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Designing Model to Identifying Optimal Services, Integrated System, Registration of Pharmaceutical

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Abstract

Background and Objectives: One of the complicated processes in the Ministry of Health is the process of registering pharmaceuticals .Since there are different soft wares for registration of products, and since parallel services concuss waste of time and money, it is necessary to provide integrated software in the form of services. This goal can be achieved when services are identified and combined in integrated soft wares.

Material and Methods: present study is an applied research, In order to identify the services of an integrated system for recording pharmaceutical supplies, first the Gray-Wolf multi-objective optimization (GWO) algorithm was proposed. Then the values of the algorithm parameters were extracted by the goal-based requirements analysis method and the algorithm was implemented. Finally the best services were extracted by the hierarchical analysis process.

Results: Considering that the results of present study are an operational project in the Ministry of Health, by implementing the algorithm proposed by Gray Wolf, services were identified, which can be used to create integrated software for registering pharmaceutical supplies**.**

Conclusion: Creating an integrated system for registering pharmaceutical supplies is one of the important challenges of the Ministry of Health. This can be achieved by identifying services and combining these services to create an integrated system.

Keywords: Integrated System, Gray-Wolf Optimizer (GWO), Hierarchical, Analysis Process (AHP), Goal-Based Requirements Analysis Method (GBRAM)

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Highlights

- In this study, software services are identified to create an integrated software for registering pharmaceutical supplies in the Ministry of Health and Treatment.

Introduction

One of the most important missions of the Ministry of Health is to assure the society about the quality, health and efficiency of health-oriented products, especially pharmaceuticals supplies, so one of the executive duties of the Ministry of Health, is register pharmaceutical supplies. Since to the fact that pharmaceutical supplies are very wide, implement these processes in the organization need to implement the system is in the form of services. There are different approaches to identifying services. During the last decade, different methodologies for implementing and developing service-oriented architecture have been introduced, and the first and main phase of all these methodologies is identifying services. Pharmaceutical supplies that are produced by different companies must be registered and approved in the Ministry of Health and the code IRC allocated to that product in order for them to be allowed to sell their product. But, concerning registering pharmaceutical supplies, there are different soft wares for registration of products, and since parallel services concuss waste of time and money, it is necessary to provide an integrated software in the form of services. This goal can be achieved when services are identified and combined in the four of an integrated soft wares. Today by the development of web service technology, implementing an integrated software is not a big challenge. But identifying the best services is for providing an integrated soft wares is challenging for a service-oriented architect.

In the last decade, various methods have been introduced to implement service-oriented architecture, and the main step of all these methods is service identification. In 2010, Qing et al, compared 30 service identification methods, without providing the details of each method (1). Yukyong et al, in 2009 divided service identification methods into three categories.

The first category include service identification methods focusing on processes. They introduced a method to identify services based on process models using graph clustering (2).The problem of this method is that it only pays attention to the relationship of activities without considering the number of repetitions of activities.

The second category of methods include the identification of services with a focus on the goal. Grandry et al, in 2009 identified services in seven stages (3). One of the problems of this method is the goals are not explicit and that all the steps of this method are analytical. Abdollahi et al, in 2011 used a set of management objectives to identify services (4). Since management objectives are conflicting, the multi-objective genetic algorithm was designed to search for Pareto optimal solutions. One of the disadvantages of the genetic algorithm is the limitation to local optimal points.

The third category of the methods include service identification focusing on entities. In 2014, Krafzig et al extracted appropriate services from the process model and entities (5). One of the problems of this method is that only the repetition of activities is the criterion for service recognition, also, in this method, standard algorithms were not used to identify the service, and the accuracy of the algorithm provided was not evaluated.

Materials and Methods

In present study, the proposed multi-objective gray wolf algorithm was presented to identify the optimal services to register pharmaceutical supplies. The GWO algorithm was inspired by the hierarchical leadership of gray wolves in nature and their hunting mechanism (6) In met heuristic algorithms, the more the number of parameters, the more the possibility of adjusting the parameters to increase the speed of convergence (7). But the only parameter that exists in the gray wolf algorithm is the parameter a, whose value decreases from two to zero (8). The advantages of

this algorithm include increased search capability, ability to avoid optimal local solutions, high accuracy, simplicity, flexibility, robustness and low computational time. The implementation of this algorithm shows that the gray wolf algorithm can have a better response than other optimization methods. In proposed algorithm, quality indicators are extracted to evaluate services.

The step of the proposed algorithm for identifying services software is as follows:

1. Initializing the parameters of the gray-wolf algorithm and creating the initial population.

In this type of algorithms, we first consider a population of answers, then we find the best answer that optimizes the objective function, among the population of answers.

2. Calculation the objective function of each solution

To implement the proposed gray wolf algorithm and identify the optimal services, the solutions are evaluated based on an objective function. Therefore, the goal-based needs analysis (GBRAM) method is used to identify indicators and criteria for evaluating services and creating an objective function. The highest level of this model is the goals of the organization and the lowest level is the supplies. Measurable indicators are then extracted according to each of the supplies. These indicators are as follows (9):

Granularity of service

Granularity of service calculates the average of the activities that a service performs. Large services automate processes. But Reusability requires services with smaller grains. Therefore, in identifying services, it is the optimal point between these two goals. How to calculate the granularity of service is as follows:

$$V_{graun} = \frac{a}{s} \qquad (1)$$

a: The total number of business activities

s: Number of all services

Coupling of service

Coupling of service indicates how much one service depends on other services. The input of one service may be obtained from the output of other services, which connects the two services. A request to a service is via a message sent to another service operation. The number of messages indicates the degree of connection, which depends on the number of entities in the message. The connection of services is calculated based on the relationship between the activities of two different services as follows:

$$V_{copl} = \sum_{s}^{S} \sum_{s\prime}^{S} \sum_{t}^{m^{ss\prime}} C_{ss\prime t} \qquad (2)$$

$m^{ss\prime}$: All services that are sent from the s service to the s' service,

$C_{ss\prime t}$: The number of connections of information entities of message t that is sent from service s to service s'

Cohesion of service

Cohesion of service refers to the degree of connection between activities within a service. Therefore, the degree of Cohesion depends on two factors: first, the number of activities within the services and second, the intensity of the relationship between activities within the service. The highest adhesion is when a service performs only one activity. Cohesion of service can be calculated as follows:

$$V_{choc} = \sum_{s}^{S} \sum_{i}^{A} \sum_{i\prime}^{A} X_{is} X_{i\prime s} r_{ii\prime} \qquad (3)$$

X_{is} : 1 If the i activity is in the s service, 0 otherwise

$r_{ii\prime}$: Total number of information entities within the business data flow of activity i and i'

Convergence of entities:

Entities are a solution for doing business. Therefore, the best combination of services is when each service performs minimal operations on the entity. Also, activities that operate on the same entity are in the same service. The convergence of entities is calculated as follows:

$$V_{conve} = \frac{1}{S} \sum_{s}^{S} \sum_{i}^{A} Y_{is} + \frac{1}{B} \sum_{i}^{A} \sum_{j}^{B} Z_{ij} \qquad (4)$$

Y_{is} : The number of business entities that are processed by i activity in the s service

Z_{ij} : The number of services that activity i operates on entity j

B: Total number of business entities

To identify the evaluation indicators of the services, the Goal Based Requirement Analysis Model (GBRAM) was used, and the macro-goals of the Ministry of Health were categorized into three levels, then the needs that can cover these goals were extracted. With each of the needs, a measurable index was extracted witch could be measured and they can be used as objective functions in the service identification algorithm. To implement the proposed algorithm, the value of the objective function must be calculated for each solution. Therefore, first, the values of relationships 1 to 4, which are the variables of the objective function, must be calculated.

One of the factors influencing the identification of services is activities." Activities "refer to 22 common activities that every company producing pharmaceuticals does to register its product in the Ministry of Health.

Another factor influencing the identification of services is entities.

Anything we want to have information about is called an entity, for example, we want to have information about the payment process, such as payment date, payment amount. Therefore, services are identified considering the concept of entities. In present study, 12 entities were considered: Application form, submitted documents, review of submitted documents, laboratory response, clinical study response, initial consent, establishment license, GMP, legal commission license, payment, registration license, IRC.

Each entity is accessed by a number of activities, and each activity performs operations on a number of entities. These operations include creating(C), reading(R), updating (U) or deleting (D) entity data. Therefore, in the identification of services, the importance of the entities must be determined. This importance is determined by the (Hierarchical analysis process) AHP method. Then, the entity-activity matrix, which indicates the type of access to the entities by the activity, is extracted. In the following, to calculate the parameters of relations 1 to 4, the activity-activity matrix is extracted considering the entity-activity matrix.

3. Extract Pareto optimal solution values

Another issue which was addressed was that in single-objective gray wolf optimization algorithms, in each iteration, alpha, beta, and delta wolves are the optimal solutions, but in present study we have a multi-objective function, and for a multi-objective optimization problem, the probability of finding an optimal solution that optimizes all the objective functions defined in the problem at the same time is very low. In this case, we will have Pareto optimal answers. So the method of (Hierarchical analysis process) AHP was used to rank and select the optimal services.

In present study, in implementing the proposed gray wolf multi-objective algorithm, each wolf shows a solution. Each solution also contains a number of decision variables. The length of each solution indicates the number of available activities. The number inside each variable indicates the number of the service to which an activity is assigned, which is between 1 and 21. That is, the activities are performed in a maximum of 21 services. To generate the initial population, these 22 activities are assigned to 2 services once. It will be given. After creating the initial population, the value of the objective function for each solution should be obtained. Therefore, then the values of the variables are calculated with relations 1 to 4. In present study, considering that the number of activities is 22, the number of services can be changed between 2 and 21, so the program written with MATLAB software is executed with 2, 3 to 21 services. The best answer is defined as an alpha wolf, the second as a beta wolf, and the third as a delta wolf. Therefore, 3 Pareto optimal responses are extracted for each run.

Finally, a criterion for validating services is defined as the criterion of fit from the point of view of experts, this relationship is as follows:

$$U = 1 - \frac{a + d}{E + a} \qquad (5)$$

E: Total number of services, d: The number of incorrect services according to experts
a: The number of services that, according to experts, should exist and should be added to the services

Results

First, the data for registration of 20 products in the Ministry of Health were gathered. In the process of registering these products, there are 22 common activities as follows:

Table1. List of activities for registering Pharmaceutical supplies

Row		Activity name
1	A	Requesting the client and preparing and presenting the initial documents
2	B	Obtaining and reviewing the initial documents and determining the product class
3	C	Inspection and issuance of GMP license for raw material production line
4	D	Issuance of initial agreement
5	E	Application for establishment license and preparation and submission of documents
6	F	Obtaining and reviewing establishment license documents
7	G	Issuance of establishment license
8	H	Apply for a product registration license by submitting a initial agreement and documents
9	I	Review in the specialized committee and review of product registration license documents
10	J	Review in the legal commission for final diagnosis and approval
11	K	Announcing the response of the legal diagnosis commission to the client
12	L	Payment of fees with the approval of the Legal Recognition Commission
13	M	Inspection and licensing of Good manufacturing Practice(GMP) for product line
14	N	Receive a product sample and present it to the laboratory along with a test request
15	O	Performing tests and announcing the laboratory response
16	P	Request for clinical studies
17	Q	Performing tests and announcing the results of clinical studies
18	R	Completion and submission of Common Technical Document(CTD)
19	S	Review of CTD documents
20	T	Issuance of product registration license
21	U	Apply for International Residential Code(IRC) licensing and prepare and submit documents
22	V	IRC issuance

Identifying the services software

Quantitative indicators were extracted using the Goal-Based Needs Analysis Model (GBRAM), which can be used as the objective function in the proposed gray wolf algorithm to identify services. The following table shows the relationship between organizational goals and quantitative indicators in table 2.

The activity entity matrix, which expresses the type of access to the entities by the activity, is formed as follows in table 3.

Finally, the elements of the sum of the two activity-activity matrices, and the activity-activity matrix, considering the entities, create the final activity-activity matrix and is as follows in table 4.

Table 2. Relationship between goals and quality indicators

Indicator	Requirement (qualitative characteristics)	Third level goals	Second level goals	First level goals
$Max\ V_{granu}$	Maximum granularity	Agility	1: Increase the speed of service 2: Upgrade the notification level	Increase customer satisfaction
$Min\ V_{copl}$	Minimum Coupling of services			
$Max\ V_{granu}$	Maximum granularity	Automation		
$Min\ V_{copl}$	Minimum Coupling of services			
$Max\ V_{chos}$	Maximum Cohesion	Reuse of services		
$Max\ V_{conve}$	Convergence of entities			
$Max\ V_{granu}$	Maximum granularity	Agility	3: Response level height 4: Upgrade the notification level 5: Feedback management	
$Min\ V_{copl}$	Minimum Coupling of services			
$Max\ V_{granu}$	Maximum granularity	Automation		
$Min\ V_{copl}$	Minimum Coupling of services			
$Max\ V_{outhorization}$	Permission to access the required data	Confidentiality	Increase information security	
$Max\ V_{outhenticate}$	Authentication	Availability		
$Max\ V_{granu}$	Maximum granularity	Agility	1: Reduce employee unemployment 2: Improve employee productivity 3: Improving the enthusiasm and abilities of employees	Human resource management
$Min\ V_{copl}$	Minimum Coupling of services	Automation		
$Max\ V_{granu}$	Maximum granularity			
$Min\ V_{copl}$	Minimum Coupling of services	Reuse of services		
$Max\ V_{chos}$	Maximum Cohesion			
$Max\ V_{conve}$	Convergence of entities			
$Max\ V_{granu}$	Maximum granularity	Agility	1: Development of integrated information systems 2: Development of network automation 3: Development of management systems	Information resource management
$Min\ V_{copl}$	Minimum Coupling of services			
$Max\ V_{granu}$	Maximum granularity	Automation		
$Min\ V_{copl}$	Minimum Coupling of services			
$Max\ V_{chos}$	Maximum Cohesion	Reuse of services		
$Max\ V_{conve}$	Maximum granularity			

Table 3. Entity-Activity matrix

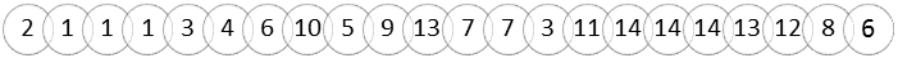
Entity Activity	1	2	3	4	5	6	7	8	9	10	11	12
1	C	C										
2	R	R	U									
3			R					C				
4						C						
5	C	C										
6	R	R	U									
7			R				C					
8	C	C										
9	R	R	U									
10			R			R	R		C			
11									R			
12										C		
13								C				
14	C											
15	R			C								
16	C											
17	R				C							
18		U	U									
19		R	R	R	R	R	R	R		R	R	
20											C	
21	C	C										R
22	R	R										C

Table 4. Activity-Activity matrix

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
1	0	1.875	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2	5.875	0	0.225	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0.225	0	1.4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.46875	1	0	0
4	1	2	1.4	0	1	0	0	1	0	0.46875	0	0	0	0	0	0	0	0	2.46875	1	0	0
5	0	0	0	1	0	1.875	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	5.875	0	2.4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	1	2.4	0	1	0	0.46875	0	0	0	0	0	0	0	0	2.46875	1	0	0
8	0	0	0	1	0	0	1	0	2.875	1	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	3.875	0	2.4	2	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	1.46875	0	0	0.46875	1	1.4	0	2.46875	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	1.46875	0	1	0	0	0	0	0	4	0	1	0	0
12	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0.46875	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2.46875	1	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	1.46875	1	0	1
16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.3125	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1.3125	0	0	1.46875	0	0	1
18	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	5.85	1	0	0
19	0	0	1.46875	1.46875	0	0	1.46875	0	0	0	0	0.46875	0.46875	1	5.46875	1	1.46875	1.85	0	1.46875	0	0
20	0	0	1	1	0	0	1	0	0	0	1	1	1	0	1	1	1	0	1.46875	0	1	0
21	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	1344
22	0	1.875	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

For Implementation of the proposed multi-objective gray wolf algorithm, each wolf represents a solution. Each solution also contains a number of decision variables. The initial population is obtained by creating a number of solutions that an example of this is in the Figure below:

Figure 1. Proposed solution with 14 services (one gray wolf)



The proposed algorithm was written by MATLAB software. The parameters of the multi-objective gray wolf optimization algorithm are selected as follows: Np = 50, maxgen = 100, p0 = 0.9, amin = 20 and amax = 55. Np is the number of members of the community and maxgen is the maximum number of iterations that is the condition for terminating the algorithm. Pareto optimal answers are then extracted for each run. These answers are as follows:

Table 5. Results obtained from the Gray Wolf algorithm

V_{chec}	V_{conse}	V_{copl}	V_{graun}	Number of services	V_graun	V_copl	V_conve	V_{graun}	Number of services	V_graun	V_copl	V_conve	V_{graun}	Number of services
3.6	10.7	21.6	6	4	4.0	13.0	24.6	4	3	3.5	14.6	24.4	5	2
4.5	12.2	18.4	4	4	3.8	16.6	22.9	5	3	3.3	17.2	23.1	3	2
6.0	11.1	22.9	6	4	4.0	14.7	21.0	4	3	4.5	11.0	21.1	5	2
3.6	14.7	18.3	5	7	3.1	13.6	24.6	5	6	4.3	11.6	20.8	3	5
5.3	11.7	20.4	4	7	5.9	13.6	22.2	4	6	4.9	16.6	22.3	4	5
4.7	12.8	19.8	6	7	5.0	17.4	19.3	4	6	4.0	17.0	18.5	4	5
5.3	12.1	18.3	5	10	4.3	17.1	19.8	3	9	3.8	17.0	18.4	6	8
5.0	14.1	19.5	6	10	3.1	10.2	21.0	3	9	4.7	10.8	21.2	6	8
4.8	12.4	22.3	3	10	5.2	17.1	23.8	4	9	5.6	15.4	19.0	6	8
4.3	17.6	18.6	4	13	5.3	13.1	24.7	4	12	4.9	15.6	18.3	5	11
5.2	12.7	24.5	6	13	4.3	16.6	19.7	5	12	5.7	13.6	20.1	4	11
3.7	15.8	20.5	4	13	3.9	10.5	20.7	4	12	3.3	11.1	24.5	4	11
3.7	11.2	19.0	5	16	4.0	12.0	19.8	5	15	3.8	12.3	20.1	3	14
3.4	15.0	22.8	6	16	4.2	13.9	20.3	5	15	3.5	17.0	23.1	3	14
5.9	10.5	20.5	5	16	3.2	16.8	23.3	4	15	5.8	13.1	21.5	4	14
4.1	17.6	23.7	6	19	3.3	12.8	19.9	5	18	5.4	16.6	22.8	5	17
4.0	17.5	23.4	3	19	4.4	15.6	24.5	4	18	5.0	16.8	21.2	3	17
4.4	17.7	24.6	6	19	4.6	14.6	22.0	6	18	5.6	14.6	23.9	4	17
					5.2	12.8	21.5	6	21	3.9	14.0	22.9	4	20
					5.1	17.9	22.2	4	21	4.9	16.3	22.6	6	20
					4.2	15.5	21.5	3	21	3.5	12.7	19.5	4	20

Finally, considering that in the previous step, 60 optimal Pareto responses were obtained, (Hierarchical analysis process) AHP method was used to obtain the best services. In present study,

the number of features is 4 and the number of options is 60!. After solving the problem by (Hierarchical analysis process) AHP method, the seven optimally identified services are as follows:

Table 6. Optimally identified services and activities of each service

Activities of each service	Optimal services	Row
Obtaining and reviewing the initial documents and determining the product class	Product class inquiry service	1
Requesting the client and preparing and presenting the initial documents , Application for establishment license and preparation and submission of documents , Apply for a product registration license by submitting a initial agreement and documents , Receive a product sample and present it to the laboratory along with a test request , Request for clinical studies , Completion and submission of CTD documents , Apply for IRC licensing and prepare and submit documents	Document registration service	2
Obtaining and reviewing establishment license documents , Review in the specialized committee and review of product registration license documents , Review in the legal commission for final diagnosis and approval , Review of CTD documents ,	Document review service according to the type of license and product class	3
Inspection and issuance of GMP license for raw material production line , Issuance of initial agreement , Issuance of establishment license , Inspection and licensing of GMP for product line , Announcing the response of the legal diagnosis commission to the client, Issuance of product registration license,IRC issuance	Licensing Service	4
Performing tests and announcing the laboratory response	Laboratory service	5
Performing tests and announcing the results of clinical studies	Clinical Studies Service	6
Payment of fees with the approval of the Legal Recognition Commission	Payment service	7

In order to validation, the accuracy and validity of the services was reviewed by experts. Amount of fit according to experts was calculated by Equation 9 and for 7 services, fit value of 97.3 is obtained, which is almost a suitable value for the fit relationship.

Discussion

In the methods of identifying services based on processes, the problems that exist are that only the relationship of activities is considered and the number of repetitions of activities is not considered (10). The advantage that exists in this research is that in addition to the relationship between activities, the relationship Inventories are also considered with activities. In the methods of service identification methods based on the goal, the problem that exists is that services are identified using classes (11). The advantage of this research is that the identification of services does not depend on classes. In the service identification methods based on entities, the problems that exist are that the repetition of activities is the only criterion for identifying services (12). The advantage of this research is that in addition to the relationship between activities, the relationship between entities and activities is also considered.

Conclusion

Creating an integrated system based on the proposed model increases customer satisfaction and reduces time and cost. The results of this study show the potential ability of the proposed algorithm to identify services, because the

creation of an integrated system by identified services has reduced time and cost in the system.

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Ethics approvals and consent to participate

The current study was carried out with the approval of the Vice-Chancellor for Research and Technology's Ethics Committee, Islamic Azad University, Science and Research branch, Tehran, Iran, with the approval code of 1202.8

Conflict of interest

The authors declare that they have no competing interests

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