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Designing an Antibiotics Resistance (ABR) monitoring system to strengthen the evidence base for facilitating responsible antibiotics prescription by physicians: A case study from India

Yogita Thakral
University of Oslo, yogitat@ifi.uio.no

Sundeep Sahay
University of Oslo, sundeeps@ifi.uio.no

Arunima Mukherjee
Department of Informatics, University of Oslo, Norway, arunimam@ifi.ui.no

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Completed Research Paper

Yogita Thakral
HISP Centre and Department of Informatics, University of Oslo[1]
HISP India, New Delhi, India[2]
Gaustadalléen 30, 0373 Oslo, Norway
yogitat@ifi.uio.no

Sundeep Sahay
Department of Informatics, University of Oslo[1]
HISP India, New Delhi, India[2]
Gaustadalléen 30, 0373 Oslo, Norway
sundeeps@ifi.uio.no

Arunima Mukherjee
HISP Centre and Department of Informatics, University of Oslo[1]
HISP India, New Delhi, India[2]
Gaustadalléen 30, 0373 Oslo, Norway
arunimam@ifi.uio.no

Abstract

Antimicrobial resistance is described as a global health emergency, particularly affecting low and middle-income countries. A key strategy to engage with this challenge is effective monitoring to improve knowledge and support evidence-based interventions. However, LMICs lack the capacity, resources, infrastructure, and culture to implement digital interventions. To engage with this challenge, empirical work is carried out within the context of a public hospital in India to study the problem of antibiotics use followed by the design, implementation, and use of an AMR monitoring system and associated challenges in its digitization. An ADR approach is used to guide the design of the system to facilitate responsible antibiotic prescriptions by physicians. Three broad design principles are proposed which can help guide future implementation efforts for other contexts. This paper makes an important contribution to IS research of immense societal value, in informing how the potential of the digital can be effectively materialized.

Keywords: ADR, ABR, Information systems, design, development, AST, ICT, monitoring system

Introduction

Non-responsible use of antibiotics is a significant driver of one of the biggest global health threats related to Antibiotic Resistance (ABR) which occurs as bacteria stop responding to antibiotics. It is estimated that annual ABR attributed mortality would reach 10 million by 2050 (O'Neill, 2016) if appropriate mitigating interventions are not taken on an urgent basis. This rising threat of ABR has led the World Health Organization (WHO) to describe ABR as a "slow-moving tsunami" threatening the "the end of modern medicine" (Chan, 2017), and endangering the future of societies (O'Neill, 2016), including the achievement of all Sustainable Development Goals (SDGs)(Cars & Jasovsky, 2015).

ABR impacts the world inequitably, with Low- and Middle-Income Countries (LMICs) amongst the worst hit. There are many factors that contribute to these uneven impacts, such as overcrowding, poor sanitation, weak access to diagnostics, high burden of infectious diseases, and inadequate monitoring. One of the largest drivers that concerns the indiscriminate and non-responsible use of antibiotics include practices of prescription, dispensing, and consumption. This problem is acute in India, referred to as the world's ABR capital (Chaudhry & Tomar, 2017), and one of the biggest producers (Srividhya, 2021) and consumers of antibiotics globally. India recorded more than a 100% increase in antibiotic use between 2000 to 2015 (Klein et al., 2018). While the National Action Plan, 2017, published by the Indian government recognizes the need to regulate the use of antibiotics and to build greater awareness about its adverse consequences, few systematic efforts have taken place within the public system to mitigate this problem. The potential of the digital technology to help strengthen the fight against these problems has largely been under-utilized (Sahay et al., 2020).

Given that non-responsible use of antibiotics is a big challenge facing India and most other LMICs, contributed to largely by poor knowledge and awareness about this problem, the question facing (Information Systems) research is what role digital interventions can play in engaging with this challenge, and how can appropriate solutions be designed and used. This is a non-trivial challenge, given the complexity and intersectional nature of the contributing factors (Charani et al., 2021). Antibiotics usage is driven by the multiplicity of interests and interconnected practices of different stakeholders involved in prescribing (doctors), dispensing (pharmacists and medical representatives), and most importantly its consumption (patients). For a start, doctors for various reasons may not even tell patients that some of the medicines they are prescribing are antibiotics, leaving no scope for the patients to be aware of the potential risks involved. Patients may rely on the word of mouth of family and friends to procure and use antibiotics, rather than relying on Antibiotic Susceptibility Test (AST) results, which is difficult and expensive to access, and patients are often unaware of the value and relation of testing to guide prescriptions. Pharmacists, driven often by profit motives (Barker et al., 2017), may deliberately without doctors' prescriptions dispense expensive higher generation antibiotics, unaware (and sometimes aware) that in some cases first-generation antibiotics could do the trick. An effort to make visible these challenges that drive the poor awareness of antibiotic use by potentially leveraging on digital solutions, provides a point of entry for IS researchers to intervene.

Action Design Research (ADR), as articulated by Sein, et. al., (2011) provides an insightful approach to guide the design and use of ICT artifacts to help engage with the "class of problems," which in this case relates to the lack of information around antibiotics use and its implications for ABR. What is attractive in ADR is its focus on building the artifact considering the problem context, through an intertwined rather than sequential process of defining the problem, building, evaluating, and reflecting on the learning processes. Such an approach is relevant in this case, given that the challenge of antibiotic use is complex, largely unknown, and is influenced greatly by socio-cultural conditions (Charani et al., 2021). These reasons make it infeasible to precisely pre-define system requirements, and then sequentially move to build and evaluate the artifact. Instead, ADR suggests that by taking an "ensemble" view of the artifact (Orlikowski & Iacono, 2001), the emerging design requirements are seen to be intertwined with influences coming from different contextual conditions and can incrementally be inscribed into the artifact as the process of design, development, and use unfolds.

Guided by ADR, this research describes a mutual shaping process between design and use, in the building and implementation of the ICT artifact. By the very nature of the problem, the ICT artifact cannot address the "whole" problem, which needs to be broken down into smaller components, incrementally making these pieces work, and linking up with solutions for other components. This requires a process of continuous reviewing, reflecting, and revising, both technically and institutionally, how the solutions are playing out in practice. Such an ADR-inspired approach helps mitigate the risks of building (expensive) pre-specified solutions in a context with inherent uncertainty, ripe with the potential for emerging unintended consequences. In understanding how an ADR inspired approach can be shaped for addressing the specific challenge of mitigating the risks of poor antibiotics usage in an LMIC context, the paper addresses the following research question: *"What are the approaches for applying ADR to design, develop and use an ABR monitoring system to facilitate responsible antibiotics prescriptions by physicians?"*

Empirically, the study is set within the public health system in India to identify the class of problems relating to awareness gaps, identify emerging design needs and build the supporting ICT artifact. The phenomenon

of antibiotic use is shaped by a larger ecosystem of stakeholders that can be addressed incrementally. Guided by the principle of problem decomposition, the focus is limited to the primary care providers, and physicians in this study. Increasing awareness of physicians about what antibiotics they prescribe, why, and for whom can have direct implications for building greater awareness more broadly. Furthermore, the general learnings and reflections that result from this study can help to incrementally expand the system to other domains, such as patients and pharmacists, to help more effective engagement with the class of problems of "lack of awareness about antibiotics." The rest of the paper is structured as follows. In the next section, the context of the use of antibiotics in India is described. In the third section, ADR and its relevance to this research is discussed. In sections 4 and 5 the methodology is described and then the case study is presented within the ADR framework. The analysis and conclusions then follow.

Literature Review

Antibiotics consumption in India

Non-responsible use of antibiotics is one of the major drivers of ABR in LMICs. The situation is particularly acute in India, given its high burden of infectious diseases (Farooqui et al., 2018), as one of the highest consumption rates of antibiotics globally of 10.7 units per person annually (Van Boeckel et al., 2014), and is also one of the biggest manufacturers of generic antibiotics. Various global and national initiatives in addition to multiple research studies have all emphasized the need to raise levels of awareness about antibiotics to fight ABR. The Global Action Plan on ABR (WHO, 2015) has described its first strategic objective to improve awareness and understanding of ABR through effective communication, education, and training. Similarly, the first strategic priority in the Indian National Action Plan (Gandra, 2017) is *improving awareness and understanding of ABR through effective communication, education, and training*. The second strategic priority stated in the Indian action plan is *strengthening knowledge and evidence through surveillance*. These action plans emphasize the key role of strengthening digital surveillance systems to better combat ABR. Despite these policy announcements, it is striking to note that despite the undoubted potential the digital technology has in fighting the problem of low awareness, the link is not explicitly made in these action plans.

In summary, this study is based on the proposition that increasing antibiotics consumption leads to a rise in ABR and the digital can potentially play an important role in enhancing the informational basis on which these practices are carried out, which can further help to better manage the challenge of non-responsible antibiotics use. How to build supporting information systems for this purpose is a challenge that this paper seeks to understand and engage with.

Action Design Research (ADR)

Sein et al. (2011) describe ADR as a structured process model for designing and building an ICT artifact by combining principles of action research (AR) (Susman & Evered, 1978) and design science research (DSR) (Hevner et al., 2004). ADR seeks to generate prescriptive design knowledge (Hevner & Chatterjee, 2010) for building and evaluating ICT artifacts intended to solve a class of problems in an organizational setting (Sein et al., 2011). ADR combines processes of design, development, reflection, and evaluation of the design intervention taking place, not as a sequential process, but one which is intertwined with each other, and where unintended consequences are inherent. Evaluation of the effectiveness of the artifact takes place through everyday use and the experiences of the users.

Formally, Sein et, al., describe ADR to unfold over 4 stages guided by respective principles: i) Problem formulation; ii) Building, Intervention, and Evaluation (BIE); iii) Reflection and learning; and iv) Formalisation of learning. The ADR approach has been applied to different application contexts, in both developed and developing countries. In the health care context, Mettler (2018) followed an ADR approach to describe practical design propositions and tensions in the contextualization of a Professional Social Network (PSN), where health workers and practitioners get in contact and socialize and share information. ADR has been used to facilitate the design and adoption of digital allergy cards by patients to strengthen its adoption. The research developed actionable knowledge relevant to the broader class of problems related to the design and adoption of Personal Health Records (Ngassam et al., 2022).

In this study, ADR is used as the approach to i) identify design approaches for an ABR reporting application that addresses a class of problems related to awareness gaps about the responsible use of antibiotics; ii) to design and develop the artifact with an iterative participatory design approach involving multiple

stakeholders including microbiologists, physicians, and system designers, etc. iii) to generate learnings and knowledge about monitoring antibiotics resistance that can be expanded from an institutional perspective into general solutions for a similar class of problems. The paper contributes in both applying the ADR approach to the complex problem of antibiotics awareness in an LMIC context and, in helping to mitigate a large and growing societal problem of ABR.

Research design

This is an ongoing longitudinal study started as a process of the AMR system design and implementation project started in 2017-2018, in which the first author was intimately involved. In 2019, as she started her PhD studies, in attempting to make theoretical sense of the system development exercise, she considered ADR as a conceptual lens. This study is a part of a larger initiative under the long-standing ongoing efforts of a national NGO (Non-governmental organization) called HISP (Health Information Systems Programme) India working on strengthening digital public health systems.

Role of the researchers

The first author of this paper is both a researcher studying the usage of antibiotics and the process of the systems development and use. Further, she is a member of the Indian NGO called HISP India, which has been tasked with the responsibility for the practical design and implementation of the ABR system. Acting as both a researcher and a part of the design team, she had the advantage of having a ringside view of the study phenomenon and the challenge of separating the boundaries of research and action, which is often inherent in ADR studies. The second and third authors of the paper are researchers, with extensive experience in the phenomenon under study, and played primarily an advisory role in the study, particularly focusing on framing the conceptual development and study contributions.

Research design and settings

ADR was used as an analytical lens to develop a historical reconstruction of the process of system design, development, and implementation, conceptualized in the framework of the four stages, not necessarily in sequential stages. However, this reflects the spirit of ADR of not being bound into sequential stages but highlighting the interconnected nature of actions, events, and learnings.

The first stage of ***problem formulation*** can be seen to include two streams of work. The first was an empirical study (March – April 2020 and January 2021) to understand patterns in antibiotics prescription by physicians at a public teaching tertiary hospital. The second (January 2019-January 2021), initially parallel to the first stream of work, was the ongoing process of the design and implementation of the AMR digital reporting system. As the study progressed and the understanding of ADR and the context increased, the two streams of research were explicitly linked.

The first stream of research helped in understanding the physicians' perspective while prescribing antibiotics, what drives their prescription practices, and their patterns of prescription. This helped to identify the potential role of digital in trying to address the issues that affect prescription practices. The empirical study was conducted at a tertiary teaching hospital in district Kangra in Himachal Pradesh as a part of the first author's research work for PhD to have a deeper understanding of the problem of antibiotic use and how it can be better addressed. The second stream of research involved the process driven by HISP India, where the first author was an integral part, to understand and address the challenges identified during the systems design and development process carried out in the setting of a tertiary public hospital located in the same teaching hospital. These two processes at this stage were not initially linked, but there was the growing realization that data on antibiotics consumption was not being captured in the existing (manual) reporting system, and there is inherent complexity in doing so in digital form.

For both streams of research, semi-structured and open-ended- interviews were conducted. An open-ended interview enabled further inquiries based on the responses received from the physicians. Amongst the participating physicians were consultants with a postgraduate degree in a specialty like medicine, surgery, cardiology etc. and senior residents' doing their residency in a post graduate subject after obtaining a degree. Each interview lasted for 30- 40 minutes. In the first, to understand the practices of prescriptions by physicians, the interview responses were grouped by different stakeholders, and themes were identified for each group. An overarching theme influencing the practices of all stakeholders was identified as a 'class of problems' to be addressed. In the second, given the busy work schedules of the staff in the microbiology

lab, mostly informal discussions were held with the microbiologists, technicians, and data entry staff in the microbiology lab to understand their work practices and respective informational requirements. The process of data collection and analysis is depicted in table 1. Further, at HISP India, together with other members of the team, the first author was constantly engaged in processes of understanding requirements, communicating with the hospital microbiology team, participating in system modifications, and understanding how these were being perceived by the hospital team. Additionally, various national and state-level policy documents were studied to understand the broader context of antibiotics use and how they were reflected or not in the work processes in the hospital. The first stream of work helped to develop an understanding of the awareness gaps in antibiotics use, while the second stream helped to understand the requirements for an ABR reporting system to support the testing-related work in the microbiology lab. This was directly fed in the next phase of BIE. The antibiotics awareness understanding did not provide specific inputs to the initial stage of the system development but provided with a broader awareness of the challenges faced by physicians, which we would try to address in the later stages of system development when we focus on enhancing the use of the test reports by the physicians.

ADR stage	Timelines	Actors involved	Activities	Data analysis
Problem formulation	March – April 2020 and January 2021	-Physicians (Consultants - 8; Senior residents – 5; Junior residents – 3) -Microbiology team (Microbiologists- 3; lab technicians- 4; data entry operator- 2; System designers- 5; researchers- 4) -The hospital management including the principal, medical superintendent (MS) and the head of the departments (HODs),	-Semi-structured, open-ended in-depth interviews with physicians -Meeting with hospital management and the microbiology team to understand the current processes and their expectations and requirements from the digital system. Discussions and observation of the workflow at the hospital (e.g.: the billing process, sample collection and transfer process etc.)	-Data collation and organization. -Transcriptions: All primary data was transcribed and translated from Hindi to English wherever needed, and digitized. - Coding to identify initial themes followed by discussions until finalization.

Table 1. Data collection for problem formulation

To facilitate data analysis, all data collected including interview notes, observations, and study of documents were organized and transcribed and translated from Hindi to English wherever needed, and digitized. A thematic analysis was done, and two researchers coded the data material individually and compared the assigned codes and sub-codes. First, responses from the physicians were grouped, and major practices were identified and coded. These practices were then grouped and categorized as themes representing the problem formulation. A discussion was done until a consensus was reached wherever the results differed.

The second stage of ***Building, intervention, and evaluation (BIE)*** shifted the site of empirical engagement to the microbiology lab initially and the broader hospital staff (physicians and hospital administrators) later as the system became increasingly mature. The problem formulation stage had heightened the understanding that awareness of antibiotics is a crucial challenge to address and that it will be complex to address in all its facets. It was thus decided to try and close the "awareness gap" related to the interactions between the physicians and patients, basically by providing more systematic information around the testing profiles being generated through the reporting system. The base for generating these testing profiles was the automation of the testing process (called AST – Antibiotic Susceptibility Tests) which was carried out in the microbiology lab. The digitization of the testing process was carried out using

an open-source digital platform called District Health Information System 2 (DHIS2) (see dhis2.org). The modular and scalable architecture of DHIS2 makes it a suitable choice for low resource settings. Additionally, a flexible metadata model managed through user interface creates space for local participation by capacity building of the users at the local level and with the routinization of data entry, the focus shifted to improving data quality and ensuring that testing results are sent to the physicians and helping them interpret and use the reports to guide their antibiotics prescribing process. Closing the awareness gap experienced by the physicians could potentially have knockdown and indirect effects on enhancing the awareness of patients. The BIE process is conceptualized over 3 build cycles described in the case study. The data collection methods are summarized in table 2:

ADR stage	Timelines	Actors involved	Activities	Deliverables
BIE cycle 1 - Understanding requirements	Jan 2019 – July 2019	Microbiologists, hospital management, lab technicians, data entry operator, System designers, researchers,	-Meeting with hospital management and microbiology team -Training of the lab technicians, staff, and data entry operators -Bi-weekly meeting with microbiologists	-Hospital specific requirements document -System design document
BIE cycle 2 - Process of customization	August 2019 – October 2020	Microbiologists, lab staff, system designers, researchers, data entry operator	-Preparation of mock-ups based on requirements from BIE I -Deployment of the patient-centric application -Weekly meetings and site visits for evaluation	-System development and deployment plan -User training guides and manuals
BIE cycle 3 – Feedback and continuous improvements	October 2020 - ongoing	Microbiologists, physicians, hospital management, system designers, data entry operator	-On-site meetings to do requirements assessment for data analytics -Weekly meetings to evaluate data entry and update the progress of the report -Deployment of the reports and analytics	-Regular evaluation, feedback incorporation -Development and deployment of data analytics and dashboards

Table 2. Data collection for system design and development

The stage of ***reflection and learning*** involved continuous interactions between the researcher and the microbiology team over issues of design, new requirements, and how to improve the usability of the system. Both on-site and remote online applications through digital means were employed to enable these interactions, which included: i) feedback from the microbiologists on the challenges they were facing in using the system and the improvements they sought; and ii) responses from the development team of how these requests are being incorporated through the system. As the system started to take stronger roots and the data entry processes became increasingly routinized, discussions were initiated with physicians and

hospital staff on aspects of the use of the reports to close the awareness gap among physicians. The kinds of reports they demanded and why helped gain deeper insights into the information gaps they were currently experiencing.

The stage of ***formalization of learnings*** includes processes of theoretical reflections to cast the problem of physician awareness in multiple ways: i) within the hospital to understand what additional measures can be taken to further enhance use by physicians and build relevance for other hospital users; ii) external to the hospital, how to identify generic features of the system to make it possible to be taken to other facilities and settings. These questions of functional and geographical scale, if appropriately approached conceptually and practically, can help engage more broadly with the class of problems of "poor awareness around antibiotics use". In this paper, the focus is primarily on the dynamics within the hospital, and not external to the hospital.

Case description and analysis

Stage I: Problem formulation

A thematic analysis of the interviews with physicians were analyzed that yielded themes pertaining to limited awareness and limited availability of information about antibiotics use.. These themes include i) Abstract process of choosing an antibiotic; ii) Delayed test results; iii) No aggregate profile of data available. Some of the responses are further described in detail: Physicians do not have a systemic ***evidence base to guide them in prescribing antibiotics*** and instead relied on their prior experiences with success rates of antibiotics or information on what other senior physicians did in similar situations. A physician mentioned: *"Antibiotics are prescribed when there is a sign of infection or there are chances for the patient to get an infection. It depends on seasonal infections as well. For example, when most patients visiting are getting fever and throat infections, we give antibiotics to all patients with the same complaints"*

Since the site is a tertiary teaching hospital, there are many junior and senior residents at the Outpatient Department (OPD) providing consultations to around 40- 50 patients each day. A junior resident during the OPD hours at the Ear nose throat (ENT) department mentioned: 'I prescribe a second-line antibiotic to all patients coming with an ear infection because all my senior physicians *prescribe the same antibiotic. There is no rule or guideline to prescribe this drug, but we have been prescribing a second-line antibiotic because senior physicians do.'*

Physicians said that they cannot prescribe a culture test to all patients because it is not practically feasible due to high costs and the limited availability of diagnostic facilities. Private testing is expensive and public facilities are limited. Physicians generally ordered a culture test when patients come to them after multiple prior consultants and courses of antibiotics. Under such circumstances, it was impossible to wait for test results, and a general physician at a hospital told that: *"A culture test is done when the patient is referred from some other physician or facility and has come after visiting 4-5 doctors. In that case, I give him/her the antibiotic she will be sensitive to no matter what class of antibiotic it is. And sometimes the patients come with small illnesses and in such cases, the test is not done. I prescribe antibiotics because if I won't some other doctor will. Sometimes the patient cannot pay for tests, in that case, the patient says I have come for medicines and the doctor is sending for tests so she would rather go to some other doctor".*

Overall, we learned that the non-responsible use of antibiotics is not only about poor awareness and individual practices but is also influenced by the unavailability of guiding information to physicians for writing evidence-based prescriptions. A key source of interaction relevant to this analysis was using the data generated by the microbiology lab testing results. We wanted to understand if those reports could help to support the doctor with questions on what antibiotics are relevant for the treatment of the patients to address the problem of lack of awareness of antibiotics use. Getting answers to this question could next help in understanding how patients could receive their test results and how that could be used to enhance their awareness.

Stage 2: Building, Intervention, and Evaluation

The BIE stage is reconstructed over three cycles i) understanding requirements; ii) processes of customization; iii) deployment, feedback, and continuous improvements

Understanding requirements

The technical team from HISP India was involved in the design and development of the application since 2018. An application designed earlier (2017) for a national research organization on an open-source platform (DHIS2) had provided an orientation to HISP India about the ABR domain and the motivation to approach a tertiary hospital site in Himachal Pradesh in October 2019. While the earlier application for the research organization had focused on aggregate reporting for regional monitoring, the hospital application was primarily for supporting microbiology lab work. The system needed to be designed from scratch, in complete collaboration with the microbiologists as the HISP India team also had limited experience of how ABR lab work takes place. Initially, a team from HISP India visited the facility to understand their workflow, information flows, and requirements to manage the testing process. The hospital staff had limited capacity and experience in managing digital systems. Both the hospitals and the HISP India team were stepping into virgin grounds.

ABR monitoring application: The application is developed on DHIS2 platform which is a tool for collection, validation, analysis, and presentation of statistical data. The application is tailored to supportthe microbiology team to capture, analyze, present, and disseminate AST test results with the possibility of configuring context specific features. In this case the workflow of the hospital under studyand the additional requirements to manage the ABR data locally needed to be digitized. The flexible and modular architecture of the platform allows possibilities of configuring the specific requirements and designing and developing specific reports. We describe the design and development of the ABR monitoring application based on hospital specific requirements in this section.

Microbiology lab workflow before digitization: The microbiology lab received samples for a culture test (AST) from both outpatient and inpatient departments every day before 13:00. The lab used a manual testing process that took 3 to 8 days depending on the type of sample being tested (blood, urine, or others). The lab had manual registers where the technicians recorded the test results daily. Once, these samples were received at the lab, the demographic details of the patients were entered in a manual register, and the test results were entered against the patient's name once testing was completed and was relayed back to the indenting department. Existing data in the registers had rarely ever been subjected to systematic analysis for resistance patterns in the hospital or the geographical area.

To initiate the ***BIE cycle I,*** a meeting was held with the hospital management and the microbiology team to understand their workflows and requirements for digitization. The earlier prototype (from the research organization) was demonstrated to the hospital teams during the meeting, and lab-specific needs were identified. The microbiology team found it difficult to articulate their requirements in absence of prior experiences with digital systems and the lack of guidelines and policies around antibiotics usage at the hospital. The microbiology team decided that they would "learn by doing", by starting to use the existing application, identify areas of improvement as they worked with it, and get HISP India to make required changes and improvements in rapid prototyping cycles. To help the team get started, HISP India provided end-user training to the lab staff, microbiologists, and data entry operators. The microbiology lab did not have a computer, so they arranged for a new system which was placed next to the table where they kept the manual registers to facilitate the process of data entry. The lab did not have the capacity to hire a full-time data entry operator, so they assigned two data entry operators from the general registration desk of the hospital who took turns coming to the lab for two hours in the afternoon after their other work. Often data entry backlogs remained as the operators skipped coming to the lab when they were held up with their primary work at the registration desk.

The HISP India team and the lab staff had regular calls and field visits to understand the requirements and how the prototypes were performing. With passing time, lab staff started to better understand the workflow of the system and provided relevant inputs to improve the system. They moved from being passive providers of requirements to active co-constructors of the design. After a few months of use, the microbiology team shared a detailed description of changes in modifying and addition of data fields and requested the addition of new antibiotics, sample types, organisms, etc. These requirements were translated into metadata design by the HISP India team and sent back to the lab to confirm the correctness of their understanding. A few back-and-forth iterations were required to finalize this metadata design. Soon, the lab staff also raised requirements for a new infection control module to enter test results of different samples, such as water and from operation theatres. Requests also came for the development of new reports, indicating that the lab team wanted to see outputs. All requests were formally documented by the HISP India team into a "systems requirement document". Unlike traditional systems development projects, this document was not

the starting point for system development but was developed through the interaction processes of understanding requirements, design, and the deployment of different versions of the prototype.

Processes of customization

HISP India followed a participatory and prototyping approach for system design, development, and customization in ***BIE cycle II***. The process included i) creating workflows and mockups based on requirements gathering and discussions with the microbiology team in BIE cycle I; ii) development of a roadmap with details of each prototype; iii) developing prototypes and sharing them with the microbiology team for their feedback; iv) merging the prototype with the live application after testing internally and by the microbiology team; v) refresher training and evaluation. The workflow is summarized in **figure 1**.

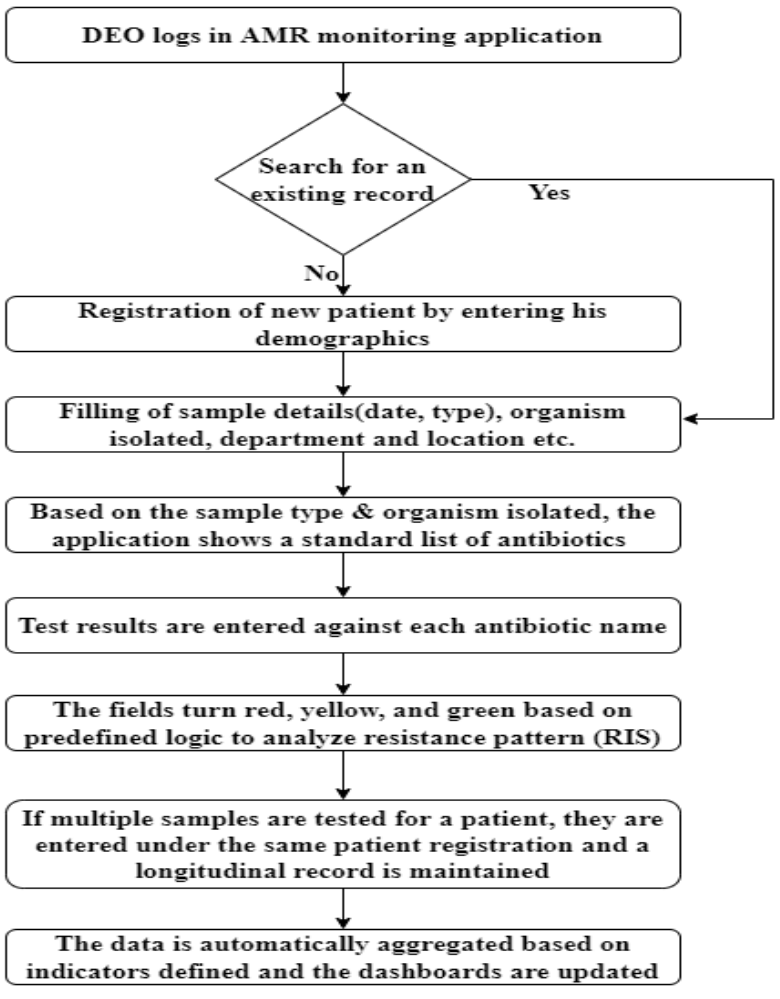


Figure 1. Finalized system design for ABR monitoring application

Various requirements were noted to support the identified workflow. HISP India prioritized those tasks which needed minimal development changes and then those which needed substantive development. The design team first developed screen mockups based on their understanding of the requirements shared by the lab team received their feedback and incorporated changes. Once the mockups were finalized, the development started on the test instance. The prototypes were released in three different cycles **(table 3)** which were subsequently tested by the microbiology team. Upon approval by the microbiology team, these changes were merged with the live application.

Activities	Timeline	Details
Release cycle 1	August 19-October 19	New reports were developed and added to DHIS2 dashboards - Addition of organism wise reports prepared by the hospital manually - Graphs, charts, and tables were added to analyze the resistance patterns1 of specific organisms New data entry fields added: - Lab ID, sample types, data entry date, sample received to date, etc.
Release cycle 2	November 19 – March 20	Minor configuration changes done - Sample type and collection date added on the home screen for easy access and search - New organisms and antibiotics added - Technical issues related to server and internet connectivity resolved
Release cycle 3	April 20 – October 20	Infection control module developed Changes in the application to make it patient-centric - Feature to see a longitudinal record of patients based on sample type and organism detected

Table 3. Release cycles (BIE2)

As the microbiology team started data entry in the existing application, the technical team worked on adding new reports. The second prototype included the addition of new data entry fields and metadata for organisms, antibiotics, samples, and the removal of the redundant fields. The third prototype included development changes including the infection control module. Once the application was tested by the microbiology team and the end-users, it was deployed at the hospital. A refresher training was organized to orient the hospital team to the new changes. Regular calls, meetings, and workshops were planned during this period to discuss the challenges and feedback. Figure 2 shows various sections of the data entry application designed, including the patient registration fields, and the predefined logic to identify the resistance pattern as soon as the results are entered against each antibiotic. A dummy longitudinal record of a patient is shown whose two samples were received at the lab.

[1] Resistance pattern is the description of the antibiotic resistance testing results for an organism identified/isolated from the sample.

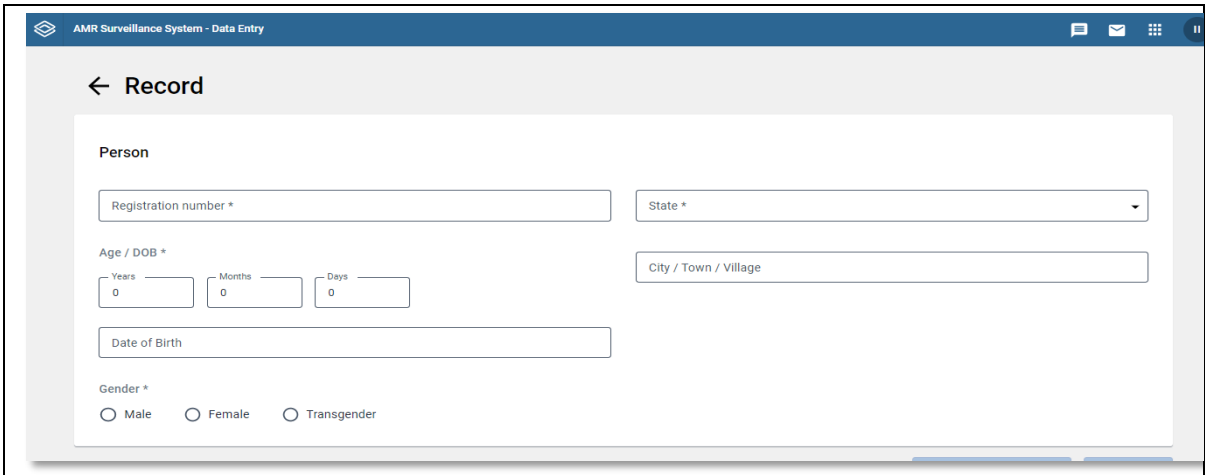
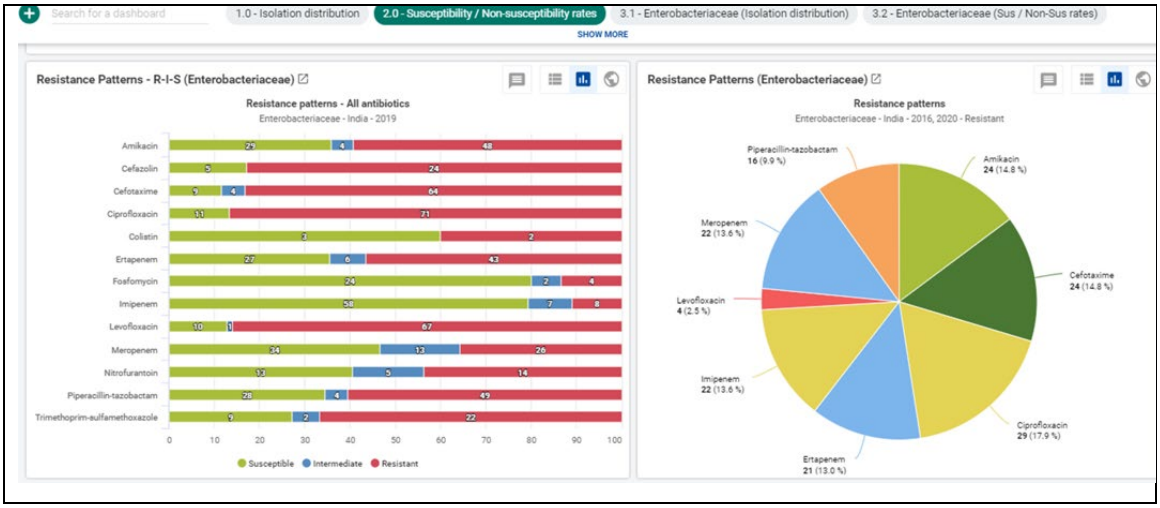


Figure 2. ABR data entry application

While the application was being developed for the particular lab, HISP India aimed to build a system based on principles of "open generification" (Gizaw et al., 2017). This is a design strategy that acknowledges the need and feasibility of a generic as well as a local and facility-specific application, enabled through the use of an open-source and flexible digital platform. To this end, HISP India also engaged with the WHO ABR team to incorporate their standard metadata for pathogens, antibiotics, and samples which made it easier to integrate with other applications and allow different facilities or countries to select the list of antibiotics they wanted to be included in the application. These reciprocal cycles of learning and action helped to raise the understanding of the HISP team about ABR, and the lab team on the potential of digital technologies.

As data entry processes started to get routinized, the HISP India team started to focus on the output side, generating reports and dashboards to increase the visibility of information. The microbiology team started downloading the reports from the dashboard and a stack of reports was sent to the state secretariat and the hospital management. DHIS2 dashboards are a collection of the reports that are designed based on the requirements of the hospital which are updated automatically based on the data entered daily. Some of the reports on the dashboard are shown in **figure 3**, including an aggregation of the sample types received at the lab, organisms identified from the samples, and the antibiotics sensitivity pattern[2].



[2] Sensitivity pattern - A sensitivity pattern tells what kind of medicine, such as an antibiotic, will work best to treat the illness or infection.

Figure 3. A sample report from the dashboard

Feedback, and continuous improvements

During the ***BIE Cycle 3,*** as the data entry stabilized, the microbiology team started articulating increasing requirements for data analysis and new reports they would like. A workshop was held in Feb 2021 to collaboratively i) evaluate the implementation process; ii) discuss how to use the generated reports to strengthen awareness of the efficacy of antibiotics being prescribed amongst the physicians; iii) understand the possibility of scaling the application to other public teaching hospitals in the area. The participatory design process went on both at the discussion and design phases by engaging the hospital management, microbiology team and other stakeholders at the hospital. After many rounds of discussions, it was decided to develop an aggregate report with department-wise trends of resistance, which could potentially help physicians to decide on the antibiotics to be prescribed based on the sensitivity patterns highlighted by the test reports. The microbiology lab takes 4-10 days from the day of sample collection to the generation of the test report. This was too long, and in the meantime, the physician would end up prescribing broad-spectrum, higher-generation antibiotics. With this report, the team identified that physicians could make better evidence-based decisions, even in the absence of the test results. For example, if a lower generation antibiotic was susceptible in 90% of cases, the physicians could start the treatment with a first-generation antibiotic rather than a higher generation one. This was followed by a discussion between the physicians, microbiologists, and the design team to discuss the requirements for such a report. The teams shared their ideas about what they would require in the report. For example; microbiology team proposed a format for the report where all relevant organisms and antibiotics can be grouped together and they have the space to write their interpretation of the report; Physicians expressed they would like to see only the sensitivity pattern in the report and not the resistance pattern to see which antibiotic can be prescribed; the management team discussed the dissemination of the report to physicians and the stewardship committee in the hospital and with a few iterations, the report was finalized and is now in regular use at the hospital. A sample report is shown in **figure 4**.

Percentage susceptibility & Location-wise distribution of Urine isolate groups
Department: ALL
Period: January 2022 to February 2022

GNB Urine			% Susceptibility of Isolates to tested antibiotics Susceptible/Tested Isolates																				
Total no. of isolates (1/patient)	Location	%/N Per Location	Amikacin	acid Amoxicillin/Clavulanic	Ampicillin	Sulbactam Ampicillin-	Aztreonam	Cefepime	Ceftazidime	Cefuroxime	Ciprofloxacin	Colistin	Doripenem	Doxycycline	Gentamicin	Imipenem	Levofloxacin	Meropenem	Piperacillin	Piperacillin/Tazobactam	Tetracycline	acid clavulanic Ticarcillin-	
Escherichia coli (N=98)	OPD	47.96													85.29								
		47	(1/1)	(19/23)	(2/12)	(1/1)		(2/2)	(5/10)	(3/5)	(3/9)				(29/34)	(2/2)		(14/15)		(3/3)	(1/1)		
	Ward	31.63																					
		31	(3/3)	(12/14)					(2/8)		(1/8)				(16/22)	(1/1)		(5/8)			(1/5)		
	ICU	6.12																					
		6							(1/1)			(1/1)	(1/1)	(1/1)				(1/1)		(1/1)		(1/1)	
	Unknown	13.27																					
		13	(1/1)	(3/5)					(1/7)						(8/10)			(3/4)		(1/2)			
	CCU	1.02																					
		1													(1/1)			(1/1)					
Pseudomonas aeruginosa (N=9)	Ward	77.78																					
		7	(1/2)				(1/1)		(4/6)		(2/4)	(1/1)			(4/5)	(2/3)		(1/3)	(1/1)	(1/2)			
	OPD	11.11																					
		1													(1/1)					(1/1)			
	CCU	11.11																					
		1										(1/1)											
Acinetobacter spp. (N=7)	Unknown	14.29																					
		1									(1/1)			(1/1)									
	Ward	14.29																					
		1																					
	CCU	28.57																					
		2							(1/2)			(1/1)	(1/1)	(2/2)	(1/1)		(1/1)	(1/1)			(1/1)		(1/
	OPD	42.86																					

Figure 4. A sample department wise report

Stage 3: Reflection and Learning

The reflection and learning stage move conceptually from building a solution for a particular instance and applying the learning to a class of problems. This is a continuous process often running in parallel with the first two stages (Sein et al., 2011). As processes of data entry stabilized, discussions were initiated on the reports side, while further strengthening of data entry was ongoing. Various operational and technical issues were continuously highlighted which the technical team would seek to address at the earliest. During the process of building the department-specific report, the teams identified several gaps and data quality issues that needed to be dealt with to be able to generate the report. For example, A data quality issue identified was that all the samples received at the lab needed to have all the corresponding details about the departments they were received from. However, about 40-50 % of samples had no such information. To address this gap a report was developed with the number and frequency of such gaps and highlighted to the team, who did multiple interventions to receive complete sample information. Another issue was that the lab did not have a standard list of antibiotics to be tested for specific organisms and samples. This adversely affected the quality of data analysis as no standard outputs were identified for the resistance patterns of some antibiotics. The issues identified and their resolutions are summarized in table 4:

Issue type	Details	Resolution
Operational	The microbiology team did not have a standard operating protocol (SOP) to test specific antibiotics for specific organisms and samples	A three-member team was identified to develop SOPs for testing
	The manual register did not have the fields to record the department and location	The microbiology team decided to change manual registers and incorporate the necessary fields required
	Human errors while writing the details in the manual register by the lab technician	The microbiology team decided to design stamps that would limit the manual data entry in the register
	Problems coordinating with the data entry operator from the registration counter	The technical team provided a full-time data entry operator
Technical	The data aggregation application required development changes to facilitate department wise analysis	A new data entry app was designed to facilitate the department wise analysis
Data quality	Department and location details were not received from the sample collection unit	Monthly data quality gaps report developed by the technical team that provided the microbiology team with evidence to facilitate necessary action (Table 5) The microbiology team wrote a letter to the medical superintendent of the hospital to tighten the regulations while filling out the form The microbiology lab trained the nursing students to collect samples and fill out the forms before they were received in the microbiology lab

Table 4. Issues identified and the resolutions done

The microbiology team with time identified that they needed a full-time resource who can help them with other issues such as data quality analysis and dissemination of reports to the physicians, along with regular data entry. A full-time resource person was hired, and the results in only a few months have been

remarkable, in terms of completeness and regularity of data entry, improvements in data quality, and wider dissemination of reports to the hospital infection control committee, and to the state level. Table 5 depicts the improvements in the data quality and the registrations and sample details captured in the digital application.

Period	Registrations in the application (N)	Total samples tested (N)	Samples tested/ Registrations (%)
Yearly average	641212	14462	2.26
Monthly average	45291	1257	2.78
Daily average	2313	52	2.25
Comparison to the previous year			
May 2021	15923	927	5.82
May 2022	49324	1826	3.70

Table 5. Total registrations and improvements in data quality

The technical and microbiology team meets every week to discuss new requirements, the feasibility of incorporating them into the applications, and strengthening ongoing user training. A process of guided emergence (Sein et al., 2011) is now firmly in place and taking the process forward, driven firmly by the hospital.

Stage 4: Formalization of Learning

The fourth stage of ADR is aimed at formalizing the learnings from the earlier stages and contributing design principles that can be relevant in diverse contexts. Three design principles relevant to a similar class of problems have been identified. These are i) Designing simultaneously for local embeddedness and global scale; ii) Building capacities to participate - from passive recipients to design co-creators; iii) Locally rooted and driven processes of guided emergence.

Designing simultaneously for local embeddedness and global scale

Designing for scale means building relevance both for the local facility and a multiplicity of contexts, within the framework of LMIC sites. Such a focus continues to enhance the local value of the informational processes while also enabling the artifact to be expanded easily to new contexts (Seebregts et al., 2018). ABR represents a unique challenge of scale and scope both geographically and functionally, as it is a global problem without geographical constraints. Functionally, ABR data is not only needed from the microbiology lab but also in other departments in the hospital (like operation theatre, water, etc) to strengthen hospital-wide activities of managing hospital-acquired infections and infection prevention and control activities. Further, since ABR must be considered within the One Health (OH) framework, which acknowledges the interconnectedness of humans, animals, and the environment (Heudorf et al., 2016), it is important the system design can also incorporate data from animals to be able to understand the transmission of infections across domains. While at this stage, this project has not attempted such functional scaling, although the system is generic enough to attempt that.

In this research, while the focus has been on supporting the facility-specific workflow, global standards have been incorporated, advised by the WHO global ABR team, of widely used ABR applications WHONET[3] and GLASS[4]. WHO is working on creating "a minimum reference" application which can be downloaded and

[3] WHONET - WHONET is a desktop Windows application for the management and analysis of microbiology laboratory data with a particular focus on antimicrobial resistance surveillance developed and supported by the WHO Collaborating Centre for Surveillance of Antimicrobial Resistance

[4] GLASS – stands for Global Antimicrobial Resistance and Use Surveillance System is an application by WHO to standardize ABR surveillance

used by any facility in an LMIC context, with the option of taking more "desired" functionalities if needed. Compatibility with WHONET will allow facilities already using it for their reporting, to share data with the application, for example only to strengthen their data analytics. HISP India has used the application developed as a reference to discuss requirements with five sub-Saharan African countries and then add on new features required in specific facilities. For example, one of the facilities needed the incorporation of an Android interface, which has been now incorporated and can become part of the minimum reference application if required. Maintaining a baseline ABR application designed with basic features to report, monitor, and analyze ABR data is allowing the use of the application in other contexts with minimal development requirements. At the same time, new requirements like the Android reporting, incorporated for new facilities, can also be made available to the original facility to add greater value to their processes. Having data reported on standard parameters can help in extending also to other medical college hospitals in Himachal Pradesh state, to strengthen the statewide reporting system. This can help develop policy interventions to mitigate ABR risks in the state while also introducing common antibiotic use guidelines across the state. This will help in closing the awareness gap around antibiotics usage across facilities in the state.

Building capacities to participate - from passive recipients to design co-creators

What became obvious in this work was that the lab and hospital staff in the initial stages did not have the necessary experience and background to articulate their "system requirements". A process of incremental "learning by doing" was adopted where successive prototypes were given to users, and as they used it, they could see how the system supported or not their everyday work, they could give concrete requirements. This increased in levels of maturity with time, starting from suggestions on what antibiotics to use to the suggestion of building an infection control module. Such active participation of end-users in the design process helped to make the artifact increasingly user-centric and helped to build local ownership. Co-creation is the process by which users take an active role in co-creating the system (Prahalad & Ramaswamy, 2004), but it does not come on its own and represents a capacity that needs to be nurtured over time. Learning by doing was the specific approach used in this research, coupled with continuous training and interaction with users.

Building such capacities is crucial, as the domain of ABR is progressively changing over time (Littmann et al., 2020) as new bacteria and resistance is developing every day, requiring evolved systems to monitor the new and emerging resistance patterns. Since the hospital staff are the domain experts, it is crucial for them to be able to raise the demand for new requirements, which can functionally be addressed by the technical team. The initial 2-3 years of experience with the system development has provided the hospital staff with the capacity to engage with such processes and would be further developed for engaging with future challenges. New capacities need also to be developed to deal with the challenges of data analysis so that users can support new institutional structures of antimicrobial stewardship (AMS) committees established by the state in every medical college facility. The committee has a monthly meeting where the head of microbiology presents the resistance patterns report downloaded from the ABR monitoring system to other members of the committee, which includes heads of departments of medicine. These reports provide information about the resistance patterns in the hospitals by specific wards and departments, which will gradually help to engage in efforts to work on the "awareness gap" more broadly in the hospital.

Locally rooted, driven, and participatory processes of guided emergence.

The process of system design and development should not only satisfy the initial requirements shared by the organization but be continuously shaped through organizational use and the engagement of multiple stakeholders (Garud et al., 2008; Sein et al., 2011). After an initial design of the artifact based on organization-specific requirements, the artifact goes through cycles of refinements ranging from major to minor design changes, through a process of "guided emergence". Requirements emerge through ongoing use experience and are guided by the continuous interaction of different stakeholders.

In this process of the initial design, the microbiology team was unable to articulate their requirements for the digital ABR monitoring system, but a collaborative evaluation of the existing application allowed the microbiology team to formulate their requirements and the technical team to understand the domain. This resulted in major and minor design changes in the application for example changes in the data entry app, the development of a new data aggregation application, addition of new data fields for organisms, antibiotics, etc. Similarly, physicians were not able to articulate their requirements for the department-wise

report, the technical and microbiology team collectively developed a prototype of the report and received feedback from the physicians on the data fields needed and some extra information to be added. An initial prototype of the report had department, samples, and antibiotics-wise resistance patterns but did not categorize the antibiotics in classes - first, second and third line. After a few iterations, and interactions with all the stakeholders, the report was finalized to be used. A microbiology staff said '*We cannot avoid sharing requirements regularly as we are constantly learning about the wide possibilities with the data being collected and possibilities of generating meaningful analysis to share with treating physicians in the form of reports to help them prescribe responsibly.'* This process of collaboration represents a form of "guided emergence" which would need to strengthen and evolved in the future.

Conclusion

The paper has emphasized the importance of process by which IS research can engage with the expanding and urgent challenge of ABR globally, particularly in the context of LMICs. A key role for IS research is in guiding the design, development, and implementation of ABR digital interventions, drawing upon learnings from other design studies, but adapting and expanding to the specific context of ABR in public settings in LMICs. Three broad design principles which can help guide future implementation efforts for other contexts have been proposed, which would need to be applied in practice and further evolved with new experiences. While here, the focus was to work with the hospital team and address the challenge of awareness of physicians, this would in due course of time need to be expanded to other stakeholder groups of patients and pharmacists.

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