5.1. Study Design and Population

5.1.1. Study Design

This study was a prospective interventional study. The prospective study involved establishment of PIC, assessment of poisoning pattern, poisoning severity, clinical outcome of the poisoned patients, provision and evaluation of poison information services. The interventional study involved assessment of impact of education on prevention of accidental poisoning among general public.

5.1.2. Study Setting

The study was conducted at two different hospitals (JSS hospital and Gopala Gowda Shanthaveri Memorial hospital) located in Mysore city over a period of three and a half years from 1 July 2010 to 30 December 2013. The JSS hospital is a 1200-bed medical teaching hospital providing primary and specialized healthcare facilities. Gopala Gowda Shanthaveri Memorial hospital is a 250-bed multi specialty hospital providing medical, surgical and diagnostic facilities. Both the hospitals are catering to the needs of the people in and around Mysore district.

5.1.3. Study Population

All poisoning and envenomation patients of either gender of any age admitted and treated at two study sites were considered for the study. The educational intervention involved the population of general public residing in and around Mysore district. The study population also included healthcare professionals (doctors, nurses, pharmacists) and general public from different regions who approached the poison information centre.
5.1.4. Institutional Human Ethical Committee Approval

Institutional Human Ethical Committee of JSS College of Pharmacy, Mysore, approved the study prior to its commencement. (Annexure I).

5.1.5. Study Criteria

5.1.5.1. Inclusion criteria

- All poisoning and envenomation cases admitted and treated at selected healthcare facility
- All inquiries pertaining to all aspects related to poisoning.
- Queries from healthcare professionals (HCPs) and general public.

5.1.5.2. Exclusion criteria

- Queries pertaining to poisoning in animals.

5.2. Acquiring Training on Establishment and Management of Poison Information Centre

The preparations for establishing a new regional PIC began by getting a required training at Victorian Poisons Information Centre (VPIC), Royal Children’s Hospital, Melbourne, Australia. The training was obtained for a period of three weeks prior to the commencement of the study. The training was mainly about establishment of PIC, handling of poison information queries, provision and evaluation of poison information services.
5.3. Establishment of PIC—Establishment of Required Facility and Policies

5.3.1. Infrastructure Facility

The basic infrastructure facilities such as computers, printers, fax, internet, and telephone have been created. A separate telephone line with toll free number (1800-425-0207) was installed to enable the general public and healthcare professionals to contact PIC for the required information on poison management without any expenditure and delay in accessing to the centre. Computers are used to create and maintain poison information database, and to prepare, storage and analyze the data. Importantly, commuters were also used for retrieval of information from electronic database, searching the required information online and completing the documentation of details related to receipt and provision of information on poison management. Printer was used to print protocols, information and other documents. Fax machine was used wherever required to send the information to enquirer. Internet connection (broadband) was used to: a) search information online, b) access the database or resources (e.g., toxicology databases) and c) communicate (e.g., e-mail communication) the information to general public and healthcare professionals. Telephones are another mode of communication used to receive and communicate the information related to management of poisoning cases.

5.3.2. Information Resources

Various information resources including Poisindex and few standard textbooks have been procured. Poison information databases and standard toxicology text books are essential for the provision of information regarding the management of poisoning cases.
and also for the development of protocols as these information resources provide reliable and current information on management and prevention of all types of poisonings.

5.3.3. Creation of E-mail ID

A separate e-mail account (pic.jsscp@jssuni.edu.in) was created for the communication purposes. In addition to other modes of communication the poisoning queries were received via e-mail from general public and healthcare professionals.

5.3.4. Design and Creation of Website

A separate website (www.picjsscp.jssuni.edu.in) was created and the link has been provided on JSS University (http://www.jssuni.edu.in/poison-information-centre/) and JSS College Pharmacy (http://picjsscp.jssuni.edu.in/) website to provide wide publicity and create awareness about poison information centre. The website was designed to: a) create awareness about new PIC, b) create awareness about poisoning, b) provide useful information to handle crisis and prevent poisoning, and c) provide contact details of PIC. The design of website is done in such a way that general public and healthcare professionals can easily get information on various topics of poisoning through navigation bar.

5.3.5. Policies and Procedures

The policies and procedures were developed for effective functioning of PIC. Policies and procedures were developed on various aspects including: introduction of PIC and PISs, vision and mission of PIC, objectives of PIC, extent of poison information service,
working hours of PIC, cost of service, staffing, handling of calls, confidentiality issues relating to call handling, follow-up of calls, documentation, and quality of services. The policies and procedures is attached in Annexure II.

5.4. Development of Poisonous Substances Database

A database on poisonous substance brand name database (Annexure III) was developed in Microsoft access to maintain critical information pertaining to locally available poisonous substances. The database consists of details pertaining to brand name, ingredients, purpose, category, class, description of the poisoning substances (e.g., state, color, odour, toxic dose specified, lethal dose specified), antidote and first aid measures. Leaflets of the pesticides and household products were collected from different pesticide shops and supermarket respectively and were used to develop the database. Also the list of brands of pesticides and their ingredients were collected from Department of Agriculture located at Mysore city. Based on the information available in the leaflets of different products and the list obtained from Department of Agriculture, a database comprising information on 4237 locally available poisonous substance and their ingredients was prepared. The developed database was used to identify the poisonous substances and to know the ingredients by brand name.

5.5. Development of Standard Poison Treatment Protocols

Standard poison treatment protocols were developed by collecting required information from textbooks, Poisindex and online database (www.lexitox.com). The standard poison treatment protocol consists of details pertaining to category, specific
substances, range of toxicity, mortality rate, clinical presentation, mechanism of toxicity, pharmacokinetics, criteria for hospital admission, monitoring parameters, first aid measures, treatment (decontamination method, specific antidote, supportive treatment, elimination enhancement method) criteria for emergency department discharge, complications and contraindications. A total of 33 standard poison treatment protocols were developed for various poisoning agents. These include: pesticides (organophosphate, carbamate, organochlorine, aluminum phosphide, zinc phosphide and pyrethroids); medicines (selective serotonin reuptake inhibitors, tricyclic antidepressants, mono amino oxidase inhibitors, paracetamol, non-steroidal anti-inflammatory drugs (NSAIDs), beta blockers, calcium channel blockers, angiotensin converting enzyme inhibitors/ angiotensin receptor blockade, diuretics, vasodilators, barbiturates (short and long acting), antihistamines, ranitidine and related drugs, sulfonylureas, metformin and related drugs); heavy metals (lead, iron, copper, mercury and arsenic); and household products (naphthalene, camphor, hydrocarbons, phenol and acetone); ethanol; and methanol. These protocols were used as first hand information resources for providing immediate information on management of respective poisoning. Sample protocol is attached as Annexure IV.

5.6. Standardization of Quality of Standard Poison Treatment Protocols

Standardization of standard poison treatment protocols was performed by using the “Appraisal of Guidelines, Research and Evaluation (AGREE)” instrument.(361) The protocols and AGREE instrument were provided to one pediatrician, physician and casualty medical officer each for standardization of the protocols. The AGREE appraisal
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Instrument consists of 23 key items organized in six domains. Each domain is intended to analyze a separate dimension of guideline/protocol quality. The six domains are, scope and purpose (items 1-3), stakeholder involvement (items 4-7), rigour of development (items 8-14), clarity and presentation (items 15-18), applicability (items 19-21) and editorial independence (items 22-23). Scoring of each item was rated on a 4-point scale ranging from “4-strongly agree” to “1-strongly disagree” with two mid points “3-agree” and “2-disagree”. A section for overall assessment was included at the end of the instrument. This contains options such as “strongly recommended”, “recommended with alterations”, “would not recommended” and “unsure”. The domain score were calculated by summing all the scores of the individual items in a domain and by standardizing the total as a percentage of the maximum possible score for that domain. Following formula used to calculate the standardized domain score.(361)

\[
\frac{\text{Obtained Score} - \text{Minimum Possible Score}}{\text{Maximum Possible Score} - \text{Minimum Possible Score}} \times 100
\]

**Maximum possible score** = 4 (strongly agree) × number of items × number of appraisers

**Minimum possible score** = 1 (strongly disagree) × number of items × number of appraisers

5.7. Development of Promotional Materials

To create awareness about newly established PIC and its services among general public and healthcare professionals, numerous banners and posters containing 14 different slogans were prepared and were displayed at different strategic locations. The
strategic locations of the hospital include: emergency and casualty department, reception area, and resting area. The public places include: medical shops and other places of mass gathering. Several pamphlets on general information about PIC, education materials on prevention of accidental poisoning in elderly, safe handling, storage and disposal of pesticides and tips on prevention of accidental poisoning in children (Annexure Va Vb, Vc and Vd) were developed and used for the purpose of creation of awareness amongst healthcare professionals and general public. The pamphlets consist of details on frequently asked questions (FAQs). These include: when should we call PIC?; why we have to call PIC?; what are the most dangerous poisons?; what are poison prevention tips?; what are the good housekeeping tips to prevent accidental poisonings?; what are the first-aid measures?; and how can we contact PIC? (location, phone number, fax number, e-mail and website address). The prepared pamphlets were distributed among healthcare professionals of different hospitals and general public.

5.8. Creating Awareness on Poison Information Services (PIs)

The awareness about new PIC and its services was created among general public and healthcare professionals. It was done by distributing pamphlets or addressing the general public and organizing meeting with healthcare professionals or setting up advertisement booth or advertising in popular English and Kannada language daily newspapers. Awareness was created amongst general public covering both rural areas (13 villages), and urban areas (schools, colleges) located at Mysore district. Awareness was created throughout the study period during the several occasions (e.g., jatras, festivals, pharma rallies, national pharmacy week, staff development programmes, guest lectures). The
geographical areas (Mandakalli, Varuna Hobli, Hoskote, Chikkahally, Biligere, Nagarle, Lalitadripura, Jeemarahalli, Hanchyakasaba hobli, ImmavuHulimavu, Belagali, Kuppalur, Suttur) that had higher incidences of poisoning were selected for creating awareness.

5.9. Hospital Authority Approvals

Prior to the commencement of the study an administrative approval from both the study sites, JSS Hospital and Gopala Gowda Shantaveri Memorial hospital, Mysore were obtained. This approval facilitated the access to patient data and medical case records of poisoned patients.

5.10. Development of Patient Data Collection Form

A suitable patient data collection form (Annexure VI) was prepared for collecting the details on different aspects of poisoning cases. These include: demographic details of the patient; poison details; severity assessment scales; treatment; treatment outcome; and total cost of the treatment. The form was used to record the details of the patients who were poisoned and admitted to both the study hospitals (JSS hospital and Gopala Gowda Shanthaveri Memorial hospital, Mysore). The developed data collection form was computerized using Microsoft Access for easy storage, retrieval and analysis of the data.

5.11. Assessment of Pattern of Poisoning

Poisoning patients admitted to the study sites (JSS Hospital and Gopala Gowda Shanthaveri Memorial hospital) and who met the study criteria were enrolled in to the
study over a period of three years. The details pertaining to patient demographic, poisoning agent (name and class of poison), route of exposure, and circumstance of poisoning, patient’s medical history, signs and symptoms, diagnosis, investigations report, decontamination methods and treatment were collected and documented in a data collection form. These data were analyzed to determine the pattern of poisoning.

5.12. Prediction of Severity and Outcome of Poisoning Using Clinical Indices

The severity and outcome of the poisoned patients were assessed using GCS and PSS scoring systems. GCS scores were calculated on the basis of motor response to pain, and verbal and eye responses. PSS scores (grade 1 or mild = mild, transient and spontaneously resolving symptoms or signs, grade 2 or moderate = pronounced or prolonged signs or symptoms, grade 3 or severe = severe or life threatening symptoms or signs, and grade 4 = death or fatal outcome) were calculated on the basis of signs and symptoms in the various systems and metabolism (e.g., acid base disturbances). The severity and outcome of snake bite was assessed using SSS. The grading of SSS ranged from 0 to 4. The grades are from no envenomation to severe life threatening symptoms and death taking into consideration of clinical signs/symptoms and/or laboratory data. (Grade 0 = None; Grade 1 = Minimal; Grade 2 = Moderate; Grade 3 = severe; Grade 4 = Fatal). The Pearson correlation was used to assess the correlation between scales, and score and clinical outcome. Chi-square test was used to assess the statistical significance of an association between categorical data. The mean scores of the different groups were compared using Kruskal-Wallis test. The probability is set at $P<0.05$ to consider statistically significant.
5.13. Designing of Poison Information Documentation Form

The 'poison information documentation form' (Annexure VII) was designed to record poisoning enquiry related information. The documentation form contains all the relevant and necessary details pertaining to poisoning query including type of population (children, adult, elderly, pregnant), poisoning agents, route of exposure, type of poisoning (intentional, accidental and environmental), poisoned patient’s demographic details (age, gender, bodyweight), enquirer details (enquirer background, place of call, mode of request), details of query (category of query, purpose of query) details of poison information (information provided, mode of provision, time taken to provide information, reference consulted etc.). The documentation form was created in both paper and electronic format (Microsoft Access) for easy storage, retrieval and analysis of the data.

5.14. Provision and Analysis of Poison Information Services

5.14.1. Preparation of Standard Operating Procedure (SOP)

The SOP on "Provide the Poison Information" was developed for the provision of poison information in time (Annexure VIII). The developed SOP contains the details including version number, authorization, scope, aim, introduction and procedure. The SOP provides systematic procedure and ensures that service is given in a timely and efficient manner.

5.14.2. Provision of Poison Information Services

The poison information was provided to both healthcare professionals and general public by following the SOP. The developed SOP contains seven systematic steps to be
followed for every poison information query. The 7 steps include, 1-Obtain requester's demographics; 2-Collect background information; 3-Assessment of condition; 4-Develop and conduct a search strategy; 5-Evaluate and provide the information; 6-Conduct follow-up and document; 7-Maintain confidentiality. All the details (Ref section number 5.13) pertaining to poisoning query were recorded in the hard copy and soft copy of “poison information documentation form”.

5.14.3 Analysis of Poison Information Data

The data related to poison information queries was analyzed according to enquirer’s status, place from query asked, mode of receiving query, category of query asked, purpose of query, demographic details of the patient/victim, type of poisoning, type of poisonous substance, reference consulted for information, mode of provision of information and time taken to provide information and their percentage values were calculated.

5.15. Evaluation of Quality of Poison Information Services

5.15.1. Development of Quality Assessment Checklist

A quality assessment checklist (Annexure IX) was prepared in accordance with DSE/WHO seminar guidelines.(362) This quality assessment checklist was used to assess the quality of poison information services provided. The checklist consisted of 10 questions with three options/choices (Yes/No/Not Applicable (NA)) for each question. The option ‘Yes’ and ‘NA’ represent 1 point; while ‘No’ represents 0 point. The score range of quality assessment checklist is 1-10.
5.15.2. Constitution of Quality Assessment Panel and Development of Guidelines

The quality assessment panel (Annexure X) was constituted to assess the quality of poison information services. The panel included 2 casualty medical officers; 1 physician; 1 pediatrician; and a qualified pharmacist. The guidelines for the assessment of quality of poison information services were developed through formal discussions amongst the panel members. The guidelines were formulated considering various parameters that will enable the panel members to adhere to the developed guidelines. The initial draft guidelines were circulated amongst the panel members for further review and feedback. The feedbacks provided were incorporated as appropriate and the final guidelines were prepared. (Annexure XI).

5.15.3. Assessment of Quality of Poison Information Services

Adopting the quality assessment guidelines and using the quality assessment checklist, the panel assessed the quality of poison information services. The quality assessment panel, with a quorum of at least three members, assembled in the first week of every month to evaluate the quality of services provided in the previous month. Two-third of the answered queries were randomly selected for the assessment of quality of services. The quality of services was assessed on the basis of information collected on: a) sufficient information related to enquirer, patient and poisonous substance; b) appropriateness of urgency of situation (proper assessment of urgency of the situation); c) appropriateness of references/resources used to retrieve the information; d) quality of gathered information (critical assessment of gathered information prior to communication); e) satisfaction of enquirer’s need; f) promptness of service (provision of
service within specified duration); g) quality of documentation of provided service (proper documentation); and h) promptness in follow up (if required). Based on criteria, the panel on consensus method graded each poison information query and documented in the quality assessment checklist. The grading was performed on the basis of scores obtained as follows: Excellent (score = 10); very good (score = 8-9); Good (score = 5-7); poor (score = 3-4); and Unacceptable (score = 1-2).

5.16. Assessment of Quality of PISs According to Healthcare Professionals Feedback

A feedback questionnaire (Annexure XII) was developed and used to obtain the feedback from healthcare professionals on quality of PISs. The questionnaire consisted of 15 questions and suggestions section for improvement. The initial 5 questions are related to awareness of PIC and its existence; and remaining questions are related to the quality of PISs. The questionnaire was distributed among healthcare professionals with ample time (1-2 days) to read, understand and provide feedback. The quality of poison information services was then graded as 'Excellent', 'Very good', 'Good', 'Poor' and 'Unacceptable' by the healthcare professionals.

5.17. Assessment of Impact of Educational Intervention

5.17.1. Development of Knowledge, Attitude and Practice (KAP) Questionnaire

Knowledge, attitude and practice (KAP) questionnaire was developed to assess the knowledge, attitude and practice of the farmers regarding the safe handling, storage and disposal of pesticides. The KAP questionnaire developed in English contained 41 questions. Of the 41 questions, 8, 18, 6 and 9 questions were related to demographic
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details, knowledge assessment, attitude assessment and practice assessment respectively
(Annexure XIII). The face validation of questionnaire or understanding of the questions
by the targeted population at different time intervals ranging from 7 to 15 days between
two successive assessments was done. The validation of content was done by 1
Forensic Medicine and Toxicology specialist, 1 poison information specialist, 1 educated
and experienced agriculturist and 1 clinical pharmacist. The validated English version of
KAP questionnaire was then translated to Kannada language (Annexure XIV) and
standardized by back translation by the Kannada language expert at Central Institute of
Indian Languages. Face validation or understanding of the questions by the targeted
population at different time interval was assessed. To accomplish this, the questionnaire
was administered twice with a time interval ranging from 7 to 15 days between two
successive assessments. A total of 20 farmers who knew English and Kannada languages
participated in the validation process. The KAP questionnaire was finalized after the
answers provided by the farmers at different time intervals were found to be consistent.

5.17.2. Preparation of Educational Materials

Education materials were prepared in English language and then translated to
Kannada language. Educational materials were standardized by back translation by a
Kannada language expert at the Central Institute of Indian Languages. Hard copies of
education materials in both English and Kannada languages were used in educational
intervention program. The educational material contained the safety tips for farmers
about proper handling, storage and disposal of pesticides. The educational material also
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contained contact details of poison information centre and guidance to reach poison information centre (Annexure Vd).

5.17.3. Selection of Geographical Area for Educational intervention program

The geographical area wherever there was a higher incidence of poisoning was identified through a prospective analysis of poisoning cases admitted to study hospitals over a period of one year (January 2011-December 2011). The data enabled to identify the common category of poisoning and most susceptible population involved in poisoning. The geographical region of each poisoning with the identified common poisoning agent was located and marked on the map by using the Mysore district map, which was obtained from District Commission office, Mysore (Annexure XV). The geographical areas that had higher incidences of poisoning were then selected for educational intervention study.

5.17.4. Educational Intervention Program

Farmers from 13 selected villages who were involved in handling of pesticides were identified for the purpose of educational intervention. The educational intervention program focused on several important aspects including: importance of understanding the labeled information; content quantity to be used; short and long term health effects of pesticides; routes of entry of pesticides into the body; symptoms based on each route of exposure; first-aid measures; safe usage; safe storage; correct method of disposal and proper use of personal protective gear while handling pesticides. While assessing the KAP of farmers on safe handling of pesticides, the KAP questionnaire was administered
in three phases through personal interviewing technique: firstly, before adopting educational intervention program; secondly 10 minutes after administering educational intervention program; and finally after 3-4 weeks interval following an educational intervention. Interviewer completed the KAP questionnaire after 1:1 interaction. A time slot of 25 minutes was provided to participants and obtained the responses of baseline questionnaire before a structured educational intervention program was conducted. The farmers were encouraged to ask any doubts they had and doubts were clarified during the educational intervention program.

5.18. Healthcare Outcome-Related and Healthcare Cost-Related Benefits of Poison Information Services

The healthcare outcome-related and healthcare cost-related benefits of PIS were assessed by collecting and analyzing the data pertaining to treatment outcome, time of hospital duration and cost of the treatment associated with patients, who were categorized into two groups, viz., patients who utilized PIS and patients that did not utilize PIS. To measure the healthcare outcome-related benefits of PIS, the outcome of poisoning was predicted using different scoring systems (GCS, PSS and SSS) and the results (patients increased or decreased \(n\) and \% in each outcome category relative to total patients in the group) were compared between two groups (patients who utilized PIS and patients who did not utilize PIS). Further, the patients hospitalization time in days was compared between patients who utilized PIS with that of patients who did not utilize PIS. The cost-related benefits were assessed by considering the direct cost associated with treatment including charges on bed, medicine, laboratory investigation. The direct cost of treatment
(in Indian Rupee) associated with patients who utilized PIS was compared with that of patients who did not utilize PIS to find out the healthcare cost-related savings provided by PIS.

5.19. Statistical Analysis

Chi-square test was used to assess the statistical significance association between categorical data of various aspects of pattern of poisoning, poison information queries, quality of poison information services provided, healthcare outcome-related and healthcare cost-related benefits of poison information services. The Pearson correlation was used to assess the correlation between scales, and score and clinical outcome. The mean scores of the different groups of scoring systems were compared using Kruskal-Wallis test. To assess the impact of educational intervention on knowledge, attitude and practice of farmers, Friedmann test was used to find the statistical significance between the different time intervals within the group and Kruskal-Wallis test was used for comparison of groups at different time intervals. The probability was set at $P<0.05$ to consider statistically significant.