

Idea for research project

1. Title of the project:

Pediatric Medications Errors in Pediatric Hospitals 2009: Incident and Management

2. Project Summary

This project will focus mainly on medication errors as it represents one of the most common types of reported medical errors. This is especially valid as medicines are the most commonly used health-care intervention.

The project development process considered mainly the global priorities in patient safety researches because there was a great demand for such information. In addition to that there are special needs for the identification of comprehensive and simple solutions within the process of quality improvement. Reports revealed that, there is no enough knowledge about effective solutions for medications adverse events in developing countries.

Understanding adverse events and its types, incidence and preventability is essential component of any patient safety program. This project design was forced to great extent by methodical approaches in implementing safer practices, which in turn requires developing safer systems. The main investigations in this study will concentrate on different components of quality system which include its structure, process and outcomes.

This project plan followed a systematic approach in developing its protocols which were formulated as evidence based. This approach was built on efforts, experiences and initiatives done in this area of work, so as to validate and/or improve the targeted interventions to suit with the local demand for these interventions.

The project team adopts the international patients' safety (High 5) initiative as important and central component in this proposal. This will support the institutionalization and promotion of patient safety culture within the project implementation areas and on mid/long terms. Project team also realized the great needs for transferring the knowledge in patient safety programs. This could be achieved by transferring knowledge from developed countries to developing countries and at the same time transferring it into practical steps in these countries.

This project will be implemented in three phases; including phase one which is considered as situational analysis step then followed by phase two that concentrate on problems identification and solutions selection and the last stage is piloting period phase for the selected solutions.

During the implementation of this project it will be important to make use of available resources (human, knowledge and money) from all supporting partners. Budget management and make use of funds will be considerably preserved during the implementation.

3. Background and Rationale:

Patient safety is defined in general as freedom of a patient from unnecessary harm or potential harm arising from, or associated with, plans or actions taken during the provision of health care rather than an underlying disease or injury. ¹

A lot of theories consider that unsafe medical care is among the major source of morbidity and mortality throughout the world. One of the major contributors for unsafe medical care is the medication errors those result in occurrence of harmful adverse events to patients, especially vulnerable populations, such as the elderly and children.

A medication error is defined by the National Coordinating Council for Medication Error Reporting and Prevention as "*any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer*". Such events may be related to professional practice, health care products, procedures and systems. This including prescribing; order communication; product labeling, packaging, nomenclature, compounding, dispensing, distribution, administration, education, monitoring and even its use.

The impact of medication errors is significant, as it harm an estimated 1.5 million people and kill several thousand each year in the United States of America (USA) and costing the health system at least US\$ 3.5 billion annually. ²

Experts agreed on fact that medication errors have the potential to cause harm within the pediatric population at a higher rate than in the adult population. Children are more prone to medication errors and resulting harm; mainly because of the physiological differences of children from adults (developing renal, immune and hepatic functions). These make them less able to tolerate medication errors. Lack of pediatric- specific formulas which increase the possibility of errors with modifications of adult formulas and difficulties around effective communication between young children and health care providers represents other contributory factors. ³

There is essential need for information about such important issue like incidence of medication errors and their associated risks among pediatric patients those received the health care at hospitals settings. There is a clear need to conduct a study as rapid assessment of the current situation in order to provide baseline data about medication errors in pediatric population.

In many developing countries, there is a considerable gap in information about the incidence and potentiality of medication errors. There is one study conducted on prescription errors (not focused on pediatric), and it was figure out only on the trends in errors associated with prescribing practice of general practitioners rather than the evaluation of errors incident and the impact of these errors.

Medication errors may occur at any point in the medication administration process - during ordering, transcription, dispensing, and administering medications. In USA one study focused on the incidence of adverse drug events and potential adverse drug events showed that the majority of errors occur during the ordering (39-49%) and administration (26-38%) stages, while errors during transcription and pharmacy dispensing represent 11-12% and 11-14% respectively. ⁴

Another study on the incidence and timing of adverse events in patients admitted to a Canadian teaching hospital showed that: incidence of adverse events is 12.7% (in which 4.8% is preventable and 0.6% led to death). Most of adverse events were due to drug treatment, operative procedures, or nosocomial infections. ⁵

In a Critical Incident Analysis done in USA to describe the types of patient safety problems that occur in pediatric medical care they found that the most common domains of medicine in which problems occurred were medication-related (40.1%), surgical and non-surgical procedures (21%), diagnostics (18.5%) and monitoring (10%). Patient identification was a factor in 8.2% of the problems and concludes that patient safety problems were described in all domains of pediatric medical care, with medication problems the most prominent.

In India a study on medical errors in pediatric practice showed that Of 457 errors identified in 1286 children cases, medication errors were 68.5%, those related to treatment procedures were 13.6% and to clerical procedures 17.9%. Physiological factors accounted for 27.3% of errors, equipment failures in 14.9%, clerical mistakes 25.8%, carelessness 21.4% and lack of training for 10.5%. Morbidity was nil in 82%, mild in 10.7%, moderate in 4.8% and severe in 2.4% errors. ⁶

It was clearly realized that pharmacovigilance center and adverse events monitoring play an important role in order to support any patient safety program in this area of work. However the availability of data and information is essential to get such support. The pharmacovigilance center is still at its very beginning activity and there are no solid reports or data that could be used in this area to serves as baseline data for this project.

All these facts indicate the great contribution of errors with pediatric medications in public health services provision. For the great majority of patient safety programs in developing countries this area could be considered less important than other areas. But still medications errors (especially in pediatric medicines) represent an enormous burden on the health system.

4. Study goal, objectives and main research questions:

4.1 Goal and objectives:

Goal:

To support the plans and policies of the national patient safety program by providing information on pediatric medications adverse events and its contributory factors. In addition to that by providing evidence based solutions for weak areas in pediatric medicines handling system.

Objectives:

- To analyze the incidence, types and preventability of medications errors and its contribution in adverse events to pediatric patients in specialized hospitals.
- To identify and test the most applicable, sustainable and reliable solutions or interventions to improve the practices to decrease pediatric medications errors in the study hospitals.
- To evaluate the impact of the projects tested in improving medical care practices in pediatric hospitals.

4.2 Research questions:

1. What is the incidence of medications errors in pediatrics hospitals?
2. Is there is any harm (s) resulting from medications errors in pediatrics hospitals?
3. If any, what is the incidence of the incidence of adverse events resulting from medications errors in pediatrics hospitals?
4. What is (are) the most applicable method or strategy (s) that could be used in order to minimize the medications errors in pediatrics hospitals?

5. Methods

This project was basically designed and developed in the following described manner in order to achieve the overall study objectives. The overall protocol was considering different patient safety research methodologies which are generally used in this research area.

In addition to that, the proposal also attempt to cover, as appropriate as possible, the key issues addressed in the global prospect regarding patient safety demanded data in the area of medication errors. Nevertheless the approach adapted will generate both current situation overview in addition to suitable solutions testing and evaluation.

This methodology is highly recognize and consider the common concept in medications use which is the “**Five Rights**” Concept (Right patient, Right drug, Right dose, Right route and Right time)

The protocol of this project was built in order to achieve its objectives after the completion of 3 complementary phases in different study settings and areas.

These phases will be as follows:

Phase 1: Situational analysis.

Phase 2: Problems identification and solutions selection.

Phase 3: Piloting period.

Phase 1: Situational analysis

This phase was designed in order to provide critical and essential information and data regarding the adverse events related to medications use in pediatric hospitals.

This phase will provide baseline data for the pediatric patients’ safety using specific operational indicators. It was devised this manner in order to focus on certain areas of work related to medications adverse events. This will include the following specific areas:

- Evaluation of **medications ordering** step and associated errors.
- Evaluation of **medications transcribing** step and associated errors.
- Evaluation of **medications dispensing** step and associated errors.
- Evaluation of **medications administration** step and associated errors.

The results obtained from this phase will provide essential information potentially could help to outline the definitions of errors incidence. The classification of these events will be of great importance regarding the weak points in the system.

In addition to that the next step in this project will be based, and depend, on the findings concluded through the development of this phase and its main findings. The methodology for conduction of this phase will be detailed below.

Phase 2: Problems identification and solutions Selection

The major objective of this phase is to, decisively; determine the main problematic areas that contribute to the key problems and triggering factors related to medications of pediatric patients'. This will be obtained through a comprehensive in-depth evaluation of the primarily collected data from phase 1.

In addition to that, the selection of appropriate solution (s) for each area will be carefully identified and designed in all aspects related to the identified problems. The development of the proposed solutions for phase three will depend mainly on the specific problem characteristics. However the overall adjustment of each solution will depend also on the specific needs and gaps in each study setting. This means that; the surrounding factors including the affordability of the proposed solutions, appropriateness and effectiveness will be considered as important selection criteria. The plan will be based on the concept of service (demand-delivery) approach rather than irrelevant implementation.

Annex no (1) contain some of (pre-proposed) solutions based on the experiences derived form other countries in this area. The presentation of these projects were only represent the prospect will be followed in selecting the specific solution to address defined problem. That mean may be one, some or all of these projects could be selected depend on the situation.

Each proposed solution will state the following issues in details:

- Project name.
- Objectives.
- Requirements.
- Targeted areas.
- Impact.
- Setup (how each project to be implemented).

As stated before that; the final selection will be decided based on the results and gathering of information form phase 1 findings evaluation. In addition to that decision makers will be involved at all selected hospitals in which the specific project will, planned to, be implemented. This will be achieved through the conduction of focus groups discussion technique which will be especially formulated for this purpose.

Following the exercise of the focus group discussion; a small working groups of relevant expertise in each area will be formulated to finalize the outcomes of groups' discussion

By the end of this phase an operational workshop will be conducted to share information with all responsible and relevant stakeholders at different levels (policy making level, patient safety program level and hospitals/health services delivery level).

The products and the outcomes delivered form this workshop will guide thoroughly the implementation of phase 3 in this project. This workshop will help to mobilize and advocate the support needed for this project.

Phase 3: Piloting period

The outcomes expected from phase 2 include to great extent the provision of guidance for the final step. The project team will be able to precisely select the appropriate solutions that address and target the priority areas in medications adverse events in pediatric hospitals.

The piloting process will be built on small scale level, but at the same time, this should consider all factors could affect the implementation of these projects at larger scale at program level; or as strategic options to solve targeted problems at national and/or sub-national levels.

The setup of the project and its implementation at each selected hospital will be forced mainly by the critical needs for such project. The cost of establishment, running and other expenses will also largely affect the development of piloting module and the overall expanding plan for large scale.

Understanding the domestic and internal environment, on which the selected projects will tested, could be of initial and important determinant issue. The culture, needs, attitudes and cooperation of health staff work at each hospital were also be among the main factors that need to be considered when each project adjusted (or re-adjusted) to suite the hospital local health system.

Each projected solution, selected for the piloting phase, will be managed through a collaborative manner between the project team and the local management in each hospital to ensure the adaptability, transparency and support.

The duration of testing period will vary from one project to another based on the interventions needed, setup required and the validity of the results obtained from these interventions. But this will be clearly identified in phase 2 workshop for each and every selected project.

After the completion of piloting period of each projected solution, this phase will also consist of evaluation component for each solution applied or implemented. The evaluation will track the same methodology used during phase 1 with the same techniques, instruments and results presentations.

This will be especially important for tow reasons. Firstly; the comparison between results of phase 1 and results of phase 3 will reflect the impact of each project implementation and measuring the improvement achieved in each targeted area. Secondly; the validity of the investigation and evaluation methods will be assured and re-tested for future use in other assessments.

After the evaluation of these projected solutions the project team will conduct second workshop for stakeholders to present and assess the outcomes obtained from this phase and to conclude the final recommendations for further improvements.

5.1 Setting:

Public sector pediatric hospitals, specialized in pediatric medicine, was targeted in as the public sector provide the major health services contribution for this group of age within the population. One teaching hospital will be included in this study setting and treated as special case study. This hospital has good academic environment that encourage and support the scientific projects to be implemented.

Within the selected pediatric hospitals, the study will be focused in the major departments that provide, or deal with, health care services directly to the targeted patients. This will include principally the inpatient ward(s), emergency room(s) and inpatient pharmacy(s).

Outpatient cases and cases admitted for less than 24 hours will be excluded from the targeted sample under the design of this study.

5.2 Study design:

The overall plan of this study structure determines, to great extent, the design formulated to achieve the objectives and aims. By applying the following approach, the study will deeply investigate the cause-effect relationships that generally outlined the problems structure. Then this will help to conduct relationships assessment based on WHO causality definitions in patients' harm and safety programs.

As describe above; 3 major phases will be implemented during the project period. Among these phases it was clear that phase 1 (situation analysis component) and phase 3 (subsequent evaluation component) were both represent the main investigational segments of this study. Since other components will include more operational and applied work.

Designs prescribed below will provide an overview of the scale of harm and adverse outcomes (assessing the nature and scale of harm). The lack of information, and even incompleteness, largely affect the planning process in any patients' safety programs. For this reason, the study will adapt the active surveillance approach in the provision of information rather than passive monitoring or assessment.

Within these 2 parts there are different approaches will be used during the study implementation. This will be represented as follows:

Design 1:

The primary target of this design is to investigate the nature and scale of harm associated with pediatric medication errors.

This will include **cross-sectional study** that aims to evaluate the errors associated with medications ordering and prescribing that classified as adverse events.

Structured **prospective records/charts review** will be conducted using pre-determined errors **domains** related to each area (annex 6).

Additional supporting data could be gathered from health professionals to support the evaluation of **preventability**; this will be collected through target oriented interviews.

Records/charts review process will be structured according to the following categorization protocol:

1. Sample unit will be determined based on the sampling technique detailed in sampling part.
2. Each chart will be evaluated using pre-formulated chart form (annexes 2&3).
3. Each event will be recorded in separated data collection instrument.
4. The review process will consider the demographic data obtained.
5. The classification of charts will be based on the occurrence of the adverse event (or not), then to follow the classification of events into the following categorization.

Design 2:

The primary target of this second design is also to investigate the nature and scale of harm associated with pediatric medication errors.

This will include **observational study** that aims to evaluate the errors associated with medications dispensing and administration that classified as adverse events.

The evaluation of administration practices will be assessed based on observation technique against **best practices** in this area.

This data will be collected using pre-prepared **checklists** upon which the data collectors will be trained to ensure the validity of data.

The evaluation process will be conducted, similar to design 1, by using pre-determined errors **domains** related to medications administration.

Additional supporting data could be gathered from health professionals to support the evaluation of **preventability**.

The same **categorization scheme** will be applied for classification of all circumstances related to administration.

5.3 Study subjects:

All public hospitals providing pediatric health services will be included in the study sample. No public pediatric hospital will be excluded from this study.

Ministry of health through these hospitals provides services for children under 5 years old, in addition to children in the age range from 5 years up to 18 years old whom were also receive health care in pediatric hospitals.

For the purpose of this study, and within the study areas, pediatric patients under 18 years of age will be included and all other patients above this age will be excluded. This will be based on the demographic data presented in the patients' charts in all hospitals during the screening process.

5.4 Sample size and sampling techniques:**Hospitals:**

The selection of hospitals for this project will follow the total coverage approach. There is limited number of pediatric specialized hospitals. Accordingly all hospitals will be included in the sample. One teaching hospital will be included as case study.

The targeted hospitals are detailed as follows:

Hospital

Classification

Cases:

The sample of cases to be reviewed, using 2 designs described above, will be determined mainly by the international validated standards in this area of researches. The total number of cases from these hospitals is 2,000 admitted cases (500 per each hospital). This was guided by the recommendations regarding medical records review for adverse events measurements.

Stratified randomized sampling technique will be used in approaching admitted cases included in the sample. The clusters will be defined depend on the admission to specialized wards or areas within the hospital. This will include emergency ward, general ward, surgery ward, inpatient pharmacy and ICU if applicable.

The admissions less than 24 hours in the hospital will be excluded from the sample depend on the charts data.

From each site equal number of cases will be selected to get overall sums of 500 cases in each hospital. Accordingly the sampling interval will be calculated based on the access rate for each site per day. The overall average daily entrance will be based on the calculation in last month admission within each specific site. This will consider the overall duration of the review period.

The same approach will be followed during the assessment component of phase three.

5.5 Data Collection methods, instruments used, measurements

5.5.1 Study definitions

The project methodology adopts and adapts the following definitions which are based mainly on standardized definitions in International Classification for Patient Safety (ICPS) developed by WHO.

This approach was followed in order to support WHO efforts for standardizing and unifying the definitions used in patients safety researches.

Medication error: is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Adverse event is an incident which results in harm to a patient.

Adverse reaction: is defined as unexpected harm arising from a justified action where the correct process was followed for the context in which the event occurred.

Circumstance: has been defined as any factor connected with or influencing an event, agent or person(s).

Contributing factor: is defined as a circumstance, action or influence which is thought to have played a part in the origin or development of an incident, or to increase the risk of an incident.

Disease: is defined as a physiological or psychological dysfunction.

Event: as something that happens to or involves a patient.

Harm implies impairment of structure or function of the body and/or any deleterious effect.

Hazard: as a circumstance, agent or action which can lead to or increase risk

Healthcare: has been defined as services received by individuals or communities to promote, maintain, monitor or restore health.

Incident is an event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.

Patient: has been defined as a person who is a recipient of healthcare.

Patient safety: is defined as freedom for a patient from unnecessary harm or potential harm associated with healthcare.

Preventable: has been defined as being accepted by the community as avoidable in the particular set of circumstances.

Safety: has been defined as freedom from hazard.

Side effect: is a known effect, other than that primarily intended, relating to the pharmacological properties of a medication.

5.5.2 Main variables and measures

The variables or indicators that could be abstracted from tools, used in the assessment components, could be divided into two levels:

Group A: Outcome Indicators

- Incident of errors associated with pediatric medications ordering.
- Incident of errors associated with pediatric medications transcribing.
- Incident of errors associated with pediatric medications dispensing.
- Incident of errors associated with pediatric medications administration.

Group B: Process Indicators

- % of medication orders clearly identified the right patient.
- % of medications order included the right drug.
- % of medication orders correctly calculated the right dose.
- % of medication orders correctly identified the right route of administration.
- % of medication orders correctly identified the right dose interval.
- % of medication transcribing steps clearly identified the right patient.
- % of medications transcribing steps included the right drug.
- % of medication transcribing steps correctly copied the right dose.
- % of medication transcribing steps correctly copied the right route of administration.
- % of medication transcribing steps correctly identified the right dose interval.
- % of medication dispensing steps carefully revised the identity of the patient.
- % of medications dispensing steps handed out the right drug.
- % of medication dispensing steps carefully revised dose calculation.
- % of medication dispensing steps handed out the right route of administration.
- % of medication dispensing steps correctly laid down the right dose interval.
- % of medication administration steps clearly identified the right patient.
- % of medications administration steps correctly directed the right drug.
- % of medication administration steps correctly directed the right dose.
- % of medication administration steps correctly directed the right route of administration.
- % of medication administration steps correctly directed the right dose interval

5.5.3 Instruments/tools

All tools that will be used during the course of this project were formulated in order to give smooth process in charts review, records evaluation and observations monitoring.

The data collection tools developed in a way that provides answers to evaluate the adherence of medications management within the context of the “**Five rights Concept**”. Each question in these tools was designed to provide critical conclusion in specific issue in the 5 rights concept. In addition to that, the components in this concept were used to drive the study variables those will be used to evaluate the situation.

The data needed for this study will be collected through different tools including:

- Data collection form (No 1) “Ordering evaluation form”.
- Data collection form (No 2) “Transcribing evaluation form”.
- Data collection form (No 3) “Dispensing evaluation checklist”.
- Data collection form (No 4) “Administration evaluation checklist”.

NB: Copies of all these instruments were attached (please see annexes 2 to 5).

5.5.5 Quality control measures

It was become clear that health services provision, especially in medications selection and handling, become more oriented toward the patient rather than concern about the products/services provided. A lot of changes were taken place among health professionals approaches. This is appearing as the practice was generally shifted from being product oriented practice to become more and more patient oriented practice.

This concept was largely driven most of good practices developed now a days. Although the project team will be guided mainly by the following important tools including best practices in different areas, however this should be always steered by the sense of patient care approach rather than product focusing even during the assessment process.

Since there are no “National” good practices guidelines, the following list of international documents will be considered during the evaluation process which include mainly (but not limited to):

1. Guide to Good Prescribing: A Practical Manual, developed by (WHO).
2. Standards for Quality of Pharmacy Services, developed by (IPF).
3. Guidelines For Good Practice - Drug Administration, developed by (NHS).

5.5.4 Techniques/ methods

While many studies has been conducted in the area of medication errors, pediatric medications, errors solutions testing; but still these studies were scattered in different areas.

This study adopted different techniques and methods during the implementations of different phases. Within the setup of each phase (especially phase one and three) the instruments used were developed by the project team. However the classification method used to classify the errors indentified were referred to USP Medication Errors Monitoring Program, and all the rights were reserved for this issue.

The instruments will be tested to evaluate its validity and relevance as described below.

Pilot Study:

Data collection forms and checklists will be tested through specific pilot study designed especially for this purpose. It will be conducted in similar study selected setting to simulate the actual study.

The results of pilot study will be discussed in a group discussion activity. This will involve multi-discipline professions (other than the study team) to give different prospective evaluation of these tools structure, relevance, validity and applicability.

The recommendations from this group on the outcomes of this pilot study will be considered to re-evaluate the study tools.

5.5.6 Data management and analysis plan:

The data analysis process will include mixed analysis methods according to the type of data and the tool of data collection, but in general it will be done using the following:

- Computer programs e.g. SPSS + MS Excel + MS Access will be used.
- Manual analysis.

To ensure the quality of data the process of data entry and data analysis will be in specific period after the completion of data collection from the study sites.

The data entry and analysis will be conducted with support of specialized personnel in the area of statistical analysis and data entry with help and support of project team.

6. Expected direct products (outputs)

Operational:

- Projected solutions which will be tested during phase three, upon the evaluation process, could be extended to operate after the project completion. This will be the case if it was proved to be successfully help to decrease the incident of medication errors within the project site.

Reporting:

- Upon the completion of phase one of this project, comprehensive situational analysis report will be produced. This will include both quantitative and qualitative data regarding the baseline assessment in the study settings. This will be considered as first progress report.
- By the end of phase two the following essential products will be produced:
 - Operational plan for phase two implementation after the workshop.
 - Second progress report regarding the project implementation.
- After phase three was completed, two sort of products were expected to be delivered:
 - Third progress report of the project implementation.
 - Final project report.

Project Final Report; will include:

- Executive summary and recommendations.
- Review of project progress and performance.
- Measurements and evaluation.
- Objectives achieved.
- Activities completed.
- Resources and budget used
- Assumptions and risks.
- Key Quality/Sustainability issues.
- Overview of practical next steps (plans) needs to be developed and/or implemented.
- Overview of inputs.

7. Implications of study results on patient safety practice and/or interventions

- Patient safety capacity improvement is one of the important component, this policy adopt the importance of developing Patient Safety Program (PSP).
- This health policy reiterates the government's resolve for the enforcement and fulfillment of country's commitment towards implementation of the program strategies in wide range of health delivery settings.
- The commitment in the government policy could be of valuable support to this project results and recommendations to be incorporated into the governmental plans at national as well as states level. This is especially important after the establishment of PSP which need to be supported by evidence based information.
- The study team will ensure that the results obtained from this project will support the national program by providing effective and scientific interventions that help to minimize the harm occur for pediatric patients due to errors associated with medications.
- One of the objectives of this project is to promote the patient safety culture regarding the safe use and safe handling of medicines. This is especially true in a country characterized by high rate of irrational use of medicines, in addition to the wide spread of self-cure approach among the public's.
- The promotional plan will focus mainly on pediatric medicines and its unique particularity.

8. Dissemination of results and publications plan

- The plan is to endorse the results and final report of this study by the higher level of political bodies in to ensure that the message of the study findings could be utilized at the higher policy making levels.
- The report and findings of the study will be discussed in the regular meeting of the national board of medical research to ensure the quality of the final report.
- The plan also included the conduction of dissemination seminar that will include all of the relevant parties with regard to the implementation patients' safety program.
- This similar will include Federal and some States Ministries of Health, patient safety program, World Health Organization, relevant civil societies, individual consultants and any other relevant bodies.
- The final draft of the project will be shared with WHO and World Alliance for Patient Safety.
- Series of articles and scientific papers (in consultation with WHO and World Alliance for Patient Safety) will be published locally and internationally. This will enrich the knowledge regarding the magnitude, causes and solutions of these kinds of problems in developing countries and among interested parties.

9. Ethical Considerations:

9.1 Ethical considerations

This project doesn't include any direct involvement of human beings and no any direct (or indirect) interventions or medications intended to be applied or used by patients.

Basically this project proposal doesn't imply any risk, or potential circumstances for risk, to the publics or people work in the study area.

The patients targeted for this study will be approached in the study settings described early based on the pre-defined selection criteria without any bias. The identity and privacy of patients included in the study (including the health professionals) will be maintained.

The study team will preserve the confidentiality of the data collected during this study; the data will be stored in secured place for documentary purposes for a period up to 3 years.

If there is any changes in this study protocol, in any issues that affect the ethical considerations, will be communicated with relevant stakeholders in the relevant program including WHO and ministry of health ethical committee. The recommendations of partners in this case will be treated with full respect and handled in a professional way.

9.2 Informed consent form

Not applicable.

9.3 Institutional ethical clearance

- Do you have an ethical review board in your institution? Yes No
- Institutional ethical clearance has been obtained for the study: Yes No

10. Bibliographic references

1. WHO Report on the Results of the Web-Based Modified Delphi Survey of the International Classification for Patient Safety, June 2007.
2. Assuring Medication Accuracy at Transitions in Care, WHO Collaborating Centre for Patient Safety Solutions, Patient Safety Solutions, volume 1, solution 6, May 2007.
3. Preventing pediatric medication errors
4. Alan J. Forster, Tim R. Asmis, Heather D. Clark, Ghiath Al Saied, Catherine C. Code, Sharon C. Caughey, Kevin Baker, James Watters, Jim Worthington, Carl van Walraven, Ottawa Hospital Patient Safety Study: incidence and timing of adverse events in patients admitted to a Canadian teaching hospital, CMAJ • APR. 13, 2004; 170
5. Pediatric Patient Safety Risks: A Critical Incident Analysis, Woods D, Bhatia MM, Ogata E, Shonkoff J, Holl J; AcademyHealth. Meeting (2003 : Nashville, Tenn.) Abstr AcademyHealth Meet. 2003; 20: abstract no. 693.
6. Medical Errors in Pediatric Practice, MANSI PARIHAR AND GOURI RAO PASSI, Department of Pediatrics, Choithram Hospital and Research Center, Indore, MP, India, February 1, 2008.
7. Fortescue EB; Kaushal R; Landrigan CP; McKenna KJ; Clapp MD; Federico F; Goldmann DA; Bates DW. Prioritizing strategies for preventing medication errors and adverse drug events in pediatric inpatients.
8. Strategies to reduce medication errors with reference to older adults. Volume 9, issue 4, 2005 ISSN 1329 – 1874.
9. Stuart R. Levine, et al. Guidelines for preventing medication error in pediatrics. JPPT. The journal of pediatric pharmacology and therapeutics 2001;6:427-429
10. Sir Liam Donaldson Chair, WHO World Alliance for Patient Safety Chief Medical Officer for England. Summary on the evidence for patient safety: implications for research. WHO 2008. Section 2:15.
11. Han YY, Carcillo JA, Venkataraman ST, et al. Unexpected increased mortality after implementation of a commercially sold computerized physician order entry system. Pediatrics. 2005;116:1506–1512.
12. Larsen GY, Parker HB, Cash J, et al. Standard drug concentrations and smart-pump technology reduce continuous medications-infusion errors in pediatric patients. Pediatrics. 2005;116:e21–e25.
13. Linda M. Strand, et al. Pharmaceutical care practice: The clinicians guide; The McGraw-Hill companies, Inc. 2005;2:64;14:337-355.
14. Stuart R. Levine, et al. Guidelines for preventing medication error in pediatrics. JPPT. The journal of pediatric pharmacology and therapeutics 2001;6:433-434.
15. Singh H, Thomas EJ, Petersen LA, et al. Medical errors involving trainees: a study of closed malpractice claims from 5 insurers. Arch Intern Med. 2007;167(19):2030–2036.
16. Kozler E, Scolnik D, Macpherson A, Rauchwerger D, Koren G. The effect of a short tutorial on the incidence of prescribing errors in pediatric emergency care.
17. Kozler E, Scolnik D, MacPherson A, Rauchwerger D, Koren G. Using a preprinted order sheet to reduce prescription errors in a pediatric emergency department: a randomized, controlled trial. erank@asaf.health.gov.il.

11. Project plan and duration

The overall management of the plan, as joint team with project sites managers, will provide valuable support to the project implementation in efficient manner. The prior communication with these partners will facilitate each phase implementation.

This project as detailed above was designed to be implemented in three phases. Each of the second and third phase are depend critically on the previous phase. According to that, the shorter each phase was implemented the shorter the project was finished.

Although this is true, the dependancy of phases implementation, but still the project team will complete any independent steps at parallel approach so as to decrease the whole project period. But still this will be observed carefully to insure the quality measurement during the implementation.

The project period was estimated to last for about 15 months starting from the beginning of phase one which is expected to be finalized after 4 months. Phase two will be the shorter phase with expected period of about 3 months. After the operational plan for phase three is finalized by the end of phase two, phase three is expected to take between 7 months to 8 months depend on the type of selected small projects during the implementation of phase three.

In the detailed workplan for this project the project team followed the description of the implementation based on the determination of products, activities and tasks. This will help both the funding agent and the project team to follow the implementation closely for monitoring and evaluation purposes.

12. Timelines:

Key milestones	MONTH (from project commencement)																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Communications for Support and team mobilization																		
Preparation/finalization and validation of instructions manual and other documents																		
Select and train data collectors																		
Conduction of the pilot study																		
Phase One commencement																		
Assessment and data collection																		
Situational Analysis report																		
Phase one completion																		
Phase two commencement																		
Technical Groups discussion activity																		
Hospitals needs assessment working group																		
Project solutions operational plan Workshop																		

13. Budget			
Budget Breakdown	Unit cost (\$US)	Budget (\$US)	Other Source (\$US)
Component 1: Personnel			
Component 2: Supplies and Equipment			
Component 3: Capacity Building			
Component 4: Data collectors Training			
Component 5: Others			
<i>Total</i>			
Miscellaneous (5% of the total above)			
GRAND TOTAL			

13.1 Budget justification

Budget management and make use of funds will be considerably preserved during the implementation.

While the project team recognize well that compering with the proposed budget comparing to the range of small grants allocation could be considerably high, but it was also valid that the inputs required for such kind of projects need considerable amount of money to face the and cover all expected request.

While the overall budgetary plan was cover multi displined areas of work, the cost per each item was kept to the minimum as much as possible.

It was clear that the component include the provision of supplies and equipment represent considerable portion of the proposed budget, but at the same time it include the most critical project needed inputs for the operational work.

It was well understood that all procurement process will be according to WHO guidelines and regulations.

The cost doesn't include any office supplies or any physical infrastructures at the projects setting. The project manger, and upon the agreement with targeted hospitals, will secure all needs required for the operational level in the implementation.

For many reasons the the cost was based on the local expenses estimation for the relavent components on which the local rate was used for such kind of items.

No similar study that could be used as a guide in the implementation, and accordingly there is no baseline for the budget comperison.

The budget for specifc budgetary components could be re-adjusted based on the advice form the reviewers.

14. Risks and assumptions

The development of the project in such manner, situational analysis and soultions testing, was expected to derive some problems or difficulties but at the same time some fevrable implementation

conditions.

Technical Aspects:

1. While the project team was considerably consist of multi-sectoral members from different careers relevent to the project, but still it was expected that some clinical issues may challenge the experience (or knowladge of the team) which will need experts advice in these issues. The project team will refer these cases (if any) to be discussed in the clinical meetings conducted within the hospital in which the case was occur. Then the advice received will be consiered, aknowlaged and registered is special reports for the sake of the records.
2. During the implemtaion of the selected solutions in phase three, it was expected that some areas in these projects may need technical assistance form some specialized persons in that areas. The project manager agreed with pharmacy directorate to provide ditrect support if availabe, or to facilitate its provision through third parties with acceptance of hospitals management on which the project implemented.
3. The data, and records in general, was expected to be of potentailly poor quality within the selected hospitals. This is not is special case in these hospitals, but this is characterizing the whole health management information system in the country. This was particularrly expected regarding the data needed to evaluate the ordering step. The project team will evaluate the degree of missing data; and any incomplete chart or record will be excluded from the review process.

Manengerial & Adminstretive Aspects:

1. Although the project team have primery contact with the partners who will be involved during the implementation, but still the high rate of staff turnover in some of the targeted hospitals was expected to affect the common understanding and agreements of this project. The team provide an operational copy of this project proposal to the managers at the tergetd hospitals, and they asked to provide written agreement to implement the propsal in case it was become eligible for funding.
2. The project could be considered as medium term project with regard to its period. The delay of each phase, specially phase one, could largely affect the project obligation to the scheduled time. If this was the case, the project team will evaluate the situation and then an alternative plan will be developed to compensate any delay to finalize the subsequesnt phases as it was planned in this proposal.
3. The project team realize that the available budget that could be allocated to this project will be limited comparing with the size of this proposed project. However the project team was also understand that this project will be small scale project for testing purpose. Therefore the budgetary management will be executed in efficient manner benefiting from all terms of support obtained from partners to implement the projected solutions.

15. Annexes:

- Annex 1:- Example of “Pre-proposed” Solutions for phase three.
- Annex 2:- Data collection form (No 1) “Odering evaluation form”.
- Annex 3:- Data collection form (No 2) “Transcriping evaluation form”.
- Annex 4:- Data collection form (No 3) “Dispensing evaluation checklist”.

- Annex 5:- Data collection form (No 4) “Administration evaluation checklist”.
- Annex 6:- Errors domains for records review.
- Annex 7:- National endorsement of the study.
- Annex 8:- Curriculum Vitae Summary - Principal Investigator.
- Annex 9:- Endorsement letter from federal directorate of pharmacy.
- Annex 10:- Study team signature.

16. Project team and project management

Name	Position	Organization	Role	Responsibilities

17. Networks/ collaborations

18. Other funding agency

Is this project part of the study funded by another funding agency: Yes No

19. Other information

19.1 Collaboration with other scientists or research institutions

19.2 Links to other projects etc.
Not applicable.

19.3 Other research activities of the principal investigator

19.4 Financing and Insurance

In the last five years pharmacy directorate received a total budget of about 150,000 USD from WHO pharmaceutical program to implement different kind of studies and researches in different areas of work. The financial system of pharmacy directorate is a part of the financial system for whole federal ministry of health. This was managed with accountability regulations and guidelines for financial management.

All grants received from WHO were financially cleared through financial reports sent from pharmacy department to WHO. In the collaboration plan with WHO or other partners no pending (or not implemented) project now exist.

Pharmacy directorate has separate researches department that provide technical support for all studies conducted in pharmaceutical sector. In addition to that it serve as documentary body for all research activities in pharmaceutical sector.

The presentation of these projects were only represent the prospect will be followed in selecting the specific solution to address defined problem. That mean may be one, some or all of these projects could be selected depend on the situation.

Each proposed solution will state the following issues in details:

- Project name.
- Objectives.
- Requirements.
- Targeted areas.
- Impact.
- Setup (how each project to be implemented).

General

The search of the literature for interventions to be suggested for the implementation in pediatric hospitals, with the aim of decreasing medications errors and increasing patient safety, reveals a number of solutions to this problem.

Of the founded interventions, computerized physician order entry with clinical decision support systems; ward-based clinical pharmacists; and improved communication among physicians, nurses, and pharmacists had the greatest potential to reduce medication errors in pediatric inpatients. Development, implementation, and assessment of such interventions in the pediatric inpatient setting are needed.⁷

The following presented projects are the foundation upon which the research team will select and adapt solutions according to the individual hospital's need.

On the other hand these projects will be implemented in small scale to cover the need of each hospital requirements, and to act as guidelines for broader implementations all around Sudan pediatrics hospitals.

1) Computerized physician order entry systems CPOE with calculators and point-of-care decision support

Objectives:

(CPOE) is to aid in improvement of patient safety. And

1. To reduce medication errors those are attributed to an occasional lapse of personal performance of every healthcare provider.
2. To prevent unintended care delays and morbidity and mortality.^{8,9}

Requirements:

1. An ideal computer order entry system with special important functions.
2. Site-specific programming choices, helping the system in prevention of medication errors.
3. Careful system integration and skillful human-machine interfaces is required in areas that are time-sensitive.⁹

Targeted areas:

This technology should be used in situations where accuracy is critical. And this will be targeting ordering medications by physicians.⁹

Impact:

(CPOE) is an element used within an overall strategy to improve the safety of our patients. And this is done only through the coordinated use of elements of a medication error reduction strategy.

This will add to healthcare a technological support by providing information, facilitating clear and accurate communication, alerting the user to potential errors, and prescribing data.⁹

Setup:

To implement an ideal computer order entry system the following functions are important:-

1. Prescriber order entry for the verification by nurse and pharmacist.

2. A common database shared with the pharmacy and the prescriber. This is for the provision of a computer-generated medication administration records.
3. Lists of current medications should be provided for each patient.
4. Two-way interface between pharmacy and other hospital systems.
5. An access to hospital patient data.
6. It must have a pediatric weight based dosing calculator and (weight or height) specific maximum and minimum doses.
7. An access to vital patient and drug information directly from order entry, medication profile, and medication administration screens.
8. Ability of system to use patient and drug information to provide accurate information during order entry to reduce potential for adverse drug events. This should be part of a comprehensive decision support program. These programs would include checking for laboratory results and advising the prescriber of the need for dosing modifications for specified medications. Automatic checking should also include drug-drug interactions, drug-nutrient interactions, drug duplication, therapeutic duplication, contraindicated medications, and weight-based dosage checking.
9. Provide a forced function by limiting the route and frequency by which a drug is ordered.⁹

Opportunities:

Availability of funds and the encouragement of the researchers by the policy makers to provide such interventions provide good chance for (CPOE) to be implemented.

Also the idea of this project is to be implemented in small scale, and the five hospitals suggested resembling this scale.

Limitations:

1. (CPOE) have been implemented in developed countries however its feasibility and cost-effectiveness in developing countries are not guaranteed.¹⁰
2. There is a great promise holds by (CPOE) in reducing human errors during healthcare delivery. However preventable unintended care delays and morbidity and mortality could be associated with (CPOE). So care areas with time-sensitive processes will require careful system integration and skillful human-machine interfaces.¹¹

However we proposed to overcome these by idea of this project, which is to be implemented in small scale, and the five hospitals suggested resembling this scale.

2) Smart pump infusion technology

Objectives:

To reduce continuous medication infusion error rates, this technology could be useful. And to be incorporated in a well-coordinated plan to improve patient safety.¹²

Requirements:

A criterion for selection of a smart syringe pump requires a multidisciplinary task force (staff from nursing, pharmacy, clinical engineering, and the neonatal and pediatric intensive care units), as well as the involvement of the hospital patient safety manager.¹²

Targeted areas:

Pediatric and neonatal intensive care units and all healthcare staff in these areas are included in the targeted areas especially administration done by nurses.¹²

Impact:

Smart pump infusion implementation increases the safety of infusion delivery. This is by providing a ready safety net for nurses to check medication orders.¹²

Setup:

1. This device incorporates sophisticated computer technologies for storing drug information as drug library, making calculations, and checking entered information against dosing parameters.
2. Many steps needed to program the pump.
3. Selection of a smart syringe pump.
4. Modification of the drug library dosing ranges to avoid 10-fold overdoses.
5. Finally generation of label changes by pharmacy to facilitate the correct transfer of information from label to smart-pump during programming by provider.
6. The time course for setup in a hospital supposed to be 1 week.¹²

Opportunity:

There is great need by ICUs in pediatric hospitals in Sudan which makes good environment for the project.

Limitations:

Although it is an example of a well-coordinated plan to improve safety, implementation may need special considerations in Sudan as developing country, as it requires stable system to assess the efficacy of the interventions driven. As well as to ensure the make use of capital expenditure invested in this project.

3) Establishing a new pharmaceutical care practice

Objectives:

1. This is to improve patient safety and outcomes by helping avoid medication errors and by recommending optimal therapies and dosages.
2. By clinical pharmacy services we can serve and provide a collaborative drug management by serving as patient-oriented, and provide consultation.^{13,8}

Requirements:

1. Qualified clinical pharmacist, with the required standards for professional behavior, which are the standard of each of these categories (quality of care, ethics, collegiality, collaboration, education, research, and resource allocation). Besides being a competent practitioner.⁷
2. Hospital policies and procedures are required for clinical pharmacy services to be directed towards these policies.¹³

3. Guidelines for building a patient care practice.¹³

Targeted areas:

The overall hospital healthcare professionals are being targeted by the service of clinical pharmacy and also patients.¹³

Impact:

It is the impact of what clinical pharmacy competition likely has.

- By a system of pediatric clinical pharmacists we can effectively characterize and prevent the inpatient prescribing pediatric medication errors.⁷
- Giving the safest drug regimen possible while offering this professional assistance.¹³

- By serving as a "gyroscope" to focus their clinical activities in cases that involve patients with numerous, complex, and difficult therapeutic dilemmas. The impact of this practice includes clinical improvement, healthcare savings, and sometimes both.¹³
- Prevention of serious morbidity from occurring.¹³

Setup:

The set of clinical pharmacy practice is by promoting clinical pharmacy team as if it were a product.¹³

1. A description of (the service we will offer, and the problem of medication errors that we will solve) given to all hospital healthcare team.
2. For organization and implementation a marketing plan should be developed.
3. Identify a supportive practice environment.
4. Accommodate the hospital organization.
5. Develops techniques to recruit patients
6. Identification of a network of pharmaceutical care practitioners.
7. Internalize the rational thought process used for making clinical decisions.
8. Add developmental programs to hospital.

9. Apply the standards of care, standards of professional behavior, and ethical principles involved in practice.
10. The time to set this service may be up to two years.

Opportunities:

Availability of two clinical pharmacists in the core of the team presenting this project, international policies for pediatric hospitals, and guidelines for developing this system, this made the promise of success.

Limitations:

Although of the existing international pediatric policies and guidelines, a lack of national unified guidelines shared by pediatrics hospital in Sudan represent a great challenge to project team.

4) Capacity building programs

Objectives:

Prevention of medication errors by providing training programs for healthcare professionals. (These programs are focused in education in medication prescribing, preparation, labeling, dispensing, monitoring, and administration).⁸ Also to develop multidisciplinary quality improvement teams.^{15, 8}

Requirements:

Training programs require availability of knowledge and skills important for provision of courses, and instructions.¹⁴

1. Expertise in pharmaceutical science.
2. Support personnel to aid in implementation of the suggested program.
3. Brochures to be as small messages to healthcare providers.

Targeted areas:

Prescribing, dispensing, and administration.¹⁴

Impact:

1. An increase in frequency and decrease in severity of medication errors reported.⁸
2. The continuum of quality improvement provides a process for reducing risk and optimizing outcomes.¹⁵

Setup:

Two phases are required in the implementation of this project⁹:-

1. This phase will be done by the identification of how and why medications errors in practice happen.
2. Then the learning programs implementation steps came and this will be done under the light of phase one.
3. The healthcare trainee will be involved in the selection of learning programs.

Opportunities:

The two phases suggested in the implementation of this project already resemble the same phases proposed by the research team.

Limitations:

Short tutorials in prescribing errors do not give the required impact¹⁶. So the capacity building programs will be implemented as a feedback to the actual reported medication errors by phase one of this research and then be a continuous available programs as required.

5) Preprinted or structured order sheet¹¹

Objectives:

This sheet is used to minimize prescription errors, and in reducing the related prolonged hospitalization, unnecessary diagnostic tests and treatments, and death.

Requirements:

1. Computers.
2. Professional personnel in information technology.
3. Doctor and pharmacist.

Targeted areas:

Doctors prescribing medications practice is the target.

Impact:

This is proposed to have a great impact in preventing prescribing errors as well as improving patient safety in pediatric emergency departments.

Setup:

By information technology, we will cover all the required issues in formatting these sheets. And this will be done under the consultation of a doctor.

Opportunity:

This experience already has been done by some hospitals in Sudan which can act as a foundation for suggestion of this project.

Limitations:

This computerized based intervention requires prior knowledge about basic tips and tactics of computer. And to overcome this, proper personnel resources will be selected.

Hospital Code:

Section A: Demographic Data

1/ Area: General ward Surgery ward Emergency ward ICU Pharmacy Other

2/ Gender: Male Female 3/ Age: 4/ Weight: Km

5/ Diagnosis.....

6/ Patient known with drug allergy Patient not known to drug allergy

7/ Medication Administered

Section B: Medication Ordering

Person 08/ Who carry out ordering process Specialist Registrar GP Other

Patient 09/ Patient was identified clearly during the ordering Yes No

Medicines 10/ Existence of unnecessary medication(s) Yes No

11/ Existence of additional therapy Yes No

Dose 12/ Dose was ordered Based on patient weight Standard dosing scheme

13/ Dose revised, and it was High dose Correct dose Low dose

Route 14/ Administration route ordered Correctly Incorrect

Time 15/ The frequency of administration ordered Correctly Incorrect

16/ Error in ordering process was identified	Yes <input type="checkbox"/>	No <input type="checkbox"/>
--	------------------------------	-----------------------------

Section C: Primary Cause Identification

17/ The primary cause of this error could be related to:

Professionals practice Communication problem knowledge problem

Product related problem Patient related problem System related problem

Section D: Classification

18/ This error could be classified as (please refer to the next page):

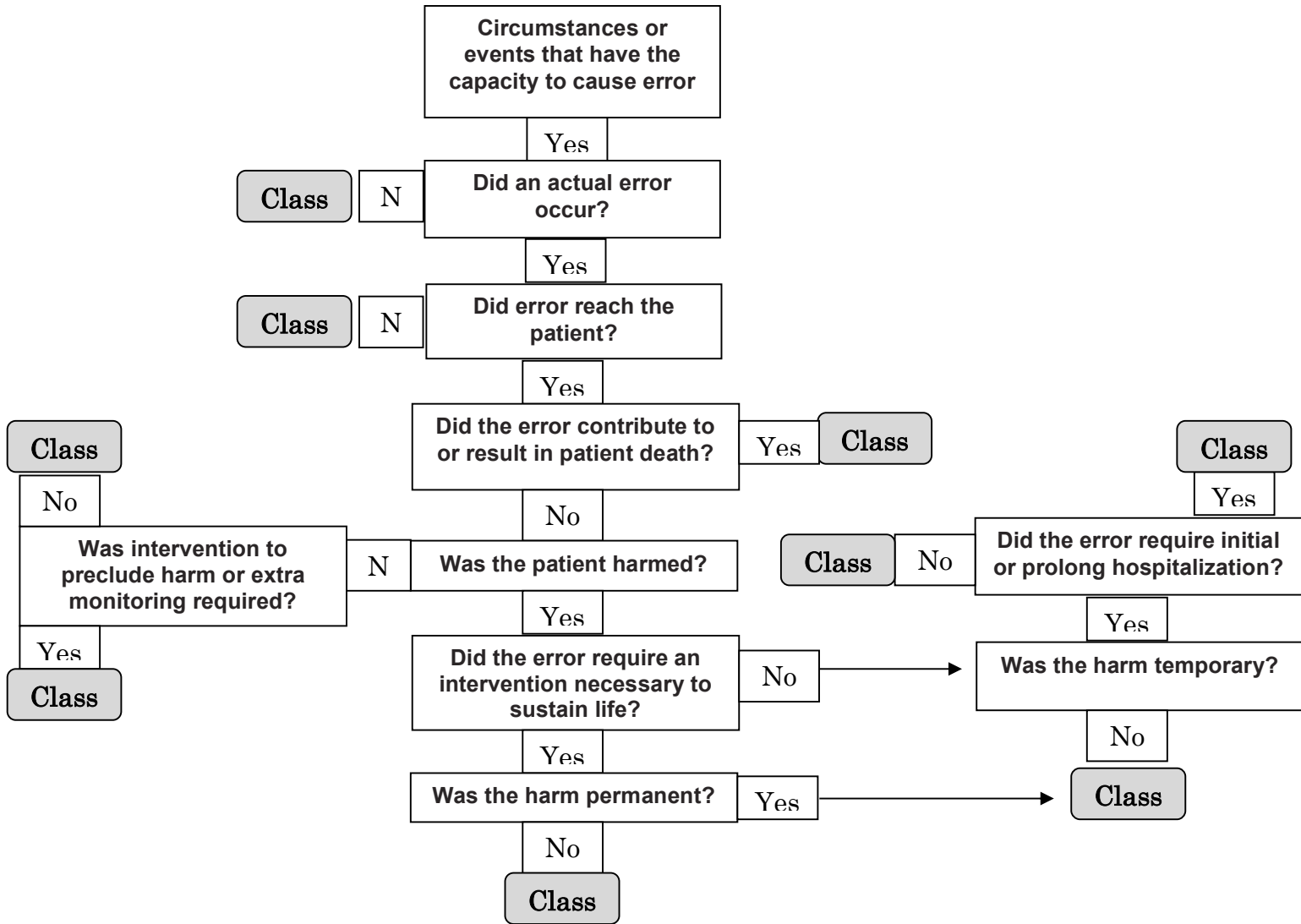
Class A Class B Class C Class D Class E Class F Class G Class H Class I

Section E: Comments

.....

Classification Scheme

This classification scheme was developed by USP for the purpose of Medication Errors Reporting program. The Copy rights were preserved to USP.



Hospital Code:

Section A: Demographic Data

- 1/ Area: General ward Surgery ward Emergency ward ICU Pharmacy Other
2/ Gender: Male Female 3/ Age: 4/ Weight: Km
5/ Diagnosis.....
6/ Patient known with drug allergy Patient not known to drug allergy
7/ Medication Administered

Section B: Medication Transcribing

- Person** 08/ Who carry out the transcribing process Doctor Nurse Other
Patient 09/ Patient was identified clearly during the transcribing Yes No
Medicines 10/ Medication the same as ordered Yes No
11/ The handwriting was clear and readable Yes No
Dose 12/ The dose was the same as ordered Yes No
Route 14/ The route of administration was the same as ordered Yes No
Time 15/ The frequency of administration was the same as ordered Yes No
16/ Error in ordering process was identified Yes No

Section C: Primary Cause Identification

- 17/ The primary cause of this error could be related to:
 Professionals practice Communication problem knowledge problem
 Product related problem Patient related problem System related problem

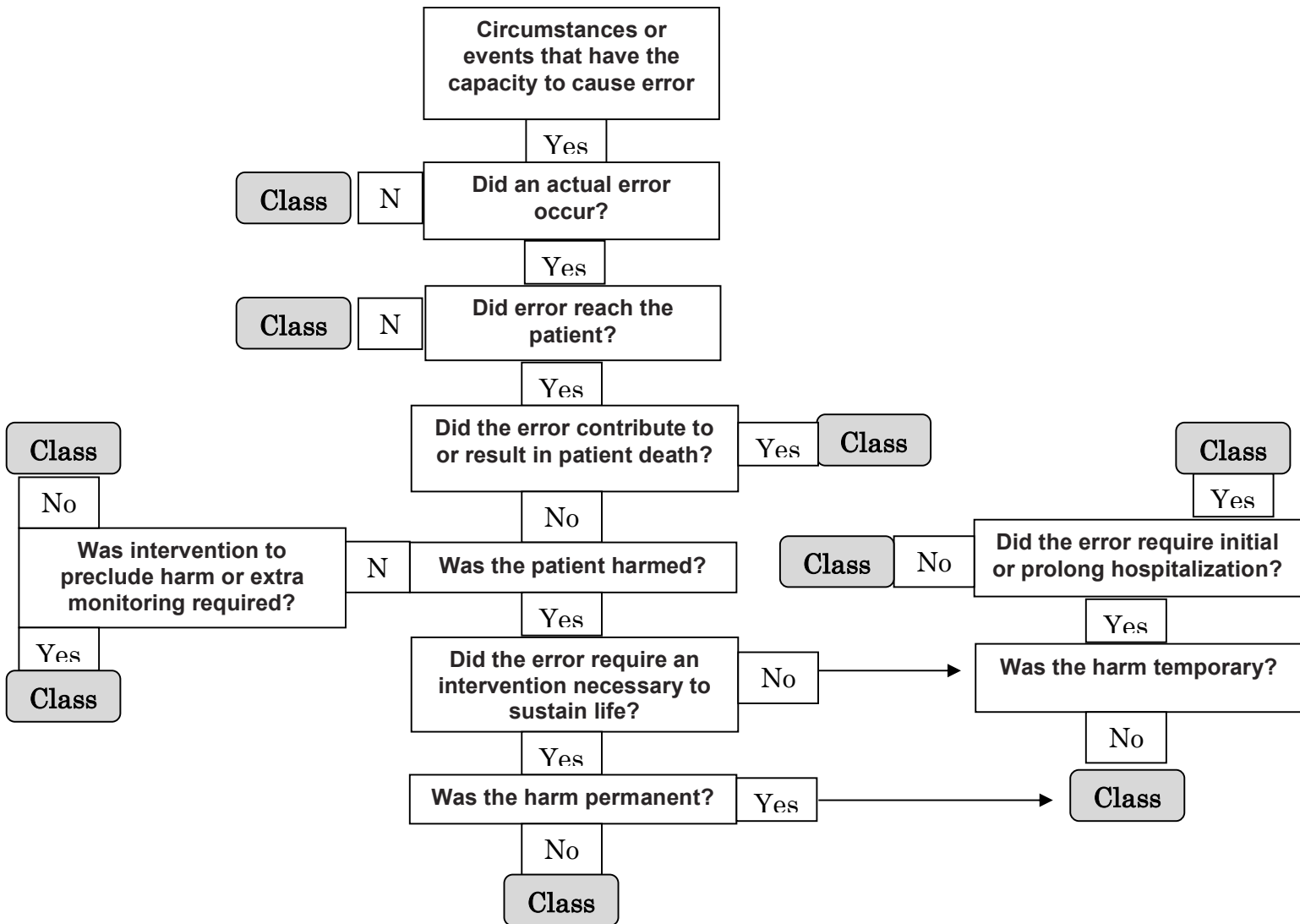
Section D: Classification

- 18/ This error could be classified as (please refer to the next page):
 Class A Class B Class C Class D Class E Class F Class G Class H Class I

Section E: Comments.....

Classification Scheme

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Hospital Code:

Section A: Demographic Data

- 1/ Area: General ward Surgery ward Emergency ward ICU Pharmacy Other
2/ Gender: Male Female 3/ Age: 4/ Weight: Km
5/ Diagnosis.....
6/ Patient known with drug allergy Patient not known to drug allergy
7/ Medication Administered

Section B: Medication Dispensing

- Person** 08/ Who carry out the transcribing process Pharmacist Assistant Other
Medicines 09/ Drug was dispensed as prescribed Yes No
 10/ If yes, the possible cause for this look like Sound like Other
Dose 11/ The dose was dispensed the same as prescribed Yes No
 12/ If yes, the possible cause for this Calculation error Complex modification from other formula Other
Route 13/ The route of administration was the same as prescribed Yes No

14/ Error in ordering process was identified	Yes <input type="checkbox"/>	No <input type="checkbox"/>
--	------------------------------	-----------------------------

Section C: Primary Cause Identification

- 15/ The primary cause of this error could be related to:
 Professionals practice Communication problem knowledge problem
 Product related problem Patient related problem System related problem

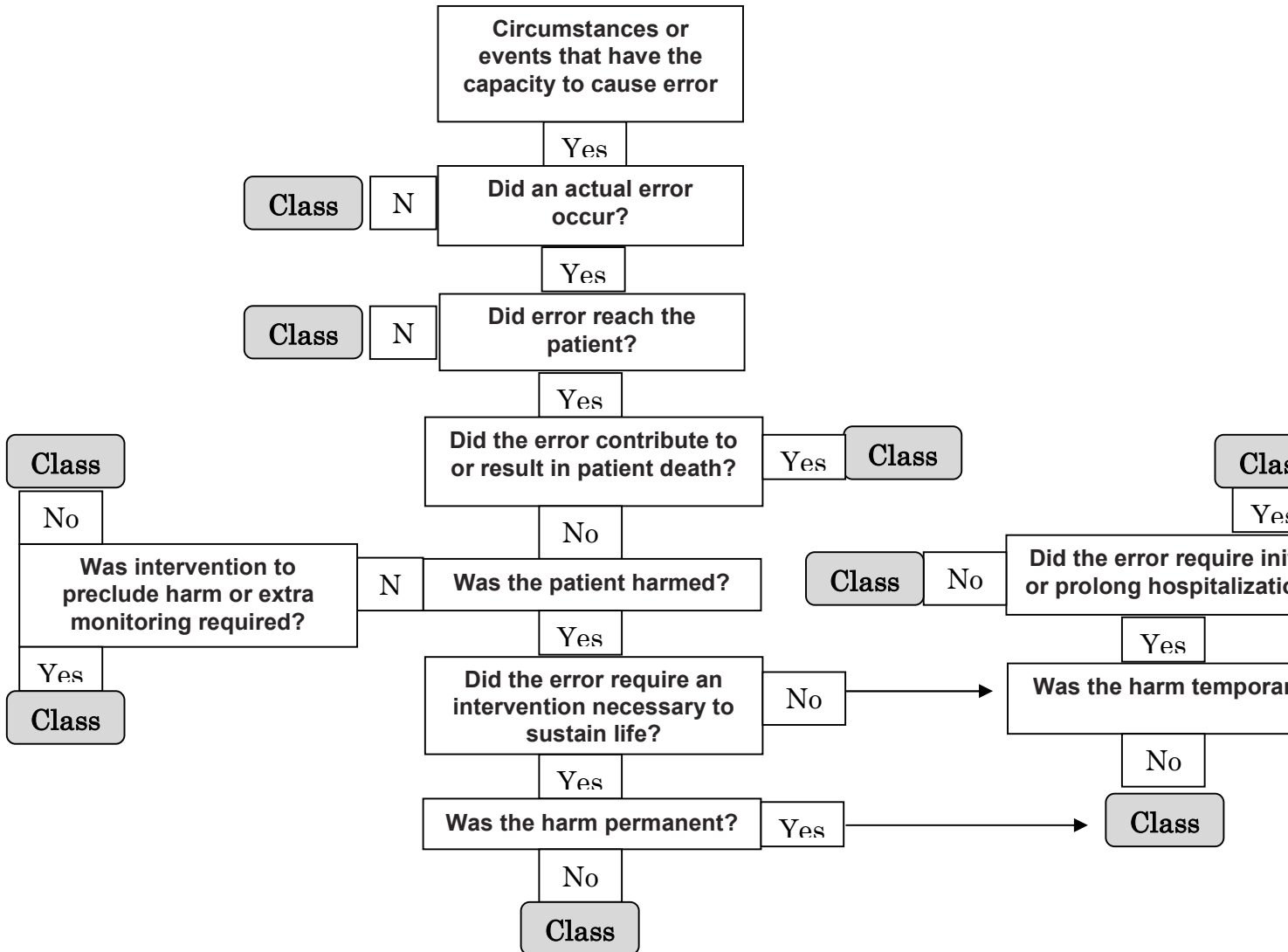
Section D: Classification

- 16/ This error could be classified as (please refer to the next page):
 Class A Class B Class C Class D Class E Class F Class G Class H Class I

Section E: Comments.....

Classification Scheme

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Hospital Code:

Section A: Demographic Data

- 1/ Area: General ward Surgery ward Emergency ward ICU Other
- 2/ Gender: Male Female 3/ Age: 4/ Weight: Km
- 5/ Diagnosis.....
- 6/ Patient known with drug allergy Patient not known to drug allergy
- 7/ Medication Administered

Section B: Medication Administration

- 08/ The medication was given by: Physician Nurse Care-giver/patient Other
- Person** 09/ The person above is authorized to do this.....
- 10/ The patient was well identified before administration.....
- Patient** 11/ Identity chart for this specific patient was visible.....
- 12/ Person provide the medication re-check the patient identity.....
- Medicines** 13/ Medication label was checked before administration.....
- 14/ Medication identity was checked with the medication record prescribing.....
- Dose** 15/ The dose was checked with the original order.....
- Route** 16/ Administration route was checked with the original order.....
- 17/ Medication was administered at the scheduled time as ordered.....
- Time** 18/ Dose should be ordered at (time)..... Given at (time).....

16/ Error in ordering process was identified	Yes <input type="checkbox"/>	No <input type="checkbox"/>
--	------------------------------	-----------------------------

Section C: Primary Cause Identification

- 17/ The primary cause of this error could be related to:
 - Professionals practice
 - Communication problem
 - knowledge problem
 - Product related problem
 - Patient related problem
 - System related problem

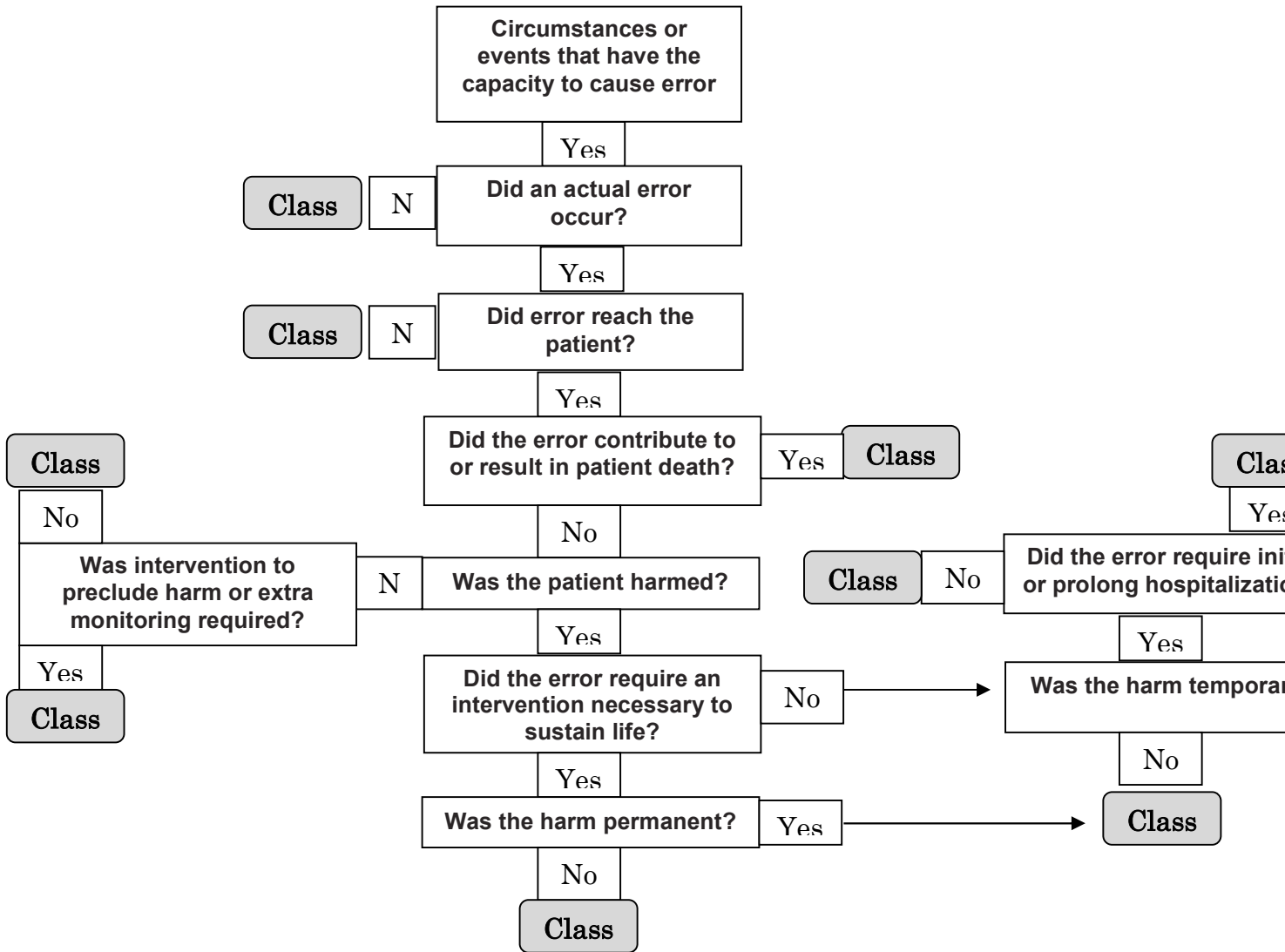
Section D: Classification

18/ This error could be classified as (please refer to the next page):

- Class A Class B Class C Class D Class E Class F Class G Class H
 Class I

Classification Scheme

This classification scheme was developed by USP for the purpose of Medication Errors Reporting program. The Copy rights were preserved to USP.



Errors domains for records review:

- Pediatric Patient Safety Taxonomy :
 - ✓ Event type
 - ✓ Domains of medical care
 - ✓ Contributing factors
 - Patient/child specific factors
 - Human factors
 - Latent conditions
 - ✓ Outcomes
 - The result of the problem
 - Level of harm