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PHASE III: CAPACITY PHASE AN INFLUX OF *IN VITRO* DIAGNOSTIC DEVICES – HOW TO ADDRESS CURRENT CHALLENGES?

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ABSTRACT

Background: The Health Technology Assessment (HTA) unit was established in 2012, under the auspices of the Quality Assurance Department at the National Health Laboratory services (NHLS) to address the national accreditation needs by supporting laboratory accreditation.

Objectives: The global trend to address the burden of disease has led to an increase in the availability of Health Technology (HT). The influx of *in vitro* diagnostic (IVD) medical devices poses a challenge to the diagnostic pathology laboratories in adopting a selection criterion for procurement. This paper describes the current IVD medical device procurement system within the NHLS and how the influx of medical devices can be managed.

Methods: Review of the organisation procurement processes; planning a strategic workshop to understand current IVD challenges within the organisation; implementation of laboratory staff training on HTA principles, practices and policy processes. Enable the drafting of a HTA policy and HT guideline documents.

Results: The review of the procurement processes identified gaps in the areas of planning and needs assessment; commissioning, installation and monitoring of medical devices. The strategic workshop and HTA training presented the laboratories with current challenges regarding the influx of new technologies and deviations in medical device evaluation processes. The HTA Policy Forum finalised the HTA policy and the four guideline documents to address current organisational challenges and how to adopt Hospital-Based Health Technology Management (HB-HTM).

Conclusion: This review enabled the organisation to initialise the HTA programme by harmonising and standardising current processes and creating the HTA unit as a single point of entry within the organisation for all new health technologies.

KEYWORDS

hospital-based health technology assessment, *in vitro* diagnostic devices, laboratory systems

INTRODUCTION

With the introduction of the policy on National Health Insurance (NHI)[1] in 2011, South Africa (SA) is embarking on reimbursement reform and putting into place a system of capacity in order to fund primary care more equitably and improve technical efficiency.[2] It is against this back drop that the selection and acquisition of IVD's are critical for health services to meet these needs as promulgated by NHI.

The Health Technology Assessment (HTA) unit was established in 2012, under the auspices of the Quality Assurance Department at the National Health Laboratory Services (NHLS). The unit will address the national accreditation needs by supporting laboratory accreditation and enabling an environment for the selection of safe, good quality and effective *in vitro* diagnostic devices (IVD's) for diagnostic testing.

Over a four year period (2014 - 2016) the unit has been instrumental in building capacity to address the influx of IVDs within the organisation as a single entry point. This evidence based approach has enabled the organisation to evaluate IVD's such as: reagents, reagent products, calibrator materials or instruments; as well as specimen receptacles intended by the manufacturer for the *in vitro* analysis of specimens derived from the human body.[3]

The development of the HTA unit is described as a tiered-phase approach namely: Phase I: 'mapping phase' – to understand how to optimise HTA for diagnostic pathology services, Phase II: 'development phase' – on understanding the challenges within the organisation and Phase III: 'capacity phase' – on how the organisation conceptualised the Hospital Based Health Technology Assessment (HB-HTA) framework to support evidence-based decision making.

Through, the 'mapping phase', the unit modelled the concept of HB-HTA, as performing HTA activities tailored to the hospital context for informing managerial decisions on different types of health technologies. It included the processes and methods used to produce HTA reports for such hospitals;[4] HB-HTA was subsequently adopted.

The 'development phase' involved the National HTA Strategic Workshop. The objective of the HTA Strategic Workshop was

to understand and record the current organisational challenges the laboratories faced in acquiring IVD medical devices. It was clear that the resource limitations would be a hindering factor towards the development of the HTA unit however, the general consensus from the meeting was to set 3 short term goals. Namely, to provide (i) NHLS staff with introductory training and understanding the concepts of HTA, (ii) to develop a Health Technology (HT) policy and (iii) to develop HT guideline documents for internal use as well as map out NHLS device evaluation processes for manufacturers and distributors. In resource-limited settings the 'capacity phase' describes the implementation of HB-HTA within the NHLS for IVD's.

METHOD

Area of study

The case study is limited to the NHLS, which is the sole provider of diagnostic pathology services to the public sector in South Africa. As such, the NHLS provides these services across the country at all tiers of health service delivery, covering over 80% of the 52 million people in South Africa. The NHLS diagnostic laboratories (currently 268), are found in provincial and district hospitals in large metropolitan centres and remote rural areas as well as in the teaching hospitals of university medical schools.[5]

Review of internal IVD management processes

Over the periods June 2012 - December 2013 all internal documents used for the acquisition of IVD's were reviewed. This involved a desk based review of current practises, observation of procurement practices, interviewing key NHLS staff members, facilitating introductory HTA training, workshops and a policy forum meeting. Key senior technical staff involved in the acquisition of new IVD medical devices and who would be responsible to draft technical specifications for the submission towards the NHLS procurement process were identified to participate in the training and workshop sessions.

The following methodology was used to establish the current status of IVD medical device management within the NHLS:

1. Review of the current literature on IVD management and procurement documentation within NHLS.
2. Provide external HTA training for NHLS staff.
3. Facilitate an introductory internal HTA training.
4. Plan a HT Policy Forum meeting to finalising HT documentation for organisational use.
5. Establishing NHLS IVD pre-qualification processes.

RESULTS

Step 1: An overview of procurement process within the NHLS for IVD's

To understand the procurement requirements of the NHLS it is necessary to elaborate on the laws that govern public finance under the Department of National Treasury in the Republic of South Africa (RSA).

The Public Finance Management Act (PFMA), 1999 (Act No. 1 of 1999) promotes the objective of good financial management in order to maximise service delivery through the effective and efficient use of the limited resources as enforced by the Department of National Treasury, in South Africa.[6] The purpose of the act is to introduce uniform treasury norms and standards, to prescribe measures that ensure transparency and expenditure control in all spheres of government, and to formulate the operational procedures for borrowing, guarantees, procurement and oversight over the various revenue funds.

The NHLS procurement requirements are in compliance to the National Treasury, in accordance to the South African's government regulatory framework act "Preferential Procurement Policy Framework Act (PPPFA) No 5 of 2000.[7] The act provides guidance on the role of procurement in acquisition of products. The NHLS Procurement Policy is based on the PPPFA that prescribes the procurement processes within the NHLS.

In summary, the NHLS Procurement Policy provides guidance based on a competitive bidding process and is action driven by the needs of the requestor. Details of the policy are listed:

- To ensure that the procurement of assets, goods and services and the appointment of consultants and service providers are done in an equitable, transparent, competitive, efficient, cost effective and consistent manner.
- To provide a guideline, educate users and create awareness for the implementation of procurement processes to ensure that NHLS complies with PFMA (Public Finance Management Act), PPPFA (Preferential Procurement Policy Framework Act), BBBEE (Broad Based Black Economic Empowerment Act)[8] and other regulations and guidelines as amended from time to time by the Department of National Treasury, RSA.
- To avoid any unnecessary costs and delays in the procuring of goods and services.
- To promote open and effective competition.
- The NHLS shall apply effort and research to get the best possible outcomes from the market.
- Bias and favouritism are eliminated.
- To ensure that BBBEE imperatives are adequately addressed.
- To provide a decision structure to facilitate effective decision making.
- To render an effective procurement function for the NHLS that will enhance value throughout the supply chain.
- To achieve continuous improvement in value for money on the total cost of ownership.
- To enhance quality and competitiveness of our suppliers.
- To award all orders, contracts, subcontracts, and supplier agreements to suppliers that are approved according to the NHLS' accreditation process.
- To report performance of the supply chain to stakeholders on a regular basis.

Step 2: External training

The University of the Witwatersrand, School of Public Health, CMeRC unit,[9] together with the Ecorys partnership[10] initiated a programme to develop capacity in HTA in lower- and middle-income countries in Africa and elsewhere. The training programme was held over three days and its aims were to offer an all-embracing vision of the role of HTA in the decision-making

process by providing didactic session (basic knowledge) that would be combined with group work (practical exercises). Two NHLS staff members attended the HTA training programme in Rotterdam, Netherlands. The details of the training programme are listed in Table 1.

Step 3: Internal NHLS introductory training on HTA – concepts and theory

The two NHLS staff members who trained at Ecorys together with support from the University of Witwatersrand, School of Public Health, CMeRC unit introduced a programme to develop capacity in HTA at the NHLS. This two-day training programme was based on HTA. A syllabus with all relevant materials was provided at the start of the training by Ecorys as well as CMeRC unit. Although the definition of health technology is broad and relates to drugs, devices, procedures, support systems; the training focused on IVD medical devices to facilitate a clearer understanding of related processes. Prior to attending the training, participants were required to identify challenges that related to medical device acquisition and use. A questionnaire relating to the Mini HTA Tool[11] was forwarded to each participant for completion prior to their attendance. The training was attended by 25 participants from the NHLS. The details of the training programme are listed in Table 2.

Step 4: HTA Policy Forum workshop

The next step, was a two-day HTA Policy Forum workshop, which offered an all-embracing vision of the role of HTA in the decision-making process. Medical devices are typically marketed at high risk by relatively small companies. Whilst their value to users and service providers is often poorly established, medical devices are increasingly subject to the scrutiny of regulatory agencies requiring (various levels of) evidence regarding clinical and safety aspects, as well as cost effectiveness of new technologies. This situation presents challenges in all stages of device development and also in the subsequent aftermarket launch. In this workshop the current role as well as the future potential of HTA to scientifically support well-informed and timely decision making in the rapidly evolving market of medical devices was discussed. These discussions highlighted the perceptions of users, regulators, as well as those in industry and academics. The specific questions the forum addressed included the following:

i. HTA in the context of multiple users: how to deal with multiple and varying user needs in the assessment of medical devices at the NHLS?
ii. Improving user access to IVD medical devices by integrating HTA within the device HTM cycle
iii. The role of HTA in introducing new technologies in a context of (various) procurement regulations.

Prior to attending the workshop, participants were required to review the HTA draft documents; identify issues/challenges/problems that related to medical device/equipment acquisition and usage. The workshop was attended by 18 participants from the NHLS and the details of the workshop agenda are listed in Table 3.

Step 5: Establishing NHLS IVD pre-qualification process

The final step was to conduct a needs analysis assessment using the WHO framework by mapping out the laboratory perform-

Table 1: Training programme: 'Developing capacity in HTA in lower and middle income countries in Africa'

AGENDA
DAY 1 Welcome and introduction to training Introduction to HTA: Priciples, practice and process of HTA HTA and health policy Practical exercise: Identification and priority setting for HTA Discussion of practical exercise How to establish an HTA programme
DAY 2 Introduction to evidence-based medicine Practical exercise: PICO and literature search (PubMed) Diagnostic research: Key concepts Diagnostic research: Critical appraisal Intervention research: Key concepts Intervention research: Critical appraisal Practical exercise: Systematic review and meta-analysis Introduction to evidence-based medicine
DAY 3 Economic evaluations Practical exercise: Economic evaluations Reporting on HTA / adapting HTA reports Practical exercise: Applying checklist for HTA report Evaluation and closing

Table 2: Health Technology Assessment training – 'Putting HTA into practice…developing capacity in HTA in lower and middle income countries in Africa'

AGENDA
DAY 1 Registration Welcome and introduction Introduction to HTA: Priciples, practice and process of HTA Application of HTA in policy and practice Economic evaluations Efficacy assessment combined with literature search and synthesising the literature
DAY 2 The mini HTA tool The mini HTA tool exercise Reporting on HTA

Table 3: Health Technology Assessment workshop policy forum – 'Putting HTA into practice…developing capacity in HTA in lower and middle income countries in Africa'

AGENDA
DAY 1 *(18 February 2013)* Welcome and introduction Introduction to HTA: Current priciples, practice and process of HTA at NHLS Application of HTA in policy and practice – document review
DAY 2 *(19 February 2013)* Review draft HTA policy and guideline document Review: The mini HTA tool – application to NHLS Reporting on HTA Discussion forum – economic evaluations
End of workshop

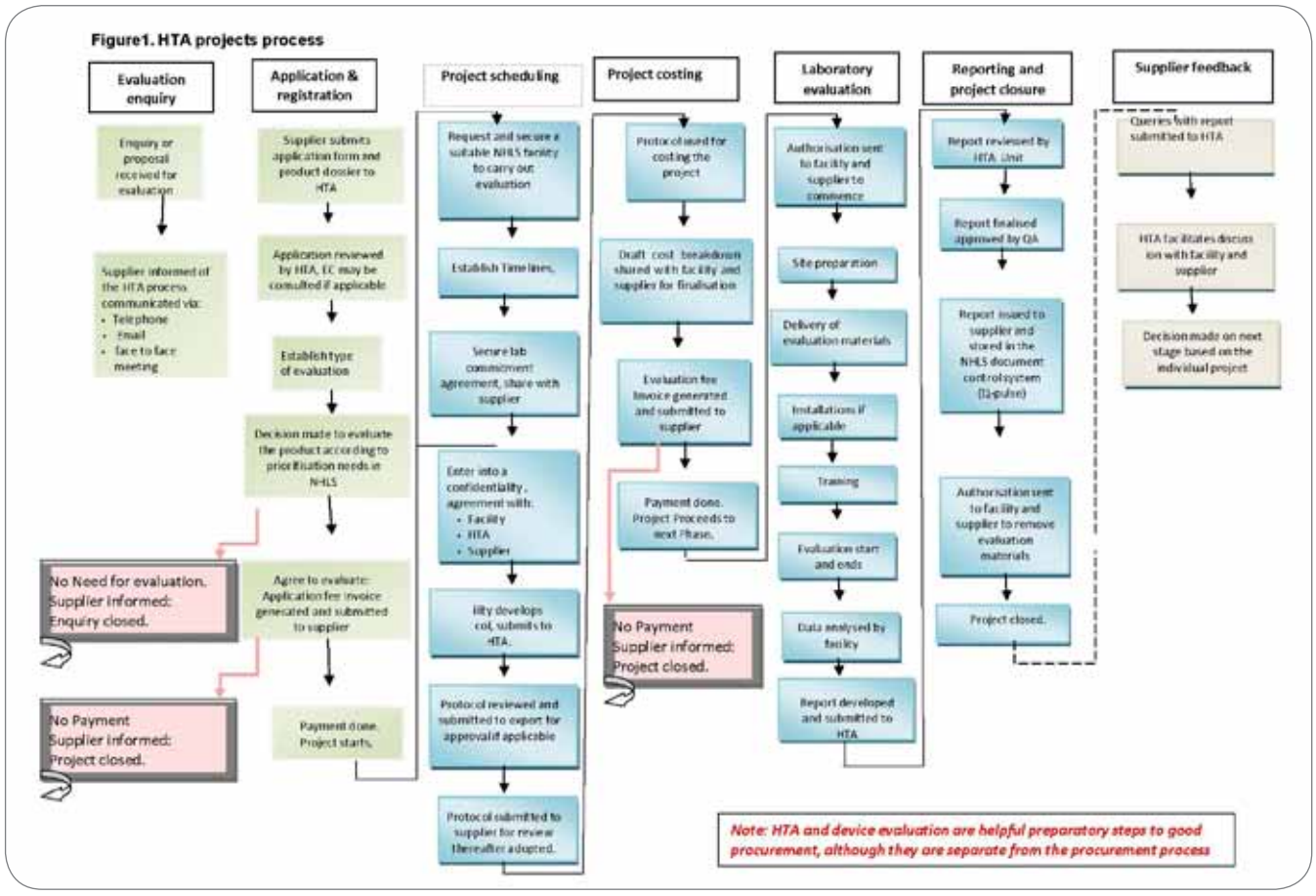

Figure 1: NHLS IVD pre-qualification process

ance evaluation processes for IVD medical devices. The WHO Procurement Process Resource guide "Summary flow chart of standard procurement technology assessment" was a tool used to guide the mapping the process as illustrated in Figure 1.[12]

DISCUSSION

A review of the NHLS procurement documents revealed that the NHLS complied with the Department of National Treasury requirements. However, it was evident that all procurement processes were driven by the "requestor". Therefore, the role of the 'Bid Specification Committee' in compiling technical specifications for IVD medical devices was an integral component to the acquisition of IVDs within the organisation.

The 'WHO Medical devices technical series' recommends that the procurement of medical devices fall under Health Technology Management, which requires a procurement plan for their acquisition. The following areas within the NHLS were identified as gaps based on the WHO Medical devices technical series:[13]

1. **Technology Assessment** – the surveillance for technology was carried out randomly depending on the requestor and the type of IVD medical device required.
2. **Device Evaluation** – device evaluation was conducted within the organisation to establish the clinical performance of the IVD however, there was no single point of entry for manufacturers/distributors and no national database register to record the evaluations completed. Furthermore, the evaluations were not standardised and sometimes did not the address the needs of the organisation.
3. **Planning and needs assessment** – the IVD medical device management was nonexistent within the organisation. This process was driven by the requestor in most instances who 'demand managed' the NHLS procurement department. Unless, the IVD medical device was part of a national tender process a needs analysis assessment with limitations on costing requirements may have been conducted.
4. **Installation** – the installation of IVD medical devices was the responsibility of the individual laboratories; the onus was on the laboratory to notify the procurement department if there was a problem for intervention and resolution.
5. **Commissioning** – the commissioning of new IVD medical devices was under the responsibility of the individual laboratory and the function of instrument verification was supported by the NHLS Quality Assurance managers and coordinators. The laboratory was expected to work with the manufacturer/distributor's service engineers to finalise the instrument commissioning; unless there were problems. Any derived problems were directed to the procurement department for intervention and resolution.

6. **Monitoring** – under the NHLS Quality Management System (QMS) the laboratory measured equipment performance by performing routine maintenance, Internal Quality Control (IQC) and participating in the National Proficiency Testing Scheme (PTS). Supplier performance was managed on a reactive bases by the laboratory. However, in the event of a deviation to the supplier contract the Procurement Department were notified to intervene. Due to limited staff resources and capacity the following areas were ignored: Technology suitability assessments, cost effectiveness assessments, forecast reviews and procurement process reviews.

The next step would be to review the gaps identified and decide on suitable plans to address these gaps with the procurement department as well as with the technical experts. A tiered implementation process would ensure HB-HTA adoption at the NHLS.

The external training afforded to the NHLS staff, enabled key HTA concepts to be formulated. The NHLS selected two staff members to attend the 3-day programme at Ecorys in the Netherlands. This international collaboration with the University of Witwatersrand, School of Public Health, CMeRC unit was a pivotal step in introducing HTA concepts to the NHLS. In summary: Day 1 was an introduction to the principles, practices and process of HTA, Day 2 covered evidence-based decision making in medicine and the tools available to support the methodology and Day 3 provided detailed course-work on economic evaluations. The training also shared experiences and challenges of low- and middle-income countries adopting HTA as well as providing the initial guidelines on how to develop a HTA programme in resource limited settings. The NHLS staff after the completion of this external training were now ready to conduct their own in-house training.

The internal introductory training on HTA was critical in ensuring understanding of HTA in the decision-making processes. The 2-day training included: Introduction to HTA – principles, practice and process of HTA; Application of HTA in Policy and Practice; The Mini-HTA Tool and Reporting on HTA. The 25 participants included senior laboratory managers from either a research or diagnostic environment. During the training the participants shared current challenges with the IVD management personnel. Those highlighted were the influx of IVD medical devices; the procurement process of drafting specifications, installation, commissioning and the continual monitoring of medical devices within ones own environment.

The participants were introduced to the Mini-HTA Tool[11] and completed practical exercises using scenarios from their respective laboratories in accessing IVD medical devices. They presented these scenarios to the group creative and interactive forum for discussion. The feedback from the participants was positive with the overall consensus that HTA training be rolled out to more NHLS staff involved with IVD management. They saw the need to provide a HT policy and draft HT guidelines to address the laboratory operational needs. It was evident from the overall feedback that the need for HB-HTA was a priority.

The NHLS was ready for the next step, to draft a HTA policy, as well as the key HT guidance documents. The HTA Policy Forum workshop was attended by 18 participants who included senior medical technologists, laboratory managers, business managers, pathologists, and research scientists. The participants were provided with the HTA Policy Forum workshop brief as well as all the HT draft documentation 4 weeks prior to the workshop. The objective of this workshop was to address specific questions on HTA and to finalise the HTA policy and HT guidance documentation for ratification by NHLS senior executive management.

In the 2-day HTA Policy Forum workshop, participants were provided with an introduction to HTA – principles, practice and process of HTA and application of HTA in Policy and Practice. Thereafter the group participated in a joint review of the HT documentation. The HTA Policy addressed the broader principles of HTA and defined the NHLS's focus on IVD medical devices performance evaluations in the context of HB-HTA. The Policy Forum highlighted that the HTA programme was in its development stages at the NHLS and due to resource constraints only 'cost effective assessments' could be included.

The HT guideline documents reviewed by the Policy Forum were: Summary of HT Processes; HT Contract Agreements; Guidelines to HT Performance Evaluations and HTA Application Forms. These guideline documents were able to address how to deal with multiple and varying user needs in the assessment of IVD medical devices. And to provide guidance to internal staff as well as the manufacturers on how to introduce new technologies within the organisation including integrating HTA within the decision making process.

The acceptance of the HT documents by the NHLS executive management signified the inception by the NHLS of the HTA programme. Now that the HTA unit had been officially established, further studies are needed to highlight the value placed on the HTA unit's contribution towards the influx of medical devices within the organisation. The value of the impact of HTM for procurement planning in producing recommendations on new technology when resources are limited, needs to be evaluated.

Research has shown that HTA can evolve as seen in a study by Kriza et al., in Sub Saharan Africa. Poor resource settings can adapt HTA tools that suit their individual needs.[14]

Furthermore, hospital based HTA studies show that procurement planning is essential as described by Miniati et al., who explored two of the most widely used HTA approaches and a Medical Equipment Replacement Model (MERM) for decision making in technology selection.[15]

Finally, the establishment of an NHLS IVD pre-qualification process was critical where the 'The Proposed Criteria for the Prioritisation of Diagnostic Technologies' was used as a tool for the selection of new or emerging technology within the NHLS.[16]

According to Bossuyt et al., a review on evaluating diagnostic accuracy is an essential step in the evaluation of medical tests: *'A series of questions should be considered when a new test is evaluated: (1) What is the exiting diagnostic pathway for the identification of the target condition? (2) How does the new test compare with the existing test, in accuracy and in other features? (3) What is the proposed role of the new test in the*

existing pathway: replacement, triage, or add-on? (4) Given the proposed role, what is the best measure of the test performance, and how can that measure be obtained efficiently?[17]

In addressing, the NHI's plan to embark on more equitable and technical efficiencies the NHLS formalised this process by adopting the HB-HTA approach in the selection and prequalification of IVDs. The purpose of this HTA Unit was to provide protocols to be followed by the suppliers of good standing, for new products for use by the NHLS in the performance of laboratory investigations and in so doing: (1) Ensuring that the product being offered is a new generation technology and may offer advantages in terms of methodology, specificity or sensitivity over older techniques; (2) Producing evidence that the product could provide either results of higher quality than the products currently in use or of the same quality with greater costs savings; (3) Allowing the organisation to hold information on similar products in order to react to inadequacies in provision of supply; (4) Providing confirmation that any product being promoted is of the highest quality at the most cost-effective price; (5) Preventing misleading and contradictory information regarding product performance from being disseminated; (6) Taking corrective actions when technical problems are experienced with the current product, which were not initially apparent during evaluation, and (7) Preventing unnecessary duplication in approach and finally wastage of staff time.

STUDY LIMITATIONS

The study was limited to diagnostic pathology services.

CONCLUSION

The review of the organisation's capacity for HTA was addressed by the implementation of external and internal training on the principles, practices and processes of HTA. Secondly, formalising the HTA processes using the HTA Policy Forum Workshop with the drafting, reviewing and implementation of HTA policy and guideline documents. These documents would lay the foundation for the HTA unit to introduce HT within the NHLS. Finally, the introduction of the NHLS IVD prequalification process to ensure transparency in evaluating diagnostic accuracythereby providingthe framework for the organisation that guides good HB-HTA practices.

Furthermore, this review highlighted the need for a formalised process to address the influx of IVD medical devices to enable decision makers to select safe, good quality and cost effective diagnostic technology for the NHLS.

Additional research is required to compare the costs of each new technology to that of the current technology. Further investigations to demonstrate the potential impact of HB-HTA in decision making and its overall influence on improving healthcare by strengthening laboratory systems is also needed.

CONFLICT OF INTERESTS

This study was developed as part of work under the Quality Assurance Department with the NHLS.

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