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# Planning the use of Lean Six Sigma as a framework for blood bank management improvements

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**Abstract**

*As a multidisciplinary process, blood bank management (often called BSM - Blood Stock Management) is designed to gain optimal use of blood products. Careful and responsible management of blood supplies, optimal use of blood products and minimizing the wastage of outdated blood are its main goals. Race for blood donors is being promoted in Serbia for past several decades by setting the following strategic parameter: 4 blood units have to be collected per 100 inhabitants (unofficially it is called a "4% donations"). Meanwhile, various important factors related to the efficiency and efficacy of the use of blood products are not treated by national strategies at all. Recent changes were done by the review of such policy initiating Serbian blood banks to improve the BSM based on adequate experience of EU and other countries. A new goal set by the national Law of transfusion practice was set: "donation should be planned in accordance with the needs of clinics and patients". Being aware of the lack of information as well as of a possibility that there are different needs in various regions, legislator set general aims, indicating the need for each blood bank to find its particular indicators of patients' and clinics' needs.*

*This paper provides descriptions of processes of planning, blood collecting, blood and products processing, storage and issuing for the use in clinics. These are the main BSM processes. With the use of DMAIC (PDCA) approach and appropriate Lean Six Sigma improvement methods, a framework for process improvements set by new strategic goals is described in this paper.*

**Key words:** *Transfusion, Blood bank, lean six sigma framework, process improvement*

## 1. INTRODUCTION

Using Lean Six Sigma approaches in health care processes is rather a new area for research. However, researchers and practitioners have already found it very useful for improving health care processes, as explained later on.

Based on significant practical work experience of authors (in building about ten various, mainly integrated management systems in the area of health care), it is obvious that quality of process is still a widely misunderstood term in Serbia. It does not denote organizing processes that only generate usable information or ones that only use very small amount of resources nor it does denote processes that only result in products or services of outstanding technical quality. It denotes processes that generate sufficient information with the lowest costs; processes that use valid information for rational managing and processes that have sufficient quality of product/service. That's not all - of course these processes have to be on a road of continual improvement. Authentic quality requires from managers not only to understand this declaratively, but to live this story every day, doing their routine jobs always having in their minds the strategy. Applying Lean Six Sigma approach might be a way to gain this state [1].

This paper is a contribution to setting a framework for Lean Six Sigma improvement project in the transfusion practice in Serbia today. It is based on experiences from one of the largest blood banks in Serbia, Transfusion Institute of Vojvodina, Novi Sad, Serbia. Being aware of particularities among blood banks, authors have made efforts to distinguish only general facts and guidelines.

## 2. BACKGROUND

In study [2] authors report successful usage of five stage "Lean Sigma" process (DMAIC - Define, Measure, Analyse, Improve and Control) to reduce RBC (Red Blood Cells) wastage from 4.4% to only 2%. Study is made during 4 year period and a total amount of around $800,000 was saved. Authors used a variety of methods (affinity diagrams, Pareto diagrams, cause-and-effect analysis, various diagrams, quality charts, etc.) as a framework for process improvements.

Attention paid to the application of Lean Six Sigma approach in health care is obviously a result of recent findings in [2] and other studies. It is than not uncommon that researchers generally emphasise these efforts and support them (see [3]).

Example of applying DMAIC approach in transfusion is found in study [4]. DMAIC is again a source for substantial process improvements. They report decrease of inappropriate transfusions of packed red blood cells from 16 to less than 5%. A number of other improvements are reported as well.

Study [5] provides some general historical and theoretical backgrounds for Lean Six Sigma approach and its use in health care. Polk emphasise that origins of Lean Six sigma approach are in Deming's PDCA cycles and that co-existence of Lean Six sigma and innovation can reduce cost and increase quality and value.

Authors of study [6] found that Lean Six sigma projects are appropriate link between approaches of improving production (and service) quality and systematic improving of health care processes. The TQM philosophy created in previous century may not be framework practical enough to be used as road to production and service improvements. Lean Six Sigma may bring in this dimension. According to [7] the use of Six Sigma framework in hospitals began in 2002, while in 2006 Lean approach was introduced. Today, they are usually mixed together in a form of Lean Six Sigma approach.

It is obvious that Lean Six Sigma is the approach that can be successfully applied in health sector.

First step in the research is getting the picture of the Blood Transfusion Institute of Vojvodina (further referred to as Institute) processes global picture. After defining processes, it became obvious that Lean Six Sigma concepts could be practically applied in order to improve Institute's processes. Planned improvements and initial analyses indicate that the effective use of a number of Lean Six Sigma related methods is possible.

## 3. RESULTS TO BE EXPECTED AND DISCUSSION

### *3.1 Basic processes of the Institute*

This section provides a framework for the application of Lean Six Sigma approach in the Institute. Since blood banks worldwide have similar processes, this paper can be considered as general for the area to a great extent.

The result of previously described analysis, a process diagram of the basic processes and their relations in the Institute was made (Fig. 1).

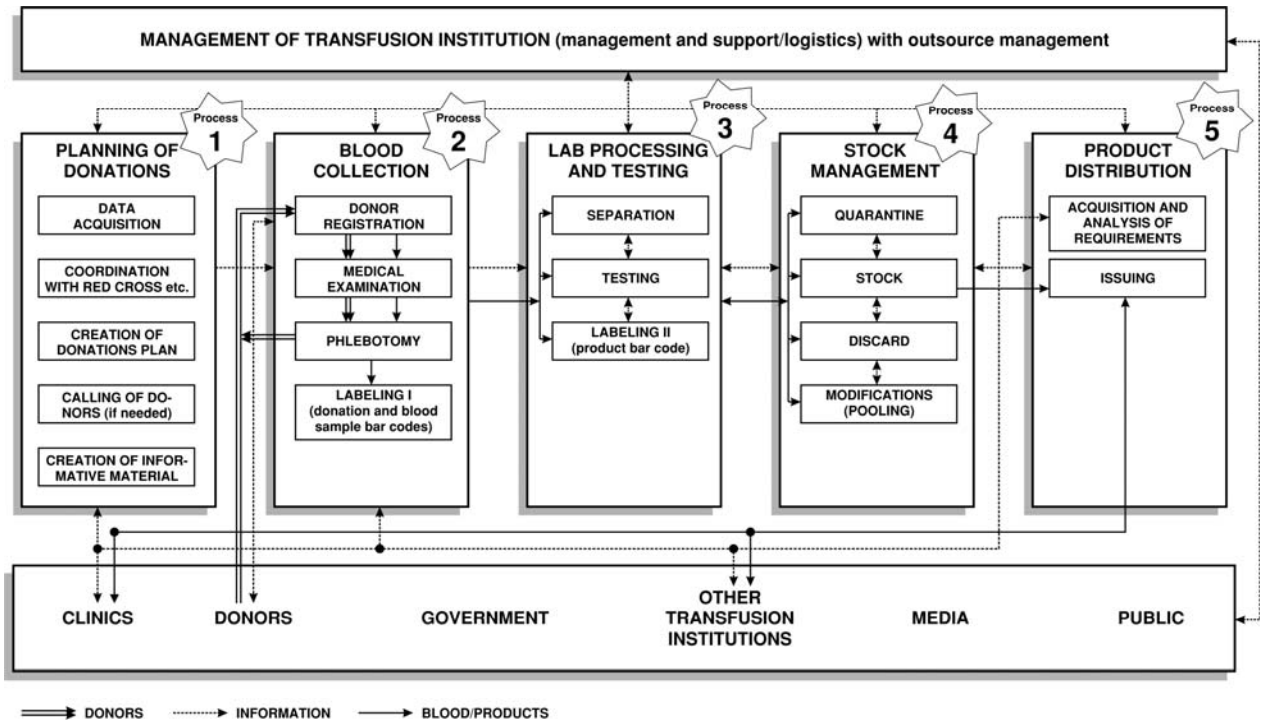


**Figure 1**. Basic processes in Blood Transfusion Institute of Vojvodina

Five basic processes were found: 1 Planning of donations, 2 Blood collection, 3 Lab processing and testing, 4 Storage and 5 Product distribution. Figure 1 shows processes and the most important external interested parties. Communication with donors, clinics and other transfusion institutions is noted in particular, while all other communications between the Institute and interested parties are noted by dotted line at the right [1].

The Institute processes are at the moment being modernized by implementing new Blood Bank management software called Progesa (http://www.mak-system.net /software-solutions/blood-banks-ep/). Software producers took into account a variety of informational needs of a blood bank (basic information needs incorporating support for routine processes, needs related to data processing covering stock, collecting and ordering management and various reports related to business intelligence needs). The following text in this section contains descriptions of Institute processes, expected changes thereof implied by the application of mentioned integral software solution for BSM, other implications related to the application of Lean Six sigma and expected overall results.

The story begins with *Donation planning process*. For the process of Donation planning (process 1, fig. 2), data is collected from clinics, population (or various institutions handling the population data) and from the Institute (such as stock levels). Adequate planning implies the use of various data from Institute's information system. Coordination with the Red Cross, National Biomedicine Agency at the Health Ministry and other institutions, the media and a number of other organizations is performed in this process for planning broader joint actions. Donation plan is based primarily on the needs for blood products. Accordingly, donors are invited in cases where specific blood collection is performed. This process prepares materials for informing the public.

Donation planning is at the moment mostly based on expected values of relevant indicators and their trends, instead of objective assessment values obtained by the use of appropriate predictive statistical methods. With the Institute's staff great experience, errors of this kind of predicting are usually not significant. However, statistical predicting especially when done upon a variety of data, using large samples and for a longer time period should provide better results, save more blood and money and make work process even more efficient and effective. Plans exist to form central national databases of blood donors, needs on clinics and blood inputs. This would enable even better predictive planning of blood products needs, while blood lacks and overages could be immediately reported to the central database and their undesired impact therefore reduced by implementing adequate reaction. At the moment blood banks send their input, output and stock data to the national Biomedicine Agency once a week. The lack of computers in blood banks in Serbia today is a reason why some of this data could be hold as inaccurate and rather unreliable. On the other hand, implementing the consistent national system could not only improve the Institute efficiency, but the efficiency (and, therefore, the effectiveness) of the overall national transfusion system. Progesa is a web oriented solution and it could ease the reporting to national services and other blood banks and incorporating into national system. Advantages of implementing computers and standardized software in Data acquisition include prompt systematization of input data, instant availability of collected blood quantities (by blood groups, Rh factor). On the other hand, coordination with Red Cross and other health institutions related to donations planning should be immeasurably more effective and more efficient. Calling of phenotyped blood donors any time when needed could also be many times efficient, even if blood is needed in different region.

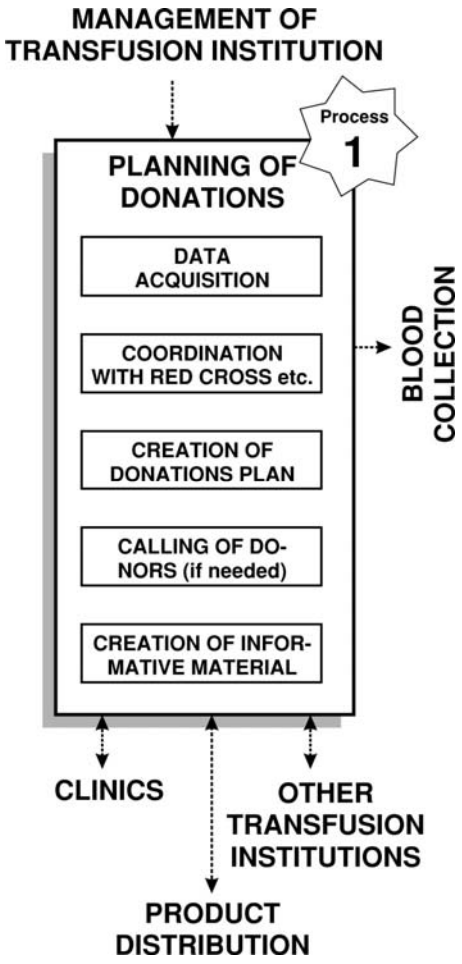


**Figure 2**. Donations planning process

A blood collecting plan is sent from the process of donations planning (process 1) to *Blood collection process* (process 2, fig. 3). This is the only process having direct contacts with donors. Donor is first being registered and medically examined. This is followed by blood donation. Employees monitor donors for a certain time after the donation and undertake appropriate actions if needed. After the donation, units of whole blood obtained from donors are labelled with the donation sticker and unique barcode. Test samples are taken from donors to test the quality of the donation and these are also labelled. The process of blood collection sends appropriate information (labels and data entered to the computer database during registration) to process of lab processing and testing (process 3), along with donated blood units and samples. With the unique or compatible software solutions used in whole health system and all relevant data entered to the database, assuming that web solution is in use, any donor would have a unique bar code recognizable within the national health system. This would enable the full traceability of all blood units in the system and their use.

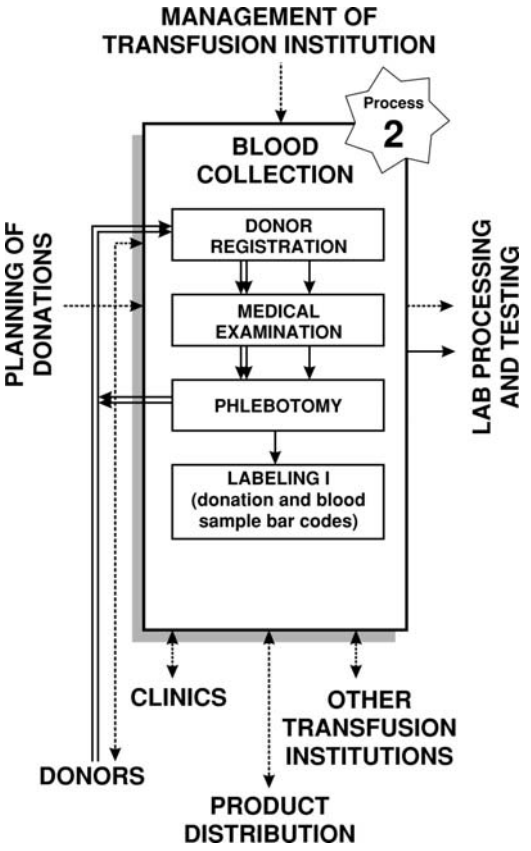


**Figure 3**. Blood collection process

*Lab processing and testing* (process 3, fig. 4) has three interlinked sub-processes. These are separation of the blood, testing and (product) labelling. Links between these processes and processes 2 and 4 are also complex. Separation results are erythrocytes, platelets and plasma units as three basic blood products. Testing involves performing a series of standard tests in accordance with the law and medical procedures, but, under specific conditions, some additional analyses are performed. Every result is recorded. Unlike the primary labelling where the whole blood units are marked, products obtained by separation, filtration, and radiation are here labelled while labels containing information about the donor, blood group / Rh factor. These labels are directly or indirectly traceable to the donor, testing, date of collection, processing, blood, date of production and other data.

The use of standard BSM software enables the traceability of a blood product all the way to the donor, date of donation, date of lab processing, time, place and storage details, and all of that just by a touch of a barcode reader. Laboratory generates data about positive marker tests. If a donor is once detected as critical marker positive, his or her blood must never be used again. The only way of reliable instant positive marker donor identification is possible if appropriate information system is in place and in function. If a system is in function on whole the country, marker positive donors could never be in a situation to donate blood. This is also a process providing inputs for database of phenotyped blood donors, treated as a part of process 1.

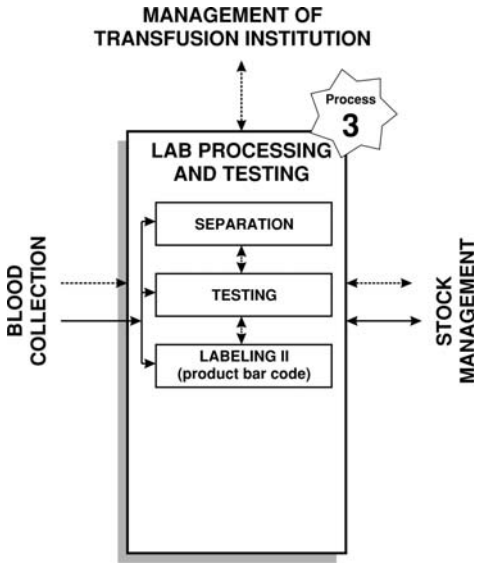


**Figure 4**. Lab processing and testing

*Storage* (process 4, fig. 5) or Stock management is carried out under strictly defined temperature. Some blood units and products are stored in quarantine for they cannot be used at the moment.

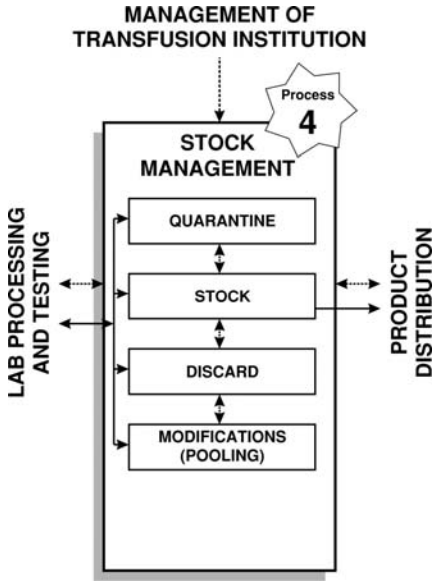


**Figure 5**. Stock management process

Reasons for this may include incomplete testing, indications of non-conformances, non-conformance of storage / packaging, expired lifetime, positive marker tests etc. When certain conditions are met, some whole blood units / products have to be rejected. Blood and blood products can arrive from previous process to be stored, and, when conditions are met, they may return for labelling and back to the storage. Modification includes filtration of leukocytes, and, in special cases, radiation is performed to eliminate lymphocytes. These modifications are made to the products after separation, when the product is sent for labelling and returned to storage. Using computer program in this process may ease whole standard stock management process (First-

In-First-Out discipline, early warning expiry system, shipping order, etc), as well as quarantine handling. Progesa has a stock management module which enables opening stock data from various blood banks. When an integrated solution is in use, all possible users of blood product (no matter where they are) could have an access all the data about a blood group, expiry date, donor and other relevant data.

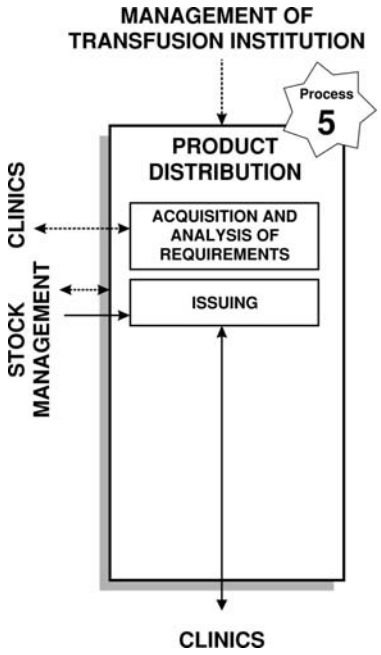


**Figure 6**. Distribution process

The last process on the list is *Distribution* of blood products (process 5, fig. 6). Blood products may be issued to clinics and to other transfusion institutions. Product is issued upon the request which is submitted on the appropriate form followed by patient data and patient's blood sample. Sample is used to conduct analysis before product is handed to the user. This process includes transport of products as needed. Issuing of blood products itself can indeed be improved by using BSM software by the following: all of the process is recorded automatically; stock management module chooses the unit to be issued; all printed records (if needed) are being generated automatically, human errors are practically removed, etc. After some period and after database is filled with data generated by described processes, application of statistic methods for planning of blood donations and blood/blood product quantities could enable creation of desired performance monitoring system and gaining planned reducing of waste and costs.

*3.2 Planned improvements*

Process 1 - Planning of donations - can be improved in several ways. The most important aspect of improving the process involves broader action for it has to include users of blood products. Specifically, planning of donations could be more effective and efficient if the Institute had a significant response to demands for careful planning at the place of product use - at a clinic. Timely sending of user requirements to the Institute (and planning information where available), with use of statistics to reduce seasonal and other random and stochastic impacts, should result in significant increase of blood products' use efficiency. Methods applicable to gain these improvements include cause and effect diagrams, different graphic data representations (histograms, box plots, pies, scatter diagrams, etc.), matrix diagrams, and methods of advanced statistics (regression, cluster and factor analysis, ANOVA structural equation modelling, etc). This all is very important for meeting the legal requirements - optimal operations of blood banks in accordance with the requirements (which, in addition to the optimal quantity of the product also include optimal use of all other resources). For planning, it is very important to determine signal and lower stock limits for different types of blood products, as well as activities to carry out when these limits are reached. Important improvements may be brought by user trainings about the importance of establishing a significant communication between the Institute and its users. It is also necessary to define the structure and frequency of these communications. For the improvement of the process, it is necessary to raise the effectiveness and efficiency of the information system in all its elements, from data acquisition to information storage/transfer and creating reports. Now, the Institute is adjusting for applying new software to support the information system. This software is an excellent ground for the application of listed methods and achieving the planned improvements.

Improving process 2 - Blood collection - is largely related to acquiring data from donors, but also using data from the Institute information system. Preliminary findings [8] indicate the presence of a high level of donor's satisfaction, but also the fact that staff training (along with some other improvements) could bring this vital parameter of the Institute performance at a higher level. Moreover, using different methods of statistics (primarily cluster analysis) various donor groups could be extracted, which would enable determining donor target groups, their motivators for donating and design of appropriate way to better inform this groups about donating ([9] is the example of studies in this area). Improvements should also include various analyses of information flows and operation related times. Improving donor surveys, the review of present questionnaires and developing research to find most efficient improvements should be carried out. In order to educate donors there is a need to undertake a number of seminars related to the conditions that are contraindicated for blood donation (medications usage, various acute and chronic diseases, inadequate body weight, etc.). It is assumed that such educations should reduce number of donors trying to donate in unfavourable circumstances. This, further, could reduce the waiting time for donation (it is recently found that waiting is a significant source of donor dissatisfaction if it interacts with other factors, see [8]) and lower the costs. For those who are interested, pre-donation questionnaires should be published on Institute Internet pages to adequately inform potential donors. The data acquired in this process can be joined with data from other Institute processes. For example, linking nonconformances of purchased materials identified in the process with information about the manufac-

turers / suppliers would allow more effective monitoring of suppliers efficiency (it is the requirement of ISO 9001, anyway). Efficiency of the Institute information system has a major impact on the planned improvements. This is just another confirmation of the findings reported in studies on the relationship between management system and information system [10], [11], [12].

Process 3 Lab processing and testing generates a series of data groups valuable for both the processes of the Institute, and for the community. Access to large amounts of data on a number of blood parameters (group, Rh, coagulation, sedimentation, number of cells, etc.), and data related to epidemiology (transfusion transmitted or contraindicated disease markers), enables the Institute to warn the public if these parameters start to indicate systematic disorders in the population (the significance of this is both national and wider). The process of making synthetic reports from data on blood analyses may be accelerated many times by introducing an integrated information system. Besides accuracy, it could increase the reliability of the results obtained (introduction of a blood bank standard software for data acquiring and processing in the Institute is currently underway; software is assumed to be a catalyst for a series of improvements that are subject of this paper). Process 1 generally does not employ medical doctors, while in processes 2 and 3 medical staff makes up the majority of employees. So, improvements of process 1 should be designed and carried out with intensive consultations with medical staff from processes 2 and 3. Some improvements could refer to the application of control charts (numeric and attribute) to monitor the stability of various parameter values. Various means of visualization can be used for clear process status display (for example different color stickers for various blood groups or writing boards). Some of the processes significant for quality can be represented by flowcharts and set to be accessible to employees and other interested parties. Risks for donors, patients, employees and the process itself can be analyzed using the FMEA technique and appropriately documented. In accordance with the results of these analyses, if necessary, follow-up actions should be carried out. Creating and maintaining an accurate database of Institute equipment and its use for effective maintenance should also be considered.

Most of the activities in the process 4 Storage is carried out by staff from processes 3 and 5. Specifically, these activities include: monitoring and keeping valid storage conditions, modification of blood products and preparing for distribution. Preparation for discard, discard itself and monitoring of storage conditions (temperature) is also performed by employees who participate in other processes. It is, therefore, clear that any activity of this process should be properly documented. Human errors in making records or storage of misplaced units can have serious consequences. Improvements could include application of various colours of labels/stickers for various categories of stored units. In addition, storage could be supported by various visual devices, and by automatic monitoring system for storage conditions. Detailed monitoring of reasons for rejecting units of blood or blood products could result in discovering ways to improve process and lower the probability of discarding the unit. For determining improvement actions with such goals there are different frames. One of them is 5 Whys - set 5 questions "why" until there is a problem found as a root of non-conformance occurrence. Creating various diagrams relating to the process, and reports with performance parameter values could be put into practice. Storage process improvements may include the application of the FMEA method for the purposes of risk analysis (or an integrated approach could be set to determine the risk analysis in the Institute process as a whole). Early alarms of reaching signal or low/high stock limits could be set for the purpose of timely reaction (Software for support of Information system could be here of a great help since it can simultaneously manage user orders and actions plans).

In the end, the distribution process (process 5) can be improved primarily treating relations with the user. Organizing training for user's medical staff about the importance of timely sending appropriate feedback information to the Institute is considered necessary. In this process, more attention has to be paid to the acquiring and processing of user complaints. Some complaints may not be caused by the operations of the Institute, but rather by the lack of will on the user part to send the timely information on the use of blood product. All of the disagreements between Institute and its users need to be resolved by cooperation since it adds value to both sides.

All of these improvements are made possible now with the use of Progesa software because it enables acquiring all the data needed for implementation of these improvements. However, using the software itself is not the only condition to be satisfied prior to reaching described improvements. One systematic step-by-step improvement project created and implemented by a multidisciplinary team of various experts in a number of fields (at least transfusion, information technology, management systems and mathematics) and appropriate financial, political and marketing support would enable such improvements to be implemented. Experience tells that implementation itself is not enough. Appropriate trainings should take place in various levels of the health system to support implementation of such system, as well as its maintenance (which can be also a very difficult and complicated task).

The Institute management should coordinate implementing described improvements (along with those to be determined) in order to enable proper trainings, needed resources, accomplishing of improvement phases, verifying results and deciding whether improvements are ready to replace existing practice or not. This activity sequence is an instance of DMAIC approach: Defining elements of process improvement, accomplishing Measurements to find out basis for analyses, accomplishing Analyses to determine improvements and implementation of those Improvements. Coordination by management is even more important after implementing improvements to enable continuous effects. That is Control section of DMAIC approach, which should become a routine all the way since new improvements are determined. DMAIC is maybe the shortest successful recipe for any improve-

ment (using this approach is never the only, but is always considered a necessary requirement for reaching a successful improvement). Similarity between DMAIC concept and Deming PDCA cycle [13] is not accidental. Both approaches are very similar. They represent maybe the simplest way to "make life easier". All of us passed this cycle many times. Every time when we were satisfied with the result of any innovation and aware of at least a little improvement it brought, we most likely used the DMAIC / PDCA cycle (no matter if we were aware of that or not).

*3.3 Results*

This paper provides framework for process improvements in Blood Transfusion Institute of Vojvodina and in national health system, as a whole. After analysis of Institute processes, proposals for improvements were given for each process. Besides proposals, paper provides information about which methods should be used for each of the improvements. One of the proposed improvements is described in the following text as a guideline how improvements could be implemented. Implementing of new information system called Progesa in the Institute is found an effective support for described improvements. What is more, this software is found to be a very good base for significant improvements of some aspects of blood use in whole the health system.

Figure 7 is a graphical representation of key elements of improvement of a donation planning process, explained earlier in this paper. Today, information base for blood donation and production planning is not sufficient and this situation should be improved. Major Institute primary users exchange information with Institute, but it is rarely related to longer periods (month or year). Some unusual situations implying higher needs for blood products are reported, but reports are rather informal and oral instead of formal and recorded. Information are also received in informal manner and written down by hand. Having in mind that work processes are carried out in shifts, the possibility of communication errors and emerging of other non-conformances is significant.

Clinics' side of the process has three key elements. Employees obliged for planning in a clinic must be aware of the importance of their job for the community as a whole. It is best if they are formally obliged for summarizing the needs for blood products within their system.

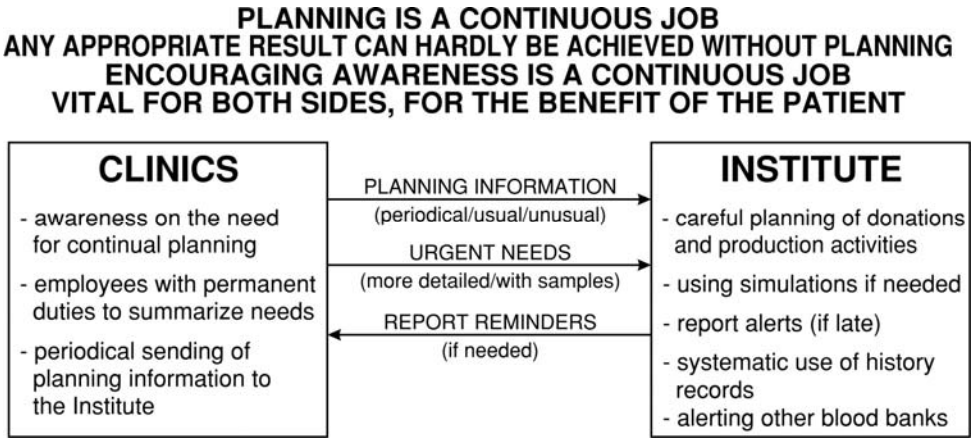


**Figure 7**. Key elements of a donation planning process improvement

On the other side, Institute may formally put in use some statistical methods for simulating the future use of blood products (based on history records from database), while sending alerts to clinics may be a good idea of reminding if a report was not received as scheduled. If situation is adequate, communication channels with other blood banks in the region may be intensified to resolve surplus or deficit of some blood products.

## 4. CONCLUSIONS

This paper sets a framework for Lean Six Sigma concept application to plan improvements in Blood Transfusion Institute of Vojvodina and national health system as a whole. The ultimate goal of applying these improvements is reaching continual optimal function of a blood bank and minimum of blood / blood products wastage.

It is assumed that improvements described in the previous sections will have the desired effect if they are based on Lean Six Sigma concept. Among the leading approaches to be implemented is the DMAIC approach. Implementing of appropriate software as a support of information system is recognized as an efficient improvement. Implementing such sophisticated software as described in this paper brings some risks that must not be overlooked, for the sake of information security, including legal requirements. for more details see [14], [15] and other available sources.

This paper is a contribution to efforts of any employee who consciously improves his/her work process. The authors' wish is that more such employees are to be employed in the health system than is the case today. Available to everyone there is a variety of process improvement methods considered an effective force for progress [16].

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# Planiranje upotrebe Lean Six Sigma kao okvira za poboljšanje upravljanja bankama krvi

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**Rezime**

*Kao multidisciplinarni proces, upravljanje bankama krvi (poznato kao BSM – Blood Stock Management) nastalo je kako bi obezbedilo optimalnu upotrebu krvnih proizvoda. Njeni osnovni ciljevi su pažljivo i odgovorno upravljanje zalihama krvi, optimalna upotreba krvnih proizvoda i minimalizacija neupotrebne - zastarele krvi. Trka za donatore krvi se promoviše u Srbiji tokom nekoliko poslednjih decenija tako što je određen sledeći strateški parametar: 4 jedinice krvi treba da budu prikupljene na 100 stanovnika (neslužbeno to se naziva „4% donacija"). Za to vreme, različiti važni faktori u vezi sa efikasnošću i uspehom upotrebe krvnih proizvoda nisu uopšte tretirani nacionalnim strategijama. Nedavne promene su učinjene nakon provere ovakve politike, što je iniciralo srpske banke krvi da poboljšaju BSM na osnovu adekvatnog iskustva EU i drugih zemalja. Novi cilj koji je postavio nacionalni zakon za transfuziju glasi: „donacije treba da budu planirane u skladu s potrebama klinika i pacijenata." Svestan nedostatka informacija kao i mogućnosti da postoje različite potrebe u različitim regionima, predlagač zakona je postavio opšte ciljeve, nagovestivši potrebu da svaka banka krvi nađe svoje posebne indikatore potreba pacijenata i klinika.*

*Ovaj rad pruža opis procesa planiranja, sakupljanja krvi, procesuiranja krvi i proizvoda, skladištenje i izdavanje za upotrebu u klinikama. To su osnovni BSM procesi. Sa upotrebom DMAIC (PDCA) pristupom i odgovarajućim Lean Six Sigma metodima poboljšanja, u ovom radu je opisan okvir za poboljšanje procesa određenih novim strateškim ciljevima.*


**Ključne reči:** *Transfuzija, banka krvi, lean six sigma okvir, poboljšanje procesa*