based documents.
 - Physical destruction of certain computer discs.
 - Safe disposal of computers and servers.

Described in existing legal/policy/ operational documents? If yes, summarize.
Yes No Summary:
More research needed?
Yes No Summary:
Who is the decision-maker? (i.e. who determines what is included in each section/sub-section of the policy)
Decision-maker:
Consultant:
Include in policy?
Yes No
Level of detail needed:
Tools/Supplementary documentation needed?
Disposal Policy/ Procedure
Yes No
Other:

8. Data Sharing

8.1

KEY PRINCIPLE

Ensure that de-identified health data can be easily accessed by all relevant government stakeholders

GUIDANCE

Open data is a key principle of good governance and transparency and one to which many governments have already committed. Further, the more widely data are shared and available, the more likely it is to be used.

- Classify different types of data based on the potential risks of sharing the data to determine who can have access to it.
 Data can be limited to authorized internal users, open to a limited set of external users based on an application, or made publicly available.
- Ensure that data that can be made publicly available are freely available on the web, in whatever format is appropriate given available resources and audience.
- Clearly define application processes for stakeholders to get access to limited access data.
- Create data sharing agreement templates that must be signed prior to sharing limited access data sets.

Described in existing legal/policy/ operational documents? If yes, summarize.
Yes No Summary:
More research needed?
Yes No Summary:
Who is the decision-maker? (i.e. who determines what is included in each section/sub-section of the policy)
Decision-maker:
Consultant:
Include in policy?
Yes No
Level of detail needed:
Tools/Supplementary documentation needed?
Data Sharing Agreement Template
Yes No
Other:

8. Data Sharing

8.2

KEY PRINCIPLE

Reinforce international reporting requirements

GUIDANCE

- Countries that are signatories of the International Health Regulations must report any event to WHO that could potentially constitute a public health emergency of international concern within 24 hours (see WHO parameters)^{xii}.
- Aggregated mortality data (by age/sex/cause) must be reported to WHO annually.

Yes	○ No	Summary:
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9. Resource Requirements

9.1

KEY PRINCIPLE

Ensure sufficient human resources are available for the HIS to function effectively

GUIDANCE

Having adequate and appropriate personnel at all levels is critical for any functioning HIS.

- Define human resource requirements for a functioning HIS at all levels.
- Potentially define levels of human resource capacity in terms of qualifications/training that are needed for the HIS to function effectively.

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9. Resource Requirements

9.2

KEY PRINCIPLE

Ensure sufficient financial resources are available for the HIS to function effectively

GUIDANCE

HIS are often under-funded, particularly by national governments, making the systems vulnerable to donor priorities rather than building a sustainable system.

- The general rule of thumb is that 5-10 % of a program budget should be allocated to monitoring and evaluation activities^{xiii}. An HIS policy can specify how much should be allocated of both government and donor funds.
- Specify what level of the health system must budget for data collection tools and other information systems requirements.

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HIS budget	:		
Yes	○ No		
Other:			

9. Resource Requirements

9.3

KEY PRINCIPLE

Ensure sufficient ICT resources are available for the HIS to function effectively

GUIDANCE

As countries start to move away from paper-based systems, it is important that HIS policies address the ICT needs of a functional HIS.

- Specify the hardware and software requirements for a functioning HIS.
- Articulate who will provide ICT support for all aspects of the HIS and how they will coordinate with those running the HMIS, if they are not the same department.
- Consider the need for interoperability across ICT systems, within health and also with other sectors, e.g. civil registration, social security, the population register, etc.

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10. Data Ownership

10.1

KEY PRINCIPLE

For each type of data, articulate who ultimately "owns" the data

GUIDANCE

Determine who ultimately "owns" the data so any follow-up that needs to be conducted regarding the data can be done with the appropriate agency.

Some factors to consider when determining data ownership include: national policy, who collected the data, who funded data collection, dissemination etc. Other points to consider include:

- Can organizations/individuals be charged to use data and/or reports? If so, describe when and how much.
- Who determines whether health data can be published?
 Can data publication be blocked under any circumstance?

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10. Data Ownership

10.2

KEY PRINCIPLE

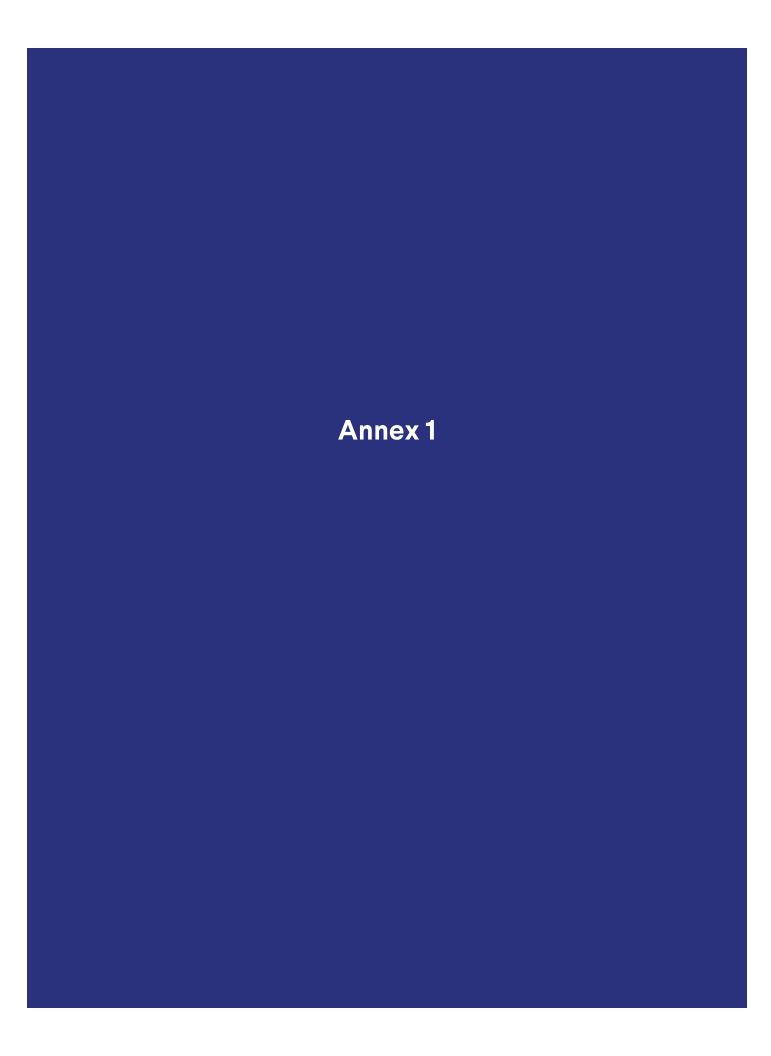
Consider the application of data sovereignty laws, as applicable to health information

GUIDANCE

Often, data sovereignty laws exist to determine ownership of government and/or private sector data at the national level. These should be researched carefully to ensure relevant application to health data.

- If there are already data sovereignty laws in place in the country, how do those apply to the HIS?
- If there are none, identify key stakeholders with whom to confer.

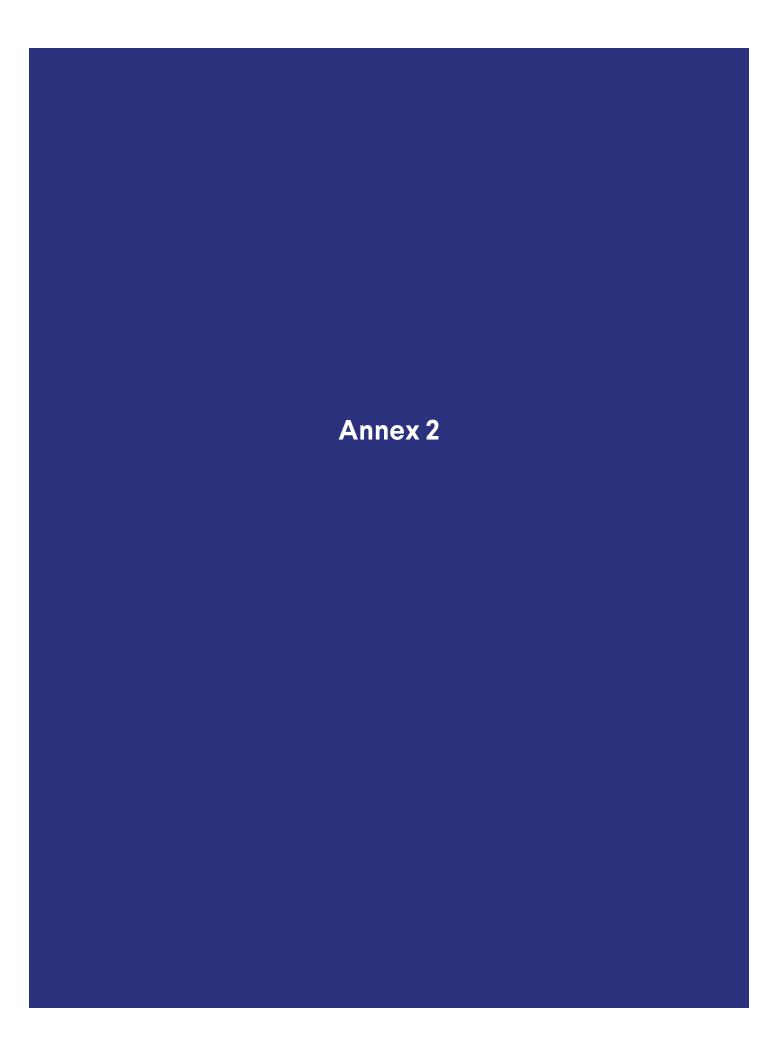
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Document Review

The following is a list of potential tools or existing documents that can be reviewed to inform the development of the HIS policy

Regional and/or global:
C Existing regional or international HIS policies
O International health reporting standards
Local:
O Previous HIS policy
Enterprise architecture
O Data Dictionary
O HIS steering committee TOR
O List and/or architecture of all of the information systems that are part of the HIS, illustrating how they are connected
Coordinated HIS Calendar
O Standard Operating Procedures for HIS data collection and reporting
List of all national indicators and definitions
National diagnosis coding system (i.e. ICD 10)
O Standard Operating Procedures for HIS data collection and reporting
O Data Quality Assessment (DQA) Guidelines
National HMIS guidelines/protocols
National Data Management Guidelines
National Data Analysis Guidelines (i.e. Data Demand and Use Guidelines)
National e-Health guidelines
MoH ICT Policy/Protocols
O Disposal Policy/Procedures
O Data Sharing Agreement Template
MoH Staffing Guidelines
O HIS budget



Sample needs assessment questionnaire

GENERAL - CAN BE ADAPTED TO SPECIFIC INTERVIEWEES

The needs assessment helps to inform the purpose and scope of the policy and is conducted during the development process (refer to step 7 in the Steps to develop a National Health Information System Policy).

me of Interviewer:
me of Interviewee:
stitution/Section:
TRODUCTION
ank you for agreeing to meet with us today. We are conducting a needs assessment to guide the generation
a policy for the Health Information System in The need for this policy was identified by
e will be taking notes during our discussion. However, your responses will be kept confidential and will not be shared
yond the small team working to develop the HIS policy guidelines.
JESTIONS
pordination and responsibility for data collection and reporting
What health-related information does your program collect?
a. Via which systems?
b. How is this data collection process coordinated with other MoH departments (i.e. M&E)?
What is your understanding of the role of the different departments of the MoH (i.e. M&E vs programs) in terms of routing
data collection and reporting?
Suggested probes: What do you think the relationship should be? To what extent do you think that these roles ar
clear to all stakeholders? How could we use these policy guidelines to clarify the roles?
What is your understanding of the role of each level of government in routine data collection and reporting?
Suggested probes: What do you think the relationship should be? To what extent do you think that these roles are
clear to all stakeholders? How could we use this policy to clarify the roles?

Suggested probes: What are some potential obstacles to the creation of an integrated system? Do you think an integrated system is a good idea? Why or why not? How could we use this policy to ensure one integrated reporting system?

4. To what extent do health development partners and the MoH work together to create one integrated

health information system?

- 5. How do you understand the relationship between the MoH and the ________ (equivalent of National Statistics Agency) in terms of (a) survey data, (b) routine data, and (c) vital statistics data (births and deaths)?
 Suggested probes: What do you think the relationship should be? To what extent do you think that these roles are clear to all stakeholders? What should the policy include about this relationship?
- 6. How do you understand reporting responsibilities are at every level in terms of routine data collection?

 Suggested probes: Are these responsibilities clear to all stakeholders? How might including this in the HIS policy improve the current system? Do you see a role for either incentives or penalties to improve reporting? If so, what?

Data quality

7. What do you consider to be critical gaps in data quality in the current HMIS routine data system (or in your own program's data system)?

Suggested probes: What are your recommendations for improving this? Who is/should be responsible for ensuring data quality? What should the policy guidelines include on data policy?

Data analysis and use

- 8. How are health data analysed and used at each level of the health system or "your organization"?

 Suggested probes: What about routine data? What about survey data? What about vital statistics data? Can you describe any standard analyses? Can you describe any feedback processes? How can we improve current practice using this policy?
- 9. Describe any existing guidance (instructions) for facilities and local government entities around the analysis and use of health data.

Suggested probes: If there is guidance, are there sufficient resources (human or financial) to follow it? What else would be needed for facilities and local government entities to systematically analyse health data?

Data confidentiality

10. What procedures are currently in place to protect the confidentiality of raw data, including personal health information? How could these procedures be improved?

Suggested probes: Specifically, how could they be improved in health facilities? At the district or regional level? At the central level? Will there need to be different procedures for computerized data, if so, what?

Data security and storage

11. What procedures are currently in place to ensure safe storage of raw data, including personal health information? How could these procedures be improved?

Suggested probes: Specifically, how could they be improved in health facilities? At the district or regional level? At the central level? Will there need to be different procedures for computerized data, if so, what?

12. What procedures are currently in place to protect and ensure safe storage of aggregate data? How could these procedures be improved?

Suggested probes: At the district or regional level? At central level? Are there limitations on who can access the data?

Data sharing

13. What health data from your organization is currently available to the general public?

Suggested probes: Which data sources from your organization produce data available to the general public: survey, routine, etc? In what form is the data available? [printed reports, reports on the internet, raw data files, aggregated data only, individual data, etc.] Is there any application required to get access to the data? How can we improve current practice with these policy guidelines?

14. What data from your organization are currently available to health stakeholders (development partners, other ministries, etc.)?

Suggested probes: Which data sources from your organization produce data available to the general public: survey, routine, etc? In what form are the data available? [printed reports, reports on the internet, raw data files, aggregated data only, individual data, etc.] Is there any application required to get access to the data? How can we improve current practice with these policy guidelines?

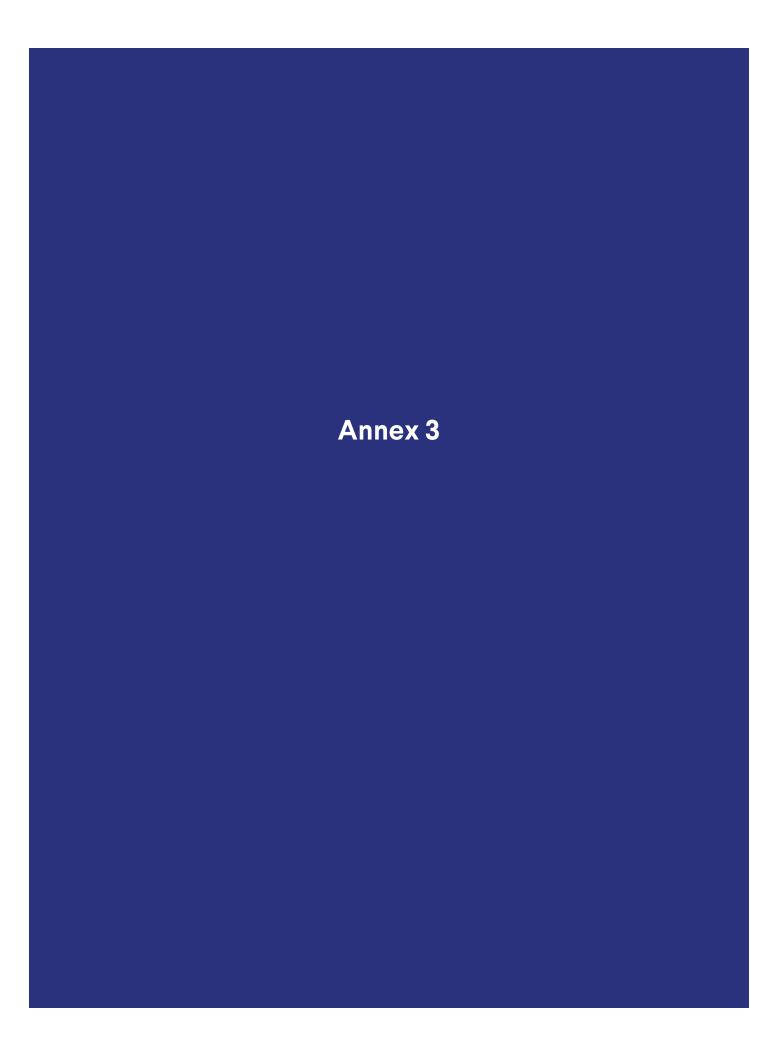
15. Are you able to access the data that you need? Please describe the data you have access to and any instances when you have not been able to get the data you need.

Resources

- **16.** What are the human resources that you consider critical to the health information infrastructure? Suggest probe: Do you think sufficient human resources are currently in place?
- 17. What are the financial resources that you consider critical to the health information infrastructure? Suggest probe: Do you think sufficient financial resources are currently in place?
- **18.** What are the ICT resources that you consider critical to the health information infrastructure? Suggest probe: Do you think sufficient ICT resources are currently in place?

Data ownership

19. When a health survey is conducted by the National Statistics Agency, in collaboration with MoH, (i.e. Demographic and Health Survey) who owns the data and how are the data shared between the two agencies?
Suggested probes: If the MoH would like to do further analysis of the survey after the initial report, are there procedures in place to allow them access to the data? What are these procedures?



Stakeholder Meeting Agenda

This agenda can be used for a meeting with stakeholders to obtain feedback on a draft version of the HIS Policy (refer to step 9 in the Steps to develop a National Health Information System Policy).

DAY 1

Time	Contents	Responsible Person
8:30-9.00	Registration	Admin staff
9:00-9:30	Opening session	MoH/lead authors
9:30-10:00	PRESENTATION: Objectives & Outputs of the meeting	Technical writer
10:00-10:30	PRESENTATION: Overview of the HIS Policy Guidelines	Technical writer
10:30-11:00	Tea Break	All
11:00-11:30	DISCUSSION: Overview of HIS policy	All
11:30-12:00	PRESENTATION: Introduction, HIS Structure & Coordination	Technical writer
12:00-1:00	GROUP WORK: Introduction, HIS Structure & Coordination	All
1:00-2:00	Lunch break	All
2:00-2:30	GROUP WORK CONTINUED: Introduction, HIS Structure & Coordination	All
2:30-4:00	GROUP FEEDBACK: Introduction, HIS Structure & Coordination	Teams
4:00-4:10	CLOSING: Day 1	All

DAY 2

Time	Contents	Responsible Person
8:30-9.00	Registration & re-cap of Day 1	Admin staff/facilitator
9:00-9:30	PRESENTATION: M&E structure and functions	Technical writer
9:30-9:45	PRESENTATION: Human and Financial Resources	Technical writer
9:45-10:30	GROUP WORK: M&E structure and functions + Human and Financial Resources	Teams
10:30-11:00	Tea Break	All
11:00-11:45	GROUP WORK CONTINUED: M&E structure and functions + Human and Financial Resources	All
11:45-12:45	GROUP FEEDBACK: M&E structure and functions + Human and Financial Resources	Teams
12:45-1:00	PRESENTATION: Data collection and quality	Technical writer
1:00-2:00	Lunch break	All
2:00-2:30	PRESENTATION: Data analysis, dissemination & use	Technical writer
2:30-3:30	GROUP WORK: Data collection and quality + Data analysis, dissemination and use	All
3:30-4:30	GROUP FEEDBACK: Data collection and quality + Data analysis, dissemination and use	Teams
4:30-4:40	CLOSING: Day 2	All

DAY 3

Time	Contents	Responsible Person
8:30-9.00	Registration & re-cap of Day 2	Admin staff/facilitator
9:00-9:30	GROUP FEEDBACK CONTINUED: Data collection and quality + Data analysis, dissemination and use	Teams
9:30-10:00	PRESENTATION: Data confidentiality & security + ownership & sharing	Technical writer
10:00-10:30	Tea Break	All
10:30-12:00	GROUP WORK: Data confidentiality & security + ownership & sharing	All
12:00-1:00	GROUP FEEDBACK: Data confidentiality & security + ownership & sharing	Teams
1:00-2:00	Lunch break	All
2:00-3:00	PRESENTATION: Next steps for the HIS Policy Guidelines	MoH/lead authors
3:00-4:00	CLOSING: Day 3	All
2:00-2:30	GROUP WORK CONTINUED: Introduction, HIS Structure & Coordination	All
2:30-4:00	GROUP FEEDBACK: Introduction, HIS Structure & Coordination	Teams
4:00-4:10	CLOSING: Day 1	All

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