A Regional Pharmacokinetic Consultation Service

Mario Bédard and William McLean

ABSTRACT
Clinical pharmacokinetics represents a way to ensure that a patient is receiving an optimal dose of a given drug for a specific indication. Pharmacokinetic consultation services have been implemented in many teaching hospitals and tertiary care facilities in the past. This project evaluated the feasibility of expanding the process to several community hospitals with one coordinator. Twenty-seven hospitals, members of the Ottawa Valley Regional Drug Information Service, were approached.

Fifty-two pharmacists from 21 sites agreed to participate. Four modules were taught: basic principles, theophylline, aminoglycosides, and digoxin. Regular follow-up meetings were arranged so pharmacists from different hospitals could share their administrative and patient-specific problems and solutions.

After two years, 16 departments have implemented a clinical pharmacokinetic service and monitor 82% of targeted drug levels. The pharmacists trained in clinical pharmacokinetics through the project recommended changes in the regimen in 45% of all their consultations. Eight-one percent of these were accepted and implemented by physicians. These results indicate that pharmacists from small community hospitals can be trained by one individual to provide clinical pharmacokinetic services with minimal supervision. It also shows that these hospitals have a need for such services.

Key words: clinical pharmacokinetics, regional services.

INTRODUCTION
The latest concept of pharmacy practice, Pharmaceutical Care, is described as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life.12 Tools to achieve this goal include medication history, patient counselling, review of drug therapy and more. One of these, clinical pharmacokinetics (CPK), is a way to ensure that a patient is receiving an optimal dose of a given drug for a specific indication. Pharmacokinetics is defined as “the specialized study of the mathematical relationships between a drug

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desage regimen and resulting drug concentrations (usually in serum or plasma)." Clinical pharmacokinetics is further defined as "the application of pharmacokinetic principles to the management of patient drug therapy." 

The importance of CPK is documented in the literature. Patients taking theophylline or aminoglycosides and who were followed by a CPK service have had better outcomes than those who were not. CPK has also been shown to be one factor involved in the decrease of mortality in patients treated for bacteremia or severe pneumonia with aminoglycosides. The same has been shown in burn patients. Furthermore, a cost-benefit analysis study showed CPK services to be beneficial in severe burn patients treated with aminoglycosides. With a CPK service in place, length of stay and cost of hospitalisation have also been shown to decrease.

CPK services are not uniformly available. Whereas pharmacies in most large teaching hospitals provide a CPK service, pharmacists from smaller community institutions do not, primarily due to lack of expertise or lack of time available to obtain adequate training to perform these duties. But patients in these institutions are taking the same drugs and are exposed to the same risks as those admitted to larger teaching hospitals. Drug levels are thus interpreted by physicians who are not always trained in CPK. Consequently, inappropriate decisions are sometimes made in drug therapy based on these results and funds are wasted in the inappropriate use of drug levels. The Canadian literature supports these observations; for instance, a study performed in Ottawa suggested that there were risks in removing a previously instituted pharmacokinetic service. It is, therefore, reasonable to suggest that expanding CPK services to regional hospitals would improve patient care. If training and support were given to pharmacists interested in starting a CPK service, interpretation of drug levels would be improved, leading to an improvement in drug therapy and a decrease in funds wasted due to their inappropriate use.

This joint venture between the Ontario Ministry of Health, the Ottawa Valley Regional Drug Information Service (OVRDIS) and the Ottawa General Hospital (OGH) evaluated the feasibility of providing training in CPK to pharmacists from 27 regional hospitals with the goal of expanding the number of hospitals with a CPK service. The base hospital (OGH) had considerable experience in CPK service. It also evaluated a regional service aimed at providing these pharmacists with support through regular meetings and telephone consultation.

METHODS
The project was open to all hospital pharmacists who were members of the Ottawa Valley Drug Information Service (OVRDIS) from September 1991 to August 1993. The Coordinator met with each director of pharmacy to explain the benefits. The six requirements of the project were: interest in setting up or expanding a CPK service; agreement to seek approval from their Pharmacy and Therapeutics Committee for a CPK service; collection of pre- and post-training data for the project; commitment to 20 hours of classroom teaching; completion of pre- and post-training tests on knowledge of pharmacokinetic principles; and performance of CPK consults once the training was complete.

It was emphasized that these training sessions were not continuing education programs but that pharmacists were expected to use their expertise in their institution. All the background information was collected by the Coordinator in late 1991 with the help of two questionnaires during a meeting with the director of pharmacy from each of the 27 hospital members of OVRDIS. Twenty-three members were community acute care institutions, two were chronic care, and two were specialty hospitals (psychiatric, pediatric).

The project had five main objectives:

**The first objective** was the training of pharmacists in the basics of CPK and the interpretation of drug levels. The baseline pharmacokinetic knowledge of the pharmacists from the 21 participating hospitals was evaluated with a pre-training test to be completed at home before the first training session. The hospitals were divided into three groups to maximize attendance at the training sessions since the 21 hospitals were located in seven different counties. The training of each group of pharmacists required 20 hours of classroom teaching. A pertinent review article was also included with each handout.

The main topics included: basic pharmacokinetic principles, theophylline, aminoglycosides and digoxin. Cases were done at home and discussed during sessions with the Coordinator. Six hours of optional training was added for the pharmacists interested in the CPK monitoring of the following drugs: carbamazepine, phenobarbital, phenytoin and valproic acid. A post-training test, of similar difficulty to the pre-training test, was given to the pharmacists. It was emphasized that these tests were not continuing education programs but that pharmacists were expected to use their expertise in their institution. All the background information was collected by the Coordinator in late 1991 with the help of two questionnaires during a meeting with the director of pharmacy from each of the 27 hospital members of OVRDIS. Twenty-three members were community acute care institutions, two were chronic care, and two were specialty hospitals (psychiatric, pediatric).
The second objective was to seek commitment of the pharmacists to review certain drug levels in their institution and to provide written consultation on a regular basis. The pharmacists were asked to officially inform and obtain approval from their Pharmacy and Therapeutics Committee for the initiation or the expansion of a CPK service in their hospital. Support for the pharmacists was offered by the Coordinator by performing literature searches on request and by giving expert advice on questions brought up by physicians. To help promote the CPK service, newsletters were prepared by the Coordinator and distributed to nurses and physicians as deemed appropriate by the director of pharmacy.

A post-training questionnaire, sent to all the directors of pharmacy who implemented a CPK service, compared the number of different drugs monitored before and after the project. One question dealt with the cost of analyzing serum samples for drugs that were monitored through a CPK service. During the training sessions the pharmacists were advised to document their CPK interventions either in the patient chart or in a consultation sheet kept in the pharmacy department. The post-training questionnaire included a question to evaluate how the pharmacists documented their CPK interventions. Another question requested a subjective evaluation by the pharmacists of the physicians’ appreciation for their CPK service. The questionnaire also asked the pharmacists to evaluate the impact of their CPK recommendations on overall patient care from “marked improvement” to “deterioration in patient care”. Finally, pharmacists were asked if they wanted to have OVRDIS continue some type of CPK consultation service after the end of the project.

The third objective was to determine the acceptability of the CPK service by the medical staff in each hospital. A brief questionnaire was hand-delivered to the mailbox of all the attending physicians working in hospitals where a CPK service had been implemented. The covering letter, signed by the Coordinator, included a three-week deadline for the return of the document in a pre-addressed envelope. The results of the questionnaire were expected to determine if: the physicians were aware that a CPK service had been implemented in their institution; they followed the CPK recommendations made by the pharmacists; they felt that these recommendations influenced patient care; and, based on their experience, they thought the CPK service should be continued or expanded.

The fourth objective was to establish a regional telephone consultation service so that pharmacists trained in CPK could obtain immediate advice from the Coordinator. Any participant needing assistance either with calculations or with a clinical decision based on information specific to a patient could call during office hours. A log was initiated to keep a record of the origin, nature, date and duration of the calls, to evaluate the workload associated with such a service and to identify the most common topics and users.

The fifth objective was to study drug level utilization in each of the participating institutions, before and after introduction of the training program and the regional consultation service. Data were collected for three weeks before and at least six months after implementation of the CPK service. The following parameters were evaluated:

1) Number of drug levels reported by the laboratory department before and after the CPK service implementation;
2) Number of drug levels falling inside or outside the therapeutic range, before and after the CPK service implementation. The therapeutic range for each drug was defined by the laboratory department of each hospital and individualized according to the patient’s indication;
3) Number of drug levels falling inside or outside the therapeutic range, before and after the CPK service implementation, subdivided into the following four drugs: aminoglycosides, digoxin, phenytoin and theophylline;
4) Number of appropriate drug levels based on the sampling time, before and after the CPK service implementation. A drug level was deemed appropriate if taken immediately prior to the next dose or at least six hours since the last dose. For the aminoglycosides, the drug levels were judged appropriate if a pre-dose sample was taken within 30 minutes of a scheduled dose AND a post-dose sample was taken 15 to 30 minutes after the end of the infusion of the drug;
5) Number of appropriate drug levels based on the sampling time, before and after the CPK service implementation, subdivided into the following four drugs: aminoglycosides, digoxin, phenytoin and theophylline;
6) Number of CPK consultations done by the pharmacist before and after the CPK service implementation. A consult was defined as an activity where a patient’s chart was reviewed; the drug regimen was re-evaluated based on drug level results and a decision was made whether to change the patient’s drug regimen;
7) Analysis of the data collected after the training period included: number of CPK consultations done by the pharmacist after the CPK service implementation; number of cases where the pharmacist recommended a change in drug therapy; and rate of acceptance of the pharmacist’s recommendations by the attending physician;
8) Analysis of the data collected after the training period as per #7, sub-
Table 1. Background information on pharmacists.

<table>
<thead>
<tr>
<th>Number of pharmacists</th>
<th>52</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average number of years since graduation (range)</td>
<td>16(1-34)</td>
</tr>
<tr>
<td>Average hospital pharmacy experience in years (range)</td>
<td>11 (1-30)</td>
</tr>
<tr>
<td>Pharmacokinetic training in school</td>
<td>Yes=33 (63%)</td>
</tr>
<tr>
<td>CPK experience since graduation</td>
<td>Yes = 23 (44%)</td>
</tr>
<tr>
<td>Control group</td>
<td>No = 19 (37%)</td>
</tr>
<tr>
<td>Continuing education program done in CPK</td>
<td>Yes = 15 (29%)</td>
</tr>
<tr>
<td>Participants</td>
<td>No = 37 (71%)</td>
</tr>
</tbody>
</table>

Table 2. Results of pre-training and post-training tests.

<table>
<thead>
<tr>
<th>Participants</th>
<th>Pre-Test Result ± SD (n)</th>
<th>Post-Test Result ± SD (n)</th>
<th>Certification exam Result ± SD (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>57.7% ± 20.0 (39)</td>
<td>95.4% ± 6.4 (30)</td>
<td>92.2% ± 7.5 (28)</td>
</tr>
<tr>
<td>Control group</td>
<td>90.0% ± 6.3 (6)</td>
<td>86.3% ± 4.8 (4)</td>
<td></td>
</tr>
</tbody>
</table>

RESULTS

Twenty-one hospitals (78%) decided to participate. Of the six which did not participate, two were excluded because they did not have a pharmacist on staff; one terminated its membership with OVRDIS; two had existing CPK services which they did not wish to change, and one declined to participate as CPK was not a priority of the pharmacy department. Of the 21 who joined the project, 16 (76%) actually had implemented some type of CPK service in their institution. Of the five departments that dropped out, two did so due to staff reduction; one had its CPK service proposal turned down by the Pharmacy and Therapeutics Committee, and two had too many other commitments.

Of the 21 hospitals initially included in the project, 11 pharmacy departments had no CPK service at all (52%). The pharmacists in six departments (29%) would help physicians with unusual drug levels upon request; they performed an average of five consults a month. Four departments already had some type of CPK service in place (19%); they documented an average of 30 consults a month on selected drugs.

The fifty-two pharmacists from the 21 hospitals completed the required 20 hours of training. See Table 1 for the details on their background.

Background information pertinent to this project was collected regarding the laboratory department of each institution. Fourteen of the 21 hospitals (67%) sent their blood samples to an outside laboratory to be analyzed and seven provided analysis on the premises. The turnaround time, defined as the number of hours between time of sampling and time of reporting to the pharmacist, was 42 hours on average, with a range of 24 to 168 hours. Blood samples were drawn by a laboratory technician in most hospitals (18/21; 86%). An important piece of information needed to evaluate a drug level is the time of sampling. It was present on most of the laboratory requisitions (18/21; 86%).

As of July 1993, the 16 pharmacy departments involved in the project had approval from their respective Pharmacy and Therapeutics Committees to institute or expand a CPK service.

Results from the first objective are summarized in Table 2. An increase was shown from pre-training to post-training test results, indicating an improvement in the pharmacokinetic knowledge base of the participants. Results from the control group remained constant between the two tests. The decrease from six to four people in the control group between the tests was due to two pharmacists leaving the region.

An increase in the number of participating hospitals monitoring drug levels for the aminoglycosides, digoxin, phenytoin and theophylline through a CPK service occurred between the pre-training and the post-training periods as seen in Table 3. It showed that 88% of all participating centres now monitor aminoglycosides; an increase from 25% in the pre-training period.

In the post-training questionnaire, the directors of pharmacy were asked to indicate the cost of a drug level analysis. The results could not be used as different centres included different units to evaluate the cost of a drug level, such as labour or handling fee.

The documentation of CPK interventions improved following the training sessions. Before the
training, 11 of 16 hospital pharmacies did not make any CPK interventions (68%); two documented interventions in a file in the pharmacy department (13%); one documented its interventions in the Progress Notes section of the patient’s chart (6%), and only two departments had documentation both in the pharmacy and in the chart of the patient (13%). After the training, all 16 departments kept a written record of their CPK interventions: two (13%) in the pharmacy department, three (19%) in the patient’s chart, and 11 (68%) at both locations.

The results from the pharmacists’ evaluation of the physicians’ appreciation of their CPK service are summarized in Table 4. Although subjective in nature, the results indicate a significant apparent acceptance.

The participants were also asked to subjectively evaluate the impact of their CPK interventions on patient care. The results in Table 5 indicate that pharmacists felt they were responsible for a moderate to marked improvement in patient care with 81.0% of their interventions.

When asked if they wished to see the pharmacokinetic consultation service continued as part of OVRDIS, 13 pharmacists answered “yes” (81%) and three abstained.

Eight hundred and nineteen questionnaires were sent to the participating pharmacy departments to be distributed to physicians from the 16 participating hospitals. Six hundred and seventy were actually distributed in 13 hospitals. The questionnaires were not distributed in three hospitals due to internal difficulties. Two hundred and seven were returned to the Coordinator and the summary of the answers is available in Table 6. Ninety-five percent of the physicians who answered the question felt that recommendations from CPK services had an impact on patient care.

### Table 3. Number of hospitals with a CPK service for specific drugs. n = 16 hospitals.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Pre-training n (%)</th>
<th>Post-training n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aminoglycosides</td>
<td>4 (25)</td>
<td>14 (88)</td>
</tr>
<tr>
<td>Digoxin</td>
<td>2 (13)</td>
<td>7 (44)</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>1 (6)</td>
<td>10 (63)</td>
</tr>
<tr>
<td>Theophylline</td>
<td>1 (6)</td>
<td>10 (63)</td>
</tr>
</tbody>
</table>

### Table 4. Subjective evaluation by the pharmacists of the physicians’ appreciation of the CPK service. 15 questionnaires were returned.

<table>
<thead>
<tr>
<th>Percentage of M.D.s who will seek your advice and generally follow your recommendations</th>
<th>Average percentage ± SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>19.1 ± 20.9</td>
<td>0 - 80%</td>
</tr>
<tr>
<td>Percentage of M.D.s who will generally follow your recommendations but will not actively ask for your opinion</td>
<td>56.1 ± 26.8</td>
<td>10 - 90%</td>
</tr>
<tr>
<td>Percentage of M.D.s who will follow your recommendations only when you discuss the case at length with them</td>
<td>10.4 ± 10.1</td>
<td>0 - 30%</td>
</tr>
<tr>
<td>Percentage of M.D.s who will rarely follow your recommendations</td>
<td>6.9 ± 6.3</td>
<td>0 - 20%</td>
</tr>
<tr>
<td>Percentage of M.D.s who actively try to prevent your involvement with their patients</td>
<td>2.3 ± 3.6</td>
<td>0 - 10%</td>
</tr>
</tbody>
</table>

### Table 5. Impact of CPK interventions on patient care: subjective evaluation by the pharmacists.

<table>
<thead>
<tr>
<th>Percentage of your CPK interventions that resulted in:</th>
<th>Average percentage ± SD</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>A marked improvement in the patient’s condition</td>
<td>34.1 ± 24.9</td>
<td>5 - 80%</td>
</tr>
<tr>
<td>(Major decrease in toxicity and/or major increase in efficacy; possible impact on patient outcome)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A moderate improvement in the patient’s condition</td>
<td>46.9 ± 23.0</td>
<td>10 - 90%</td>
</tr>
<tr>
<td>(Noticeable change in toxicity or efficacy; probably no impact on patient outcome)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A minimal impact in the patient’s condition</td>
<td>17.4 ± 13.5</td>
<td>0 - 50%</td>
</tr>
<tr>
<td>(Small or no change in toxicity or efficacy; no impact on patient outcome)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A deterioration in the patient’s condition</td>
<td>1.0 ± 2.0</td>
<td>0 - 5%</td>
</tr>
<tr>
<td>(Increase in toxicity and/or decrease in efficacy)</td>
<td></td>
<td></td>
</tr>
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</table>

A telephone log documented calls from November 1991 to July 1993. Over the 20-month period, 167 calls were made to the consultation service. The average duration of the calls was 9.4 minutes with a range of two to 28 minutes. Aminoglycosides were the topic of 62% of the calls followed by general pharmacokinetic information (16%), and
phenytoin (13%). The remaining 9% of the calls were divided into vancomycin (3%), theophylline (2%), digoxin (2%), valproic acid (1%) and carbamazepine (1%). Four hospitals accounted for 46% of all the calls received.

Results for the fifth objective are summarized in Tables 7 to 10. A global evaluation of the results comparing pre-training and post-training data collection of drug levels is shown in Table 7. A 17% decrease in the number of drug levels ordered occurred between the pre-training and the post-training periods. The most noticeable change was seen in the percentage of drug levels for which a pharmacokinetic consult was done by a pharmacist. It rose from 36% to 62% between the two data collection periods.

The drug levels were evaluated based on the therapeutic range for each of the four drugs most commonly followed by a CPK service, and the results are shown in Table 8. Whereas no difference was seen globally in the percentage of drug levels falling inside therapeutic range between the pre-training and the post-training periods, the results for individual drugs showed some changes. We noted an increase in the number of drug levels falling inside the therapeutic range for the aminoglycosides (35% to 47%) but a decrease for theophylline (51% to 28%). The latter can be partially explained by the decrease in the number of drug levels collected in the post-training period compared to the pre-training period (small sample size).

The evaluation of the drug levels based on the sampling time is compiled in Table 9. The number of drug levels that were sampled at the appropriate time increased for each drug category in the post-training period. The same was seen in the global results. The category “unable to assess” accounted for a large percentage of all drug levels and did not change between the two data collection periods (55% to 56%).

Table 10 summarizes the involvement of the participants with drug levels after the training period. Overall, the pharmacists recom-
The post-training data collection of drug levels included all categories of drugs, whether or not they were actually part of the CPK service of a specific institution. Upon elimination of drugs not monitored by the CPK service of each institution, the total number of drug levels that could potentially be monitored by a pharmacist went down to 254. Based on that number, the percentage of drug levels for which a consultation was actually done by a pharmacist increased to 82% (208 of 254) from 36% (147 of 405) in the pre-training period.

DISCUSSION
Efficiency is an important aspect of a CPK service. The time between blood sampling and pharmacist’s recommendation should be as short as possible to make a difference in the care of a patient. One limiting factor was the turnaround time between the blood collection and the reporting of the result. The average turnaround time in this group was 42 hours, longer than in most teaching hospitals where a result is usually available within 24 hours. Improvement would require the cooperation of the laboratories.

Evaluation of the potential cost savings due to more rational use of drug levels was a part of this project. However, as stated in the results section, the evaluation of the cost of a drug level was very different from one hospital to the next. The cost of a drug level varied from $3 to $50, with an average of $13. Savings were nevertheless noted during the project since the number of inappropriate drug levels decreased, as did the overall number of drug levels ordered by physicians.

The acceptance of a CPK service by physicians is essential since they will ultimately implement the changes suggested by the pharmacists. A CPK service will not influence patient care unless it receives full support from the Pharmacy and Therapeutics Committee and by the Medical Advisory Committee. In our project, three indicators confirmed that physicians from the participating institutions were supportive of their CPK service. The physician survey indicated that 95% of the respondents were willing to have the pharmacists involved with their patients. Ninety-four percent also thought that the service was worth continuing. But the questionnaire had limitations, such
as a low response rate (31%) and potential bias in results since unsatisfied MD's may not have returned it. The physicians’ acceptance rate (81%) of the recommendations made by the pharmacists was the third indication of their cooperation in the service. The telephone consultation proved to be useful in the early stages of the CPK service implementation in each institution. The busiest time for the consultation service occurred in the first six months after the training sessions. The number of calls then decreased until it reached a low at the end of the project. The calls received in the last six months of the consultation service generally dealt with more complicated cases where the participants needed expert advice.

As indicated in the results section, 81% of the participants wished to see OVRDIS continue some type of CPK consultation service after the end of the project. Consultation for difficult cases, refresher courses, yearly updates on CPK and training of new staff seemed to be the major areas in which the participants wanted OVRDIS to be involved. These services would need to be handled by a resource person qualified in the field of CPK and would increase the workload of OVRDIS. By the end of the project no decision had been made yet at the OVRDIS Board of Directors regarding the continuation of CPK consultation services.

Only a small increase in the percentage of drug levels falling within the therapeutic range was seen between the two data collection periods (49% to 51%). Even though we might have expected to see a larger increase in that category, several factors could explain this result. The information provided with the data collection did not allow for discrimination between a first drug level and a repeat drug level on the same patient. The pharmacist usually did a CPK consult after an initial drug level was reported. If a change in therapy was recommended and implemented then a repeat level was suggested. The true impact of the CPK service would be seen in this case. Unfortunately, repeat levels were not always done. The impact of the pharmacist’s intervention was, therefore, difficult to evaluate since such a high number of levels were pre-intervention. The lack of improvement in the number of drug levels falling inside the therapeutic range may also reflect a lack of change in the prescribing habits of the physicians. A period of only six months was allotted between the implementation of a CPK service and the follow-up data collection. It may take longer to influence the prescribing habits of physicians.

An important aspect of this project was to evaluate the impact of a CPK service on patient care. The pharmacists recommended a change in therapy in 45% of the consults, indicating that these patients were not getting an optimal drug regimen initially. Since 81% of their recommendations were accepted by physicians, it may be suggested that pharmacists had an impact on the care of these patients.

The most important impact of the CPK service was on aminoglycoside monitoring. Almost half of the levels collected were in that drug category and so were 68% of all accepted recommendations. This category also had the largest increase in the percentage of drug levels falling within therapeutic range in the post-training data collection.

This project has shown that it is feasible for one regional coordinator to train and provide consultation to pharmacists from different hospitals on the basics of CPK. The participants now have a direct impact on patient care based on their recommendations and the support of the physicians to implement them.

We feel that a regional clinical pharmacokinetic training program similar to ours can be implemented in other regions of Canada, particularly if a network is already established by a regional drug information service. The most important limitations are the size of the territory to be covered by a single person and the number of pharmacists to be trained. A ratio of one coordinator for eight to ten students is optimal for classroom teaching. Smaller hospitals cannot afford to pay the salary of one pharmacist solely for the purpose of setting up and running a CPK consultation service. But, by pooling their resources, several hospitals from a region can use the services of a trained pharmacist to help them with CPK related issues. Our project has clearly indicated its feasibility.

REFERENCES


