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A Primer on Parsimonious Global Health Information Systems for Low- and Middle-Income Countries

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David A. Butz, *University of Michigan Ross School of Business*
Senior Research Fellow, *William Davidson Institute at the University of Michigan*

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Contents

Abbreviations and Acronyms

AIDS	Acquired Immunodeficiency Syndrome		**HIE**	Health Information Exchange
AEFI	Adverse Events Following Immunization		**HIS**	Health Information System(s)
ADI	Addis Declaration on Immunization		**HL7**	Health Level Seven International
API	Active Pharmaceutical Ingredient(s)		**HMIS**	Health Management Information System(s)
ADT	Admission-Discharge-Transfer System		**HBR**	Home-Based (Paper) Records
API	Application Programming Interface		**HOPD**	Hospital Outpatient Department
BID	Better Immunization Data (Initiative)		**HIV**	Human Immunodeficiency Virus
BMGF	Bill & Melinda Gates Foundation		**HRIS**	Human Resource Information System(s)
CMS	Centers for Medicare & Medicaid Services (United States)		**ID4D**	Identification for Development
CCMDD	Central Chronic Medicine Dispensing and Distribution (South Africa)		**IIS**	Immunization Information System(s)
			ICT	Information and Communications Technology
CXR	Chest Radiography/X-Ray		**IHME**	Institute for Health Metrics and Evaluation
CRVS	Civil Registration and Vital Statistics		**IP**	Intellectual Property
CCLF	Claim and Claim Lines Feed (for Administrative Data)		**ICD**	International Classification of Diseases (ICD-10 refers to10th Revision)
CCS	Clinical Classification Software (Healthcare Cost and Utilization Project)		**ILO**	International Labour Organization
			INN	International Nonproprietary Names (Expert Group)
CDA	Clinical Document Architecture		**ISCO**	International Standard Classification of Occupations
CHW	Community Health Worker			
CPOE	Computerized Provider Order Entry		**IoT**	Internet of Things
DOB	Date of Birth		**ISO**	International Organization for Standardization
DHS	Demographic and Health Surveys			
DCXR	Digital Chest Radiography/X-Ray		**LHR**	Legal Health Record
DICOM	Digital Imaging and Communications in Medicine		**LCR**	Local Civil Registrar
			LMIS	Logistics Management Information System(s)
DHIS2	District Health Information Software, Version 2		**LOINC**	Logical Observation Identifiers Names and Codes
EVM	Effective Vaccine Management		**MMIS**	Materials Management Information System
EHR	Electronic Health Record(s)			
EMR	Electronic Medical Record(s)		**MDG**	Millennium Development Goal(s)
ERP	Enterprise Resource Planning System(s)		**MA4Health**	Measurement and Accountability for Results in Health
EML	Essential Medicines List(s)			
EPI	Expanded Program on Immunization		**MFL**	Master Facility List(s)
GIS	Geographic Information System(s)		**MPI**	Master Patient Index
GPS	Global Positioning System		**MCP**	Maternal and Child Protection (Card)
GAVI	Global Alliance of Vaccines and Immunizations		**MGI**	McKinsey Global Institute
GFATM	Global Fund to Fight AIDS, Tuberculosis & Malaria		**M&E**	Monitoring and Evaluation
GOe	Global Observatory for eHealth (WHO)		**MoH**	Ministry of Health
HCUP	Healthcare Cost and Utilization Project (US Government)			

MICS	Multiple Indicator Cluster Surveys (United Nations Children's Fund)
NCD	Non-Communicable Disease
NCHS	National Center for Health Statistics (United States)
NDC	National Drug Codes
cMYP	National Multi-Year Plans (for Immunization)
NPI	National Provider Identifier
PAN	Permanent Account Number (India)
PACS	Picture Archiving and Communication Systems for Filmless Imaging
PRISM	Performance of Routine Information Systems Management Tool (USAID)
PUP	Pick Up Point
PPE	Property, Plant and Equipment
PO	Purchase Order
RFID	Radio Frequency Identification
RIS	Radiology Information System(s)
RHIS	Routine Health Information System(s)
SDP	Service Delivery Point
SQL	Structured Query Language

SBA	Skilled Birth Attendant
SDG	Sustainable Development Goal(s)
STG	Standard Treatment Guideline(s)
SAGE	Strategic Advisory Group of Experts (on Immunization)
SLMTA	Strengthening Laboratory Management Toward Accreditation
SNOMED	Systematized Nomenclature of Medicine
TB	Tuberculosis
UNAIDS	Joint United Nations Program on HIV/AIDS
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
UHC	Universal Health Coverage
UI	User Interface
VAERS	Vaccine Adverse Event Reporting System
VQC	Vaccine Qualified Clinic
VAN	Visibility Analytics Network (for Health Commodities Supply Chains)
WIFM	What's In It For Me? (Test of Incentive Compatibility)'

1. The Urgency Behind Integrated Health Information Systems

The dearth of data that has historically enfeebled efforts to advance global health in low- and middle-income countries (LMICs) is very recently turning in some settings into a data deluge, even if many of these data are presently hidden in plain view. These data are collected, but they are still often written by hand only as paper records, for example, or digitized but unreliable or going unused, underused, or unconnected. Much of the deluge is also vexingly uneven across different components of these health information systems (HIS).

This study is the first to describe all in one place the individual data assets and systems that together comprise the working foundations of health information systems (HIS). The focus here is on the specific data fields and elements that comprise these various assets, how these data track clinical and operational workflow, and how the distinct systems connect, one with another. The study targets a non-technical audience of end users to make a case for ranking HIS as the global health community's top investment priority. The study is long but has no prerequisites, moves quickly, and aims to be comprehensive and up-to-date. The person who reads it can join comfortably and confidently in discussions of this topic even if they have no formal background in HIS. Nearly all footnotes take readers to free, easily accessed, non-technical resources. Indeed, together these footnotes can proxy for a full intermediate course syllabus for non-technical readers interested in more than just a primer. (All footnotes have been accessed in December 2018 using a conventional Internet search engine.)

The twenty or so individual HIS components covered here include patient electronic medical records (EMR), civil registration and vital statistics (CRVS), health management information systems (HMIS) and other public health data (e.g., household surveys), logistics management information systems (LMIS), and human resource information systems (HRIS). Each system is important on its own and can join and integrate with other HIS in ways that offer nearly unbounded value.

These systems are the linchpin for all else that global health communities aim to achieve. Prioritizing HIS is a necessary condition for making significant headway toward the very ambitious goals set by the global health community, some coming due as early as 2020.[1] Functional HIS does not guarantee progress, but these HIS will quickly and surely catalyze profound changes in service of these goals.

An important conclusion from this primer is that the time is ripe to build and fully deploy integrated, digital HIS to advance the health of populations in ways that were implausible even five years ago. Throughout the global health community there is remarkable optimism, urgency, and resolve, leading to much recent progress. Still, the work ahead is daunting and extends far beyond just linking together HIS already in place. Moreover, these HIS will be joined with other waves of digital innovations that have originated and advanced entirely outside of health care (and outside the public sector), so that in LMICs the waves envelop HIS from without rather than drive change from within.

Consider, as the first of two examples of such outside forces from this study, the "The Internet of Things" (IoT). Laboratory and imaging equipment (e.g., for blood tests and ultrasounds) is shrinking in size and up front cost. The equipment is becoming mobile, accessible to more patients, connected through the Internet, and better utilized, with fuller amortization (i.e., the spreading of fixed costs) driving cost per patient much lower. Diagnostic results and images, more often available at the point of care, are improved. Equipment is more standardized and connected across manufacturers, and the results are more reliably archived and thereafter accessible for many more different ends (e.g., patient care, e-prescribing, disease surveillance, and clinical registries). Temperature-sensitive "cold chain" storage equipment can be monitored remotely and in real time. **Section 3** provides details.

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1   Family Planning 2020. http://www.familyplanning2020.org/.

As a second example, innovations in mobile payments and more generally "fintech" (technologies that specifically support or enable banking and financial services) promise to revolutionize the commercial underpinnings of health care, even as they enable massive flows of patient- and encounter-level data to populate various HIS. **Section 6** discusses fintech further.

These IoT and fintech advances, along with other innovations, may seem distinct from HIS and even from one another. Over time, though, it is as likely as not that in hindsight they will be viewed as converging and eventually inseparable displays of similar underlying technological and market forces.

The unfolding deluge is not quantifiable, say, in millions of terabytes of data. Innovations are not at all "big data" driven, and thinking strictly in these terms is unhelpful. Indeed, progress as envisioned here (and that many LMIC experts also recommend) likely requires a disciplined, parsimonious approach initially with small numbers of carefully chosen, highly structured data fields. For progress to proceed as quickly as it must, the volume and complexity of the data must be kept manageable—indeed "lean." A better metric for this data deluge may therefore be "unique interfaces and nodes," many latent to start, where end users can log on to access actionable information to guide their decisions. Progress can be measured by asking, "Who is using these data?" The number is small to start, with a few simple, inflexible user interfaces (UI) and application program interfaces (APIs). But end users and UIs grow in number quickly as new information systems come online; as they access more integrated systems more often; as they connect routinely with other end users; as they construct new metrics, visualizations, and functionality (e.g., to download, drill down, or access new data). The deluge comes from exponential growth in end users, use cases, UIs and information streams.

This expansion is growing and extending outward at impressive rates, but the changes are nascent and vulnerable. The global health community must think deliberately through all of the end user demands that will be made on these systems. This community must deliberately and strategically address gaping holes, widespread disconnects, and unnecessary duplication in (and proliferation of) HIS infrastructure; even as it struggles with scaling the initiatives and dramatically broadening their scope. These include patient identification and EMRs first and foremost, along with all of the closely related and integrated information systems, such as CRVS. Overall, HIS design is critically important and so far largely missing. There are already considerable efforts under way to merge and integrate some of the proliferation of separate HIS components, each with its own compelling use case, and this marks a huge step forward. But there are as yet few widely shared forums where HIS designers are deliberating either core data elements or the optimal way to gather, store, secure, access, analyze, or broadly exchange and distribute these elements once they have been documented.

The next section provides a short HIS timeline from 2000 to the present. Individual HIS are outlined one by one, beginning with patient and care provider information systems in **Sections 3** and **4**, public and population health information systems in **Section 5**, financial and administrative information systems in **Section 6**, supply chain information systems in **Section 7**, and external information in **Section 8**. These outlines include simple and non-technical descriptions, a sense of the progress that has been made to date in LMICs, and the near-term prospects going forward. **Section 8** speaks to the many ways of linking, integrating, and thereafter exchanging information from many separate silos, so that data collected for one purpose can be leveraged for many others ("Collect once, use many").

This study lays out a huge array of data assets and intellectual property (IP), but its core message is categorically optimistic: 1) the information systems are individually tractable; 2) successful models have already been built; 3) all have common building blocks and overlap to make the journey clear and doable even with limited financial and workforce resources; 4) barriers to success are fast falling away; 5) the payoffs are massive, beyond even our imaginations; and 6) the talents and passions of those working in this field are nearly limitless. The concluding section asserts that by the early 2020s the remaining hurdles will revolve more around ownership, stewardship and governance; designing and executing workable HIS business models; issues of access and data security; agreeing upon and adhering to core data principles that are intuitive and compelling but neither

obvious beforehand nor always individually rational after the fact (e.g., due to externalities and free rider problems). These are hurdles surmounted mostly by common understanding, a consensus around first principles of data stewardship and governance, and political will and resolve. It will help enormously if advocates for these HIS investments can describe clearly and persuasively how they can be systematically and comprehensively successful. This study contributes to that narrative.

2. A Short, Selective Post-2000 Literature Review of LMIC HIS Initiatives

Interest in HIS dates back for decades but picked up markedly after 2000. Along the way, various key publications helped to catalyze major information systems investments.[2,3,4,5,6,7,8,9] The United Nations' health-related Millennium Development Goals (MDGs) also focused significant attention, not only because HIS is necessary to measure progress toward these goals but also because improved information systems are critical to strengthening health systems and moving these goals forward.[10,11]

Although the importance of HIS has been well known for decades, with significant investments in such specific initiatives as civil registration and vital statistics (CRVS), the "moon shot" aspects of HIS investments in LMIC date back no more than ten years. Indeed, the scale and scope of quite recent efforts to build out integrated health systems are stunning and worth outlining.

Beginning from a strong and principled foundation built up over many years,[12] an important inflection point among recent efforts to frame broad HIS strategies and national frameworks came in 2010 with the publishing of a call for action on health data from eight global health agencies: the Bill & Melinda Gates Foundation, GAVI, the Global Fund to Fight Aides, Tuberculosis & Malaria (GFATM), UNAIDS, UNFPA, UNICEF, the World Bank (WB), and the World Health Organization (WHO). This call highlighted the urgency of the current situation and identified specific required actions in developing countries around main data sources, including household surveys, birth and death registration, census, health facility reporting systems, and administrative data.[13] This call has catalyzed formal and rigorous LMIC strategies, rigorous and ambitious national plans, and significant new

2   Lippeveld T, Sauerborn R, Bodart C. *Design and Implementation of Health Information Systems.* Geneva, Switzerland: World Health Organization; 2000.

3   Lippeveld T. Routine health information systems: the glue of a unified health system. Keynote address at the Workshop on Issues and Innovation in Routine Health Information in Developing Countries, Potomac, March 14–16. Washington, DC: JSI; 2001.

4   Evans T, Stansfield S. Health information in the new millennium: a gathering storm? Bulletin of the World Health Organization 2003;81:856.

5   AbouZahr C, Boerma T. Health information systems: the foundations of public health. Bull World Health Organ 2005; 83: 578–83.

6   Bchir A, Bhutta Z, Binka F, et al. Better health statistics are possible. Lancet 2006; 367: 190–93.

7   World Health Assembly Resolution 60.27: Strengthening Health Information Systems, World Health Organization, Geneva, 2007.

8   Aqil A, Lippeveld T, Hozumi D. PRISM framework: a paradigm shift for designing, strengthening and evaluating routine health information systems. *Health Policy and Planning.* 2009;24(3):217-228. doi:10.1093/heapol/czp010.

9   World Health Organization. Framework and standard for country health information system. 2008. Available from: http://www.who.int/healthmetrics/documents/hmn_framework200803.pdf.

10   Carraro L, Khan S, Hunt S, Rawle G, Robinson M, Antoninis M, et al. Monitoring the millennium development goals: current weaknesses and possible improvements. Glasgow: Oxford Policy Management, Department for International Development; 2003.

11   Godlee F, Pakenham-Walsh N, Mcayiyana D, Cohen B, Packet A. Can we achieve health information for all by 2015? Lancet 2004;364:295-300. http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(04)16681-6/abstract.

12   Fundamental Principles of Official Statistics. United Nations Economic Commission for Europe (UNECE). 1992. Periodic updates, including 2009. Also see Bruengger H. How Should a Modern National System of Official Statistics Look? UNECA. January 2008.

13   Chan M, Kazatchkine M, Lob-Levyt J, et al. Meeting the demand for results and accountability: a call for action on health data from eight global health agencies. PLoS Med. 7(1) e1000223.

investments in HIS. The underlying call has been reinforced repeatedly and in many different ways, including a June 2015 Summit on Measurement and Accountability for Results in Health (MA4Health) and a renewed five-point call for action.[14]

At roughly the same time, the Geneva-based International Organization for Standardization (ISO) began work on overarching projects specifically designed for LMICs, culminating in two important reports. The first, published in 2012, informs the architectural structuring of HIS, reviews countries' experiences in the construction of national eHealth architectures, and introduces a methodology for strategic HIS development.[15] The second report, published in late 2014, offers best practice guidelines in LMIC for the implementation and use of information and communications technology (ICT).[16]

In 2013, the United Nations General Assembly established a 30-member Open Working Group that culminated in the 2030 Agenda for Sustainable Development, which was adopted by all United Nations Member States in 2015. ICT has figured prominently in setting and pursuing these goals.[17]

Recent HIS research has also led to organized initiatives, such as the United States Agency for International Development's (USAID's) MEASURE Evaluation Project,[18] the Health Data Collaborative,[19] the Institute for Health Metrics and Evaluation (IHME) at the University of Washington,[20] and multi-faceted internal efforts by leading global health actors such as the World Health Organization (WHO),[21,22] to name a few. The expected payoffs from these investments are high and diverse, for example covering overarching statistical frameworks,[23] civil registration and vital statistics,[24] and data standards for Routine Health Information Systems (RHIS).[25]

There is a vast HIS literature spanning hundreds of topics and thousands of documents. Several less technical sources merit mentioning. The WHO's 2017 Data Quality Review Toolkit[26] covers some of the same ground as this primer and serves as an excellent companion piece. The United States Agency for International Development's (USAID) MEASURE Evaluation project has resources that cover many different aspects of countries' HIS. These include toolkits; a Performance of Routine Information Systems Management (PRISM)[27] tool providing structured methods to assess the quality of data and use of information in routine health information systems; and even a full curriculum spanning many of the most critical aspects of building and leveraging RHIS.

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14   Health Measurement and Accountability Post-2015: Five-Point Call to Action. World Bank Group, USAID, and World Health Organization. June 2015.

15   Health informatics—Capacity-based eHealth architecture roadmap—Part 1: Overview of national eHealth initiatives. International Organization for Standardization. ISO/TR 14639-1:2012. August 2012.

16   Health informatics—Capacity-based eHealth architecture roadmap—Part 2: Architectural components and maturity model. International Organization for Standardization. ISO/TR 14639-2:2014. October 2014.

17   Wu J, Guo S, Huang H, Liu W, and Xiang Y. Information and communications technologies for sustainable development goals: State-of-the-art, needs and perspectives. IEEE Communications Surveys & Tutorials, vol. 20, no. 3, pp. 2389–2406, Third Qu. 2018.

18   https://www.measureevaluation.org/

19   http://www.healthdatacollaborative.org/

20   http://www.healthdata.org/

21   World Bank Group. Global Civil Registration ad Vital Statistics. Scaling up Investment Plan 2015–2024. 2014.

22   http://www.who.int/features/2016/health-data-collaborative/en/

23   Principles and Recommendations for a Vital Statistics System. Statistics Division Statistical Papers, Series M No. 19/Rev.3. Department of Economic and Social Affairs. United Nations. New York, 2014.

24   Civil registration: why counting births and deaths is important. Fact Sheet 324. World Health Organization. May 2014.

25   Guidelines for Data Management Standards in Routine Health Information Systems. USAID. February 2015. Accessed online October 2016: http://pdf.usaid.gov/pdf_docs/PA00KB8N.pdf.

26   https://www.who.int/healthinfo/tools_data_analysis/dqr_modules/en/

27   https://www.measureevaluation.org/resources/publications/ms-11-46-d

Recent publications provide comprehensive histories of LMIC HIS.[28,29,30] These histories identify other significant publications and developments, including:

- Bellagio State on eHealth Evidence (September 2011)[31]
- National eHealth Strategy Toolkit (WHO and International Telecommunication Union, 2011)[32]
- Twelve Common Applications Framework (WHO and others; August 2013)[33]
- WHO Guide to Conducting Research and Assessment (December 2016) [34]
- WHO Classification of Digital Health Interventions v1.0 (December 2017)[35]

Interested readers can turn to these histories for further details.

3. Individual Patient and Care Provider Information

The building blocks of HIS involve simple and basic but up-to-date, comprehensive, accurate and complete data on individual patients and their health care providers. This section elaborates.

A. Digital Identification

The first step in describing HIS is to make a practical determination whether LMIC governments and other institutions can digitally identify all patients and providers individually, systematically, and reliably. Without exception, each person living within a country should have a single, unique number (or mix of numbers and letters) used in all information systems as a means to connect. Every person should be counted. The threshold is that every identity must be unique to an individual, permanent, portable, and private. Until recently, few LMIC governments could demonstrate this competency, and the World Bank estimates that at least 1½ billion people worldwide remain without an identity.[36] If patients and providers cannot be identified, then most HIS components in this primer are foreclosed.

Practically, it is also important to remediate fragmented data that muddle identities. In many LMICs, individuals have separate, unlinked identifications via birth certificate, paying taxes, residential address, business ownership, licensures (e.g., to operate a motor vehicle), government programs, banking, and so forth. They may also be identifiable along some important dimensions but not others. Around the world four billion people, for example, lack a reliable address.[37]

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28   Labrique A, Vasudevan L, Weiss W, Wilson K. Establishing standards to evaluate the impact of integrating digital health into health systems. Glob Health Sci Pract. 2018;6(suppl 1):S5-S17. https://doi.org/10.9745/GHSP-D-18-00230.

29   Marcolino MS, Oliveira JAQ, D'Agostino M, Ribeiro AL, Alkmim MBM, Novillo-Ortiz D. The Impact of mHealth Interventions: Systematic Review of Systematic Reviews. JMIR Mhealth Uhealth. 2018 Jan 17;6(1):e23. doi: 10.2196/mhealth.8873.

30   Iribarren SJ, Cato K, Falzon L, Stone PW. What is the economic evidence for mHealth? A systematic review of economic evaluations of mHealth solutions. PLoS One. 2017;12(2):e0170581

31   Fraser H, Bailey C, Sinha C, Mehl G, Labrique AB. Call to Action on Global eHealth Evaluation. Consensus Statement of the WHO Global eHealth Evaluation Meeting, Bellagio, Italy. Bellagio, Italy: Bellagio eHealth Evaluation Group. 2011.

32   World Health Organization (WHO), International Telecommunication Union (ITU). National eHealth Strategy Toolkit. Geneva: WHO and ITU; 2012.

33   Labrique AB, Vasudevan L, Kochi E, Fabricant R, Mehl G. mHealth innovations as health system strengthening tools: 12 common applications and a visual framework. Glob Health Sci Pract. 2013; 1(2):160–171.

34   World Health Organization (WHO), Johns Hopkins University Global mHealth Initiative, United Nations Foundation. Monitoring and Evaluating Digital Health Interventions: A Practical Guide to Conducting Research and Assessment. Geneva: WHO. 2016.

35   World Health Organization (WHO). Classification of Digital Health Interventions v1.0: A Shared Language to Describe the Uses of Digital Technology for Health. Geneva: WHO; 2018.

36   Estimates by the World Bank ID4D Dataset, as of February 2016.

37   Plummer R. Giving everyone in the world an address. BBC News. 30 April 2015.

Although this primer's focus is on health, the need for identity extends far beyond. Formal identification is a precursor to participation in government programs and to individual engagement in modern society. Identification is consistently represented as a human right, a prerequisite for basic services, a gateway to economic opportunity, a key support for gender equality, and an enabler of global development.[38] Simply put, the urgent and inexorable forces driving demand for identification are intrinsic and multi-dimensional, and universal digital identification has long been a foundational goal in global health and development. It is embedded into its own SDG (16.9): "By 2030, provide legal identity for all, including birth registration." And it is needed to advance many other SDGs.

It is best to create unique national identification at birth. This timing enables a child to have a birth certificate, established family ties, and going forward a complete record of major life events (e.g., marriage and death). Regardless of age, governments have had longstanding needs to identify large populations (e.g., to issue passports, for military conscription, or to pay civil and military pensions), and various high-income countries (e.g., the United States following passage of the Social Security Act and the introduction of British National Insurance Numbers, both in the 1930s) have full national identification programs dating back to before 1960.[39,40,41] Roughly 100 countries around the world have mandatory national identification cards today, most conforming to international standards set out by ISO/IEC 7810:2003.[42] In short, this is a basic competency that countries must establish.

Whether identification comes at birth or some time later, there has been a great mobilization of resources and spectacular progress in just the past several years. In 2014, the World Bank established Identification for Development (ID4D) specifically to advance identification.[43] The ID2020 Alliance, with its government, NGO, and private sector partners, held its inaugural conference in May 2016.[44] In June 2017, Microsoft and Accenture announced a breakthrough in digital identification using block chain technology.[45] The trade association that represents the interests of mobile telephony operators worldwide, GSMA, has its Mobile Connect[46] and M4D Digital Identity[47] program to leverage significant member infrastructure, resources, and technical expertise to support mobile birth registration in many LMICs.[48] Many others in the private sector are fully engaged in identification through mobile banking and payments, as well as fintech (See **Section 6.D**).

Digital identification combined with increasingly ubiquitous mobile telephony make it possible to track patients, providers, and their activities everywhere. China is in front building out this universal connectivity. India, Bangladesh, Ethiopia, Indonesia, Kenya, Malawi, Nigeria, Tanzania, Uganda, Zambia, Thailand, Peru, Pakistan

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38   http://id2020.org/digital-identity-1/

39   Historical Background And Development Of Social Security. United States Social Security Administration. https://www.ssa.gov/history/briefhistory3.html.

40   Documenting Individual Identity: The Development of State Practices in the Modern World. J Caplan and J Torpey, Editors. Princeton University Press. 2001.

41   Iriye A and Saunier PY, eds. The Palgrave Dictionary of Transnational History. Basingstoke England: Palgrave Macmillan, 2009. xli + 1226 pp. EUR 165.00 (cloth), ISBN 978-1-4039-9295-6. Jan Palmowski. Oxford Dictionary of Contemporary World History. New York: Oxford University Press, 2008. 768 pp. ISBN 978-0-19-929567-8.

42   ISO/IEC 7810:2003 Preview. Identification cards—Physical characteristics. International Organization for Standardization. https://www.iso.org/standard/31432.html.

43   http://www.worldbank.org/en/programs/id4d

44   http://id2020.org/

45   Accenture and Microsoft plan digital IDs for millions of refugees. BBC. June 20, 2017. Accessed online August 2017: http://www.bbc.com/news/technology-40341511.

46   https://www.gsma.com/identity/

47   https://www.gsma.com/mobilefordevelopment/

48   Innovations in Mobile Birth Registration: Insights from Tigo Tanzania and Telenor Pakistan. GSMA. Jan 12, 2017.

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and other LMICs have also launched national programs.[49,50,51] Rural settings pose great challenges, but a significant majority of people in these areas live in modestly large and accessible population agglomerations with, for example, at least 20,000 people and population densities of at least 150–200/km2. These agglomerations are more than sufficient to amortize the cost of cell towers and other infrastructure; and indeed mobile phone operators have much work in progress and ambitious plans in these settings to extend their networks—and in short order.[52]

The India Stack may be the best recent example of digital identification. It represents a stunning leap forward. The foundation of India Stack is Aadhaar,[53] which provides a free, unique 12-digit number for every resident of India. To enroll in Aadhaar, each India resident provides their name, date of birth (DOB), age, gender, address, and (optionally) mobile phone number and email, along with biometric information (facial photo, ten fingerprints, and two iris scans). The 12-digit number is then used online as reliable proof of identity and proof of address.

Like many other innovations in this area, Aadhaar is new. (It succeeds India's Permanent Account Number, PAN, as an identifier.[54] PAN is a unique lifetime code issued by the Indian Income Tax Department and has been mandatory for most financial transactions.) The logo and brand name were launched in April 2010. Online verification began in February 2012 and by 2017 more than 99% of Indians aged 18 and older are enrolled. Using Aadhaar, the India Stack, and their smartphones, India residents can use e-signature protocols to transact online, open online bank accounts, utilize digital document lockers to replace paper, make mobile payments, apply for credit, send/receive invoices, enjoy encrypted data-sharing, and tap into other digital financial services in a comprehensive and ultra low-cost financial ecosystem. Private parties can use the India Stack as a platform to build their businesses. Governments can target taxes more effectively; and they can more directly, cheaply, and reliably subsidize fuel, food, health care, and other goods and services for those most in need.

Aadhaar has been beset by various controversies[55] but continues to advance at impressive rates.

B. Patient and Provider De-Identification

It is important to understand that many of the HIS components described in this primer also require systematically reliable methods to *de*-identify patient and provider data, so that before they are shared these data are stripped of elements that could be used to identify individuals. Identifiers that must be stripped include but are not limited to: names, small geographic subdivisions, most dates (date of birth and death, admission and discharge dates, and for example, all ages over 89), telephone numbers, email addresses, medical record numbers, account numbers, and license numbers.[56]

De-identification protects patient and provider privacy. For example, the data deposited in a country's birth registry and immunization information system (IIS) could be aggregated up in ways that allow precise forecasts of vaccine demand facility-by-facility several years in advance. Such forecasts would be invaluable for logistics

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49   http://www.worldbank.org/en/programs/id4d

50   CL Anderson, P Biscaye, S Coney, E Ho, B Hutchinson, M Neidhardt, and T Reynolds. Review of National Identity Programs. International Telecommunications Union ITU-T Focus Group Digital Financial Services. Accessed Sept 2017: https://www.itu.int/en/ITU-T/focusgroups/dfs/Documents/09_2016/Review%20of%20National%20Identity%20Programs.pdf

51   List of national identity card policies by country. Wikipedia. Accessed Sept 2017: https://en.wikipedia.org/wiki/List_of_national_identity_card_policies_by_country

52   Meloán M and Iacopino P. Scaling digital health in developing markets: Opportunities and recommendations for mobile operators and other stakeholders. GSMA Intelligence. June 30, 2017. https://www.gsmaintelligence.com/research/2017/06/scaling-digital-health-in-developing-markets/628/.

53   https://en.wikipedia.org/wiki/Aadhaar#cite_note-WhatIs.3F-12

54   Permanent Account Number. Wikipedia. https://en.wikipedia.org/wiki/Permanent_account_number.

55   Mundy S. Indian companies tussle with courts over prized citizen data. Financial Times. Oct 31, 2018.

56   A Visual Guide to Practical Data De-Identification. The Future of Privacy Forum.

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and procurement purposes, as well as community outreach and education programs that aim to increase immunization rates. But those who are making the forecasts, designing outreach programs, or performing various other tasks do not need to (and truly must not) know patients' identities to conduct their work. Hence, records must be de-identified before they are shared.

There are larger, complex questions around access to patient and provider records even when they have been rigorously de-identified, but these issues are beyond this primer's scope. A simple Internet search reveals dozens of useful manuscripts, some specifically targeting non-technical audiences.[57]

The import of sweeping innovations in digital identification and de-identification extend beyond the sheer volume of health care data that they enable or the greatly enhanced interoperability (i.e., the capacity to connect data assets) and health information exchange. Just as important is access to detail. For the first time, HIS can have systematic, end-to-end visibility to individual patients, providers, encounters, and the specific details of every encounter. And for the first time, HIS can permanently string together these specific details contemporaneously or longitudinally in countless ways. A medication ordered by Prescriber X for Patient α during a visit on June 8, 2018 (and captured through its barcode) can be linked to α's other medications ordered before or afterward, or to X's overall prescribing patterns. Medication orders can be aggregated by prescriber, facility, precinct, or time period to analyze prescribing patterns, for example. These aggregates can help to improve forecasts for future procurement and logistics management. The actionable insights are nearly endless.

The innovations are transformative for all components of HIS discussed in this primer. Without both digital identification and de-identification, clinical delivery systems cannot be patient-centered, since patients are invisible. Rigorous birth, death, and immunization registries are foreclosed. LMIC health commodities supply chains are stuck with the methods used by, say, Nordstrom's or Macy's to order winter coats in 1975; because, if visibility extends only as far as in-store stock on hand, then of necessity logistics management focuses only on stockouts and expiry.

As such, it is key to make explicit the maintained assumption throughout this primer that the HIS described here are built on a foundation **soon** made possible by broad LMIC digital identification and de-identification. To believe that the HIS described in this primer are practicable, readers must be persuaded that history is likely to look back on the period 2015–2025 as the window in which digital identification became widespread, and shortly thereafter ubiquitous. This is the aim of a consensus of the global health community and it is realistic based upon all evidence to date.

C. The Problem-Oriented Electronic Medical Record (EMR)

The importance and centrality of electronic medical records (EMR) cannot be exaggerated. By many expert accounts, the first and most important principle of HIS is that everyone have a simple, complete longitudinal EMR around which all other information systems are organized. EMRs serve both as the nexus of all other HIS and the basic unit of account, meaning that they organize data patient-by-patient and are typically updated and populated with each new patient encounter.

As important as EMRs are in principle, they have been difficult to implement even in high-income countries with universal digital identification, ample resources and extensive software and HIS infrastructure. Until recently, EMRs have been beyond the reach of LMICs that cannot yet even identify individual patients. Even though technology is advancing rapidly, as a practical matter the aim of having universal, functional EMRs is surely still years away in most LMICs. Even as EMRs advance, they are likely to be incomplete or only locally or regionally available. Put simply, efforts to integrate national HIS around individual EMRs will take time.

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57   Polonetsky J, Tene O, and Finch K. Shades of Gray: Seeing the Full Spectrum of Practical Data De-identification. 56 Santa Clara L. Rev. 593 (2016).

While progress on other fronts cannot wait for EMRs to be built (most LMICs do not have requisite infrastructure but the technology and resources are within reach), it is the maintained assumption of this primer that from the outset the basic architecture of all HIS must recognize that the single most important objective is to put ready and reliable access to actionable information into the hands of patients and frontline workers. Other goals matter, but every other goal is subordinate. This defines "patient-centered," and there are many ways to make progress toward this goal even in the short term.

The terms EMR and electronic health record (EHR) are used interchangeably here, with EMR the favored term. Elsewhere, EMR is sometimes defined as the record of an individual in one specific, provider-centric setting, whereas the EHR is the patient-centric longitudinal electronic record of an individual across multiple EMRs. For simplicity, no such distinction is made here.

For all that follows, a "problem-oriented" EMR is defined as containing a full medical accounting across health care providers of the 'longitudinal, comprehensive, person-centered, individualized, collaborative care of the medically complex patient.'[58] The EMR usually contains:

- Patient identification – This includes name, address, phone, and a *unique*/standardized identifier.
- Problem list – A statement of the patient's most important ongoing and recently resolved health problems, along with basic background information (e.g., date of first diagnosis) to provide a clear description of issues that require medical intervention or consideration.
- Medication list – A list of medications (and doses) prescribed for and later administered to the patient, as well as allergies and contraindications.
- Reports – Results from imaging and x-rays, laboratory, operations, and pathology, as well as consultations and the "history and physical" giving background on illnesses and surgeries that the patient has had, and any family history of disease.
- Legal and administrative information – These may include, for example, consent and authorization forms, documentation of services rendered, and billing and reimbursement.
- Plan of action and progress notes – A description of the process of following up, and thereafter the providers' assessment of the response to treatment, with feedback and adjustments over time.

Two noteworthy ventures, KwaMoja[59] and OpenMRS,[60] are making great progress building affordable EMRs with open source methodologies.

The EMR also overlaps with the legal health record (LHR), which establishes those elements of the patient's or provider's records that would be admissible or stand as evidence in a legal proceeding or dispute, or a formal clinical audit to establish professional liability. The extent of overlap is beyond the scope of this paper. The reason for introducing the concept of a LHR is to make clear that the EMR's applications extend in various directions beyond clinical, operational, and financial realms.

The EMR is important, as well, for the data elements and functionality that it does *not* include. Once the capacity has been created to keep detailed and enduring records patient-by-patient, different stakeholders may assert their own competing proprietary interests in the particular data that are collected. Clinicians, billers and coders, insurers, administrators, risk managers, compliance officers, public health agencies, and other parties have their own interests and prioritize their own data needs.

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58   Kernisan L. The Problem-Oriented Medical Record. The Health Care Blog. May 10, 2013.

59   https://www.kwamoja.org/

60   http://openmrs.org/

As a foreshadowing, in high-income countries this has created chronic conflict with health care providers, who advocate for using the EMR primarily as a means to inform and document care:[61]

> *"Clinical documentation was developed to track a patient's condition and communicate the author's actions and thoughts to other members of the care team. Over time, other stakeholders have placed additional requirements on the clinical documentation process for purposes other than direct care of the patient."*

Competition also extends to governance of EMRs, in part because data elements collected for EMRs also populate other HIS components and conversely. Historically separate information systems have worked independently of one another, mostly on contemporaneous tasks (e.g., collecting and processing a laboratory specimen from a specific patient) and without benefit of a functional, enduring EMR. As such, some functionality that historically has been essential to these systems' capacities to "stand alone" is rendered unnecessary after the components are integrated together and organized around EMRs as a nexus. Functions that become redundant may work as impediments to effective integration, if for example, pathologists strongly prefer the functionality that their systems have built up over years while radiologists, pharmacists, physicians or administrators prefer their own set ups.

The EMR is such an important, compelling, and rich resource, as described throughout this study, that there must be strong institutional arrangements to intermediate the interests of all stakeholders.

D. Medical Record Matching and Master Patient Indexes (MPI)

Regarding digital identification, this primer is emphatic: Without exception, every person's identity must be unique; it must be permanent, portable, and private. Otherwise, most HIS components in this primer are foreclosed. With this written, circumstances require pragmatism. The immediate aim of digital identification within the context of HIS is narrowly focused on medical record matching, which is difficult but specific and involves just what the term suggests:[62]

> *"Recognizing that Mary Jane Smith at 123 Elm Road in the 2009 clinical laboratory system is also Mary Collins of 78 Oak Street in the 2011 patient registration system is a challenge for any organization."*

Individuals, in other words, change locations, phone numbers, and names and they tap into different HIS components at different times. Even with ample resources it is a tall order to match patients reliably with their entire individual encounter records to create longitudinal EMR.

Reliable, secure digital identification provides a comprehensive solution to this problem. If every health care encounter is flagged with the patient's unique digital identification, then record matching becomes straightforward and over time reliable, though perhaps never actually "easy."

Yet digital identification is not *necessary* to remediate record matching problems. One simple workaround is "concatenation." Imagine, for example, a paper-based record system where every newborn nationwide is given a

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61 Kuhn T, et al. for the Medical Informatics Committee of the American College of Physicians. Clinical Documentation in the 21st Century: Executive Summary of a Policy Position Paper From the American College of Physicians. Ann Intern Med. 13 Jan 2015. doi:10.7326/M14-2128.

62 Shah S. Techniques for Matching Patient Record Data Across Disparate EHRs and Other Systems. Digital Health Nexus & Data Innovators Advisory Service. 8 Feb 2012.

two-digit code that is unique to each facility each day. The first child born at any random facility on a given day is assigned "A1." The facility assigns "A2" to the second newborn, and thereafter A3, A4, A5, A6, A7, A8, A9, B0, B1, B2, … The facility begins anew the next day, beginning again with A1. This two-digit number is recorded in the facility's records and also on the child's home-based record (see below) or immunization card at discharge. Thereafter, nationwide the child is always identified by combining the facility number (copied from the MFL) with the child's DOB and this two-digit code (e.g., 2017-11-09-MFL8765-A5).

This is not an elegant approach, for example, because it is neither secure nor failsafe. Moreover, it does little good to have such a means to match patient records if the individual records are committed only to paper and as such impossible or impractical to co-locate (e.g., move across facilities) during subsequent encounters. If records are unavailable, even a good manufactured identifier is pointless.

Yet as basic as this concatenation may be, it offers a start and opens the way for higher aspirations, which eventually include a nationwide master patient index (MPI). This MPI is very much like a unique national identification system except that it applies only to health care. It is not designed to secure commercial transactions, for example, or to enable voting or passports; and indeed for privacy (and perhaps other) reasons it may be best to have a national MPI that is separate and distinct from other national digital identifiers.

Significantly, record-matching methodologies can be invaluable today even if they are not deployed until days or even years into the future. To take a concrete hypothetical, suppose that a country plans to launch a national digital identification program in 2022 and to migrate all paper medical records to electronic formats shortly thereafter. Even if there is no near-term case for matching troves of individual patient records that through 2021 are all committed to paper and housed in many different locations, it is not too early to begin adapting paper records in anticipation of the migration.

To embellish on this hypothetical, consider modifying facilities' 2018–2022 paper immunization forms to include a top box with only a few of the most essential patient data fields, including the facility number, child's and mother's full name, child's and mother's date of birth (DOB), cell phone number (if available), and check boxes for all immunizations administered at that facility. Suppose that this top box is machine-readable even if the more detailed fields recorded below the box are not. This modest modification disrupts little or nothing of frontline health workers' status quo processes.

When 2022 arrives (or even before), this top box provides more then enough information to match 99.999% of all immunization records dating back to 2018 and to create a national MPI for children under the age of six. Machine scanners read all data in the top boxes and store low-resolution images of every full-length form; and then almost immediately and at very little expense the migration of paper records to digital formats is considered complete. (There is never any manual keypunching of 2018–2021 records.) For every child born after 2017 there is a reliable history of all administered vaccines, and where there is confusion or questions, images of the full records can be called up from each facility, examined, and reconciled. Default tracing is streamlined even as it becomes more ambitious, and in the process many more children—sometimes at later ages—end up fully immunized. National immunization (and perhaps birth) registries take great leaps forward. More data become available to inform demand forecasts, so that vaccine supply chains also improve. Facility-level data become more comprehensive, accessible, actionable.

E. Home-Based Paper Records (HBR)

In high-income countries, patients can increasingly access the same electronic data and health information systems as their care providers, usually with an Internet-based user interface (UI) referred to as a "patient portal." Individual patients simply log in to their customized portal using a username and password to find nearly all of their patient records organized, visualized and explained in ways that make this information straightforward to understand (in theory of not always in practice).

In low-resource settings, though, patients do not directly access *any* of the data or information systems discussed throughout this primer. Instead they receive and take home *paper* records:[63]

> When properly used, child immunization cards provide a relatively inexpensive and effective instrument in the promotion of childhood immunization and child health more generally…
> [T]he cards [add] essential health information including a record of birth data such as the birth date and birth weight, a visual record of the child's growth, factors that may affect the child's ability to develop normally or adapt to a new environment, as well as a continuous and permanent record of the child's development by recording the medical and social history. These more comprehensive child health cards are … advantageous because they [emphasize] immunization within the context of the child's overall health and development rather than being viewed as an end in itself. Regardless of type (immunization card or health card), the utilization of cards has been associated with improvements in the uptake of preventive health services, such as immunizations, and with up-to-date and fully immunized children as well as serving as a reference for health care workers.

> Immunization cards also … [improve] parental awareness and involvement in their child's health care. Research has shown that missed opportunities for immunization are often the result of parental lack of awareness of the benefits of vaccines as well as a lack of awareness of the vaccination schedule and when their child is due for his/her next vaccine.

Patients advocating for themselves or family members must know much more than might at first be imagined or that any individual could ever commit to memory. Absent basic written documentation to organize and update all of this knowledge, patients and family members are routinely lost.

A written account made available to patients and families in low-resource settings is referred to as a home-based record (HBR). A newborn's immunization card (discussed in the next Section) is one example of such a HBR. One function of a HBR is to provide a record of care received: encounters, diagnoses, diagnostics, vaccinations, medications, counseling, and other goods and services. This HBR should also record dates, times, locations, caregiver identification, payments made, if any, and perhaps other details. At discharge, patients may be given explanations of the care they received, as well as guidance (e.g., how to deal with adverse events) and instructions (on when to return for follow up or a next round of care). The HBR may document that this has all been executed according to an established protocol, and it may itself summarize at least some of this information in case the patient cannot recall key details later. Put differently, the HBR may serve as an important educational tool.

F. Human Resource Information Systems (HRIS) and National Provider Identifiers (NPIs)

For the same reasons that HIS must account for individual patients, encounter-by-encounter, as a top priority health systems must account for every care provider, even if this accounting to start is remedial. If a prescription is ordered, information systems must confirm that this order comes from a licensed pharmacist, physician, nurse, or community health worker—or at least a pre-approved and qualified proxy. The order for every lab test must also come consistently from an accredited source, and thereafter the results must be reported out to a caregiver who is certified competent, with the authority to interpret the results and work with the patient to frame a care plan.

Moreover, the health care workforce requires both the most up front investments (in human capital) and ongoing expenditures (in wages and benefits, training, compliance, and other outlays) of any other health care resource. Even in low-resource settings it is crucial to have systems that document the most critical capacities of these people and the vital work that they do.

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63   Brown D. Child immunization cards: Essential yet underutilized in national immunization programmes. Open Vaccine Journal. 2012.

Human resource information systems (HRIS) span the tools and data needed to manage accounting and pay-roll, as well as a framework for workforce planning, performance measurement, licensure, and other human resource functions (e.g., reporting and tracking such recurring activities as requests for time off). A lean but rigorous HRIS is also necessary to enable such basic tasks as medicine and laboratory administration (e.g., prescribing medications and ordering tests), or claims adjudication (for insurance purposes) and cost recovery (for budgeting).

The WHO provides common definitions and classifications for health workers that improve comparability and generalizability of data,[64] while the International Standard Classification of Occupations (ISCO), maintained by the International Labour Organization (ILO), groups jobs according to specific tasks and duties.[65] Interested readers can also turn to other sources for broader surveys of HRIS in LMIC.[66,67] There are also useful peer-reviewed publications detailing individual countries' work on HRIS (e.g., Ethiopia,[68] Rwanda[69] and Uganda[70]). Finally, IntraHealth,[71] an organization founded in 1979 that has as its mission "to improve the performance of health workers and strengthen the systems in which they work," has resources and additional country-by-country accounts. Among these resources is iHRIS, which is "open source software, [that] helps countries … track and manage their health workforce data to improve access to services."[72]

A national provider identifier (NPI) is a unique number issued to medical professionals for use by health facilities, insurers, government agencies, and other institutions. An individual's NPI never changes, even if that professional's legal name, address, or other information change. As with other "master data," creating a uniform and standardized means of identifying medical professionals improves efficiency and enhances the ability of stakeholders to exchange health information.

G. Master Facility Lists (MFL)

In recent years, leading health agencies and LMIC ministries of health (MoH) have prioritized mundane but vitally important efforts to create and maintain reliable "master facility lists" (MFL). These can be thought of as digital spreadsheets that identify all retail service delivery points (SDPs) and pick up points (PUPs) in a country where health care is delivered (in rows), along with data fields describing such attributes as name and unique identifier, address, location, facility type, ownership (e.g., MoH, private, faith-based), regulatory body, number of beds, hours of operation, available equipment (e.g., for imaging studies) and specific services rendered (in columns). A country such as Kenya has roughly 10,000 such facilities. A country may already have many different facilities lists, and there are typically conflicts between them. Some lists are more up-to-date or inclusive than others; naming conventions do not align; different data fields are collected and reported; some lists are less completely populated or reliable; and so forth. The point of a MFL is to sort out all of these differences and to standardize around common "master" data.

64 Sources and classification of health workforce statistics. WHO. https://www.who.int/hrh/statistics/workforce_statistics/en/

65 International Standard Classification of Occupations. International Labour Organization. Accessed Sept 2017: http://www.ilo.org/public/english/bureau/stat/isco/index.htm.

66 For example, Riley P, Zuber A, Vindigni SM, Gupta N, Verani A, Sunderland NL, et al. Information systems on human resources for health: a global review. Hum. Resour. Health 10 (7). 2012.

67 Human Resources for Health Information System—Minimum Data Set for Health Workforce Registry. Geneva: World Health Organization, 2015.

68 Dilu E, Gebreslassie M, Kebede M. Human Resource Information System implementation readiness in the Ethiopian health sector: a cross-sectional study. *Hum Resour Health.* 2017;15(1):85. Published 2017 Dec 20. doi:10.1186/s12960-017-0259-3.

69 Waters K, Zuber A, Simbini T, Bangani Z, Krishnamurthy R: Zimbabwe's Human Resources for health Information System (ZHRIS)-an assessment in the context of establishing a global standard. Int J Med Inform 2017, 100:121-128.

70 Spero JC, McQuide PA, Matte R. Tracking and monitoring the health workforce: a new human resources information system (HRIS) in Uganda. Human Resources for Health. 2011;9:6. doi:10.1186/1478-4491-9-6.

71 https://www.intrahealth.org/

72 https://www.ihris.org/

It has become a priority for LMICs to have a definitive master list of their facilities, with regular updates. This requires ownership and accountability for maintaining this list, significant resources to build and improve upon it, cooperation and compliance from other stakeholders who come to rely upon it,[73] and a vision for improving and integrating this list with other HIS.

As it matures, the MFL may add other important data fields. These may include, for example, documentation and detail on each facility's *licensure* (i.e., legal approval to operate), *certifications* to participate in various programs, and *accreditations* (involving external reviews by outside agencies that recognize the facility's ability to meet predetermined performance and outcomes standards).

The USAID has recently published an outstanding, exhaustive MFL Resource Package[74] and accompanying guidebook, while the Measure Evaluation Project maintains a quasi-exhaustive online list of national MFL projects.[75] An older guidebook from the WHO is also helpful.[76]

H. Property, Plant, and Equipment (PPE)

A well-functioning MFL is an important but first step toward cataloging each SDP. Over time it is critically important to take stock of all essential physical property, plant and equipment (PPE), covering for example, imaging and laboratory equipment. Data fields could include equipment brand, year of purchase, functionality, and past capacity utilization. Such details are important for many reasons: effective capital planning and budgeting, operations, equipment maintenance, and community outreach and marketing. (To utilize assets well, facilities must offer them up to referring providers.) This published PPE inventory is critical to managing the costly and valuable assets of individual enterprises and also to building out integrated regional and national health systems.

Simple PPE innovations long term will connect with efforts that have come to be known as the "Internet of Things" (IoT), which involves using ICT to advance the ways that physical assets work and interact. These IoT efforts join together equipment, devices, and machinery (e.g., using inexpensive sensors) ranging from cellphones and washing machines to airplanes and pacemakers into massive networks. These networks also include people. Many of the world's largest equipment manufacturers have made the IoT central to their strategies and their actions demonstrate both commitment and resolve.

The IoT may seem far removed and far off in time for health care systems in LMICs, but it is not too early to begin considering how the surge of IoT innovation will affect HIS. Significantly, the great majority of health care providers' capital investments revolve around equipment purchases—for labs, imaging, monitoring, cold chain transport and storage, and so forth—that have as a primary purpose the generation and dissemination of information. The great push for connectivity, interoperability, and health information exchange for PPE of all kinds has been ongoing for many years and is simply the IoT by other names. If the IoT is as revolutionary as its champions assert, it will surely have a profound long-term impact on HIS, even if the innovations take time to disseminate to LMICs.

A thorough accounting of facilities and PPE is a stepping-stone to inclusive regional health care delivery systems. Not every SDP can support or even needs its own mobile ultrasound or x-ray equipment, for example, but each SDP must know that some particular local facility has such capacity. Each clinic should know, as well, the terms on which they can direct patients to that facility. The IoT/interoperability imperative applies not only to

73   Monitoring results with health facility information systems: A technical consultation. Summary Report. Glion-sur-Montreux, Switzerland, 11–12 June 2014. Organized by the World Health Organization.

74   Master Facility List Resource Package, USAID, May 2017. https://wiki.ohie.org/download/attachments/28836615/1-Introduction%20 to%20the%20MFL_May.pdf?version=1&modificationDate=1495728412295&api=v2

75   Master Facility List. Health Information Systems Strengthening Resource Center. USAID Measure Evaluation Project. Accessed Sept 2017: https://www.measureevaluation.org/his-strengthening-resource-center/resources/master-facility-list.

76   Creating a Master Health Facility List, Geneva, World Health Organization. WHO. March 2012.

health facilities, but also to physical infrastructure throughout the supply chain. Indeed, bar codes, radio frequency identification (RFID), and many other sensors and other early IoT innovations have their roots in supply chains.

4. Information Directly Supporting Care Delivery

The information systems described in this section all help to manage contemporaneous care delivery within rigorous, structured, reliable systems. They span medicines, laboratory diagnostics, diagnostic imaging, and vaccines. Even within the lowest-resource settings, providers have long relied upon these systems to consistently channel the right resources to the right patient at the right time and place. As such, the technology underlying these systems is relatively mature, even in paper-based settings. The discussion here is kept brief, but excellent (only modestly longer) non-technical surveys are available elsewhere.[77,78,79]

A. Pharmacy Information Systems (PIS)

In many low-resource settings throughout the world patients secure medications on their own through unregulated private pharmacies. Otherwise, the basic approach for ordering medications until recently has barely changed in a century,[80] even as the actual ordering of prescriptions has shifted in many parts of the world from paper to computers. The longstanding process is face-to-face and "retail," meaning one patient at a time. Orders are prescriber-initiated, often with various controls that regulate prescriber licensure and access, required documentation of medical necessity (e.g., by linking the medication and dose to a specific diagnosis code), and a limited formulary (i.e., the agreed upon list of drugs that offer the greatest overall value). Even in the lowest-resource, paper-based settings, at least simple controls and information infrastructure are critical, because of risks of adverse drug events, drug allergies, incorrect dosing, side effects, drug-drug interactions, overuse of antibiotics or other therapies, patient non-compliance, and various other medication-related issues.

Computerized provider order entry (CPOE) refers to the process of a medical professional entering a prescription or other instruction (e.g., for a lab test or imaging study) digitally rather than on paper, and most CPOE systems have been designed to follow the same workflow as a paper chart. Computerization is challenging: even in high-income countries CPOE implementations have been costly, disruptive, and protracted (as the rollout proceeds in different departments and venues sequentially). Most CPOE systems are strictly intra-hospital (i.e., covering inpatient care and often the hospital's on site outpatient department, or HOPD). The standard process of designing and implementing a CPOE initiative is well-documented.[81]

Electronic prescribing, or "e-prescribing," refers to the use of strictly medication-related CPOE in outpatient, non-hospital settings. With e-prescribing, the prescribers send their orders electronically to an outpatient pharmacy (or in some cases an intermediary such as a pharmacy benefits manager) to be filled and dispensed. The potential benefits of (inpatient) CPOE and (outpatient) e-prescribing include streamlining physician and pharmacy workflow, improving clinical documentation, reducing errors, and raising patient satisfaction and medication compliance.[82]

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77   Troiano D. A Primer on Pharmacy Information Systems. Journal of Healthcare Information Management, vol. 13, no. 3, Fall 1999. Healthcare Information and Management Systems Society and Jossey-Bass Inc., Publishers.

78   Laboratory Quality Management System Handbook. (Specifically, Ch. 17: Information Management). WHO. 2011.

79   Shuman L. A Revolution in Radiology: PACS (Picture Archiving and Communication System) 101 (Parts 1 and 2). Journal of Lancaster General Hospital. Summer 2011 • Vol. 6 – No. 2 and No. 3.

80   Fincham JE. e-Prescribing: A Move Toward Appropriate Medication Use. *American Health & Drug Benefits.* 2008;1(9):6-8.

81   Computerized Provider Order Entry (CPOE) Wiki. Healthcare Information and Management Systems Society.

82   Porterfield A, Engelbert K, Coustasse A. Electronic prescribing: Improving the Efficiency and Accuracy of Prescribing in the Ambulatory Care Setting. Perspectives in Health Information Management, 11(Spring), 1g. 2014.

Pharmacy information systems (PIS) also entail much more than ordering and dispensing medications, and more even than the broader and immediate operational and financial aspects of running the pharmacy, such as billing, inventory management, and report generation. Indeed, the pharmacy information system is (or at least should be) a central pillar of every health information system across many diverse clinical service lines and physical venues.

To start, the PIS must be failsafe at identifying (and recording for later recall) both patient and provider, integrating with and leveraging both the EMR and the HRIS for more information. Having the patient's complete demographic and clinical profile is essential for determining the right medication and dose, for example, and documentation of the prescriber is crucial for many reasons that extend beyond simply restricting access to qualified and authorized personnel.

Even in basic, low-resource, paper-based settings, a PIS must aim for the following functionality:[49]

- Order entry, management, and dispensing system-wide (e.g., inpatient, outpatient, ambulatory and community settings)
- Inventory and purchasing management
- Basic reporting (utilization, workload, and financial)
- Clinical monitoring and documentation
- Manufacturing and compounding (i.e., drug preparation)
- Intervention management
- Medication administration (e.g., to assist inpatient nursing staffs with patients' medications)
- Integration with other information systems
- Pricing, charging, cost accounting and billing

The roles that pharmacists play have increased significantly over time, and PIS support the broader range of services that they have come to provide. These include leading health systems' decisions regarding which medications to include in the formulary, comprehensive medication and utilization reviews, identification of gaps in care, and consultation to other caregivers on individual patients.

As in other HIS, it is crucial to maintain and deploy master and hierarchical data that standardize terminology across clinical settings and end users. (See **Section 8.A**.) For example, International Nonproprietary Names (INNs) for pharmaceutical substances were a development on the part of the WHO in the 1950s for the naming of new pharmaceutical substances and to allow for standard referencing to existing substances.[83] These "generic" names are in the public domain (i.e. a drug may have multiple brand names owned by different companies, but all can be referenced with the same INN) and help governments, businesses, and doctors to order medications accurately and safely across borders with "globally recognized" names. INN use facilitates pharmaceutical data sharing and is thought to help reduce prescription errors and pharmaceutical costs.

Because INNs are developed for specific formulations and active pharmaceutical ingredients (APIs) there should be no difference in the clinical effects between the same INNs that may be sold under different brand names. INN use in prescribing systems offers a way to standardize references to pharmaceuticals between different information systems.

A consideration on the use of INNs is that the full list is updated with new proposed or replacement names at least twice a year by the INN Expert Group.[84] Therefore, in order for all HIS using INNs to remain interoperable

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83   http://infocollections.org/medregpack/documents/d0107/d0107.pdf

84   International nonproprietary names. WHO. https://www.who.int/medicines/services/inn/en/

(i.e., share information) with each other, they must all frequently update the master data they are using. INN Expert Group members are a part of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations. The Expert Group aims to be geographically and professionally diverse across pharmaceutical and chemical fields and may select advisors from relevant fields to facilitate decision-making.[85]

Typically, in designing and managing their formularies, pharmacy leaders also make basic and ongoing use of an essential medicines list (EML), which is compiled and routinely updated to satisfy the priority health care needs of a country or health system. Consideration is given to "disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness;" and having been selected:[86]

"Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford."

Many national EMLs are modeled after WHO's recommendations, which in their most recent (June 2017) version contain 433 medications (up from 212 when WHO published its first EML).[87] These are divided into core and complementary medications. Core medications are the most cost effective for key health problems and require few additional health care resources. Complementary medications require additional infrastructure or are considered less cost effective.

WHO currently tracks 156 countries with national EMLs; more than 100 countries with national drug policies; 135 countries with therapeutic manuals and formularies (to advise health professionals on the rational use of drugs); and a network of 83 countries that monitor for adverse drug reactions.[88] EMLs are often accompanied by standard treatment guidelines (STGs), which summarize for the benefit of health professionals the recommended treatment options for a specific disease(s) or medical condition(s). EMLs and STGs thereby advance rational medicine use and simplify supply, treatment decisions, and billing and reimbursement.[89]

In LMICs, functional PIS of the sort described in this section are rare outside of hospital settings. As such, it is likely not coincidental that historically pharmacists have figured prominently in "upstream" leadership positions in health commodities procurement, supply chains and last-mile delivery.

B. Laboratory Information Systems (LIS)

To frame laboratory information systems (LIS), it is helpful to understand that in key respects the framework is nearly orthogonal to PIS. Medications are usually homogeneous, made in large batches far from patients (often with a months-long shelf life) and without any individual patient in mind, brought to patients and linked to them individually late in the process. Standardized doses are packaged automatically so that the most salient information is knowable to the naked eye, with bar codes available to ascertain much other information.

In contrast, laboratory specimens (e.g., for a blood, sputum or urine test) are taken and processed one at a time, from individual patients. Each unique specimen's key attributes must be discerned using various machine tests and professional interpretations, usually at some distance from the patient and then reported back with a rapid

85   International nonproprietary names: revised procedure. World Health Organization. Geneva. 2005. http://apps.who.int/gb/ebwha/pdf_files/EB115/B115_11-en.pdf.

86   Essential medicines and health products. WHO. http://www.who.int/medicines/services/essmedicines_def/en/.

87   20th WHO Essential Medicines List. World Health Organization. March 2017. http://www.who.int/medicines/publications/essentialmedicines/en/.

88   http://www.who.int/medicines/events/fs/en/

89   Standard Treatment Guidelines and Essential Medicines Lists. Systems for Improved Access of Pharmaceutical Services (SIAPS). USAID.

turnaround. Specimens are individually packaged at the time they are taken and often labeled by hand, with the most critical information gathered not about the specimen itself but about its links back to the individual patient, provider, date, and location.

Put simply, laboratory processes are different from other care delivery processes. They are especially complex. A recent (2014) survey conveys this about LIS with its opening (emphasis added):[90]

> Laboratory computing has been at the leading edge of health information systems application development for the past five decades and fully integrated laboratory information technology systems have become the *de facto* prerequisites for efficient clinical service delivery and laboratory management. This assertion is borne out by the observation that ***laboratory systems are usually the most sophisticated systems in any health organisation anywhere in the world.*** However the health informatics landscape is changing with the development of ever more sophisticated electronic patient record systems and pathology computing is in danger of falling behind. The fundamental models of laboratory system design were elaborated in the 1970s …, and these models are still at the core of the latest systems being installed at present.

Data from the LIS involve many media: numbers, text, graphs, or other images, together with interpretative data; and these data come from various types of specimens, equipment, and methods.

High-income countries' LIS have been digitized in recent years, and in the process laboratory throughput has expanded impressively:[52]

> Most general readers will not appreciate the data processing requirements of laboratories. Analysis of data from the UK suggest that an average multi-disciplinary pathology service typically handles between 1 and 3 million patient specimens per year each, generating 10–30 million reportable test results on populations ranging from 0.5 to 1.5 million. In the UK, the median laboratory repertoire of tests is 189; such a laboratory will serve approximately 500–1500 consultant clinicians and a similar number of general practitioners within an average of 300 practices. Such operations are of industrial scale. It is a tribute to the systems designed and developed in the early 80s that they can handle this volume of work.

An important consideration when evaluating capital investments in laboratory equipment and digital LIS, therefore, is that throughput can often be increased significantly. Because equipment and human capital both involve high up front and ongoing fixed costs, high utilization brings down unit costs through a simple process of amortization (i.e., spreading fixed costs over many more patients). This is a consideration and worth emphasizing: high utilization is critically important, because the marginal (i.e., incremental) costs of many laboratory tests are quite low. If the equipment is at one point utilized 20% and then at some later point utilized 80%, then unit fixed costs drop from, say, 100 per patient to 25. If a local pathologist had been interpreting an average of 100 tests per week with a paper-based LIS and after investments in digital equipment and LIS is able to review 400 tests in the same time, then the cost of is reduced in the same way and proportion.

The case for making these investments becomes even more compelling to the extent that laboratory tests are a bottleneck to treatment and stabilization of patients. It may take two decades to increase the pathology workforce appreciably, but laboratory system redesigns can perhaps triple or even quadruple the productivity of each pathologist, and in short order.

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90   Jones RG, Johnson OA, Batstone G. Informatics and the clinical laboratory. Clin Biochem Rev 2014;35:177-92.

Electronic LIS can often also assist with clinical decision support, data analysis, audit functions, clinical risk management, disease surveillance and epidemiology (e.g., creating patient registries and screening programs). Wherever possible, LIS must also link with other HIS components so that, for example, interpretation of lab results can factor in patient medications and demographics such as age.

Turning to core functions, laboratory workflow for ordering and processing tests involves various individual steps and LIS data inputs attending each step.[91,92] To start, a standardized request form (paper or digital) uniquely identifies the patient and the requester and provides basic information on each. Contact information is critically important, for example, to route the final laboratory report. The request must also spell out the specific test that is being ordered, the materials collected (e.g., blood, urine), and other salient details. The sample, once taken, must also be given a unique identifier, a link directly to patient and requester at all times, and a label for tracking purposes. (In digital systems, this label often contains a bar code generated by the LIS or LIS-linked software.) If the sample is shipped to a different location (e.g., a centralized laboratory), then that location must also be identified uniquely, ideally through the MFL. These individual steps, and all steps thereafter, must record the time and date of both receipt and subsequent release, as well as any other steps in between (e.g., methods used to process the sample or to ensure and document quality controls).

Laboratory results must be routed to the professional tasked with interpreting and reporting. (This may be the requester, but could also be a pathologist who is consulting on the test.) The report must then be routed back to the requester. Worklists help to schedule and manage workflow and various statistics help to measure performance (e.g., turnaround times) and inform process improvements.

A well-functioning LIS also makes extensive use of master data (discussed in greater detail in **Section 8.A**), including Logical Observation Identifiers Names and Codes (LOINC).[93] LOINC is a database and universal standard for terminology used for identifying laboratory orders and results.

Finally, there are rigorous, structured methods for evaluation and accreditation of laboratory systems themselves.[94] These are critically important to LIS but beyond this primer's scope. Readers interested in accreditation can seek out the WHO's Strengthening Laboratory Management Toward Accreditation (SLMTA)[95] and other freely accessible non-technical resources.[96]

Circumstances in LMICs make laboratory systems even more challenging. In their 2013 global survey of pathology informatics, Park et. al provide lengthy details of the histories of laboratory systems and LIS around the world.[97] The narrative is discouraging. A three-article series on pathology and laboratory medicine in LMICs appearing in the March 2018 journal Lancet reinforces this grim accounting, providing an exhaustive accounting

91   Sepulveda JL, Young DS. The ideal laboratory information system. Arch Pathol Lab Med. 2013;137:1129–40.

92   de Kieviet W, Frank E, and Stekel H. Essentials of Clinical Laboratory Management in Developing Regions. Committee on Clinical Laboratory Management. Education and Management Division. International Federation of Clinical Chemistry and Laboratory Medicine. 2008.

93   https://loinc.org/

94   ISO 15189:2007. Medical laboratories–particular requirements for quality and competence. Geneva: International Organization for Standardization, 2007.

95   Yao, K. Maruta, T., Luman, E. Nkentgasong, J.. The SLMTA programme: Transforming the laboratory landscape in developing countries. African Journal of Laboratory Medicine, 3, sep. 2014.

96   Laboratory Quality Management System Handbook. (Specifically, Chapter 11: Assessment— norms and accreditation). WHO. 2011. http://www.who.int/ihr/publications/lqms/en/.

97   Park S, Parwani AV, Aller RD, et al. The history of pathology informatics: a global perspective. J Pathol Inform. 2013;4:7.

of crucial gaps in these systems,[98] a roadmap to solutions[99] and a call to action.[100] Discussion of LIS are integrated into each of the studies in this series, including an overall assessment that even in 2018, "examples of the successful implementation of laboratory information systems in LMICs are scarce."[99]

C. Radiology Information Systems (RIS) and Picture Archiving and Communication Systems for Filmless Imaging (PACS)

Over two decades there has been revolutionary innovation in radiology, so far adopted mostly though not entirely in high-income countries. In the foreseeable future, the advances will have as much impact in LMICs as elsewhere. Radiology information systems (RIS) and related ICT innovations will play a central role in disseminating these advances.

Writing from the United States in 2011, radiologist Leigh Shuman offered this account of progress:[47]

> In the dark ages of imaging, a mere 10 years ago, life was very different; imaging studies were performed and recorded on film. Films were processed in a darkroom or the equivalent; given to the radiologist who dictated a report; then stuffed into jackets for storage. After the reports were typed and signed, couriers took them to the floors or they were put into mailing envelopes. A clinician who wanted to see the images made a trip to the radiology department, hoping and praying the films could be found in a timely fashion. Since there were often many people trying to see the same studies, and many places where they could hide (radiologists' offices, surgeons' car trunks, etc.) the process was often intensely frustrating and decisions about patient care were frequently delayed.

As unwieldy as these processes were in high-income countries, they were usually entirely unworkable outside of hospital settings in LMICs. Historically, there is little evidence of radiology services being widely offered. Nonetheless, it is important to understand how these services are offered and how information systems are organized, because there is significant potential in LMICs going forward.

The RIS stands as the nexus for managing effective and efficient clinical operations for imaging.[101] The RIS coordinates enterprise workflow, including: ordering of imaging studies, gathering patient data, scheduling and tracking of orders, radiologist worklists, documentation, results distribution, resource utilization, billing, performance measurement, and integration with both individual patient EMRs and other HIS components. Advanced RIS analytics include digital dashboards and data mining, technologist feedback, and population surveillance and outcomes metrics.

The radiology revolution goes beyond streamlining workflow. Images are vastly improved with better resolution and quality, and automatic and enhanced peer review (e.g., so that radiologists can seek colleagues' opinions). There are all new modalities, some very low cost (e.g., digital mammography).

In the same timeframe and driven by the same technological, clinical and economic forces, there has been a complete overhaul in how health systems process, store, and access images using picture archiving and communication systems (PACS), which have become the standard in radiology for managing digital images across all modalities.

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98   Wilson ML, Fleming KA, Kuti MA, Looi LM, Lago N, Ru K. Access to pathology and laboratory medicine services: a crucial gap. Lancet 2018; 391: 1927–38.

99   Sayed S, Cherniak W, Lawler M et al. Improving pathology and laboratory medicine in low-income and middle-income countries: roadmap to solutions. Lancet 2018; 391: 1939–52.

100   Horton S, Sullivan R, Flanigan J, et al. Delivering modern, high-quality, affordable pathology and laboratory medicine to low-income and middle-income countries: a call to action. Lancet 2018; published online March 15. http://dx.doi.org/S0140-6736(18)30460-4.

101   McEnery K. Radiology Information Systems and Electronic Medical Records. American Coll of Radiology. 2013.

With RIS and PACS in place, images from all modalities are now reliably attributed to individual patients and they are more easily viewed locally and exchanged among providers and across venues. This exchange is made possible using Digital Imaging and Communications in Medicine (DICOM).[102] DICOM provides standardized methodologies and processes for recording, storing, documenting and sharing images. DICOM and other elements of imaging exchange have been significantly refined and improved in the past few years, with ongoing progress.[103,104]

Because of this great progress, global health agencies have just begun revisiting longstanding policies, including for example, chest radiography (CXR) and digital chest radiography (DCXR) for diagnosis of tuberculosis (TB). In 1974, the WHO called to end mass screening of TB using CXR, citing the technology and expense, among other considerations; but effective 2013 the WHO reversed course and again recommended CXR as a principal tool for diagnosing high-risk populations.[105] The WHO released a reinforcing DXCR factsheet and summary of current recommendations and guidance in 2016.[106,107] The potential for portable DXCR and analysis of DXCR images via computer-based algorithms are also imminent and with near-term potential for application in LMICs (including a pilot launched in Ghana in 2016).[108]

This sort of reversal in LMICs is likely to happen often over the next few years, especially among various low-cost imaging modalities that have all along offered tremendous value for money. A basic x-ray or ultrasound, for example, is key to diagnosing traumatic injuries and maternal and fetal health; and for many clinical applications there is simply no good substitute for these low-cost diagnostics.

With workflow and information exchange greatly enhanced, throughput can rise dramatically even as the information value of each imaging study advances. Better amortization of costly equipment and very scarce human capital shows all of the benefits that were described immediately above for laboratory systems. Here too, if diagnostics bottlenecks impede the treatment and stabilization of patients, and if shortages of capital equipment and clinical expertise in turn impede diagnostics, then the case for aggressively advancing simple RIS and PACS becomes even more compelling.

D. Paper-Based Immunization Information Systems (IIS)

Immunization information systems (IIS) differ from other HIS components, so much so that this primer spends two sub-sections describing them. This first describes paper-based IIS, which have changed little since the late 1970s, largely because of insurmountable technological constraints.[109] The second presents the electronic IIS that promise to revolutionize vaccine supply chains and delivery.

As background, a typical immunization schedule has five or six rounds within the first year of a child's life (e.g., at birth, then at months 2, 4, 6, and 12), often with additional rounds at, say, 18 months, 5 years, and one or more thereafter. There are defined immunization catch up schedules for children who start late or fall behind. Vaccines are administered at vaccine qualified clinics (VQC), through various outreach and mobile strategies, or

102 http://dicom.nema.org/

103 Mendelson DS, Erickson BJ, Choy G. ACR Imaging IT Reference Guide: Image Sharing: Evolving Solutions in the Age of Interoperability. *Journal of the American College of Radiology : JACR.* 2014;11(12 0 0):1260-1269. doi:10.1016/j.jacr.2014.09.013.

104 Vreeland A, Persons KR, Primo H (Rik), et al. Considerations for Exchanging and Sharing Medical Images for Improved Collaboration and Patient Care: HIMSS-SIIM Collaborative White Paper. Journal of Digital Imaging. 2016;29(5):547-558. doi:10.1007/s10278-016-9885-x.

105 Aviram G. Chest radiography for tuberculosis screening: a valuable tool. Isr Med Assoc J. 2015 Jan;17(1):50-1.

106 Radiography TB factsheet. Geneva: World Health Organization; 2018.

107 Radiography in tuberculosis detection. Summary of current WHO recommendations and guidance on programmatic approaches. Geneva: World Health Organization; 2016.

108 Boyle D. Tuberculosis Diagnostics Technology Landscape. Fifth Edition. Unitaid Secretariat. May 2017.

109 A Case for Better Immunization Information Systems. PATH and WHO. May 2013. http://www.path.org/publications/detail.php?i=2337

during occasional regional or national immunization campaigns. Other services may be integrated into these programs (e.g. vitamin A and tetanus toxoid distribution), and for mother as well as child. These added elements are beyond this primer's scope. The focus here is on routine patient-centered data flow, data collection and reporting.

The details of what follows reflect a composite of methods used in India mainly,[110] but also Uruguay[111] and South Africa.[112] The details also reflect lessons learned from a broader literature review and case studies around other types of paper registers.[113] In short, different countries adopt somewhat different paper-based systems; the one that follows is representative.

The data flow begins when a woman first registers her pregnancy with a health care provider. She is given a multi-fold paper *maternal and child protection (MCP) card* and instructed to bring this with her to all visits. The card provides the woman with critically important information about care (and self-care) for herself and her child, including recommended schedules for perinatal care and first-year vaccinations. It also provides two separate, locally generated identifiers. Going forward from the first visit the MCP card serves as a repository for records of the mother's and child's care.

The MCP card may itself record an immunization history for the woman and her child, or this history may be on a separate *immunization card*. Regardless, the card reminds parents to return for the next dose, and for the health worker it determines immunization history and status. The card may have multiple counterfoils, meaning parts of the form that can be torn off (like tickets) one by one and kept as a record by the clinic. Each counterfoil can then be arranged by the VQC, for example, as a reminder that the woman or child is due for a subsequent dose.

The MCP card and immunization card (if it is separate) serve as the critical information system for the woman and child. This HBR is not the only record, but it is an IIS linchpin. MCP data are organized around the patients, and they are available even as the woman visits different facilities.

Each VQC collects data using various forms, including a *tally sheet*. After each patient is administered a vaccine, the provider marks this tally sheet with basic information, including type of vaccine. Other details may include utilization of syringes, vaccine vials, or adverse events following immunization (AEFI) detected during the session. AEFI are also recorded and tracked on separate forms.

The tally sheets are later aggregated across workers at the same VQC and perhaps over the course of a week. Totals are used to track overall vaccine usage, reconcile utilization with inventories on hand, report out to district or national agencies, and generally manage stocks and enhance compliance.

The VQC also maintains an *immunization register*. For each patient, this register dedicates one full line (or sometimes a full page) to record all of that patient's visits and vaccines. The register records the date of each dose, the specific vaccine, and other services rendered. With each visit and dose, more of the line (or page) fills, until the entire schedule of vaccines and related services is full. At this point the patient is fully immunized.

110   Health Managers Modules for Immunization: Information Management in Immunization. UNOPS-Norway India Partnership Initiative (NIPI) and National Child Health Resource Center (NCHRC) at the National Institute of Health and Family Welfare (NIHFW). Undated. http://www.in.undp.org/content/dam/india/docs/NIPI/Resources_CapacityBuildingMaterials_Immunization-Module5.pdf.

111   Westley E, Greene S, Tarr G, Hawes S. Paper Health Registers Project Case Study: Uruguay's National Immunization Program Register. University of Washington Global Health Start Program. May 2014.

112   Vaccinator's Manual: Immunisation That Works. Expanded Programme on Immunisation in South Africa (EPI-SA). 4th Edition, October 2012. https://www.health-e.org.za/wp-content/uploads/2014/03/Vaccinators_Manual_Final.pdf.

113   Westley EW, Greene SA, Tarr GAM, Ryman TK, Gilbert SS, Hawes SE. Strengthening paper health register systems: strategies from case studies in Ethiopia, Ghana, South Africa and Uganda. Journal of Global Health. 2016;6(2):020303. doi:10.7189/jogh-06-020303.

Each VQC's name-based *due-list* compiles all of the individuals who are due for services or vaccines. The due list is compiled from the immunization register or counterfoils. This list includes the specific vaccines that are scheduled next in the series for each patient. Each VQC also compiles other periodic *facility reports* to document information on aggregate counts by antigen, AEFIs, other services rendered, inventories of vaccines and other commodities, temperature records, and so forth. Other reports describe outreach and mobile programs and occasional vaccination campaigns.

Each VQC tracks patients who do not present as scheduled for immunization. The due-list and other records are used to maintain *a default tracer,* which is a cumulative list of all those who may not have received their full dosing regimen, along with a reason, if known (e.g., the patient has moved or died), and efforts either already taken or planned for follow up. Defaulter tracking is especially difficult considering that children routinely receive vaccinations at two or more different venues.

The performance of paper-based IIS varies significantly across settings. Critical success factors start with adequate resources and infrastructure, not only for data collection and information systems but also for patient access to affordable care and well-functioning vaccine supply chains that secure adequate and safe supplies. A well-trained and fully invested frontline workforce is also critical—invited to participate in the design and local implementation of their processes, empowered to seek out grassroots solutions to problems, encouraged to utilize the data that they collect and to improve data quality over time; and motivated to hold an overall sense of IIS "ownership."[49]

Newborns are much more likely to be enrolled in IIS (and national birth registries) if they are born in facilities. Data are more likely to be reliable and interoperable if forms and processes are standardized across all VQCs (public and private), if master data are everywhere the same, if all records are ultimately centralized in a single regional or national registry (sooner is better than later), and if patient and provider compliance are both consistently high.

One appeal of paper-based systems is that they tend to be simple and thus straightforward to understand. Important advances in paper-based IIS include electronic backup, standardized data and interoperability, so that records collected at one location can be integrated and exchanged with records collected at other locations. Mixed paper- and electronic-based systems can represent an important step forward, as well as an expedient bridge to transition from paper-based to digital IIS.

Conversely, paper-based IIS have intrinsic limitations. First, at present strictly paper-based patient identification is nearly impossible except at the local level. If patients travel to multiple venues for care, data are typically unavailable and can be permanently lost. There is some remediation, for example, if i) a woman always carries her MCP card, and ii) on every visit this MCP card is reliably filled out, and iii) these data are thereafter regularly transposed by hand in order to be consolidated at one facility or another. In this case, at least the patient's MCP card has a full record, and it can serve as a reliable reference at the point of care. Otherwise, the immunization record can be highly fragmented, incomplete and inaccessible.

Second, the arrangement is maddeningly inefficient for frontline health workers and inherently error-prone. Every data element is recorded by hand several times (on the patient's MCP or immunization card, in the facility's immunization register, and also transcribed on counterfoils, in AEFI reports, and later at regional or national data centers) and often kept in multiple places.

Third, because the same basic data are replicated many times across multiple cards and forms, paper-based systems must be parsimonious. They must aim to capture only the most essential data elements. Trimming these data elements to a vital few can be contentious, since competing interests (e.g., clinical versus public health versus supply chain) can value these elements quite differently. Thereafter, a culture of good data stewardship is also essential (e.g., leave no valuable data behind).

It is also worth noting that there is great overlap between the data collected on paper for IIS and data needed to advance i) perinatal care, ii) individual EMRs, iii) birth registries and other civil registration and vital statistics, and iv) national identification programs. Childbirth is a natural event to organize and ground all of these initiatives and not only because the event itself is so visible and significant. The time horizon between registering a pregnancy and concluding a full round of early childhood immunizations involves intense resource utilization, repeated interactions between patients and providers, and high-impact "value for money" care delivery. If there exists a window of time to focus on building out the best possible HIS, this must be among the most compelling.

At the same time, the urgency in remediating the intrinsic limitations of paper-based IIS is growing acute as African nations step up their commitments to national vaccine programs. These commitments are demonstrated in the February 2016 Addis Declaration on Immunization (ADI),[114] which aspires to universal access to immunization as a cornerstone for health and development in Africa. In January 2017 at the 28th African Union Summit, member Heads of State endorsed the ADI, "prioritizing immunization on a continental scale" by 2020.[115] By June 2017, the WHO provided an implementation roadmap.[116] This roadmap called for new IIS, along with improved supply chains and greater funding.

E. Electronic Immunization Information Systems (IIS)

To summarize, the paper-based IIS *status quo* is dated and there is great need and opportunity to leap forward. Among various recent electronic IIS initiatives, one stands out: the Better Immunization Data (BID) Initiative.[117] Launched in 2013 by Seattle-based PATH[118] and funded by the Bill and Melinda Gates Foundation (BMGF), the BID Initiative is country-owned and country-led. It is designed "… to introduce information system products and immunization practices that can be tested in a few [demonstration] countries, packaged for dissemination, and then deployed at scale in many countries."[119] Long term, the BID Initiative aims to expand into nutrition and maternal, newborn, and child health,[120] but the effort is proceeding step-wise, starting in local areas of Zambia and Tanzania, and soon broadening to national efforts as preparations are also made to launch elsewhere in Sub-Saharan Africa. The Initiative's architects aim for a person-centric approach along the lines of what this primer has described, with identification, birth registration, and EMRs all critically important:[49]

> In this future state, babies born in urban facilities are assigned a unique identifier (ID) and a barcode label with this ID is affixed to the antenatal care card and to the baby's immunization card. There is also a national eHealth system that includes an immunization registry. One of the roles of the immunization registry is to help identify children using whatever personal IDs may be available to Lucy such as a phone number, a birth certificate number, or a mother's national identification card.

114   Declaration on Universal Access to Immunization as a Cornerstone for Health and Development in Africa. ("The Addis Declaration on Immunization") World Health Organization and African Union Commission. Feb 25, 2016.

115   African Heads of State make historic commitment on immunisation. GAVI. January 31, 2017.

116   Roadmap for Implementing the Addis Declaration on Immunization: Advocacy, Action, and Accountability. WHO. June 27, 2017.

117   http://bidinitiative.org/

118   http://bidinitiative.org/path/

119   BID Initiative. Product Vision for the Better Immunization Data Initiative. Seattle, WA: PATH; 2014.

120   BID Initiative Global Factsheet. October 2016. http://bidinitiative.org/wp-content/uploads/BID_GlobalFactSheet.pdf.

The immediate aim is to improve immunization coverage dramatically, and the payoffs also extend in many other ways, including these examples:

For Patients and Frontline Workers:	For VQCs and Other Local Facilities:
• Streamlined data flows and operations	• More integrated HIS and patient care services
• More complete, accurate, accessible records	• Higher workforce productivity, less turnover
• Better default tracking, outreach, follow up	• Better stock management, fewer stock-outs/expiry
• Automatic and customized reporting	• Richer, more complete data (e.g., from barcoding)
• Enhanced safety (e.g., AEFI management)	• Augmented auditing and cost accounting
• Simple decision support (e.g., dose tracking)	• On the margin, much lower operating costs
• Enriched training, professional development	

Public health agencies are able to undertake more robust surveillance of both vaccine-preventable diseases and adverse events following immunizations. Data are more easily aggregated at the facility, district and national levels to enhance procurement and supply chain visibility. The procurement benefits include better demand forecasts.

5. Public and Population Health Information

Health information systems must take and use many thousands or even millions of individual EMRs to analyze patients and providers in the aggregate, "rolling up" different patient populations and subpopulations using various filters. They must also be able to "drill down" into thousands or millions of encounters, for example, to determine use of a particular medication.

This section begins by introducing interoperability and health information exchange (HIE). It then draws conceptual distinctions between three important ways to parse a known and well-defined patient or provider population: i) patient (or provider) registries, ii) patient panels, and iii) patient censuses. It applies these concepts in its description of civil registration and vital statistics (CRVS); and it concludes with brief explanations of population surveillance and household surveys.

A. Interoperability: Joining Secure Digital Identities with Health Information Exchange (HIE)

Section 3 of this primer begins by describing extraordinary recent progress in digital identification. While there will surely be sustained co-existence of paper-based and digital HIS far into the future, including an increasingly integrated role for paper HBR, the discussion that follows can reasonably assume that digital identification and digital HIS will increasingly replace paper. This transition will soon accelerate for at least a few LMICs and perhaps remain as far off as a decade for others; but in any event the shift will be soon enough that design and planning can begin to shift strongly toward building ubiquitous digital, person-centered HIS.

One lesson recurring throughout **Sections 3–6** is that digital systems must aim to do more than track individual patients and providers and keep their data together and intact. Digital technologies have already transformed immunizations, pathology, radiology, mobile communications and payments, and fintech (e.g., credit scoring and proof of insurance), for starters; and any letup in the remarkable pace of change seems unlikely. The information systems supporting all of these innovations have changed radically as well. Many of these changes will take some time to reach LMICs, but the diffusion may also come faster and more comprehensively than is generally thought. In any event, there is some urgency in anticipating, planning for, and where possible catalyzing these changes.

As such, beyond digital identification a top priority goal is HIS interoperability, which refers to the ability of two different information systems or devices to exchange data in all of their detail and thereafter present those data in ways that can be understood by end users. Interoperability's purpose, in turn, is to advance and support pervasive health information exchange (HIE)—to "collect once, use many"—and this must be the even grander ambition. Through HIE, data gathered for any one purpose also inform many other activities and decisions. The creation of a newborn's unique identifier, for example, can also establish an EMR, a direct link to the child's mother, an entry into the national birth registry, the opening of a record in the local and national IIS, and a claim for reimbursement from the provider to the patient's insurer. This child's data effortlessly combine with data from other newborns to create digital vaccine "due-lists" and default tracing for the local VQC, and the data help build local and national forecasts of vaccine demand for the coming year. These forecasts are then used to inform both logistics management and vaccine procurement.

Information exchange involves using the same parsimonious core data elements again and again, aggregated and disaggregated to meet the needs of diverse stakeholders. The return to this rigorous and systematic sharing of data involves much fuller amortization of the considerable expense of collecting the original data. When data are widely shared, demonstrable value compounds and health systems can afford to collect modestly more. The scrutiny that comes with more stakeholders using more of the same data for more tasks helps to improve data quality and confidence in the data, and in the ways they are aggregated, combined (e.g., in numerators and denominators of various metrics) and disseminated. Stakeholders whose data are being used regularly and systematically to make key decisions also become more invested in overall stewardship of information systems.

Moreover, data cannot be shared unless they are standardized, so that to assure clarity they mean the same thing in every setting; and so HIE fosters data standards, the use of master data (introduced throughout this primer and explained fully in **Section 8**), and fuller integration of both HIS and the clinical delivery systems that they support.

The overarching ambition of ubiquitous digitally driven HIE is simple, intuitive, and compelling. It can also be daunting. Disparate data assets coming from fragmented information silos must be connected using specific data fields that they share in common. (**Section 8** provides details on building relational databases.) These common fields must be populated in precisely the same way, using the same units of measure and standards and, if relevant, the same updated master data. A common facility data field cannot join two data sets, for example, if one uses a MFL that is up-to-date while the other uses a MFL that is three years old. Many facilities will not connect, definitions of other data fields will have changed, and so the join will not work.

Once data assets are joined, it may become obvious that many data are incomplete or incompatibly reported. One data silo may measure time in weeks, while another uses days. One data asset may use districts as geographic boundaries while others use cities and townships. Some data assets may reasonably insert "0" into any data field for which there is no reported value, whereas others, in an abundance of caution, leave those fields blank. The stewards of some data assets may diligently clean their data of errors and duplicates, whereas the stewards of other assets may not make that effort. Some data assets may overwrite old values once new values are reported (e.g., recording a patient's weight); others may keep both values; others may rarely go to the trouble of updating values.

The bringing together and "harmonization" of disparate data assets is a critically important first step, but it does not generally yield a "single version of the truth," as many management consultancies routinely promise. At the outset, at least, the combinations just as likely yield a hotly contested mess, with different stakeholders championing their own data assets and methods over others, if only because they have so much invested in their "legacy" systems and cannot easily or quickly change. Sorting out, remediating, and resolving differences takes time, resources, strong governance, and good will. Moreover, once data assets are joined and made interoperable, they must stay interoperable. There is much ongoing work required.

Information exchange also means aggregating and dis-aggregating records in many different ways, which is the focus of this section, without compromising privacy or leaving any valuable data behind. A trauma registry, for example, should not simply report out aggregated data (e.g., on patient counts and mortality) to end users. The detail on all patients making up the aggregates should be retrievable by those end users and linked directly to the data that each end user may have collected, so that anyone given access to this registry can drill back down from the aggregates, or perhaps recreate the detail from the original registry. Moreover, end users of this trauma registry should be able to filter their data by age, cohort, district, diagnosis code, or perhaps by survivors versus non-survivors. Data become more valuable if end users can pose their own queries and customize their own analyses.

Even beyond master data and compliance with standards, HIE requires a tractable number of UIs and APIs to enable and facilitate secure, high-impact collection and sharing of data. This may be the greatest challenge of all, as there will be many hundreds of different stakeholders asserting reasonable and often-necessary claims for broad, customized HIS access. LMIC HIS presently have very few of these UIs and APIs, indicating that data will remain "bottled up" for some time, even after interoperability has advanced significantly.

Finally, the core HIE concept of "collect once, use many" creates potential for market failure. Data ownership and control become diffuse and incompletely or ambiguously defined. Parties tasked with collecting data no longer serve one narrow, easily identified "use case." Instead they collect data on behalf of other stakeholders, and they go to the trouble and bear the expense of making their data interoperable with other systems. What is their incentive to take on this added responsibility and to conform when resources are already so stretched? Will they daily follow through? Will they invest adequately to improve their data over time? If they shirk, will other stakeholders even know? The moral hazard problems are large, clear and obvious, as are the "free rider" problems attending the many other stakeholders who benefit from these efforts but shoulder little of the effort or expense.

The most obvious remediation of this market failure may be to add funding for those who bear the direct costs of collecting data, financed through general funds (e.g., from the MoH), by donor organizations, or perhaps from a modest tax on most or all of the many beneficiaries. This may yield a sustainable business model, but the risks and pitfalls are also obvious. General and donor funding is already stretched and successful governance and administration of complex, comprehensive cross-subsidies is a dubious proposition under even ideal conditions.

An alternate business model cuts to the core idea of information *exchange*. It posits that the party tasked with collecting and supplying the primary data shall be given back actionable information from other end user beneficiaries that has a value commensurate with what the primary data collector is giving up. Under this arrangement every stakeholder creates and shares value, if not by collecting primary data then by transforming those data into more valuable information that benefits others. The constraint imposed by this business model is what has come to be known as the "WIFM" test—What's In It for Me? This test serves as a simple, across-the-board incentive compatibility constraint: each actor invests in information production and sharing in proportion to the difference between how much they benefit from doing so and how much this participation and sharing costs them. As a practical matter, the WIFM constraint is not everywhere met, and so some direct subsidies or mandates may be needed. Yet the WIFM mindset keeps the required subsidies manageable.

This core concept of information *exchange* is introduced at this juncture, because at this point attention shifts away from recording and organizing data on narrow and specific encounters between individual patients and providers. From this point in the primer forward, individual patient and provider data are aggregated into larger populations, supply chains, facility or MoH budgets, and so forth. The act of "rolling up" the data assumes some level of interoperability, and the discussion may give the impression that information flows only (or at least primarily) in one direction—from the patient and provider "up" to higher levels, with little of real value coming back in the other direction.

The aim here is to emphasize that information flows not one way but in many different directions, including back to the parties gathering and recording primary patient- and encounter-level data. In patient-centered HIS, primary data mostly originate at the point of care and so information starts by flowing "up" and out to other stakeholders. But customized information (or UIs with user initiated filters or queries) in large and actionable quantities must also come back "down," and in similar proportions. The reader is asked in all that follows to keep this multi-directional flow in mind and to ask what information (and UIs) patients and frontline health workers might value. Each section provides examples, but readers are encouraged to imagine many more opportunities.

These challenges—technical interoperability, secure and broad end user access to data (via more and better UIs), meaningful and ubiquitous sharing of data, and a sustainable business model—are only the *basic* requirements. Technological, operational, and practical hurdles to interoperability and HIE are falling away. Other challenges remain, but the time is right to begin planning for HIS that can provide the functionality and HIS components described in this section.

B. Patient Registries, Panels, and Censuses

Health care providers, public health agencies, and others must be able to identify and follow groups of individuals over time. A patient registry is "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes."[121] These are patient-level data routinely (not always) taken from individuals' EMRs. Using carefully and precisely defined inclusion and exclusion criteria, a registry may identify patients who have been diagnosed with cancer or a serious traumatic injury. A registry may track patients who have been immunized, given birth, or used a specific medication.

By construction a registry provides a longitudinal (i.e., historical) account. Its purposes may include but are not limited to the following:

- Describe the natural history of disease
- Determine clinical effectiveness or cost-effectiveness
- Measure or monitor safety and harm
- Measure quality of care
- Inform process improvement efforts
- Reinforce governance structures and accountability
- Secure accreditation
- Facilitate operations, capital budgeting, planning, staffing and human resources, and other management functions

In contrast, a patient panel (also drawn from patient EMRs) is a *contemporaneous* rather than longitudinal counting and accounting of a defined patient population. Panels are routinely constructed for operational or financial considerations, also with carefully articulated inclusion and exclusion criteria. A primary care physician, for example, may identify and track all patients with at least three office visits in the previous two years. This panel captures all (or perhaps nearly all) of the patients that this physician is actively managing.

The purposes of such a panel may include but are not limited to the following:

- Identify all patients for whom the physician has a professional relationship

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121   Registries for Evaluating Patient Outcomes: A User's Guide: 3rd Edition Addendum. AHRQ. March 2018.

- Measure and understand both individual and aggregate patient needs

- Improve patient surveillance, manage individual patient relationships, and over time improve the continuity of patient care

- Improve patient outreach and education

- Measure operational and clinical performance, as well as ongoing patient health and outcomes

- Determine if/when to hire another provider, add staff, or otherwise increase services or capacity

- Forecast and manage demand and scheduling both day-by-day and long-term

- Negotiate better reimbursement with insurance companies

- Inform and guide effective practice planning and business strategy

- Determine when to close, restrict, or open the panel to new patients

The payoffs from utilizing patient panels include surer and more timely patient access to care, more appropriate utilization by patients of the physician's capacity, and fuller amortization of fixed costs.

Finally, a patient census involves a specific counting of patients who are actively engaged in care and co-located at a particular moment in time, for example, as inpatients at a particular hospital.

In short, there are various simple and proven ways to identify and track groups of similarly situated patients. EMRs offer invaluable ways to create and thereafter leverage registries, panels, and censuses.

C. Civil Registration and Vital Statistics (CRVS)

Governments have various interests in collecting data on the significant events that may occur at any point during the lifetimes of residents of its country. They may seek to record the events themselves, along with relevant characteristics of these events (e.g., cause of death[122]). These events may include:

- Births
- Deaths

- Fetal Deaths
- Marriages

- Divorces
- Annulment of Marriage

- Adoption
- Change of Name

The process of gathering these data is called "civil registration." Thereafter governments compile, analyze, present, and disseminate data surrounding these acts in a system of "vital statistics." Together they comprise a data infrastructure known as civil registration and vital statistics (CRVS). Country governments need comprehensive (though perhaps simple) CRVS to know who lives within their borders, how they live and die, and how they are related to one another and to the state.

Registration is typically the responsibility of local governments through officials or units known as local civil registrars (LCRs). The actual task of recording these acts usually falls to hospitals, clinics, rural health units, funeral homes, health professionals who attend these events, clergy, and various other actors. Civil registration enables countries to maintain a continuous and complete record, including historical, of all of these vital acts.

Civil registration in high-income countries has evolved over three centuries, beginning with church registries. International standards and guidelines for setting up civil registration systems have been developed by United Nations agencies,[123] with the premise that the establishment of fully functional CVRS may require several decades. The World Health Organization (WHO) estimates that nearly half of the world's children still go

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122   WHO Application of ICD-10 for low-resource settings initial cause of death collection. The Startup Mortality List (ICD-10-SMoL) V2.1. World Health Organization. 2018.

123   Principles and recommendations for a vital statistics system, Revision 3. United Nations, 2014.

unregistered and that globally, two-thirds (38 million) of 56 million annual deaths are not registered.[124] Where civil registration is not possible, censuses, household surveys, and sample registration can be used to generate estimates, but these estimates in practice are often uncertain and dated; and they rarely provide details, such as causes of death.

D. Health Surveys and Public Health Surveillance

Often it is impractical or too costly to take a full accounting of an entire patient panel, registry, or population. In these instances, health surveys can provide an expedient and economical alternative to: estimate prevalence of illnesses, risk factors, or behaviors; monitor various types of interventions; take stock of community atti-tudes; or measure trends in health and disease outcomes. Health surveys can query individuals, households, facilities, or occasionally other stakeholders, such as commodities manufacturers and other vendors. There are many standardized, proven formats (several discussed below) capable of collecting data simply and cost-effectively from a large number of respondents, often remotely through online, mobile, email, or telephone communications.

An individual or household survey involves the systematic collection of data from a statistically representative sample of individuals. Individual surveys usually take the form of standardized questionnaires that include socioeconomic variables such as age, gender, education, income level, marital status, occupation, and family size; as well as various measures (some possibly subjective) of each individual's overall health status. Health facility surveys collect a range of facts surrounding clinical, operational, administrative, financial, or public health activities.

There are many kinds of surveys. For example, a cross-sectional survey profiles a single population at one spe-cific point in time, whereas a group comparison survey compares two distinct populations at roughly the same time. Longitudinal surveys track changes in populations over the course of time.

Early public health surveys from the 1970s and 1980s collected demographic, fertility and family planning data. This was done through World Fertility Surveys and Contraceptive Prevalence Surveys funded by the United Nations, USAID, and the UK Overseas Development Administration.[125] To expand upon these, the United States Agency for International Development (USAID) worked with others to launch the Demographic and Health Surveys (DHS) project in 1984.[126] To date more than 300 DHS surveys in more than 90 countries have been conducted. Additional DHS modules cover other subjects, including human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), malaria, reproductive health, child mortality, immunization and survival, nutrition among women and children, and domestic violence.[127] The DHS Program aims to improve and institutionalize data for LMIC monitoring and evaluation and for policy development decisions;

Other organizations also have expertise with surveys, including WHO, which uses surveys to collect and pro-duce national health indicators[128] and statistics in its Global Health Observatory.[129] WHO provides a repository of surveys with the goal of expanding access to and use of survey data[130] and many other data, as well.[131] The United Nations Children's Fund developed Multiple Indicator Cluster Surveys (MICS) to profile the situations

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124   Civil registration: why counting births and deaths is important. Fact Sheet 324. World Health Organization. May 2014.

125   Anderson JE and Cleland JG. The World Fertility Survey and Contraceptive Prevalence Surveys: A Comparison of Substantive Results. Population Council. Studies in Family Planning, Vol. 15, No. 1 (Jan.–Feb., 1984), pp. 1-13.

126   Corsi DJ, Neuman M, Finlay JE, Subramanian SV. Demographic and health surveys: a profile. Int J Epidemiol. 2012 Dec;41(6):1602-13. doi: 10.1093/ije/dys184. Epub 2012 Nov 12. https://doi.org/10.1093/ije/dys184.

127   https://dhsprogram.com/

128   Global Reference List of 100 Core Health Indicators, 2018. World Health Organization (WHO).

129   http://www.who.int/gho/en/

130   Central Microdata Catalog. World Health Organization (WHO). http://microdata.worldbank.org/index.php/catalog.

131   Data Catalog. World Health Organization (WHO) Open Data Initiative. https://data.worldbank.org/data-catalog.

of women and children, with a total of six rounds to date, beginning in 1995–1996 and thereafter in 2000, 2006, 2011–2013, 2012, and 2016. The MICS resemble DHS, with technical assistance and implementation often proceeding in close collaboration.

Whereas surveys are one-off or discrete efforts to profile a population, WHO defines public health surveillance as "the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice."[132]

6. Financial and Administrative Information

In LMICs, patient- and provider-level information systems described previously hold huge potential to guide the management of health care systems and to coordinate care. Yet EMRs, in particular, are designed and dedicated to inform the care of individual patients rather than to aid in running a national health care system, and HRIS, MFL, and even an extensive catalog of PPE provides only a baseline inventory of the stock of physical and human capital. More information is needed to meet the financial and administrative requirements of well-functioning local, regional, and national health systems. This section describes some of the more important financial and administrative HIS.

A. Health Care Providers' Administrative Claims and Methods for Cost Recovery

The concept of an administrative claim is usually attached to "fee-for-service" reimbursement. By submitting such claims, each health care provider bills patients for the care that these patients receive. These providers thereby obtain payments, possibly from several sources (e.g., insurance plus patient co-pays). Patient-by-patient and encounter-by-encounter, a service is rendered, a claim is generated and submitted, costs are accounted for, and fees are collected (or recorded as not).

In LMICs, such cost recovery is routinely inconsistent, whether by this mechanism or through other means. Patient insurance remains uncommon and the out-of-pocket payments that patients often make are made in cash at the point and time of care, and as such rarely tracked. Global health agencies have shown little commitment to building the administrative infrastructure that would be necessary to create or intermediate such claims. A survey of the sources cited throughout this study, as well as a thorough search of leading agencies' websites or even a broad Internet search would turn up no groundswell for LMIC investments in administrative claims infrastructure.

Lack of attention to claims data often leaves a gaping hole in LMICs' HIS. As a practical matter, patient-by-patient and encounter-by-encounter claims are necessary under any cost recovery system, and not just fee-for-service. Put differently, claims administration is a necessary precursor—the backbone—of managerial accounting functions whether reimbursement comes via fee-for-service methods, universal health coverage (UHC), or other means (e.g., allocating costs against an annual facility budget). Claims also provide the most important financial and operational control available to run any care provider's organization. It is implausible, for example, to design a fiscally functional health insurance infrastructure in any LMIC without rigorous and reasonably complete claims data, as well as processes, business models, and governance structures for exchanging claims data, scrutinizing and validating them, and assigning responsibility for paying.

In practice, claims data (where they operate effectively) also serve as a critical source of important data elements for other information systems. In high-income countries, for example, the codes that providers apply to document individual patients' diagnoses and procedures (e.g., via the International Classification of Diseases, or ICD) and thereby to establish medical necessity are also used routinely to populate EMRs. As another

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132   http://www.who.int/topics/public_health_surveillance/en/

example, claims data are indispensable to process improvement efforts and to care coordination, because they confirm that a patient has presented, that services have been rendered, and (often) that plans have been made to extend and manage care (e.g., through a referral).

Because providers have keen incentives to submit complete and accurate claims—otherwise they cannot recover their costs—these data are also among the most credible available. More generally, claims data provide the most comprehensive and reliable means to track patients as they proceed through the health system and to match patient activity to the health systems' available capacities and resources. Claims data, where available, are among the most valuable applications of the basic data management principle of "collect once, use many."[133]

B. Health Management Information Systems (HMIS)

Even a small hospital in high-income countries generates huge volumes of administrative data, much of it standalone and in silos. Table 1 lists examples of hospital data sources and the infrastructure required to maintain them.[134] These silos share (or at least should share) data fields in common, and these commonalities make it possible to join and integrate otherwise separate data streams. Yet even in high-income countries efforts to link them have been frustrated historically by incompatible hardware or software, inconsistent measures or terminology, a dearth of tools and methods to access and exchange this information, or a lack of expertise or even awareness of the bridges among the many domains. The information is not, in a word, interoperable between and among silos.

TABLE 1:
Examples of Health IT for Hospitals and Physicians

Administrative and Financial
Billing
General Ledger
Patient Registration
Admission-Discharge-Transfer (ADT) System
Patient Scheduling
Personnel and Payroll
Materials Management

Clinical
Computerized Provider Order Entry
Electronic Medical Record
Picture Archiving and Communication Systems (PACS) for Filmless Imaging
Results Reporting of Laboratory and Other Tests
Clinical Decision Support Systems
Prescription Drug Fulfillment, Error-Alert, Transcriptions
Electronic Monitoring of Patients in ICUs
Clinicians' Online References and Clinical Guidelines/Protocols
Electronic Prescribing
Email/Text Communications with Patients

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133   Cimino JJ. Collect once, use many. Enabling the reuse of clinical data through controlled terminologies. J AHIMA. 2007;78(2):24–9.

134   Report to the Congress: New Approaches in Medicare. Chapter 7: Information Technology in Health Care. Medicare Payment Advisory Commission. June 2004. (Adapted modestly from Table 7-1.)

Infrastructure
Desktop, Laptop, Cart-Based, and Tablet Computers
Servers and Networks
Wireless Networks
Smartphones and Other Handheld Devices
Voice Recognition Systems (e.g., for Transcription)
Bar-Coding Technologies and Sensors
Information Security Systems

Hospitals are the largest organizations in a broad array of healthcare provider types, each using different sources and widely ranging media. Provider ownership and control can be highly fragmented. Some individuals may see dozens of different providers and pay for care in various ways (insurance, co-pays, out-of-pocket). Provider data link to payer data (so that the latter may compensate the former). Data also come and go from vendors, suppliers, public health agencies, and census data (e.g. for marketing, planning or outreach).

Of course, HMIS in LMIC must pare back on and greatly simplify some of this infrastructure, and yet the World Health Organization (WHO) has a remarkably mature and impressive open source toolkit to guide LMIC governments toward quite similar HMIS ends.135 Its OpenClinic, for example, "is an open source integrated hospital information management system covering management of administrative, financial, clinical, lab, x-ray, pharmacy, meals distribution and other data, [along with] extensive statistical and reporting capabilities."

C. District Health Information Software (Version 2, DHIS2) as HMIS Digital Platform

Many of us quite reasonably think of HIS hardware, software, data, ICT platforms and surrounding architectures and infrastructure as all one and the same, with application programming interfaces (API) on the "back end" and user interfaces (UI) on the "front end" combining everything into "HIS writ large." Still, these various elements are quasi independent and separable even as they are each indispensable for the larger undertaking. Data can be deployed from different hardware or software platforms and yet serve the same ends, for example, and provide similar insights. The lens used in this study focuses on data architectures, asking how are the underlying data elements organized and linked?

In practice, of course, these data architectures are mixed with other features of these HIS. In the realm of HMIS, one important integration of these various HIS elements is District Health Information System, Version 2 (DHIS2). This product combines software, data architectures, and an ICT platform. It represents the work of many collaborators and originates from the Health Information Systems Programme (HISP) based at the Department of Informatics at the University of Oslo. DHIS2 is managed and coordinated from there.

As the leading information platform in LMIC, it may be helpful to think of DHIS2 as first and foremost a HMIS. Indeed the DHIS2 website represents DHIS2 as "the preferred health management information system in 47 countries and 23 organizations across four continents."136 In its original scope, dating to the late 1990s, DHIS2 was mostly limited to routine primary health center data, including routine facility data, staffing, and equipment.

Yet over time the platform and capabilities have expanded systematically and impressively, to the extent that it has become much more than a HMIS. At points the DHIS2 website depicts DHIS2 (consistent with its name) as "free and open source software," and elsewhere as a platform for "national health information systems."

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135   Health facility & community data toolkit. World Health Organization. 2014.

136   https://www.dhis2.org.

D. Mobile Data and Payments, Claims Adjudication and Financial Intermediation

Within the past several years many of the world's LMICs have achieved an abrupt leap forward in their potentials for documenting, storing and exchanging data, including individualized, encounter-based data. The adoption of inexpensive smart phones and other mobile devices and apps can now put information systems within reach of most stakeholders in countless settings, often in real or near-real time. Tens or hundreds of millions of smartphone users will come on line each year for years to come. Data costs have plummeted, with more dramatic declines imminent. Functionality has soared. As Apple CEO Tim Cook asserts, "[O]ver time every person in the world will have a smartphone."[137]

In many LMICs, smartphones have been ubiquitous for perhaps five years, allowing technologies to come to market, capture users, and build outward. To illustrate, consider this account of 2015 China mobile technology from the Economist magazine:[138]

> [T]here is nothing outside China that offers WeChat's combination of features. It has over 700m monthly users, and combines messaging, voice calls, browsing, gaming and payments. It can be used for everything from paying parking tickets to booking a hospital appointment, ordering food or paying for a cup of coffee. WeChat is not so much an app as an entire mobile operating system …
>
> WeChat … is not the only example. Alibaba kick-started Chinese e-commerce with the clever trick of holding payments in escrow, helping buyers and sellers establish trust. It now offers services that exploit its vast customer database, including credit-scoring, digital marketing, and vetting visa applicants and users of dating sites. Didi's ride-hailing app [which arranged 1.4 billion rides in 2015 alone] includes novel features such as on-demand bus services and the option to request a test-drive of a new car. Sina Weibo, the Chinese equivalent of Twitter, has a built-in payments system and supports premium content, both features that Twitter lacks. With revenue from payments, virtual goods and gaming, Chinese internet firms are also much less dependent on online ads than Western rivals.

China has made great progress in the three years since this account, and significant advances are ongoing in many emerging markets.[139,140] At the close of 2016 there were an estimated 3.3 billion Internet users worldwide, with sustained growth still approaching 10% annually. India Internet users alone climbed to 277 million in 2015, a 40% increase over 2014 and nearly double 2013. The number of smartphone users worldwide is only modestly behind and growing even faster,[141] in short order appearing to converge to levels exhibited in high-income countries such as the US.[142] A September 2016 McKinsey Global Institute (MGI) report estimates that African smartphone penetration will rise from 18% in 2015 to 50% by 2020,[143] and that "electronic payments are sweeping across the region." The report singles out East Africa, Nigeria, and South Africa.

This connectivity will be critically important not only for administering mobile payments and care providers' claims but also for building and *scaling* other forms of financial intermediation, including but not limited to third-party remittances, credit, health insurance, and scheduling of patient care.

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137   McGregor J. Tim Cook, the interview: Running Apple 'is sort of a lonely job.' Washington Post. August 13, 2016.

138   China's Tech Trailblazers. The Economist. August 6, 2016.

139   Aglinby J. Safaricom banks strong growth as mobiles become tool of life. Financial Times. May 11, 2016.

140   Aglionby J. Fintech takes off in Africa as lenders tap mobile technology. Financial Times, May 16, 2016.

141   Internet 2016—Code Conference. Mary Meeker, Kleiner Perkins Caufield Byers. 1 June 2016. Accessed online May 2017: http://www.kpcb.com/internet-trends.

142   Smith A. U.S. Smartphone Use in 2015. Pew Research Center. April 1, 2015.

143   Lions on the Move II: Realizing the Potential of Africa's Economies, MGI, September 2016. Accessed October 2016: http://www.mckinsey.com/global-themes/middle-east-and-africa/realizing-the-potential-of-africas-economies. MGI uses forecasts from The mobile economy: Sub-Saharan Africa 2015, GSMA, 2015; UN Population Division.

E. HIS for Bundled Care, Risk-Sharing, Essential Benefits, and Health Insurance

In LMICs, if health care providers generate direct revenue for the patient services that they render, it is typically through a "fee-for-service" transaction, meaning out-of-pocket cash from the patient or an encounter-based reimbursement from a government or third-party insurer covering visits individually. Yet mobile payments, fintech, and simple, interoperable EMRs and HRIS enable other options.

To illustrate, the table below shows costs and payments for a hypothetical newborn. Suppose that the parent pays the provider $7 to cover all costs for childbirth (this is basic fee-for-service) and at the same time an additional $2 to enroll the newborn in an immunization program (thereby committing to the bundle). Thereafter, the parent pays $1 for each of three rounds of immunization, well below the $17 total cost of providing them. This table shows how the government and a donor organization can partner to split the $12 subsidy evenly, and to time the payments to cover providers' costs exactly as they are incurred.

	Provider Cost	Parent Pays	Government Pays	Donor Pays
Childbirth	$7	$9	-$2	
Immunization 1	$1	$1		
Immunization 2	$5	$1	$2	$2
Immunization 3	$11	$1	$6	$4
Total:	**$24**	**$12**	**$6**	**$6**

Rather than price each encounter separately, an intermediary bundles the four encounters for each of four stakeholders. The package costs $24 to supply, with nearly half of this, $11, attributable to just the last of the three vaccine rounds. The bundle could be arranged with patients never paying anything at the point of care. Mobile payments allow the intermediary to uncouple fees charged onsite from the underlying costs of providing services rendered and to schedule payments in various ways. Simple, interoperable EMRs and HMIS allow the patient to switch providers at any point.

Most important, the arrangement can use a premium charge on one transaction (e.g., childbirth) to secure patient buy-in and also help finance others (Immunization 3). The government and donor can target subsidies more narrowly and effectively. Overall, a bundle such as this greatly expands the possibilities for organizing and underwriting the costs of care.

The required technology includes only simple EMRs and HRIS and a mobile payments mechanism. In this simple example, at least, these three HIS components are both necessary and sufficient. Without enduring, longitudinal EMRs and HRIS there would be no way even to construct the bundle. There is no practicable means other than EMRs and HRIS to string encounters together, and if encounters cannot be linked, then even rudimentary bundling of the sort described here is foreclosed.

Yet once the basic EMR-HRIS framework is in place, the same data used to populate that EMR over time suffices to submit four separate claims for mobile payment. Of course, more complex arrangements may require additional data. For example, a third-party payer (government, donor organization, or perhaps private insurer) may insist upon fuller documentation around the facility (e.g., from the MFL) to ensure that the claims being made come from a licensed or accredited provider. To repeat, though, the basic elements of bundling do not require an elaborate HIS infrastructure. They demand little more infrastructure or functionality than Amazon or Alibaba would require to sell toothpaste or bicycle tires in these same settings.

This illustration expands nearly without end, because bundling opens up so many pricing tools. It is a short leap to extend the bundle to cover antenatal, well baby, or primary care. Bundled care is not the same as health insurance, but it can mitigate risks, for example, by securing a defined but uncertain set of services at a fixed

price (e.g., up to six annual visits in a primary care bundle). Subsidies from governments or donor organizations can cap the total paid by any patient or create other avenues for cost sharing. If EMRs hold enough information on patients' incomes, payments can even be "means-tested," enabling government and donor subsidies to target patients who are most vulnerable.

F. Other Technology Stacks and Fintech Implications for HIS

Financial innovation extends far beyond using mobile payment methods encounter-by-encounter. To take the broadest possible view, a **technology stack** is a set of software components, programming languages, and integrating interfaces (called application program interfaces, or APIs) that together comprise a complete and integrated platform (often an operating system) for running applications or services. Each layer builds onto features of other layers, thereby creating a stack. Stacks have front-ends and back-ends. The back ends are crucial, of course, but end users see and interact with the stack using only the front-end interface, often through a web browser or a mobile app. Other applications may also "run on top" of the platform, but to the end user all come together in a seamless service.

Technology stacks are ubiquitous and include, for example, Uber, Dropbox, Pinterest, Yelp, and Spotify. Each of these solutions offers up to end users a compelling front-end interface that wraps around a bundle of software tools. These and many other technology stacks have also enabled a range of services that would not otherwise be possible in spot (i.e., one-off "cash") markets or traditional brick-and-mortar retail settings; and they scale to an unlimited number of users at rapidly falling costs.

Fintech refers to those technology stacks that specifically support or enable **banking and financial services.** In its early days (just a few years ago), fintech was employed mostly by banks and other financial institutions to shore up the back ends of their businesses. Increasingly, though, fintech is disrupting all aspects of financial services, beginning with mobile payments, money transfers, and loans, but soon extending to most aspects of business and commerce.

Among the many stunning aspects of fintech is its remarkably *small* scale, among both innovators and adopters, with financial *dis*-intermediation a critical competitive advantage of many successful fintech firms. Dis-intermediation involves taking one or a very narrow financial services, unbundling them from the hundreds of other services that banks have historically offered, and supplying just those narrow services to customers.

It would be difficult to exaggerate how abrupt and prodigious this fintech/dis-intermediation revolution has been, even in its infancy. Over many decades, economies of scale and scope among financial intermediaries have been overwhelming, increasingly rendering all but the largest banks, insurers, and others uncompetitive. As evidence, for example, the world's largest publicly traded corporations are all banks, as are the largest corporations country-by-country throughout much of the world. In just the past few years, though, thousands of fintech startups, nearly all small and agile at the outset, have sought to "cherry pick" specific aspects of these banks' services (i.e., dis-intermediating); and in many cases they are turning their simple innovations into viable businesses. Collectively, these relatively small fintech startups suddenly pose an existential threat to the world's financial behemoths.

The reason for broaching fintech and technology stacks in a primer on LMIC HIS is not to point to specific applications but rather to raise awareness of the tsunami of innovation that will be coming over the next few years. These innovations will have direct and substantial implications for health care services. Writing on the nascent fintech services offered in emerging markets, experts routinely focus narrowly on just two services, mobile payments and credit. But the more expansive reporting on fintech in high-income countries foreshadows what is likely imminent in emerging markets, as well. Some of the new functionality is quite simple, such as i) consumers being able to check their account balances and move funds easily between them; and ii) better, fuller, and perhaps simpler disclosures, so that individuals better understand the competing financial services that they

are purchasing and the terms on which they are doing so. Many other fintech developing innovations may seem one or more steps removed from the consumer (as when apps leverage enormous pools of cloud-based data to search for or evaluate available options or to guide decision-making) but are also high potential.[144]

7. Supply Chain Information

Supply chains span the value-added flows of materials, final goods, finances and related information from upstream production (e.g., factories) through to downstream consumers. A firm's supply chain enlists many different actors, including its suppliers, resellers, transportation providers, third-party logistics and financial intermediaries, and final consumers.

Put simply, a supply chain leader manages the buying and delivery of goods or services on behalf of a company or client. This is accomplished by: i) securing the best commercial terms possible with all actors (while building strong relationships); ii) efficiently coordinating storage and inbound and outbound transportation (including, for example, tracking all consignments); iii) keeping people and goods safe and secure; and iv) building cost-effective supply chain information systems.

A large enterprise's supply chain management is typically a highly complex undertaking requiring resources and expertise from a broad array of actors, many of them operating independently of that enterprise. Day-to-day management covers purchases of goods and services, maintenance of physical infrastructure (e.g., trucks and warehouses) and coordination of ongoing activities (transportation and storage). Management longer term includes strategic planning, relationship building, human resources and professional/workforce development, legal and regulatory proficiencies, development of advanced technologies, and capital investments.

Supply chains aim for efficient fulfillment of demand, exceptional customer value, enhanced organizational responsiveness, strong network resiliency, and maximum financial success. Generically, specific supply chain functions usually include:[145]

- Sourcing[146] – Strategic needs identification and analysis; thereafter scouting/locating a single provider (or short list of providers) as the best and least-expensive supplier for goods or services.

- Procurement – Negotiation and setting of terms (e.g., through a formal tendering or bidding process) for purchasing and taking title to (and possession of) goods and services, including policies and standards for quality, timeliness, packaging, and other essential elements.

- Quantification – Estimation of monthly, quarterly and annual quantities demanded for all health commodities at key distribution and end points throughout the supply chain (e.g., central stores, regional and district warehouses, and last-mile service SDPs).

- Requisition and Ordering – Structuring of a standardized format (sometimes using paper forms) by which health care workers request and then submit purchase orders (PO) for specific goods or services, including such details as the particular item(s) requested, date of the request, individual and department making the request, and location where the goods should be delivered.

- Storage and Warehousing – The safe, secure positioning of inventories proximate to distribution points and consumers so that orders can be fulfilled quickly and efficiently.

- Transport – Safe, secure and efficient movement of inventories throughout the supply chain, from sources all the way through to final consumers.

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144   Brainard L. Where Do Consumers Fit in the Fintech Stack? Remarks presented at the University of Michigan Conference "FinTech Risks and Opportunities: An Interdisciplinary Approach." November 16, 2017.

145   World Health Organization (WHO), PATH. Integration of Vaccine Supply Chains with Other Health Commodities Supply Chains: A Framework for Decision-Making. Seattle, WA: WHO, PATH; 2013.

146   Cavinato JL. Supply Management Defined. Institute for Supply Chain Management. January 2010.

This section describes two information systems critical to getting essential health commodities from the manufacturing facility to in-country central medical stores and ultimately on to retail pharmacies and last-mile service delivery points. The section concludes with the outlines of a "control tower" approach for organizing and controlling ever more complex supply chains.

A. Logistics Management Information Systems (LMIS)

At the core of all supply chains are logistics management information systems (LMIS). These provide a structured arrangement of records and reports that are used to capture, aggregate, organize, analyze, validate and visualize the data required to manage a commodities supply chain. This management spans procurement, the movement and storage of raw materials, parts and finished inventories through the supply chain, fulfillment of orders, and an extended (and growing) list of other functions. To be more concrete, a bare bones LMIS is tasked with tracking a small set of measures on a relatively few commodities, and specifically these elements:[147]

- Sources of supply
- Products distributed
- Number of levels in the system
- Number and types of facilities at each level

- Types of delivery points (e.g., clinic)
- Storage capacities and constraints
- Type of inventory control system
- Maximum/minimum stock levels

- Periodicity of orders/deliveries
- Lead times
- Inter-facility transport modes/ mechanisms
- Management/supervision structure of the distribution system

The data collected include "beginning and ending balances, quantities received, quantities issued, quantities distributed to clients, consumption, lead time, losses and adjustments, quantities needed."

In short, the LMIS provides timely and accurate information that stakeholders need to perform their supply chain roles. Important stakeholders include donors and governments, suppliers of raw materials, commodities manufacturers, in-country program managers at ministries of health and central medical stores, managers at regional distribution centers and point-of-care facilities, and clinicians and patients. Logistics and LMIS primers for non-technical readers are readily available.[148]

Supply chains for health commodities are complex and to date largely dis-integrated due to their highly diverse array of supply- and demand-side characteristics. Each set of commodities has historically had its own supply chain arrangements—for example, for vaccines, medications for acute conditions (e.g., malaria), medications for chronic conditions (HIV/AIDS), family planning, laboratory specimens and testing, and so forth.[149] In 2011, the WHO looked across thirteen countries to find an average of 18 distinct procurement agencies in each country and 84 distribution channels.[150] Having commodities- and disease-specific supply chains has enabled a tighter alignment of logistics with program strategies, but with the tradeoff that such dis-aggregation leads to greater complexity and redundancy even as it forecloses efficiencies, for example, from economies of scale and scope. To date, efforts to integrate these fragmented commodities supply chains have usually come up short.

Among various initiatives taking place in LMIS, three merit close attention here. First, the most advanced and promising investment in LMIS is the OpenLMIS initiative, which describes itself as "a collaboration of domain

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147   John Snow, Inc. Family Planning Logistics Management (FPLM). 2000 Logistics Management Information System Assessment Guidelines. Arlington, Va.: FPLM/John Snow, Inc., for the U.S. Agency for International Development.

148   USAID | DELIVER PROJECT, Task Order 1. 2011. The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities. Arlington, Va.: USAID | DELIVER PROJECT, Task Order 1. Second edition (First edition 1998).

149   World Health Organization (WHO), PATH. Integration of Vaccine Supply Chains with Other Health Commodity Supply Chains: A framework for decision-making. Seattle, WA: WHO, PATH; 2013.

150   Yadav P, Tata HL, Babaley M. Supply Chain Management, World Medicines Situation Report 2011. Geneva: World Health Organization (WHO); 2011.

experts in logistics and supply chains, eHealth information systems, software development for low-resource settings, and process improvement."[151] Its aims to cover "LMIS planning, requirements and system design, and promoting interoperability between systems."

Second, the Visibility & Analytics Networks (VAN) Project through 'policy, process, technology and end-to-end visibility aims to make the supply chain more collaborative, aligned, agile, and demand-driven.'[152] This project is recent but well-funded and gaining traction in various LMIC settings. Third, RxSolution is an electronic pharmaceutical management system used specifically for medications. It has been applied at more than 200 sites in five African countries.[153]

B. Next-Generation Logistics Management Information Systems (LMIS) for Vaccines

If one supply chain stands out for its own consideration, it is vaccines. As background, few vaccines were available anywhere in the world until the 1960s. In 1966 the WHO launched a global campaign to end smallpox, and within two decades it had been eradicated. More generally and by various accounts, vaccines have long been 'the most effective and cost-effective health tool ever invented,'[154] recently averting an estimated two to three million deaths each year.[155,156] Vaccines are inexpensive and straightforward to administer. Vaccine supply chains are among the oldest, most ambitious, highest-impact, and complex of all health commodities supply chains.

One key distinguishing feature of vaccines is that they require cold chain storage (to protect from both heat and freezing) from the time they leave the manufacturing facility through the last mile and to the point of use, even in remote areas. Cold storage requirements create complexity and dramatically raise the prospect of bottlenecks and other logistical issues. Innovations to address these issues include, for example, equipment to refrigerate vaccines, methods to monitor exposure of vaccines to heat during transport and storage, and measures to record and communicate temperatures in vaccines stores.[157] Innovation is ongoing, of course, and many other vexing challenges remain. These include workforce and management training, equipment maintenance and repair, and overcoming the lack of reliable electricity to power equipment in many remote areas.

The Expanded Program on Immunization (EPI)[158] was established in 1974 to ensure that infants, children and mothers have access to routinely recommended vaccines. The EPI offers a set of standard procedures with the aim of achieving high coverage for specific vaccines.

Gavi, the Vaccine Alliance, was created in 2000 to bring together public and private actors with the aim of creating equitable access to new and underused vaccines for children living in the world's poorest countries.[159] The WHO's ambitious Global Vaccine Action Plan (GVAP) 2011–2020, a collaborative effort of many immunization experts and stakeholders, was endorsed by 194 Member States of the World Health Assembly in May 2012.[160] This

151   http://openlmis.org/.

152   Goel V, Llewellyn E. Visibility & Analytics Networks (VAN) Project Blueprint Reference Document. Accenture Development Partnerships on behalf of the Bill & Melinda Gates Foundation. 2015.

153   http://siapsprogram.org/tools-and-guidance/rxsolution/.

154   Gates B. Annual Letter 2011. Bill and Melinda Gates Foundation. https://www.gatesfoundation.org/Who-We-Are/Resources-and-Media/Annual-Letters-List/Annual-Letter-2011.

155   WHO Fact Sheet on Immunization. http://www.who.int/mediacentre/factsheets/fs378/en/.

156   Ozawa S, Clark S, Portnoy A, Grewal S, Brenzel L, Walker DG. Return on investment from childhood immunization in low- and middle-income countries, 2011–20. Health Aff (Millwood). 2016;35:199–207. 10.1377/hlthaff.2015.1086.

157   Lloyd J and Cheyne J. The Origins of the Vaccine Cold Chain and a Glimpse of the Future. Vaccine. 2017;35:2115-2120.

158   World Health Organization (WHO). The Expanded Programme on Immunization. http://www.who.int/immunization/programmes_systems/supply_chain/benefits_of_immunization/en/

159   Brooks A, Habimana D, Huckerby G. Making the leap into the next generation: A commentary on how Gavi, the Vaccine Alliance is supporting countries' supply chain transformations in 2016–2020. Vaccine 2017;35(17):2110–4.

160   World Health Organization (WHO). Global Vaccine Action Plan 2011–2020.

plan frames the "Decade of Vaccines."[161] It provides the foundation for advancing vaccine access and rigorous means for monitoring and evaluation of the plan's progress.[162] This includes the Effective Vaccine Management (EVM) initiative, launched by WHO and UNICEF in 2010, to help countries evaluate the performance of their immunization supply chains.[163] The EVM offers an assessment tool around standards in nine areas of vaccine management that together cover all crucial supply chain components:

1. Vaccine arrival procedures

2. Vaccine storage temperatures

3. Cold storage capacity

4. Buildings, cold chain equipment and transport

5. Maintenance of cold chain equipment and transport

6. Stock management

7. Effective vaccine delivery

8. Vaccine management practices

9. Information systems and supportive management systems

The EVM also offers guidelines and technical assistance for improvement. By 2014, over 70 LMICs had assessed their immunization supply chains using EVM. Furthermore, WHO lists and summarizes 86 national multi-year plans for immunization (cMYP) as of March 2016.[164]

Notwithstanding these impressive advances and national planning frameworks, progress in vaccine coverage has come up short of the global health community's remarkably ambitious goals, both across countries and also within—and specifically in rural areas and among the poorest, vulnerable, and most marginalized communities. The introduction of new vaccines has added to costs and increased the logistical burdens on supply chains that are already oversubscribed.

The Strategic Advisory Group of Experts (SAGE) on Immunization, the WHO's principal advisory group, writes this as part of its 2017 summary:[165]

> Progress therefore still remains too slow for most goals to be reached by the end of the Decade of Vaccines in 2020. … As the Decade of Vaccines draws to a close, there is a need to intensify global efforts to promote immunization and to address the systemic weaknesses that are limiting equitable access to life-saving and life-changing vaccines …

Gavi has authored an updated strategic plan covering 2016–2020.[166] It is based on five fundamentals: 1) supply chain leadership, 2) data for management, 3) better cold chain equipment, 4) continuous improvement plans, and 5) system design.[167] The plan encourages countries to design flexible, adaptable "next-generation" immunization supply chains driven by evidence-based decision-making.

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161   http://www.who.int/immunization/global_vaccine_action_plan/DoV_GVAP_2012_2020/en/

162   http://www.who.int/immunization/global_vaccine_action_plan/en/

163   WHO/UNICEF Joint Statement. Achieving Immunization Targets with the Comprehensive Effective Vaccine Management Framework. http://www.who.int/immunization/documents/general/WHO_IVB_16.09/en/.

164   http://www.who.int/immunization/programmes_systems/financing/countries/en/

165   2017 Assessment Report of the Global Vaccine Action Plan Strategic Advisory Group of Experts on Immunization. Geneva: World Health Organization; 2017.

166   Gavi. Supply and Procurement Strategy 2016–20. http://www.gavi.org/library/publications/gavi-fact-sheets/gavi-supply-chain-strategy/.

167   PATH. Investing in Next-Generation Health Supply Chains Saves Lives. http://www.path.org/publications/files/APP_iscl_fs_en.pdf.

With this background in mind, what specific contributions can vaccines LMIS offer in meeting the urgent need to design and implement next-generation vaccine supply chains? The organizations, programs, initiatives, and joint statements highlighted here (and in **Section 4.E** on immunization information systems) all stress the importance of "data" in transforming vaccines supply chains into their next generation. The February 2016 Addis Declaration (see **Section 4.D**), for example, calls for "the strengthening of data collection, reporting, and use at all levels …" The widely championed concept of "data for management" has been well summarized recently as follows:[168]

> The continuous improvement process also relies on data visibility across the whole supply chain. Today many countries still rely on largely paper-based data collection systems, based on few quality standards, collected and processed once per month and flowing in just one direction. With rapidly flowing, more robust data will come better precision and efficiency across the full system, which in turn will help to simplify the work of healthcare staff, saving time and money. For example, accurate stock information and tracking helps to reduce vaccine wastage and missed opportunities to vaccinate, which in turn safeguards country and Gavi investments in vaccines, helping deliver their full value. The Vaccine Alliance has defined new norms to standardise how supply chain key performance indicators are defined and calculated. These "dashboards for immunisation supply chains" began roll-out in 2015, and come with comprehensive guidance for data standards as well as complete reference sheets for the choice of data indicators, better facilitating the work of the end users.

> Better data must, in turn, flow through effective logistics management information systems (LMIS). The Vaccine Alliance is currently evaluating options for data standardisation across countries and this information will help to shape the market for appropriate information systems. These efforts will also help ensure the interoperability of LMIS with health information systems. In this way—irrespective of data maturity—countries will be able to collect critical supply chain data points to inform better decision-making and policy development. Efforts around LMIS also contribute to the Alliance's wider strategic focus on country health management information systems and sustainability.

Toward these ends, and specifically in service of interoperating and integrating LMIS with other HIS, consider once again the extraordinary recent advances in digital identification outlined in **Section 3.A** and the patient- and provider-centered immunization information systems (IIS) described in **Sections 4.D** and **4.E**. Through the BID Initiative and other programs these IIS offer abrupt and quantum leaps, not only from paper to electronic systems, but just as important to highly detailed and dis-aggregated data on each and every patient, provider, and vaccine dose; and all reinforced with master data (e.g., barcoding), geographic information systems (GIS), and other HIS infrastructure.

To start, therefore, it would be a straightforward, relatively rapid undertaking to merge IIS and vaccines LMIS, with direct logistical payoffs around quantification, for example, and stock management. The larger aim of integrating vaccines supply chains with other supply chains is also accelerated by making integration of these specific information systems a first and top priority:[128]

> When looking at integration across product categories distributed by the same company, we find that even when physical supply chains are segmented and separate, there is a common information architecture that allows multiple unique supply chains to reconcile their inventory status, physical flow, and financial information at the highest level.

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168   Brooks A, Habimana D, Huckerby G. Making the leap into the next generation: A commentary on how Gavi, the Vaccine Alliance is supporting countries' supply chain transformations in 2016–2020. Vaccine 2017;35(17):2110–4.

This sort of integration has the potential to transform vaccines supply chains so that they are soon "patient-centered" in every key respect and focused, as well, on streamlining point-of-care processes and enhancing the productivity and effectiveness of frontline health workers.

C. Hospital and Health Systems Materials Management Information Systems (MMIS)

By convention, health commodities supply chains conclude at the final facility's loading dock. Thereafter, internal movements of various medical supplies—within and throughout a hospital campus, for example—enter the realm of what is known as "materials management," usually run by a dedicated team of hospital employees working closely with the hospital's medical professionals. Yet the internal commodities flows are so large, expansive and complex logistically that materials managers often refer to them as "internal supply chains," and in ways that indicate that the loading dock offers an entirely arbitrary divide.169 The functions, performance metrics (e.g., around stock outs and expiry), methods and expertise are much the same whether the commodities are being moved from factory to loading dock or from loading dock to bedside.

Indeed, effective materials management requires clear visibility into upstream supply chains and conversely, which implies in turn that materials management information systems (MMIS) must interoperate seamlessly with LMIS. To start, for example, both information systems must draw upon the same master product files. Moreover, the MMIS must interoperate with various other hospital-based information systems (PIS, LIS, RIS, EMR, NPI, MPI, CPOE, …) so that, as a second example, a dose of insulin ordered for a particular patient by a specific prescriber and administered by yet another medical professional can be tracked in all relevant dimensions, including the batch and manufacturing facility.

D. Health Commodities Supply Chain Control Towers and Visibility Analytics Networks (VAN)

Across many industries manufacturers' global supply chains have grown unworkably large and complex, with many tasks and functions outsourced to third parties—contract manufacturers, various suppliers, transportation carriers, logistics providers, and other intermediaries and niche service providers. To make the work even harder, supply chain managers must meet rising expectations that their services are omnichannel, two-way, secure, low-cost and efficient, profitable, environmentally and socially responsible, and responsive in real time to changing circumstances. Many supply chains are also expected to integrate and contribute significantly and company-wide to other management functions, including but not limited to prescriptive and predictive analytics, financial reporting, and corporate regulatory compliance.

Many manufacturers are recently using supply chain "control towers" as a platform to address this complexity and better manage all of these many demands. This control tower concept has also been adopted for public health commodities supply chains, where the common term is "visibility analytics networks" (VAN). Notwithstanding some basic conceptual confusion (e.g., a network conveys a sense of distributed resources and decision-making, whereas a control tower focuses narrowly on hubs of centralized information and authority), the global health community is launching this control tower concept in various LMICs' health commodities supply chains.170

Unfortunately, explanations of both airport control towers and supply chain VAN are neither clear nor consistent across sources. The aim in this section is to stay true to this control tower idea while providing intuition and practical details. Toward this end, begin with this definition:

169   Guida R, Iannone R, Miranda S, and Sarno S. Hospital Materials Management: Information Flow Integration towards Optimization. In book: 1st Annual Global Healthcare Conference (GHC 2012), Publisher: Global Science and Technology Forum, pp.65–70. August 2012. DOI: 10.5176/2251-3833_GHC12.57.

170   Sarley D, Mahmud M, Idris J, Osunkiyesi M, Dibosa-Osadolor O, Okebukola P, and Wiwa O. Transforming vaccines supply chains in Nigeria. Vaccine. 2017 Apr 19;35(17):2167-2174. doi: 10.1016/j.vaccine.2016.11.068.

> A control tower is a **nexus** of information, communication technologies, APIs and UIs, people, processes and policies, together tasked with bringing data visibility and effective supply chain governance across and throughout multiple local network nodes.

This definition captures much that is common to most definitions of control towers, except perhaps that it replaces the emphasis on centralization and hubs with a "nexus" of control. Nexus can mean "the central and most important point or place," but it can also be defined as "a connection or series of connections linking two or more things." Nexus is a more neutral term than "centralized." It is also the term that grounds much of the modern-day theory of the firm,[171] which has the potential to offer many practical as well as intellectual insights into the control tower framework.

To embellish, imagine an airport control tower that interfaces using APIs and UIs with many data sources (e.g., the weather service) and also with pilots and flight attendants using cockpit instrument panels and audio links. Other UIs connect and engage other local network nodes with the control tower and one another. These nodes include airport personnel: gate attendants, baggage handlers, ticket takers, maintenance crews, the caterers restocking planes with food, and so forth. Passengers awaiting flights have their own UIs, both within the airport and en route (e.g., using mobile apps).

Much data and decision-making are indeed centralized inside the airport control tower. Airports have high-cost and fixed capacities. To meet commercial and operational imperatives, airports must therefore wield tight control. Even momentary delays have huge cumulative costs, and yet with such closely sequenced takeoffs and landings, coordination must be failsafe with very small margins for error. Thus, centralized data, control, accountability and decision rights all align closely in the tower.

Still, centralization of data and decision-making is not the defining feature even of airport control towers. For example, pilots gather and input their own data and make local decisions; and if an airplane part or flight system is not working, the maintenance crew has visibility to the issue and the immediate and definitive power to make decisions. Put simply, the control tower delegates many responsibilities to better-situated local nodes.

Given the vast work to be done, and the prospect for error, how else could the control tower be organized? In real time the control tower is intermediating information, processes, policies and key decisions using APIs and UIs that are tailored to the specific needs of local and specialized experts. The tower is routinely and expediently *controlling* inputs and outputs rather than itself gathering every bit of data and making all decisions.

More generally, the extent to which information and authority are centralized or disseminated is dictated by circumstances. Health commodities supply chains exhibit very different economic features (e.g., health commodities costs are mostly variable and it is errors made at the SDP that can be fatal). As such, information and decisions must be **patient**-centered. Since patients are highly dispersed, all of them residing at the end of "the last mile," decision-making must also be dispersed.

Still, absent the focus on "centralization," the control tower metaphor remains especially useful for health commodities supply chains. Crucial to the concept are 1) end-to-end data **visibility** across all HIS and 2) effective network **control**. Control does not require a centralized party to make each important decision one at a time, or to have authority to do so. It is better to have *ex ante* alignment of localized decisions through agreed upon policies, processes, and procedures (these are the controls!); and thereafter, effective coordination and communication of decisions by local actors. This is best achieved through fully interoperable HIS, effective health information exchange, and tightly linked connections. The control tower's purpose is to intermediate

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171   Jensen MC and Meckling WH. The Theory of the Firm: Managerial Behavior, Agency Costs, and Ownership Structure, 3 J.Fin. Econ. 305. 1976.

flows of data and decisions that pass throughout the network and to push passively for compliance with standard treatment guidelines, master data standards, and other critical elements (more controls!) of integrated delivery systems.

8. Imported and Manufactured Information

Previous sections have described these types of information systems: patient and provider (**Sections 3** and **4**), public and population health (**Section 5**), financial and administrative (**Section 6**), and supply chain and procurement (**Section 7**). These add up to an impressive collection of health data assets. Yet there is much more. The data described in this section are imported from outside sources or manufactured from other data.

To start, it is helpful to parse all HIS data into five data categories: i) transactional, ii) master, iii) hierarchical, iv) metadata, and v) unstructured. This section explains master data, hierarchical data, and metadata. First, though, as the name implies, transactional data relate to the specific interactions among stakeholders anywhere within the scope of a country's broad HIS infrastructure. When we think of health care data, we often imagine transactional data. Transactional data answer basic questions about what happened in a particular interaction. Who were the patient and provider? What were the time and place? What laboratory results were reported? What medications were prescribed? How much, if anything, did the patient pay for the visit? And so forth.

Unstructured data, also as the name suggests, offers a catchall for data that are not formally organized or integrated into formal information systems, such as emails and other communications.

The discussion here is around basics. It targets a broad, non-technical audience. A full description is beyond this primer's scope but is available elsewhere, and the explanations below aim to summarize and distill one of the best short explanations of master data available.[172]

A. Master Data and Hierarchical Data

Examples of master data appear throughout this primer, and there are various definitions of master data in the literature. As a start, it may be helpful to think of master data as lists of 'the critical nouns of an enterprise or system, usually falling into [one of] four groups—people, things, places, and concepts.'117 A core driver of master data is HIE and specifically the need for repeated re-use of specific nouns across many APIs and UIs. Precisely because master data are widely and routinely shared across applications and among many end users, they need to be standardized. When one user (or application) shares master data with other users (or applications), all parties know that other parties have a precise and common understanding of what these nouns mean. Toward this end, master data should come with careful documentation (e.g., data dictionaries, measures, and sources).

This primer has already described master data in lists naming and describing people (e.g., MPIs and NPIs), clinical venues (MFL), and property, plant and equipment (PPE). More master data lists—of places, diseases and disorders, medications, vaccines, procedures, essential benefits, commodities, laboratory tests, treatments, and medical terms come from hundreds of sources.

Various "back office" APIs also import master data from many sources, including for example, the World Health Organization, GS1 (for bar coding),[173] and the International Organization for Standardization (ISO).[174] Master

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172 Wolter R and Haselden K. The what, why, and how of master data management. Microsoft Development Network Library. November 2006. https://msdn.microsoft.com/en-us/library/bb190163.aspx.

173 https://www.gs1.org/barcodes

174 https://www.iso.org/home.html

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data also include thousands of standardized metrics, such as the WHO's Global Health Observatory data repository, which includes global health statistics as well as health master data.[175] The University of Michigan maintains a similar repository.[176]

Finally, master data are pouring in from outside health care and merging with HIS. These surround digital identification, geographical information systems (GIS), mobile payments, other private sector fintech, the IoT, and much more.

Master data require disciplined management. Consider an illustration. For its own purposes, every SDP should keep track of all of its equipment, including the number and key characteristics (e.g., manufacturer and age) of computers and handheld devices. But no one outside of Facility A needs an exhaustive list of every computer that A owns. These are of little concern to others. Yet there may be a few critical pieces of equipment at Facility A that many stakeholders might like to know about, such as laboratory and imaging equipment (e.g., x-ray). For example, if a CHW can access a reliable list of critically important imaging equipment, facility-by-facility, on her mobile phone, then she can better triage the patient who may have fractured his leg and is in need of an x-ray that is not available nearby. Before sending her patient on a long trip to Facility A, she may want to know that A's equipment is available and in good working order, and the hours during which a technician is staffed.

The illustration shows that data are typically chosen to be master data because of their clinical, operational, or business attributes. Some data do not need to be standardized or widely shared. Other data should be used and reused—and with the same meaning to all interested parties. Because master data management is imperative, difficult, and often resource-intensive, good master data stewardship and strong governance must be a priority.

Master data are a linchpin of HIS and of health information exchange (HIE). They help to streamline data sharing and are indispensable elements of interoperability and information systems integration. As integration, interoperability and HIE jump start in many LMICs, governments, donor organizations and other global health actors can expect inexorable, rapidly growing demand for master data among diverse end user communities, most without formal training or prior HIS experience but intrinsic stakes and keen interest.

Notwithstanding the great challenges, the upside potential is huge. Suppose, for example, that health workers reference the same facilities, essential medicines, disease codes, and treatment guidelines over and over again using simple apps and UIs on their mobile devices; and that they join these master data to their own customized and dis-aggregated patient-, provider-, and encounter-level (transactional) data using just a few apps on their mobile devices. Because the master data are collected once and used many times, these workers become expert, confident in these data's reliability, and over time vested in making both the master data and the transactional data better.

Indeed, it is this interaction that makes HIS work. In much of their daily work, many stakeholders use the same master data again and again, combining them in most instances with transactional data:

> "Master data can be described by the way that it interacts with other data. For example, in transaction systems, master data is almost always involved with transactional data. A *customer* buys a *product*. A *vendor* sells a *part,* and a *partner* delivers a crate of materials to a *location*. An *employee* is hierarchically related to their *manager,* who reports up through a *manager* (another *employee*). A product may be a part of multiple hierarchies describing their placement within a *store*. This relationship between *master data* and *transactional data* may be fundamentally viewed as a noun/verb relationship. Transactional data capture the verbs, such as sale, delivery, purchase, email, and revocation. Master data are the nouns."

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175   http://apps.who.int/gho/data/node.home

176   http://guides.lib.umich.edu/healthstats

In this architecture, hierarchical data detail the relationships between and among the master data.

After a brief description of metadata, the balance of this section highlights just a few of the thousands of important master data sets used within HIS, many of them important for "front end" user interfaces (UIs) but others crucial for "back office" applications that end users rarely see. Other examples of master data (e.g., master facility lists and patient indexes) appear throughout this primer.

B. Metadata

Literally, metadata means "data about data." Metadata describe other data, explain their structure, or help to manage data. Some metadata may have their own formal repository, but much metadata are everywhere and take many forms. For any given data within an information system, there may be metadata about the underlying data:

- Name
- Creation
- Definitions
- Type (e.g., document)
- Location

- Purpose
- Topic
- Features
- Format
- Attributes

- Log Files
- Owner
- Accessibility
- History
- Configuration

- Allowed Values
- Default Values
- Data Maintenance
- Sources
- Uses

Metadata summarizes basic information. Metadata make finding, sharing and working with particular instances of other data much easier and more productive. Metadata may be set entirely apart from data, but occasionally they are mixed in with the data, as is the case with "markup languages."

The distinctions between metadata and the data that they describe can be ambiguous and as a practical matter not necessarily important, since metadata are often generated, stored, and deployed just as other data (e.g., in relational data bases).

C. Geographic Information Systems (GIS)

As a first source of master data, consider geographic information systems (GIS), which span any digitally based information system that edits, analyzes, stores, and displays geographic information. GIS, put simply, is about spatial locations on a map. This information can be specified in many ways, such as latitude and longitude, address, postal code, district, region or country. Technologically, GIS is enabled by global positioning systems (GPS), which determine the position of an object on earth's surface. GIS users typically use GPS to gather data. In recent years even inexpensive mobile phones have embedded rudimentary but effective GPS technology, so that GIS data has become ubiquitous and essentially costless.

Increasingly inexpensive, accurate, and detailed, GIS computer software can layer buildings, rivers, roads, political boundaries and various other landmarks and link their locations to descriptive information. It can establish distances between locations and (combined with other software) determine optimal transit routes and travel times.

D. Diagnosis and Procedure Coding

The World Health Organization (WHO) has been maintaining lists classifying diseases and causes of death since 1893. Its International Classification of Diseases (ICD) is in its 10th version (May 1990) and the 11th version is due to be finalized in 2018.[177] The ICD's purpose is to be the comprehensive international standard for defining, collecting, classifying, processing, and reporting data on diseases and health conditions. ICD-10 enables a

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177   International Classification of Diseases and Related Health Problems. World Health Organization. http://www.who.int/classifications/icd/en/.

common language for health information systems even as the ICD itself has been translated into 43 languages. ICD-10 is the standard for all clinical, research, and commercial uses, including medical record keeping, disease monitoring and surveillance, claims reporting and reimbursement, registries of births, deaths, immunizations, and other public health data, and much more. Its users span nearly all medical and public health professions.

The ICD provides a system of diagnostic codes, including sub-classifications covering indications, symptoms, abnormal findings, and external causes. Health conditions are grouped into generic categories so that major categories include a set of similar diseases.

It is worth mentioning that there are various methods for coding *procedures,* including the ICD-10 Procedure Coding System (ICD-10-PCS), newly development by the United States National Center for Health Statistics (NCHS).[178] There are also readily available—free and in the public domain—classification systems and much other intellectual property to add to these troves of master data.[179]

E. The Systematized Nomenclature of Medicine (SNOMED), Health Level 7 International (HL7), and Clinical Data Architectures (CDA)

In order for the different and often separate components of HIS to communicate and understand one another, they must share a common language. The Systematized Nomenclature of Medicine (SNOMED) provides this language.[180] SNOMED is a multilingual, comprehensive collection of medical and healthcare terminology spanning clinical findings, symptoms, diagnoses, procedures, body structures, organisms and other etiologies, substances, pharmaceuticals, devices and specimens. It is fundamental to interoperability and information exchange, and also to organizing, standardizing, and managing HIS. This nomenclature is maintained by SNOMED International, an international non-profit standards development organization.

Health Level 7 International (HL7) is a not-for-profit organization that provides international standards for *transferring* clinical and administrative data between software applications.[181] HL7 refers to the framework for the actual exchange, integration, sharing, and retrieval of electronic data, including for example, methods for packaging and sending data from one party to another.

As part of HL7, Clinical Document Architecture (CDA) is a flexible standard for structuring documents, such as discharge summaries and progress notes, which often contain relatively unstructured text, images, and other media. CDA provides building blocks to capture, store, access, display and electronically exchange data elements in many different formats. It greatly facilitates document management and in turn the compilation of documents into each patient's EMR.

9. Collect Once, Use Many: Integrating Health Information Systems

Even the short list of important data assets and HIS outlined in this primer's table of contents may seem overwhelming, especially to non-technical readers. This section offers up reasons for optimism and basic guidelines for keeping investments in HIS reasonable and the overall effort manageable.

A. Relational Databases, Automated Data Entry, and HIS Integration

It is important to visualize how these HIS might all join together, because the legacy of paper records in LMICs may create the sense that all of the many data assets described here would require an enormous and ongoing amount of time simply to input data. But if HIS are built on sound principles, with a "lean" mindset and full

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178   Centers for Medicare & Medicaid Services (CMS). ICD-10-PCS Reference Manual. 2017. https://www.cms.gov/Medicare/Coding/ICD10/downloads/pcs_refman.pdf

179   US Agency for Healthcare Research and Quality. Healthcare Cost and Utilization Project.

180   https://www.snomed.org/

181   http://www.hl7.org/index.cfm

integration ("collect once, use many"), then a modest investment can yield impressive results. The imperative for those who design and implement these HIS is to keep the data inputs simple, small, structured and each with a broad purpose. Specifically, HIS architects must strictly limit the overall number of base data fields, use standardized ICD codes, include drop down menus to guide the inputs, make all HIS interoperable, and thereafter leverage data collected once for multiple well-defined ends. These ends must have clear and demonstrable payoffs to a broad spectrum of stakeholders, and especially payoffs to those providers and patients at the service delivery point (SDP) who bear the cost of inputting these data. Data collected locally must (and can) have significant payoffs to local providers and patients. For all those tasked with inputting data, the effort must (and can) pass the WIFM test—what's in it for me?—so that their efforts are reliable and credible.

The most likely approach for organizing, integrating, and deploying these HIS is through simple and "lean" relational databases anchored in EMRs. For those who are unfamiliar, relational data are organized in a set of tables that can be accessed and reassembled in many different ways using a structured query language (SQL).

The basic concept of a relational database can be explained using a simple illustration. Imagine that the two tables below are extracted from an EMR and HRIS, respectively. Jane Lee lives in Ann Arbor, Michigan, USA with health insurance coverage from United Health, a large national company. Jane seeks out antenatal care from Elaine Lee, a local nurse practitioner. Data on the patient and provider appear in separate tables, with fields that include (but are not limited) to Tables 2 and 3:

TABLES 2 AND 3
Hypothetical Elements Included in the EMR and HRIS

EMR Field	Patient Data	HRIS Field	HRIS
Patient ID	98-7654	Clinician ID	A9X65
Last Name	Doe	Last Name	Lee
First Name	Jane	First Name	Elaine
Street Address	111 Main Street	Specialty	Nurse Practitioner
City	Ann Arbor	Licensed?	Limited License
State	Michigan	Certified?	Yes
Postal Code	48104	Employer	Ann Arbor Hospital
Insurance Plan	UH 0341A	Employer ID	XYZ999

The unique patient and clinician IDs serve as the linchpin for all other data relationships. At the outset of their first antenatal encounter, Jane provides her patient ID, 98-7654, which Elaine enters into her mobile device. ***This one input is all that needs to be done*** to open wide all of the information in both tables (including dozens or even hundreds of elements from each table not listed here), since Jane's clinician ID, A9X65, is already stored on that device. Thus, a single entry establishes the patient, insurer, clinician, and employer. It is not necessary to input any other information, since the other fields in Tables 2 and 3 have been pre-populated and permanently and automatically linked.

Since Jane has her own pre-existing EMR, the patient ID links to yet another table with Jane's problem list, medications, and so forth. (If Jane does not yet have her own EMR, the software automatically opens a few new tables to provide her with one.) Elaine may undertake a brief history and physical and enter in additional information (e.g., blood pressure).

After evaluating Jane, Elaine then inputs just a handful of ICD diagnosis and procedure codes from a set of perhaps 100 options. The codes each link to two other tables that provide unique diagnosis and procedure descriptors, such as "basic ultrasound." If patient Jane requires a new medication, a standardized code and dosage can be entered manually (or automatically if the prescription is filled at the SDP and the package has a bar code), and these link to yet another table holding the INN and EML (both are master data on medications).

Throughout this encounter, drop down menus and other HIS functionality guide Elaine's workup with Jane, helping to ensure that Elaine gathers all basic information and that the medications she orders are consistent with the diagnoses she documents.

Using GIS, Elaine's mobile device automatically identifies the encounter location, and this confirms the specific SDP, which is described in yet another table, which is generated from the MFL and PPE. Rich data on that SDP are thereby made available. The mobile device also inserts the date and time.

At the end of their encounter, Elaine uses these same data fields—no incremental data are necessary—to generate an administrative claim to secure compensation for services rendered and medicines ordered, or to charge the attendant costs against a facility or operating unit budget. Her incentives to document all work carefully extend beyond the immediate financial payoff to span patient safety, continuity of care, inventory control, and risk management (i.e., professional liability/malpractice). All data needed to inform basic analytics around these basic functions are already collected, and relational databases make pivoting the data around these functions quick, simple and costless.

Months later, a reasonably complete account of childbirth for both mother and newborn is also possible, again with just a few data inputs into Elaine's mobile device. Elaine again inputs Jane's unique ID. Again, GIS and MFL location data effortlessly and automatically unlock a tractable number of fields describing the venue (e.g., patient residence, birthing clinic, hospital). A mobile or Internet link (asynchronous if there is no immediate connectivity) updates the mother's EMR, produces a new EMR and electronic birth certificate for the newborn, and opens an entry, as well, in the country's birth and immunization registries. The EMRs of all family members are also linked and with the same fields the mobile device generates another claim for reimbursement or cost recovery.

With only a few additional keystrokes Elaine can use the mobile device to schedule follow up care (or create a prompt for later), and then order or document medications, contraceptives, or other commodities. Any orders can be logged at the same time into the LMIS in real or near-real time.

Elaine's employer or facility administrator has short-term incentives to assist in this documentation, for example, to recover the costs of medicines and equipment such as the ultrasound. Long term, this administrator can pivot the data tables to demonstrate that the ultrasound equipment is well utilized, that medicines are well administered, and that reimbursement or allocated revenues, category by-category, are sufficient (or in some cases not) to cover costs. Doing so has direct positive implications for the facility's operating budget and helps to make the case for incremental capital investments.

The simple financial machinery unfolds in parallel with care delivery. Just before Elaine takes Jane on as a patient, Jane supplies Elaine with digital proof of health insurance or an electronic credit score (or both) and perhaps a down payment using her phone. An electronic means is established for payments coming from Jane, her insurer, third-party remittances, or some combination of all. As Elaine and Jane enter into a months- or years-long relationship, these measures ensure payment to Elaine long term and documentation showing at each step that Jane has paid. This is invaluable at the outset even if Jane pays for each encounter immediately at the point of service.

If Elaine's financial incentives underlying all of this documentation are inadequate to get her full buy in (i.e., the arrangement fails the WIFM test), then third parties such as insurers or government agencies can make a small transfer to Elaine's mobile bank account, for example, each time Elaine enters a newborn into the national birth registry. Elaine can thereby recoup any prior investment in hardware or training in a reasonable time, and on the margin the payment thereafter ensures that Elaine is committed to collecting good data.

The imperative for building out HIS is to focus relentlessly on a parsimonious approach. Consider, for example, a bare bones EMR infrastructure launched solely for antenatal care and childbirth (and thereafter updated as

children are immunized and mothers present for postnatal care and family planning). Focusing only on young women and their children to start yields a trove of information. Because countries with high birth rates nearly all rank among the world's low-income states, roughly half of these countries' residents would have a functional and rigorous EMR within fifteen years.[182]

The aim in putting forward this example is not to make what would surely be a "moonshot" appear simple or assured. Rather it is to put structure around building out fully integrated, functional, and useful HIS. The narrative: i) puts EMRs at the center of HIS; ii) grounds the venture in concrete public health and patient care systems (maternal and newborn care); iii) references specific, concrete, intuitive, and useful links from EMRs to LMIS, CRVS, HRIS, HMIS and other HIS, so that there is not simply interoperability (i.e., a navigable pathway from one HIS component to the next) but also a clear demonstration that data collected once for the EMR end up being used for dozens of other purposes; and iv) sets forth both a local payoff to patients and their caregivers and overall return on investment and a critical timeline (i.e., all children and one half or more of the total population with an EMR within fifteen years). The required technology—and in particular mobile or Internet connectivity, possibly asynchronous—is sufficiently mature in many countries to aspire to a near-term rollout. In all of its design and implementation dimensions the effort resembles the HIS of high-income countries, so that over time, decades perhaps, these parsimonious LMIC HIS can mature and take on added features and functionality using IP that is already proven and in the public domain.

B. Transitioning to Patient-Centered HIS

This primer thus far lays out many HIS components and describes how they inter-relate and work once they are all up and running. Yet precisely because interoperable and integrated HIS are so mutually reliant on each individual piece, there is a clear and potentially debilitating "weakest link" dilemma. In the absence of a HRIS, for example, any kind of e-prescribing would seem to be foreclosed, since authorities cannot allow just anyone to log in and start ordering medications. Since e-prescribing relies upon dozens of components and many master data sets, one might reasonably conclude that each component is useless until all are ready. The obvious question arises: How could we launch HIS until every individual component has been fully formed in advance?

More generally, beyond digital identification and EMRs for all, which HIS components must have priority? How do we move from a landscape that for decades has had no visibility to individual patients and providers to one that is systematically and comprehensively patient-centered?

The thesis here is that these questions are backwards, because they picture HIS first and mostly in the abstract. Clinical delivery systems are taken up only after each HIS component is designed, built, and integrated. This ambition is too grand. The necessary resources and technologies would overwhelm. The more expedient approach is to design clinical delivery systems first and then ask this question: "What *incremental* HIS components are needed to make the clinical delivery system work well?"

The description of paper-based immunization systems in **Section 4.D** and the follow on discussion of relational databases in **Section 9.A** demonstrate the potential for this approach. These sections describe the short time elapsed, numerous patient encounters and intense but high "value for money" resource utilization beginning at the time that a woman registers her pregnancy and concluding with a full round of early childhood immunizations roughly eighteen months later. In most LMICs, the systems of care are already in place, but the paper-based HIS that support them are inadequate.

With the innovations recently taking place in digital identification, digitalization of record-keeping and ICT more generally, suppose that we ask how best to improve upon perinatal care, immunization programs, and

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182 Example: Uganda has a median age of 16 years, a birth rate of 43/1,000, and a population growth rate of 3.2%. The newborns and mothers with this hypothetical EMR would add up to one half of Uganda's total population in 12 years. (CIA World Factbook: https://www.cia.gov/library/publications/the-world-factbook/geos/ug.html.)

early childhood programs. The focus to start is on the clinical delivery systems and the step-by-step workflow under the *status quo,* with local care providers fully involved in the clinical redesign at all stages. What steps can be streamlined? Where can resources be saved? How can existing services improve? What new services do these innovations enable? And then … what data are needed to do all of this?

This appears to be exactly how the architects of the Better Immunization Data (BID) Initiative have proceeded.[92] Throughout the BID Initiative's Product Vision document, there is great interest in the overlap between the data collected on paper for IIS and data needed to advance better i) perinatal care, ii) individual EMRs, iii) birth registries and CVRS, and iv) national identification programs.

As a second example, consider South Africa's Central Chronic Medicine Dispensing and Distribution (CCMDD) program, which serves chronic stable patients whose care management consists of bi-annual clinic visits and check-ups. Rather than ask patients to travel to health facilities and wait hours to collect their medications each month between visits, as has often been the case in the past, the CCMDD allows patients to obtain medications at community pick up points (PUPs). To work, the CCMDD demands rigorous ongoing coordination, surveillance, and patient documentation, including their individual medical diagnoses, medications, prescribers, clinic visits and PUPs.

This new arrangement profoundly enriches underlying HIS and LMIS. For the first time, there is clear visibility to patients beginning at the initial point of care, contemporaneously (for the original purpose of dispensing medications), longitudinally, and extending end-to-end throughout the supply chain. Over time, the CCMDD's electronic prescribing platform will store cumulative records on each stable patient that would be sufficient on its own to enable simple, quasi-complete EMRs for millions of South Africans.[183] This prescribing platform also integrates a basic but rigorous human resource information system (HRIS) that allows logon and access only to qualified prescribers. As such, it provides invaluable opportunities to collate and analyze prescriber patterns by type of training and clinical venue. The clinical delivery system comes first; the data roll in; and only thereafter do the architects begin developing UIs and APIs that enable many different end users to have EMR, HRIS, or HMIS portals and access.

Other HIS initiatives will benefit from a similar focus first on clinical delivery. Before designing radiology or laboratory information systems, for example, it is helpful to ask how they will be deployed. What imaging modalities are involved (e.g., in ambulatory settings perhaps only x-rays and ultrasound to start), and what type and volume of laboratory tests are anticipated? Put simply, HIS should be designed to meet the direct and immediate needs of patients and caregivers.

10. The Urgency of Principled Stewardship of Patient-Centered LMIC HIS

"Today [in 2005] we find ourselves in the paradoxical situation in which a large unmet need for reliable information coexists with considerable investment of effort and resources in data collection."[184]

Ten years ago, great momentum was building for investments in reliable and comprehensive LMIC HIS, and there was a keen sense within the global health community of truly massive unmet needs. A decade later, it would be difficult to exaggerate the worldwide level of interest, the cumulative progress made, or the huge and imminent potential for HIS lying just ahead. A dearth of data is giving way to a data deluge, as HIS investments and broader technological innovations such as digital identification and mobile payments are showing tangible results.

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183   South African National Department of Health: Use of Electronic Prescribing and Master Data. YouTube Video. May 2017.

184   Zahr C, Boerma T. Health information systems: the foundations of public health. Bull World Health Organ 2005; 83: 578–83.

This primer has inventoried the major components of LMIC HIS, including a concise landscape for each component, and all together the primer offers a fundamentally optimistic, quasi-comprehensive near-term narrative. The breadth and depth of these individual HIS, the accelerating progress along many so-far mostly distinct pathways, and the potential for these pathways to converge are stunning.

The urgent needs of these LMIC HIS going forward are also coming into clearer focus; and this must be a welcome development for key decision-makers who must commit even greater resources as they build consensus around how to proceed. There are now recognizable starting points: digital identification and ubiquitous mobile telephony together make it possible to 1) *count every person.* Also, digital identification can 2) *set up universal EMRs and HRIS,* which can in turn 3) *provide the basic building blocks for other integrated and interoperable HIS component.*

This approach defines what is meant by patient-centered health systems: digitally identify every patient, enable enduring EMRs and HRIS, and from this foundation inform all other HIS components. These EMRs and HRIS are obviously not the sole sources of information and they may not even come first; but they are the nexus long term around which other HIS components revolve.

By juxtaposing all of these HIS components, this primer shows the relationships and substantial HIS overlap data element-by-data element. When a newborn is given an EMR, the same data create a record in the national birth registry and feed other CRVS tables; they open up a pre-populated digital record for that child in the nation's IIS; and they aggregate upward with other birth records to create reliable local, regional and national forecasts several years ahead for vaccine procurement. These EMR-based IIS should inform LMIS and VAN and ground other supply chain data (and not only vaccine supply chains). As each vaccine is thereafter delivered and administered, a swipe of the barcode fills in the child's immunization record and EMR, updates the immunization registry and supply chain forecast at the MoH, logs the provider's identity and activities into the HRIS, and generates an administrative claim for the local provider's HMIS. A simple GIS physically locates and time-stamps the encounter. Master data from many different sources enrich these assets even more.

Of course, opportunities may not unfold as quickly as the primer's narrative describes. There are risks, because along these individual pathways any number of forces could create volatility and uncertainty, delay forward progress, create bottlenecks, or otherwise impede progress. Visibility into patient-level data will show up pervasive problems that have been present throughout but previously unseen, including medication errors and adverse drug events. (These must be urgently addressed as soon as they become known.) Yet the technologies are all in place in late 2017; they continue to disseminate, improve, and fall in cost; and the recent past suggests that the global health community like the world at large may be as likely to underestimate the scale-scope-pace of change as it is to exaggerate it.